



Urgent Field Safety Notice
EnSite™ X EP System Amplifier
Model: ENSITE-AMP-02, ENSITE-R-AMP-02
GTIN: 05415067034755 and 05415067034748

Electrophysiology
Abbott Laboratories, Inc.
One St Jude Medical Drive
St. Paul, MN 55117 USA

April 21, 2021

Dear Abbott Customer,

Abbott is advising customers using the EnSite™ X EP System Amplifier (models ENSITE-AMP-02 and ENSITE-R-AMP-02) that there is the potential for depressed pins in the HD port used to connect the 80-pin Catheter Input Module (CIM) to the amplifier (used for connecting non-Abbott catheters). All reported instances were identified during installation and we have received no reports of patient harm related to this issue. Abbott has received two (2) complaints potentially related to this issue. In both cases, the issue presented during installation of the unit prior to customer use, and there were no patients involved.

Our records indicate that your institution received one or more of the affected model numbers listed above.

Scope of Problem

This issue is isolated to the HD port highlighted in yellow in Figure 1. The HD port is only used to connect an 80-pin CIM to the amplifier. The 80-pin CIM is used to connect non-Abbott catheters. **There is no impact to any of the other ports or connectors of the amplifier. All Abbott catheters can be connected using the direct connect ports on the amplifier.**

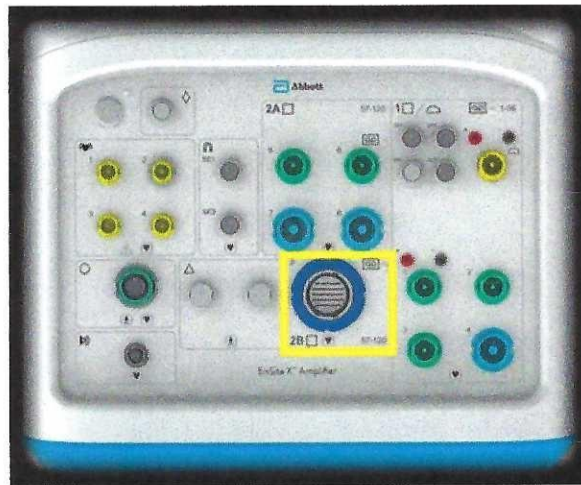


Figure 1 – Highlighted HD Port of EnSite X EP System Amplifier

Associated Risks

If a device is affected, the issue would present during use with a non-Abbott catheter as either a bad electrode or the pop up for the 80-pin CIM connection will not appear. This may lead to delayed or cancelled procedures. Continued use of the affected EnSite X EP System Amplifier is considered safe.



Recommendations and Next Steps

When using Abbott catheters, it is recommended to use the direct connect catheter connections, as this issue does not impact those ports.

Abbott is working to resolve the issue, and Abbott will notify you when a replacement EnSite™ X EP System Amplifier is available for installation.

Please forward this notice as appropriate within your organization. Please maintain a record of this notice along with the recommendations to ensure effectiveness of this communication. There is no additional action necessary by you or your hospital. Abbott will facilitate all actions necessary.

Reporting and Customer Assistance

- Abbott will notify all applicable regulatory agencies about this matter.
- Please share this notification with others in your organization, as appropriate.
- Adverse reactions or quality problems experienced with the use of this product may be reported directly to Abbott.
- Should you have questions about this issue, please contact your local Abbott Representative.

Abbott is committed to providing the highest quality products and support. We sincerely apologize for any inconvenience this action may cause you, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Thank you for your continued support.

