O-arm® Imaging System Supplemental Guide

Indications for Use

The O-arm® Imaging System is a mobile X-ray system designed for 2D fluoroscopic use and 3D imaging and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high X-ray attenuation such as bony anatomy and metallic objects. The O-arm® Imaging System is compatible with certain Image Guided Surgery Systems.

⚠️

DISCLAIMER: Users should be familiar with the User Manual prior to operating the O-arm Imaging System. Please refer to the O-arm User Manual (BI-500-00142) for warnings and precautions related to the safe use of the system.

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Setup/Storage

Bring in, Set Up System

1. Turn on the O-arm® System (turn ignition style switch ① to right, then release).

2. Drive O-arm System to surgical suite.
Note: While driving the system, be careful not to contact doors, other equipment or people. Make sure that it does not run over cables on the floor - its weight can crush them.

3. Move the Mobile Viewing Station (MVS) into the surgical suite, and plug it into a power outlet.

4. Plug the interconnect cable from the MVS into the O-arm System. Do not twist it.
Note: Line up the red dot on the cable end ③ with the red dot on the cable port ④.
Note: Make sure the battery charge indicators ② on the O-arm System power panel are scrolling. If they are not, check the cable connection and line power to the MVS.

5. Turn on the MVS.

6. If you are using the O-arm System with surgical navigation, connect the network cable between the MVS and the network port on the StealthStation® System.

***Figure 1.** O-arm System control panel*

***Figure 2.** Plugging in the Interconnect Cable*

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Shutting Down and Storing the System

1. When the O-arm® System is no longer needed in the procedure, open the gantry door completely and prepare to move the system away from the table.

   LOOK to make sure the paths of the O-arm System and the gantry are clear of any cables, tubes, wires, bars, booms, equipment, personnel and patient drapes before you move the system away from the table (key area of concern is clearance under the table).

2. Disconnect the cable between the MVS and O-arm System. Wrap it around post of MVS.

3. Dock the O-arm gantry (always put it in docked position before you transport or store it).

   ☞ To dock the gantry, PUSH AND HOLD the Dock button ① on the Pendant, until the docking pins beneath the gantry settle into the corresponding holes in the platform.

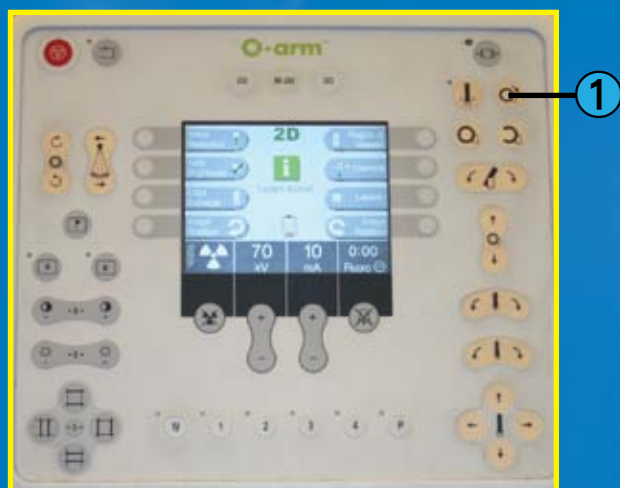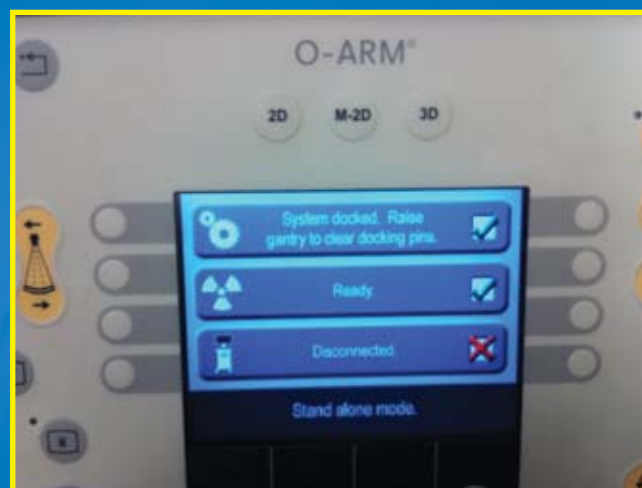**Figure 3.** *Pendant display when MVS plugged in*

Figure 4. *Pendant display when MVS NOT plugged in*

4. Turn off the MVS.

5. Disconnect the MVS from the power outlet.

6. Move the O-arm System and MVS to their storage location.

7. Once you've reached the storage location, plug the MVS into a power outlet, and re-connect the interconnect cable between the MVS and O-arm System.

   Verify that O-arm System is charging (battery indicator lights scrolling).

8. Turn off the O-arm System.

Cleaning the System

- To clean the system cover panels and cables, wipe them with a cloth dampened with a suitable disinfectant.

- Avoid use of phenol-based, corrosive or solvent disinfectant agents that may harm system surfaces. If you are not sure of the properties of a disinfectant agent, do not use it.

- Be careful not to drip or splash any liquid into the interior of the system.

O-arm® Imaging System Supplemental Guide

Entering Exam Information/
O-arm® Positioning

Entering Exam Data

Once the system powers on, the *Exam Information* page opens on the MVS console. If it is not open, press **<ESC>** on the keyboard to open it.

Entering Data Before a Session

- Enter data in as few or as many of the fields as you wish. You do not have to fill in any data to start an imaging session. Imaging sessions started without any exam data entered are saved by their date and time stamp.

- Use the touch pad to move the cursor, or use the **<Tab>** key on your keyboard to move between fields.

- When you have entered all the data you want, click **[Accept]** to start the imaging session, or **[New]** to save the data to the *Scheduled Exam* list.

Finding and Editing Patient Data for Completed Sessions

- Completed imaging sessions are saved under *Saved Exams*, most recent exam listed first.

- Imaging sessions started without any exam data entered can be identified by their date and time stamp.

- You can edit the exam information for a patient by opening their session under *Saved Exams*, and clicking **[Edit]**.

Opening Data for Scheduled Sessions

- To open patient exam info for a scheduled exam (data saved or imported earlier), find the patient's name in the list under *Scheduled Exams*. Double click on the patient's name to open it in the *Exam Information* screen and press **[Accept]** to start the imaging session.

Figure 5. *Exam Information Page*

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Positioning the O-arm® System and Gantry

For storage and transport, the gantry should be in the docked position.

Note: for all pendant controls except Lift and Shift, you must press and hold the button until the gantry has completed the entire desired range of motion.

