



MADE IN ITALY

# VISIOFOCUS<sup>®</sup> SMART



- Product name:** VisioFocus Smart<sup>®</sup>  
**Series:** 06470  
**Model:** 06470  
**Description:** Together with the other products belonging to the Thermofocus and Visiofocus families, VisioFocus Smart is the most advanced medical thermometer working at distance.
- Manufacturer:** Tecnimed srl, Vedano O. (VA) Italy  
**Designed by:** Tecnimed srl, Vedano O. (VA) Italy  
**Patent holder:** Tecnimed srl, Vedano O. (VA) Italy  
**Classification:** Medical Device Class IIa (Class II in USA and Canada) - CE 0051
- Patents:** US 6,196,714 - US 7,001,066 EP0909377 - EP1283983B1 - US 6,527,439 - EP1051600B1. and other international patents pending.
- Compliance:** 93/42/EEC Directive and following amendments  
Quality System ISO 9001:2015  
ISO 13485:2016  
ISO 14971:2012 (Risks analysis), EN 60601-1, EN 60601-1-2 (electromagnetic compatibility) EN 60601-1-6, EN 60601-1-11.  
UNI CEI EN ISO 14971:2012  
ASTM (American Society for Testing Materials) E 1965-98(2009)  
In compliance with RoHS guideline (Pb-free)

## Technical background

All objects and living beings emit infrared radiations of a wavelength which varies in relation to their surface characteristics. Particularly, the human body emits infrared radiations of a wavelength between 5 and 14 micrometers.

Like Thermofocus and VisioFocus 06400, VisioFocus Smart uses a sensor (thermopile) which, when stimulated by infrared radiations, sends an electrical signal, amplified and then converted into a digital signal which gives the correct body temperature, after the device's automatic adjustment to room temperature.

Visiofocus Smart, with all Visiofocus family's products, uses the the proven technology and the measuring system used by Thermofocus developed and tested with the collaboration of the Paediatric Clinic "De Marchi" (University of Milan). ThermoFocus and VisioFocus families products are currently used in a number of qualified centres in America, Europe, Asia, Africa, Middle East and Oceania.

## Description

Together with the other products belonging to the Thermofocus and VisioFocus families, Visiofocus Smart is the most advanced thermometer a family or a doctor can own to precisely measure body temperature. Totally hygienic, **without touching the skin**, VisioFocus Smart reads infrared radiation naturally emitted by the surface of the skin and calculates the whole body temperature. Does not need to be disinfected and does not require the use of hygienic disposables. Therefore VisioFocus Smart is totally hygienic and the possibility of cross contamination is eliminated.

### Useful Features

#### PROJECTION

VisioFocus Smart, along all VisioFocus family's products, is the only thermometer in the world able to project the temperature directly on the forehead. This system is protected by a number of patents as the system used in Thermofocus.



## 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 we cannot control at all.

Thanks to its patented aiming system, VisioFocus Smart clearly indicates the correct distance and the correct point for an accurate measurement to be taken.

No other thermometer in the world can do it, apart from Thermofocus.

### TEMPERATURE MEASUREMENT

Body temperature is easily measured as follows:

-press the "Face" button and hold it down: the two aiming lights will come on and you will begin to see the temperature value projected on the forehead.

-The display will start to show the temperature.

-Approach VisioFocus Smart **perpendicularly to the middle of the forehead** and move it closer to the forehead until the temperature comes inside the rectangle.

-When you can read **the temperature exactly between the rectangle** the thermometer is at the correct distance for an accurate temperature reading to be taken: release the button, and hold the device steady until the lights start to blink. You can read the temperature also on the display, which will light up with green.

NO: TOO FAR



NO: TOO CLOSE



YES: CORRECT DISTANCE



There is no need to worry if the aiming lights are pointed into the eyes: the beams are absolutely harmless.

Objects' temperature is measured exactly in the same way, but using the "Home" button.

### MEMORY FUNCTION

It allows to recall the last 9 measurements by the use of "Mem" button.

