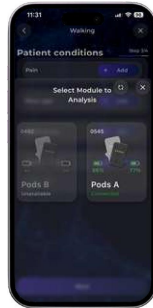


Using the Mobile Application

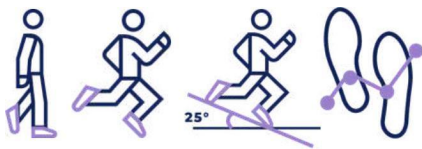
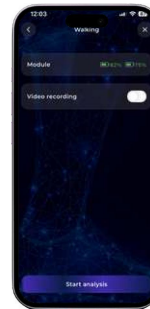
Performing a Mobility Analysis



Select the pair of Mov-Scan®Pods to use

If you want to take a video of your patient performing the analysis, toggle the video recording button.

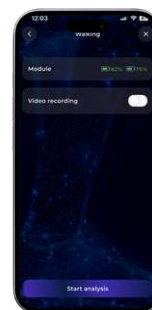
*Only if included in your subscription



Get your patient ready to perform the required movements

Analysis starts within 3 seconds after tapping 'Start analysis'

Tap 'Start Analysis' to begin the data capture



A mobility analysis can only be performed from a mobile or tablet.

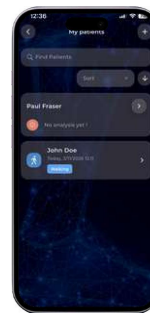
Using the Mobile Application

Viewing Analysis Results



After an analysis has been completed the results will automatically be displayed

To return to past analyses, select the relevant patient profile



Navigate to the 'Analyses' section

Tap the analysis you want to review



Using the Web Interface

Logging in to the Web Interface

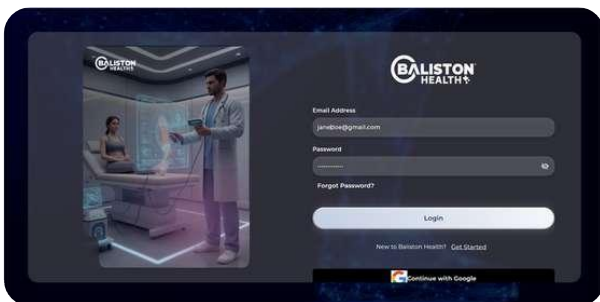
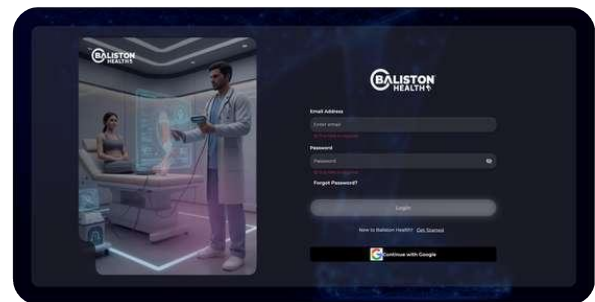


Navigate to the Baliston Health platform in your web browser:

<https://app.baliston-health.com>



Enter the email address and password associated with your account



Login

If two-factor authentication is enabled, you will be prompted to enter the verification code generated by your authentication application

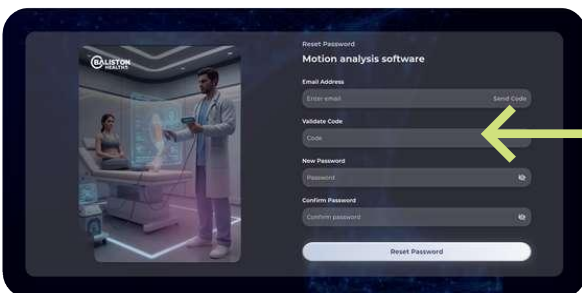
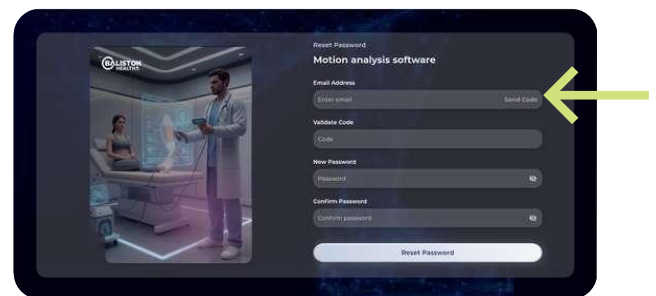
Using the Web Interface

