

# ***EXERGEN*** TemporalScanner™

TAT-2000 with  
Bluetooth®



**Instruction Manual**

# Important Safety Instructions!

## READ ALL INSTRUCTIONS BEFORE USING

**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, and nursing assistants 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](http://www.exergen.com/s), and recommended for first time users.

TAT-2000 Series thermometers are used by medical professionals in clinical environments. Such medical professionals include physicians, nurses, nurses' aides, patient care technicians, and others who are trained to take the temperature of patients. 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 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 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 FAQ section of this manual. 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](http://www.exergen.com) or call customer service at +1 617-923-9900.

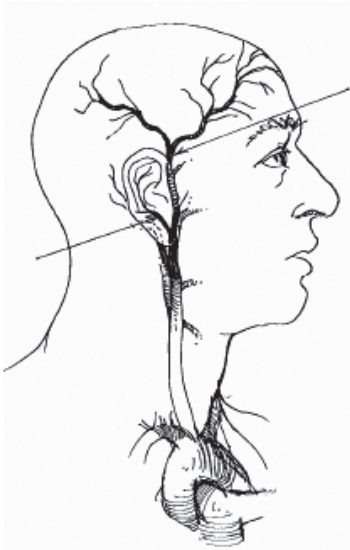
**WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**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 series thermometer. Otherwise, degradation of the performance of this equipment could result.

## SAVE THESE INSTRUCTIONS.

# 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 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.

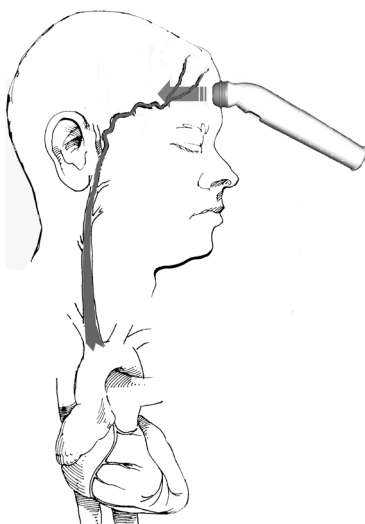
## How accurate is it?

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

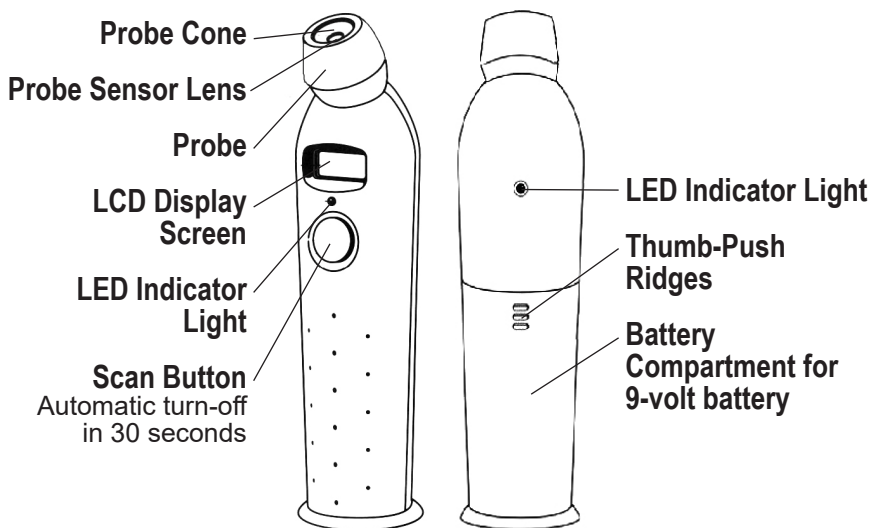
## What are the benefits of TA thermometry?

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).



