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Section I — Introduction

This operator's manual was prepared for the operator of the McKesson Lumeon® Series Infrared Tympanic Electronic Thermometer. This manual contains instructions for use, precautions, and available maintenance and service information. To achieve satisfactory results, the operator must read this manual thoroughly before attempting to use the thermometer.

Initial Set Up

- Unpack the infrared tympanic electronic thermometer and examine it for structural integrity.
- If using the wall or cart mount options (sold separately) for the base unit, consult the installation sheet provided with the respective system.
- When first used, the infrared tympanic electronic thermometer will show the factory preset settings: ear mode (EAR) and the Celsius scale (°C).

Section II — General Information

The McKesson Lumeon® Series Infrared Tympanic Electronic Thermometer is a fast, accurate, and convenient clinical instrument for measuring patient temperatures. The infrared tympanic electronic thermometer is an ear canal thermometer with measurement site equivalence modes including oral, core, and rectal equivalent temperatures. The equivalence modes are explained further in Section V, Instructions for Use.

Features

- Very fast temperature acquisition that meets CEN and ASTM standards - see Section XI.
- Peak Select System™
- Temperature measurement range of 33.0°C to 42.0°C (91.4°F to 107.6°F).
- Once temperature has been acquired, the °C/°F button alternates the displayed temperature between °C and °F.
- Audible and visual indication of completed temperature acquisition.
- Disposable single use probe covers aid in the prevention of a cross contamination of infectious diseases.
- Low and dead battery indicators.
- "Sleep" mode stores the last temperature and conserves battery life.
- 15, 30, 45, and 60 second pulse timer functions.
- The thermometer housing can be cleaned with common cleaning agents. See Section VII, Cleaning for instructions.
- Base unit protects the thermometer tip and stores probe covers for easy access.
- Easy to read LCD display with icons.
- Unit is designed for ambidextrous use.
- Improved probe design to allow ease of use on the pediatric population.

Section III — Important Precautions

- The thermometer is a precision optical instrument. For reliable operation, handle carefully and do not drop.
- Read the operator's manual thoroughly before using the infrared tympanic electronic thermometer.
- WARNING: No modification of this equipment is allowed.
- Prior to use, ensure that the probe tip is clean and clear of any material. If the thermometer tip becomes soiled,

gently clean with a lens wipe or lint free swab. The tip should appear shiny and free of fingerprints and/or debris. For further cleaning instructions refer to section VII Cleaning.

- Always install a new probe cover prior to taking a temperature. The probe cover membrane should be smooth with no holes, tears, or wrinkles.
- The thermometer was designed to be used only with McKesson Lumeon® Series Infrared Tympanic Electronic Thermometer Probe Covers. Use of probe covers manufactured by any company other than McKesson may result in erroneous readings.
- Ensure that the probe tip seals the ear canal prior to taking a temperature. Failing to seal the ear canal will result in a loss of accuracy.
- When not in use, the infrared tympanic electronic thermometer should be placed in the thermometer base unit.
- The infrared tympanic electronic thermometer should not be used on patients with ear drainage, blood, cerebrospinal fluid, vernix, ear wax plugs, or foreign bodies in the ear canal.
- Patients with removable hearing aids should remove the device at least 10 minutes prior to ear temperature assessment. Implanted devices generally do not affect ear temperature.
- Pressure equalization (PE) or tympanostomy tubes will not adversely affect accuracy. For patient comfort, wait one week after surgery before using infrared tympanic electronic thermometer.
- When assessing patient temperatures during cold weather conditions, allow the patient to equilibrate to room temperature before use.
- Excessive eardrum scarring may cause lowered temperature readings.
- Under normal conditions, ear wax does not affect accuracy. However, cerumen plugs or impactions containing debris can lower the temperature measurement by several tenths of a degree.
- Always wait at least two minutes before taking another measurement in the same ear.
- Used probe covers must be treated as infectious biological waste and disposed of in accordance with current medical practices and local regulations.
- Alkaline batteries must be disposed of in accordance with local environmental and institutional policies.
- Do not use lithium batteries with this device.
- Do not mix alkaline and rechargeable batteries.
- Removal of the batteries is recommended if the unit is not going to be used for an extended period of time.
- Expired or old equipment must be disposed of in accordance with institutional policy.
- Fluid ingress may cause a reduction in battery life and interfere with unit functionality. Cleaning guidelines should be followed as per section VII to prevent fluid entering the unit.
- Do not use this device near flammable anesthetics. Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide, or in an oxygen rich environment.

