GE Healthcare

EC DECLARATION OF CONFORMITY

Following the provisions of the Medical Devices Directive 93/42/EEC, Annex II and of the directive 2011/65/EU

We

Manufacturer

GE Healthcare Japan Corporation
7-127, Asahigaoka 4-chome, Hino-shi, Tokyo
191-8503 Japan

EU Authorized Representative

GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France

Manufacturing site

GE Healthcare Japan Corporation
7-127, Asahigaoka 4-chome, Hino-shi, Tokyo
191-8503 Japan

GE Medical Systems, LLC
3000N. Grandview Blvd, Waukesho, WI, 53188 USA

GE Hangwei Medical Systems Co., Ltd.
West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Development Area, Beijing 100176 China

Digitally signed by Chicu Natalia
Date: 2021.07.21 14:07:00 EEST
Reason: MoldSign Signature
Location: Moldova

Declare under our sole responsibility that the device:

Revolution EVO

<X-ray system, diagnostic, computed tomography, full body >

Ref.: Revolution EVO CT system Product Configuration Master

5463926-31PCM, 5463926-32PCM, 5463926-33PCM, 5463926-34PCM

GMDN Code: **37618**

Classification rule (93/42/EC Annex IX): **Rule 10 Class IIb**

To which this declaration relates is in conformity with the requirements of the Medical Devices Directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous or state of the art substances in electrical and electronic equipment.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ *réf.*: **DOC1732895** of the product to which this declaration relates.
  - EC certificate: approval of full quality assurance system (Annex II of the Medical Devices Directive 93/42/EEC) delivered by G-MED (Notified Body No. 0459) / Certificate N°7834
  - Harmonized standards applied on the product to which this declaration relates
- For the directive 2011/65/EU (RoHS)
  - Technical Documentation/DHF Ref./ réf: **DOC1732895**, of the product to which this declaration relates

Tokyo, 6 February 2020

Tomohiro Ito
Sr. Regulatory Affairs Leader

This EC declaration of conformity supersedes the previous declaration dated **25 October 2019.**

Reference of the Declaration: DOC1568331

CONFORM CU ORIGINALUL

ADDENDUM TO THE DECLARATION OF CONFORMITY DOC1568331

Harmonized Standards	
EN 60601-1:2006/A1:2013	EN 60601-2-44:2009/A2:2016
EN 60601-1-2:2015	EN 62304:2006/AC:2008
EN 60601-1-3:2008/A11:2016	EN 62366-1:2015
EN 60601-1-6:2010/A1:2015	EN ISO 10993-1: 2009/AC:2010

CONFORM CU ORIGINALUL

Traducere din limba engleză)

GE

GE Healthcare

DECLARAȚIE DE CONFORMITATE CE

(Care respectă prevederile Directivei Dispozitivelor Medicale 93/42/CEE, Anexa II și ale directivei 2011/65/UE)

Noi

Producătorul
GE Healthcare Japan Corporation
7-127, Asahigaoka 4-chome, Hino-shi, Tokio
191-8503 Japonia

Reprezentant Autorizat UE
GE Medical Systems SCS
283 rue de la Miniere
78530 BUC, Franța

Locația de fabricație
GE Healthcare Japan Corporation
7-127, Asahigaoka 4-chome, Hino-shi, Tokio
191-8503 Japonia

GE medical Systems, LLC
3000 N. Grandview Blvd., Waukesha,
WI, 53188 SUA

GE Hangwei Medical Systems Co., Ltd.
Zona de Vest a Clădirii Nr. 3, No. 1 Yongchang North Road, , Zona de Dezvoltare Economică și Tehnologică, Beijing, 100176, China.

Declarăm sub unica noastră responsabilitate că dispozitivul:

Revolution EVO
Sistem cu raze X, de diagnostic, tomografie computerizată, întregul corp

Ref.: Sistem Revolution EVO CT, Configurația de Bază a Produsului
5463926-31 PCM, 5463926-32 PCM, 5463926-33 PCM, 5463926 – 34PCM

Cod GMDN: **37618**

Regula de clasificare (93/42/CEE Anexa IX): **Regula 10 Clasa IIb**

La care se referă această declarație este în conformitate cu cerințele Directivei Dispozitivelor Medicale 93/42/CEE care i se aplică și cu cerințele directivei 2011/65/UE privind restricția de folosire a anumitor substanțe periculoase la echipamentele electrice și electronice.

Conformitatea se bazează pe următoarele elemente:

- Pentru directiva 93/42/EEC (MDD)
  - Documentația Tehnică/DHF Referitor: **DOC1732895** a produsului la care se referă această declarație.
  - Certificat CE: aprobarea întregului sistem de asigurarea calității (Anexa II a Directivei Dispozitivelor Medicale 93/42/CEE) acordată de G-MED (Organism Notificat Nr. 0459) /Certificat Nr. 7834
  - Standardele armonizate aplicate produsului la care se referă această declarație.
- Pentru directiva 2011/65/UE (RoHS)
  - Documentația Tehnică/DHF Referitor: **DOC1732895** a produsului la care se referă această declarație.

Tokio, 6 februarie 2020

(Semnătură indescifrabilă)
Tomoshiro Ito
Lider Senior Afaceri de Reglementare

Această declarație de conformitate CE anulează declarația anterioară din data de 25 octombrie 2019.
Referința Declarației: DOC1568331

CONFORM CU ORIGINALUL

TENTU ILEANA ENGLEZĂ-RUSĂ AUT 14126

ANEXĂ A DECLARAȚIEI DE CONFORMITATE DOC1568331

Standarde armonizate	
EN 60601-1: 2006/A1: 2013	EN 60601-2-44: 2009/A2: 2016
EN 60601-1-2: 2015	EN 62304: 2006/AC: 2008
EN 60601-1-3: 2008/A11: 2016	EN 62366-1: 2015
EN 60601-1-6: 2010/A1: 2015	EN ISO 10993-1: 2009/AC: 2010

Referința Declarației: DOC1568331

CONFORM CU ORIGINALUL

TENTU ILEANA ENGLEZĂ-RUSĂ AUT. 14126

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 7834 rev. 6**
Délivrée à Paris le 06 novembre 2019
Issued in Paris on November 5th, 2019

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

GE HEALTHCARE JAPAN CORPORATION
7-127, Asahigaoka 4-chome, Hino-shi
TOKYO 191-8503 JAPAN

Catégorie du(des) dispositif(s) / *Device(s) category*

Tomodensitomètre (scanner)

Computed tomography system (scanner)

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P159699, P601195, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P159699, P601195, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **November 5th, 2019 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED

Lionel DREUX
Certification Director

CONFORM CU ORIGINALUL

GMED_1623-F-V6-07-2018

GMED - 7834 rev. 6
Renouvelle le certificat 7834-5

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Tomodensitomètre (scanner) *Computed tomography system (scanner)*	Revolution EVO	IIb
Tomodensitomètre (scanner) *Computed tomography system (scanner)*	Optima CT660	IIb

2 alinéas / *2 indented lines.*

Identification du site couvert et des activités / *Identification of location and activities*

GE HEALTHCARE JAPAN CORPORATION - 7-127, Asahigaoka 4-chome, Hino-shi - TOKYO 191-8503 - JAPAN
Conception, fabrication et contrôle final
Design, manufacture and final control

GMED 0459

Lionel DREUX
Certification Director

CONFORM CU ORIGINALUL

(Traducere din limba engleză)

GMED
GROUPE LNE

CERTIFICAT Nr. 7834 revizia 6
Emis la Paris în data de 05 noiembrie 2019

CERTIFICAT CE
Aprobarea întregului sistem de asigurarea calității
ANEXA II exclusiv secțiunea 4 a Directivei 93/42/EEC privind dispozitivele medicale
Pentru dispozitivele din clasa III, este necesar un certificat de proiectare CE

Producător

GE HEALTHCARE JAPAN CORPORATION
7-127, Asahigaoka 4-chome, Hino-shi
TOKIO 191-8503 JAPONIA

Categoria dispozitivelor

Sistem de tomografie computerizată (scanner)

Vedeți atașamentul pentru informații suplimentare

GMED certifică că, pe baza rezultatelor conținute în dosarul cu numărul de referință P159699, P601195, sistemul calității – pentru proiectarea, fabricarea și inspecția finală – a dispozitivelor medicale menționate aici mai sus respectă cerințele Directivei 93/42/CEE, anexa II exclusiv secțiunea 4.

Valabilitatea prezentului certificat este supusă verificării periodice sau neașteptate.

Data intrării în vigoare: **5 noiembrie 2019 (inclusiv)**
Data expirării: **26 mai 2024 (inclusiv)**

GMED – 7834 revizia 6
Reînnoiește certificatul 7834-5.

Lionel DREUX
Director de Certificare
(Semnătură indescifrabilă)
(Ștampilă indescifrabilă)

CONFORM CU ORIGINALUL

TRADUCĂTOR AUTORIZAT DE MINISTERUL JUSTIȚIEI
TENTU ILEANA
ENGLEZĂ-RUSĂ
AUT. 14126
ROMÂNIA

Anexa certificatului nr. 7834 revizia 6
Dosare nr. P159699, P601195

Identificarea dispozitivelor

Desemnarea dispozitivului/accesorii marcate CE	Referința comercială a dispozitivului sau codul articolului	Clasa DM
Sistem de tomografie computerizată (scanner)	Revolution EVO	IIb
Sistem de tomografie computerizată (scanner)	Optima CT660	IIb

2 alineate

Identificarea locației și activităților

GE HEALTHCARE JAPAN CORPORATION – 7-127, Asahigaoka 4-chome, Hino-shi – TOKIO 191-8503 – JAPONIA

Proiectarea, fabricarea și controlul final

GMED 0459

Lionel DREUX
Director de Certificare
(Semnătură indescifrabilă)
(Ștampilă indescifrabilă)

TRADUCERE AUTORIZATĂ DE MINISTERUL JUSTIȚIEI ROMÂNIA
TENTU ILEANA
ENGLEZĂ-RUSĂ
AUT. 14126

Certificate

TÜVRheinland

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2066093-1

Organization: GE Healthcare Japan Corporation
7-127, Asahigaoka 4-chome
Hino-shi, Tokyo
191-8503 Japan

Scope: Design, development, manufacture, installation and service of computed tomography systems (scanners), ultrasound diagnostic probes and medical software.
Design and development of ultrasound diagnostic devices and systems.
Manufacture of magnetic resonance imaging devices and systems.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150228999-310

Effective date: 2020-12-15

Expiry date: 2023-12-11

Issue date: 2020-12-15

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Balazs Bozsik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

CONFORM CU
ORIGINALUL

Traducere din limba engleză

TÜVRheinland®

Certificat

Sistemul de Management al Calității
EN ISO 13485:2016

Nr. înregistrare:	SX 2066093-1
Organizația:	GE Healthcare Japan Corporation 7-127, Asahigaoka 4-chome Hino-shi, Tokyo 191-8503 Japonia
Domeniul:	Proiectarea, dezvoltarea, fabricarea, instalarea și deservirea sistemelor de tomografie computerizată (scanere), sonde de diagnosticare cu ultrasunete și software medical. Proiectarea și dezvoltarea de dispozitive și sisteme de diagnosticare cu ultrasunete. Fabricarea de dispozitive și sisteme de imagistică cu rezonanță magnetică.

Organismul de certificare TÜV Rheinland LGA Products GmbH certifică faptul că organizația a pus la punct și aplică un sistem de management al calității pentru dispozitivele medicale.
Au fost furnizate dovezi despre faptul că cerințele specificate în standardul menționat mai sus sunt îndeplinite. Sistemul de management al calității este supus supravegherii anuale.

Raport nr.	150228999-310
Data intrării în vigoare:	15.12.2020
Data expirării:	11.12.2023
Data emiterii:	15.12.2020

(*semnătură indescifrabilă*)
(*Ștampilă: TÜV Rheinland LGA Products GmbH*)
Balasz Bozsik
TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg, Germania

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

MINISTERUL JUSTIȚIEI
Traducător Autorizat
MORARU GEORGE
Limba Autorizația nr. 5190/2004

CONFORM CU ORIGINALUL

CERTIFICATE

Extract from certificate #
30724 rev. 5

GMED Certifies that the company :

General Electric Medical Systems Romania S.R.L.
Str. Barbu Vacarescu, nr.
301-311,
Cladirea Lakeview, etaj 3, biroul 1, sector 2
020276 BUCURESTI
ROMANIA

has implemented and maintains a Quality Management System for the activities :

Sales, installation, repairing and servicing of GEHC medical imaging devices, patient monitoring, anaesthesia, ventilation, cardiology, maternal and infant care systems, clinical information systems and associated accessories. Sales of medical equipment and the related services to independent distributors.

This Quality Management System complies with the requirements of the international standard:

ISO 9001 : 2015

The certificate # 30724 rev. 5 is valid until : 2022-01-27

Lionel DREUX
Certification Director

Date : 2019-05-02

(Traducere din limba engleză)

GMED
GROUPE LNE

CERTIFICAT

Extras din certificatul #
30724 rev. 5

GMED certifică că societatea

General Electric Medical Systems Romania S.R.L.
Str. Barbu Văcărescu, nr. 301-311
Clădirea Lakeview, etaj 3, biroul 1, sector 2
020276 BUCUREŞTI
ROMÂNIA

a implementat şi menţine un Sistem de Managementul Calităţii pentru activităţile:

Vânzarea, instalarea, repararea şi service-ul pentru dispozitivele de imagistică medicală GEHC, sistemele de monitorizare a pacienţilor, de anestezie, ventilare, cardiologie, sisteme de îngrijire a mamelor şi noilor născuţi, sistemele de informaţii clinice şi accesoriile asociate.
Vânzarea echipamentelor medicale şi serviciile aferente către distribuitori independenţi.

Acest Sistem de Managementul Calităţii respectă cerinţele standardului internaţonal:

ISO 9001: 2015

Certificatul # 30724 rev. 5 este valabil până la: 2022-01-27

Lionel DREUX
Director de Certificare
(Semnătură indescifrabilă)

Data: 2019-05-02

CONFORM CU ORIGINALUL

TRADUCĂTOR AUTORIZAT DE MINISTERUL JUSTIŢIEI
TENTU ILEANA
ENGLEZĂ-RUSĂ
AUT. 4126
ROMÂNIA

CERTIFICATE

Extract from certificate #
18094 rev. 19

GMED Certifies that the company :

General Electric Medical Systems Romania S.R.L.
Str. Barbu Vacarescu, nr.
301-311,
Cladirea Lakeview, etaj 3, biroul 1, sector 2
020276 BUCURESTI
ROMANIA

has implemented and maintains a Quality Management System for the activities :

Sales, installation, repairing and servicing of GEHC medical imaging devices, patient monitoring, anaesthesia, ventilation, cardiology, maternal and infant care systems, clinical information systems and associated accessories. Sales of medical equipment and the related services to independent distributors.

This Quality Management System complies with the requirements of the international standard:

ISO 13485 : 2016

The certificate # 18094 rev. 19 is valid until : 2022-01-27

Lionel DREUX
Certification Director

Date : 2019-05-02

CONFORM CU ORIGINALUL

(Traducere din limba engleză)

GMED
GROUPE LNE

CERTIFICAT

Extras din certificatul #
18094 rev. 19

GMED certifică că societatea

General Electric Medical Systems Romania S.R.L.
Str. Barbu Văcărescu, nr. 301-311
Clădirea Lakeview, etaj 3, biroul 1, sector 2
020276 BUCUREȘTI
ROMÂNIA

a implementat și menține un Sistem de Managementul Calității pentru activitățile:

Vânzarea, instalarea, repararea și service-ul pentru dispozitivele de imagistică medicală GEHC, sistemele de monitorizare a pacienților, de anestezie, ventilare, cardiologie, sisteme de îngrijire a mamelor și noilor născuți, sistemele de informații clinice și accesoriile asociate.
Vânzarea echipamentelor medicale și serviciile aferente către distribuitori independenți.

Acest Sistem de Managementul Calității respectă cerințele standardului internațonal:

ISO 13485: 2016

Certificatul # 18094 rev. 19 este valabil până la: 2022-01-27

Lionel DREUX
Director de Certificare
(Semnătură indescifrabilă)

Data: 2019-05-02

CONFORM CU ORIGINALUL

TRADUCĂTOR AUTORIZAT DE MINISTERUL JUSTIȚIEI
TENTU ILEANA
ENGLEZĂ-RUSĂ
AUT. 1475

GUVERNUL ROMÂNIEI
COMISIA NAŢIONALĂ PENTRU CONTROLUL ACTIVITĂŢILOR NUCLEARE
Bd. Libertăţii nr. 14, Bucureşti 5
Telefon 021 316 34 76
Fax 021 316 14 36
Operator date cu caracter personal nr. **35647**

AUTORIZAŢIE
PENTRU
DESFĂŞURAREA DE ACTIVITĂŢI ÎN DOMENIUL NUCLEAR
Nr. RR 216 / 2021

În temeiul art. 8 din Legea Nr. 111/1996, republicată, cu modificările şi completările ulterioare, privind desfăşurarea în siguranţă, reglementarea, autorizarea şi controlul activităţilor nucleare, cu Normelor privind cerinţele de bază de securitate radiologică şi al Normelor specifice de securitate radiologică;

Ca urmare a analizării documentaţiei înregistrată la C.N.C.A.N. cu nr. 11780/34074 din 03.12.2020 şi a completărilor ulterioare înregistrate la C.N.C.A.N. cu 1198/27233 din 05.02.2021, 1199/27234 din 05.02.2021,

Constatând că sunt îndeplinite prevederile legale,

COMISIA NAŢIONALĂ PENTRU CONTROLUL ACTIVITĂŢILOR NUCLEARE

AUTORIZEAZĂ

S.C. GENERAL ELECTRIC MEDICAL SYSTEMS ROMÂNIA S.R.L.
din Bucureşti, str. Barbu Văcărescu, nr. 301-311, Clădirea Lake View, Biroul 1, et. 3, sector 2, cod poştal 020276, tel. 0372041543 persoană juridică înregistrată la Oficiul Registrului Comerţului cu nr. J40/3734/2000

SĂ

FURNIZEZE

instalaţii radiologice, în conformitate cu documentaţia prezentată şi prevederile impuse în anexele nr. 1, 2, care fac parte integrantă din prezenta autorizaţie.

Intră în vigoare la data de: 12.02.2021

Expiră la data de: 11.02.2026

PREŞEDINTE,
Gheorghe IONIŢĂ

CONFORM CU ORIGINALUL

ANEXA Nr. 1
la autorizaţia pentru desfăşurarea de activităţi în domeniul nuclear nr. RR 216 / 2021

I. LIMITE:

Prezenta autorizaţie este valabilă pentru instalaţiile radiologice de tomografie computerizată, tip **REVOLUTION EVO**, multi-slices, produse de GE HEALTHCARE JAPAN COR., GE HANGWEI MEDICAL SYSTEMS Co. Ltd.- China, GE MEDICAL SYSTEMS LLC, WAUKESHA – S.U.A., având furnizor autorizat în UE GE MEDICAL SYSTEMS SCS FRANCE si descrise mai jos

1. **Gantry**, cu următoarele caracteristici:
   - dimensiuni: 2050 mm x 1039 mm (lățime x grosime/lungime);
   - greutate: 1620 kg;
   - înclinare: +/- 30^0 , cu viteza de 1°/sec;
   - apertura: 70 cm;
   - distanţa focar-izocentru: 54 cm;
   - distanţa focar-detector: 95 cm;
   - max. SFOV: 50 cm;
   - timp de rotaţie: axial scan: 360° în 0,35; 0,4; 0,5; 0,6; 0,7; 0,8; 0,9; 1,0 şi 2,0 sec./full scan; pentru cine scan: 360° în 0,35; 0,4; 0,5; 0,6; 0,7; 0,8; 0,9; 1,0 sec/full scan, pentru cardiac: 0,35 sec.; "single acquisition cine": max. 120 sec.

care contine:

1.1. **Generatorul de înaltă tensiune/frecvenţă**, (model no. 2371333-6), cu parametrii:
   - înalta tensiune radiogenă: max. 140 kV, selectabilă pentru valorile: 80 kV, 100 kV,120 kV şi 140 kV;
   - intensitatea curentului în tubul RX: max. 600 mA, reglabilă în trepte 10 ÷ 600 mA, cu un increment de 5 mA;
   - puterea maximă: 72 kW;

1.2. **Ansamblul tub RX-cupola, tip PERFORMIX 40 PLUS** (model no. 2137130-X): pentru tubul Rx (model no. 5401074-X):
   - focar dublu, având dimensiunea nominală a petei focale:
     focar mic: 0, 9 mm x 0, 7 mm (conform CEI 60336/2005);
     focar mare: 1, 2 mm x 1, 1 mm (conform CEI 60336/2005).
   - unghiul anodului: 7°;
   - tensiunea aplicată: 80/100/120/140 kV;
   - puterile nominale corespunzatoare celor 2 pete focale: 55,1 kW (focar mare) şi 24 kW (focar mic);
   - 8400 RPM;
   - intensitatea curentului în tubul RX este reglabilă: 10 ÷ 600 mA (cu un increment de 5 mA)

CONFORM CU ORIGINALUL

- capacitatea termică maximă a anodului: 5, 0 MJ (7 MHU);
- puterea maximă disipată a anodului: 1070 kHU/min. (13,2 kW);
- filtrarea minima a ansamblului tub RX-cupolă: echiv. 3, 91 mmAl/ 70kV;
- filtrarea totală: echiv. 4, 90 mm Al/70-75 kV (IEC 60601-1-3/2008);
- capacitatea termică maxima a ansamblului tub RX-cupola: 7,7 MJ (=10,8 MHU).

