December 2021

# IMPORTANT PRODUCT INFORMATION

| Product Name |
| --- |
| i-STAT Alinity Instrument with OSi15 software A-500.3.35-1 |

Dear Valued Abbott Point of Care Customer,

This letter contains important information regarding the i-STAT® Alinity Instrument and product software version OSi15(A-500.3.35-1).

Our records indicate that your facility is an i-STAT Alinity Instrument user. If your facility:
- has recently upgraded to product software version OSi15(A-500.3.35-1) **and**
- transmits all data wirelessly to a data management system using enterprise level wireless security

please review the information below as your facility is impacted, and further review and action is required.

If your facility has not yet upgraded to OSi15(A-500.3.35-1), your facility is **not** impacted, and no further review or action is required.

## BACKGROUND
The i-STAT Alinity instrument with i-STAT cartridges is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity system is intended for the quantitative measurement of various analytes in arterial, venous and capillary whole blood.

Software updates for the i-STAT Alinity Instrument, identified as OSi, are delivered twice a year. The OSi software may be downloaded and installed on i-STAT Alinity instruments either by a network connection to the Abbott Managed Server, or from the Abbott Point of Care website via a USB memory device.

Abbott Point of Care has identified an issue with the recently released i-STAT Alinity product software, version OSi15(A-500.3.35.-1). This issue prevents the instrument from completing authentication to wireless (Wi-Fi) networks using WPA/WPA2 Enterprise Authentication Protocol (EAP) level security (EAP-TLS, EAP-TTLS/MCHAPv2, EAP-PEAPv0/PEAP-MSCHAPv2). In EAP mode, the i-STAT Alinity instrument will not transmit via Wi-Fi. The Alinity instrument Wireless Network Status will display the following symbol indicating no Wi-Fi connection.



To transmit data from your i-STAT Alinity Instrument with OSi15(A-500.3.35-1), Wi-Fi can be disabled, the i-STAT Alinity instrument placed in an Alinity base station and connected to a wired network to transmit. Alternatively, the i-STAT Alinity Wi-Fi configuration can be changed using the AlinIQ NCi utility to use WPA/WPA2 Pre-Shared Key (PSK). Please consult with your Information Technology department/contact to discuss these alternatives.

Abbott Point of Care has made the decision to communicate this information to the potentially affected marketplace. This action is not being conducted to reduce risk to health.

## RECOMMENDED ACTIONS
A new version of OSi15 (OSi15(A-500.3.**36**-1) was posted to the Abbott Managed Server and Abbott Point of Care website (www.globalpointofcare.abbott) on December 14, 2021 that will address the issue related to completing authentication to wireless (Wi-F) networks using WPA/WPA2 Enterprise Authentication Protocol (EAP) level security (EAP-TLS, EAP-TTLS/MCHAPv2, EAP-PEAPv0/PEAP-MSCHAPv2).

**Abbott Point of Care recommends updating all i-STAT Alinity Instruments currently on product software versions OSi14 or OSi15(A-500.3.35-1) to OSi15(A-500.3.36-1).**

If you have provided any i-STAT Alinity Instruments to another facility, please provide a copy of this letter to them.

**ADDITIONAL INFORMATION**
To determine which version of OSi15 is running on an i-STAT Alinity Instrument, from the Home screen select *More Options → Instrument Status* and view the Firmware version identified on the screen.

Old version:  **Firmware:** OSi15(A-500.3.**35**-1)
New version: **Firmware:** OSi15(A-500.3.**36**-1)

Additionally, it should be noted that the i-STAT Alinity Instrument OSi software only supports TLS v1.0 for enterprise authentication.

If you have any questions regarding this information, please contact Abbott Point of Care Technical Support at 1-800-366-8020 option 1 or via email at techserv@apoc.abbott.com.

Abbott Point of Care sincerely apologizes for any inconvenience this may create for your facility. We appreciate your understanding in this matter and thank you for your continued support of Abbott and Abbott products.