ADC® Adtemp™ Digital Infrared Ear Thermometer

Instructions for Use

Model 424N

AMERICAN DIAGNOSTIC CORPORATION

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MD

Made in China
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AMERICAN DIAGNOSTIC CORPORATION

Adtemp™
Digital Ear Thermometer

WARRANTY

This product was manufactured with the utmost care according to international quality standards.

This product is warranted for two years against manufacturing defects. Claims beyond this, including claims for damages, are excluded.

- The warranty covers the instrument. Packaging is not included.
- Opening or altering the instrument, except to replace batteries, invalidates the warranty.
- The warranty does not cover: transportation charges to ADC; batteries, where supplied; damages caused by improper handling or discharged batteries; accidents; or non-compliance with the operating instructions.

Some states do not allow the exclusion or limitation of incidental, special, or consequential damages, so this limitation may not apply to you.

To Obtain Warranty Service: Send item(s) postage paid to ADC, Attn: Repair Dept., 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, phone no., proof of purchase, and a brief note explaining the problem.

Implied Warranty: Any implied warranty shall be limited in duration to the terms of this warranty and in no case beyond the original selling price (except where prohibited by law).

This warranty gives you specific legal rights and you may have other rights which vary from state to state.

To register your product visit us at
www.adctoday.com/support/warranty-registration

A SPECIAL THANK YOU

Congratulations on your purchase of the ADC® Adtemp™ 424N Digital Infrared Ear Thermometer. ADC® professional diagnostic products are the instruments of choice in hospitals and physician's offices worldwide, where accuracy and dependability are critical. Adtemp thermometers meet or exceed all relevant international performance standards.

DEVICE DESCRIPTION/INTENDED USE

This device measures body temperature for indications of screening for illness and conditions related to elevated or low body temperature. It may be operated by adults capable of understanding the instructions for use and operating general household electrical appliances or by healthcare professionals and personnel.

CONTRAINDICATIONS

The device should not be used on sites with any breached or compromised skin.

WARNINGS AND CAUTIONS ⚠

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.

Warning: The measurement result of this device is not a medical diagnosis and not intended to substitute for consultation and diagnosis by a qualified professional healthcare provider (e.g., physician, pharmacist, or other licensed healthcare professionals).

Warning: Do not use this device for self-diagnosis or for self-treatment of a medical condition. Seek advice from a healthcare professional immediately if the patient is clearly unwell and/or is having physiological or medical symptoms.

Warning: Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed.

Warning: Do not attempt to measure temperature of the body sites that are not specified in these instructions.

Warning: Professional users must follow the country specific applicable medical devices ordinance.

Warning: Do not use this device close to strong electromagnetic fields and portable radio frequency communication devices. Keep a minimum distance of 0.3m from such devices when using this device.

Warning: This device is not certified to be used in vicinity of medical equipment including high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) and computerized tomography (CT) instruments.

Caution: Use of ADC probe cover, or cleaning and/or disinfection of device is recommended before/after measurement to avoid cross-contamination between users and patients.

Caution: Do not re-use probe cover. The probe cover is intended only for single use to prevent cross-contamination of the device between measurements.

Caution: Do not use this device if you think it is damaged or notice anything unusual. Do not attempt to repair, modify, or open this device.

Caution: A basic physiological effect called vasoconstriction can occur in the early stages of fever, resulting in a cool skin effect. The temperature measured during this time will be lower than core body temperature.

SPECIFICATIONS Cont.

Operating conditions	50.0 - 104°F (10 - 40°C) 15 - 90 % relative maximum humidity. 700 - 1060 hPa Atmospheric pressure
Storage and Transport conditions	-13 - 131°F (-25 - 55°C) 15 - 90% relative maximum humidity. 700 - 1060 hPa Atmospheric pressure
Automatic Power off	Approx. 1 minute after last measurement has been taken.
Battery	2 x 1.5 V alkaline batteries; size AAA.
Battery lifetime	Approx. 2000 measurements (using new batteries).
Ingress Protection (IP) Rating	IP22: Protected against solid foreign objects of 12.5 mm Ø and greater. Protected against vertically falling water drops when enclosure tilted up to 15°.
Expected service life	5 years or 12000 measurements

