Proactive
medical products

Non-contact Infrared Thermometer
Model:40010

CONTENTS

I. SAFETY PRECAUTIONS

- Follow the maintenance advice stipulated in this instruction manual.
- This device may be used for professional purposes or for personal home use.
- This device must only be used for the purposes described in this instruction manual.
- This device must only be used in an ambient temperature range of between 50°F and 104°F.
- This device must always be kept in a clean, dry area.
- Do not expose this thermometer to electric shocks.
- Do not expose this thermometer to extreme temperature conditions of ＞131°F or ＜-4°F.
- Do not use this device in relative humidity higher than 85%.
- The protective glass over the lens is the most fragile part of the thermometer.
- Do not touch the glass of the infrared lens with your fingers.
- Clean the glass with a cotton bud lightly moistened with 95° alcohol.
- Do not expose the thermometer to sunlight or to water.
- Never drop the device.
- Should a problem occur with your device, please contact your retailer. Do not attempt to repair this device yourself.

THE MANUFACTURER RESERVES THE RIGHT TO ALTER
THE SPECIFICATIONS OF
THE PRODUCT WITHOUT PRIOR NOTIFICATION

II. INTENDED USE

The device is an infrared thermometer intended to measure forehead temperature of infants and adults without contacting human body. It can be used by consumers in household environment and doctor in clinic as reference.

III.INTRODUCTION

The 40010 Non-contact Infrared thermometer has been developed by using the latest infrared technology. This technology allows temporal artery (TA) temperature to be taken at a distance of about 3cm~5cm away from the forehead. Precise, Instantaneous and without Contact, the 40010 is, up to now, the most suitable thermometer for no risk on temperature measurement. It has been demonstrated that this method of TA temperature measurement is more precise than the tympanic thermometry and better tolerated than rectal thermometry (1).

However, as with other types of thermometer, it is essential to use the 40010 properly in order to obtain reliable and stable results. You are therefore advised to read this instruction manual and the safety precautions carefully before use.

(1)Greenes D, Fleisher G. Accuracy of a Noninvasive Temporal Artery Thermometer for Use in Infants. Arch Pediatr Adolesc Med 2001;155:376.

IV.PRECAUTIONS BEFORE USE

The 40010 is pre-set at the factory.
It is not necessary to calibrate the device when starting it up.

In order to obtain reliable and stable results, you are advised each time there is a significant change in the ambient temperature due to a change in environment, to allow the 40010 to acclimatize to this ambient temperature for 15 to 20 minutes before using it.

It is important to allow 3~5 seconds interval between two measurements.

V. OPERATING PRINCIPLE

All objects, solid, liquid or gas, emit energy by radiation. The intensity of this energy depends on the temperature of the object.The 40010 infrared thermometer is therefore able to measure the temperature of a person by the energy the person emits. This measurement can be taken thanks to an external temperature probe on the device which permanently analyses and registers the ambient temperature. Therefore, as soon as the operator holds the thermometer near the body and activates the radiation sensor, the measurement is taken instantly by detection of the infrared heat generated by the arterial blood flow. Body heat can therefore be measured without any interference from the heat of the surrounding environment.

THE DIFFERENT METHODS OF TEMPERATURE MEASUREMENT

Core temperature

Core temperature is the most precise measurement and involves measuring the temperature in the pulmonary artery by means of a catheter equipped with a thermal probe which can read the temperature in situ. The same method is employed for probes measuring the oesophageal temperature. However, such invasive temperature measurement methods require specific equipment and expertise.

Rectal thermometry

Rectal temperature adjusts slowly in comparison to the evolution of the body's internal temperature. It has been demonstrated that rectal

temperature remains raised long after the internal temperature of the patient has started to drop and vice versa. Furthermore, rectal perforations have been known to occur as a result of this method and without appropriate sterilisation techniques, rectal thermometry can spread germs often found in faeces.

Oral thermometry

Oral temperature is easily influenced by recent ingestion of food or drinks and by breathing through the mouth. To measure oral temperature, the mouth must remain closed and the tongue lowered for three to four minutes which is a difficult task for young children to accomplish.

Axillary (armpit) temperature

Although it may be easy to measure axillary temperature, it has been proven that it does not provide an accurate measurement of the child's internal temperature. To take this type of temperature, the thermometer must be wedged tightly over the axillary artery. Despite the low sensitivity and relative inaccuracy of axillary temperature in detecting fever, this method is recommended by The American Academy of Pediatrics as a screening test for fever in newborns.

Tympanic thermometry

In order to obtain a precise temperature reading, good command of the measurement technique is required. The thermometer probe must be placed as close as possible to the warmest part of the external ear canal. An incorrectly placed probe could lead to a false temperature reading.

