

EXERGEN

TEMPOTHERM™

TEMPORALSCANNER™ TAT-2000 SERIES

TECHNICAL MANUAL
INSTRUCCIONES DE USO
INSTRUÇÕES DE UTILIZAÇÃO
GEBRAUCHSANWEISUNG
MODE D'EMPLOI
ISTRUZIONI D'USO
GEBRUIKSAANWIJZING
BRUKSANVISNING
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KULLANIM TALİMATLARI
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تعليمات الاستخدام

WWW.INTERNATIONAL.EXERGEN.COM

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TEMPOTHERM™

TEMPORALSCANNER™ TAT-2000 SERIES



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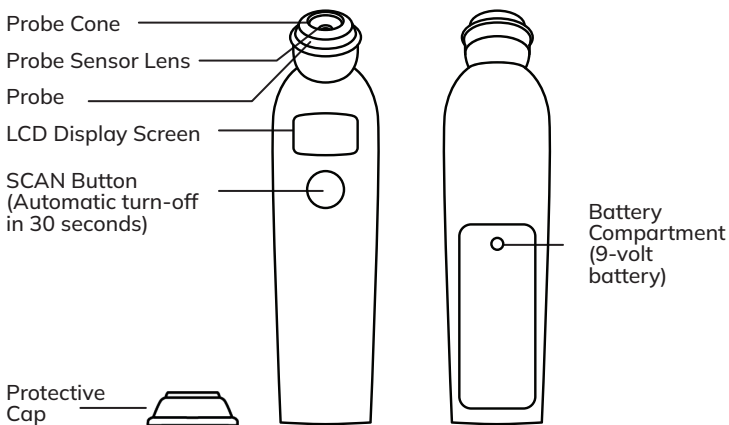
HOW TO USE THE EXERGEN TEMPOThERM™ THERMOMETER

This information is about using the TempoTherm thermometer for measuring body temperature and/or a possible fever. These instructions should help you use the thermometer safely and effectively.

The TempoTherm is part of the TAT-2000C series invented, design, assembled, tested, and packaged in the USA by Exergen Corporation.

FAMILIARISE YOURSELF WITH THE INSTRUMENT

- Push and hold the button to scan for temperature.
- Beeping and LED lights show temperature changes.
- Reading stays on display for 30 seconds.
- To restart, hold the button again.



TAKING A TEMPERATURE



Remove the protective cap.



Place probe flush on the middle of the forehead, press and hold the button.



Slide the thermometer in a straight line to the hairline while it beeps (don't touch glasses and/or hair).



Release the button and read the temperature.

IF PERSPIRATION IS PRESENT ON FOREHEAD:

1. Press and hold the SCAN button.
2. Place the probe on the neck just behind the ear lobe.



3. Release the SCAN button and remove the thermometer to get a reading.

WHEN NOT IN USE:

Thermometer will shut off automatically after 30 seconds. To turn off immediately press and release the SCAN button quickly. Always replace the cap to protect the sensor when not in use.

SAFETY INSTRUCTIONS (PAGE 1 OF 2)

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

- This product is intended for household use only. For information on thermometers for professional use, please see www.international.exergen.com or call +31 6 53226285
- Use this product only for its intended use as described in this manual.
- Use of this product is not intended as a substitute for consultation with your physician.
- Do not take temperature over scar tissue, open sores or abrasions.
- Basic safety precautions should always be observed, especially when this product is used by, on or near children or invalids.
- The operating environmental temperature range for this product is 15.5 to 40°C (60 to 104°F).
- The thermometer is not shockproof. Do not drop it or expose it to shocks.
- This thermometer is not intended to be sterile. Do not try to sterilize it.
- 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.
- Do not operate where aerosol spray products are being used or where oxygen is being administered.
- Do not take temperatures with this thermometer near places that are very hot, such as fireplaces and stoves.

