

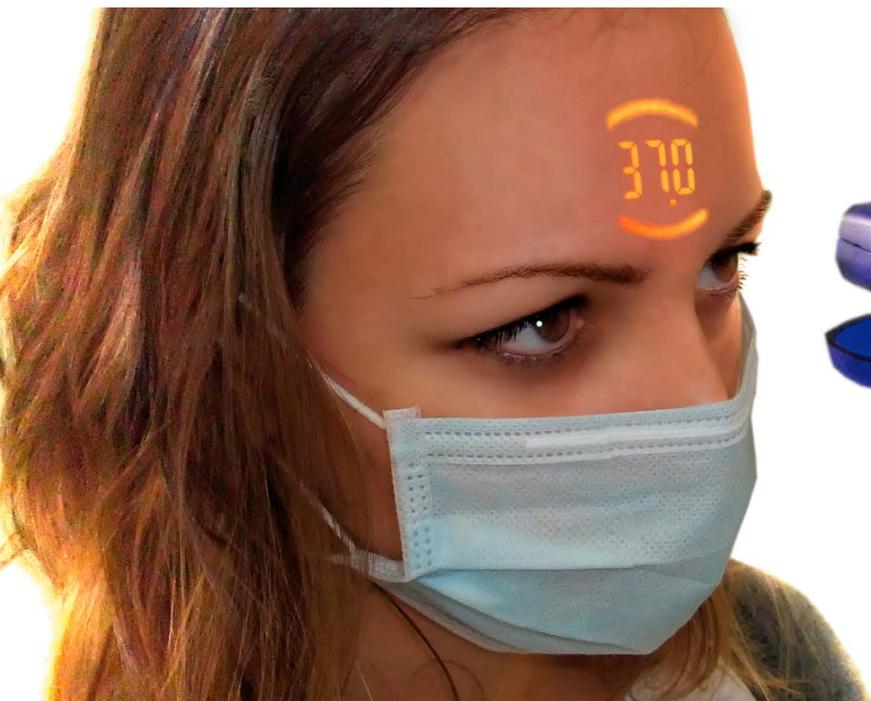


MADE IN ITALY

VISIOFOCUS[®]

PRO

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



- Product name:** VisioFocus[®] PRO
Model: 06480
Description: infrared medical thermometer for measuring body temperature of children and adults without touching their body. VisioFocus PRO 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).
Designed by: Tecnimed srl, Vedano O. (VA), Italy
Manufactured by: Tecnimed srl, Vedano O. (VA), Italy
Technology: 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.
Classification: class IIa medical device - CE 0051
Tecnimed 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 10302619 and other international patents pending.
Quality system: ISO 9001:2015, ISO 13485:2016
Product compliance:
- 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)



IN SHORT:

- **Projection** of the temperature on forehead
- **Accuracy** guaranteed by:
 - **exclusive patented aiming system**, which ensures correct reading distance and measuring area
 - measurement with “face” button, which is **automatically adjusted** for room temperature
 - **AQCS e MQCS, exclusive and patented systems**, which allows the thermometer to maintain correct and constant its temperature during long periods of use or when moving between rooms with different temperatures.
- **Totally hygienic for patients and users:** no touch and no need for disposables.
- **NO LASER:** safe for patients, travellers and users.
- **Made in Italy:** VisioFocus PRO is manufactured at the company’s site in Vedano Olona (Varese, Italy) in a Temperature Controlled Clean Room equipped with robotic machines for assembly, calibration and testing, which guarantee high quality and maximum flexibility.
- **CE certified** (compliant with MDR), and cleared by FDA (USA), MHLW (Japan), TGA (Australia), MFDS (Korea), NMPA (China, for VisioFocus 06400), and others.

SUITABLE FOR INTENSIVE USE:

- **Instantaneous reading:** detects temperature in less than 1 second.
- **High performance:** up to 1,000 measurements per hour
- **Low cost of use:** thanks to the speed of measurement, the number of thermometers and operators can be reduced.
- **A version with a handle** (VisioFocus PRO SCAN), more comfortable for intensive use, is available on request.
- **Extended working temperature range:** from -10 to +45°C.
- **Clinically proven technology** in hospitals and universities worldwide and widely used in 2003 for SARS, in 2009 for Swine Flu, in 2014 for Ebola and between 2020 and 2022 for COVID-19.



