



December 2020

**Urgent Field Safety Notice**

Product Name	List Number	Product Name	List Number
i-STAT CG8+ cartridges	03P88-25	i-STAT EG7+ cartridges	03P76-25

Dear Valued Abbott Point of Care Customer,

This letter contains important information regarding the i-STAT® CG8+ and EG7+ cartridges noted above. If you are using these cartridges, your facility may be impacted, and further review and action may be required.

Note: information in this letter is lot number specific.

**PRODUCT DESCRIPTION**

The i-STAT CG8+ cartridge contains eight measured tests (sodium, potassium, ionized calcium, pH, pCO<sub>2</sub>, pO<sub>2</sub>, glucose and hematocrit) and the i-STAT EG7+ cartridge contains seven measured tests (sodium, potassium, ionized calcium, pH, pCO<sub>2</sub>, pO<sub>2</sub>, and hematocrit).

The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of ionized calcium in arterial, venous, or capillary whole blood.

**DESCRIPTION OF THE ISSUE**

The i-STAT CG8+ and EG7+ cartridge Instructions for Use (IFU) indicate that these cartridges can be stored for 2 months at room temperature (18 to 30°C). Abbott routinely tests the performance of i-STAT cartridges, including stability testing of the i-STAT CG8+ and EG7+ cartridges at various time intervals after storage in the refrigerator and at 30°C.

Through this internal testing process after storage at 30°C for 14 days, Abbott Point of Care observed approximately 5.2% of cartridges reporting higher than expected results for ionized calcium. Abbott Point of Care observed ionized calcium on **some** i-STAT CG8+ and EG7+ cartridges may **exhibit higher than expected reported results** when stored at room temperature (18 to 30°C) for periods of time in excess of:

- 3 days for lot numbers \*20100 to \*20339
  - 7 days for lot numbers \*20340 and above
- Where \* = lot letter A, K, L, M, N, W or Y.

Abbott Point of Care has **not** observed higher than expected reported results for the ionized calcium test when i-STAT CG8+ and EG7+ cartridges are removed from refrigerated storage and warmed to room temperature for use within the number of days indicated above.

**Abbott Point of Care has not observed this issue for any tests on the i-STAT CG8+ or EG7+ other than the ionized calcium test.**

Abbott Point of Care is communicating this information to potentially impacted customers. Clinicians should be advised to consider a patient's signs, symptoms, history, and results of other diagnostic tests when interpreting the ionized calcium results from these cartridges. If the results do not match the patient's clinical presentation, the patient sample should be retested using an alternate i-STAT cartridge or method. Treatment of falsely high ionized calcium may result in harm, by precipitating hypocalcemia. Abbott Point of Care has determined that the overall likelihood of harm associated with this issue is rare. The most common symptoms of hypocalcemia include paresthesia, muscle spasms, cramps, tetany, circumoral numbness, and seizures. Although improbable, in the most extreme cases, hypocalcemia could potentially result in sudden cardiac death. Abbott Point of Care has **not** received any reports of patient harm associated with this issue.

**RECOMMENDED ACTIONS**

Our records show that your facility is an i-STAT CG8+ or EG7+ cartridge user. While Abbott Point of Care continues to investigate this issue, if reporting ionized calcium is required, **it is recommended that the i-STAT CG8+ and EG7+ cartridges be used only:**

- within 3 days of removal from refrigerated storage for lot numbers between \*20100 and \*20339
- within 7 days of removal from refrigerated storage for lot numbers \*20340 and above

Where \* = lot letter A, K, L, M, N, W and Y

If your facility is unable to manage to the recommended action outlined above, Abbott Point of Care recommends that your facility disable and not report the ionized calcium test on the i-STAT CG8+ and EG7+ cartridges and use an alternate i-STAT cartridge or method for reporting ionized calcium. Please see additional information below on how to disable the ionized calcium test for these cartridges.

