



- Digitsole Pro - User manual (EN)
- Gait Analysis Interpretation Manual
- Run Analysis Interpretation Manual
- FAQ - Digitsole Pro



User Manual & Technical documentation

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Before you begin:

Before using your Device, please read this manual carefully. It contains all the information you will need to use the device safely

Precautions to take before use

WARNING:

There is a risk of injury or accident to yourself or others, as specified in this manual.

CAUTION:

This manual indicates that there is a risk of material damage to this or any other device.

The Digitsole Pro® solution is not intended to be used as a diagnostic tool. Digitsole Pro® can be used to assist a healthcare practitioner or any user in completing a clinical evaluation using the data offered by the product. The healthcare practitioner is responsible for making the diagnosis.

The Digitsole Pro® is a device that can be used to examine the walking and running gait of patients aged 7 and older who have a shoe size of ≥ 30 (EU size = 12-12,5 US Kids). The size of the insole should correspond to the patient's foot size. With Digitsole Pro® and DSPods insoles, it is mandatory that patients wear clean socks.

Analyses should be carried out on patients who are able to:

- Walk and run (depending on the type of analysis the healthcare provider wishes to perform)
- Understand, follow, and apply simple mobility instructions

WARNING

- Do not open, puncture, or punch.
- If a DSPod is damaged, do not attempt to repair it; instead, contact the seller.
- Do not throw it in the fire.
- Shoes with a metal plate on the lower part should not be worn.
- Avoid bending or twisting your DSPods.
- If your DSPods have deteriorated, do not use them.
- A wound must not come into direct touch with the insole or DSPod.
- Please contact Digitsole support at contact@digitsole.com if the device produces results that differ from your observations.
- If the device displays conflicting information or text, clear the browser cache and refresh the page with the F5 key.
- Do not use the DSPods near a magnetic resonance device. *

*The product's safety in a magnetic resonance environment has not been investigated. It has not been tested in the magnetic resonance environment for heating or undesired movement. The product's safety is unclear in the magnetic resonance environment. A magnetic resonance exam performed on a person who has this medical device may result in damage or device malfunction.

RF Warning

The device has been tested to ensure that it meets general RF exposure criteria. The device can be utilized without restriction under portable exposure conditions. This device conforms with the RF radiation exposure limitations established by the EC, FCC, and Industry Canada for the general population (uncontrolled exposure). This device must not be co-located with any other antenna or transmitter, nor may it be used in conjunction with any other antenna or transmitter.

You can request a paper copy of this notice by emailing us at contact@digitsolepro.com

Intended use

Digitsole Pro® standard version is a solution for healthcare practitioners that displays objective data based on spatio-temporal and kinematic patient mobility metrics. Mobility reports provide the following information to healthcare practitioners:

- A set of biomechanical metrics with a visual comparison to literature standards,
- The digital “gaitline” linked to pressure,
- Basic interpretations of mobility parameters,
- The evolution of mobility parameters as a result of various analyses.

A standardized test can be selected by the healthcare practitioner to focus on the biomechanical factors connected to the patient's mobility.

The healthcare practitioner will use these reports to conduct a more in-depth medical investigation in order to decide a diagnosis.

Contraindication

There is no specific medical contraindication; nonetheless, testing should only be undertaken on patients who can:

- Walk and run (depending on the type of analysis the healthcare provider wishes to perform)
- Understand, follow, and apply simple mobility instructions.

Adverse effects

To date, no adverse effects have been identified

Product description

Health practitioners, paramedics, sports coaches, caregivers, and anyone who is qualified to perform quantified mobility analyses can use the Digitsole Pro[®] device (gait and run).

Digitsole Pro[®] can be used as part of a standard mobility analysis protocol (walking or running) at a patient's session with their health practitioner, whether or not they have reported mobility issues as a result of various reasons.

Digitsole Pro[®] can be used in adults and children over the age of 7, with a shoe size of ≥ 30 (EU size = 12-12,5 US Kids), and in the following situations:

- Mobility assessment
- Follow-up/monitoring on-site or remotely
- Rehabilitation follow-up

Digitsole Pro insoles and DSPods can be utilized on several patients.

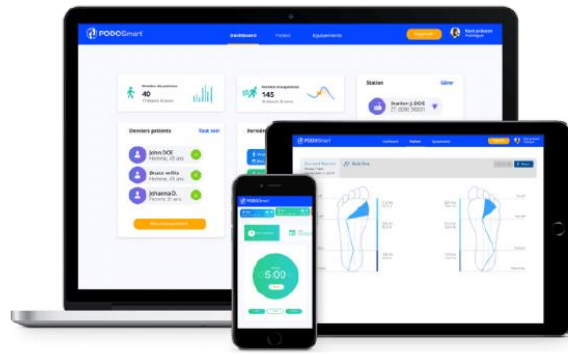
The Digitsole Pro[®] device is intended for usage in a medical professional context. However, the system can be utilized in other settings (hospital, exterior, interior type house or healthcare structure) to monitor and collect daily mobility data for patients (adults and children aged 7 and over).

The Digitsole Pro[®] system can be used to track people's mobility data and provide warnings to patients, family caregivers, health practitioners, and paramedical professionals, as well as to export data analyses from a group of patients in the form of dashboards that show compiled product data. This information can be downloaded and organized into a dashboard, which can then be shared with health practitioners, paramedics, sports coaches, family caregivers, or anyone who is qualified to interpret gait or running parameters.

Kit contents

The Digitsole Pro[®] kit comes with a case containing the following items:

- 6 insoles with the following sizes:
 - (EU size) 36/37, 38/39, 40/41, 42/43, 44/45 and 46/47
 - (US Men size) 4.5/5.5, 6-7, 7.5-8.5, 9-10 and 10.5-11.5
 - (US Women size) 5.5/6.5, 7-8, 8.5-9.5, 10-11 and 11.5-12.5
- 2 DSPods (1 right, 1 left)
- 1 DSPods charger kit, consisting of a charger plug and a charger dock
- 1 document indicating where the user manual may be found and how DSPods can be inserted into Digitsole insoles
- 1 document describing how to use the charger kit
- A strap



Authorized accessories

Kit of a pair of DSPods	DSPS001-KIT10
Charger Kit	DSPS001-KIT00
- DSPods charger socket	DSPS001-CAB00
- DSPods charger dock	DSPS001-CAB10
Digitsole Pro case	DSPS001-PCK00
Digitsole Pro 30-32 insole (US 12-1,5)	DSPS001-INS30
Digitsole Pro 33-35 insole (US 2-4)	DSPS001-INS33
Digitsole Pro 36-37 insole (US Men 4.5-5.5 – US Women 5.5-6.5)	DSPS001-INS36
Digitsole Pro 38-39 insole (US Men 6-7 – US Women 7-8)	DSPS001-INS38
Digitsole Pro 40-41 insole (US Men 7.5-8.5 – US Women 8.5-9.5)	DSPS001-INS40
Digitsole Pro 42-43 insole (US Men 9-10 – US Women 10-11)	DSPS001-INS42
Digitsole Pro 44-45 insole (US Men 10.5-11.5 – US Women 11.5-12.5)	DSPS001-INS44
Digitsole Pro 46-47 insole (US Men 12-13 – US Women 13-14)	DSPS001-INS46

Recommended Computer/Phone Specifications

The Digitsole Pro interface is compatible with both PCs and tablets.

The interface: MacOS/iOS - Windows - Android.

Web browser: Mozilla Firefox – Google Chrome – Microsoft Edge.

The Digitsole Pro application is compatible with mobile phones.

OS: Android 6.0+/iOS 14.0+.

Product Installation

Product operation

Insert the DSPods into your insoles as follows:

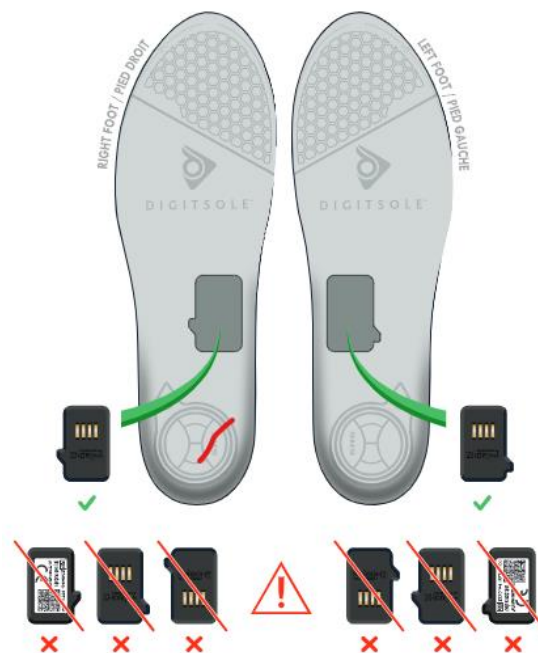
- Identify left and right DSPods



- Identify the left insole and the right insole



Place the left DSPod in the left insole and the right DSPod in the right. Please keep in mind that the DSPods must be inserted in the correct direction for the data capture to work (see image below)

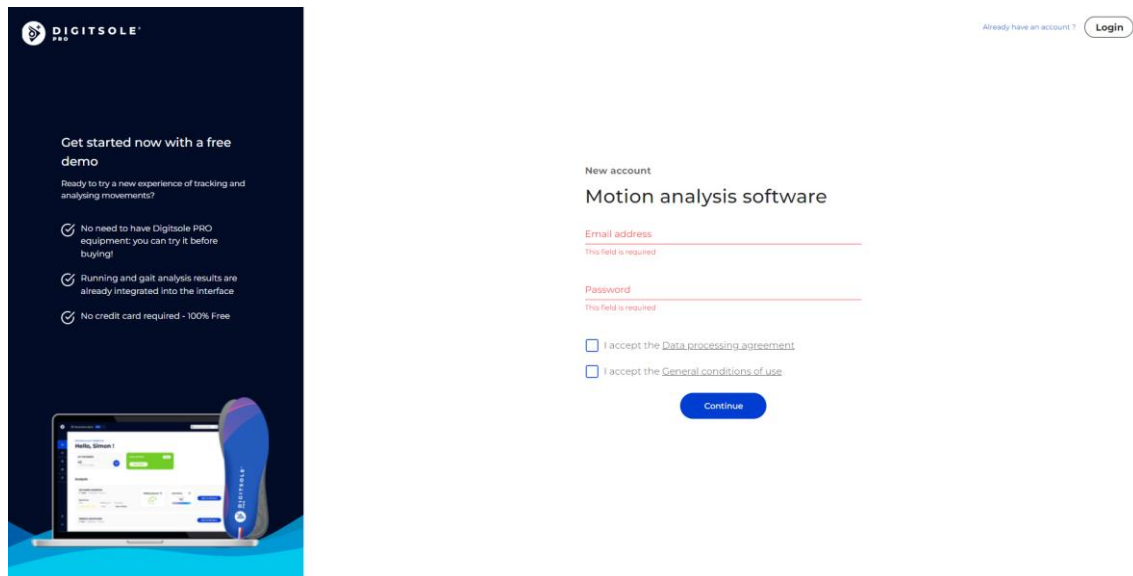


The data acquisition can also be done with the use of DSPods positioned on the bottom of the foot. As long as the positioning of the DSPods avoids any unexpected slippage.

Account creation

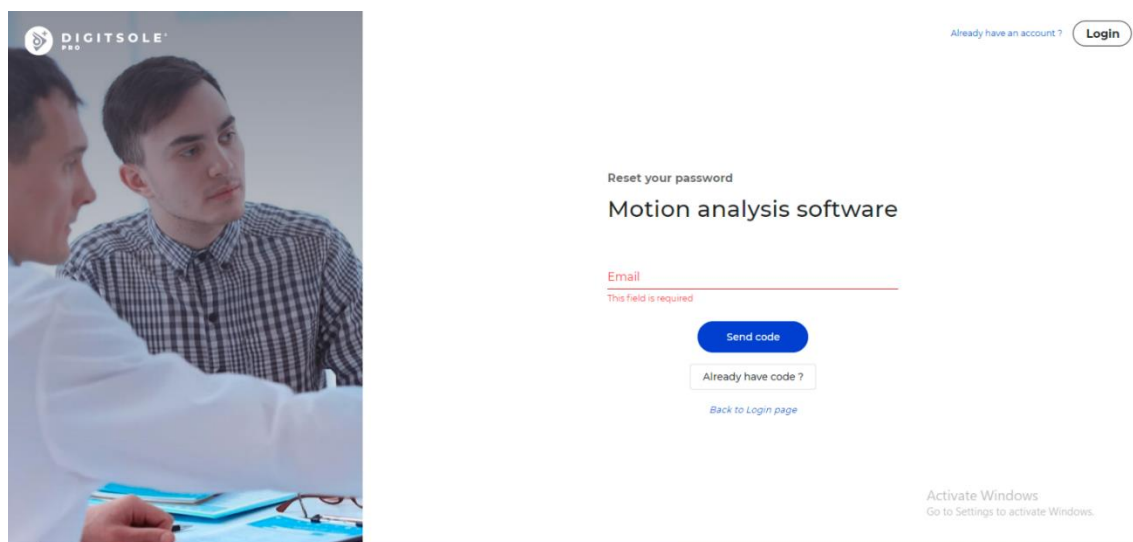
If you have not already done so, go to the following page to create a Digitsole Pro[®] account:

<https://app.digitsolepro.com/auth/sign-up>



After reading the data processing contract, enter the email address and password you want to use for your Digitsole Pro[®] account.

Your password must have at least eight characters, contain at least one number, one lower case letter, one capital letter, and one special character for security purposes.



After that, you will receive an email with a code to confirm your registration. Please enter it in the field provided.

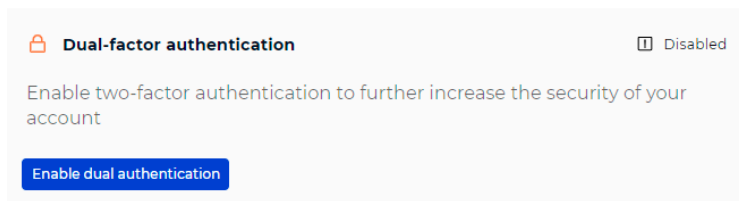
Then enter your personal data to finish your account creation.

Two-factor authentication activation

To activate the two-factor authentication, go to the **Your account** in the top right corner



Then select **Enable dual authentication** in the menu.



Scan the QRCode with your two-factor authentication app (for example, Google authenticator) and enter the code in the area specified for this purpose.

Enable dual authentication

Scan the QR code below with your dual authentication application



[Problem scanning the code?](#)

Download the mobile application

The Digitsole Pro® app is free and works with iOS 14.0+ and Android 6.0+ mobile devices. Please check the firmware version on your phone to see which devices are compatible with the apps.



Enter Digitsole Pro® in the search bar to locate the application:

- For iOS devices, go to the App Store®
- For Android devices, go to the Google Play™ store

It is necessary to use the browsers Mozilla Firefox, Google Chrome, Safari or the latest version of Microsoft Edge. Please refer to <https://www.digitsolepro.com/customer-support/compatibility> section for compatible browser versions. It is necessary to use a phone with Android 6.0+ or iOS 14.0+.

Use of the mobile application

Connection to the application

📶 62% 11:47 am



Welcome to Digitsole Pro

Email address

my-email@address.com

Password

•••••

Login

To access the application, ensure that you have already created your account on the web interface, and you can connect to this application using the same credentials.

To log in, enter your account email address and password.

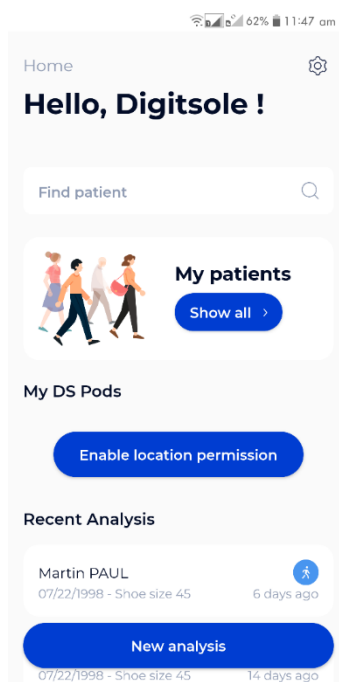
If you have forgotten your password, go to the Digitsole Pro® interface and create a new one.

DSPods management

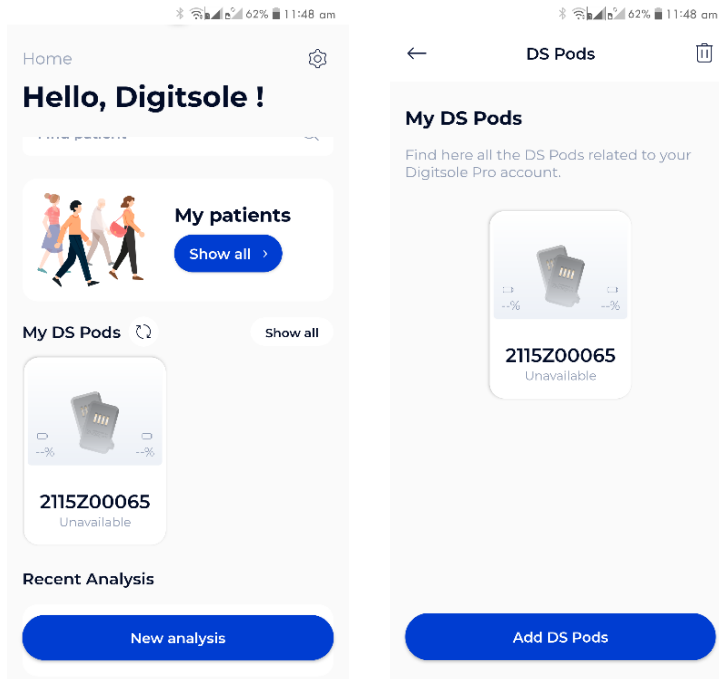
[Add DSPods](#)

To add DSPods to your account from the main app screen, follow these steps:

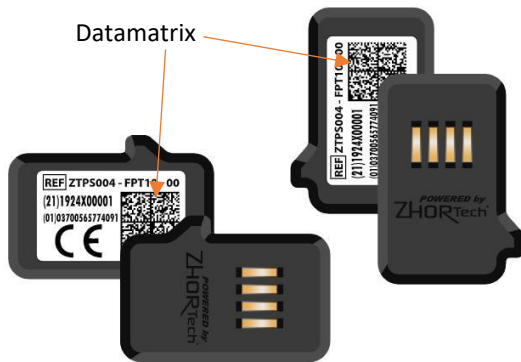
- If you do not already have DSPods, go to the "DSPods" area and click Add



- If you already have DSPods, go to the "My DSPods" area and click on "**See all**," which will redirect you to a list of your DSPods. Select **Add DSPods** from the menu.

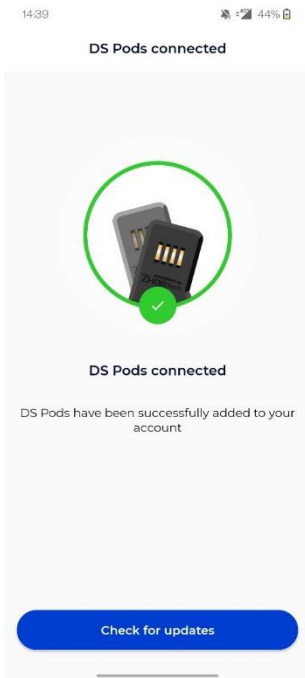


To add your DSPods to your account, go to a new page and scan the Datamatrix code on your pair of DSPods. If you have more than one pair of DSPods, repeat the procedure.



Datamatrix code example

Update DSPods

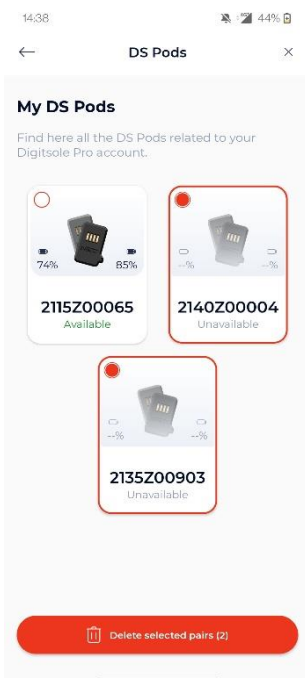


Click on **Check for updates** to check the DSPods version and see if they need to be updated.

You will have the choice to perform the update now or later.

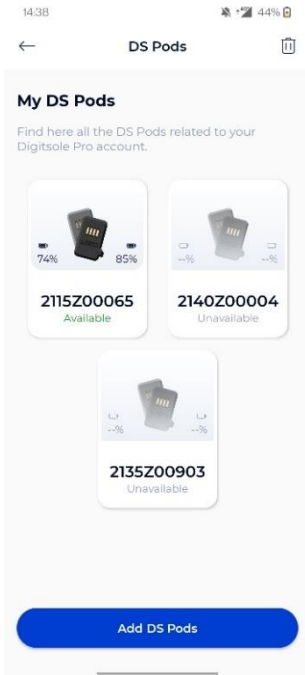
We advise you to do it now but if you choose to do it later, you will just have to rescan your Pods by adding them again to your account so that the update is proposed to you.

Remove DSPods



Click on **"See all"** in the **"My DSPods"** section from the main application screen to be redirected to a list of your DSPods. Click the trash can icon in the upper right corner of the screen, select the pair(s) you want to delete, and then click **Delete selected pairs**. To exit delete mode, click on the cross icon in the upper right corner of the screen.

Check battery levels



When the DSPods are charging, you cannot see the charge level of your DSPods because they are plugged in and charging.

To check the charge level of your DSPods, go to the DSPods page. The battery charge levels of the left and right DSPods are displayed. By scrolling down on the screen, you can refresh the battery levels.

In the event of a problem:

If you still can't view the battery charge level after reloading the page, your DSPods may be "asleep" (to save power, they automatically turn off after about 20 minutes). Shake them vigorously to "wake them up" (please DO NOT hit them on a hard surface as this may damage the sensors). Then, by swiping down on your screen, you can reload the website and see the battery of the DSPods, this action can take 30 seconds.

Application settings

Units

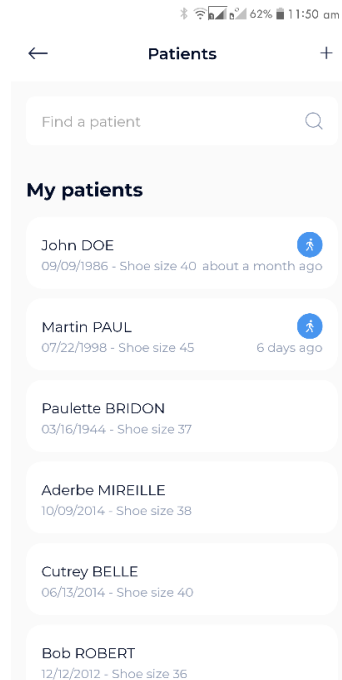
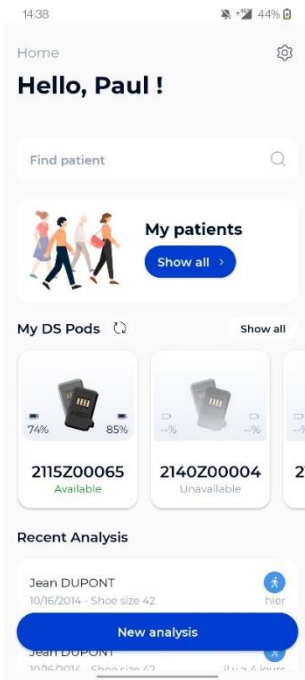
In the "Settings" section, you can choose the system of units you want to use in the application. You can choose between the metric and imperial systems.

Languages

Our application is available in several languages. The choice of the language is defined according to the language set as the main language in your phone.

Patient management

Add a patient



To add a new patient to your account from the main application screen, click on **See all** under the "My patients" area, then on the + logo at the top right of your screen.

A screenshot of the 'New patient' form. It has tabs for 'Information', 'Pathology', and 'Contact'. The 'Information' tab is active. The form fields are: Last name, First name, Birth date, Height (cm), Weight (kg), Shoe size (dropdown), and Gender.

A form appears; complete the patient file by filling out at least the information and pathology pages. If your patient has no pathology, select "Healthy patient."

It is critical to select the correct pathology because it will affect the interpretations and standards of the analyses.

The Contact tab is optional. However, it allows you to add your patient's contact information so you may easily reach them.

NB: If you are using imperial units, to have access to men's or women's sizes, it is necessary to choose the gender of your patient first.

[Edit a patient](#)

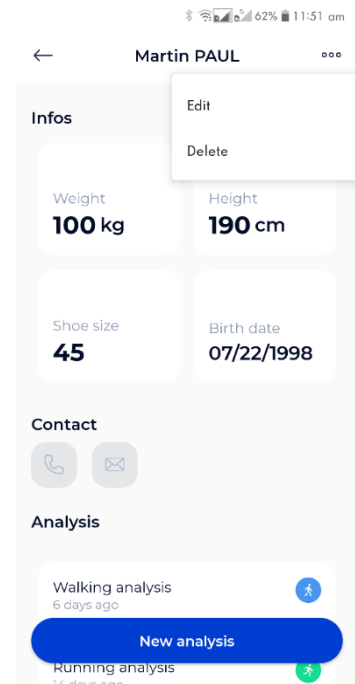
Click on the patient you want to edit from the list of patients, and the patient file will open. Select **Edit** from the menu at the upper right of the screen. When the form appears, fill it out with the requested information and then click **Submit** to save your changes.

After that, the patient's file will be updated.

[Delete a patient](#)

Click on the patient you want to delete from the patient list, and the patient file will open. Select **Delete** from the menu at the upper right of the screen, then confirm the deletion. After that, you will be taken to the newly updated patient list.

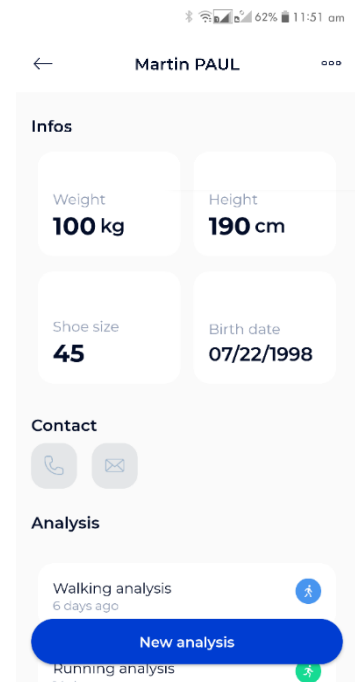
Please note: This is an irreversible action.



[Contact a patient](#)

Click on the patient you want to contact from the patient list and the patient file will open.

