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HEART FAILURE

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**HEARTMATE TOUCH™
COMMUNICATION SYSTEM
REFERENCE GUIDE**





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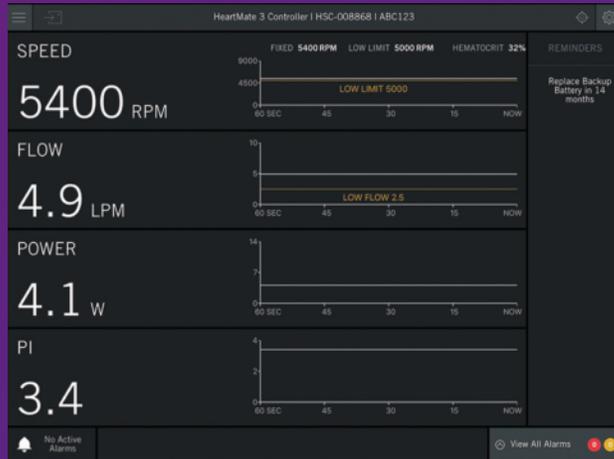
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HEARTMATE TOUCH™ APP VIEWS



MONITOR VIEW

- Initial view displayed upon Bluetooth® wireless technology connection.
- Displays primary pump parameters with trendlines.
- Reminders panel displays when to replace the Backup Battery.



CLINICAL VIEW

- Intended to be used during the implant procedure.
- Only view to start, stop and prime the pump.
- Displays pump parameters with trendlines for speed and flow.
- Implant checklist lists items to complete prior to leaving the OR.



HeartMate 3 Controller | HSC-099100 | ABC 123

FIXED: 5600 RPM LOW LIMIT: 5200 RPM HEMATOCRIT: 32%

SPEED: 5650 RPM FLOW: 4.5 LPM POWER: 4.0 W PI: 3.8

EVENT RECORDS

Graph Table View Export

Timestamp	Flow (LPM)	Speed (RPM)	Power (W)	Average PI	PI Event	Alarms
12/26/19 04:14:15	5.3	5600	4.7	3.0		Power Cable Disconnect
12/26/19 03:36:23	5.2	5600	4.5	4.7	●	No active alarms
12/26/19 00:51:25	5.1	5600	4.5	4.7	●	No active alarms
12/26/19 00:34:19	5.3	5600	4.7	4.5	●	No active alarms
12/25/19 23:51:17	5.2	5600	4.4	3.2	●	No active alarms
12/25/19 17:03:06	5.1	5600	4.4	3.2		No active alarms
12/25/19 17:03:01	5.1	5600	4.5	3.2		Power Cable Disconnect Alarm
12/25/19 17:02:56	5.2	5650	4.4	3.1		Power Cable Disconnect

No Active Alarms View All Alarms

HISTORICAL VIEW

- Displays pump parameters without trendlines.
- View System Controller event and periodic records in graph or table format.
- Exports System Controller and LVAD data files to a flash drive.

INTERFACE OVERVIEW – NAVIGATION BAR

The **Navigation Bar** is displayed on all views (Monitor, Clinical and Historical).

MENU

- Tap **Menu** to switch views or disconnect from the Wireless Adapter.

COMMUNICATION

ICON

- Flashing icon indicates active communication between the System Controller and HeartMate Touch™ App.

