



THERMOFOCUS® 0800H5

Professional



Name :	<i>Thermofocus® 0800H5</i>
Description :	Infrared non-contact clinical thermometer which allows an instant, hygienic and extremely accurate measurement of body temperature without any contact with the subject / patient
Manufacturer :	Tecnimed srl, plant in Vedano Olona, Varese
Project :	Tecnimed srl, Vedano O. (VA) Italy
Owner Patents :	Tecnimed srl, Vedano O. (VA) Italy
CE classification :	Class IIa Medical Device CE 0051
Other certifications :	FDA (USA), TGA (Australia), Koseisho (Japan), KFDA (Korea), CFDA (China), etc.
Patents :	<i>MI 1.284.119, EP 0909.377, US 6.196.714, IL 127.876, JP 504.769/98, EP 1.283.983, US 7.001.066, JP 3.863.919, and other International Patents Pending</i>
Conformance :	CE approved according to 93/42/EEC Directive and s.m.i, Quality System ISO 9001:2015, ISO 13485:2016 EN 60601-1, EN 60601-1-2, EN 60601-1-6, EN 60601-1-11 UNI CEI EN ISO 14971:2012 ASTM (American Society for testing Materials) E 1965-98(2009) Accordance with RoHS (Pb-free) directive

Thermofocus® 0800H5 is the first infrared non-contact thermometer specifically studied for professional use (i.e. in hospitals and sanitary facilities), having an exclusive aiming system in order to provide doctors and healthcare professionals a precise, hygienic and easy-to-use tool to measure body temperature in any kind of condition.

HOW IT WORKS

Thermofocus® reads infrared radiations naturally emitted by the surface of the skin and calculates the whole body temperature. It can also be used for measuring the temperature of both solid and liquid objects.

Body temperature is measured by pointing Thermofocus® at the middle of the forehead. Simply hold the thermometer close to the middle of the forehead and press the “face” button: the correct distance between the skin and the thermometer is easily determined thanks to the aiming system emitting two amber-colored LED lights. As the thermometer is moved closer to the skin, when the two lights converge into a single spot you are at the right distance (approx. cm 3 / 1.2 inch). At that point, release the “face” button and keep the thermometer still until the lights flash: the temperature appears in the LCD display.

In case the subject has a perspiring forehead or is crying (i.e. a child) or for elderly people – especially with wrinkled forehead (a low supplying of blood may cause a low temperature) - or with oxygen mask, the measurement must be taken on alternative areas such as preferably on the middle of the closed eyelid. If the measurement on the closed eyelid is not feasible (i.e. due to inflammation, surgery or other) the third recommended area to measure the body temperature is on the neck in correspondence with the jugular vein.

ADVANTAGES

The use of Thermofocus® 0800H5 ensures a series of great and concrete advantages for both the user - doctor, nurse, etc. - and the patient:

- while other kinds of thermometers require disinfection after each use or need expensive hygienic and disposable covers, Thermofocus® does not need these actions at all. **The non-contact measuring system totally eliminates all disinfection procedures and caps substitution charges**, with a saving that for a hospital results very high in terms of both time and money. Let's try to calculate how much it is: usually the cost of a probe cover for ear thermometer is between 4 and 10 euro cents (depending on the type of device). Let's assume an average cost of 5 eurocents each and to make 2 measurements per day in a ward with 50 beds. The cost will be $0,05 \times 2 \times 50 = 5$ Euros per day spent in disposable covers. After 1 year (365 days) the total annual cost will be 1.825 Euros for each thermometer. A complete waste of money!
- with other thermometers, for each measurement you should calculate: putting the cover on the probe, positioning the device in the ear canal, taking away and disposing the cover, which takes about 15 seconds in total. So $(15'' \times 0,5 \text{ eurocents/second}) \times (2 \text{ measurements} \times 50 \text{ beds} \times 365 \text{ days}) = \text{more than } 2,700$ Euros per year. The **battery** needing is also favorable to Thermofocus®. Hence, we can assume that **each Thermofocus® makes the Hospital saving from 4,000 to 5,000 Euros per year!**
- thanks to its new patented quick stabilization technology MQCS, **Thermofocus® 0800H5 stabilizes to room temperature very quickly**. A “plus” which makes it particularly indicated for hospital use, where room temperature can change from room to room, as well as on ambulances;
- **Thermofocus® 0800H5 avoids disturbing the patients during the measurement of body temperature**, thanks to its display backlight function. This function makes Thermofocus® 0800H5 perfect to be used with children, elderly people, sleeping patients, also during the night, without needing to turn on the light in the room. More attention to the comfort of the patient and less troubles, without any additional cost.

