



MADE IN ITALY

# VISIOFOCUS®

**The non-contact thermometer  
that projects the temperature value on the forehead**



<b>Product name:</b>	VisioFocus®
<b>Model:</b>	06400
<b>Description:</b>	infrared medical thermometer for measuring body temperature of children and adults without touching their body. VisioFocus 06400 belongs to VisioFocus family, which includes the only thermometers in the world able to project the temperature value (on the forehead or any other surface).
<b>Designed by:</b>	Tecnimed srl, Vedano O. (VA), Italy
<b>Manufactured by:</b>	Tecnimed srl, Vedano O. (VA), Italy
<b>Technology:</b>	thermometers belonging to the VisioFocus family are the most advanced result of the technology developed by Tecnimed, which has been manufacturing non-contact infrared thermometers for 22 years: Tecnimed is the company that invented forehead body temperature measurement and non-contact measurement.
<b>Classification:</b>	class IIa medical device - CE 0051
<b>Tecnimed patents:</b>	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 10302619 and other international patents pending.
<b>Quality system:</b>	ISO 9001:2015, ISO 13485:2016
<b>Product compliance:</b>	- regulation (EU) 2017/745 (MDR) - standards EN 60601-1, EN 60601-1-2, EN 60601-1-6, EN 60601-1-11, EN 62471, EN ISO 80601-2-56, ASTM-E 1965-98:2016 - RoHS Directive (Pb-free)

## TECHNICAL BACKGROUND

All living beings and objects emit infrared radiation of wavelength that varies depending on the characteristics of their surface. In particular, the human body emits infrared radiation at wavelengths between 5 and 14 micrometres.

The thermometers in the VisioFocus family, like their predecessors Thermofocus, use a sensor (thermopile) that emits an electrical signal when excited by infrared radiation. This signal is amplified and processed by a sophisticated microprocessor depending on the ambient temperature, until a temperature value comparable to the axillary (or oral or rectal or internal, depending on the setting chosen) temperature is obtained.

The measuring system used by Tecnimed thermometers was developed and tested in collaboration with the "De Marchi" Paediatric Clinic (University of Milan). Tecnimed thermometers are currently used in a number of qualified centres in Europe, America, Asia, Africa, and Oceania.

## DESCRIPTION

VisioFocus thermometers are the most advanced thermometers that families and doctors can use to accurately measure body temperature. Comfortable and non-invasive, without touching the subject, they allow instantaneous, accurate and hygienic measurement: they do not need to be disinfected, do not require any disposable protection and reduce the risk of cross-contamination.

## MAIN FEATURES

### • PROJECTION

The thermometers in the VisioFocus family are the only thermometers in the world that **project temperature value** directly on the forehead. **Temperature at first sight.**



AS SEEN ON TV



## • "6 in 1" MULTIFUNCTIONALITY



VisioFocus can read:

- 1) body temperature of children and adults  
and the temperature of any object and liquid with a temperature between 1 and 80°C, for example:
- 2) food
- 3) feeding bottle
- 4) bathwater
- 5) room temperature
- 6) skin surface temperature  
but also temperature of wine, coffee, and so on



## • MEMORY FUNCTION

With the 'Mem' button, user can recall the last 9 measurements taken.



## FUNCTIONAL FEATURES

### • AIMING SYSTEM

One of the most important things in measuring the body temperature at a distance is that the distance from the skin is correct. If the distance is correct, the temperature is correct. If the distance changes the temperature changes accordingly, in a way that cannot be controlled at all. Thanks to its patented aiming system, VisioFocus clearly indicates the correct distance and the correct point for an accurate measurement to be taken.

As this system is patented, no other thermometer in the world can use it, apart from Thermofocus and the other thermometers in the VisioFocus family.