VisioFocus Pro 06480 during COVID-19 emergency

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 PRO is the most advanced thermometer that healthcare professionals can use to accurately measure body temperature.

Comfortable and non-invasive, it allows instantaneous and accurate readings without touching the patient.

For this reason, VisioFocus PRO does not need to be disinfected, does not require any disposable protection, and guarantees maximum hygiene, thus greatly reducing the risk (which with traditional thermometers is high) of cross-contamination during body temperature measurement, protecting both patients and operators.

In fact, the use of Tecnimed thermometers during epidemics (COVID-19, Ebola, A/H1N1, SARS) has shown how they were an essential tool for controlling the spread of virus in hospitals, airports, schools, factories, etc.: VisioFocus PRO is particularly fast, accurate and easy to use, and, allowing several consecutive temperature readings, is ideal for intensive use.



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.**

• SETTINGS

VisioFocus PRO is provided with the **MQCS** technology (mandatory procedure when set to “Nurs”) and AQCS technology (automatic procedure when set to “Doct”) and comes with a special lanyard that allows the device to be carried safely in order to use it at any time.

VisioFocus PRO has several setting possibilities:

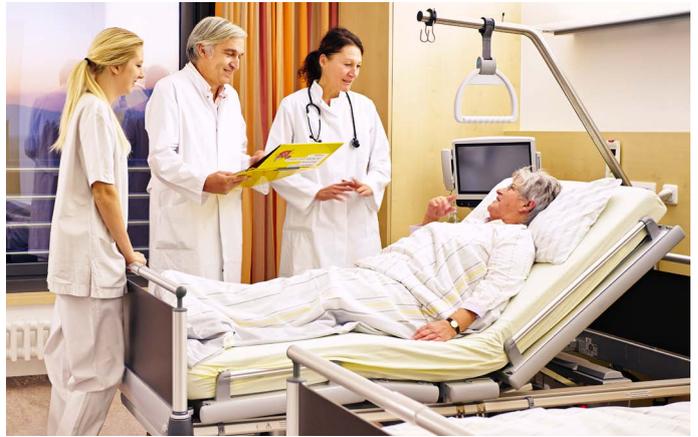
- Reference temperature:	oral, rectal, axillary or core
- Working settings:	<p>“nurs” setting (factory setting, recommended for use by nurses for measurements in the various rooms of the wards and in intensive use) which includes:</p> <ul style="list-style-type: none"> - HOME and MEM buttons disabled to avoid the risk of errors in intensive use; - manual quick calibration system MQCS (see next paragraph) required and mandatory every 60 minutes <p>“doct” setting (suggested for use by doctors in their offices), which provides:</p> <ul style="list-style-type: none"> - HOME and MEM buttons enabled; - enabled automatic AQCS and optional MQCS
- Air conditioning adjustment:	this setting can be activated in the presence of intense air conditioning to limit the cooling effects on the forehead
- Temperature level alarm:	it can be set to $\geq 37.0^{\circ}\text{C}$, $\geq 37.5^{\circ}\text{C}$ or $\geq 38.0^{\circ}\text{C}$ ($\geq 98.6^{\circ}\text{F}$, 99.5°F or $\geq 100.4^{\circ}\text{F}$). Above the selected alarm threshold, the detected temperature will flash alternately with the message ‘Hi.2’.

A version with an acoustic alarm is available on request, which can be activated at the end of the measurement or only in the event of a temperature exceeding the preset threshold.

• **MULTIFUNCTIONALITY**

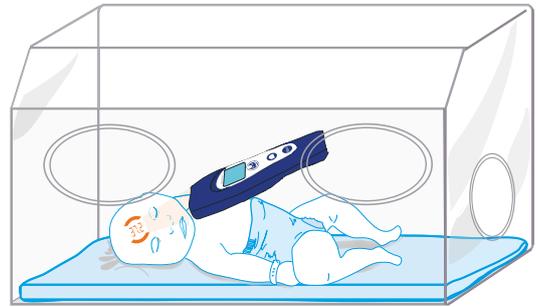
VisioFocus PRO can take body temperature of children and adults and it can also:

- 1) monitor the temperature of inflammations, ulcers, wounds (e.g. on diabetics);
- 2) monitor the temperature of internal organs during surgery ensuring maximum hygiene thanks to the total absence of contact;
- 3) detect the temperature of intravenous fluid bags.



