

- X-Ray field size at the measuring detector.
- Positioning of phantom.
- Positioning of measuring detector.

For each of these factors, a value is assigned and is indicated prior the radiation data stated (see hereafter in the user instructions specific to each IGS X-Ray system) they must absolutely be used in case of measurement of radiation data.

These factors are indicated for the radiation data stated in [23.3 Dose to Patient on page 517](#). The given values must absolutely be used in case of radiation data measurement.

Positioning of phantom and measuring chamber

The phantom is placed near the image receptor, leaving as much of the available distance as possible between the X-Ray Tube assembly and the entrance surface of the phantom. (This is to minimize the effect of scattered radiation on the measurements). Refer to radiation data in the user instructions specific to each IGS X-Ray system.

Recommendation:

Position the measuring chamber at a point half way between the focal spot and the entrance surface of the phantom. (This will minimize the contribution of stray radiation to the reading). The dose at Interventional Reference Point (see [3.4.3 Concept of Interventional Reference Point on page 49](#)) is then determined by using the inverse square law. Any other position that would minimize stray radiation may be used.

Checking the test conditions

When performing dosimetric measurements to check compliance with radiation data stated in [23.3 Dose to Patient on page 517](#), verify that the equipment settings and the measuring arrangements correspond to the ones given in [23.3.1 Dose Measurement Configuration on page 517](#).

Dose measurements

Measure the dose rate (air kerma rate) for each of the radioscopic settings.

Measure the air kerma per frame for each radiographic settings.

Measurements to be done for each available Field of View and Frame Rate using the 20 cm phantom.

3.4.11.3 Compliance Criteria

From the measured values obtained in the tests, calculate the corresponding values of reference air kerma (rate) at Interventional Reference Point by using the inverse square law if necessary.

Compliance is verified if:

- No value stated in the instructions for use (refer to [23.1 Modes of Operation on page 511](#)) differs from the corresponding calculated value by more than 35% of the stated value;
- The precision of the values in any group, stated for a common test geometry, is +/-15 % or better; (operator repeatability);
- In respect with the two radioscopic modes of operation i.e. "LOW" the lowest level and "NORMAL" the highest level, the ratio of the "NORMAL" value to the "LOW" value is not less than 2.

The values are only valid for the factory settings. When settings are changed they may deviate.

3.5 Protection against electrical hazards

Protection against electrical shocks

WARNING



TO AVOID THE RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

WARNING



DO NOT REMOVE COVERS OR PANELS FROM THE SYSTEM, AS THEY CONTAIN HAZARDOUS VOLTAGE, EVEN WHEN THE SYSTEM IS OFF. THERE ARE NO OPERATOR SERVICEABLE OR ADJUSTABLE PARTS INSIDE THE CABINETS AND GANTRY. ONLY TRAINED AND QUALIFIED PERSONNEL SHOULD BE PERMITTED ACCESS TO THE INTERNAL PARTS OF THE SYSTEM. FOR SAFE SERVICE OPERATION, FOLLOW THE LOTO PROCEDURE FROM THE GENERAL SERVICE MANUAL BEFORE ANY INTERVENTION ON THE SYSTEM.

The system is provided with an emergency power off button in the technical room. Additional emergency power off buttons can be installed in the control room or the technical room following the instructions contained in the Pre-Installation Manual of the system.

Figure 3-2 Emergency Power-Off/Stop button



In case of hazardous situation, press the emergency power off button. Once the button is pressed, the system can be returned to normal operation by using the steps described in [6.3 System Power-up on page 164](#).



NOTE

Third party equipment (e.g. third party monitors, Magnus Maquet OR Table) are not powered by the system, and the emergency power off buttons of the system will not power off this equipment. Refer to the equipment operating instructions for the procedures to follow before any intervention on this equipment.

WARNING



NO EQUIPMENT SHALL BE CONNECTED TO THE POWER STRIP OF THE CONTROL ROOM EXCEPT THOSE EXPLICITLY SPECIFIED IN THE GENERAL SERVICE MANUAL. ANY SUCH MODIFICATION OR ADDITION LEADS TO A MODIFIED MEDICAL SYSTEM THAT IS NOT COVERED BY MEDICAL STANDARD IEC60601-1 AND CAN RESULT IN A REDUCED LEVEL OF SAFETY.

Protection against fire hazard

Respect the minimum distance between components defined in the Pre-Installation Manual of the system. Do not obstruct the fans of the components of the system. It is not allowed to store objects on cabinet top, or to stack cabinets one on another.

Restriction for Table Side Electrical Accessories

Use only compatible injectors.

3.6 Protection against mechanical hazards

The system embeds multiple mechanisms to protect against mechanical risks. However, they cannot be completely eliminated. There are residual risks related to collision, entrapment and interferences with other devices, as well as patient fall. This section describes the precautions related to these risks.

3.6.1 Movement of Patient on the Table

With Magnus Maquet OR Table

Refer to the table manufacturer Operating Instructions.

With Omega or Innova^{IQ} Table

WARNING



NEVER LEAVE THE PATIENT UNATTENDED. AN UNATTENDED PATIENT COULD FALL FROM THE TABLE, ACTIVATE A MOTION CONTROL, OR ENCOUNTER OTHER PROBLEMS, WHICH COULD BE HAZARDOUS.

WARNING



ALWAYS USE PROPER ACCESSORIES TO HOLD THE PATIENT AND PREVENT RISK OF INJURY DURING THE MOTION OF THE EQUIPMENT. THE RESTRAINTS LIMIT, BUT DO NOT ELIMINATE THE RISK FOR THE PATIENT TO FALL; IN NO WAY CAN THEY BE USED TO SUPPORT THE PATIENT WEIGHT.

For Innova^{IQ} Table, Velcro[®] straps are not appropriate to immobilize the patient when the table is tilted. The patient could slightly slide over the mattress and get hurt.

The Omega table top mattress is provided with three mattress strips on each side. While loading or unloading the patient, it is recommended to grip the mattress strips to avoid the mattress shifting.

Ensure the mattress strips are well stuck on the table top prior to loading or unloading the patient.

3.6.2 2" Mattress with Innova^{IQ} Table

WARNING



THE MATTRESS CONTRIBUTES TO SAFETY WHEN THE TABLE IS TILTED BY PREVENTING THE PATIENT FROM SLIDING. IN CASE THE MATTRESS IS DAMAGED AND REQUIRES REPLACEMENT, IT IS MANDATORY TO REPLACE IT WITH THE SAME MODEL. THERE IS A RISK OF PATIENT FALL WHEN THE TABLE IS TILTED IN CASE ANOTHER MATTRESS MODEL IS USED.

WARNING

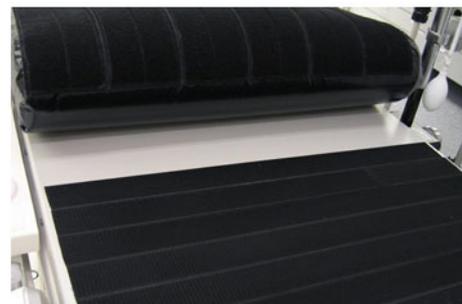
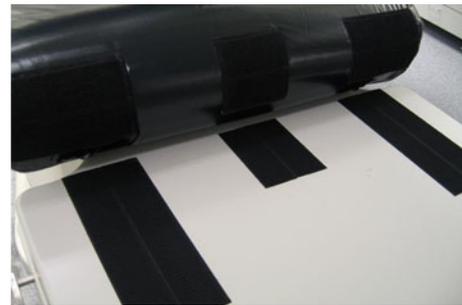


TO PREVENT ANY PATIENT FALL RISK DURING A TABLE TILT, ENSURE THAT THE MATTRESS IS SECURED TO THE TABLE TOP BY THE SET OF MATTRESS STRIPS.

In case the mattress needs to be removed from the table top, pull up the mattress at foot end, then at the mid section to release the mattress strips.

To install the mattress, start from head end.

- Align the mattress head end to the table top head end.
- Roll out the mattress aligned to the table top longitudinal axis.
- Check that the mattress strips are facing each other and press on the mattress to engage the straps at mid section and foot end.



3.6.3 Table Side User Interfaces

CAUTION



While clamping table side user interfaces on rail, it is important to double check that it is correctly clamped. It could fall, if not correctly clamped.

In case table tilt is required during a procedure, always position the table side controls in such a way that it stays reachable in any table tilt angulation.

WARNING

UNINTENTIONAL ACTIVATION OF SYSTEM MOVEMENTS (E.G: WHEN LEANING OVER THE CONTROL PANEL, BY THE PATIENT, OR OTHER MEANS) MAY CAUSE SERIOUS INJURY TO THE PATIENT OR ANY OTHER PERSON. BEFORE STARTING ACTIVITIES CLOSE TO THE CONTROL PANEL, ALWAYS LOCK GANTRY AND TABLE MOTION BY

USING MOTION LOCK BUTTON



LOCATED ON THE CONTROL PANEL.