**Disposable Caps**



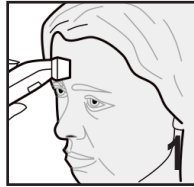
Scan QR Code to reorder

Ancillary items, including disposable caps are available from many distributors, or by calling Exergen Customer Service at 1-351-204-7406, or by emailing [service@exergen.com](mailto:service@exergen.com).

# Measuring TA Temperature

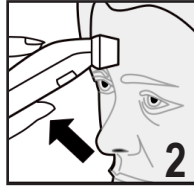
## What you should know before using the TAT:

- 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.
- Solid green lights mean the device is powered, but not scanning, and is not taking a temperature. Restart the measurement by pressing and holding the scan button and scanning correctly.
- Flashing green lights mean the sensor is actively scanning



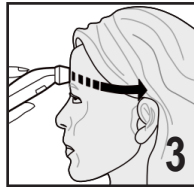
Brush hair aside if covering the TA area

**Place the probe flush on the center of the forehead.**

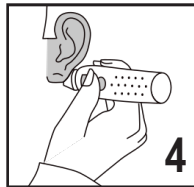


**Press the Scan button,**

Keep depressed throughout measurement...

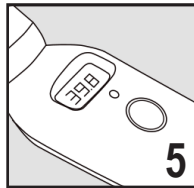


**While button is still depressed, slowly slide the probe midline across the forehead to the hair line**



Brush hair aside if covering ear

**Lift probe from forehead and touch on the neck just 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, press 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  $\approx 1^{\circ}\text{C}$  ( $2^{\circ}\text{F}$ ) higher than axillary and  $\approx 0.5^{\circ}\text{C}$  ( $1^{\circ}\text{F}$ ) higher than oral temperature.<sup>1</sup>

### 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  $\approx 0.4^{\circ}\text{C}$  ( $0.8^{\circ}\text{F}$ ) 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  $\geq 1^{\circ}\text{C}$  ( $1.8^{\circ}\text{F}$ ) above the mean standard deviation at the site of recording.<sup>2</sup>

A single oral temperature of  $\geq 38.3^{\circ}\text{C}$  ( $101^{\circ}\text{F}$ ) in the absence of obvious environmental causes is usually considered fever. An oral temperature of  $\geq 38.0^{\circ}\text{C}$  ( $100.4^{\circ}\text{F}$ ) over at least 1 hour indicates a fever state.<sup>3</sup>

A single arterial temperature  $> 38.8^{\circ}\text{C}$  ( $101.8^{\circ}\text{F}$ ) in the absence of obvious environmental causes is usually considered fever. An arterial temperature  $> 38.4^{\circ}\text{C}$  ( $101.2^{\circ}\text{F}$ ) 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.<sup>4</sup> 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:

<b>Arterial:</b>	<b>36.3-37.8°C</b> 97.4-100.1°F
<b>Oral:</b>	<b>35.9-37.5°C</b> 96.6-99.5°F
<b>Esophageal:</b>	<b>36.9-37.8°C</b> 98.4-100.0°F
<b>Rectal:</b>	<b>36.5-37.9°C</b> 97.7-100.3°F
<b>Axillary:</b>	<b>35.3-37.1°C</b> 95.5-98.8°F
<b>Oronasal:</b>	<b>35.9-37.2°C</b> 96.6-99.0°F

# 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,<sup>5</sup> 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."<sup>6</sup>

### 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

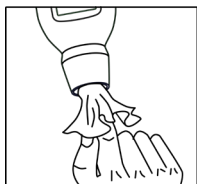
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# Cleaning the Instrument

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.

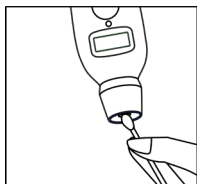
Probe lens and cone should be shiny clean, if not, wipe with an alcohol prep, or with a swab moistened in alcohol or water.



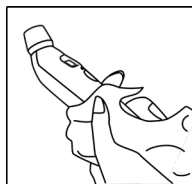
Do not hold the TemporalScanner under the faucet or submerge in water. It is not waterproof.



