



DIGITSOLE[®]
PRO



User Manual & Technical documentation

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Before you begin:

Before using your Device, please read this manual carefully. It contains 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.

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, and the 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

A module allows you to capture videos during your analyses with the mobile application. However, this video module is not part of the medical device scope.

WARNING

- Do not open, puncture, or punch the DSPods.
- If a DSPod is damaged, do not attempt to repair it; instead, contact the seller.
- Do not throw it in a fire.
- Shoes with a metal plate on the lower part should not be worn.
- Avoid bending or twisting your DSPods.
- If the 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. *
- Only the supplied or authorized accessories should be used to ensure the performance of the device (safety, electro-magnetic compatibility, etc.).

*The product's safety in a magnetic resonance environment has not been investigated. It has not been tested in the magnetic resonance environment for 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

Extra pair of DSPods	DSPS001-KIT10
Extra Charger	DSPS001-KIT00
- DSPods charger socket	DSPS001-CAB00
- DSPods charger dock	DSPS001-CAB10
Complete Kit of Digitsole Pro Adult Insoles (7 pairs)	DSPS001-KIT20
- Digitsole Pro Adult Insole Size 30-32 (US 12-1,5)	DSPS001-INS30
- Digitsole Pro Adult Insole Size 33-35 (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
- Digitsole Pro 48-49 insoles (US Men 13.5-14.5)	DSPS001-INS48

A pair of Digitsole Pro 30-32 insole (US 12-1,5)	DSPS001-KIT30
A pair of Digitsole Pro 33-35 insole (US 2-4)	DSPS001-KIT33
A pair of Digitsole Pro 36-37 insole (US Men 4.5-5.5 – US Women 5.5-6.5)	DSPS001-KIT36
A pair of Digitsole Pro 38-39 insole (US Men 6-7 – US Women 7-8)	DSPS001-KIT38
A pair of Digitsole Pro 40-41 insole (US Men 7.5-8.5 – US Women 8.5-9.5)	DSPS001-KIT40
A pair of Digitsole Pro 42-43 insole (US Men 9-10 – US Women 10-11)	DSPS001-KIT42
A pair of Digitsole Pro 44-45 insole (US Men 10.5-11.5 – US Women 11.5-12.5)	DSPS001-KIT44
A pair of Digitsole Pro 46-47 insole (US Men 12-13 – US Women 13-14)	DSPS001-KIT46
A pair of Digitsole Pro 48-49 insoles (US Men 13.5-14.5)	DSPS001-KIT48
Kit of 6 pairs of Digitsole Pro spares parts	DSPS001-KIT50
- 3 pairs of Digitsole Pro 30-32 insole (US 12-1,5)	DSPS001-INS30
- 3 pairs of Digitsole Pro 33-35 insole (US 2-4)	DSPS001-INS33
Digitsole® Pro Kit	DSPS001-KIT60

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 15.0+.

Functioning of the DSPods LEDs

- LEDs are red: DSPods are charging.
- LEDs are off:
 - DSPods are plugged in, which means they are fully charged.
 - DSPods are not charged, which means that they are in standby mode. Simply shake them to bring them out of this mode.
- LEDs are blinking: DSPods are ready for use.

Product Installation

Product operation

Insert the DSPods into your insoles as follows:

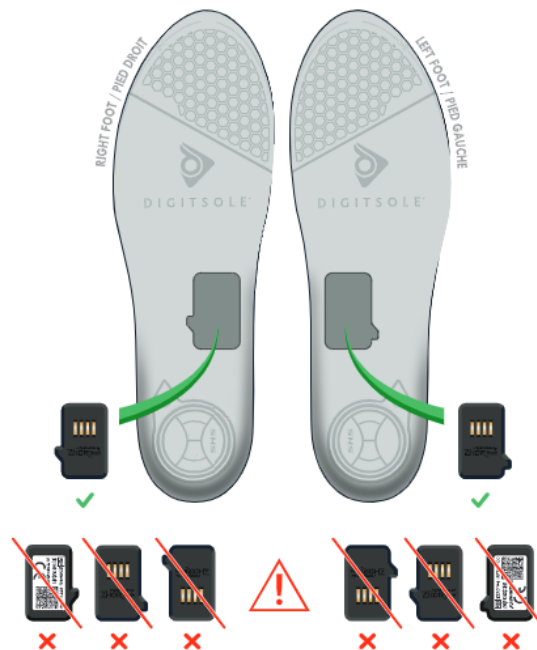
- Identify left and right DSPods



- Identify the left insole and the right insole



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

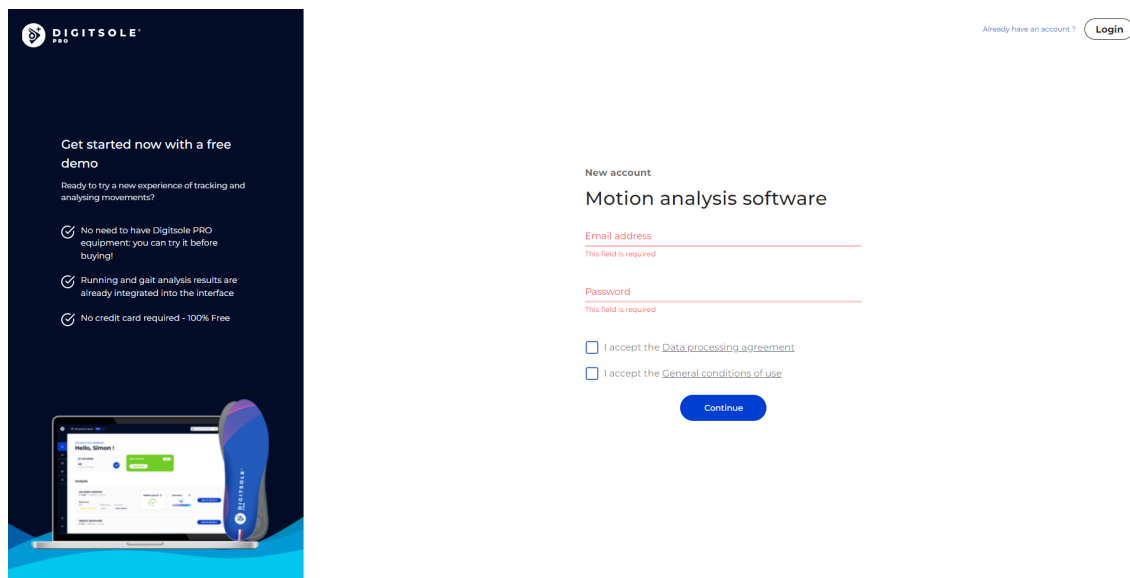


The data acquisition can also be done with the use of DSPods positioned on the bottom of the foot if the positioning of the DSPods avoids any unexpected slippage.

Account creation

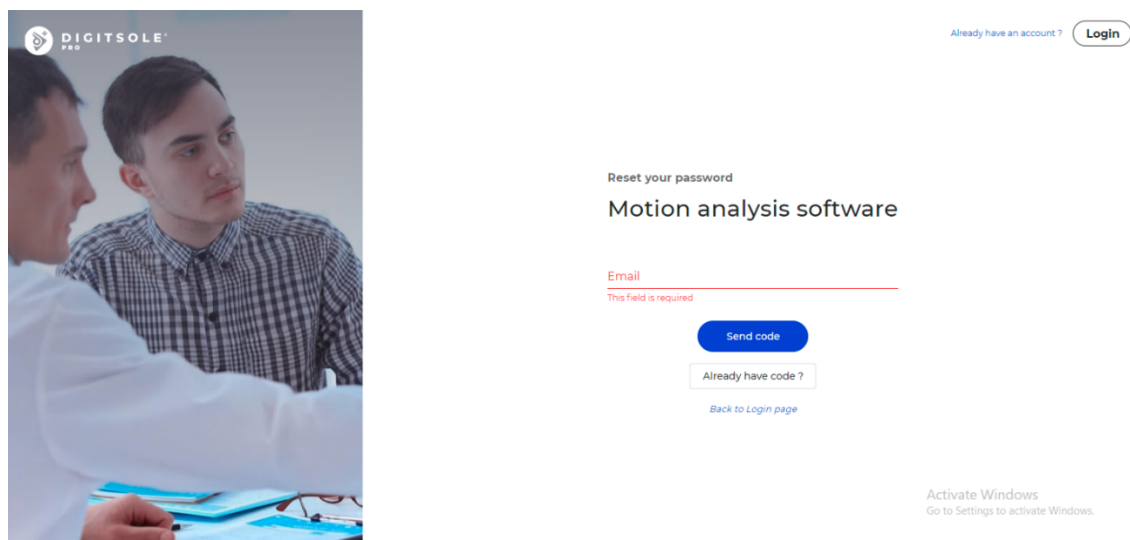
If you have not already done so, go to the following page to create a Digitsole® Pro account:

<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.

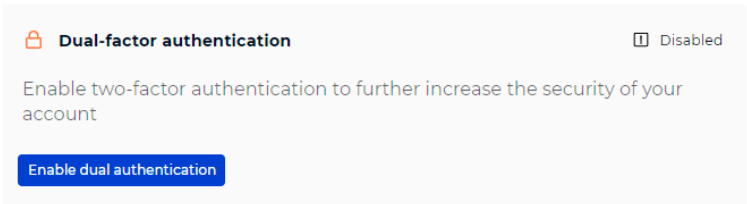
Then enter your personal data to finish your account creation.

Two-factor authentication activation

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



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



Scan the QR Code 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 15.0+ 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

Must be used with 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. Must be used with a phone with Android 6.0+ or iOS 15.0+.

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.

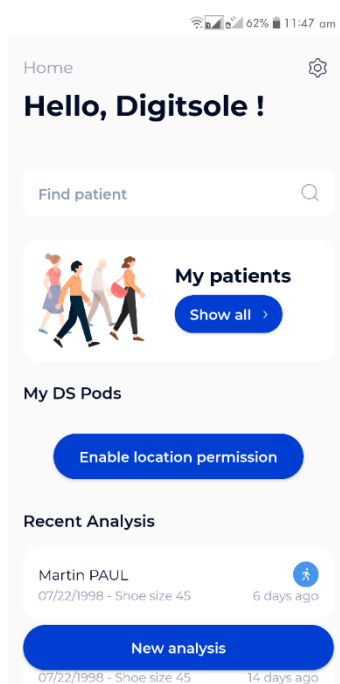
If you have forgotten your password, go to the Digitsole® Pro interface and create a new one.

DSPods management

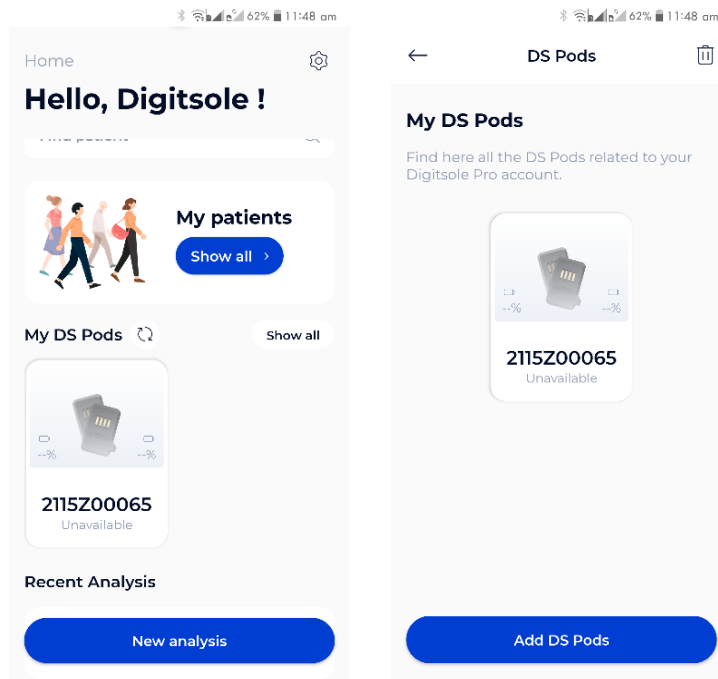
[Add DSPods](#)

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

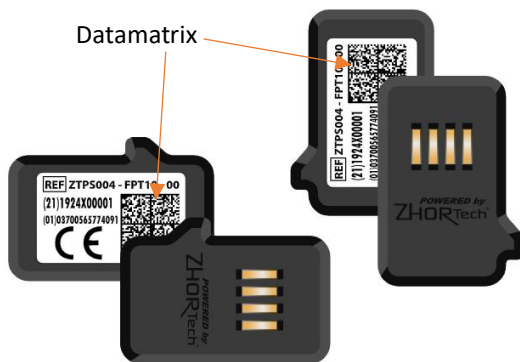
- If you do not already have DSPods, go to the "DSPods" area and click Add



- 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.

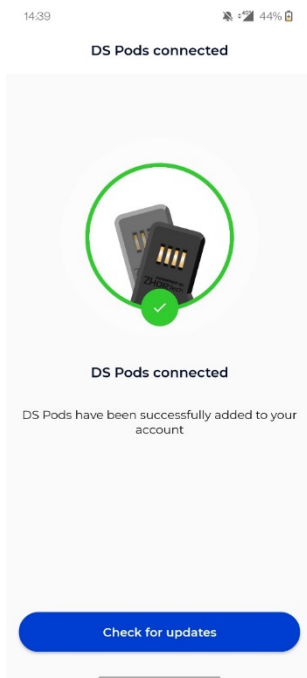


To add your DSPods to your account, go to a new page and scan the Datamatrix code from your pair of DSPods. If you have more than one pair of DSPods, repeat the procedure.



Datamatrix code example

Update DSPods

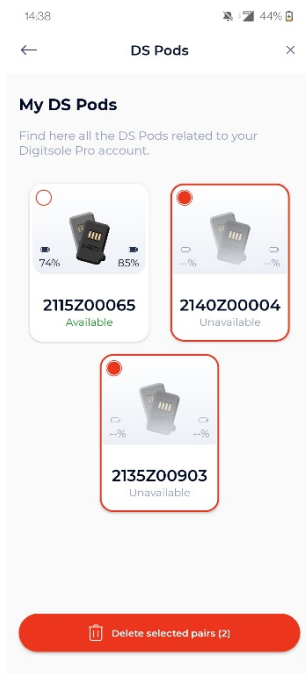


Click on **Check for updates** to check the DSPods version and see if they need to be updated.

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

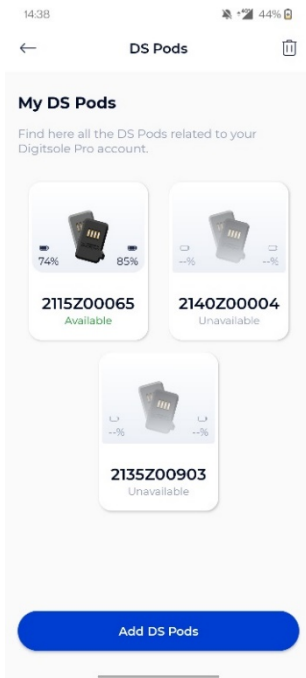
We advise you to do it now but if you choose to do it later, you will have to rescan your Pods by adding them to your account again.