CURRENT SETTINGS

- Displays set values for fixed speed, low speed limit and hematocrit.*

CONNECTED DEVICE INFORMATION

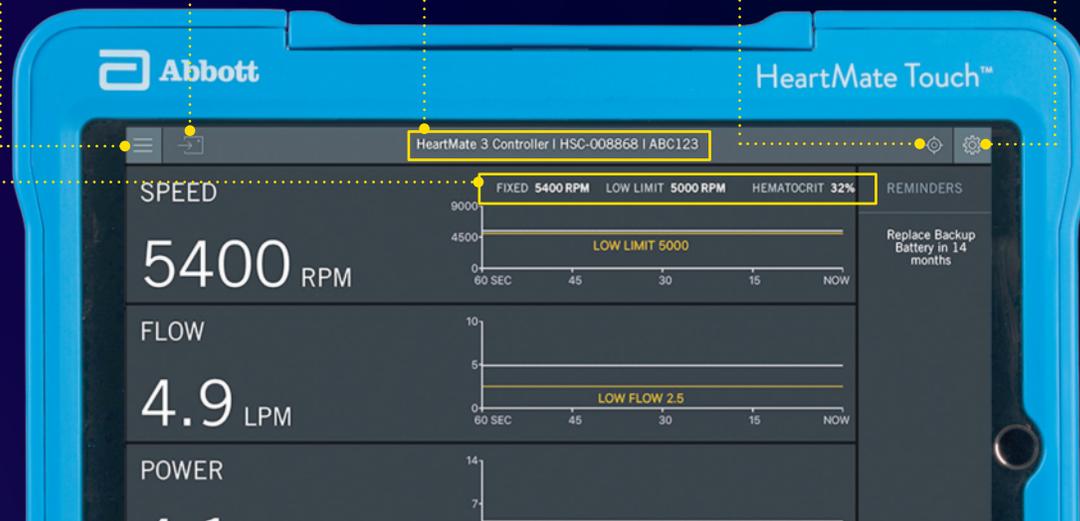
- Displays System Controller, controller serial number* and session name.

LOCATE

- Tap **Locate** to identify and confirm the wireless device to which you are connected.

SETTINGS

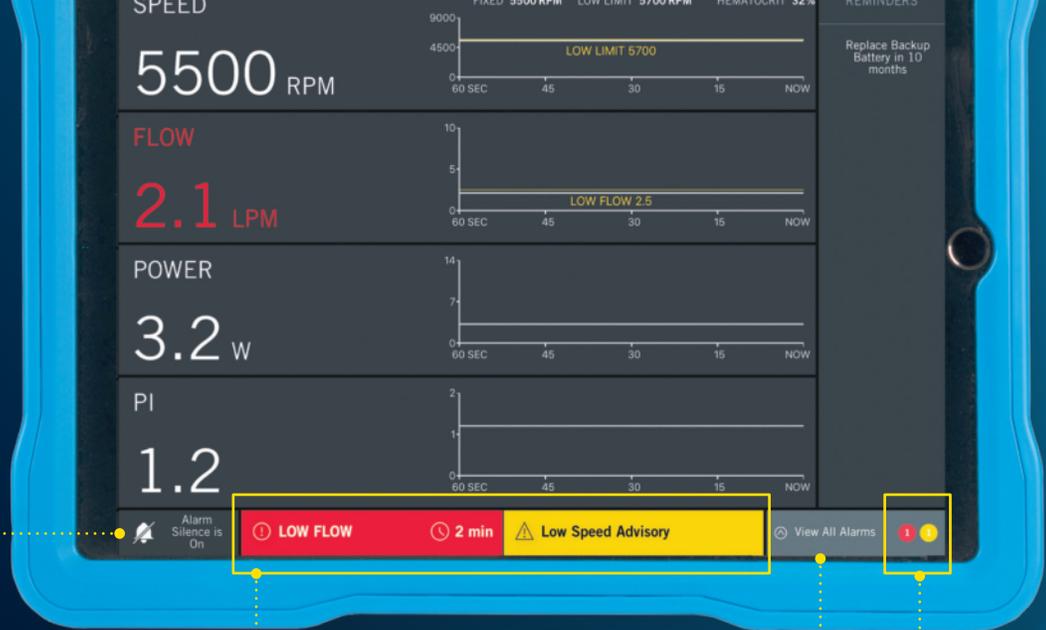
- Tap **Settings** to access Pump, Controller and Backup Battery Tabs to adjust and view settings and information.





INTERFACE OVERVIEW — ALARM STATUS BAR

The **Alarm Status Bar** is displayed on all views (Monitor, Clinical and Historical).



ALARM SILENCE

- Displays the alarm silence status.
- Silence active alarms by tapping **Silence Alarms**.

ALARM STATUS

- Displays the top two priority active alarms.

