Installation Guide

MOBOTIX EST Thermal Camera for Adjunctive Screening of Body Temperature

Mx-M16TB-EST © 2020 MOBOTIX AG



IMPORTANT NOTE

The body temperature measurements from the MOBOTIX EST Thermal Camera should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19 or any other disease.



Beyond Human Vision

V01_10/15/2020

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Support

If you need technical support, please contact your MOBOTIX dealer. If your dealer cannot help you, he will contact the support channel to get an answer for you as quickly as possible.

If you have internet access, you can open the MOBOTIX help desk to find additional information and software updates. Please visit:

www.mobotix.com > Support > Help Desk



Imprint

This document is part of the camera manufactured by MOBOTIX AG (called manufacturer in the following); the document describes how to use and to configure the camera and its components. Subject to change without notice.

Copyright Information

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Support

See Support, p. 4.

Safety Notices

- This product must not be used in locations exposed to the dangers of explosion.
- This product must not be used in oxygen-enriched environments.
- Do not use this product in a dusty environment.
- Protect this product from moisture or water entering the housing.
- Make sure that you install this product as outlined in this document. A faulty installation can damage the product!
- Do not replace batteries of the product. Batteries can explode if they are replaced by an incorrect type.
- Only install this system in a separate network without any connections to other networks.
- Electrical systems and equipment may only be installed, modified and maintained by a qualified electrician or under the direction and supervision of a qualified electrician in accordance with the applicable electrical guidelines. Make sure to properly set up all electrical connections.
- If using a Class I adapter, the power cord shall be connected to a socket-outlet with proper ground connection.
- To comply with the requirements of EN 50130-4 regarding the power supply of alarm systems for 24/7 operation, it is highly recommended to use an uninterruptible power supply (UPS) for powering the product.

Legal Notes

Legal aspects of video and sound recording:

You must comply with all data protection regulations for video and sound monitoring when using MOBOTIX AG products. Depending on national laws and the installation location of the MOBOTIX EST Thermal Camera, the recording of video and sound data may be subject to special documentation or it may be prohibited. All users of MOBOTIX products are therefore required to familiarize themselves with all applicable regulations and to comply with these laws. MOBOTIX AG is not liable for any illegal use of its products.

Declaration of Conformity

The products of MOBOTIX AG are certified according to the applicable regulations of the EC and other countries. You can find the declarations of conformity for the products of MOBOTIX AG on www.mobotix.com under Support > Download Center > Certificates & Declarations of Conformity.

RoHS Declaration

The products of MOBOTIX AG are in full compliance with European Unions Restrictions of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS Directive 2011/65/EC) as far as they are subject to these regulations (for the RoHS Declaration of MOBOTIX, please see www.mobotix.com, Support > Download Center > Documentation > Brochures & Guides > Certificates).

Disposal

Electrical and electronic products contain many valuable materials. For this reason, we recommend that you dispose of MOBOTIX products at the end of their service life in accordance with all legal requirements and regulations (or deposit these products at a municipal collection center). MOBOTIX products must not be disposed of in household waste! If the product contains a battery, please dispose of the battery separately (the corresponding product manuals contain specific directions if the product contains a battery).

Disclaimer

MOBOTIX AG does not assume any responsibility for damages, which are the result of improper use or failure to comply to the manuals or the applicable rules and regulations. Our General Terms and Conditions apply. You can download the current version of the General Terms and Conditions from our website at www.mobotix.com by clicking on the COS link at the bottom of every page.

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Setup Instructions

Intended Purpose

The MOBOTIX EST Thermal Camera is intended to be used by health care professionals and others to measure the relative temperature variations of the surface of the body to provide an initial body temperature assessment for triage use. The MOBOTIX EST Thermal Camera can be used in a health care facility or other non-medical locations, including airports, public buildings, etc.

IMPORTANT NOTES:

- The MOBOTIX EST Thermal Camera is not FDA-cleared or approved. It is authorized to be distributed in the U.S. for the duration of the COVID-19 public health emergency in accordance with FDA's Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 2020).
- The body temperature measurements from the MOBOTIX EST Thermal Camera should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19 or any other disease.

