VISIOFOCUS® PRO

06480

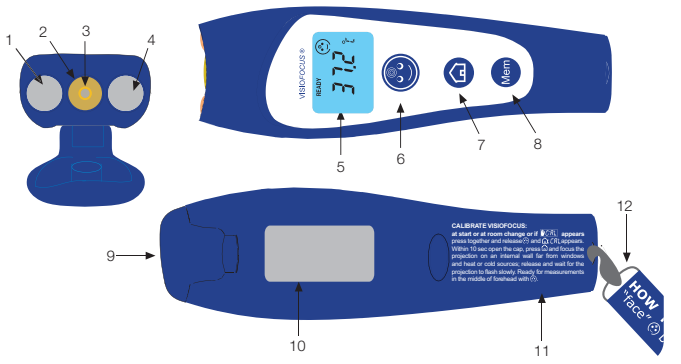
EN Operating instructions

Read these instructions carefully before using the thermometer

CAUTION: read the warnings

Rev. 9/6480-2021-09

Fig. **1**



1. Aiming light
2. Waveguide
3. Sensor (at the bottom of the waveguide)
4. Aiming light
5. LCD display
6. FACE button for forehead temperature readings
7. HOME button for other readings
8. MEMORY button (intended for reactivating the display backlight for 3 seconds, showing the last 9 measurements - if “Mem” is enabled - and to changing the settings/modes)
9. Protective cap
10. Label with serial number
11. Battery door (4 x AAA) with brief instructions
12. Special lanyard with additional brief instructions - to be worn around the neck

INTENDED USE: VisioFocus® PRO is an infrared medical thermometer intended for non-contact measurement of body temperature in children and adults (professional use). It can also be used to monitor the temperature of inflammations, ulcers, wounds (e.g. on diabetics), internal organs during surgery or to detect the temperature of intravenous fluid bags.

IMPORTANT: Each non-contact thermometer needs to be stabilized at the room temperature. VisioFocus PRO is equipped with 2 quick calibration systems, which allow the thermometer to quickly stabilize itself at the room temperature: the MQCS (Manual Quick Calibration System) and the AQCS (Automatic Quick Calibration System). See par. #8. Additionally, VisioFocus PRO foresees two different settings:
- "**NURS**" (default setting): the MQCS is requested and mandatory every 30 or 60 minutes, depending on the version. This setting is highly recommended for nurses who take many measurements moving from room to room as well as for any intensive use, such as in airports etc.
The "HOME" button is disabled in "NURS" mode. The "Mem" button is disabled and it can be enabled by changing the settings (see par. #7).
- "**DOCT**" mode: the MQCS is not mandatory, but if the thermometer's temperature is changing, the AQCS system is automatically activated and allows the rapid stabilization of the thermometer at room temperature: the display shows a countdown indicating the time required for its stabilization. To make a measurement it is necessary to wait for the end of the countdown without touching the device. Alternatively, at any time, it is possible to do the manual MQCS (suggested procedure).
Please note that if the thermometer set in "DOCT" is used too frequently and intensively (as in a hospital department) the system will ask the user to make the MQCS anyway (although with some delay).
In "DOCT" mode the "HOME" and the "Mem" buttons are enabled.
To change the setting from "NURS" to "DOCT" – and vice-versa – see par. #7.
ATTENTION: in some versions the DOCT setting is disabled; to enable it write to info@tecnimed.eu and specify the new use, the reason for change and the serial number.

1. FOREWORD

VisioFocus PRO is specifically studied to be used in hospitals, ambulances or clinic environments, but also airports, schools, factories, etc. in case of emergency and/or pandemic situations where it is necessary to take several fast and hygienic temperature readings. VisioFocus PRO is:
- hygienic: it never touches the patient, it does not need disinfection and does not require expensive disposable caps;
- comfortable: as it is totally not invasive, there is no need to wake up the patient or to ask for his cooperation while taking the temperature;
- accurate: detects the body temperature with constancy, repeatability and accuracy;

- unique: it cancels all variables which cannot be monitored by and do not depend on the healthcare worker (i.e. the presence of earwax during a tympanic measurement or. the displacement of the thermometer during the armpit or oral measurement).
With VisioFocus PRO the user can be sure of having the total control on all measurements made in the hospital ward.

2. WARNINGS

Read these instructions carefully before using the thermometer

2.1 Precautions

1. To avoid reading anomalies, use VisioFocus PRO according to this user manual.

2. Use VisioFocus PRO in a draft-free room, at a steady temperature between 16,0 and 40,0°C (60.8/104°F). It can also work if room temperature is in the ranges from -10,0 to 15,9°C (14.0/60.7°F) and from 40,1 to 45,0°C (104.1/113.0°F), but accuracy is not guaranteed - see also par. #13.

