PROFESSIONAL MEDICAL PRODUCTS

- Sensore del termometro
- Thermometric sensor
- Czujnik termometryczny
- Senzor termometric
- Termometrické čidlo
- Toplomjerni osjetnik
- Temperatursensor
- Lämpömittarianturi

- Tasto ON/OFF
- ON/OFF Button
- Przełącznik WŁ/WYŁ
- Buton ON/OFF
- Tlačítko ON/OFF
- Gumb za OALJENJE/ GAŠENJE
- ON/OFF-knapp
- ON/OFF-painike

- Vano batteria
- Battery compartment
- Komora baterii
- Compartiment pentru baterie
- Přihrádka na baterie
- Odjeljak a bateriju
- Batterifack
- Paristokotelo

- Punta del termometro
- Thermometric tip
- Koncówka termometra
- Vârf termometru
- Hrot teploměru
- Vrh toplomjera
- Termometerspets
- Lämpömittarin kärki

- LCD
- LCD
- LCD
- LCD
- LCD
- LCD
- LCD
- Nestekidenäyttö

ENGLISH

DIGITAL THERMOMETER (Not Waterproof)

Note: The exterior of each model has a little difference.
Congratulations on your purchase of this product. Please read the instructions carefully before using the thermometer for the first time, and keep these in a safe place. This product is intended for the measurement of human body temperature. this product is for home and hospital use, operator shall be at least 11 years old and patient can be operator.

Operating Instructions

Before using, please disinfect the probe at first. To switch on, press the ON/OFF button next to the display; a short beep will sound, indicating that the thermometer is operational. At the same time the thermometer runs a self-check test, during which all the digital segments appear on the LCD. When the letters "Lo" and a flashing "°C" display, the thermometer is now ready for use. If the ambient temperature is below 32°C, then "Lo°C" or will appear on the LCD and if it is more than 42.9°C , then "HI°C" " will appear on the LCD.
During the reading, the current temperature is displayed continuously and the "°C" symbol flashes. The measurement is completed when a constant temperature value has been reached. The temperature value is considered constant when the temperature rises less than 0.1°C within 16 seconds. As soon as the constant temperature value is reached, a beep will sound ten times, and the "°C" symbol will stop flashing. The highest temperature measured appears on the LCD. However, please note that this thermometer is a maximum thermometer, i.e. the displayed temperature can increase slightly if measurement continues after the beep. This is particularly the case with axillary measurements, should a temperature value be recorded which approximates the core body temperature.
In this instance please note the description under "Methods of measuring temperature". When the measurement is completed, please switch the thermometer off by pressing the ON/OFF button. After the temperature has been displayed, the thermometer will shut off automatically in 10 minutes.

Memory function

Switch the thermometer on, a short beep will sound. At the same time the thermometer runs a self-check test, during which all the digital segments appear on the LCD. After that the last measured value with "C" will appear automatically on the LCD for about 2 seconds. The reading is only over-written when a new temperature value is recorded.

Methods of measuring temperature

It is important to remember that the body temperature reading depends on the site where it is measured. For this reason, the measurement site must always be specified in order to ensure that a correct temperature reading is recorded.

In the rectum (rectal)

This is the most accurate method from a medical point of view, because it comes closest to the core body temperature. The thermometer tip is inserted carefully into the rectum for a maximum of 2 cm.
The usual measuring time is approximately 40 to 60 seconds.

Under the arm (axillary)

Placing the thermometer in the armpit provides a measurement of surface temperature that can fluctuate by around 0.5°C to 1.5°C from rectal temperature readings in adults. The usual measuring time for this method is approximately 80 to 120 seconds. It should be noted, however, that an exact reading cannot be obtained if, for example, the armpits have been allowed to cool. If this is the case, we recommend extending the measuring time by around 5 minutes in order to obtain the most precise possible reading that corresponds as closely as possible to the core body temperature.

In the mouth (oral)

There are different heat zones in the mouth. As a general rule, the oral temperature is 0.3°C to 0.8°C lower than the rectal temperature. To ensure that reading is as accurate as possible, place the thermometer tip to the left or right of the root of the tongue. The thermometer tip must have constant contact with the tissue during the reading and be placed under the tongue in one of the two heat pockets at the back, keep the mouth closed during the reading and breathe evenly through the nose. Do not eat or drink anything before the measurement. The usual measuring time is approximately 50 to 70 seconds.
Note: We strongly recommend the rectal method as the most accurate method for identifying the basal temperature, and advise you to extend the measuring time by 3 minutes after the beep.

Cleaning and disinfection

The best way to clean the thermometer tip is by applying a disinfectant (e.g. 70% medical alcohol) with a damp cloth.
It shall be disinfected before each use. This thermometer is warned not waterproof and can not be immersed in liquid or lukewarm water for through cleaning and disinfection.

Summary of use specification

This usability engineering process assesses and mitigated risks caused by usability problems associated with correct use and use errors, it shows the digital thermometer is complied with and acceptance criteria documented in the usability validation plan have been met, then the residual risk as defined in ISO14971, associated with usability of a medical device are acceptable.

