

Dual-mode infrared

# **Thermometer**

Instructions for Use



# Thank you for purchasing the Elle TENS Infrared Thermometer.

Please read the User Manual carefully to make sure safe and proper use of this thermometer. Please read and fully understand the Safety Precautions before use. Keep the Instruction Manual with this thermometer for future reference.

This thermometer is intended for consumer use and the patient or their quardian is the intended operator.

# Take your baby's temperature regularly and when to seek medical advice

Once your baby is here life takes a wonderful turn. It can be a rollercoaster of emotions ranging from stress to complete and utter happiness. Changes are inevitable as your baby continues to develop and one of those changes to look out for is your baby's body temperature. A high temperature or fever will typically be indicated by a temperature of 38 °C or above. If you find that your baby's temperature is 38°C or higher and they're under 3 months old, or is 39°C or higher and they're 3 to 6 months old, it is best to seek medical advice as soon as you can.

One of the most accurate ways to check body temperature is to use a thermometer. Now that you have the Elle TENS Dual-mode Infrared thermometer to hand, you can take the guess work out of knowing when your little one can be treated at home, or when medical assistance is needed.

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## Package Contents

Please open the package carefully before use, checking whether all of the contents listed below are present and whether any component has been damaged during transportation. If everything is satisfactory, you may operate this device following these instructions for use. Where any damage is discovered or any operational problems occur, please contact Elle TENS directly. You will need the following information to hand: name of device, serial number (this can be found on the box), purchase date, and vour contact information and address.

No.	Name	Quantity
1	Infrared Thermometer	1
2	Pouch	1
3	Battery (AAA)	2
4	Instruction Manual	1



# Precautions and contraindications

#### Read the following precautions carefully before using the thermometer.

- Take care of the temperature probe lens, which is fragile.
- Dispose of used batteries with care. To protect the environment, you are recommended to send the used batteries to a designated collection point.
- Remove the batteries if the thermometer will not be used for more than two. months
- · Do not immerse the thermometer in water or any other liquid. Do not expose it to lint, dust or light including direct sunlight.
  - Do not expose the thermometer to pets or pests. This avoids sensors being degraded that can lead to degraded performance or other issues.
- Do not subject the thermometer to vibration or impact.
- The normal body temperature varies from person to person. Tracking a person's body temperature will help determine whether they have a fever.
- Do not take body temperature readings within 20 minutes after you do physical exercises or get excited.

- · Do not use the thermometer if it soiled or its infrared optical components are damaged.
- Do not modify this thermometer or use it with accessories or detachable parts or materials that are not provided with the device as described in these instructions.
- Do not use the thermometer on newborns or for continuous temperature monitoring purposes. The eardrum mode and probe may only be used for habies over 3 months old
- Do not use the thermometer for purposes that are not specified in this User Manual. Follow the instructions for measuring temperatures on pages 18-21 and carefully operate the thermometer when measuring children's temperatures.
- Clean and disinfect the thermometer following instructions on page 24.
- Do not touch the tip of the temperature probe, on which a precise temperature sensor resides.
- Clean the thermometer probe after each use.
- Keep the temperature probe clean to ensure accurate readings.
- Before measuring the temperature from the ear canal, clean any earwax off the temperature probe.
- The ambient temperature must not be extremely high or low. To ensure accurate readings, keep the thermometer at room temperature for more than 30 minutes before use. • Do not use the thermometer under an ambient temperature higher than 40°C (104°F) or lower than 10°C (50°F). which is beyond the operating temperature range of the thermometer.
- This is a device that must be disposed of safely. When you decide to dispose of used batteries or if you ever choose to dispose of your thermometer, please do so safely using official recycling facilities for electrical waste.
- 2 AAA batteries of 1.5V are the only replaceable accessories of the thermometer. Please do not use the batteries of other voltages or specifications.

