VISIOFOCUS®

The only "NO CONTACT" thermometer for Pandemic Situations that projects the temperature on the forehead

Advantages of VISIOFOCUS®

- **Exclusive patented aiming system** guarantees correct point and distance.
- **Projection of the temperature on the forehead** and correct distance
- **Face button** automatically adjusts forehead temperature to the environment (room) temperature for accurate result.
- **Exclusive and patented AQCS and MQCS** systems to maintain correct and constant temperature of device during long periods of use or when moving between rooms with different temperatures.
- **Highly Accurate:** based on the above 4 exclusive points.
- **Clinically tested:** in Hospitals and Universities around the world.
- **Totally Hygienic for patients and users:** no touch & no disposables.
- **NO LASER:** absolutely safe for travellers and users.
- **CE, FDA, Koseisho, TGA, CFDA** and other APPROVALS.
- Widely used in 2003 for **SARS** and in 2009 for **Swine Flu.**
- **Instantaneous:** gives temperature in less than 1 second.
- **Highly Versatile**: can take temperature of up to 1,000 travellers per hour.
- **Very low cost of using** thanks to the long battery life and speed of measurement that allows to reduce the number of thermometers and of operators.
- **Made in Italy** in our factory with a class 100 clean room and automatic implantations that assure very high quality and very high flexibility.

Product name:	***VisioFocus® for pandemic situations***
Series:	VisioFocus®
Model:	*06400*
Description:	*VisioFocus® for pandemic situation - 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/EC Directive and following amendments Quality System ISO 9001:2008 ISO 13485:2003 e ISO 13485:2003 CMDCAS EN 60601-1 and EN 60601-1-2 (electromagnetic compatibility)*

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 our ThermoFocus® thermometer, 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® is currently used in a number of qualified centres in America, Europe, Asia, Africa, Middle East and Oceania.

Description

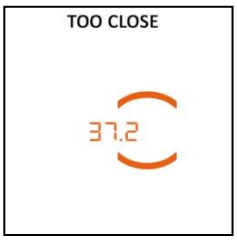
VisioFocus® is the most advanced thermometer to precisely measure body temperature. Totally hygienic, **without touching the skin**, VisioFocus reads infrared radiation naturally emitted by the surface of the skin and calculates the whole body temperature. Does not need to be disinfected and does not require the use of hygienic disposables. Therefore VisioFocus® is totally hygienic and the possibility of cross contamination is eliminated. Thanks to its exclusive technology, VisioFocus® is an essential tool for controlling the spread of a virus (such as Ebola) in pandemic situations. Indeed, VisioFocus® guarantees the best hygiene, thus **reducing considerably the risk of transmission of the virus** during the measurement of body temperature, for both patients and operators.

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 are situations in which the detection of the temperature on the forehead is not possible. When a person has a sweaty forehead the detected temperature may be lower than real. In this case it is good to know that our body uses forehead as a way of cooling the head to protect the brain, so even if the droplets of sweat are removed, the forehead will still be cold and will not reflect the correct body temperature. Also when is necessary to take the body temperature to a elderly person, in particular with the wrinkled brow, the temperature detected on the forehead may be lower than real one. This because the elderly person have a reduced and slowed blood flow, consequently the forehead may not reflect the body temperature.

In these cases, it is recommended to take the body temperature in correspondence of the **eyelid**.

There is no harm if the person eyes are open while the measurement is taken: the lights are totally harmless.

The eyelid becomes a viable alternative since it is able to provide a temperature comparable to the internal body temperature and is less subject to thermal excursions due to perspiration.

N.B.: in contrast to the majority of no contact thermometers available on the market that use lasers, VisioFocus® aiming lights are totally safe, they are not lasers but simple LED diodes!
The other thermometers are equipped with laser or have no aiming system for give the correct distance. In the first case there is the risk of damaging permanently the eyes of the person. In the second one, it isn't possible to identify the correct distance of temperature detection. VisioFocus® is the only one thermometer, together with Thermofocus®, that allow to take the body temperature on the eyelid when the forehead is not accessible.

