GAIT ANALYSIS SYSTEMS

User Manual

GaitSmart® 2

Instructions for Use

Hardware

IFU0006

Dynamic Metrics Ltd. (DML), Codicote Innovation Centre, St. Albans Road
Codicote, Herts SG4 8WH, United Kingdom

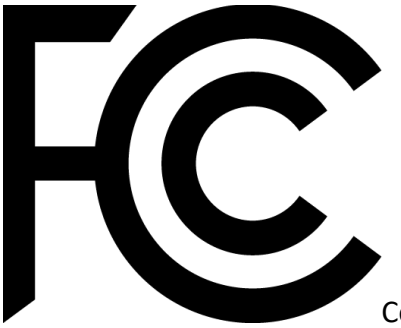
Table of Contents

Document History

Version	Date	Changes
1.0	03/10/2023	Initial Issue
2.0	9/10/2023	Added information for FCC
3.0	16/10/2023	Updated date errors, updated labelling images
4.0	07/11/2023	Updated the sensor labels
5.0	8/11/2023	Removed statement around sensor labelling

For the latest version of this IFU contact info@dynamicmetrics.com

GaitSmart® App Version 1.6.0
GaitSmart® Cloud Version 3.1.4



Certificate of test 13840-3

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

This device complies with the RF Exposure 1mW exemption per 1.1307(b)(3)(i)(A) for a single RF source device, regardless of separation distance.

This device must not be co-located with any other Antenna or transmitter. This device has been approved with its integral antenna.

Antenna Model: 712-ANT-2.45-CHP-T. Type: Ceramic Chip antenna

Manufacturer: Linx Technology Max Gain: +0.5 dBi.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

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.

—Consult the dealer or an experienced radio/TV technician for help.

Canada/ISED compliance section.

This device complies with ISED Canada License-exempt RSS standard(s). Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

This device complies with the RF Exposure limits for routine evaluation requirements of RSS-102 Clause 2.5.1 Table 1 for the frequency band 2.4-2.483 for a single RF source device, and a separation distance of ≤5mm.

This device must not be co-located with any other Antenna or transmitter. This device has been approved with its integral antenna.

Antenna Model: 712-ANT-2.45-CHP-T. Type: Ceramic Chip antenna

Manufacturer: Linx Technology Max Gain: +0.5 dBi.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

French Language

Cet appareil est conforme aux normes RSS exemptes de licence d'ISED Canada. Le fonctionnement est soumis aux deux conditions suivantes:

1. Cet appareil ne doit pas causer d'interférences nuisibles, et

2. Cet appareil doit accepter toute interférence reçue, y compris les interférences susceptibles de provoquer un fonctionnement indésirable.

Cet appareil est conforme aux limites d'exposition RF pour les exigences d'évaluation de routine de RSS-102 Clause 2.5.1 Tableau 1 pour la bande de fréquence 2,4-2,483 pour un seul appareil source RF, et une distance de séparation de ≤ 5 mm.

Cet appareil ne doit pas être situé à côté d'une autre antenne ou d'un autre émetteur. Cet appareil a été homologué avec son antenne intégrée.

Modèle d'antenne : 712-ANT-2.45-CHP-T. Type : antenne à puce en céramique

Fabricant : Linx Technology Gain maximum : +0.5 dBi.

Les changements ou modifications non expressément approuvés par le fabricant peuvent annuler le droit de l'utilisateur à utiliser l'équipement.

1 FCC ID/ISED – GS2 Sensor

An example of this label is shown below, and its location is included in section 8.2 photograph:

Declaration of Conformity (QMF 54)

DML Dynamic Metrics Limited	QMF
	QMF 54 – Declaration of Conformity

Declaration of Conformity

for GaitSmart2(Product Name)

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	GaitSmart2
Legal Manufacturer:	Dynamic Metrics Ltd. Codicote Innovation Centre, St. Albans Road, Codicote, Hertfordshire, SG4 8WH, United Kingdom.
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	GaitSmart2 intended purpose is to measure the movement of the lower limbs of a human.
MDD Classification:	Class I Measuring in respect of Annex II concerned with the metrological requirements of gait analysers.
Notified Body:	BSI notified body number 2797
CE Certificate Reference:	CE 709431
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Fl, Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Full Quality Assurance outlined in Annex II, in respect of Annex II concerned with the metrological requirements of gait analysers.

Name Diana Hodgins **Position** CEO

Signed D Hodgins **Date** 26/03/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Date	Version	Authorised	Page Number
02/03/2021	3	Joe Meeks	Page **1** of **2**

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN 300 328v2.1.1	Radio Type Testing
EN 301 489-17v3.2.0	EMC Type Testing
EN 60601-1-2:2015	EMC Type Testing

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
MU0069	GaitSmart 2	35757

Version History

Version	Compiled by	Date	Description
1	Denis Hodgins	26/03/2021	First issue of new format for DoC

2 Definitions

2.1 Product Information

GMDN code 35757 Gait Analysis system

UDI-DI Issuing Entity GS1 AISBL

Basic UDI-DI Number 5065010464MU0069NJ

FCC ID: 2A9NE-GS2
IC ID: 29856-GS2
Model: MU0057

℞ - For Professional Use Only

2.2 Definitions

- GaitSmart 2 or GS2 – Gait analysis system designed and manufactured by Dynamic Metrics Limited (DML).
- GaitSmart App – The android specific application designed and developed by DML that controls the function of the GS2 sensors. This comes preloaded onto the tablet provided.
- GaitSmart 2 Sensors – The inertial measurement units (IMU) that recorded data from a client/patient walking.
- GaitSmart Cloud – The cloud computing where data is stored and processed, accessed via the chrome web browser.
- Client – The person who the GaitSmart test is being performed upon, also commonly referred to as the patient.
- User – The person who performs the GaitSmart test, they have access to information on the GaitSmart cloud.
- Tablet – The android tablet computer provided with the GaitSmart 2 system
- Association – The groups of files that can be accessed by users with permissions to view or edit. This allows for flexible data sharing.
- Straps – the fabric bands that are placed onto the client that hold the sensors in place while the test is being carried out

- GaitSmart Report – The output of doing the gait analysis test is a document showing the results of a person's gait, it is RAG coded for easy interpretation of the results for both User and Client.
- vGym – an additional protocol that adds 6 personalised exercises to the GaitSmart report that address issues within a client's gait.

