



# Manuel d'utilisation & documentation Technique

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## Before you start:

Please read this manual carefully before using your device. It contains the information necessary for safe use of the device

## Precautions for use

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### WARNING:

Means in this manual that there is a danger of injury or accident to yourself or others.

### CAUTION:

Means in this manual that there is a possibility of property damage to this or any other appliance.

The PodoSmart® solution is not a diagnostic device. PodoSmart® may be used to assist the healthcare professional or any user to complete their clinical examination based on the data provided by the product. Diagnosis is the responsibility of the healthcare professional.

PodoSmart® is a device that can be used to analyse walking and running in patients aged 7 years or older with a shoe size  $\geq 30$  (EU size). The sole size should match the size of the patient's foot. It is preferable that patients wear clean socks with the PodoSmart® and DSPods insoles.

Tests should be performed with patients who are able to :

- Walk and run (depending on the type of test the health professional wishes to perform)
- Understand, follow and apply simple instructions related to mobility

### WARNING

- Do not open, pierce or knock
- Do not attempt to repair DSPods if they are damaged - contact the seller
- Do not throw into fire
- Do not use shoes with a metal plate in the bottom
- Do not bend or twist your DSPods
- Do not use your DSPods if they have deteriorated
- The sole or DSPod should not come into direct contact with a wound
- If the device gives different results from your observations please consult Digitsole support: [contact@digitsole.com](mailto:contact@digitsole.com)
- If the device gives inconsistent information or text please clear the browser cache and press F5 to refresh the page.

### RF Warning

The device has been evaluated to meet general RF exposure requirements. The device can be used in a portable exposure condition without restriction. This device complies with CE and FCC, and with Industry Canada RF radiation exposure limits established for the general population (uncontrolled exposure). This device must not be co-located or operated in conjunction with any other antenna or transmitter.

You can obtain a hard copy of this manual by contacting us at [contact@digitsole.com](mailto:contact@digitsole.com)

## Intended use

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PodoSmart® standard version is a solution for healthcare professionals to display objective reports based on spatio-temporal and kinematic parameters related to patient mobility. The mobility reports provide the healthcare professional with:

- A selection of biomechanical parameters with a visual comparison to literature standards,
- The digital gaitline related to pressure.
- Basic interpretations related to mobility parameters,
- The evolution of mobility parameters through different analyses.

The healthcare professional can select a standardized test to focus on the biomechanical parameters related to the patient's mobility.

Based on these reports, the health professional will perform a more in-depth medical analysis to establish a diagnosis.

## Contraindication

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There are no specific medical contraindications, however, the tests should be performed with patients who are able to

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

## Undesirable effects

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No known adverse effects to date

# Product description

The users of the Podosmart® device can be: health professionals, paramedical professions, sports coaches, caregivers, anyone able to perform quantified mobility analysis (walking and running).

Podosmart® can be used as part of a standard mobility analysis protocol (walking or running) during an appointment between a patient and their healthcare professional whether or not they have declared mobility problems as a result of various circumstances.

PodoSmart® can be used in adults and children over the age of 7 and/or with a shoe size  $\geq 30$  (EU size) and as part of:

- Mobility assessment
- Follow-up / monitoring at the office or at a distance
- Rehabilitation follow-up

Digitsole insoles and DSPods can be used on several patients.

The PodoSmart® device is intended to be used in an environment with healthcare professionals. However, it is possible that the solution could be used to monitor and record daily mobility data for patients (adults and children aged 7 years and over) in a variety of environments (hospital, outdoor, indoor home, or nursing home).

The Podosmart® solution can be used to record people's mobility data and send alerts, either to patients directly, to family caregivers, or to healthcare professionals or paramedics and can be used to export analyzed data from a group of patients in the form of dashboards with the product data compiled. This data can be exported and aggregated into a dashboard and shared with healthcare professionals, paramedics, sports coaches, caregivers or anyone who can analyze walking or running data related to mobility.

## Contents of the kit

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The Podosmart® kit includes a case with 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 which includes a charger plug and a charger dock
- 1 document explaining where to find the user manual and how to insert the DSPods into the Digitsole insoles
- 1 document explaining how to use the charger kit
- A shoulder strap



## Authorized accessories

Kit of one pair of DSPods	DSPS001-KIT10
Charger Kit	DSPS001-KIT00
- DSPods Charger Socket	DSPS001-CAB00
- DSPods Charger Dock	DSPS001-CAB10
Podosmart Case	DSPS001-PCK00
Podosmart Insole 30-32	DSPS001-INS30
Podosmart Insoles 33-35	DSPS001-INS33
Podosmart Insole 36-37	DSPS001-INS36
Podosmart Insole 38-39	DSPS001-INS38
Podosmart Insole 40-41	DSPS001-INS40
Podosmart Insole 42-43	DSPS001-INS42
Podosmart Insole 44-45	DSPS001-INS44
Podosmart Insole 46-47	DSPS001-INS46

## **Recommended computer features**

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The PodoSmart interface works on computers and tablets.

Interface: MacOS / IOS - Windows - Android.

Internet browser: Mozilla Firefox - Google Chrome - Microsoft Edge.

The PodoSmart application works on mobile phones.

OS: Android 6.0+ / iOS 13.0+.

Translation validation in Progress

# Installation of the product

## Installation of the product

To insert the DSPods into your insoles:

- Identify left and right DSPods



- Identify the left and right soles



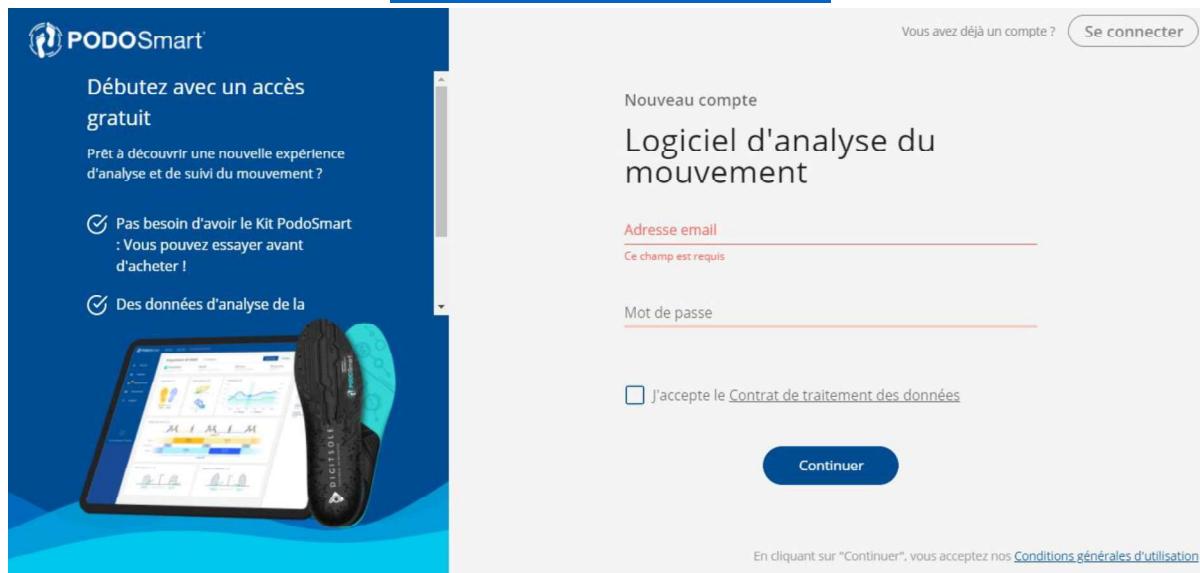
- Insert the left DSPod into the left shoe and the right DSPod into the right shoe. Attention for the acquisition to work, it is necessary to insert the DSPods in the right direction (see image below)



The acquisition can also be carried out with the use of DSPods positioned on the foot if their positioning avoids any unwanted slipping.

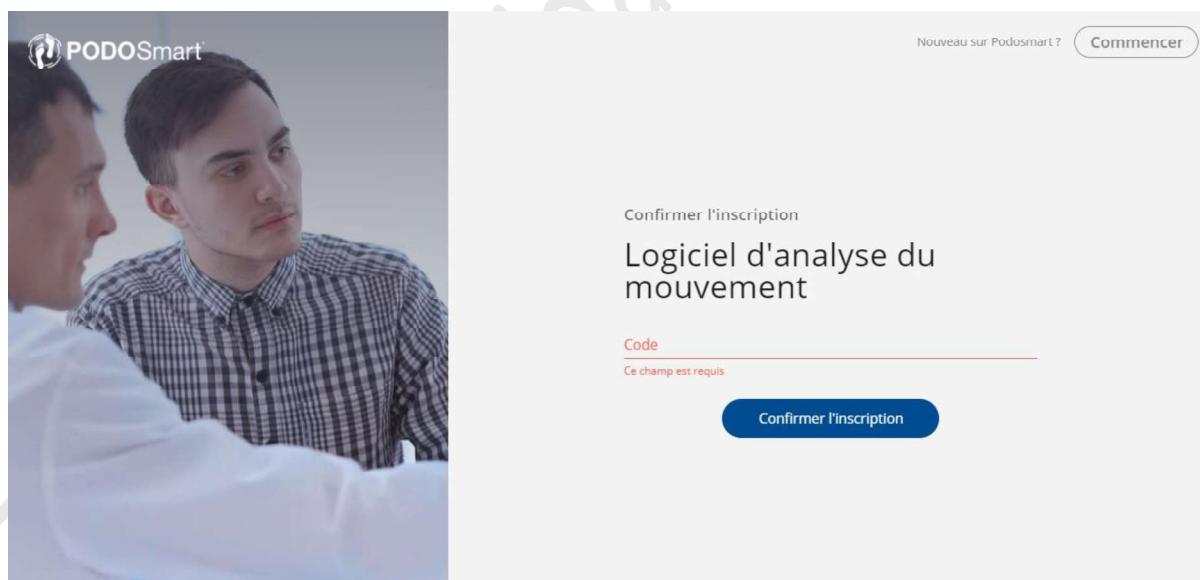
# Account creation

If you have not yet created a PodoSmart® account, please register via the following link:  
<https://podosmart.app/auth/sign-up>



Enter the email address and password you would like to use for your PodoSmart® account, accept the data processing agreement after reading it.

