thermpix

ThermPix
Thermovisual Camera, version 2

(EN) **Instructions for Use**
Read carefully before using the camera

ThermPix is a Trademark of USA Therm Inc.

USA·THERM
see the invisible

Class 1 medical device
Patents pending

ThermPix Thermovisual Camera – Instructions For Use (IFU)

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Document Control and Review

Version History

Version	Date	Initials	Comments/ Alterations
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Current version

1.1	Name	Date	Signature
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Reviewed by	Russell Payne		
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Documents cited in this document

Referenced here as	Document name & location
none	

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File Name	Location
ThermPix Instructions For Use v1.3.docx	ThermPixQA/IFU

Content

1   Descriptive Information

1.1   Intended Use / Indications for Use

The ThermPix Thermovisual Camera's intended use is to view, measure, and record heat patterns and variations. It is intended for use as adjunctive diagnostic imaging for thermally significant indications stemming from heat emitted from the human body. The significance of these thermal patterns and variations is determined by professional investigation. This device is intended for use by qualified technical personnel. Clinical judgement and experience are required to review and interpret the information transmitted.

The ThermPix Thermovisual Camera is only for use in addition to other diagnostic devices. It does not provide an absolute measurement of temperature and should not be used for sole screening or diagnosis for any disease or condition.

The system is not intended to be used as a thermometry device.

1.2   Description of the Device

1.2.1   How ThermPix Works

The ThermPix Thermovisual Camera uses 2 cameras: a normal visual color camera and a thermal camera that shows the temperature of objects in the scene encoded in colors using one of several user-selectable color scales. Both cameras capture live video that is displayed side by side on the ThermPix monitor. The user can choose to overlay the live video feed with outlines of body parts such as arms, legs and trunk or parts thereof such as feet or hands. These overlays allow the user to capture images in a consistent and repeatable in order to make subsequent image comparison easier.

The devices allows users to create patient accounts that hold information such as the patients date of birth, contact details, ID, medical notes and also still images that were captured and stored from the live video feed. All data are automatically transferred via wifi to secure cloud storage that is associated with the device. No patient data are held on the device after switch off.

1.2.2   Controls, Labels & Markings

The device is switched on and off via a push button ⬇ at its top marked IO. Next to it is the volume control button ⬇ marked + Vol -.

The two cameras are located at the front of the device.

visual →
infrared →

The charger socket and its label ⬇ are located at the right hand side of the device.
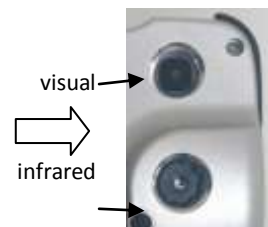
The main device label is located at it back, providing manufacturer address and contact details, serial number, manufacturing date and other relevant information

1.2.3 Skills, Training & Knowledge Required by the User

For the process of image capture the device must be used by a trained clinician or by a technician or laboratory assistant under the supervision of a clinician.
For the interpretation and analysis of the images the clinician should be familiar with human thermal physiology and acquainted with thermal regulatory processes of the human body. Dependent on the clinical application area specialist knowledge will be of advantage, e.g. for analysing images of diabetic feet the influence of neuropathy on arterio-venous shunts is an important parameter for correct interpretation.

1.2.4 Performance and Limitations

The visual camera of the device captures images at high, sufficient to resolve skin surface features of at least 1mm at the typical working distance of 1.5m. The camera is focused in the range between 1m and infinity and automatically adjusts white balance and image brightness to varying lighting conditions (the user can override this if required).

The thermal infrared camera produces images at a lower resolution of 320 x 240 pixels. However, a higher resolution is not required for human skin imaging since the thermal pattern of the skin is a smooth continuum with no sharp edges or corners.

The thermal infrared camera produces temperature values that may have a small offset (bias, inaccuracy) of up to ± 3.6°F (± 2.0°C) at the typical room temperatures recommended for thermal physiology examinations (ca. 68 to 72°F, 20 to 22°C).

In unfavourable conditions, in particular when used at room temperatures below 64°F (18°C) or above 86°F (30°C) and in the first 15 seconds after switching the camera offset may be higher.

Data are not stored on the device but in secure online cloud storage. Therefore the **storage space** for images and patient data is limited only by the terms of the individual user licence.

The device **does not** interpret captured thermal images and/or patient information in any form. It **does not** provide outputs or recommendations to users other than unprocessed thermal images.

1.1.5 Device Identification

REF	ThermPix
LOT	001
SN	TP1-
MD	Class I
factory icon	2023-01-31

The **hardware version** is shown next to the **REF** marker on the label at the back of the device. The **serial number** is next to the **SN** marker and the **manufacturing date** next to the **factory icon**

The device is remotely managed and is therefore always on the latest **software version**. This can be found on the Setup screen of the device (see section 2.1). An example is shown here: →

APP VERSION
0.0.8

1.3 Contraindications

- The ThermPix Thermovisual Camera should **not be used as the sole device to diagnose or screen for breast cancer or any other condition**.
- The ThermPix Thermovisual Camera should **not be used in place of mammography** and is only for use in addition to other diagnostic or screening devices.
- Incorrect use of the ThermPix Thermovisual Camera carries the **risk of delayed or missed diagnosis, or unnecessary additional tests**.
- The ThermPix Thermovisual Camera **is not intended to be used as a thermometry device**.

1.4 Benefits and Risks
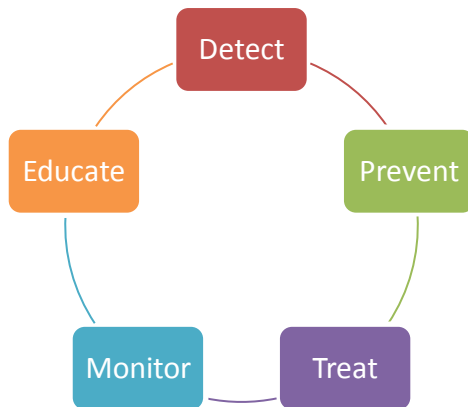
A clinician with experience and training in the area of thermology, thermal physiology and human thermoregulatory processes the ThermPix camera can use the recorded heat patterns and their variations as an adjunctive diagnostic imaging tool for thermally significant indications stemming from heat emitted from the human body.

The significance of these thermal patterns and variations is determined by professional investigation using clinical judgement and experience to review and interpret the information transmitted.

The findings derived from interpreting the thermal information may then contribute to the formulation of treatment approaches.

