Part no.	311-8255200-044
Product name	機器說明書/MbH/英文_CE+FDA共用/.標準品/
Spec	L288*W250mm/雙面/雜誌紙/6折 (短邊彈簧3折+長邊對3折)完成尺寸L36*W62.5mm/65P/黑/無
Designer	Tsaiyi
Color	■ K100 ■ K20

MbH
Mobile Health
TD - 8255

Version 2.0 2020/12
311-8255200-044

Fingertip Pulse Oximeter

Operation Instructions

Manufactured by
TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Rd.,
Wugu Dist., 24888 New Taipei City, Taiwan
www.taidoc.com

EC REP **MedNet EC-REP GmbH**
Borkstraβe 10, 48163 Münster, Germany

CE 0123

Read instructions before use.
Caution, consult accompanying documents.

⚠ WARNINGS

- Do not use the oximeter in a MRI or CT environment.
- The oximeter is not intended for use in the diagnosis of any symptoms or diseases. The data measured is for reference only; do not base a definitive diagnosis on the results of a single test. A physician or healthcare provider should make a diagnosis after all other clinical and laboratory findings are evaluated.
- If subjects have trauma, disabilities or other medical statuses that could make results inaccurate, please consult doctors before use.
- The oximeter has to measure the pulse properly to obtain accurate SpO_2 measurement. Blood flow restrictors (e.g., blood pressure cuffs) may hinder pulse measurements. Remove any objects that may hinder the performance of the oximeter.
- Rx only.
- Keep the batteries out of reach of small unsupervised children. Children may end up choking from inhaling or swallowing the batteries detached from the device.
- The device is only applied to use under indoor environment.
- This device complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.
- Federal law (USA) restricts this device to sale by or on the order of a physician.
- The device is not recommended to wear for a long period.

⚠ CAUTIONS

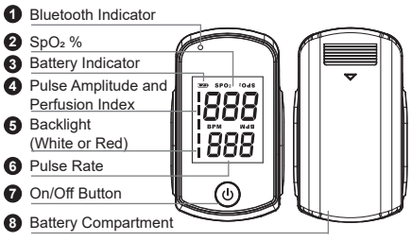
- The oximeter determines the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carbonxyhemo globin or methemoglobin may affect the accuracy of the measurement.
- Cardio green and intravascular dyes, depending on the concentration, may affect the accuracy of SpO_2 measurements.
- The performance of the oximeter might be affected by the presence of a defibrillator.
- The oximeter may not work on all subjects. If you are unable to achieve stable readings, discontinue use.
- The oximeter is equipped with a motion tolerant software that avoids interpreting every detected movement as good pulse quality. However, misinterpretations are still possible in some circumstances. Minimize motions as much as possible while in use.
- Do not use caustic or abrasive cleaning agents on the oximeter or probes.
- Do not mix new and old batteries at the same time. It may cause the batteries to leak. Dispose of batteries properly.
- The oximeter is not an apnea monitor.
- Batteries might leak chemicals if unused for a long period of time. Remove the batteries if the oximeter is going to be stored for more than one month.
- The oximeter is a precision electronic instrument and must be repaired by trained personnel only.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.
- Always store the oximeter in a cool and dry place: temperatures between -25°C to 70°C / -13°F to 158°F relative humidity between 15% to 93%. Avoid direct sunlight.
- Always contact the manufacturer or the manufacturer's representative to report unexpected operation or event. Do not try to fix it by yourself.
- Do no expose the device to strong electrostatic fields or strong magnetic fields to avoid affecting the measurement accuracy.
- Used in close proximity to others, EMC must be tested and verified.
- When in use, you should stay away from electromagnetic radiation, such as the mobile in use.

INTRODUCTION

► Intended Use
The MbH TD-8255 Fingertip Pulse Oximeter is indicated for use in measuring oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for patients during no-motion condition. The patients are limited to adults and children. (weight above 40 kg or 88lb) This device is indicated for non-invasive spot checking or monitoring.

► Principle of Measurement
The MbH TD-8255 Fingertip Pulse Oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.

