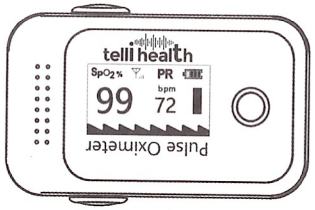
telli health

User Manual
Fingertip Pulse Oximeter

Model: BM1000



Telli Health LLC

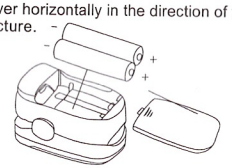
Quick Operation Guide:

1. Install Battery

1) To remove the back cover compartment, push the white button and follow the direction of the printed arrows.

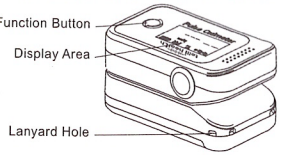
2) Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage to the oximeter may occur.

3) Slide the battery door cover horizontally in the direction of the arrow as shown in the picture.

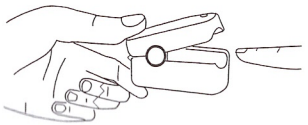


2. Measurement

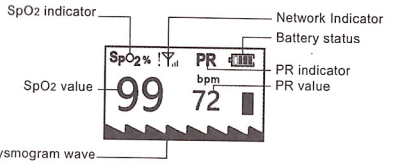
1) Press the Power/Function button as shown below:



2) Place one finger into the rubber hole of the oximeter (it is best to plug the finger thoroughly) before releasing the clamp, with the nail upward, as indicated below:



3) The data (SpO_2 and Pulse Rate) will read as below. Don't move the finger; be sure to remain motionless during the reading.



4) Once the measurement is finished, it will display "Thank you" as shown below. Remove finger. The device will turn off automatically.

Thank you

Main page

Product Description

The pulse oximeter is an important, common device that checks oxygen saturation (SpO2) and pulse rate. It is a small, compact, simple, reliable, and durable physiological monitoring device. It contains the mainboard, OLED display, and dry batteries.

Intended Use

The pulse oximeter is a reusable device intended for intermittent checks of oxygen saturation and pulse rate for adults in a clinical environment. This medical device is not intended for continuous monitoring.

Applicable Users and Scope

The pulse oximeter is intended for monitoring adults. It is used in clinical settings, outpatient departments, and sickrooms. It can also be used in recovery and healthcare organizations as well as community medical treatment centers.

Contraindications

The pulse oximeter only applies to adults. It is not suitable for injured skin tissue.

Measurement Principle

Arterial oxygen saturation is measured via a method called oximetry. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin (called the spectrophotometer principle).

The data processed by the device is obtained via a formula based on the Lambert Beer Law, according to the spectrum absorption characteristics of hemoglobin (Hb) and oxyhemoglobin (HbO_2) in glow and near-infrared zones. The instrument operates on the principle of Photoelectric Oxyhemoglobin Inspection Technology. Two beams of different wavelengths of light (666nm visible red light and 905nm near-infrared light) can be focused on the human nail tip via emitters by adopting the Capacity Pulse Scanning and Recording Technology. It will obtain a measured signal via a photosensitive element. The amount of light absorbed relates to the amount of oxygen in the blood during these pulses. The ratio of the two absorbed spectrums can be calculated via the microprocessor, and the results are compared with the saturation value in the memory. This is how the blood oxygen saturation value is obtained.