1.3. **Colimatorul** (max. HVL: 8, 40 mm/140 kVp): model no. 5345001;

1.4. **Sistemul de detectie, digital, tipul CLARITY Detector**: este format din 54272 detectori dispuși pe 64 rânduri cu grosimea egală cu 0,625 mm, având o eficiență de absorbție de 98 %.

1.5. **DAS** (Data Acquisition System): Sistemul de achiziție a datelor CLARITY - cu o frecvență max. 2460 Hz; 861...1968 date/rotație.

1.6. **Dispozitivul cu laser pentru alinierea fasciculului RX**;

1.7. **Xtream Display** ("multi-purpose LCD Display"): pentru informații pacient; parametrii de scanare/poziționare a pacientului; parametrii ECG.

2. **Masa de examinare/scanare pacient, tipurile *VT 1700V și GT 1700V, VT2000,* VT2000,** având dimensiunile:
   - VT 2000x: lățime x lungime: 650 mm x 2910 mm;
   - VT 2000: lățime x lungime: 650 mm x 2910 mm;
   - VT 1700V și tip GT 1700V: lățime x lungime: 650 mm x 2360 mm;

   Posibilitățile de deplasare:
   - Verticală: 480 mm...991 mm (VT1700V și GT 1700V, VT2000); 525 mm...991 mm (VT2000x);
   - Domeniul scanabil (pe verticală): 791 mm ... 991 mm (valabil pentru orice tip);
   - Orizontală: 1745 mm (VT1700V și GT 1700V); 2045 mm (VT2000, VT2000x);
   - Domeniul scanabil (pe orizontală) – axial: 1730 mm (VT1700V și GT 1700V) și 2000 mm (VT2000, VT2000x) și helicoidal: 1580 mm (VT1700V și GT 1700V) și 1890 mm (VT2000, VT2000x).
   - Încărcarea maximă: 227 kg (VT 1700V și GT 1700V, VT 2000) sau 306 kg (VT2000x).

3. **Consola de comandă:**
   - Computer gazdă, cu procesor Dual Intel Xeon E5-2640, 2,5 GHz; 64 bit; RAM: 32 GB DDR3-1333MHz;
   - Procesor de imagine, tip Nvidia Quadro2000 PCI Express 16x;
   - Capacitate de stocare: 300 GB; Scan Data Storage: 5x300GB;
   - DVD-Ram: 9,4 GB; DVD-R/CD-R: 4,7 GB (SVD);
   - Compatibilitate DICOM;
   - Software pentru comandă, achiziție și reconstrucție:
   - *ASIR-V (Adaptive Statistical Iterative Reconstruction-Veo):* technologie de reconstrucție iterativă – care are ca rezultat îmbunătățirea calității imaginii și a detecției imaginilor cu contrast scăzut; reducerea zgomotului (artifact reduction) și a dozei necesare imaginilor de rutină; Organ Dose Modulation (ODM) – program de reducere a dozei/organ în funcție de modulația/variația ("modulation") aplicată tubului RX (de ex. pentru țesuturile superficial/sân); ASIR-V poate reduce doza la pacient în funcție de scopul clinic al examinării, dimensiunile pacientului, locația anatomică și procedura clinică aleasă astfel încât pentru o anumită doză să fie obținută o calitate foarte bună a imaginii digitale pentru zona anatomică examinată (scanată);

- *2 Monitoare color LCD (19 inch/rezolutie: 1280*1024 dots);*

4. *Accesorii: Fantome pentru asigurarea calității:* 20 cm; 48 cm; 35 cm, modele 2144715, 2144721-2 respectiv 2144721; injectoare pentru substanța de contrast (Xtream Injector); UPS.

Caracteristici achiziție imagine digitală:

- matricea de reconstrucție: 512 x 512;
- matricea de vizualizare (display matrix): 1024 x 1024;
- matricea imaginii afișate pe monitor: 1280 x 1024;
- min. DFOV: 5,0 cm;
- moduri de scanare: axială, helicoidala, cine, scout;
- dimensiune pixel: min. 0,10 mm (reconstr. imagini helicoidale); 0,1875 mm (reconstr. imagini axial/cine);
- viteza de deplasare a mesei: 20/39/55/61 (mm/rotație) (în funcție de pitch: 0,516:1; 0,984:1; 1,375:1; 1,531);
- grosimea secțiunii CT: 0,625 – 10 mm (0,625/1,250/2,50/3,75/5,00/7,50/10,00);
- pitch helicoidal: 0,516…1,531; cardiac pitch: 0,16…0,325;
- domeniul numerelor CT: ± 31743 HU;
- maximum DFV (Display Field of View): 32 cm pediatric cap/corp; 32 cm cap/corp; 50 cm corp; 32 cm cardiac sau 50 cm;
- grosimi slices în reconstrucție (în funcție de colimare):
  - 40 mm: 64 x 0,625 mm – recon. slice: 128 i – 0,625 mm; 64 i – 0,625 mm; 32 i-1,25 mm; 16 i-2,50 mm; 8i – 5 mm; 4i – 10 mm;
  - 20 mm: 32 x 0,625 mm – recon. slice: 32 i-0,625 mm; 16i-1,25 mm; 8 i-2,50 mm; 4i-5 mm; 2i-10 mm;
  - 10 mm:16 x 0,625 mm – recon. slice: 16i-0,625 mm; 8i-1,25 mm; 4i-2,50 mm; 2i-5 mm; 1i-10 mm;
  - 5 mm:8 x 0,625 mm- recon. slice: 4i-1,250 mm; 2i-2,50 mm; 1i-5 mm;
  - 2,50 mm:4 x 0,625 mm-recon. slice: 2i-1,25 mm și 1 i-2,50 mm;
  - 1,25 mm:2 x 0,625 mm –recon. slice: 1i-1,250 mm.
- indicele de doză CT (120kV, 240 mAs, 0,5+1 s, grosimea secțiunii:10 mm):

Tehnica de examinare	$CTDI_{VOL}$ (mGy/100mAs), 0,984:1 pitch
Cap	17,00
Corp	8, 80

- Instalația radiologică, tip **REVOLUTION EVO** afișează valorile mărimilor: $CTDI_{vol}$ (mGy), DLP (mGy x cm) și Dose Efficiency, în timpul scanărilor.

II. Clasificarea instalațiilor radiologice pentru tomografie computerizată, **tip REVOLUTION EVO: II b**, în conformitate cu reglementarile Directivei Europene pentru aparatura medicală nr. 93/42/EEC/14.06.1993.

CONFORM CU ORIGINALUL

III. Producătorul deține pentru instalațiile radiologice de tomografie computerizată tipul **REVOLUTION EVO:** *EC CERTIFICATE no. 7834* (rev. 6) emis în data de 05.11.2019, valabil până în data de 26.05.2024 de catre *LNE/G-med* – organism notificat in UE având nr. de identificare: *0459*.

IV. Conform "Declarației de Conformitate CE" a producătorului **GENERAL ELECTRIC MEDICAL SYSTEMS** instalațiile radiologice pentru tomografie computerizată, tip REVOLUTION EVO, îndeplinesc cerințele standardelor:

- **IEC/EN 60601-1: 2006**: "*Medical electrical equipment. Safety requirements for Medical Electrical Systems*".
- **IEC/EN 60601-1-3:2008:** "*Medical electrical equipment. Collateral standard. General requirements for radiation protection in diagnostic X-ray equipments*".
- **IEC/EN 60601-1-4:2001:** "*Medical electrical equipment. Collateral standard. General requirements for safety; Programmable Electrical Medical Systems*".
- **IEC/EN 60601-2-44:2009:** "*Particular requirements for the Safety of X-Ray Equipment for Computed Tomography*".
- **IEC/EN 60601-1-6:2010:** "*Medical Electrical Equipments – Part 1-6: General requirements for basic safety and essential performance*".

Lista societăților care au acceptul furnizorului să comercializeze instalațiile radiologice specificate la Capitolul I, în conformitate cu art. 29, alin. (1) lit. a) din Normele privind procedurile de autorizare, publicate în M.Of. nr. 576 bis/2017:

1. *S.C. MEDIST IMAGING & P.O.C. SRL*
2. *S.C. MEDIST S.A.*
3. *DUCOS TRADING SRL*
4. *MINIMED SOLUTIONS SRL*
5. *EDITRONIC INTERNATIONAL SRL*

II. CONDITII:

1. Instalațiile radiologice vor fi furnizate numai de către unități autorizate de C.N.C.A.N. conform Legii nr.111/1996, republicată, cu modificările și completările ulterioare, privind desfășurarea în siguranță, reglementarea, autorizarea și controlul activităților nucleare.
2. La livrare instalațiile radiologice vor fi însoțite de documentația tehnică aferentă, instrucțiuni de utilizare în limba română, certificat de calitate și copia autorizației de furnizare fără ASR valabilă la data furnizării.
3. Instalarea, montarea, punerea în funcțiune, mentenanța (întreținerea și verificarea), inclusiv service-ul se vor face numai de către firme autorizate de C.N.C.A.N. conform Legii nr.111/1996, republicată, cu modificările și completările ulterioare, privind desfășurarea în siguranță, reglementarea, autorizarea și controlul activităților nucleare.

PREȘEDINTE

CONFORM CU ORIGINALUL

4. Conform specificaţiilor producătorului, instalaţia radiologică de tomografie computerizată tipul REVOLUTION EVO (gantry + masa pentru examinare pacient) este recomandat să aibă o suprafaţă minimă:
S ≈ 22, 3 m² (L x l = 5,56 m x 4,00 m), în cazul mesei de examinare tip VT1700V,
S ≈ 5563 mm x 3327 mm (L x l), în cazul mesei de examinare tip GT 1700V; şi
S ≈ 25, 0 m² (L x l = 6,23 m x 4,00 m), în cazul meselor de examinare tipurile VT2000, VT2000x.

Consola de comandă a instalaţiei de tomografie computerizată tipul REVOLUTION EVO se instalează într-o cameră separată de camera de expuneri RX; camera de comandă fiind adiacentă camerei de expuneri RX, conform recomandărilor date de producător.

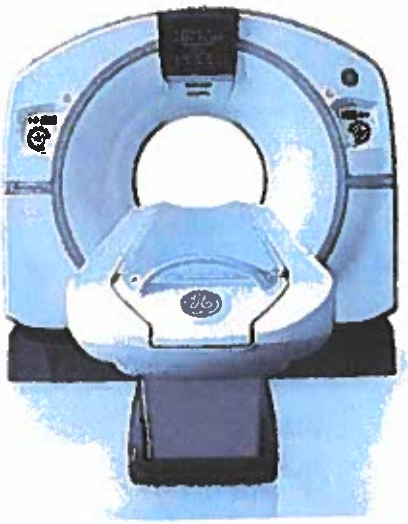
5. Utilizarea instalaţiilor radiologice este permisă numai persoanelor legal constituite şi autorizate de către C.N.C.A.N., conform Legii nr.111/1996, republicată, cu modificările şi completările ulterioare, privind desfăşurarea în siguranţă, reglementarea, autorizarea şi controlul activităţilor nucleare
6. În conformitate cu prevederile art. 15, alin. (1) din Normele privind procedurile de autorizare, publicate în M.O. nr. 576 bis/2018 autorizarea instalaţiilor radiologice tip **REVOLUTION EVO** se face pe faze de realizare, prin amplasare-construcţie şi utilizare.
7. Furnizorul este obligat să asigure, la cerere, dezafectarea instalaţiei radiologice.
8. Se va menţine evidenţa livrărilor efectuate şi a destinatarilor acestora, precizând pentru fiecare instalaţie radiologică: seria, numărul, anul de fabricaţie şi producătorul.
9. Se va notifica, în scris, la C.N.C.A.N. fiecare operaţiune de furnizare, în termen de 48 de ore şi se va preciza beneficiarul acesteia.
10. Titularul de autorizaţie are obligaţia să anunţe de îndată orice eveniment radiologic la Centrul de Notificare al C.N.C.A.N. (telefon: 021/351.50.80, fax: 021/351.50.88).

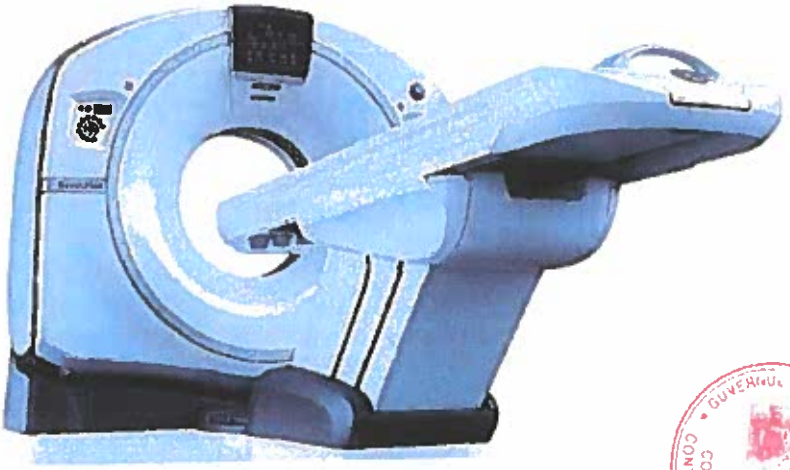
III. PERSOANA RESPONSABILĂ: **AURA GICA**

CONFORM CU ORIGINALUL

ANEXA Nr. 2
la autorizaţia pentru desfăşurarea de activităţi în domeniul nuclear nr. RR 216 / 2021

INSTALAŢIA RADIOLOGICĂ DE TOMOGRAFIE COMPUTERIZATĂ
TIP REVOLUTION EVO





GUVERNUL ROMÂNIEI
COMISIA NAȚIONALĂ PENTRU CONTROLUL ACTIVITĂȚILOR NUCLEARE
PREȘEDINTE

CONFORM CU ORIGINALUL

GUVERNUL ROMÂNIEI
COMISIA NAŢIONALĂ PENTRU CONTROLUL ACTIVITĂŢILOR NUCLEARE
Bd. Libertăţii nr. 14, Bucureşti 5
Telefon 021 316 34 76
Fax 021 316 14 36
Operator date cu caracter personal nr. **35647**

AUTORIZAŢIE
PENTRU
DESFĂŞURAREA DE ACTIVITĂŢI ÎN DOMENIUL NUCLEAR
Nr. RC 2361 / 2020

În temeiul art. 8 din Legea Nr. 111/1996, republicată, cu modificările şi completările ulterioare, privind desfăşurarea în siguranţă, reglementarea, autorizarea şi controlul activităţilor nucleare, al Normelor privind cerinţele de bază de securitate radiologică şi al Normelor specifice de securitate radiologică,

Ca urmare a analizării documentaţiei înregistrată la C.N.C.A.N. cu nr. 9941/32916 din 12.10.2020 şi a completărilor ulterioare înregistrate la C.N.C.A.N. cu nr. 10653/33373 din 29.10.2020, nr. 10900/33529 din 04.11.2020,

Constatând că sunt îndeplinite prevederile legale,

COMISIA NAŢIONALĂ PENTRU CONTROLUL ACTIVITĂŢILOR NUCLEARE

AUTORIZEAZĂ

S.C. GENERAL ELECTRIC MEDICAL SYSTEMS ROMÂNIA S.R.L.

din Bucureşti, str. Barbu Văcărescu, nr. 301-311, Clădirea Lakeview, Biroul 1, et. 3, sector 2, tel. 0372/044.543
persoană juridică înregistrată la Oficiul Registrului Comerţului cu nr. J40/3731/19.04.2000 şi CUI 12924986

să
MANIPULEZE

surse de radiaţii şi instalaţii radiologice, în cadrul:

Formaţiei de service instalaţii radiologice

situată în: Bucureşti, str. Barbu Văcărescu, nr. 301-311, Clădirea Lakeview, Biroul 1, et. 3, sector 2, *tel. 0372074511*

în conformitate cu documentaţia prezentată şi prevederile impuse în anexa nr. 1, care face parte integrantă din prezenta autorizaţie.

Intră în vigoare la data de: 24.12.2020

Expiră la data de: 24.06.2023

PREŞEDINTE,
Gheorghe IONIŢĂ

ANEXA Nr. 1
la autorizaţia pentru desfăşurarea de activităţi în domeniul nuclear nr. RC 2361 / 2020
privind *manipularea instalaţiilor radiologice*

I.LIMITE:

Activitatea de manipulare presupune în condiţiile specifice ale acestei autorizaţii instalarea, montarea, mentenanţa (întreţinerea şi verificarea), repararea şi dezmembrarea instalaţiilor radiologice la sediul beneficiarilor autorizaţi de CNCAN în conformitate cu prevederile Legii nr. 111/1996, republicată, cu modificările şi completările ulterioare, privind desfăşurarea în siguranţă, reglementarea, autorizarea şi controlul activităţilor nucleare.

Manipularea este valabilă pentru următoarele tipuri de instalaţii radiologice, în conformitate cu prevederile art.1 din Ordinul nr. 176/2017 al Preşedintelui CNCAN şi publicat în M.Of. nr. 709/2017.

INSTALAŢIILE RADIOLOGICE produse de General Electric Medical Systems

1. **Echipamente de tomografie computerizată**: HiSpeed XI Series ADVANCE, Sytec Synergy, CT LIGHTSPEED PRO ADVANCED, BrightSpeed (4, 8, 16), LIGHTSPEED (VCT, VCT Select), Discovery CT 750HD (64 şi 128 slices), Discovery 590RT, Optima CT 520 (16 slices), Optima CT 660, Optima CT 540, CT 9000, Optima CT 580RT, Optima CT 580W, CT Pace, CT/e, CT Sytec 3000i, CT ProSpeed Power Highlight, BrightSpeed Family (Excel, Edge, Elite), LIGHTSPEED RT (4,16, Xtra), Brivo CT 325, Revolution Discovery CT, Revolution Evo, Discovery RT, Revolution Act, Revolution CT, Revolution Frontier, Revolution Frontier ES, CT Revolution APEX, CT Revolution MAXIMA, Revolution CT ES.
2. **Instalaţii de röntgendiagnostic pentru mamografie**: Alpha (ST, RT), Performa, Senograph (DMR, DMR+, 700T, 800, 2000D, DS, Essential), Senovision, Diamond, Senographe Crystal, Senographe Pristina.
3. **Instalaţii de röntgendiagostic fixe**: Prestige SI, Proteus XR/e, Proteus XR/Ie, Innova Biplane, PRECISION XR/I, RXi versiunea e, RXi-D, BRIVO DR-F, BRIVO XR 575, Discovery XR 650, Discovery XR 656, Discovery XR656 HD, Definium AMX 700, Radiography and Fluoroscopy Connexity, Innova Serie IGS 520, IGS 530, IGS 540, Innova Serie IGS 620, IGS 630, XR LEGEND 210, Innova 2100, Innova 2121, Definium (6000, 8000), XR 6000, Optima XR646, Proteus XR/a, Optima IGS 320, Optima IGS 330, Innova IGS 5, Innova IGS 6, Innova IGS 7, Innova IGS 7 OR, Discovery IGS 7, Discovery IGS 7 OR, Discovery RF180, Optima XR646 HD.