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 will not see the charge level of your DSPods.

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 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

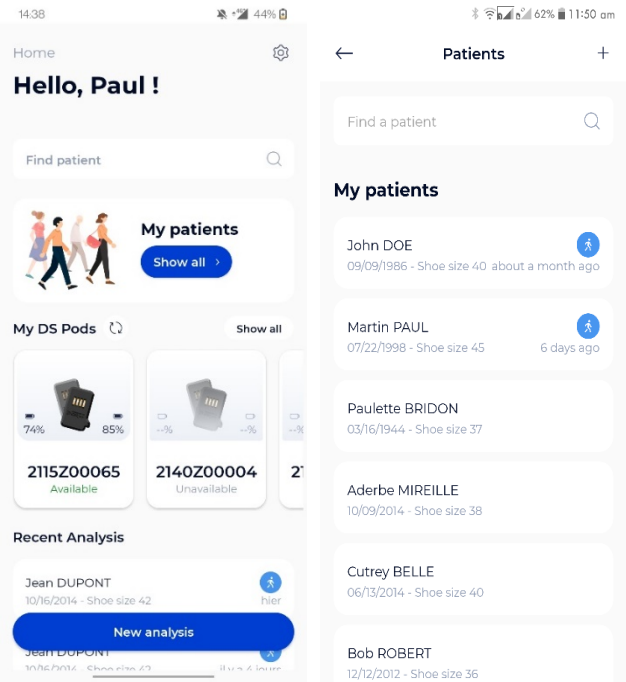
In the "Settings" section, you can choose the system of units you want to use in the application. You can choose between the metric and imperial systems.

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 + sign at the top right of your screen.

Cancel **New patient** Add

Information Pathology Contact

Last name
Last name

First name
First name

Birth date
Birth date

Height Weight
Height cm Weight kg

Shoe size
Select

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 can easily communicate with them.

NB: Note that with imperial units, choose the gender of the patient first to access the men or women's sizes.

[Edit a patient](#)

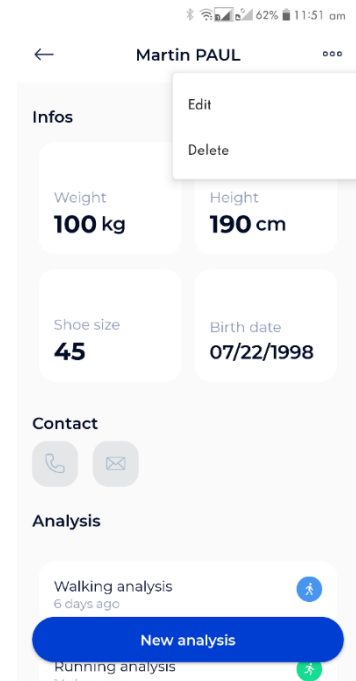
Click on the patient you want to edit from the list of patients, and the patient file will open. Select **Edit** from the menu at the upper right of the screen. When the form appears, fill in the fields and then click **Submit** to save your changes.

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.

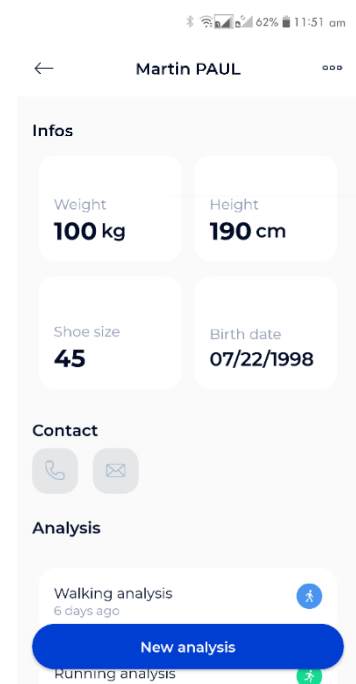
Please note: This is an irreversible action.



[Contact a patient](#)

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

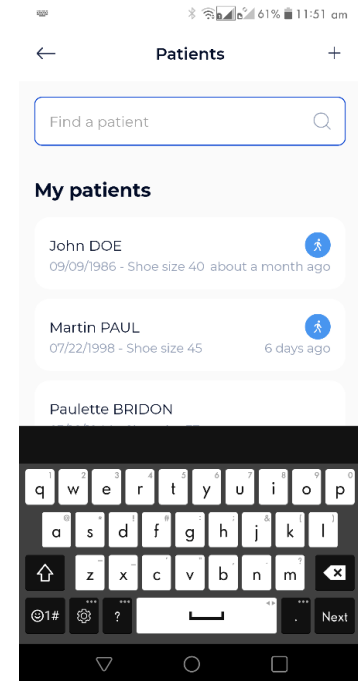
If you have entered your patient's phone number, you can call them by clicking the **Call** button. If you have entered your patient's email address, you can send a message by clicking the **Send a message** button



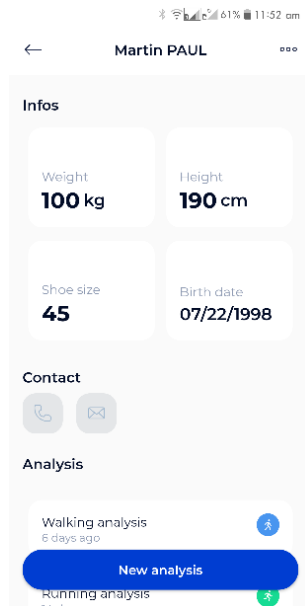
Search a patient

Type either 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.

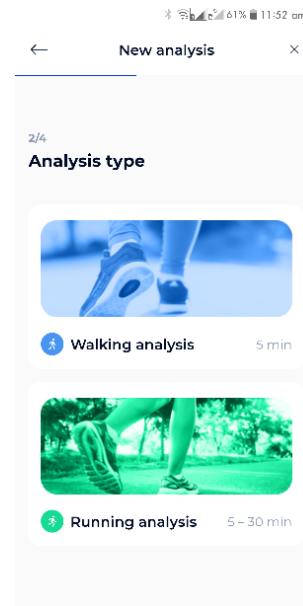
Note: The patient search only works with one word, so if you write your patient's first and last name in the search bar, you will not find any matches.



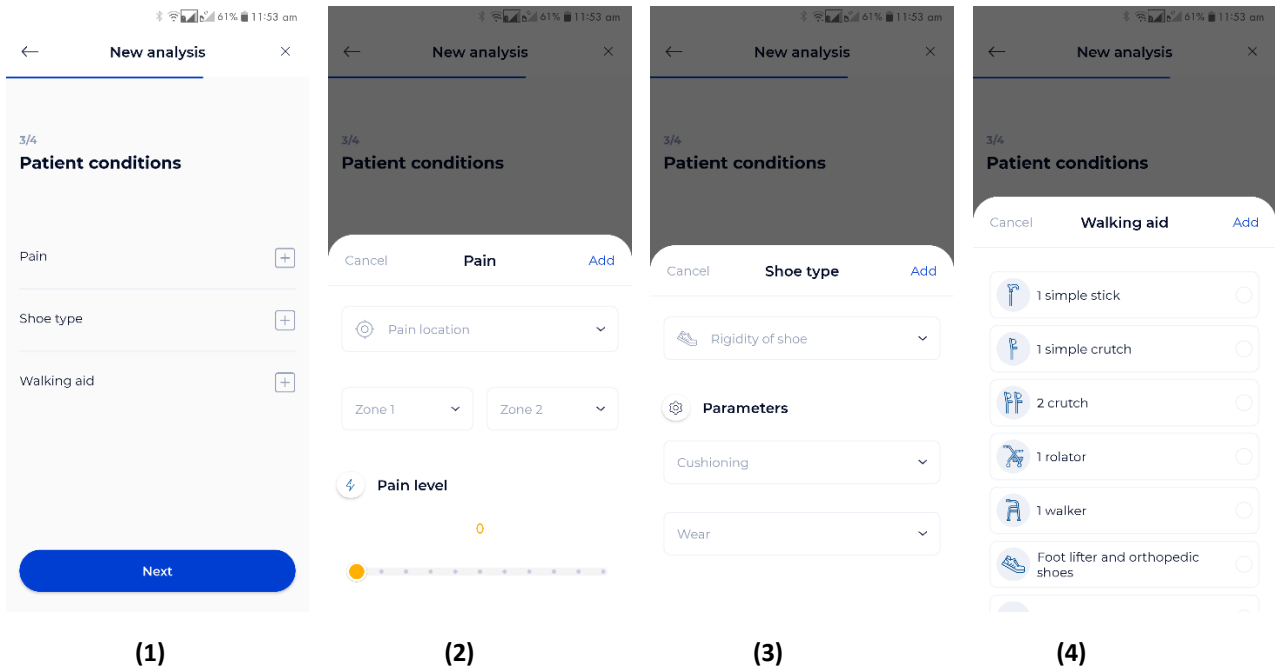
Start and stop data capture



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**.

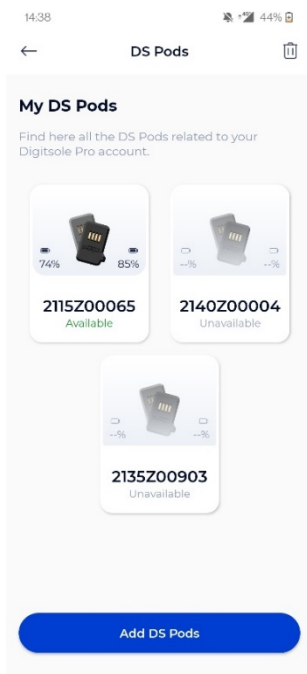


2 - Next, choose the type of analysis



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).



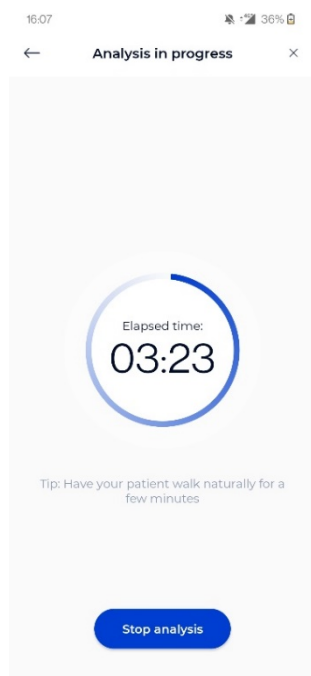
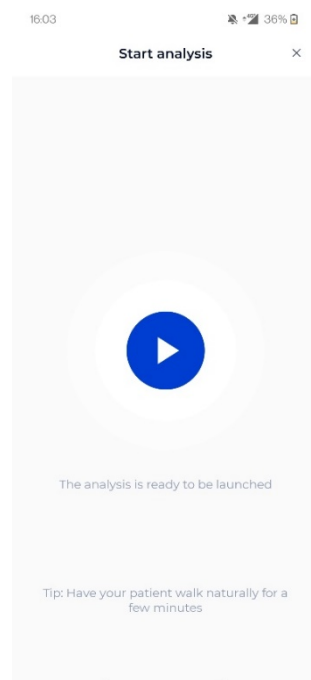
- Then pick the pair of DSPods with which you will use for the data capture; the application will then establish a connection to the DSPods and send you to the screen where you can begin the analysis.



CAUTION: Make sure to choose the ones that correspond to the insoles in your patient's shoes.

- If you have only one pair of DSPods, you will be directly redirected to the screen where you can begin the analysis.

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 transmitted to the Digitsole Pro® web interface.

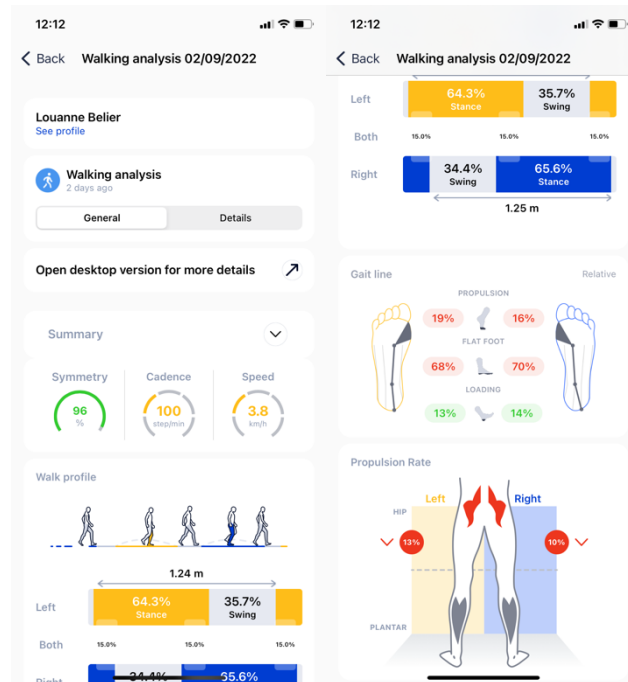
Note: If you share a workspace with a practitioner, it is not possible to perform an analysis at the same time on the same patient, nor is it possible to perform simultaneous acquisitions on the same Digitsole Pro account. In both cases this could block your account and create errors.

View the data

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



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.

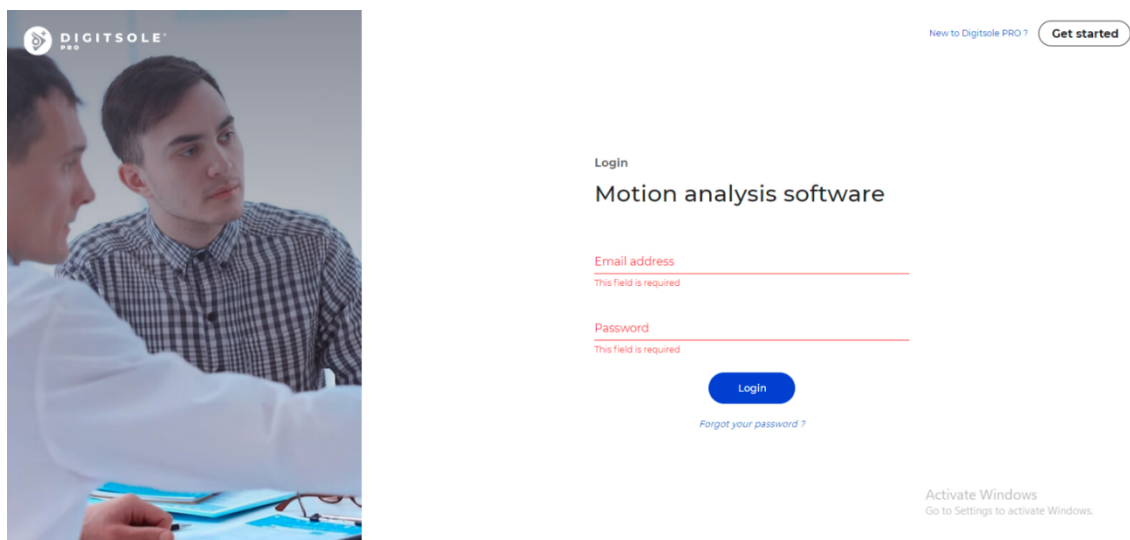
NB: If you see "Not enough steps" at the end of your activity:

- 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 the walking analysis, make sure more than 20 steps have been taken during the acquisition.
- In the running analysis, make sure the run speed is more than 8 km/h or 5 m/h.

