Patient Safety Alert

Veterans Health Administration Warning System
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This Patient Safety Alert AL12-01 replaces and supersedes Patient Safety Alert AL11-03 issued April 27, 2011

Item: 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

Specific Incident: As described in Patient Safety Alert AL11-03, a patient's multiple low blood glucose readings were not transmitted to the VAMC using the Viterion user interface, VISNET. The patient was using the Roche Accu-Chek Aviva blood glucose meter and connecting into the Telehealth system using the Roche infrared receiver, which is connected to the Viterion V100 BGM Home Telehealth hub device. The patient had set Hypo-alert flags on his blood glucose meter; in this setting, the infrared interface of the Viterion V100 BGM Home Telehealth hub device did not transfer results flagged by the hypoglycemic alert to the VA and the patient had no way of knowing this. In the April 27, 2011, Patient Safety Alert (AL11-03), Home Telehealth staff were given specific instructions on the use of the Roche Aviva with the Viterion V100 BGM Home Telehealth hub device in order to ensure patient safety.

Updated Information: Since Patient Safety Alert AL11-03 was released, Viterion, in collaboration with Roche, developed a software upgrade that resolves this patient safety issue. 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. A live demonstration of this software upgrade solution was successfully demonstrated by Viterion to the National Center for Patient Safety and Office of Telehealth Services staff. Viterion has already upgraded any returned or new Viterion V100 BGMs in their inventory to the new 3.3.0 version. In order to upgrade units assigned to patients in the field, and

units in stock at VA Home Telehealth program sites, Viterion will be contacting VISN Home Telehealth staff as they proceed with a VISN by VISN software upgrade of all existing Viterion V100 BGM units at no additional cost (see Attachment 1). Viterion will also be working with the Denver Acquisition and Logistics Center (DALC) to ensure that all Viterion V100 BGM units in the centralized supply are also upgraded to version 3.3.0.

Actions:

NOTE: These Actions replace and supersede previous guidance issued on this subject by the Office of Telehealth Services. However, this guidance does NOT supersede other guidance regarding date/time stamp issues via Patient Safety Alert AL08-19 dated July 30, 2008.

1. 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.

2. By COB March 16, 2012, **HT staff** must follow the software upgrade process, as instructed by Viterion to upgrade when their site is scheduled by Viterion (see Attachment 2). **ALL** Viterion V100 BGM units with software version 3.2.0 are to be upgraded – both those in stock and those assigned to patients - whether or not patients are currently using a blood glucose meter and the home Telehealth device to submit blood glucose readings. Viterion will verify that all units at the site are upgraded successfully (see Attachment 1). Once Viterion confirms the successful upgrade of all units at the site, the site may then allow patients to use the Roche Aviva infrared cabled blood glucose meter to transmit blood glucose readings, directly from the blood glucose meter to the Viterion V100 BGM hub device, for transmission to the Viterion user interface (VISNET) for care coordinator review.

3. By COB March 30, 2012, the **Patient Safety Manager** must document on the VHA Hazard Alerts and Recalls website that Administration has reviewed and implemented these actions or that they are not applicable to your facility.

Additional Information:

At this time, the scope and similar vulnerabilities of other Home Telehealth appliances such as Health Buddy (Bosch Health Hero Network, Inc.), Turtle (Bosch VitelCare) and inLife (American TeleCare), and associated blood glucose meters (e.g., Roche, Abbott and Bayer), have not been fully investigated. If you suspect or are aware of issues with the

	combination of any of these devices, please notify one of the contact persons listed below.
Source:	A VA Medical Center and supplier
Attachments:	1) V100 BGM v3.2.0 to v3.3.0 Remote Upgrade Rollout Plan 2) Viterion Timeline and Schedule of Software upgrade by VISN
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, National Center for Patient Safety, Biomedical Engineer at (734) 930-5890, bryanne.patail@va.gov.

ATTACHMENT 1: V100 BGM v3.2.0 to v3.3.0 Remote Upgrade Rollout Plan

The upgrade to V100 BGM software version 3.3.0 resolves the issue with the Roche Accu-Chek Aviva blood glucose meter where, in automatic data transmission mode (via cable and infrared), any blood glucose result that is tagged with a hypoglycemic or a general asterisk (*) flag will not be transmitted to the Viterion 100 BGM monitor or the server (VISNET). V100 BGM software version 3.3.0 validates and allows the upload of any measurements, both flagged and non-flagged, which are being sent from the Roche Aviva meter to the V100 BGM monitor and subsequently to the Reports page for the specific patient on VISNET (vendor website).