VIEW ALL ALARMS

- Displays a full list of active and inactive alarms.
- Access to Extended Alarm Silence button.

ALARM COUNTER

- Displays the total number of active hazard and advisory alarms.

SETTINGS PANEL

PUMP TAB

- Set fixed speed, low speed limit and graph trendline duration.
- Set hematocrit and view LVAD information only for HeartMate 3™ LVAD.
- Prime pump only available from Clinical view.

The screenshot shows the 'Settings' application with the 'Pump' tab selected. It features three sliders: 'Fixed Speed' at 5200 RPM, 'Low Speed Limit' at 5000 RPM, and 'Hematocrit' at 32%. Below these is a 'Graph Trendline Duration' dropdown set to '1 minute'. At the bottom is an 'LVAD Information' table.

LVAD Information	
Mode	Pulse
Motor Number	2194
Serial Number	MLP-002958
Application 0 Version	6.3.2.0.41
Application 1 Version	6.3.2.0.41
IPL Version	2.1.1.0.11
Loader Version	3.1.1.0.14
PCBT	36

CONTROLLER TAB

- Set controller clock, controller period log data collection rate and controller language.
- Set LVAD period log data collection rate only for HeartMate 3 LVAD.
- View controller information.

The screenshot shows the 'Settings' application with the 'Controller' tab selected. It displays 'Controller Date & Time' as 08.06.2020 04:13 PM, with 'Sync with iPad' and 'Edit' buttons. Below are dropdown menus for 'Controller Periodic Log' (1 hour), 'LVAD Periodic Log' (1 hour), and 'Controller Language' (English). At the bottom is a 'Controller Information' table.

Controller Information	
Serial Number	HSC-065543
App Bootloader Version	1.0.5
App Version	1.5.0.3821
LCD Version	2.0.3
LCD Bitmap Version	3.0.1
Stored LVAD SW Version
Fuse A Status	ok
Fuse B Status	ok



BACKUP BATTERY TAB

- View detailed Backup Battery information.

The screenshot shows the 'Settings' application with three tabs: 'Pump', 'Controller', and 'Backup Battery'. The 'Backup Battery' tab is selected. Below the tabs, the 'Backup Battery Information' section is displayed as a table with the following data:

Backup Battery Information	
Status	Installed
Serial Number	SR179-028
Manufacture Date	06.28.2017
Maximum Time	10950 minutes
Maximum Service Life	36 months
Maximum Shelf Life	24 months
Last Full Recharge Date	08.06.2018
Cumulative Time	20 minutes
Patient Use	38 times
Replace Information	10 months

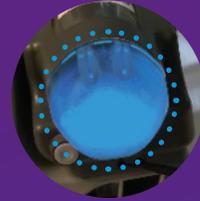
At the bottom of the screen, there are two buttons: 'CLOSE' and 'APPLY'.

HEARTMATE TOUCH™ WIRELESS ADAPTER STATUS



POWERED ON: SOLID WHITE LIGHT 1 SECOND

- Upon connection of the Wireless Adapter to a Power Module on AC power.



READY TO CONNECT: BLINKING BLUE LIGHT 60 SECONDS

- Press and hold the Wireless Adapter round button to initiate connection.
- Blinking blue light indicates the Wireless Adapter is ready to accept a wireless connection to the HeartMate Touch™ App for up to 60 seconds.



CONNECTED: SOLID BLUE LIGHT

- Wireless Adapter is connected to and communicating with the HeartMate Touch App.



**STANDBY MODE:
NO LIGHTS**

- Wireless Adapter is in standby mode.
- Not wirelessly connected to the HeartMate Touch™ App.



