



HITNA SIGURNOSNA OBAVIJEST

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

18. prosinca 2022.

GEHC Ref. # 40901

Za: Ravnatelj kliničke službe/radiologije
Upravitelj rizika/administrator bolnice
Ravnatelj biomedicinske tehnike

Predmet: **GE Healthcare zahtijeva PREKID UPORABE određenih sustava serije 600/800 za nuklearnu medicinu dok se ne pregledaju**

Ovaj dokument sadržava važne informacije koje se odnose na vaš proizvod. Osigurajte da svi potencijalni korisnici u vašoj ustanovi budu upoznati s ovom sigurnosnom obavijesti i radnjama. Čuvajte ovaj dokument u svojoj evidenciji.

Sigurnosna pitanja Za neke sustave nuklearne medicine (vidi Pojediniosti proizvoda na koje se ovo odnosi i Dodatak), GE Healthcare je postala svjesna da smanjenje možda neće biti ispravno primijenjeno. Ako je to slučaj, detektor možda neće očitati ozljedu tijela opasnu po život.

Nisu zabilježene ozljede koje bi bile posljedice ovog problema.

Radnje koje mora poduzeti kupac/korisnik GE Healthcare od vas zahtijeva **PREKID UPORABE** vašeg sustava nuklearne medicine ako je vaš sustav naveden u Pojediniostima proizvoda na koje se ovo odnosi i Dodatku ovog pisma, dok GE Healthcare ne obavi pregled vašeg sustava i dok vam ne da pismo kojim se naznačava da se sustav može vratiti u kliničku uporabu.

Molimo popunite priloženi obrazac Odgovor o potvrdi pisma za hitnu ispravku medicinskog uređaja i pošaljite na **Recall.40901@ge.com**

Pojediniosti proizvoda na koje se to odnosi: Sustavi serije 600/800 za nuklearnu medicinu na koje je ovo utjecalo su 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

Molimo pogledajte Dodatak za popis sustava na koje je ovo utjecalo. Kako biste pronašli serijski broj vašeg sustava, molimo kontaktirajte svog servisnog predstavnika usluge ili pronađite serijski broj na etiketi pločice s ocjenom koja se nalazi dolje lijevo na portalu nuklearne medicine:



SN	Ser. br.:	
	Proizvedeno:	
	Mjesec/GGGG	
Nominalni napon: 3N ~ 380/400/420/440/460/480 V		
Trenutačna snaga: 90 kVA, 0,85 pf		
Stalna snaga: 22 kVA		
Frekvencija: 50/60 Hz		
Klasa I		
GE MEDICAL SYSTEMS, ISRAEL FUNCTIONAL IMAGING 4 Hayozma Street TIRAT HACARMEL, 30200 ISRAEL		
5482652-HR		

**Popravak
proizvoda**

GE Healthcare će ispraviti sve zahvaćene proizvode bez ikakvih troškova za vas. GE Healthcare će pregledati vaš sustav kako bi osigurala da je odgovarajuće smanjenje ispravno primijenjeno kako bi se riješio ovaj potencijalni problem koji ugrožava život. Predstavnik tvrtke GE Healthcare će vas kontaktirati kako bi dogovorili ispravak.

**Kontakt
informacije**

Ako imate bilo kakvih pitanja ili dvojbi u vezi s ovom obavijesti, obratite se servisu tvrtke GE Healthcare ili lokalnom servisnom predstavniku.

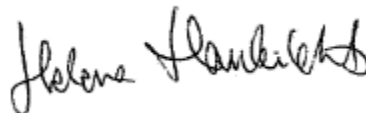
GE Healthcare potvrđuje da su o postojećem nedostatku obaviještene odgovarajuće regulatorne agencije.

Budite uvjereni da je osiguranje visoke razine sigurnosti i kvalitete naš najviši prioritet. Ako imate bilo kakvih pitanja, obratite nam se odmah putem gornjih podataka za kontakt.

S poštovanjem,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Helena Haukilehto
Medical Director
GE Healthcare



**PRIZNANJE O HITNOJ ISPRAVCI MEDICINSKOG UREĐAJA
POTREBAN ODGOVOR**

Ispunite ovaj obrazac i vratite ga tvrtki GE Healthcare odmah po primitku, a najkasnije u roku od 30 dana od primitka. Ovim potvrđujemo da smo primili i shvatili Pismo o hitnoj ispravci medicinskog uređaja.

