

How to Use the

Tempa•DOT™ Single-Use Clinical Thermometer

ORAL USE

1. Open Package

Fold along perforation and tear off a single Tempa•DOT Thermometer strip. Peel back top of wrapper to expose handle of thermometer. Remove thermometer by pulling exposed handle.

2. Insert Thermometer

Place thermometer into patient's mouth under tongue, as far back as possible into either heat pocket, as you would any oral thermometer (see diagram). Generally, adult lips should touch the middle of the Tempa•DOT logo. The dots can face either up or down. Have patient press tongue down on thermometer while keeping mouth closed.

3. Wait 60 Seconds, but less than 2 minutes

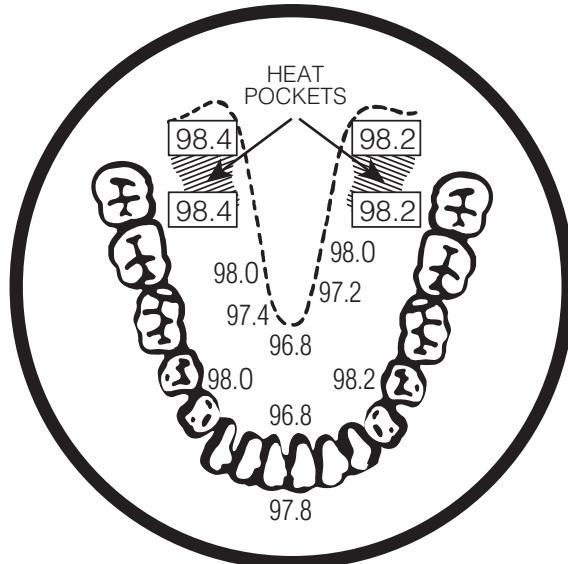
4. Remove Thermometer

Before reading, wait approximately 10 seconds for dots to lock in.

5. Read Temperature

The last blue dot on the matrix indicates the correct temperature.

6. Discard Thermometer



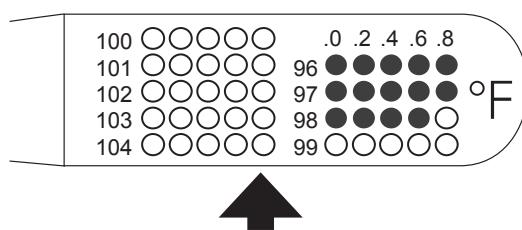
Reminder

Before taking oral temperatures, wait at least 15 MINUTES:

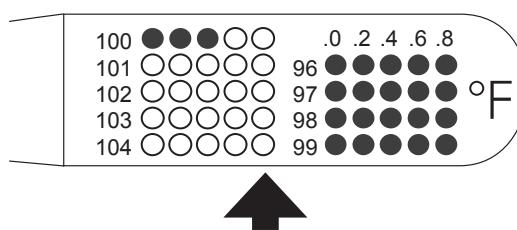
- After ingesting hot or cold food or drink
- After exposure to extremely hot or cold weather.
- After smoking

HOW TO READ

The last blue dot indicates the correct temperature



This example reads 98.6° Fahrenheit



This example reads 100.4° Fahrenheit

Also available in Celsius.

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AXILLARY USE

1. Open Package

Fold along perforation and tear off a single Tempa•DOT® Thermometer strip. Peel back top of wrapper to expose handle of thermometer. Remove thermometer by pulling exposed handle.

2. Insert Thermometer

Place thermometer high in the axilla with the dot matrix side against the torso and parallel to the length of the body (see diagram). Use the patient's arm to hold thermometer in place.

3. Wait 3 Minutes, but less than 5 minutes

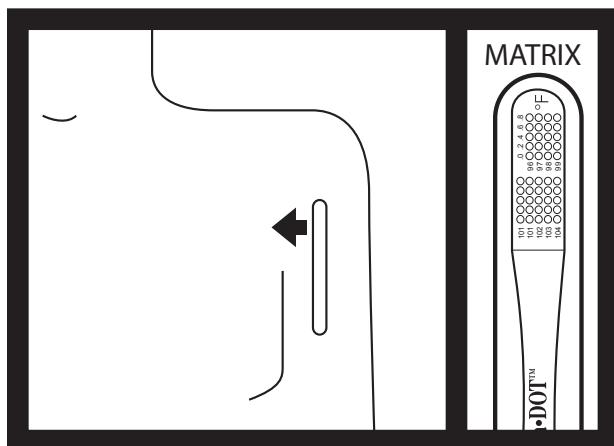
4. Remove Thermometer

Before reading, wait approximately 10 seconds for dots to lock in.