### • TEMPERATURE MEASUREMENT SYSTEM

Temperature measurement is performed in a few simple steps:

- press the “face” button and hold it down;
- while keeping the thermometer perpendicular **to the centre of the forehead**, move it in or back away from the forehead until the temperature reading is set squarely between the two arches. If the thermometer is too far away, or too close, the temperature will not fall between the two arches.
- **When you see the temperature at the midpoint between the two arches**, the thermometer is at the right distance for an accurate measurement: release the button and keep the device steady while the lights flash.

#### IMPORTANT:

the aiming lights are absolutely harmless, even if pointed in the eyes.

To take the temperature of objects, proceed in the same way, but using the “home” button.

### • ROOM CALIBRATION SYSTEMS

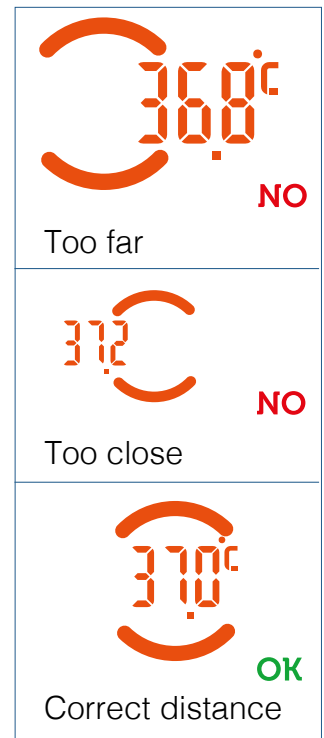
All infrared thermometers have to know the ambient temperature, for this reason all the manufacturers indicate to wait a certain time (usually from 10 to 30 minutes or even longer, depending on the temperature difference) before using the thermometer in the case it is brought from one room to another with different temperatures.

VisioFocus, as Thermofocus, eliminates this waiting time thanks to two exclusive quick stabilization systems: the AQCS and MQCS.



If the device notices a sudden temperature change, a countdown will appear on the display indicating the time required for stabilisation: simply wait until the end of the countdown for the thermometer to stabilise automatically. This system is called **AQCS (Automatic Quick Calibration System)** and is normally able to stabilise the thermometer in approximately 3-4 minutes.

As an alternative, it is possible to use the **Manual Quick Calibration System (MQCS)**, which allows the thermometer to immediately stabilise its temperature at room temperature in just 3 seconds. The MQCS consists of having the thermometer acquire the temperature of the room where it is to be used and is performed by pointing it against a reference point representative of the room temperature (e.g. an interior wall or a cupboard away from sources of heat or cold).



### HOW TO USE



## • DISPLAY BACKLIGHTING SYSTEM IN 5 DIFFERENT COLOURS

The display lights up in a different colour depending on the procedure performed or function used:

- light blue: when measurement is made with “face” button (in the middle of the forehead for measuring body temperature);
- green: when measuring with home” button (for measuring all other temperatures);
- purple: when the memory function is activated (when, with the thermometer in stand-by mode, the “Mem” button is pressed two or more times);
- orange: when displaying the room temperature (when, with thermometer in stand-by, the “Mem” button is pressed once);
- blue: when activating the MQCS (Manual Quick Calibration System) procedure.



## MANUFACTURING AND CERTIFICATIONS

VisioFocus is manufactured by Tecnimed in its factory, located in Vedano Olona (VA), ITALY, according to a Quality System ISO 9001:2015 and ISO 13485:2016 certified.