4. **Instalaţii de röntgendiagnostic mobile**: OEC (9800 PLUS, 9900), SERIES 7700, COMPACT 7700, OEC Fluorostar, INNOVA (3100, 3131, 4100), TMX+, TMXR+, C-arm Brivo OEC 850, BRIVO OEC 865/715/785, OEC 9800, XR EverView 7500, OEC FlexiView (6800, 8800), STENOSCOP 9000, Optima XR220amx, OEC ONE, OEC ELITE CFD&II, OEC MiniView.
5. **Instalaţii de osteodensitometrie:** Lunar, Hologic QDR 4500C, iDXA, Prodigies Series (Prodigy, Prodigy Advance, Prodigy Pro, Prodigy Primo).
6. **Instalaţii de medicină nucleară** model gamacameră: MILLENIUM M Series, INFINIA, INFINIA HAWKEYE, Discovery NM 530c, Millenium VG Hawkeye.
7. **Instalaţii de medicină nucleară tip SPECT/CT**: Discovery NM/CT 670, Discovery NM 630, Optima NM/CT 640, Brivo NM 615, Discovery NM/CT 670 Pro, Discovery NM/CT 670 DR, Discovery NM/CT 670 CZT, Discovery NM/CT 670 DR, TRACEIab FX2 C, NM/CT 850, NM/CT 860, NM/CT 870 DR, NM/CT 870 CZT, NM 830.
8. **Instalaţii PET/CT**: DISCOVERY (ST 4, ST 8, ST 16, STE 8, STE 16, VCT), Discovery PET/CT 600 Family (8 slices, 16 slices, 16 slices Elite), Discovery PET/CT 690 Elite, Discovery PET/CT 690 FX, Discovery PET/CT 610, 710, Discovery ML, Discovery IQ, Discovery MI Digital Ready, OPTIMA PET/CT 560.
9. **FASTlab Synthesizer**
10. **Ciclotron MINItrace Qilin Tracer, Ciclotron GENtrace, Ciclotron PETtrace 800 family (840, 860, 880, 890).**

2. APARATURA DOZIMETRICĂ:

- Monitor universal de radiaţii tip Umo LB 123 seria nr. 157613-3262, ASR nr. SM 24/2004.
- Dozimetru tip DIADOS seria nr. 11003-1282, ASR nr. ŞV 131/2001.
- Dozimetru VICTOREEN 451B seria nr. 133, ASR nr. ST 007/2004.
- Dozimetre individuale cu citire directă şi prag de alarmare tip DMC 2000 X (8 bucăţi), seriile nr. 273659, 273832, 288469, 287413, 287771, 287830, 287837 şi 288128, ASR nr. VI 095/2010

II. CONDIŢII:

1. Începând cu data emiterii prezentei autorizaţii de manipulare, autorizaţia nr. RC 1830/2020 îşi încetează valabilitatea.

2. Se vor revizui procedurile de lucru pentru activităţile de manipulare (instalare-montare, mentenanţă, reparare, dezmembrare) a instalaţiei radiologice tip Azurion 5. Procedurile vor fi vizate de către un expert în protecţie radiologică domeniul GR, specialitatea manipulare.
Termen: 01.02.2021

3. Activităţile de manipulare ale instalaţiilor radiologice tip ciclotron menţionate la punctul **10** se vor efectua numai cu asistenţă tehnică de la producător şi se va documenta corespunzător

4. În situaţia în care în urma verificării unei instalaţii radiologice se constată că aceasta nu corespunde se eliberează un buletin de verificare cu concluzia "instalaţia nu corespunde", se comunică utilizatorului neconformitatea constatată şi se opreşte instalaţia. Aceste situaţii se notifică de îndată la CNCAN.

5. După remedierea neconformităţii constatate, de către o firmă autorizată să repare aceste tipuri de instalaţii, se vor efectua testele de acceptanţă de către firma care a efectuat reparaţia, aceasta urmând să emită un nou buletin de verificare tehnică şi să ateste faptul că instalaţia corespunde.

6. Titularul de autorizaţie are obligaţia să anunţe de îndată orice eveniment radiologic la Centrul de Notificare al CNCAN (telefon: 021/351.50.89, fax: 021/351.50.88)

7. În afara condiţiilor generale din Normele privind cerinţele de bază de securitate radiologică şi din Normelor privind procedurile de autorizare este necesar să se respecte următoarele cerinţe specifice:

INSTALARE MONTARE:

a) Se vor instala-monta numai instalaţiile radiologice pentru care s-a obţinut în prealabil autorizaţia de securitate radiologică (ASR). Pentru instalaţiile procurate după data de 01.01.2007, care nu au ASR, proprietarul instalaţiei trebuie să facă dovada achiziţionării de la un furnizor autorizat de CNCAN sau a faptului că a notificat la CNCAN intenţia de aprovizionare a instalaţiei conform Ordinului nr. 181/2006 al Preşedintelui CNCAN, dacă aceasta a fost achiziţionată direct de la un furnizor extern.

b) Instalaţiile a căror utilizare nu este supusă regimului de autorizare prin înregistrare, se vor monta numai în spaţii (amenajări) pentru care s-au obţinut în prealabil autorizaţii de amplasare şi construcţie emise de CNCAN., valabile, cu respectarea eventualelor condiţii impuse prin autorizaţie.

c) Montarea instalaţiilor radiologice a căror utilizare este supusă regimului de autorizare prin înregistrare se va face în condiţiile prevăzute de normele specifice în vigoare.

d) Instalaţiile radiologice a căror utilizare se exceptează de la autorizare, în conformitate cu prevederile Normele privind cerinţele de bază de securitate radiologică, se vor monta conform cerinţelor producătorului.

CONFORM CU ORIGINALUL

e) Se vor respecta instrucţiunile de instalare-montare emise de producător pentru fiecare tip de instalaţie. Se vor utiliza sculele şi aparatura de măsură şi control recomandate de producător în cazurile în care instrucţiunile de instalare-montare specifică acest lucru.

f) Se va instrui personalul beneficiarului în manipularea aparatului asigurându-se, în acelaşi timp, ca beneficiarul să dispună de instrucţiunile de utilizare (operare) în limba română şi de manualul de întreţinere.

g) Se va demonstra practic, în faţa beneficiarului, buna funcţionare a aparatului, eficacitatea măsurilor de radioprotecţie luate şi încadrarea în prevederile Normelor privind radioprotecţia persoanelor în cazul expunerilor medicale la radiaţii ionizante.

h) Se va emite un buletin de verificare a parametrilor instalaţiei în conformitate cu instrucţiunile producătorului. Se va emite un buletin chiar şi în cazul în care instrucţiunile producătorului nu prevăd verificarea după montare; buletinul va demonstra existenţa şi buna funcţionare a elementelor care condiţionează securitatea radiologică a instalaţiei. O copie a acestui buletin se va anexa de către beneficiar la documentaţia de funcţionare.

i) Se va ţine evidenţa instalaţiilor la care s-a făcut instalarea-montarea şi a beneficiarilor şi se va comunica anual la CNCAN.

MENTENANŢĂ (ÎNTREŢINERE ŞI VERIFICARE):

a) Se vor executa activităţile de mentenanţă pentru aparatele pentru care există autorizaţie de utilizare valabilă sau certificat de înregistrare valabil emis de CNCAN şi pentru cele care, prin autorizaţia de securitate radiologică sau prin autorizaţia de furnizare, sunt exceptate de la autorizarea utilizării.

b) Se vor executa numai acele activităţi de mentenanţă care sunt specificate de producător în manualul de întreţinere al produsului respectiv.

c) Se vor consemna operaţiunile executate într-un registru de evidenţă păstrat de beneficiar pentru fiecare aparat.

d) Se va ţine evidenţa instalaţiilor radiologice la care s-a făcut mentenanţa şi a beneficiarilor şi se va comunica anual la CNCAN.

REPARARE:

a) Se vor efectua toate activităţile de reparare conform manualelor de service şi reparare furnizate de producător.

b) Pentru instalaţiile care nu sunt exceptate de la autorizarea utilizării se vor efectua activităţi de reparare numai dacă unităţile sunt autorizate de CNCAN.

CONFORM CU ORIGINALUL

c) Nu se vor face modificări la instalaţiile radiologice, de natură a afecta securitatea radiologică, asigurându-se măsurile de radioprotecţie.

d) Se vor înlocui piesele defecte ale unei instalaţii radiologice numai cu componente originale sau compatibile, recomandate de producător.

e) Nu se vor modifica, schimba sau îndepărta etichetele sau semnele de avertizare puse de producător pe instalaţiile radiologice.

f) După reparare, se vor face reglajele necesare pentru a aduce instalaţia la parametrii de funcţionare declaraţi de producător în specificaţia tehnică a aparatului.

g) Se va elibera un buletin de verificare a instalaţiei după reparare, verificându-se parametrii de funcţionare stabiliţi de producător în specificaţia tehnică a aparatului. O copie a acestui buletin se va anexa la documentaţia de funcţionare a instalaţiei radiologice.

h) Se vor consemna operaţiile executate într-un registru de evidenţă pentru fiecare aparat.

i) Se va menţine un sistem de management al calităţii în activitatea desfăşurată.

j) Se va ţine evidenţa instalaţiilor radiologice la care s-a făcut repararea şi a beneficiarilor şi se va comunica anual la CNCAN.

k) În cazul schimbării generatoarelor de radiaţii la instalaţiile menţionate la capitolul I Limite din prezenta autorizaţie, se va notifica de îndată la CNCAN acest lucru.

III. PERSONALUL CU RESPONSABILITĂŢI:

Responsabil cu protecţia radiologică

- **SÎNGEORZAN GEORGE Nr. permis 720/2020**
- **GORGAN OVIDIU – ADRIAN Nr. permis 1114/2020**

IV. CATEGORIA DE RISC RADIOLOGIC: 2

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂŢII
AGENŢIA NAŢIONALĂ A MEDICAMENTULUI
SI A DISPOZITIVELOR MEDICALE
Str. Av. Sănătescu nr. 48, sector 1, 011478 Bucureşti
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

AVIZ DE FUNCŢIONARE
Nr. 5778 din 07.01.2019

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătăţii, republicată, cu modificarile si completarile ulterioare şi în baza documentaţiei înaintate, Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale avizează funcţionarea unităţii

GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

cu sediul social în Bucuresti, Str. Barbu Vacarescu nr. 301-311, cladirea Lakeview, biroul 1, etaj 3, sectorul 2 şi puncte de lucru în:
-Bucuresti, Str. Barbu Vacarescu nr. 301-311, cladirea Lakeview, biroul 1, etaj 3, sectorul 2 – *activitate de reparare, mentenanţă şi punere în funcţiune/instalare pentru dispozitive medicale*
-Magurele, Str. Sulfinei nr. 96, judetul Ilfov – *activitate de distributie si depozitare dispozitive medicale*
pentru activităţi de:

import dispozitive medicale | ~~DA~~ | NU | ;

distribuţie dispozitive medicale | DA | ~~NU~~ | ;

depozitare dispozitive medicale | DA | ~~NU~~ | ;

protezare | ~~DA~~ | NU | : ☐ **ortopedică;** ☐ **auditivă;** ☐ **alte tipuri;**

optică medicală | ~~DA~~ | NU | ;

reparare, mentenanţă şi punere în funcţiune/instalare | DA | ~~NU~~ |

pentru dispozitive medicale din urmatoarele domenii:

-diagnostic si tratament cu radiatii (conform autorizatiei CNCAN in vigoare);

-ATI (monitoare functii vitale, aparate de ventilatie artificiala, aparate de anestezie);

-imagistica medicala (RMN-uri).

Unitatea este distribuitor al producătorilor:

Nume producator	Tara	N	SH	CR
AGFA HEALTHCARE NV	BELGIA	Da		
CODONICS INC.	S.U.A.	Da		
DATEX OHMEDA INC.	S.U.A.	Da		
EIZO GMBH	GERMANIA	Da		
GE BE PRIVATE LIMITED	INDIA	Da		
GE HANGWEI MEDICAL SYSTEMS CO.LTD	CHINA	Da		
GE HEALTHCARE (TIANJIN) COMPANY LIMITED	CHINA	Da		
GE HEALTHCARE AUSTRIA GMBH & CO OG	AUSTRIA	Da		
GE HEALTHCARE COILS	S.U.A.	Da		
GE HEALTHCARE FINLAND OY	FINLANDA	Da		
GE HEALTHCARE GMBH	GERMANIA	Da		
GE HEALTHCARE JAPAN CORPORATION	JAPONIA	Da		
GE HEALTHCARE SUA	S.U.A.	Da		
GE HUALUN MEDICAL SYSTEMS CO.LTD	CHINA	Da		
GE HUNGARY KFT	UNGARIA	Da		
GE MEDICAL SYSTEMS (CHINA) CO.LTD	CHINA	Da		
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC.	S.U.A.	Da		
GE MEDICAL SYSTEMS ISRAEL LTD	ISRAEL	Da		
GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	ISRAEL	Da		
GE MEDICAL SYSTEMS LLC	S.U.A.	Da		
GE MEDICAL SYSTEMS SCS	FRANTA	Da		
GE MEDICAL SYSTEMS ULTRASOUND & PRIMARY CARE DIAGNOSTICS LLC	S.U.A.	Da		
GE OEC MEDICAL SYSTEMS GMBH	GERMANIA	Da		
GE OEC MEDICAL SYSTEMS INC	S.U.A.	Da		
GE ULTRASOUND COREEA LTD	COREEA	Da		
GE VINGMED ULTRASOUND AS	NORVEGIA	Da		
GENERAL MEDICAL MERATE S.P.A.	ITALIA	Da		
IMAGE DIAGNOST INTERNATIONAL	GERMANIA	Da		
MEDRAD INC.	S.U.A.	Da		
MIPM - MAMMENDORFER INSTITUT FUR PHYSIK UND MEDIZIN GMBH	GERMANIA	Da		
NEMOTO KYORINDO CO.LTD	JAPONIA	Da		
OHMEDA MEDICAL A DIVISION OF DATEX - OHMEDA INC.	S.U.A.	Da		
PARALLEL DESIGN SAS	FRANTA	Da		

Nume producator	Tara	N	SH	CR
WIPRO GE HEALTHCARE PRIVATE LTD	INDIA	Da		

Unitatea este reprezentant autorizat în Uniunea Europeană al producătorului:

Nu este cazul.

Orice modificare a condiţiilor stabilite prin reglementările Agenţiei Naţionale a Medicamentului şi a Dispozitivelor Medicale, care au stat la baza avizării, atrage anularea prezentului aviz de funcţionare.

Valabilitatea prezentului aviz poate fi verificata prin solicitare scrisa adresata Agenţiei Naţionale a Medicamentului şi a Dispozitivelor Medicale.

PREŞEDINTE,

ADRIANA COTEL

MINISTERUL SĂNĂTĂŢII • AGENŢIA NAŢIONALĂ A MEDICAMENTULUI ŞI A DISPOZITIVELOR MEDICALE PREŞEDINTE

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂŢII
AGENŢIA NAŢIONALĂ A MEDICAMENTULUI
ŞI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu, nr. 48, Sector 1, 011478 Bucureşti
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

ANEXA din data 29.10.2019
LA AVIZUL DE FUNCŢIONARE
Nr. 5778/07.01.2019 al GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătăţii, republicata şi în baza documentaţiei înaintate, Avizul de functionare nr. 5778/07.01.2019 se completează după cum urmează:

Urmare a raportului de evaluare nr 851/21.10.2019 se extinde avizarea functionarii unitatii cu activitatea de reparare, mentenanta si punere in functiune /instalare pentru dispozitive medicale din urmatoarele domenii :

- ATI (incubatoare nou nascuti – incubatoare inchise, hibride; incalzitoare nou nascuti – incubatoare deschise, mese radiante; lampi de fototerapie, dispozitive de resuscitare STAR)

Prezentul document este valabil numai însoţit de avizul iniţial.

PRESEDINTE,

Marius Daniel ŞIŞU

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu, nr. 48, Sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

ANEXA din data 22.11.2019
LA AVIZUL DE FUNCȚIONARE
Nr. 5778/07.01.2019 al GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătăţii, republicata şi în baza documentaţiei înaintate, Avizul de functionare nr. 5778/07.01.2019 se completează după cum urmează:

Unitatea este distribuitor al producatorilor:

Nume producator	Tara	N	SH	CR
AGFA HEALTHCARE NV	BELGIA	Da		
CODONICS INC.	S.U.A.	Da		
DATEX OHMEDA INC.	S.U.A.	Da		
EIZO GMBH	GERMANIA	Da		
GE BE PRIVATE LIMITED	INDIA	Da		
GE HANGWEI MEDICAL SYSTEMS CO.LTD	CHINA	Da		
GE HEALTHCARE (TIANJIN) COMPANY LIMITED	CHINA	Da		
GE HEALTHCARE AUSTRIA GMBH & CO OG	AUSTRIA	Da		
GE HEALTHCARE COILS	S.U.A.	Da		
GE HEALTHCARE FINLAND OY	FINLANDA	Da		
GE HEALTHCARE GMBH	GERMANIA	Da		
GE HEALTHCARE JAPAN CORPORATION	JAPONIA	Da		
GE HEALTHCARE SUA	S.U.A.	Da		
GE HUALUN MEDICAL SYSTEMS CO.LTD	CHINA	Da		
GE HUNGARY KFT	UNGARIA	Da		
GE MEDICAL SYSTEMS (CHINA) CO.LTD	CHINA	Da		
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC.	S.U.A.	Da		
GE MEDICAL SYSTEMS ISRAEL LTD	ISRAEL	Da		
GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	ISRAEL	Da		

Nume producător	Țara	N	SH	CR
GE MEDICAL SYSTEMS LLC	S.U.A.	Da		
GE MEDICAL SYSTEMS SCS	FRANTA	Da		
GE MEDICAL SYSTEMS ULTRASOUND & PRIMARY CARE DIAGNOSTICS LLC	S.U.A.	Da		
GE OEC MEDICAL SYSTEMS GMBH	GERMANIA	Da		
GE OEC MEDICAL SYSTEMS INC	S.U.A.	Da		
GE ULTRASOUND COREEA LTD	COREEA	Da		
GE VINGMED ULTRASOUND AS	NORVEGIA	Da		
GENERAL MEDICAL MERATE S.P.A.	ITALIA	Da		
IMAGE DIAGNOST INTERNATIONAL	GERMANIA	Da		
MEDRAD INC.	S.U.A.	Da		
MIPM - MAMMENDORFER INSTITUT FUR PHYSIK UND MEDIZIN GMBH	GERMANIA	Da		
NEMOTO KYORINDO CO.LTD	JAPONIA	Da		
OHMEDA MEDICAL A DIVISION OF DATEX - OHMEDA INC.	S.U.A.	Da		
PARALLEL DESIGN SAS	FRANTA	Da		
ULRICH GMBH & CO KG	GERMANIA	Da		
WIPRO GE HEALTHCARE PRIVATE LTD	INDIA	Da		

Prezentul document este valabil numai însoţit de avizul iniţial.