Section IV — Icon Identification


Eject Button


Dispose of as Electrical and Electronic Waste

°C/°F Button


Type BF Protection (Degree of protection against electrical shock - there is no conductive connection to the patient)

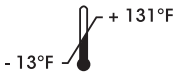

Timer Button

DEHP-free


Operating Instructions


Use By


Non-ionizing electromagnetic radiation



Temperature Limitations


Keep away from sunlight

By prescription only


Scan Button

Latex-free


Choking Hazard

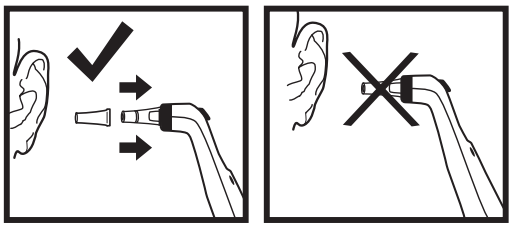
Non-Sterile

Lot Number

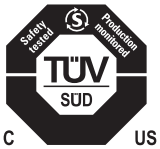

Keep dry


Date of manufacture

Humidity limitations


Probe cover installed

Probe cover not installed



Medical Electrical Equipment

Infrared Tympanic Electronic Thermometer

(1) Classified with respect to electical shock, fire and mechanical hazards in accordance with UL60601-1

(2) Classified with respect to electrical shock, fire, mechanical and other specified hazards in accordance with CAN/CSA C22.2 No. 60601-1-08

The infrared tympanic electronic thermometer is a reliable and accurate temperature-taking device. The reason for the accuracy of the infrared tympanic electronic thermometer is the design, controlled calibration methods and stringent manufacturing controls. One of the most critical functional parts of a thermometer is the probe cover. The infrared tympanic electronic thermometer probe cover, when placed on a infrared tympanic electronic thermometer, serves as an infection control barrier between the patient and the device and the medium for heat transmission from the patient to the thermometer. The functionality of the infrared tympanic electronic thermometer probe cover is extremely important for preventing device contamination and also for allowing accurate patient temperature measurements.

The reason the infrared tympanic electronic thermometer and probe covers have satisfied our customers' expectations is due to the integration of these two parts during the manufacturing process. The infrared tympanic electronic thermometer probe cover molding process parameters are tightly controlled to minimize variation and produce consistent and reliable products. The special grades of thermoplastic materials are also tightly controlled and are specifically chosen to deliver consistent temperature measurements with infrared tympanic electronic thermometers. The factory calibration and final determination of an acceptable infrared tympanic electronic thermometer is dependent on the use of acceptable probe covers. The use of generic probe covers or other probe covers not produced by McKesson Medical-Surgical Inc. is not supported or sanctioned. The use of unauthorized infrared tympanic electronic thermometer probe covers could jeopardize the accuracy of the infrared tympanic electronic thermometer. Check your probe cover carton for the McKesson Lumeon ® Series logo to be certain that your thermometer will deliver an accurate temperature every time it is utilized.

Section V — Instructions for Use

Peak Select System™

The infrared tympanic electronic thermometer uses the patented Peak Select System. This system is different than what is found in other similar thermometers in that it reduces technique errors by taking multiple readings and automatically selects the most accurate temperature for display. Whereas other systems only use 32 readings, the Peak Select System uses 100 readings for the infrared tympanic electronic thermometer.

