## 3.8.14.1 System localized with poor accuracy

The localization system estimates the quality of its measurement. In case the system determines the vehicle's position with poor accuracy, the system functions at reduced speeds and the following message is displayed on the in-room monitor:

`[System location imprecise, degraded speed; check reflectors visibility.]`

If the message appears the user has to verify if objects are obscuring either the laser's view or a reflector (e.g. vertical poles, display screens, suspensions and booms) and perform adequate actions to ensure that as many reflectors as possible remain visible.

## 3.8.14.2 System lost

In case the system fails to determine the vehicle's position, the vehicle motions are disabled for safety reasons. The user can still perform C-arm motions at reduced speeds and perform X-Rays, and the following message is displayed on the in-room monitor:

`[!! Collision risk. Collision prediction failure. Move with care (2.14)]`, in alternance with other messages.

If this message appears the user has to verify if objects are obscuring either the laser's view or a reflector (e.g. vertical poles, display screens, suspensions and booms) and perform adequate actions to ensure that as many reflectors as possible remain visible.

As soon as the system recovers its location, it will function again normally. If user's action do not solve the localization issue, reset the system.

## 3.8.14.3 Motion failure recovery

### Recover from trajectory exit

The gantry is equipped with a safety mechanism that will prevent it from moving outside of its usual trajectory. If this mechanism detects that the gantry is in motion beyond the allowed tolerance of movement, it will stop automatically.

To recover, the gantry needs to return within the allowed limits (in distance and in angle). This can be done by using the user interface at the rear of the gantry. The touch screen will display an icon showing that the gantry needs to return to the trajectory to recover. Press the 2 buttons ([**1**] and [**2**]) of the AGV handle to trigger this motion. When the gantry is back on its trajectory, reachable positions are highlighted and can be selected again.
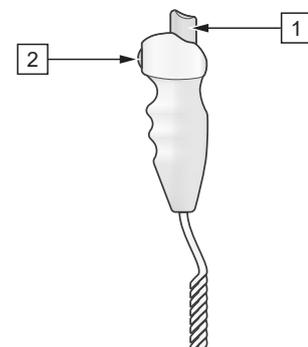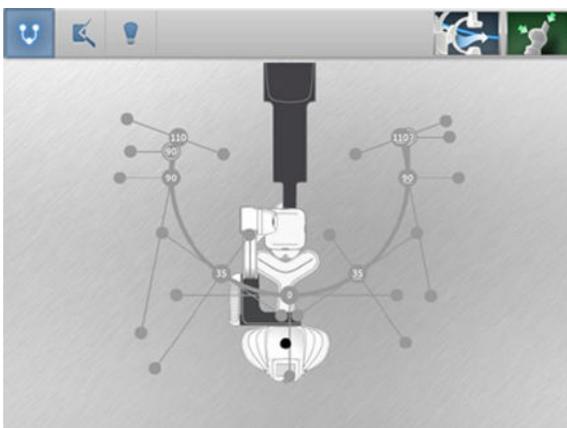


If the gantry is too far from its limits (gantry displayed outside its trajectory and no icon displayed), the gantry cannot recover with the motorized motion.

## "Freewheel" mode

In case AGV movements are totally locked (example power failure) and there is an absolute need to move the gantry, the system is equipped with a jack which can be used to lift the gantry driving wheels and move the gantry by pushing on it (freewheel mode). This mode should not be used for operating the gantry in normal conditions.

Freewheel mode quick guide:

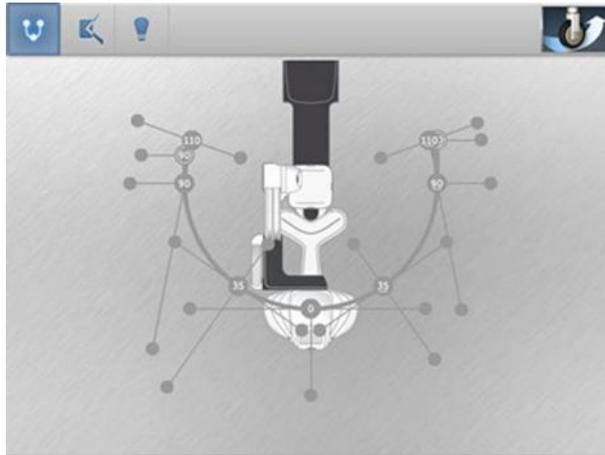1.  Open the bottom cover located at the rear of the AGV.

Spare wheels

2.  Use the crank to lift the AGV on its spare wheels.

While the gantry is on the jack, motorized motion of the gantry on the floor is not possible.

The following icon  appears on the top right of the AGV touch screen.

3.  Roll the AGV by pushing it manually.
    At least two persons are required to perform this operation. Wheels are unidirectional allowing only forward and backward translations. Other gantry motions are not available in this mode.

    > **NOTE**
    > Do not push on detector, tube, laser, mast or AGV covers, as they are not designed to withstand such pushing.

| **Figure 3-8 AGV translation** | **Figure 3-9 AGV rotation** |
|---|---|
|  |  |

To roll the AGV forward or backward:

- Grab the two handles at the rear.
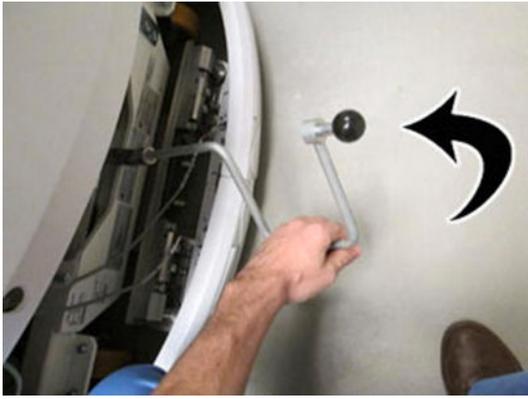- Push it forward or pull it backward.

To rotate the AGV:

- Push on the C-arm.
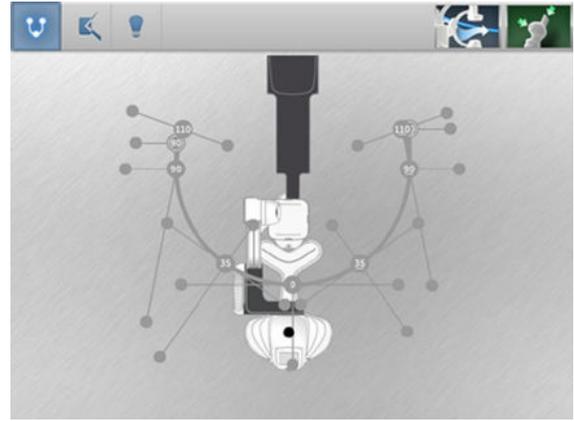- Front wheels have to roll on the floor.

4.  Exit freewheel mode



Before lowering the AGV with the crank, roll the AGV close to the circuit until the icon appears, indicating that AGV can be brought back to circuit automatically.

Turn the handle counter-clockwise.

When the crank is in normal position, free wheel icon disappears.



Proceed as described in the previous section to recover from trajectory exit by pressing both **AGV handle** buttons.

## 3.8.15 Importance of proper data management

**CAUTION**

The user shall take special care on proper data management.

## 3.8.16 Extra Iodine Injection

When used in automatic mode, the injector can be triggered by the system before or after X-Ray (X-Ray delay or Inject delay).

When the injector is fired before X-Ray, there is always an unpredictable residual risk that X-Ray will not start, resulting in useless injection (our internal data give a very low occurrence rate).

Use preferably the X-Ray delay mode (injection first then X-Ray) if clinically appropriate.

## 3.8.17 3rd Party Imaging/Data Medical Device

For 3rd party imaging/data medical devices, refer to the safety recommendations in Third-Party Interfaces on page 477.

## 3.8.18 Patient positioning in case of Emergency (Power Loss, Equipment Failures)

### With Innova$^{IQ}$ Table

**WARNING**

IN CASE OF FAILURE OF THE TABLE BRAKES, OR POWER LOSS WITH THE PATIENT POSITIONED BETWEEN THE IMAGE RECEPTOR AND TABLE IT IS STILL POSSIBLE TO OVERCOME THE TABLE BRAKES LOCK BY MANUALLY ROTATING THE TABLE WITH SUFFICIENT STRENGTH IN ORDER TO FINISH THE PROCEDURE OR TO CLEAR THE PATIENT. THIS OPERATION MAY REQUIRE MORE THAN ONE PERSON.

### With Omega Table

**WARNING**

IN CASE OF FAILURE OF THE TABLE BRAKES, OR POWER LOSS WITH THE PATIENT POSITIONED BETWEEN THE IMAGE RECEPTOR AND TABLE IT IS STILL POSSIBLE TO OVERCOME THE TABLE BRAKES LOCK BY MANUALLY ROTATING AND PUSHING THE TABLE WITH SUFFICIENT STRENGTH IN ORDER TO FINISH THE PROCEDURE OR TO CLEAR THE PATIENT. THIS OPERATION MAY REQUIRE MORE THAN ONE PERSON.

# 3.9 Protection against electromagnetic interference hazards

**WARNING**

PORTABLE RF COMMUNICATIONS EQUIPMENT INCLUDING PERIPHERALS (SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE USED NO CLOSER THAN 30 CM (12 INCHES) TO ANY PART OF THE IGS SYSTEM INCLUDING CABLES SPECIFIED BY THE MANUFACTURER. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THIS EQUIPMENT COULD RESULT.