3. If the thermometer was stored in another room (or even in a drawer, etc…), before using it, run the manual calibration procedure (MQCS – par. #8). No matter if it is set in "NURS" or "DOCT".

4. To take the temperature on newborns in incubators, first stabilize the thermometer inside the temperature of the incubator (see par. 4.3)

5. Do not take a temperature reading in the following situations:

• if the subject is sitting in a draft or has come from another room that was ventilated or at a different temperature than the room where the thermometer is used; in these cases, wait for the stabilization of the subject's temperature or, in case it is not possible, take the measurement on the closed eyelid (par. 4.2);

• if, in the minutes before the reading, the subject has:

- been walking, running or exercising;
- been wearing a cap, hat or scarf;
- been cool sponged on the forehead;
- been exposed to agents that could alter forehead temperature, e.g. shower, shampoo, hair-drier, direct sunlight, fireplace heat, cold compresses therapies, air conditioner flow etc.; even touching the forehead can alter the temperature.

In all the above cases, interrupt the exposition of the subject to these agents and wait a few minutes for the forehead temperature to stabilize.

6. Changing the reading point will bring to different results. Therefore, remember, **always aim the projection on the same spot, precisely at the centre of the forehead** (midway between the top of the nose and the hairline) a**nd keep the thermometer perpendicular to the forehead. Do not take measurements on areas other than the centre of the forehead**, except for the case at #4.2.
ATTENTION: measurements on areas other than the centre of forehead (e.g. temples, neck, wrists) have not been clinically validated.

7. The temperature reading is taken in the area where the temperature is projected. Make certain that a 1 cm area is free all the way around the temperature projection area: it is of major importance to make sure that this area does not include eyebrows,

hair or clothing. If necessary, brush away any hair from the forehead but remember, this must be done a few minutes beforehand or the temperature reading will be higher than the actual body temperature.

8. When taking a temperature reading, please note that in the presence of oils, make-up or an oxygen mask, and in the case of elderly, the temperature detected may be lower than the actual body temperature (see also par. #4.2).

9. The forehead temperature reading can be affected by profuse sweating, superficial wounds or head injury.

10. Do not use the thermometer on a sweaty forehead, since the temperature reading would be unreliable. Read the par. #4.2.

11. In the cases at #7, #8, #9, take the temperature reading on the alternative area (read the par. #4.2.).

12. The gilt waveguide (fig. 1) is the most delicate part of the thermometer. It is composed of a gold-plated concave mirror that must be kept clean, crystal clear and intact. Any damage, dust or dirt will alter the temperature reading. To prevent dust or dirt infiltrations in the waveguide, always close the cap.

13. Do not handle the thermometer for longer than strictly necessary before taking the reading.

14. Do not use the thermometer in direct contact with the ear or other parts of the body.

15. Do not use the thermometer in direct contact with objects or liquids. Do not submerge the thermometer in water or other liquids and keep it away from sources of heat and out of direct sunlight. If water seeps into the thermometer, contact your Dealer im-mediately for Technical Service.

16. Do not use VisioFocus PRO on a subject making a call with a mobile or cordless telephone or in the presence of strong electromagnetic fields.

17. Avoid knocking and dropping it, and do not use it if damaged or if not functioning properly.

2.2 Attention

1. **Failure to observe the above-mentioned precautions (par. #2.1) may lead to very low or very high temperature readings**, which cannot be attributed to product's malfunctions.

2. **The aiming lights meet the photo-biological safety requirements outlined in standard EN 62471**. No harm can be caused should the aiming lights be accidentally pointed in the eyes: the beams are harmless!

3. The unit is a delicate measurement instrument and must not be used by little children. It is not a toy. Keep it out of the reach of children or persons with limited sensorimotor skills. Small parts can be ingested or inhaled.

4. If the patient's fidgeting makes it difficult to take a correct reading (especially in case of children), first become familiar with the device in order to take the measurement rapidly.

5. Since it never comes into contact with the body, VisioFocus PRO does not require any disposable protection covers.

6. ATTENTION: any serious incident that occurs in relation to the device should be reported to the manufacturer (info@tecnimed.eu) and the competent authority of your

country.

3. HOW IT WORKS

VisioFocus PRO detects the infrared radiation naturally emitted by the body and, in particular, from the human forehead.
The forehead is the ideal site for taking a temperature reading because it is crossed by the temporal artery which receives blood flowing from the aorta and carotid artery. Moreover, the forehead is the only part of the head in direct contact with the brain that is not covered by hair. The brain is the most important, most delicate organ in the human body and it is the most susceptible to injury from fever. The head is also the first part of the body to change its temperature as a fever rises and falls.