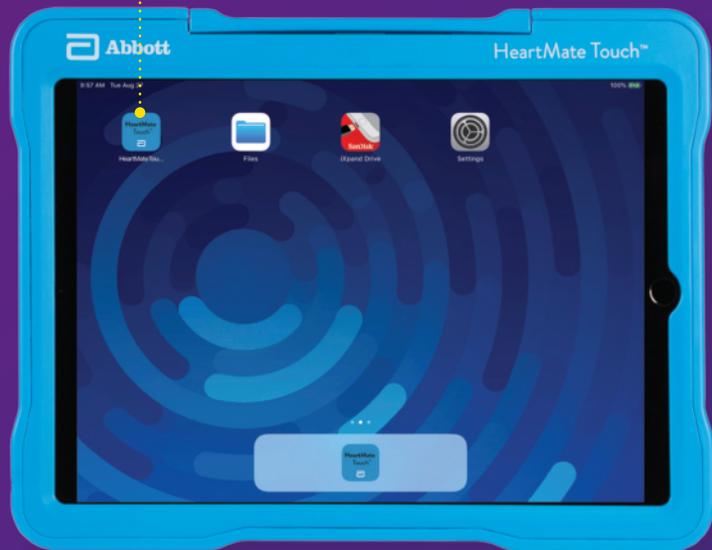
**LOCATE: ALTERNATING
BLINKING BLUE AND
WHITE LIGHTS 10 SECONDS**

- HeartMate Touch App is locating and identifying the Wireless Adapter it is connected to.

ESTABLISHING BLUETOOTH® WIRELESS TECHNOLOGY CONNECTION

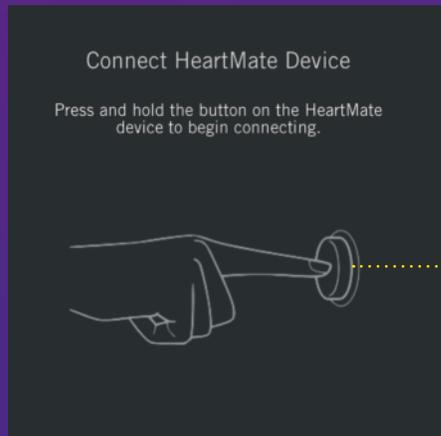


1 **OPEN THE HEARTMATE TOUCH™ APP.**



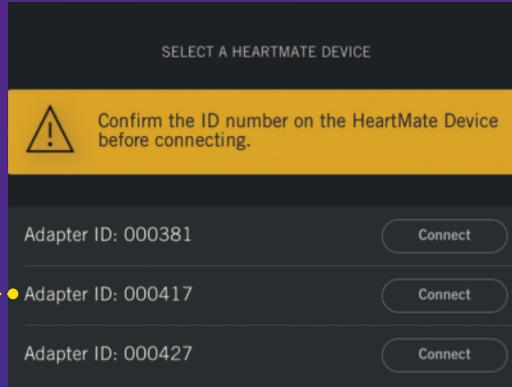
2 **TURN ON BLUETOOTH® WIRELESS TECHNOLOGY**

Press and hold the gray button on the Wireless Adapter for 3 seconds until a blinking blue light appears.

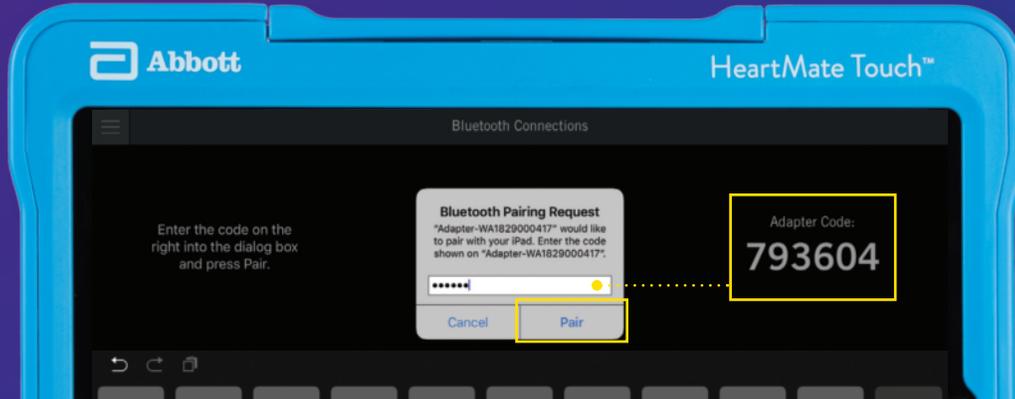
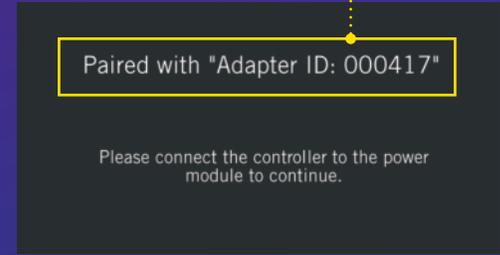


