

Reminder of caution to maintain backup Automated Impella Controller, Impella pumps, and accessories

Reason for Notification

Abiomed would like to remind the healthcare professional community about the caution in the Instructions for Use (IFU) regarding having a backup Automated Impella Controller, purge cassette, connector cable, and Impella Catheter available in the unlikely event of a device failure. This caution is for situations in which the Automated Impella Controller may malfunction, be damaged, or cease to operate.

Recommendations

Please refer to your IFU cautions regarding having a backup Automated Impella Controller, purge cassette, connector cable, and Impella Catheter available in the unlikely event of a device failure.

Products In Scope

Product Manuals/Instructions for Use (IFU)	IFU Reference Number
Left-Side Impella™ Ventricular Support Systems	0042-9028
Impella 5.5™ with SmartAssist™	0550-9002
Impella 5.5™ with Smart Assist™ S2	10003049
Impella CP™ with SmartAssist™	0048-9007
Impella RP™ System with Automated Impella Controller (AIC)	0046-9062
Impella RP™ with SmartAssist™	0052-9013
Impella RP™ Flex with SmartAssist™	10003286

