

MDS Installation and Operation Manual

L280-0960 Rev D



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ABOUT IMAGE DIAGNOSTICS, INC.

IDI is a leading manufacturer of specialized equipment and accessories for surgical and diagnostic imaging applications. Our company focus is on mobile equipment solutions for these applications, including C-arm compatible tables and mobile video display systems. IDI is headquartered in a modern 38,000 sq. ft. facility in Fitchburg, Massachusetts, USA, where IDI products are both designed and manufactured.



ORDER: sales@imagediagnostics.com SUPPORT: techsupport@imagediagnostics.com WEBSITE: https://imagediagnostics.com +1-978-829-0009 Monday through Friday 8am to 5pm, Eastern

The text of this manual was originally written, approved, and published by the manufacturer in English.

OVERVIEW

This manual pertains to the specified devices only and does not intend to replace or substitute for certified training in the application of this equipment. The device is intended for qualified medical personnel who have been trained in the use of medical equipment.

Functional capabilities and operation of the equipment described herein can be employed in a variety of diagnostic, therapeutic, and surgical applications.

OWNER RESPONSIBILITIES

The owner of this device is responsible to ensure system compatibility, the qualifications of the operator and maintenance personnel. The operator must be properly trained and have obtained credentials from the appropriate authorities.

This equipment must be installed in an area provided with the proper electrical power.

The owner of this device is responsible for verifying continued compliance with all applicable regulations and standards. Consult local, state, federal and/or international agencies regarding specific requirements and regulations applicable to the use of this equipment.

Image Diagnostics, Inc. certifies only the equipment. After-sale operating practices and safety are the responsibility of the owner and operator. Image Diagnostics, Inc. assumes no liability or responsibility for after-sale operating or safety practices; nor can it be responsible for personal injury or damage resulting from misuse.

Never make modifications or adjustments to the equipment unless directed by a qualified Image Diagnostics representative. This equipment, when properly assembled, meets US federal regulations and standards. Unauthorized modifications to the equipment may impact adherence to these standards and make the equipment unsafe to operate.

CUSTOMER SUPPORT

Image Diagnostics will make available, on request, circuit diagrams, component part lists, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.

For technical assistance, call IDI at (978) 829-0009. Be prepared to give the complete model and serial number found on the data label on the base of the MDS (Mobile Display System) at the time of contact.

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SYMBOL IDENTIFICATION

| Ţ i | Attention! Consult accompanying documents. Failure to follow these instructions could cause serious personal injury or damage to equipment. Consult all accompanying documents. |
|------------|---|
| | Warning! Information or instructions shown near this symbol must be adhered to in order to prevent a potentially hazardous situation which if not avoided, could result in death, personal injury or damage to the equipment. |
| | Recyclable material. |
| | Protective Ground. This is the common tie point between the AC Electrical Power Cord Ground, Frame Ground, and Controller Ground. |
| SGS | SGS North America, Inc. Testing Service. |
| | Date of manufacture of the Video Integration System. |
| | Location where the Video Integration System was manufactured. |
| ~ | Alternating Current (AC). |

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INTENDED USE AND ESSENTIAL PERFORMANCE

The MDS (Mobile Display System) is a mobile solution for video display and image management. This system features flexibility with its video display positioning combined with video signal routing and multiple image management options. The MDS is designed to configure and control images from C-arm fluoroscopy, endoscopy, patient monitoring, etc.

SAFETY INSTRUCTIONS

Review the SAFETY HAZARDS and OPERATING INSTRUCTIONS before operating MDS.

All persons using this equipment must fully understand its operation instructions, emergency procedures, capabilities including total range of motion and be aware of all potential safety hazards.

This manual should be accessible to all personnel installing, operating, or servicing this equipment.

Only a qualified technician may install or service this equipment.



Warning

Failure to follow safety precautions may result in serious injury to patient or user or damage to equipment.

