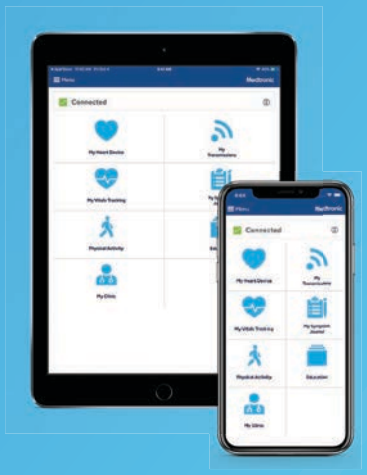
MyCareLink Heart™ App

For Heart Devices with BlueSync™ Technology



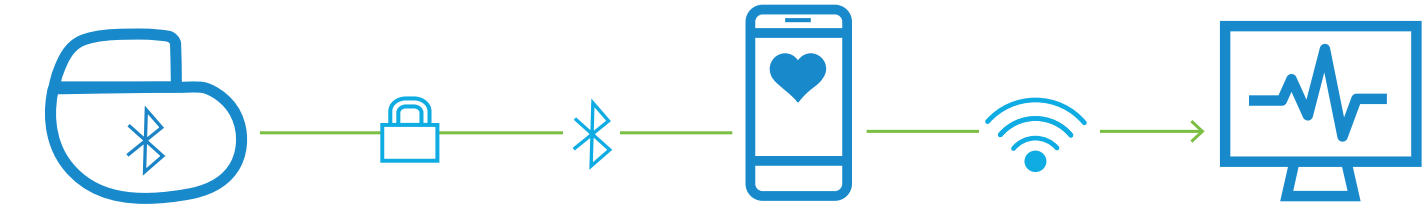
CLINICIAN
USER GUIDE

Medtronic

MyCareLink Heart™ Mobile App for Pacemakers with BlueSync™ Technology

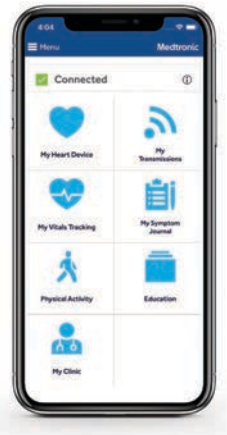
Patients can now use their smartphone* to automatically transfer device data via the MyCareLink Heart mobile app.

How It Works



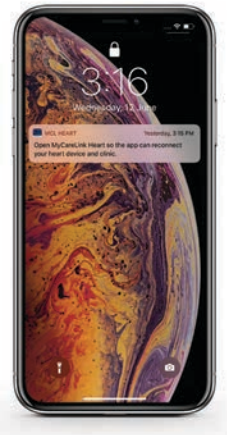
MyCareLink Heart allows the patient to view select data (content of transmissions and alerts is not visible to the patient)

Select Features



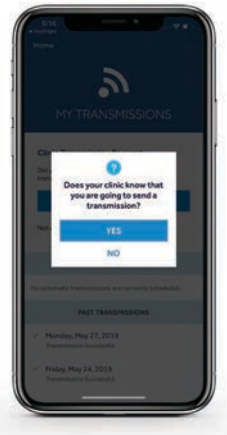
Connectivity Status

Green checkmark confirms connectivity.



Automatic Notifications

- Patient notified if not connected within 4 days.
- Patient notified when transmission is received.
- Reduces clinic time spent on disconnected monitor follow-up.



Send a Manual Transmission

- Patient can send manual transmission with the app.
- Prompts — "Does your clinic know that you are going to send a manual transmission?" to minimize non-requested sends.

*Please visit MCLHeart.com for a list of compatible smartphones and tablets.

REIMAGINED CONNECTIVITY

Set the foundation for the future of connected health

The MyCareLink Heart app for BlueSync pacemakers has been designed to provide the following benefits to both patients and the clinic:

Patient Engagement Promotes Patient Satisfaction[1]

- Integrate remote monitoring into your patient's daily life using a patient-owned smartphone and eliminate the need for a bedside monitor.
- Provides patients peace of mind with access to select heart device data, such as transmission status.
- Activated patients are significantly more likely to engage in healthy behaviors.[2]

Patient Compliance Results in Increased Clinic Efficiencies[3]

- Patient monitoring — even outside the home — helps deliver quality of care in line with HRS guidelines.
- Reduce clinic time spent on follow-up activities.
- Automatic notifications help patients stay connected.

Upgradeability Sets the Foundation for Future Technologies

Similar to consumer apps, as technology advances, so will MyCareLink Heart — throughout the life of the pacemaker. Patients need to keep their mobile technology up to date to use the app for monitoring.

BlueSync Security[4]

Security for the new connectivity and features was **designed to protect** the device, patient data, and connectivity. In addition to its extensive internal product **security testing,** Medtronic has also engaged outside specialized security testing firms.

Pacemaker Protection

- **Device is not connected to the internet.** Pacemaker does not have an IP address, unlike connected consumer products.
- MyCareLink Heart acts as a pass-through only.

