

Feetsee™

Patient Instructions for Use (IFU)

Remote Monitoring for Feet



Part No. 01
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www.feetsee.us



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These Instructions For Use (IFU) are subject to periodic review, update and revision.

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- The device has been used according to the operating instructions in these IFU.
- All fittings, extensions, readjustments, changes or repairs have been carried out by **Diabetis JSC** authorized representative.

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Revision	Date	Description
1.0	July 2021	Initial Release
2.0	February 2025	Reflecting Pro and Plus Feetsee version updates

Support and Contact Information

If any technical issues arise concerning our device, please contact us directly.

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IFU can be downloaded from Feetsee website, or a hard copy can be requested via email.

Website: <https://www.feetsee.us/support>

Email: support@feetsee.us



Conventions Used in This IFU

 **CAUTION** Caution indications are used to indicate practices that are necessary for the effective use of the device. Caution indications also relate to conditions or practices that may damage the equipment or other property or that may potentially result in minor or moderate injury to the user.

 **WARNING** Warnings describe potential serious adverse reactions and safety hazards. They may also indicate conditions or practices that could result in serious injury.

 **Note** – Notes provide additional important information.

 **TIP** – A tip provides helpful information, such as a recommendation or a shortcut for doing something.

General Warnings and Cautions

 **CAUTION** Do not use the Feetsee device without reading this IFU.

 **CAUTION** Do not use the Feetsee device if it appears damaged or contaminated.

 **CAUTION** Only use the Feetsee device with clean, dry feet.

 **CAUTION** Do not place the device close to heating or cooling sources when in use. It is recommended to keep heaters, fans, heated floors, direct sunlight, and other heating or cooling objects at least 7 feet (2 meters) away from the Feetsee device when it is used.

 **CAUTION** The device is for indoor use only. Only use the device in room temperatures of 64.4 – 77 °F (18 – 25 °C).

 **CAUTION** Do not place other objects on the Feetsee device or accessory when using it.

 **CAUTION** Be careful not to scratch yourself on the edges of the thermal camera while plugging it into the mobile device.

 **WARNING** If you observe any changes in a Feetsee device's performance or any damage caused by shipping or use, do not start or continue use, Contact Diabetes JSC for further instructions. Do not open or modify this device or its accessories in an attempt to correct the malfunction. There are no user-serviceable parts inside.



About These Instructions for Use

These document For Use (IFU) are intended for a patient using Feetsee. Please read this entire manual before using Feetsee.

This document contains the following chapters:

- **Chapter 1, Introduction**, page 7, describes the Feetsee system, its indications for use, and how it works.
- **Chapter 2, Using Feetsee**, page 11, describes how to use Feetsee to examine your feet in the comfort of your own home.
- **Chapter 3, Care and Maintenance**, page 24, describes the care and maintenance of the Feetsee stand and thermal camera.
- **Chapter 4, Troubleshooting**, page 25, describes how to handle potential issues that may arise when using the Feetsee.
- **Chapter 5, Technical Specifications**, page 29, lists the technical specifications of the provided Feetsee thermal camera, as well as the mobile device on which to run the Feetsee application.
- **Chapter 6, Labels and Symbols**, page 31, lists the labels and safety symbols that are used on the Feetsee stand and thermal camera.

Terms and Abbreviations

Table 1 – Glossary

Term	Description
HCP	A Healthcare Professional
IFU	Instructions for Use
JSC	Joint Stock Company
OTP	One-time Password



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1

Introduction



This chapter describes the Feetsee system, its indications for use and how it works.

1.1 Introducing the Feetsee System

Feetsee is an innovative at-home medical device designed to support patients in the early detection and monitoring of foot health conditions. The Feetsee device collects thermal and optical images of the soles of the feet to provide information that may be suggestive of localized temperature asymmetry associated with inflammation, including early signs potentially related to diabetic foot complications.

Feetsee's proprietary system combines non-invasive, non-contact thermographic and optical imaging hardware with software algorithms. Images are captured during brief daily scans and transmitted securely to the Feetsee cloud platform, where they can be reviewed by a designated HCP.