Ready to Connect:
Blinking
Blue Light

- 3 Select the Wireless Adapter ID number for pairing, and tap **Connect**.



- 4 Confirm correct pairing between the Wireless Adapter and the HeartMate Touch™ App.



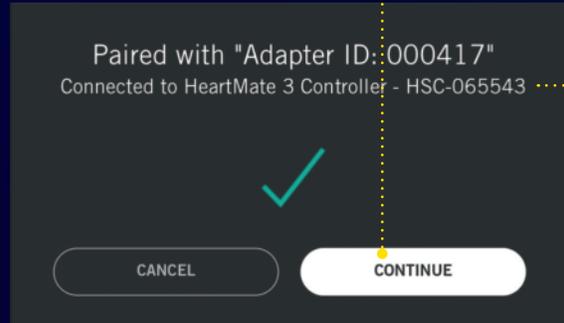
If pairing for the first time, enter the numeric passcode displayed on the screen into the command box. Then tap **Pair**.

CONNECTING TO THE PATIENT

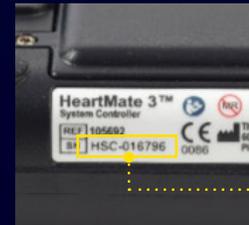
Connect the System Controller to the Power Module.



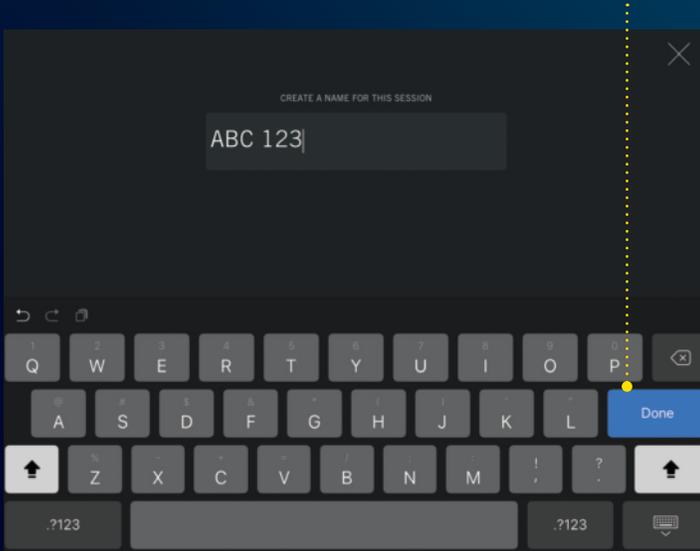
1 Tap **CONTINUE**.



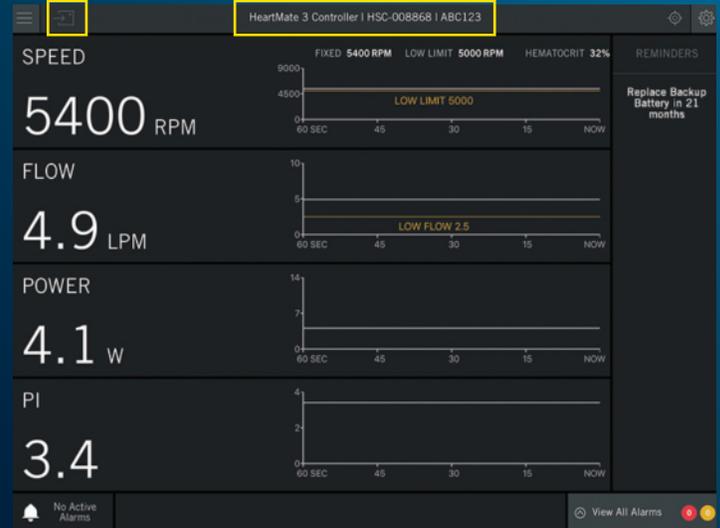
Verify the System Controller serial number on the screen matches the label on the HeartMate 3™ System Controller.