Equivalence Modes

The infrared tympanic electronic thermometer is an ear canal thermometer for neonates, newborns, children, and adults.

Prior to the introduction of tympanic thermometry, patient temperatures were measured in the mouth (oral), in the rectum (rectal), or in special cases with an indwelling Swan-Ganz™* catheter (core). If a patient's temperature was measured simultaneously with each of these methods, different absolute temperatures would be obtained. The infrared tympanic electronic thermometer compensates for the average difference in temperature at each of these sites by adjusting the displayed temperature.

A checker / calibrator is available for this device. The device should be checked if it is dropped or if it is stored at less than -25°C or above 55°C.

"ASTM laboratory accuracy requirements in the display range of 37 to 39°C (98 to 102°F) for Infrared thermometers is ± 0.2°C (± 0.4°F), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E 667-86 and E 1112-86 is ± 0.1°C (± 0.2°F)."

The following equivalence modes are available on the infrared tympanic electronic thermometer. Data is available from Covidien on request.

Ear: In ear (EAR) mode, the display will indicate the absolute temperature without adjustment.

Oral: In oral (ORL) mode, the tympanic temperature is adjusted to display an oral temperature equivalent. Oral Mode = Ear Mode + 0.60°C.

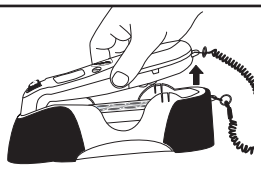
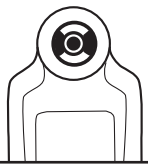
Core: In core (CORE) mode, the tympanic temperature is adjusted to display the core temperature equivalent. Core Mode = Ear Mode + 1.04°C.

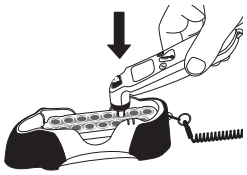
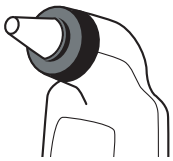
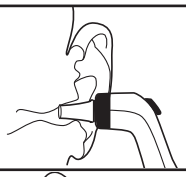
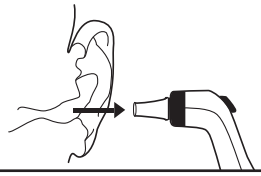
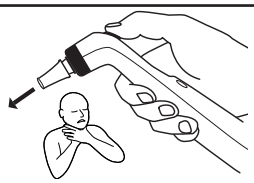
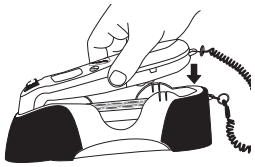
Rectal: In rectal (REC) mode, the tympanic temperature is adjusted to display the rectal temperature equivalent. Rectal Mode = Ear Mode + 1.16°C.

Probe Covers

The infrared tympanic electronic thermometer utilizes a single use disposable probe cover during temperature measurement. The probe cover was designed especially for use with the infrared tympanic electronic thermometer. The use of probe covers produced by any company except McKesson Medical-Surgical Inc. will result in erroneous temperature measurement. In order to aid in infection prevention and control, always install a new probe cover prior to taking a temperature. The probe covers are contained in a cassette that is located in the thermometer base. To load a probe cover on the thermometer, firmly insert the probe tip into the probe cover. When installed on the thermometer, the probe cover membrane should be smooth with no holes, tears, or wrinkles. After the patient temperature has been taken, eject the probe cover by pressing the eject button and then dispose of properly.

Temperature Measurement

	1. Remove the infrared tympanic electronic thermometer from the base.
	2. Inspect the probe lens. If any debris is present, clean the probe tip per the directions in Section VII, Cleaning. If the probe tip is clean, proceed to step 3.