**WARNING**

USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THIS EQUIPMENT COULD RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THIS EQUIPMENT AND RESULT IN IMPROPER OPERATION.

**WARNING**

USE OF THE IGS SYSTEM ADJACENT TO OR STACKED WITH OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THE IGS SYSTEM AND THE OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.
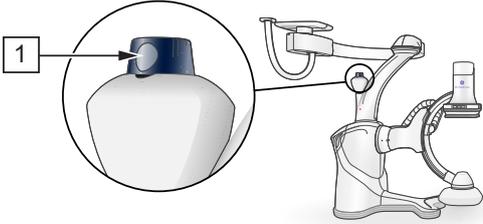
Compatibility with high frequency surgical equipment:

- The IGS system configurations that could be used in operating room are compatible with HF surgical equipment. During HF surgery, the IGS system shall remain idle (no motions or X-Ray acquisition) when the HF surgical equipment is activated.

- Provide as much distance as possible between the high frequency surgical generator and the IGS system. An activated high frequency surgical generator may cause interference with the IGS system and can temporarily disrupt its functionality.

- When high frequency surgical equipment is used, make sure that the HF surgical knife cables do not come in contact with the Touch Panel.

# 3.10 Protection regarding Laser Radiation Hazards (Class 1 Laser Product)

The Allia IGS 7 and Allia IGS 7 OR products integrate a Class 1 laser product for localization purposes. The laser is mounted on the vehicle's pole above 2 meters height and continuously

rotates to scan its environment. It emits an infrared laser beam invisible for the human eye. The emitted beam poses no risk to a person's eyes or skin.
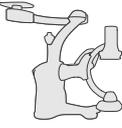
| Allia IGS 7<br>Allia IGS 7 OR | Protection class: | Class 1 (in accordance with IEC60825-1 and certified devices according to 21 CFR) |
| --- | --- | --- |
| | Wavelength range: | 770 - 800 nm |
| | Warning label: | Class I<br>Laser Product |
| | Position in the system: |  |
| | **[1]** Laser aperture | |

**WARNING**

PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO HAZARDOUS LASER RADIATIONS:

DO NOT PERFORM LASER ASSEMBLY, LASER MAINTENANCE OR LASER CONFIGURATION OPERATIONS.

DO NOT OPEN THE LASER PROTECTIVE HOUSING.

# 3.11 Protection against effect of incorrect output data sent to network (Dicom)

Attention of users is drawn on the fact that data sent through Dicom network are not fail-safe.

**WARNING**

FOR EVERY EQUIPMENT CONNECTED ON THE NETWORK AND USING DICOM, USERS MUST VERIFY THE COMPATIBILITY THROUGH DICOM CONFORMANCE STATEMENT. REFER TO HTTPS://WWW.GEHEALTHCARE.COM/PRODUCTS/INTEROPERABILITY/ DICOM/XRAY-MAMMOGRAPHY-DICOM-CONFORMANCE-STATEMENTS.

The only available input/output is the firewall to be connected to the Hospital network. This connection is inside the C-FRT Cabinet and is therefore intended for qualified service personnel only.

Stenosis Analysis used on networked devices and using data acquired on the angiography equipment must be used with the equivalent precautions as those described for the equipment (See 11.1 Stenosis Analysis (Option) on page 331).

# 3.12 Symbols

Symbols used on the IGS system and in its accompanying documents are shown and explained in this section.

# 3.12.1 Symbols used in this Manual

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

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

# 3.12.2 Symbols used on the IGS system

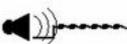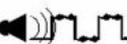These symbols may be used on the System depending on the configuration and the control.
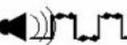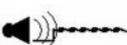
## Special Notices

| Symbol | Description |
|---|---|
|  | Follow Operating Instructions. |
|  | Follow instructions for use. |
|  | Dangerous voltage. Indicates an avoidable dangerous high voltage hazard. |

| Symbol | Description |
|---|---|
| ⚠ (dangerous voltage) | Warning: dangerous voltage. |
| ⚠ (general caution) | General Caution. This symbol is used to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. |
| ⚠ (general warning) | General warning sign. |
| ❗ (mandatory action) | General mandatory action sign. |
| 🚫 (prohibition) | General prohibition sign. |

## Audio/Visual Indications

This table provides a summary of the major audio/visual indications provided by the console.

| INDICATIONS | | | CAUSE | COMMENT |
|---|---|---|---|---|
| **VISUAL** | **AUDIO** | **OTHER** | | |
| X-RAY ON | Medium, low-pitched, continuous tone. | None. | Normal procedure during all modes of X-Ray exposure except for fluoroscopy (in this case, there is only a visual indicator but no tone). **NOTE** For Japan, Normal procedure during all modes of X-Ray exposure including fluoroscopy (in all this case, there is a visual indicator and a tone). | Normal operation. |
| X-RAY ON | Brief tone. | Brief flash on VCIM at the initiation of fluoro. | Normal procedure during fluoroscopy X-Ray exposure (Fluoro): brief audible signal at the initiation of irradiation. | Normal fluoroscopy operation. |
| X-RAY TIMER RESET  FLASHING | Pulsed tone. | None. | X-Ray Timer reaches 5.0 minutes. | Press the X-Ray Timer Reset button to silence the audible signal and reset timer to 0 minute. In Italy, X-Rays are disabled after 10 minutes without reset. |
| | High, continuous tone. | None. | HUA (Heat Unit Available) value is below or equal to 20%. 6.1.2 | Wait for X-Ray Tube to cool (HUA greater than 20%). |
| | None. | None. | Shows status of ECG signal | Green means signal is detected and online, yellow means system is stabilizing, orange may need reset and white means system is offline. |

Buzzer Kit: Allows to propagate all audio indications in the exam room.

The loudness of the loudspeaker was adjusted at installation. Contact your GE HealthCare representative for any further modification.

Fluoro (Radioscopy) and Record (Radiography) audible signals may be configured. Push Fluoro icon **[1]** or Record icon **[2]** in monitoring bar to open the sound configuration window:

Allia IGS 5

Allia IGS 7
Allia IGS 7 OR



The following settings are available for Fluoro (Radioscopy) and Record (Radiography). By default at installation, the system is configured with a short beep for Fluoro and a continuous tone for Record.

|        | None | Beep | Continuous |
|--------|------|------|------------|
| Fluoro | No audible signal | Short tone at the initiation of irradiation | - |
| Record | No audible signal | Short tone at the initiation of irradiation | Continuous tone during irradiation |

**NOTE**

**(For Japan with IntelIQ)** As described in 23.3.8  Fluoroscopy Dose to Patient in Japan on page 533, the usage of special high level Fluoroscopy mode is indicated permanently on the Live in room monitor by the removal of dose limiter icon and by a permanent audible signal. Therefore, Fluoro and Record beep settings do not apply in this special mode.

**NOTE**

With the continuous tone setting, slower frame rates will sound like a beep signal.

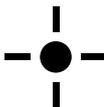Fluoro and Record sound can be selected from the respective drop-down menu:
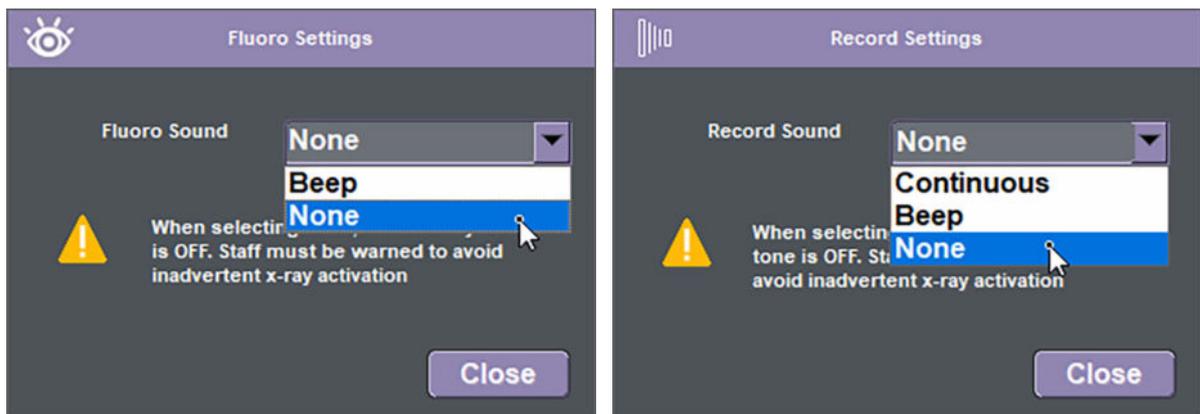


**CAUTION**

Extra caution should be taken if the Fluoro or Record sound is set to "None". Inadvertent X-Ray activation and unknowingly activating the footswitch will not be detectable by an audible signal because the sound will be deactivated.

