Securitas Healthcare

URGENT: MEDICAL DEVICE CORRECTION

Arial Mobile Application for Mobile Devices utilizing the Apple iOS 17.4 and Forthcoming iOS 17.5 Operating Systems as part of the Arial® Emergency and Nurse Call System

April 11, 2024

Dear Valued Client:

Problem Description

Securitas Healthcare LLC ("Securitas Healthcare") is issuing an Urgent Medical Device Correction to share information about the use of the Arial Mobile Application on mobile devices utilizing the Apple iOS 17.4 operating system ("Apple iOS 17.4") and forthcoming, but not yet released, Apple iOS 17.5 operating system ("Apple iOS 17.5").

Securitas Healthcare has become aware that the Arial Mobile Application running on mobile devices utilizing Apple iOS 17.4 is frequently restarting, which causes Arial Mobile Application users to: (1) receive alerts for all pending alarm notifications and other events when the Arial Mobile Application restarts; (2) experience difficulty in placing and maintaining staff-to-staff phone calls; and (3) frequently appear offline while the application restarts.

Apple has published a beta version of Apple iOS 17.5 which is in the process of testing with the Arial Mobile Application. Preliminary testing indicates that the Arial Mobile Application experiences frequent disconnections when run on mobile devices running this beta version of Apple iOS 17.5, and is unable to restart and reconnect after disconnection. This will cause Arial Mobile Application users to be unable to use the Arial Mobile Application on mobile devices running Apple iOS 17.5 because such users will not receive or be able to view and respond to notifications and system warnings on these mobile devices, including alerts for alarms and other events. Notifications and system warnings, including alerts for alarms and other events, will, however, continue to be received by the Arial Server and Arial workstations.

This communication applies only to those users of the Arial Mobile Application running on mobile devices using Apple iOS 17.4 and forthcoming, but not yet released, Apple iOS 17.5.

This communication does not apply to users using mobile devices with an Android operating system.

Aside from the issues described herein for the Arial Mobile Application running on mobile devices utilizing Apple iOS 17.4 and forthcoming, but not yet released, Apple iOS 17.5, the remainder of the Arial Emergency and Nurse Call system is not impacted by this communication and is functioning as intended. Notifications and system warnings, including alerts for alarms and other events, will continue to be received by the Arial Server and Arial workstations.

Affected Product

The Arial Mobile Application running on mobile devices utilizing Apple iOS 17.4 and forthcoming, but not yet released, Apple iOS 17.5 as part of the Arial Emergency and Nurse Call system.

Hazard Involved

The Arial Mobile Application running on mobile devices utilizing Apple iOS 17.4 is frequently restarting, which causes the Arial Mobile Application users to: (1) receive alerts for all pending

notifications of alarms and events when the Arial Mobile Application restarts; (2) experience difficulty in placing and maintaining staff-to-staff phone calls; and (3) appear offline frequently.

Preliminary testing of the forthcoming, but not yet released, beta version of Apple iOS 17.5 indicates that the Arial Mobile Application experiences frequent disconnections when run on mobile devices utilizing Apple iOS 17.5, and the Arial Mobile Application is unable to restart and reconnect after disconnection. This will cause Arial Mobile Application users to be unable to use the Arial Mobile Application on mobile devices running Apple iOS 17.5 because such users will not receive or be able to view and respond to notifications and system warnings, including alerts for alarms and other events, on these mobile devices.

Necessary Actions to be Taken by Clients

For Users that HAVE NOT already upgraded their mobile devices utilizing Apple iOS 17.3 or earlier to Apple iOS 17.4 or Apple iOS 17.5

To avoid the issue described in this notice, users using mobile devices with Apple iOS operating systems that have not already upgraded their operating system to Apple iOS 17.4 should not upgrade their operating system to Apple iOS 17.4 and disable automatic updates. See <u>Exhibit A</u> for instructions on disabling automatic updates. Users should carefully consider the risks, if any, associated with not upgrading to the current Apple iOS operating system.

For Clients that HAVE already upgraded their mobile device operating system to Apple iOS 17.4

There is no current mitigation to the issue described above for users that have upgraded to Apple iOS 17.4. Securitas Healthcare is working to identify and develop a mitigation and permanent solution. Alerts for alarms and other events will continue to be received by the Arial Server and Arial workstations. In the interim, Securitas Healthcare suggests that users use the Arial Server or Arial workstations to view and respond to notifications and system warnings.

Users using mobile devices with Apple iOS 17.4 should not upgrade their operating system to Apple iOS 17.5 and disable automatic updates. See <u>Exhibit A</u> for instructions on disabling automatic updates. Users should carefully consider the risks, if any, associated with not upgrading to the current Apple iOS operating system.

For Users that HAVE already upgraded their mobile device operating system to Apple iOS 17.5

Based upon current preliminary testing, users should not use the Arial Mobile Application with Apple iOS17.5. Notifications and system warnings, including alerts for alarms and other events, will, however, continue to be received by the Arial Server and Arial workstations. Users should use the Arial Server or Arial workstations to view and respond to notifications and alerts, including alerts for alarms and other events.

Users May Use the Arial Mobile App on mobile devices utilizing an Android Operating System
The Arial Mobile Application running on mobile devices utilizing an Android operating system are not affected by this issue. Therefore, users may use the Arial Mobile Application on mobile devices utilizing an Android operating system.

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| **Further Information Support** | For general questions concerning this communication please contact Securitas Healthcare Technical Support at **1 (800) 380-8883**. |

For customers that have licensed the Arial Mobile Application, we ask that you please complete and return a copy of the acknowledgement form attached hereto as <u>Exhibit B</u>.

This notification is being performed with the knowledge of the US Food and Drug Administration (FDA).

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch
- 1 (888) 463-6332

Securitas Healthcare is committed to providing quality products and services to our clients. We apologize for any inconvenience this situation may cause.

Sincerely,

Garth Jack
Senior Director of Quality & Regulatory Compliance

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Exhibit A
How to turn on or turn off automatic updates in you iPhone or iPad

- Open the 'Settings' app on your Apple mobile device
- Select 'General' then 'Software Update'.
- Click on 'Automatic Updates'

Image showing updates enabled.

- Slide each of the switches to the left position to turn them off. Notably iOS updates must be turned off.

Image showing updates disabled.

- Close the "Settings" screen.

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Exhibit B
MEDICAL DEVICE FIELD SAFETY NOTICE RETURN RESPONSE
Acknowledgement and Receipt Form
Response Required

Please execute this acknowledgment regarding Securitas Healthcare's Medical Device Correction Notice for the Arial Mobile Application running on mobile devices utilizing Apple iOS 17.4 as part of the Arial® Emergency and Nurse Call system and return it to the address noted below:

By signing below, you Acknowledge and Certify, that your facility has returned all affected units listed herewith.
Facility Name:
Address:
Print Name:
Signature:
Title:
This facility does not have any affected product in its inventory to date. Initials:_____
This facility has affected product in inventory. _____Units were found and returned. Initials:_____

Please return a copy of this acknowledgment to:

Mr. Garth L. Jack
Senior Director of Quality & Regulatory Compliance
Securitas Technology Corporation
4600 Vine Street, Lincoln, NE 68503
Phone: 402-742-9335