NOTE : some tests stop automatically after the movement is completed or after a fixed amount of time (f.ex. 2min walking test, 5 sit to stand test). For more information about the test, check the complementary instructions which can be accessed by clicking on the question mark button on the right side of the test title on the instructions screen.

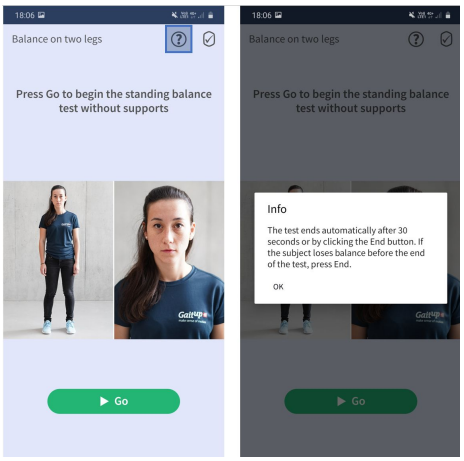


Fig. 65. Complementary instructions

Test type	**Stop automatically after:**
Monopodal balance comparison	30 seconds (x 2)
One leg balance	30 seconds
Balance on two legs	30 seconds
Semi-tandem balance	30 seconds
Tandem balance	30 seconds
Romberg test	30 seconds (x 2)
Sit to stand transfer	5 sit to stand detected
Vertical jump 1 leg	1 jump detected (x 2)
Vertical jump 2 legs	3 jumps detected
2 minutes walking test	2 minutes
Timed Up and Go	1 Timed Up and Go detected
Timed Up and Go in dual task	1 Timed Up and Go detected

Table 4. Automatic test end criteria

When the participant has understood the instructions and is ready to perform the test, press “Go”, In that moment, the Participant can start to perform the movement explained in the instructions shown in the user interface of the application.

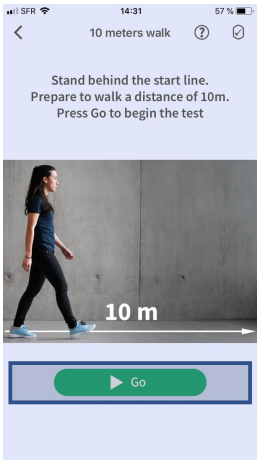


Fig. 66. Instruction and test start - iOS

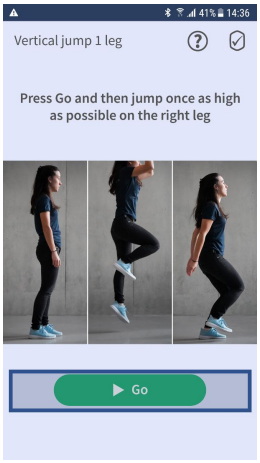


Fig. 67. Instruction test start - Android

NOTE: The wireless communication between the Physilog6 sensor device accessory and the mobile phone / tablet is limited in distance. Do not separate the sensor device from the Gait Up GO mobile application further than 5 meters (16 feet).

At the end of the test, if it did not automatically stop, tap the “End” button appearing on your screen to complete the recording. The Gait Up GO medical device will analyze the recorded data.

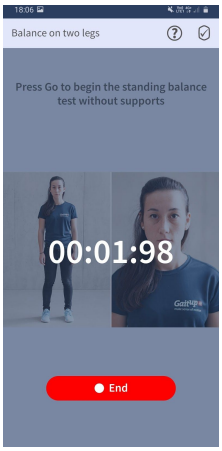
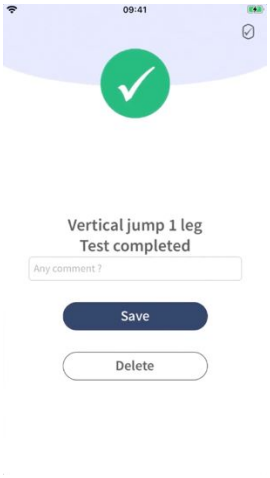


Fig. 68. Recording ongoing

If the test has been successfully performed, a green check mark will appear on the screen, together with the name of the test. Any comment about the performance of the test (f.ex. pain at the left hip) can be optionally added. This comment will be displayed on the test report. Tap “Save” to register the results and be able to generate a report.



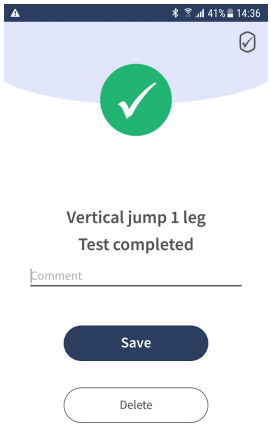


Fig. 69. Screen after completing a test - iOS

Fig. 70. Screen after completing a test - Android

The user can delete the test result in case of any problem happening with the execution of the instructions provided by the mobile application or if the test had to be interrupted by any cause. In this case, the performed test data is deleted and no report can be generated later.

NOTE: Data analysis problems can arise due to a bad quality movement or recording. In those cases, an error message is popping up on the screen warning the user, who has the choice of deciding whether the recorded raw data (no personal or clinical data contained in the recorded raw data) is shared with Gait Up or not. Data sharing has uniquely the goal of helping Gait Up SA to improve the product. To share such data, a user account must be registered on the mobile phone/tablet and internet access is required.

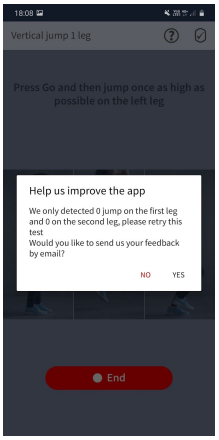


Fig. 71 Pop-up in case of error during the recording

NOTE: The previous test is an example (jump test) in the Gait Up GO application but the same procedure should be used for all the tests contained in the mobile application.

End of the test with no direct access to the results

During the test assignment it is possible to select “Direct access to results” or “No direct access to results” Please refer to the “Assign test” section to check how to activate or inactivate this setting.

