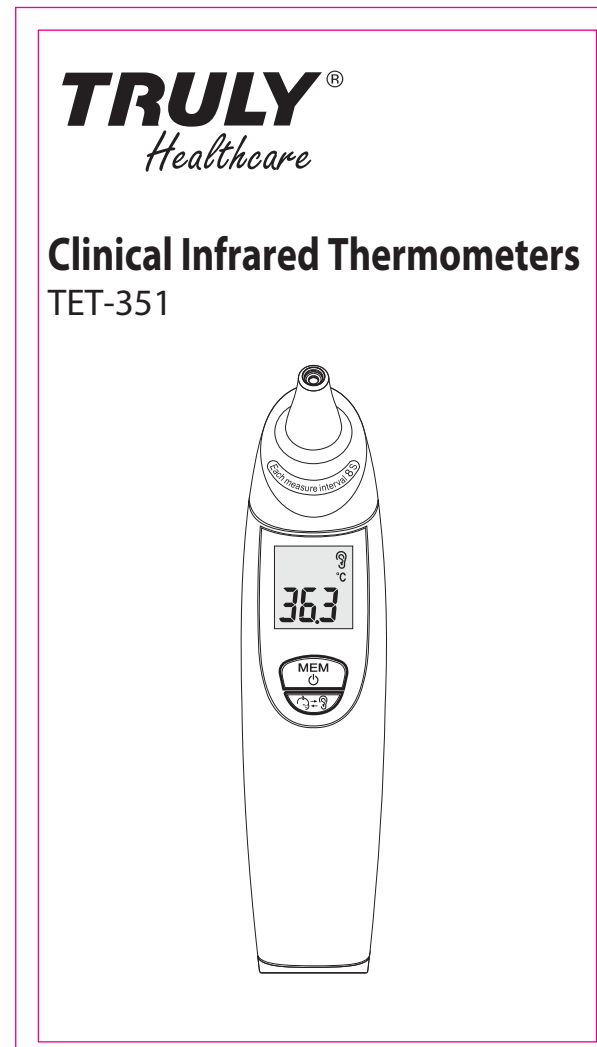


DHF  
标准品样稿  
SIZE: 80\*140MM 黑白印刷/整本



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**Statement**  
If replacing the original parts with parts not provided by the manufacturer may cause measurement errors. When the unit or accessories in the end of the service life, it should be handled in accordance with local regulations or returned to the manufacturer, and cannot be discarded at will.

**Intended use**  
The TRULY Infrared Thermometer TET-351 is an electronic clinical thermometer using an infrared sensor to detect human body temperature from the auditory canal and from the forehead in the neonatal, pediatric and adult population used in the home setting.

CE 0123	Authorized Representative in the European Community
IP22	*CE Mark conforms to essential requirements of the Medical Device Directive 93/42/EEC
SN	IP is short for Ingress Protection which means that Protection's level.
	Date of manufacture.
	Manufacturer
	Specifies serial number
	Type BF applied part
	Direct current
	The device should not be used after the end of the shown on the label
	DISPOSE: Do not dispose this product as unsorted municipal waste. Collection of such waste separates for special treatment is necessary.
	Caution
	Follow instructions for use
FCC ID:2AB67-TET-351	

Thank you for purchasing the electronic thermometer. Please read through this manual before using the product.

**Cautions**

- Please handle the unit with care. Do not drop or shock the unit.
- Do not expose the unit under the sunlight. Do not immerse the unit in water.
- Keep the device out of reach of infants, children or pets, since inhalation or swallowing of small parts (e.g. carpet feet, batteries) can be dangerous or even fatal.
- Avoid touching the lens with bare hands.
- Do not use in areas with strong electromagnetic interference.
- When the measurement data exceeds the normal temperature of the human body, please consult your doctor.
- If the unit is not working properly, please contact customer service.
- Do not disassemble the unit. Open the battery cover only when replacing batteries. Dispose of the replaced battery in accordance with local waste battery recycling requirements.
- If the unit needs to be scrapped after the expiration date, please dispose of it properly according to local regulations.
- Please contact manufacturer if the unit enter calibration mode.
- Use the thermometer at room temperature, or within 10-40°C.
- Do not store the unit long period of time under -25°C or above 70°C, or relative humidity above 90%.
- For other precautions, please follow "Cleaning and Care" in this manual.
- The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- The operator shall not touch battery compartment and the patient simultaneously.
- Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