Using the web interface

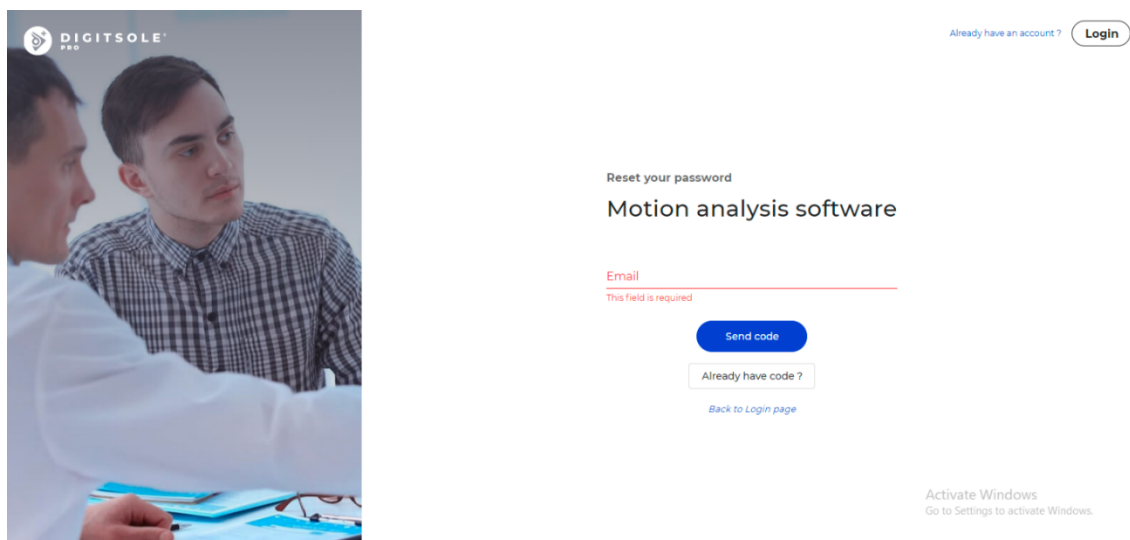
Login to the interface

To access the interface, ensure that you have already made your account on the web interface. You can connect to this application using the same credentials. Log in via the following link: <https://app.digitsolepro.com/auth/sign-in>

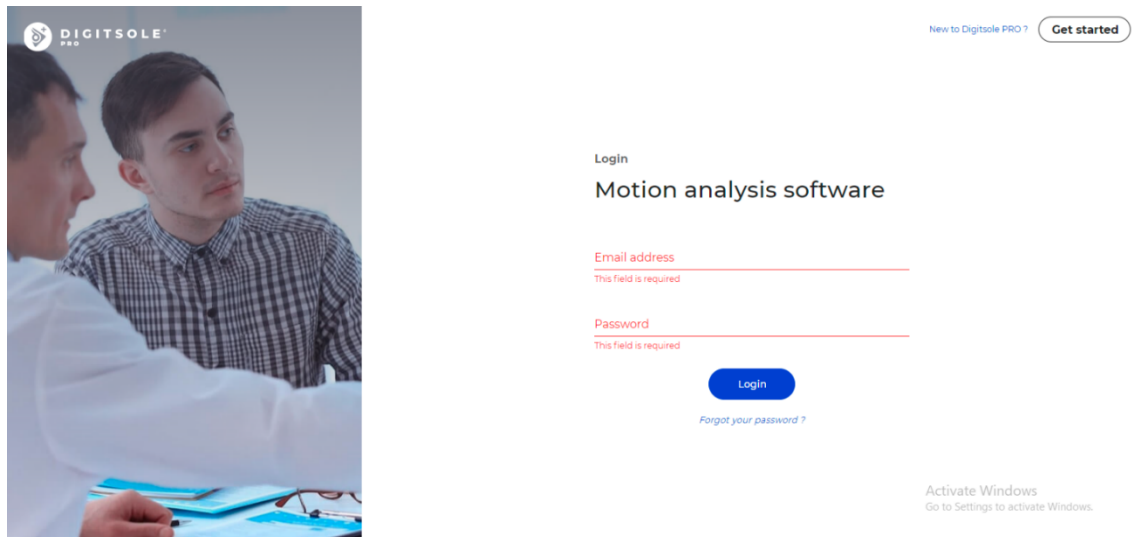


To log in, enter your account's email address and password.

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

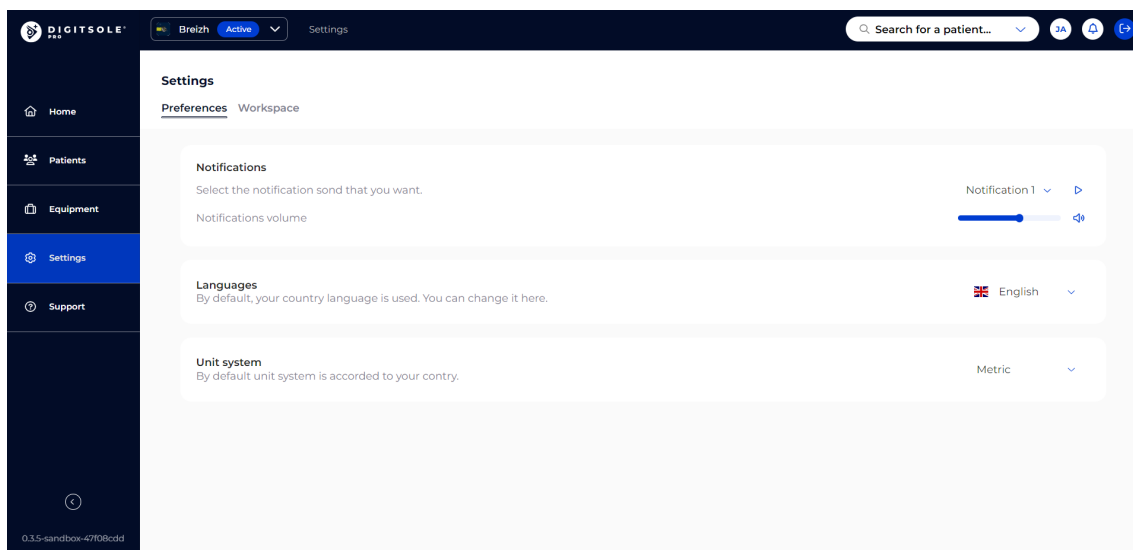


Along with your new password, enter the code you received through email. When you click **Submit**, your password will be changed.



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

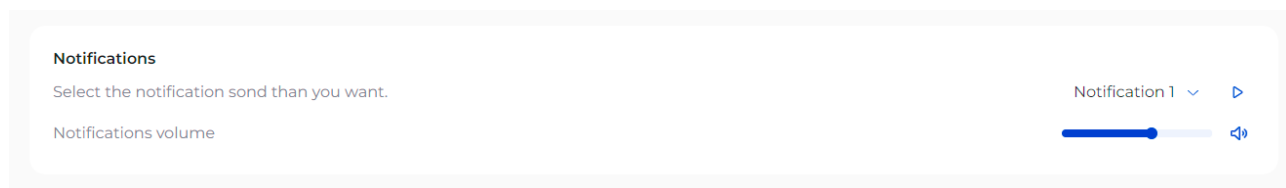
In the "Settings" section, choose between the metric or imperial systems of units to use on the web interface.

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

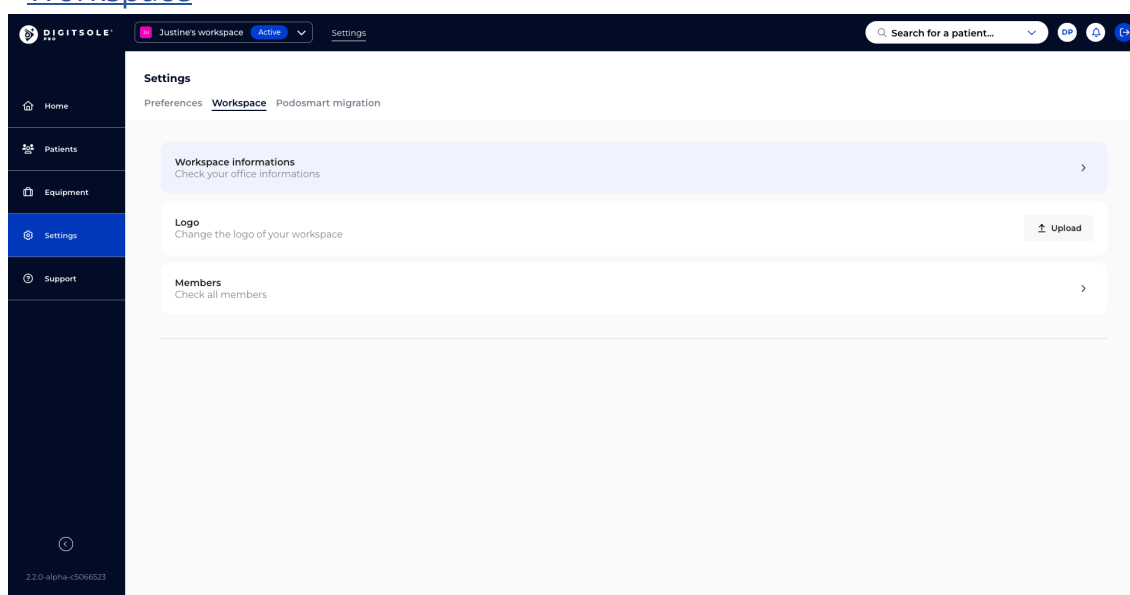
Notifications

Once you have performed a Digitsole Pro® analysis 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 section in the settings. By clicking on it you will have direct access to the analysis results of your patient.



You can change the sound of the notification in the settings of the web interface. You can choose between several sounds.

Workspace



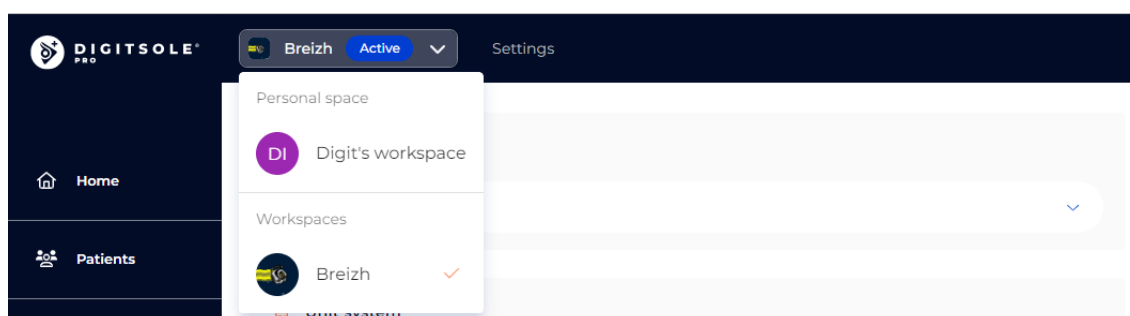
In the “Settings” section, you can change the information of your workspace, add members and features.

In the "Logo" section, you can add, modify or delete the logo. This logo will appear in the exports of your patients' test results.

In the section “Members”, click on top right of your screen on "Invite a new member" to add a Digitsole® Pro user to your workspace.

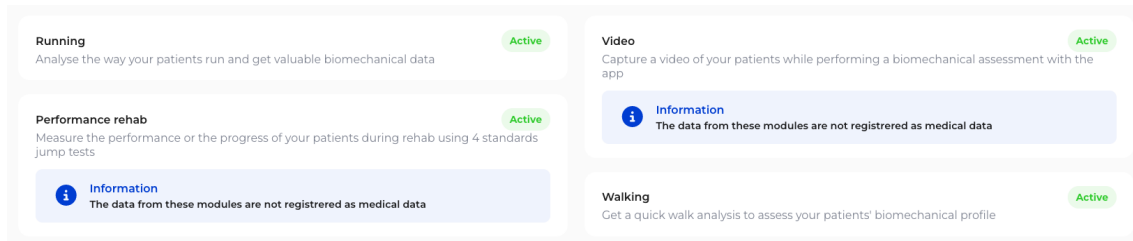
Once added, they will have access to all patients and analyses already performed in this workspace. They will also be able to perform analyses on the patients in this workspace. However, you will not have access to the patients and test results present in the workspace of the member added to your workspace.

To navigate between several workspaces, select the desired workspace in the bar at the top left of your screen.



Features

In the “Workspace” section, you can find the features you have subscribed to.



Changes to my account

Information management for health practitioners

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



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

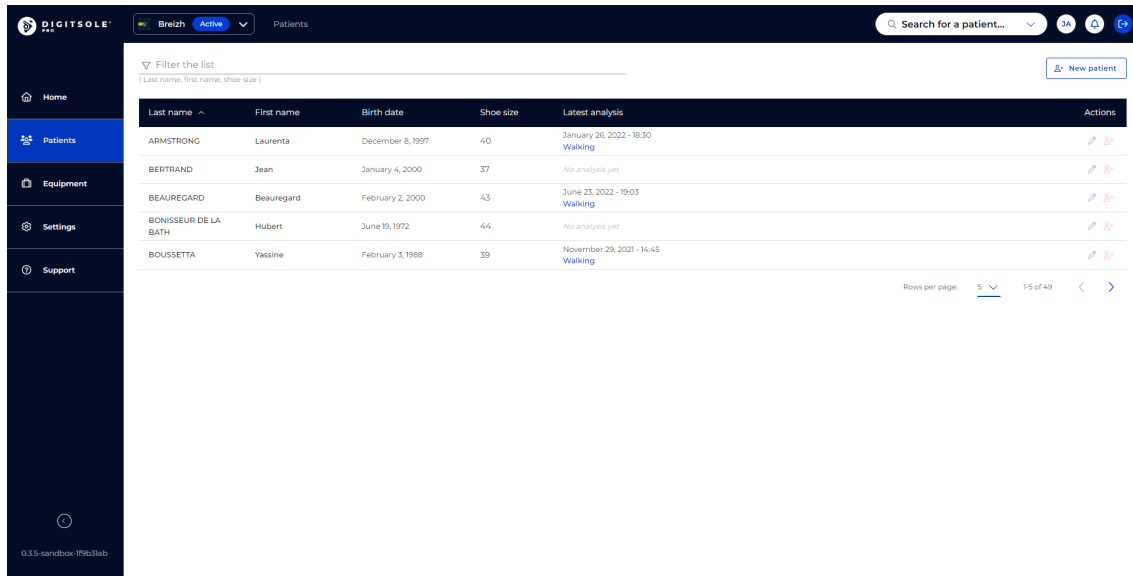
The screenshot shows a 'Profile' form with a title bar containing a person icon and the word 'Profile'. To the right of the title bar is a blue pen icon. The form has three main sections:

- First name ***: A text input field with the value 'Digitsole'.
- Last name ***: A text input field with the value 'Pro'.
- Professions ***: A section with three colored buttons: 'Neurologist' (pink), 'Osteopath' (pink), and 'Physiotherapist' (purple).

