EN

EXERGEN

Temporal*Scanner*™

TAT-2000-EC

Please read the safety information before using.

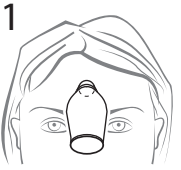
#1 in proven accuracy, supported by more than 100 peer-reviewed published studies for all ages from neonate to geriatric, in all clinical settings.

Questions: contact wwmed@exergen.com

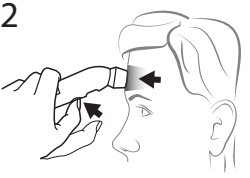
QUICK START INSTRUCTIONS

Do NOT push the Scan button before starting the measurement. This is not an on/off button

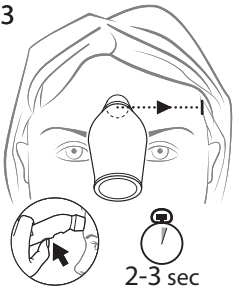
1. Brush hair aside if covering the (temporal artery) TA area. **Place the probe flush on the center of the forehead.**



2. Press the Scan button, keep pressed throughout measurement



3. Slowly slide the probe midline across the forehead to the hair line in 2-3 seconds



Do NOT scan over the hair with the TAT-2000-EC, brush hair aside before measuring.

QUICK START INSTRUCTIONS (cont'd)

Slide the thermometer straight across the forehead, not down the side of the face.

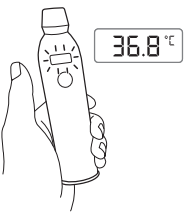
4. Scan behind the ear.

4

5. 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

5



Safety Information

READ ALL INSTRUCTIONS BEFORE USING

SAVE THESE INSTRUCTIONS.

Intended Use: The Exergen TemporalScanner is a handheld infrared thermometer used by medical professionals for the intermittent measurement of human body temperature of people of all ages, by scanning the forehead skin over the temporal artery. Intended users are physicians, nurses, nurses' aides, nursing assistants, patient care technicians, and others who are trained to take the temperature of patients at all levels who normally provide patient care. The thermometer provides a peak temperature reading from plural readings during the step of scanning. Electronic circuitry processes the measured peak temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature, the electronic circuitry computing an internal temperature of the body as a function of ambient temperature and sensed surface temperature. Training materials that are supplementary to this instruction manual are available at www.exergen.com/s, and recommended for first time users.

TAT-2000 Series thermometers are used by medical professionals in clinical environments. Clinical environments include areas where medical professionals are providing medical services for patients, including hospitals, outpatient clinics, primary care offices, and other settings where temperature is taken as part of patient care. Clinical environments do not include Emergency Medical Services environments.

Additionally, the TAT-2000 series thermometers are not for use aboard aircraft or near High Frequency Surgical Equipment or Radio Frequency shielded rooms, such as MRI (Magnetic Resonance Imaging) areas.

When using the product basic safety precautions should always be followed, including the following:

- Use this product only for its intended use as described in this manual.
- Do not take temperature over scar tissue, open sores or abrasions.
- The operating environmental temperature range for this product is 16 to 40°C (61 to 104°F).
- Always store this thermometer in a clean, dry place where it will not become excessively cold (-20°C/-4°F), or hot (50°C/ 122°F) or humid (max RH 93% non-condensing, at 70 to 106 kPa).
- The thermometer is not shockproof. Do not drop it or expose it to electrical

Safety Information (cont'd)

shocks.

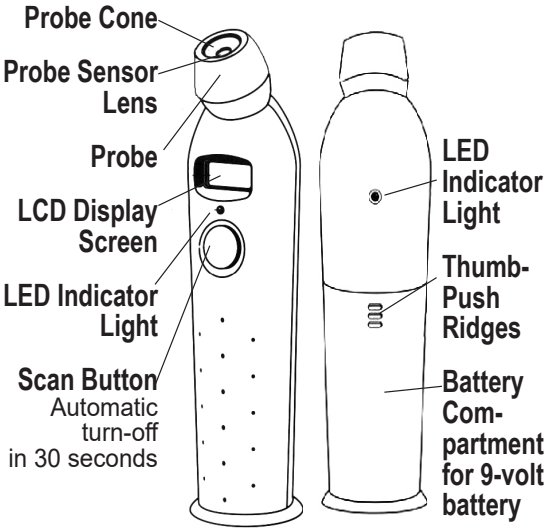
- This thermometer is not intended to be sterile. Do not try to sterilize it. Do not autoclave. Please note cleaning procedures in this manual. Do not use bleach or other cleaning solutions on the sensor lens.
- Do not use this thermometer if it is not working properly, if it has been exposed to temperature extremes, damaged, been subject to electrical shocks or immersed in water.
- There are no parts that you can service yourself except for the battery, which you should replace when low by following the instructions in this manual. For service, repair, or adjustments, return your thermometer to Exergen. Warning : no modification of this equipment is allowed.
- Never drop or insert any object into any opening, unless stated in this manual. Never put any foreign object into the battery compartment.
- If your thermometer is not used regularly, remove the battery to prevent possible damage due to chemical leakage.
- Not designed for lithium battery. Do not use lithium battery.
- Follow the battery manufacturer's recommendations or your hospital policy for the disposal of used batteries.
- Not suitable for use in the presence of flammable anesthetic mixtures.
- Do not use corrosive substances on the thermometer.
- Do not use this thermometer outdoors.
- If the device fails to operate as described above, see the Additional Display Messages section of this manual and the full IFU at www.exergen.com/ta2kec. Additionally, ensure that you are not in the presence of electromagnetic disturbances.
- If you have any additional questions regarding use or care of the thermometer, please see www.exergen.com or call customer service at 1-351-204-7406.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