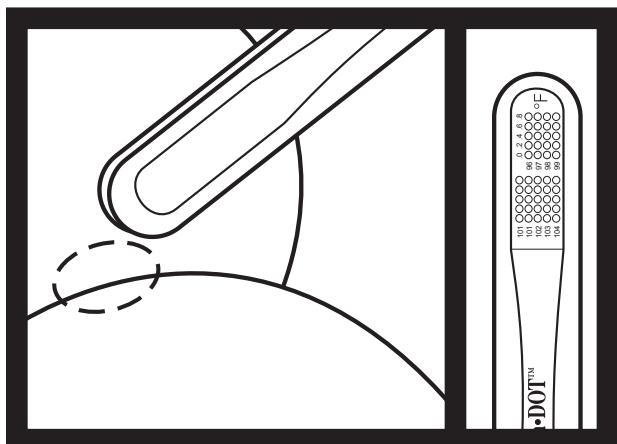
5. Read Temperature

The last blue dot on the matrix indicates the correct temperature.

6. Discard Thermometer



RECTAL USE - Tempa•DOT PLUS THERMOMETER



CAUTION: Any object inserted into the rectum could cause perforation. DO NOT USE FORCE. Axillary method is recommended by the American academy of Pediatrics for infants.

1. Open Package

Remove Tempa•DOT® PLUS Thermometer from the dispenser on top of the box. Do not remove the plastic sheath.

2. Insert Thermometer

Lubricate thermometer and insert into rectum until the dot matrix and numbers are completely covered.

3. Wait 3 Minutes, but less than 5 minutes

4. Remove Thermometer

Withdraw thermometer and sheath from rectum and discard sheath. Wait approximately 10 seconds for dots to lock in.

5. Read Temperature

The last blue dot on the matrix indicates the correct temperature.

6. Discard Thermometer.

STORAGE INFORMATION:

Store Tempa•DOT Single-Use Clinical Thermometer in an area where temperatures do not exceed 95°F.

When exposed to high temperatures, matrix dots will turn blue. If this occurs:

1. Place in freezer for one hour per box of 100.
2. Let stand at room temperature for one day.
3. Thermometers are now ready for use.

This process will not affect the accuracy of the thermometers.

Tempa•DOTTM

Single-Use Clinical Thermometer

Technical Information

SUMMARY OF CAPABILITIES

The Tempa•DOT Single-Use Clinical Thermometer provides an accurate, reliable and safe method for routine clinical temperature monitoring. Compared with other thermometry systems, it provides reduced risks of cross-infection and reinfection, significant time and labor saving benefits, plus greater convenience and easier readability. Consistent accuracy and reliability are inherent in the basic thermometric principle utilized in this type of thermometer.

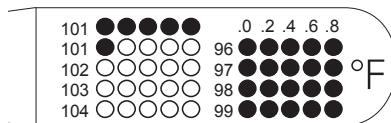
PRODUCT DESCRIPTION

The Tempa•DOT Single-Use Clinical Thermometer is an accurate, single-use instrument for measuring body temperatures either in the Fahrenheit range of 96.0° to 104.8°, or in the Celsius range of 35.5° to 40.4°.



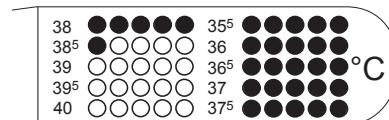
Tempa•DOT Thermometer (Fahrenheit) removed from wrapper and ready for use.

The sensor matrix, which is the heart of the instrument, consists of temperature indicating dots. Each dot contains a different chemical mixture that will melt and change color at a specific temperature. The Fahrenheit thermometer contains 45 dots arranged as shown in the illustration below. For accurate temperature reading, each dot changes color at a temperature 0.2°F higher than the preceding dot.