End-to-end Encryption

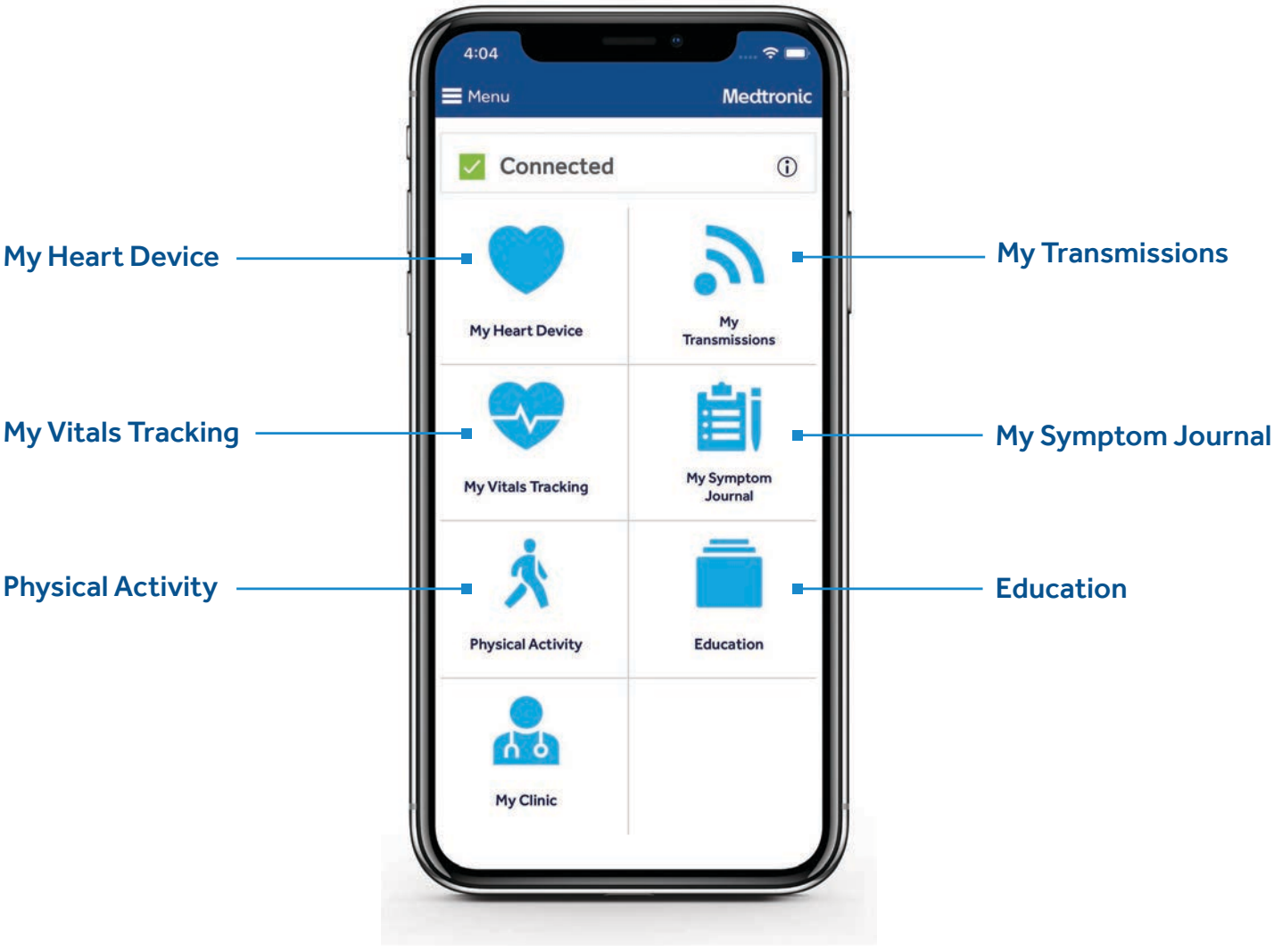
Data are encrypted in the pacemaker using NIST† government standard for security (used in critical applications like banking) before they are transmitted to CareLink via the app.

†NIST: National Institute of Standards and Technology.

APPLICATION OVERVIEW

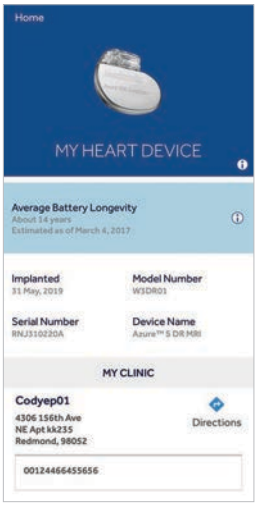
This guide describes how to use the MyCareLink Heart mobile app (called "app" from now on) for patients with pacemakers with BlueSync technology.