With each temperature measurement, your VisioFocus PRO takes a series of 125 readings a tenth of a second. Its sophisticated microprocessor then amplifies and processes this information along with the room temperature and shows the correct body temperature through the projection.

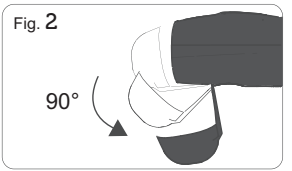
Please note that that **body temperature varies among individuals: moreover, individual temperature varies according to the measurement's site and throughout the day, also in response to physical or mental effort** (for example a baby's crying).
Moreover, the body temperature can be affected by the outside temperature and, depending on the type of reading taken, other factors may also come into play.

Due to heat dispersion from uncovered parts of the body, the actual temperature at the forehead is generally lower than that in covered zones. Therefore, when the "FACE" button is pressed, the VisioFocus PRO software automatically applies a correction factor and thus the resulting value is comparable to that given by other more usual temperature reading sites commonly used in the countries where the unit is sold - axillary, oral or rectal reading, or internal temperature reading -, according to the customer's choice.
Nevertheless, the reference value can be changed. Remember, an "oral" reading is generally 0,2°C (0.4°F) higher than an axillary reading while a "rectal" or "core" reading is 0,8°C (1.4°F) higher (see par. #7).

The VisioFocus PRO temperature reading taken on the forehead of a healthy person can range between 35,0 and 37,5°C (95.0 and 99.5ºF), in axillary mode, although in an adult it may even be below 35,0°C (95.0°F).

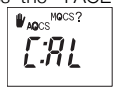
4. HOW to USE IT

4.1 Taking the body temperature: FOREHEAD



• At the first use, insert 4 AAA batteries as explained at #9.

• Open the protective cap by rotating it 90° (fig. 2).

• Press the "FACE" button. If the display shows 

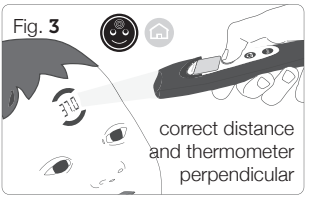
it indicates that it is necessary to stabilize the thermometer (AQCS or MQCS) before proceeding with the body temperature measurement.
Proceed as follows:

- press and release at the same time "FACE" and "HOME" buttons: the word CAL will appear on the display;
- within 10 seconds point the thermometer towards an internal wall (not the inside of an external wall), pressing the "HOME" button;
- release the button: lights will flash twice slowly and then the display will show the acquired temperature.

VisioFocus PRO is now ready to take a measurement.
For more details about MQCS see par. #8.

• **To take a reading**, press the "FACE" button and hold it down.
The two aiming lights turn on and you will begin to see the temperature reading, projected onto the forehead between two arches. The display starts to show the temperature, together with the symbol .

• While keeping the VisioFocus PRO **perpendicular to the center of the forehead**, move it in or back away from the forehead until the temperature reading is set squarely between the two arches (fig. 3).
If the thermometer is too far away, or too close, the temperature will not fall between the two arches (fig. 4 and 5).



• When you see the temperature at the midpoint between the two arches (fig. 6), the thermometer is at the right distance: release the button and keep the device steady while the lights flash. You can also read the temperature on the display, lit in light blue. If necessary, you can immediately take another reading.

Fig. **6**

• Close the protective cap.

When the thermometer remains idle for 20 seconds, it reverts to stand-by mode and will display the room temperature for 45 minutes (“DOCT” mode) or 30 minutes (“NURS” mode) before shutting off.

4.2 In case of sweating, oxygen mask, elderly patients: take the reading on the eyelid

In case of perspiring forehead, oxygen mask, elderly patients - especially with wrinkled forehead -, the measurement must be taken on the eyelid.

Proceed as you would do for a forehead reading using the “FACE” button (fig. 7).

No need to worry that the patient could open its eyes while you are taking the reading: the lights are harmless.

Precision is not guaranteed, but such reading can be considered a valid approximation of one’s body temperature.

Such reading is also indicated when one has oil or make-up on the forehead. or when the subject is not perfectly stabilized in the environment, like for example in the case of readings in airports or when entering in stations, companies, schools, emergency room.

Fig. **7**

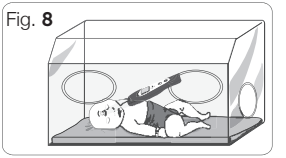
4.3 Use on newborns in incubators

Before taking the temperature on newborns in incubators, first you need to do the MQCS inside the incubator, as follows (see par. #8):

• press simultaneously “FACE” and “HOME” buttons. The word CAL appears on the display;

• within 10 sec open the protective cap and, handling the device according to the position of the forehead of the baby, introduce it in the incubator, press the “HOME” button and focus the lights on the inner wall of the incubator.