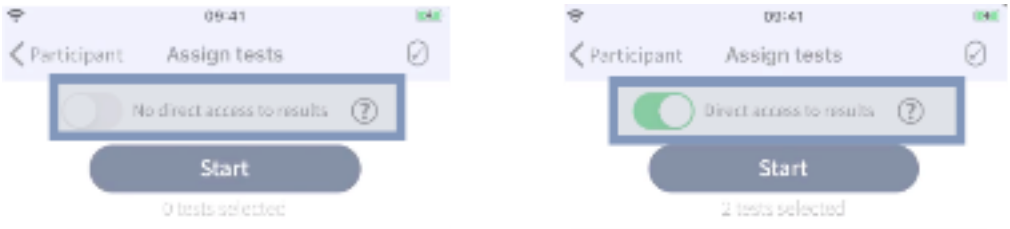


Fig. 72. Direct access to results option

If the direct access to the report results is inactivated, a message will pop up informing that the test results have been saved. The report can be unlocked later by the medical professional.

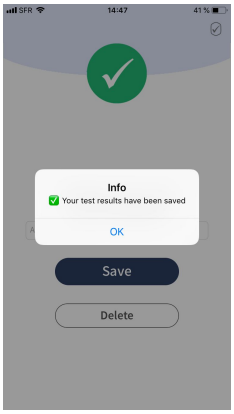


Fig. 73. Test has been saved - iOS

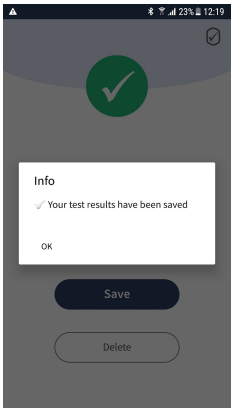


Fig. 74. Test has been saved - Android

After tapping “OK” on the information text box, the mobile application displays the session screen from where the user can select another test in the list.

The test report can later be accessed by the medical professional inside the password protected part of the Gait Up GO mobile application (see section 4.5.8).

End of the test with Limited admin mode (direct access to the results)

If the “Direct access to results” is activated, the User will be able to spend credits and access the reports immediately at the end of the test after clicking “Save”. A confirmation request will be generated for the user to confirm the spending of one credit to generate and display the report (see section 4.5.8 for more information).

After closing the report, The Gait Up GO mobile application displays the session screen from where the user can select another test from the list.

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

4.5.8 Generate, manage and interpret test reports

The Gait Up GO medical device works with a pay per report model, where the user can perform as many tests as wanted for free and needs to spend credits only when generating and displaying the result reports. For each credit, one report can be generated. For frequent users it is possible to purchase an “unlimited license” which allows to generate as many reports as wanted for a yearly flat rate fee. The “unlimited license” is linked to the Physilog6 serial number which allows a group of users who are using the same Physilog6 but with distinct login accounts to benefit from the unlimited number of reports.

There are two ways to generate and display reports:

Limited admin mode - Direct access to results is activated: the user can spend credits and display the test report directly after performing and saving a test. This direct access needs to be activated by the medical professional before starting a new session (see section 4.5.6 - “Limited Admin mode”). Generated reports must always be analysed and interpreted by a medical professional.

Inside password protected space - Direct access to results inactivated by the medical professional: the user cannot generate a test report directly at the end of the test. In order to generate the report for the performed test, it is required to login to the password protected part of the Gait Up GO mobile application. This must always be done by the medical professional.

The two modes respond to different use scenarios. The unlimited admin mode with direct access to results is useful during therapy sessions where the medical professional is using the device to assess a Participant and wants to see the report immediately after the test. For the home use case where the Participant is using the device without physical presence of the medical professional, the inactivation of direct access to the result allows the medical professional to control the spending of credits from his account. In addition, it ensures that the Participant is not confronted to the results without the presence of a medical professional who can interpret and explain the outcomes to the Participant.

Generate a report using Limited admin mode (direct access to the results)

If the “Direct access to results” is activated, the participant will be able to spend credits and access the reports immediately at the end of the test after clicking “Save”. After saving the test result, a confirmation request is displayed. If “Confirm” is selected, the report will be unlocked by using one credit and it will be displayed inside the Gait Up GO mobile application.

NOTE: for tests performed with a Physilog6 sensor accessory linked to an unlimited license, the report will automatically be displayed after clicking “Save”, if the direct access to reports is activated.

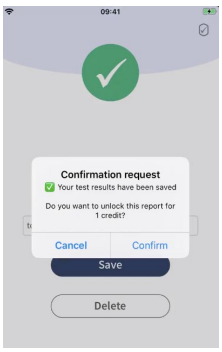


Fig. 75. Confirmation request - iOS

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

Fig. 76. Report generated - iOS - Android

After generating the report, it will always be available inside the password protected space (see section 4.5.8).

Generate and manage reports inside the password protected part

In order to access and manage all past reports and generate reports in case the direct access to results is not activated, the medical professional needs to login to the password protected part of the Gait Up GO mobile application.

Go to the login screen by pressing the “Login” or back button. The medical professional logs in with his/her account used to start the assessment session. Then the participant for which a report should be displayed can be selected from the Dashboard and the associated test results opened by clicking on “Reports”.