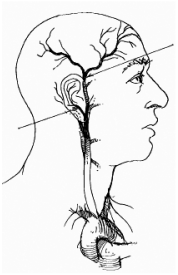
WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TAT-2000 thermometer. Otherwise, degradation of the performance of this equipment could result.

Product Map



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.

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 non-invasive 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 (AHB™) 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.

Temporal Artery Thermometry (cont'd)

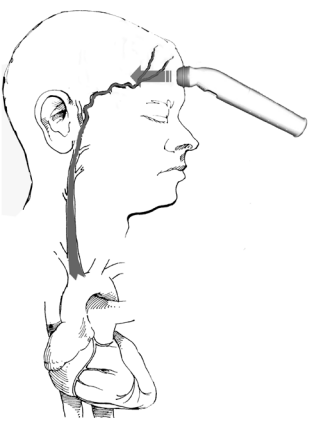
How accurate is it?

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.



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.

Measuring TA Temperature (cont'd)

- 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.

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?

Measuring TA Temperature (cont'd)

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.

Probe Caps

TemporalScanner Model 2000 can be used either with disposable caps (Part No. 134203). If using disposable caps, they are easily applied on the probe as illustrated in Fig 1, and easily ejected by a gentle push of your thumb as illustrated in Fig 2.

Fig 1

Fig. 2

Clinical Information

Normal Body Temperature (BT)
Normal BT is not a single temperature, but a range of tempera- tures influenced by age, time of day, and measurement site.

General Rule of Thumb
Rectal temperature is ≈ 1°C (2°F) higher than axillary and ≈ 0.5°C (1° F) higher than oral temperature.[1]

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 ≈ 0.4°C (0.8°F) 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°C (1.8°F) above the mean standard deviation at the site of recording.[2]
   A single oral temperature of ≥ 38.3°C (101°F) in the absence of obvious environmental causes is usually considered fever.
   An oral temperature of ≥ 38.0°C (100.4°F) over at least 1 hour indicates a fever state.[3]
   A single arterial temperature > 38.8°C (101.8°F) in the absence of obvious environmental causes is usually considered fever.
   An arterial temperature > 38.4°C (101.2°F) over at least 1 hour indicates a fever state.

Clinical Information (cont'd)

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.[4] 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:	**36.3-37.8°C**	(97.4-100.1°F)
Oral:	**35.9-37.5°C**	(96.6-99.5°F)
Esophageal:	**36.9-37.8°C**	(98.4-100.0°F)
Rectal:	**36.5-37.9°C**	(97.7-100.3°F)
Axillary:	**35.3-37.1°C**	(95.5-98.8°F)
Oronasal:	**35.9-37.2°C**	(96.6-99.0°F)

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]

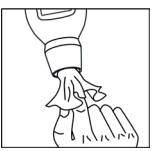
References:

1. Kuzucu EY. Measurement of temperature. Int Anesthesiol Clin, 3(3):435-49, May, 1965
2. El-Radhi AS, Carroll JE. Fever in Paediatric Practice, Ch 2, pp 15-49, Oxford Blackwell Scientific Publications, 1994
3. Hughes WT et al. 1997 Guidelines for the use of antimicrobial agents in neutropenic patients with unexplained fever. Infectious Diseases Society of America (IDSA)
4. Tandberg D et al. Effect of tachypnea on the estimation of body temperature by an oral thermometer. NE J Med, 308, 945-46,1983
5. 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

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.

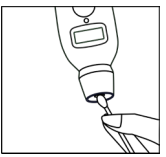
Probe lens and cone should be shiny clean, if not, wipe with an alcohol prep, or with a swab moistened in alcohol or water.



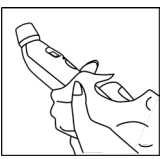
Cleaning the Instrument (cont'd)

Do not hold the TemporalScanner 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.



