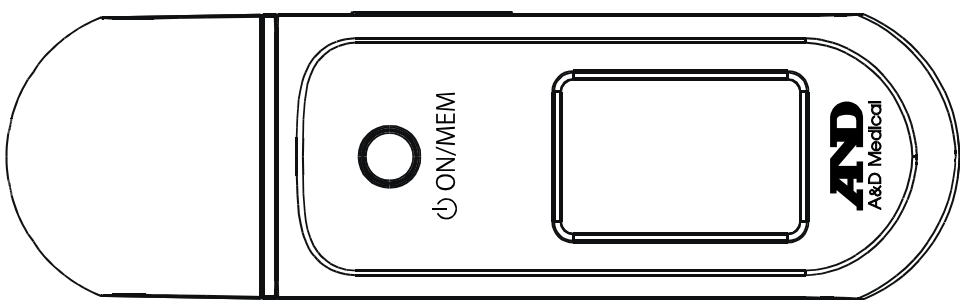
A&D Medical

Multi-function Infrared Thermometer

Model UT-801



Instruction Manual
Original
ENGLISH

Manuel d'instructions
Traduction
FRANÇAIS

Manual de Instrucciones
Traducción
ESPAÑOL

Manuale di Istruzioni
Traduzione
ITALIANO

使用手冊
翻譯
中文

دليل التعليمات
ترجمة
عربي

1WMPD4003399E Date of issue: 2024-09-12

Contents

Dear Customers

Congratulations on purchasing a state-of-the-art A&D thermometer, one of the most advanced thermometers available today. Designed for ease of use and accuracy, this device will facilitate your health care regimen.
We recommend that you read through this manual carefully before using the device for the first time.

Preliminary Remarks

- This device conforms to the European Directive Regulation 2017/745 for Medical Products. This is proved by the CE conformity marking CE 1639 (1639: The identification number of the Notified Body).
- Environment for use: This device is designed for use indoors.
- This device [the Ear/Forehead thermometer] is electronic thermometer using an infrared detector(thermopile detector) to detect body temperature from [ear canal: Ear mode/forehead: Forehead mode] in people of all ages.

Precautions

- Precision components are used in the construction of this device. Extremes in temperature, humidity, direct sunlight, water, shock or dust should be avoided.
- There is no gender and age limitation for using the infrared thermometer.
- Do not let children use the device by themselves and do not leave the device in a place within the reach of infants.

- Intended use: The ear/forehead thermometer is electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from ear canal/forehead in people of all ages.
- Intended operator: The intended operator should have at least eight years of education, including patients or other operators.
- Clinical benefits: The multi-function infrared thermometer can be quick and safe to measure body temperature because it used a noninvasive method.
- This thermometer has been designed for everyday use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. Please consult with doctor if you have health concerns.
- Wireless communication devices, such as home networking devices, mobile phones, cordless phones and their base stations, and walkie-talkies can affect this thermometer. Therefore, a minimum distance of 3.3 meters (11 feet) should be kept from such devices.
- Measurements may be distorted if the device is used close to televisions, microwave ovens, X-ray or other devices with strong electrical fields.
- There are small parts that may be a choking hazard if swallowed accidentally by infants.
- No AP/APG (not suitable for use in the presence of flammable anesthetics or oxygen)

Symbols

	Follow instructions for use	CE 1639	The CE mark and Notified Body Registration Numbers, the requirement of ANNEX IX excluding Chapter II of MDR (EU) 2017/745 are met.		BF type applied part
	Please do not dispose of the product in the household waste at the end of its useful life. Disposal can take place at appropriate correction points provided in your country.				
MD	Medical device	UDI	Unique device identifier	SN	Serial number
IP22	Classification for water ingress and particulate matter		Manufacturer	EC REP	EU-representative
	To protect the environment, dispose of empty batteries at your retail store or at appropriate collection sites according to national or local regulations.				
	Stand-by		Caution		Paper Recycling		Manufactured Date

Cautions

Please read the instructions carefully before using this device,

⚠ Choking from swallowing small parts and batteries by children or pets is possible, please keep small parts and batteries at places where children and pets can't reach.

⚠ The device should not submerge into any liquids and expose it to direct moisture, and please keep away from direct sunlight.

