

# THERMOFOCUS®

**Serie 0800 - 0800 Series  
versione ospedaliera  
hospital version**

**Modello 01500A/H1N1  
01500A/H1N1 Model**



modello 0800H4  
0800H4 model

## IT Manuale d'uso

## EN User Manual

### THERMOFOCUS®

Dispositivo medico di classe IIa - *Class IIa medical device*  
Clinicamente testato - *Clinically tested*

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Manufacturing Ideas

Cod. 908A6/1 r. 01 110519



Ai sensi dell'art. 13 del D. Lgs. 25 luglio 2005, n. 151 e ai sensi dell'art. 22 del D. Lgs. 20 novembre 2008, n. 188: il simbolo del cassettoni barrato indica che l'apparecchio, alla fine della propria vita utile, deve essere raccolto separatamente dagli altri rifiuti, così come le pile esauste. La raccolta differenziata della presente apparecchiatura giunta a fine vita è organizzata e gestita dal produttore. L'utente dovrà quindi contattare il produttore e seguire il sistema adottato per consentire la raccolta differenziata dell'apparecchiatura. L'adeguata raccolta differenziata per l'avvio successivo dell'apparecchiatura dismessa e delle pile esauste al riciclaggio, al trattamento e allo smaltimento ambientalmente compatibile contribuisce ad evitare possibili effetti negativi sull'ambiente e sulla salute e favorisce il riimpiego e/o riciclo dei materiali di cui è composta l'apparecchiatura. Lo smaltimento abusivo del prodotto da parte del detentore comporta l'applicazione delle sanzioni amministrative previste dalla normativa vigente.

According to 2002/95/EC, 2002/96/EC and 2003/108/EC Directives and according to 2006/66/EC Directive: the crossed-out wheeled bin indicates separate collection for electrical and electronic equipment and for batteries and accumulators. Please dispose of device and used batteries in compliance with current law. The separate collection of your device and batteries will prevent potential effects on the environment and human health and will facilitate treatment and recycling.

## THERMOFOCUS®

0800 Series and 01500A/H1N1 model

Thermofocus® 0800H4 hospital is specifically studied to be used in a hospital or clinic environment.

Thermofocus® 01500A/H1N1 is specifically designed for airports, schools, factories, hospitals, etc. in case of emergency and/or pandemic situations where it is necessary to take several fast and hygienic temperature readings.

### IMPORTANT

The manual calibration to ambient temperature ("MQCS" - see page 7) is mandatory with the default setting. There are two possible settings: "NURS": "HOME" button disabled (oFF) and manual calibration MQCS mandatory. This setting is highly recommended for nurses that take many measurements moving from room to room; "DOCT": "HOME" button enabled and manual calibration MQCS suggested but not mandatory. This setting is recommended for the doctor who uses Thermofocus® mainly in his/her studio. Please note that if the thermometer set in "doct" is used too frequently and intensively (as in an hospital department) the system will ask the user to make the MQCS anyway. The 0800 series is set in "nurs" mode by default. To change the setting from "NURS" to "DOCT" - and vice-versa - see paragraph "Change of settings/modes" on page 8.

### PREFACE

Thermofocus® is the first non-contact clinic thermometer in the world: to take body temperature simply point it close to the forehead at the distance indicated by its exclusive optical aiming system.

Thermofocus® is:

- **hygienic**: never touches the patient, does not need disinfection and does not require expensive disposable caps;
- **comfortable**: as Thermofocus® is totally non-invasive, there is no need to wake up the patient or to ask for his cooperation while taking the temperature;
- **precise**: detects the body temperature with constancy, repeatability and precision;
- **unique**: Thermofocus® cancels all variables which can't be monitored by and do not depend on the health worker (i.e. the presence of earwax during a tympanic measurement or the displacement of the thermometer during the armpit or oral measurement). With Thermofocus® only the user can be sure of having the total control on all measurements made in the hospital ward.

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### DISPLAY BACKLIGHT (0800H4 model only)

The display of the 0800 series automatically lights up when you make a measurement, as soon as the button is released, and remains lighted up for about 2 seconds (4 seconds in case of temperature values alternating with error messages). It can be easily reactivated by pushing the "LIGHTBULB" button

### INSERTING/CHANGING THE BATTERIES

1. Press with a nail or a pen inside the small square button in the rear of the device, as indicated in the fig. 9. Lift the cover up.
2. Remove the old batteries and discard safely.
3. Insert 4 new batteries (AAA or LR03, preferably alkaline) taking care to insert them in the correct position as indicated.
4. Replace the cover.
5. After changing the batteries wait for about 20 minutes before using the device or do the MQCS.
6. Remove batteries if the device is not in use for a significant length of time.

