

## Electronic Signature Information

<b>Name</b>	DOC1996667
<b>Revision</b>	5
<b>Type</b>	Product Data Sheets
<b>Title</b>	Product Data Sheet Innova IGS 6
<b>Originator</b>	100004647_jean-sebastien__feldmann
<b>Release Date</b>	04/03/2018 06:42:27 AM
<b>Obsolete Date</b>	

File Name	File Description	File Size (Bytes)
PDS Cerber B IGS 6 180308 DOC1996667_510K CLEAN.docx		1087663

Route	Signer	Function	Status	Comments	Completion Date
R-9030900	100006386_romain__chatelin		Approve	doc reviewed - ok to release	19 Mar 2018 12:36:02 GMT
R-9033928	100000234_michel__genuer		Approve	Approved Without Comments	28 Mar 2018 10:28:41 GMT

### Periodic Review

**There are no signatures or routes related to this business object.**

### Obsolescence Approval

**There are no signatures or routes related to this business object.**

\* Printed versions are For Reference Only \*

+ Indicates a task was reassigned from an original assignee

GE Healthcare

# Innova™ IGS 6

## PRODUCT DATA SHEET



# Table of Contents

I Image Chain.....	3
II Dose .....	6
III Applications.....	7
IV Gantry .....	11
V Patient Table .....	12
VI User interface.....	13
VII In room display.....	14
VIII Image management, connectivity and workflow.....	16
IX Privacy and Security.....	17
X Room Requirements.....	18

# 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)

Tube Cooling Unit	COOLIX 4100
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, 0.3, 0.6 and 0.9 mm of copper (20cm detector) 0.1, 0.2, 0.3 mm of copper (30cm detector) 1 integrated contour filter blades (20cm detector) 3 integrated contour filter blades (30cm detector) motorized, tapered filter blade that can be rotated 360° as well as translated in and out using a simple joystick control at tableside

## Detector<sup>1</sup>

Detector manufacturer	GE
Size of the detector	20.5 cm x 20.5 cm (20cm detector) 31 cm x 31 cm (30cm detector)
Material	Amorphous silicon photodiode array on a continuous-substrate
Pixel size	200 x 200 µm
Image matrix	1024 x 1024 (20cm detector) 1536 x 1536 (30cm detector)
Bit acquisition	14 bit

The Innova IGS 6 system comes with 2 detector configurations : 20cm detector and 30cm detector.

Mode @ Dose/Fr	
DQE values at average fluoro and record dose operating points	
Record, e.g. DSA 175 nGy (20 uR)	80% (20cm detector), 84% (30cm detector)
Fluoro 8.8 nGy (1 uR)	77% (20cm detector), 81% (30cm detector)
Additional DQE values at minimum fluoro dose operating point	
Fluoro 2.2 nGy (0.25 uR)	68% (20cm detector), 73% (30cm detector)
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).

<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

Grid ratio	13:1
Focal distance of the grid Frt	100 cm (39 in)
Focal distance of the grid Lat	115 cm (45 in)
Grid Line frequency	70 LP/cm

## Image acquisition

Fluoroscopy modes	Non-subtracted, subtracted, roadmap, Blended Roadmap†
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	Error! Bookmark not defined.
Angio Acquisition Package	<ul style="list-style-type: none"> <li>DSA (digital subtracted angiography) at 0.5 - 7.5 fps</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 (20cm detector) 30 cm, 20 cm, 16 cm and 12 cm (30cm detector)
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

## 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.

#### InnovaSense (frontal gantry) †

InnovaSense is an advanced patient contouring technology that uses an intelligent algorithm during gantry motion to select the optimal position for the image receptor relative to the patient. By reducing the distance from receptor to patient, the system optimizes imaging geometry and helps reduce radiation exposure. The user also can position both the gantry and detector with one integrated operation. Capacitive sensor technology and optimized collision avoidance software enable a speed of pivot and C-arm, of up to 20° per second.

