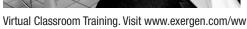
<u>EXERGEN</u>

TAT-2000 Series

TemporalScanner[™]







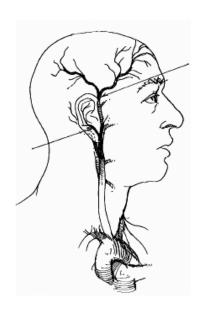


Accuracy supported by more than 70 peer-reviewed published studies for all ages from neonate to geriatric, and in all clinical settings.

Contact medical@exergen.com

Changing the Way the World Takes Temperature

Temporal Artery Thermometry





The temporal artery (TA) area has a long history of temperature assessment dating back thousands of years with recorded references to palpation of the head for fever assessment. Branching from the external carotid, the superficial TA courses within about a millimeter of the skin's surface over the lateral forehead, providing good heat conduction to the skin surface, is readily accessible, and provides no risk of injury from being touched. Since it is not an anastomosing vessel, perfusion remains high and stable, ensuring the reliability of conditions for the patented Arterial Heat Balance method to compute accurate temperatures.

This new, superior class of thermometry has been shown to improve outcomes and reduce costs by noninvasively measuring temperature with a degree of clinical accuracy unachievable with other methods of thermometry.

Temporal Artery Thermometry

What is arterial temperature?

Arterial temperature is the same temperature as the blood flowing from the heart via the aorta. It is the best determinate of body temperature, and unaffected by the artifactual errors and time delays of oral and rectal methods.

What is the TemporalScanner?

The TemporalScanner is an infrared thermometer designed for noninvasive temperature assessment at the temporal artery (TA). It is a kinder, gentler way to take temperature, and a better method for patient and clinician alike. It is breakthrough technology.

How does it work?

Temperature is measured by gently stroking the TemporalScanner across the forehead, and includes a momentary touch of the probe to the neck area behind the ear lobe, to account for any cooling of the forehead as a result of diaphoresis. The patented arterial heat balance technology (AHBTM) automatically measures the temperature of the skin surface over the artery and ambient temperature, synthesizing the two to produce arterial temperature by sampling and calculating these paired readings some 5000 times with each use.

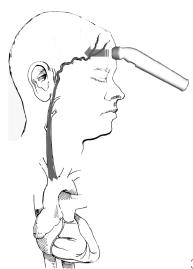
How accurate is it?

It has been clinically proven in all departments for all patients in premier university hospitals and proven to be more accurate than ear thermometry.

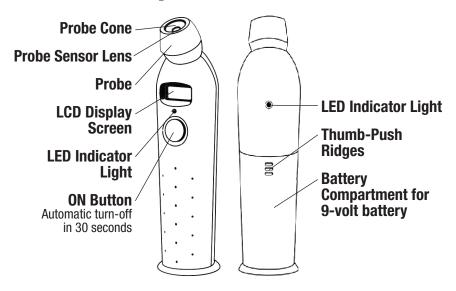
What are the benefits of TA thermometry?

Besides the inherent accuracy, as a site for temperature measurement, TA presents many benefits: no risk of injury for patient or clinician, eliminates the need for disrobing or unbundling, and is suitable for all ages from preemies to geriatrics.

Unique to infrared thermometry, the instrument can be used with or without disposable covers, thereby providing a substantial cost savings unavailable with other methods of thermometry.



Product Map



Probe Caps & Dispenser

TemporalScanner Model 2000 can be used either with disposable caps (Part No. 134203), or if preferred, without disposable caps by simply wiping the probe with alcohol or other disinfectant between patients.

If using disposable caps, they are easily applied on the probe as illustrated in Figure 1, and easily ejected by a gentle push of your thumb as illustrated in Figure 2.

A convenient wall-mounted dispenser holding 100 disposable caps is available, illustrated in Figure 3 (Part No. 134315).



Ancillary items, including disposable caps are available from many distributors, or by calling Exergen Customer Service at 617-923-9900 or 800-422-3006, or by emailing service@exergen.com.

Measuring TA Temperature

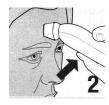
What you should know before using the TAT:

- Measure only the side of the head exposed to the environment. Anything covering the area to be measured (hair, hat, wig, bandages) would insulate the area, resulting in falsely high readings.
- Slide the thermometer straight across the forehead, not down the side of the face. Midline on the forehead, the TA is about a millimeter below the skin, whereas at the side of the face, the TA is much deeper, and measuring there would result in falsely low readings.
- When taking a temperature behind the ear lobe, first push away any hair, exposing the area. Then, tuck the thermometer on the neck under the ear lobe, in the soft conical depression below the mastoid, (the place where perfume is typically applied).
- Wait about 30 seconds before measuring the same patient again to avoid excessive cooling of the skin.
- An infant frequently presents with blankets and clothing covering the neck area. Since the perfusion rate is normally strong for infants, and unless visibly diaphoretic, one measurement at the TA area is typically all that is required. Should you feel the temperature is low, then push aside any clothing or blankets covering the neck area for ~30 seconds or so, and repeat the measurement behind the ear.



