idi

Image Diagnostics, Inc.



ilex D

Operator's Manual

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

Made in the USA

L280-1129 REV C

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.

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, 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, and request service department. Be prepared to give the complete model and serial number found on the data plate on lower side of the monitor stand on the upper column assembly at the time of contact.

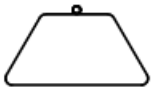
Image Diagnostics, Inc.
310 Authority Drive
Fitchburg, MA 01420 USA

Made in the USA

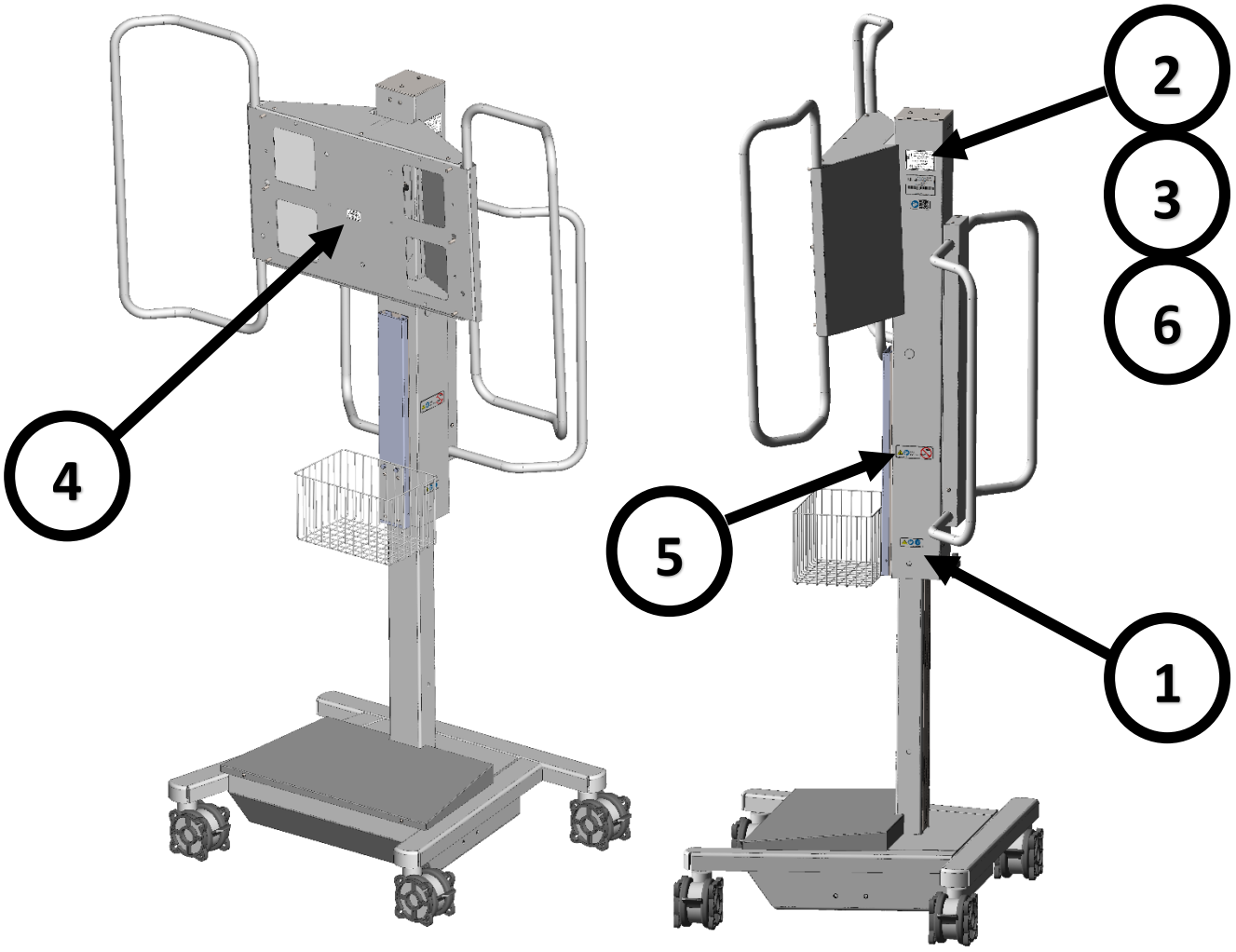
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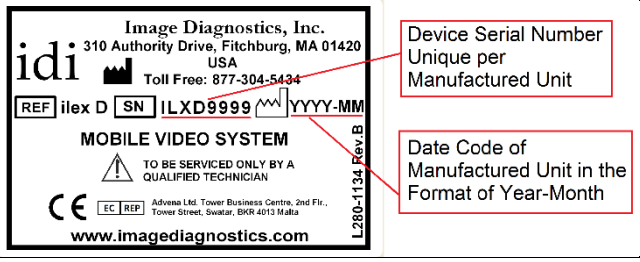
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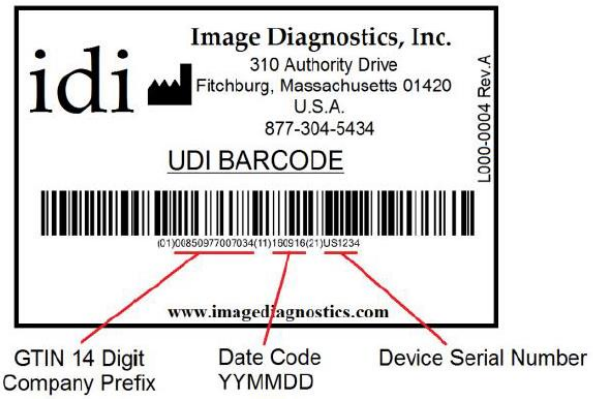
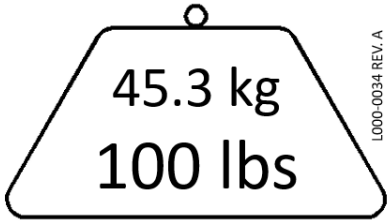
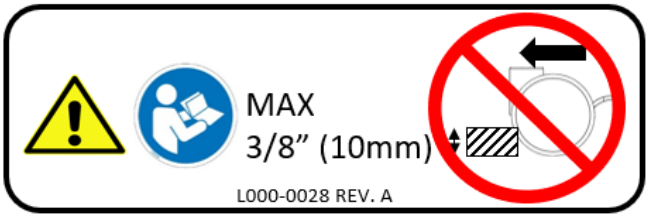
1. Symbol Identification