About GaitSmart®2 by DML

Our vision at Dynamic Metrics Ltd (DML) is to provide affordable access to gold-standard gait quantification and personalised rehabilitation, to ensure that everyone has the opportunity to remain mobile and healthy. We believe that measurement and analysis of human kinematics should be a regularly taken metric as a marker of health, similar to Blood Pressure or BMI.

To achieve this our GaitSmart® 2 (GS2) system offers the accuracy and precision of a gait analysis lab in a portable system that can take less than 10 minutes to perform a gait test. The system is applicable to all those who are able to walk, including the use of walking aids or prosthetics and tests can be carried anywhere that a user can perform 10-15 strides on flat even surface.

GaitSmart® 2 has been researched, developed & manufactured by Dynamic Metrics Limited. GaitSmart® 2 is a class 1m medical device and the systems angular tolerance is ±1˚.

If there is any doubt or question from the results provided by GaitSmart® 2 system then consult a healthcare professional or Dynamic Metrics Limited (DML)

If there is a serious incident that has occurred in relation to GS2 then either inform DML or BSI, all serious incidents must be reported to the competent authority.

Any and all feedback is truly valued at DML, it is how we will continue to improve. Please contact us with any feedback, issues, queries or questions.

info@dynamicmetrics.com

3 Safety Notice

3.1 Introduction

This safety notice summarises information basic to the safe operation of the equipment described in this manual. The international symbol displayed above is a reminder that all safety instructions should be read and understood before setting up and operation of this GaitSmart®2 system. When you see the symbol on other pages, pay special attention to the safety information presented. Observance of safety precautions will also help to avoid actions that could damage or adversely affect the performance of GaitSmart®2 system.

Read all the product manual and consult with DML personnel before attempting to operate GaitSmart®2. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labelling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your DML representative.

3.2 Intended Use

The GaitSmart®2 device intended purpose is to measure the movement of the lower limbs of a human.

3.2.1 Patient Selection Criteria

The requirement to be tested using the GS2 product is that the person being measured has the ability to be able to walk 10 strides, turn around and walk back. The use of prosthetics and walking aids (sticks, crutches and frames etc.) are permissible. The GaitSmart 2 product is used over clothing.

GaitSmart 2 should not be used if any object is impeding the lower limb movement (such as a catheter bag) or limits the ability to attach the straps correctly.

3.2.2 Indications

- The system is applicable to all those who are able to walk, including the use of walking aids or prosthetics and tests can be carried anywhere that a user can perform 10-15 strides on flat even surface.
- The instructions are designed for an experienced user. New users should read the full manual and have completed their training before using these instructions.
- To use the system training is required by Dynamic Metrics Ltd. There is no requirement, previous experience or qualifications to receive this training.
- The GaitSmart 2 product is used over clothing.
- It is essential that the client/patient is comfortable to do each of the exercises.
- The following rules must be followed when using the vGym exercises;
    - A client / patient must demonstrate all the exercises provided before they are allowed to leave with a report.
    - All exercises can use walls, sturdy furniture or other fixed objects to assist with the exercises, this should be recommend for clients who find an exercise/s hard.
    - The range of motion for an exercise can also be varied depending on a client/patient and must be kept in a comfortable range for each individual.
    - If for any reason the exercises causes pain, which does not dissipate, you must stop immediately and refer back to the relevant health professional.

3.2.3 Contra-Indications

- GaitSmart 2 should not be used if any object is impeding the lower limb movement (such as a catheter bag) or limits the ability to attach the straps correctly.
- No other browser apart from Chrome should be used to access the GaitSmart Cloud as the reports and layouts have been optimised for this browser.

3.2.4 Warnings

- Lower limbs must be covered, GS2 straps must not be placed onto bare skin.
- The system must not be used if the client has any object impeding lower limb movement, such as a catheter bag.
- Do not open the power supply unit, charger or sensor. There are no serviceable parts inside

3.2.5 Precautions

- Do not attempt to perform any procedure before carefully reading all instructions.
- If some sensors cannot be found try to put them closer to the tablet, ensure you are far away from microwave ovens, wireless speakers, video senders or any other wireless devices that operate in the 2.4 GHz or 5 GHz bandwidth. Also remove any obstacles on the way from sensors to the tablet. If there are still problems with finding sensors try to reset them.
- Do not commence the test within a metre of any object.
- Ensure all objects are removed from the patient's pockets; mobile phone, keys etc. and if possible the patient should remove their belt.
- Ensure that the environment for the test is clear of obstructions and the internet connection is stable
- Before charging the sensors check all the cables for the charging system are not damaged in anyway
- Make sure that the matching wall outlet receptacle is properly wired and earth-grounded.
- Check that the line voltage agrees with the voltage listed on the name-rating plate affixed to the GaitSmart®2 charger.
- Do not attach the GaitSmart®2 power supply to any non GaitSmart®2 product.
- Always unplug the power supply before cleaning the equipment.
- Do not use liquid or aerosol cleaners of any kind.
- Use a dry cloth or clinical disposable wipes for cleaning.
- Use clinical disposable wipes or dry cloth on the external of the sensors, charger and straps only.
- Keep your device away from radiators and heat sources.
- Do not use the equipment device near water (e.g. near a bathtub, sink, fish tank, in a wet basement or near a swimming pool).
- Do not use this device in areas with high humidity (e.g. steam room).
- If the device gets wet contact your service provider and do not use the device until told they have approved.

