1 Foreword

1.1 Electronic User Manual

This device is delivered with an electronic User Manual.

This section explains how to access the electronic User Manual that contains the instructions necessary to use the system.

NOTE
Some User Manual addendums are delivered in paper only. Some options or accessories are delivered with a paper User Manual.

Symbol indicating that the Instruction For Use (User Manual) is supplied in electronic format.

The User Manual is available on the system itself (see 7.1.2 Utilities Key on page 171).

The User Manual is also available on the Internet at: https://www.gehealthcare.com/documentationlibrary. Then follow the instructions to access the Customer Documentation Portal.

On the search page of the Customer Documentation Portal, enter the part number of the User Manual in the search field **[1]** and click on magnifying glass **[2]**.

The following screen capture is given as an example and is not legally binding:

A paper copy of the User Manual can be ordered at no additional cost. Please, send a request to your Sales or Service representative. They will transfer your request to gehc_manuals@gehealthcare.com. In application of the EU Commission Regulation on electronic instructions for use of medical devices, in European Union, your request should be treated within 7 days.

The part number is indicated in the table below. Choose the one matching your language.

UM part-no	Language
5973217-1BG	Bulgarian
5973217-1CS	Czech
5973217-1DA	Danish

UM part-no	Language
5973217-1DE	German
5973217-1EL	Greek
5973217-1EN	English
5973217-1ES	Spanish
5973217-1ET	Estonian
5973217-1FI	Finnish
5973217-1FR	French
5973217-1HR	Croatian
5973217-1HU	Hungarian
5973217-1ID	Indonesian
5973217-1IT	Italian
5973217-1JA	Japanese
5973217-1KK	Kazakh
5973217-1KO	Korean
5973217-1LT	Lithuanian
5973217-1LV	Latvian
5973217-1NL	Dutch
5973217-1NO	Norwegian
5973217-1PL	Polish
5973217-1PT-BR	Portuguese (Brazil)
5973217-1PT-PT	Portuguese (Portugal)
5973217-1RO	Romanian
5973217-1RU	Russian
5973217-1SK	Slovakian
5973217-1SR	Serbian
5973217-1SV	Swedish
5973217-1TR	Turkish
5973217-1UK	Ukrainian
5973217-1VI	Vietnamese

2 Introduction

2.1 General Introduction

Product name: Medical X-Ray angiography equipment.

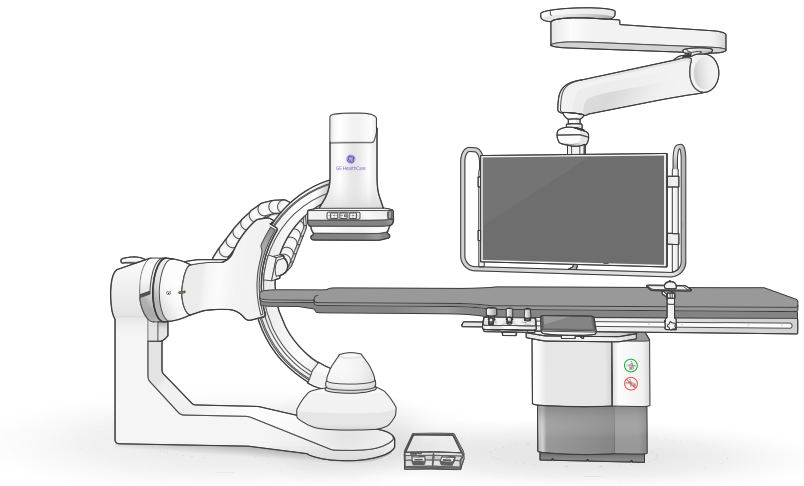
Product model name	Product Symbol	Product description
Allia IGS 3 and Allia IGS 5	Allia IGS 5 	Fixed single interventional angiographic X-Ray system with a three-axis C-arm and Digital Detector.
Allia IGS 7 and Allia IGS 7 OR	Allia IGS 7 Allia IGS 7 OR 	Permanently installed single plane interventional angiographic X-Ray system with a three-axis C-arm and Digital Detector.

NOTE

Throughout this operating manual, the term “IGS system” refers to Allia IGS 3, Allia IGS 5, Allia IGS 7 and Allia IGS 7 OR product models.

(For Allia IGS 5)

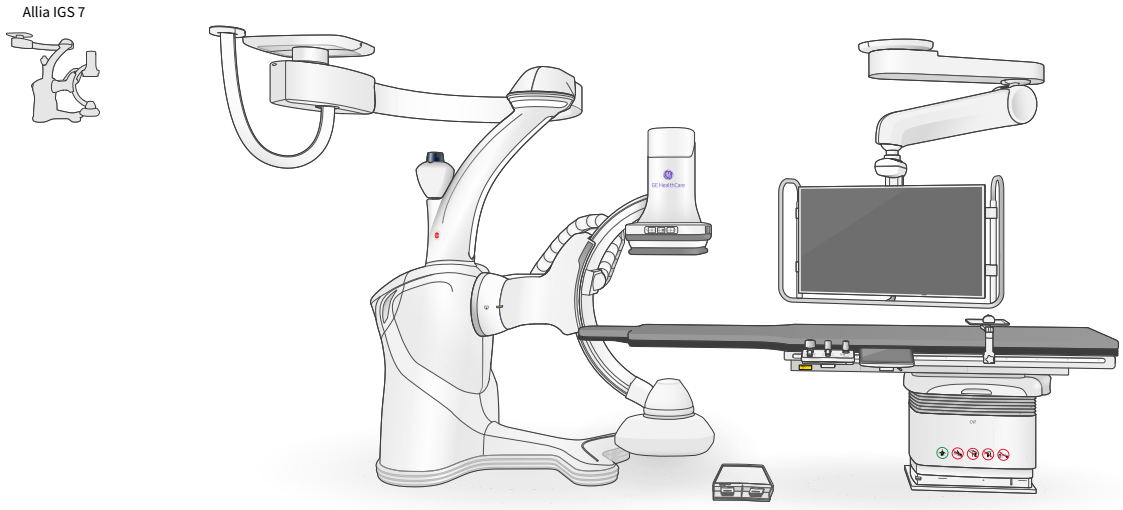
Allia IGS 5



NOTE

- Allia IGS 3 is a product model based on Allia IGS 5. It is equipped with Omega V table and a 30 cm Digital Detector. Through this operating manual,
  - "Allia IGS 5" refers to Allia IGS 5 product model including Allia IGS 3 product model,
  - "IGS 530" refers to Allia IGS 5 product model including Allia IGS 3 product model, within the limits of specificities described above.
- IGS 520, IGS 530 are product configurations of Allia IGS 5.
- IGS 520 is equipped with 20.5 cm x 20.5 cm Digital Detector (in this document this detector will be named 20 cm detector).
- IGS 530 is equipped with 31 cm x 31 cm Digital Detector (in this document this detector will be named 30 cm detector).
- Systems equipped with 20 cm Digital Detector have a gantry name containing ‘20’ (i.e., ‘LC DET. 20’). This gantry name is visible in the gantry identification label, present on the gantry.
- Systems equipped with 30 cm Digital Detector have a gantry name containing ‘30’ (i.e., ‘LC DET. 30’). This gantry name is visible in the gantry identification label, present on the gantry.

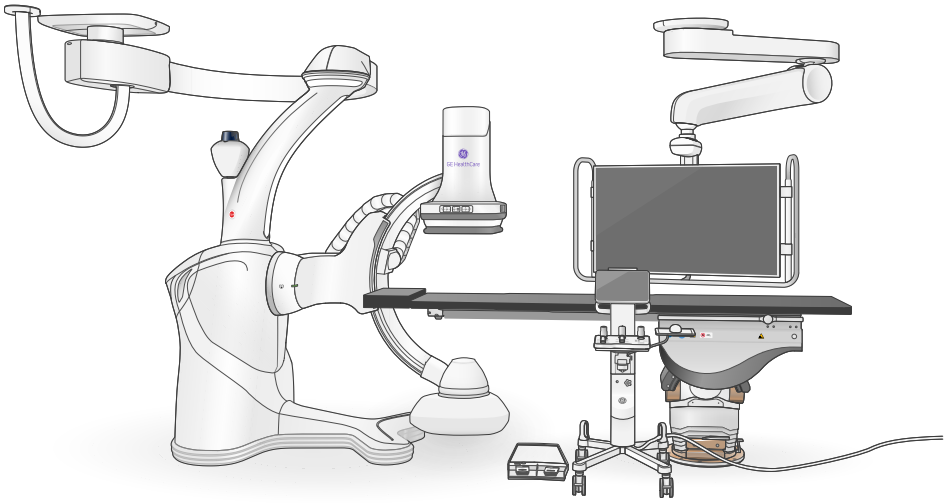
(For Allia IGS 7)



(For Allia IGS 7 OR)

Allia IGS 7 OR

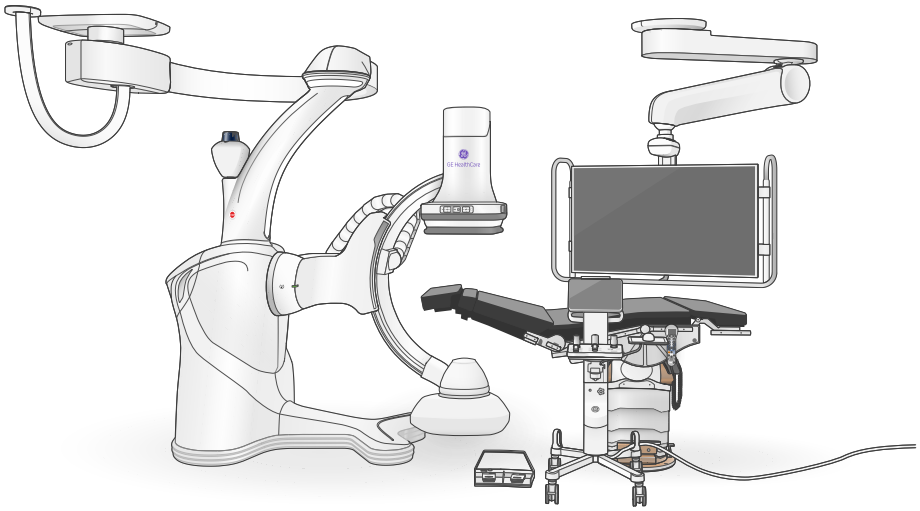
With flat table top:



There are two flat table tops: reference 1180.16A2 or 1180.16F2 (represented in illustration above) and reference 1180.16A6 or 1180.16F6.

