Scan Feet, Save Lives

Podium Professional Model v1.4.1

Thermal Foot Scanner



Information for use

Read carefully before using the foot monitor These instructions are also available on the touch-screen tablet supplied with podium



Podium Professional® Class 1 medical device Patents pending





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Podium Professional IFU Thermal Foot Scanner

Version	Date	Initials	Comments/ Alterations	
0.1	Sept 19	JS	irst Draft	
0.2	30.01.20	RP	Next draft	
0.4	11.03.20	RP	Next draft	
0.5	18.06.20	RP	Next draft – updating to include cool-down screens	
0.6	29.06.20	RP	Next draft – finished maintenance section.	
0.7	30.06.20	RP CS	Next draft – incorporating user case study considerations	
1.0	28.04.2021	PP	 Version for publication/release Updated Indication for Use statement Added Contra-Indications Update links to the privacy notice, warranty terms & conditions 	
1.1	20/10/2022	AS	Updated for 1.4.1	
1.2	15/04/2024	PP	Updated with section 13 – Regulatory Information. Updated link to privacy policy	

Document Control and Review

Indication for use

A healthcare professional will use a Podium system to record the visual and thermal images and conditions of the soles of feet for signs of thermal patterns and appearance that may be consistent with pathological conditions as an adjunct and not as a diagnosis. It is not a replacement for professional foot care.

A layperson will use the Podium system under the guidance of a healthcare professional.

Under the guidance of a medical professional, the Podium system can be used in a home or a clinical situation and environment.

Contra-Indications

The Podium system is not to be used to make a diagnosis. The Podium system is not a temperature measurement (thermometry) device.

1. Introduction

Welcome, and thank you for purchasing your new Podium Professional system. Your Podium is supplied in conjunction with a dedicated control tablet and a web portal for retrieval of historical Podium scan results.

Taking a scan is easy by simply following the software application on the touch-screen tablet. This guide is split into the following sections:

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2. Warnings

Read carefully before using Podium Professional. Please also read our privacy notice: <u>https://www.podium.care/Materials/Privacy_Policy.pdf</u>

2.1 Precautions

- 1. Use Podium in a room that is draft free and at a steady temperature between 18 and 24°C
- 2. If the Podium was stored in a room with a temperature outside the specified range, please wait 45 minutes to allow the unit to stabilise with the environmental temperature before use.
- 3. Ensure the clear footplates and thermal plates are cleaned before use using the specified cleaning fluids (see section 11).
- 4. The feet must remain still during the scanning procedure.
- 5. For the best experience, use the Podium device in the proximity of a Wi-Fi signal to facilitate the storage of information on the Podium Portal.
- 6. The Podium device can be used offline once logged in; however, the user needs it to connect to a Wi-Fi signal to share or print the results.
- 7. For repeatability is essential to ensure the following:
 - a. The scan is taken at approximately the same time of the day.
 - b. The scan is taken in a room at the same temperature as previous scans.
 - c. The patient has not consumed alcohol, caffeine, nicotine or other drugs before using Podium.
 - d. The patient tries to place their feet in the same location on the Podium device.
- 8. Do not use Podium on a patient with an open wound on their feet, as this may cause inaccurate results.
- 9. Podium is optimised to perform thermal scans of foot plantar. Do not use the Podium on any other parts of the body.
- 10. Do not use the device on a patient making a call with a mobile or cordless telephone or in the presence of strong electromagnetic fields.
- 11. Store Podium and ancillary equipment in a carry case or shipping packaging to prevent dust infiltration.
- 12. Avoid kicking or dropping the Podium, and do not use it if damaged or not functioning correctly.

2.2 Attention

- 1. Failure to observe the previously mentioned precautions may lead to inaccurate scan results that cannot be attributed to product malfunctions.
- 2. Podium Professional is a delicate instrument and must not be used by small children. It is not a toy. Keep out of reach of children or persons with limited sensorimotor skills.
- 3. Using the Podium Professional must not replace medical consultation.
- 4. If the patient's feet are at the same temperature as the Thermochromic Liquid Crystal plates, the results may contain irregular information. See section 9- troubleshooting if foot scan results do not show a full image of the patient's feet.
- 5. Any severe incident arising from using the Podium must be reported to Thermetrix Ltd using any of the contact details at the start of this guide.

