# **Safety and Performance Information**

# THAC2F, THD2FE, THi0F, TH02F, TH03F, TH09F, Thermoeas(02023033000000), THD2FE (00010796000000), 423035, THF850, 10256380, TH48FE Non-contact Forehead Thermometer

**English** 

#### General

#### Intended use:

The non-contact forehead thermometer is electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from forehead center in people of all ages.

#### Intended operator:

The intended operator should have at least eight years of education, including patients or other operators.

#### Symbols

Symbol Descriptions							
<b>C</b> € 1639	The CE mark and Notified Body Registration Numbers, the requirement of ANNEX IX excluding Chapter II of MDR (EU) 2017/745 are met.	X	Please do not dispose of the product in the household waste at the end of its useful life. Disposal can take place at appropriate collection points provided in your country.	EC REP	Authorized representative in the European community		
$\triangle$	Caution		Follow instructions for use		Manufacturer		
MD	Medical device	UDI	Unique device identifier	SN	Serial number		
<b>汶</b>	BF type applied part	X	To protect the environment, dispose of empty batteries at your retail store or at appropriate collection sites according to national or local regulations.		Paper Recycling		
IP22	Classification for water ingress and particulate matter.	Ф	Stand-by (THD2FE, THi0F)				

## Safety Information

⚠ Choking from swallowing small parts and batteries by children or pets is possible, please keep small parts and batteries at places where children and pets can't reach.

- The device should not submerge into any liquids and expose it to direct moisture, and please keep away from direct sunlight.
- ⚠ If there is certain temperature difference between the locations where the device is stored and where you are going to measure, subject and the device should stay in the same room for at least 15 minutes before measurement.
- Always make sure the probe lens is clean without any damage.
- ⚠ Insert the batteries correctly, with the flat positive (+) side up. (TH02F, TH03F, TH09F, Thi0F, 10256380, THAC2F, Thermoeas (02023033000000))
- ⚠ If the device is not to be used for a long time, turn the power off, remove and store the batteries in a cool and dry place. (THD2FE, THD2FE (00010796000000), 423035, THF850, TH48FE)
- ⚠ Turn the rotary cap back in place to prevent dirt and scratches from damaging the device. (THAC2F, Thermoeas (02023033000000))
- ⚠ Store the thermometer with the cap in place to prevent dirt and scratches from damaging the device. (THi0F, 10256380)
- A No modification of this equipment is allowed.

#### Technical Information

- Forehead mode Temperature measurement range: 34~42.2°C (93.2~108°F) (TH02F, THAC2F, Thermoeas (02023033000000))

Forehead mode Temperature measurement range: 28~43°C (82.4~109.4°F) (TH09F, TH48FE)

- Forehead mode Temperature measurement range: 34~42.2°C (93.2~108°F); Surface mode Temperature measurement range: -22~80°C (-7.6~176°F) (THD2FE,THD2FE (00010796000000), (423035),THF850, TH03F, THi0F, 10256380)
- Operating temperature range: 10~40°C (50~104°F), 15%~85% RH
- Storage temperature range: It should be stored at room temperature between -20~+50°C, RH≤85% Transportation temperature shall be less than 70°C, RH≤95%
- Atmospheric pressure: 800~1013 hPa
- Comply with ASTM E1965-98, EN ISO 80601-2-56, IEC/EN60601-1-2(EMC), IEC/EN60601-1(Safety) standards, ISO10993, RoHS.
- Accuracy: Forehead mode: ±0.2°C (0.4°F) within 35~42°C (95~107.6°F), ±0.3°C (0.5°F) for other range.
- Accuracy: Surface mode: ±0.3°C (0.5°F) within 22~42.2°C (71.6~108°F), others ±4% or ±2°C (4°F) whichever is greater.
- Temperature Awareness Signal °C / °F switch function.
- 25 sets memory (TH03F, THD2FE, THD2FE (00010796000000), 423035, THF850, THAC2F, Thermoeas (02023033000000), Thi0F, 10256380, TH48FE)
- 1 sets memory (TH02F, TH09F)
- Blue LED Backlight & Mute mode (THD2FE)
- Color LCD Display & Mute mode (TH48FE)
- Battery: one lithium cell battery CR2032 \*1pcs (TH02F, TH03F, TH09F, THAC2F, Thermoeas (02023033000000), Thi0F, 10256380,)
- AAA x 2 pcs (THD2FE, THD2FE (00010796000000), 423035, THF850, TH48FE)
- Battery life: around 3,000 continuous readings.
- Enclosure Rating: IP22
- Expected Service Life: 4 years

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# **Safety and Performance Information**

TH709LE, TH809, TH809S, TH809J, TH819SJE, TH839S, TH889S, TH889SE, TH889J, THi09Z, THP59J(U), THP79JU, Comfort quick (00000656000000), MD1882, THIR-2, TH839, 42302041, 25575, 100-00102-00, THR86JE, THR96JE, THP86JE, THP86JEU

English

Ear Thermometer

#### General

#### Intended use:

The ear thermometer is electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from ear canal in people of all ages.