3.6.4 IGS Control Center (Option)

The IGS Control Center is a cart provided to the customer fully installed and ready to use.

Any mechanical configuration modification must be performed by qualified and trained engineers only.

Never position the IGS Control Center in a location where it could enter in collision while the table is tilted or moved up or down.

WARNING

WHEN POSITIONING OR MOVING THE IGS CONTROL CENTER, AVOID COLLISION WITH OTHER EQUIPMENT. FAILURE TO DO SO MAY LEAD TO SEVERE DAMAGE ON BOTH THE IGS CONTROL CENTER AND OTHER EQUIPMENT. IN CASE OF SEVERE COLLISION OR EQUIPMENT DAMAGE, IMMEDIATELY STOP OPERATION OF THE SYSTEM. KEEP THE AREA AROUND THE IGS CONTROL CENTER CLEAR OF ANY EQUIPMENT.

To prevent the IGS Control Center from falling over, never move or use it on a slope greater than 10°.

**NOTE**

Always ensure the rotary switch is selected towards the correct side of the Control Panel to consistently align the configuration with the position of the IGS Control Center. Failure to do so may result injury to a patient or staff due to motion in an unintended direction.

3.6.5 Use Extreme Care when Positioning the Equipment

The operator using the controls is responsible for the safety of each person around the equipment. Although collision sensors are provided on the image receptor and collimator, they are not intended to be a substitute for careful operation. Be sure the equipment path is clear before starting a motion. When positioning the equipment, carefully observe the moving parts, and stop the motion before making contact. The sensors are provided for added protection in case of inadvertent contact, and are not to be relied on as a normal means for stopping the motion. Each motion control device has an enable and a move control (some with speed control), the release of the enable will stop the motion.

Improper equipment positioning could result in serious injury or equipment damage.

WARNING



PAY ATTENTION WHEN MOVING THE IN-ROOM MONITOR SUSPENSION. BEFORE MOVING THE GANTRY OR THE TABLE, ALWAYS POSITION THE MONITOR SUSPENSION IN A WAY TO AVOID COLLISIONS WITH THE PATIENT AND EQUIPMENT. FAILURE TO ADHERE TO THIS RECOMMENDATION MAY LEAD TO PATIENT INJURY AND/OR EQUIPMENT DAMAGE.



NOTE

During the use of "follow the gantry" mode, the operators attention will be drawn to the AW in-room monitor and away from the moving gantry. Whilst in this mode, use extreme caution when moving the gantry to avoid collision.

WARNING

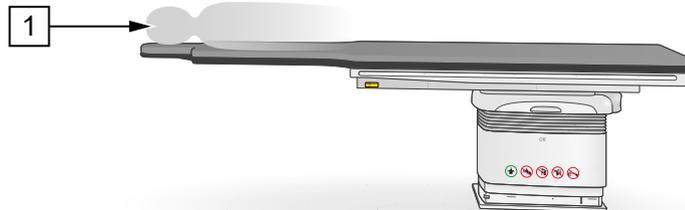


BE CAREFUL ABOUT THE POSITIONING OF ALL OF THE PATIENT'S HEALTH LINES (IV, OXYGEN, ETC.) AND OTHER DEVICES, TUBES OR WIRES CONNECTED TO THE PATIENT TO AVOID THAT THEY ARE CAUGHT OR WITHDRAWN WHEN MOVING THE EQUIPMENT; IT MAY CAUSE INJURY TO THE PATIENT.

3.6.6 System Collision

The system contains anticollision devices at the essential locations (detector, tube ...) and an anticollision software which is based on a virtual volume representing the patient lying on the table top in "standard position".

This "standard position" is defined with the head of the patient located at head end (gantry side) of the table top.



Item	Description
[1]	Patient Head

For any other patient positioning on the table (table head extender usage, patient positioned lower on the table, patient head to toes reversed...), operators should exercise extreme caution when moving the gantry around the patient, as the virtual patient volume will not be in the same location as the actual patient.

Anticollision software and sensors are provided for patient safety. The sensor pads, which surround the X-Ray Tube and the Image Receptor, contain pressure sensitive collision sensors. There is one level of collision sensing for the X-Ray Tube sensor and there are two levels for the Image Receptor sensor.

In the configuration compatible with Magnus OR Table system, the virtual volume is adapted on the head side. Due to the geometrical differences between the different types of head holder and the specific head positioning for each one, you need to check and select the head holder

type installed on the table to enable dynamic adaption of the collision avoidance model per user selection.

WARNING

WHEN USING THE BENDABLE HEAD REST, HORSE SHOE OR SKULL CLAMP, YOU MUST SELECT THE ACCESSORY FROM THE TOUCH PANEL. FAILURE TO DO SO MAY LEAD TO PATIENT INJURY AND/OR EQUIPMENT DAMAGE DUE TO COLLISION.

In addition, when the skull clamp is selected, you need to define through a guided workflow the optimized volume including the real position of the patient head and the skull clamp. Upon completion of this optimization step, the user defined volume is used by anticollision software to slow down and stop gantry and/or table axis motions to minimize risk of collision.

WARNING

TO MINIMIZE PATIENT HEAD COLLISION RISK WHEN USING THE SKULL CLAMP DURING NEURO-SURGICAL PROCEDURES, YOU MUST SELECT THE ACCESSORY FROM THE TOUCH PANEL AND PERFORM THE VOLUME OPTIMIZATION STEP.

Precaution regarding Detector Anti-Collision Device

WARNING

ATTENTION OF OPERATORS IS DRAWN REGARDING THE PRESSURE THAT MAY BE APPLIED ON THE PATIENT BODY IN CASE OF ACTIVATION OF DETECTOR ANTI-COLLISION DEVICES (BUMPER, SWITCH PLATE). THIS PRESSURE (70 N) IS BELOW THE MAXIMUM PRESSURE (200 N, 20 KG) RECOMMENDED BY THE SAFETY STANDARD FOR INTERNATIONAL APPLICATION OF AN ACCESSORY ONTO THE PATIENT BODY FOR CLINICAL PURPOSE. HOWEVER: EXTRA CARE SHOULD BE TAKEN TO AVOID COLLISION FOR PATIENTS HAVING UNDERGONE RECENT SURGERY (ON THE THORAX/ABDOMEN FOR INSTANCE), YOUNG PATIENTS (I.E. BABIES), NARROW AND SMALL HUMAN OBJECTS (I.E. NOSE)... IN ADDITION, IT IS RECOMMENDED THAT THE PATIENT'S HEAD BE TURNED TO THE RIGHT/LEFT AND TO REDUCE GANTRY SPEED WHEN IN THE VICINITY OF THE PATIENT'S HEAD.

Unprotected parts

Some parts of the system are not equipped with protection against collision. They present a residual risk of crushing described below.

- Patient - Side of the table top

WARNING

THERE IS A RISK THAT THE PATIENT GETS CAUGHT BETWEEN THE SIDE OF THE TABLE TOP AND THE GANTRY. ENSURE THE PATIENT (IN PARTICULAR HIS HANDS AND ARMS) IS SAFE BEFORE MOVING THE GANTRY OR THE TABLE. IF NEEDED, USE ARM RESTRAINTS.

- Patient - Accessories

WARNING

THERE IS A RISK THAT THE PATIENT GETS CAUGHT BETWEEN THE GANTRY AND AN ACCESSORY MOUNTED ON THE TABLE TOP. ENSURE THE PATIENT (IN PARTICULAR HIS HANDS AND ARMS) IS SAFE BEFORE MOVING THE GANTRY OR THE TABLE.

- External device - Gantry
Medical devices could get caught and damaged between the gantry and the table or along the walls. The gantry could also damage tubes and cables when they are lying on the gantry trajectories. Ensure the medical devices are not in the way before moving the gantry.
- Staff foot – Tube

CAUTION

Make sure to not leave your foot under the tube. It could get caught underneath when the tube moves.

- Staff - Gantry - Table

WARNING

DO NOT STAND BETWEEN THE TABLE TOP AND THE GANTRY UNLESS THE GANTRY AND TABLE MOTIONS ARE DISABLED. THERE IS A RISK OF GETTING CAUGHT IF THE TABLE IS MOVED TOWARD THE GANTRY.

Check Equipment after collision

In case of collision between two parts of the system (e.g. gantry against a monitor) have the parts carefully inspected before resuming the procedure.

3.6.7 Split or Punctured Table

A split or punctured table top may injure patient and operator hand. Significant table top damage will reduce structural integrity and require immediate replacement of the table top. Minor damage, splinters, and chips; will not reduce integrity but require care in use and patient positioning to avoid injury.