SAVE THESE INSTRUCTIONS

SAFETY INSTRUCTIONS (PAGE 2 OF 2)

- Do not use this scanner outdoors.
- **WARNING:** TAT-2000C is not for use aboard aircraft or near High Frequency Surgical Equipment or Radio Frequency shielded rooms, such as MRI (Magnetic Resonance Imaging) areas.
- Never drop or insert any object into any opening.
- If scanner will not be used regularly, remove battery to prevent possible damage due to chemical leakage. If the battery leaks, remove carefully. Do not allow bare skin to touch leaking fluid.
- Dispose of used batteries properly according to your local regulations. Do not wrap them in metal or aluminum foil. Do not burn them. Battery may explode if overheated.
- Not designed for lithium battery. Do not use lithium battery. Use only alkaline or heavy duty 9V battery.
- Always store scanner in a clean, dry place where it will not become too cold (-20°C/-4°F), or hot (50°C/122°F) or humid (max RH 95% non-condensing, at 70 to 106 kPa).
- Time required for scanner to warm from minimum storage temperature to ambient or to cool from maximum storage temperature to ambient is 30 minutes. Allow 30 minutes for equilibration from storage limits.
- There are no parts that you can service yourself except for the battery, which you should replace when low. Follow the instructions in this manual. For service, examination, repair, or adjustments, return your scanner to Exergen.
- Warning: No modification of this equipment is allowed.
- Not suitable for use in the presence of flammable anesthetic mixtures.
- If lint or dust is on the sensor, clean the sensor. Follow cleaning instructions under Maintenance section. Do not leave scanner in sunlight before using; unit should be at ambient temperature before using.
- Keep scanner away from pets and pests. Scanner not intended to be operated by children.
- Follow cleaning instructions as described in this manual. Frequency of cleaning should be determined by visual inspection of sensor. If sensor is not clean, follow cleaning instructions.
- Unit does not create any physiological effect that is not obvious to the user.

SAVE THESE INSTRUCTIONS

SCANNING THE TEMPORAL ARTERY (TA)

- Measure only the side of the head exposed to the environment. Anything covering the area to be measured (hair, hat, wig, bandages) insulates the area. This results in falsely high readings.
- Slide the scanner 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. Measuring there would result in falsely low readings.
- When taking the temperature behind the ear (if there is perspiration on the forehead), first push away any hair, exposing the area. Then, tuck the scanner on the neck below the ear lobe, in the soft conical depression, (the place where perfume might be applied).
- Wait about 60 seconds before measuring the same person again to avoid excessive cooling of the skin.
- An infant is frequently swaddled in blankets and clothing covering the neck area. Unless visibly sweaty, 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 on the neck behind the ear.
- There are factors that may affect measurement accuracy.
- The patented Arterial Heat Balance (AHB) technology in your scanner actually makes two separate measurements. (1) the temperature of the skin over the temporal artery, and (2) the temperature of the room. To get the most accurate reading, it measures skin temperatures some 1000 times a second as you sweep the scanner across the forehead. The AHB system then calculates how much the blood has cooled down during its trip from the heart to the skin over the temporal artery and makes allowance for this in the temperature it displays. The result is a highly accurate reading - delivered extremely fast and with no discomfort.

DISPLAY MESSAGES



Scn means it's measuring.



HI indicates a very high temperature.



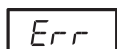
LO indicates a very low temperature.



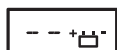
HI A means: move the device to a cooler location.



LO A means: move the device to a warmer location.



Err may appear due to interference; wait or replace the battery. If Err messages continue, contact Exergen.



Blinking battery icon warns of low battery.

SELECTING °C OR °F MODE

- Starting from a blank display tap the button until the flashing F - C appears (2 taps). The current temperature mode will appear in the upper right indicated by the small °F or °C. The factory setting is °C.
- To change from the °C to the °F mode, press and hold button until the small °C in the upper right of the display changes to °F. A beep will indicate that the setting has been changed, and the TemporalScanner scanner will automatically shut off.
- To change from the °F to the °C mode, repeat step 2, and press and hold the button until the small °F in the upper right of the display changes to °C.

TURN THE AUDIBLE BEEPER OFF OR ON

Your scanner is equipped with a beeper and front/back flashing LED's. These give you a soft audible and visual feedback as you scan over the temporal artery on the forehead. The original factory setting is with the beeper and LED's ON.

If the beeper is on and you are concerned that the sound or flashing LED may wake a sleeping child (or adult), they can be turned off as follows:

- Starting with a blank display, tap the power button until the display flashes "loud". Tap 3 times, past F-C display.
- Press and hold the button until "Shh" is displayed (Shh means quiet mode). A beep will indicate that the setting has been changed. The scanner will automatically shut off.
- To turn the beeper and front LED back on, repeat step 1 to find Shh. Then repeat step 2 to change into loud.

The scanner will automatically shut off 30 seconds after the last button press, from any mode of operation. The scanner must be OFF (blank screen) before taking a temperature. The scanner can be turned off from any programming mode by pressing and holding the button for 3 seconds.