	Attention! Consult accompanying documents. Failure to follow these instructions could cause serious personal injury or damage to equipment.
	Read the manual.
CE	The system was tested and found to be in compliance with the requirements of all relevant directives and standards in effect within the European Union at the time of manufacture.
REF	Model of ilex D.
SN	Serial Number of ilex D.
	Date of manufacture of the device.
	Location where device was manufactured.
	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.
	Electric Shock hazard. 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, some material can be recycled rather than discarded.
	Maximum allowable Weight Limits.
EC REP	**EC REPRESENTATIVE:** Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

2. Label Identification



Item No.	Part No.	Description	Qty.	Label
1	L000-0029	Connect to properly grounded hospital grade outlet. For safety and proper function of equipment, connect power cord to a properly grounded outlet.	1	
2	L280-1134	Serial Number Tag	1	

3	L000-0004	UDI BARCODE	1	
4	L000-0034	Maximum load capacity for monitor. Do not exceed capacity	1	
5	L000-0028	Warning Do not jump any steps or "Curbs" over 3/8" (10mm) in height with this equipment. Approach obstacles slowly. Operator must use a ramp to allow the casters to roll up and over the vertical edge.	1	
6	L000-0035	Operator Manual QR code Scan with compatible device to view operator manual online. Will be linked to the current revision of the user manual.	1	

3. Intended Use

The ilex D is intended to be used in the medical procedure room as a secondary display. It is intended to allow professional healthcare industry to connect a video output signal to the monitor on the cart. It has been designed to be a totally mobile solution for video display of images from C-arm fluoroscopy, endoscopy, patient monitoring, or similar devices.