The professional user should be aware of two limitations that, if not taken into account, carry the **risk** of misinterpreting the results and in the potentially harming patients:

1. **Thermography is not a diagnostic tool**

    The technique must not be used on its own to arrive at a diagnosis or treatment decision. The reason is that the temperature gradients are an indicator of radiated heat e.g. of blood flow, but in themselves do not diagnose a particular disease or condition. Thermography can only suggest that there may be a problem and it is then up the training, knowledge and experience of the physician to establish the exact clinical cause and treatment.

2. **The medical value of absolute temperatures is limited**

    The professional user must question and interpret the apparent accurate readouts of any thermographic device. This has 3 reasons:

    a. The equipment itself is, as any measurement tool such as rulers, voltmeters or normal thermometers, subject to accuracy limitations;
    b. All parts of the human body are subject to the body's natural thermal regulation system and skin surface temperature naturally fluctuates within a wide range.
    c. The user will also have to consider environmental factors (room temperature, humidity, time to acclimatise to room), clothing and the use of drugs (alcohol widens, nicotine constricts capillaries) prior to thermographic examination when considering the temperature readouts.

For these reasons the contraindications statement in 1.3 above says that "The ThermPix Thermovisual Camera **is not intended to be used as a thermometry device**." and ThermPix does not show any temperature readouts.

1.5   Expectations of the Device and Procedure Associated with the Device

For the use of the ThermPix Thermovisual Camera best practice consensus recommendations provided by learned societies and in expert literature[1] should be followed. These recommendations provide guidance on:

- device preparation and use - e.g. environmental temperature, cleaning, perpendicular orientation towards skin surface;
- examination room preparation - e.g. temperature, humidity, absence of drafts and reflections from thermal sources such as radiators;
- patient preparation - e.g. no smoking, alcohol or physical activity before the examination. Clothing, acclimatisation to the examination room;
- examination process – this depends on the type of examination and may be entirely passive of involve active stimulation such as mild cold or warm stresses;
- interpretation of thermal images – dependent on the type of examination the interpreting clinician will require knowledge in human thermal physiology and thermal regulation processes.

1.6   General Warnings

- Incorrect use of the ThermPix Thermovisual Camera carries the risks of delayed or missed diagnosis, or unnecessary additional tests.
- Do not touch the lenses of the camera with your fingers. Finger sweat is highly corrosive to the lens material. If this happened refer to section 11.
- The device does not store any patient data or images after being switched off. Ensure a good wifi connection to allow the device to upload data to the secure ThermPix cloud storage.
- Federal law restricts this device to use on the order of a licensed practitioner.
- No modification of the ThermPix Thermovisual Camera is allowed.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ThermPix, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

1.7   Precautions

- Use ThermPix in a room that is draft free and at a steady temperature between 64 and 77 degrees Fahrenheit (18 and 25°C)
- If ThermPix was stored in a room with a temperature outside the specified range, please wait 45 minutes to allow the unit to stabilize with the environmental temperature before using.
- Ensure the device is clean. Using the specified cleaning agents (see section 11).

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[1] For example: Ring, E.F.J. & Ammer, Kurt. (2000). The Technique of Infra red Imaging in Medicine. Thermology International. 10. 7-14. 10.1088/978-0-7503-1143-4ch1.

- For best experience, use ThermPix in proximity of a strong wifi signal to facilitate storage of information on secure ThermPix cloud storage.

- For repeatability is important to ensure that patient images are taken under repeatable conditions. Adhere to an image capture protocol that is adequate for the respective examination. Guidelines are available from reputable thermography organisations. Typically these include stipulations such as:

  - The images are taken in a room at the same temperature as at previous imaging sessions,
  - The patient has not consumed alcohol, caffeine, nicotine or other drugs prior to the imaging process ,
  - Patient acclimatisation time to room temperature and the respective clothing worn is the same as for previous imaging sessions,
  - Patient and camera are in the same positions and orientation towards each other.

- Do not use the device in the presence of strong electromagnetic fields (e.g. MRI scanner).

- To prevent dust infiltration, store ThermPix and ancillary equipment in a carry case or a closed location such as a cupboard.

- Avoid dropping ThermPix. If you suspect that the device may have been damaged contact the manufacturer (contact details on cover page) and do not use it.

- Any serious incident arising as a result of using the ThermPix must be reported to the manufacturer using any of the contact details on the cover page of this document.

1.8   Importance of the Need to Adhere to a Care Regimen

It is important that you read and understand the instruction in this document in their entirety and that you pay close attention, in particular to those sections that are marked with the symbols for:

 important information,

 warning,

 danger / risk.

It is also important that you understand how to set up the device, to administer patient data, to save and to retrieve information. Failure to do so may lead to unintended consequences.

2   How to use it

2.1   Switching on/off, Stand-by Mode, Reset and Login

On/Off switch

The ThermPix Thermovisual Camera is switched on and off via the push button switch located on its top left hand side. Switching on and switching off takes a few seconds.

Switching on. Press down the button indicated by the 'I O' symbol next to it. The device will start up. Once you see the login screen the device is operational.
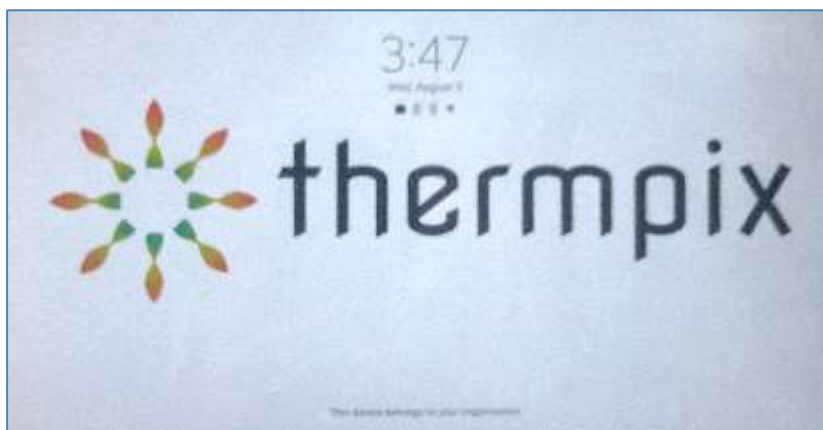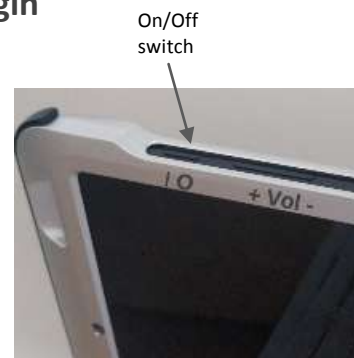
> Note that for patient safety reasons the device cannot take images while connected to a charger.

