



## IMPORTANT PRODUCT INFORMATION

GE Healthcare

3000 N. Grandview Blvd. - W440  
Waukesha, WI 53188, USA

< Date of Letter Deployment >

GEHC Ref# 26864

To: Hospital Administrators / Risk Managers  
Managers of Radiology/Cardiology  
Radiologist/Cardiologist  
Chairman Medical Board  
Relevant Head of Departments for hospital

**RE: GE Healthcare Revolution EVO, Optima CT660 and Optima CT680 CT SmartPrep function issue**

**Please ensure that all potential users in your facility are made aware of this notification and the recommended actions.**

**Issue** GE Healthcare has become aware of a potential issue on Revolution EVO, Optima CT660 and Optima CT680 CT Systems that could cause additional radiation exposure during use of the SmartPrep feature.

If the system software options are loaded improperly, the system may not transition from the monitor to diagnostic scan phase when the selected Hounsfield unit (HU) trigger value is reached during a SmartPrep procedure. This can result in additional monitoring scans to be performed and may require rescan of the patient. Both of these situations result in additional X-ray radiation exposure to the patient.

**Instructions** You can continue using your system.

Until GE Healthcare can check your system, the following workaround is recommended:

- Monitor the HU level during SmartPrep scans.
- Should the trigger not execute when the desired HU level is reached, manually initiate the diagnostic scan.

**Affected Product Details**

- Revolution EVO (certain software versions - see appendix)
- Optima CT660 (certain software versions - see appendix)
- Optima CT680 (certain software versions - see appendix)

You are being contacted because you have been identified as an owner of one or more of these systems.

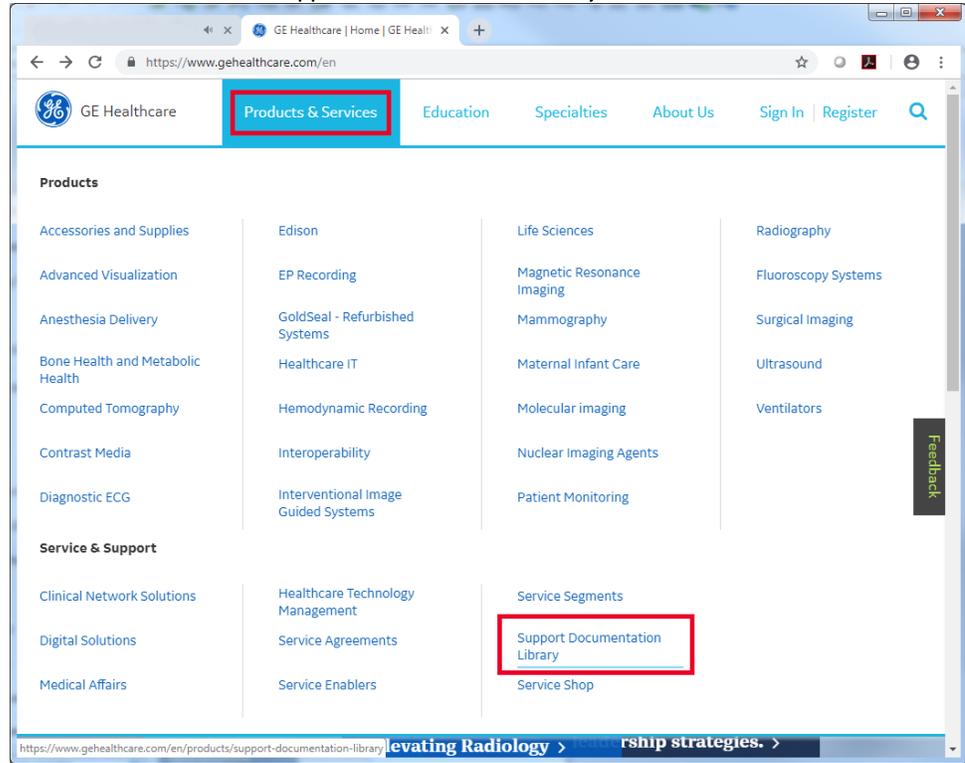
**Product Correction** If your system is affected by this issue and requires software options reloading, a GE Healthcare Service Engineer will, without charge, correct your system by reloading the software options.