- Do not spill food or liquids on your system components, and never operate the equipment in a wet environment.
- Do not place containers holding liquid on or near the GaitSmart®2 charger or sensors. If they spill, liquid may get into the equipment and damage electrical or mechanical components.

3.2.6 When operating your equipment

- Do not use AC powered equipment during an electrical storm. The battery powered sensors may be used if all cables have been disconnected.

- If your equipment does not operate normally - in particular, if there are any unusual sounds or smells coming from it - unplug it immediately and contact an authorized distributor or DML directly.

- Ventilation clearances: 100mm around the charger.

If you drop or damage your equipment.

- Disconnect the Power supply from the electrical outlet, and then, if possible, disconnect the AC adapter from the charger cradle.
- Check for physical damage to the casing. If there is damage consult DML for advice.

- If the device does not start, or if smoke or unusual odours are detected, then disconnect the device from the mains outlet and consider finding a fire blanket or electrical fire extinguisher before contacting DML.

3.2.7 Power Sources

Observe and follow service markings;

- Do not push any objects into the openings of your equipment unless consistent with the authorized operation of the device.
- The powering of this equipment must adhere to the power specifications indicated for this product.
- Do not rest anything on the power cord or on the device.
- Position power cables carefully; route cables so that they cannot be stepped on or tripped over.
- Operate the equipment only from the external power supply supplied with the equipment.

- Ensure that attached devices are electrically rated to operate with the power available in your location.
- To help prevent an electrical shock, plug the equipment and peripheral power cables into properly grounded electrical outlets.
- To help protect your device from sudden, transient increases and decreases in electrical power, use a surge suppressor, line conditioner, or uninterruptible power supply (UPS).
- Do not modify power cables or plugs. Consult a licensed electrician or your power supply company for site modifications. Always follow your local/national wiring rules.

3.3 Claims

- GaitSmart®2 provides affordable access to gold-standard gait quantification and personalised rehabilitation, to ensure that everyone has the opportunity to remain mobile and healthy.

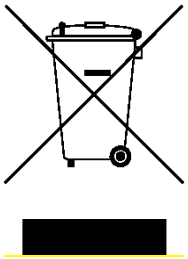
- The report uses a traffic light colour system to quickly and easily show results, there are also numerical values for all the results for detail if further interrogation is desired.
- Green is normal movement, amber is a moderate issue and red is severe issue.
- There are also coloured borders to show if an issue is close to a limit for either getting worse or better.
- The GaitSmart® score is the culmination of all the sagittal movement, and describes how well the hips and knee are moving
- Pelvis is the stability of the trunk, showing if a user is swaying or turning their body to move, this should be a lower number showing the client is moving from the hip joint.
- The Hip is the angle between the pelvic and thigh sensors
- The Thigh is the angle at the sensor on the thigh
- The knee is the angle between the thigh and calf
- The Calf is angle of the calf sensor.
- The Quality score is looking the potential for future issues, regarding out of plane movement and knee loading
- Thigh and calf side to side movement describes out of plane movement that would cause balance issues and incorrect joint loading
- Knee stance flexion is the angle at the knee when in load.
- The GaitSmart® symmetry score provides a quick and easy way of identifying differences between left and right for the joints and segments

- If using a protocol for a test that features vGym then exercises will be provided for the client on the report as well as basic instructions and images for how to do each exercise, these are on the pages following the report.
- The results can be viewed after the test in the form of a report. Results are displayed in a traffic light format, with green meaning normal movement, amber representing a moderate issue and red identifying a potentially severe problem. The person who performs the test (user) to the patient (client) will be able to:
    - See all your previously done tests.
    - Add search filters.
    - Select number of tests visible on the screen.
    - View the reports.

4 Regulatory

Important Information
GaitSmart® 2 is a Medical Device. If there is any incident involving the equipment it must be reported either to DML, the contact details are below; Dynamic Metrics Limited Codicote Innovation Centre St Albans Road Codicote SG4 8WH UK info@dynamicmetrics.com UK Phone Number - **(+44) 1438 822 822** US PHONE NUMBER – **(+1) 315 944 2408**

5 Recycling Label



This equipment is marked with the above recycling symbol. It means that at the end of the life of the equipment contact DML who will organise collection of the equipment for safe disposal. This will benefit the environment for all.

6 Glossary

User = the trained person who administer the GaitSmart test

Client or Patient = the person who the GaitSmart test is being performed upon. In this document Client and Patient are used interchangeably

GaitSmart Cloud = A cloud database where all GaitSmart tests, reports, users, clients are processed and stored, may also be referred to in this document as the cloud or cloud.

GaitSmart App = An application designed, built and maintained by DML to control the GaitSmart hardware using an Android tablet, may also be referred in this document as the app or app.

HTML = Hypertext Mark-up Language

LED = Light Emitting Diode, the type of indicator on the sensors.

L-Ion = Lithium Ion, referring to types of battery used

.pdf = file in Portable Document Format (by Adobe Systems)

Trial = a test, using the *GaitSmart®2 System* to gather and analyse data

s = time in seconds

M/s = speed in metres per second

m = length in metres

º = Degrees per gait cycle

7 Introduction

This manual is designed to acquaint you with the GaitSmart®2 Gait Analysis System, its functions, specifications, operation, and routine operator care and maintenance. We recommend that you read this entire manual.

Every effort has been made to ensure the accuracy of the images shown. However, there may be minor discrepancies between the images and your system, if there is any doubt in the instructions and images provided please contact DML.

8 Product Description

GaitSmart®2 (GS2) is a gait analysis system; developed, designed, manufactured and tested by Dynamic Metrics Limited (DML). GS2 objectively measures the kinematics of walking. The system is portable and equipment required is included. The measurement can be carried out in under 10 minutes, is applicable to all those who are able to walk, including the use of walking aids or prosthetics, and the results can be viewed after the test in the form of a report. Tests can be carried anywhere that a user can perform 10-15 strides on flat even surface. Results are displayed in a traffic light format, with green meaning normal movement, amber representing a moderate issue and red identifying a potentially severe problem.