For security reasons, your password must contain at least eight characters, including at least one number, one lower case letter, one upper case letter and one special character.



You will then receive a code by email to confirm your registration. Please enter it in the field provided.



**PODO Smart**

Débutez avec un accès gratuit

Prêt à découvrir une nouvelle expérience d'analyse et de suivi du mouvement ?

Pas besoin d'avoir le Kit PodoSmart : Vous pouvez essayer avant d'acheter !

Des données d'analyse de la

Vous y êtes presque !

Logiciel d'analyse du mouvement

Prénom \*  
Ce champ est requis

Nom de famille \*

+1 Téléphone

Professions \*

S'abonner à la newsletter

Valider

Then enter your personal information to complete the creation of your account.

## Enabling two-factor authentication

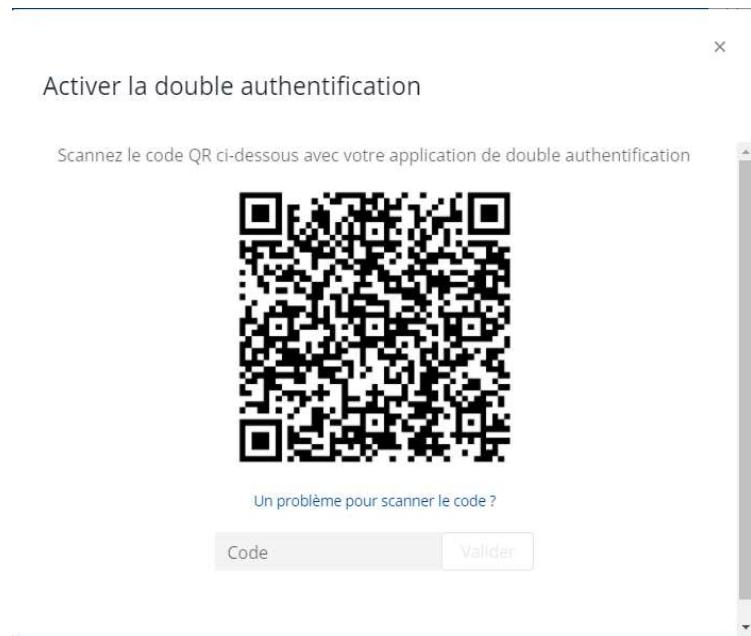
To add your practice, click on the **Your Account** tab in the top right-hand corner



Then click on **Enable dual authentication**.



Scan the QRCode with your dual authentication application (e.g. Google authenticator) and enter the code in the box provided.



## Adding a practice

To add your practice, click on the **Your Account** tab at the top right



Then click on **Add a practice**.



Enter your practice information and click **Save**

## Downloading the mobile app

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The PodoSmart® app is free and compatible with mobile devices that support iOS 13.0 and Android 6.0. To find out which devices are compatible with the apps, please check the firmware version on your phone.

To find the app, type PodoSmart® in the search bar:

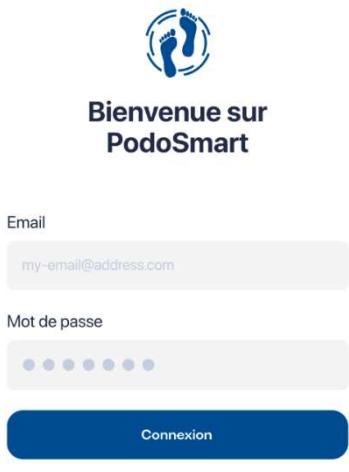
- From the App Store® for iOS devices
- From the Google Play™ store for Android devices

You will need to use Mozilla Firefox, Google Chrome, Safari and the latest version of Microsoft Edge. Please refer to the page <https://www.podosmart.tech/fr/customer-support> configuration paragraph for compatible browser versions. It is necessary to use a phone with Android 6.0+ or iOS 13.0+.

# Using the mobile application

## Connection to the application

9:41        



To access the application, make sure you have created your account on the web interface beforehand, these are the same credentials that will allow you to log into this application.

Enter the email address and password of your account to log in.

If you forget your password, go to the PodoSmart® interface to generate a new one.

## Management of DSPods

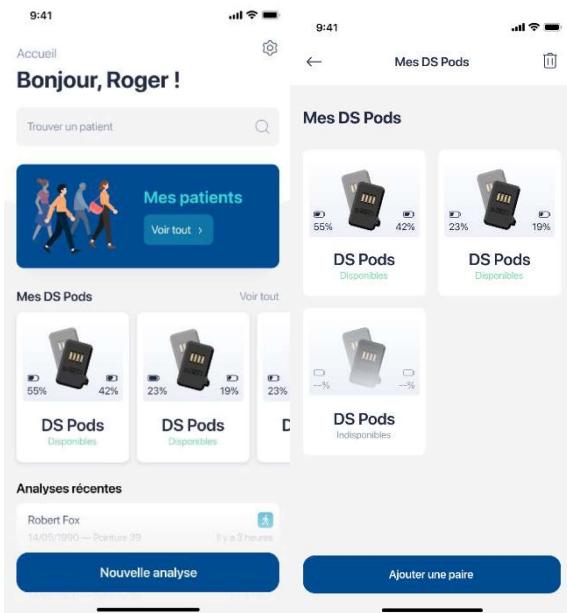
### Adding DSPods

To add DSPods to your account from the main application screen:

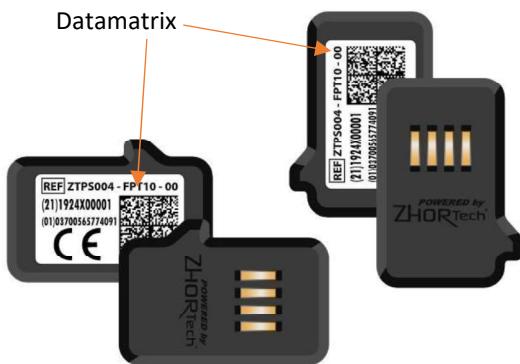


- If you do not have any DSPods yet, click on Add in the "DSPods" section

- If you already have DSPods, click on View All in the "My DSPods" section, you will be redirected to the list of your DSPods. Click on Add a pair.



A new page will open, scan the Data matrix code located on your pair of DSPods to add it to your account. Repeat the process if you have several pairs of DSPods.



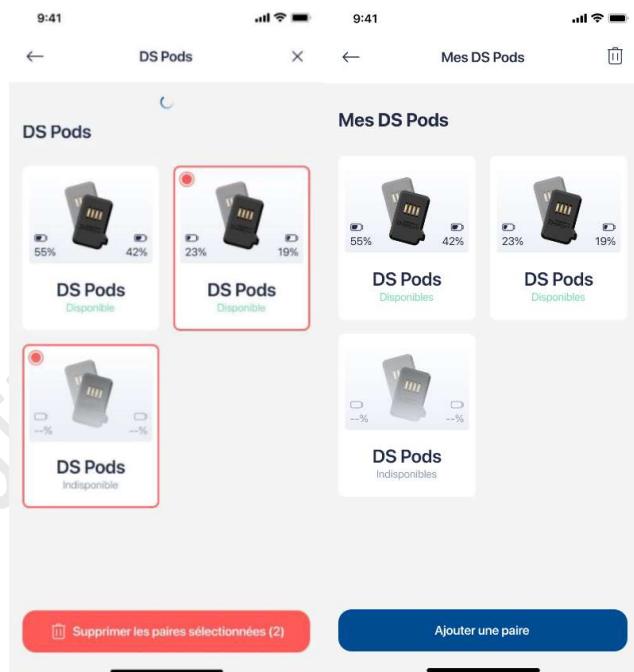
*Example of a Datamatrix code*

## Updating DSPods



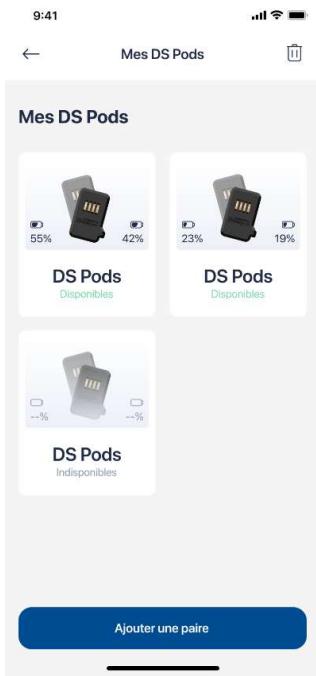
When you add a new pair of DSPods, a version check of your DSPods is performed. If they need to be updated, you will be asked to do so.

## Removing DSPods



From the main screen of the application, click on View All in the "My DSPods" section, you will then be redirected to the list of your DSPods. Click on the bin icon at the top right of the screen, select the pair(s) you wish to delete and then click on Delete Selected Pairs. Click on the cross icon at the top right of the screen to exit the delete mode.

## Checking battery levels



When the DSPods are charging, it is not possible to view the charge level of your DSPods while they are connected and charging.

Go to the DSPods page, to see the charge level of your DSPods. The battery levels of the left and right DSPods appear. You can refresh the battery levels by sliding the screen down.

### **In case of problems:**

If you cannot see the battery level even after refreshing the page, your DSPods may be "asleep" (to save power, they automatically turn off after about 20 minutes). To "wake them up", shake them firmly (please DO NOT hit them on a hard surface as this may damage the sensors). Then you can refresh the page by swiping down on your screen.