Fig. 77. How to access the report in the password protected part - iOS

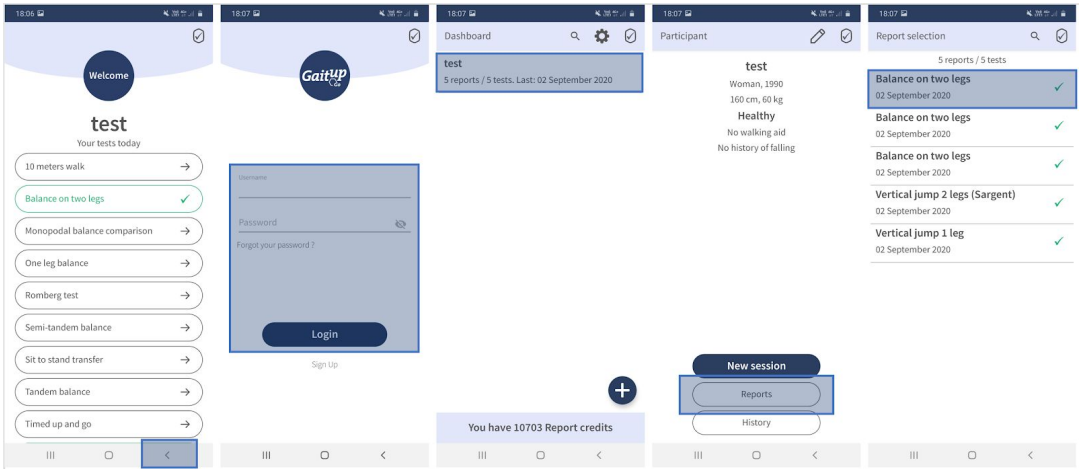


Fig. 78. How to access the report in the password protected part - Android

The reports are ordered according to their date with the most recent at the top. Newly performed tests for which the report has not yet been generated appear with a lock sign. To generate the report, select the report from the list. A confirmation message allows to validate the spending of one credit to generate and unlock the report.

NOTE: All tests recorded with a Physilog6 attributed to an unlimited license are automatically unlocked.

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

NOTE: A report which was unlocked once stays unlocked for the future, each report needs to be paid for only once and can be displayed as many times as wished.

The report list can be filtered according to the test name using the search bar like on the Dashboard screen.

It is highly recommended to save the results to the patient folder and/or the medical professional's computer. The data collected using Gait Up GO is locally stored on the mobile phone / tablet and the loss or damage of said mobile device implies that the results are no longer accessible.

Delete a report

It is possible to delete reports from the list of reports available for a given Participant. Reports are deleted from the list by sliding the list entry to the left or right of the screen. To permanently delete the report, press confirm in the pop-up window. Be careful, deleted reports cannot be recovered and will no longer appear in report comparisons (see section 4.5.9.). It is recommended to save all reports to a computer to avoid loss of data due to bad manipulation inside the Gait Up GO mobile application (see section 4.5.8). Credits spent to unlock reports are not restituted when deleting a report.

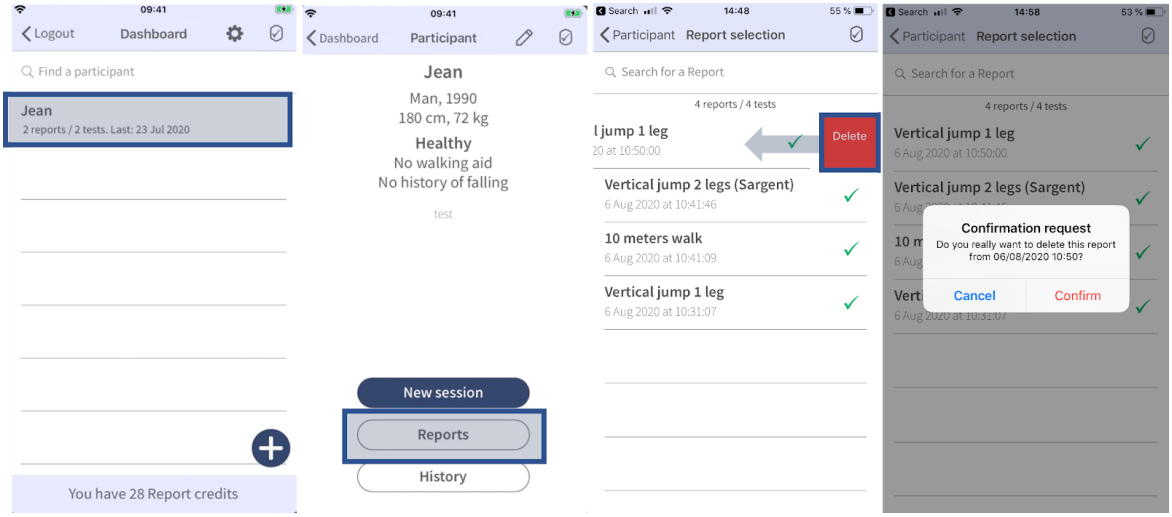


Fig. 79. How to delete a report - iOS

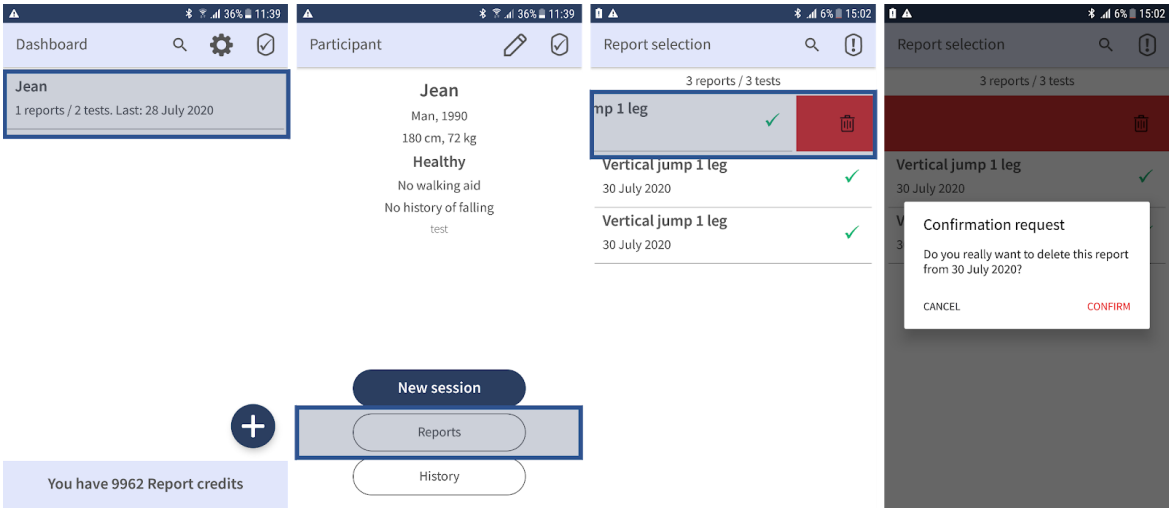


Fig. 80. How to delete a report - Android

Sharing a report

The Gait Up GO mobile application should never serve as a storage unit for the generated reports. Each time a report is generated for a specific patient, it is recommended that it is shared and saved in a computer where the Participant folder is located.

