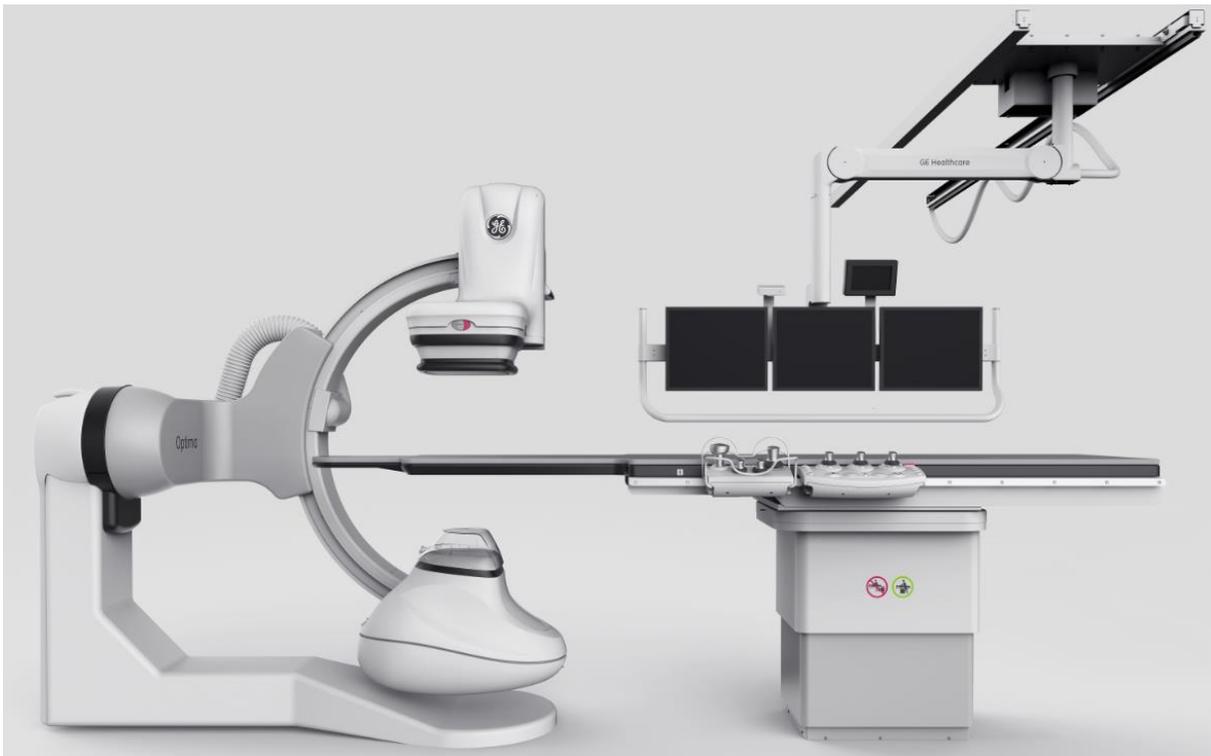




# Optima™ IGS 320

## PRODUCT DATA SHEET



# Table of Contents

I Image Chain .....	3
II Dose .....	6
III Applications .....	7
IV Gantry .....	10
V Patient Table.....	11
VI User interface .....	12
VII In room display .....	13
VIII Image management, connectivity and workflow.....	14
IX Privacy and Security .....	15
X Room Requirements .....	16

# I Image Chain

## X-Ray Generator

The IGS system uses a 100 kW high-frequency Jedi three-phase power unit that provides grid pulsed fluoroscopy capability.

Maximum power available	100 kW
Maximum kVp available	125 kVp
Maximum continuous input power	3200W for the tube unit
Pulse frequency	0.5 to 50 fps
Radiographic/recording mode	50 to 125 kVp
Radiographic mA ratings	1 - 1000 mA
Max. continuous power in fluoro mode	3200 W
Fluoroscopy mode	60 - 120 kVp
Fluoroscopy mA ratings	1 – 130 mA (up to 140 mA with PCI ASSIST)
Fluoroscopic timer	Yes

## X-Ray Tube

The IGS system is equipped with the high-performance, highly reliable Performix™ 160A metal X-ray tube, which meets requirements for all vascular applications.

