

CareLink[™]USB



User Guide



Medtronic

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REF MMT-7305

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Paradigm® is a registered trademark of Medtronic MiniMed.

CareLink™ is a trademark of Medtronic MiniMed.

U.S., international, and foreign patent applications pending.

Introduction

Indications for use

The Medtronic CareLink™ USB is indicated for use by patients at home and clinicians in a medical office setting to facilitate communication between Medtronic diabetes therapy management devices that use Paradigm-compatible RF telemetry and a personal computer that uses data management application software.

Contraindications

None known.

Warnings

Product may pose a choking hazard for young children.

Compliance information

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. The 868.35 MHz version (MMT-7305WW) conforms to the essential requirements of the Council Directive 1999/5/EC (R&TTE).

The following information is provided in accordance with Federal Communications Commission (FCC) regulations.

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 undesirable operation.

This device does not interfere with any radio frequency signals transmitted from outside sources. These FCC standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference.

Important: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

RF interference from other wireless devices

Common consumer electronic devices that transmit in the same frequency band used by the MMT-7305 CareLink USB may prevent the CareLink USB from receiving the data sent by Medtronic diabetes therapy management devices. Most cellular phones and 900 MHz cordless phones, when transmitting or receiving, may cause significant interruption of transmitter-receiver communication. It is likely that other devices operating in similar frequency ranges will have a similar effect. This interference, however, will not cause any incorrect data to be sent and will not cause any harm to your CareLink USB.

Communication problems can typically be resolved by ensuring that the distance between transmitter and receiving device is less than 6 feet, and by turning off or moving away from other RF transmitting devices. You can also reorient or relocate the CareLink USB and/or the transmitting device to try to correct the interference. Testing conducted with several different cellular phones suggests that interference will not be a problem if the phone is at least 12 inches from the transmitter or receiving device while the phone is being used (greater separation distance may be required for certain devices).

RF Compatibility

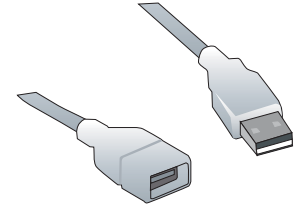
Medtronic diabetes therapy management devices transmit in different radio frequency (RF) bands, depending on the region of the world in which they are sold. If you purchased your Medtronic diabetes therapy management device and CareLink USB in different regions, they may not work together. If your CareLink USB does not seem to recognize your device, this may be the reason. Contact the HelpLine for assistance.

Installing the CareLink USB on your computer

Your CareLink USB must be properly installed before it can transfer data from Medtronic diabetes therapy management devices. Please follow these installation instructions.

Do not plug your CareLink USB into your computer until you have installed the associated drivers and/or are prompted by the CareLink software.

It is recommended that the CareLink USB be plugged directly into a USB port on the computer. USB extension cables can be used if you do not have easy access to your computer's USB ports, but it is recommended that you use only USB cables with a covered female end (see illustration).



Installing the CareLink USB drivers:

- Refer to the user guide of your Medtronic Diabetes data management application software for instructions on how to load the CareLink USB drivers onto your computer.
- After you have followed the user guide instructions, plug your CareLink USB into your computer.

The illustrations show the CareLink USB being plugged into the USB port on the back of a personal computer. You may also plug your CareLink USB into USB ports on the front of your personal computer, or into any USB port on a laptop computer.

Troubleshooting

- If you plug your CareLink USB into a USB port on your computer and it does not work, remove it and plug it into another USB port on your computer. This is a rare but continuing issue with USB ports and many type of USB devices. If your CareLink USB does not work in any USB port on your computer, call the HelpLine for assistance.
- Electrostatic discharge (ESD) may temporarily prevent the CareLink USB from transmitting. If you touch the metal of the CareLink USB or the uncovered end of a USB cable while it is connected to your computer, and your CareLink USB stops transmitting, remove it and plug it back in, being careful not to touch the metal parts.