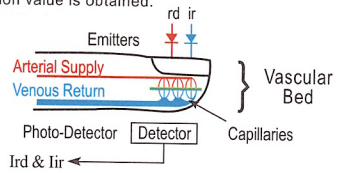


Diagram of Measurement Principle

Safety Information

- **Anyone who uses the pulse oximeter must receive adequate training before use.**
- **The pulse oximeter is only meant to assess patients' physiological conditions. It must be used in conjunction with clinical symptoms. It is not intended for treatment.**
- **When using the pulse oximeter in conjunction with the electrical surgery equipment, the user should ensure safety of the patient.**
- **EXPLOSION HAZARD: Do not use the pulse oximeter in the presence of flammable anesthetics, explosive substances, vapors, or liquids.**
- **It is forbidden to use the pulse oximeter in MRI (magnetic resonance imaging) scanning or CT (Computed Tomography) because the induced current could cause potential burning.**
- **The pulse oximeter does not include an alarm function. Therefore, continuous monitoring for long periods of time is not suitable.**
- **Modification of the pulse oximeter is not allowed. Any product maintenance should be done by manufacturer-approved, professional maintenance personnel.**
- **Please shut off the power before cleaning the pulse oximeter. Disinfecting the pulse oximeter via high-pressure and high-temperature methods is prohibited. Any cleaning agents/ disinfectants other than recommended ones listed in the operation manual are not allowed for use.**
- **The pulse oximeter is not waterproof. Keep its surface dry and clean and prevent any liquid from infiltrating the product.**
- **The pulse oximeter is fragile and requires precision to function properly. Avoid any pressure, jostling, strong vibrations, or other potential mechanical damage. Hold it carefully and lightly. If it is not in use, the pulse oximeter should be appropriately stored.**
- **Do not dispose of the pulse oximeter randomly. Disposal procedure should follow local regulations or hospital policy regarding disposal of the pulse oximeter and accessories.**
- **Use AAA alkaline batteries. Do not use carbon or poor-quality batteries. Remove the batteries if the pulse oximeter hasn't been used for a long time.**
- **A functional tester can't be used to assess the accuracy.**
- **If the patient is the intended operator, the patient must read the operation manual carefully or consult with a doctor and/ or manufacturer before usage. If there's any discomfort while using the pulse oximeter, stop usage immediately and go to the hospital.**
- **To avoid any static electricity damage to the pulse oximeter, direct or indirect static electricity should be discharged before usage.**
- **Try to keep the pulse oximeter away from any radio receivers when in use.**
- **If the pulse oximeter is used in a configuration which does not pass the EMC test, it can enhance electromagnetic radiation or reduce anti-electromagnetic interference performance. Please use the specified configuration.**
- **The pulse oximeter should not be in close proximity (or stacked) with other devices. If that cannot be avoided, it should be observed and verified that the oximeter can run normally with the close proximity/stacked configuration.**
- **There should be no dirt or wound on the tested surface (i.e., finger).**
- **Federal law restricts this device to sale by the order of a physician.**

Precaution

- **Check the pulse oximeter for damage before use. If it's damaged, don't use it.**
- **Don't put the pulse oximeter on extremities with arterial catheter or venous syringe.**
- **Don't perform SpO_2 and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO_2 value.**
- **Don't use the pulse oximeter to measure patients whose pulse rates are lower than 30bpm (this may cause incorrect results).**
- **The well perfusion of the measuring instrument should fully cover the test window of the sensor. Clean and dry the measurement part before storing the pulse oximeter.**
- **Cover the sensor with opaque material under strong light. Otherwise, the light can cause inaccurate measurements.**
- **Make sure there is no contamination or scarring on the tested finger. Otherwise, the results may be incorrect.**
- **The product is prone to cross-contamination when used on different patients. Disinfection is recommended before using the product on other patients.**
- **Incorrect placement of the sensor may affect the accuracy of the measurements. To achieve the best measurements, hold the device in the same horizontal position (parallel) with the heart.**
- **Do not use the device if the temperature exceeds 41°C.**
- **Change sensor location and check skin integrity and circulatory status at least every 2 hours.**

Factors affecting measurement accuracy:

- **The measurements depend on absorption of a special wavelength ray by oxidized hemoglobin and deoxyhemoglobin. The concentration of non-functional hemoglobin may affect the accuracy of the measurement.**
- **Shock, anemia, hypothermia, and vasoconstrictive drugs may decrease arterial blood flow to an unmeasurable level.**
- **Pigments or deep colors (i.e., nail polish, artificial nails, dyes, or pigmented cream) may cause inaccurate measurements.**

Product Structure

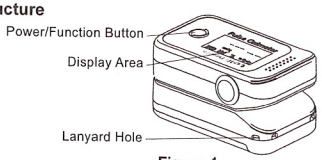


Figure 1

Display Introduction

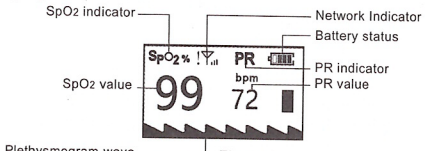


Figure 2

Battery and Lanyard Installation

To remove the back cover compartment, push the white button and follow the direction of the printed arrows.

Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage to the oximeter may occur.

Slide the battery door cover horizontally in the direction of the arrow as shown in **Figure 3, 4.**

Note:

- Please remove the batteries if the pulse oximeter will not be used for long periods of time.
- Please replace the batteries when the power indicator starting flickering.

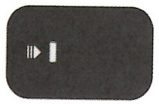


Figure 3

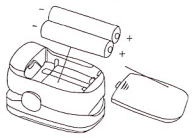
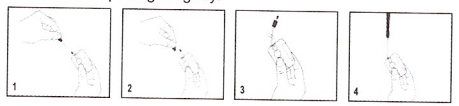


Figure 4

Using the Lanyard

- Thread the thinner end of the lanyard through the hanging hole.
- Thread the thicker end of the lanyard through the threaded end before pulling it tightly.



Warning!

Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.

Directions for Use

1. After properly installing two AAA batteries, push down on the lid's press sign as shown in the **Figure 5** and open the clip. Place the testee's finger between the rubber cushions of the clip. Make sure the finger is in the right position as shown in **Figure 5**, then release the clip.
2. The device takes only a moment to take the reading. The SpO_2 value and PR value will be displayed on the OLED screen after the plethysmograph wave and measured values are stable, as shown in **Figure 6.**

- **Be sure to place the patient's finger in the device in the correct orientation. The LED part of the sensor should be on the end that is closer to the patient's wrist. Be sure to insert the finger deep enough into the sensor so that the fingernail is opposite the light emitted from the sensor.**
- **Don't move the finger; remain motionless during the process.**
- **Data update period is less than 30 seconds.**

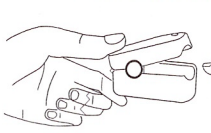


Figure 5

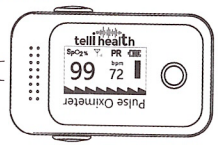


Figure 6

Function Description

1. Press the "POWER/FUNCTION" button to power on the device. Press it again to rotate the display orientation, as shown in **Figure 7** and **Figure 8.**

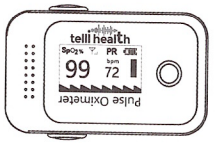


Figure 7

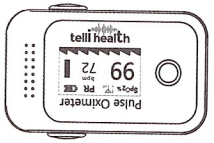


Figure 8

2. Press and hold the "POWER/FUNCTION" button for more than 3 seconds to show the IMEI and SIM card number. Press it again to exit, as shown in **Figure 9.**
3. When there is no finger inserted, the invalid value "-- ---" will be displayed on the screen, as shown in **Figure 10.**

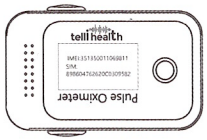


Figure 9

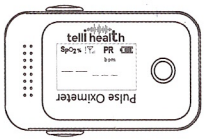


Figure 10

4. When the measurement is finished and the network is available, the upload procedure will be started automatically, as shown in **Figure11.** It will end with "Success" or "Failed," as shown in **Figure12** and **Figure13.** If the upload failed, the current measurement record will be saved automatically and re-uploaded next time.

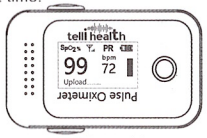


Figure 11

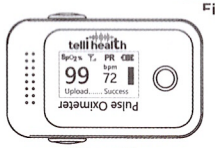


Figure 12

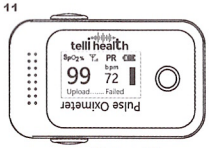


Figure 13

5. The product will automatically shut down when there is no finger inserted for more than 10 seconds or after upload is finished.