To share the reports, tap on the text or pdf symbols located in the upper right corner of the screen. There are different sharing options such as via email or bluetooth.

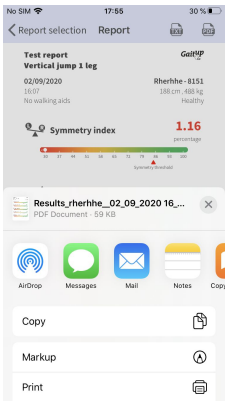


Fig. 81. How to share a report - iOS

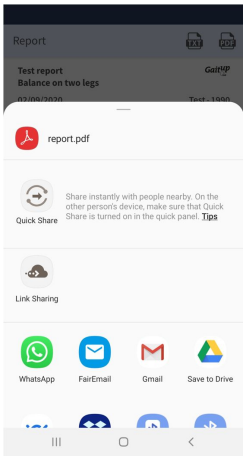


Fig. 82. How to share a report - Android

Report interpretation

Each test provides a given set of result parameters which are presented in a test report.

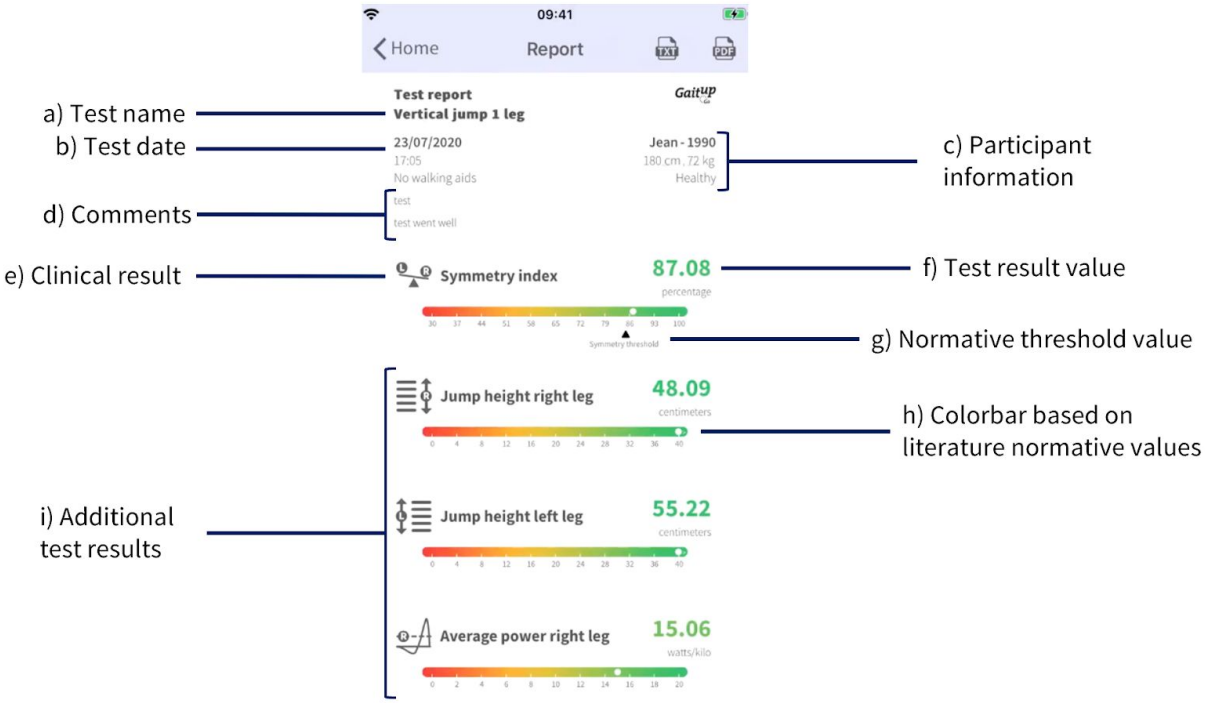


Fig. 83. Test report example and its components

Report component	Description
a) Test name	Name of the performed test
b) Test date	Date and time when the test was performed
c) Participant information	Summary of participant information including: ● Name ● Birth year ● Height and weight ● Use or not of Walking aid ● Health condition
d) Comments	The comment added to the participant profile and the comment added at the end of the test
e) Clinical result	The first result is for all tests the main clinical result associated with the clinical test. This is the result obtained from performing the same clinical test without Gait Up GO medical device.
f) Test result value	Result value for a given parameter. The color adapts accordingly to the

	position of the result on the colorbar. The units of the result value are also indicated.
g) Normative threshold value	For some result parameters, specific values are highlighted by a triangle below the colored bar. These are threshold values which indicate interesting reference points such as the average of the population of the same age or physiological reference values.
h) Colorbar based on literature normative values	All result parameters are displayed with respect to normative data from scientific literature. Where the color is red means that the achieved result is poor compared to Participants of similar age and health condition (if literature is available). Results in the green area are equal or better than the result of similar Participants presented in the literature.
i) Additional results	Additional result parameters which are calculated thanks to Gait Up GO and the presence of the Physilog6 sensor which records the movement data during the test.

Table 5. List of report components and their description

The report can be exported by pressing the text or pdf icon on the top right hand corner. This allows for example to send the report directly to an electronic patient folder or share the result via email.

4.5.9. Report comparison

The “History” button accessible from the participant profile screen allows to open the report comparison view of the Gait Up GO mobile application.