Switching off. You can switch the device off at any time by pushing down the on/off button AND the volume down button at the same time. Hold them both down for 5 seconds and the device will present the power off menu options. Select the Power Off option and then confirm the Power Off selection one more time, then the device will power off. The software will make sure that all data are securely synchronised to the ThermPix cloud and that all internal housekeeping processes are finished. When the power off sequence is complete device is fully deactivated and all data are synchronised with the server.

Stand-by mode. The camera will go into a power saving stand-by mode after a user definable time. The default is 10 minutes. This can be changed as shown in section 2.2.1.
Press the on/off push button and the device will immediately wake up again.

Logging in. The ThermPix Administrator can decide for each user if the logging-in process after device lock out (see section 2.2.1) should be via a 4 digit PIN or a password – or either. The first login must always be made via a username / password combination. If enabled individual users can disable login via PIN in their individual account settings (see section 2.3).

> You have **5 attempts to enter the correct password or PIN**. After that you are automatically blocked from the device and the details of the administrator who can unlock it for you are shown.

2.2   Initial Device Setup

2.2.1   First time use

When you switch the device on for the first time you will be presented with:

1. The **ThermPix Privacy Policy**. Please study it carefully and when in agreement tab on the agreement box at the bottom:

☐ I accept the privacy policy   Tab on the "Next" button in the bottom right hand corner to continue.

2. The **Terms of Service**. Again read this carefully, and when in agreement tab on the agreement box at the bottom:

☐ I accept the terms and conditions   Tab on the "Next" button in the bottom right hand corner to continue.

3. The setup functions of ThermPix are activated by tapping on the cogwheel icon located in the icon strip on the left hand side of the screen. Changes made here affect all user of the device. For individual user setting see section 2.2.

Hint: Thermpix has a "quick preview" function where you can view life infrared and visual images without logging-in. However, in this mode you cannot store any images or patient data.

A tab on the cogwheel icon 🔧 will open the device setting described in the following section.

2.2.2   Setting the Device Lock-Out Time

10 Minutes   The device lock-out is primarily a safety feature to make sure that patient data are protected if the device is being left on while unattended. After the defined time the device will log the current user out and patient data are no longer accessible.

The default time is 10 Minutes. Tapping on the button will open a numerical keypad where a new time can be entered.

After lock-out users will have to enter their credentials (username/password or PIN – dependent on device setup by the system administrator) again to regain access to the device functions.

Note: The device screen will switch off automatically after a few minutes to preserver battery power. This is not the same as the device lock-out. After the screen goes dark due to this power saving feature a new logging-in process is not required. (unless the lock-out is set to a shorter time than the power saving time).

2.2.3 Camera Alignment

The infrared and the visual camera are not in the same position but have a small offset with respect to each other. As a result the two images can only show exactly the same scene if they are aligned properly. To activate the alignment process tap on the text 'Check Camera Alignment':
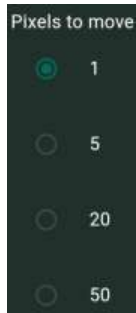
Both images will now be shown side by side. The arrows at the bottom right allow you to move the visible image with respect to the infrared one.

The selection circles '1' to '50' define the amount of pixels the visual image will move with every click of the arrow bottoms.

Once the alignment process is completed the 'X' button in the upper right hand corner closes the interface and returns to the Setup menu.

2.2.4 Defining the Server URL (Administrators ONLY)

This function is only available to device administrators. It selects the server for storing patient data. Tap on the button with text starting "https:// ....." to bring up the onscreen keyboard to change the server location.

2.2.5 User Account Setup
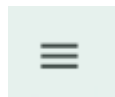
Clicking on the "hamburger" menu icon located in the upper right hand side of the screen opens a pane on which the individual user account settings can be changed. Enter the setting by tapping on the "Account Setting" text.
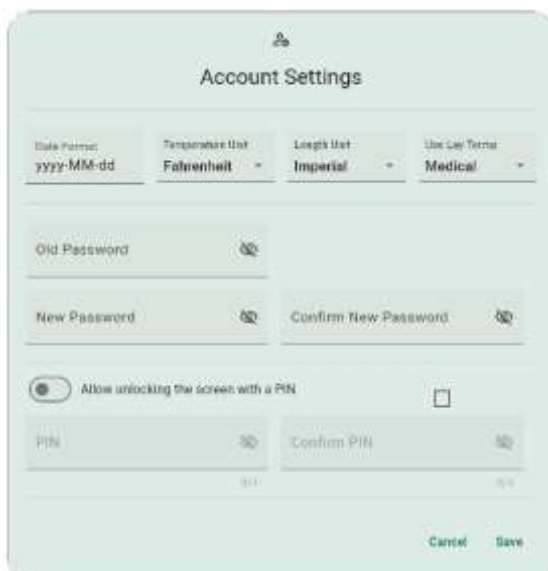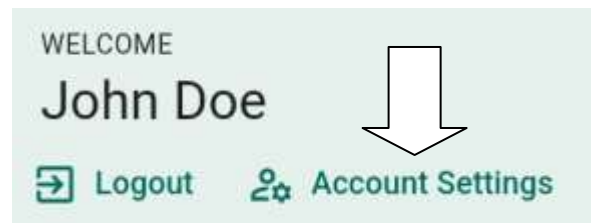
On this interface users can adjust their preferences individually. This will not affect the preferences of other users of the device.

If the slide switch "Allow unlocking the screen with a PIN" is greyed-out and can't be activated then the device administrator has disabled this function for the individual users on security grounds.

2.3   Patient Management

2.3.1   Adding a Patient

Clicking on the '+' button brings up a dialog box where you can enter details for a new patient. At a minimum enter family name, given name and data of birth as these are used for organising the patient list and are parts of the searching and indexing system.

Note that <u>without</u> **Storage Consent** no images and user data will be saved to the ThermPix servers. All information recorded in a session will be lost after the user logs out. This may be useful for a one-off examination where the operator knows that the data are unlikely to be needed in the future.
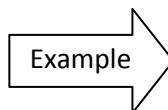
2.3.2   Editing and Archiving Patient Data
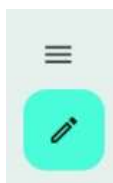
When an existing patient is selected from the patient list a click on the pen icon brings up the patient data entry dialog mask again (see above) and you can make changes.

