Ilex DUO - User Manual

Ilex DUO

IDI Imaging Table

The text of this manual was initially 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 applying this equipment. The device is designed 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 various diagnostic, therapeutic, and surgical applications.

OWNER RESPONSIBILITIES

The owner of this device is responsible for ensuring system compatibility and the qualifications of the operator and maintenance personnel. The operator must be adequately trained and have obtained credentials from the appropriate authorities.

This equipment must be installed in an area 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 from misuse.

Never modify or adjust the equipment unless directed by a qualified Image Diagnostics representative. When correctly assembled, this equipment meets US federal regulations and standards. Unauthorized modifications may impact on adherence to these standards and make the equipment unsafe.

CUSTOMER SUPPORT

Image Diagnostics will make available, on request, circuit diagrams, part lists, instructions, or other information that will assist the user's appropriately qualified technical personnel in repairing equipment parts designated by the manufacturer as repairable. For technical assistance, call IDI at (978) 829-0009.

SYMBOL & Label IDENTIFICATION

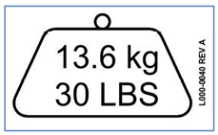
Attention! Please consult the accompanying documents. Failure to follow these instructions could cause severe personal injury or damage to equipment.

WARNING: Disregarding this could compromise the personal safety of the patient, end user, or technician. Not following instructions may result in injury.

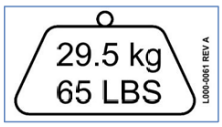
CAUTION - indicates that a particular procedure or precaution must be followed to avoid system irregularity or damage to the product.

MANUFACTURER CONTACT – Provides manufacturer contact information.

HOSPITAL GRADE OUTLET – indicates connection should only be made to a hospital grade outlet.



MONITOR MOUNT WEIGHT CAPACITY – indicates maximum weight of monitor that can be affixed to the monitor mount.

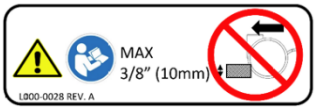


SHELF WEIGHT CAPACITY – indicates total equipment weight that can be placed on an individual shelf.

USER MANUAL ACCESS QR CODE – Please consult the accompanying documents. Failure to follow these instructions could cause severe personal injury or damage to equipment.

Recyclable Material.

CONFIGURE DEVICE FOR TRANSPORT – Indicates boom arm configuration during transport. Please refer to "Moving the DUO".



MAXIMUM THRESHOLD HEIGHT – Indicates the maximum threshold height that the duo can safely pass over.

LOCK CASTERS WHEN DUO IS IN USE – Instructs to lock casters when system is in use.

AVOID COLLISION WHEN OPERATING BOOM ARMS – Instructs to use caution when interacting with boom arms.

MAXIMUM LOAD ON INTERNAL POWER STRIP – Indicates maximum load for internal power strip.

MAXIMUM LOAD ON ELECTRICAL OUTLETS

Protective Ground. This is the standard tie point between the AC Electrical Power Cord Ground, Frame Ground, and Controller Ground.

ETL Mark - a proof of product compliance with North American safety standards. It indicates that a product has been tested by Intertek and found in compliance with accepted national standards. Retail buyers and authorities accept it as proof of product safety and compliance.

NOTE: A NOTE indicates special information to facilitate product maintenance or clarify important details.

Ilex® DUO is an FDA-registered Class I Medical Device (see Standards & Compliance)

INTENDED USE AND ESSENTIAL PERFORMANCE

The Ilex DUO is a mobile solution for video displays and equipment management. This system features flexibility in its video display positioning, video signal routing, and multiple image management options. It is designed to configure and control images from C-arm fluoroscopy, endoscopy, patient monitoring, etc.

⚠ **NOTICE: The Ilex DUO is not intended to directly contact the patient nor indirectly contact the patient via the operator. The system is designed for equipment management and visualization only, maintaining appropriate separation from the patient care field.**

Safety & Usage Guidelines

⚠ **General Safety**

- **Read the SAFETY HAZARDS and OPERATING INSTRUCTIONS before using Ilex DUO.**
- **Users must understand the operation, emergency procedures, range of motion, and safety hazards.**
- **This manual must be accessible to all personnel.**
- **Only qualified technicians may install or service this equipment.**

⚠ **Installation & Maintenance**

- **Apply tension to the Spring Arm Vertical Limit Adjustment Screw before installing or removing displays.**
- **Do not service equipment while in use.**
- **Use proper lifting techniques; components are heavy.**

⚠ **Handling & Positioning**

- **Be aware of Booms and attached equipment to avoid injury.**
- **Keep equipment out of patients' reach.**
- **Do not attach extra loads to Booms to prevent tipping or damage.**

⚠ **Electrical & Safety Considerations**

- Consult your facility's **Biomedical Engineering department (qualified hospital personnel responsible for inspecting, maintaining, and approving medical equipment for patient care areas)** before connecting any additional devices.
- **Do not use in flammable environments or pooled liquids.**

⚠ **WARNING: Only certified equipment compliant with relevant IEC or ISO standards may be connected to the user-accessible power outlets on the DUO. Use of uncertified equipment may pose safety risks to patients, staff, and the system itself.**

⚠ **WARNING:** The system must not be loaded beyond 12 Amps total current draw from the provided outlets. Overloading may result in equipment failure, fire hazards, or electrical shock.

