



State of California—Health and Human Services Agency
California Department of Public Health



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

**GE Medical Systems Israel Recalls Nuclear Medicine 600/800 Series
 Products due to Potential Detector Fall**

Recall Date	Product Description	Recalling Firm	Recall Reason
2/15/2023	<p>GE Nuclear Medicine 600/800 series systems a) 870, b) 870 DR 3/8 inch NM GANTRY WITH NEW ROTOR - MEA, c) 870 DR / Dismount, d) 870 DR / Dismount / 60HZ, e) 870 DR 3/8 inch WSO, f) 870 DR 3/8 inch NM Gantry, g) 870 DR 3/8 inch, h) 870 DR 3/8 inch CH, i) 870 DR 5/8 inch NM GANTRY, j) 870 DR BJ / Dismount, k) 870 DR CyberDefense 3/8 inch NM Gantry, l) 870 DR NM GANTRY FINAL - NEW ROTOR, m) 870 DR China, n) D670 NM GANTRY WITH NEW ROTOR, o) D670 DR 3/8 inch 16 SL, p) D670 DR 3/8 inch MEA, q) D670 DR 3/8 inch, r) D670 DR 3/8 inch 16SL, s) D670 DR 3/8 inch 16SL NR, t) D670 DR 3/8 inch BJ, u) D670 DR 3/8 inch MEA, v) D670 DR NM Gantry 3/8 inch, w) D670 DR NM Gantry 5/8 inch, x) D670 DR with new rotor, y) D670 ES NM Gantry 3/8 inch, z) D670 ES NM/CT 3/8 inch O540+ NM Gantry, aa) D670 ES NM/CT DR 3/8 inch, bb) D670 GANTRY, cc) D670 PRO NM Gantry 3/8 inch, dd) D670 PRO NM GANTRY 3/8 inch, ee) DISC NM/CT670 DR 3/8 inch, ff) DISC</p>	<p>GE Medical Systems Israel, Functional Imaging Tirat Carmel, Israel</p>	<p>A mitigation may not be correctly implemented. If this is the case, the detector can fall, leading to life-threatening bodily injury.</p>

	<p>NM/CT870 DR 3/8 inch, gg) DISC NM/CT870 DR 3/8 inch, hh) DISC NM/CT870 DR 5/8 inch, ii) DISCOVERY 670 (TANDEM), jj) DISCOVERY NM 670, kk) DISCOVERY NM/CT 670 3/8 inch PRO, ll) DISCOVERY NM/CT 670 3/8 inch PRO NR, mm) HP Z420 WS Config 1 Hardware Specs Take 3 - E5-1620-8G-1TB- NVS, nn) NM/CT 870 DR, oo) NM/CT 870 DR 3/8 inch CYBER DEFENCE, pp) NM/CT 870 DR 3/8 inch WSO, qq) NM/CT 870 DR O540 3/8 inch, rr) NM/CT 870 DR O540 3/8 inch BJ, ss) NM/CT 870 DR O540 5/8 inch, tt) NM/CT 870 ES 3/8 inch, uu) NM/CT 870DR China for China, vv) NM/CT870 DR 3/8 inch O540, ww) NM/CT D870 DR O540 3/8 inch, xx) TANDEM DISCOVERY 670 INT; Emission Computed Tomography System</p>		
2/14/2023	<p>GE Nuclear Medicine 600/800 series systems a) 830, b) 830 / Dismount, c) 830 /, d) 830 / 5842894-20, e) 830 / Dismount / 50HZ, f) 830 / Dismount / 60HZ, g) 830 3/8 inch Detector, h) 830 BJ, i) 830 BJ / 5144407, j) 830 BJ / Dismount, k) 830 ES DEM, l) 830 NM Cyber Defense Configuration Gantry 3/8 inch, m) 830 NM Gantry 3/8 inch, n) 830 NM Gantry 5/8 inch, o) 870 DR NM GANTRY FINAL - NEW ROTOR, p) B615 to D630 UPG, q) D630 NM GANTRY, r) D630 NM GANTRY 3/8 inch WITH NEW ROTOR - MEA, s) D630 NM Gantry 3/8 inch, t) D630 NM GANTRY FINAL ASSEMBLY_, u) D630 with new rotor, v) D630 with new rotor/ 5144407 / Dismount, w)</p>	<p>GE Medical Systems Israel, Functional Imaging Tirat Carmel, Israel</p>	<p>Potential Detector Fall</p>

	<p>D630 with new rotor/ Dismount, x) DISCOVERY D630 X 3/8 inch, y) DISCOVERY D630 X 3/8 inch, z) DISCOVERY D630 X 3/8 inch, aa) DISCOVERY D630 x 3/8 inch BHW, bb) DISCOVERY D630 X 3/8 inch BJG, cc) DISCOVERY D630 X 3/8 inch MEA, dd) DISCOVERY NM 830 3/8 inch, ee) DISCOVERY NM 830 3/8 inch, ff) NM 830 3/8 inch, gg) NM 830 3/8 inch BJ, hh) NM 830 ES, ii) NM DISCOVERY D630 3/8 inch, jj) NUC GOLDSEAL D630 X 3/8 inch. Emission Computed Tomography System</p>		
2/14/2023	<p>GE Nuclear Medicine 600/800 series systems a) BRIVO B615 3/8 inch DHP BJG NR, b) BRIVO 615 3/8 inch, c) BRIVO B615 3/8 inch DHP BJG NR, d) B615 with new rotor, e) BRIVO B615 3/8 inch BJG, f) BRIVO B615 3/8 inch DHP BJG NR, g) B615 with new rotor; Emission Computed Tomography System</p>	<p>GE Medical Systems Israel, Functional Imaging Tirat Carmel, Israel</p>	Potential Detector Fall
2/14/2023	<p>GE Nuclear Medicine 600/800 series systems a) OPTIMA O640 X 3/8 inch NR, b) DISCOVERY O640 X 3/8 inch, c) NM OPTIMA O640 X 3/8 inch, d) O640 NM Gantry 3/8 inch, e) O640 NM GANTRY FINAL ASSY, f) OPTIMA O640 X 3/8 inch; Emission Computed Tomography System</p>	<p>GE Medical Systems Israel, Functional Imaging Tirat Carmel, Israel</p>	Potential Detector Fall
2/14/2023	<p>GE Nuclear Medicine 600/800 series systems a) 870 CZT O540+ Gantry 7.25mm, b) D670 CZT Gantry 7.25mm, c) DISCOV NM/CT</p>	<p>GE Medical Systems Israel, Functional Imaging Tirat Carmel, Israel</p>	Potential Detector Fall

	870 CZT, d) Discovery NMCT 670 CZT O540+, e) NM/CT 870 CZT CYBER DEFENCE, f) NM/CT 870 CZT O540, g) NM/CT 870 CZT WSO, h) NM/CT 870 CZT, i) NM/CT 870 CZT O540+ 7.25MM; Emission Computed Tomography System		
2/14/2023	<p>GE Nuclear Medicine 600/800 series systems</p> <p>a) 850, b) 850 / Dismount, c) 850 3/8 inch NM Gantry, d) 860 / Dismount, e) 860 3/8 inch NM Gantry, f) 860 5/8 inch NM Gantry, g) 860 BJ, h) NM 830 3/8 inch BJ, i) NM/CT 850 3/8 inch BJ, j) NM/CT 850 3/8 inch ROW, k) NM/CT 850 3/8 inch ROW_, l) NM/CT 850 CT 850 3/8 inch, m) NM/CT 850 ES 3/8 inch, n) NM/CT 850 ES 3/8 inch ROW, o) NM/CT 860 3/8 inch, p) NM/CT 860 3/8 inch BJ, q) NM/CT 860 3/8 inch ROW, r) NM/CT 860 ADVANCE, s) NM/CT 860 advance 3/8 inch NM Gantry, t) NM/CT 860 BEYOND, u) NM/CT 860 beyond 3/8 inch NM Gantry, v) NM/CT 860 China for China, w) NM/CT 860 CT 860 3/8 inch, x) NM/CT 860 ES 3/8 inch, y) NM/CT 860 ES 3/8 inch ROW, z) NM/CT 850 3/8 inch, aa) NM/CT 850 ES 3/8 inch ROW, bb) NM/CT 860 3/8 inch CH, cc) XELERIS 4 DR WORKSTATION; Emission Computed Tomography System</p>	<p>GE Medical Systems Israel, Functional Imaging</p> <p>Tirat Carmel, Israel</p>	Potential Detector Fall