For each test assigned to a specific Participant for which at least two reports have been generated, a comparison of the results is possible. The history is available when several reports of the same test have been generated for the same Participant. This feature allows the Healthcare Professional to have and visualise factual data about the progression of the Participant over the time.

It is possible to export history reports into pdf or text format for sharing and sending it to a computer or electronic patient record file.

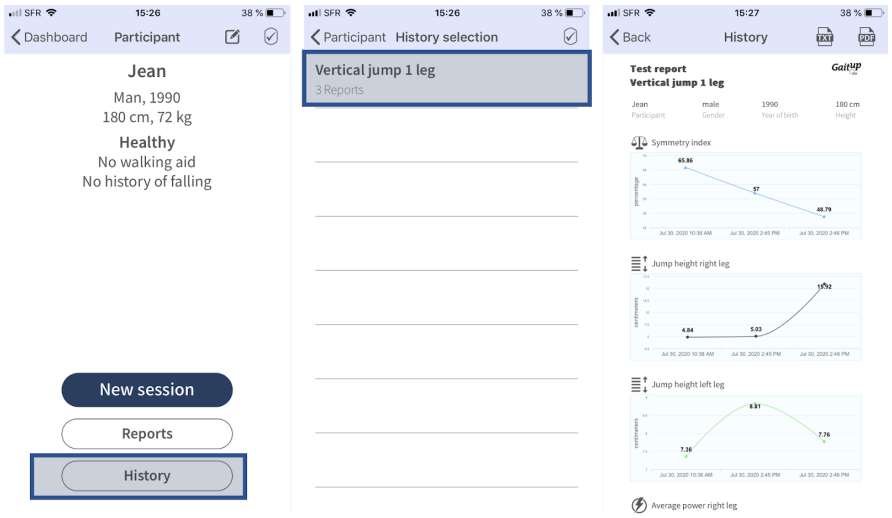


Fig. 84. How to access to the “History” section - iOS

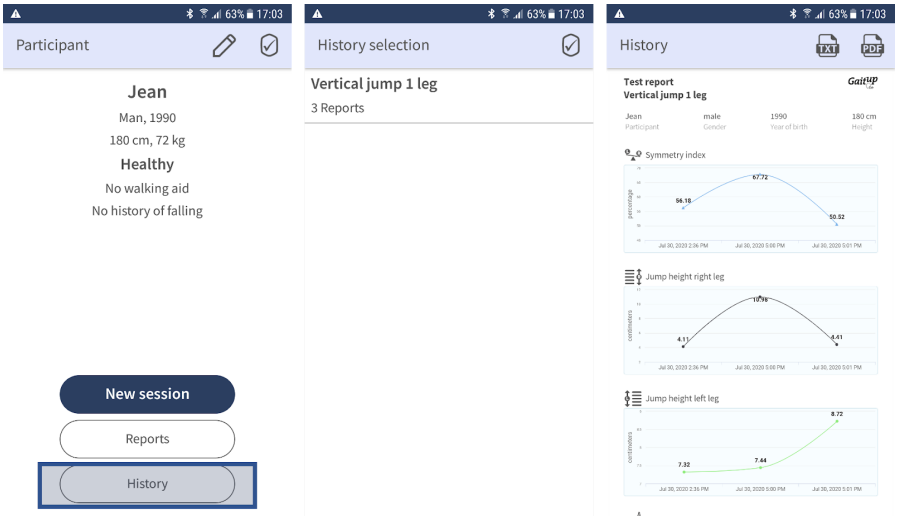


Fig. 85. How to access to the “History” section - Android

Comparison report interpretation

Fig. 86. Comparison report example and its components

Report component	**Description**
a) Test name	Name of the performed test
b) Participant information	Summary of participant information including: ● Name ● Gender ● Birth year ● Height
c) Parameter name	Name of the result parameter with its icon
d) Result values	For each report generated for this test and participant, the test result value of the parameter is displayed. A line is drawn between values in order to visualize the evolution of the test result.
e) Test dates	For each test result value the date at which the test has been performed is shown. The order of displayed results is chronological with the most recent on the right side.

Table 6. List of comparison report components and their description

5. Cleaning, Maintenance and Storage

Please, refer to section 1 Safety Information.

Both, the Physilog6 sensor device and the clip accessories can be manually cleaned and disinfected carefully using wipes with different chemicals (available at drugstore or pharmacy) detailed under section 5.1 of the present document.

5.1. Cleaning

Clean and disinfect the Physilog6 sensor device and the clip accessories before the first use at home as follows:

- Unpair the Physilog6 sensor device from the Mobile Application by closing the Gait Up GO mobile application prior to cleaning
- Unclick the Physilog6 sensor device from the clip accessories prior to cleaning
- Unplug the Physilog6 sensor device from the USB cable/power prior to cleaning
- Use Hydrogen peroxide 3%, bleach solution 50% or saline solution to clean and disinfect the Physilog6 sensor device's clip accessories. Do not use a cleaning spray, but carefully wipe it using a humid wipe.
- Use 96% ethanol solution or 70% isopropyl solution to clean and disinfect the physilog6 sensor device's plastic enclosure. Do not use a cleaning spray, but carefully wipe it using a humid wipe.
- Liquids and foreign material (e.g. dust) must not be allowed to enter the Physilog6 accessory device. Do not clean the device with excessive liquid.
- Ensure that the Physilog6 sensor device and the clip accessories are dry prior to being used again.

5.2. Maintenance

The Gait Up GO medical device is tested and calibrated prior to distribution. Under normal conditions, the characteristics of the device do not vary.

- The Physilog®6 should be handled carefully.
- If the Gait Up GO medical device (incl. all its accessories) shows functional instabilities or any visual defects, stop using it and contact the customer service.

The Physilog®6 firmware is updated using the Gait Up GO mobile application provided by Gait Up SA according to the instructions of use section 4.5.5.

The Physilog®6 sensor device does not include any consumables (one-time use).