Comments and questions regarding safety should be addressed to:



Technical Support Image Diagnostics, Inc. 310 Authority Drive Fitchburg, MA 01420 USA



Or call IDI at (978)-829-0009

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SAFETY HAZARDS

It is imperative that all personnel operating the MDS be familiar with the equipment's operation, transport and all documentation supplied by IDI. The MDS system is intended to be used in typical clinical or research environments in accordance with national medical standards. When transporting the MDS from room to room, it is imperative that the device be moved while in its storage configuration with the security strap in place and the arms folded into the unit so that the magnetic stops are engaged. The MDS should be plugged into the appropriate medical grade electrical outlet, not to exceed the rated amp values as stated on the MDS serial number label.

| Safety Hazard Level | Potential Consequences with Use |
|---------------------|--|
| DANGER | Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. |
| WARNING | Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. |
| CAUTION | Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or equipment damage. |

| <u> </u> | WARNING | Do not jump any curbs or steps over 3/8" in height with this equipment. Approach all obstacles slowly. Operator must use a ramp to allow the casters to roll up and over the vertical edge. |
|----------|---------|---|
| <u>^</u> | WARNING | It is the user's responsibility to make sure the equipment is safe and operates properly prior to use. |
| <u>^</u> | WARNING | Do not modify this equipment without authorization of the manufacturer. |
| <u> </u> | CAUTION | Caution should be used when moving the system over uneven or sloped surfaces. |
| | CAUTION | Confirm that the monitor arm heights are appropriate for the clinical application, otherwise store in transportation mode. |
| <u>^</u> | CAUTION | Prior to each clinical placement, confirm that there is no vertical drift on the horizontal arms and that the swivel and tilt mechanisms are functioning correctly. |
| <u>^</u> | CAUTION | Injury may occur if the operator inadvertently runs into the extended monitor arms. Be aware of the arm's location at all times during the installation and while in use. |
| | CAUTION | If upper Locking Collars are loose, they may inadvertently drop and prevent free vertical arm |
| | CAUTION | Do NOT store liquids on the unit above any electrical devices. |

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EMC (ELECTROMAGNETIC COMPATIBILITY) STATEMENT

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment including the ones used with the MDS. Use special precautions regarding EMC (Electromagnetic Compatibility) when these Mobile Display Systems are installed, operated, and maintained.

The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.



Warning

If MDS is used adjacent to or stacked with other medical electrical equipment, the equipment and the MDS should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

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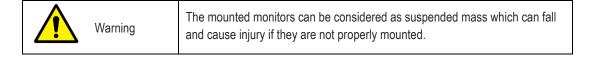
INSTALLATION INSTRUCTIONS

This section describes the process of preparing the MDS for Video Integration. The MDS monitor arms are counter-balanced with a series of steel plates (behind the rear cover) that are sized to accommodate the weight of a variety of medical monitors. Each MDS system is factory balanced to the specifications based on the weight of the Monitors supplied with the system. The Monitors are removed for shipment and the weights are secured in place via upper and lower Locking Collars

| Warning | Loosening the Shipping Locking Collars without the monitors being installed will create a severe imbalance and uncontrolled rapid arm movement! |
|---------|---|
| Caution | When mounting or removing the monitors, confirm that the vertical travel lock is engaged, and the upper/lower collar locks are secured. |

Note: The upper and lower Locking Collars are used to secure the arms for shipping only. After relocating the Collars, the Vertical Travel Lock Hooks should ONLY be utilized during transportation of the unit.

Note: The original factory balance weight is noted on the face of the VESA Monitor Support Bracket and the Face Balance Plates. If Monitors are upgraded to smaller or larger sizes, it will be necessary to rebalance the Monitor Arms with the new monitor weight. Additional plates can be ordered from IDI if needed. Please contact customer service prior to changing Monitors. It is recommended that two persons assist in the mounting/un-mounting of Monitors.



Tools Required for Installation

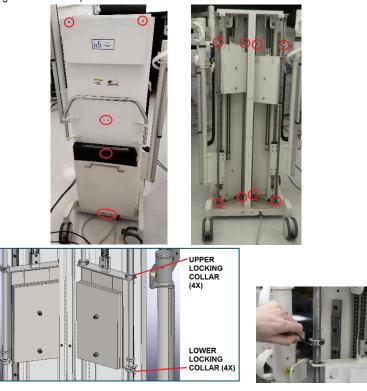
Tools Required: 5/32" Hex Key, 3/16" hex key, Phillips (Cross) Screwdriver, #222 Loctite, a level and Orange Torque Seal.

Components Required: MDS main stand. The following components ship in their original boxes: 2X monitors, router control unit, touchscreen monitor, video cables, touchscreen monitor mount. All of the required hardware ships in the original packaging. These boxes are packaged together with the MDS unit when they ship from the manufacturer.