Recall Class	Product Identification	Distribution	Affected Dates
I	<p>GE Nuclear Medicine 600/800 series systems</p> <p>a) 870: Catalog number To be provided, UDI/DI Not Applicable,</p>	557 units worldwide	December 2022 and prior

Serial Numbers:
NT3DG2200004,
NT3DG2200009,
NT3DG2200018,
NT3DG2200002; b) 870 DR
3/8" NM GANTRY WITH NEW
ROTOR - MEA: Catalog number
5376204-70-60-1, UDI/DI Not
Applicable, Serial Numbers:
NT3DG2100018BH; c) 870 DR /
Dismount: Catalog number To be
provided, UDI/DI To be provided,
Serial Numbers:
NT3DG2100006; d) 870 DR /
Dismount / 60HZ: Catalog
number To be provided, UDI/DI
To be provided, Serial Numbers:
NT3DG2000016BH; e) 870 DR
3/8" WSO: Catalog number
H3906EM, UDI/DI Not
Applicable, Serial Numbers:
870B64224, 870Z64148; f) 870
DR 3/8" NM Gantry: Catalog
number H3100AS, UDI/DI Not
Applicable, Serial Numbers:
870Y64064, 870Y64040,
870A64172, 870Z64145,
870A64161, 870Z64111,
870Z64126, 870Y64081,
870A64210, 870X64003,
870A64180, 870Y64047,
870Y64044, 870Y64079,
870Y64050, 870Z64130,
870X64011, 870Y64095,
870Y64037, 870Y64074,
870Y64067, 870Y64051,
870A64162, 870X64024,
870A64163, 870A64165,
870X64002, 870Y64072,
870Z64107, 870Z64108,
870X64032, 870A64192,
870A64183, 870A64164,
870B64229, 870A64176,
870A64185, 870Z64137,
870Z64117, 870X64001,
870Y64055, 870Y64088,
870B64235, 870Y64078,
870Y64080, 870Z64125,
870Z64098, 870A64204,
870A64205, 870B64306,
870B64305, 870A64182,
870B64261, 870Y64069,
870Z64104, 870Y64042,
870Y64039, 870Y64086,

870Z64146, 870A64179,
870Y64085, 870A64168,
870Z64103, 870Y64094,
870Z64101, 870A64160,
870B64300, 870Y64046,
870B64302, 870A64199,
870Y64056, 870Z64121,
870A64174, 870X64004,
870X64012, 870X64007,
870Y64048, 870X64009,
870Z64124, 870X64026,
870Z64119, 870Z64122,
870Y64049, 870Y64089,
00000870Y64035, 870Z64134,
870Y64052, 870Y64076,
870Y64063, 870A64159,
870Z64133, 870B64286,
870B64247, 870B64244,
870A64184, 870B64240,
870B64264, 870B64287,
870A64196, 870A64187,
870B64307, 870A64208,
87EB77017, 870X64016,
870X64005, 870Z64136,
870Y64033, 870A64153,
870A64154, 870B64227,
870Y64091, 870B64231,
870B64292, 870Z64149,
87EA77011, 870X64022,
870Y64053, 870Z64114,
870Z64115, 87EZ77003,
87EB77016, 87EZ77004,
870B64233, 870Z64141,
87EB77014, 870A64175,
87EB77015, 870X64019,
870A64188, 870Y64059,
870Y64068, 870Y64071,
870Y64082, 870B64265,
870Z64102, 870X64020,
870Y64090, 870B64262,
870B64274, 870B64268,
870B64275, 870Z64128,
870B64270, 870B64271,
870B64272, 870B64273,
870B64266, 870B64280,
870B64267, 870Z64116,
870B64276, 870B64277,
870B64278, 870B64279,
870B64269, 870B64281,
870B64282, 870B64283,
870Z64142, 870Y64065,
870A64158, 870X64025,
87EZ77001, 870Z64120,
870Y64038, 870B64236,

870Y64077, 870A64202,
870A64207, 870B64251,
870B64221, 870A64197,
870X64010, 870Y64073,
870Y64036, 870Y64092,
870Y64087, 870X64027,
870X64029, 870Y64084,
870X64030, 870X64023,
870X64028, 87EA77010,
87EA77012, 870B64222,
870A64155, 870B64226,
870B64225, 87EB77018,
870B64297, 870B64299,
870B64293, 87EB77019,
870B64258, 870A64209,
87EZ77007, 870B64253,
870A64217, 870Z64127,
870B64285, 870Y64083,
870B64257, 870B64259,
870X64013, 870B64252,
870Z64105, 870Y64061,
870B64284, 870B64254,
870B64260, 870B64308,
870B64296, 870B64303,
870Z64110, 870Z64144,
870Y64075, 870A64171,
870A64215, 870A64212,
870Z64129, 870X64021,
870A64198, 870B64230,
870Z64113, 870Z64131,
870Z64132, 870Y64070,
870Z64140, 870B64263,
870B64294, 870A64190,
870Y64058, 870B64241,
870Z64135, 870Y64097,
870Z64099, 870Z64151,
870Y64057, 870A64157,
870B64242, 870B64243,
870B64250, 870Z64109,
870B64237, 870Z64106,
870A64173, 870X64008,
870A64152, 870B64218,
870B64234, 870B64238,
870B64239, 870A64200; g)
870 DR 3/8": Catalog number
H3100AP, UDI/DI Not
Applicable, Serial Numbers:
870Y64034; UDI/DI
010084068214083621870X6401
511180900, Serial Numbers:
870X64015; h) 870 DR 3/8"
CH: Catalog number H2402AG,
UDI/DI To be provided, Serial
Numbers: NT3DG1900005BH;

UDI/DI Not Applicable, Serial Numbers: NT3DG1800002BH; i) 870 DR 5/8" NM GANTRY: Catalog number H3100Q, UDI/DI 010084068214083621870X6401 811181000, Serial Numbers: 870X64017; UDI/DI 010084068214083621870Y6406 611190700, Serial Numbers: 870Y64066; UDI/DI Not Applicable, Serial Numbers: 870Y64045, 870A64201, 00000870X64014, 870Y64041; j) 870 DR BJ / Dismount: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3DG1900013BH; k) 870 DR CyberDefense 3/8" NM Gantry: Catalog number H3906FF, UDI/DI Not Applicable, Serial Numbers: 87CA83004, 87CA83001; , UDI/DI To be provided, Serial Numbers: 87CA83002, 87ZA83005; l) 870 DR NM GANTRY FINAL - NEW ROTOR: Catalog number H3100AS, UDI/DI To be provided, Serial Numbers: 870B64288, 00000870Z64139; m) 870 DR China: Catalog number To be provided, UDI/DI To be provided, Serial Numbers: NT3DG2100016BH; n) D670 NM GANTRY WITH NEW ROTOR: Catalog number 5791566, UDI/DI To be provided, Serial Numbers: 870A64203, 87EA77013, 870B64255; o) D670 DR 3/8" 16 SL: Catalog number 5791566, UDI/DI To be provided, Serial Numbers: DRGY56031, DRGY56025; UDI/DI Not Applicable, Serial Numbers: 00000DRGZ56044; Catalog number H3100BT, UDI/DI To be provided, Serial Numbers: 00000DRGX56017, 00000DRGZ56042; UDI/DI 010084068213935921DRGY560 3011190700, Serial Numbers: DRGY56030; p) D670 DR 3/8" MEA: Catalog number 5376204-70-61-1, UDI/DI To be provided, Serial Numbers:

NT2RG1900005BH; q) D670 DR 3/8": Catalog number H3100AK, UDI/DI Not Applicable, Serial Numbers: 00000589470GE4; r) D670 DR 3/8" 16SL: Catalog number 5791566, UDI/DI Not Applicable, Serial Numbers: DRGY56024; Catalog number H3100BT, UDI/DI Not Applicable, Serial Numbers: DRGY56026, DRGX56023, DRGX56009, DRGZ56047, DRGZ56049, DRGZ56045, DRGZ56051, DRGZ56056, DRGZ56046; s) D670 DR 3/8" 16SL NR: Catalog number H3100BT, UDI/DI Not Applicable, Serial Numbers: DRGZ56050; t) D670 DR 3/8" BJ: Catalog number 5376204-70-61-1, UDI/DI Not Applicable, Serial Numbers: NT2RG1800002BH, UDI/DI 01008406821393111119030021 NT2RG1900001BH, Serial Numbers: NT2RG1900001BH; u) D670 DR 3/8" MEA: Catalog number 5376204-70-61-1, UDI/DI To be provided, Serial Numbers: NT2RG2200001BH; v) D670 DR NM Gantry 3/8": Catalog number H3100BT, UDI/DI Not Applicable, Serial Numbers: DRGX56002, DRGY56028, DRGX56005, DRGY56033, DRGX56004, DRGY56037, DRGX56003, DRGX56008, DRGX56007, DRGY56033, DRGZ56039, DRGX56011, DRGX56006, DRGX56021, DRGZ56054, DRGZ56040, DRGY56038, DRGY56032, DRGX56019, DRGZ56052, DRGX56012, DRGY56029, DRGY56027, DRGZ56048, DRGX56014, DRGZ56053, DRGZ56055, DRGY56034, DRGX56020, DRGX56016, DRGY56036, DRGX56022, DRGX56015, DRGZ56041; UDI/DI To be provided, Serial Numbers: DRGX56018, DRGA56057, DRGA56058; UDI/DI