⚠ If there is certain temperature difference between the places where the device is stored and where you are going to measure, subject and the device should stay in the same room for at least 15 minutes before measurement.

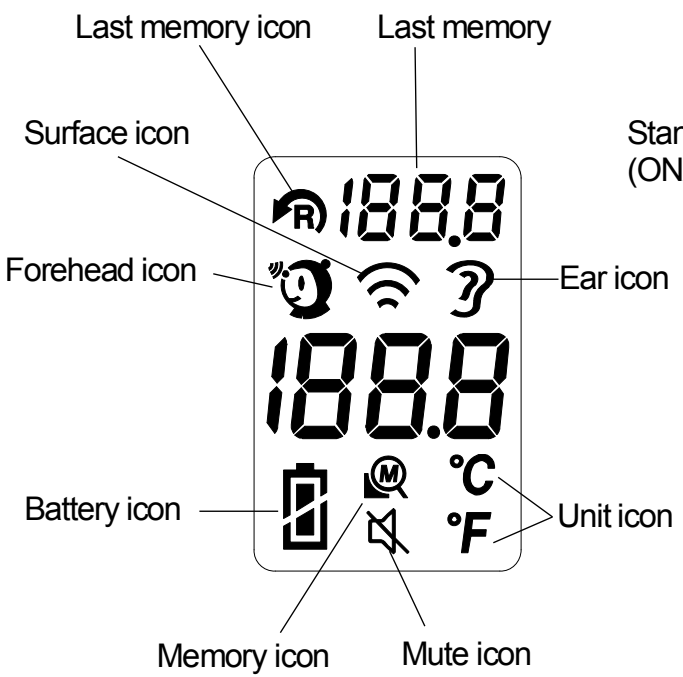
⚠ Insert the batteries correctly with the flat positive (+) side up.

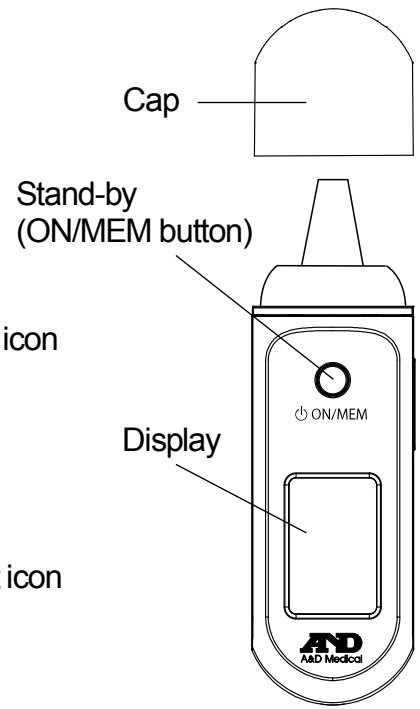
⚠ Proper installation of the probe cover and using the specific probe cover ensure accurate measurements.

⚠ Always make sure the probe lens is clean without any damage.

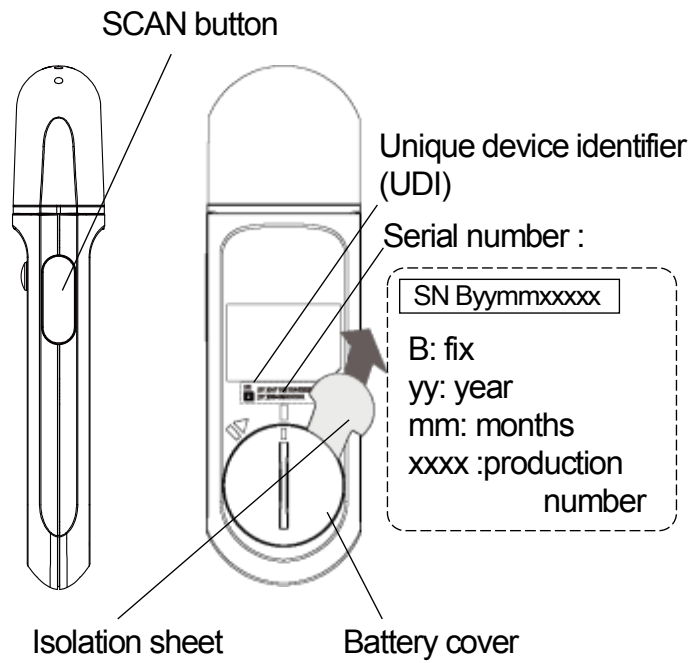
⚠ No modification of this equipment is allowed.

