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Non-Contact Infrared Body Thermometer

SPECIALIST



User Manual

HTD8813
(Ref: QM7422)

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FOREWARD:

The non contact Infrared body thermometer operating Instructions intend to provide the necessary information for proper operation of HTD8813 (Ref: QM7422), thermometer model.

Only body mode was reviewed and certified by notified body.

General knowledge of Infrared thermometer and an understanding of the features and functions of the HTD8813 (Ref: QM7422) thermometer model are prerequisites for proper use.

The non contact infrared body thermometer is a medical device, and can be used repeatedly, which using life is 5 years.

Please read the manual first before using it, if you do not fully understand the usages, please stop using the thermometer.

Do not operate any of the models HTD8813 (Ref: QM7422) thermometer without completely reading and understanding these instructions.

Notice

Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

SAFETY INFORMATION:

This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.

The non contact infrared body thermometer is designed to minimize the possibility of hazards from errors in the software program by following sound and light engineering design processes, Risk Analysis and Software Validation.

WARNING

- The Non Contact Infrared Body Thermometer is to be operated by consumers in the home setting and primary care setting as screening tool. This manual, accessories, Directions for Use, all precautionary information, and specifications should be read before use.
- This product is designed to measure human body temperature on the forehead. Do not use it for any other purpose.
- This product is intended in the home setting and primary care setting as screening tool.
- Do not use the thermometer if it malfunctions or has been damaged in any matter.
- When the ambient temperature of the thermometer changes too much, such as moving the Thermometer from one place of lower temperature to another place of higher temperature, Allow the thermometer to remain in a room for 30 minutes where the temperature is between 15°C to 40°C (59°F - 104°F).
- Remove primary batteries if equipment is not likely to be used for long time.
- This product is not waterproof, do not be immersed in water or other liquid; If cleaning and disinfection, please follow the "Care and Storage" section requirements.
- Do not touch the sensor of infrared detection with your fingers.
- If a cold compress on the forehead fever patients, or take other measures to cool down the temperature data will low, should be avoided in this case to measure body temperature.
- If measure human forehead temperature, please select "body" mode; for measure other objects, liquids, food and other temperature please select "surface" mode.

SAFETY INFORMATION:

- This product must be operated in a stable environment, if the ambient environment was mutations, please should be note whether there is fog on the sensor, if any, before using accordance with the “Care and Storage” section to removing the fog.
 - Do not near strong electrostatic field or strong magnetic fields, thus avoiding the impact on the accuracy of the measurement data.
 - Do not mix the old and new batteries to avoid damage to the product.
 - It may affect the accuracy of measurements when the forehead is covered by hair, perspiration, cap or scarf.
 - The measuring result of this product is only for your reference. If you have any doubt, please measure the temperature in other methods.
- ⚠ The device should be kept out of the reach of children/pets. When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
- ⚠ Do not throw batteries into fire.
- ⚠ Only use recommended batteries. Do not use rechargeable batteries.
- ⚠ This thermometer will irreplaceable the diagnostic in hospitals.
- ⚠ Do not fall, disassemble or modify the device.
- ⚠ Do not use this device if you think it is damaged or notice anything unusual.
- ⚠ This device comprises sensitive components and must be treated with caution.
- ⚠ Observe the storage and operating conditions described in the ‘Technical Specifications’ section.
- ⚠ Not servicing/maintenance while the thermometer is in use.
- ⚠ When using, shall not touch battery and the patient simultaneously.
- ⚠ Do not use the device if it is damaged/ degraded/loosened in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
- ⚠ Based on the current science and technology, other potential allergic reactions are unknown.
- ⚠ This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS.

OVERVIEW:

Intended Use

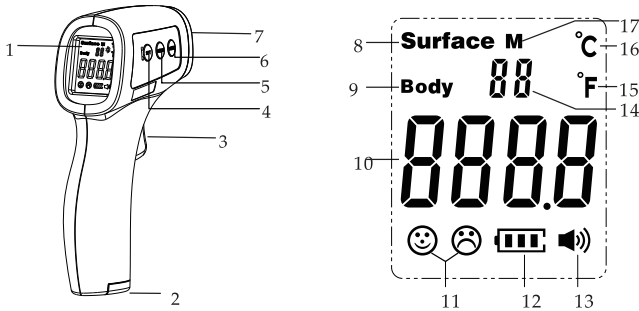
The Non Contact Infrared Body Thermometers are designed to be used for intermittent measurement and monitoring of human body temperature by consumers in the home setting and primary care setting as screening tool.

