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 Medical Systems LLC
3000 North Grandview Blvd
Waukesha, WI 53188, USA

EU Authorized Representative

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

Declare under our sole responsibility that the device:

Revolution Apex

X-Ray System, Diagnostic, Computed Tomography, Full-body

Ref: 5995000-5PCM; 5995002-7PCM, 5995002-8PCM.

GMDN Code: **37618** UDI-DI code: 00840682146616 (Revolution Apex)

Classification rule (93/42/EEC Annex IX): **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 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: **DOC1520191**, of the product to which this declaration relates
  - EC certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by G-MED (Notified Body #0459/ Certificate No. 7856
  - harmonized standards applied on the product to which this declaration relates
- For the directive 2011/65/EU (RoHS)
  - Technical Documentation/DHF Ref./ réf: **DOC1520191**, of the product to which this declaration relates
- List of harmonized standards applied for CE marking :

  EN 60601-1:2006/A1:2013
  EN 60601-1-2:2015
  EN 60601-1-3: 2008/A11:2016
  EN 60601-2-44: 2009+A1:2012+A2:2016

Waukesha, WI, USA,

17 Dezember 2021

Amy Yang
Regulatory Affairs Manager

This EC declaration of conformity supersedes the previous declaration of conformity dated 14-May-2021

CONFORM CU ORIGINALUL

DECLARAȚIE DE CONFORMITATE

În conformitate cu prevederile Directivei 93/42/CEE referitoare la dispozitivele medicale,
Anexa II și ale Directivei 2011/65/UE

Subscrisa,

Producător

GE Medical Systems LLC
3000 North Grandview Blvd
Waukesha, WI 53188, SUA

Reprezentant autorizat UE

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

Declară pe proprie răspundere că dispozitivul:

Revolution Apex

Sistem cu raze X, diagnosticare, tomografie computerizată, tot corpul

Ref: 5995000-5PCM; 5995002-7PCM, 5995002-8PCM.

Cod GMDN: **37618** Cod UDI-DI: 00840682146616 (Revolution Apex)

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

La care se referă această declarație este conform cu cerințele Directivei privind dispozitivele medicale 93/42/CEE care i se aplică și cu cerințele Directivei 2011/65/UE privind restricțiile de utilizare a anumitor substanțe periculoase în echipamente electrice și electronice.

Această conformitate se bazează pe următoarele elemente:

- Pentru Directiva 93/42/CEE (DDM)
  - Documentația tehnică/DHF Ref./ réf: **DOC1520191**, a produsului la care se referă această declarație
  - Certificat CE: aprobarea sistemului complet de asigurare a calității (Anexa II a directivei 93/42 CEE) livrat de G-MED (Organ notificat #0459/ Certificat Nr. 7856
  - standarde armonizate aplicate produsului la care se referă această declarație.
- Pentru Directiva 2011/65/UE (RoHS)
  - Documentația tehnică/DHF Ref./ réf: **DOC1520191**, a produsului la care se referă această declarație
- Lista de standarde armonizate aplicate pentru marcajul CE:

EN 60601-1:2006/A1:2013
EN 60601-1-2:2015
EN 60601-1-3: 2008/A11:2016
EN 60601-2-44: 2009+A1:2012+A2:2016

Semnătură indescifrabilă
Mențiune olografă: 17 decembrie 2021
Amy Yang
Director Departament reglementare

Waukesha, WI, SUA,

Această declarație de conformitate o înlocuiește pe cea precedentă datată 14 mai 2021

CONFORM CU ORIGINALUL

Subsemnata, **ANDREESCU ADELINA IONELA** traducător autorizat pentru limba Engleză, în temeiul autorizaţiei nr. 23469, eliberată de Ministerul Justiţiei, certific exactitatea traducerii efectuate din limba engleză în limba română, că textul prezentat a fost tradus în intregime şi că prin traducere, înscrisului nu i-au fost denaturate conţinutul şi sensul.

ANDREESCU ADELINA-IONELA
Traducător Autorizat
Nr. Aut. 23469

CONFORM CU ORIGINALUL

GMED
GROUPE LNE

Règlement (UE) 2017/745, Annexe IX Chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
Regulation (EU) 2017/745, Annex IX Chapters I and III

Certificat/*Certificate:* N° 38701 rev. 4

Délivré le /*Issued on:* November 27th, 2023

Certificat délivré à/*Certificate issued to:* **GE MEDICAL SYSTEMS, LLC**
3000 North Grandview Blvd
WAUKESHA, WI 53188 UNITED STATES
SRN: US-MF-000018315

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P603587, P607902, P603588, P606273, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/745 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) referenced P603587, P607902, P603588, P606273, the quality management system complies with the relevant provisions of the regulation (EU) 2017/745 for the following products:

Tomodensitomètre (scanner)

Computed tomography device or system

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de classe IIb implantables et/ou de classe III, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/745 est requis.

For the purpose of placing on the market implantable class IIb and / or class III devices, another certificate issued in accordance with the provisions of the regulation (EU) 2017/745 is required.

Début de validité /*Effective date:* November 27th, 2023 (included)

Valable jusqu'au /*Expiry date:* November 7th, 2026 (included)

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and from the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

GMED

DocuSigned by:
Lionel DREUX
A1D80E08C80D47A...

Lionel DREUX
President

GMED
GROUPE LNE

Addendum au certificat N° 38701 rev. 4
Addendum of the certificate N° 38701 rev. 4
Dossiers / *Files N° P603588, P607902, P603587, P606273*

1. **Le cas échéant, le nom et l'adresse du mandataire** / *If applicable, the name and address of the authorized representative:*
GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE
78530 BUC, FRANCE
SRN : FR-AR-000000344

2. **Identification des sites** / *Identification of sites:*
GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd
WAUKESHA, WI 53188, USA

3. **Identification des dispositifs** / *Identification of devices:*

Nom du dispositif médical *Medical device name*	**Nom commercial** *Commercial name*	**Destination (DM classe IIb uniquement)** *Intended use (MD Class IIb only)*	**Classe du DM** *MD Class*
Revolution CT	Revolution CT	X-ray system, diagnostic, computed tomography, full body	IIb
Revolution CT ES	Revolution CT ES		
Revolution Apex	Revolution Apex		
Revolution Apex Plus	Revolution Apex Plus		
Revolution CT with Apex edition	Revolution CT with Apex edition		
Revolution CT ES with Apex edition	Revolution CT ES with Apex edition		
Revolution Apex Elite	Revolution Apex Elite		
Auto Segmentation	Auto Segmentation	X-ray system, diagnostic, computed tomography, application program software	IIb

DocuSigned by:
GMED
Lionel DREUX
A1D60E08C60047A...

Lionel DREUX
President

4. **Historique du certificat** / *Certificate history:*

Référence au certificat précédent *Reference to the preceeding certificate*	**Date de délivrance** *Date of issue*	**Modifications apportées** *Identification of the changes*
38701 rev. 0 *38701 rev. 0*	**08/11/2021** *11/08/2021*	**Ajout d'un dispositif au sein d'une catégorie de dispositif existante** *Addition of a device to the existing device's category*
38701 rev. 1 *38701 rev. 1*	**17/02/2022** *02/17/2022*	**Ajout d'un dispositif au sein d'une catégorie de dispositif existante** *Addition of a device to the existing device's category*
38701 rev. 2 *38701 rev. 2*	**22/12/2022** *12/22/2022*	**Ajout d'un dispositif au sein d'une catégorie de dispositif existante** *Addition of a device to the existing device's category*
38701 rev. 3 *38701 rev. 3*	**01/06/2023** *06/01/2023*	**Ajout du numéro de projet du nouveau cycle d'audit** *Addition of the project number of the new audit cycle*

5. **Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat** / *If applicable, specific information relating to the limitations to the validity of the certificate :* **Non applicable** / *Not applicable*

6. **Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat** / *If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate :* **Non applicable** / *Not applicable*

CONFORM CU ORIGINALUL

DocuSigned by:
Lionel DREUX
A1D[illegible]E08C80D47[illegible]

Lionel DREUX
President

GMED
GROUPE LNE

CERTIFICAT SISTEMUL DE MANAGEMENT AL CALITĂȚII UE

Regulamentul (UE) 2017/745, Anexa IX capitolele I și III

Certificat: Nr. 38701 rev. 4

Emis la: 27 noiembrie 2023

Certificat emis pentru:

GE MEDICAL SYSTEMS, LLC

3000 North Grandview Blvd

WAUKESHA, WI 53188 Statele Unite

SRN: US-MF-000018315

GMED certifică faptul că, pe baza rezultatelor enumerate în raportul (raporturile) de audit al (ale) sistemului de management al calității la care se face referire în P603587, P607902, P603588, P606273, sistemul de management al calității respectă prevederile relevante ale regulamentului (UE) 2017/745 pentru următoarele produse:

Tomodensitometru (scaner)

Dispozitiv sau sistem de tomografie computerizată

Consultați actul adițional pentru informații suplimentare

Cu excepția scopului introducerii pe piață a dispozitivelor implantabile de clasa IIb și/sau clasa III, este necesar un alt certificat eliberat în conformitate cu prevederile regulamentului (UE) 2017/745.

Data intrării în vigoare: 27 noiembrie 2023 (inclusiv)

Data expirării: 7 noiembrie 2026 (inclusiv)

Valabilitatea acestui certificat este condiționată de respectarea obligațiilor care decurg din sistemul de management al calității aprobat și din supravegherea efectuată de Organismul notificat conform prevederilor regulamentului. Acest certificat este legat de condițiile contractului.

CONFORM CU ORIGINALUL

GMED
Document signed by:
Lionel DREUX
A1D80E09C60047A...

Lionel DREUX
Președinte

GMED - 38701 rev. 4
Modifică certificatul 38701--3

720 ROM 0701-75 rev 2

1. *Dacă este cazul, numele și adresa reprezentantului autorizat:*
GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE
78530 BUC, FRANȚA
Număr unic de înregistrare: FR-AR-000000344

2. *Identificarea unităților de producție:*
GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd
WAUKESHA, WI 53188, SUA

3. *Date de identificare a dispozitivelor:*

Denumirea dispozitivului medical	*Denumire comercială*	*Utilizarea prevăzută (doar Clasa IIb DM)*	**Clasă DM** *Clasă DM*
Revolution CT	**Revolution CT**	**Sistem cu raze X, diagnosticare, tomografie computerizată, întregul corpul**	**IIb**
Revolution CT ES	**Revolution CT ES**		
Revolution Apex	**Revolution Apex**		
Revolution Apex Plus	**Revolution Apex Plus**		
Revolution CT cu ediție Apex	**Revolution CT cu ediție Apex**		
Revolution CT ES cu ediție Apex	**Revolution CT ES cu ediție Apex**		
Revolution Apex Elite	**Revolution Apex Elite**		
Auto Segmentare	**Auto Segmentare**	**Sistem de raze X, diagnosticare, tomografie computerizată, software-ul programului aplicației**	**IIb**

DocuSigned by:
GMED
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Președinte

4. *Istoricul certificatului:*

Trimitere la certificatul precedent	*Data emiterii*	*Identificarea modificărilor*
38701 rev. 0	*08.11.2021*	*Adăugarea unui dispozitiv la categoria dispozitivului existent*
38701 rev. 1	*17.02.2022*	*Adăugarea unui dispozitiv la categoria dispozitivului existent*
38701 rev. 2	*22.12.2022*	*Adăugarea unui dispozitiv la categoria dispozitivului existent*
38701 rev. 3	*01.06.2023*	*Adăugarea numărului de proiect al noului ciclu de audit*

5. *Dacă este cazul, informații specifice referitoare la limitările valabilității certificatului: Nu este cazul*

6. *Dacă este cazul, informații specifice referitoare la supravegherea efectuată în contextul menținerii certificatului: Nu este cazul*

CONFORM CU ORIGINALUL

GMED
Docusigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Președinte

Subsemnata, ENESCU TEODORA, traducator autorizat pentru limbile engleza si spaniola, in temeiul autorizatiei nr. 7158, eliberata de Ministerul Justitiei, certific exactitatea traducerii efectuate din limba engleza in limba romana, ca textul prezentat a fost tradus in intregime si ca, prin traducere, inscrisului nu i-au fost denaturate continutul si sensul.

TRADUCĂTOR ȘI INTERPRET AUTORIZAT
ENESCU
TEODORA
AUT. NR. 7158
ENGLEZĂ
SPANIOLĂ
MINISTERUL JUSTIȚIEI

CONFORM CU ORIGINALUL

Lionel DREUX
Președinte

GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 38495 rev. 1

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd
WAUKESHA, WI 53188 UNITED STATES

pour les activités
for the activities

Conception, développement et fabrication de dispositifs ou systèmes de diagnostic tomodensitomètre par émission de positron, de dispositifs ou systèmes de diagnostic tomodensitomètres (scanners), de dispositifs ou systèmes de diagnostic X-Ray et d'application logicielle.

Design, development and manufacture of medical diagnostic positron emission tomography devices or systems, diagnostic computed tomography devices or systems, medical diagnostic X-Ray devices or systems, and software application.

réalisées sur le(s) site(s) de
performed on the location(s) of

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd - WAUKESHA, WI 53188 - USA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016

Début de validité */ Effective date :* **November 7th, 2023 (included)**
Valable jusqu'au */ Expiry date :* **December 17th, 2026 (included)**
Etabli le */ Issued on :* **November 7th, 2023**

DocuSigned by: Lionel DREUX

Lionel DREUX
President

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0508
Liste des sites accédités et portée disponible sur www.cofrac.fr

GMED_SG-F-V0-07-2018

GMED N° 38495-1
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 38495-0

CERTIFICAT DE INREGISTRARE
Nr. 38495 rev. 1

GMED certifică că sistemul de management al calității dezvoltat de

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd
WAUKESHA, WI 53188 STATELE UNITE

pentru activitățile

Proiectarea, dezvoltarea și fabricarea de dispozitive sau sisteme de tomografie cu emisie de pozitroni pentru diagnosticare medicală, dispozitive sau sisteme de tomografie computerizată de diagnosticare, dispozitive sau sisteme de diagnosticare medicale cu raze X și aplicații software.

efectuate în locația (locațiile)

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd - WAUKESHA, WI 53188 - SUA

respectă cerințele standardelor internaționale

ISO 13485: 2016

Data intrării în vigoare: **7 noiembrie 2023 (inclusiv)**
Data expirării: **Decembrie 2026 (inclusiv)**
Emis la: **7 noiembrie 2023**

DocuSigned by:
Lionel DREUX
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GMED SAS GMED SAS GMED

GMED N° 38495–1

Acest certificat este eliberat conform regulilor de certificare GMED

Reînnoiește certificatul 38495-0

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n° 4-0608
Liste des sites accrédités et domaines d'application disponibles sur www.cofrac.fr

GMED_SQ-F-V10-07-2018

CONFORM CU ORIGINALUL

Subsemnata, **Lascu Raluca Teodora, interpret şi traducător autorizat pentru limbile străine engleză şi franceză, în temeiul Autorizaţiei nr. 20862 din data de 12/11/2007, eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba engleza în limba română , că textul prezentat a fost tradus complet, fără omisiuni, şi că, prin traducere, înscrisului nu i-au fost denaturate conţinutul şi sensul.**

CONFORM CU ORIGINALUL

Test Report issued under the responsibility of:

GE Medical Systems, LLC

TEST REPORT

IEC 60601-1-6

Medical electrical equipment

Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices

Report Reference No. ..... :	**GE DOC1450064 Rev 15**
Date of issue ..... :	**10Jun2019/15Mar2019/ 22Oct2018 / 09Aug2018 / 27Jul2017 / 11Apr2017 / 13Jul2016 / 03Dec2015 / 09Jul2015 / 29Sep2014 / 08Aug2014 / 30Oct2013 / 20Jan2020 / 06Apr2020 / 01Dec2020**
Total number of pages..... :	**10**
CB Testing Laboratory ..... :	**GE Medical Systems, LLC**
Address..... :	**3000 N. Grandview Blvd, Waukesha, WI 53188 USA**
Applicant's name..... :	**GE Healthcare**
Address..... :	**3000 N. Grandview Blvd, Waukesha, WI 53188 USA**
Test specification:	
Standards..... :	IEC 60601-1-6:2010 (Third Edition) for use in conjunction with IEC 60601-1: 2005 (Third Edition)
Test procedure..... :	CB Scheme
Non-standard test method……..:	N/A
Test Report Form No. ..... :	IEC60601_1_6E
Test Report Form Originator..... :	TÜV Rheinland North America
Master TRF..... :	Dated 2011-07

Test item description..... :	**Computed Tomography System**
Trade Mark ..... :	**GE Medical Systems, LLC**

Manufacturer ..... :	**GE Medical Systems, LLC**
Model/Type reference ..... :	**Revolution CT, Revolution CT ES, Revolution Apex**
Ratings ..... :	Powered by Certified PDU Model 2326492-61: 3~ 380//480 Vac, 50/60Hz, Momentary: 150kVA@0.85PF, Continuous: 30kVA Powered by Certified PDU Model 2326492-91: 3~ 380//480 Vac, 50/60Hz, Momentary: 200kVA@0.85PF, Continuous: 40kVA

Testing procedure and testing location:	
☐ **CB Testing Laboratory:**	
Testing location/ address ..... :	
☐ **Associated CB Test Laboratory:**	
Testing location/ address ..... :	
Tested by (name + signature) .... :	
Approved by (+ signature) ..... :	
☒ **Testing procedure: TMP**	**(Testing on Manufacturer's Premises)**
Tested by (name + signature) ... :	**Judy Graney**
Approved by (+ signature) ..... :	**Shawn Ray**
Tested by (name + signature) ... :	**R7 -- Chelsey Lewis / Shawn Ray; R8 – Chelsey Lewis / Shawn Ray; R9 – Chelsey Lewis / Shawn Ray; R10 – Chelsey Lewis / Shawn Ray; R11 – Chelsey Lewis / Shawn Ray; R12 – Chelsey Lewis / Shawn Ray; R13 – Shawn Ray; R14 – Shawn Ray; R15 – Eric Aasen/Shawn Ray**
Approved by (+ signature) ..... :	**R7 – Shawn Ray; R8 – Chelsey Lewis; R9 – Chelsey Lewis; R10 – Chelsey Lewis; R11 – Chelsey Lewis; R12 – Chelsey Lewis; R13 – Chelsey Lewis; R14 – Chelsey Lewis; R15 – Chelsey Lewis**
Testing location/ address ..... :	**3000 N. Grandview Blvd, Waukesha, WI 53188**
☐ **Testing procedure: WMT**	
Tested by (name + signature) .... :	
Witnessed by (+ signature) ..... :	
Approved by (+ signature) ..... :	
Testing location/ address ..... :	
☐ **Testing procedure: SMT**	
Tested by (name + signature) ... :	
Approved by (+ signature) ..... :	
Supervised by (+ signature) ..... :	
Testing location/ address ..... :	

List of Attachments (including a total number of pages in each attachment):

None

Summary of testing

Tests performed (name of test and test clause):	Testing location:
None	**3000 N. Grandview Blvd, Waukesha, WI 53188 USA**

Summary of compliance with National Differences

List of countries addressed: None

☒ The product fulfils the requirements of IEC 60601-1-6:2010 (Edition 3.0)

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

See IEC 60601-1 Test Reports

CONFORM CU ORIGINALUL

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	M3rdict
4.0	**General requirements**		
4.2	**USABILITY ENGINEERING PROCESS complies with IEC 62366 including amended definitions**	**See DOC1450065 for IEC62366:2007 Assessment**	**P**
	Inspection of the USABILITY ENGINEERING FILE Verified that the MANUFACTURER		
	– established a USABILITY ENGINEERING PROCESS	Process GE Global Quality Work Instruction GEHC_GQP_10.01.013 Design Controls Usability (DOC0804338) *Appendix shows mapping to standard*	**P**
	– established acceptance criteria for USABILITY; and	Process GE Global Quality Work Instruction GEHC_GQP_10.01.013 Design Controls Usability (DOC0804338) *Appendix shows mapping to standard* Implementation Acceptance criteria is established in the Usability Validation Plans (DOC1579665/DOC1916206)(DOC2187072/DOC2290722) (DOC2478387)	**P**
	– demonstrated that the acceptance criteria for USABILITY have been met.	Process GE Global Quality Work Instruction GEHC_GQP_10.01.013 Design Controls Usability (DOC0804338) *Appendix shows mapping to standard* Implementation System Clinical Scenarios Reports / System Verification (DOC1487954/DOC1591971) (DOC1975643/DOC1975640) (DOC2187074/DOC2291685) (DOC2465171) Summative Testing Reports (DOC1599715/DOC1602767) (DOC1916281/DOC2290724) (DOC2483221)	**P**