This method of body temperature detection, accurate and safe, is the unique method for detecting the body temperature to women who wear the burqa.

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. This is important because if the distance between the thermometer and object is correct, the temperature will be correct; conversely if the distance is not correct then temperature readings change in an uncontrollable way.
This is the reason why VisioFocus® is designed with an exclusive and patented aiming system to indicate the correct distance and the correct point where to take the temperature.

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.

If VisioFocus® is set in **doct** mode, in case of a very fast change of the device's temperature, the display will show, through a countdown, 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.
If VisioFocus® is set in **nurs** mode, the manual calibration MQCS is requested and mandatory every 30 minutes. Through MQCS the thermometer is always perfectly stabilized to the ambient temperature and ready to take a series of measurements no matter how long the device is handled by the user.

To perform the **MQCS (Manual Quick Calibration System)** proceed as follow in an environment with an ambient temperature between 10 and 40 °C (50.0 – 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.

Special 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®.

Available setting

VisioFocus® is specifically suited for use in hospitals, airports, schools, factories, etc. in case of **emergency and/or pandemic situations**. This model is particularly quick, accurate and easy to use, allowing several fast and hygienic temperature readings. VisioFocus® is provided with the **MQCS** technology (mandatory procedure in the "nurs" setting) and with the **AQCS** technology (automatic in the "doct" setting) and comes with a special lanyard which allows to safely carry the device, in order to use it anytime it is needed.

- 3 different reference modes: **Oral**, **Rectal** and **Axilla**
- default setting "**nurs**": HOME button disabled; MQCS requested and mandatory every 30 minutes (when used by nurses as well as for any intensive use, like in airports etc.;

- optional setting "**doct**": HOME button enabled; AQCS automatic and optional MQCS (for doctors' use);
- **Air conditioning** adjustment **On** or **Off.**
- **Temperature level alarm**: it's possible to chose the temperature threshold beyond which the thermometer alternates the message Hi.2 to the data. The possible threshold levels are ≥37,0°C (≥98.6°F) or ≥38,0 °C (≥100.4°F).

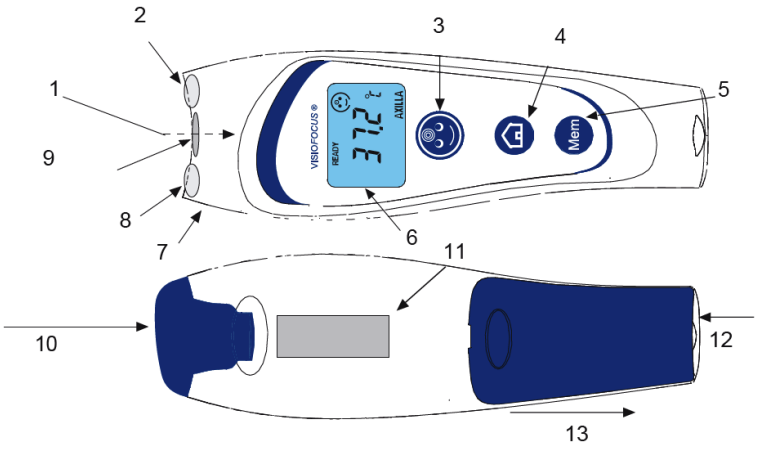
VisioFocus® can take more than thousand of accurate readings every hour, with no need to stop at all between consecutive measurements.
On request, it can also be available with a working range from 5° to 40°C (=41° to 104°F), instead of 10° to 40°C.

MEMORY FUNCTION
That allows to recall the last 9 measurements

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)

VisioFocus® Diagram

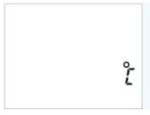
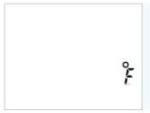
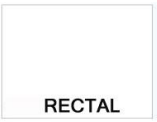
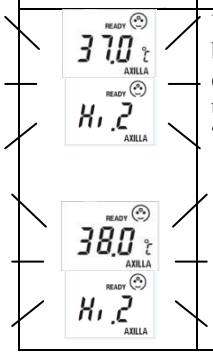


1. sensor (at the bottom of the gilt guide wave)
2. aiming light
3. "face" button for body temperature (forehead's measurement)
4. "home" button for other measurements
5. memory button
6. LCD display
7. tip
8. aiming light
9. parabolic gilt guide wave
10. protective cup
11. label with serial number
12.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

Manufacturing and QA

VisioFocus® is manufactured by Tecnimed under the ISO 9001:2008 and ISO 13485:2003 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.