The ilex D is **NOT** intended to contact patient. It is **NOT** intended to supply power to electrocautery equipment. The ilex D has not been tested in an oxygen rich environment and should not be used in such an environment. The ilex D has **NOT** been tested for use with HF surgical equipment, nor cardiac defibrillator.

4. Safety



Review the SAFETY HAZARDS and OPERATING INSTRUCTIONS before operating video transmission unit

- All persons using this equipment must fully understand its operation instructions, emergency procedures, capabilities 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.



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

It is imperative that all personnel operating the ilex D be familiar with the equipment operation, transport and all documentation supplied by IDI.

- The ilex D is intended to be used in typical clinical or research environments in accordance with national standards.
- When transporting the ilex D from room to room, it is imperative that the device be moved in the storage position. Storage position is achieved by lowering the monitor to its midpoint in travel, so that the height of the device does not hit doorways.
- When transporting ilex D, it is required that the device be moved by two personnel.
- To ensure proper grounding, a medical grade electrical outlet must be used to provide power to the monitor stand.
- The ilex D does not have any essential performance functions that pose a risk due to failure or degradation of the unit or any of its components.

Comments and questions regarding safety should be addressed to:

	Customer Support Image Diagnostics, Inc. 310 Authority Drive Fitchburg, MA 01420 USA		Or call IDI at (978) 829-0009.

5. Safety Hazards



WARNING!
Do NOT jump any curbs or steps over 3/8" (10mm) 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 for over 3/8" (10mm).



WARNING!
It is the user's responsibility to make sure the equipment is safe and operates properly prior to use.



WARNING!
Do not modify this equipment without authorization of the manufacturer.



CAUTION!
Caution should be used when moving the system over uneven or sloped surfaces.



WARNING!
To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.



WARNING!
Use caution when adjusting the height of the monitor. Verify no objects are under the monitor when adjusting the height.

EMC (Electromagnetic Compatibility) Statement

This equipment may generate and use radio frequency energy. The equipment must be installed and used according to this manual in order to avoid radio frequency interference.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment including the ilex D. Use special precautions regarding EMC when these stands are installed with any external accessories, maintained or operated adjacent or stacked with other equipment. The equipment or system must be observed to verify normal operation in the final configuration in which it will be used.

