

Specificația tehnică completată

Sistem radiografic digital

Model: Proteus XR/f; Producător: GE Helthcare si SEDECAL; Țara: SUA si Spania

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină solicitată de către oferant
<p>Sistem radiografic digital</p> <p>Descriere Sistem radiografic pentru uz general, libertate de mișcare și multiple configurări. Aria largă de mișcare a mesei, cu posibilitatea de ajustare a limitelor, bucky-ului și a stativului vertical permit expuneri de la cap pînă la degetul piciorului fără să fie necesară re poziționarea pacientului.cu posibilitate de control a mișcarilor sistemului din trei puncte: stația de lucru, panou de comandă general, panou de comandă suspensie-tub.</p> <p>Parametru Specificația</p> <p>Modul radiologic Digital Detector unic da</p> <p>Tip masă Tip Piedestal</p> <p>Suport electric da</p> <p>Mișcarea mesei Longitudinală, cm de la 80</p> <p>Laterala, cm de la 20</p> <p>Caracteristici Densitatea mesei <1 mm Al</p> <p>Dimensiunea minim 220 cm x 82,5 cm</p> <p>Înălțimea de la podea- fixa intre valorile 70-80 cm</p> <p>Miscarea mesa tip manuala</p> <p>Controlul mesei este prin intermediu comutatorul de picioare da</p> <p>Firina/ sistem de blocare tip electromagnetice</p> <p>Greutatea maximă a pacientului, kg de la 250 kg</p> <p>Spatiu pentru detector cm $\geq 35 \times 43$</p> <p>Sistemul BUCKY a mesei</p> <p>Tip control manual</p> <p>Braț Orizontal complet controlabel da</p> <p>Mișcarea logitudionala a tubului ≥ 140 cm</p> <p>Mișcarea verticala a tubului ≥ 150 cm</p> <p>Punctul focal de la podea minim de la 40 pina la 190 cm</p>	<p>Sistem radiografic digital DA</p> <p>Descriere Sistem radiografic pentru uz general, libertate de mișcare și multiple configurări. Aria largă de mișcare a mesei, cu posibilitatea de ajustare a limitelor, bucky-ului și a stativului vertical permit expuneri de la cap pînă la degetul piciorului fără să fie necesară re poziționarea pacientului.cu posibilitate de control a mișcarilor sistemului din trei puncte: stația de lucru, panou de comandă general, panou de comandă suspensie-tub. DA</p> <p>Parametru Specificația</p> <p>Modul radiologic Digital Detector unic DA</p> <p>Tip masa Tip Piedestal DA</p> <p>Suport electric DA</p> <p>Mișcarea mesei Longitudinală, cm 90 cm (+45; 0;-45) pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Laterala, cm 23 (+ 11,5; 0; -11,5) pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Caracteristici Densitatea mesei <1 mm Al pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Dimensiunea 220 cm x 82,5 cm pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Înălțimea de la podea- fixa 77 cm DA pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Miscarea mesa tip manuala DA pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Controlul mesei este prin intermediu comutatorul de picioare DA 4 comutaotede picioare pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Firina/ sistem de blocare tip electromagnetic DA pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Greutatea maximă a pacientului, kg - 300 kg DA pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Spatiu pentru detector cm maxim 43x43 cm DA pag. 3 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Sistemul BUCKY a mesei DA Bucky fără posibilitate de inclinare. pag. 5 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Tip control manual DA pag. 5 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Braț Orizontal complet controlabel DA pag. 5 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Mișcarea logitudionala a tubului - 148 cm DA pag. 2 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Mișcarea verticala a tubului - 150 cm DA pag. 2 din Proteus XR-f ST - Product Data Sheet_R4</p> <p>Punctul focal de la podea minim de la 40 pina la 190 cm</p>

Rotia tubului X-ray $\geq 180^\circ (+90^\circ, 0^\circ, -90^\circ)$	DA pag. 2 din Proteus XR-f ST - Product Data Sheet_R4 Rotia tubului X-ray - $180^\circ (+90^\circ, 0^\circ, -90^\circ)$
Sistem de blocare electromagnetic	DA pag. 2 din Proteus XR-f ST - Product Data Sheet_R4 Sistem de blocare electromagnetic DA pag. 2 din Proteus XR-f ST - Product Data Sheet_R4
BUCKY vertical Spatiu pentru detector $\text{cm} \geq 35 \times 43$	BUCKY vertical Spatiu pentru detector cm maxim $43 \times 43 \text{ cm}$ DA pag. 5 din Proteus XR-f ST - Product Data Sheet_R4
Punerea detectorului minim din dreapta si stinga	Punerea detectorului din dreapta si stinga DA pag. 5 din Proteus XR-f ST - Product Data Sheet_R4
Sistem de blocare electromagnetic	Sistem de blocare electromagnetic DA pag. 5 din Proteus XR-f ST - Product Data Sheet_R4
Deplasarea verticala, cm minim 150 cm (de la 40 -190 cm)	Deplasarea verticala, cm 150 cm (de la 40 -190 cm) DA pag. 5 din Proteus XR-f ST - Product Data Sheet_R4
Control Manual	Control Manual DA pag. 5 din Proteus XR-f ST - Product Data Sheet_R4
Detector Mărimea detector, $\text{cm} \geq 35 \times 43$	Detector Mărimea detector, cm 35×43 DA pag. 8 din Proteus XR-f ST - Product Data Sheet_R4
Configurare detector Rezoluția matricei, pixeli minim 1900x2000	Configurare detector Rezoluția matricei, pixeli 1994x2430 pag. 8 din Proteus XR-f ST - Product Data Sheet_R4
Caracteristicile detectorului Distanța dintre pixel $\leq 175 \mu\text{m}$	Caracteristicile detectorului Distanța dintre pixel $175 \mu\text{m}$ DA pag. 8 din Proteus XR-f ST - Product Data Sheet_R4
Tip de ransmiter Wi-fi	Tip de ransmiter Wi-fi DA pag. 8 din Proteus XR-f ST - Product Data Sheet_R4
Funcția AED da B	Funcția AED DA pag. 8 din Proteus XR-f ST - Product Data Sheet_R4
loc / Sistem de incarcare separat fara cablu de interconectare da	Bloc / Sistem de incarcare separat fara cablu de interconectare DA nu necesită conectare unui cablu la detector pentru alimentarea / incarcarea acumulatorului AeroDR Docking Station II
Scintilator / materialul de dectie CsI	Scintilator / materialul de dectie CsI DA pag. 8 din Proteus XR-f ST - Product Data Sheet_R4
Acumulator intern inclus tip Lithium Ion Tipul de lucru in regim AED ≥ 125 de expuneri	Acumulator intern inclus tip Lithium Ion DA Tipul de lucru in regim AED - 250 de expuneri pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
Greutatea admisibila pe tota suprafata este de minim 300 kg	Greutatea admisibila pe tota suprafata este de 300 kg DA
Conectarea Fără fir Wi-fi	Conectarea Fără fir Wi-fi DA
Generator de raze X	Generator de raze X
Caracteristici	Caracteristici
Intensitatea maximă la 120 kV $\geq 50 \text{ kW}$	Intensitatea maximă la 125 kV - 50 kW DA pag. 6 din Proteus XR-f ST - Product Data Sheet_R4
Timpul de expunere in intrevalul minim 0.001-10 sec	Timpul de expunere in intrevalul 0.001-10 sec DA pag. 6 din Proteus XR-f ST - Product Data Sheet_R4
Intervalul mAs minim 0.1mAs-640mAs	Intervalul mAs 0.1mAs-640mAs DA pag. 6 din Proteus XR-f ST - Product Data Sheet_R4
Tubul de raze X	Tubul de raze X
Dimensiunea spotului focal, mm 0.6 si 1.2	Dimensiunea spotului focal, mm 0.6 - 1.2 DA pag. 6 din Proteus XR-f ST - Product Data Sheet_R4
Voltajul anotic minim 150 kVp	Voltajul anotic 150 kVp DA pag. 6 din Proteus XR-f ST - Product Data Sheet_R4

Rata de răcire, HU/min \geq 300000	Rata de răcire, HU/min - 300 KHU = 300.000,00 HU DA pag. 7 din Proteus XR-f ST - Product Data Sheet_R4
Panou de control pe tubul radiologic da Controlul razelor X a tubului montat da Spot focal mic \leq 20 kW	Panou de control pe tubul radiologic DA Controlul razelor X a tubului montat DA Spot focal mic -20 kW DA pag. 7 din Proteus XR-f ST - Product Data Sheet_R4
Spot focal mare \geq 50 kW	Spot focal mare -50 kW DA pag. 7 din Proteus XR-f ST - Product Data Sheet_R4
Colimator Tip obligatoriu LED	Colimator Tip obligatoriu LED DA pag. 4 din Proteus XR-f ST - Product Data Sheet_R4
Puterea \geq 160 lx	Puterea - 160 lx DA pag. 4 din Proteus XR-f ST - Product Data Sheet_R4
Filtrul 2.0 mm aluminiu	Filtrul 2.0 mm aluminiu DA pag. 4 din Proteus XR-f ST - Product Data Sheet_R4
Suspensia tubului Control razelor x a tubului montat da Statia de lucru	Suspensia tubului Control razelor x a tubului montat DA Statia de lucru
Calculator Procesor minm I5 la 3,0 MHz	Calculator Procesor minm I5 la 3,0 MHz DA pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
Memorie RAM minim 4 GB	Memorie RAM 4 GB DA pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
HDD minim 320 GB HDD	HDD 320 GB HDD DA pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
Sistem de operare minim Win 7 PRO	Sistem de operare Win 7 PRO DA pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
Placa de reata Standartul RJ-45 minim 2 porturi	Placa de reata Standartul RJ-45 2 porturi DA pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
Display tip LCD Multi-Touch DA	Display tip LCD Multi-Touch DA pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
Rezoluția minim 1920x1080	Rezoluția 1920x1080 DA pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
Diagonala \geq 23 inch	Diagonala - 23 inch DA pag. 9 din Proteus XR-f ST - Product Data Sheet_R4
Soft de achizitie Implimentarea unei baze de pacienti (nume, prenume, anul de nastere sex etc) da	Soft de achizitie Implimentarea unei baze de pacienti (nume, prenume, anul de nastere sex etc) DA pagina 16, 88, 100 din CS7
Comunicarea cu date tip DICOM da Protocole de lucru preinstalte sa indice denumirea protocalleor de catre ofertant disponibile da	Comunicarea cu date tip DICOM DA Protocole de lucru preinstalte sa indice denumirea protocalleor de catre ofertant disponibile DA CAP, GIT, PIEPT, ANDOMEN, SPINARE, TORAX, UPE, LOE etc iar fiecare din menul de sus are sub meniuri pentru crea fiecarei imagine fata, spate, lateral dreapta lateral stinga etc ca exemplu este indicat protocolul CHEST pag. 42 - 43 131 din CS7
Pozibilitatea de cautarea in baza de date dupa parametri ca ID, Nume, Prenume etc. da	Pozibilitatea de cautarea in baza de date dupa parametri ca ID, Nume, Prenume etc. DA 6.2.3 Display of examinations with refied search pag. 125, 126 din cs7
Instrume de prelucrarea a imaginilor da	Instrume de prelucrarea a imaginilor DA pag. 67 din cs7
Posibilitate de modificare a protocoalelor de lucru da	Posibilitate de modificare a protocoalelor de lucru DA se face impreuna cu trainirul de la producator
Modul de iradier	Modul de iradier Capitolul 3.5 din cs7