Patient management

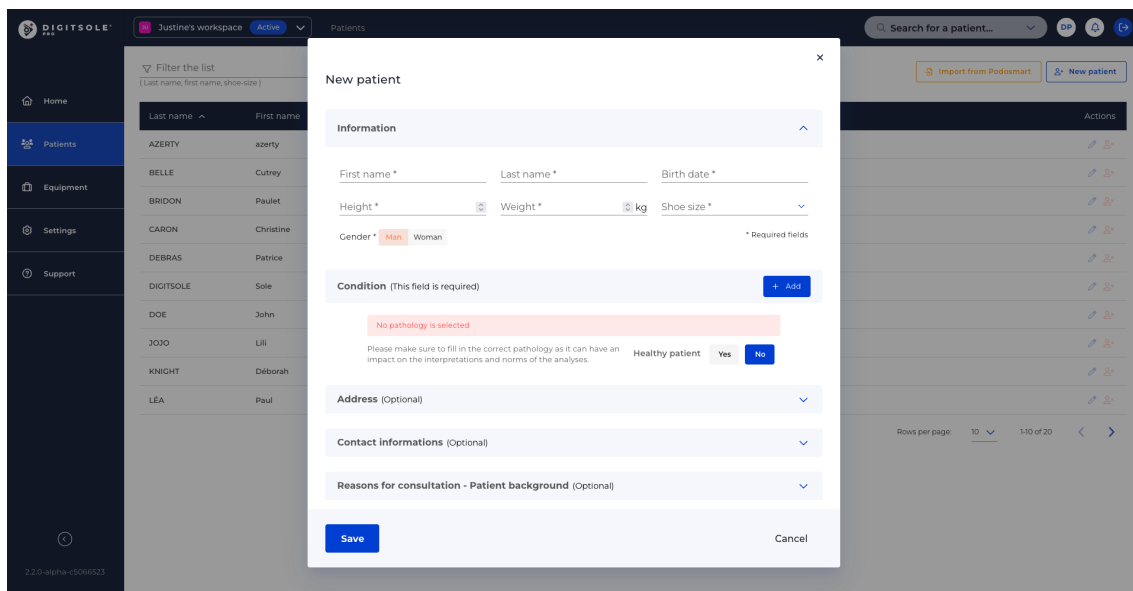
Add a patient

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**



NB: Note that with imperial units, choose the gender of the patient first to access the men or women's sizes.

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 **Edit** to modify information or on **Add** to enter new information.

The screenshot shows the patient profile for YASSINE BOUSSETTA. The interface includes a sidebar with navigation options: Home, Patients, Equipment, Settings, and Support. The main content area is titled 'YASSINE BOUSSETTA' and has tabs for Dashboard, Patient file, Practitioner analysis, and Evolution. The 'Dashboard' tab is active, showing a 'Pathology' section with a text input field 'What's Yassine's condition?' and an 'Add +' button. Below this is a 'Summary' section with a 'Pain' scale (Right Thigh: 2/10), 'Walking aids' (1 crutch), and 'Shoes' (Rigidity: Soft). To the right, there are two circular gauges for 'Cadence' (85 steps/min) and 'Symmetry' (77%). At the bottom, there are four activity logs for 'Walking' with timestamps and 'SEE IN DETAILS' buttons. An 'Edit patient' button is located in the top right corner.

Delete a patient

To delete a patient, click on the **Patient** tab, on the right of your screen, on the line corresponding to the patient you want to delete then click on the red logo **Delete patient**.

Please note: This is an irreversible action.

The screenshot shows the patient list table in the DIGITSOLE application. The table has columns for Last name, First name, Birth date, Shoe size, Latest analysis, and Actions. The data rows are as follows:

Last name	First name	Birth date	Shoe size	Latest analysis	Actions
ARMSTRONG	Laurenta	December 8, 1997	40	January 26, 2022 - 18:30 Walking	
BERTRAND	Jean	January 4, 2000	37	No analysis yet	
BEAUREGARD	Beauregard	February 2, 2000	43	June 23, 2022 - 19:03 Walking	
BONISSEUR DE LA BATH	Hubert	June 19, 1972	44	No analysis yet	
BOUSSETTA	Yassine	February 3, 1988	39	November 29, 2021 - 14:45 Walking	

At the bottom right, there is a 'Rows per page' dropdown set to 5, and a pagination indicator showing '1-5 of 49'.

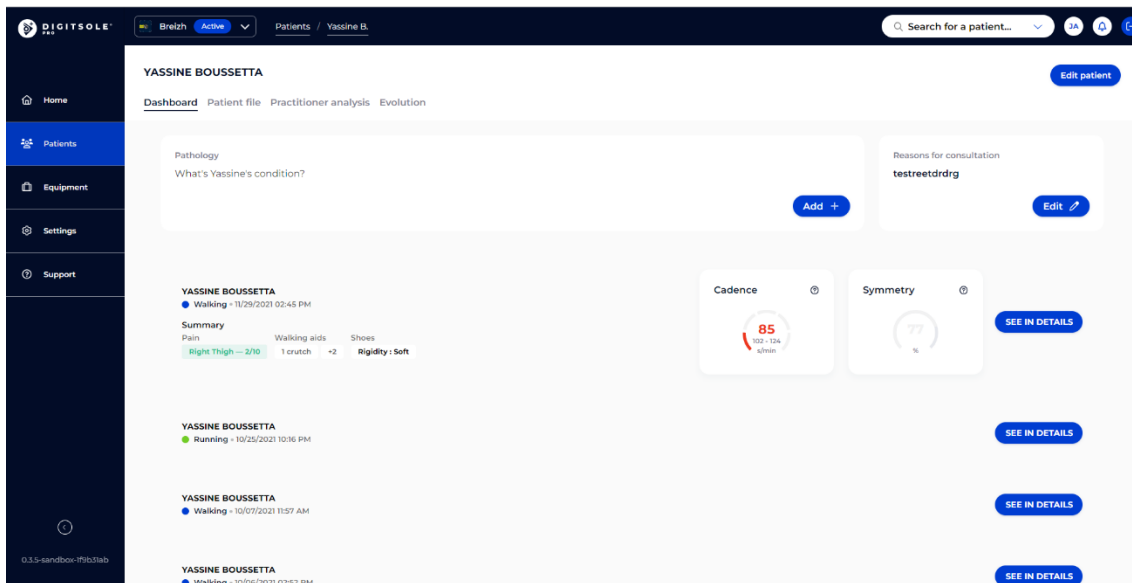
Search a patient

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.



Patient's file

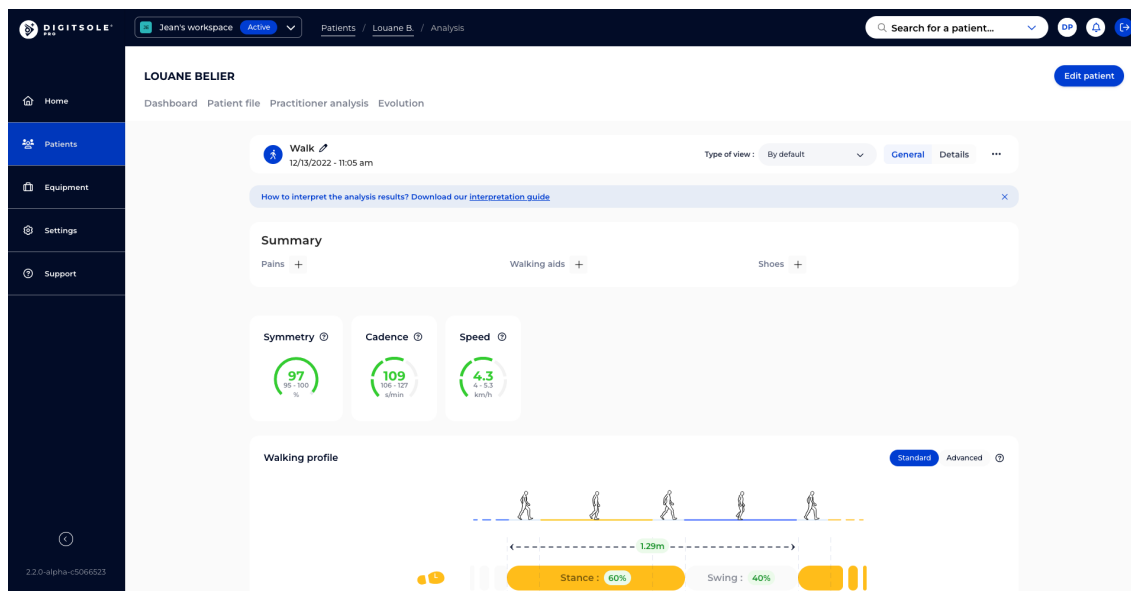
From the patient file you will have access to different tabs:



- **Dashboard** - You will find the recent analysis of your patient as well as their eventual pathologies and reason for consultation that you can add or modify.
- **Patient file** - You will find the information of your patient that you can modify. From this tab, you can also add or modify any pathologies, reasons for consultation and patient background.
- **Practitioner analysis** - You will find all the analyses performed on this patient.
- **Evolution** - You will find the evolution of your patient's analysis results classified by type of analysis.

Acquisition management

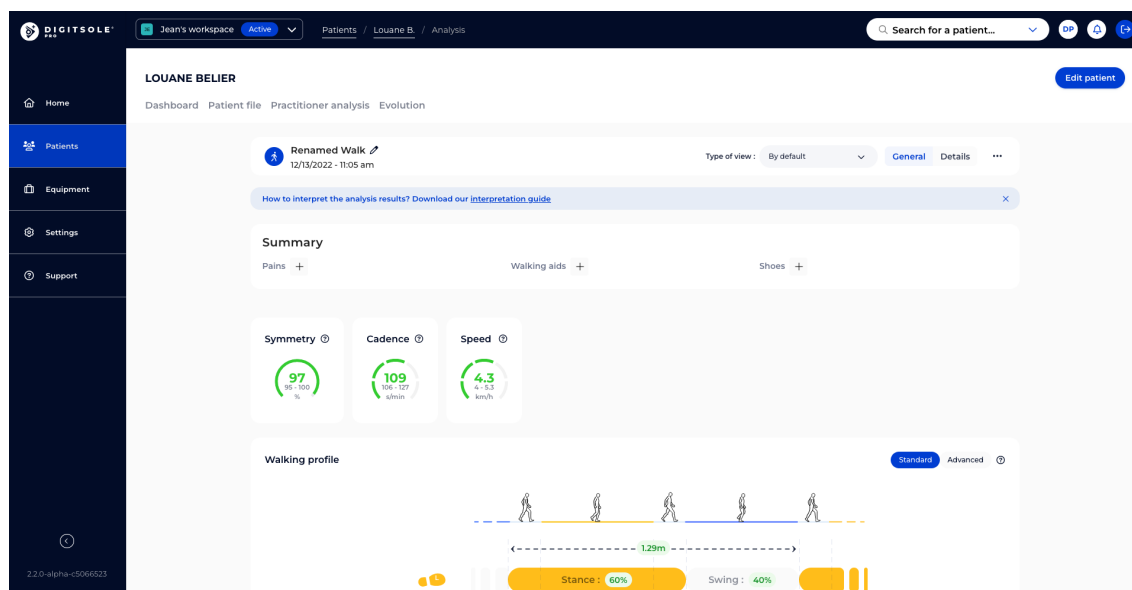
Rename an analysis



From the tab "Practitioner's analysis" on the patient record or directly from the analysis results, you can rename your analysis.

To do this, click on the Pen icon, rename the analysis and then click on Save. Your analysis is now renamed.

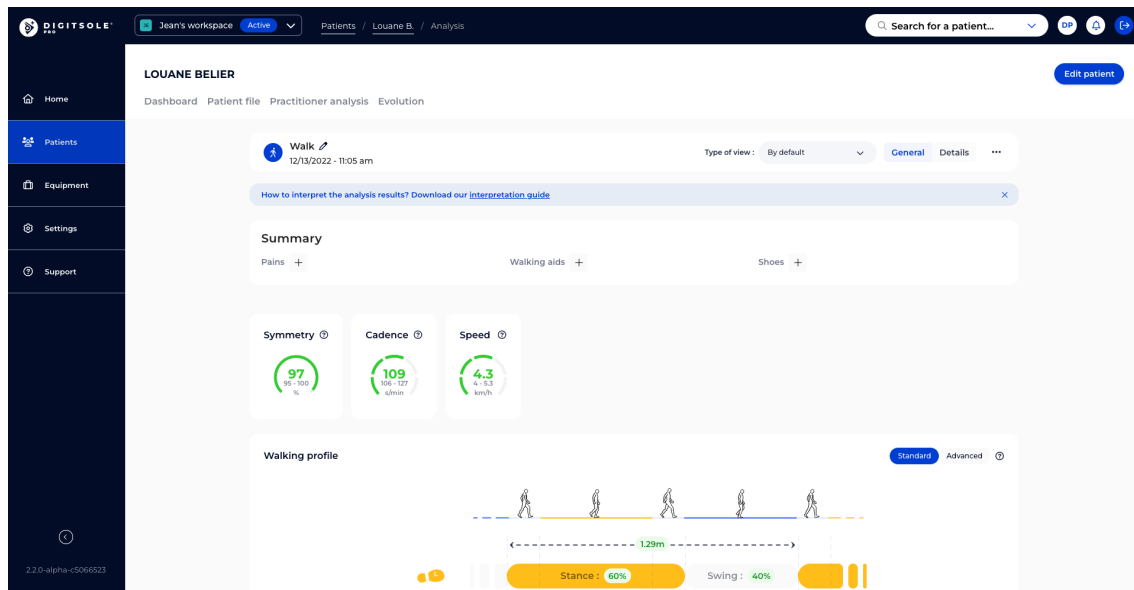
The 'Rename analysis' dialog box is shown, allowing the user to rename the analysis. The name field is filled with 'Renamed Walk'. The dialog has 'Save' and 'Cancel' buttons.



