CareLink[™] USB



CareLink™ USB User Guide

Indications for use

The Medtronic CareLink USB (MMT-7306) is indicated for use by patients at home and clinicians in a medical office setting to facilitate communication between Medtronic diabetes therapy management devices (600-series) and a personal computer that uses Medtronic therapy management software for diabetes.

Contraindications

None known.

Warnings

Product may pose a choking hazard for young children.

Getting Started

IMPORTANT: If the CareLink USB drivers are not yet installed, or if you are not sure if the drivers are installed, do not connect the CareLink USB. See the instructions below for installing the CareLink USB drivers.

Healthcare professionals: If you are a healthcare professional using CareLink™ Pro Therapy Management Software for Diabetes, the CareLink USB drivers will be installed as part of the CareLink Pro program installation.

Patients: If you are a patient using CareLink[™] Personal Therapy Management Software for Diabetes, you must follow these instructions BEFORE connecting the CareLink USB to your computer.

Note: If you are not using Windows Vista, Windows 7, Windows 8 or Windows 8.1, continue directly with step 2.

1. Make sure that User Account Control is enabled. By default, User Account Control is already

- enabled, so it is likely that you do not have to enable it.
- a. Close Internet Explorer. (If you are using Windows 8 or 8.1, close Internet Explorer and do not use Internet Explorer from the start screen.)
- b. Navigate to Start > All Programs (or Programs). (If you are using Windows 8 or 8.1, from the Start screen, click on the Desktop tile.)
- c. Right-click on the Internet Explorer menu item. (If you are using Windows 8 or 8.1, right-click on the Internet Explorer icon from the task bar. Then right-click on Internet Explorer in the pull-up menu.)
- d. Select Run as Administrator.
- e. When the User Account Control window is displayed, click **Allow** or **Yes**.

Note: If you are not logged in as an administrator on your computer, you may be asked to enter an administrator user's password.

- 2. Navigate to the CareLink Personal website and register.
- U.S. residents, use https://carelink.minimed.com
- Non-U.S. residents, use https://carelink.minimed.eu

Once registered, you will be able to sign in and upload your device data.

- Click the Upload tab or Upload data from My Device link and follow the on-screen instructions.
- 4. If you need more assistance, click the **Help** link near the top of the screen.

Connecting the CareLink USB to your computer

Plug the CareLink USB into your computer when prompted by the CareLink software. It is recommended that the CareLink USB be plugged directly into a USB port on your computer, rather than into a peripheral device, such as a USB port on your monitor or keyboard. You can use a USB extension cable if you do not have easy access to the USB ports on your computer, but it is recommended that you use only a USB cable with a protected female end (see image).



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. If your CareLink USB does not work in any USB port on your computer, call the HelpLine for assistance or your local Medtronic representative.
- Electrostatic discharge (ESD) may temporarily prevent the CareLink USB from functioning. If you touch the metal components 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.
- If you are a healthcare professional, see the *CareLink Pro User Guide* for more information about supported devices, troubleshooting, or other instructions.
- This device cannot be used to upload pumps other than the MiniMed 600-series pumps.

Compliance information

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. The CareLink USB (MMT-7306) 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 Medtronic Minimed, Inc. 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 CareLink USB (MMT-7306) may prevent the CareLink USB from receiving the data sent by Medtronic diabetes therapy management devices. If significant RF interference is present, the CareLink USB and the device it is communicating with will switch to another channel and communications will continue.

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 increasing the separation between the equipment and receiver.

In the unlikely event that communications does not resume by switching to other channels,

communication problems can typically be resolved by ensuring that the distance between transmitter and receiving device is less than 1.8 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. Note that RF interference will not cause any incorrect data to be processed and will not cause any harm to your CareLink USB.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Wireless coexistence summary

The CareLink USB (MMT-7306) was tested against the data listed in the two tables for wireless phones and wireless networks. The test results are described after the two tables.

Wireless phones

Telephones	Frequency	Recommended Separation Distance (meters)	Recommended Separation Distance (inches)
WCDMA		0.3	12
TDMA	800 - 960 MHZ,	0.3	12
GSM	1700-2200 MHZ	0.3	12
DECT		0.254	10

Wireless Networks

Networks	Frequency	Recommended Separation Distance (meters)	Recommended Separation Distance (inches)
802.11b/g/n	2.4 GHz	1	39
Bluetooth	2.4 GHz	0.1	3.93
ZigBee	2.4 GHz	0.1	3.93

Data integrity: Each interference event was evaluated for current and latent anomalies. The upload for each pump showed complete and uninterrupted functionality with no corrupted or missing data.