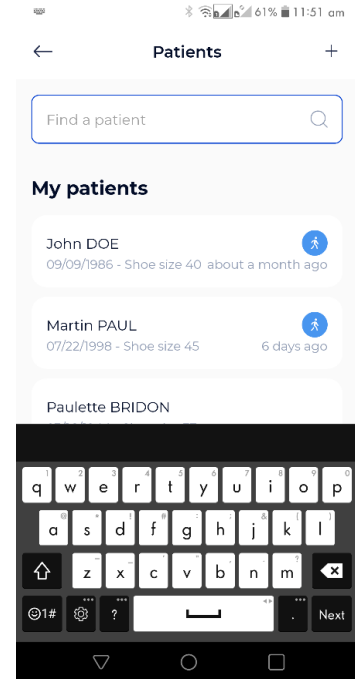
If you have entered your patient's phone number, you can call them by clicking the **Call** button. If you have entered your patient's email address, you can send a message by clicking the **Send a message** button



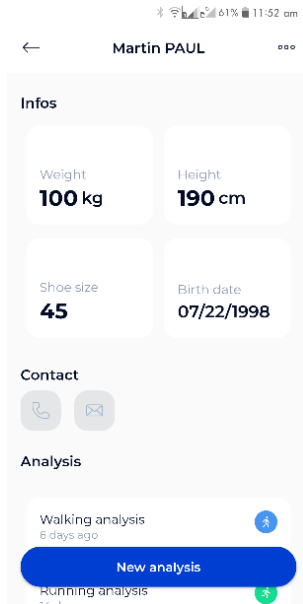
Search a patient

Type the last name and/or the first name of the patient you want from the patient list in the text field at the top of the screen.

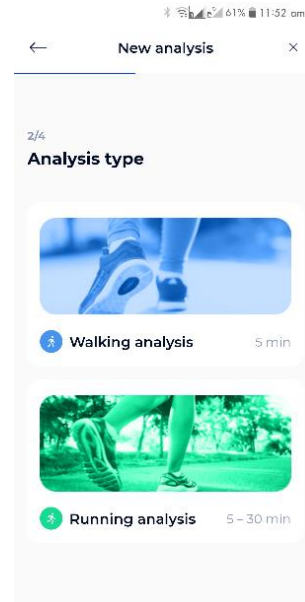
Note: The patient search only works with one word, so if you write your patient's first and last name in the search bar, you will not find any matches.



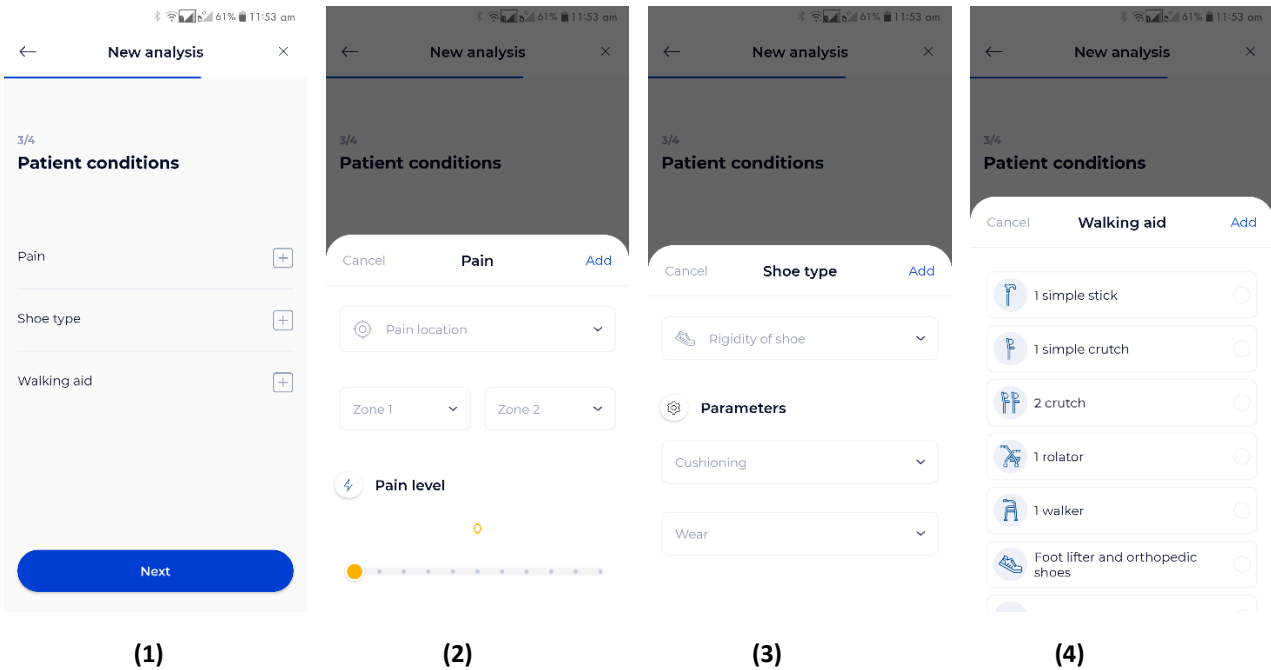
Start and stop of data capture



1 – Go to your patient's file once your patient is created and your DSPods have been added to your account. Click on the button New Analysis.

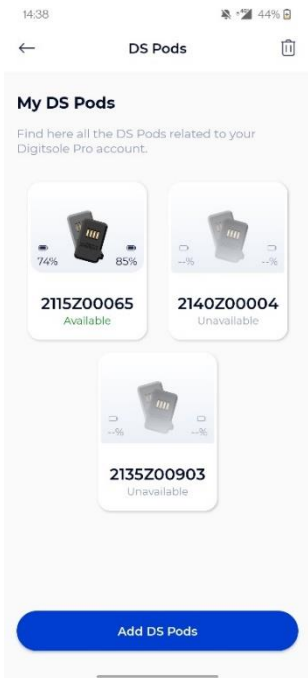


2 - Next, choose the type of analysis you want to run.



3 -Using the menu above, you can then enter further information about your patient. **(1)**

- You can enter the location and intensity of your patient's pain(s) in the **Pain** tab **(2)**.
- You can specify the stiffness and cushioning of your patient's shoes in the **Shoe type** tab **(3)**.
- Any walking aid device used by your patient should be listed in the **Walking aid** tab **(4)**.

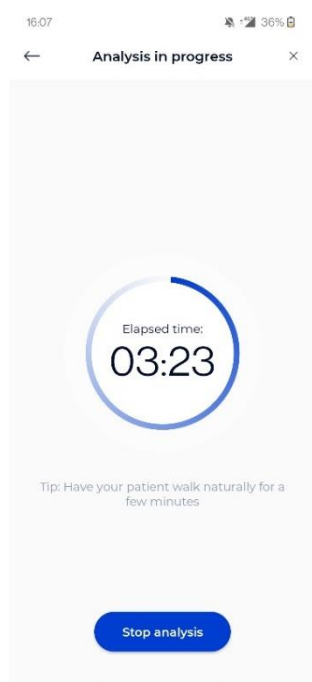
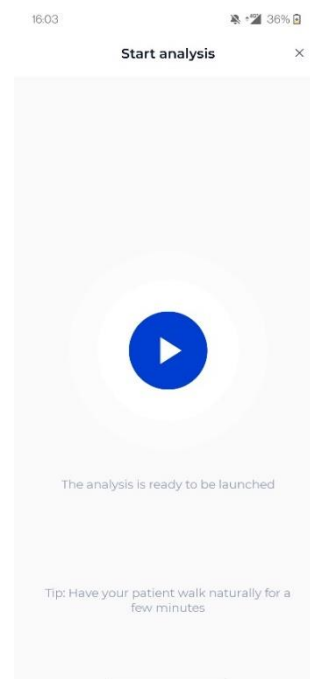


Then pick the pair of DSPods with which you will use for the data capture; the application will then establish a connection to the DSPods and send you to the screen where you can begin the analysis.



CAUTION: If you have multiple pairs of DSPods, make sure to choose the ones that correspond to the insoles in your patient's shoes.

Once the DSPods have been placed in the insoles and the insoles have been placed in the patient's shoes, click the **Play** button to begin the data capture. Following the appearance of the stopwatch, your patient should remain in a static position for 3 to 5 seconds for initialization before they start to walk or run.



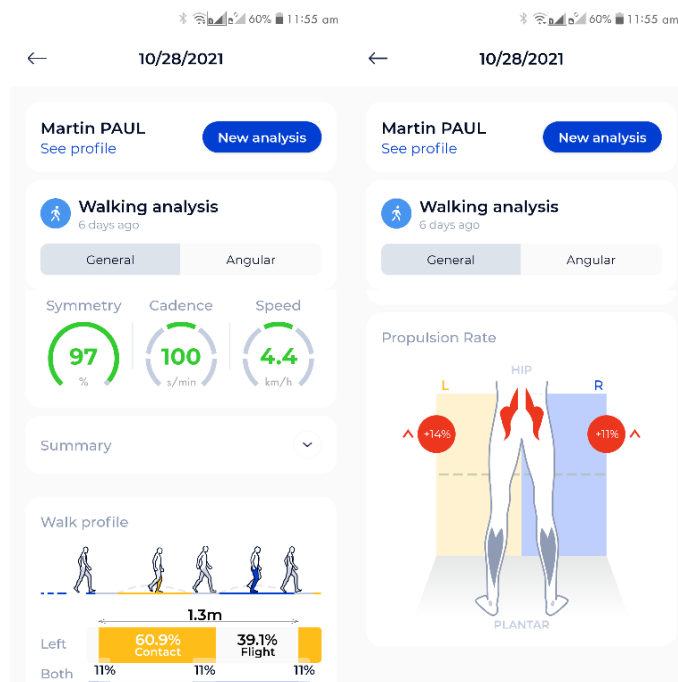
Click the **Stop Analysis** button to end the data capture. When the data capture is complete, the data is directly sent to the Digitsole Pro® web interface.

View the data

In the "My patients" area, click **See all**, then pick the relevant patient.
You are now on the patient file.

Click on the analysis you want to see in the "Analyses" section.

You can select the sort of view you want at the top: General or Angular.



Clicking the **For more details** option will automatically link you to the Digitsole Pro web interface, where you may perform a more intensive analysis of the results.

NB: If you have "Not enough steps" at the end of your activity:

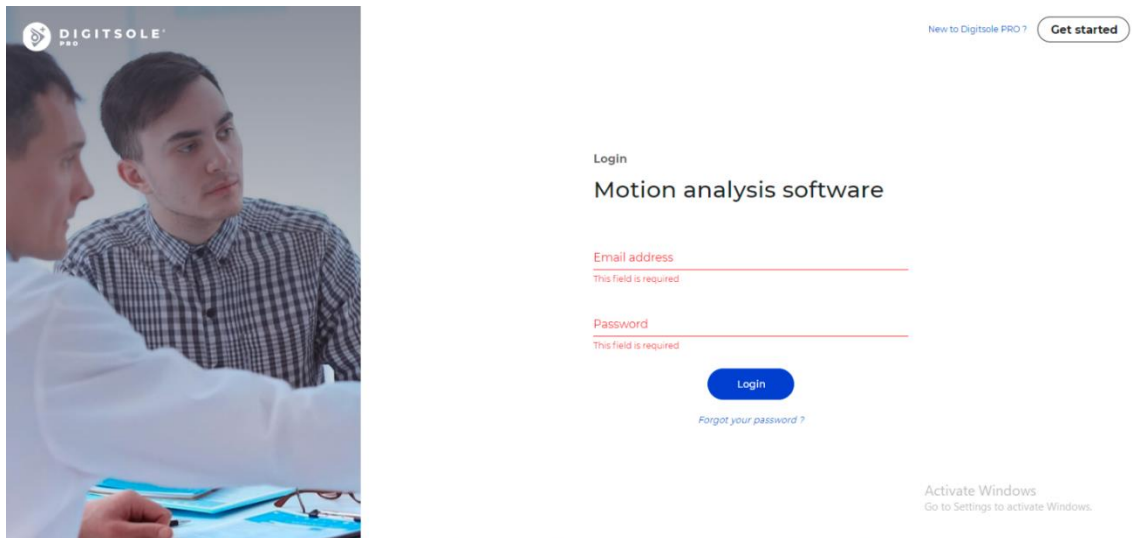
- Make sure to place the DSPods in the right position in the insoles. (Refer to page 9)
- Make sure you stay still during the initialization phase.
- In walking analysis, make sure you have taken more than 20 steps during the acquisition.
- In running analysis, make sure you run at a speed of more than 8 km/h.

Using the web interface

Login to the interface

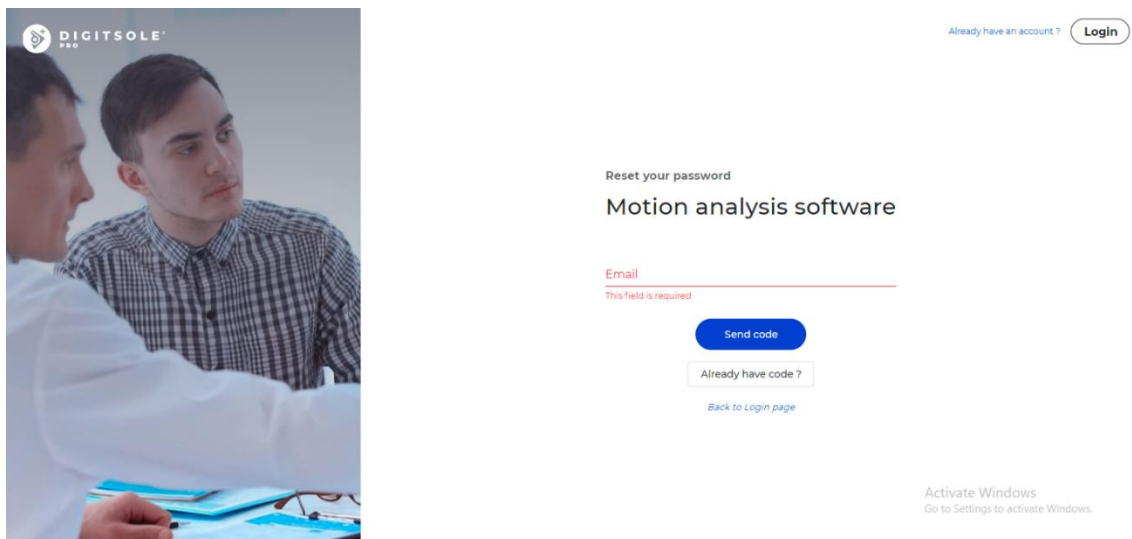
To access the interface, ensure that you have already made your account on the web interface. You are able to connect to this application using the same credentials. Log in via the following link:

<https://app.digitsolepro.com/auth/sign-in>

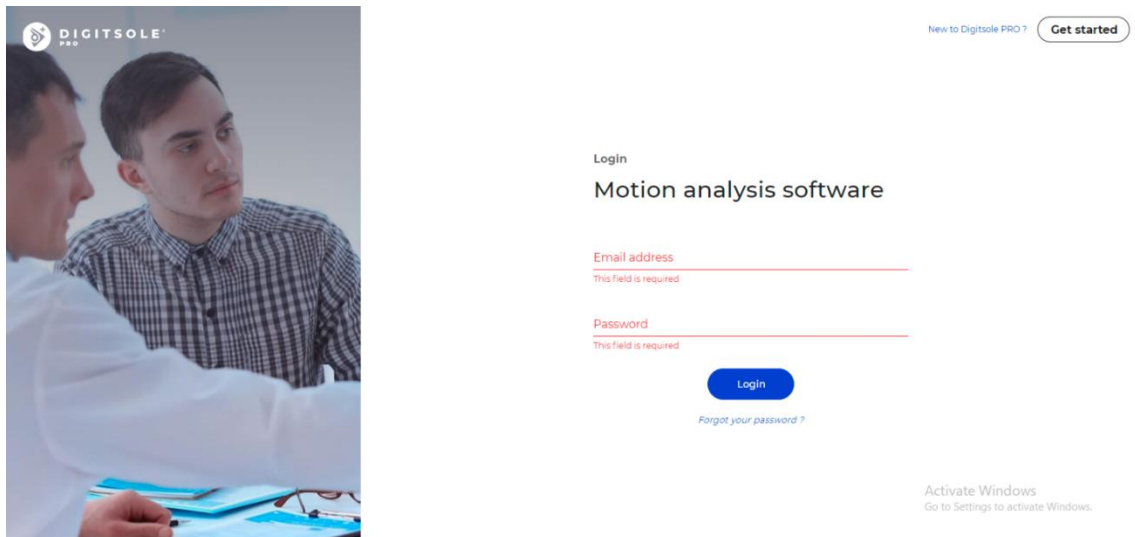


To log in, enter your account's email address and password.

If you have forgotten your password, click **Forgot password**, enter your email address in the provided box, and then click **Send code**.

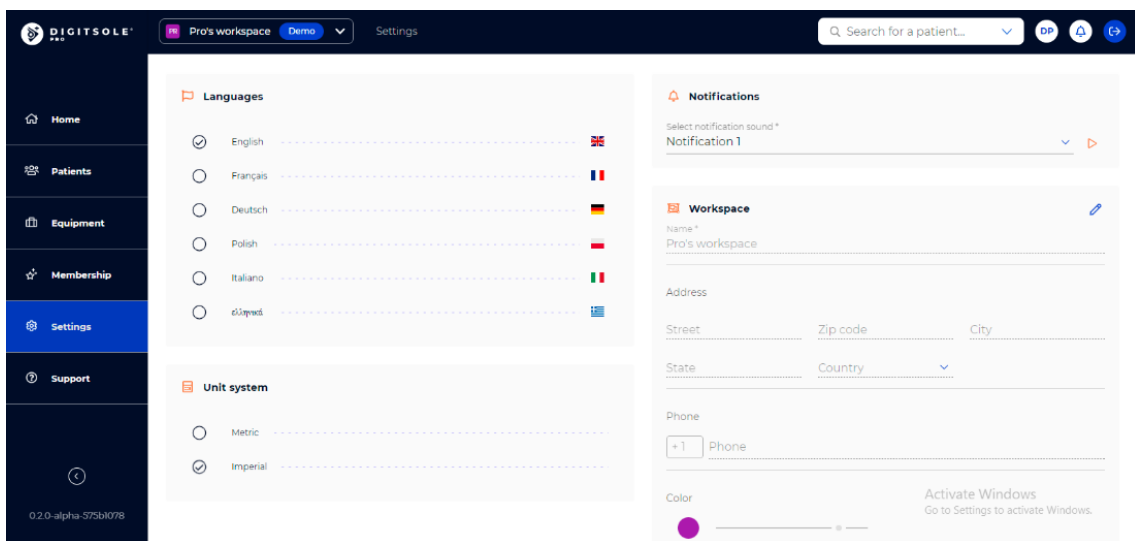


Along with your new password, enter the code you received through email. When you click **Submit**, your password will be changed.



You then proceed to the login screen, where you enter your email address and your new password to use Digitsole Pro®.

Web interface settings



Units

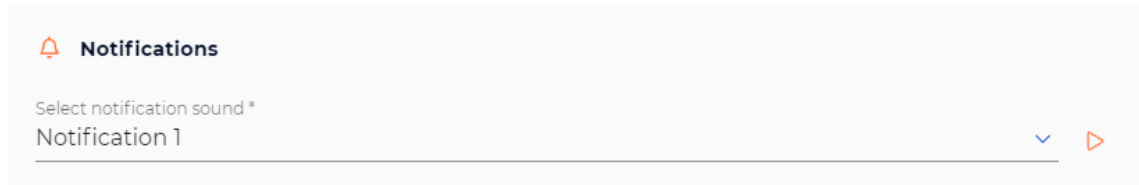
In the "Settings" section, you can choose the system of units you want to use on the web interface. You can choose between the metric and imperial systems.

Languages

Our web interface is available in several languages. In the "Settings" section, you can choose the language you want to use on the web interface

[Notifications](#)

Once you have performed a Digitsole Pro acquisition via the mobile application, the results are transmitted directly to the web interface. You will be notified by a sound. The notification can be found in the dedicated tab at the top right of your screen, by clicking on it you will have direct access to the analysis results of your patient.



You can change the sound of the notification by going into the settings of the web interface. You can choose between several sounds.

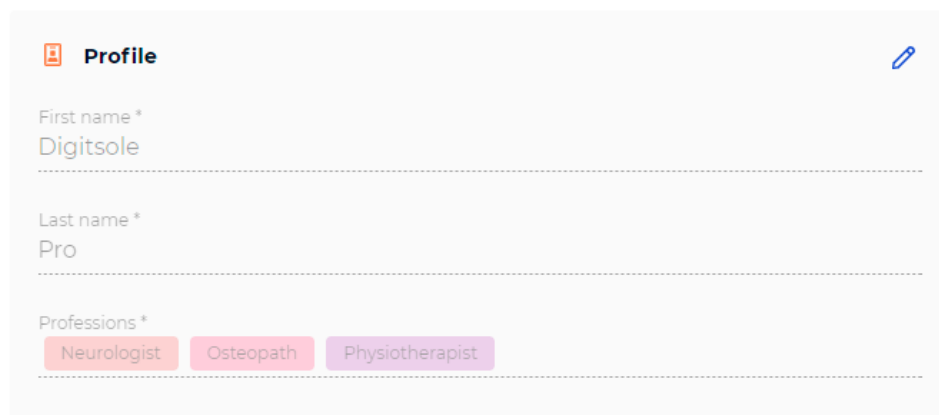
Changes to my account

[Information management for health practitioners](#)

To change your practitioner information, go to the **Your account** button at the top right



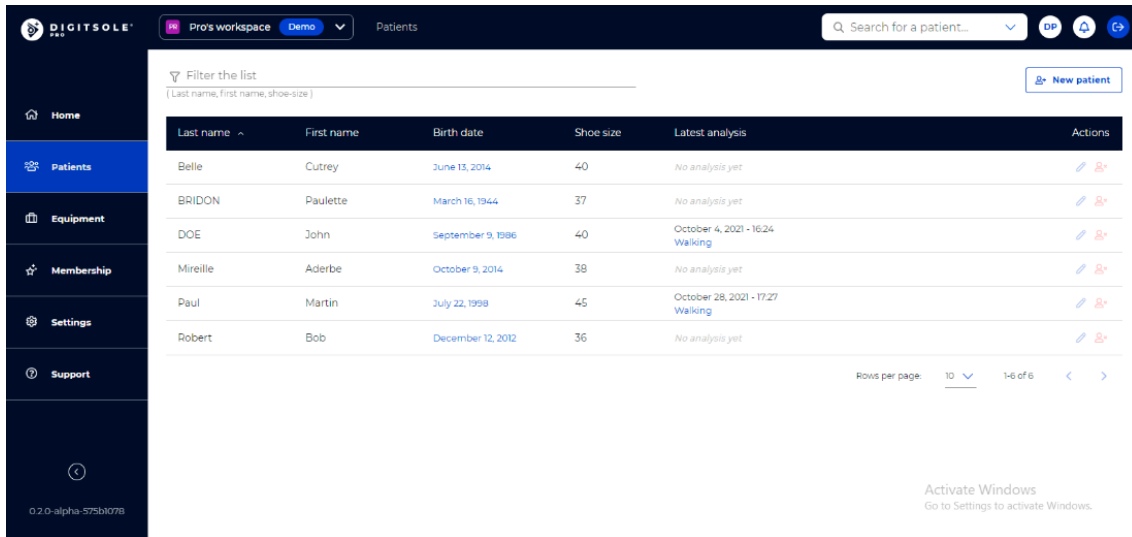
Then, to change your practitioner information, click the **Pen** icon.

A screenshot of a 'Profile' settings form. At the top left is a person icon followed by the text 'Profile'. At the top right is a blue pen icon. The form contains three sections: 'First name *' with the text 'Digitsole' below it; 'Last name *' with the text 'Pro' below it; and 'Professions *' with three colored buttons: 'Neurologist' (orange), 'Osteopath' (pink), and 'Physiotherapist' (purple).

Patient management

Add a patient

Select the **Patients** tab, then **New patient** on the top right.



A new window opens, allowing you to enter your patient's details, address, preferred method of contact, purpose for consultation, and any history and pathologies.

Mandatory fields are indicated with an Asterisk (*) in the "Information" section and in the "Pathology" section. When finished, click **Add**

×

New patient

Information

First name * Last name * Birth date *

Height * ft Weight * lbs Shoe size *

Gender * Man Woman * Required fields

Pathology (This field is required)

No pathology is selected

Please make sure to fill in the correct pathology as it can have an impact on the interpretations and norms of the analyses.

Healthy patient Yes No

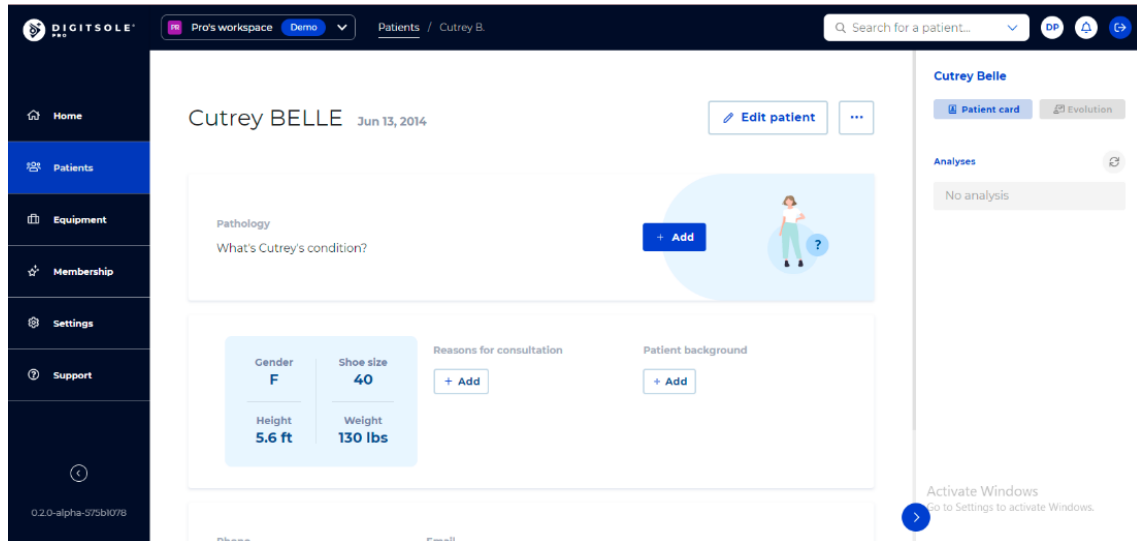
NB: If you are using imperial units, to have access to men's or women's sizes, it is necessary to choose the gender of your patient first.