SPECIFICATIONS

Device Name	Digital Infrared Ear Thermometer
Operating Mode	Adjusted Mode
Measurement Site	Ear
Reference body site	Sublingual
Measurement time	1 Second Measurement
Measurement range	89.6 - 109.4 °F (32.0 - 43.0 °C)
Resolution	0.1 °C / °F
Measurement accuracy (Laboratory)	±0.4 °F, 95.0 ~107.6 °F (±0.2 °C, 35.0 ~ 42.0 °C) ±0.5 °F, 89.6 ~ 94.8 °F and 107.8 ~ 109.4 °F (±0.3 °C, 32.0 ~ 34.9 °C and 42.1 ~ 43.0 °C)
Clinical results	Clinical Repeatability: 0.34 °F (0.19 °C) Clinical Bias: 0.05 °F (0.03 °C) Limits of Agreement: 2.4 °F (1.33 °C)
Acoustic	Turn ON device and ready for the measurement: 1 short beep. Complete the measurement: 1 long beep. Out of operating range or system error/malfunction: 3 short beeps. High body temperture: 10 short beeps.
Memory	30 memories recorded with time and date.
Backlight	Turn ON device, the display light will be GREEN for 1 second. The display light will be GREEN for 5 seconds, when a measurement is completed with a reading less than 37.5°C / 99.5°F. The display light will be RED for 5 seconds, when a measurement is completed with a reading equal to or higher than 37.5°C / 99.5°F or out of operating range.

Caution: If the patient's temperature is influenced (e.g., incubator, heating blanket) the measurement result provided by this device shall not be used to determine the presence/absence of fever.

Caution: Doctors recommend rectal measurement for newborn infants within the first 6 months, as all other measuring methods might lead to ambiguous results. If using a forehead thermometer on those infants, we always recommend verifying the readings with a rectal measurement.

Caution: Patients should not drink, eat, or exercise 30 minutes before, or while taking the measurement.

Caution: When taking multiple measurements for comparison, allow a 30-second interval between each measurement.

SYMBOLS DEFINITION

The following symbols are associated with your thermometer.

Symbol	Definition
	Consult instructions for use
	Caution!
	Warning! The general warning sign indicates a possible dangerous situation that can lead to serious injuries.
	Not made with natural rubber latex
	Phthalate free
	Applied Part: Type BF
REF	Catalog Number
MD	Medical Device
#	Model Number
LOT	Lot Number
	Manufacturer
	Temperature Limitation

Symbol	Definition
	Humidity Limitation
	Dispose in accordance with Waste Electrical and electronic equipment (WEEE) directive.
	Importer
UDI	Unique Device Identifier
	Single Use Only
	Keep Dry
	Country of Manufacture

CONTROLS AND FEATURES

Includes storage cradle with built-in pop-up probe cover dispenser. Store on desk or counter, or use enclosed screws to mount cradle on wall.

Display Icon Descriptions

Startup Display Check		Ready to Take New Measurement	
Measurement Complete		Ready to Take Next Measurement	

Recommended separation distances between portable and mobile RF communications equipment and the Adtemp™ 424N.

The Adtemp™ 424N is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Adtemp™ 424N can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Adtemp™ 424N as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
W	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

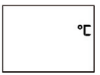
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

Guidance and manufacturer's declaration – electromagnetic immunity			
The Adtemp™ 424N is intended for use in the electromagnetic environment specified below. The customer or the user of the Adtemp™ 424N 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	N/A	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Adtemp™ 424N, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 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). b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2700 MHz	10 V/m	
NOTE 1 At 80 MHz and 800 MHz, 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.			
a. Field strengths from fixed transmitters, 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 strength in the location in which the Adtemp™ 424N is used exceeds the applicable RF compliance level above, the Adtemp™ 424N should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Adtemp™ 424N. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

SWITCHING TEMPERATURE SCALE

Your ADC Adtemp thermometer can display measurements in either Fahrenheit or Celsius. The default temperature scale is Fahrenheit. To change the scale:

1. With the device powered off, press and hold the MEM button for 5 seconds. The °C / °F icon will flash.
2. Press MEM button to select °C or °F, then press START to confirm. If no button is pressed for 5 seconds, the device will return to measurement mode.



SETTING THE DATE AND TIME

1. With the device powered off, press and hold the MEM button for about 10 seconds until the year number flashes.
2. Press the MEM button to change to the current year. To confirm, press the START button.

3. The month will flash. Press the MEM button to change to the current month. To confirm, press the START button.
4. The AM/PM setting will flash. Press the MEM button to change to AM or PM. To confirm, press the START button.

5. The hour will flash. Press the MEM button to change the hour. To confirm, press the START button.
6. The minutes will flash. Press the MEM button to change the minutes. To confirm, press the START button
7. Wait 5 seconds. The device will display the updated settings and then enter measurement mode.

DISABLING THE AUDIO TONE

By default, audio tone will sound when a reading is completed and when device is powered off. To mute this sound:

1. With the device powered off, press and hold the START button for 5 seconds.
2. Press the MEM button to turn the sound on or off. A line through the sound icon indicates that the tone is off.

Sound On **Sound Off**

3. To confirm, press the START button. The device will enter measurement mode.

PREPARING FOR A MEASUREMENT

For Best Results

- With infants: Lay the child flat with their head turned sideways so that one ear is facing upwards.
- With older children or adults: Stand behind and slightly to the side of the patient.
- Always take the temperature in the same ear, as readings may vary between ears.
- Patients should not drink, eat, or exercise 30 minutes before, or while taking the measurement.
- When taking multiple measurements for comparison, allow 30 second interval between each measurement for measurement reliability.