Brush hair aside if covering the TA area

Place the probe flush on the center of the forehead.

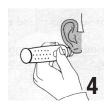


Depress the ON button.

Keep depressed throughout measurement...



Slowly slide the probe midline across the forehead to the hair line



Brush hair aside if covering ear

Lift probe from forehead and touch on the neck iust behind the ear lobe



Release button, read and record

- Display will remain for 30 seconds, before automatic turn-off.
- To turn off immediately, press and release
- To restart immediately, depress button and continue as above

Measuring TA Temperature

What else should I know?

- A dirty probe lens and cone can cause a low reading. If not shiny, clean the lens and cone with an alcohol prep or a Q-tip moistened in alcohol.
- It is preferable to hold the instrument sideways.
 Approaching your patient with the instrument



straight up and down could be somewhat intimidating, especially to an agitated patient.

 If you are right handed, you might find it easier to measure the left side of your patient; a left



hander would find measuring the right side of the patient to be easier.

- Consider holding the thermometer like a pencil or pen as illustrated.
- If your patient is agitated, or squirms away before you have completed your measurement, just keep the button depressed and you can continue the measurement without having to wait.

Why measure behind the ear lobe (BE) as well as the temporal artery?

To avoid any possibility of false low temperature caused by diaphoresis, which many times is not obvious. Think of it as a touch of insurance.

How does diaphoresis affect readings?

Moisture cools the skin over the temporal artery area.

Why behind the ear lobe?

If your patient is sweaty, vasodilation will always be present, and blood flow BE will be as high as the TA area were it dry.

What if the TA area has been traumatized by burns or lacerations, or is completely covered with dressings?

With head trauma, surgical or accidental, the temperature can be obtained from the alternative site on the neck BE. Just as with diaphoresis, the perfusion will be high.

Why not use the area BE as a sole site?

Without diaphoresis or head trauma, this area is just too variable to be reliable as a sole site.

Clinical Information

Normal Body Temperature (BT)

Normal BT is not a single temperature, but a range of temperatures influenced by age, time of day, and measurement site.

General Rule of Thumb

Rectal temperature is \approx 2°F (1°C) higher than axillary and \approx 1°F (0.5°C) higher than oral temperature.

Expect the Differences

Arterial temperature measurement (PA Catheter, TA Thermometry) leads all other methods in identifying fever or defervescence, and is unaffected by activities of daily living. Accordingly, it will sometimes be different from your present methods — but accurate.

Guidelines for Patient Temperature Assessment

- 1. Normal TA Temperature: On a stable resting patient, TAT is ≈0.8°F (0.4°C) higher than an optimum oral temperature, and is about the same as a rectal temperature. However, during febrile episodes, the difference can be much higher, mainly because of the artifacts of oral and rectal sites.
- 2. Fever Definition: Clinically, fever is defined as a BT ≥1.8°F (1°C) above the mean standard deviation at the site of recording.²

A single oral temperature of ≥101°F (38.3°C) in the absence of obvious environmental causes is usually considered fever. An oral temperature of ≥100.4°F (38.0°C) over at least 1 hour indicates a fever state.³

A single arterial temperature >101.8°F (38.8°C) in the absence of obvious environmental causes is usually considered fever. An arterial temperature >101.2°F (38.4°C) over at least 1 hour indicates a fever state.

While the above are recommended guidelines, not all fevers require laboratory tests, and clinical assessment in concert with standard hospital protocol for fever workups should always prevail.

3. Oral Temperature Risks: Oral temperature can be clinically misleading, and many febrile patients can have a "normal" temperature. Mouth breathing, tachypnea, heated gases, and hot or cold fluids can distort the reading, as can intubation or inability of the patient to cooperate. Accordingly, comparisons with TA may not be reliable.

Normal Body Temperature Ranges at Various Measurement Sites:

Arterial: 97.4-100.1°F

36.3-37.8°C

Oral: 96.6-99.5°F

35.9-37.5°C

Esophageal: 98.4-100.0°F

36.9-37.8°C

Rectal: 97.7-100.3°F

36.5-37.9°C

Axillary: 95.5-98.8°F

35.3-37.1°C

Oronasal: 96.6-99.0°

35.9-37.2°C

Clinical Information

4. Rectal Temperature Risks:

Rectal temperature should only be considered as a good approximation of core temperature when the patient's thermal balance is stable, but is not suitable during and after surgery,⁵ and may be misleading after antipyretics, physical exercise, or other intervention that may change temperature quickly.