► Meter Appearance and Key Function



1 Bluetooth Indicator
Blue light appears when bluetooth is turned on.

2 SpO_2 %
The measurement result of oxygen saturation in percentage.

3 Battery Indicator

4 Pulse Amplitude and Perfusion Index (PI)
Pulse Amplitude – The strength of the signal is detected by the oximeter.
Perfusion Index (PI) – The Perfusion Index indicates the percentage of pulsatile signal to non-pulsatile signal (pulse strength) on a 5 bar indicator.

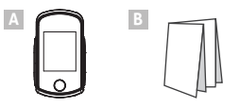
5 Backlight (White or Red)
Backlight is white while in measuring mode.
Backlight blinks red when the oxygen saturation value falls below 85% (high priority visual alarm).

6 Pulse Rate
The measurement result of pulse rate in beats per minute.

7 On/Off Button
Press here to turn on/off the device.

8 Battery Compartment

► Contents of the System
The MbH TD-8255 Fingertip Pulse Oximeter includes the following items:



A. MbH TD-8255 Fingertip Pulse Oximeter x 1
B. Operation Instructions x 1

Confirm that the items listed are packed with the MbH TD-8255 Fingertip Pulse Oximeter. If any item on this list is missing or damaged, contact your distributor. **The device and its accessory are provided in non-sterile condition.**

BATTERY REPLACEMENT

Make sure the oximeter is off when replacing the batteries. The oximeter is powered by two 1.5V AAA size alkaline batteries. Take the following steps to replace the battery.

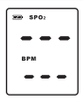
1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
3. Close the battery cover carefully and make sure the cover is snug and fits correctly. It is important that the cover is closed correctly to ensure the oximeter remains waterproof.

NOTE

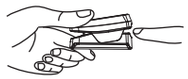
Use only 1.5V AAA new batteries with this device. Replace the batteries as soon as possible after a low battery symbol appears.

OPERATION

1. Turn on the oximeter by pressing ⏻. Do not move your finger when starting test. Do not move your body while testing.



2. Open the clamp and put one of your fingers into rubber hole of the oximeter (it is better to let your finger touch the bottom.) before releasing the clamp.



NOTE

- Consult healthcare professionals before you start to use the oximeter.
- If the PI reading is 1 bar or less, the PI might be too low for a reliable SpO_2 reading. Warm or rub the finger to increase circulation or reposition the sensor.
- The patient's condition may require changing the measurement site periodically.
- The oximeter sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
- Check the sensor application site frequently to determine circulation, positioning and skin sensitivity. **The recommended maximum application time at a single site is 4 hours.**

3. After detecting the pulse signal, the oximeter shows the readings of SpO_2 and pulse rate on the display. The readings will be updated based on the signal received with each pulse.

4. While testing, if you press ⏻, the screen will rotate 180 degrees.

NOTICE

The pulse rate reading with the maximum (250) or minimum (30) values may not be the actual pulse rate, it may be inaccurate.

NOTE

The backlight blinks red if the oxygen saturation value is below 85%.

5. Keep pressing ⏻ for at least 3 seconds to turn off the oximeter. It turns off in 15 seconds once the finger is removed.

NOTE

Below is the frequency of displaying and transmitting SpO_2 values along with pulse rate data:
- data averaging for 8 seconds,
- the data update period for 1 second,
- the alarm condition delays for 1 second,
- alarm signal generation delays for 1 second including the effects of any selectable operating mode that affects these properties.

DATA TRANSMISSION VIA BLUETOOTH

You can transmit your SpO_2 and pulse rate data from the meter to your device (e.g. the smart phone, tablet and personal computer…) via Bluetooth. If you need assistance, please contact your local customer service or place of purchase. Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

For Healthy Check / Healthy Check Pro:
1. Download "Healthy Check" or "Healthy Check Pro" app on your mobile device.
2. Turn on Bluetooth function on your mobile device.
3. Turn on the oximeter. Then open the app and search for available devices. Click "add" once you see the oximeter on the app.
4. Click back button and save.
5. After successfully pairing the app with the Oximeter, keep the app enabled and take a reading with the Oximeter. The test results will continuously be imported to the app. The Oximeter will turn off automatically after detaching from finger in 15 seconds.

