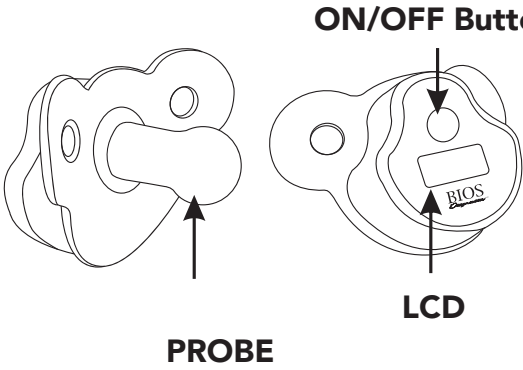


Thank you for purchasing the BIOS Diagnostics™ Pacifier Thermometer. To correctly utilize all the advantages of this product, please familiarize yourself with these operating instructions before using the thermometer for the first time. Keep the instructions in a safe place for future reference.



INDICATIONS FOR USE:

This digital thermometer (455DI) is intended to measure the human body’s temperature in regular mode, orally. This device was designed to be reusable for clinical or home use, on people of all ages, including children under the age of 8 as long as there is adult supervision.

SAFETY INFORMATION:

- High, prolonged fever requires medical attention, especially for young children. Please contact your physician should this occur.
- The battery cover is permanently connected to the main housing of the thermometer; the battery is securely sealed inside the thermometer to reduce the risk of being swallowed by children.
- **Choking Hazard:** Thermometer cap and battery (if broken open) may be fatal if swallowed. **Do not** allow children to use this device without parental/adult supervision.
- The thermometer is designed for oral use only.
- **Do not** place thermometer battery near extreme heat as it may explode.
- The use of temperature readings for self-diagnosis is dangerous. Always consult your doctor or a healthcare professional for malady diagnoses.
- **Do not** bite the thermometer. Doing so may lead to breakage and/or injury.
- **Do not** attempt to disassemble or repair the thermometer. This will void the warranty, and may result in inaccurate readings, or harm.
- After each use, disinfect the thermometer especially if the device is used by more than one person.
- If the unit has been stored at temperatures over 40°C (104°F), ensure it is left in an environment between 5°C-40°C (41°F-104°F) for approximately 15 minutes before use.
- Use of this equipment adjacent to or stacked with other equipment should be avoided, as it can result in improper operation. If such use is necessary, this and the other equipment should be closely observed to verify that they are operating normally.
- This device is not intended for use in an oxygen rich environment or in the presence of flammable anesthetic mixtures of air, oxygen, or nitrous oxide.
- **Do not** store in direct sunlight or in areas of extreme heat.

°C/°F SWITCHABLE:

Temperature readings are available in Celsius or Fahrenheit (°C/°F; located in the upper right corner of display field).

To confirm the measurement temperature display, turn the device on by pressing the **ON/OFF** button. After a short system check, ‘Lo’ and either °C or °F will be displayed. This is the set temperature display.

To change between °C and °F, with the device off, press and hold the **ON/OFF** button for approximately 3 seconds until you see the temperature symbol change. The device is now ready to take a reading.

HOW TO TAKE A TEMPERATURE:

1. Ensure the thermometer has been cleaned following the directions in section **CLEANING AND DISINFECTING** before use.
2. Press the **ON/OFF** button on the front of the Pacifier Thermometer. A tone will sound, and the screen will show **LO** while it does a short system check.
3. After the system check, the thermometer will display the last recorded temperature. Immediately after, ‘Lo’ with a flashing °C or °F will be displayed, indicating that the thermometer is ready to take a temperature.
4. Place the probe (pacifier nipple) into the child/user’s mouth.
5. The degree symbol will flash throughout the testing process. When the flashing stops and the alarm sounds for approximately 10 seconds, the measured reading will be shown on the LCD.
NOTE: Minimum measurement time has been reached when the degree symbol flashing stops, the alarm sounds, and the temperature is displayed on the LCD. Temperature measurement continues after this. It is recommended that the pacifier thermometer remain in the child/user’s mouth for at least 2 minutes to achieve a more accurate temperature reading.
NOTE: If a fever is detected during a measurement (temperature over 37.8°C), the alarm function will change to a higher and more rapid patterned alarm sound.
6. To prolong the product’s battery life, press the **ON/OFF** button after testing is complete to turn the device off. If no action is taken, the unit will automatically turn off after approximately 10 minutes.

WHAT IS “NORMAL” BODY TEMPERATURE?:

“Normal” body temperature varies from person to person and changes according to time of day and body location. The following table shows the temperature ranges:

	Fever Temperature	Temperature Ranges
Rectal*	Over 38°C/100.4°F	36.6°C-38°C/97.8°F-100.4°F
Oral (Mouth)*	Over 37.5°C/99.5°F	35.5°C-37.5°C/95.9°F-99.5°F
Axillary (Underarm)*	Over 37.2°C/99°F	36.5°C-37.2°C/97.7°F-99°F

*Fever definitions according to the Canadian Paediatric Society
IMPORTANT: It is recommended to measure the body temperature when healthy to establish the specific “normal” temperature.

MEMORY RECALL:

This thermometer has a memory that recalls the last temperature taken. To obtain this information, with the thermometer off, press the **ON/OFF** button. After a short system check, the screen displays the last measurement, which will be deleted after the next temperature is taken.