5. Axillary Temperature Risks:

Based on strong evidence cited by the NIH, "axillary temperature is contraindicated in critically ill adults, and its use in the general patient population should be discouraged due to its unreliable correlation with core temperature and its poor reproducibility."6

References:

- 1. Kuzucu EY. Measurement of temperature. Int Anesthesiol Clin, 3(3):435-49, May, 1965
- El-Radhi AS, Carroll JE. Fever in Paediatric Practice, Ch 2, pp 15-49, Oxford Blackwell Scientific Publications, 1994
- Hughes WT et al. 1997 Guidelines for the use of antimicrobial agents in neutropenic patients with unexplained fever. Infectious Diseases Society of America (IDSA)
- Tandberg D et al. Effect of tachypnea on the estimation of body temperature by an oral thermometer. NE J Med, 308, 945-46,1983
- O'Grady NP, Barie PS, Bartlett JG, et al. Practice guidelines for evaluating new fever in critically ill adult patients. Task Force of the Society of Critical Care Medicine and the Infectious Diseases Society of America. Clin Infect Dis 1998 May: 26(5):1042-59
- 6. Houdas Y, et al. Human body temperature. Ch 5, p89, Plenum Press, 1982, USA, UK

Product Specifications

Clinical Accuracy: Meets ASTM E 1965-98 and EN60601-1 standards for

electronic and radiation thermometers to the extent applicable to thermometers which measure the surface of

the skin over the temporal artery.

EMI/RFI Protection: Error message displayed
Calibration Protection: Error message displayed
Error message displayed
15.5 to 42°C (60 to 107.6°F)
Operating Environment: 15.5 to 40°C (60 to 104°F)

Resolution: 0.1°C or °F

Response Time: Approximately 0.03 second

Time Displayed on Screen: 30 seconds before automatic shutdown

Battery Life: Approximately 7,500 readings

Size: 7.0 in x 1.75 in x 1.25 in (17.8 cm x 4.45 cm x 3.18 cm)

Weight: 4.2 oz (120 grams) incl batt

Display Type: High contrast LCD's

Construction Method: Impact resistant casing, hermetically sealed sensing system

Warranty: 3 years

Patents: Listed at www.exergen.com/patents

ASTM laboratory accuracy requirements in the display range of 37° to 39° C (98 to 102° F) for IR thermometers is $+/-0.2^{\circ}$ C ($+/-0.4^{\circ}$ F) whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM standards E667-86 and E1112 is $+/-0.1^{\circ}$ C ($+/-0.2^{\circ}$ F).

^{*}Full responsibility for this product meeting applicable portions of this standard is assumed by Exergen Corporation, Watertown, MA 02472

Cleaning the Instrument

The TemporalScanner is an optical instrument. Like a camera or eye glasses, a dirty lens will distort the view. If the thermometer is unable to see the heat clearly, it will be unable to measure it accurately, resulting in low readings.

Probe lens and cone should be shiny clean, if not, wipe with an alcohol prep, or with a swab moistened in alcohol or water.



Do not hold the Temporal *Scanner* under the faucet or submerge in water. It is not waterproof.



Hold upside-down to prevent excess moisture from entering the sensor area. It will not harm the sensor, but if it becomes too wet, you will be unable to take a temperature until it dries.



Thermometer case can be cleaned with any hospital approved disinfectant, alcohol, even bleach solutions. Avoid gritty, abrasive cleaners as they can scratch the thermometer.

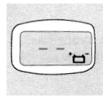


Changing the Battery

Blinking battery icon with temperature displayed: battery is low but will still operate correctly. Replace soon.



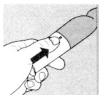




Insert a 9-volt battery as illustrated, with the positive (small terminal) always on the right.



Replace the battery compartment door as indicated, with a push of your thumb on the ridges.





Smart Glow Features





Soft Glow Display: Soft lighting for easy reading in any light. Perfect for checking the temperature of a sleeping infant (or adult) in a darkened room.



8 Temperature Memory: Automatically retains the last 8 temperature readings for instant recall to check on fever progression.

°F↔°C Programmable °F or °C: Select most convenient temperature scale.



Programmable Beeper: Beeping sound indicating scanning can be turned off or on to avoid waking a sleeping child (or adult). The flashing LED facing the forehead while scanning turns off when the beeper is turned off.



One-button Programming: Elegant one-button programming & memory access.