5	**Replacement of requirements given in IEC 62366**		
	The instructions for use include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY	Process GE Global Quality Work Instruction GEHC_GQP_10.01.013 Design Controls Usability (DOC0804338) Implementation URM	**P**

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	M3rdict
	The same information is also included in the technical description, if this is provided as a separate document from instructions for use	Process GE Global Quality Work Instruction GEHC_GQP_10.01.013 Design Controls Usability (DOC0804338) Implementation TRM	**P**
	The instructions for use contain a summary of the application specification	Process GE Global Quality Work Instruction GEHC_GQP_10.01.013 Design Controls Usability (DOC0804338) Implementation URM TRM	**P**

Traducere din limba engleză

Raport de testare emis sub responsabilitatea:
GE Medical Systems, LLC

RAPORT DE TESTARE
IEC 60601-1-6
Echipament electric medical
Partea 1-6: Cerințe generale de siguranță - Standard colateral: Utilizabilitate inclusiv IEC 62366: Aplicarea ingineriei de utilizabilitate la dispozitive medicale

Nr. referință raport:	GE DOC1450064 Rev 15
Data emiterii:	10 iunie 2019 / 15 martie 2019 / 22 octombrie 2018 / 09 august 2018 / 27 iulie 2017 / 11 aprilie 2017 / 13 iulie 2016 / 03 decembrie 2015 / 09 iulie 2015 / 29 septembrie 2014 / 08 august 2014 / 30 octombrie 2013 / 20 ianuarie 2020 / 06 aprilie 2020 / 01 decembrie 2020
Număr total de pagini:	10
Laborator de testare CB:	GE Medical Systems, LLC
Adresa:	3000 N. Grandview Blvd, Waukesha, WI 53188 SUA
Denumirea solicitantului:	GE Healthcare
Adresa:	3000 N. Grandview Blvd, Waukesha, WI 53188 SUA
Specificație test:	
Standarde:	IEC 60601-1-6:2010 (Ediția a treia) de folosit împreună cu IEC 60601-1:2005 (Ediția a treia)
Procedură de testare:	Schemă CB
Metodă de testare non-standard:	Nu este cazul
Nr. formular raport de testare:	IEC60601_1_6E
Inițiator formular raport de testare:	TÜV Rheinland North America
FRT master:	Datat 2011-07

CONFORM CU ORIGINALUL

MURESAN FLORIN VASILE
INTERPRET-TRADUCATOR
ENGLEZA/FRANCEZA
BAIA MARE - ROMANIA

Descriere articol testat:	Sistem de tomografie computerizată
Marcă comercială:	*(logo GE)* GE Medical Systems, LLC
Fabricant:	GE Medical Systems, LLC
Referință model/tip:	Revolution CT, Revolution CT ES, Revolution Apex
Rating:	Alimentat de Model PDU certificat 2326492-61:3 ~ 380/480 Vac, 50/60 Hz, Momentan: 150 kVA la 0,85 PF, Continuu: 30 kVA Alimentat de Model PDU certificat 2326492-91:3 ~ 380/480 Vac, 50/60 Hz, Momentan: 200 kVA la 0,85 PF, Continuu: 40 kVA

Procedură de testare și locație de testare:

☐ Laborator de testare CB:
Locația/adresa de testare:

☐ Laborator de testare CB asociat:
Locația/adresa de testare:

Testat de către (nume + semnătură):
Aprobat de către (nume + semnătură):

☒ Procedură de testare: TSF (testare în spațiile fabricantului)

Testat de către (nume + semnătură):	Judy Graney
Aprobat de către (nume + semnătură):	Shawn Ray
Testat de către (nume + semnătură):	R7 - Chelsey Lewis / Shawn Ray; R8 - Chelsey Lewis / Shawn Ray; R9 - Chelsey Lewis / Shawn Ray; R10 - Chelsey Lewis / Shawn Ray; R11 - Chelsey Lewis / Shawn Ray; R12 - Chelsey Lewis / Shawn Ray; R13 - Shawn Ray; R14 - Shawn Ray; R15 - Eric Aasen / Shawn Ray;
Aprobat de către (nume + semnătură):	R7 - Shawn Ray; R8 - Chelsey Lewis; R9 - Chelsey Lewis; R10 - Chelsey Lewis; R11 - Chelsey Lewis; R12 - Chelsey Lewis; R13 - Chelsey Lewis; R14 - Chelsey Lewis; R15 - Chelsey Lewis;
Locația/adresa de testare:	3000 N. Grandview Blvd, Waukesha, WI 53188 SUA

☐ Procedură de testare: WMT

Testat de către (nume + semnătură):

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MUREȘAN FLORIN VASILE

Asistat de către (+ semnătură):

Aprobat de către (+ semnătură):

Locația/adresa de testare:

☐ Procedură de testare: SMT

Testat de către (nume + semnătură):

Aprobat de către (+ semnătură):

Supravegheat de către (+ semnătură):

Locația/adresa de testare:

Lista anexelor (inclusiv numărul total de pagini din fiecare anexă):
Niciuna

Rezumatul testării

Teste efectuate (denumirea testului și clauza testului):	Locație de testare:
Niciunul	3000 N. Grandview Blvd, Waukesha, WI 53188 SUA

Rezumatul conformării cu diferențele naționale

Lista țărilor abordate: niciuna

☒ Produsul îndeplinește cerințele IEC 60601-1-6:2010 (Ediția 3.0)

Copie a plăcii de marcare

Lucrarea de mai jos poate fi numai un proiect. Folosirea de marcaje de certificare pe un produs trebuie să fie autorizată de ONC-urile respective care dețin aceste marcaje.

Vezi Rapoarte testare IEC 60601-1

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MUREȘAN FLORIN VASILE
INTERPRET - TRADUCĂTOR
ENGLEZĂ/FRANCEZĂ
BAIA MARE - ROMÂNIA

IEC 60601-1-6			
Clauză	Cerință + test	Rezultat - observație	Verdict
4.0	Cerințe generale		
4.2	PROCESUL DE INGINERIE DE UTILIZABILITATE se conformează cu IEC 62366 inclusiv definițiile modificate	Vezi DOC1450065 pentru evaluarea IEC 62366:2007	T
	Inspectarea DOSARULUI DE INGINERIE DE UTILIZABILITATE a confirmat că fabricantul		
	- a stabilit un PROCES DE INGINERIE DE UTILIZABILITATE	Proces GE Global Quality Work Instruction GEHC_GQP_10.01.013 Utilizabilitate controale proiect (DOC0804338) *Anexa arată cartografierea la standard*	T
	- a stabilit criterii de acceptare pentru UTILIZABILITATE; și	Proces GE Global Quality Work Instruction GEHC_GQP_10.01.013 Utilizabilitate controale proiect (DOC0804338) *Anexa arată cartografierea la standard* Aplicare Criteriul de acceptare este stabilit în Planurile de validare a utilizabilității (DOC1579665 / DOC1916206) (DOC2187072 / DOC2290722) (DOC2478387)	T
	- a demonstrat că au fost îndeplinite criteriile de acceptabilitate pentru UTILIZABILITATE.	Proces GE Global Quality Work Instruction GEHC_GQP_10.01.013 Utilizabilitate controale proiect (DOC0804338) *Anexa arată cartografierea la standard* Aplicare Rapoarte scenarii clinice sistem / Confirmare sistem (DOC1487954 / DOC1591971) (DOC1975643 / DOC1975640) (DOC2187074 / DOC2291685) (DOC2465171) Rapoarte de testare sumative (DOC1599715 / DOC1602767) (DOC1916281 / DOC2290724) (DOC2483221)	T
5	Înlocuirea cerințelor date în IEC 62366		
	Instrucțiunile de utilizare includ o scurtă descriere a ECHIPAMENTULUI ME, principiilor sale de funcționare fizică și caracteristicilor semnificative fizice și de performanță relevante pentru UTILIZABILITATEA sa	Proces GE Global Quality Work Instruction GEHC_GQP_10.01.013 Utilizabilitate controale proiect (DOC0804338) Aplicare URM	T
	Aceleași informații sunt cuprinse și în descrierea tehnică, dacă aceasta este furnizată cadocument separat de instrucțiunile de utilizare	Proces GE Global Quality Work Instruction GEHC_GQP_10.01.013 Utilizabilitate controale proiect (DOC0804338)	T

		Aplicare TRM	
	Instrucțiunile de utilizare conțin un rezumat al specificației aplicației	Proces GE Global Quality Work Instruction GEHC_GQP_10.01.013 Utilizabilitate controale proiect (DOC0804338) Aplicare URM TRM	T

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PERSOANA FIZICĂ AUT. 5164/2001 MUREȘAN FLOPIN VASILE BAIA MARE - ROMÂNIA

EC DECLARATION OF CONFORMITY

(Following the provisions of the medical devices directive 93/42/EEC, Annex II)

We

Manufacturer

GE Medical Systems SCS
283 rue de la Miniere,
78530 Buc, France

Manufacturing site

GE Medical Systems SCS
283, rue de la Miniere
78530 Buc, France

Declare under our sole responsibility that the device:

AW VolumeShare 7
(version: AW4.7)

Workstation, picture archiving and communication system

Ref.: see addendum

GMDN Code: **40943**

Classification rule (93/42/EEC Annex IX): **10** Class IIa

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: **DOC1700611**, of the product to which this declaration relates
  - EC certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by GMED (Notified Body 0459) / Certificate N° 15218
  - Harmonized standards applied on the product to which this declaration relates:

    EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012

    EN 62304:2006/AC:2008, EN 62366:2008

Buc, 16th of February, 2023

Elizabeth Mathew
Senior Regulatory Affairs Manager

This EC declaration of conformity supersedes the previous declaration dated 6th of January, 2022.

CONFORM CU ORIGINALUL

ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 16th of February, 2023

Product Description	Part Number
AW4.7 SW and Docs Media	5694566-x
AW 4.7 Full SW & Docs Set	5883175-x

End of Document

Traducere din limba engleză

GE Healthcare

DECLARAȚIE DE CONFORMITATE CE

(Urmare a prevederilor directivei dispozitivelor medicale 93/42/CEE, Anexa II)

Subscrisa

Fabricant

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

Locație de fabricație

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

Declarăm pe răspunderea noastră exclusivă că dispozitivul:

AW VolumeShare 7
(versiunea: AW4.7)
Stație de lucru, sistem de arhivare a imaginilor și comunicații

Ref.: Vezi anexa

CONFORM CU ORIGINALUL

Cod GMDN: **40943**

Regulă de clasificare (93/42/CEE Anexa IX): **10** Clasa IIa

la care se referă această declarație, este în conformitate cu cerințele directivei dispozitivelor medicale 93/42/CEE care i se aplică .

Această conformitate se bazează pe următoarele elemente:

- Pentru directiva 93/42/CEE (DDM)
  - Documentație tehnică ref.: **DOC1700611** a produsului la care se referă această declarație.
  - Certificat CE: aprobarea sistemului complet de asigurare a calității (Anexa II a directivei 93/42 CEE) transmisă de GMED (Organ Notificat nr. 0459) / Certificat nr. 15218
  - Standarde armonizate aplicate produsului la care se referă această declarație:
    EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012
    EN 62304:2006/AC:2008, EN 62366:2008

Buc, 16 februarie 2023

(semnat): Elizabeth Mathew
Elizabeth Mathew
Senior Regulatory Affairs Manager

Această declarație de conformitate înlocuiește declarația anterioară datată 6 ianuarie 2022.

MUREȘAN FLORIN VASILE INTERPRET / TRADUCĂTOR ENGLEZĂ FRANCEZĂ

GE Healthcare

ANEXĂ LA DECLARAȚIA DE CONFORMITATE datată 16 februarie 2023

Descriere produs	Număr piesă
Medii AW4.7 SW și documente	5694566-x
Set complet AW4.7 SW și documente	5883175-x

Sfârșitul documentului

TUBE STATEMENT

Date: **August 22, 2024**

To: **Centrul Pentru Achiziții Publice Centralizate în Sănătate**

Tender No.: **LP 21261932**

We, **GE Medical Systems, Société en Commandite Simple**, a company duly existing under the laws of France and having a registered seat at 283 rue de la Minière, 78530 Buc, France, with commercial name of GE HealthCare, established and reputable manufacturer of medical equipment and in its capacity as European MDR Authorized Representative of **GE Medical Systems LLC.**, 3000 North Grandview Blvd, Waukesha, WI 53188, USA, the manufacturer of computed tomography system:

- **Revolution Apex Plus**

in relation to the documents submitted in the tender no. LP 21261932, do hereby declare that the X-ray tube for the computed tomography system Revolution Apex is Quantix X ray Tube. We declare that the expected tube life during the warranty period of the equipment is of at least 300.000 scan seconds or minimum 24 months, whichever occurs first.

On behalf and for GE Medical Systems SCS

Jennifer Thery

GE MEDICAL SYSTEMS
Société en Commandite Simple
283, rue de la Minière
78530 BUC - FRANCE
RCS Versailles B 315 013 359
Tél. +33.(0)1.30.70.40.40

GE Medical Systems SCS
Jennifer Thery - EMEA Contract Specialist
Authorized Signatory

CONFORM CU ORIGINALUL

Date of signature: August 22, 2024

Traducere din limba engleză

GE HealthCare

DECLARAȚIE TUB

Data: **22 august 2024**

Către: **Centrul pentru Achiziții Publice Centralizate în Sănătate**

Nr. licitație: **LP 21261932**

Subscrisa **GE Medical Systems Société en Commandite Simple**, o societate comercială existând legal conform legilor Franței și având sediul social în 283 rue de la Minière, 78530 Buc, Franța, cu denumirea comercială GE HealthCare, fabricant consacrat și reputat de echipamente medicale, în calitate de Reprezentant European Autorizat RDM al **GE Medical Systems LLC**, 3000 N. Grandview Blvd., Waukesha, WI 53188 S.U.A., fabricantul sistemului de tomografie computerizată:

- **Revolution Apex Plus**

în legătură cu documentele depuse în licitația nr. LP 21261932 prin prezenta declarăm că tubul cu raze x pentru sistemul de tomografie computerizată Revolution Apex este Tub cu raze x Quantix. Declarăm că durata de viață estimată a tubului în perioada de garanție a echipamentului este de cel puțin 300.000 de secunde de scanare sau minim 24 de luni, oricare ar fi prima.

Din partea și pentru GE Medical Systems SCS,

(semnat): Jennifer Thery *(ștampila GE MEDICAL SYSTEMS)*
GE Medical Systems SCS
Jennifer Thery – Specialist Contracte EMEA
Semnatar Autorizat

Data semnării: 22 august 2024

CONFORM CU ORIGINALUL

GE Medical Systems Société en Commandite Simple
cu capital de 96 210 630 euro
Sediu social: 283, rue de la Minière
78530 Buc
Franța
RCS Versailles B 315 013 359

MUREȘAN FLORIN VASILE

TECHNICAL STATEMENT

Date: **August 22, 2024**

To: **Centrul Pentru Achiziții Publice Centralizate în Sănătate**

Tender No.: **LP 21261932**

We, **GE Medical Systems, Société en Commandite Simple**, a company duly existing under the laws of France and having a registered seat at 283 rue de la Minière, 78530 Buc, France, with commercial name of GE HealthCare, established and reputable manufacturer of medical equipment and in its capacity as European MDR Authorized Representative of **GE Medical Systems LLC**, 3000 North Grandview Blvd, Waukesha, WI 53188, USA, the manufacturer of computed tomography system:

- **Revolution Apex Plus**

in relation to the documents submitted in the tender no. LP 21261932, do hereby declare that our system mentioned above, will be delivered with the following characteristics and features:

1. Digital Software capabilities which provide reformatted images with the right orientation +/-30 degree.
2. All software will be provided for the reporting procedure with export availability in DICOM, pdf, rtf format to allow the transfer of teleradiology images to electronic medical records, other medical facilities or other persons as needed.
3. HIS/RIS or PACS connections can be made in the future with no addition costs.

On behalf and for GE Medical Systems SCS

Jennifer Thery
_____

GE MEDICAL SYSTEMS
Société en Commandite Simple
283, rue de la Minière
78530 BUC - FRANCE
RCS Versailles B 315 013 359
Tél. +33.(0)1.30.70.40.40

GE Medical Systems SCS
Jennifer Thery - EMEA Contract Specialist
Authorized Signatory

Date of signature: August 22, 2024

CONFORM CU ORIGINALUL

Traducere din limba engleză

GE HealthCare

DECLARAȚIE TEHNICĂ

Data: **22 august 2024**

Către: **Centrul pentru Achiziții Publice Centralizate în Sănătate**

Nr. licitație: **LP 21261932**

Subscrisa **GE Medical Systems Société en Commandite Simple**, o societate comercială existând legal conform legilor Franței și având sediul social în 283 rue de la Minière, 78530 Buc, Franța, cu denumirea comercială GE HealthCare, fabricant consacrat și reputat de echipamente medicale, în calitate de Reprezentant European Autorizat RDM al **GE Medical Systems LLC**, 3000 N. Grandview Blvd., Waukesha, WI 53188 S.U.A., fabricantul sistemului de tomografie computerizată:

- **Revolution Apex Plus**

în legătură cu documentele depuse în licitația nr. LP 21261932 prin prezenta declarăm că sistemul nostru menționat mai sus va fi livrat cu următoarele caracteristici și elemente:

1. Capacități software digitale care oferă imagini reformatate cu orientarea corectă +/- 30 grade.

2. Tot software-ul va fi furnizat pentru procedura de raportare cu disponibilitate de export în format DICOM, pdf, rtf pentru a permite transferul de imagini de teleradiologie către evidențe medicale electronice, alte unități medicale sau alte persoane conform garanției.