3. How it works

Podium takes thermal images of a patient's foot plantars. Increased thermal differences (i.e. hotspots) can indicate inflammation caused by various adverse conditions such as Diabetic Foot Ulcers, Plantar Fasciitis, Osteomyelitis, and Charcot's foot, amongst other pathologies. Cold areas can indicate circulatory problems such as Peripheral Arterial Disease, heart conditions and other arterial issues.

3.1 Choice of Thermal plate

Podium Professional is supplied with 3 different thermal plates. Each plate is optimised for a particular temperature range:

- The **'Cool'** plate. To be used if feet feel cold to touch. The temperature range is 18°C to 27°C.
- The **'Warm'** plate. To be used if feet feel very warm (e.g. typical diabetic person with advanced neuropathy). The temperature range is 26°C to 36°C.
- The '**Medium'** plate. For feet which are neither noticeably cold nor warm. The temperature range is 21°C to 32°C.



Note: The podium plates may also give results outside the ranges specified above due to sheet batch tolerances. The specific ranges for plates will be recorded on the histogram scan output.

To obtain a good scan without prior knowledge of the patient's foot temperature, it is advisable to select the 'Medium' plate in the first instance.

The results example on the right illustrates a typical temperature profile captured using the correct thermal plate.

If the majority of bars are towards the upper or lower end of the plate, then the patient's foot temperature is largely outside the range of the plate.



The example below shows a plate that is too warm for the patient's feet. A cooler plate is needed to capture more of the thermal foot information.



Alternatively, if the majority of the bars were at the top of the histogram, as shown in the image on the right, then a warmer plate is needed.

4. How to use it

The Podium Professional System is comprised of the following:

- Podium Professional Device
- Control Tablet
- Professional Portal

4.1 Set-up and Pairing

Podium Professional Device

Top View

Podium Control Tablet

Step 1: Switching on your Podium Professional and Control Tablet Press the power button on the Podium and on the tablet as per the illustration below. *Note: the tablet may need charging before use.*

Switching on Podium Professional

Switching on Control Tablet

The tablet should launch the Podium control software on start-up.

Step 2: Pairing your Podium Professional and Control Tablet

On the first run, the tablet will ask you to review Thermetrix terms, conditions and privacy policy before entering the Podium set-up screen.

Once you are happy to proceed, press the radio button and then the continue button confirming you agree.

Once you have agreed to the terms, conditions and privacy policy, you will be presented with the Podium Professional set-up screen.

You must complete **pairing** and **practice log-in** sections before using the Podium device.

The Podium and accompanying tablet should be paired before leaving the Thermetrix manufacturing facilities.

If this is the case, the **Pair my Podium** option in the set-up menu will be ticked.

If this is not the case or you are pairing with a different Podium, pressing the '**Pair my Podium'** button in the set-up menu will start the pairing process between your Podium device and tablet.

the list of devices found.

When prompted, select your Podium from Once connected, press the continue button to move to the next section in the set-up menu.

4.2 Practice log in

To log in or sign up, you must ensure the tablet is connected to your local Wi-Fi network.

This should only be performed once per location unless the Wi-Fi network is altered (i.e. change in broadband provider/router).

The Podium app will initiate the 'Connect to Wi-Fi wizard' if no network is detected.

Touch the light blue pull-down list (labelled 'Compare' in the example image) to view all Wi-Fi networks in range.

The screen should switch to the operating system Wi-Fi connection manager screen, which should resemble the example image.

Select your Wi-Fi from the list and enter the Wi-Fi password for your network.

Once the tablet has connected to your network, press the back arrow at the bottom of the screen.

To return to the Podium software application.

The connection wizard should now show your Wi-Fi in the pull-down box.

Depending on the security of your network, you may see the label '<unknown ssid>' as in the example image. The software application still knows it is your network.

Press the continue button to return to the sign-up or login screen.

To finish the set-up process, you will need to input some information regarding your practice.

Press the '**Practice Login'** button to begin the sign-up process.

Press the **'Practice Log in'** button to begin the login process.

Enter the Practice username and password provided. This should be provided to you by us. If not, please contact the Podium support line for more help

4.3 **Selecting a Clinician**

Tap on the 'Select Clinician' button and is insert the initial letters of a clinician already added to your practice. Select the clinician from the ld pull-down list and enter the password.

main menu, even if the tablet is rebooted, unless the practice has been previously logged out or the app data deleted.