Anode diameter	160 mm brazed graphite
Anode rotation	7800 rpm/ 130 HZ
Anode Target angle	11,25°
Anode heat storage capacity	2.7MJ (3.7 MHU)
Anode steady state heat dissipation	6.72 kW
Cathode	Bi-filament design
Coincident focal spot sizes	0.3, 0.6 and 1.0
Fluoroscopic power	<ul style="list-style-type: none"><li>• 3200 W (continuous)</li><li>• 4500 W (peak capability for maximum of 10 minutes)</li></ul>
Maximum casing heat storage	5.14 MJ (6.9 MHU)
Continuous casing heat dissipation	3200 W
Maximum anode cooling rate	544 KHU/min (6.72 kW)
Total filtration (IEC 60601-1-3)	1.0 mm Al
Leakage radiation (IEC 60601-1-3)	<50mR/h measured at 3.2kW (125kv, 25.4mA)

<b>Tube Cooling Unit</b>	<b>COOLIX 4100</b>
Cooling type	Closed-loop remote water chiller
Maximum Cooling capacity	4100 W
Flow rate	12 l/min
Coolant volume	23 liters in chiller + 17 liters in pipes
Dry weight	120kg+/- 5

Collimation	
Number of collimation blades	2 pairs
Spectral filtration	0.1, 0.2, 0.3, 0.6 and 0.9 mm of copper 1 integrated contour filter blades motorized, tapered filter blade that can be rotated 360° as well as translated in and out using a simple joystick control at table side

## Detector<sup>1</sup>

Detector manufacturer	GE
Size of the detector	20.5 cm x 20.5 cm
Material	Amorphous silicon photodiode array on a continuous-substrate
Pixel size	200 x 200 µm
Image matrix	1024 x 1024
Bit acquisition	14 bit

Mode @ Dose/Fr	
DQE values at average fluoro and record dose operating points	
Record, e.g. DSA 175 nGy (20 uR)	80%
Fluoro 8.8 nGy (1 uR)	77%
Additional DQE values at minimum fluoro dose operating point	
Fluoro 2.2 nGy (0.25 uR)	68%
Note: DQE values given are typical at f = 0 cycles/mm with RQA5 conditions as defined by IEC62220-1-3 standards	

**Anti-scatter Grid:** The system is configured with an anti-scatter grid to enhance image quality during routine imaging. Removal of the grid can improve the X-ray dose efficiency for infants (e.g. less than one-year-old) for field of view (FOV) smaller than 20 cm (7.9 in).

Grid ratio	13:1
Focal distance of the grid	100 cm (39in)
Grid Line frequency	70 LP/cm

<sup>1</sup>In clinical use, the results of dose reduction techniques will vary depending on the clinical task, patient size, anatomical location and clinical practice. Physicians assisted by a physicist as necessary have to determine the appropriate settings for each specific clinical task

## Image acquisition

Fluoroscopy modes	Non-subtracted, subtracted, roadmap, Blended Roadmap <sup>†</sup>
Fluoroscopy frame rate	30 fps, 15 fps, 7.5 fps and 3.75* fps
Fluorostore	450 fluoro images (up to 900)
Sub/no Sub simultaneous display <sup>†</sup>	Yes
Angio Acquisition Package	<ul style="list-style-type: none"> <li>• DSA (digital subtracted angiography) at 0.5 - 7.5 fps including Automated Pixel Shift</li> <li>• Multi-segment DSA with flexible frame rate and duration and single shot capabilities</li> </ul>
Dynamic Acquisition Package	30 fps, 15 fps and 7.5 fps
Innova Chase acquisition	5 fps
Digital output	1024 x 1024
Field-of-view adjustment from tableside with four magnification selections (records mode)	20 cm, 17 cm, 15 cm, and 12 cm
Image flip capability	Horizontal and vertical image flip capability for all acquisition
Shutter	Automated electronic shutter matched to collimated portion of image
Integrated X-ray dose tracking and in-room display of air kerma and dose area product	
A configurable audible tone is activated when using the fluoro mode	

\*: non-subtracted Fluoro mode only

## Image Processing and Review

Immediate auto-review of acquisition
Next and prior sequences or images
Slow and fast review of sequences, forward and reverse
Pause, adjust brightness and contrast during review
Image review with or without edge enhancement filters
Mask select, pixel shift
Store/recall reference images

## AutoRight™: Intelligent Image Chain Powered by Edison

AutoRight is the neural network-based image chain powered by Edison and digital twin, including embedded applied intelligence and advanced modelization featuring a complete re-design of GEHC IGS image chain.