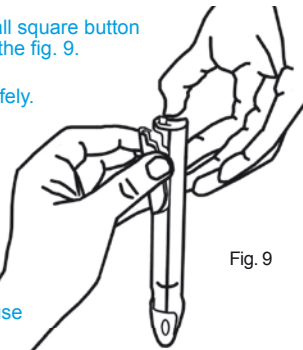


Fig. 9

### CLEANING

**CLEANING THE GILT GUIDE WAVE:** it is important never to touch the gilt guide wave with your fingers or with any other object, as it is very delicate. For this reason, we recommend to protect the thermometer by closing its protective cap when not in use. If the guide wave need cleaning, lightly moisten a cotton bud with alcohol, and apply gently to the guide wave without pressing. Make sure that you clean away from the direction of the sensor, located at the bottom of the guide wave. Avoid cleaning with any other objects or liquids, which could scratch or in any way damage the guide wave. While cleaning, ensure that no liquid penetrates between the guide wave and the sensor.

**CLEANING THE BODY OF THE THERMOMETER:** use a soft cloth slightly dampened with soapy water.

**DO NOT USE** the thermometer for at least 30 minutes after cleaning.

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### WARNINGS

Please read all the instructions carefully before using the thermometer

1. Thermofocus® is extremely precise, sensitive and easy to use.
2. To avoid incorrect measurements, use Thermofocus® according to this user manual.
3. Use Thermofocus® in a draft-free room at a constant temperature between 16°C (60.8°F) and 40°C (104°F). No matter if it is set in "NURS" or "DOCT", if the thermometer is taken from a room (or drawer or gown's pocket) with a temperature different from that in which it is being used, use the MQCS in order to calibrate the device to the room temperature before using it. Please see the section on calibrating your thermometer (page 7).
4. **Do not use the thermometer on a perspiring forehead**, as this may affect the reading. Read the appropriate chapter (page 5).
5. Avoid taking the subject's temperature:
  - in a drafty location;
  - if the subject has exerted him/herself;
  - if the subject has been in a drafty room or a place where the temperature is significantly different from that in which the thermometer is being used;
  - if the subject has recently had a cold cloth or cold compress on the forehead;
  - if the subject has recently been wearing a hat or a scarf;
  - if the subject has been exposed to any activity which may affect the normal temperature of the head such as bathing, showering, shampooing, hair drying, etc..
6. The area from which the temperature is taken has a radius of about 2 cm (3/4 inch) around the point of light. It is very important to ensure that this area is not obstructed by hair or clothing and does not include eyes or eyebrows. If you change the point of measurement on the forehead you will get different results. For this reason, it is important that the two aiming lights are directed towards the middle of the forehead (between the nose and the hairline) and that the thermometer is held perpendicular to the forehead, taking care to hold aside any hair to clear an area of at least 4 cm (1,5 inch) around the light point.
7. Oils or cosmetics on the forehead may give a lower temperature reading than the actual one, while hair obstructing the forehead may cause a slightly higher reading.
8. The gilt guide wave (see fig. 10) of the thermometer is the most delicate part of the device. It consists of a small concave gold-plated mirror, which must be kept clean and undamaged. The accuracy of the reading may be affected if the guide wave is damaged or dirty. For guide wave cleaning see page 6.

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### MQCS: ROOM TEMPERATURE CALIBRATION

The exclusive Manual Quick Calibration System (MQCS) immediately corrects the internal temperature of the thermometer, adapting it to the actual ambient temperature of the room in which the measurement will be taking. This system is extremely useful in case you have to move quickly from one room to another - having different temperature - and you cannot wait too long to have the thermometer stabilized to room temperature: for example, if you move from room to room in a hospital department, especially if rooms have different exposures (North, South, etc.) OR in case of ambulance use for home-care.

With a room temperature between 16 and 40°C (60.8 /104.0°F), proceed as follows:

- press and release the "FACE" and "HOME" buttons at the same time (fig. 6). The word "CAL" will appear;
- within 10 seconds open the protective cap and point the thermometer towards the white label of the "Target Disc", already positioned in the room, pressing the "HOME" button (fig. 7);
- release the button: the aiming lights will flash twice slowly and the display will then indicate the reading as a reference room temperature;
- Thermofocus® is now ready to take the temperature: the symbol "RE" on the display indicates that the thermometer has been stabilised with the MQCS.