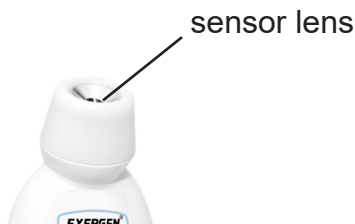
Hold upside-down to prevent excess moisture from entering the sensor area. It will not harm the sensor, but if it becomes too wet, you will be unable to take a temperature until it dries.



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



# Cleaning the Sensor Lens to Maintain Accuracy



The sensor lens is an optical component, similar to a camera lens. Anything obstructing the sensor lens will reduce the signal received by the sensor. To ensure measurement accuracy, the sensor lens should be inspected regularly and cleaned every two weeks as part of routine maintenance.

BEFORE

AFTER



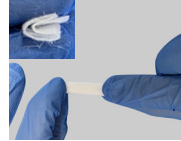
EXAMPLES of DIRTY  
SENSOR LENS



# Maintenance Cleaning: Option A

Step 1. Inspect the sensor lens.  
Check for dust, smudges, or debris on the sensor lens surface. Use a flashlight if necessary. An Exergen penlight can be used for this.

Step 2. Remove 70% IPA prep pad from packaging and fold 2 times as shown.



Step 3. Using one end, wipe the sensor lens in a circular motion.



Step 4. Flip the prep pad and repeat with the other end.



Step 5. Repeat steps 2 through 4, using a new prep pad each time, as needed until the sensor lens has a mirror-like appearance.

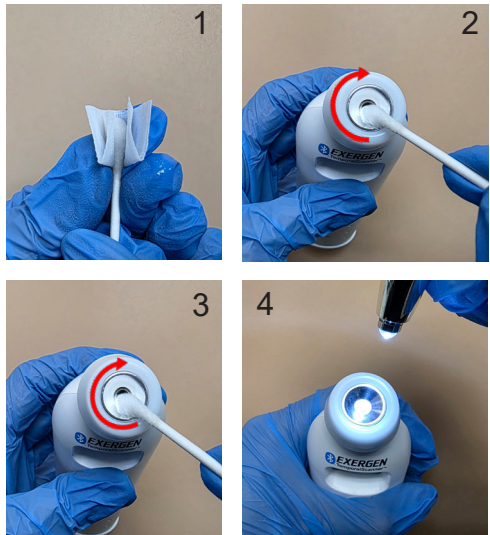


If needed, use the Exergen penlight to shine light on to the sensor lens when checking cleanliness.

Step 6. Allow the TAT to sit for about 30 minutes to ensure that all alcohol has evaporated.

# Maintenance Cleaning: Option B

1. Saturate one end of a cotton swab with alcohol by squeezing an IPA prep pad over it.
2. Clean the window using the dampened end, twirling the cotton swab around the sensor lens and cone as shown.
3. Repeat the motion with the dry end of the cotton swab to soak up the alcohol.
4. Repeat steps 1 through 3, using a new prep pad and cotton swab each time, as needed until the sensor window has a mirror-like appearance. Depending on the amount of debris this may require several repetitions. Varying the angle and rotation direction of the cotton swab can help remove debris from the sensor lens.
5. Allow the TAT to sit for about 30 minutes to ensure that all alcohol has evaporated.



# Disinfection

The thermometer housing is molded from a specialty polymer and is compatible with most hospital approved disinfectants.

## Disinfection process:

Hold the thermometer with the probe head facing down and wipe all exterior surfaces except for the sensor lens. Pointing the head down lowers the amount of disinfectant that can contact the sensor lens, which is to be only cleaned with isopropyl alcohol per the maintenance cleaning process. Follow the wipe manufacturer's directions for use.



## Verification Testing

All Exergen infrared thermometers are designed to permanently maintain their accuracy, and feature a patented hermetically-sealed optical system which protects the internal optical system against contamination by dirt, dust, moisture, and solvents.