NORMAL TEMPERATURES ACCORDING TO MEASUREMENT METHOD

MEASUREMENT METHOD	NORMAL TEMP°
RECTAL	36.6°C ~ 38°C
ORAL	35.5°C ~ 37.5°C
AXILLARY	34.7°C ~ 37.3°C
AURICULAY	35.8°C ~ 38°C
TEMPORAL	35.8°C ~ 37.8°C

The temperature of the human body varies throughout the day. It can also be influenced by numerous external factors: age, sex, type and thickness of skin…

ADVANTAGES OF TEMPORAL ARTERY (TA) TEMPERATURE

Infrared arterial temperature can be measured using a device placed on the forehead, in the temporal artery region. It has been demonstrated that this relatively new method of measuring temperature is more precise than tympanic thermometry and better tolerated than rectal thermometry.

The 40010 thermometer has been designed to produce an instant forehead temperature reading without any contact with the temporal artery. As this artery is quite close to the surface of this skin and therefore accessible and given the blood flow is permanent and regular, it allows precise measurement of the temperature. This artery is linked to the heart by the carotid artery which is directly linked to the aorta. It forms part of the main trunk of the arterial system. The efficiency, speed and comfort of taking a temperature from this area make it ideal compared with other temperature measurements methods.

NORMAL TEMPERATURES ACCORDING TO AGE

Age	°C	°F
0-2 years	36.4-38.0	97.5-100.4
3-10 years	36.1-37.8	97.0-100.0
11-65 years	35.9-37.6	96.6-99.7
> 65 years	35.8-37.5	96.4-99.5

PRACTICAL CONSIDERATIONS WHEN TAKING A TEMPERATURE

- In order to ensure that precise and accurate temperature measurements are obtained, it is essential that each user has received adequate information on and training in the temperature measurement technique when using such a device.
- It is essential to remember that although procedures such as taking a temperature may be simple they must not be trivialised.
- Temperature should be taken in a neutral context. The patient must not have undertaken vigorous physical activity prior to taking his/her temperature and the room temperature must be moderate.
- Be aware of physiological variations in temperature which must be taken into consideration when evaluating the results: temperature increases by 0.9°F between 6 am and 3 pm. Women have a temperature that is higher, on average, by around 0.4°F. Their temperature also varies in accordance with their ovarian cycle. It rises by 0.9°F in the second half of the cycle and at the early stages of pregnancy.
- When sitting, temperature is lower by about 0.6 to 0.8°F than when standing.

HOW TO TAKE A TEMPERATURE

Aim at the FOREHEAD, over the right temporal region, from a distance of about 3cm~5cm, press the thermometer's measurement button and the temperature is instantly displayed.

The reliability of the measurement cannot be guaranteed if the temperature is measured over another part of the body (e.g.arm, torso…)

CONSTRAINTS

Please observe the following before any temperature measurement to ensure a stable and reliable result:

- Push back hair from the forehead
- Wipe away any perspiration from the forehead
- Avoid any drafts (e.g. from nasal specs, air conditioning…)
- Allow a 3~5 seconds interval between two measurements.
- Each time there is a significant change in the ambient temperature due to a change in environment, to allow the 40010 to acclimatise to this ambient temperature for at least 15 minutes before using it.

VI. BASIC INSTRUMENT

The type BF applied part: Sensor.

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Non-contact Infrared Thermometer
Model No.:40010
Batteries:2xAA(1.5V) 3V
Measuring distance:1.25"-2"
www.proactivemedical.com
Tel:845-205-6004 Made in China

VII. FEATURES

1.Special design to take the Human Body Temperature with a 3cm~5cm (1.2~2 in) distance from forehead.
2.Reliable and stable measurement, thanks to the advantage Infrared Detection System.
3.Audible alarm if temperature is more than 100.4°F.
4.Memorize the last 32 temperature measurements.
5.Three color backlits LCD digital display screen.
6.Temperature unit can be displayed in either Celsius or Fahrenheit.
7.Automatic power-off (<30 secs) to conserve energy.
8.Longevity use (100,000 readings).
9.Practical, easy to use.

ADDITIONAL USAGE:

40010 can also be used to measure the temperature of a baby-bottle or bath (by using the Surface Temp Mode), or room temperature (by using the Room Mode).

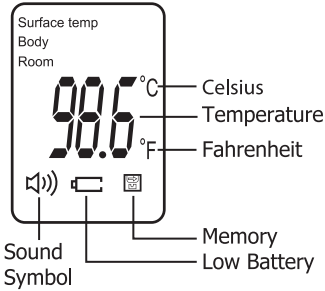
VIII. INSTRUCTIONS

1.Install battery.
2.For the first use or when inserting new Battery, wait from 10~15 minutes for the warm-up of the unit. This will allow the unit to become acclimated to the temperature of the room.
3.Press On/Scan button, aim towards the forehead (see the diagram below for the 40010 positioning), from a distance of 3cm~5cm, When press the “On/Scan” button in the standby mode, the measuring is done when the temperature is showing in the screen or the beep is anouncing, measuring time is one second.

