Installation and Operating Manual

AXELERO GAIT&BALANCE |

Device for training gait pattern disturbances and balance

Manufacturer:	Service and repair:

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1. Introduction

Congratulations on making the right choice. We wish you satisfaction from operating AXELERO Gait&Balance training device for gait and balance pattern disorders. Please read this manual carefully. It contains important information and remarks from the manufacturer on correct installation, use and maintenance of the product. Hereinafter referred to as AXELERO G&B.

General information:

1. The product should be operated by qualified personnel who have read this manual.
2. Using, operation and servicing of the product in a manner inconsistent with this manual is not allowed and may result in damage that is the responsibility of the user and not the manufacturer.
3. If the operation and parameters of the product are inconsistent with the description contained in this manual, you may not use this product. Report it immediately to the manufacturer or supplier.
4. Product repairs must be carried out by the manufacturer's service or by a service authorized by the manufacturer.
5. A list of spare parts of the product and instructions on how to replace them is available from the manufacturer on request.
6. Any serious incident related to the AXELERO Gait&Balance training device must be reported immediately to the authority of the Member State in which the user or patient resides.

The warranty conditions will not be respected if the user misuses the product or fails to comply with the rules of use given in this Operating Manual.

The manufacturer is not responsible for the consequences resulting from improper (incompatible with the conditions specified in this Operating Manual) use of the AXELERO Gait&Balance training device.

2. Specifications of the AXELERO Gait&Balance training device

CAUTION!

The manufacturer reserves the right to make changes, not presented in the current version of the document, that will not cause deterioration of the functional conditions and safety of the product.

2.1 Intended Use

The AXELERO Gait&Balance training device is intended for use by patients with neurological and lower limb musculoskeletal system disorders. The device is used to determine gait parameters, balance disorders to support rehabilitation, alleviate the symptoms of diseases and the effects of injury or impairment. AXELERO G&B is used to train the gait symmetry, improve balance and overall motor skills of the patient. The device has a belt speed adjustment function and a posturographic plate installed under the running belt. The plate determines the position of the CoP (Center of Pressure) and allows to detect the presence of the patient on the device.

2.1.1 Users

The users of the AXELERO G&B product are:

- qualified medical personnel who have read this user manual;
- patients under the supervision of medical personnel.

The device is intended for use in hospitals, clinics, outpatient clinics, outpatient centers and specialized medical offices.

2.1.2 Intended target group

The AXELERO Gait&Balance training device is designed for training balance and stabilization of the body in patients qualified by a specialist physician. Patients can be 120 to 200 cm tall due to the range of adjustment of the handrail and weigh from 25 kg due to the stability of the strain gauges to the maximum permissible patient weight of 160 kg.

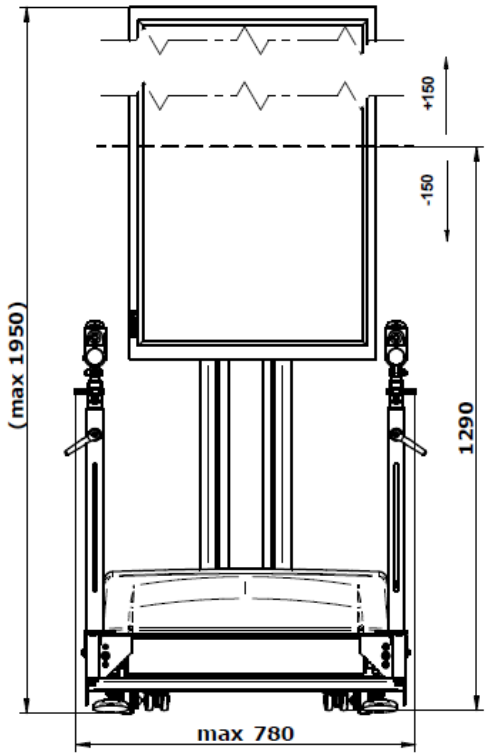
2.2 CE mark

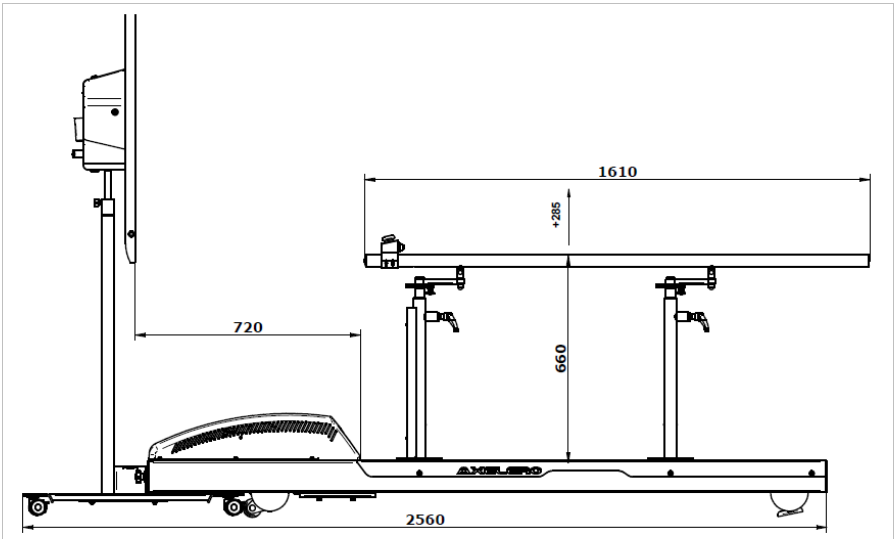
The AXELERO G&B training device for gait and balance disorders is made in accordance with the requirements of the European Parliament and the Council (EU) 2017/745 on medical devices (class 1, rule 13) and has the CE marking, in accordance with the manufacturer's declaration.

2.3 Symbols

	This indicates actions which may impair conditions or endanger the safety of the person training on the device and/or the personnel operating the device, if not carried out in compliance with this manual.
	Such marking is applied on the device where it is essential to read the Operating Manual and follow its recommendations when using the device.
	Applied part, type B
	Manufacturer
	In accordance with the provisions of the Act on Waste from Electrical and Electronic Equipment, it is forbidden to dispose of waste equipment marked with the crossed-out wheeled bin symbol with other household waste. Waste electrical and electronic equipment should be taken to the appropriate collection point. These statutory obligations were introduced in order to reduce the amount of waste generated from waste electrical and electronic equipment and to ensure an adequate level of collection, recovery and recycling of waste equipment. The proper implementation of these obligations is particularly important when there are hazardous components in the used equipment, which have a particularly negative impact on the environment and human health.
	Indication of the maximum safe load on the running belt
	Do not place feet under the device
	Description of the treadmill emergency stop button
ON/OFF	Marking of the device's mains switch position
	Medical Device

2.4 Technical Specifications

Technical Specifications	AXELERO Gait&Balance	
		
Dimensions	Length	2560 mm
	Max. width	780 mm
	Max. height	1950 mm



Dimensions	Width of the handrail	430 – 690 mm	
	Height of the handrail	660 – 945 mm	
	Monitor height (Center)	1290 mm	
	Diagonal length of the monitor	43"	
	Belt width	520 mm	
	Belt length	1400 mm	
Features	Belt speed adjustment range	0.2 – 10.0 km/h, resolution 0.1 km/h	
	CoP* indication range	ML – X-axis (medial – lateral)	AP – Y-axis (anterior - posterior)
		504 mm	990 mm
	Application part (running belt, handrails)	Type B	
	Patient weight	25 – 160 kg	
	Power supply	230 V 50 – 60 Hz 15 A	
	Unit protection class	IP20	
	Weight of the device	200 kg	

3. Device for training gait pattern disturbances and balance AXELERO Gait&Balance appearance and functions

3.1 Components

CAUTION!

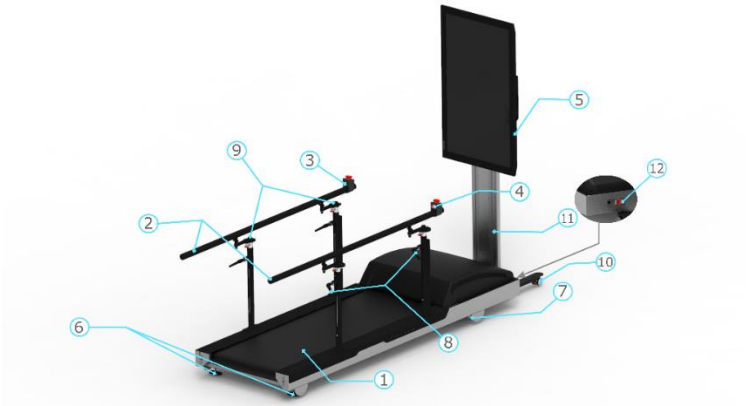
The manufacturer reserves the right to make changes to the design of the device which do not affect the basic requirements of functionality and safety.

CAUTION!

The illustrations in this manual are for reference only.

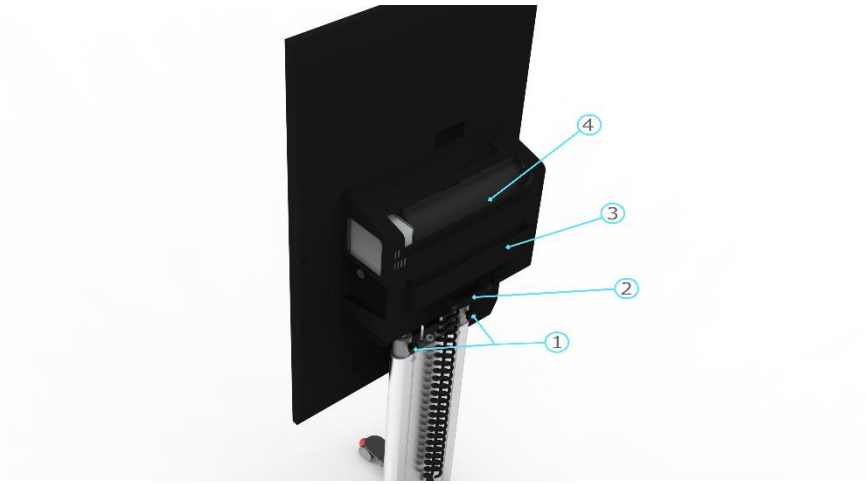
The construction of AXELERO G&B is made of powder coated steel profiles, running belt made of polyester fiber, polyvinyl chloride, plastic ABS and TPU.