Allia IGS 7 OR

With universal table top:



NOTE

- IGS 730 is product configuration of Allia IGS 7. This is declined in sub-configurations:
  - IGS 730 with Innova^{IQ} - whose table is also referred to as “Innova^{IQ} standard table”.
  - IGS 730 with Innova^{IQ} OR table - whose table is also referred to as “Innova^{IQ} table OR configuration”.
- IGS 730 OR with Maquet table is product configuration of Allia IGS 7 OR.
- IGS 730 and IGS 730 OR with Maquet table are equipped with 30 cm Digital Detector.
- Systems equipped with 30 cm Digital Detector have a gantry name containing ‘30’ (ie, ‘LC DET. 30’, ‘AGV-C 30’). This gantry name is visible in the gantry identification label, present on the back of the Advanced Guided Vehicle (AGV).

NOTE

The MAGNUS OR table is a medical equipment distributed by Maquet.

Some of the operating instructions written in this document describe the features and procedures relevant to the operation of Magnus Table in combination with Allia IGS 7 OR system. "System with Magnus Maquet OR Table" refers to this combination.

3 Safety and Regulatory

3.1 Safety Information

The following symbols are used in this document to highlight safety information.

	**WARNING** WARNING ADVISES OF AN AVOIDABLE CONDITION THAT MAY ALLOW OR CAUSE A PERSONAL INJURY OR THE CATASTROPHIC DESTRUCTION OF EQUIPMENT OR DATA.
	**WARNING** FOR X-RAY PROTECTION WARNING ADVISES OF AN AVOIDABLE CONDITION THAT MAY ALLOW OR CAUSE A PERSONAL INJURY OR THE CATASTROPHIC DESTRUCTION OF EQUIPMENT OR DATA.
	**CAUTION** Caution advises of an avoidable condition that could cause minor physical injury, or damage to equipment or data.
	**NOTE** Notes are used to draw attention to information that is important to know, but not related to a hazard.

WARNING

IMPORTANT... X-RAY PROTECTION

IF NOT PROPERLY USED, X-RAY EQUIPMENT MAY CAUSE INJURY. ACCORDINGLY, IT IS YOUR OBLIGATION TO CONFIRM THAT THE INSTRUCTIONS HEREIN CONTAINED ARE THOROUGHLY READ AND UNDERSTOOD BY EVERYONE WHO WILL USE THE EQUIPMENT BEFORE YOU ATTEMPT TO PLACE THIS EQUIPMENT IN OPERATION. GE HEALTHCARE WILL BE GLAD TO ASSIST AND COOPERATE IN PLACING THIS EQUIPMENT IN USE. ALTHOUGH THIS APPARATUS INCORPORATES A HIGH DEGREE OF CERTAIN PROTECTIONS AGAINST X-RADIATION OTHER THAN THE USEFUL BEAM, NO FEASIBLE DESIGN OF EQUIPMENT CAN PROVIDE COMPLETE PROTECTION FROM ALL POTENTIAL INJURY. NOR CAN ANY FEASIBLE DESIGN FORCE THE OPERATOR TO TAKE ADEQUATE PRECAUTIONS TO PREVENT THE POSSIBILITY OF ANY PERSONS CARELESSLY EXPOSING THEMSELVES OR OTHERS TO RADIATION. IT IS IMPORTANT THAT ANYONE HAVING ANYTHING TO DO WITH X-RADIATION BE PROPERLY TRAINED AND FULLY KNOWLEDGEABLE ABOUT THE RECOMMENDATIONS OF THE NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS AS PUBLISHED IN NCRP REPORTS AVAILABLE FROM NCRP PUBLICATIONS, 7910 WOODMONT AVENUE, ROOM 1016, BETHESDA, MARYLAND 20814, AND OF THE INTERNATIONAL COMMISSION ON RADIATION PROTECTION. IT IS YOUR OBLIGATION AND RESPONSIBILITY TO TAKE ADEQUATE STEPS TO PROTECT AGAINST INJURY.

THE EQUIPMENT IS SOLD WITH THE UNDERSTANDING THAT GE HEALTHCARE, ITS AGENTS, AND REPRESENTATIVES HAVE NO RESPONSIBILITY FOR INJURY OR DAMAGE, WHICH MAY RESULT FROM IMPROPER USE OF THE EQUIPMENT. VARIOUS PROTECTIVE MATERIALS AND DEVICES ARE AVAILABLE. IT IS URGED THAT SUCH MATERIALS OR DEVICES BE USED IN ACCORDANCE YOUR SITE'S CLINICAL PRACTICE.

CAUTION

US federal law restricts this device to sale by or on the order of a physician.

This symbol stands for the above prescription statement.

If detailed information cannot be found, please consult the additional specific User Manuals.

Read and understand all the instructions in the User Manual before attempting to use the system and request additional training from GE HealthCare if needed.

Periodically open the User Manual to review the procedures and safety precautions.

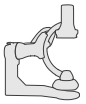
NOTE
For Magnus Maquet OR Table and Accessories and auxilliary devices, refer to the manufacturer operating instructions.

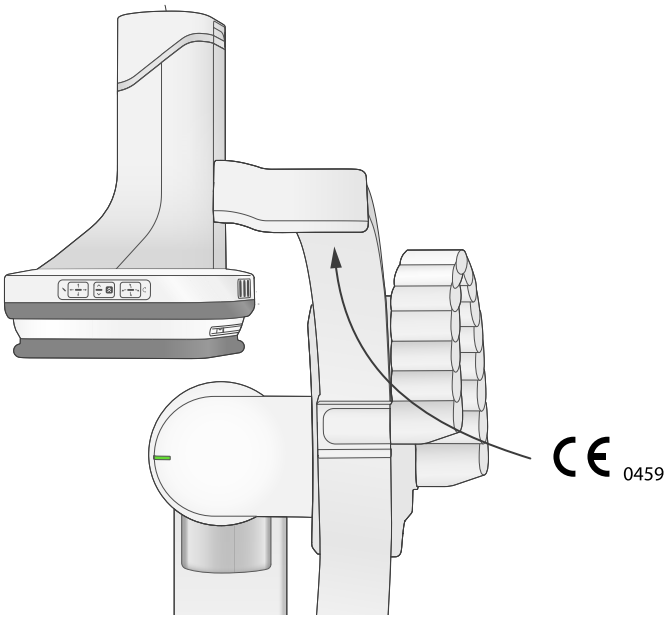
3.2 Regulatory Requirements

3.2.1 Compliance with Regulatory Requirements

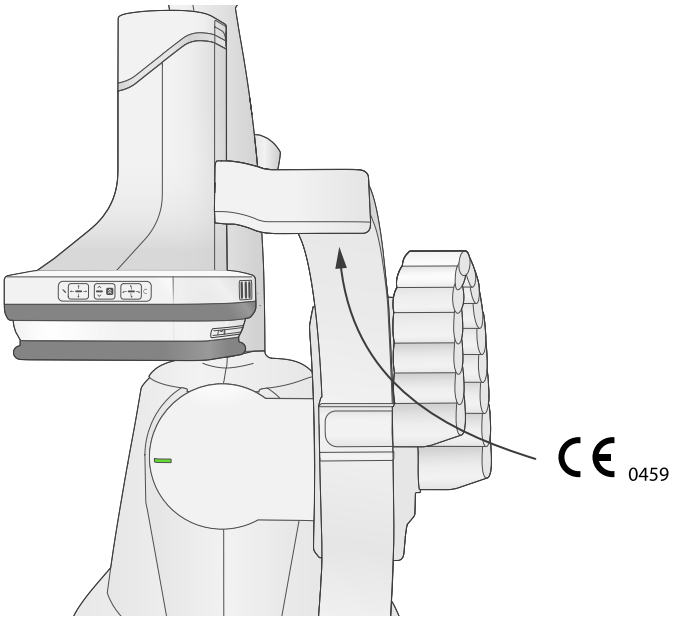
- This product complies with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (MDR) when it bears the CE marking of conformity on the C-arm of the gantry as shown below:

Allia IGS 5





Allia IGS 7
Allia IGS 7 OR



The first year Allia IGS 3 and Allia IGS 5 were CE marked is 2022.

The first year Allia IGS 7, Allia IGS 7 OR were CE marked is 2021.

- Manufacturer’s name and address, address of the manufacturing site and European registered place of business (the two addresses correspond to the same entity):

Manufacturer Address	
GE MEDICAL SYSTEMS SCS 283 RUE DE LA MINIERE 78530 BUC - FRANCE Tel: +33 1 30 70 40 40	GE Medical Systems SCS 283 rue de la Minière BP 34 78533 Buc Cedex France Tel: +33 1 30 70 40 40

NOTE
For continuous compliance with the CE marking, consult your GE HealthCare representative before adding options or accessories other than those indicated in this manual.

Every IGS system has a unique marking for identification. The Unique Device Identification (UDI) marking appears on the product labels which are located on the C-arm of the gantry. Scan or enter the information from these labels into the patient health record as required by the governing laws.

System type symbol	Product Model Name
Allia IGS 5 	Allia IGS 3
	Allia IGS 5
Allia IGS 7 Allia IGS 7 OR 	Allia IGS 7
	Allia IGS 7 OR

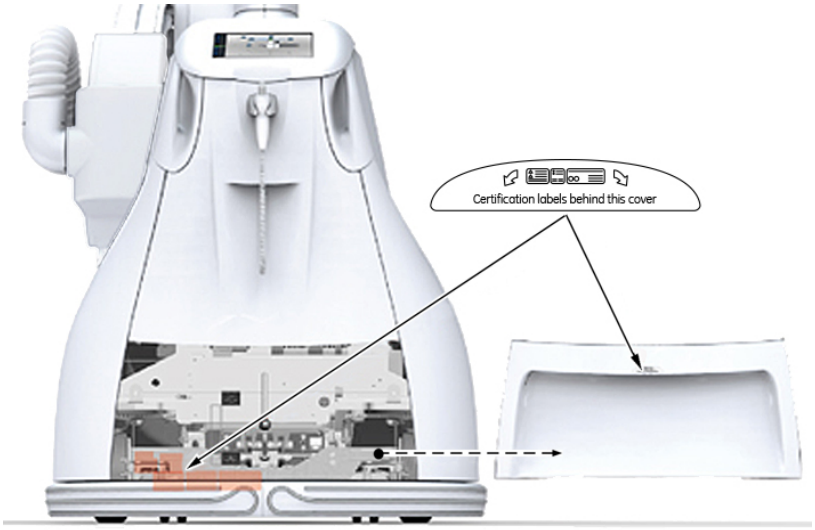
These products comply with the regulatory requirements of the following:

- IGS system has been designed, manufactured and tested to meet the applicable requirements of 21 CFR 1020.30, 1020.32. When IGS system is installed and tested according to the manufacturer instructions, the system meets the applicable requirements. Each component falling under the performances regulated in 21 CFR 1020.30 bears a certification label mentioning the following text:
  'COMPLIES WITH DHHS RADIATION PERFORMANCE STANDARDS 21 CFR SUBCHAPTER J'.
  - CDRH certification label of the C-FRT Cabinet can be found on the door of the cabinet.
  - CDRH certification label of the generator can be found on this part inside the C-FRT Cabinet.
  - The VCIM (Vascular Control Interface Module) is the control panel according to 21CFR 1020.30 and it display a CDRH certification label.