1. Press and hold the Up arrow on the up/down control ① to undock the gantry.

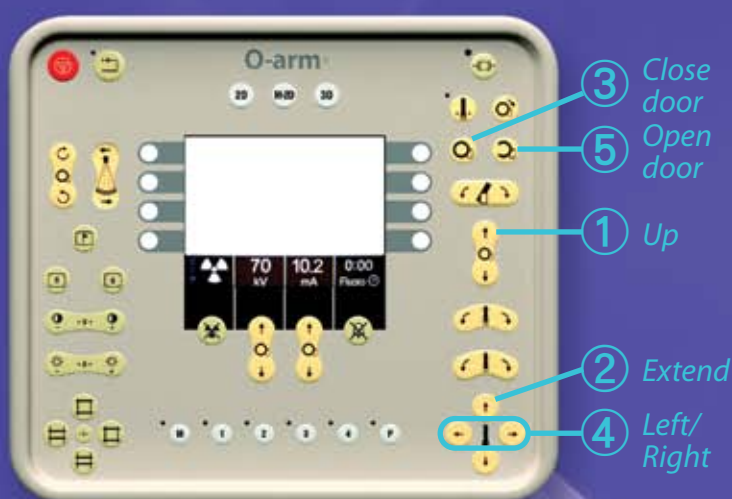   No other positioning button will function until the system is undocked.

***Figure 6.** Pendant controls for initial positioning*

2. Extend the gantry ② away from the cabinet until you can see the pinch hazard labels on the side.

   Note: Do not extend it completely. Leave a margin of about 4 inches in case you need to extend it further once it is around the table.

3. Open the gantry door ⑤.

   If you are going to drape the gantry, do so now (See Draping the Gantry).

   If you are going to leave the gantry around the table during the procedure, and want to set a park position, offset the gantry to the side opposite where you will park it (left/right - ④).

4. Drive the system forward to bring it around the table.

   LOOK carefully as the O-arm System is brought around the table. Other OR personnel should watch and assist to make sure that the system does not contact the patient, table, booms, drapes, tubes, etc. as you bring it into place.

5. Once the gantry is around the table and patient, close the gantry door ③ (finish the draping procedure as you do so, if you are using the tube drape). Have others watch and assist to make sure that the door closes without contacting or pinching anything.

Gantry Motion Ranges

Motion	Range
Up/Down *Note: Maximum "down" range only reachable when gantry extended beyond base.*	18" total range
Left/Right	±7° in either direction
In/Out	18° away from cabinet
Tilt	±45° around center axis
IsoWag® Motion	±12°
Wag	±15°

O-arm® Imaging System Supplemental Guide

Installing the Tube Drape
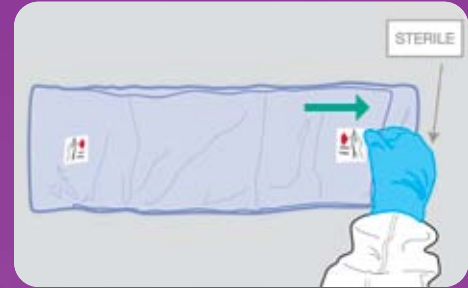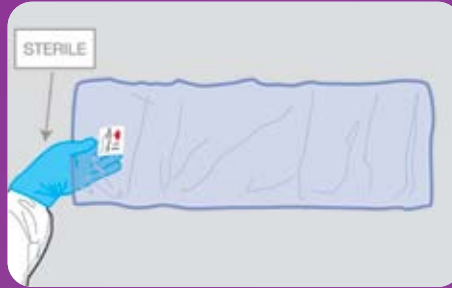
The Tube drape is part number 9732722. Check the revision number on the package and follow the instructions that apply. Before you begin, open the door of the gantry.

1. Remove the drape from the sterile pack and place it on a sterile table with the left hand label up and facing you.

2. Grip the drape under the fold beneath the Left-hand label with your left hand and unfold it to the left, and then grip the drape under the Right-hand label fold with your right hand and unfold it to the right.
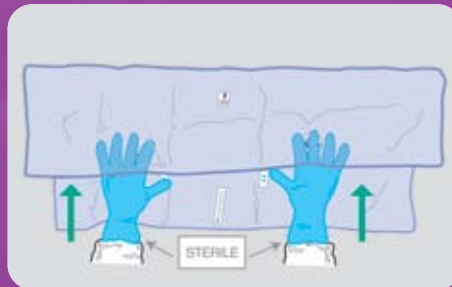

3. Unfold the top fold of the drape toward you.

4. Following the hand indicators, put your hands into the drape main fold.

5. Raise your hands and lift the drape up, allowing the drape to hang open in front of you.
Note: for best results, don't grip the drape; just tilt your fingertips up as you lift.

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Installing the Tube Drape, continued

6. Walk to the opening of the gantry and hold the drape so that the opening aligns with the upper part of the gantry.

7. A non-sterile assistant takes ahold of the drape at a "GRIP HERE" tab on one side of the gantry, and pulls the drape over the top of the gantry to the positioner, following the "THIS END OVER UNIT" indicator. It helps if another non-sterile assistant does this at the same time on the other side.
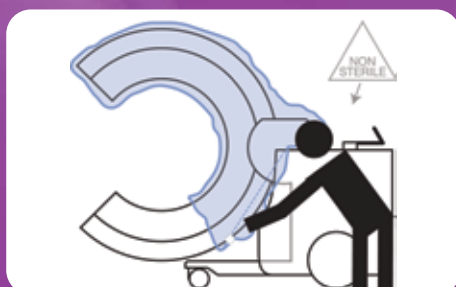
8. At the positioner end of the gantry, there is a piece of tape with backing. The non-sterile assistant removes the tape backing and applies the tape to the positioner, near the top.

9. If the side folds of the drape are held up by tabs, break the tabs and let the drape hang down. There are also pieces of tape on the bottom of the side folds that can be used to attach the drape to the underside of the gantry.

10. Have the operator position the gantry over the patient.

11. (Sterile) Break the perforation between the green arrows on the two (2) door tear tabs, and gently shake the drape folds out.

12. Have the O-arm® operator start to close the gantry door, while the sterile person holds the drape so that it hangs down just below the closing door. *Note: as the door closes, communicate with the operator to stop closing it at any time that there is danger of the drape snagging or tearing.*

13. As the door reaches the bottom part of the gantry, a non-sterile assistant makes sure that the drape opening fits around the lower portion of the gantry, and is kept clear of the door as the door closes.

Installing the Tube Drape, continued
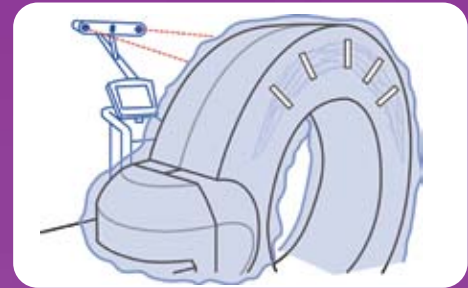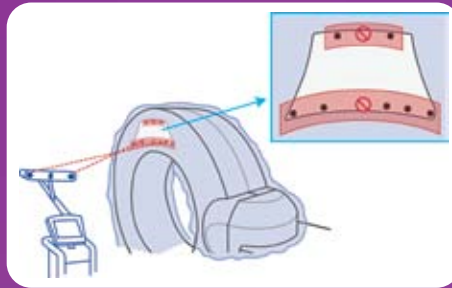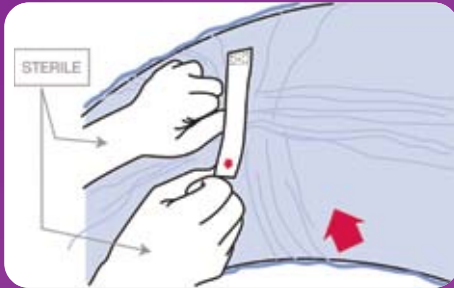
14. The sterile person now tapes up the drape slack. If you are using the O-arm system with a StealthStation® navigation system, do this on the side of the gantry **opposite** to where the StealthStation camera will be positioned during imaging.