AutoRight, is designed to deliver repeatable & faster choices, making image optimization fully automated, dynamically throughout the entire procedure, from acquisition, to processing and display, regardless of patient size, anatomy or C-arm angulations, which helps remove the burden of manual adjustment.

AutoRight is the right platform to address the growing demand for full combination capabilities in the interventional suite.

AutoRight's live parameter optimization provides consistent image quality with the patient's arms down throughout the whole spin. Not only is the image quality of these difficult acquisitions consistent and repeatable, which can reduce dose exposure, but it also enables the use of advanced applications such as virtual injection planning in 3D and the ability to simulate therapy efficacy. Overall, it allows the clinical team to better plan for, guide, and assess complex procedures in their daily practice.

AutoRight makes the machine an integral part of the team, capable of relieving clinicians and technologists of the tedious yet complex task of optimizing IQ and dose, helping them focus all their attention and expertise on their patients.

## II Dose

### - Dose Reduction

#### **Dose Personalization**

Several image-quality and dose strategies are available and can be customized for the various clinical acquisition protocols in both fluoro and record acquisitions.

### - Dose Awareness

#### **Integrated dose monitoring**

The user can monitor air kerma rate, integrated air kerma over the exam, and the total dose area product received by the patient during a procedure. The threshold of cumulated dose displayed on a gauge icon is customizable to warn operator when such threshold has been reached. The threshold is customizable depending on the protocol.

#### **Dose reporting**

The system provides DICOM\*\* compatible Radiation Dose Structured Report allowing the export of the dose and related acquisition parameters.

# III Applications

## 2D Applications

### InnovaChase™

InnovaChase™ is a dynamic, unsubtracted acquisition at a fixed frame rate of 5 fps with manual and remote panning of the table. It is optimized for visualization of a run off.

### Quantitative Analysis Package†

Stenosis Analysis† and Ventricle Analysis† allow the user to perform stenosis and left ventricle measurements and analysis. With OneTouchQA†, the user can select measurement points with a fingertip directly on the selected image frame displayed on the Central Touch Screen at tableside – no mouse or joystick is required. OneTouchQA† is available for stenosis analysis and distance measurements.

### PCI ASSIST†

**PCI ASSIST†** is an ASSIST package containing StentViz and StentVesselViz applications and including High Contrast Fluoro that increases the mA peak up to 36%, and decreases the pulse width by 38%. While the dose is equivalent, it is delivered in an efficient way that helps significantly reduce the blurring in the image due to organ motion.

### StentViz†

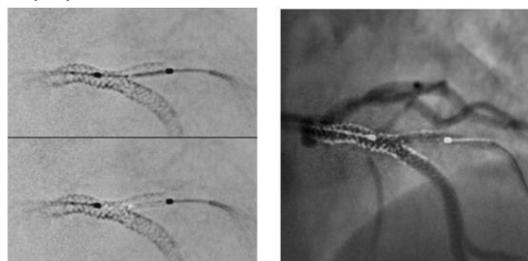
The StentViz option enhances visibility of the stent structure. It is particularly useful in verifying placement and deployment of stents during coronary interventions where moving arteries could make visibility challenging. StentViz† processing is fully automated and can be launched at the press of a button on the Central touch screen. The result is automatically displayed on the reference monitor and shows two zoomed and enhanced images of the stent: One with the guidewire in view and a second one where the guidewire is subtracted out in the area between the two balloon markers to allow better visualization of the stent struts or borders.

### StentVesselViz†

Being able to see the position of stent into the vessel is especially critical in cases of complex clinical situations such as bifurcations or calcified lesions. A complete apposition of stent onto vessel wall can contribute to prevent stent thrombosis & restenosis.

StentVesselViz† improves the user confidence in the assessment of the position, correct deployment and shape of the stent in relation with the vessel in 2D versus cine.

