

FSN Ref: 2025-FSN-000110

FSCA Ref: 2025-FA-000110

Dear valued customers,

As a response to FSCA Ref: 2025-FA-000110 Abiomed will implement physical controls to deter and detect potential tampering. These controls will consist of an ethernet lock, dongle lock, and tamper evident labels. Final version of these steps will be found in the IFU when available. For the time being, please use this leaflet to check for correct implementation of the controls.

Inspect the Automated Impella Controller for Tampering Before Each Use

Check the Automated Impella Controller for evidence of tampering before each use. Refer to Figure 1 for an Automated Impella Controller without evidence of tampering and Figure 2 for evidence of tampering. If tampered with, the tape adhering to the Automated Impella Controller or Impella Connect body will show a checkerboard pattern indicating the device may have been tampered with. In the event of suspected tampering, **do not use**. Use an alternate Automated Impella Controller, and contact your Abiomed Representative.

Figure 1.
Automated Impella Controllers **without**
evidence of
tampering.



Figure 2.
Automated Impella Controllers **with**
evidence of
tampering.



This guide is intended for use by cardiologists, surgeons, nurses, perfusionists, and cardiac catheterization lab technicians who have been trained in the use of the Automated Impella Controller.