## **Patient management**

### Add a patient

To add a patient to your account from the main screen of the application:

- If you do not have a patient yet, click on **Add** in the "My patients" section



- If you already have patients, click on **View All** in the "My Patients" section



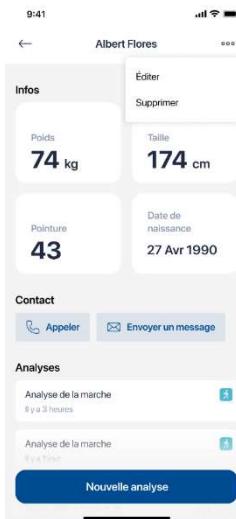
You will then be redirected to your patient list. Click on the + icon at the top right of the screen. A form will open, complete the patient form by filling in at least the Information tab, it contains the mandatory information to create a patient.

In the Pathology tab, you can add your patient's pathology(s) and in the Contact tab their address, email address and phone number.

Click on **Add**

The screenshot shows the 'Nouveau patient' form. At the top are buttons for 'Annuler', 'Nouveau patient', and 'Ajouter'. Below is a tab bar with 'Informations', 'Pathologie', and 'Contact'. The 'Informations' tab is selected. The form fields include: Nom (BOLT), Prénom (Usain), Date de naissance (dropdown menu 'Sélectionnez'), Taille (175 cm) and Masse (75 kg), Pointure (dropdown menu 'Sélectionnez'), and Genre (radio buttons for Femme and Homme, with Homme selected).

## Modify a patient

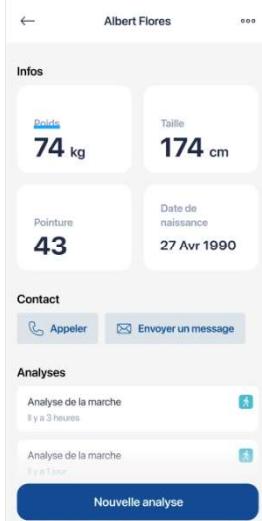


From the list of patients, click on the patient you wish to edit, the patient record will open. Click on the menu at the top right of the screen and select **Edit**. A form opens, fill in the additional information you wish to enter or modify the information already entered. Click on **Validate** to save your changes. The patient record will then be updated.

## Delete a patient

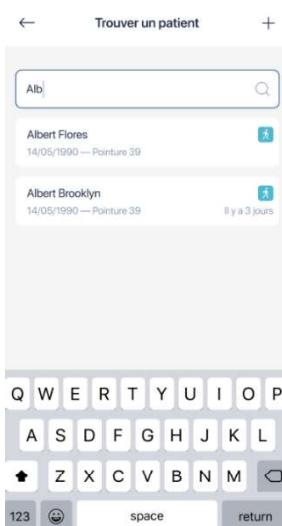
From the list of patients, click on the patient you wish to delete, the patient record will open. Click on the menu at the top right of the screen and select **Delete**, then confirm the deletion. You will then be redirected to the list of updated patients.

Note: This action is irreversible.



## Contact a patient

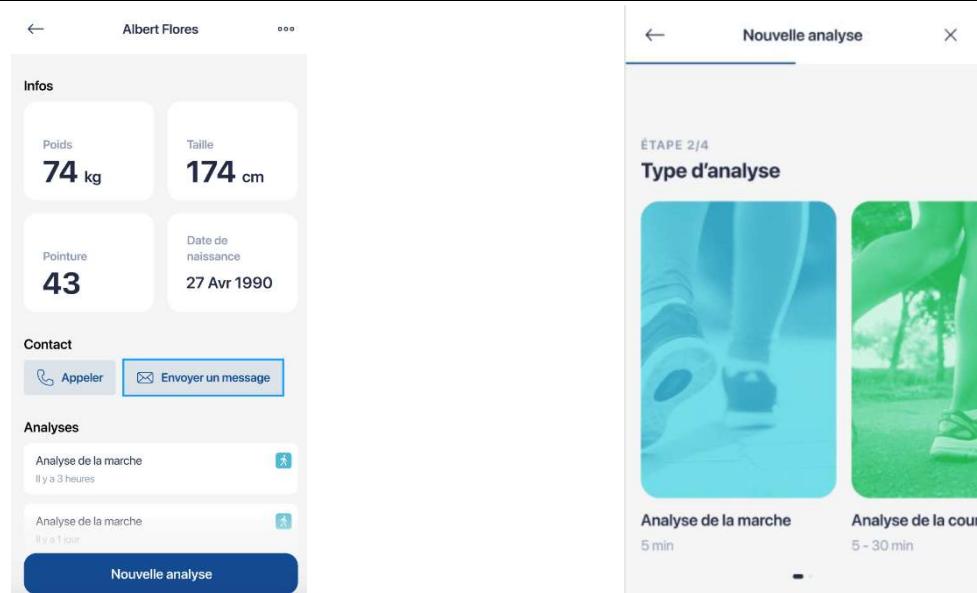
From the list of patients, click on the patient you wish to contact and the patient record will open. If your patient's phone number has been entered, you can click on the **Call** button. If your patient's email address has been entered, you can click on the **Send a message** button.



## Search for a patient

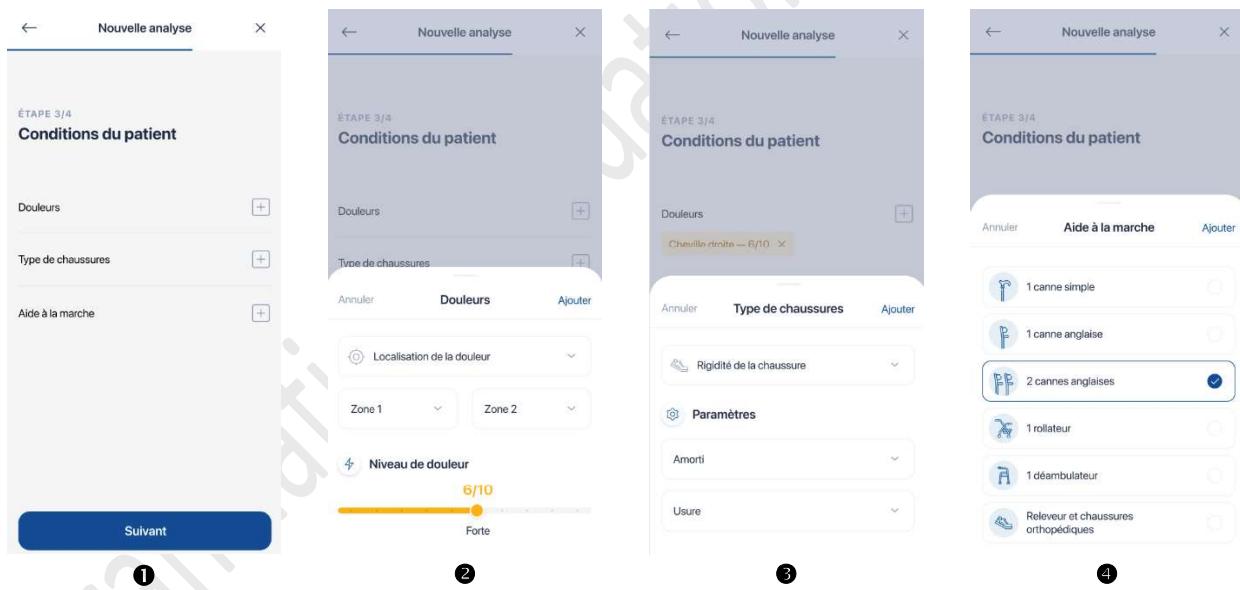
From the patient list, in the text field at the top of the screen, type the name and/or surname of the patient you are looking for.

# Starting and stopping an acquisition



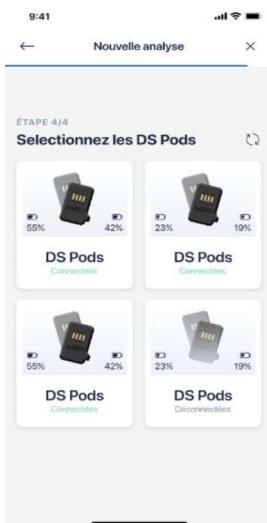
1 - Once your patient has been created and your DSPods added to your account, go to your patient's file. Click on the **New analysis** button.

2 - Then select the type of analysis you wish to perform.



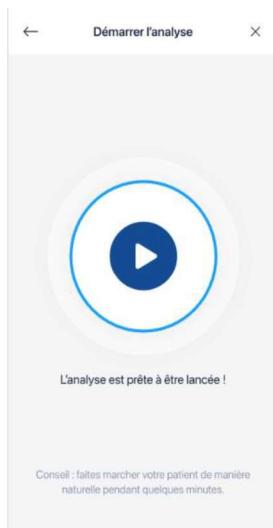
3 - You can then add additional information about your patient via the menu above. ①

- In the **Pain** tab ②, you can add the location of your patient's pain and its intensity.
- In the **Footwear Type** tab ③, you can add the stiffness and cushioning of your patient's shoes.
- In the **Walking Aid** tab ④, the possible walking aid used by your patient.

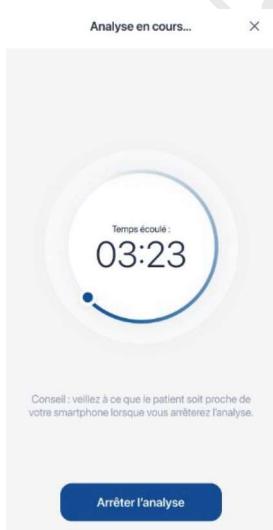


Then select the pair of DSPods with which you are going to perform the acquisition, the application will then initiate a connection to the DSPods and you will be redirected to the screen for starting the analysis.

**⚠ CAUTION:** If you have more than one pair of DSPods, be sure to select the DSPods that match those in your patient's insoles.



