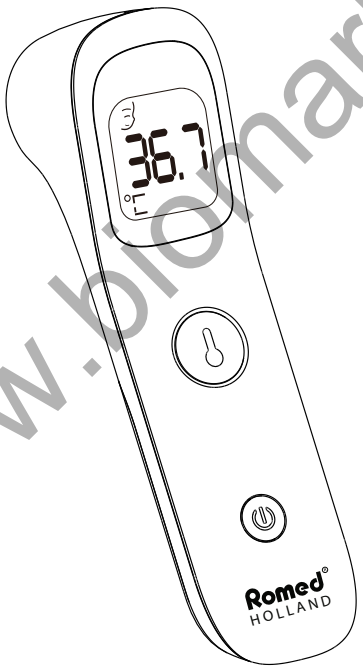
Romed®
HOLLAND

USER MANUAL
INFRARED FOREHEAD THERMOMETER



REF : THERM-IR

Thank you for purchasing the Romed Infrared Forehead Thermometer.

Be sure to read this Instruction Manual before using the unit in order to use it safely it safely and correctly. The instruction manual should be well kept for your reference at any time.

- There are no contraindications
- You should stop using the device and should consult with your physicians if you experience adverse reactions caused by the device the device.
- This device can be applied to all people. No special training is needed, but the user shoul read the manual carefully before use.

INDEX

1 FOREWORD

WARNINGS

- This unit is used for temperature measurement and not for disease diagnosis; it cannot be used for emergency and continuous measurement in surgery. The patients cannot diagnose the disease and get treatment by themselves on the basis of the measurement results, they must follow the instruction of doctors. Please ask medical professionals to explain the measured value of the body temperature.
- The main material of the enclosure is plastic. Be careful to the potential allergic reactions to these materials.
- Please do not use with infectious wound.
- Please do not touch or blow on the infrared sensor.
- No mobile phones are allowed to be used around this product. Please do not use equipment that generates electromagnetic fields near the product.
- The use of heat and cold producing devices (such as electric heating blankets, heating pads or ice packs) may impair the performance of the device and increase the risk of injury to the patient.
- Do not store the unit under sunlight, at a high temperature, in high humidity or dust. Performance may be degraded.
- Please do not disassemble or repair this device by yourself including modifying the device.
- Please do not clean or perform maintenance on the device while in use.
- Please wait for 30 minutes before use if the environment has a sudden change (e.g. from under sunlight to an air-conditioned room), or the accuracy may be influenced.
- Degraded sensors and electrodes, or loosened electrodes, can degrade performance or cause other problems.
- DO NOT open the battery cover around any source of ignition which has the potential to ignite the batteries and cause a fire.
- Please keep the device out of reach of infants, children or pets, inhalation or swallowing of small parts is dangerous or even fatal.

PRECAUTIONS

- This product is intended to be used by lay users. It is not intended to be used by children under 12 years. The user can take measurements and change the battery under normal circumstances and can maintain the device and its accessories according to the user manual.
- Please do not bend, or stretch, hit, drop this device or expose this device to heavy shock.
- Performance of the device may be degraded if: operated or stored outside stated temperature and humidity ranges or if the patient's temperature is below the room temperature. If the thermometer has been stored at below freezing temperatures, please warm it naturally to room temperature before use.
- Clean the thermosensor (probe) before storage.