FREQUENTLY ASKED QUESTIONS

WHY MEASURE TEMPERATURE ON YOUR FOREHEAD?

The best place to measure temperature accurately is the heart, but only doctors can do that. Doctors can tell your body temperature by measuring the temperature in a major artery in your body. The TempoTherm thermometer is made to measure the temperature on your forehead over the temporal artery, which is a big artery in your head. It is connected to your heart through the carotid artery, which comes from the main blood vessel in your body. This artery always has blood flowing through it, so it is a good place for measurement. It is the only major artery close enough to the skin to get an accurate reading. This thermometer is easy to use because it is placed conveniently on your forehead. The TempoTherm is more comfortable and easier to use than other thermometers. It does not need to go inside the mouth, rectum, under the arm, or inside the ear, making it an easy and gentle way to measure your temperature.

WHY AM I GETTING LOW READINGS?

Smudgy/dirty lens: Smudgy/dirty lens may be the cause. The most common reason for low readings is a smudgy/dirty lens. An alcohol-dampened Q-tip should be twirled directly on the lens every 2-3 weeks. Like a camera or eyeglasses, the TempoTherm uses optical technology. In the case of the thermometer, the infrared sensor behind the lens must “see” the heat in order to measure it. If you have had the TempoTherm a little while, it might just need a lens cleaning. Make sure you use a Q-tip or generic cotton swab. Don't use a twisted paper towel or tissue. The little lens should be cleaned as follows below:

1. Dampen the Q-Tip with either an alcohol prep/swab, or dip the Q-Tip in a little alcohol, but do not use the alcohol prep/swab to clean the lens as it will not provide the leverage needed.
2. Twirl the Q-Tip directly on the little lens deep in the center of the probe head.
3. This preventive maintenance should be routinely done (every few weeks).
4. Following the alcohol cleaning, wait about five minutes to let the infrared sensor behind the little lens recover from the coldness of the alcohol cleaning before using it again.

WHAT IS THE CORRECT TECHNIQUE?

When you use the scanner, make sure to start with a blank screen. Then while holding the button down, touch the center of the forehead and scan horizontally in a straight line over to the hairline, before releasing the button. Do not curve down to the temple. If you do, you could miss the important part of the temporal artery which is up in the forehead. The artery is naturally trapped between the skin and the skull, so it's never too deep. At the temple, the artery can go deep, even on an infant, and won't provide the correct temperature.

WILL SWEAT CAUSE LOW TEMPERATURE READINGS?

If the individual is sweaty, the effect of evaporative cooling on the forehead will result in low temperatures when using the scanner. However, sweat is a sign the fever has broken and, as a result, the temperature is rapidly falling back to normal. If sweaty, wait until the forehead has dried before taking a temperature. Wiping the forehead will not work. However, when the individual is just beginning to sweat, taking the temperature in the little soft depression on the neck just below the earlobe will work since we sweat last on the neck. But if both forehead and neck are wet/moist, wait until the sweating has subsided before taking a temp.

WHY ARE FOREHEAD READINGS DIFFERENT FROM RECTAL TEMPERATURE?

The scanner shows temperature changes quickly because it measures the heat from the blood right from the heart (a true core temperature). With rectal temperature, it can take a long time, like 60-90 minutes on babies, to show any changes in temperature. It takes even longer on older kids and grown-ups to see a temperature change in a rectal reading.

WHY IS MY READING HIGH?

The scanner measures a core temperature, which is like a rectal reading. The TemporalScanner gives a temperature about a degree Fahrenheit higher than an oral temperature. For most people, the TemporalScanner shows a temperature about two degrees Fahrenheit higher than a reading taken under the arm. However, babies under 6 months have a consistent body temperature. So their readings are similar to temps taken under the arm or rectally.

SHOULD I BELIEVE MY HAND OR THE TEMPORALSCANNER?

Touching the forehead is just not an accurate method (although we all do it). Many studies have proven that the hand (or a kiss on the forehead) will be correct 98% of the time when there is no fever, but wrong half of the time when the individual actually has a fever. The reason is that body heat is released or retained to keep our body temperature in the normal range. This contributes to the erroneous assessment as felt by the hand or lips. The core body temperature stays normal by the release of heat (like opening the windows when the house is too hot) or by retention of the heat (closing the windows when the house is too cold).