3. Conexiunile HIS/RIS sau PACS pot fi realizate în viitor fără costuri suplimentare.

Din partea și pentru GE Medical Systems SCS,

(ștampila GE MEDICAL SYSTEMS)

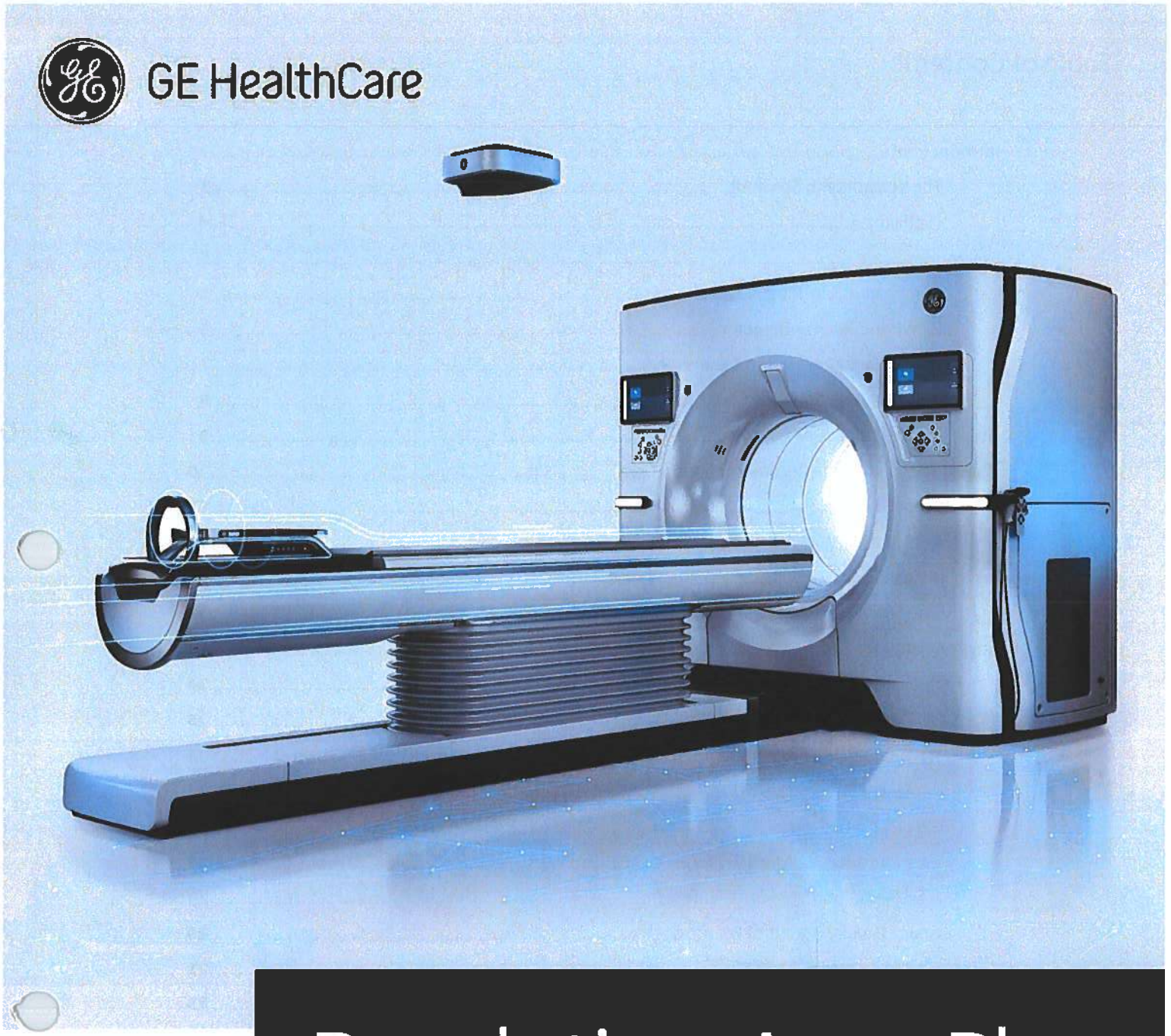
(semnat): Jennifer Thery
GE Medical Systems SCS
Jennifer Thery – Specialist Contracte EMEA
Semnatar Autorizat

Data semnării: 22 august 2024

CONFORM CU ORIGINALUL

PERSOANA FIZICĂ AUT. 3184/2001
MURESAN FLORIN VASILE
INTERPRET-TRADUCĂTOR
ENGLEZĂ-FRANCEZĂ
BAIA MARE - ROMÂNIA

GE HealthCare



Revolution™ Apex Plus

The versatility to see it all

PRODUCT DATA SHEET (GLOBAL)

GEHealthCare.com

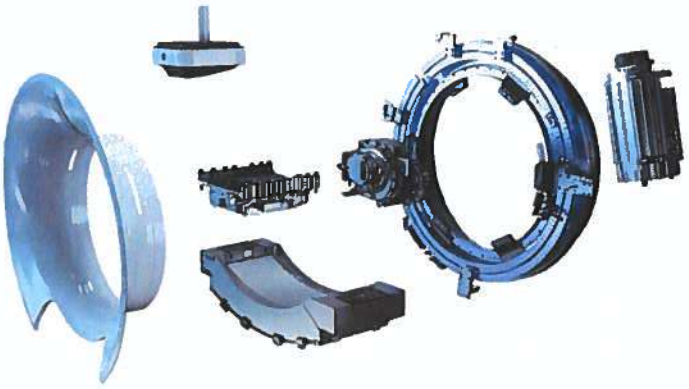
*Latest update: January 2023
Global version | Not for distribution or use in mainland China.
Commercial availability may vary by country due to regulatory limitations.
DOC2696321, Rev4

Table of Contents

Introduction

The Versatility to See it All

The **Revolution Apex Plus** was engineered to deliver breakthrough image quality at the unprecedented speed you need to meet a wide range of clinical cases. It features our 80 mm Gemstone Clarity Detector with a record-breaking 0.28 second rotation speed and powerful 1,300 mA output via the Quantix™ X-ray tube[1]. From acute care to CT-guided intervention to radiation therapy planning, with Revolution Apex Plus you have the versatility required to see it all.



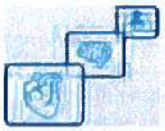
Experience the clinical potential of power combined with speed: Surpass your expectations for CT with the versatility of unprecedented scan speed and no trade off in coverage for ultra-fast, ultra-clear image quality.

Elevate your diagnostic confidence with breakthrough image quality: Experience remarkably clear image texture in both your single energy and GSI applications with TrueFidelity images created using our innovative Deep Learning Image Reconstruction technology.

Explore a wide range of clinical solutions: Diversify your clinical offering with a versatile range of capabilities, including oncology, cardiovascular, MSK and pediatrics as well as acute care.

Work more efficiently with Effortless Workflow: Incorporate the latest AI-enhanced applications into every step of the scanning process to swiftly move from one scan to the next.

Best-in-class technology in every dimension of the CT imaging chain



Unprecedented clinical solutions across a wide range of care areas

Future-ready platform ensures quick access to the next generation of CT innovation

1. The full commercial name of the X-ray Tube is Quantix 160. The commercial name is abbreviated to Quantix throughout this document.

Introduction *(cont.)*

Highlights

Revolution Apex Plus has achieved a breakthrough in image quality to have outstanding image definition, preferred image appearance, and low dose, all at the same time. Key technologies include:

- Maximum 1,300 mA X-ray output
- 80 mm z-coverage in a single axial exposure
- 80 cm bore size with Whisper drive
- TrueFidelity CT images generated by Deep Learning Image Reconstruction (DLIR)
- 0.28 sec rotation and SnapShot Freeze 2[2] delivers up to 24 msec temporal resolution to freeze cardiac motion[3]
- High definition imaging with an exceptional 0.23 mm spatial resolution
- HyperDrive[4] providing 437 mm/s volumetric scanning reconstructed to a maximum 50 cm field-of-view (FOV)
- GSI Xtream[5] for 0.25 ms ultrafast kVp and synchronized mA switching to enable Volume Spectral CT designed to improve small lesion detection, tissue characterization and metal artifact reduction
- Smart MAR,[6] single energy metal artefact reduction, provides metal artefact reduction with seamless integration into scanning protocols

Revolution Apex Plus delivers an uncompromised set of clinical solutions, for your most challenging patients to ensure you achieve your best images for all patients:

Motion free CCTA

High definition, motion free coronary images at any heart rate is enabled by a prospectively ECG-gated cardiac axial acquisition protocol that utilizes 80 mm of high-definition coverage with 0.28s rotation speed and real-time control to ensure robust, low dose and high definition cardiac imaging for all heart rates, with or without beta blockers.

Neurology

Routine non-contrast brain scans are reconstructed using Volume HD reconstruction technology to ensure CT number uniformity across the whole brain. Iterative MMAR can reduce the beam hardening artifacts at bone / brain interface and posterior fossa region. Enhanced Contrast can achieve excellent gray white matter differentiation. Smart Stroke,[7] the stroke-dedicated hardware, software and post-processing solution on Revolution Apex Plus, can help physicians to reduce "CT scan-to-report" time and "door-to-treatment" time, thus to save more brain tissue of a patient with a stroke.

Workflow

Effortless workflow comes with advanced hardware and software capabilities to provide a seamless scanning experience. Powered by high computing power and GE developed artificial intelligence and deep learning technologies, Effortless workflow provides highly automated scan operations that provides ease of use, consistency and streamlined workflow. The solution has been designed to accommodate different clinical indications, varying patient positions and orchestration of several scan parameters in order to achieve the ultimate imaging outcome, for every patient. Effortless workflow enables automatic selection of scan protocol, automatic positioning and centering of your patient, automatic definition of scout and scan ranges, automatic definition of scan parameters tailored to your patients' needs and their clinical indication for the scan, so your focus can be on the well-being of your patient.[8]

Fast Emergency and Trauma Imaging

The Revolution Apex Plus allows for robust Triple RuleOut™ acquisition for all patients providing high resolution, motion free coronaries, PE & aortic dissection in a single exam covering the entire thorax. ECG gating and mA modulation along with flexible collimations enable low dose acquisition personalized to the patient. 80 mm helical mode combined with table speed of up to 437.5 mm/s allows for ultra-fast scanning and the potential to reduce the effect of breathing and other motion during the scan. The Smart Trauma feature can enable recon priority for trauma scan, prospective DMPR settings and faster reconstruction throughput.

High Resolution Scan mode

The clinical needs for better image quality never stops. Visualizing the finest image details significantly enhances diagnostic confidence. Equipped with the 80 mm Gemstone Clarity Detector and the Quantix X-Ray tube, the Revolution Apex Plus achieves best-in-class 0.23 mm spatial resolution across all detector coverage, all fields of view, all applications, even obese patients.

Pediatrics

Split second pediatric acquisition is enabled by wide 80 mm z-axis coverage, can potentially reduce the need for sedation and eliminate unnecessary repetition of scans in young children due to failed sedation. TrueFidelity images and 70 kV scans allow you to minimize the radiation dose while improving image quality and diagnostic confidence.

Contrast Optimized Scanning

X-ray radiation and iodine hazards have become the major concerns associated with CT scan with contrast enhancement. Due to increased use of iodinated contrast media in diagnostic imaging and interventional procedures, Contrast-induced nephropathy has become a significant source of hospital morbidity and mortality. Equipped with the ASiR-V and Low kVp scanning, Revolution Apex Plus addresses these two challenges with one unique solution: achieving lower dose scan with optimized contrast usage.

2. SnapShot Freeze 2 is a purchasable option available on the AW workstation or via the cardiac package on Smart Subscription.
3. SnapShot Freeze 2, in conjunction with 0.28 s/rotation gantry speed, provides a reduction in coronary motion artifacts that is equivalent to a 0.047 s/rotation equivalent gantry rotation speed with effective temporal resolution of 24 msec. As demonstrated in phantom testing using a commercially available motion phantom and also with a mathematical cardiac phantom with linear motion of variable velocity. The 0.047 s/rotation images are modeled without application of SnapShot Freeze 2. Results may vary in clinical applications.
4. HyperDrive is a purchasable option.
5. GSI Xtream is a purchasable option.
6. Smart MAR is a purchasable option.
7. Smart Stroke requires post-processing applications such as Stroke VCAR, AutoBone and VesselIQ Xpress, Dynamic 4D CTA and CT Perfusion 4D Neuro.
8. Automated functions require confirmation by the user prior to exposing X-rays.

System Hardware

Gantry and Slip Ring

The Revolution Apex Plus gantry platform has been designed from the ground up and tested to support fast rotation speeds. It also features a wide 80cm diameter bore to facilitate scanning larger patients and to ensure flexible access and patient positioning in the gantry. The Slip Ring is designed for transferring data at 40 Gbps to ensure safe & reliable performance at these fast rotation speeds.

Gantry and Slip Ring Descriptions	
Whisper Drive System	Reduces audible noise during gantry rotation at 0.28 sec by more than 50%, as compared to a typical belt driven system rotating at 0.28 s/rotation speed, thus improving patient comfort (audible gantry noise is measured at 69 dBA).
Contactless Slip Ring	Transfers power and data to and from the rotating side of the gantry (Slip Ring) to the stationary side through contactless RF technology. This eliminates carbon dust due to brush wear-out thereby increasing the reliability of the system. 
Fail-Safe Mounts	The gantry frame features redundant fail-safe mounts for all major components that are designed and tested to stringent standards to ensure safe and reliable operation at sub second rotation speeds.
Laser Alignment Lights	Defines both internal and external scan planes to ±1 mm accuracy. Activated any time during the exam (with tube stationary).

Gantry and Slip Ring Specifications	
Aperture	80 cm
Focus-to-Detector Distance	109.7 cm
Focus-to-Isocenter Distance	62.6 cm
Scan FOV	50 cm 80 cm with MaxFOV 2[9]
Rotation Speed	0.28 sec, 0.35 sec, 0.5 sec, 0.6 sec, 0.7 sec, 0.8 sec, 0.9 sec, 1.0 sec per 360° acquisition
Data Chain Bandwidth	40 Gbps
Xtream Tablet	Xtream Tablet is a 15.6 inch multi-purpose user interface located on each side of the front gantry with touch screen operation and forms part of Effortless Workflow.
Table and Gantry Control Panels	The table and gantry controls are located below the Xtream Tablet on both the left and right of the front and back of the gantry.  The gantry also includes a built-in patient breathing light and countdown timer.
Flexible Cable Management System	Coordinated straps attached to the gantry sides are present to keep cables connected to the gantry and away from the floor to reduce clutter.

9. MaxFov 2 is a purchasable option. The image quality for the area outside the standard 50 cm scan field does not meet the image quality specifications shown in the technical data sheet and image artifacts may appear, depending on the anatomy scanned.

System Hardware *(cont.)*

Gemstone Clarity Detector

The Revolution Apex Plus system features the Gemstone Clarity Detector inclusive of the Gemstone scintillator that boasts the industry's leading primary speed and afterglow specifications.

The Gemstone Clarity Detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts usually associated with wide coverage systems. Combined with Volume HD (VHD) reconstruction technology, the system delivers excellent image quality at full 80 mm coverage. Further, the 3D Collimator can reduce the scatter to primary ratio.

The Gemstone Clarity Detector also features a revolutionary ultra-low capacitance photo diode with new ASIC technology that redefines electronic noise at the quantum limit to less than 3 photons @ 120 keV (3100 electrons). The detector includes acquisition electronics which allows 4x faster bandwidth and 3x faster trigger rate than previous generations and reduces electronic noise by 25%, which may improve image quality and reduce artifacts in low signal conditions, as may be encountered in large patients.

Gemstone Clarity Detector Descriptions	
Gemstone Scintillator	The Gemstone Clarity Detector enables high definition CT imaging with a revolutionary, extremely fast scintillator. The scintillator material is an isotropic ceramic with cubic structure which is highly uniform and translucent. Cubic structures offer better transparency than that of Gadolinium Oxysulfide (GOS) which has a hexagonal lattice. The relative speed of the scintillator enables high definition technologies such as high resolution imaging capability, with less noise, and the ability to perform fast kV switching to enable applications such as dual energy acquisitions. • Scintillator speed: 0.03 µs (100 times faster than GOS) • Afterglow: 0.001% (4 times lower than GOS) • Radiation damage: 0.03% (20 times less than GOS) • Scatter to Primary Ratio: <10% • Detection efficiency: 98% @ 120 kV
Gemstone Clarity Data Acquisition Subsystem (DAS)	The Gemstone Clarity Data Acquisition Subsystem (DAS) features 3 times faster trigger rates capable of supporting features such as high definition imaging up to 2,496 views per rotation. 

Gemstone Clarity Detector Specifications	
3D Collimator Scatter Reduction Technology	Reduces scatter to primary ratio by more than 50% and results in a significant improvement in image quality and reduction in beam hardening and metal artifacts.
Z-coverage/360° Rotation	80 mm[10]
Number of Slices	256 slices
Number of Detector Rows	128 rows
Number of Detector Elements	106,496 cells with individual electronic/ DAS channels for excellent data fidelity
Sampling Rate	Up to 2,496 views per rotation (up to 8,914 Hz)
Electronic Noise	Less than 3 photons noise (3100 electrons)
Effective Analog to Digital Conversion Range	>2,000,000:1

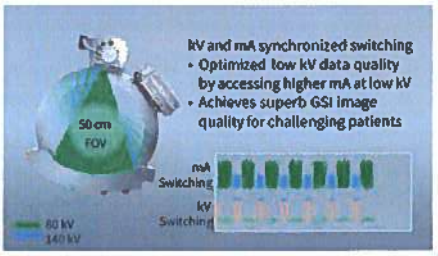
10. Upgrade to 160 mm detector coverage is a purchasable option.

System Hardware *(cont.)*

Power Management and Generator

Power Management Descriptions	
Power Distribution Unit	The Power Distribution Unit (PDU) supplies power to various parts of the system including gantry components, table and operator console. On the front of the PDU are controls to indicate that power is on, a push button to turn power on/off to the gantry and table, and an Emergency Stop button.
System Emergency Off Button	When pressed, the power to all system components is removed, stopping all table and gantry motion and generation of X-rays. Use the System Emergency Off button for catastrophic emergencies, such as fire or earthquake.
Main Disconnect	A dedicated main distribution panel, also known as A1 Mains or MDP (Mains Disconnect Panel), shall be used to supply power to the scanner. The MDP (A1) mains shall be located in the same room as the PDU.
Partial UPS with SmartPower	Eaton Powerware 9355-15-14GE with SmartPower allows Eaton's 14.4 kVA 3-Phase partial system Uninterruptible Power Supply (Partial UPS) to provide clean, reliable and constant power to the Revolution Apex Plus system. In the event of power outages, SmartPower can allow the partial UPS to provide the backup power to maintain CT system components including scan and image data base; to allow critical non-X-ray scanner operations and provide time for the operator to safely remove the patient and execute an orderly system shutdown before the UPS runs out of battery. If the primary power is restored within the UPS battery hold-up time and the system shutdown is not executed, SmartPower can restore the system automatically to the operational state. The feature also enables the UPS dashboard user interface to provide the real-time battery status update.

Generator Specifications	
Generator Maximum Peak Power	108 kW with PowerXtream option constrains the maximum power level for systems with Quantix X-ray Tube and 2326492-91 PDU. 101 kW with PowerPro option constrains the maximum power level for systems with Quantix X-ray Tube and 2326492-61 PDU.
Main Power Nominal Voltage	380 – 480 V
Nominal Line Frequency	50/60 Hz ± 3 Hz
Maximum Power Demand: PowerXtream Option	Requires 200 kVA electrical power supplied for PowerXtream, in addition to a Partial UPS that is included as standard.
Maximum Power Demand: PowerPro Option	Requires 150 kVA electrical power supplied for PowerPro, in addition to a Partial UPS that is included as standard.
Ultra-fast kV and mA Synchronized Switching Generator	The X-ray generator features independent control of kV and mA to achieve ultra-fast kV and mA synchronized switching for GSI acquisition.[11] This feature can alternate between 80 kVp and 140 kVp within 0.25 msec, and simultaneously match the optimal mA with each kV. The breakthrough can optimize low kV data quality by having access to higher mA at low kV, and achieve superb GSI image quality especially in low keVs and material images for all patient exams and presentations.

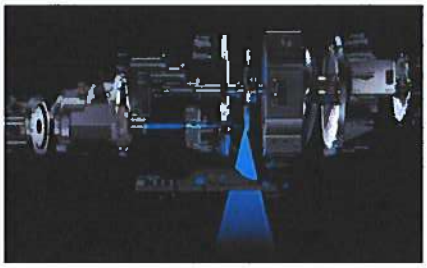


11. GSI Xtream is a purchasable option.

System Hardware *(cont.)*

Quantix X-ray Tube[12]

GE Healthcare's Quantix X-ray tube is the most advanced and powerful X-ray tube we've ever made. It provides the world's first combination of 1,300 mA output and 80 mm z-coverage in a single axial exposure, a momentous achievement for X-ray tube. The Quantix X-ray tube has three key technology breakthroughs; the Digital Cathode, the Wide-view Anode and a liquid bearing.

Quantix Tube Descriptions	
Digital Cathode	The Digital Cathode is the most powerful and intelligent cathode we've ever designed. Its patented dual flat emitter has 400% larger emission area than conventional coiled filament, can generate a bigger electron cloud to output maximum 1,300 mA. The Digital Cathode also utilizes a digitally controlled magnetic field to focus and shape the electron beam in microseconds. As a result, the position, shape and size of the focal spot can be controlled with the highest precision. It enables view-by-view mA modulation and high definition scanning with focal spot deflection.
Wide-view Anode	The wide-view anode has a 10°-angle target to expose the high-quality X-ray with 80 mm z-coverage in a single axial exposure.
Liquid Bearing	The Liquid Bearing utilizes liquid gallium to form a liquid-metal bearing to support the rotating anode. It allows the quiet and reliable performance of the Quantix X-ray tube. The Liquid Bearing can support ultra-high gravity forces greater than 75 G. 