- Elevated body temperature in the context of use should be confirmed with secondary evaluation methods (e.g., a non-contact infrared thermometer (NCIT) or clinical-grade contact thermometer).
- Public health officials, through their experience with the device in the particular environment of use, should determine the significance of any fever or elevated temperature based on the skin telethermographic temperature measurement.
- The MOBOTIX EST Thermal Camera should be used to measure only one subject's temperature at a time.
- Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement.
- Always use the MOBOTIX EST Thermal Camera in a manner that is consistent with ISO/TR 13154: 2017: Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph.
- The camera performs an internal self calibration every minute, indicated by a yellow frame. During this time frame, the camera cannot be used for measurements (see figure below).



Fig. 1: Camera running internal self-calibration (once a minute)

System Components

Black Body Radiator	MOBOTIX EST Thermal Camera Mx-M16TB-EST

- The **black body radiator** is used to generate an area with a specific temperature that will be used by the MOBOTIX EST Thermal Camera.
- The **MOBOTIX EST Thermal Camera** measures the difference between the reference temperature of the black body in the **Offset Correction Reference Area** and the temperature of the hottest spot in the **Measurement Area**.



Fig. 2: Live image with Measurement Area and Offset Correction Reference Area (black body)

General Procedure Overview

- The operator will observe the monitor that shows the person's face and the black body reference area.
- Depending on the **frame color** of the camera image, the operator can decide on what to do next:



Performance Specifications

The MOBOTIX EST Thermal Camera fulfills the performance requirements stated in the FDA's Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 2020) based on IEC-80601-2-59 2017 "*Medical electrical equipment - Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening.*" and a ca. 60x60 pixel measurement and reference window:

- Laboratory Accuracy: < 0.5 °C
- **Stability and Drift**: < 0.2 °C

For more information, please check the Technical Specifications, p. 31.

Calibration

- The MOBOTIX EST Thermal Camera needs to be calibrated once per year by MOBOTIX to keep its performance level. Please contact your authorized MOBOTIX distributor for further information.
- Beside this, the MOBOTIX EST Thermal Camera needs to be calibrated by the installer or operator as described in the Installation Guide and the User Guide to compensate for different installation conditions.

Black Body Reference Source Description

The system requires a black body reference source for temperature offset correction in the temperature range between 34 °C to 39 °C with an accuracy of \pm 0.03 °C and a stability of 0.0005 °C and a 60x60 pixels reference window, at least, to meet the stated performance requirements.

The **MOBOTIX EST Thermal Camera** measures the difference between the reference temperature of the black body in the **Offset Correction Reference Area** and the temperature of the hottest spot in the **Measurement Area**.



Fig. 3: Live image with Measurement Area and Offset Correction Reference Area (black body)

Reference Body Site Used for Temperature Estimation

The system automatically detects the hottest spot within the **Measurement Area** and measures the temperature at that spot (marked by crosshairs, see figures below).



Fig. 4: Live image with Measurement Area and Offset Correction Reference Area (black body)

The crosshairs should be where the **inner cantus** of one eye is located in the image (see enlarged area below).



Installation

Before setting up the measurement area, you need to make sure that the following prerequisites are met and the instructions are followed.

Environmental Prerequisites

Make sure that the following environmental prerequisites are met when setting up the measurement system.

- Room temperature should be 20 to 24 °C/68 to 76 °F and relative humidity 10 to 50 percent.
- Add a low-reflective background to minimize reflected infrared radiation (avoid, for example, glass, mirrors, or metallic surfaces behind the person).
- Avoid moving air in the measurement area as much as possible (no fans, vents, draft, etc.).
- Avoid strong lighting (for example, direct sunlight, incandescent, halogen, and quartz tungsten halogen light bulbs).