The device consists of the following components:



1. Running belt (with built-up plate with strain gauge sensors).
2. Handrails (handrails with adjustable height and width).
3. Emergency STOP button with safety cord.
4. Emergency STOP button.
5. Monitor.
6. Feet (adjustable for levelling).
7. Wheels.
8. Handrail height adjustment locks.
9. Handrail width adjustment.
10. Wheels of the stand with a brake.
11. Computer and monitor stand.
12. Power switch.

Figure 1 – AXELERO Gait&Balance Components



1. Monitor height adjustment lock.
2. Monitor height adjustment handle.
3. Keyboard pocket.
4. Tablet compartment.

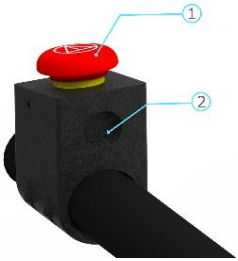
Figure 2 – Computer and Monitor Stand (rear view)

Distinctive features of the AXELERO G&B device:

- robust construction with handrails;
- low suspension of the running belt that facilitates access to the device;
- running belt with built-up strain gauges;
- a special running belt for the device with an alignment mechanism;
- smooth and quiet drive operation in the full belt speed range;
- a system for the smooth increase of the belt speed during take-off;
- accurate increasing and decreasing the speed of the belt movement;
- emergency stop safety cord of the belt clipped to the patient's clothing;
- emergency stop buttons on both sides of the device accessible to the medical personnel, enabling manual interruption of operation and switching off the drive in an emergency;
- acoustic signal after pressing the emergency stop button of the treadmill;
- acoustic signal of the running belt stop as a result of detecting an internal failure of the product;
- easy cleaning and maintenance.

3.2 Safety cord

On the left handrail there is an emergency STOP button with a safety cord socket. Plug the safety cord pin into the safety cord socket.



1 – Emergency STOP switch

2 – Safety cord socket

Figure - 3 - Emergency STOP Switch with Safety Cord

The safety cord is equipped with a regulator to change its length. The clip is used to attach the safety cord to the patient's clothing.

1 – Safety cord pin

2 – Regulator

3 – Hook

Figure 4 - Safety cord

3.3 Wireless remote control

1 – LED Indicator

2 – STOP button

3 – Protective case

4 – Arrow buttons (up/down/ left/right) and green confirmation button

5 – Wrist strap

Figure 5 - Wireless Remote Control (front view)

6 – Battery 3V CR2032

7 – Battery cover

Figure 6 - Wireless Remote Control (rear view)

The remote control can be used to control training parameters and the information displayed on the screen or navigate through the menu. The remote control has 6 buttons: up/down/left/right arrows, a green confirmation button and a functional training STOP button. For details, please refer to Neuroforma Gait&Balance Software User Manual.

Silicone protective case provides a secure grip and protects the remote control from the effects of falling. The special tabs on the STOP button and the green button facilitate orientation on the remote-control keyboard.

The power supply is a disposable, replaceable lithium battery with a 3V voltage and the designation CR2032. To replace the battery:

1. Remove the protective case.
2. Remove the battery cover on the back of the remote.
3. Replace the battery with a new one.
4. Close the battery cover.
5. Put the protective case on.

The LED indicator informs the user about the remote control's operating status in accordance with the following table:

LED color	orange	low battery, recommended replacement
	green	battery replacement not required
Time Between Flashes	2 s.	connecting
	5 s.	successful connection
	0.5 s.	pairing mode

Table 1 – Remote control LED indicator

The first time any button is pressed, the remote-control switches on and automatically attempts to establish a connection. If the connection is not established within 30 seconds, the remote control will switch off. After a period of inactivity (no button pressed) for more than 30 minutes, the remote control switches off automatically.

The pairing mode is activated by pressing and holding the left and right arrow buttons until the LED indicator starts flashing 2 times per second. The remote control will be visible to the computer under the name Axelero Remote. To pair it with a computer, follow the standard procedure for adding a wireless keyboard/mouse/headset device.

3.4 Tablet

CAUTION!

After the first star of the device, it is recommended to change the network password in the computer settings.

CAUTION!

After changing your password, you must update the password saved on your tablet.

The tablet is intended for use by personnel. It is used by personnel to select a user account, set the training goal and its initial parameters. During the training, the personnel have the opportunity to view the current gait parameters.

The tablet connects to your computer via 2.4GHz wireless Wi-Fi. The computer provides a wireless network called "Axelero Gait&Balance" and the default password "meden123".

3.5 Accessories and additional equipment

Full equipment includes:

1. Treadmill with posturographic plate.
2. Computer stands.
3. Monitor.
4. Wireless remote control.
5. Safety cord.
6. Tablet.
7. Neuroforma Gait&Balance Software.
8. User manual with a warranty card.

The AXELERO Gait&Balance for training device for training gait pattern disturbances and balance is designed to work with the ELEVEO dynamic patient lift.

3.6 Transportation

The AXELERO G&B is transported to the customer in a cardboard box on a pallet. It is allowed to stack the device for transport in a maximum of three layers on specially prepared pallets. Transport should not be carried out in conditions exceeding those given in the table below:

Environmental conditions			
	Operation	Storage	Transportation
Ambient temperature	10 - 40°C	5 – 45°C	-10 – 45°C
Relative humidity, non-condensing	30 – 75%	< 75%	20 – 95%
Atmospheric pressure	700 – 1060 hPa		

Table 2 – Optimal environmental conditions for AXELERO Gait&Balance

4. Safety measures

CAUTION!

Never jump on a moving treadmill. The running belt must be stopped in order to start exercising. Do not jump off a moving treadmill. The patient must step off the motionless belt at the end of the training.

CAUTION!

Medical personnel are required to inform the patient of the possibility of dizziness and imbalance as a result of prolonged exertion. If the patient reports such symptoms, the training should be stopped immediately.

CAUTION!

Do not leave items of clothing, towels, footwear near or on any part of the device (particularly on the handrails, the mechanism cover and the running belt) - them being drawn in by rotating parts may cause damage to the mechanisms and/or fall of a person on the device

CAUTION!

The AXELERO Gait&Balance for training gait pattern disturbances and balance has a limited load capacity. The patient's weight during exercise should not exceed the maximum safe load of the device.

CAUTION!

The state of the running belt stopping as a result of the detection of an internal failure of the device by the control system is signaled by a series of beeps, the number of which corresponds to the error code (information for service).

CAUTION!

Do not hold on to the handrails for longer than 60 minutes due to the accompanying vibrations during the training.

The following points must be adhered to when using the device:

1. Press the ON/OFF button, to start the machine.
2. The patient performing the training should be dressed in appropriate clothing, without loose, overhanging elements that could get entangled in the moving parts of the device.
3. The patient should always have a safety cord attached to the clothing.
4. The height and width of the handrail should always be adapted to the patient's individual needs.
5. The patient should always wear full footwear, must not have heels and soles should not slip on the surface of the belt.
6. Step onto the running belt facing the handrail and only when the belt is still (stopped motion).
7. Make sure to remove any rings, chains, brooches, or other similar ornaments before starting your workout or test.
8. The device has moving parts. Personnel supervising the training should keep a safe distance.

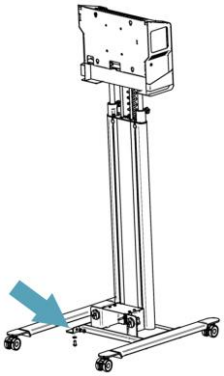
5. Preparation for use

5.1 Assembling and disassembling the monitor stand

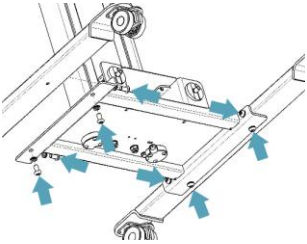
CAUTION!

Before installing or removing the stand, switch off the appliance and disconnect the power cord from the mains socket.

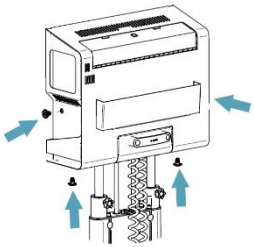
To assemble the stand, prepare screws with washers and allen wrenches (nr 5 and 6).



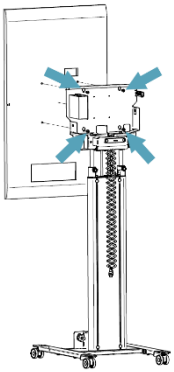
1. Set the feet of the stand in the position shown in the picture.



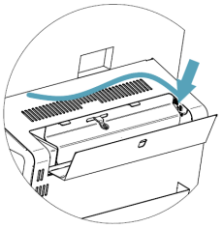
2. Tighten the screws and washers in the places indicated in the picture. Place the stand on the feet and lock them.