3.6.8 Driving the Table

Secure all devices or equipment located on the table top prior to tilting the table to avoid injury to patients and staff.

3.6.9 Cardiopulmonary Resuscitation (CPR)

CPR with Magnus Maquet OR Table

Cardiopulmonary resuscitation is possible on the Magnus Maquet OR Table in every position. Please refer to the table manufacturer operating instructions.

In the event of a medical emergency requiring CPR, move the gantry away from the patient.

In case of power outage, the gantry and table movements remain available.

In case the IGS system is in degraded mode, use remaining gantry motions and Maquet commands to access the patient for CPR.

CPR with Innova^{IQ} Table

If Cardiopulmonary Resuscitation (CPR) is required while the patient is on the table, the table top shall be moved toward the foot end, positioning it over the base of the table as demonstrated by the two labels located on the side of the table base. The table is centered laterally and CPR can then be performed. At no time should an additional person or heavy equipment be placed on the table top while performing CPR. Always maintain sufficient clearance around the patient so as to be able to conduct CPR.



In addition the table allows positioning for CPR by using the CPR thumbnail available on the Auto Positioning page on the Touch Panel.

When the CPR thumbnail is selected, a message appears on the monitors until the CPR position is reached. Holding down the **Move** button (button [14] in [12.1.4 Control Panel on page 401](#)) will automatically move all table and gantry axis in such a way that:

- The table tilt is moved back to horizontal position.
- The table top is moved toward the foot end.
- The table height is moved to at least 15 cm below the gantry isocenter.

CPR can be performed when the system is in the above position. In addition to reaching the CPR position as described above, the Auto Positioning also reaches the following positions:

- The gantry pivot and gantry C-arm are moved to PA position (0°).
- The detector is moved to its highest position.
- The table height is lowered to 20 or 25 cm below the gantry isocenter (depending on your configuration).



NOTE

If the table is tilted, it is recommended to move to a CPR position using the CPR feature on the Touch Panel.

A CPR command cannot be completed when gantry and table motions are disabled on the Control Panel (button [9] in [12.1.4 Control Panel on page 401](#)). In case a CPR command is required, enable the gantry and table motions first (button light off).

The CPR auto positioning cannot be completed in case of collision or if one of the table or gantry axis is not functional (i.e. table or gantry working in degraded mode). In such case, use manual commands to move the patient to CPR position.

The gantry and table CPR automatic motions may be slowed down in the case of a collision risk. In this case, it may be faster to use manual commands to move the patient to a CPR position.

WARNING



IN CASE OF UNAVAILABILITY OF TABLE MOTION TO PERFORM CPR:

- IF THE TABLE IS TILTED, THE PATIENT NEEDS TO BE MOVED TO A TILTING BED/GURNEY. THE PATIENT SHOULD BE SECURELY HELD BY THE HOSPITAL STAFF AS THE TRANSFER IS MADE FROM TABLE TO BED/GURNEY.
- IF THE TABLE IS HORIZONTAL THE PATIENT NEEDS TO BE PULLED BACK TOWARDS THE FOOT END OF TABLE TO ACHIEVE CPR POSITION.

CPR with Omega Table

If Cardiopulmonary Resuscitation (CPR) is required while the patient is on the table, the table top shall be moved toward the foot end, positioning it over the base of the table as demonstrated by the two labels located on the side of the table base. CPR can then be performed. At no time should an additional person or heavy equipment be placed on the table top while performing CPR. Always maintain sufficient clearance around the patient so as to be able to conduct CPR.



NOTE

The gantry and table motions may be slowed down because of a near collision risk. In this case, it may be faster to use manual commands to move the patient to a CPR position.

CPR position can be reached by manually moving all needed axes. To reach CPR position, move the table top toward the foot end. CPR can be performed when the system is in this position.

In addition to reaching the CPR position as described above, the table height may be lowered and Detector may be moved to its highest position.

3.6.10 Patient Loading/Unloading

Hold the patient during loading/unloading on the table.

With Magnus Maquet OR Table

WARNING



BEFORE LOADING OR UNLOADING THE PATIENT ONTO OR OFF THE TABLE:

- CHECK / BRING BACK THE TABLE TOP TO HORIZONTAL POSITION.
- ADJUST THE TABLE HEIGHT AND MOVE THE TABLE TOP TOWARD THE FOOT END FOR THE BEST PATIENT ACCESS.
- ENSURE THAT THE TABLE ROTATION IS SECURED WITH THE LOCKING LEVER.
- LOCK GANTRY AND TABLE MOTION BY USING THE **MOTION LOCK** BUTTON LOCATED ON THE CONTROL PANEL TO ENSURE THAT THE TABLE AND GANTRY WILL NOT MOVE.
- DISABLE X-RAY.
- REMOVE ALL ACCESSORIES AND CONTROLS.
- HOLD THE TABLE TOP.

ALSO, THE PATIENT SHOULD BE SECURELY SUPPORTED BY HOSPITAL STAFF AS THE TRANSFER IS MADE FROM BED/GURNEY TO TABLE AND VICE VERSA

For **Motion lock** and **X-Ray disable** buttons, refer to section [12.1.4 Control Panel on page 401](#).

With Innova^{IQ} Table

Assist patients on and off the table.

WARNING



BEFORE LOADING OR UNLOADING THE PATIENT ONTO OR OFF THE TABLE:

- CHECK / BRING BACK THE TABLE TOP TO HORIZONTAL POSITION.
- ADJUST THE TABLE HEIGHT AND MOVE THE TABLE TOP TOWARD THE FOOT END FOR THE BEST PATIENT ACCESS.
- LOCK GANTRY AND TABLE MOTION BY USING THE **MOTION LOCK** BUTTON LOCATED ON THE CONTROL PANEL TO ENSURE THAT THE TABLE AND GANTRY WILL NOT MOVE.
- DISABLE X-RAY.
- REMOVE ALL ACCESSORIES AND CONTROLS.
- HOLD THE TABLE TOP.

ALSO, THE PATIENT SHOULD BE SECURELY SUPPORTED BY HOSPITAL STAFF AS THE TRANSFER IS MADE FROM BED/GURNEY TO TABLE AND VICE VERSA

For **Motion lock** and **X-Ray disable** buttons, refer to section [12.1.4 Control Panel on page 401](#).

Motion lock: activate this button to disable all table/gantry axis commands (button light is blue).

Press again on this button to reactivate all table/gantry axis commands (button light is white).

WARNING



IF THE TABLE LOCKS UP WHEN TILTED AND DOES NOT RECOVER AFTER A SYSTEM RESET, THE PATIENT NEEDS TO BE MOVED TO A TILTING BED/GURNEY. IT IS MANDATORY TO COMPLY WITH THESE INSTRUCTIONS IN ORDER TO MINIMIZE THE RISK OF PATIENT FALLING FROM TABLE DURING UNLOADING.

With Omega Table

WARNING



BEFORE LOADING OR UNLOADING THE PATIENT ONTO OR OFF THE TABLE:

- CHECK / BRING BACK THE TABLE TOP TO HORIZONTAL POSITION.
- ADJUST THE TABLE HEIGHT AND MOVE THE TABLE TOP TOWARD THE FOOT END FOR THE BEST PATIENT ACCESS.
- LOCK GANTRY AND TABLE MOTION BY USING THE **MOTION LOCK** BUTTON LOCATED ON THE CONTROL PANEL TO ENSURE THAT THE TABLE AND GANTRY WILL NOT MOVE.
- DISABLE X-RAY.
- REMOVE ALL ACCESSORIES AND CONTROLS.
- HOLD THE TABLE TOP.

ALSO, THE PATIENT SHOULD BE SECURELY SUPPORTED BY HOSPITAL STAFF AS THE TRANSFER IS MADE FROM BED/GURNEY TO TABLE AND VICE VERSA

For **Motion lock** and **X-Ray disable** buttons, refer to section [12.1.4 Control Panel on page 401](#).

Motion lock: activate this button to disable all table/gantry axis commands (button light is blue).

Press again on this button to reactivate all table/gantry axis commands (button light is white).

3.6.11 GE HealthCare table rails

WARNING



THE MAXIMUM LOAD A TABLE RAIL CAN HANDLE IS 40 KG.

Typical installation on the front table accessory rail is Control Panel, Touch Panel, Table panning device and cables support.

Here is the weight of the GE HealthCare controls:

Devices on table rails	Weight (kg)
Control Panel with cables	3.6
Touch Panel with rail clamp and cables	3.7
Touch Panel on arm with cables	4.3
Mouse Tray	2.5
Cable support	0.5
Table Panning Device (TPD)	1.0

On each screw of the table accessory rail, the maximum allowed torque is 64 N.m. All GE HealthCare accessories listed above are compliant with this specification. In case of non GE HealthCare accessory installation on the table accessory rail, make sure the torque remains below 64 N.m., according to the following formula:

Torque = 10 x weight (kg) x distance to the rail (m).