Most reported problems are the result of a dirty lens. As infrared thermometers take an optical measurement, a dirty lens can result in a low reading. Cleaning the lens will result in an immediate return to normal calibration.

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 an Exergen Calibration Verification Kit (CVK), described in the following section.

## Verification Using Optional Calibration Verification Kit (CVK)

The calibration of a TAT-5000S can be verified using an optional Calibration Verification Kit. Calibration verification is a commonly required part of routine quality assurance programs, and also is used if a question is raised about the accuracy of a particular thermometer. Actual recalibration of an Exergen thermometer is never required unless it has been physically damaged or experiences component failure, in which case the calibration verification test identifies the problem device, which then is returned to the factory for repair.

The kit consists of a special TAT-5000S Certified Master (CM) reference thermometer of the same calibration type (Arterial or Oral) in use by the institution and one or more portable heaters. The CM is tested on the heater(s), as well as the institution's device(s), and the results are compared. If the results differ by more than a predetermined limit, then the device is considered still in calibration.

## Verification Using Optional CVK (cont'd)

Two versions of CVKs are available. One with 1 heater, and one with 3 heaters. The version with 3 heaters have the heaters set at 3 different temperatures. All heaters are portable hand-held reference blackbodies that can be powered by 9-volt alkaline batteries (included) for portable use, or international plug-in adapter (also included) for long term use. The CVK is supplied in a rugged storage case.

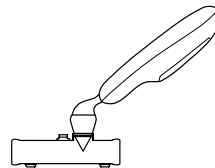
The main users of the CVK are biomedical/clinical engineering, blood donor and pheresis units, and many nursing units where accurate temperature is critical such as hematology/oncology, and bone marrow and organ transplant units. Exergen thermometers can quickly be checked for calibration accuracy using the portable blackbody (PBB) and master thermometer.



CVK



CVK-3TGT



Portable black body is used to verify the calibration of any TAT-5000S vs. a Certified Master, by comparison of readings.

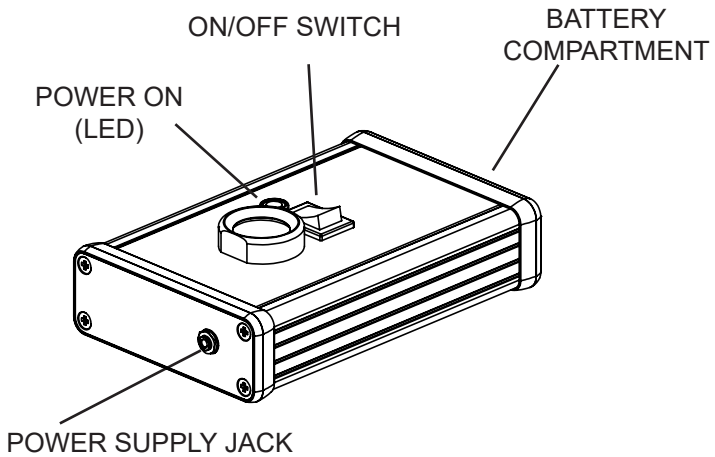


S/N Label



A for Arterial

Each portable blackbody heat generator in the CVK provides a stable source of heat in a small cavity. These are used as target references to verify the calibration of any of Exergen's medical instruments against an Exergen Certified Master (CM) reference instrument, also included in the kit. The CM instrument must be of the same type calibration as the units to be tested (S/N label letters A or O need to match). If this is not the case, please contact Exergen.



