EXERGEN

TemporalScanner™

TAT-5000S Series

Accurate Temperature with a Gentle Forehead Scan

Operation Manual

Changing the Way the World Takes Temperature

Important Safety Instructions!

Device Information and Safety Instructions

Read instruction manual prior to operating device to ensure proper operation and accurate results.

Summary: The Exergen TemporalScannerTM 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/Indications for Use: The TAT-5000S Standalone Series thermometers are indicated for measuring the body temperature of patients, and are not intended for use with other devices or equipment.

Intended User(s): The TAT-5000S Series thermometers are for professional use. The intended users are physicians, nurses, nurses' aides, patient care technicians, and others who are trained to take the temperature of patients.

Intended Patient Population: The TAT-5000S Series thermometers are utilized for intermittent measurement of human body temperature assessment in patients of all age groups.

Medical Conditions to be diagnosed, treated, or monitored: The TAT-5000S Series thermometers play a crucial role in measuring body temperature to monitor health and diagnose illnesses, particularly focusing on fever, a prevalent symptom in many medical conditions.

Intended Clinical Benefit to the Patient:

The TAT-5000S Series thermometer's intended clinical benefit to patients include:

- Early detection of fever which is often an indicator of underlying infection or illness, and timely detection allows for prompt medical evaluation and treatment.

Detecting fever early can help:

- Early detection of hypothermia, which can pose significant risks to health and well-being.
- Patient comfort and reassurance, TAT-5000S thermometers provide a non-invasive and relatively quick method for measuring body temperature, which can enhance patient comfort and compliance.
- Regular temperature monitoring may also provide reassurance to patients and caregivers, particularly during times of illness or recovery.

CONTRAINDICATIONS

The TAT-5000S Series thermometers are contraindicated for the following:

- In patients with scar tissue, open sores or abrasions on the forehead or temporal lobe, do not take temperature over these areas.

Training: Supplementary training materials, including specialized clinical guides, are are available at www.exergen.com/s, and recommended for first-time users.

Intended Use Environment: Clinical environments include areas where medical professionals provide medical services for patients, including hospitals, outpatient clinics, primary care offices, and other settings where temperature is taken as part of patient care.

WARNING !

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) may affect the TAT-5000S device. Maintain separation distances / avoid use in known high-EMI environments.
- The TAT-5000S 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.

WARNING !

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation, which may lead to inaccurate temperature readings.

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, or transducers 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 may disturb other nearby devices.

WARNING !

Failure to thoroughly clean and disinfect this device between each patient's use may result in contamination and pose a risk of infection, rash or possibly an allergic reaction to the user, including use between patients. Pathogenic microorganisms, including bacteria, viruses, and fungi, can persist on the device surface and contribute to the transmission of infectious diseases. Refer to cleaning instructions under the "Care and Maintenance" section.

WARNING !

Not suitable for use in the presence of flammable anesthetic mixtures.

WARNING !

The thermometer contains certain substances, including nickel, that may cause hypersensitivity reactions in susceptible individuals. Information on compliance with RoHS, REACH, and other applicable requirements, including relevant material declarations, is available upon request from Exergen Customer Service.

PRECAUTIONS

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

- **The instruction manual/booklet must be read prior to operating this device!**
- Use this product only for its intended use as described in this manual.
- 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).

- The thermometer is not shockproof. Do not drop it or expose it to electrical shocks.
- 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 the manual. For service, repair, or adjustments, return your thermometer to Exergen.
- No modification of this equipment is allowed.
- Never drop or insert any object into any opening, unless stated in this manual.
- If your thermometer is not used regularly, remove the battery to prevent possible damage due to chemical leakage.
- Follow the battery manufacturer's recommendations or your hospital policy for the disposal of used batteries.
- Do not use corrosive substances on the thermometer.

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 or call customer service at 617-923-9900.

The TemporalScanner is an infrared thermometer designed for accurate, completely non-invasive temperature assessment by scanning the temporal artery (TA).

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 the ambient temperature. It samples these readings some 1,000 times a second, ultimately recording the highest temperature measured (peak) during the course of the measurement.

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. The TemporalScanner emits nothing - it only senses the natural thermal radiation emitted from the skin.