PRESEDINTE,

Marius Daniel ŞIŞU

SI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 Bucureşti
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

ANEXA din data 09.07.2020
LA AVIZUL DE FUNCŢIONARE
Nr. 5778/07.01.2019 al GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătăţii, republicata şi în baza documentaţiei înaintate, Avizul de functionare nr. 5778/07.01.2019 se completează după cum urmează:

Unitatea este distribuitor al producatorilor:

Nume producator	Tara
AGFA HEALTHCARE NV	BELGIA
CODONICS INC.	S.U.A.
DATEX OHMEDA INC.	S.U.A.
EIZO GMBH	GERMANIA
GE BE PRIVATE LIMITED	INDIA
GE HANGWEI MEDICAL SYSTEMS CO.LTD	CHINA
GE HEALTHCARE (TIANJIN) COMPANY LIMITED	CHINA
GE HEALTHCARE AUSTRIA GMBH & CO OG	AUSTRIA
GE HEALTHCARE COILS	S.U.A.
GE HEALTHCARE FINLAND OY	FINLANDA
GE HEALTHCARE GMBH	GERMANIA
GE HEALTHCARE JAPAN CORPORATION	JAPONIA
GE HEALTHCARE SUA	S.U.A.
GE HUALUN MEDICAL SYSTEMS CO.LTD	CHINA
GE HUNGARY KFT	UNGARIA
GE MEDICAL SYSTEMS (CHINA) CO.LTD	CHINA
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC.	S.U.A.
GE MEDICAL SYSTEMS ISRAEL LTD	ISRAEL
GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	ISRAEL
GE MEDICAL SYSTEMS LLC	S.U.A.
GE MEDICAL SYSTEMS SCS	FRANTA
GE MEDICAL SYSTEMS ULTRASOUND & PRIMARY CARE DIAGNOSTICS LLC	S.U.A.
GE OEC MEDICAL SYSTEMS GMBH	GERMANIA
GE OEC MEDICAL SYSTEMS INC	S.U.A.
GE ULTRASOUND COREEA LTD	COREEA
GE VINGMED ULTRASOUND AS	NORVEGIA
GENERAL MEDICAL MERATE S.P.A.	ITALIA

Nume producator	Tara
IMAGE DIAGNOST INTERNATIONAL	GERMANIA
KONICA MINOLTA INC.	JAPONIA
MEDRAD INC.	S.U.A.
MIPM - MAMMENDORFER INSTITUT FUR PHYSIK UND MEDIZIN GMBH	GERMANIA
NEMOTO KYORINDO CO.LTD	JAPONIA
OHMEDA MEDICAL A DIVISION OF DATEX - OHMEDA INC.	S.U.A.
PARALLEL DESIGN SAS	FRANTA
ULRICH GMBH & CO KG	GERMANIA
WIPRO GE HEALTHCARE PRIVATE LTD	INDIA

Prezentul document este valabil numai însoţit de avizul iniţial.

PREŞEDINTE

Bujor Eugen ALMĂŞAN

PREŞEDINTE

AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
INTRARE/IEȘIRE Nr. DM 4015/5
Ziua 10 Luna 07 Anul 2020

Catre,

GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

Tel : 0733 104253

Prin prezenta, va inaintam anexa avizului de functionare, aferent cererii nr DM 4015/30.06.2020 emisa de Agentia Nationala a Medicamentului si a Dispozitivelor Medicale din Romania – DA.

Cu stima,

PREȘEDINTE

Bujor Eugen ALMĂȘAN

MINISTERUL SĂNĂTĂȚII AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE PREȘEDINTE

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

ANEXA din data 11.11.2020
LA AVIZUL DE FUNCȚIONARE
Nr. 5778/07.01.2019 al GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată și în baza documentației înaintate, Avizul de funcționare nr. 5778/07.01.2019 se completează după cum urmează:

Unitatea este distribuitor al producătorilor:

Nume producator	Tara
AGFA HEALTHCARE NV	BELGIA
CODONICS INC.	S.U.A.
DATEX OHMEDA INC.	S.U.A.
EIZO GMBH	GERMANIA
FLEXICARE MEDICAL LIMITED	MAREA BRITANIE
GE BE PRIVATE LIMITED	INDIA
GE HANGWEI MEDICAL SYSTEMS CO.LTD	CHINA
GE HEALTHCARE (TIANJIN) COMPANY LIMITED	CHINA
GE HEALTHCARE AUSTRIA GMBH & CO OG	AUSTRIA
GE HEALTHCARE COILS	S.U.A.
GE HEALTHCARE FINLAND OY	FINLANDA
GE HEALTHCARE GMBH	GERMANIA
GE HEALTHCARE JAPAN CORPORATION	JAPONIA
GE HEALTHCARE SUA	S.U.A.
GE HUALUN MEDICAL SYSTEMS CO.LTD	CHINA
GE HUNGARY KFT	UNGARIA
GE MEDICAL SYSTEMS (CHINA) CO.LTD	CHINA
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC.	S.U.A.
GE MEDICAL SYSTEMS ISRAEL LTD	ISRAEL
GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	ISRAEL
GE MEDICAL SYSTEMS LLC	S.U.A.
GE MEDICAL SYSTEMS SCS	FRANTA
GE MEDICAL SYSTEMS ULTRASOUND & PRIMARY CARE DIAGNOSTICS LLC	S.U.A.
GE OEC MEDICAL SYSTEMS GMBH	GERMANIA
GE OEC MEDICAL SYSTEMS INC	S.U.A.
GE ULTRASOUND COREEA LTD	COREEA
GE VINGMED ULTRASOUND AS	NORVEGIA
GENERAL MEDICAL MERATE S.P.A.	ITALIA
IMAGE DIAGNOST INTERNATIONAL	GERMANIA

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Nume producator	Tara
KONICA MINOLTA INC.	JAPONIA
MASIMO CORPORATION	S.U.A.
MEDRAD INC.	S.U.A.
MIPM - MAMMENDORFER INSTITUT FUR PHYSIK UND MEDIZIN GMBH	GERMANIA
NEMOTO KYORINDO CO.LTD	JAPONIA
OHMEDA MEDICAL A DIVISION OF DATEX - OHMEDA INC.	S.U.A.
PARALLEL DESIGN SAS	FRANTA
ULRICH GMBH & CO KG	GERMANIA
VINCENT MEDICAL MANUFACTURING CO. LTD.	HONG KONG
WIPRO GE HEALTHCARE PRIVATE LTD	INDIA

Prezentul document este valabil numai însoțit de avizul inițial.

PREȘEDINTE

Agenția Națională a Medicamentului și a

Dispozitivelor Medicale din România

Cristina RACOCEANU

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
INTRARE NR. DM 5867/2
IEȘIRE NR.
Ziua 12 Luna 10 Anul 2020

Către,

GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

Tel : 037.2074545

Prin prezenta vă înaintăm anexa avizului de funcționare aferentă cererii cu numărul: DM 5867/02.10.2020.

Cu stimă,

PREȘEDINTE

Agenția Națională a Medicamentului și a

Dispozitivelor Medicale din România

Cristina RACOCEANU

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

ANEXA din data 12.01.2021
LA AVIZUL DE FUNCȚIONARE
Nr. 5778/07.01.2019 al GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată și în baza documentației înaintate, Avizul de funcționare nr. 5778/07.01.2019 se completează după cum urmează:

Unitatea este distribuitor al producătorilor:

Nume producator	Tara
AGFA HEALTHCARE NV	BELGIA
CODONICS INC.	S.U.A.
DATEX OHMEDA INC.	S.U.A.
EIZO GMBH	GERMANIA
FISHER & PAYKEL HEALTHCARE LIMITED	NOUA ZEELANDA
FLEXICARE MEDICAL LIMITED	MAREA BRITANIE
GE BE PRIVATE LIMITED	INDIA
GE HANGWEI MEDICAL SYSTEMS CO.LTD	CHINA
GE HEALTHCARE (TIANJIN) COMPANY LIMITED	CHINA
GE HEALTHCARE AUSTRIA GMBH & CO OG	AUSTRIA
GE HEALTHCARE COILS	S.U.A.
GE HEALTHCARE FINLAND OY	FINLANDA
GE HEALTHCARE GMBH	GERMANIA
GE HEALTHCARE JAPAN CORPORATION	JAPONIA
GE HEALTHCARE SUA	S.U.A.
GE HUALUN MEDICAL SYSTEMS CO.LTD	CHINA
GE HUNGARY KFT	UNGARIA
GE MEDICAL SYSTEMS (CHINA) CO.LTD	CHINA
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC.	S.U.A.
GE MEDICAL SYSTEMS ISRAEL LTD	ISRAEL
GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	ISRAEL
GE MEDICAL SYSTEMS LLC	S.U.A.
GE MEDICAL SYSTEMS SCS	FRANTA
GE MEDICAL SYSTEMS ULTRASOUND & PRIMARY CARE DIAGNOSTICS LLC	S.U.A.
GE OEC MEDICAL SYSTEMS GMBH	GERMANIA
GE OEC MEDICAL SYSTEMS INC	S.U.A.
GE ULTRASOUND COREEA LTD	COREEA
GE VINGMED ULTRASOUND AS	NORVEGIA
GENERAL MEDICAL MERATE S.P.A.	ITALIA

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Nume producator	Tara
IMAGE DIAGNOST INTERNATIONAL	GERMANIA
KONICA MINOLTA INC.	JAPONIA
MASIMO CORPORATION	S.U.A.
MEDRAD INC.	S.U.A.
MIPM - MAMMENDORFER INSTITUT FUR PHYSIK UND MEDIZIN GMBH	GERMANIA
NEMOTO KYORINDO CO.LTD	JAPONIA
OHMEDA MEDICAL A DIVISION OF DATEX - OHMEDA INC.	S.U.A.
PARALLEL DESIGN SAS	FRANTA
ULRICH GMBH & CO KG	GERMANIA
VINCENT MEDICAL MANUFACTURING CO. LTD.	HONG KONG
WIPRO GE HEALTHCARE PRIVATE LTD	INDIA

Prezentul document este valabil numai însoțit de avizul inițial.

PREȘEDINTE

Agenția Națională a Medicamentului și a

Dispozitivelor Medicale din România

Cristina RACOCEANU

PREȘEDINTE AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
INTRARE Nr. DM 7400
IEȘIRE
Ziua 14 Luna 01 Anul 2021

Către,

GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

Tel : 037.2074545

Prin prezenta vă înaintăm anexa avizului de funcționare aferentă cererii cu numărul: DM 7400/09.12.2020.

Cu stimă,

PREȘEDINTE

Agenția Națională a Medicamentului și a

Dispozitivelor Medicale din România

Cristina RACOCEANU

PREȘEDINTE

CONFORM CU ORIGINALUL

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

ANEXA din data 21.01.2021
LA AVIZUL DE FUNCȚIONARE
Nr. 5778/07.01.2019 al GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată și în baza documentației înaintate, Avizul de funcționare nr. 5778/07.01.2019 se completează după cum urmează:

Unitatea este distribuitor al producătorilor:

Nume producator	Tara
AGFA HEALTHCARE NV	BELGIA
CODONICS INC.	S.U.A.
DATEX OHMEDA INC.	S.U.A.
EIZO GMBH	GERMANIA
FISHER & PAYKEL HEALTHCARE LIMITED	NOUA ZEELANDA
FLEXICARE MEDICAL LIMITED	MAREA BRITANIE
GE BE PRIVATE LIMITED	INDIA
GE HANGWEI MEDICAL SYSTEMS CO.LTD	CHINA
GE HEALTHCARE (TIANJIN) COMPANY LIMITED	CHINA
GE HEALTHCARE AUSTRIA GMBH & CO OG	AUSTRIA
GE HEALTHCARE COILS	S.U.A.
GE HEALTHCARE FINLAND OY	FINLANDA
GE HEALTHCARE GMBH	GERMANIA
GE HEALTHCARE JAPAN CORPORATION	JAPONIA
GE HEALTHCARE SUA	S.U.A.
GE HUALUN MEDICAL SYSTEMS CO.LTD	CHINA
GE HUNGARY KFT	UNGARIA
GE MEDICAL SYSTEMS (CHINA) CO.LTD	CHINA
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC.	S.U.A.
GE MEDICAL SYSTEMS ISRAEL LTD	ISRAEL
GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	ISRAEL
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GE MEDICAL SYSTEMS SCS	FRANTA
GE MEDICAL SYSTEMS ULTRASOUND & PRIMARY CARE DIAGNOSTICS LLC	S.U.A.
GE OEC MEDICAL SYSTEMS GMBH	GERMANIA
GE OEC MEDICAL SYSTEMS INC	S.U.A.
GE ULTRASOUND COREEA LTD	COREEA
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GENERAL MEDICAL MERATE S.P.A.	ITALIA

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Nume producator	Tara
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KONICA MINOLTA INC.	JAPONIA
MASIMO CORPORATION	S.U.A.
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PARALLEL DESIGN SAS	FRANTA
SOCIEDAD ESPANOLA DE ELECTROMEDICINA Y CALIDAD S.A. (SEDECAL)	SPANIA
ULRICH GMBH & CO KG	GERMANIA
VINCENT MEDICAL MANUFACTURING CO. LTD.	HONG KONG
WIPRO GE HEALTHCARE PRIVATE LTD	INDIA

Prezentul document este valabil numai însoțit de avizul inițial.

PREȘEDINTE
Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România
Roxana Ștefania STROE

MINISTERUL SĂNĂTĂȚII
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Către,

GENERAL ELECTRIC MEDICAL SYSTEMS ROMANIA SRL

Tel : 037.2074545

Prin prezenta vă înaintăm anexa avizului de funcționare aferentă cererii cu numărul: DM 192/13.01.2021.

Cu stimă,

PREȘEDINTE

Agenția Națională a Medicamentului și a

Dispozitivelor Medicale din România

Roxana Ștefania STROE

GE Healthcare

TO WHOM IT MAY CONCERN

The undersigned as the lawful representatives of the company under the name "GE Medical Systems Société en Commandite Simple", a company acting in the capacity of the European headquarters for GE Healthcare, having its registered office and principal business at 283, Rue de la Minière, 78530 Buc, France, hereby confirm that company under the name **"General Electric Medical Systems Romania SRL"** with resident offices at 301-311 Barbu Vacarescu St., Lakeview Building, 3rd Floor, 2nd district, Bucharest, Zip 020276, Romania, is the authorized provider of maintenance services of the following medical devices of the GE Healthcare Group of Companies in Romania:

Magnetic Resonance, Computed Tomography, Positron Emission Tomography, Nuclear Medicine, Bone Mineral Densitometry, Vascular, Classic and Digital X-Ray, Mammography Systems and their options and spare parts.

Made in Buc on July 6th, 2018,

On behalf of GE Medical Systems Société en Commandite Simple

GE MEDICAL SYSTEMS
Société en Commandite Simple
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RCS Versailles B 315 013 359
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Jean-Luc Procaccini
Gérant, GE Medical Systems SCS
Vice President & General Manager, GEHC Services Europe

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Au capital de 90 029 280 euros
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78530 Buc,
France
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CONFORM CU ORIGINALUL

Traducere din limba engleză

GE Healthcare

PENTRU CEI INTERESAȚI

Subsemnații, în calitate de reprezentanți legali ai companiei sub denumirea de „GE Medical Systems, Societate în Comandită Simplă", o companie care acționează în calitate de sediu european pentru GE Healthcare, cu sediul și principalul punct de lucru în 283, Rue de la Minière, 78530 Buc, Franța, confirmăm prin prezenta că societatea comercială sub denumirea de „General Electric Medical Systems Romania SRL", cu sediul social în Strada Barbu Văcărescu, Nr. 301-311, Clădirea Lakeview, Etaj 3, Sector 2, București, Cod Poștal 020276, România, este prestatorul autorizat de servicii de întreținere pentru următoarele dispozitive medicale de la Grupul de Companii GE Healthcare din România:

Sisteme de Rezonanță magnetică, Tomografie computerizată, Tomografie cu emisie de pozitroni, Medicină nucleară, Densitometrie minerală a osului, Sisteme vasculare, clasice și digitale cu raze X, sisteme de mamografie, precum și opțiunile și piesele de schimb pentru acestea.

Întocmit la Buc, 6 iulie 2018

În numele GE MEDICAL SYSTEMS, Societate în Comandită Simplă

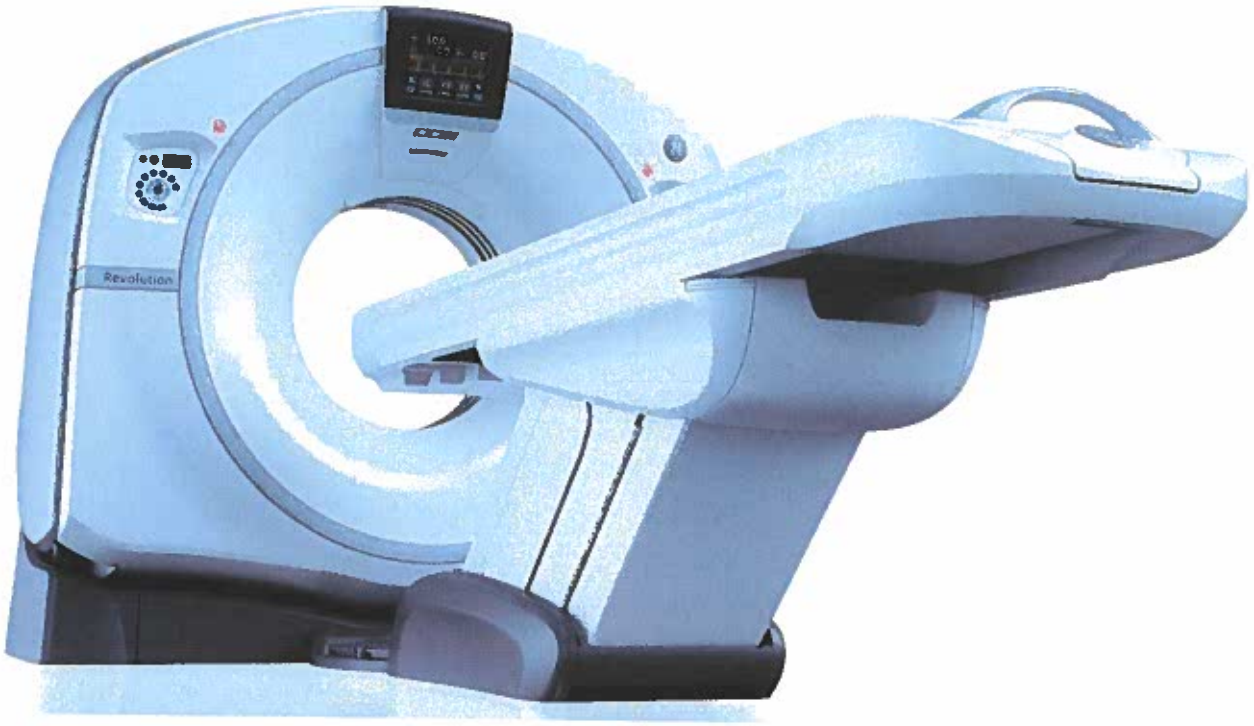
(*semnătură indescifrabilă*)
Jean-Luc Procaccini
Administrator, GE Medical Systems SCS
Vicepreședinte și Director General, GEHC Services Europa

(*Ștampilă: GE Medical Systems, Societate în Comandită Simplă*)

CONFORM CU ORIGINALUL

MINISTERUL JUSTIȚIEI
MORARU GHEORGHE

GE Healthcare



Revolution™ EVO

Product Data Sheet – Rev5

Contents

Introduction

Introduction

Revolution™ EVO is the next generation Volume CT with Clarity Imaging Chain and ASiR-V™ [1] *. Clarity Imaging Chain consists of Clarity Detector, DAS, Performix™ 40 Plus X-ray Tube and ASiR-V reconstruction and delivers high resolution imaging to meet various customer needs in real clinical situations. Clarity Imaging Chain delivers high spatial resolution, low noise, or less-artifact.