**Warning:**

- When the body has a fever or the ambient temperature is low, the exposed forehead is affected by the low temperature of the environment. The human body will have a high body temperature and a low forehead temperature. If the digital thermometer tests the forehead with low value, please test the temples, ear roots or other parts of the human skin covered with clothing with higher temperature.
- The detector may not be directly point to the eardrum due to the small ear holes of children, the curved ear holes of adults, or affected by earwax and ear hair. If the digital thermometer tests the ear temperature with low value, please test the temples, or other parts of the human skin covered with clothing with higher temperature.
- The human body is a very complex biological integrated system. Affected by the environment and human body, the electronic thermometer may sometimes display abnormal body temperature (such as when body fever but forehead temperature or ear temperature show low value). Test the armpit temperature by mercury thermometer and consult a doctor in time.
- Please do not test children's ear temperature continuously. Insert the probe into child in the ear canal, can lead to infrared sensor temperature rise and cause each measurement data inconsistency. Wait a while after each measured test, which can guarantee the accuracy of temperature measurement.

**Correct use is the key to accuracy of measurement , otherwise it may cause measurement error. Since infrared measurement has higher requirements on the surrounding environment, please follow the instructions as below**

- When measuring ear temperature it's best to try to aim at the eardrum. It helps measure the temperature more accurately.
- When the person to be measured comes from a place with a large temperature deference from the measurement environment, it should stay in the test environment for at least 5 minutes, and then measure after the temperature is consistent with the environment, otherwise it will affect the measurement result.
- When the instrument is taken from a place with a large temperature deference from being measured and used, the instrument should be placed in the used environment for 20 minutes before use.
- The surrounding environment of the person to be tested must be stable, and it cannot be tested in places with large airflows such as fans and air outlets of air conditioners.
- Do not use the instrument in strong sunlight.
- When measuring, it is recommended to measure about 3 times each time, the most displayed set of data shall prevail.

**Special Features**

- Measurement Range: Body: 32~43°C.
- Accuracy ±0.2°C, (Outside 35~42°C measurement range, accuracy ±0.3°C).
- 1 second measurement time.
- LCD display.
- Red/orange and green backlight reminder
- Ear temperature and forehead temperature can store 30 latest measured values each.
- Automatic power off when thermometer is not in use after 1 minute.
- Unit of Measurement: °C/°F.

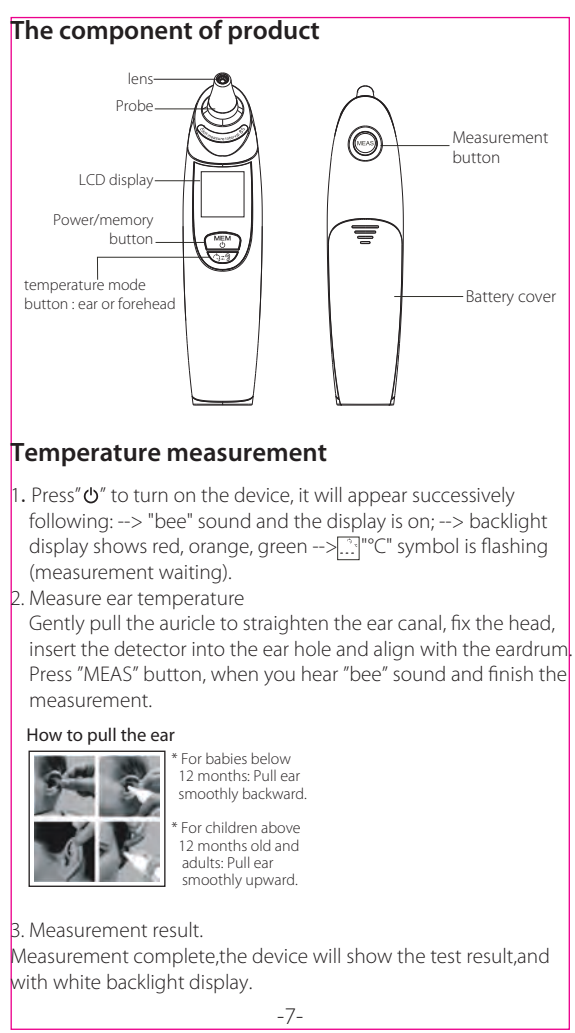
**Measurement Principle**  
All objects, solids, liquids and gases radiate infrared energy to the surrounding environment. The energy that the human body radiates to the outside world is basically based on infrared radiation. The electronic thermometer can accurately measure the body temperature by accurately measuring the weak infrared energy released by the human body, and then through complex calculation processing and various compensation corrections. The product is composed of a built-in infrared probe head and related hardware and software, can sense, analyze and record the temperature of the measured object and the environment.