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Mount Two Main Monitors

- 1. Using a 5/32" Hex Key, remove the MDS Back Panel by removing all the upper and lower Socket Head Cap Screws. The 8 screws on the back panel are identified in the images below.
- Locate and confirm the upper and lower rail Locking Collars are secure and in place against the top and bottom
 Counterweight Bracket Flanges as shown in the photos below. The unit is shipped in this configuration but should be
 confirmed before moving to the next step.





Warning

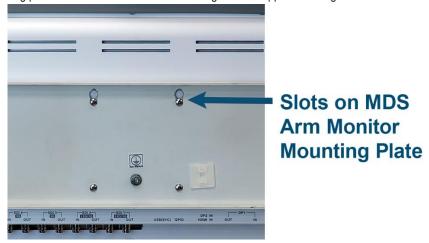
If the Locking Collars are found to be loose, tighten the collar in place using a Hex Key before proceeding.

NOTE: The upper and lower Locking Collars are used to secure the Arms for shipping only, and after they are relocated the Vertical Travel Lock Hooks should ONLY be utilized during transportation of the unit. The lock hook is explained further down in the instructions.

- 3. Locate and unpack the two main Monitors carefully and lay them face down on a protective surface.
- 4. Locate and remove the bottom two screws on the back panel of the monitor.

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5. Loosen the two top screws, allow enough of a gap below the screw heads so they can easily slide into the top slots of the VESA mounting plates on the MDS arm while still being able to support the weight of the Monitor. See photo below.

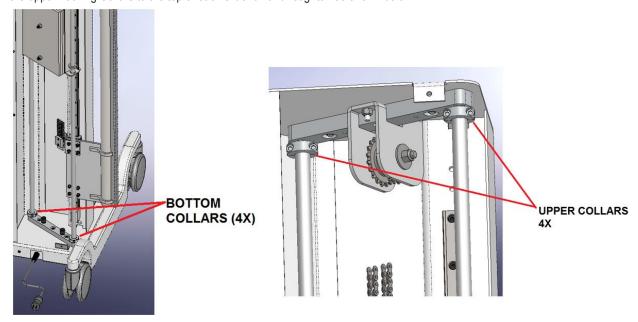


- 6. With assistance from another individual, lift the Monitor with the partially installed upper screws and slide the screws into the upper slots of the VESA Mounting Plates on the MDS arm.
- 7. Install the two remaining screws into the bottom holes of the VESA Mounting Plates on the MDS arm. Torque all four screws to 23in*lbf. (2.6N-m).
- 8. Connect the power cable from the arm to the monitor. Connect the video cables to the appropriate input port. Video cables and monitors are color coded for ease of installation.
- 9. Repeat steps 1 through 8 on the second monitor.
- 10. Once the monitors have been mounted power them up and ensure the input selection is set to the proper input selection.
- 11. Monitor settings may be adjusted depending on the equipment in the room. This will be done by going into the monitor menu screens and adjusting contrast, brightness, gamma, color, etc.

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Release Monitor Counterbalance

- 12. Once both main Monitors are mounted and secure, the counterweight Locking Collars are ready to be relocated from their storage positions.
- 13. With a 3/16" Hex Key, loosen the lower Locking Collars and lower them to the bottom of the slide rail. Loosen and raise the upper Locking Collars to the top of each slide rail and retighten as shown below.



NOTE: Arms will not move vertically until Vertical Travel Lock Hooks are disengaged.

14. Release the red Vertical Travel Lock Hooks shown below and each monitor arm should lower and raise with minimal physical effort.



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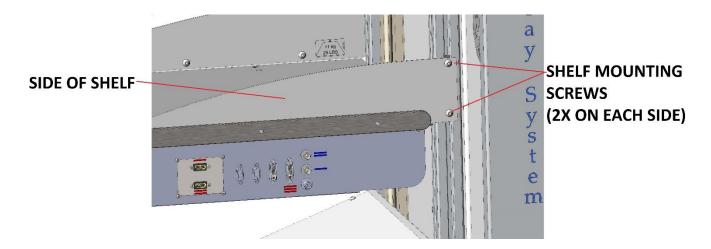




15. Monitor arms are pre balanced during assembly at the factory, In the rare occurrence that the monitor arm drifts up or down easily or drift in one direction or another, the unit may need to be rebalanced. Pease contact IDI technical support for parts and step by step instructions.

Shelf Adjustment

- 16. Remove all devices off the Shelf that is to be repositioned.
- 17. Have an assistant hold onto the sides of the Shelf to be moved.