The upgrade will be completed by site and VISN including preparation as follows:

The upgrade rollout preparation steps for each site include the following:

- Generation of a report by Viterion (immediately prior to the start of the upgrade at each site) which identifies monitors with version 3.2.0 to be upgraded. The report will list units by patient and monitor serial number. The report will also include unassigned units in inventory. The report will be shared securely with the site's Lead Home Telehealth Care Coordinator via the Viterion Business Manager.
- Bayer Viterion will place the monitor(s) into an upgrade queue.
- Bayer Viterion will create a schedule message for the patients which advises them to initiate the upgrade by turning the monitor off, then on, and following instructions on the monitor screen. This will be repeated for two 48 hour cycles. A schedule message is a message that appears to the patient when they go thru their daily questions.
- Upgrades will begin to occur within 24 hours of monitors being placed in the upgrade queue. Actual upgrade is dependent on patient use behaviors.
- If a monitor is turned off (e.g. patient on vacation), the upgrade will initiate automatically when the unit is turned on. Similarly, unassigned monitors in inventory will initiate the upgrade when they are turned on following assignment.
- If additional follow-up is needed, communication document is available from Bayer Viterion for clinicians to distribute to patients who do not initiate upgrades.

Bayer Viterion Business Managers will also work with each site's Lead Home Telehealth Care Coordinator to ensure that the site has been trained on changes they will see for AVIVA data in VISNET as a result of the upgrade.

Viterion will monitor the units upgraded and generate a weekly report of upgraded monitors and communicate to the sites as well as the Office of Telehealth Services (OTS) to advise clinicians of patients who have not executed the upgrade (for progress and compliance). The data for this reporting is available thru the Bayer Viterion database

The proposed rollout schedules follows. The sites listed are those who currently use the Viterion 100 BGM unit. If a site is missing from this list, please contact the site's Viterion representative. It is expected to take 8 weeks from start (anticipated January 2012) and is balanced to complete all sites within a VISN prior to initiating upgrades at a new VISN as per agreement with OTS.

ATTACHMENT 2: Viterion Timeline and Schedule of Software upgrade by VISN

Week	VISN	Site	Number of V100 BGM hub devices with v 3.2.0 (will be verified immediately prior to upgrade)
complete	17	VA Health Care Center at Harlingen	92
1	17	VA San Antonio	473
2	20	Puget Sound	93
2	20	VA Spokane	97
2	20	VA White City	177
3	20	Boise VA Medical Center	245
3	20	Walla Walla VA	312
3	20	Alaska VA Healthcare System	28
2	20	Portland VA Med Center	4
2	20	Roseburg Healthcare System	1
4	18	Phoenix VAMC	147
4	18	VA New Mexico	215
4	18	VA Tucson	3
5	16	Oklahoma City VA	252
5	16	VA 16 Fayetteville	15
5	16	VA Little Rock	55
5	16	Houston VA	38
5	16	Fayetteville VAMC	2
5	16	VA Alexandria	5
5	16	VA Shreveport	3
5	16	VAMC Jackson MS	3
5	16	VA New Orleans	1
5	16	VAMC Gulf Coast	25
5	16	Muskogee VA	8
6	4	VA Philadelphia	53
6	4	Coatesville VAMC	51
6	4	VA Pittsburgh HCS	264
6	4	VA Clarksburg	1
6	4	Wilkes-Barre VA	1
6	9	Lexington VAMC	103
7	9	VA Tennessee Valley	261
7	9	Louisville VAMC	63
7	9	Mountain Home VAMC	5
7	5	Washington DC	126
7	8	Baltimore VAMC	218
7	8	VA San Juan	2
8	21	VA Palo Alto	85
8	22	VA San Diego	1
8	22	VA Loma Linda	15
8	23	Iowa City VAMC	66

ATTACHMENT 2 (continued)

Week	VISN	Site	Number of V100 BGM hub devices with v 3.2.0 (will be verified immediately prior to upgrade)
8	23	Sioux Falls	20
8	1	VAMC Manchester	5
8	2	Syracuse VAMC	75
8	2	Canandaigua VAMC	4
8	3	East Orange Campus of the VA New Jersey Health Care System	1
8	3	Northport VA Medical Center	1
8	3	New York Campus of the VA NY Harbor Healthcare System	1
8	6	Salisbury VAMC	10
8	7	Wm. Jennings Bryan Dorn VAMC	25
8	7	VA Atlanta	2
8	11	VA Illiana Healthcare	10
8	N/A	DALC	68