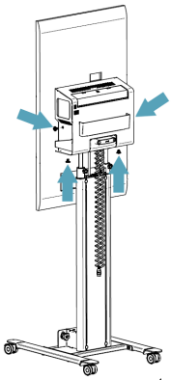
3. Remove the monitor cover by unscrewing the screws marked on the picture.



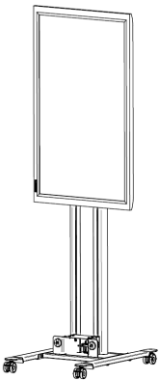
4. Screw the monitor to the stand so that the bottom of the display is on the left side (looking at the screen). The screws are pre-screwed into the stand.



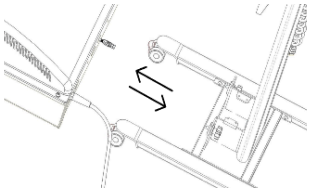
5. Open the cover with the key provided with the device. Route the USB cable under the cover so that it exits at the point marked on the figure.



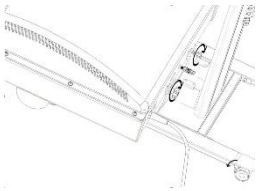
6. Tighten the screws securing the cover and connect the power cord and HDMI cable to the HDMI1 input of the monitor.



7. View of a correctly mounted monitor.



8. Unlock the wheels of the stand. Drive the stand up to the device. Plug in the wires.



9. Using the knobs, screw the stand to the treadmill. Lock the wheels of the stand.

Perform the above steps in reverse order for disassembly.

5.2 Initial start

Turn the power on by pressing the switch to the ON position. The computer and monitor turn on automatically. The Neuroforma Gait&Balance software will start when the operating system is started. The therapist panel is then displayed.

The first run requires the user to activate the program. To do this, open the therapist panel on the tablet, enter the serial number of the device. Then fill in your contact details along with the activation code included in the product. The serial number can be found on the warranty card and on the product label. Example of the serial number: 06474-2021.

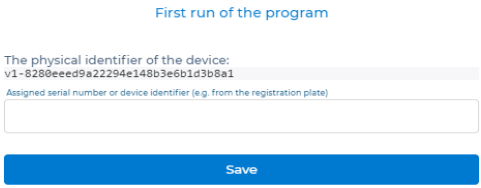


Figure 7 - First Run of the Program

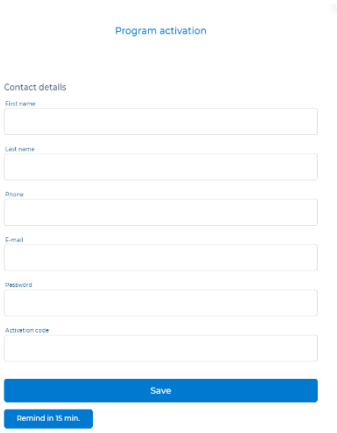


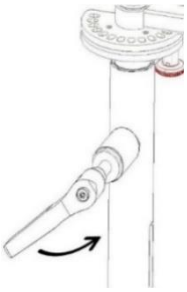
Figure 8 – Program Activation

6. Adjusting the device to the patient's needs

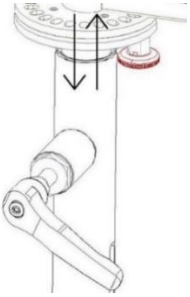
The AXELERO Gait&Balance for training gait pattern disturbances and balance is equipped with height- and width-adjustable handrails and a height-adjustable monitor.

6.1 Handrail height adjustment

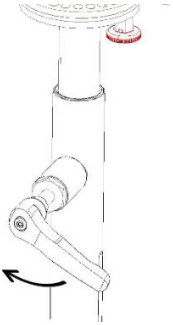
To change the height of the handrail, hold the handrail with one hand and release both height adjustment locks by turning them counterclockwise. Then set the desired height. Lock the handrails by turning the locks clockwise. Repeat for the second handrail.



1. Hold the handrail with one hand and release both height adjustment locks by turning them counterclockwise.



2. Set the desired height.



3. Lock the handrails by turning the locks clockwise.

Figure 9 – Handrail Height Adjustment

6.2 Adjusting the width of the handrail

The width adjustment of the handrail is equipped with a step adjustment mechanism to ensure stability during training.

1. Pull down the locking pin and turn it slightly so that it does not return to its original position.

2. Preset the desired width.

3. Turn the pin in any direction until it jumps into place. Change the width of the handrail until it locks.

Figure 10 – Handrail Width Adjustment

6.3 Adjusting the monitor position

To adjust the monitor height, hold the monitor handle with one hand, and loosen the monitor height adjustment knobs with the other hand by turning them counterclockwise. Adjust the expected height of the monitor and lock the adjustment mechanism by turning the knobs twice in the opposite direction.

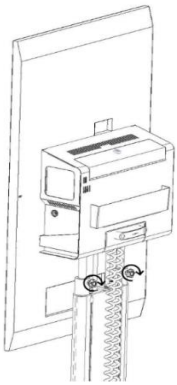


Figure 11 – Monitor Height Adjustment

6.4 Adjusting the length of the safety cord

CAUTION!

⚠ The length of the safety cord must be set after adjusting the height of the handrail.

The safety cord is equipped with a regulator that allows to change its length depending on the individual characteristics of the patient. This makes it possible to adjust the safety cord in such a way that the patient's exit from the work area or a fall causes it to disengage from the socket and stop the running belt. The length of the safety cord should be set after adjusting the height of the handrail.

7. Description of the treadmill emergency stop button

CAUTION!

Recovery of the emergency stop button or voltage return after a power failure is signaled by a single tone, repeated intermittently every 1.5 seconds.

CAUTION!

An acoustic signal is activated when there is no safety cord or when the emergency stop button of the treadmill is pressed.

The manufacturer of AXELERO Gait&Balance for training gait pattern disturbances and balance has made every effort to ensure maximum safety for the patient and personnel when using the device for its intended purpose. In case of overstraining the patient during training, e.g., as a result of incorrect assessment of the physical condition and capabilities of the body or in other unforeseen circumstances, there may be a sudden need to stop the test or training. This is enabled by the emergency stop button, which disconnects the supply voltage from the drive and stops the running belt when pressed. Restarting the device is possible after releasing (unlocking) the emergency stop button.

If the safety cord is removed from the safety cord socket as a result of excessive cord tension, the power supply will be disconnected and the belt will stop. It is possible to restart the device after reinserting the safety cord into the socket.

8. Operation of the AXELERO Gait&Balance for training gait pattern disturbances and balance

The AXELERO G&B is operated by both the therapist and the patient.

The therapist's panel is operated by medical personnel who have read the manual. **The patient panel** is operated by the patient using a wireless remote control. The patient should be instructed by the personnel on how to use the **Patient Panel**.

During exercise, the patient should wear sports shoes and clothing that does not restrict movements. Before the patient enters the treadmill, set the handrails at a height and width appropriate to the patient and adjust the height of the monitor to the patient's height.

The tablet is used to operate the device by medical personnel. The tablet connects to your computer via a wireless connection. Medical personnel using the app on the tablet selects (or adds a new) patient account and sets the parameters for the workout. During the training, the personnel and the patient can view the gait parameters on their screens. Depending on the configuration in which the platform is used and the patient profile, the therapist selects the appropriate test, training or exercise.

8.1 Icon explanation

delete patient

patient details

interface language

therapist account menu

8.2 Patient Panel

The patient panel is operated by a wireless remote control. The direction buttons allow you to navigate between the options displayed on the screen. The green button on the remote control, located between the directional buttons, confirms the selection. The red stop button on the remote control stops the training. When you use the software, the screen displays tips to help you navigate the app.

Figure 12 – Button arrangement on the remote control

8.2.1 Patient's choice of training

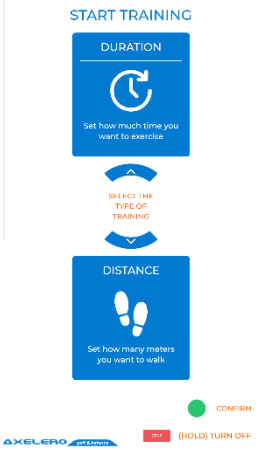


Figure 13 - Training Selection Screen

The patient can choose between two workouts:

- time-measured training;
- distance training.

Time-measured training ends after a certain amount of time. The **distance training** is carried out until the set number of meters has been reached. The selection is made using the direction buttons corresponding to the arrows on the screen.

Figure 14 - Parameter setting screen, e.g. duration

After selecting the training, set its parameters:

- the initial speed of the treadmill in km/h;
- the training time in minutes in the case of time-measured training;
- training distance in meters in the case of distance training.

8.2.2 Training Screen

Confirmation of the set parameters displays the countdown screen until the beginning of the exercise. When the countdown is complete, the current training information will be displayed on the screen.

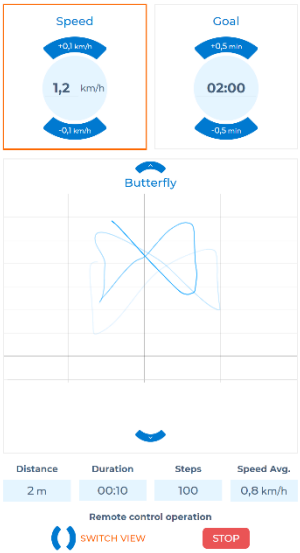


Figure 15 - Screen displayed during training with the "Speed" parameter marked and the "Butterfly" graph

The screen displays the training parameters, i.e. the time or distance remaining and the current speed, a graph of the training course in the form of a butterfly or the symmetry of the gait pattern, the distance travelled, time, number of steps or average speed.

