

EXERGEN

TemporalScanner™



Accurate Temperature with a Gentle Forehead Scan



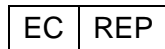
www.exergen.com/s

Exergen TAT-5000S-TTL Supplemental Instructions for Use

For additional specifications, see GE Healthcare CARESCAPE™ V100 Vital Signs Monitor Operator's Manual, Section 12.

	Symbol for Manufacturer
	Degree of Protection Against Electrical Shock Defibrillation-Proof Type BF Applied Part, Battery Operated
	Caution
	Consult Instructions for Use
	"On" (only for part of Equipment)
	Do not throw this device away in the trash, contact Exergen Corp. for disposal and recycling instructions.
IPX0	Ordinary Equipment
	MEDICAL EQUIPMENT ANSI/AAMI/ES60601-1: 2005/(R)2012 3 rd Edition including Amendment 1; CAN/CSA-C22.2 No. 60601.1:2014; IEC 60601-1-6; ISO 80601-2-56: Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers For Body Temperature Measurement

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



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Changing the Way the World Takes Temperature

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www.exergen.com

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 (Ta) and sensed surface temperature. Training materials that are supplementary to this instruction manual are available at www.exergen.com/s, and recommended for first time users.

The TAT5000S 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 include Emergency Medical Services environments.

Additionally, the TAT5000S 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 60° to 104°F (15.5° to 40°C).
- Always store and transport this thermometer in a clean, dry place where it will not become excessively cold (-4°F/-20°C), or hot (122°F/50°C). Relative humidity 93% Maximum non-condensing, atmospheric pressure 50 kPa to 106 kPa.
- 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 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.
- 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.
- Not suitable for use in the presence of flammable anesthetic mixtures.

- Communication cables for the TAT5000S that are field replaceable are specific to the model and patient monitor. Only compatible cables may be used, to maintain compliance of the TAT5000S thermometers with requirements for Emissions and Immunity.
- 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.



BF Applied Part indicates degree of patient protection against electrical shock. The product is internally battery powered and electrically isolated from earth.

WARNING: Use of this equipment adjacent to or stacked with other equipment (other than TAT5000S compatible patient monitors) 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.

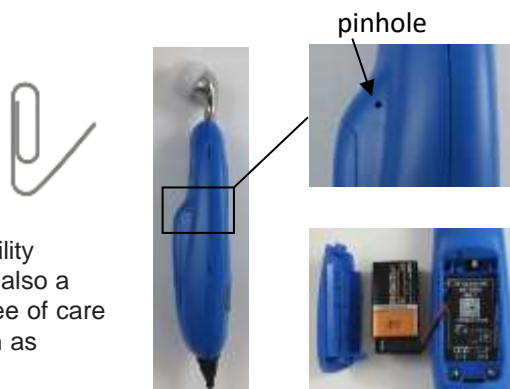
WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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 TAT5000S thermometer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

SAVE THESE INSTRUCTIONS.

Care and Maintenance

- **Battery:** 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.
- **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 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 dampened with an alcohol wipe. 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. Use 70% isopropyl alcohol.
- **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. See the repair instructions below for the return process.



Instructions for Fahrenheit or Celsius Conversion

The TemporalScanner can be used in either °F or °C. The TemporalScanner will come preset based on your preference at the time of purchase. To convert from one scale to the other, the only tool necessary is 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 in the battery compartment (shown in the photo), and with the tip of the screwdriver, slide left or right to the desired scale.
- Remove the screwdriver.
- Replace battery and cover.



Repair

If repair is required:

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

Exergen Corporation
400 Pleasant Street
Watertown, MA 02472
USA

- Include the address the instrument should be returned to.

FAQs

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

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 1°F (0.5°C) higher than an oral temperature and 2°F (1°C) 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 Arterial/Oral and has a serial number beginning with "O" (standard model start 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 98.6°F (37°C) mean normal oral temperature, in the range of 96.6 - 99.5°F (35.9 - 37.5°C).

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.

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


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	3Vrms	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 $d=1,2 \cdot P^{1/2}$ $d=1,2 \cdot P^{1/2}$ 80 MHz to 800MHz $d=1,2 \cdot P^{1/2}$ 800MHz to 2,7 GHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2,7 GHz	10V/m	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: 

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 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 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) for 5 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 characteristic 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 $d=1,2 P^{1/2}$	80 MHz to 800 MHz $d=1,2 P^{1/2}$	800 MHz to 2,7 GHz $D=2.3 P^{1/2}$
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.