Once the DSPods are in the insoles and the insoles are inserted into the patient's shoes, click the Play button to start the acquisition. Your patient can now walk or run.

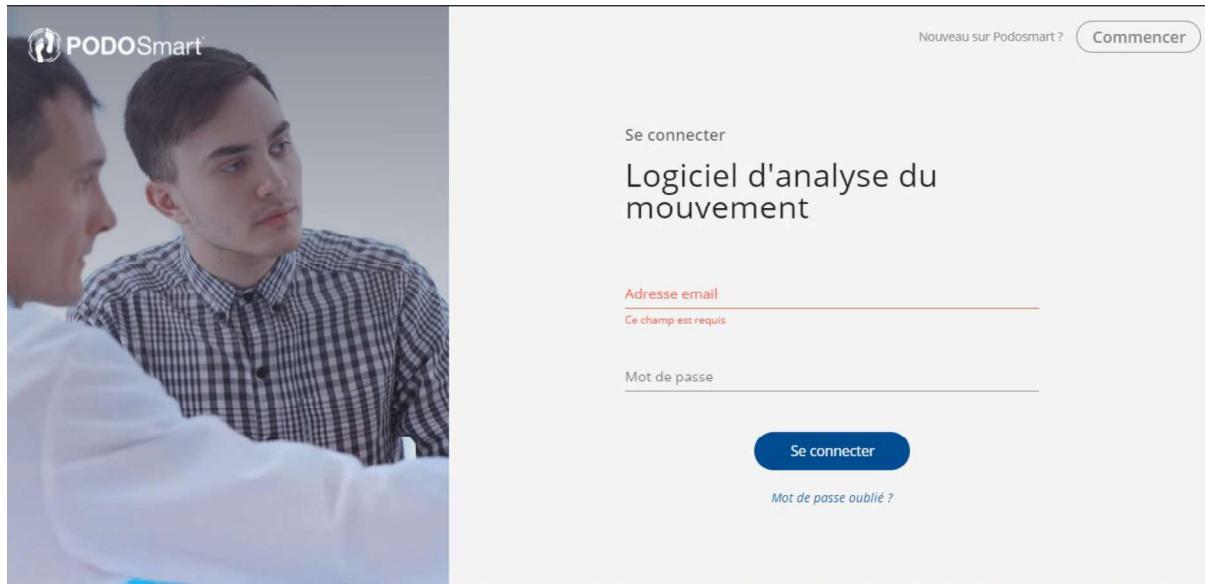


To stop the acquisition, click the Stop Analysis button. Once the acquisition is complete, the data is transferred directly to the PodoSmart® web interface.

# Using the web interface

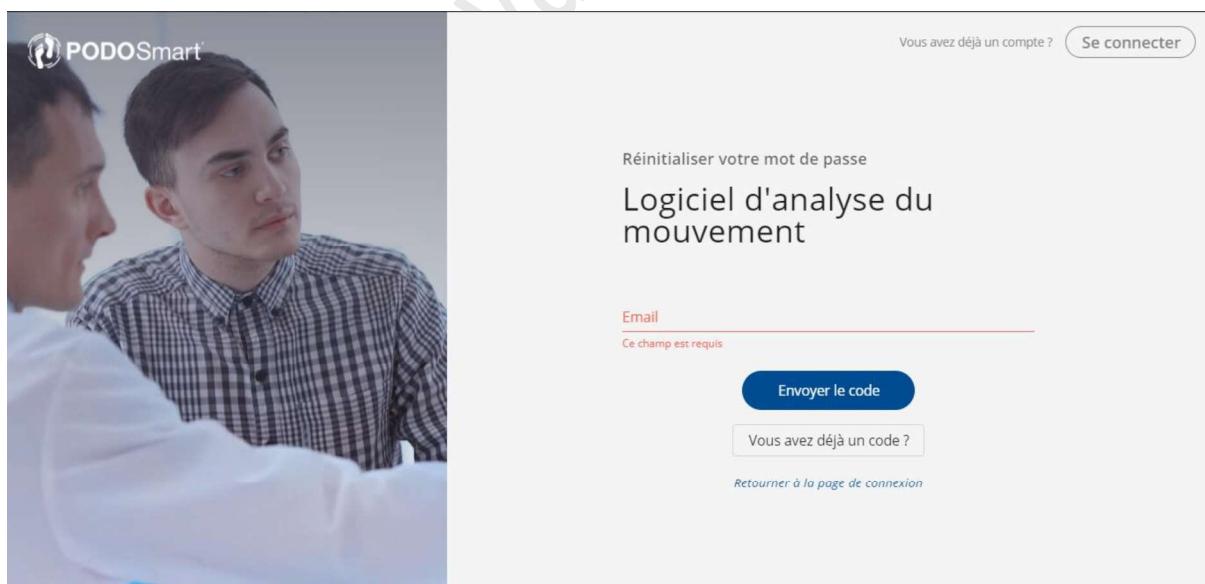
## Connection to the interface

To access the interface, make sure you have created your account on the web interface beforehand, these are the same credentials that will allow you to connect to this application. Log in via the following link: <https://podosmart.app/auth/sign-in>



Enter your account email address and password to log in.

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



Enter the code you received by email and your new password. Click on **Validate**, your password is now changed.



You will then be taken to the login page, enter your address and new password to log into PodoSmart®.

## Edit my account

### Health professional information management

To change your practitioner information, click on the **Your Account** tab in the top right corner



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

Profil

Prénom \*

Podo

Nom de famille \*

SMART

Professions \*

Coach sportif

1 / 6

## Practice management

### Add a new practice

To add a new practice, click on the **Your Account** tab at the top right



Then click on **Add a practice** to add a new practice.

Cabinets  Ajouter un cabinet

PodoSmart Place Stanislas, 54000, NANCY, FR	
PodoSmart Rue Héré, 54000, Nancy, FR	

### Delete a practice

To delete a practice, click on the **Your account** tab in the top right corner



Then click on the **Trash** icon to delete a practice.

Please note: To delete a practice, it is necessary to have several practices.

Cabinets  Ajouter un cabinet

PodoSmart Place Stanislas, 54000, NANCY, FR	
PodoSmart Rue Héré, 54000, Nancy, FR	

### Changing the practice

To change your practice, click on the **Your Account** tab at the top right



Then click on the checkbox next to the practice you wish to use to select it.

Please note: In order to change the practice, you need to have more than one practice.



**Cabinets**

**Ajouter un cabinet**

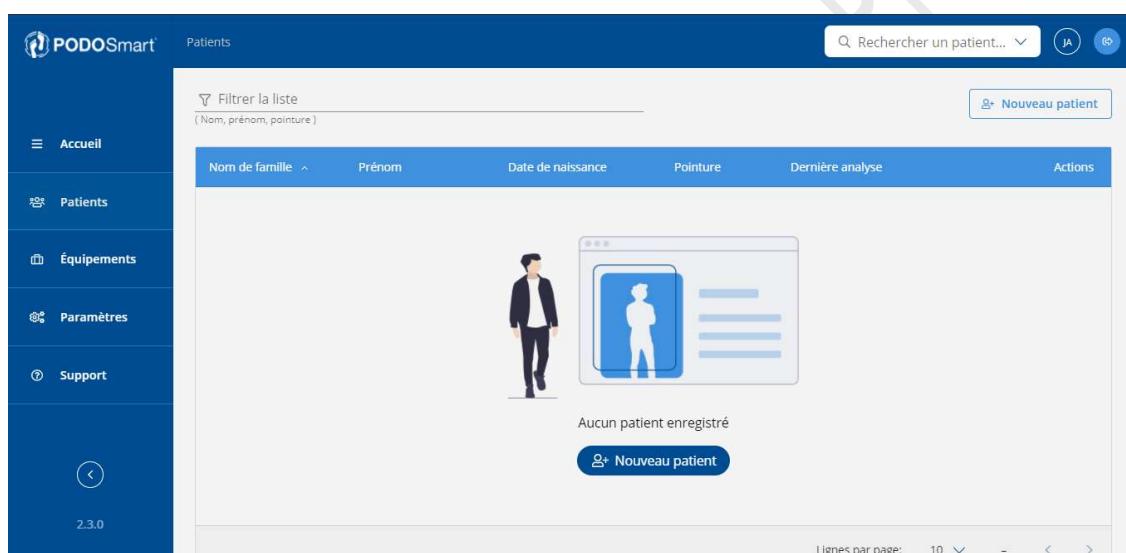
**PodoSmart**  
Place Stanislas, 54000, NANCY, FR

**PodoSmart**  
Rue Héré, 54000, Nancy, FR

### Patient management

Add a patient

Click on the **Patients** tab, then on **New Patient**



**PODOSmart** Patients

Rechercher un patient... JA

**Accueil**

**Patients**

**Équipements**

**Paramètres**

**Support**

2.3.0

Filtrer la liste  
(Nom, prénom, pointure)

Nouveau patient

Nom de famille	Prénom	Date de naissance	Pointure	Dernière analyse	Actions

Aucun patient enregistré

Nouveau patient

Lignes par page: 10 < >

A new window opens in which you can fill in your patient's information, address, how you wish to contact him/her, the reason for consultation and any history or pathology.

The mandatory fields are marked with \*, they are all located in the "Information" section. Once completed, click on **Save**

Nouveau patient

**Informations** ⚠️ ✓

Adresse (Facultatif)

Contact (Facultatif)

Motifs de la consultation - Antécédents (Facultatif)

Pathologie (Facultatif) + Ajouter

Sauvegarder Annuler

## Modify a patient

To edit a patient record, click on the **Patient** tab, then click on the desired patient.

To modify the personal information of the patient, his address and the means of contact, click on **Edit** patient.

To modify or add known pathology, reason for consultation and history, depending on the data already filled in, you will have the possibility to click on the **pen** logos to modify this information or on **Add** to add new information.

