# CareLink



User Guide



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REF MMT-7305

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# Introduction

#### Indications for use

The Medtronic CareLink<sup>™</sup> 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 (MWT1)\* 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 1.9 meters (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 2.3 meters (7.5 feet) 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 your local HelpLine for assistance.

\* MWT1 is the brand name for the Medtronic MiniMed proprietary RF telemetry protocol.

# 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.

#### 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 at right 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.



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

USB extension cables, female ends



protected (recommended)

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 USB devices. If your CareLink USB does not work in any USB port on your computer, call your local 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 unprotected 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: 0° 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	
Harmonic emissions IEC 61000-3-2	Not applicable	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
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	supplies buildings used for domestic purposes.

## 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)	±6 kV contact	±6 kV contact	The CareLink USB should not be affected by	
IEC 61000-4-2	±8 kV air	±8 kV air	electrostatic discharge that might occur under normal conditions of use.	
Electrical fast transient/burst	±2 kV for power supply lines	Not applicable	Not applicable	
IEC 61000-4-4	±1 kV for input/output lines			
Surge	±1 kV line(s) to line(s)	Not applicable	Not applicable	
IEC 61000-4-5	±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% ${\rm U_T}$ (>95% dip in ${\rm U_T})$ for 0.5 cycle	Not applicable	Not applicable	
	40% ${\rm U_T}(60\%$ dip in ${\rm U_T})$ for 5 cycles			
	70% $U_T$ (30% dip in $U_T$ ) for 25 cycle			
	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 seconds			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable	
<b>NOTE:</b> <i>U<sub>t</sub></i> is the a.c. mains voltage prior to	application of the test level.	1	,	

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
			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.
			Recommended separation distance
Conducted RF EC 61000-4-6	3V rms 150 kHz to 80 MHz	Not applicable	Not applicable
Radiated RF EC 61000-4-3	3V/m 80 MHz to 6 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz-800 MHz
			$d = 2.3 \sqrt{P}$ 800 MHz-6 GHz
			Where $P$ is the maximum output power rating of the transmitter in watts (V 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, <sup>a</sup> should b less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the
			following symbol:
			((·•·))

#### Guidance and Manufacturers Declaration – Electromagnetic Immunity

**NOTE 1:** At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.

<sup>a</sup> 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.

<sup>b</sup> 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	Separation distance according to the frequency of transmitter (m)			
transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 6 GHz	
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	
0.01	Not applicable	0.12	0.23	
0.1	Not applicable	0.38	0.74	
1	Not applicable	1.2	2.3	
10	Not applicable	3.8	7.4	
100	Not applicable	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 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2:** 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 MiniMed 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:	$\wedge$
One Per Container/Package:	(1x)
Batch code:	LOT
Catalogue number:	REF
Storage temperature range:	*
Recycle:	8
CE mark by notified body as a medical device:	<b>C€</b> 0459
CE mark as a radio transmitter under the R&TTE 1999/5/EC directives. Applies to 868 MHz (MMT-7305WW):	<b>CE</b> 0976
Date of manufacture:	M
Signifies compliance with Australian EMC and Radiocommunications requirements:	C
Fragile product:	Ţ
Radio communication:	()
Authorized Representative in the European Community:	EC REP
Signifies compliance with Industry Canada EMC and Radiocommunications requirements:	IC

#### International Contact Information

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