For example, a 5 kg load, located 10 cm away from the rail, has a torque of : 10 x 5 (kg) x 0.1 (m) = 5 N.m.

In any case, always make sure the weight of devices on the table rail remains below 40 kg, and below 20 kg on the optional table foot end rail. Also, make sure the torque on each screw is below 64 N.m,

Below is the weight & load capacity of the Sleeve & accessories that get mounted on it. This table must be considered when loading accessories to ensure the maximum permissible load limits are not exceeded.

Sleeve and accessories	Quantity	Weight/Unit (kg)	Maximum load
Removable rails (also called sleeve or removable table rails or surgical size rails)	1	5 kg	20 kg / rail
Rail extender	2	0.7 kg	15 kg
Adaptor rail for table side controls	1	1 kg	15 kg
Head widener with pad (also called head support widener)	1	1.5 kg	15 kg
Width extender with pad	2	1 kg	15 kg
Armboard with thick pad (also called armrest)	2	1.8 kg	15 kg
Universal clamp (also called socket)	1	0.3 kg	15 kg
Round post clamp (also called easy lock socket)	2	0.6 kg	15 kg
Patient restraint strap	1	1 kg	-
Anesthesia screen holder (also called flexible anesthesia screen holder or post)	1	1.6 kg	1.1 kg

WARNING



THE MAXIMUM LOAD A SURGICAL SIZE RAIL CAN HANDLE IS 20 KG.

WARNING



SOME OF THE ACCESSORIES THAT CAN BE MOUNTED ON THE TABLE RAILS, REMOVABLE RAILS, OR TABLE TOP CAN POTENTIALLY COLLIDE WITH THE GANTRY DURING TABLE OR GANTRY MOTIONS. SPECIAL ATTENTION MUST BE PAID REGARDING POSITIONING OF THE EQUIPMENT TO AVOID COLLISION WITH THE PATIENT OR THE ACCESSORIES THEMSELVES.



NOTE

For Magnus Maquet OR Table compatible accessories, refer to the manufacturer documentation.

3.6.12 Lead Shield Positioning

WARNING



SPECIAL ATTENTION MUST BE GIVEN WHEN MOVING THE LEAD SHIELD CLOSE TO THE PATIENT DURING A PROCEDURE. BEFORE MOVING IT ALWAYS VERIFY THAT THE CATHETER CANNOT BE ACCIDENTALLY WITHDRAWN FROM THE PATIENT.

3.7 Protection against contamination / infection / allergy / toxicity hazards / biological hazards

**NOTE**

Always cover the table top and accessories directly in contact with the patient with a sheet or a mattress before installing the patient on the table, to prevent the direct contact of the patient with the table top and other accessories.

Mattress or sheets in direct contact with the patient must be ISO 10993 certified.

(For System with 2" mattress)

WARNING

THE MATTRESS IS WATERPROOF IN NORMAL CONDITIONS. DO NOT USE A SLICKER WITH THIS MATTRESS TO AVOID MATTRESS OR PATIENT SLIPPAGE DURING TILT PROCEDURES. IN CASE OF CONTAMINATION INSIDE THE MATTRESS COVER DUE TO FLUID ABSORPTION, IT IS MANDATORY TO REPLACE THE MATTRESS WITH THE SAME MODEL.

WARNING

IN CASE OF CONTAMINATION INSIDE THE PAD OF HEAD WIDENER, ARMBBOARD OR WIDTH EXTENDER DUE TO FLUID ABSORPTION, IT IS MANDATORY TO REPLACE THE PAD.

(For System with 1" mattress)

**NOTE**

Always cover the table top with a mattress before installing the patient on the table.

Slickers in direct contact with the patient must be ISO 10993 certified.

WARNING

THE 1" MATTRESS DELIVERED WITH THE OMEGA TABLE IS NOT FULLY WATERPROOF. TO AVOID MATTRESS CONTAMINATION DUE TO FLUID ABSORPTION AND BIOLOGICAL HAZARDS, ALWAYS USE A SLICKER (COVER THE MATTRESS WITH A FULLY WATERPROOF SHEET OR COVER) BEFORE INSTALLING THE PATIENT ON THE MATTRESS.

(For System with Magnus Maquet OR Table)

**NOTE**

Refer to the manufacturer documentation.

3.7.1 General Information

WARNING



IN ORDER TO PREVENT ANY PATIENT CONTAMINATION AND ACCORDING TO THE LOCAL REGULATION, AFTER EACH PROCEDURE, THOROUGHLY CLEAN AND DISINFECT ANY PARTS LIKELY TO BECOME SOILED DURING USE. THIS INCLUDES PARTS WHICH WERE IN PATIENT VICINITY OR IN CONTACT WITH THE PATIENT AND ANY PARTS THAT COULD BE CONTAMINATED BY OPERATORS.

WARNING



IMPROPER CLEANING METHODS CAN DAMAGE THE EQUIPMENT, CAUSE POOR IMAGING PERFORMANCE OR INCREASE THE RISK OF ELECTRIC SHOCK.

Never allow liquids to enter the internal parts of the equipment: do not apply cleaning sprays or liquids directly to the equipment (except table). Always use a clean cloth dampened with the spray or liquid.

If you become aware of liquid entry, disconnect the electrical supply and have the equipment inspected by qualified service personnel before returning it to use.

Do not expose equipment parts to steam or high temperature sterilization.

3.7.2 Equipment Cleaning

Recommended Cleaning Agents

Soap with lukewarm water.

Cavicide product including CaviWipes (Supplier: Metrex Research Corporation or KERR TotalCare) can be used except on gantry covers and Omega tables covers.

System cleaning

In the exam room, the entire system surfaces should be scrubbed as needed by using a soft, damp gauze or cloth to remove all visible residue. Scrubbing with a soft bristle brush (such as a toothbrush) may be necessary to reach corners or to remove debris that has dried onto the surface.



NOTE

- Pan the table to its maximal positions (lateral and longitudinal) to ensure a better access to the surfaces located below the table top.
- For gantry cleaning, put the gantry in Lat or oblique position to ensure a better access to surfaces located below the tube covers.

Subsequent disinfection may not be effective if the surfaces are not thoroughly clean.

Rinse all surfaces with clean water to remove visible soap residue, taking care to avoid liquid entry to internal equipment parts. Dry surfaces with a soft cloth to remove any visible residue.

It is recommended not to remove the cover from the mattress. Otherwise, it would then be extremely difficult to reposition the mattress in its cover.

Special attention is required to clean suspended equipment as per device recommendation and Preventive Maintenance. This particular attention is even more important in a surgical environment with specific airflow installations, for any equipment that can potentially be found above the table.

In Allia IGS 7 and Allia IGS 7 OR systems, the cable chain management device of the moving gantry can potentially come above the table. It is recommended to pay particular attention to clean this suspended equipment before each intervention, to avoid dust rejection above the table. This particularly applies in operating rooms with vertical laminar flow above the table.

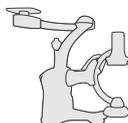
CAUTION



The footswitch could fail if excessive cleaning agents, bodily fluids or contrast agents remain on the pedal mechanism, causing it to get stuck and remain permanently depressed. Ensure it is properly cleaned and dried. If using a drape to cover it, make sure the drape is not keeping the pedal down accidentally.

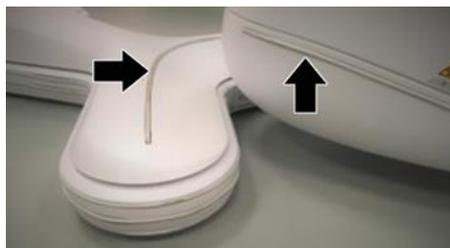


Allia IGS 7
Allia IGS 7 OR



NOTE

If necessary, it is possible to access the underside of the sensor of Y cover and Tube cover collision device.



Pinch the extremity of the white part and carefully unclip the anti-collision device (start from the side with the cap, not the side with the wire) as shown on the following picture. Carefully clip back after the cleaning.



For the right and left bottom covers (see picture below), the sensor is permanently fixed to the covers and can be scrubbed on surface as needed. Do not pull the sensor.



Suspensions Cleaning

At least once a month, external metallic surfaces and exposed tracks should be wiped to remove any foreign material that may have accumulated.

If the tracks are wiped with a cloth slightly moistened with oil, sufficient lubrication will be provided to insure smooth operations and to protect against rust. Enamelled surfaces should be cleaned using a clean cloth moistened slightly with a good mild cleaner and polish acceptable for such use.