### - Dose Efficiency

#### Dynamic exposure optimization – AutoEx

A neural network technology allows advanced exposure management algorithms to dynamically control X-ray technique and beam filtration. The user can select system settings, from maximizing image quality to minimizing skin dose.

Based on those settings, the system automatically optimizes in real time the contrast-to-noise ratio within the image by selecting the optimal technique factors and spectral filter thickness.

### - 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.

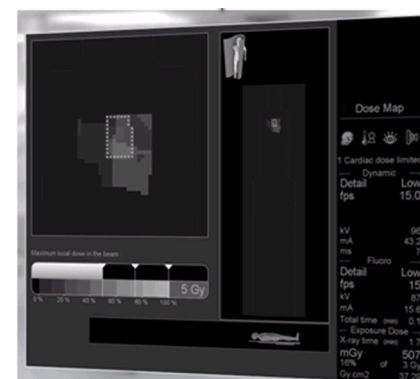
#### Dose reporting

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

#### Dose Map (Procedures with Frontal Gantry only with Lateral Gantry parked) †

Dose Map is a feature used to calculate, display and record an estimated local cumulated dose during procedures done on the GE X-Ray angiographic system. It is designed to provide to the user a visualization of the distribution of the local cumulated dose throughout the exam as well as the current projection of the beam.

Estimated local cumulated dose	Yes
Pediatric patient	Yes
Real-time calculation	Yes
Configurable alert	Yes



## 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.

#### ECG acquisition package†

With the ECG acquisition package the heart rate is displayed on the console and live monitor.

The ECG acquisition package is compatible with recording system outputs providing analog ECG signals comprised between +/-5 V. Connection cables compatible with Mac-Lab™†, CardioLab™†, Combolab† and some third party recording systems are provided with this package.

#### Quantitative Analysis Package†

Stenosis Analysis† and Left 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.

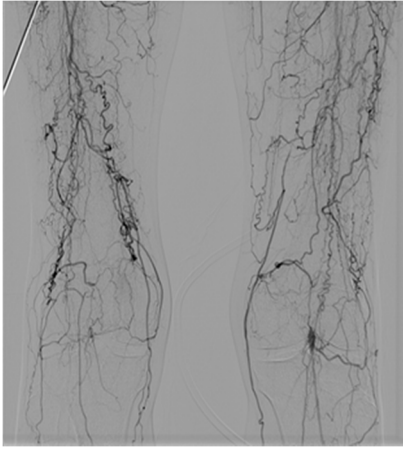
StentVesselViz† improves the user confidence in the assessment of the position, correct deployment and shape of the stent in relation with the vessel in 2D versus cine.

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.



### InnovaBreeze™ peripheral angiography†

InnovaBreeze† available with 30cm detector configuration lets the user follow the contrast using variable panning speed control in the control room while looking at subtracted images in real time. InnovaBreeze† includes Advantage Paste



### Advantage Paste\*

Advantage paste is an application running on AW VolumeShare Workstation that provides the ability to reconstruct and visualize the entire length of the subtracted bolus chasing acquisition on a single image.

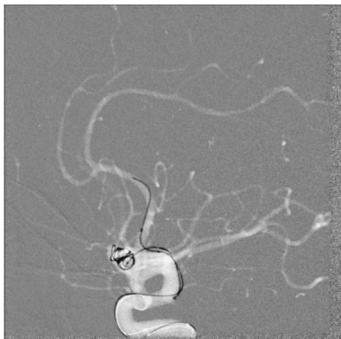
### Blended Roadmap†

Blended Roadmap† is a vascular road mapping application that superimposes a previously acquired vascular image over live fluoroscopy. This advanced application helps clinicians view the progression of guidewires and devices through the vessels.

Clinicians can select any DSA or bolus image as a reference roadmap image. By using this image multiple times, Blended Roadmap has the potential to minimize contrast media injections during road mapping.

Blended Roadmap† provides additional features to enhance road mapping procedures, including:

- Adjustment of the subtraction level
- Adjustment of vessel transparency
- Automatic resizing of the roadmap image to adapt to the fluoroscopic field-of-view
- Automated Pixel shift of the vessel image to compensate for motion



### 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 (limited to five on a tilting table). 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.