Note: if you don't have any clinicians added. Clinicians can be added by an administrator in the admin portal. Please contact customer support for further information.

4.4 Taking your first scan

After selecting Clinician, your main menu should look like the image below

Press 'Scan now' to start the scanning wizard and follow the on-screen instructions.

Note: the patient must not place their feet on the Podium device until instructed by the scanning wizard.

If the patient places their feet on too early, a warning message will appear containing a countdown until the device is ready for another scan.

This can be ignored if you are changing the thermal plate, but the quality of the results could be affected if you use the same plate before it has cooled down.

Once the scan is complete, it can be tagged with patient details.

If patients have been added previously, they will automatically appear in the patient details field as you type.

If a patient has not been set up previously, they can be added by scrolling down in the enter patient details field and then taping on the add patient.

Note: the inclusion of an email address is to facilitate a direct method of allowing clinicians or patients to reset the password in the event it is forgotten. If you decide not to enter an email address, a password reset can also be performed via the Practice portal.

Note: if instructions are followed, a scan should take around 5 minutes (including the time taken to answer the post-scan questionnaire). However, it is advisable to allow 15 minutes between scans to allow for feet being placed on the Podium too early and the cool-down process – this will help ensure the best scan results possible.

Press ' scan now' to start the When the scanning wizard and follow the on- comfortable screen instructions. front of the l

NOTE: it is important that the the 'Start' button. patient does not place their feet on the Podium device until instructed.

When the patient is in a comfortable seated position in front of the Podium device, push the 'Start' button.

If the patient places their feet on too early, a warning message will appear containing a countdown until the device is ready for another scan. This can be ignored, but the quality of results could be affected.

Sheet selection (see section 3.1) Starting with the 'Medium' sheet is good practice, and use an alternative if the histogram illustrates that a cooler or warmer sheet is needed.

When you see the above screen, you can instruct the patient to place their feet onto the device. For best results, it is advisable to place one foot at a time at least 3 seconds apart.

When adequate pressure has been applied, you should hear a voice informing you the scan has started.

Once the scanning is over Podium will begin processing the data – this may take 30s.

After processing, a message asking if you would like to take a photo of the foot will appear. If you do, remove or flip the thermal sheet and the user can place their feet directly on the clear plastic. Press 'Photo' to continue or 'Skip' to skip. If you opt to take a photo, the same scan process and vocal instructions will sound. Whilst this is happening, hand the tablet to the patient. The patient must decide if the photo is suitable for viewing by others.

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To add a new patient simply fill out the details similar to the set-up process and click **'Continue'**.

Once the scan is complete, the scan can be tagged with the patient' details. Click on already entered patient details or to add a patient tap on **'Enter patient details'** and then on **'Add Patient'**

Note: the inclusion of an email address is to facilitate a direct method of allowing clinicians or patients to reset the password in the event they forget it. If you decide not to enter an email address, a password reset can also be performed via the Practice portal.

Note: usernames must be unique – therefore the portal will prefix the practice name in front of staff, e.g. <Practice name>_<staff name or identifier>.

with a patient, you can select whether or not the patient should answer any foot health risk questions. If selected, you will be presented with around 10 patient questions designed to reflect the NICE guidelines for assessing foot health and risk of DFU. After performing a scan a period of time (5mins) is required for the thermal sheet to cool. This can be ignored, but quality of results could be affected.

Once the questions are completed or skipped, the scan results are displayed.

4.5 Viewing Results

On completion of the scan process, the results are presented in the form of 3 reports automatically.

The Thermal scan results show an indicative temperature map of a patient's foot plantar for visual inspection. Thermal variation across the foot and asymmetrical differences can be seen in this report. The Statistic scan results illustrate the amount of foot area within each temperature range for asymmetrical comparison. Hot or cold abnormalities can be viewed here.

If selected, the photo of the patient's plantars will be available by pressing the Photo result tab. This saves a visual record of the physical patient's feet.

Notes can be added to each set of scan results by pressing the notes button on any of the scan reports.

When you have finished viewing the scans, press 'Continue' on any of the reports, and a confirmation message shall **Note:** All scan reports are automatically backed up to the Podium Portal (see later section) under the Staff and Patient details used to tag the scan.