Fig. **8**



• Release the button. Now, using the “FACE” button, take the temperature on the forehead of the baby as described in par. 4.1 (fig. 8).

4.4 Readings of skin surface temperature

In “DOCT” mode, using the “home” button, VisioFocus PRO can also be used to:
1) monitor the temperature of inflammations, ulcers, wounds (e.g. on diabetics);
2) monitor the temperature of internal organs during surgery ensuring maximum hygiene thanks to the total absence of contact;
3) detect the temperature of intravenous fluid bags.
These measurements are not entirely accurate and must be considered as relative rather than absolute values. If taken on the skin, they can show the difference between two close or symmetrical areas.

Proceed as you would for a forehead reading **but press the “home” button**; the display will light up in green and show the “home” symbol .
NOTE: skin surface temperature is NOT body temperature. To measure body temperature, proceed as described in par. 4.1.

4.4 Other readings (non-medical use)

In “DOCT” mode, VisioFocus PRO can also be used to read the temperature of objects, food and liquids in the 1,0-80,0°C (33.8-176.0°F) temperature range.

Proceed as you would for a forehead reading **but press the “home” button**; the display will light up in green and will show the “home” symbol .
NOTE: this intended use is not subject to assessment by the Notified Body.

5. ROOM TEMPERATURE

When the thermometer is in stand-by, the room temperature and the flashing symbol appear and remain displayed automatically for 45 minutes (DOCT mode) or 30 minutes (NURS mode) after the last reading is taken.
To display the room temperature on the backlit display, while the thermometer is in stand-by mode, press the “Mem” button **once**: the display illuminates in orange showing the room temperature and the symbol flashing.

6. MEMORY FUNCTION

The “Mem” button (in DOCT mode or in NURS mode if it is enabled) lets you call up the last 9 temperature readings.

To activate this function, press the “Mem” button **twice**: the display will light up in violet and the value of the last reading will be shown accompanied by the number 1 and the symbol or depending on which button was used for that reading.
Pressing the button again calls up the second to last, third to last reading and so on, accompanied by the numbers 2, 3, etc.

7. HOW TO CHANGE the SETTINGS

Depending on where it is going to be sold, your thermometer leaves the factory as follows:

• preset to Celsius (**°C**) or Fahrenheit (**°F**)

• referred to oral ("**ORAL**") or rectal ("**RECTAL**") or axillary ("**AXILLA**") or internal temperature readings ("**CorE**") or only internal temperature readings (no symbol will be shown);

• **"NURS" mode**, (highly recommended if used by nurses, in ambulances and for any intensive use, such as in airports, factories, etc: "HOME" and "Mem" buttons are disabled; MQCS is requested and mandatory every 30 minutes) or
"DOCT" mode, (suggested for doctors' use: "HOME" and "Mem" buttons are enabled; AQCS is automatic and MQCS is optional);

• **≥37.0°C (≥98.6°F), ≥37.5°C (≥99.5°F) or ≥38.0°C (≥100.4°F) temperature level alarm**: you can choose the temperature threshold beyond which the thermometer alternates the projection of "Hi.2" and the temperature (for 7 seconds);

• **memory function** enabled (**MEM on**) or disabled (**MEM oFF**);

• **"air" function** enabled (**AIR on**) or disabled (**AIR oFF**): to be activated in case of high air conditioning in the room, to minimize the cooling effect on the subject/patient.

If necessary, these settings can be modified as follows:

1. while the thermometer is off or in stand-by mode, press the "Mem" Mem button and hold it down; after about 8 seconds the visualization on the display changes showing in rotation the following combinations:

The current settings are highlighted by the green backlight.

2. When the new desired setting appears, release the button. The purple backlight will turn green. Only one setting can be modified at a time.

Notes:

- The measurement of the body temperature must be taken always at the centre of the forehead (par. #4.1) or at the eyelid (par. #4.2), no matter what the current setting is: in fact, the axillary, oral, rectal or core settings provide a forehead temperature value that is a valid approximation of the axillary, oral or rectal/internal temperature respectively (see par. #3).

- if the thermometer was produced with the sole internal temperature setting, the ORAL, RECTAL, AX-ILLA and CORE settings would not be available for changing.

- In some versions the DOCT setting is disabled; to enable it write to info@tecnimed.eu and detail the new use, the reason for change and the serial number.

