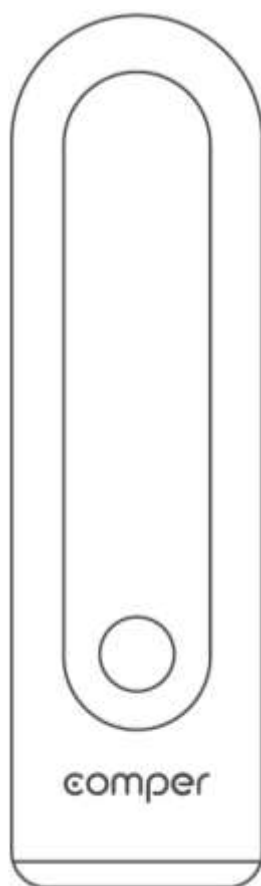


User Manual

of Infrared Forehead Thermometer

Model: IR-FT



Comper Chuangxiang (Beijing) Technology Co., Ltd

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1. Information on registrant/manufacture

Name of registrant: Comper Chuangxiang (Beijing) Technology Co., Ltd

Address of registrant: 102,103 - F1, Room 203,213 - F2, Building 4, No. 1 Kangding Street, Beijing
Economic-Technological Development Area, Beijing

Contact information of registrant: +86 10-57480968

Name of manufacturer: Comper Chuangxiang (Beijing) Technology Co., Ltd

Address of manufacturer: 102,103 - F1, Room 203,213 - F2, Building 4, No. 1 Kangding Street,
Beijing Economic-Technological Development Area, Beijing

Address of manufacturing site: Room 102,103, F1, Building 4, No. 1 Kangding Street, Beijing
Economic-Technological Development Area, Beijing

Contact information of manufacturer: +86 10-57480968

Production date: See the labels;

Batch No./Serial No. of product: See the labels;

Service life: 3 years.

After-sales service unit: Comper Chuangxiang (Beijing) Technology Co., Ltd

Address of after-sales service unit: Room 102,103, F1, Building 4, No. 1 Kangding Street, Beijing
Economic-Technological Development Area, Beijing

Contact number: +86 10-57480968

Fax: +86 10-57480968

Version: A/0

Date of issuance: November 28, 2018

2. Product introduction

This Forehead Thermometer takes the body temperature by measuring the infrared energy emitted from the forehead skin above the eyebrows. The Forehead Thermometer adopts gentle-touch, user friendly and non-invasive measurement design. It instantly displays the accurate reading of the body temperature with just a gentle forehead touch.

3. Indication for use:

This device is a non-sterile, reusable, contact Infrared thermometer intended for intermittent determination of human body temperature in a touch on the center of the forehead as the measurement site on people of all ages.

This device can be used in clinical hospital and home.

4. Structural composition:

The product is mainly composed of a temperature sensor, a housing, a circuit board and a battery compartment.

5. Name of components:

As shown in Figure 1, the product is composed of five components:

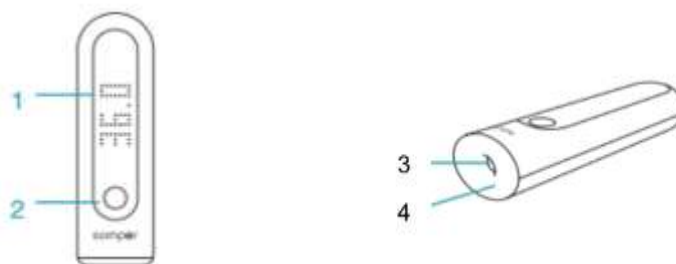


Figure 1

① LED Display ② Power/Temperature Measurement Button ③ Temperature Sensor ④ Temperature Measuring Probe

Declaration of replaceable parts

1. Use AAA manganese or alkaline dry batteries (two AAA batteries) only, otherwise device failure may occur.

2. Mount the positive and negative poles of batteries correctly. Replace the dying batteries in time to avoid overheat, fluid leakage and damage of the batteries, which may further damage the device.
3. Do not attempt to repair the product by yourself. In case of any quality issue or any doubt about the measurement accuracy of thermometer, please contact the dealer or the manufacturer.
4. Please dispose of the replaced components (e.g. dry batteries) and the device reaching the end of service life according to the local laws and regulations.