Note: All scan reports contain the following information:

- Podium serial number
- Sheet/plate batch number
- Sheet/plate name used in the scan, e.g. 'cool' and its corresponding temperature.

V1.4.1 and onwards of the podium system contain additional dynamic temperature scales in the reports. Swipe left to for Dynamic scale and right for absolute. The dynamic thermal profile and histogram scan results provide a higher degree of detail into the small temperature differences recorded across the patient's foot.

Scan History

You can view past scans in the main menu by tapping on the 'scan history'. Additionally, the scan history can be filtered by date, clinician or patient details. To do this tap on the 'Date' or 'Filter' button in the scan history.

5. Interpreting the scan results

The following **4** assessments can be made using the thermal image and temperature chart:

5.1 Assessment 1: Temperature Distribution Pattern

The temperature distribution in a normal foot is characterised by the following:

- Very good left-right (contralateral) symmetry with point-topoint differences of less than 1.8 °C (usually much less)
- The temperature gradient from medial arch to toe and heel is positive with the gradient between ca. 0 °C and 7 °C
 - 2nd to 5th toes have approx. the same temperature
- No hot spots, no extended cold areas
- Average foot temperature 26 °C (at the toes) to 29 °C (at the medial arch)

Any deviation from the above may be a cause for concern

The healthy foot has, on average, the temperature distribution shown on the right. The warmest area is found in the instep region, where most of the arterial blood supply comes to the surface. Towards the plantar periphery, gradual cooling is observable, most prominently in the toes, where the body's active temperature regulation system causes capillaries to open or dilate first in response to external (environmental temperature) and internal (body core temperature) parameters.

In people with neuropathy, for example, this thermal regulation is compromised, and the toes tend to assume a temperature close to that of the instep area.

A **deviation from this pattern** may indicate problems that warrant further examination. If, for example, the heel area is colder than the toes, then there may be an underlying vascular.

The presence of **hot spots or cold areas** may also hint at a problem. Generally, if a well-defined region differs by more than 2.2°C from its surroundings, there may be an underlying problem.

5.2 Assessment 2: Absolute Temperatures

Not every foot will show the temperatures in the above image. Some people are "naturally warm", others colder and environmental temperature, clothing, footwear, and other factors also play a part. The image on the right shows the variation amongst healthy subjects. The colours do not represent absolute temperatures as in the image above, but temperature variation (1 standard deviation, i.e. 68% of all healthy people show this variation or less). The spot \bigcirc on the big toe, for example, is in a red area in the image on the right and in the green area in the image above. This means that in 68% of healthy subjects, this point will have a temperature of 27.6°C (the green in the above image) plus/minus approximately 3.6°C (the red in the image on the right). This means a temperature between 24°C and 31.2°C is within the normal range for 68% of healthy people.

- The fixed scales always show the same colours for the same temperatures
- There are 3 scales, one for each plate:

Exceeding this normal range may be indicative of problems that warrant further examination. A particularly warm toe, for example, may be caused by an ingrown toenail, a joint problem caused by a traumatic event, an infection or some other factor.

5.3 Assessment 3: Temperature Symmetry

The healthy human body is thermally highly symmetrical. The figure above shows a histogram of the *left-right* differences at 33 regions of interest in the feet of 103 healthy subjects (more than 3,000 data points).

The dark grey rectangle highlights the *interquartile range* (IQR) of ± 0.45 °C, i.e. in 50% of all healthy people, no part of one foot is warmer or colder than 0.45 °C than the same part on the other foot. The larger light grey area highlights a range covering 4 times the width of the interquartile. This means that in 99% of healthy people, a particular part of one foot differs by less than 1.8 °C from the same part in the other foot.

A breach in contralateral symmetry may indicate an underlying problem:

- In the scan, compare left/right temperatures point-by-point (e.g. big toe left vs big toe right, heel centre left vs heel centre right)
- A difference of more than 2 °C is indicative of a problem
- The histogram helps to do the assessment (note that the histogram does not compare pointby-point, just the overall symmetry)

A breach is often associated with a deviation from the normal temperature distribution pattern (see *Assessment 1* above) and/or hot spots or cold areas (See *Assessment 2* above), and the causes may be similar.

5.4 Assessment 4: Changes in Time

The Professional Portal stores all images taken over time and allows you to compare a change in the temperature distribution of a patient's foot over time.