## X-Ray Tube

| Symbol | Description |
|---|---|
| | X-Ray emission. X-Ray Tube head is emitting X-Rays. Take adequate precautions to prevent the possibility of any persons carelessly, unwisely, or unknowingly exposing themselves or others to radiation. |
| | X-Ray source assembly. Indicates a reference to an X-Ray source assembly. |
| | X-Ray Tube. Indicates a reference to the X-Ray Tube, i.e. to mark the surface of a grid that is to be oriented towards the X-Ray Tube. |
| | Identifies controls or indicators associated with normal rotational speed of the X-Ray anode. |
| | Identifies the plane where the X-Ray Tube focal spot is located in the system. |

## Tube cooling unit

| Symbol | Description |
|---|---|
| | Health hazard. |

## Power On and Off

| Symbol | Description |
|---|---|
| | System power on / power off push-button: applies and removes power to part of the system. |
| | **SYSTEM RESET** push-button. Use this button to reset the IGS system. |

| Symbol | Description |
|---|---|
| | Emergency stop control device. |

## PDU

| Symbol | Description |
|---|---|
| OFF | System shutdown indicator |

## Type B applied part

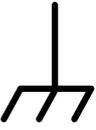| Symbol | Description |
|---|---|
| | Applied part complying with the specified requirements of the IEC60601-1 standard to provide protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current. |

## Electrical Class

| Symbol | Description |
|---|---|
| | Class II Equipment. Protection against electrical shock does not rely on basic insulation only, but in which additional safety precautions such as double or reinforced insulation are provided. There is no provision for protective earthing or reliance upon insulation conditions. |

## Electrical Current

| Symbol | Description |
|---|---|
| ∼ | Alternating Current. Indicates equipment that is suitable for alternating current only. |
| --- | Direct Current. Indicates equipment that is suitable for direct current only. |

| Symbol | Description |
|---|---|
|  | Both direct and alternating current. Indicates equipment that is suitable for both direct and alternating current. |

## Ground

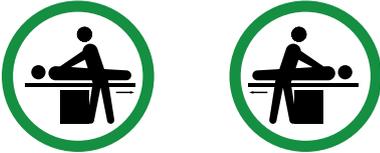| Symbol | Description |
|---|---|
|  | Functional Earth (ground) Terminal. Terminal directly connected to a point of a measuring supply or control circuit or to a screening part which is intended to be earthed for functional purposes. |
|  | Noiseless (clean) earth (ground). Identifies any terminal of a specially designed earthing system where noise from earth of leads will not cause a malfunction of the equipment. |
|  | Protective earth (ground). Identifies any terminal which is intended for connection of an external protective conductor to protect against electrical shock in case of a fault. |
|  | Frame or chassis. Identifies the frame or chassis terminal. |
|  | Potential Equalization terminal<br>Identifies terminals that bring the various parts of equipment or systems to the same potential when connected together. These terminals are not necessarily at earth (ground) potential. |

## Collimator

| Symbol | Description |
|---|---|
|  | Identifies controls for opening the collimator blades, or indicates partially or fully open state. |

## Digital Detector

| Symbol | Description |
|---|---|
|  | Emergency Back-out Button. |

## Cardiopulmonary Resuscitation (CPR)

| Symbol | Description |
|---|---|
|  | Move the table top toward the foot end and center it laterally over the table base before performing a CPR procedure. |
|  | Do not perform a CPR procedure if the table is not centered over the table base. |

## Maximum Patient Weight

| Symbol | Description |
|---|---|
|  | The maximum patient weight the table can accept is limited to the value written on the table label. |

## Maximum permissible table load

| Symbol | Description |
|---|---|
|  | The maximum permissible load including accessories the Innova$^{IQ}$ Table can accept is 320 kg. |

| Symbol | Description |
|---|---|
| | The maximum permissible load including accessories the Omega Table can accept is 304 kg. |

## Minimum "trapping zone" safety clearance

| Symbol | Description |
|---|---|
| | Risk of entrapment with imaging equipment. If the room layout does not meet minimal requirements, this symbol will be present on the walls in the appropriate areas. |

## Table

| Symbol | Description |
|---|---|
| or | This sticker is located on the top right and top left of the bellows surrounding the table base. Do not leave hand/fingers on the bellows. There is a potential risk of hand/fingers pinch when the table is moving down. |
| | Located on each side of the table base, close to the "CPR" stickers. Do not stand or leave any material under the table top while tilted; potential risk of crushing. |

| Symbol | Description |
|---|---|
|  | Do not stand between the table top head end and the gantry pivot unless gantry and table motions are disabled.<br>Risk of severe injury when the table top is moving towards the gantry pivot. |
|  | Omega Table end rail maximum load. |

## Footswitch and Table Panning Device (TPD)

| Symbol | Description |
|---|---|
| <br>or<br> | Do not use the footswitch cover as a foot rest or stand on it. |
|  | Table Top Longitudinal and Lateral Brakes Release (on footswitch and TPD). |

## Table Head Extender

| Symbol | Description |
|---|---|
|  | Label for maximum weight on table head extender. |

## Reflectors

| Symbol | Description |
| --- | --- |
|  | This symbol is located on each reflector and means "Do not move or hide the reflector (the Allia IGS 7 and Allia IGS 7 OR system positioning function may be altered)." |

## Grid Out

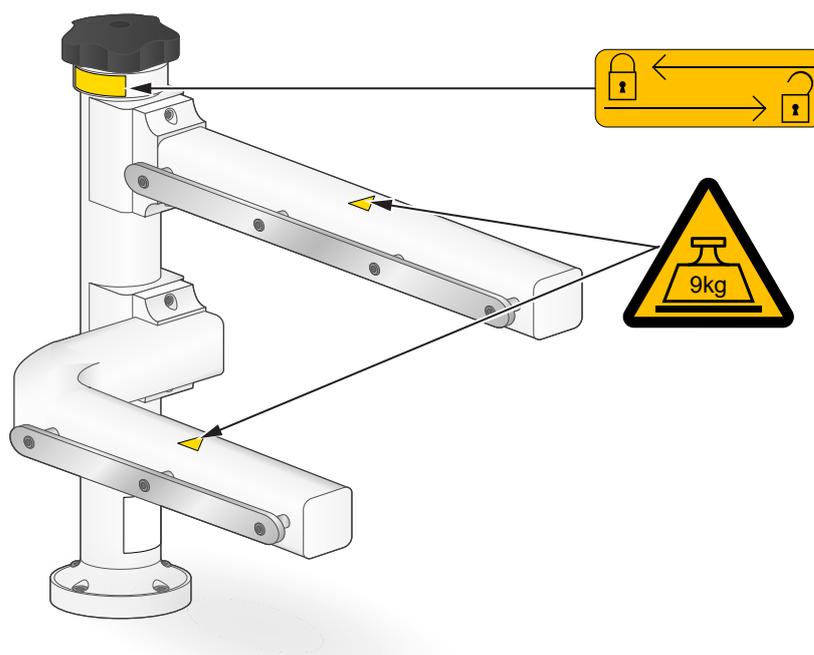| Symbol | Description |
| --- | --- |
|  | Displayed on the left side on the live display, in the Geometry area, to show that the anti-scatter grid has been removed and is not in the X-Ray beam. |

## Acquisition

| Symbol | Description |
| --- | --- |
| <br>or<br> | Displayed at the bottom of the DL screen to show that a fluoroscopic or record acquisition is in progress. |

## Status Icons

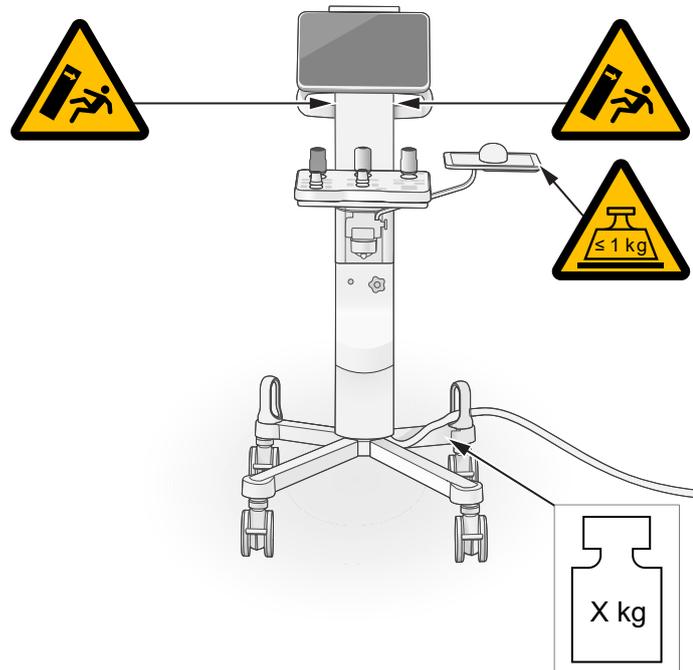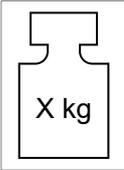| Symbol | Description |
| --- | --- |
|  | Displayed on the system monitors to show that the screen is locked and that alarms display is disabled. |

## Remote Stand (Option)



| Symbol | Description |
|---|---|
|  | Label for Locking Direction Note:<br>The direction label also posted on the backside to take care of both RH and LH Installations. |
|  | Label for Maximum Load Warning Note:<br>The warning labels are also posted on the bottom side of the arms to reference both the right handed or left handed installations. |

## IGS Control Center



| Symbol | Description |
|---|---|
|  | This sticker is located on the top of the IGS Control Center on each side of the cover. Risk of overbalancing. |
|  | Label for Mouse tray Maximum Load Warning. |
|  | Label for maximum weight of the IGS Control Center including the Touch Panel, Control Panel, Mouse tray, footswitch, wireless footswitch receiver holder and IGS Control Center cable. |

### VCIM

| Symbol | Description |
|---|---|
|  | Radiation Hazard Symbol.<br>This sticker is located on VCIM. Caution X-Rays. |

### Bottom back cover of the AGV

| Symbol | Description |
|---|---|
| <br>Certification labels behind this cover | Certification labels behind this cover. |

### Patient Browser Network Status Icons

The below icons appear in the Network Status column of the Patient, Exam, Sequence and Photo Browser.