- 18. Using a 3/16" Hex Key, loosen the Button Head Socket Screws (2 on each side of Shelf) just to the point where it can rotate freely but DO NOT remove.
- 19. The assistant can now slide the Shelf up or down to a desired location.
- 20. Using a level, verify that it is level and then re-tighten all four Screws.
- 21. Replace devices onto the shelf and tuck power or video cords into the side Channels of the Cart or wrap around cable hooks provided on sides of the shelf.

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Installing Touchscreen Monitor and arm



- 22. Locate the VESA mount arm, then slide the arm onto the shelf accessory rail. Using the locking screw lock the mount in place.
- 23. Locate the 15" touchscreen monitor. Install the monitor onto the VESA mount from the previous step, by inserting the 4 mounting screws through the VESA mount and into the monitor threaded inserts.
- 24. Route the HDMI, power cable, and USB cable from the touchscreen monitor to the back of the IPS4000. secure cables in place with either zip ties or Velcro® straps as neatly as possible.
- 25. The USB cable can plug into any port on the IPS 4000, the HDMl cable must plug into the HDMl output that states monitor screen.
- 26. The power brick should be plugged into the splitter that powers the IPS4000.

Install the IPS 4000

- 27. Locate the FSN IPS 4000 and place it either on the first or second shelf. A power supply cord should be plugged into the back of the unit to power it.
- 28. Video input and output cables will be installed and configured by an idi team member during installation and in service of the MDS product.

CLEANING THE DEVICE

Use a soft cloth and one of the following approved cleaners:

Approved Cleaners

- Sodium hypochlorite (generic household bleach) in a solution of 5.25% sodium hypochlorite diluted between 1:10 and 1:100 with water.
- · Alcohol (generic).
- Envirocide®
- 1. Unplug the MDS system prior to cleaning the unit.
- Wipe clean the surfaces of the MDS system with a diluted mixture of mild detergent (listed above) and water using a soft cloth

NOTE: For cleaning Video Routers and Monitors, please consult corresponding literature for these devices. NEVER use alcohol to clean the monitors.

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Electronics Installation

All electronic devices are to be installed according to their perspective manufacturer's IFU (Information for use) documentation

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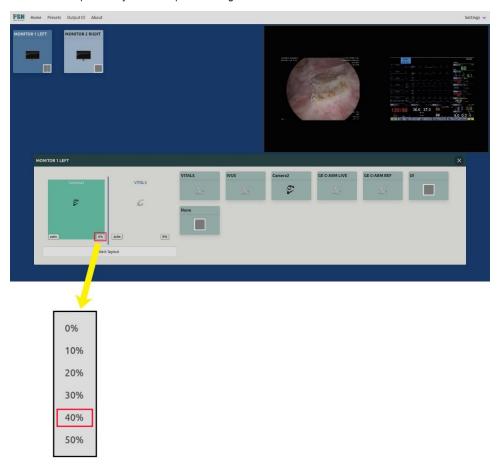
OPERATOR INSTRUCTIONS

Selecting and Manipulating inputs/outputs

To change inputs, click on the monitor to be changed. The screen will appear like below. Select the desired input by clicking on it, then click on the left side of the screen to map the input to the monitor.

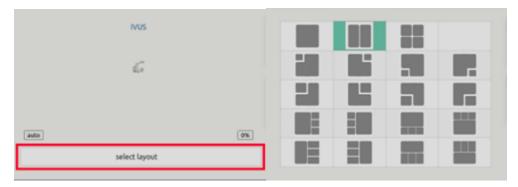


When images require zooming in, adjust the zoom factor by clicking on the 0% and applying the appropriate zoom for that input. This will be required anytime an input is changed.



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If more than one image is desired, click on select layout, and select the appropriate layout required. Typically, the single, split screen and PIP are used. However additional options are available if desired.



Moving the MDS unit

Tools: Security strap and a second person to assist with moving.



Warning

Always use a minimum of two persons while transporting the MDS unit to aid in maneuverability and to aid with visibility.