It has been clinically proven in premier university hospitals to be more accurate than ear thermometry, and better tolerated than rectal thermometry, and is supported by more than 100 peer-reviewed published studies covering all ages from premature infants to geriatrics in the intended use environment. It is a superior method for patient and clinician alike.

A 40-page compendium on Temporal Artery Temperature Assessment is available at www.exergen.com/medical/PDFs/tempassess.pdf,

and a complete list of peer-reviewed published clinical studies is available at www.exergen.com/c.

Complete multilanguage information on clinical use, instruction manuals, and training is available at www.exergen.com/s.

Paper copies of this manual are available within seven (7) calendar days at no additional cost by calling Customer Service at (617) 923-9900 or by e-mail request to:

mailto:service@exergen.com.

The link to www.exergen.com/s appears on the front label of the instrument as a scannable "QR" symbol for easy linking to the site.

FACTORS AFFECTING PERFORMANCE OF THE THERMOMETER

The performance of the device may be degraded should one (1) or more of the following occur:

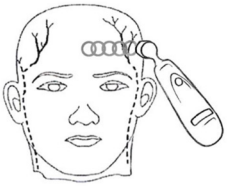
- Operation outside the stated temperature and humidity range: 16°C to 40°C (61°F to 104°F) Max 93% RH, noncondensing;
- Storage outside the stated temperature and humidity range: -20°C to 50°C (-4°F to 122°F) Max RH 93%, noncondensing;
- Mechanical shock to the thermometer; and/or,
- Patient temperature is below low ambient temperature (or above high ambient temperature):
  <16°C (<61°F) - Low Ambient or
  >40°C (>104°C) - High Ambient

SAVE THESE INSTRUCTIONS!

exergen.com/s

Introduction to Temporal Artery Thermometry

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, this 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.

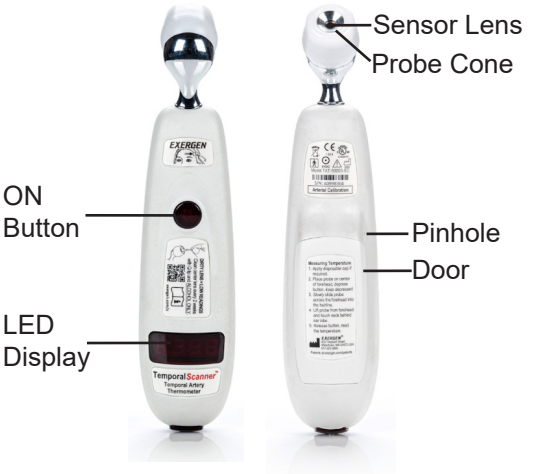
Before Using, Familiarize Yourself with the Instrument

- **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.

Alternate sites when temporal artery or behind ear 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.

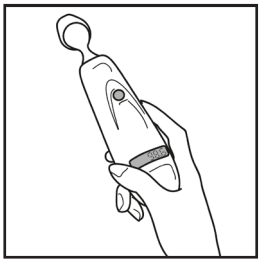
Let the instrument acclimatize for at least 10 minutes in the area in which it will be used.



2-Step Infant Temperature Measurement

Step 1

Place probe flush on center of forehead and depress button. Keeping button depressed, slowly slide probe mid-line across forehead to the hair line.



Step 2

Release button, remove from head and read.

How to improve the accuracy of your measurements on infants.

The preferred site is the temporal artery area. Unless visibly diaphoretic, one measurement here is typically all that is required.

If the temporal artery is covered, then the area behind the ear, if exposed, can be an alternate site.

Measure straight across the forehead and not down side of face.

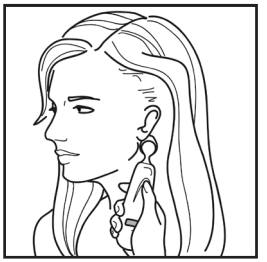
At mid-line, the temporal artery is about 2 mm below the surface, but can go deeply below the surface on the side of the face.

Brush the hair aside if covering the area to be measured. Measurement site must be exposed.