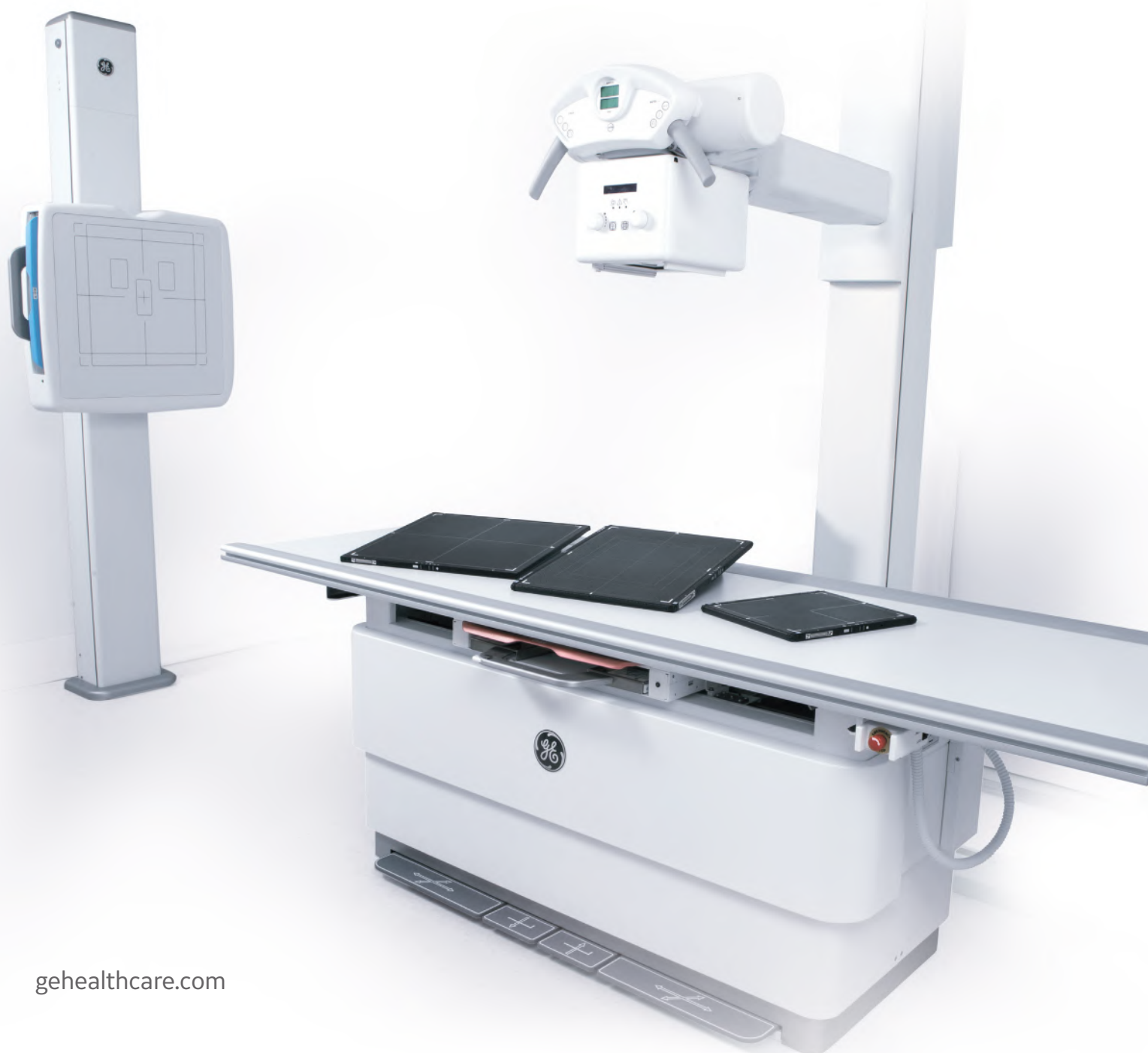
Manual Automat Automatizare in prelucarea imaginii da Posibilitatea de conectare minim 2 Printere DICOM minim 4 Statiti DICOM UPS Conform caracteristicilor electrice a calculatorului da Accesorii DAP metru inlcus da Cerințe față de alimentarea electrică Standard Prezenta inginerului calificat cu training de la producător pentru sisteme radiologice da Prezentarea graficului de venire a ingienrului pentru mententa in perioada de garantie da Certicate CE valabil da Declaratie de conformitate pentru produsul propus da Autorizatie de la producator pentru ofertant da	Manual DA Automat DA Automatizare in prelucarea imaginii DA Posibilitatea de conectare 2 Printere DICOM DA 4 Statiti DICOM DA UPS Conform caracteristicilor electrice a calculatoruluida DA Accesorii DAP metru inlcus DA Cerințe față de alimentarea electrică DA Standard DA Prezenta inginerului calificat cu training de la producător pentru sisteme radiologice DA Prezentarea graficului de venire a ingienrului pentru mententa in perioada de garantie DA Certicate CE valabil DA Declaratie de conformitate pentru produsul propus DA Autorizatie de la producator pentru ofertant DA
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Proteus XR/f

The logical step to digital radiography

Now a single digital x-ray room accommodates nearly all your radiographic studies



gehealthcare.com

Acquire **high-quality, dose-efficient** images

Optimize dose and get consistent image quality with the proven, robust AeroDR cesium iodide wireless flat-panel detectors from Konica Minolta.

- Choose from a range of standard cassette size detectors to suit your most common exam types and patient population: 10 x 12 inch/25 x 30 cm, 14 x 17 inch/35 x 43 cm or 17 x 17 inch/43 x 43 cm.
- Complete exams quickly with an image preview that is available in one second. Fully processed images can be seen within six seconds.
- Detectors charge in the wall stand and table bucky and can last an entire shift, up to 8.2 hours or 300 images.
- Panel drop sensors and monitoring provide data on panel handling, helping to avoid failures while reducing repair costs.
- Detectors are built to withstand extreme environments, everyday bumps and mishaps. With no external battery, they are fully sealed and can be wiped clean with approved cleaners in order to fulfill infection prevention protocols.



Image anyone with ease and comfort



The flexible table accommodates patients of all sizes

- The bariatric table supports a capacity of up to 770 pounds/350 kg and the table measures 86 x 31 inches/220 x 80 cm.
- The four-way float elevating tabletop makes it easy for patients to get onto the table, lowering from 35 inches/90 cm to 19 inches/49 cm above the floor.
- The table moves longitudinally and transversely across a wide travel range to position patients for the optimum field of view and imaging.



Expanded tube coverage increases patient positioning flexibility

- The floor-beam-mounted tube stand travels to clear the table for imaging at the wall stand.
- The tube can be lowered for below-the-knee exams or untethered exams with the wireless detector to image patients in wheelchairs or on gurneys.
- The tube stand travel distance is 79 inches/201 cm longitudinal, 59 inches/150 cm vertical, and 12 inches/30 cm lateral from mid-table. Rotation is +/- 180 degrees.



The versatile and robust floor-mounted design enables you to perform a wide range of dose-efficient radiographic exams, from head-to-toe on patients of all sizes and ages. With extended tube coverage and wireless detectors, Proteus XR/f gives you full flexibility to image patients on the table, at the wall stand, or anywhere in the room.

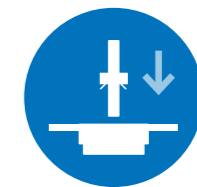
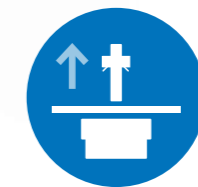


Make exams **easy** for patients and staff

The Proteus XR/f is incredibly easy to use. It is so intuitive that operators who are familiar with analog or digital X-ray systems can walk right up and get to work. Ergonomic design and easy patient positioning make exams nearly effortless.



- Technologists use a single interface and workstation to preview images, view final images and send images to the PACS with strong system integration.
- Detectors are lightweight, easy to carry and manipulate at 5.7 pounds/2.6 kg. Handy grip strips make positioning easy.
- Position controls are intuitive and handy. The tabletop responds to foot pedal controls, moving the table laterally or longitudinally and adjusting the field of view.
- The system can be configured for auto-tracking, so that the tube and table or wall stand track each other – when one moves, the other moves with it, preserving source-to-image distance.