Model PBB-EC Portable Blackbody Calibration Verifier

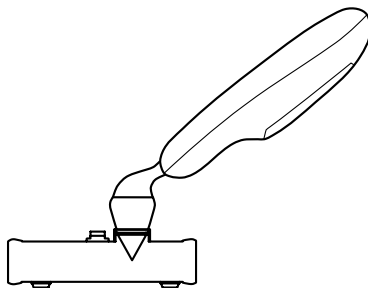
Each verifier operates with either a 9-volt power supply plugged directly into a 90 to 264 VAC electrical outlet allowing its extended use, or for portable use on nursing floors, it can be completely powered by a 9-volt battery. A new alkaline battery can be expected to maintain the blackbody reference temperature up to five hours.

## Calibration Verification Procedure Using Optional CVK

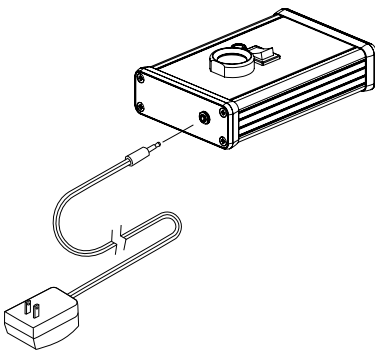
- 1. Getting started.** Turn on each verifier device, making sure the LED is illuminated. If not, check the battery to assure it is installed correctly. If using the power supply, simply insert the plug into the power supply jack, and plug the power supply into any 90 to 264 VAC electrical outlet.

Check the serial numbers of both the Certified Master and the thermometer to be tested. Both should start with the letter 'A' (Arterial) or both with the letter 'O' (Oral) indicating that the calibration types are correct. If the serial numbers do not have matching letter prefix type codes, please contact Exergen.

2. **Allow devices to stabilize.** Once turned on, allow approximately 5 minutes for warm-up and stabilization time. If on battery power the LED should be on and bright. If it dims or goes out, the battery will no longer be able to maintain the stable reference temperature of the blackbody. Do not use the portable blackbody for comparative measurements if the LED is not on and bright.
3. **Allow both the Certified Master and instruments to be tested to acclimate to the same ambient temperature.** Allow to equilibrate to room temperature for at least 10 minutes. Allow extra time if the master thermometer or the thermometers to be verified have recently been brought from either very cold or very warm ambient temperature conditions.
4. **Assure lens is clean.** Make sure the lens at the tip of the probe of all instruments, including the Master Reference, is clean. To clean, use an alcohol dampened cotton tipped applicator (Q-tip) which is required to get directly on the lens. (See p. 10 in this instruction manual for more details on cleaning the sensor lens.)
5. **Do not use disposable caps when checking thermometer calibration with the CVK.**
6. **Conversion of Master thermometer from F to C:** The CM thermometer can be converted from Fahrenheit to Celsius and back by means of a switch, which is accessible in the battery compartment.
7. **Measure the blackbody target** with both the master thermometer and thermometer being verified by pointing sensor head to the black heated target as shown in the picture below.



- 8. Compare CM Reference Thermometer readings to test thermometer.** Alternately insert the CM thermometer and the thermometer being verified into the portable blackbody calibration verifier opening, comparing readings to the CM. One measurement reading using the CM thermometer should be adequate if multiple thermometers are to be verified. If larger quantities of thermometers are to be verified, it is recommended to measure the blackbody target with the CM thermometer once for every ten (approximately) thermometers being verified. This is done to prevent possible drift errors that could be induced into the CM thermometer.
- 9. Accuracy Limits:** Comparison between CM and tested thermometer readings should be within  $\pm 0.2^{\circ}\text{C}$  ( $0.4^{\circ}\text{F}$ ) for acceptable field limits for TAT-5000S series of professional thermometers and  $\pm 0.3^{\circ}\text{C}$  ( $0.6^{\circ}\text{F}$ ) TAT-2000 series of professional thermometers. If not, repeat the process. In the event they still differ by more than the acceptable limits, call Exergen Corporation for replacement of the failed instrument.
- 10. Heat Balance Awareness:** All TAT series models employ the patented arterial heat balance method to adjust to their surrounding ambient temperature for precise, absolute accuracy. If left sitting on the heat well, they will assume the warmer temperature of the well, and thus will be at a different ambient than the instrument being tested (assuming it is at room temperature), and this could make a difference in the comparison of displayed temperatures.
- 11. Reminder:** Comparisons between the CM and the instrument being tested should always be conducted under the same ambient temperature conditions.