010084068213935921DRGY560
3511190900, Serial Numbers:
DRGY56035; UDI/DI
010084068213935921DRGZ560
4311200400, Serial Numbers:
DRGZ56043; w) D670 DR NM
Gantry 5/8": Catalog number
H3100CM, UDI/DI Not
Applicable, Serial Numbers:
DRGX56010; x) D670 DR with
new rotor: Catalog number To be
provided, UDI/DI Not Applicable,
Serial Numbers:
NT2RG1900003,
NT2RG2000001BH; y) D670
ES NM Gantry 3/8": Catalog
number H3100XF, UDI/DI Not
Applicable, Serial Numbers:
ESGY53002, ESGY53001,
ESGY53003, ESGZ53005,
ESGA53008, ESGB53011,
ESGZ53004, ESGA53007,
ESGZ53006, ESGA53010,
ESGA53009; z) D670 ES
NM/CT 3/8" O540+ NM Gantry,
aa) D670 ES NM/CT DR 3/8":
Catalog number H3100BM,
UDI/DI Not Applicable, Serial
Numbers: ESPX54001,
ESPY54002; bb) D670
GANTRY: Catalog number
H3100BM , UDI/DI Not
Applicable, Serial Numbers:
ESPY54003; cc) D670 PRO NM
Gantry 3/8": Catalog number
H3100NC, UDI/DI UDI Not
Required, Serial Numbers:
21128; dd) D670 PRO NM
GANTRY 3/8": Catalog number
H3100XB, UDI/DI Not
Applicable, Serial Numbers:
PRGZ52045, PRGY52027,
PRGA52061, PRGY52021,
PRGY52023, PRGY52018,
PRGZ52057, PRGY52013,
PRGZ52048, PRGY52020,
PRGZ52058, PRGX52008,
PRGZ52046, PRGA52063,
PRGA52068, PRGX52007,
PRGZ52047, PRGZ52059,
PRGA52066, PRGA52070,
PRGY52039, PRGY52012,
PRGZ52051, PRGX52004,
PRGZ52055, PRGY52016,

PRGX52009, PRGY52015,
PRGZ52054, PRGY52031,
PRGY52036, PRGY52024,
PRGY52028, PRGY52025,
PRGY52037, PRGY52032,
PRGY52029, PRGZ52050,
PRGX52005, PRGA52064,
PRGY52030, PRGZ52056,
PRGA52069, PRGX52002,
PRGX52006, PRGX52003,
PRGA52060; , UDI/DI
UDI_Not_Required_2, Serial
Numbers: PRGY52035; , UDI/DI
To be provided, Serial Numbers:
PRGA52077, PRGA52072,
PRGA52073, PRGA52075,
PRGB52083, PRGA52076,
PRGA52079, PRGB52080,
PRGB52081, PRGB52082,
PRGA52071, PRGA52074,
PRGB52084, PRGA52078;
UDI/DI
010084068213937321PRGX520
0111180700, Serial Numbers:
PRGX52001; UDI/DI
010084068213937321PRGX520
1011181200, Serial Numbers:
PRGX52010; UDI/DI
010084068213937321PRGY520
1111190100, Serial Numbers:
PRGY52011; UDI/DI
010084068213937321PRGY520
1711190300, Serial Numbers:
PRGY52017; ee) DISC
NM/CT670 DR 3/8": Catalog
number 5376204-70-61-1,
UDI/DI Not Applicable, Serial
Numbers: NT2RG1900002BH;
UDI/DI To be provided, Serial
Numbers: T2RG1900004BH;
ff) DISC NM/CT870 DR 3/8":
Catalog number H3100AS,
UDI/DI Not Applicable, Serial
Numbers: 87EA77009,
870A64177, 870A64156,
870Y64043, 870Z64112,
870Z64150; UDI/DI UDI Not
Required, Serial Numbers:
870Y64096; UDI/DI To be
provided, Serial Numbers:
870B64304, 00000870Z64147,
870Y64093, 870B64245; gg)
DISC NM/CT870 DR 5/8":
Catalog number 5791566,

UDI/DI To be provided, Serial Numbers: 870X64018; hh) DISCOVERY 670 (TANDEM): Catalog number H3100XB , UDI/DI To be provided , Serial Numbers: PRGZ52040; ii) DISCOVERY NM 670: Catalog number 5474053, UDI/DI To be provided, Serial Numbers: 27053; kk) DISCOVERY NM/CT 670 3/8" PRO: Catalog number H3100XB, UDI/DI Not Applicable, Serial Numbers: PRGZ52044, PRGA52065, PRGY52033, PRGZ52041, PRGZ52043, PRGZ52052, PRGY52026, PRGY52022, PRGY52014, PRGA52067, PRGY52034, PRGA52062; UDI/DI UDI_Not_Required_2, Serial Numbers: PRGZ52049, PRGZ52042; UDI/DI To be provided, Serial Numbers: PRGY52019; ll) DISCOVERY NM/CT 670 3/8" PRO NR, mm) HP Z420 WS Config 1 Hardware Specs Take 3 - E5-1620-8G-1TB-NVS: Catalog number H3100AS, UDI/DI To be provided, Serial Numbers: 00000870Y64060; nn) NM/CT 870 DR: Catalog number H3100AS , UDI/DI To be provided, Serial Numbers: 87EZ77008; oo) NM/CT 870 DR 3/8" CYBER DEFENCE: Catalog number H3906FF, UDI/DI To be provided, Serial Numbers: 87ZB83006, 87CA83003; pp) NM/CT 870 DR 3/8" WSO: Catalog number H3100AS, UDI/DI To be provided, Serial Numbers: 870A64189, 870A64216, 870B64228, 870B64220, 870B64223, 870A64181, 870A64211, 870A64213, 870B64249; Catalog number 5376204-70-60, UDI/DI 010084068214083621870A6421411211100, Serial Numbers: 870A64214; UDI/DI 010084068214083621870A6419511210900, Serial Numbers:

870A64195; UDI/DI
010084068214083621870A6419
411210800, Serial Numbers:
870A64194; UDI/DI
010084068214083621870B6425
611220500, Serial Numbers:
870B64256; UDI/DI
010084068214083621870A6419
311210800, Serial Numbers:
870A64193; UDI/DI
010084068214083621870B6423
211220200, Serial Numbers:
870B64232; UDI/DI
010084068214083621870B6424
611220300, Serial Numbers:
870B64246; UDI/DI
010084068214083621870B6424
811220300, Serial Numbers:
870B64248; UDI/DI
010084068214083621870A6419
111210800, Serial Numbers:
870A64191; Catalog number To
be provided, UDI/DI To be
provided, Serial Numbers:
870B64295; qq)NM/CT 870 DR
O540 3/8": Catalog number
5376204-70-60-1, UDI/DI Not
Applicable, Serial Numbers:
NT3DG1900012BH,
NT3DG2000001BH; Catalog
number 5376204-70-61-1,
UDI/DI Not Applicable, Serial
Numbers: NT3DG2200013BH;
Catalog number H3100AS,
UDI/DI Not Applicable, Serial
Numbers: 870X64031,
87EZ77006, 87EZ77005,
870Z64143, 870Y64062,
870Z64123, 870Z64118,
870A64169, 870A64166; :
Catalog number To be provided,
UDI/DI
010084068214083621870B6429
111221100, Serial Numbers:
870B64291; Catalog number To
be provided, UDI/DI
010084068214083621870B6430
111221100, Serial Numbers:
870B64301; rr) NM/CT 870 DR
O540 3/8" BJ: Catalog number
5376204-70-60-1, UDI/DI
01008406821421201121050621
NT3DG2100005BH, Serial
Numbers: NT3DG2100005BH;

