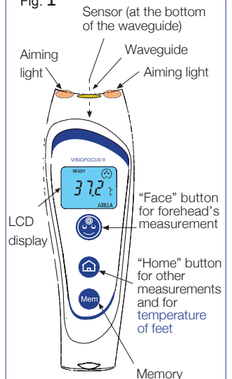
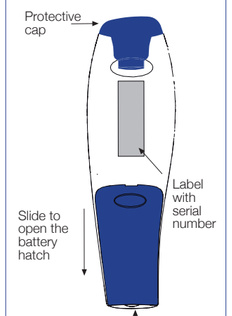
Fig. 1





VISIOFOCUS

06400

USER MANUAL

Read carefully the instruction before using the thermometer

Follow instructions for use

ATTENTION: read the warnings

Class IIa medical device
Patents no. 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) and other international Patents Pending.

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VisioFocus is an infrared thermometer intended for intermittent measurement of human body temperature in people of all ages. It takes the BODY TEMPERATURE with the FACE button (measuring area: forehead).
It can also take the SKIN (SURFACE) TEMPERATURE with the HOME button (example of measuring area: your foot; this will help you monitoring the inflammation previous to neuropathic and diabetic foot ulceration. **Note the SKIN (SURFACE) TEMPERATURE is NOT your BODY TEMPERATURE.**

1. INTRODUCTION

Dear Client, thank you for buying **VisioFocus**, the evolution of Thermofocus® - the world's first non-contact thermometer. **VisioFocus** is very easy to use. It is capable of measuring the temperature without ever coming into contact with the skin: just bring it close to the forehead (for BODY TEMPERATURE) or to the skin (for SURFACE TEMPERATURE), at the correct distance that the thermometer itself will show you.

2. WARNINGS

Read carefully before using **VisioFocus**

2.1 General Precautions

1. Use **VisioFocus** in a draft-free room, at a steady temperature between 16 and 40°C (60.8-104°F).
2. Changing the reading point will bring to different results.
3. The temperature reading is taken from the area where the temperature is projected. If necessary, remove any caps or clothing: this must be done a few minutes beforehand or the temperature reading will be higher than the actual temperature.
4. The dark disc at the tip of the device (fig. 1) is the window of the sensor and the most delicate part of the thermometer. It must be kept clean as any damage, dust or dirt will alter the temperature reading. Please do not touch the sensor.
5. Do not handle the thermometer for longer than strictly necessary before taking the reading.
6. Do not use the thermometer in direct contact with the ear or other parts of the body.
7. Do not use the thermometer in direct contact with objects or liquids. Do not submerge it 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 Distributor immediately for Technical Service.
8. Do not use **VisioFocus** on a subject making a call with a mobile or cordless telephone or in the presence of strong electro-magnetic fields.
9. Avoid knocking and dropping it, and do not use it if damaged or if not functioning properly.

2.2 Precautions WHEN READING BODY TEMPERATURE

1. 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. You can wait at least 5 minutes, without touching the device, for the temperature to stabilize, or you can stabilize the device manually: see par. #7.
2. 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-dryer, direct sunlight, fireplace heat, cold compresses therapies, strong air conditioner flow, etc.;
In all the above cases, interrupt exposure of the subject to these agents and wait a few minutes for the forehead temperature to stabilize.
3. 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 thermometer perpendicular to the forehead. **Do not take readings on areas other than the centre of the forehead**.
4. The temperature reading is taken from the area where the temperature is projected. Ensure this area does not include eyebrows, hair or clothing (such as caps or hats). 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.
5. When taking a temperature reading, remember 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.
6. The forehead temperature reading can be affected by sweating, superficial wounds o head injury. **Do not use the thermometer on a sweaty forehead,** since the temperature reading would be unreliable.

2.3. Attention

1. **Failure to observe the above mentioned precautions may lead to very low or very high temperature readings, which cannot be attributed to the product malfunctions.**
2. The aiming lights meet the photo-biological safety requirements outlined in standard EN 62471.
3. The unit is a delicate measurement iinstrument and must not be operated by little children. It is not a toy. Small parts can be ingested or inhaled.
Keep it out of the reach of children or persons with limited sensorimotor skills.
4. Using this thermometer should not substitute medical consultation. Tell your physician 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 turn the aiming lights on before bringing the thermometer close to the forehead.
6. When taking your own forehead temperature, use a mirror, or a smartphone to get your own image, or, you can teach a child over six years of age how to use **VisioFocus**.
7. Since it should not come into contact with the body, **VisioFocus** does not require any additional protection covers.

