



Fore Health

**Fore Health Smart Ear Thermometer
Instructions booklet**

ACT8000-TG

ACT8000-TB



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Introduction

Thank you for purchasing Fore Health Smart Ear Thermometer ACT8000 series. This product features special structure for the probe and has been calibrated by strict procedure. This product conforms to all requirements of EN ISO 80601-2-56 and ASTM E1965-98. It is simple for use. Just 1 second, the user can get the rapid and accurate ear temperature.

Intended Use

Smart Ear Thermometer ACT8000 series are used to measure body temperature from ear canal. This product is intended for household and hospital use on people of all age.

Safety Precautions

Be sure to read the following instructions before using the thermometer.



Warning:

Indicates a potentially hazardous situation which it may result in death or serious injury.

- Keep the thermometer out of the reach of children and pets to avoid inhalation or swallowing of small parts.
- Do not left children unattended to take their own temperatures. Children could hurt themselves when using the thermometer.
- Do not use or store the thermometer near highly flammable substances, liquid, or gases. It could cause an explosion.

**Caution:**

Indicates a potentially hazardous situation which it may result in injury or property damage. The property damage refers to consequential damage to buildings, household, belongings, livestock, and pets.

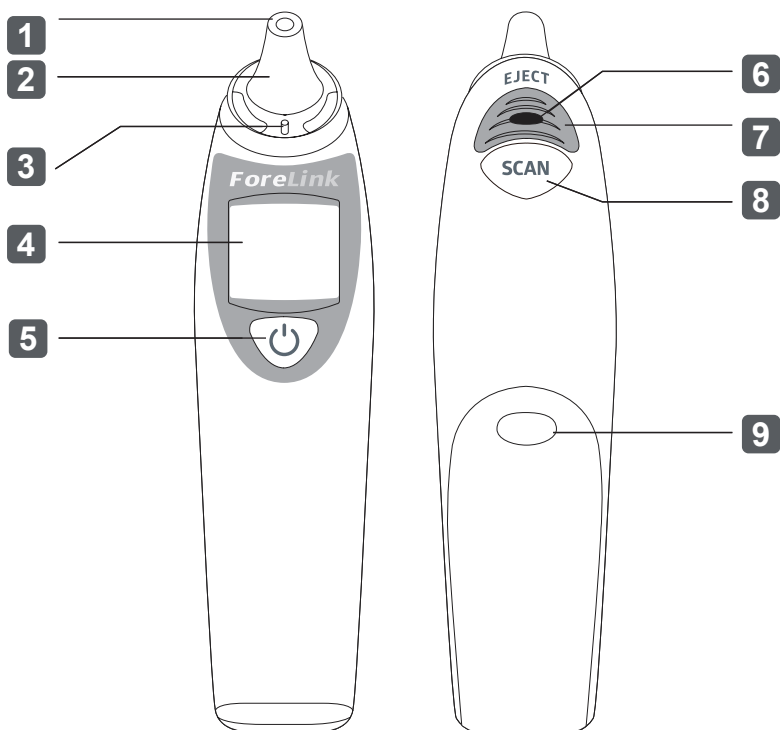
- Do not use measurement results for self-diagnosis and self-treatment. Use of this thermometer is not intended to substitute professional consultation by your physician, always consult your physician.
- Do not touch and blow the Ear Probe.
- Do not disassemble, drop, twist, shake, or bend the thermometer. Do not change any parts of the unit except for replacing the battery.
- Do not use thermometer near a portable and mobile HF (high-frequency) communication equipment (e.g. mobile phones). This could cause malfunction.
- Do not operate the thermometer under extreme temperatures or extreme humidity. Doing so may cause inaccurate measurement.
- Both the thermometer and the person whose body temperature is measured should be in the same environment for at least 30 min.
- Please wait for at least 1 min between two measurements. A temperature measurement taken in a row may affect the latter one result.
- Do not use the thermometer on mountains higher than 3,000 metres.
- Do not use the thermometer when the ears are wet (e.g. after showering, swimming, or bathing). It may not be possible to obtain an accurate body temperature within 30 min after taking a bath or exercise.
- The manufacturer shall not be liable for any damage resulting from usage not specified in this instruction. Do not perform any repairs, modifications, adjustments, etc. without the authorized service center's approval.