Home Screen on App



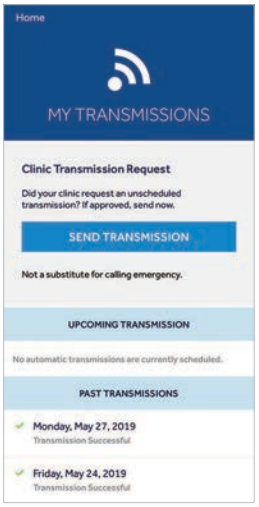
Download on the App Store

GET IT ON Google Play



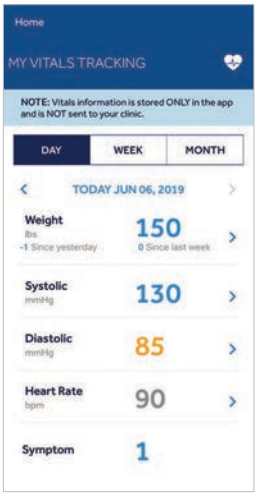
My Heart Device Tile

Displays implant date, pacemaker's name, model number, and serial number — as well as patient's clinic information.



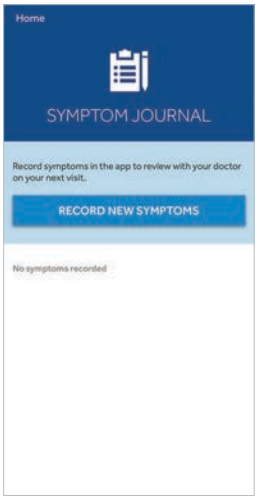
My Transmissions Tile

Has information about transmissions sent from a patient's pacemaker to their clinic.



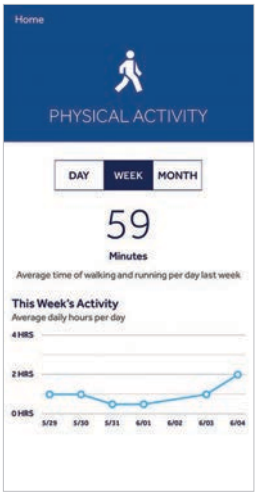
My Vitals Tracking Tile

Used to record weight, blood pressure, and heart rate measurements — and track these measurements over time.



My Symptoms Journal Tile

Used to create a log of symptoms to share with doctor at an in-office visit.



Physical Activity Tile

Has information about a patient's activity level. The app uses data from patient's pacemaker to create daily, weekly, and monthly views of physical activity.

Education Tile

Provides information about living with a heart device.

DOWNLOAD AND SETUP OVERVIEW

Determine phone or tablet compatibility with the app and download the app.

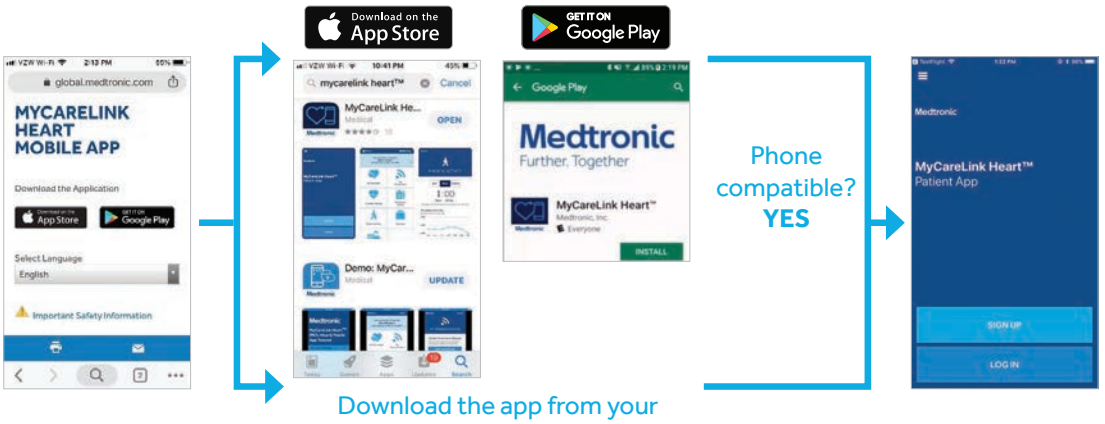
Visit MCLHeart.com for a full list of supported devices and operating systems.

Before starting, check the following items:

- Does the patient have an active App Store® ID and password? This is required in order to download the app.
- Verify your patient has a valid email address.

Download App

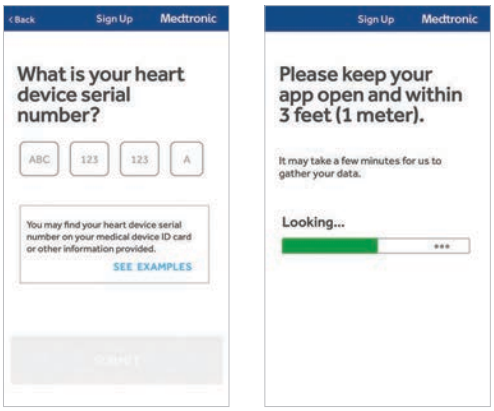
Download via landing page or directly from the App Store. This is also a way to screen patients* for phone compatibility.