- 2 Enter a session name using letters, numbers, underscore and/or period that is compliant with the hospital's patient privacy policy. Then tap **Done**.



- 3 Confirm the Communication Status icon is flashing. Verify System Controller, serial number* and session name.



*Only for HeartMate 3™ LVAS.

DISCONNECTING BLUETOOTH® WIRELESS TECHNOLOGY AND ENDING THE SESSION



1 Tap the **Menu icon**.



2 Tap **Disconnect HeartMate Device**.

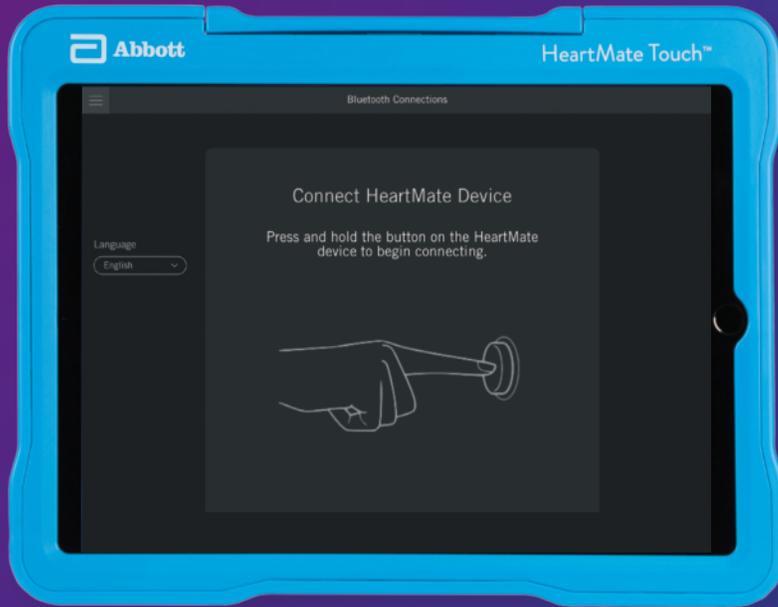
3 Tap **YES** to confirm and end the session.





WHAT YOU SEE

The Bluetooth Connections screen is displayed and the Wireless Adapter light turns off.