Laser glass cleaning on Allia IGS 7 and Allia IGS 7 OR

If necessary, the Laser can be cleaned externally as follows: for the window and top cap of the laser use air duster EAD400D to remove dust etc. and wipe over with cleaning solvent such as IPA400H. For more stubborn contamination use Purosol Optical Cleaner and wipe clean using Prematex Low Lint wipes.

Parts Required	Manufacturer	Reference
EAD400D	available from Farnell	No. 249-737
IPA400H	available from Farnell	No. 279-511
Purosol Optical Cleaner	available from Edmund Optics	No. 57727
Prematex Low Lint Wipes	available from Edmund Optics	No. 53983

After cleaning, there shall be no visible mark on the laser glass.

Do not use harsh detergents, abrasive cleaners, high alcohol concentration or Methanol at any concentration.

3.7.3 Equipment Disinfection

Exam room equipment including system, monitors, suspensions and accessories, can be disinfected with suitable liquid chemical germicide bactericide and antiviral. Equipment parts should be wiped with a damp cloth as directed by the instructions for use provided with the disinfecting liquid. Floor can be mopped or wet-vacuumed with disinfectant after scheduled cases are completed. Surfaces must first be cleaned of all visible contamination (see above). The disinfecting liquid must have the adequate contact time with the surface to be effective (refer to the disinfectant manufacturer's instructions). Further rinsing or wiping with clear water and drying with a soft cloth should be done to remove any disinfecting liquid residue that may remain. Take care to avoid liquid entry to internal equipment parts.

For non GE HealthCare equipment refer to respective device manufacturers instructions and recommendations for cleaning and disinfection.

Recommended Disinfecting Agents

The following legally marked products have been used on GE HealthCare equipment without causing equipment damage.

- Surfanios (Supplier: Anios)
- Cleansinald (Supplier: Taski) or TASKI DS 5001
- Morning Mist (Supplier: Butchers)

In addition, for OR configuration, the following products have also been tested on Allia IGS systems except Gantry covers:

- Cavicide (Supplier: Metrex Research Corporation or KERR TotalCare)
- Madacide FD (Supplier: Mada Medical Products, Inc)
- Virex II 256 (Supplier: Johnson Diversey)
- Bleach 2.6%/Water (1 :25)



NOTE

This is not an exhaustive list, it is a recommended list of products. In case you do not use the recommended disinfectant, choose one that is suitable for metal/plastic/painted surface. If you have any doubt about the nature of a disinfecting agent, do not use it. If the system appears to be damaged by the disinfectant, immediately stop using this disinfectant. Contact GE HealthCare service for repair.



NOTE

For the Large Display Monitor, use only Surfanios, Cleansinald and Morning Mist.

Always follow the cleaning and disinfecting agents manufacturer's instructions and precautions for mixing, storage, method of application, contact time, rinsing requirements, protective clothing, shelf life and disposal to help assure effective and safe use of the product.

CAUTION

Before cleaning/decontaminating the equipment, always check components and recommendations of the cleaning agent to make sure that it cannot permanently damage the equipment: gantry, table, cabinets, all accessories... Always avoid using cleaning agents which contain components that could corrode the equipment. Always wash as soon as possible parts of the equipment which could be in contact with corrosive components. Failure to follow these recommendations could cause permanent damage to the equipment and result in a complete system outage.

Wheels disinfection on Allia IGS 7 and Allia IGS 7 OR

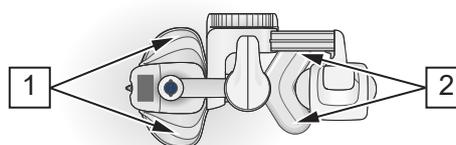
**NOTE**

To disinfect the wheels, it is possible to pour disinfecting product on the floor and make the system roll in it. Translation movements are most appropriate for that purpose. Ensure the right people are operating the system during such procedures. Note that every 6 months, the wheels are inspected during preventive maintenance, they are then accessible which would enable thorough cleaning and disinfection.

**NOTE**

Always try to avoid making the system roll in liquids, especially blood. Always try to mop liquids on the floor before moving the system. If this happens, follow the disinfection procedure as stated in the previous note.

The following scheme shows the position of the wheels:



Item	Description
[1]	Rear wheels
[2]	Front wheels

High Level Disinfection

In the event that you feel a high level disinfection is necessary due to equipment contact with open wounds, or being used with infected or immune compromised patients, the same patient contact surfaces may be high level disinfected with a liquid chemical germicide rated for high-level disinfections.

The same process used as that for intermediate level disinfections is generally followed; however, the time of contact is usually much longer for high-level disinfections.

3.7.4 Draping

Always cover the table top and other accessories directly in contact with the patient with a sheet or a mattress before installing the patient on the table, to prevent the direct contact of the patient with the table top and other accessories.

WARNING



TO PROTECT AGAINST POSSIBLE BIOLOGICAL HAZARDS, DRAPES SHALL BE USED ON THE DETECTOR, IN DIAGNOSTIC AND INTERVENTIONAL CONTEXTS. ALL THE DRAPES USED ON ACCESSORIES, ON MATTRESS AND ON DETECTOR SHALL BE ISO 10993 CERTIFIED.

WARNING



TO PROTECT AGAINST POSSIBLE PARTICLE REJECTION, A FULL DETECTOR AND LIFT DRAPING MUST BE SET UP FOR ALL PROCEDURES COMBINING IMAGING AND SURGERY.

CAUTION



Bodily fluids may damage internal components if they are allowed inside the equipment. Use drapes, if necessary, to protect equipment when performing procedures.

You can choose among the following solutions. Contact your local GE HealthCare representative for more information on how to order these solutions.

Draping of the equipment

Figure 3-3 Image Receptor



Figure 3-4 X-Ray Tube - Collimator assembly



Figure 3-5 Control Panel and Touch Panel



Figure 3-6 Mouse tray

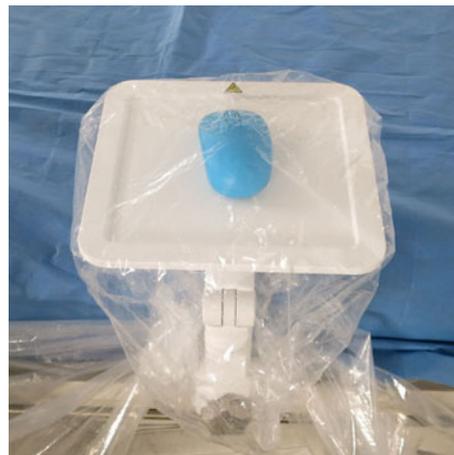
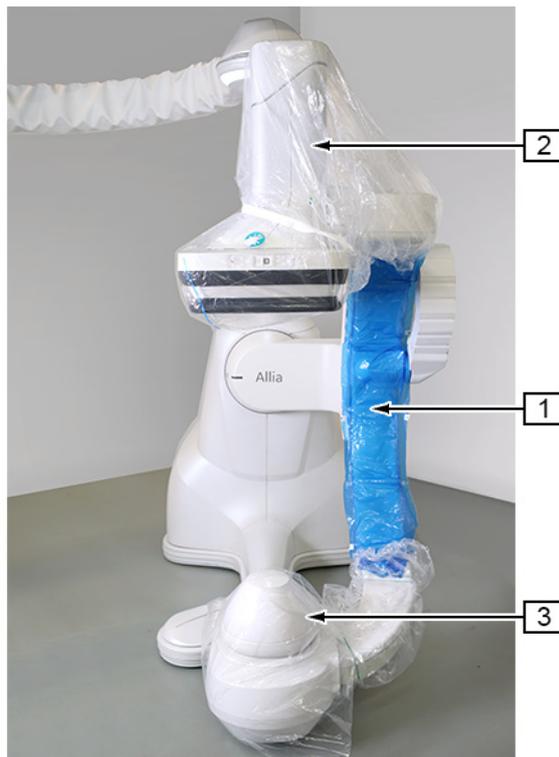


Figure 3-7 Touch Panel on arm



An elastic band can be used to adjust the drape around the Touch Panel to improve comfort of use.

Full drape kit



1. How to position the C-arm drape [1]:



NOTE

For a safe and easy mounting of the drapes, 2 people are necessary.

- Remove the C-arm drape from the kit.
- Position the gantry in the PA position and rotate the table to provide proper clearance.
- Apply the C-arm drape by snapping the clips at the hose connection point:



- Break the “Tear Here” stickers (4 pieces) at the perforation lines and slide the drape to expand over the top and bottom sections of the C-arm.



**NOTE**

Particular attention should be paid to avoid any contact between the sterile operator and the detector.