UDI/DI Not Applicable, Serial Numbers: NT3DG1900014BH, NT3DG1900015BH, NT3DG2100010BH, NT3DG2100007BH, NT3DG2200005BH, NT3DG1900002BH, NT3DG2100011BH, NT3DG2200003BH, NT3DG2200014BH, NT3DG2000012BH, NT3DG1900001BH, NT3DG1800001BH, NT3DG2100003BH, NT3DG2200007BH, NT3DG2100001BH, NT3DG2100012BH, NT3DG2100008BH; UDI/DI To be provided, Serial Numbers: NT3DG1900009BH, NT3DG2200004BH, NT3DG2000013BH, NT3DG1900006BH, NT3DG2100002BH, NT3DG1900004BH, NT3DG1900011BH, NT3DG2100013BH; : Catalog number 5376204-70-61-1, UDI/DI Not Applicable, Serial Numbers: NT3DG2200019BH, NT3DG2000003BH, NT3DG2000005BH, NT3DG2000006BH; : Catalog number To be provided, UDI/DI Not Applicable , Serial Numbers: NT3DG2000004BH, NT3DG2200011BH, NT3DG2200017BH, NT3DG2000014BH; ss) NM/CT 870 DR O540 5/8": Catalog number H3100Q, UDI/DI Not Applicable, Serial Numbers: 870A64170; Catalog number 5791566, UDI/DI Not Applicable , Serial Numbers: 870Z64138, 870B64219; tt) NM/CT 870 ES 3/8": Catalog number H3100AS, UDI/DI Not Applicable, Serial Numbers: 87EZ77002; uu) NM/CT 870DR China for China: Catalog number 5376204-70-60-1, UDI/DI Not Applicable, Serial Numbers: NT3DG2200010BH; NT3DG2200015BH,

	<p>NT3DG2100015BH, NT3DG2200006BH, NT3DG2200001BH; : Catalog number 5376204-70-61-1, UDI/DI Not Applicable, Serial Numbers: NT3DG2200016BH, NT3DG2200012BH; vv) NM/CT 870 DR 3/8" O540: Catalog number 5376204-70-60-1, UDI/DI Not Applicable, Serial Numbers: NT3DG2000008BH, NT3DG2000010BH, NT3DG2000011BH, NT3DG2100009BH, NT3DG2100014BH, NT3DG2100004BH; Catalog number 5376204-70-61-1, UDI/DI Not Applicable, Serial Numbers: NT3DG2200008BH ww) NM/CT D870 DR O540 3/8": Catalog number 5376204-70-60- 1, UDI/DI Not Applicable, Serial Numbers: NT3DG1900010BH, NT3DG1900003BH, NT3DG2000015BH; Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3DG2000002BH; Catalog number To be provided, UDI/DI To be provided, Serial Numbers: 870A64186; xx) TANDEM DISCOVERY 670 INT: Catalog number H3100XB, UDI/DI Not Applicable, Serial Numbers: PRGY52038.</p>		
<p>I</p>	<p>GE Nuclear Medicine 600/800 series systems a) 830: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3AG2200003, NT3AG2000015BH, NT3AG2100015BH, NT3AG2200006BH; b) 830 / Dismount: Catalog number To be provided, UDI/DI Not Applicable, Serial numbers: NT3AG2100016BH; c) 830 /: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3AG2100009BH; d) 830 / 5842894-20: Catalog number</p>	<p>748 units worldwide</p>	<p>December 2022 and prior</p>

To be provided, UDI/DI Not Applicable, Serial Numbers: NT3AG2200013; e) 830 / Dismount / 50HZ: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3AG2000017BH; f) 830 / Dismount / 60HZ: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3AG2100001; g) 830 3/8 inch Detector: Catalog number H3910AC, UDI/DI Not Applicable, Serial Numbers: 830Y60105; h) 830 BJ: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3AG1900009BH; Catalog number 5376204-32-1, UDI/DI Not Applicable, Serial Numbers: NT3AG1900015BH; i) 830 BJ / 5144407: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3AG1900008BH; j) 830 BJ / Dismount: Catalog number 5376204-32-1, UDI/DI To be provided, Serial Numbers: NT3AG1900016BH; k) 830 ES DEM: Catalog number H3910AC, UDI/DI Not Applicable, Serial Numbers: 83EZ88002, 830Z60256; l) 830 NM Cyber Defense Configuration Gantry 3/8 inch: Catalog number H3910AG, UDI/DI Not Applicable, Serial Numbers: 830Z60185, 830Z60224, 830Z60225; m) 830 NM Gantry 3/8 inch: Catalog number H3910AC, UDI/DI Not Applicable, Serial Numbers: 830Y60050, 830Z60199, 830A60284, 830A60290, 830X60001, 830X60004, 830Y60056, 830Y60069, 830Z60158, 830Z60182, 83EA88010, 830Z60183, 830A60282, 830Z60192, 830A60271, 830Y60122, 830A60298, 830A60289, 830Y60048, 830Y60036, 830Z60239, 830A60294, 830Y60046,

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830Z60201, 830Y60045,
830X60019, 83EZ88001,
830Y60124, 830A60306,
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830Z60226, 830Z60262,
830X60007, 830Z60259,
830Z60212, 830Y60065,
830Y60135, 830Z60204,
830Y60072, 830Z60160;
UDI/DI UDI_Not_Required_2,
Serial Numbers: 830Y60113; ,
UDI/DI UDI_Not_Required_6,
Serial Numbers: 830A60299;
UDI/DI
010084068214082921830A603
2811210700, Serial Numbers:
830A60328; UDI/DI
010084068214082921830Z601
5011200100, Serial Numbers:
830Z60150; UDI/DI
010084068214082921830A602
7211210100, Serial Numbers:
830A60272; UDI/DI
010084068214082921830B604
2411220500, Serial Numbers:
830B60424; UDI/DI
010084068214082921830Z601
9011200400, Serial Numbers:
830Z60190; UDI/DI
010084068214082921830A602
7311210100, Serial Numbers:
830A60273; UDI/DI
010084068214082921830Z601
8911200400, Serial Numbers:
830Z60189; UDI/DI
010084068214082921830Y600
7511190600, Serial Numbers:
830Y60075; UDI/DI
(01)00840682140829(21)830B6
0400(11)220200, Serial
Numbers: 830B60400; UDI/DI
010084068214082921830Z601
7011200200, Serial Numbers:
830Z60170; UDI/DI
(01)00840682140829(21)830A6

0346(11)211100, Serial Numbers: 830A60346; UDI/DI 010084068214082921830Y601 0311190900, Serial Numbers: 830Y60103; UDI/DI 010084068214082921830Y601 4511191200, Serial Numbers: 830Y60145; UDI/DI 010084068214082921830A603 0311210500, Serial Numbers: 830A60303; UDI/DI (01)00840682140829(21)830A6 0345(11)211000, Serial Numbers: 830A60345; UDI/DI 010084068214082921830A602 9511210300, Serial Numbers: 830A60295; UDI/DI 010084068214082921830Z602 3311200900, Serial Numbers: 830Z60233; UDI/DI 010084068214082921830Z602 0911200600, Serial Numbers: 830Z60209; UDI/DI (01)00840682140829(21)830B6 0386(11)220100, Serial Numbers: 830B60386; UDI/DI (01)00840682140829(21)830B6 0434(11)220600, Serial Numbers: 830B60434; UDI/DI 010084068214082921830Y601 0911191000, Serial Numbers: 830Y60109; UDI/DI 010084068214082921830Z601 6211200200, Serial Numbers: 830Z60162; UDI/DI 010084068214082921830Z601 7911200300, Serial Numbers: 830Z60179; UDI/DI 010084068214082921830Z601 8611200300, Serial Numbers: 830Z60186; UDI/DI 010084068214082921830B604 2711220500, Serial Numbers: 830B60427; UDI/DI 010084068214082921830A603 7811211200, Serial Numbers: 830A60378; , UDI/DI To be provided, Serial Numbers: 830B60383, 830A60337, 830A60373, 830A60368, 830B60387, 830B60458, 830B60459, 830B60460, 830B60462, 830B60464, 830B60465, 830B60466,