8.2.3 Modification of training parameters

During the training, it is possible to modify the selected parameters at the beginning of the training: target (time/distance) and speed. Use the directional buttons to select the area with the parameter to be changed. The currently selected parameter has an orange frame.

8.2.4 "Butterfly" Graph

The first graph displayed on the screen is the **Butterfly** graph. It shows the change in CoP over time. The intensity of the blue color in the graph indicates the time at which the recording was created. The less intense the color, the older the record. The intersection of the bold grey lines in the graph determines the center of the running belt.

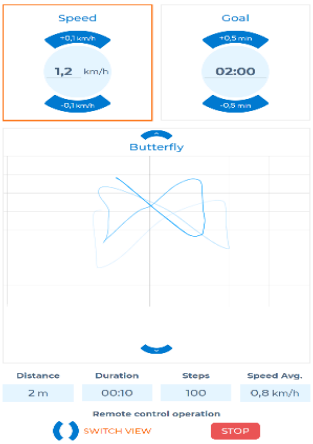


Figure 16 - The "Butterfly" Graph

8.2.5 Indications of gait pattern symmetry

Gait pattern symmetry indications are also available for stride length, mean load, maximum load, support phase time, or transfer phase time. The selection can be displayed using the directional buttons. To do this, select the central area, then use the up and down buttons to select the parameter of interest.

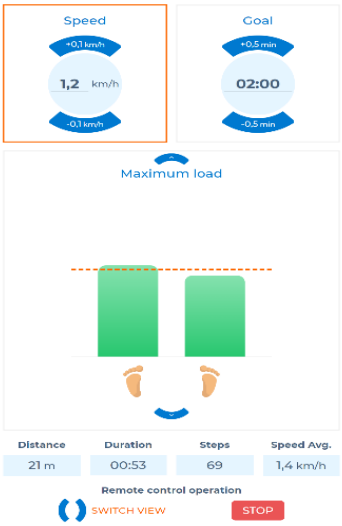


Figure 17 - Gait pattern symmetry screen showing the distribution of maximum load

8.2.6 Goal Progress Screen

In addition to the gait waveform graphs, the progress of the currently set target (time or distance) is also displayed. Similarly, to choosing the gait pattern symmetry indication, the operator selects the central area and then presses the up or down arrow until the screen shows the goal progress.

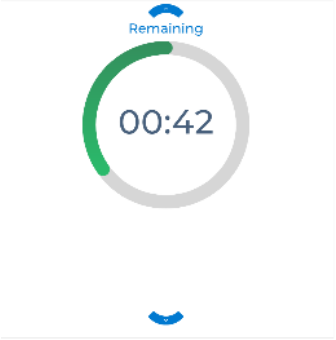


Figure 18 - Goal Progress Screen

8.2.7 Other parameters

Regardless of the training stage, the basic parameters of your training are displayed at the bottom of the screen:

- distance – the distance travelled in meters;
- time – in minutes and seconds from the start of the training;
- steps – the number of steps from the beginning of the training;
- average speed – average speed of movement during training.

8.2.8 Summary Screen

When the target is reached or the red button on the remote control is pressed, the screen will display information about the completed training. The summary displayed on the screen shows the duration of the training in minutes and seconds, the distance travelled in meters and the number of steps made. Pressing the green button on the summary will return you to the parameter selection screen.

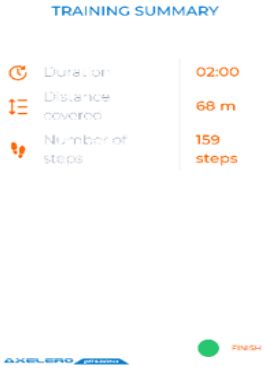


Figure 19 - Training Summary Screen

8.2.9 Disabling the PC from the Patient Panel

Once you have completed your planned workout and approved the summary, the workout selection screen reappears. The patient can switch off the device by pressing the STOP button on the remote control.

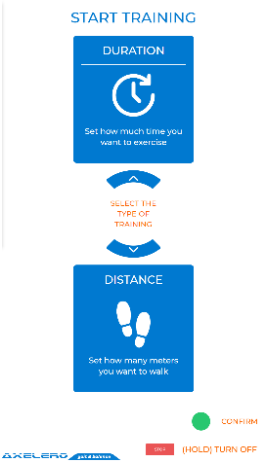


Figure 20 - Training Selection Screen – Switching off the computer from the patient panel

8.3 Therapist Panel

Neuroforma Gait&Balance software has a touch panel dedicated to the therapist's work. It is accessible from the tablet attached to the AXELERO G&B device. On the desktop of the tablet screen there is the "Neuroforma G&B" icon that runs  the program.

8.3.1 Login

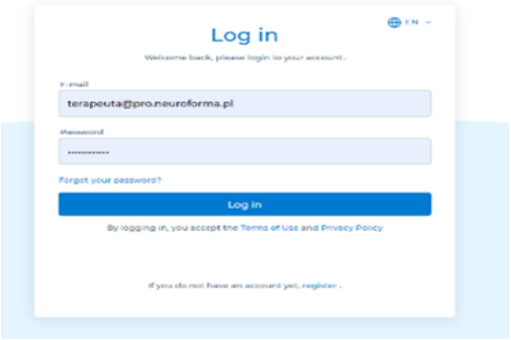


Figure 21 - Login Screen

In order to ensure the confidentiality of patient data, each access to the patient list requires the therapist to log in. The data for the first login will be provided together with the AXELERO G&B device. To register a new therapist, select **Register** and follow further instructions. After entering the correct data and pressing the **Log In** button, a list of patients will be displayed.

8.3.2 Patient List

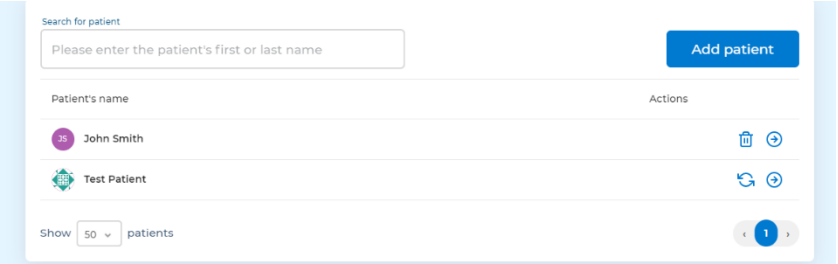


Figure 22 – Patient List

After logging in, you must create a new patient or select an existing one from the list. You can add a new patient by pressing the **Add Patient** button and entering the patient's details. You can filter the list of patients by typing the patient's name and surname in the "Search Patient" field. The search takes place on an ongoing basis. The selection from the list is made by clicking on the name or icon. You can also delete the selected profile from the patient list by pressing the icon. Selecting a patient opens the **Patient Profile** tab.

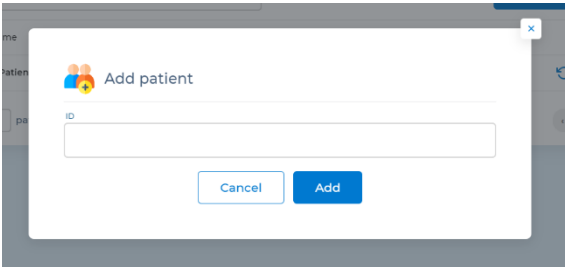


Figure 23 - Add Patient Window

8.3.3 Patient Profile

The patient profile contains information about the selected user, such as the date the account was created, the date of the last exercise, and the distance/time the exercise was completed in the last week and month.

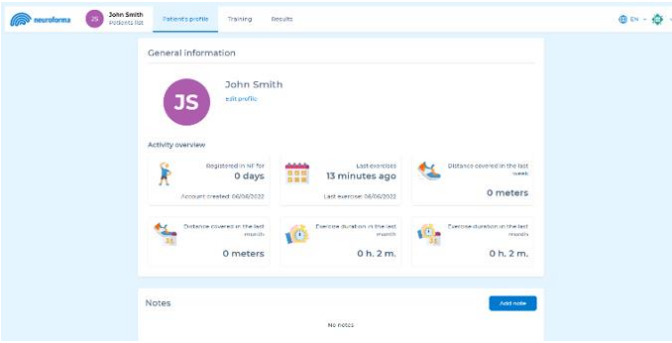


Figure 24 – Patient Profile Screen

8.3.4 Editing Patient Data

You can change the patient data by clicking the **Edit Profile** button under the patient ID. Then confirm the changes with the **Save** button.

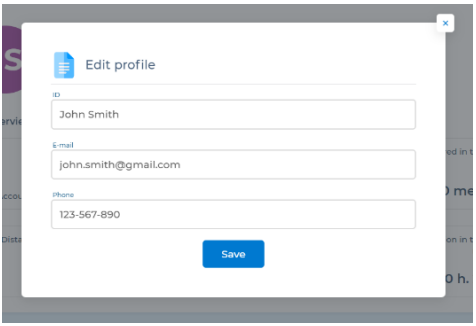


Figure 25 - Patient Data Edit Screen

8.3.5 Adding Notes

At the bottom of the Patient Profile screen, you can find **Notes**. The therapist can post information in a text form. Adding a note is done by pressing the **Add a note** button on the patient's profile, entering its content and confirming or cancelling the changes.

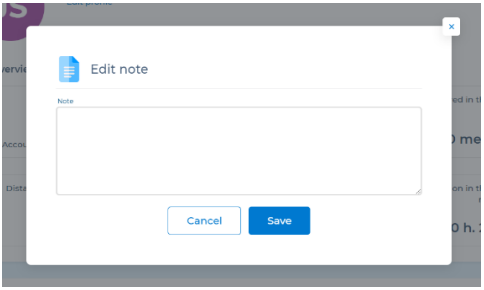


Figure 26 - Add Notes Screen

8.3.6 Training

The **Training** tab is located at the top of the application. It is divided into two segments. Top – gait training, allows you to set the training parameters: the type of target the patient will aim at during training, the value of the target, i.e. the time in minutes and seconds or the distance in meters, the initial speed in km/h with which the running belt will move. Once the parameters have been set, clicking on **Run** will start the workout and show a screen with workout analysis.