Network Status refers to the consolidated transfer status of all the network activities in the DICOM network.

Network activity of the IGS system includes:

- DICOM Worklist
- DICOM MPPS
- DICOM Image Push
- DICOM Image Storage commitment
- DICOM Dose Structured Report Push
- DICOM Dose Structured Report Storage commitment

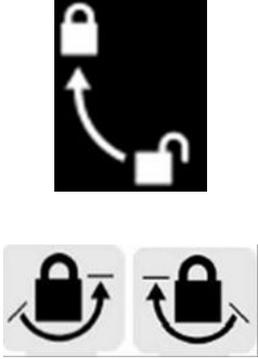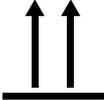| Indications | Cause | Comment |
|---|---|---|
| <br>Empty | No network activity available | Can either be deleted (if not used) or perform some actions. |
| <br>Sending | Some network activity is in-progress | Recommended not to perform a delete operation.<br>If deletion is still required, the system will provide warnings and perform the deletion operation after user's confirmation. |

| Indications | Cause | Comment |
|---|---|---|
| <br>Archiving | Archival is in-progress (Image or Dose Structured Report) | This activity can take some time. Depends on the Archiving station setup.<br><br>Recommended not to perform a delete operation.<br><br>If deletion is still required, the system will provide warnings and perform the deletion operation after user's confirmation. |
| <br>Information | Some network activity did not take place (or) all the network activities completed but the patient exam is still active. | Recommended to place the mouse over the icon to read and perform the action required.<br><br>Recommended not to perform a delete operation. |
| <br>Completed | All network activities completed. | Can be safely deleted. |
| <br>Failed | Some network activity failed. | Recommended to place the mouse over the icon to read and perform the action required.<br><br>Recommended not to perform delete operation. |

## Electronic User Manual

| Symbol | Description |
|---|---|
|  | Symbol indicating that the Instruction For Use (User Manual) is supplied in electronic format. It is located on:<br>• the C-arm on Allia IGS 5 systems.<br>• the AGV on Allia IGS 7 and Allia IGS 7 OR systems. |

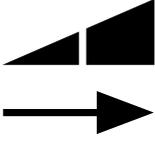## Surgical and Patient Comfort Accessories (with Innova^IQ Table)

| Symbol | Description |
|---|---|
|  | Caution label for maximum load for surgical and patient comfort accessories:<br>• Head widener with pad,<br>• Width extender with pad,<br>• Armboard with thick pad,<br>• Anesthesia screen holder.<br><br>**NOTE**<br>Refer to the table in 3.6.11 GE HealthCare table rails on page 65 for the weight values. |

| Symbol | Description |
|---|---|
| | Warning label for maximum load for surgical and patient comfort accessories: <br> • Mouse tray, <br> • Removable rails, <br> • Rail extender, <br> • Adaptor rail for table side controls, <br> • Universal clamp, <br> • Round post clamp. <br><br> **NOTE** <br> Refer to the table in 3.6.11 GE Health-Care table rails on page 65 for the weight values. |
| | Lock/Unlock symbol. |
| | Side Up symbol. |

## Bolus Handle

| Symbol | Description |
|---|---|
| | Bolus button |
| | Table Speed |

## AGV Handle

| Symbol | Description |
|---|---|
|  | AGV Motion Enable |
|  | AGV Speed Command |

## X-Ray Led

| Symbol | Description |
|---|---|
|  | X-Ray Ready. |

## Filtration
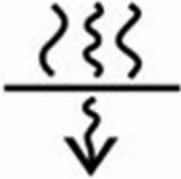
| Symbol | Description |
|---|---|
|  | To indicate a reference to a radiation filter or a value of filtration. |

## Product identification
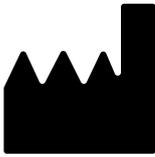
| Symbol | Description |
|---|---|
|  | Indicates the medical device manufacturer. |

| Symbol | Description |
|---|---|
| ⬛ (factory symbol) | Indicates the date when the medical device was manufactured. |
| **REF** | Indicates the manufacturer's catalogue number so that the medical device can be identified. |
| **SN** | Indicates the manufacturer's serial number so that a specific medical device can be identified. |
| **MD** | Indicates this product is a medical device. |

## UDI

| Symbol | Description |
|---|---|
| Allia IGS 7<br>(barcode)<br>(01) 0 0000123 00001 7 (11) 200700 (21) SS-SS-SSS<br>Product name, Bar code and GS1-Data matrix code on this drawing is for information only. | Unique Device Identifier<br>A UDI is a unique numeric or alphanumeric identification code assigned to medical devices by the manufacturer of the device.<br>A unique device identification marking is applied to a product model that is designated as a medical device as required per the regulations of product's target market. |

## Rx Only

| Symbol | Description |
|---|---|
| **℞ ONLY** | This symbol stands for the prescription legend statement "Caution: US federal law restricts this device to sale by or on the order of a physician." |

## Regulatory Conformity Marking

| Symbol | Description |
|---|---|
| CE 0459 | European conformity mark. |

| Symbol | Description |
|---|---|
|  | CSA Conformity marking for USA and Canada. |
|  | State standards of the Russian Federation and the CIS countries. |

## Regulatory Symbol

| Symbol | Description |
|---|---|
| CH REP | Indicates the Authorized representative in Switzerland. |

# 4 Radiation Safety Tutorial

## 4.1 Learning objective

Increase your knowledge and help you develop safe work habits. Quick overview of X-Ray radiation and dose through a simple explanation of the equipment, technology and to discuss the different techniques available to reduce dose.

## 4.2 Teaching points

- Radiation dose is a natural consequence of X-Ray imaging.
- Displayed Dose Parameters.
- Effects of ionizing radiation on humans.
- Dose reduction measures for the patient.
- Dose reduction measures for the staff.
- Pediatrics Case.
- Legal Provisions.

## 4.3 Radiation dose is a natural consequence of X-Ray imaging
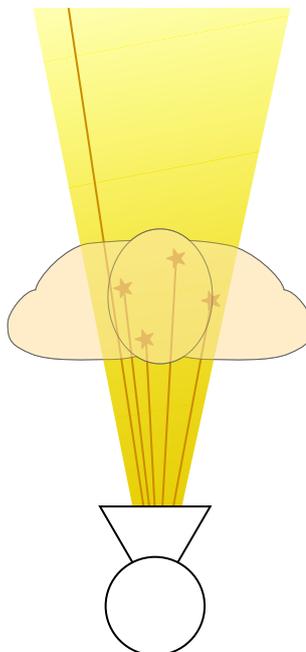


- Images are created by the interaction of X-Rays with materials.
- During this interaction X-Rays leave some energy in the patient.
  Energy at the Image Detector is about 100 to 1000 less than energy entering the patient.

- Absorbed dose = mean energy imparted by the X-Ray beam per unit mass at a point in the tissue.

- Air Kerma = mean energy imparted to air.

  ◦ Usual way of reporting radiation dose.

  ◦ Compared to actual Skin dose, the Air Kerma differs in the material absorption of dose (a few % effect) and do not include backscatter from underlying tissue (a 10-40% effect).

- By standard, Air Kerma is determined for a fixed distance to the isocenter for isocentric C-arm: Interventional Reference Point or Patient Entrance Reference Point.
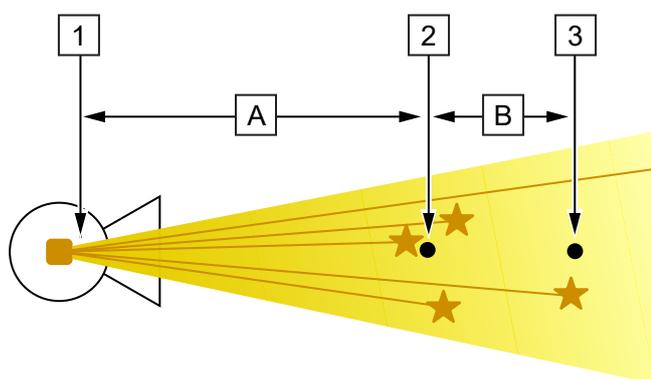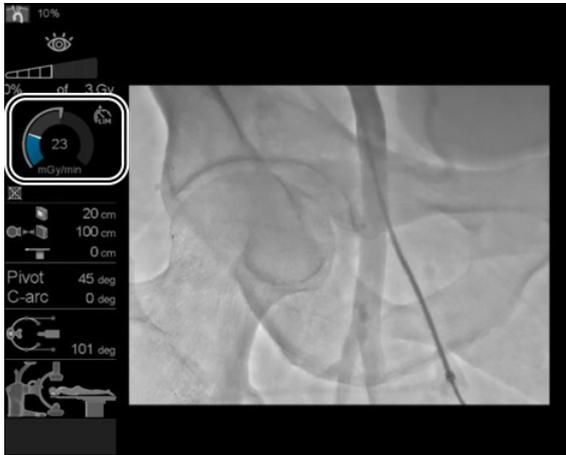


| Item | Description |
|---|---|
| **[1]** | Focal Spot |
| **[2]** | Reference Point |
| **[3]** | Isocenter |
| **[A]** | **(For IGS 520, IGS 530)** 57 cm<br>**(For IGS 730)** 67 cm |
| **[B]** | 15 cm |