Please confirm receipt and understanding of this communication by responding to the business reply form included with this letter.

**APOC2020-007**

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.



If you have forwarded any i-STAT CG8+ and EG7+ cartridges to another facility, we request that you please provide a copy of this letter to them.

We are providing, as an attachment, a list of the potentially impacted i-STAT CG8+ and EG7+ cartridge lots that have been distributed as of the date of this letter. Please continue to follow the recommended actions in this communication for all newly received i-STAT CG8+ and EG7+ lots until your facility receives an updated communication from Abbott Point of Care.

#### **ADDITIONAL INFORMATION**

Your Abbott Point of Care sales and support team are available to review interim solutions for the challenges this communication may bring. If you have any questions regarding this information, please contact your local Abbott Point of Care Support services representative. Additionally, please report any questions or concerns about the performance of the ionized calcium test on the i-STAT CG8+ and EG7+ cartridges to your local Abbott Point of Care Technical Support or via [oustechsvc@apoc.abbott.com](mailto:oustechsvc@apoc.abbott.com).

If your facility decides to proceed with disabling the ionized calcium test, resources are included at the end of this communication. If ionized calcium is interfaced through the Laboratory Information System (LIS) interface, disabling the analyte may require a change to the interface. Please contact your interface vendor.

Abbott Point of Care is fully committed to addressing this situation as a top priority and supporting you throughout this process. **Abbott Point of Care will provide timely follow up communications when there is data to support longer storage at room temperature and after completion of the investigation.**

The appropriate Competent Authorities have been made aware of this action.



#### Resources for customization for the i-STAT Alinity instrument:

- Go to <https://www.pointofcare.abbott/int/en/home> and navigate to Support > i-STAT Alinity Resources Login > Operator Documentation > i-STAT Alinity System Operations Manual (Language: English) :
  - **Customers using AlinIQ CWi**, refer to i-STAT Alinity System Operations Manual, Section 3.1 - AlinIQ CWi - Customization Workspace for i-STAT, *Analyte Settings Category, Enable/Disable Analyte* for information on customizing this option.

**NOTE: To customize this feature AlinIQ Cwi is required.**








#### Resources for customization for the i-STAT 1 Analyzer:

- Go to <https://www.pointofcare.abbott/int/en/home> and navigate to Support > i-STAT 1 Resources Login > Administrator Documentation > Technical Bulletins (Language: English United Kingdom) > Data Management User Documentation and select i-STAT DE Documentation:
  - Refer to the i-STAT DE User Guide v2.10 Art:754472, Section 3.15 Customizing Analyte Enable Options
- Go to <https://www.pointofcare.abbott/int/en/home> and navigate to Support > i-STAT 1 Resources Login > User Documentation > i-STAT 1 System Manuals
  - i-STAT **Customers without i-STAT/DE or CDS**, refer to the i-STAT System Manual, i-STAT 1 Analyzer 2 Art:714364, *Changing the Profile* for guidance on navigating to the Results menu, then the Units and Ranges menu to change the setting.



## Customizing Analyte Enable Options using the i-STAT 1 Analyzer Keypad

New analyzers or replacement analyzers will have standard unit sets installed and all analytes enabled. To disable or set a different unit of measurement for a particular analyte globally, access *Change Customization > Units and Ranges*. Perform the following steps:

**NOTE:** This setting will apply globally to all cartridge types used. To disable analytes by i-STAT Cartridge panel, users must use i-STAT/DE or CDS.