Technical indicators

Product name	Infrared Forehead Thermometer
Model/specification	IR-FT
The type of temperature measurements	Infrared, Forehead
Temperature display range	32.0°C~43.0°C (89.6°F-109.4°F)
Maximum allowable error	≤±0.2°C (0.4°F), for the range 35°C-42°C (95°F-107.6°F); ≤±0.3°C (0.5°F), for the range 32°C-34.9°C (89.6°F-94.8°F) and 42.1-43°C (107.8°F-109.4°F).
Clinical repeatability	≤±0.3°C (0.5°F)
Temperature unit	°C/ °F
Display resolution	0.1°C (0.1°F)
Operating environment	Temperature: 10°C~40°C(50°F-104°F); Relative humidity: ≤95%; Atmospheric pressure: 70 kPa~106 kPa; Power supply conditions: internal DC power supply, D.C. rated value (1+5%) V and D.C rated value (1-10%) V
Transportation and storage conditions	Temperature: -20°C~+55°C (-4°F-131°F); Relative humidity: ≤95%; Atmospheric pressure: 70 kPa~106 kPa
Power supply	D.C. 3 V (2 AAA dry batteries)
Time required for the device to obtain a steady state reading	2 Seconds
Dimensions (mm)	125mm×35mm×26mm
Service life	3 years
Prompt functions	A prompt message will appear when the temperature is lower than 32°C (89.6°F); A prompt message will appear when the temperature is higher than 43°C (109.4°F);

	Four short beeps are emitted to signal low battery when the actual supply voltage of the product is ≤ 2.51 V.
	Three short beeps are emitted to signal low environment temperature: When the temperature is lower than $10\pm 1^{\circ}\text{C}$ ($50\pm 1^{\circ}\text{F}$); Three short beeps are emitted to signal high environment temperature: When the temperature is higher than $40\pm 1^{\circ}\text{C}$ ($104\pm 1^{\circ}\text{F}$).
	A prompt message will appear after batteries are installed and device starts up;
	A “beep” is emitted to indicate that the measurement is completed.
Automatic shutdown function	The product will automatically shut down after 60 s of inactivity.
Safety requirements	<ol style="list-style-type: none"> 1. Classification according to the type of protection against electric shock: Internally powered equipment; 2. Classification according to the degree of protection against electric shock: Type BF applied part; 3. Classification according to the degree of protection against liquid ingress: IP22; 4. Classification according to the safety degree of the product used in the flammable anesthetic gas mixed with air, oxygen or nitrous oxide: This equipment shall not be used in the flammable anesthetic gas mixed with air, oxygen or nitrous oxide; 5. Classification according to the mode of operation: Continuous operating equipment; 6. Power supply: D.C. 3 V (2 AAA dry batteries); 7. Whether the equipment has the defibrillation-proof applied part: No; 8. Whether the equipment has the signal input or output part: No; 9. Permanently installed equipment or non-permanently installed equipment: None-permanently installed equipment; 10. Input power: Not applicable; 11. Electromagnetic compatibility is classified into Group 1, Class B according to CISPR 11.

The patient is an intended operator and can perform the maintenance the equipment.

6. Correct application methods

1) Preventive inspections:

- Measure and check the functions of each component to maintain good condition of Forehead Thermometer.


- Check to make sure the batteries have enough power.
- The packaged product can be transported via common vehicles. However, it is necessary to prevent the product from rain, damp, extrusion and mechanical collision.

2) Unpacking:

Open the individual-packed color box, take out the package with Forehead Thermometer and remove the Forehead Thermometer from the plastic tray.