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830B60473, 830B60384,
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830A60317, 830B60401,
830B60432, 830B60422,
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830B60398, 830A60364,
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830A60326, 830B60411,
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830B60389, 830A60333,
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830B60447, 830A60313,
830A60375, 830A60374,
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830B60461, 830B60463,
830B60470, 830A60365,
830B60446, 830B60397,
83EB88034, 83EB88025,
83EA88011, 830B60431,
830B60428, 830B60416,
830B60441, 830A60363; n)
830 NM Gantry 5/8 inch:
Catalog number H3910AD,
UDI/DI To be provided, Serial
Numbers: 830B60468,
830B60379; o) 870 DR NM
GANTRY FINAL - NEW
ROTOR: Catalog number
5376204-32-1, UDI/DI Not
Applicable, Serial Numbers:
NT3AG2000009BH; p) B615 to
D630 UPG: Catalog number To
be provided, UDI/DI To be
provided, Serial Numbers:
NT2UG2100001; Catalog
number To be provided, UDI/DI
Not Applicable, Serial Numbers:
NT2UG2100002; q) D630 NM
GANTRY: Catalog number
H3100JY, UDI/DI
01008406821392742163GX500
2611180700, Serial Numbers:
63GX50026; Catalog number
H3100JY, UDI/DI Not
Applicable, Serial Numbers:
0000063GX50023; r) D630
NM GANTRY 3/8 inch WITH
NEW ROTOR - MEA: Catalog
number 5376204-31-1, UDI/DI
To be provided, Serial
Numbers: NT2PG2000001BH;
s) D630 NM Gantry 3/8 inch:

Catalog number H3101RH,
UDI/DI Not Applicable, Serial
Numbers: 63GY50074,
63GX50024, 63GZ50134,
63GY50110, 63GY50119,
63GY50067, 63GY50123,
63GX50001, 63GX50037,
63GX50060, 63GY50089,
63GY50087, 63GY50098,
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63GX50019, 63GZ50150,
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63GX50004, 63GY50086,
63GZ50132, 63GX50056,
63GX50066,
63GX50059;UDI/DI
01008406821392742163GY500
7611190200, Serial Numbers:
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01008406821392742163GX500
5111181000, Serial Numbers:
63GX50051; UDI/DI
01008406821392742163GX500
5211181000, Serial Numbers:
63GX50052; UDI/DI
01008406821392742163GY500
7011190100, Serial Numbers:
63GY50070; UDI/DI
01008406821392742163GY500
9511190400, Serial Numbers:
63GY50095; UDI/DI
01008406821392742163GY501
2111191100, Serial Numbers:
63GY50121; UDI/DI
01008406821392742163GX500
2711180700, Serial Numbers:
63GX50027; UDI/DI
01008406821392742163GX500
3611180700, Serial Numbers:
000063GX50036; UDI/DI
01008406821392742163GY500
9611190400, Serial Numbers:
63GY50096; UDI/DI
01008406821392742163GX500
0711180500, Serial Numbers:
63GX50007; UDI/DI
01008406821392742163GX500
0611180500, Serial Numbers:
63GX50006; UDI/DI
01008406821392742163GX500
1011180600, Serial Numbers:
63GX50010; UDI/DI
01008406821392742163GX500
1511180600, Serial Numbers:
63GX50015; UDI/DI
01008406821392742163GY501
1711190900, Serial Numbers:
63GY50117; UDI/DI
01008406821392742163GY500
7111190100, Serial Numbers:

63GY50071; UDI/DI
01008406821392742163GY500
7211190100, Serial Numbers:
63GY50072; UDI/DI
(01)00840682139274(21)63GY
50106(11)190700, Serial
Numbers: 63GY50106; UDI/DI
01008406821392742163GY500
7311190100, Serial Numbers:
63GY50073; UDI/DI To be
provided, Serial Numbers:
63GX50041, 63GY50105,
63GA50161, 63GB50165,
63GA50162, 63GA50157,
63GA50159, 63GA50160,
63GA50156, 63GA50163,
63GB50166; t) D630 NM
GANTRY FINAL ASSEMBLY, :
Catalog number 5791570,
UDI/DI To be provided, Serial
Numbers: 830B60423,
830B60429; u) D630 with new
rotor: Catalog number
H2405AC, UDI/DI To be
provided, Serial Numbers:
NT2PG1900006,
NT2PG1900005; v) D630 with
new rotor/ 5144407 / Dismount:
Catalog number To be
provided, UDI/DI Not
Applicable, Serial Numbers:
NT2PG1900007BH; w) D630
with new rotor/ Dismount:
Catalog number 5376204-31-1,
UDI/DI Not Applicable, Serial
Numbers: NT2PG1800001BH;
x) DISCOVERY D630 X3/8
inch: Catalog number 5376204-
31-1, UDI/DI Not Applicable,
Serial Numbers:
NT2PG1900009BH,
NT2PG1900008BH; y)
DISCOVERY D630X 3/8 inch:
Catalog number 5791570,
UDI/DI Not Applicable, Serial
Numbers: 0000063GZ50139;
z) DISCOVERY D630X3/8 inch:
Catalog number H3101RH,
UDI/DI
01008406821392742163GY500
9111190400, Serial Numbers:
63GY50091; UDI/DI Not
Applicable, Serial Numbers:
63GY50093, 63GY50099,

63GZ50144, 63GZ50140,
63GY50122, 63GY50092,
63GB50164, 63GX50064,
63GX50028, 63GX50058,
63GY50081, 63GY50109,
63GZ50143; aa) DISCOVERY
D630x3/8 inch BHW: Catalog
number H2405AC, UDI/DI
0100840682139328111906002
1NT2PG1900010BH, Serial
Numbers: NT2PG1900010BH;
bb) DISCOVERY D630X3/8
inch BJB: Catalog number
5376204-31-1, UDI/DI Not
Applicable, Serial Numbers:
NT2PG1900004BH,
NT2PG1900001BH,
NT2PG1900002BH,
NT2PG1900012BH; cc)
DISCOVERY D630X3/8 inch
MEA: Catalog number
5376204-31-1, UDI/DI
0100840682139328111910002
1NT2PG1900011BH, Serial
Numbers: NT2PG1900011BH;
dd) DISCOVERY NM 830 3/8
inch: Catalog number
5376204-32-1, UDI/DI Not
Applicable, Serial Numbers:
NT3AG2200012BH; UDI/DI To
be provided, Serial Numbers:
NT3AG2100004BH,
NT3AG2200007BH; UDI/DI Not
Applicable, Serial Numbers:
NT3AG2200012BH; ee)
DISCOVERY NM 830 3/8 inch:
Catalog number H3910AC,
UDI/DI Not Applicable, Serial
Numbers: 830Y60110,
830Z60164; ff) NM 830 3/8
inch: Catalog number 5791570,
UDI/DI To be provided, Serial
Numbers: 830A60336,
830Y60031; Catalog number
5376204-31-1, UDI/DI To be
provided, Serial Numbers:
NT3AG2000005BH; Catalog
number 5376204-32, UDI/DI
010084068214082921830A603
5511211100, Serial Numbers:
830A60355; UDI/DI
010084068214082921830A603
2511210700, Serial Numbers:
830A60325; UDI/DI

010084068214082921830A603
7111211200, Serial Numbers:
830A60371; UDI/DI
010084068214082921830B604
0911220300, Serial Numbers:
830B60409; UDI/DI
010084068214082921830B604
3911220700, Serial Numbers:
830B60439; UDI/DI
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1411220400, Serial Numbers:
830B60414; UDI/DI
010084068214082921830A603
2411210700, Serial Numbers:
830A60324; UDI/DI
010084068214082921830B604
1511220400, Serial Numbers:
830B60415; UDI/DI
010084068214082921830B604
3311220600, Serial Numbers:
830B60433; UDI/DI
010084068214082921830A603
2911210800, Serial Numbers:
830A60329; UDI/DI
010084068214082921830B604
4211220700, Serial Numbers:
830B60442; UDI/DI
01008406821408292183EB880
3111220700, Serial Numbers:
83EB88031; UDI/DI
010084068214082921830B604
4411220700, Serial Numbers:
830B60444; UDI/DI
010084068214082921830A603
4411211000, Serial Numbers:
830A60344; UDI/DI
010084068214082921830B604
0411220300, Serial Numbers:
830B60404; UDI/DI
010084068214082921830A603
3211210800, Serial Numbers:
830A60332; UDI/DI
010084068214082921830A603
2311210700, Serial Numbers:
830A60323; UDI/DI
010084068214082921830B604
0211220200, Serial Numbers:
830B60402; UDI/DI
010084068214082921830A603
5211211100, Serial Numbers:
830A60352; UDI/DI
010084068214082921830B604
4811221000, Serial Numbers:
830B60448; UDI/DI