Download the app from your smartphone- or tablet-compatible App Store

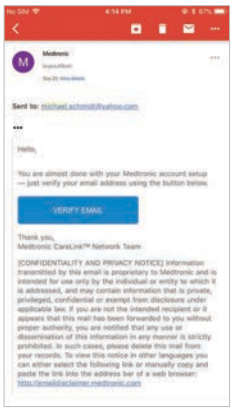
Pair App with Pacemaker and CareLink

- Enter name, email, create password, and input device serial number.
- Submit and wait a few minutes for pairing to complete.



Verify Email

Navigate to email and select "Verify Email."



*For detailed, step-by-step instructions on download and setup, refer to MCL Heart Download and Setup Guide for Apple® or Android™, or visit MCLHeart.com.

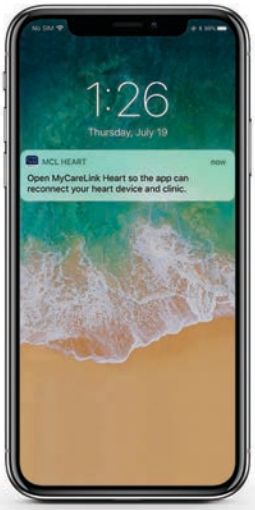
For more information on download and setup, visit **MCLHeart.com**

Enroll in CareLink

In addition to pairing and email verification, the patient needs to be enrolled in CareLink to be remotely monitored and to see app content. Select smartphone or tablet as the patient's monitoring choice when associating a monitor to the pacemaker.

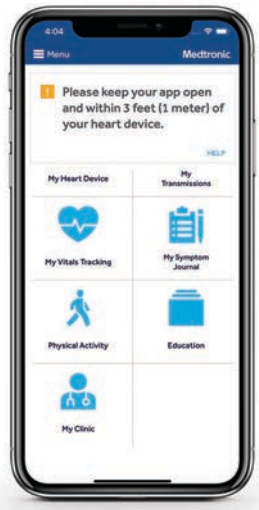
Automatic Notifications

- Designed to reduce clinic time spent on follow-up activities.
- Can also be delivered via text message and email.



Text	Event
"You are now enrolled and connected to your clinic."	Enrolled in CareLink
"Open MyCareLink Heart so the app can reconnect your heart device and clinic."	No recent connection
"Your transmission was successful. It was received by your clinic on the following date: <Date>."	Successful transmission received
"Your scheduled transmission was not received on <Date>. Open the app to send a transmission."	Missed scheduled transmission

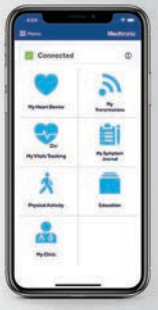
Connectivity Status Notifications



Text	Event
"Bluetooth® is off."	Bluetooth is turned off on mobile device
"Check Wi-Fi/cellular connections."	Mobile device is not connected to the internet
"Please keep your app open and within 3 feet (1 meter) of your heart device." **Note:** Because the app is shared across device types, the notification will display 3 feet versus the required 5 feet.	App is out of range of heart device

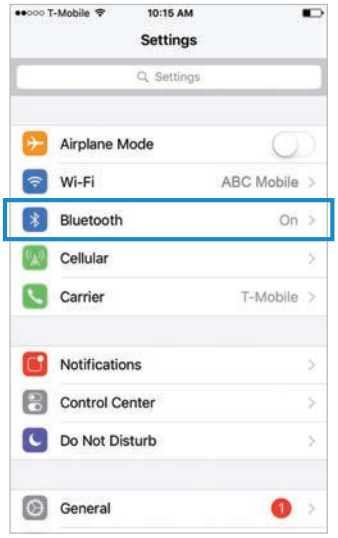
CONDITIONS FOR USE

To ensure the patient is being consistently monitored, the following must be done:

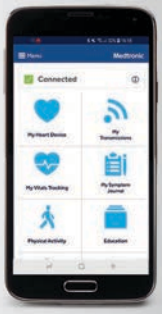


FOR APPLE DEVICES

1. Bluetooth ON

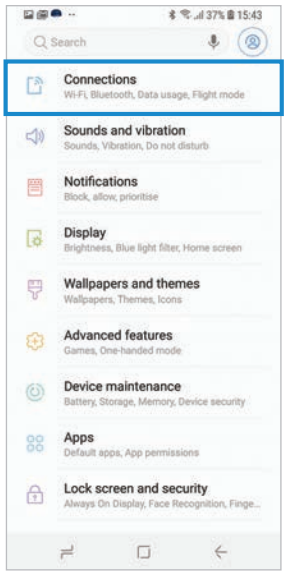


2. Internet connectivity: cellular or Wi-Fi ON



FOR ANDROID DEVICES

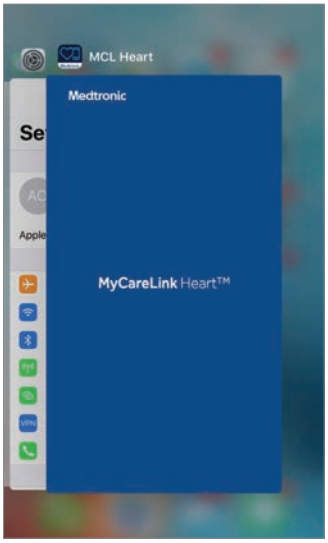
1. Bluetooth ON



2. Internet connectivity: cellular or Wi-Fi ON

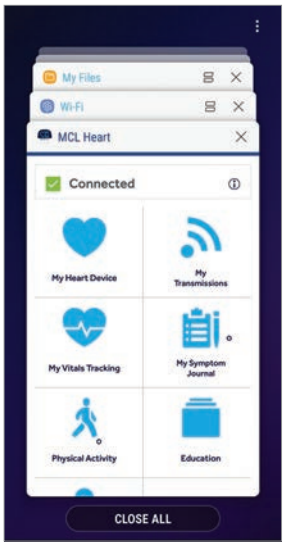
3. Phone/tablet within 3 feet (1 meter) of device

4. App open in background or foreground



3. Phone/tablet within 3 feet (1 meter) of device

4. App running in background or foreground

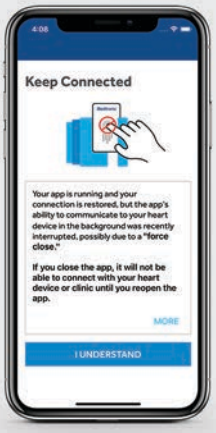


KEEP CONNECTED FEATURE

For Apple iOS devices

The "Keep Connected" on MyCareLink Heart app recognizes when users* swipe up and force the app to close. This feature provides timely and actionable patient education.

Automatic Notification

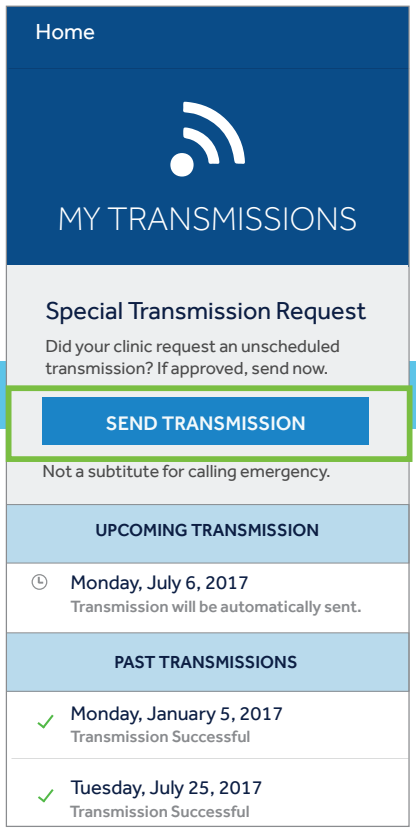


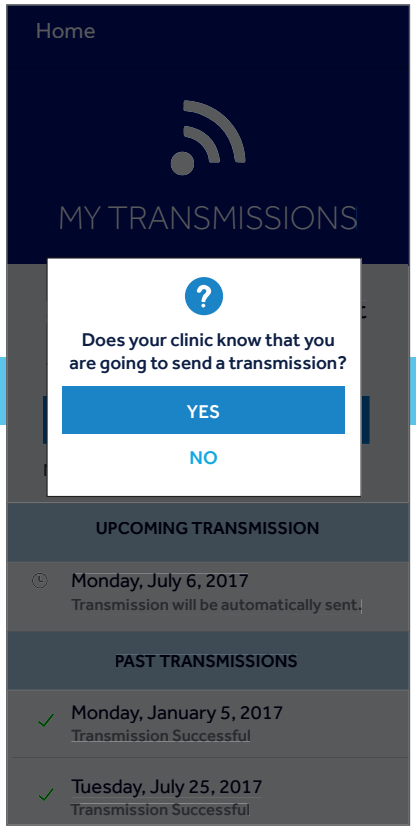
In-app Education

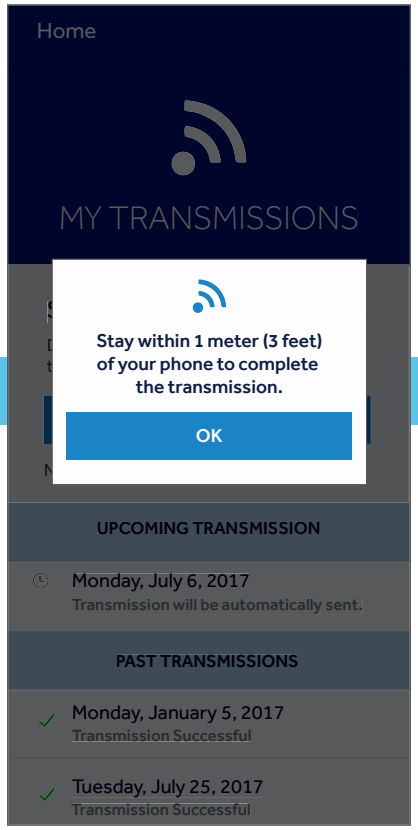
*Apple iOS users only.