3. HOW IT WORKS

VisioFocus detects the infrared radiation coming from the human body.

Body Temperature Measurement

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** 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.

It is important to remember that body temperature varies amongst individuals. Moreover, individual temperature varies according to the measurement's site and throughout the day and also in response to physical or mental effort (for example a baby's crying). The body temperature can also be affected by the outside temperature and other factors depending on the type of reading taken.

Due to heat dispersion from uncovered parts of the body, the actual temperature of the forehead is generally lower than that in covered zones.
Therefore, when the "face" button is pressed, the **VisioFocus** 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 core 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°F) higher (see par. #8).
The **VisioFocus** temperature reading taken on the forehead of a healthy person can range between 35 and 37,5°C (95 and 99.5ºF), although in an adult it may even be below 35°C (95°F) (in axillary mode).
To correctly interpret the core body temperature as given by the device, you need to know the body temperatures of you and your family members when they are in good health condition and at various times of the day. To help you with this, download the table from www.visiofocus.com and dully fill it in.

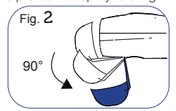
Surface Temperature Measurement

When you press the "home" button the thermometer reads the skin temperature **(which is not the body temperature)** of any area of your body. Knowing the temperature of your feet may be useful as an early warning to detect the inflammation previous to foot ulceration and other complications of the diabetic foot as indicated by clinical evidence, by measuring the temperature on the sole of the foot in the morning and evening.

4. HOW TO USE

• At the first use, insert 4 AAA batteries as explained in par. #12.
• Open the protective cap by rotating it 90°.

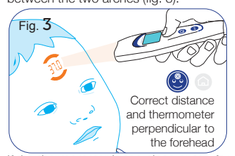
Fig. 2



4.1 Taking the body temperature: FOREHEAD

• Approach **VisioFocus** to the forehead.
• Press the "face" button and hold it down. The two aiming lights go on and the temperature reading will be projected onto the area of the body between two arches.
• While keeping the VisioFocus perpendicular to the area of the body, move it in or back away from the area until the temperature reading is set squarely between the two arches (fig. 3).

Fig. 3



If the thermometer is too close or too far away, the temperature will not fall between the two arches (fig. 4 and 5).

Fig. 4



Fig. 5



• When you see the temperature at the midpoint between the two arches (fig. 6), the thermometer is at the right distance.

Fig. 6



Release the button and keep the thermometer steady while the lights flash. You can also read the temperature on the display screen, lit in light blue. If necessary, you can immediately take another reading.
• 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 4 hours before shutting off ("Peak Performance" mode). If you want it to shut down immediately after the 20 second interval, set it on "Energy Saving" mode (see par. #8).

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 temperatire reading. Drying the forehead is not enough. In this case, you can take the temperature reading on the closed eyelid. No need to worry that the child could open his eyes while you are taking the reading as the lights are harmless.
Precision is not guaranteed, but such reading can be considered a valid approximation of the body temperature. This reading is also valid for adults with make-up on or have an oily forehead and elderly persons.

4.3 Taking the temperature of OTHER READINGS

VisioFocus can also be used to read the SURFACE TEMPERATURE as well as the temperature of objects, food, liquids in the 1-80°C temperature range.
Proceed as you would do for a forehead reading (par. #4.1), but press the "home" button ; the projection will appear on the surface.
This thermometer can read:
1. Temperature of your foot (fig. 7).

Fig. 7



REMEMBER: this will be the temperature of the skin of your foot (not your body temperature), in the area where the temperature is projected. You can move the projection in different areas of your foot or you can aim the thermometer to the other foot: differences in the detected temperature between two close or symmetrical areas may suggest possible inflammation or any other problem which may cause an alteration of the surface skin temperature.
2. Temperature of a wound inflammation, scar (for medical use). This thermometer can be also used on open wounds or burns, ensuring maximum hygiene thanks to the total absence of contact.
3. Temperature from the bath water, the baby's feeding bottle, the food, etc. In the above cases, mix the liquid well before taking the reading. 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;
4. Room temperature, pointing the thermometer against a wall or a piece of furniture (see also par. #5);

5. AMBIENT TEMPERATURE

When the thermometer is in stand-by mode ("Peak Performance" - see par. #4.1 and #8), the room temperature remains displayed automatically for 4 hours after the last reading is taken and the symbol flashes.
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” (Mem) button calls up the last 9 temperature readings (memory function). Proceed as follows: 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 (Mem) again calls up the second to last, third to last reading and so on, accompanied by the numbers 2, 3, etc.