	3. Press the scan button to verify functionality and mode selection on the LCD screen. Install a probe cover by firmly inserting the probe tip into a probe cover. After the probe cover is installed, the thermometer will perform a system reset. The thermometer will then display dashes, the equivalence mode, and the thermometer icon.
	4. Inspect the probe cover to make sure it is fully seated (no space between cover and tip base) and no holes, tears, or wrinkles are present in the plastic film.
	5. Place the probe in the ear canal and seal the opening with the probe tip. For consistent results, ensure that the probe shaft is aligned with the ear canal.
	6. Once positioned lightly in the ear canal press and release the scan button. Wait for the triple beep before removing the thermometer.
	7. Remove the probe from the ear as soon as the triple beep is heard.
	8. The patient temperature and the probe eject icons will be displayed.
	9. Press the eject button to eject the probe cover into a suitable waste receptacle.
	10. Always return the thermometer to base for storage.

Temperature Recall

After a temperature has been acquired, the thermometer will enter “off“ mode after approximately 10 seconds. Recall the temperature by pressing and releasing the scan button or by pressing and holding the °C/°F button.

Temperature Display - Toggle °C or °F

When a temperature is in the display, the user may press and hold the °C/°F button to toggle between degrees Celsius and degrees Fahrenheit.

Sleep Mode

The infrared tympanic electronic thermometer enters sleep mode after 30-40 seconds of non-use. To wake up the thermometer, eject the attached probe cover and/or install a new probe cover. This energy conserving function optimizes battery life.

Pulse Timer Mode

1. Press and hold the timer button to enter Timer mode. Press again to start the timer. The timer will run from 0 to 60 seconds.
2. The thermometer will issue a single beep at 15 seconds, a dual beep at 30 seconds, a triple beep at 45 seconds, and four beeps at 60 seconds.
3. Press the timer button at any point during the timer function to return the thermometer to “off“ mode.
4. At the end of the 60 seconds, the thermometer will wait two seconds and then enter sleep mode.
5. Return the thermometer to base for storage.

Thermometer Display Icons and Alarms

Thermometer operation is communicated to the user via the LCD display and an audible device contained inside the thermometer case. After the probe cover is installed or the batteries have been changed, the thermometer will perform a system reset. The thermometer will perform an internal test to verify that the system components are functioning properly.

Alarm Condition	**Display Mode**
Patient temperature above specified range	
Patient temperature below specified range	
Ambient Temperature above specified range	

Ambient Temperature below specified range

Low Battery

The LCD displays the low battery icon. The low battery icon will remain on until the battery is replaced or until the dead battery icon is displayed. After the low battery icon is displayed, the user may take approximately 100 temperatures until the dead battery icon is displayed.

Dead Battery

The LCD displays the dead battery condition. When any button is pressed, the battery icon will flash several times and then the LCD will turn OFF. After the battery icon is displayed, the batteries must be changed before the thermometer can be used.

If the display shows a system error 4 and the system error icon, the ambient conditions are changing too rapidly for the device to be used. Allow the device to equilibrate for 20 minutes before using.

If the display shows any other system error, then reset the thermometer by installing a probe cover. If the system error does not clear, then contact the factory for available service options. The applicable manufacturer addresses are located in Section XII, Customer Service.

Biotech Mode

The biotech function is used to select the operational mode of the thermometer and to verify the installed software version. All operational mode settings in biotech mode are stored in nonvolatile memory and retained through system power cycles, such as changing batteries. All factory calibration parameters are also stored in nonvolatile memory.

The factory default settings are shown below:

Temperature mode	°C (unlocked)
Site mode	Ear
Site text	On

The biotech mode is accessed by pressing and holding the timer and °C/°F buttons for four seconds. All LCD segments will light for one second, the thermometer will issue a single beep, and the display will show scrolling dashes. Pressing the timer button cycles through the biotech modes. When options are available within a mode, the °C/°F button cycles through the options.