- Temperature level alarm: if you choose 37.0°C (98.6°F) the thermometer alternates, for 7 seconds, the projection of «Hi.2» and the temperature above 37.0°C (98.6°F); if you choose 37.5°C or 38.0°C (99.5°F or 100.4°F) the thermometer alternates, for 7 seconds, the projection of «Hi.2» and the temperature above 37.5°C or 38.0°C (99.5°F or 100.4°F).
- Air function: choose **on** in case of high air conditioning in the room (in case of high air conditioning in the room, when **AIR** appears, wait for **on** and release the button - the display will show alternately the word **AIR** and the temperature value); otherwise choose **oFF**.

8. ROOM TEMPERATURE CALIBRATION

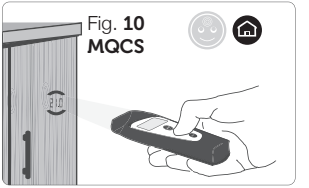
8.1 MQCS

The exclusive Manual Quick Calibration System (MQCS) promptly corrects the device's internal temperature and adapts it to the real temperature of the room where the reading is to be taken.
This system is extremely useful in case of prolonged use, when you need to keep the temperature of the thermometer steady, or in case you have to move quickly from one room to another – having different temperature – and you cannot wait too long to have the thermometer stabilized to room temperature: for example, if you move from room to room in a hospital department, especially if rooms have different exposures (North, South, etc.) or in case of ambulance use for homecare.
This system is very useful also if the device is kept in the pocket or if handled for long time for example during screening of passengers in airports.
Proceed as follows:
• open the protective cap and press and release the "FACE" and "HOME" buttons (fig. 9) simultaneously: the symbol CAL will appear, and the display will light up in blue.
• within 10 seconds focus the thermometer on an internal wall (not the inside of an external wall) or wardrobe with uniform temperature and at a point approximately 80/150 cm from the floor.

Fig. **9**
MQCS

Press the "HOME" button (fig. 10);
• once the right distance is reached (temperature value between the arches, fig. 5), release the button: the lights flash slowly and the display shows the room temperature.

Fig. **10**
MQCS



To ensure a reliable temperature reading, do not focus the thermometer on an outside wall, window, source of heating or cooling (radiator, air conditioner, lamp, computer, surface in contact with the human body, etc.).

The thermometer is now ready to take a reading and will keep the MQCS for 30 or 60 minutes (depending on the version). “MQCS” on the display indicates that manual quick calibration has been performed.
This system enables the thermometer to take accurate readings.
The MQCS can also be performed in case of count-down (see par. #8.2).
In “NURS” setting, the MQCS is mandatory every 30 or 60 minutes.
In “DOCT” setting, see the par. #8.2.

8.2 AQCS – countdown (only DOCT MODE)

In DOCT setting, if the thermometer is handled at length or if there is a significant temperature difference with respect to the room temperature, a count-down will appear on the display indicating that you should wait until automatic temperature calibration AQCS (Automatic Quick Calibration System) has been completed.
The countdown will continue updating as long as differences in temperature are detected (for example, because the thermometer has been continuously handled).
At this point you have 2 options:
1. make the MQCS as described in par. #8.1
or
2. without touching the thermometer, wait until the countdown has run its course and automatic quick calibration AQCS (countdown) is completed.
At the end of the countdown, the thermometer can take accurate readings.
“AQCS” appears on the display indicating that automatic quick calibration has been performed.

9. REPLACING the BATTERIES

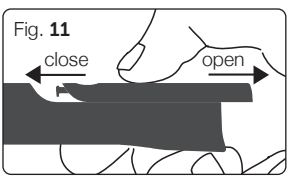


Fig. **11**

• Set your thumb in the oval hollow on the back of the unit, press down and slide the battery hatch out as shown in fig. 11.
• Remove the battery hatch.
• Remove the old batteries and dispose of them as required in the containers provided for this purpose.
• Insert 4 new AAA - LR03 batteries, preferably alkaline, carefully complying with the position indicated in their housing.
• To close the hatch, slide it in the opposite direction from which it was opened.
• After changing the batteries, let the thermometer stabilize for 20 minutes before taking a temperature reading, or run a manual quick calibration (MQCS, par. #8).
Remove the batteries if you do not expect to use the thermometer for a long time.