Description of Non Contact Infrared Body Thermometer

The Non contact infrared body thermometer are hand-held, reusable, battery operated devices, which can measure human body temperature on forehead, the skin temperature on one's forehead.

The operation principle is based on Infrared Sensor technology. The IR sensor can output different signal when measuring different object temperature or in different ambient temperature, and the ASIC can turn the signal from IR Sensor to a digital value and display it on the LCD.

Description on Controls, Indicators, and Symbols









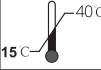









1. Liquid Crystal Display
2. Battery Cover
3. ON/Measure Button
4. SET button
5. MEMO button
6. MODE button
7. IR sensor
8. Surface mode
9. Body mode
10. Data indicator
11. Indicator of measurement result
12. Low Battery indicator
13. Volume on/off indicator
14. Memory Number
15. Fahrenheit
16. Celsius
17. Memory indicator

OVERVIEW:

Thermometer Applications

Model Number	Thermometer Style	Adult		Pediatric	
		Ear	Forehead	Ear	Forehead
HTD8813 (Ref: QM7422)	Non Contact Infrared Body Thermometer		✓		✓

Equipment Symbols

	Warning		Restriction of Hazardous Substances
	Non sterile packaging		Batch code
	Refer to operating instructions		Compliance with WEEE Standard
	Operating Temperature		DO NOT THROW AWAY Intended for multiple use
	Operating Humidity		Operating atmospheric pressure
	This device complies with Part 15 of FCC (Federal Communications Commission) Rules.		Indicates this device is in compliance with MDD 93/42/EEC. 0598 is the Notified Body Number
	Manufacturer		Authorized Representative in the European community
	Recyclable		Serial number
IP22	IP22: The first number 2: Protected against solid foreign objects of Φ 12.5 mm and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°		

OVERVIEW:

Technical Specifications

Measurement Unit	°C / °F
Operating Mode	Adjusted mode (Body mode) Direct mode (Surface mode)
Reference Body Site	Axillary
Rated Output Range	Body mode: 34.0 - 43.0°C / 93.2° - 109.4°F Surface mode: 0 - 100.0°C / 32 - 212°F
Output Range	Body mode: 34.0 - 43.0°C / 93.2° - 109.4°F Surface mode: 0 - 100.0°C / 32 - 212°F
Laboratory Accuracy	Body mode: 34.0 - 34.9°C ($\pm 0.3^{\circ}\text{C}$) / 93.2 - 94.8°F ($\pm 0.5^{\circ}\text{F}$); 35.0 - 42.0°C ($\pm 0.2^{\circ}\text{C}$) / 95.0 - 107.6°F ($\pm 0.4^{\circ}\text{F}$); 42.1 - 43.0°C ($\pm 0.3^{\circ}\text{C}$) / 107.8 - 109.4°F ($\pm 0.5^{\circ}\text{F}$); Surface mode: ($\pm 2^{\circ}\text{C}$ / $\pm 3.6^{\circ}\text{F}$)
Display Resolution	0.1°C / 0.1°F
Three-Colour Backlight (Colour Alarm)	35.5 - 37.3°C / 95.9 - 99.1°F (Green - Normal Temperature) 37.4 - 38.0°C / 99.3 - 100.4°F - Alarm point (Yellow - Slight Fever) 38.1 - 43.0°C / 100.6 - 109.4°F (Red - High Fever) Note: Surface mode results shown with green light. Body mode 34.0 - 35.4°C results is shown with green light.
Auto Power Off Time	$\leq 18\text{s}$
Measuring Time	$\leq 2\text{s}$
Measuring Distance	1 - 5cm (0.4 - 2in)
Memory	50

OVERVIEW:

Power Supply Requirements	
Batteries	15.V (AAA) alkaline battery x2 (IEC Type LR03)
Adaptable Range	2.6V-3.6V
Environmental	
Operating Condition	Operating temperature: 15 - 40°C (59 - 104°F) Relative humidity: ≤85% Atmospheric pressure: 70-106Kpa
Transport and Storage Condition	Operating temperature: 20 - 55°C (-4 - 131°F) Relative humidity: ≤93% Atmospheric pressure: 70-106Kpa
Dimension and Weight	
Weight (without batteries)	90g
Size	138(L) x 95(W) x 40(H)mm
Compliance	
Equipment Classification	Safety Standards: EN 60601-1: 2006+A1:2013, EN 60601-1-2: 2015
Type of Protection	Internally powered equipment (on battery power)
Degree of Protection	Non Applied part
Front Panel and Case Labeling	EN ISO15223-1:2016
Temperature	EN ISO80601-2-56:2017
Home Healthcare Environment	EN 60601-1-11:2015

OVERVIEW:

Calculated values of the indicators according to ISO 80601-2-56

Forehead Mode:

	Group A1	Group A2	Group A3	Group A4
Bias	0.015	0.000	-0.042	-0.040
Standard deviation	0.123	0.121	0.121	0.137
Limits of agreement	0.245	0.243	0.243	0.274
Clinical repeatability (for All Group)	0.071			

Note: the above value is calculated from clinical data of HTD8818A.