# 4.4 Displayed Dose Parameters

## Air Kerma Rate

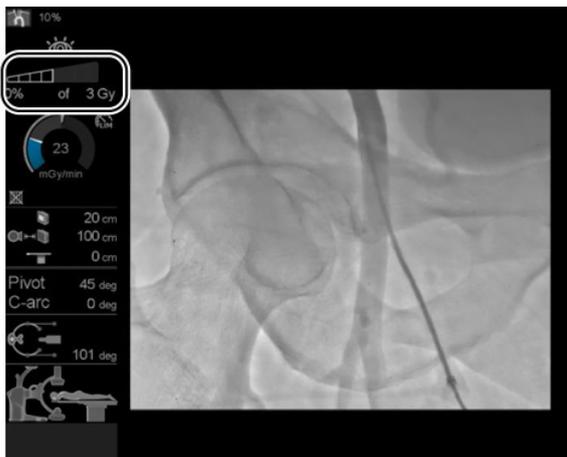Live display                                                              Reference display



- Air kerma rate (AKR) is the amount of air kerma per unit of time expressed in mGy/min. The digital value of the AKR displayed is the reference air kerma rate display for dose management. The digital value of the air kerma rate and its visual representation over the accessible range of the selected acquisition mode are displayed during acquisition. Outside acquisition, this meter displays the air kerma rate value of the previous acquisition: the digital value and the colored representation correspond to the last determined air kerma rate from the previous sequence, while the white arrow points zero.

## Cumulated Air Kerma

Live display                                                              Reference display
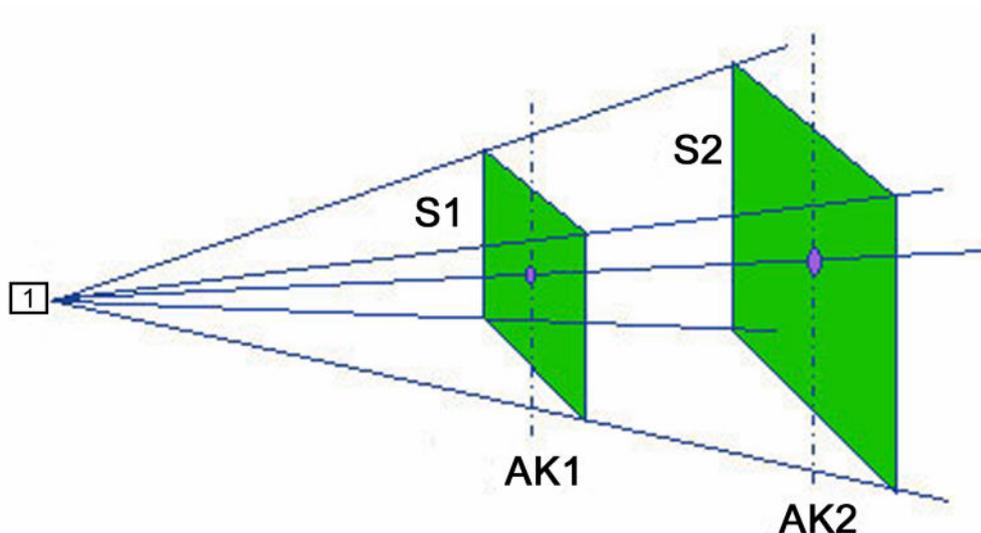


- Air Kerma is cumulated over the course of exam and displayed.
- The cumulated Air Kerma is related to the patient skin dose to some extent:
  - The reference point is only an "average" representation of the patient skin location.
  - The accumulation is performed over all gantry angulations and table positions.

The estimation of the total dose (cumulated Air Kerma) (mGy) delivered to the patient is continuously displayed and updated on the reference display. On the live display, the ratio (in percentage) of the actual Total Dose of the Dose Threshold value is set within the protocol. The

Dose Threshold value and a gauge icon visualizing the Dose percentage of the Threshold are displayed during acquisition.

## Cumulated Dose Area Product (DAP)



| Item | Description |
|---|---|
| [1] | Focal Spot |
| S: | Surface of Area |
| AK: | Air Kerma |
| DAP: | Dose (Air Kerma) Area Product |

- DAP is the product of Air Kerma and exposed area and is cumulated over the course of exam and displayed.
  By nature, it is independent of distances to the focal spot.

- The cumulated DAP is related to the patient skin dose to some extent:

  ○ DAP should be more representative of long-term risk (stochastic risk).

  ○ The accumulation is performed over all gantry angulations and table positions.

  ○ Several guidance levels based on DAP.
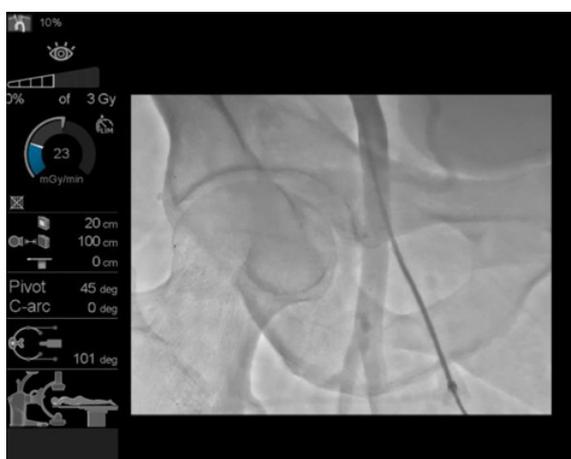
Live display                                          Reference display

# 4.5 Effects of ionizing radiation on humans

## Deterministic effects

- The table describes several possible effects to the patient skin/hair for different approximate range of Skin Dose estimate.

- Skin Dose estimate is not equal to cumulated Air Kerma.

- Approximate 3/5 ratio between Skin Dose estimate and cumulated Air Kerma.

  ◦ Due to gantry/table movements and different distance.

  ◦ From SIR-CIRSE recommendation: *Stecker MS, Balter S, Towbin RB, et al. Guidelines for patient radiation dose management. J Vasc Interv Radiol 2009 20 (7 suppl) S263 - S273.*

**Table 4-1 Summary of tissue reactions from single-delivery Radiation Dose to Skin**

| Approximate Range (Gy) | Reactions |
|---|---|
| 0 to 2 | None Expected |
| 2 to 5 | Transient erythema/epilation |
| Above 5 | Erythema/epilation transient or permanent |
| | Possible Moist desquamation, dermal atrophy above 10 Gy |

For full table, refer to *S. Balter et al. Fluoroscopically Guided Interventional Procedures: A Review of Radiation Effects on Patients' Skin and Hair Radiology 254(2) 2010.*

## Stochastic effects

- Absorbed doses lower than deterministic threshold may increase natural risks of cancer or mutations.

- This risk is stochastic i.e. is a random effect. Within "linear non threshold hypothesis" the same collective dose will generate the same number of pathologies regardless of the number of persons who receive it (100 mSv to 1000 persons each is equivalent to 10 mSv to 10 000 persons each, or to 1 mSv to 100 000 persons).

- Pediatrics patients are at greater risk with stochastic effects compared to adult, due to their longer potential life and increased sensitivity to such effects.

# 4.6 Dose reduction measures for the patient

## List

Several dose reduction means (non-exhaustive):

- Select the appropriate protocol.

- Appropriate use of Equipment distances (SID: Source to Image Distance, Table position).

- Change Gantry angulations during procedure.

- Minimize Sequence duration.

- Use of LIH (Last Image Hold).

- Adjust collimation without radiation.

- Select largest FOV with small exposed area with collimation.

- Select a lower dose rate:

  ◦ Use as low Frame rate as possible.

◦ Use as low level as possible.

## Appropriate protocols

- Select the appropriate protocol by target or anatomy:

  ◦ Use protocols preselected with lower dose setup: Fluoro dose strategy, Level and Frame rate compatible with the medical requirement.

  ◦ Specific pediatric protocol optimized in terms of dose and temporal resolution.

  ◦ EP protocols specifically set to further low-dose setup.

  ◦ Changes in default values, protocols names and order of appearance (by alphabetical order) can be made in protocol by Service or Application specialist.
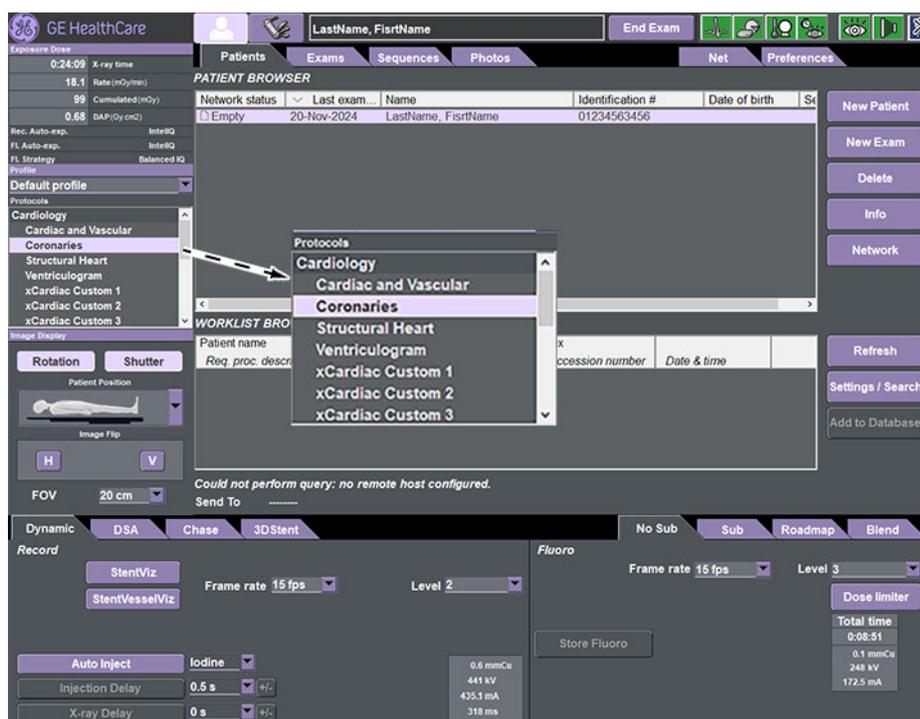


## Equipment distances and angulations

- Use of Equipment distances (SID: Source to Image Distance, Table position):

  ◦ Minimize distance between patient, Image detector.