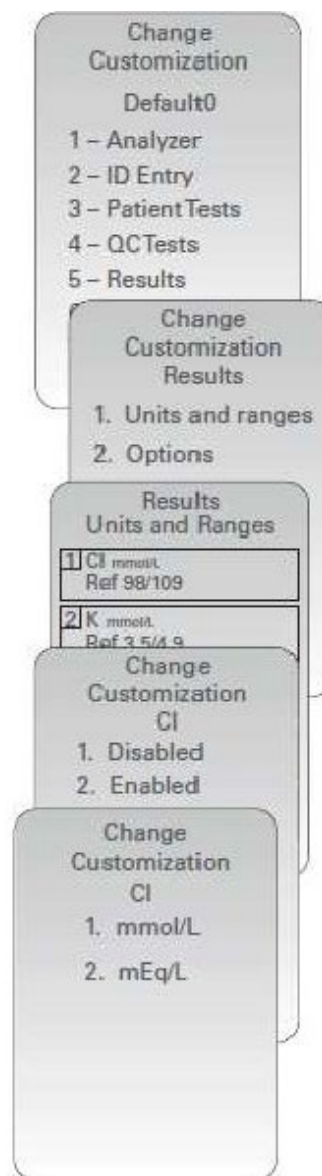
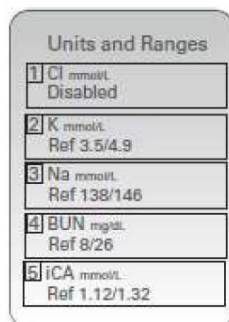
1. Press  to turn on the analyzer.
2. Press  to change to the Administration Menu
3. Press  (Customization)
4. Press  (Change)
5. Press  (when enabled, enter password)
6. Press  (Results)
7. Press  (**Units and Ranges**)

8. Press the number key corresponding to the analyte you wish to disable or change units for.

Press  or  arrow keys to navigate between the pages to view analytes.

9. Press 1- (Disabled), to disable the analyte OR Press 2- (Enabled) to change the units.
10. When changing units, press the number key corresponding to the units in which you would like the analyte reported.
11. Once all analytes are set as you wish to report, press twice to save and return to the Main Menu.

**NOTE:** When an analyte is disabled, it will be noted on the Units and Ranges Menu screen. No reference units and ranges will be displayed for the analyte.



**Abbott****i-STAT CG8+ and EG7+ cartridge lots**

List of the potentially impacted i-STAT CG8+ and EG7+ cartridge lots that have been distributed as of 22 December 2020. Please continue to follow the recommended actions in this communication for all newly received i-STAT CG8+ and EG7+ lots until your facility receives an updated communication from Abbott Point of Care.

Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number
EG7+	L20106A	EG7+	W20149	EG7+	N20200	EG7+	N20244	EG7+	N20295
CG8+	W20106	EG7+	N20150	EG7+	N20200A	CG8+	W20244	EG7+	N20295A
CG8+	W20108	EG7+	N20150A	CG8+	W20200	EG7+	N20245	EG7+	N20295B
EG7+	L20107	EG7+	W20152	EG7+	N20201	CG8+	W20245	CG8+	W20295
EG7+	L20108A	CG8+	W20152A	EG7+	N20201A	EG7+	N20246	CG8+	W20295A
CG8+	W20110	CG8+	W20153	EG7+	N20202	CG8+	W20246	EG7+	N20296
EG7+	L20110A	CG8+	W20154	EG7+	N20203	EG7+	N20247A	EG7+	N20296A
CG8+	W20111	EG7+	N20155	EG7+	N20204	EG7+	N20251A	EG7+	N20297
CG8+	W20112A	CG8+	W20155	EG7+	N20204A	EG7+	N20252	EG7+	N20297A
CG8+	W20113	CG8+	W20156	CG8+	W20204	CG8+	W20253	EG7+	N20298
EG7+	N20113	EG7+	N20158	CG8+	W20205	EG7+	N20254	EG7+	N20298A
EG7+	N20114	EG7+	N20159	CG8+	W20205A	EG7+	N20255	EG7+	N20300
CG8+	W20113A	CG8+	W20159	EG7+	N20206A	CG8+	W20255	CG8+	W20300
CG8+	W20114	EG7+	N20160	EG7+	N20206B	EG7+	N20256	EG7+	N20301
EG7+	N20115	CG8+	W20160	EG7+	N20207	CG8+	W20256	CG8+	W20301
CG8+	W20116	CG8+	W20161	EG7+	N20207A	CG8+	L20257	EG7+	N20302
EG7+	N20117	EG7+	W20161A	EG7+	N20208	EG7+	N20257	EG7+	N20302A
CG8+	W20117	EG7+	N20162	EG7+	N20208A	CG8+	W20257	EG7+	N20303
CG8+	W20117A	CG8+	W20162	EG7+	N20209	EG7+	N20258	CG8+	W20303
CG8+	W20118	EG7+	N20163	EG7+	N20209A	CG8+	W20258	EG7+	N20304
EG7+	N20119	CG8+	W20163	CG8+	W20209	CG8+	L20259	CG8+	W20304
CG8+	W20119	EG7+	N20164	CG8+	W20209A	CG8+	W20259	EG7+	N20305
EG7+	N20120	EG7+	N20166A	EG7+	N20210	CG8+	W20260	EG7+	N20305A
CG8+	W20120	CG8+	W20167	CG8+	W20210	CG8+	W20261	CG8+	W20305
EG7+	N20121	CG8+	W20167A	CG8+	W20211	EG7+	N20262	CG8+	W20305A
EG7+	N20121A	EG7+	W20168	EG7+	N20212	CG8+	W20262	CG8+	W20306
CG8+	W20122	EG7+	N20170	CG8+	W20212	CG8+	W20263	EG7+	N20307
EG7+	N20124	EG7+	L20175	EG7+	N20213	CG8+	W20263A	EG7+	N20308
CG8+	W20124	EG7+	N20175	EG7+	N20214	CG8+	W20265	EG7+	W20308
CG8+	W20126	CG8+	W20176	EG7+	N20214A	CG8+	W20266	EG7+	N20309
CG8+	W20126A	CG8+	W20176A	CG8+	W20214	CG8+	W20268	EG7+	W20309
EG7+	N20127	CG8+	W20178	CG8+	W20215	EG7+	N20269	EG7+	W20309A
CG8+	W20127	EG7+	L20179	CG8+	W20216	CG8+	L20270	EG7+	N20310
EG7+	N20128	CG8+	W20179	EG7+	N20220	CG8+	L20270A	CG8+	W20310A
EG7+	L20129	EG7+	W20179A	EG7+	N20220A	CG8+	W20270	EG7+	N20311
CG8+	W20129	EG7+	W20179B	EG7+	N20222	CG8+	W20271	CG8+	W20311
EG7+	N20130	EG7+	W20180	EG7+	N20223	CG8+	W20272	EG7+	N20312