### INTERACT - ViewX<sup>†</sup>

INTERACT View X enables display of the Live X-Ray or fusion of Pre-Op CT with Live X-Ray, on the Vivid E95 / S70N (with ViewX) as a picture in picture. With INTERACT View X, the echo cardiologist is able to follow the whole workflow of the procedure from the echo display, helping facilitate communication between the echo cardiologist and the Interventional Cardiologist.

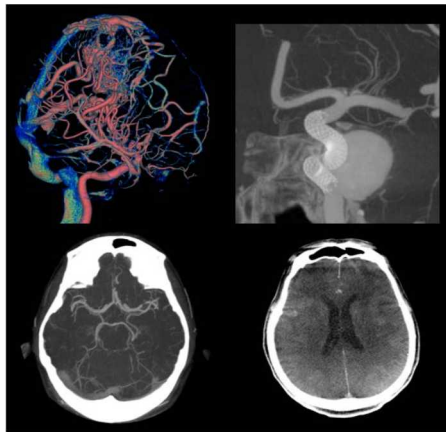
## 3D Applications

### 3DCT<sup>†</sup>

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 **Error! Bookmark not defined.**<sup>†</sup>

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.

### MAR<sup>†</sup>

3DCT HD MAR reduces streak artifacts induced by the presence of small metallic devices such as coils or clips within the 3D field of view.

### Motion Freeze<sup>†</sup>

3DCT HD Motion Freeze is designed to reduce artefacts caused by involuntary respiratory motion during the rotational acquisition and recover small detail visibility impacted by motion.

#### INTERACT - Active Tracker†

3DCT HD Active Tracker automatically detects the omniTRAX™ Active Tracked device and adds its location to the 3DCT HD datasets. GE LOGIQ E9 can use the Active Tracked locations in order to facilitate fusion with live ultrasound images.

#### Subtracted 3D\*†

Subtracted 3D† enhances the 3DCT / 3DCT HD application by adding automated sequential mask and contrast spin acquisitions with processing protocols to produce subtracted 3D vascular images. Clinicians may use Subtracted 3D† to quickly visualize vessels without the need to remove surrounding bone, tissue, and implanted devices. The output of the 3D processing provides convenient side-by-side and separate visualization of the mask series, the subtracted vascular anatomy and the standard segmented 3D vascular images.

Interventional devices such as coils, stents, glue and clips, as well as calcified plaque, are visible on the mask image and can be fused onto the subtracted image. Their transparency can be adjusted for optimal visualization of the implanted devices in relationship to the vascular anatomy.

#### 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. It allows the use of real-time image fusion applications through a dedicated communication interface: fastlink (1Gb/sec).

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

### Frontal positioner specifications

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° (Up to 20°/sec with InnovaSense <sup>†</sup> )
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) – 20cm detector configuration 89 cm to 119 cm (35 in to 47 in) – 30cm detector configuration
Tube Focal Spot distance to Isocenter (SOD)	72 cm (28 in)
Isocenter to floor distance	107 cm (42 in)
Support	Floor-mounted
Weight	~ 670 kg (20cm detector configuration) ~ 705 kg (30cm detector configuration)

### Lateral positioner specifications

LP-arm angulation	Up to 115° LAO
LP-arm motorized angulations	45° cranial to 90° caudal
Off isocenter imaging	±20 cm (7.9in) of LP travel
Biplane angulation speed	Up to 10°/s
Motorized detector lift	13 to 49 cm (5.1 to 19.3 in) to isocenter – X-ray authorized
Variable focal spot to isocenter	71 to 88 cm (27.9 to 34.6 in)
Support	Ceiling-mounted
Weight	~ 705 kg (20cm detector configuration) ~ 800 kg (30cm detector configuration)

## V Patient Table

Omega V	
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	333 cm (131")
Tabletop width	46 cm (18") in patient trunk area
Horizontal Float Movement	8-way
Longitudinal travel	Up to 170 cm (67")
Longitudinal Speed	15cm/s
Imaging coverage with table panning	Up to 187 cm (73") – 20cm detector configuration Up to 195 cm (76") – 30cm detector configuration
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** or **SmartHandle** (A second SmartBox or SmartHandle can be added at tableside or in the control room) provide simple gantry and table motion access throughout the exam. SmartBox or SmartHandle control system motions, disable/enable patient contouring, system lock/unlock and emergency stop.