To tape up the slack, break the perforation between the green arrows on the poly ties, remove the tape backing near the bottom of each tie, and use the tape to cinch up the excess drape.

Removing the Tube Drape
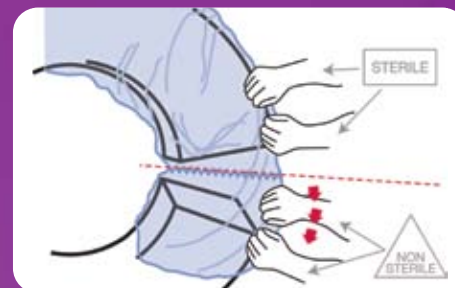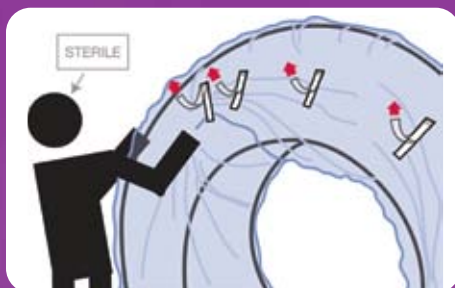
1. (Sterile person) Release the poly ties that are holding up the drape slack.

2. At the door end of the gantry is a "TEAR AWAY AFTER USE" sticker that indicates a fine perforation in the drape. The sterile person holds the drape above the perforation, to keep it in place while the gantry door opens. Once the gantry door is fully open, a non-sterile person tugs downward to tear at the end.
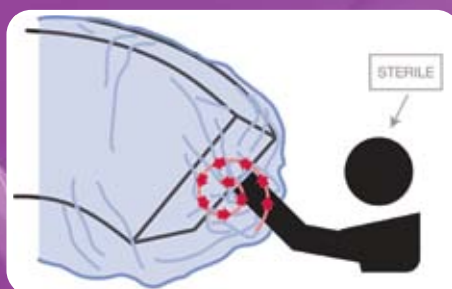
3. Sterile person rolls up the upper portion of the drape while taking care not to contact the contaminated drape interior. Tip: Putting on a second pair of gloves before doing this reduces chance of contamination, and allows you to use the removed outer glove to secure the rolled-up drape.

4. Stuff the rolled drape into the opening in the top of the gantry door.

5. Have the operator remove the O-arm® System from the sterile field.

6. Once the system is clear of the sterile field, remove the tape on the rear cabinet and pull the drape off of the gantry.

2D/3D Image Acquisition

Taking 2D Images

For each 2D shot, to maximize image area, increase sharpness, and reduce radiation dose to the patient, position the gantry so that the patient is as far as possible from the X-ray tube.

Note: The short set of LEDs in the gantry light ring denotes the position of the X-ray tube, the long set of LEDs denotes the position of the detector.

1. Use the Pendant buttons to position the gantry around the patient so that the patient is as far as possible from the X-ray tube, for each shot angle.

2. Make sure the system is in 2D mode (press 2D button at top of Pendant).

3. Set pendant control "Auto Brightness Control" ON whenever possible.

4. To take the image, press 👁 on the hand switch or foot switch to take a standard shot, or 👁+ for a high-definition (boost) shot, if the anatomy is particularly dense.

    Note: high-definition fluoro (boost) is a higher radiation dose. Always consider patient radiation exposure before increasing dose.

    Make a long enough exposure to allow the auto brightness feature to stabilize. Watch your image on the MVS and terminate exposure when an acceptable image is displayed.

5. Make any adjustments necessary to achieve desirable image quality (see page 11 for "Tips to Improve 2D Image Quality").
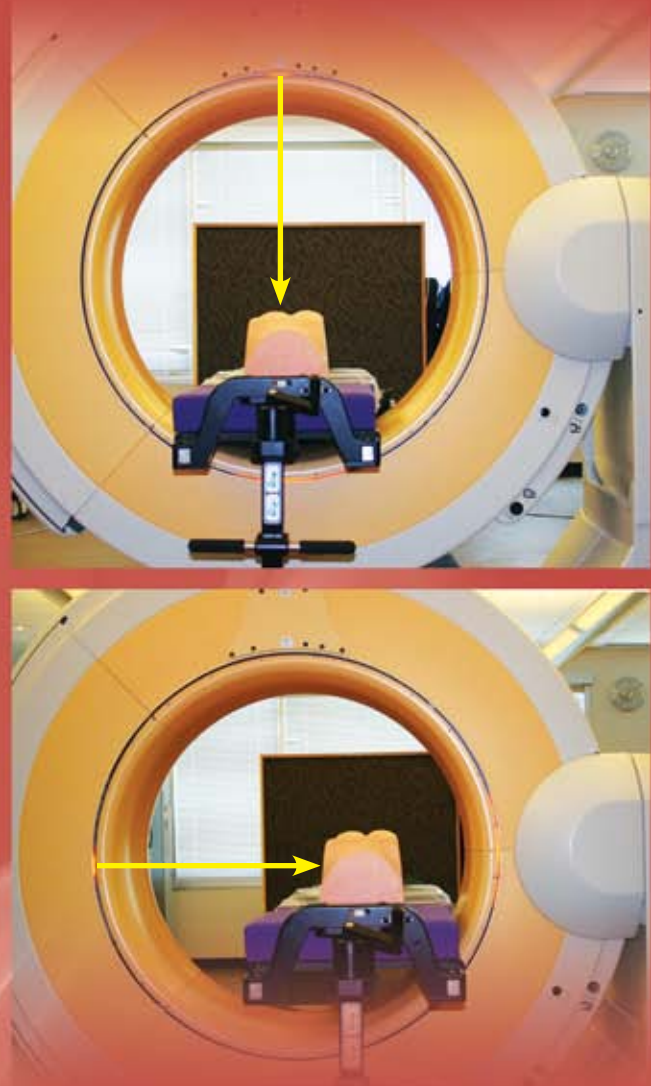

Figure 7. *Positioning for a PA shot (top) or a lateral shot (bottom)*

2D/3D Image Acquisition

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Taking 3D Images

Figure 8.
3D mode
softkeys

1. Put the system in 3D mode (Press 3D button ① at top of Pendant).

2. Select each of the following to match the intended imaging, using the Pendant Softkeys (Figure 8):

   ✣ Patient Orientation (L/R, Prone/Supine)

   ✣ Anatomy Imaged (head, thorax, abdomen and extremity)

   ✣ Patient Thickness (S, M, L, XL)

   ✣ Dose (Standard or HD3D - high definition) -

   Note: always consider ALARA principles before increasing dose.

