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Medical infrared forehead thermometer Product manual

(for emergency use only)

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1. Product introduction

This product is a professional non-contact remote infrared thermometer for measuring body temperature. Easy to use, light and portable, with LCD display, buzzer prompt, Celsius/Fahrenheit switching display, memory reading, automatic shutdown and other functions.

Product model: HFGY-05

1. [structure composition] consists of shell, circuit board, infrared sensor, display screen and dry battery.
2. [main performance]
 - A) temperature test range: 32.0°C - 42.0°C.
 - B) maximum allowable error:
In temperature mode, the maximum allowable error is ±0.2°C.
 - C) temperature measurement time: 1 second.
 - D) measuring distance: 5 - 12cm.
 - E) power supply: AA battery ×2.
3. [operating environment]
 - A) ambient temperature range: -16°C - 35°C;
 - B) relative humidity range: ≤85%;
 - C) atmospheric pressure range: 70kPa - 106kPa;
 A person who needs to take a temperature

2. Basic working principle

Understanding the principles of infrared temperature measurement can help you use the product correctly and make the test data more accurate.

1. All objects radiate energy into their surroundings.
 2. The temperature of an object is proportional to the intensity of the radiant energy, that is, the higher the temperature, the greater the radiant energy.
 3. The energy radiated from human body is mainly infrared radiation, so the body temperature can be calculated by measuring the intensity of infrared energy radiated from human body to the surrounding area.
 4. The non-contact medical infrared thermometer can accurately measure the weak infrared radiation energy released by the human body, and accurately obtain the body temperature after complex calculation and compensation. The product has a built-in infrared detector and related hardware and software components, can receive, analyze and record the measured object and the ambient temperature. Therefore, once the user places the product close to a specific part of the body (the forehead) and presses the measurement button, the infrared sensor can be immediately activated, and the thermal energy generated by arterial blood flow can be quickly detected by the passive infrared sensor, so as to accurately measure the body temperature.
- The world health organization (WHO) provides the reference value of normal body temperature:

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Forehead temperature	35.8 °C to 37.8 °C
Cochlear temperature	35.8 °C to 38.0 °C
Axillary temperature	34.7 °C to 37.3 °C
Oral temperature	35.5 °C to 37.5 °C
The anus temperature	36.6 °C to 38.0 °C

The normal range of body temperature varies from person to person, and the temperature measured in different parts and at different times varies from person to person. The temperature of the forehead of most people is higher than the temperature of the mouth and the temperature of the armpit, but the temperature of the forehead is lower than the temperature of the armpit. To correctly judge the state of fever, check the normal temperature of a family member.

5. Calibration mode is used to calibrate and test the product. In this model, the measured value is the measurement result of the black body. The body temperature pattern is used to measure the body temperature. In this mode, the measured values are obtained on the basis of the calibration mode values and the necessary statistical corrections, i.e.

Temperature indication = calibration mode value + correction value
 The temperature of the measurement part of the human body (the calibration mode value) of the medical infrared forehead thermometer is measured, and the correction value is determined according to the statistical law of a typical population under certain environmental conditions, rather than the actual characteristics of a measured individual.

6. Clinical deviation Δ specifies the temperature of the device under test measurement and the average deviation between the reference thermometer to measure temperature of the object. Clinical bias is a method of verifying the site deviation specified on the instructions for use of the thermometer under test.

All age groups of clinical deviation Δ respectively calculated by the following formula: t_{0i}

$$\Delta t_{0i} = \frac{1}{n} \sum_{j=1}^n \Delta t_{0ij} \quad \Delta t_{0i} = \frac{1}{n} \sum_{j=1}^n (t_{0ij} - t_{0i})$$

Type:

Δ object - - - - - | deviation; t_{0i}
 t_{0i} -- the JTH reading temperature of object I;
 t_{0i} -- reference temperature of object I read;
 n -- the number of objects in the corresponding age group.
 The clinical deviation of this product is 0.08.

3. Matters needing attention

Warning:

1. It is dangerous for patients to judge and treat themselves based on the

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measurement results alone, so please follow the doctor's instructions.

2. Do not touch the infrared sensor with your hand or blow it with your mouth, or let the sensor face the steam. Damaged or soiled infrared sensors may result in abnormal measurements.

3. If there is a temperature difference between the storage place and the measurement place, the product should be placed at room temperature (the measurement place) for about 30 minutes before the measurement, otherwise abnormal measurement results may be obtained.

4. Please keep the device out of the reach of children to avoid accidents.

5. When taking the temperature, please do not go near the position of warm and cold air or tycure, so as not to affect the accuracy of the measurement.

6. when the infrared sensor is dirty, please gently wipe it clean with a wet cotton swab.

