

Impella Connect®

Instructions for Use



 **ABIOMED®**
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IMPORTANT NOTICE: Read this entire manual before using the Impella Connect®

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IMPELLA CONNECT®

INSTRUCTIONS FOR USE

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TABLE OF CONTENTS

Introduction.....	1
Overview	1
Intended Use	1
Precautions.....	2
User Interface	3
Indicators and Operating Modes.....	4
Technical Specifications	5

INTRODUCTION

OVERVIEW

The Impella Connect system consists of two parts:

- A web-based user portal that allows authorized users to remotely view the screen of the Automated Impella Controller™ (AIC).
- A small box (0042-4100) attached to the back and side of an Automated Impella Controller™ (AIC), as shown below.

The box connects to the VGA output of the AIC and transmits the display of the AIC screen to a cloud based server. The transmitted image can be viewed by authorized remote users, which may include hospital clinicians, Abiomed local support staff and Abiomed Customer Support Center (CSC) team members. The Impella Connect only enables passive viewing the AIC video screen. Changes to the controller settings can only be made using the physical controls on the AIC. Impella Connect may be configured and connected to the hospital's secured Wi-Fi network or be plugged in directly via Ethernet cable to the secured hospital network in order to transmit the video image to a web-based portal.



INTENDED USE

Impella Connect is intended to be used to enable remote viewing of the AIC's user interface by clinicians and by trained Abiomed personnel who assist clinicians with troubleshooting AIC alarms or other issues. Impella Connect transfers the video stream from the AIC (via the VGA output) to a cloud-based remote viewing portal. Communication between the AIC and Impella Connect is one-way (AIC to Impella Connect), and the streamed video is limited to Impella device operating parameters and alarm messages with no patient identifiable information. Impella Connect is powered directly by the AIC.

PRECAUTIONS

- The Impella Connect is not intended to provide real-time information for monitoring patient status on the AIC.
- During use of the Impella Connect, there will be a delay between when an image appears on the AIC screen and when it is displayed at a remote viewing location.
- The Impella Connect is not a source of patient alarms, nor is its use intended as a replacement for monitoring the AIC's alarms.
- During use of Impella Connect, receipt of the displayed controller information is not confirmed by the AIC, nor is the delivery of the displayed AIC information to the authorized remote users guaranteed.
- Impella Connect is not designed for use during transport.
- When Impella Connect is configured to use the hospital's secured Wi-Fi network, signal quality and strength is dependent on the hospital's Wi-Fi.
- When Impella Connect is configured to use the hospital's secured Wi-Fi network, connection may be lost in physical locations of low Wi-Fi signal.
- No modification of this equipment is permitted.
- Radiated and conducted electromagnetic interference can affect the performance of the Impella Connect, causing a temporary loss of connectivity. To clear interference, either increase the distance between system components and the EMI source or turn off the EMI source. Any electromagnetic interference related to the Impella Connect will have no impact on any of the AIC functional specifications.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- During use, no USB devices should be inserted.
- When in use, the Ethernet cables connecting the Impella Connect to the wall could represent a tripping hazard and should be placed where foot traffic is minimal.
- Keep excess cabling on the cable wrap when not needed.
- Disconnect, when in use, the Ethernet cables from the wall outlet before moving the AIC.
- Impella Connect is not interpretive.
- Impella Connect is not intended to control or interact with any drugs.

USER INTERFACE



Interface

- A. Connection Indicator
- B. Flight Mode / Maintenance Mode Button
- C. USB Port
- C. Ethernet Port
- D. External VGA Output

Overview

- Alerts User to connection Status
- Allows user the ability to enter Flight Mode for air transport. It is also used to enter Maintenance Mode.
- Connection for data downloading by Abiomed maintenance or service personnel
- Allows the Impella Connect to connect to the cloud.
- Connection for connecting the controller to another monitor to slave the display