WHY DO I GET A DIFFERENT READING WITH EACH SCAN?

Multiple scans in rapid succession will change the temperature of the skin and result in variability of the readings. It is important to wait a full minute before repeating the scan to allow the skin over the temporal artery to recover from the cooler temperature of the probe head. The probe head is at room temperature and about 17 degrees C (30 degrees F) lower than body temperature.

MAINTENANCE

The TempoTherm is an optical instrument. Like a camera or eyeglasses, 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 the silver cone with a small cloth moistened with alcohol.



Lens should be cleaned with an alcohol dampened Q- tip. 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.



Scanner case can be cleaned with a clean cloth with alcohol. Avoid gritty, abrasive cleaners as they can scratch the thermometer.



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

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



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

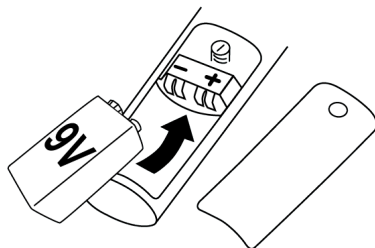
Replace battery.

Remove the battery compartment door by using a
small flathead screwdriver and turning counter-
clockwise almost one full turn. The door will pop out.

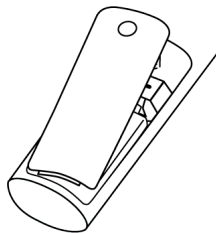


Insert an alkaline or heavy-duty 9-volt
battery.

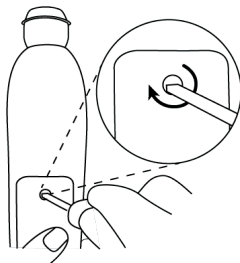
The positive (small terminal) should
always be on the right.



Replace the battery compartment door by seating the
bottom tab of the door in the compartment opening.



Firmly hold the door, insert screwdriver in screw slot
and turn clockwise to the lock position.



SPECIFICATIONS

- Clinical Accuracy: Meets ASTM E1965-98 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.
- EMI/RFI Protection: Error message displayed.
- Calibration Protection: Error message displayed.
- Temperature Range: 15.5 to 42 °C (60 to 107.6°F).
- Operating Environment: 15.5 to 40 °C (60 to 104 °F) with non-condensing humidity.
- Resolution: 0.1 °C or °F.
- Sensor Response Time: Approximately 0.04 second.
- Time Displayed on Screen: 30 seconds before automatic shutdown.
- Battery Life: Approximately 1000- 5000 readings depending on 9V battery type.
- Size: 17.8 cm x 4.45 cm x 3.18 cm (7.0 in x 1.75 in x 1.25 in).
- Weight: 120 grams (4.2 oz) including battery.
- Display Type: High contrast LCD.
- Construction Method: Impact resistant casing, hermetically sealed sensing system.
- Environmental Rating: IP22
- Storage Range: -20 °C to 50 °C (-4 °F to 122 °F) with non-condensing humidity.
- Laboratory Error: ASTM laboratory accuracy requirements in the display range of 37 to 39 °C (98 to 102 °F) for IR thermometers is +/-0.2 °C(+/-0.4 °F).

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

The clinical thermometer is an adjusted mode clinical thermometer. Correction method is proprietary. Laboratory testing protocol for laboratory accuracy available upon request.

Clinical accuracy validation results available at
www.exergen.com/professional-medical-products/clinical-studies

Patents: Listed at www.exergen.com/patents.

3 YEAR WARRANTY

Exergen Corporation warrants each new Exergen TempoTherm against defects in materials or workmanship for a period of 3 years for the TAT-2000C marketed as TempoTherm, 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 non-authorized 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 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 +31 6 53226285 or tempotherm@exergen.com or contact your local distributor.

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

*Read enclosed instructions carefully.


GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The infrared forehead thermometer model TAT-2000C series is intended for use in the electromagnetic environment specified below. The user of the TAT-2000C 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-2000C 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-2000C series thermometer is suitable for use in a typical home healthcare environment.
Harmonic emissions	Not applicable	
Voltage fluctuations	Not applicable	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY.

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

Immunity test	IEC 60601 test level	Compliance level	<p>Portable and mobile RF communications equipment should be used no closer to any part of the TAT-2000C series including cables if applicable, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1,2 \cdot P^{1/2}$ 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:</p> 
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	Not applicable	
Radiated RF IEC 61000-4-3	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-2000C series thermometer is used exceeds the applicable RF compliance level above, the TAT-2000C 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-2000C.
- 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'D).