010084068214082921830A603
1511210600, Serial Numbers:
830A60315; UDI/DI
010084068214082921830A603
1811210600, Serial Numbers:
830A60318; UDI/DI
010084068214082921830B604
2511220500, Serial Numbers:
830B60425; UDI/DI
010084068214082921830A603
1911210600, Serial Numbers:
830A60319; UDI/DI
010084068214082921830A603
6611211200, Serial Numbers:
830A60366; Catalog number
H3910AC, UDI/DI Not
Applicable, Serial Numbers:
830Y60147, 830B60455,
830Z60261, 830Z60221,
830Z60215, 830Y60070,
830Y60083, 830Y60037,
830Z60161, 830Y60039,
830A60302, 830Z60216,
830Z60242, 830Z60241,
830Z60251, 830Y60086,
830Z60243, 830Z60208; UDI/DI
UDI_Not_Required_2, Serial
Numbers: 830Y60116; UDI/DI
To be provided, Serial
Numbers: 830A60356,
830B60449, 830A60350,
83EB88032, 830A60322,
830B60445, 830B60435,
830A60358, 830B60408,
830A60349, 830B60453,
830A60357, 830A60335,
830B60410, 830B60395,
830A60354, 830B60385,
830A60331, 830B60396,
830A60360, 830B60381,
830B60406, 830B60403,
830A60320, 830A60321,
830B60426, 830B60388,
830A60369, 830B60399,
830B60419, 830A60377,
830A60316, 830B60382,
830B60452, 830A60370,
830A60376, 830B60413,
830A60314, 830A60367,
830B60394, 830B60436,
830A60342, 830A60362,
830B60440, 830B60407,
830A60312, 830B60380,
830B60418, 830A60353,

830A60330, 830B60390,
830A60372, 830A60359,
830A60341, 830A60338,
830A60327, 830B60405,
830A60361, 830B60454,
830A60340, 830A60351;
Catalog number To be
provided, UDI/DI To be
provided, Serial Numbers:
830B60437, 830B60393,
830B60420, 830B60438,
830A60343; gg) NM 830 3/8
inch BJ: Catalog number
5376204-32-1, UDI/DI Not
Applicable, Serial Numbers:
NT3AG2200001BH,
NT3AG2100007BH,
NT3AG2100003BH,
NT3AG2000008BH,
NT3AG2000002BH,
NT3AG2200010BH,
NT3AG1900002BH ,
NT3AG2200009BH,
NT3AG1900014BH,
NT3AG1900012BH,
NT3AG2000006BH,
NT3AG2100008BH,
NT3AG2000013BH,
NT3AG2100010BH,
NT3AG2200005BH,
NT3AG1900011BH,
NT3AG2000016BH,
NT3AG2100002BH,
NT3AG2200011BH,
NT3AG2100011BH,
NT3AG1900018BH,
NT3AG2000001BH,
NT3AG1900003BH,
NT3AG1900001BH,
NT3AG1800001BH,
NT3AG2100014BH,
NT3AG1900010BH,
NT3AG2000003BH,
NT3AG2000012BH,
NT3AG1900006BH,
NT3AG2100005BH,
NT3AG2000011BH,
NT3AG2200008BH,
NT3AG1800002BH,
NT3AG2000010BH; UDI/DI To
be provided, Serial Numbers:
NT3AG2200014BH,
NT3AG1900013BH,
NT3AG2200002BH,

NT3AG2100012BH,
NT3AG2100013BH; Catalog
number H2406AA, UDI/DI Not
Applicable, Serial Numbers:
NT3DG1800003BH,
NT3AG1900004BH,
NT3AG2200016,
NT3AG2200015BH; Catalog
number H3910AC, UDI/DI Not
Applicable, Serial Numbers:
83EZ88003; Catalog number
To be provided, UDI/DI Not
Applicable, Serial Numbers:
NT3AG2200004BH; Catalog
number To be provided, UDI/DI
To be provided, Serial
Numbers: NT3AG1900005BH,
NT3AG2000004BH; hh) NM
830 ES: Catalog number
5376204-32, UDI/DI
01008406821408292183EA880
1811211000, Serial Numbers:
83EA88018; UDI/DI
01008406821408292183EA880
1411210800, Serial Numbers:
83EA88014; UDI/DI
01008406821408292183EB880
1911220100, Serial Numbers:
83EB88019; UDI/DI
01008406821408292183EB880
2311220200, Serial Numbers:
83EB88023; UDI/DI
01008406821408292183EB880
3011220500, Serial Numbers:
83EB88030; UDI/DI
01008406821408292183EA880
1211210600, Serial Numbers:
83EA88012; UDI/DI
01008406821408292183EA880
1511210900, Serial Numbers:
83EA88015; UDI/DI
01008406821408292183EA880
1311210800, Serial Numbers:
83EA88013; UDI/DI
01008406821408292183EB880
2411220200, Serial Numbers:
83EB88024; Catalog number
H3910AC, UDI/DI To be
provided, Serial Numbers:
83EB88029, 83EB88022,
83EA88016; UDI/DI Not
Applicable, Serial Numbers:
83EB88021; Catalog number
To be provided, UDI/DI To be

	<p>provided, Serial Numbers: 83EB88020; ii) NM DISCOVERY D630 3/8 inch: Catalog number 5474054, UDI/DI To be provided, Serial Numbers: 22404; jj) NUC GOLDSEAL D630X3/8 inch: Catalog number S9630NU, UDI/DI Not Applicable, Serial Numbers: NT2QG1900003BH.</p>		
I	<p>GE Nuclear Medicine 600/800 series systems a) BRIVO B615 3/8 inch DHP BJJ NR: Catalog number 5376204-16, UDI/DI Not Applicable, Serial Numbers: NT2QG1900001BH; b) BRIVO 615 3/8 inch: Catalog number 5376204-16, UDI/DI To be provided, Serial Numbers: NT2QG2000002BH; c) BRIVO B615 3/8 inch DHP BJJ NR: Catalog number 5376204-16, UDI/DI Not Applicable, Serial Numbers: NT2QG2000001BH; d) B615 with new rotor: Catalog number 5376204-16, UDI/DI To be provided, Serial Numbers: NT2QG1900002BH; e) BRIVO B615 3/8 inch BJJ: Catalog number 5376204-16, UDI/DI Not Applicable, Serial Numbers: NT2QG1800001BH; f) BRIVO B615 3/8 inch DHP BJJ NR: Catalog number H2402MP, UDI/DI To be provided, Serial Numbers: 00000168527HL0; g) B615 with new rotor: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT2QG2000003BH;</p>	7 units worldwide	December 2022 and prior
I	<p>GE Nuclear Medicine 600/800 series systems a) OPTIMA O640X3/8 inch NR: Catalog number 5376204-41, UDI/DI Not Applicable, Serial Numbers: 64GY51002, 64GY51003, 64GY51004, 0000064GY51011, 64GY51005; b) DISCOVERY O640X 3/8</p>	34 units worldwide	December 2022 and prior

	<p>inch: Catalog number H3101RL, UDI/DI Not Applicable, Serial Numbers: 64GY51021; c) NM OPTIMA O640X3/8 inch: Catalog number To be provided, UDI/DI To be provided, Serial Numbers: 26043; d) O640 NM Gantry 3/8 inch: Catalog number 5376204-41, UDI/DI Not Applicable, Serial Numbers: 64GY51022; , UDI/DI Not Applicable, Serial Numbers: 64GY51024, 64GY51007, 64GY51019, 64GY51018, 64GY51016, 64GX51001, 64GY51006, 64GY51013, 64GZ51026, 64GY51025, 64GY51012, 64GY51023, 64GY51014, 64GZ51027; UDI/DI To be provided, Serial Numbers: 64GY51008, 64GY51009, 64GY51020, 64GZ51028, 64GZ51030, 64GY51015, 64GY51011; e) O640 NM GANTRY FINAL ASSY: Catalog number H3100JZ, UDI/DI To be provided, Serial Numbers: ONMX26515; f) OPTIMA O640X3/8 inch: Catalog number H3101RL, UDI/DI Not Applicable, Serial Numbers: 64GZ51029, 64GZ51031; Catalog number 5376204-41, UDI/DI Not Applicable, Serial Numbers: 64GY51017; UDI/DI To be provided, Serial Numbers: 64GY51010.</p>		
I	<p>GE Nuclear Medicine 600/800 series systems a) 870 CZT O540+ Gantry 7.25mm: Catalog number H3906CW , UDI/DI 01008406821408432187CZ630 4211200300, Serial Numbers: 87CZ63042; UDI/DI 01008406821408432187CA630 5311210100, Serial Numbers: 87CA63053; UDI/DI 01008406821408432187CX630 1111181000, Serial Numbers: 87CX63011; UDI/DI</p>	86 units nationwide	December 2022 and prior