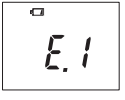
10. CLEANING and MAINTENANCE

CLEANING THE WAVEGUIDE: the thermometer waveguide (fig. 1) is very delicate. Therefore, when the thermometer is not being used, we recommend that you always keep the cap on. However, if you need to remove dust or dirt from the waveguide or sensor at its base, use a cotton swab that has been slightly dampened with alcohol. Remove all dirt and make certain that nothing accumulates at the bottom of the waveguide where the sensor is located. Do not use any other objects or liquids as the surface of the sensor could easily be scratched or damaged. Never let any excess liquid penetrate into the wave-guide and sensor.
CLEANING THE THERMOMETER BODY: use a soft cloth dampened with soap and water and possibly re-wipe with a sodium hypochlorite disinfectant.
A high disinfection level may be performed using neutral detergent and tuberculocidal virucide disinfectants (0,1% hypochlorite solution or 70% concentration of ethanol) as suggested by international guidelines.
DO NOT USE the thermometer for at least 30 minutes after cleaning.
When this thermometer is intensively used in hospitals or similar environments, a periodic calibration is recommended: contact the manufacturer or your dealer for more information on this matter.

11. MEANING OF DISPLAY MESSAGES

Messages about batteries

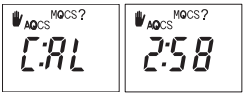
DESCRIPTION: during normal operation, the symbol appears on the display.
PROBLEM: the batteries are running low but it is still possible to take several readings.
SOLUTION: obtain new batteries for changing them when the signal "E.1" appears.



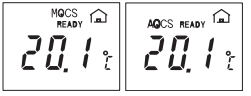
DESCRIPTION: "E.1" and the symbol appear on the display, or the unit does not turn on at all.
PROBLEM: the batteries are dead.
SOLUTION: remove the batteries immediately and replace them when necessary (see par. #9).

Messages about thermometer's stabilization

DESCRIPTION: the projection/display shows "E.8".
PROBLEM: the thermometer was moved before the light started flashing, or the area is subject to strong electromagnetic fields.
SOLUTION: wait until the lights flash before moving the thermometer; make certain that there are no mobile or cordless telephones in the vicinity.

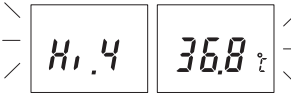


DESCRIPTION: the display shows a countdown (in minutes and seconds) and/or C:AL, a pictogram of a hand inviting to stop , and the messages AQCS and MQCS?
PROBLEM: the thermometer has not stabilized. The symbols prompt you to choose between:
SOLUTION:
- wait until the AQCS countdown has run its course without touching the thermometer, or
- perform an MQCS (par. #8).

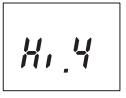


DESCRIPTION: while in stand-by mode, the room temperature displayed is accompanied by the symbol MQCS or AQCS.
MEANING: the thermometer has undergone quick automatic or manual calibration.

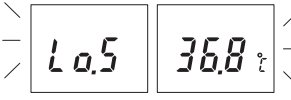
Messages about room temperature working range



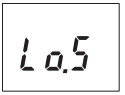
DESCRIPTION: when you press the "face" button, the projection/display shows "Hi.4" and the value alternately.
PROBLEM: the room temperature is between 40,1 and 45,0°C (104.1 and 113.1ºF).
SOLUTION: the temperature reading can be taken but accuracy is not guaranteed.



DESCRIPTION: the projection/display shows "Hi.4".
PROBLEM: the room temperature is too high (above 45,0°C/113.0°F).
SOLUTION: move to another, cooler site and, if you are taking the body temperature, wait for the stabilization of the device and of the subject.

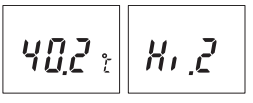


DESCRIPTION: the projection/display shows «Lo.5» and the value alternately.
PROBLEM:
- reading with "face" button: the room temperature is between 10,0 and 15,9°C (50.0 and 60.6ºF).
- reading with "home" button: the room temperature is between 5 and 9,9°C (41 and 48.2ºF).
SOLUTION: the temperature reading can be taken but accuracy is not guaranteed..

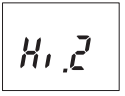


DESCRIPTION: the projection/display shows “Lo.5”.
PROBLEM: the room temperature is too low (below 10,0°C/50.0°F).
SOLUTION: move to another, warmer room and, if you are taking the body temperature, wait for the stabilization of the device and of the subject

Messages about the detected temperature



DESCRIPTION: the projection/display shows «Hi.2» and the value alternately.
MEANING: ATTENTION! The temperature is 40,0°C/104.0°F or more**.**

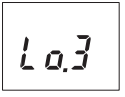


DESCRIPTION: the projection/display reads “Hi.2”.
PROBLEM:
- reading with “face” button: the temperature detected exceeds the limit for operation with this button (>43,0°C / >109.4ºF).

- reading with “home” button: the temperature detected exceeds the limit for unit operation (>80,0°C / >176.0°F).

