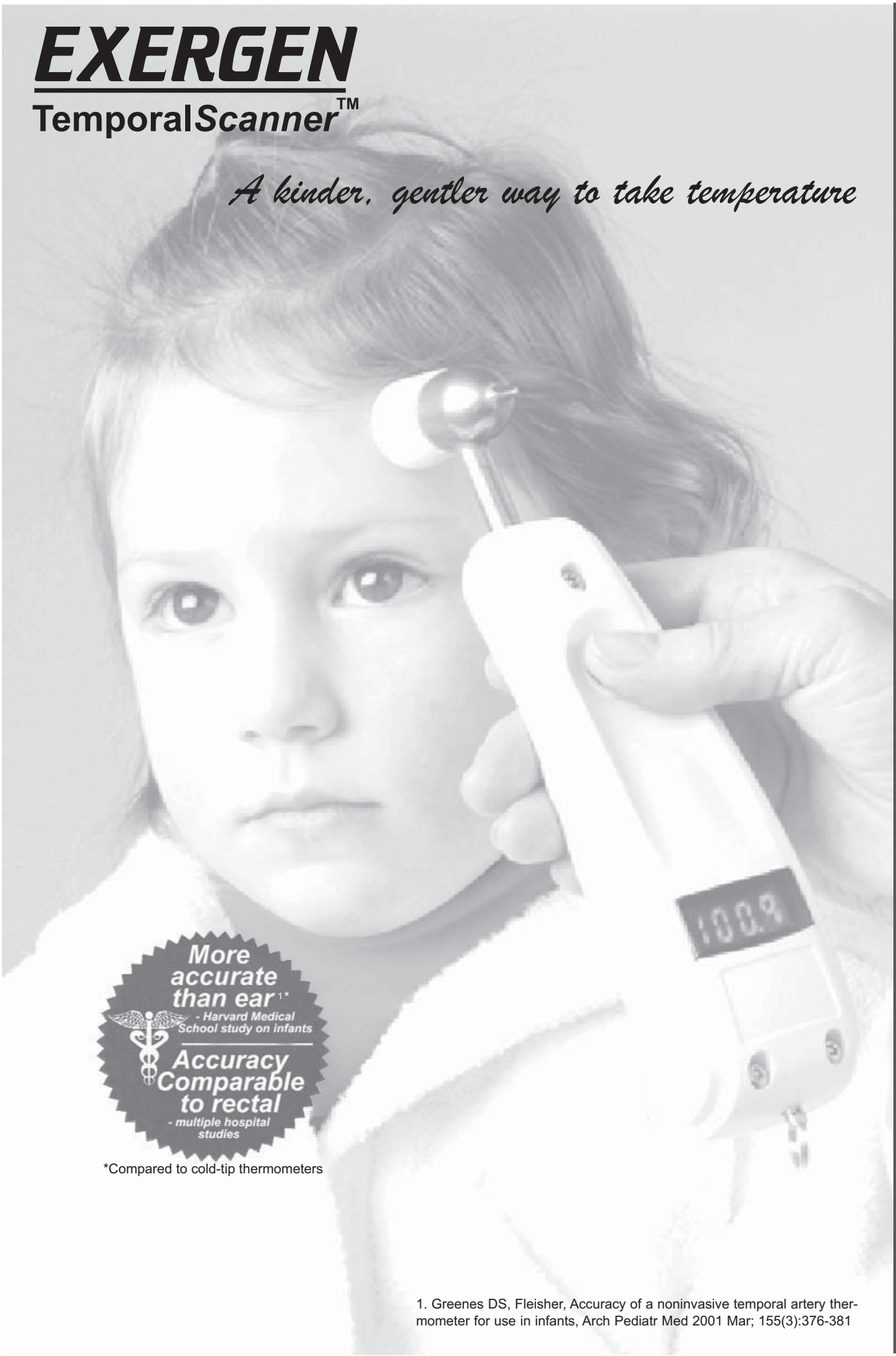
EXERGEN

TemporalScanner™

A kinder, gentler way to take temperature



*Compared to cold-tip thermometers

1. Greenes DS, Fleisher, Accuracy of a noninvasive temporal artery thermometer for use in infants, Arch Pediatr Med 2001 Mar; 155(3):376-381

Model TAT-5000

Reference Manual

Important Safety Instructions

READ ALL INSTRUCTIONS BEFORE USING

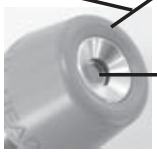
When using the product, especially when children are present, basic safety precautions should always be followed, including the following:

- If you have any additional questions regarding use or care of the thermometer, please see www.exergen.com or call customer service at 617-923-9900.
- 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 60 to 104°F (15.5 to 40°C).
- Always store this thermometer in a clean, dry place where it will not become excessively cold (-4°F/-20°C), or hot (122°F/50°C).
- The thermometer is not shockproof. Do not drop it or expose it to electrical shocks.
- Do not Autoclave - Please note cleaning and sterilizing procedures in this manual.
- 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 following the instructions in this manual. For service, repair, or adjustments, return your thermometer to Exergen.
- Never drop or insert any object into any opening.
- If your thermometer will not be used regularly, remove the battery to prevent possible damage due to chemical leakage. If the battery leaks, remove carefully. Do not allow bare skin to touch leaking fluid.
- Dispose of used batteries properly. Do not wrap them in metal or aluminum foil. Wrap them in newspaper before disposing of them. Do not burn them. Battery may explode if overheated.
- Not suitable for use in the presence of flammable anaesthetic mixtures.

SAVE THESE INSTRUCTIONS.

Product Map

Probe Cone



Probe Lens

ON Button

Automatic turn-off in 30 seconds (when measuring in body temperature range, otherwise 5 seconds)

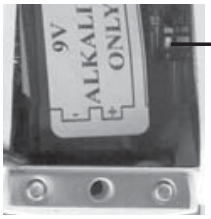
LED Display Screen

Battery Compartment
9-volt battery

Battery Compartment Door

9-Volt Battery

Compartment Door Screw



F/C Switch

Introduction to Temporal Artery Thermometry

The Method

Temporal artery thermometry (TAT) is a completely new method of temperature assessment, using infrared technology to detect the heat naturally emitting from the skin surface. In addition, and of key importance, the method incorporates a patented arterial heat balance system to automatically account for the effects of ambient temperature on the skin.

This method of temperature assessment has been shown to improve results and reduce costs by non-invasively measuring body temperature with a degree of clinical accuracy unachievable with any other thermometry method.

Temperatures are more reliable than with other methods. Fevers are identified sooner. Treatment can be initiated sooner. We trust you will find temporal artery thermometry is simply a better method.

Why the Temporal Artery

The TAT method was developed in response to the clinical requirements for a truly non-invasive, accurate method of thermometry. Oral thermometry is subject to many artifactual errors; rectal temperature meets with strong resistance from patients, parents, and even many clinicians. Ear thermometers, although convenient, are sensitive to technique. Some brands are known to miss fevers, and it's difficult to consider the use of an aural thermometer when 95% of pediatric visits concern ear infections.