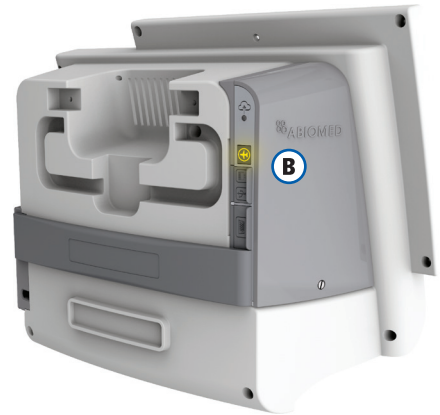
Interface

- E. I/O Panel Cover

Overview

- Open to Access
 - Equipotential Stud
 - AIC Fuses

INDICATORS AND OPERATING MODES



Connection Indicator

Mode	Blue Cloud Indicator (A)	Amber Flight Mode Indicator (B)	Notes
No Status	Off	Off	No Power.
Connected	On	Off	Connected to Wi-Fi network.
Maintenance	Flashing	Off	Device in Maintenance Mode.
Initialization in Progress	Flashing	Flashing	Device Powering up.
No Network Configured	1 Blink 5 sec off	Off	No Wi-Fi networks are configured.
Carrier Connecting	2 Blinks 5 sec off	Off	Configured Wi-Fi is out of range OR the device has failed to authenticate with the network.
IP Configuration	3 Blinks 5 sec off	Off	No IP from DHCP. The device has authenticated with the network, but no IP address has been assigned. ¹
RLFS/RLFS2 Connecting	4 Blinks 5 sec off	Off	RLFS/RLFS2 Not Connecting. ^{2,3}
RLR Connecting	5 Blinks 5 sec off	Off	RLR not connecting. ²
RLV Connecting	6 Blinks 5 sec off	Off	RLV not connecting. ²

1. Confirm the DHCP setting are correctly configured in the maintenance mode are correct.
 2. Confirm firewall settings and ensure that deep packet inspection is turned off and MAC addresses are in the allow list.
 3. RLFS2 requires proxy server configuration.

The Impella Connect will automatically connect to the cloud when in range of an approved* Wi-Fi network

In locations where Wi-Fi is not available, the Impella Connect can be connected to the cloud via the Ethernet port located on the Impella Connect.

To enter Wi-Fi configuration mode, press and hold the Flight Mode button for >10 seconds. The Connection Indicator light will turn to a continuous flashing blue indicating the Impella Connect is now in Maintenance Mode.

To exit Maintenance Mode, press the Flight Mode button for >1 second and release.

* Approved network means SSID and password/credentials have been configured in the Impella Connect by an authorized IT administrator.

Flight Mode Indicator (B)

Flashing Amber

Amber

Mode

Entering Flight Mode

Flight Mode

To disable the Wi-Fi transmitter prior to air transport, press the Flight Mode button for between 3 and 10 seconds and release to enter Flight Mode. The Flight Mode indicator will flash then turn solid amber.

To exit Flight mode, press the Flight Mode button for >1 second and release.

TECHNICAL SPECIFICATIONS**Table 1 Impella Connect Wi-Fi Transmitter / Receiver Specifications**

IEEE Protocols		802.11a, 802.11b, 802.11g, and 802.11n		
Receiver bandwidth		120 MHz/ 40 MHz		
Effective radiated power		<0.071 watts		
Frequency Bands		2412 MHz to 2462 MHz US 2412 MHz to 2472 MHz EU 2412 MHz to 2684 MHz JP 5180 MHz to 5825 MHz US 5180 MHz to 5700 MHz EU 5180 MHz to 5700 MHz JP		
IEEE	802.11a	802.11b	802.11g	802.11n
Modulation	OFDM	D5.55	OFDM	MxMO OFMD
Video Frame Rate		20 fps (Maximum)		
Data Rate		512 Kbps (Average)		
Certified Wi-Fi Module				
Manufacturer:		Texas Instruments		
Part number:		WL18MODGI		
FCC ID:		Z64-WL18DBMOD		



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