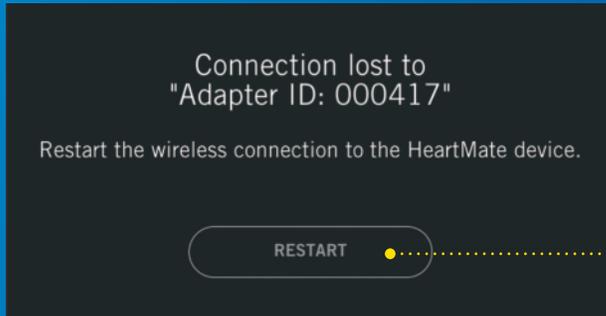


WIRELESS ADAPTER
LIGHT IS OFF

TROUBLESHOOTING GUIDE

Connection Lost to the Wireless Adapter

WHAT YOU SEE



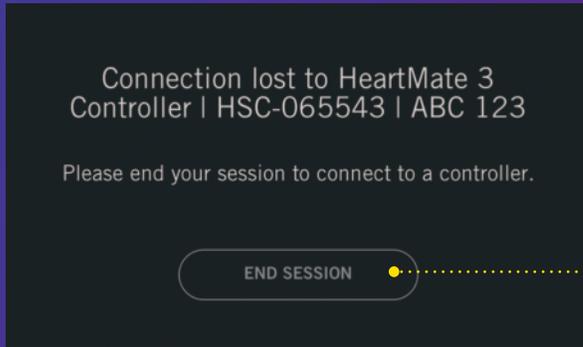
WIRELESS ADAPTER
LIGHT IS OFF

WHAT YOU SHOULD DO

- 1 Verify the Power Module is plugged in to a properly tested and grounded (three-prong) AC main outlet. Note: If the Wireless Adapter is flashing blue, wait for it to stop flashing before continuing to step 2.
- 2 Tap **RESTART**.
- 3 Press and hold the round button on the Wireless Adapter for 3 seconds until a blinking blue light appears.
- 4 Connect the HeartMate Touch™ App to the Wireless Adapter.

Connection Lost to the System Controller

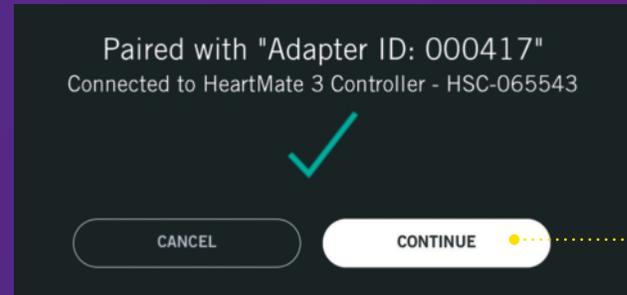
WHAT YOU SEE



WIRELESS ADAPTER
LIGHT IS SOLID BLUE

WHAT YOU SHOULD DO

- 1 Tap **END SESSION**.
- 2 Check that the System Controller is fully connected to the Power Module.
- 3 Tap **CONTINUE**.

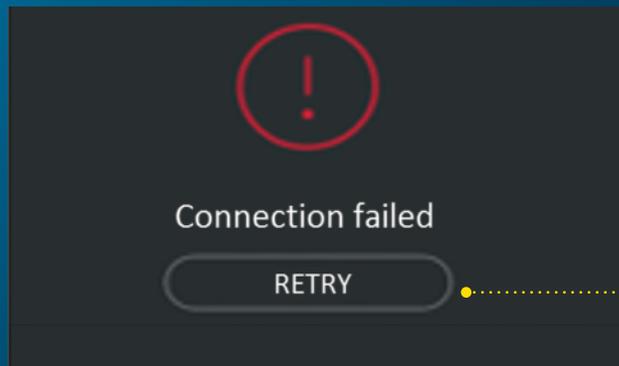


WARNING: Do not disconnect the System Controller or Power Module Patient Cable from the Power Module when troubleshooting.

TROUBLESHOOTING GUIDE

Connection to the Wireless Adapter Failed

WHAT YOU SEE



WHAT YOU SHOULD DO

- 1 Tap **RETRY**.
- 2 Close the HeartMate Touch™ App.
- 3 Remove then reinsert the Wireless Adapter into the Power Module socket.
- 4 Restart the HeartMate Touch App.
- 5 Press and hold the round button on the Wireless Adapter until a blinking blue light appears.
- 6 Connect the HeartMate Touch App to the Wireless Adapter.