• **USE ON NEWBORNS IN INCUBATORS**

The ambient temperature inside the incubator is different from the room temperature. Thanks to MQCS, VisioFocus PRO can also correctly measure the temperature of a newborn baby in an incubator: simply perform the MQCS inside the incubator before taking the measurement on the baby's forehead.



• **MEMORY FUNCTION**

If enabled, it allows to recall the last 9 measurements taken.

HOW TO USE



FUNCTIONAL FEATURES

• AIMING SYSTEM

One of the most critical aspects in measuring non-contact body temperature is that the distance from the surface whose temperature is to be determined (the forehead in the case of body temperature) is the distance for which the thermometer was calibrated. This is important because if the distance between the thermometer and the object is correct, the temperature will be correct; if the distance changes, the temperature reading will change uncontrollably due to the conical shape of the field of view of the sensor.

VisioFocus PRO is designed with a unique pointing system that can indicate the correct distance and precise point where to take the temperature.

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.

IMPORTANT: VisioFocus PRO IS NOT A LASER THERMOMETER; the projection lights are simple LED diodes.

It is important to know that several thermometers currently on the market and also used in the latest pandemics are either equipped with lasers that simulate an aiming system, or have no aiming system at all. In the first case, apart from the fact that a laser aiming system is only indicative of a point and not of a distance, there is a risk of permanently damaging the patient's eyes. In the second, it is not possible to identify the correct reading distance.

• 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.

Reading on eyelid

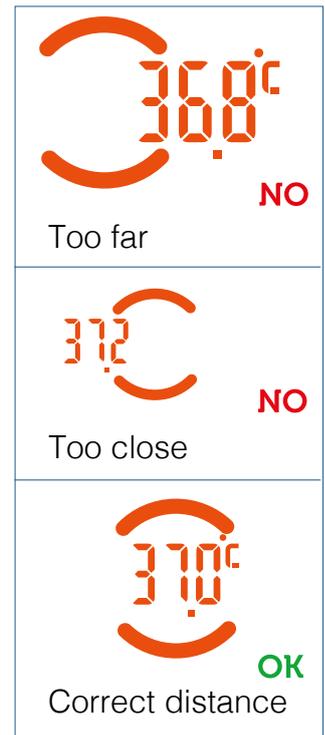
There are situations in which the detection of the temperature on the forehead is not possible.

- when the forehead is sweaty: our body, in fact, cools the head through the forehead to protect the brain and, even if sweat droplets are removed, the forehead will still be cold and will not reflect the correct body temperature;
- when the patient is wearing an oxygen mask: oxygen coming out of the mask affects the temperature of the forehead, altering the detected temperature;
- when the forehead is very wrinkled: in this case, the temperature measured on the forehead may be lower than it actually is due to reduced surface vascularisation.

In all these cases, it is recommended to take the body temperature on the eyelid, which can provide a temperature similar to the forehead temperature and is less subject to temperature fluctuations.

IMPORTANT: there is no danger if the person should open their eyes during the temperature measurement: the lights are totally harmless (they are simple LED diodes, NOT LASER).

The thermometers in the VisioFocus family are the only ones that allow that body temperature is measured on the eyelid, when the forehead is not accessible. This method of detecting body temperature therefore allows body temperature to be taken with respect to anyone wearing clothing such as a **burqa** or **chador**.



• ROOM CALIBRATION SYSTEMS

All infrared thermometers need to perfectly know the ambient temperature in order to be able to correctly process the temperature measured at the forehead. 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 VisioFocus PRO is set in Doct mode and if it 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).



If VisioFocus PRO is set in Nurs mode, it requires manual calibration MQCS, which is mandatory every 60 minutes.

Through the MQCS system, the thermometer is always perfectly stabilised at ambient temperature regardless of room temperature and even if it is continuously handled by the user.

• 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 PRO 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 PRO are carried out in a Temperature Controlled Clean Room, by means of purpose-built machines.