3) Battery installation or replacement

- Open the battery cover and replace the batteries. Mount the positive and negative poles of the batteries correctly.
- Please use disposable batteries instead of rechargeable batteries, especially using the alkaline dry batteries.
- In long period storage, it is recommended to remove the batteries to prevent battery leakage thus damaging the product since the device's quiescent current is very low when it is not working.
- Do not use expired batteries for the device.

The device adopts D.C. 3 V manganese or alkaline dry batteries (2 AAA batteries). When the LED shows “”, it indicates that it is in low battery state and the batteries must be replaced as soon as possible to ensure measurement accuracy. Please dispose of the replaced components (e.g. dry batteries) and the hosts reaching the end of service life according to the local laws and regulations.

<div data-bbox="213 1632 272 1688" data-label="Image"> </div> <p>Precautions</p>	<ol style="list-style-type: none"> 1. When opening the battery cover to replace the batteries, pay attention to the positive and negative poles. Dying batteries should be removed immediately. Incorrect mounting will cause damage to the product. 2. In long period storage, please remove the batteries to prevent damage to the thermometer by fluid leakage. 3. Do not use the product in case of battery leakage or mold. 4. Do not take the battery close to the fire or put it into fire to avoid battery explosion. 5. Do not store the battery in a high-temperature or high-humidity environment. 6. To avoid short circuit, do not place the battery together with metal objects such as coins or keys in the same pocket or other containers that may cause battery short circuit. 7. In case of exposure of eyes to the electrolyte in the battery by mistake, rinse immediately with plenty of water. In case of any hazard causing injuries such as blindness, go to the nearest hospital for medical treatment immediately. 8. In case of exposure of skin or clothes to the electrolyte in the battery by mistake, rinse immediately with plenty of water, otherwise it may damage the skin.
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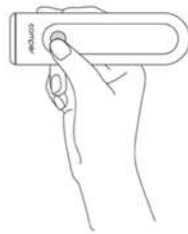
Prompt: The emissivities of various materials may be different. Please refer to the material

emissivity. The default emissivity of this product is 1.0. The measured temperature will deviate from the actual value for different emissivities.

4) Operation procedures

4.1 Measurement

- Power On/Off: In the Off state, lightly press the “Power/Temperature Measurement Button” for to start up. The device will start self-inspection and the LED screen will be fully on. It will be ready for measurement after the self-inspection.



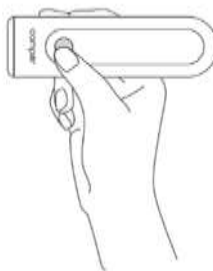
- Measurement and body temperature judgment

Ensure that the temperature measuring probe of Forehead Thermometer is in full contact with the center of forehead. Lightly press the “Power/Temperature Measurement Button”. The measurement is completed after hearing a long “Click” sound. The LED will display the temperature measurement result. The next measurement can be performed after hearing a short “Click” sound.




- Sleep/Wakeup

If there is no further operation, the Forehead Thermometer will enter the sleep state 10 s after displaying the measurement result. It is feasible to wake up the device by lightly pressing the “Power/Temperature Measurement Button”.



- Shutdown

After 1 min of inactivity, the Forehead Thermometer will automatically shut down.

 Precautions	<ol style="list-style-type: none"> 1. Be sure to read the IFU carefully prior to use. 2. The ambient temperature applicable to this product is 10°C (50°F) to 40°C (104°F), where 25°C (77°F) is optimal. 3. Please do not take this product too close to a charged object to avoid electric shock. 4. Please do not use this product in an environment with a relative humidity greater than 95%. 5. Please do not take this product too close to an electromagnetic environment (such as radio and mobile phone). 6. Please do not expose this product to the sun or close to a stove, or even water. 7. Please do not hit or drop this product. Do not use the product if it is damaged. 8. The hair and sweat on the forehead, hat or scarf may affect the accuracy of measured data. 9. Please validate that the measurement distance shall not be greater than 1 cm. 10. In order to obtain accurate, stable and reliable measured data, when the room temperature varies greatly, the product should be placed in the same environment with the measured object for 30 min prior to use. 11. In case of forehead sweating or other circumstances that the forehead temperature cannot reflect the body temperature normally for other reasons, please measure behind the earlobe. 12. When cleaning is required, gently wipe the surface of probe with alcohol. 13. In case of any problem with the product, please contact the company at 010-57480968. Do not try to repair it by yourself. 14. Please do not use the product with wet hands. 15. The product is not waterproof and should not be exposed to water.
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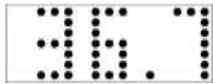