   Note: You can further adjust kV and mA as needed to get optimal image quality.

3. Position the gantry so that the patient is isocenter (see Figure 9).

4. Doing the following, if appropriate, can improve 3D image quality:

   ✣ Using a carbon-fiber (non-metal) surgical table

   ✣ Removing all unnecessary metal (leads, wires, instruments) from the surgical field

   ✣ In spine procedures, performing the 3D scan before rods are inserted (reduces metal artifact)

   ✣ Filling the surgical opening with saline solution prior to initiating a 3D exposure.

   ✣ Pausing patient respiration during the time of image acquisition (about 20 seconds for standard exposure)

5. If the 3D image is to be used for surgical navigation, check now that:

   ✣ The O-arm® MVS is connected to the StealthStation® System and the systems are communicating (green check mark on Pendant)

   ✣ The StealthStation software is on the Acquire Scans screen, and the status bar is green

   ✣ The StealthStation System camera can see the reference frame on the patient and the O-arm tracker

6. Make sure all personnel are positioned outside the room to minimize radiation exposure, or are using lead protective gear, before you initiate 3D image acquisition (see Figure 17).

7. Press AND HOLD the 👁━ button/pedal on the hand switch or foot switch.

   KEEP HOLDING THE BUTTON/PEDAL for the complete duration of the spin, until the exposure is complete and you no longer hear audible beeping.
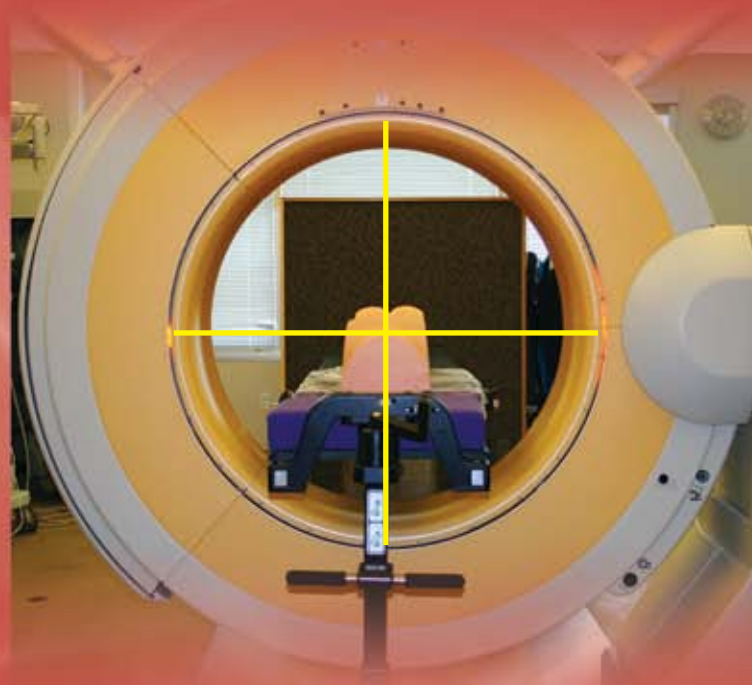

Figure 9. *For 3D Images, patient anatomy should be isocenter in the gantry*

Imaging Tips and Tricks

Tips to Improve 2D Image Quality

- With Auto Brightness ② ON, you can improve contrast by using the "Region of Interest" softkey ① to select an area (dashed green line) inside the image on which automatic brightness and gray scale will be based.

  Note: Each successive press of the ROI softkey reduces the size of a green frame within the image. Once ROI reaches its smallest size, pressing the ROI softkey again restores it to full size.

- If a patient has poor bone density, you can improve contrast by disabling Auto Brightness ② and using the up/down arrows on the kV softkey ③ to control technique manually. The mA settings track the kV settings automatically.

- Adjust contrast and brightness of an image using the contrast and brightness buttons ④.

- Collimate as appropriate, using the collimation buttons ⑤. The center button resets the aperture to fully open.

  Note: Please be aware that the settings for collimation using 2D memory preset #4 will translate to your 3D Spin.
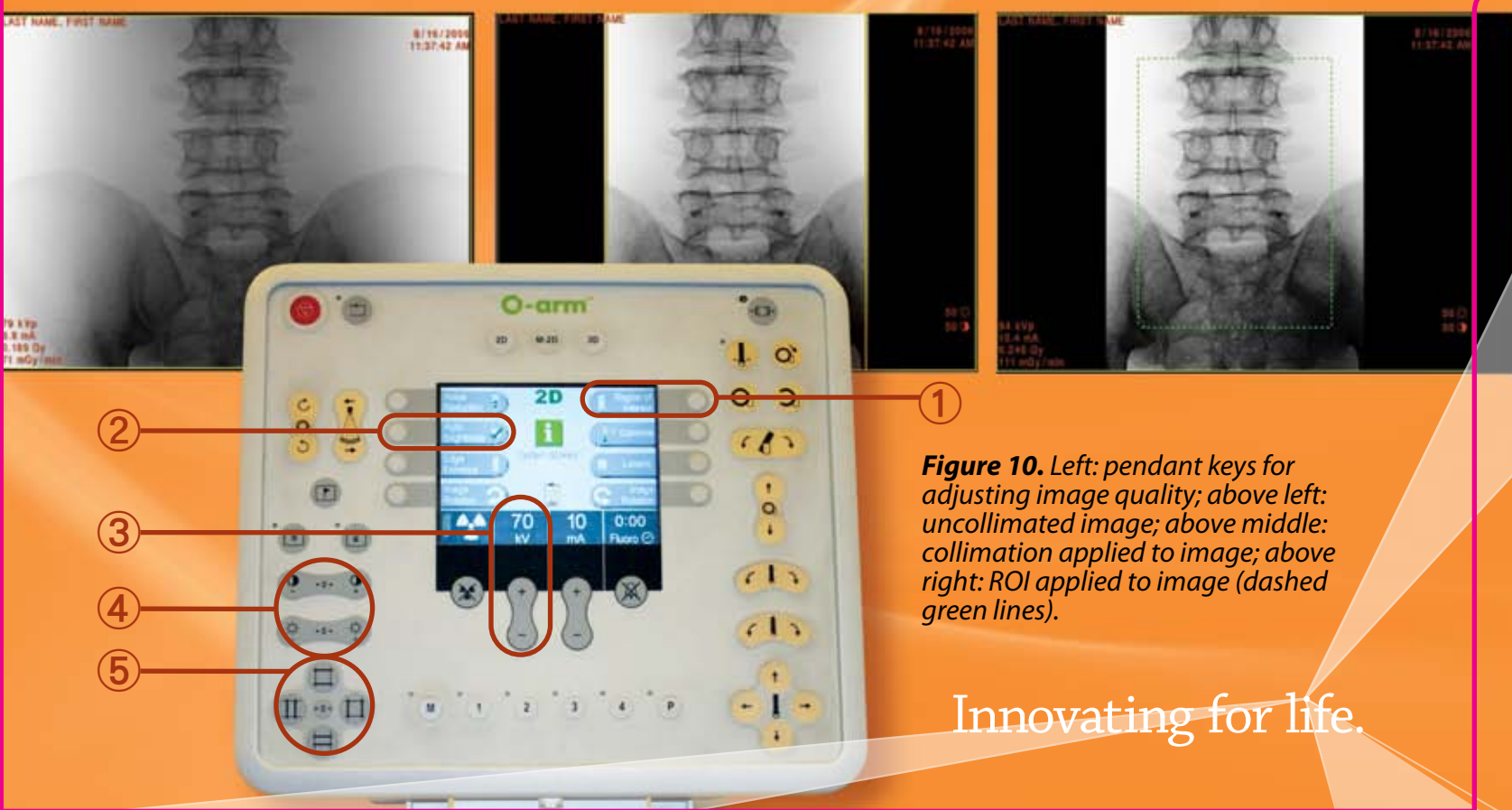