The system enables remote foot monitoring while preserving clinical oversight, supporting proactive patient engagement, and timely intervention when temperature patterns may indicate localized inflammation.

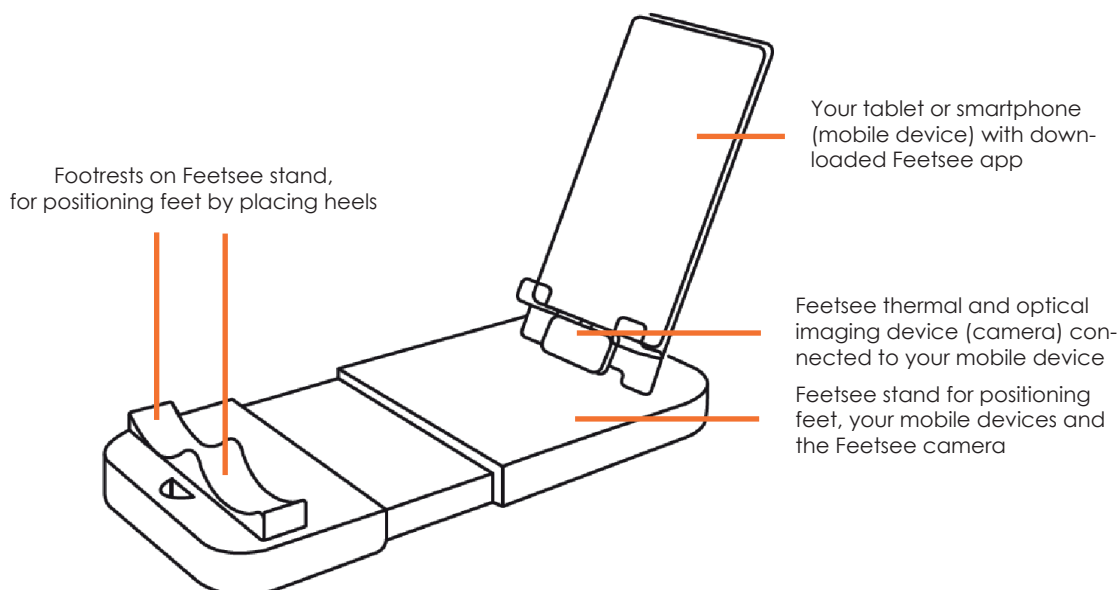


Figure 1 – The Feetsee Device



The Feetsee system includes:

- 1 thermal + optical imaging device (also called the *Feetsee camera*) with a charger.
- The Feetsee app runs on your own mobile device (smartphone or tablet). Specifications are provided on page 29.
- A Quick Start Guide.
- Patient instructions.
- 1 Feetsee Stand for positioning feet and a mobile device. The Feetsee stand is optional, as it is not required when a patient's feet are being checked with the assistance of another person.

For Patients

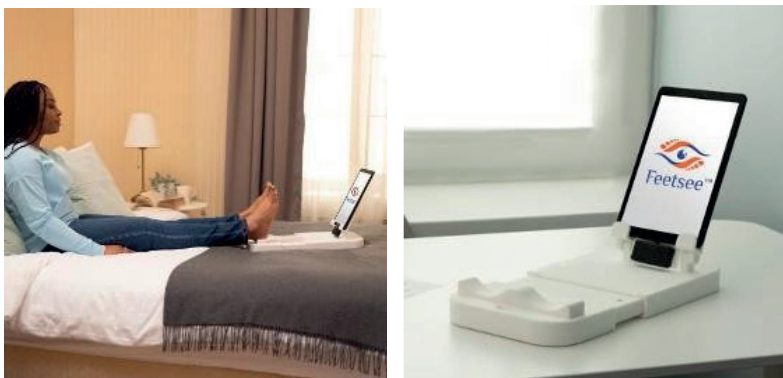


Figure 2 – Feetsee Patients

Patients can monitor their feet from the comfort of their own home.