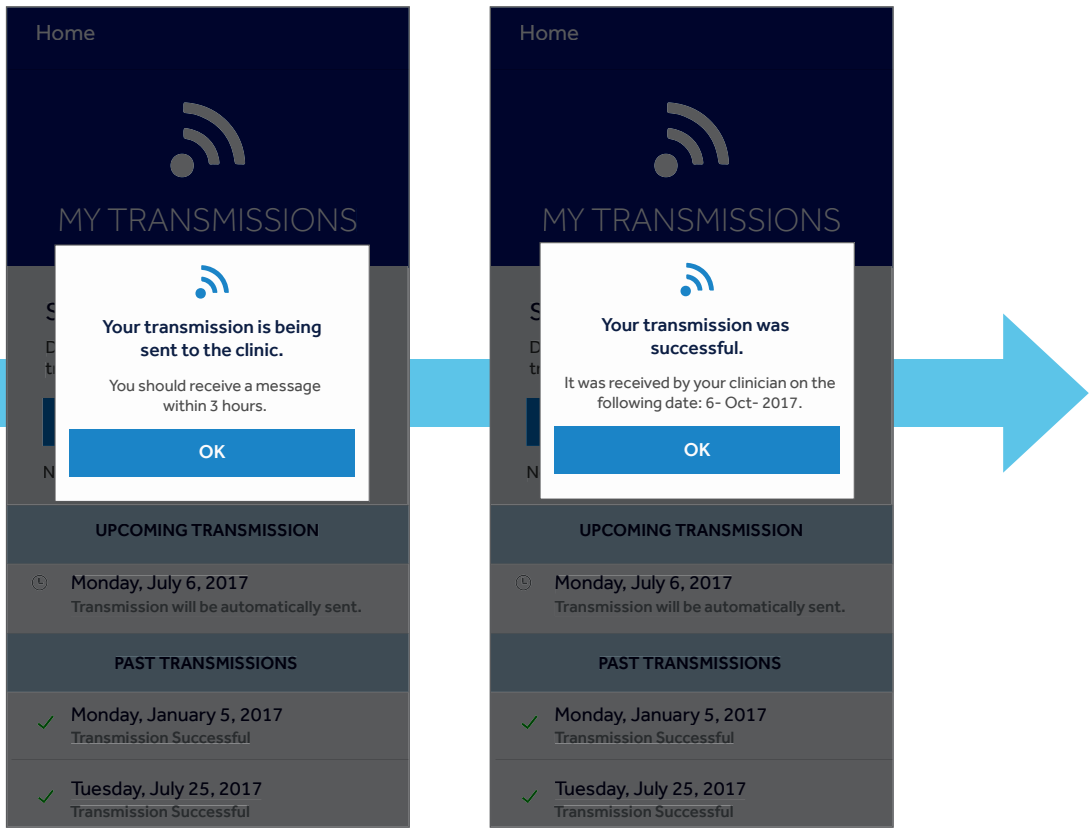
SEND MANUAL TRANSMISSION

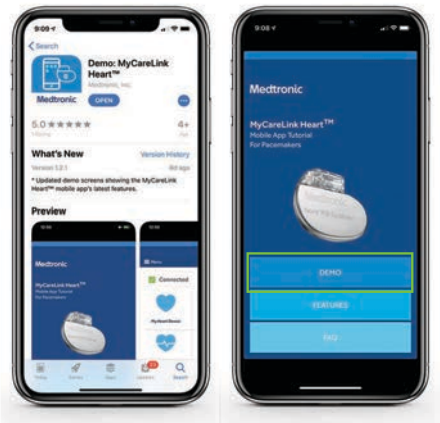
Conduct Manual Transmission (at clinic request)











Download the tutorial app

Medtronic

- Go to your App Store®. Search keywords "Demo MyCareLink" to download the app.
- Explore the app.

Available on:

Download on the App Store

GET IT ON Google Play

FREQUENTLY ASKED QUESTIONS

FAQ

What phones and tablets will be compatible?
Apple and Samsung devices. See **MCLHeart.com** for an up-to-date list of compatible devices. The app has minimum system requirements for the mobile device and operating system version. The patient will need to update or replace their mobile device to continue to use the app to transfer data.

Can multiple patients use the same phone/tablet?
No. Only one heart device can be connected to the MCLHeart app at a time. MyCareLink Heart does not look for and cannot simultaneously connect to multiple heart devices from multiple patients.

Can a patient log in to the app on multiple phones/tablets?
Yes. Before using their second phone/tablet, the patient needs to have paired their first phone/tablet. Then they can use their username and password to log in with their second phone/tablet.

How many languages does the MyCareLink Heart app come in?
Initially, 14 languages. See MCL Heart for update information. The app language can be changed within the user's phone/tablet settings. If the user's phone/tablet is not set to one of the 14 languages, the MyCareLink Heart app will display in English.