Quantix Tube Specifications	
Tube Voltage	70, 80, 100, 120, 140 kV
Tube Current Range PowerXtream Option	70 kV: 10 – 1,300 mA 80 kV: 10 – 1,300 mA 100 kV: 10 – 1,080 mA 120 kV: 10 – 900 mA 140 kV: 10 – 750 mA
Tube Current Range PowerPro Option	70 kV: 10 – 1,200 mA 80 kV: 10 – 1,080 mA 100 kV: 10 – 940 mA 120 kV: 10 – 820 mA 140 kV: 10 – 720 mA
Digital Cathode Emitter Technology	Dual flat emitter with 4x larger emission area (compared to conventional coil emitter)
Digital Cathode Focal Spot Control	Magnetic focusing and deflection with precise digital control
Digital Cathode Independent kV and mA Control	Achieve kV and mA synchronized switching to match the optimal mA to each kV in GSI acquisition
Wide-view Anode Target Angle IEC 60601-2-28	10° with respect to reference axis
Target Material IEC 60601-2-28	Tungsten-Rhenium alloy
Z-coverage in a Single Axial Exposure	Up to 80 mm in iso-center
Liquid Bearing Technology	Liquid metal (gallium) bearing
Target Effective Heat Storage	33 MHU
Target Maximum Cooling Rate	3100 KHU/min
Focal Spot Size IEC 602336	S: 1.0 x 0.7 L: 1.6 x 1.2 XL: 1.8 x 1.5

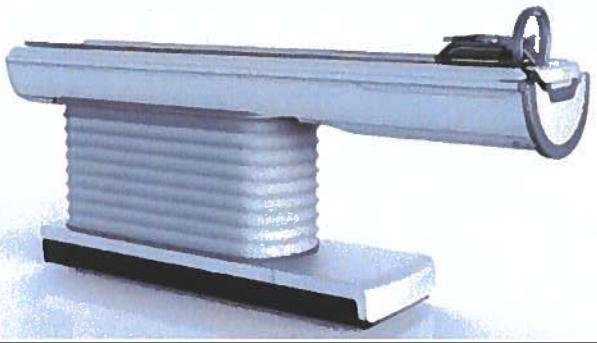
12. Revolution Apex Plus is designed to only work with the Quantix X-ray tube. The full commercial name of the X-ray Tube is Quantix 160. The commercial name is abbreviated to Quantix throughout this document.

System Hardware *(cont.)*

Table (Patient Positioner)

The table provides support and vertical/longitudinal motion of the patient relative to the CT scanner. The Table also mechanically houses and electrically interfaces to the integrated ECG unit. This subcomponent includes patient positioning and support accessories (pads, straps, poles, head holders) as well as foot pedals.

Table Descriptions	
Patient Table Design	Revolution Apex Plus features a next generation patient table design with the following highlights: • 10x stiffer design with minimal deflection under heavy load with RTP Flat Table top overlay setup to comply with the recommendations in the report of AAPM Radiation Therapy Committee Task Group No. 66 • Maximum 437 mm/s[13] horizontal travel speed to enable fast volumetric scanning with 50 cm scan FOV • X-strong foot switch cover, capable of supporting 1,350 lbs (612 kg) load, has been specially designed to support physicians standing on it while performing diagnostic and/or treatment procedures on patients • Optional integrated ECG module with waveform and configuration through the gantry display • The patient grounding strap with Connection into the optional Integrated Cardiac Module improves ECG waveform signal quality for ECG gated scans • Workflow hub area with a see through tray to give you the most flexibility in placing scanning related supplies, etc. without limiting visibility to the integrated ECG inputs • IV Pole integrated at the foot-end of the table helps to prevent IV lines from becoming crossed and tangled and helps keep lines in place during patient table travel • Optional Table Paper Dispenser for CT Tables is designed to conveniently hold and dispense a roll of hygienic table paper for CT patient positioning tables. The Dispenser can hold up to a 21 inch (534 mm) length roll. Note: paper roll is not included



	NG2000V Standard Table	NG2000V Heavy Table[14]	NG1700V Heavy Table[15]
Table Load Capacity	227 kg/500 lbs	306 kg/675 lbs	306 kg/675 lbs
Positional Precision	± 0.25 mm over entire scannable range	± 0.25 mm over entire scannable range	± 0.25 mm over entire scannable range
Horizontal Scannable Range (Metal Free)	Up to 2,000 mm	Up to 2,000 mm	Up to 1,700 mm
Horizontal Travel Speed	Up to 300 mm/s Up to 437 mm/s with HyperDrive	Up to 300 mm/s Up to 437 mm/s with HyperDrive	Up to 300 mm/s Up to 437 mm/s with HyperDrive
Vertical Range	500 – 1,030 mm	560 – 1,030 mm	560 – 1,030 mm
Vertical Scannable Range	757 – 1,002 mm (at table top)	757 – 1,002 mm (at table top)	757 – 1,002 mm (at table top)
Vertical Travel Speed	15 mm/s (±3 mm/s) 40 mm/s (±8 mm/s)	15 mm/s (±3 mm/s) 40 mm/s (±8 mm/s)	15 mm/s (±3 mm/s) 40 mm/s (±8 mm/s)

13. 437 mm/s table speed is enabled by HyperDrive option.
14. NG2000V heavy table is a purchasable option.
15. NG1700V heavy table is a purchasable option.

Scan Modes and Image Reconstruction

Scout Scan

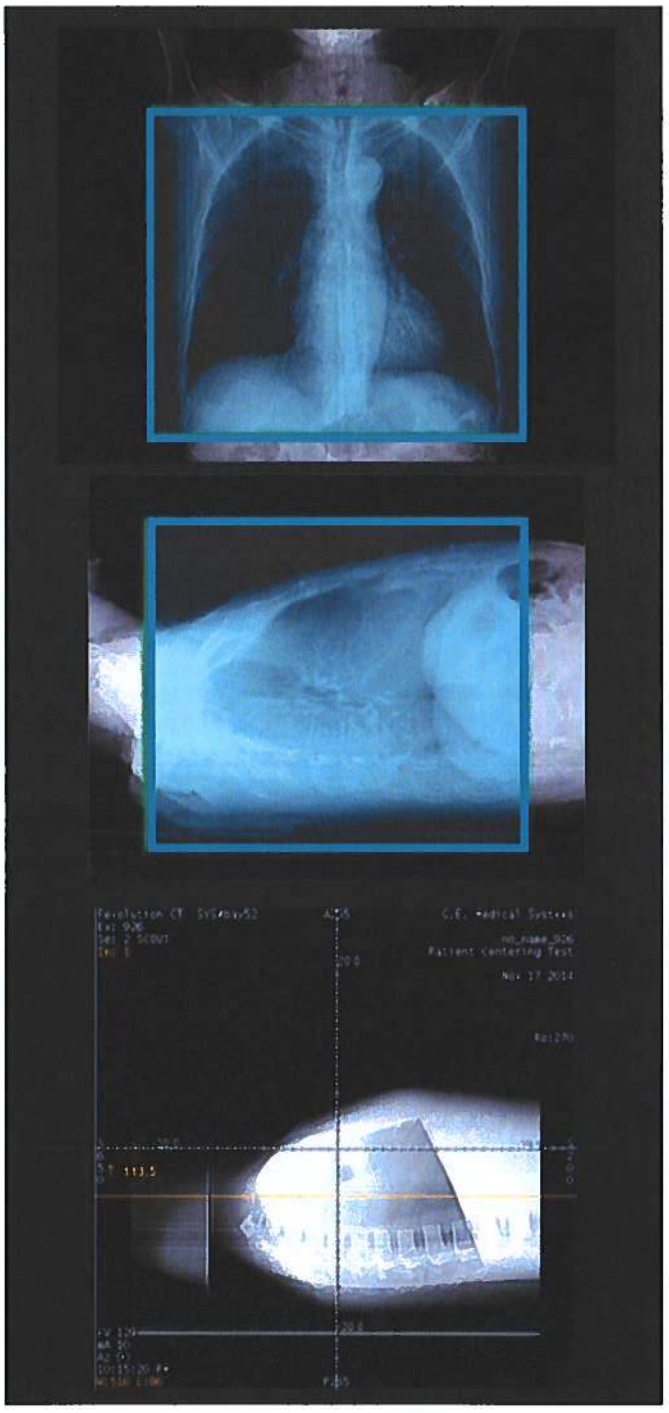
Scout imaging is used for anatomical location in conjunction with scan and recon prescription, to provide an anatomical cross-reference for axial images, and to provide quick feedback to the user as the anatomy is scanned.

Revolution Apex Plus offers two user selectable scout scan modes: SmartScout mode and regular scout mode.

When SmartScout mode is selected, the system can auto-select the scout scanning parameters to achieve optimal scout image quality and radiation dose. SmartScout also allows for performance of tube warmups during scout acquisition with improved workflow and eliminate user intervention and wait times for tube warmup.

Scout Scan Parameters	
kVp	• 70, 80, 100, 120, 140 kVp • Manual selection in regular scout mode • Auto selection in SmartScout mode
mA	• 10 to 250 mA, 5 mA increments • Manual selection in regular scout mode • Auto selection in SmartScout mode
Detector Coverage	5 mm
Table Speed	• Up to 200 mm/s • Manual selection in regular scout mode • Auto selection in SmartScout mode
Orientation	0, 90, 180, 270 (preset)
Scout Range	• 50 to 2,000 mm with NG2000V tables • 50 to 1,700 mm with NG1700V table • Scouts longer than 1,000 mm are auto minified to fit the display

Scout Scan Image Reconstruction	
Max. Display FOV	50 cm
Scout Scan Based Smart Patient Centering	The smart patient centering feature helps to detect suboptimal centering prior to the diagnostic scan. When scout is acquired, the system will assess patient centering. If the patient is off centered greater than 2 cm, the system will display the table height location and an up or down arrow to indicate the elevation needed to reach that height.



Scan Modes and Image Reconstruction *(cont.)*

Axial Scan

Axial scanning is the traditional "step and shoot" method of acquiring data. The X-ray tube and Data Acquisition System (DAS) expose and rotate one 360° loop. The table and patient move a preset distance (interval) and the process is repeated.

Axial Scan Parameters	
kVp	70, 80, 100, 120, 140 kVp
mA	10 to 1,300 mA
Rotation Speed	0.28 sec, 0.35 sec, 0.5 sec, 0.6 sec, 0.7 sec, 0.8 sec, 0.9 sec, 1.0 sec per 360° acquisition
Focal Spot Selection @ 120 kVp	• Focal Spot S (Small): Up to 455 mA • Focal Spot L (Large): Up to 730 mA • Focal Spot XL (Extra Large): Up to 900 mA
Detector Coverage	5, 20, 40, 80 mm
Inter Scan Delay (ISD)	• 1.0 sec with no table move • 1.5 sec with 40 mm table move • 1.7 sec with 80 mm table move
Inter Group Delay (IGD)	Minimum IGD is the same as minimum ISD; also user-selectable
High Resolution Scan Mode	High Resolution scan mode provides the capability to acquire 2.5 more views using deflection of the X-ray beam in both non-cardiac and cardiac axial acquisitions. The additional views can be used to improve image quality to reduce aliasing, improve off-center imaging, or improve resolution.
Maximum Scan Field View	• 32 cm for pediatric head and body, adult head and small body, small cardiac • 36 cm for medium cardiac • 50 cm for medium and large body, large cardiac

Axial Scan Image Display and Reconstruction	
Number of Reconstructed Slices	Up to 256 slices per rotation
Reconstruction Matrix	512 x 512 1024 x 1024[16]
Display Matrix	1024 x 1024
CT Number Scale	-1,024 to 3,072 (normal range) and -31,743 to 31,743 (extended range)
Recon Types	Soft, Soft # (Small Head, Head, Ped Head only), Standard, Standard # (Small Head, Head, Ped Head only), Detail, Lung, Bone, Bone Plus, Edge, Chest, Ultra, HD Standard, HD Lung, HD Detail, HD Bone, HD Bone Plus, HD Edge, HD Ultra
Image Enhance Filter to Enhance Anatomical Structure	E1, E2, E21, E22, E23, E3 or S1, S11, S2, S21, S3 and LU • Edge Enhancement filters (E) sharpen the image and are useful for bone windows. • The smoothing filters (S) decrease the appearance of noisy images or enhance low-contrast areas on soft tissue. • The Lung Enhancement filter (LU) is designed specifically to use for lung windows. • E21, E22, E23, S11, S21 are only available as image display filters
Fine Z for Neuro Scanning	Recon option designed for high resolution imaging tasks such as assessing detail in the inner ear. Only available for Axial Hi-Res Head SFOV with slice thickness of 0.625z.
Enhanced Contrast for Neuro Scanning	Enhanced Contrast is a special reconstruction option to boost the differentiation between the gray and white matter regions in the brain. Enhanced Contrast is allowed with Axial scan types, Head, Small Head and Ped Head protocols, 100, 120 and 140 kV, Hi Res Off, Number of Passes: 1, and Soft, Soft #, Stnd or Stnd # recon types.
Reconstructed Slice Widths (mm)	0.625, 0.625z, 1.25, 1.25z, 1.25i, 2.5, 2.5z, 5.0 and 5.0z
Prospective Multiple Reconstruction (PMR)	Up to 99 sets of recons can be pre-programmed.

16. 1024 matrix is compatible with 40 mm coverage and ASiR-V.

Scan Modes and Image Reconstruction *(cont.)*

Helical Scan

Helical or spiral scanning is a method of acquiring images in a continuous data set. The X-ray tube and DAS expose and rotate continuously through 360° while the patient is passed through the area of exposure at a set rate of movement, depending on the rotation time and helical pitch. The information gathered is then reconstructed into images of the prescribed slice thickness and interval.

Helical Scan Parameters	
kVp	70, 80, 100, 120, 140 kVp
mA	10 to 1,300 mA
Rotation Speed	0.28 sec, 0.35 sec, 0.5 sec, 0.6 sec, 0.7 sec, 0.8 sec, 0.9 sec, 1.0 sec per 360° acquisition
Pitch Range	0.508:1, 0.516:1, 0.984:1, 0.992:1, 1.375:1, 1.531:1
Focal Spot Selection @ 120 kVp	• Focal Spot S (Small): Up to 455 mA • Focal Spot L (Large): Up to 730 mA • Focal Spot XL (Extra Large): Up to 900 mA
Detector Coverage	20 mm, 40 mm, 80 mm
Max. Single Acquisition Time	60 seconds
Inter Group Delay (IGD)	1 second between adjacent helical scans
High Resolution Scan Mode	High Resolution scan mode provides the capability to acquire 2.5 more views using deflection of the X-ray beam in helical acquisitions. The additional views can be used to improve image quality to reduce aliasing, improve off-center imaging, or improve resolution.
Maximum Scan Field View	• 32 cm for pediatric head and body, adult head and small body • 50 cm for medium and large body

Helical Scan Image Display and Reconstruction	
Reconstruction Matrix	512 x 512 1024 x 1024[17]
Display Matrix	1024 x 1024
CT Number Scale	-1,024 to 3,072 (normal range) and -31,743 to 31,743 (extended range)
Recon Types	Soft, Soft # (Small Head, Head, Ped Head only), Standard, Standard # (Small Head, Head, Ped Head only), Detail, Lung, Bone, Bone Plus, Edge, Chest, Ultra, HD Standard, HD Lung, HD Detail, HD Bone, HD Bone Plus, HD Edge, HD Ultra
Image Enhance Filter to Enhance Anatomical Structure	E1, E2, E21, E22, E23, E3 or S1, S11, S2,S21, S3 and LU • Edge Enhancement filters (E) sharpen the image and are useful for bone windows. • The smoothing filters (S) decrease the appearance of noisy images or enhance low-contrast areas on soft tissue. • The Lung Enhancement filter (LU) is designed specifically to use for lung windows. • E21, E22, E23, S11, S21 are only available as image display filters
Enhanced Contrast for Neuro Scanning	Enhanced Contrast is a special reconstruction option to boost the differentiation between the gray and white matter regions in the brain. Enhanced Contrast is allowed with Axial scan types, Head, Small Head and Ped Head protocols, 100, 120 and 140 kV, Hi Res Off, Number of Passes: 1, and Soft, Soft #, Stnd or Stnd # recon types.
Reconstructed Slice Widths (mm)	0.625, 1.25, 2.5, 3.75, 5.0
Prospective Multiple Reconstruction (PMR)	Up to 99 sets of recons can be pre-programmed

17. 1024 matrix is compatible with 40 mm coverage and ASiR-V.

Scan Modes and Image Reconstruction *(cont.)*

Cine Scan

Cine is a method of scanning that rotates the gantry 360° continuously with no delay in between passes. Cine mode is acquired in a continuous exposure that supports table movement equal to the beam collimation or no table movement, where the scan is taken at one table position. You may set the acquisition in groups expanding the time to be scanned. The duration at each location can be up to 60 seconds. This is especially beneficial when determining the function of anatomy and physiology (example: hemangioma).

Cine Scan Parameters	
kVp	70, 80, 100, 120, 140 kVp
mA	10 to 1,300 mA
Rotation Speed	0.28 sec, 0.35 sec, 0.5 sec, 1.0 sec per 360° acquisition
Focal Spot Selection @ 120 kVp	• Focal Spot S (Small): Up to 455 mA • Focal Spot L (Large): Up to 730 mA • Focal Spot XL (Extra Large): Up to 900 mA
Detector Coverage with table movement	40 mm
Detector Coverage without table movement	40, 80 mm
Max. Scan Time	60 seconds
Maximum Scan Field View	• 32 cm for pediatric head and body, adult head and small body, small cardiac • 36 cm for medium cardiac • 50 cm for medium and large body, large cardiac

Cine Scan Image Display and Reconstruction	
Number of Reconstructed Slices	Up to 256 slices per rotation
Reconstruction Matrix	512 x 512 1024 x 1024[18]
Display Matrix	1024 x 1024
CT Number Scale	-1,024 to 3,072 (normal range) and -31,743 to 31,743 (extended range)
Recon Types	Soft, Standard, Detail, Lung, Bone, Bone Plus, Edge, Chest, Ultra
Image Enhance Filter to Enhance Anatomical Structure	E1, E2, E21, E22, E23, E3 or S1, S11, S2, S21, S3 and LU • Edge Enhancement filters (E) sharpen the image and are useful for bone windows • The smoothing filters (S) decrease the appearance of noisy images or enhance low-contrast areas on soft tissue • The Lung Enhancement filter (LU) is designed specifically to use for lung windows • E21, E22, E23, S11, S21 are only available as image display filters
Reconstructed Slice Widths (mm)	0.625, 1.25, 2.5, 5.0
Prospective Multiple Reconstruction (PMR)	Up to 99 sets of recons can be pre-programmed.

18. 1024 matrix is compatible with 40 mm coverage and ASiR-V.

Image Quality

Specifications

The Revolution Apex Plus detector provides best in class high contrast spatial resolution of 0.23 mm.

The optimized X-ray source (focal spot shape and dynamics, as well as reduced off focal radiation) allows for improved measurement methods to fully characterize the limiting resolution of the Revolution Apex Plus system design.

Spatial Resolution		
MTF	**X-Y lp/cm**	**Z lp/cm**
50%	13	7.3
10%	18	12.2
0%	21.4	21.2
	Typical MTF is demonstrated on a 0.05 mm tungsten wire in GE QA Phantom.	Typical MTF is demonstrated on a 1.0 mm x 0.025 mm gold foil phantom.

Image Noise	
Phantom	20 cm water phantom
Noise	0.475% ± 0.05%
CTDIvol	7.8 mGy
Technique	• Scan type: helical • Slice thickness: 5 mm • Recon type: Standard with ASiR-V

Low Contrast Detectability	
Phantom	Catphan 20 cm
Object Size	5 mm
Contrast Difference	3 HU
CTDIvol	5.0 mGy
Technique	• Scan type: axial • Slice thickness: 10 mm • Recon type: Std with TrueFidelity / S3
Phantom	Catphan 20 cm
Object Size	3 mm
Contrast Difference	3 HU
CTDIvol	13 mGy
Technique	• Scan type: axial • Slice thickness: 10 mm • Recon type: Std with TrueFidelity / S3

HU Accuracy	
HU Accuracy	Improves quantitative uniformity of iodinated contrast down to within 10 HU (3% variation) across the whole 80 mm z-coverage.

Effortless Workflow

Revolutionizing CT From Referral to Report

Effortless Workflow comes with advanced hardware and software capabilities providing seamless scanning experience. Powered by high computing power and GE developed artificial intelligence and deep learning technologies, Effortless Workflow provides highly automated scan operations that provides ease of use, consistency and streamlined workflow.

Effortless Workflow is designed with a vision to relieve you from the most burdensome CT scanning tasks and provides the user a view of the patient that may not typically access. Effortless Workflow introduces new features and improves existing functionality compared to previous generation GE scanners, in order to make your CT easier to operate, and far more capable over time.

Effortless Workflow features require active CT operator and do not make the CT scan autonomous. The solution has been designed in order to accommodate different clinical indications, varying patient positions and orchestration of several scan parameters in order to achieve the ultimate imaging outcome, for every patient. Effortless Workflow enables automatic selection of scan protocol, automatic positioning and centering of your patient, automatic definition of scout and scan ranges, automatic definition of scan parameters tailored to your patients' needs and their clinical indication for the scan so all you need to focus on is the well-being of your patient.