Edit a patient

To make changes to a patient's file, go to the Patient tab and then choose the patient.

Click **Edit patient** to make changes to the patient's personal information, address, and contact information.

Depending on the data already entered, you will be able to change or add a known pathology, cause for consultation, and history by clicking on the **pen** icons or on **Add** to add new ones.

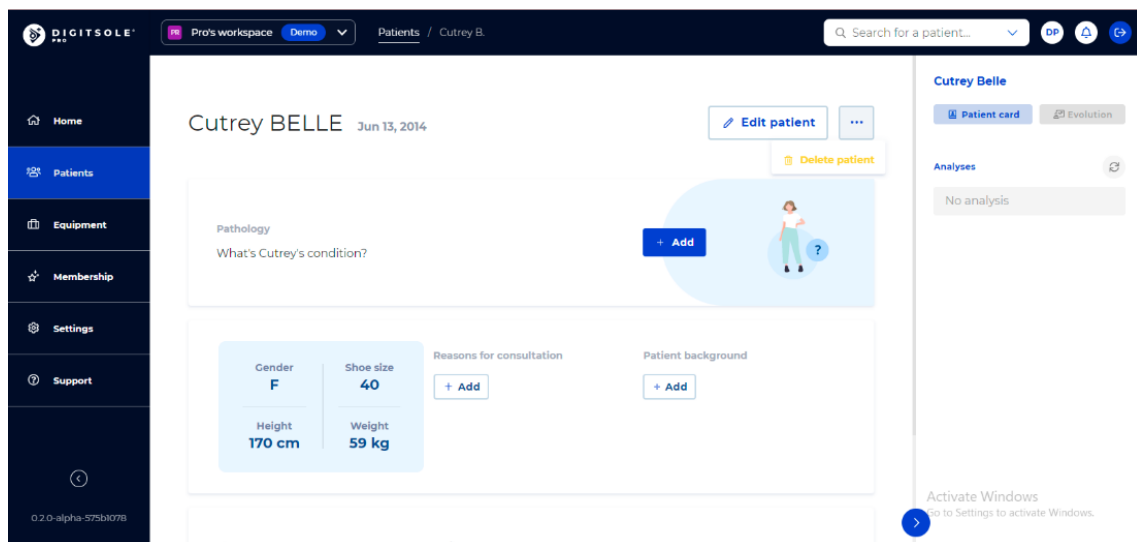


Delete a patient

To make changes to a patient's file, go to the **Patient** tab and then choose the patient.

To change the patient's personal information, address, or method of contact, click... at the top right, then **Delete patient**.

Please note: This is an irreversible action.



Search a patient

Type the last name and/or first name of the patient you are looking for in the **search for a patient** section at the top right of the **Home** page, and then click on their name to access their patient file.

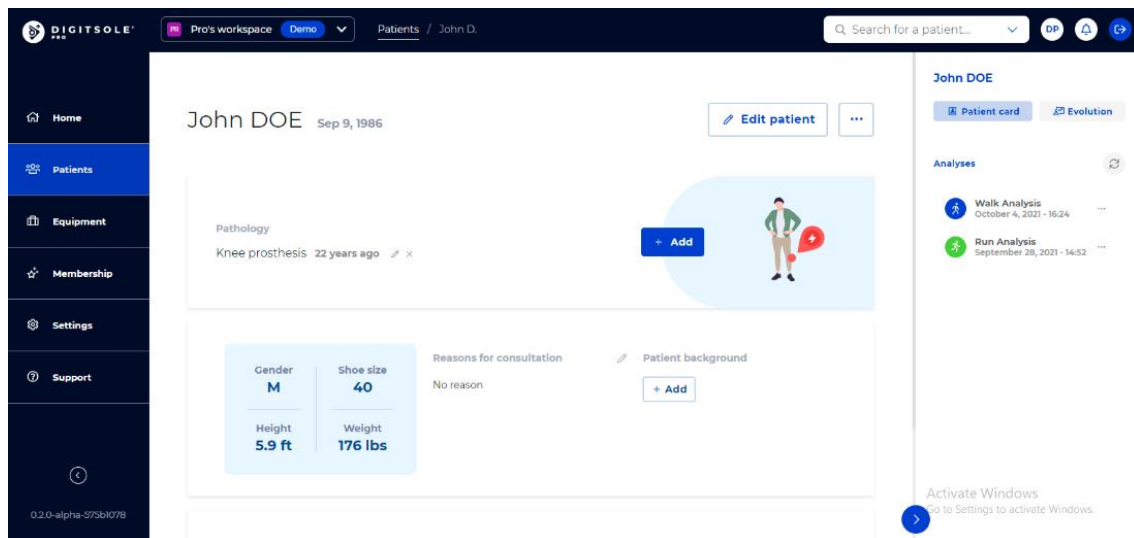


Delete a data capture

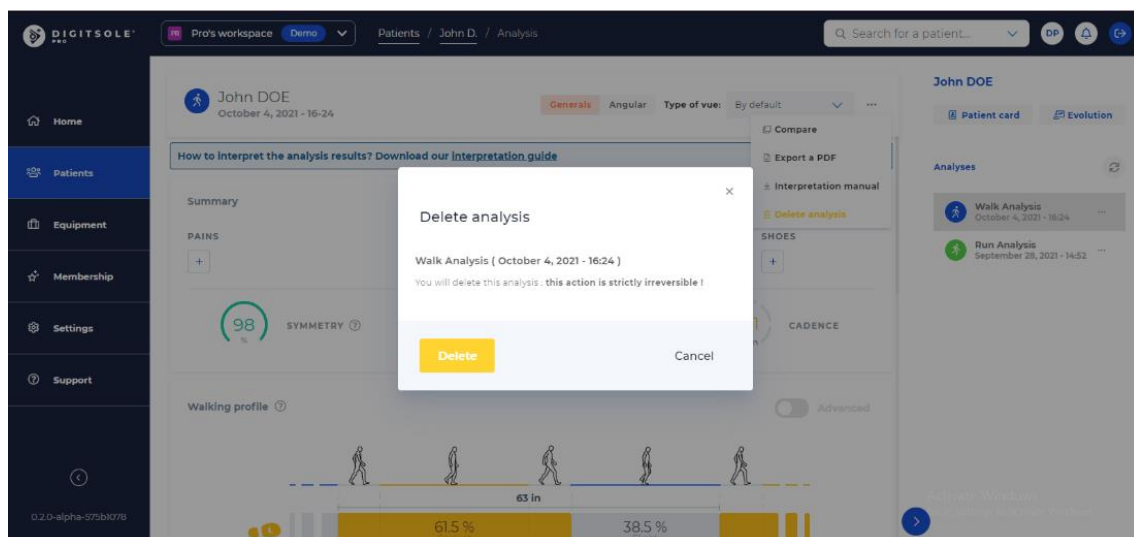
Select the **Patients** tab, then the selected patient's line.
You are now on the patient file.

The “Analyses” section is on the right.

Click... and select **Delete analysis** next to the data capture you want to delete.



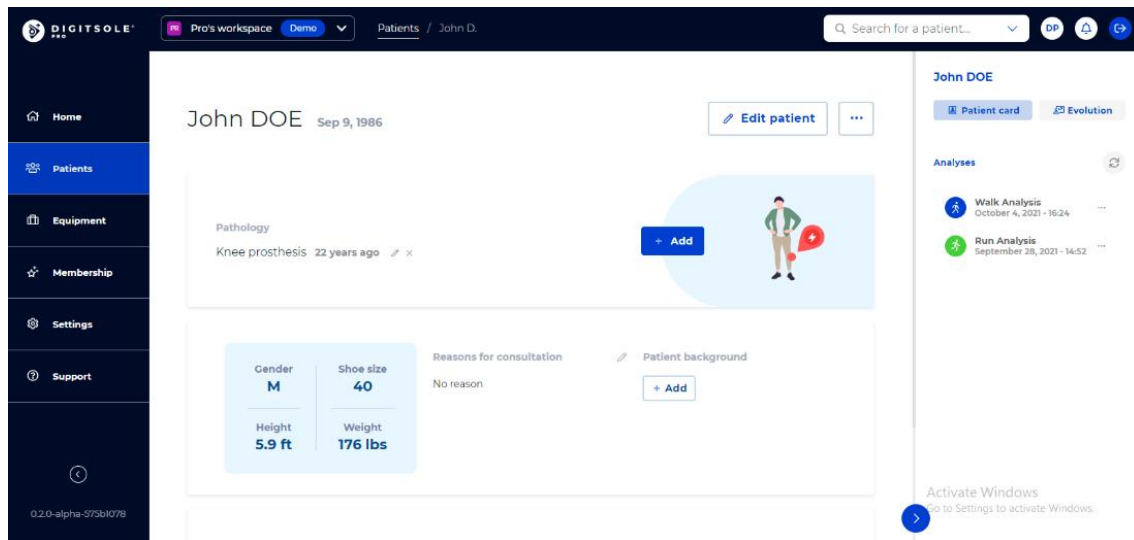
A window appears, asking you to confirm your deletion request.
The data capture will be permanently deleted if you click **Delete**.



View the data

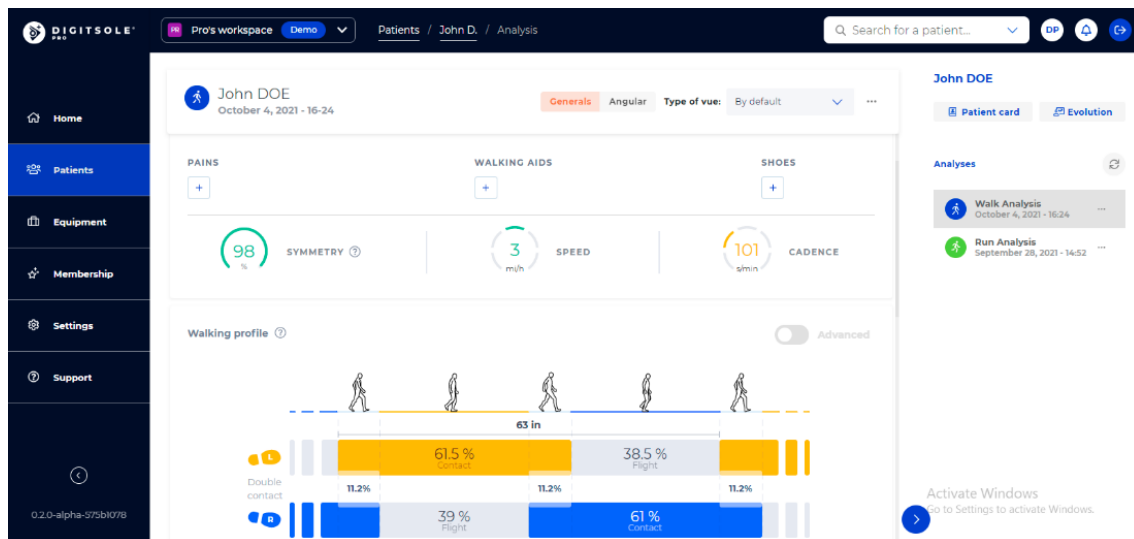
Select the **Patients** tab, then the selected patient's line.
You are now on the patient file.

The “Analyses” section is on the right. Select the analysis you wish to view by clicking on it.



The patient analysis is now displayed.

In the top right corner, you can select the type of view you want: General or Angular, then: Neurological, trauma, rehabilitation. You can also select the default view or edit it with the settings that you want to see.

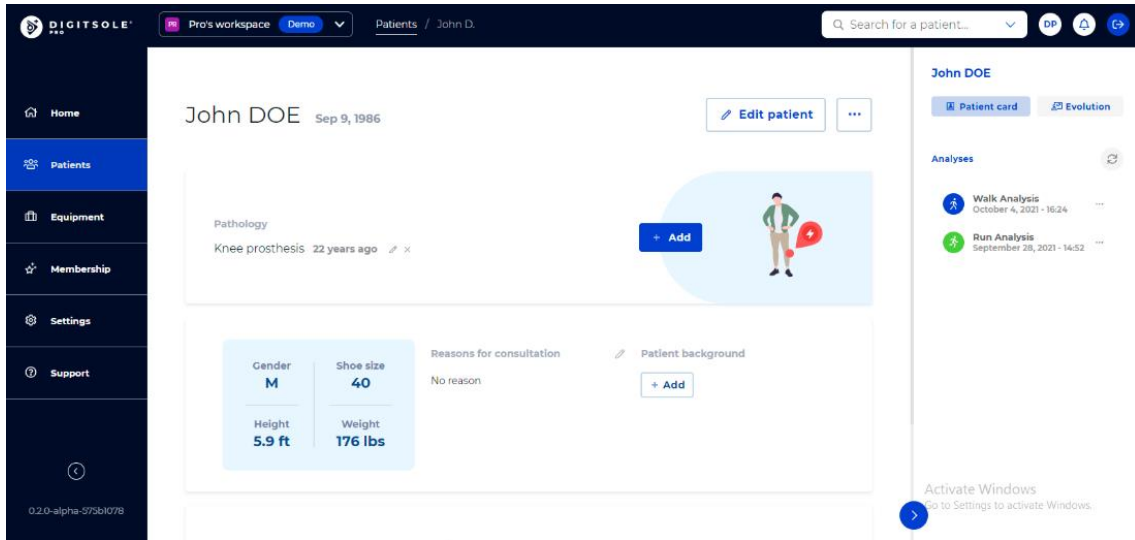


Generate report

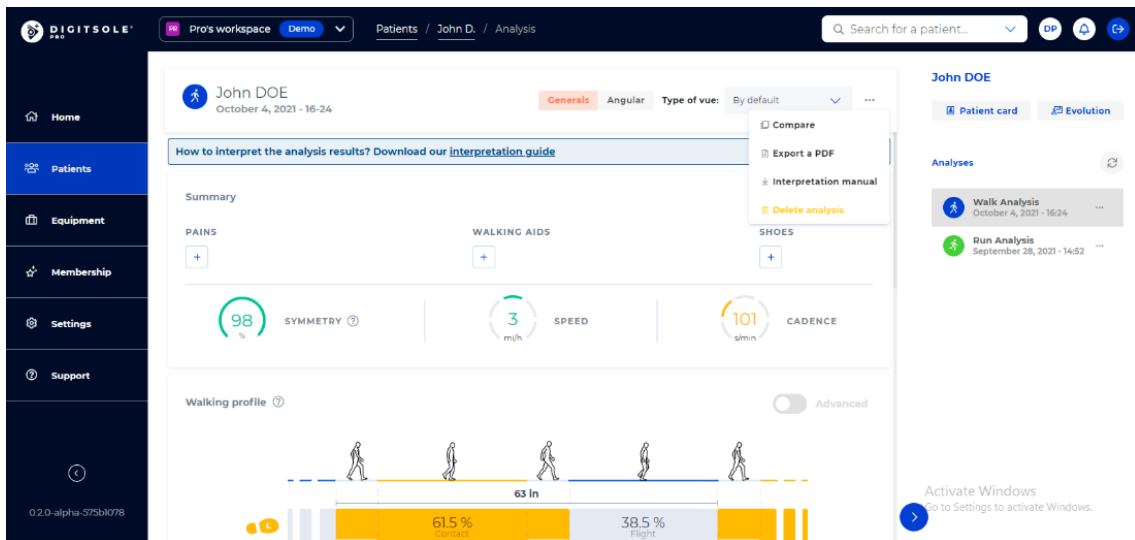
Export report

Select the **Patients** tab, then the selected patient's line.
You are now on the patient file.

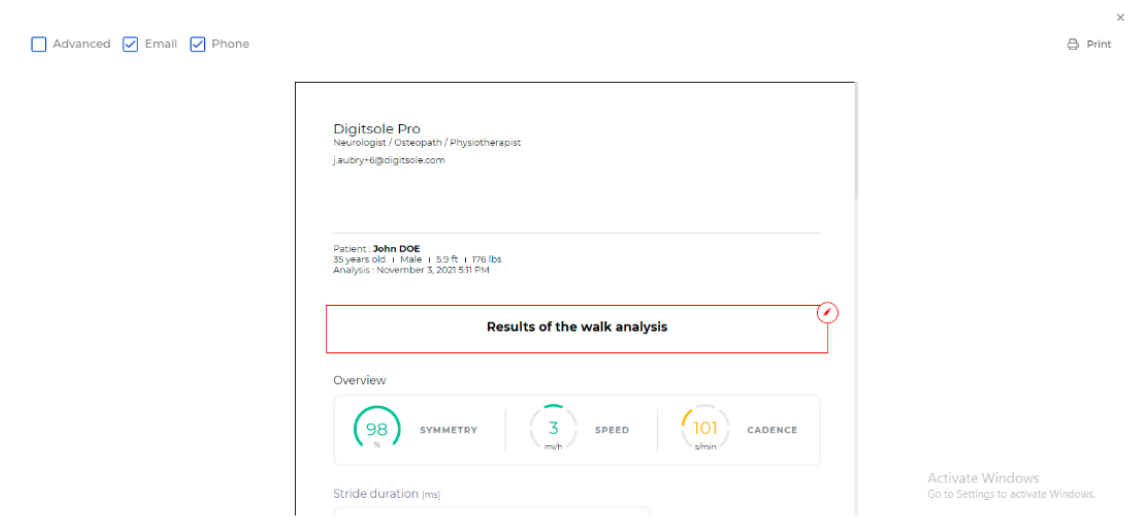
The “Analyses” section is on the right. Select the analysis you wish to view by clicking on it.



Once the analysis is open, click the ... button in the upper right corner, followed by **Export PDF**.



The export analysis page will appear.

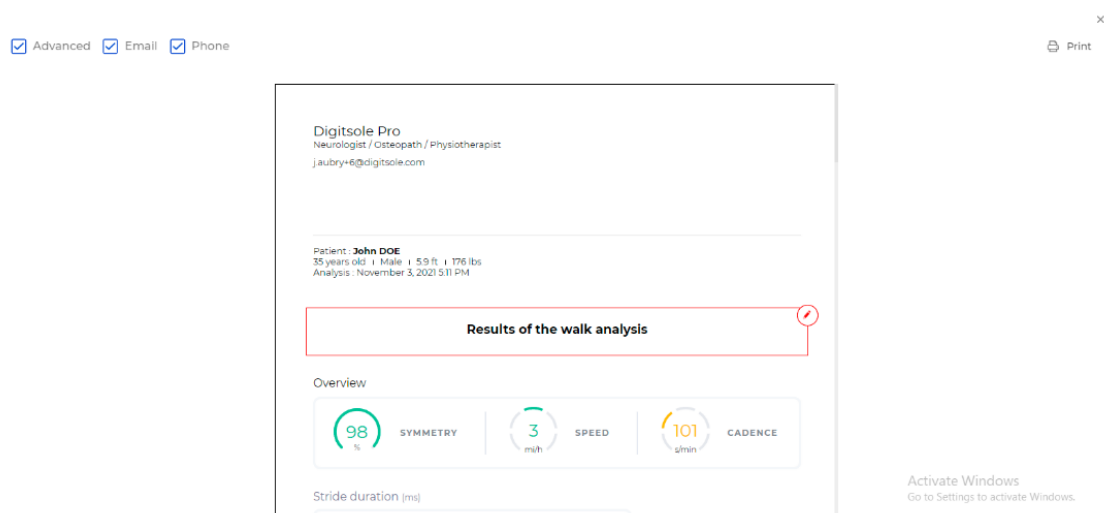


[Change the information about the healthcare practitioner that appears on the report](#)

Following the completion of your analysis export, you can:

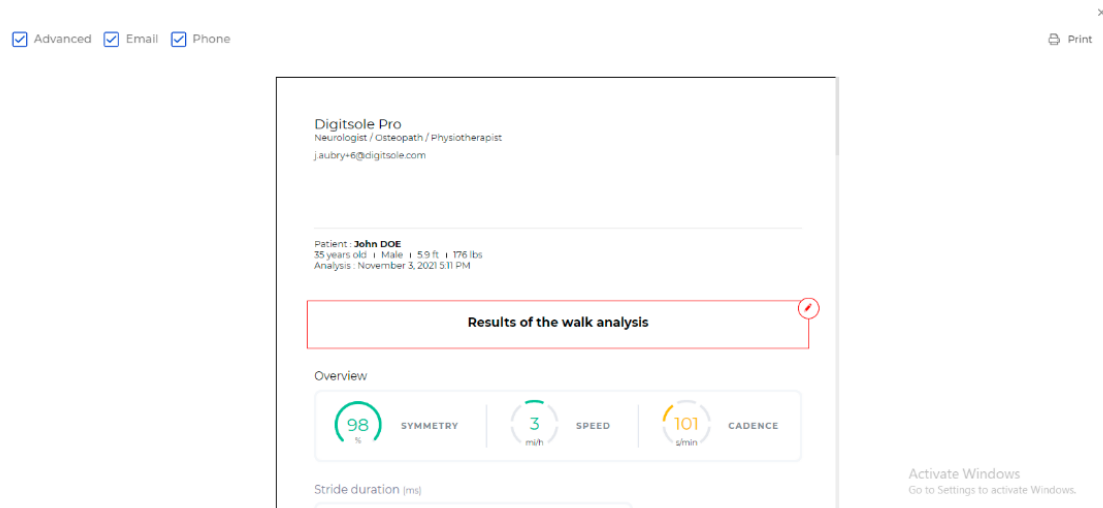
- Check the "Advanced" box to generate a more advanced report
- By clicking on the **Eye** icons, you can choose whether or not to show your email address and/or phone number.

Note: A crossed-out eye indicates that the parameter will not be presented on the report; an uncrossed-out eye indicates that the parameter will be displayed on the report.



Print report

When your analysis export is finished, you can print the report by clicking on the **Print** button at the upper right of the screen.

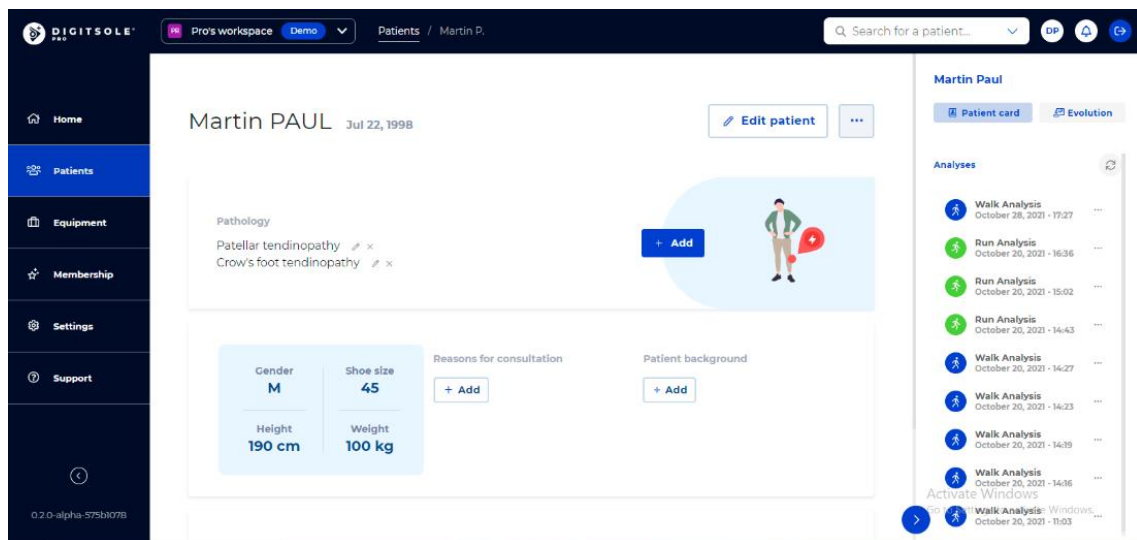


Compare data captures

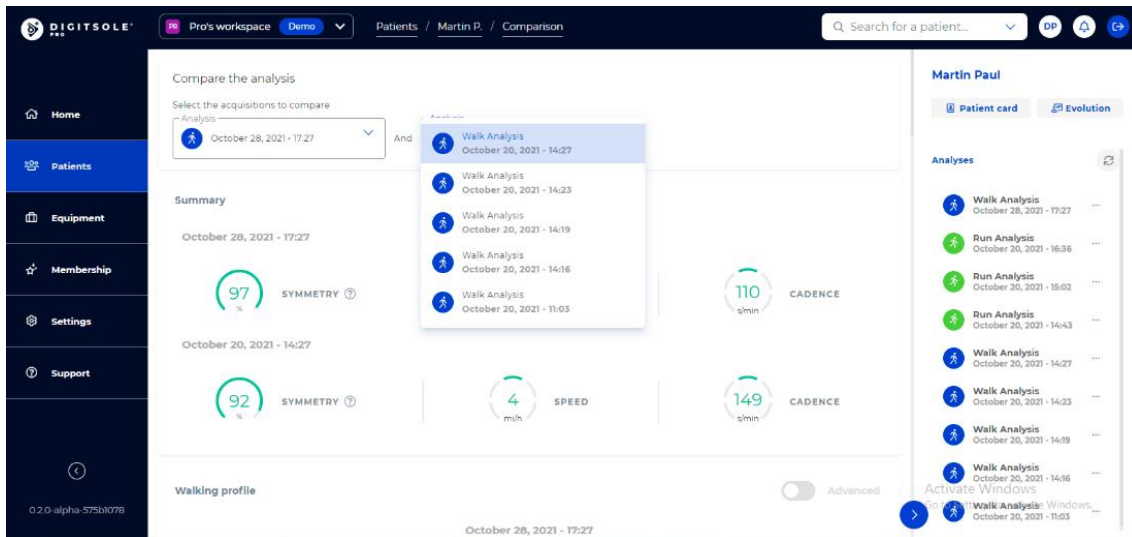
Select the **Patients** tab, then the selected patient's line.

You are now on the patient file.

The "Analyses" section is on the right. Select the analysis you wish to compare by clicking on it.