4.2 Sleep/Wakeup


If there is no further operation, the Forehead Thermometer will enter the sleep state 10 s after displaying the measurement result. It is feasible to wake up the device by lightly pressing the “Power/Temperature Measurement Button”.

4.3 Shutdown

After 1 min of inactivity, the Forehead Thermometer will automatically shut down.

4.4 Display icon definition

Function definition	Icon	Status description	
Battery prompt		Display and flash	The battery is extremely low and the product is not working properly. Replace the batteries immediately.
		No display	Full battery
Temperature unit	°C/°F	Degrees Celsius/ Degrees Fahrenheit	
Displayed value		Measured temperature value	
Low temperature warning		In body temperature mode, if the measured temperature is lower than 32.0°C (89.6°F)	

High temperature warning		In body temperature mode, if the measured temperature is higher than 43.0°C (109.4°F)
Error prompt	Err	When the ambient temperature range is beyond 10°C~40°C (50°F-104°F)
	ErrH	Hardware fault
	ErrE	Storage hardware fault

7. Contraindications, precautions, warnings and prompts

1) Contraindications

Currently none

2) Precautions

- The product is an infrared forehead thermometer for professional measurement of body temperature. The measured temperature will vary depending on the skin of human body.
- When the measured object and the forehead thermometer are not in the same environment, place the infrared forehead thermometer in the same environment with the measured object for 30 min prior to use.
- The environment around the measured object should be stable. Do not make measurement at places with large airflow such as air outlet of fan and air conditioner, etc.
- Do not use the device outdoors or under strong sunlight.
- Do not hold the front end of thermometer while measuring.
- The measurement site cannot be covered by hair. In case of any sweat stain, wipe clean with a dry towel before measuring. Otherwise, it will affect the measurement result.
- The measurement result will be lower after taking cooling measures such as cold compress and sweating on the forehead of patients with fever. Therefore, do not make measurement in such cases.
- There is no standard value specified for body temperature. Please consult a doctor to see if you are in fever.
- The device is MR unsafe.

3) Warnings

It is very dangerous to make self-judgment on the measurement result or carry out treatment. Please follow the doctor's instructions.

- Self-judgment may lead to illness exacerbation.

Medical care is needed in case of excessive body temperature or high body temperature for a long time, especially for infants. Please consult the doctor promptly.

- It may lead to illness exacerbation.

If the device is to be left idle for a long time (over 3 months), remove the batteries and keep out of the reach of children.

- Otherwise, it may cause ingestion by children.

Keep the product out of the reach of children. At the same time, please prevent the children from using the device alone.

- Otherwise, it may cause injury to children or damage to the equipment.

Please dispose of the used-up batteries according to the local requirements.

- Otherwise, it may cause fire due to battery explosion, thus resulting in burns and injury.

Do not collide, drop, step on or vibrate the product intensively. Otherwise, it may cause product damage, thus resulting in injury.

8. Maintenance, cleaning, repair and maintenance period

Before use of product, we recommend thorough cleaning of the device according to the method below, and if the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device, so that a visibly soiled device is not used again.

1) Please clean and maintain the product as follows:

- Step 1: Power off the thermometer by switch.
- Step 2: Examine the thermometer for visual contamination.
- Step 3: Wipe with a soft cloth dipped with 70% isopropyl alcohol, until the probe surface is clean and free of dirt by visual test.