    NOTE
    The user interface device named "control panel" is not a control panel according to 21CFR 1020.30.
  - CDRH certification label of the Collimator, X-Ray Tube and X-Ray flat panel Detector are located on each listed parts.
  - CDRH certification label of table top for Omega and Innova^{IQ} Table can be found on the backside of the table top.
  - **(For Allia IGS 5)** CDRH certification label of the gantry 'Fluoroscopic imaging assembly' is located on the C-Arm.

- **(For Allia IGS 7 and Allia IGS 7 OR)** CDRH certification label of the gantry 'Fluoroscopic imaging assembly' can be found on the back of the Advanced Guided Vehicle (AGV).
- A copy of the label of the generator Tank module can be found on the door of the C-FRT Cabinet.
- **(For Allia IGS 7 and Allia IGS 7 OR)** A copy of the labels of the certified CDRH components that are not accessible to view (collimator, X-Ray Tube, X-Ray flat panel detector and Laser) is provided on the back of the Advanced Guided Vehicle (AGV).

Allia IGS 7
Allia IGS 7 OR



Behind the AGV cover, you will find CDRH labels for:

- A copy of the CDRH certification labels for the following certified components:
  - X-Ray Tube
  - AGV Laser
  - X-Ray flat panel detector
  - Collimator
- the CDRH certification label of the AGV gantry 'Fluoroscopic imaging assembly'.

- **(For Allia IGS 5)** A copy of the CDRH certification labels of the Collimator, X-Ray Tube is provided on the C-arm. A copy of the CDRH certification label of the X-ray flat panel detector is provided on the Gear cover.

- The products are compliant with IEC60601-2-43.
- Canadian Standards Association (CSA).
- International Electrotechnical Commission, international standards organization, when applicable.
- Regulatory markings for a specific country are only in the concerned local language. In general, these markings are designated by the related country code as per ISO 3166-1.
- France:
  Fluoroscopy performed at 3.75 fps with IntelIQ Level1, does not meet the French Quality Control (2016) acceptance criteria on detector spatial resolution and shall not be used.

  Additional recommendation to apply the quality control test procedures:
  - To set the system in manual control during fluoroscopy, refer to 19.3 X-Ray Control Parts Test on page 485.

- All dosimetric indications are displayed without the table attenuation and without backscatter effect. Air Kerma Rate (AKR) and Cumulated Air Kerma (CAK) are displayed at the Interventional Reference Point (for the distance value, see 3.4.3 Concept of Interventional Reference Point on page 49). While in the QC mode, the operator of the equipment does not have patient Dose related information (CAK and DAP).
- Remove the anti-scatter grid for Detector dose testing.
- If the 3D CT mode or 3D CT HD mode or 3D CT sub mode or 3D CT HD sub mode is present, the inspection procedure for quality control is available in the QC mode UM Addendum.

NOTE
Coverage of the 3DStent mode is carried out by the quality control of 3DCT.

- This product complies with the Technical Regulation on Medical Devices #753 when it bears the following Ukrainian mark of conformity:

3.2.2 Product Storage and Handling limits

Post-delivery warm up period

After delivery, and before unpacking the system components, allow 12 hours for the equipment to adjust to room temperature to avoid condensation or rapid temperature change.

For the monitors and UPS, allow 48 hours before the first power on if they have been exposed to higher than specified humidity level.

This warm up period is not required if the shipping environment has met the same temperature and humidity requirement as the destination room and the system components are already at steady room temperature.

NOTE
The temperature, humidity, pressure limits shown in Table 3-1 Transport Requirement on page 26 either equal to or more strict than the limits on actual label, it is acceptable.

Table 3-1 Transport Requirement

Component	TEMPERATURE		HUMIDITY		PRESSURE	
	MIN	MAX	MIN	MAX	MIN	MAX
All components except those listed below	-20°C (-4°F)	+55°C (+131°F)	10%	95%	700 hPa	1030 hPa
Touch Panel	-20°C (-4°F)	+55°C (+131°F)	20%	95%		
All UPS	-20°C (-4°F)	+40°C (+104°F)	10%	90%		
All Monitors	-20°C (-4°F)	+55°C (+131°F)	10%	80%		
Detector	+10°C (+50°F)	+40°C (+104°F)	10%	90%		

System Storage

If storing a system prior to installation, the system shall be stored in its original packaging in a temperature and humidity controlled environment protected from water and dust.

NOTE
The temperature, humidity, pressure limits shown in Table 3-2 Storage requirements on page 27 either equal to or more strict than the limits on actual label, it is acceptable.

Table 3-2 Storage requirements

Component	TEMPERATURE		HUMIDITY		PRESSURE	
	MIN	MAX	MIN	MAX	MIN	MAX
All components except Touch Panel	+10°C (+50°F)	+40°C (+104°F)	10%	80%	700 hPa	1030 hPa
Touch Panel	+10°C (+50°F)	+40°C (+104°F)	20%	80%	700 hPa	1030 hPa

It is recommended that the temperature for storage does not exceed +25°C (+77°F).

Systems with the Fluoro UPS shall be stored for less than 6 weeks if the storage temperature is above 30°C (86°F), and less than 12 weeks if the storage temperature is above +25°C (+77°F).

Systems with the 8 kVA UPS shall be stored for less than 14 weeks if the storage temperature is above 30°C (86°F), and less than 25 weeks if the storage temperature is above +25°C (+77°F).

The overall storage time for the system shall be less than 6 months.

Special instructions for the detector:

The detector is shipped separately from the system and is very sensitive to temperature and humidity, as irreparable damage to the detector scintillator will occur. As defined in the previous table, it shall be stored between +10 and +40°C (+50 to +104°F) and less than 80% RH inside its unopened shipping box, the lowest temperature and humidity being preferable. If it is to be stored outside of its shipping box or if the plastic wrapping has been removed, it should be stored at +20°C (68°F) or less and 30% RH or less.

3.2.3 Specific Requirements for product with a third party monitor suspension

If the customer does not order any of the suspension model proposed in the catalog, then GE HealthCare provides a kit to interface the system with a third party monitor suspension which will have to comply with GE HealthCare specifications and be installed in accordance with GE HealthCare instructions.

In this case, the IGS System is delivered without the standard fully integrated Mavig overhead suspension and its associated suspension rails and cables, to allow customers (purchasers) to choose their own monitors suspension(s). Only GE HealthCare monitors are permitted as primary image display.

In this case, the overhead monitor suspension shall be installed by strictly following the GE HealthCare installation instructions. The manufacturer specifically disclaims any and all liability arising out of or relating to the use or performance of the monitor suspension (including cables), including, without limitation, any liability or claims relating to patient injury, death, or the reliability of such monitors suspension(s).

NOTE
It does not modify the Control room monitor configuration delivered with the IGS system.

Where an overhead monitor suspension(s) is supplied by the purchaser of the IGS System, the overhead monitors suspension(s) shall comply with the applicable Regulation enforced in the country (e.g., when installed in a European Community country, the associated monitors suspension(s) shall comply with applicable local regulations and shall conform with IEC 60601-1 standards).

The association of IGS system and the third party monitors suspension is not covered by IGS product certification.

3.2.4 Electromagnetic Compatibility (EMC)

The IGS systems are compliant with electromagnetic compatibility IEC60601-1-2 Edition 4.1 (2020) and YY9706.102 standards for medical devices.

In order to achieve the Electromagnetic Compatibility for a typical installation, and this medical system, further detailed data & requirements are described at the 26.1 Detailed Electromagnetic Standard Compliance conditions on page 567, and in the PIM document (Pre-Installation Manual).

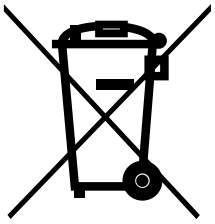
The IGS system has no significant intentional radio emitter, which radiates electromagnetic energy and electromagnetic fields (EMF) susceptible to induce known adverse health effects.

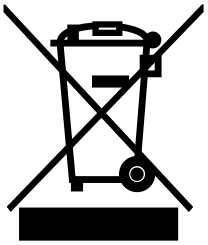
The level of these non-ionizing radiations was assessed under the required and recommended limits, addressing the workers and general public located nearby the IGS system.

Compliance with these limits will ensure that workers and the general public exposed to the electromagnetic fields are protected against all known adverse health effects in the 0 Hz to 300 GHz bandwidth.

3.2.5 Recycling

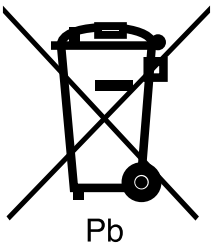
- Instruments or accessories at end of life span:
  Disposal of equipment and accessories must meet the applicable national regulations for waste treatment. Equipment and accessories at the end of their life span must have all materials or components that can be hazardous to the environment (such as accumulators, batteries, transformer oil, etc) removed. Please consult your local GE HealthCare contact before disposing of these products.
- Packaging:
  The materials used for our equipment packaging are recyclable. These materials must be collected and processed according to the regulations applicable in the countries in which equipment or accessories are unpacked.
- Waste Electric, Electronic Equipment (WEEE - 2012/19/EU):





These symbols indicate that electrical waste and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

- Battery recycling (Battery 2006/66/EC):



The separate collection symbol is affixed to a battery, or its packaging, to advise you that the battery must be recycled or disposed of in accordance with local or country laws. The letters below the separate collection symbol indicate whether certain elements (Pb=Lead) are contained in the battery. To minimize potential effects on the environment and human health, it is important that all marked batteries that you remove from the product are properly recycled or disposed.