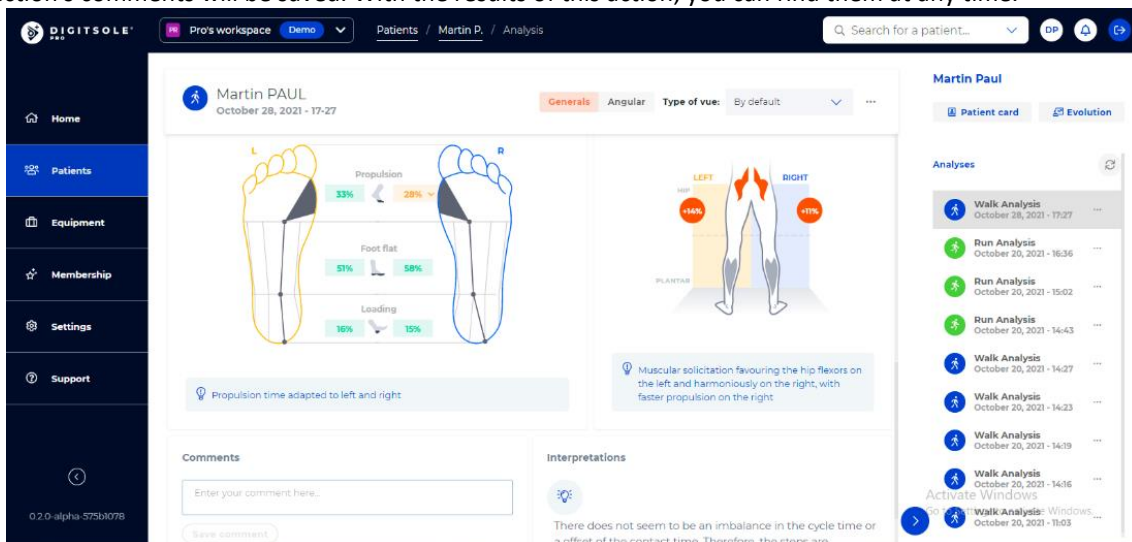
Once the analysis is open, click the... button in the upper right corner, followed by **Compare**.



Then select the analysis that you want to compare it with.

Add comments

You can make a comment in the section provided for this purpose at the bottom of the analysis results of an activity. This section's comments will be saved. With the results of this action, you can find them at any time.

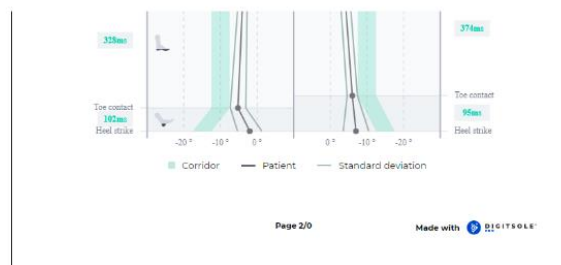


After the report has been exported, you can write a comment in the sections designated for this purpose. The comments you enter here will not be saved on the interface.

You can, however, save them by printing the report, emailing it to the patient, and saving it as a PDF.

Advanced Email Phone

Print



Practitioner's comments

Recommended actions

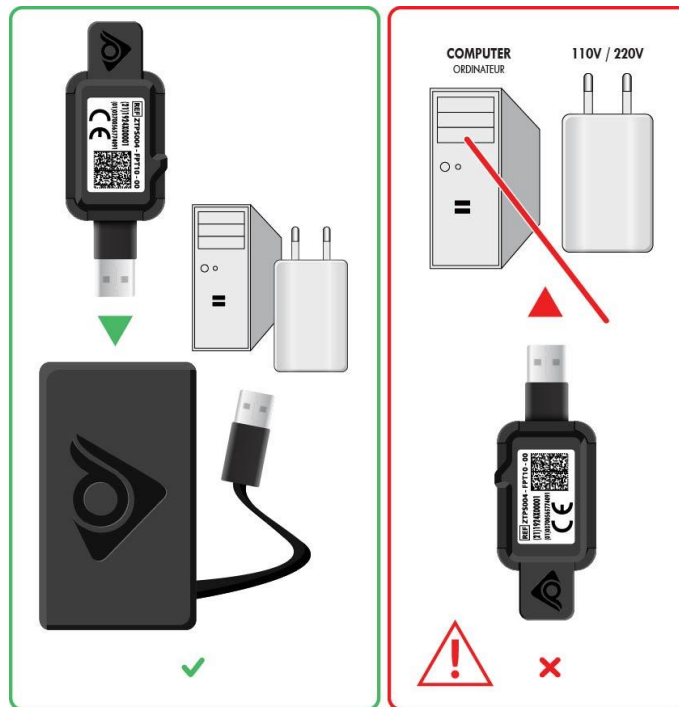
Activate Windows
Go to Settings to activate Windows.

Maintenance

Charging DSPods

Remove the DSPods 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 DSPods before leaving them disconnected for extended periods of time to avoid damaging the battery.

To maximise the lifespan of your DSPods, charge them at temperatures ranging from 10°C (50°F) to 40°C (104°F).

Cleaning instructions for your device



Warning: Use the insole only with a clean sock.

You can use disposable socks -

It is recommended that the following operations be performed on a regular basis and before the first use:

- Use a disinfectant that meets the following 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

- We recommend the STERIMED wipes for EU and the SANI-CLOTH product for US, which are available from Digitsole at: contact@digitsolepro.com and satisfies the requirements.
- Allow to air dry before reusing, or wipe with a clean, dry, lint-free cloth.

CAUTION



- Do not clean the device with corrosive chemicals, oil, acetone, or petroleum-based products
- Do not place the device in a washing machine, dryer, hand dryer, or other piece of equipment.
- Avoid immersing the device in water

Technical Specifications

Battery

- Battery: Li-Ion Polymer
- Nominal voltage: 3.7V
- Charging voltage: 4.2V
- Life cycle ~ 500 cycles
- Full charge time: 2h30
- Active mode: 1.2 mA
- In standby mode (while not in use), total autonomy is: 1750 h

Charger

CAUTION



Charging equipment must comply with IEC60601-1 standards

Entry: 100-240 V - 50/60 Hz

Exit: 5.0V with an output current greater than 30mA

Radio module

Frequency band: 2400-2483.5MHz

Maximum power: 10 mW

This device conforms with the EMC directive 2014/30/EU and the IEC 60601-1-2:2014 standard for electromagnetic compatibility of medical equipment and/or medical electrical systems. These parameters are intended to offer reasonable interference protection in a residential installation.

However, because of the use of radio frequency transmitting equipment and other sources of interference in healthcare and other settings, significant levels of interference from the proximity or power of the source may interfere with the operation of this device.

Usage environment



CAUTION

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

Maximum body pressure:	50 kg/cm ² (or 500 n/cm ²)
Maximum load of the insoles	200 kg
Atmospheric pressure	Between 70-106Kpa
Relative humidity at the time of use (humidity level)	10 ~ 95%
Recommended operating temperature	Between 0°C and 60°C (between 32°F and 140°F)

Product performance

Product life	2 years
Warranty duration	2 years
Storage time	1 year. If you charge the DSPods every six months, you can extend the storage time

[Detailed performance](#)

Gait parameters

- o **Stride length:** Distance travelled by the foot in a gait cycle.
- o **Pace:** Number of steps taken per minute.
- o **Cycle time:** Time between two successive contacts of the same foot.
- o **Contact time:** The duration between heel strike and toe lift for each foot during the stride cycle is used to determine gait stance time, which is the length of the period of the gait cycle when the limb is in contact with the ground.
- o **Swing time:** The duration between foot lift and heel strike for each foot during the stride cycle is used to determine the swing time, which is the length of the section of the gait cycle when the limb is not in contact with the ground.
- o **Double contact:** This is the percentage of the gait cycle during which both limbs make contact with the ground.
- o **Speed:** The speed at which the body moves in a straight line while walking.
- o **Pronation and supination angles:** The average angle of inclination between the foot and the earth's surface. Supination is a negative angle, while pronation is a positive angle.
- o **Duration of the support phase:** The stance phase's first sub-component. When the heel strikes the ground and absorbs the impact, the support phase begins. It comes to an end when the toes touch the ground.
- o **Duration of the flat foot phase:** The support phase's second sub-component. The flat foot phase begins when the full foot is in contact with the ground and ends when the heel is removed.
- o **Duration of propulsion phase:** The stance phase's third sub-component. The time between the heel and toe lifting events is referred to as propulsion.
- o **Symmetry:** The ratio of the exposure time of the right foot (respectively, the left foot) and the sum of the exposure times of the right and left feet.
- o **Gait line:** The gait line is estimated using the pronation/supination angles at four important events (heel strike, toe strike, heel lift, and toe lift) to determine the trajectory of the center of pressure during the unrolling of the foot.

- o **Propulsion ratio:** The ratio of the speed at which the foot is removed from the ground to the average speed during the swing
- o **Stepping:** During initial contact, the angle of flexion/extension of the foot on the earth's surface.
- o **Circumduction:** Perpendicular to the progression line, the distance between the centre of each foot's heels
- o **Clearance:** Minimum toe height at swing.
- o **Step progression angle:** During the flat foot phase, the angle between the walking path and the foot's orientation.

Running parameters

- o **Stride length:** Distance travelled by the foot in a gait cycle.
- o **Analysis time:** Running time during data capture.
- o **Speed:** The average speed at which the body moves in a straight line while running.
- o **Pace:** Number of steps taken per minute.
- o **Asymmetry:** The ratio of the exposure time of the right foot (respectively, the left foot) and the sum of the exposure times of the right and left feet.
- o **Attack type:** Defined as the part of the foot that makes contact with the ground at the start of a stride
- o **Attack angle:** Angle between foot and ground at initial contact.
- o **Contact:** Contact is calculated as the interval between initial contact and toe lift off for each foot throughout the stride cycle as a percentage of the length of the period of the stride cycle during which the limb is in contact with the ground.
- o **Swing:** The swing is the proportion of time during the running cycle when the limb is not in contact with the ground, measured as the interval between foot lift and initial contact for each foot during the stride cycle.
- o **Double swing:** For a running cycle, the percentage of time when no foot makes contact with the ground.
- o **Pronation and supination angles:** Angle of inclination between the foot and the earth's surface. Supination is a negative angle, while pronation is a positive angle.
- o **Impact force:** Maximum vertical ground reaction force in the gait support phase.
- o **Parameter changes during running:** Allows for the comparison of two running moments.

Conditions of shipping and storage



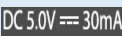




















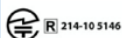







CAUTION



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

The recommended battery charge level for storage is	between 75 and 100%.
Temperatures for storage and shipping	between -10°C and 60°C (between 14°F and 140°F)
Atmospheric pressure	0 ~ 100% HR
Recommended humidity (humidity level)	between 50-106Kpa

Symbols definitions

Symbol	Description	Symbol	Description
	The device meets the requirements of European Directive 93/42/EC, which covers medical devices.		Medical device
	DC power supply 5 V 30mA.		When a device reaches the end of its useful life, it must be disposed separately from household waste. See the section "Product End-of-Life" for more information
	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 into the washing machine
	Please do not put on fire		Please do not bend
IP54	Device protected from powerful water sprays		Charger side to download data
	This symbol on the box indicates "Atmospheric pressure limit" during shipping and storage.		This symbol on the box means "Relative humidity limit".
	This symbol on the box means "Temperature limit".		This symbol on the box means "Keep dry," because the product must be protected from humidity and water.
	USA: Federal Communication Commission (FCC) statement		Before using, consult the user manual.
	Prevent the risk of suffocation		Type B applied part (this device is protected from leakage current and electric shocks)
	The product is type certified in compliance with Japanese Ordinance MPT No. 37 of 1981 (Technical Regulation Conformity Certification of Specified Radio equipment)		Keep out of the reach of children. It may cause suffocation.
	Indicate a potential danger associated with the device's use		It contributes financially to the organization of recycling in accordance with European Directive 94/62/EU and national Law.
	Normal charger use	REF	Commercial reference of the device.
	Do not use near a magnetic resonance device		Prohibited use of the charger
	Inform that some information for use are available on the web		

Regulatory conformity

The risks associated with this medical equipment have been appraised in accordance with the ISO 14971 standard, particularly in terms of the overall residual risk.

Digitsole Pro complies with the following directives and standards:

- Council Directive 93/42/EEC relating to medical devices, as amended by European Directive 2007/47/EC.
- European Parliament and Council Directive 2014/53/EU of 16 April 2014 on the harmonisation of the legislation of Member States on the commercialisation of radio equipment (RED).
- European Parliament and Council Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).
- The European Parliament and the Council Directive 2012/19/EU (WEEE) on waste electrical and electronic equipment of 4 July 2012
- Directive CEM 2014/30/UE
- IEC 60601-1:2005 + AC1:2006 + AC2:2007 + Amd1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014: Medical electrical equipment. First part: General safety rules. Collateral standard: Electromagnetic compatibility - Requirements and tests

The declaration of conformity can be found on the [Compliance Centre's website \(digitsole.com\)](http://Compliance Centre's website (digitsole.com)), or it can be requested by emailing contact@digitsole.com

FCC-FCCID: 2AQ4H-DSI

United States: Federal Communications Commission (FCC) declaration. This device complies with FCC Part 15 FCC Rules. Its operation is subject to the following two conditions:

"Changes or modifications not expressly approved by Digitsole 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 provided that 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.

End of product life

Electronic components and lithium-ion batteries are subject to recycling regulations which vary by country and region. Please observe the legislation in effect in your region before disposing of these insoles in order to respect good environmental practices.

As a result, the device should be returned to your healthcare provider, distributor, or manufacturer.

Assistance and help

Help - Troubleshooting

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

Contact

Do you have a question or a suggestion? Don't hesitate to get in touch!

Contact us:

+33 (0)3 55 91 40 55

+1 720 798 4452

contact@digitsole.com

Please email us at Vigilance@digitsole.com if you have an unpleasant incident that is directly or indirectly related to the use of the device.

CE marking

Date of CE marking: May 2021

REF DSPS001-FPT00

UDI-DI: 3700565774633



DIGITSOLE
13 Rue Héré
Place Stanislas
54000 Nancy
France



DIGITSOLE[®]
PRO

Walking Analysis Manual




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Definitions

Colors and Arrows

For better visibility, in general in this new interface, the left side is represented in Orange and the right side in Blue. The inserts containing the durations of the contact phases are represented in:

-  Deviating from the norm
-  Close to the norm boundary ends
-  Close to the norm

Arrows complete this information by indicating whether they are:

above: 

or below: 

the norm, respecting the color code corresponding to their distance from this norm, taken from the literature and adapted to our measurement system.

The parameters

We present two categories of parameters:

Metrics:

Metrics are the parameters we measure directly from the data recorded by the insoles.

Spatio-Temporal Parameters

- **Speed (km/h):** Average speed of the patient.
- **Pace (steps/min):** Number of steps taken per minute, this is the combined total of the two feet.
- **Cycle time (ms):** Time between two successive heel landings of the same foot.
- **Cycle length (cm):** The length of time between two successive heel landings of the same foot.
- **Contact time (ms and %):** The length of time the foot is in contact with the ground, standardized to be expressed as a percentage of the cycle time.
- **Flight time (ms and %):** Time during which the foot is not in contact with the ground, standardized to be expressed as a percentage of the cycle time.
- **Double contact time (%):** Percentage of the cycle during which both feet are in contact with the ground at the same time.

Kinematics

- **Pronation/Supination angles (°, deg):** Defined between the foot and the ground to express the inclination in the coronal (frontal) plane of the foot at the four key moments of the stride sequence: heel landing, toe landing, heel lift-off and toe lift-off.
- **Step progression angle (°, deg):** Defines the relationship between the orientation of the foot and the patient's path of travel.
- **Circumduction (cm):** Maximum distance of lateral displacement of the foot during the flight phase.
- **Toe clearance (mm):** Minimum height between the toes and the ground during the flight phase.
- **Steppage (°, deg):** Angle between the foot and the ground in the sagittal plane at the moment of heel landing.
- **Propulsion angle (°, deg):** Angle between the foot and the ground in the sagittal plane at the moment of toe lift-off.

Biomarkers:

Biomarkers are parameters that we have calculated using one or more parameters at a given time or for a whole period of the walk.

- **Symmetry (%):** Expresses the congruence between the values obtained on the left and right foot for contact and flight time. Symmetry determines whether one leg is used more than the other when walking.
- **The Digital Gait Line:** Based on the analysis of pronation/supination angles, it represents the trajectory of the center of support during the contact phase at the foot.
- **Propulsion Ratio:** Calculated as the ratio of the propulsion speed (standardized speed of the foot at lift-off of the toes) to the average stride speed (average speed of the foot during the entire flight phase). **It provides information on the muscles during the flight phase (triceps surae or hip flexors).**

Observations

Below each graph, you will find a short text presenting the results in relation to the literature standards, directly informing you if the said parameter is in excess or in default. A recommendation may be made in relation to a condition or other information to look for in that patient.

Comments

At the bottom of each page, an insert is reserved for you to annotate all your comments. You will then be able to find them when you export the analysis in pdf format.

Interpretations

At the bottom of each page, you will find an insert reserved for interpretations which will inform you on a possible limp, on the propulsion and the walking sequence of the patient.

Presentation of results

Abstract

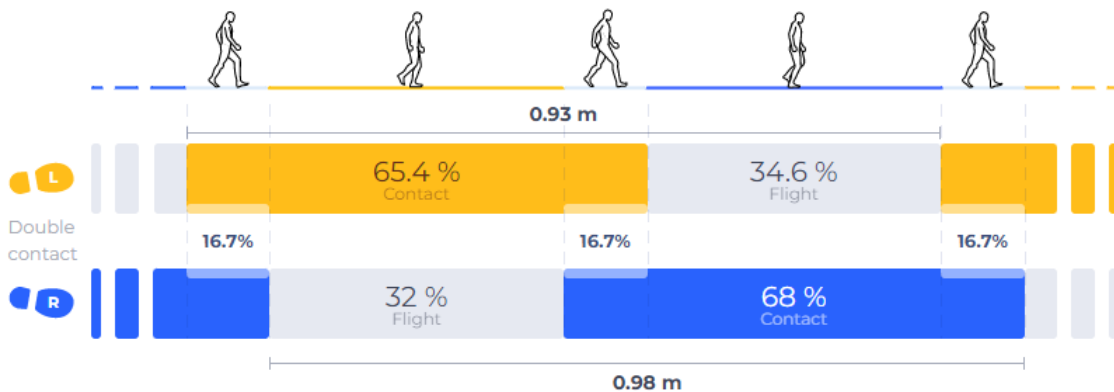


Gives the general values of the recording, which are independent of laterality. Symmetry close to 100% indicates good congruence between left and right steps. On the other hand, less symmetry may indicate different behaviors of the lower limbs and therefore either an abnormality in one foot only or both feet are affected in different ways.

Speed is a good indicator of walking quality and range. Walking too fast or too slow may be the first sign of a locomotion problem.

Pace is strongly correlated with speed and will therefore also be a qualitative indicator of walking

Walking phases

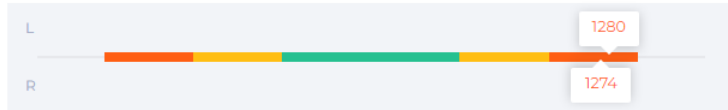


This figure shows the percentage durations of the different running phases: contact, flight and double contact phase, and the length of the cycle. As in the rest of this document, the left foot is represented in orange and the right foot in blue, the contact times are in a darker color while the flight phase are in a lighter color.

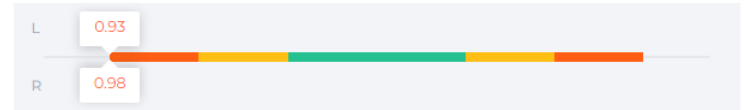
Double contact is located between the two feet, in grey. Finally, the cycle lengths are at the top for the left side (orange) and at the bottom for the right side (blue).

Advanced mode

Stride duration (ms)



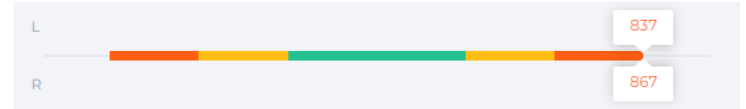
Stride length (m)



Swing time (ms)



Contact time (ms)



By activating the advanced mode, you will be able to access the graphical representation of the averages of the above parameters in relation to the literature standard, which is also available at the end of this document.

You will therefore be able to assess the situation of these parameters and determine whether they are in excess or in deficit, while considering the distance from this norm.

This information will complement the observations you will be able to make when comparing the two graphs.

The color code used is as follows: green includes the average measurement plus or minus one standard deviation. Orange includes data from the norm that is between one and two standard deviations away from the mean. Finally, red corresponds to values above the mean plus or minus two standard deviations.

Digital Gait Line



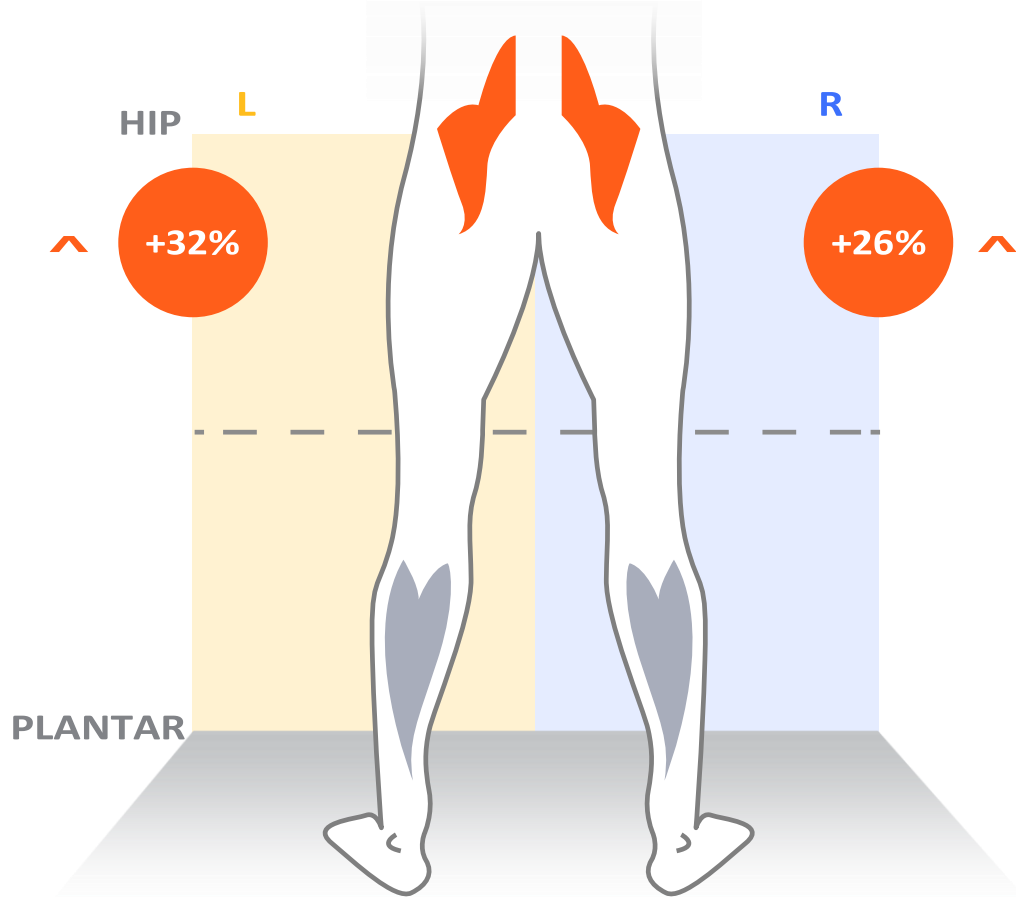
This diagram represents the displacement of the center of support (black line) at the foot during the contact phase. We can assess the pronation and supination of the foot through the displacement of the center of support, for each key moment of the stride sequence (heel and toe landing, heel and toe lift-off).

This information is supplemented by the duration of each phase (between key moments), expressed in milliseconds (as above) when the cursor is in the "Absolute" position and in percentages of the contact time when it is in "Relative".

Finally, thanks to this presentation, it is easy to compare the sequence of the two feet and to appreciate their symmetry.

It will then be possible to identify the spatial and temporal location of the disorder in order to adapt your treatment.

Propulsion ratio

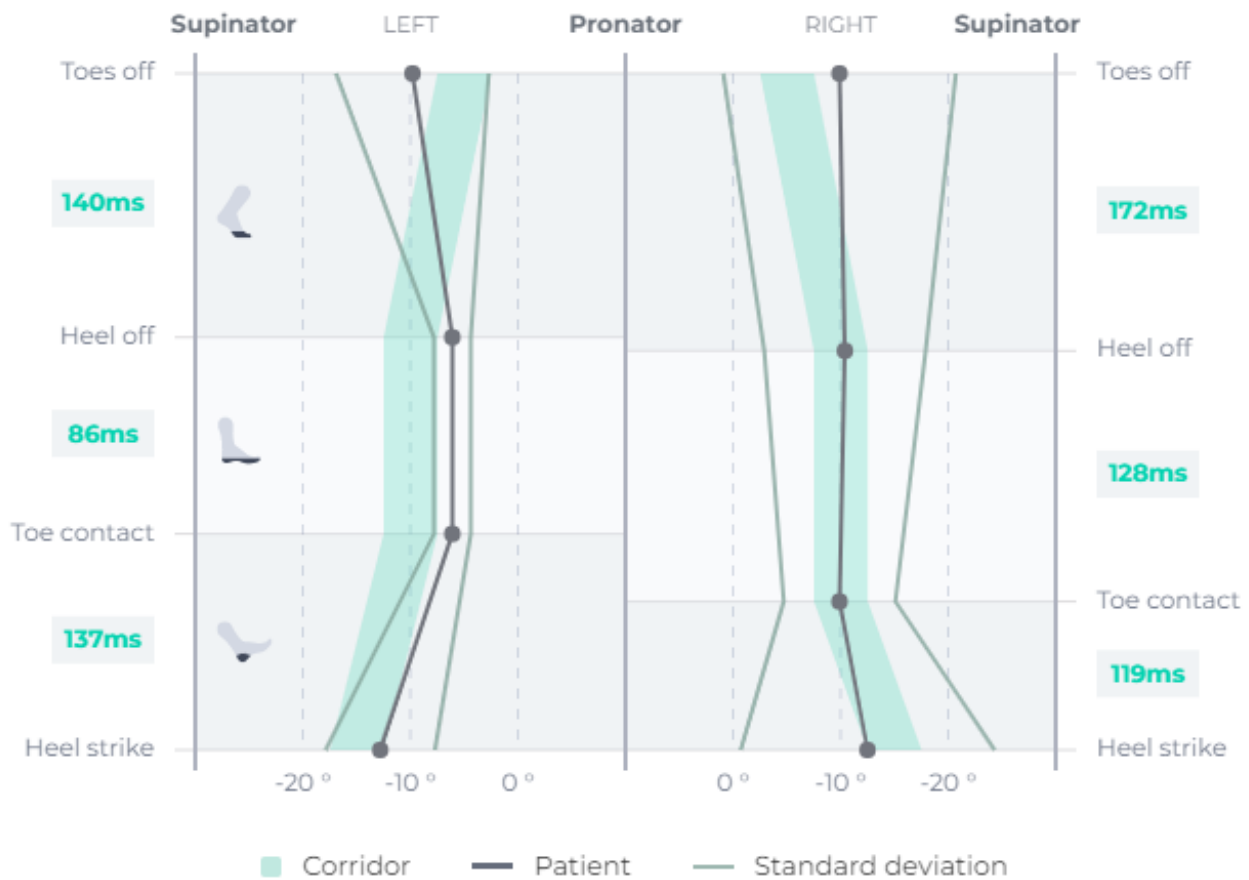


The propulsion ratio is the ratio of the propulsion speed (foot speed at lift-off of the toes) to the average stride speed (average foot speed during swing phase).