The fixation clips used to fix the Physilog6 sensor device on the Participant's body are spare parts. If they get damaged, please contact Gait Up SA support to purchase new ones.

5.3. Storing and transporting the device

- Do not store the Physilog6 sensor device connected to the USB cable.
- Unclip the Physilog6 sensor device from the shoelace clip accessory before storing it.
- Place all components within the original packaging, each of them in its dedicated space inside the casing.
- Store it in a cool (-20 - +60°C) and dry place at a stable temperature and ambient humidity (25%-70%, non-condensing).

5.4. Environmental conditions for operation.

The Gait Up GO medical device must be used in accordance with the following conditions:

- Temperature: [0-30] °C
- Humidity: [10-70]%
- Pressure: [600-1070] hPA

The Gait Up GO medical device must be stored in accordance with the following conditions:

- Temperature: [-20-+60]°C
- Humidity: [25-70]%
- Pressure: [600-1070] hPA

The Gait Up GO medical device must be transported in accordance with the following conditions:

- Temperature: [-20-60]°C
- Humidity: [25-70]%
- Pressure: [600-1070] hPA

6. TROUBLESHOOTING

What do you see/hear	Problem	What to do	More Information
The Gait Up GO mobile application displays an error pop-up after you select a test, indicating that it cannot connect to the Physilog6 sensor device	There is a problem with the connection to the Physilog6 sensor device	Make sure that the sensor device accessory is in proximity of your mobile device. Control that the sensor device accessory has enough battery to be connected to the application. Click on the sensor information button () to check that the linked sensor device accessory corresponds to the sensor in your possession (last four digits of serial number on the back of the sensor corresponding to the number indicated in the mobile application).	Before handing a Gait Up GO device to a Participant for independent use, make sure that the linked sensor corresponds to the sensor device accessory you provide and is correctly connecting to the mobile application. The setting of the linked sensor device accessory is managed inside the password protected part of the application to which the end user does not have access.
The Gait Up GO mobile application displays an error pop-up after you select a test, indicating that the sensor device accessory has incompatible firmware	The Physilog6 sensor device accessory has incompatible firmware version.	Update the sensor device firmware by pressing the "Update Physilog" button.	This error can appear during the first use after you update the Gait Up GO mobile device or after installation of the application on a new mobile device.
The Gait Up GO mobile application	There is a problem with the Physilog6	The recording is interrupted, acknowledge the error	Depending on the problem, the error message will display a recommendation

indicates an error pop-up during a recording	sensor device accessory	message inside the Gait Up GO mobile application and follow the recommendation in the error message.	to the user. It can be for example that the sensor device accessory does not have enough battery to start or continue a recording and that you should recharge it. In case that the mobile application can solve the sensor device accessory problem on it's own, the sensor device accessory will perform a reset without your intervention and a new recording can be started.
The Physilog6 sensor device accessory emits a beep sound and briefly blinks red and orange	The Physilog6 sensor device accessory has performed a reset	Nothing needs to be done, the sensor device accessory just solved its issue on its own.	The Gait Up GO mobile application can trigger a reset of the sensor device accessory without your intervention if it detects a problem.
The Physilog6 sensor device accessory is blinking yellow during the recording	The battery of the sensor device accessory is getting low	Complete the test, then recharge the sensor device accessory	During recording, the sensor device accessory normally blinks green. If the battery gets low, the blinking turns orange.

Table 7. Troubleshooting

When and how to perform a manual reset of the Physilog6 sensor device accessory

In case the Physilog6 sensor cannot be connected to the Gait Up GO mobile application, after controlling that the correct sensor is linked, that it has enough battery and is in proximity and after restarting the Gait Up GO mobile application, a reset of the Physilog6 device can solve the problem.

- Unplug Physilog6 if it is charging.
- Press the sensor button for 15 seconds, it will blink orange and beep.
- Release the button and wait until the blinking stops.

Customer Support

The customer support is provided by:

Gait Up SA
EPFL Innovation Park
Bâtiment C
CH-1015 Lausanne
Switzerland

Phone: +41 21 633 7527 (office hours: 8h30 to 17h30 CET, Monday to Friday)
General contact email: contact@gaitup.com
Email: support@gaitup.com

Reporting an adverse event

If any serious incident occurs that is directly or indirectly related to the use of Gait Up GO medical device, please report it immediately to the legal manufacturer (Mindmaze SA) and to the competent authority of your country and of where the Participant is established (if different).

7. WARRANTY

30 Days Return Policy:

If you are not satisfied with any Gait Up product that you have purchased directly from Gait Up you can return the product within 30 days following the date of shipment by Gait Up. If the item is returned unused, undamaged, and in its original condition we will exchange it or offer a refund of the purchase price paid. All returned products must be packed in the original packaging including any accessories, manuals, documentation, and registration that shipped with the product. Damage and missing part restocking fees may apply. Shipping and handling charges, as well as taxes paid (e.g., state, customs, VAT) are not refundable. You are responsible for and must prepay all shipping charges and you shall assume all risk of loss or damage to the product while in transit to Gait Up.

24 Months Limited Warranty:

Gait Up warrants all products sold or offered directly by Gait Up against defects in materials and workmanship under normal use for a period of 24 months from the date of retail purchase by the original purchaser ("Warranty Period"). Under this warranty, if a defect arises and a valid claim is received by Gait Up within the Warranty Period, at its option and to the extent permitted by law, Gait Up will either (1) repair the product at no charge, using new or refurbished replacement parts or (2) exchange the product with a new or refurbished product. A replacement product or part assumes the remaining warranty of the original product. To obtain warranty service, you must deliver the product at your expense, to the address specified by Gait Up. For specific instructions on how to obtain warranty service on your product contact Gait Up at support@gaitup.com. Gait Up does not warrant that the operation of the product will be uninterrupted or error-free and is not responsible for damage arising from failure to follow instructions relating to proper usage of the product. This warranty does not apply to a product or part of a product that has been altered or modified. In addition, this warranty does not apply: (a) to damage caused by use with non-Gait Up products; (b) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (c) to damage caused by operating the product outside of the permitted or intended uses described by Gait Up or with improper voltage or power supply; or (d) to damage caused by service (including upgrades and expansions) performed by anyone who is not a representative of Gait Up. Recovery and reinstallation of software programs and user data are not covered under this warranty.

