

## Electromagnetic Compatibility Information



**Note:** Portable RF communications equipment should no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer.

The M4 Pro complies with IEC60601-1-2:2014+A1:2020, EN60601-1-2:2015+A1:2021, ISO7176-21:2025 standard electromagnetic compatibility requirements.

Users should install and use the product in accordance with the EMC information provided in the accompanying documentation.

The M4 Pro generates, uses, and radiates radio frequency energy. The equipment may cause radio frequency interference to other medical or non-medical devices and to radio communications.

If this equipment is found to cause interference, which can be determined by turning on and off the equipment, the operator or qualified service personnel should take following actions:

- Reorient or relocate the affected device;
- Increase the distance between the equipment and the affected equipment;
- Power the equipment by another power source;
- Consult the service engineer for further suggestions.



### NOTICE

- The M4 Pro should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed and verified that it can operate normally under the configuration it is used in.
- It is customer's responsibility to assure that this equipment and nearby equipment comply with the contents of IEC 60601-1-2 4th Edition.
- Do not use any device that might send out RF signals, including cell phone, radio transceiver and radio control products, which might cause operation parameters beyond the standards. Please shutdown these devices when the user is near the equipment. Operator has the responsibility to warn user or any others to comply with this rule.
- Manufacturer will not be responsible for any unauthorized actions that cause interference.
- The M4 Pro cannot be used together with HF surgical equipment.

Table 1

| Guidance and Manufacture's Declaration - Electromagnetic Emission   |            |  |
|---|------------|--|
| The M4 Pro is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment. |            |  |
| Emissions Test  | Compliance | Electromagnetic Environment - Guidance   |
| RF emissions<br>CISPR 11  | Group 1    | The M4 Pro uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic. |
| RF emissions<br>CISPR 11  | Class B    | The M4 Pro is suitable for direct connection to public low-voltage power supply networks.  |
| Harmonic emissions  | Class A    |  |

|   |   |  |
|---|---|--|
| IEC 61000-3-2   |   |  |
| Voltage fluctuations/flicker emissions<br>IEC 61000-3-3 | / |  |

Table 2

| <b>Guidance and Manufacture' s Declaration - Electromagnetic Immunity</b>   |   |   |  |
|---|---|---|--|
| The M4 Pro is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment. |   |   |  |
| <b>Immunity Test</b>  | <b>IEC60601 Test Level</b>  | <b>Compliance Level</b>   | <b>Electromagnetic Environment - Guidance</b>  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | ±8kV contact (elec.)<br>±2kV, ±4kV, ±8kV, ±15kV air                         | ±8kV contact (elec.)<br>±2kV, ±4kV, ±8kV, ±15kV air                         | Floors should be wood, concrete or ceramic tile. Humidity should be at least 30% if it is synthetic materials.                                   |
| Electrical fast transients/bursts (EFT)<br>IEC 61000-4-4  | ±2kV<br>100kHz repetition frequency   | ±2kV<br>100kHz repetition frequency   | Main power quality should be that of a typical commercial or hospital environment.   |
| Surges<br>IEC 61000-4-5   | ±0.5kV, ±1kV line-to-line<br>±0.5kV, ±1kV, ±2kV line-to-ground              | ±0.5kV, ±1kV line-to-line<br>±0.5kV, ±1kV, ±2kV line-to-ground              |  |
| Voltage dips<br>IEC 61000-4-11  | 0 % UT; 0.5 cycle<br>At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° | 0 % UT; 0.5 cycle<br>At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° | Mains power quality should be typical commercial or hospital environment. UPS power is recommended if this device needs to be used continuously. |
|   | 0 % UT; 1 cycle and<br>70 % UT; 25/30 cycles<br>Single phase: at 0°         | 0 % UT; 1 cycle and<br>70 % UT; 25/30 cycles<br>Single phase: at 0°         |  |
| Voltage interruptions<br>IEC 61000-4-11   | 0% UT; 250/300 cycle  | 0% UT; 250/300 cycle  |  |
| RATED power frequency   | 30A/m<br>50Hz or 60Hz   | 30A/m<br>50Hz or 60Hz   | Power frequency  |

|   |   |   |   |
|---|---|---|---|
| magnetic fields<br>IEC 61000-4-8  |   |   | magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| IMMUNITY to proximity magnetic fields<br>IEC 61000-4-39                           | 65A/m,<br>Modulation: Pulse modulation, 2.1KHz<br>Test frequency:134.2KHz;<br>7.5A/m,<br>Modulation: Pulse modulation, 50KHz<br>Test frequency:13.56MHz;<br>See Table 6 | 65A/m,<br>Modulation: Pulse modulation, 2.1KHz<br>Test frequency:134.2KHz;<br>7.5A/m,<br>Modulation: Pulse modulation, 50KHz<br>Test frequency:13.56MHz;<br>See Table 6 | --  |
| <b>Note:</b> UT is the A.C. mains voltage prior to application of the test level. |   |   |   |

**Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF**

| Guidance & Declaration - Electromagnetic immunity   |  |  |  |
|---|--|--|--|
| The M4 Pro are intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such environments. |  |  |  |
| Immunity test   | IEC 60601 test level                               | Compliance level   | Electromagnetic environment - guidance   |
| Conducted RF<br>IEC 61000-4-6   | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM bands | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM & amateur radio bands | Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any |
| Radiated RF<br>IEC 61000-4-3  | 10 V/m<br>80 MHz to 2.7 GHz                        | 20V/m<br>26MHz to 25GHz<br>10 V/m                                  |  |

|  |  |   |   |
|--|--|---|---|
|  | 385MHz-<br>5785MHz Test<br>specifications for<br>ENCLOSURE PORT<br>IMMUNITY to RF<br>wireless<br>communication<br>equipment (Refer<br>to table 9 of IEC<br>60601-1-<br>2:2014+A1:2020) | 80 MHz to 2.7 GHz<br><br>385MHz-<br>5785MHz Test<br>specifications for<br>ENCLOSURE PORT<br>IMMUNITY to RF<br>wireless<br>communication<br>equipment (Refer<br>to table 9 of IEC<br>60601-1-<br>2:2014+A1:2020) | part of the<br>M4 Pro, including<br>cables specified<br>by the<br>manufacturer.<br>Otherwise,<br>degradation of<br>the<br>performance of<br>this equipment<br>could result. |
|--|--|---|---|

Table 4 -Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

| Test frequency (MHz)   | Band <sup>a)</sup> (MHz) | Service <sup>a)</sup>   | Modulation  | IMMUNITY TEST LEVEL (V/m) |
|--|--------------------------|---|---|---------------------------|
| 385  | 380 to 390               | TETRA 400   | Pulse modulation <sup>b)</sup><br>18 Hz             | 27                        |
| 450  | 430 to 470               | GMRS 460, FRS 460   | FM <sup>c)</sup><br>± 5 kHz deviation<br>1 kHz sine | 28                        |
| 710  | 704 to 787               | LTE Band 13, 17   | Pulse modulation <sup>b)</sup><br>217 Hz            | 9                         |
| 745  |                          |   |   |                           |
| 780  |                          |   |   |                           |
| 810  | 800 to 960               | GSM 800/900, TETRA 800,<br>iDEN 820, CDMA 850,<br>LTE Band 5          | Pulse modulation <sup>b)</sup><br>18 Hz             | 28                        |
| 870  |                          |   |   |                           |
| 930  |                          |   |   |                           |
| 1 720  | 1 700 to 1 990           | GSM 1800; CDMA 1900;<br>GSM 1900; DECT; LTE Band<br>1, 3, 4, 25; UMTS | Pulse modulation <sup>b)</sup><br>217 Hz            | 28                        |
| 1 845  |                          |   |   |                           |
| 1 970  |                          |   |   |                           |
| 2 450  | 2 400 to 2 570           | Bluetooth, WLAN,<br>802.11 b/g/n, RFID 2450,<br>LTE Band 7            | Pulse modulation <sup>b)</sup><br>217 Hz            | 28                        |
| 5 240  | 5 100 to 5 800           | WLAN 802.11 a/n   | Pulse modulation <sup>b)</sup><br>217 Hz            | 9                         |
| 5 500  |                          |   |   |                           |
| 5 785  |                          |   |   |                           |
| 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.     |                          |   |   |                           |
| <sup>a)</sup> For some services, only the uplink frequencies are included.   |                          |   |   |                           |
| <sup>b)</sup> The carrier shall be modulated using a 50 % duty cycle square wave signal.   |                          |   |   |                           |
| <sup>c)</sup> As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case. |                          |   |   |                           |

Table 5 - Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

| Test frequency  | Modulation                                | IMMUNITY TEST LEVEL (A/m) |
|---|---|---------------------------|
| 30 kHz <sup>a)</sup>  | CW  | 8                         |
| 134,2 kHz   | Pulse modulation <sup>b)</sup><br>2,1 kHz | 65 <sup>c)</sup>          |
| 13,56 MHz   | Pulse modulation <sup>b)</sup><br>50 kHz  | 7,5 <sup>c)</sup>         |
| <sup>a)</sup> This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.<br><sup>b)</sup> The carrier shall be modulated using a 50 % duty cycle square wave signal.<br><sup>c)</sup> r.m.s., before modulation is applied. |   |                           |