Sensor matrix of Fahrenheit Tempa•DOT Thermometer showing a temperature of 101.0°F.

In the Celsius thermometer (see illustration below), each of the 50 dots represents an increase of 0.1°C above the preceding dot.



Sensor matrix of Celsius Tempa•DOT Thermometer showing a temperature of 38.5°C.

Easy temperature readings are facilitated by highly legible numbers, arrangement of dots in rows of 5 and the high-contrast color change from beige to vivid blue.

HOW THE Tempa•DOT SINGLE-USE CLINICAL THERMOMETER WORKS

By varying the ratio of two organic chemicals that are completely soluble in each other (each having a distinct melting point), the melting point of the mixture can be adjusted anywhere between the melting points of the two component chemicals. This is the thermometric principle utilized in the Tempa•DOT Single-Use Clinical Thermometer. Every dot in the sensor matrix of the thermometer is a different temperature point with calibrated accuracy to $\pm 0.2^{\circ}\text{F}$ or $\pm 0.1^{\circ}\text{C}$.

When the mixture melts, a vivid color change occurs. The last dot that turns and remains blue indicates the highest temperature reached.

The temperature-indicating dots are made by filling indentations in the thermometer matrix with the mixtures and sealing these with a multi-layered transparent plastic film.

Temperature offset - When tested in vitro in a controlled-temperature water bath, the thermometer will read 0.6°F (0.3°C) higher than the actual temperature of the water. This is because of its “temperature offset,” which compensates for the difference in heat-transfer characteristics between sub-lingual tissues and a water bath. The temperature sensor incorporates a consistent temperature offset of +0.6°F (+0.3°C) throughout the recording range. This special thermometric design facilitates accurate in vivo measurement of oral temperature in 60 seconds.

Efficacy studies - In vivo accuracy of Tempa•DOT Single-Use Clinical Thermometers was evaluated in a special study at the American Enka Medical Center, Enka, North Carolina. The Tempa•DOT Thermometer was compared to glass-mercury thermometers selected for their higher-than-normal accuracy. This study involved 376 patients and 1,500 temperature measurements. Based on this study, it was concluded that in a reasonably conditioned mouth, the accuracy of the Tempa•DOT Thermometer is equivalent to that of the glass-mercury thermometers used in the study. In this study, a mean temperature difference of less than 0.1°F was noted.

In a second study,¹ the temperatures of 95 hospital patients were measured for 3 minutes with a calibrated glass-mercury thermometer. This was followed by a 60-second reading with a Tempa•DOT Thermometer, and another 3-minute glass-mercury thermometer reading. The average temperatures were 98.00°F, 98.12°F and 98.06°F, respectively. Analysis revealed no statistical differences between the average temperatures obtained by these two types of thermometers. Copies of other accuracy studies done by independent institutions are available upon request.

Accuracy - When tested in accordance with the manufacturer's methodology, the mean accuracy of the Tempa•DOT Single-Use Clinical Thermometer will be within 0.2°F (0.1°C) for all of the temperature dots on the thermometer.

The Tempa•DOT Thermometer conforms to the accuracy requirements specified in ASTM specification E 825-98 (Reapproved 2009) for disposable fever thermometers.

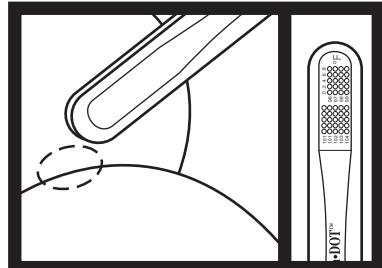
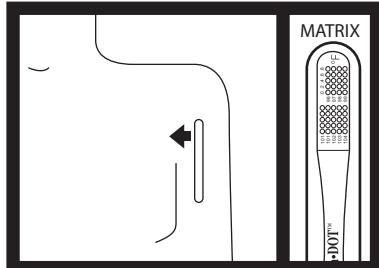
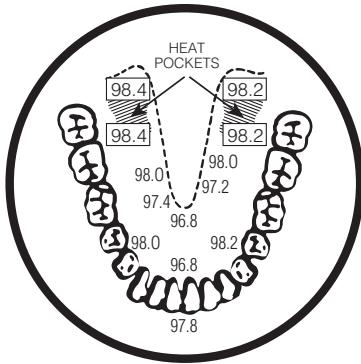
Fahrenheit Scale		Celsius Scale	
Range	Maximum Error	Range	Maximum Error
Below 98.0°F	±0.4°F	35.8°C to 36.9°C	±0.2°C
98°F to 102°F	±0.2°F	37.0°C to 39.0°C	±0.1°C
Above 102°F	±0.4°F	39.1°C to 40.4°C	±0.2°C