For information on how the battery may be safely removed from the device, please consult the General Service Manual or equipment instructions.

3.2.6 Control of Pollution caused by Electrical and Electronic Product (EEPs)

The following product pollution control information is provided according to SJ/T11364-2014 *Marking for* Restriction of Hazardous Substances *caused by electrical and electronic products*.

Explanation of Pollution Control Label

This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572 Requirements of concentration limits for certain restricted substances in electrical and electronic products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the hazardous substances contained in electrical and electronic products will not leak or mutate under normal operating conditions so that the use of such electrical and electronic products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is “Year”.

In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual.

Consumables or certain parts may have their own label with an EFUP value less than the product.

This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

Name and Concentration of Hazardous Substances

Table 3-3 Hazardous substances' name and concentration

Component Name	Hazardous substances' name					
	Pb	Hg	Cd	Cr (VI)	PBB	PBDE
Omega and Innova^{IQ} Table	O	O	O	O	O	O

Table 3-3 Hazardous substances' name and concentration (Table continued)

Component Name	Hazardous substances' name					
	Pb	Hg	Cd	Cr (VI)	PBB	PBDE
User Interfaces	O	O	O	O	O	O
(For Allia IGS 5) LC Gantry	X	O	X	O	O	O
(For Allia IGS 7 and Allia IGS 7 OR) Gantry	X	O	O	O	X	X
C-FRT Cabinet	O	O	O	O	O	O
PDU	O	O	O	O	O	O
Tube Cooling Unit	O	O	O	O	O	O
Detector conditioner	O	O	O	O	O	O
19” monitors	X	O	O	O	O	O
Large Display Monitor	O	O	O	O	O	O
20 kVA UPS	X	O	O	O	O	O
8 kVA UPS	X	O	O	O	O	O

This table is prepared according to SJ/T 11364.

O: Indicates that this hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in GB/T 26572.

X: Indicates that this hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in GB/T 26572.

1. Data listed in the table represents best information available at the time of publication.
2. Applications of hazardous substances in this medical device are required to achieve its intended clinical uses, and/or to provide better protection to human beings and/or to environment, due to lack of reasonably (economically or technically) available substitutes.

3.2.7 Dose setting for pediatrics (Germany)

For details about how the system optimizes the exposure techniques and how it complies with regulation about dose settings for pediatrics, (SV-Richtlinie, DIN 6868-150 concerning dose reduction for pediatric), please refer to 4.8 Pediatrics Case on page 130 or the following article:

Barry Belanger, John Boudry: Management of pediatric radiation dose using GE fluoroscopic equipment. Pediatr Radiol (2006) 36 (Suppl 2): 204–211.

3.2.8 Reporting of serious incidents

Any serious incident related to the use of this GE HealthCare device should be reported to both the manufacturer and the health authority/competent authority where the device is installed.

To report to GE HealthCare, either contact your local representative or report to

In-box.complaints@gehealthcare.com.

Please provide the following information:

- The catalogue number or the model designation of the device as stated on its identification plate affixed on the device
- The SystemID/serial number/lot number of the device
- Date of incident
- Description of incident, including any patient or user impact/injury

- Your contact information (facility, address, contact name, title, and telephone number)

3.2.9 Patient Confidentiality

For some maintenance operations related to image quality, it may be necessary for the Service people to get some images back to the manufacturer for analysis. The images may be sent through CDs or via insite connection.

The images may contain patient identification information (name, social security number) in the annotations. Some countries have laws related to medical secret that require respect of patient confidentiality by the health care professionals.

To meet the obligations of these laws, the IGS system can suppress the patient identification field before archiving the images for non medical purposes (image quality investigation).

To suppress patient identification from the images, follow this procedure:

1. If the images are still on hard disk: suppress the patient identification:
   - Enter the patient information screen.
   - Click on the Patient identification field.
   - Suppress manually the patient identification.
   - Click on Apply to confirm. Then, archive this exam.
2. If the images were already networked, first restore the images on the AW or CA1000 workstation, then use the anonymous maker to remove patient identification prior to burn images on CD/DVD.

3.2.10 Auto Exposure Rate Control System

AutoExposure Control System automatically sets X-Ray technique factors (spectral filter, focal spot, kVp, mA, pulse width) optimized for image quality and dose.

The procedure to verify the AutoExposure Control is available in the General Service Manual.

3.3 General Safety

In case of a difference between a generic and a specific instruction for use, the specific instruction will always prevail.

This system contains operating safeguards to provide maximum safety. Before calling for service, be certain proper operating procedures are being used.

Satisfactory equipment performance requires the use of service personnel specially trained on X-Ray equipment. GE HealthCare is responsible for the effects on safety, reliability and performance only if the following conditions are met:

- The electrical wiring of the relevant rooms complies with all national and local codes as well as the Regulations for the Electrical Equipment of Buildings published by the Institution of Electrical Engineers.
- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by GE HealthCare's authorized service representatives.
- The equipment is used in accordance with the instructions for use.

Connection of external equipment on the operator-accessible connectors is restricted to equipment approved by GE HealthCare.

WARNING

ALWAYS BE ALERT TO SAFETY WHEN YOU OPERATE THIS EQUIPMENT. YOU MUST BE FAMILIAR ENOUGH WITH THE EQUIPMENT TO RECOGNIZE ANY MALFUNCTIONS THAT CAN BE A HAZARD. IF A MALFUNCTION OCCURS OR A SAFETY PROBLEM IS KNOWN TO EXIST, DO NOT USE THIS EQUIPMENT UNTIL QUALIFIED PERSONNEL CORRECT THE PROBLEM.

WARNING

THIS PRODUCT MUST BE SERVICED WITH MANUFACTURER APPROVED ORIGINAL REPLACEMENT PARTS ONLY. FAILURE TO FOLLOW THIS RECOMMENDATION WILL VOID THE MANUFACTURER'S WARRANTY AND WILL RELEASE THE MANUFACTURER FROM LIABILITY AND WARRANTY CLAIMS. THE MANUFACTURER CANNOT BE HELD LIABLE FOR UNAUTHORIZED MODIFICATIONS MADE TO THE SYSTEM OR USE OF THE SYSTEM FOR UNINTENDED PURPOSES. SINCE IMPROPER MODIFICATIONS MAY IMPAIR PROPER OPERATION, SAFETY, OR RELIABILITY OF THE SYSTEM, ALL MODIFICATIONS NEED TO BE AUTHORIZED BY THE MANUFACTURER.

NOTE
The system shall not be serviced or maintained while in use with a patient.

3.3.1 Equipment Classifications

The following equipment classifications are applicable to the product:

Classification category	Equipment classification
Protection against electric shock	Class I.
Degree of protection against electric shock	(For Omega and Innova^{IQ} Table) Type B applied parts  Applied parts complying with the specified requirements of the IEC60601-1 standard to provide protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current include: • Table Mattress • Table accessories and detachable parts: table head extender, clear-vu arm, head widener with pad/cushion, width extender with pad/cushion, armboard with thick pad/cushion, rail extender and patient restraint strap with cushion. Considered as applied parts: detector cover, removable rails (sleeve). **NOTE** **(For Magnus Maquet OR Table)** Refer to the manufacturer system operating instructions.

Classification category	Equipment classification
Degree of protection against harmful ingress of water	Ordinary equipment (enclosed equipment without protection against ingress of water, IPX0). Except: • Footswitch (protected against the effects of permanent submersion, IPX8). • Innova^{IQ} OR Table, Control Panel, Touch Panel, Table Panning Device (all protected against splashing, IPX4). **NOTE** **(For Magnus Maquet OR Table)** Refer to the manufacturer system operating instructions.
Method(s) of sterilization or disinfection recommended by the manufacturer	Sterilization: not applicable. Disinfection: refer to User Manual (Recommended Disinfecting Agents on page 71).
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. The system does not fulfill the requirements for AP/APG classification (IEC60601-1)
Mode of operation	Continuous operation with intermittent loading.
Types of use/reuse	multiple patient multiple use
(For Allia IGS 7 and Allia IGS 7 OR) Specification of Laser system	Protection class: Class 1 (in accordance with IEC60825-1 and certified devices according to 21 CFR).  Location of Laser Aperture: Through front clear window of the scanner (see picture in 3.10 Protection regarding Laser Radiation Hazards (Class 1 Laser Product) on page 98) Laser Wavelength: 780 nm nom. Pulse Duration: 0.5 µs nom. Scanner Average Output Power: 20 µW max Internal Laser Source Power: 1.8 mW max Divergence: Horizontal <0.5 mrad Vertical 25 mrad nom. Beam Out of Plane: <60 mm @ 10 m The product integrates a laser product for localization purposes. The laser is mounted on the vehicles pole above 2 meters height and continuously rotates to scan its environment. It emits an infrared laser beam invisible for a human eye. The emitted beam poses no risk to a person's eyes or skin.

(For InnovaIQ Table) The 2" mattress has antistatic properties. As it is connected to the ground and placed on a conductive table top, this provides an antistatic leakage path for the surgical configuration: it is mandatory to use the table mattress provided with the equipment.

3.3.2 Equipment Application Specification

3.3.2.1 Intended purpose

3.3.2.1.1 Intended use / Indication for use

The angiographic X-Ray systems are indicated for use for patients from newborn to geriatric in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures.

Additionally, with the OR Table, the angiographic X-Ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR Table is suitable for interventional and surgical procedures.

3.3.2.1.2 OR Table Configurations

The OR Table can be:

- the Innova^{IQ} Table in the operating table configuration.
- the qualified compatible MAGNUS Maquet OR Table system (1180.01B4 table column)

Systems with Innova^{IQ} OR Table

The OR configuration of the product corresponds to the IGS system product equipped with:

- The Innova^{IQ} Table which has covers with an "OR" branding.
- Dedicated surgery protocols.

NOTE
The Innova^{IQ} OR Table does not have a breakable table top (articulated joints) and lateral tilt (cradling). Procedures requiring these functions are not recommended to be performed with this device.

Allia IGS 7 OR system with Magnus Maquet OR Table

All table tops, elements and accessories described in this paragraph are supplied by Maquet.

There are three table top configurations with Magnus Maquet OR Table:

- Flat table top reference 1180.16A2 or 1180.16F2,
- Flat table top reference 1180.16A6 or 1180.16F6,
- Optional ‘universal table top reference 1180.10A0 or 1180.10F0’

All three mounted on the Column (reference 1180.01B4).