Figure 10. *Left: pendant keys for adjusting image quality; above left: uncollimated image; above middle: collimation applied to image; above right: ROI applied to image (dashed green lines).*

Imaging
Tips and Tricks

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Troubleshooting - Taking Images

Unable to get a 2D image

1. Are you in 2D mode?
    If not, select 2D button ① at top of Pendant.

2. Did you press the 👁 or 👁+ button on the hand or footswitch?
    This is how you activate imaging.

3. Is the Emergency Stop button ② activated?
    If so, press the RESET button ③.

4. Has the X-ray On/Off button ④ been pressed?
    If so, press it again to restore X-ray function.

2D Image Not Penetrated (No detail or anatomical definition)

-   Hold 👁 hand switch button down for longer exposure.

-   If that doesn't work, take shot again using boost button. 👁+

2D Image Overexposed (too bright)

-   Once AutoBrightness is off, decrease kVp or mA to desired brightness.

-   Decrease brightness control on pendant.

2D Image is Grainy

1. Activate X-ray (hand switch or foot switch button) long enough for a good exposure.

2. Use collimation and adjust ROI (see page 11).

3. Adjust Noise Reduction softkey as needed to reach desired smoothness.

3D Image is Grainy

1. Make sure size and anatomy selections match patient size and anatomy.

2. Increase mA until desired image quality achieved.

3. Use HD acquisition as appropriate, adjusting mAs to match standard scan technique.

Anatomy cut off in image

1. Open collimation to see anatomy.

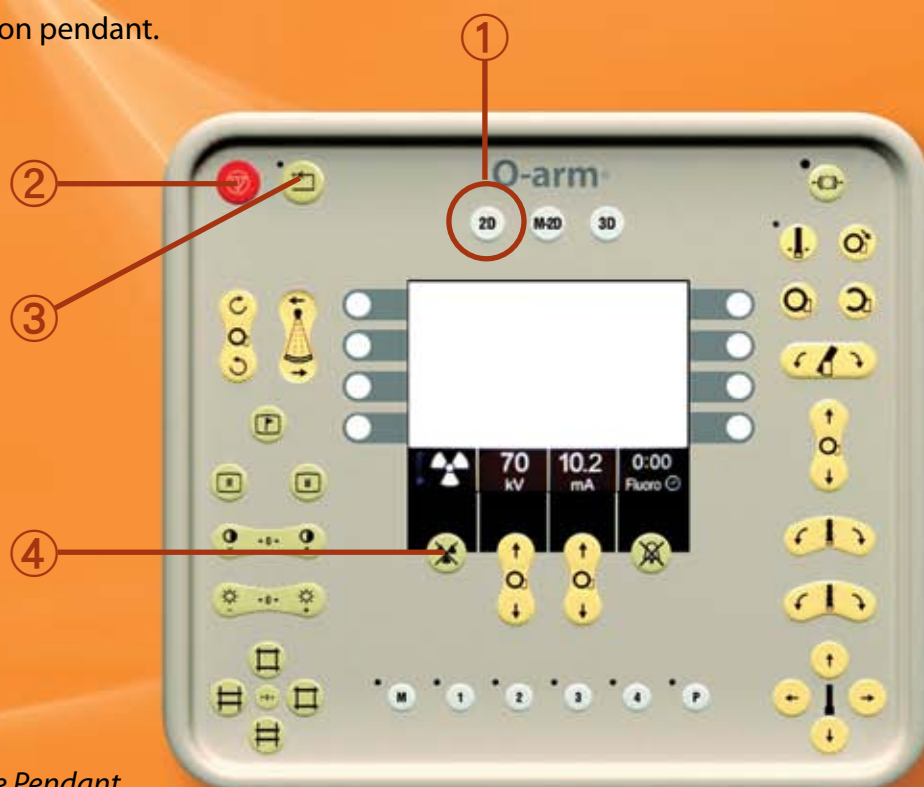2. Reposition anatomy to the center of the imaging panel.

Figure 11. *The Pendant*

Manipulating 3D Reconstructions

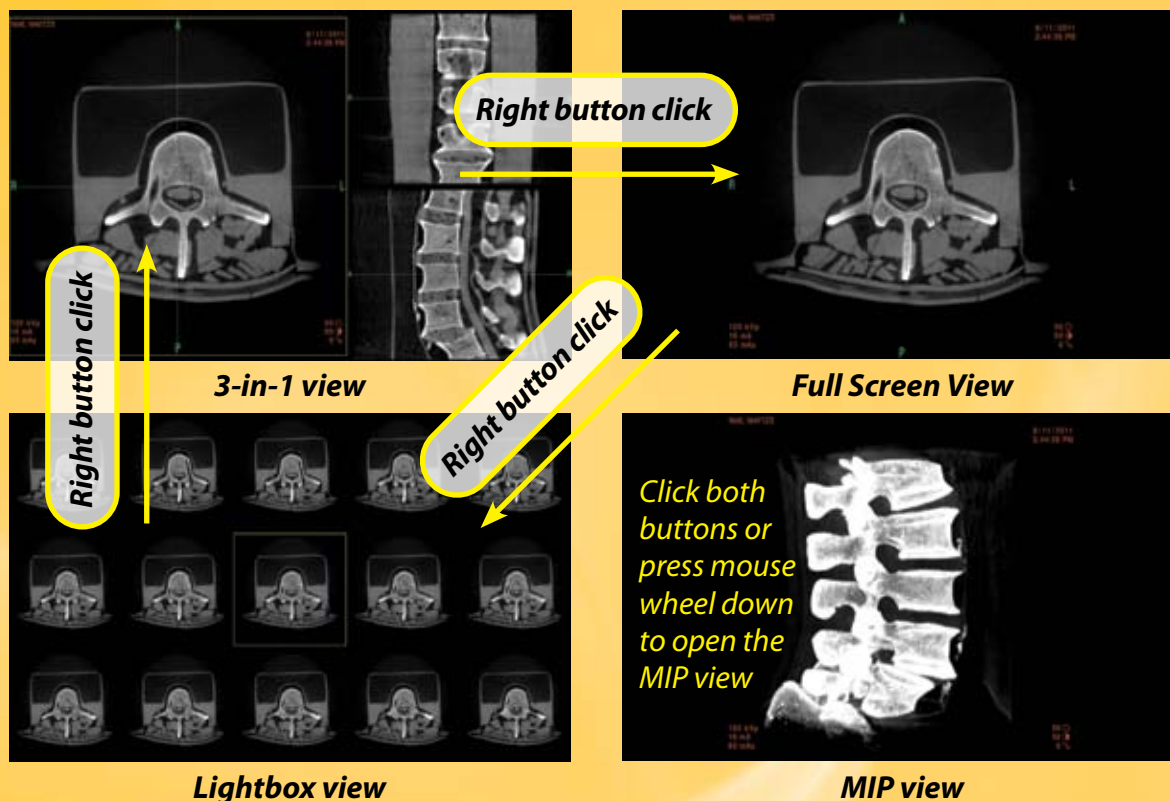To manipulate a 3D image set, you can use either the wireless mouse or the keyboard touchpad.