What happens if the app requirements for use are not met (e.g., app closed, Bluetooth OFF, or phone not within range of pacemaker)?
After four days without communication between the app and the heart device or the app and CareLink, the patient will receive a notification (or text or email if enabled in app settings) with instructions on how to reconnect.

Will Bluetooth telemetry drain the pacemaker's battery?
Yes. Like any telemetry, Bluetooth Low Energy telemetry uses the battery of the heart device. However, Azure™ and Percepta™ have same or better longevity than Medtronic pacemakers'/CRT-Ps' previous platforms. Longevity gains come from a combination of:

- Redesigned hardware architecture that optimizes current drain
- Bluetooth Low Energy designed for implanted device use

Wireless remote monitoring details are included in the longevity projections within the Projected Service Life section of the device manual (e.g., Azure).

Will others be able to use the pacemaker's Bluetooth?
The heart device protects itself from unauthorized access. Communication to devices enabled with BlueSync technology is only accepted from Medtronic apps and monitors. Connection attempts by non-Medtronic devices or apps are rejected by the heart device.

*https://www.att.com/esupport/data-calculator/index.jsp.

Will the pacemaker interact with a car's Bluetooth functionality?

Automobiles typically use Bluetooth Classic. The Azure/Percepta devices use Bluetooth Low Energy and are not compatible with Bluetooth Classic. The car will not attempt to establish a connection with the pacemaker, and the pacemaker won't be able to detect Bluetooth Classic transmissions.

What happens when there is a mobile operating system update?

When phone manufacturers issue OS updates, Medtronic will work diligently to evaluate whether the MyCareLink Heart application (app) has to be updated to remain compatible with the new OS version. However, if the app needs to be updated, there will generally be a delay between a new OS release and an app update. It is important for Medtronic to fully test the performance of the app with the new OS version before making it available to patients. The patient will receive a notification on their phone/tablet if the app is NOT compatible with a new OS version. In addition, if the patient updates their phone/tablet to an incompatible OS version, an in-app message will be displayed.

When new mobile devices are released, Medtronic will evaluate whether the MyCareLink Heart app is compatible with the new mobile device. Until the evaluation is complete, the patient will not be able to download the app to the new mobile device from the App Store.

What happens if the pairing gets interrupted (e.g., patient steps away from phone, loss of connectivity, phone out of battery)?

The patient may receive a message that their app setup was not complete if there is an interruption during the app and pacemaker pairing process. If that occurs, the patient will need to log back into the app to restart the process.

How much cellular data does the MyCareLink Heart app use each month?

The app consumes 8.7 MB/month. This is equivalent to 1 minute of web surfing per day.

The app consumes data for three reasons: Remote monitoring, patient viewing data on the app, and diagnostic logging (to ensure app performance).

If the phone/tablet is stolen, what will someone see in the app?

Just like other apps, if the phone/tablet has Wi-Fi or cellular connection, the data on the app will be available on the phone/tablet for a viewer to see. We recommend protecting the phone/tablet with a PIN code, swipe gesture, or fingerprint. Also, like other apps, the "remote wipe" feature will delete the app.

References

[1] Varma N. Remote monitoring of patients with CIEDs following the updated recommendations — Easing or adding to postimplant responsibilities? *Cont. Cardiol Educ.* December 2016;2(4):198-204.

[2] Fowles JB, Terry P, Xi M, Hibbard J, Bloom CT, Harvey L. Measuring self-management of patients' and employees' health: further validation of the Patient Activation Measure (PAM) based on its relation to employee characteristics. *Patient Educ Couns.* October 2009;77(1):116-122.

[3] Cronin EM, Ching EA, Varma N, Martin DO, Wilkoff BL, Lindsay BD. Remote monitoring of cardiovascular devices: a time and activity analysis. *Heart Rhythm.* December 2012;9(12):1947-1951.

[4] Medtronic Azure XT DR MRI SureScan Device Manual. M964338A001B. October 22, 2016.

Brief Statement

Percepta™/Percepta™ Quad, Serena™/Serena™ Quad, and Solara™/ Solara™ Quad CRT-P MRI SureScan™ System (Percepta/Serena/ Solara CRT-P MRI SureScan Systems) Implantable Cardiac Pacemakers with Cardiac Resynchronization Therapy

Indications: The Percepta/Serena/Solara CRT-P MRI SureScan Systems are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrythmias in patients with one or more of the above pacing indications. A complete SureScan pacing system is required for use in the MR environment. A complete SureScan pacing system includes a SureScan device with Medtronic SureScan leads or a Model 6725 pin plug for the right atrial port. To verify that components are part of a SureScan system, visit mrisurescan.com.

Contraindications: The Percepta/Serena/Solara CRT-P MRI SureScan Systems are contraindicated for concomitant implant with another bradycardia device and concomitant implant with an implantable cardioverter defibrillator. There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. Anti-tachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway.