Through this ratio, we can determine whether the speed of foot movement is created more by the plantar flexors or the hip flexors, we can then highlight the muscle group and the deviation from perfect balance.

In this example, it is the hip flexor muscles that are mainly used, so that the feet accelerate during the flight phase in a quasi-symmetrical way since there is a difference of 6 percentage points between the left and right foot.

Pronation and supination angles



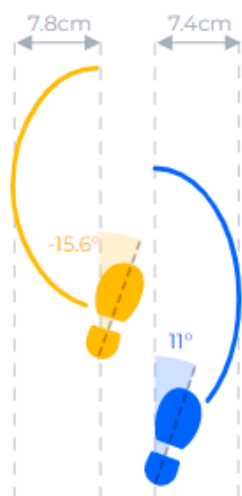
During the contact phase, we measure pronation/supination angles at the four key moments of the step sequence, heel landing, toe landing, heel lift-off, and toe lift-off. This angle corresponds to the lateral inclination of the foot in relation to the ground.

We propose a corridor of normality (green) based on the literature and adapted to Digitsole Pro with health professionals, representing the sequence of a healthy subject, to compare the mean value (black line) and the variability (grey lines) of your patient.

In this example, we can see the left foot pronate for the first 3 events of the stance phase. On the toe off event, the foot goes back to supination. Right foot follows the norms for the first three events and leave the ground with more supination than the norm. Standard deviation shows the variability is higher on the right side than the left side.

As on the Digital Gait Line, on each side of the graph we find the duration of each phase of the sequence: loading, unipodal, and propulsion. As this representation is dynamic, the spaces corresponding to these durations and the juxtaposition of the curves of the angles during the sequence make it possible to appreciate their symmetry.

Step Progression Angle and Circumduction



The Step Progression Angle (SPA) is expressed in degrees and corresponds to the orientation of the foot in relation to the patient's gait trajectory.

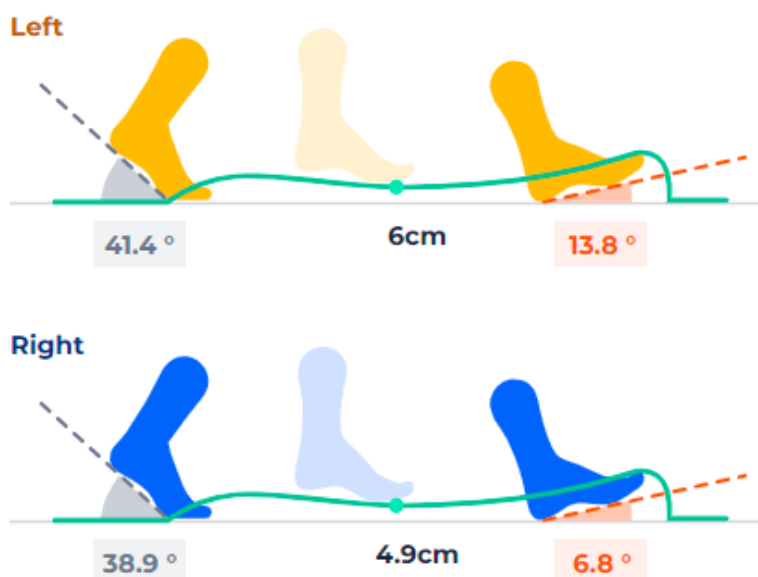
To be precise, it is a question of opening or closing the feet.

A healthy person is supposed to walk with a slight opening of the feet towards the outside.

Step Progression Angle and Circumduction represented on this graph. This is the maximum lateral distance the foot travels during the flight phase, relative to the line joining two consecutive landings of the same foot. For a healthy subject, this value is close to zero.

It will then tend to be high for subjects with a neurological/spastic type of limp.

Clearance and Steppage



In the center of this graphic representation, we find the Clearance, which is the minimum height between the toes and the ground during the flight phase of the step. It is a question here of having information on the free passage of the step, indeed, with a height that is too low, the flight of the foot could meet an obstacle and cause a loss of balance at the very least and a fall in the worst case.

On the left, there is the propulsion angle. It is the plantar flexion angle between the ground and the foot in the sagittal plan at toe off. This angle can be related with the capability to create a good propulsion so it should be different than 0.

Finally, you can find on the right, the Steppage also known as angle of attack. This is the angle between the foot and the ground in the sagittal plan at heel strike. A healthy person does not place the foot flat or walk with the toes

Tips

- If you have a case where the pace is too high and the speed is slow, this patient may be looking for balance. You can objectify this phenomenon by observing that the sum of the two double legs will be greater than 25%.

- **Asymmetry of contact time :**

If the cycle times are equivalent and the percentage of contact time is not symmetrical, this means that the patient is spending more time on one limb, which is described as "stronger". This may be due either to pain on the other side, or to a lack of sensitivity or "confidence", which will prevent one from putting his weight on that leg for long.

- **The Step Progression Angle :**

It completes the information given by the pronation-supination angles and the gait line to better understand the plantar sequence and thus explain certain situations such as excessive pronation or supination during the loading and propulsion phases.

It is also of great importance in the analysis of propulsion, because during this phase, the leverage on the foot is the most pronounced and an angle that is too open could eventually modify or explain a change in the skeletal architecture of the foot due to the high forces to which the forefoot is subjected. An abnormality measured on this angle can thus highlight architectural modifications of the foot, secondary to an inadequate contraction of certain muscles causing an inversion, an eversion (combined with the angles of pronation and supination) or an inadequate rotation of the hip, knee, femur, or tibia (to be checked with the alignment of the patella and a static analysis). - Inward: look for a possible varus adductus foot, or internal rotation of the hip, shin, or femur

(checking the orientation of the patella and hip)

- Outward: monitor pronation in propulsion, check for a possible valgus adductus foot, or external rotation of the hip, shin, or femur (checking patella orientation and hip rotation)

- **The circumduction :**

It is often a sign of a deficit in knee flexion, to clear the way for the footfall, or to prevent the minimum toe height (clearance) being too low. It can potentially be due to spasticity of the rectus femoris, or a dorsal flexion deficit of the ankle. This could itself be due to an inappropriate contraction of the plantar flexors, which can be found, for example, in certain pathologies such as multiple sclerosis or poststroke during hemiparesis. It is therefore interesting from this point of view to relate it to clearance and step progression angle (which are likely to be disturbed in the presence of this gait anomaly).

- **The Clearance :**

The minimum toe height is normally reached at peak foot speed during the flight phase. This parameter tells us about the patient's ability to lift the foot sufficiently so that it does not hit the ground or any obstacle during its trajectory, which could lead to a loss of balance and potentially a fall. Moreover, several authors in the clinical literature have identified it as an important parameter to take into account when assessing the risk of falling.

- **If there is an excess or lack of minimum toe height, look for a possible problem with proprioception or motor control of the knee flexors**

- **Steppage :**

Three possible situations are considered:

- The angle is > 0 : The patient makes contact with their heel first
- The angle = 0: the patient places the foot flat
- Angle < 0 : the patient makes contact with the forefoot first

This parameter informs us about the way the patient starts his or her step, which will condition the whole process that will follow.

This information is important for determining a dorsiflexion defect of the foot, which may potentially be related to weakness of the dorsal flexors, inappropriate muscular activity of the plantar flexors (spasticity, muscle retraction) or limitation of the knee or ankle joint amplitudes compelling an abnormal approach either with the foot flat or with the forefoot.

It is, therefore, relevant to look for, during the clinical assessment:

- Possible locking of the knee in flexion ($> 30^\circ$)
- Spasticity or retraction of the plantar flexors
- A true equinus (knee and hip in extension, and ankle in equinus) in the unipodal phase
- An apparent equinus (ankle at 90° , knee and hip flexed)
- A jumping step (foot in equinus, knee and hip flexed)
- A squatting walk (ankle in hyper-dorsiflexion, knee and hip in hyperflexion)

- **The Risk of Falling:**

Difficult to assess objectively, many tests and scales are dedicated to it, including information on the patient's life, social and health situation (pathologies and medication intake, psychotropic drugs for example), fall history and clinical assessments (Timed Up & Go test, One leg contact, Romberg test, etc.).

In the literature, several behaviors and in particular certain parameters in relation to the norm have been identified as being characteristic of a population at risk of falling.

The parameters include:

- Cycle length: decrease, but increase in variability
- Duration of the use of both legs: increase in duration and variability
- Propulsion ratio: decrease (increased use of hip flexors at the expense of plantar flexors to advance the foot)
- Pace: increase
- Speed: decrease
- Contact time: increase in duration and variability
- Duration of loading and propulsion: increase (linked to the increase in the duration of the use of both legs).
- Cycle time: increase.

Walk analysis

<i>Parameters</i>	<i>Definitions</i>	<i>Accuracy</i>
Stride length	Distance travelled by the foot in a gait cycle.	+/- 5cm
Pace	Number of steps taken per minute.	+/- 5pas/min
Cycle time	Time between two successive contacts of the same foot.	+/- 100ms
Contact time	The duration between heel strike and toe lift for each foot during the stride cycle is used to determine gait contact time, which is the length of the period of the gait cycle when the limb is in contact with the ground.	+/- 50ms
Flight time	The duration between foot lift and heel strike for each foot during the stride cycle is used to determine the flight time, which is the length of the section of the gait cycle when the limb is not in contact with the ground.	+/- 50ms
Double contact	This is the percentage of the gait cycle during which both limbs make contact with the ground.	+/- 50ms
Speed	The speed at which the body moves in a straight line while walking.	+/- 0.2km/h
Pronation and supination angles	The average angle of inclination between the foot and the earth's surface. Supination is a negative angle, while pronation is a positive angle.	+/- 7°
Duration of the support phase	The contact phase's first sub-component. When the heel strikes the ground and absorbs the impact, the support phase begins. It comes to an end when the toes touch the ground.	+/- 50ms
Duration of the flat foot phase	The support phase's second sub-component. The flat foot phase begins when the full foot is in contact with the ground and ends when the heel is removed.	+/- 50ms
Duration of propulsion phase	The contact phase's third sub-component. The time between the heel and toe lifting events is referred to as propulsion.	+/- 50ms
Symmetry	The ratio of the exposure time of the right foot (respectively, the left foot) and the sum of the exposure times of the right and left feet.	+/- 5%
Gait line	The gait line is estimated using the pronation/supination angles at four important events (heel strike, toe strike, heel lift, and toe lift) to determine the trajectory of the center of pressure during the unrolling of the foot.	+/- 0.5
Propulsion ratio	The ratio of the speed at which the foot is removed from the ground to the average speed during the swing.	NA
Steppage	At initial contact, the angle of flexion/extension between the foot and the ground.	+/- 5°
Propulsion angle	At toes off, the angle of flexion/extension of the foot on the earth's surface.	+/- 10°
Circumduction	Perpendicular to the progression line, the distance between the center of each foot's heels.	+/- 1cm
Clearance	Minimum toe height at swing.	+/- 2cm
Step progression angle	During the flat foot phase, the angle between the walking path and the foot's orientation.	+/- 5°

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Help and assistance

Help

Full information is available at:
<https://www.digitsolepro.com/>

Contact

Do you have a question or a suggestion? Do not hesitate to contact us.



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Date of CE marking: 2021, April





DIGITSOLE[®]
PRO

Running analysis interpretation manual

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Parameters definition

- **Recording time (min):** Duration of the recording.
- **Running speed (km/h):** Average running speed during the recording.
- **Pace (steps/min):** Average number of cumulative steps (right + left) per minute during the recording.
- **Stride duration (ms):** Period between two consecutive touchdowns of the same foot on the ground.
- **Contact time (ms and %):** Average time the foot is in contact with the ground, can be expressed as a percentage of the stride time.
- **Flight time (ms and %):** Time during which the foot is not in contact with the ground, can be expressed as a percentage of the stride duration.
- **Stride length (m):** The distance covered in a stride between two consecutive touchdowns of the same foot.
- **Approach type:** Expresses the predominance of heel or forefoot approaches on the ground during recording.
- **Symmetry:** Expresses the congruence of the contact times of the two lower limbs

Overview

PAINS



WALKING AID



SHOES



PATHOLOGIE



As with walking analysis, you can fill in the elements directly related to the recording before and after the recording to obtain a "snapshot" of the conditions in which the recording took place and thereby improve the relevance of your comparisons.

This information includes:

- Pain: locoregional and intensity.
- Any walking aids used.
- Footwear: rigidity, cushioning and wear area.
- Pathology.

Standard
ANALYSIS TYPE

00:47
ANALYSIS DURATION

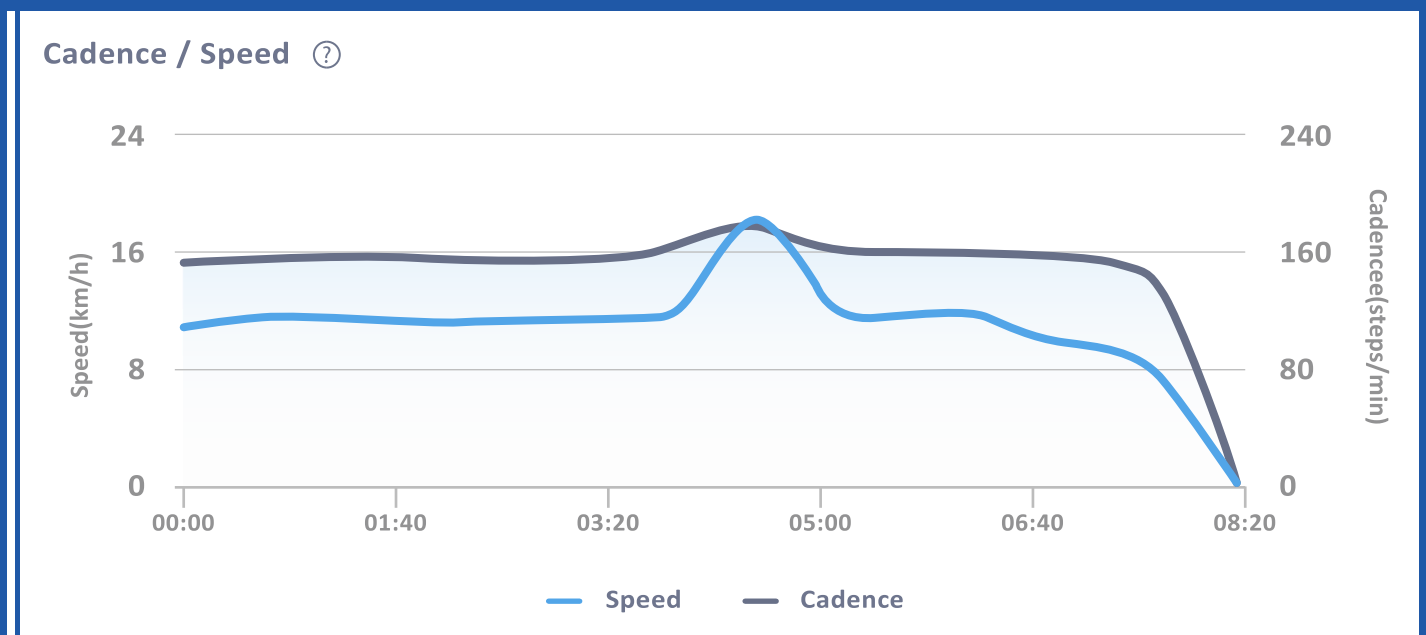
7.1 km/h
SPEED

163
s/min
CADENCE

The interface presents in this initial screen the general parameters of the recording:

- The analysis type.
- The analysis duration.
- The average speed.
- The cadence.

Running Speed and Pace



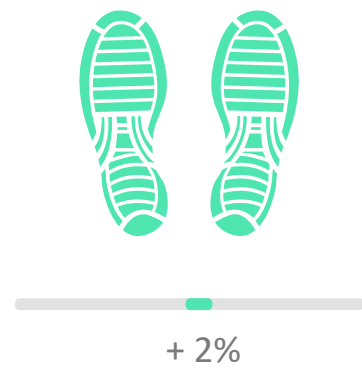
This graph provides dynamic monitoring of average running speed and pace. The aim here is to gain an insight into the development of the running session as a whole.

In this graph, we are looking for information on a possible disruption of the running process to distinguish between:

- On one hand, timing: the time of onset of the problem
- On the other hand, the type of development: continuous (lasting development of the disturbance) or acute (break in the development of the curve) and the significance of this disturbance.

Asymmetry

In this first panel, we find an index of **symmetry of the contact phases**, highlighting the extent of asymmetry between the two lower limbs, as well as **the limb that appears to be the strongest**



Type of Approach and Force of Impact



The type of approach is the way in which the foot is placed on the ground, starting either with the heel, the midfoot (foot flat to the ground), or the forefoot.

Note that this is the "average" of the approaches carried out during this recording.

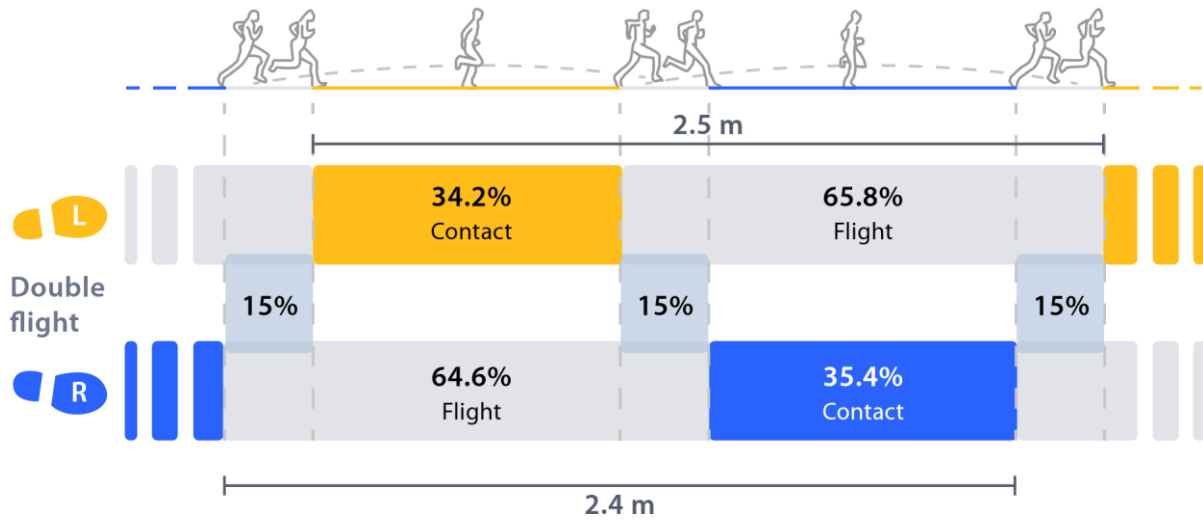
The impact force is the deceleration force experienced by the foot on first contact with the ground for each stride.

This force depends on the patient's weight, the elevation of the pelvis during the stride, the length of the stride and the running speed.

The risk of injury may increase with the magnitude of this force, although there is no scientific consensus on this issue.

Running profile

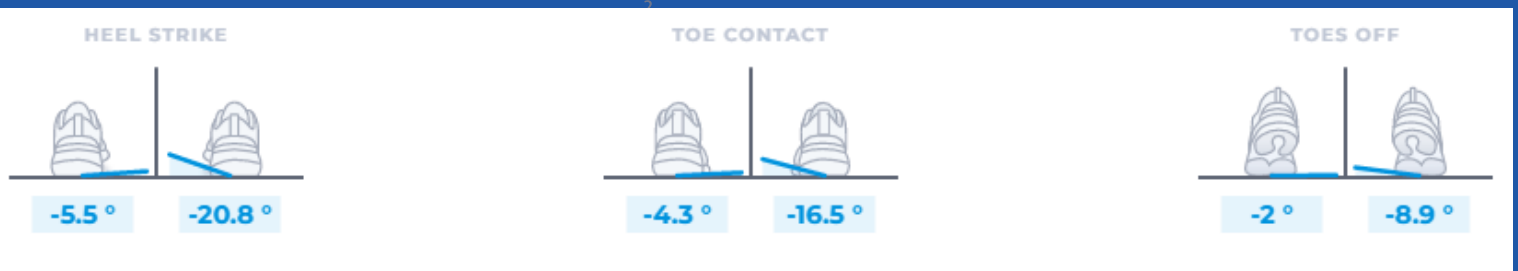
Running profile ?



This graph shows all the average spatio-temporal parameters of this recording.

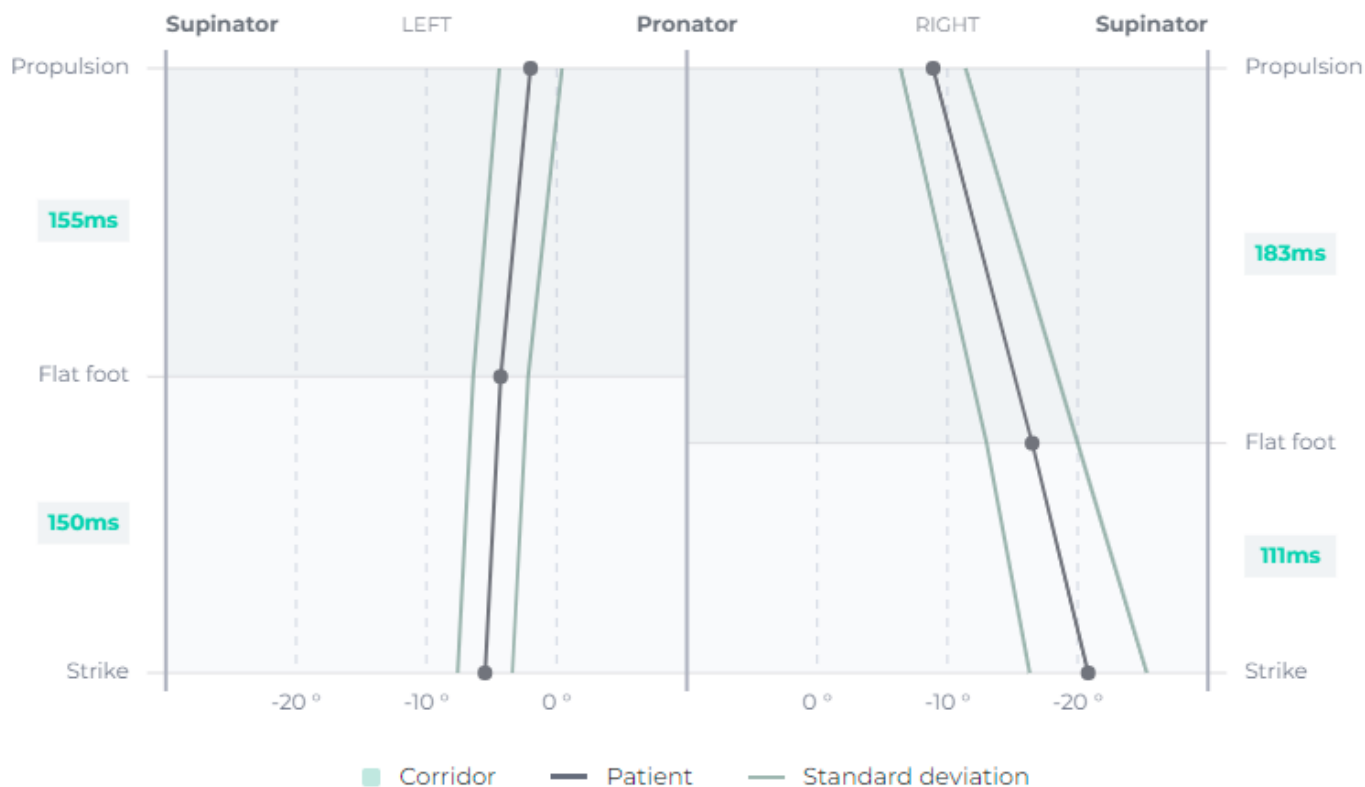
The average stride length, the distribution of contact, flight, and double flight phases for each limb are assessed.

Approach Angle and Propulsion Angle



This is the angle of pronation/supination measured at the moment the foot lands on the ground (approach angle), at the moment the foot is stationary, either on the ground during a heel or midfoot approach, or in the air, where the heel no longer descends and does not yet rise in the case of a forefoot approach (flat foot angle) and at the take-off of the toes (propulsion angle).

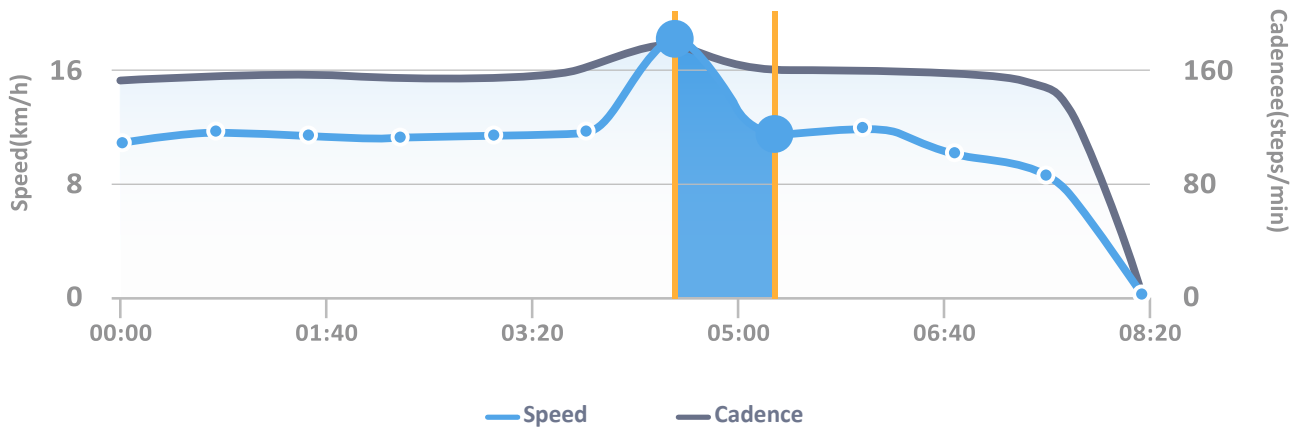
This angle makes it possible to highlight the quality of the plantar movement, from the approach to the propulsion, and to highlight certain high-risk behaviors or those that reveal pathologies.