Meaning of available setting

ITEM DISPLAYED	DESCRIPTION	MEANING	**HOW TO OBTAIN IT:** If you want to change one of the available setting, proceed as follow: with thermometer in stand-by mode press the "mem" button and hold it down; after about 8 seconds the visualization on the display changes showing in rotation the following combinations: °C, °F, ORAL, RECTAL, AXILLA, DOCt, NURs, 37,0°C (98,6°F), 38,0°C (100.4°F), Air - yes, not.
	on the display appears "°C".	Celsius degrees is the chosen measurement unit	When "°C" appears on the display release the "mem" button .
	on the display appears "°F".	Fahrenheit degrees is the chosen measurement unit	When "°F" appears on the display release the "mem" button .
	Using the "face" button on the display appears "ORAL".	The thermometer is set in oral reference. The temperature is always measured in the middle of the forehead. The thermometer will provide a temperature comparable to the temperature measured with a traditional thermometer in the mouth.	When "ORAL" appears on the display release the "mem" button.
	Using the "face" button on the display appears "RECTAL".	The thermometer is set in rectal reference The temperature is always measured at the middle of the forehead. The thermometer will provide a temperature comparable to the temperature measured with a traditional thermometer in the rectum.	When "RECTAL" appears on the display release the "mem" button.
	Using the "face" button on the display appears "AXILLA".	The thermometer is set in axilla reference. The temperature is always measured in the middle of the forehead. The thermometer will provide a temperature comparable to the temperature measured with a traditional thermometer under the armpit.	When "AXILLA" appears on the display release the "mem" button.
		HOME button disabled; MQCS requested and mandatory every 30 minutes (Highly recommended when used by nurses as well as for any intensive use, like in airports etc.)	When the "nurs" message appears on the display release the "mem" button.
	When you turn on the device, the display shows "doct" before the measurement	HOME button enabled; AQCS automatic and optional MQCS (suggested for doctors' use)	When the "doct" message appears on the display release the "mem" button.
	At the end of the measurement shows "air".	**Air conditioning** adjustment The "Air" function (yes or not) allows to minimize the cooling effect of intense air conditioning on the subject/patient.	When the display will show "yes" release the "mem" button.. If you want disable the Air conditioning mode, release the button when "not" appears on the display.
	Using the "face" button. The display alternate the temperature to "Hi.2".	The temperature detected exceeds the threshold levels chosen for "face" button (≥37,0°C (≥98.6°F) or ≥38,0 °C (≥100.4°F).	When "37°C (98,6°F) or 38,0°C (100.4°F) appears on the display release the "mem" button.

TECHNICAL DATA

TECHNICAL CHARACTERISTICS	
No. of buttons	3
Room temperature detection	√
Measurement time	< 0,5 seconds
time between consecutive measurements	<2 seconds
AVAILABLE SETTINGS:	
nurs (default)	HOME button disabled, MQCS mandatory every 30’
doct	HOME button enabled, MQCS not mandatory AQCS automatically activable
AIR YES *(air conditioning on)*	✓
AIR NOT *(air conditioning off)*	✓
MQCS (Manual Quick Calibration System)	NURS: mandatory every 30 minutes
Temperature level alarm	≥37,0°C (≥98.6°F) or ≥38,0 °C (≥100.4°F)
Brief additional instructions on battery door	✓
Lanyard with additional brief instructions	1 included
Batteries (included)	4 AAA/LR03 type (preferably alkaline)
Batteries life	<30.000 measurement
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)
Room temperature working range:	*10/40°C (50/104°F)
**VisioFocus® can work also in environments with a temperature between 10 and 16°C (50/60,8°F), but in this case the accuracy and the range temperature of working is not guaranteed.*	

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 the optical projection

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