Logging in to the Web Interface



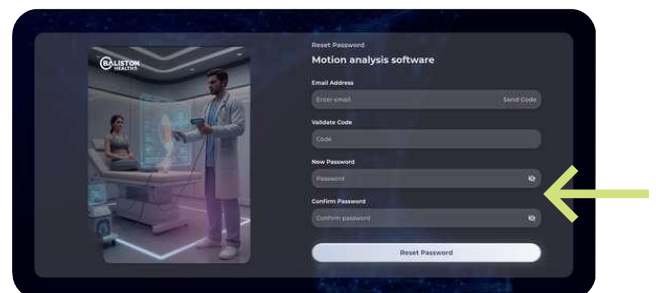
If you have forgotten your password, click 'Forgot password?'

Enter your email address and click 'send code'



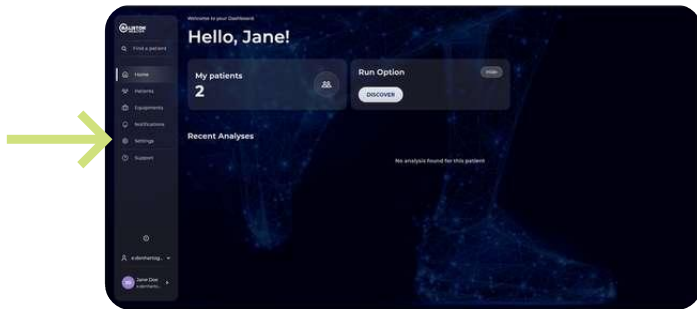
Enter the code received in your email inbox

Change your password to a new, secure password and confirm it



Using the Web Interface

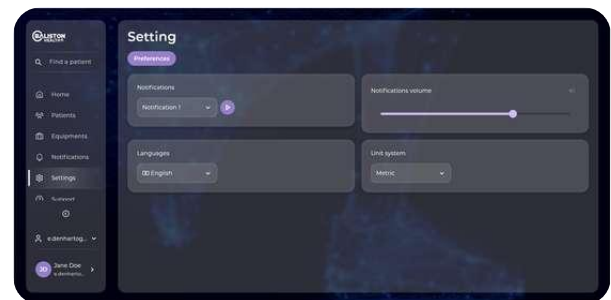
Managing Your Settings



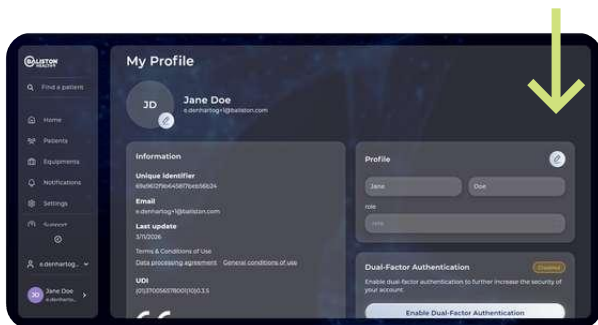
Open the Setting view in the left-hand side menu

In this view it is possible to change your settings relating to

- Notifications
- Notifications Sound
- Language
- Units



Managing Health Practitioners' Information

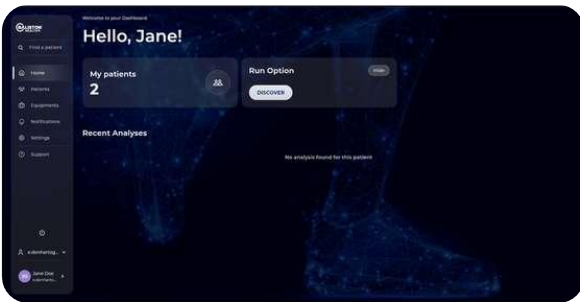


In your account menu, under the 'profile section' section, click the pen icon to update the relevant practitioner information.

Using the Web Interface

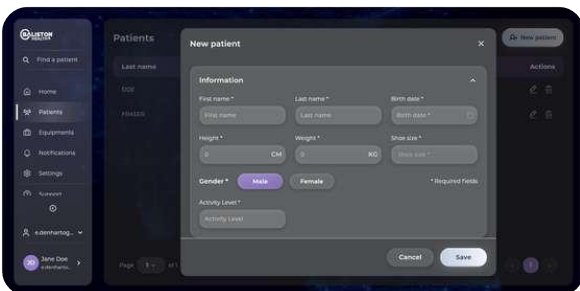
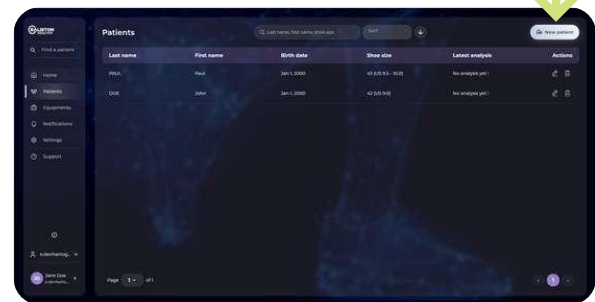
Managing Your Patients