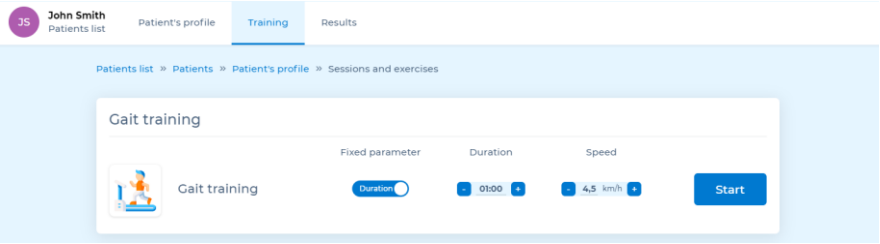


Figure 27 – Training Tab – Top Segment

The analysis of the training course allows you to read the results obtained during the exercises and edit the parameters. In the upper left corner of the screen, you will find information about the current workout, the distance travelled, the time and the number of steps taken. Below it is possible to change the parameters of the ongoing training, save data and stop the training session. The form of presentation of the training course depends on the selected tab at the top of the screen. The available tabs are **Butterfly, Path, Symmetry, Analysis, Statistics**.

Bottom segment - tests and exercises, allows you to choose exercises and tests that can be performed using AXELERO G&B.

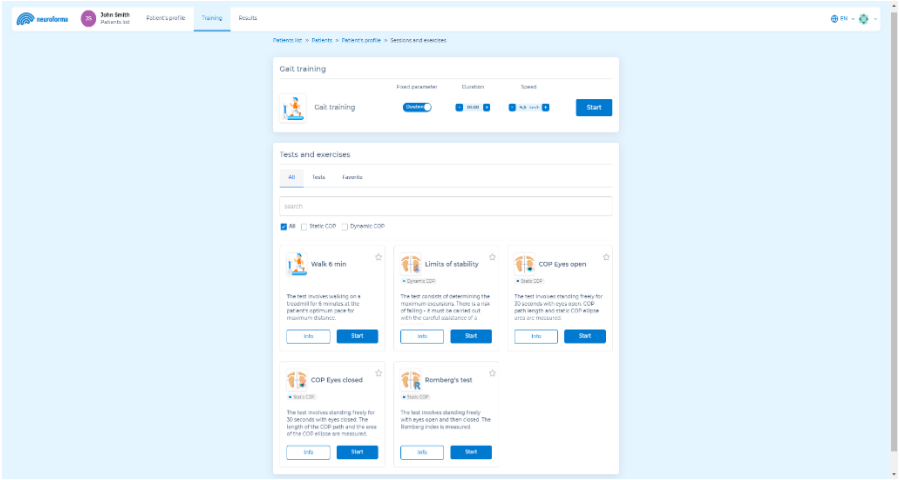


Figure 28 – Training Tab – Bottom Segment

8.3.6.1 Gait Pattern Representation – Butterfly

The representation of the **Butterfly** gait pattern shows the change in the center of gravity over time. The intensity of the blue color in the graph indicates the time at which the recording was created. The less intense the color, the older the record. The intersection of the bold grey lines in the graph determines the center of the running belt.

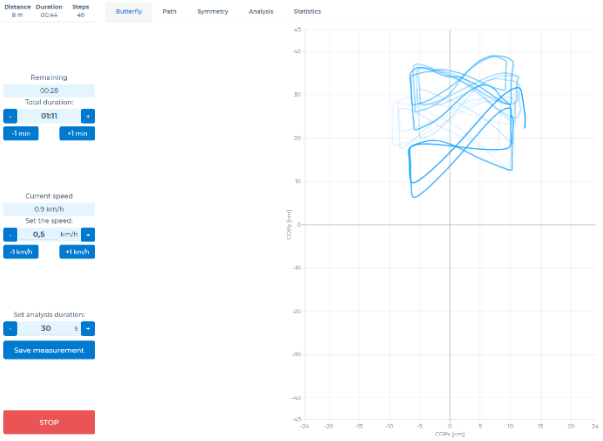


Figure 29 - Training Course – Butterfly

8.3.6.2 Gait Pattern Representation – Path

The gait pattern tab **Path** shows the graph of changes in the center of gravity showing it in relation to the moving running belt.

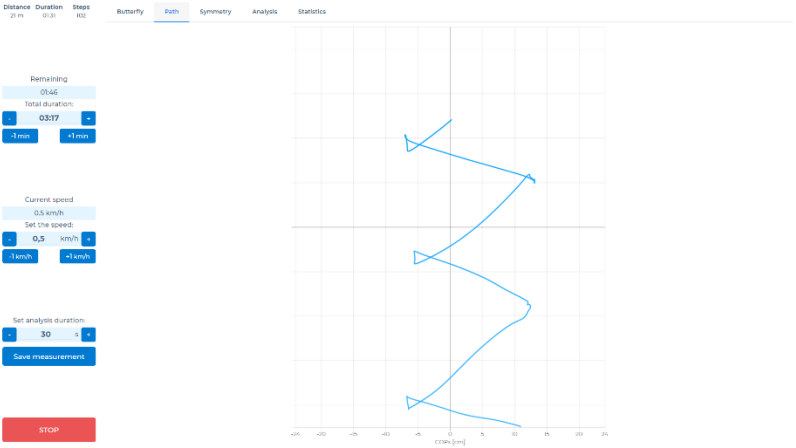


Figure 30 - Training Course – Path

8.3.6.3 Gait Symmetry Representation

The **Symmetry** tab shows any occurrences of asymmetry between the left and right legs for different gait parameters:

- stride length;
- medium load;
- the maximum load;
- time of the support phase;
- time of the transfer phase.

Parameter	Asymmetry
Stride length	39,1% →
Average load	← 0,1%
Maximum load	0,5% →
Stance duration	8,1% →
Swing duration	← 34,9%

Figure 31 - Training Course – Symmetry

8.3.6.4 Data Analysis

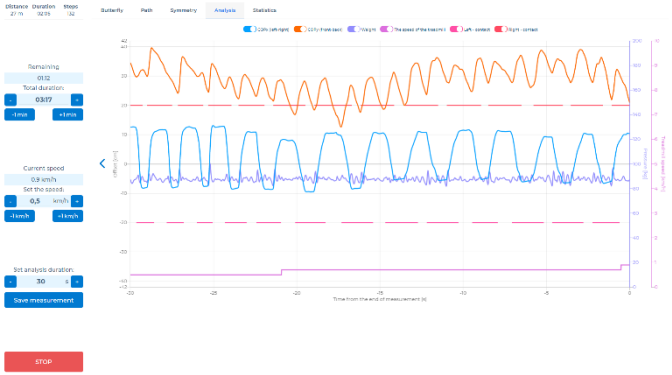


Figure 32 - Training Course – Analysis

The Analysis and **Statistics** tabs present and summarize the course of training in the form of a graph and a table with parameters. In the **Analysis** tab, the graph shows the current and past data for:

- CoP in the x-axes (left/right) and y-axes (front/rear);
- pressure on the running belt;
- treadmill speed;
- contact of the left and right legs with the running belt.

The **Statistics** tab shows a table with averaged gait parameters. Where possible, split into left and right legs.

Data collected in Data Analysis and Statistics cannot be used for diagnostic purposes.

Parameter	Page	Value	Asymmetry
Length of the analysis		00:30	
Stride length	Left	0,19 m	
	Right	0,42 m	+54,8%
Average load	Left	87,0 kg	+0,5%
	Right	86,6 kg	
Maximum load	Left	91,8 kg	+2,2%
	Right	89,8 kg	
Stance duration	Left	1,36 s	
	Right	1,69 s	+19,5%
Swing duration	Left	0,57 s	+7,0%
	Right	0,53 s	
Cadence		44,0 spm	
Step width		0,15 m	
Number of steps	Left	11	
	Right	11	+22
Distance covered		9 m	

Figure 33 - Training Course – Statistics

8.3.6.5 Saving Data

Regardless of the selected tab, you can save data from the selected period of time in the **Training** tab. After the set time for **Show last data** has elapsed, press **Save this data**. The saved data is available in the **Results** tab described later in the manual.