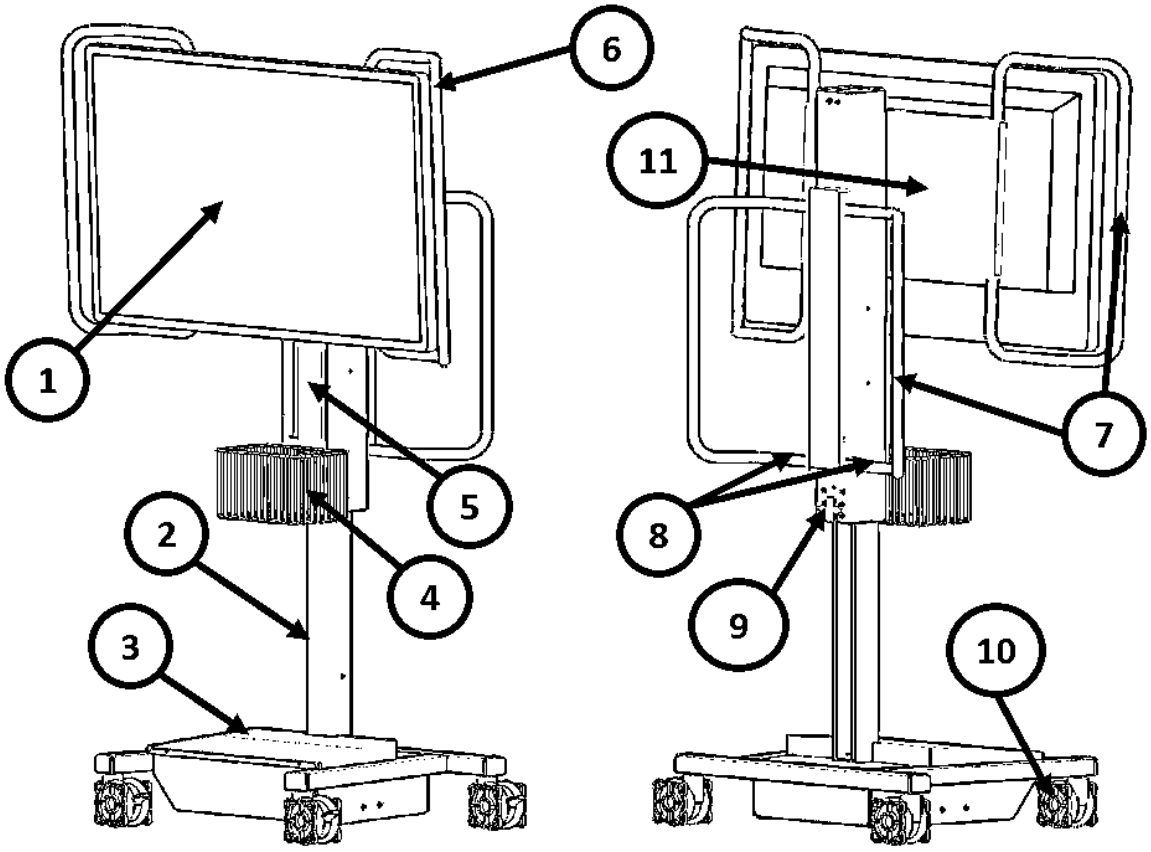


The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

If this equipment generates or receives interference:

1. Verify that the equipment is the cause by turning the system off and on.

6. Basic Setup and Use Instructions



Item	Description	Qty
1	Monitor	1
2	Base	1
3	Base Cover	1
4	Cable Storage	1*
5	Cable Management	1
6	Monitor Guard	2

Item	Description	Qty
7	Push Handle	2
8	Lifting Handle	2
9	Brake Mechanism	1
10	Total Lock Casters	4
11	Monitor Cover	2

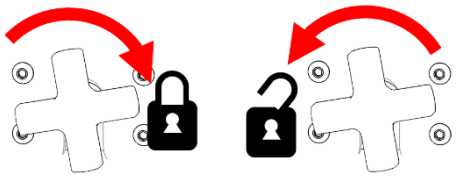
*Some ilex D models do not have a cable storage basket.

Power Cord

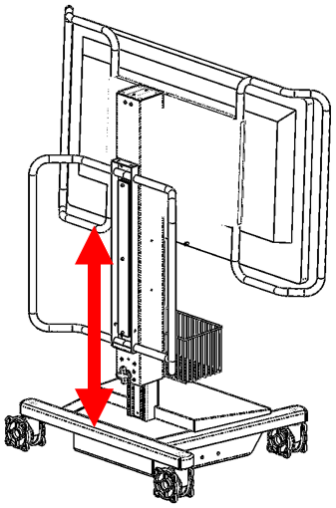
In order to ensure proper grounding the power cord must be plugged into a hospital grade power outlet.

Monitor Height adjustment

The monitor height can be adjusted with the following combination of brake pressure and lifting of the column. A brake handle is equipped on the rear of the column to lock the monitor at a desired height. To lock the brake, turn the handle in a clockwise motion until the monitor



does not move. To unlock the brake, turn the handle in a counterclockwise position until the monitor is free to move.