The infrared radiation sensor is activated when the user places the thermometer near certain parts of the body and space presses the Power/Measure button. The thermal energy generated by the arterial blood flow is quickly detected by the infrared sensor, so that the body temperature is accurately measured.

**Product scope**  
For measurement of body temperature through eardrum and forehead.

Normal body temperature range according to World Health BODY TEMPERATURE:

Measurement site	Normal temperature
Ear temperature	35.8°C~38°C
Forehead temperature	34.7°C~37.8°C
Oral temperature	35.5°C~37.5°C
Armpit temperature	34.7°C~37.3°C
Anal temperature	36.6°C~38°C



Green: 35.8°C~37.3°C  
Orange: 37.4°C~38.0°C  
Red: 38.1°C~43°C, high temperature, please consult your doctor. No backlight: 32°C~35.7°C

**Interval Between Measurements**  
If you need to take another measurement, allow an interval of 8 seconds until the signal "C" / "F" flashes. If you press the measurement button within 8 seconds, the beep signal will be sounded. And there is no measurement result displayed.

**5. The temperature is automatically recorded.**  
\* Push Power/memory button until the "OFF" signal is displayed.  
\* the thermometer will turn off automatically without use for 1 minute.

**Forehead measurement**

- Turn on the thermometer.
- Press the button to select the forehead mode.
- Place the detector at the position of the eyebrow, press the measurement button, and the measurement is completed after hearing the sound "bee".
- While taking the temperature, the screen indicates and audible "bip" sound.
- Release the measurement button, wait for the validation sound, beep before removing the thermometer.
- Read the temperature on the screen.
- The temperature is automatically recorded.
- Interval time is same to the ear mode.

**Note:**  
When the ambient temperature is low, the skin temperature of the forehead is quite different, and the detector is not aligned with the eyebrow, which will cause the forehead temperature measurement to be low.

This temperature reading must be considered as an estimation. The temperature reading of the forehead can be influenced by environmental conditions because the probe is more sensitive to perspiration, sebaceous activity and environmental temperature.

It is recommended that you wipe the forehead before taking a reading. In case of important differences in any doubt, the ear measurement must be pointed out, we remind you that there is a significant difference between an ear temperature reading and a forehead temperature reading.

**When the Measurement Result is Abnormal**

- Possible causes for high temperature:  
\* After exercise, meal, or crying.  
\* Prolong is staying in high temperature environment.  
\* Thermometer is taken out from low temperature environment.  
Keep the thermometer in room temperature for at least 30 minutes before using.
- Possible causes for low temperature:  
\* The probe is dirty.  
\* Just exposed in cold temperature environment before taking measurement.  
\* Forehead: The probe is not facing forehead in straight.  
\* The thermometer is pulled out from the ear before measurement complete.  
\* The probe is not fitted snugly into the ear canal.  
\* The probe is not facing the ear drum or is not placed in a corrective position in the canal. See "Correct Measurement Method".  
\* Excess ear wax build-up.
- Temperatures measured from left and right ears are different:  
There could be slight difference in temperatures when taking from both ears. Therefore, always take the temperature from the same ear.