Imaging Distances

Powerence between black body and camera: see table

Set up the system according to the following drawing:

Distance between black body and camera: see table Distance between person and camera: same as above

Fig. 5: General system setup

Imaging Distances in Relation to Focal Length

MOBOTIX EST Thermal Camera	Focal Length	Distance Between Person/Black Body and Camera
Mx-M16TB-EST237	237 mm	1.05 m/3 ft 5.3 in
Mx-M16TB-EST119	119 mm	0.72 m/2 ft 4.3 in
Mx-M16TB-EST079	79 mm	0.42 m/1 ft 4.5 in

Minimum Pixel Requirements

When setting up and operating the MOBOTIX EST Thermal Camera system, make sure that the minimum pixel requirements specified below are met.

Definitions

- Workable Target Plane: This is the entire measurement area in which the person's face should be fully inside.
- **Face Pixels**: Number of pixels within the *Workable Target Plane* that is covered of the person's face.

Item	Minimum Number of Pixels (Horizontally)	Minimum Number of Pixels (Vertically)
Workable Target Plane	320	240
Face Pixels	180	240

Physical Installation

General Setup of the System

- The distance between the person and the camera must be the same as the distance between the person and the black body. See the table in the Imaging Distances in Relation to Focal Length, p. 7 section to get the recommended distance for your MOBOTIX EST Thermal Camera version and focal length.
- Install the camera and the black body on stands that allow for easy height adjustment.
- Take measures to secure the stands of the camera and the black body to prevent them from being moved or toppled over.
- Provide a table and chair for the laptop/computer and PoE switch for powering the camera and the black body.
- Prevent tampering with the computer and ensure data privacy by taking these measures:
 - Create an isolated network that only consists of the PoE switch, the computer, the camera, and the black body (in case it's PoE-powered, too).
 - Activate the automatic screen lock of the computer when not in use after a short period of time (i.e., two minutes). Make sure that the computer requires a password for again activating the user interface.
 - Change the **default password** on the MOBOTIX EST Thermal Camera as described in Physical Installation, p. 8.
- Make sure that neither operators nor measured persons trip over any wires or cables. Tape down or otherwise secure any cables that may cause persons to trip.
- Print the User Guide chapter of this document and provide it to the operators so they can read the instructions.
- Mark the spot for people to stand on during measurement using non-slip type adhesive or any other suitable material.
- Provide a cleaning mat when entering the room to prevent injury in wet conditions, if required.
- Provide a suitable table, rack or similar for people to store garments, hats and glasses while measuring.

- Test the setup with persons of various height in order to determine the minimum/maximum height for proper testing.
- An adjustable stepper can help when measuring smaller persons so that their faces are within the measurement area.

Computer Setup

- Only install this system in a separate network without any connections to other networks.
- Make sure you have administrative access to the computer you are using.
- Set up the network interface of the computer to use an IP address of 10.1.1.10 with a netmask of 255.0.0.0, for example. This will ensure that you have instant access to the MOBOTIX EST Thermal Camera, since its factory IP address is 10.x.x.x with the same netmask.

Setting Up the Camera

Prerequisites

Before you start setting up the system, please make sure that the camera meets these prerequisites:

- The camera is a MOBOTIX EST Thermal Camera with an order code of Mx-M16TB-EST.
- The camera is running an EST firmware as indicated at the end of the Initial Camera Setup, p. 9.

Initial Camera Setup

The steps in the following are taking place on the computer you have set up in the sections above.

- Start a web browser (Microsoft Edge, Internet Explorer, Mozilla Firefox, or similar will do).
- Enter the IP address of the camera (see sticker on camera or packaging) in the address line of the browser.
- When you see the camera website, click on **Admin Menu** on the left hand side. Your browser may ask you to allow popups for this address, so please allow these popups.

Change the password for the admin user to prevent tampering with the camera (see figure below). Make sure to write down that password and store it in a safe place. When asked for a password, use the new password from now on.