Thanks to an intuitive workflow, StentVesselViz† is operated smoothly and can help the user position and expand stent appropriately. The StentVesselViz† option delivers from a single acquisition a StentViz† image and then the fusion of this one with an image of the injected vessel. Those two images are automatically fading together for optimized and simultaneous visualization of stent into the vessel pre and post deployment.



### InnovaSpin™†

The offset C-arm permits fast-spin rotational angiography over a maximum range of 200° at variable speeds from 20° to 40°/sec (maximum speed of 30°/s from LAO to RAO) with flexible cranio/caudal oblique angulations. The enhanced InnovaSpin™ trajectories are not constrained to a single transverse plane and can be used at oblique angulations within physical constraints. A total of seven trajectories can be preset. The entire workflow for the test run and spin acquisition can take place at tableside. The spin acquisitions can be performed in the cardiac record mode for coronaries, or peripheral image quality can be optimized in the InnovaChase™ mode.

## 3D Applications

### 3DCT\*\*

3DCT is intended for imaging vessels, bone and other internal body structures. It helps physicians in diagnosis, surgical planning, interventional procedures and treatment follow-up. 3DCT performs at 40 degree/sec and can be used with 4 different field of views. It utilizes automatic exposure technique to optimize image quality and dose all along the rotational acquisition.

### 3DCT HD\*\*

3DCT HD is intended for imaging vessels, bone, soft tissues, and other internal body structures. It helps physicians in diagnosis, surgical planning, interventional procedures and treatment follow-up. 3DCT HD offers 3 rotation speeds: 16, 28 and 40 degree/sec, and 4 different field of views. It utilizes automatic exposure technique to optimize image quality and dose all along the rotational acquisition.

	3DCT	3DCT HD
Spin duration	5 sec.	5, 7, 13 sec.
Frame rate	50 fps	50 fps
Reconstructed 3D model resolution	512x512x512 256x256x256	512x512x512 256x256x256



Transfer of the acquired data to the AW workstation is automated including image reconstruction, processing and display. The resulting 3D model can be visualized as axial slices and volume rendering.

Slice reconstruction for 3DCT / 3DCT HD can be exported as DICOM CT format.

## Workstations

Two optional workstations, the AW and the CA1000 workstations, can be connected to the system depending on site requirements.

AW is a multi-modality (CT, MR, XR, TEP, CBCT...) image review, comparison, and processing workstation.

CA1000 provides comprehensive image viewing capabilities for nearly all DICOM\*\* images in a cardiology-specific display protocol and it also provides advanced cardiac X-ray analysis tools.

## IV Gantry

<b>Positioner specifications</b>	
L-arm rotation on vertical axis	±100° (±95° motorized limit set)
C-arm angulation	50° cranial and 45° caudal
Combination of movements of the C-arm and L-arm	Permits -/+55° cranial and caudal angulations
C-arm angulations speed	0 to 15°
Offset C-arm	-117°/+105° RAO/LAO rotations
offset C-arm throat depth	107 cm (42 in) with L-arm at 0° provides femoral coverage on most patients without rotating the L-arm
Fully motorized SID	8.9 cm/s (3.5 in/s)
SID range	85 cm to 119 cm (33 in to 47 in)
Tube Focal Spot distance to Isocenter (SOD)	72 cm (28 in)
Isocenter to floor distance	107 cm (42 in)
Positioning modes	<ul style="list-style-type: none"><li>• Anatomical mode to hold the view while moving the L-arm to an optimum patient access position.</li><li>• Mechanical angulation allows movement of any one of the three axes independently for maximum positioning flexibility and vessel profiling</li></ul>
Support	Floor-mounted
Weight	~ 750 kg

## V Patient Table

<b>Omega IV</b>	
Maximum total load	304 kg (670 lbs.)
Maximum patient weight	204 Kg (450 lbs.)
Maximum accessories weight	100kg (220 lbs.) while complying with the following -maximum weight requirements: <ul style="list-style-type: none"> <li>• 40 kg (88lbs.) on each of the two fixed side rails</li> <li>• 20 kg (44 lbs.) of accessories on the table foot-end rail (option)</li> </ul>
CPR	50 kg (110 lbs.) additional maximum load
Tabletop absorption	Less than 0.85mm Al Equivalence, 100KVp
Tabletop Material	Radio translucent carbon fiber tabletop
Tabletop length	300 cm (118 in)
Tabletop width	46 cm (18") in patient trunk area
Horizontal Float Movement	8-way
Longitudinal travel	Up to 110 cm (43.3")
Longitudinal Speed	15cm/s
Imaging coverage with table panning	Up to 127 cm (50")
Transverse Travel	± 14 cm (± 5.5")
Vertical travel above floor	From 78 cm (30.7") to 108 cm (42.7")
Vertical Speed	2 cm/s (0.8"/s) at 50Hz. 2.5 cm/s (1"/s) at 60 Hz
Accessories rails	Available on the base section of the tabletop to mount tableside controls and IV pole
Table weight	~ 590 kg