Adding a Patient



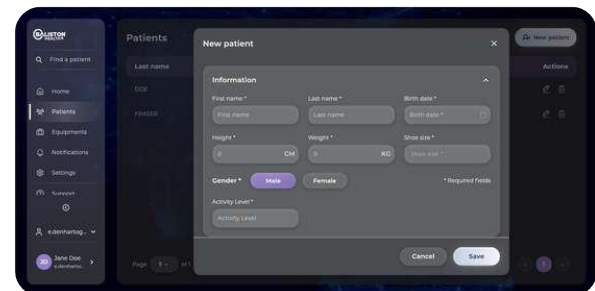
Open the 'My Patients' section

Click 'New Patient' in the top right-hand corner



Enter the required patient information

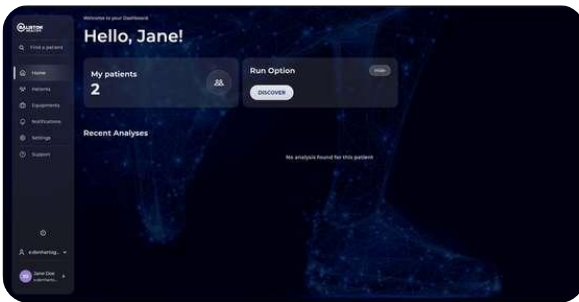
Click 'Save' to add the patient



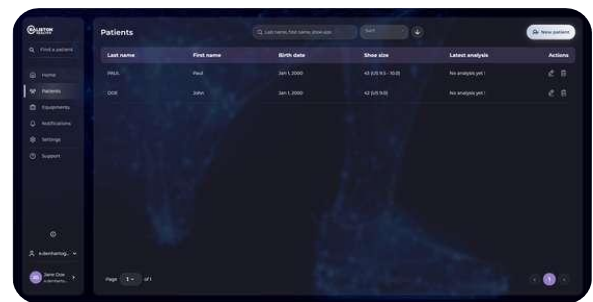
Using the Web Interface

Managing Your Patients

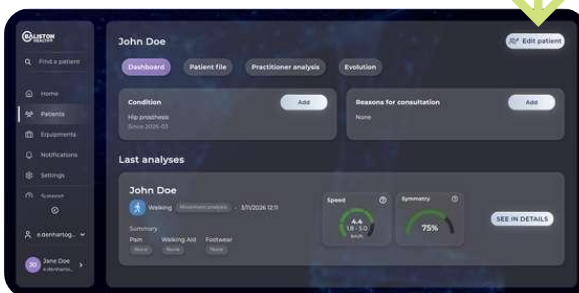
Editing a Patient



Open the 'My Patients' section

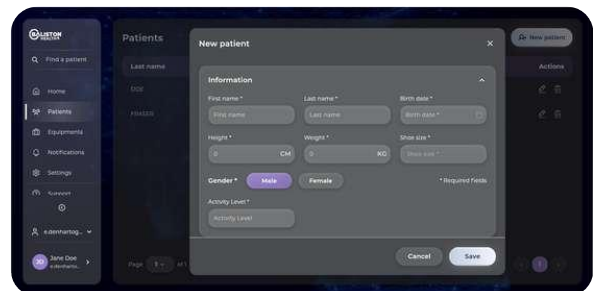


Select the patient you wish to modify



Click 'Edit Patient' in the top right-hand corner

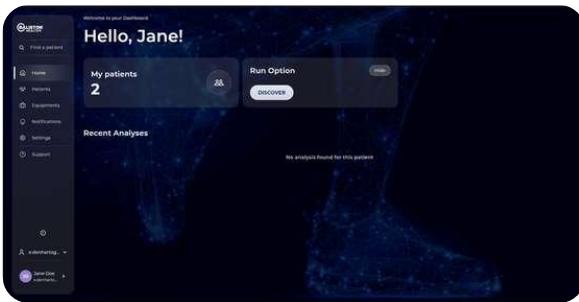
Update the information and save the changes