01008406821408432187CY630
2011190300, Serial Numbers:
87CY63020; UDI/DI
01008406821408432187CY630
3511191100, Serial Numbers:
87CY63035; UDI/DI
01008406821408432187CZ630
4011200100, Serial Numbers:
87CZ63040; UDI/DI
01008406821408432187CX630
0411180700, Serial Numbers:
87CX63004; UDI/DI
01008406821408432187CX630
0911180900, Serial Numbers:
87CX63009; UDI/DI
01008406821408432187CB630
7211220700, Serial Numbers:
87CB63072; UDI/DI
01008406821408432187CA630
6111211100, Serial Numbers:
87CA63061; UDI/DI
01008406821408432187CY630
3211191000, Serial Numbers:
87CY63032; UDI/DI To be
provided, Serial Numbers:
87CB63075, 87CA63058,
87CB63070, 87CB63069,
87CB63071, 87CB63077,
87CA63063, 87CB63064,
87CB63078, 87CA63062,
87CB63067, 87CA63057,
87CA63060, 87CB63065,
87CB63068, 87CB63074;
UDI/DI Not Applicable, Serial
Numbers: 87CY63019,
87CA63054, 87CZ63043,
87CA63055, 87CY63028,
87CY63037, 87CZ63044,
87CZ63045, 87CZ63048,
87CZ63041, 87CY63024,
87CY63017, 87CX63007,
87CX63008, 87CX63006,
87CX63014, 87CY63022,
87CX63015, 87CY63025,
87CX63010, 87CZ63052,
87CY63027, 87CY63026,
87CY63030, 87CZ63046,
87CX63013, 87CY63036,
87CZ63047, 87CY63033,
87CY63016, 87CX63005,
87CZ63039, 87CX63002,
87CX63012, 87CX63001,
87CY63023, 87CY63018; b)
D670 CZT Gantry 7.25mm:

Catalog number H3906DD,
UDI/DI Not Applicable, Serial
Numbers: CZGA55003,
CZGA55004, CZGY55001; ,
UDI/DI To be provided, Serial
Numbers: CZGB55006,
CZGA55005, CZGB55007; c)
DISCOV NM/CT 870 CZT:
Catalog number H3906CW,
UDI/DI
01008406821408432187CY630
3811191200, Serial Numbers:
87CY63038; d) Discovery
NMCT 670 CZT O540+: Catalog
number H3906DD , UDI/DI Not
Applicable, Serial Numbers:
CZGZ55002; e) NM/CT 870
CZT CYBER DEFENCE:
Catalog number H3906FK,
UDI/DI To be provided, Serial
Numbers: 87DB82001; f)
NM/CT 870 CZT O540: Catalog
number H3906CW , UDI/DI Not
Applicable, Serial Numbers:
87CY63021, 87CZ63050,
87CZ63049, 87CZ63051,
87CY63034; g) NM/CT 870
CZT WSO: Catalog number
5376204-70-20, UDI/DI
01008406821408432187CA630
5911210800, Serial Numbers:
87CA63059; UDI/DI
01008406821408432187CB630
7611221000, Serial Numbers:
87CB63076; UDI/DI
01008406821408432187CB630
7311220800, Serial Numbers:
87CB63073; : Catalog number
H3906CW, UDI/DI To be
provided, Serial Numbers:
87CB63066; : Catalog number
To be provided, UDI/DI To be
provided, Serial Numbers:
87CA63056; h) NM/CT 870
CZT: Catalog number
H3906CW, UDI/DI Not
Applicable, Serial Numbers:
87CY63031; i) NM/CT 870 CZT
O540+ 7.25MM: Catalog
number H3906CV, UDI/DI
01008406821408432187CX630
0311180700, Serial Numbers:
87CX63003; UDI/DI
01008406821408432187CY630

	2911190800, Serial Numbers: 87CY63029		
I	<p>GE Nuclear Medicine 600/800 series systems</p> <p>a) 850: Catalog number 5376204-50-1, UDI/DI Not Applicable, Serial Numbers: NT3BG2200006BH; b) 850 / Dismount: Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3BG2100003BH; c) 850 3/8 inch NM Gantry: Catalog number H3907AD, UDI/DI Not Applicable, Serial Numbers: 85EY67037, 850Z61033, 85EY67039, 85EY67048, 850Y61018, 850Y61009, 85EY67035, 85EX67001, 85EX67020, 85EY67045, 85EX67023, 85EY67032, 85EY67046, 850A61063, 850Z61047, 85EY67047, 850Z61053, 850Y61006, 850Y61010, 850X61005, 850Y61021, 85EZ67062, 85EX67019, 85EX67021, 85EA67063, 850A61069, 85EX67008, 85EY67040, 850Z61051, 850Z61038, 850A61075, 850Y61025, 850Z61030, 85EY67015, 85EX67017, 85EY67043, 850Z61042, 850Z61061, 85EY67026, 850A61065, 85EX67012, 850Y61023, 85EY67041, 850A61062, 850A61076, 850Y61012, 850A61064, 85EZ67058, 85EX67006, 850Z61043, 850Z61055, 85EY67042, 85EZ67055, 85EY67036, 85EX67024, 85EY67038, 85EX67022, 85EY67025, 85EZ67060, 850Z61058, 850Z61044, 850Z61045, 850Y61020, 850Z61032, 85EZ67056, 85EA67065, 85EY67028, 850Z61041, 85EX67002, 85EX67009, 850A61072, 850Z61036, 850A61068, 850A61071,</p>	380 units nationwide	December 2022 and prior

850Z61060, 850Z61034,
850Z61039, 850Z61035,
850Z61040, 85EY67031,
850Z61056, 850Z61057,
850Y61016, 85EX67016,
85EA67066, 85EX67004,
850Z61029, 850Z61031,
85EX67011, 85EX67010,
850Y61013, 850Y61015,
850Y61017, 850A61070,
85EX67005, 850A61073,
85EX67018, 85EY67033,
850Z61027, 85EX67013,
850Z61054, 850X61001,
85EZ67053, 85EZ67054,
85EZ67057, 850X61004,
850Z61059, 850Z61052,
850Y61014, 850Z61048,
850Y61026, 850Y61019,
85EY67044, 850Z61037,
850X61002, 85EX67003,
85EX67014, 850Y61007,
85EY67049, 85EZ67052,
850A61067, 850A61074,
85EY67050, 85EZ67051,
85EY67027; UDI/DI
(01)00840682140775(21)850B6
1120(11)220700, Serial
Numbers: 850B61120; UDI/DI
010084068214077521850Y610
1111190300, Serial Numbers:
850Y61011; UDI/DI To be
provided, Serial Numbers:
850A61083, 85EA67080,
850B61127, 850B61128,
850B61129, 850B61130,
85EB67087, 850B61133,
850B61134, 850B61135,
850B61101, 85EA67070,
850B61119, 850B61102,
850B61115, 85EA67076,
CHBB65669, 850B61122,
850B61132, 850B61131,
85EA67075, 85EA67077,
85EB67088, 850A61093,
85EB67086, 850B61126,
850A61089, 85EA67078,
850B61112, 850B61111,
850B61110, 850B61107,
850B61109; Catalog number To
be provided, UDI/DI To be
provided, Serial Numbers:
60B62111; d) 860 / Dismount:
Catalog number To be provided,

UDI/DI Not Applicable, Serial Numbers: NT3CG2100006BH; e) 860 3/8 inch NM Gantry: Catalog number H3908AD, UDI/DI Not Applicable, Serial Numbers: 860Y62009, 860Y62010, 860Z62027, 860Y62005, 860A62049, 860Y62019, 860Y62014, 860Y62025, 860Z62028, 860Y62024, 860Z62038, 860A62063, 860Z62042, 860Y62017, 860A62065, 860A62058, 860Z62046, 860A62057, 860Z62041, 86EA76004, 860B62118, 860Z62043, 860A62060, 860Z62026, 860Y62006, 860Y62015, 860Y62004, 860Z62047, 860Y62020, 860A62050, 860Z62030, 860Y62007, 860X62002, 860Z62032, 860Y62021, 86EA76003, 860Z62040, 860Z62037, 860Z62031, 860A62062; , UDI/DI 010084068214075121860A6207711211000, Serial Numbers: 860A62077; UDI/DI (01)00840682140751(21)860B62097(11)220300, Serial Numbers: 860B62097; UDI/DI 010084068214075121860B6209611220300, Serial Numbers: 860B62096; UDI/DI 010084068214075121860A6205911210400, Serial Numbers: 860A62059; UDI/DI 010084068214075121860A6206811210600, Serial Numbers: 860A62068; UDI/DI 010084068214075121860Y6202311191100, Serial Numbers: 860Y62023; UDI/DI 010084068214075121860Y6201311190600, Serial Numbers: 860Y62013; UDI/DI To be provided, Serial Numbers: 860A62067, 860Y62016, 860B62117, 860B62100, 860B62105, 860B62090, 860A62072, 860B62108, 860B62110, 860A62078, 860A62083, 860B62094,