7. ROOM TEMPERATURE CALIBRATION

ONLY BODY TEMPERATURE (forehead readings) 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” 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 handled). At the end of the countdown, the thermometer can take sufficiently accurate readings.

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 is to be taken.

Proceed as follows:

• press the “face” and “home” buttons (fig. 8) simultaneously: the symbol CAL will appear and the display will light up in blue. Open the cap.

• 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

Fig. 8
MQCS

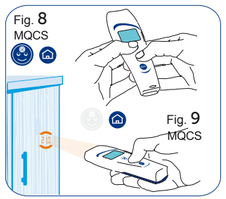


Fig. 9
MQCS

• once the right distance is reached (fig. 5), release the button: the projection will flash **slowly** showing 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 15 minutes.

Manual quick calibration (MQCS) can also be performed without the thermometer’s suggestion if, for example, you moved through rooms having different temperatures. This system, too, enables the thermometer to take sufficiently accurate readings.

The MQCS is possible only if the room temperature is in the 16-40°C (60.8-104°F) temperature range.

8. HOW to CHANGE the SETTINGS

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

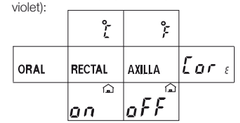
• preset to Celsius (°C) or Fahrenheit (°F)

• referred to axillary (“AX.”), oral (“ORAL”) or rectal (“RECTAL”) or internal temperature readings (“CorE”) - (NOTE: these settings are related only to BODY TEMPERATURE – FACE button: forehead readings);

• 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:

• while the thermometer is off or on stand-by, press and hold the “Mem” button; after about 8 seconds the display changes, showing the settings in sequence (in some versions the display is backlit in green in correspondence of the active settings; while for non active settings the display is always backlit in violet):



• when the desired setting appears, release the button. In some versions, the colour of the display will change from violet to green.

Only one setting can be modified at a time.

Note: the measurement of the body temperature (FACE button: forehead readings) must be taken always at the centre of the forehead (par. #4.1), **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).

9. QUICK TROUBLESHOOTING

1. The projection/display does not turn on: the batteries are completely dead or incorrectly inserted; replace or reinsert them (par. #12).

2. The temperature is not projected inside the rectangle: the device 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 Distributor as soon as possible for technical service.

5. The thermometer temperature reading is too low:

- ensure that the warnings (par. #2) have been met;
- check that the sensor (fig. 1) is not soiled or damaged; if it is, clean it as indicated in par. #11 or contact your Distributor for technical service;
- check that the thermometer is perpendicular to the forehead (fig. 2).

6. The thermometer temperature reading is too high: ensure that the warnings have been met (par. #2).

7. The thermometer appears blocked, for instance, some lights keep themselves on for longer than 2 minutes: reset the thermometer by removing and reinserting the batteries.

10. MEANING of ERROR/ALARM MESSAGES



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.
PROBLEM: the batteries are dead.
SOLUTION: remove the batteries immediately and replace them when necessary (see par. #12).



DESCRIPTION: the display reads “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; ensure that there are no mobile or cordless telephones in the vicinity.



DESCRIPTION: the display shows CAL, a pictogram of a hand inviting to stop, the messages AQCS and MQCS?
PROBLEM: the device shall be calibrated at the room temperature
SOLUTION: perform an MQCS (par. #7)



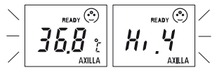
DESCRIPTION: the display reads a countdown (in minutes and seconds), a pictogram of a hand inviting to stop, and the messages AQCS and MQCS?
PROBLEM: the thermometer has not stabilized. The symbols prompt you to choose between:
SOLUTION: • wait until the AQCS countdown has run its course without touching the thermometer, or
• perform an MQCS (par. #7).



DESCRIPTION: While in stand-by mode, the room temperature displayed is accompanied by the symbol MQCS or AQCS.
MEANING: The thermometer has undergone automatic or manual quick calibration: precision is guaranteed, but to ensure a perfect reading, wait until normal thermometer calibration has been completed (from 10 to 30 minutes).