A site for detecting fevers with roots dating back to centuries before Christ, the temporal artery demonstrated the necessary requirements to meet the stringent demands of clinical medicine today: it is easily accessible, contains no mucous membranes, and notably, maintains a relatively constant perfusion rate, ensuring the stability of blood flow required for the measurement method.

As a site for temperature measurement, the temporal artery presents many benefits: it poses no risk of injury for patient or clinician, eliminates any need for disrobing or unbundling, and is suitable for all ages.

Table of Contents

Before Using, Familiarize Yourself with the Instrument

- **To Scan:** Depress the red button. The instrument will continually scan for the highest temperature (peak) as long as the button is depressed.
- **Clicking:** Each fast click indicates a rise to a higher temperature, similar to a radar detector. Slow clicking indicates that the instrument is still scanning, but not finding any higher temperature.
- **To Retain or Lock Reading:** The reading will remain on the display for 30 seconds after button is released. If measuring room temperature, the temperature will remain on the display for only 5 seconds.
- **To Restart:** Depress the button to restart. It is not necessary to wait until the display is clear, the thermometer will immediately begin a new scan each time the button is depressed.
- **Pulse Timer:** The thermometer has a built-in pulse timer. To activate, you should touch something >90 °F (32 °C) (skin), press the red button once and release. The display will remain on for 30 seconds.

The Scan

One of the most important features of the thermometer is its ability to scan. It is a patented feature of the instrument. Scanning is critical in obtaining the correct temperature, since there are temperature gradients present not only inside the body, but across the entire surface of the body.

The object of scanning is to capture the highest temperature, the peak, in the area being scanned. As long as the button is depressed, the thermometer will be continually sampling and recording the highest temperature it measures.

Test it first on your hand to get comfortable with the concept.

Depress the red button, and keep it depressed. Scan the probe over the center area of your palm, keeping the probe about a half an inch off the surface to avoid cooling the skin. The display will flash **SCAN**, and there will be a soft but rapid clicking sound each time the sensor detects a temperature higher than the one before. When the flashing and clicking slow to a little less than 1 per second, the peak temperature has been reached. Any of the above indications can be used to assure the peak temperature has been reached.

Remove the instrument from your palm and release the button and note the reading on the display.

The reading will be locked on the display for 30 seconds unless you press the button before that time. Repeat the above steps and you should get the same, or very close to the same number, since your hand will usually not appreciably change temperature very quickly.

Practice Holding Your Temporal*Scanner*

The Temporal*Scanner* is ergonomically designed specifically for its application. It's best to hold the instrument with your thumb on the red button, much like you would hold a remote control. Along with allowing you to easily read the temperature display, you will automatically be using finger dexterity to gently position the probe, providing comfort and safety for your patient, and consistently accurate temperature readings.


1

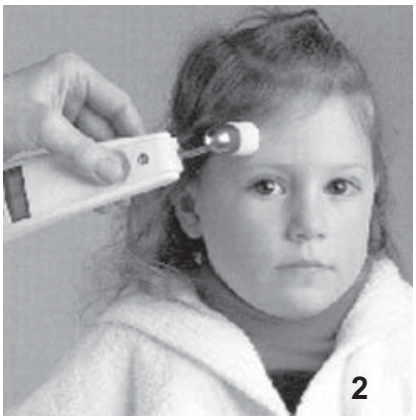
Things To Know Before Taking Temperatures

- Measure only the exposed side. Anything covering the area to be measured would insulate it and prevent the heat from dissipating, resulting in *falsely high readings*. Brush hair aside if covering the TA, or the area behind the ear.

- Slide the thermometer straight across the forehead (midline), and not down the side of the face. Midline over the TA area, the TA is less than 2mm below skin surface, whereas as the TA winds down the side of the face, it is further from the skin surface. Although anatomically correct, sliding downwards would result in *falsely low readings*.

- It is preferable to hold the instrument sideways, as illustrated in Figure 2. Approaching your patient with the instrument straight up and down could be somewhat intimidating.

- When making the measurement behind the ear as in Figure 3, tuck the thermometer under the ear lobe in the soft conical depression on the neck just below the mastoid. This is the place where a dab of perfume is typically applied.


2


3

Using on an Infant

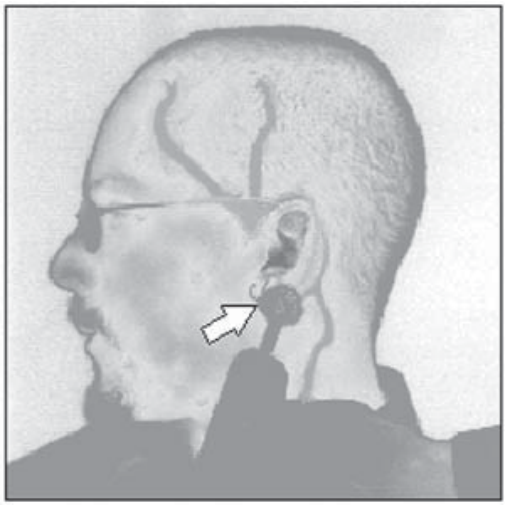
- An infant is apt to present bundled, with blankets and clothing covering the neck area. Fortunately, the perfusion rate is normally strong for infants, and unless visibly diaphoretic, one measurement at the TA is typically all that is required.

  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.


4

Basics of Using the Temporal*Scanner*

Measure only the exposed side. Brush hair aside if covering the TA area.



Brush hair away if covering ear.

1. With probe flush on the center of forehead, depress red button, *keep depressed…*
2. Slowly slide probe midline across forehead to the hair line, *not down side of face*.
3. Lift probe from forehead and touch on the neck just behind the ear lobe.
4. Release the button, read, and record temperature.

Alternate sites when TA or BE are unavailable:

- Femoral artery: slowly slide the probe across groin.
- Lateral thoracic artery: slowly scan side-to-side in the area ~midway between the axilla and the nipple.
- Axilla: insert probe in apex of axilla for 2-3 seconds.

Questions? Please call us at 800-422-3006

Using the Temporal*Scanner* on a New Mother

- **Measure exposed skin**
- **Keep the red button depressed throughout measurement**

(Brush bangs aside if present)

1. With probe flush on center of forehead, depress red button.
2. *Slowly* slide probe across the forehead into the hair line.
3. Lift probe from forehead.

(Brush hair away if covering ear)

4. Touch probe to neck just behind the ear lobe.
5. Release button, read, and record temperature.
    - *Temperature will remain on display for 30 seconds after the red button is released.*
    - *Sequence can be restarted at any time without waiting for display to clear.*

Questions? Please call us at 800-422-3006

Temping Baby in Bassinette, Open Crib, or with Mom

- Instrument should be in same temperature environment as the baby for approximately 20 minutes.
- Measurement site must be exposed.
- One measurement, preferably at the TA, is all that is required.