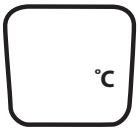
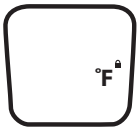
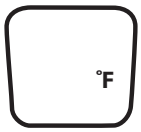
Pressing the timer button after the site text display will return the user to the installed software version. To exit biotech mode, two options are available: (1) press and hold the °C/°F and timer buttons for one second, or (2) the device will automatically exit biotech mode after about 30 seconds of inactivity. Any changes are saved.

The biotech mode sequence is shown below:

Software version

Displays the installed software version of device. Where "00" is the current software version.

Temperature mode

Option	**Display**
°C (unlocked)	
Locked °C	
Locked °F	
°F (unlocked)	

Site mode

Option	Display
Oral	
Core	
Rectal	
Ear	

Site text

Pressing the °C/°F button when in this mode turns the body site text labels on or off. The labels will remain on when an “X” appears inside the box icon, and the text will remain off when the box is empty.

Section VI — Preventative Maintenance

Functional checks must be performed by technicians and based on the procedure in the infrared tympanic electronic thermometer checker operation manual. The device must be checked for calibration every 25 weeks or whenever calibration is in question. Contact your McKesson Medical-Surgical Inc. representative for details. Harsh use or harsh environmental conditions may result in the need for more frequent checks. If the unit is dropped, abused, or stored at less than -25°C, or above 55°C, check the unit prior to next use.

Section VII — Cleaning

- The infrared tympanic electronic thermometer body may be wiped clean with a damp cloth. Water temperature should not exceed 55°C (130°F). Do not soak, rinse, or submerge the infrared tympanic electronic thermometer under water. When cleaning the thermometer body a probe cover should be installed on the thermometer. This will prevent harsh chemicals from damaging the tip and probe lens.

- A mild detergent or detergent wipe may be used for cleaning purposes. Do not use cleaners such as Spray Nine™*, Phisohex™*, Hibiclens™*, Vesta-Syde™* , Anios DDSH™*, Sufanios Citroen™*, Perasafe powder™*, Sekusept Pulver, Classic™*, Sekulyse™*, Diesin HG™*, Incides N™*, Surfa`Safe™* disinfectants as they may result in damage to the thermometer case or electronics.
- Cleaning agents that contain Chlorine are not recommended, but if it is necessary, use a 10:1 water hypochlorite mixture. A damp isopropyl alcohol wipe, Cidex™*, Manuklenz™*, VIROX™* or CaviWipes™* cleansing agents are acceptable. However, prolonged or repeated use of these chemicals may result in damage to the thermometer case, display or electronics. When cleaning the thermometer, make sure the wipe has all excess fluid squeezed from it. If too wet, the chemical may penetrate the handset and affect the thermometer functionality. Never spray the thermometer directly with cleaning chemicals. Spray a cloth or sponge lightly dampening it with the cleaning agent and then apply it to the thermometer.
- The probe tip can be cleaned using an Isopropyl alcohol wipe such as Webcol™* or Curity™*. Remove all foreign matter from the thermometer tip. After the foreign matter has been removed, dry the window at the end of the probe tip using a lint free swab, cotton ball or lens wipe. The thermometer lens must be free from fingerprints and / or smudges for proper operation. After cleaning the tip allow the thermometer to air dry for 30 minutes prior to use.
- Use of a cloth or sponge is recommended for cleaning. Never use an abrasive pad or an abrasive cleaner on the infrared tympanic electronic thermometer.
- The thermometer is non-sterile. Do not use ethylene oxide gas, heat, autoclave, or any other harsh method to sterilize this thermometer.
- Allow sufficient time for drying before attempting to use the thermometer.

Section VIII — Battery Replacement

The infrared tympanic electronic thermometer batteries should be replaced when the low battery icon is shown on the LCD display. After the low battery icon is displayed, the user will be able to take approximately 100 temperatures before the dead battery icon is displayed and the unit will not allow a temperature to be taken. To replace the batteries, access the battery compartment by unscrewing the battery door that retains the battery cover. Note the polarity of the installed batteries. Remove the old batteries and install fresh batteries, ensuring the correct polarity. Reinstall the battery cover and secure it with the screw.

