



URGENT FIELD SAFETY NOTICE

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 76188

To: Hospital Administrators / Risk Manager
Biomedical Engineering
Head of Cardiac Ultrasound Department

RE: Unexpected system shutdown of Vivid Ultrasound Systems v204 when using DICOM Modality Worklist fields containing non-ASCII characters

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

GE Healthcare became aware that certain Vivid ultrasound systems can unexpectedly shut down when manually or automatically storing images to PACS. This could occur if non-ASCII characters such as "Ø" or "Æ" are contained in the scheduled procedure descriptions or accession number in the DICOM Modality Worklist. This situation is unlikely to occur. If this situation does occur and the system shuts down during an interventional procedure, it may result in loss of imaging during the procedure. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use the system. To avoid this issue, do not select any exams from the Archive screen. Exams must be manually entered by pressing the "Create Patient" or "Add Exam" buttons. When manually entering a new exam, you must populate the accession number in the DICOM Modality Worklist with ASCII characters only. ASCII characters are shown in Figure 1 (below).

Figure 1: Allowed characters.

	!	"	#	\$	%	&	'	()	*	+	,	-	.	/
0	1	2	3	4	5	6	7	8	9	:	;	<	=	>	?
@	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
P	Q	R	S	T	U	V	W	X	Y	Z	[\]	^	_
`	a	b	c	d	e	f	g	h	i	j	k	l	m	n	o
p	q	r	s	t	u	v	w	x	y	z	{		}	~	

Affected Product Details

Affected product software versions:
Vivid E95/E90/E80: 204.41.2
Vivid S70N/S60N: 204.41.2 and 204.41.3
Vivid iq: 204.39.0
Vivid T8/T9: 204.39.0 and 204.39.1

**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.

After the GE Healthcare representative has updated your system, be sure to destroy the affected software installation media at your site.

**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 per the contact information above.

Sincerely,





**MEDICAL DEVICE 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 Medical Device Correction Notice.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

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): _____

Please return completed form by scanning or taking a photo of the completed form and email to:

Recall.76188@ge.com