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Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number
CG8+	W20131	CG8+	W20181	CG8+	W20223	CG8+	W20272A	CG8+	W20312A
EG7+	N20132	CG8+	W20181A	CG8+	W20223A	EG7+	N20273	EG7+	N20313
CG8+	W20132	CG8+	W20182	EG7+	N20224	CG8+	W20273	EG7+	N20314
EG7+	N20133	CG8+	W20182A	EG7+	N20224A	EG7+	N20274	EG7+	N20315
CG8+	W20133	EG7+	L20183	CG8+	W20224	CG8+	W20275	CG8+	W20316
CG8+	W20134	CG8+	L20183A	EG7+	N20225	EG7+	N20276	EG7+	N20317
CG8+	W20135	CG8+	W20183	CG8+	W20226	CG8+	W20276	CG8+	W20317
EG7+	N20136	CG8+	W20184	EG7+	N20227	EG7+	N20277	EG7+	N20318
CG8+	W20136	CG8+	W20184A	CG8+	W20227	CG8+	W20277	CG8+	W20318
EG7+	N20137	CG8+	W20187	EG7+	N20228	CG8+	W20279	CG8+	W20319
CG8+	W20137	EG7+	N20188	EG7+	N20228A	CG8+	W20279A	CG8+	W20319A
CG8+	W20137A	CG8+	W20188	EG7+	N20229	CG8+	W20280	EG7+	N20320
CG8+	W20138	CG8+	W20188A	CG8+	W20229	CG8+	W20280A	CG8+	W20321
EG7+	N20139	EG7+	L20189	CG8+	W20229A	EG7+	N20281A	EG7+	N20323
CG8+	W20139	CG8+	W20191	EG7+	N20230	EG7+	N20282	EG7+	N20324
EG7+	N20140	CG8+	W20191A	EG7+	N20230A	CG8+	W20282	CG8+	W20324
CG8+	W20140	CG8+	W20191B	CG8+	W20230	EG7+	N20283	EG7+	N20325
CG8+	W20140A	CG8+	W20191C	CG8+	W20231	CG8+	W20284	CG8+	W20325
CG8+	W20141	CG8+	W20192	CG8+	W20231A	CG8+	W20285	CG8+	W20325A
CG8+	W20142A	CG8+	W20192A	CG8+	W20231B	EG7+	N20286	EG7+	N20327
EG7+	N20143A	EG7+	N20193	EG7+	N20233	CG8+	W20287	CG8+	W20327
CG8+	W20143	CG8+	W20193	CG8+	W20233	EG7+	N20288	EG7+	N20329
CG8+	W20143A	CG8+	W20194	CG8+	W20233A	EG7+	N20288A	EG7+	N20330
CG8+	W20144	CG8+	W20194A	CG8+	W20234	EG7+	N20289	EG7+	N20331
EG7+	N20145B	EG7+	W20194B	EG7+	N20236	EG7+	N20290	CG8+	W20331
CG8+	W20145	EG7+	N20195	CG8+	W20236	CG8+	W20290	CG8+	W20332
CG8+	W20145A	EG7+	N20196	EG7+	N20237	EG7+	N20291	EG7+	N20333
EG7+	L20146	EG7+	N20196A	CG8+	W20237	EG7+	N20291A	EG7+	N20334
EG7+	N20146	EG7+	N20197	EG7+	N20238	CG8+	W20291	EG7+	N20335
CG8+	W20146	CG8+	W20197	CG8+	W20238	CG8+	W20292	CG8+	W20336
EG7+	N20147	EG7+	N20198	CG8+	W20240	CG8+	W20293	CG8+	W20337
CG8+	W20147	EG7+	N20198A	CG8+	W20240A	EG7+	N20294	EG7+	N20338
EG7+	N20148	CG8+	W20198	EG7+	N20241	EG7+	N20294A	CG8+	L20339
CG8+	W20148	CG8+	W20198A	EG7+	N20241A	CG8+	W20294	EG7+	N20339
EG7+	N20149	EG7+	N20199	CG8+	W20242	CG8+	W20294A	CG8+	W20339
EG7+	N20149A	CG8+	W20199	EG7+	N20243	CG8+	W20294B	CG8+	W20339A

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**BUSINESS REPLY FORM**

**Abbott Point of Care  
Product Action Program**

**APOC2020-007**

**Please complete this form and return** within **ten (10)** business days by fax (**X-XXX-XXX-XXXX**) or e-mail (**XXXXXX@XXXX.com**).

Return of this form acknowledges that you have read and understood the instructions and have taken the appropriate action. Refer to letter included for additional information. Your timely response to this notification is requested.

Customer Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ Country \_\_\_\_\_ Zip \_\_\_\_\_

Contact Name (please print) \_\_\_\_\_ Telephone # \_\_\_\_\_

Contact Signature \_\_\_\_\_ Date \_\_\_\_\_

Product Description	List Number
i-STAT CG8+ cartridges	03P88-25
i-STAT EG7+ cartridges	03P76-25

If you have any questions regarding this form please contact XXXX at 1-XXX-XXX-XXX.

**Please fax this form to: 1-XXX-XXX-XXXX or E-mail XXXXX@XXXXXX.com**