**°C / °F unit conversion formula**  
\*F=1.8x°C+32

**Unit (°C / F) Switch**  
When the product is in off state, press and hold "power/memory" Button for 10 seconds until the display shows "°C" or "°F" alternately.  
Release the button when the display is showing your desired unit.

**Correct Measurement Method**

- Ensure the probe is facing eardrum in straight line. Otherwise, the measured temperature will be lower than the actual body temperature.
- For accurate result, clean the probe with cotton bud before measuring.

**Memory function**  
This thermometer stores the last 30 temperature readings.  
\* When power on, press power/memory button to recall first reading.  
\* Repeat pressing power/memory button to recall the next reading.  
\* Delete memory:  
Press both power/memory and measurement buttons and hold for 3 seconds. The signal "Clr" displayed and the memory will be deleted.

**Replacing the Batteries**  
This thermometer is powered by 2 AAA batteries. When the power is low, the low battery signal is displayed. To replace batteries:  
1. Press and push the battery cover to open it.  
2. Remove the old batteries and replace with new ones.  
3. Make sure the batteries are in right polarity direction.  
4. Close the battery cover.

**Note:**  
To protect the environment, dispose of empty batteries at your retail store of at appropriate collection sites according to national or local regulations.

**Disposal**  
This product includes removable parts and accessories, and cannot be disposed with household waste. All users must return electrical and electronic equipment to a separate waste collection and collection center that specializes in electrical and electronic equipment for disposal in order to comply with 2002/96 / EC. Otherwise, you can recycle it for the retailer you purchased. Violations of this rule will result in severe penalties.

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

**Cleaning and Maintenance**  
When using the product, please follow the prompts when you find the following conditions:  
1. External dirt: Wipe the dirt with a clean soft cloth with water, or use a cotton swab with medical alcohol. Wiping with medical alcohol can also have sterilization purpose. Take care not to add too much water or alcohol to prevent damage to the inside of the instrument.  
2. Internal dirt: The black glass lens of the internal probe is an important device. Do not touch or press with your fingers or other objects, otherwise it will affect the accuracy of the measurement. When the glass lens surface is dirty, please wipe the lens surface with 95% anhydrous alcohol with a cotton swab.  
3. Storage: Keep in a dry, dark place out of direct sunlight.

**Note:**  
Do not wipe the lenses with 75% sterile alcohol (residual water marks). Do not use other chemical agents to wipe the lens (damage the lens).

**Display Message**

Display message	Situation	Solution
	Ambient temperature is out of operating range (10-40°C) or the environment temperature is not stable.	Allow the thermometer to remain in room temperature (10-40°C) for 30 minutes.
	Temperature measured is higher than normal human temperature (above 43°C)	Check the measured object and take a new measurement.
	Temperature measured is lower than normal human temperature (below 32°C)	Check the measured object and take a new measurement.
	Low battery	Replace batteries.

**Product specification**

Project	Content
<b>Measuring type</b>	Infrared Thermometer
<b>Measuring mode</b>	Ear/Forehead temperature
<b>Accuracy</b>	±0.2°C (Surrounding: 16°C~35°C)
<b>Measurement range</b>	32°C~43°C
<b>Indicator Functions</b>	LCD display
<b>Low voltage tip</b>	< 2.6V±0.1V
<b>Display resolution</b>	0.1°C
<b>Unit</b>	°C, °F
<b>Operation Environment</b>	Ambient temperature: 10°C~40°C; Relative humidity: 15% to 90%; Atmospheric pressure: 70kPa ~ 106kPa
<b>Storage temperature</b>	Ambient temperature: 25°C~70°C; Relative humidity: <90%; Atmospheric pressure: 70kPa ~ 106kPa
<b>Automatic shutdown</b>	1 minute after not being used
<b>Memory</b>	30 groups memory
<b>Battery</b>	2 x AAA
<b>Used Life Span of Battery</b>	1000 times
<b>Service life</b>	5 Year
<b>Software version</b>	AD1
<b>Contents of the packaging</b>	batteries, manual
<b>Size</b>	152x52x36 mm
<b>Weight</b>	About 66g (Not including batteries)

**Note:** Subject to modification without prior notice.

**Normative references**

- TET-351 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
- Portable and mobile RF communications equipment can affect TET-351.