Tapping on the 'Archive Patient' button at the bottom of the dialog mask box brings up a box where you can select to archive a patient. This function is useful for removing those patients from the device's patient list for whom it is known that they are unlikely to return for another examination.

Note that **patient records are never deleted**. This is an audit requirement for medical records. The patient data are compressed and moved to the ThermPix Archive on the Cloud Server. An Administrator can retrieve the data from there for audit purposes and, if necessary reinstate them back as an active record that is accessible on the device again.

2.3.3 Searching for a Patient

The Patient list provides 3 functions to find a particular patient record:

1. Search. Entering some letters of a patient's name in the search box (magnifying icon) will show all those patients in the patient list whose names (first/given and last/family) contain these letters.
   For example, entering "er" will show people such as 'John Mill<u>er</u>' and 'M<u>er</u>lin Smith'.

2. Alphabetical, by first/given name.
   In this mode the letters A to Z are shown on the right hand side of the patient list. The letters of existing patients are highlighted in bold and tapping on them scrolls the patient to those patients whose first/given name starts with that letter.

3. Chronological. The patient last seen by the device will be shown first on the list.
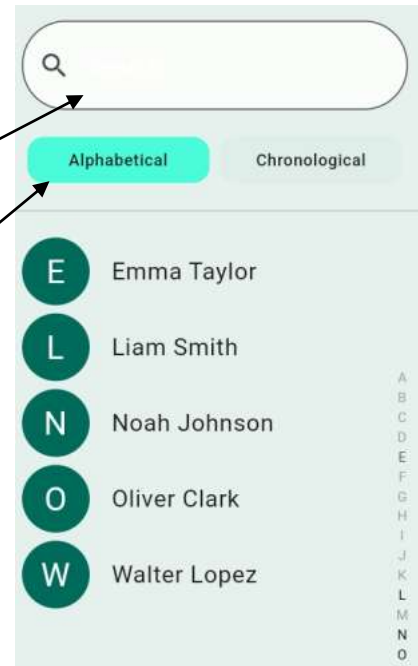
2.4 Image Site Management

2.4.1 Creating a Site and a View

All images taken with ThermPix are assigned a Site and a View. Otherwise images cannot be taken.

- **A Site** is a particular anatomical region of the human body such as arm, upper leg or foot.

- **A view** is the orientation of the ThermPix Thermovisual Camera towards the Site (e.g. frontal, distal and lateral).

Users can decide if they want to automatically apply medical or lay terminology, e.g. "plantar foot" or "sole of the foot" (see 3.5.1, User Editing).

Process of Site and View creation:

1. Select a patient from the patient list by tapping on the respective name.

2. If no Site exists tap the '+' icon in the panel that opens up for the selected patient.

3. Tap on the desired **Site** on the person mannequin, e.g. the upper torso or the left leg. The selected region will be highlighted. ⟶

4. Click on the 'Next' button. Next →

5. A zoomed-in view of the selected region will appear. In this zoomed view select the **View**, e.g. the left proximal leg. You can use the "Rotate X-Axis" slider to select, for example, "left lateral" or "posterior" Views.

6. Tap on 'Save' to create the Site and View for the selected patient.

The new Site and View will now appear in the selected patient's site panel.
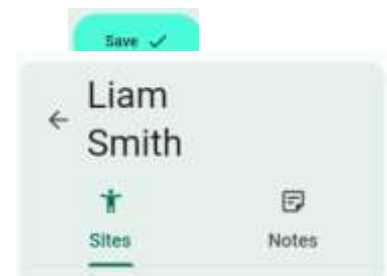
Note that Site definition is on a per-patient basis, i.e. all patients will have their own individual Site list.

2.4.2 Selecting a Site

Once a Site-View has been defined it can be selected by simply clicking on it. This selection is now used to filter the images of the selected patient and for automatically tagging a new infrared + visual image pair.
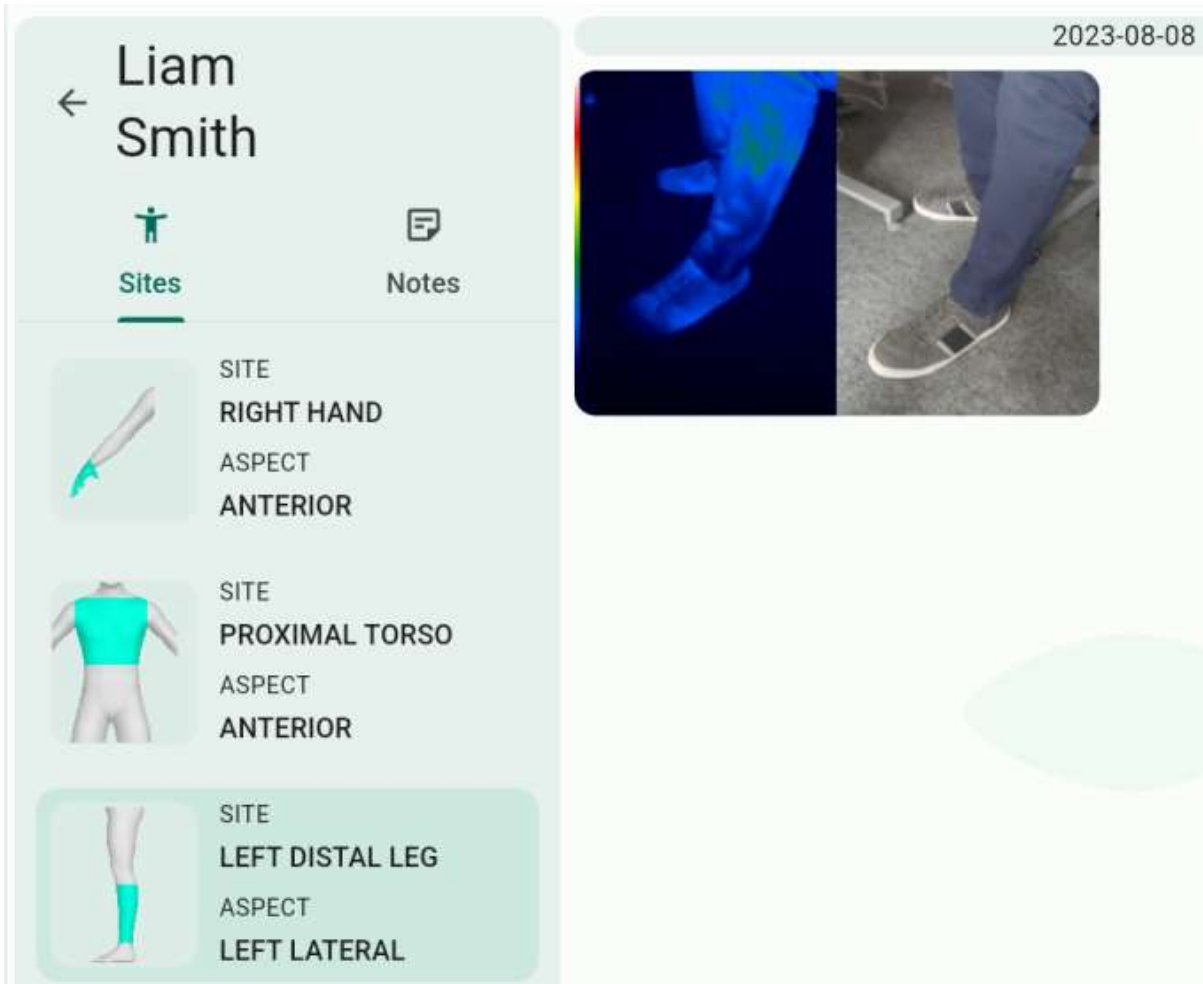
2.4.3 Archiving a Site

