



MADE IN ITALY

VISIOFOCUS®

The **only** family of thermometers that projects the temperature on the forehead



Product name: VisioFocus®

Series: 06400

Model: 06400

Description: VisioFocus - the evolution of Thermofocus, the first non-contact thermometer in the world - 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 9001:2008

ISO 13485:2012 and ISO 13485:2003 CMDCAS

ISO 14971:2007 (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)

Conforme alla Direttiva RoHS (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, VisioFocus 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.

The measuring system used by Thermofocus and VisioFocus has been developed and tested with the collaboration of the Paediatric Clinic "De Marchi" (University of Milan). ThermoFocus and VisioFocus are currently used in a number of qualified centres in America, Europe, Asia, Africa, Middle East and Oceania.

Description

VisioFocus is the most advanced thermometer a family or a doctor can own to precisely measure body temperature. Totally hygienic, **without touching the skin**, VisioFocus 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 is totally hygienic and the possibility of cross contamination is eliminated.

Useful Features

PROJECTION

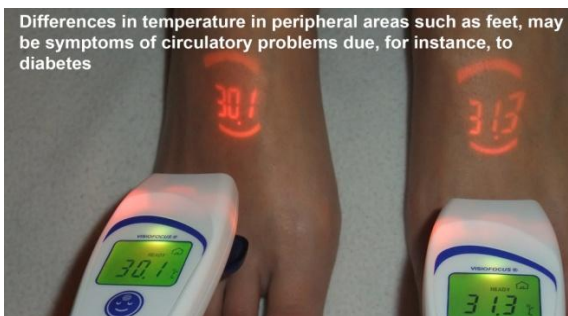
VisioFocus is the only thermometer in the world able to project the temperature directly on the forehead. This system is protected by a number of patents as the system used in Thermofocus.



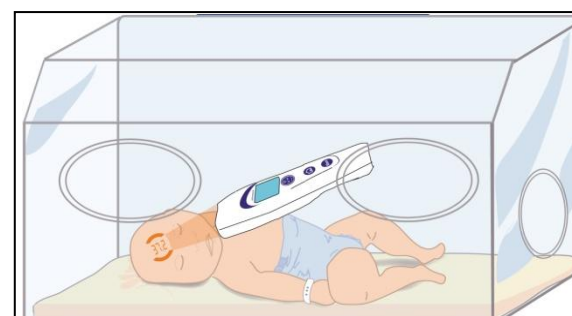
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6 IN 1: VisioFocus is able to take:

- 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) food
 - 3) feeding bottle
 - 4) bathwater
 - 5) skin temperature
 - 6) ambient temperature
- but also wine, coffee, and so on



Differences in temperature in peripheral areas such as feet, may be symptoms of circulatory problems due, for instance, to diabetes



MEMORY FUNCTION

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

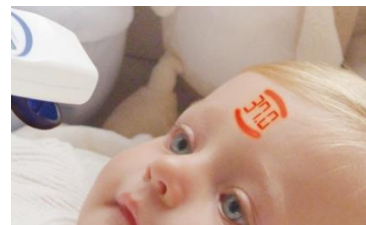
Functional Features

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 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.



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 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 3 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 open the protective cap and point the thermometer towards a suitable reference point that must reflects the room temperature on an internal wall (or wardrobe) far from heat or cold sources at head height, pressing 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 is now ready to take the temperature: the symbol "MQCS" on the display indicates that the thermometer has been stabilized with the MQCS.

TEMPERATURE MEASUREMENT

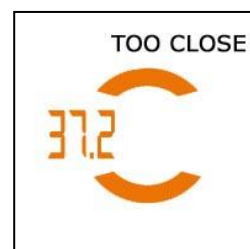
Body temperature is easily measured as follows:

- 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.

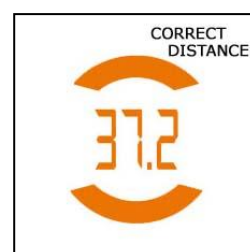


- Approach VisioFocus **perpendicularly to the middle of the forehead** and move it closer to the forehead until the temperature comes between the two brackets.

If the thermometer is too close or too far away from the forehead, you will see the temperature outside of the brackets.



- When you can read **the temperature exactly between the brackets** 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 light blue.



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.