Guidance and manufacturer's declaration - electromagnetic emissions			
Emissions test	Class	Requirement	Compliance
EM emissions (EN 55011)	Class B	EN 55011	Not applicable
EM emissions (EN 55012)	Class B	EN 55012	Not applicable
Voltage Fluctuation/Flicker emissions (IEC 61000-3-2)	Not applicable	IEC 61000-3-2	Not applicable
Harmonics emissions (IEC 61000-3-3)	Not applicable	IEC 61000-3-3	Not applicable

Normative references (Continued)			
Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity Test	IEC 60825-1-2 Test level	Requirement	Compliance
Electrostatic discharge (ESD) (IEC 10000-4-2)	±8 kV contact, ±12 kV air discharge	IEC 10000-4-2	Not applicable
Electromagnetic field (EMF) (IEC 10000-4-3)	10 V/m	IEC 10000-4-3	Not applicable
Power Frequency magnetic field (IEC 10000-4-8)	30 A/m	IEC 10000-4-8	Not applicable
Conducted RF (IEC 10000-4-6)	Not applicable	IEC 10000-4-6	Not applicable
Radiated RF (IEC 10000-4-3)	30 MHz ~ 27 GHz	IEC 10000-4-3	Not applicable

**NOTE:** U is the a.c. mains voltage prior to application of the test level.

**Normative references (Continued)**

Guidance and manufacturer's declaration - electromagnetic immunity						
IEC 10000-4-3 Test level	Frequency (MHz)	Field Strength (V/m)	Service	Modulation (dB)	Distance (m)	Minimum TEST LEVEL (V/m)
100	300	100	Pulse	0	3.0	0.3
400	400	100	Pulse	0	2	0.5
1000	1000	100	Pulse	0	1.5	0.5
1500	1500	100	Pulse	0	1.2	0.5
1800	1800	100	Pulse	0	1.0	0.5
2000	2000	100	Pulse	0	0.8	0.5
2500	2500	100	Pulse	0	0.6	0.5
3000	3000	100	Pulse	0	0.5	0.5
3500	3500	100	Pulse	0	0.4	0.5
4000	4000	100	Pulse	0	0.3	0.5
4500	4500	100	Pulse	0	0.2	0.5

**1 Main safety features of infrared electronic thermometer**

- Type of anti-shock: Internal power supply
- Type of anti-shock: BF type application
- Degree of protection against ingress: Not applicable
- Degree of safety when used under flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non AP/AG type.
- Operating mode: Continue to operate
- Rated voltage: d.c. 3V
- Input power: Not applicable
- The thermometer has no application part with protection against defibrillation discharge effects
- The thermometer has no signal output section or input section
- The thermometer is a portable device.

**2 The Temperature sensor is treated as the applied part.**

**Connect device via Bluetooth**

**1. Installation**  
Prior to first use, Download and install "TRULY Healthcare" application on your device. (Bluetooth 4.0 capabilities, iOS 11.0 or Android 7.0.)  
**download link**  
iOS: <https://www.pgryer.com/1gi>  
Android: <https://www.pgryer.com/sp3j>  
Login account: Mobile account  
Install password: 123456

- Open "TRULY Healthcare" application Pressure icon on Measurement screen.

- Turn on Bluetooth "Allow".
- Click "Thermometer".
- Press the "Start" button.
- When the measurement is complete, the temperature will display on Thermometer monitor & press "Save" Measurement data.
- All the measurement data will be saved in the app.

**FCC Statement**  
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

This equipment should be installed and operated with a minimum distance of 0mm between the radiator and your body.

**TRULY Healthcare**

**CONTACT INFORMATION**  
TET-351 is manufactured by:  
Truly Instrument Ltd.  
Address: 2/F, Chung Shun Knitting Centre, 1-3 Wing Yip St, Kwai Chung, NT, HONG KONG  
TEL: (852) 24879883  
FAX: (852) 21465756

Facility:  
Truly Instrument Ltd.  
Truly Industrial Area, Shan Wei City, 516600, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

**Authorized European Representative:**  
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