

# Data Sheet

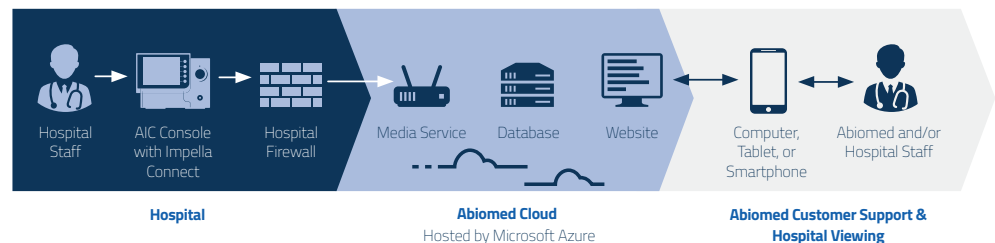
## Impella Connect®



Impella Connect enables hospital clinicians and Abiomed's Clinical Support team to remotely view a near real-time stream of the Automated Impella Controller™ (AIC) through a secured website, without downloading any app or software. Impella Connect is a stand-alone solution that does not integrate into any internal hospital systems (does not access EMR, databases, etc).

- ▲ No protected health information (PHI) accessed, transmitted, or stored
- ▲ 24 hour remote-monitoring of pump performance data by the clinical team may enhance patient care and improve outcomes for patients in the ICU
- ▲ Pump performance data is transmitted outbound only via the hospital Wi-Fi network
- ▲ Allows for more effective assistance provided by our 24/7 Clinical Support Center that responds to customer calls
- ▲ Hospital clinicians with an ImpellaConnect.com account will be able to view pump performance data, alerts, and device settings at any time during the duration of a patient's case

### Abiomed AIC Impella Connect Data Flow



*Note: The Abiomed cloud depicted above is a simplified model.*

The purpose of the Impella Connect system is to enable a connection from the Abiomed AIC to a cloud-based website accessible by authorized login to Abiomed employees and hospital staff, who only see data from their own institution.

This connection takes place through an Ethernet or Wi-Fi connection, so these connection types will have to be allowed by the hospital network.

Within the hospital, the connection may be initiated from any location with a stable Ethernet or Wi-Fi signal.

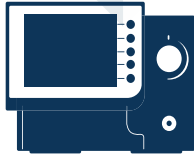
Information may be accessed during support involving an Abiomed AIC with Impella Connect installed, and may be stored through the same website for review at any time during the case.

Specifically, the system uses a hardware-based device which takes the VGA output of the AIC and streams it using RTMPS to a cloud-based system over port 443. All connections are secured with TLS 1.2 256-bit encryption.

# Impella Connect<sup>®</sup>

## Specifications

### Automated Impella Controller with Impella Connect Module



Broadcast VGA output from the Automated Impella Controller (AIC) to the Cloud Database

- ▲ Hardware: Solid State with no fans
- ▲ Power Requirements: Powered by the Automated Impella Controller (AIC)
- ▲ Connection Method: Wi-Fi

### Cloud Database



Cloud database for AIC temporary video storage and recall

- ▲ Data Management: Wowza streaming media  
Microsoft Azure cloud
- ▲ Server Location: Microsoft Azure cloud (USA only)
- ▲ Third Party Vendors Used: Wowza (media service), Microsoft Azure (cloud), JW Player (video player), Google Analytics (OCR)

### Online Portal



Registered user access to approved Impella case information

- ▲ Online Portal Address: <https://www.impellaconnect.com>
- ▲ Access Type: Secure web-based portal (username/password required)
- ▲ Access Administration: Abiomed admin enrolls and manages user accounts
- ▲ Data Management: Wowza streaming media  
Microsoft Azure cloud
- ▲ PHI Accessed: None
- ▲ Institution Data Accessed: None

#### INTENDED USE

Impella Connect<sup>®</sup> transfers a video image of the screen on the Automated Impella Controller<sup>™</sup> to an authorized remote user. The transmitted image can be viewed by authorized remote users. The users can include the hospital's clinicians, Abiomed local support staff, and Clinical Support Center (CSC) team members.

#### PRECAUTIONS

- Impella Connect is not intended to provide real-time information for monitoring patient status on the Automated Impella Controller.
- During use of the Impella Connect, there will be a delay between when an image appears on the controller 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 controller's alarms.
- During use of the Impella Connect, receipt of the displayed controller information is not confirmed by the Automated Impella Controller, nor is the delivery of the displayed controller information to the authorized remote users guaranteed.
- The Impella Connect is not designed for use during transport.
- 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 controller functional specifications.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

In addition to the information above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices. Visit <http://www.abiomed.com/important-safety-information> to learn more.

Impella Connect Technical Support [impellaconnect@abiomed.com](mailto:impellaconnect@abiomed.com)

ICO-0022.v3

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