SOLUTION:
- reading with “face” button: please make certain that you’ve pressed the correct button, with regard to the measured object, and that the warnings have been met.

- Reading with “home” button: the temperature cannot be taken.



DESCRIPTION: the projection/display shows “Lo.3”.
PROBLEM:
- reading with “face” button: the forehead temperature appears to be too low (<34,0°C / <93.2°F).

- reading with “home” button: the surface temperature read is below the operating limit (<1.0°C / <33.8°F).

SOLUTION:
- reading with “face” button: make certain the sensor is not soiled or damaged and that the subject has not come from a cold room.

- reading with “home” button: the temperature reading cannot be taken.

DESCRIPTION: the display shows «off».
PROBLEM: the button that you’ve pressed is disabled when the device is set in NURS.
SOLUTION: if you want to enable it. see par. #7.

12. TROUBLESHOOTING

1. The projection/display does not turn on: the batteries are completely dead or incorrectly inserted; replace or reinsert them (par. #9).

2.The temperature is not projected between the two arches: the unit is not at the correct distance; move the thermometer forward or back until the projected temperature falls precisely between the two arches (fig. 6).

3. The projected temperature is not clearly visible: there is too much light in the room or the batteries are low; cast a shadow over the subject or replace the batteries.

4.The sensor (fig. 1) is damaged or water has seeped into the thermometer: contact your Dealer right away for technical service.

5.The thermometer temperature reading is too low:

- make certain that the conditions outlined in the warnings (par. #2) have been met;
- check that the waveguide (fig. 1) is not soiled or damaged; if it is, clean it as indicated in par. #10 or contact your Dealer for technical service;
- check that the thermometer is perpendicular to the forehead as indicated in fig. 3.

6. The temperature reading is too high: make certain that the conditions outlined in the warnings have been met (par. #2).

7. The thermometer appears blocked or does not revert to stand-by after being idle for 20 seconds, or the aiming LEDs remain on after the button is released: reset the thermometer by removing and reinserting the batteries.

13. TECHNICAL CHARACTERISTICS

13.1 Measuring specifications

Resolution: 0.1

Room temperature working range:
- standard range: 16,0/40,0°C (69.8/104.0°F)
- extended range: -10,0/45,0°C (14.0/113°F) (1)

Body temperature readings

Measurement range: 34,0/43,0°C (93.2/109.4°F)
Accuracy:

from 34,0 to 35,9°C:	±0,3°C
from 36,0 to 39,0°C:	±0,2°C (2)
from 39,1 to 43,0°C:	±0,3°C

from 93.2 to 96.7°F:	±0,5°F
from 96.8 to 102.2°F:	±0,4°F (2)
from 102.3 to 109.4°F:	±0,5°F

Other readings
Measurement range: 1,0/80,0°C (33.8/176.0°F)

Accuracy:

from 1,0 to 33,9°C:	±0,3°C
from 34,0 to 35,9°C:	±0,3°C
from 36,0 to 39,0°C:	±0,2°C
from 39,1 to 43,0°C:	±0,3°C
from 43,1°C to 80,0°C:	±1,0°C

from 33.8 to 93.1°F:	±1.8°F
from 93.2 to 96.7°F:	±0,5°F
from 96.8 to 102.2°F:	±0,4°F
from 102.3 to 109.4°F:	±0,5°F
from 109.5 to 176.0°F	±1.8°F

Ambient temperature (shown when in stand-by)
Measurement range: 5,0/45,0°C (41.0/113.0°F)
Accuracy: ±1.0°C (±1.8°F)

(1) In rooms where the temperature is between -10 and 15,9°C (14 and 60.7°F) and when the FACE button is used, or in rooms where the temperature is between -10 and 9,9°C (14 and 49.9°F) and when the HOME button is used, accuracy and the operating range are not guaranteed and the message "Lo.5" and the temperature value are displayed alternately. In rooms where the temperature is between 40,1 and 45,0°C (104.1 and 113.0°F), accuracy and the operating range are not guaranteed and the message "Hi.4" and the temperature value are displayed alternately.
(2) ASTM E1965-98-(2016) laboratory accuracy requirements in the display range of 37 to 39°C (98 to 102°F) for IR thermometers is ±0,2°C (±0.4 °F), whereas for mercury in-glass and electronic thermometers, the requirement per ASTM Standards E 667-86 and E 1112-86 is ±0,1°C (±0.2°F).

