January 5, 2012

Frequently Asked Questions (FAQs) for Patient Safety Alert AL12-01

"Software upgrade to resolve Bayer Viterion V100 BGM Home Telehealth hub device not transmitting all of Roche Accu-Chek Aviva blood glucose meters' data via Roche infrared peripheral"
(*http://www.patientsafety.gov/alerts/AL12-01-TelehealthPatientSafetyAlertAL11-03Replacement.pdf*)

Question 1: What is the overall purpose of Patient Safety Alert AL12-01, issued on December 19, 2011?

Answer 1: Since Patient Safety Alert AL11-03 was released on April 27, 2011, Viterion, in collaboration with Roche, developed a software upgrade that resolves the patient safety issues discussed in Patient Safety Alert AL11-03 (flagged data associated with the Hypo Flag not being transmitted to the user-interface, VISNET). The new software (version 3.3.0) allows the transmission of all blood glucose readings from an infrared-cabled Roche Aviva blood glucose meter to the VISNET website despite any flag or alert settings the patient makes on their blood glucose meter. The December 19, 2011 Patient Safety Alert AL12-01 was issued since there are new Actions that replace the previous Actions of Patient Safety Alert AL11-03.

Question 2: Action 1 of AL12-01 states "By close of business (COB) January 13, 2012, Home Telehealth (HT) staff will identify all patients using a Viterion V100 BGM unit as well as all units in stock." What action must I take at this time to identify patients?

Answer 2: Prepare the list of affected patients and devices in stock as follows:

1. Visit the vendor's website (VISNET) to determine all patients using Viterion devices assigned to your facility.
2. Work with your facility's Prosthetics Department to confirm models, identifying all patients with the Viterion V100 BGM unit and all Viterion V100 BGM units in stock.
3. If there is any uncertainty as to the model of Viterion device that a patient is using, contact the patient to have them verify the device they are using (the Viterion 100 BGM units have a label on the front identifying them as V100 BGM). If there is no uncertainty (i.e., there is adequate documentation of model), patients do not need to be contacted.

The list of patients using Viterion 100 BGMs does not need to be submitted, but rather be used as a verification tool once Viterion contacts your site for the software upgrade.

NOTE: Do not contact Bayer Viterion for a list of affected patients and devices to meet the January 13, 2012, Action 1 deadline for Patient Safety Alert AL12-01. While facilities will be provided a list of affected patients and devices from Bayer prior to the facility's planned upgrade, the intention is that each facility will compare their own list to the list they will receive from Bayer, to ensure all patients and devices are accounted for. Be aware that the list of patients that your facility created earlier in 2011 for the initial Patient Safety Alert (AL11-03) included only those patients using the Viterion V100 BGM and the Roche blood glucose meter. HT staff should now be identifying any patient using the Viterion V100 BGM whether or not they are using it with the Roche Aviva blood glucose meter.

Question 3: I have Viterion units, but my site is not on the list (Attachment 2 of Patient Safety Alert AL12-01), what should I do?

Answer 3: This upgrade pertains ONLY to Viterion V100 BGM model devices with software version 3.2.0. If you don't have this specific product, then your site was not included on the list.

Question 4: My facility has recently purchased Viterion V100 BGM devices. Do these need to be upgraded?

Answer 4: All Viterion V100 BGM devices shipped since October 2011 were shipped with version 3.3.0 software and do not need to be upgraded.

Question 5: If I have Viterion V100 BGM devices and I am not sure which software version they have, how can I find out?

Answer 5: There is no need to check the software version of any Viterion 100 BGM that is in a patient's possession or in stock. All of the Viterion 100 BGM units shipped prior to October 2011 came with version 3.2.0 and require upgrading.

Question6: Whom should I contact if I have further questions or need a copy of Patient Safety Alert AL12-01?

Answer 6: Please contact:

- Ms. Catherine Buck, OTS Clinical Nurse Analyst at (804) 675-5558, catherine.buck@va.gov, or
- Ms. Marcia Dunn, OTS Program Analyst at (202) 461-6761, marcia.dunn@va.gov, or
- Mr. Bryanne Patail, NCPS, Biomedical Engineer at (734) 930-5890, bryanne.patail@va.gov.