

Medtronic

CareLink Express Online Help

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Adapta, Attesta, CareLink, CareLink Express, EnPulse, Kappa, Medtronic, Medtronic CareLink, Sensia, Sphera, Versa, Vitatron

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1 Configuration

1.1 About CareLink Express

Device Description

The CareLink Express™ mobile app (called the “CL Express app” from now on) is installed on a compatible mobile device with Internet access. The CL Express app communicates with the Medtronic 24965 Patient Connector or the Medtronic 24967 Patient Connector¹ (called the “patient connector” from now on) and sends implanted cardiac device data to Medtronic’s proprietary CareLink Network for clinical review. The CL Express app should be used by healthcare personnel only in a clinical or hospital environment.

Intended Use

The CareLink Express app is intended for interrogating Medtronic cardiac devices and uploading the data to the CareLink Network.

Contraindications

There are no known contraindications.

Implantable Device Information

During interrogation of EnPulse/Kappa, Adapta/Versa/Sensia, Attesta/Sphera, and select Vitatron² pacemakers, a battery and lead measurement will temporarily set the pacemaker to asynchronous pacing at 100 min⁻¹ for several beats. 2:1 block can be produced in some patients at the time of interrogation in the presence of higher intrinsic atrial rates. Patients with tracked high atrial rates should be observed during initial interrogations to assess their tolerance of a rapid change in heart rate to their programmed Lower Rate.

Patients should be sitting comfortably while the interrogation is performed.

Electronic instructions for use/manuals

To view, download, print, or order manuals for this product, go to www.medtronic.com/manuals, or contact a Medtronic representative.

Software requirements

Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

Paper manuals

Paper manuals are available to customers free of charge. They should arrive in 3 - 7 days. To order, go to www.medtronic.com/manuals, or contact a Medtronic representative.

Prescription Statement for the United States

! USA

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

¹ All model numbers may not be available in your geography.

² Vitatron models Q70A2, Q80A2, G70A2, Q50A2, G20A2, Q20A2. All model numbers may not be available in your geography.

CE Mark of Conformity






CE0123
2016

Applicable Model Numbers

31301
31302

Select the About screen from the Home menu to determine the model number for your CL Express app. All model numbers may not be available in your geography.

Symbols

	For US audiences only
	Authorized representative in the European Union
	Manufacturer
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts.
	Menu icon

1.2 IT Network, Mobile Device, and Data Information

Required IT network characteristics and configuration

The use of the CareLink Express system requires your network to have Internet access and Bluetooth® enabled on your mobile device for the following purposes: ³

- Install and update the CL Express app from the app store.
- Communicate with the CareLink Network

Failure to provide IT network access results in the following effects:

- Installation and updates to the CL Express app cannot be completed if the mobile device is unable to access the app store.
- Clinical review of the implanted device data cannot be completed if the CL Express app is unable to transmit the data to the CareLink Network.
- Communication with the implantable device cannot occur if the mobile device is unable to establish a Bluetooth connection with the patient connector.

Follow your organization’s processes and policies to configure your network.

Supported mobile devices and technical specifications

For the list of supported mobile devices, and their specifications including network connectivity specifications, go to the following website:

³ The Bluetooth® word mark is a registered trademark of Bluetooth SIG, Inc. and any use of this mark by Medtronic is under license.

Precautions when connecting to your IT network

Connecting the CL Express app to an IT network that includes other equipment could result in unforeseen risks to patients, operators, or third parties. Changes to your IT network could also introduce additional risks. Analyze, evaluate and control any risks identified.

Intended information flows

Implantable cardiac device data and system logs are sent for processing through the system components in the following sequential order:

1. Implanted cardiac device
2. Patient connector
3. CL Express app installed on the mobile device
4. Internet
5. CareLink Network

In response, a confirmation receipt is sent from the CareLink Network via the Internet to the CL Express app.

The clinic location ID is sent from the CL Express app via the Internet to the CareLink Network for validation. In response, the clinic location ID's validation status is sent by the CareLink Network via the Internet to the CL Express app to allow clinic location ID to be stored in the CL Express app.

All information in transit is protected for security.

Security

Data in the CL Express app is protected by application level encryption.

It is recommended to use the following security measures to protect the CareLink Express system:

- The CL Express app and patient connector should only be used on a managed, trusted, secured network.
- Secure your network with anti-virus software, a firewall, or both in-line with your IT department's policies.
- To help protect patient health information, security measures for your mobile device should include implementation of a passcode and PIN to protect the mobile device.