Furthermore, it is recommended to handle the clips as shown below, to avoid any contact between sterile operator and non-protected gantry parts:

**2. How to position the Image detector drape [2]:****NOTE**

For a safe and easy mounting of the drapes, 2 people are necessary.

In order to get proper clearance and access, you can position the gantry and the table top away from one another by rotating the table top or by moving the gantry in backout or parking.

- Remove the image detector drape from the kit.
- Lower the detector to the lowest position. Lay the drape on a table, unfold the left and right and fan folds keeping the label “this side up” exposed.
- Insert hands (left and right) at the bottom of the drape in the layer where hand labels are indicated.



- Lift drape up with hands inside (the inside of the drape will be exposed).
- Start positioning the drape over the detector.



NOTE

Particular attention should be paid to avoid any contact between non sterile body parts of the operator (like head) and the drape.

At this stage of the draping procedure 2 people are necessary.

- Uncurl the drape completely.



- Match the drape's trim sealed blue corners to the detector's front corners.



- Raise the detector to its maximum height and fasten the first strap at its landing point area (if this strap is not placed in the right spot, the drape will sag and not fit tightly to the detector).



- Lower the detector to the lowest position and fasten the second strap. Fasten the strap such that no C-arm clip is entrapped.



3. How to position the Tube drape [3]:

- Remove the X-Ray Tube drape from the kit.
- Rotate the gantry to LAO 90 or greater to decrease the opportunity of floor contact (if the drape needs to stay sterile). (**For Allia IGS 7**), this operation is possible when the gantry is in imaging position.
- Apply the drape. The tube drape should overlay the C-arm drape, but should not entrap any C-arm drape clip.



- Apply the first rubber band.



- Gather the excess material at the top of the C then place the second rubber band around the drape.
- Using the adhesive bands at the drape's corner, it is possible to improve the fitting of the drape.

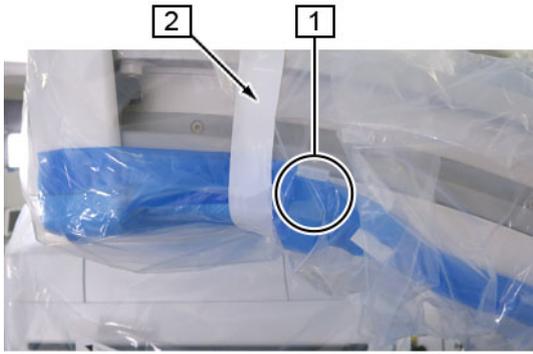
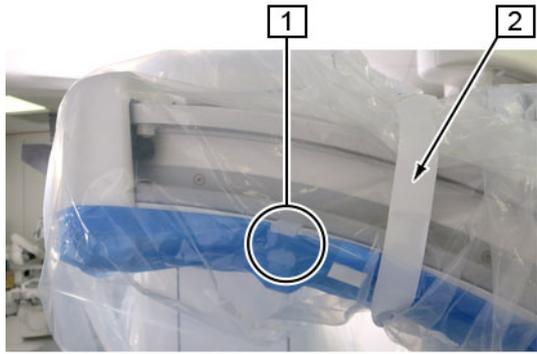


4. At the end of the draping, verify that:
- No side clips have been ripped out during mounting:



If yes, re-clip and try to be smoother when sliding the drape over the C-arm the next time. Be sure to break the "Tear Here" stickers before sliding the drape.

- No C-arm clip has been entrapped in the image detector drape or tube drape, as shown on the following pictures. If so, there is a risk for the clips to be ripped out during extreme angulations of the C.

Image detector drape is correctly positioned, the poly tie is attached above the last clip.	Image detector drape is not correctly positioned, the poly tie is attached too low on the C-arm.
[1] Clip	[1] Clip
[2] Poly tie well positioned, above the last clip	[2] Poly tie badly positioned, below the last clip
	
The poly tie is attached above the last clip.	The poly tie should be attached above the last clip.
Tube drape is correctly positioned, last clip is outside the bag	Tube drape not correctly positioned, last clip is inside the bag
	
Clip is outside the tube drape.	Clip should be outside the tube drape.

Half drape

This drape is covering the entire image receptor assembly, and the upper half of the C-arm. The mounting instructions are identical to the image detector drape above 2. There is an additional poly tie to attach around the C-arm, at the end of the mounting.

This drape is to be used for procedures not requiring any C-arm movement. Pivot, swivel and detector movements are allowed.



NOTE

For surgical configurations where the system is brought very close to the table, additional generic drapes can be used to cover up non-protected gantry parts that are located in the sterile zone.



Draping of the IGS Control Center

If necessary, the IGS Control Center can be covered with sterile drapes.

Three steps are recommended for draping:

1. Cover it entirely with sterile cover.



2. To improve comfort of use, place elastic bands or strap below the controls.



3. Ensure that the controls can be rotated without pulling the sterile drapes.

3.7.5 Latex

There is no presence of latex in the system so no part in contact with the patient contains latex.

3.8 Protection regarding Functional Hazards

Although the system is designed to meet high reliability standards, there is a residual risk that the system or some of its features stop working during a procedure (recoverable or unrecoverable). Failure to follow or understand the instructions may also cause functional failures. Depending on the situation, this could compromise patient safety though delay in procedure, need to repeat contrast injection or X-ray, and device navigation errors.

3.8.1 3rd Party Software

WARNING



INSTALLING AND USING UNVALIDATED SOFTWARE MAY CAUSE SYSTEM TO FAIL OR NOT WORK AS INTENDED. SOFTWARE INSTALLATION TO BE DONE ONLY BY AUTHORIZED AND QUALIFIED PERSONNEL.

3.8.2 Loss of Imaging



WARNING

ESTABLISH PROCEDURES FOR HANDLING THE PATIENT IN CASE OF THE LOSS OF FLUOROSCOPIC IMAGING OR OTHER SYSTEM FUNCTIONS DURING AN EXAM. SOME FAILURES OF IMAGING MAY HOWEVER BE RECOVERED BY FOLLOWING THE PROCEDURE SET BELOW.

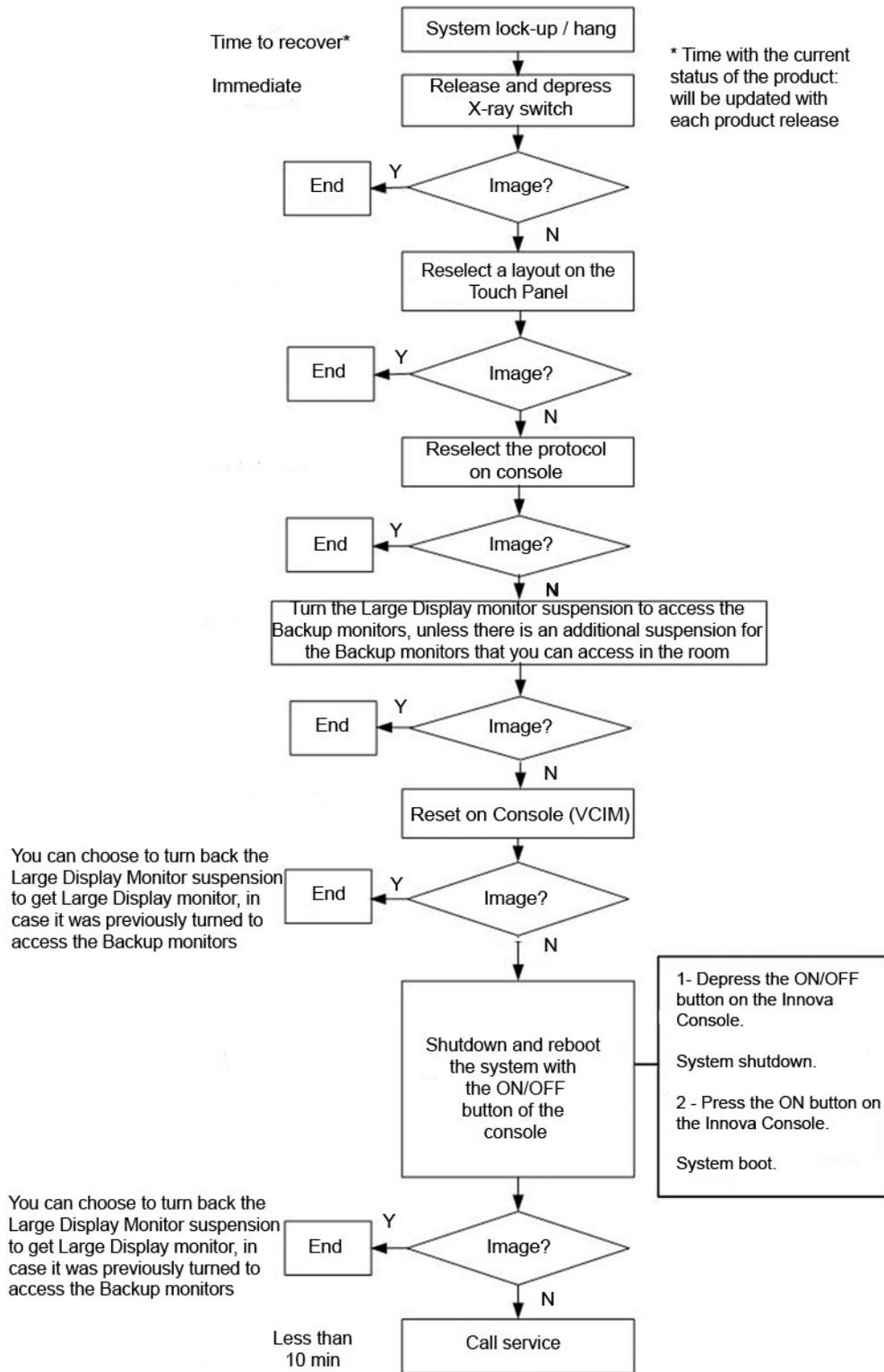
3.8.3 Emergency Procedure for Image Recovery or System Lock Up

In case of failures that are recoverable by pressing VCIM reset, the operator can recover the X-Ray fluoroscopy function and all interventional X-Ray functions in less than 3 minutes.