Clicking the 'Archive Site' button of a selected Site brings up a confirmation message ("A*re you sure you want archive the Site [Name of the site] ?*"). After confirming this, the Site and all images of that Site are removed from the active records and transferred to the Archive on the ThermPix cloud server.   An Administrator can retrieve them from there for audit purposes and, if necessary reinstate them back as an active record on the device.

2.4.4 Archiving Individual Images

If images are no longer required for clinical decision making they can be place in the patient's image archive on the ThermPix cloud server.

1. In the Site view first tap on 'Select Images'.

2. Tap onto those images you want to send to the archive. A tick mark will appear on the selected image(s). Tapping again unselects the images.

3. Click on "Archive Images' to send the images to the ThermPix cloud archive for the patient.
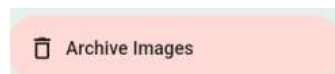
As with all archiving functions an Administrator can retrieve the images can retrieve the images and associated data from there for audit purposes and, if necessary reinstate them back as an active record on the device.

2.5   Making Notes
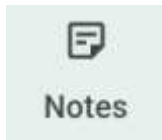
Tapping on the 'Notes' icon in the patient panel opens up the Notes Editor.

To create a new Note tap on the '+' icon.

The Notes editor opens up where you can enter text using the onscreen keyboard.
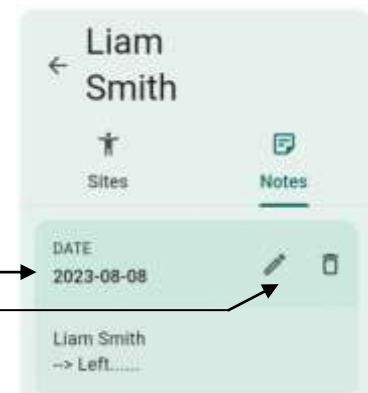
Notes are automatically annotated with a date.
They can be edited (pencil icon) or deleted (trash icon).

The ThermPix camera will generate an outline or **silhouette** from the selected Site and View. This silhouette can be overlaid onto live video feeds in order to help you framing the image in the correct orientation and magnification.

2.6   Taking Images

Once you have created

- a Patient and   (see 2.41. above)
- a Site and View   (see 2.5.1 above)
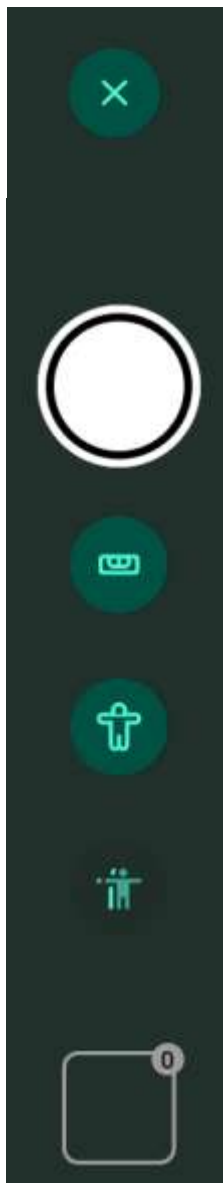
you are ready to take images.

Process:
1. Select a Patient
2. Select a Site
3. Tap on "Add Images"   Add Images
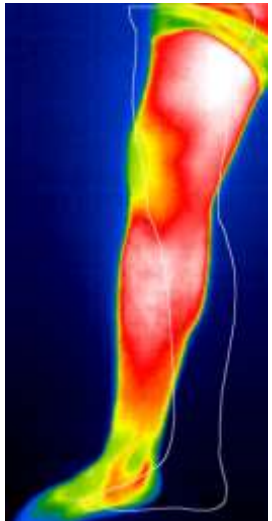
The image capture screen will appear. On the right hand side you find the control functions for image capture:

Exit the image capture screen.

The capture button. Tapping on it will take a snapshot of the current live video of the visual and thermal image.

The inclination "spirit level". This overlay helps to record images as parallel to ground level as possible. This is helpful for achieving image repeatability.

The silhouette overlay. This shows a standard outline of the selected Site and View.

"Ghost" image overlay showing a semi-transparent version of the previously captured image of the patient.

Saving progress indicator. When saving to the ThermPix cloud is completed the icon show the save image. The number in the upper right hand corner shows the amount of images taken during the session.

Silhouettes and ghost images act as a reminders which Site and View was selected and they help you to take images in a repeatable orientation for subsequent ease of direct comparison. The outline and/or the ghost images are not stored in the images.

2.7   Image Analysis

2.7.1   Comparing Images Side by Side

1. To compare patient images side by side, e.g. for a before-and-after analysis, select the patient and the Site you want to compare. Assuming that you have at least 2 images visible in the image view area tap on the "Select Images" button on the bottom right.
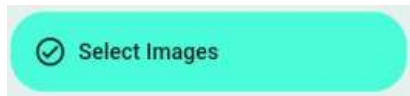
⊘ Select Images

2. Tap on 2 images you want to compare. A tick mark appears on the selected image(s). Tapping again unselects the images.