Section IX — Mounting Instructions

If using the wall or cart mount options (sold separately) for the base unit, consult the installation sheet provided with the respective system.

Section X — Troubleshooting

If the infrared tympanic electronic thermometer is not functioning properly, check the following items:

Symptom	Action
Temperature reading unusually high	Check the probe cover for tears or gaps
Temperature reading unusually low	Check the probe cover and thermometer tip for obstructions. Check the patient ear canal for obstructions.
Low battery indicator lit	Replace battery

Dead battery indicator lit	Replace battery
Display blank	Replace battery
System error displayed	If system error “4”, then let the thermometer equilibrate in the room for 20 minutes before using. For all other system errors, reset the thermometer by installing a probe cover. If the system error does not clear, send the thermometer to the facility Biomedical Engineering department or contact the factory for available service options. The service information is located in Section XII, Customer Service.

The infrared tympanic electronic thermometer advisory and alarm conditions are described in the Thermometer Display Icons and Alarms subheading of Section V, Instructions for Use.

Section XI — Specifications

Clinical accuracy characteristics and procedures are available from the manufacturer on request. To verify accuracy, use a certified blackbody as specified in EN 12470-5-2003, Annex C or use the Checker/Calibrator.

Calibrated Accuracy Limits:

Ambient Temperature	Target Temperature	Accuracy
16°C to 33°C (60.8°F to 91.4°F)	33°C to 42°C (91.4°F to 107.6°F)	± 0.2°C (± 0.4°F)

Displayed Temperature Measurement Range:

Temperature Range Depends On Site Mode as follows:

Mode	Range °C	Range °F
Ear	33.0 to 42.0	91.4 to 107.6
Oral	33.6 to 42.0	92.5 to 107.6
Core	34.0 to 42.0	93.2 to 107.6
Rectal	34.2 to 42.0	93.6 to 107.6

Ambient Temperature Range:

16°C to 33°C (60.8°F to 91.4°F) where as CEN defines the standard as 16°C to 35°C (60.8°F to 95°F), 10 to 95%RH, non-condensing

Transport and Storage Temperature Range:

-25°C to 55°C (-13°F to 131°F), up to 95% RH non-condensing. If the unit is stored at extremes, it is recommended that the unit be checked on the field calibration checker or at the factory before returning to service.

Clinical Repeatability:

Meets Section A.5 of EN 12470-5: 2003 (E) per Covidien technical report. Data is available from Covidien on request.

Response Time:

Less than 2 seconds

Pulse Timer:

60 seconds

Temperature Resolution:

0.1°C or 0.1°F

Power:

Internally Powered ME Equipment
3 AAA alkaline batteries

Battery Life:

Minimum of 15,000 temperature readings

Size:

Thermometer — 17.8 cm (7")
Base — 20.3 cm (8")

Weight:

Thermometer (with batteries) — 160 grams
Base — 100 grams

Degree of Protection Against Electrical Shock:

Type BF

Mode of Operation:

Continuous

Degree of Protection Against Ingress of Fluids:

Not Protected-IPX0

Regulatory and Safety Standards:

The infrared tympanic electronic thermometer follows international regulatory standards.

- EN 12470-5:2003 (E) Clinical Thermometers – Part 5: Performance of infrared ear thermometers where sections 6.3.4 and 6.5.5 were met based on technical report. Data is available from Covidien on request.
- UL 60601-1
- EN 60601-1:2006
- EN 60601-1-2:2007
- MDD 93/42/EEC
- BS EN 980: 2003
- ASTM E1965-98
- IEC 1000-4-2: 1995
- IEC 1000-4-3:1995

The device meets EN12470-5:2003 (E) and ASTM E1965-98 subject to the following conditions:

1. The software was modified during testing to increase the precision of the measurements taken from one significant digit to two significant digits.