- 40mm coverage Clarity Detector /DAS
- 0.35sec* rotation speed in routine scan
- 0.28mm spatial resolution
- ASiR-V, up to 82% dose reduction relative to FBP at the same image quality[2+]

Key technologies enablers include:

- Clarity imaging chain with new X-ray tube, Detector and IR technology overcome Image performance challenges such as noise, spatial resolution, low contract detectability or artifact.
- Performix 40 Plus with liquid bearing tube realizes 0.35sec* rotation speed in routine and enables 6sec in 1000mm, combined with high helical pitch 1.531.
- ASiR-V* combines the speed of ASiR with additional capabilities from Veo™, GE's full model-based iterative reconstruction technology. By applying more advanced modeling and optimization technologies in projection- and image-space as part of the iterative reconstruction process. ASiR-V provides dose reduction well beyond that of ASiR, while maintaining low-contrast detectability, like Veo.
- SnapShot Freeze* is designed to reduce blurring artifacts due to motion in coronary vessels that cannot be addressed by gantry speed alone. Providing up to a 6X improvement, while maintaining high spatial resolution.
- SnapShot Pulse* mode is for low dose imaging of the coronary arteries. SnapShot Pulse can also be used to image structures that are near to the heart and may be affected by heart motion such as thoracic aorta's or pulmonary arteries.
- Organ Dose modulation provides reduction of radiation dose via X-ray tube current modulation for superficial tissues, such as breasts. ODM may enable equivalent pixel noise standard deviation without decreasing productivity as with the use of conventional superficial dose reduction techniques.
- Exceptional one stop scanning mode provides a streamlined workflow on the Xtream Display such as "Patient selection", "Protocol selection" and "Confirm". Pre-scanning can be accomplished in as few as five touches.
- Volume Helical Shuttle is a continuous scan technique that is a bi-directional scan mode, covers up to 312.5mm for 4D imaging.
- Smart MAR* helps reducing photon starvation, beam hardening and streak artifacts caused by metal in the body, such as hip implants.

Indications for Use

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results. The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.
The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

[1] In clinical practice, the use of ASiR-V may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

[2] Image quality as defined by low contrast detectability.

Asterisk*: Option and Option may not be available in all markets.

Clarity Imaging Chain

Clarity Imaging Chain

Revolution EVO's Clarity Imaging Chain consists of Clarity Detector, DAS, Performix40 Plus X-ray Tube and ASiR-V reconstruction, to deliver high resolution imaging.

For better performance Volume CT, Clarity Imaging Chain provides enhancement of spatial resolution up to 20% compared with previous GE technology.

Clarity Detector and Data Acquisition System

- Designed as analog cable free between ASIC and Diode and has a capability to reduce electric noise.
- Designed for less heat generation, up to 90% compared with previous GE technology and all in one DAS / Detector. It has capability to reduce electric noise.
- Designed for less floor-noise, up to 44% compared with previous GE technology and it has capability to reduce electric noise.
- Optimized collimator with ability to reduce scatter noise.

Performix™ 40 Plus X-ray Tube

- Performix40 Plus X-ray tube provides less focus movement.
- A liquid bearing tube that has a capability of less-wear of Tube bearing and is enabled up to 0.35sec rotation speed with a routine scan. Revolution EVO allows users to utilize helical pitches up to 1.531 and 0.35sec rotation speed that meets GE's image quality specifications for lower pitch acquisitions. This high pitch and 0.35sec rotation speed enables faster scan times which may allow for shorter breadth holds, and may help to avoid sedation, simultaneously (or "as well as") reducing motion artifacts from patient and organ movement. As an example, using this higher pitch, a full-body trauma scan of 1000 mm can be acquired in as little as 6 seconds.

Asterisk*: Option and Option may not be available in all markets.

Clarity Imaging Chain

its unique adaptive restoration algorithm.

Lower dose

ASiR-V reduces dose by **50% to 82%** relative to FBP at the same image quality[2]*

Low contrast detectability improvement

ASiR-V improves low contrast detectability by **59% to 135%** at the same dose*

Image Noise improvement

ASiR-V reduces image noise up to **91%** at the same dose*

Spatial resolution enhancement

ASiR-V improves spatial resolution up to **2.07X (107%)** at same image noise*

Artifact reduction

ASiR-V image reconstruction has the capability to reduce low signal artifact such as streak artifact compared to FBP*

ASiR-V™*

ASiR-V is the newest technology in GE's family of industry-leading iterative reconstruction techniques.

ASiR-V allows healthcare providers to lower dose by 50 to 82% as compared to standard filtered back-projection (FBP) reconstruction at the same image quality[3]*

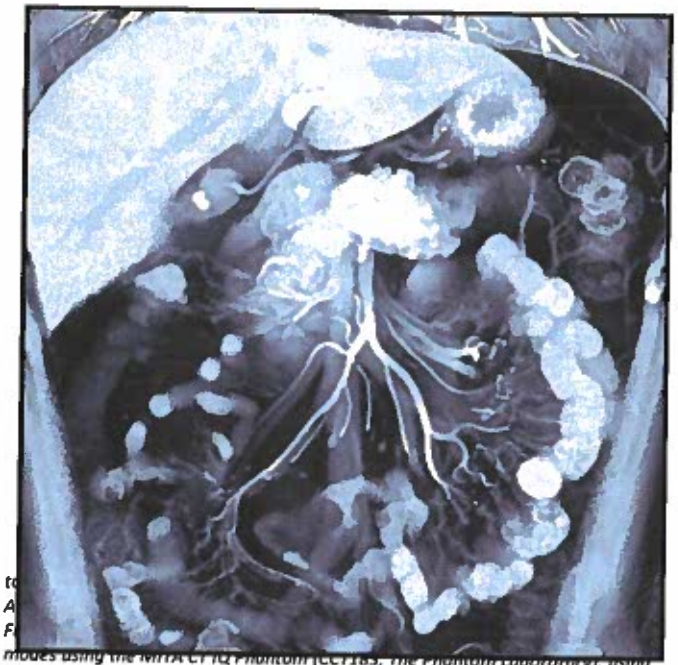
ASiR-V combines the speed of ASiR with additional capabilities from Veo, GE's full model-based iterative reconstruction technology. By applying more advanced modeling and optimization technologies in projection- and image-space as part of the iterative reconstruction process. ASiR-V provides dose reduction well beyond that of ASiR, while maintaining low-contrast detectability, like Veo.

ASiR-V extends the advanced noise and dose reduction technologies of ASiR. Existing iterative reconstruction, such as ASiR, models the noise in a way that is adaptive to the mA, kV and body habitus of the patient.

ASiR-V enhances the noise modeling of ASiR in two ways: 1) ASiR-V performs sophisticated statistical modeling of the projection samples by taking into account the confidence of each projection measurement in the reconstruction process; and 2) ASiR-V incorporates the user's special clinical needs, such as enhanced spatial resolution, into the statistical treatment of the samples.

Compared to ASiR, ASiR-V offers:

- Improved noise & dose performance beyond what is possible with ASiR.
- Improved spatial resolution without compromise in image noise.
- Reduced streak artifacts due to better handling of photon-starvation with



model observer method.

** In clinical practice, the use of ASiR-V may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical*

Asterisk*: Option and Option may not be available in all markets.

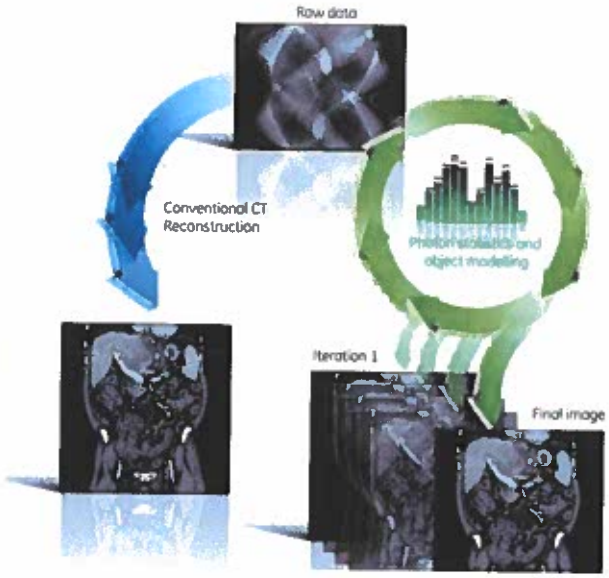
Primary Benefit – Imaging Performance

ASiR™ (Adaptive Statistical Iterative Reconstruction)*

An advanced Iterative Reconstruction technique delivers the following benefit to users.

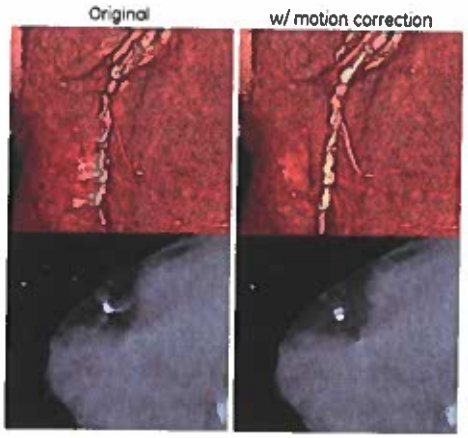
- ASiR may enable an improvement up to 25% in LCD.
- ASiR may help clinicians achieve confident diagnosis with up to 40% lower dose while maintaining image performance.
- Utilizing ASiR, images obtained can have equivalent image performance to an acquisition with up to 1.67 times the mA
- ASiR enables up to 40% shorter acquisition times with faster rotation speeds.

Note: In clinical practice, the use of ASiR may reduce CT patient dose and improve low contrast detectability depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.



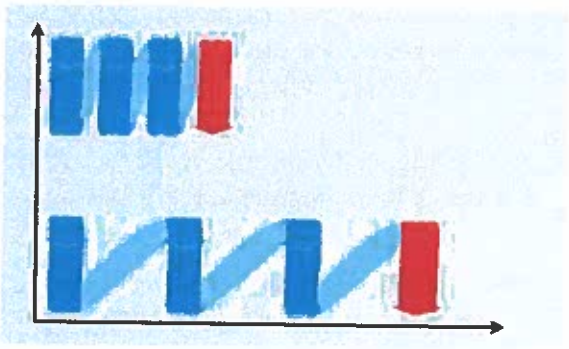
SnapShot Freeze*

Revolution EVO provides intelligent motion correction with SnapShot Freeze[3]. SnapShot Freeze is designed to reduce blurring artifacts due to motion in coronary vessels that cannot be addressed by gantry speed alone. Providing up to a 6X improvement, while maintaining high spatial resolution, the reduction in motion artifacts is equivalent to a 0.058s Equivalent Gantry Rotation Speed with Effective Temporal Resolution of 29msec[4].



High helical pitch

Revolution EVO allows users to utilize helical pitches up to 1.531 and 0.35sec rotation speed that meet GE's image quality specifications for lower pitch acquisitions. This higher pitch and 0.35sec rotation speed enables faster scan times which may allow for shorter breadth holds, and may help to avoid sedation, simultaneously (or "as well as") reducing motion artifacts from patient and organ movement. As an example, using this higher pitch, a full body trauma scan of 1000 mm can be acquired in as little as 6 seconds.



[3] SnapShot Freeze requires CardIQ Xpress 2.0 Reveal on AW VS6 or AW Server

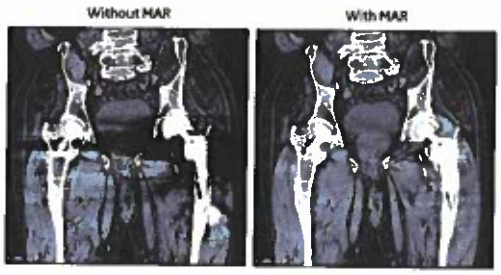
[4] As demonstrated in cardiac phantom testing

Asterisk*: Option and Option may not be available in all markets.

Primary Benefit – Imaging Performance

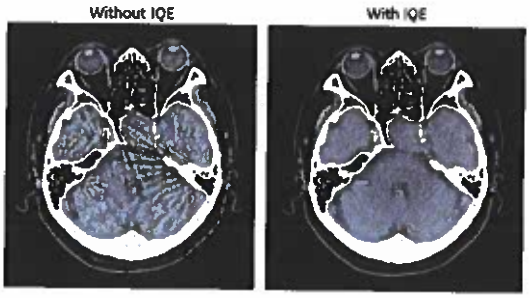
Smart metal artifact reduction (MAR) – Smart MAR*

Smart MAR* helps reducing photon starvation, beam hardening and streak artifacts caused by metal in the body, such as hip implants.



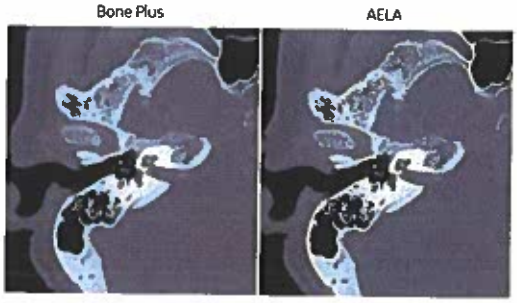
IQ Enhance (Pitch Booster)

IQ Enhance (IQE) reconstruction reduces helical Artifact Index in thin slice helical scanning. This reduction in artifacts makes it possible to scan at faster helical pitches.



Ultra Kernel: AELA

Adaptive Enhance Level Adjustment (AELA) may improve visual spatial resolution while maintaining pixel noise standard deviation and without introducing new artifacts.



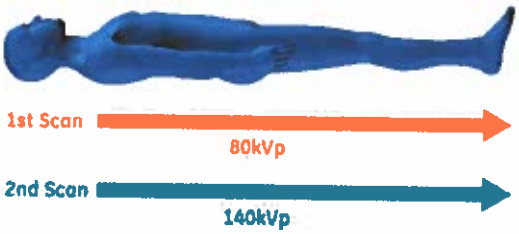
Asterisk*: Option and Option may not be available in all markets.

AAR – Advanced artifact reduction

Advanced Artifact Reduction (AAR) Filter significantly reduces streaking artifacts when highly absorbent objects are in the field of view – ie: large shoulder.

Two Path Dual-Energy Acquisitions

GE's protocol management is improved with the addition of a workflow improvement feature, which allows easy configuration of back to back Axial or helical scans of the same anatomy at two different X-ray energies (kVps). To further improve registration accuracy, patient immobilization may be utilized. The additionally acquired dual energy data can be post-processed on console or AW workstation using Add/Sub function to gain additional clinical information.

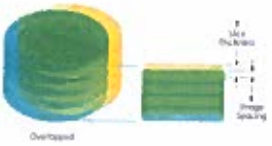


Overlapped reconstruction

For 64ch based system, the overlapped reconstruction feature enables 128 slices per rotation in axial scanning modes and delivers improved Z-axis visualization performance relative to non-overlapped reconstruction.

For 32ch based system, the overlapped reconstruction feature enables 64 slices per rotation in axial scanning modes and delivers improved Z-axis visualization performance relative to non-overlapped reconstruction.

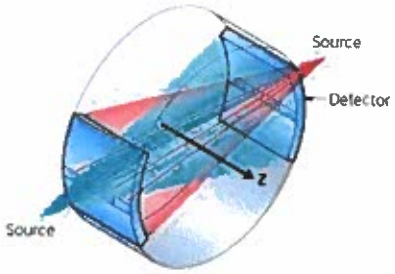
Primary Benefit – Imaging Performance



Conjugate Cone-Beam Back Projection

For 64ch based system, Conjugate Cone-Beam Back Projection utilizes two sets of counter-opposed projections to provide 128 distinct projection measurements per rotation for axial and a helical acquisition mode to significantly improve Z-resolution.

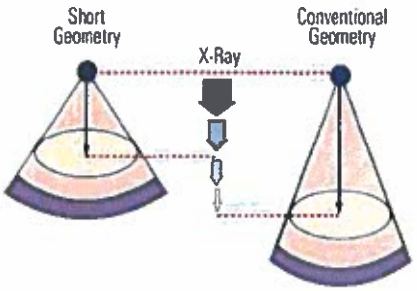
For 32ch based system, Conjugate Cone-Beam Back Projection utilizes two sets of counter-opposed projections to provide 64 distinct projection measurements per rotation for axial and a helical acquisition mode to significantly improve Z-resolution.



Conjugate Sampling

Short geometry design

The "Short Geometry Design" improves geometry efficiency compared to conventional long geometry system. For example, Revolution EVO's distance between the focus to the iso center is 541 mm. The distance in a conventional long geometry system is 600 mm. The geometry efficiency of Revolution EVO is approximately 19% higher than that of long geometry scanner. This means that Revolution EVO 72kW generator power is equivalent to 89kW generator power in a long geometry.



Thinner FWHM at Helical

GE's exclusive helical reconstruction technologies, crossbeam correction, conjugate ray interpolation and hyper plane helical reconstruction with alpha smoothing method, allow scanning at thin slice 0.66mm typically (40mm aperture, 0.516 helical pitch).

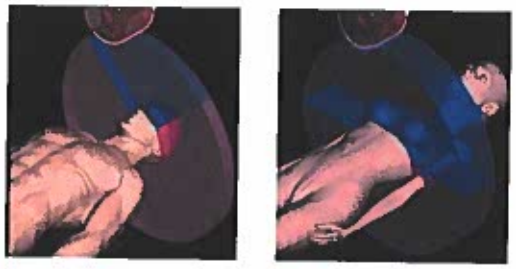
Asterisk*: Option and Option may not be available in all markets.

Primary Benefit – Advanced Dose reduction technology

Organ Dose Modulation

ODM provides reduction of radiation dose via X-ray tube current modulation for superficial organs and tissues, such as breasts while maintaining diagnostic quality without decreasing productivity (as the result of not using externally applied shields).

Because attenuation data from the Scan Projection Radiograph is used to determine the mA modulation for acquisitions using Automatic Exposure Control, it is understood that when using externally applied shields that these shields should not be put in place prior to acquiring the scan projection radiograph(s). Placement of externally applied shielding prior to obtaining the scan projection radiograph(s) may adversely affect the AEC performance.

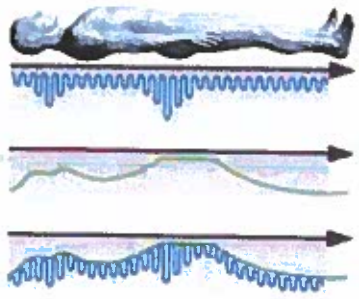


Dynamic Z-axis tracking

Dynamic Z-axis tracking provides automatic and continuous correction of the x-ray beam shape to block unused x-ray at the beginning and end of a helical scan to reduce unnecessary radiation.

3D mA Modulation utilizing SmartmA and AutomA

Having this kind of volumetric knowledge before you scan allows you to personalize protocols and optimize dose for every patient – large and small. During the scan, real-time, 3D dose modulation helps deliver consistent image quality because it automatically accounts for the changing dimensions of your patient's anatomy. 3D mA modulation acquisitions may reduce dose compared with fixed mA acquisitions. [4]



[4] mA modulation is designed to optimize the dose for the user prescribed noise index. Its effect on dose depends on the patient body habitus, and prescribed noise setting.

Asterisk*: Option and Option may not be available in all markets.

Primary benefit – Xtream Display

Xtream Display – General function

Xtream Display is a multi-purpose LCD display.

Xtream Display can show basic patient information on the gantry monitor. The user can confirm patient information in the scan room, improving workflow improvement with preset positioning (Default Patient positioning) on gantry display.

Xtream Display has a video function to assist the user in explaining the CT examination to patients.

Movie Change provides function to upload user created image and video.

One stop scanning mode*

Revolution EVO's exceptional one stop scanning mode provides a streamlined workflow on the Xtream Display such as "Patient selection", "Protocol selection" and "Confirm". Pre-scanning can be accomplished in as few as five touches.

ECG Waveform on Gantry Display*

ECG trace provides users the capability to display the heart rate and ECG waveform based on the data from the ECG equipment on the Xtream Display.

Asterisk*: Option and Option may not be available in all markets.

Workflow – Productivity Enhance

Image Check - Real time reconstruction*

Image Check provides 340x340 matrix images for confirming reconstructed image coverage in real time and tracking up to 1800mm length with less than 1 sec delay.

Reconstruction time is up to 55 fps.