MAIN FEATURES

Thermofocus® 0800H5 implements a list of new functions, created to maximize its performances and its use in a sanitary contest:

- **MQCS technology (Manual Quick Calibration System)**, a new exclusive and patented function which allows doctors, nurses and hospital staff to take temperatures easily and precisely even if they are moving quickly from room to room. Thanks to this feature, Thermofocus® 0800H5 is ideal for use by ambulance personnel when working at patient's home;
- **special lanyard** with additional brief instructions - to be worn around the neck - and special "**mirror Target Disc**", to be put in the rooms, which allows to better and quicker accomplish the MQCS (additional mirror target discs are available on request);
- **amber - colored LED lights** (completely harmless);
- default setting "**nurs**": MQCS requested and mandatory every 15 minutes (when used by nurses as well as for any intensive use, like in airports etc.);
- optional setting "**doct**": if the thermometer's temperature is changing, the AQCS (Automatic Quick Calibration System) is automatically activated and allows the rapid stabilization of the thermometer to the room temperature: the display shows a countdown indicating the time required. To make a measurement is necessary to wait the end of the countdown without touching the device or **is possible to do the manual MQCS (suggested procedure)**. Using the "face" button it is possible to take also surface temperatures (different from the body temperature) between 1 to 55°C (33.8° to 131°F). The display will show alternatively the temperature value and "Lo.3", if the value is <34°C (93.2°F), or "Hi.2", if it is > 40°C (104°F). These measurements are not entirely accurate and must be considered as relative rather than absolute values. If taken on the skin, these values will show the difference between two close or symmetrical areas (i.e. the two hands, the two knees, etc.). This setting is studied for doctor's use and also for the use in a specific ward as the Emergency Room;
- **Temperature level alarm**: in order to attract the attention of the operator if the temperature is $\geq 37,0$ °C (≥ 98.6 °F) or ≥ 38.0 °C (≥ 100.4 °F), the optical aiming system flashes quickly for 6 seconds (instead of the normal 2 seconds), and the display shows alternating the message Hi.2 to the data.
- **air conditioning On or Off** in case of high air conditioning in the room;
- **display backlight**, which lasts for 2 seconds after each measurement;
- "**light bulb**" button which permits to reactivate the display backlight for 2 seconds, to show the last measurement and to change the settings/modes;
- **additional instructions on the battery door**;
- Using the "FACE" button, it is possible to take any temperature from 1 to 55°C/33.8 to 131.0°F. The display will show alternately the temperature value and "Lo.3", if the recorded value is <34°C/93.2°F or "Hi.2", if it is >37°C or 38°C (98.6 or 104°F) depending on the Alarm level.



With Thermofocus® 0800H5, flexibility, accuracy and repeatability of the measurement are always guaranteed, thanks to its innovative and patented optical aiming system, which allows to determine in any condition the correct distance between the thermometer and the measurement area.



APPLICATIONS

Thermofocus® 0800H5 is multipurpose and can be used for:

- *measuring the body temperature;*
- *scanning specific areas of the skin, in order to detect the temperature difference between healthy areas and areas where there are anomalies due to inflammations, circulatory diseases, diabetes;*
- *measuring the temperature of open wounds or organs during surgical interventions, in order to know the difference from healthy areas, ensuring maximum hygiene thanks to the total absence of contact.*

MANUFACTURING AND QA

THERMOFOCUS® is manufactured by Tecnimed within its factory in Vedano Olona (Italy) under the ISO 9001:2015, the ISO 13485:2016 Quality System.

The production, control and calibration of THERMOFOCUS® are performed in a temperature-controlled room. Packaging is done in an ambient-controlled room. The quality of the product is further certified by external independent institutes.

PATENTS

Thermofocus® is protected by following patents: MI 1.284.119, EP 0909.377, US 6.196.714, IL 127.876, JP 504.769/98, EP 1.283.983, US 7.001.066, JP 3.863.919 and other international patents pending.

TECHNICAL FEATURES	
No. of buttons	2
LED lights color	Amber
Room temperature detection	✓
Resolution	0.1°C (0.1°F)
Measurement time	< 0,5 seconds
Time between consecutive measurements	<2 seconds
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)
MQCS (Manual Quick Calibration System)	NURS: mandatory every 15 minutes
	DOCT: available but not mandatory
Room temperature working range for measurement on the forehead	16/40°C (50/104°F)*
Room temperature working range for other measurements	5/40°C (41/104°F)*+
<small>* Thermofocus 01500 A/H1N1 can work also in environments with a temperature between 5 and 15.9°C (41/60.6°F), but in this case the accuracy is not guaranteed and the message "Lo.5" and the temperature value are displayed alternatively.</small>	
Protective cap	Standard
Display backlight	At request
Weight	92 grams
Batteries (included)	4 AAA/LR03 type (alkaline)
Batteries life	Up to 20.000 measurements

AVAILABLE SETTINGS:	
nurs (default)	MQCS mandatory every 15 minutes
doct	AQCS automatically activable and MQCS not mandatory. Measuring range from 1 to 55 °C (from 33.8 to 131°F)
AIR YES (air conditioning on)	✓
AIR NOT (air conditioning off)	✓
Temperature level alarm	≥37,0 °C (≥98.6°F) or ≥38,0 °C (≥100.4°F)

ACCURACY LEVEL (IN INSTRUMENTAL TESTS ACCORDING TO ASTM E 1965-98 (2009) STANDARD)	
Forehead measuring range	
from 36 to 39°C (96.8/102.2°F) =	+/-0.2°C (+/-0.4°F)
from 34 to 35.9°C (93.2/96.6°F) =	+/-0.3°C (+/-0.5°F)
from 39.1 to 42.5°C (102.4/108.5°F) =	+/-0.3°C (+/-0.5°F)
General measuring range out of the body temperature	
from 1 to 55°C (33.8/131°F)	The measurements are not entirely accurate and must be considered as relative rather than absolute values.
Distance from the subject during operation: about 3 cm (1.2 inch), set through an optical signal	

ACCESSORIES	
Brief additional instructions printed on battery door	1 included
Lanyard with additional brief instructions	1 included
Batteries	N° 4 AAA/LR03 type (alkaline) included