Effortless Workflow Descriptions	
Clarity Operator Environment	The new Clarity Operator Environment user interface allows simultaneous scanning, image reconstruction, display, processing and analysis, as well as networking and archive. The benefits of the new interface include: • Manage patient flow better with the ability to prepare scan prescription for the next patient while the current patient is getting off the table • Quickly select scan protocols through global search, anatomical selection or user specific favorites in the newly designed protocol management system • Facilitates protocol consistency by controlling access to changes and simplifying inputs required • "Plan ahead" task list as part of scan setup automates repetitive tasks such as reconstructions, image transfer, image processing, etc. • Seamless multi-tasking through multiple open patient sessions, with one active patient for acquisition and the rest for post-acquisition tasks • Supports real-time adaptive capabilities, enabling dramatically improved SmartPrep timing, including Dynamic Transition to acquisition within as little as 1 second of reaching the HU threshold • Better dose awareness through clearly visible real-time projected dose indicator for the selected protocol • Ability to prospectively prescribe multi planar reconstructions as part of the protocol, thus automating the workflow • Integration with AW allows prescribing automatic image processing steps to be performed on the AW/AW Server post acquisition

Effortless Workflow Descriptions	
Xtream Camera[19]	AI based automatic patient positioning is an innovative, next generation technology. It is powered by Xtream camera that enables automatic landmark detection, orientation detection and auto patient centering. The Xtream camera captures patient information, then uses a dedicated AI algorithm to detect the anatomical landmark automatically based on protocol input. It also provides automatic patient centering by determining the patient center within the scan range and aligning this patient center with CT isocenter automatically. There is no patient image storage associated with the Xtream Camera. 
Xtream Tablet	Xtream Tablet is a multi-purpose user interface located on each side of the gantry and includes the following features: • Wide monitor: 15.6 inch • Touch screen operation • Patient protocol display and selection • Patient information display • Related Protocols • Assisted Patient Positioning • ECG waveform display from the integrated ECG module • Collision indication • Unknown patient entry
Bar Code Reader on Gantry[20]	The Bar Code Reader can be fully integrated into the gantry and allows operators to scan patient information or the Accession number to realize a simple and faster workflow.

19. The Xtream camera with AI based auto-positioning is a purchasable option.
20. The Bar Code reader on the gantry is a purchasable option.

Effortless Workflow *(cont.)*

Revolutionizing CT From Referral to Report *(cont.)*

Effortless Workflow Descriptions	
Remote Control Suite with 3-Video Monitoring System[21]	Remote Control Suite is designed to remotely position patients, moving the table, load/unload and start exams directly from the scan control room. This allows the technologist to remain isolated from the patient while still having the ability to remote start and end the exam from the console room. Not entering the gantry room, may help minimize potential contamination risks between the gantry and console rooms. Remote Control Panel includes two main parts: Remote Control Panel directly on the User Interface and the AVIMOS – Assisted Video Monitoring System, a 3-Video Monitoring System with three high resolution cameras, CCTV monitor and computer, is to assist the technologists for observing the patient from the console room.
Auto Positioning[22]	Auto Positioning activates automatic table elevation motion to the centering height, and cradle motion to the scout start position, with one single click. Moreover, it safeguards the positioning motion by checking for a possible collision of the patient body, arm board or health lines with the CT gantry. Auto Positioning with AI technology realizes the auto scout scan range, anatomical reference detecting and centering by specifying the position and shape in three dimensions keeping consistency across users. This unique technology provides better patient throughput, ease of use, consistent image quality, standardization, and less error. Auto centering optimizes the radiation dose and image quality, and it helps in minimizing positioning errors compared to manual positioning Avoid a wrong scout scan by matching the direction of the patient orientation captured with the Xtream camera and the selected protocol information.
Intelligent Protocolling[23]	Intelligent Protocoling is an application leveraging machine algorithms to help guide users to effortlessly assign the most commonly used protocol for an exam order using a standard protocol library and patient clinical information. This helps to reduce time on protocoling, and ensure the right exam is delivered for the patient in an efficient manner.

Effortless Workflow Descriptions	
Related Protocols	Matches order information transferred from the RIS (Radiology Information System) with an existing user protocol and shows only associated protocols. These protocols are shown on the gantry side Xtream Tablet and contribute to the optimization of scanning preparations.
SmartPlan	SmartPlan is a workflow enhancer that will recommend the scan range from the patient scout based on the clinical indication of the scan protocol, for a faster and more standardized workflow. SmartPlan is designed to identify specific anatomical landmarks within a scout image for the following anatomical regions: head, chest, abdomen, pelvis, as well as multi-group acquisitions such as chest/abdomen, abdomen/pelvis and chest/abdomen/pelvis. The SmartPlan feature is enabled through protocol management. When enabled within a group, SmartPlan uses the prescribed Clinical Identifier (CID) to determine specific anatomic landmarks. SmartPlan will recommend the Start and End locations and identify the appropriate DFOV, AP Centering and RL Centering for each group.
Auto Prescription	Auto Prescription is a profile driven feature that selects scan parameters defined for a specific patient by patient size and works with Smart mA to optimize dose and image quality. The benefits of Auto Prescription include providing a consistent desired image quality across a wide range of patient sizes, eliminating multiple size-based protocols and reducing the amount of patient size dependent scan parameter adjustments at scan time. The user must confirm the scan parameters prior to initiating X-rays.
Prospective Multiple Reconstruction (PMR)	Up to 99 sets of recons can be preprogrammed per examination.
Smart DMPR	Smart DMPR can automatically generate reformatted views with prospectively set window width and window level and display them in 512 or 1024 image matrix size. These image datasets can automatically transfer to the designated PACS destination for fast review and diagnosis.

21. Remote Control Suite with 3-Video Monitoring System is a purchasable option.
22. The Xtream camera with AI based auto-positioning is a purchasable option.
23. The Intelligent protocoling application software is optional via the Workflow package on Smart Subscription. It is run on the Edison Healthlink server used with the Revolution Apex Plus. The application is not part of the CT system. Please refer to the Smart Subscription Product Data Sheet for further informatic

User Console and Interface

System Computer

The Revolution Apex Plus is capable of fast and efficient personalized patient set-up, simplified and automated scan prescriptions, easy-to-use reference protocols, all with simultaneous scanning, image reconstruction, display, processing and analysis, networking and archive.

System Computer Specifications	
Scan Desktop Computer	Intel Xeon Performance Processor: • 3.00 GHz/8-Core CPU (or equivalent) • Nvidia High Performance GPU (or equivalent) • 64 GB DDR4 Registered ECC 2133 MHz (or equivalent) • 64-bit architecture operation system
Monitors	24" dual monitors • Screen resolution: 1,920 x 1,200 • Optional DIN console monitors to comply with DIN 6868-157 standard
Image Data Storage	Up to 2,000,000 Uncompressed DICOM® images (512 x 512)
Additional Storage	USB 3.0 Port for External Hard Disk Drive Connectivity (scan data storage and image data storage are supported)

System Computer Specifications	
Total Hard Drive Capacity	Up to 3.5 TB
Reconstruction Server	• High performance CPUs and GPUs to perform over 58 trillion operations per second to achieve fast deep learning based image reconstruction • Up to 65 fps with FBP • Up to 55 fps with ASiR-V
Image Transfer/ Networking	Interface is supplied for the transfer of medical images and information using the DICOM standard. Enabled for facilities communication with devices from different manufacturers. Smart Transfer technology enables priority and parallel image transfer. Image transfer time using DICOM protocols is > 16 fps on a 1,000 baseT network.

User Console and Interface *(cont.)*

User Interface Standard Features

User Interface Standard Feature Descriptions	
Protocol Management System	Protocols can be copied, built and edited intuitively. • GE Reference Protocols are factory installed and are a set of predefined protocols for adult patients that cannot be modified but can be copied and used. They have been developed in collaboration with clinical partners to provide users with a convenient and clinical relevant starting point for tailoring departmental protocols • Recently Scanned Protocols is a copy of the last 90 protocols that reside exactly as they were used, for review purposes only. These protocols can be copied and used into the departmental protocols • Anatomical Selector is used to select a specific anatomical region to show only protocols related to that region • Favorites allow the user to add a list of favorite protocols commonly used by the department
Protocol Tagging	Protocol tagging has added selections for Draft, Radiation Therapy, Research and Trauma to help further classify protocols.
Clinical ID	Clinical ID is designed to streamline the clinical application specific workflow from protocol setup to reconstruction prioritization and automate reformatted views for timely diagnostic decisions.
AutoVoice™	AutoVoice provides recorded breathing instructions for the patient. Consistent breathing instructions assist with more precise timing during an exam. The system has three, pre-recorded messages in 23 selectable languages that cannot be deleted. You can also record up to 17 additional messages for each language.
Microphone	The system comes equipped with microphones at the console and gantry for communicating with the patient.
Digital Tilt	The system has preset protocols that can be selected prospectively, which allows images to be reformatted at a specified tilt angle.
Show Localizer Group Color	This preference allows to the user to differentiate groups within Graphic Rx Show Localizer. The chosen color palette is applied to both Graphic Rx viewports and secondary reconstructions. Color indication is also displayed on each group task in the Series scan task list and the group in primary focus is indicated with the color in the group tab of the scan settings.

User Interface Standard Feature Descriptions	
SmartPrep™ with Dynamic Transition	Enables real-time monitoring of IV contrast and a user selectable mode to dynamically transition to the diagnostic scan phase when a user entered Enhancement Threshold is reached in the Transition ROI. AutoVoice also provides a pre-message in the SmartPrep feature.
Unknown Patient Entry	Use this procedure to assign Patient ID and Patient Name when information about the patient is unknown.
Smart Trauma	Smart Trauma can enable prioritization of recons for trauma scans, prospective DMPR settings and faster reconstruction throughput.
Filming	Images can be filmed to either a DICOM printer or a postscript printer. Images can be filmed from the exam review session or from the File Manager viewer. Preset film layouts as well as custom film layouts are available.
Prospective Exam Split	Allows the operator to specify how to split images from a scan into separate requested procedures/accession numbers in protocol management. This capability is especially useful in cases of full body trauma or for chest, abdomen and pelvis exams. Prospective Exam Split works with primary, secondary and reformatted images.
Retrospective Exam Split	Exam Split provides the capability of selecting procedures that were not selected prior to scanning. This feature provides easy series and image selection and the ability to edit the Series description if required.
Smart Patient Centering	The smart patient centering feature helps to detect suboptimal centering prior for the diagnostic scan. When the scout is acquired, the system will assess patient centering. If the patient is off-centered greater than 2 cm, the system will display the table height location and an up or down arrow to indicate the elevation needed to reach that height.
Volume Viewer On-Console[24]	Volume Viewer features excellent 3D visualization and processing capabilities and a broad portfolio of high performance analysis tools, automating routine tasks and helping to make 3D image processing a stress-free component of your routine workflow.

24. Volume Viewer is standard on the operator console. Volume Viewer is available as standard on the AW workstation or Server. The AW workstation and AW Server are both purchasable options.

User Console and Interface *(cont.)*

Dose Reduction Standard Features

Standard Features Designed for Dose Reduction	
Automatic Exposure Control (AEC)	AEC is a versatile and powerful tool designed to tailor the scanner's radiation output to each patient based on the patient's size, age, shape and attenuation and the user's requested level of image noise/quality criterion. AEC technology uses estimated patient attenuation values to adjust the mA dynamically in order to achieve the requested level of image noise/quality criterion.
3D Dose Modulation Utilizing Smart mA	Volumetric knowledge prior to scanning 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. In addition, the system provides guidance to assist in centering the patient to maximize the benefit of mA modulation.
Organ Dose Modulation (ODM)	ODM builds on the Smart mA feature to enable even further patient dose reduction. By reducing the mA exposure profile as a function of the X-ray tube angle, radio sensitive organs towards the anterior surface of the patient, such as the eyes, breasts and thorax, can benefit from enhanced dose reduction while maintaining diagnostic image quality.
70 kV Scanning	70 kVp scan mode enables low dose pediatric and small patient scans.
Color Coding for Kids	Based on the Broselow-Luten Pediatric System, the Color Coding for Kids was developed to help operator to select the correct pediatric CT protocol. The system divides the protocols into nine color zones based on height and weight, and incrementally increases scan technique as the patient's size increases. This arrangement of protocols assists you in reducing the variations in pediatric protocol selection. If the patient weight is unavailable, a Broselow-Luten Tape can also be used to obtain the weight based on the length.
Smart Track	Advanced hardware and software for X-ray beam tracking minimizes patient dose.
Smart Beam	Optimizes X-ray beam filtration independently for body, head, and cardiac applications.

Standard Features Designed for Dose Reduction	
Soft Shutter	Reduces the over-beaming dose in helical scans by using an advanced reconstruction algorithm for helical scans that makes more efficient use of acquired data through intelligent view weighting and back projection.
Dose Check	Provides the user with tools to help 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 Association (NEMA). Dose check provides: • Check against a Notification Value for cases where the estimated dose for the scan is above the departments established threshold • Check against an Alert Value where the user needs specific authority to continue the scan at the current estimated dose without changing the scan parameters for cases where the estimated dose exceeds the Alert Value • The ability to define Alert Values for adult and pediatrics studies based on age threshold • Audit logging and review capabilities • Protocol change control provided by a robust protocol management interface
Dose Computation, Display and Reporting	CTDIvol (CTDI volume), DLP (Dose Length Product), and Dose Efficiency computation and display during scan prescription provide dose information to the operator. Dose Reporting saves the CTDIvol, DLP, and phantom type in a DICOM Structured Dose Report and a secondary screen capture. Series and cumulative exam values are saved. Saved values can be networked or archived.
Iterative Reconstruction (ASiR-V)	ASiR-V is a model based iterative reconstruction technology, designed to deliver reduced noise levels, improved low contrast detectability and may enable up to 82% dose reduction[25] for all clinical applications. It contains improved noise and object modeling and also applies the physics model used in the full model-based iterative reconstruction while excluding complex system optics in the modeling process to achieve fast reconstruction workflow.

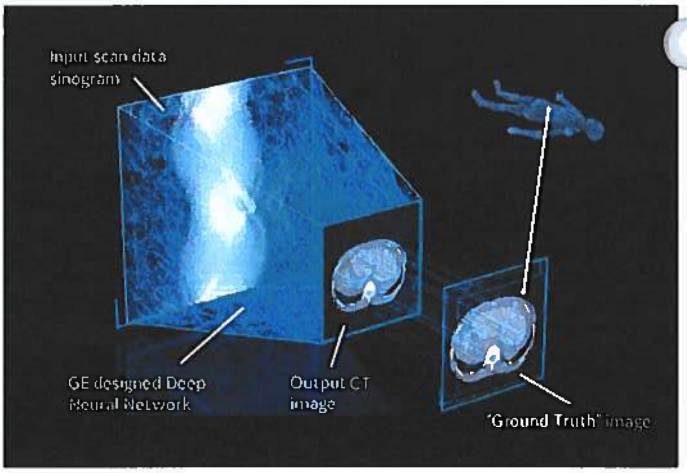
25. In clinical practice, the use of ASiR-V may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the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

User Console and Interface *(cont.)*

Image Quality Standard Features

Image Quality Standard Feature Descriptions	
Volume HD Reconstruction	The system features state of the art image reconstruction technology designed to mitigate cone beam artifacts associated with wide coverage systems. The algorithm preserves temporal uniformity and provides excellent image quality at full 80 mm coverage. It further reduces variation in iodinated contrast HU uniformity across the full 80 mm Z coverage, typically caused due to heel effect. In addition, Multi-Material Artifact Reduction (MMAR) technology utilizes material physics learnings from GSI incorporated in single energy acquisition. In conjunction with the 3D Collimator, this reduces beam hardening artifacts due to iron, bone, metal & other dense objects.
High Resolution Scan Mode	High Resolution scan mode provides the capability to acquire 2.5 more views using deflection of the X-ray beam in both gated and non-gated acquisitions. The additional views improve image quality by reducing aliasing, improve off-center imaging, or improve resolution. These images can be used to help the physician with tasks such as quantifying stenosis in coronaries and other vascular structures, injuries in MSK images and disease of the inner ear. Hi-res algorithms include HD Stnd, HD Detail, HD Lung, HD Edge, HD Ultra, HD Bone and HD Bone Plus.
1024 Reconstruction Matrix	1024 matrix is an additional image reconstruction matrix selection, to the normal 512 matrix. 1024 matrix is for improved local detail resolution in lung exams acquired with a large DFOV and IAC's in the axial plane and better resolution for cardiac stents. 1024 matrix can be used with 40 mm Axial, Helical, Cine and Cardiac scan modes. It is also compatible with ASiR-V, Smart MAR, IQ Enhance and Enhance Filters.
Enhanced Contrast (EC) and Enhanced Boundary (EB) for neuro scanning	EC is a special reconstruction option to boost the differentiation between the gray and white matter regions in the brain. The EC reconstruction option enables improved visual contrast between gray and white matter regions without the noise amplification present when using a narrow window width display setting. EC selections focus on CT number separation of gray and white matter for better differentiation, EB selections focus on improving the gray and white edge boundary resolution for better differentiation.

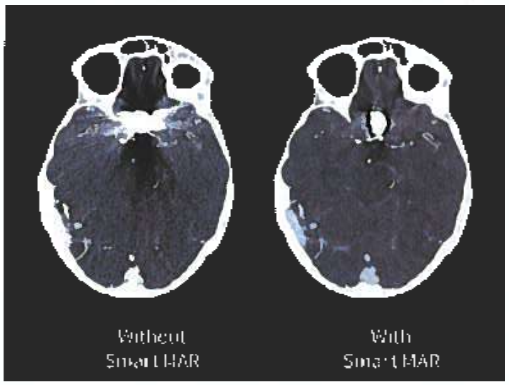
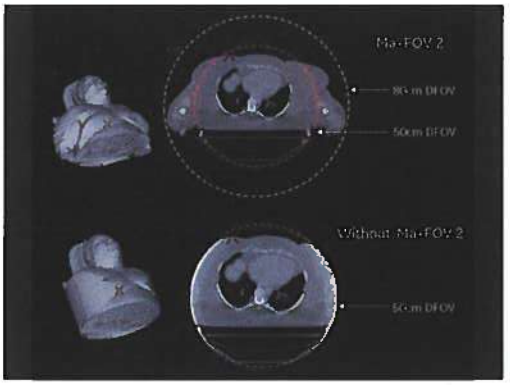
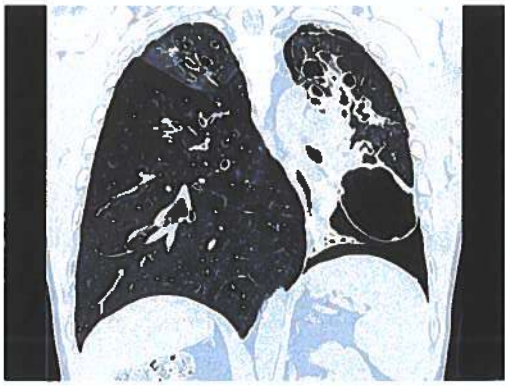
Image Quality Standard Feature Descriptions	
Image Reconstruction Algorithms	There are a broad range of reconstruction algorithms used by the operator depending on the body area scanned. The algorithms are listed in order of increasing spatial resolution and decreasing low contrast detectability. They are named for ease of recognition by the operator. Soft, Soft #, Stnd, Stnd #, Detail, Lung, Bone, Bone Plus, Edge, Chest, Ultra.
TrueFidelity CT Images	Deep Learning Image Reconstruction is the next generation image reconstruction option that uses a dedicated Deep Neural Network (DNN) to generate TrueFidelity CT Images. Compared to current iterative reconstruction technology, TrueFidelity CT Images can elevate every image to a powerful first impression with distinguished image quality performance,[26] and preferred image sharpness[27] and noise texture,[28] at the same dose. TrueFidelity CT Images have the potential to improve the reading confidence in a wide range of clinical applications such as head, whole body and cardiovascular, for patients of all ages. The user can select three strengths of DLIR: Low, Medium or High. The strength selection will vary based on user preference in specific clinical applications. Natively running on Recon Server Xtream, the DLIR engine is incredibly powerful to achieve fast reconstruction for routine CT use, even in acute care settings.



