Data Sheet
Impella Connect®

The Impella Connect enables hospital clinicians and staff, along with Abiomed's Clinical Support Team to view a live stream of the screen of the Automated Impella Controller (AIC) through a secure website, allowing them to track, review, and share that information from any internet-capable phone, tablet, or computer.

◢ Remote access to this information can enhance patient care and may improve outcomes for patients in the ICU.

◢ The information being streamed refers to Impella pump performance only and is HIPAA compliant as no Protected Health Information (PHI) is being transmitted.

◢ Information is transmitted one-way through the hospital network.

◢ Abiomed operates a 24/7 Clinical Support Center that responds to customer calls. Many of the calls are questions regarding how the device is operating. Adding the Impella Connect streaming capability to the AIC will allow Abiomed support to see what the hospital staff are seeing in order to provide a higher level of assistance, avoiding the need to use non-HIPAA compliant technology, such as FaceTime to transmit images.

◢ In addition to live assistance, the Impella Connect will provide the opportunity for hospital staff to review cases at any time, capturing information such as alerts, device settings, and recorded video of the AIC screen.

Abiomed AIC Impella Connect Data Flow

| Hospital Staff | AIC Console w/Impella Connect | Hospital Firewall | Media Service | Database | Website | Computer, Tablet, or Smartphone | Abiomed/ Hospital Staff |

Hospital — **Abiomed Cloud** Hosted by Microsoft Azure — **Abiomed Customer Support & Hospital Viewing**
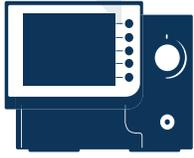
Note: The Abiomed cloud depicted above is a simplified model.

The purpose of the Impella Connect 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 recorded and 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 with certificates provided by Entrust.

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Impella Connect®
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: Ethernet cable or Wi-Fi

Cloud Database

Cloud database for AIC temporary video storage and recall

- ▲ Data Management: Wowza Streaming Media Software
Microsoft Azure Cloud
- ▲ Server Location: Microsoft Cloud
- ▲ Third Party Vendors Used: Wowza (media service), Microsoft (Azure Cloud), JW Player (video player), Google Analytics, OCR/Google Vision

Online Portal

Registered user access to approved Impella case information

- ▲ Online Portal Address: *https://www.impellaconnect.com*
- ▲ Access Type: Authorized access only (username/password required)
- ▲ Access Administration: Abiomed admin enrolls and manages user accounts
- ▲ Data Management: Wowza Streaming Media Software
Microsoft Azure Cloud
- ▲ PHI Accessed: None
- ▲ Institution Data Accessed: None

INTENDED USE

The Impella Connect® transfers the video image of the screen on the Automated Impella® Controller 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 Customer 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, learn more about Abiomed and Impella: Visit *www.abiomed.com/important-safety-information*

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