The Target Disc (provided with the 0800H4 model only) - or any other suitable reference point - must be properly and previously positioned on an internal wall (or wardrobe) far from heat or cold sources at head height (fig.8) by a person in charge. If a Target Disc is not available, it is possible to use directly the surface of an internal wall or wardrobe. Please avoid any external wall or windows. However, to prevent the user from having to choose a suitable surface, it is recommended to stick on the reference area a precise reference point, known by the whole staff (a label, a post-it, a circle drawn on the wall by outlining a coin, etc.). ATTENTION: the Target Disc CANNOT be either moved or removed from the chosen position.

When you do the MQCS, the 0800H4 model maintains the detected room temperature for 15 minutes, the 01500A/H1N1 model for 30 minutes. After this lapse of time, the thermometer will ask to make the MQCS again. Of course, it is possible to repeat the MQCS, which will then be kept for other 15/30 minutes.

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9. Avoid touching the thermometer, particularly the tip, more than necessary before taking a reading.
10. Do not use the thermometer in contact with the ear or any other surface area of the body.
11. Do not use the device near large electromagnetic fields such as found with cordless or cell phones.
12. Keep the device away from water and heat, including direct sunlight. Do not drop or knock the device, and do not use it if damaged.
13. **Failing to follow these guidelines may result in excessively high or low readings which are in no way attributable to a faulty device.**
14. No harm can be caused should the aiming lights be accidentally pointed in the eyes: the beams are absolutely harmless!
15. Abrupt movements of the patient (i.e. a baby) may not allow an accurate reading. Approaching the patient with the aiming lights already on may help, as it makes the measurement quicker.

### HOW IT WORKS

Thermofocus® receives infrared radiations naturally emitted by every subject or object, and in particular from the forehead of human beings. The forehead is the ideal part of the body from which to take a temperature because it is supplied by the temporal artery, which receives blood through the aorta and the carotid artery, guaranteeing a considerable flow of blood. Moreover, the forehead is the only part of the body close to the brain, which is not covered by hair. The brain is the most important and delicate organ in the body, and the one most liable to damage from excessive temperature. Furthermore, the head is the first part of the body to modify its temperature in case of fever, whether rising or falling.

At every measurement, Thermofocus® carries out every hundredth of a second a sequence of 125 readings, which are amplified and computed by its sophisticated microprocessor, together with the value of the ambient room temperature. The result of these data processing is the correct temperature, shown on the display.

**It is important to be aware that no single "normal" temperature applies to everyone: each person has his/her own temperature, which changes not only during the day, but also according to certain physical activities undertaken by the subject** (for example, if a baby has been crying). Moreover, an individual's temperature may change in the different regions of the body, and may be influenced by the ambient temperature and other external factors, depending on how the temperature is being taken.

Because of the heat loss from parts of the body uncovered by clothing, the normal temperature measured on a person's forehead is usually lower than that of covered parts of the body.

For this reason, an infrared thermometer should automatically adjust to ambient temperature before any measurement.

### CHANGE OF SETTINGS/MODES

Depending on the Country of destination your thermometer has been set up to:

- Centigrade (°C) or Fahrenheit (°F) degrees;
- Axilla, ORAL or RECTAL settings;
- two different modes: "NURS" ("HOME" button disabled - oFF - and compulsory calibration MQCS) or "DOCT" ("HOME" button enabled and calibration MQCS possible but not mandatory);
- "Air" function: to be activated in case of high air conditioning in the room. It is possible to change the device settings by proceeding as follows:
  1. With the thermometer in stand-by mode press the "FACE" 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, AX, doct, nurs, Air, yes, not (Air function: choose "yes" in case of high air conditioning in the room - the display will show alternately the word "Air" and the temperature value - otherwise leave the setting on "not").
  2. When the preferred setting appears, release the button. The thermometer is ready to be used. You can change only one setting at a time.

### POSSIBLE PROBLEMS AND THEIR SOLUTIONS

1. Display does not switch on:
  - batteries are flat or low or have been incorrectly inserted; replace the batteries immediately or reinsert them correctly.
2. Two bright points of light are visible on the subject's forehead:
  - the distance from the device to the forehead is incorrect; move the thermometer closer or further away until you see a single bright point of light.
3. The point of light is hard to see:
  - there is too much light in the room; position yourself to cast a shadow over the subject.
4. The gilt guide wave is damaged or water has penetrated the thermometer:
  - contact the distributor for assistance.
5. The temperature shown on the thermometer appears too low:
  - check that the device has been used correctly (see "WARNINGS" section of this handbook);
  - check that the thermometer is held correctly perpendicular to the forehead, as shown in figure 2;
  - check that the gilt guide wave is not dirty or damaged; if so, clean as indicated in the appropriate section of this manual or, if damaged, contact the distributor.
6. The temperature shown on the thermometer appears too high:
  - check that the device has been used correctly (see "WARNINGS" section of this booklet).
7. The aiming lights remain constantly on after releasing the button, or the thermometer appears to be stuck or frozen in process:
  - reset the thermometer by removing and reinserting the batteries.