Using the Web Interface

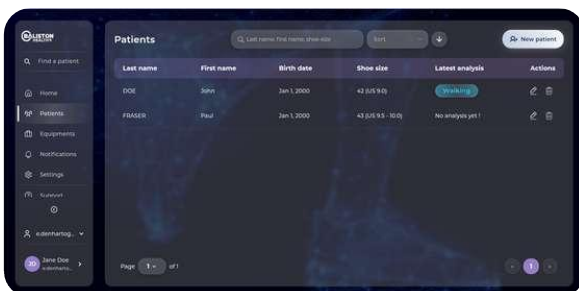
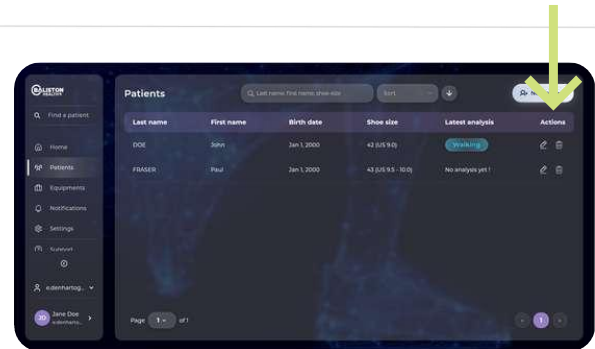
Managing Your Patients

Deleting a Patient



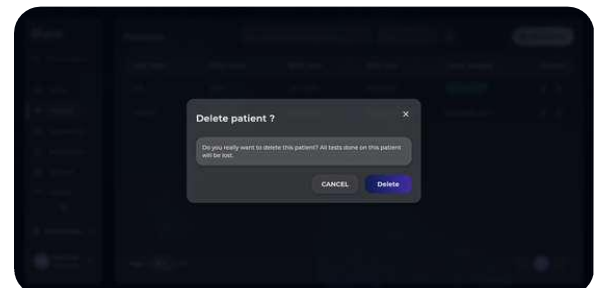
Open the 'My Patients' section

In the Actions column, find the trash bin icon on the right-hand side



Click the trash bin icon and confirm the deletion

Deleting a patient profile is permanent, thus all previous test results will be lost



Using the Web Interface

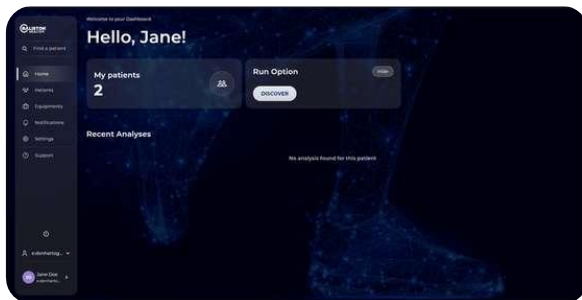
Managing Mobility Analyses

Viewing Analyses



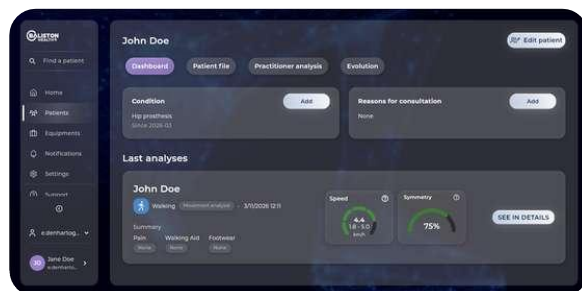
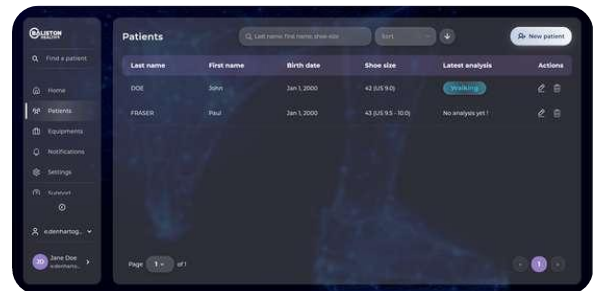
Analyses performed using the mobile application are automatically synchronized with the Baliston Health web platform.

Analyses can only be performed on a mobile or tablet, but can be viewed from a mobile, tablet and web interface.