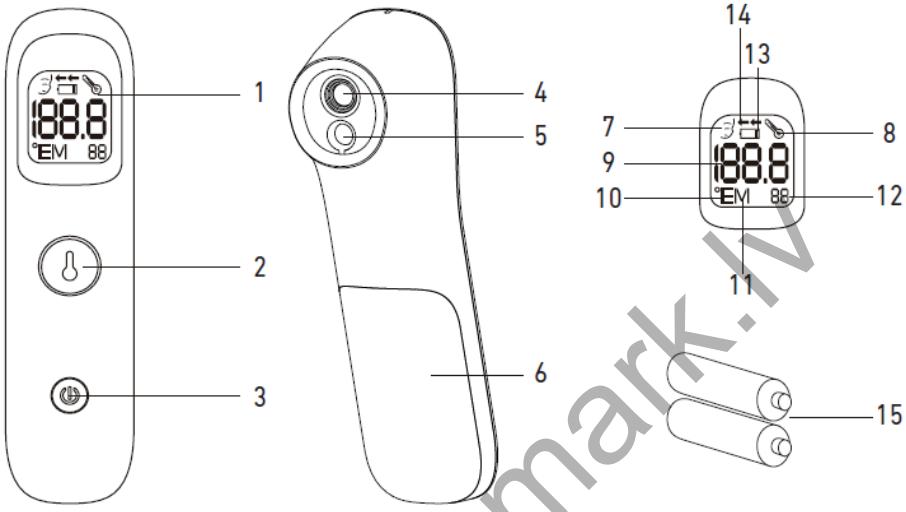
2 DEVICE DESCRIPTION

PRODUCT INSTRUCTION

The Romed Infrared Forehead Thermometer is intended to measure human body temperature by measuring at the forehead. It is suitable for displaying the body temperature by measuring the heat radiation from the forehead.

	Probe: Type BF Applied part
SN	Serial number
LOT	Batch code
REF	Catalogue number.
CE 0044	CE Mark
	Date of manufacture
	Manufacturer
	Keep dry
	Keep away from sunlight
	Temperature limit
	Collect separately from other household waste
IP22	IP classification
	Refer to user manual
	Consult instructions for use
	Caution

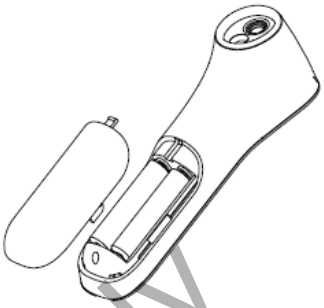
COMPONENTS/ACCESSORIES



1. LCD Display
2. Temperature / Memory Button
3. Power / Mode Button
4. Thermosensor
5. Distance Sensor
6. Battery Cover
7. Body Mode Indicator
8. Object Mode Indicator
9. Temperature reading / distance indicator
10. °C / °F / CM
11. Memory Indicator
12. Memory Times / Remaining time
13. Battery Charge
14. Measure Distance
15. Batteries

3 INSTRUCTIONS FOR USE

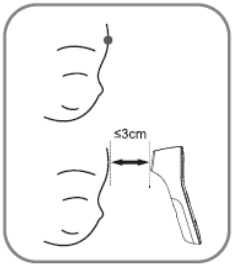
1. Press the battery cover and it will bounce open automatically. Prepare 2 pieces of 1.5V AAA batteries, install them into the battery chamber according to correct positive and negative poles and close the cover.



2. Press and release the power button once. Backlight will come on and the start-up sequence will begin. When the thermometer is ready and correctly positioned, a horizontal line of dashes (“- - -”) will appear on the screen.

Remark: The environmental temperature variation can significantly affect the device measurement accuracy. This device can detect the environmental temperature. If the fluctuation goes beyond the normal range (e.g. the device is moved from the outside to a room winter or the other way round during winter), or the environmental temperature goes beyond 10°C-40°C (50°F-104°F), the device would display "Err". To avoid such "Err", leave the device for 30 minutes before operation if it is moved from different environment and make sure the device always works in the correct range temperature.

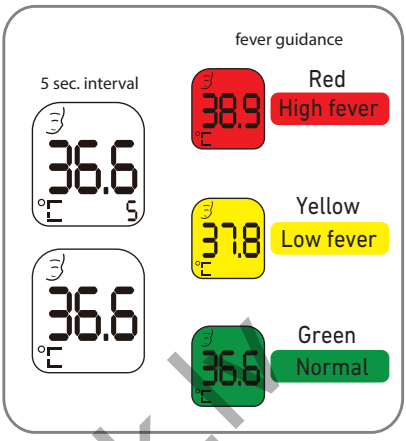
3. Position thermometer up to 3 cm away from the centre of the forehead, just between the eyebrows. If the eyebrow area is covered with hair, sweat or dirt, please clean the area beforehand to improve the reading accuracy. It is important to hold the thermometer and the forehead steady during measurement. Movement will impact the temperature reading.



4. Press the temperature button. When the thermometer is placed correctly, the display shows the temperature reading. The appropriate fever light colour is displayed on screen and the confirmation beep is heard. If the thermometer is positioned too far away from the forehead, it will prompt you to move the thermometer closer by displaying diagram and “0-3 cm”. Slowly move the thermometer toward the forehead until hear the beep sound and the temperature reading is displayed. Backlight will remain on 5 seconds and auto turn off.