Preferred site is the temporal artery area. In this case, behind the ear could be alternate site, as both are exposed.

Temporal artery area is the only option in this case, as the neck area is not exposed.

Temperature at the Temporal Artery Area

1) Gently touch probe to center of forehead.
   - ♥ *Depress red button and keep depressed.*
2) Slide probe over the TA area into hairline.
   - ♥ *If more convenient, slide from hairline towards center of forehead.*
3) Release button, remove from head, and record.

Temperature Behind the Ear

1) Gently nestle probe on neck behind the ear.
   - ♥ *Depress red button and keep depressed.*
2) Maintain skin contact until numbers stop.
3) Release button, remove from head, and record.

Questions? Please call us at 800-422-3006

Frequently Asked Questions

What is the Temporal*Scanner*?

The Temporal*Scanner* is an infrared thermometer designed for accurate, completely non-invasive temperature assessment by scanning the temporal artery (TA). *It is breakthrough technology.*

How does it work?

Temperature is measured by gently stroking the Temporal*Scanner* 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 the ambient temperature. It samples these readings some 1000 times a second, ultimately recording the highest temperature measured (peak) during the course of the measurement. The Temporal*Scanner* emits nothing - it only senses the natural thermal radiation emitted from the skin.

How accurate is it?

It has been clinically proven in premier university hospitals to be more accurate than ear thermometry, and better tolerated than rectal thermometry. It is a superior method for patient and clinician alike.

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 behind the ear lobe. As with diaphoresis, the perfusion will be high in the presence of head trauma.

Why measure behind the ear lobe?

Sweat causes evaporative cooling of the skin on the forehead, and introduces the possibility of a false low temperature. Fortunately for the method, during diaphoresis the area on the head behind the ear lobe will always exhibit the high blood flow necessary for the arterial measurement.

Why not use only the area behind the ear lobe?

Since the arterial branch is deeper behind the ear lobe than at the temple, under normal conditions it is less accurate because of its variability. But under diaphoretic conditions, the blood flow behind the ear lobe is as high as at the TA, making it as accurate as the TA, *but only during diaphoresis or with head trauma as previously mentioned.*

What are the benefits of using temporal artery thermometry?

Besides the inherent accuracy of the method, TAT presents no risk of injury for patient or clinician, eliminates the need for disrobing or unbundling, and is suitable for all ages.

What is arterial temperature?

Arterial temperature is the same temperature as the blood flowing from the heart via the pulmonary artery. It is the best determinant of body temperature, and unaffected by the artifactual errors and time delays present with oral and rectal methods.

How does the Temporal*Scanner* compare to our old method?

Arterial temperature is close to rectal temperature, approximately 0.8ºF (0.4°C) higher than oral temps. Expect larger differences at times, however, as the dynamics of thermoregulation favor the temporal artery method.

High readings?

Temperatures measured with Temporal*Scanner* may be higher than your current method, especially if you are used to oral or axillary temps. Oral and axillary temperatures can be misleadingly lowered due to patient activity such as mouth breathing, drinking, tachypnea, coughing, talking, etc, and periods of vasoconstriction during the fever process. Any or all of these conditions may even mask fevers that the Temporal*Scanner* will detect.

Low readings?

A patient's temperature measured with the Temporal*Scanner* is normally never appreciably lower than oral temperature. Lower temperatures are usually from scanning too fast, not keeping the button depressed, a dirty lens, or a sweaty forehead.

What else should I know?

False high readings:

- Measure only skin that is exposed to the environment. Any covering, hair, hat, bandages, etc, would prevent the heat from dissipating, causing the reading to be falsely high.

False low readings:

- Multiple readings can cool the skin, so if you take another measurement immediately, expect a slightly lower reading.
- Slide the thermometer straight across the forehead, not down the side of the face where the TA could be embedded under cartilage or fat.
- Keep the probe flush on the skin, as in the picture on the right. If angled, you will be measuring ambient air as well as the TA area.

Memorable solutions?

- Measure only the side exposed to the environment. The Temporal*Scanner* assumes the skin it measures has equilibrated to ambient, so a down or covered side could be falsely high as heat is trapped and the skin is unable to equilibrate.
- If the up side is not the side closest to you, try scanning *from* the hairline towards the center of the forehead.
- Scan *slowly* across the TA area; if you scan too quickly you can miss the peak.

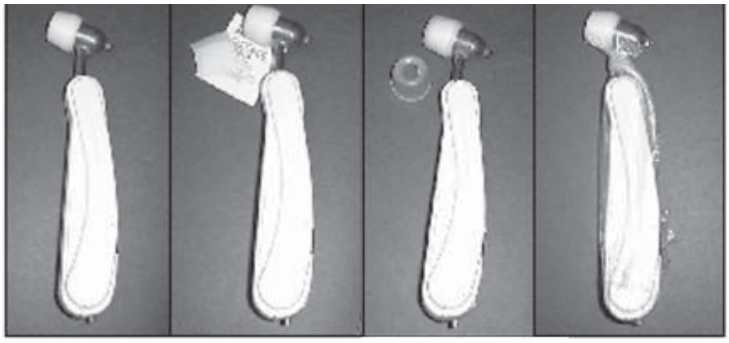
Conditions that could affect a reading	...and their solutions
• Bandages or pressure dressings covering the forehead.	• If accessible and dry, measure on the area behind the ear lobe only.
• Forehead abrasions, burns, sweat.	• Consider using the alternate sites: femoral artery, lateral thoracic, or axillary areas.
• Agitated or combative patient.	
• Patient's forehead in direct draft from vent or fan.	
• Thermometer in different ambient temperature than patient: i.e. window ledge directly exposed to hot sun or cold weather, or in direct line of air conditioning or fan.	• The Temporal*Scanner* should be kept in the same ambient temperature as your patient. Each 10° difference in ambient can cause a 1° error in the reading.

What should I know about the instrument?

- TAT-5000 can be used with either disposable caps or full sheath. Can be used without disposables if terminally cleaned between patients.
- Can be cleaned with any hospital approved disinfectant, alcohol, and even bleach solutions. *Use only alcohol solution for sensor lens*.
- ”bAtt” on the display indicates a low battery. Replace with a 9-volt alkaline battery.
- Probe lens should be shiny clean. If not, wipe with an alcohol prep or Q-tip dipped in alcohol. Occassionally follow with a damp wipe of water to remove any alcohol residue buildup.
- A low or high reading outside body temperature range is indicative of the instrument’s failsafe mode, signifying a mechanical failure.
- Can be used in either ºC or ºF.

Disposable Cover Options

(Model Illustrated: TAT-5000)



No Cover	No Cover	Probe Cap	Full Sheath
Terminal Cleaning at Patient.	Disinfectant Wipe Between Patients.	Covers Entire Probe.	Covers Entire Instrument.