Open the 'My Patients' section

Select the relevant patient



Navigate to the 'Last Analyses' section and choose the analysis you want to review

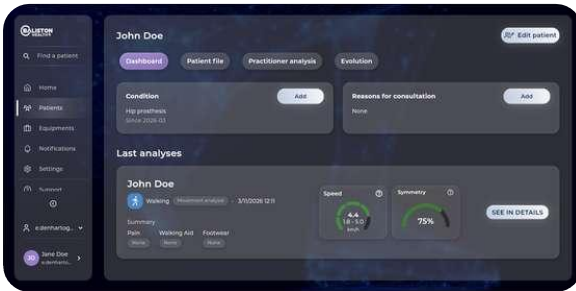
You can leave comments at the bottom of analyses

Analyses can also be managed in the mobile application using the same steps.

Using the Web Interface

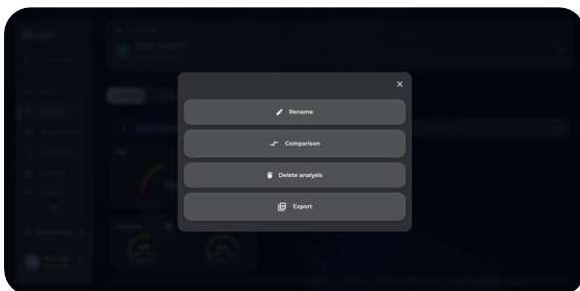
Managing Mobility Analyses

Personalising Analyses



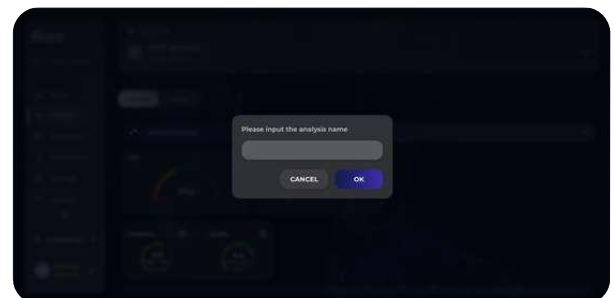
In the relevant patient's profile select the analyses you want to personalise

Click the three dots on the top right-hand side



Choose 'Rename'

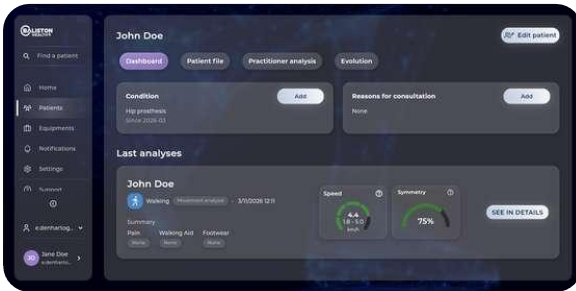
Change the name of the analysis in order to differentiate easier between different analyses



Using the Web Interface

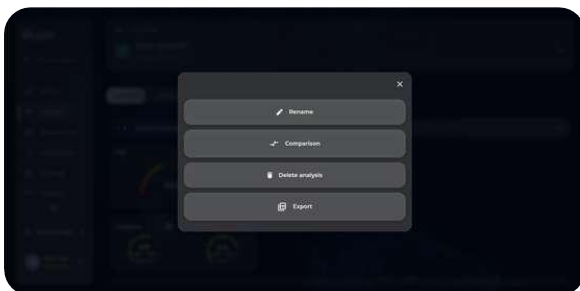
Managing Mobility Analyses

Generating Reports



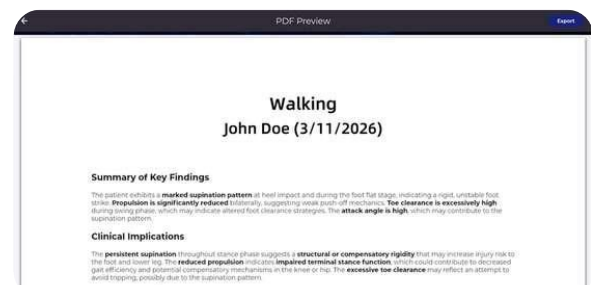
In the relevant patient's profile select the analyses you want to export

Click the three dots on the top right-hand side and choose 'Export'



Click Export

Click 'Export' in the top right-hand corner
Download happens immediately
Reports can be shared with patients or included in clinical documentation