Users should contact the Manufacturer or the Distributor for assistance with the following issues: assistance in setting up this device, using or maintaining the equipment when needed, or to report an unexpected operation or event

# Warnings

- Do not force the temperature probe of the thermometer into an ear canal. Otherwise, the ear canal may get injured.
- · Keep the thermometer out of the reach of children.
- The results may be inaccurate if you use a faulty or damaged thermometer
- The thermometer is not intended to diagnose or treat any health problem or disease. The measurement results are for reference only.
- It is dangerous to make a self-diagnosis or self-treatment based on the obtained measurement results. For such purposes, please consult a doctor.
- Do not charge an alkaline dry-cell battery or throw it in fire. Otherwise. the battery may explode.
- Do not disassemble the thermometer or attempt to repair it. Otherwise, the thermometer may be damaged permanently.
- Do not take temperature measurements on body parts other than the forehead and ears. Otherwise, the temperature readings may be inaccurate.
- While taking a measurement, do not use a mobile phone or any other device that may cause electromagnetic interference.
- Do not use the thermometer in an environment where flammable. anesthetic mixture with air or with oxygen or nitrous oxide is available.
- Do not use the thermometer if the ear is infected with otitis or suppuration.
- Do not open the battery cover when using the thermometer.
- No service /maintenance while the equipment is in use.

# Explanation of symbols on unit

ⅉ

Type BF applied part.



Attention must be paid.



The action is prohibited.



Information about the manufacturer.



Date of manufacture.



Consult the instructions for use.



This product complies with the Regulation (EU) 2017/745 requirements.



Waste electrical materials should be sent to a dedicated collection point for recycling.



Degree of protection against the Ingress of water.



Humidity



Temperature Limitation



Atmospheric Pressure



A personal injury or damage to the thermometer may occur if the thermometer is not used correctly.



Inaccurate reading or damage to the thermometer may occur if the thermometer is not used correctly.



Medical device



EC rep for Europe market



UK rep only for UK market

# Body temperature basics

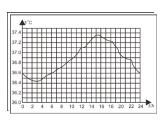
Generally, you can take a body temperature on the forehead, in the ear canal, under the armpit, in the mouth, or in the anus. The temperature measured at different parts of the body may differ slightly. With this thermometer, you can take body temperature on the forehead or in the ear canal only.

Body Part	Normal Temperature Range
Forehead	36.1°C-37.5°C / 97.0°F-99.5°F
Ear canal	35.8°C-38.0°C / 96.4°F-100.4°F
Mouth	35.5°C-37.5°C/95.9°F-99.5°F
Armpit	34.7°C-37.3°C / 94.5°F-99.1°F
Anus	36.6°C-38.0°C / 97.9°F-100.4°F

The normal body temperature range slightly varies with age and gender. Generally, younger adults have higher body temperatures than the elderly. Women's body temperatures are appropriately 0.3°C higher than men's. Since the normal range varies by body site, measurements from different sites should not be compared directly. In addition, to determine if an individual is experiencing an elevated body temperature and/ or having a fever, it is critical to know the individual's normal body temperature at particular body sites when they are well. Take multiple readings to obtain this information.

# Variation in body temperature

Normal body temperature varies by the time of day and is also affected by external factors. The body temperature of an individual is lowest between 2:00 a.m. and 4:00 a.m. and highest between 14:00 p.m. and 20:00 p.m. An individual's body temperature typically changes by less than 1°C each day.



#### Product description

#### 1) Overview

The Elle TENS Infrared Thermometer measures the body temperature based on the infrared energy emitted from the eardrum or the forehead. Users can quickly get measurement results after properly positioning the temperature probe in the ear canal or in front of the forehead. It can also be used to measure the surface temperature of an object, such as milk or water.

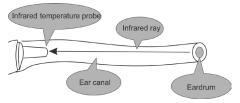
#### 2) Structure

The Elle TENS Infrared Thermometer consists of a shell, an LCD, a measure button, a beeper, an infrared temperature sensor, and a Microprocessor.

#### 3) Operating principle

The infrared temperature sensor collects infrared energy emitted by the eardrum or the skin surface. After being focused by a lens, the energy is converted into a

temperature reading by the thermopiles and measurement circuits.