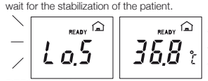
DESCRIPTION: the display reads “Hi.4”.
PROBLEM: the room temperature is too high (above 45°C/113°F).
SOLUTION: move to another, cooler site and wait for the stabilization of the patient.



DESCRIPTION: the display shows “Hi.4” and the value alternately.
PROBLEM: if you’ve pressed the “face” button: the room temperature is between 40,1 and 45°C (104.2 and 113°F)
SOLUTION: the temperature reading can be taken but accuracy is not guaranteed.



DESCRIPTION: the display reads “Lo.5”.
PROBLEM: if you’ve pressed the “face” button: the room temperature is too low (below 10°C/50°F). If you’ve pressed the “home” button: the room temperature is too low (below 5°C/41°F).
SOLUTION: move to another, warmer room and wait for the stabilization of the patient.



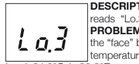
DESCRIPTION: “Lo.5” and the temperature value are displayed alternately.
PROBLEM: if you’ve pressed the “face” button: the room temperature is between 10 and 15,9°C (50 and 60.6°F). If you’ve pressed the “home” button: the room temperature is between 5 and 9,9°C (41 and 49.8°F).
SOLUTION: the temperature reading can be taken but accuracy is not guaranteed.



DESCRIPTION: the display reads “Hi.2”.
PROBLEM: if you’ve pressed the “face” button: the temperature detected exceeds the limit for operation with this button (>42,5°C/ 108.5°F). If you’ve pressed the “home” button: the temperature detected exceeds the limit for unit operation (>45°C).
SOLUTION: if you’ve pressed the “face” button: please ensure that you’ve pressed the correct button, with regards to the measured object, and that the warnings have been met.
If you’ve pressed the “home” button: the temperature reading cannot be taken.



DESCRIPTION: “Hi.2” and the value are alternated.
MEANING: attention! The temperature is 40°C/104°F or more.



DESCRIPTION: the display reads “Lo.3”.
PROBLEM: if you’ve pressed the “face” button: the forehead temperature appears to be too low (<34,0°C / <93.2°F).
If you’ve pressed the “home” button: the surface temperature read is below the operating limit (<1°C / <33.8°F).
SOLUTION: if you’ve pressed the “face” button: make certain the sensor is not soiled or damaged and that the subject has not come from a cold room.
If you’ve pressed the “home” button: the temperature reading cannot be taken.

11. CLEANING

CLEANING THE SENSOR: the guide wave contains the delicate sensor (fig. 1), and must be kept clean. Store the device in a dry, clean place, away from dust. If you need to remove dust or dirt from the sensor, use a cotton swab slightly dampened with alcohol. Remove all dirt and ensure that nothing accumulates on the guide wave area. 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 the thermometer.

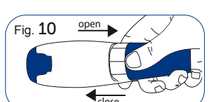
CLEANING THE THERMOMETER BODY: use a soft cloth dampened with soap and water and re-wipe with a sodium hypochlorite disinfectant, if needed.

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

12. 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 figure 10.

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 MQCS (par. #7).

• Remove the batteries if you do not expect to use the thermometer for a long time.

13. TECHNICAL CHARACTERISTICS

Non-contact infrared thermometer
VISIOFOCUS series
VISIOFOCUS 06400 model

Taking the body temperature at the forehead

• Room temperature working range:
16/40°C (60.8/104°F) [1]
• Resolution: **0,1**
• Measurement range: **34,0/42,5°C (93.2-108.5°F)**

Accuracy °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 42,5°C:	**±0,3°C**
Accuracy °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 108.5:	**±0.5°F**

Other readings

Measurement range: **1,0/80,0°C (33.8-176°F)**
• Room temperature working range:
10/40°C (41/104°F) [1]
• Resolution: **0.1**

Accuracy °C	from 1,0 to 19,9°C:	**±1,0°C**
	from 20,0 to 35,9°C:	**±0,3°C**
	from 36,0 to 39,0°C:	**±0,2°C**
	from 39,1 to 42,5°C:	**±0,3°C**
	from 42,5 to 80°C:	**±1,0°C**
Accuracy °F	from 33.8 to 67.9°F:	**±1.8°F**
	from 68.0 to 96.7°F:	**±0.5°F**
	from 96.8 to 102.2 °F:	**±0.4°F**
	from 102.3 to 108.5°F:	**±0.5°F**
	from 108.7 to 176 °F:	**±1.8°F**