This accuracy standard is the same as that for glass thermometers.

Test method and lot acceptance criteria - Due to the destructive nature of accuracy tests, statistically valid samples (usually between 315 and 500 thermometers per manufacturing lot) are tested in water baths at 20 points distributed throughout the thermometer scale. One thermometer is used per datum point. Lot acceptance is based on a 4% AQL.

NOTE: To compensate for the temperature offset, 0.6°F (0.3°C) is added to the temperature of each water bath.

From concept to reality - The Tempa•DOT Single-Use Clinical Thermometer represents the culmination of many years of intensive research and development to incorporate this thermometric technique into a product that is accurate, safe, stable, easy to use, and economical. It is a story of hundreds of progressive modifications and refinements not only in the chemistry and crystallography of the temperature-sensitive indicating system but also in the physical design and selection of suitable materials for the instrument and its package.



METHOD OF USING Tempa•DOT SINGLE-USE CLINICAL THERMOMETER

Directions for use - Recording and reading oral temperatures with the Tempa•DOT Single-Use Clinical Thermometer is an extremely simple procedure, but to assure most accurate results it must be done in accordance with directions.

1. *Remove thermometer from wrapper.* Peel back top of wrapper to expose handle end of thermometer. Remove thermometer by pulling exposed handle, taking care not to touch the dot matrix portion which is to be placed in the patient's mouth.
2. *Place thermometer under tongue.* Insert thermometer into patient's mouth under tongue as far back as possible into either heat pocket. Indicator dots may face either up or down. Have patient press tongue down on thermometer while keeping mouth closed. Remove after 60 seconds.
3. *Read temperature.* Wait approximately 10 seconds for dots to stabilize. The last blue dot on the matrix indicates the correct temperature. Discard thermometer.

Attention to proper usage - Since the Tempa•DOT Thermometer is highly sensitive, failure to register accurate temperature may result from:

1. *Improper placement in the mouth* - be sure to place the thermometer at the base of the tongue as far back as possible on either side.
2. *Failure of patient to keep mouth closed* for 60 seconds without displacing the thermometer by movement of tongue.
3. *Inadequate thermometer placement time* - less than 60 seconds.
4. *Failure to wait at least 10 seconds* for dots to stabilize after removal.

5. *Exposure to cold weather, smoking, eating or drinking* - wait at least 15 minutes before inserting thermometer so that mouth temperature may stabilize.
6. *Prolonged thermometer placement time* - longer than 2 minutes

In rare instances, a dot may not "fire" (change to blue). Always read the last dot that has fired as the correct temperature.

Rectal temperature taking - The Tempa•DOT Single-Use Clinical Thermometer is designed primarily for oral temperature measurement. Rectal temperatures can be obtained in 3 minutes by using the Tempa•DOT PLUS Single-Use Clinical Thermometer in accordance with the instructions included in the package. Axillary temperatures are recommended for children under one year of age.

Axillary temperature taking - The Tempa•DOT Thermometer is completely suited to taking axillary temperatures whenever oral use is not feasible (e.g., in young children, comatose patients, patients with recent oral or jaw surgery). In this use, the sensor tip should be placed into the axilla with the dot matrix side against and parallel to the length of the body and held in place by the arm for 3 minutes. Temperatures recorded in this manner may be about 0.5°F lower than oral temperatures and as much as 1.0°F lower than rectal temperatures.

This variation also holds true for glass-mercury thermometers since it is not a function of the method of temperature measurement, but is, instead, related to the lower thermal security of the axillary site.