Specifications

Operating conditions	Temperature: 3° C to 40° C Humidity: 0% to 95 % Atmospheric pressure: 70.0kPa to 106.0kPa
Storage conditions	Temperature: -20° C to +55° C Humidity: 0% to 95%, non-condensing Atmospheric pressure: 50.0kPa to 106.0kPa
Transmitter frequency	868.35 MHz (MMT-7305WW) 916.50 MHz (MMT-7305NA)

Guidance and manufacturers declaration

Guidance and Manufacturers Declaration – Electromagnetic Emissions

The CareLink USB (MMT-7305) is intended for use in the electromagnetic environment specified below. The customer or the user of the CareLink USB should make sure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The CareLink USB 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 CareLink USB is suitable for use in all establishments other than domestic 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	

Guidance and Manufacturers Declaration – Electromagnetic Immunity


The CareLink USB (MMT-7305) is intended for use in the electromagnetic environment specified below. The customer or the user of the CareLink USB should make sure 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The CareLink USB should not be affected by electrostatic discharge that might occur under normal conditions of use.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Level 1 0.5 kV 5 kHz repetition rate	Level 1 criteria per Table 1, 61000-4-4. Mains power quality should be that of a typical commercial or hospital environment. The CareLink USB should not be affected by fast transients along the input power of the host PC that might occur under normal conditions of use.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable Not applicable	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 seconds	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and Manufacturers Declaration – Electromagnetic Immunity

The CareLink USB is intended for use in the electromagnetic environment specified below. The customer or user of the CareLink USB should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3V rms 150 kHz to 80 MHz	3 V emf	<p>Portable and mobile RF communications equipment should be used no closer to any part of the CareLink USB than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz}-800 \text{ MHz}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 6 GHz	3 V/m	$d = 2.3 \sqrt{P} \quad 800 \text{ MHz}-6 \text{ GHz}$ <p>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 meters (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:</p> 

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

NOTE: 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 broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To access 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 CareLink USB is used exceeds the applicable RF compliance level above, the CareLink USB should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CareLink USB or the transmitting device from which it is receiving signals.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the CareLink USB

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

Rated maximum output power of transmitter (W)	Separation distance according to the 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 6 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	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.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Warranty

Medtronic MiniMed warrants the Medtronic CareLink™ USB against defects in materials and workmanship for a period of six (6) months from the date of purchase.

During the warranty period, Medtronic Diabetes will replace, at its discretion, any defective Medtronic CareLink USB, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event that a Medtronic CareLink USB is replaced, the warranty period will not be extended.

This warranty is valid only if the Medtronic CareLink USB is used in accordance with the manufacturer's instructions. This warranty will not apply:












- If damage results from changes or modifications made to the Medtronic CareLink USB by the user or third persons after the date of manufacture
- If damage results from service or repairs performed by any person or entity other than the manufacturer
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer
- If damage results from negligence or improper use, including but not limited to: improper storage, deliberate submersion in water, physical abuse, such as dropping or otherwise

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product. Any statutory rights granted to consumers under any applicable legislation are reserved.

All other warranties, express or implied, except any applicable mandatory statutory warranties, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Icon table

Meaning	Symbol
Attention: See instructions for use:	
One Per Container/Package:	(1x)
Batch code:	
Catalogue number:	REF
Storage temperature range:	
Recycle:	
CE mark by notified body as a medical device:	
CE mark as a radio transmitter under the R & TTE 1999/5/EC directives. Applies to 868 MHz (MMT-7305WW):	
Date of manufacture:	
Signifies compliance with Australian EMC and Radiocommunications requirements:	
Fragile product:	
Radio communication:	
Authorized Representative in the European Community:	
Signifies compliance with Industry Canada EMC and Radiocommunications requirements:	IC

International Contact Information

USA: Medtronic Diabetes

Global Headquarters

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