* Ime kupca/primatelja: _____

Adresa: _____
Grad/Županija/Poštanski broj/Država: _____

* Adresa e-pošte kupca: _____

* Broj telefona kupca: _____



Shvaćamo da smo prekinuli uporabu sustava nuklearne medicine na kojeg se ovo odnosi i nećemo nastaviti uporabu dok GE Healthcare ne dovrši pregled. Potvrđujemo primitak i razumijevanje popratne Obavijesti o ispravci za medicinski uređaj, te da smo obavijestili odgovarajuće osoblje, poduzeli i poduzet ćemo odgovarajuće radnje u skladu s tom Obavijesti.

Navedite ime odgovorne osobe koja je ispunila ovaj obrazac.

Potpis: _____

* Ime tiskanim slovima: _____

* Naslov: _____

* Datum (DD/MM/GGGG): _____

* Označena obvezna polja

Pošaljite ispunjeni obrazac skeniranjem ili fotografiranjem ispunjenog obrasca i pošaljite e-poštu na: Recall.40901@ge.com



Dodatak - Serijski brojevi na koje FMI Ref 40901 utječe

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DRGZ56050	NT2RG1900004BH	NT3AG2100004BH	NT3BG2200005	NT3DG1900012
DRGZ56051	NT2RG1900005	NT3AG2100005	NT3BG2200006	NT3DG1900013
DRGZ56052	NT2RG2000001	NT3AG2100006BH	NT3CG1900002	NT3DG1900014
DRGZ56053	NT2RG2200001	NT3AG2100007	NT3CG1900003	NT3DG1900015
DRGZ56054	NT2UG2100001	NT3AG2100008	NT3CG1900005	NT3DG2000001
DRGZ56055	NT2UG2100002	NT3AG2100009	NT3CG1900006	NT3DG2000002
DRGZ56056	NT3AG1800001	NT3AG2100010	NT3CG1900007	NT3DG2000003
ESGA53007	NT3AG1800002	NT3AG2100011	NT3CG1900008	NT3DG2000004
ESGY53001	NT3AG1900001	NT3AG2100012	NT3CG1900009	NT3DG2000005
ESGY53002	NT3AG1900003	NT3AG2100013	NT3CG1900010	NT3DG2000006
ESGY53003	NT3AG1900006	NT3AG2100014	NT3CG2000001BH	NT3DG2000008
ESGZ53004	NT3AG1900007BH	NT3AG2100015	NT3CG2000002BH	NT3DG2000010
ESGZ53005	NT3AG1900008	NT3AG2100016	NT3CG2000003	NT3DG2000011
ESGZ53006	NT3AG1900009	NT3AG2200001	NT3CG2000004	NT3DG2000012
ESPX54001	NT3AG1900010	NT3AG2200002BH	NT3CG2100001	NT3DG2000014BH
ESPY54002	NT3AG1900011	NT3AG2200004	NT3CG2100002	NT3DG2000015
ESPY54003	NT3AG1900012	NT3AG2200005	NT3CG2100003	NT3DG2000016
NT2PG1900001	NT3AG1900013	NT3AG2200006	NT3CG2100004	NT3DG2100001
NT2PG1900002	NT3AG1900014	NT3AG2200007BH	NT3CG2100005	NT3DG2100002BH
NT2PG1900003	NT3AG1900016	NT3AG2200008	NT3CG2100006	NT3DG2100003
NT2PG1900004	NT3AG1900017	NT3AG2200009	NT3CG2200001	NT3DG2100004

NT3DG2100006	PRGA52069	PRGZ52041
NT3DG2100007	PRGA52070	PRGZ52042
NT3DG2100008	PRGX52001	PRGZ52043
NT3DG2100009	PRGX52002	PRGZ52044
NT3DG2100010	PRGX52003	PRGZ52045
NT3DG2100011	PRGX52004	PRGZ52046
NT3DG2100012	PRGX52005	PRGZ52047
NT3DG2100013	PRGX52006	PRGZ52048
NT3DG2100014	PRGX52007	PRGZ52049
NT3DG2100015	PRGX52008	PRGZ52050
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	
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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	