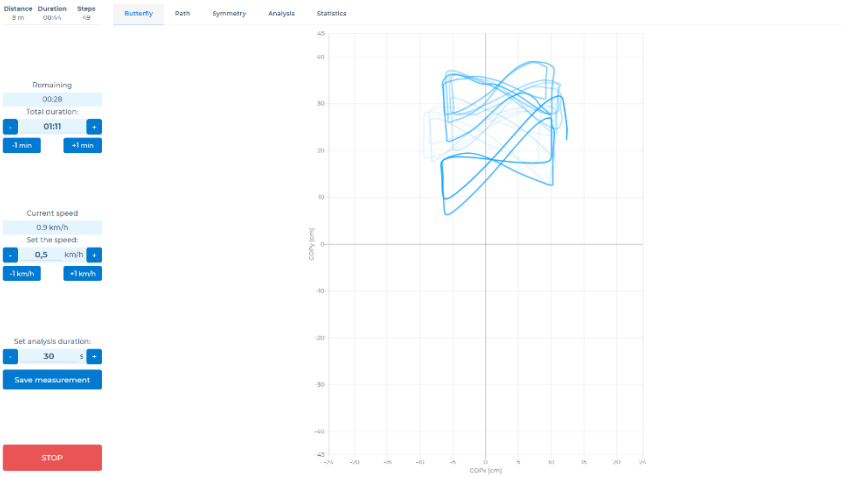


Figure 34 – Recording training progress data

8.3.7 Tests

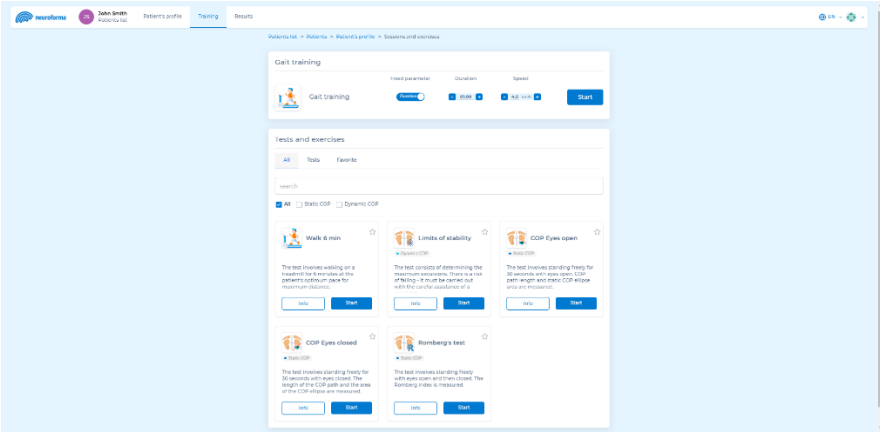


Figure 35 – Test Selection

The **Tests and Exercises** tab allows you to perform one of five tests that will help you check the progress of your previous therapy. The following tests are available:

- 6-minute patient gait record;
- maximum deflection of the centre of gravity;
- **CoP eyes open/closed** recording changes in the patient's CoP position with eyes open or closed;
- **A Romberg test** that records CoP changes with the eyes open and then closed.

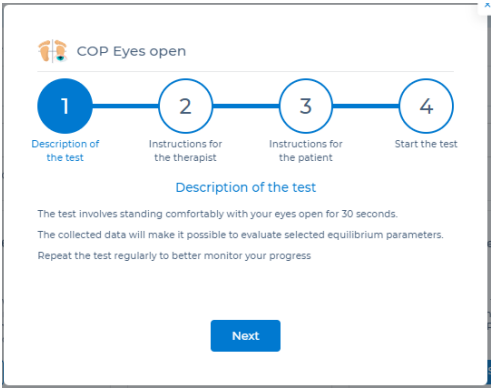


Figure 36 - Starting the Test

Each test has an **Information** button leading to a detailed description of the test. Starting the test opens a window describing the test and containing instructions for the therapist and the patient. The patient instructions enabled on the therapist screen are displayed at the same time in the patient panel. Clicking **Next** takes the user to the further screens of the test process until it starts. After completing the test, a summary is displayed in the therapist's panel to record the results. The only way to run the tests is through the therapist panel.

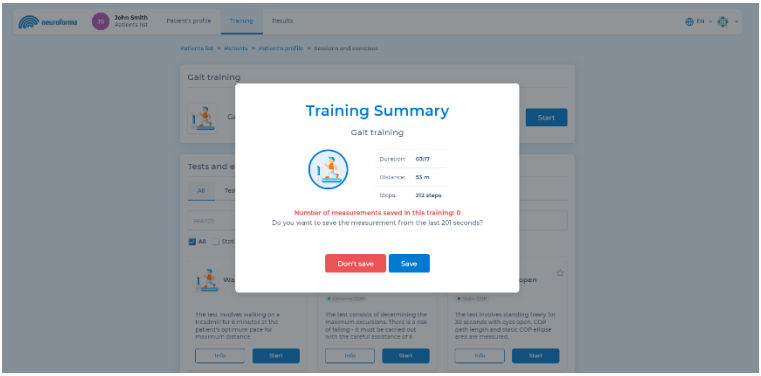


Figure 37 - Test Summary

8.3.7.1 6-Minute Patient Gait Training

The test involves walking on a treadmill for six minutes at the patient's optimum pace, for the longest possible distance.

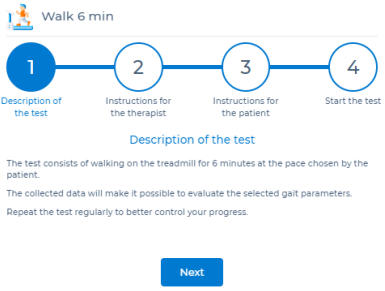


Figure 38 - Instructions for the therapist 6-Minute Gait Training

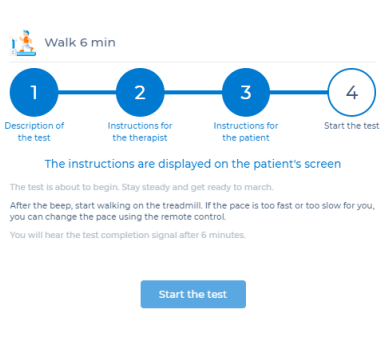


Figure 39 - Patient Instructions 6-Minute Gait Training

8.3.7.2 Limits of stability

The test consists in determining the maximum deflections of the center of gravity. The test should be performed with the assistance of the therapist.

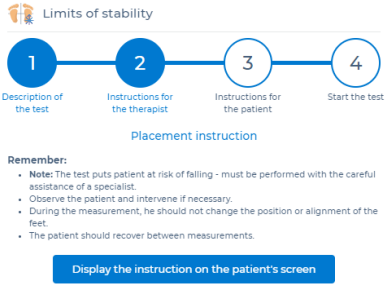


Figure 40 - Instructions for the therapist Limits of stability

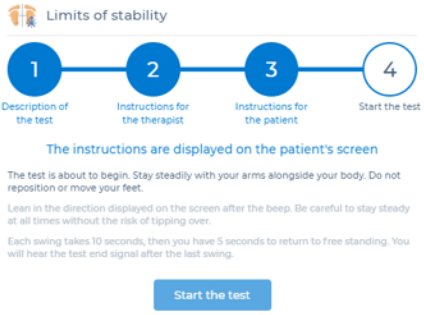


Figure 41 - Patient Instructions - Limits of stability

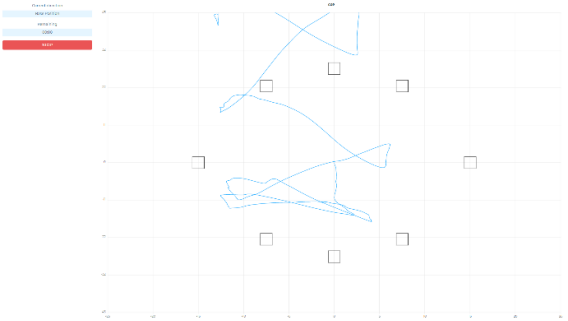


Figure 42 - View of the running test in the Therapist Panel

8.3.7.3 CoP Eyes Open

The test consists of standing freely for 30 seconds with your eyes open. The length of the CoP path and the CoP ellipse field are indicated. The patient panel displays a red dot on which the patient should focus his/her eyesight.

During the test, a graph is opened in the therapist's panel with the sensor indications in the form of the CoP ellipse field.

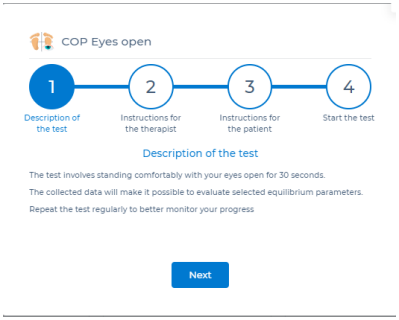


Figure 43 – Instructions displayed in the CoP Eyes Open Therapist Panel

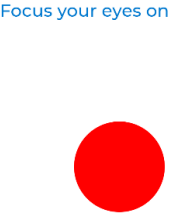


Figure 44 - View of the running test in the Patient Panel

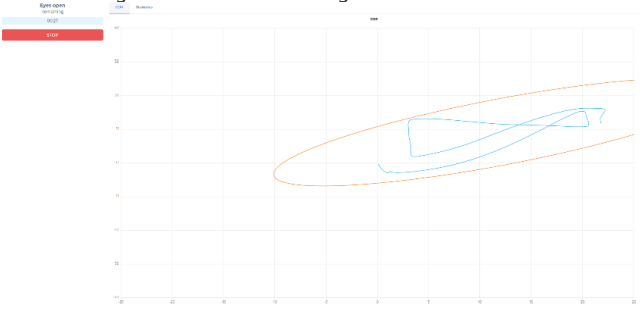


Figure 45 - View of the running test in the Therapist Panel

8.3.7.4 CoP Eyes Closed

The test consists of standing freely for 30 seconds with your eyes closed. The length of the CoP path and the CoP ellipse field are indicated. The patient panel displays a message to the patient to close their eyes. During the test, a graph is opened in the therapist's panel with the sensor indications in the form of the CoP ellipse field.

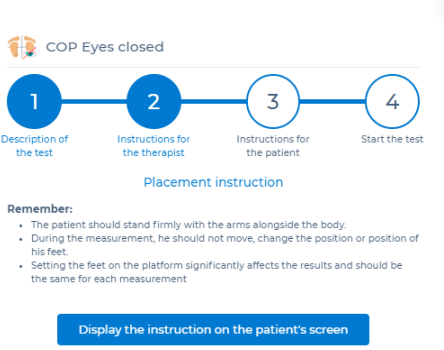


Figure 46 - Instructions for the therapist CoP Eyes Closed

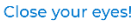


Figure 47 - View of the running test in the patient panel

8.3.7.5 Romberg's Test

The test consists of standing freely, first with eyes open for 30 seconds and then with eyes closed for another 30 seconds. This test determines the Romberg's coefficient, which is the ratio of the magnitude of the parameters obtained in tests conducted with the eyes open to the magnitude of the parameters obtained in tests conducted with the eyes closed. During the test, the patient receives a command on the screen to focus on the dot and then close the eyes. The coefficient is presented in the form of a graph in the therapist's panel.