Outfit your facility easily and affordably

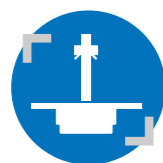
The compact, floor-mounted design and range of power options enable simple, economical siting in a variety of environments, including hospitals, outpatient clinics, imaging centers, urgent care centers, orthopedic clinics and even physician's offices.

Good fit for smaller rooms

- Proteus XR/f helps remove space, infrastructure and budget constraints in creating x-ray rooms.
- The compact footprint of the system makes it easy to fit into smaller spaces, while floor mounting helps you avoid the expense of ceiling-mounted suspension systems.
- The system is available in auto tracking, elevating table and standard table configurations tailored to your clinical needs.

Flexible power options

- A range of generator power options add more siting versatility and power saving opportunities.
- Choose from single-phase (50 kW) or three-phase (65 kW and 80 kW) generators.



Get expert service you can trust

Proteus XR/f comes backed by a local GE service team with a proven record of prompt response, accurate diagnosis and fast, definitive repairs – so you can expect high uptime and uninterrupted patient care.

- You have access to one of the largest support teams and knowledgeable field engineers with high qualification and training.
- Remote technical support with GE Healthcare experts is available 24/7 to solve your service calls 3x quicker* than on-site intervention helping you drive productivity and minimal downtime.



Stay sharp with training and clinical education

Effective training enables clinicians with the knowledge and skills to use the Proteus XR/f system and other GE technologies to their full potential. GE Healthcare offers numerous clinical and applications training options, on site and online, to fit your needs and schedule.

Bring your team up to speed quickly, keep up with new advanced applications, train new hires, provide refreshers for existing staff, and provide continuing education credits, all with minimal impact on patient flow.

- **GE Healthcare Learning System** - The online platform where you can view courses online, view recorded Live Experts of webinars, download pocket guides, and assign courses to your team to help them grow personally and be more productive.
- **AppsLinq™** - Provides a two-way interactive live remote training session where the trainee can watch the trainer perform step-by-step actions and repeat them for an immediate application of newly learned skills without the cost of distance training.
- **@Live Expert** - Learn from experts who share their clinical and/or technical expertise during a one-hour interactive live session to win maximum confidence on a specific topic in no time.
- **GE Cares** - Your community from collective intelligence, fueled by GE equipment users, radiographers and radiologists on any topic of interest. You can participate, share, connect and learn from your peers, at any time.





GE Healthcare



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GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world.

GE (NYSE: GE) works on things that matter - great people and technologies taking on tough challenges.

From medical imaging, software and IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients.

GE imagination at work

Data subject to change

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JB48390XXa



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zgl.de
 BS-MDR-099



Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
 (Class IIa and Class IIb Devices)

No. G10 075707 0078 Rev. 00

Device Group
 Echographic Instruments

Risk Classification
 IIa

**The validity of this certificate
 depends on conditions and/or
 is limited to the following:** None

**Revision History including
 Changes:** 00 / 2020-05-13 / 713175299

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



Certificate of Completion

This certifies that

Andrei Guranda

has successfully completed

Proficient_MR Service Qualification

Completed on 1/19/2018



CERTIFICATE OF ACHIEVEMENT

PRESENTED TO: **Andrei Guranda**

IN RECOGNITION OF HAVING COMPLETED THE PRESCRIBED COURSE OF STUDY FOR

CT Modality Level 1 with MRTS Service Training (DL)

GEHC-TT-97028475

05.10.2015 – 08.10.2015



AS

Trainer

Andrei Guranda

Training & Education Manager



GE imagination at work

*This certificate is valid for two years starting from the date of issue

GE Healthcare – Europe Training Center

Certificate of Achievement

Presented to:

Guranda Andrei

In recognition of having completed the prescribed course of study for:

X-Ray Systems Fundamentals Service Training



The validity of this certificate is contingent upon continued employment with GE Healthcare or employment with an authorized service organization.

Date: 18th of January 2019

Tamás Erős / trainer

Charles Eve
Europe Services Training Manager



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu
SEONGNAM-SI, GYEONGGI-DO
Republic of Korea

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-03-17
Certificate Registration No.: SX 60146260 0001
An audit was performed. Report No.: 32090188 001
This Certificate is valid until: 2021-11-04

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-03-17



Balazs Bozsik

Balazs Bozsik

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60146260 0001
Report No.: 32090188 001

Organization: GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu
SEONGNAM-SI, GYEONGGI-DO
Republic of Korea

Scope: Design and Development, Manufacture and Final Test of
Ultrasound Diagnostic Devices and Systems

Site Included:
GE Ultrasound Korea, Ltd.
65-1, Sangdaewon-dong, Jungwon-gu
Seongnami-si, Gyeonggi-do
462-120 Republic of Korea

Design and Development, Manufacture and Final Test of
Ultrasound Diagnostic Devices and Systems

Certification Body



Date: 2020-03-17

Balk Balazs
Balazs Bozsik



GE Healthcare
Technologies

Kuortaneenkatu 2
Helsinki, FI-00031 GE
Finland

T +358 10 39411
F +358 9 146 3310

25.08.2021

Manufacturer's Authorization Form

To: **Centrul pentru Achizitii Publice Centralizate pentru Sanatate**

Tender: **21042698 - Privind Achiziția Dispozitivelor medicale, conform necesităților beneficiarilor lista suplimentară 11, pentru anul 2021 prin procedura de achiziție**

WHEREAS we, **GE Healthcare**, reputable manufacturers respectively suppliers of the offered

X-Ray Systems Proteus XR/f

do hereby guarantee the quality and the performances of the offered products and authorize **Intermed SRL, office 618, 65 Tighina Street, 2001 Chisinau, Republic of Moldova**, to submit a bid and subsequently negotiate and sign the Contract with you against a.m. tender, organized by Centrul pentru Achizitii Publice Centralizate pentru Sanatate, for the above goods manufactured respectively supplied by us.

Also, Intermed SRL is the authorized company to provide service for the GE products on the territory of the Republic of Moldova.

GE Healthcare Finland Oy

Name:
Title: **Mikko Kauppinen**
Date: **Financial Controller**

GE Healthcare Finland Oy

Name:
Title: **Jorma Seppälä**
Date: **Accounting Manager**

General Electric Company
GE Healthcare Finland Oy

Business ID 1897064-6
Domicile Helsinki
VAT No. FI18970646

Nordea Bank
Aleksis Kiven katu 3-5
FI-00500 Helsinki, Finland
Bank SWIFT-address
Nordea Bank NDEAHFIHH



EC Certificate Full Quality Assurance System: Certificate ES97/9864

The management system of

Sociedad Española de Electromedicina y Calidad, S.A. (SEDECAL)

Poligono Industrial Rio de Janeiro, C/ Pelaya, 9-13
28110 Algete, Madrid. Spain

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 04 March 2017 until 19 July 2020
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 19 July 2018

Issue 51. Certified since 20 May 1997

Certification is based on reports numbered ES/MAD 133585

This is a multi-site certification.

Additional site details are listed on subsequent pages.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

2026 World Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0311 M6

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Released



EC Certificate Full Quality Assurance System: Certificate ES97/9864, continued

Sociedad Española de Electromedicina y Calidad, S.A. (SEDECAL)

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 51

Detailed scope

X-Ray Generator SHF:

SHF-1010, SHF-1015, SHF-1020, SHF-1025, SHF-1030, SHF-1035,
SHF-1610, SHF-1615, SHF-1620, SHF-1625, SHF-1630, SHF-1635,
SHF-210, SHF-215, SHF-220, SHF-225, SHF-230, SHF-235,
SHF-310, SHF-315, SHF-320, SHF-325, SHF-330, SHF-335,
SHF-410, SHF-415, SHF-420, SHF-425, SHF-430, SHF-435,
SHF-510, SHF-515, SHF-520, SHF-525, SHF-530, SHF-535,
SHF-610, SHF-615, SHF-620, SHF-625, SHF-630, SHF-635, SHF-835,
SHF-1610 PSU, SHF-1615 PSU,
SHF-210 PSU, SHF-215 PSU,
SHF-310 PSU, SHF-315 PSU,
SHF-410 PSU, SHF-415 PSU, SHF-510 PSU, SHF-515 PSU
SHF-1610-C, SHF-1615-C,
SHF-210-C, SHF-215-C,
SHF-310-C, SHF-315-C,
SHF-410-C, SHF-415-C,
SHF-510-C, SHF-515-C
SHF-0510-M, SHF-0530-M, SHF-1010-M, SHF-1030-M,
SHF-0510-MPSTA, SHF-1010-MPSTA

X-Ray Generator SHFR:

SHFR100, SHFR200, SHFR300, SHFR400, SHFR500, SHFR600, SHFR800

X-Ray Generator HERCULES:

HERCULES-32, HERCULES-40, HERCULES-50, HERCULES-65, HERCULES-80

Battery Mobile X-Ray Unit EASY MOVING:

SM-20HF-Batt, SM-32HF-Batt, SM-40HF-Batt, SM-50HF-Batt
SM-20HF-B-D-C, SM-32HF-B-D-C, SM-40HF-B-D-C, SM-50HF-B-D-C
SM-20HF-B-D-V, SM-32HF-B-D-V, SM-40HF-B-D-V, SM-50HF-B-D-V
SM-20HF-B-D-T, SM-32HF-B-D-T, SM-40HF-B-D-T, SM-50HF-B-D-T
SM-20HF-B-D-TEZ, SM-32HF-B-D-TEZ, SM-40HF-B-D-TEZ, SM-50HF-B-D-TEZ
SM-20HF-B-D-S, SM-32HF-B-D-S, SM-40HF-B-D-S, SM-50HF-B-D-S
SM-20HF-B-D-FDX, SM-32HF-B-D-FDX, SM-40HF-B-D-FDX, SM-50HF-B-D-FDX
SM-20HF-B-D-FDXW, SM-32HF-B-D-FDXW, SM-40HF-B-D-FDXW,
SM-50HF-B-D-FDXW
SM-20HF-B-D-KM (AeroDR X30), SM-32HF-B-D-KM (AeroDR X30),
SM-40HF-B-D-KM (AeroDR X30), SM-50HF-B-D-KM (AeroDR X30)