Thanks to the advanced mode, by clicking on the corresponding button, you can follow the development of this angle during the course of the ground contact.

You will be able to assess the duration of the cushioning and propulsion phase, by finding the average angle (black line) at the three time points described in the paragraph above, as well as the standard deviation of these measurements (grey lines), which gives information on the variability of this angle and therefore of the patient's ability to reproduce the same movement at each stride.

Analysis



By selecting two distinct time points on the speed and pace graph for the running session, you can **compare all of the spatio-temporal and kinematic parameters** relating to these time points.

The objective here is to be able **to locate one or more events or disturbances** that occurred during the recording and to be able **to compare** the parameters of the running process **before and after** this event, in order **to understand the consequences**, trace the source of the disorder and explain it objectively.

	T = 00:31		T = 00:47	
	Spe. 7.61 km/h Cad. 164 steps/min		Spe. 6.81 km/h Cad. 163 steps/min	
BIOMARKERS	L	R	L	R
Asymmetry i	+ 7%		+ 6%	
Strike pattern i				
Attack angle	-18 °	-20 °	-19 ° ↓	-14 ° ↑
Impact force	21 dN	25 dN	21 dN →	24 dN ↓
METRICS				
Stride length i	1.44 m	1.67 m	1.44 m →	1.35 m ↓
Contact time i	42 %	38 %	41 % ↑	39 % ↑
Double flight i	9.6 %		9.1 % ↓	
Attack duration	46 %	43 %	49 % ↑	38 % ↓
Propulsion duration	54 %	57 %	51 % ↓	62 % ↑
ANGULATION				
Strike angulation	-8 °	0 °	-4 °	-1 °
Mid foot angulation	-17 °	-4 °	-19 °	-11 °
Propulsion angulation	-5 °	-27 °	-3 °	-23 °

Tips

Pace : it is ideal at around 180 bpm for running while it can be lower (~160 bpm) for jogging. Increasing the pace decreases the vertical movement and therefore decreases the load rate, decreases the oxygen consumption, increases the elastic stresses, and therefore reduces the muscular workload.

Running speed : Increased pace should not be confused with acceleration. Trying to increase speed with a higher pace has many advantages, but is 10 times less effective than lengthening your stride.

Approach type : There are three ground approach methods:

- o **Through the heel :** With a back to front movement, the knee and hip flexed and the pelvis in retroversion. This type of approach is more economical, but the workload and force of impact is greater, so the risk of injury to the shin, knee, hip, pelvis and back is increased. Also, due to the repetition of the impacts, it is possible that this type of approach induces talalgia (8 ;11)

- o **Through the midfoot:** Just in between the heel and forefoot approach, during the midfoot approach, the foot is placed flat on the ground, without movement from back to front or vice versa, but just from top to bottom.

This approach has a very limited braking component (related to the back-to-front movement) and is therefore less traumatic for the lower limb. It allows a better loading of the elastic components of the muscles and tendons to restore the stored force than during a heel approach, but is nevertheless less effective than a forefoot approach.

- o **Through the forefoot:** With a "clawing" movement from front to back, this is more efficient and brings the elastic components into play more, with the leg stretched and the pelvis high.

This type of approach is still more demanding but has the advantage of being less traumatic, although it can cause foot or ankle injuries if the force of the impact becomes too intense. A change in the type of approach that favours the forefoot may be a sign of possible compensation for talalgia (8 ;11)

Generally speaking, impact is not the main cause of injury, but it increases weaknesses and fragility, and therefore the severity of pathologies.

Symmetry : There is a natural level of asymmetry, greater for running than walking, between the two lower limbs, even in healthy runners.

This can depend on differences in length, muscle strength or running patterns between the two legs. However, there is no correlation between a slight (natural) asymmetry and an increased risk of injury.

On the other hand, too little or no asymmetry may be considered problematic and indicate a degree of stiffness in the lower limbs.

On contrary, too much asymmetry, due to the repetitions linked to the activity, will have harmful consequences on the limb most solicited and subject to the most stress on the structures that can lead to injuries.

Stride length : There are two types of strides

o **Longer strides:** Improve recovery because gas exchanges only occur during the oscillating phase, but are more energy consuming, increase vertical movement (decrease in efficiency) and increase muscle workload during the landing and propulsion phases. They are therefore less efficient.

o **Short strides:** They are more efficient and more effective (more economical), because they reduce vertical oscillations and reduce the muscular stresses for landing and propulsion as the foot is closer to the projected center of gravity. Finally, since they go hand in hand with an increase in pace, the stress on the elastic components is greater.

The stride length will be considered suitable if it does not slow down the landing and propulsion phases and if the vertical movement and workload are reduced.

Contact time : It is about 40% of the stride for a normal run and decreases with increasing speed to about 25% for sprinters.

This parameter is interesting to study in order to compare the two lower limbs and to define the stronger one (the longer duration)

Flight time : This is approximately 60% of the stride for a normal run and increases with speed or stride length, resulting in greater kinetic energy on landing and propulsion, and therefore a higher workload.

Duration of the double flight phase : It is about 10% of the stride at the beginning and end of the airborne phase and its value tends to increase with speed.

Approach, flat foot and propulsion angles : These angles are relevant in the search for elements that may favor the appearance of certain pathologies specific to running, notably as a result of the repetition of movements and the load imposed.

Thus, certain pathologies could potentially be identified, such as:

- Iliotibial band syndrome ^(1;2;3): extension (approach, flat foot and propulsion) or at least supinated approach.
- Achilles tendon tendonitis ^(4;5;6;7): supinated propulsion, indicated by a predominantly forefoot approach or a pronated heel approach.
- Pes Anserinus tendinitis ^(9;10): pronated extension.

Run analysis

<i>Parameters</i>	<i>Definition</i>	<i>Accuracy</i>
Stride length	Distance travelled by the foot in a gait cycle.	+/- 5cm
Analysis time	Running time during data capture.	+/- 5%
Speed	The average speed at which the body moves in a straight line while running.	+/- 0.7km/h
Pace	Number of steps taken per minute.	+/- 5pas/min
Asymmetry	The ratio of the exposure time of the right foot (respectively, the left foot) and the sum of the exposure times of the right and left feet.	+/- 2%
Attack type	Defined as the part of the foot that makes contact with the ground at the start of a stride.	NA
Attack angle	Angle between foot and ground at initial contact.	+/- 7°
Contact	Contact is calculated as the interval between initial contact and toe lift off for each foot throughout the stride cycle as a percentage of the length of the period of the stride cycle during which the limb is in contact with the ground.	+/- 50ms
Flight	The swing is the proportion of time during the running cycle when the limb is not in contact with the ground, measured as the interval between foot lift and initial contact for each foot during the stride cycle.	+/- 50ms
Double flight	For a running cycle, the percentage of time when no foot makes contact with the ground.	+/- 70ms
Pronation and supination angles	Angle of inclination between the foot and the earth's surface. Supination is a negative angle, while pronation.	+/- 7°
Impact force	Maximum vertical ground reaction force in the gait support phase.	+/- 0.5kN
Parameter changes during running	Allows for the comparison of two running moments.	NA

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7. **Becker, J., James, S., Wayner, R., Osternig, L., & Chou, L.-S. (2017).** Biomechanical Factors Associated With Achilles Tendinopathy and Medial Tibial Stress Syndrome in Runners. *The American Journal of Sports Medicine*, 45(11), 2614–2621. doi:10.1177/0363546517708193
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10. **LaPrade RF, Flinn, SD.** “Pes Anserine Bursitis”, e-Medicine, www.emedicine.com/SPORTS/topic100.htm, 2002
11. **Cardenuto Ferreira R.** Talalgias: fascite plantar. *Rev Bras Ortop.* 2014;49:213–217.

Help and assistance

Help

Full information is available at:
<https://www.digitsolepro.com/>

Contact

Do you have a question or a suggestion? Do not hesitate to contact us.



Digitsole France : 13 Rue Héré 54000 Nancy

DigitsolePro.com
contact@digitsolepro.com



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France



Date of CE marking: 2021, April





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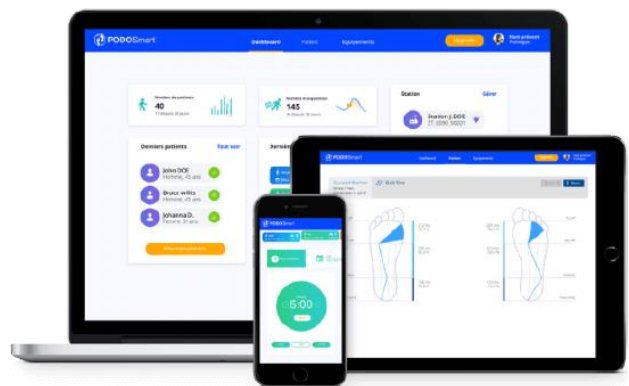
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Product information

What is the content of my Digitsole Pro® kit?

The Digitsole Pro® kit comes with a case containing the following items:

- 6 insoles with the following sizes: (EU size) 36/37, 38/39, 40/41, 42/43, 44/45 and 46/47
- 2 DSPods (1 right, 1 left)
- 1 DSPods charger kit, consisting of a charger plug and a charger dock
- 1 document indicating where the user manual may be found and how DSPods can be inserted into Digitsole insoles
- 1 document describing how to use the charger kit
- A strap



What is the compatibility of the web interface?

The Digitsole Pro® interface is compatible with both PCs and tablets (iOS, Android and Microsoft). We advise you to use Google Chrome (version 87 to 90), Firefox (version 82 to 85) or Edge (version 86 to 87).

What is the compatibility of the application?

The Digitsole Pro® app is free and works with iOS 13.0 and Android 6.0 mobile devices.

Insoles & DSPods

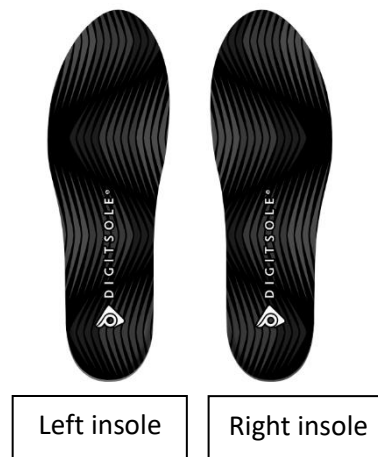
How to insert the DSPods into the Digitsole Pro® insoles?

Insert the DSPods into your insoles as follows:

- Identify left and right DSPods



- Identify the left insole and the right insole



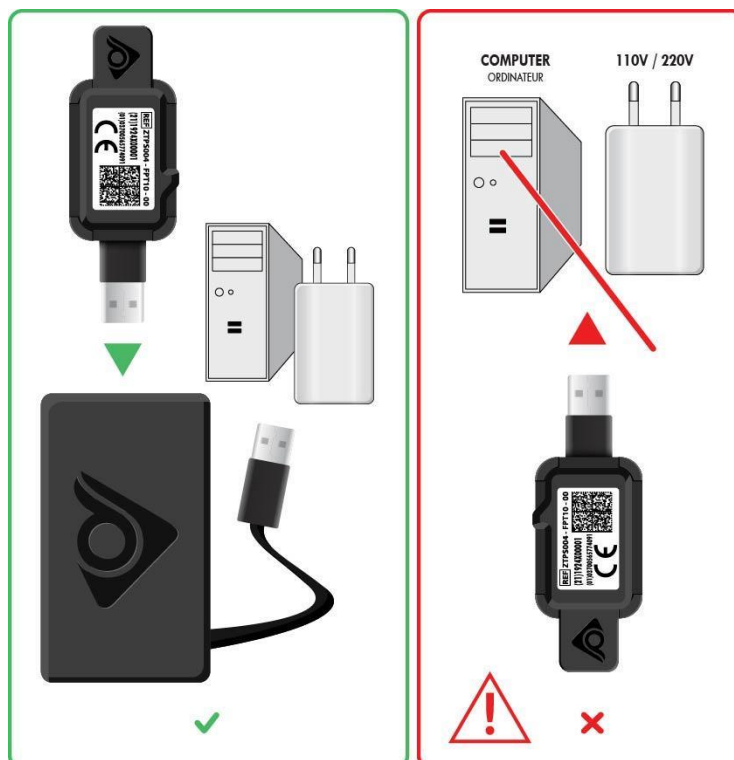
- Place the left DSPod in the left insole and the right DSPod in the right. Please keep in mind that the DSPods must be inserted in the correct direction for the data capture to work (see image below)



How to charge my DSPods

Remove the DSPods 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 approximately 2.5 hours.



CAUTION



Remember to charge DSPods before leaving them disconnected for extended periods of time to avoid damaging the battery.

To maximise the lifespan of your DSPods, charge them at temperatures ranging from 10°C (50°F) to 40°C (104°F).

How to know if my DSPods are fully charged?

- While charging: The LED of a charging DSPod will be on. When the light is off it means that the DSPod is fully charged.
- On mobile app: Battery levels are displayed on the app. Check the corresponding card to your DSPods to see the levels. If the pods are not shown in the insoles list, you need to pair them.

The QR code of my DSPod is erased, what can I do?

If your Datamatrix is erased contact us at support@digitsolepro.com

To save time, please send us a picture of your DSPods and the email address you used to create your account on Digitsole Pro®.

Are the DSPods waterproof?

Regarding IEC 60529:2013, DSPods are IP56 which means the devices can be used on a rainy day and while walking in puddles of water.

Can I connect to my DSPods while another Bluetooth device is paired with my mobile?

You can connect your DSPods while another Bluetooth device is paired with your mobile.

How to clean my devices?

It is recommended that the following operations be performed on a regular basis and **before the first use**:

- Use a disinfectant that meets the following 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

- We recommend the STERICID S-3DM product, which is available from Digitsole at: contact@digitsolepro.com and satisfies the requirements.
- Allow to air dry before reusing, or wipe with a clean, dry, lint-free cloth.

CAUTION

- !
 - Do not clean the device with corrosive chemicals, oil, acetone, or petroleum-based products
 - Do not place the device in a washing machine, dryer, hand dryer, or other piece of equipment.
 - Avoid immersing the device in water

What to do at the end of product life?

Electronic components and lithium-ion batteries are subject to recycling regulations which vary by country and region. Please observe the legislation in effect in your region before disposing of these insoles to respect good environmental practices.

As a result, the device should be returned to your healthcare provider, distributor, or manufacturer.

I can't connect the DSPods, what can I do?

Make sure that the DSPods are charged, unplugged from the charger and not in standby mode.

To make sure the DSPods are not on standby, shake them to wake them up. You can also plug and unplug them.

If the problem persists, delete and re-add your DSPods to the application.

I can't manage to update the insoles, what can I do?

Make sure that the DSPods are charged, unplugged from the charger and not in standby mode.

To make sure the DSPods are not on standby, shake them to wake them up. You can also plug and unplug them.

If the problem persists, delete and re-add your DSPods to the application.

What is the range of the DSPods? Do I have to stand next to the phone?

The insoles communicate with the device only at the launch of the acquisition and at the end of it. During these two periods, the DSPods must be at a maximum distance of two meters from the phone.

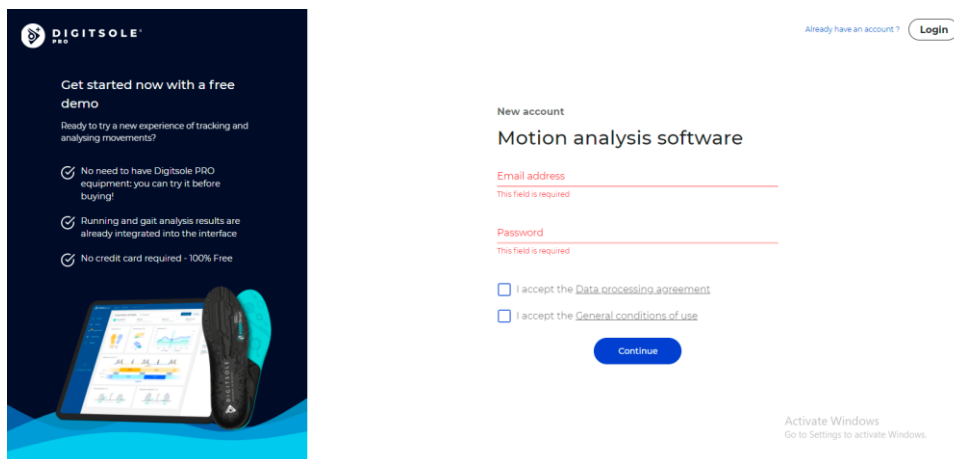
However, during the acquisition, the DSPods keep all the information and transmit it to the phone at the end of the acquisition.

Web app

How to create an account on Digitsole Pro®?

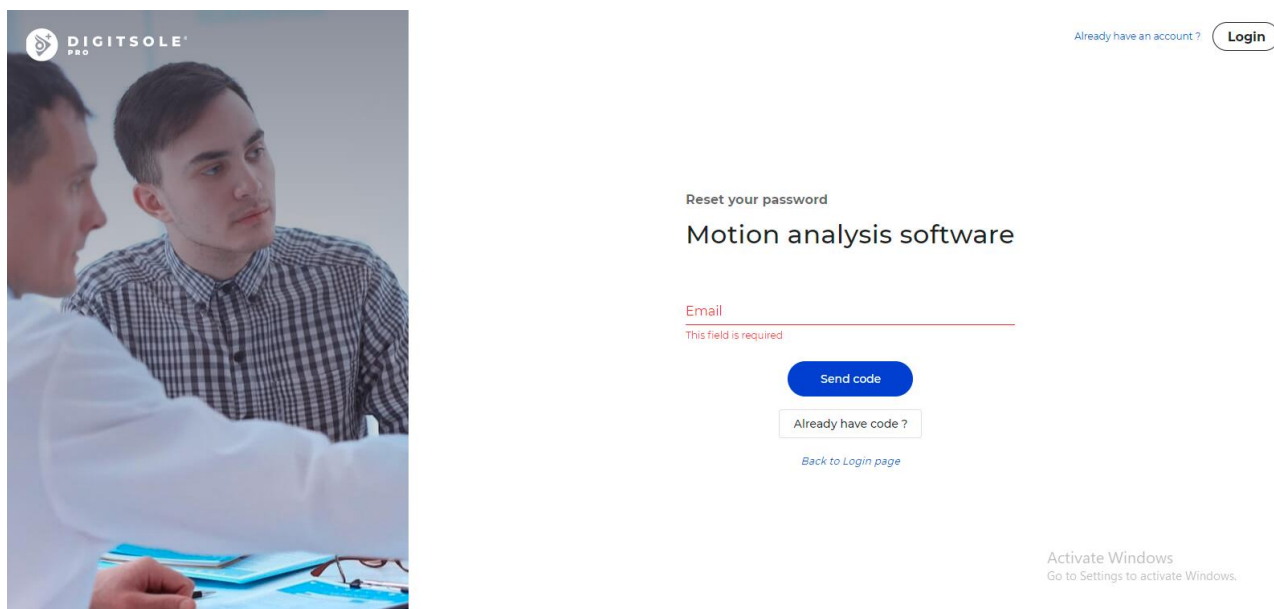
If you have not already done so, go to the following page to create a Digitsole Pro® account:

<https://app.digitsolepro.com/auth/sign-up>



After reading the data processing contract, enter the email address and password you want to use for your Digitsole Pro® account.

Your password must have at least eight characters, containing at least one number, one lower case, one capital, and one special character for security purposes.



After that, you will receive an email with a code to confirm your registration. Please enter it in the field provided.

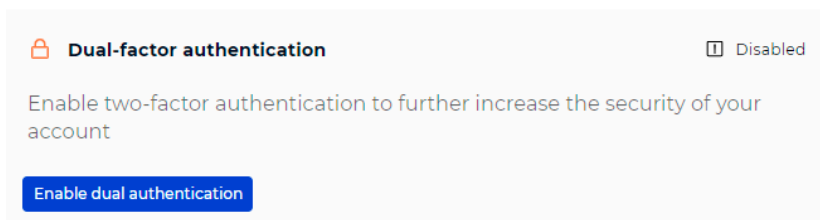
Then enter your personal data to finish your account creation.

How to activate the two-factor authentication?

To add two-factor authentication, go to the **Your account** in the top right corner



Then select **Enable two-factor authentication** in the menu.



Scan the QRCode with your two-factor authentication app (for example, Google authenticator) and enter the code in the area specified for this purpose.

Enable dual authentication

Scan the QR code below with your dual authentication application

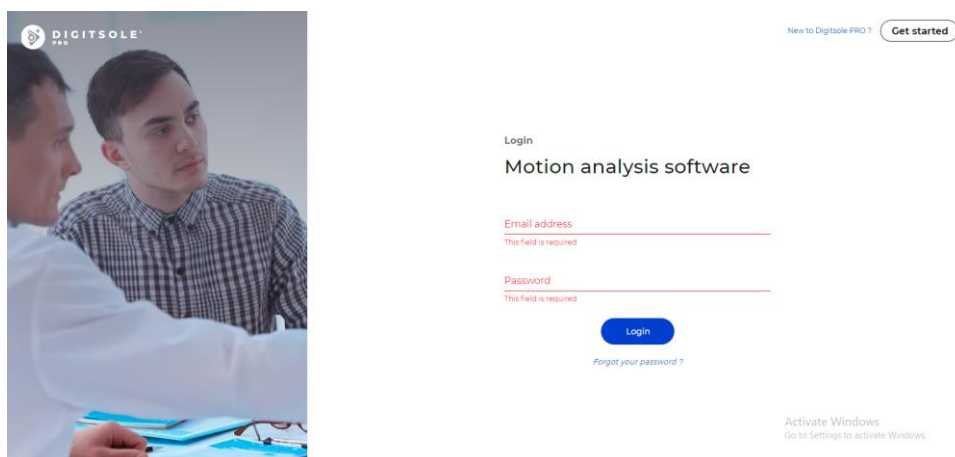


[Problem scanning the code?](#)

How to login to the interface?

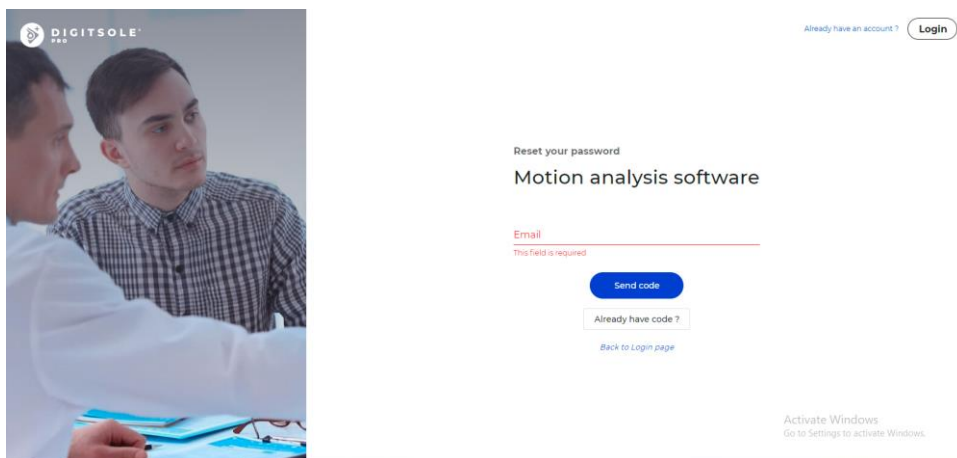
To access the interface, ensure that you have already made your account on the web interface. You are able to connect to this application using the same credentials. Log in via the following link:

<https://app.digitsolepro.com/auth/sign-in>

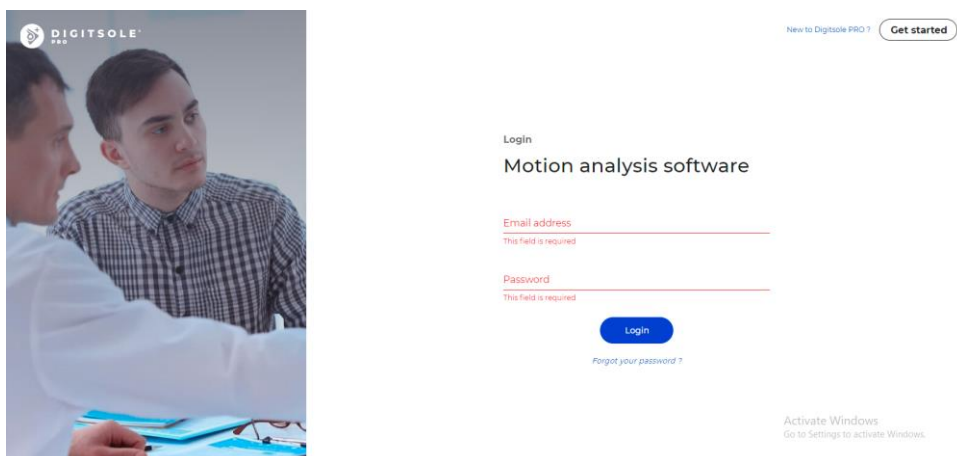


To log in, enter your account's email address and password.

If you have forgotten your password, click **Forgot password**, enter your email address in the provided box, and then click **Send code**.



Along with your new password, enter the code you received through email. When you click **Submit**, your password will be changed.




You then proceed to the login screen, where you enter your email address and your new password to use Digitsole Pro®.

How to change my practitioner information?

To change your practitioner information, go to the **Your account** button at the top right



Then, to change your practitioner information, click the **Pen** icon.

Profile 

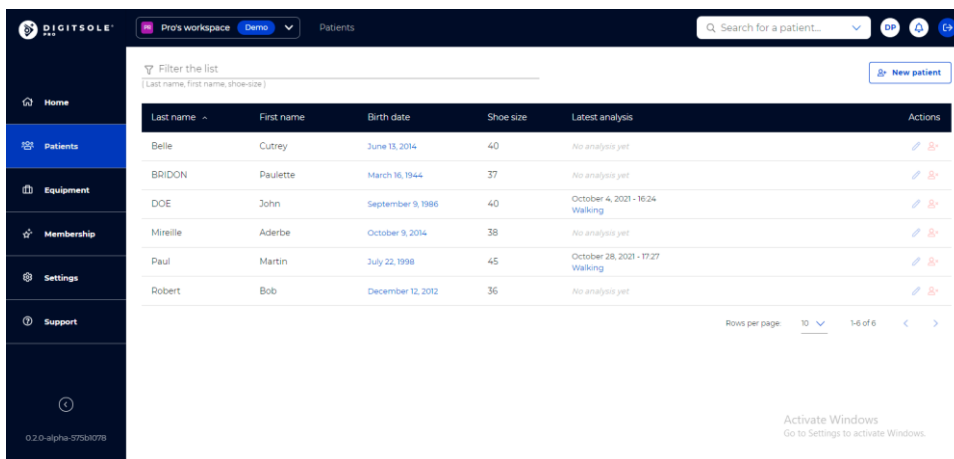
First name *
Digitsole

Last name *
Pro

Professions *
Neurologist Osteopath Physiotherapist

How to add a patient?