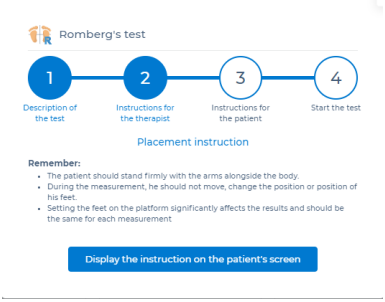


Figure 48 - Instructions for the therapist the Romberg's Test

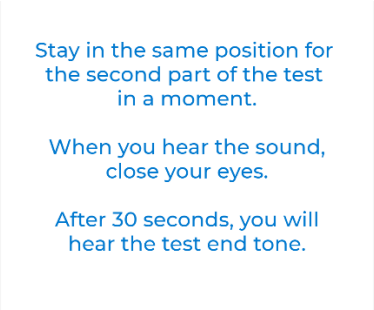


Figure 49 - Instructions displayed in the Patient Panel during the Romberg's Test

8.3.8 Outcomes

The **Results** tab allows you to check the patient's activity. From this tab it is possible to read the results of completed training and tests.

8.3.8.1 Activity Summary

The **Activity Summary** displays statistics. At the top of the screen, you will find information about the activity during the period. Below the header with information about the period, there is an activity graph. Select what information should appear on the graph from the tabs at the top:

- total exercise time – time that was spent in all exercises together;
- number of launched exercises – the number of individual launches of exercises;
- number of steps – the number of steps performed in a given period.

Below the graph there is a list of launches from a given period. In addition to the date and type of training, information about the data saved for a specific activity and its duration is displayed.

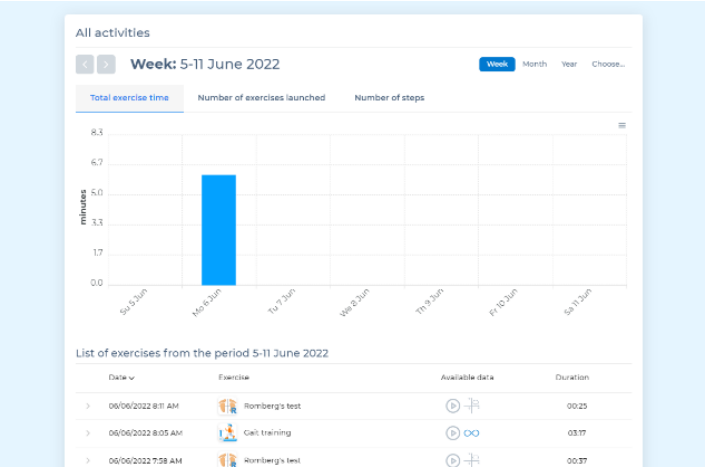


Figure 50 - Activity section

The **Achievements** tab is located at the bottom of the screen. At the top of the screen, you set the period for which achievements are to be presented. On the left side of the screen, select the test or exercise for which the data will be displayed. On the right side there is a graph. The icons above the graph change the view of individual elements of the graph.

Below the graph there is a **list of launches** for a given period. Clicking on a row in the launch list opens the detailed data view for that launch.

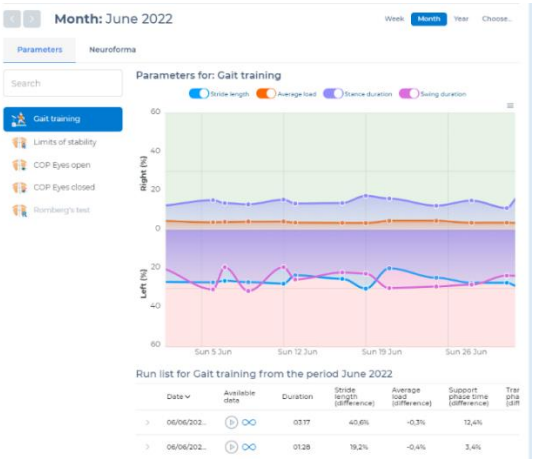


Figure 51 - Achievement Section

8.3.8.2 Training Results - Detailed Data View

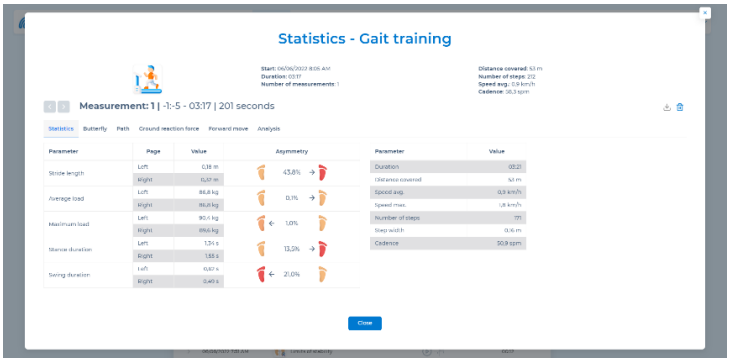


Figure 52 - Results of gait training

In the **Training Results** tab, all stored data is available. If more data has been saved during the indicated launch (using the **Save data** button several times on the training screen), you will be able to select the appropriate **Observation** using the arrows. On the following tabs the following data are available for the selected observation:

- **Statistics** – collected data summarized in numerical form;
- Step cycle **Graphs** with the step cycle characteristic points (FC - contact with the ground, FO - detachment from the ground) and the determined averaged cycle:

- **Butterfly** – distribution of CoP changes for individual step cycles;
- **Path** – distribution of CoP changes taking into account the movement of the running belt;
- **Pressure force** – a graph showing the total pressure on the ground during the step cycle, separately for the left and right legs;
- **Forward** – CoP offset shown in one plane only;

• **Analysis** – a graph with all data collected during a given observation with the zoom function.

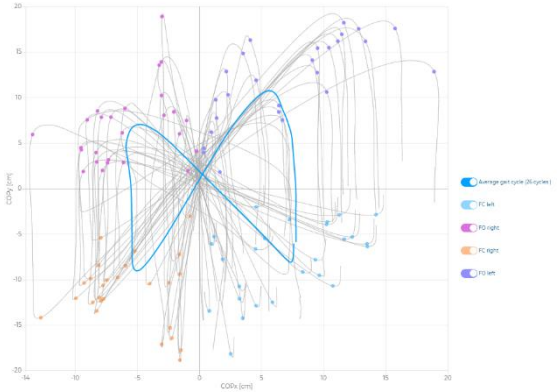


Figure 53 – Butterfly – CoP distribution for individual step cycles

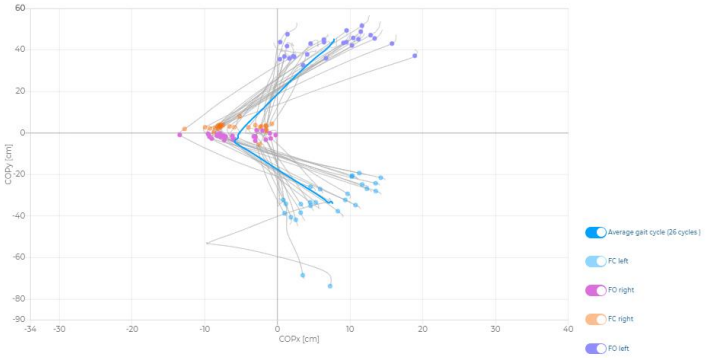


Figure 54 - Path – CoP distribution including the running belt movement

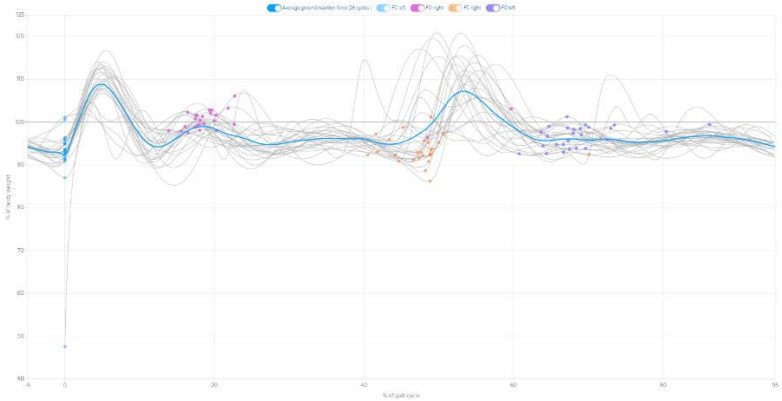


Figure 55 - Forward movement – CoP offset representation in one plane only

8.3.9 Settings and Information

Access to the therapist's profile settings and general information about the current installation of the software is located in the upper right corner of the screen, after pressing the icon.