Package Components

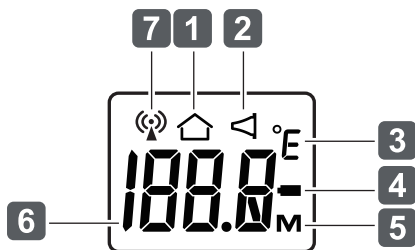
- 1 x Thermometer
- 1 x Instruction manual
- 2 x 1.5V AAA Battery
- 20 x Probe Cover

Identification Parts

- | | |
|-----------------------------------|-------------------------------------|
| 1 Probe Lens | 6 Measuring Indicator |
| 2 Probe Head(applied part) | 7 Probe Cover Ejector Button |
| 3 Probe Cover Sensor | 8 SCAN Button |
| 4 LCD Window | 9 Battery Cover |
| 5 On/Off Button | |

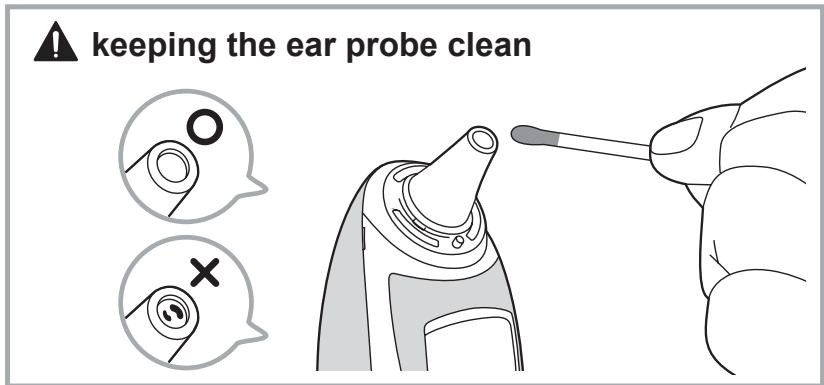


LCD Display



- 1** Ambient temperature indicator
- 2** No probe cover indicator
- 3** °C & °F display
- 4** Battery indicator
- 5** Memory mode
- 6** Temperature display
- 7** Data Transmission Indicator

Cleaning and Care



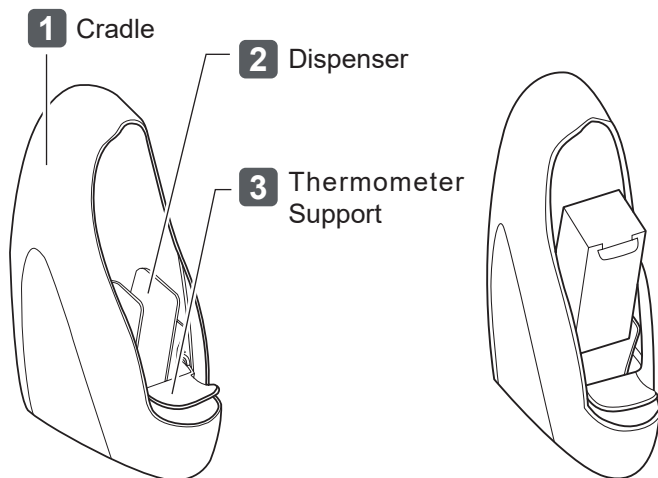
In order to achieve precise measurements, particularly protect the ear probe of the thermometer against moisture, dirt and damage. If you think you have contaminated the ear probe, please clean it.

Please clean the probe head, probe-head protector, LCD window, thermometer body, dispenser, and base with dry soft cloth or soft cloth slightly moistened with 70% alcohol.

- Do not clean the thermometer with corrosive liquid.
- Do not put the thermometer into water or other liquid. It is not waterproof.
- Please do not touch or wipe the ear probe of the thermometer with your bare hands.
- Keep the ear probe clean, intact, and neat to make sure the measurement is accurate.
- If the thermometer is used accidentally without probe cover, please hold the thermometer with the probe head facing down to avoid liquid entering the probe head.

How to use the Cradle (For Dispenser Model)

Install the earmuff box



Insert the probe cover box upon the dispenser with its open side out. Do probe-cover box, the button of probe-cover box will automatically open while you insert the probe-cover box into the dispenser.