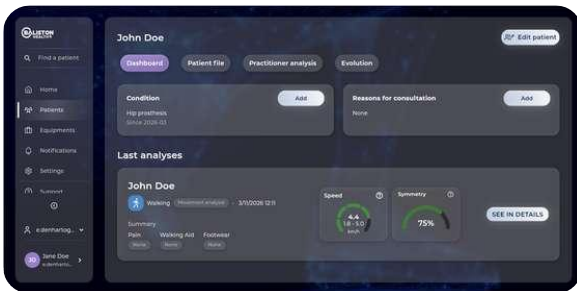
Using the Web Interface

Managing Mobility Analyses

Comparing Analyses

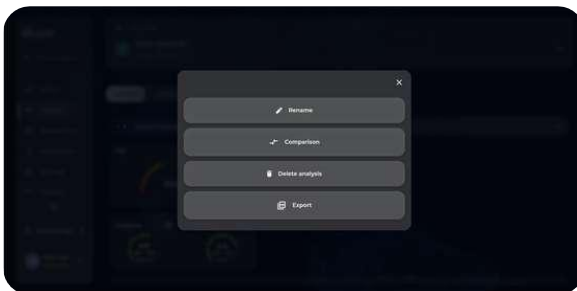


Evaluating changes in mobility metrics across different session



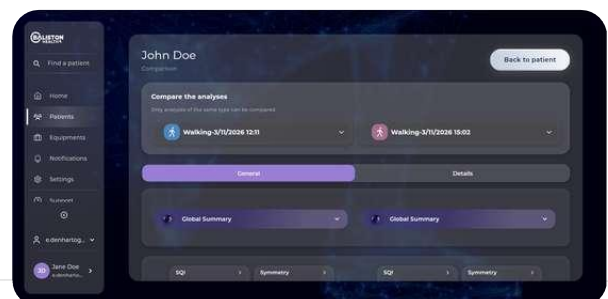
Select the relevant patient profile and select one of the analyses that you wish to compare

Click the three dots on the top right-hand side



Click Compare

Select the analysis you want to compare it with



Understanding Results

The Mov-Scan® system provides objective mobility metrics derived from walking and running analyses. These metrics help healthcare professionals evaluate patient mobility and monitor changes over time.

Gait Parameters

The following parameters may be displayed when analysing walking activity:

Parameter	Description
Stride Length	Distance traveled by the foot during one gait cycle.
Pace (Cadence)	Number of steps taken per minute.
Cycle Time	Time between two consecutive contacts of the same foot.
Contact Time	Duration of time the foot remains in contact with the ground during a step.
Swing Time	Duration of time the foot is in the air during the gait cycle.
Double Contact	Percentage of the gait cycle where both feet are in contact with the ground.
Speed	The forward movement speed of the individual during walking.
Pronation / Supination Angle	Angle between the foot and the ground. Positive values correspond to pronation and negative values correspond to supination.
Gait Line	Estimated trajectory of pressure from heel strike to toe-off.
Step Progression Angle	Angle between the direction of walking and the orientation of the foot.



Understanding Results

The Mov-Scan® system provides objective mobility metrics derived from walking, jumping, and running analyses. These metrics help healthcare professionals evaluate patient mobility and monitor changes over time.

Running Parameters

The following parameters may be displayed when analyzing walking activity:

Parameter	Description
Stride Length	Distance traveled by the foot during one gait cycle.
Pace (Cadence)	Number of steps taken per minute.
Cycle Time	Time between two consecutive contacts of the same foot.
Contact Time	Duration of time the foot remains in contact with the ground during a step.
Swing Time	Duration of time the foot is in the air during the gait cycle.
Double Contact	Percentage of the gait cycle where both feet are in contact with the ground.
Speed	The forward movement speed of the individual during walking.
Pronation / Supination Angle	Angle between the foot and the ground. Positive values correspond to pronation and negative values correspond to supination.
Gait Line	Estimated trajectory of pressure from heel strike to toe-off.
Step Progression Angle	Angle between the direction of walking and the orientation of the foot.



Maintenance

Charging Your Mov-Scan® Pods

Remove the Mov-Scan® Pods from the insoles and position them on either side of the Plug USB charger. After connecting the two boxes to the USB plug, place everything in the charger connector provided for this purpose.

To power the device, plug the connector into a USB port on your computer or into a power supply that fulfils IEC 60601-1: 2005 (1MOOP) medical specifications.

The recharging time is roughly 2.5 hours.



CAUTION



Remember to charge Mov-Scan®Pods before leaving them disconnected for extended periods of time to avoid damaging the battery. To maximise the lifespan of your Mov-Scan®Pods, charge them at temperatures ranging from 10°C (50°F) to 40°C (104°F).