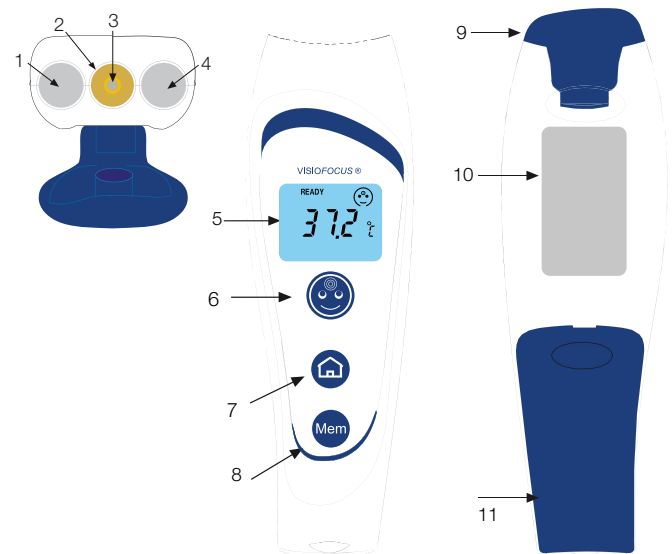
Production, calibration and testing of VisioFocus are carried out in a Temperature Controlled Clean Room, by means of purpose-built machines.

VisioFocus has obtained MDR certification according to Regulation (EU) 2017/745 and has also been cleared for marketing outside Europe, e.g. in the USA by the FDA and in several other countries (Japan, Korea, Australia and others) by the relevant local bodies.

The VisioFocus® trademark is registered in Italy and extended internationally.

## DEVICE DIAGRAM

1. Aiming light
2. Waveguide
3. Sensor (at the bottom of the waveguide)
4. Aiming light
5. LCD display
6. “FACE” button for measuring body temperature from forehead
7. “HOME” button for other readings
8. “Mem” button
9. Protective cap
10. Label with serial number
11. Battery door



## AVAILABLE PACKAGING

Packaging in carton box containing:

- 1 VisioFocus 06400
- 1 instruction manual
- 4 AAA batteries

Display with 6 units



Protective case  
available under  
request



## TECHNICAL CHARACTERISTICS

Number of buttons:	3
Room temperature detection:	√
AQCS (Automatic Quick Calibration System):	√
MQCS (Manual Quick Calibration System):	√
Batteries (included):	4, AAA/LR03 (preferably alkaline)
Lifespan of high quality batteries:	up to 3 years or 30.000 readings
Distance from the subject during measurement:	indicated using an optical aiming system (approx. 6 cm/2.36 inches)

### Measuring specifications:

Resolution:	0.1			
Body temperature readings range ("face" button):	from 34.0 to 43.0°C (93.2/109.4°F)			
Other readings range ("home" button):	from 1.0 to 80.0°C (33.8/176.0°F)			
Laboratory accuracy: <i>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).</i>	from 1.0 to 33.9°C =	±1.0°C	from 33.8 to 93.1°F =	±1.8°F
	from 34.0 to 35.9°C =	±0.3°C	from 93.2 to 96.7°F =	±0.5°F
	from 36.0 to 39.0°C =	±0.2°C	from 96.8 to 102.2°F =	±0.4°F
	from 39.1 to 43.0°C =	±0.3°C	from 102.3 to 109.4°F =	±0.5°F
	from 43.1 to 80.0°C =	±1.0°C	from 109.5 to 176.0°F =	±1.8°F
Room temperature working range ("face" button):	- standard range: 16,0/40,0°C (60.8/104.0°F) - extended range: 10,0/45,0°C (50.0/113.0°F) <sup>(1)</sup> <sup>(1)</sup> In rooms where the temperature is between 10,0 and 15,9°C (50.0/60.7°F) or between 40,1 and 45,0°C (104.1/113.0°F), accuracy and the operating range are not guaranteed and the message "Lo.5" or "Hi.4" respectively, and the temperature value are displayed alternately.			
Room temperature working range ("home" button):	- standard range: 16,0/40,0°C (60.8/104.0°F) - extended range: 5,0/45,0°C (41.0/113.0°F) <sup>(2)</sup> <sup>(2)</sup> In rooms where the temperature is between 5,0 and 9,9°C (41.0/49.9°F) or between 40,1 and 45,0°C (104.1/113.0°F), accuracy and the operating range are not guaranteed and the message "Lo.5" or "Hi.4" respectively, and the temperature value are displayed alternately.			