



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
4 Hayozma St. PO Box 170
Tirat Ha Carmel, 30200, Israel

December 18, 2022

GEHC Ref. # 40901

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

RE: **GE Healthcare requests STOP USE of certain Nuclear Medicine 600/800 series systems until inspected**

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

Safety Issue

For certain Nuclear Medicine systems (see Affected Product Details and Appendix), GE Healthcare has become aware that a mitigation may not be correctly implemented. If this is the case, the detector can fall leading to life-threatening bodily injury.

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

Actions to be taken by Customer/User

GE Healthcare asks that you **STOP USE** of your Nuclear Medicine system, if your system is listed in the Affected Product Details and Appendix of this letter, until an inspection of your system is completed by GE Healthcare and you have been provided with a letter indicating the system can be returned to clinical use.

Please complete the attached Urgent Medical Device Correction Letter Acknowledgement Response form and send to **Recall.40901@ge.com**

Affected Product Details

The impacted Nuclear Medicine 600/800 Series systems are Brivo 615, Discovery NM 630, Optima 640, Discovery NM/CT 670 DR, Discovery NM/CT 670 ES, Discovery NM/CT 670 Pro, Discovery NM/CT 670 CZT, NM 830, NM 830 ES, NM/CT 850, NM/CT 850 ES, NM/CT 860, NM/CT 860 ES, NM/CT 870 CZT, NM/CT 870 DR, NM/CT 870 ES

Please refer to the Appendix for a list of impacted systems. To locate the serial number of your system, please contact your local Service Representative or find the serial number on the rating plate label which is on the lower left of your Nuclear Medicine gantry:



Product Correction

GE Healthcare will correct all affected products at no cost to you. GE Healthcare will inspect your system to ensure that the appropriate mitigation is correctly

implemented to address this potential life-threatening concern. A GE Healthcare representative will contact you to arrange for this correction.

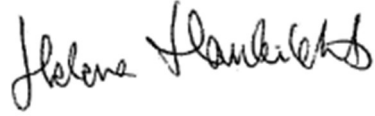
Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Helena Haukilehto
Medical Director
GE Healthcare



**URGENT MEDICAL DEVICE CORRECTION 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 Urgent Medical Device Correction Letter.

*Customer/Consignee
Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

We acknowledge that we have stopped use of the affected Nuclear Medicine system and will not resume use until an inspection is completed by GE Healthcare. We acknowledge receipt and understanding of the accompanying Urgent Medical Device Correction Letter, 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: Recall.40901@ge.com



Appendix - Serial Numbers Impacted by FMI Ref 40901

21128	63GX50009	63GX50053	63GY50094	63GZ50135
22404	63GX50010	63GX50054	63GY50095	63GZ50136
26043	63GX50011	63GX50055	63GY50096	63GZ50137
27053	63GX50012	63GX50056	63GY50097	63GZ50138
NT2PG1800001	63GX50013	63GX50057	63GY50098	63GZ50139
NT3AG1900004	63GX50014	63GX50058	63GY50099	63GZ50140
NT3AG1900005	63GX50015	63GX50059	63GY50100	63GZ50141
NT3AG1900015	63GX50016	63GX50060	63GY50101	63GZ50142
NT3AG2000004	63GX50017	63GX50061	63GY50102	63GZ50143
NT3AG2200003	63GX50018	63GX50062	63GY50103	63GZ50144
NT3DG2100005	63GX50019	63GX50063	63GY50104	63GZ50145
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63GX50002	63GX50045	63GY50087	63GY50128	64GY51018
63GX50003	63GX50046	63GY50088	63GY50129	64GY51019
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ESGY53002	NT3AG1900003	NT3AG2100013	NT3CG1900010	NT3DG2000006
ESGY53003	NT3AG1900006	NT3AG2100014	NT3CG2000001BH	NT3DG2000008
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NT3DG2100014	PRGX52007	PRGZ52049
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NT3DG2100018	PRGX52009	PRGZ52051
NT3DG2200001	PRGX52010	PRGZ52052
NT3DG2200002	PRGY52011	PRGZ52053
NT3DG2200003	PRGY52012	PRGZ52054
NT3DG2200004	PRGY52013	PRGZ52055
NT3DG2200004BH	PRGY52014	PRGZ52056
NT3DG2200005	PRGY52015	PRGZ52057
NT3DG2200006	PRGY52016	PRGZ52058
NT3DG2200007	PRGY52017	PRGZ52059
NT3DG2200008	PRGY52018	
NT3DG2200009	PRGY52020	
NT3DG2200010	PRGY52021	
NT3DG2200011	PRGY52022	
NT3DG2200012	PRGY52023	
NT3DG2200013	PRGY52024	
NT3DG2200014	PRGY52025	
NT3DG2200015	PRGY52026	
NT3DG2200016	PRGY52027	
NT3DG2200017	PRGY52028	
NT3DG2200018	PRGY52029	
NT3DG2200019	PRGY52030	
ONMX26515	PRGY52031	
PRGA52060	PRGY52032	
PRGA52061	PRGY52033	
PRGA52062	PRGY52034	
PRGA52063	PRGY52035	
PRGA52064	PRGY52036	
PRGA52065	PRGY52037	
PRGA52066	PRGY52038	
PRGA52067	PRGY52039	
PRGA52068	PRGZ52040	