DISPLAY BACKLIGHTED IN 5 DIFFERENT COLOURS

One colour for each function:

- light blue: when the measurement is made by the "face" button (in the middle of the forehead for the body temperature)
- green: when the measurement is made by the "home" button (for the object measurements)
- violet: when the memory function is activated (if the thermometer is in stand-by mode, you have to press twice or more the "Mem" button)
- orange: if the device is in stand-by mode pressing just once the "Mem" button you will see the room temperature orange highlighted
- blue: when the MQCS procedure is activated (Manual Quick Calibration System)

BODY TEMPERATURE	OBJECTS	MEMORY	AMBIENT	CALIBRATION MQCS

Manufacturing and QA

VisioFocus is manufactured by Tecnimed under the ISO 9001:2008 and ISO 13485:2012 Quality System.

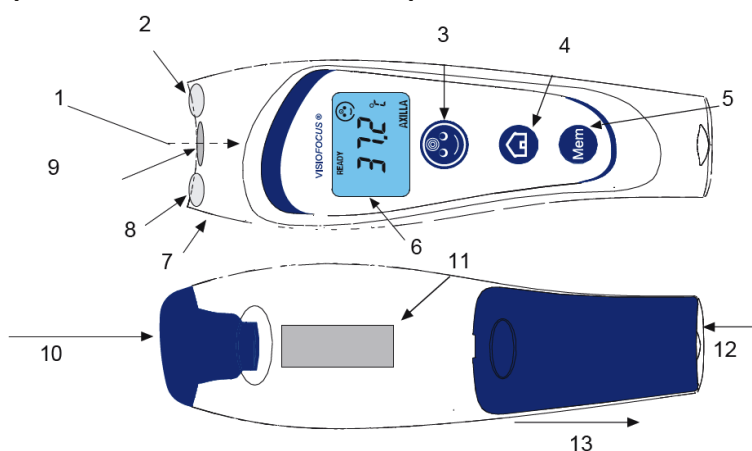
The production, control and calibration of VisioFocus are performed by Tecnimed in a Class 100 Clean Room. Packaging is done in an Ambient Controlled Room.

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

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

VisioFocus Diagram

1. sensor (at the bottom of the gilt waveguide)
2. aiming light
3. "face" button for body temperature (forehead's measurement)
4. "home" button for other measurements
5. memory button
6. LCD display
7. tip
8. aiming light
9. parabolic gilt waveguide
10. protective cup
11. label with serial number
12. battery door (4 x AAA batteries - included)
13. press into its cavity and slide the cover toward the outside to remove it



Packagings available



TECHNICAL DATA

TECHNICAL CHARACTERISTICS	
No. of buttons	3
Room temperature detection	✓
AQCS (Automatic Quick Calibration System)	✓
MQCS (Manual Quick Calibration System)	✓
Batteries (included)	4 AAA/LR03 type (preferably alkaline)
Resolution	0.1°
Forehead measuring range	34.0/42.5°C (93.2/108.5°F)
General measuring range (apart from forehead)	1.0/55°C (33.8/131°F) 1.0/80.0°C (33.8/176.0°F) from winter 2015
Room temperature working range:	*10/45°C (50.0/113.0°F)
*VisioFocus can work also in environments with a temperature between 5 and 15.9°C (41/60.6°F) and 40.1 and 45°C (104.1/113.0°F), but in this case the accuracy is not guaranteed and the message "Lo.5" and the temperature value are displayed alternatively.	

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 55.0°C =	+/-1.0°C	from 33.8 to 67.9°F and from 108.1 to 131°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

See the videos at: <https://www.youtube.com/watch?v=jbNsR6GHg0c>

<http://www.youtube.com/watch?v=JdN1ndHUrnw>



<http://www.youtube.com/watch?v=iMM5GNhOtAw>

<http://www.youtube.com/watch?v=wiHK9mNoHMK>

<https://www.youtube.com/watch?v=7R41JxevyqM>

http://www.youtube.com/watch?v=p3lvD0J9Uuw&feature=share&list=PLwI6T8IE5bfSLWjvswq-mFYILJ_nJ2BJr&index=4

<https://www.youtube.com/watch?v=RmTLvAqKIQw>

<https://www.youtube.com/watch?v=XjFyEi8h3-c>