# VI User interface

## In the examination room

### Table and gantry controls

- **SmartBox** provide simple gantry and table motion access throughout the exam. SmartBox control system motions, disable/enable patient contouring, system lock/unlock.

**The Tableside Status Control (TSSC)** provides simple access to key acquisition and review parameters throughout the exam. A second TSSC can be added at tableside or in the control room. TSSC controls: Acquisition preference settings, Fluoro level, Fields-of-view, Subtracted/non-subtracted fluoro, Fluoro landscape, Room light on/off, Fluoro timer reset, Fluorostore and Auto Positioner.

The **Central touch screen**<sup>†</sup> provides safe and simple access to key features throughout the exam. It lets the user control the system functions as well as integrated equipment. Central Touch Screen controls: Image acquisition, image review, dose settings, Mac-Lab™ hemodynamic recording systems<sup>†</sup>, CardioLab™ EP recording systems<sup>†</sup>, Favorite tab where functionalities can be grouped based on user preferences.

**Smart Nav** is an innovative solution to control some IGS system functionalities from tableside and from the control room. It allows fast function access in displaying menu controls on the reference monitor upon user request. With Smart Nav, the user can keep his/her attention on the screen monitors where clinical images are also displayed. Smart Nav is controlled from the Central Touch Screen, local keypad or remote keypad, providing intuitive and context-based navigation. **Smart Nav controls:** In-room Browser, Review and processing tools, Review sequence/photo, Stopwatch (play, pause, stop, reset), StentViz<sup>†</sup>, StentVesselViz<sup>†</sup>

## In the control room

The IGS system includes one 48 cm (19 in) LCD monitor for display of live images in the control room. Additional reference and subtracted roadmap repeater monitors<sup>†</sup> are available

Dedicated keypad for convenient control of commonly used review functions provides an image shuttle knob to control playback and one-touch access to image review functions

Pause, adjust brightness and contrast during review

Flat graphic display with easy point-and-click mouse control supports patient management and advanced processing and analysis features

Keyboard enables patient data entry

## VII In room display

IGS system can be installed with 48 cm (19 inch) LCD monitors as display.

### 48 cm (19in) live and reference imaging monitors

<b>RX 150</b>	
Diagonal	48cm (19in)
Active Display	376 x 301 mm
Display matrix	1280 x 1024
Brightness	800 cd/m <sup>2</sup> (typical) 400 cd/m <sup>2</sup> (calibrated)
Viewing angles	176°, 176° (typical)
LUT	10 Bit
Frequency	50 – 75 Hz
Contrast ratio	1000:1 (typical)
Greyscale Tones	1024
Power consumption	65 W

## VIII Image management, connectivity and workflow

Record images stored in 8 bits, maximum 450 images per sequence. Storage capacity: 136,000 record images

DSA images with 12 bits data stored in 16 bits, maximum 450 images per sequence. Storage capacity: 68,000 DSA images

DICOM image output on 100Mbit Ethernet with Autosend and background transfer for fast transmission with minimal user interaction.

Patient Worklist capability provides a single point of entry of patient data, increasing staff productivity and eliminating clerical errors: patient information can easily be imported into the digital system from information systems that support DICOM Worklist Service Class Provider.

Multi-destination Push enables images to be sent to multiple remote DICOM destinations sequentially (one after another). Multi-destination helps to support a clinical scenario of handling post processing and archival activities in multiple destinations independently of each other (workstation, PACS). Multi-destination provides a seamless integration of the system into clinical workflow.

MPPS: Modality Performed Procedure Step allows the IGS system to share the main exam parameters with the hospital information system.