3. Tap on "Compare Images".   ⊘ Compare Images

You will now see the two selected images enlarged and side by side. For comparison the following tools are helpful:
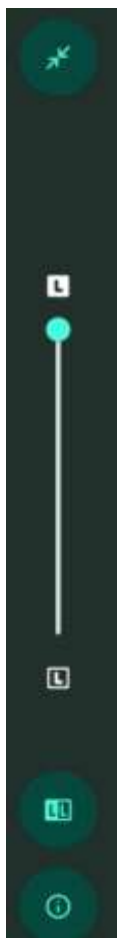
Exit the comparison tool and return to the image selection screen.

Overlay slider. By moving the green position point dynamically move from pure visible light view (top position) via a mixed infrared/visible view (middle positions) to a purely infrared image view (bottom position).

Side-by-side view. Show all infrared and visible views of both selected images.

Information. Show image metadata information (date, time, user capturing the image).

2.7.2 Annotating (drawing) and Tagging Images

After taking images (and at any later point in time) it is possible to create additional information that helps you to describe and tag them. The annotation functions are accessed via the pencil icon on the right hand side of the ThermPix Dashboard.

Process
1. Select a patient, then a patient Site in order to see the stored images. Tab on the image you want to annotate/tag.
2. Tab on the "Edit/Annotate" button

You will see the image you have selected and next to it the annotation and tagging toolbar with the following functions:

Exit the Annotation / Tagging mode and return to the image view

Change the color for annotations (drawings). This opens up a color manipulation tool.

Freehand tool for drawing any shapes on the images in the color defined by the color changing tool.

Tool to draw rectangles and circles for marking areas of interest.

Tagging tool. Brings up a pop-up screen where a range of pre-defined states for Rheumatism and vascular disease can be selected.

Copying tool. Copies drawings made on the infrared image over to the visible image.

Delete tool. Erases all annotations an dtags.

Undo / redo tool. Allows you to undo the last annotation(s) and/or tag(s)

Save button to save all annotations and tags to the ThermPix cloud server

3   Setup and System Information

3.1   Battery and Charging

Warning: use **ONLY** the supplied Hospital Grade charger for your own and your patients' safety. The manufacturer accepts no liability in the event of a user or patient coming to harm as a result of using a different charger.

Note that for safety reasons the device cannot be switched on or operated while connected to a charger.

- Do not leave device unattended during charging
- If the case is broken do not use or charge
- If you plan not to use ThermPix for a longer period of time (e.g. a month) discharge or charge the battery to approximately 75%.
- Use **ONLY** the supplied Hospital Grade charger

Charging

ThermPix can be recharged from any charger with a standard **USB Type C** plug (supplied).

In contrast to the older micro USB plug used for cell phones the USB Type C plug can be inserted into the charging socket **in any orientation**.

The duration of the charging process will depend on the capability of the charger. On a charger able to deliver 1 Ampere (A) the process will take up to 9 hours. On the charger supplied with ThermPix charging from empty should not take longer than 5 hours.

General Battery Care

In order to extend the lifetime of the ThermPix battery observe the following guidance:
- Do not use ThermPix and do not charge in temperatures outside of the range indicated on the label on its back (the thermometer symbol).
- If you plan not to use ThermPix for a longer period of time (e.g. a month) discharge or charge the battery to approximately 75%. and then switch the device off (i.e. do not leave it in standby mode).
- Do not leave ThermPix on the charger for longer periods of time (days).
- If possible stop charging when the unit is 90% charged. This extends the life time of the battery.

3.2　Locking ThermPix

In the event of ThermPix being lost or stolen you can lock the device for access by:

- Contacting the manufacturer. The contact details are on the front page of this guide.
- Administrators can also enter the online web app for the ThermPix cloud Server and deactivate the device there (Entity > Devices > Enable/Lock)

After a ThermPix device has been locked it will be notified of this status at its next connection to the Cloud Server. From that point onwards the device will only show a single screen with the Entity's contact details and it is impossible to log in.

Patient details are not retrievable at any point because they are only ever stored in volatile system memory and never on the device's hardware memory locally. Consequently all patient data are automatically deleted when the device is switched off.

4 Maintenance

4.1 Battery Care

Battery life time

ThermPix is equipped with a rechargeable lithium polymer battery. Like all rechargeable batteries it will lose a certain percentage of its usable capacity over time. The battery manufacturer guarantees that 80% of its capacity is still available after 500 charging cycles – which equates to approximately 2 years of daily use for several hours from fully charged to the point that the unit needs recharging.

The lifetime of the battery can be greatly extended by not charging and discharging it fully. For this reason it is recommended that you start recharging when the battery is down to 10% of its charge and stop charging at 90%

Exchanging the Battery

The battery must not be changed by the user. Do not attempt to open the device and to replace it. This voids the manufacturer's warranty and it may cause serious harm or death to you and your patients. ThermPix devices with exhausted batteries must be shipped back to the manufacturer (address on the front page of this guide).

How Long Does a Battery Charge Last

Under normal use, assuming a pattern of 20% image capture time and 80% review time a new and full battery could last approximately 6 hours of continuous use. Since the device will go into power saving mode after a user definable time ThermPix could be available throughout a full working day of 7 to 9 hours without needing to be recharged.

4.2 Cleaning

4.2.1 Cleaning the ThermPix Body

The ThermPix Thermovisual Camera has been tested with several off-the-shelf cleaning products, e.g. :
- Super Sani-cloth Germicidal Wipes
- Zeiss Ultra Clarity® Lens Cleaner

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 cleaning agents.
Coarse and abrasive cleaning material should be avoided to prevent the scratch-resistance coatings (e.g. on the touch screen) being destroyed.

4.2.2 Cleaning the Camera Lenses

As a general rule **do not clean the camera lenses** as part of your usual cleaning routine. Do not apply a spray cleaning fluid to the lenses either. In particular the lens of the infrared camera (the larger of the two) is extremely sensitive to chemical agents and abrasion. Doing so will void the warranty.

The **exception** to this cleaning rule is a situation where a lens has been touched by a finger (finger sweat is corrosive to camera lenses) or if a lens is visibly soiled, stained or obstructed by a particle. In such cases, where you cannot avoid cleaning the lenses, use a soft cotton swab (e.g. Q-tips) moistened with a lens cleaning solution (e.g. for glasses, ask your local optician). Apply the swab with great care, do not apply pressure and do not rub.