Performance: The wireless functions operated safely and effectively in an intended use environment.

Quality of service:

- All of the wireless functions operated as intended.
- All operations required of system-paired devices functioned as intended.
- In an active RF environment, the system pairs identified and relocated to a clear channel within 3 minutes of uninterrupted download operation.

Latency: The wireless function operated when commanded. There was no latency when establishing the wireless connection or transmitting data via the wireless connection in the adverse RF environment.

Specifications

Operating conditions	Temperature: 5° C to 40° C. Humidity: 20% to 90%. Atmospheric pressure: 70.0 kPa to 106.0 kPa
Storage conditions	Temperature: -20° C to +55° C. Humidity: 5% to 95%, non-condensing. Atmospheric pressure: 49.5 kPa to 106.0 kPa

Specifications

Transmitter frequency	2.4 GHz
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Guidance and manufacturers declaration

Table 1. Guidance and Manufacturers Declaration - Electromagnetic Emissions

This CareLink USB (MMT-7306) 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	network that supplies buildings used for domestic purposes.

Table 2. Guidance and Manufacturers Declaration - Electromagnetic Immunity

This CareLink USB (MMT-7306) is intended for use in the electromagnetic environment specified below. The customer or the user of the Carel ink 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)	±4 kV contact	±4 kV contact	The CareLink USB should not be affected by electrostatic discharge that		
IEC 61000-4-2	±8 kV air	±8 kV air	might occur under normal conditions of use.		
Table 2, continued ne	Table 2, continued next page				

Table 2. Guidance and Manufacturers Declaration - Electromagnetic Immunity

This CareLink USB (MMT-7306) 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		
Electrical fast transient/burst	±2 kV for power supply lines	Not applicable			
IEC 61000-4-4	±1 kV for input/ output lines	±1 kV for input/output lines			
Surge	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)			
IEC 61000-4-5	±2 kV line(s) to earth	±2 kV line(s) to earth	For use in a typical domestic, commercial, or hospital environment.		
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% 0.5 cycles 0% 1 cycle 70% 25 cycles 0% 250 cycles	0% 0.5 cycles 0% 1 cycle 70% 25 cycles 0% 250 cycles			
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.		
Table 2, continued nex	Table 2, continued next page				

Table 2. Guidance and Manufacturers Declaration - Electromagnetic Immunity

This CareLink USB (MMT-7306) 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	
Conducted RF IEC 61000-4-6	3V rm 150kHz to 80 MHz	3V rms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the CareLink USB than the recommended separatio distance calculated from the equation applicable to the frequency of the transmitter.	
			Recommended separation distance	
Radiated RF	3V/m	10V/m	$d = 1.2 \sqrt{P} 80 \text{ MHz} - 800 \text{ MHz}$	
IEC 61000-4-3		$d = 2.3 \sqrt{P800} \text{ MHz-6 GHz}$		
	GHz	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 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.	
			Interference may occur in the vicinity of equipment marked with the following symbol:	

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.

^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.

Table 3. 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	Separation distance according to the frequency of transmitter (m)			
power of transmitter	80 MHz to 800 MHz	800 MHz to 6 GHz		
(W)	<i>d</i> = 1.2 √ <i>P</i>	d = 2.3 √P		
0.01	0.12	0.23		
0.1	0.38	0.74		
1	1.2	2.3		
10	3.8	7.4		
100	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.

Icon Table

Symbol	Meaning	Symbol	Meaning
\triangle	Caution: Consult accompanying documents	444	Manufacturer
[]i	Consult instructions for use	₩	Date of manufacture

Icon Table

Symbol	Meaning	Symbol	Meaning
SN	Device serial number		Signifies compliance with Australian EMC, EME and Radio communications requirement
REF	Catalogue number	((° <u>1</u> 3))	Radio communication
<u></u>	Humidity limitation	EC REP	Authorized representative in the European Community
1	Storage temperature range	IC	Signifies compliance with Industry Canada EMC and Radio communications requirements
(1x)	One per container/package		Complies with Japan Radio Law Notice 88
	Manufacturing site	CE	This symbol means that the device fully complies with MDD 93/42/EEC and R&TTE Directive 1999/5/EC.

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