Select the **Patients** tab, then click on **New patient** on the top right.



Pro's workspace **Demo** Patients

Filter the list (Last name, first name, shoe-size) [New patient](#)

Last name	First name	Birth date	Shoe size	Latest analysis	Actions
Belle	Cutrey	June 13, 2014	40	No analysis yet	
BRIDON	Paulette	March 16, 1944	37	No analysis yet	
DOE	John	September 9, 1986	40	October 4, 2021 - 16:24 Walking	
Mireille	Aderbe	October 9, 2014	38	No analysis yet	
Paul	Martin	July 22, 1998	45	October 28, 2021 - 17:27 Walking	
Robert	Bob	December 12, 2012	36	No analysis yet	

Rows per page: 10 1-6 of 6

0.2.0-alpha-575b3d78 Activate Windows
Go to Settings to activate Windows.

A new window opens, allowing you to enter your patient's details, address, preferred method of contact, purpose for consultation, and any history and pathologies.

×

New patient

Information ^

First name* Last name* Birth date*

Height* ft Weight* lbs Shoe size* v

Gender* Man Woman * Required fields

Pathology (This field is required) + Add

No pathology is selected

Please make sure to fill in the correct pathology as it can have an impact on the interpretations and norms of the analyses. **Healthy patient** Yes No

Save Cancel

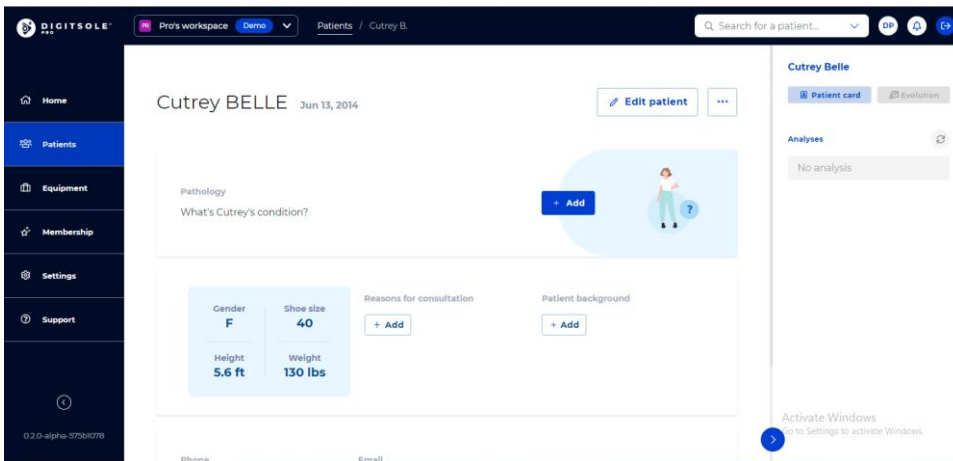
Mandatory fields are indicated with an Asterisk (*) in the "Information" section and in the "Pathology" section. When finished, click **Add**.

How to edit a patient?

To make changes to a patient's file, go to the Patient tab and then choose the patient.

Click **Edit patient** to make changes to the patient's personal information, address, and contact information.

Depending on the data already entered, you will be able to change or add a known pathology, reason for consultation, and history by clicking on the **Pen** icons or on **Add** to add new ones.

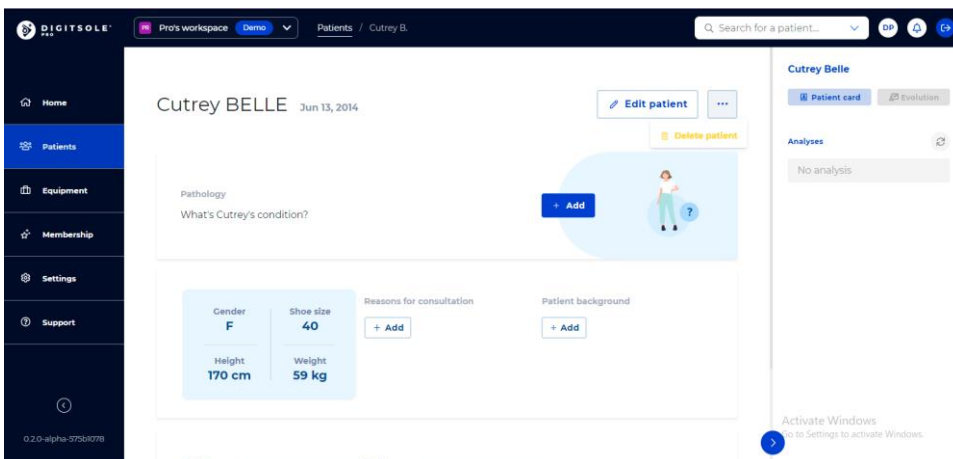


How to delete a patient?

To make changes to a patient's file, go to the **Patient** tab and then choose the patient.

To change the patient's personal information, address, or method of contact, click “...” at the top right, then **Delete patient**.

Please note: This is an irreversible action.



How to search a patient's name

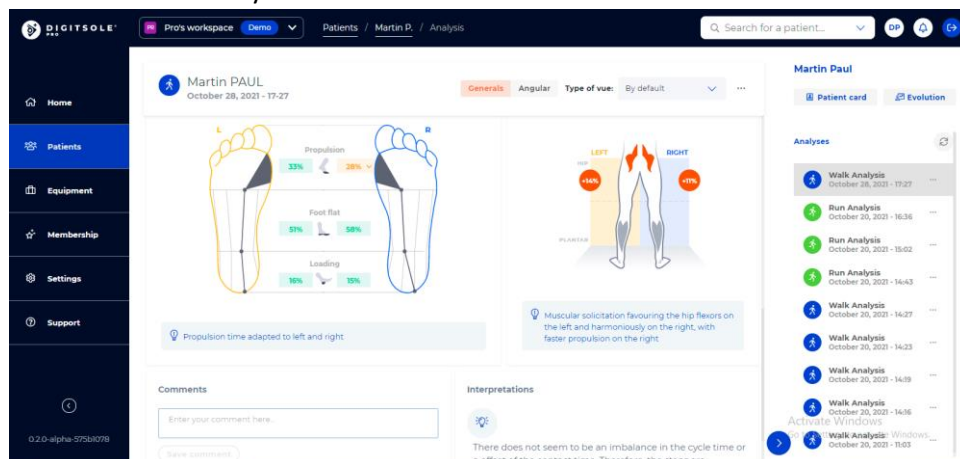
Type the last name and/or first name of the patient you are looking for in the **Search for a Patient** section at the top right of the **Home** page, and then click on their name to access their patient file.



How to add comments on a report or an acquisition?

In the analysis results of an activity, at the bottom of the results, you can leave a comment in the dedicated section.

When leaving your comments here, they will be saved. You will be able to find them at any time with the results of this activity.



Once the report is exported, you can leave a comment in the dedicated section. Comments in the export will not be kept or appear later in the interface. Nevertheless, you can print them, send them by email to the patient or save them as a PDF.

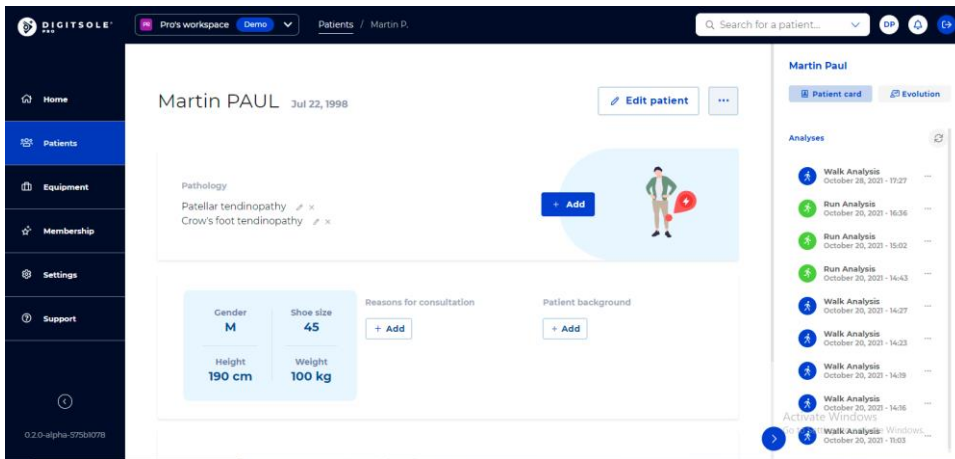


How to compare analysis?

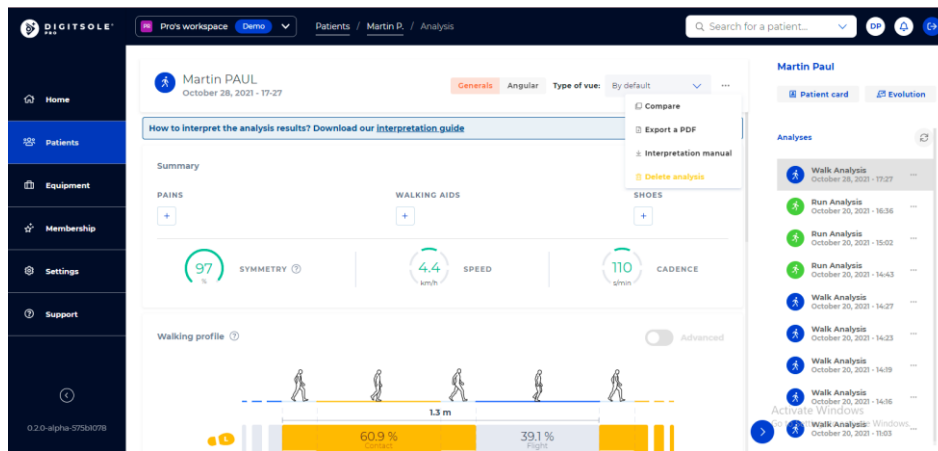
Select the **Patients** tab, then the selected patient's line.

You are now in the patient file.

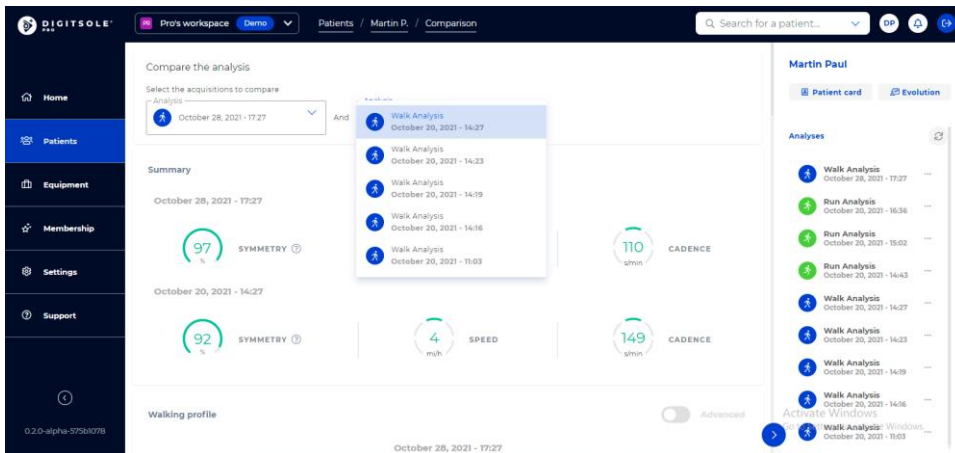
The "Analyses" section is on the right. Select the analysis you wish to compare by clicking on it.



Once the analysis is open, click “...” button in the upper right corner, followed by **Compare**.



Then select the analysis that you want to compare it with. Then select the analysis you want to use as a comparison

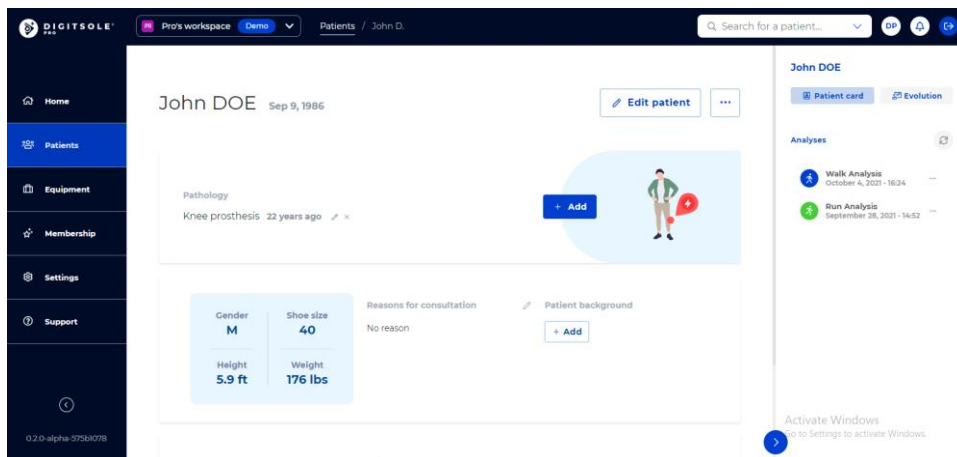


How to delete an analysis?

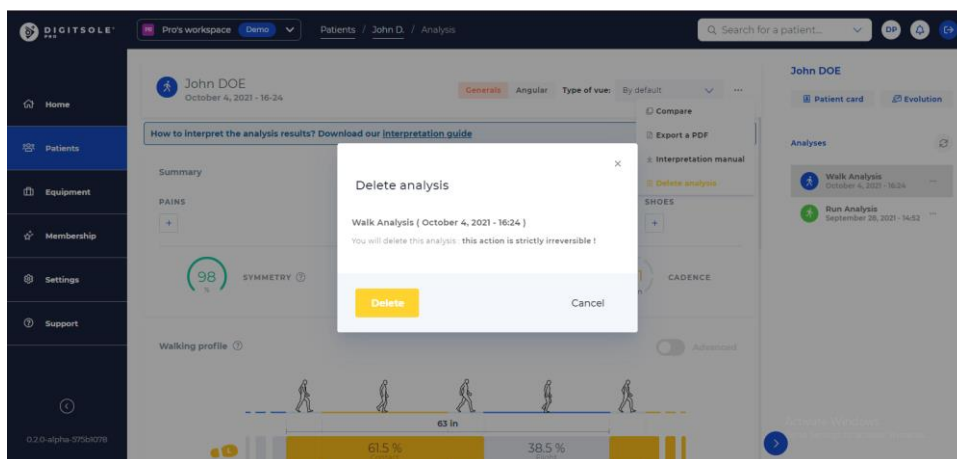
Select the **Patients** tab, then the selected patient's line.
You are now in the patient file.

The “Analyses” section is on the right.

Click... and select **Delete analysis** next to the data capture you want to delete.



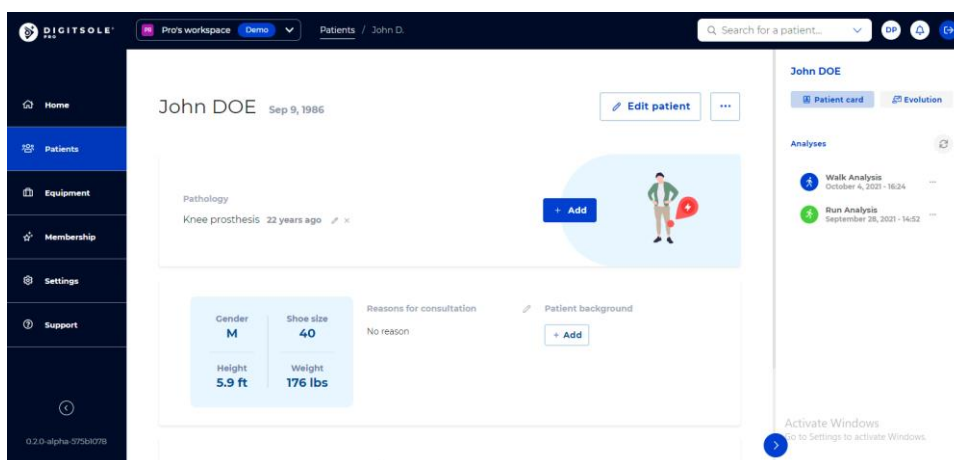
A window appears, asking you to confirm your deletion request.
The data capture will be permanently deleted if you click **Delete**.



How to see analysis results?

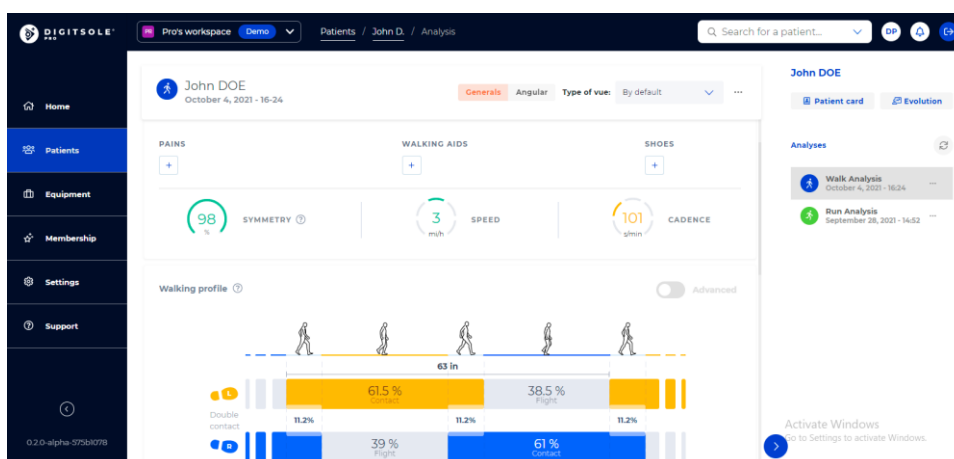
Select the **Patients** tab, then the selected patient's line.
You are now on the patient file.

The “Analyses” section is on the right. Select the analysis you wish to view by clicking on it.



The patient analysis is now displayed.

In the top right corner, you can select the type of view you want: General or Angular, then: Neurological, trauma, rehabilitation. You can also select the default view or edit it with the settings that you want to see.



How to delete my account?

To delete your account, contact us at the following email address: support@digitsolepro.com

SaaS (use Licensing Information or Subscription Information)

Can I upgrade or downgrade?

You can upgrade or downgrade and don't have to wait until the end of the license (6 months for Standard). You can change at any time by reaching out to us.

Is there a warranty on the chip?

Everything will be replaced at no charge within 12 months of purchase.

If I upgrade, do I reset the 6 months agreement? (for Standard)

If you upgrade or downgrade your contract, it will not impact the original ongoing 6 months (for standard) agreement.

If after 6 months (for Standard) I want to stop my agreement, do I get charged?

If you want to stop the agreement after 6 months (for standard, you will not be charged)

If I cancel before 6 months (for Standard), do I get charged?

If you want to cancel before the end of the 6 months, the remaining balance must be paid.

Settings

How to change language?

- From the web interface: In the settings section you can change interface language.
- From the app: You can't change the language on the app. The language of the application depends on the language in which your phone is configured

How to change unit system?

- From the web interface: In the settings section, you can change the unit system (metric or imperial).
- From the app: In the settings section you can change units system.

Security

How can I be sure that the website is secure?

Check the address bar of your browser: a small padlock before the address of the interface will indicate the communications are encrypted with an SSL certificate

What should I do if the URL is blocked by my antivirus?

During the configuration, if your URL is blocked, just go to your antivirus settings, and unblock it.

PDF

What should I do if I have difficulties with PDF export?

We advise you to use Google Chrome, Mozilla Firefox, Safari, or the latest version of Microsoft Edge.

How to send the report to the patient by email?

The only way to send the report directly to the patient is by clicking on Print but instead of selecting your printer, choose "Save as PDF".

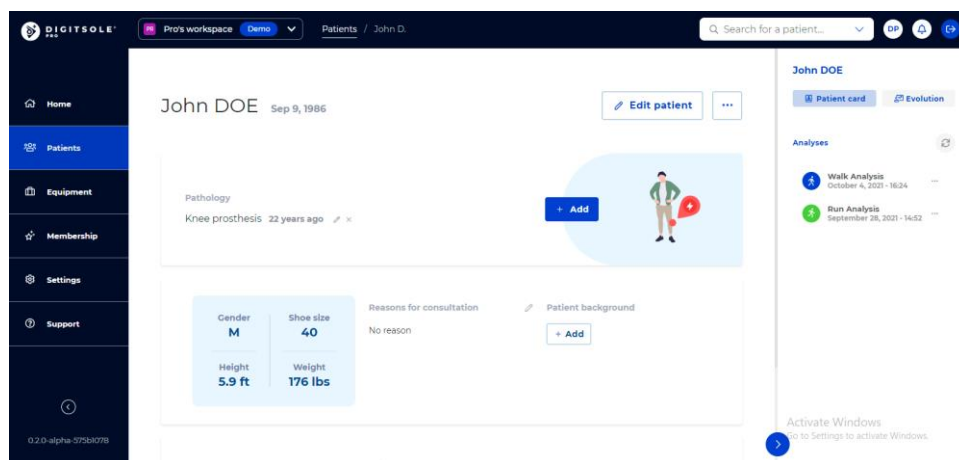
You will then be able to send the PDF by email to your patient as an attachment.

How to generate a report?

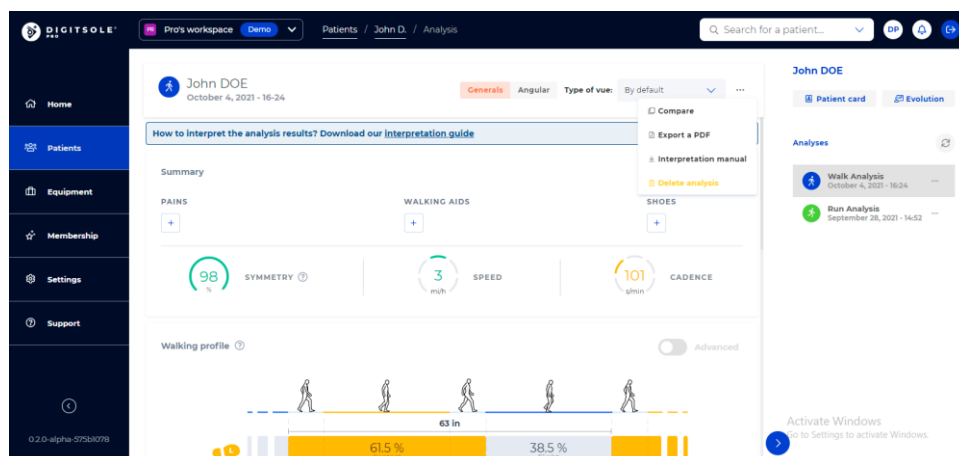
Select the **Patients** tab, then the selected patient's line.

You are now on the patient file.

The "Analyses" section is on the right. Select the analysis you wish to view by clicking on it.



Once the analysis is open, click "..." button in the upper right corner, followed by **Export PDF**.



The export analysis page will appear.

Advanced Email Phone x
Print

Digitsole Pro
Neurologist / Osteopath / Physiotherapist
j.aubry@digitsole.com

Patient: **John DOE**
35 years old • Male • 5'9 ft • 176 lbs
Analysis: November 3, 2021 5:11 PM

Results of the walk analysis

Overview

98 %	3 mph	101 steps/min
SYMMETRY	SPEED	CADENCE

Stride duration [ms]

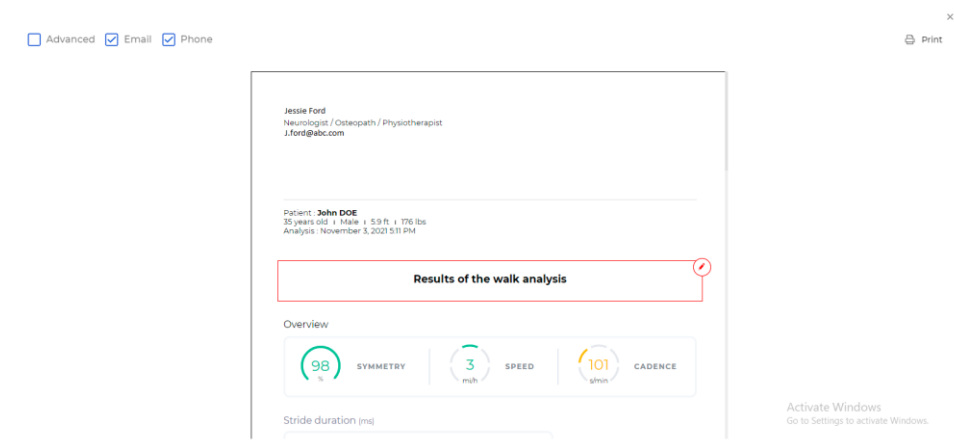
Activate Windows
Go to Settings to activate Windows.

How to hide practitioner information on the report?

Following the completion of your analysis export, you can:

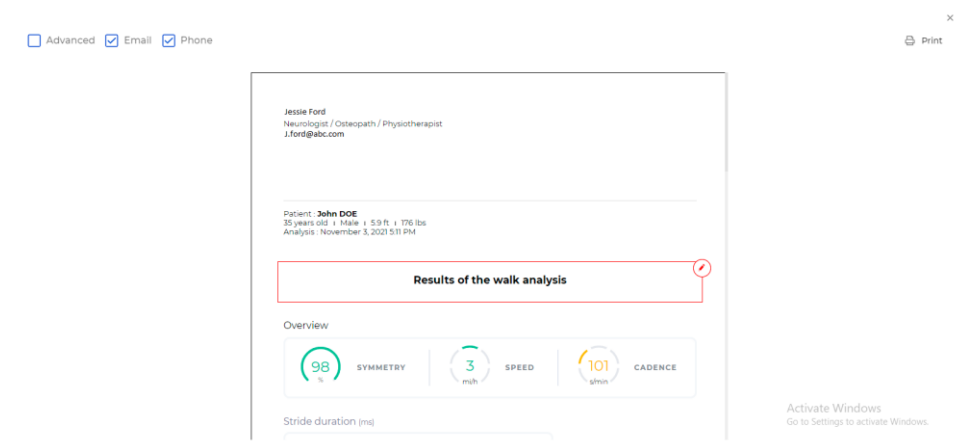
- Check the "Advanced" box to generate a more advanced report
- By clicking on the **Eye** icons, you can choose whether or not you'd like your email address and/or phone number to be shown.