1.3 Initial Setup

During the procedure, you may be asked to enter the model number, security code, or serial number of the patient connector. This information is found on the bottom of the patient connector. You can also refer to the instructions for use provided with the patient connector for help in locating this information.

1. Ensure that Bluetooth® is enabled on your mobile device. For most mobile devices, tap **Settings > Bluetooth** to enable it.
2. Ensure that your mobile device is connected to the Internet. Consult your IT department for support with connecting your device to the Internet.
3. Open the CL Express app.
4. On the **Welcome** screen, tap **Continue**.
5. When prompted by the app, enter the patient connector model number you are using and tap **CONTINUE**.

6. Press the button on the patient connector to turn it on.
The Bluetooth light on the patient connector first flashes when the Bluetooth is discoverable, and then turns solid when the Bluetooth connection is established.
7. When prompted, select the patient connector you are using from the list.
8. If you are prompted by the mobile device to accept a Bluetooth Pairing Request, confirm that the serial number in the request matches the serial number on the back of the patient connector.
 - Decline the request if the serial number does not match the serial number on the back of the patient connector.
 - Accept the request to pair the patient connector with the CL Express app.
9. Tap **Continue**.
10. Enter the security key code and tap **Continue**.
11. The **Enter your Location ID** screen is displayed. Enter the numerical portion of your Location ID and tap **Continue**. You can find your Location ID by logging into the CareLink Express website or contacting your CareLink Network administrator.
12. Re-enter the numerical portion of your Location ID and tap **Continue**.
13. The CL Express app verifies your Location ID with the CareLink Network.
 - a. Tap **Continue** if the facility name and location name are correct.
 - b. Tap **Cancel** if the facility name and location are not correct. If you tap **Cancel**, you will be required to repeat the setup process.

The **Home** screen is displayed. The CL Express app and patient connector are ready to use.

1.4 Change Location ID

Under certain circumstances CareLink Express may need to be used at a different location. In those circumstances the Location ID will need to be updated to match the new location as configured in CareLink Network. To change to a different Location ID, the following steps will be required.

During the procedure, you may be asked to enter the model number, security code, or serial number of the patient connector. This information is found on the bottom of the patient connector. You can also refer to the instructions for use provided with the patient connector for help in locating this information.

To view the current Location ID, tap **Menu** and refer to the Location ID listing.

1. Tap **Menu > Location ID**.
2. Ensure that Bluetooth® is enabled on your mobile device. For most mobile devices, tap **Settings > Bluetooth** to enable it.
3. Ensure that your mobile device is connected to the Internet.
4. Press the button on the patient connector to turn it on.
The Bluetooth light on the patient connector first flashes when the Bluetooth is discoverable, and then turns solid when the Bluetooth connection is established.
5. The patient connector pairs with the CL Express app.
If prompted by the CL Express app, select the patient connector you want to use from the list.
If you are using a new patient connector, you will have to pair the app and the patient connector. See Section 2.1.

6. The **Enter your Location ID** screen is displayed. Enter the numerical portion of your Location ID and tap **Continue**. You can find your Location ID by logging into the CareLink Express website or contacting your CareLink Network administrator.
7. Re-enter the numerical portion of your Location ID and tap **Continue**.
8. The CL Express app verifies your Location ID with the CareLink Network.
 - a. Tap **Continue** if the facility name and location name are correct.
 - b. Tap **Cancel** if the facility name and location are not correct. If you tap **Cancel**, you will be required to repeat the setup process.

The **Home** screen is displayed. The CL Express app and patient connector are ready to use.

2 Patient Connector

2.1 Adding a Patient Connector

The app will guide you through the following steps when you add a new patient connector.

During the procedure, you may be asked to enter the model number, security code, or serial number of the patient connector. This information is found on the bottom of the patient connector. You can also refer to the instructions for use provided with the patient connector for help in locating this information.

1. Ensure that Bluetooth® is enabled on your mobile device. For most mobile devices, tap **Settings > Bluetooth** to enable it.
2. Press the button on the patient connector to turn it on.