Factory Password Change		
The factory default password has not been changed yet. This poses a security risk. Please set a new password for the admin user.		
admin		
New password		
Repeat password		
Note: If the camera provides an ONVIF interface, the passwords of the default ONVIF users are also changed. Caution: If the administrator password is no longer available, you will have to send the camera back to MOBOTIX for a factory reset!		
Check and apply		

Fig. 6: Set a new password

Make sure the camera is running an EST firmware (figure below, left) and is running in EST mode (figure below, right):

Verify EST Firm	ware	Verify EST Mode	
		Live screen: Click on Setup Menu and in the trol section, click on Thermal Sensor Setti	U U
MOBOTIX ▼ System Model Serial Number	mx10-22-255-55 Camera Sta M16TB-EST 10.22.255.55	MOBOTIX M16 mx10-26-217-236 Thermal Sense Attribute Value Thermal EST Mode 🕑	Sor Settings Explanation Thermal EST Mode: Activate Thermal Elevated Skin Temperatur mode. Note: After changing this parameter a rebo required. Factory default: On
Hardware Image Sensor Software	T3r6.4, 996 MHz L: b/w 6MP, L20/B036,F1.8, 9 R: Thermal, L43,F1.4, SN 900 MX-V5.4.1.2-#12-g15235c4		
Service Update Date and Time Current Uptime ▼ Networking	#998 StL: Developer Patch (2 2020-10-15 12:39:46 CEST 00:02:52		
Camera Name	mx10-22-255-55		

- If others handled the camera before, you should **reset the camera to factory defaults**:
 - Open the camera website in a browser.
 - Enter the password you set above.
 - Click on **Admin Menu** on the left hand side.
 - Scroll all the way down and in the Configuration section, click on <u>Reset</u> configuration to factory defaults.
 - In the Reset Configuration to Factory Defaults defaults, make sure that the Replace is set to Completely replace the current configuration, then click on Reset.
 - Click on the store link on the next page to open the **Permanently Store Configuration** dialog.
 - In that dialog, click on **Store Permanently**.
 - Click on the **reboot** link on the next page
 - In the **Reboot the Camera** dialog, click on **Reboot Now**. The camera will reboot and return to the live image.

Note

Resetting the camera to factory defaults will also reset the default password. You will need to set a new password in the **Factory Password Change** dialog (see Fig. 6: Set a new password).

Set Up Camera for Temperature Measurement

Before starting these steps, make sure that the **black body** is up and running. You will see the initial live screen of the camera, which looks similar to the figure below.



Fig. 7: Initial live camera image

The live image contains two boxes:

- 1. **Measurement Area**: The camera measures temperatures in this area. You will later adjust this area to where the faces of the measured persons will be.
- 2. **Offset Correction Reference Area**: This area must be entirely within the surface of the black body used as a temperature reference.

Adjusting the Areas

You will adjust two thermal measurement profiles in this section: one for triggering alerts if the temperature is too high, one for showing that the measured temperature is OK.

- Open the camera's web interface in a browser by entering its factory IP address (e.g., 10.32.15.152).
- Click on **Setup Menu** in the camera's Live screen.
- In the Setup Menu dialog, click on General Event Settings:
 - Activate Enable Arming.

🏠 🔶 МОВОТІХ М16	mx10-22-252-202 General Event Settir	ngs 📀 🕄
Activity	Value	Explanation
Arming	Off CS1 CS2 CS3	Arming for Recording and Action Groups: Enabled: activate all. Graphed: activate all. Graphic activate and action of the activate and activate Sr. activate activate and activate activate CS: arming controlled by custom signal as defined below. From Master: copies Main Event Arming state from master camera.
Custom Signals	CS4 CS5	Explanation
Custom Signal 1 (CS1)	CSL From Master	Source: Specify how to generate custom signal CS1. Off: set to false. Off: set to true. Signal input. Time Table: derive from signal input. Time Table: derive from the table. From Master copy CS1 from the master camera. By Action: control state via action groups. By Illumination: derive from Illumination value.
Note: Configuring	g arming sources as From Master requires you to Master/Slave below.	properly configure and enable
Master/Slave	Value	Explanation
Master/Slave	0	Enable Master/Slave: Specify whether or not this camera supports the processing of signals imported from a master camera and whether or not slave cameras are allowed to log in and to fetch local camera signals.
		Master Camera: Camera to fetch remote signals from. Only relevant if you specified <i>From Master</i> at least once as source to arming controls (camera main arming, recording, actions, messaging) or to custom signals (CS1, CS2, CSL). Note: You must use the primary IP address/subnet of the master/slave camera in this context. The additional IP address/subnet cannot be used in this context.
	60000	Replication Protocol Port: IP port used by the network protocol that replicates master camera signals among a set of slave cameras.
Set Fact	ory Restore Close	More

- At the bottom of the dialog, click on **Set**.
- At the top of the dialog, click on **Go back to previous page**.