Tips: Do not move the position of the thermometer before the testing is done.

4.Before taking the temperature, make sure to remove hair and perspiration from the forehead.

IX. SETTING AND FUNCTION OF MENU



1.Switch on the device

Press the “On/Scan” button, one second after the screen panel in full display, it will enter the standby mode with the sign “---°C” or “----°F”. Then press the “On/Scan” button again, you will get the measuring result in 1 second. But if there is no more operation, it will turn off in 30 seconds automatically.

2.In the switch on state, Setting the mode

a. Press “MODE” button, and the screen will display: Body…°C

b. Press again “MODE” button and the screen will display: Room…°C

c. Press again “MODE” button and the screen will display: Surface Temp…°C

Note: The thermometer default is set to BODY mode.

Important!

The surface temperature differs from the internal body temperature. To obtain the internal temperature, always use the “BODY” mode. Please make sure to select “SURFACE TEMP”mode for an external area reading.

3.F1:Choosing the temperature unit

In the switch on state, Press “MODE” button for 2 seconds, the screen will display “F1”, then press “MODE” button to transfer between degree Celsius and Fahrenheit, Comfirm by pressing “MEM” button.

4.F2:Alarm setup

In the switch on state, Press “MODE” button for 2 seconds, the screen will display “F1”, then press “MEM” button once, the screen will display “F2”, press “MODE” button to choose the alarming temperature from 99.1°F to 102.4°F, Comfirm by pressing “MEM” button.

Note: The alarm threshold default value is 38°C(100.4°F)

5.Recalibration of device via the F4 MENU

When there is the difference between 40010 and mercury thermometer, and you believe mercury thermometer from its temperature but it is not convenient to use. You can use recalibration function to adjust the 40010 to make it the same test result with mercury thermometer after recalibration.

Besides, when you use 40010 for the people with different skin color (For example: the yellow race, the white race, black people and so on) you can use recalibration too.

Instructions for recalibration:

In the switch on state, Press “MODE” button for 2 seconds, the screen will display “F1”, then press “MEM” button twice ,the screen will display “F4”, press “MODE” button to choose the Offset value from -5.4°F to 5.4°F, Comfirm by pressing “MEM” button.

In the cases of seasonal or environmental changes a verifica tion and adjustment should be carried out.

6.In the switch on state, Press “MEM” (Memory) button, which will then display the last temperature, and allows for a view of the last 32 measurements.

In the switch on state,Press "MEM" button and hold for 5 seconds, all data in memory will be deleted. Then press "MEM" button again, the display will show "CLr"

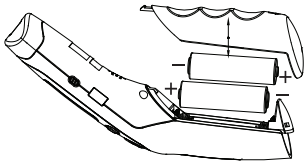
7.In the switch on state, press the “SOUND” button will display a choice

of three languages, and an “OFF” setting, which will be silence the talking feature of the unit.

8.CHANGING THE BATTERIES

Display: when the LCD screen displays the flashed symbol "", the battery is used.

Operation: Open the lid and change the batteries, taking great care with the correct positioning. A mistake with this could cause damage to the apparatus and compromise the guarantee of your 40010. Never use rechargeable batteries. Use only batteries for single usage.



X. TECHNICAL SPECIFICATIONS

1.Normal using condition

Ambient temperature: 10°C ~ 40°C (50°F ~ 104°F)

Relative humidity: ≤85%

2.Batteries: DC 3V (2 pcs AA batteries)

3.Unit size: 175 x 50 x 52 mm (L x W x H)

4.Unit weight (including batteries): 80g

5.Temperature display resolution: 0.1°C (0.1°F)

6.Measuring range:

In body mode: 32°C ~ 42.9°C (89.6°F ~ 109.2°F)

Under body mode, there is three color backlits:

Green color backlit: ≤37.3°C (99.1°F), means normal temperature.

Orange color backlit: 37.4°C~37.9°C (99.3°F~100.2°F), means low fever.

Red color backlit: ≥38°C (100.4°F), means high fever.