The Bluetooth light on the patient connector first flashes when the Bluetooth is discoverable, and then turns solid when the Bluetooth connection is established.
3. Select the available option:
 - Tap **SELECT NEW PATIENT CONNECTOR**.
 - Tap **Cancel** from the pop-up dialog.
4. When prompted by the CL Express app, enter the patient connector model number you are using and tap **Continue**.
5. If prompted, select the patient connector you are using from the list.
6. If prompted, enter the security key code and tap **Continue**.
7. If you are prompted by the mobile device to accept a Bluetooth Pairing Request, confirm that the serial number in the request matches the serial number on the back of the patient connector.
 - Decline the request if the serial number does not match the serial number on the back of the patient connector.
 - Accept the request to pair the patient connector with the app.

The patient connector is paired and ready to use.

2.2 Charging

Medtronic recommends that you charge the patient connector and your mobile device before conducting a CareLink Express session.

For information on charging the patient connector, refer to the instructions for use provided with the patient connector.

3 CareLink Express Session

3.1 Conducting a CareLink Express Session

1. Tap **Start**.
2. Press the button on the patient connector to turn it on.
3. The patient connector pairs with the CL Express app.

If prompted by the CL Express app, select the patient connector you want to use from the list.

If you are using a new patient connector, you will have to pair the app and the patient connector. See Section 2.1.

4. When prompted, hold the patient connector over the implanted cardiac device. You can hold the patient connector either snugly against the clothing or bare skin.

The telemetry indicator light on the patient connector turns on when you have established telemetry with the implanted device.

Caution: Do not place the mobile device directly over the implanted cardiac device. Keep the mobile device at least 6 in (15 cm) away from the implanted cardiac device.

5. The patient connector communicates with the implanted cardiac device. The CL Express app displays a transmitting signal and a green progress bar.

Note: The CL Express app clears alerts triggered by implanted cardiac devices at the end of the communication with the patient connector. These triggered alerts are included in the data transmission sent to the Medtronic CareLink Network for review.

6. Set the patient connector aside when the communication between the implanted cardiac device and the patient connector completes.
7. The CL Express app automatically transmits the data to the CareLink Network when the mobile device has adequate connectivity to either a cellular or Wi-Fi network.

Note: You may need to move the mobile device to a location that has an adequate cellular or Wi-Fi network signal to complete the transmission.

8. Watch the CL Express app to follow the status of the data transmission from the app to the Medtronic CareLink Network.

The CL Express app will try to send the data for 15 min. If the data has not been successfully sent after 15 min, the session will need to be repeated.

4 Lock Mode

4.1 Lock Mode

Lock Mode restricts the CL Express app to interrogate and transmit data to the CareLink Network only and prevents unauthorized access to the Menu options.

4.2 Enabling Lock Mode

1. Tap **Menu > Lock**.
2. Enter your **Location ID**.
3. Tap **Lock**.

The **Home** screen is displayed and the CL Express app configuration cannot be changed.

4.3 Disabling Lock Mode

1. Tap the **Menu** button.
2. Enter your **Location ID**.
3. Tap **Unlock**.

The **Home** screen is displayed. The **Menu** icon is enabled and the CL Express app settings are available.

5 Troubleshooting

5.1 Issue and System Messages

Table 1. Issue Messages

Error Code	Message	Description	How to fix
8239	-	The implanted cardiac device is not supported by the CL Express app and cannot be interrogated.	<ul style="list-style-type: none">• Tap Cancel.• Download the latest version of the CL Express app from the app store and try again.• If the issue persists, contact your Medtronic Representative to determine if the implanted cardiac device is compatible with the CL Express app.
4514	-	The implanted cardiac device has experienced a flash failure state and has been reset to its ROM backup.	<ul style="list-style-type: none">• Tap Cancel.• Contact your Medtronic Representative or the clinician managing the patient.
8786	Registered Clinic Location ID Lookup Failed	The Location ID could not be found or matched.	<ul style="list-style-type: none">• Tap Cancel.• Verify that the Location ID is configured correctly.• Contact your CareLink Network administrator.
7309	CareLink Maintenance	CareLink is temporarily unavailable due to maintenance and cannot process the request.	<ul style="list-style-type: none">• Tap Cancel.• If the data has not been successfully sent after 15 min, the session will need to be repeated.• Contact your CareLink Network administrator.