3-Step Adult Temperature Measurement for Children, Adolescents and Adults

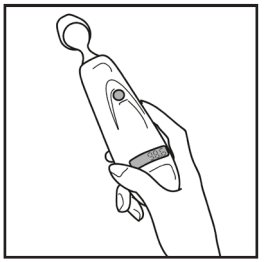
Step 1

Slide across forehead.
Place probe flush on center of forehead and depress button. Keeping button depressed slowly slide probe mid-line across forehead to the hair line.



Step 2

Slide behind ear.
Keeping button depressed, lift probe from forehead, touch behind ear halfway down the mastoid process and slide down to the soft depression behind the earlobe.



Step 3

Release button, remove from head and read.

How to improve the accuracy of your measurements on adults.

Measure only the up-side on a patient in a lateral position. The down-side will be insulated preventing the heat from dissipating, resulting in falsely high readings.

Think of a sweatband. Measure straight across the forehead and not down the side of the face. At mid-line, the temporal artery is about 2 mm below the surface, but can go deeply below the surface on the side of the face.

Measure exposed skin.

Brush the hair and bangs aside if covering the area to be measured.

Minimum measuring time: 2 seconds.

Minimum time between successive measurements: 30 seconds

Frequently Asked Questions

Q: How does the temperature from a temporal scanner relate to core temperature?

A: Temporal artery temperature is considered a core temperature because it has been demonstrated as accurate as the temperature measured by a pulmonary artery and esophageal catheter, and as accurate as a rectal temperature on a stable patient. Rule of thumb: Rectal temperature is about 0.5°C (1°F) higher than an oral temperature and 1°C (2°F) higher than an axillary temperature. It will be easy to remember if you think of core temperature as a rectal temperature, and apply the same protocol you would use for a rectal temperature.

If your thermometer is marked Oral and has a serial number beginning with "O" (standard model starts with "A"), it is programmed to compute the normal average cooling effect at the mouth, and automatically reduces the higher arterial temperature by that amount. This calibration allows the hospital to maintain existing protocols for fever workups based on oral temperature, and results in a reading consistent with the 37°C (98.6°F) mean normal oral temperature, in the range of 35.9 - 37.5°C (96.6 - 99.5°F) you now see.

Q: What should I do if I get an abnormally high or low reading, how do I confirm my reading?

- Repeat the reading with the same Temporal Scanner; a correct reading will be reproducible.
- Repeat the reading with another Temporal Scanner. Two Temporal Scanners with the same reading will confirm the reading.
- Sequential readings on the same patient in rapid succession will cool the skin; it is best to wait about 30 seconds for the skin to recover from the cold probe.

Possible causes of abnormal readings.

Type of Abnormal Temperature	Possible Cause	Helpful Hint
Abnormally Low Temperature	Dirty Lens	Clean lens of scanner every two weeks.
	Releasing the button before finished measuring	Release the button after finished measuring.
	Measuring when an ice pack or wet compress is on the forehead	Remove ice pack or wet compress, wait 2 minutes, and re-take temperature.
	Measuring a completely diaphoretic patient	Complete diaphoresis includes diaphoresis of area behind the ear and suggests that the temperature is rapidly dropping. Use an alternative method of temperature measurement in these cases until the patient is dry and the temporal artery measurement can be repeated.
	Improperly scanning down the side of the face	Scan straight across forehead. The temporal artery is closest to skin in that area.
Abnormally High Temperature	Anything covering the area to be measured would insulate and prevent heat from dissipating, resulting in false high readings.	Confirm measurement site has not recently been in contact with heat insulators such as hats, blankets, and hair. Scan the area not covered or wait about 30 seconds for the previously covered area to equilibrate to the environment.

Care and Maintenance

- **Handling:** The TemporalScanner 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 TemporalScanner case can be wiped down using a cloth dampened with 70% isopropyl alcohol. The industrial grade housing and design of the electronic components allow for completely safe cleaning with 70% isopropyl alcohol but should not be immersed in fluid or autoclaved.
- **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, 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. See detailed instructions on the next page.