For the 3DCT / 3DCT HD option, users can direct-push the 3D acquisition directly to the pre-configured AW, even if the images of the exam are pushed to a PACS or another archiving system.

For further information about DICOM\*\* conformance statement:

[http://www3.gehealthcare.com/en/products/interoperability/dicom/x-ray\\_and\\_mammography\\_dicom\\_conformance\\_statements](http://www3.gehealthcare.com/en/products/interoperability/dicom/x-ray_and_mammography_dicom_conformance_statements)

---

## IX Privacy and Security

The IGS system incorporates **IGSDefense**, our multi-layer approach to cybersecurity and data privacy, to help protect the IGS system operation and patient data from cyber threats and unauthorized access.

<b>Access Controls</b>	The provisioning of password-protected user accounts allows controlling the access to sensitive information of the clinical application and the Operating System. The clinical application can be accessed through local accounts as well as centralized enterprise accounts. Local accounts of the clinical application and the Operating System support password changes, and configuration of complex password rules and account policies.
<b>User Authorization</b>	The user accounts are members of role-based groups, which grants the users with the group's permissions. It allows restricting the access by unauthorized users to specific parts of the application. An unauthenticated Emergency Access mode can be configured, which makes the clinical application available for clinical procedures
<b>Audit Trails</b>	The audit trail capability generates and exports to a central server the audit records of events related to security and privacy: system state changes, user authentication, account management, patient data manipulation, malware detection, network communications and service operations. This provides means to remotely monitor such events, and to protect the system against individuals falsely denying having performed actions to be covered by non-repudiation.
<b>Firewall</b>	The IGS system provides two levels of network firewall: (1) Operating System Firewall, and (2) external firewall/router device. These firewalls isolate network traffic to only those systems required for communication. The firewalls can manage inbound and outbound traffic rules to deny-all and allow-by-exception based on authorized ports and/or IP addresses.
<b>Data Privacy</b>	The IGS system provides de-identification and encryption capabilities to limit privacy risks to sensitive information. The patient data exported during clinical workflow may be encrypted by using the DICOM TLS protocol. The person names and patient identifying attributes that are collected for service purposes are anonymized by using FIPS 140-2 compliant one-way hashing algorithms.

## X Room Requirements

Load distribution for the gantry	2660 kg/m <sup>2</sup>
Load distribution for the Omega Table	2410 kg/m <sup>2</sup>
Minimum ceiling height	2.71 m with dual arm fix point suspension or 2.74 m with rails and bridge suspension (9 ft)
Minimum Room dimensions with Omega IV table (without accessories)	5.47 m (17 ft 11 in) length & 4.4 m (14 ft 5 in) width
Humidity	20 to 70 % in exam room
Range of temperature	15 to 32 °C in exam room
<b>Atmospheric pressure</b>	70 to 106 kPa

