

VISIOFOCUS[®]

SMART

06470



EN

Operating instructions



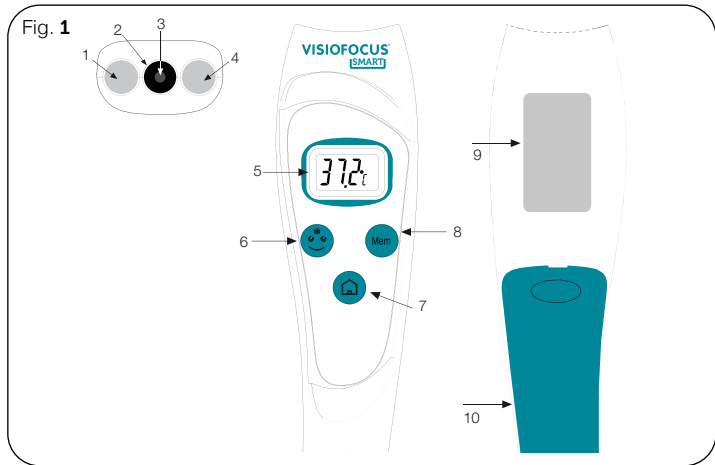
Read these instructions carefully before using the thermometer



CAUTION: read the warnings



Rev. 9/6470-2021-09



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
9. Label with serial number
10. Battery door (4 x AAA)

INTENDED USE: VisioFocus® SMART is an infrared medical thermometer intended for non-contact measurement of body temperature in children and adults. It can also be used to monitor the temperature of inflammations, ulcers, wounds (e.g. on diabetics and under medical supervision).

1. FOREWORD

Dear Client, thank you for buying VisioFocus SMART, the evolution of Thermofocus® - the world's first non-contact thermometer - and of VisioFocus®.

VisioFocus SMART is truly easy to use. It is capable of measuring a child or adult's temperature without ever coming into contact with the skin: just bring it close to the forehead, at the distance that the thermometer itself will tell you. VisioFocus SMART does not need to be placed in any parts of your child's body. If your baby is sleeping, you can use VisioFocus SMART without waking him up; and, if the child is awake, VisioFocus SMART will not bother him.

2. WARNINGS



Read these instructions carefully before using the thermometer

2.1 Precautions

1. To avoid reading anomalies, use VisioFocus SMART according to this user manual.
2. Use VisioFocus SMART in a draft-free room, at a steady temperature between 16,0 and 40,0°C (60.8 and 104.0°F). VisioFocus SMART can also work if room temperature is in the ranges 10,0-15,9°C (50.0-60.7°F) and 40,1-45,0°C (104.1-113.0°F), but accuracy is not guaranteed - see also par. #13.
3. If the device comes from a room having an ambient temperature different from the one of the room in which you are taking the reading (or even from a drawer, etc.), it needs to be stabilized. Do the MQCS before using it (see par. #8). As alternative, wait at least 5 minutes or the end of the countdown (if any), for the temperature to stabilize through the AQCS (see par. #8), without touching the device.
4. Do not take a temperature reading if the person is sitting in a draft or if the subject has:
 - been walking, running or exercising;
 - come from another room that was ventilated or at a different temperature than the room where the thermometer is used;
 - been wearing a cap, hat or scarf;
 - been exposed to agents that could alter forehead temperature, e.g. shower, shampoo, hair-drier, sponging, etc.

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.

5. 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) **and keep the ther-**

momometer 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.**

6. The temperature reading is taken in the area where the temperature is projected. Make certain that a 1 cm (0,4 inches) 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.

7. 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).

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

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

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

11. The dark disc at the bottom of the waveguide (fig. 1) is the window of the sensor and the most delicate part of the thermometer. It must be kept clean and intact. Any damage, dust or dirt will alter the temperature reading.

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

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

14. 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 immediately for Technical Service.

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

16. 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. Using this thermometer should not substitute medical consultation. Tell your phy-

sician what type of thermometer you are using and in which part of the body the temperature reading was taken.