Sensor accuracy is obtained from a reference standard at the National Physical laboratory and system results are validated against optical gait laboratory results.

The class 1m medical device is a non-sterile, reusable system. Made up of ABS sensors and charging cradle and medical grade AC-DC power supply. There are straps for attaching the sensors to the calves, thighs and pelvis, these are made from elasticated fabric and silicone for stiction to clothing. The system also requires the use of the GaitSmart® App that runs on an Android tablet and needs internet access. All components are in a case provided, that is easy to transport.

8.1 Specifications

Humidity restrictions storage and use: <75% (noncondensing)

Temperature charging and in use: 10 – 45 °C

Temperature for storage: 15 - 35 °C

Do not leave system exposed to high temperatures such as direct sunlight for extended periods of time.

Weight: 3 kg (full system including case)

Soft Case Size: 300 x 230 x 120 mm

Finishes [material finishes for sensor and charger, straps.] Sensor and Charger = 27 VDI.

Electrical Supply: Class II.

Electrical Input:

Voltage Range 80 – 264 VAC

Frequency Range 47 – 63 Hz

AC Current 1A / 115VAC 0.6A / 230 VAC

Electrical Output (supplied Power supply):

DC voltage 5V

Rated Current 5A

Current Range 0 – 5A

Rated Power (max) 25W

Time to charge a sensor from zero volts: 35 – 45mins (0-99%)

Usage time for recording is limited to 8 hrs by the memory in the sensor.

System Outputs:

Mean angular error static <= 1^{o}

Mean angular error dynamic <=2^{o}

Set up time to start a test <= 5 minutes

Android tablet minimum specification;

Display size Minimum - 10”
Wi-Fi Connectivity - 2.4G

Bluetooth version – classic 4.0 plus

Processor CPU Speed – 1.3 GHz

Ram Size (GB) – 1GB

Available Memory – 1GB

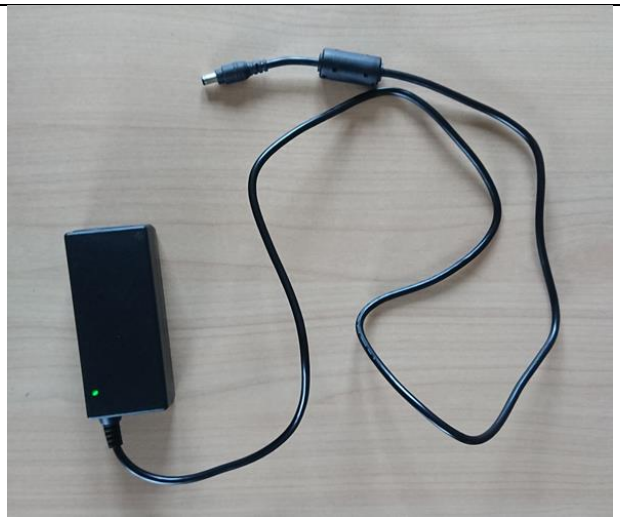
Running at least android version – V6.0 Marshmallow

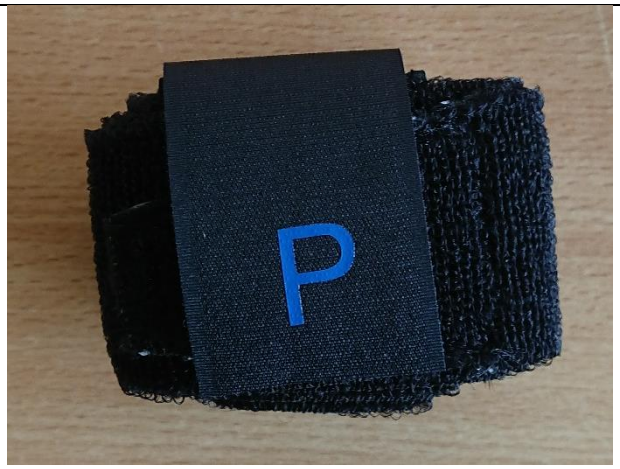
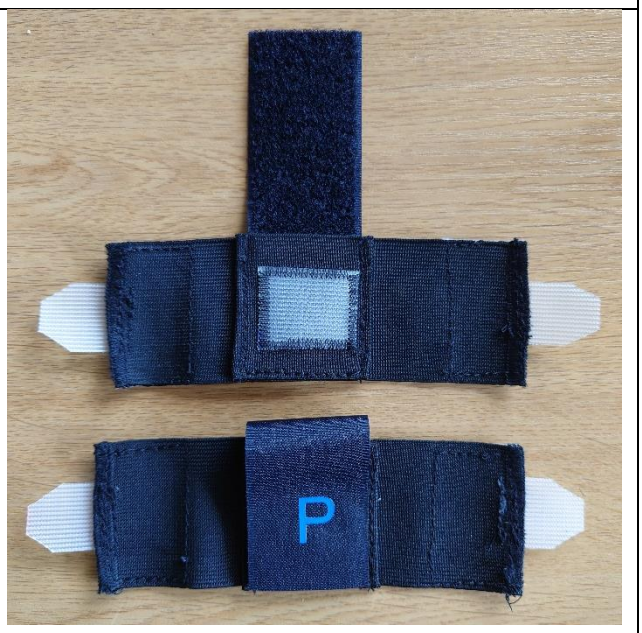
Product is not made with natural rubber latex