Maintenance

Cleaning Your Mov-Scan® Pods



WARNING

Use the insole only with a clean sock.

Proper maintenance of the Mov-Scan® system helps ensure reliable operation and prolongs device lifespan.

Mov-Scan® insoles should always be used with clean socks (you can use disposable socks). For hygiene and infection control, it is recommended to clean the device regularly and before the first use.

Recommended cleaning procedure:

1. Use disinfectant wipes compatible with medical equipment.
2. Ensure the disinfectant meets standard bactericidal and virucidal requirements:
 - EN1276*, EN13727*, EN13697*, EN14561 bactericide (including SARM).
 - Mycobacterium Terrae EN14348* and EN14563* tuberculocide.
 - Fungicide EN14562* (on Aspergillus Fugimatus).
 - Levuricide EN1650, EN13697*, EN13624*, EN14562* on Candida albicans.
 - Virucide EN14476 on HBV, HCV, Adenovirus, Coronavirus, Norovirus, RSV, H1N1, HSV-1, Polyomavirus* and Rotavirus*.

*Unless it is very soiled

3. Allow the device to air dry before reuse with clean socks.

*We recommend the STERIMED wipes for EU and the SANI-CLOTH product for US, which are available from Baliston Health at: contact@baliston-health.com and satisfies the requirements.

CAUTION

DO NOT:



- immerse the device in water
- use corrosive chemicals or solvents
- place the device in a washing machine or dryer
- expose the device to excessive heat

Technical Information

Battery



The Mov-Scan® Pods contain a rechargeable lithium-ion battery:

- **Battery type:** Li-ion polymer
- **Nominal voltage:** 3.7 V
- **Charging voltage:** 4.2 V
- **Charging time:** approximately 2.5 hours
- **Estimated lifecycle:** 500 charging cycles

Active mode consumption is approximately 1.2 mA, providing extended operating autonomy.

Charger

Charging equipment must comply with IEC 60601-1 standards for medical electrical equipment:

Input specifications:

- 100–240 V
- 50–60 Hz

Output specifications:

- 5.0 V
- Minimum output current 30 mA

Only use approved charging equipment with the Mov-Scan®Pods.

Radio Module

The Mov-Scan®Pods communicate with the mobile application using Bluetooth technology.

Radio specifications:

Frequency bands	Maximum output power
Bluetooth-LE	2.29 dBm (EIRP)

The device complies with Directive 2014/30/EU and IEC 60601-1-2:2014 electromagnetic compatibility requirements. These standards are designed to limit interference with other electronic devices in residential or healthcare environments.

Technical Information

Technical Specifications

Component	Specification
System Name	Mov-Scan® System
Sensors	Inertial measurement sensors
Connectivity	Bluetooth Low Energy
Battery Type	Rechargeable lithium-ion battery
Charging Method	Charging dock with USB power supply
Typical Charging Time	Approximately 2.5 hours
Data Transmission	Wireless synchronization with the Baliston Health application
Supported Platforms	iOS and Android mobile devices

Operating Environment

Parameter	Operating Range
Maximum Body Pressure	50 kg/cm ² (or 500 n/cm ²)
Maximum Load of the Insoles	200 kg
Operating Temperature	10 °C to 40 °C
Relative Humidity	30% to 75% non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa



CAUTION

In order to use the device safely, observe the environmental conditions



Technical Information

Product Performance

Parameter	Operating Range
Product lifetime	2 years
Warranty duration	2 years
Storage time	1 year. If you charge the Mov-Scan®Pods every six months, you can extend the storage time

Storage and Transport

CAUTION



Follow the storage instructions to ensure the product has the longest potential shelf life. To avoid damaging the batteries, remember to charge the insoles before putting them away for an extended period of time

Parameter	Storage and Shipping Range
Recommended Battery Charge Level for Storage	75% to 100%
Atmospheric pressure	0 ~ 100% HR
Temperature for Shipping and Storage	-10 °C to 50 °C
Relative Humidity	10% to 90% non-condensing

RED Warning

- 1.Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.
- 2.Adapter shall be installed near the equipment and shall be easily accessible.
- 3.The operating temperature of the EUT can't exceed 50°C and shouldn't be lower than -10°C .
- 4.The plug considered as disconnect device of adapter.
- 5.The product shall be connected to a USB interface of version USB2.0 or higher.
6. This product can be used across EU member states.

Regulatory Information

Symbols

The following symbols may appear on the device, packaging, or documentation.