Key	Name of substance
BN	Chemical #1
CN	Chemical #2
ID	Indicator dye
Numbers in parentheses after the substance abbreviation in the charts below show the proportion tested.	

TOXICITY TESTING

The chemicals and structural materials used in the Tempa•DOT Single-Use Clinical Thermometer have been tested for toxicity, irritation and sensitization potential. Findings from these tests indicate no untoward effects of clinical significance from the use of this thermometer.

Chemical entities and combinations of chemicals were administered orally to laboratory animals to determine toxicity. Results are summarized below:

Oral Toxicity Data	
Substance	Lethal Dose Level
ID	LD ₅₀ > 1.00 g/kg (rats)
BN	LD ₅₀ – 0.468 g/kg (rats)
CN	LD ₅₀ – 0.472 g/kg (rats)
BN/CN (75/25)	LD ₅₀ – 0.468 g/kg (rats)
BN/CN (54/46)	LD ₅₀ – 0.458 g/kg (rats)

Even the chemical combination showing the greatest toxicity (LD₅₀ – 0.458 g/kg) in the laboratory has no clinically significant hazard, since the corresponding amount for a 50kg adult would require ingesting these chemicals from more than 5,000 Tempa•DOT Thermometers as a single dose.

Extracts of the matrix portion of the thermometer were prepared in saline solution (at 50°C for 72 hours) and administered orally to rats. The toxicity rating of 100% extract (as determined by LD₅₀ –): >40 g/kg.

Multiple studies were carried out to evaluate the potential of Tempa•DOT Thermometer components to cause eye irritation and/or eye damage. The three chemical substances - CN, BN and BN/CN (75/25) - passed the FHSAs eye irritation test in rabbits; mild and transient redness in the conjunctivae was occasionally seen. In no case was corneal opacity or injury to the iris noted.

In addition, an aqueous extract of 150 thermometers was placed in a rabbit's eye and the rabbit was observed for 14 days. The conclusion from the results was that the extract is not an irritant.

Rabbits were also used for skin irritation tests by applying 0.5 g of the various chemicals and combinations under an occlusive patch

on areas of shaved skin. Patches remained occluded for 24 hours; results are shown below:

Skin Irritation	
Substance	Result
BN	Not primary irritant (FHSAs)
CN	Not primary irritant
BN/CN (75/25)	Not primary irritant

As summarized below, dilute solutions of Tempa•DOT Thermometer chemicals instilled intra-vaginally in dogs twice daily for five days produced no significant or lasting erythema in any of the tested animals:

Vaginal Irritation	
Substance	Result
BN/CN (75/25)	No significant irritation

To evaluate sensitization potential, tests were conducted on laboratory animals and humans. Using the "Maguire Guinea Pig Maximization Test," blended chemicals in two solution strengths - 5 mg/ml and 0.5 mg/ml - were tested on the shaved skin of Hartley-strain guinea pigs. As shown below, no indication of sensitization was observed:

Sensitization Tests	
Substance	Reaction
BN/CN (mixture 96)	None
BN/CN (mixture 108)	None

Patch-testing in 10 human subjects consisted of applying test materials to the skin for 24 hours on 10 alternate days. After a 14-day washout period, the skin was challenged by 24 hour application of the same substance at the same sites. No evidence of primary irritation, sensitization or photo-sensitivity was found at any test site in any subject. Test substances and results are summarized below:

Human Irritation/Sensitization	
Substance	Reaction
BN/CN (mixture 96) (50 µg/patch)	Negative
BN/CN (mixture 104)	Negative