5. Read the temperature. If the temperature range is < 32°C or > 43°C, you can hear a single short beep. For normal (green backlight) and low fever (yellow backlight) temperature range, you will hear a single long beep for 1 second. For high fever (red backlight) temperature range, you will hear 10 short beeps. Backlight will remain on 5 seconds and auto turn off.

To keep each measurement accurate, the thermometer requires a 5-second interval between measurements. The user can see the countdown from 5 to 0 in screen. To repeat the measurement go to step 3.



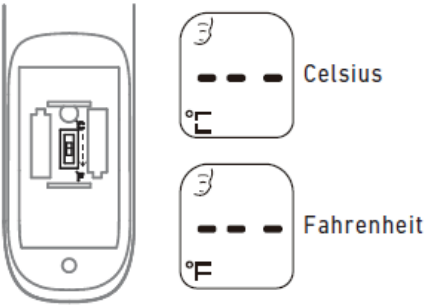
FEVER GUIDANCE FEATURE

Fever guidance helps you to better understand the meaning of the temperature with the colour indicated on the display. The screen displays green is normal, yellow when the temperature is low fever and a red alert for a possibly high fever. 10 audible beeps indicate temperatures above 38.5 °C (101.3 °F) to alert the user that the patient may have a fever.

Backlight Colour	Temperature	Meaning
Green	<37.5°C	Normal
Yellow	≥37.5°C and ≤38.5°C	Low fever
Red	>38.5°C	High fever

SWITCHING BETWEEN TEMPERATURE SCALES

In the battery chamber, press the °F / °C change button to switch between Fahrenheit degree (°F) and Celsius degree (°C) .



VIEW MEMORY STORAGE

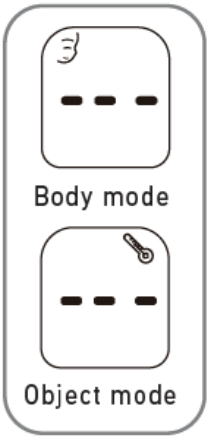
In OFF status, press the temperature button, the screen will display 30 groups of measurement in reverse order. Switch the display value by pressing the temperature button. Thermometer stores body temperature only, no object temperature. It will turn off automatically without operating for approx. 30 seconds or press power button to turn off.

In the memory view interface, press and hold the measurement button for approx. 5 seconds to display "CLR" and delete the all memories.

CHANGING MEASUREMENT MODE

In the ON status, press the power button to switch between the object mode and the body temperature mode. Object mode is able to measure the surrounding environment or object temperature.

To ensure the accuracy of measurement, please do not conduct forehead measurement in object mode. No matter what mode it is before turning off, its default is always body mode after power on.



4 SPECIFICATIONS

Product Name	Infrared Forehead Thermometer
Model	THERM-IR
Power Consumption	Max. 50 mW in measurement mode
Rating	2×1.5V AAA alkaline batteries
Battery Life	More than 1000 Times of continuous operation
Auto Power-off	Approx 30 seconds
Dimension	149(L) x 34(W) x 52(H) mm
Weight	Approx 95g (excluding batteries)
Display Screen	Green <37.5°C Normal Yellow ≥37.5°C and ≤38.5°C Low fever Red > 38.5°C High fever
Measurement Range	Body Mode 32°C ~ 43°C (89.6°F ~ 109.4°F) Object Mode 0°C ~ 100°C (32°F ~212°F)
Measurement Mode	Body Mode / Object Mode
Minimum Scale	0.1°C/0.1°F
Measurement Accuracy	±0.2°C, for range 35.0°C ~ 42.0°C ±0.3°C, outside this temperature range at standard room temperature of 25°C (77.0°F)
Memory	30 recorded measurements
Button	3 buttons: Power/Model Button, Measurement/Memory Button, °C / °F Button
Alarm	Sound when peak temperature reached
Calibration	No need for calibration before use. To ensure the measurement accuracy, please use and store the device in appropriate environment described below.
Working Environment	Temperature: 15°C ~ 40°C (59°F ~ 104°F) Relative humidity: 15%RH-93%RH Pressure: 70KPa to 106KPa
Storage and Transportation Environment	Temperature: -25°C ~ 60°C (-13°F ~ 140°F) Relative humidity: 0%RH-90%RH, non-condensing Pressure: 70KPa to 106KPa
Expected Service Life	5 years

