

PRODUCT UPDATE

March 2021



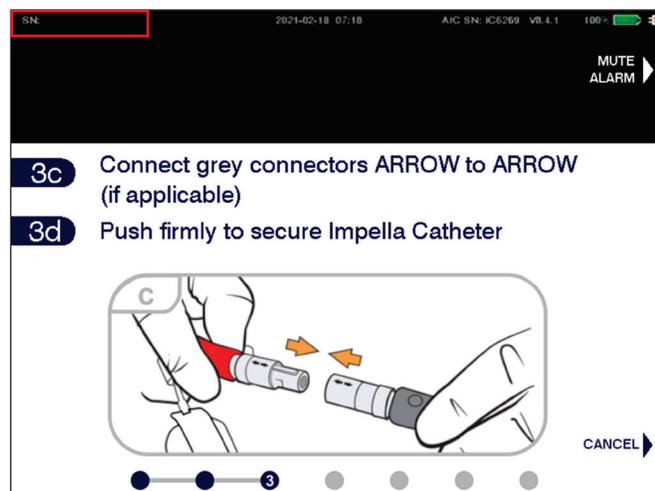
AIC Version 8.5 Software Update Available

What's New

The Impella version 8.5 software for the Automated Impella Controller™ (AIC) contains bug fixes and additional data sent to Impella Connect®. This software will resolve an occasional issue seen in version 8.4 where a pump is not recognized by the AIC. While version 8.5 is being rolled out, instructions are provided on troubleshooting should this error occur.

Background

During Case Start, if the pump is connected to the AIC but the Impella pump type and serial number are not displayed (shown in red) and the AIC continues to instruct a user to connect the pump, then this is likely an issue with the console recognizing the pump. This is a rare occurrence, however if it does happen this is not an issue with the pump itself, rather the AIC software.



AIC Screen if Pump is Not Recognized

It is recommended that you follow the troubleshooting steps if this occurs.

Troubleshooting Steps:

After plugging in the catheter, confirm that the serial number is displayed on the AIC screen. If not, follow the below steps:

1. Disconnect the pump
2. Reboot the AIC
3. Reconnect the pump and push firmly to ensure complete connection, continue Case Start
4. If the pump is still not recognized, switch to backup controller*
5. If a backup controller is not available, call Field Service to discuss getting a loaner sent

* For patients in immediate need of support, consider switching directly to a backup controller

Version 8.5 Software

A fix for this issue has been released in version 8.5 software. This software will begin to be distributed through preventative maintenance and for new AIC consoles. It is recommended that all consoles are upgraded to this version of software as soon as possible.

Please return all version 8.4 USB Upgrade kits to Field Service via FedEx to Attn: eMFG at 24 Cherry Hill Drive. The version 8.5 USB Upgrade kits will be distributed end of March.

Summary

The AIC version 8.5 software is now available, and it is recommended that all sites upgrade to this as soon as they can. Consoles that are returned to Abiomed for their annual service will be updated to version 8.5 moving forward. Please return AIC version 8.4 USB Upgrade kits to help expedite the distribution of AIC version 8.5 USB Upgrade kits. Additionally, do not upgrade any additional consoles with version 8.4 software and for any consoles that are currently at version 8.4 software, please upgrade them to version 8.5 when Upgrade kits are made available. In the meantime, ensure your teams are aware of the above troubleshooting steps in case an issue with the console recognizing the pump is encountered.

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: www.abiomed.com/important-safety-information

*This bulletin is intended for dissemination of technical information only.

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