Probe Covers

A probe cover is required for each measurement. If none has been placed on the measuring sensor, the probe cover icon will begin flashing on the display. If you attempt to start the measurement without a cover, the backlight will turn red.

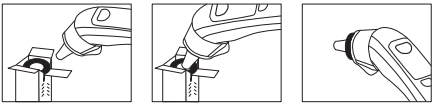
Guidance and manufacturer's declaration – electromagnetic immunity			
The Adtemp™ 424N is intended for use in the electromagnetic environment specified below. The customer or the user of the Adtemp™ 424N should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment--guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±15 kV 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	±2 kV for power supply lines and patient coupled lines	N/A	Battery power only
Surge IEC 61000-4-5	±1 kV line(s) and neutral	N/A	Battery power only
Voltage dips, short 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 5s	N/A	Battery power only
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level			

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: reorient or relocate the receiving antenna, increase the separation between the equipment and receiver, connect the equipment into an outlet on a circuit different from that to which the receiver is connected, consult the dealer or an experienced radio/TV technician for help. This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance.

ELECTROMAGNETIC COMPATIBILITY

This device is compliant with IEC 60601-1-2 Electromagnetic Disturbances standard.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Adtemp™ 424N is intended for use in the electromagnetic environment specified below. The customer or the user of the Adtemp™ 424N should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	The Adtemp™ 424N uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	



Note: This device is calibrated exclusively for use with ADC probe covers. Only use probe covers designed for the Adtemp 424N thermometer.

TAKING A MEASUREMENT

1. With the device off and a probe cover in place, press the START button. All on-screen icons will flash briefly. You'll hear a short beep when the thermometer enters measurement mode. The °C or °F icon will begin flashing.
2. Straighten the ear canal by gently pulling the ear to give a clear view of the eardrum.

   For children under 1 year, pull the ear straight back.

   For all other patients, pull the ear up and back.
3. Place the measuring sensor/probe firmly into the ear canal. Press the START button.
4. A long beep will sound when the reading is complete. Remove the thermometer from the ear canal. The display shows the measured temperature.

- For a temperature reading less than 99.5F (37.5C), you'll hear a long beep and the green backlight will illuminate.
- For a temperature reading at or above 99.5F (37.5C), you'll hear 10 short beeps and the red backlight will illuminate.

5. Press and release the probe cover ejector to remove the used probe cover before starting a new measurement.

Taking Additional Measurements

To take another measurement, wait until the °C and °F icon is flashing and follow the above steps.

Powering Off

The device will power off automatically after about 60 seconds.

To power off manually, press and hold the START button for three seconds. The backlight display will flash green three times along with three long beeps as the thermometer powers off.

Additional Recommendations

In certain situations, we recommend taking three measurements in the same ear and using the highest reading:

- Children less than three years old with a compromised immune system and for whom the presence or absence of fever is critical.
- When the user is first learning how to use the thermometer until they are familiar with the device and obtain consistent readings.
- If the measurement is surprisingly low.

"**Normal**" body temperature varies by measuring site, so readings from different parts of the body should not be compared. Readings can also vary by time of day, being highest in the evening and lowest about one hour before waking up.

Axillary:	94.5 - 99.1 °F	(34.7 - 37.3 °C)
Oral:	95.9 - 99.5 °F	(35.5 - 37.5 °C)
Rectal:	97.9 - 100.4 °F	(36.6 - 38.0 °C)
ADC 424N:	95.7 - 99.3 °F	(35.4 - 37.4 °C)

DISPOSAL

This device is medical electrical equipment. Dispose of this device and its batteries in accordance with the Waste Electrical and Electronic Equipment (WEEE) directive and any applicable local regulations. Do not dispose of the device and batteries with domestic or commercial waste.

CALIBRATION

This thermometer is calibrated at the time of manufacture. If the thermometer is operated in accordance with these instructions, periodic readjustment is not required. ADC recommends checking calibration every two years or whenever clinical accuracy of the thermometer is in question.

Caution: An attempt to service or calibrate the device yourself will void the warranty.

COMPLIANCE STANDARDS

IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; ISO 80601-2-56

FCC

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications to the product are not approved by ADC and could void the user's authority to operate the equipment under FCC jurisdiction. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

Ensure that no liquid enters the interior of the device.

3. Let the disinfectant dry for 10 minutes before using the thermometer.
4. Check that the thermometer is still functional after cleaning and disinfecting.

Caution: Do not scratch the surface of the sensor lens or the display.

Caution: Do not use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the device in water or other cleaning liquids. Do not immerse or wipe the display with cleaning liquids.