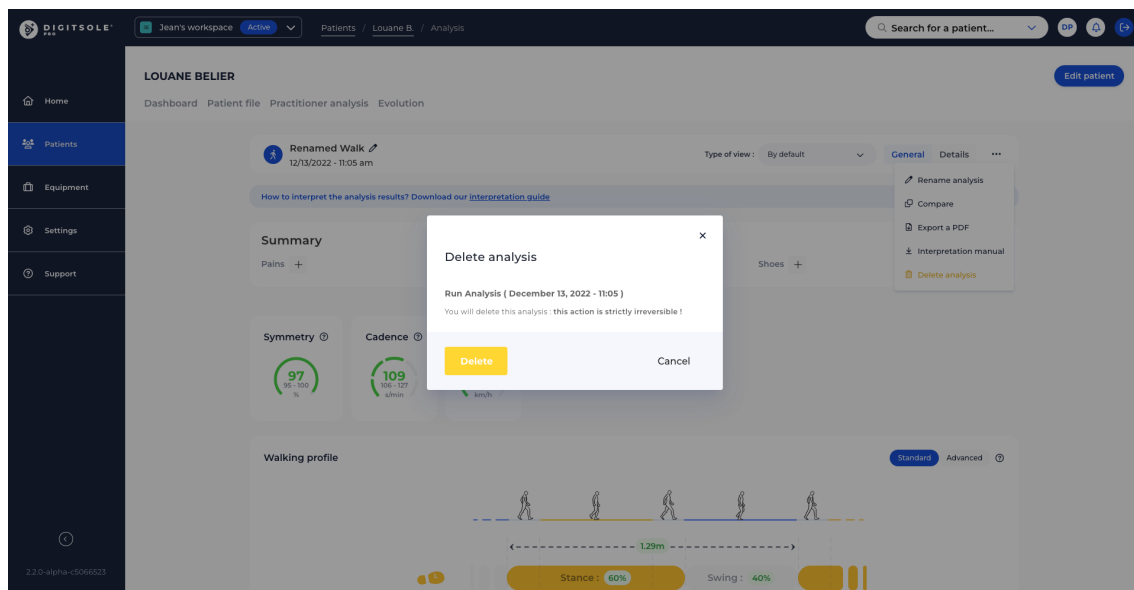
Delete an analysis

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

Click on the analysis you want to delete, then on the top right click ... and select **Delete analysis**



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

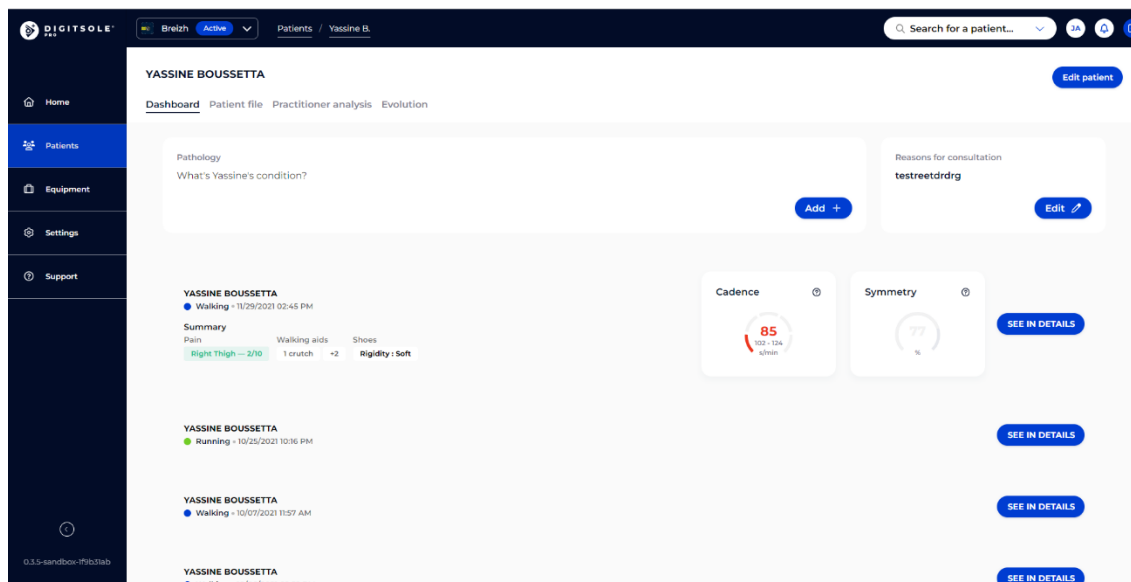


View the analysis

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

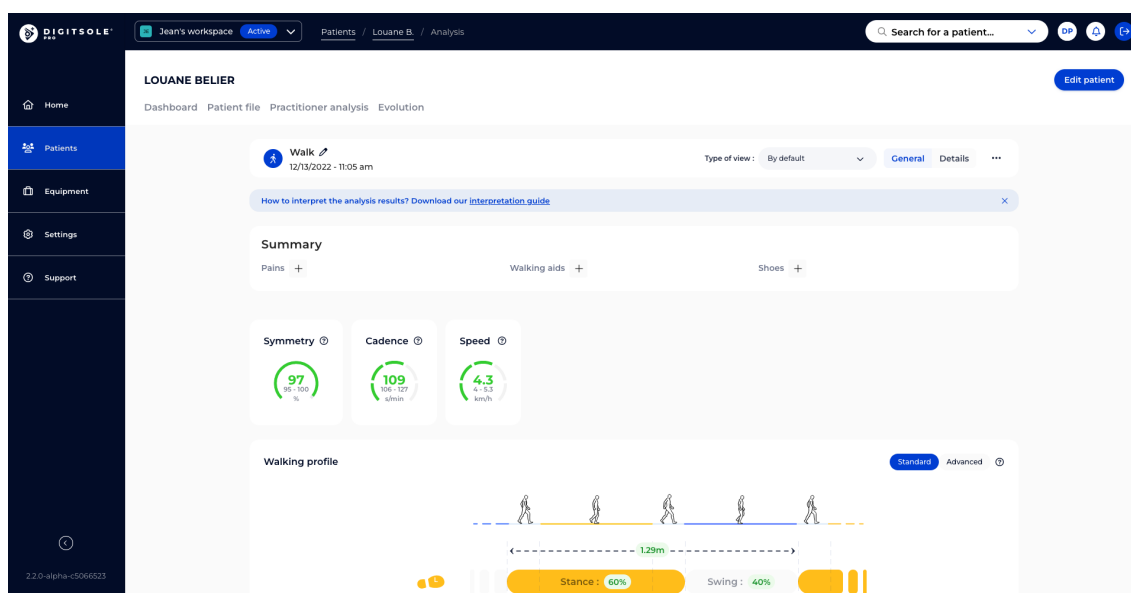
You are now in the patient file.

Select the analysis you wish to view by clicking on it.

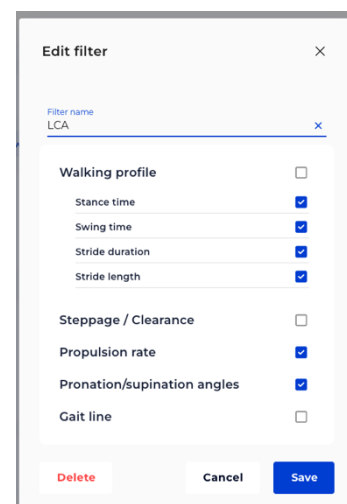
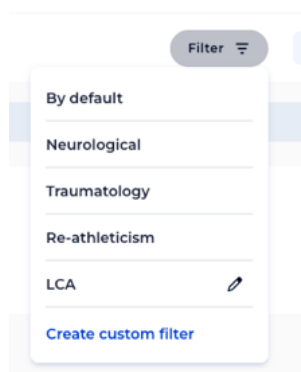


The patient analysis is now displayed.

On the top right, choose the type of view you want to see - General or Details, then you can choose one of five filters: Neurological, Traumatological, Rehabilitation, a Custom filter or Default view.



You can also choose to customize your filter by clicking on Create My Custom Filter. When creating it, you will be able to choose the parameters you want to display and custom name it.

Once you have created your custom filters, by clicking on the Pen icon, you will be able to rename it, modify it, and delete it.

The gait analyses performed with the "Embedded" version of our algorithms, i.e. with a data calculation previously performed in the DSPods (Digitsole Pro 1.0) will be marked with this logo:



Gait analyses without this logo, will correspond to analyses performed with the "Raw" version of our algorithms, i.e. with a data calculation performed in the cloud from the raw information recorded by the insoles (Digitsole Pro 2.0).

Generate report

[Export report](#)

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

You are now in the patient file.

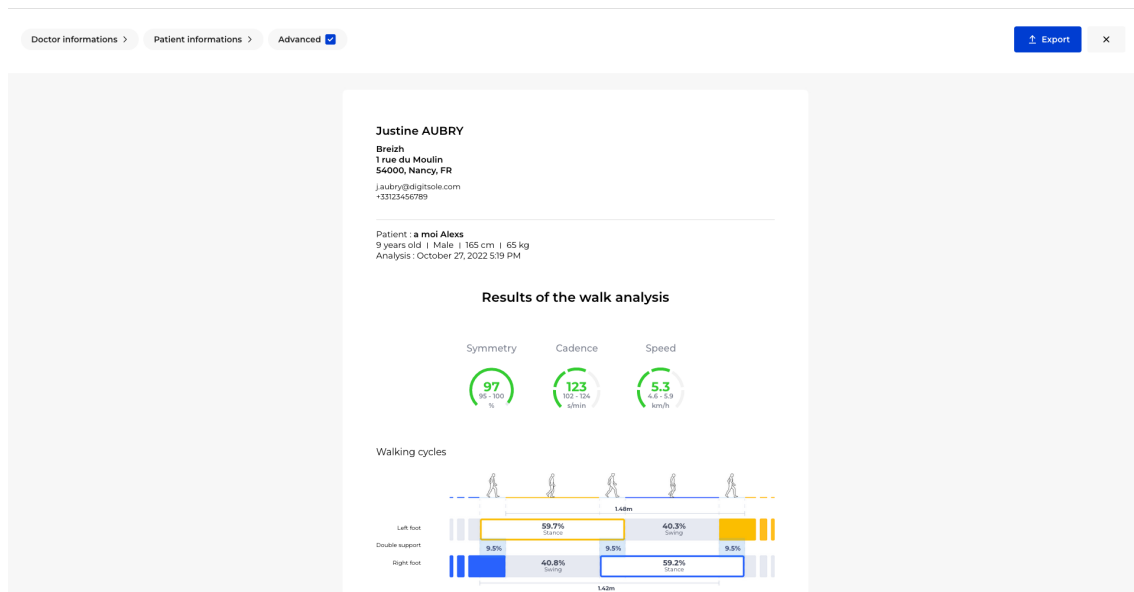
Select the analysis you wish to view by clicking on it.

The screenshot shows the DIGITSOLE interface for patient YASSINE BOUSSETTA. The left sidebar contains navigation links: Home, Patients (selected), Equipment, Settings, and Support. The top header shows the patient's name and a search bar. The main content area displays the patient's profile with a 'Pathology' section asking 'What's Yassine's condition?' and a 'Reasons for consultation' section with the text 'testreetdrdrg'. Below these are three analysis cards: 'Walking' (11/29/2021 02:45 PM), 'Running' (10/25/2021 10:16 PM), and 'Walking' (10/07/2021 11:57 AM). Each card shows a 'Summary' section with 'Pain' (Right Thigh - 2/10), 'Walking aids' (1 crutch - +2), and 'Shoes' (Rigidity : Soft). To the right of the cards are two circular gauges for 'Cadence' (85 s/min) and 'Symmetry' (77 %). A 'SEE IN DETAILS' button is visible next to each analysis card.

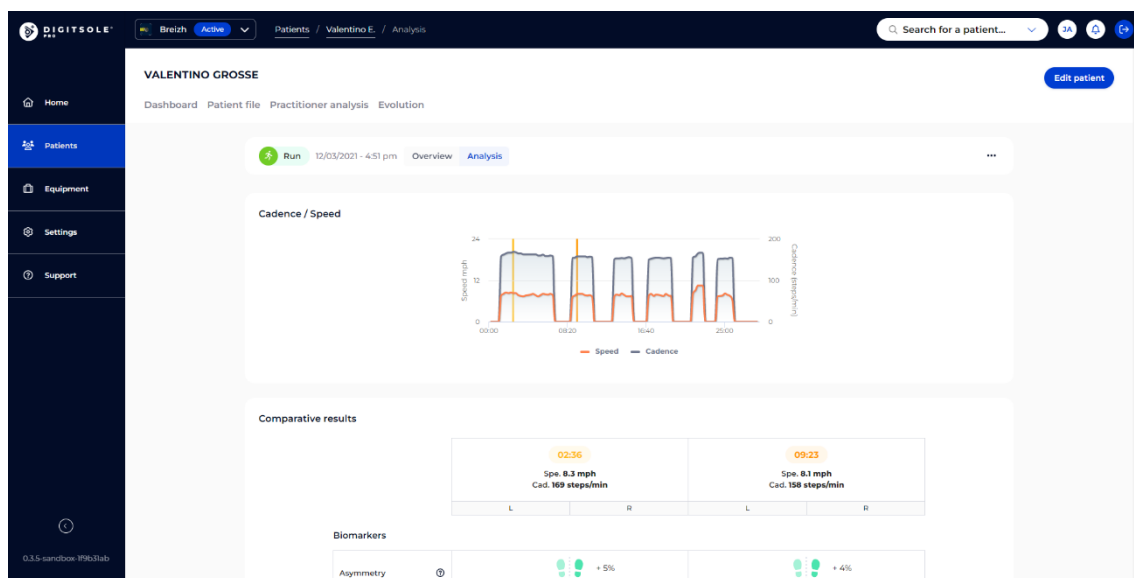
Once the analysis is open, click on the three dots in the upper right corner, followed by **Export PDF**.

The screenshot shows the DIGITSOLE interface for patient LOUANE BELIER. The left sidebar contains navigation links: Home, Patients (selected), Equipment, Settings, and Support. The top header shows the patient's name and a search bar. The main content area displays the patient's profile with a 'Walk' analysis (12/13/2022 - 11:05 am). Below the analysis title is a 'Summary' section with 'Pains' (+), 'Walking aids' (+), and 'Shoes' (+). To the right of the summary are three circular gauges for 'Symmetry' (97 %), 'Cadence' (109 s/min), and 'Speed' (4.3 km/h). Below these is a 'Walking profile' section showing a gait cycle diagram with 'Stance' (60%) and 'Swing' (40%) phases. A 'SEE IN DETAILS' button is visible next to the walking profile.