Do not touch the temperature sensor. In case it is dirty, do not clean with water or detergent. Please use 70% isopropyl alcohol to wipe it clean instead.

The product is not waterproof. Do not clean with detergent or immerse the thermometer into water or other liquids.

- Step 4: Allow the thermometer to air dry completely for at least 1 min.
- Step 5: After cleaning and drying, visually examine the thermometer for any remaining contamination; if contamination is present, please repeat Step 3-4 until the contaminants are no longer present.

2) Do not store the product in the following places, as it may cause damage:

- Places prone to water splashing;

- Places with high temperature, moist, direct sunlight exposure, dust and being salty.
- If the product is to be left idle for a long time (over 3 months), please remove the batteries for safekeeping.

3) About safekeeping

- When not in use, store it in a locker/box.

4) Maintenance period

- The product shall be cleaned and maintained after each use.

Product repair

Do not repair the product by yourself. In case of any quality issue or any doubt about the measurement accuracy of thermometer, please contact the dealer or the manufacturer.

Recommended cleaning and disinfection procedures



After each use of the product, wipe clean the dirt place with a clean soft cloth or wipe clean the surface of product and the probe with a soft cloth soaked with 75% (volume ratio) ethanol solution.












9. List of accessories

In case of any inconsistency between the physical object and the following information, please contact the manufacturer.

No.	Accessory	Quantity
1	Forehead Thermometer Host	1
2	Battery (AAA manganese or alkaline dry battery)	2
3	Instructions for Use	1
4	Qualification Certificate	1

10. Interpretation on the contents such as figures, symbols and abbreviations used by the medical device labels

Marks and graphic symbols			
Marks on the product and package			
	Consult the Instructions for Use		Caution, consult accompanying documents

	Type BF applied part		Keep dry
	Low battery prompt		Avoid sunlight
	Straight up		Fragile; Handle with care
	Discarded electronic or electrical equipment		Radio transmitting equipment
	Serial number		Date of manufacture
	Manufacturer		

11. Troubleshooting

Failure/issue	Possible cause	Measures that can be taken
Higher measurement result	Make measurement immediately after taking the forehead thermometer into a room under normal temperature when it is stored in a cold environment.	Make measurement 30 min later after placing the forehead thermometer in the room where using the product.
	The probe is always exposed to direct sunlight.	Make measurement 30 min later after placing the forehead thermometer in the room where using the product.
	Make measurement immediately when the measured object is in excited emotion.	Excited emotion can rise the facial temperature. Please make measurement after the measured object gets calm.
Lower measurement result	Body sweating	Do not use the product after swimming, bathing or sweating after exercise because the skin temperature will drop in such circumstances. Wipe off water and wait for 30 min before measuring.
	The probe is dirty.	Please clean the probe with soft cotton cloth dipped with 75% alcohol.
	Make measurement on the measured object immediately after he/she enters indoor space from outdoors in cold weather.	Please wait until the forehead has warmed up before measuring.
	Measure the body temperature at other sites except the forehead.	Please use the product only for temperature measurement at forehead.
Difference in measurement results	Measurements were not made at the same site.	Make measurements at the same site.
	The measurement site was covered by foreign matters such as hair during	Ensure that the measurement site is not covered before measurement.

	measurement.	
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12. Clinical accuracy:

The normal body temperatures are within a certain range. The body temperatures measured at different sites will be different. See the specific differences in the following table:

Measurement site	Normal body temperature	Deviation
Forehead temperature	34.7°C~37.8°C (94.5°F-100°F)	0.3°C~0.5°C (0.5-0.9°F) lower than the oral temperature

The product is applicable to people of all ages. The body temperatures of different groups will be different. See the specific differences in the following table:

Age group	Normal body temperature	Clinical deviation
At the age of 0-2	36.4°C~38.0°C (97.5°F-99.5°F)	$\leq \pm 0.3^{\circ}\text{C}$ (0.5°F)
At the age of 3-10	36.1°C~37.8°C (97°F-100°F)	$\leq \pm 0.2^{\circ}\text{C}$ (0.4°F)
At the age of 11-65	35.9°C~37.5°C (96.6°F-99.5°F)	$\leq \pm 0.2^{\circ}\text{C}$ (0.4°F)
At the age of 65 above	35.8°C~37.4°C (96.4°F-99.2°F)	$\leq \pm 0.3^{\circ}\text{C}$ (0.5°F)

Caution: Depending on the person's skin color, thickness and body part and great changes of ambient temperature, the measured body temperature values will be different, which is quite normal. The reason is that the body parts more frequently exposed to the external environment will be more affected by the ambient temperature.

13. Statement

The product is intended to measure heat radiation from the forehead to display body temperature. It has been verified for clinical accuracy. The performance verification method for the product can be accessed by contacting our Customer Service Department.

14. Description on the replacement cycle and method of consumables and batteries

The detachable components of this product mainly include the batteries. Before installing the accessories, please confirm whether the specifications of accessories are consistent with the original specification. Please use the components of models specified by the company. Contact the dealer or manufacturer if necessary.

Battery mounting and replacement:

When a low battery prompt symbol appears on the display screen, please replace with dedicated batteries. Battery mounting and replacement should follow Part 3 "Battery mounting and replacement methods" in "Correct application methods" of the Instructions for Use.

15. Thermometer modes

Comper Smart Infrared Forehead Thermometer has the measurement mode and calibration mode. The measurement mode is the normal use mode for the user, while the calibration mode is only available for the manufacturer for production and is not open to the user.

16. Relevant EMC information



Cautions:

- IR-FT Infrared Forehead Thermometer meets the relevant requirements for electromagnetic compatibility in IEC60601-1-2;
- Users should assemble and operate the equipment according to the EMC information provided in the accompanying documents;
- Portable and mobile RF communication equipment may affect the performance of IR-FT Infrared Forehead Thermometer. Therefore during use, the product should be kept away from electromagnetic interference resources, such as mobile phones and microwave ovens, etc.;
- See details of guidance and manufacturer's statement in the subsequent **“Guidance and Manufacturer's Statement”**.



Warnings:

- IR-FT Infrared Forehead Thermometer shall not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, it shall be observed to verify normal operation in the configuration in which it will be used;
- If the physiological parameters measured by the equipment are lower than the specified minimum values, the measurement results may be inaccurate.

Table 1: Electromagnetic emission

Guidance and manufacturer's statement - Electromagnetic emission		
IR-FT Infrared Forehead Thermometer is intended for use in the electromagnetic environment as specified below. The buyer or user of IR-FT Infrared Forehead Thermometer should assure that it is used in such an environment:		
Emission test	Compliance	Electromagnetic environment - --Guidance
RF emission	Group 1	IR-FT Infrared Forehead Thermometer uses RF energy


CISPR 11		only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emission CISPR 11	Class B	IR-FT 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 emission IEC61000-3-2	Not applicable	
Voltage fluctuation/flicker emission IEC61000-3-3	Not applicable	

Table 2: Electromagnetic immunity 1

Guidance and manufacturer's statement - Electromagnetic immunity			
IR-FT Infrared Forehead Thermometer is intended for use in the electromagnetic environment as specified below. The buyer or user should assure that it is used in such an environment:			
Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment - – Guidance
Electrostatic discharge IEC61000-4-2	± 6 kV, contact discharge ± 8 kV, air discharge	± 6 kV, contact discharge ± 8 kV, air discharge	Floors shall be wood, concrete or ceramic tile. If floors are covered with the synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC61000-4-4	± 2 kV, for power supply lines ± 1 kV, for input/output lines	Not applicable	Not applicable
Surge IEC61000-4-5	± 1 kV, differential-mode voltage ± 2 kV, common-mode voltage	Not applicable	Not applicable
Voltage dip, short interruption and voltage variation on power supply input lines IEC61000-4-11	$< 5\%$ U_T , for 0.5 cycle ($> 95\%$ dip in U_T) 40% U_T , for 5 cycles (60% dip in U_T) 70% U_T , for 25 cycles (30% dip in U_T) $< 5\%$ U_T , for 5 s ($> 95\%$ dip in U_T)	Not applicable	Not applicable
Power-frequency magnetic field (50/60 Hz)	3A/m	3A/m, 50/60 Hz	The power-frequency magnetic field shall be at the level characteristic of

IEC61000-4-8			a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test voltage.			