8.2 What is in the box

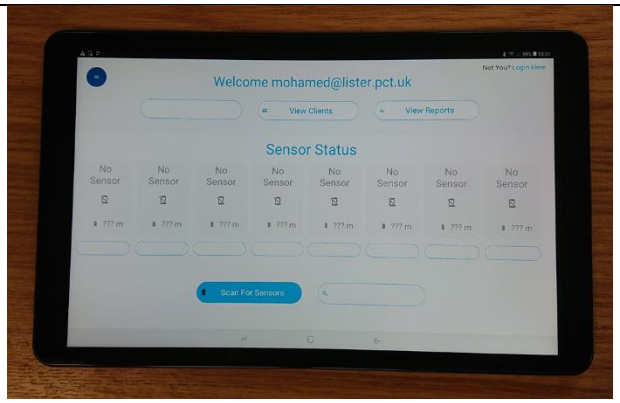

GaitSmart
GaitSmart®
DYNAMIC METRICS

Item	Quantity		Part Number	Image
GS2 Sensors	8		MU0057	 

GS2 Charger Cradle	1		MU0056	
AC-DC Power Supply	1		PU0027	
Power Cable	1		Code is dependent on plug type	 

Waist Strap 	1		ST0032	
Pelvis Pouch 	2		ST0033	
Pelvis Extension 	1		ST0036	

Thigh Strap Left LATEX	1		ST0034	
Calf Strap Left LATEX	1		ST0035	
Thigh Strap Right LATEX	1		ST0038	
Calf Strap Right LATEX	1		ST0039	

Tablet	1		PU 0048	
USB Power Outlet (vary depending on location)	1		Country Specific	
USB Tablet Power Cable	1		PU 0047	

Tablet IFU	1		PU 0048	
Tablet SIM slot removal tool, this is also the reset tool for the charger	1		PU 0049	
Case	1		PU0075	

If you think there is anything wrong with your system, parts missing or items are not clear please contact DML.

9 Operation Guide

9.1 GS2 System Setup

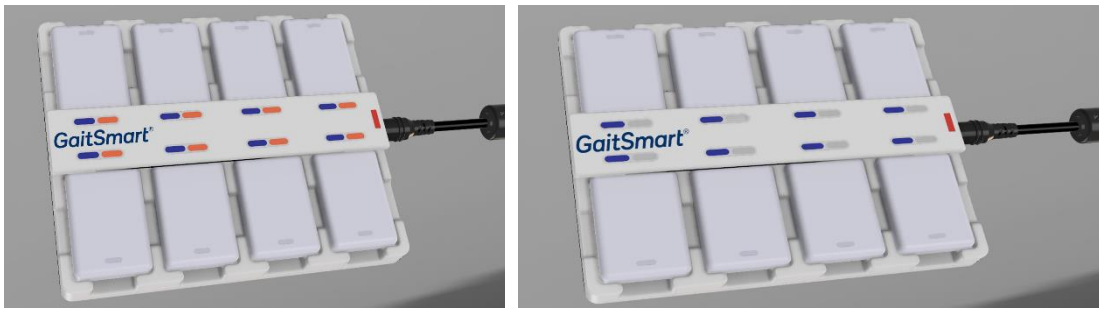
Check area to perform test is free from any objects. The client needs be at least 1 metre away from any hard objects in the start position, hard objects such as, but not limited to walls, furniture or appliances.

Ensure the full test area where the client will be walking is flat, clear from obstructions and safe to walk.

Remove the charger and sensors and place them on a level surface.

Connect the Power Supply Unit to the charger a red light will illuminate if the charger has power. Then place the sensors into the charger, upon contact, a blue light should illuminate. The orange charging light may also illuminate. When the sensors are fully charged the orange lights will stop illuminating. See Figure 1 Charging and Charged Sensor in Charging Unit

a) and b) for sensors being charged, and sensors fully charged. Ensure that sensors have been on charge for at least 15 minutes before use.



a) Charging b) Fully charged

Figure 1 Charging and Charged Sensor in Charging Unit

Make sure the tablet has been sufficiently charged, ideally above 50% battery level. Place the tablet on charge if below 20%, the tablet is still able to perform a test while on charge.

9.1.1 Attaching the straps to the Client

Clients / patients must have their legs covered for a test, do not place the straps onto bare skin.

If a client has and obstructions when placing the straps, such as catheters do not perform a test.

After choosing the client, you will be asked to confirm your choice. Then, it's time to put straps onto the patient and fit the sensors in correct pockets. For now, you can put the tablet away and attach the straps in correct positions.

First check the client's footwear and clothing is suitable: closed shoes with a low heel and trousers are required, belts with metallic buckles should also be removed. Next ensure that the client has nothing in their pockets, items such as phones or wallets may affect readings.

You should be provided with 2 calf straps (with label "LC" & "RC"), two thigh straps (with label "RT" & "LT") and a belt strap for pelvis, with 2 short pockets to attach to the belt (with label "P"). To mount the straps, you have to first unroll them. The silicone should be facing the users clothing and the pocket should open at the top. Put the strap against the clothing of the patient in a correct location and wrap it around the leg. Then put the end of the strap through the buckle and pull back to make the hook and loop end connect on the strap. Calf straps should be mounted on the middle segment of the calf muscle (gastrocnemius) with the pocket facing the lateral (outer) side of the leg. Similarly, with the thigh straps, they must be mounted on the middle segment of the thigh on both legs with pockets also facing the lateral (outer) side of the leg. Ensure that both calf and thigh straps are at similar heights on each leg. The long pelvis strap has to be located on the height of the iliac crest with the pocket in the middle of the back, in line with the spine, the smaller pockets should be placed on the each side of the patient's pelvis on the bony landmark. It is important that all pockets are aligned on the lateral (outer) side of the leg. Figure 2 shows the correct location of the straps.