- 1. Lower both arms of the MDS unit to a comfortable height to ease in the installation of monitor covers.
- 2. Fold the arms into themselves so that the stainless-steel covers are facing towards the outside.
- 3. The MDS arms are equipped with rotational stops with built in magnets that help prevent inadvertent arm movement. Confirm that arms are pushed in, and magnets are engaged.
- 4. Lift the arms so that the base of the monitor clears the upper most device placed on the top shelf and rotate the face of one of the monitors inward and gently lower the monitor on to the top shelf. Repeat the process for the other monitor.
- 5. With both monitors facing inward, place the security strap over the top of each monitor handle and secure snugly.
- 6. Disengage caster motion locks on all four casters by pushing up on caster lock levers with top of foot.
- 7. MDS unit can now be transported by two individuals using the handles located on the sides and back to maneuver the unit.
- 8. Once the MDS unit is relocated to its final position, all four casters should be motion locked by stepping down on the caster lock pedal until they are fully engaged.
- 9. To move monitor position, grab the monitor handle just below the monitor.
- 10. Push and pull monitor to desired location within the limits of the articulating arms they are mounted to.
- 11. To tilt monitor position downward, hold the top of the monitor mount and push the monitor handle away from the operator.
- 12. To tilt monitor position upward, hold the top of the monitor mount and pull the monitor handle away toward the operator.
- 13. To raise the monitor position, grab the monitor handle and push upward.
- 14. To lower monitor position, grab the monitor handle and pull downward.

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MAINTENANCE, SERVICE, & REPAIR

All maintenance procedures should be done by an experienced and qualified technician with demonstrated knowledge and skills (electrical and mechanical) in the service of medical equipment.

This individual must have access to this manual and the proper tools.

Lubrication of this device is not required.

Recommended Periodic Performance Checks

| Daily | Inspect all external cables and electrical components for wear and damage. | | |
|--------|--|--|--|
| | Damaged cables must be replaced promptly. The MDS uses a medical | | |
| | grade power cord which is not user serviceable. Replacement must be | | |
| | performed only by a qualified service technician. | | |
| Weekly | Move the monitors through their full range of motion to verify that they are | | |
| | not worn or damaged. | | |

Service and Repair Statement

Only qualified personnel should perform repairs on this equipment. Please read this entire document before performing any diagnostics or repairs. Some procedures listed require this device to be energized while repairs are performed; please exercise extreme caution while working with electrical components. Always exercise appropriate lockout/tag out procedure while performing any diagnostics and service on the unit.

TROUBLESHOOTING

| Problem/Symptom | Possible Cause | Remedy |
|--|------------------|---|
| MDS generates or receives electrical interference. | Incompatibility. | Verify that the equipment is the cause by turning the system or individual components off and on. Use only high quality video cables to avoid electrical noise. |

DISPOSAL OF COMPONENTS



The IDI MDS base and arms are made up of mostly steel and aluminum parts which are easily recycled. The casters are made of mostly plastic. It is recommended that some components be disassembled before disposal for recycling.

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SPECIFICATIONS/PRODUCT DATA

Type of Equipment

- Class I (as defined by IEC 60601-1, 3rd Edition)
- CENELEC EN 60601-1, ANSI/AAMI ES60601-1, and IEC 60601-1, 3rd Edition)

Electrical

- Supply Voltage:
 - 120±5% Vac 60Hz through NEMA 5-15P hospital grade plug.
 - 230±10% Vac 50Hz through country specific plug.
- Output Voltage: 120 VAC 60Hz (1800VA) or 230 VAC 50Hz (1800VA).
- Current Rating: Less than 12 Amps @ 120.
- Isolation transformer limits leakage current to 50µA.
- Isolation transformer is certified to meet Medical Safety Standards ANSI/AAMI ES60601-1.

Environmental

- Operating Temperature Range: 41°F to 95°F (5°C to 35°C)
- Operating Humidity Range: 10% to 85% relative humidity, noncondensing.
- Operating Pressure Range: 500 hPa to 1060 hPa.
- Transport & Storage Temperature Range: 32°F to 113°F (0°C to 45°C).
- Transport & Storage Humidity Range: 10% to 85% relative humidity, noncondensing.
- Transport & Storage Pressure Range: 500 hPa to 1060 hPa.
- Not suitable for oxygen rich environment.
- Not suitable for flammable anesthetic mixtures

Product Features included with MDS

- 1. Thermal protector AC input module.
- 2. Medical Grade output strip for Monitor & Ancillary power.
- 3. Individual cables for monitor power and video input.

WARRANTY

Warranty details for IDI Products can be obtained directly from Image Diagnostics, Inc.



Image Diagnostics, Inc. 310 Authority Drive Fitchburg, MA 01420 USA



Or call IDI at (978)-829-0009

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