In addition, your service provider should update their Service Manuals with the latest version as described below, in order to prevent the issue from happening in the future.

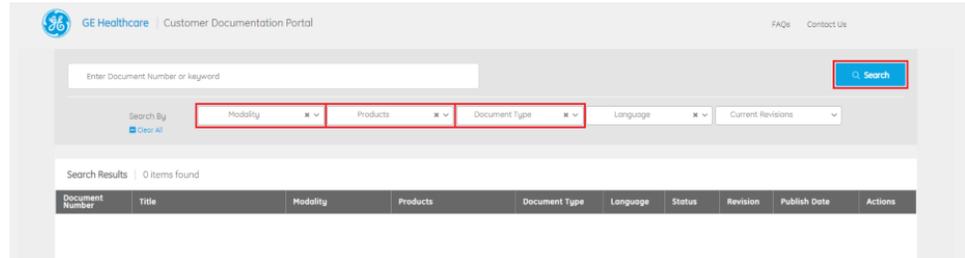
The latest versions of the Service Manuals are available on the Internet:

1. Open an internet browser.
2. Enter URL: [http://www3.gehealthcare.com/en/Global\\_Gateway](http://www3.gehealthcare.com/en/Global_Gateway).
3. Select the appropriate language.

4. Click the Menu icon **Support Documentation Library**.



5. Click Enter **Customer Documentation Portal**.

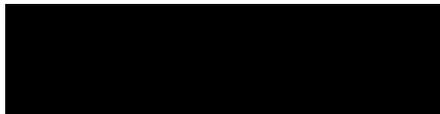


6. From the Customer Documentation Portal, enter the **Modality** = CT, **Product** = (your Product Model), **Documentation Type** = Service Manual, and click Search.

### Contact Information

If you have any questions or concerns regarding this notification, please call the following phone number: United States: 1-800-437-1171 or your local GE Healthcare Service Representative.

Sincerely,



Laila Gurney  
Senior Executive, Quality & Regulatory  
GE Healthcare



Jeff Hersh, PhD MD  
Chief Medical Officer  
GE Healthcare

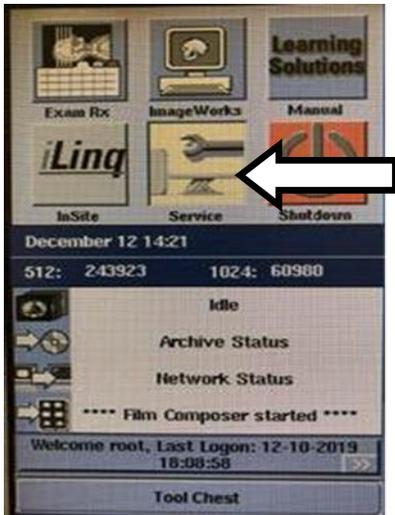
## Appendix

### Affected Software version list

Product	Affected Software Versions
Optima CT660	12HW28.8 14HW30.3 15HW25.2 13HW38.14 15HW13.7
Revolution EVO	14HW17.4 15HW13.7
Optima CT680	13HW38.14 15BW21.2

The installed software version is listed on the Service Desktop, located on the Display/Image Monitor. To check the software version of your system perform the following steps:

1. Select Service Icon. Located on the upper left corner of the Display (Right) Monitor.



2. Select the "Home" Tab along the top of the open window.



3. Locate the Application Software Version in the "Current System Status" box. The software version is represented by the characters up to the first underscore ("\_"). In the example below, the software version is 15HW25.2

Current System Status	
Item	Information
System Date	Thu, Sep 3, 2015
System Time	13:55:40 EDT
Application Software	15HW25.2_SP1-0-1.H40_PN_5564_G_GMV
Next Patient Exam	3208
SW Updates	Manual Installation Required
Recon Status	Idle
Archive Status	There is no media in the drive.
Network Status	Sent: 3205/602 (integrad)
Filming Status	**** Film Composer started ****