- Difficult to standardise (patients may be overall warmer or colder on different days, shoes or socks, nicotine, caffeine, room temperature, the time between socks off and scan, etc.)
- Therefore focus on comparing patterns, not so much on absolute temperatures
- Useful for monitoring the impact of treatment. Example:

Note: For information relating to different foot conditions that can be observed through temperature assessment and the corresponding podium images, please review the accompanying technical document 'Thermography of The Diabetic Foot'.

5.5 Assessment : Dynamic Scale

The Podium software can apply a dynamic scale to each scan, creating a new scan image. The software finds the coldest spot in a scan and assigns the colour dark blue to it. It then finds the hottest spot of the image and assigns the colour red. It then stretches the remaining colours of the full rainbow colour scale over the temperatures between the coldest and the hottest spot.

The dynamic scale stretches all available colours between the coldest (dark blue) and hottest (red) parts of a scan, maximising contrast.

- Easy to see small temperature differences
- Difficult to compare scans from different dates/patients
- Chance of misinterpretation (e.g. red does not necessarily mean "hot" as in the example image shown here)

This means that all colours are always used, no matter if the temperature difference between the coldest and hottest parts of a foot in a given scan is very small or very large. Red always represents the hottest part of a foot, even if it is quite a cold one. Dark blue is always assigned to the coldest part of the foot, even if the foot is quite warm.

While this makes it easy to discern even small temperature differences, it can be misleading: red, for example, does not mean "it's a hot area"; it just means "it's the warmest area of this particular foot".

Using the same colours for different temperatures in different scans also makes it difficult to compare temperatures between different scans. Therefore Podium always shows images of a scan in both scale representations in the Podium Report: the static one to allow comparison between images and the dynamic one to show small temperature differences, thereby combining the advantages that each representation brings.

6. The Professional Portal

The Professional Portal can be viewed on any device with an internet connection; however, it is best viewed on a PC or laptop screen as they usually contain a greater colour resolution. The portal can be accessed using the URL: <u>https://portal.podium.care</u>

The Professional Portal has two login levels, Clinician and Practice.

The Clinician login provides access to features more relevant to the practice staff (i.e. patient-related functionality).

To log in, input the staff information entered previously at the end of the scan process.

The Practice login provides access to features more relevant to the practice owner or manager.

To log in, input the practice information entered previously when setting up the tablet.

6.1 Using the Clinician Portal

The Clinician portal facilitates the sharing of information between the patient and the Clinician. Its primary function is to access the historical database of scans taken using the Podium device and associated tablet.

Getting started - Logging in

You can log in to the podium portal at <u>https://portal.podium.care/login</u>

Change or Forgotten Password

If you have forgotten your password or want to change it, click on 'Forgot password?' and then enter your username to be emailed a link to reset your password.

Data Tables

The **Scans** and **Patient** sections (top right post login) all contain data tables that vary slightly in their contents; however, the sort and filter features remain the same.

On the first visit, you will be presented with a data table containing all the information for that section, e.g. all the patients you have taken scans for (see example on next image). All the tables have the following:

- column heading allows you to sort the table contents in forward or reverse order by clicking on the heading.
- a Search box that allows you to filter the table presented. Search
- action shortcuts relevant to that section Action
- number of items per page and page number control
- The Scans table also has a favourite icon to allow you to filter just selected scans. 🏫

Scans – viewing

The Podium Clinician Portal allows staff to view all the scans taken at their organisation.

To view scans, click on the **Scans** section to generate the scan table.

Similar to all other data tables, the contents can be sorted or filtered for you to find the scans you are looking for.

You can also click on the star by any scans you wish to flag for viewing later or quick sorting.

Previous Scan.

Printing, exporting and emailing - Scans

Whilst viewing a scan report, you can also transfer the information out of the Podium Clinician Portal for external review.

At the bottom of the scan report, 3 options are available, these are:

- Print This sends the scan report to a printer of your choice
- Export PDF This converts the scan report to a PDF file and gives the option to save
- Email PDF This allows you to email a PDF of the scan to anyone of your choosing

Select save	location		
22/04/21 @ 13:55 - Patient 1			Patents Podatosts Inc. Account
Scans	Risk	Questions	
- 26	Save As	×	no
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Monitoring – viewing historical questions

In addition to viewing historical scan reports, the clinician portal can also allow staff to view patient statistics in the form of charting risk ratings and answers to questions taken with scans to allow you to see how the data has varied over time.