**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.

To provide more AW capabilities at tableside, an interface kit<sup>†</sup> enabling to connect an in room wireless mouse to drive the AW from table side is available.

The IGS system fluoro/acquisition footswitch can optionally come as **wireless footswitch<sup>†</sup>**

The **Central touch screen** 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>, AW advanced applications<sup>†</sup>, Large Display Monitor<sup>†</sup> layout management, Favorite tab where functionalities can be grouped based on user preferences.

## In the control room

A remote stand is provided to use the second tableside user interface<sup>†</sup> in the control room

The IGS system includes one B&W 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 primary display or GE Large Display Monitor as primary 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

### AW color monitor

<b>MX 193</b>	
Diagonal	48cm (19in)
Active Display	376 x 301 mm
Display matrix	1280 x 1024
Brightness	330 cd/m <sup>2</sup> (typical)
Viewing angles	178°, 178° (typical)
Frequency	31-64 Hz
Contrast ratio	900:1 (typical)
Power consumption	< 31W

### GE Large Display Monitor†

The GE Large Display Monitor† (LDM) is an in-room primary monitor designed to streamline procedure workflow. It includes a video server solution and is fully integrated with the Central Touch Screen at tableside.

<b>GE Large Display Monitor specifications</b>	
Diagonal	148 cm (58in)
Active Display	127 x 72 cm
Display matrix	8 megapixels 3840 x 2160-pixel array
Brightness	At least 560 cd/m <sup>2</sup>
Viewing angles	176°, 176° (typical)
Frequency	59.7 – 60.3 Hz
Contrast ratio	At least 3500:1
Video inputs	<ul style="list-style-type: none"> <li>19 video inputs for Live, Reference, AW and optional subtracted Fluoro monochrome signals as well as for a wide variety of other video signals usually used in an interventional environment - including 3 free open inputs compatible with VGA and DVI video formats.</li> </ul>

Layouts	<ul style="list-style-type: none"><li>• over 120</li><li>• Organized into user or application groups</li><li>• Digital zoom (up to 200%)</li></ul>
User interface	Layouts are selectable from the Central Touch Screen
Back-up monitors	48 cm (19 in) live and reference monitors attached at the back of the LDM or on another suspension†
Additional HD output†	For HD video compatible solutions (second 8MP monitor, 2MP HD monitor, recorder...)

An optional kit to interface a third-party suspension according to GE Healthcare specifications allows users to install another third-party suspension instead of the standard GE Healthcare monitor suspension offering.



## 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 a broad assortment of capabilities to enable Privacy & Security, thus preserving the system integrity, availability and confidentiality.

<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>Anti-Malware†</b>	A whitelisting-based malware protection contains a list of all authorized executables to create a closed protected system. It blocks any kind of modification to the whitelisted files as well as the execution of any unauthorized program. This provides a complete endpoint security against malware.
<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	2678 kg/m <sup>2</sup>
Load distribution for the Omega Table	3065 kg/m <sup>2</sup>
Minimum ceiling height	2.85 m (9 ft 4 in)
Minimum room dimensions	6.9 m (22 ft 8 in) length & 4.4 m (14 ft 5 in) width
Humidity	30 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