Bluetooth indicator on the oximeter:

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is on and waiting for connection.
Solid Blue	The Bluetooth connection is established.

WARNINGS

- Make sure your device supports Bluetooth LE Technology. Also make sure the Bluetooth setting on your device is turned on and the monitor is within the receiving range before transmitting the data.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers; the compatibility issue between your mobile device and the meter may occur.

NOTE

- Pairing is required in these two situations: (A) When you first receive and begin to use the meter. (B) When you need to import results to a new mobile device.
- If pairing is unsuccessful, please check the following: (A) Your mobile device supports Bluetooth LE Technology. (B) Bluetooth function is turned on before transmitting the data. (C) Meter is within the receiving range of your mobile device. (D) For OS version requirement, please find app information on App Store or Google Play.

CLEANING

Cleaning of the oximeter is just as important as proper use. For surface-cleaning and disinfecting the oximeter and reusable SpO_2 probes, we recommend the following procedures:

1. Turn off the oximeter before cleaning.
2. Wipe the exterior surfaces thoroughly with a soft cloth containing 75% isopropyl alcohol solution.
3. oximeter surface to air dry completely.
4. Discard the used wipes and never reuse them.

NOTE

Do not spray, pour, or spill any liquid on the oximeter, accessories, switches or openings.

MAINTENANCE AND STORAGE

- Replace the batteries as soon as you find low voltage indicator is on display.
- Clean surface of the oximeter before use.
- Remove the batteries inside the battery compartment if the oximeter will not be used for a long time.
- It is best to preserve the product in a place where ambient temperatures range from -25°C to 70°C / -13°F to 158°F and humidity is between 15% to 93% R.H.
- It is recommended that the product be kept in a dry place. A damp ambient might affect its lifetime and even damage the product.

FCC Statement

FEDERAL COMMUNICATIONS COMMISION (FCC) STATEMENT

15.21
You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)
Federal Communications Commission (FCC) Statement

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. 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 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 of the device.

FCC RF Radiation Exposure Statement:
1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

TROUBLESHOOTING

Symptom	Possible Causes	Solutions
Fail to turn on the oximeter.	The batteries are dead.	Replace all batteries.
	The batteries are installed incorrectly.	Verify battery orientations.
SpO_2 or pulse rate displays are missing.	Defective LCD displays.	Displayed values may not be reliable; discontinue use of the oximeter.
SpO_2 or pulse rate displays unstably.	The finger might not be steady or placed incorrectly on the probe.	Try not to move or retry by placing the finger at the correct position on the probe.
Disruption in the oximeter performance.	Electromagnetic interference (EMI).	Remove the oximeter from the EMI environment.
Battery is low and " ▭ bAt Lo " is on display.	The batteries are low.	Replace the batteries immediately.
Backlight turns to blinking red (visual alarm is activated).	Oxygen saturation value is below 85%.	Consult healthcare professional immediately.

SPECIFICATION

Model No.: TD-8255
Dimension & Weight: 63(H) x 37(W) x 32(D) mm, 40 g without batteries
Display: LCD
Power Source: Two 1.5V AAA alkaline batteries
Battery Life: Batteries can be used continuously for 8 hours (for reference only. It depends on different brands of AAA alkaline batteries.)
External Output: Bluetooth
Measurement and Displayed Range: 0% to 100%
Increment: 1%
Accuracy: 100% to 80%: ±2%; 79% to 70%: ±3%; others are undefined.
Method: Dual wavelength LED
Operating Conditions: 5°C to 40°C / 41°F to 104°F; between 15% to 93% R.H. (non-condensing)
Storage / Transportation Conditions: -25°C to 70°C / -13°F to 158°F; between 15% to 93% R.H. (non-condensing)
Product Warranty: At least 1 year (warranty period depends on local jurisdiction)
Range of Peak Wavelengths: 660 nm and 880 nm
Maximum Optical Output Power of Light Emitted by Oximeter Probe: 100 mW
Mode of Operation: Spot Check / Monitoring