# 4) Intended use

The Elle TENS Infrared Thermometers take human body temperature via the eardrum or forehead for both professional and home use. The forehead mode is intended for use on people of all ages and the eardrum mode is intended for use on people above three months old.

# 5) Contraindications

The device has no side-effects if administered correctly and residual risk is acceptable.

#### **Features**

#### Safe

· Passive infrared receiving technology.

#### 2. Easy to Operate

- · Ergonomic design
- · One button measurement

#### 3. Quick measurement

· 1-second measurement

#### 4. Highly Accurate

- · Advanced infrared temperature sensor, with high sensitivity
- · High accuracy with automatic temperature calibration

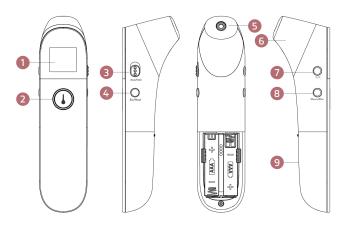
#### 5. Multiple functions

- · 20 readings recalled
- Fever alert
- · Switching between °C and °F
- · Automatic power-off, power saving

# 6. Extensive application scope

- Intended patient population
- Forehead mode applies to all age groups
- Ear mode applies to people above 3 month

#### **Product overview**



- LCD display screen
- Power button / Measure button
- Adult mode / Child mode
- Mode button (Forehead / Ear / Object)
- 5 Probe (take off the cover when measuring the ear temperature)
- 6 Probe cover (put the cover on when measuring the forehead temperature)
- Unit switch button (°C/°F)
- Memory button / Sound switch
- Battery cover

# Display description

- Object temperature mode
- Adult forehead temperature mode
- 3. Child mode
- 4. Ear temperature mode
- 5. Mute / un-mute
- 6. Temperature unit (°C / °F)
- 7. Low battery
- 8. Memory recall
- 9.Temperature value



# Sounds and backlight colour instructions

Range	Sounds	Backlight	
Forehead Tempera	eture (Adult / Child)		
22.0°C-37.5°C/71.6°F-99.5°F	A long beep	Orange	
37.6°C-43°C/99.6°F-109.4°F	3 short double beeps	Red	
Ear temperature (Adult / Child)			
34.0°C-37.5°C/93.2°F-99.5°F	A long beep	Orange	
37.6°C-43.0°C/99.6°F-109.4°F	3 short double beeps	Red	
Object temperature			
0°C-100°C/32.0°F-212°F	A long beep	Orange	

Note: When the forehead temperature is between 22.0°C/71.6°F and 37.5°C/99.5°F, the ear temperature is between 34.0°C/93.2°F and 37.5°C/99.5°F, there will be a long beep and a green backlight. This indicates that your body temperature is normal.

When the forehead and ear temperature is between 37.6°C/99.6°F and 43.0°C/109.4°F, there will be 3 short double beeps and a red backlight. This indicates that your body temperature is a little high. You may have a fever. Please consult your doctor if you are not sure.

# Display and operating instructions

Screen Display	Operating Instructions Displayed State	Sound and backlight color
	Measuring Ear temperature (Adult / Child	)
9 °C	Remove the probe cover, press and release the <b>Power button</b> for 1 second to turn on the thermometer. Press the Mode button, until the Ear symbol """ is displayed on the screen. Now you are in the <b>Ear mode</b> .	See the table in
Ear temperature for adult	Select the adult or child measurement mode by moving the adult/child mode switch. Slide up for adult and down for child.	the "Sounds and backlight color instructions" section.
36.5° Ear temperature for child	Insert the temperature probe into the ear canal as shown above. Press the Measure button to start a measurement.	
Me	asuring Forehead temperature (Adult / Cl	nild)
Qt	Put the cover on the probe, press and release the Power button for 1 second to turn on the thermometer. Press the Mode button, until the Head symbol "Q" is displayed on screen. Now you are in the <b>Head mode</b> .	See the table in
Forehead temperature for adult	Select the adult or child measurement mode by moving the adult/child mode switch. Slide up for adult and down for child.	the "Sounds and backlight color instructions" section.
36.8° Forehead temperature for child	Position the thermometer about 1-3cm away from the skin's surface. Press and release the <b>Measure button</b> . The temperature will be displayed on the screen.	