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The internal software of Thermofocus adjusts to ambient temperature and when the "FACE" button is pressed, it applies automatically a corrective in order to give an approximate value, comparable with the oral or armpit temperature, according to the current device setting. To change the settings please refer to the appropriate paragraph on page 8.

The normal temperature taken from the forehead of a healthy person, using Thermofocus®, can vary between 35°C (95°F) and 37.5°C (100.4°F), but in an adult it can also be below 35°C (95°F).

### HOW TO USE THERMOFOCUS®



#### Taking the temperature on the forehead

1. Press and release the "FACE" button to activate Thermofocus® and open the protective cap.
2. On the display will appear the symbol "hand" together with the word "CAL", which reminds to do the MQCS if necessary before proceeding with the body temperature measurement. If the MQCS is compulsorily requested by the device and/or appears to be necessary, please proceed as follows:
  - press and release the "FACE" and the "HOME" buttons at the same time: the word "CAL" will appear on the display;
  - within 10 seconds open the protective cap and point the thermometer against the white label of the "Target Disc", or another proper reference area, opportunely placed in the room, pressing the "HOME" button;
  - release the button: lights will flash twice slowly and then the display will show the acquired temperature;
  - Thermofocus® is now ready to take a measurement. For more details about MQCS see page 7.
3. To make the measurement press once the "FACE" button to bring the device on the READY status (in case it went on stand-by). Press the same button again and hold it down: the two aiming lights will switch on and the display will start to show the temperature, together with the symbol .
4. Hold Thermofocus® perpendicular to the **middle of the forehead** and move it closer to or further from the forehead until a single point of light appears. If the thermometer is too far away from the forehead, you will see two blurred points of light (fig. 1). If the thermometer is too close, you will see two separate points of light. When you see a single point of light on the subject's forehead, it means that the thermometer is at the correct

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WHAT THE SYMBOLS ON THE DISPLAY MEAN			
WHAT IS SHOWN ON THE DISPLAY	DESCRIPTION	PROBLEM	SOLUTION
	The display shows the battery symbol during normal use.	The batteries are running low.	Change the batteries as soon as possible (see the appropriate chapter at page 6).
	The display shows "E.1" and the battery symbol, or it does not switch on.	The batteries are flat.	Change the batteries (see the appropriate chapter at page 6).
	The display flashes, alternating between showing the measurement and the figures "H.2".	The subject has very high fever (over 40°C - 104°F).	Consult a doctor.
	The display shows "H.4".	The ambient temperature is too high (over 40°C - 104°F).	Move to a cooler location.
	The display shows "H.4".	The ambient temperature is too high (over 40°C - 104°F).	Move to a cooler location.
	Measurement with button  the display shows "Lo.5". Measurement with button  the display flashes, alternating between showing the measurement and the figures "Lo.5".	The ambient temperature is too low (below 16°C/60.8°F).	Move to a warmer location.
	The display shows "E.8".	The device was moved before the lights flashing or a large electromagnetic field is affecting the measurement.	Take the measurement again, making sure that the lights flash before moving the thermometer and/or that there are no cell or portable phones in the immediate area.
	The display shows "E.8".	The device was moved before the lights flashing or a large electromagnetic field is affecting the measurement.	Take the measurement again, making sure that the lights flash before moving the thermometer and/or that there are no cell or portable phones in the immediate area.
	Measurement with button  the display shows the figures "H.2".	The temperature of the surface being measured exceeds the working limits of the device.	Make sure you have pressed the correct button.
	Measurement with button  the display shows the figures "H.2".	The temperature of the surface being measured exceeds the working limits of the device.	The temperature cannot be taken.
	Forehead measurement with button  the display shows the figures "Lo.3".	The forehead temperature appears too low.	Check that the guide wave is not dirty, and that the subject has not just come from a location with a lower ambient temperature.
	Measurement with button  the display shows the figures "Lo.3".	The temperature of the surface being measured is below the working limits.	The temperature cannot be taken.
	The display shows CAL, the symbols "home", "hand" and the word CALIBR?.	The symbols suggest to make the MQCS calibration.	If necessary, make the MQCS (pag. 7).
	Whilst on stand-by, Thermofocus® indicates the room temperature as well as the symbol "RE".	The thermometer has been rapidly stabilized.	