7. Before and after use, the instrument shall be sterilized: swab with 75% alcohol shall be used to wipe the shell, and only after the alcohol has evaporated can it be used.

8. Mechanical damage caused by heavy fall or collision should be avoided.

Note:

1. When measuring human forehead temperature, the product must be operated in temperature mode (see detailed operating procedures). The boldface mode is only used for factory inspection and laboratory calibration.

2. The distance of the product to the forehead must be between 5 and 12cm, so as not to affect the accuracy of measurement.

3. Do not drink, eat or exercise before or during measurement. Do not measure during sweating to avoid affecting the accuracy of measurement.

4. Do not discard the battery to the danger area or carelessly, so as not to pollute the environment.

5. Cosmetics and skin color, due to different infrared radiation rate, will affect the accuracy of temperature measurement.

If the black skin before the measurement needs to manually adjust the temperature compensation value after the measurement.

6. The product shall not be exposed to water or direct sunlight.

Advice:

1. When you tell your doctor your temperature, state that you are using a medical infrared thermometer.

2. Please do not force the collision, fall, step and shake the product.

3. Do not disassemble, repair or modify the product.

4. This product is not waterproof, please be careful not to let liquid (alcohol, water droplets, hot water, etc.) into the product.

5. The product must be kept clean and stored in a dry place.

6. If you find any problems, please contact the sales, can not repair the product.

7. This product is vulnerable to radiation interference, do not use in a strong

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electromagnetic interference environment.

8. Please dispose of the waste and residue at the end of the service life of the product according to local laws and regulations.

4. Symbol description

	Recycling marks for waste products
	Pay attention to
	Low voltage
	The rain proof

Note: this product has no applied parts

5. scope of application

The body temperature of the subject is shown by measuring the thermal radiation from the forehead of the subject.

6. contraindications

Local lesions such as site inflammation, trauma and postoperative were measured.

7. External structure

- ① "-" key
- ② "SET" key
- ③ "+" key
- ④ the trigger button

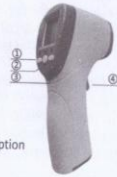


Fig.3-1 key function description

8. Display icon definitions

- ① calibration mode
- ② Body temperature pattern
- ③ temperature data
- ④ Remember temperature data
- ⑤ battery power
- ⑥ units
- ⑦ a buzzer



Fig 4-1 display interface description

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9. Technical parameters

Technical parameters		
Measuring range	Temperature mode	32 °C ~ 42.0 °C
	The calibration model	0 °C ~ 99 °C
precision	Temperature mode	± 0.2 °C
Operating ambient temperature		16 °C ~ 35 °C
Ambient humidity		85% or less
Storage ambient temperature		- 20 °C ~ 55 °C
Humidity of storage environment		93% or less
The power supply voltage		DC3V
The battery specification		AA battery × 2
According to the unit		Degrees Celsius or Fahrenheit
Automatic shutdown		For 20 seconds or less
Electricity prompt		2.4 ± 0.15 V or less
Number of sets of memory		32 groups
Overall dimensions		150mm × 90mm × 40 mm
The weight of the		160g (including battery)

10. Directions for use

1. Install the battery. Open the back cover of the battery.



Note: after the first use or just after the new battery is put in, wait 10 minutes to warm up.

If the instrument has not been used for a long time, the ambient temperature will be detected for the first time, and the start-up time will be extended by 1-2 seconds.

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2. Measurement operation

After starting, set the running mode to the temperature mode, and then aim at the forehead, about 5-12cm away, press the measuring switch, the temperature will be displayed immediately. Also make sure there is no hair, sweat, makeup or hat covering.

When ambient temperature changes affect forehead temperature or forehead sweating, please measure after aligning the earlobe. The measuring distance is 5-12cm. Also make sure there is no hair, sweat, makeup or hat covering.

Note: the temperature measured will vary according to the difference of human skin and the part of the body to be tested, because the more exposed the part of the body is, the more affected by the ambient temperature.

3. Operation instructions of the button (refer to the outline construction drawing)

"SET" key: in the shutdown state, press this key to start; in the boot state, short press this key to shut down.

"-" key: in the shutdown state, press this key to enter the memory to read menu, press "+" key to browse the memory of the temperature data, up to 32 groups.

"+" key: press this key to switch the display unit of temperature (°C or °F).

"Trigger button": press this button to measure the temperature when the buzzer is turned on. After the buzzer is finished, the temperature data will be displayed on the LCD screen.

4. Backlight

When the machine is turned on, the backlight will show red. When the machine is turned on, the backlight will show green.

Replace the battery

When the battery is low, the low power sign will be displayed on the display screen. At this time, the battery cover needs to be opened and a new battery needs to be replaced.