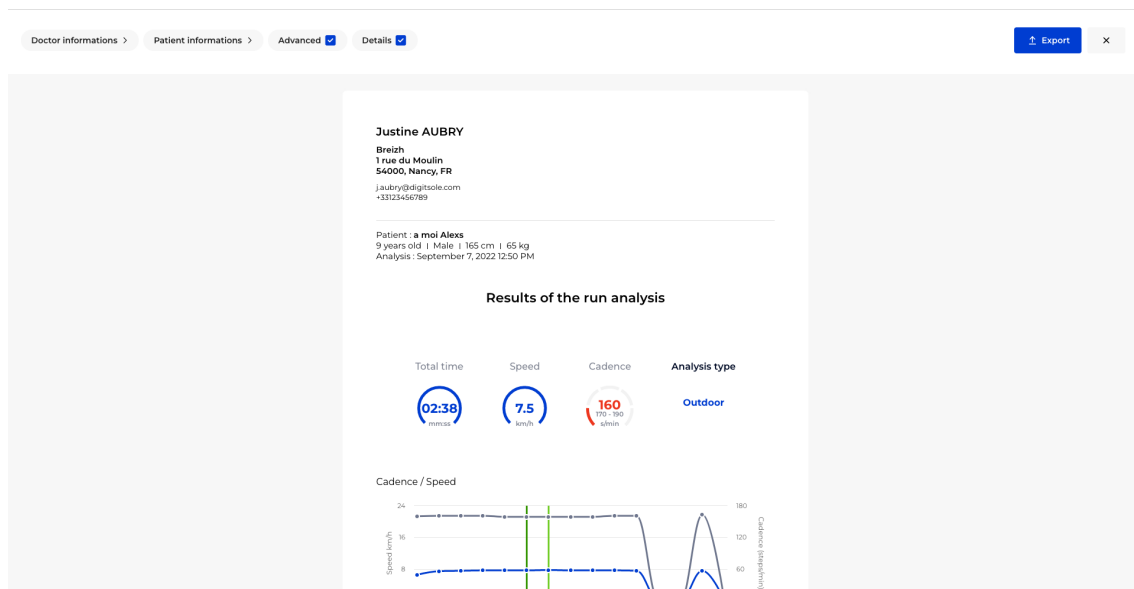
The export analysis page will appear.



For more details about exporting a run analysis, select two points on the details tab chart as below:



You can then click **Export PDF** which opens the analysis export page. By checking the details box, you will have access to a more detailed PDF including the comparison of the two points you selected earlier.

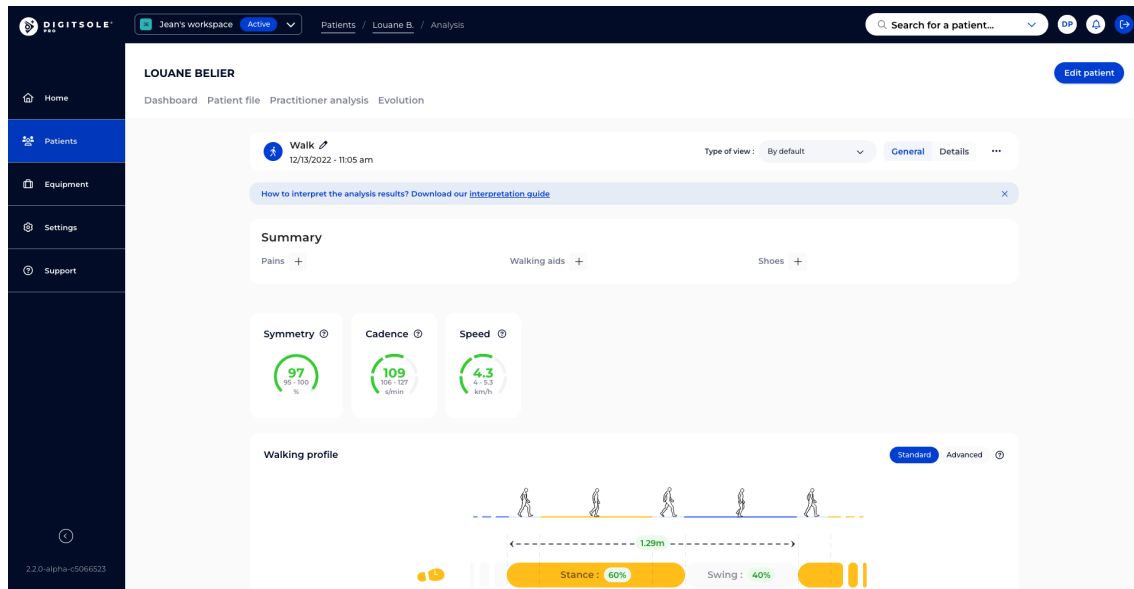


Export a Comparative Report

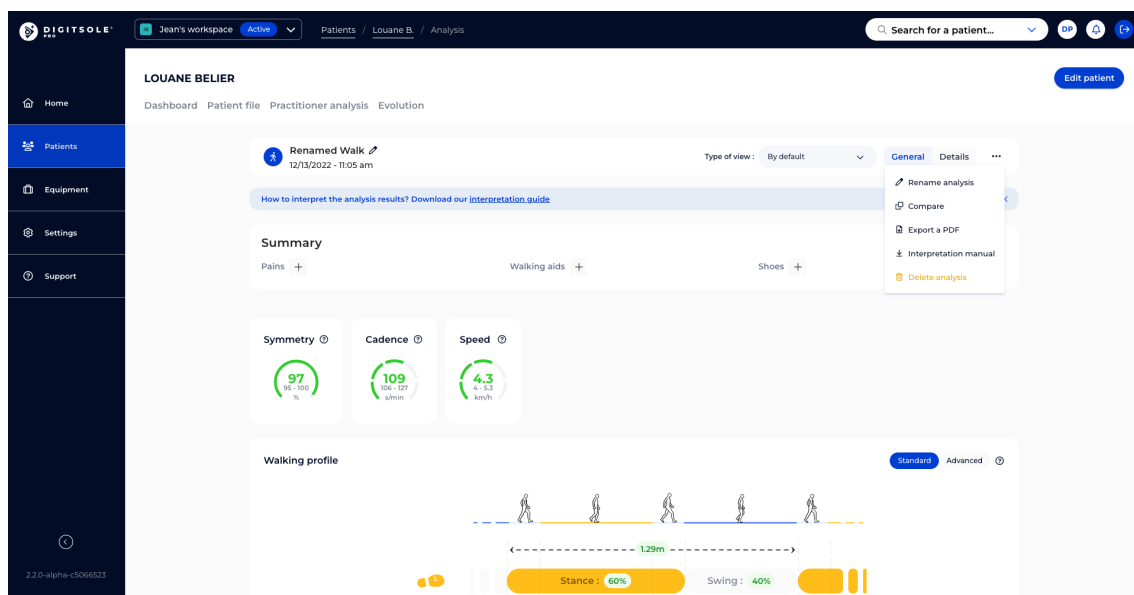
Click on the **Patients** tab and then on the line of the desired patient.

You are now in the patient's file.

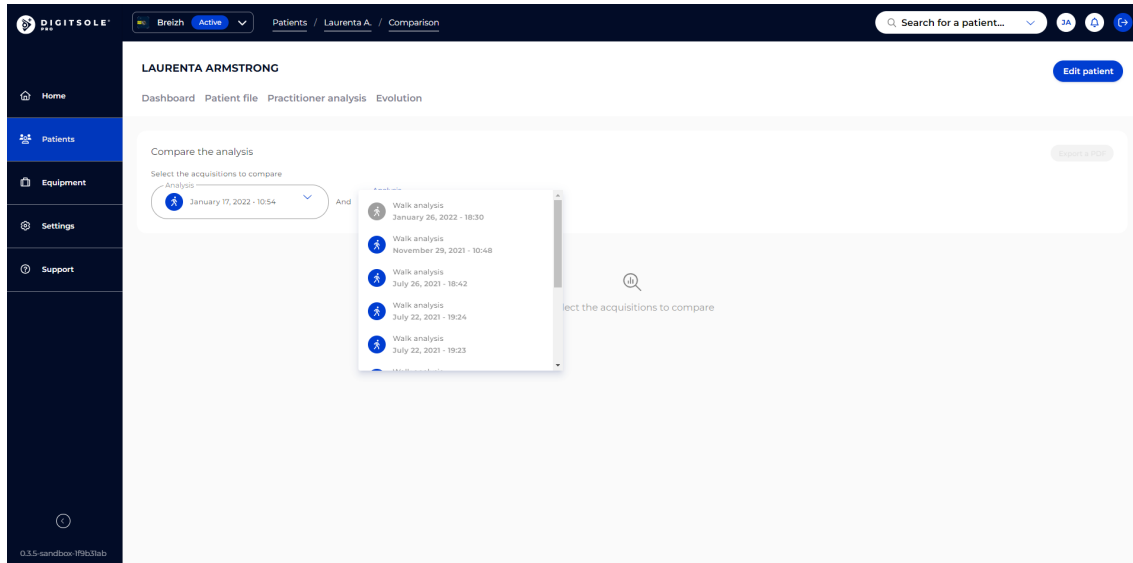
Click the scan you want to access.



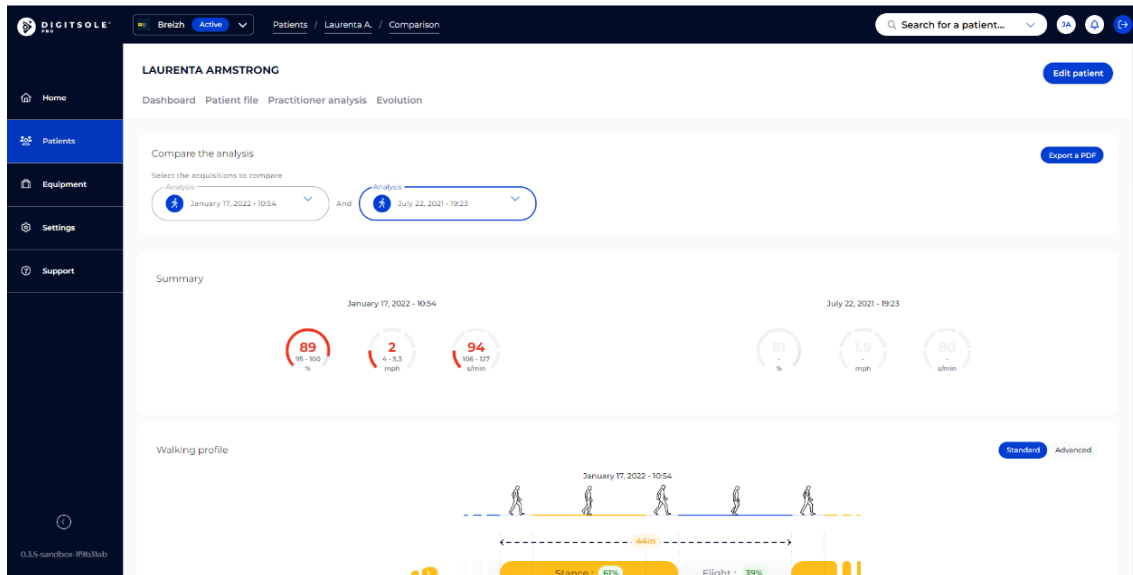
Once the scan is open, click on the three dots button at the top right and then click **Compare**.



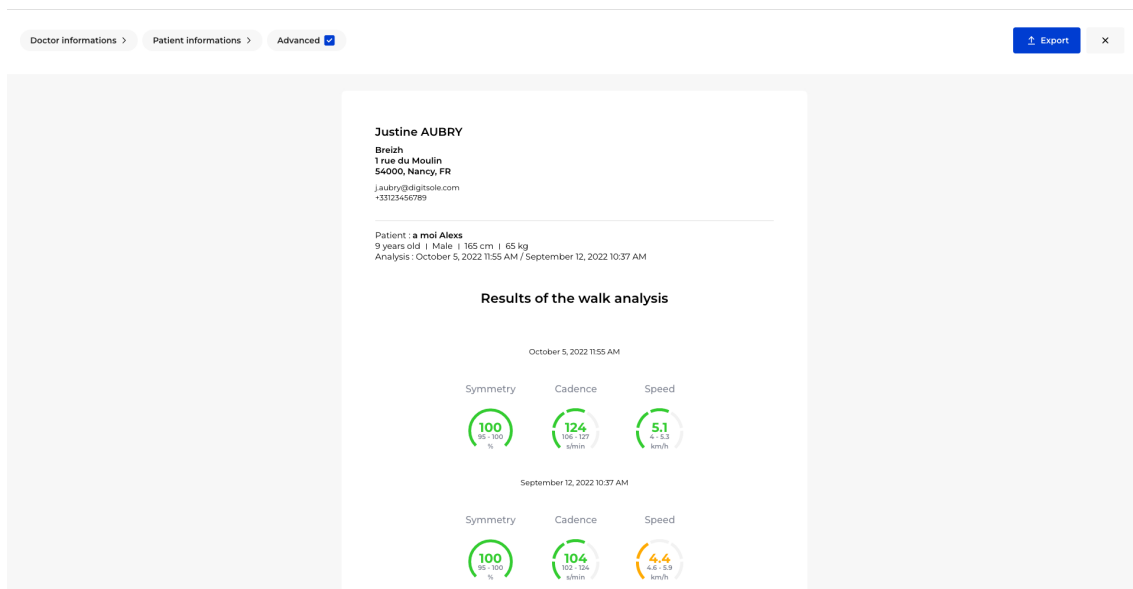
Then select the second analysis for comparison.



Then click **Export PDF**.



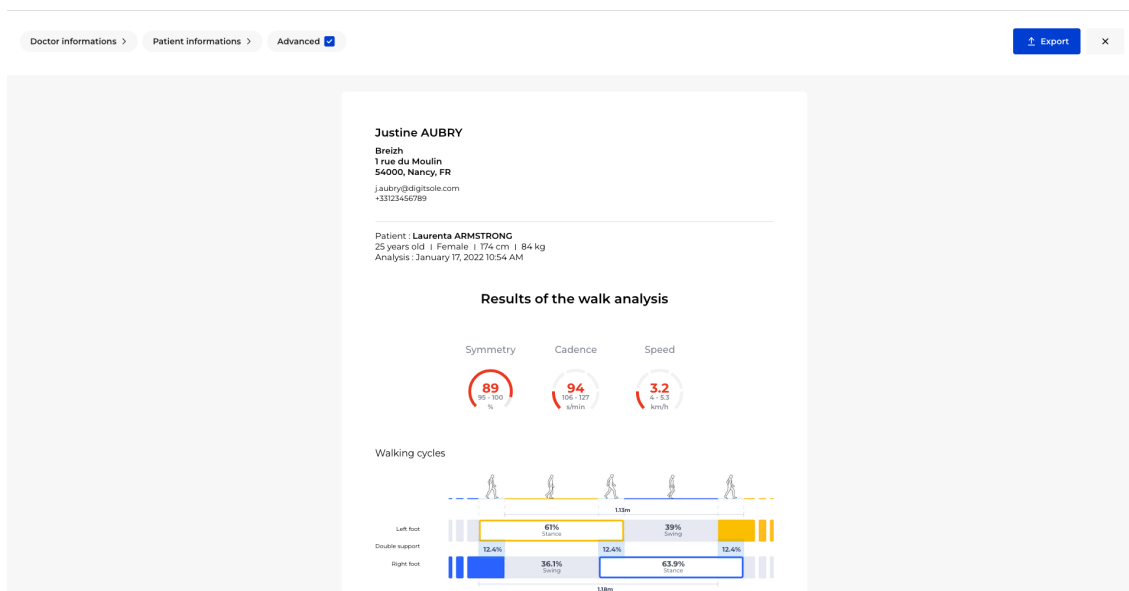
The analysis export page will open and you can chose how you'd like to export the report.