Warnings and Precautions: A complete SureScan pacing system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions. A complete SureScan pacing system includes a SureScan device with Medtronic SureScan leads or a Model 6725 pin plug for the right atrial port. Any other combination may result in a hazard to the patient during an MRI scan. Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Certain programming and device operations may not provide cardiac resynchronization. Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols. Patients and their implanted systems must be screened to meet the following requirements for MRI: no implanted lead extenders, lead adaptors, or abandoned leads; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; a SureScan pacing system implanted in the left or right pectoral region. Additionally, for patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is programmed to On, no diaphragmatic stimulation is present at a pacing output of 5.0 V and at a pulse width of 1.0 ms.

Potential Adverse Events or Potential Complications: Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. Potential MRI complications for the SureScan system include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse; spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan is programmed to On; potential for VT/VF induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan; device heating resulting in tissue damage in the implant pocket or patient discomfort or both; or damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer.

See the appropriate Percepta/Serena/Solara product Device Manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/ adverse events. See the appropriate Percepta/Serena/Solara product MRI SureScan Technical Manual before performing an MRI Scan. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com *or* mrisurescan.com.

Azure™ MRI SureScan™ SR and DR IPG

Indications: The Azure DR MRI and Azure SR MRI SureScan systems are indicated for the rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Accepted patient conditions warranting chronic cardiac pacing include symptomatic paroxysmal or permanent second- or third-degree AV block, symptomatic bilateral bundle branch block, symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders, or bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias. The Azure DR MRI devices are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output, VVI intolerance (e.g, pacemaker syndrome) in the presence of persistent sinus rhythm, or vasovagal syndromes or hypersensitive carotid sinus syndromes. Antitachycardia pacing (ATP)

is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

MRI Conditions for Use: Medtronic SureScan pacing systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. Pacemaker SureScan system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete SureScan pacing system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. To verify that components are part of a SureScan system, visit mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.

Contraindications: The Azure DR MRI and Azure SR MRI SureScan systems are contraindicated for concomitant implantation with another bradycardia device or with an implantable cardioverter defibrillator. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. ATP therapy is contraindicated in patients with an accessory antegrade pathway.

Warnings and Precautions: Changes in patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Use of the device should not change the application of established anticoagulation protocols. Patients and their implanted systems must be screened to meet the following requirements for MRI: no lead extenders, lead adaptors or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; the device must be operating within the projected service life, and the system must be implanted in the left or right pectoral region.

Potential Adverse Events or Potential Complications: Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myocardial irritability, and pneumothorax. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

See the appropriate Percepta/Serena/Solara product Device Manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/ adverse events. See the appropriate Percepta/Serena/Solara product MRI SureScan Technical Manual before performing an MRI Scan. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com *or* mrisurescan.com.

Medtronic CareLink™, MyCareLink™, MyCareLink Smart™ Patient Monitors, MyCareLink Smart™ Application, Medtronic CareLink™ Network, CareLink™ Mobile Application, and Medtronic MyCareLink Connect™ Patient Website

Intended Use: The Medtronic CareLink, MyCareLink, MyCareLink Smart patient monitors, MyCareLink Smart application, CareLink network, and the CareLink mobile application are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices to the Medtronic CareLink network based on physician instructions and as described in the product manual. Medtronic CareAlert™ notifications are not intended to be used as the sole basis for making decisions about patient medical care. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. The CareLink mobile application is intended to provide current CareLink network customers access to CareLink network data via a mobile device for their convenience. The CareLink mobile application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation.

The CareLink mobile application and the MyCareLink Smart mobile application have minimum requirements for the mobile device and operating system. The minimum requirements for the mobile device and operating system are expected to change over time. Periodically, the patient may need to update their mobile device's operating system, or replace their mobile device to continue to use the app to transfer data to the CareLink network.

The MyCareLink Connect patient site is intended to provide patients, their friends/family, and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink Network. The MyCareLink Connect patient website is dependent on certain browser software, and that software is expected to change over time. Patients that are experiencing technical issues with the MyCareLink Connect patient website should contact Medtronic Patient Services at the number below. Data availability, alert notifications, and patient messages are subject to internet connectivity, access, and service availability. The CareLink and MyCareLink patient monitors and the MyCareLink Smart reader must be on and in range of the device. The MyCareLink Smart reader must also be within range of the patient's mobile device. The CareLink network and mobile device accessibility to the CareLink network may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the internet is required for the CareLink mobile app and the MyCareLink Smart monitoring system and subject to coverage availability. Standard data and text message rates apply. Message frequency depends on account settings and clinic scheduling.

Contraindications: There are no known contraindications.

Warnings and Precautions: The CareLink, MyCareLink, and MyCareLink Smart patient monitors must only be used for interrogating compatible Medtronic implantable devices. While using the CareLink or MyCareLink patient monitor, do not use a cellular phone while the antenna is positioned over the implanted device. The CareLink and MyCareLink monitors are intended for use within the prescribing country. The MyCareLink Smart patient monitors may be used internationally. Standard mobile device availability and rates apply. *See the device manuals for detailed information regarding the instructions for use, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-929-4043 and/or consult the Medtronic website at* medtronic.com.

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

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