Model TAT-5000 All Options

Accessories

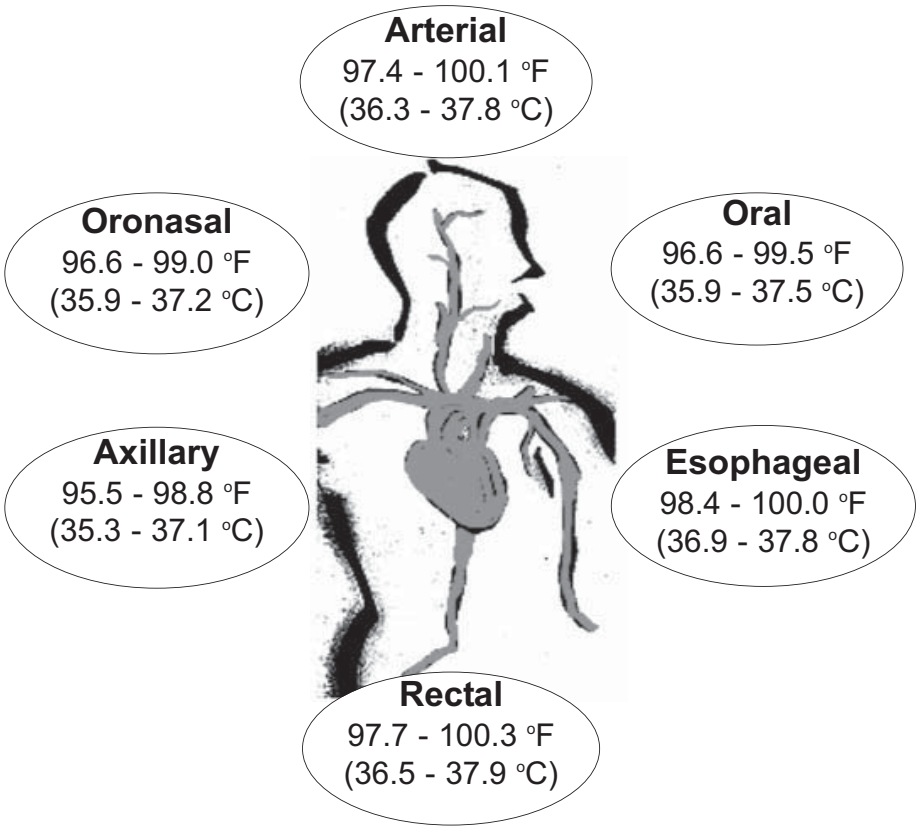
1. Combination Unit
   PN 134200
2. Instrument Holder (shown with security cable)
   PN 134201
3. Cap Dispenser
   PN 134202
4. Disposable Caps
   PN 134203
5. Security Cables
   8 ft. coiled cable PN 124309
   8 ft. coiled cable - Latex free - PN 124311
   6 ft. vinyl-covered steel - PN 134302
   8 ft. vinyl-covered steel - PN 134030
6. Keyless Self-Locking Wall Mount
   PN 124305
7. Keyless Self-Locking Wall Mount
   (shown with resposable cap dispenser)
   PN 124306

Guidelines for Patient Temperature Assessment

Comparing with Other Methods of Thermometry: *Expect the Differences*

Unless you are using PA catheters or Exergen aural thermometers with AHB for temperature assessment, expect to see differences compared to your current thermometers. Arterial temperature measurement leads all other methods in identifying fever or defervescence, and is unaffected by patient activity. Accordingly, it will be sometimes be different — *but correct*.

The following chart presents the mean normal temperature at the common temperature measurement sites under normal resting conditions.



Normal Body Temperature (BT)

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

General Rule of Thumb

On a stable, resting patient, rectal temperature is ~2°F (1°C) higher than axillary and ~1°F (0.5°C) higher than oral temperature.[1]

On a stable, resting patient, arterial temperature ~ rectal temperature.

Expect the Differences

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

Guidelines for Patient Temperature Assessment

1. **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]

2. **Oral Temperature Risks:** Oral temperature can be clinically misleading, and many febrile patients can have a "normal" temperature, even when tachypnea was unobserved.[4]

3. **Rectal Temperature Risks:** Rectal temperature should only be considered as a good approximation of core temperature when the patient's thermal balance is stable. When monitored during or after surgery, rectal temperature measurement is not suitable, and the possible delay in diagnosis of a thermal abnormality could lead to an irreversible crisis.[5]

4. **Axillary Temperature Risks:** 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]

5. **Temporal Artery Temperature (TAT) Values:** On a stable resting patient, TAT is ~0.8°F (0.4°C) higher than an optimum oral temperature, and close to a rectal temperature.[7] However, during febrile episodes, the difference can be much higher, mainly because of the artifacts of oral and rectal sites.

6. **Comparison Between Sites:** Review of published literature reveals mean differences between non-TA sites of 0.4° to 3.1°F (0.2° to 1.7°C) with the actual differences of up to 6.5°F (3.6°C) routinely reported, especially in febrile patients.[8]

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.
7 Exergen Corporation. Manufacturer's data on file.
8 Review of subject material peer-reviewed journals.

Determining a Fever Threshold for Temporal Artery Thermometry

Threshold Defining Fever

- A threshold for defining fever is the temperature level above which false positives due to normal variations in temperature, including range of normal mean + circadian effects + other effects (metabolic, ovulation, etc.) are unlikely.

Threshold for Fever Workup

- Not all fevers require a fever workup. A fever workup is an early management tool in assessment of the likelihood of septicemia or bacteremia, and initiated whenever an infectious source is suspected. The level of temperature triggering such that investigatory workup is sufficiently high to avoid false positives resulting in unnecessary discomfort and expense for the patient, but low enough for early identification and intervention.

Primary Points

- Temperatures measured with temporal artery thermometry may be higher than normally seen with other clinical methods, and therefore require an adjustment in both protocol and perception.
- No one value can apply to every temperature measurement site. Note old rule of thumb: Rectal temperature is ~1°F higher than oral temperature and ~2°F higher than axillary temperature.
- Recommended threshold for fever workup using arterial temperature assessment is a single temperature >101.8°F, or a temperature >101.2°F sustained for more than 1 hour.
- Adjustment of ~1°F is necessary to raise the temperature level normally mandated for fever workups to prevent false positives, unnecessary cultures and blood tests, etc.

Physician Recommended Guidelines for Fever Workup[1]

Temperature Site	Core & Temporal Artery	Oral & Temporal Artery in Oral Calibration	Axillary
Fever Workup Recommendation	**Single value >101.8 Sustained values (>1h) >101.2**	**Single value >101 Sustained values (>1h) >100.4**	**Single value >99**

[1]Source on file at Exergen Corporation

Body Sites for Temperature Assessment

An Overview of Temperature Measuring Sites

Oral Temperature

Oral temperature measurement is by far the most common clinical method in use today, and is responsible for masking the greatest number of fevers. Oral temperature can be misleadingly lowered by patient activity such as tachypnea, coughing, moaning, drinking, eating, mouthbreathing, snoring, talking, etc. Alarmingly, another cause of low oral temperatures is the fever itself. For each 0.6°C (1°F) temperature elevation, the pulse rate usually increases approximately 10 beats per minute, there is a 7% increase in oxygen consumption, increasing the respiratory rate approximately 2 cycles per minute. The resulting increase in respiration can further lower oral temperature sufficiently to mask a fever.