VisioFocus PRO 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.

VERSIONS

VISIOFOCUS PRO 06480

with protective case and lanyard



VISIOFOCUS PRO BT 06480BT

with protective case and lanyard and connection to Visio PRO BT App



VISIOFOCUS PRO SCAN 06490

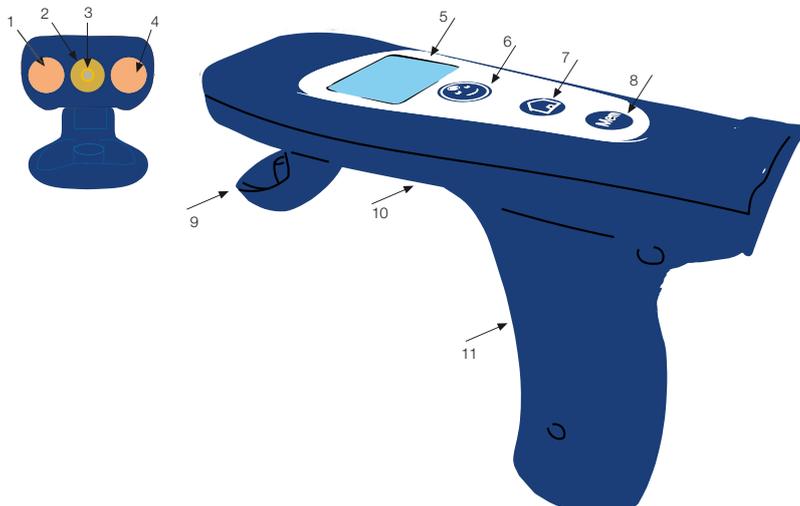
with handle, intended for intensive screening at entrances to hospitals, stations, airports, supermarkets, factories, etc.



DEVICE DIAGRAM

VISIOFOCUS PRO 06480 and PRO BT 06480BT

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
12. Special lanyard with additional brief instructions - to be worn around the neck



VISIOFOCUS PRO SCAN 06490

1. Aiming light
2. Waveguide
3. Sensor (on 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

TECHNICAL CHARACTERISTICS

Number of buttons:	3
Room temperature detection:	√
AQCS (Automatic Quick Calibration System):	√
MQCS (Manual Quick Calibration System):	√
Measurement time	<0,5 seconds
Time between consecutive measurements	<2 seconds
Measurements/hour	up to 1.000
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:	- standard range: 16,0/40,0°C (60.8/104.0°F) - extended range: -10,0/45,0°C (14.0/113.0°F) ⁽¹⁾ ⁽¹⁾ In rooms where the temperature is between -10 and 15,9°C (14 and 60.7°F) and when the "face" button is used, or in rooms where the temperature is between -10 and 9,9°C (14 and 49.9°F) and when the "home" button is used, accuracy and the operating range are not guaranteed and the message "Lo.5" and the temperature value are displayed alternately. In rooms where the temperature is between 40,1 and 45,0°C (104.1 and 113.0°F), accuracy and the operating range are not guaranteed and the message "Hi.4" and the temperature value are displayed alternately.			

Available settings:

nurs (default)	recommended for use by nurses, in hospitals and ambulances, and in all cases of intensive use	HOME button disabled MQCS mandatory every 60 minutes
doct	recommended in emergency rooms, doctors' rooms and situations where the thermometer remains in the room and is not manipulated for a long time	HOME and MED button enabled MQCS not mandatory AQCS is activated if and when needed
AIR On (in the presence of air conditioning) or OFF (in the absence of air conditioning)		Yes
Temperature alarm threshold (visual alarm) VISIOFOCUS PRO SCAN version (with handle) is equipped with a visual and acoustic alarm, and possibly a tactile alarm on request		≥37,0°C or ≥37,5°C or ≥38,0°C (≥98.6°F or 99.5°F or ≥100.4°F)

Equipped with:

User manual	1 included
Brief additional instructions printed on battery door	√ (not in the version with handle)
Lanyard with additional brief instructions	1 included (not in the version with handle)
Batteries	4 AAA/LR03 alkaline, included
Protective case	1 included (not in the Essential version and in the one with handle)