Table 1. Issue Messages (continued)

Error Code	Message	Description	How to fix
5409	No Wi-Fi Connection	Certain features of this software require a connection to the Internet. You cannot transmit data to the CareLink Network or receive software updates.	<ul style="list-style-type: none">• To enable all features, ensure that Wi-Fi or cellular data service is enabled and connected.• To enable Wi-Fi, tap Cancel, enable the Wi-Fi setting on your mobile device and connect to your network.
5704	No Cellular Connection	Certain features of this software require a connection to the Internet. You cannot transmit data to the CareLink Network or receive software updates.	<ul style="list-style-type: none">• To enable all features, ensure that Wi-Fi or cellular data service is enabled and connected.• To enable cellular connectivity, work with your IT department to get the mobile device configured.
2108	Transmission Failure	Your mobile device was unable to connect to a network with access to CareLink Network to complete a transmission.	<ul style="list-style-type: none">• Check that your Wi-Fi is enabled and connected to the Internet.• Contact your CareLink Network administrator.• Attempt to resend the data later.• Contact your Medtronic Representative.
3269	Patient Connector Out of Range	The mobile device cannot communicate with the patient connector.	<ul style="list-style-type: none">• Move the mobile device closer to the patient connector.• Check your Bluetooth connection.
3269	Bluetooth Failure	The mobile device cannot connect to the patient connector using Bluetooth.	<ul style="list-style-type: none">• Move the mobile device closer to

Table 1. Issue Messages (continued)

Error Code	Message	Description	How to fix
			<p>the patient connector.</p> <ul style="list-style-type: none"> • Check your Bluetooth connection.
3517	No Device Found	No supported implanted cardiac device was found.	<ul style="list-style-type: none"> • Tap Cancel to close the message. • Place the patient connector over the implanted cardiac device and attempt the communication session again. • Contact your Medtronic Representative.
3314	Reading device interrupted	The communication session between the patient connector and the implanted cardiac device was interrupted.	Restart the communication session between the patient connector and the implanted cardiac device.
0056/2316	-	An error has occurred in the CL Express app.	Contact your Medtronic Representative and tap Cancel to close the CL Express app.
3230	Bluetooth connection lost	Bluetooth pairing failed. The CL Express app is unable to connect to the requested patient connector at the beginning of a session.	Tap CANCEL and try pairing again.
8260	Software update waiting (Lock Mode).	The CL Express app is in Lock Mode and is unable to accept a software update.	<p>Perform the following steps:</p> <ol style="list-style-type: none"> 1. Unlock the CL Express app. 2. Accept the update.
8287	Application Software Update Required to Match Firmware/Hardware Revision	The app may require an update to support new/updated telemetry hardware.	Connect to the appropriate app store and update to latest version.

Table 2. System Messages

Message	Description	How to fix
Application update available	You must update the application to continue.	Tap Update to install the update and continue. Tap Cancel to close the CL Express app and install the update later.
Patient connector update in progress	You must wait for the update to complete.	Tap OK and wait for the patient connector update to complete.

5.2 Charging

Table 3. Patient Connector Messages

Error Code	Message	Description	How to fix
3248	-	The patient connector battery is low and must be charged for continued use.	Connect the patient connector to the Medtronic-supplied charger or switch to a different patient connector and follow the prompts on the app.

5.3 Updates

Medtronic will periodically push updates to the CL Express app on the mobile device and updates to the software on the patient connector.

If a CL Express app update is available, you will be prompted to update the CL Express app unless you have enabled automatic updates on your mobile device. Medtronic requires accepting all CL Express app updates when they are available if automatic updates are not enabled on your mobile device. If you are in a CareLink Express session, updates to the CL Express app will happen either before the device interrogation or after the data has been sent to CareLink Network.

If the CL Express app is in Lock Mode when an app update is detected, unlock the CL Express app and then accept the app update.

CL Express App Updates

If the CL Express app displays a message that the CL Express app must be updated, select one of the following options:

- Accept the update to update the CL Express app to the latest version.
- Decline the update to keep the CL Express app at the same version.

If you decline the update, the CL Express app will close. You cannot use the CL Express app until you accept the app update.

Patient Connector Software Updates

When an update to the patient connector software is available, the update begins automatically after the patient connector pairs with the CL Express app.

The patient connector software update process occurs automatically. You do not need to take any action for the process to start or complete.

When the patient connector software is updating, a software update screen displays and a progress bar shows the status of the software update. When the progress bar fills completely, the patient connector software is updated and the software update screen closes.

If you navigate away from the patient connector software update screen during the software update, the software update continues until the patient connector software update completes. You cannot cancel the patient connector software update.

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