# 6 in 1

**6 IN 1:** VisioFocus Smart is able to take:

- 1) the body temperature as well as the temperature from any object, and liquid with temperatures between 1 to 80°C (33.8 to 176°F) such as:
  - 2) feeding bottle
  - 3) food
  - 4) bathwater
  - 5) skin temperature
  - 6) ambient temperature
- but also the wine, the coffee, the wall, the floor and so on



## CALIBRATION SYSTEMS

All infrared thermometers have to know the ambient temperature, for this reason all the other 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 Smart, as Thermofocus, eliminates this waiting time thanks to two exclusive stabilization systems: the AQCS and MQCS.

In case of a very fast change of the device's temperature, the display will show, through a countdown in minutes and seconds, the time that is necessary to wait in order to have the device quickly stabilized. This system is called **AQCS (Automatic Quick Calibration System)** and is normally able to stabilize the device in about 4 minutes.



As an alternative, it is possible to use the **MQCS (Manual Quick Calibration System)** which allows the device to immediately stabilize its temperature to the room temperature in just 3 seconds.

To do the MQCS, proceed as follow in a room with an ambient temperature between 16 and 40 °C (60.8 – 104.0 °F):

- press and release the "Face" and "Home" buttons at the same time. The word "CAL" will appear;
- within 10 seconds point the thermometer towards a suitable reference point that reflects the room temperature such as an internal wall (or wardrobe) far from heat or cold sources at head height, and press the "Home" button;
- release the button: the aiming lights will flash twice slowly and the display will then indicate the reading as reference room temperature;
- VisioFocus Smart is now ready to take the temperature: the symbol "MQCS" on the display indicates that the thermometer has been stabilized with the MQCS.

## Manufacturing and QA

VisioFocus Smart is manufactured by Tecnimed under the ISO 9001:2015 and ISO 13485:2016 Quality System.

The production, control and calibration of VisioFocus Smart are performed by Tecnimed in a Class 100 Clean Room. Packaging is done in an Ambient Controlled Room.

The quality of the product is further certified by external independent institutes.

VisioFocus® is a trade mark registered in Italy and extended internationally.

## VisioFocus Smart Diagram

1. sensor (at the bottom of the gilt waveguide)
2. aiming light
3. parabolic waveguide
4. tip
5. "face" button for body temperature (forehead's measurement)
6. "home" button for other measurements
7. memory button
8. label with serial number
9. battery door (4 x AAA batteries - not included)
10. press into its cavity and slide the cover toward the outside to remove it



## Packagings available



## TECHNICAL DATA

<b>TECHNICAL CHARACTERISTICS</b>	
No. of buttons	3
Room temperature detection	√
AQCS (Automatic Quick Calibration System)	√
MQCS (Manual Quick Calibration System)	√
Batteries (not included)	4 AAA/LR03 type (preferably alkaline)
Life of high quality batteries	30.000 measurements or 3 years
Resolution	0.1°C /°F
Forehead measuring range	34.0/42.5°C (93.2/108.5°F)
General measuring range (apart from forehead)	1.0/80.0°C (33.8/176.0°F)
Room temperature working range with face button:	*16/40°C (60.8/104.0°F)
Room temperature working range with home button:	*5/45°C (41/113.0°F)
<p><i>VisioFocus Smart can operate with the face button also in the room temperatures between 10-15.9°C (50-60.6°F) and 40-45°C (104-113°F) but the accuracy is not guaranteed and the display shows "Lo.5" or "Hi.4" alternated to the value</i></p> <p><i>With the home button the accuracy for measurements in room temperatures between 5 and 16°C or over 40°C is not guaranteed.</i></p>	

Accuracy level (in instrumental tests according to ASTM E 1965-98:2009 standard):

Celsius		Fahrenheit	
from 34 to 35.9°C =	+/-0.3°C	from 93.2 to 96.7°F =	+/-0.5°F
from 36 to 39°C =	+/-0.2°C	from 96.8 to 102.2°F =	+/-0.4°F
from 39.1 to 42.5°C =	+/-0.3°C	from 102.3 to 108.5°F =	+/-0.5°F
from 1.0 to 19.9°C and from 42.3 to 80.0°C =	+/-1.0°C	from 33.8 to 67.9°F and from 108.1 to 176.0°F =	+/-1.8°F
from 20 to 33.9°C =	+/-0.3°C	from 68.0 to 93.1°F =	+/-0.5°F

Distance from the subject during operation: about 6 cm (2.36 inches), set through an optical signal