► **A Feetsee patient can:**

- **Examine** their own feet for signs of findings that may be suggestive of early signs of inflammation, which can lead to diabetic foot ulcers.
- **Automatically notify their HCP (with a Pro version)** when findings are identified during an at-home examination.
- **Get an HCP's feedback (with a Pro version)** – Feetsee provides information that helps patients determine whether they should communicate with HCPs for evaluation, consultation, diagnosis, and/or treatment regarding potential inflammation observed on the patient's feet.

⚠ CAUTION Feetsee examination does not replace self-examination and periodic footcare and examination conducted by an HCP as part of the standard care.



How Does Feetsee Work?

Feetsee provides information that helps determine when a patient and their health-care professional (HCP) should communicate for further evaluation regarding potential localized temperature changes on the feet. The system uses an electronic temperature-sensing and optical imaging platform with remote data visualization to support early recognition of temperature asymmetry that may be associated with inflammation.

The Feetsee system captures both thermal and optical images of the feet. These images are processed by Feetsee's proprietary software algorithms, which identify the contours of each foot and calculate temperature distribution values across the soles. The resulting thermogram highlights localized temperature differences that may be suggestive of inflammation or areas of concern.

The system then provides an informational output indicating whether a significant localized increase in temperature has been observed, prompting the user and HCP to determine whether follow-up clinical evaluation is appropriate. The device does not diagnose, predict, or treat any medical condition.

1.2 Intended Use/Indications for Use

The Feetsee System is a non-invasive, non-contact thermographic and optical imaging device intended to be used by a patient, in conjunction with a healthcare professional (HCP) or caretaker, for periodic evaluation of the temperature distribution across the soles of the feet.

The system provides information that may be suggestive of localized temperature asymmetry associated with inflammation, enabling the patient and healthcare professional to determine whether further clinical evaluation is warranted.

The Feetsee System is intended as an adjunct to, not a replacement for, standard self-examination and periodic foot care and examination conducted by an HCP.

The device does not diagnose or predict any specific disease or condition, and is intended to be used under the direction of a healthcare professional.

The Feetsee System may be used in a clinical or home environment, by the patient or by an assisting person, as prescribed.



1.3 Contraindications

Feetsee should not be used if the soles of the feet have the following artifacts on them: tattoos, drawings, plasters/bandages, wound dressings, or jewelry.

General Cautions

 **CAUTION** The Feetsee System is intended to be used under the direction of a health-care professional as an adjunct to, and not in replacement of, self-examination and periodic footcare and examination conducted by an HCP and does not diagnose any specific disease state.

 **CAUTION** Feetsee recommendations are based on capturing a thermal and optical image of the feet and rely on Feetsee's proprietary algorithm, which identifies the contour of each foot and generates temperature data values indicative of inflammation. Patients' clinical history and other personal information, such as age, gender, other diseases, and medications, are not considered in the analysis.



2

Using Feetsee



This chapter describes how to use Feetsee to examine your feet in the comfort of your own home.

2.1 System Versions

The Feetsee System is available in 2 versions: the Plus version and the Pro version. In both versions, the Feetsee device automatically identifies the outline of each foot from the thermal and optical images, compares the temperature map of both feet, and informs the user that the algorithm results may be suggestive of signs of inflammation.

Plus and Pro version comparison table:

Feature	Feetsee Plus	Feetsee Pro
Access and Login	The Feetsee app login credentials are provided automatically upon completion of an online order.	The Feetsee app login credentials are issued by the prescribing healthcare professional.
At-Home Feet Monitoring	Supported.	Supported.
Patients Alerts for Signs of Inflammation	The app provides notifications to the user if signs of potential inflammation are detected.	The app provides notifications to the user if signs of potential inflammation are detected.
Clinician Alerts for Signs of Inflammation	Not available.	The system automatically sends alerts to the assigned clinician if signs of inflammation are detected.
Optical Foot Image Review	Images are available for review by the user only.	Images are available for review by both the user and the assigned clinician.

The Feetsee system provides information that helps HCPs and patients determine whether they should communicate for evaluation, consultation, and assessment regarding potential inflammation observed on the patient's feet.