Symbol	Description	Symbol	Description
	Device meets the requirements of the European Directive 93/42/EEC relating to medical devices (CE mark)		Medical device
	This device complies with 5 V 30 mA DC power supply		This device meets the requirements of European Directive 2014/53/EU relating to radio equipment
	Manufacturer		Non-ionizing radiation device with an RF transmitter
	Please do not hit		Manufacture date
	Please do not repair		Please do not puncture
	Please do not immerse the insole in water		Please do not place in the washing machine
IP54	IP54 – Device protected from powerful water sprays		Charger side to download data
	Atmospheric pressure limit during shipping and storage		Relative humidity limit
	Temperature limit during shipping and storage		Federal Communications Commission (FCC) statement
	Consult instructions for use before using the device		Type B applied part
	Prevent the risk of suffocation		Japanese certification compliance mark
	Keep out of reach of children		Indicates a potential danger associated with device use
	Normal charger use		REF – Commercial reference of the device
	Do not use near a magnetic resonance device		Prohibited use of the charger
	Some instructions for use are available on the web		This symbol on the box means "Keep dry," because the product must be protected from humidity and water.

Regulatory Information

Regulatory Conformity

The Mov-Scan® system has been designed and manufactured in accordance with applicable regulatory requirements for medical devices.

Risk management for the device has been performed in accordance with ISO 14971, including the evaluation of overall residual risks associated with the device.

The Mov-Scan® system complies with the following directives and standards:

Regulation / Standard	Description
93/42/EEC (as amended by Directive 2007/47/EC)	European Medical Device Directive
2014/53/EU	Radio Equipment Directive (RED)
2011/65/EU	Restriction of Hazardous Substances Directive (RoHS)
2012/19/EU	Waste Electrical and Electronic Equipment Directive (WEEE)
2014/30/EU	Electromagnetic Compatibility Directive
IEC 60601-1:2005 + AC1:2006 + AC2:2007 + Amd1:2012	Medical electrical equipment – General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Electromagnetic compatibility requirements and tests

The Declaration of Conformity is available on the Baliston Health website or may be requested by contacting Baliston Health at:



contact@baliston-health.com

Hereby, BAL Inc. declares that this product is in compliance with essential requirements and other relevant provisions of Directive 2014/53/EU. This product is allowed to be used in all EU member states.



Regulatory Information

FCC Statement

United States: Federal Communications Commission (FCC) declaration.

FCC ID: 2BUJC-ZT6S

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

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

Changes or modifications not expressly approved by Baliston may result in the user's right to use the equipment being terminated.

Note: This equipment has been evaluated according to section 15 of the FCC Rules and determined to meet the requirements for a Class B digital device. These parameters are intended to offer reasonable interference protection in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and may cause harmful interference to radio communications if not installed and used according to the instructions. However, no guarantee can be if interference will not occur in a specific installation.

If this device causes harmful interference to radio or television reception, which can be determined by turning it off and on again, the user is advised to try one or more of the following actions to rectify the interference:

- Adjust the position of the receiving antenna or relocate it.
- Increase the distance between the equipment and the receiver.
- Connect the device into an outlet on a different circuit than the one to which the receiver is connected.
- Seek assistance from a dealer or an expert radio/TV technician.

Regulatory Information

End of product life

Mov-Scan® devices contain electronic components and lithium-ion batteries.

At the end of the product life:

- Do not dispose of the device with household waste
- Follow local electronic recycling regulations
- Return the device to the distributor or manufacturer if required

Proper disposal ensures environmental protection and compliance with applicable regulations.

FCC Caution:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

FCC RF Radiation Exposure Statement:

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

2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Support

Full information is available on: <https://www.baliston-health.com/customer-support>

Troubleshooting

Issue	Possible Cause	Recommended Action
Pods do not turn on	Battery discharged	Charge the pods
Pods not detected	Bluetooth disabled	Enable Bluetooth
Pods not responding	Device in sleep mode	Place pods on charger
Data capture cannot start	Pods not connected	Verify connection in the app
Results not visible	Synchronization delay	Refresh application or check internet connection

Contact

For technical support or product inquiries:

Baliston Health

France

+33 (0)3 55 40 91 55

United States

+1 720 798 4452

Email

contact@baliston-health.com

Vigilance / incident reporting

Vigilance@baliston-health.com

Supra

CE Marking



Date of CE marking: TBD

REF BAHE001-FPT00

UDI-DI: 3700565774633

0476



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Place Stanislas
54000 Nancy
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MOV  SCAN