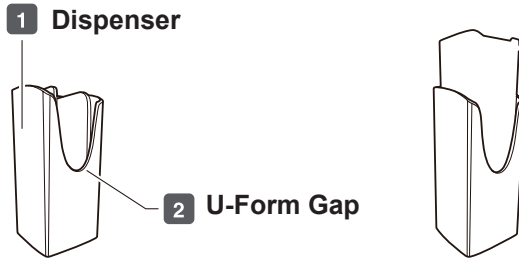
Because the special design of dispenser, the probe-cover box goes down automatically while a probe cover is picked up. The next probe cover goes up near the opening and is ready for use.

Pick up/ Put back ear thermometer

Push the ear thermometer down, take out the probe head of ear thermometer from the cradle, then pick up the ear thermometer. The probe cover box springs out at the same time and is ready to offer probe covers.

By putting back the ear thermometer, put it on the support and press it down, push the probe head into the cradle, release your hand from the ear thermometer and it fix in the cradle automatically.

How to use The Dispenser (For Dispenser Model)



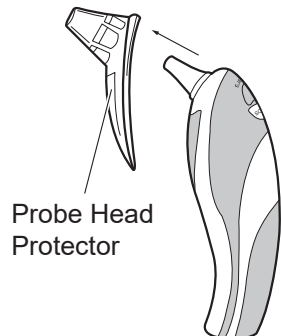
The 20-count probe cover fits into the fixed To install probe cover box in the dispenser, firmly insert probe cover box into the probe cover dispenser. The opening on the top of probe cover box and the U-form gap of probe cover dispenser must be in the same direction as shown Do not open the button of probe cover box. With the special design of probe cover box, the button of probe cover box will automatically open while you insert the probe cover box into the dispenser.

Because the special design of dispenser, the probe cover box goes down automatically while a probe cover is picked up The next probe cover goes up near the opening and is ready for use.

Probe Head Protector (For Dispenser Model)

Probe head protector is for protecting probe head from collision or abrasion Please cover probe head with probe head protector when the ear thermometer is not in use.

Same as for releasing probe cover, please press probe cover ejector button for taking off the probe head protector.



Install and Eject Probe Cover

Installing the Probe Cover

1. Open the probe cover packaging and take out a new probe cover. Attach it to the probe head.
2. Gently insert the thermometer probe cover into the top cover and press down (see Fig. 1).
3. You'll hear an audible "click" when the probe cover is securely in place.
4. Your thermometer is now ready to use.

Note1:

If there are not enough probe covers to easily attach to the thermometer, manually tear open the packaging along the perforated line (see Fig. 2) to expose more probe covers. Then, proceed to attach the probe cover as instructed.

Note2:

The ACT8000 includes a probe cover sensor (see Fig. 3) that requires a probe cover for operation. If a probe cover is missing or not correctly applied, a flashing no probe cover indicator will appear on the display.

Removing the Used Probe Cover

After taking a measurement, press the EJECT button to release the probe cover (see Fig. 4). Before each measurement, please ensure to use a new and clean probe cover.

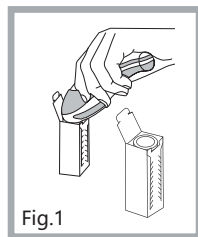


Fig.1

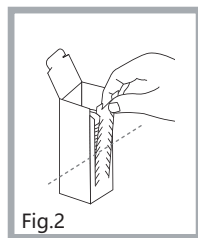


Fig.2

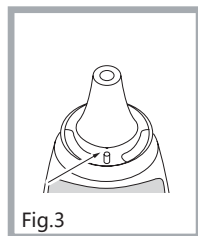


Fig.3

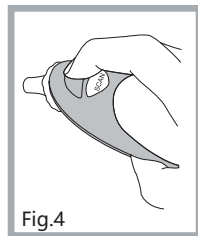


Fig.4

Setting Up Your Thermometer and Smartphone

1. Please download the APP "Fore Health" (See Fig 1.) before using device, and then turn on the Bluetooth of your phone/device.



Fig.1

2. Launch the "Fore Health" application on your device. Click "Device Management" on homepage and then select "No Paired Device" to add the specified product model.