Note: A crossed-out eye indicates that the parameter will not be presented on the report; an uncrossed-out eye indicates that the parameter will be displayed on the report.



How to print report?

When your analysis export is finished, you can print the report by clicking on the **Print** button at the upper right of the screen.

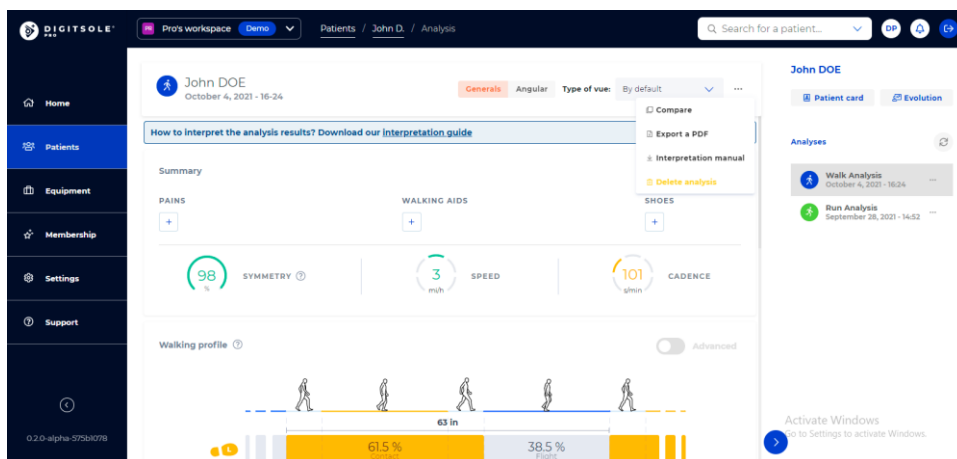


Acquisition

Where can I find the walking and running interpretation manuals?

Click on a walking or running activity.

At the top of the activity analysis, click on the three small dots and then click on **Interpretations Manual**.



By clicking on **Interpretations Manual** via a walk analysis, you can download the manual for walking.
By clicking on **Interpretations Manual** via a running analysis, you can download the manual for running.

Why is my acquisition invalid?

Make sure you have taken more than 10 steps during the acquisition, if this is the case you can stop the acquisition and refresh the web page.

Make sure to place the DSPods in the right position in the insoles. (Refer to : How to insert the DSPods into the Digitsole Pro® insoles)

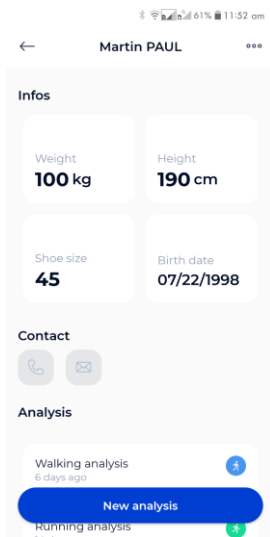
If the problem appears again, please contact us and send us the **error report**.

What is the minimum running speed?

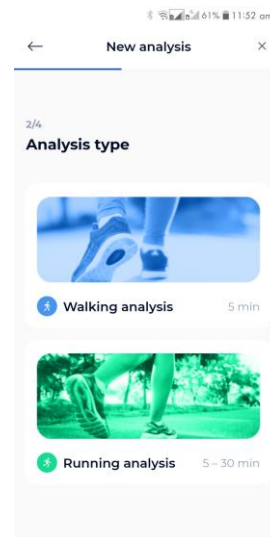
We advise you to run at a minimum speed of 8 km/h.

How to start and stop an analysis?

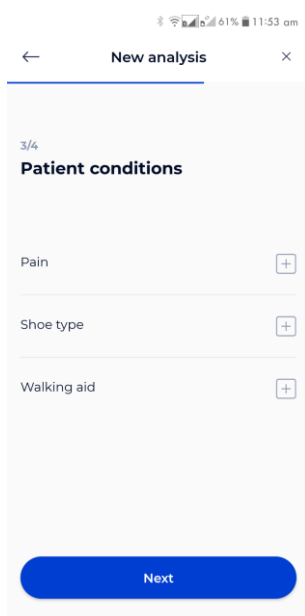
To start an activity, you must use the application on your phone.



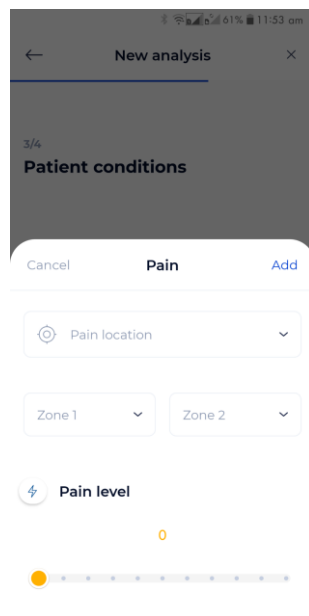
1 – Go to your patient's file once it's been created and your DSPods have been added to your account. Click on the button **New Analysis**.



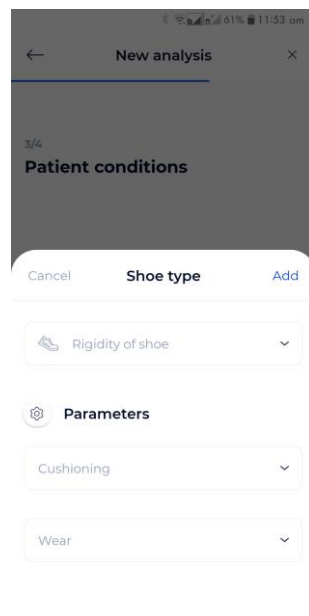
2 - Next, choose the type of analysis you want to run.



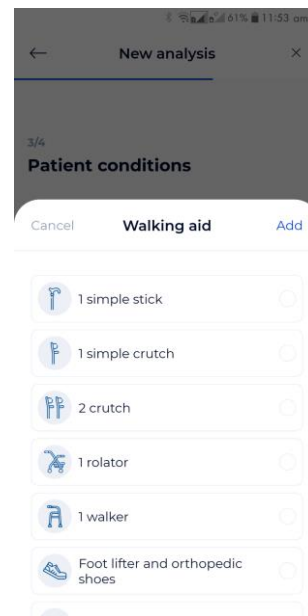
(1)



(2)



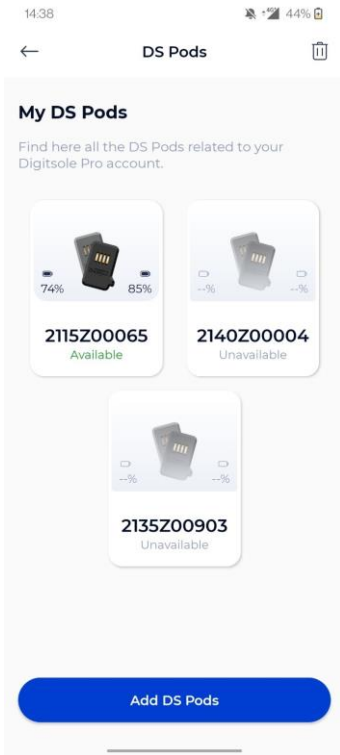
(3)



(4)

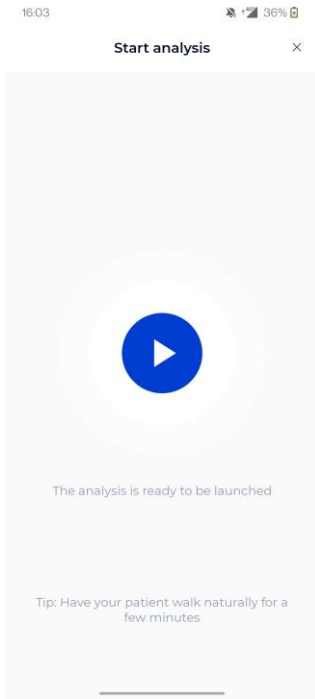
3 -Using the menu above, you can then enter further information about your patient. (1)

- You can enter the location and intensity of your patient's pain(s) in the **Pain** tab (2).
- You can specify the stiffness and cushioning of your patient's shoes in the **Shoe type** tab (3).
- Any walking aid device used by your patient should be listed in the **Walking aid** tab (4).

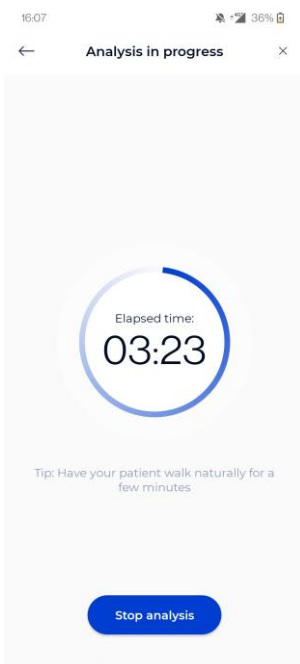


Then pick the pair of DSPods you will use for the data capture; the application will then establish a connection to the DSPods and send you to the screen where you can begin the analysis.

! CAUTION: If you have multiple pairs of DSPods, make sure to choose the ones that correspond to the insoles in your patient's shoes.



Once the DSPods have been placed in the insoles and the insoles have been placed in the patient's shoes, click the **Play** button to begin the data capture. Following the appearance of the stopwatch, your patient should remain in a static position for 3 to 5 seconds for initialization before they start to walk or run.



Click the **Stop Analysis** button to end the data capture. When the data capture is complete, the data is sent directly to the Digitsole Pro® web interface.

Mobile application

How to download the application?

The Digitsole Pro® app is free and works with iOS 13.0 and Android 6.0 mobile devices. Please check the firmware version on your phone to see which devices are compatible with the apps.

Enter Digitsole Pro® in the search bar to locate the application:

- For iOS devices, go to the App Store®
- For Android devices, go to the Google Play™ store



How to connect to the Digitsole Pro® application?



Welcome to Digitsole Pro

Email address

my-email@address.com

Password

.....

Login

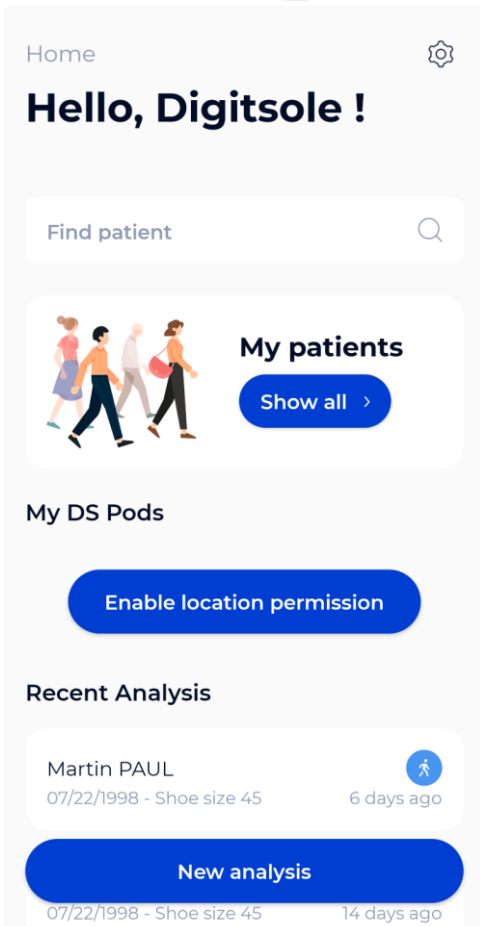
To access the application, ensure that you have already created your account on the web interface (<https://app.digitsolepro.com/auth/sign-up>), and you can connect to this application using the same credentials.

To log in, enter your account email address and password.

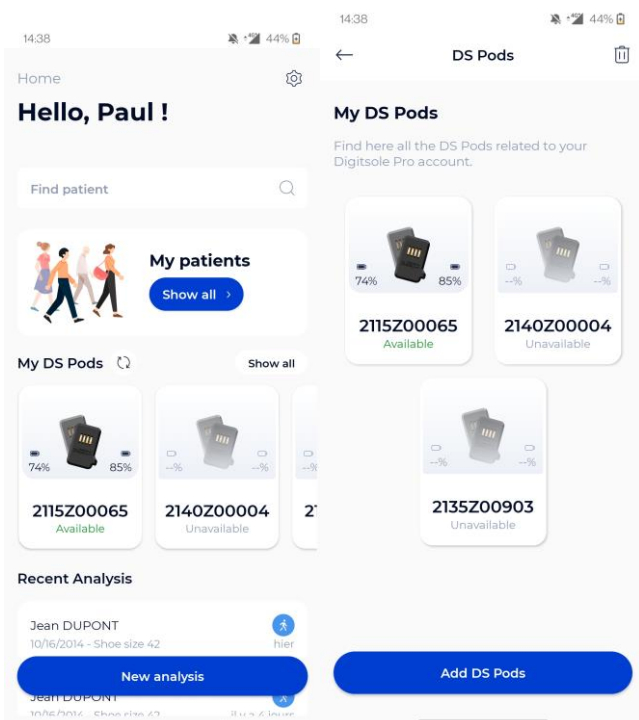
If you have forgotten your password, go to the Digitsole Pro® interface and create a new one.

How to add DSPods?

To add DSPods to your account from the main app screen, follow these steps:



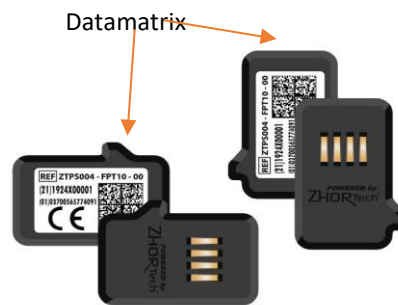
- If you do not already have DSPods, go to the "DSPods" area and click Add



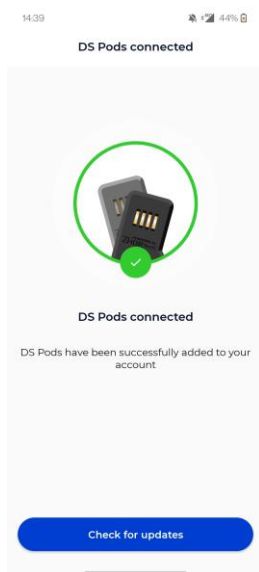
- If you already have DSPods, go to the "My DSPods" area and click on "**See all**," which will redirect you to a list of your DSPods. Select **Add DSPods** from the menu.

To add your DSPods to your account, go to a new page and scan the Data Matrix code on your pair of DSPods. If you have more than one pair of DSPods, repeat the procedure.

If your Data Matrix code is unreadable, please open a ticket on <https://www.digitsolepro.com/customer-support>

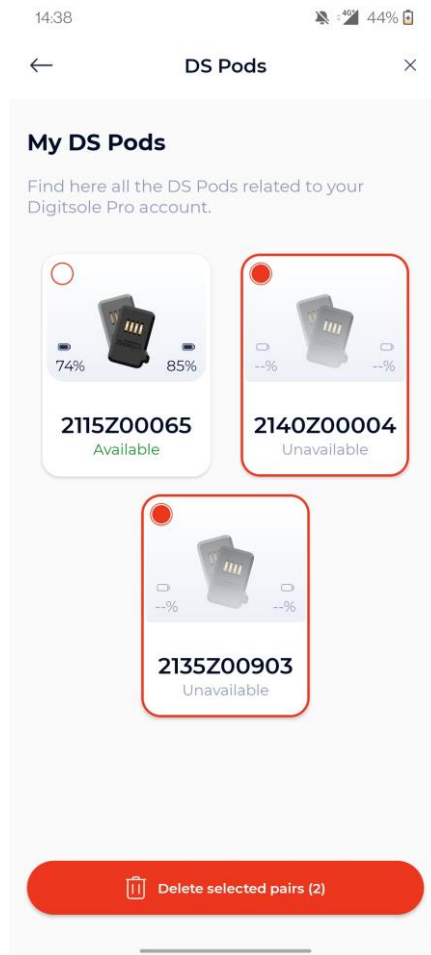


How to update DSPods?



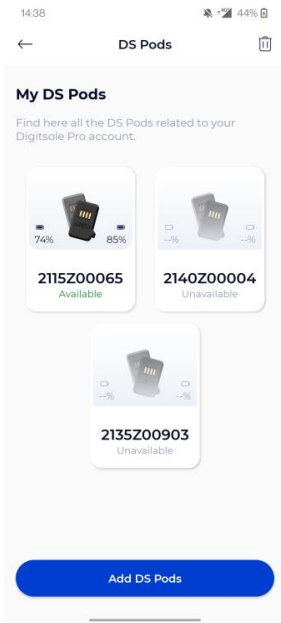
Click on **Check for updates** to check the DSPods version and see if they need to be updated.

How to remove DSPods?



Click on **"See all"** in the **"My DSPods"** section from the main application screen to be redirected to a list of your DSPods. Click the **Trash can icon** in the upper right corner of the screen, select the pair(s) you want to delete, and then click **Delete selected pairs**. To exit delete mode, click on the **Cross out** icon in the upper right corner of the screen.

How to check DSPods battery levels?

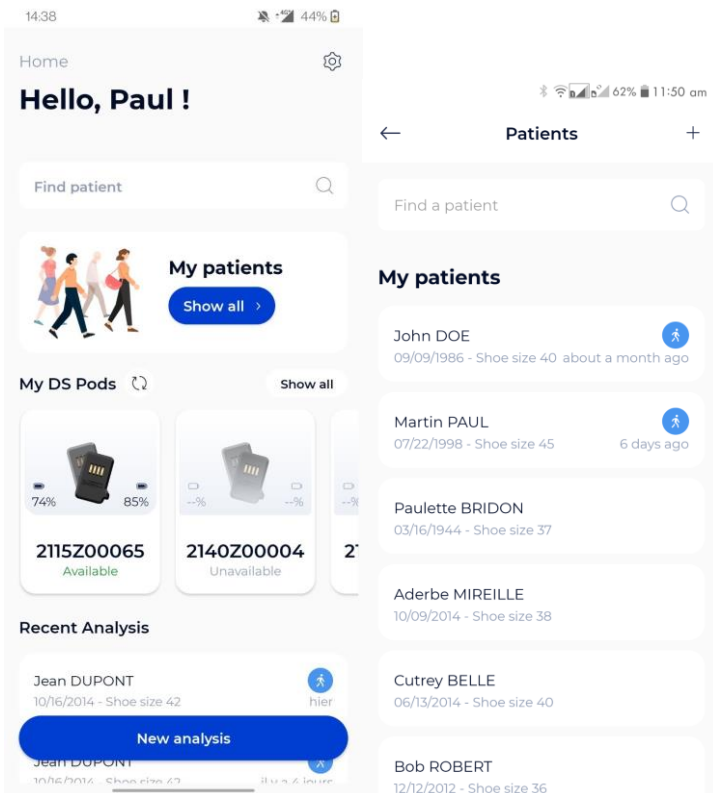


When DSPods are charging, you cannot see the charge level of your DSPods because they are plugged in and charging.

To check the charge level of your DSPods, go to the DSPods page. The battery charge levels of the left and right DSPods are displayed. By scrolling down on the screen, you can refresh the battery levels.

If you still can't view the battery charge level after reloading the page, your DSPods may be "asleep" (to save power, they automatically turn off after about 20 minutes). Shake them to "wake them up" (Please DO NOT hit them on a hard surface as this may damage the sensors). Then, by swiping down on your screen, you can reload the charge levels.

How to add a patient?




To add a new patient to your account from the main application screen, click on **See all** under the "My patients" area, then click on the **+** logo at the top right of your screen.

Cancel **New patient** Add


Information Pathology Contact

Last name

First name

Birth date
 

Height Weight
 cm kg

Shoe size
 

Gender

The New Patient form appears; enter the info for the patient file. Note that the Information and Pathology pages must be filled out while others can be left blank. If your patient has no pathology, select "**Healthy patient.**"

It is critical to select the correct pathology because it will affect the interpretations and standards of the analyses.

The Contact tab is optional. However, it allows you to add your patient's contact information so you may easily reach them.

How to edit a patient?

Cancel Edit patient Save

Information Pathology Contact

Last name
Paul

First name
Martin

Birth date
07/22/1998

Height 190 cm Weight 100 kg

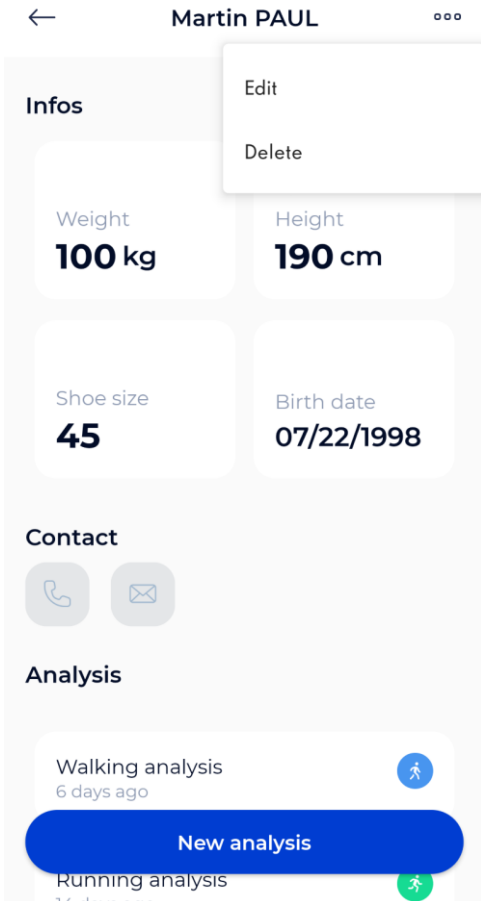
Shoe size
45

Gender

Click on the patient you want to edit from the list of patients, and the patient file will open. Select **Edit** from the menu at the upper right of the screen. When the form appears, complete with the requested information and then click **Submit** to save your changes.

After that, the patient's file will be updated.

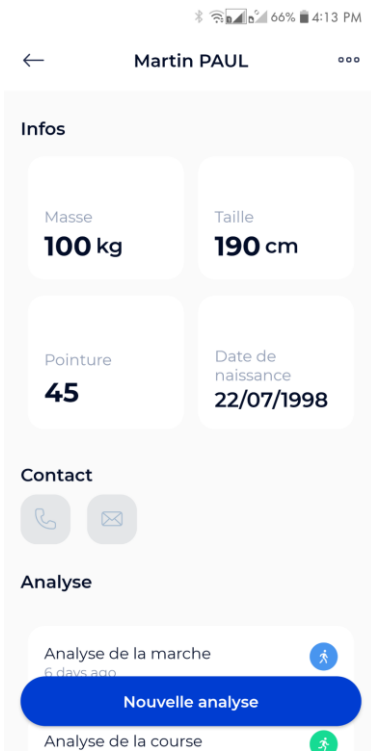
How to delete a patient?



Click on the patient you want to delete from the patient list, and the patient file will open. Select **Delete** from the menu at the upper right of the screen, then confirm the deletion. After that, you will be taken to the newly updated patient list.

Please note: This is an irreversible action.

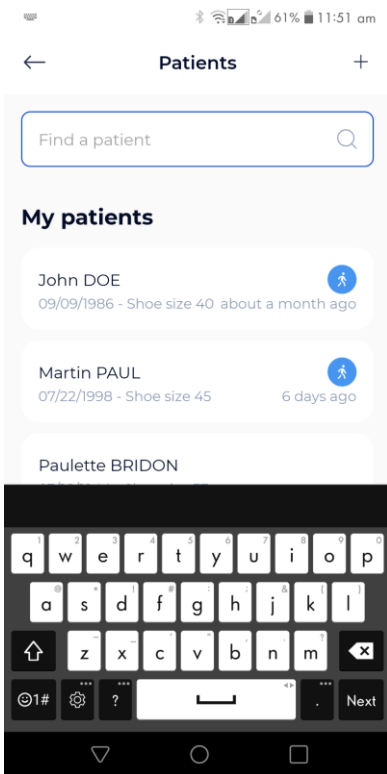
How to contact a patient?



Click on the patient you want to contact from the patient list and the patient file will open.

If you have entered your patient's phone number, you can call them by clicking the **Call** button. If you have entered your patient's email address, you can send a message by clicking the **Send a message** button

How to search for a patient?

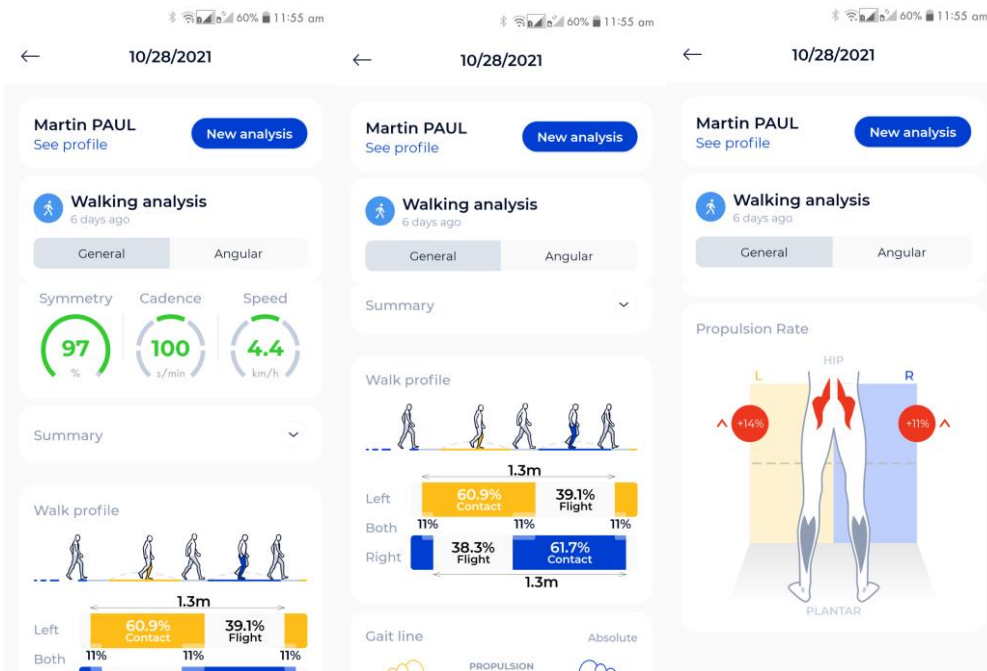


Type the last name and/or the first name of the patient you want from the patient list in the text field at the top of the screen.

How to see analysis results?

In the "My patients" area, click **See all**, then pick the relevant patient.
You are now on the patient file.

Click on the analysis you want to see in the "Analyses" section.



You can select the sort of view you want at the top: General or Angular.

Clicking the **For more details** option will automatically link you to the Digitsole Pro® web interface, where you may perform a more intensive analysis of the results.