In case of system lock up or X-ray exposure sequence interruption, handle emergency or at risk procedures with precaution.

With Large display monitor

The large display option includes 2 backup monitors, that are located either behind the suspension or on an additional suspension, they provide the frontal live image and regulatory information to operate the IGS system in case the large display image is not available.



3.8.4 Loss of Credentials

In case of loss of login credentials, the IGS system provides unauthenticated Emergency Access mode that makes the clinical application available for clinical procedures without requiring user credentials. The Emergency Access mode is optional and may be enabled or disabled based on your site security policies (defined by your system administrator). Refer to [6.1.1.2 Emergency Access on page 159](#).

WARNING

LOSS OF LOGIN CREDENTIALS MAY RESULT IN PROHIBITED SYSTEM ACCESS FOR CLINICAL PROCEDURES, IN CASE OF EMERGENCY ACCESS MODE DISABLED ON THE SYSTEM. WHEN THE EMERGENCY ACCESS MODE IS DISABLED, MAKE SURE TO BE AWARE ABOUT THE OTHER SITE-SPECIFIC EMERGENCY ACCESS PROCEDURES, SET BY YOUR SYSTEM ADMINISTRATOR.

3.8.5 Loss of Supply Mains Power

The IGS system is provided with one UPS among:

- Mainstream UPS
- Fluoro UPS

The specificities of each configuration are listed below.

WARNING

THE INTERRUPTION OF THE MAIN POWER SUPPLY TO THE EQUIPMENT DURING ITS USE COULD LEAD TO IMAGING BEING NOT AVAILABLE. THE EQUIPMENT MAIN POWER SUPPLY MUST BE PROVIDED THROUGH AN UNINTERRUPTIBLE POWER SUPPLY (UPS) AT FACILITY LEVEL OR THROUGH A STAND-BY GENERATOR COMPLIANT WITH THE CLINICAL USE OF THE ROOM. REFER TO **24.1 SYSTEM LINE VOLTAGE ON PAGE 549** FOR THE CHARACTERISTICS OF THE INPUT LINE.

WARNING

THE AUTONOMY TIME IS GUARANTEED IF:

- THE BATTERY IS FULLY CHARGED.
- A REGULAR MAINTENANCE CHECK IS ENSURED BY PERIODIC PREVENTIVE MAINTENANCE. (REFER TO YOUR SERVICE CONTRACT).

If the system is unpowered for more than 3 months, recharge the UPS battery to prevent any battery damage and provide safe system operation.

**NOTE**

The Magnus Maquet OR Table has its own battery to fulfill the safety function.

In case of main power failure, the IGS system will automatically switch to UPS power when the system is ON. The message Powered with UPS will be displayed at the bottom of the live display. If the system is off, UPS does not allow to boot the system when the main power is lost.

While the system is running under UPS mode:

- When less than 3 minutes of UPS power are available, the following message is displayed: !!! 3 min estimated until shutdown. UPS is low. Secure patient.
- When less than 2 minutes of UPS power are available, the following message is displayed: !!! 2 min estimated until shutdown. UPS is low. Secure patient.
- When less than 1 minute of UPS power is available, the following message is displayed: !!! 1 min estimated until shutdown. UPS is low. Secure patient.

If the UPS reaches low battery level, the system automatically shuts down.

The UPS can report internal or external failure conditions to the system. The message !! Exam interruption risk if power is lost. UPS failure. Call Service (2.15) will then be displayed. This message will be cleared if the failure condition disappears. With the Fluoro UPS

only: if the operator presses the Mute button on the UPS, the message will also disappear though the error condition remains and will remain unnoticed until the next UPS automatic test. Contact GE HealthCare service when pressing the Mute button on the UPS.

For System with the mainstream UPS:

The mainstream UPS recharge time is at least 3 h for 90% of battery capacity and 48 h for a full charge.

Functions maintained in case of power supply main failure	System	With a stand-by generator	With a facility UPS
Preservation of stored images	Yes	Yes	Yes
Availability of imaging	No	Yes, up to 40 seconds after power recovery	Yes
Availability of equipment motion	Yes, until battery time is available	Yes	Yes

For System with the Fluoro UPS:

The autonomy may reach up to 5 minutes of fluoroscopy depending on the UPS battery level. The UPS recharge time is:

- Fluoro UPS "UL" (operating at 480 V and 60 Hz) at least 8 h for 90% of battery capacity and at least 10 h for a full charge.
- Fluoro UPS "CE" (operating at 380/400/415 V and 50/60 Hz) at least 8 h for 80% of battery capacity and 72 h for a full charge.

It allows to complete an exam in fluoroscopy mode.

Functions maintained in case of power supply main failure	System	With a stand-by generator	With a facility UPS
Preservation of stored images	Yes	Yes	Yes
Availability of fluoroscopy	Yes	Yes*	Yes
Availability of record	No	Yes, up to 10 seconds after power recovery	Yes
Availability of equipment motion	Yes	Yes	Yes

* In case of mains power supply recovery during fluoroscopy, the message `Power restored. Release fluoro for full functionality` is displayed. The system will switch back to normal mode only after the Fluoro pedal is released.

If the system does not recover full acquisition functionality after the main power returns, re-select the protocol in use and resume.

3.8.6 System Recovery after a power interruption

Refer to [6.3 System Power-up on page 164](#) for the description of the procedure to restart the system after the shutdown following a power interruption.

Power interruption may cause prohibition of the access to the last exam (error message: Database inconsistency). If this happens, call a GE HealthCare representative.

3.8.7 Latency and Polymerization Time

Latency is defined as the time lag between the operator action and the display of that action on the monitor. This lag varies depending on the acquisition frame rate:

- about 200 ms for frame rates over 15 fps.
- about 850 ms for frame rate of 1.9 fps.

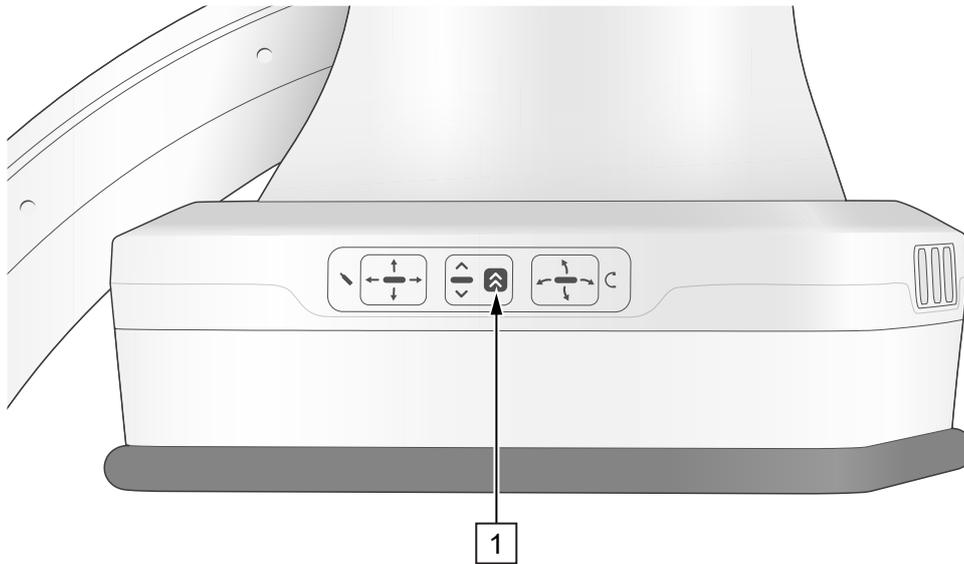
The operator should have this latency in mind when making a choice of embolic agents used during interventions in relationship to polymerization time.