The **Patient Statistics** charts can be accessed by selecting the **Monitoring** section to generate the table containing a list of patients.

Once you have searched/filtered to find a patient, then click on the chart icon to generate the Patient Statistics chart v w.

The Patient Statistics chart window can also be generated using the same icons in the **Actions** column in the other sections.

Viewing patient statistical variation over time

Patients - viewing

Patient information added using the Podium Tablet App or edited via the Podium Practice Portal can be viewed in the Clinician Portal.

To view patient information, click on the **Patients** section to generate the table.

Similar to all other data tables, the contents can be sorted or filtered for you to find the patient you are looking for.

Once you have found the patient you wish to view, click on the (i) icon for the information window to appear

Patient info		×
Patient:	Patient 1	
Location:	London	
Date of Birth:	04.02.1958	
Invite Status:	Accepted	
Last used Podium:	04.02.1958	
Last appointment:		

My Account - edit my details & device information

6.2 Using the Practice Portal

The Practice portal is designed to facilitate the management of staff and their patients that are using Podium at your practice. Similar to the Clinician Portal, on first use (and until the 'do not show again' box is ticked), a brief tutorial gives an overview of sorting and searching through the tables of information within the portal. The practice portal is one step above the clinician portal as it can not only do whatever the clinician portal can do but also the practice can add or lock Clinicians and transfer patients across different clinicians.

Clinician - adding

Similar to the previous section, the practice portal allows you to add (Register) clinicians in the **Clinician** section.

But that is not all; you can also edit a clinician's stored information and even lock them out of the Podium system, which prevents them from being able to log in to both the Podium Practice and Clinician portals.

To add a clinician, simply click on the + Add Clinician

The **Register Clinician** dialogue will open, allowing you to specify a username and password.

Register clinician	8
Username:	
Username	
Password:	
Password	0
	Abort Register

Clinicians - editing

To edit a clinician's stored information, click on the pencil icon in the **Clinician's** section in the **Action** section of the Clinicians table.

Edit Clinician		8
First name:	Last name:	
First name	Last name	
E-Mail:		
E-Mail		
Phone:		
Phone		
Address line 1:	Address line 2:	
Address line 1	Address line 2	
Town:	County:	
Town	County	
Postcode:	Country:	
AL5 2BL	Country	

Once you have finished adding new or editing existing information, scroll down and click the Save button.

You can also reset the clinician's password it in the Edit Clinician dialogue.

Clinicians - locking

Clinicians can also be locked out of the podium system by clicking on the padlock icon in the **Action** section of the Clinicians table.

Once the padlock is set to red, the clinician is prevented from being able to log in to both the Podium Practice and Clinician portals.

Clinicians – transferring patients

Whilst logged in to the Podium Practice Portal, all patient information is viewable to the practice manager. However, a clinician can only see the scan results they have taken with a patient when logged into the Clinician Portal.

Patients can be transferred from a clinician by clicking on the relevant transfer icon in the Action section of the Clinicians table.

Transfer patients 🛞
Transfer patients for Clinician 1
Toggle ali Select ali Deselect ali
Patient 1
Patient 2
Patient 3
Patient 4
Transfer to:
Clinician 2 🔹
Abort Transfer

Once you have selected the desired patients, you can choose the clinician you wish to transfer them to and click Transfer

6.3 Minimum browser specification

The majority of browsers from 2017 onwards work with the Professional Portal. A more detailed list of minimum browser requirements is below:

- IE/Edge 11
- Firefox 52
- Chrome 57
- Safari 10.1
- Opera 44
- iOS Safari 10.3
- Android Browser 80
- Opera Mobile 46
- Chrome for Android 80
- Firefox for Android 68

7. Thermochromic liquid crystal sheets/plates

The Podium device uses thermochromic liquid crystal plates to create a thermal impression of the patient's foot.

The plates must be stored between 15 and 25° C in a dry environment away from direct sunlight to maintain their effectiveness.

Podium Professional is supplied with 3 plates, each differing in the temperature range they can cover.

Cool	=	18-27 °C
Medium	=	21-32 °C
Warm	=	26-36°C

For information on which sheet to use when scanning, please see section 3.1 – choice of the thermal sheet.