Occasionally Gait Up engages in more interactive support or consulting. Interactive support is at customer courtesy and is provided at Gait Up's discretion. It does not invalidate the support policy described above. There is no guarantee of performance, timeliness, or establishment of a continuous support relationship. Consulting is subject to acceptance of a formal statement of work.

Warranty and Support conditions may change without prior notice. Please refer to the Sales terms and conditions on Gait Up's website.

8. DISPOSAL

The expected service life of the Gait Up GO medical device and all its accessories is 2 years of normal usage (300 assessment sessions per month under the specified operating conditions).

Disposal of Gait Up GO medical device (incl. all its accessories)

The Gait Up GO medical device is composed of electrical and electronic components such as the battery included in the Physilog6 sensor device.

In case of rejection, it is recommended to follow this procedure:

- Clean carefully the Physilog6 sensor device and the clip accessories following the cleaning procedure described under section 5
- Contact Gait Up SA customer support to get shipping information

Gait Up SA will take care of the treatment, collection, recycling and disposal of all the components of the Gait Up GO medical device.

9. TECHNICAL SPECIFICATIONS

9.1. Specifications

Gait Up GO medical device	
Regulatory Classification	MDD: Class I medical device according to Rule 12 of Annex IX 93/42/EEC
Size	Physilog6 sensor device: 43 x 33 x 15 mm Fixation accessories: ● shoe lace clip: 50 x 26 x 13 mm ● belt clip: 64 x 27 x 21 mm USB cable: length 50cm
Weight	Physilog6 sensor device: 0.015 kg Fixation accessories: ● shoe lace clip: 0.03 kg ● belt clip: 0.08 kg USB cable: 0.02 kg
Applied parts materials	Physilog6 sensor device casing: POLYLAC® PA-765 - Flame retardant acrylonitrile butadiene styrene (ABS) copolymer Clip accessories: CYCOLAC RESIN HMG94MD. Acrylonitrile Butadiene Styrene (ABS) for medical applications. USP grade IV. USB cable: PVC
Power source	Internally powered. Rechargeable battery. Lithium- Ion rechargeable battery 3.7V nominal.
Power plug	USB-C
Battery life	Number of recharging cycles > 500 cycles
User indicators	● Gait Up GO mobile application: User Interface ● Physilog6 sensor device: LED and beeper
Communications	Bluetooth Low Frequency (BLE). frequency band: 2.402-2.480 GHz (TX & RX) Effective radiated power (max): 11.11 dBm
Environmental conditions (use-transport-storage)	Use: ● Temperature:[0-30] °C ● Humidity:[10-70]% ● Pressure: [600-1070] hPA Storage: ● Temperature:[-20- +60]°C

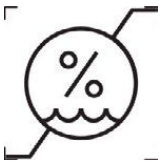
	● Humidity:[25-70]% ● Pressure: [600-1070] hPA Transportation: ● Temperature:[-20-60]°C ● Humidity:[25-70]% ● Pressure: [600-1070] hPA
Protection	IP64
Mobile phone charger	
Minimum specifications	● Input voltage: 100-240V AC, 50-60 Hz ● Output voltage: DC 5V 3A/9V 2A/12V 1.5A ● Efficiency: >85% ● CE-marked & ROHS compliant ● USB-A connection
Mobile Phone	
CISPR 32 compliant	Yes
RoHS compliant	Yes
Wi-FI connectivity	Yes
Bluetooth wireless communication	Bluetooth 4.0 or higher with BLE frequency of 128Hz or higher
Minimum screen size	4,7 inch
Minimum screen resolution	750x1334
OS	Android (7.0 or higher) and iOS (11.0.0 or higher)
Battery life	> 3 hours
Tablet	
CISPR 32 compliant	Yes
RoHS compliant	Yes
Wi-FI connectivity	Yes
Bluetooth wireless communication	Bluetooth 4.0 or higher
Minimum screen size	8 inch
Minimum screen resolution	1200x1920

OS	Android (7.0 or higher) and iOS (11..0.0 or higher)
Battery life	> 3 hours

Table 8. Technical specifications

9.2. Symbols

Symbol	Description
	Legal manufacturer
	Reference number
	CE mark
	Read Accompanying document
	Do not send the device or any of its accessories to a standard garbage
	Caution Logo
	Warning Logo

	Applied part logo
	Accepted humidity range
	Accepted temperature range
	Non-ionizing radiation
	FCC symbol (USA)
IC	IC symbol (Canada)
	Fragile; handle with care
	Storage logo keep away from sunlight
	Storage logo Keep away from rain

	Lithium battery handling label
	Device under prescription logo

Table 9. Symbols

9.3. EMI emissions

System Characteristics	Description
Function	Recording
Frequency (mHz)	2402-2480
Max. declared output power (dBm)	8
Max. antenna gain (dBi)	1
Max. E.I.R.P (dBm)	11.11
Max E.I.R.P (mW)	12.91

Table 10. EMI emissions

9.4. Guidance and manufacturer's declaration - Electromagnetic emissions

The Gait Up GO medical device has been developed for electromagnetic compatibility according to IEC 60601-1-2 international standard.