Paul PIERRE 20 mai 1995

Éditer le patient
...

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Pathologie

Tendinopathie du Tibial postérieur il y a 4 mois ✖

+ Ajouter

Genre	M
Taille	187cm
Pointure	43
Masse	85kg

Motifs de la consultation

+ Ajouter

Antécédents

+ Ajouter

## Delete a patient

To edit a patient record, click on the Patient tab, then click on the desired patient.

To modify the personal information of the patient, his address and the means of contact, click on ... in the top right-hand corner and then on **Delete the patient**.

Note: This action is irreversible.

Paul PIERRE 20 mai 1995

Pathologie  
Tendinopathie du Tibial postérieur il y a 4 mois + Ajouter

Genre M  
Pointure 43  
Taille 187cm  
Masse 85kg

Motifs de la consultation + Ajouter

Antécédents + Ajouter

## Search for a patient

On the Home page, in the top right-hand corner, in the **search for a patient** section, type the name and/or surname of the patient you are looking for and then click on their name to access their patient file.

jean

Jean  
Dupont

## Delete an acquisition

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

You are now on the patient's file.

On the right hand side is the section "Analysis".

Next to the acquisition you wish to delete, click on ... and choose **Delete Analysis**.

The screenshot shows the PODOSmart software interface. On the left, a sidebar with a dark blue background contains icons for Accueil, Patients, Équipements, Paramètres, and Support, along with a version number 2.3.0. The main area is titled "Dupont JEAN" and shows the date "22 avr. 1973". A "Pathologie" section asks "Quelle est la pathologie de Dupont ?" with a "Ajouter" button and a help icon. Below it, a "Motifs de la consultation" section shows "Genre M", "Pointure 43", "Taille 180cm", and "Masse 74kg". On the right, a sidebar titled "Analyses" lists several entries: "Analyse de la course" (27 avril 2021 - 11:15), "Analyse de la course" (27 avril 2021 - 11:12), "Analyse de la course" (27 avril 2021 - 11:11), "Analyse de la course" (27 avril 2021 - 11:09), "Analyse de la course" (27 avril 2021 - 09:54), "Analyse de la course" (23 avril 2021 - 16:37), and "Analyse de la marche" (22 avril 2021 - 15:58). Each entry has a "..." button next to it.

A window will open to validate your deletion request.

If you click on **Delete**, the acquisition will be permanently deleted.

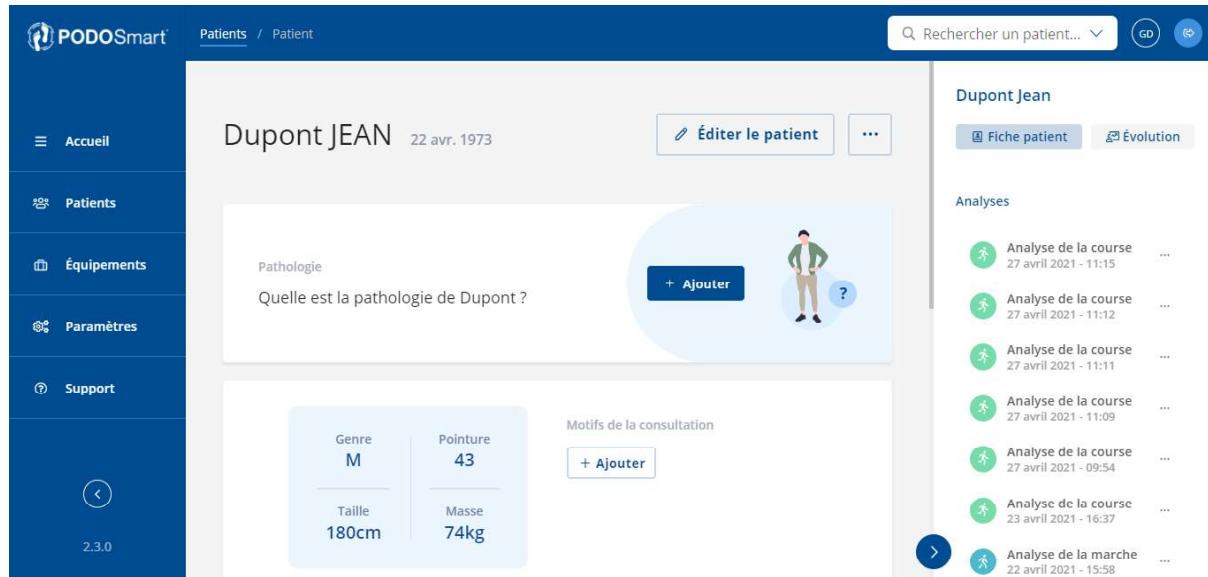


# Viewing the data

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

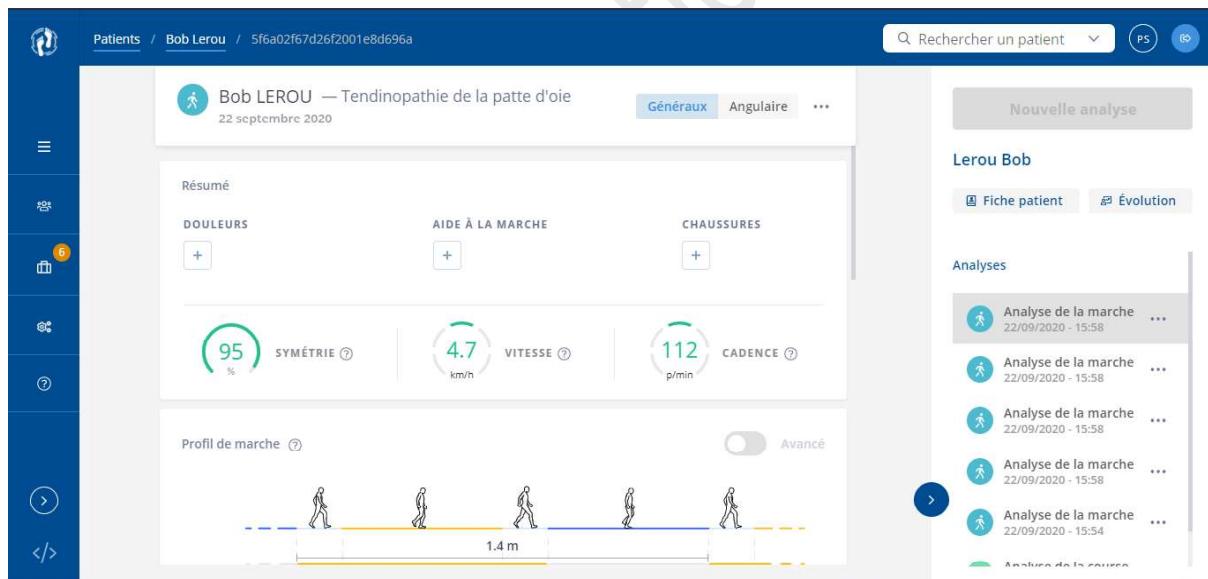
You are now on the patient's file.

On the right hand side is the section "Analyses". Click on the test you want to access.



The screenshot shows the PODOSmart software interface. On the left, a sidebar with icons for Accueil, Patients, Équipements, Paramètres, and Support. The Patients section is selected. The main area displays a patient profile for "Dupont JEAN" (22 avr. 1973). The profile includes fields for Pathologie (with an "Ajouter" button), Motifs de la consultation (with an "Ajouter" button), and physical parameters: Genre M, Pointure 43, Taille 180cm, and Masse 74kg. On the right, a sidebar shows the patient's name "Dupont Jean" and links to "Fiche patient" and "Évolution". Below these, a section titled "Analyses" lists several "Analyse de la course" entries with dates ranging from 27 avril 2021 to 23 avril 2021, each with a "..." button.

You are then taken to your patient's data analysis.



The screenshot shows the PODOSmart software interface for a patient named "Bob LEROU". The main area displays a summary for "Bob LEROU — Tendinopathie de la patte d'oie" (22 septembre 2020). It includes sections for "Résumé", "DOULEURS", "AIDE À LA MARCHE", and "CHAUSSURES". Key metrics shown are SYMÉTRIE (95%), VITESSE (4.7 km/h), and CADENCE (112 p/min). Below this is a "Profil de marche" diagram showing a sequence of walking frames. On the right, a sidebar shows the patient's name "Lerou Bob" and links to "Fiche patient" and "Évolution". Below these, a section titled "Analyses" lists several "Analyse de la marche" entries with dates from 22/09/2020 to 22/09/2020, each with a "..." button. A "Nouvelle analyse" button is also visible.

# Generate a report

## Exporting a report

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

You are now on the patient's file.

On the right hand side is the section "Analyses". Click on the test you want to access.

Once the analysis is open, click on the ... at the top right and then click on **Export PDF**.