Feature	Feetsee Plus	Feetsee Pro
Thermal Foot Image Review	Not available.	Thermal images are accessible for review by the assigned clinician only.
Feet Scan Reminders	The app provides periodic reminders to the user to perform foot scans.	The app provides periodic reminders to the user to perform foot scans.
Review scans done by clinician	Not available.	Scans performed by clinician will be accessible in scan history, next to scans done at home.

 **CAUTION** Alerts are informational only and do not constitute a clinical diagnosis.

 **CAUTION** Clinical judgment is required to interpret any Feetsee output.



2.2 Getting Started with Feetsee

Getting Started with the Feetsee Application

The Feetsee app runs on your own iOS or Android (not provided) mobile device (smartphone or tablet). You may refer to page 30 for the specifications of this mobile device.

Installation instructions are below; for uninstall instructions for the Feetsee app, refer to page 28.

► To get started with the Feetsee application

- 1 Download the Feetsee application to your iOS or Android mobile device (smartphone or tablet) and launch it, as follows:

On an iPhone:

- Find the App  Store
- Search for **Feetsee**  icon and launch it.
- Select **GET** or **INSTALL**. If Feetsee has already been installed on this device, then click the  icon.

After installation has completed, the **Feetsee icon**  appears on your device.

On an Android device:

- Find the **Play Store** 
- Search for **Feetsee**  icon and launch it.
- Select **INSTALL**.

After installation has completed, a **Feetsee icon**  appears in your app drawer.

If the download fails, contact Feetsee for assistance, as described on page 2.



- 2 Launch the Feetsee application on your mobile device. The following displays the first time you access Feetsee:

Enter your email and One-Time Password that you have received, and click "Confirm".

- 3 Review your account details, set up a password, and the user must also read through and agree with the Terms of Use and the Privacy Policy.

 **Note** – After successful login, selecting the **Menu** icon  and then the **My Account** option enables you to edit your own details (by clicking the **EDIT ACCOUNT** button), as well as to change your password.



- 4 Go through the onboarding steps, which are automatically displayed the first time you log in.

Getting Started with the Feetsee Device

► To get started with the Feetsee device:

- 1 No special facilities or special training of medical software for Feetsee users is required.
- 2 Use both hands to remove the feet stand from its box.
- 3 Remove the protective covering of the stand and place it on a flat surface where you will sit down for the feet examination. Extend the stand fully before use.

 **CAUTION** Do not use the feet stand if it appears damaged or contaminated.

- 4 Take out the thermal and optical imaging device (also called the *Feetsee camera*) and
 - Connect it to your mobile device (smartphone or tablet) on which the Feetsee app is installed. For instructions on setting up, connecting, and using the thermal camera, refer to this document.
 - Click on the camera's power button. The camera light blinks green and the camera is ready to use when the green light stays on.
 - Check the camera's battery indicator in the app and charge it if necessary. Use only the provided charger.

 **CAUTION** Be careful not to scratch yourself on the edges of the thermal camera while plugging it into the mobile device.



2.3 Performing Your Daily Examination

TIP – It is highly recommended to log into your account and to use Feetsee to examine your feet on a daily basis, as described below.

Before You Start

 **CAUTION** Always follow your HCP's instructions and continue to perform your usual daily foot self-examination, as instructed by your HCP, such as to examine your feet for signs of ulcers, cuts, tissue damage, redness, or open wounds.

 **CAUTION** Do not use Feetsee if there are any artifacts on your feet, such as piercings, rings, jewelry, socks, other feet images, band aids, large scars on the foot, missing toes, and so on.

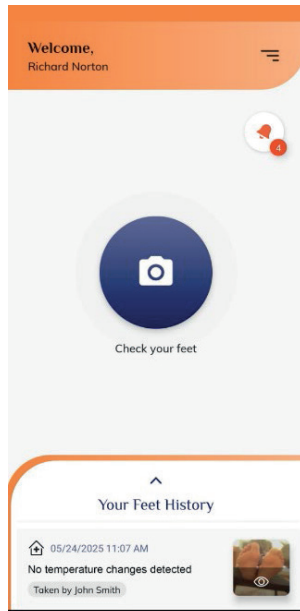
An Internet connection is necessary for using Feetsee. Open a WiFi or cellular data connection on your mobile device.