26. Image quality comparisons between DLIR and ASiR-V, were evaluated by phantom tests of MTF, SSP, axial NPS, standard deviation of image noise, CT Number accuracy, CNR, and artefact analysis. Additionally, LCD was demonstrated in phantom testing using a model observer with the head and body MITA CT IQ Phantoms (CT191, CT189 The Phantom Laboratory). DLIR and ASiR-V reconstructions were performed using the same raw data.
27. As demonstrated in a clinical evaluation consisting of 60 cases and 9 physicians, where each case was reconstructed with both DLIR and ASiR-V and evaluated by 3 of the physicians. In 100% of the reads, DLIR's image sharpness was rated the same as or better than ASiR-V's. This rating was based on each individual reader's preference.
28. As demonstrated in a clinical evaluation consisting of 60 cases and 9 physicians, where each case was reconstructed with both DLIR and ASiR-V and evaluated by 3 of the physicians. In 91% of the reads, DLIR's noise texture was rated better than ASiR-V's. This rating was based on each individual reader's preference.

User Console and Interface *(cont.)*

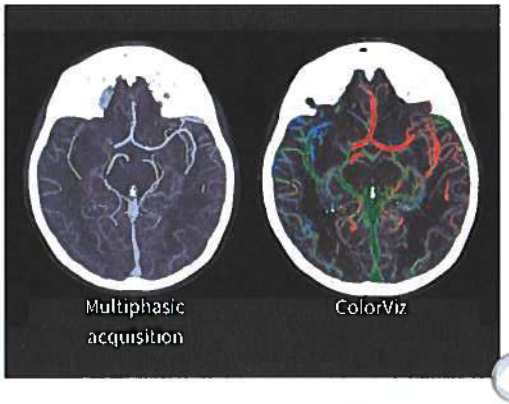
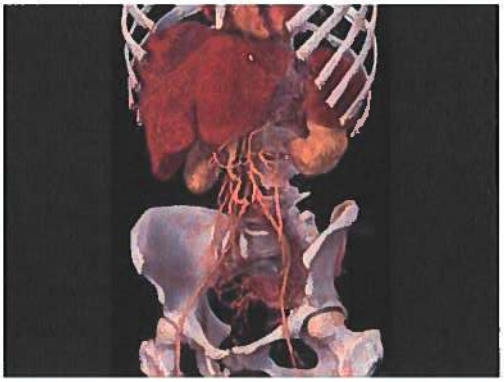
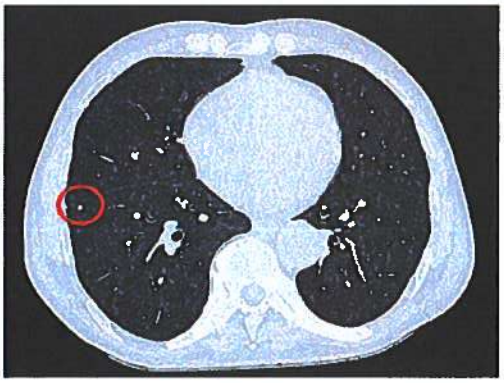
Optional Features

Optional Feature Descriptions		
Smart MAR[29]	Smart MAR is a single energy metal artifact reduction solution that uses an automated, three-stage projection-based process. Smart MAR is designed to reveal anatomic details obscured by metal artifacts by reducing photon starvation, beam hardening and streak artifacts caused by metal such as hip implants, surgical clips, endovascular coils, and dental fillings. Smart MAR requires one single energy scan and can be enabled in secondary reconstructions, making the metal artifact reduction workflow fast and efficient.	
MaxFOV 2[30]	MaxFOV 2 is a deep learning powered CT image reconstruction option to extend the display field-of-view (DFOV) up to 80 cm with high accuracy of skin line and density detection sufficient for accurate dose calculations in radiation therapy planning (as demonstrated in phantom testing). MaxFOV 2 can also be used for visualization of patient anatomy in cases not involving therapy planning and is intended for patients of all ages, especially bariatric patients.	
HyperDrive[31]	HyperDrive provides ultrafast scan speed with uncompromised 50 cm FOV and high quality images for challenging patients. It enables 0.28 sec and 0.35 sec rotation time with 1.375 and 1.531 pitch modes for Helical scanning for 437 mm/s scan speed using 80 mm collimation. Resultant images are high quality across the full 50 cm SFOV and may minimize the need for breath hold and sedation, important in ER and pediatric scans.	

29. Smart MAR is a purchasable option.
30. MaxFOV 2 is a purchasable option. The image quality for the area outside the standard 50 cm scan field does not meet the image quality specifications shown in the technical data sheet and image artifacts may appear, depending on the anatomy scanned.
31. HyperDrive is a purchasable option.

User Console and Interface *(cont.)*

Optional Features *(cont.)*

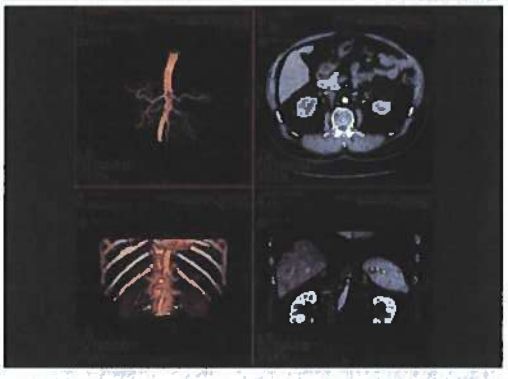
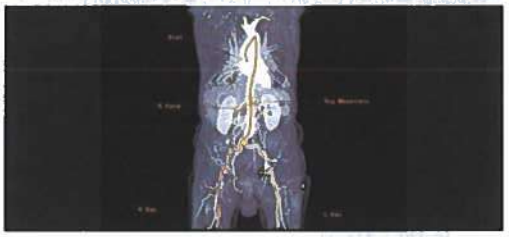
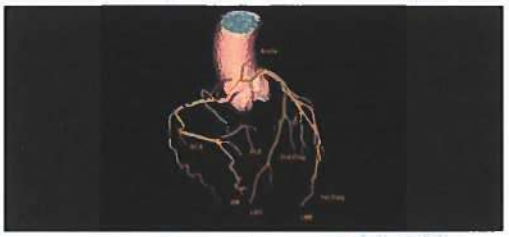
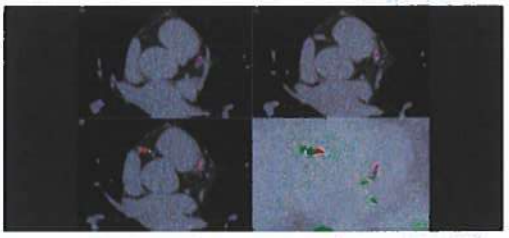
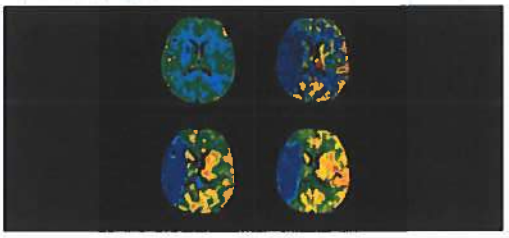
Optional Feature Descriptions		
Neuro Multi-phase CT Angiography Protocols[32]	Multiphase CT angiography is an imaging tool that provides three time-resolved images of pial arterial filling in the whole brain, unlike conventional single-phase CT angiography. Utilizing ColorViz on the FastStroke package[33], provides an intelligent color coded display of vascular enhancement within the multi-phase acquisitions. Each phase is registered into a single composite view. Vascular enhancement is color coded based on arrival time for easy and confident identification.	
Enhanced Xtream Injector[34]	The Enhanced Xtream Injector provides synchronization of the start of the scan and the start of the contrast injector using the start scan button on the Scan Control Interface or the gantry controls. The Enhanced Xtream Injector also allows setting of the contrast injector parameters within the CT scan protocol and creation of an Injector Report at End Exam of what was delivered by the injector. The system and injector are operated independently after the start scan button is pressed on the system.	
Lung Cancer Screening[35]	Scanners with the Lung Cancer Screening Option installed are indicated for using low-dose CT for lung cancer screening. The screening must be performed within the established inclusion criteria of programs/protocols that have been approved and published by either a governmental body or professional medical society.	

32. Neuro multi-phase CT angiography protocols are a purchasable option.
33. The FastStroke application on AW workstation or AW Server are all purchasable options. It is also optionally available via the neuro package on Smart Subscription.
34. Enhanced Xtream injector is a purchasable option.
35. Lung Cancer Screening protocols are optional.

User Console and Interface *(cont.)*

Advanced Clinical Applications On-Console

Get access directly from the operator console to the main post-processing applications to streamline your workflow.

Applications On-Console Descriptions		
Volume Viewer On-Console[36]	Volume Viewer provides excellent 3D visualization and processing capabilities for reading and comparing CT, MR, 3D X-ray, PET, PET/MR and PET/CT datasets. Volume Viewer also features a broad portfolio of high performance analysis tools, automating routine tasks and helping to make 3D image processing a stress-free component of your routine workflow. Volume Viewer is the pre-requisite to the following Image analysis tools on-console: • AutoBone Xpress and Vessel IQ Xpress • CardIQ Xpress 2.0 • CT Perfusion 4D Neuro Volume Viewer is standard on the console.	
AutoBone™ and VesselIQ Xpress On-Console[37]	AutoBone and VesselIQ software option provides you with accessible, user-friendly tools to analyze 3D angiographic data including stenosis analysis, thrombus, pre and post stent planning procedures, and directional vessel tortuosity visualization.	
CardIQ Xpress 2.0 On-Console[38]	The CardIQ Xpress 2.0 Reveal software option can be used to 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.	
SmartScore 4.0 On-Console[39]	SmartScore 4.0 software option is designed to identify the presence of regional and global coronary artery calcification from a CT scan, then measure and score the results. Scores can be calculated using a standard Agatston/Janowitz (AJ) method. When correlated with a patient's personal information, the score can yield an estimation of a patient's risk for coronary artery disease.	
CT Perfusion 4D Neuro On-Console[40]	Perfusion 4D Neuro software option is a fast, easy-to-use automated software for analyzing CT Perfusion images related to stroke. Its simple user interface and automated perfusion post-processing make it easy to diagnose quickly and accurately. The protocol-driven design leads the user step-by-step, reducing keystrokes and improving repeatability so you get the information you want quickly and reliably.	

36. Volume Viewer is standard on the operator console. Volume Viewer is available as standard on the AW workstation or Server. The AW workstation and AW Server are both purchasable options.
37. AutoBone and VesselIQ Xpress application on-console, AW workstation or AW Server are all purchasable options. It is also optionally available via the general package on Smart Subscription.
38. CardIQ Xpress 2.0 application on-console, AW workstation or AW Server are all purchasable options. It is also optionally available via the cardiac package on Smart Subscription.
39. The SmartScore application on-console, AW workstation or AW Server are all purchasable options. It is also optionally available via the cardiac package on Smart Subscription.
40. CT Perfusion 4D Neuro application on-console, AW workstation or AW Server are all purchasable options. It is also optionally available via the neuro package on Smart Subscription.

Smart Subscription[41]

A CT That Keeps Getting Better

Smart Subscription's design, started with a broad vision: to help you deliver exceptional patient care, not just today but for the life of your CT investment. We understand your challenges: declining reimbursements, increased workloads, shortage of radiologists, workflow challenges, aging fleets and lack of capital funds. In response, we designed Smart Subscription, a subscription service that provides convenient and continuous access to the latest commercially available software for your CT scanners.

Smart Subscription gives you access to the latest innovations designed to improve image quality, reduce dose or minimize artifacts and applications designed to further automate your CT workflow from Pre-Scan to Post-Scan. Smart Subscription will also enable automated post-processing applications directly accessible from the operator console or via a virtual remote workstation to streamline your workflow.

Smart Subscription Implementation	
Smart Subscription Connection	The Revolution Apex Plus base software is capable to connect to the Smart Subscription service. This service is designed to provide continuous access to the latest CT software thereby extending the life of Revolution Apex Plus. Applications can be selected based on a hospital or health system's unique needs, with options ranging from intelligent protocoling, intelligent cardiac motion correction, stroke management to AI-enabled offerings.

Package Name	Application Name
Base Package	Get access to the latest CT system software and enabling hardware[42] and latest innovations to improve image quality, reduce dose, and minimize artifacts. Current package includes: • CT Console and OS Non-Obsolescence protection • Reconstruction and image quality package – TrueFidelity CT images[43] – TrueFidelity GSI Images[43] – MaxFOV2[43] – Smart MAR[43]
Cardiology Package	Automate Cardiac CT post processing and streamline your workflow. The Smart Subscription Cardiology Package provides also access to cardiac post-processing applications directly from the operator console or from a remote client, to speed up your image review and diagnostic workflow. Current package includes: • SnapShot Freeze 2 • CardIQ Xpress 2.0[44] • SmartScore 4.0[44]
Neurology Package	Simplify the Stroke CT workflow and the communication within the stroke team. The Smart Subscription Neurology Package provides you access to stroke CT post-processing applications directly from the operator console or from up to 4 remote clients, simultaneously to speed up your image review and diagnostic workflow within your stroke team. Current package includes: • FastStroke[44] • CT Perfusion 4D Neuro[44] • Dynamic Shuttle[44]

Package Name	Application Name
General Imaging Package	Streamline the processing and reading of routine CT exams. The Smart Subscription General Imaging Package provides you access to CT vascular and spine imaging applications directly from the operator console or from another remote client, to speed up your image review and diagnostic workflow. Current package includes: • Bone VCAR[44] • VesselIQ™ Xpress and AutoBone Xpress
Spectral Imaging Package	Enable spectral imaging studies and simplify the reading and analysis of spectral datasets. The Smart Subscription Spectral Imaging Package provides you access to GSI Xtream acquisition mode and to post-processing applications directly from the operator console or from another remote client, to simplify your spectral imaging experience. Current package includes: • GSI Xtream[43] • GSI Neuro[43] • GSI Viewer[44]
Workflow Package	Optimize the workflow and output of your CT scanner. The Smart Subscription Workflow package helps you simplify protocol management and automate the protocol selection. Current package includes: • Intelligent Protocoling (IP)[45] • Imaging Protocol Manager (IPM)[46]

41. Smart Subscription is optional on Revolution Apex Plus.
42. GE Healthcare may provide additional hardware (e.g., a server) to enable functionality. If hardware is provided by GE Healthcare to implement Smart Subscription, you are responsible for its safe keeping while on your site and for removing any data on it before returning the hardware to GE Healthcare at the conclusion of your subscription.
43. Each feature is available on the CT console with the subscription service.
44. The AWS 3.2 or later is deployed on Smart Subscription platform as a virtual machine. These applications run on AWS 3.2 or later.
45. The Intelligent protocolling application software is optional via the Workflow package on Smart Subscription. It is run on the Edison Healthlink sever used with the Revolution Apex Plus. The application is not part of the CT system. Please refer to the Smart Subscription Product Data Sheet for further information.
46. Imaging Protocol Manager (IPM) is a cloud-based application and dose not technically depend on Edison PC. Availability of the product itself is indicated on the IPM product datasheet.

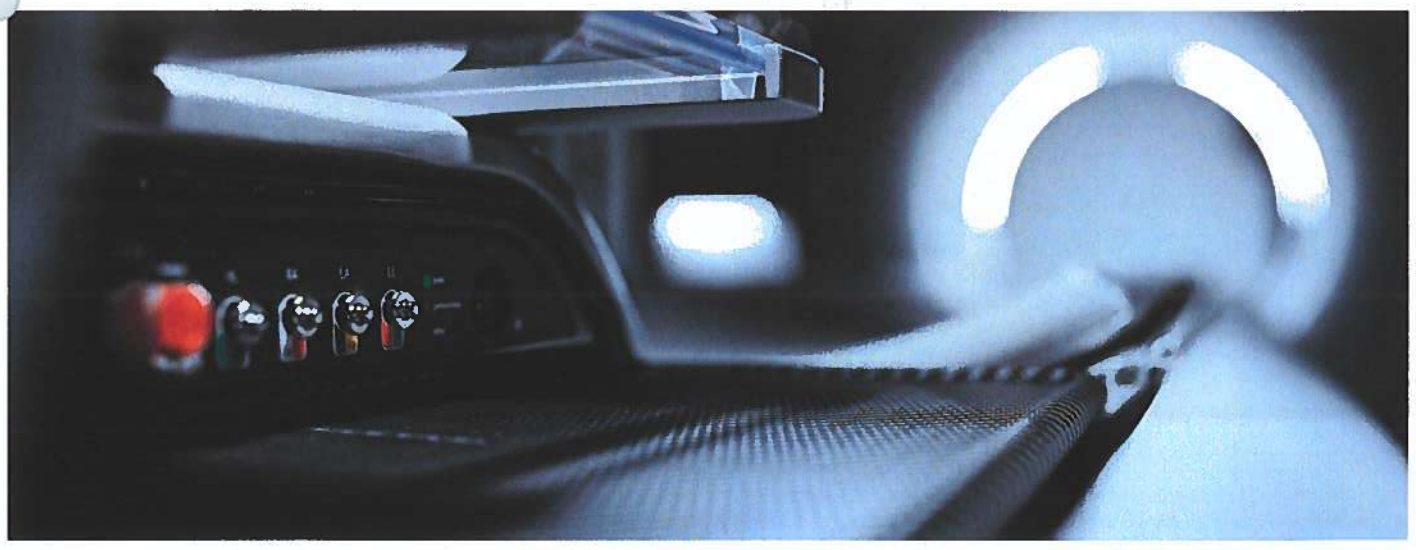
Advanced Clinical Applications

Cardiovascular Imaging

High definition, motion free coronary images at any heart rate is enabled by a prospectively ECG-gated cardiac axial acquisition protocol that utilizes 80 mm of high-definition coverage with 0.28 sec rotation speed and real-time control to ensure robust, low dose and high definition cardiac imaging for all heart rates, with or without beta blockers.

Cardiac Scan Modes and Feature Descriptions	
Cardiac Axial	Cardiac Axial acquisition is a prospectively ECG-gated scan mode, where the heart rate is monitored and the R-Peak triggers the acquisition of data for a specified range of phases in the cardiac cycle (using R-peak to R-peak phase percent or ms after R-peak). If there are multiple gated acquisitions protocolled along the Z axis, the table is designed for rapid acceleration immediately after each acquisition, in order to minimize the scan duration.
Cardiac Helical	Cardiac helical is a lower pitch helical scan and is available for cardiac applications in conjunction with the Cardiac Helical option. In this scanning mode, heart rate monitoring is performed during the helical acquisition and the associated EKG gating information is stored with the scan data such that a cardiac gated SnapShot reconstruction algorithm can be applied for prospective and retrospective images. SnapShot reconstruction is used to minimize the motion of the heart in the resultant images. The pitch factor for the cardiac helical scan is determined by the system and is a function of the patient heart rate and scan speed.

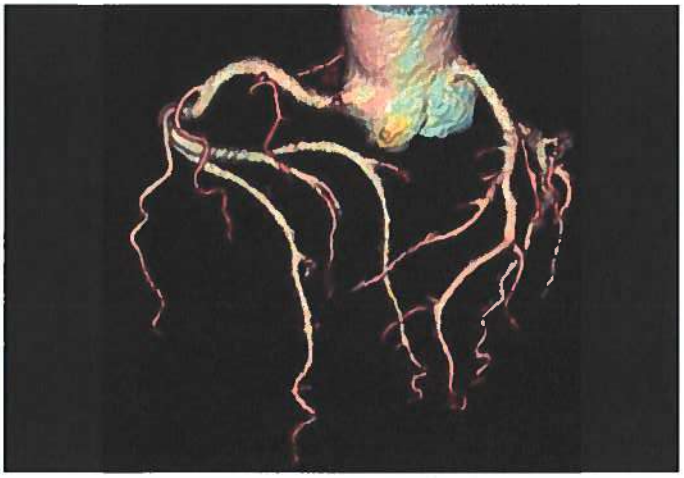
Cardiac Scan Modes and Feature Descriptions	
Auto Gating	When Auto Gating is enabled, the system uses the heart rate measurements from the most recent breath hold recording with the Auto Gating Profile table, to automatically recommend the optimal phase, phases, or phase ranges, even handling the uncertainty associated with some heart-rate irregularities. Even bolus timing and tracking are efficient and predictable.
Smart Arrhythmia Management	• Allows the system to automatically re-scan a cardiac scan if significant heart rate variation is detected during exposure • Works seamlessly with existing cardiac technologies including: Auto Gating, Adaptive Gating, SnapShot Freeze and SmartPhase
ECG Signal Loss Simulated R-peak Scanning	Simulated R-peak scanning has been added to provide scanning when the ECG signal is lost after Start Scan is pressed with simulated R-peaks corresponding to the last recorded patient heart rate. The system displays a message indicating that simulated R-Peaks are being used.