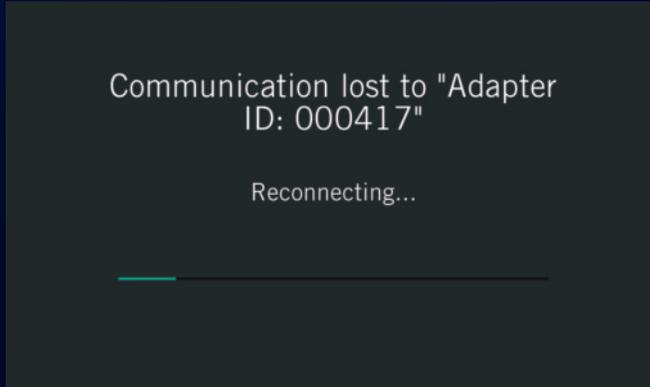


WIRELESS ADAPTER
LIGHT IS OFF
OR BLINKING WHITE



Communication Lost to the Wireless Adapter

WHAT YOU SEE



WIRELESS ADAPTER
LIGHT IS
BLINKING BLUE

WHAT YOU SHOULD DO

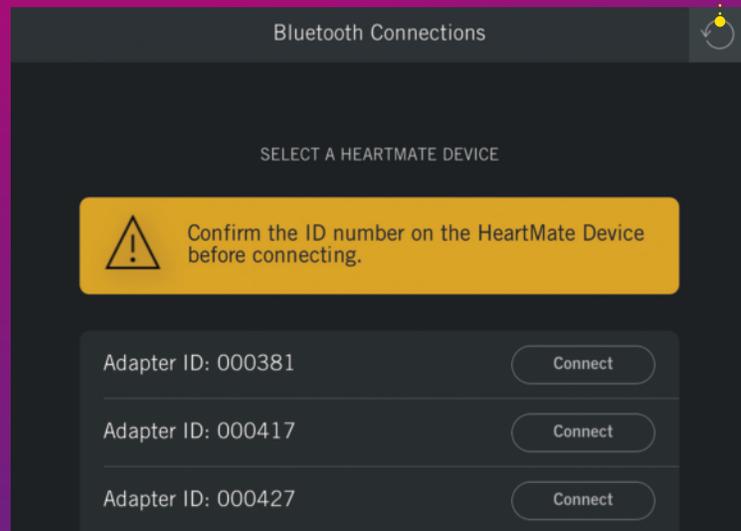
- 1 Verify the tablet is within communication range of the Wireless Adapter.
 - No other action is required.
 - It may take up to 30 seconds to get reconnected.

TROUBLESHOOTING GUIDE

Wireless Adapter Not Detected

WHAT YOU SEE

The HeartMate Touch™ App does not detect the Wireless Adapter ID number.



WHAT YOU SHOULD DO

- 1 Tap **REFRESH**.
- 2 If not resolved, tap **SETTINGS** on the tablet home screen.
 - Verify Bluetooth® wireless technology is turned on.



WIRELESS ADAPTER
LIGHT IS
BLINKING BLUE



Rule of Thumb

OTHER RARE ISSUES

- The HeartMate Touch™ App shuts down or freezes.
- The System Controller is not detected on the wireless connection screen.
- The Wireless Adapter does not illuminate a blinking blue light even though the conditions for setup and connection have been met.

RESOLUTION

- 1 Close the HeartMate Touch App.
- 2 Remove then reinsert the Wireless Adapter into the Power Module socket.
- 3 Restart the HeartMate Touch App.
- 4 Press and hold the round button on the Wireless Adapter until the light flashes blue.
- 5 Connect the HeartMate Touch App to the Wireless Adapter.

IF THE ISSUE IS NOT RESOLVED WITH THE ABOVE STEPS

- 1 Turn the tablet off.
- 2 Turn the tablet back on.
- 3 Perform steps 2–5 above.



HeartMate Touch™ Communication System Overview: The HeartMate Touch™ Communication System is intended for use by clinicians in the hospital to wirelessly monitor a patient's HeartMate II™ Left Ventricular Assist System or HeartMate 3™ Left Ventricular Assist System. The HeartMate Touch Communication System is required during implant procedures and any time close monitoring of system operation is needed. It provides clinicians with the ability to program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data.

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HeartMate3.com

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

HeartMate 3™ LVAS Indications: The HeartMate 3 Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

HeartMate II™ LVAS Indications: The HeartMate II Left Ventricular Assist System is indicated for use as a “bridge to transplantation” for cardiac transplant candidates who are at risk of imminent death from non-reversible left ventricle failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class III or IV end-stage left ventricular failure, who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II Left Ventricular Assist System is intended for use both inside and outside of the hospital, or for transportation of Left Ventricular Assist Device patients via ground ambulance, airplane, or helicopter.

HeartMate 3™ and HeartMate II™ LVAS Contraindications: The HeartMate 3 and HeartMate II Left Ventricular Assist Systems are contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3™ and HeartMate II™ LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 or HeartMate II Left Ventricular Assist System are listed below: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and possible pump thrombosis.

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