The flat table tops are suited for interventional, minimally invasive and for surgical procedures.

The universal table top is suited for surgical procedures and enables intra-operative use of X-Ray equipment.

The flat table top mandatory elements are as follows:

Carbon fiber table top 1180.16A2 or 1180.16F2
Joystick 1180.93A0 or 1180.93F0
Flat head rest 1002.82A0

or

Carbon fiber table top 1180.16A6 or 1180.16F6
Joystick 1180.93A0 or 1180.93F0

In addition to these elements, the following elements are needed for the universal table top configuration:

Universal table top 1180.10A0 or 1180.10F0

Joint module 1180.11A0 or 1180.11F0
Carbon fiber back plate 1180.37A0 or 1180.37F0
Head rest 1180.50A0 or 1180.50F0 (foot side)
Corded Hand Control 1180.90A0 (only suitable for universal table top)
Head rest (adjustable/bendable) 1002.83A0

Some optional accessories are available for all three table top configurations (flat table top reference 1180.16A2 or 1180.16F2 as well as reference 1180.16A6 or 1180.16F6 and universal table top):

Arm board/support 1001.42A0
Skull Clamp support 1005.48B0 and Skull Clamp 1005.49B0 *
Flat head rest 1002.82A0
Horseshoe head rest 1002.03A0 *
Head rest (adjustable/bendable) 1002.83A0 *

(*)These accessories can be used instead of the flat head rest and are NOT compatible with table top 1180.16A6 or 1180.16F6.

Some optional accessories are available for two configurations, flat table top reference 1180.16A2 or 1180.16F2 and universal table top:

Skull Clamp support 1005.48B0 and Skull Clamp 1005.49B0 *
Flat head rest 1002.82A0
Horseshoe head rest 1002.03A0 *
Head rest (adjustable/bendable) 1002.83A0 *

(*)These accessories can be used instead of the flat head rest.

This optional accessory is available for two configurations, flat table top reference 1180.16A2 or 1180.16F2 as well as reference 1180.16A6 or 1180.16F6:

Accessory rail/adapter 1180.72A0 or 1180.72F0

NOTE
For detailed information and operating instructions on Magnus Maquet Operating table, table tops and its accessories, refer to the user manual from Maquet Manufacturer delivered with these devices.

CAUTION

Any additional material located in the X-ray Beam (such as patient support accessories, table articulated joints, metallic parts...) are not radio transparent. The additional filtration may result in image artifacts and increase the dose to the patient and to the staff.

Refer to Table Head Extensions (with Magnus Maquet OR Table) on page 210 and Skull Clamp collision avoidance with Magnus Maquet OR Table on page 437

3.3.2.1.3 Patient Population

- Age: newborn to geriatric.
- Weight:
  - **(For InnovaIQ Table) (For Omega Table)** Patient weight is limited to the value written on the table label.

- **(For Magnus Maquet OR Table)** Refer to the manufacturer operating instructions.

3.3.2.1.4 Medical Conditions to be Diagnosed, Treated, and/or Monitored

Patients requiring any of the following procedures:

- Diagnostic and interventional cardiac, peripheral vascular, and neurovascular procedures as well as procedures of cardiac electrophysiology and surgical procedures requiring fluoroscopic guidance (OR configuration).
- Percutaneous transluminal procedures for catheter-based delivery of devices, pharmaceuticals, and energy, as well as mechanical removal or modification.
- Percutaneous non-vascular procedures for material removal, material placement and device placement, and ablative therapies.

3.3.2.1.5 Intended operator

Operator Profile: interventional radiology (IR) and surgical specialists, and such who specialize in diagnosis and treatment of IR cardiovascular, oncologic interventions and musculoskeletal injuries and conditions. Certified Radiology Technologists can be qualified intended operators. Nurses qualified to operate the System with training may be allowed in some states and countries. Physicians and Support staff may be qualified to operate the System with training as allowed in some states and countries.

People using, moving, working with the system must have acquired such knowledge and skills during their education curriculum.

3.3.2.1.6 Contrast agents

When an imaging procedure requires a contrast medium, the compatible contrast agent types to be used with the IGS system are:

- Iodine-containing compounds that in part are specifically designed to absorb X-Rays.
- Carbon dioxide (CO_2).

3.3.2.2 Contraindications

None.

3.3.2.3 Expected Clinical Benefit

The benefit of the equipment is to visualize anatomy for diagnostic purposes and to utilize image guidance of instruments to treat patients. This technology enables the physician to perform techniques capable of smaller, less invasive incisions with minimal scarring. Such minimally invasive approaches can reduce tissue disruption and blood loss, lower the length of surgery and anesthesia time over conventional open methods, and allow for a quicker recovery time with improvements to quality of life.

3.3.2.4 Undesirable side effects

The undesirable side effects of the system are those related with X-Ray radiation. There are two types of effects: deterministic and stochastic. Deterministic effects can appear shortly after an acute exposure to high levels of radiation and may include skin reddening, hair loss, radiation burns and potential changes to the lens of the eye. Stochastic effects (such as cancer incidence and DNA mutations) represent an increase in the likelihood of long-term health effects due to length and time of exposure to radiation.

3.3.2.5 Training

- Language Understanding:
  User Manual and System Screens are translated* in the following languages. Users must understand one of these languages before using the system.

Code	User Manual	System Screens (GUI)
BG	Bulgarian	English
HR	Croatian	English
CS	Czech	English
DA	Danish	Danish
NL	Dutch	Dutch
EN	English	English
ET	Estonian	English
FI	Finnish	Finnish
FR	French	French
DE	German	German
EL	Greek	English
HU	Hungarian	English
ID	Indonesian	English
IT	Italian	Italian
JA	Japanese	English
KK	Kazakh	English
KO	Korean	English
LV	Latvian	English
LT	Lithuanian	English
NO	Norwegian	Norwegian
PL	Polish	English
PT-BR	Portuguese (Brazil)	English
PT-PT	Portuguese (Portugal)	Portuguese (Portugal)
RO	Romanian	English
RU	Russian	English
SR	Serbian	English
ZH-CN	Simplified Chinese	English or Simplified Chinese
SK	Slovakian	English
ES	Spanish	Spanish
SV	Swedish	Swedish
TR	Turkish	English
UK	Ukrainian	English
VI	Vietnamese	English

NOTE
* Depending on the region of sale, some translations may not be available.

- Equipment Training: training is available from GE HealthCare. Some country regulations require that equipment training be followed before any use of the system. The facility's management should assess the initial and continuous training needs of qualified users, radiologists or other physicians responsible for the interpretation and / or acquisition parameters. The facility should identify the individuals that should take part in the training relative to dose-reduction features, and dose related acquisition parameters.
  Contact GE HealthCare representative for training options.
- Training Options: from in person application training to self-training with the Online User Manual delivered with the IGS System and the safety instructions of the paper booklet, User Manual DVD. The User Manual DVD shall be placed in a location easily accessible to the operator in case of emergency.
- Training Frequency Recommendation: GE HealthCare recommends that each user of the equipment reviews the procedures and safety precautions at least on annual basis and specially for dose management, GE HealthCare recommends a semestrial training.
  Contact GE HealthCare representative for refresher training options as part of the Radiological Technologists continued education requirements for a licensure maintenance.
- It is highly recommended that physicians be provided adequate time to participate in training and image quality feedback.

3.3.2.6 Application Environment

- General
  - Indoor use only.
  - The IGS system is suitable for Interventional X-Ray procedures (angiograms, device placement, non vascular or minimally invasive surgery) and can be used either in an Interventional Room or in a dedicated lab within an Operating Room Environment which is outside a location designated for marked "AP" or "APG" Equipment. The Operating Room Environment is an environment which has environmental characteristics equivalent to an Operating Room for infection control.
  - Additionally, when equipped with an OR Table and if installed in a dedicated Operating Room, the system is also suitable for open surgery and image guided surgery.

    CAUTION

    Do not use equipment in the presence of flammable gases.

    Special attention is required to clean suspended equipment as per device recommendation and Preventive Maintenance.
- Conditions of Visibility
  Ambient luminance: 150 lux maximum.

  Germany: Ambient luminance of 100 lux maximum required to maintain room class 2 according to DIN 6868-157.
- Environmental Room Condition:

	Exam Room	Control Room	Technical Room
Temperature range	15°C to 32°C	15°C to 35°C	Up to 2000 m: +15°C +25°C Above 2000 m: +15°C +20°C
Relative humidity range	20% to 70%, non condensing	20% to 75%, non condensing	

	Exam Room	Control Room	Technical Room
Altitude range	Sea level to 3000 m (15-32°C)		
Atmospheric pressure range	700 hPa to 1060 hPa		

The time needed for system installation ensures that the system is stabilized in operating conditions: no additional time period is required after installation prior to powering the system on.

WARNING

FAILURE TO FOLLOW THE OPERATING INSTRUCTIONS AND SAFETY PRECAUTIONS PROVIDED IN MANUFACTURER'S INSTRUCTIONS OF HIGH FREQUENCY SURGICAL TOOL, CARDIAC DEFIBRILLATORS AND CARDIAC DEFIBRILLATOR-MONITOR COULD RESULT IN SERIOUS INJURY TO THE PATIENT, OTHERS OR YOURSELF. ATTENTION IS DRAWN TO THE FACT THAT THE IGS SYSTEM IS NOT PROTECTED AGAINST DEFIBRILLATION SHOCKS.

3.3.2.7 Operator Position

(For Allia IGS 7 OR)

The operator should position in the exam room **[1]** around the table or near table side user interface and two meters maximum from the monitors or in the control room **[2]** behind the Console.

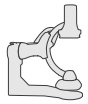
For the Table standalone configuration, refer to the manufacturer operating instructions.