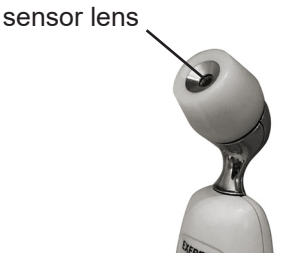
- **Calibration:** Factory calibration data is installed via a computer which communicates with the TemporalScanner's microprocessor. The instrument automatically self-calibrates each time it is turned on using this data, and will never require recalibration. If readings are not correct, the instrument should be returned for repair.
- **Battery:** An alkaline or rechargeable NiMH 9V battery can be used. A standard alkaline 9V battery provides approximately 15,000 readings.*
  To replace, insert the end of a bent paper clip into the pinhole on the side of the unit to release the battery compartment door. Disconnect the old battery and replace with a new one in the same location. Replace the cover. Use only high quality alkaline batteries.

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

WARNING: DO NOT MAKE CONTACT WITH THE PATIENT AND THE BATTERY AT THE SAME TIME, DURING BATTERY REPLACEMENT!

Cleaning the Sensor Lens to Maintain Accuracy

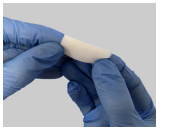
The sensor lens of a TAT-5000S series thermometer is an optical component. Like a camera lens, anything obstructing the sensor lens will reduce the signal received by the sensor. To ensure measurement accuracy, the sensor lens should be inspected regularly and cleaned every two weeks as part of routine maintenance.

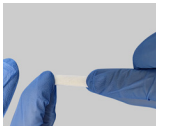


Maintenance Cleaning: Option A

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.

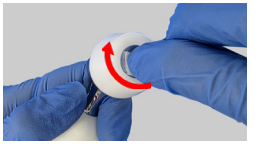
Step 2. Remove 70% IPA prep pad from packaging and fold 2 times as shown.



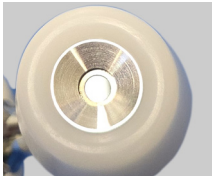


Step 3. Using one end, wipe the sensor lens in a circular motion.

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.



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

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

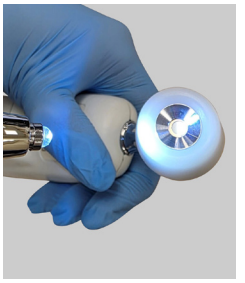
Maintenance Cleaning: Option B

Step 1. Saturate one end of a cotton swab with alcohol by squeezing an IPA prep pad over it.

Step 2. Clean the window using the dampened end, twirling the cotton swab around the sensor lens and cone as shown.

Step 3. Repeat the motion with the dry end of the cotton swab to soak up the alcohol.

Step 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 window.



Step 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, including quaternary ammonium based products.

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.

The following can be used on the exterior of the TemporalScanner.

- DisCide Ultra Disinfecting Wipes
- Hydrogen Peroxide
- Isopropyl Alcohol 70% (can also be used on sensor lens)
- Minncare
- Oxivir
- PDI Sani-Cloth Plus (Red Top)

Display Diagnostics Chart

The following chart summarizes the conditions that may occur while the TemporalScanner is in use, and the associated indications:

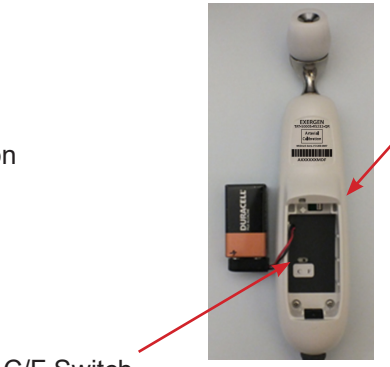
Condition	Display	Range
High Target	HI	> 43 °C (110° F)
Low Target	LO	< 16 °C (61° F)
High Ambient	HI A	> 40 °C (104° F)
Low Ambient	LO A	< 16 °C (61° F)
Low Battery	bAtt	N/A
No or Very Low Battery	blank display	N/A
Processing Error	Err	Restart. Return to Exergen for repair if error message persists.
Scanning (Normal Operation)	- - - -	N/A

Fahrenheit or Celsius Conversion

The TemporalScanner can be used in either °F or °C. To convert from one scale to the other, the only tools necessary are a paper clip and the tip of a small screwdriver.