Heart Rate

Measurement and Displayed Range: 30 to 250 beats per minute (bpm)
Resolution: 1 bpm
Accuracy: ±1 bpm or ±1%, whichever is greater

Classification

Degree of Protection: Type BF Applied part
Safety: IEC60601-1
EMC: IEC60601-1-2
Harmonized Standard: ISO 80601-2-61
Home Use Medical Device: IEC60601-1-11
Water-resistance: IP22

SYMBOL INFORMATION

	Type BF applied part
	Caution
	Manufacturer
EC REP	Authorized representative in the European Community
	Temperature limitation
RoHS	RoHS Compliance

SN	Serial number
IP22	Resistant to liquid ingress
	Humidity limitation
	Alarm
CE 0123	CE mark

	This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with local regulations for separate collection of spent batteries.
	Refer to instruction manual / booklet NOTE On ME EQUIPMENT "Follow instructions for use"

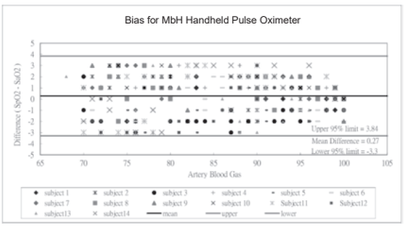
CLINICAL PERFORMANCE

Tables below show Arms values measured using Finger Type Pulse Oximeter in a clinical study. The individual and pooled measured Arms values in the discrete SpO_2 ranges of all 14 subjects are reported.

Subject	70% - 80% SaO_2		80% - 90% SaO_2		90% - 100% SaO_2	
	Mean Bias	Arms	Mean Bias	Arms	Mean Bias	Arms
1	-1.00	1.89	1.25	1.80	0.00	1.03
2	1.27	1.71	-0.17	1.58	-0.81	1.20
3	-2.00	2.00	-1.90	1.97	-1.15	1.33
4	2.17	2.27	1.14	1.51	0.81	1.64
5	-1.11	2.11	1.25	1.94	-0.74	1.26
6	-0.57	2.07	-1.25	1.94	-1.00	1.22
7	1.00	1.78	2.00	2.00	0.20	1.06
8	1.30	1.97	0.50	0.71	-0.64	1.16
9	2.29	2.33	0.40	1.79	0.78	1.63
10	1.30	2.07	1.20	2.00	0.50	0.89
11	-2.18	2.73	1.33	1.73	1.90	1.97
12	-1.71	2.26	-1.00	1.96	0.07	1.07
13	0.25	2.54	-1.50	1.87	-0.25	1.53
14	-1.56	1.94	1.20	1.67	0.83	1.35

Pooled	70% - 80% SaO_2	80% - 90% SaO_2	90% - 100% SaO_2
Mean Bias	0.16	0.21	0.21
Arms	2.00	1.87	1.29

Figure 1 Plot of difference (SpO_2 - SaO_2) versus artery blood gas (SaO_2) with linear regression fit and upper 95% and lower 95% limits of agreement of all subjects. Each color or symbol represents a different patient in the clinical study.



Difference plot of Finger Type Pulse Oximeter and artery blood gas

GUIDANCE AND MANUFACTURER'S DECLARATION

Manufacturer's declaration-electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below.
The customer or the user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The device 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 device 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	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below.
The customer or the user of the device 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	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 %.
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 home and professional healthcare environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8 U	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The device power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below.
The customer or the user of the device should assure that it is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Not applicable Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1,2 √P d = 1,2 √P 80MHz to 800 MHz d = 2,3 √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). Interference may occur in the vicinity of equipment marked with the following symbol:
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	

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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the device

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d =1,2√P	80 MHz to 800 MHz d =1,2√P	800 MHz to 2,7 GHz d =2,3√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 device is intended for use in the electromagnetic environment specified below.
The customer or the user of the device 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
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	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	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	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	28
5240 5500 5785	5100 – 5800	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.