2. The increased precision numbers were then averaged to account for the known variance in measurements taken due to human factors.

3. Post-calibration with the Checker/Calibrator, the infrared tympanic electronic thermometer has been tested to meet the accuracy requirements of ASTM E1965-98 at 90% reliability with 95% confidence.

Section XII — Customer Service

In the event that it is necessary to return a unit for repair, please contact McKesson Medical-Surgical Inc. customer information desk at **800-777-4908.**

Parts Listing

To order repair parts, contact our customer service center or your sales representative for the parts listed below.

Description	Order Part Number
McKesson Lumeon ® Series Infrared Tympanic Electronic Thermometer Probe Covers	3068
McKesson Lumeon ® Series Infrared Tympanic Electronic Thermometer	3069

Section XIII — Warranty

LIMITED WARRANTY: Your McKesson Lumeon ® Series Infrared Tympanic Electronic Thermometer is manufactured exclusively for McKesson Medical-Surgical Inc. by Covidien, LLC. Covidien warrants to the original purchaser ("Customer") that this product will be free of defects in materials and workmanship, under normal use, for one (1) year from the date of original purchase from McKesson Medical-Surgical Inc. If this product does not operate as warranted above during the applicable warranty period, Covidien may, at its option and expense, replace the defective part or product, or, if neither replacement nor repair is reasonably available, refund to Customer the purchase price for the defective part or product. Dated proof of original purchase will be required.

Covidien does not assume any liability for loss arising from unauthorized repair, misuse, neglect, or accident. Removal, defacement, or alteration of serial lot number voids warranty. Covidien disclaims all other warranties, expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose or application other than expressly set forth in the product labeling.

Section XIV — Electromagnetic Conformity Declaration

The infrared tympanic electronic thermometer and base has been built and tested according to UL 60601-1 IEC60601-1, CAN/CSA C22.2 No. 60601-1-08, and EN60601-1-2 Standards.

Guidance and manufacturer's declaration - electromagnetic emissions		
The infrared tympanic electronic thermometer and base is intended for use in the electromagnetic environment specified below. The user of the infrared tympanic electronic thermometer and base should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions (CISPR 11)	Group 1	The infrared tympanic electronic thermometer and base uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class B	The infrared tympanic electronic thermometer and base is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The infrared tympanic electronic thermometer and base is intended for use in the electromagnetic environment specified below. The user of the infrared tympanic electronic thermometer and base should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) (EN 61000-4-2 per EN 60601-1-2: 2007)	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 ± 1 kV for input/output lines	not applicable not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	not applicable not applicable	Mains power quality should be that of a typical commercial or hospital environment.
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 5 sec	not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Infrared Tympanic Electronic Thermometer and Base requires continued operation during power mains interruptions, it is recommended that the P-STIM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field (EN 61000-4-8 per EN 60601-1-2: 2007)	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.			

Recommended separation distances between portable and mobile RF communications equipment and the Infrared Tympanic Electronic Thermometer and Base

The infrared tympanic electronic thermometer and base is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the infrared tympanic electronic thermometer and base can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the infrared tympanic electronic thermometer and base recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d=1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
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.

Guidance and manufacturer's declaration - electromagnetic immunity

The infrared tympanic electronic thermometer and base is intended for use in the electromagnetic environment specified below. The customer or the user of the infrared tympanic electronic thermometer and base 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 Radiated RF (EN 61000-4-3 per EN 60601-1-2: 2007)	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	Not applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the infrared tympanic electronic thermometer and base, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** Not applicable $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] 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: 

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 infrared tympanic electronic thermometer and base is used exceeds the applicable RF compliance level above, the infrared tympanic electronic thermometer and base should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the infrared tympanic electronic thermometer and base.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Questions? Call 1-800-777-4908

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For complete details, please visit
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