A **damaged /or scratched infrared camera lens** may result in false readouts and may subsequently lead to misdiagnosis and harm to patients. If you observe such a lens problem do not use ThermPix and ship it back to the manufacturer (address on the front page of this guide) for repair.

4.3   Storage & Environment

The ThermPix Thermovisual Camera should be used and stored indicated by the icons on the label on the camera's back side:

keep away from sunlight   keep dry   use only indoors   86°F / 30°C use within these temperature ranges   65°F / 18°C

4.4   Accessories

ThermPix is supplied with a Hospital Grade charger that fits into a standard household mains socket. Read the instructions that are supplied within the packaging of the charger.

Warning: use **ONLY** the supplied charger for your own and your patients' safety. The manufacturer accepts no liability in the event of a user or patient coming to harm as a result of using a different charger.

4.5   Updates

The ThermPix Thermovisual Camera has the ability to be updated to a new software version remotely. This ensures that you can keep the software up-to-date with improvements, security updates and bug-fixes.
Updates are rolled out automatically and in the background. You do not have to do anything.

5   Troubleshooting

5.1   Unable to Connect to Wifi and/or the ThermPix Cloud Server

Error Message / Symptom	Potential Reason(s)	What to Do
Server or connection error, syncing clinic <clinicName> to server failed.	Wifi: • No wifi connection • Wifi access point (router) not working • Wifi access point (router) working but not connected to the internet • Wrong wifi password entered • Weak wifi signal • RF interference from Cell phones or other wireless devices	Is your access point (router) switched on and working (try to connect to it using another wifi device). Check if you entered the correct wifi password. Low signal strength, move closer to the access point (router). Move cell phones and other wireless devices away from the ThermPix.
Server or connection error, syncing user data for <userName> to server failed.		
Wifi connected but no internet access		
No WiFi network found, please turn off the device and place it near a WiFi enabled access point then turn it on.		
Unable to connect, wrong password or low signal		
Server URL is not valid, please enter a valid one.	_____	_____
Could not connect to server, IP address (URL) might be wrong or it's unreachable.	Cloud Server: • All of the wifi points above • Incorrect cloud server IP address entered • Cloud server down • License expired	Check all the above points Check that the server IP address (URL) is correct Contact manufacturer

5.2   Setup and Data Entry

Error Message / Symptom	Reason	What to Do
Please mark at least one user as admin before continuing.	ThermPix needs at least one user to be registered as an administrator	Click the "Administrator" check box in User Setup (section 3.5.4)
Username for <userFullName> is already used, please enter a new one.	This user is already registered on the device.	Search for this user and edit details if required
Email for <userFullName> is already used, please enter a new one.	Each user should have a different e-mail address	Choose a different e-mail address
You can't delete the current user. Logout and delete it from another admin account.	You are logged in to ThermPix as the administrator you are trying to delete. This is not possible.	Log out. Then log in as a different administrator.
Please fill required fields for user <userFullName>.	Check that all mandatory fields in the input mask have been filled.	Complete all mandatory inputs

5.3   ThermPix does not start

Possible Reason	What to Do
Battery flat	Charge battery
Firmware or software hang-up	Contact manufacturer (see cover page of this guide)
Electronics faulty	

5.4   ThermPix does not shut down

Possible Reason	What to Do
Internal firmware or software hang-up	Contact manufacturer (see cover page of this guide)
Electronics faulty	

5.5   One or both cameras do not work

Possible Reason	What to Do
Internal firmware or software hang-up	Contact manufacturer (see cover page of this guide)
Electronics faulty	

6   Additional Information

6.1   Adverse Events

Please report any adverse event, however small to the manufacturer. The contact details can be found on the front cover page of this guide.

In the vent of ThermPix **malfunction** you <u>may</u> voluntarily report to the FDA using MedWatch form FDA 3500 and the guidance document "Medical Device Reporting for User Facilities",

Any event involving the ThermPix Thermovisual Camera that resulted in **serious injury or death** events <u>must</u> be reported to the FDA using the FDA 3500 route outlined above.

For advice see also: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

6.2   User Assistance

For issues or queries with regards to the operation of the device, or to report a fault please contact the ThermPix technical support team in office hours Monday to Friday. Contact details are provided on the cover page of this manual..

6.3   Disposal

Do not dispose ThermPix in household waste. Use facilities for the disposal of electronic waste. If the device is still starting up fully discharge the battery before disposal. Alternatively contact ThermPix customer support for end of life uplift advice.

6.4   Warranty

Please see: www.USATherm.com/info/ThermPixWarranty.doc

6.5 Travelling with ThermPix / International Use / Sending by Post

6.5.1 Air Transport

Air transport safety regulations restrict certain electronic items using rechargeable batteries based on Lithium technology. At the time of writing (see date in footer of this page) ThermPix was allowed to be transported both in the airplane's cargo hold (as checked baggage) and as carry-on hand luggage.

These regulations change from time and you are therefore advised to check[2] before your travel with your air travel operator. You may need to provide the following information:

- Watt per hour rating (Wh):   30 Wh
- Lithium metal content: less than 2g
- Device type: Class 1 PMED (personal medical device)
- Spare batteries: none

6.5.2 Export Restrictions

In the USA thermal infrared cameras are restricted export items and fall under the International Traffic in Arms Regulations (ITAR). Violations of ITAR are extremely serious and can result in **fines, debarment, and criminal sanctions**.

The regulations change from time to time. You are therefore strongly advised to determine before travelling or exporting to other countries if ThermPix may be restricted by US Government restrictions. As a first rule check the list of Embargoed Countries (e.g. North Korea, Iran, Venezuela, Libya, etc). Moving ThermPix to these countries is almost certainly not allowed.

If your travel destination is not on this list you are most likely allowed to travel with ThermPix. However, you are advised to assure yourself. To do so you will need the following information on the infrared camera used in ThermPix:

- Camera Pixel pitch: 12 µm
- Frequency: 9 HZ
- Resolution: 320 x 240 pixels
- Export control classification (ECCN) number: 6A993

6.5.3 Shipping / Posting ThermPix

Since the Lithium Polymer battery is enclosed inside the device shipping and posting of ThermPix is possible provided you observe the following rules:

- You need to include a **handling label**, accompanied by a **Transport Document**. Your courier or shipping / posting agent will advise you on the correct labels and procedures.
- Turn off ThermPix and to use strong **tape to seal the On/Off switch** to prevent it from being turned on accidentally during transport.
- You must put ThermPix in a **strong plastic bag** before you ship it. It creates an extra barrier against fire, as well as decreasing the risk of static interference.
- You must not ship ThermPix if you suspect that the battery may be faulty.
- When shipping lithium batteries abroad, you must check the specific rules regarding lithium batteries of the country you are shipping to.