  ◦ Maximize distance between Patient and X-Ray Tube.

  ◦ Use Skin Spacer.

  ◦ Keep distance between detector and patient at minimum, can be facilitated with the auto contouring option (InnovaSense patient contouring 🖵 ).

- Use of Gantry angulations during procedure: change angulations during the procedure, to avoid cumulating dose on the same patient area.

## Sequence duration, Last Image Hold

- Sequence duration:

  ◦ Minimize Radiation time, use the X-Ray timer indications.

  ◦ The X-Ray time flashes and emits an audible signal after 5 minutes of X-Ray time.

- Use of LIH (Last Image Hold):

  ◦ LIH provides an image in between the live fluoro images to use as a reference image and eliminates the need for extended fluoro exposures.

  ◦ Further reducing the need for additional fluoro exposure can be facilitated by storing the last frames (up to 450) of the fluoro sequence with the fluorostore function.

## Virtual collimation

Adjust collimation without radiation (Virtual Collimation):

- Enables positioning of collimator blades without irradiation.

- Means to visualize the virtual position of collimator blades by lines displayed over the live display image (regardless if there is an image, a LIH or blank screen).

- Uses the regular joystick for positioning the collimator blades.
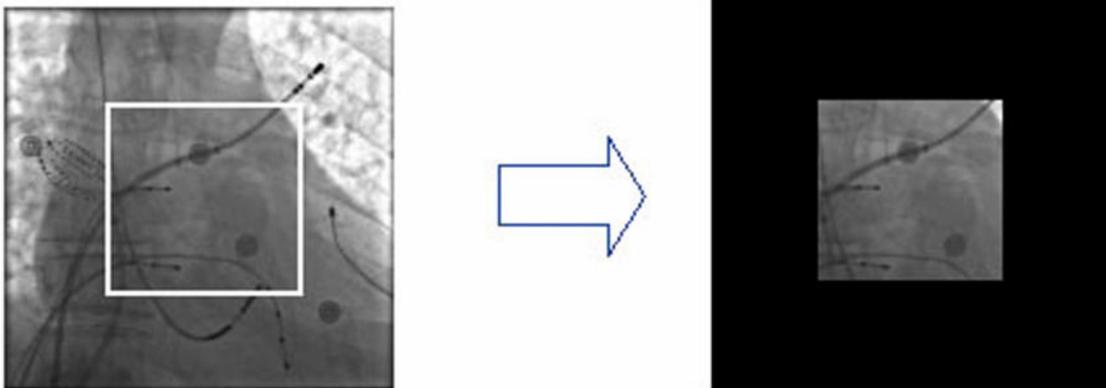


## FOV selection

Select largest FOV with small exposed area with collimation:

- When compatible with medical requirements for anatomy and/or tool(s) visibility at the current viewing distance to the display monitors.

- The dose rate is increased at smaller FOV (except in DSA for FOV smaller than 20 cm, and in 3D CT and 3DStent) to provide increased visibility from both magnification effect and reduced noise content.

- Collimating within the FOV decreases the overall exposure.

Lower dose can be achieved by using less magnified view, using a larger FOV with some collimation inside as appropriate (except in DSA for FOV smaller than or equal to 20 cm, and in 3D CT and 3DStent).
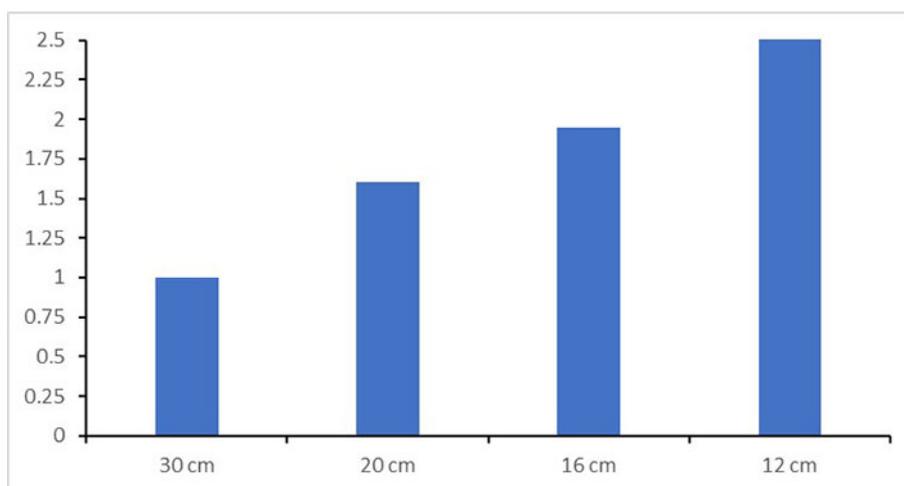
FOV: Field of View

Typical example in Fluoroscopy from the "Dose to patient" section of the User Manual, for system with 30 cm detector, IntelIQ, Balanced IQ/Dose, 15 fps, level 3, at 20 cm patient size (PMMA cm). Refer to the 23.3  Dose to Patient on page 517 section of this User Manual to find the data corresponding to your system configuration.
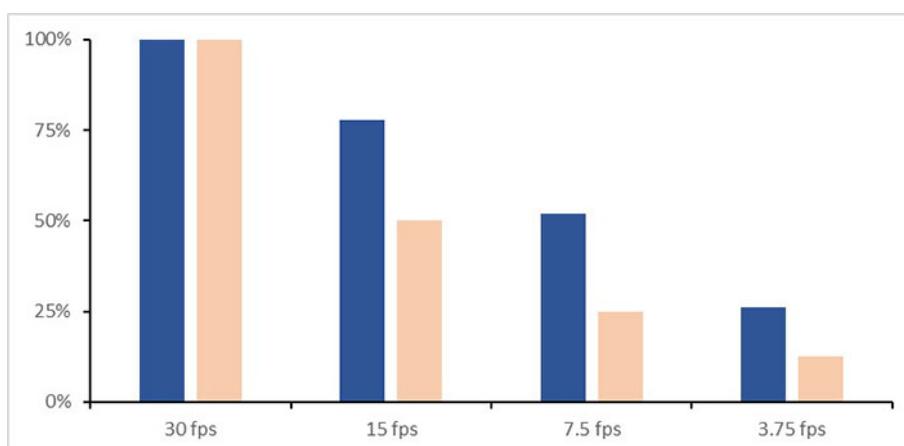
## Frame Rate

Two Dose Strategies for reduction of dose with the frame rate are provided on the system for Fluoro Mode: "Max Dose Reduction" and "Balanced IQ/Dose". In "Max Dose reduction", the system drops dose rate proportionally with frame rate whereas in "Balanced IQ/Dose" the dose rate is reduced more gradually with frame rate.

Lower dose rate:

- Use as low Frame rate as possible (at tableside or on the DL screen) compatible with medical requirements for the image refresh rate (versus anatomy and/or tool(s) movements or changes).
- Have protocols preselected with lower dose setup (fluoro dose strategy).

Pulsed fluoroscopy with a choice of frame rate: 30 fps, 15 fps, 7.5 fps, 3.75 fps.

Choice of Dose Strategy preferences to be preset within protocol by Service or Application specialist and displayed on DL screen.



☐ Max Dose Reduction: Dose rate drops directly with fluoro frame rate.

■ Balanced IQ/Dose: Maintains static object detectability, noise appearance. Based on perception experiment (Case Western University, OH, from the D.L. Wilson group).
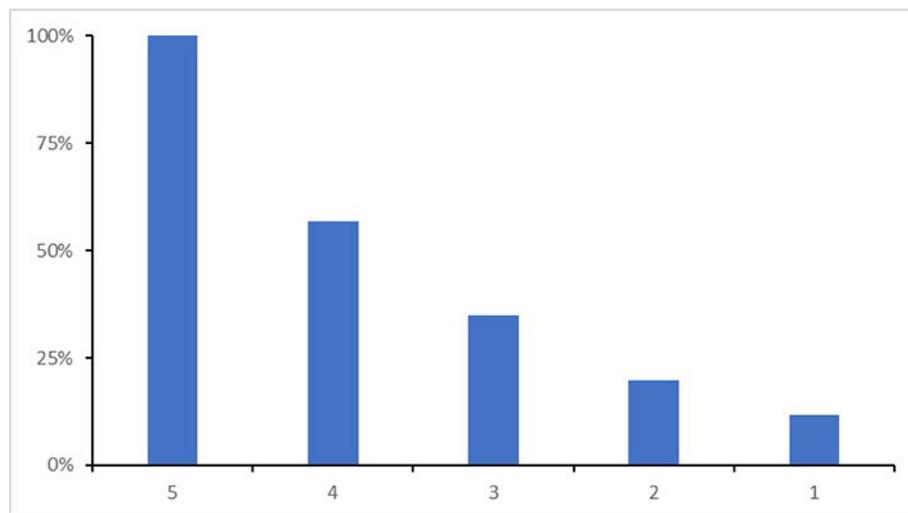
Typical example from the "Dose to patient" section of the User Manual, for system with 30 cm detector, InteIIQ, Level 3, 20 cm FOV, at 20 cm patient size (PMMA cm). Refer to the 23.3  Dose to Patient on page 517 section of this User Manual to find the data corresponding to your system configuration.