 **Note** – Internet connectivity of at least 10 Mbps per second is required in order to get examination results within approximately 10 seconds.

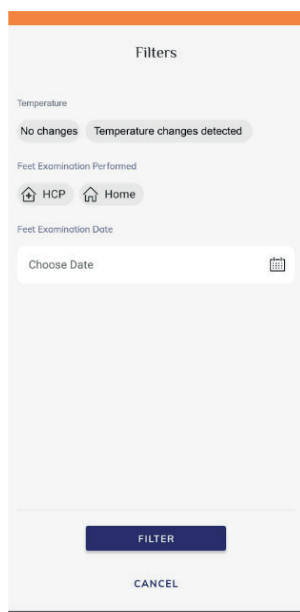
Before starting a Feetsee feet examination, rest without any type of footwear or socks for at least 15 minutes. Your feet should not touch or come close to any type of heating or cooling elements during this time.



Launch the Feetsee application  on your mobile device and log in.
The following screen displays



The **Your Feet History** area at the bottom of the screen lists your previous Feetsee examination sessions. These previous results can be filtered (as shown below) to only show the examinations you performed at **Home** (by clicking the **Home**  button), or examinations performed within a specific range of dates (**Choose Date**).





Starting the Examination

Feetsee provides the option to perform self-examination using the Feetsee stand. During self-examination, you can start the examination of your feet using either the timer or the voice command option, which gives you enough time to position your feet in front of the thermal camera before it actually examines your feet. Feetsee also enables you to perform the examination with the assistance of another person.

Make sure that there are no heating or cooling sources touching or near your feet.

► **To start the examination:**

- 1 Click the **Examine your feet**  button in the Feetsee app.
- 2 **Positioning the Feetsee Camera**
 - **With Assistance** – if someone is assisting you during the feet examination, then they should hold the thermal camera facing your feet so that they see the image of your feet on the screen of the mobile device, as shown below.

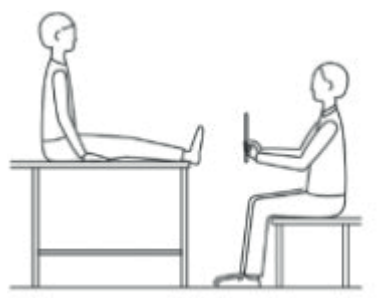


Figure 3 – Examination with the Help of Another Person

- **On Your Own – If you are performing the examination yourself**
 - Extend the Feetsee stand.
 - Position the feet stand (shown in Figure 1) on a flat floor or a bed, where you can sit comfortably.
 - Place both your heels on the footrests of the feet stand, as shown below



Figure 4 – Placing Your Heels on the Feetsee Stand



3 Position Your Feet in the Camera's View

Position your feet so that they are both at least 15 cm from the camera and are both inside the camera's view.

Both feet must be inside the feet outlines on the Feetsee app's screen, as shown below

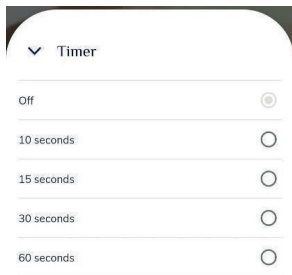


4 Capturing an Image – Use one of the following options to instruct Feetsee to capture an image:

- **Voice Control** – If voice control  is set to ON, you can activate the camera shutter by saying “Check Feet” loudly and clearly. If it is OFF, simply tap this button to turn it on.
– OR –
- **Automatic Timer** – If you are using a timer. A countdown is displayed on the screen. Simply wait until the examination is complete. By default, the timer is set to 15 seconds.
– OR –
- If you are being helped by another person, then that person can tap this button  on the mobile device.



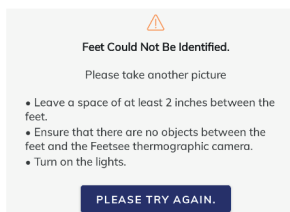
To change the timer setting, click the **Clock**  icon. The following menu displays from which you can select the number of seconds until the camera captures the image.