Parts Identification





When first time using, please pull out the isolation sheet.



Functions

Ear temperature

This thermometer has been designed for everyday use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement results to your regular body temperature. Please consult with doctor if you have health concerns.

Forehead Temperature

This thermometer has been designed for everyday use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement results to your regular body temperature. Please consult with doctor if you have health concerns.

Room temperature

Suitable ambient temperature is important for the baby and patient. The thermometer always helps you recognize the room temperature.

Surface Mode

The surface mode shows the actual surface temperature which is different from the body temperature. It can help you monitor if the object temperature is suitable, for example the baby's milk.

Temperature Awareness Signal

If the thermometer detects a body temperature above 37.5°C, there will be a long beep followed by three short beeps to warn the user of potential fever.

Last Reading

When you get a new temperature reading in ear mode or forehead mode, the last reading will be shown on the screen (in the top right corner) with the last reading icon.

Memory Locations

There are a total of 25 memory sets for the body temperatures. --- When powered on, press the “ON/MEM” button to see the temperatures stored with memory icon.

°C / °F Switch

In “Power Off” mode, press and hold the “SCAN” button, then press the ON/MEM button for 3 seconds. The temperature icon “°C” will switch to “°F”. You can also use the same process to change from °F to °C.

Memory clear and Celsius/Fahrenheit switch are together. Once the unit change is made, the memory will also be cleared.

Mute mode

The buzzer setting defaults to on. You can toggle the buzzer on/off in mute mode. With the power on, press and hold the “ON/MEM” button for 3 seconds. The mute icon will flash on the display. Release the “ON/MEM” button to turn on MUTE. Now you will not hear beeps. You can also use the same process to turn off the mute function.

NOTE: If you keep pressing the "ON/MEM" button for 5 seconds after the mute icon flashes, the device will turn off WITHOUT setting mute.

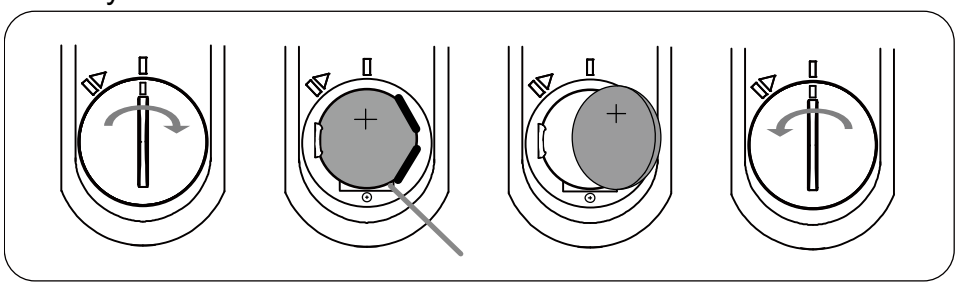
Auto power off

Device will automatically shut off(stand-by) if left idle for more than 1 minute. And the device can only be powered off automatically.

Device is always displayed the ambient temperature in stand-by and you cannot turn off all displays on LCD.

Installing/changing batteries

1. Open the battery cover: Insert a coin into the groove of battery cover at the rear of the device and twist it clockwise. The battery is located under the cover.
2. Hold the device and flip the battery out with a small screwdriver.
3. Insert the new battery under the metal hook on the left side and press the right side of the battery down.
4. Close the battery cover and twist it counter-clockwise until you hear a click.



⚠CAUTION

- Keep the battery away from children.(This device is supplied with one CR2032 lithium cell.)
- Keep the positive (+) side up and the negative (-) side pointed down.
- Comply with local regulations for the disposal of used batteries.