## Level settings

The IGS system is provided with the InteIIQ AutoExposure Preference. The InteIIQ levels are identified by numbers on DL screen and by a visual representation on display monitors. The lowest level is designated "LOW" level and the highest "NORMAL" level producing different reference air kerma rates, such that the value for the low mode does not exceed 50 % of the value for the normal mode (in conditions defined in IEC60601-2-43).

Lower dose rate:

• Select the lowest level (at tableside or on the DL screen) compatible with medical requirements for anatomy and/or tool(s) visibility.
  At least 50% less Air Kerma rate in "Low" versus "Normal" level, except at max Fluoro dose limits (limits explained in next section).



Typical example in Fluoroscopy from the "Dose to patient" section of the User Manual, for system with 30 cm detector, 15 fps, Balanced IQ/ Dose, 20 cm FOV, at 20 cm patient size (PMMA cm). Refer to the 23.3  Dose to Patient on page 517 section of this User Manual to find the data corresponding to your system configuration.

**NOTE**
Depending on country regulations, some of the choice in Levels in "InteIIQ" may not be available.

## Fluoro Air kerma rate limit

There is a mean to set the Air Kerma Rate (AKR) limit at a lower level compared to the country regulatory limit by using the Dose limiter button. This AKR limit is defined in a plane representative of patient skin dose, and positioned 30 cm from the entrance of the Image Receptor cover.

Activating dose limiter button limits dose rate at pre-defined values for high radiological thickness anatomies.
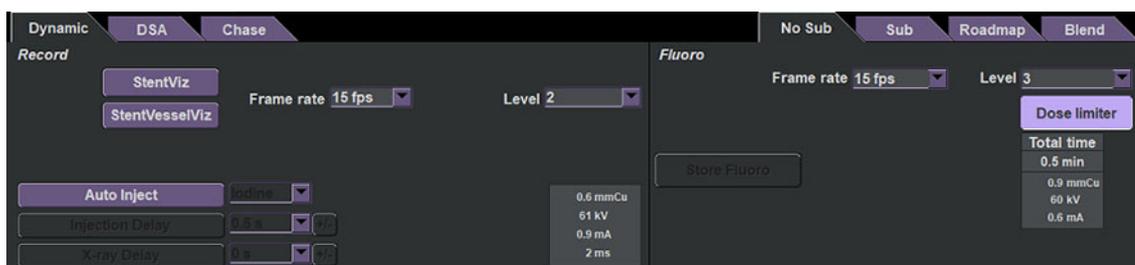
4

Radiation Safety Tutorial
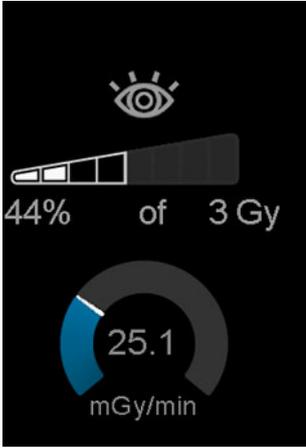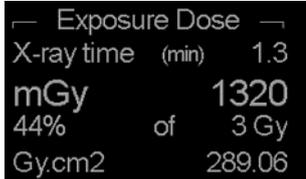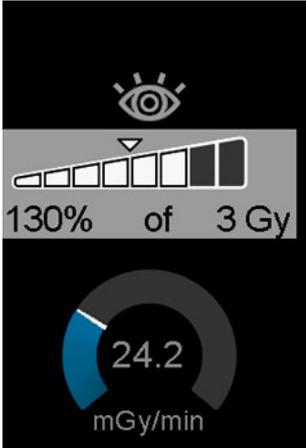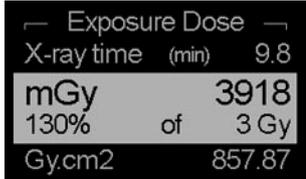
**Table 4-2 Dose Limiter**

| Highest reference dose (mGy/min) at 30 cm from image receptor | | Low Frame-rate Dose Reduction Strategy | | | |
| | | Balanced IQ/Dose | | Max Dose Reduction | |
| Frame Rate (fps) | Level | Dose Limiter Off | Dose Limiter On | Dose Limiter Off | Dose Limiter On |
| 30 | 5 | 87.6 | 43.8 | 87.6 | 43.8 |
| | 4 | 87.6 | 43.8 | 87.6 | 43.8 |
| | 3 | 87.6 | 43.8 | 87.6 | 43.8 |
| | 2 | 87.6 | 43.8 | 87.6 | 43.8 |
| | 1 | 87.6 | 21.9 | 87.6 | 21.9 |
| 15 | 5 | 87.6 | 43.8 | 43.8 | 21.9 |
| | 4 | 87.6 | 43.8 | 43.8 | 21.9 |
| | 3 | 87.6 | 43.8 | 43.8 | 21.9 |
| | 2 | 87.6 | 43.8 | 43.8 | 21.9 |
| | 1 | 87.6 | 21.9 | 43.8 | 21.9 |
| 7.5 | 5 | 87.6 | 43.8 | 21.9 | 21.9 |
| | 4 | 87.6 | 43.8 | 21.9 | 21.9 |
| | 3 | 87.6 | 43.8 | 21.9 | 21.9 |
| | 2 | 87.6 | 21.9 | 21.9 | 21.9 |
| | 1 | 87.6 | 21.9 | 21.9 | 21.9 |
| 3.75 | 5 | 87.6 | 43.8 | 21.9 | 21.9 |
| | 4 | 87.6 | 43.8 | 21.9 | 21.9 |
| | 3 | 87.6 | 21.9 | 21.9 | 21.9 |
| | 2 | 87.6 | 21.9 | 21.9 | 21.9 |
| | 1 | 87.6 | 21.9 | 21.9 | 21.9 |

## Threshold

- Watch the cumulated dose display and apply dose reduction means as appropriate. The display changes above the predefined threshold.

- Other recommendations exist for procedural dose warning.

  - e.g.: Values above 5 Gy indicates that the patient should have clinical follow-up for deterministic radiation-induced injury (SIR-CIRSE recommendations).

  - e.g.: Use 500 Gy.cm$^2$ as significant radiation threshold (SIR-CIRSE).

  - e.g.: Use 3000 mGy as first notification, then each further additional 1000 mGy (SIR-CIRSE).

  - e.g.: Use first notification 3000 mGy, then second one at 6000 mGy (ACR).

SIR-CIRSE recommendation: *Stecker MS, Balter S, Towbin RB, et al. Guidelines for patient radiation dose management. J Vasc Interv Radiol 2009 20(7 supp) S263-S273.*

ACR recommendation: *Mahdevappa, M, Detorie, N. How to prepare for the joint commission's sentinel event policy pertaining to prolonged fluoroscopy. American College of Radiology. The Medical Physics Consultant 2008 601-603.*

| Description | Live display | Reference display |
|---|---|---|
| Display prior to the predefined Dose Threshold value being reached: |  |  |
| Display after the predefined Dose Threshold value has been exceeded (above 100%): |  |  |
| Display on live display after double of the predefined Dose Threshold value has been reached: |  |  |
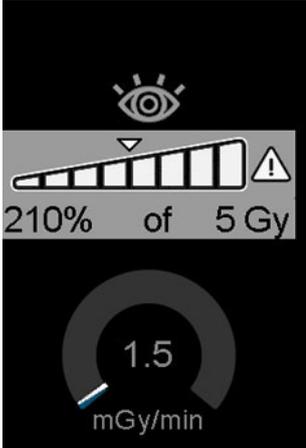
**4**

Radiation Safety Tutorial
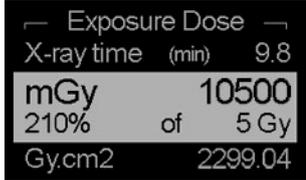
# 4.7 Dose reduction measures for the staff



- Minimize patient dose.
  Staff dose related to the patient dose scattered X-Rays mostly comes from the patient dose entry points.

- Stand as far as possible.
  Radiation decreases as the inverse square of distance.

- Minimize your time near radiation sources when possible.

- Use radiation shield:

  ◦ Wear your personal protection equipment.

  ◦ Position shields between you and the patient dose entry location, or locate yourself behind shields whenever possible.

  ◦ Do not stay in the procedure room when your attendance at tableside is not needed.

- Monitoring.
  Wear your personal dosimeter.

# 4.8 Pediatrics Case

The IGS system is specifically designed to minimize radiation exposure while providing good image quality for the intended pediatric and adult patients. Exposure to ionizing radiation is of particular concern in pediatric patients as younger patients are more radiosensitive than adults and have a longer potential lifetime for the effects of radiation exposure to manifest as cancer. Thus, the use of equipment and exposure settings designed for pediatric patients are different from the ones used for adult patients.