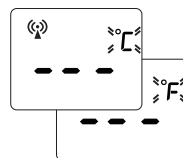


Fig.2

3. Turn on the ear thermometer, which will connect to the device to set up.

*** Must check "No Paired Device" to set the specified thermometer as the default model.**

4. Click "Quick add" on the App to add your body temperature, and the LCD will display "Data Transmission Indicator" (See Fig 2.). Press "SCAN" for measuring (See Fig 3.) and the measured temperature will be shown on the App automatically.



Fig.3

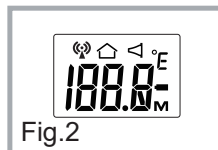
5. Click "Finish" to save the data.

Ear Measurement

1. Apply a probe cover to the thermometer. The thermometer will not work without a probe cover (See Fig. 1).



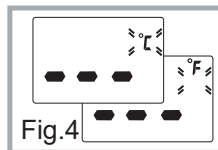
2. Press and release the ON/OFF button.
The thermometer will beep and perform a brief self-test, during which all indicators on the LCD Window will be shown (See Fig. 2), followed by "OK" (See Fig. 3).



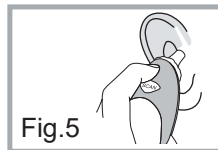
3. The thermometer display will show three short dashes with a flashing °C or °F, indicating that the thermometer is ready for measurement (See Fig. 4).



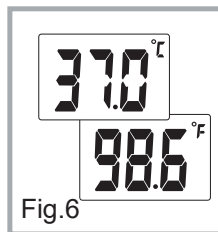
4. Gently insert the probe head into the ear canal, press SCAN button, and then keep the probe head in the place. (See Fig. 5). When the thermometer completes the measurement, the measured temperature will display on the LCD window with one long beep (approx. 1 sec).



5. At the same time, the measuring indicator also lights for approximately 1 sec.



6. The temperature reading will be shown on the LCD window (See Fig. 6).



7. When the measurement is finished with a beep, the backlight turns on for 6 sec.
8. The thermometer is automatically turned off after 1 min of inaction.

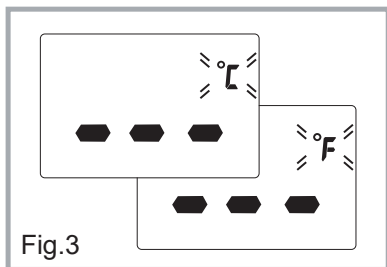
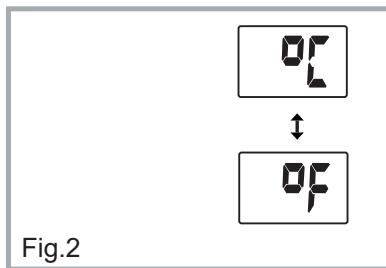
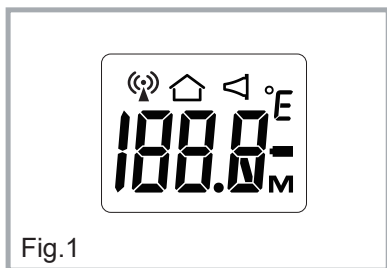


Caution of Ear Measurement

- The thermometer is used only with Fore Health Probe Cover (Model IR20). The thermometer will not work without a probe cover. Make sure to check the probe cover before using it. If there is any damage on the probe cover, please replace a new one. The use of other probe covers or damaged probe covers may cause inaccurate readings.
- The temperature taken in right ear might be different from the temperature taken in left ear. It is recommended that the ear's temperatures should be taken in the same ear and make sure the sensor faces eardrum every time, otherwise it may vary in the measurement results.
- Do not use the thermometer on people suffering from inflammatory diseases, ear injuries (e.g. eardrum injury), or during the healing phase after a surgical procedure. It could cause the infection to other people and an aggravation of the patient's symptoms.
- Clean the probe head and ear probe with dry soft cloth or soft cloth slightly moistened with 70% alcohol. After cleaning, allow at least 20 min of drying time before taking temperatures.
- Do not use the thermometer if the probe head or other parts have been damaged. The continuous use of a damaged thermometer may cause injury, inaccurate results, or serious danger.
- The probe cover is for single use only. Please use a new probe cover for each measurement. The reuse of probe covers may result in inaccurate measurements or cross-infection caused by contaminated probe covers.