[1] The device can operate also in the following temperature ranges:
10-16°C (50-60.8°F) with “face” button
5-16°C (41-60.8°F) with “home” button
40-45°C (104-113°C).
When the temperature is between 10 and 15,9°C (50 and 60.6°F) and the “face” button is used, or when the temperature is between 5 and 9,9°C (41 and 49.8°F) and the “home” button is used, accuracy and operating range are not guaranteed and the display shows “Lo.5” and the value alternately.
When the room temperature is between 40,1 and 45°C (104.2 and 113°F), and the “face” or “home” buttons are pressed, accuracy and operating range are not guaranteed and the display shows “Hi.4” and the value alternately.

[2] The ASTM E1965-98-2009 standard requires ±0,2°C (±0.4°F) accuracy for infrared thermometers in the 37-39°C (98.6-102.2°F) temperature range while the ASTM E667-86 and E1112-86 standards require ±0,1°C (±0.2°F) precision for mercury and electronic thermometers in the same temperature range.

Power supply:	4 AAA (LR03) alkaline batteries - 1.5 V
Life of high quality batteries:	3 years or thirty thousand 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).

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 and MQCS).

Atmospheric pressure range of operating conditions: from 700 hPa to 1.060 hPa.
Relative humidity range of operating conditions: from 15 % to 90 %, 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 -18°C (0.4°F) or higher than +70°C (158°F).

Expected life: 10 years.

VisioFocus is a class IIa medical device (compliant with the 93/42/EEC Directive and subsequent amendments and interpretations).
Tecnimed srl, P.le Cocchi, 12 - 21040 Vedano Olona (VA) - Italy undertakes full responsibility for this product’s compliance with the reference standards.
VisioFocus is compliant with the pertinent ASTM standard (E1965-98:2009) and EN 60601-1, 60601-1-2, 60601-1-11 standards.
Internally powered equipment for continuous operation.
The VisioFocus LEDs emit low light radiation in compliance with IEC 62471.

	Direct current
	Applied part: type BF
IP22	Protected against insertion of objects >12,5 mm and against vertical dripping water when tilted up to 15°.
	Recyclable material

Dispose of the device in compliance with applicable legislation regarding electrical equipment and batteries.

14. WARRANTY

A.Algeos Ltd. 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 A.Algeos Ltd.
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 are found), A.Algeos Ltd. reserves the right to charge a handling fee for technical verification and delivery.
Under no circumstance may A. Algeos Ltd or Tecnimed be held responsible for damages related to the improper use of the product or for costs exceeding the original price of the product.

ERRATA/ADDITIONAL INFORMATION

INTENDED USE: VisioFocus® 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).

Par. 2.1 4) 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 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.**

Par. 2.2 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.

Par. 3 You can find the table "FAMILY MEMBER TEMPERATURES" here:
www.tecnimed.it/download/

Par. 4.3 Readings of skin surface temperature
VisioFocus 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 for a forehead reading but press the "home" button; the display will light up in green. NOTE: skin surface temperature is NOT body temperature. To measure body temperature, proceed as described in par. 4.1.

Par. 4.4 Other readings (non-medical use)
VisioFocus 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 a baby's feed bottle (fig. 8), food, bathwater: in this case, remember to mix the liquid 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 minutes before taking another reading.
Proceed as you would for a forehead reading but press the "home" button; the display will light up in green. NOTE: this intended use is not subject to assessment by the Notified Body.

Par. 10 - Hi.2 message and par. 13: the upper limit for body temperature is 43.0°C (instead of 42.5°C).

Par. 13 "Other readings": accuracy is ±1.0°C in the range 1.0-33.9°C and ±0.3°C in the range 34.0-35.9°C.

Declaration of Conformity UE
Tecnimed srl, P.le Cocchi, 12 - 21040 Vedano Olona (VA) - Italy is the manufacturer of the VisioFocus 06400 non-contact clinical infrared thermometer. TECNIMED guarantees that VisioFocus 06400 meets all the provisions applicable in the Regulation (EU) 2017/745. VisioFocus 06400 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	
MD	Medical Device
#	Model
UDI	UDI code
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)

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