Caution: Other cleaning agents or cleaning methods may cause malfunction or damage to the product and will void the warranty.

CARE AND STORAGE

To avoid damaging the device, protect it and its accessories from the following:

- Water, other liquids, and moisture
- Extreme temperatures
- Impacts and vibrations
- Direct sunlight
- Contamination and dust

Store the thermometer and probe covers in a dry, cool place away from sunlight, with ambient conditions within the temperature and humidity ranges.

Operate the thermometer under suitable temperature and humidity.

If the thermometer is not going to be used for a prolonged period, batteries should be removed.

Caution: Storing the device unused for an extended period without removing the batteries increases the risk of battery fluid leakage, which may cause device damage and skin irritation upon contact. If battery fluid comes into contact with your eyes or skin, wash the affected area immediately with plenty of clean water. Consult a doctor if irritation or discomfort persists.

USING THE MEMORY

This thermometer stores the last 30 readings with a record of both time and date taken.

1. With the device powered off, press the **MEM** button to enter memory mode. The M icon will show on the display.

2. Press the **MEM** button again to recall the last reading. The reading number (i.e., 1) appears first, followed by the reading value. The display will alternate showing the date and time of the reading.

3. Press the **MEM** button again to view the next saved reading. Continue scrolling through the stored readings as needed. After reading 30 is shown the memory will begin again at reading 1.

Note: Once 30 measurements are in the memory, each new measurement will overwrite the oldest.

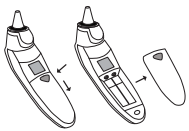
Clearing the Memory

1. With the device powered off, press the **MEM** button to enter memory mode. The M icon will show on the display.

2. Press and hold the **MEM** button for 10 seconds. The LCD displays "**Clr**"
3. Press the **MEM** button again. "**Clr**" will flash on the display and all readings will be deleted.

REPLACING THE BATTERIES

Batteries need replacing when the “low battery” icon is shown on the display.

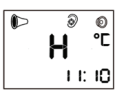
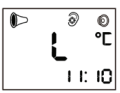


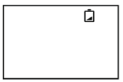
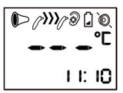
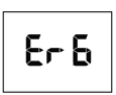
1. Remove the battery compartment cover by sliding it down.
2. Remove the old batteries.
3. Insert two new 1.5V AAA batteries, ensuring the correct polarity as indicated.

Note: Remove the batteries before storing the thermometer for an extended period of time.

Note: Opening or altering the device, except for replacing the batteries, voids the warranty.

DEVICE ERRORS AND TROUBLESHOOTING

Error message	Situation	Solution
The measured temperature is too high/too low   	The temperature taken is not within the typical human temperature range 89.6-109.4°F (32.0-43.0°C). **H** = too high, measured temperature is higher than 109.4 °F (43.0 °C). **L** = too low, measured temperature is lower than 89.6 °F (32 °C). *The device will show the red backlight for 5 seconds, then go to ready for measurement.	Make sure the measurement sensor/probe is clean, and a new probe cover is attached. Make sure the thermometer is properly inserted. Then, take a measurement again.
Ambient temperature is too high/too low   	Temperature taken is not within normal ambient temperature range 10.0 - 40.0°C (50.0 - 104.0°F). **AH** = too high, ambient temperature is higher than 40.0°C / 104.0°F. **AL** = too low, ambient temperature is lower than 10.0 °C / 50.0 °F. *The device will show the red backlight for 5 seconds, then Auto-off in 10 seconds.	Allow the thermometer to rest in a room for at least 30 minutes at ambient temperature (10 - 40°C / 50.0 - 104.0°F). Then, take a measurement again.

Error message	Situation	Solution
Blank display 	The battery/battery's polarity (<+> and <->) has not been loaded correctly.	Check if the battery/ battery polarity (<+> and <->) has been loaded correctly.
Depleted battery indicator 	The batteries are empty.	The batteries should be replaced immediately.
Low battery indicator  	The batteries are low, but the device is still working.	Replace the batteries as soon as possible.
No probe cover on the measuring sensor 	Probe cover is **NOT** attached correctly.	Put on a new undamaged probe cover or adjust the probe cover position correctly.
Error function  	The device has a malfunction.	Remove and reload the batteries and restart the device. If the message still appears, please contact your retailer or ADC's Customer Service line at: 1-800-ADC-2670

CLEANING AND DISINFECTING

Cleaning or disinfecting the thermometer is recommended before and after use, especially if it is dirty, contaminated, or has been in storage.

1. To clean, use an alcohol swab or cotton tissue moistened with 70% Isopropyl alcohol.
2. Wipe the surface around the measuring probe/sensor clockwise once and then wipe the whole contact surface from the probe to the inside (towards the main device body) three times.