Table 3: Electromagnetic immunity 2

Guidance and manufacturer's statement - Electromagnetic immunity			
IR-FT Infrared Forehead Thermometer is intended for use in the electromagnetic environment as specified below. The buyer or user of IR-FT Infrared Forehead Thermometer should assure that it is used in such an environment:			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - -- Guidance
RF conduction IEC61000-4-6	3 V (r.m.s.) 150 kHz~80 MHz	Not applicable	Portable and mobile RF communication equipment shall be used not closer to any part of IR-FT Infrared Forehead Thermometer, including cables, than the recommended separation distance. The distance shall be calculated according to the formula applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz~800 MHz $d = 2.3\sqrt{P}$ 800 MHz~2.5 GHz where: P —The maximum rated output power of the transmitter in watts (W) according to the transmitter's manufacturer; d —The recommended separation distance in m ^b . Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^c , should be less than the compliance level in each frequency range ^d . Interference may occur in the vicinity of equipment marked with the following symbols. 
RF radiation IEC61000-4-3	3 V/m 80 MHz~2.5 GHz	3 V/m	
Note 1: At 80 MHz and 800 MHz, the formula used for higher frequency range applies.			
Note 2: These guidances may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and human bodies.			

- 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 of fixed RF transmitters, an electromagnetic site survey shall be considered. If the measured field strength in the location in which the IR-FT Infrared Forehead Thermometer is used exceeds the applicable RF compliance level above, the IR-FT Infrared Forehead 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 IR-FT Infrared Forehead Thermometer.
- b. Within the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended safe distance

Recommended separation distance between portable and mobile RF communication equipment and the IR-FT Infrared Forehead Thermometer			
IR-FT Infrared Forehead Thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The buyer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the equipment or system, according to the maximum rated output power of the communication equipment.			
Maximum rated output power of transmitter/W	Separation distance according to the frequency of transmitter/m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the formula applicable to the frequency of the transmitter, where P is the maximum rated output power of the transmitter in watts (W) provided by the transmitter's manufacturer.			
Note 1: At 80 MHz and 800 MHz, the formula used for higher frequency range applies.			
Note 2: These guidances may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and human bodies.			

Warranty Information

From the date of purchasing the equipment, you can enjoy the following after-sales services provided by comper with the purchase invoice: One-year Warranty.

- Warranty principle:**
1. Free warranty for products with host quality issues within one year;
 2. Please deliver the product to the address of after-sales service unit of comper for repair.
 3. The issues arising from battery leakage, repair and disassembly on one's own, man-made damage, natural disasters and force majeure, etc. are beyond the warranty coverage.

Declaration of Conformity

The IR-FT Infrared Forehead Thermometer meets requirements established in ASTM E 1965 for the thermometer system. And Comper Chuangxiang (Beijing) technology Co., Ltd (Add: Room 102,103 1st Floor, Unit 4, No.1 Kangding Street, Beijing Economic Technology Development Area, Beijing, China) take full responsibility for the conformance of the thermometer to the standard.

The IR-FT Infrared Forehead Thermometer conforms to the following standards:

IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

ISO-80601-2-56 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

ASTM E 1965-98:2016 Standard specification for infrared thermometers for intermittent determination of patient temperature.

ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

IEC60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.

IEC 60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Federal Communications Commission (FCC) Statement

- 1) This device may not cause harmful interference and
- 2) This device must accept any interference received, including interference that may cause undesired operation.

15.21

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC RF Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.



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