Page 2 of 5

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EC Certificate Full Quality Assurance System: Certificate ES97/9864, continued

**Sociedad Española de
Electromedicina y Calidad, S.A.
(SEDECAL)**

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)

Issue 51

Capacitor Mobile X-Ray Unit MOBIXRAY:
SMR-16, SMR-20, SMR-32

Portable X-Ray Unit SPL:
SPL-HF-2.0, SPL-HF-4.0, SPL-HF-8.0

Portable X-Ray Unit DRAGON X:
SPSL-HF-4.0, SPSL-HF-8.0,
SPSL-HF-4.0-APR, SPSL-HF-8.0-APR,
SPSLW4, SPSLW8
SPSL4HC, SPSL8HC

Radiographic System SEDECAL X:
SEDECAL X BRS (BRX),
SEDECAL X URS,
SEDECAL X PLUS LP,
SEDECAL X PLUS LP PLUS

Radiographic System MILLENNIUM:
MILLENNIUM (Proteus XR/i), Composed of:
Tube stand MILLENNIUM: MILL-FMFS
Tube stand AD MILLENNIUM: MILL-FMFSAD
Fixed height Table MILLENNIUM: MILL-FWFTT-B
Elevating Table MILLENNIUM: MILL-EL-B
Wall Stand MILLENNIUM: MILL-WBS
Tomography MILLENNIUM: MILL-TOMO
Power Supply: BRAKE BOX

MILLENNIUM PLUS AT, Composed of:
Tube stand MILLENNIUM PLUS AT: MILL-FMFSAT-PLUS
Elevating Table MILLENNIUM PLUS AT: MILL-ELAT-PLUS
Wall Stand MILLENNIUM PLUS AT: MILL-WBSAT-PLUS
Wall Stand Manual Tilting: TWBS-TILT
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS

MILLENNIUM PLUS TPC, Composed of:
Tube stand MILLENNIUM PLUS TPC: MILL-FMFSAT-PLUS
Elevating Table MILLENNIUM PLUS TPC: MILL-ELTTPC-PLUS
Wall Stand MILLENNIUM PLUS TPC: MILL-WBSTPC-PLUS
Wall Stand Manual Tilting: TWBS-TILT
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS

Page 3 of 5

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EC Certificate Full Quality Assurance System: Certificate ES97/9864, continued

Sociedad Española de Electromedicina y Calidad, S.A. (SEDECAL)

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 51

Radiographic System PROTEUS XR/f:

PROTEUS XR/f ET, Composed of:
 Tube stand MILLENNIUM: MILL-FMST
 Tube stand AD MILLENNIUM: MILL-FMSTAD
 Fixed height Table MILLENNIUM: MILL-FWFTT-B
 Elevating Table MILLENNIUM: MILL-EL-B
 Wall Stand MILLENNIUM: MILL-WBS
 Tomography MILLENNIUM: MILL-TOMO
 Power Supply: BRAKE BOX

PROTEUS XR/f AT, Composed of:
 Tube stand MILLENNIUM PLUS AT: MILL-FMSTAT-PLUS
 Elevating Table MILLENNIUM PLUS AT: MILL-ELAT-PLUS
 Wall Stand MILLENNIUM PLUS AT: MILL-WBSAT-PLUS
 Wall Stand Manual Tilting: TWBS-TILT
 Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS

PROTEUS XR/f ST, Composed of:
 Tube stand MULTIRAD: MULT-FMS
 Table MULTIRAD: MULT-FWFTT
 Wall Stand MULTIRAD: MULT-WBS
 Power Supply: BRAKE BOX

Radiographic System MULTIRAD:
 MULTIRAD (Proteus XR/e), Composed of:
 Tube stand MULTIRAD: MULT-FMS
 Table MULTIRAD: MULT-FWFTT
 Wall Stand MULTIRAD: MULT-WBS
 Power Supply: BRAKE BOX

MULTIRAD NET, Composed of:
 Tube stand MULTIRAD: MULT-FMS
 Elevating Table NET 4000: NET 4000-ST
 Wall Stand MULTIRAD: MULT-WBS
 Wall Stand MILLENNIUM: MILL-WBS
 Power Supply: BRAKE BOX

Page 4 of 5

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EC Certificate Full Quality Assurance System: Certificate ES97/9864, continued

**Sociedad Española de
Electromedicina y Calidad, S.A.
(SEDECAL)**

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)

Issue 51

Radiographic System NOVA:

NOVA FA Composed of:
Ceiling Suspension NOVA: NOVA FA
Elevating Table NET 4000: NET 4000-AU
Moving Elevating Table: FLEXI-DT
Wall Stand NBS 2100: NBS 2100-AU

NOVA AT Composed of:
Ceiling Suspension NOVA: NOVA AT
Elevating Table NET 4000: NET 4000-AT
Moving Elevating Table: FLEXI-DT
Wall Stand NBS 2100: NBS 2100-AT
Wall Stand Manual Tilting: TWBS-TILT

NOVA ST Composed of:
Ceiling Suspension NOVA: NOVA ST
Elevating Table NET 4000: NET 4000-ST
Moving Elevating Table: FLEXI-DT
Wall Stand NBS 2100: NBS 2100-ST
Wall Stand Manual Tilting: TWBS-TILT

X Ray Generator Console:
CTSC

Ozone Generator:
OM-302, OM302E, OM302IE, OM302IU, OM302IJ
OZONOBARIC P
OZONETTE

Radiographic Unit Control Software:
SedewareControl1

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

**Poligono Industrial Río de Janeiro C/ Rafael Pillado Mourelle, 6 Nave C-5
28110 Algete, MADRID, Spain**

Poligono Industrial Río de Janeiro C/ Navas, 3, 28110 Algete, MADRID, Spain

Page 5 of 5

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Proteus XR/f

The logical step to digital radiography

Image any patient who comes in the door

Proteus XR/f



-  Image anyone with ease and comfort
-  Fit your facility easily and affordably
-  Acquire high-quality, dose-efficient images
-  Make exams easy for patients and staff
-  Get expert service you can trust
-  Stay sharp with training and clinical education



Image anyone with ease and comfort

Flexible table to image anyone with ease and comfort.

- The 86 x 31-inch (220 x 80 cm) bariatric table has a 770-pound (350 kg)* capacity to accommodate patients from smallest to largest.
- The four-way float elevating tabletop travels from 35 inches (90 cm) above the floor to 19 inches (49 cm), helping patients get on as easily as if sitting down in a chair.
- It moves longitudinally and transversely over a wide travel range to position patients for the optimum field of view and imaging.

*Available on the Proteus XR/f ET



Image anyone with ease and comfort

Expanded tube coverage from table to wallstand

- The floor-beam-mounted tube stand travels to clear the table for imaging at the wall stand.
- It can be lowered for below-the-knee exams or used for untethered exams with the wireless detector to image patients in wheelchairs or on gurneys.

Some technical specs.

- Tube stand travel is 79 inches/31 cm longitudinal, 59 inches/23 cm vertical, and 12 inches/4.7 cm lateral from mid-table.
- Rotation is 180 degrees.



Fit your facility easily and affordably



Good fit for smaller rooms.

- The compact, floor-mounted design enable simple, economical siting in a variety of environments: Hospitals, outpatient clinics and imaging centers, urgent care and orthopedic centers, physician's offices and others.
- Proteus XR/f helps remove space, infrastructure and budget constraints in creating X-ray rooms. The compact footprint accommodates smaller spaces; floor mounting avoid the expense of ceiling-mounted suspension systems.



Acquire high-quality, dose-efficient images



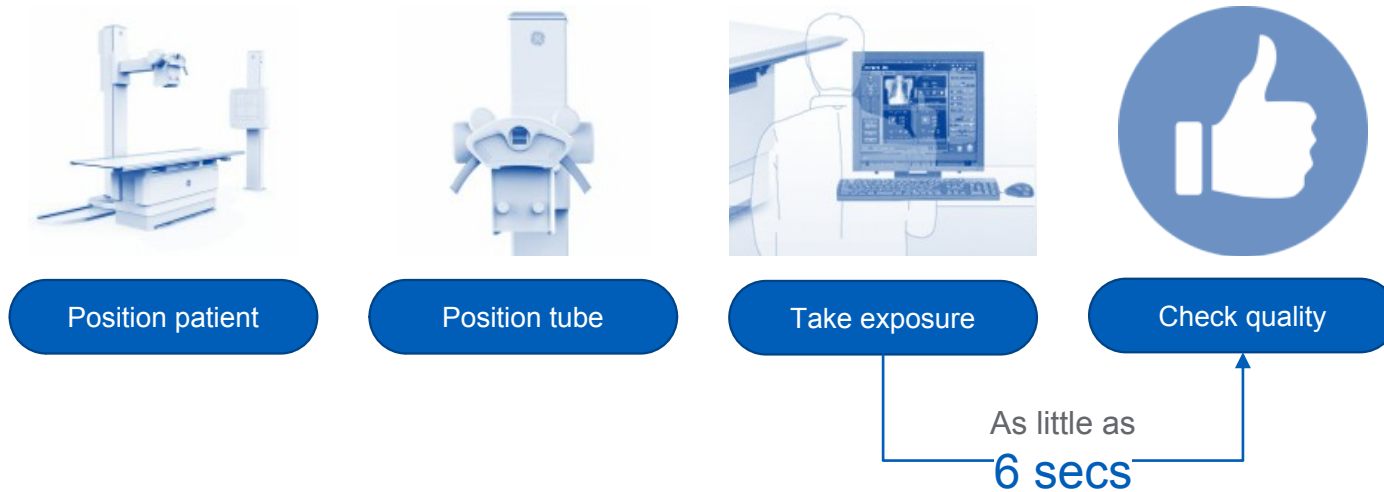
Proven, robust Konica Minolta Aero DR cesium iodide wireless flat-panel detectors deliver consistent image quality at efficient dose.