5. If the child's fidgeting makes it difficult to take a correct reading, first become familiar with the device and, anyway, turn the aiming lights on before bringing the thermometer close to the forehead.

6. When taking your own temperature, use a mirror, or the black screen of a smartphone, or, if you have a child over six years of age, you can teach him how to use the device.

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

8. 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 SMART detects the infrared radiation coming from the human body.

The forehead is an ideal site for taking a temperature reading, as it is crossed by the temporal artery and in direct contact with the brain. 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 SMART takes a series of 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 SMART 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. An "oral" reading is generally 0,2°C (0.4°F) higher than an "axillary" reading while a "rectal" or "internal" reading is 0,8°C (1.4°F) higher (see par. #7).

Remember, the measurement of the body temperature should 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 or rectal/internal settings provide a forehead temperature value that is a valid approximation of the axillary, oral or rectal/internal temperature respectively (see par. 7).


The VisioFocus SMART temperature reading taken on the forehead of a healthy per-

son can range between 35 and 37,5°C (95 and 99.5°F), although in an adult it may even be below 35°C (95°F) (in axillary mode). To correctly judge a fever, you need to know the usual temperatures of your family members when they are in good health condition and at various times of the day. To help you with this, fill out the table “FAMILY MEMBER TEMPERATURES at different times of day and when in good health conditions” and keep it as a reference: <https://www.tecnimed.it/download/Tables.pdf>

4. HOW to USE IT

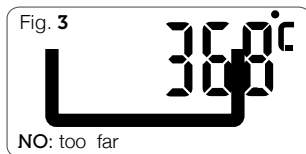
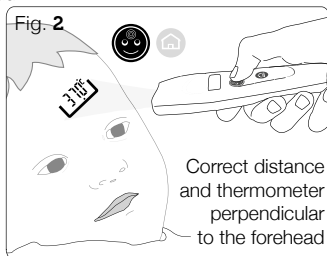
4.1 Taking the body temperature: FOREHEAD

- At the first use, insert 4 AAA batteries as explained at #9.
- Approach VisioFocus SMART to the forehead.

- 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 or overlapping the sides of the projected rectangle shape.

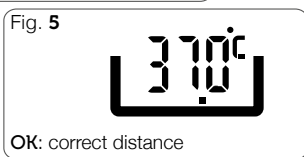
- While keeping the VisioFocus SMART **perpendicular to the center of the forehead**, move it in or back away from the forehead until the temperature reading is positioned evenly inside the rectangle (fig. 2).

If the thermometer is too far away, or too close, the temperature will overlap the sides of the rectangle (fig. 3 and 4).



- When you see the temperature reading sits **evenly inside the rectangle** (fig. 5), the thermometer is at the right distance: release the button and keep the device steady while the lights flash.

If necessary, you can immediately take another reading.



When the thermometer remains idle for 20 seconds, it reverts to stand-by mode and will display the room temperature for 4 hours before shutting off. If you want it to shut down immediately after the 20 second interval, read the chapter on “Energy Saving”

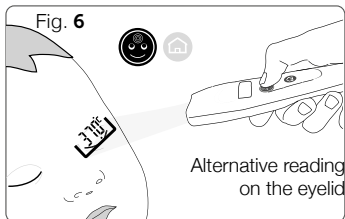
mode (par. #7).

4.2 In case of sweating: take the reading on the eyelid

At times, the forehead can show signs of sweat, for example as a fever drops, and this can result in a low reading. Dry the forehead is not enough. In this case, you can take the temperature reading, again at distance on the closed eyelid (fig. 7).

Proceed as you would do for a forehead reading. No need to worry that your child 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. In adults, such reading is also indicated when one has oil or make-up on the forehead; moreover it is also valid for the elderly as well as in case of oxygen mask.



4.3 Readings of skin surface temperature

VisioFocus SMART can also scan the skin surface temperature: this can be useful to monitor the temperature of inflammations, ulcers, wounds (for example on diabetic patients and under control of your physician).

Proceed as you would do for a forehead reading **but press the “home”**  **button.**

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)

VisioFocus SMART 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.