#### Intended operator:

The intended operator should have at least eight years of education, including patients or other operators.

#### Symbols

Symbol Descriptions							
<b>CE</b> 1639	The CE mark and Notified Body Registration Numbers, the requirement of ANNEX IX excluding Chapter II of MDR (EU) 2017/745 are met.		Please do not dispose of the product in the household waste at the end of its useful life. Disposal can take place at appropriate collection points provided in your country.	EC REP	Authorized representative in the European community		
$\triangle$	Caution	<b>(3)</b>	Follow instructions for use		Manufacturer		
MD	Medical device	UDI	Unique device identifier	SN	Serial number		
χ̈́	BF type applied part	X	To protect the environment, dispose of empty batteries at your retail store or at appropriate collection sites according to national or local regulations.		Paper Recycling		
IP22	Classification for water ingress and particulate matter.	Ф	Stand-by (THR86JE, THR96JE, THP86JEU)				

#### Safety Information

⚠ Choking from swallowing small parts and batteries by children or pets is possible, please keep small parts and batteries at places where children and pets can't reach.

⚠ The device should not submerge into any liquids and expose it to direct moisture, and please keep away from direct sunlight.

⚠ If there is certain temperature difference between the locations where the device is stored and where you are going to measure, subject and the device should stay in the same room for at least 15 minutes before measurement.

⚠ Always make sure the probe lens is clean without any damage. (TH709LE, Comfort quick (00000656000000), TH809, TH809S, MD1882, TH809S, TH809J, TH819SJE, TH839S, THIR-2, TH839, TH889S, TH889SE, (42302041), TH889J)

⚠ Insert the batteries correctly, with the flat positive (+) side up. (TH709LE, Comfort quick (00000656000000), TH809, TH809S, MD1882, TH809S, TH809S, TH819SJE, TH839S, THIR-2, TH839, TH889S, TH889SE, (42302041), TH889J, TH109Z, THP59JU, (25575), THP79JU, 100-00102-00)

⚠ If the device is not to be used for a long time, turn the power off, remove and store the batteries in a cool and dry place. (THR86JE, THR96JE, THP86JE, THP86JEU)

- ⚠ Store the thermometer with the cap in place to prevent dirt and scratches from damaging the device.
- A No modification of this equipment is allowed.

#### Technical Information

- Ear mode Temperature measurement range: 34~42.2°C (93.2~108°F) (TH709LE, Comfort quick (00000656000000),

TH809, TH809S, MD1882, TH809S, TH809J, TH819SJE, TH839S, THIR-2, TH839, TH889S, TH889SE, (42302041), TH889J)

Ear mode Temperature measurement range: 28~43°C (82.4~109.4°F) (THP86JE, THP86JEU)

- Ear mode Temperature measurement range: 34~42.2°C (93.2~108°F); Surface mode Temperature measurement range:

### -22~80°C (-7.6~176°F) (THR86JE, THR96JE)

- Operating temperature range: 10~40°C (50~104°F), 15%~85% RH
- Storage temperature range: It should be stored at room temperature between -20~+50°C, RH≤85%

Transportation temperature shall be less than 70°C, RH≤95%

- Atmospheric pressure: 800~1013 hPa
- Comply with ASTM E1965-98, EN ISO 80601-2-56, IEC/EN60601-1-2(EMC), IEC/EN60601-1(Safety) standards, ISO10993, RoHS.
- -Accuracy: Ear mode:  $\pm 0.2^{\circ}$ C (0.4°F) within 35~42°C (95~107.6°F),  $\pm 0.3^{\circ}$ C (0.5°F) for other range.
- -Accuracy: Surface mode: ±0.3°C (0.5°F) within 22~42.2°C (71.6~108°F), others ±4% or ±2°C (4°F) whichever is greater.
- Temperature Awareness Signal °C / °F switch function.
- 1 sets memory (THP86JE, THP86JEU)
- 9 sets memory (TH809, TH809S, MD1882, TH809S, TH809J, TH819SJE, TH839S, THIR-2, TH839, TH889S, TH889SE, (42302041), TH889J)
- 25 sets memory (TH709LE, Comfort quick (00000656000000), THP59JU, (25575), THP79JU, 100-00102-00), THR86JE, THR96JE)
- Mute Function (THP86JE, THP86JEU, THR96JE)
- Last Reading (TH709LE, Comfort quick (00000656000000))
- LED Backlight (TH709LE, Comfort quick (00000656000000), TH819SJE, TH889SE)
- Blue LED Backlight (THR86JE, THR96JE, THP86JEU)
- Battery: one lithium cell battery CR2032 \*1pcs (TH709LE, Comfort quick (00000656000000), TH809, TH809S, MD1882,