Xtream Injector

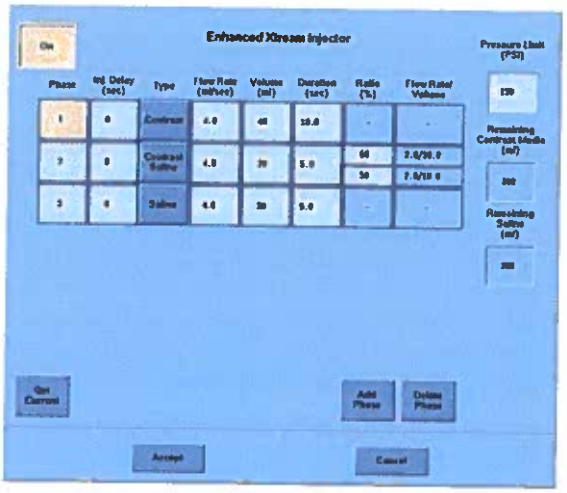
Xtream Injector allows the start of a CT scan to be synchronized with an approved injector. Pressing the Start Scan button makes the CT scan and armed injector start simultaneously.

The injector is CiA425 compliant.

There are two classes of Xtream Injector.

- Xtream Injector*, which is the same as Class 1 in CiA425, allows only ON/OFF.
- Enhanced Xtream Injector*, which is the same as Class 4 in CiA425, allows synchronized start of the CT scan and setting injection parameters from the CT scan.

The CT scan and injector are operated independently after the start button is pressed on the system.



AWE connection*

The AW Server client on the CT console is a software option that provides access to applications hosted on an AW Server, at the CT console.

It offers customers the use of applications on the CT console for improved workflow and productivity.

Direct MPR

Direct MPR with Auto-Batch feature, affording automatic real-time direct reconstruction and transfer of fully corrected multi-planar images, also allows user to move from routine 2D review to prospective 3D image review of axial, sagittal, coronal, and oblique planes while enabling automated protocol-driven batch reformats to be created and networked to their desired reading location.

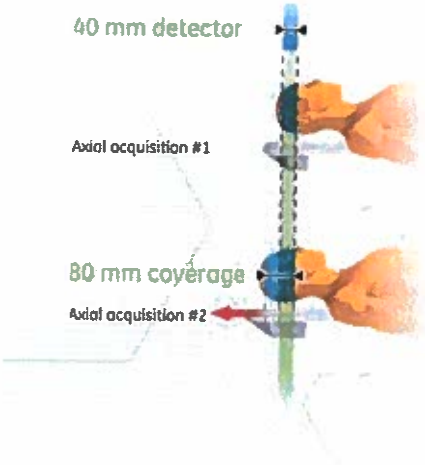
Asterisk*: Option and Option may not be available in all markets.

Increased Coverage

Volume Shuttle*

Revolution EVO provides a single-injection 80mm (2x wider coverage, 128 slice-width) Volume Shuttle acquisition scan.

Volume Shuttle is a repetitive axial scan mode where the table shuttles back and forth between two consecutive imaging locations (X-ray is off during table movement). Each location covers 40 mm in the Z-direction for a total of 80 mm of Z- coverage. The shuttle action repeats over a defined duration to enable evaluation of tissue changes over time.



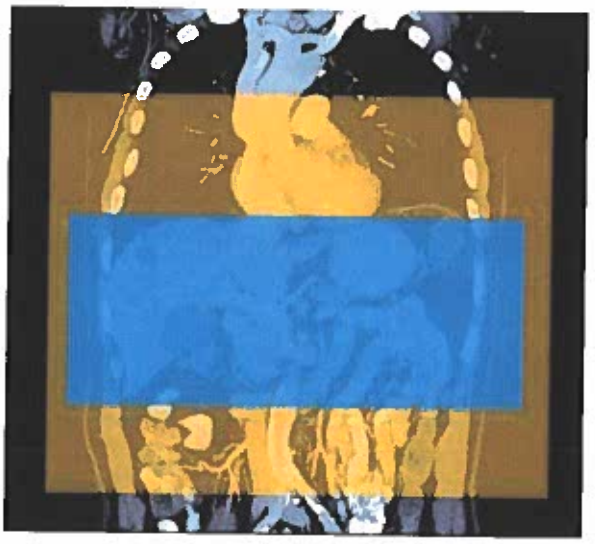
Volume Helical Shuttle*

Volume Helical Shuttle is a continuous scan technique that is a bi-directional scan mode, covers up to 312.5mm or 500 slices (0.625mm x 500 slice) for 4D imaging.

Volume Helical Shuttle provides data to support up to 140 mm of coverage repeatability within 3.2sec.

Dynamic Pitch Reconstruction extends Z-coverage and improves temporal sampling by utilizing acquired scan data during table acceleration and de-acceleration.

Pre-requisite: 64ch based system and 0.4sec rotation speed



Asterisk*: Option and Option may not be available in all markets.

Cardiac

5-Beat Cardiac*

Revolution EVO has the ability to cover the heart in as little as 5 beats.

The following calculation is based on a patient heart rate of 60bpm, and a total coverage of 120mm (nominal scan length to cover the heart), using a helical pitch of 0.22:1, and a rotation speed of 0.35 sec rotation.

44msec cardiac temporal resolution with 0.35 second rotation and SnapShot scan algorithm. Revolution EVO not only offers fast acquisition speed, it builds on GE's exclusive variable speed technology that has now been expanded for cardiovascular imaging to include 0.35, 0.375, 0.40, 0.425, 0.45, 0.475 and 0.50 second scans.

SnapShot Imaging provides software and hardware to perform retrospective helical ECG-gated reconstructions of the heart with three SnapShot-imaging modes.

- SnapShot Segment is a single sector protocol.
- SnapShot Burst is a multi-sector protocol using up to two sectors.
- SnapShot Burst Plus is a multi-sector protocol using up to four sectors.

Variable image thickness: 0.625, 1.25 and 2.50mm

SnapShot™ Freeze*

SnapShot Freeze is designed to reduce blurring artifacts due to motion in coronary vessels that cannot be addressed by gantry speed alone. Providing up to a 6X improvement, while maintaining high spatial resolution, the reduction in motion artifacts is equivalent to a 0.058s Equivalent Gantry Rotation Speed with Effective Temporal Resolution of 29msec[5]

SnapShot Freeze requires CardIQ Xpress 2.0 Reveal on AW VS6, VS7 or AW Server

SnapShot Freeze is only available for 64ch based system

SnapShot™ Pulse*

SnapShot Pulse mode is for low dose imaging of the coronary arteries. SnapShot Pulse can also be used to image structures that are near to the heart and may be affected by heart motion such as thoracic aorta's or pulmonary arteries.

Prospective Gating based SnapShot Pulse achieves significant dose reduction compared to ECG gated helical acquisition mode.

SnapShot Pulse is only available for 64ch based system.

SnapShot™ Assist*

Helps users Optimize ECG-gated CT acquisitions based on patient heart rate characteristics. SnapShot Assist uses the patient's recorded heart rate information to display scan parameters (including scan mode, cardiac phases, padding and pitch) that could be used during the cardiac CT scan.

SnapShot Assist generates a cardiac scan parameter recommendation using the patient's ECG analysis and user defined protocol selection algorithm. It uses the patient's recorded heart rate information to predict the heart rate behavior during a CCTA scan to assist the user with optimization of the parameters on a per-patient basis.

Acquisition parameters displayed include scan mode (Cine SnapShot Pulse, Helical SnapShot Segment, etc.), cardiac phases, padding, and pitch. User Profiles define scan parameters within the heart rate and variability categories for a specific patient group and cardiac scan mode.

SnapShot Assist is only available for 64ch based system

SmartScore™ Pro*

Acquires prospective ECG gating measurements, which provide information that is valuable for scan timing. Using the measurements, the system synchronizes the collection of data with the cardiac cycle.

Cardiac enhance features

Cardiac Image Filters* provides users the capability to reconstruct filtered images using three steps of noise (pixel noise standard deviation) reduction for helical and axial cardiac imaging, which may allow a reduction of mA while maintaining an acceptable level of image performance.

ECG mA Modulation*: For cardiac applications, prospective ECG mA modulation automatically adjusts the mA to minimize the patient's exposure to X-rays – reducing mA during systolic phases of the cardiac cycle. This provides clear images and allows you to reduce mA primarily in the systolic phases of the cardiac cycle. – yet gives you enough power to obtain quality images for functional analysis.

ECG Waveform on the Console* will allow users to visualize the ECG waveform directly on the CT scanner console during the scan.

ECG trace on Xtream Display*

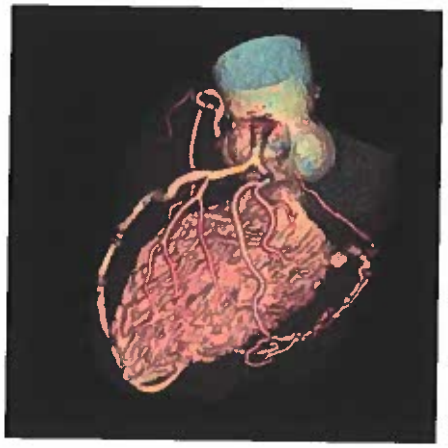
ECG trace provides users the capability to display the heart rate and ECG waveform based on the data from the ECG equipment on the Xtream Display to review the patient heart rate during cardiac scanning.

ECG Viewer / Editor* provides users the capability to view and retrospectively modify intervals and adjust location of triggers for cardiac cycles based on the ECG waveform displayed on the console. This capability may improve successful cardiovascular acquisition rate in cases with suboptimal triggers or irregular heartbeats such as PVCs, PACs and arrhythmias.

[5] As demonstrated in cardiac phantom testing

Asterisk*: Option and Option may not be available in all markets.

Cardiac



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Emergency

High helical pitch

Revolution EVO allows users to utilize helical pitches up to 1.531 and 0.35sec rotation speed that meet GE's image quality specifications for lower pitch acquisitions. This higher pitch and 0.35sec rotation speed enables faster scan times which may allow for shorter breadth holds, and may help to avoid sedation, simultaneously (or "as well as") reducing motion artifacts from patient and organ movement. As an example, using this higher pitch, a full-body trauma scan of 1000 mm can be acquired in as little as 6 seconds.

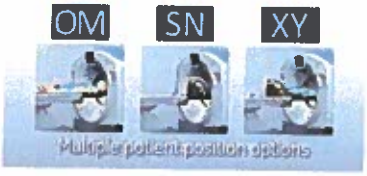
VT2000 Table*

VT2000 is designed for flexible positioning with 2000mm long scannable range and 500lb (227kg) patient weight capacity.

Default Patient Positioning (DPP)

Xtream Display provides workflow improvement by preset positioning (Default Patient Positioning) on the gantry display.

Default Patient Positioning provides user friendly positioning. After patient is positioned on the table, the operator touches the target reference point button on the Xtream Display. The table is transferred to the target reference point, once the foot pedal has been pressed.



One-stop scanning*

Revolution EVO's exceptional one stop scanning mode provides a streamlined workflow on the Xtream Display such as "Patient selection", "Protocol selection" and "Confirm". Pre-scanning can be accomplished in as few as five touches.

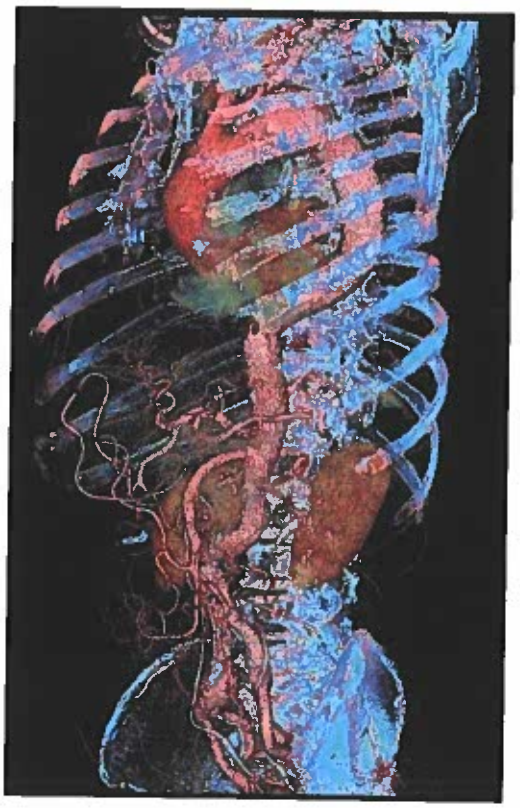
Emergency patient mode

Revolution EVO has a dedicated User Interface (UIF) for emergency cases to start the examination quickly. Patient Name and Patient ID are assigned automatically. Once a protocol is selected, scan setup interface displays.

Real time reconstruction - Image Check

Image Check provides 340x340 matrix images for confirming Axial images in real time and tracking to up to 1800mm length with less than 1 sec delay.

Reconstruction time is up to 55 fps



Asterisk*: Option and Option may not be available in all markets.

Intervention

SmartView™*

SmartView provides continuous, real-time CT fluoroscopy at 24 fps (3view ports at 8fps each) with in-room viewing and manual X-ray control. The intuitive user interface provides six user-selectable display layouts, in-room image review and WW and WL control. Features ceiling-mounted in-room LCD monitor and full-featured handheld, cradle-mounted controller.

Real time performance

- FPS at single display mode: 12fps
- FPS at three display mode: 24fps
- Nominal image lag: 0.2sec

Specifications for SmartView

Viewport	Slice thickness (mm)	Rotation speed (Sec)	Tilt
Single	2.5, 5.0, 10	0.5*, 0.8, 1.0	±30
Three	1.25, 2.5, 5.0		

SmartStep*

SmartStep is an interventional mode providing step-and-shoot imaging with in-room viewing and manual X-ray control.

The three interventional viewports automatically update each time an exposure is made with the foot pedal.

Biopsy mode

Biopsy Mode improves the efficiency of setting up and acquiring slices during a biopsy. All biopsy scan parameters are available on a single screen from which you can launch the biopsy scan.

Asterisk*: Option and Option may not be available in all markets.

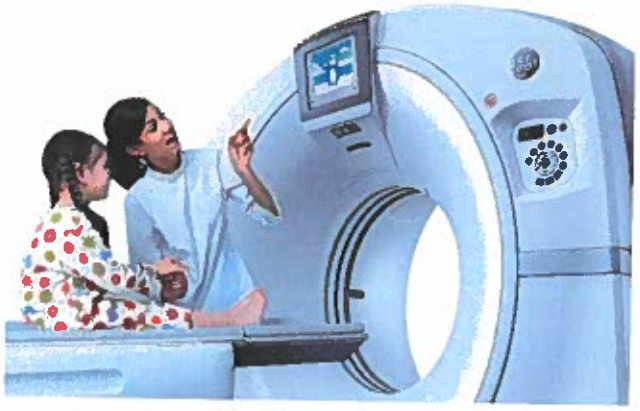
Dose Technology and Management

Revolution EVO introduces Volume CT capabilities while incorporating the following GE dose reduction features.

OptiDose™

For years GE has followed the ALARA principle in helping its customers optimize dose. GE has provided many tools to help the clinician minimize dose while achieving diagnostic quality images.

- **ECG mA Modulation***: For cardiac applications, prospective ECG mA modulation automatically adjusts the mA to minimize the patient's exposure to X-rays – reducing mA during systolic phases of the cardiac cycle. This provides clear images and allows you to reduce mA primarily in the systolic phases of the cardiac cycle – yet gives you enough power to obtain quality images for functional analysis.
- **CT 4Kids**: The pediatric protocols are based upon a child's size, age, and weight and tailor the dose or treatment to the size of the patient. The Head and Orbit categories are age based. The rest of the categories are height and weight based protocols.
- **Color Coding Kids™** provides pediatric scan protocols based on the Broselow-Luten system™ Pediatric System. This Color Coding system is incorporated into the protocol selection on the operator's console.
- **SmartTrack**: The tracking collimator keeps the beam focused only on the active detector cells, and makes sub-millimeter scanning possible with high dose efficiency.
- **SmartBeam™**: The collimator contains two independently controlled tungsten cams. The rotation of the cams provides continuous variable beam thickness and Z-axis position. The collimator also contains three bowtie beam filters that filter and shape the beam to optimize dose and image performance.



Dose Check

Dose Check provides users with tools to help them manage CT dose in clinical practice and is based on the standard XR-25-2010 published by The Association of Electrical and Medical Imaging Equipment Manufacturers (NEMA).

Dose Check provides the following

- Checking against the Notification Value if the estimated dose for the scan is above your site established dose value.
- Checking against the Alert Value where the user needs specific authority to continue the scan at the current estimated dose without changing the scan parameters if the estimated dose exceeds the alert value.
- Alert Values for Adult and Pediatric with age threshold
- Audit logging and review capability
- Protocol Change Control capability

Dose Display

$CTDI_{vol}$ (Volume $CTDI_w$), DLP (Dose Length Product) and Dose Efficiency are displayed during scan prescription and provide dose information to the operator.

Dose Reporting

Dose Reporting: $CTDI_{vol}$, DLP, Dose Efficiency displays during scan prescription and provides dose information. The $CTDI_{vol}$, DLP and Phantom size used to calculate dose is automatically saved once the user selects End Exam.

DICOM Structured Dose Report generates a CT Dose Report, which can enable tracking of dose ($CTDI_{vol}$ and DLP) for the patient by the hospital radiation tracking system/RIS/HIS.

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Main Productivity features

Direct MPR

Direct MPR with Auto-Batch feature, affording automatic real-time direct reconstruction and transfer of fully corrected multi-planar images, also allows customer to move from routine 2D review to prospective 3D image review of axial, sagittal, coronal, and oblique planes while enabling automated protocol-driven batch reformats to be created and networked to their desired reading location.

SmartPrep

SmartPrep, which allows intermittent monitoring of IV contrast enhancement in an area of interest. The contrast flow is monitored by Low-Dose scans until the contrast enhancement reaches the preferred point and then the user initiates the scan prescription.

Dynamic Transition

With SmartPrep procedure, Dynamic Transition allows the scan phase to start automatically when the HU of the transition ROI reaches the desired enhancement threshold.

Graphic Retro

Graphic Retro provides the capability to graphically prescribe retro reconstructions using an existing axial plane image as a reference image.

10 PMR

Prospective Multiple Reconstruction (PMR). Up to 10 sets of reconstructions can be pre-programmed as part of the scan protocol prior to acquisition. The operator can select different start/end location, slice thickness, interval, reconstruction algorithms and display fields of view for each reconstruction.

Copy PMR & Series

Automatically copy the parameters of an existing series when "Copy series" is selected. The series parameters include: start location, end location, interval, DFOV, A-P center, and R-L center.

Connect Pro

With the Connect Pro option, the user can view other valuable information about a patient such as allergies, pregnancy status, and medical alerts. This information is gathered from the HIS/RIS using a DICOM connection.

Connect Pro can be customized to fit the department's needs by using "filters" to pull only the information in which the user is interested. It can collect more than standard patient demographic information.

Prospective Exam Split*

Prospective Exam Split allows multi-anatomical exams to be read in separate anatomic sections. This allows specialists to review only those images needed for a given requested procedure. Prospective Exam Split provides users with the capability to specify how to split the exam into separate billing groups for each scan.

Grayscale Presentation State

GrayScale Presentation State (GSPS) is a DICOM object which saves a range of images along with the image state and graphic annotations. The GSPS object can be displayed on the CT scanner or networked to a remote host that supports DICOM GSPS.

Direct Connect

AW VolumeShare 5 supports a direct connection between AW VolumeShare 2, 3 or 4 workstations. This feature requires a Gigabit Network between the AW's and HP XW8200 (minimum hardware requirement). Post processing can be done on image residing on Direct Connect linked systems by launching applications without having to DICOM transfer the exam to the AW.

CD/DVD/USB

The CD/DVD/USB allows users to store DICOM images and a DICOM Viewer to a CD-R or DVD-R or USB media that can be played back on a PC or laptop with a Window® XP/Vista/7 operating system. Images stored on a CD-R, DVD-R or USB can be restored to the AW system or Revolution EVO system.

Data Export

Data Export allows images to be stored on a CD-R or FTP or USB images as JPEG, PNG, AVI, MPEG, or MOV formats.