Safety classification of ME EQUIPMENT

Protection against electric shock	Internally powered ME equipment
Applied part	Non Applied part
Protection against harmful ingress of water or particulate matter	IP22
Mode of operation	Continuous operation

OPERATION:

Battery installation

Caution: The Non Contact Infrared Body Thermometer does not operate with dead batteries and does not work with external power. Install new batteries.

1. Pull the battery downward, toward the bottom of the Non Contact Infrared Body Thermometer, and remove the battery access door;
2. Insert two pieces AAA size batteries according to the "+" and "-"; Close the battery cover.

HOW TO OPERATE:

Before Applying the Thermometer

Be sure to read and understand all warnings listed of the instructions before use.

- The thermometer is aligned with the middle of the forehead to measure body temperature (between the eyebrows above) and keep the vertical distance, press the On/measure button, temperature display immediately, see Figure 2.

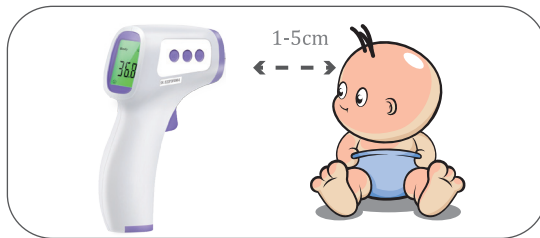


Figure 2: Measuring position and distance

- When the ambient temperature of the thermometer changes too much, such as moving the Thermometer from one place of lower temperature to another place of higher temperature, Allow the thermometer to remain in a room for 30 minutes where the temperature is between 15°C to 40°C.

HOW TO OPERATE:

- The ambient temperature around the test person should be stable, should keep away from the larger flow fan, air-conditioning vents and so on.
- When people moving from one place of lower temperature to another place of higher temperature, should at least remain in the test environment more than 5 minutes, to be consistent with the ambient temperature after the re-measurement.
- Wait at least 1 second for the next measurement. If the continuous measurement of five times, it is recommended to wait at least 30 seconds and then continue measurement.
- You cannot use the thermometer in place where the sun is strong.
- If for some reason the low forehead temperature measurement can try to align behind the ears. See Figure 3.

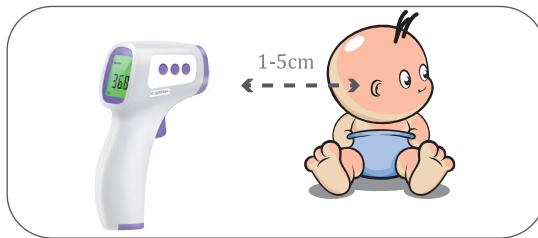


Figure 3: Align behind the ears to measurement

General Setup and Use

Start measuring

1. Turn on the thermometer by pressing the On/measure button. The thermometer will perform self-test with all segments displayed for 2 seconds.
2. Align staff forehead to keep the distance, and then press the On/measure button to start the measurement, read the data.

Note: After full display over, you will hear a rattle or “beep beep beep” three times, which means that the measurements have been completed, while the target value of the measured temperature is displayed on the LCD, while backlit display according to the appropriate setting among the three colors red, green, yellow one of.

HOW TO OPERATE:

Green means ready for next measurement. When 37.4°C-38.0°C, it's yellow, means slight fever warning. Please pay attention to body temperature. When the body temperature is above 38.1°C, it's red, means high fever. Please take action to cool down or go for a doctor.

To ensure the accuracy of the measurement, wait at least 30 seconds after 5 consecutive measurements.

Mode conversion

When the device is running, pressing the MODE button to cycle conversion between "body" mode and "surface" mode.

"body" mode is used for measuring human body temperature, the "surface" mode is used to measure the surface temperature. (The factory default is "body" mode).

Recalling and Erasing Memory Data

The last temperature taken before the thermometer powers off is stored in memory, up to 50.

1. In the boot or shutdown state, short press the MEMO button to view the history of measured values.
2. An empty memory cell shows "---°C" or "---°F".
3. Temperature readings can be stored in memory. Up to 50 temperature readings can be stored into the memory cells and automatically overwrite historical data.
4. In boot mode, press the MEMO button until the LCD display "CLR", which means that all stored data is cleared completely after the long beep.