Network Indicator Description

SYMBOL	DESCRIPTION
	SIM card is not inserted
	No signal
	Signal is weak
	Signal is normal
	Signal is good
	Signal is perfect
!	Network is unattached

Cleaning and Disinfection

- Do not immerse the oximeter and any relevant accessories in water or disinfectant.
- We recommend that the product be disinfected only when necessary to avoid long-term damage to the product.
- Don't use cleaning agents/disinfectants other than the recommended models.
- Don't disinfect the device via high-pressure or high-temperature methods.
- Shut off the power and take out the batteries before cleaning and disinfecting.

Cleaning

1. Clean the product with cotton or a soft cloth moistened with water.
2. After cleaning, wipe off the water with a soft cloth.
3. Leave the device to dry naturally.

Disinfection

1. The recommended disinfectants include the following: ethanol 70%, isopropanol 70%, glutaraldehyde (2%) solution disinfectants.
2. Clean the product as instructed above.
3. Disinfect the product with cotton or a soft cloth moistened with one of the recommended disinfectants.
4. After disinfection, be sure to wipe off the disinfectant left on the product with a soft cloth moistened with water.
5. Leave the device to dry naturally.

Packing List

THE STANDARD CONFIGURATION	
Pulse oximeter	1pc
Lanyard	1pc
The operation manual	1pc
Alkaline battery	2pcs

Expected service life: 3 years

Technical Specifications

1. Display Mode: OLED

2. SpO_2:
Measurement range: 0~100%
Accuracy: ±3%(70%~100%)

3. Pulse Rate:
Measurement range: 25~250bpm
Accuracy: ±2bpm

- **Pulse Rate accuracy has passed verification and comparison with the SpO_2 simulator.**

4. Low Perfusion:
Range: 0.5%~20%
SpO_2 Accuracy: ±3%(70%~100%)
PR Accuracy: 25~250bpm ±2bpm

5. Electrical Specifications:
Working Voltage: D.C.2.2V~D.C.3.4V
Battery Type: Two 1.5V AAA alkaline batteries
Battery Life: Measurement and upload in normal conditions over 500 times

6. Product Specifications:
Size: 58 (H) × 34 (W) × 30(D) mm
Weight: 50g (includes two AAA batteries)

7. Environment Requirements:
Temperature:
Operation: +5~+40°C
Transport and Storage: -10~+50°C
Humidity:
Operation: 15%~80% (noncondensing)
Transport and Storage: 10%~90% (noncondensing)
Atmospheric Pressure:
Operation: 860hPa~1060hPa
Transport and Storage: 700hPa~1060hPa

NOTE:

- **A functional tester can't be used to assess this product's accuracy.**
- **The purpose of confirming the blood oxygen measurement's accuracy is to compare the oximetry measurement value with the value of a blood gas analyzer.**

LED:
Wavelength: 666nm/905nm
Output Power: <0.1mW

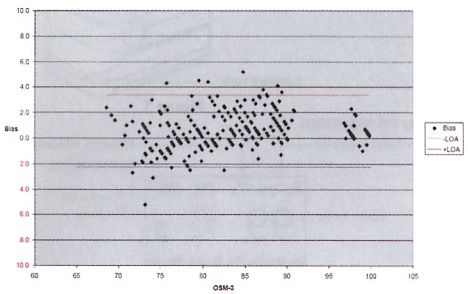
Arms Specifications

1. SpO_2 Arms:

SPO2 RANGE	ARMS SPECIFICATION
70% – 80%	1.65
80% – 90%	1.22
90% – 100%	1.11

2. Clinical Data Graphical Plot:

Hemoximeter Range	60-80	80-100	60-100	70-100	60-70	70-80	80-90	90-100
Mean	0.27	0.74	0.58	0.57	0.90	0.25	1.00	0.12
Count	102	185	287	284	3	99	131	54
Missing Data	0	2	2	2	0	0	0	2
Standard Deviation	1.64	1.25	1.42	1.42	1.23	1.65	1.22	1.11
Standard Error	0.16	0.09	0.08	0.08	0.71	0.17	0.11	0.15
95% Confidence Interval	0.32	0.18	0.16	0.17	1.39	0.33	0.21	0.30
Upper LOA	3.55	3.22	3.38	3.38	N/A	3.55	3.42	2.29
Lower LOA	-3.01	-1.73	-2.23	-2.24	N/A	-3.05	-1.42	-2.05
Maximum	4.50	5.20	5.20	5.20	1.80	4.50	5.20	2.40
Minimum	-5.20	-3.10	-5.20	-5.20	-0.50	-5.20	-1.60	-3.10
Root Mean Square	1.66	1.45	1.53	1.53	1.35	1.67	1.57	1.11