860A62066, 860A62084,
860A62071, 860A62070,
860A62073, 860A62069,
860B62095, 860A62086,
860A62081, 860A62085,
860B62099, 860B62115,
860A62082, 860B62114,
860A62074, 860Z62034,
86EB76006, 860B62122,
860B62119, 860B62121,
860B62089, 86EB76007,
860A62076, 860A62079,
860B62116, 86EB76009,
860B62120, 860B62093,
860A62080, 860B62098,
860B62091, 860B62103; f) 860
5/8 inch NM Gantry: Catalog
number H3908AE, UDI/DI To be
provided, Serial Numbers:
860X62001; , UDI/DI Not
Applicable, Serial Numbers:
860Z62035; g) 860 BJ: Catalog
number To be provided, UDI/DI
Not Applicable, Serial Numbers:
NT3CG1900007BH,
NT3CG1900008BH,
NT3CG1900009BH; h) NM
830 3/8 inch BJ: Catalog
number 5376204-50-1, UDI/DI
To be provided, Serial Numbers:
NT3AG1900007BH,
NT3AG2100001BH,
NT3AG2100006BH; i) NM/CT
850 3/8 inch BJ: Catalog
number 5376204-50-1, UDI/DI
Not Applicable, Serial Numbers:
NT3BG2000003BH,
NT3BG2100001BH,
NT3BG2200001BH,
NT3BG1900001BH,
NT3BG2200002BH,
NT3BG2000004BH,
NT3BG2100004BH,
NT3BG2200005BH; : Catalog
number H2407AA, UDI/DI Not
Applicable, Serial Numbers:
NT3BG2000001BH; , UDI/DI To
be provided, Serial Numbers:
NT3BG2100002BH; : Catalog
number To be provided, UDI/DI
Not Applicable, Serial Numbers:
NT3BG2000002BH; j) NM/CT
850 3/8 inch ROW: Catalog
number 5376204-50-1, UDI/DI

Not Applicable, Serial Numbers:
NT3BG2100005BH,
NT3BG1900002BH; Catalog
number H3907AD, UDI/DI Not
Applicable, Serial Numbers:
850Y61022, 850Z61046,
850Y61008; UDI/DI To be
provided, Serial Numbers:
850B61100; k) NM/CT 850 3/8
inch ROW: Catalog number
5782013, UDI/DI To be
provided, Serial Numbers:
860Y62008; l) NM/CT 850 CT
850 3/8 inch: Catalog number
5782013, UDI/DI To be
provided, Serial Numbers:
850A61092, 850B61108,
850B61096, 850A61080,
850Z61050, 850B61106,
850B61097, 850A61077,
850B61118, 860B62112;
Catalog number 5376204-50,
UDI/DI
010084068214077521850A610
9511211200, Serial Numbers:
850A61095; UDI/DI
010084068214077521850A610
8811210900, Serial Numbers:
850A61088; UDI/DI
010084068214077521850B611
2111220700, Serial Numbers:
850B61121; UDI/DI
010084068214077521850B611
0411220400, Serial Numbers:
850B61104; UDI/DI
010084068214077521850A610
8711210900, Serial Numbers:
850A61087; UDI/DI
010084068214077521850A610
8211210800, Serial Numbers:
850A61082; UDI/DI
010084068214077521850B611
0511220400, Serial Numbers:
850B61105; Catalog number
H3907AA, UDI/DI To be
provided, Serial Numbers:
850A61081; Catalog number
H3907AD, UDI/DI Not
Applicable, Serial Numbers:
850Z61049, 850A61066; UDI/DI
To be provided, Serial Numbers:
850B61098, 850B61099,
850A61084, 850B61123,
850B61113, 850B61117,

850B61116, 850A61090,
850A61079, 850A61091,
850B61114, 850A61078,
850A61086; : Catalog number
To be provided, UDI/DI To be
provided, Serial Numbers:
850B61125, 850B61103; m)
NM/CT 850 ES 3/8 inch:
Catalog number 5782013,
UDI/DI To be provided, Serial
Numbers: 85EA67068; Catalog
number 5376204-50, UDI/DI
01008406821407752185EA670
7411210800, Serial Numbers:
85EA67074, 85EA67067,
85EA67073; Catalog number
5376204-50-1, UDI/DI To be
provided, Serial Numbers:
NT3BG1900003BH; Catalog
number H3907AA, UDI/DI To be
provided, Serial Numbers:
85EA67071; Catalog number
H3907AD, UDI/DI Not
Applicable, Serial Numbers:
85EX67007; UDI/DI To be
provided, Serial Numbers:
85EA67069, 85EA67072,
85EA67079, 85EB67084; n)
NM/CT 850 ES 3/8 inch ROW:
Catalog number H3907AD,
UDI/DI Not Applicable, Serial
Numbers: 85EZ67059,
85EA67064, 85EY67034; o)
NM/CT 860 3/8 inch: Catalog
number H3908AD, UDI/DI To be
provided, Serial Numbers:
00000860Z62033; p) NM/CT
860 3/8 inch BJ: Catalog
number H2408AA, UDI/DI To be
provided, Serial Numbers:
NT3CG2000001BH; Catalog
number 5376204-60-1, UDI/DI
Not Applicable, Serial Numbers:
NT3CG2100001BH,
NT3CG1900010BH,
NT3CG2100003BH,
NT3CG1900005BH,
NT3CG1900003BH,
NT3CG2100004BH,
NT3CG1900006BH,
NT3CG2100005BH,
NT3CG2000004BH,
NT3CG1900002BH,
NT3CG2100002BH; q) NM/CT

860 3/8 inch ROW: Catalog number 5782013, UDI/DI To be provided, Serial Numbers: 00000860Y62018; Catalog number H3908AD, UDI/DI Not Applicable, Serial Numbers: 860A62056, 860Y62011, 860A62048, 860Z62039, 860Z62044, 860A62052, 860A62055, 860Y62012, 860Y62022, 860A62054; Catalog number To be provided, UDI/DI Not Applicable, Serial Numbers: NT3CG2000003BH; UDI/DI To be provided, Serial Numbers: 860B62102; r) NM/CT 860 ADVANCE: Catalog number H3908AD, UDI/DI Not Applicable, Serial Numbers: 860Z62045, 860A62064, 860A62061; UDI/DI To be provided, Serial Numbers: 860A62075; Catalog number H3908BB , UDI/DI Not Applicable, Serial Numbers: 8BBB30002, 8BBB30001; s) NM/CT 860 advance 3/8 inch NM Gantry: Catalog number H3908BB, UDI/DI To be provided, Serial Numbers: 8BBB30003, 8BBB30004; t) NM/CT 860 BEYOND: Catalog number H3908BC, UDI/DI Not Applicable, Serial Numbers: 8BCB40001; u) NM/CT 860 beyond 3/8 inch NM Gantry: Catalog number H3908BC, UDI/DI To be provided, Serial Numbers: 8BCB40002; v) NM/CT 860 China for China: Catalog number 5376204-60-1, UDI/DI Not Applicable, Serial Numbers: NT3CG2200004BH, NT3CG2200003BH, NT3CG2200002BH; , UDI/DI To be provided, Serial Numbers: NT3CG2200001BH; w) NM/CT 860 CT 860 3/8 inch: Catalog number 5782013, UDI/DI To be provided, Serial Numbers: 860B62109, 860Z62029, 860B62101, 860B62113; Catalog number H3908AD, UDI/DI Not Applicable, Serial

	<p>Numbers: 860Z62036, 86EZ76001, 860A62053; UDI/DI To be provided, Serial Numbers: 860B62092, 860A62088; x) NM/CT 860 ES 3/8 inch: Catalog number 5782013, UDI/DI To be provided, Serial Numbers: 86EB76005; y) NM/CT 860 ES 3/8 inch ROW: Catalog number H3908AD, UDI/DI Not Applicable, Serial Numbers: 86EA76002; z) NM/CT 850 3/8 inch: Catalog number H3907AA, UDI/DI Not Applicable, Serial Numbers: 850Y61024; aa) NM/CT 850 ES 3/8 inch ROW: Catalog number H3907AH, UDI/DI Not Applicable, Serial Numbers: 85EY67030; bb) NM/CT 860 3/8 inch CH: Catalog number H2408AA, UDI/DI Not Applicable, Serial Numbers: NT3DG1900007BH; cc) XELERIS 4 DR WORKSTATION: Catalog number 5782013, UDI/DI To be provided, Serial Numbers: 850B61124, 850A61094</p>		
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