Right button click

Right button click

Right button click

3-in-1 view

Full Screen View

Click both buttons or press mouse wheel down to open the MIP view

Lightbox view

MIP view

Figure 12.
Manipulating 3D image sets

Desired Action	Mouse or Touch Pad action
To shift the active pane (yellow frame) through the images (axial, coronal, sagittal)	Press the left button on the mouse or keyboard touch pad
To scroll through the images	Turn the mouse wheel or press the up/down buttons on the keyboard
To cycle the image display between: • default 3-in-1 • full-screen display of the active image • lightbox presentation	Press the right button on the mouse or keyboard touch pad
To switch to MIP view	Press both left and right buttons together
With the MIP view displayed: To rotate the MIP view around the selected axis... To toggle the rotational axis between vertical and horizontal...	With the MIP view displayed: ...Press the right or left arrow on the keyboard or turn the mouse wheel ...Press the left touchpad or mouse button

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Viewing 3D Images Using Oblique Slicing (optional feature)

To view slices at an oblique angle through the 3D reconstruction, use the left/right arrow keys ① on the MVS keyboard. This changes the "slice" planes represented by crosshairs in the active image.

Use the left or right arrow key to rotate the crosshairs in the active image clockwise or counter clockwise. The slice images in the other views adjust to show cross-sections based on the crosshair angle you selected. The adjustment angle is limited to ±45°.

To reset the image to the original oblique slice, press the zero key ② on the alpha keypad (0).

Figure 13. *MVS Keyboard*

② *Zero Key On The Alpha Keypad*

① *left/right arrow keys*

Figure 14. *3D Oblique Slicing Image*

Archiving

Reviewing, Archiving and Deleting Patient Studies

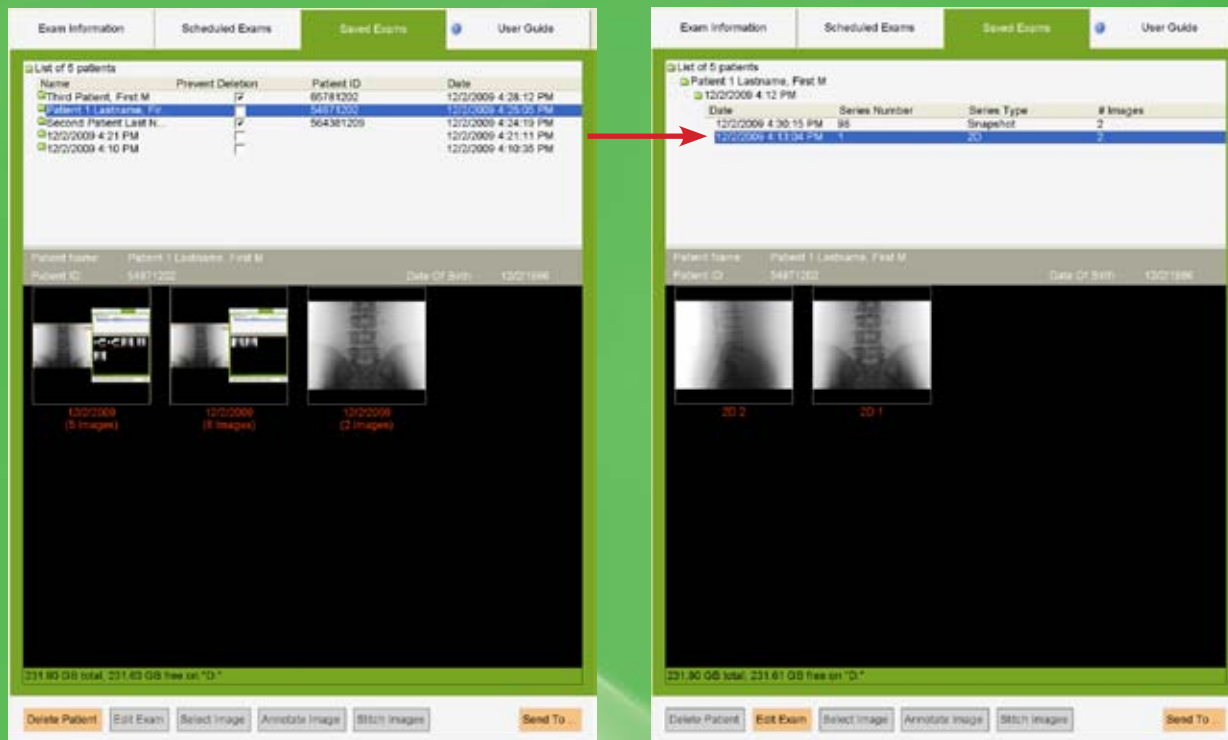Completed imaging sessions are stored on the Saved Exams page.

Figure 15. *Opening a patient exam and session in Saved Exams*

To open images from a session to view on the MVS:

1. Double click on the patient's name, then double click on the imaging session.

2. Find the image set in the preview area and double click to open it.

• A 3D set loads and opens in a 3-in-1 view in the MVS monitor (See pages 13 and 14).

• A 2D image or snapshot opens as a preview in the left-hand pane of the MVS monitor.

   ☞ To open the Annotation Editor to annotate 2D images, stitched 2D images, or snapshots, press **<A>** on the keyboard.

   ☞ To stitch up to nine (9) 2D images together, select them all in the imaging session (Press and hold **<Ctrl>** + click on each image), and then press **<Stitch Image>** to open the first screen for image stitching. <u>For further information on stitching images, refer to the O-arm® User Guide.</u>

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To archive patient data:

1. Insert your external media or connect to the network or system to which you are exporting images.

2. On the Saved Exams page, select an entire patient record, an imaging session, or an image set. You can also click on the thumbnail for a Dose Report, to save it.

3. Click [Send To].

4. In the dialog that opens, select the radio button for the export media/device. To save the data to a CD or DVD, select **CD-ROM**; to save it to a USB drive, select **Removable Storage Device**.

5. Under Options, select either **Send Patient Images**, **Send Snapshots** or both.
    Note: You cannot export snapshots across a network.
    If you do not want patient information to appear on the transferred images, select [Anonymize].