TH809S, TH809J, TH819SJE, TH839S, THIR-2, TH839, TH889S, TH889SE, (42302041), TH889J)

- AAA x 2 pcs (THR86JE, THR96JE); AA x 2 pcs (THP86JE, THP86JEU)
- Battery life: around 3,000 continuous readings (TH709LE, Comfort quick (00000656000000), TH809, TH809S, MD1882,

TH809S, TH809J, TH819SJE, TH839S, THIR-2, TH839, TH889S, TH889SE, (42302041), TH889J, THR86JE, THR96JE)

- Battery life: around 20,000 continuous (THP86JE, THP86JEU)
- Enclosure Rating: IP22
- Expected Service Life: 4 years

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# **Safety and Performance Information**

# THAD0K, THCT0K, THi0K, THi0KZ, TH50Z, TH520, TH52Z, UT-801, CTD711 Multi-function Infrared Thermometer

**English** 

#### General

#### Intended use:

The ear/forehead thermometer is electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from ear canal/forehead in people of all ages.

#### Intended operator:

The intended operator should have at least eight years of education, including patients or other operators.

#### Symbols

Symbol Descriptions							
<b>C</b> € 1639	The CE mark and Notified Body Registration Numbers, the requirement of ANNEX IX excluding Chapter II of MDR (EU) 2017/745 are met.	X	Please do not dispose of the product in the household waste at the end of its useful life. Disposal can take place at appropriate collection points provided in your country.	EC REP	Authorized representative in the European community		
$\triangle$	Caution	<b>(3)</b>	Follow instructions for use		Manufacturer		
MD	Medical device	UDI	Unique device identifier	SN	Serial number		
<b>汶</b>	BF type applied part	Ā	To protect the environment, dispose of empty batteries at your retail store or at appropriate collection sites according to national or local regulations.		Paper Recycling		
IP22	Classification for water ingress and particulate matter.	<del>Q</del>	Stand-by (TH50Z, THAD0K, UT-801, THCT0K,CTD711)				

#### Safety Information

- ⚠ Choking from swallowing small parts and batteries by children or pets is possible, please keep small parts and batteries at places where children and pets can't reach.
- The device should not submerge into any liquids and expose it to direct moisture, and please keep away from direct sunlight.
- ⚠ If there is certain temperature difference between the locations where the device is stored and where you are going to measure, subject and the device should stay in the same room for at least 15 minutes before measurement.
- ⚠ Insert the batteries correctly, with the flat positive (+) side up.
- A Proper installation of the probe cover and using the specific probe cover ensure accurate measurements.
- Always make sure the probe lens is clean without any damage.
- ⚠ No modification of this equipment is allowed.

#### Technical Information

- Ear / Forehead mode: 34~42.2°C (93.2~108°F), Surface mode: -22~80°C (-7.6~176°F)
- Operating temperature range: 10~40°C (50~104°F), 15%~85% RH
- Storage temperature range: It should be stored at room temperature between -20~+50°C, RH≤85% Transportation temperature shall be less than 70°C, RH≤95%
- Atmospheric pressure: 800~1013 hPa

- Comply with ASTM E1965-98, EN ISO 80601-2-56, IEC/EN60601-1-2(EMC), IEC/EN60601-1(Safety) standards, ISO10993, RoHS.
- -Accuracy: Ear / Forehead mode:  $\pm 0.2^{\circ}$ C (0.4°F) within 35~42°C (95~107.6°F),  $\pm 0.3^{\circ}$ C (0.5°F) for other range.
- -Accuracy: Surface mode: ±0.3°C (0.5°F) within 22~42.2°C (71.6~108°F), others ±4% or ±2°C (4°F) whichever is greater.
- Temperature Awareness Signal °C / °F switch function.
- 25 sets memory (THAD0K, UT-801, THi0K, THi0KZ)
- 9 sets Memory under "Ear/Forehead mode" (TH50Z, TH520, TH52Z, THCT0K, CTD711)
- Room Temperature, Last Reading, Mute Mode (THAD0K, UT-801, THi0K, THi0KZ)
- Real Time Clock, Room Temperature, (THCT0K, CTD711)
- Real Time Clock, Room Temperature, Stopwatch (TH50Z, TH520, TH52Z)
- Zone Indicator (TH50Z, TH52Z)
- Battery: one lithium cell battery CR2032 \*1pcs
- Battery life: around 3,000 continuous readings.
- Enclosure Rating: IP22
- Expected Service Life: 4 years

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