Figure 1 is of interest as it illustrates fever masking even when clinicians had eliminated all obvious mouthbreathers from the study. This emergency room study presents the temperature difference (rectal minus oral) in 310 patients with a wide range of respiratory rates. The straight line of best fit is shown. The stippled area demonstrates the traditional normal difference between rectal and oral temperature (0.3°- 0.65°C). The investigators concluded that many patients with tachypnea would have oral temperatures in the normal range despite the presence of clinical fever, seriously misleading the clinician.

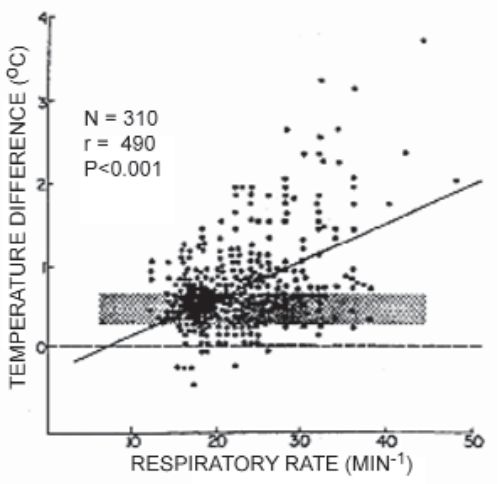


Figure 1 Temperature Difference (Rectal minus Oral) in 310 Patients with a Wide Range of Respiratory Rates. The straight line of best fit is shown. The stippled area demonstrates the traditional "normal" difference between rectal and oral temperature (0.3 to 0.65°C).

Rectal Temperature

Generally, rectal temperature is considered an indicator of deep tissue and critical tissue temperatures, but long standing data demonstrate that rectal temperature can be a lagging and unsatisfactory index. Fifty years ago, Eichna et al reported differences between intracardiac, intravascular and rectal temperatures on afebrile patients to be so insignificant that for all practical purposes, the temperatures may be considered to be the same. Certainly rectal temperature is far less invasive than a pulmonary artery catheter, however, in the same study, data on febrile patients support sizeable differences.

Other comparisons between rectal, esophageal and aortic temperatures undertaken on hypothermic patients by different researchers also confirm similar differences. Subsequent but equally comprehensive comparisons on healthy volunteers further confirmed not only temperature differences, but also quantified significant lags in rectal temperature vs. hypothalamic temperature by times of order one hour. This is of interest since the blood as it enters and affects the critical tissue in the hypothalamus should have considerable significance in thermal homeostasis. However, this early data on hypothalamic temperature was measured by a thermocouple inserted against (and often times perforating) the tympanic membrane. With significant improvements in the methodology, more recent clinical observations show that the time constant of rectal temperature in critically ill patients may be considerably longer, and in some cases, as much as a day.

Under certain conditions, rectal temperature is even contraindicated; for example, severe arterial insufficiency in one or both legs might be associated with falsely low readings, or in conditions affecting peripheral blood flow such as cardiogenic shock. More common contraindications include neutropenia, severe hemorrhoids, and recent anorectal surgery. A less common but serious complication of rectal temperature measurement is perforation of the rectum, which has even occurred in the absence of predisposing rectal pathology.

Rectal temperature measurement is not well tolerated, by either the patient or the caregivers, and is uncomfortable and embarrassing. Rectal temperature is subject to inaccuracies of placement, environment, and time of insertion. And although it is well established that a rectal temperature requires two to five minutes or more to reach optimum measurement with a glass mercury thermometer, in practice many are withdrawn in just one minute, a technique responsible for misleadingly low readings.

In fact, it is difficult to attribute any thermal significance at all to the rectal area. It is not known to contain any thermoreceptive elements and its geographical location distances it from both the CNS and the crossroads of circulation at the heart, which are the vital informational elements.

Tympanic Membrane and Ear Temperature

A temperature site of more recent onset is the ear. It is a compelling site, accessible, free from bodily fluids, and not easily influenced by patient activity. This temperature is measured using infrared technology, and there are three types of infrared thermometers: tympanic, ear, and arterial heat balance. It has, however, become common practice to refer to any thermometer making the measurement at the ear as a tympanic thermometer. Although the terms tympanic and ear may be used interchangeably, they actually describe quite different measurements.

True Tympanic Membrane Temperature

The tympanic membrane is deep inside the skull, and is not subject to the artifactual errors that can affect oral, rectal, axillary and ear temperatures. True tympanic thermometers provide an uncorrected, direct reading of the temperature of the tympanic membrane, and are preferred for continual measurement during certain surgical procedures, and for use in extreme conditions such as military use, research, and sporting events.

There are two types of instruments used to make the measurement. One is a long thin thermocouple probe, usually fitted with cotton at the end, that must come in contact the tympanic membrane. There is much historical data on the efficacy of tympanic thermometry using contact thermocouples, stemming originally from work done over thirty years ago. However, this method never gained wide acceptance due to the risk of injury to the delicate membrane. The second is an infrared device, the Exergen Ototemp 3000SD, which is inserted deep into the ear canal and scanned to view the membrane, and is used in military and sports medicine.

Ear Temperature

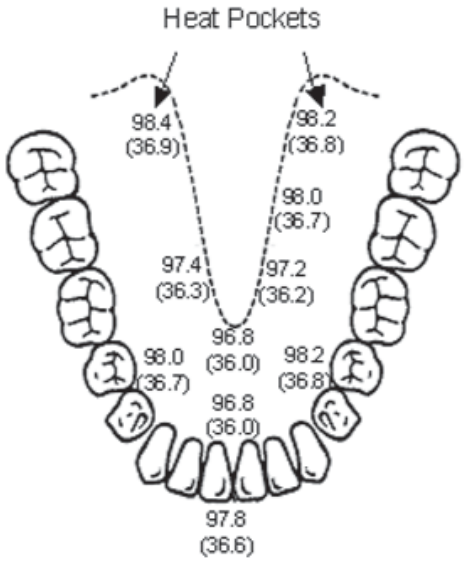
Ear thermometry is a method of measuring the temperature of the external portion of the ear canal. For routine clinical use, ear thermometry has been preferred as a simpler, faster, and more convenient alternative to true tympanic thermometry. The absolute temperature of the outer ear, however, is lower, and more variable than tympanic membrane temperature. It is subject to a cooling effect resulting from the body heat being radiated to the environment, and a heat balance method is required in order to produce the requisite accuracy. When combined with an arterial heat balance method, ear thermometry provides a highly accurate indication of body temperature, but those ear thermometers without it have high rates of missed fevers.