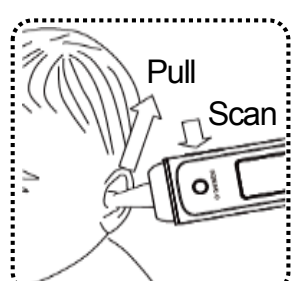
Measurement

1. Always make sure the probe is clean and undamaged.
2. Remove the cap.
3. Power on: Press the “ON/MEM” button.
4. Mode selection:
   - Ear mode: Press the “ON/MEM” button, the default mode of thermometer is ear mode. The thermometer is can be used after you see the ear icon on the display and hear two beep sounds. In this mode, you can measure the body temperature by ear measurement.
   - Forehead mode: After power on, press and hold the “ON/MEM” button, and press the “SCAN” button one time for forehead mode. The forehead icon will display and you will hear two beeps. In this mode, you can measure the body temperature by forehead measurement.
   - Surface mode: After power on, press and hold the “ON/MEM” button, and press the “SCAN” button one time for surface mode. The surface icon will display. In this mode, you can measure surface temperature of an object.
5. Measuring temperature:

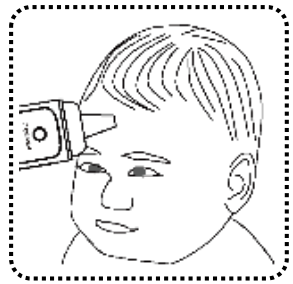
Ear temperature measuring. Points for attention:

(1) Gently pull the ear back to straighten the ear canal and snugly position the probe into the ear canal, aiming towards the membrane of the eardrum to obtain an accurate reading.

(2) Press and hold the “SCAN” button until you hear a beep sound. Remove the probe from the ear and read the temperature measurement on the LCD.



Forehead temperature measuring: Points for attention:



(1) Check the icon on the LCD.

(2) Hold the thermometer within 1~2 cm from the central forehead (See picture).

(3) Press the "SCAN" button to get the forehead measurement. While scanning, you will hear a beep sound, which indicates you the newest measurement is taking place. Measurement has been completed after a long beep is heard and the forehead icon stops flashing. The time consuming for measurement might be 1 second.

(4) After two short beeps are heard, the forehead icon stops flashing to be ready for next measurement.

Measuring temperature in surface mode:

(1) When you press the “SCAN” button, you will get the real time temperature immediately. If you press and hold the “SCAN” button, the measurement will be continuously updated.

(2) Applications include temperature measurements of water, milk, cloth or other objects.

When the distance is between 1~2 cm, it can get the target surface temperature.

NOTE

This mode shows actual, unadjusted surface temperatures, which are different from body temperature.

“This product is certified as a medical device in the European Union under the Medical Device Regulation 2017/745 by SGS CE1639, exclusively for the indication(s) of non-contact forehead temperature measurement. Other non-medical uses ascribed to this device are not within the scope of CE certification, and users should be aware product performance and/or safety has not been evaluated by SGS for those purposes.”

6. After measurement:

(1) Power off:

Device will automatically shut off(stand-by) if left idle for more than 1 minute. And the device can only be powered off automatically.

(2)Clean the probe after each use to ensure accurate readings and avoid cross contamination. (See the section on "Care & Maintenance" for details.)

(3) Device is always displayed the ambient temperature in stand-by and you cannot turn off all displays on LCD.

NOTES

- This thermometer has been designed for everyday use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. Please consult with doctor if you have health concerns.
- Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.

<table>
<tr><td rowspan="2">NOTES</td><td colspan="2">- Before the measurement, the subject should stay in a stable environment for 5 minutes and avoid exercise, bath for 30mins.
- To avoid the risk of cross contamination, please clean the probe according to “Care & Maintenance” section after each use</td></tr>
<tr><td><u>Taking Ear Temperature</u>
-The different temperature varies in healthy persons between different parts of the body can be between 0.2~1°C
-The “Clinical Bias” is 0.24°C.
-The “Limits of Agreement” is 1.76.
-The "Repeatability" is 0.06°C.</td><td><u>Taking Forehead Temperature</u>
-Remember to keep the forehead area clean and away from sweat, cosmetics and scar while taking temperature.
-The “Clinical Bias” is 0.68°C.
-The “Limits of Agreement” is 1.27.
-The "Repeatability" is 0.06°C.</td></tr>
</table>