For example, you can take the temperature of:

- 1 a baby's feed bottle (fig. 8),
2. food,
3. bathwater.


Mix liquids well before taking the reading and, with hot liquids or foods, take the reading quickly to prevent condensation from forming on the lens and wait 30 min. before taking another reading.



Proceed as you would do for a forehead reading **but press the “home”**  **button.**

NOTE: this intended use is not subject to assessment by the Notified Body.







5. ROOM TEMPERATURE

When the thermometer is in stand-by mode (“Peak Performance” - see par. #4.1 and #7), the room temperature remains displayed automatically for 4 hours after the last reading is taken and the symbol  flashes.

To display the room temperature when the display is off, press the “Mem” button  once: the display shows the room temperature and the symbol  flashing.

6. MEMORY FUNCTION



The “Mem”  button lets you call up the last 9 temperature readings.

To activate this function, press the “Mem”  button **twice**: 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.

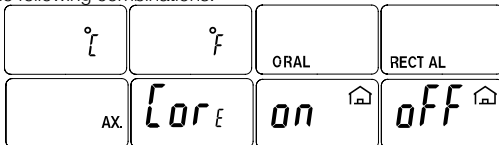
7. HOW TO CHANGE the SETTINGS

Depending on where it is 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 (“AX.”) or internal temperature readings (“CorE”) or only internal temperature readings (no symbol will be shown);
- with display off when in stand-by mode (“Energy Saving”, off ) or always on (“Peak Performance” - on ).

If necessary, these settings can be modified as follows:

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



2. When the new desired setting appears, release the button. Only one setting can be modified at a time.


Note:

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

8. ROOM TEMPERATURE CALIBRATION

If the thermometer is handled at length or if there is a significant temperature difference with respect to the room temperature, a countdown will appear on the display indicating that you should wait until automatic temperature calibration has been completed.




Pressing the “face”  button, the projection shows “CAL”.

At this point you have 2 options:

1. **Automatic Quick Calibration System (AQCS):** without touching the thermometer, wait until the countdown has run its course and automatic quick calibration is completed. The countdown will continue updating as long as differences in temperature are detected (for example, because the thermometer has been continuously handled). At the end of the countdown, the thermometer can take sufficiently accurate readings. When the thermometer is in stand-by mode, “AQCS” appears on the display indicating that automatic quick calibration has been performed.

2. **Manual Quick Calibration System (MQCS):** the alternative is to promptly correct the thermometer temperature, adapting it to the real temperature of the room where the reading has to be taken.

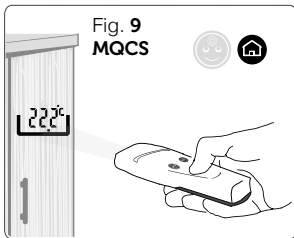
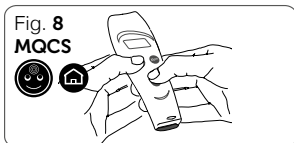
Proceed as follows:

- press the “face”  and “home”  buttons (fig. 8) simultaneously: the symbol CAL will appear.
- 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 (30 to 60 inches) from the floor. Press the “home”  button (fig. 9);
- once the right distance is reached (temperature value inside the rectangle, fig. 5), release the button: the lights flash **slowly** and the display shows the room temperature.

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 minutes.

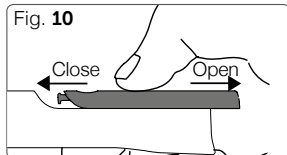
Manual quick calibration (MQCS) can also be performed without the countdown if, for



example, you are moving between rooms with different temperatures. This system, too, enables the thermometer to take sufficiently accurate readings. In this case, "MQCS" appears on the display indicating that manual quick calibration has been performed. The MQCS is possible only if the room temperature is in the 10,0-45,0°C (50.0-113.0°F) temperature range.

9. REPLACING the BATTERIES

- 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. 10.
- 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

CLEANING THE WAVEGUIDE: the thermometer waveguide (fig. 1) is very delicate and must be kept clean. Store the device in a dry, clean place, away from dust. 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.