In surface temp mode: 0°C ~ 60°C (32°F ~ 140°F)

In room mode: 0°C ~ 40°C (32°F ~ 104°F)

7.Precision:

32.0°C ~ 34.9°C (89.6°F ~ 94.8°F) ±0.3°C(±0.6°F)

35.0°C ~ 42.0°C (95°F ~ 107.6°F) ±0.2°C(±0.4°F)

42.1°C ~ 42.9°C (107.8°F ~ 109.2°F) ±0.3°C(±0.6°F)

8.Consumption: ≤450mW

9.Accuracy: ± 0.3°C (0.6°F)

10.Measuring distance: 3cm ~ 5cm (1.2in ~ 2in)

11.Automatic power-off: <30 secs

12.Memory: 32 sets

※ Note: The Non-contact Infrared Thermometer Model 40010 can take temperature readings below 32°C or above 42.9°C (89.6°F to 109.2°F) but precision is not guaranteed outside of this range.

LONGEVITY OF THE PRODUCT

The 40010 was conceived for an intense and professional use, its longevity is guaranteed for 100,000 takings.

XI. MAINTENANCE OF THE PRODUCT

- The protective glass over the lens is the most important and fragile part of the thermometer, please take great care of it.
- Clean the glass with cotton fabric, wet with 95° alcohol.
- Do not use other batteries than mentioned batteries, do not recharge non rechargeable batteries, do not throw in fire.
- Remove the batteries when thermometer is not used for an extended period of time.
- Do not expose the thermometer to sunlight or water.
- An impact will damage the product.

XII. ACCESSORIES

User manual in English	1 pc
AA alkaline batteries	2 pcs
Carry bag	1 pc

XIII. GUIDELINES

This device complies with the ISO 80601-2-56 and the European Standard EN60601-1-2 and is subject to particular precautions with regard to electromagnetic compatibility.

XIV. TROUBLESHOOTING

If you have problems while using your thermometer, please refer to this guide to help resolve the problem. If the problem persists, please contact our customer service.

THE SCREEN DISPLAYS TEMPERATURE HIGHER THAN 42.9°C (109.2°F):

The temperature is in Fahrenheit. Change the measurement to Celsius by pressing the "°C/ °F" button.

THE SCREEN DISPLAYS TEMPERATURE LOWER THAN 32°C (89.6°F):

To take the surface temperature, press the "Mode" button and set to the reading called "Body" , If the device is in Surface Temp Mode, the 32°C (89.6°F) temperature displayed is showing the external temperature of your body, rather than the internal.

THE SCREEN DISPLAYS THE MESSAGE HI

When using the 40010 Thermometer, the message "HI" can show on the screen.

In this case,the temperature is above the measurement range selected, either above 42.9 °C (109.2°F) in Body Mode.

THE SCREEN DISPLAYS THE MESSAGE LO

When using the 40010 Thermometer, the message "LO" can show on the screen.

In this case, the temperature analyzed is under the measuring range selected, either less than 32°C (89.6°F) in Body Mode.

This message displays for various reasons. Please find below a list of the main issues:

Reasons for LO message display	Advice
Temperature reading hampered by hair or perspiration.	Make sure there is no obstruction or dampness prior to taking temperature.
Temperature hampered by an air draft or dramatic change in ambient temperature.	Make sure there is no air blowing in the area of use; this could affect the infrared reading.
Temperature readings are too close together, and the thermometer did not have time to reboot.	Pause for 3~5 seconds minimum between readings; a 15 seconds pause is recommended.
The measuring distance is too far.	Take measurements at the recommended distance (app. 3~5 cm; 1.2in~2.0in).

XV. EXPLANATION OF SYMBOLS

Symbol	Reference
Proactive medical products	Trade mark
	IEC 60417-5333,Type BF applied part
	IEC 60417-5031 Direct current
IP22	Protected against access to hazardous parts with a finger and against vertically falling water drops when enclosure tilted up to 15°
	Refer to instruction manual / booklet
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
SN	Specifies serial number

XVI. EMC DECLARATION

Guidance and manufacturer's declaration – electromagnetic immunity

The "40010" is intended for use in the electromagnetic environment specified below. The customer or the user of the "40010" should ensure that it is used in such an environment.nt.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered withsynthetic material, the relative humidityshould be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions andvoltage variationson power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the "40010" requires continued operation during powermains interruptions, it is recommended that the "40010" be powered from an uninterruptible power supply or a battery.
Power requency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercialor hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The "40010" is intended for use in the electromagnetic environment specified below. The customer or the user of the "40010" should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the "40010", including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	$d=[\frac{3,5}{V1}]\sqrt{P}$ $d=[\frac{3,5}{E1}]\sqrt{P}$ 80MHz to 800MHz $d=[\frac{7}{E1}]\sqrt{P}$ 800MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	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 from 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: 

NOTE 1 At 80 MHz and 800 MHz, 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.

a Field strengths from fixed 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 "40010" is used exceeds the applicable RF compliance level above, the Medical 40010 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "40010".

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Medical 40010

The "40010" is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Medical 40010 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the "40010" as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0,01	/	0.12	0.23
0,1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	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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