13.2 General specifications

- Power supply: 4 AAA (LR03) alkaline batteries - 1.5 V (included)
- Life of high quality batteries: up to 3 years or 30,000 readings (depending on use)
- Dimensions: 144 x 43,5 x 21,5 mm (5.67 x 1.71 x 0.85 inches) - including cap.
- Weight: 98 gr. (3.46 oz.) - batteries included
- Distance from the subject: calculated using an optical aiming system (approx. 6 cm/2.36 inches).
- Large, clearly visible, backlit display in 5 colors: light blue, green or violet, depending on the button used (respectively, "face", "home" or "Mem"); orange and blue depending on the function (respectively, room temperature – par. 5 and MQCS – par. 8)
- Expected life: 10 years.
- Atmospheric pressure range of operating conditions: from 700 hPa to 1,060 hPa.
- Relative humidity range of operating conditions: from 15% to 93%, non-condensing.
- Protection degree IP22
- Keep in a clean, dry place, preferably at a temperature ranging between +16 and

+40°C (60.8 and 104°F). Store at a temperature not lower than -25°C (-13°F) or higher than +70°C (158°F).
- Internally powered equipment; mode of operation: continuous.
- The VisioFocus PRO LEDs emit low light radiation in compliance with EN 62471.
- Measuring system tested in hospitals, private clinics and medical offices. Clinical accuracy, characteristics and procedures are available from the manufacturer on request.

13.3 Declaration of Conformity UE

Tecnimed srl, P.le Cocchi, 12 - 21040 Vedano Olona (VA) - Italy is the manufacturer of the VisioFocus PRO 06480 non-contact clinical infrared thermometer.
TECNIMED guarantees that VisioFocus PRO 06480 meets all the provisions applicable in the Regulation (UE) 2017/745.
VisioFocus PRO 06480 is a class IIa medical device manufactured following appropriate production processes in accordance with an EN ISO 9001:2015 and EN ISO 13485:2016 certified Quality System, with GMP requirements and with the following standards: EN 60601-1, EN 60601-1-2, EN 60601-1-6, EN 60601-1-11, EN 62366, EN 62471, EN 62304, EN 80601-2-56, ASTM E 1965-98.
Full responsibility for the conformance of this product to the standards is assumed by Tecnimed srl, P.le Cocchi, 12 - 21040 Vedano Olona (VA) – ITALY.
Complete Declaration of Conformity is available from the manufacturer on request: info@tecnimed.eu

SYMBOLS on the thermometer, on its packaging or in this user manual:

	Manufacturer	UDI	UDI code
MD	Medical Device	SN	Serial Number
CE 0051	European Conformity mark. The product conforms to: - Regulation (EU) 2017/745 on medical devices. The Conformity to the Regulation (EU) 2017/745 applies to the medical use only and it is verified by the notified body no. 0051 (IMQ). - 2014/30/EU directive for the non-medical use (ref. par. 4.4)		
	Operating instructions		Refer to the instruction manual
	CAUTION: read the warnings	⎓	Direct current

	Applied part: type BF		Recyclable material
IP22	Protected against insertion of objects >12,5 mm (>0.5 inches) and against vertical dripping water when tilted up to 15°		
	Crossed-out wheeled bin (WEEE and batteries) **Instructions for disposal**: this product contains electrical and electronic components and batteries that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.		

WARRANTY

Tecnimed s.r.l. guarantees this product against any lack of conformity for 24 months as of the date of purchase (indicated on the cash register receipt or other fiscal document). Follow the instructions given by your Dealer for the technical service procedures.

This warranty does not cover the batteries and any damage caused by defective or run down batteries or damage to the casing due to carelessness or improper use. The warranty is also voided if:

- the product is tampered with, damaged or used improperly;
- the label on the back bearing the serial number is removed, damaged or rendered illegible;
- the product is opened or repaired by unauthorized personnel;
- the product has been damaged due to non-compliance with the instructions given in this manual.

If Technical Service is required, contact the Manufacturer or your Dealer.

In case the Product was purchased through an Online-store, warranty service can only be provided through the Internet Seller, where the product was purchased. In case of any lack of conformity, the product will be either repaired or replaced, as decided by the Manufacturer or Dealer, at their sole discretion. Any repaired or replaced product does not extend the original warranty beyond the period of 2 years from original date of purchase.

If, after technical evaluation, the Product is found not to be covered by the terms and conditions of this Warranty (because no lack of conformity is found), Tecnimed reserves the right to charge a handling fee for technical check and delivery.

Under no circumstance may Tecnimed be held responsible for damages related to the improper use of the product or for costs exceeding the original price of the product.

Product name: **VisioFocus® PRO**
Model: **06480**

Classe IIa medical device

Patents: US 7,001,066 - US 7,651,266B2 - US 8,128,280 - US 8,821,010 - EP 1.283.983 - EP 1.886.106 - EP 2577242(B1) - KR 10-1898897 - CN 103026192B.
Other international patents pending.

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