CLEANING AND DISINFECTING:

- For Cleaning:**
1. Immerse the thermometer probe in distilled water for at least 1 minute;
 2. Using a clean, soft cloth, wipe the thermometer down to remove any residue;
 3. Repeat steps 1 and 2 three times through until no soil is seen with visual inspection after cleaning.
- For Disinfection:**
- Method A (High Level Disinfection):
1. Immerse the thermometer probe in 0.55% OPA (O-Phthalaldehyde), such as CIDEX OPA, at a temperature of 20°C for at least 12 minutes.
 2. Follow steps 1-3 under **For Cleaning** to remove disinfectant chemicals.
- Method B (Low Level Disinfection):
1. Using a clean soft cloth dipped in 70% medical alcohol (Ethanol or Isopropyl), thoroughly wipe the thermometer probe 3 times (1 minute per wipe, 3 minutes total).
 2. Follow steps 1-3 under **For Cleaning** to remove disinfectant chemicals.

To prevent damage to the thermometer please note and observe the following:

- **Do not** use benzene, paint thinner, gasoline or other strong solvents to clean the thermometer.
- **Do not** attempt to disinfect the sensing probe (tip) of the thermometer by immersing in alcohol, OPA, or in hot water (above 122°F (50°C)) for a long time.
- **Do not** use ultrasonic washing to clean the thermometer.

TROUBLESHOOTING:

Error Message	Possible Problem	Solution
Lo	1. When the thermometer is first turned on and ready to take a temperature ‘Lo’ will be displayed on the LCD. 2. Temperature taken is lower than 32.0°C (90.0°F).	1. This is normal. Proceed with temperature reading. 2. Turn thermometer off, wait one minute, then attempt to take a new reading.
Hi	Temperature taken is higher than 42.9°C (109.9°F).	Turn thermometer off, wait one minute, then attempt to take a new reading.
Err	The system is not functioning properly.	Turn thermometer off, wait one minute. Upon turning the thermometer back on if Err message reappears, contact Thermor Ltd. Customer Service.
	Battery is dead: icon is flashing, temperature reading cannot be taken.	Product is at the end of its service life. Please replace if it is outside of the warranty window.

SPECIFICATIONS:

Thermometer Type:	Digital Thermometer (Not Predictive)
Temperature Measurement Range:	32.0°C-42.9°C (90.0°F-109.9°F)
Accuracy:	±0.1°C (±0.2°F) for measurements between 35.5°C-42.0°C (95.9°F-107.6°F) at 18°C-28°C (64.4°F-82.4°F) ambient operating range ±0.2°C (±0.4°F) for all other measuring and ambient operating ranges
Display:	LCD (liquid crystal display)
Power Source (non-replaceable):	1x 1.5 V DC. button battery (size LR41or SR41, UCC 392)
Expected Battery/Service Life:	Approx. 200 hours (3 years at average usage rate) (1 year at usage rate of 3 measurements per day)
Dimensions:	5.8 cm x 4.1 cm x 4.3 cm (L x W x H)
Weight:	Approx. 13 g (including battery)
Operating Environment:	Temperature: 5°C-40°C (41°F-104°F) Relative humidity: 15%-95%RH Atmospheric Pressure : 700hPa-1060hPa
Storage and Transportation Environment:	Temperature: -20°C-55°C (-4°F-131°F) Relative humidity: 15%-95%RH Atmospheric Pressure : 700hPa-1060hPa

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Follow instructions for use. This document provides important product operation and safety information. Please read this document thoroughly before using the device and keep for future reference.
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Type BF applied part.
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Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

IP22: Protected against solid foreign objects of 12.5 mm diameter and greater. Protected against vertically falling water drops when the device is tilted up to 15°.

This appliance conforms to the following standards:
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,
EN 60601-1-11 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 and complies with the requirements of EN 60601-1-2(EMC), IEC/EN60601-1(Safety) standards.
The manufacturer is ISO 13485 certified.

CALIBRATION:

The thermometer is initially calibrated at the time of manufacture. If the thermometer is used according to the use instruction, periodic readjustment is not required.

TEST PROTOCOL (LABORATORY USE ONLY):

1. Set the temperature of a high-precision water bath to 33.00°C.
2. Turn the thermometer on, and insert probe into the bath. Check the laboratory accuracy of the thermometer.
3. Ensuring temperature remains stable for 10 minutes, repeat steps above for 37.00°C and 42.00°C.

1 YEAR LIMITED WARRANTY:

This thermometer has a one year limited warranty to be free of manufacturing defects under normal use by the original owner. The warranty does not cover damage from misuse or tampering. This warranty does not cover batteries or other power sources that may be provided with, or used with the thermometer.

100% Satisfaction Guarantee

If at any time, you are not completely satisfied with the performance of this device, call our BIOS Medical Hotline and speak with a customer service representative, who will make arrangements to have the device tested or replaced to your full satisfaction.

If you have questions regarding the operation of your thermometer call the **BIOS Medical Hotline: 1-866-536-2289, or email support@biosmedical.com**
Should correction be necessary, return the unit with all component pieces. Enclose proof of purchase and \$5.00 for return shipping and insurance. Ship the unit prepaid and insured (at owners option) to:

Thermor Ltd.
Returns Department
16975 Leslie Street
Newmarket, ON L3Y 9A1
www.biosmedical.com

Please include your name, return address, phone number, and email address. Thermor Ltd. will test or replace (at Thermor Ltd.’s option) free of charge any parts necessary to correct the defect in material or workmanship.

Please allow 10 days for return shipping.



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