- **Choice of sizes.** Select 10 x 12-inch, 14 x 17-inch or 17 x 17-inch standard cassette size detectors to suit your most common exam types and your patient population.
- **Reliable performance.** With a lithium ion capacitor, detectors last an entire shift, up to 8.2 hours or 300 images. Panel drop sensors and monitoring provide data on panel handling, helping to avoid failures and reduce repair costs.
- **Extreme durability.** Detectors are built to withstand extreme environments and everyday bumps and mishaps. Fully sealed with no external battery, they can be wiped clean with approved cleaners to fulfill infection prevention protocols.



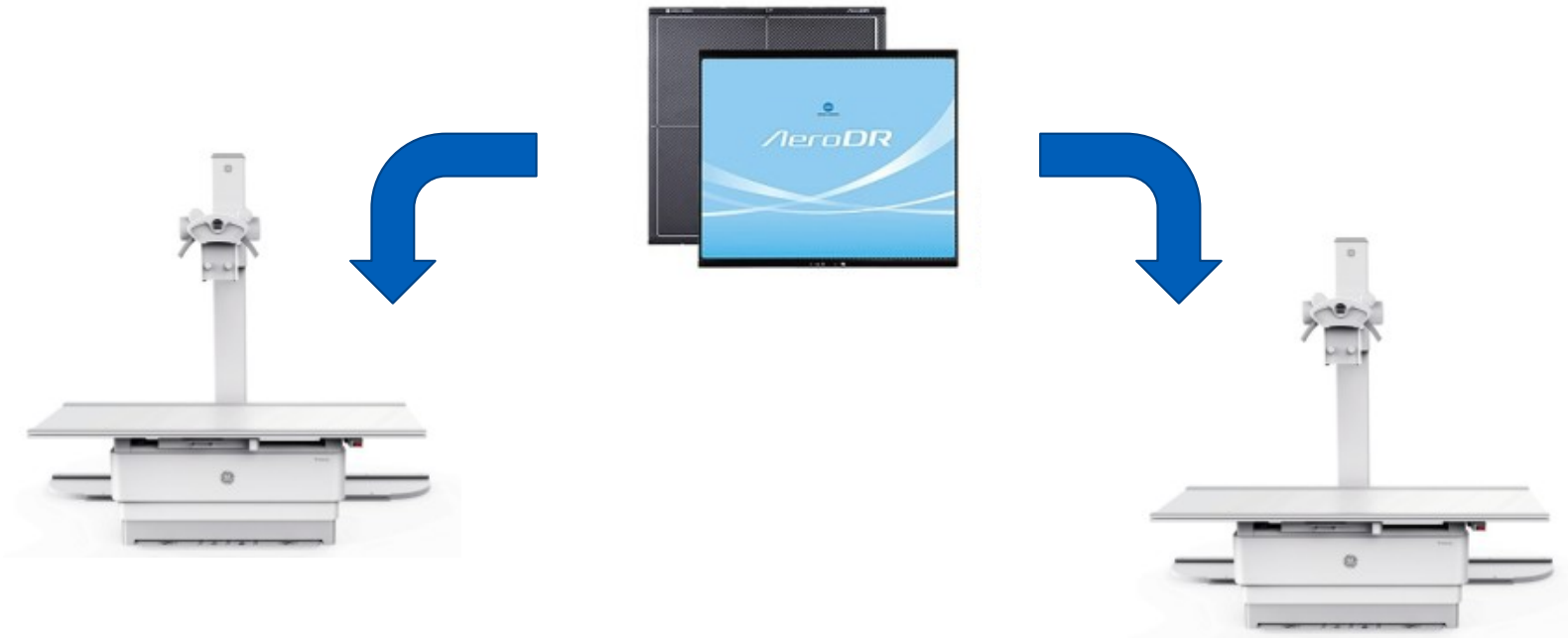
Simple to use

Complete exams fast with image preview in one second and fully processed images in as little as six seconds.



Shareability

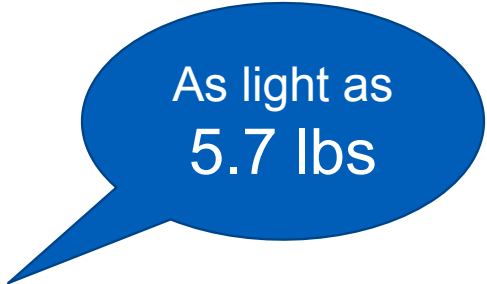
Wireless detectors can be shared between general radiography rooms, DR mobile systems, and retrofit rooms. They can be used with non-GE systems that are already registered with the Konica Minolta detectors.



Make exams easy for patients and staff

The Proteus XR/f is incredibly easy to use. It is so intuitive that operators familiar with analog or digital X-ray systems can walk right up and go to work. Ergonomic design and easy patient positioning make exams nearly effortless.

- **System integration.** Technologists use a single interface and workstation to preview images, view final images and send to PACS.
- **Lightweight detectors.** Konica Minolta detectors are easy to carry and manipulate at 5.7 pounds/2.6 kg. Handy grip strips make positioning easy.
- **Pushbutton positioning.** Position controls are intuitive and easy to use. The tabletop responds button-based controls, moving the table laterally or longitudinally and adjusting the field of view.



As light as
5.7 lbs



Get expert service you can trust

Proteus XR/f comes backed by a local GE service team with a proven record of prompt response, accurate diagnosis and fast, definitive repairs – so you can expect high uptime and uninterrupted patient care.

**Minimized
unplanned
downtime**
Securing
patient
throughput

**Clinical
excellence**
with continuous
education
program

**Return on
investment**
Thanks to
predictable
costs



Stay sharp with training and clinical education



Effective imaging requires clinicians with the knowledge and skills to use the Proteus XR/f system and other GE technologies to their full potential.

- GE Healthcare offers numerous clinical and applications training options, on site and online, to fit your needs and schedule. Bring your team up to speed quickly, keep up with new advanced applications, train up new hires, provide refreshers for existing staff, and provide continuing education credits, all with minimal impact on patient flow.





SEDECAL

DECLARACIÓN CE DE CONFORMIDAD CON EL MARCADO CE
 (DIRECTIVA DE PRODUCTOS SANITARIOS 93/42/CEE ENMIENDA 2007/47/CE-REAL
 DECRETO 1591/2009)

EC DECLARATION OF CONFORMITY FOR CE MARKING
 (FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICE DIRECTIVE 93/42/EEC & AMENDMENT 2007/47-
 SPANISH ROYAL DECREE 1591/2009)

Nosotros
 We

SEDECAL, Sociedad Española de Electromedicina y Calidad, S.A.
C/Pelaya 9, Polígono Industrial Río de Janeiro, 28110 Algete (Madrid), España

Declaramos bajo nuestra responsabilidad que los productos Clase IIb:
 Declare under our sole responsibility that the Products Class IIb:

Sistema Radiográfico PROTEUS XR/f (Radiographic System PROTEUS XR/f):
PROTEUS XR/f ET

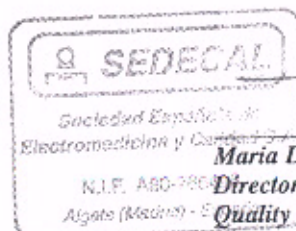
GMDN Code: 37645.

están en conformidad con los Requisitos Esenciales que le son aplicables (Anexo I).
 are in compliance with the Essential Requirements which apply to them (Annex I)
 y con las normas armonizadas que le son de aplicación:
 and with the applicable harmonized standards:
 EN 6001-1:2006, EN 60601-1-2:2007, EN 60601-1-3:2008, EN 60601-2-28:2010 and EN 60601-2-54:2009.

Esta conformidad está basada en los siguientes elementos:
 This conformity is based on the following elements:

- La información contenida en los “Archivos Técnicos 30 y 74” de los productos al que esta declaración hace referencia.
 Information included in the “Technical Files 30 & 74” of the Product to which this declaration relates.
- Certificado CE de aprobación del Sistema completo de Aseguramiento de la Calidad (Anexo II) emitido por el Organismo Notificado Nº 0120, SGS United Kingdom Ltd. Certificate No. ES97/9864.
 CE certificate : approval of full of Quality Assurance System (Annex II) delivered by the Notified Body No. 0120, SGS United Kingdom Ltd., Certificate No. ES97/9864.

Fecha (Date): 17/ 05 / 2017



Maria Luisa Gómez de Agüero Gómez
Directora de Calidad y Reglamentación
Quality & Regulatory Director

Released

SEDECAL

DECLARACIÓN CE DE CONFORMIDAD CON EL MERCADO CE
(DIRECTIVA DE PRODUCTOS SANITARIOS 93/42/CEE ENMIENDA 2007/47/CE-REAL
DECRETO 1591/2009)

EC DECLARATION OF CONFORMITY FOR CE MARKING
(FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICE DIRECTIVE 93/42/EEC & AMENDMENT 2007/47-
SPANISH ROYAL DECREE 1591/2009)

Nosotros
We

SEDECAL, Sociedad Española de Electromedicina y Calidad, S.A.
C/Pelaya 9, Polígono Industrial Río de Janeiro, 28110 Algete (Madrid), España

Declaramos bajo nuestra responsabilidad que los productos Clase IIb:
Declare under our sole responsibility that the Products Class IIb:

Sistema Radiográfico PROTEUS XR/f (Radiographic System PROTEUS XR/f):
PROTEUS XR/f ST

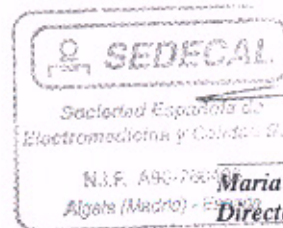
GMDN Code: 37645.

están en conformidad con los Requisitos Esenciales que le son aplicables (Anexo I).
are in compliance with the Essential Requirements which apply to them (Annex I)
y con las normas armonizadas que le son de aplicación:
and with the applicable harmonized standards:
EN 6001-1:2006, EN 60601-1-2:2007, EN 60601-1-3:2008, EN 60601-2-28:2010 and EN 60601-2-54:2009.