Notes –

- **Sound On/Off**  – Click this button to toggle on/off the camera shutter sound that is played when an image is acquired.
- **Battery Charge Indicator** 

- 5 Keep your feet still until the app indicates that the examination has been completed. If the scanning process was unsuccessful, you will be asked to retake the picture –



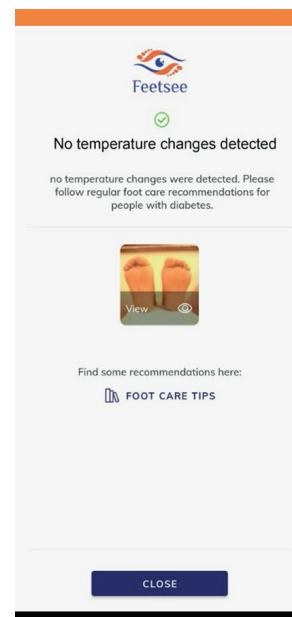


Completing the Examination

Keep your feet still until the app indicates that the examination has been completed. Follow the instructions that are displayed on the screen of your mobile device.

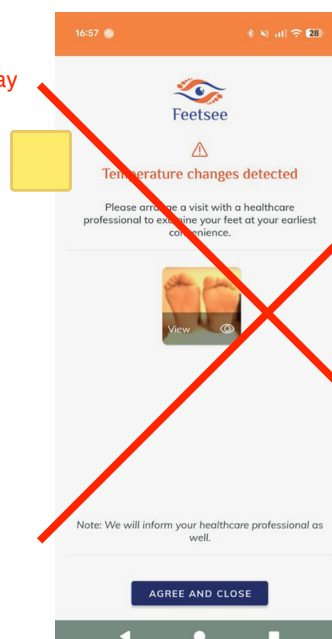
Good Results – No temperature changes detected (no need to repeat the scan)

The following message is displayed



Changes detected – If temperature changes are detected it is recommended to repeat the scan after resting for 15 minutes. In this case you should contact your HCP, if you're using Feetsee Pro, HCP will be informed when temperature changes are detected.

The following message is displayed



Pakeisti i Image003



Being Asked to Repeat the Examination

If the results of the first examination are inconclusive or temperature differences are detected, a message is displayed telling you to repeat the examination the next day.

After examination, press and hold the camera button for 2s to turn the camera off.

Cia pridėti image001, layout toks kaip aukščiau kad būtų

HCP's Review – Feetsee Pro version

After the examination has been completed, the app automatically transmits the data through the Internet connection to the HCP.

Feetsee does not provide healthcare advice.

Please follow your regular footcare routine advised by your HCP.

Your Feetsee HCP will periodically monitor and review the data acquired from your feet examination for signs of inflammation.

The HCP may contact you for further evaluation based on their observations.



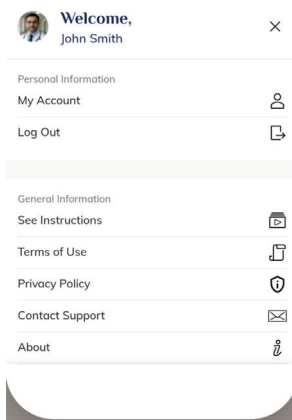
Getting Notifications

Feetsee sends notifications to your mobile device and emails, such as to notify you that an HCP has been assigned to monitor your feet examinations.

Feetsee Menu

The **Menu** icon in the top right of the screen provides a variety of options that are self-explanatory.

The **My Account** option provides the option to change your password.



HIPAA/CCPA

The Feetsee is HIPAA and CCPA compliant. For more information about your privacy rights and data, you can contact us via email: info@feetsee.us

Alternatively, you can contact us by  icon at the top right of the selecting the **Menu** screen and then the **Contact Support** option.

This **Contact Support** option can be used to request that all your personal data be erased immediately.



3



Care and Maintenance

This chapter describes the care and maintenance of the Feetsee stand and thermal camera.