Figure 2 Position of Straps

9.1.2 Fitting the Sensors

Once all straps are mounted tight on the patient, you can proceed with fitting the sensors. Tap on the tablet on the body part that you want to add a sensor to the corresponding pocket. It will change colour into yellow and one of the sensors will light its green LED. Pick it up and fit it in the appropriate pocket. Place the sensor in

the pocket in such a way that you can see the LED at the top. When the sensor is fully in the pocket you should see only the LED, then you can close the pocket, Figure 3.

Figure 3 Fitting a sensor in pocket

After the sensor is correctly positioned, you have to tap on the same body part again on the app, so it changes the colour into green and the sensor light will go off. Repeat the procedure for the remaining sensors. Figure 4 shows how the screen should look like after centre spine sensor is fitted and the left pelvis is being fitted.

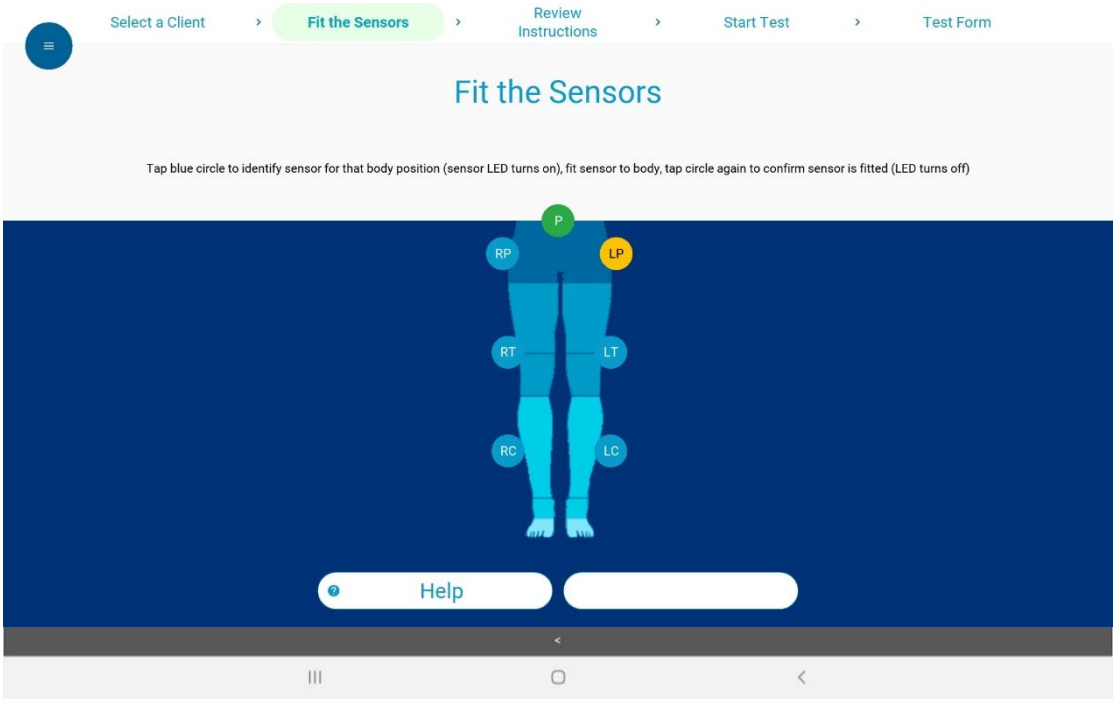


Figure 4 Fitting the sensors page

9.2 Tidying Up

When all tests have been done for the day and reports have been received then tidying up needs to be done, this will ensure that the system. First remove all the sensors and put them in the charging unit. Sensors can be stored in the charger. Then, you can unstrap the client. In order to have more space on your desk or to be able to pack the straps back in the provided case, it is recommended to roll the straps. To do so you have to open the pocket, roll the strap around the pocket and close the tab on the Velcro end, see Figure 5.

Figure 5 Steps of rolling the straps.

10 Resetting the Sensors

Place all sensors in the charging unit in a way so the connecting pins on the sensor will touch the pins on the charger. Plug the charging unit to the provided power cable and plug the power cable to a regular socket. The red light in the front of the charger will illuminate to indicate that the charger unit is on. The blue lights next to all sensors should illuminate, they indicate the sensor connection with the charger. If you can see the amber light next to the blue light, it means that the sensor is charging. The full assembly with all sensors charging should look like Figure 6.

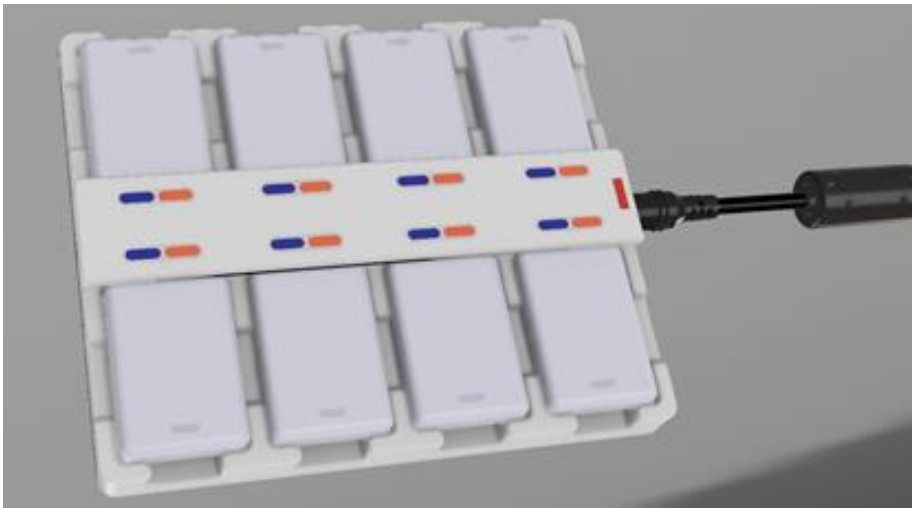
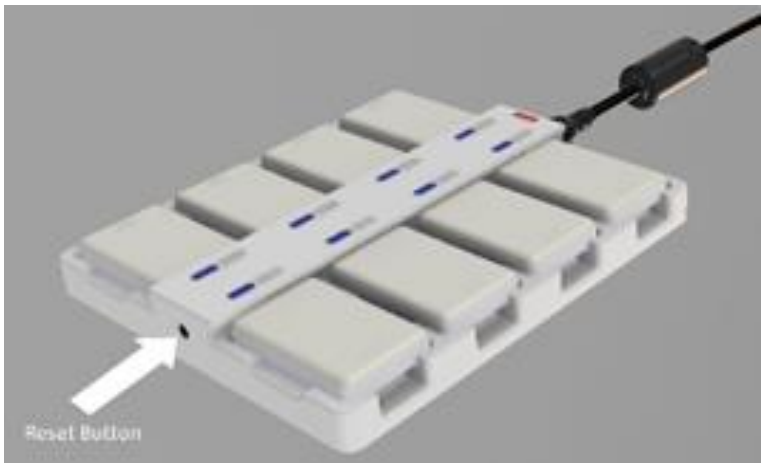