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distance to get an accurate temperature reading to be taken (fig. 9).

5. Release the button and holding the device steady until the lights flash.

6. Read the value shown on the display. The device is ready to proceed immediately with another measurement.

After about 20 seconds of non-use, Thermofocus® will go on stand-by and indicate the room temperature for 15 minutes if set in "NURS" and for 45 minutes if set in "DOCT" (30 minutes for the 01500A/H1N1 model) before switching off automatically.

For an optimal use we suggest to watch the descriptive DVD included in the box.



#### Sweat, oxygen mask, elderly patients: alternative measurements

In case of perspiring forehead, oxygene mask, old patients - especially with wrinkled forehead - or crying babies, the measurement must be taken on one of the following alternative areas:

- preferably on the middle of the closed eyelid (fig. 3)
- on the neck, in correspondence with the jugular vein: point Thermofocus® about 2 cm under the ear and move it perpendicularly to the neck, in order to cover an area of about 5 cm (fig. 4). These measurements do no guarantee the same accuracy you get on the forehead, so they should be used only when the forehead measurement is not possible. However, they can be considered as a valid approximation of the body temperature and a fever indicator. They are also recommended when the forehead measurement is altered by oils or cosmetics.



#### Other measurements

In "DOCT" mode, using the "HOME" button, you can also:

- take any temperature from 1 to 55°C/33.8 to 131.0°F (canteen meal, liquids, incubator, professional tools, room-temperature, etc.);

- scanning the skin temperature of different body areas (fig. 5), in order to detect possible inflammations and/or circulatory diseases or any other problem which may cause an alteration of the surface skin temperature. Of course Thermofocus® can be used on open wounds or organs during surgical interventions, ensuring maximum hygiene thanks to the total absence of contact.

Proceed as for a forehead body temperature measurement, but press the "HOME" button.

In case of hospital use only - in the different rooms of a hospital department - to measure the body temperature, it is highly recommended to disable the "HOME" button by setting the thermometer in "NURS", in order to avoid pushing the wrong button.

The 0800 series is usually supplied set in "NURS" by default.

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### TECHNICAL CHARACTERISTICS

Celsius scale	THERMOFOCUS® Infrared no contact thermometer	Fahrenheit scale
<b>Body temperature in medical use</b>		
34.0/42.5°C	Forehead measuring range	93.2/108.5°F
16/40°C	Ambient temperature working range	60.8/104.0°F
0.1	Resolution	0.1
ASTM (E 965-98-2009) laboratory accuracy requirement 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 from 37 to 39 °C (98/102 °F) is +/- 0.1 °C (+/- 0.2 °F).		
+/- 0.2°C	accuracy from 36 to 39 °C (96.8 to 102.2 °F)	+/- 0.4°F
+/- 0.3°C	accuracy from 34.0 to 35.9°C (93.2/96.7°F) and from 39.1 to 42.5°C (102.3/108.5°F)	+/- 0.5°F
<b>Other uses</b>		
1.0/55.0°C	Measuring range	33.8/131.0°F
* 16/40°C	Ambient temperature working range	* 60.8/104°F
0.1	Resolution	0.1
+/- 1.0°C	accuracy from 1.0 to 19.9°C (33.8/67.9 °F)	+/- 1.8°F
+/- 0.3°C	accuracy from 20.0 to 35.9°C (68.0/96.7°F)	+/- 0.5°F
+/- 0.2°C	accuracy from 36 to 39°C (96.9 to 102.2°F)	+/- 0.4°F
+/- 0.3°C	accuracy from 39.1 to 42.5°C (102.3/108.5°F)	+/- 0.5°F
+/- 1.0°C	accuracy from 42.6 to 55°C (108.1/131 °F)	+/- 1.8°F

\* The device can work also in environments with a temperature between 5 and 16°C (41-60.8°F), but we do not guarantee the accuracy and the measuring range. Besides the readings are alternate to "Lo.5".

Power supply: 4 batteries alkaline type AAA (LR03) 1.5 V (included)  
Life span of high-quality batteries: up to 3 years or 20,000 measurements according to use.  
Dimensions: mm 165 x 40 x 21.9 (inch 6.5 x 1.45 x 0.86) protective cap included  
Weight: gr. 90 (3.17 oz.) - (batteries included)

Distance of operation from the subject fixed through optical signal: about cm 2.5 (1 inch)  
Wide and visible display  
Store in a clean and dry place preferably at a temperature between +16 and +40°C (60.8 and 104°F).

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