HOW TO OPERATE:

Parameter settings

This product can be set according to the subjects of different colors and different environments data to meet the different characteristics of populations or individuals.

Long press the SET button to modify the measurement parameters HTD8813 (Ref: QM7422) as:

1. Unit Set-F1

Under the boot mode .Long press SET button to enter F1, press the "MODE" or "MEMO" button to switch Celsius and Fahrenheit temperature units, press the SET button to confirm the unit settings (factory default is Celsius).

2. Fever alert set-F2

Under F1 state, press SET button to enter the F2, press the "MODE" button to decrease 0.1 °C, press the "MEMO" button plus 0.1 °C, long press to accelerate the speed of temperature regulation, and finally press the SET button to save. (The factory default is 38.1 °C)

3. Prompt sound settings-F3

Under F2 state , short press SET button to enter F3, press MODE button or MEMO button to set voice switch, and press the SET button to confirm the settings. (The factory default is the voice Prompt to open).









Prompt sound settings ON/OFF function

Under the boot mode .Short press SET button to take on or take off the Prompt sound function.

Restore to factory setting function

Under the boot mode, long press MODE button until LCD display "rst". Two seconds later ,former F1-F3 parameter back to factory setting.

TROUBLESHOOTING:

MESSAGE	SITUATION	SOLUTION
	Temperature taken in not within Typical human temperature range. (34.0–43.0°C or 93.2°F–109.4°F).	Make sure the forehead thermometer is for forehead measurement, not other human body site.
		
	Measured over the distance:1-5cm (0.4-2in)	Optimum measurement distance is 1cm
	Incorrect test position.	See Figure 2 Measuring position and distance.
	Subjects forehead hair, Antipyretic stickers, head with sweat, etc.	Subjects sit quietly 5-10 minutes before the test.
	Some people's body temperature is lower than the general population.	The main concern fever temperature
	Operating temperature exceeds the range of specified temperature.	Move to a room within the operating range wait 30 minutes before taking temperature.
	The screen flicker, automatic turn off.	Replace battery or the product has been damaged, needs repairs.
	Battery capacity is too low. Taking Temperature is not allowed.	Install a new battery
	Ambient temperature changes too fast	Wait until the ambient temperature is stably.
	(1) Power is off. (2) Improper battery installation. (3) The battery is exhausted. (4) Display remains blank.	(1) Press ON button again. (2) Check the battery polarity. (3) Replace with a new battery. (4) Contact the retailer or service center.

REPLACING THE BATTERY:

1. Open and release battery cover following indicator on the surface of battery cover. Before changing the battery be sure the system is already power off.
2. Remove the battery and replace with 2 new one, type AAA, Make sure align properly as indicated inside the battery cover .
3. Slide the battery cover back in until it snaps in place.
Do not dispose of used batteries in household waste. Take them to special local collection sites.
4. In case, if system is latched up after changing battery. You may not follow up the process of rule one. Just take off battery, waiting 30 sec, then load battery again.



WARNING

Do not recharge, disassemble or dispose of in fire.

1. The typical service life of the new and unused batteries is 2000 measurements for the operation time is 18s.
2. Only use the recommended batteries, do not recharge non-rechargeable batteries and do not burn them.
3. Remove the batteries if the thermometer is not to be used for a long period.

CLEANING, CARE AND STORAGE

The lens is very delicate.

It is very important to protect the lens from dirt and damage.

Use a clean, soft cloth to clean the surface of the device and LCD. Do not use solvents or immerse the device into water or other liquids.

Always keep the thermometer within the storage temperature range (- 20°C to 55°C or - 4°F to 131°F) and humidity range ($\leq 93\%$ non-condensing).

It is recommended to store the thermometer in a dry location free from dust. Do not expose the thermometer to direct sunlight, high temperature/humidity or any extreme environment, otherwise the function will be reduced.

When the ambient temperature of the thermometer changes too much, such as moving the thermometer from one place of lower temperature to another place of higher temperature, allow the thermometer to remain in a room for 30 minutes where the temperature is between 15°C to 40°C.

DISPOSAL

Used batteries should not be disposed of in the household rubbish. Used Batteries should be deposited at a collection point.

At the end of its life, the appliance should not be disposed of in household rubbish. Enquire about the options for environment-friendly and appropriate disposal. Take local regulations into account.

WARRANTY

For warranty claims, please provide the bill of purchase.

The warranty does not cover the following:

- Damage to the device resulting from mis-connection with other devices, or resulting from accidents.
- Changes performed by users without the prior written authorization of the manufacturing company
- Batteries and packaging are not covered under warranty

Products outside the warranty term period will be charged accordingly.