Figure 6 Charging Unit.

Now you can press the reset button (small black button located at the back of the charging unit, on the opposite side of the power connector and the red light). You can do using the reset tool provided. While the button is pressed all the lights should go off, except the main red one. Once you let go of the button, all the sensors should light the green LED briefly. The steps are shown in Figure 7.



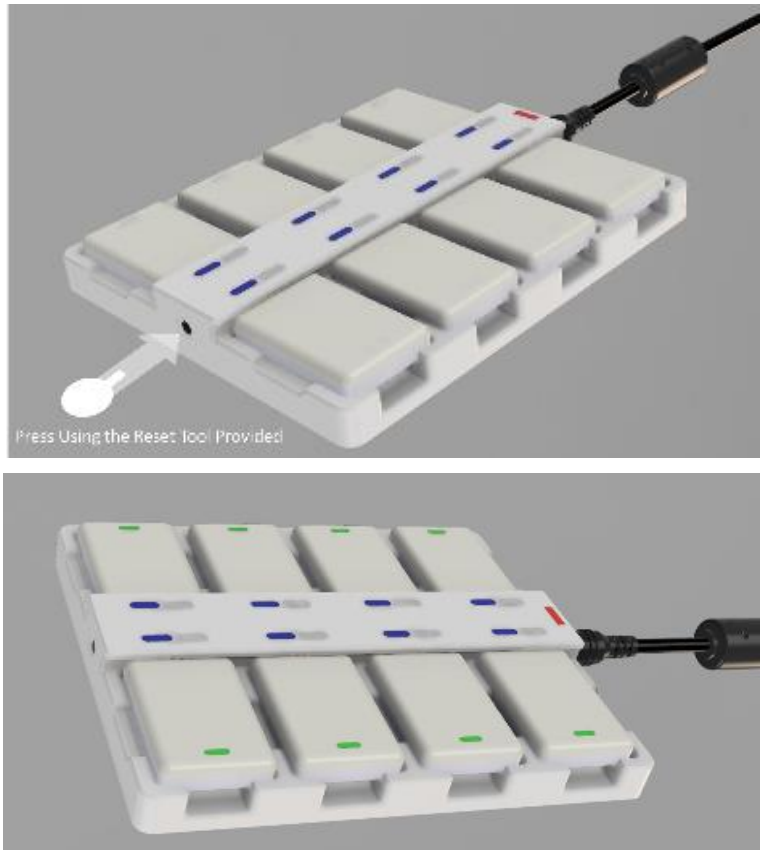


Figure 7 Resetting the sensors.

11 Trouble Shooting

This section provides advice of what to do in case of common problems while using the system such as finding sensors, starting the test or downloading the report.

If some sensors cannot be found try to put them closer to the tablet, ensure you are far away from microwave ovens, wireless speakers, video senders or any other wireless devices that operate in the 2.4 GHz or 5 GHz bandwidth. Also remove any obstacles on the way from sensors to the tablet. If there are still problems with finding sensors try to reset them. The instructions of how to reset the sensors can be found in the resetting the sensors section. In case of further problems contact Dynamic Metrics Ltd.

Internet access for the tablet is required, it is important to ensure that access will be allowed using Wi-Fi, this may require authorisation from an IT department.

12 Maintenance Activities

This section contains care and maintenance procedures that should be performed regularly. For maintenance not covered in this manual, contact DML UK support service on +1 315 944 2408 during office hours. Otherwise email Support on info@dynamicmetrics.com.

12.1 Servicing

There are no serviceable parts inside the GaitSmart®2 Product.

12.2 Cleaning

Clean the outside of the sensors, charger and straps with a clinical wipe (Clinell Universal Wipe).

Straps and sensors should be cleaned before and after test/s have been completed on each individual client/patient.

13 Frequently Asked Questions

There is a good chance that if an issue does arise, you will be able to deal with it, and this section is intended to help you. We recognise that any interruption in normal operation is inconvenient, so we want issues to be resolved as quickly as possible.

Q – Why is the app not finding any/all the sensors?

A – Battery may be low ensure the sensors have been charged or are in the charger. Sensors may also require resetting, section 10. If the problem persists then please contact DML.

Q – Do I need to be experienced in physiotherapy, metrology, biomechanics etc. to use the GaitSmart® system?

A – No, the GaitSmart® system has been designed for ease of use and easy understanding. We maintain rigorous standards in our gait analysis through training of users.

Q – Can I let someone else, a colleague or friend, perform a test who has not be trained by DML?

A – No, the sensors are highly accurate and very sensitive, we provide full quality training to those who will be performing the test. We also monitor results gathered to ensure that the best results are provided. If untrained people performed tests it would compromise the accuracy of the results we pride ourselves in.

Q – The screen has gone blank during a test, what should I do?