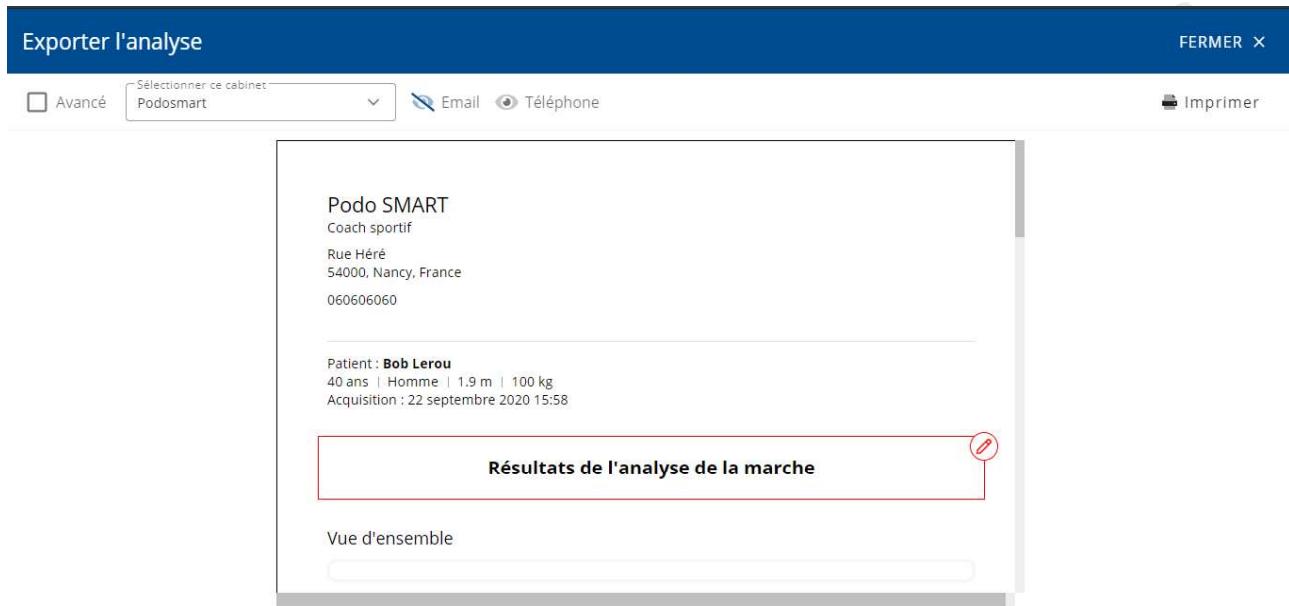
The analysis export page opens.

# Modify the health professional information displayed on the report

Once your analysis export is complete, you can:

- Generate a more advanced report by checking the "Advanced" box
- Select the desired practice if you have more than one registered practice
- Display or not your email and/or phone number by clicking on the Eye icons.

A crossed out eye means that the parameter will not be displayed on the report, an uncrossed out eye means that the parameter will be displayed on the report.



Podo SMART  
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Rue Héré  
54000, Nancy, France  
060606060

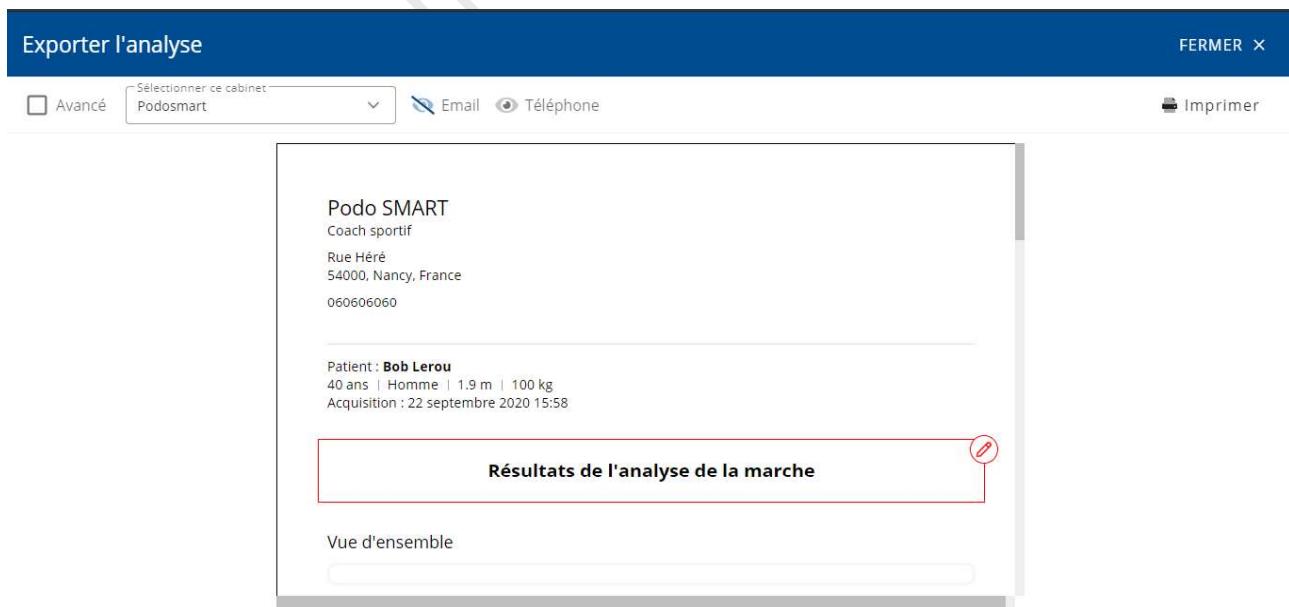
Patient : **Bob Lerou**  
40 ans | Homme | 1,9 m | 100 kg  
Acquisition : 22 septembre 2020 15:58

Résultats de l'analyse de la marche

Vue d'ensemble

## Printing a report

Once you have completed your analysis export, you can choose to print the report by clicking on **Print** at the top right of the screen.



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Rue Héré  
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060606060

Patient : **Bob Lerou**  
40 ans | Homme | 1,9 m | 100 kg  
Acquisition : 22 septembre 2020 15:58

Résultats de l'analyse de la marche

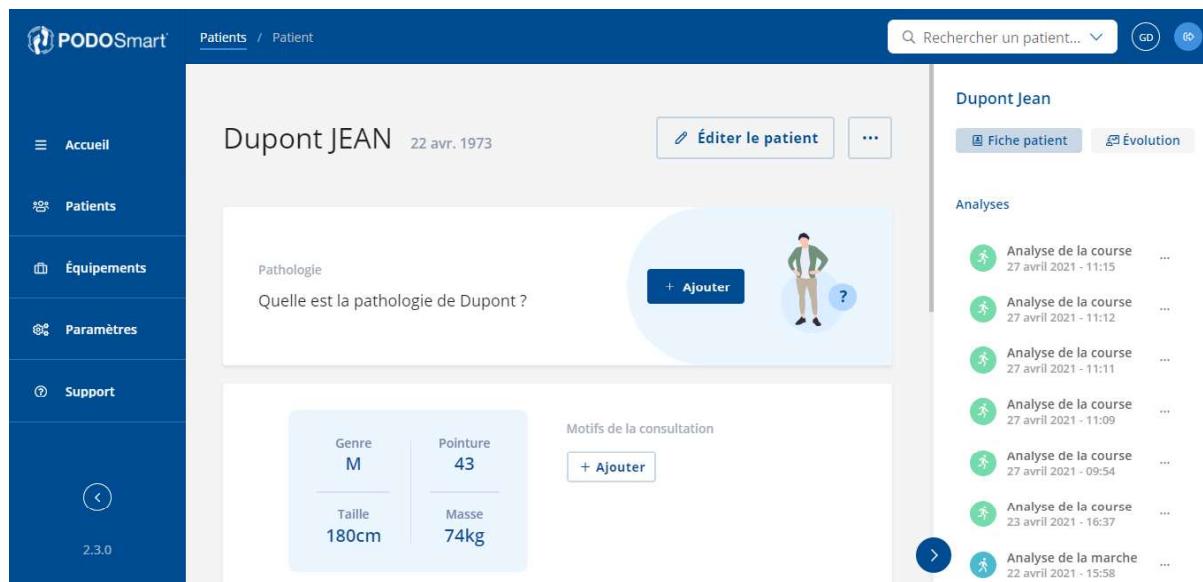
Vue d'ensemble

# Compare acquisitions

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

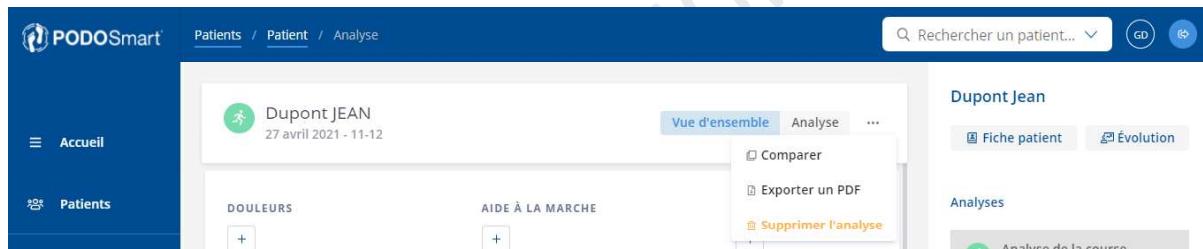
You are now on the patient's file.

On the right hand side is the "Analyses" section. Click on the test you wish to compare.



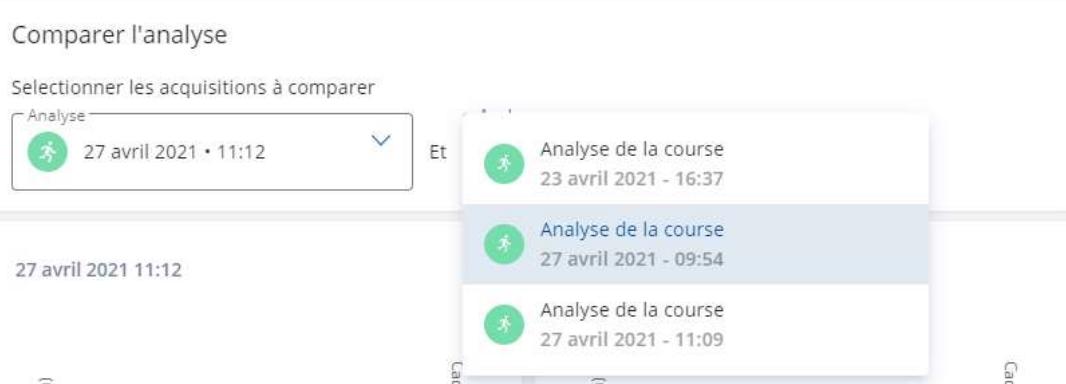
The screenshot shows the PODOSmart software interface. On the left, a sidebar menu includes 'Accueil', 'Patients' (which is selected and highlighted in blue), 'Équipements', 'Paramètres', and 'Support'. The version '2.3.0' is also visible. The main content area displays a patient profile for 'Dupont JEAN' (22 avr. 1973). The profile includes sections for 'Pathologie' (with a placeholder 'Quelle est la pathologie de Dupont ?' and an 'Ajouter' button), 'Motifs de la consultation' (with an 'Ajouter' button), and basic demographic information: 'Genre M', 'Pointure 43', 'Taille 180cm', and 'Masse 74kg'. On the right, a sidebar for 'Dupont Jean' shows 'Fiche patient' and 'Évolution' buttons. The 'Analyses' section lists several running and walking analyses with their dates and times: 'Analyse de la course 27 avril 2021 - 11:15', 'Analyse de la course 27 avril 2021 - 11:12', 'Analyse de la course 27 avril 2021 - 11:11', 'Analyse de la course 27 avril 2021 - 11:09', 'Analyse de la course 27 avril 2021 - 09:54', 'Analyse de la course 23 avril 2021 - 16:37', and 'Analyse de la marche 22 avril 2021 - 15:58'. Each entry has a three-dot menu icon to its right.