There is a residual possibility of a frozen image being displayed on the live display if a failure occur during Fluoro or Record, although it has never been observed. In this case, the image will remain still, while the X-Ray on indicator is active, X-Ray acquisition in progress message is displayed, and the X-Ray on light remains on. Check that the live image is refreshed correctly during navigation and intervention.

3.8.8 SID Failure - Degraded mode

In case the system fails to determine the Source to Image Distance (SID), the following message is displayed on the in-room monitor:

SID failure. Collimation ON. To raise detector, use double arrow button



If this message appears on the in-room monitor, the user has to move the detector towards its highest position in using the **emergency back-out** button [1] placed on the detector as shown above. X-Rays are available even if the error message is shown, applied X-Ray parameters ensure minimal dose to the user and the patient.

3.8.9 Prevent Unnecessary Interruption of a Procedure Arising from a Collision



NOTE

Different measures have been implemented to prevent unnecessary interruption of a procedure arising from a collision and should not be mis-interpreted as system failures. At obstacle approach:

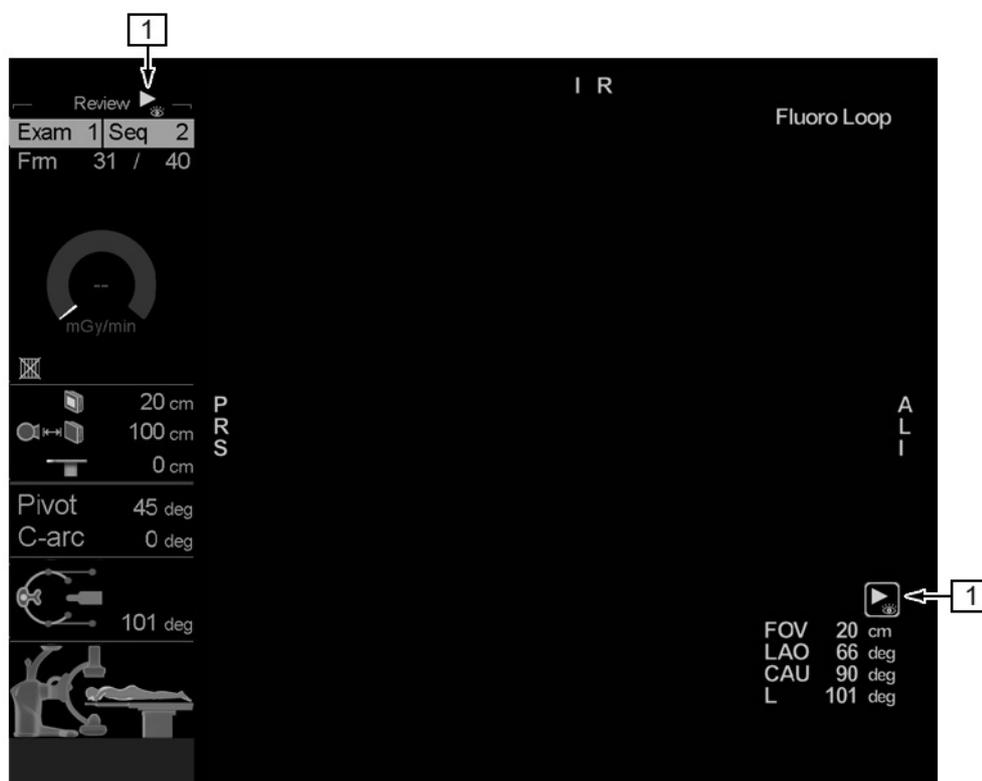
- The gantry slows down (half speed).
- Warning icons are displayed on live display.
- An optional audible signal warns the operator of an imminent close collision.

3.8.10 Image Orientation

The Image Orientation does not automatically follow the patient position on the table top (Prone, Supine, Feet first...). It is the responsibility of the Operator to control the patient orientation on the image. Failure to control may lead to misinterpretation of the image displayed for diagnostic purposes.

3.8.11 Risk of confusion between live Fluoro images and automatic replay of stored Fluoro images

The operator's attention is drawn to a potential misinterpretation between live fluoro images and replay of fluorostore images. When the operator who depresses the fluoro pedal (exposure) is different from the operator performing the intervention, there is a risk this operator undertakes an interventional gesture on the mistaken assumption that a currently displayed image is live while it is actually a fluoro review image. Always ensure the review pictograms [1] are not displayed, prior to undertaking an interventional gesture.



3.8.12 Misregistration in blended roadmap

Fluoro roadmapping is used to navigate devices under subtracted fluoroscopy, while having the vessel anatomy visible as an overlay to help for device guidance. Blended Roadmap is a feature used for creating a roadmap of the vessel anatomy from a previously acquired acquisition (a DSA, a Bolus or a subtracted 3D CT) avoiding the need to inject contrast during fluoro.

There is a residual risk that a misregistration between the vessel anatomy and the underlying subtracted fluoroscopy is unnoticed, in case the operator does not assess the position of the devices compared to the vessels, or fails to assess it correctly which could lead to a device navigation error.

3.8.13 Comfort accessories for Innova^{IQ} Table

CAUTION

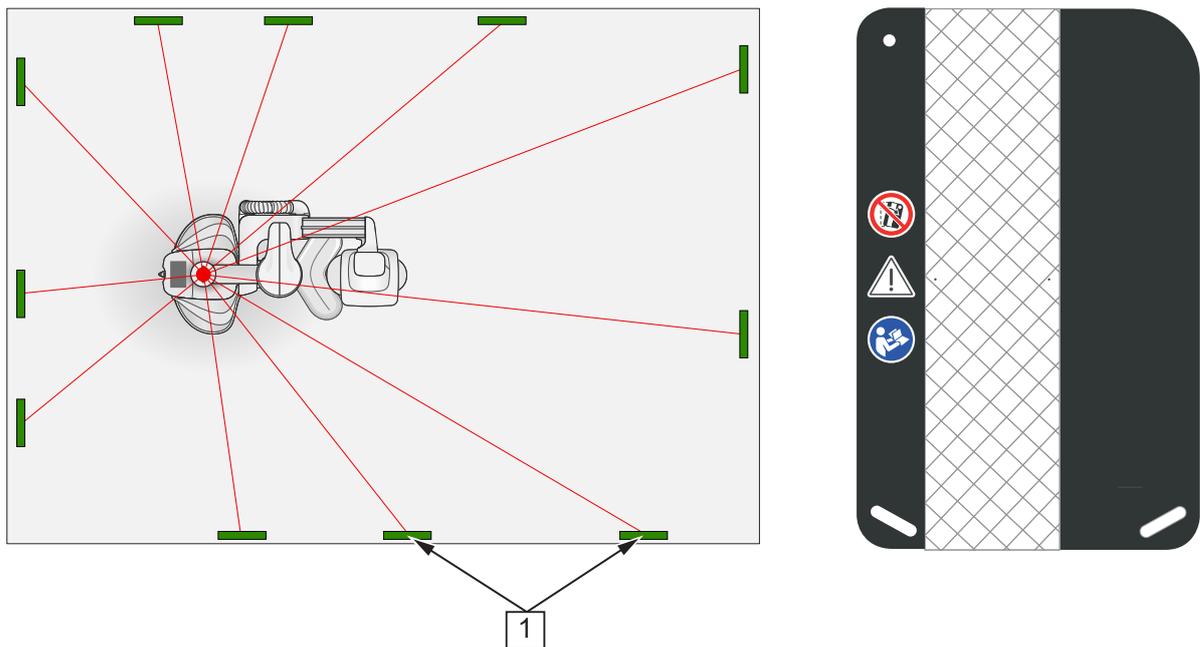


Some parts of the comfort accessories are not radiolucent and may cause image quality artifacts that require distinguishing them from anatomical structures.

3.8.14 Localization failure and recovery modes for Allia IGS 7 and Allia IGS 7 OR

The Advanced Guided Vehicle (AGV) uses an optical-based localization system and fixed reflectors positioned in the room to determine its position in the exam room. At positions where positioning accuracy is required, the localization system requires 5 or more visible reflectors and a consistent reflectors arrangement.

Since the room may be equipped with other medical devices obscuring the laser’s view, not all reflectors are detected during the vehicle’s motions. Also, highly reflective objects can create interference reflections. Examples of such reflective objects are windows, metallic tubes or contrasted surfaces. Obscured reflectors and interference reflections can both lead to localization issues.



Item	Description
[1]	Reflectors



NOTE

Do not hide the reflectors. This could result in system localization failure and loss of gantry movements.