Reproducibility in Temperature Measurement

Multiple temperature readings in the same area, mouth, rectum, axilla, ear or temporal artery, make for variability with each separate measurement. This can be confusing for clinicians, since they expect the same number with each measurement. The non-reproducibility of the readings, however, is not a function of the devices, but simply a function of physiology. The human body is a myriad of small gradients, and variability of readings will occur on every method of temperature measurement. In addition, thermometers are at room temperature, nearly 30°F (17°C) cooler than the tissue being measured. That said, it is then easily recognized how time of insertion, probe placement, and tissue cool down all affect reproducibility of temperature readings, no matter what device is employed.

Oral Temperature

By far, the most common method of temperature measurement is sublingual measurements. Placement of the probe under the tongue, however, can result in substantial differences, and caused by just a slight repositioning of the probe. The standard heat chart commonly used by manufacturers of electronic thermometers on the right illustrates a difference of nearly 2°F (1°C) depending on exactly what area is being touched by the probe.



Differences from repeated oral temperatures can vary even further, as they can superimpose artifactual errors over the thermal gradients. Patient activities also affect the reading, these varying by individual and activity. In fact, one large manufacturer cautions waiting at least 15 minutes after ingesting hot or cold food or drink, after exposure to extremely hot or cold weather, and after smoking.

Ear Temperature

The journals abound with citations addressing the lack of reproducibility of ear thermometers. In fact, Thermoscan instructs the user to take three separate temperature measurements, and to select the highest of the three. While much of this has to do with the device, physiology also plays a large part. In such a small area, the difference of 30°F (17°C) between the room temperature probe and the temperature of the ear being measured results in a noticeable tissue cool down. Geriatric patients typically have a lower rate of perfusion than a younger individual, and it can take several minutes for the ear to equilibrate following the use of an ear thermometer.

Rectal Temperature

Time and placement is critical for rectal temperature measurement. It has long been recommended that the measurement be taken for at least five minutes or more for accuracy. The measurement is also dependent on the depth of insertion, and just a few centimeters can result in a noticeable difference.

Temporal Artery Temperature

Because of the expanse of area being measured, and the normally strong perfusion of the artery in particular, temporal artery temperatures should be as reproducible as any other method. There may be slightly more variability observed in normothermic conditions compared to febrile conditions, but it is minimal. Of interest, the temporal artery area will equilibrate in the shortest period of time compared to any other site. For absolute accuracy, however, it is recommended to wait 30-60 seconds before repeating a temperature on the same side, although, depending on the individual, the time involved can certainly be much shorter. The limitation in time is almost entirely the behind-the-ear measurement, as the perfusion rate per tissue mass is not quite as high as the temporal artery. Since the method employs the area behind-the-ear with every measurement, this area is the time limitation.

Your Temperature

Normal Temperature

Normal human temperature is around 98.6 degrees. But did you know that only 8% of the people in the world have a normal temperature of exactly 98.6?

A temperature that is normal for you may even be a whole degree or so above or below "normal." It is good to know what is normal for you. Try taking your temperature at different times, like in the morning, after a cold shower, or a five-mile hike.

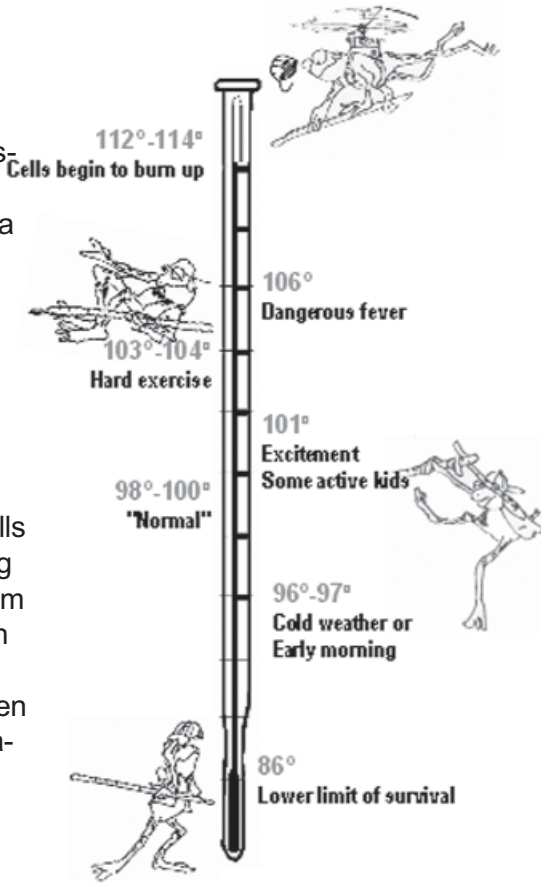
Fever

Fever is when your body's temperature control is set above normal. Fever is a sign that your body is fighting off an infection. It is thought that fever does two things.

When the temperature rises, the body's chemical actions speed up so that damaged tissues can be repaired more quickly. Also, virus or bacteria invaders don't survive well at high temperatures. Perhaps fever is the body's attempt to cook them into submission.

Chills

You have a high temperature and cold skin. You are hot inside, but still you shiver. Chills are your body's way of creating a fever. The muscle action from shivering produces heat, which raises your temperature in an effort to fight off infection. When the crisis is over, your temperature is set back to normal, the skin warms, and you sweat.



Hot Blood or Cold Blood?

A frog in a 70 degree pond is a 70 degree frog. A frog in a 40 degree pond is a 40 degree frog, and is moving very slowly, if at all.

A kid in a 70 degree pond is a 98 degree kid. A kid in a 40 degree pond is still a 98 degree kid, although you can bet he's swimming as fast as he can to get out.

One difference between kids and frogs is the difference between warm-blooded and cold-blooded beings. People have automatic climate control inside their bodies.

Their bodies keep themselves at an even temperature by carefully controlling the rate of burning in their cells.

Frogs are cold blooded, their temperature changes depending on where they are.

Cold blooded creatures have no internal temperature control. Their rate of metabolism is determined by their environment. When the outside temperature drops way down, all their body processes slow way down.

Humans, and all mammals, are souped-up hot-blooded beings. Their metabolisms are speedy, but are kept at an even keel. So no matter what the temperature is outside, the climate on the inside is ever warm and ready for action.[1]

[1]Excerpts from Blood and Guts: A Working Guide to Your Own Insides, Allison L. Katz., Little , Brown and Company, Boston, New York, Toronto, London

Perspiration

The Temporal*Scanner* relies on the skin over the temporal artery to help provide an accurate body temperature. In fact, it is measuring the inside by measuring the outside. Your skin is a sensor, controlling body temperature in two ways: radiation and evaporation. Since most of us don't think about our skin as a sensor, this might be a good time to discuss a little physiology.

We live our entire lives with a body temperature that changes only a few degrees. This is thanks to a very sophisticated climate control, of which the skin is a very important part. Sweating, goose bumps, and heat loss from the skin all help maintain our normal temperature, keeping us comfortable.

When your internal temperature rises, your brain signals your blood to increase circulation to the skin. In this way, the body's internal heat is carried to the surface by the blood, where it is lost by radiation.