Once the analysis is open, click on the ... at the top right and then click on **Compare**.



The screenshot shows the PODOSmart software interface with the 'Analyses' section open for 'Dupont JEAN'. The analysis '27 avril 2021 - 11:12' is selected. The 'Comparer' button is highlighted in blue. The 'Analyses' sidebar on the right shows a single entry: 'Analyse de la course' (27 avril 2021 - 11:15). The 'Vue d'ensemble' and 'Analyse' buttons are also visible in the top right of the main content area.

Then select the analysis you wish to compare it with.

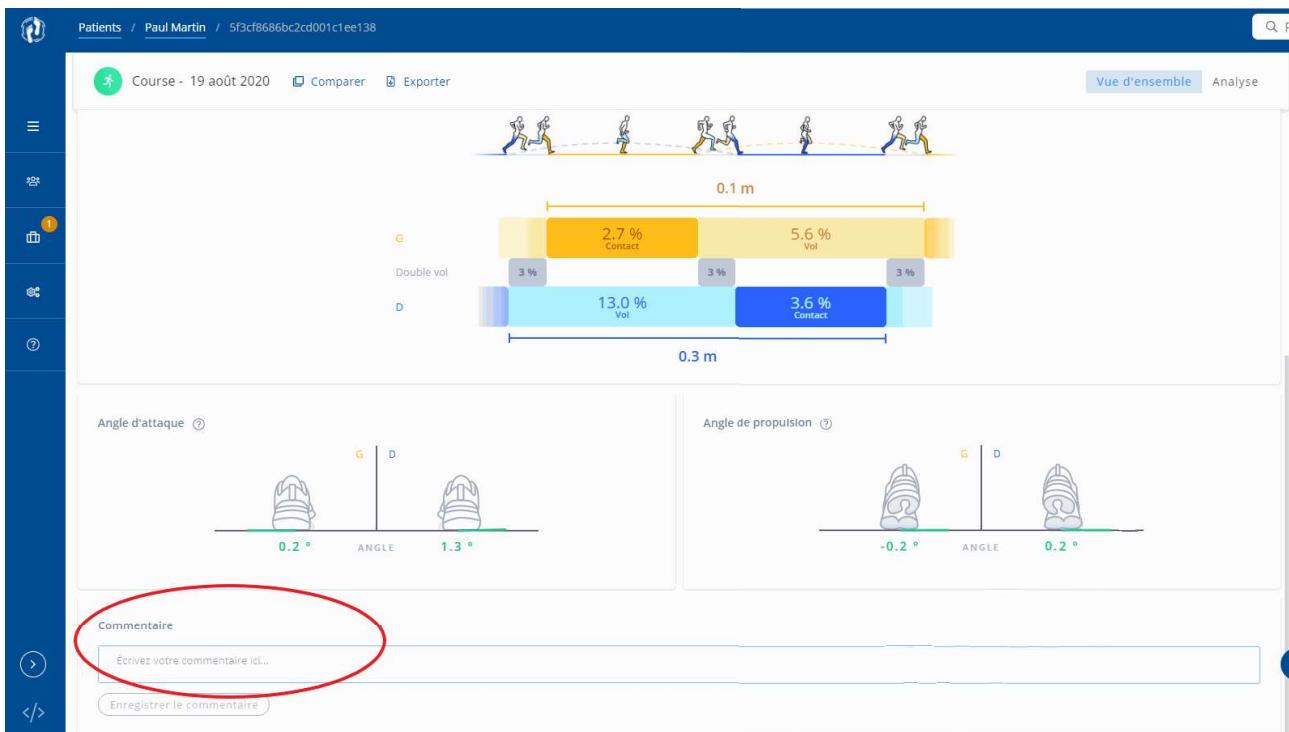


The screenshot shows the 'Comparer l'analyse' (Compare analysis) dialog box. It has two dropdown menus under 'Selectionner les acquisitions à comparer'. The first dropdown shows '27 avril 2021 • 11:12'. The second dropdown shows '23 avril 2021 - 11:15', '27 avril 2021 - 09:54', and '27 avril 2021 - 11:09'. The 'Et' (And) button is highlighted in blue. The 'Analyse' button is also visible in the top right of the dialog box.

# Adding comments

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

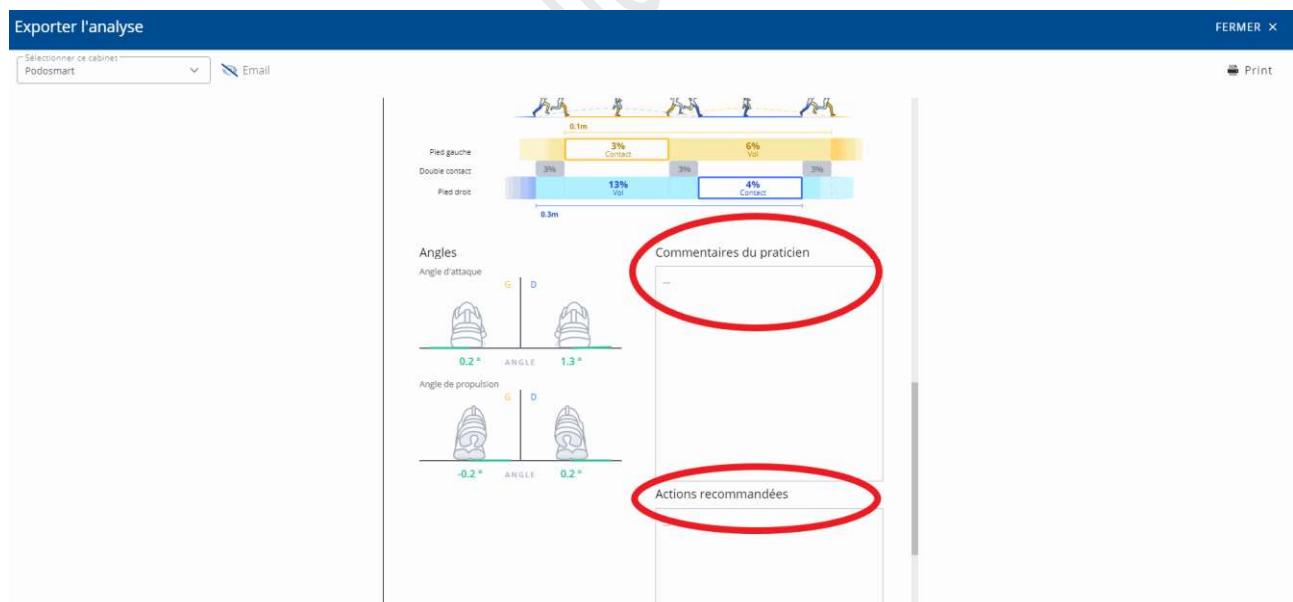
The comments entered in this section will be saved. You will be able to find them at any time with the results of this activity.



To leave a comment in the report, once it has been exported, you can leave a comment in the appropriate sections.

The comments entered here will not be kept in the interface.

However, you can keep them by printing the report, sending it by email to the patient and saving it as a PDF.

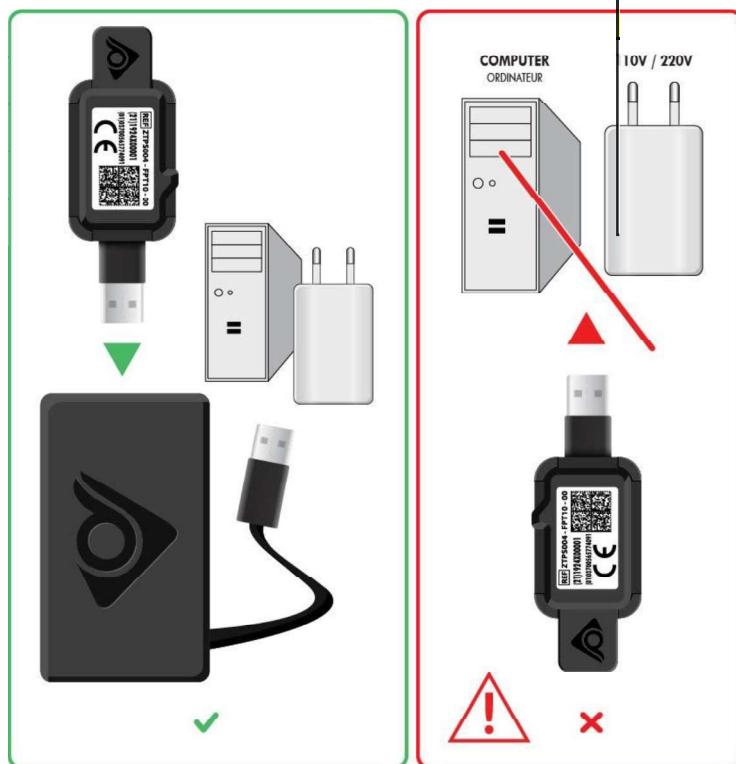


# Maintenance

## Charging the DSPods

Remove the DSPods from the soles and place them on either side of the USB plug charger. Once the two boxes are connected to the USB plug, insert them into the USB plug charger receptacle. To power the unit, plug the receptacle into a USB socket on your computer or into a power supply that meets the medical requirements as defined by IEC 60601-1:2005 (1MOOP) or EC62368 or IEC 60950.