To Use the 8 Temperature Memory Recall Mode

In memory mode, a small "M" will appear on the display with memory location (1,2,3,4,5,6,7,8) and the memory location will alternate with the temperature stored in that location. The most recent temperature is stored in location 1 and the earliest temperature is stored in location 8. A reading of 188.8 means that no temperature reading is stored in that memory location. Readings already in the memory when you first use it are from the factory tests.

<u>102.4°</u> м

- To enter memory recall mode, start from a blank display, and tap the button. 1[™] will appear and alternate with the temperature stored in that memory location.
- To access previously stored readings, tap the power button again. 2[™] will alternate
 with the temperature in that memory location. Repeat through 8[™] to access all
 recent memory readings.
- To exit memory recall mode and take a temperature, press and hold the button for 1-2 seconds until the display turns off.

Programmable Beeper



Your TemporalScanner is equipped with a beeper and front/back flashing LED's which gives you a soft audible and visual feedback as you scan over the temporal artery on the forehead. The original factory setting is with the beeper and LED's ON.

If the beeper is on and you are concerned that the sound or flashing LED may wake a sleeping child (or adult), the beeper and front LED can be turned off as follows:

- Starting with a blank display, tap the power button until the display flashes loud. (tap 10 times, past the 8 memory locations and the F-C display)
- Press and hold the button until Shh is displayed, indicating the quiet mode. A beep will indicate that the setting has been changed, and the TemporalScanner will automatically shut off.
- To turn the beeper and front LED back on, repeat step 1 to find **Shh** then step 2 to change into **loud**.

Display Messages

To Select °F or °C Mode

	9	R	F	°F
--	---	---	---	----

Your TemporalScanner can be programmed to display the temperature in either °F or °C, as indicated by the small °F or °C in the upper right of the display.

37.0°

The original factory setting is ${}^{\circ}F$. If you wish to change it to ${}^{\circ}C$, follow the steps below:



- Starting from a blank display tap the button until the flashing F-C appears after the 8 memory locations (9 taps). The current temperature mode will appear in the upper right indicated by the small °F or °C.
- 2. To change from the °F mode to the °C mode, press and hold button until the small °F in the upper right of the display changes to °C. A beep will indicate that the setting has been changed, and the TemporalScanner will automatically shut off.
- 3. To change from the °C mode to the °F mode, repeat step 2, and press and hold the button until the small °C in the upper right of the display changes to °F.

Additional Display Messages



A flickering Scn on display is visible during measurement. At completion, releasing the button will display and lock temperature on the screen for 30 seconds.

H !

The target temperature measured is higher than 107.6°F (42°C).

LO

The target temperature measured is lower than 60° F (15.5°C).

HI.A

Temperature of the thermometer is higher than 104°F (40°C). Let the instrument acclimatize for about 10 minutes or so in the area in which it will be used.

LO.R

The temperature of the thermometer is lower than 60°F (15.5°C). Let instrument acclimatize for about 10 minutes or so in the area in which it will be used.



EMI/RFI (like static on a radio) protection is preventing a temperature from being taken. Wait a minute and you should be able to proceed. If not, reset by removing and replacing the battery. Be sure battery is tightly connected.

Three Year Warranty

Exergen Corporation warrants each new Exergen TemporalScanner 2000 Series (except battery) against defects in materials or workmanship for a period of three years from the date of purchase, and agrees to repair or replace any defective product without charge.

IMPORTANT: This warranty does not cover damage resulting from accident, misuse or abuse, lack of reasonable care, the affixing of any attachment not provided with the product or loss of parts or subjecting the product to any but the specified battery.* Use of unauthorized replacement parts will void this warranty.

Exergen Corporation will not pay for warranty service performed by a nonauthorized repair service and will not reimburse the customer for damage resulting from warranty service performed by a non-authorized repair service. No responsibility is assumed for any special, incidental or consequential damages.

In order to obtain warranty service, simply call Exergen Corporation Customer Service, 617-923-9900, for a Return Material Authorization number (RMA). Then send the product, postage or shipping prepaid, to Exergen in accordance with the instructions given with the RMA number. It is suggested that for your protection, you ship the product, insurance prepaid. Damage occurring during shipment is not covered by this warranty.

NOTE: No other warranty, written or verbal, is authorized by Exergen Corporation. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.

*Read enclosed instructions carefully.

To evaluate, email: medical@exergen.com

For general information: www.exergen.com

For clinical information, visit: www.TAThermometry.org

For educational videos, clinical studies, and manuals: www.exergen.com/ww



Invented, designed, assembled, tested, and packaged in the U.S.A. by Exergen.



www.exergen.com/s



Exergen Corporation 400 Pleasant Street Watertown, MA, 02472 Phone: 617.923.9900

Fax: 617.923.9911 www.exergen.com