Safety precautions

- Do not allow the device to come into contact with hot water.
- Do not expose to high temperatures or direct sunlight.
- Do not drop the thermometer. It is neither shock-proof nor impact-resistant.
- Do not modify this device without the authorization of the manufacturer.
- Do not bend or open the device (except the battery compartment).
- Do not clean with thinners, petrol or benzenel. Only clean with disinfectant.
- Do not immerse the thermometers in liquid.
- The thermometer contains small parts (battery, battery compartment) which can be swallowed by children. For this reason, do not leave the thermometer unattended in the hands of children.
- Avoid bending the thermometer tip which contact patient with stainless steel cover.
- If the ambient temperature is over 40°C dip the thermometer tip in cold water for approx. 5 to 10 seconds prior to measuring the temperature.
- Persistent fever, in particular in children, has to be treated by a doctor please get in touch with your doctor!
- Do not use near strong electromagnetic fields, i.e. keep it away from any radio systems and mobile phones.

Battery replacement

The battery is empty and needs replacing when the " " or " " battery symbol appears on the right of the LCD. Remove the battery cover and remove the battery by toothpick, replace it with a battery(preferably non mercury) of the same type.
Please note: the " + " sign up and " - " sign down.
We advise you to remove the batteries if the device is not going to be used for a longer period of time.

Technical data

Type: maximum thermometer
Measurement range: (32.0~42.9)°C
Measurement accuracy: +/- 0.1°C (35.5°C~42.0°C), +/- 0.2°C (32.0°C~35.5°C (42.0°C~42.9°C)
Storage/transportation temperature: (-25~55)°C, ≤95%RH
Ambient temperature during use: (5~40)°C, ≤80%RH
Min Scale: 0.1°C
Atmospheric pressure:700~1060hPa
Mode of operation of the clinical thermometer: direct mode
Transient response time: 12s
Battery type: Alkaline battery, type LR41, 1.5V, service life minimum 100 hours under continuous operation.
Weight: Approx. 10g
Shelf life: 3 years

Explanation of symbols

	Battery check
	WEEE disposal
Lo°C	Temperature under 32°C
HI°C	Temperature over 42.9°°C
	Stand by

	Type BF applied part
	Caution: read instructions (warnings) carefully
	Keep away from sunlight
	Keep in a cool, dry place

	Consult instructions for use
	Manufacturer
	Date of manufacture
CE	Medical Device complies with Directive 93/42/EEC
REF	Product code

LOT	Lot number
IP22	Covering Protection rate
	Temperature limit
	Atmospheric pressure limit
	Humidity limit

Legal requirements and guidelines

This product complies with the European Directive for Medical Device 93/42/EEC and carries the CE mark, the device also complies with the specifications of below standard for:
ISO 80601-2-56:2017/AMD 1:2018
EN 60601-1
EN 60601-1-11
EN 60601-1-2
The CE Marking confirms that this is a medical device with a measuring function in the sense of the medical device Act which has undergone a conformity assessment procedure. A Notified body confirms that this product fulfills all the appropriate statutory regulations

Calibration check

This thermometer is initially calibrated at the time of manufacture. If this thermometer is used according to the operation instruction, periodic re-adjustment is not required.
The calibration check has to be carried out immediately, if there are indications that the product does not keep the defined error limits or the calibration properties could have been affected by an intervention or by any other means.
Please also observe any national statutory regulations. The calibration check can be carried out by the competent authorities or by authorised service providers.
A test instruction for calibration check can be provided to the relevant authorities and authorised services providers on request.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This device is suitable for home healthcare environment and professional healthcare facility environment
WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
The essential performance is the digital thermometer can offer the temperature measurement.
Do not use mobile (cellular) telephones and other devices, which generate strong electrical or electromagnetic fields, near the medical device. This may result in incorrect operation of the unit and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 30cm. Verify correct operation of the device in case the distance is shorter.

Guidance and manufacture's declaration – electromagnetic emissions		
The device is suitable for use in the specified electromagnetic environment and it has meets the following standard's emission requirements		
Phenomenon	**Profession healthcare facility environment**	**Home healthcare environment**
Home healthcare environment	CISPR 11, Group 1, Class A or B	CISPR 11, Group 1, Class B
Harmonic distortion	IEC 61000-3-2, Class A or not applicable	N/A
Voltage fluctuations and flicker	IEC 61000-3-3 or not applicable	N/A

Guidance and manufacture's declaration – electromagnetic immunity			
The device is suitable for use in the specified electromagnetic environment and it has meets the following immunity test levels. Higher immunity levels may cause the device's essential performance lost or degraded.			
Phenomenon	**Basic EMC standard or test method**	**Professional healthcare facility environment**	**Home healthcare facility environment**
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	
Radiated RF EM fields	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz or 2Hz	10V/m 80MHz-2.7GHz 80% AM at 1kHz or 2Hz
		1kHz or 2Hz can be specified by the manufacturer	
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances	
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m; 50 Hz or 60Hz	
Electric fast transients bursts	IEC 61000-4-4	N/A	
	For input a.c. power port d.c. power lines or signal input/output lines whose length exceeding 3m		
Surges	IEC 61000-4-5	N/A	
Conducted disturbances induced by RF fields	IEC 61000-4-6	N/A	
	For 1. input a.c. power port; 2. all d.c. power ports connected permanently to cables >3m 3. all patient-coupled cables 4. SIP/SOP whose maximum cable length ≥ 3m		
Voltage dips	IEC 61000-4-11	N/A	
Voltage interruptions	IEC 61000-4-11	N/A	
UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz			

Recommended minimum separation distances
Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This device has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this device as recommended below.

Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power W)**	**Distance (m)**	**Immunity test level (V/m)**
385	380-390	TETRA400	Pulse modulation 18Hz	1,8	0,3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	707-787	LTE Band 13, 17	Pulse modulation 217Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0,3	28
2450	2400-2750	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0,2	0,3	9

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

REF 25565

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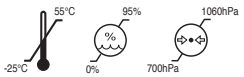

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IP22

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