Recharge time is approximately 2.5 hours.



### CAUTION

⚠ Remember to charge the DSPods before extended periods of non-use to avoid damage to the battery.  
It is recommended that the DSPods be charged at temperatures between 10°C (50°F) and 40 C (104°F) to maximize their life.

# Instructions for cleaning the device



**Caution:** Do not use the insole without a clean sock.

You can use disposable socks

- It is recommended that the following operations be carried out regularly and before the first use:
  - Clean with a disinfectant that meets the following characteristics:
  - Bactericide EN1276\*, EN13727, EN13697\*, EN14561 (including MRSA).
  - Tuberculocid on *Mycobacterium Terrae* EN14348\* and EN14563\*.
  - Fungicide EN14562\* (on *Aspergillus Fugimatus*).
  - Levuricid EN1650, EN13697\*, EN13624\*, EN14562\* on *Candida albicans*.
  - Virucidal EN14476 on HBV, HCV, Adenovirus, Coronavirus, Norovirus, RSV, H1N1, HSV-1, Polyomavirus\* and Rotavirus\*.

\*Except if very dirty

- We recommend the product STERICID S-3DM which meets your needs and can be obtained by contacting Digitsole: [contact@digitsole.com](mailto:contact@digitsole.com)
- Allow to air dry or wipe with a clean, dry, lint-free cloth before re-use.

## CAUTION



- Do not use corrosive products, oil, acetone or petroleum-based products to clean the device
- Do not put the device in the washing machine, tumble dryer, hand dryer or any other equipment.
- Do not immerse the device in water

# Technical data

## 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
- Total autonomy in standby mode (without use): 1750 h

## Charger

### CAUTION

⚠ The charging equipment must meet the requirements of IEC60601-1  
Input: 100-240V - 50/60Hz  
Output: 5.0V with an output current greater than 30mA

## Radio module

Frequency band: 2402-2480MHz

Max power: 0.29 mW

This equipment complies with the EMC Directive 2014/30 / EU and IEC 60601-1-2:2014 relating to the electromagnetic compatibility of medical equipment and/or medical electrical systems. These limits are designed to provide reasonable protection against interference in a residential installation.

However, due to the use of radio frequency transmission equipment and other sources of interference in healthcare and other environments, it is possible that high levels of interference from source proximity or power may interfere with the operation of this device.

# Operating environment



## CAUTION

Observe the environmental conditions for safe use of the device

Maximum body pressure	50 kg / cm <sup>2</sup> (or 500 n / cm <sup>2</sup> )
Maximum sole load	200 kg
Atmospheric pressure	Between 70-106Kpa
Operating relative humidity (humidity level)	10 ~ 95%
Recommended operating temperature of use	Between 0°C and 40°C (between 32°F and 140°F)

## EDZ

### 附注

工作环境温度60度不合适，要改为40度

# Product performance

Product lifetime	2 years
Warranty period	2 years
Storage life	1 year. The storage life can be increased by charging the DSPods every 6 months

## Detailed performance

### Walking parameters

- o Stride length: Distance covered by the foot during a walking cycle
- o Cadence: Number of steps taken per minute
- o Cycle time: Time between two successive contacts of the same foot
- o Contact time: The stance time is the duration of the part of the gait cycle during which the limb is in contact with the ground, calculated as the time between heel strike and toe-off for each foot during the stride cycle.
- o Time of flight: The time of flight is the duration of the part of the gait cycle during which the limb is not in contact with the ground, calculated as the time between foot lift and heel strike for each foot during the stride cycle.
- o Double contact: This is the percentage of the gait cycle where both limbs are in contact with the ground
- o Speed: Speed of linear movement of the body in the gait path
- o Pronation/supination angles: Average angle of inclination between the foot and the ground plane. Pronation is defined as a positive angle, supination as a negative angle.
- o Duration of loading phase: First sub-component of the stance phase. The loading phase begins when the heel touches the ground and cushions the impact. It ends when the toes touch the ground.
- o Duration of flat-foot phase: Second sub-component of the stance phase. The flatfoot phase begins during the flatfoot phase and ends when the heel takes off.
- o Propulsion phase duration: Third sub-component of the stance phase. Propulsion is the duration between the heel lift-off event and the toe lift-off.
- o Symmetry: Defined as the ratio of the right (resp. left) foot landing time to the sum of the right and left foot landing times.

### Running parameters

- o Stride length: Distance covered by the foot during a running cycle
- o Analysis time: Running time during the acquisition

- o Speed: Average speed of the linear movement of the body in the path of the run
- o Cadence: Number of steps taken per minute
- o Asymmetry: Defined as the ratio of the right (resp. left) foot strike time to the sum of the right and left foot strike times.
- o Type of attack: Defined as the part of the foot that makes contact with the ground at the start of the stride
- o Angle of attack: The angle between the foot and the ground at the moment of initial contact
- o Contact: Contact is the percentage of the duration of the part of the stroke cycle during which the limb is in contact with the ground, calculated as the interval between initial contact and toe-off for each foot during the stride cycle
- o Flight: Flight is the percentage of the duration of the part of the stroke cycle during which the limb is not in contact with the ground, calculated as the interval between toe-off and initial contact for each foot during the stride cycle
- o Double flight: Over a stroke cycle, the percentage of time that no foot is in contact with the ground
- o Pronation/supination angles: Angle of inclination between the foot and the ground plane. Pronation is defined as a positive angle, supination as a negative angle.
- o Impact force: Maximum vertical reaction force of the ground during the stance phase.
- o Evolution of parameters during the run: Allows comparison of two moments of the run

## Transport and storage conditions

### ATTENTION



Respect the storage conditions for an optimal life of the product

Remember to recharge the insoles before prolonged non-use to avoid damage to the batteries

Recommended battery charge level for storage	between 75% and 100%.
Storage and transport temperature	between -10 ° C and 60 ° C (between 14 ° F and 140 ° F)
Atmospheric pressure	0 ~ 100% RH
Recommended humidity (humidity level)	between 50-106Kpa

## Definitions of pictograms

Symbol	Description	Symbol	Description
	Device complies with the requirements of the European Directive 93/42/EC on medical devices.		End of life device, to be disposed of separately from household waste. See paragraph "End of life of the product".
	Power supply DC 5 V >30mA.		Device with RF transmitter, non-ionising radiation.
	Manufacturer		Date of manufacture
	Do not hit		Do not puncture
	Do not repair		Do not put in washing machine
	Do not immerse the sole		Do not bend
	Do not put in fire		Charger side to download data

Symbol	Description	Symbol	Description
IP54	IP54 Device protected against strong water jets		On the packaging, this symbol means "Relative humidity limit".
	On the packaging, this symbol means "Atmospheric pressure limit" during transport and storage.		On the packaging: this symbol means "Keep dry", as the package must be protected against moisture and water.
	On the packaging this symbol means "Temperature limit".		Refer to the user's manual before use.
	USA: Federal Communication Commission (FCC) statement		Type B applied part (this device is protected from leakage current and electric shocks)
	Prevent choking		Do not leave within reach of infants. May cause shocking.
	Product conforms to the type certification according to Japanese MPT No. 37 of 1981 (Technical Regulation Conformity Certification of Specified Radioequipment)		Contributes financially to a recycling organization in accordance with the European Directive 94/62/EU and complies with national laws.
	Indicates a potential hazard associated with the use of the device		Trade reference of the device.
	Normal use of the charger		Prohibited use of the charger

## Regulatory compliance

The risks associated with this medical device have been assessed in accordance with ISO 14971, including the overall residual risk.

Podosmart complies with the following directives and standards:

- Council Directive 93/42/EEC concerning medical devices, as amended by EU Directive 2007/47/EC.
- Directive 2014/53 / EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of Member States relating to the making available on the market of radio equipment (RED).
- Directive 2011/65 / EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances (ROHS) in electrical and electronic equipment.
- Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)
- EMC Directive 2014/30/EU
- 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. Part 1: General requirements for safety. Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-2:2015: Medical electrical equipment. Part 1: General requirements for safety. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

The Declaration of Conformity is available on request from [contact@digitsole.com](mailto:contact@digitsole.com)

#### FCC ID: 2AQ4H-ZT004

United States: Federal Communications Commission (FCC) Statement. This device complies with FCC Part 15 rules. Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference, and
- 2) this device must accept any interference received, including interference that may cause undesired operation.

"Changes or modifications not expressly approved by Digitsole could void the user's authority to operate the equipment"

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement.

## **End of life of the product**

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Electronic components and lithium-ion batteries are subject to recycling regulations that vary by country and region. In the interest of responsible environmental practices, please follow the regulations in your area before disposing of these insoles.

The device must therefore be taken back by your health care provider, distributor or manufacturer.

# Support and help

## Help - Troubleshooting

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Full information is available at:

<https://www.podosmart.tech/fr/customer-support>

## Contact

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

Contact us at:

+33 (0)3 83 36 72 72

[contact@digitsole.com](mailto:contact@digitsole.com)

If you experience an adverse event directly or indirectly related to the use of the device, please contact us at [Vigilance@digitsole.com](mailto:Vigilance@digitsole.com)

## CE Marking

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Date of CE marking: May 2021



REF DSPO01-FPT00

**UDI-DI** : 3700565774640



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France