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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 in Figure 1.

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 of 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.
- 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
- **D.** Ethernet Port
- **E.** 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

### INDICATORS AND OPERATING MODES

**Interface**
- **E.** I/O Panel Cover

**Overview**
- Open to Access
  - Equipotential Stud
  - AIC Fuses
A. Connection Indicator

- Blue: Connected
- Flashing Blue: Maintenance Mode
- Off: Not Connected

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.

B. Flight Mode Indicator

- Flashing Amber: Entering Flight Mode
- Amber: 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

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEEE Protocols</td>
<td>802.11a, 802.11b, 802.11g, and 802.11n</td>
</tr>
<tr>
<td>Receiver Bandwidth</td>
<td>120 MHz/ 40 MHz</td>
</tr>
<tr>
<td>Effective radiated power</td>
<td>&lt;0.071 watts</td>
</tr>
<tr>
<td>Frequency Bands</td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>2412 MHz to 2462 MHz</td>
</tr>
<tr>
<td>EU</td>
<td>2412 MHz to 2472 MHz</td>
</tr>
<tr>
<td>JP</td>
<td>2412 MHz to 2684 MHz</td>
</tr>
<tr>
<td>US</td>
<td>5180 MHz to 5825 MHz</td>
</tr>
<tr>
<td>EU</td>
<td>5180 MHz to 5700 MHz</td>
</tr>
<tr>
<td>JP</td>
<td>5180 MHz to 5700 MHz</td>
</tr>
</tbody>
</table>

Table 2 Impella Connect Wi-Fi Transmitter / Receiver Specifications (continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEEE Protocols</td>
<td>802.11a, 802.11b, 802.11g, and 802.11n</td>
</tr>
<tr>
<td>Modulation</td>
<td>OFDM, 05.55, OFDM, MxMO, OFMD</td>
</tr>
<tr>
<td>Video Frame Rate</td>
<td>20 fps (Maximum)</td>
</tr>
<tr>
<td>Data Rate</td>
<td>512 Kbps (Average)</td>
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<tr>
<td>Certified Wi-Fi Module</td>
<td></td>
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<tr>
<td>Manufacturer:</td>
<td>Texas Instruments</td>
</tr>
<tr>
<td>Part number:</td>
<td>WL18MODGI</td>
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<tr>
<td>FCC ID:</td>
<td>Z64-WL18DBMOD</td>
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