Screen Display	Operating Instructions Displayed State	Sound and backlight color
	Measuring Object temperature	
a 26.0°	Press and release the Power button for 1 second to turn on the thermometer. Press the Mode button, until the House symbol "\(\omega)" is displayed on screen. Now you are in the Object mode.  Point the thermometer at the center of the object. Press and release the Measure button. The temperature will be displayed on the screen.	See the table in the "Sounds and backlight color instructions" section.
	Out of the measuring range display	
<b>H</b> **	In Ear mode, a temperature reading of more than 43.0°C (109.4°F) In Forehead mode, a temperature reading of more than 43.0°C (109.4°F) In Object mode, a temperature reading of more than 100°C (212.0°F)	Three short beeps the backlight is red.
Lo	In Ear mode, a temperature reading of less than 34.0°C (93.2°F) In Forehead mode, a temperature reading of less than 22.0°C (71.6°F) In Object mode, a temperature reading of less than 0°C (32.0°F)	Three short beeps,the backlight is red.

Screen Display	Operating Instructions Displayed State	Sound and backlight color
	Recall 20 memories	
01	When the thermometer is on, press the Memory button on the left hand side to enter the memory mode.	
<b>9</b>	When the Memory button is released, the number 1 will be shown, followed by the recorded reading.	
36.5 %	Press the Memory button again for the next recorded data. The number 2 will be shown, followed by the recorded reading.	Silent, the backlight is orange.
02	A maximum of 20 temperature readings can be recalled.	
36.8°	When the maximum number of records is exceeded, the oldest memory data will be overwritten.	
	Note: 1 represents the newest data.	
No memory data / Clear memory data.  When the power is turned back on, there will be a long beep and the backlight is turning from orange to red.		
°	When the memory data is queried and there is no memory data under the current serial number, the display is as shown.	Silent, the backlight is orange.
	Remove the batteries then put them back in the thermometer to clear all memory data.	backlight is draffge.

Screen Display	Operating Instructions Displayed State	Sound and backlight color
Switching between mute and un-mute		
Q 4	When the power is on, press and hold the Sound switch button for about 2 seconds to switch the sound on or off. When the sound is turned on, it will beep once. The mute symbol will be displayed when the sound is off.  The "\( \mathre{\mathre{G}}\) "symbol is displayed in Mute	When the sound is turned on, it sounds a long beep and the backlight is orange.
	mode and disappears in Un-mute mode.	
Switching	between object temperature and body to	emperature
	Press the Mode button to switch between object temperature and body temperature.  Body temperature contains the Forehead temperature and Ear temperature.	Silent, the backlight is orange.
	Switching between °F/°C	
QT	In the power on state, press the unit Switch button to toggle between Celsius (°C) and Farenheit (°F) measurements.	Silent.

Screen Display	Operating Instructions Displayed State	Sound and backlight color
	Error information & low battery	
Erl	The ambient temperature is higher than $40.0^{\circ}\text{C}$ ( $104.0^{\circ}\text{F}$ ) or lower than $10.0^{\circ}\text{C}$ ( $50.0^{\circ}\text{F}$ ).	A long beep,the backlight is red.
<b>Er</b> [	An error occured when data is being read from or written to the memory, or the temperature correction is not complete.	A long beep,the backlight is red.
<b>D</b>	When the battery voltage is lower than 2.5V ± 0.1V, the low battery symbol will appear on the display. Please replace the batteries.	Silent.