■ In the Setup Menu dialog, click on Event Overview:

🏠 🔶 МОВОТІХ М16	mx10-22-252-20	02 Event Overview			0 (
Environment Events	EST_OK	Thermal Elevated Skin Temperature	Inactive	Delete	Edit
	EST_NOK	Thermal Elevated Skin Temperature	Inactive	Delete	

Fig. 8: Event Overview: edit event profiles

■ In the **Environment Events** section, click on **Edit**. You will see these two event profiles:

Events	Value	Explanation
► EST_OK		Inactive Delete
EST_NOK		Inactive Delete

Fig. 9: Event profiles

- EST_OK: This profile is used for triggering the alerts.
- EST NOK: This profile is used for showing that the temperature is OK.

Adjust the EST_OK Profile

.

The camera will use this profile to indicate that the **temperature is OK**. Click on the small triangle in front to the profile name to see its contents:

Ever	Value	Explanation
• EST_OK		Inactive Delete
EST_NOK		Inactive Delete

Fig. 10: Edit EST_OK event profile

Setup Instructions

Installation

 EST_OK 		Inactive Delete
	5 3	Event Dead Time: Time to wait [0.3600 s] before the event can trigger anew.
Event Sensor Type	Shock Delector Microphone Passive Infrared Detector Temperature Thermal Radiometry Thermal Radiometry Thermal Elevated Skin Temperature Trigger an event based on the temperature measure	
	This event type supports standard variables to be displa	Edit Measurement Area: For a detailed description of window dofinitions and additional variables, please refer
		to the help page. Measurement areas can also be defined by Shift-click+click in the live image and pressing Set Rectangle.
		Set Rectangle
	Thermal Range	Alarm Type: Select the alarm type.
	°C 🖸	Temperature Unit: Select the temperature unit.
	35	Thermal Range Lower Level: Enter the trigger for the thermal range lower level [3439 "C][93103 "F].
	37,4	Thermal Range Upper Level: Enter the trigger for the thermal range upper level [3439 *C][93103 *F].
	Within range	Comparison: Select the trigger condition.
	1,5 ©	Temperature Offset: Offset to adjust measured skin temperature to body temperature.
	35 🛞	Calibration Source Temperature: The actual temperature of the used calibration source. For a detailed description please refer to the https:page.
	0,876,403,127,138	Edit Offset Correction Reference Area: For a detailed description of window definitions and additional variables, please refer to the heip page. For a detailed description please refer to the heip page.
		Reference areas can also be defined by Shift-click+click in the live image and pressing Set Rectangle.
		Set Rectangle
	First	Action Type: Select If the trigger remains true while the condition is fulfilled, or if it is only true when the condition becomes fulfilled.
	Auto 🗘	Show Measurement Area: Show measurement area of selected profile in the live image.
	0	Show Thermal Radiometry Level Meter: Show a Level Meter with the current temperature within the measurement area according to the specified comparison conditions.
	Auto 🖸	Show Thermal Radiometry Level Temperature: Show the current temperature within the measurement area according to the specified comparison conditions.
	Off C	Show Thermal Radiometry Level Coordinates: Show the coordinates of the highest/lowest measured temperature within the measurement area, depending on the comparison condition.
	Auto 😳	Show Thermal Radiometry Level Crosshairs: Show crosshairs indicating the position of the highest/lowest measured temperature depending on the comparison condition.
	Off	Show Thermal Radiometry Profile Name:

Fig. 11: Contents of EST_OK event profile

- Define the **Measurement Area** so that the **person's head** will later be fully within this area:
 - In the Live image, use Shift-click to set the top left corner of the measurement area rectangle, then click again to set the bottom right corner of the rectangle. A yellow frame appears in the live image.