If this is not sufficient, your sweat glands sprint into action, and perspiration is released through the pores. This liquid evaporates on your skin and you cool right down. When your temperature drops, your brain signals that heat must now be saved. Less blood circulates to the skin, and sweating stops.

Since there is a lot of cooling going on when you are sweating, both inside and out, it is a good idea to wait till your forehead is dry before taking your temperature with the Temporal*Scanner*. If your forehead is sweaty, the reading would be low. Drying your forehead could help shorten the wait, but there is another place to measure an accurate temperature when perspiring. It is still on the head, but in the little soft depression just behind the ear lobe, the place where young ladies are usually taught to apply perfume.

During perspiration, taking a temperature with the Temporal*Scanner* in the area behind the ear lobe has been proven to be as accurate as a temperature taken at the temporal artery area, were it not wet. Since we sweat first on the forehead, then on the hands and feet, the chances of the area behind the ear lobe remaining dry for the measurement are excellent. And since we already have increased circulation to the skin during perspiration, this area will have the high blood flow necessary for the measurement.

Another instance when a high rate of blood flow on the neck can be assured is following head trauma, either surgical and accidental. At such times the neck area behind the ear lobe can be used as a primary site if the forehead is not available.

If perspiration or head trauma is not present, the area on the neck behind the ear lobe may not have sufficient blood flow to be reliable, and should not be used as the primary measurement site.

If there is heavy perspiration, including moisture behind the ears, wait until area is dry. For use on exercising athletes or other non-clinical subjects, contact Exergen.

For Kids Only

Did you know you always have a temperature? Bet you thought you only had a temperature when you were sick. Absolutely everything has a temperature, even icicles. ***Brrrrrr!***

When you don't feel well, your mom or a nurse might say "let's see if you have a temperature," but what they really mean is "let's see if your temperature is different from normal."

So, when you have your temperature taken, don't be fooled. Your mom and your doctor already know you have a temperature, and are just getting an idea of how things are going inside your body.

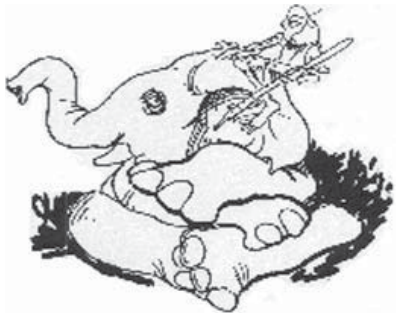
Places to measure your temperature.

Your bum. Babies and little kids get their temperature taken is in their bum. Poor little kids, ***how embarrassing!*** The temperature taken in your bum is the hottest of all the places to take temperature. It's around **99.6°F** most of the time.

Your armpit. When kids get a little bit older, they might have their temp taken under the arm instead of the bum. This is better, but you have to keep the thermometer in ***your armpit*** with your arm tight against your chest for a long time. It's hard to keep it from falling out and breaking, especially if you fly! I wonder if flying causes the armpit temperature to be the lowest in your body. It's around **97.6°F** most of the time.

Your mouth. Now, if you're reading this, you're probably a big kid and so you would most likely have your temperature taken in your mouth. Not too bad, but everyone knows you can trick your mom or your doctor into thinking you're sick by doing stuff with that thermometer. *Bet you already know of ways to do that!* Most of the time, a temperature in your mouth is about **98.6°F.** ***Well sort of...***

Your ears. Now we're down to ears. And please pardon us, *ears beat rears*. But, having your ear pulled sure isn't fun, and when you have an ear infection, it even hurts. Temperature taken in your ear should be higher than in your mouth, but not as high as in your rear.



Your heart. If we were to pick the best place to measure temperature it would be in the center of your heart. But that's pretty dangerous, and surely not be something you would think was fun. ***Arrrrghhh!*** In case you'd like to know, though, temperature in your heart is around **99.4°F.**

Your temporal arteries. There is a special place on your head where we can measure the same temperature as the blood in the middle of your heart. This is because blood is pumped directly from your heart to your head through little tubes called arteries that carry blood up the sides of your neck, up the side of your face just under your skin, and stop at at a place on your forehead called your temple. Guess what they're called?

Wow! Isn't this the same place your mom touches with her hand when you don't feel good?

Did you know that the forehead has been used to detect fevers as far back in time that anyone can remember, over 2000 years? There's a new technology that scans the same place your mom touches, and it's almost as gentle. It's an infrared thermometer called the **Temporal*Scanner***. It measures your temperature with a quick and gentle scan across your forehead. Most of the time, temperature here is around **99.4°F**, same as your heart. Nothing goes in your mouth, your ear, or your rear, and in just a second or two, done!

Now, where is the best place to take your temperature?

Care and Maintenance

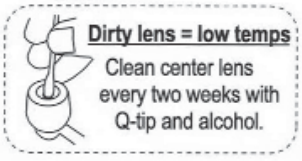
- **Battery:** A standard alkaline 9V battery provides approximately 15,000 readings. **

  To replace, loosen the single screw at the bottom of the instrument and remove the battery cover. Disconnect the old battery and replace with a new one in the same location. Replace the cover, and tighten the screw. Use only high quality alkaline batteries or equivalent.

- **Handling:** The Temporal*Scanner* is designed and built to industrial durability standards in order to provide long and trouble-free service. However, it is also a high precision optical instrument, and should be accorded the same degree of care in handling as you would provide other precision optical instruments, such as cameras or otoscopes.

- **Cleaning the case:** The Temoral*Scanner* case can be wiped down with any hospital approved disinfectant, including bleach.

- **Cleaning the sensor lens:** With normal use, the only maintenance required is to keep the lens on the end of the probe clean. It is made of special mirror-like, coated silicon infrared-transmitting material. However, dirt, greasy films or moisture on the lens will interfere with the passage of infrared heat and affect the accuracy of the instrument. Regularly clean the lens with a cotton swab dipped in alcohol in accordance with the instruction label on the instrument (see below). Use only light force for cleaning, to avoid damaging the lens. Water can be used to remove any residual film left by the alcohol. Do not use bleach or other cleaning solutions on the sensor lens.



CLEANING INSTRUCTIONS ON THE TAT-5000

- **Sterilization:** The industrial grade housing and design of the electronic components allow for completely safe disinfecting with any accepted solution.

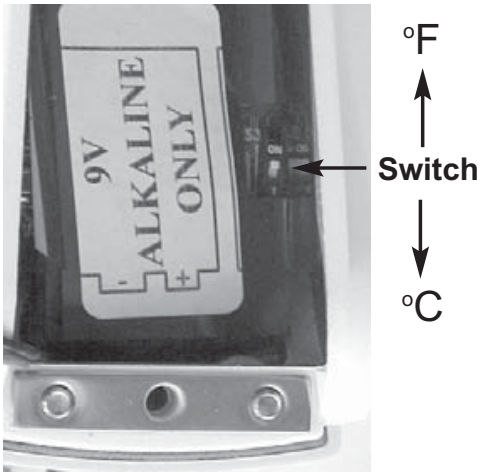
- **Calibration:** Factory calibration data is installed via a computer which communicates with the Temporal*Scanner's* microprocessor. The instrument automatically self-calibrates each time it is turned on using this data, and will never require recalibration. If readings are not correct, the instrument should be returned for repair.

