

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 30121

To: HealthCare Administrator / Risk Manager
Director of Cardiology Department

RE: **CASE™ v7– Thermal Printer Assembly**

Safety Issue

GE HealthCare has become aware of a potential for electrical sparking at the printer head of CASE v7 Systems. In the unlikely situation that the Electrostatic Discharge (ESD) printer brush becomes dislodged, electrical sparking at the printer head can result in charring or discoloration of the thermal printer paper. In rare cases, ignition of the paper could result in serious thermal injury.

There have been no injuries reported to GE HealthCare as a result of this issue.

Actions to be taken by Customer/User

Pending corrections from GE HealthCare, please perform a visual inspection of the printer assembly to verify proper positioning of the ESD brush by following the steps below:

1. Open the printer door and visually inspect the ESD brush.
2. Using Figures 1 and 2 below, assess the location and alignment of the ESD brush
 - a. If the brush is properly positioned and aligned as shown in Figure 1: you can continue to use the device.
 - b. If the brush appears misaligned or displaced as shown in Figure 2: stop using the device and contact a GE HealthCare Service representative.

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

Please retain this document for your records.

Please complete and return the attached acknowledgement form electronically via [FMI 30121 Digital Response Form](#) or print, fill out manually, scan, and email to DCAR.Recall@gehealthcare.com

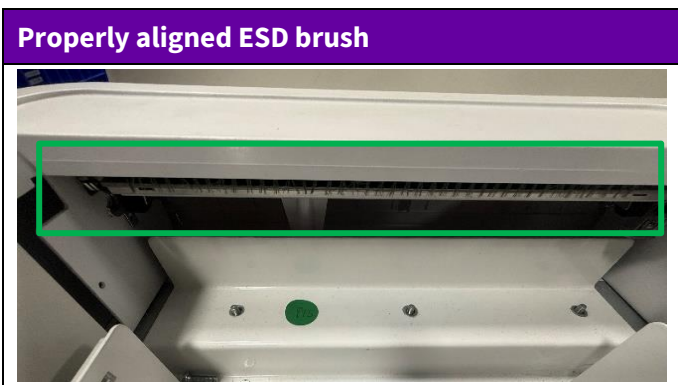


Figure 1: Properly aligned ESD brush.

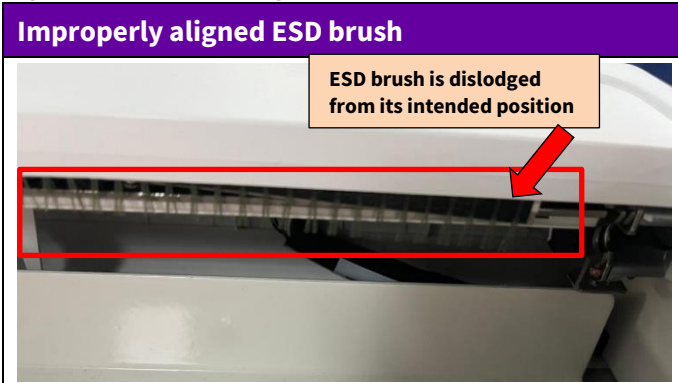


Figure 2: Improperly aligned ESD brush

Affected Product Details

Product	Product Code	GTIN Number
CASE™ v7	SU3	00195278617644

Intended Use:

The CASE v7 System is designed to acquire, process, record, archive, analyze and output ECG data (12 and 15 leads) during a period of physiologic stress or during a resting ECG test and acquire data from ancillary devices, such as spirometry and ambulatory blood pressure devices. Furthermore, it provides median morphology recordings and records ECG in real-time with and without arrhythmia detection.

The CASE v7 System is intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients.

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.

1800 992 557
 healthcareserviceireland@gehealthcare.com

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact GE HealthCare per the contact information below.

Sincerely,

Handwritten signature of Laila Gurney in blue ink, featuring a stylized 'L' and 'G' followed by a long horizontal flourish.

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Handwritten signature of Scott Kelley in blue ink, consisting of the letters 'SK' followed by a loop and a tail.

Scott Kelley
Chief Medical Officer
GE HealthCare

**FIELD SAFETY NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

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 Field Safety Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Field Safety Notification, and that we have informed all potential users 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: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

<p>To complete this form electronically, please scan the QR Code below or click this link: https://gehealthcare-svc.my.site.com/publicForm/s/?formId=aGjUr000003505h</p> 	<p>To complete this form via email, scan or take a photo of the completed form and email to: DCAR.Recall@gehealthcare.com</p> 
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