Esta conformidad está basada en los siguientes elementos:
This conformity is based on the following elements:

- La información contenida en los "Archivos Técnicos 51 y 74" de los productos al que esta declaración hace referencia.
Information included in the "Technical Files 51 & 74" of the Product to which this declaration relates.
- Certificado CE de aprobación del Sistema completo de Aseguramiento de la Calidad (Anexo II) emitido por el Organismo Notificado Nº 0120, SGS United Kingdom Ltd. Certificate No. ES97/9864.
CE certificate : approval of full of Quality Assurance System (Annex II) delivered by the Notified Body No. 0120, SGS United Kingdom Ltd., Certificate No. ES97/9864.

Fecha (Date): 17/05/2017



Maria Luisa Gómez de Agüero Gómez
Maria Luisa Gómez de Agüero Gómez
Directora de Calidad y Reglamentación
Quality & Regulatory Director

SEDECAL

DECLARACIÓN CE DE CONFORMIDAD CON EL MERCADO CE
(DIRECTIVA DE PRODUCTOS SANITARIOS 93/42/CEE ENMIENDA 2007/47/CE-REAL
DECRETO 1591/2009)

EC DECLARATION OF CONFORMITY FOR CE MARKING
(FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICE DIRECTIVE 93/42/EEC & AMENDMENT 2007/47-
SPANISH ROYAL DECREE 1591/2009)

Nosotros
We

SEDECAL, Sociedad Española de Electromedicina y Calidad, S.A.
C/Pelayo 9, Polígono Industrial Río de Janeiro, 28110 Algete (Madrid), España

Declaramos bajo nuestra responsabilidad que los productos Clase IIb:
Declare under our sole responsibility that the Products Class IIb:

Sistema Radiográfico PROTEUS XR/f (Radiographic System PROTEUS XR/f):
PROTEUS XR/f AT

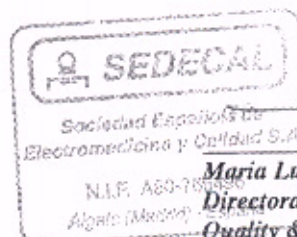
GMDN Code: 37645.

están en conformidad con los Requisitos Esenciales que le son aplicables (Anexo I).
are in compliance with the Essential Requirements which apply to them (Annex I)
y con las normas armonizadas que le son de aplicación:
and with the applicable harmonized standards:
EN 6001-1:2006, EN 60601-1-2:2007, EN 60601-1-3:2008, EN 60601-2-28:2010 and EN 60601-2-54:2009.

Esta conformidad está basada en los siguientes elementos:
This conformity is based on the following elements:

- La información contenida en los “Archivos Técnicos 59 y 75” de los productos al que esta declaración hace referencia.
Information included in the “Technical Files 59 & 75” of the Product to which this declaration relates.
- Certificado CE de aprobación del Sistema completo de Aseguramiento de la Calidad (Anexo II) emitido por el Organismo Notificado N° 0120, SGS United Kingdom Ltd. Certificate No. ES97/9864.
CE certificate : approval of full of Quality Assurance System (Annex II) delivered by the Notified Body No. 0120, SGS United Kingdom Ltd., Certificate No. ES97/9864.

Fecha (Date): 17/ 05 / 2017



Maria Luisa Gómez de Agüero Gómez
Directora de Calidad y Reglamentación
Quality & Regulatory Director



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declarații de conformitate CE

Введите текст для поиска...										
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			proteus xr/f							
DM000189467	UNITATE DE RADIODIAGNOS DIGITALĂ		PROTEUS XR/F ST		Spania	SEDECAL, SOCIEDAD ESPAÑOLA DE ELECTROMEDIC Y CALIDAD, S.A.	INTERMED S.R.L.	A07.PS-01.Rg04-363	10-12-2018	
DM000189466	UNITATE DE RADIODIAGNOS DIGITALĂ		PROTEUS XR/F ET		Spania	SEDECAL, SOCIEDAD ESPAÑOLA DE ELECTROMEDIC Y CALIDAD, S.A.	INTERMED S.R.L.	A07.PS-01.Rg04-363	10-12-2018	
DM000189468	UNITATE DE RADIODIAGNOS DIGITALĂ		PROTEUS XR/F AT		Spania	SEDECAL, SOCIEDAD ESPAÑOLA DE ELECTROMEDIC Y CALIDAD, S.A.	INTERMED S.R.L.	A07.PS-01.Rg04-363	10-12-2018	

[Содержит\(\[Model\], 'proteus xr/f'\)](#) [Очистить](#)



Proteus XR/f

Patient positioning guide



PROTEUS XR/F

Now a single digital x-ray room accommodates nearly all your radiographic studies. With extended tube coverage and wireless detectors, Proteus XR/f gives you full flexibility to image patients on the table, at the wall stand, or elsewhere in the room. With its versatile and robust floor-mounted design, you can perform a wide range of dose-efficient radiographic exams, from head to toe, on patients of all sizes, ages, and degrees of mobility.

Cross table hip - right

Positioning:

- Patient supine on the table, arms across upper chest
- Cushion for patients head
- Flex and elevate unaffected leg so that the thigh is as near vertical position as possible and outside of the collimation field. Support the leg in this position with (sponge, chair or on the collimator)
- Check to ensure no rotation of the pelvis
- Place detector in crease above iliac crest and adjust so that it is parallel to femoral neck and perpendicular to central ray (use a dedicated detector holder)
- Internally rotate affected leg 15° to 20° (do not attempt to internally rotate if fracture or dislocation suspected), sandbags may be used to maintain this position

Imaging technique:

FOV: 24 x 30 cm
SID: 100 cm

Alignment:

CR perpendicular to long axis of femoral neck and centered at mid point.

Notes:



Cross table hip - left

Positioning:

- Patient supine on the table, arms across upper chest
- Cushion for patients head
- Flex and elevate unaffected leg so that the thigh is as near vertical position as possible and outside of the collimation field. Support the leg in this position with (sponge, chair or on the collimator)
- Check to ensure no rotation of the pelvis
- Place detector in crease above iliac crest and adjust so that it is parallel to femoral neck and perpendicular to central ray (use a dedicated cassette holder)
- Internally rotate affected leg 15° to 20° (do not attempt to internally rotate if fracture or dislocation suspected), sandbags may be used to maintain this position

Imaging technique:

FOV: 24 x 30 cm
SID: 100 cm

Alignment:

CR perpendicular to long axis of femoral neck and centered at mid point.

Notes:



Sunrise (tangential patella)

Positioning:

- Patient supine on the table with feet resting on table
- Cushion for patients head
- Have patient flex affected knee/s slowly until patella is perpendicular to IR, if condition permits.
- Check to ensure CR perpendicular to detector
- Adjust leg so that no rotation occurs

Imaging technique:

FOV: proper to anatomy
SID: 100 cm

Alignment:

CR perpendicular to joint space. Angulation depends on degree of flexion of the knee.

Notes:



Modified merchant view (tangential patella)

Positioning:

- Patient supine on the table with feet resting on table
- Cushion for patients head
- Have patient flex affected knee/s slowly until patella is perpendicular to detector, if condition permits
- Adjust leg so that no rotation occurs

Imaging technique:

FOV: Proper to anatomy
SID: 100 cm

Alignment:

CR perpendicular to joint space. Angulation depends on degree of flexion of the knee.

Notes:



Axial shoulder (superior-inferior) at table

Positioning:

- Have the patient seated close to the end of the table
- Place the detector close to the patient
- Ask the patient to hold the hand of the affected side and raise the arm to a position near as possible at right angles to the long axis of the body
- Then have the patient lean laterally over the detector until the shoulder joint is over the center of the detector
- Bring the elbow to rest on the table
- Flex the patient elbow and place the hand in a prone position
- Have the patient tilt the head towards the unaffected shoulder

Imaging technique:

FOV: 24 x 30 cm
SID: 100 cm

Alignment:

CR to shoulder joint at an angle of 5° to 15° towards the elbow.

Notes:



Wheelchair (seated) chest

Positioning:

- Have the patient seated in wheelchair with erect positioning
- Place the detector behind the patient
- Have the patient place sufficient pressure against the detector and back of wheelchair

Imaging technique:

FOV: 35 x 43 cm
(landscape or portrait)
SID: 180 cm

Alignment:

CR centered at level
of T7, perpendicular
to detector.

Notes:



Knee weight bearing

Positioning:

- Patient erect, standing
- Posterior portion of knee of patient against the upright receptor
- Position feet straight ahead with weight evenly distributed on both feet (support handles may be required for some patients)
- Align and center bilateral legs and knees to detector

Imaging technique:

FOV: Collimated to part
SID: 100 cm

Alignment:

CR perpendicular to detector or 5° to 10° caudal on thin patients, directed to a midpoint between the knee joints, 1.2cm below the apex of the patella.

Notes:



Weight bearing feet/ankles

Positioning:

- Patient is erect with weight evenly distributed
- Have patient stand on step stool
- Provide support for patient to hold onto
- Long axis of the foot centered to long axis of cassette

Imaging technique:

FOV: 24 x 30 cm
SID: 100 cm

Alignment:

CR perpendicular to detector at midfoot.