For °F/°C Conversion:

- Insert the end of a bent paper clip into the pinhole on the side to release and remove the cover. Remove the battery from the compartment.
- Locate the switch, and with the tip of a screwdriver, slide left or right to the opposite position.
- Remove the screwdriver.
- Replace cover.



Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The infrared forehead thermometer model TAT-5000S series is intended for use in the electromagnetic environment specified below. The user of the TAT-5000S 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-5000S series thermometer uses no RF energy therefore any emissions are unlikely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The TAT-5000S series thermometer 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-5000S series thermometer is intended for use in the electromagnetic environment specified below. The user of the TAT-5000S 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-5000S 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*P1/2 d=1,2*P1/2 80 MHz to 800MHz d=1,2*P1/2 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	10V/m	

Note 1 At 80MHz and 800MHz, the higher 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.

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-5000S series thermometer is used exceeds the applicable RF compliance level above, the TAT-5000S 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-5000S.
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.

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

The TAT-5000S series thermometer is intended for use in the electromagnetic environment specified below. The user of the TAT-5000S series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environ-ment-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 health care environment.
Surge IEC 61000-4-5	1kV line(s) to line(s) 2kVline(s) to earth	Not applicable	Mains power quality should be that of a typical health care 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) for5 sec.	Not applicable	Mains power is not applicable. The TAT-5000S 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 characteris-tic of a typical location in a typical health care 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-5000S Series

The TAT-5000S series forehead thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled or the user of the TAT-5000S series thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TAT-5000S 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 P1/2	80 MHz to 800 MHz d=1,2 P1/2	800 MHz to 2,7 GHz d=2,3 P1/2
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.

Specifications

Specification †	TAT-5000S
Laboratory Accuracy * per ASTM E1112-00	± 0.1°C or 0.2°F (at 37 to 39°C or 98.6 to 102.2 °F) ± 0.2°C or 0.3°F (outside above range and at 35.8 to 41.0°C or 96.4 to 105.8 °F) ± 0.3°C or 0.2°F (outside 35.8 to 41.0°C or 96.4 to 105.8°F)
Clinical Characteristics** 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
Reference Body Site	Pulmonary Artery
Measuring Sites	Forehead (Light contact scan) Mastoid (Touch behind the ear)
Temperature Range	16 to 43°C (61 to 110°F)
Arterial Heat Balance Range for Body Temperature ***	34.5 to 43°C (94 to 110°F)
Operating Environment	16 to 40°C (61 to 104°F)
Resolution	0.1° C or F
Response Time	~0.04 seconds
Time Displayed On Screen	30 seconds
Size	Instrument : ~21 cm X 5 cm X 4 cm (8.3" X 1.8" X 1.6")
Weight	0.24 kg (0.53 lb)
EMI and RFI Protection	Alloy cast enclosure on upper part inside of casing
Storage Conditions	-20 to 50°C (-4 to 122°F)
Display Type and Size	Large bright LEDs
Construction Method	• Industrial duty impact resistant casing • Chemically resistant casing and lens • Hermetically sealed sensing system • Chrome-plated alloy cast head
Warranty	Lifetime

† The values of quantities stated in SI units are to be regarded as the standard. The values of quantities in parentheses are not in SI and are optional.
* Laboratory Accuracy outside of Patient Temperature Range of 37 to 39°C (or 98.6 to 102.3 °F) is up to +/-0.3 °C (0.5 °F).
** See link below for clinical characteristics and list of published studies.
Clinical Validation Results
***Automatically applied when temperature is within normal body temperature range, otherwise reads surface temperature..
The CLINICAL THERMOMETER is an ADJUSTED MODE CLINICAL THERMOMETER.
Correction method is proprietary. Laboratory testing protocol for laboratory accuracy available upon request.

Disposable Cap Options

No Cap
Terminal Cleaning
at Patient

No Cap
Alcohol Wipe
Between Patients

Disposable Cap
Covers Entire
Probe

Disposable caps, which can be used once and discarded, or reused on the same patient, are available for all levels of cross-contamination protection should they be preferred for certain patient populations, and are still very cost effective.

Using the Disposable Caps:

1. Apply cap by pushing onto the probe head with fingers.
2. Remove cap by pushing edge forward with thumb.
3. Caps may be reused on the same patient.