The Gait Up GO medical device is intended for use in the electromagnetic environment specified below. The user and/or end-user of the Gait Up GO medical device should ensure it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Gait Up GO medical device is a medical electrical equipment which uses RF energy only for its internal function. Therefore, its RF emissions are

		very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Gait Up GO medical device is intended to be used in home environment
Harmonic emissions IEC 61000-3-2	N/A	N/A
Voltage fluctuations/ Flockers emissions IEC 61000-3-3	N/A	N/A

Table 11. Electromagnetic emissions

9.5. Guidance and manufacturer's declaration - Electromagnetic immunity

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 15 kV Air +/- ± 2/4/8/15 kV Contact	+/- 15 kV Air +/- ± 2/4/8/15 kV Contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Note: Some ESD events might cause the unexpected reset of the Physilog6 sensor device. If after the unexpected reset, the device seems blocked, please perform a manual reset (see section 6.1)
Electrical fast transients/burst IEC 61000-4-4	Supply: ± 2 kV I/O lines : ± 1 kV Frequency : 100 kHz	Supply: ± 2 kV I/O lines : ± 1 kV Frequency : 100 kHz	USB cable must be the one provided by the manufacturer
Surges	N/A (DC supply with cable < 3m)		

IEC 61000-4-5			
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	N/A (DC supply)		
Frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50 or 60 Hz tested in X, Y and Z axes.	30 A/m, 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Radiated RF immunity IEC 61000-4-3	10 V/m @ 80MHz-2.7GHz 80% AM à 1kHz	10 V/m @ 80MHz-2.7GHz 80% AM à 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Physilog6 sensor device, including the USB cable, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Minimum separation distance shall be calculated by following equation: **E= (6/D)*sqrt(P)** Where: ● E is the immunity test level in V/m ● P is the maximum output power rating of the transmitter in watts (W) according to the transmitter

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>manufacturer and
● D is the recommended separation distance in meters (m) (b).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b)

Interference may occur in the vicinity of the equipment marked with the non-ionizing radiation symbol</td>
</tr>
<tr>
<td>Proximity fields emitted by RF wireless communication devices
IEC 61000-4-3</td>
<td colspan="3">
<table>
<tr><th>Frequency (MHz)</th><th>Modulation</th><th>Level (V/m)</th><th>Conformity level (V/m)</th></tr>
<tr><td>385</td><td>Modulation pulsée: 18 Hz</td><td>27</td><td>27</td></tr>
<tr><td>450</td><td>Modulation pulsée: 18 Hz</td><td>28</td><td>28</td></tr>
<tr><td>710 – 745 - 780</td><td>Modulation pulsée 217 Hz</td><td>9</td><td>9</td></tr>
<tr><td>810 – 870 - 930</td><td>Modulation pulsée: 18 Hz</td><td>28</td><td>28</td></tr>
<tr><td>1720 – 1845 - 1970</td><td>Modulation pulsée 217 Hz</td><td>28</td><td>28</td></tr>
<tr><td>2450</td><td>Modulation pulsée 217 Hz</td><td>28</td><td>28</td></tr>
</table>
</td>
</tr>
</table>

	5240 – 5500 - 5785	Modulation pulsée 217 Hz	9	9
Conducted RF immunity IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands, between 0,15 MHz and 80 MHz 80 % AM @ 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands, between 0,15 MHz and 80 MHz 80 % AM @ 1 kHz	If the measured field strength in the location in which the Physilog 6 is used exceeds the applicable RF compliance level, the Physilog 6 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Physilog 6 .	

Table 12. Electromagnetic immunity

Note (a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the Gait Up GO medical device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation of the Gait Up GO medical device.

Note (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m

9.6 Recommended separation distances between portable and mobile RF communications equipment bas the Gait Up GO medical device

Rated maximum output power of transmitter	80 KHz to 1000 Mhz outside ISM bands	1GHz to 2.7GHz outside ISM bands	2.7GHz to 6GHz outside ISM bands
	d=0.6*sqrt(P)**	d=0.6*sqrt(P)**	d=2*sqrt(P)**
0.01W	0.06	0.06	0.2
0.1W	0.19	0.19	0.63
1W	0.6	0.6	2
10W	1.90	1.90	6.32
100W	6	6	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres [m] can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

$$E = \frac{6}{d}\sqrt{P}$$

*The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765-6.795 MHz, 13.553-13.567 MHz, 26.957-27.283 MHz and 40.66-40.7 MHz.

**Formulas coming from the IEC 60601-1-2

9.7 FCC - Information to user

This document, which describes the instructions for use for an intentional radiator, cautions the user that changes or modifications not expressly approved by the Manufacturer could void the user's authority to operate the equipment.

[54 FR 17714, Apr. 25, 1989, as amended at 68 FR 68545, Dec. 9, 2003]

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.

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 instruction, 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 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 circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC human exposure limits

This device complies with FCC radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.
Caution: the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: The separation distance between the user and/or bystander and the antenna and/or radiating element of the device is of at least 20mm.

9.8 Product Compliance - IC statement

IC statement - English version

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication. This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. This device complies with Industry Canada radiation exposure limits set forth for general

population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- This device may not cause interference.
- This device must accept any interference, including interference that may cause undesired operation of the device.

IC human exposure limits - English version

This device complies with ISED radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Note: The separation distance between the user and/or bystander and the antenna and/or radiating element of the device is of at least 20mm.

Déclaration IC - Version Française

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante. Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement. Le présent appareil est conforme aux niveaux limites d'exigences d'exposition RF pour la population globale définies par Industrie Canada. L'appareil ne doit pas être installé à proximité ou être utilisé en conjonction avec une autre antenne ou un autre émetteur.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- L'appareil ne doit pas produire de brouillage;
- L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

IC Exposition humaine - Version française

Le présent appareil est conforme aux niveaux limites d'exigences d'exposition RF aux personnes définies par ISDE. L'appareil ne doit pas être installé à proximité ou être utilisé en conjonction avec une autre antenne ou un autre émetteur.

Note : La distance de séparation entre l'utilisateur et/ou le spectateur et l'antenne et/ou l'élément rayonnant de l'appareil est d'au moins 20 mm.

9.9 RF exposure compliance - Europe

Maximum RF Output power (11.11 (13mW) peak EIRP at Cmid, Tmax) of the equipment is under 20mW, and then test result is compliant without additional measurement. So, EN 62311 (2008) "low power / inherent compliance decision" is applied

10. ALPHABETICAL INDEX

11. Legal Manufacturer

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