Notes:



Shoulder AP

Positioning:

- Patient standing with back to upright receptor (can be performed supine)
- Check the patient is standing up straight (their upper mid-coronal plane is vertical and parallel to detector)
- Rotate the patient slightly, if necessary, so that their affected shoulder is in contact with the upright receptor

Imaging technique:

FOV: 24 x 30 cm landscape
SID: 100 cm

Alignment:

CR Directed to the glen humeral joint, perpendicular to the detector.

Notes:



Chest PA WS

Positioning:

- Patient erect, standing or seated, facing the receptor
- Arms relaxed at the sides
- Centre the midsagittal plane of the patient to the midline of the detector
- Have the patient relax their shoulders and rolled forward to touch the receptor
- Adjust the height of the receptor so that the upper border of the IR is 5cm (2 inches) above the shoulders
- Raise the chin and rest on or above the receptor
- Clear the scapulae off the lung fields by getting the patient to either:
 - A. "Hug" the bucky by bringing the forearms behind the bucky, or
 - B. Place the back of their hands against their lower hips

Imaging technique:

FOV: 35 x 43 cm landscape usually, but may be portrait depending on body habitus.
SID: 180 cm

Alignment:

CR Directed to the midsagittal plane at the level of T7, perpendicular to the detector.

Notes:



C Spine AP

Positioning:

- Take care to ensure no rotation of either the head, neck or torso
- Using the upright receptor, position the patient in an AP position. (This allows the patient to rest their back against the receptor, and may help to minimize patient movement)
- Position the midsagittal plane so that it is perpendicular to the IR
- Position the interpupillary line so that it is parallel to the IR (in an erect patient, this will also be parallel to the floor)
- Raise the chin slightly, so that the line of the occlusal plane superimposes the base of the skull

Imaging technique:

FOV: 24 x 30 cm
SID: 100 cm

Alignment:

Directed to the level of C4, which is approximately the level of the angle of the mandible 15 degrees cephalad.

Notes:



Elbow lateral table

Positioning:

- Patient seated at end of table
- Elbow flexed to 90°
- Raise table or drop shoulder so that humerus and forearm are at the same plane
- Rotate hand and wrist into a true lateral position, with thumb up
- Place support under hand and wrist to elevate hand and distal forearm (so forearm is parallel to detector)

Imaging technique:

FOV: 24 x 30 cm
SID: 100 cm

Alignment:

To the mid elbow joint
4cm medial to posterior
surface of olecranon
process perpendicular
to detector.

Notes:



Abdomen

Positioning:

- Patient is supine on the table
- Cushion for head
- Patient's arms slightly abducted from the torso
- Positioned without rotation of the pelvis and torso
- Center to the midsagittal plane of the patient to the midline of the detector

Imaging technique:

FOV: 24 x 35 cm
SID: 100 cm

Alignment:

CR directed to the midsagittal plane at the level of the iliac crests.

Notes:





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GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter - great people and technologies taking on tough challenges.

From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients.

GE imagination at work

Data subject to change

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Proteus XR/f ST

PRODUCT DATA SHEET



TECHNICAL DATA:

FLOOR MOUNTED TUBE STAND	
Design	Manual movement, with fully counter balanced horizontal tube arm
Longitudinal tube travel	148 cm (248 cm optional)
Vertical tube travel	150 cm
Focal spot-to-floor distance	Variable from 40 to 190 cm
X-ray tube rotation	± 180° (detents at +90°, 0°, -90°)
Tube stand column rotation	± 90° (detents at +90°, 0°, -90°) (optional)
Locks	Electromagnetic brakes
Transverse table top travel	30 cm (±15 cm) (optional)
Table locks	Electromagnetic brakes
Tube arm console controls	Longitudinal, transverse, vertical, and rotational lock control buttons
Options	Floor-Mounted Tube stand PROTEUS XRF longitudinal tube travel 148 cm. With telescopic Arm and rotation
	Floor-Mounted Tubestand Tracking bucky fix SID, longitudinal travel 148cm

FIXED TABLE

Table top dimensions	220 cm x 82,5 cm
Height from floor	77 cm
Table top composition	Laminated structure (according to EN 438 standard)
Table top-to-film distance	10.2 cm
Table top Al. equivalence	< 1 mm Al. at 100 kVp
Table top weight limit	300 kg
Table top movement	Manual, 4-way floating top
Longitudinal travel	90 cm (±45cm)
Transverse table top travel	23 cm (±11.5 cm)
Table locks	Electromagnetic brakes
Table lock controls	Full-length foot switch along table base
Bucky travel	51.8 cm Total center-to-center
Radiographic coverage	180 cm
Grid*	40 lines/cm - 12:1 linear ratio Focused at 100 cm
Detector Bucky Sizes	Sizes from 35x43 cm either orientation and 43x43 cm
Auto-charging system with LED indicator	
Easy rotational detector	
Options	Mechanical attachment allows for detector Auto-tracking with x-ray beam

*See optional grids available

COLLIMATOR

Collimator type	Manual (Multilayer, square field X-ray collimator, 6 pairs of lead-lined shutters)
Field lamp	100 W, 24 VAC
Lighting timer	30 sec.
Average luminosity	160 lx.
Alignment light	LED
Inherent filtration	2.0 mm aluminum (EN 60601-1-3)
SID measuring	Retractable measuring tape

OPTIONS

External DAP for Manual Collimator	External DAP with rails for a Manual collimator upgrade. Dose area meter VacuDAP 2004 inter-phased with the generator. cable 15m.
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WALL STAND

Standard type	Non-tilting Bucky
Vertical Bucky travel	150 cm (from 40 to 190 cm)
Vertical movement	Manual, fully counterbalanced
Film center to Floor	43 cm
Minimum distance	40 cm
Detector Bucky Sizes	Sizes from 35x43 cm either orientation and 43x43 cm
Auto-charging system with LED indicator	
Easy rotational detector	
Grid*	40 lines/cm - 12:1 - linear ratio Focused at 150 cm
Al. equivalence	< 0.85 mm at 100 kVp
Locks	Electromagnetic brakes
Detector load	Left or Right load
Weight	145 kg

*See optional grids available

HIGH FRECUENCY GENERATOR SHF

	50 KW	65 KW	80 KW
KW Maximum Power	Single-Phase 220/240 VAC		Three-Phase 380/480 VAC
KVp Range (1kVp steps)	40 – 125 Kvp (150Kvp optional) Accuracy: ±(3% + 1 kVp)		40 – 150 Kvp Accuracy: ±(3% + 1 kVp)
mA Range	10 – 640 mA (19 steps, Renard scale)	10 to 630**	10 to 800mA (20 steps, Renard scale)
	10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100, 125, 160, 200, 250, 320, 400, 500/ 630** Accuracy: ±(4% + 1 mA)		
Power Output (0,1s)	640 mA @ 78 KVp 500 mA @ 100 KVp 400 mA @ 125 KVp 320 mA @ 150 KVp	630 mA @ 100 kVp 630 mA @ 103 kVp 500 mA @ 125 kVp 500 mA @ 130 kVp 400 mA @ 150 kVp	500 mA @ 150 KVp 640 mA @ 125 KVp 800 mA @ 100KVp
Exposure Time Range	0.001 – 10 seconds Accuracy: ± (2% + 0.1 ms)		
mAs Range	0.1 mAs – 640 mAs (38 steps Renard scale) Accuracy: ± (10% + 0.2 mAs)		
High Voltage Ripple (Typ.)	<1kVp @ 100 kVp		
Anatomical Programming	534 Anatomical Views		
Battery Powered (option)	110 / 230 VAC - 500 W (1Phase) (Uninterruptible Power Supply)	N.A	
Automatic Line Comp.	± 15%		

Low Speed or High Speed (optional) Rotor Controller 1 Tube

Microprocessor Controlled

Auto diagnostic System

Tube overload protection monitoring of the remaining X-Ray Tube Heat Units

Prep./ Exposure X-ray Hand-switch

AEC

TUBE




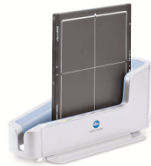
E7884X	X-ray tube Toshiba 12° 150 kVp dual focal spots 0,6 and 1,2 mm 300KHU LS 20/50 Kw (50Hz) 22/54 Kw (60Hz)
HSS-1T	High speed starter (3.000/9.000 r.p.m.) for one x-ray tube

Rad. X-Ray Tube			
Generator output power	50KW	65KW	80 KW
Tube Type	Rotating Anode (LS)	Rotating Anode (HS)	
Anode Voltage	150 kVp		
Speed starter	3,000 r.p.m.	(3,000 / 9,000) r.p.m.	
Focal spots	0.6 - 1.2 mm		
Power ratings			
Small Focal Spot	20 kW	27 kW	40 kW (180 Hz)
Large Focal Spot	50 kW	75 kW	102 kW (180 Hz)
Anode heat storage capacity	300 KHU		400 KHU
Target angle	12°		

GRIDS
Grid 103 Lines (40 lines/cm), 10 :1, Focalized at 1 m
Grid 103 Lines, 10 :1, Focalized at 1,5 m
Grid 103 Lines 12:1, Focalized a 1,8 m
Grid 103 Lines, 10:1, Focalized at 1 m Carbon Fiber Cover
Grid 103 Lines, 12 :1, Focalized at 1,5 m Carbon Fiber Cover
Grid 103 Lines, 12 :1, Focalized at 1,8 m Carbon Fiber Cover

OPTIONS
Hands support for Wall stand
Hand Grip for Wall stand
Compression Band for table
Lateral detector Holder up to 35x43 cm
Lateral detector Holder movable on tabletop
Lateral detector size on trolley with wheels

WIRELESS DETECTORS

Manufacturer	Konica Minolta	Konica Minolta	Konicaminolta	Konicaminolta
Product Name	AeroDR 2 1417HQ AeroDR XE	AeroDR 1417LT	AeroDR 1717HQ 17"x17"	AeroDR 1012HQ 10"*12"
				