⚠ **WARNING:** Additional multiple socket outlets (e.g., power strips) must not be connected to the outlets provided on the DUO. Doing so may compromise system safety and increase the risk of electrical hazard.

⚠ **WARNING:** Devices intended to be powered by the provided DUO outlets should not be connected directly to a wall outlet. Powering devices directly from the wall may bypass the DUO's protective electrical design and introduce safety risks.

⚠ **NOTICE:** There are risks associated with connecting equipment to the DUO's integrated power outlets. Improper use may cause electrical shock, equipment malfunction, or interference with clinical operations. Always consult with your Biomedical Engineering department prior to connecting new devices.

⚠ **Operational Readiness**

- **Verify all signals before patient treatment.**
- **Keep a backup display available in case of failure.**
- **Ensure equipment is stable on shelves and that shelf weight limit is not exceeded.**

⚠ **Electromagnetic Precautions**

- **Follow EMC guidelines for safe installation and use.**
- **Portable RF devices may interfere with medical equipment.**

Pre-Use Inspection

⚠ **Before each use, check the following:**

- **Mechanical, electrical, and video-routing functionality.**
- **The system is locked in place.**
- **Securely fasten all items on shelves.**
- **Confirm that monitor arm heights suit the clinical application; otherwise, store them in transportation mode.**
- **Ensure no vertical drift on horizontal arms and proper function of swivel and tilt mechanisms.**

⚠ **Equipment Handling & Safety**

- **Use caution when moving over uneven or sloped surfaces.**
- **Maintain awareness of Booms, displays, and mounted equipment to prevent collisions and injuries.**
- **Exceeding the range of motion may cause device damage.**
- **Do not exceed weight limits for Arms, Booms, or shelves.**
- **Avoid collisions with surgical luminaires or other equipment.**
- **Excessive force on displays, Booms, or Spring Arms may cause unexpected movement or damage.**

⚠ **Electrical & Environmental Precautions**

- **Do not use in the presence of combustible gases.**
- **Limited Access—Only open the electronics enclosure for servicing.**
- **Do not store liquids on or above the cabinet.**
- **Do not connect additional portable socket outlets or extension cords.**
- **Only use hospital-grade plugs.**
- **Ensure display power switches are ON before use.**