TECHNICAL SPECIFICATIONS

Length	91 millimeters	Storage	Avoid excessive heat and humidity. Store in cool area (below 86°F/30°C). Warning: Exposure to temperatures greater than 95°F (35°C) will activate thermometer.
Width of sensor matrix	9 millimeters		
Temperature range	Fahrenheit thermometer: 96.0° to 104.8° Celsius thermometer: 35.5° to 40.4°	Regeneration of fired thermometers	The Tempa•DOT Single-Use Clinical Thermometer may fire (turn blue) if accidentally exposed to elevated temperatures. The thermometers can be returned to functional condition by placing them in a standard freezer. The storage time required for regeneration ranges from 1 hour for a box of 100 thermometers to 16 hours for a case of 2.000. After regeneration, the fired dots may not return to their original beige appearance but could be slightly off-color. This will not affect accuracy nor can it be confused with the vivid blue color the dots turn in normal use. <u>Full function and accuracy will return after 16 hours storage at room temperature.</u>
Temperature increments from one dot to the next	Fahrenheit thermometer: 0.2° Celsius thermometer: 0.1°		
Matrix arrangement	Fahrenheit thermometer: Two arrays-one of 4 rows x 5 dots measures temperatures from 96.0° to 99.8°, the other of 5 rows x 5 dots measures temperatures from 100.0° to 104.8°. Celsius thermometer: Two arrays-one of 5 rows x 5 dots measures temperatures from 35.5° to 37.9°; the other of 5 rows x 5 dots measures temperatures from 38.0° to 40.4°.	Shelf-life	Two years from date of manufacture as established by the expiry date.
Sterility	Extensive precautions are taken during the manufacturing process to guard the sterile integrity of the Tempa•DOT Single-Use Clinical Thermometer. Thermometers are sterilized by cobalt-60 gamma irradiation to assure sterility for patient protection. Tempa•DOT Thermometers are also available in non-sterile form.		

Animal delayed hypersensitivity - To test delayed hypersensitivity, 0.2 ml of an aqueous extract of 150 Tempa•DOT Single-Use Clinical Thermometers was rubbed into excoriated skin on the shoulder of guinea pigs on days 0, 2, 4 and 7. The guinea pigs were challenged 21 days later, and no signs of delayed hypersensitivity were elicited.

Summary of toxicology findings - The entire program of toxicity testing was carried out by independent laboratories according to standard procedures and protocols recommended by government and industrial testing groups. None of the tests showed evidence of clinically significant toxicity or indication that the Tempa•DOT Thermometer components cause primary irritation, sensitization or photo-sensitivity of the skin.

The conclusion reached after analysis of all the evidence is that the Tempa•DOT Thermometer is innocuous to patients in its intended use as an oral, rectal or axillary thermometer. Furthermore, the chemicals on the sensor matrix are fully shielded from any contact with the oral mucosa or saliva by a sealed plastic laminate that covers both the top and bottom surfaces of the entire sensor matrix. The plastic is tough and resilient and, consequently, resistant to puncturing or tearing even if bitten by the patient.

PRINCIPLE OF THERMOMETRY

A major source of error in glass-mercury thermometers is usually traced to nonlinearity, which usually results in an error throughout most of its range. The principle utilized in the single-use thermometer avoids this completely since each dot is a separate thermometer that acts independently of all other dots. Thus, there can be no cumulative error.

QUALITY CONTROL STANDARDS

The Tempa•DOT Single-Use Clinical Thermometer undergoes numerous separate quality control tests. The procedures that follow are typical of the tests that are performed to ensure the chemical and physical integrity, accuracy, uniformity and stability of the thermometers.

Raw materials - Precise determination 91 melting points; gas chromatography to determine chemical purity; Instron Universal Testing Machine determinations of the strengths of films, adhesives and laminated structures; identification of plastic films by IR spectroscopy printing, film and laminate dimensions.

In-process testing and monitoring - Dimensional requirements by mechanical and optical methods; online monitoring to ensure chemical fill level; Instron peel-strength testing of assembled laminations; temperature - bath checks on melting points of chemical mixtures; and the correct location and completeness of sealing of the dot mixtures.

Final product testing - A statistically valid sample, per MIL-STD-105, is drawn from each lot. Water baths are used to verify accuracy. These water baths are adjusted by a thermometer whose calibration is traceable to the National Institute of Standards and Technology. The thermometer and its sterilizable package are determined to be free of mechanical defects.

Retention of samples, all identified by lot number for traceability
- Raw materials, subassembly materials and finished product are retained for a period of three years.

American Society for Testing and Materials - The Tempa•DOT Single-Use Clinical Thermometer conforms to the requirements established in ASTM Standard E 825-98 (Reapproved 2009) for disposable fever thermometers.