Disposable caps can be discarded in normal trash. The operator is responsible for checking the compatibility of the thermometer, and the probe cover. Incompatible components can result in degraded performance.

Exergen p/n	Description
134203	Disposable Caps, box of 1000
134205	Disposable Caps, box of 5000

Convenience Options

Exergen p/n	Description
134315	Disposable Cap Dispenser

Other convenience options and accessories are available at https://www.exergen.com/store/

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 pages.

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.

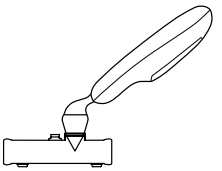
The kit consists of a special TAT-5000S Certified Master (CM) reference thermometer of the same calibration type (Arterial or Oral) in use by the institution and one or more portable heaters. The CM is tested on the heater(s), as well as the institution's device(s), and the results are compared. If the results differ by no more than a predetermined limit, then the device is considered still in calibration.

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

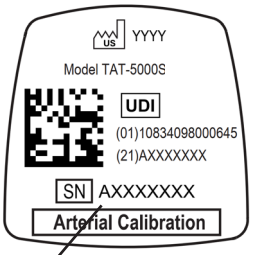
CVK-3TGT



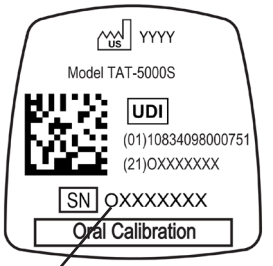
Portable black body is used to verify the calibration of any TAT-5000S vs. a Certified Master, by comparison of readings.

Verification Using Optional CVK (cont'd)

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.



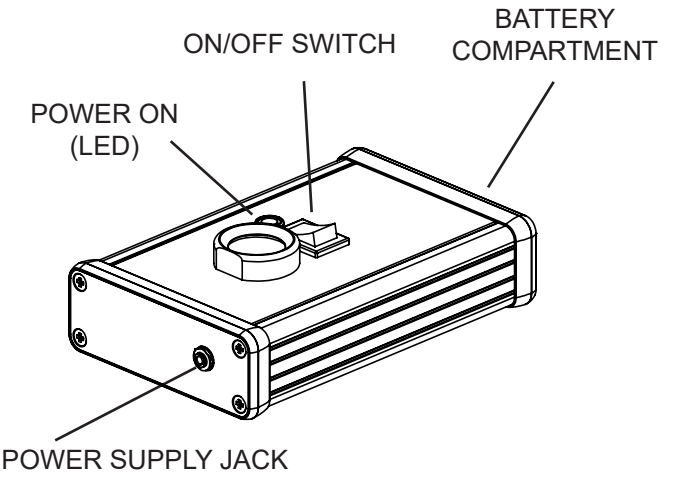
A for Arterial



O for Oral

Example labels

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.



Model PBB-EC Portable Blackbody Calibration Verifier

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.

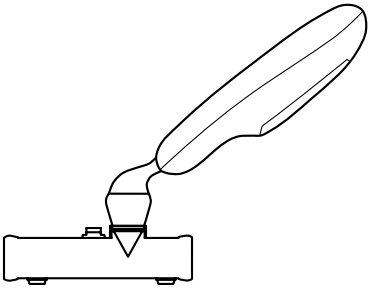
4. **Assure lens is clean.** Make sure the lens at the tip of the probe of all instruments, including the Master Reference, is clean. To clean, use an alcohol dampened cotton tipped applicator (Q-tip) which is required to get directly on the lens. (See p. X in this instruction booklet for more details 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 accessable in the battery compartment.

Calibration Verification Procedure Using Optional CVK (cont'd)

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 to the right.



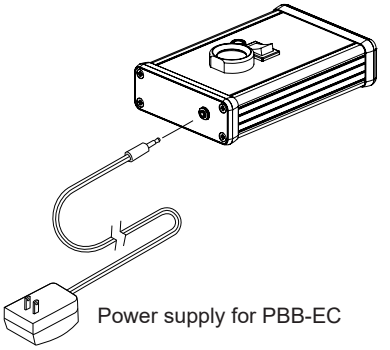
8. **Compare CM Reference Thermometer readings to test thermometer.** Alternately insert the CM thermometer and the thermometer being verified into the portable blackbody calibration verifier opening, comparing readings to the CM. One measurement reading using the CM thermometer should be adequate if multiple thermometers are to be verified. If larger quantites 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 ± 0.2°C (0.4°F) for acceptable field limits for TAT-5000S 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-5000S 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.