 **WARNING** Before each use, wipe the surface of the Feetsee stand with an evaporating disinfectant cleaner, a clean cloth, or cleaning wipes in order to remove any dirt or residue. Do not use water. Do not use Acetone.

 **CAUTION** Do not clean the stand with soap, as it may leave a slippery residue.



4



Troubleshooting

This chapter describes how to handle potential issues that may arise when using the Feetsee.

Table 2 – Troubleshooting

#	Issue	Description
1	Connection issues on your mobile device (smartphone or tablet).	1 Turn on Mobile data. 2 Turn WiFi off and then on again. 3 Try connecting to different WiFi hotspots. 4 Reboot your WiFi router. 5 Restart your mobile device by turning it off and then back on. 6 Update the Feetsee app to the latest version. 7 Upgrade your Android/iOS operating system to the latest version available for your mobile device. If you still have connection issues, contact the network administrator.
2	The Feetsee app is not starting due to the required Feetsee app update	Follow the instructions shown in the app.
3	The Feetsee app is not updating.	1 Update the Feetsee app manually from the App Store or Google Play. 2 Make sure your mobile device is connected to Wi-Fi or that Mobile data is turned on. 3 Uninstall and reinstall the Feetsee app.
4	You are not receiving Feetsee emails.	1 Check your e-mail Junk folder. 2 Add the Feetsee email address to your email's Trusted senders list. The email is support@feetsee.us. 3 If you still are not receiving emails from Feetsee, email our support team at support@feetsee.us, so that we can check the server logs.
5	The feet examination image is not saved.	Try to log out and then log back into the Feetsee app.



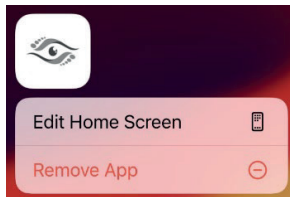
#	Issue	Description
6	The Feetsee app does not open, does not respond, or is crashing.	1. Restart your mobile device. 2. Update the Feetsee app. 3. Clear the app's cache and data, as described below. 4. Uninstall the Feetsee app.
7	The Feetsee app is not working properly, and various actions, such as relaunching the app do not help.	Clear the cache of Android devices or reinstall iOS devices, as follows: Android – Open Settings → click Storage to open its settings page → click Other Apps to see a list of your installed apps → find the Feetsee app and click its listing → click the Clear cache button. iOS – Open Settings → select General → iPhone Storage → select the Feetsee app → click Delete App and afterwards reinstall the Feetsee app.
8	The Feetsee app's General information pages (Privacy Policy, Terms of Use, Instructions, Feet Care Tips) do not load.	1. Try to log out and then log back into the application. 2. Turn Wi-Fi off and then on again. 3. Turn Mobile data on.
9	The device does not permit the use of Voice recognition.	Android – Open Settings → select Apps → select the Feetsee app → click Permissions → switch the Microphone toggle button on and try to examine your feet using Voice recognition again. iOS – Open Settings → select the Feetsee app → switch the Microphone toggle button on and try to examine your feet using Voice recognition again.
10	Bad image quality because: 1. feet are not placed correctly; 2. feet are moving; 3. feet are not bare or are unclean; 4. unclean camera lens; 5. substandard camera.	Read the user training instructions provided in this document. Make sure the camera lenses are cleaned at least once a month. Feetsee is provided with a suitable camera; do not use a different one.
11	The app does not recognize the camera.	Ensure that your mobile device case is removed and that the connection is not obstructed. Verify that your camera meets the required specifications outlined in Section 5. Check if the camera is charged. Use only the provided charger.



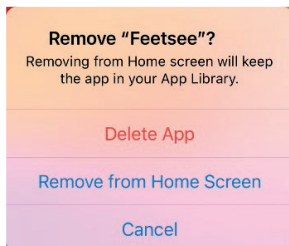
To remove the Feetsee app from your device, complete the following steps:

- **On an iPhone:**

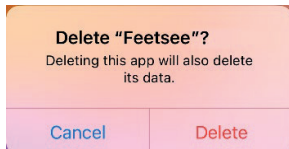
- Locate the Feetsee app in the app drawer, press and hold the Feetsee  icon.
- Select "Remove App".