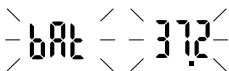
Remove all dirt and make certain that nothing accumulates at the bottom of the waveguide where the sensor is located. Do not use any other objects or liquids as the surface of the sensor could easily be scratched or damaged. Never let any excess liquid penetrate into the waveguide and sensor.

CLEANING THE THERMOMETER BODY: use a soft cloth dampened with soap and water and possibly re-wipe with a sodium hypochlorite disinfectant.

DO NOT USE the thermometer for at least 30 minutes after cleaning.

11. MEANING OF DISPLAY MESSAGES

Messages about batteries



DESCRIPTION: during normal operation, the symbol “bAt” appears.

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” appears, 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).

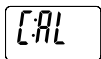
Messages about thermometer's stabilization



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.

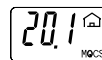


DESCRIPTION: the display shows “C:AL” and/or a count-down (in minutes and seconds).

PROBLEM: the thermometer has not stabilized. The symbols prompt you to choose between:

SOLUTION:

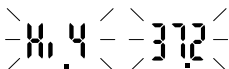
- wait until the AQCS countdown has run its course without touching the thermometer, or
- perform an MQCS (par. #8).




DESCRIPTION: while in stand-by mode, the room temperature displayed is accompanied by the letters 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 113.1°F).

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 60.6°F).

- reading with "home"  button: the room temperature is between 5 and 9,9°C (41 and 48.2°F).

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 if you've pressed the "face"  button or below 5,0°C/41.0°F if you've pressed the "home"  button).

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 when you press the "face"  button.


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 / >109.4°F).

- 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 reading cannot be taken.



Lo3

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.

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 inside the rectangle: the unit is not at the correct distance; move the thermometer forward or back until the projected temperature falls precisely inside the rectangle (fig. 5).

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. 2.

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. Measuring specifications

Resolution: 0.1

Body temperature readings

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

Room temperature working range:

- standard range: 16,0/40,0°C (69.8/104.0°F)

- extended range: 10,0/45,0°C (50.0/113°F) ⁽¹⁾

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

⁽¹⁾ When the FACE button is used in rooms where the temperature is in the range 10,0-15,9°C (50.0-60.7°F) or 40,1-45,0°C (104.1-113.0°F), accuracy and operating range are not guaranteed, and the temperature value is displayed alternately with the message "Lo.5» or "Hi.4" respectively.

⁽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).

Other readings

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

Room temperature working range:

- standard range: 16,0/40,0°C (69.8/104.0°F)

- extended range: 5,0/45,0°C (41.0/113°F) ⁽³⁾

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 ⁽²⁾
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 ⁽²⁾
from 102.3 to 109.4°F:	±0,5°F
from 109.5 to 176.0°F:	±1.8°F

⁽³⁾ When the HOME button is used in rooms where the temperature is in the range 5,0-9,9°C (41.0-49.9°F) or 40,1-45,0°C (104.1-113.0°F), accuracy and operating range are not guaranteed, and the temperature value is displayed alternately with the message "Lo.5» or "Hi.4" respectively.

Ambient temperature (shown when in stand-by)

Measurement range: 5,0/45,0°C (41.0/113.0°F)

Accuracy: $\pm 1.0^{\circ}\text{C}$ ($\pm 1.8^{\circ}\text{F}$)

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: mm 138 x 43,5 x 21,5 (inches 5.67 x 1.71 x 0.85)
- Weight: gr. 90 (3.17 oz) - (included batteries)
- Distance from the subject: calculated using an optical aiming system (approx. 6 cm/2.36 inches).
- 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.
- 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 SMART 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 SMART 06470 non-contact clinical infrared thermometer.

TECNIMED guarantees that VisioFocus SMART 06470 meets all the provisions applicable in the Regulation (UE) 2017/745.














VisioFocus SMART 06470 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 code
	Medical Device		Serial Number
 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
	Keep dry		
	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® SMART**
Model: **06470**

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.

CE
0051



Manufactured in Italy by:

TECNIMED srl

P.le Cocchi, 12 -21040 Veduggio O. (VA) - ITALY

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