6. Click [Send]. A popup indicates the progress of the transfer.

To delete patient data:

1. Select the patient's name in the Saved Exams page.

2. Highlight the exam to delete.

3. If the Prevent Deletion box is checked for that exam, un-check it.
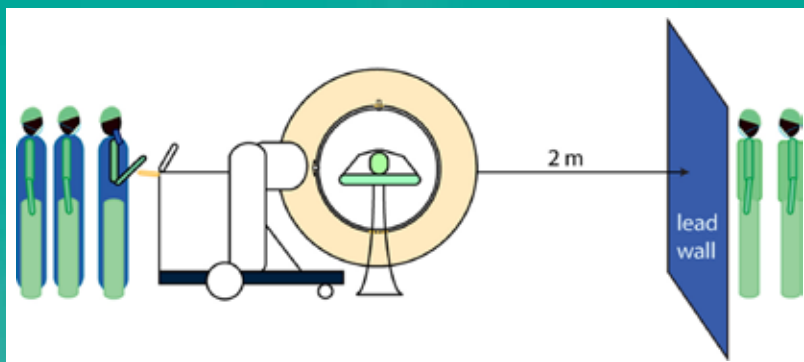
4. Click [Delete Patient].

Figure 16.
The "Send To" dialog to export data
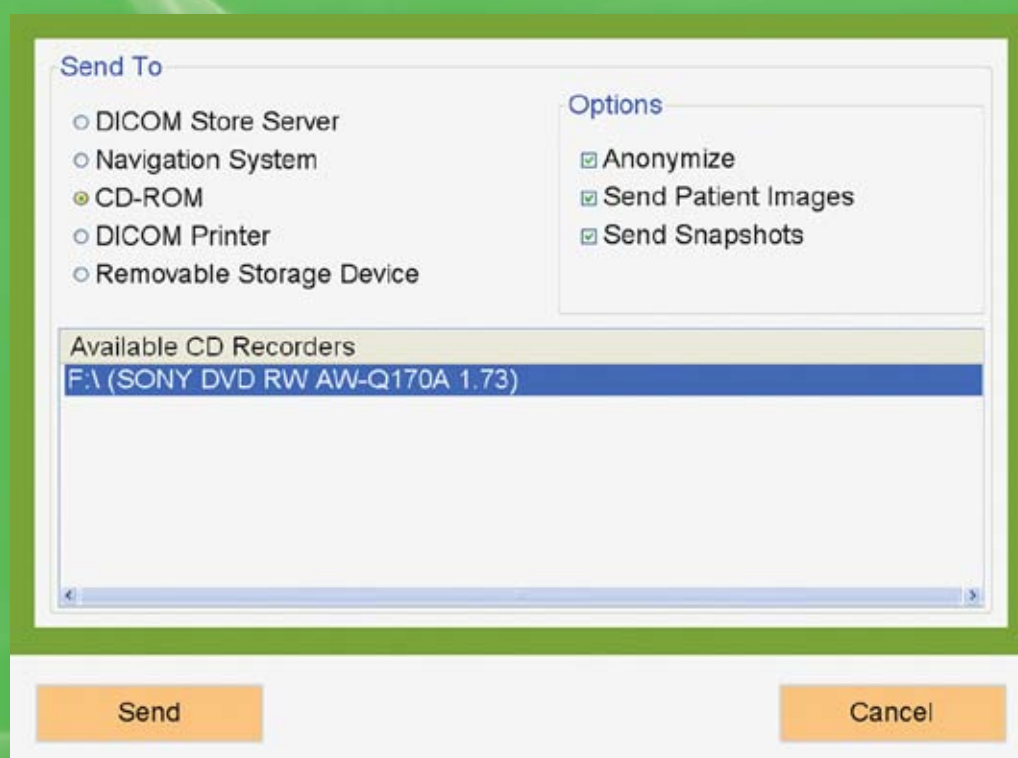
Radiation Safety / Emergency Procedures

Radiation Safety - Personnel Positioning

Figure 17. *During 3D spin acquisition, personnel who remain in the room should be at either end of the gantry, two (2) meters away, and protected by a barrier of not less than 0.5mm of lead.*

Radiation Safety - Patient Dose

When imaging with the O-arm® System, always follow ALARA guidelines for patient radiation exposure. ALARA = As Low As Reasonably Achievable

- Reduce exposure time whenever possible
- Position the patient for lowest exposure with highest image quality (see page 9)
- Use the lowest exposure dose that gives adequate image quality:

Radiation Dose Reports

To view the current dose report:

1. Open the Exam Info page.

2. Click on **[Dose...]**. The current dose report opens in the left-hand window.

   ☞ To save the report to the exam database and close it, click **[Save and Close]**.

   ☞ To close it without saving, click **[Close]**.

   Note: The system saves an image of the current report to the exam database.
   If the report changes, save it again to have a copy with the latest data;
   it does not automatically update.

Fluoro Dose

Mode of Op	Exposure Time (sec)	Exposure (mGy)	DAP (mGy cm2)
Fluoro	32.01	13.01	2917.28
High Level Fluoro	13.09	3.64	816.37
Total	45.11	16.65	3733.65

3D Dose

ID	kVp	mAs	CTDI (mGy)	DLP (mGy cm)	Phantom (cm)
3D #1	120.00	93.75	11.91	190.42	Head 16
3D #2	120.00	195.50	14.08	225.13	Body 32
Total				415.55	

Figure 18. *Sample dose report*

Radiation Safety / Emergency Procedures

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Emergency Procedures

Emergency Stop and Emergency Stop Reset

There are two Emergency Stop buttons: One on the O-arm® System control panel ①, the other on the Pendant ②.

- When pressed, these do NOT shut off the entire system; they only stop battery-driven motions and X-ray imaging functions.

- They may be used either in an emergency, if the system were to act in an unexpected way, or they may be used as a fail-safe to prevent unintended actuation of the drive wheels or the X-ray functions.

- To return the system to full functionality after pressing Emergency Stop, press the Emergency Stop Reset button ③.

Emergency Gantry Door Opening

If the gantry door does not open upon pressing the Door Open button on the pendant ④, first try the electronic override; if the door remains stuck, try the manual override.

Electronic Override

Locate the yellow Door Override button ⑤ on the side of the gantry (right side if gantry viewed from cabinet end).

Press the yellow door override button AND the door open button ④ on the pendant simultaneously.

Note: you can swing the Pendant around on its pivot (as shown in image below), to allow you to reach both buttons at the same time.

Manual Override

Step by step directions on opening the gantry door are in the right-side pocket of the MVS, attached to the T-shaped Rotor Alignment Pin.