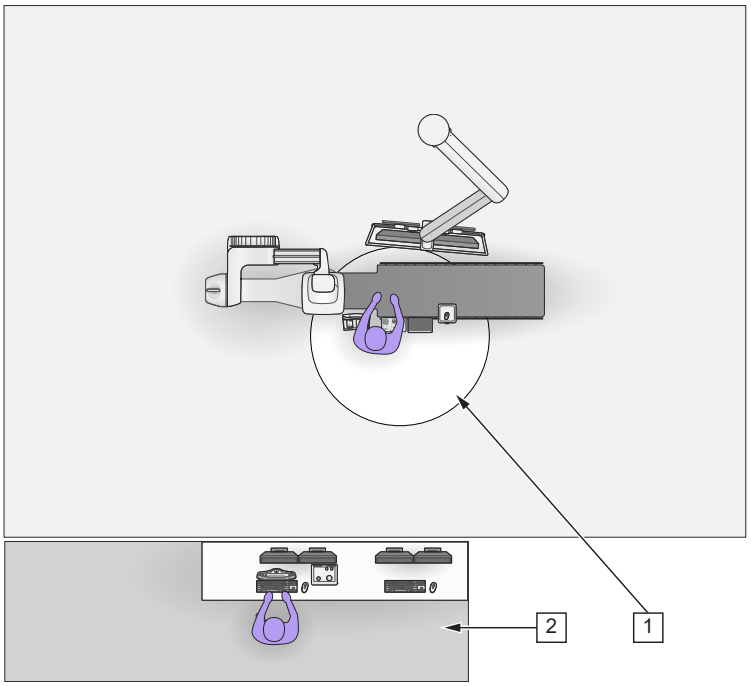
(For System with Omega or Innova^{IQ} Table)

The operator should position in the exam room **[1]** around the table or near table side user interface and two meters maximum from the monitors or in the control room **[2]** behind the Console.

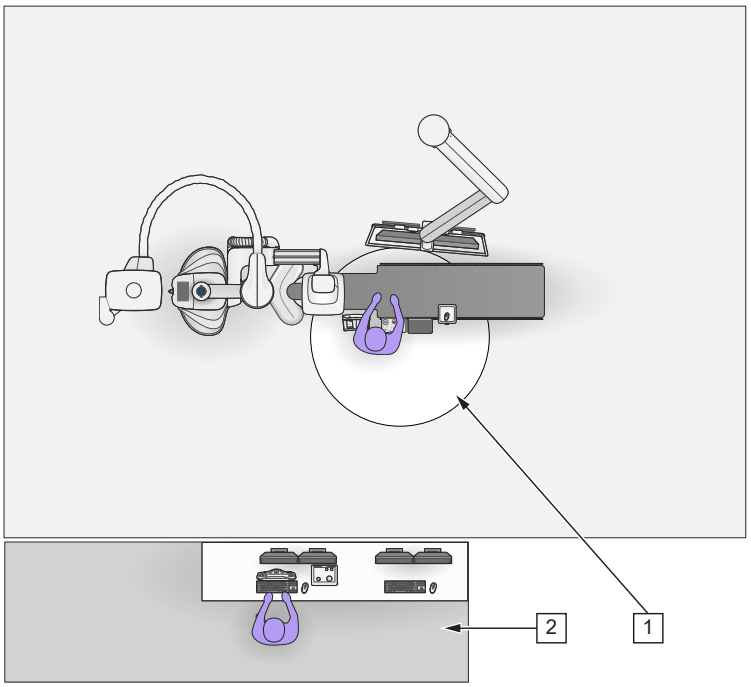
The size of area **[1]** depends on usage of the IGS Control Center option.

Allia IGS 5





Allia IGS 7



3.3.3 Be Sure the Equipment is Functioning Before each Use

Visually inspect the equipment for damage and missing parts. Do not turn on electrical power if any of the cover panels are not in place or broken; hazardous electrical or mechanical parts could be exposed. Damaged parts may lose their degree of protection against harmful ingress of liquids or may fall. Replace the damaged or missing parts.

Verify that the following controls are operating correctly:

- Motion Controls, Motion Enables, and Table Top Brakes. 6.1.1
- Motion emergency stop.
- Collision sensors and the routine for clearing collisions.

Verify no alarm message is displayed on the DL screen or on the live & reference displays (refer to 13.6 List of Alarm Messages on page 453), and that there is no audible alarm.

Damaged controls could result in unintended motion. Do not operate the equipment if the controls are not operating properly.

CAUTION

When covering the equipment with sterile drapes or other protective covering, be sure the covering does not interfere with the Motion Controls or Motion Enables that could lead to unintentional motion activation.

NOTE
As per local regulations, record of these functional checks may have to be kept with the equipment.

Motion Controls, Motion Enables, and Table Top Brakes

- Perform a daily check of the gantry pivot axis (RAO/LAO rotation) position by moving it to PA position by using the PA command (Bring the table back to horizontal position first).
  Check that the gantry C-arm is in vertical position and that "RAO/LAO 0 deg" +/- 1 deg is displayed on the Geometry area, left on the live display.

  Move the gantry pivot axis and check that the displayed angle is updated.

  In case of mismatch detected, call your local Service Representative.

- Perform a daily check of the table Up/Down axis by moving the table to its lowest position.

  Check that 

 is displayed on the Geometry area, left on the live display.

  Move the table Up and check that the displayed value is updated.

  In case of mismatch detected, call your local Service Representative.

Collision Sensors and the routine for clearing collisions

WARNING

CHECK THE COLLISION BUMPER AROUND THE IMAGE RECEPTOR DAILY BY DEPRESSING IT.

Large Display Monitor suspension

Check daily the presence of the live image and the reference display on the 2 backup monitors that are located either at the back of the suspension or on an additional suspension.

3.3.4 Establish Emergency Procedures

It is not always possible to determine when some components, such as X-Ray Tubes, are nearing the end of their operating lives. There is a residual risk that a patient examination is interrupted because of a component unrecoverable failure.

WARNING

ESTABLISH PROCEDURES FOR HANDLING THE PATIENT IN CASE OF THE LOSS OF FLUOROSCOPIC IMAGING OR OTHER SYSTEM FUNCTIONS DURING AN EXAM.

3.3.5 Equipment Installed in Patient Vicinity

NOTE
Patient vicinity is defined as a space within the room 1.83 m beyond the perimeter of the examination table and extending vertically 2.29 m above the floor.

The following equipment may be installed in patient vicinity, depending on availability:

- Table
- Mattress and slicker
- Gantry
- Monitors
- Injector
- Rad-shield
- Control Panel
- Table Panning Handle
- Touch Panel
- Accessories and auxiliary devices
- **(For InnovaIQ Table) (For Magnus Maquet OR Table)** IGS Control Center
- Magnus OR table control interfaces
- Footswitch

All these components are suitable for use within the patient environment.

3.3.6 Periodic maintenance and inspection

WARNING

FAILURE TO PERFORM THE PERIODIC INSPECTION AND MAINTENANCE COULD ALLOW DETERIORATING CONDITIONS TO DEVELOP WITHOUT BEING DETECTED. THIS DETERIORATION COULD RESULT IN EQUIPMENT FAILURES WHICH COULD CAUSE SERIOUS INJURY OR EQUIPMENT DAMAGE. QUALIFIED PERSONNEL SHOULD PERFORM PERIODIC MAINTENANCE AS SPECIFIED IN THE MAINTENANCE SCHEDULE OF THE GENERAL SERVICE MANUAL AND USER MANUAL.

NOTE

(For Allia IGS 7 OR) Maintenance activities on the Magnus Maquet OR Table system may affect the Allia IGS 7 OR System functions and performances (e.g. Vision). A specific maintenance (Augmented Calibration - CAL0129), provided in the Service documentation supplied with the equipment, may be required to restore the system functions and performances. It is the owner's responsibility to supply or arrange for this service.

- Descriptions and scheduled frequency of the required periodic maintenance are provided in the Service documentation supplied with the equipment. It is the owner's responsibility to supply or arrange for this service. Refer to 22.2 Periodic Maintenance for all countries on page 503 for the list of the periodic maintenance requirements.
- Inspection intervals are based on average daily use of one eight-hour shift. More frequent inspection is appropriate where equipment use is above average. Refer to 3.3.3 Be Sure the Equipment is Functioning Before each Use on page 40. Additionally, the following checks have to be done.

Monthly checks	
Actions	**Refer to**
Suspensions cleaning	Suspensions Cleaning on page 70
QAP check	Frequency on page 481

Check Once every 3 months	
Actions	**Refer to**
UPS battery recharge if not used	3.8.5 Loss of Supply Mains Power on page 89

3.3.7 Storage media

Put storage media such as the User Manual DVD in safe conditions: temperature (see the instructions on CD packages).

3.3.8 Exposure to toxic fluid

The cooling fluid used in the system contains: Diala S4 ZX-IG & Diala S5 BD.

WARNING

IN CASE OF LEAKAGE OF THE COOLING SYSTEM, AVOID SKIN OR EYE CONTACT. PREVENT FROM SPREADING BY MAKING A BARRIER WITH CONTAINMENT MATERIAL. PLEASE INFORM THE SERVICE PERSONNEL.

- IN CASE OF SKIN CONTACT: REMOVE CONTAMINATED CLOTHING. FLUSH EXPOSED AREA WITH WATER AND FOLLOW BY WASHING WITH SOAP IF AVAILABLE. IF PERSISTENT IRRITATION OCCURS, OBTAIN MEDICAL ATTENTION.

- IN CASE OF EYE CONTACT: FLUSH EYE WITH COPIOUS QUANTITIES OF WATER. REMOVE CONTACT LENSES, IF PRESENT AND EASY TO DO. CONTINUE RINSING. IF PERSISTENT IRRITATION OCCURS, OBTAIN MEDICAL ATTENTION.

Pushing the emergency power off button of the system will stop the cooling pump.

The following information may be useful should a leak occur.

Protection of first-aiders:

- The cooling fluid may be fatal if swallowed and enters airways. Symptoms may include coughing, choking, wheezing, difficulty in breathing, chest congestion, shortness of breath,

and/or fever. The onset of respiratory symptoms may be delayed for several hours after exposure. Defatting dermatitis signs and symptoms may include a burning sensation and/or a dried/cracked appearance. Ingestion may result in nausea, vomiting and/or diarrhea.

- When administering first aid, ensure that you are wearing the appropriate personal protective equipment according to the incident, injury and surroundings.
- Chemical resistant gloves are to be worn; chemical resistant suit is indicated if large contact with spilled product is expected.
- Slippery when spilt. Avoid accidents, clean up immediately. Prevent from spreading by making a barrier with containment material.
- Reclaim liquid directly or in an absorbent. Use appropriate containment to avoid environmental contamination.

If inhaled: No treatment necessary under normal conditions of use. If symptoms persist, obtain medical advice.

If swallowed: Call the emergency number for your location / facility or a poison center. Do not induce vomiting: transport to nearest medical facility for additional treatment. If vomiting occurs spontaneously, keep head below hips to prevent aspiration. If any of the following delayed signs and symptoms appear within the next 6 hours, transport to the nearest medical facility: fever greater than 101° F (38.3°C), shortness of breath, chest congestion or continued coughing or wheezing.