# Measuring ear temperature

1. When using the thermometer for the first time, ensure batteries are installed according to the stated polarities.





2. Take the probe cover off of the thermometer before measuring the ear temperature\*.

\*For adults and babies over 3 months only - for babies below 3 months you must measure the forehead temperature only



- Press the Power button to turn on the thermometer.
- 4. Press the Mode button, to enter the Ear mode. The "Ear" symbol is displayed on the screen.
- 5. When measuring an adult, put the device in the "adult" mode. When measuring a child, put the device in the "child" mode and check that the symbol is displayed on the screen.
- 6. Insert the temperature probe into the ear canal.
- 7. Press and release the Measure button. The ear temperature reading will be displayed on the screen instantly.

Children over 3 months but under 1year: Notes:

Pull the ear straight back.

Children aged 1 year to adult: Pull the ear up and back.











Do not force the thermometer into the ear canal. Otherwise, the ear canal may get injured.



When taking the temperature on an adult, gently pull the ear up and back to make sure the ear canal is straight, so that the temperature probe can receive an infrared ray from the eardrum.



Be careful when taking temperature on a child, whose ear canal is small

# Measuring forehead temperature

- 1. Put the cover on the probe of thermometer.
- 2. Press the Power button to turn on the thermometer.
- 3. Press the Mode button, to enter The Forehead mode. The "Head" symbol is displayed on the screen.
- 4. When measuring adults, place the device in the "adult" mode. When measuring a child, place the device in "child" mode and check that the symbol is displayed on the screen.
- 5. Point the thermometer probe towards the centre of the forehead, about 1-3cm away from the skin surface.





- Press and release the Measure button for 1 second. The temperature reading will be displayed on the screen instantly.
- 7. If no activity is detected, the thermometer will power off automatically after 10 seconds.

# Measuring object temperature

- 1. Put the cover on the probe of thermometer.
- 2. Press the Power button to turn on the thermometer.
- 3. Press the Mode button, to enter the Object mode. The "House" symbol is displayed on the screen.
- 4. Point the thermometer probe at the center of the object, about "1-3cm" away from the surface of the object.
- 5. Press and release the Measure button for 1 second. The temperature reading will be displayed on the screen instantly.
- 6. If no activity is detected, the thermometer will power off automatically after 10 seconds



#### After a measurement

- After each measurement, you can enter the recall mode and query earlier temperature readings. For more details, see "Recall 20 memories" in the preceding table.
- 2. After each measurement, clean the temperature probe with a soft cloth, and put the thermometer in a dry and well-ventilated place.



It is dangerous to make a self-diagnosis or self-treatment based on the obtained measurement results. For such purposes, please consult a doctor.

#### Notes

- The thermometer is suitable for use in an indoor environment without strong air convection (for example, wind from a fan, air-conditioner, or heater) between the thermometer and the person.
- Make sure that the ear canal is clean and dry before starting a measurement.
   It is recommended to clean the ear canal with a cotton swab before measurement. Otherwise, the temperature probe may be polluted and temperature readings may be inaccurate.
- Do not hold the thermometer for a long time, because it is sensitive to the ambient temperature.
- Make sure the sensor head is clean and unobstructed before use.
- Make sure the forehead is free from sweat and hair before measuring the forehead temperature otherwise, the result could be incorrect.
- Refrain from engaging in vigorous physical activity or experiencing strong emotions prior to taking a measurement.
- After measuring the data once, you should wait for the backlight to turn off and measure the next data.

# Replacing batteries

- 1. Slide the battery cover off along the marked direction and take it off.
- 2. Insert the two AAA batteries into the compartment according to the stated polarities.



Make sure that the batteries are installed correctly. Otherwise, the thermometer may be damaged.



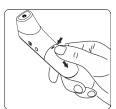
If the low-battery symbol is displayed on the screen, replace the batteries.



Batteries of a same type should be used. Dispose of used batteries in accordance with local environmental policies.



The thermometer is shipped with batteries. First open the battery cover, then remove the insulating sheet preventing contact between the battery and battery connector.





# Cleaning and disinfection

#### Cleaning

#### Recommended detergents

- · Medical detergents.
- · Home use mild detergents.

#### Cleaning steps

- 1. Take the batteries out before cleaning.
- 2. Clean the temperature probe with a soft cloth. Clean the lens of the temperature probe with a cotton swab.
- 3. Wipe the thermometer body with a slightly damp soft cloth.