мовотіх м	16 mx10-2	22-252-202	Live					00
	16 fps 🟮	Image Size	🖸 🗘	GA (640x480)	0	ð	√HiQ	JPG ->
Admin Menu	HUH. MOBOTI	IX.CON				2929-19	-13 CEST	11:59:22
Setup Men. Oper	Administration	1						
Arm & Record								
Audio on								
MxPEG on	1							
MxPEG off								
UC Event								Second Second
LEDs Blink	10000	35.91°C	36.63°C					
Play Sound							1	1000000
Play Last Event								-
Event List	1		- T					
Multiwatcher								
1x Zoom			+					
Zoom +								
Zoom -								1000000
Center Pan								
								2362.88975
								1
Help								

Fig. 12: Yellow frame shows future Measurement Area

Below the Edit Measurement Area field, click on Set Rectangle to enter the coordinates of the yellow frame.



Fig. 13: Setting the measurement area

- Define the **Offset Correction Reference Area** so that the **black body** is fully within this area:
 - In the Live image, use Shift-click to set the top left corner of the measurement area rectangle, then click again to set the bottom right corner of the rectangle. A yellow frame appears in the live image.



Fig. 14: Yellow frame shows future Offset Correction Reference Area for the black body

Below the Edit Offset Correction Reference Area field, click on Set Rectangle to enter the coordinates of the yellow frame.



Fig. 15: Setting the offset correction reference area

Set the Calibration Source Temperature to the temperature of the black body's surface (usually in the range of 34 °C to 39 °C):



Adjust the EST_NOK Profile

The camera will use this profile to trigger an alert if the **temperature is above the specified value**. Click on the small triangle in front to the profile name to see its contents:

Events	Value	Explanation
) • E5		Inactive Delete
EST_NOK		Inactive 🗆 Delete

Fig. 16: Edit EST_NOK event profile

- Copy the **area definitions** from the EST OK profile to the same fields in the EST NOK profile:
 - Copy the entire contents of the Edit Measurement Area field from the EST_OK profile to the same fields in the EST NOK profile.
 - Copy the entire contents of the Edit Offset Correction Reference Area field from the EST_OK profile to the same fields in the EST_NOK profile.
- Copy the Calibration Source Temperature from the EST_OK profile to the same field in the EST_ NOK profile:



Calibration Source Temperature: The actual temperature of the used calibration source. For a detai please refer to the help page.	ed description

Check the Result

Once you are done, test the setup using a helper. The outcome should look like this:



Fig. 17: Live screen after defining the Measurement Area and the Offset Correction Reference Area

Note

The crosshairs in the figure above show the hottest temperature of the image. This spot should be where the **inner cantus** of one eye is located in the image (see enlarged area below).



Test and Calibrate the Configuration

After installation and setup, the system needs to be tested and calibrated by the installer or operator.

Attention

Calibration needs to be repeated **daily or after any change of the system setup** or environmental conditions to keep the stated performance level.

- One to three persons should be measured first by an NICT or clinical thermometer and then by the MOBOTIX EST Thermal Camera.
- If the temperature measured by the thermal camera differs from the one of the thermometer, adjust the **Temperature Offset** until both show approximately the same value. This step is required, because the body temperature measured by the clinical thermometer is usually 1 to 1.5 °C higher than the temperature measured at the inner cantus and to compensate for different environmental and setup-up factors.





Fig. 18: Adjusting the Temperature Offset parameter

■ For testing the alarm condition, put an object with slightly higher temperature (above the **Thermal Range Lower Level** of the EST NOK profile) into the measurement area.



Temperature Unit: Select the temperature unit.	
Thermal Range Lower Level: Enter the trigger for the thermal range lower level [3439 °C][93103 °F].
Thermal Range Upper Level: Enter the trigger for the thermal range upper level [3439 °C]]	93103 °F].
Comparison: Select the trigger condition.	

