URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 28066

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator
Director of Biomedical Engineering

RE: **Potential smoke or flame on CT Revolution ACTs**

Safety Issue

Some CT Revolution ACTs systems may produce smoke or flame in the vicinity of the gantry scan window under certain conditions. If smoke or flame occurs, it may pose a risk to people in the scanning room. GE HealthCare (GEHC) has received three reports of damage to systems related to this issue. No patient injuries have been reported.

Actions to be taken by Customer /User

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

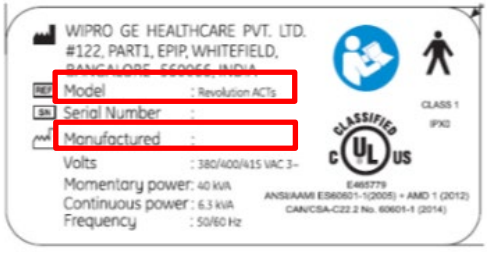
You can continue to use your system. In accordance with operator manuals and good clinical practices, maintain direct supervision of all patients and the scanning room when patients are present. If you see a spark, flame, or smoke coming from your system:

1. Immediately de-energize the system using the nearest Emergency Stop (E-stop) button.
2. Follow your local response procedures.
3. Contact your service engineer.

Please complete and return the attached acknowledgement form to RecallFMI28066.mailbox@ge.com.

Affected Product Details

All CT Revolution ACTs (CT Revolution ACTs ES, CT Revolution ACTs EX, and CT Revolution ACTs Expert Edition) manufactured between March 25, 2015 and December 23, 2020. The model and manufacture date are located on the rating plate which can be found on the back of the CT gantry on the lower right hand side as pictured below.



Product Correction	GE HealthCare will correct all affected products at no cost to you. A GE HealthCare representative will contact you to arrange for the correction.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

GE HealthCare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,

[redacted]

Chief Quality & Regulatory Officer
GE HealthCare

[redacted]

Chief Medical & Safety Officer
GE HealthCare

GE HealthCare Ref. # 28066

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE Healthcare promptly upon receipt of this letter and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

There are two options for your convenience:

1) Electronic response form (this page)

   OR

2) Manual filled and scanned response form (next page)

Please scan the QR code or follow the link below to complete the workflow

https://supportcentral.ge.com/esurvey/GE_survey/takeSurvey.html?form_id=18446744073710514868

Alternatively, if the workflow on the previous page is not possible, please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: RecallFMI28066.mailbox@ge.com