Switch Between °C & °F

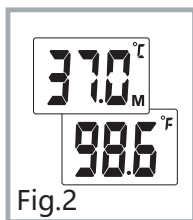
- The Thermometer can display results in either degrees Celsius (°C) or degrees Fahrenheit (°F).
- When the thermometer shuts off, press the On/Off button 2 times (one right after another) (See Fig. 1) to switch between Celsius (°C) and Fahrenheit (°F). For the 2nd press, please press and hold before the full display disappears on the LCD window(See Fig. 2). Then release the On/Off button(See Fig. 3).
- After the symbol °C or °F appears, the thermometer returns to measuring mode.



Recall the 10 Stored Measurements

The thermometer can store the 10 latest measurement results.

- When the thermometer shuts off, press and hold down the On/Off button approximately 2 sec.
- A flashing “01” will appear with a small M at the lower right of the display (See Fig. 1).
- Then the memory is shown on the display for about 2 sec, (See Fig. 2). Before its disappearance, press the On/Off button one time within 2 sec for the next memory, and do so one after one to display the rest of stored measurements. Otherwise, the thermometer returns to measuring mode.



Backlight-Helper In the Dark

Only when the ear thermometer shuts off, press the On/Off button while battery cover close well, and after measuring body temperature from ear canal, a backlight will appear.

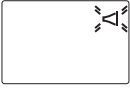
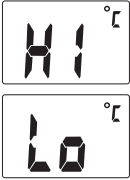
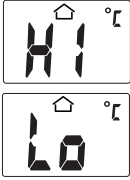
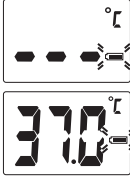


Storage Methods

- Please avoid mechanical shock, otherwise the thermometer will be damaged.
- Store the thermometer and batteries in a location inaccessible to children and pets.
- Do not store the thermometer at extremely high or low ambient temperatures or in extremely dry or damp environments, since this could result in inaccurate measurement results.
- Please store the thermometer in a dry and clean place. Do not leave the thermometer exposed to any chemical solvent, lint, dust, direct sunshine, or high temperatures.
- Do not store the thermometer in a location near open fire or locations that are exposed to vibration or impact (this includes during transportation).
- Keep the thermometer away from any liquids while in use, and above all, never immerse it in liquids.

Normal Body Temperature Reference

Measuring Site	Temperature range in celsius	Temperature range in Fahrenheit
armpit :	35.0 °C ~ 37.0 °C	95.0 °F ~ 98.6 °F
forehead :	35.0 °C ~ 37.0 °C	95.0 °F ~ 98.6 °F
mouth :	35.5 °C ~ 37.4 °C	95.9 °F ~ 99.3 °F
rectum :	36.2 °C ~ 37.9 °C	97.2 °F ~ 100.2 °F
ear :	35.7 °C ~ 37.9 °C	96.3 °F ~ 100.2 °F

Troubleshooting

Error Message	Situation	troubleshooting
	No probe cover is detected.	Please install a new and clean probe cover.
	The measured temperature is not within the measuring range. HI=Measured temperature is too high. Lo=Measured temperature is too low.	Please make sure the probe head is installed with a new and clean probe cover. Insert it into the ear canal gently and re-take temperature.
	The ambient temperature is not within the operating range. HI=Ambient temperature is too high. Lo=Ambient temperature is too low.	Please put the thermometer in a room of proper temperature (refer to Specifications) for approximately 30 min, and then re-operate it.
	The battery is running low, but the thermometer can work as normal.	Please replace the batteries as soon as possible.
	The battery is running out. The thermometer cannot function properly.	Please replace the batteries immediately.
	System error.	After the thermometer shuts off, please restart it. The thermometer is automatically turned off after 1 min of inaction.

RE : The temperature unit is °C and °F switchable. The temperature of °C shown in the figures above is cited as example only.

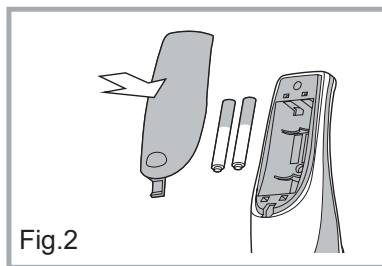
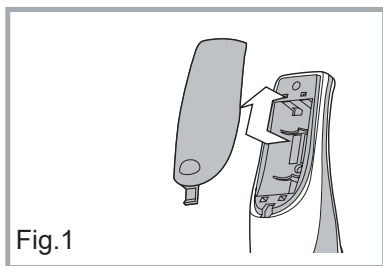
Calibration

- The thermometer has been calibrated at the time of manufacture. Any improper care or use of your thermometer may result in inaccurate readings. Please follow all the instructions to obtain the accurate body temperature.
- It is recommended to have the thermometer inspected every year by the application laboratory and authorized service center to ensure the function and accuracy are correct. If at any time you question the accuracy of the measurement, please contact the retailer immediately.