3.4 Protection against ionizing radiation hazards

3.4.1 Introduction to dose

3.4.1.1 Doses parameters

There are different types of dose depending on where and how the measurement is taken and if the measurement is for the patient or the detector dose.

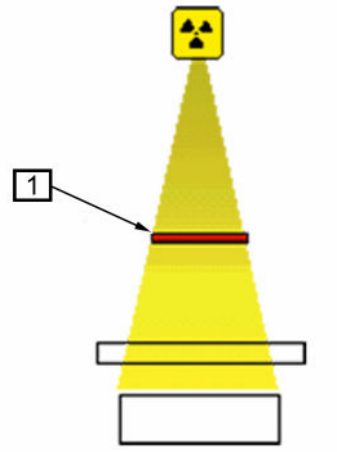
Incident dose

The incident dose is the dose measured in the middle of a radiation field on the surface of a body or a phantom. However, it is only measured at this point if there is no body in the path of the X-Ray beam. Thus, there is no scatter radiation from the body during this measurement. When radiation strikes a substance, there is always a certain scattering of X-Rays. This is comparable to light striking a glass surface; a certain portion of the light is always reflected.

Incident dose = the dose measured on the intended surface of the patient, but without the presence of the patient.

The System International unit (SI unit) used to measure the incident dose is the Gray, where 1 Gy = 1 J/kg.

But because today's doses are generally very small, they are usually described using the "mGy" unit, that is, 0.001 Gy.



Item	Description
[1]	Incident dose

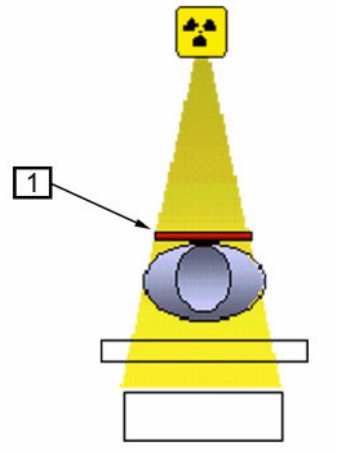
Surface dose

The surface dose is measured with the body in the path of the beam. Because of the scattered radiation that results on the surface and in the depths of the body, the surface dose differs from the incident dose by including the amount of scattered radiation.

Thus we can say:

Surface dose = incident dose + scattered radiation from the body

The SI unit used to measure the surface dose is the Gray (Gy).

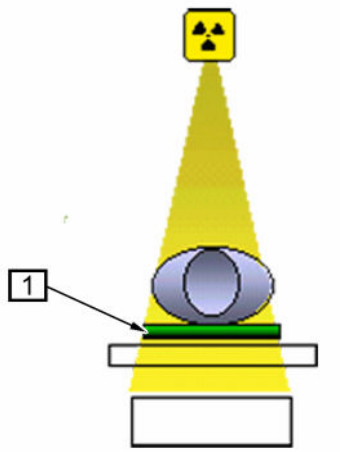


Item	Description
[1]	Surface dose

Exit dose

The exit dose serves in the evaluation of the X-Ray image. It is measured in the radiation field in immediate proximity to the surface of the body where the beam exits from the body.

The SI unit used to measure the exit dose is the Gray (Gy).



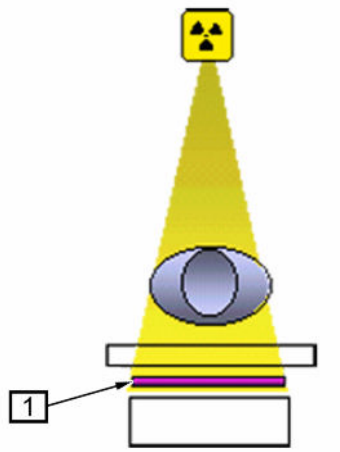
Item	Description
[1]	Exit dose

Image receptor dose

The image Receptor dose is measured at Revolution Digital Detector. The image receptor dose is generally smaller than the exit dose, because the radiation weakens before it reaches the image receptor, for example by encountering objects after the patient's body such as the anti-scatter grid.

Image receptor dose $\leq$ exit dose

The SI unit used to measure the image receptor dose is the Gray (Gy).



Item	Description
[1]	Image receptor dose

Dose rate

In order to measure a dose, the beam must operate for a certain period of time. The dose rate therefore represents the measured dose for the amount of time required to complete the dose measurement. If the image receptor dose is measured in the process, then the dose rate is the image receptor dose rate. If the dose is measured at a different site, then the dose rate is determined using one of the previously mentioned dose parameters.

$$\text{Dose rate} = \frac{\text{measured dose}}{\text{required time}}$$

The SI unit used to measure the dose rate is Gray per second: (Gy/s) or in usual unit (mGy/min).

Dose per frame

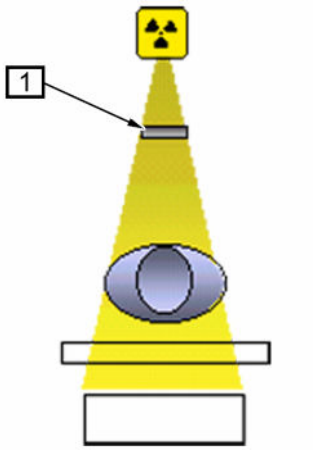
The dose per image is the amount of dose measured during the acquisition of one image (frame).

The SI unit used to measure dose per frame is Gray per frame (Gy/frame).

Dose-area product

The dose-area product is a measurement of the amount of radiation that the patient receives. The dose-area product is independent of the distance between the X-Ray Tube and the measuring device because the further away from the X-Ray Tube this measurement is taken, the more the size of the device increases, and the dose itself decreases (see diagram). The dose to the patient can be calculated from the dose-area product, the size of the measuring device, and the distance to the X-Ray Tube and the patient.

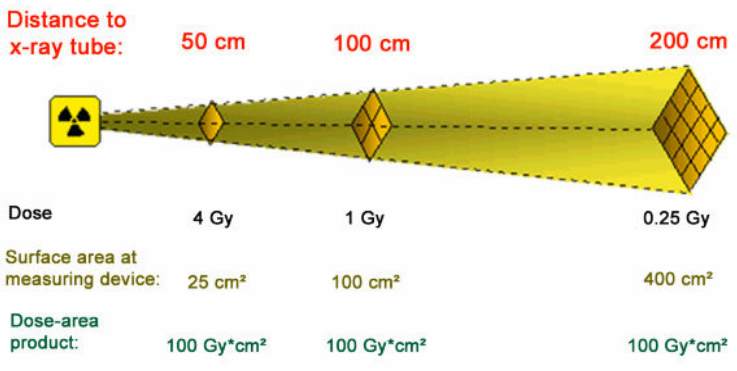
Dose-area product (DAP) = dose * surface area of the measuring device



Item	Description
[1]	Dose-area product

The SI unit used to measure the dose-area product is the Gray.meter^2 (Gy.m^2) or in usual unit cGy.cm^2, Gy.cm^2 or mGy.cm^2.

Figure 3-1 Dose-area product



The dose-area product at 50 cm from X-Ray Tube is just as great as dose-area for 100 cm or 200 cm, because the size of the measuring device increases with greater distance to the X-Ray Tube. But the dose itself decreases with greater distance to the tube. Thus the dose-area product is the same at each position if the size of the measuring device enables it to detect all of the radiation.

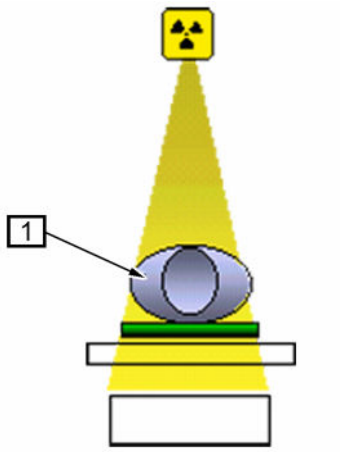
Body dose and effective dose

The body dose is the comprehensive concept for the organ or partial-body dose equivalent and the effective dose. In the practical application of radiation protection, however, local and individual doses are monitored, because body doses cannot be measured directly. The Radiation Protection Regulations therefore use the concept of effective dose, in which all the individual doses to the irradiated organs or parts of the body are multiplied by a factor and then added together. The resulting value may not exceed the dose limit for the effective dose that a patient is allowed to receive.

Body dose = sum of all organ or partial-body doses

Effective dose $\leq$ patient dose limit

The SI unit used to measure the body dose and the effective dose is the Sievert (Sv), where 1 Sv = 1 J/kg = 1 Gy



Item	Description
[1]	Body dose

Maximum Symmetrical Radiation Field

The maximum symmetrical radiation field for a high voltage of 75 kV at a distance from the focal spot of 1 meter according to IEC 60806:2022, for a 100% opened collimation, is: **(For IGS 520)** 200 mm/200 mm, **(For IGS 530)** 305 mm/305 mm, **(For IGS 730)** 305 mm/305 mm. For the assembly, the smallest distance from the focal spot (SID) is described in 5.3.3 Gantry on page 150.

Actual values may vary according to the system alignment accuracy i.e., within 3% SID along each of the two major axes according to the applicable clause 203.8.5.3 third dash point (a) from IEC 60601-2-54.

3.4.1.2 Radiation filtration / hardening

Spectral filtration is added filtration that is inserted between the X-Ray Tube source and the patient in order to harden the beam and reduce the soft radiation.

The system automatically inserts appropriate additional copper filtration for each fluoroscopy or record acquisition to optimize patient dose and image quality.

3.4.1.3 Fluoro Strategy

Fluoroscopy is typically performed at a lower dose compared to record, which inherently results in more noise in the image (as the quantum noise is a direct function of the quantity of X-rays). When the frame rate is reduced, the human visual system's inherent temporal averaging becomes less effective, and images may look a bit noisier at lower frame rate. This can be mitigated by

appropriately increasing the dose per frame, while still achieving dose saving in reduced frame rate mode to the possible extent, by using the dose reduction strategy called Balanced IQ/Dose. For more details, refer to Frame Rate on page 126. Additionally, images may appear slightly jerky at lower frame rates.

3.4.2 Biological Deterministic Effects of Dose

Biological effects of any dose should be divided into low and high levels. During most procedures, the effects of patient irradiation are low. However, some long, X-Ray demanding procedures could give the patient high doses of radiation, and this can be the cause of injuries to the patient (e.g.: skin injuries, alopecias). In order to minimize this risk without adversely affecting the clinical objectives of the procedure, it is currently admitted that precautions should be taken when skin dose in a single location can exceed 1 Gy.