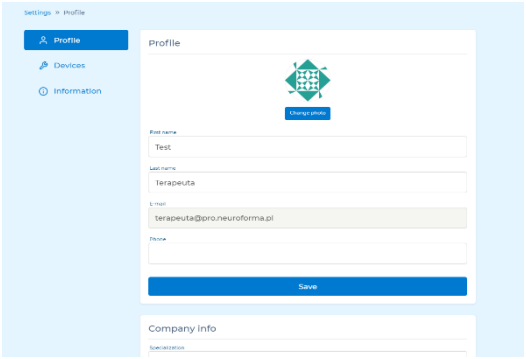


Figure 56 - Setup Menu

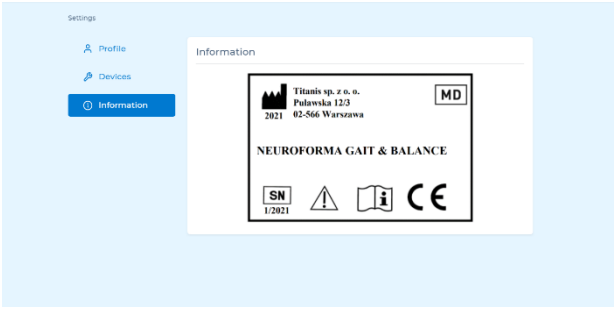


Figure 57 - Software Information

9. Centering and adjusting the belt tension level

CAUTION!

The device is delivered to the customer with the running belt ready for operation.

9.1 Adjusting the belt tension

If the running belt slips or deflects too much after climbing it, then tension the belt as follows:

Insert a hex key no. 6 into the hole at the rear of the device, into the sockets of the passive roller tensioning screws of the running belt (Fig. 57). Then turn the key (clockwise) by ½ turn for both sides of the roller. Repeat the operation until the belt is properly tensioned.

Care must be taken not to overtighten the belt, as this can cause the components to work with too much resistance and damage the bearings. If the belt is too tight, loosen it by turning the key counterclockwise.

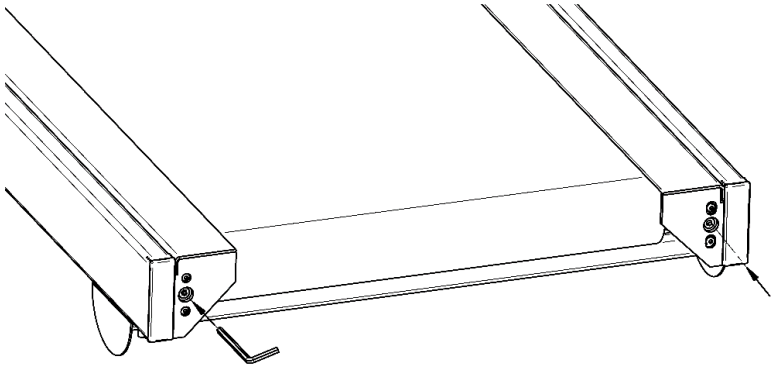


Figure 58 – Tension screw holes of the passive roller on the back of the treadmill

9.2 Centering the running belt

AXELERO G&B is equipped with a running belt with a guide profile to facilitate proper work. If the running belt goes to the right or left side during operation, it must be centered.

If the running belt descends to the right, tighten the right screw by ½ turn counterclockwise.

If the running belt descends to the left, tighten the left screw by ½ turn counterclockwise.

10. Cleaning and Maintenance

CAUTION!

Do not use solvents or corrosives to clean the running belt and the surface of the guards.

CAUTION!

Disconnect the device from the power supply, when cleaning and lubricating it.

Lubricate the treadmill periodically to extend its lifetime. Lubricate only the underside (contact points of the belt with the plate). It is recommended to use vaseline oil for this purpose. Sequence of operations:

1. Disconnect the appliance from the mains.
2. Apply lubricant to the inside of the belt, on both sides.
3. Pull the belt manually.
4. Start the device for approx. 2 minutes at 5-6 km/h.

For disinfection of the handrails, use products such as for example Incidin Foam.

It is recommended to use a soft cloth dampened with soap and water to clean the surface of the housing covers and the running belt.

11. Calibration

Once a year or if there are doubts as to the correct functioning of the equipment, a check and possible calibration of the treadmill speed and posturographic plate indications should be carried out.

Such operations may only be performed by the service of the manufacturer, or the entities authorized by the manufacturer. Each check should be recorded in the card provided with the instruction manual.

11.1 Conditions for technical operation of the device

The expected service life of the device is 7 years. After the 7-year period, the manufacturer is not responsible for defects of the device and its equipment and the consequences thereof.

12. Electrical supply conditions

CAUTION!

To avoid the risk of electric shock, AXELERO G&B must be connected to a power supply network with protective earth.

CAUTION!

Connect the power cord to a nearby power outlet which must be easily accessible when using the AXELERO G&B.

CAUTION!

Do not connect the AXELERO G&B to the mains if the power cord, plug or socket is damaged.

CAUTION!

To effectively disconnect the power supply of the AXELERO G&B from the mains, unplug the power cord from the mains socket.

CAUTION!

The state of the running belt stopping as a result of the detection of an internal failure of the device by the control system is signaled by a series of beeps, the number of which corresponds to the error code (information for service).

CAUTION!

When you have finished operating the device, switch off the power supply to the AXELERO G&B.

The power supply circuit of the AXELERO G&B device should have:

- a residual current circuit breaker with a rated residual current ≤ 30 mA;
- overcurrent protection with a value of 16 A and a type C characteristic.

13. Periodic inspection of electrical safety

The user's technical services must carry out or have the periodic (at least once a year and each time after failure or repair of the device) electrical safety inspection carried out according to EN 62353:

- equipment leakage current (from test point A);
- grounding resistance (from test point B);
- insulation resistance (between points A and C).

The tests should be documented each time with a report of their results. The correct operation of the residual current circuit breaker must be checked independently, as specified in its technical documentation. The operating personnel must follow the instructions contained in this manual.

A – Device leakage measurement point and insulation resistance measurement reference point

B – Access point for ground resistance measurement point

C – Metal body USB connector point for measuring insulation resistance

Figure 59 – Test points for electrical safety periodic inspection

14. Electromagnetic compatibility - Guidance and manufacturer's declaration

CAUTION!

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.

CAUTION!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic immunity of this equipment and result in improper operation.

CAUTION!

The EMISSIONS characteristic of this equipment makes it suitable for use in industrial areas and hospital (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re - orienting the equipment.

CAUTION!

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 equipment *, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION!

Device may be susceptible to electromagnetic disturbances, but Basic Safety and Essential Performance are maintained.

Essential Performance – the documentation of the risk management process shows lack of essential performance characteristic for this product *.

**AXELERO GAIT&BALANCE*

Guidance and manufacturer's declaration – electromagnetic emissions		
The equipment* is intended for use in the electromagnetic specified below. The customer or the user of the equipment * should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The equipment* 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 A	The equipment* is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV (contact) ± 2/4/8/15 kV (air)	± 8 kV (contact) ± 2/4/8/ kV (air)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz	±2 kV for power supply lines 100 kHz	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° i 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° i 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment* requires continued operation during power mains interruptions, it is recommended that the equipment* be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the ac mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF 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 at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	WARNING: 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 equipment*, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,7GHz	3 V/m 80MHz to 2,7GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	EN 60601-1-2:2015, Table 9 *(see below)*	Complies	
	☒ *Professional healthcare facility environment*	☒ *Professional healthcare facility environment*	

Proximity fields from RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum power (W)**	**Distance (m)**	**Immunity test level (V/m)**
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
NOTE If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50 % duty cycle square wave signal. [c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

15. Warranty card

1. The seller (authorized representative, distributor) provides a 24-month warranty on the delivered product and a 12-month warranty on its upholstered parts, starting from the date of original consumer purchase, as indicated in a proof of purchase.
2. The seller (authorized representative, distributor), it is responsible for the quantitative and qualitative deficiencies found immediately after unpacking the subject of the contract at the customer. The consignee shall, within 2 working days, inform in written form of quantified deficiencies.
3. The warranty will be fulfilled only by the authorized service team of the seller (authorized representative, distributor) or other technical service authorized by manufacturer.
4. A repair time exceeding 3 days, regardless of the reason that caused the delay, shall result in the extension of the warranty period by a time that is equivalent to the total time during which the device was out of order.
5. In case a subassembly that breaks down has already been repaired twice, the manufacturer shall be obliged to replace a faulty subassembly with a new one.
6. All defective components / parts replaced during warranty repair become the property of the service.
7. The user shall be obliged to ensure that both the equipment and its supply systems are regularly maintained; failure to comply with this requirement may result in loss of the user's warranty rights.
8. The warranty excludes defects resulting from natural wear of components, ie. wear that is not a result of defects in material or workmanship and also excludes damage due to lack of maintenance (eg. bearings, guides, etc.).
9. The warranty does not cover consumable materials and components (eg. gaskets, cables, etc.).
10. The seller (authorized representative, distributor) it is not responsible for the safety of the user or the patient during the operation of the installed equipment in case of failure to comply with the supplied installation and operating instructions.
11. User bear the risk of using the equipment covered by the warranty. The seller (authorized representative, distributor) the warranty is not liable for loss of expected benefits and costs incurred due to the use or inability to use this equipment.
12. Any defect during the warranty period not reported by the user in writing (letter, fax, e-mail) is not covered by the warranty.
13. The costs incurred by unreasonable failure notification are the responsibility of the user.
14. The warranty shall not cover equipment:
    - with name plate and/or serial number or factory seals removed or damaged;
    - damaged due to its use in a manner other than defined in the operation manual;
    - where repairs or modifications have been done by unauthorized personnel;
    - damaged mechanically due to improper handling;
    - damaged due to force majeure.
15. In case the equipment covered by the warranty has been re-sold, there will be no new warranty document issued.
16. No duplicate warranty document will be issued.
17. This warranty, in the case of consumer sales, does not exclude, limit or suspend the buyer's rights resulting from the non-conformity of the goods with the sales contract.

AXELERO Gait&Balance											Date, signature and warranty stamp:
SN						-					

Repair registry	User comments