Component Identification

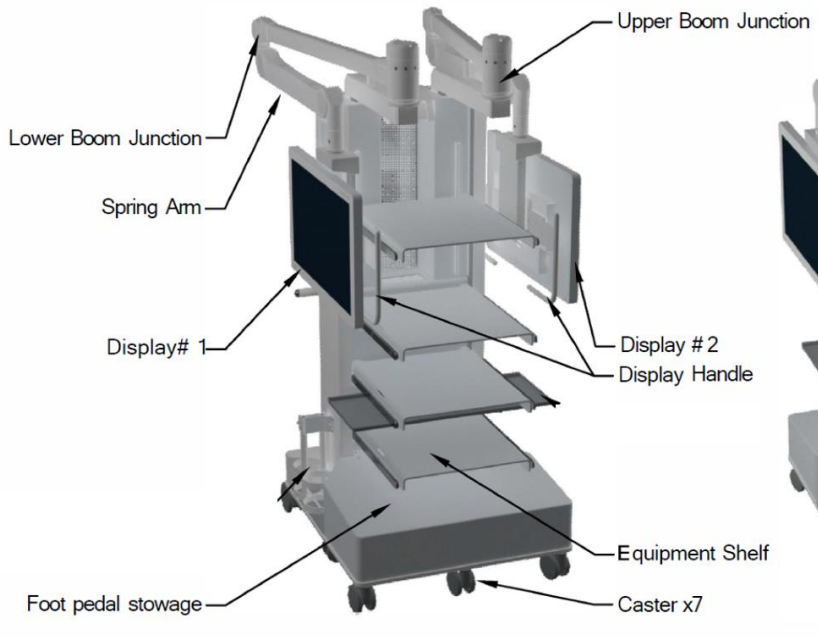


Figure #1

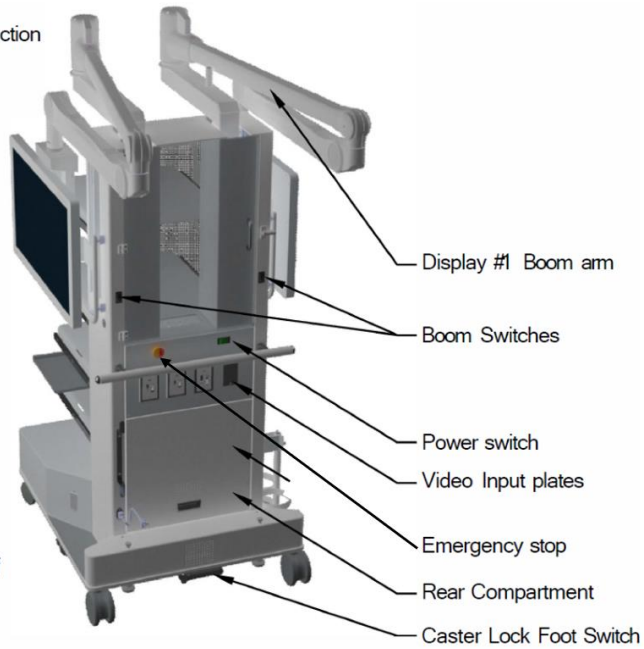


Figure #2

Operating Procedure

⚠ **CAUTION:** This section details the steps that must be followed before and while using the DUO.

1. Move the DUO into the desired position while the DUO is in transport mode. See “Moving the DUO” for transport mode setup.

2. When desired position is attained, lock the casters using the caster lock foot switch. Two additional locking casters are found on the front corners of the DUO. Press each individual pedal on these casters all the way down to engage the lock.

3. Detach monitor handles from clips.

4. The Left-side boom switch can raise and lower the left boom arm, and the Right-side boom switch can raise and lower the right boom arm. Booms should only be raised and lowered with the arms configured for transport mode (see figure 1 and 2 above), but unclipped. Special attention must be paid to the boom arms and monitors so that the left and right boom arms and monitors do not interfere while raising or lowering the boom arms. Contact during raising or lowering between the left and right booms or other equipment and personnel can cause damage to the DUO and the user or other personnel nearby. Use these switches to raise or lower each boom arm to the desired height.

5. Detach monitor handles from clips. Using the monitor handles, move monitors to approximate the desired location.

6. Make any final adjustments to monitor positioning.

7. Use the provided power cord to plug the duo into a hospital grade outlet and turn the DUO on by switching the power switch to the on position.

Moving the DUO

⚠ **CAUTION:** This section details the steps that must be followed before and while moving the DUO.

Note: Touch points on the DUO are BLUE.

Put the DUO into transport mode:

1. Place the provided screen protectors over the Displays.
2. Lower the booms to their lowest position (see “Boom Hight Adjustment”).
3. Bring the Displays to the DUO with the booms pointing to the rear. The displays screen should be pointing away from the DUO (see figures #1 and #2).
4. Press the handles into the securing clips.

Releasing the brakes:

1. Release the two front casters by lifting the lever shown in figure #3.
2. Release the rear two caster locks by lifting on the pedal at the rear of the DUO shown in figure #4.

Note: The pedal in figure #4 has three settings, as follows:

- Up = Float – All wheel's role and turn.
- Middle = Steer – the rear two casters lock in the forward position and still roll.
- Down = Lock – the rear two casters lock into position and will not roll.

Figure #3

Figure #4

Pushing the DUO:

⚠ **Caution:** The DUO is heavy. Do not attempt to move it along an incline. Use caution when pushing the DUO across thresholds of a doorway. Proceed slowly and maintain spatial awareness.

Note: The DUO has two push handles, one in the rear and one in the front. IDI recommends using the rear handle when pushing long distances down open hallways and the front handle when navigating tight corners or doorways.

Component Adjustments:

⚠ **WARNING:** Care must be taken to properly move these components while maintaining awareness of the spatial orientation of Booms, Spring Arms and Displays to prevent injury to staff and patients, as well as damage to other equipment.

⚠ **CAUTION:** Use of excessive force to position Booms and/or Spring Arms may result in unexpected movement and potential equipment damage; always use Display Handles to reposition the Spring Arms, move a boom, or adjust a Display—never move a Display by grasping the Display itself.

Boom Height Adjustment:

1. Move the displays close to the DUO, ensuring no obstacles are above or below the Displays and/or Spring Arms/Booms.
2. Press the toggle switch at the rear of the DUO of the corresponding side. Press the upper side of the switch to move the boom up and the lower side of the switch to move the boom down.

NOTE: Lower the booms to their lowest position before transporting.

NOTE: By design, the booms lower to an overall height of 78” and can be raised up to 9” to allow for a walk-under height of 6’5”.