Troubleshooting

TROUBLE	POSSIBLE REASON	SOLUTION
The SpO_2 and PR can't be displayed normally and the value disappeared.	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Please try again. 2. Try again. Go to a hospital for a diagnosis if you are sure the device is working correctly.
The SpO_2 and PR display are unstable.	1. The finger is not placed deep enough inside the device. 2. The finger is shaking or the testee is moving.	1. Place the finger properly and try again. 2. Encourage the testee to keep calm.
The device can't be powered on.	1. The batteries are drained or almost drained. 2. The installation of the batteries is not correct. 3. The device has malfunctioned.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the supplier.
The screen suddenly turned off.	1. The product will automatically shut down when there is no finger inserted for more than 10 seconds or after upload is finished. 2. The power of the batteries is exhausted.	1. Normal. 2. Replace the batteries.

Symbol Meaning

SYMBOL	MEANING
	"CAUTIOUS"! Please refer to the operation manual.
	Type **BF** Equipment.
	The product does not contain alarm function.
	When the end-user wishes to discard this product, it must be sent to a separate collection facilities for recovery and recycling.
	Information of manufacture, including name and address.
	Date of manufacture.
SN	Serial Number.
LOT	Batch Code.
REF	Type Number.
IP22	Degrees of protection provided by enclosure.

Shanghai Berry Electronic Tech Co., Ltd.
Unit 104, 1st Floor, 7th Building, No.1188 Lianhang Road,
Minhang District, Shanghai, China 201112
TEL.: +86-21-5853 1958 FAX: +86-21-5853 0420
WEB: www.shberrymed.com

If you need additional information, please contact with the manufacturer.

Appendix A EMC Declaration

Guidance and manufacturer's declaration - electromagnetic emissions - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emission		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment		
Emission Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF emissions CISPR 11	Group 1	The Pulse Oximeter 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 CISPR11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
ELECTROSTATIC DISCHARGE [a] IEC 61000-4-2	±8 KV contact ±2 KV, ±4 KV, ±8 KV, ±15 KV air	±8 KV contact ±2 KV, ±4 KV, ±8 KV, ±15 KV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
RATED power frequency magnetic fields [b] [c] IEC 61000-4-8	30A/m [d] 50 Hz or 60 Hz	30A/m [d]	Mains power quality should be that of a typical commercial or hospital environment.

[a] Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.
[b] Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.
[c] During the test, the ME EQUIPMENT or ME SYSTEMS may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).
[d] This test level assumes a minimum distance of at least 15 cm between the ME EQUIPMENT or ME SYSTEMS and sources of power frequency magnetic field. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEMS will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS that are not LIFE - SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Conducted disturbances included by RF fields [a] IEC 61000-4-6	3 V [b] 0.15 MHz - 80 MHz 6 V b) in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V [b] 6 V [b]
Radiated RF EM fields [c] IEC 61000-4-3	10 V/m [b] 80 MHz – 2.7 GHz [d] 80% AM at 1 kHz [b]	10 V/m [b]

[a] The following apply:
- All PATIENT-COUPLED cables shall be tested, either individually or bundled
- PATIENT-COUPLED cables shall be tested, using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

[b] Before modulation is applied
[c] The interface between the PATIENT physiological simulation, if used, and the ME EQUIPMENT or ME EQUIPMENT shall be located within 0, 1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT of ME SYSTEM.
[d] ME EQUIPMENT and ME SYSTEM that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.
[e] Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380—390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430—470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704—787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800—960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700—1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2450	2400—2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100—5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	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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