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[2] IATA information page:
https://www.iata.org/contentassets/6fea26dd84d24b26a7a1fd5788561d6e/passenger-lithium-battery.pdf

6.6   Regulatory Information

6.6.1 Manufacturer's EMC Declaration

Emissions			
Standard	**Description**	**IEC60601-1-2:2014 Compliance Level**	**IEC60601-1-2:2014 Test Level**
Cispr 11/EN55011	Radiated RF Emissions	Group 1, Class B	Group 1, Class B
Cispr 11/EN55011	Conducted RF Emissions	Class B	Class B
47CFR part 15	Radiated RF Emissions	Class B	Class B
IEC61000-3-2	Harmonics	Class A	Class A
IEC61000-3-3	Flicker	Complies	Complies

Immunity			
Standard	**Description**	**IEC60601-1-2:2014 Compliance Level**	**IEC60601-1-2:2014 ed Test Level**
IEC61000-4-2	ESD	8 kV contact, 15 kV air	8 kV contact, 15 kV air
IEC61000-4-3	Radiated RF Immunity (Including Table 9)	80-2700MHz :10 V/m, 80% AM, 1 kHz 385MHz :27 V/m, PM,18Hz 450MHz :28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz :9 V/m, PM, 217 Hz 810, 870, 930MHz :28 V/m, PM, 18Hz 1720, 1845, 1970MHz :28 V/m, PM, 217 Hz 2450MHz :28 V/m, PM, 217 Hz 5240, 5500, 5785MHz :9 V/m, PM, 217 Hz	80-2700MHz :10 V/m, 80% AM, 1 kHz 385MHz :27 V/m, PM,18Hz 450MHz :28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz :9 V/m, PM, 217 Hz 810, 870, 930MHz :28 V/m, PM, 18Hz 1720, 1845, 1970MHz :28 V/m, PM, 217 Hz 2450MHz :28 V/m, PM, 217 Hz 5240, 5500, 5785MHz :9 V/m, PM, 217 Hz
IEC61000-4-4	EFT Immunity	2kV mains, 1 kV I/O, 100 kHz PRR	2kV mains, 1 kV I/O, 100 kHz PRR

IEC61000-4-5	Surge Immunity	2 kV	2 kV
IEC61000-4-6	Conducted RF Immunity	3V rms 150kHz - 80 MHz, 80% amplitude modulation at 1 kHz and 6 Vrms for ISM frequencies between 150kHz-80MHz	3V rms 150kHz - 80 MHz, 80% amplitude modulation at 1 kHz and 6 Vrms for ISM frequencies between 150kHz-80MHz
IEC61000-4-8	Magnetic Immunity	30 A/m, 50 and 60 Hz	30 A/m, 50 and 60 Hz
IEC61000-4-11	Low Voltage Immunity	=0 % UT for 0.5 cycle (at 50 Hz) At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° =0 % UT for 1 cycle (at 50 Hz) =70% UT for 25 cycles (at 50Hz) =0% UT for 250 cycles (at 50 Hz)*	=0 % UT for 0.5 cycle (at 50 Hz) At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° =0 % UT for 1 cycle (at 50 Hz) =70% UT for 25 cycles (at 50Hz) =0% UT for 250 cycles (at 50 Hz)*
IEC61000-4-39	IEC 60601-1-2:2020 Table 11 Magnetic Immunity	134.2kHz, 2.1kHz PM, 65A/m 13.56MHz, 50KHz PM, 7.5A/m	134.2kHz, 2.1kHz PM, 65A/m 13.56MHz, 50KHz PM, 7.5A/m

6.6.2 Essential Performance

ThermPix has to remain responsive to user inputs at all times. Occasional camera output freeze both infrared and visual) is acceptable as it is also an expected time-out feature following prolonged lack of user input, as long as the camera(s) 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).

6.6.3 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

6.6.4 WiFi Data

- 2.4 GHz and 5.0 GHz IEEE 802.11a/b/g/n/ac wireless, VHT80 MIM
- TX FCC ID: A3LSMP613
- Contains IC: unknown
- This device complies with Part 15 of 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.

FCC Part	Lower Freq (MHz)	Upper Freq (MHz)	Power (Watts)
15C	2402	2480	0.0017
15C	2412	2462	0.0214
15C	2422	2452	0.219
15E	5180	5240	0.0275
15E	5190	5230	0.0269
15E	5210	5210	0.0148
15E	5260	5320	0.0282
15E	5270	5310	0.0275
15E	5290	5290	0.0141
15E	5500	5700	0.0095
15E	5510	5670	0.0214
15E	5530	5530	0.0214
15E	5745	5825	0.0170
15E	5755	5795	0.0209

6.7   Technical Data

ThermPix Thermovisual Camera, version 2

Physical	Weight	880 g
	Dimensions	268 (L) x 164 (W) x 33 (H) mm
Touch screen	Resolution	1024 (H) x 600 (V) pixels
	Screen size	10.4" (263mm), TFT, 16M colors
Visual Camera	Spatial resolution	3280 x 2464 pixels setting used
	Number of pixels	8 MPix, RGB color
	Automatic white balance	yes
	Automatic exposure (gain) control	yes
	Working distance (in focus)	1m to infinity
Infrared Camera	Spatial Resolution	240 x 320 thermal pixels
	Thermal resolution	0.1°C , 0.18°F
	Accuracy (bias, offset)	± 2 °C (within operational temperature range)
	Pixel pitch	12µm
	Image frequency	9Hz
	Warm-up time to reach accuracy	30 seconds (within operational temperature range – otherwise up to 30 minutes)
Environmental	Storage temperature range	0°C to 40°C
	Operational temperature range	18°C to 25°C
	Humidity range	80% relative humidity
Battery	Voltage	3.7V
	Capacity	7.04 mAh (typical)
	Charging time	approx. 3 hours (with supplied charger),
	Working time from fully charged	approx. 6 hours of continuous use, longer if intermittently in standby
	Charger	5V, 3A dc, Hospital Grade
	Charger plug	USB type C
Operating system	Version	Android 13 (managed by Mobile Device Management System MDM)
FCC ID	A3LSMP613	

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Notes