- Select "Delete App".



- Confirm the selection by clicking "Delete".

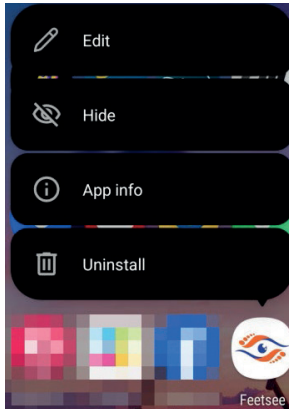


- The Feetsee app has been removed.

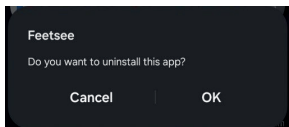


- **On an Android device –**

- Locate the Feetsee app in the app drawer, press and hold on the Feetsee  icon.
- Select “Uninstall”.



- Select “OK”.



- Feetsee app is removed.



5



Technical Specifications

This chapter lists the technical specifications of the provided Feetsee thermal camera, as well as the mobile device on which to run the Feetsee app.

5.1 Thermal Camera Specifications

The following are the specifications of the provided thermal camera to be used with the Feetsee system. You may refer to the IFU (this document) for more information.

Table 3 – Thermal Camera Specifications

Operating range	0 to 45°C (32 to 113 °F)
Storage and transport	-20 to 45 °C (-4 to 113 °F)
Temperature accuracy	± 0.5 °C (± 1 °F)
Resolution	0.1 °C (0.2 °F)
Normal image acquisition time	5 seconds
Device dimensions	2.59 x 2.04 x 0.7 inches
Thermal and optical device weight	0.105 lbs (0.048 kg)
Service life	2 years of normal, daily use
Battery	Rechargeable lithium-ion battery, 3.7 V, 300 mAh
Battery charger	Any CE marked wall charger with 5 V/0.5A output and USB type-C connector, without any fast-charging protocols
Product certifications	EN/IEC 60601-1 Ed.3.1 EN/IEC 60601-1-11:15 EN/IEC 60601-1-6:10+A1:13 IEC 60601-1-2 Ed 4
Patents	US and Foreign Patents Approved and Pending



5.2 Mobile Device Specifications

The Feetsee application can be downloaded and run on an iOS or Android mobile device (smartphone or tablet) that has the following specifications –

Table 4 – Mobile Device Specifications

Mobile application shall allow deployment on Android version 16.0 and up
Mobile application shall allow deployment on IOS version 18.0 and up



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Labels and Symbols

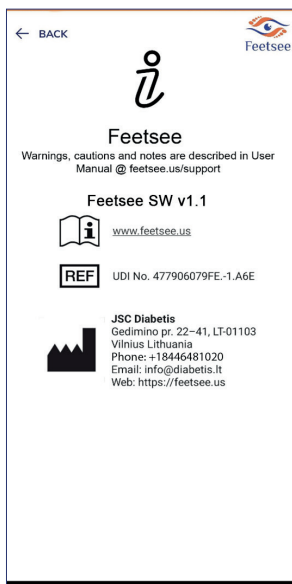
This chapter lists the Labels and safety symbols that are used on the Feetsee stand and thermal camera.

Table 5 – Feetsee Labels and Symbols

	Do not use the product if the packaging is damaged.
	See the instructions of use and Terms of @ feetsee.us.
IPXX	This product is rated IP42. It is protected against inserted fingers and dripping water.
REF	04779060790102
	See the back of the IFU
	Humidity Limitation
	Temperature Limitation
	JSC Diabetis, Gedimino pr. 22-41, LT-01103, Vilnius, Lithuania
	This product contains electronics. Do not dispose of this device in municipal waste facilities.



Feetsee application about the information screen:





Feetsee



About Feetsee

Feetsee provides information indicating when the patient and health-care professional (HCP) should communicate for further evaluation regarding any potential localized inflammation signs observed on the feet via the thermal imaging system and remote visualization of its data.