Keep water out of the lens during the cleaning process. Otherwise, the lens may be damaged.



The lens may be scratched if it is cleaned with a hard object, which might result in inaccurate readings.



Do not clean the thermometer with corrosive cleansers. During the cleaning process, do not immerse any part of the thermometer into liquid, or allow liquid to penetrate the thermometer.

#### Disinfection

#### Recommended disinfectants

- Isopropyl alcohol solution (concentration: 70%)
- Medicinal alcohol (concentration: 75%)
- · Sodium hypochlorite solution (concentration: 3%)

# Disinfecting steps

- 1. Wet the clean soft cloth with a small quantity of disinfectant, wipe the thermometer and quickly dry it.
- Disinfect the thermometer body and the area around the temperature probe with a cloth slightly moistened with 75% medical alcohol.

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Do not use hot steam or ultraviolet radiation for disinfection Otherwise, the thermometer may be damaged.



It is recommended to disinfect the thermometer before and after each use. Disinfection takes one minute, and the number of repetitions per disinfection should not exceed two times.



Clean and disinfect the thermometer under the temperature of  $+10^{\circ}\text{C} + 40^{\circ}\text{C} (50^{\circ}\text{F} - 104^{\circ}\text{F})$ , the relative humidity of 15%~85%RH (no condensation) and the barometric pressure of 86kPa~106kPa.

#### Maintenance

#### Preventive inspection & maintenance period

- Ensure the safety of thermometer, and check whether it has potential
  safety hazards in normal use each week, e.g. whether the lens is broken,
  the shell has cracks, or the sensing head is polluted. Do not use the
  thermometer with potential safety hazards. Clean the thermometer if it
  has not been used for a long time.
- 2. After each use, clean the temperature probe as described in the "Cleaning and Disinfection" chapter.
- Store the thermometer in a dry, dust-free, and well-ventilated place. Make sure that the thermometer is not exposed to sunlight. Make sure that the storage and transportation environments meet the requirements.
- 4. Check regularly whether safety risks exist.
- 5. Remove the batteries if the thermometer will not be used for more than two months.

# Troubleshooting

Problem	Possible Cause	Solution
	Low battery.	Change the batteries.
The thermometer fails to turn on.	Polarities of the batteries are reversed.	Make sure that the batteries are installed correctly.
	The thermometer is damaged.	Contact Elle TENS.
"Er1" is displayed.	The ambient temperature is lower than 10°C (50.0°F) or higher than 40°C (104°F).	Take a measurement under an ambient temperature between 10°C (50.0°F) and 40°C (104°F).
	The lens of the temperature probe is dirty.	Clean the lens using a cotton swab.
The temperature reading is lower than the typical body temperature range.	The thermometer probe is not aligned to the eardrum.	Reposition the thermometer probe so that it is aligned to the eardrum.
	The thermometer is used within 30 minutes after being taken from a cold environment.	Wait for more than 30 minutes after the thermometer is moved into the measurement environment.
The temperature reading is higher than the typical body temperature range.	The temperature probe is damaged.	Contact Elle TENS.