The infrared forehead thermometer model TAT-2000C series is intended for use in the electromagnetic environment specified below. The user of the TAT-2000C 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- 2000C 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-2000C SERIES

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

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-2000C 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.

EXERGEN TEMPORALSCANNER™ THERMOMETER

TAT-2000C-EC

**IF YOU HAVE ANY ISSUE OR CONCERNS PLEASE CONTACT EXERGEN OR LOCAL
COMPETENT AUTHORITY**

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The Netherlands


















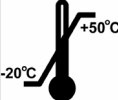
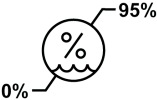




MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

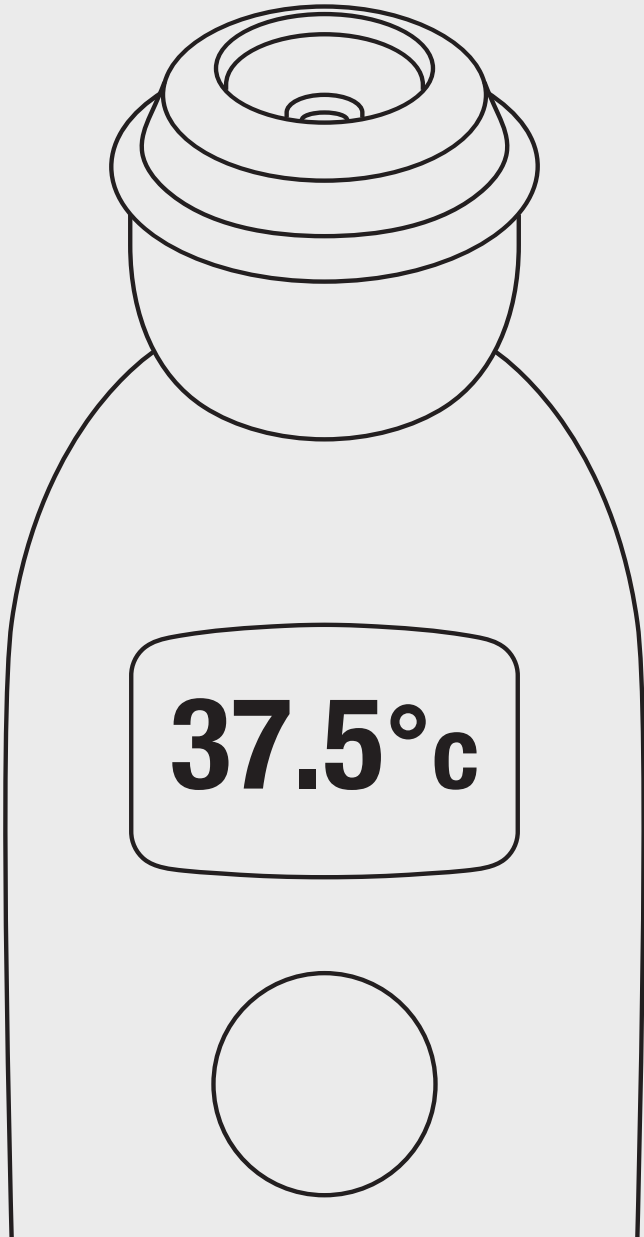


MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 –
Suite 123
2595 AM The Hague
The Netherlands

SYMBOL LEGEND

	Consult Instructions for Use		Degree of Protection Against Electrical Shock Type BF Applied Part, Battery Operated
	This symbol on the product's nameplate means it is listed by Underwriters' Laboratories, Inc.	IP22	Protected against ingress of solid objects greater than 12,5 mm diameter. Protected against dripping water up to 15 degrees from vertical position.
	Manufacturer	   	Medical Device Catalogue Number Batch code Unique Device Identifier
	Swiss Authorized Representative		Conformité Européene Authorized representative in the European Community/ European Union
	UK Conformity Assessed		
	UK Responsible Person		
	UK Responsible Person		
Segurança  	INMETRO		Importer
	Temperature limit		Humidity limitation
	Keep dry		Do not throw this device away in the trash, contact Exergen Corp. for disposal and recycling instructions.

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



37.5°C

**CHANGING THE WAY
THE WORLD TAKES
TEMPERATURE**



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TEMPORALSCANNER™ TAT-2000 SERIES
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