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

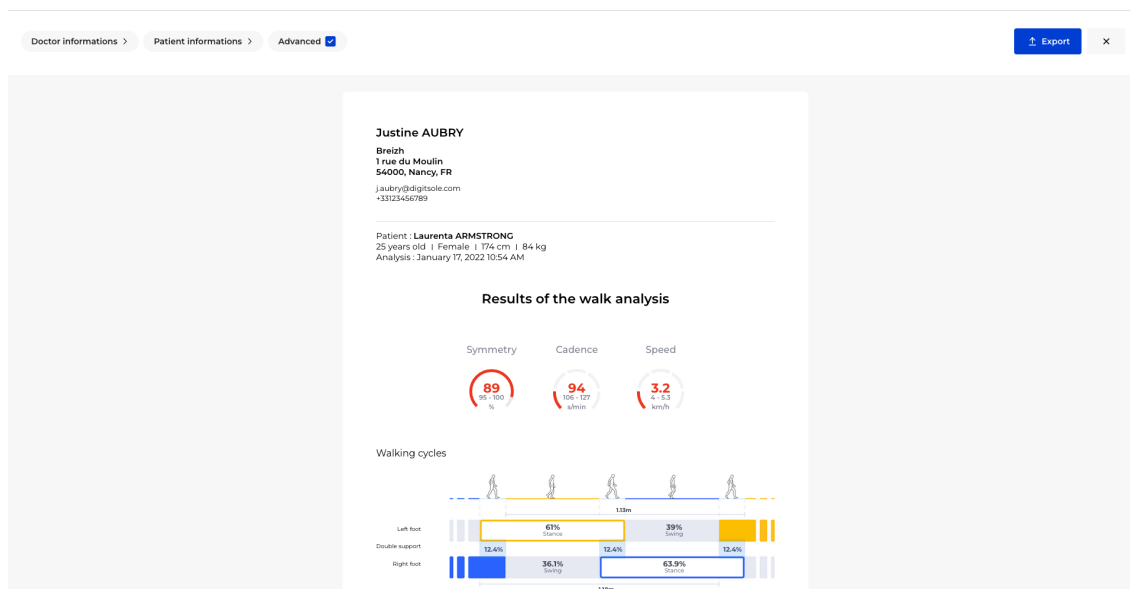
Following the completion of your analysis export, you can:

- Check the "Advanced" box to generate a more advanced report
- Choose whether or not to show your information (e-mail, phone number and logo) by checking the corresponding boxes.
- Choose whether or not to show patient information (name, age, gender, height and weight) by checking the corresponding boxes.



[Print report](#)

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

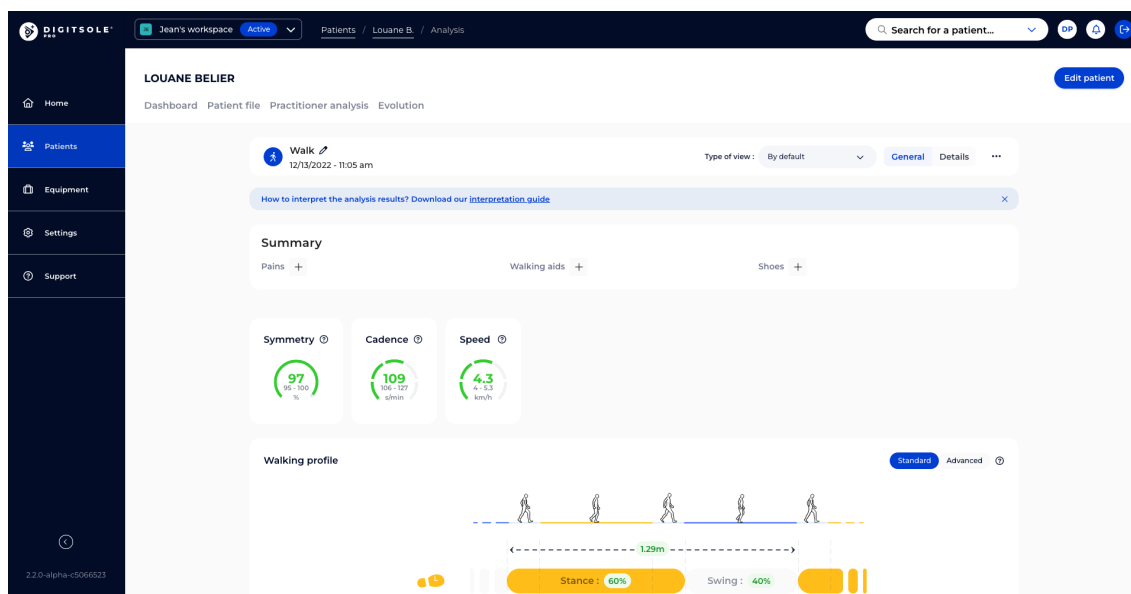


Compare analyses

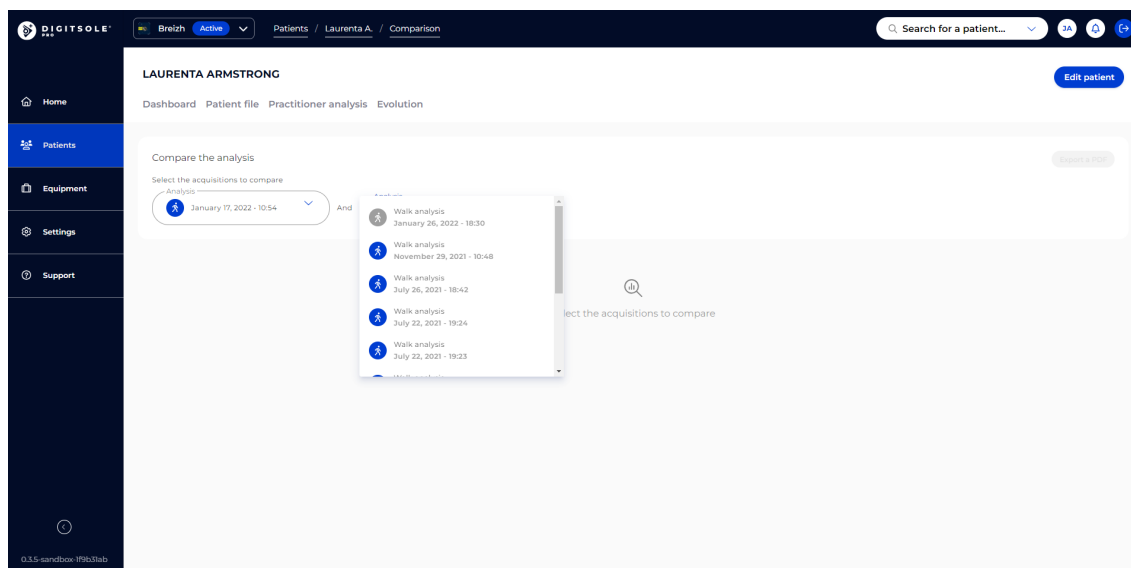
Select the **Patients** tab, then the selected patient's line.

You are now on the patient file.

Select the analysis you wish to compare by clicking on it.



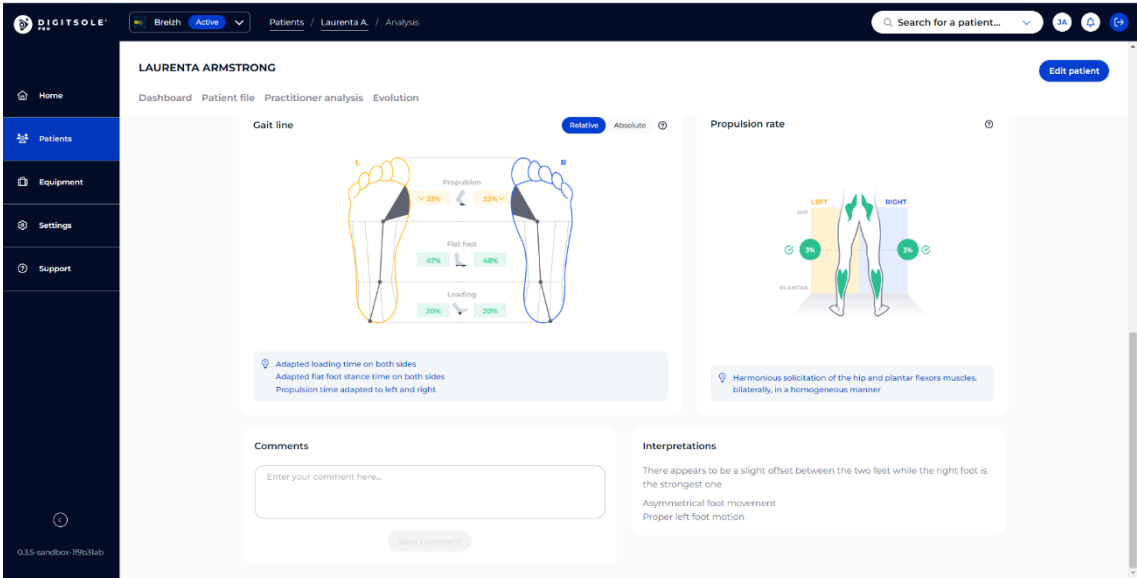
Once the analysis is open, click the three dots button in the upper right corner, followed by **Compare**.



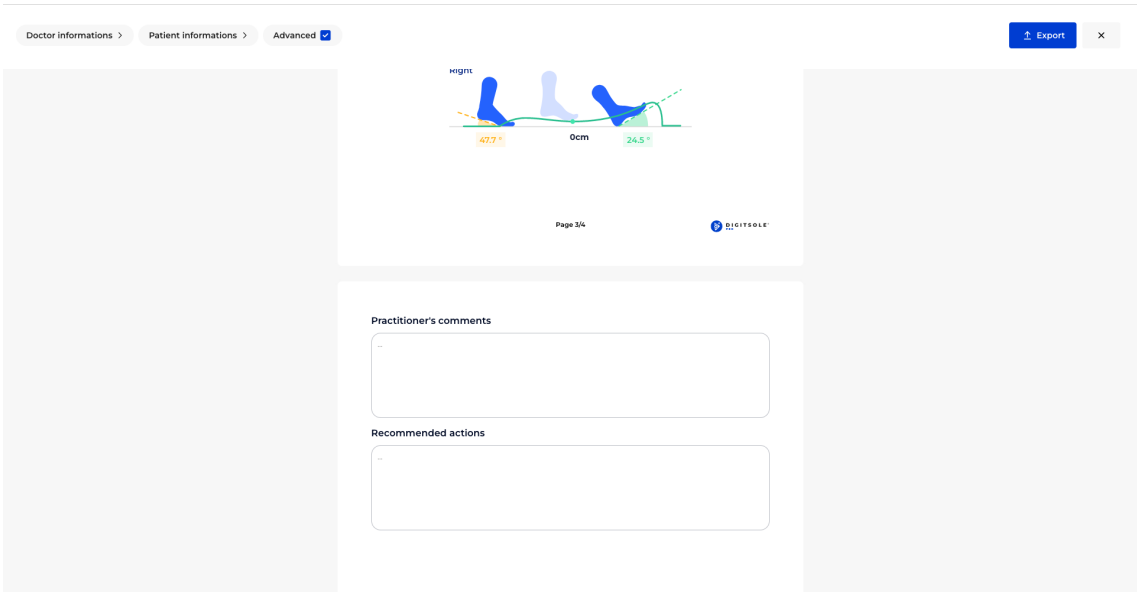
Then select the analysis that you want to compare it with.

Add comments

Notes can be added to the Comments section at the bottom of the analysis results. Comments will be saved with the results to be viewed at any time.



After the report has been exported, you can add notes in the Comments section. 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/or saving it as a PDF.

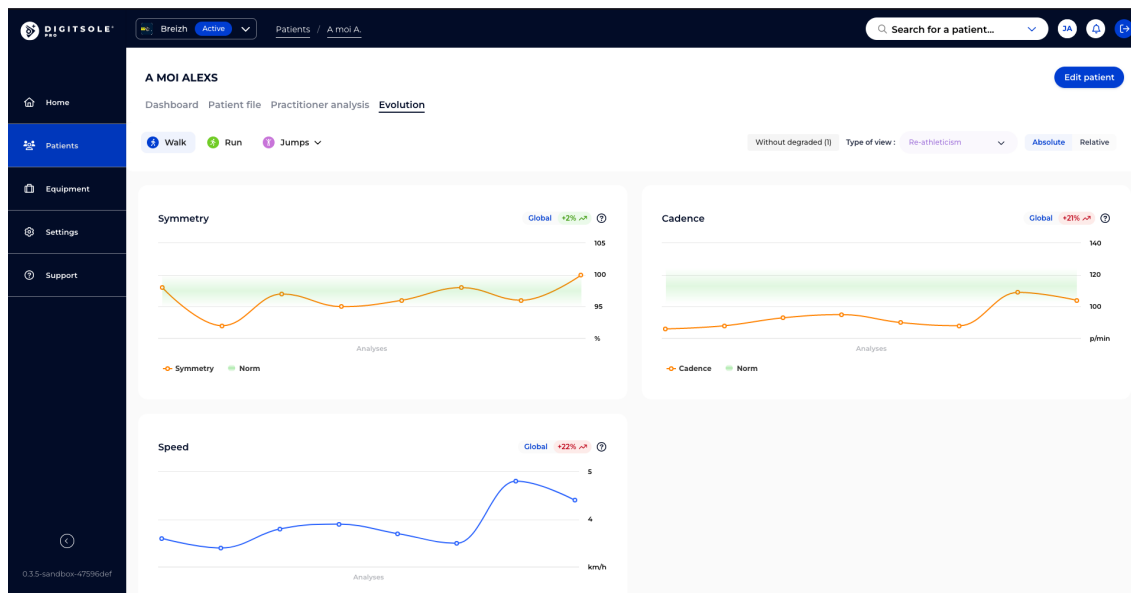


See the evolution of the parameters

Click on the Patients tab and then on the line of the desired patient.