The JPEG, PNG, AVI, MPEG, or MOV images can be viewed from a PC or laptop with a Windows® 2000 or XP operating system using Internet Explorer® 5.5 or later.

AutoVoice™

Three pre-recorded voices are available in 13 languages (English-Male, English-Female, Japanese, French, German, Spanish, Mexican Spanish, Italian, Korean, Chinese, Portuguese, Brazilian Portuguese and Russian.). The operator can record an additional 17 voice instructions.

Learning Solution

The User Manual contains all the user information required to operate the scanner. It has detailed information as well as step-by-step procedures. The User Manual can be displayed on the Display monitor by clicking on the Learning Solution icon.

Asterisk*: Option and Option may not be available in all markets.

Main Productivity features

Helical scan mode is a continuous 360 degrees scanning with table incrementation and no inter scan delay.

Multiple-Thickness Reconstruction

40mm Aperture / 20mm Aperture

Helical Modes : Table Speed (mm/rotation)				
Slice Thickness	0.516:1/0.531:1	0.984:1/0.969:1	1.375:1/1.375:1	1.531:1/1.531:1
0.625mm 1.25mm 2.5mm 3.75mm 5mm 7.5mm 10mm	20/10 mm/rot	39/19 mm/rot	55/27 mm/rot	61/30 mm/rot

For 64ch based system, generating images at 0.1mm intervals, enables reconstructed images that exceed 128 slices (images) per gantry rotation. The number of slices able to be generated per gantry rotation is a function of rotations and coverage.

Rotations	Z-coverage (mm)	Generated slices (Images/rotation*)
1.71	30	176
2.00	46	230
3.00	101	337
4.00	156	390
5.00	211	422
6.00	266	443
64 slice x 0.625mm & 1.375:1 helical pitch		

For 32ch based system, generating images at fine intervals, as small as 0.1mm, enables reconstructed images that exceed 64 slices (images) per gantry rotation. The number of slices able to be generated per gantry rotation is a function of rotations and coverage.

Rotations	Z-coverage (mm)	Generated slices (Images/rotation*)
1.71	30	140
2.00	46	184
3.00	101	269
4.00	156	312
5.00	211	337
6.00	266	354
32 slice x 1.25mm & 1.375:1 helical pitch		

Helical Scan Parameters

Helical Scan Speed: 360° rotational scans: 0.35*, 0.4*, 0.5*, 0.6*, 0.7, 0.8, 0.9, and 1.0

Cardiac Scan Speeds*: 0.35, 0.375, 0.40, 0.425, 0.45, 0.475, and 0.50.

Helical Pitch (nominal): 0.516 to 1.531

Asterisk*: Option and Option may not be available in all markets.

Cardiac Pitch: 0.16 to 0.325

Selectable kV: 80, 100, 120, 140

Selectable mA at 120kV

10 to 560mA, 5mA increment for 72kW based system

10 to 400mA, 5mA increment for 48kW based system

Single Acquisition: 120 second scan maximum

Minimum Inter-Group Delay (IGD): 1 second between adjacent helical scans

Maximum Display Fields of View:

- 32cm for pediatric head
- 32cm for pediatric body
- 32cm for head
- 32cm for body, small
- 50cm for body, large
- 32cm for cardiac – small
- 50cm for cardiac – large

Helical Image Reconstruction

Reconstruction Algorithms: Soft Tissue, Standard, Detail, Chest, Bone, Bone Plus, Lung, Ultra, Edge, Edge Plus, Soft# and Standard#.

Reconstruction Matrix: 512 x 512

Display Matrix: 1024 x 1024

CT Number Scale: ±31,743 HU

Minimum DFOV: 5.0 cm

Minimum Pixel Size: 0.10 mm

Helical Scan Protocols

72kW based system

Under 120kV scans (Maximum mA subject to system configuration)

Single Helical Scans:

Scan time(s)	Maximum mA
3	560
5	560
10	560
20	445
30	385

Multiple Helical Scans (IGD = 5 seconds):

	Max mA				
No scans	3s scan time	5s scan time	10s scan time	20s scan time	30s scan time
2	560	560	460	360	315
3	560	550	425	335	285
4	560	530	405	315	240

48kW based system

Under 120kV scans (Maximum mA subject to system configuration)

Single Helical Scans:

Scan time(s)	Maximum mA

Scan mode – Helical

30	385
40	350
50	325
60	310

Multiple Helical Scans (IGD = 5 seconds):

	Max mA		
No scans	10s scan time	20s scan time	30s scan time
2	400	360	315
3	400	335	285
4	400	315	240

Asterisk*: Option and Option may not be available in all markets.

Scan mode – Axial & Cine

Axial scan mode: axial slices acquired simultaneously with each 360 degree rotation, with the time between scans set by the user-selected interscan delay (ISD) or intergroup delay (IGD).

Cine scan mode: contiguous axial slices acquired simultaneously with each 360 degree rotation. Half-scan imaging and segmented reconstruction is supported with acquisitions times of 0.6S times that of the scan speed.

Multiple-Thickness Reconstruction

64ch based system

Collimation	Slice thickness	Recon Slice thickness
40mm / 64 x 0.625mm	0.625	128i – 0.625mm$^{\diamond}$ 64i – 0.625mm$^{\bullet}$ 32i – 1.25mm$^{\bullet}$ 16i – 2.5mm 8i – 5mm 4i – 10mm
20mm / 32x 0.625mm	0.625	32i – 0.625mm 16i – 1.25mm 8i – 2.5mm 4i – 5mm 2i – 10mm
10mm / 16 x 0.625mm	0.625	16i – 0.625mm 8i – 1.25mm 4i – 2.5mm 2i – 5mm 1i – 10mm
5mm / 8 x 0.625mm	0.625	4i – 1.25mm 2i – 2.5mm 1i – 5mm
2.5mm / 4 x 0.625mm	0.625	2i – 1.25mm 1i – 2.5mm
1.25mm / 2 x 0.625mm	0.625	1i – 1.25mm

$^{\bullet}$Retro Recon Only, $^{\diamond}$Overlapped Reconstruction

32ch based system

Collimation	Slice thickness	Recon Slice thickness
40mm / 32 x 1.25mm	1.25	32i – 1.25mm$^{\bullet}$ 16i – 2.5mm 8i – 5mm 4i – 10mm
20mm / 32x 0.625mm	0.625	64i – 0.625mm$^{\diamond\bullet}$ 32i – 0.625mm 16i – 1.25mm 8i – 2.5mm 4i – 5mm 2i – 10mm
10mm / 16 x 0.625mm	0.625	16i – 0.625mm 8i – 1.25mm 4i – 2.5mm 2i – 5mm 1i – 10mm
5mm / 8 x 0.625mm	0.625	4i – 1.25mm 2i – 2.5mm 1i – 5mm
2.5mm / 4 x 0.625mm	0.625	2i – 1.25mm 1i – 2.5mm
1.25mm / 2 x 0.625mm	0.625	1i – 1.25mm

$^{\bullet}$Retro Recon Only, $^{\diamond}$Overlapped Reconstruction

Axial and Cine Scan Parameters

Axial: Scan Speeds: 0.35*, 0.4*, 0.5*, 0.6*, 0.7, 0.8, 0.9, 1.0, and 2.0 second full scans (360° acquisition).

Cine: Scan Speeds: 0.35*, 0.4*, 0.5*, 0.6*, 0.7, 0.8, 0.9 and 1.0 second full scans (360° acquisition).

Cardiac Scan Speeds*: 0.35

Asterisk*: Option and Option may not be available in all markets.

Scan mode – Axial & Cine

Selectable kV: 80, 100, 120, 140

Selectable mA at 120kV:

10 to 600mA, 5mA increment for 72kW based system

600mA is available only for ShapShot Pulse*

10 to 400mA, 5mA increment for 48kW based system

Single Acquisition at Cine: 120 second scan maximum

Scan Plane Geometry: ± 30° gantry tilt, 0.5° increments

GD between scans is from 1sec to 600sec

Inter-scan Delay (ISD)

Table Movements	Minimum ISD
0 to 10 mm	1.0s
10 mm to 20 mm	1.3s
20 mm to 30 mm	1.6s
30 mm to 40 mm	1.7s

Maximum Display Fields of View:

- 32cm for pediatric head
- 32cm for pediatric body
- 32cm for head
- 32cm for body, small
- 50cm for body, large
- 32cm for cardiac – small
- 50cm for cardiac – large

Axial and Cine Image Reconstruction

Reconstruction Algorithms: Standard, Soft Tissue, Detail, Chest, Bone, Bone Plus, Lung, Ultra, Edge, Edge Plus, Soft# and Standard#.

Reconstruction Matrix: 512 x 512

Display Matrix: 1024 x 1024

CT Number Scale: ±31,743 HU

Minimum DFOV: 5.0 cm

Minimum Pixel Size: 0.1875 mm

Axial and Cine Scan Protocols

72kW based system. Under 120kV scans

Scan time(s)	ISD(s)	mA	Number of slice
1	1	560	16
1	1	520	26
1	1	480	37
1	1	440	45
1	1	400	55

48kW based system. Under 120kV scans

Scan time(s)	ISD(s)	mA	Number of slice
1	1	400	55
1	1	360	68
1	1	320	86
1	1	280	110
1	1	240	135
1	1	200	168

Asterisk*: Option and Option may not be available in all markets.

Scan mode - Scout

Scout imaging is used for anatomical location in conjunction with scan and recon prescription, to provide an anatomical cross-reference for axial images, and to provide quick feedback to the user as to the anatomy scanned. Revolution EVO supports real time scout

Scout Scan Parameters

Aperture: 8 x 0.625 mm effective aperture

Table speed: 100 mm/s or 175mm/s

Maximum Display FOV: 50 cm

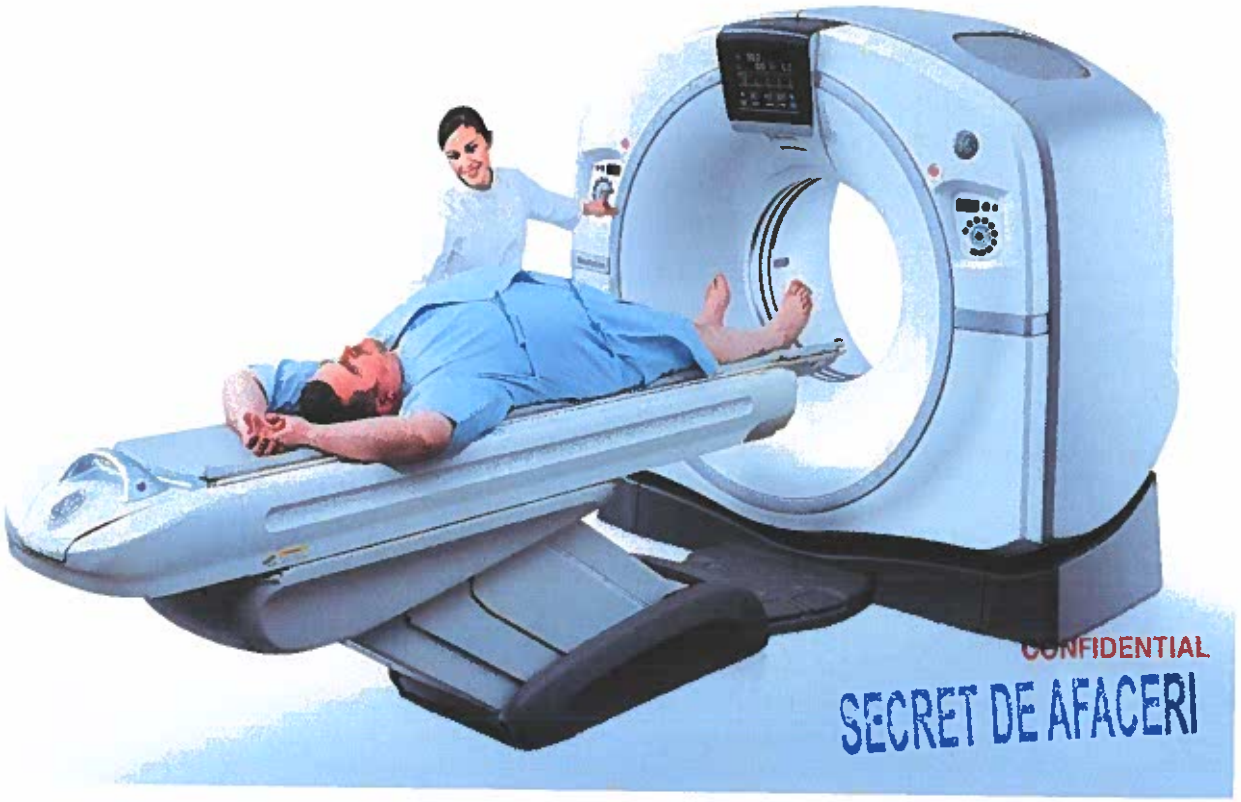
Selectable KV: 80, 100, 120, 140

Selectable mA at 120kV:

10 to 560mA, 5mA increment for 72kW based system

10 to 400mA, 5mA increment for 48kW based system

Orientation: AP, RLAT, PA, LLAT (preset); or angle from 0° - 359° (manually selected).



Imaging Performance Specifications

Helical Scan Image Quality

High resolution: 0.28mm

3D MTF:

Typical MTF is demonstrated on a 0.05mm tungsten wire and a 1.0mm x 0.025mm gold foil phantom for in-plane and z-plane, respectively.

High resolution algorithm

	X/Y lp/cm	Z lp/cm
50%	12.1	7.3
10%	16.0	12.2
4%	18.3	14.2
0%	>18.3	19.7

Low-Contrast Detectability:

On 8 inch (20cm) Catphan® phantom:

Reconstruction Mode	Object Size	% Contrast	Dose Level (mGy CTDIvol) 10mm slice
ASiR-V with Standard Algorithm	5mm	0.30%	4.87

Reconstruction Mode	Object Size	% Contrast	Dose Level (mGy CTDIvol) 10mm slice
ASiR with Standard Algorithm	5mm	0.32%	5.69

Noise:

On either an AAPM water phantom or GE Quality Assurance phantom with 5mm slice thickness equivalent:

0.43% at 4.70 mGy CTDIvol with ASiR-V Reconstruction Algorithm

0.43% at 11.1 mGy CTDIvol with ASiR Reconstruction Algorithm

CTDI:

On CTDI Head and Body Dose Reference Phantoms:

$CTDI_{vol}$ expressed in mGy/100 mAs (0.984:1 Pitch):

Head: 17.0mGy/100 mAs
Body: 8.8 mGy/100 mAs

Axial Scan Image Quality

High Contrast Spatial Resolution:

Typical in-plane MTF is demonstrated on a 0.05mm tungsten wire.

High resolution algorithm

	X/Y lp/cm
50%	12.1
10%	16.0
4%	18.3
0%	>18.3

Low-Contrast Detectability

On 8 inch (20cm) Catphan® phantom:

Reconstruction Mode	Object Size	% Contrast	Dose Level (mGy CTDIvol) 10mm slice
ASiR-V with Standard Algorithm	5mm	0.30%	4.57

Reconstruction Mode	Object Size	% Contrast	Dose Level (mGy CTDIvol) 10mm slice
ASiR with Standard Algorithm	5mm	0.32%	6.09

Noise:

On either an AAPM water phantom or GE Quality Assurance phantom with 5mm slice thickness equivalent:

0.43% at 4.95 mGy CTDIvol with ASiR-V Reconstruction Algorithm

0.43% at 11.0 mGy CTDIvol with ASiR Reconstruction Algorithm

CTDI

On CTDI Head and Body Dose Reference Phantoms:

CTDIw expressed in mGy/100 mAs:

Head: 16.7mGy/100 mAs
Body: 8.7Gy/100 mAs

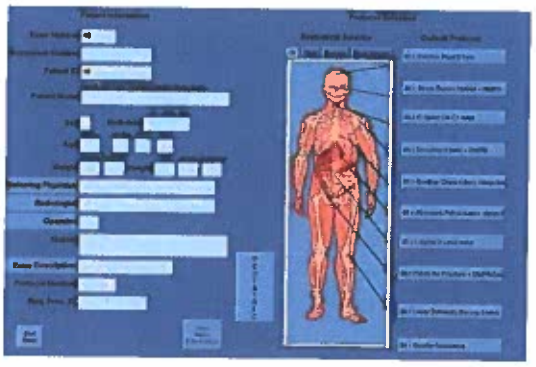
Asterisk*: Option and Option may not be available in all markets.

Desktop – Exam RX

The Exam Rx desktop environment provides the clinical tools necessary for comfortable, efficient control of patient studies. These tools include patient scheduling and data entry, exam protocol selection, protocol viewing and editing, scan data acquisition, image reconstruction, image display and routine analysis, AutoFilm or manual filming, AutoStore and AutoTransfer.

Patient Scheduling

Patient Schedule allows users to preprogram patient information and exam protocols prior to the patient's arrival. At scan time, select from the created list, enter the patient ID number, enter the Accession number, or use the optional Bar Code Reader to call up patient information. Patient information can be easily added or deleted from this list.

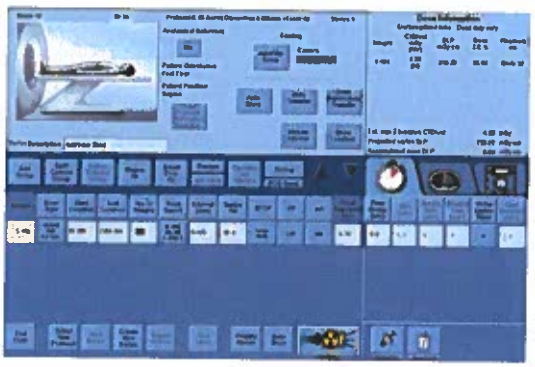


Patient Data Entry

Patient data can be entered as part of New Patient set-up or can be recalled from the list of pre-scheduled patients. Common inputs for new patients include: physician, radiologist, technologist and contrast type (oral and IV).

Exam Protocol Selection

Two Anatomical Programmers - one for adults and one for pediatrics - provide quick and easy access to 6840 user-programmable protocols (total). Each programmer has ten anatomical regions with 90 protocols for each region



Protocol View/Edit

When used in conjunction with the Show Localizer, changes made in the View/Edit table that affect the number of scans, image interval, starting/ending locations, tilt, or display FOV are automatically shown on the Show Localizer.

Imaging Protocol Manager*

GE Healthcare's Imaging Protocol Manager is a cloud-based multimodality, protocol-management solution that provides access, insight, and governance for protocols on imaging devices to help providers effortlessly deliver the right exam for each patient and meet regulatory and accreditation requirements in an efficient manner.

See Imaging Protocol Manager datasheet for more functionalities

Auto Image Management

The Exam Rx work environment conveniently provides for selection of AutoFilm, and AutoTransfer (across a network).

Manual Image Filming

On-screen filming is available for digital camera using a DICOM protocol.

Asterisk*: Option and Option may not be available in all markets.

Desktop – ImageWorks

ImageWorks software is designed to take advantage of the Revolution EVO computer and image processor. This desktop environment includes image management and networking.

Image Analysis software

Revolution EVO series support following Image analysis tools on console.

- Volume Viewer 5*
- Reformat
- AVA Xpress*
- AutoBone Xpress*
- Advantage CTC Pro3D EC*
- Perfusion 4D - Multi Organ*
- Perfusion4D – Neuro*
- CardIQ Xpress 2.0 Reveal*
- Card EP*
- Denta Scan*

Image Display

- Viewer
- Mini Viewer

Image Management

Local Database

The Source menu controls the contents of the Patient List and displays the host databases to which the user is currently connected.

CD/DVD/USB

Allows storage of DICOM images and a DICOM Viewer to a CD-R or DVD-R or USB media.

Data Export

Allows storage of images on a CD-R or FTP or USB images as JPEG, PNG, AVI, MPEG, or MOV formats.

Filming

On-screen filming is available for digital camera using a DICOM protocol.

Image Networking

Exams can be selected and moved between the Revolution EVO and the imaging system supporting the DICOM protocol for network send, receive and pull/query.