Power supply for PBB-EC

Portable Blackbody Specifications	
Power Source	9-volt alkaline battery, or 9-volt power supply with adapter blades options for North America, Europe, the United Kingdom, Australia and China.
Battery Life	approximately 5 hr.
Low Voltage Indicator	red LED shuts off when battery voltage drops below ~5.4 volts. Blackbody target temperature is not stable for comparative measurements in this condition.
Temperature	body temperature range 36 - 40°C (97 - 104°F).
Cleaning	wipe down with alcohol or mild cleaning solution; do not immerse in any liquid.

## Ordering Information for CVKs

The order must include the serial number of any one of the TAT-5000S thermometers that will be verified. This identification assures an exact calibration match to the CM reference thermometer.

Exergen p/n	Description
129060	CVK, Arterial, deg C
129061	CVK, Oral, deg C
129062	CVK, Arterial, deg F
129063	CVK, Oral, deg F
129050	CVK-3TGT, Arterial, deg C
129051	CVK-3TGT, Oral, deg C
129052	CVK-3TGT, Arterial, deg F
129053	CVK-3GTG, Oral, deg F

## Calibration of Master Reference Thermometer

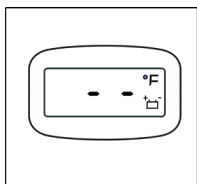
The calibration of the CM thermometer should be checked and factory re-certified yearly. This is indicated by the due date on the calibration sticker affixed to the CM thermometer. On or before the due date the CM thermometer should be returned to Exergen for re-certification. The Exergen part number for re-certification is 139000.



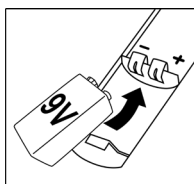
For details, please visit our website at <https://www.exergen.com/calibration-verification-kits/>

## Changing the Battery

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

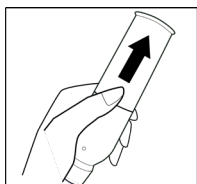


Insert a 9-volt battery as illustrated, with the positive (small terminal) always on the right.

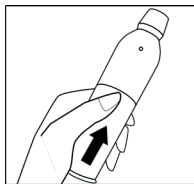


Use an alkaline or a heavy-duty 9V battery.

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



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



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

## Smart Glow



**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.



The TAT-2000 with Bluetooth TemporalArtery Scanner is equipped with a Bluetooth system to automatically transmit the temperature data and device serial number to an app or a monitor. The temperature reading is automatically transmitted when connection to the application is established.

Visit [exergen.com/bt](http://exergen.com/bt) for third-party apps that can connect to the TAT-2000 with Bluetooth.



# Display Messages

A rectangular box containing the characters 'Scn' in a digital font.

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.

A rectangular box containing the characters 'HI' in a digital font.

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

A rectangular box containing the characters 'LO' in a digital font.

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

A rectangular box containing the characters 'HIA' in a digital font.

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.

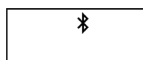
A rectangular box containing the characters 'LOA' in a digital font.

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.

A rectangular box containing the characters 'Err' in a digital font.

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.

## Bluetooth Display Messages

A rectangular box containing a small, solid Bluetooth symbol.

A blinking Bluetooth icon appears on the display during search for a device to link up with.

A solid Bluetooth icon appears on the on display when the TAT-2000 with Bluetooth is linked.

The Bluetooth icon is not displayed when the TAT-2000 with Bluetooth is neither trying to connect nor is connected.


## Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The infrared forehead thermometer model TAT-2000 series is intended for use in the electromagnetic environment specified below. The user of the TAT-2000 series should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The TAT-2000-BT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The TAT-2000-BT is suitable for use by a healthcare professional in a typical health care environment.
Harmonic emissions	Not applicable	
Voltage fluctuations	Not applicable	

## Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The TAT-2000 series thermometer is intended for use in the electromagnetic environment specified below. The user of the TAT-2000 series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the TAT-2000 series including cables if applicable, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance  $d = 1,2 \cdot P^{1/2}$ $d = 1,2 \cdot P^{1/2}$ 80 MHz to 800MHz $d = 1,2 \cdot P^{1/2}$ 800MHz to 2,7 GHz  Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from the fixer RF transmitters, as determined by an electromagnetic site survey, a. should be less than the compliance level in each frequency range and b. interference may occur in the vicinity of equipment with the following symbol: 
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2,7 GHz 80% AM at 1kHz	10V/m	

- a. Field strengths from fixed transmitter, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strengths in the location in which the TAT-2000 series thermometer is used exceeds the applicable RF compliance level above, the TAT-2000 series thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TAT-2000.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.
- c. Portable and mobile RF communications equipment can affect performance.

**WARNING:** Electronic equipment may be influenced by Radio Frequency (RFI). Caution should be exercised with regard to the use of portable communications in the area around such equipment. 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 ME Equipment or ME System. Degradation of the performance of this equipment could result. In a strong electromagnetic field, "Err" or erratic readings may result.

**WARNING :** This equipment shall not be used adjacent to or stacked with other equipment.

**WARNING :** TAT-2000 with Bluetooth 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.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (cont.)

The TAT-2000 series thermometer is intended for use in the electromagnetic environment specified below. The user of the TAT-2000 series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	8kV contact 15kV air	8kV contact 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	2kV for power supply lines 1kV for input output lines	Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	1kV line(s) to line(s) 2kV line(s) to earth	Not applicable	Mains power quality should be that of a typical home healthcare environment.
Interruptions and voltage variations on power supply Input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 sec.	Not applicable	Mains power is not applicable. The TAT-2000 series is powered by battery and battery only.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at the level characteristic of a typical location in a typical home healthcare environment.

Note UT is the a.c. mains voltage prior to the application of the test level

Recommended separation distances between portable and mobile RF communication equipment and the TAT-2000 Series

The TAT-2000 series forehead thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled or the user of the TAT-2000 series thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TAT-2000 series thermometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz d=1,2 P <sup>1/2</sup>	80 MHz to 800 MHz d=1,2 P <sup>1/2</sup>	800 MHz to 2,7 GHz d=2,3 P <sup>1/2</sup>
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Bluetooth RF Communication	
Frequency	2.402-2.480 GHz
Type & Frequency Characteristics	GFSK
Effective Radiated Power	4 dBm

# Product Specifications

<b>Laboratory Accuracy</b>	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.
<b>Clinical Characteristics:</b>	Per EN ISO 80601-2-56. Clinical bias: Rectal 0.04 °C, Oral 0.52 °C. Limits of agreement: Rectal 1.03 °C, Oral 1.24 °C. Clinical Repeatability 0.13 °C.
<b>Reference Body Site:</b>	Pulmonary Artery
<b>Measuring Sites:</b>	Forehead (Light contact scan); Mastoid (Touch behind the ear)
<b>EMI/RFI Protection:</b>	Error message displayed
<b>Calibration Protection:</b>	Error message displayed
<b>Temperature Range:</b>	16 to 42°C (61 to 107.6°F)
<b>Operating Environment:</b>	16 to 40°C (61 to 104°F)
<b>Resolution:</b>	0.1 °C or °F
<b>Response Time:</b>	Approximately 0.03 second
<b>Time Displayed on Screen:</b>	30 seconds before automatic shutdown
<b>Battery Life:</b>	Approximately 1000 to 5000 readings with alkaline battery, depending on Bluetooth usage
<b>Size:</b>	7.0 in x 1.75 in x 1.25 in (17.8 cm x 4.45 cm x 3.18 cm)
<b>Weight:</b>	120 g (4.16 oz) incl batt
<b>Display Type:</b>	High contrast LCD
<b>Bluetooth:</b>	Bluetooth 4.2 BLE, Health Thermometer Service (HTS)**
<b>Construction Method:</b>	Impact resistant casing, hermetically sealed sensing system
<b>Warranty:</b>	3 years
<b>Patents:</b>	Listed at <a href="http://www.exergen.com/patents">www.exergen.com/patents</a>

