

URGENT: MEDICAL DEVICE CORRECTION

Arial Mobile Application v11.0.0.2 for Android Devices Downloaded from the Google Play Store

January 24, 2023

Dear Valued Client:

Problem Description

Securitas Technology Corporation, transacting under the brand name "Securitas Healthcare" ("Securitas Healthcare") is issuing an Urgent Medical Device Correction to share information about the use of Arial Mobile Application v11.0.0.2 downloaded from the Google Play Store on or after January 14, 2023 on mobile devices utilizing an Android operating system ("Android Devices").

Securitas Healthcare has become aware that versions of the Arial Mobile Application v11.0.0.2 for Android Devices downloaded from the Google Play Store do not load and function on Android Devices, preventing caregivers from receiving, viewing, or responding to notifications and system warnings on their Android Devices.

This communication applies only to those versions of the Arial Mobile Application v11.0.0.2 for Android Devices downloaded from the Google Play Store and **DOES NOT** apply to versions received directly from Securitas Healthcare.

This communication does not apply to clients using mobile devices with an iOS operating system.

Aside from the issues described herein for the Arial Mobile Application v11,0.0.2 for Android Devices downloaded from the Google Play Store, the remainder of the Arial Emergency and Nurse Call system is not impacted by this communication and functioning as intended. Notifications and system warnings will, however, continue to be received, viewed, and responded to via the Arial Server and Arial Web Client.

Affected Product

Arial Mobile Application v11.0.0.2 for Android Devices downloaded from the Google Play Store as part of the Arial® Emergency and Nurse Call system.

Hazard Involved

Arial Mobile Application v11.0.0.2 for Android Devices downloaded from the Google Piay Store will not properly load and function on Android Devices.

Clients that download Arial Mobile Application v11.0.0.2 for Android Devices from the Google Play Store will be unable to use the Arial Mobile Application and will not receive or be able to view and respond to notifications and system warnings on their Android Devices.

Notifications and system warnings will, however, continue to be received, viewed, and responded to via the Arial Server and Arial Web Client.

Necessary Actions to be Taken by Clients

For Clients that HAVE already upgraded to Arial Mobile Application v11.0.0.2 for Android Devices

For clients that have already upgraded their Android Devices to Arial Mobile Application v11.0.0.2 for Android from the Google Play Store, please contact Securitas Healthcare

Securitas Healthcare

Technical Support Team at 1 (800) 380-8883 for instructions on how to obtain and install a working version of the Arial Mobile Application for Android Devices.

In the interim, clients should use the Arial Server or Arial Web Client to view and respond to notifications and system warnings.

Actions for Clients that HAVE NOT yet updated to Arial Mobile Application v11.0.0.2 for Android Devices

Clients may continue to use the version of the Arial Mobile Application (pre version 11.0.0.2) that is currently installed on its Android Devices. Clients, should, however:

- not download or upgrade version of the Arial Mobile Application running on your Android Devices to Arial Mobile Application v11.0.0.2 from the Google Play store
- set the Mobile Device Management package (MDM) to not push Arial Mobile Application v11.0.0.2 updates automatically to your Android Devices
- inform staff and caregivers not to download or install Arial Mobile Application v11.0.0.2 on their own or if prompted by their Android Device
- disable automatic updates on your Android Devices

Actions for all Clients:

- Please disseminate this notice to all affected areas within your facility and any satellite facilities which may be using the mobile application.
- Please complete the attached response form, even if your facility does not use the mobile application.

Further Information Support For general questions concerning this communication or for instructions on installing a working version of the Arial Mobile Application for Android Devices, 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 attached acknowledgement form.

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