Storing the Configuration

Caution

Failing to complete this step will remove all changes you made after a power failure or a camera reboot.

Proceed as following to store the configuration:

- At the bottom of the dialog, click on **Set**.
- At the bottom of the dialog, click on **Close**. When prompted to store the configuration in the camera's permanent memory, click on **Yes**.

User Instructions

Intended Purpose

The MOBOTIX EST Thermal Camera is intended to be used by health care professionals and others to measure the relative temperature variations of the surface of the body to provide an initial body temperature assessment for triage use. The MOBOTIX EST Thermal Camera can be used in a health care facility or other non-medical locations, including airports, public buildings, etc.

IMPORTANT NOTES:

- The MOBOTIX EST Thermal Camera is not FDA-cleared or approved. It is authorized to be distributed in the U.S. for the duration of the COVID-19 public health emergency in accordance with FDA's Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 2020).
- The body temperature measurements from the MOBOTIX EST Thermal Camera should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19 or any other disease.

- Elevated body temperature in the context of use should be confirmed with secondary evaluation methods (e.g., a non-contact infrared thermometer (NCIT) or clinical-grade contact thermometer).
- Public health officials, through their experience with the device in the particular environment of use, should determine the significance of any fever or elevated temperature based on the skin telethermographic temperature measurement.
- The MOBOTIX EST Thermal Camera should be used to measure only one subject's temperature at a time.
- Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement.
- Always use the MOBOTIX EST Thermal Camera in a manner that is consistent with ISO/TR 13154: 2017: Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph.
- The camera performs an internal self calibration every minute, indicated by a yellow frame. During this time frame, the camera cannot be used for measurements (see figure below).



Fig. 19: Camera running internal self-calibration (once a minute)

System Components

Black Body Radiator	MOBOTIX EST Thermal Camera Mx-M16TB-EST

- The **black body radiator** is used to generate an area with a specific temperature that will be used by the MOBOTIX EST Thermal Camera.
- The **MOBOTIX EST Thermal Camera** measures the difference between the reference temperature of the black body in the **Offset Correction Reference Area** and the temperature of the hottest spot in the **Measurement Area**.



Fig. 20: Live image with Measurement Area and Offset Correction Reference Area (black body)

General Procedure Overview

- The operator will observe the monitor that shows the person's face and the black body reference area.
- Depending on the **frame color** of the camera image, the operator can decide on what to do next:



Things to Observe When Measuring

Make sure that the following conditions are met when operating the MOBOTIX EST Thermal Camera system:

- You have been properly trained on the system to avoid the risk of not detecting persons that be COVID-19-positive (false negatives).
- A person with administrative access to the camera is present once a day before starting measurements to recalibrate the system (see Preparing the Equipment for Measuring, p. 25).
- The measurement is only finished if a green or red frame indicates the result.
- The camera performs an internal self calibration every minute, indicated by a yellow frame. During this time frame, the camera cannot be used for measurements.
- The person's face is properly within the measurement area and covers as many pixels as possible to meet the Minimum Pixel Requirements, p. 29.

Things to Avoid When Measuring

• Avoid reflective backgrounds (for example, glass, mirrors, metallic surfaces) to minimize reflected infrared radiation.

- Avoid moving air in the measurement area as much as possible (no fans, vents, draft, etc.).
- Avoid strong lighting (for example, incandescent, halogen, and quartz tungsten halogen light bulbs).

Preparing the Equipment for Measuring

- Room temperature should be 20 to 24 °C/68 to 76 °F and relative humidity 10 to 50 percent.
- Turn on the entire system 30 minutes before use to warm it up.
- Make sure that the black body device is running properly.
- Calibration needs to be repeated daily or after any change of the system setup or environmental conditions to keep the stated performance level:
 - One to three persons should be measured first by an NICT or clinical thermometer and then by the MOBOTIX EST Thermal Camera.
 - If the temperature measured by the thermal camera differs from the one of the thermometer, adjust the **Temperature Offset** until both show approximately the same value. This step is required, because the body temperature measured by the clinical thermometer is usually 1 to 1.5 °C higher than the temperature measured at the inner cantus and to compensate for different environmental and setup-up factors.