A – This may be due to the app on the tablet communicating with the cloud and as a result there may be no information ready to be shown on the tablet. Leave the tablet to perform the communication and when the results are ready to show the tablet show display them.

Q – I think the tablet or application may have frozen, what should I do?

A – It may happen that the tablet or the application freezes and will not perform any actions. There different responses for a tablet freezing or the application freezing, if a test is being performed when a freeze occurs then the data for the test will not be valid and the test will need to be repeated.

If the tablet is completely unresponsive, it is not reacting to any gestures or buttons, then performing a 'soft reset' should put the tablet back into a working state. To do this hold the power button and volume down button for 10-15 seconds, this should reset the tablet so the test can be repeated.

If the application is no longer responsive, it has not be reacting to any gestures and the screen has not changed for longer than 10 minutes, then the app will need to be closed and reopened to do this press the 3 lined icon (III) on the bottom of the menu, this will open up all the opened apps current on the tablet, then press the icon that says 'Close all'. The application can now be reopened the test repeated.

Q – There was an issue during the clients walk phase; they didn't walk far enough, there was an obstacle in the way etc. What should I do?

A – If you feel there was an issue during the walk phase, for whatever reason, then we recommend to press the back button on the app and repeat the walk phase of the test.

14 Storage

To store the GaitSmart®2 product, place all components into the case. See section 7.1 for the environmental conditions for storage. If the GaitSmart®2 system is to be stored for an extended time, it should have the battery charged at least once every 3 months.

15 To Get Help From DML

E-mail: **info@dynamicmetrics.com** e-mail is generally our preferred option since for anything other than simple queries, it gives us time to attempt to reproduce the problem. Please try to provide a detailed description of the problem, giving as much detail as you can. Particularly helpful are screen shots copied into a document to show where things appear to be going wrong. Sensor serial number, firmware issue and *GaitSmart®* software version may also be useful.

Telephone: (UK office hours, weekdays. Answer-phone facility for out-of-hours):

UK +44 (0)1438 822822

USA +1 315 944 2408

16 Appendix 1 – Full Report Example

GaitSmart

Report: 5f72070b91ab6fbcf83d7b75

Your Exercises

1. Knee Drive Right
2. Single Leg Squat Left
3. Squat
4. Weight Transfer
5. Single Leg Squat Right
6. Forward Raise Right

GaitSmart Score™ 90.9%

An assessment of stability & strength when walking

GaitSmart Quality Score™ 100.0%

Left	Right	
21.37%	26.7%	Thigh: side to side movement
10.0%	12.82%	Calf: side to side movement
21.02°	24.55°	Knee Stance Flexion
-10.04°	-16.72°	Knee Angle at Heel Lift
53.76%	59.25%	Swing Flexion (% of gait cycle): from same-foot heel lift to strike

GaitSmart Symmetry Score™ 54.5%

27.09%	Hip
2.34%	Thigh
-14.83%	Knee
-7.25%	Calf
-15.51%	Stance Flexion

Key to Colours

Normal Movement | Moderate Issue | Severe Issue

If you have any other conditions that can affect balance or your ability to perform the exercises, or if you have any questions or concerns, please contact your healthcare specialists. Visit www.gaitsmart.com/exercises for more information for more information.

GaitSmart Exercise Program & Advice

We suggest performing the exercises little and often throughout the day on both legs will benefit your recovery and rehabilitation.

Include the exercises in your daily routine, for example, in the midst of making tea, brushing your teeth or completing a task which you perform multiple times daily.

If for any reason the exercises causes pain, which does not dissipate, you must stop immediately and refer yourself back to the relevant health professional.

Follow Up

- We would normally expect to see improvement over a 3 to 4-week period.
- Each GaitSmart analysis allows us to change the exercises as we see improvement.
- Many people achiveve optimal movement within 3 to 4 appointments.
- If the condition is more involved then treatment could take longer.

Knee Drive Right

1. Start in a standing position with the [right/left] foot slightly behind the body and your hands on your hips.
2. Keep the chest lifted and an upright posture.
3. Lift the [right/left] leg that is positioned behind the body forwards, until it is level with the hip, as shown in the example picture.
4. Allow the knee bend throughout the movement.
5. Once the [right/left] leg is level with the hip and in front of the body, lower your leg back down to the floor returning to the start position. Repeat the exercise.
6. When ready you can repeat the exercise on your other leg.

Single Leg Squat Left

1. Stand, holding onto a support if necessary.
2. Transfer your bodyweight onto the left leg and bring the right leg off the floor.
3. Now bend your left knee, lowering your body slightly.
4. Maintain your balance by keeping your head up and continue to look forward.
5. Straighten the left knee and return to start position

Squat

1. Stand with your feet shoulder width apart and your chest lifted
2. Throughout the movement look straight ahead of you.
3. Bend the knees whilst sitting the hips back and down. Keep your feet flat on the floor.
4. Squat as low as you feel comfortable then return back to the standing position.
5. Repeat the exercise.


Weight Transfer

1. Stand, with your feet a shoulder-width apart.
2. Transfer your bodyweight onto the right leg.
3. You may keep the left leg on the ground or lift the left leg slightly off the ground.
4. Return both feet to the floor and transfer your bodyweight to the left leg.
5. You may keep the right leg on the ground or lift the right leg slightly off the ground.
6. Repeat the cycle up to ten times then return to the start position


Single Leg Squat Right

1. Stand, holding onto a support if necessary
2. Transfer your bodyweight onto the right leg and bring the left leg off the floor.
3. Now bend your right knee, lowering your body slightly.
4. Maintain your balance by keeping your head up and continue to look forward.
5. Straighten the right knee and return to start posit

Forward Raise Right

1. Stand, holding onto a support if necessary.
2. Lift the [right/left] leg out in front of you with a straight leg, taking care not to lean backwards at the same time.
3. Hold for a few seconds, relax and repeat 10 times.