

Omnipod 5 System Notice Concerning Interference

Caution: DO NOT make changes or modifications to any component of the Omnipod 5 System that has not been authorized by Insulet Corporation. Unauthorized tampering with the System can revoke your right to operate it.

The Omnipod 5 Automated Insulin Delivery System is designed to comply with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

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 the equipment does cause harmful interference to radio and television reception, the user is encouraged to try to correct the interference by one of the following measures:

- Move or relocate the Omnipod 5 System.
- Increase the separation between the Omnipod 5 System and the other device that is emitting or receiving interference.
- Consult the dealer or an experienced radio/TV technician for help.

Quality of Service

The Omnipod 5 System includes two wireless transmission pathways. Insulet defines the quality of service of the Omnipod 5 System for each of the two pathways:

Omnipod 5 App to Pod wireless communication definition

Successful transfer of commands, data, and alarms between the Controller or smartphone running the Omnipod 5 App and Pod when in communication range (within 5 ft during normal operation). The Omnipod 5 App informs the user when transfer of commands, data, and alarms is unsuccessful. For Insulin Delivery commands, the system performance requirements state that communication between the Pod and the Controller or smartphone running the Omnipod 5 App occurs within 8 seconds at a reliability rate of 95%. The Omnipod 5 App will inform the user when there are communication errors between the Pod and the Controller or smartphone. When such an error occurs, the Omnipod 5 App will beep once every 10 seconds and the communication failure will continue to be indicated within the Omnipod 5 App until the communication error is resolved.

Pod to sensor wireless communication definition

The percentage of sensor glucose values successfully received by the Pod when the sensor and Pod attempt to communicate every 5 minutes. The System performance requirements state that at least 80% of sensor glucose values will be successfully received by the Pod when the sensor is worn within line of sight of the Pod. The System informs the user of missing sensor glucose values in real time by the dashes on the home screen or by missed dots on the Sensor Graph.

To maintain quality of service when other devices operating in the 2.4 GHz band are around, the Omnipod 5 System uses the coexistence features provided by Bluetooth® wireless technology.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod 5 System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

The Omnipod 5 System has been tested and found to have acceptable immunity to emissions from RFID and EAS systems.

The Omnipod 5 System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment.

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod 5 System fails due to electromagnetic disturbances, you may need to replace it.

Portable and mobile radio frequency (RF) communications equipment can affect the function of medical electrical equipment.

Caution: Use ONLY the charging adapter and orange or black charging cable that came with your Controller, as they are designed to limit the power to safely charge the battery. Third-party accessories may allow much higher power, increasing the risk of overheating, spark, or fire, which may lead to minor injuries or serious burns.

Caution: ALWAYS follow safe guidelines for charging your Controller. Before each charge, check the Controller, cable, and adapter, and do not use them if they are damaged. Do not force or bend the end of the charging cable into the Controller charging port. Monitor the Controller while it’s charging. Always charge your Controller on a hard, flat surface away from flammable items (like bedding or paper), and never cover your Controller while charging. Unplug your Controller immediately if it feels too hot, and make a habit of unplugging it when it reaches 100% charge.

Appendix

Care should be taken if the Omnipod 5 System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod 5 System should be observed to verify normal operation in this setting.

The Omnipod 5 System communicates by low-level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The Omnipod 5 System communicates with the following characteristics:

Frequency: 2.402-2.480 GHz, digitally modulated, with a max Effective Radiated Power of 1.23mW

The Omnipod 5 System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2:2014+AMD1:2020.

Caution: DO NOT use portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 12 inches (30 cm) to any part of the Omnipod 5 System, as it may impact the communication between your smartphone or Controller and your Pod.

Electromagnetic Emissions		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should ensure that is used in such an environment.		
Emissions	Compliance according to	Electromagnetic environment
RF Emissions (CISPR11)	Group 1	The Pod, Controller, and compatible sensors emit low-level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected. The System is suitable for use in all establishments, including domestic establishments.
CISPR B Emissions Classification	Class B	
Harmonic Emissions (IEC 61000-3-2)	Class A	
Voltage Fluctuations/ Flicker Emissions (IEC 61000-3-3)	Pst ≤ 1.0 Plt ≤ 0.65 dc ≤ 3.3% dmax ≤ 4% d(t) ≥ 200 ms during a voltage change should be ≤ 3%	

Appendix

Electromagnetic Immunity			
The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.			
Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ±2 kV ±4 kV ±8 kV ±15 kV	contact discharge: ±8 kV air discharge: ±2 kV ±4 kV ±8 kV ±15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Electrical Fast Transient/ burst (IEC 61000-4-4)	± 2 kV power supply lines ± 1 kV input/output lines	± 2 kV power supply lines ± 1 kV input/output lines	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Conducted Disturbances induced by RF fields (IEC 61000-4-6)	3Vrms 150 KHz-80 MHz 6Vrms in ISM and amateur radio bands between 150 KHz and 80 MHz	10Vrms 150 KHz-80 MHz 6Vrms in ISM and amateur radio bands between 150 KHz and 80 MH	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

Electromagnetic Immunity			
Voltage Dips, Short Interruptions, Voltage Variations on Power Supply input lines (IEC 61000-4-11)	70% UT (30% dip in UT) for 25 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250 cycles	70% UT (30% dip in UT) for 25 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250 cycles	Mains power quality should be that of a typical domestic, commercial, or hospital environment. If the user requires continued operation during power mains interruptional, it may be necessary to use an uninterruptible power supply or a battery.
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	30 A/m and 400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz–2.7 GHz	20 V/m at 80 MHz–1 GHz 10 V/m at 1 GHz–2.7 GHz 3 V/m at 2.7 GHz–6 GHz	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

Appendix

The table below lists the immunity levels at specific test frequencies for testing the effects of some wireless communication equipment. The frequencies and services listed in the table are representative examples in various locations where the System may be used.

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)18Hz	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	704–787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800. ODEM 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
870						
930						
1720	1700–1990	G GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2450-2570	Bluetooth WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	0.2	0.3	9
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
5500						
5785						
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.						

This table lists the immunity levels at specific test frequencies for Proximity Magnetic Fields Range of 9 kHz to 13.56 MHz.

Test Frequency	Modulation	Immunity Test Level (A/m)
30kHz a)	CW	8
134.2 kHz	Pulse modulation b) 2.1 kHz	65 c)
13.56 MHz	Pulse modulation b)	7.5 c)
a) This test is applicable only to ME equipment and ME systems intended in a HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) RMS before modulation is applied.		

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.

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. In order 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.