## System Power

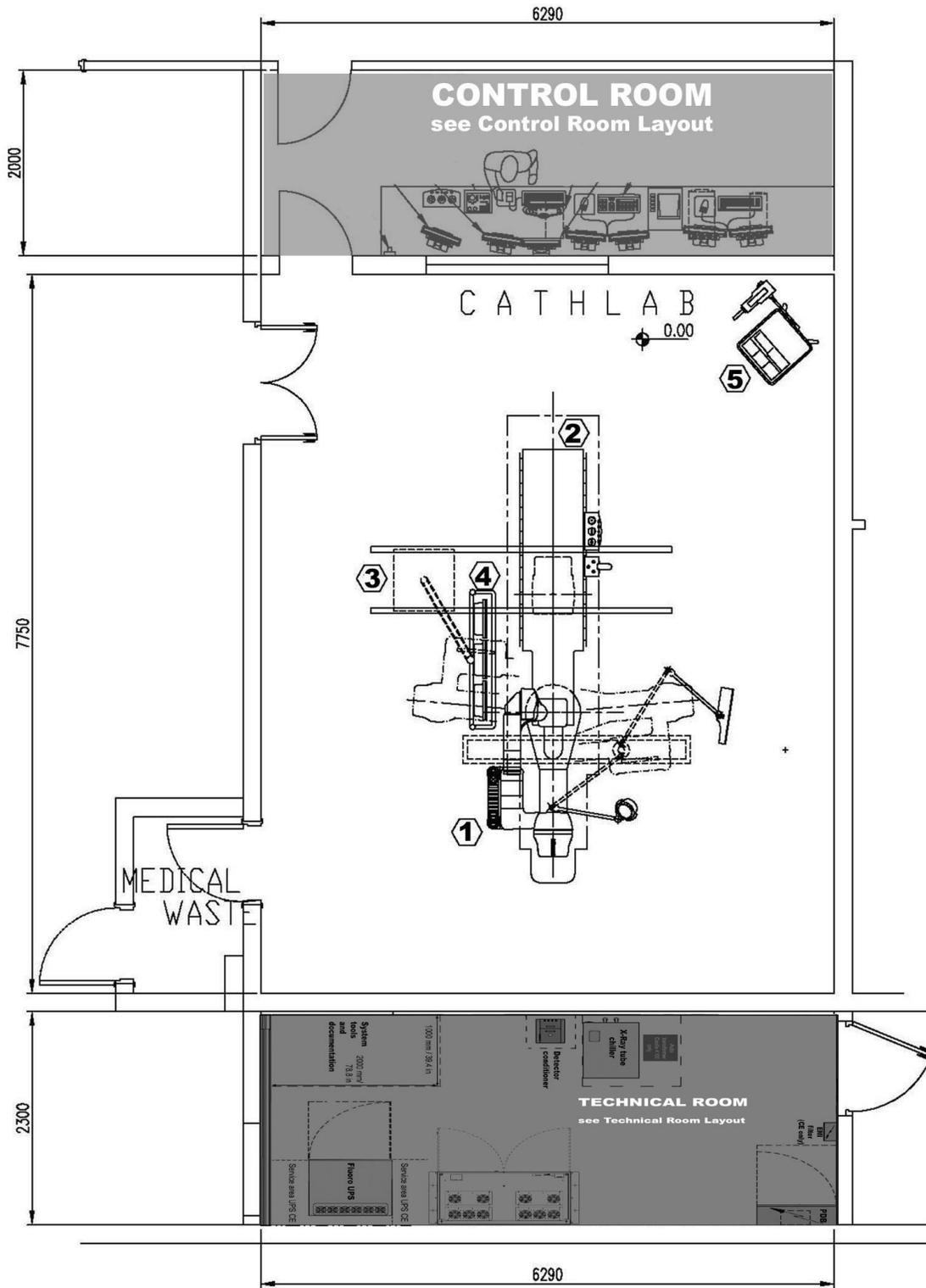
Nominal 380 to 480 Volts AC, three phase 50 or 60 Hz without neutral.
Maximum momentary power demand: 150 kVA

## Emergency power supply

In case of power outage, an Uninterruptible Power Supply (UPS) supports the system.

<b>1kVA UPS</b>
Available with IGS system
Supports proper system shutdown in case of power outage

# Typical room layout



Room layout example for Ergo suspension configuration

## Customer service

Advanced remote connectivity allows GE to monitor systems and intervene if necessary.

### Serviceability

The Digital System Manager simplifies troubleshooting and minimizes downtime with built-in equipment error logging and power-up diagnostics in real time. Resident software monitors the entire system, including peripheral hardware. The IGS system features 24-hour InSite™ remote service diagnostics and repair. InSite™ service is available to systems covered by the original warranty or by a GE service contract (broadband required).

### Extended service†

An optional full-service contract ensures uptime even after the original warranty expires and provides advanced remote diagnostics through a broadband or phone connection.



Product may not be available in all countries and regions.

Cannot be placed on the market or put into service until it has been made to comply with all required regulatory authorizations.

Full product technical specification is available upon request.

Contact a GE Healthcare Representative for more information.

Please visit [www.gehealthcare.com/promotional-locations](http://www.gehealthcare.com/promotional-locations).

Data subject to change.

© 2020 General Electric Company. DOC2434364

GE, the GE Monogram, imagination at work are trademarks of General Electric Company.

<sup>†</sup> Option

\*Requires AW.

\*\*DICOM is a registered trademark of National Electrical Manufacturers Association, All third party trademarks are the property of their respective owners.

IGS system refers to Optima IGS system

Reproduction in any form is forbidden without prior written permission from GE. Nothing in this material should be used to diagnose or treat any disease or condition. Readers must consult a healthcare professional.