Advanced Clinical Applications *(cont.)*

Cardiovascular Imaging *(cont.)*

Cardiac Scan Parameters	
kVp	70, 80, 100, 120, 140 kVp
mA	10 to 1,300 mA
Rotation Speed	0.28 sec, 0.35 sec per 360° acquisition
Detector Coverage	• Axial: 40 mm to 80 mm with smart collimation • Helical: 40 mm
Temporal Resolution	• 140 ms cardiac temporal resolution without using SnapShot Freeze 2 • 24 ms effective temporal resolution using SnapShot Freeze 2.[48,49]
ECG Gated Acquisition Mode	• Auto Gating mode • Manual mode (phase types: % ms or beats)
Maximum Scan Field-of-View	• 32 cm Cardiac Small • 36 cm Cardiac Medium • 50 cm Cardiac Large



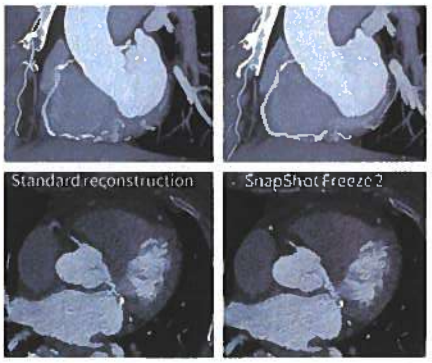
Cardiac Scan Image Display and Reconstruction	
Reconstruction Matrix	512 x 512 1024 x 1024[50]
Display Matrix	1024 x 1024
CT Number Scale	-1,024 to 3,072 (normal range) -31,743 to 31,743 (extended range)
Recon Phases	Single phase, Multi phase, center phase, center phase (All), Earliest to Latest, Earliest to Latest (All), SmartPhase, SmartPhase (All).
Interactive ECG Editor	Interactive ECG Editor allows the user to adjust gating information such as R-peak trigger time and reconstruction timing relative to the ECG trace.
Recon Types	Soft, Standard, Detail, Lung, Bone, HD Soft, HD Standard, HD Standard Plus, HD Detail, HD Detail Plus, HD Lung, HD Edge.
Image Enhance Filter to Enhance Anatomical Structure	E1, E2, E21, E22, E23, E3 or S1, S11, S2, S21, S3 and LU • Edge Enhancement filters (E) sharpen the image and are useful for bone windows • The smoothing filters (S) decrease the appearance of noisy images or enhance low-contrast areas on soft tissue • The Lung Enhancement filter (LU) is designed specifically to use for lung windows • E21, E22, E23, S11, S21 are only available as image display filters
Reconstructed Slice Widths	0.625, 1.25, 2.5 mm

48. SnapShot Freeze 2, in conjunction with 0.28 s/rotation gantry speed, provides a reduction in coronary motion artifacts that is equivalent to a 0.047 s/rotation equivalent gantry rotation speed with effective temporal resolution of 24 msec. As demonstrated in phantom testing using a commercially available motion phantom and also with a mathematical cardiac phantom with linear motion of variable velocity. The 0.047 s/rotation images are modeled without application of SnapShot Freeze 2. Results may vary in clinical applications.
49. SnapShot Freeze 2 on the AW workstation are purchasable options. It is also optionally available via the cardiac package on Smart Subscription.
50. 1024 matrix is compatible with 40mm coverage and ASiR-V.

Advanced Clinical Applications *(cont.)*

Cardiovascular Imaging *(cont.)*

Cardiac Standard Feature Descriptions	
Smart Arrhythmia Management	The system has been designed to improve the robustness of cardiac exams for patients with high or irregular heart rates and in situations involving irregular heartbeats, arrhythmia, atrial fibrillations, PVC's, etc. The system can monitor and alert the user to these situations and also recommend turning on Smart Arrhythmia Management mode. This mode avoids scanning during an irregular beat and rescans during the next regular beat using the same contrast bolus.
High Spatial Resolution	High spatial resolution at 18.2 lp/cm in z-direction and 14.8 lp/cm in X-Y direction (measured at 2% MTF). This spatial resolution provides clear images to help the physician with tasks such as accurately quantifying stenosis in coronaries and other vascular structures.
Calcium Scoring Acquisition	The system also allows single beat acquisition for cardiac calcium scoring. SmartScore 4 software, for workup, is available on-console, on the optional standalone AW workstation or AW Server or the optional Smart Subscription.[51]
Triple RuleOut™	The system enables robust Triple Rule Out studies with motion free coronaries, PE and aorta evaluation in a single exam. ECG gating and mA modulation along with flexible collimations enable low dose acquisition personalized to the patient. 80 mm helical mode combined with table speed of up to 437.5 mm/s[52] allows for ultra-fast scanning, thus reducing the effect of breathing and other motion during the scan.
TAVR Planning	Dedicated TAVR/TAVI scanning protocols allow mixed acquisitions of the heart, aorta, and femoral arteries, with ECG-gated axial scans and non-ECG-gated axial or helical scans, using a single injection of contrast media. TAVI Analysis Advanced software is available on the optional AW workstation or AW Server.[53]

Cardiac Optional Feature Descriptions	
Smart Phase[54]	Analyzes the motion of the coronaries throughout the volume to auto-select the best cardiac phase with the least motion. SmartPhase also searches across multiple table positions for the best phase.
Intelligent motion correction with SnapShot Freeze 2[55]	Intelligent motion correction with SnapShot Freeze 2 provides a 6x improvement of motion- blur reduction while maintaining high spatial resolution. In conjunction with optional 0.28 sec rotation speed, the reduction in motion artifacts is comparable to a 0.047 sec equivalent gantry rotation speed with an effective temporal resolution of 24 msec, as demonstrated in mechanical and mathematical phantom testing.[56] 

51. The SmartScore application on-console, AW workstation or AW Server are all purchasable options. It is also optionally available via the cardiac package on Smart Subscription.
52. Enabled by HyerDrive. HyperDrive is a purchasable option.
53. The TAVI Analysis application on AW workstation or AW Server are all purchasable options.
54. SmartPhase is a purchasable option.
55. SnapShot Freeze 2 on the AW workstation are purchasable options. It is also optionally available via the cardiac package on Smart Subscription.
56. SnapShot Freeze 2, in conjunction with 0.28 s/rotation gantry speed, provides a reduction in coronary motion artifacts that is equivalent to a 0.047 s/rotation equivalent gantry rotation speed with effective temporal resolution of 24 msec. As demonstrated in phantom testing using a commercially available motion phantom and also with a mathematical cardiac phantom with linear motion of variable velocity. The 0.047 s/rotation images are modeled without application of SnapShot Freeze 2. Results may vary in clinical applications.

Advanced Clinical Applications *(cont.)*

Neuro/Stroke Imaging

Routine non-contrast brain scans are reconstructed using Volume HD reconstruction technology to ensure CT number uniformity across the entire volume. Iterative MMAR can reduce the beam hardening artifacts at the bone/brain interface and posterior fossa region. Enhanced Contrast and Enhanced Boundary can assist in achieving excellent gray white matter differentiation.

Neuro Feature Descriptions	
Brain CT Perfusion	CT Brain Perfusion with 70kVp and variable sampling can acquire temporally uniform dynamic blood flow information to achieve accurate volumetric perfusion values at lower dose. Single phase or dynamic 4D CTA can be acquired within a single exam to achieve comprehensive functional & anatomical assessment of the brain.
Smart Stroke[57]	Stroke-dedicated hardware, software and post-processing solution can help physicians to reduce "CT scan-to-report" time and "door-to-treatment" time, to save more brain tissue of patients with stroke. Single phase or dynamic 4D whole brain CTA can be acquired within a single exam of whole brain CT perfusion to achieve comprehensive functional and anatomical assessment of the brain. The system can also acquire cardiac function, CCTA and a head/neck angio in a single exam using a single contrast bolus to perform a comprehensive cardiovascular and neuro assessment using multi-volume scan mode.
Reconstruction Queue Priority Order	When utilizing Xtream Stroke, reconstruction priority has different behavior based on the Clinical Identifier selected for the reconstruction. When the Clinical Identifier is Stroke.Perfusion these reconstructions will always have the highest priority and will be moved to the top of the image reconstruction priority after any pending scout or Smart Prep reconstruction is completed.
Neuro Multi-phase CT Angiography Protocols[58]	Multi-phase CT angiography is an imaging tool that provides three time-resolved images of pial arterial filling in the whole brain, unlike conventional single-phase CT angiography. Utilizing ColorViz on the FastStroke package on AW or AW Server,[59] provides an intelligent color-coded display of vascular enhancement within the multi-phase acquisitions. Each phase is registered into a single composite view. Vascular enhancement is color coded based on arrival time for easy and confident identification.
Neuro GSI	Enables GSI Neuro scan modes, profiles and reference protocols specific to neuro imaging in GSI.

Neuro Scan Image Display and Reconstruction	
Enhanced Contrast for Axial and Helical Scan Types with Head SFOV	Enhanced Contrast is a special reconstruction option to boost the differentiation between the gray and white matter regions in the brain. The Enhanced Contrast reconstruction option enables improved visual contrast between gray and white matter regions without the noise amplification. Six levels of Enhanced Contrast are selectable: EC1, EC2, EC3, EB1, EB2 and EB3 where the higher number corresponds to additional differentiation between gray and white matter. EC selections focus on CT number separation of gray and white matter for better differentiation, EB selections focus on improving the gray and white edge boundary resolution for better differentiation. If you select Axial or Helical scan type with Head, Small Head or Ped Head SFOV, 100, 120 or 140 kV, Hi-Res Off, Soft, Soft #, Stnd or Stnd # algorithm and Number of Passes: 1. EB is also selectable within GSI neuro protocols.
Fine Z for Neuro Scanning	This reconstruction option is designed for high resolution imaging tasks such as assessing detail in the inner ear. It is only available for Axial Hi-Res Head SFOV with slice thickness of 0.625z.
Smart MAR[60]	Smart MAR is a single energy metal artifact reduction solution designed to reveal anatomic details obscured by metal artifacts by reducing photon starvation, beam hardening and streak artifacts caused by metal such as surgical clips, endovascular coils, and dental fillings.
DLIR for Routine Neuro Imaging[61]	DLIR for neuro imaging is a reconstruction optimized for deep learning reconstruction of thick-slice soft tissue neuro imaging. This soft tissue reconstruction is designed for non-contrast and delayed contrast scanning (C-) and (C+), wherein the images are typically viewed in thicker slices (e.g. 2.5 mm or 5 mm).

57. Smart Stroke requires post-processing applications such as Stroke VCAR, AutoBone & VesselIQ Xpress, Dynamic 4D CTA and CT Perfusion 4D Neuro.
58. Neuro multi-phase CT angiography protocols are a purchasable option.
59. The FastStroke application on AW workstation or AW Server are all purchasable options. It is also optionally available via the neuro package on Smart Subscription.
60. Smart MAR is a purchasable option.
61. This reconstruction is used when the scan field-of-view is Small Head, Ped Head or Head AND the Clinical Identifier is one of the following: (Neuro.Routine Head, Neuro.Routine Head w Contrast, Trauma. Routine Head, or Trauma.Routine Head w Contrast, Stroke.Routine Head, or Stroke.Routine Head w Contrast) AND Recon Type is Stnd and Enhanced Contrast is: [Off, EB1, EB2, or EB3], not applied with 100 kV

Advanced Clinical Applications *(cont.)*

Gemstone Spectral Imaging (GSI) Xtream[62]

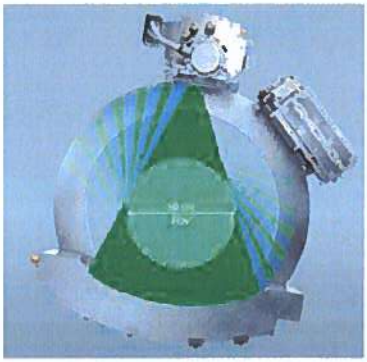
GSI Xtream is the first volume spectral CT technology designed to improve small lesion detection, tissue characterization and metal artifact reduction, across different anatomies and clinical use cases, with a simplified workflow you can make part of your daily practice.

GSI Xtream utilizes ultrafast kVp switching X-ray source (0.25 msec switching between two different energy levels of X-rays from view to view during a single rotation) and ultra-fast response Gemstone Clarity Detector to acquire almost perfectly registered volumetric dual energy CT data. The data is processed through projection domain material decomposition algorithms to generate material density maps (MD), monochromatic images (MC) and virtual unenhanced images (VUE). This data can be utilized to identify material specific differences in attenuation in terms of Water, Iodine, Calcium, Uric Acid, Fat and Hydroxyapatite (HAP) basis-pair images, allowing monochromatic and material representations. Metal Artifact Reduction (MAR) algorithms can also be applied to all GSI images to reduce artifacts due to the presence of metal.

GSI Xtream can provide:

- Almost perfect temporal and spatial registration to avoid mis-registration artifacts due to motion in dual energy CT
- Advanced material differentiation, classification and quantification
- Optimization of contrast-to-noise ratio (CNR)
- Reduction in artifacts due to beam hardening and metal
- Up to 80 mm GSI z-collimation, 245 mm/s GSI volumetric scan speed, dose neutrality and simplified routine workflow

GSI Scan Parameters	
kV	Ultra-fast switching between 80 kVp and 140 kVp (0.25 msec interval)
mA	Up to 1,300 mA
Sampling Rate	Up to 1968 views per rotation
Rotation Speed	0.5 sec, 0.6 sec, 0.8 sec, 1.0 sec per 360° acquisition
Pitch Range	0.508:1, 0.516:1, 0.984:1, 0.992:1, 1.375:1 and 1.531:1
Detector Coverage	40 and 80 mm
Max. Single Acquisition Time	60 seconds
Inter Group Delay (IGD)	1 second between adjacent helical scans



GSI Image Display and Reconstruction	
Reconstruction Matrix	512 x 512
Display Matrix	1024 x 1024
CT Number Scale	-1,024 to 3,072 (normal range) -31,743 to 31,743 (extended range)
Recon Types	Soft, Standard, Detail, Bone, Bone Plus
Image Enhance Filter to Enhance Anatomical Structure	E1, E2, E21, E22, E23, E3 or S1, S11, S2, S21, S3 and LU • Edge Enhancement filters (E) sharpen the image and are useful for bone windows • The smoothing filters (S) decrease the appearance of noisy images or enhance low-contrast areas on soft tissue • The Lung Enhancement filter (LU) is designed specifically to use for lung windows • Not valid with the GSI datafile • E21, E22, E23, S11, S21 are only available as image display filters
Enhanced Contrast for Neuro Scanning	EB1, EB2 AND EB3 Enhanced Contrast is a special reconstruction option to improve the gray and white edge boundary resolution for better differentiation. Enhanced Contrast is allowed with GSI scans using Head, Small Head and Ped Head protocols, reconstructed in monochromatic 60, 65 or 70 keV images.
GSI Native Reconstructed Image Type (On-Console and Can Be Directly Transferred to PACS)	• Monochromatic image (40 to 140 keV) • Material density image (iodine, calcium, water, Uric Acid, fat, Hydroxyapetite) • Virtual unenhanced image • GSI MAR

62. GSI Xtream is a purchasable option.

Advanced Clinical Applications *(cont.)*

Gemstone Spectral Imaging (GSI) Xtream[63] *(cont.)*

GSI Image Display and Reconstruction	
Reconstruction Optimization Technology	GSI Smart Recon to achieve 2-8 times faster GSI recon throughput
Prospective Multiple Reconstruction (PMR)	Up to 99 sets of recons can be pre-programmed
TrueFidelity GSI Images[64]	Deep Learning Image Reconstruction for GSI is the new generation dual energy spectral CT image reconstruction technology that uses a dedicated Deep Neural Network (DNN) to generate high quality TrueFidelity GSI Images. Integrated into the existing raw data-based reconstruction chain, DLIR for GSI can natively reconstruct the following TrueFidelity GSI images: • Monochromatic images at 101 user selectable energy levels (40 keV – 140 keV) • Material decomposition images of Iodine, Water, Calcium, Hydroxyapatite (HAP), Fat, Uric Acid • Virtual unenhanced (VUE) images • GSI MAR images Compared to current iterative reconstruction at the same radiation dose level in body applications, TrueFidelity GSI Images are designed to reduce image noise,[65] improve contrast-noise-ratio[66] and low contrast detectability,[67] generate preferred image noise texture,[68] without impacting high contrast spatial resolution,[69] material density quantification accuracy[70] and CT number accuracy.[71] TrueFidelity GSI images can achieve the 0.5 mg/ml minimal Iodine concentration detection.[72] The user can select three reconstruction strengths: Low, Medium or High. The strength selection will vary based on user preference in specific clinical applications. Natively running on Recon Server Xtream, DLIR for GSI is designed to achieve fast reconstruction for routine CT use, even in acute care settings.

GSI Xtream Technology Enablers	
Gemstone Clarity Detector and Volume GSI Scan	Fast response Gemstone scintillator is the key to receiving and converting ultra-fast kVp switching X-ray to dual energy datasets, because its garnet crystal structure enables fastest speed of light emission (0.03 microsecond) and shortest afterglow (0.001% @ 40ms) compared with conventional scintillators. Clarity data acquisition system (DAS) with ultra-low capacitance photo diodes allows for 25% reduction in electronic noise and better 80 kVp data. The inherent challenge of wide-cone detector CT is increased scatter and CT number shift, these can impact dual energy CT's quantification accuracy and image quality. Gemstone Clarity detector has focally aligned detector layout and 3D collimator to reduce the scatter to ensure CT number uniformity and material quantification consistency across and 80 mm GSI collimation[73] GSI Xtream can utilize 80 mm GSI collimation with up to 1.5 helical pitch to achieve up to 245 mm/s fast volumetric spectral acquisition with 50 cm FOV.
Ultra-fast kVp and mA Synchronized Switching	Quantix X-ray tube and high frequency generator enable ultrafast kV and mA synchronized switching to alternate between 80 kVp and 140 kVp within 0.25 msec and simultaneously match the optimal mA with each kV. The breakthrough can optimize low kV data quality by having access to higher mA at low kV, and achieve superb GSI image quality especially in low keVs and material images for all patient exams and presentations. Also faster dual energy spectrum rise-and-fall capability results in increased energy separation between the low and high energies.[74]
GSI Xtream's Routine Workflow	From setup to post processing, GSI Xtream is as intuitive as a single energy exam. Workflow innovations, like GSI Assist, Clinical ID, Smart Recon help standardize, automate and streamline protocol setup, images reconstruction and enable GSI images to be directly transferred to PACS for review and/or AW for additional post processing.
ASiR-V and Dose Neutral	ASiR-V is an advanced model based iterative reconstruction technology, which can reduce the image noise by utilizing the models of the system noise statistics, objects, and physics. ASiR-V is integrated, as standard, in the GSI Xtream reconstruction process to enable dose neutral GSI.[75]

63. GSI Xtream is a purchasable option.
64. Deep Learning Image Reconstruction for GSI is a purchasable option.
65. Reduced image noise: demonstrated in testing using the uniform section of the Catphan® 600 with the CTP579 oval body annulus comparing pixel standard deviation in images reconstructed from the same raw data, at 0.625 mm with DLIR-H and ASiR-V 50%.
66. Improved contrast-noise-ratio: Demonstrated in testing using images of the CT ACR464 Phantom (Gammex) and its 25 mm low contrast cylinder reconstructed from the same raw data with DLIR-L, DLIR-M, and DLIR-H and ASiR-V 50%.
67. Improved low contrast detectability: Evaluated using the body MITA CT IQ Low Contrast Phantom (CCT189, the Phantom Laboratory) with the CTP579 oval body annulus and a model observer with images reconstructed from the same raw data with DLIR-H and ASiR-V 50%.
68. Preferred image noise texture: Demonstrated in a clinical evaluation consisting of 40 cases and 5 physicians, where each case was reconstructed with both DLIR for GSI and ASiR-V and evaluated by 3 of the physicians. In 88% of the reads, DLIR's noise texture was rated better than ASiR-V's. This rating was based on each individual reader's preference.
69. High-contrast spatial resolution: evaluated by 50% MTF and 10% MTF.
70. Material Density quantification accuracy: Demonstrated using the water, Iodine (5, 10, 15, and 20 mg/ml), and 30% CaCO3 inserts in the Gammex Multi-Energy CT Phantom and reconstructed material basis pairs (Water/Iodine, Calcium/Iodine, HAP/Iodine, Fat/Iodine, Water/Calcium, Water/HAP, HAP/Uric Acid, Uric Acid/Calcium, Calcium/Uric Acid, and Water/Fat. The reconstructions were performed on the same raw data with DLIR-H and ASiR-V 50%.
71. CT number accuracy: Demonstrated with images in air, a 20 cm water phantom, and a 30 cm water phantom reconstructed from the same raw data with DLIR-H and ASiR-V 50%.
72. Iodine concentration detection: as low as 0.5 mg/ml in density at a dose as low as 8 mGy, evaluated the head portion of the Gammex Multi-Energy CT Phantom with water and 16, 8, 4, 2, 1, and 0.5 mg/ml Iodine inserts. 8 mGy based on the 32 cm dosimetry phantom.
73. Within 1.5 mg/mL is demonstrated in body phantom testing using 5, 10, and 15 mg/mL Iodine solid rods at ~11 and 19 mGy.
74. Compared to previous generation Fast kVp switching scanners using an average 400 mA acquisition technique.
75. Demonstrated in phantom testing using small, medium, and large objects. Noise is defined as the standard deviation o

Advanced Clinical Applications *(cont.)*

Gemstone Spectral Imaging (GSI) Xtream[76] *(cont.)*

GSI Xtream Image Generation	
Material Density (MD) Images	GSI Xtream performs material decomposition analysis in the projection domain to directly reconstruct the material density (MD) images (e.g., iodine, calcium, water, Uric Acid, Fat, Hydroxyapatite). Material density images show the distribution and concentration of a given material within the tissue, thus can be used to segment and measure the object's chemical composition. For example, Iodine images demonstrate the amount of iodine (mg/ml) within an image voxel and its distribution in tissues. Because iodine images are independent of inherent tissue attenuation, they are a more reliable measure of enhancement compared to conventional contrast-enhanced studies. When quantifying iodine content, GSI Xtream can detect iodine in concentrations as low as 0.5 mg/cc at radiation dose as low as 8 mGy.[77] With fully consistent projection domain decomposition, MD images can reduce beam-hardening artifacts.
Virtual Unenhanced (VUE) images	GSI Xtream can generate virtual unenhanced images (VUE) by subtracting iodine from images. The VUE algorithm is based on multi-material decomposition (MMD), a technique that allows for material separation and characterization in dual energy CT images. The VUE algorithm replaces the volume fraction of contrast by the same volume fraction of blood, producing iodine-suppressed images. The VUE images can provide attenuation information in Hounsfield units. The HU values in the VUE images were similar to the HU values in the non-contrast images.
GSI Metal Artifact Reduction (GSI MAR)	GSI metal artifact reduction (GSI MAR) is a multi-stage projection space reconstruction algorithm that is designed to reduce artifacts from metal due to beam hardening, photon starvation and scatter. GSI MAR can reveal anatomic details obscured by metal artifacts by generating metal corrected images while preserving spatial resolution and data integrity in the vicinity of the metal.