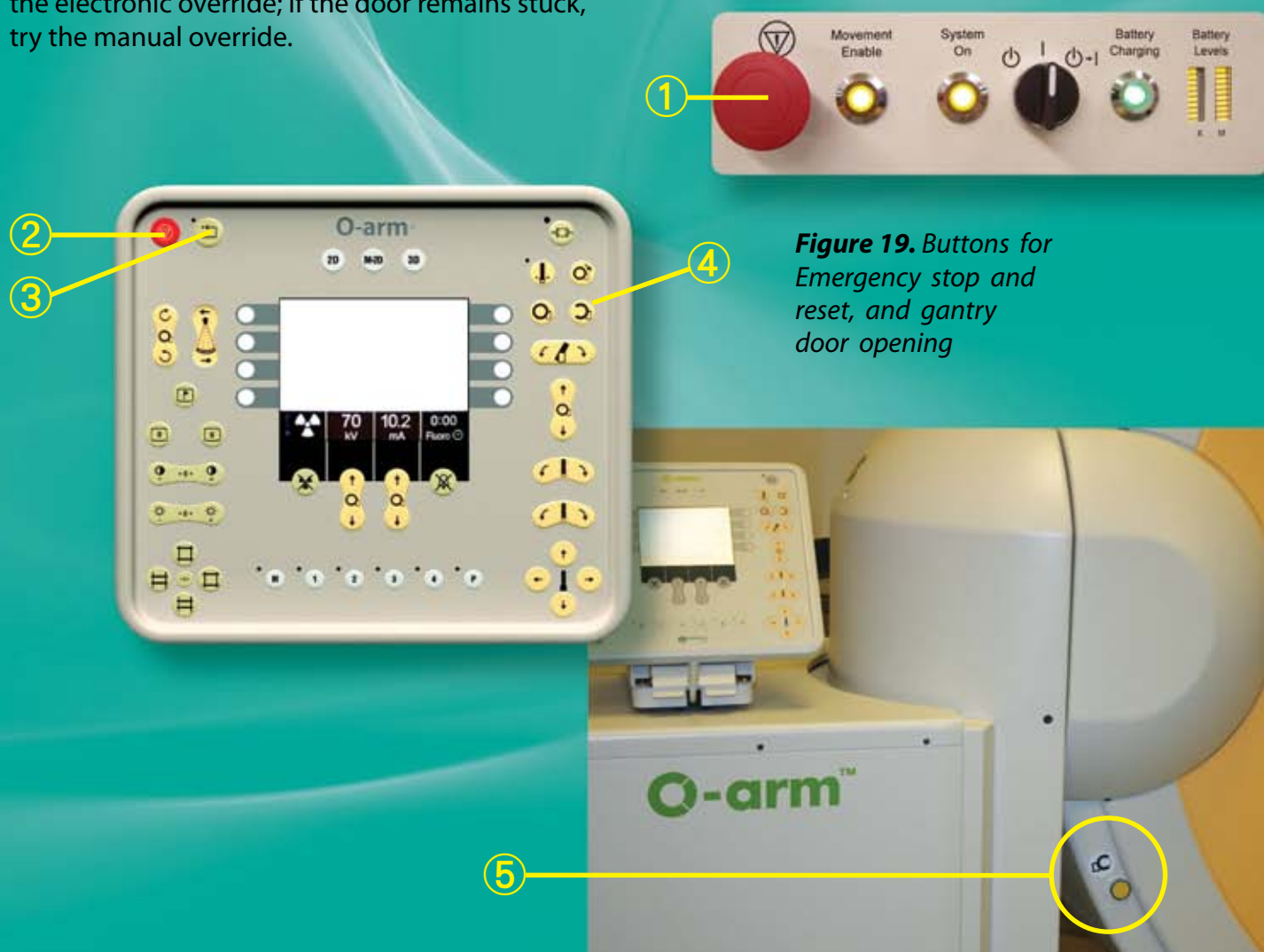Follow the step by step directions to open a stuck gantry door.

Figure 19. *Buttons for Emergency stop and reset, and gantry door opening*

Miscellaneous Functions

Storing the 2D Image to the Session File.

- To store the captured image (The one that appears on the left side of MVS) to the patient's session, press the "store" ✑ button on the appropriate button on the hand switch or footswitch.

Saving Gantry Positions and Image Settings as Memory Presets

- To save gantry position and image quality settings for a 2D shot, press M ① on the pendant, and then a preset button (1-4) ②.

- The preset LED lights up. These settings are saved until you start a new imaging session.

- To overwrite a preset, press M, and then the preset button again.

- Gantry positions can only be saved while in 2D mode.

  Note: It may help to write down on note cards which positions and settings are saved to which presets, i.e., "M1=AP, M2=Lateral")

  Note: Presets only apply during a single session.

  Note: Presets save the gantry position relative to the cabinet of the O-arm® System, not to the anatomy. If you reposition the entire system, the presets will no longer apply to the anatomy.

Saving a Park Position

- Position the gantry as far out of the way left/right as possible (without compromising line of sight to the reference frame and instru-ments, if using a StealthStation® System camera)

- Wag or tilt the gantry, as appropriate, in whatever direction gives the surgical team better access.

- Press M on the pendant, and then the P preset button ③.

Figure 20. *Memory preset buttons*

Moving the O-arm System laterally

1. Press the lift and shift button ④ to lower the wheels that allow lateral movement.
   When the lift and shift wheels are down, the system emits a regular "chirp". This alert is to remind you that having the lift and shift wheels lowered drains the battery.

2. Move the O-arm® System to the desired position.

3. As soon as the system is where you want it, press the lift and shift button a second time.

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Miscellaneous Functions

Troubleshooting
Transferring Images

3D Image does not transfer to StealthStation® Navigation System

1. Check for the green check mark beside an image of the StealthStation camera on the O-arm® pendant prior to 3D acquisition to ensure readiness of the StealthStation.

2. Maintain hand or foot switch contact during entire 3D acquisition or image data may be lost.

3. Ensure that the StealthStation and O-arm Systems are connected via a network cable and that they remain connected until the images have transferred completely to the StealthStation System.

4. Do not unplug the interconnect cable between the O-arm System and MVS immediately after acquiring an image, or data may be lost; wait until data transfer is confirmed at the MVS before detaching the cable.

5. Check that the StealthStation System has sufficient hard drive capacity. If it is above 80% full, delete studies and re-send the current study from the O-arm system.

Image Transfer Issues across a network

- Network connections can be made either before system is turned on or after it has completely booted up. Make sure that the network cables are secure in the ports.

   Note: The system should not be connected to the network during a surgical procedure.

- Axial images are the only ones that can be transferred to PACs at this time; coronal images and sagittal images cannot be transferred.

- Snapshots are in TIFF format. They cannot be saved to PAC systems that do not accept TIFF files.

### Re-home / Recalibration of Mechanical Robotics

On occasion, the O-arm System will need to have its robotics recalibrated. The system alerts you of the need to do this, and displays messages guiding you through the procedure.

1. Before you begin, move the system away from any patient table or other equipment, since the system will reposition the gantry through its full range of motions.

2. Press the M button on the Pendant. This is the same M button used for Memory presets.

3. Hold the M button down until the system has performed its mechanical activities.

O-arm System does not move even though the system is on

Check to see if clutch is engaged.
(At lower left of O-arm System cabinet)
Lever should be in the DOWN position
for motorized transport ①.
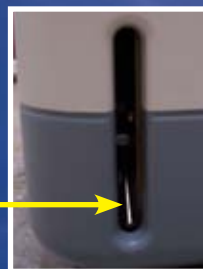
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