Replace/ Install the Battery

1. Loosen the screw to open the battery cover by pressing the battery cover upwards (See Fig. 1).
2. Remove the old batteries. Please ensure to match the indicated polarity before inserting two AAA batteries into the battery compartment. Then replace the battery cover (See Fig. 2).
3. The thermometer can take about 3000 measurements with completed new batteries.

Note: After replacing the batteries, then using a screw to ensure that the battery cover is securely closed. The data transmission function requires the battery cover to be properly closed for normal operation.



Dispose Battery

- If your thermometer will not be used on a regular basis, remove batteries to prevent possible damage due to chemical leakage.
- If the battery does leak, remove it carefully. Do not allow bare skin to touch the leaking fluid.
- Be sure to dispose of the used batteries as soon as possible.
- Never throw the thermometer and its batteries into fire. The battery is likely to explode in fire.
- Keep the battery out of reach of children as they could choke on it if they mistakenly swallow it.
- Should a child swallow the battery, there are risks of chemical burns, penetration of the mucous membrane, and other complications that could lead to death. It is therefore important to seek immediate medical attention to remove the battery.
- Never mix old and new batteries or use batteries made by different manufacturers. Immediately remove exhausted batteries if doing so.
- Be sure that the + and - poles of batteries are oriented correctly.
- Please follow your government's environment policy to recycle the thermometer, accessories, and batteries.

Specifications

Measuring Range	26.0°C ~ 43.9°C / 78.0°F ~ 111.9°F
Accuracy	±0.2°C(±0.4°F) within 34.0°C ~ 43.9°C (93.0°F ~ 111.9°F) ±0.3°C(±0.5°F) outside the conditions above
Operating Ambience	Ambient temperature: 10° C ~ 40° C or 50° F ~ 104° F Relative humidity: 15% ~ 90% Atmospheric pressure : 700 ~ 1060hPa
Transport and Storage Ambience	Ambient temperature: -25°C ~ 70°C or -13°F ~ 158°F Relative humidity: 15% ~ 90% Atmospheric pressure : 700 ~ 1060hPa
Display resolution	0.1 °C or °F
Ingress Protection Storage	IP22
Stored Temperature Memories	10 memories
Battery	1.5V type AAA alkaline battery (LR03)*2 (battery life is over 3000 measurements)
Weight	ca.100g
Life Time	3 years
Dimensions	15.5cm x 5.5cm x 3.5cm
Operating Mode	Adjusted Mode

Standards

ISO 80601-2-56:2017/Amd 1:2018 - Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement — Amendment 1

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

IEC 60601-1-2:2014/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances - Requirements and tests.

IEC 60601-1-11:2015/AMD1:2020 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.

EN ISO 14971:2019 +A11:2021 Medical devices. Application of risk management to medical devices.

This product conforms to the provisions of the EC directive 93/42/EEC.

Icon Identification



European Union's Waste Electrical and Electric Equipment in accordance with Article 11 (2) of Directive 2002/96/EC WEEE). To protect the environment, used batteries must be accumulated at the definite places according to your national or local regulations.



Type BF equipment. The insulation is required between the (patient circuit) and all other parts of the equipment, which are earthed regulations.



The product meets the legal requirements of the European Union.

IP22

This product complies with international electrical safety rating IP22 with regard to ingress of dust, other foreign objects, and water as required by IEC 60601-1-11.



Atmospheric pressure limitation.



Follow instructions for use.



Humidity limitation.



Temperature limitation.



Medical device.



Batch code.



REF ACT8000-TG

REF ACT8000-TB



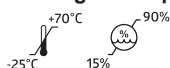
MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany



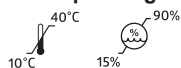
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523858 Dongguan City, Guangdong Province,
PEOPLE'S REPUBLIC OF CHINA



Storage/Transport



Operating



IP22