You are now on the patient's file.

Click on evolution.



From the evolution tab, you will find the evolution of your patient's analysis results classified by type of analysis.

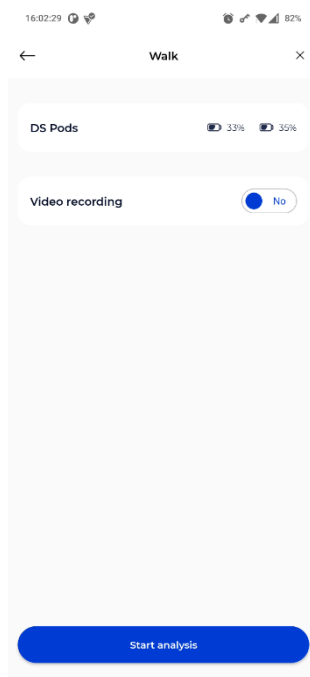
On the top right you can choose the type of view you want to have: Default, Neurological, Traumatological, Reathletization. You can also choose the default view or customize it with the parameters you wish to display.

Optional feature

Video Module

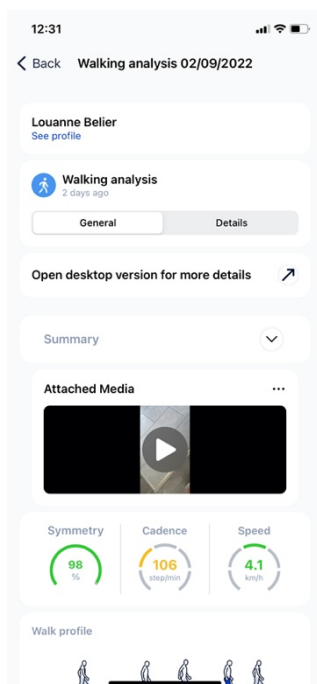
Recording the patient while they are doing their acquisition is now an optional feature. The video module is a purchasable module compatible with all different types of available analyses. You can then view it in the mobile application or from the web interface.

Mobile application



To record a patient during the acquisition, start an activity as usual. Once you have selected your pair of DSPods, you can choose to activate the video recording.

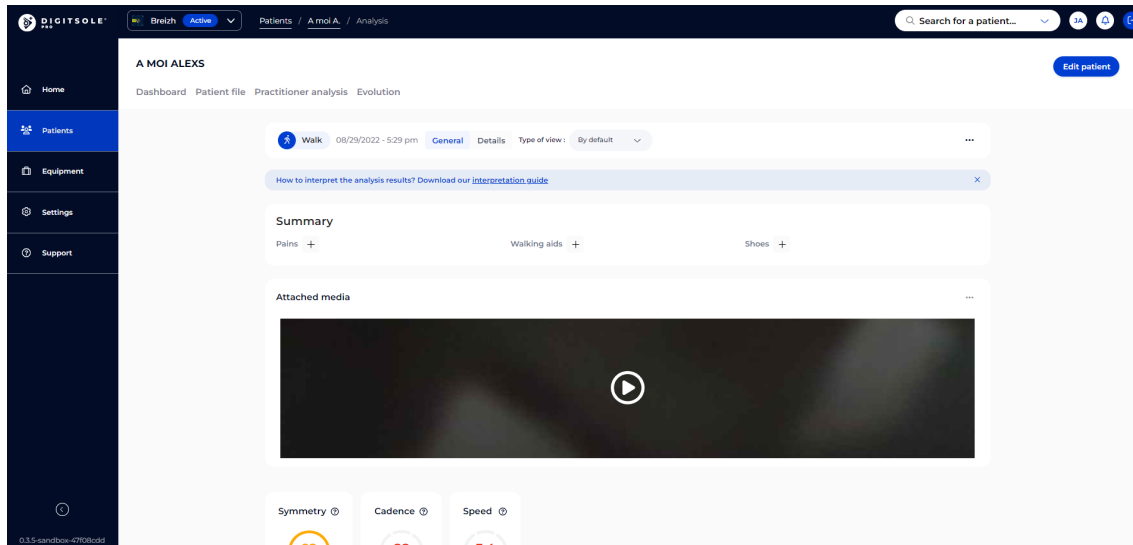
If you choose to activate the video, it will start at the beginning of the analysis and will be automatically recorded until you stop the activity.



At the end of the activity, you can find the video in the same place as the results of the analysis.

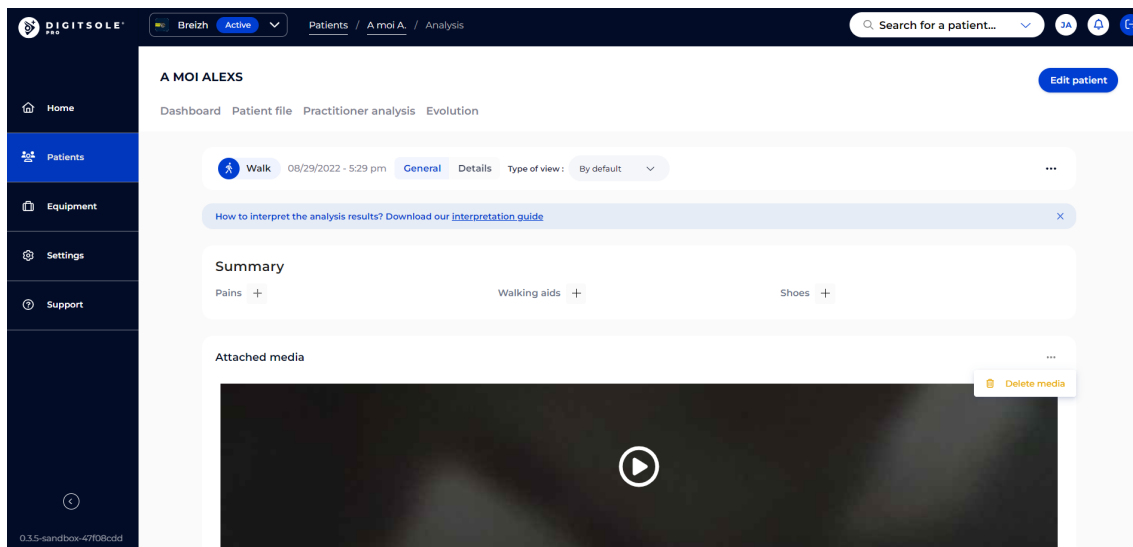
Web interface

If you use the Mobile application and chose to record the analysis of your patient, the video will be available in the results of the analysis.



From the web interface, you cannot add a video to your patients' analysis.

By clicking on the button ... at the top right of the video, you can delete the video associated with the analysis. **This action is irreversible.**



PodoSmart migration

If you are a Podosmart user and want to migrate your account, patients and analyses to a Digitsole Pro account follow the guide below.

[You have a Podosmart account but don't have a Digitsole Pro account](#)

If you don't have a Digitsole Pro account, please refer to the "Product installation" section of this document and follow the steps to create an account.

Then, cnfirm with your dealer that you have access to the "Podosmart Migration" option with your account.

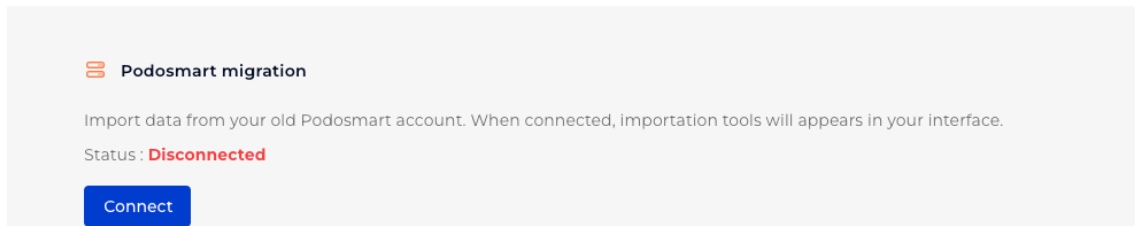
If you are set for the migration, you can proceed to the rest of the instruction.

[You have a Digitsole Pro account and can migrate your Podosmart data](#)

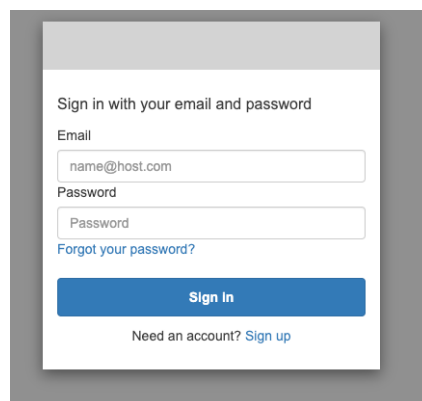
- On the Digitsole Pro web interface, go to the Settings menu, and go to the "Podosmart migration" tab
- You will see a "Status: Disconnected" indicator, click on the "connect" button below

Settings

Preferences Workspace Podosmart migration




- A new page will appear, enter your Podosmart credentials and click on "Sign in" to link your Podosmart account to your DS Pro account



- Once you entered your credentials, you will be redirected to the Digitsole Pro Settings page with a status changed to “Connected”

Settings

Preferences Workspace Podosmart migration

 **Podosmart migration**

Import data from your old Podosmart account. When connected, Importation tools will appear in your interface.


Status : **Connected**


ID
369a8be7-9fb2-44d3-949c-eac8e4153b2e











Date
a few seconds ago

IP
MASKED


- Then, go to the patients' menu and click on “Import from Podosmart”

 Import from Podosmart




 New patient

	Actions
	 
	 
	 
	 
	 

- Once the list of your Podosmart patients appears, you can click on “migrate” to import the patient onto your Digitsole Pro account, including the patient files, and the analyses. This process can take up to a few minutes, depending on the number of analyses needed to be imported.





Filter the list
(Last name, first name, shoe-size)

Last name 	First name	Birth date	Shoe size	Actions
3.	Elderly Fell down Rehab	March 20, 1931	36	
ACL	Surgery	June 2, 1994	44	




- When a patient is migrated, it will create a new patient in your DS Pro account that will be tagged as “Migrated from Podosmart”, and the migrated analyses will have the same tag as well

ELDERLY FELL DOWN REHAB 3. Migrated from Podosmart Edit patient


Dashboard Patient file Practitioner analysis Evolution

 **Walk** 

04/16/2021 - 1:43 PM

IMPORTANT INFORMATION:

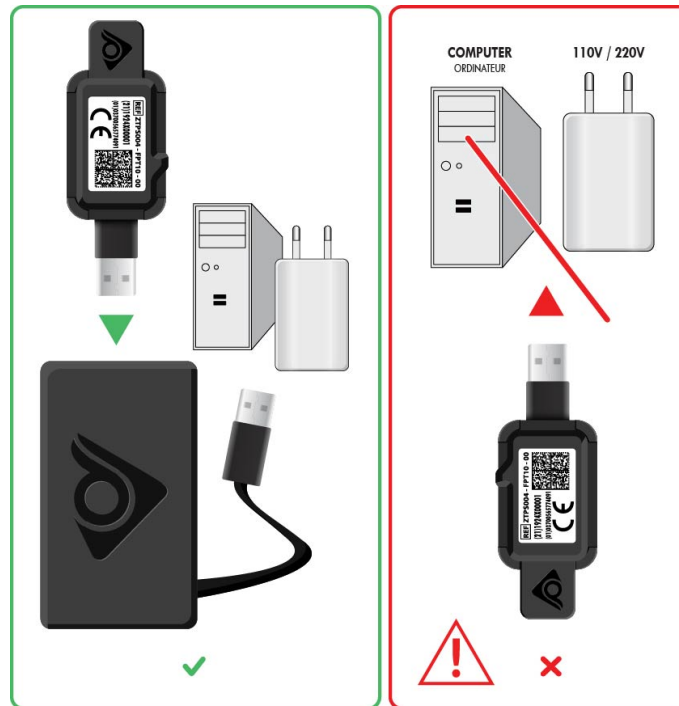
- Depending on the number of activities a patient has on your Podosmart account, the migration can take a few minutes, we would advise you to migrate a patient before the appointment with your patient
- Once a patient has been migrated, it will no longer be possible to migrate again, so please make sure that no new analyses are being made with Podosmart once a patient has been migrated to Digitsole Pro
- If you are making Digitsole Pro analyses with an imported patient, Podosmart analyses will be tagged as “migrated from Podosmart” and will also appear in the evolution with the new Digitsole Pro analyses done.
- Please keep in mind that Podosmart is an older system, it is possible that you see small differences in the data between Podosmat analyses and Digitsole Pro analyses
- The migrated analyses from Podosmart are marked with this logo: 

Maintenance

Charging DSPods

Remove the DSPods from the insoles and position them on either side of the USB charger plug. 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-group 1 class B) 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

Category: Group 1 Class B (according to CISPR 11) for homecare environment

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.

However, an electromagnetic disturbance could block an acquisition and this one would have to be redone following error feedback from the application at the end of the acquisition. We recommend keeping any electromagnetic emission device at more than 30cm from the DSPods.

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 length²: 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 Stance 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 support: This is the percentage of the gait cycle during which both limbs contact 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^{1,2}: 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 angle²: Angle between foot and ground at initial contact.
- o Stance: 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 float: For a running cycle, the percentage of time when no foot makes contact with the ground.
- o Pronation and supination angles²: 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.

Note: The accuracies of these measurements are only validated on limited analysis results namely cadence, speed and stride length in the context of the following pathological walks:


- Shuffling gait, Parkinsonian gait,
- Crouch gait,
- Diplegic gait, spastic gait,
- Equine gait,
- Steppage gait,
- Hemiplegic walk, circumduction walk.

¹: The clearance does not appear for activities performed with sizes 30 to 35 (US 12 to 4).

²: DS Pods placed on top of the foot:

- The placement of the pods on the top of the foot offers a more limited precision than the placement in the sole, notably linked to the less good repeatability of the positioning of the sensor and to the parasitic movement which can intervene on the top of the foot.
- For walking and running, the angles of pronation and supination, and of stepping or angle of attack are returned only in relative angle.
- The clearance does not appear.

Conditions of shipping and storage

























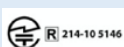










CAUTION

Follow the storage instructions to ensure the product has the longest potential shelf life.
To avoid damaging the batteries, remember to charge the DSPods 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	between 50-106Kpa
Recommended humidity (humidity level)	0 ~ 100% HR

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
	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		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 \(digitsole.com\)](https://www.digitsole.com/compliance), 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. In the interest of responsible environmental practices, please follow the regulations in your area before disposing of DSPods. 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 40 91 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: 03700565774633



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