Troubleshooting

Error	Problem	Recommended Action
Er	Other errors, the system is not functioning properly.	Take out the battery, wait for 1 minute and reinsert it. If this message reappears, contact the retailer for service.
Er 1	Measurement before device stabilization.	Wait until all the icons stops flashing before measuring.
AbH	The ambient temperature is >40°C (104°F)	Allow the thermometer to rest in a room for at least 15 minutes at room temperature: 10°C to 40°C (50°F to 104°F).
AbL	The ambient temperature is <10°C (50°F)	
Hi	In ear/forehead mode: Temperature taken is higher than +42.2°C (108°F) In surface mode: Temperature taken is higher than +80°C (176°F)	Please select the target within specifications. If a malfunction still occurs, please contact the nearest retailer.
Lo	In ear/forehead mode: Temperature taken is lower than +34°C (93.2°F) In surface mode: Temperature taken is lower than –22°C (–7.6°F)	
	Device cannot be powered on to the ready stage.	Replace battery with a new one.

Care & Maintenance

- After measurement, please use a cotton swab with alcohol (70 to 75% concentration) to clean the lens (on the inside of the probe).
- Allow the probe to fully dry for at least 1 minutes. Then reattach the cap.
- This device should be stored at a temperature between -20 to +50°C and humidity 85% or less.
- Keep this device dry and away from any liquids and direct sunlight.
- The probe should not be submerged into liquids.

NOTES

- The probe is the most delicate part of the thermometer. Use with care when cleaning the lens to avoid damage.
- Please check the device for damage if it is dropped. If you are unsure how to, please send the complete device to the nearest retailer for recalibration.
- Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make body temperature measurement lower than usual.

Technical Data

Dimensions	125 mm × 37 mm× 22 mm
Weight	Approx. 41g, excluding the battery.
Temperature measurement range	Ear/Forehead mode: 34 to 42.2°C(93.2 to 108°F), Surface mode: -22 to +80°C(-7.6 to 176°F),
Operating temperature range	10 to 40°C (50 to 104°F) ,15 to 85%RH
Storage temperature range	Device should be stored at a room temperature between -20 to +50°C and humidity 85% or less. Transportation temp. shall be less than 70°C ,RH≦95%, Atmospheric pressure:800 to 1013hPa.
Accuracy	Ear/Forehead mode: ±0.2°C (0.4°F) within 35 to 42°C (95 to 107.6°F) (Ambient Temp: 15 to 35°C), ±0.3°C (0.5°F) for other range. Surface mode: ±0.3°C (0.5°F) within 22 to 42.2°C (71.6 to 108°F) others ±4% or 2°C (4°F) whichever is greater.
Memory	25 memory slots and last memory.
Battery	CR2032×1

・Battery life: around 3000 continuous readings. ・Expected Service Life: 4 years.

・This thermometer is an adjusted mode thermometer that converts the ear/forehead temperature to display its “oral equivalent.”

・Comply with ASTM E1965-98, EN ISO 80601-2-56, IEC/EN60601-1-2(EMC), IEC/EN60601-1(Safety) standards, ISO10993, RoHS.

NOTE: Specifications are subject to change for improvement without prior notice.

INFORMATION & NOTE: Please report to the manufacturer and the competent authority of the Member State in which you are established about any serious incident that has occurred in relation to this device.

Appendix: EMC Information

Manufacturer's declaration-electromagnetic emissions		
The UT-801 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the UT-801 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home healthcare environment)**
RF emissions CISPR 11	Group 1	The UT-801 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 UT-801 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.

Manufacturer's declaration-electromagnetic immunity

The UT-801 is intended for use in the electromagnetic environment (for home healthcare) specified below.

The customer or the user of the UT-801 should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Electrostatic discharge(ESD) IEC61000-4-2	Contact:±8 kV Air±2 kV,±4 kV, ±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV, ±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50,60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The UT-801 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

Manufacturer's declaration-electromagnetic immunity

The UT-801 is intended for use in the electromagnetic environment (for home healthcare) specified below.

The customer or the user of the UT-801 should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 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 metres (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: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 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 UT-801 is used exceeds the applicable RF compliance level above, the UT-801 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UT-801.

Recommended separation distance between
portable and mobile RF communications equipment and the UT-801

The UT-801 is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the UT-801 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UT-801 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 $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	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.
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The UT-801 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the UT-801 should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) 5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13,17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							

1 720 1 845 1 970	1 700 – 1 990	GSM 1800; CDMA1900; GSM1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240 5 500 5 785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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