Detection Technology	Indirect-Conversion	Indirect-Conversion	Indirect-Conversion	Indirect-Conversion
Scintillator	CsI - Hi Quality Type	CsI - Standard Type	CsI - Hi Quality Type	CsI - Hi Quality Type
Dimensions (mm) (Width x Depth X Height)	383. x 460.27 x 15.9	383. x 460.27 x 15.9	459 x 460.2 x 15.9	281.1 x 333.0 x 15.9
Weight	2.6 kg (including battery)	2.5 kg / 5.5 Lbs. (including Power cel)	3.6 kg (including battery)	1.7 kg
WLAN Standard	IEEE 802.11a, 5 GHz IEEE 802.11n, 5 GHz/2.4GHz	IEEE 802.11a, 5 GHz IEEE 802.11n, 5 GHz/2.4GHz	IEEE 802.11a, 5 GHz band	IEEE 802.11a, 5 GHz band
DQE	at 1 mR, RQA5 65% (@ 0 cycle/mm) 51% (@ 1 cycle/mm)	at 1 mR, RQA5 42% (@ 0 cycle/mm) 35% (@ 1 cycle/mm)	at 1 mR, RQA5 65% (@ 0 cycle /mm) 51% (@ 1 cycle/mm)	at 1 mR, RQA5 65% (@ 0 cycle /mm) 51% (@ 1 cycle/mm)
MTF	Over 0.53 at 1cycle/mm	Over 0.53 at 1cycle/mm	Over 0.53 at 1cycle/mm	Over 0.53 at 1cycle/mm
Pixel Spacing	175µ	175µ	175µ	175 µ
Image Area Size (mm)	348.95 x 425.25 (1994x2430 Pixels)	348.95 x 425.25 (1994x2430 Pixels)	424.9 x 424.9	245.7 x 296.8
Image Pixel Size (pixels)	1,994 x 2,430	1,994 x 2,430	2,428 x 2,428	1,404 x 1,696
Preview time	less than 2 seconds (S-SRM Portable: approx. two seconds)	less than 2 seconds (S-SRM Portable: approx. two seconds)	less than 3 seconds	less than 2 seconds
Cycle Time (Exposure linkage with X-ray)	(CS-7) Approx. 4 seconds (wired) Approx. 6 seconds (wireless)	(CS-7) Approx. 4 seconds (wired) Approx. 6 seconds (wireless)	8.0 seconds with wired connection / 13.8 seconds with wireless connection	7 seconds with wired connection 9 seconds with wireless connection
AED function	Y	Y	Y	Y
Battery Technology	Lithium Ion Capacitor	Lithium Ion Capacitor	Lithium Ion Capacitor	Lithium Ion Capacitor
Battery Life time	Same duration as panel	Same duration as panel	Same duration as panel	Same duration as panel
Battery recharging time empty to full	Within 0.5 hour with AeroDR battery charger, AeroDR battery charger 2, AeroDR I/F cable	Within 0.20 hour (13 minutes) with AeroDR Docking Station II or AeroDR I/F cable	Within 0.5 hours when an AeroDR battery charger is used / within 1 hour when a decicated cable is used	Within 0.5 hours

Battery Performance (Exposure linkage with X-ray)	Up to 300 exposures and 8.2 hours	Up to 150 exposures and 4.1 hours *	Up to 173 exposures or 4.8 hours * under condition that the time interval between each study is five minutes and three images are captured in each study, assuming that it takes 20 seconds to position a patient. * Three minute recharging enables more than 10 images to be captured.	Up to 146 exposures or 4 hours * under condition that the time interval between each study is five minutes and three images are captured in each study, assuming that it takes 20 seconds to position a patient.
Battery Performance (AED)	Up to 250 exposures and 6.8 hours (General X-ray)	Up to 125 exposures and 3.4 hours (General X-ray)		
Memory function inside a panel	YES - Back-up only	YES - Back-up only		
Battery duration	Approx. 20 hours in standby mode	Approx. 16 hours in standby mode		Approx. 7.6 hours
Water resistance	IPX6	IPX6		
Drop impact resistance	Drop test from the height of 1m has been cleared.	Drop test from the height of 1m has been cleared.		
Digital shock sensor	Yes	Yes		
Max. withstanding load	150 kg @ 40 mm in diameter/ 300kg @ whole area	150 kg @ 40 mm in diameter/ 300kg @ whole area	150 kg @ 40 mm in diameter 300kg @ whole area	150 kg @ 40 mm in diameter 300kg @ whole area

CS-7 Universal Control Station Hardware

- Intel Core i5-2520 vPro processor, 3.2GHz, CD/DVD RW,
 - 4GB RAM
 - Win 7 PRO
 - 320 GB HDD
 - Intel PRO/1000 GT Network Connection
- 23" LCD Multi-touch Monitor - 178 degree Viewing Angle
 - 1920 x 1084 Native Resolution

Also Includes:

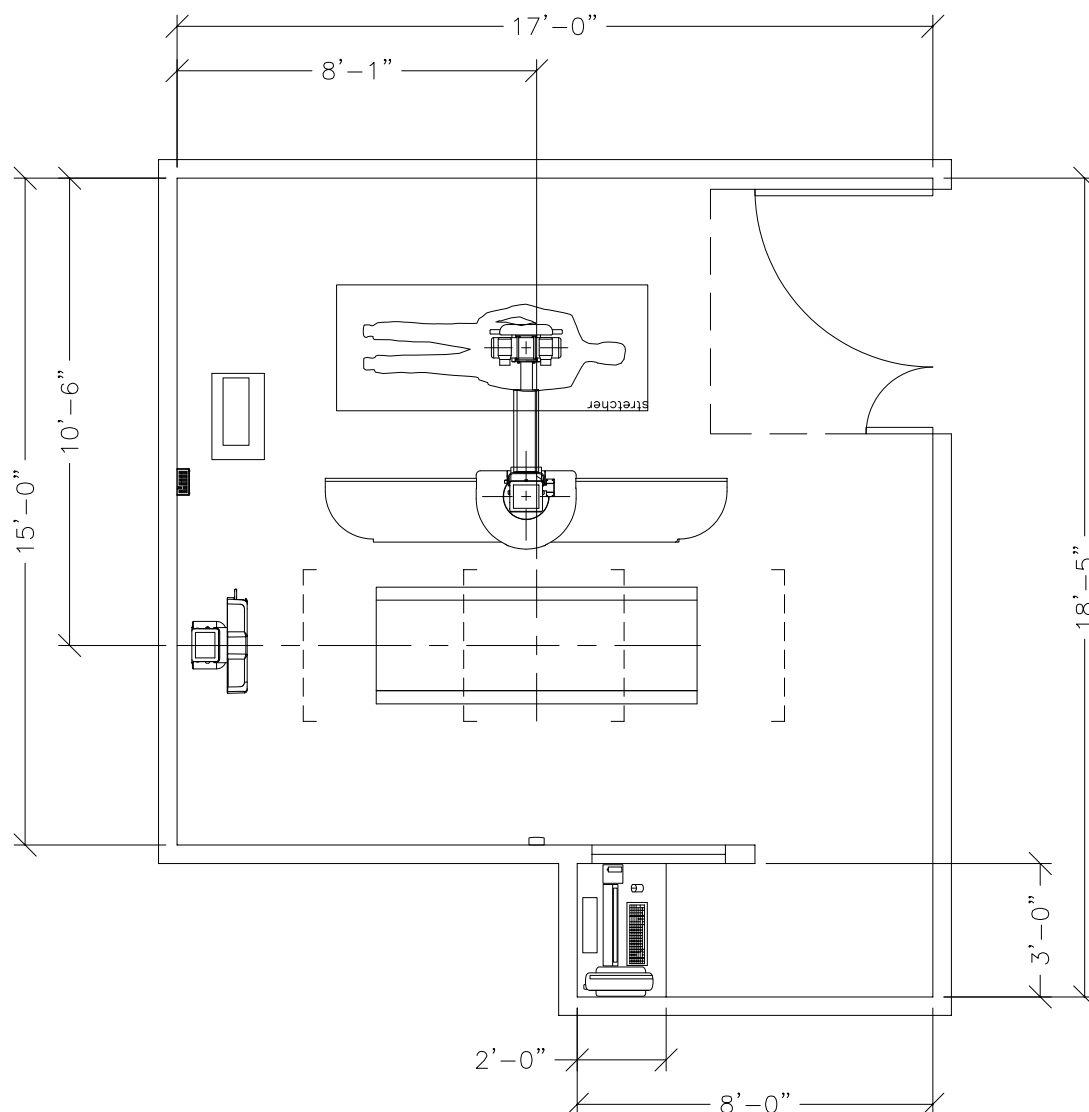
- Image Quality Optimization
- DICOM Store (x4 connections)
- DICOM Print (x2 connections)
- DICOM Modality Worklist
- MPPS Software License
- Aero DR Gen I/F SSRM kit
- Procedure Code Mapping
- Installation and Applications Training

CS-7 Universal Control Station Software

Features:

- CS-7 Operating Platform
- Hybrid Premium Image Processing Algorithm
- Equalization, Frequency & Gradation Processing
- Study Append
- Multi-Study capability
- Free Text Annotation
- Automatic Masking
- Study List Filter
- History Search
- Image Zoom
- Grid Suppression
- HIPAA compliance enabling features (Audit trail, Auto log-out)

ROOM LAYOUT



FULLY FUNCTIONAL LAYOUT:

NOTE: Layout allows for 3.5" deep surface wall duct between wall stand and generator. X-ray tube cable will drape from a ceiling box. This layout is ADA compliant.



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CERTIFICATE OF ACHIEVEMENT

This certifies that
Sergiu Sorocovici
has successfully completed

CT PROFICIENT SERVICE TRAINING

on

June 05, 2017



GE, Global Services Training & Documentation



imagination at work