GSI Xtream Image Generation	
Monochromatic (MC) Images	Because of the nearly coincident spatial co-registration of the two energy datasets, GSI Xtream allows effective reconstruction of virtual Monochromatic (MC) images from the projection data. The resultant MC images, ranging from 40 keV to 140 keV, depict objects as if they were imaged with a theoretical monochromatic beam, and the X-ray energy is measured in kiloelectron volts (keV) instead of peak kilovoltage (kVp). These single photon–energy images provide more reliable attenuation values than conventional polychromatic CT images. In general, MC images depict more subtle contrast enhancement and have improved attenuation than the default polychromatic images of single energy CT. Low energy MC images are suggested for studies with high contrast between lesions and adjacent tissues (e.g., CT angiography; 45-55 keV). Intermediate-energy MC images (60-75 keV) are ideal for evaluation of soft tissues due to the balance between adequate contrast and reduced image noise. High energy MC images (90-140 keV) is used to reduce artifacts from metal implants. MC images have many clinically relevant benefits, including beam-hardening correction, optimization of image quality, optimization of contrast media, lesion characterization and metal artifact reduction. • **Beam-hardening correction:** High energy MC images can reduce beam-hardening artifact due to high contrast material such as metal up to 50% compared to single energy CT • **Metal artifact reduction:** The MC images can decrease beam-hardening artifacts and thus improve image quality in the presence of metal • **Optimization of CNR:** Low energy MC images can be used to improve the contrast-to-noise ratio (CNR) between a high attenuation region and background

76. GSI Xtream is a purchasable option.
77. Detection of 0.5 mg/mL at 8 mGy is demonstrated in head phantom testing.

Advanced Clinical Applications *(cont.)*

SmartStep[78]

SmartStep enables an imaging mode for performing biopsies and other interventional procedures on Revolution Apex Plus. A 24 inch in-room monitor, hand-held controller, X-ray exposure foot pedal and cradle handle provide in-room control for image acquisition and image review.

SmartStep Scan Parameters	
kVp	70, 80, 100, 120, 140 kVp
Max. mA	10 to 300 mA across all kVp settings
Rotation Speed	0.5 sec per 360° acquisition
Detector Coverage	5 mm, 10 mm, 20 mm
Max. Scan Time	90 seconds
Bore Size	80 cm
Maximum Scan Fields of View	• 32 cm for pediatric head and body, adult head, small head and small body • 50 cm for medium body • 50 cm for large body
Viewport Orientation	Provides the ability to choose the orientation of the image in the viewport to match their position in relation to the patient. 

SmartStep Image Reconstruction	
Number of Reconstructed Slices	• Up to 32 rows of data are collected • 1 or 3 slices are reconstructed
Reconstruction Matrix	512 x 512
Max. Display Matrix	1024 x 1024
CT Number Scale	-1024 to 3,072 (normal range) -31,743 to 31,743 (extended range)
Recon Types	Soft, Standard, Detail, Lung, Bone, Bone Plus
Prospective Image Interval	• 1i mode • Overlap 3i mode • Non-overlap 3i mode

SmartStep Accessories and Components	
SmartStep Kit (GE Approved)	Inclusive of hand controller and footswitch, GE5149705-4
SmartStep Monitor Boom (GE Approved)	Inclusive of LCD monitor and mountings GE5115174-30, GE 5115174-33

SmartStep Feature Descriptions	
In-room Hand-held Controller (HHC) and Foot Witch	During interventional procedures, the clinician makes exposures using the foot switch, and uses HHC to move the cradle in and out, unlatch and latch the cradle, and review images displayed on an in-room monitor. Other system controls include: • Prep the system for X-ray acquisitions • Position the cradle to the start location • Move the cradle to the last scanned location • Move the cradle a predefined bump distance • Displays and toggle through acquired images • Scroll through window width and level settings • Enable laser lights The cradle may also be positioned with the HHC or by unlatching the cradle to manually position the patient.
Graphic RX	Enhancements of Graphic Prescription (Graphic Rx) tools provides the option to plan the biopsy location from a scout or axial images. Once a location and field-of-view (FOV) is set graphically on the axial image; the table position and RAS co-ordinates for SmartStep are applied with a single click.
SmartStep Dose Display	CTDIvol mGy displays the CTDIvol information for the Z location with the highest accumulated dose in the current imaging range during the SmartStep procedure.
Dose Check	Dose Check for a SmartStep series is based on the estimated dose for the series when the user selects confirm. If a Dose Check Notification Value or Alert Value is exceeded for a SmartStep series, the user would see the Dose Check Notification Confirmation or Dose Check Alert Confirmation screen only once prior to beginning scanning of the SmartStep series. This is to prevent interruption during interventional scanning by avoiding excessive Dose Check Confirmation screens.

78. SmartStep is a purchasable option.

Accessories[79]

GE Approved Accessories, Components and Compatible 3rd Party Medical Devices

We have carefully selected a large range of products aimed at the professionals of CT scanners and offer a wide range of products for the CT segment, many of which are truly exclusive and carefully validated so to optimize your GE equipment.

GE Approved Accessories (Standard)	
Axial Head Holder	2115996-4 Attached via tongue and socket for ease of latching and removal. Made of carbon fiber construction for low attenuation
Cradle Extender	2115993-4

GE Approved Accessories (Optional)	
Coronal Head Holder	2115990-3 Designed to be used for patient head or facial coronal scanning in the supine position.

GE Approved Components (Standard)	
Patient Grounding Strap	• Wrist band GE 5788434 • GE 5802939 • Ground cord GE 5788435
Cardiac ECG Wrist Strap And Cable	5812787
Water Phantom	543878
QA Phantom	5477995
Metalless Compatible Phantom Holder	2331933-2
Carrying Case for Phantom	5537763
Cradle Pad	5433273 46-278986P2 (part of 46-229452G1) The cradle pad is attached to the top of the cradle with Velcro for ease of removal and cleaning.
Extender Pad	5122945-5
Knee/Head Support Pad	46-278986P2 (part of 46-229452G1)
Shoulder/Ankle Support Pad	46-278986P2 (part of 46-229452G1)
Positioning Straps	P9150SN Body Strap A: 2152502 P9150SP Body Strap B: 2152503 P9150SQ Body Strap C: 2152504 P9150TS Body Strap A: 2169679 P9150TT Body Strap B: 2169680 P9150TU Body Strap C: 2169681 Head strap: 5835369 (part of 5835306 kit) Chin strap: 5835370 (part of 5835306 kit) Head Strap (Qty 3): 46-237412P1 Strap Security: 46-229450P1 (part of 46-229452G1) Strap: 46-297629P1
Table Tray and IV Pole	Table tray: 2329064-2 IV holder : 2309994-2

GE Approved Components (Optional)	
External Hard Drive	Seagate 2 TB USB 2.0/3.0
Bar Code Reader	Honeywell 1300G
GE CT Flat Tabletop AAPM TG-66 Kit	GE 5924000

GE Approved Compatible 3rd Party Medical Devices (Optional)	
Cardiac Trigger Monitor	IVY 7800 IVY CTM-400
Patient Contrast Injector for Enhanced Xtream Injector	Nemoto Dual Shot Alpha 7 (CiA425 Class IV) Nemoto Dual Shot Alpha (GE CiA425 Class IV) Nemoto Dual Shot GX (GE CiA425 Class IV) Medrad Stellant D (GE CiA425 Class IV) Medrad Stellant Flex (GE CiA425 Class IV) Medrad Centargo (GE CiA425 Class IV) Medrad ISI900 (for Stellant D) (Class IV)/GE
RTP Flat Tabletop (CT Cradle Overlay)	Diacor OGS-4 (GE E6315JE) CIVCO MTIL3311 (GE E8505MJ)
Respiratory Monitor	Varian RGSC 1.1 Varian Respiratory gating for scanners System (RGSC) 1.1 includes RGSC cabinet, couch-mounted or wall/ceiling mounted camera, marker block, breathing phantom and 24 inch monitor
Table Slicker for Revolution Apex	GE 5538512
Foot Slicker for Revolution Apex	GE 5603918

79. Not all accessories are available in all markets.

Site Planning

Pre-installation Guidance

For a complete guide to siting requirements, see "Revolution Apex Plus Pre-Installation Manual."[80]

System Dimensions				
Dimensions	**Height mm (in)**	**Length mm (in)**	**Width/Depth mm (in)**	**Weight kg (lb)**
Revolution Apex Plus Gantry With Covers Installed	2029.5 (79.9)	2293.6 (90.3)	1331.0 (52.4)	2798.7 (6170)
NG2000V Patient Table (only)	1232 (48.5)	2960.4 (116.5)[81]	600.2 (243.6)	670.0 (1474.0)[82]
NG1700 Patient Table (only)	1233.0 (48.5)	2660.5 (104.7)[81]	600.2 (23.6)	650.0 (1430.0)[82]
Scanner Desktop Computer (Open Console)	576 (22.7)	616.0 (24.3)	400.0 (15.7)	48.1 (106)
PDU -61 (Power Pro Option)	1062.0 (41.8)	701.0 (27.6)	551.0 (21.7)	361.4 (796.0)[83]
PDU -91 (Power Xtream Option)	1062.0 (41.8)	701.0 (27.6)	551.0 (21.7)	423.1 (933.0)[83]
UPS	1244.6 (49.0)	812.8 (32.0)	304.8 (12.0)	281.5 (620.0)
Reconstruction System Cabinet V	1420 (55.9)	1358 (53.5)	614 (24.2)	260 (573.2)[83]

Power Requirements	
Nominal Voltage	380 – 480 V AC
Nominal Line Frequency	50/60 Hz ± 3 Hz
Maximum Power Demand: PowerXtream Option	Requires 200 kVA electrical power supplied for PowerXtream, in addition to a Partial UPS that is included as standard.
Maximum Power Demand: PowerPro Option	Requires 150 kVA electrical power supplied for PowerPro, in addition to a Partial UPS that is included as standard.
Partial UPS with SmartPower (Standard)	Eaton Powerware 9355-15-14GE with SmartPower allows Eaton's 14.4 KVA 3-Phase partial system Uninterruptible Power Supply (Partial UPS) to provide clean, reliable and constant power to the Revolution Apex Plus system.

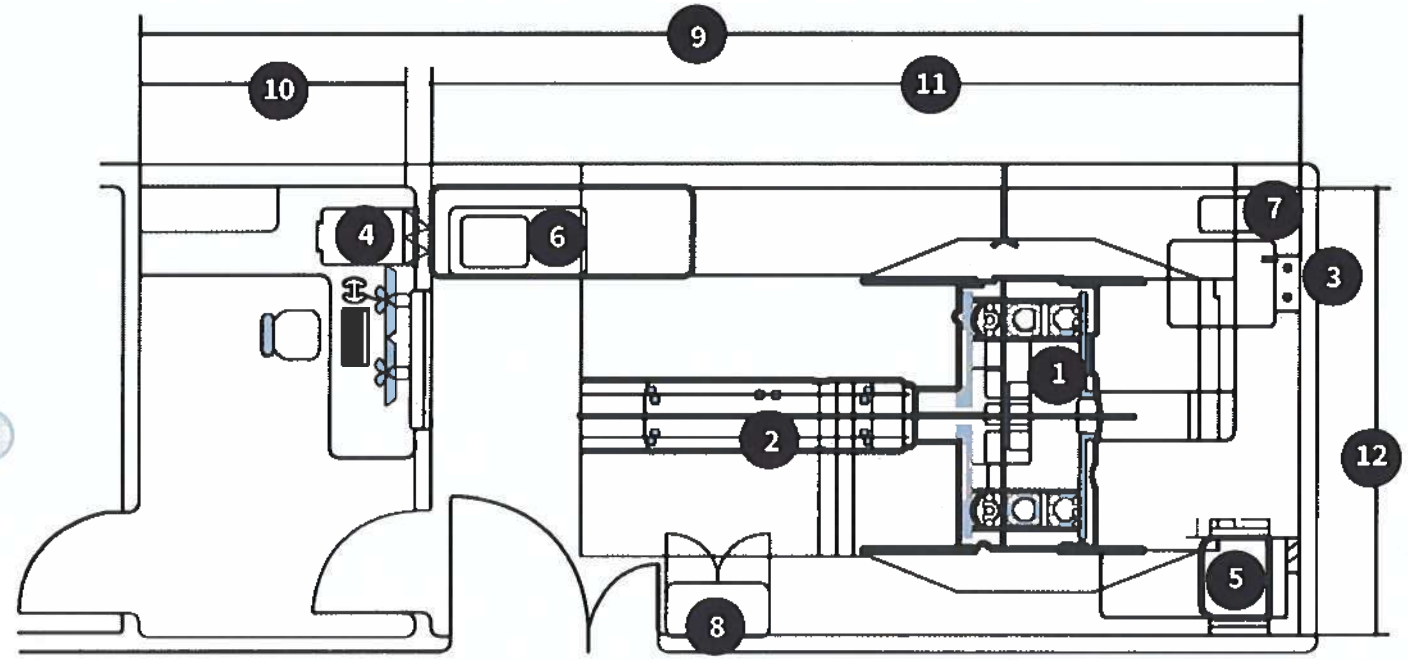
Environmental Requirements	
Temperature	• Gantry room: 18° C (64° F) to 25° C (77° F) • Storage/transport: +4 to +27° C (+40 to +80° F)
Humidity	• Installed: 30% to 70% (non-condensing) • Storage: 20 to 60% (non-condensing)
Heap Dissipation (Maximum) BTU/HR	• Gantry and patient table: 27,150 • PDU: 1,200 • Scan desktop (incl. 2 x monitors): 5,100 • System (recon) cabinet: 10,578 • UPS: 3,000

80. Speak to your local GE Healthcare representative for the most updated Pre-installation manual for detailed information.
81. Does not include extender of 400.00 mm (16 in).
82. Does not include patient load.
83. Does not include optional seismic brackets of 10.0 kg (22.0 lbs).

Site Planning *(cont.)*

Pre-installation Guidance *(cont.)*

Suggested Room Layout



1	Gantry
2	Table
3	A1 (Mains)
4	Scanner desktop
5	PDU
6	System (recon) cabinet
7	Partial UPS
8	Service (storage) cabinet – space requirements vary
9	Minimum regulatory scan suite length: • For NG2000V: 8,316.0 mm (27 ft 3.4 in) • For NG1700V: 7,716.0 mm (25 ft 3.8 in)
10	Minimum regulatory control room length: 1,499.0 mm (4.0 ft 11.0 in)
11	Minimum regulatory scan room length: • For NG2000V: 6,691.0 mm (21 ft 11.25 in) • For NG1700V: 6,091.0 mm (19 ft 11.8 in)
12	Minimum regulatory scan suite width: 3,560.0 mm (11.0 ft 8.2 in)

Cybersecurity, Warranty and Standards Compliance

Cybersecurity Controls

Revolution Apex Plus base software contains the Cybersecurity Controls to enhance the security and integrity of the system:

Enhanced access control is enabled by Role-based Access Controls (RBAC) and stronger password policies.

RBAC create role-based user accounts to provide users with exact privileges in order to perform their duties. It can protect data and critical components on the system by preventing unauthorized users from performing unintended operations. Additionally, password strength and change policies can be configured and enforced for all user accounts to allow stronger access control to both operating systems and clinical applications. Passwords stored on the system are encrypted with algorithms that are FIPS 140-2 compliant.

Inbuilt firewall protection reduces the attack surface and shields applications from Denial of Service (DoS) attacks.

Two levels of network firewall are provided:

- Operating System Firewall is on by default to prevent any attacks as well as spread of viruses or worms throughout the network;
- Router Firewall can be configured to manage inbound and outbound traffic only from pre-configured authenticated external systems, including back-office and cloud sources.

Audit Trails enables IT administrators to track, monitor and investigate cybersecurity events.

The Audit Trails tool can generate audit records of cybersecurity events including system state changes, user authentication, account management, patient data manipulation, network communications and service operations. It can also export audit records to a central server for long term data storage.

Data privacy is enabled with de-identification and encryption functions.

The Transport Layer Security (TLS) protocol is used to encrypt patient information when DICOM data is transferred from the CT scanner to DICOM destinations such as PACS, reading workstations, archive nodes and filmers. The Federal Information Processing Standards (FIPS) 140-2 compliant encryption algorithm is used to anonymize patient identification attributes when the data is collected for service purposes.

Anti-virus software

McAfee Anti-Virus software included as standard

Optional EPO – Enterprise

McAfee ePolicy Orchestrator (McAfee ePO) provides a centralized management console that simplifies and accelerates your security effectiveness with visibility and control from device to cloud. Requires connecting to EPO server for Virus Definition updates and license verification.

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.

Standards Compliance

This product complies with a wide variety of industry standards to facilitate more rapid adoption of features and performance improvements as the computing and medical imaging industry evolves.

This product is designed to comply with applicable standards under the Radiation Control for Health and Safety Act of 1968.

This product complies with the performance standards of 21 CFR, sub-chapter J, and the applicable IEC 60601-1 series.

This product complies with NEMA XR 29-2013.

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 laser standard IEC 60825-1

This product complies with laser standard IEC 60825-1:2007-03.
IEC Class 1M Laser Product.
LASER RADIATION. DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS. DO NOT EXPOSE USERS OF TELESCOPIC OPTICS.
Max Power Per IEC: 0.39mW,
Wavelength: 635nm

This product satisfies regulations regarding Electro-Magnetic Compatibility (EMC) and Electro-Magnetic Interference (EMI), pursuant to IEC 60601-1-2.

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