# **Specifications**

Product Name	Infrared Thermometer	
Product Model	JPD-FR410	
Power Supply Mode	Internal power supply	
Operating Voltage	DC 3V	
Battery Model	AAA x 2	
Operating Mode	Continuous operating	
Display	Segment LCD	
Measure time	About 1 second	
Latency Time	About 3 second	
	Forehead mode: 22.0°C-43.0°C (71.6°F-109.4°F)	
Measuring Range	Ear mode:34.0°C-43.0°C (93.2°F-109.4°F)	
	Object mode:0.0°C-100.0°C (32.0°F-212.0°F)	
	Forehead mode: ±0.2°C (36.0°C-39.0°C) ; ±0.3°C (22.0°C-35.90°C / 39.1°C-43.0°C)	
Accuracy (Laboratory)	Ear mode: ±0.2°C (36.0°C-39.0°C) ; ±0.3°C (34.0°C-35.9°C / 39.1°C-43.0°C)	
	Object mode: ±1.0°C/±2.0°F	
Accuracy (Clinical)	±0.3°C (±0.6°F)	
Resolution	0.1°C (0.1°F)	
Measuring site	Ear canal, Forehead (keep distance 1–3 cm from forehead)	
Reference body site	Armpit	
Mode of operation	Adjusted mode	
Memory	20 temperature readings	
Low-battery Alert	The low-battery symbol is displayed if the power voltage is lower than 2.5 V±0.1V	
Automatic Power-off	The thermometer automatically powers off if it is not used in $10\pm1$ seconds.	
Outer dimensions (mm)	149.3×38.1×43.4mm	
Weight (g)	Thermometer (with batteries): 86.7 g	
Manufacturing date	See the label	
Service life	2 years	
Battery life	Alkaline dry battery for around 20000 measurements	
	Temperature: 10°C- 40°C (50°F-104°F)	
Operating Environment	Humidity: 15%–95% RH, non-condensing	
	Atmospheric pressure: 86–106 kPa	
	Temperature -20°C to 50°C (-4°F–122°F)	
Storage and Transporation	Humidity 15%-95% RH, non-condensing	
	Atmospheric pressure 50-106 kPa	
Software Version	7 13	

The infrared thermometer has been tested and conforms to the standard ASTM E1965-98. ASTM laboratory accuracy requirements in the display range of 96.8°F to102.2°F (36°C-39°C) for ear canal IR thermometers is  $\pm 0.4^{\circ}F$  ( $\pm 0.2^{\circ}C$ ). Note that for mercury-in-glass and electronic hermometers, the requirement per ASTM Standards E667-86 and E1112-86 is ±0.2°F (±0.1°C).

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# **Security Class**

Type of protection against electric shock: internally powered equipment. Degree of protection against electric shock: Type BF applied part.

- · Degree of protection against ingress of water: IP22
- · Safety degree of using in flammable anesthetic gas blending with air, oxygen or nitrous oxide: Non-AP/APG
- · No application parts of the thermometer prevents defibrillation charge effect.
- The signal output is not the applied part.
- The thermometer is an impermanent installed device.

## Storage and Transportation

The thermometer can be transported using general transportation tools. Severe vibration, shock, or rain must be avoided during transportation. The thermometer must be packaged and then stored in a well-ventilated room without corrosive gas. The ambient temperature must be between  $-20^{\circ}$ C and +55°C (4°F-131°F), the relative humidity must be between 15-95% (non-condensing), and the atmospheric pressure must be 50–106 kPa.

#### EMC Information-Guidance and Manufacturer's Declaration

- 1 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.
- 2 WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 3 WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

#### Table 1

Declaration - electromagnetic emission		
Emissions test	Compliance	
RF emissions CISPR 11	Group 1	
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Immunity test	IEC 60601 test level	Compliance level	
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable	
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	

#### Table 3

Declaration - electromagnetic immunity					
Immunity test	IEC 60601 test level	Compliance level			
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable			
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m			

# Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment							
Immunity test	IEC60601 test level				Compliance		
	Test frequency	Modulation	Maximum power	Immunity level	level		
Radiated RF IEC 61000-	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m		
4-3	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m		
74 78 81 87	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m		
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m		
	1720 MHz 1845 MHz 1970 MH	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m		
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m		
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m		

Note\* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note\*\* - The carrier shall be modulated using a 50 % duty cycle square wave signal.

# Warranty and After-Sale Service

The device is under warranty for one year from the date of purchase. The batteries, the packaging, and any damage caused by improper use are not covered by the warranty.

The warranty excludes the following user-caused failures:

- 1. Failure resulting from unauthorized disassembly and modification.
- Failure resulting from an unexpected dropping during application or transportation.
- 3. Failure resulting from not following the instructions in the user's manual.

#### Elle TENS

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## EC REP Authorised European Representative:

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> Model No. JPD-FR410 April 2024 (1) THERM-IFU-1