5 CLEANING AND DISINFECTION

- For the thermosensor (probe): if there is dust or other dirt in the mirror or tunnel of the sensor, clean the probe with a cotton swab dipped in anhydrous alcohol. Don't place the product directly under the faucet to wash.
- For the product itself: please wipe the product with a soft and dry cloth to avoid scratching of the product. Do not clean the product directly with water.
- Because infrared temperature adopts a highly sensitive technique to detect the temperature of the target object, any dust layer not only may affect the measurement accuracy, but also may cause a bacterial infection.

6 MAINTENANCE

- Before every use, check the device. Do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
- Store and use the device at a cool, dry and ventilated environment. Avoid approaching fire and heat sources, or it will cause the battery to explode.
- If you have any problems with this device, such as setting up, maintaining or using, or in the case of an unexpected operation or event, please contact Van Oostveen Medical B.V (don't open or repair the device by yourself).

7. TROUBLESHOOTING

Problem	Possible causes	Try this Solution
	If the steady battery icon is the only symbol shown on the display, the device cannot work. The battery should be replaced immediately.	Replace batteries
	No display. Thermometer does not have power.	Please check if the batteries have been loaded correctly or are out of power. Also check polarity (<+> and <–>) of batteries. Contact customer service if thermometer still does not function.

	This message displays when the measured temperature is lower than 32 °C (89.6 °F) in the body mode.	Re-measure the temperature carefully following the instructions in “Instructions for use” section.
	This message displays when the measured temperature is higher than 43 °C (109.4 °F) in the body mode.	
	This message displays when the room temperature is outside the operating range of 10 °C – 40 °C (50 °F – 104 °F).	Please wait for 30 minutes before use if the fluctuation goes beyond the normal range (e.g. from outside to a room in winter or from under sunlight to an air-conditioned room), carefully following the instructions about Working Environment in the "Specifications" section.

8 DISPOSAL

DO NOT dispose the batteries in domestic waste. Dispose of the batteries according to the local regulations dealing with the disposal of these special materials (e. g. to the collecting points).

The device is made of a combination of plastic and stainless steel. Be sure to dispose of it in accordance with local regulations as unsorted municipal waste. You may recycle it at your local community or appliance recycling centre.

9 ELECTROMAGNETIC COMPATIBILITY

The Romed Infrared Forehead Thermometer has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

CAUTION:

Do not use this device simultaneously with devices having high EMI levels.

MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The Romed Infrared Forehead Thermometer is intended for use in the electromagnetic environments specified below. The customer or the user of the Romed Infrared Forehead Thermometer should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Romed Infrared Forehead Thermometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Romed Infrared Forehead Thermometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The Romed Infrared Forehead Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of The Romed Infrared Forehead Thermometer should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 5 sec	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level.			

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC

The Romed Infrared Forehead Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of The Romed Infrared Forehead Thermometer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz 6 Vrms in ISM bands	Not applicable Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of The Romed Infrared Forehead Thermometer , including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{v_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths form fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz 385MHz-5786MHz Test specification for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(refer to table 9 IEC 60601-1-2:2 014)	3V/m 80MHz to 2.5GHz 385MHz-5786MHz Test specification for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(refer to table 9 IEC 60601-1-2:2014)	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

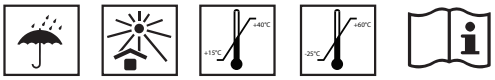
a Field strengths from transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which The Romed Infrared Forehead Thermometer is used exceeds the applicable RF compliance level above, The Romed Infrared Forehead Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating The Romed Infrared Forehead Thermometer .
b Over the frequency range 150kHz to 80 MHz, filed strengths should be less than 3V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE

RF communications equipment and the EQUIPMENT or SYSTEM

- For EQUIPMENT and SYSTMES that are not LIFE - SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Romed Infrared Forehead Thermometer			
The Romed Infrared Forehead Thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Romed Infrared Forehead Thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Romed Infrared Forehead Thermometer as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{v_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



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