Due to the duration of total fluoroscopic time and the number of acquisition sequences in a single location, the risk is particularly important in cardiac and neurology procedures.

GE HealthCare equipment includes dose limitations mechanisms; in particular, the conventional entrance skin dose rate is maintained below 88 mGy/min (10 R/min), or at a lower level depending of local regulation, in a plane representative of patient skin dose, and positioned 30 cm from the entrance of the Image Receptor. Therefore, in this plane, the value of 1 Gy may be reached in 10 to 12 minutes of fluoroscopy (usual levels of fluoroscopy of the head are 2 to 5 times lower).

In particular configurations required for an examination, patient skin could be significantly closer to the X-Ray source, with dose rate increased as the inverse square of the distance.

WARNING

IN CASE OF LONG PROCEDURES AND/OR WHEN X-RAY IS FOCUSED ON A SINGLE LOCATION, REDUCE FLUORO AND RECORD LEVEL IN ORDER TO REDUCE RISK OF PATIENT INJURY DUE TO IONIZING RADIATION AND FOLLOW OTHER RECOMMENDATIONS LISTED IN SECTION "**3.4.7 HOW TO REDUCE RADIATION EXPOSURE DOSE ON PAGE 51**" AND RADIATION SAFETY TUTORIAL.

The danger of radiation exposure is increased as the area of the body that receives the exposure is increased. Certain tissues such as bone marrow are more sensitive to radiation than others. Genetic effects of radiation are considered as a special hazard when the gonads are exposed to radiation. Lens of the Eyes, the Thyroid, blood forming organs or a developing embryo is the most radiation sensitive. For suspected or pregnant patients, extra precautions against ionizing radiation exposure should be taken.

Radiation damage to the body is generally greater when the dose is given in a one shot exposure than if the dose is spread over a greater period of time. The effects of large doses or radiation usually show up in a short period of time. However, delayed effects of radiation may show up after many years in a form such as cancer or leukemia.

3.4.3 Concept of Interventional Reference Point

The INTERVENTIONAL REFERENCE POINT (IRP) or PATIENT ENTRANCE REFERENCE POINT, is intended to be representative of the point of intersection of the X-Ray beam axis with the patient. For the IGS systems including an isocenter, the IRP is the point on the reference axis 15 cm from the isocenter towards the focal spot.

This distance is assumed to represent a good approximation of the value of the actual focal spot to skin distance during interventional procedures. If one considers currently available methods to estimate absorbed doses to selected tissues for radioscopic and cine-angiographic examinations of the coronary arteries of adults, these methods rely on the use of distinct operating conditions commonly used in radiological examinations of the heart.

These operating conditions are associated with a view, an arterial projection, and technique factors on the X-Ray equipment such as the X-Ray Tube voltage (kV), the half value layer (HVL), and the focal spot to skin distance, the focal spot to image receptor distance and the entrance field size.

A review of the operating conditions derived from analyses of cardiac practice indicates that the defined interventional reference point is, in fact, a fair approximation of the focal spot to skin distance for each field. Unfortunately, similar data are not available for non-cardiac diagnostic and interventional procedures.

- Isocenter
  The isocenter is the point at which the rotational axes of the Pivot and the C-arm intersect.
- Focal Spot to Interventional Reference Point Distance:
  (For Allia IGS 5) : 57 cm (22.4").

  (For Allia IGS 7 and Allia IGS 7 OR) : 67 cm (26.4").

3.4.4 Dose Monitoring

Dose monitoring is a feature of the system, computing:

- Dose rate (air kerma), labeled "Exposure Dose" / "Rate").
- Exam cumulated dose, labeled "Exposure Dose" / "Cumulated".
- Dose Area Product (DAP) labeled "DAP".

Output parameters are displayed on the DL screen and on the live & reference displays.

The dose levels are determined with a measurement method based on the measured Generator X-Ray Technique parameters (kVp, mAs), on the Spectral Filtration position reported by the Collimator, on measured mR/mAs calibration values obtained with a radiation dosemeter, and on a transfer function (computation).

The dose rate and exam dose are computed for the INTERVENTIONAL REFERENCE POINT.

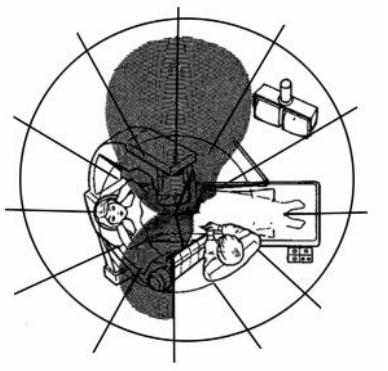
The DAP is computed based on collimator opening (field of view and collimation).

The accuracy of the displayed dose values for dose rate, cumulated dose and Dose Area Product is +/-35%. Additionally, for DAP it is +/-30% at 80 kVp.

3.4.5 Dosimetric Calibration

To maintain the calibrations of all dosimetric indications, the "mR/mAs" calibration procedure shall be strictly made following the Periodic Maintenance (PM) interval for that calibration (6 months). (Refer to the *Logbook*).

3.4.6 Significant Zone of Occupancy



There is a significant zone surrounding the table that identifies proximity to the radiation source. Included in the significant area is the table side area where the Physician stands to perform the procedure.

All equipment within this zone 1.5 m around the patient are medical components that must be in compliance with medical device regulations.

3.4.7 How to Reduce Radiation Exposure Dose

Follow instructions listed in Chapter Radiation Safety Tutorial on page 119 to use the proper means to reduce radiation exposure for both patient and staff.

Radiation Time

In Fluoro: check and control the elapsed fluoroscopy time. When possible change the entry point of the beam in order to reduce local dose.

In Record: try to keep the frame rate at the lowest value compatible with medical requirements; minimize the total sequence.

Protection

When the tube is positioned under the table, the scattered radiation reaching the staff is weaker because of the absorption of the patient.

Additional lead aprons and protective devices such as lead gloves, glasses and thyroid shields are also effective in limiting occupational exposure dose.

CAUTION

In order to reduce risks associated with ionizing radiation and facilitate compliance with local regulation concerning radiation protection, always use radiation shielding devices (ceiling mounted and table-side Rad-shields). They will protect the operator against stray radiation (radiation leakage plus radiation scattered by the patient); This protection should be considered as particularly critical when performing interventional or long procedures.

Protective devices and Accessories

Refer to the accessories catalog for a complete list of available radio-protection devices (Rad shield, gloves, apron, glasses, etc.).

NOTE

(For System with Magnus Maquet OR Table) the only Rad shield reference validated by the table manufacturer is 1101.6777 (Lower body X-Ray Shield).

Other Methods to decrease Exposure Dose

- Use lowest level whenever possible.

- Use lowest available frame rate whenever possible.
- Select a protocol with "Max Dose Reduction" setting instead of "Balanced IQ/Dose" setting for Fluoro 15 fps, 7.5 fps and 3.75 fps (only for no sub fluoroscopy).
- Maximize the distance between the patient and the X-Ray Tube.
- Minimize the distance between the patient and the Image Receptor.
- Collimate.
- Remove grid only for infants up to 1 year old at Field of View smaller than 20 cm.

NOTE
For all anatomies, except for infants (patients up to 1 year old) at Field of View smaller than 20 cm, it is preferable to use the grid with minimum air gap.

3.4.8 Skin Spacer Use

Exposure rate is approximately 1.5 times greater at 305 mm from the focal spot than at 380 mm. Use the skin spacer to ensure a minimum distance of 380 mm.

3.4.9 Maximal irradiation times between the exposure switch release and the last X-ray pulse end

In compliance with applicable standards, fluoroscopy exposure can continue up to 0.1 s after the X-ray control is released.

3.4.10 Avoid Unnecessary Exposure to Radiation

Retake - Improper Use

CAUTION

Improper use of the system could lead to retakes of diagnostic images, thus requiring additional patient and operator exposure to radiation. Therefore, observe operating instructions.

Disable X-Ray Whenever X-Ray Are Not Necessary

CAUTION

X-Ray should be disabled whenever they are not necessary to prevent the possibility of irradiation being emitted through the inadvertent actuation of an irradiation switch.

Press on the X-Ray disable button on the Control Panel or the DL screen (monitoring bar) to disable/re-enable X-Ray.

When X-Rays are disabled, the button on the Control Panel is lit in blue while the buttons on the DL screen are enabled.

For additional information concerning the X-Ray disable button on the DL screen please refer to 7.1.1 Monitoring Bar on page 170.

X-Ray without image

In case of obvious X-Ray emission (sound and/or red light signal on) without image on the live display, quickly perform the following actions:

- Release the footswitch.
- If X-Ray are still emitted, depress the **RESET** button on the VCIM until the system resets.
- If X-Ray are still emitted, push the emergency power off button of the system.

3.4.11 Dose and Dose Rate Measuring Procedure

This section provides radiation data measurement instructions according to the radiation data documented in the user instructions specific to each IGS system.

NOTE
When measuring dose, always do a fluoro run prior to the run, otherwise spectral filter selection (and thus the measured dose) may not be reproducible.

3.4.11.1 Test Equipment

Phantom

Material: Polymethyl-methacrylate (PMMA)

Rectangular blocks with sides equal to or exceeding 25 cm.

Nominal thickness: 20 cm (the phantom may be fabricated from layers of material).

Area density of the nominal 20 cm phantom: 23.5 gcm^{-2} +/- 5%.

Dosimeter

The measuring probe must be small enough to cover not more than 80 % of the area of the X-Ray beam in the plane of measurement and the area of its surface perpendicular to the source-detector axis must not exceed 30 cm^2.

3.4.11.2 Dose and Dose Rate Measurement procedure

Relevant parameters

The following are the factors that need to be referenced, when relevant to the equipment settings concerned:

- Equipment configuration:
  - Orientation of the X-Ray BEAM (vertical unless otherwise specified).
  - PATIENT SUPPORT in or out.
  - ANTI-SCATTER GRID in or out.
  - Appropriate ENTRANCE FIELD SIZE selected (FOV).
- Operating settings (representative of normal use):
  - Technical details of parameters included in each mode of operation.
  - Frame rate.
  - Selectable added filters automatically applied.
- Test geometry:
  - Focal spot to image receptor distance (SID).
  - Focal spot to detector distance.