varian

Varian Medical Systems 3100 Hansen Way Palo Alto, CA 94304 650.493.4000 800.544.4636 varian.com



TECHNICAL ADVISORY

Subject: Patient selection in ARIA OIS workspaces from

the "Workspace Bar"

Commercial Name of Affected Product: ARIA® Oncology Information System for

Radiation Oncology

Affected Version(s) / Lot(s): 15.1, 15.5, 15.6
Reference / FSCA Identifier: CP-2018-03295
Date of Notification: 2018-12-28

Type of Action: Notification and Correction

DESCRIPTION OF ISSUE:

Varian Medical Systems has identified a problem in ARIA Oncology Information System (OIS) for Radiation Oncology such that a user may inadvertently chart medical record information in an unintended patient's chart.

There have been no reports of injury due to this issue.

DETAILS:

Steps to reproduce the issue --

Prerequisites: Configure favorites in the "Workspace Bar" of ARIA OIS

- 1) Login to User Home
- 2) Navigate to an ARIA OIS workspace e.g. Diagnosis, Documents, Summary, etc...
- 3) Open Patient "A" (at this point, the expected patient is loaded in the workspace)
- 4) Open Patient "B"
- 5) Change workspace before Patient B's medical record had finished loading.

Expected behavior: Patient B's name displays and the new workspace loads with Patient B's medical record

Actual behavior: Patient B's name displays briefly and then reverts to Patient A's name and the new workspace loads with Patient A's medical record.

The behavior may appear random to the user, and its frequency is related to system performance, volume of data in a patient's chart and how quickly another workspace is selected.

RECOMMENDED USER ACTION:

Varian recommends that Users close each patient prior to opening a new one. This will prevent this issue from occurring.

VARIAN MEDICAL SYSTEMS ACTION:

Varian Medical Systems is investigating this issue. The timeline of a technical solution is currently unknown. Varian will contact users as a fix is available.

TECHNICAL ADVISORY

This document contains important information for the continued safe and proper use of your equipment.

- Please retain a copy of this document along with your most current product labeling.
- Advise the appropriate personnel working in your radiotherapy department of the content of this letter.

In compliance with regulatory requirements, we request that you complete the Return Response form provided with this notification. Kindly return the completed form to returnresponse@varian.com.

We sincerely apologize for any inconvenience and thank you in advance for your cooperation. If you require further clarification, please feel free to contact your local Varian Medical Systems service manager. This notice will be provided to the appropriate Regulatory Authorities as required.

Jeff Semone, Vice President Product & Quality Surveillance Varian Medical Systems

Varian Clinical Help Desk Contact Information:

Phone: +1.888.827.4265 Email: support@varian.com