Instructions for Fahrenheit or Celsius Conversion

The Temporal*Scanner* can be used in either °F or °C. To convert from one scale to the other, the only tool necessary is a paper clip or the tip of a small screwdriver.

For °F/°C Conversion:

- Loosen single screw on bottom of case and remove battery cover.
- Lift battery out of the way.
- Locate the little switch to the right of the battery as indicated in the drawing, and with the tip of the paper clip or screwdriver, slide up or down to the opposite position.
- Remove the paper clip or screwdriver.
- Replace battery and cover.



DISPLAY DIAGNOSTICS CHART

The following chart summarizes the fault conditions, and the associated indications:

Condition	Display	Range
High Target	HI	>110 °F (43 °C)
Low Target	LO	<61 °F (16 °C)
High Ambient	HI A	>104 °F (40 °C)
Low Ambient	LO A	<60 °F (16 °C)
Low Battery	bAtt	
Dead Battery	blank display	
Processing Error	Err	Restart. Return to Exergen for repair if error message persists.

*Specifications	TAT-5000
Clinical Accuracy	±0.2° F or 0.1° C Per ASTM E1112
Temperature Range	61 to 110° F (16 to 43°C)
Arterial Heat Balance Range for Body Temperature*	94 to 110° F (34.5 to 43° C)
Operating Environment	60 to 104° F (16 to 40° C)
Resolution	0.1° F or C
Response Time	~ 0.04 seconds
Battery Life	15,000 readings**
Time Displayed on Screen	30 seconds
Size	2.0" x 8.0" x 1.25" (5 cm x 20 cm x 3 cm)
Weight	7.5 oz (213 gm)
EMI and RFI Protection	Complete copper coating on inside of casing
Display Type and Size	Large bright LED's
Construction Method	• Industrial duty impact resistant casing • Hermetically sealed sensing system • stainless steel probe
Warranty	Lifetime

*Automatically applied when temperature is within normal body temperature range, otherwise reads surface temperature.

** Approximate number of readings when scanning for 5 seconds and reading the temperature display for 3 seconds before turning thermometer off.

Calibration Verification Procedure

All Exergen infrared thermometers are designed to permanently maintain their accuracy and normally recalibration is not required unless the thermometer has been physically damaged or experiences component failure. In the unlikely event recalibration might be required, the thermometer must be returned to Exergen for the procedure.

However, calibration can be verified in the lab or clinical units quite easily using a device known as a portable blackbody. A portable blackbody is a reference heat generator (Figure 1), which is a self-contained device providing a stable reference target temperature in the clinical temperature range.

The device is then used to verify the calibration of any Exergen thermometer in question, or for quality checks done on a routine basis. The verifier operates with either a 9-volt power supply plugged directly into any 120 vac wall receptacle, allowing extended use in the laboratory, or it can be completely powered by a 9-volt battery for portable use on the nursing floors.

There are two ways to use the portable blackbody to verify the calibration accuracy of the thermometer in question, either (1) with a certified master reference infrared thermometer, or (2) by using two identical thermometers as a reference against the one in question.

Using the Portable Blackbody

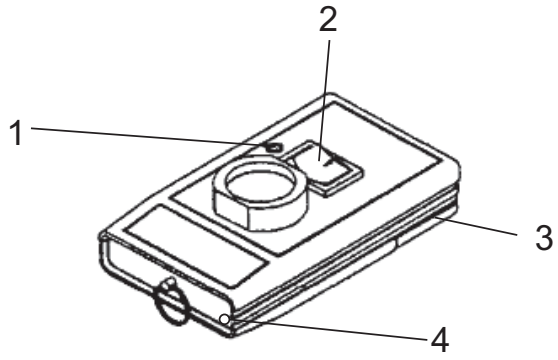
1. Turn on the verifier device, using either a 9-volt battery or the power supply. Make sure the red LED is illuminated.

2. Allow device ~5 minutes for warm-up and stabilization time.

3. Allow certified master or the two reference thermometers and the instrument to be tested to acclimate in the same ambient temperature for at least 10 minutes.

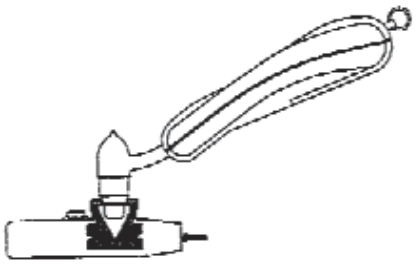
4. For all instruments, make sure the lens at the tip of the probe is clean. To clean, use an alcohol prep or a swab dipped in alcohol, followed by a damp wipe with water to remove any residue.

5. Alternately insert the reference instrument(s) and the instrument being verified into the aperture opening, comparing the readings.



Portable Blackbody Calibration Verifier

1. Power On LED
2. ON/OFF Switch
3. Battery Compartment
4. Power Supply Jack



Using a Certified Master Reference Thermometer in a Portable Blackbody to Verify Calibration

Figure 1

- Accuracy Limits: Comparison between the reference instrument(s) and the instrument being verified should be within ±0.4 ºF (0.2 ºC) for acceptable limits. If not, repeat the process. In the event they still differ by more than the acceptable limits, call Exergen for repair or replacement of the failed instrument.

Verifier Specifications:

Power Source	9-volt battery, or 9-volt power supply.
Battery Life	Approximately 1 hour continuous use.
Low Voltage Indicator	Red LED shuts off when battery voltage drops below ~5 volts.
Temperature Range	97-104 ºF (36-40 ºC)
Cleaning	Wipe down with alcohol or any hospital approved disinfectant. Do not immerse.

Repair

If repair is required:

- Contact Exergen at (617) 923-9900 for a Return Materials Authorization (RMA) Number.
- Mark the RMA number on the outside of your package and packing slips.
- Include a description of the fault if possible.
- Send the instrument freight/postage prepaid to:

  Exergen Corporation
  400 Pleasant Street
  Watertown, MA 02472

- The instrument will be returned freight/postage prepaid.

 Symbol for Date of Manufacture

 Symbol for Manufacturer

 Type Bf, Applied Part

 Attention, Consult Accompanying Documents

 "On" (only for part of Equipment)

 Do not throw this device away in the trash, contact Exergen Corp. for disposal and recycling instructions.

IPXO Ordinary Equipment

Degree of Protection Against Electric Shock Type Bf, Battery Operated

C US 228641 CE 0197

EXERGEN
Straight From the Heart®

EXERGEN CORPORATION • 400 PLEASANT STREET • WATERTOWN, MA 02472 • PH 617.923.9900
www.exergen.com

p/n 818528 r5