Shelf Adjustments:

⚠ **CAUTION:**

1. Remove the center bolt on each shelf bracket and loosen all other bolts two full turns.
2. Lift the shelf up and away from the DUO and place the shelf down on a dry, flat surface.
3. Remove the remaining bolts and relocate them into the desired shelf position.
4. Leave ¼" thread exposed.
5. Reinstall the shelf using a downward motion as shown in figure #5.
6. Reinstall center bolt and tighten to 60 ft lbs.
7. Tighten the remaining bolts to 60 ft lbs.

Getting ready for Surgery

⚠ **WARNING:** Care must be taken to properly move these components while maintaining awareness of the spatial orientation of Booms, Spring Arms and Displays to prevent injury to staff and patients, as well as damage to other equipment.

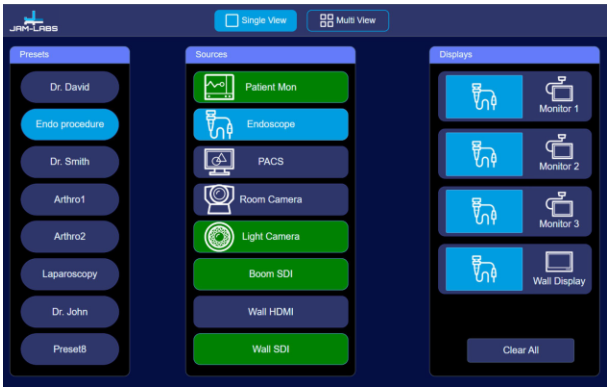
⚠ **CAUTION:** Use of excessive force to position Booms and/or Spring Arms may result in unexpected movement and potential equipment damage; always use Display Handles to reposition the Spring Arms, move a boom, or adjust a Display—never move a Display by grasping the Display itself.

Note: The DUO should be setup and tested with ample time before the start of surgery. All external devices should be securely mounted and tested before use. All video connections should be checked at the device and the rear of the DUO, if applicable.

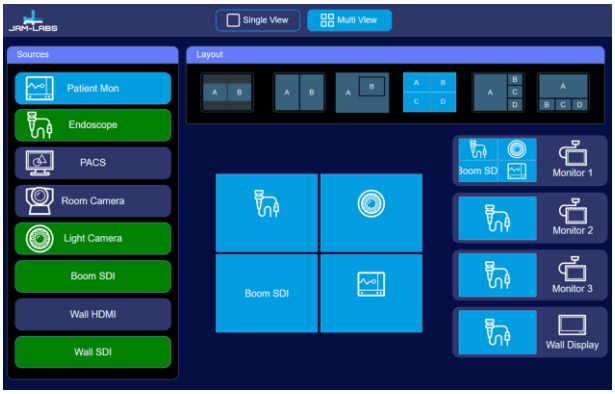
1. Place the DUO in the room to best suit your needs for workflow. Follow this link for example placements. [add link]
2. Lock the rear and front casters. See “Moving the Ilex DUO”
3. With the provided power cord, plug the DUO into a hospital grade 120v 15a power outlet.
4. Turn the power switch on at the rear of the DUO.
5. Position each display for optimal viewing.
6. Route video from source to desired display.

Routing video signals

1. Video routing full screen
    a. First select a source by pressing it shortly. It will be colored blue to indicate the source is selected.
    b. Then click a display to route that source to that display.



2. Video routing Multi View
    a. First click the Multi View button on the top of the GUI.
    b. Next, choose between the pre-defined layouts.
    c. Then the sources can be routed to the individual video allocations in the layout.
    d. Lastly, the user can click any number of displays to activate the configured layout on those displays.



3. Saving a Preset
    a. First configure the system how you would like the preset to look by following the above steps
    b. Next, press and hold the Preset button you would like to assign. A pop-up will appear.
    c. Name the preset and touch save.

Note: For additional information on setting up the system, please refer to the Connect Pro Users Guide (JMMAN00012).

Cleaning the DUO

Frame/Exterior Covers

1. Unplug the DUO and ensure that all external covers are intact and in place.
2. Use a soft, non-abrasive cloth to wipe down surfaces.
3. Different cleaning solutions can be used in conjunction with the cloth.

- Sodium hypochlorite (generic household bleach) in a solution of 5.25% sodium hypochlorite diluted between 1:10 and 1:100 with water.

- Envirocide®

- Alcohol (generic)

Monitors/Electronics

1. NEVER use alcohol to clean the monitors.
2. Unplug the DUO.
3. Use lint-free, antistatic wipes to clean monitor screens.

Environmental Conditions

• 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

Warranty

- 1 Year parts and labor

Additional warranty options

- Extended warranty coverage
- Preventative Maintenance Agreement

Warranty Process:

If your DUO is within its warranty period, please follow the following steps for speedy support.

ORDER: sales@imagediagnostics.com

SUPPORT: techsupport@imagediagnostics.com

WEBSITE: https://imagediagnostics.com

ADDRESS: 310 Authority Dr, Fitchburg, MA 01420

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