## Dose-related parameters default values

Depending on the anatomical region and patient's age, a set of imaging system settings are categorized by protocols. Pediatric protocols are optimized in terms of dose and temporal resolution.

**Table 4-3 Dose-related parameters default values of adult vs. pediatric protocols**

| Dose-related pa-rameters | Adult | Pediatric cardiac protocol | Pediatric cardiac protocols for neo-nates | Pediatric angio pro-tocols |
|---|---|---|---|---|
| Dose Threshold | 2 or 3 Gy | 1 Gy | 1 Gy | 1 Gy |
| Fluoro Level | 3* | 2 | 2 | 2 |
| Fluoro FPS | 15 fps** | 15 fps | 30 fps | 15 fps |
| Dose Limiter | On | On | On | On |

**Table 4-3 Dose-related parameters default values of adult vs. pediatric protocols** (Table continued)

| Dose-related parameters | Adult | Pediatric cardiac protocol | Pediatric cardiac protocols for neonates | Pediatric angio protocols |
|---|---|---|---|---|
| Dynamic Level | 2* | 1 | 1 | 1 |
| Dynamic FPS | 15 fps** | 15 fps | 30 fps | 15 fps |
| DSA/Single Shot Level | 3 | N/A | N/A | 1 |

\* Few adult protocols have Fluoro and Dynamic Level set at a lower value (protocols in Electrophysiology category).

\*\* Few adult protocols have Fluoro or Dynamic FPS default value different from 15.

In addition to the dose-related default values, the system is able to optimize temporal resolution for pediatric patients. The system also adapts a smaller ROI in dynamic fluoroscopy and in dynamic record, based on the exam type (Angio or Cardiac) and the patient type (Adult or Pediatric). These correspond to attributes of a patient protocol, and are set according to its usage. Further, there is a minimal spectral filtration of 0.1 mm for pediatric protocols due to a higher radiosensitivity.

## List of pediatric protocols

For pediatrics imaging, select a protocol on the DL screen under the "Pediatrics" category, or where the name contains "Pediatric". For details concerning how to select a protocol on the DL screen, please refer to .

**Table 4-4 List of pre-configured pediatric protocols by category:**

| Protocol name | Category |
|---|---|
| Pediatric Abdomen | Pediatrics |
| Pediatric Cerebral | |
| Pediatric Chest | |
| Pediatric Lower Limbs | |
| Pediatric Upper Limbs | |
| Pediatric Cardiac | |
| Pediatric Cardiac Neonate | |

If an adult protocol is selected while the patient's age is below the "Pediatrics limit age threshold", the following events are triggered at start exam:

• An informative popup is displayed on the DL.

• A message is displayed on live monitors.

Both recommend using a pediatric protocol for young patients.

> **NOTE**
> The "Pediatrics limit age threshold" is editable before the start of an exam in the Preferences tab on the DL screen. It is used to set the maximum patient age defined for pediatrics. The range is from 0-21 years of age.

> **NOTE**
> The patient's age is calculated from his date of birth or his age if it has been modified in the Patient exam information screen.

Further to using pediatric protocols, also consider the application of:

- For infants up to 1 year old, remove the anti-scatter grid from acquisitions performed at Field Of View smaller than 20 cm.

- Use collimation to the specific area of interest.

- When possible, use a gonad shield.

> **NOTE**
> Dose rates for pediatrics are automatically reduced as the system senses a small patient thickness from the dose signal to the detector. Refer to  Dose settings for pediatrics in IGS systems on page 132, for more details.

## Dose settings for pediatrics in IGS systems

IGS products are designed to automatically set the optimal X-Ray technique parameters (kVp, mAs, focal spot size, and spectral filtration) for a variety of operational modes, e.g. fluoroscopy, DSA, and digital cardiac record.

For this, an equivalent patient thickness (EPT) is determined based on the dose signal to the detector and the technique values used for that exposure, and then the optimized technique parameters are set for the next exposure using the patient thickness value and predetermined look-up tables (or "trajectories") designed to give an appropriate image quality for the lowest possible patient entrance dose.

Predefined procedure protocols contain default settings for clinical procedures. In pediatric protocols, default level is lower than adult protocols one and default frame rate is optimized for temporal resolution.

See an example of patient dose dependence on patient thickness on figure below. (Measured values for other pulses per second and other settings are given in Dose and Technical Factors Description on page 511 for 20 cm PMMA thickness).

**Figure 4-1 Typical air kerma rates at IRP with IntelIQ 30 fps fluoroscopy level 1, 2, 3, 4, 5**
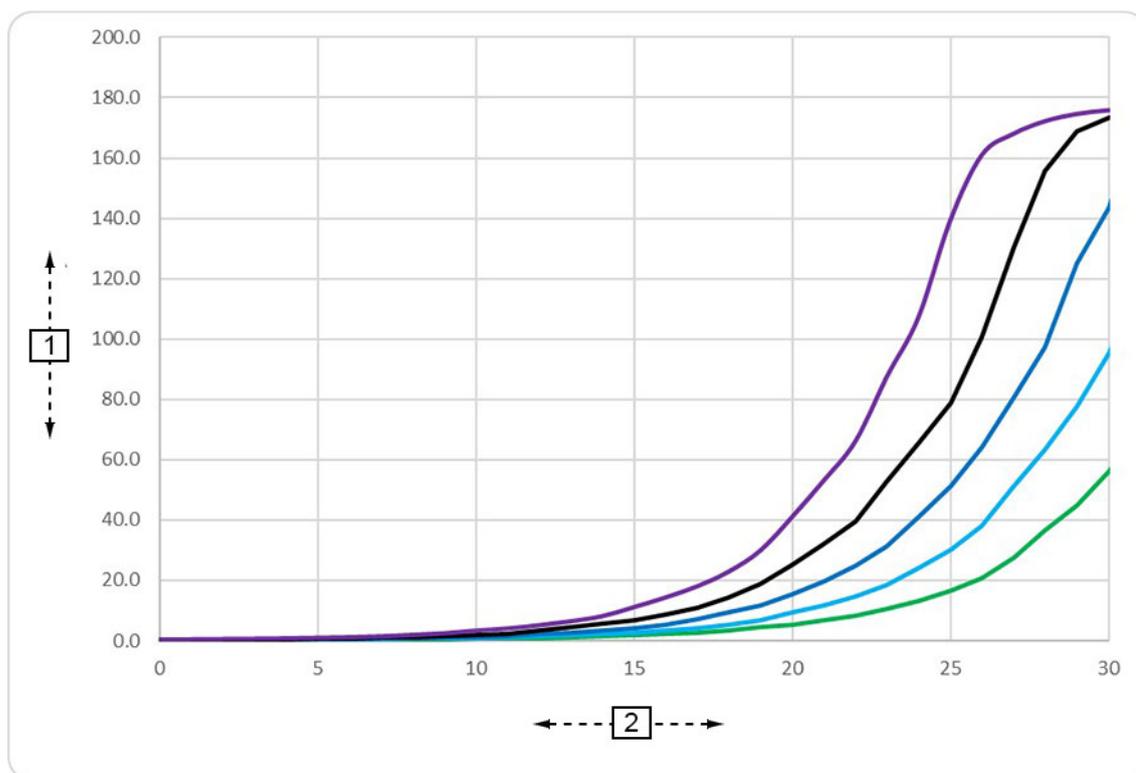
| Item | Description |
|------|-------------|
| **[1]** | Air Kerma rate (mGy/min) |
| **[2]** | PMMA thickness (cm) |
| ———— | Level 1 = "Low" |
| ———— | Level 2 = intermediate level |
| ———— | Level 3 = intermediate level |
| ———— | Level 4 = intermediate level |
| ———— | Level 5 = "Normal" |

Air Kerma rates at the interventional reference point (IRP) in case of fluoroscopy with 30 pulses per second, IntelIQ Level 1, 2, 3, 4, 5 settings in FOV20 for different thicknesses.

# 4.9 Electrophysiology (EP) Exam Case

Electrophysiology (EP) exams often require long fluoro times and are often less demanding in object visualization, allowing in these cases to have radiation dose rate set to lower values compared to other exam types.

- Select an appropriate protocol when long fluoro times are expected for an EP exam. Use a protocol with the lowest dose rate value compatible with the medical requirement. Several protocols are preset to lower radiation dose rate, refer to the list of available protocols with "EP" or "Electrophysiology" in their name or category name.

- When compatible with medical requirement, apply the means presented in previous chapters to minimize dose:

  ◦ Monitor cumulative dose.

  ◦ Appropriate use of Equipment distances.

  ◦ Minimize Sequence duration.

  ◦ etc.

# 4.10 Legal Provisions

- In many countries or states, by means of rules, guidelines or regulations, lawmakers have contributed to improving radiation protection for patients and medical personnel.

- On an international level, guidelines are laid down by the International Commission on Radiological Protection (ICRP). Many of the rules, guidelines or regulations are governed by the ALARA concept (As Low As Reasonably Achievable), meaning the production of a diagnostically relevant image at minimum possible dose.

- The material presented in this tutorial contains ways to improve radiation safety with the usage of IGS system but is not deemed to be exhaustive, read the 3.4  Protection against ionizing radiation hazards on page 44 section for more details. Local legal provisions also prevails over the ways presented in this document when applicable.