11. Troubleshooting

Error message	why	Processing method
Hi	In the body temperature mode, the temperature of the measured object exceeded 42.0°C	Please use it within the range of measurable temperature. If it appears all the time, please contact the after-sale service
Lo	In the body temperature mode, the temperature of the measured object was lower than 32.0°C	Please use it within the range of measurable temperature. If it appears all the time, please contact the after-sale service

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Battery icon flashing	Low battery	Please replace the battery
The LCD screen is not displayed when the power is turned on	Battery is used up	Please replace the battery
	Battery polarity wrong	The polarity of the battery is consistent with that of the battery case
Low measurement temperature	Wrong measuring position	Measure correctly according to instructions
	Sensor or something on the forehead	Please measure after removing dirt
Continuous measurement of temperature fluctuates greatly	Subject to changes in airflow	Please do not measure the position of air or air

12. Transportation and storage

1. Transportation and storage environment: temperature: -20°C ~ 70°C, relative humidity ≤ 85%.

2. After the product is packaged, the packaging and transportation simulation test shall be conducted. Common means of transport are allowed, but rain, dampness, extrusion and mechanical collision should be avoided.

3. The product should be kept in a well ventilated and dry room. The packing box should be more than 500mm above the ground, and strong sunlight and other corrosive gases should be avoided indoors.

13. Electromagnetic compatibility

1. This section is a special tip on electromagnetic compatibility. This product is safe to use according to the electromagnetic compatibility information in this section.

2. Portable and mobile rf communication equipment may affect this product. When using this product normally, it is recommended to stay away from or turn off the portable and mobile rf communication equipment.

3. See table 1.

4. This product should not be used in close proximity or overlapping with other equipment with the same or similar operating frequency. If it must be used in proximity or overlapping, it should be observed and verified that it can operate normally under the configuration used.

5. See table 2.

6. The basic energy of the product: under the condition of interference, the deviation between the measured temperature and the temperature provided by the high-precision constant temperature tank (37.0°C) should not exceed ±0.2°C.

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7. See table 3 and table 4.

Table 1

Guide and manufacturer's statement - electromagnetic launch		
The product is intended to be used in the following electromagnetic environment, and the purchaser or user shall ensure that it is used in such electromagnetic environment:		
Emission test	compliance	Electromagnetic environment - a guide
Rf launch GB 4824	1 set of	This product USES rf energy for its internal functions only. As a result, it emits very little radio frequency and has little chance of interfering with nearby electronics.
Rf launch GB 4824	Class B	
Harmonic emission GB 17625.1	Do not apply	The product is suitable for use in all facilities, including household and directly connected to the residential public low voltage power supply network.
Voltage fluctuation /scintillation emission GB 17625.2	Do not apply	

Table 2

Guide and manufacturer's statement - electromagnetic immunity			
The product is intended to be used in the following electromagnetic environment, and the purchaser or user shall ensure that it is used in such electromagnetic environment:			
Immunity test	IEC 60601 test level	In line with the level	Electromagnetic environment - a guide
Electrostatic discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor shall be wood, concrete or tile, and if the floor is covered with synthetic materials, the relative humidity shall be at least 30%.

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Electrical fast transient pulse group GB/T 17626.4	±2 kV on the power cord ±1 kV on input /output line	Do not apply	This product is the internal power supply equipment
surge GB/T 17626.5	Plus or minus 1 kV line to line Plus or minus 2 kV line to ground	Do not apply	This product is the internal power supply equipment
Voltage sag, short interruption and voltage change on power input line	< 5%U _n , duration 0.5 period (on U _n , > 95% dip) _T ; 40% U _n , 5 cycles (on U _n , 60% dip) _T ; 70% U _n , 25 cycles _T	Do not apply	This product is the internal power supply equipment
GB/T 17626.11	(30% dip on U _n) _T ; < 5% U _n , 5s _T ; (on U _n , 95% dip of >) _T		
Power frequency magnetic field (50Hz/60Hz) GB/T 17626.8	3 A/m	3 A/m	The power frequency magnetic field should have the horizontal characteristics of the power frequency magnetic field in a typical place in a commercial or hospital environment.

Note: U refers to the ac network voltage before the test voltage is applied.

