



October 2023

IMPORTANT PRODUCT INFORMATION

Product Name	List Number
<i>i-STAT EG7+</i> cartridge	03P76-25
<i>i-STAT EG6+</i> cartridge	03P77-25
<i>i-STAT G3+</i> cartridge (white)	03P78-25
<i>i-STAT CG4+</i> cartridge (white)	03P85-25
<i>i-STAT CG8+</i> cartridge	03P88-25
	600-9001-25

Note: not all cartridges are available in all regions

Dear Valued Abbott Customer,

Abbott is pleased to announce that, with the Fall 2023 *i-STAT* System Software and User Documentation update, the manual calculation will no longer be required to adjust PCO_2 results for patient samples with elevated PO_2 levels for the cartridges noted above.

This is a follow up to the September 2020 communication, where the factor affecting the PCO_2 result of PO_2 sensitivity was added to the cartridge-based Instructions for Use (IFU).

Our records indicate that your facility utilizes one or more of the *i-STAT*[®] cartridges associated with this communication. This letter contains important information regarding the *i-STAT* PCO_2 test contained in the *i-STAT* cartridges noted above.

Please review the information below as it may apply to cartridges in use at your facility.

BACKGROUND and DETAILS

The test for PCO_2 , as part of the *i-STAT* System, is intended for use in the *in vitro* quantification of carbon dioxide partial pressure in whole blood. PCO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.

The **Fall 2023 *i-STAT 1* and *i-STAT Alinity* software** will include the correction to the PCO_2 result for the PO_2 sensitivity factor affecting result. Therefore, after the software update, **the manual calculation, as detailed below, should no longer be used for the cartridges noted above.**

Additionally, the following will be **removed** from the Factors Affecting Results section of the cartridge-based Instructions for Use (IFU).

<i>Factor</i>	<i>Analyte</i>	<i>Effect</i>
PO_2 sensitivity	PCO_2	<p>In patient samples where the PO_2 is > 100 mmHg above the normal range (80-105 mmHg) an increase in PCO_2 of approximately 1.5 mmHg (with a range of 0.9 to 2.0 mmHg) may be observed for every 100 mmHg increase in PO_2.</p> <p>For example, if an oxygenated patient has a measured PO_2 of 200 mmHg, and a normal PO_2 is 100 mmHg, the impact to the PCO_2 result may be increased by approximately 1.5 mmHg.</p>



This information is being communicated in advance of the Fall 2023 User Documentation and software update, to allow for the appropriate planning and adjustments to your facility's documentation regarding this information, if required.

Abbott has not received any reports of patient harm associated with this IFU update. This communication is not being done to reduce risk to health.

RECOMMENDED ACTIONS

Facilities should review the information contained in this letter with clinicians and end users and use this to plan for any adjustments to documentation, if required. Starting the week of October 16, 2023 for *i-STAT 1* and the week of October 30, 2023 for *i-STAT Alinity*, download the updated *i-STAT* System software and review the cartridge Instructions for Use (IFU) from the Abbott Point of Care website (www.globalpointofcare.abbott). PCO_2 results should not be manually corrected after the Fall 2023 Software Update is applied to *i-STAT 1* analyzers or *i-STAT Alinity* instruments.

If you have forwarded any of the *i-STAT* cartridges listed above to another facility, we request that you please provide a copy of this letter to them. Please use this communication to update the recommendations provided in the previous APOC2020-006 communication for the cartridges listed above.

ADDITIONAL INFORMATION

The following cartridges are not included in this communication and do **not** have an update in the Fall 2023 Software and User Documentation for the factor affecting the PCO_2 result of PO_2 sensitivity and **will continue to require the manual correction**.

Product Name	List Number
<i>i-STAT G3+</i> cartridge (blue)	03P78-50
<i>i-STAT EC8+</i> cartridge	03P79-25
<i>i-STAT CG4+</i> cartridge (blue)	03P85-50 03P85-51

Note: not all cartridges are available in all regions

If you have any questions regarding this information, please contact your local Abbott Point of Care Technical Support by phone or via email or contact your local Abbott Point of Care representative.

We appreciate and thank you for your continued support of Abbott and Abbott products.