8. Touch-screen Tablet

The tablet is supplied with a 5v Micro B USB charging adapter. Alternative adapters may be used – however, should a fault occur caused by using a different adapt, the warranty may be affected. Please see our terms & conditions <u>https://podium.care/info/default.html</u> It is advisable to charge the tablet when not in use.

9. Troubleshooting

9.1 Lack of foot shape when feet are the same temperature as the plate/sheet.

On the rare occasion, a patient's feet are the same temperature as the foot plate the Podium is not able to differentiate from between the background and the actual foot temperature. Whilst this may not result in a foot-shaped result image – the results are still interpretable given a hotspot or cold area should still show up on the scan result, if present. This means that whilst part of the foot shape of both feet may be missing – those areas are not likely to contain any significant information. The image on the right illustrates the lack of foot shape.

If the issue occurs in only one foot or a partial area – then the lack of a result could be significant and warrant further

investigation. Please review the accompanying technical document 'Thermography of The Diabetic Foot' for examples of causes and podium outputs that could be observed through various temperature differences across each foot and asymmetrically.

What to do if a scan shows only partial foot shapes

In the case that only a partial foot shape is shown in a podium scan result (similar to the image above), you can try the following steps:

- Check the histogram to see if your selection of plate is correct see section 3.1 on correct foot plate selection.
- Ensure the scan is performed correctly, i.e. without ignoring any calibration or cool-down warning screens.
- Cool the plate slightly. This may help in a warm environment.
- Minimise the time the patient's feet are exposed to the environment, i.e. keep socks and shoes on until ready to scan. It can take 10 minutes + for feet to warm back up after being cooled.
- Ask the patient to increase blood flow to the area through movement if possible.

We have tried to make the Podium intuitive and provide instructions through this manual. If you are experiencing unexpected results or think your Podium is faulty – please do not hesitate to contact us in writing to:

Thermetrix Ltd, F12 Suite Ty Menter, Navigation Park, Abercynon, CF45 4SN, UK By phone: +44 (0) 1443 805769

By email: <u>customer.support@podium.care</u>

10. Maintenance of your podium device

10.1 Batteries & auto power-off

The podium is powered by 6 AA batteries located on the underside of the device. These are designed to last around 3 months of daily scans. If the Podium is in constant use, the battery life is greatly reduced to around 2 days.

It is advisable to switch the Podium off when not in use. By default, the auto power-off feature of Podium should switch off the unit after 15 minutes of inactivity.

Different makes of batteries may have slightly different voltages and life spans. Alkali batteries perform better than other types in this application.

Rechargeable batteries should not be used in this device due to polarity issues when incorrectly placed and general lower voltage output.

As the battery voltage drops, the podium low battery indicator will illuminate and flash to alert the user that the battery level has started to drop. This will only occur whilst the unit is powered on. The warning light is beneath the power and communication lights on the central on/of switch of the podium unit.

The low battery indicator has 2 stages of flash to indicate an increasing need to change the 6 AA batteries:

- 1. No flashing the battery voltage is suitable to maintain the Podium
- 2. Slow blinking every 2s the battery voltage has started to drop. It is advisable to replace batteries at the next opportunity.
- 3. Fast blinking every 0.5s the battery voltage has dropped to a critical level. The batteries must be replaced immediately. In this scenario, it is not advisable to take a scan as the unit may not be able to operate correctly.

10.2 Updates

The podium system has the ability to be updated to the latest software version remotely. This ensures we can keep the software up-to-date with improvements and bug fixes.

The updates come in two parts:

1. Updates to the software application that resides on the controlling tablet.

2. Updates to the core podium software that resides on the computer inside the device. These may be in isolation or sent in close succession.

The updates arrive as notifications inside the tablet software application.

Click here to update app Click here to update Podium

Once you have clicked one of the buttons above, simply follow the on-screen instructions to perform the update.

If updating the software application, the reinstallation procedure should appear as below:

\$ 🖤 🛢 10:14am	5 8	≵ 💎 💼 10:14 am	b 8	ak 💎 🗎 10:15 a
Podium App Remote (Dev)	Podium App Remote (Dev)		Podium App Remote (Dev)	
a want to install this application? It does not require any special				
an				
	1 A A A A A A A A A A A A A A A A A A A			×.
	T		\checkmark	
	Installing		App insta	led.
CANCEL INSTALL		CANCEL		DONE OPE

Press install at the bottom right and wait for the installation to complete.