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

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

\*\* Contact Exergen for Bluetooth interface details.

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

## Warranty & Repair

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.





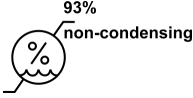
















Exergen Corporation will not pay for warranty service performed by a nonauthorized repair service and will not reimburse the customer for damage resulting from warranty service performed by a non-authorized repair service. No responsibility is assumed for any special, incidental or consequential damages.

If repair is required, please go to our website at [www.exergen.com/rma](http://www.exergen.com/rma) to request a Return Materials Authorization (RMA) number. You will receive an email response with an RMA number and instructions on where to return your unit. Alternatively, you may contact Exergen customer service at +1 (617) 923-9900 or [service@exergen.com](mailto:service@exergen.com) or contact your local distributor.

NOTE: No other warranty, written or verbal, is authorized by Exergen Corporation.

# SYMBOL LEGEND

Note: Not all symbols may be included in the labeling of this product.

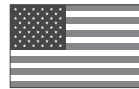
	Caution ISO 15223-1, 5.4.4		Consult instructions for use ISO 15223-1, 5.4.3
	Degree of Protection Against Electrical Shock Type B Applied Part, Battery Operated IEC 60601-1		Do not throw this device away in the trash, con- tact Exergen Corp. for disposal and recycling instructions.
	Humidity Limitation ISO 15223-1, 5.3.8		Keep dry ISO 15223-1, 5.3.4
	Temperature limit ISO 15223-1, 5.3.7		Medical Device ISO 15223-1, 5.7.7
IPX0	No protection against water. IEC 60601-1, D.3		Serial Number on Device Label ISO 15223-1, 5.1.7
	ON (only for part of equipment) IEC 60601-1		Unique device identifier ISO 15223-1, 5.7.10
	The Bluetooth® word mark and logos are reg- istered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Exergen is under license. Other trademarks and trade names are those of their respective owners.		Symbol for Manufacturer ISO 15223-1, 5.1.1: Exergen Corporation 400 Pleasant Street Watertown, MA, 02472 USA Phone: +1 617.923.9900 www.exergen.com
	Do not re-use ISO 15233-1, 5.4.2		Country of manufacture US ISO 15233-1, 5.1.11
	Emergo Consulting (UK) Limited Compass House Vision Park Histon c/o Cr360 – UL International Cambridge CB24 9BZ England, United Kingdom		This symbol on the prod- uct's nameplate means it is listed by Underwriters' Laboratories, Inc.
	Recycle		Conformité Européenne
	MedEnvoy Switzerland Gothardstrasse 28 6302 Zug Switzerland		Authorized representative in the EC/EU ISO 15223-1, 5.1.2 Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

Any serious incident that has occurred in relation to the device should be reported to the Manufacturer (Exergen [service@exergen.com](mailto:service@exergen.com)), and your local Competent Authority.

To evaluate, email:  
[medical@exergen.com](mailto:medical@exergen.com)



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

For general information:  
[www.exergen.com](http://www.exergen.com)

For clinical information, visit:  
[www.TAThermometry.org](http://www.TAThermometry.org)



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To contact Customer Service, email:  
[service@exergen.com](mailto:service@exergen.com)

**EXERGEN**  
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