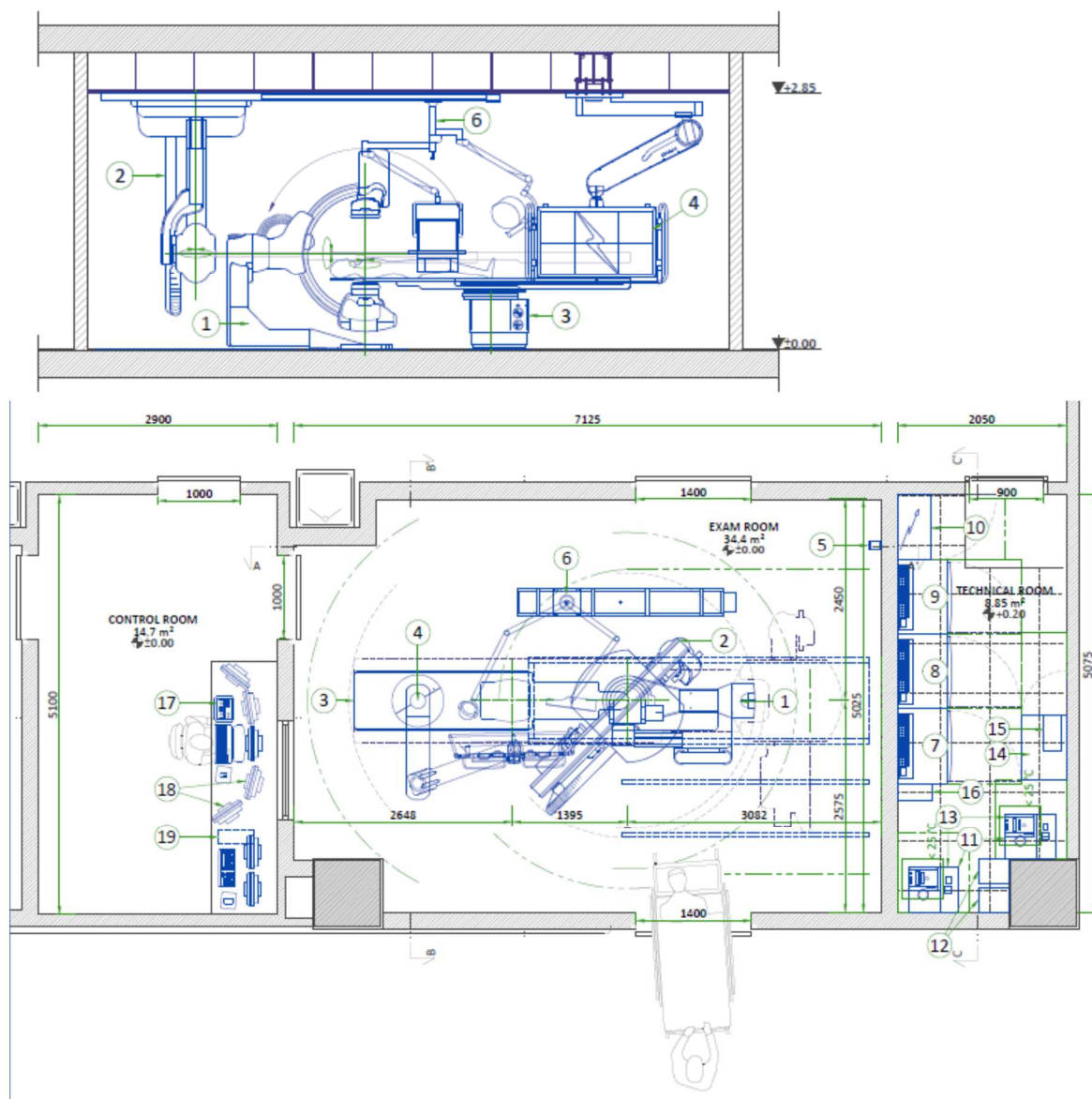
Nominal 380 to 480 Volts AC, three phase 50 or 60 Hz without neutral.

Maximum momentary power demand: 150 kVA

### Emergency power supply

In case of power outage, a 20kVA Uninterruptible Power Supply (UPS)<sup>†</sup> provides vital minutes of emergency table control and fluoroscopy to position the table in an optimal position and continue critical aspects of a case in progress, should power be interrupted.

## Typical room layout



## 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 including the Medical Device Directive requirements for CE marking.  
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.

© 2017 General Electric Company. DOC1996667

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

† 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 Innova IGS 6 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.