Please note:

1. If you have any problems with this device, such as setting up, maintaining or using, please contact us.
2. The thermometer is calibrated initially at the time of manufacture, and if used according to the instruction manual, then periodic re-adjustment is not required.
3. The patient is an intended operator. The patient can measure and change battery. Under normal circumstances and maintain the device and its accessories according to the user manual.

EMC DECLARATION

1. This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2. *Caution: Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3. *Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4. *Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission	
The Infrared Body Thermometer is intended for use in the electromagnetic environment specified below. The customer of the user of the Infrared Body Thermometer should assure that it is used in such an environment.	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable

EMC DECLARATION

Guidance and manufacture's declaration – electromagnetic immunity		
<p>The Infrared Body Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of Infrared Body Thermometer should assure that it is used in such an environment.</p>		
Anti-interference detection	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 KV Air: $\pm 2, \pm 4, \pm 8, \pm 15$ KV	Contact: ± 8 KV Air: $\pm 2, \pm 4, \pm 8, \pm 15$ KV
Electrical fast transient/burst IEC 61000-4-4	The input a.c. power ports: ± 2 KV The input d.c. power ports: ± 2 KV Signal input/output ports: ± 1 KV	Not applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable
Voltage dips IEC 61000-4-11	0.5 cycles for $> 95\%$ (sync angle [degrees]: 0, 45, 90, 135, 180, 225, 270, 315) 1 cycles for $> 95\%$ UT (sync angle [degrees] : 0) 25 (50Hz)/30 (60Hz) cycles for 30% U T (sync angle [degrees] : 0)	Not applicable
Voltage interruption IEC 61000-4-11	250 (50Hz)/300 (60Hz) cycles for $> 95\%$ UT (sync angle [degrees] : 0)	Not applicable
Power frequency (50 Hz / 60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

EMC DECLARATION

Guidance and manufacture's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable
Radiated RF IEC 61000-4-3	Professional healthcare environment: 3 V/m Home healthcare environment: 10 Vm 80 MHz to 2700 MHz	Professional healthcare environment: 3 V/m Home healthcare environment: 10 Vm 80 MHz to 2700 MHz

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 Non Contact Infrared Body Thermometer is used exceeds the applicable RF compliance level above, the Non Contact Infrared Body Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Non Contact Infrared Body Thermometer.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EMC DECLARATION

Guidance and manufacturer`s declaration - RF wireless communication equipment immunity						
Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz (b)	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM (c) \pm 5 kHz Standard Deviation 1 kHz Sine Wave	2	0.3	28
710	704-787	Band LTE 13, 17	Pulse Modulation 217 Hz (b)	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; Band LTE 5	Pulse Modulation 18 Hz (b)	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, Band LTE 1, 3, 4, 25 ;UMTS	Pulse Modulation 217 Hz (b)	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, Wireless LAN, 802.11 b/g/n, RFID 2450, Band LTE 7	Pulse Modulation 217 Hz (b)	2	0.3	28
5240	5100-5800	Wireless LAN 802.11 a/n	Pulse Modulation 217 Hz (b)	0.2	0.3	9
5500						
5785						

- a. Some services include only upload frequencies.
- b. The carrier wave should be modulated using a 50% duty cycle square wave modulation.
- c. As an alternative to frequency modulation, 50% pulse modulation at 18Hz can be used, although it does not represent actual modulation, it would be the less accurate option.

BODY TEMPERATURE:

- Body temperature varies from person to person and fluctuates during the course of the day. For this reason, it is suggested to know one's normal, healthy forehead temperature to correctly determine the temperature.
- Body temperature runs approximately from 35.5°C to 37.8°C (95.9°F - 100°F). To determine if one has a fever, compare the temperature detected with the person's normal temperature. A rise over the reference body temperature of 1°C(1°F) or more is generally indication of fever.
- Different measurement sites (rectal, axillary, oral, frontal, auricular) will give different readings. Therefore it is wrong to compare the measurement taken from different sites.

ASTM laboratory accuracy requirements in the display range of 37°C to 38.9°C (98°F to 102°F) for IR thermometers is $\pm 0.2^{\circ}\text{C}$ ($\pm 0.4^{\circ}\text{F}$), whereas for mercury in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E1112-86 is $\pm 0.1^{\circ}\text{C}$ ($\pm 0.2^{\circ}\text{F}$).

Caution: This infrared thermometer meets requirements established in ASTM Standard (E1965-98) Except of clause 5.2.2. It displays subject's temperature over a range of 34.0~43.0°C.



Wellkang Ltd (www.CE-marking.eu)

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