Asterisk*: Option and Option may not be available in all markets.

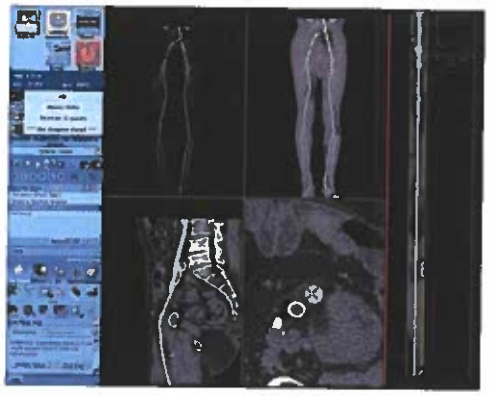
Application on console software

Volume Viewer 5

Volume Viewer 5 is designed to be the environment of choice for 3D processing. Its power goes beyond Clinical Review, providing exceptional tools for analysis, segmentation, measurements, annotation, filming and exporting of clinically relevant images.

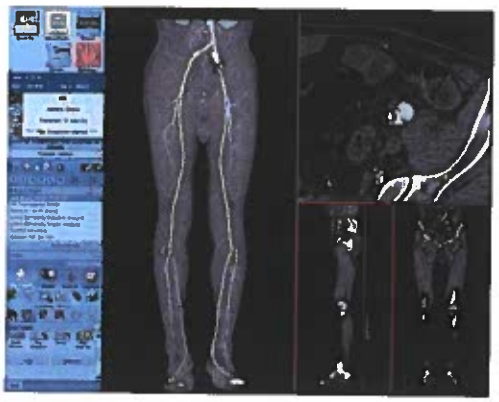
AVA Xpress*

AVA Xpress is intended to provide an optimized non-invasive application to analyze vascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic



AutoBone™ Xpress*

AutoBone XPress is an image analysis software package that is intended to facilitate segmentation of bony structures and calcifications for CT Angiography exams.



CardIQ Xpress 2.0 Reveal *

CardIQ Xpress 2.0 Reveal is an integrated post processing imaging analysis software dedicated for the application of cardiovascular imaging. The CardIQ Xpress 2.0 Reveal software option can be used to effectively display, reformat and analyze 2D or 3D cardiac CT images for qualitative or quantitative assessment of heart anatomy and coronary artery vessels from a single or multiple cardiac phase image data set.

CardEP*

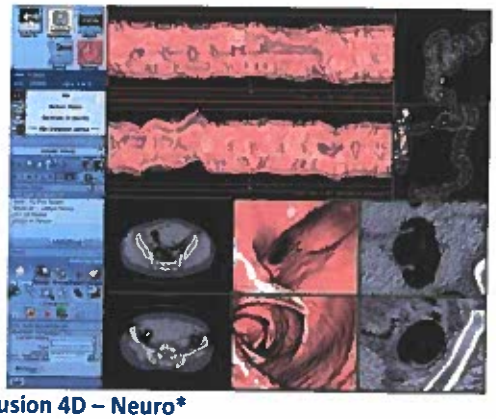
CardEP is a software post-processing package. It is an additional tool for the analysis of 3D angiographic data providing a number of display, measurements and batch filming/archive features to study the left atrium, pulmonary veins and coronary veins. The features include but are not limited to; automatic volume rendering models of the left atrium and heart, vessel analysis for pulmonary veins and coronary veins, navigator views of the veins, along with guided double oblique reviews of the left atrial appendage and the pulmonary veins.

Advantage CTC Pro3D EC*

AdvantageCTC is a post-processing application. Data of the colon acquired on a CT Scanner can be processed using Colon Advantage CTC software. Patients who have suspected colonic diseases are the targeted population for this software.

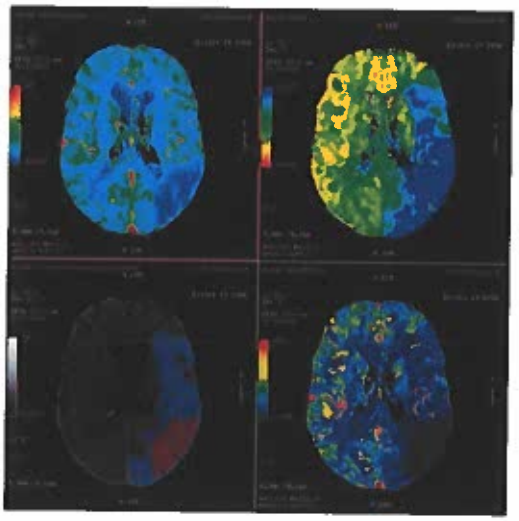
Asterisk*: Option and Option may not be available in all markets.

Application on console software



CT Perfusion 4D – Neuro*

CT Perfusion 4D – Neuro is an image analysis software package that allows the evaluation of dynamic CT data following an injection of a compact bolus of contrast material and generating information regarding changes in image intensity over time.



CT Perfusion 4D – Multi Organ*

CT Perfusion 4D – Multi-organ is an image analysis software package that allows the evaluation of dynamic CT data following an injection of a compact bolus of contrast material and generating information regarding changes in image intensity over time.

Advantage Denta Scan*

A Dental Surgical Planning Package. Utilized to Plan Dental Implants and other Surgeries Involving the Maxilla and Mandible. Creates Cross-Referenced Composite Axial, Panorex, and Oblique Planar Reformations of the Mandible and Maxilla.

Asterisk*: Option and Option may not be available in all markets.

Gantry specification

Gantry

Silent design of Revolution EVO gantry allows significant reduction of audible noise compared with previous GE technology.

Aperture	70 cm
Tilt	± 30°
Tilt Speed	1°/s or 1.5°/s
Focus to Detector	95 cm
Focus to Iso-center	54 cm
Maximum SFOV	50 cm

Performix™ 40 Plus X-ray Tube

Dual Focal Spots

Focal Spot	IEC 60336: 1993	IEC 60336: 2005
Small	0.7x0.6	0.9x0.7
Large	0.9x0.9	1.2x1.1

Maximum mA for each kV selection:

72kW based system

kV	Small Spot: Max mA	Large Spot: Max mA
80	300	400
100	240	480
120	200	600
140	170	515

48kW based system

kV	Small Spot: Max mA	Large Spot: Max mA
80	300	400
100	240	450
120	200	400
140	170	340

Thermal Ratings:

Maximum Anode Heat Content (Reference: IEC 60613):

Maximum X-ray Tube Assembly heat content: 7.7MJ (10.8 MHU)

Equivalent anode heat capacity with ASiR-V: 39MHU+

Equivalent anode heat capacity with ASiR: 12MHU++

The maximum anode heat capacity: 5.0 MJ (7.0MHU)

Anode heat dissipation: 1070 KHU/min (13.2kW)

+ Tube equivalence is based on the image noise ratio value between ASiR-V and FBP. The ratio calculation between image noise and dose corresponding mAs is defined as $[(SD_{FBP})^2/(SD_{ASiR\text{-}V})^2 \times \text{tube rating}]$

++ Tube equivalence is based on the image noise ratio value between ASiR and FBP. The ratio calculation between image noise and dose corresponding mAs is defined as $[(SD_{FBP})^2/(SD_{ASiR})^2 \times \text{tube rating}]$

Asterisk*: Option and Option may not be available in all markets.

High Voltage Generation

72kW based system

kV: 80, 100, 120, 140

Power: 72kW

Equivalent power with ASiR-V: 400 kW+++

Equivalent power with ASiR: 120kW++++

mA range at 120kV: 10 to 600mA, 5mA increment

48kW based system

kV: 80, 100, 120, 140

Power (Hardware): 72kW

Equivalent power with ASiR-V: 270kW+++

Equivalent power with ASiR: 80kW++++

mA range at 120kV: 10 to 400mA, 5mA increment

+++ kW equivalence is based on the image noise ratio value between ASiR-V and FBP. The ratio calculation between image noise and dose corresponding mAs is defined as $[(SD_{FBP})^2/(SD_{ASiR\text{-}V})^2 \times \text{generator rating}]$

++++ kW equivalence is based on the image noise ratio value between ASiR and FBP. The ratio calculation between image noise and dose corresponding mAs is defined as $[(SD_{FBP})^2/(SD_{ASiR})^2 \times \text{generator rating}]$

Clarity Detector

64ch based system

54,272 individual elements composed by 64 rows of 0.625mm thickness at isocenter. All data is acquired as thin slice at 0.625mm with the option of thicker slice from image reconstruction or processing.

98% absorption efficiency.

32ch based system

54,272 individual elements composed by 64 rows of 0.625mm thickness at isocenter. All data is acquired as thin slice at 1.25mm with the option of thicker slice from image reconstruction or processing.

32x 0.625mm or 32x1.25mm scan mode.

98% absorption efficiency.

Gantry specification

Clarity Data Acquisition System

2,460 Hz maximum sample rate.

861 - 1968 views per rotation.

Asterisk*: Option and Option may not be available in all markets.

Scan control unit and Table specification

Scan control unit

3,000GB Disk(system, image, scan disks) stores up to 460,000 512 x 2images and 3520 scan rotations at 64 slice mode or up to 1,500 scan data files, or up to 300 exams.

Reconstruction speed with Standard reconstruction: Up to 50 frames per second.

Host computer	Specifications
CPU	Dual Intel Xeon 4116 2.1GHz 12Core
O/S	64-bit
Cache	L3 x 16.5MB shared
RAM	96GB DDR-4-2666MHz or equivalent
Graphics card	Nvidia Quadro P620 PCI Express 16x or equivalent
Reconstruction unit	Commercial-Off-The-Shelf Graphics Processor add-in card
Storage	**Specifications**
Application and image desk	2 x 1000G8 SATA HDD
Scan data storage	2 x 512GB SSD

Table

Two configurations with 500lb (227kg) patient weight capacity, and up to 2000 mm scannable range (or 1700mm), for longer runoff studies, flexible patient positioning, and easy room siting. An option providing 675lb (306kg) patient weight capacity with up to 2000 mm scannable range to accommodate a wider range of patients.

Table configurations and specifications

	VT1700V Table	VT2000 Table	VT2000x Table
Vertical Range*	430mm to 991mm	430mm to 991mm	525mm to 991mm
Vertical Scannable Range*	791mm to 991mm	791mm to 991mm	791mm to 991mm
Elevation Speed Full range motion	Less than 22sec (Fast) Less than 45sec (Slow)	Less than 22sec (Fast) Less than 45sec (Slow)	Less than 20sec (Fast) Less than 38sec (Slow)
Elevation Accuracy Position repeatability	±1.5mm	±1.5mm	±1.5mm
Horizontal Range	1745mm	2045mm	2045mm
Horizontal Scannable Range (Axial)**	1730mm	2000mm	2000mm
Horizontal Scannable Range (Helical)**	1580mm	1890mm	1890mm
Horizontal Scannable Range (Scout)**	1600mm	1900mm	1900mm
Cradle Speed Max Horizontal Speeds	175(150***) mm/sec	175(150***) mm/sec	175(150***) mm/sec
Cradle Speed. Operator-controlled slow speed operation	5 or 10mm/sec ±3%	5 or 10mm/sec ±3%	5 or 10mm/sec ±3%
Cradle Speed. Operator-controlled fast speed operation	125 or 175mm/sec ±2%	125 or 175mm/sec ±2%	125 or 175mm/sec ±2%
Position repeatability	±0.25mm	±0.25mm	±0.5mm (Table load > 227kg) ±0.25mm (Table load ≤227kG)
Longitudinal accumulated position error	±0.25mm±0.06%	±0.25mm±0.06%	±0.5mm±0.06% (Table load > 227kg) ±0.25mm (Table load ≤227kG)
Table Load Capability	227kg(500lbs)	227kg (500lbs)	306kg (675lbs)

* The distance from the Table bottom to the cradle upper side surface
** Accuracy is +/- 1%. Table Height, Gantry Tilt and scanning software determine the scannable range.
*** During Move to scan operation

Asterisk*: Option and Option may not be available in all markets.

Peripherals/Networking/DICOM/Filming protocol/Anti-virus SW

Peripherals

Scan control keyboard assembly with intercom speaker, microphone and volume controls.

Color LCD monitors (2 standard):
- 19 inch diagonal width
- 1280 x 1024 dot resolution
- Horizontal & Vertical viewing angle: 170 degrees
- Horizontal synchronization range: 31.0 – 80.0 kHz
- Vertical synchronization range: 50 - 75 Hz

DVD-RAM (Scan Data)
- 9.4 GB total. 4.7 GB per side
- Assigned for Scan Data

DVD-R/CD-R (DICOM Interchange):
- 4.7 GB capacity (DVD)
- Approximately 7000 image storage (DVD)
- Supports CD-R, DVD-R

2-Button + Scroll Wheel Mouse

Image Networking

Image transfer time using DICOM protocols is 10fps on a 1000baseT network.

DICOM Conformance Standards

For detailed information, a DICOM conformance statement is available upon request.

- DICOM Storage Service Class
- Service Class User (SCU) for image send
- Service Class Provider (SCP) for image receive
- Service Class User (SCU) for storage commitment
- DICOM Query/Retrieve Service Class
- DICOM Storage Commitment Class Push
- DICOM Modality Worklist
- DICOM Modality Performed Procedure Step
- DICOM Print
- DICOM Structured Dose Report

Filming Protocol

- DICOM protocol

Important note: The Revolution EVO comes standard with a DICOM Print Interface configurable for multiple DICOM Print destinations. Connections with cameras that do not support DICOM Print may require a filming interface (purchased separately).

Anti-Virus software

McAFee Anti-Virus software

Asterisk*: Option and Option may n

Compatible options

Mandatory Selectable Options

Slice
32ch/32sl
32ch/64sl
64ch/64sl
64ch/128sl
Generator power
48kW
72kW
Rotation speed
0.7sec rotation
0.5sec rotation
0.4sec rotation
0.35sec rotation for cardiac
0.35sec rotation
Iterative reconstruction
ASiR
ASiR-V
Patient table
VT1700V
VT2000
VT2000x
Cable collector
Standard cable collector
Long cable collector
Keyboard
English
French
German
Italian
Swedish
Finnish
Asian
Danish
Dutch
Norwegian
Spanish
Portuguese
European Misc
Euro port
Br. Portuguese

ECG Trace
Cardiac Enhance
Card IQ Snapshot
ECG Wave on Gantry
CardIQ Xpress 2.0 Reveal
CardEP
SmartScore Package
SmartScore
ECG Trace
Cardiac Enhance
ECG Wave on Gantry
SmartScore 4.0
CT Angiography Package
AVA Xpress
AutoBone Xpress
Head Perfusion Package
Volume Shuttle
CT Perfusion 4D Neuro
Multi-Organ Perfusion / 4D package
Volume Shuttle
Volume Helical Shuttle
CT Perfusion 4D Multi Organ
Application on Console Package
AVA Xpress
Advantage CTC Pro3D EC
AutoBone Xpress
CT Perfusion 4D Multi-Organ
CardEP
CardIQ Xpress 2.0 Reveal
Denta Scan
Workflow package
Image check
One stop scanning mode

Application Package Options

The following options are available on the Revolution EVO and console. See Advantage Workstation (AW) product data sheet for list of available AW options.

Advanced Cardiac Package
SmartScore Pro
ECG Trace
Cardiac Enhance
Card IQ Snapshot
SnapShot Pulse
ECG Wave on Gantry
SnapShot Assist
Temporal Enhance
CardIQ Xpress 2.0 Reveal
CardEP
Cardiac Package
SmartScore Pro

Asterisk*: Option and Option may not be available in all markets.

Compatible options

Compatible Options

Software option
Integrated Injector
Smart MAR
Advanced CTC Pro3D EC
Prospective Exam Split
Denta Scan
AWE Connection
Tube License
Interventional option
SmartView
SmartStep
Oncology option
Flat Table Top
Advantage 4D
Patient Accessary
Low Profile head holder
Coronal head folder
Child positioner
Table Slicker
Table pad
CT Straps
Hardware option
Bar code reader (USB)
External HDD
Rear control panel
UPS option
Anti-sesmic kit
Console desk
Chair
Big Cabnet
Connectable option
Imaging Protocol Manager
Revolution Smart Subscription

Asterisk*: Option and Option may not be available in all markets.

Energy Saving

GE Healthcare's High Efficiency CT systems are designed to reduce electricity consumption for operation and ambient cooling by optimizing energy use based on a customer's usage profile. The Revolution EVO system and its associated site cooling systems consume approximately 48,200 kWh of electricity per year, about 29% less than the previous-generation GE system it replaces. For customers actively pursuing energy efficiency strategies, use of the innovative Energy Saving Mode software during evenings and weekends when the CT system is not in use can reduce annual electricity consumption by an additional 19,100 kWh, or a total of 58% per system compared to the previous-generation GE system.

		Previous-generation GE system	Revolution EVO without ESM	Revolution EVO with ESM
CT system*	Yearly Energy(kWh)	32722.8	12505.0	10588.4
	Reduction Energy (kWh)	-	20217.8	22134.4
	Reduction Energy (%)	-	62%	68%
Associated site cooling systems	Yearly Energy(kWh)	35708.4	35708.4	18008.7
Total	Yearly Energy(kWh)	68431.2	48213.4	28597.1
	Reduction Energy (kWh)	-	20217.8	39834.1
	Reduction Energy (%)	-	29.5%	58.2%
*Value of CT system was measured based on COCIR (European Coordination Committee of the Radiological) procedure.				

Asterisk*: Option and Option may not be available in all markets.

Siting requirement

Rating

The system operates on three-phase power that meets the following specifications:

48kW based system

- Voltage: 200 to 240 VAC, 380 to 480 VAC
- Capacity: 75 kVA
- Frequency: 50 or 60 Hz ± 3 Hz
- Maximum power demand = 75kVA @ 0.85 PF at a selected technique of 120kV, 400mA
- Average (continuous) power demand at maximum duty cycle = 20 kVA.
- Idle power demand (without rotation and X-ray) = 5.0 kVA.

72kW based system

- Voltage: 200 to 240 VAC, 380 to 480 VAC
- Capacity: 100 kVA
- Frequency: 50 or 60 Hz ± 3 Hz
- Maximum power demand = 100 kVA @ 0.85 PF at a selected technique of 140 kV, 515 mA.
- Average (continuous) power demand at maximum duty cycle = 20 kVA.
- Idle power demand (without rotation and X-ray) = 5.0 kVA.

System components	Net Weight Kg (lb.)	Overall Width x Depth mm (in.)
Gantry	1820 (4012)	2050 x 1039 (81 x 41)
VT2000x Table with 306 kg (675 lb) patient	815(1797)	650 x 2910 (25.6 x 114.5)
VT2000 Table with 227 kg (500 lb) patient	732 (1613)	650 x 2910 (25.6 x 114.5)
VT1700V Table with 227 kg (500 lb) patient	672 (1481)	650 x 2360 (25.6 x 93.3)
Power Distribution Unit	370 (816)	700 x 550 (27.6 x 21.7)
Console	65 (143)	400 x 672 (15.7 x 26.5)
Monitor – LCD (each)	9 (20)	420 x 247 (16.5 x 9.7)
Standard desk	57 (126)	1300 x 895 (51.2 x 35.2)

Floor loading and component weights

Asterisk*: Option and Option may not be available in all markets.

License/Warranty/Regulatory compliance

DOC2194950 rev5

License

ASiR, ASiR-V, Volume Helical Shuttle and Cardiac scan are licensed for use with a GE X-ray tube. Use of a third party X-ray tube will require an additional license for these features.

Warranty

The published Company warranty in effect on the date of shipment shall apply. The Company reserves the right to make changes.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.

Regulatory Compliance

Laser alignment devices contained within this product are appropriately labeled according to the requirements of the Center for Devices and Radiological Health.

This product complies with NEMA Standard XR-29-2013

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This version of Revolution EVO is not CE marked and cannot be placed on the market or put into service until it has obtained all required regulatory approvals.

This data sheet is prohibited to distribute to the USA.

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About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services helps our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access, and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com.

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imagination at work