Table 3

Guide and manufacturer's statement - electromagnetic immunity			
The product is intended to be used in the following electromagnetic environment, and the purchaser or user shall ensure that it is used in such electromagnetic environment:			
Immunity test	IEC 60601 test level	In line with the level	Electromagnetic environment - a guide

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The radio frequency transmission GB/T 17626.6 Radiofrequency radiation GB/T 17626.3	3v (valid value) 150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.5 GHz	Do not apply [3] V/m	Portable and mobile rf communication equipment shall not be used closer to any part of the product than the recommended isolation distance, including cables. The distance shall be calculated by a formula corresponding to the frequency of the transmitter. Recommended isolation distance: $D = 1.2\sqrt{P}$ $D = 1.2$ 80 MHz ~ 800 MHz, \sqrt{P} $D = 2.3800$ MHz ~ 2.5GHz, \sqrt{P} Type: P-- the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W); D -- recommended isolation distance in meters (m). The field strength of a stationary rf transmitter is determined by surveying the electromagnetic field and should be lower than the coincidence level at each frequency range. ^a Interference may occur in device accessories marked with the following symbols.
			
Note 1: at 80 MHz and 800 MHz, the formula of higher frequency band is used. Note 2: these guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and human bodies.			
^a The field strength of stationary transmitters, such as base stations for wireless (cellular/cordless) telephones and ground mobile radios, service radios, am and FM radio broadcasts, and television broadcasts, cannot be accurately predicted in theory. In order to evaluate the electromagnetic field should be considered. If the field strength at the site of the product is measured to be higher than the applicable rf coincidence level, the product shall be observed to verify its normal operation. If abnormal performance is observed, additional measures may be required, such as reorientation or positioning of the product. ^b In the whole frequency range of 150 kHz ~ 80 MHz, the field intensity should be lower than [3] V/m.			

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Table 4

Recommended isolation distance between portable and mobile rf communication equipment and the product			
The product is intended to be used in an electromagnetic environment where rf radiation harassment is controlled. Depending on the maximum output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile rf communication equipment (transmitter) and the product.			
Maximum rated output of transmitter W.	The isolation distance/m corresponding to different frequencies of the transmitter		
	150 kHz ~ 80 MHz $D = 1.2\sqrt{P}$	80 MHz to 800 MHz $D = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $D = 2.3\sqrt{P}$
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 the maximum rated output power of the transmitter not listed in the table above, the isolation distance d is recommended, in meters (m), which can be determined by the formula in the frequency bar of the corresponding transmitter. Here, P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W). Note 1: at 80 MHz and 800 MHz, the formula of higher frequency band is used. Note 2: these guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and human bodies.			

14. Annexes

- Operating instructions × 1
- Certificate of approval × 1
- AA battery × 2

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15. Cleaning, disinfection, maintenance and calibration

1. Cleaning and disinfection:

There is no need to sterilize the product, but the product and accessories should be kept clean. If there is pollution, should promptly clean, disinfection. After use by an infected or suspected infected person, disinfect the portion of the patient in contact. In order to avoid long-term damage to the product, we recommend that you disinfect the product only when the regulations of your hospital deem it necessary.

1.1 cleaning method:

- A) turn off the main engine power before cleaning the product;
- B) wipe the outer surface with a soft and clean gauze, not the inside of the product;
- C) the use of detergent shall be prohibited when cleaning the outer surface of the machine case and the display screen;
- D) do not use worn materials for cleaning;
- E) do not soak the product in liquid and do not let the liquid flow into the product to prevent damage to the product.

1.2 disinfection method:

- A) it is recommended that users soak a piece of clean dry gauze with 70% ~ 80% ethanol disinfectant (volume ratio), and then wipe the surface of the part to be disinfected with this gauze twice for 3min. Air dry naturally or wipe off residual disinfectant with clean, dry cloth;
- B) clean the product before disinfection;
- C) ethanol is inflammable, please keep away from the source of fire during the disinfection with ethanol disinfectant;
- D) alcohol disinfectant should be used with caution for those allergic to alcohol;
- E) rubber products and plastic products will become hard after prolonged contact with alcohol disinfectant, and the residual disinfectant should be removed in time after disinfection;
- F) do not use gamma rays or steam for disinfection;
- G) if the user USES peroxides or chlorine-containing disinfectants for disinfection, note that the disinfectant should avoid metal parts.

2. Storage and maintenance

2.1 do not store the product in direct sunlight, high temperature, humidity, dust, close to fire, vulnerable to vibration.

2.2 when the product is not used for a long time, the battery should be removed to avoid battery leakage.

3. Measurement and calibration 3.1 shall be conducted in accordance with national laws and regulations. It is recommended to measure once a year. If you suspect that the product is damaged or aging, please contact the agent or manufacturer for maintenance.

16. Others

Production date: see outer packing

Service life: 5 years

Medical device production license no. :

Registration certificate no. / technical requirement no. :

Registrant/manufacturer/after-sales service unit: hangzhou huifei technology co., LTD

Production address: 302, floor 3, building 3, no. 1418-66, moganshan road, hangzhou city, zhejiang province.

Contact number: 0571-86903206.

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