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.



Power supply for PBB-EC

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 the link below.

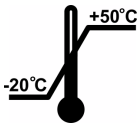
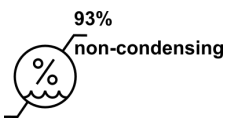
https://www.exergen.com/calibration-verification-kits/

Symbol Legend

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

US	Country of Manufacture ISO 15223-1, 5.1.11		Do not throw this device away in the trash, contact Exergen Corp. for disposal and recycling instructions.
	Manufacturer ISO 15223-1, 5.1.1:: **EXERGEN CORPORATION** 400 PLEASANT STREET WATERTOWN, MA 02472 PH (617) 923-9900 www.exergen.com		Keep dry; Protect from Moisture ISO 15223-1, 5.3.4
	Caution is necessary when operating the device. ISO 15223-1, 5.4.4	IPX0	Ordinary Equipment -Not protected against ingress by liquids IEC 60601-1, D.3
	Consult Instructions for Use or consult electronic Instructions for Use ISO 15223-1, 5.4.3		"On" (only for part of Equipment) IEC 60601-1
	Degree of Protection Against Electrical Shock Type BF Applied Part, Battery Operated IEC 60601-1	UL CERTIFIED SAFETY US-CA E466615	Medical – general medical equipment as to electrical shock, fire and mechanical hazards only in accordance with (Current Revision): ANSI/AAMI ES 60601-1; CAN/CSA-C22.2 No. 60601-1:14; IEC 60601-1-6; ISO 80601-2-56
	Regulatory Importer(s): **EU: MedEnvoy Global B.V.** Prinses Margrietplantsoen 33 - Suite 123 2595 AM The Hague The Netherlands **CH: MedEnvoy Switzerland** Gotthardstrasse 28 6302 Zug Switzerland **UK: MedEnvoy UK Limited** 167-169 Great Portland Street, 5thFloor London, W1W 5PF United Kingdom	Segurança UL BR	**INMETRO** **Brazilian Registration Holder:** **Cedrs Gestao Empresarial Ltda** Rua Silva Bueno, 1660 – CJ 1001 – Ipiranga, Sao Paulo- SP, Brazil. CEP- 04208-001 **ANVISA Registration: 81832589062** **CNPJ: 27.242.567/0001-11**
		Rx	Intended for Doctor or Healthcare Professional use only 21 CFR 801.109
EU REP	**EU Authorized Representative:** **MedEnvoy Global B.V.** Prinses Margrietplantsoen 33 - Suite 123 2595 AM The Hague The Netherlands	UK RP	**UK Responsible Person** **MedEnvoy UK Limited** 167-169 Great Portland Street, 5thFloor London, W1W 5PF United Kingdom
CH REP	**Swiss Authorized Representative:** **MedEnvoy Switzerland** Gotthardstrasse 28 6302 Zug Switzerland		Refer to instruction manual/booklet IEC 60601-1

Symbol Legend (continued)

UDI	Unique Device Identifier ISO 15223-1, 5.7.10	CE 0297	Conformité Européenne
UK CA 0843	UK Conformity Assessed	MD	Medical Device ISO 15223-1, 5.7.7
	Temperature limit (-20°C to +50°C) ISO 15223-1, 5.3.7		Humidity limitation (max RH 93% non-condensing). ISO 15223-1, 5.3.8

Repair

If repair is required, please go to our website at 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 (617) 923-9900 or service@exergen.com or contact your local distributor.

Any serious incident that has occurred in relation to the device should be reported to the Manufacturer (Exergen service@exergen.com), and:

FDA (US only)

Local Competent Authority (EU only)

Relevant local authorities (Worldwide Distribution only)

UK Responsible Person (United Kingdom only); Healthcare professionals and users may also report suspected problems with medical devices to the MHRA in accordance with local policy.

EXERGEN
TemporalScanner™

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Changing the Way the World Takes Temperature