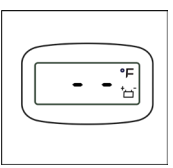
Thermometer case can be cleaned with any hospital approved disinfectant, alcohol, even bleach solutions. Avoid gritty, abrasive cleaners as they can scratch the thermometer.



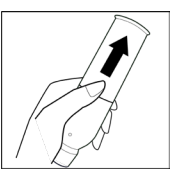
Changing the Battery

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

Blinking battery icon with 2 dashes: not enough energy in the battery to measure correct temperature. Replace battery.

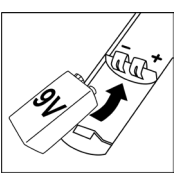


Remove the battery compartment door by squeezing on the ridges with your thumb, and pushing away as indicated. Use both thumbs if necessary.

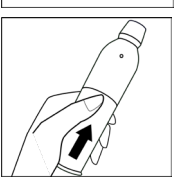


Insert a 9-volt battery as illustrated, with the positive (small terminal) always on the right.

Use an alkaline or a heavy-duty 9V battery.



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



Additional Information

To evaluate, email:wwmed@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/international-tat-2000

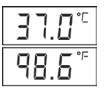
For EMC Guidance, visit exergen.com/emc.
For Calibration information, visit exergen.com/cvk.
For Returns and Repair, visit exergen.com/rma.
For Customer Service, email wwmed@exergen.com.

Display Messages

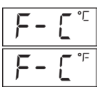
To Select °F or °C Mode

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. The original factory setting is °C. If you wish to change it to °F, follow the steps below:

1. Starting from a blank display tap the button until the flashing **F - C** appears. The current temperature mode will appear in the upper right indicated by the small **°F or °C**.



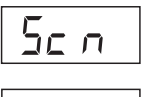
2. To change from the °C mode to the °F mode, press and hold button until the small **°C** in the upper right of the display changes to **°F**. A beep will indicate that the setting has been changed, and the TemporalScanner will automatically shut off.



3. To change from the °F mode to the °C mode, repeat step 2, and press and hold the button until the small **°F** in the upper right of the display changes to **°C**.

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.



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

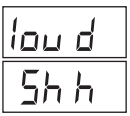
- The target temperature measured is lower than 16°C (61° F).

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

- The temperature of the thermometer is lower than 16°C (61°F). 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.

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 LEDs 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:

1. Starting with a blank display, tap the power button until the display flashes **loud**.
2. 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.
3. To turn the beeper and front LED back on, repeat step 1 to find **Shh** then step 2 to change into **loud**.

Product Specifications

Clinical Accuracy: Meets ASTM E 1965-98 and EN60601-1 standards for electronic and radiation thermometers to the extent applicable to thermometers that measure the surface of the skin over the temporal artery.
EMI/RFI Protection: Error message displayed
Calibration Protection: Error message displayed
Temperature Range: 16 to 42°C (61 to 107.6°F)
Operating Environment: 16 to 40°C (61 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 14,000 readings** (9V alkaline battery)
Size: 17.8 cm x 4.45 cm x 3.18 cm (7.0 in x 1.75 in x 1.25 in)
Weight: 130 g (4.59 oz) incl batt
Display Type: High contrast LCD
Construction Method: Impact resistant casing, hermetically sealed sensing system
Warranty: 7 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°C (+/-0.4°F) whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM standards E667-86 and E1112 is +/-0.1°C (+/-0.2°F).

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

**Approximate number of readings when scanning for 3 seconds and reading the temperature display for 5 seconds before turning thermometer off. Low battery indication will be visible when half of the battery life is used. If all measurements allow the full 30 sec on time for the display, total readings per battery is approximately 2600.

The CLINICAL THERMOMETER is an ADJUSTED MODE CLINICAL THERMOMETER. Correction method is proprietary. Laboratory testing protocol for laboratory accuracy available upon request.

	Symbol for Manufacturer		Consult instructions for use
	Degree of Protection Against Electrical Shock Type B Applied Part, Battery Operated		Do not throw this device away in the trash, contact Exergen Corp. for disposal and recycling instructions.
IPX0	No protection against water.	LOT	Batch code
	Caution	 9VDC	ON (only for part of equipment)
 MADE IN USA	Made in USA	MD	Medical Device

Seven Year Warranty Exergen Corporation warrants each new Exergen TemporalScanner 2000-EC (except battery) against defects in materials or workmanship for a period of seven 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. **NOTE:** No other warranty, written or verbal, is authorized by Exergen Corporation. *Read enclosed instructions carefully.

EC REP **EMERGO EUROPE**
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6827 AT Arnhem
The Netherlands

CH REP **MedEnvoy Switzerland**
Gotthardstrasse 28
6302 Zug Switzerland

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Clinical studies, multiple language videos, & user manuals:
exergen.com/international-tat-2000

document 818580r2

Invented, designed, and manufactured in the U.S.A. in factories owned by Exergen.