Temperature Offset to adjust	Offset: measured skin temperature to body temperature.
	urce Temperature: perature of the used calibration source. For a detailed description
please refer to	the help page.

Fig. 21: Adjusting the Temperature Offset parameter

■ For testing the alarm condition, put an object with slightly higher temperature (above the **Thermal Range Lower Level** of the EST NOK profile) into the measurement area.



emperature Unit:	
Select the temperature	e unit.
hermal Range Lowe	r Level:
	e thermal range lower level [3439 °C][93103 °F].
hermal Range Uppe	r Level:
Enter the trigger for the	e thermal range upper level [3439 °C][93103 °F].
Comparison:	
Select the trigger cond	lition.

Preparing the Person for Measuring

The person handling the system should make sure that the following conditions are met.

- Any face obstructions must be removed before measurement (such as a mask, glasses, hat, headband, or scarf), hair must be pulled away from the face.
- The person's face must be clean and dry.
- The person does not have a higher or lower face temperature from wearing excessive clothing or head covers (for example, headbands, bandanas) or from using facial cleansing products (for example, cosmetic wipes).

 The person has waited at least 15 minutes in the measurement room or 30 minutes after exercising, strenuous physical activity, bathing, or using hot or cold compresses on the face.

Conducting the Measurement

Positioning the Person

Position the person at a fixed distance (1 to 1.5 m/3 to 5 ft) from the thermal imaging system, directly facing the camera:



Distance between person and camera: same as above

Measuring the Person's Temperature

- Measure only one person's surface skin temperature at a time.
- Make sure the person has prepared for the measurement as described in Preparing the Person for Measuring, p. 25:
 - Any face obstructions have been removed.
 - The face is clean and dry.
 - No excessive clothing, head covers, or the like.
 - Person has adjusted to room temperature.

- When measuring, follow these rules:
 - The black body must be fully visible and the reference window must be completely in the Offset Correction Reference Area (black body area; see figure below).



Fig. 22: Live image with Measurement Area and Offset Correction Reference Area (black body)

- The face must cover the full height of the thermal image and the eyes must be completely visible in the **Measurement Area** (see figure above).
- The person must not move while the system is measuring the temperature (up to six seconds). A colored frame (red or green) indicates the end of the measurement.

Note

The crosshairs in the figure above show the hottest temperature of the image. This spot should be where the **inner cantus** of one eye is located in the image (see enlarged area below).



The camera performs an internal self calibration every minute, indicated by a yellow frame. During this time frame, the camera cannot be used for measurements (see figure below).



Fig. 23: Camera running internal self-calibration (once a minute)

Depending on the **frame color** of the camera image, you can decide on what to do next:



If an increased temperature is detected (red frame), you should use a different method to confirm a fever. Public health officials can help you determine if the fever is a sign of infection.

Minimum Pixel Requirements

When setting up and operating the MOBOTIX EST Thermal Camera system, make sure that the minimum pixel requirements specified below are met.

Definitions

- Workable Target Plane: This is the entire measurement area in which the person's face should be fully inside.
- **Face Pixels**: Number of pixels within the *Workable Target Plane* that is covered of the person's face.

Item	Minimum Number of Pixels (Horizontally)	Minimum Number of Pixels (Vertically)
Workable Target Plane	320	240
Face Pixels	180	240

Technical Specifications

MOBOTIX EST Thermal Camera Mx-M16TB-EST

Note

The table below only lists the technical specifications of the MOBOTIX EST Thermal Camera that are different as compared to a standard MOBOTIX M16 Thermal Camera. For a list of technical specification of the standard camera, please see the PDF document available on Technical Specifications M16B.

Item	MOBOTIX EST Thermal Camera Mx-M16TB-EST
Laboratory Accuracy	< 0.5 °C
Stability and Drift	< 0.2 °C
Operating Temperature	

Black Body Requirements

Item	Value
Accuracy	± 0.03 °C
Stability	0.0005 °C
Surface temperature range	34 °C to 39 °C