You may also see a permissions notification pop-up similar to the screen below – ensure the radio button is switched on to allow the installation.

* 8		1	\$ 🛡		11:58 am
Install unk	known apps				
Φ	Podium App Pro (Dev) 2.2.5				
Allov	w from this source				
Your By in: dama	tablet and personal data are more vulnerable t stalling apps from this source, you agree that y age to your tablet or loss of data that may resu	o attack by ou are resp It from their	unkn onsit use.	iowr ble fe	n apps. or any

The podium update will occur inside the podium computer and as a result there will not be information screens as per the app update procedure.

A pop-up message will notify you when the update is complete.

11. Cleaning

The podium device has been tested with several off-the-shelf cleaning products:

- Canonbury hard surface spray (ethanol)
- Alibeiss lens and screen cleaning wipes
- Bright wipe streak-free clarity
- Opticlear lens wipes
- Medca Pre-moistened lens cleaning towelette

In a clinic setting it is advisable to use alcohol wipes/sprays to clean between patient use.

We recommend using a micro fibre cloth to wipe away any streaks caused by the cleaning agent.

Course cleaning material should be avoided to prevent the scratch-resistance coatings being destroyed.

12. Warranty

The podium warranty is covered by an additional software and maintenance contract.

Full terms and conditions can be found at: https://www.podium.care/Info/Terms And Conditions.pdf

For any queries, please do not hesitate to contact us in writing to: Thermetrix Ltd, F12 Suite Ty Menter, Navigation Park, Abercynon, CF45 4SN, UK By phone: +44 (0) 1443 805769 By email: <u>customer.support@podium.care</u>

13. Regulatory Information

13.1 Manufacturer's EMC Declaration

Hereby, Thermetrix Ltd. declares that this product is in compliance with

- (EU) 2017/745 MDR
- 2014/53/EU Radio Equipment Directive
- 2011/65/EU Restriction of Hazardous Substances
- and the relevant statutory requirements

For a copy of the full text of the UK and EU Declaratrions of conformity please access the following URL: <u>https://podium.care/AboutUs.html</u> There: 'Regulatory' tab at the bottom.

The following table shows the maximum radio frequency output power for this product's wireless capability for the frequency bands it can operate.

Frequency Band (GHz)	2.41 to 2.48
Maximum RF Power	+20dBm

ID	Standard:	Test:	Range:	Level:	Result:	Comment:
E3	EN 55032:2012	Radiated Emissions	30 – 1000MHz	As per Standard	Pass	Class B limits achieved
E3c	EN 55032:2012	Radiated Emissions	1 – 12GHz	As per Standard	Pass	Class B limits achieved

EN Immunity Results

ID	Standard:	Test:	Range:	Applied Level:	Result:	Performance Criteria:
12	EN 61000-4-2	Electrostatic Discharge	N/A	+/- 8KV Air	Pass	С
13	EN 61000-4-3	Immunity from Radiated Fields	80MHz – 1GHz 1Ghz – 2.7GHz	10V/m 10V/m	Pass	A

13.2 Federal Communications Commission (FCC)

- This device complies with Part 18 of the FCC rules.
- This device contains a radio module with FCC ID 2ABCB-RPIOW
- Operation is subject to the following two conditions:
 - o This device may not cause harmful interference
 - This device must accept any interference received including interference that causes undesired operation.

13.3 Essential Performance

Podium has to remain responsive to user inputs at all times. Occasional freeze or power-off is acceptable as it is also an expected time-out feature following prolonged lack of user input, as long as the device can be restarted by the user.

If Essential Performance is lost, i.e. the device does no longer respond to user inputs the device should be restarted. If that fails to correct the problem then the manufacturer should be contact (see cover page for contact details).

13.4 Risks and Mitigations of Wireless Use

The ThermPix Device is of negligible risk for wireless use.

However, as a precaution, pacemaker and implantable medical devices should have a minimum of 15 cm (6 inches) when the device is switched on.

Specific Absorption Rate (SAR) minimum distance for device: 0mm

13.5 Bluetooth Data

Podium contains a Raspberry Pi Zero W computing module with FCC ID 2ABCB-RPIOW. This device uses Bluetooth (Low Energy) and complies with Part 15.209(a) and 15.247 of the FCC Rules

Operation is Subject to following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received including interference that cause undesired operation.