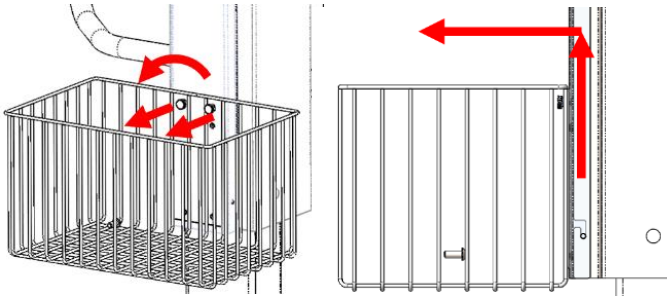
Internally, a gas spring is equipped to assist with adjusting the height of the monitor. To move the monitor, loosen the brake mechanism and grasp the rear handle and either push up or pull down to desired height. Hold the column at the desired height and turn the brake handle clockwise to tighten and hold the monitor in position. For transportation mode the monitor must be lowered to a height of 76" [193cm] or less (measured from floor to topmost part of device) so that it may pass through a doorway.



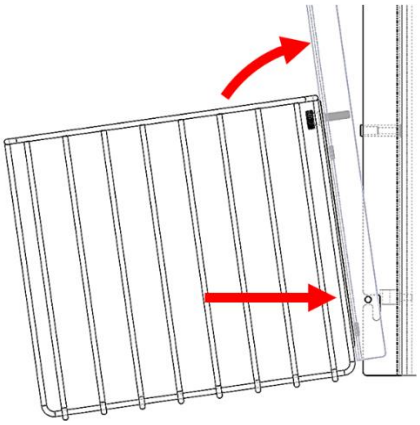
WARNING!

Use caution when adjusting the height of the monitor. Verify no objects are under the monitor when adjusting the height.

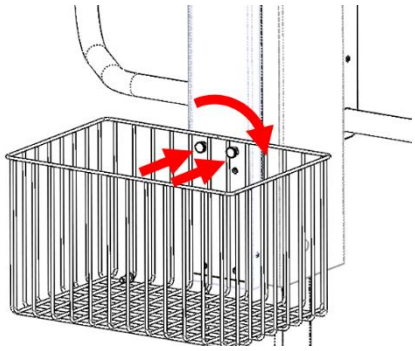
Cable Management



A cable management channel is provided on the front of the device to assist with organizing monitor cables. To remove the channel cover, unscrew the two thumb screws from inside the wire basket. Keep screws as they will be installed later. Lift up on the cable channel and rotate out away from column. Install or remove cables as required. *Wire basket is shown for reference only. Some ilex D models do not have a basket but it may be added at anytime using this procedure.



To re install cable channel cover, place the bottom rod into the bottom slot, then rotate the channel towards the column to engage the top pin, then let it slide down until it stops. Re install the two thumb screws to secure the channel in place.
A wire basket is provided to allow for storage of video and power cables. Use caution not to wrap cables too tight as this may damage cables. Cables should be stored prior to moving the unit.



Video Cables

The ilex D is equipped with industry standard HDMI or DP cables. A few adapters are also provided to assist with connecting to proper video output cables. When connecting video cables do NOT use excessive force to join cables. If there is a large resistance this means that the connectors are not compatible, as connections should be easily assembled.

Monitors

Monitors may vary depending on configuration purchased, for exact specifications of the monitor please refer to instructions for use documentation from manufacturer of monitor set with each cart or contact Image Diagnostics, Inc. Please have serial number available when calling.

Moving and Positioning the cart

The cart is equipped with 4 locking casters that can be individually locked to prevent the cart from moving. The device has two different push handles, one surrounding the monitor and the other off the rear of the column. Cart should be pushed rather than pulled when transported around the facility. Verify the overall height of the cart is less than 76" [193cm] prior to moving between rooms.

To move the cart, unlock all 4 casters by gently pulling up on the caster lever of each caster, then use the front and rear push handles to move the stand. The same handles may be used to move the cart closer or further away from procedure table.



Do NOT move cart over cords or uneven, soft or sloping surfaces. Failure to comply may result in cart instability leading to equipment damage or personal injury.



Use handles to move cart with the help of an assistant to avoid collision with other equipment and walls.

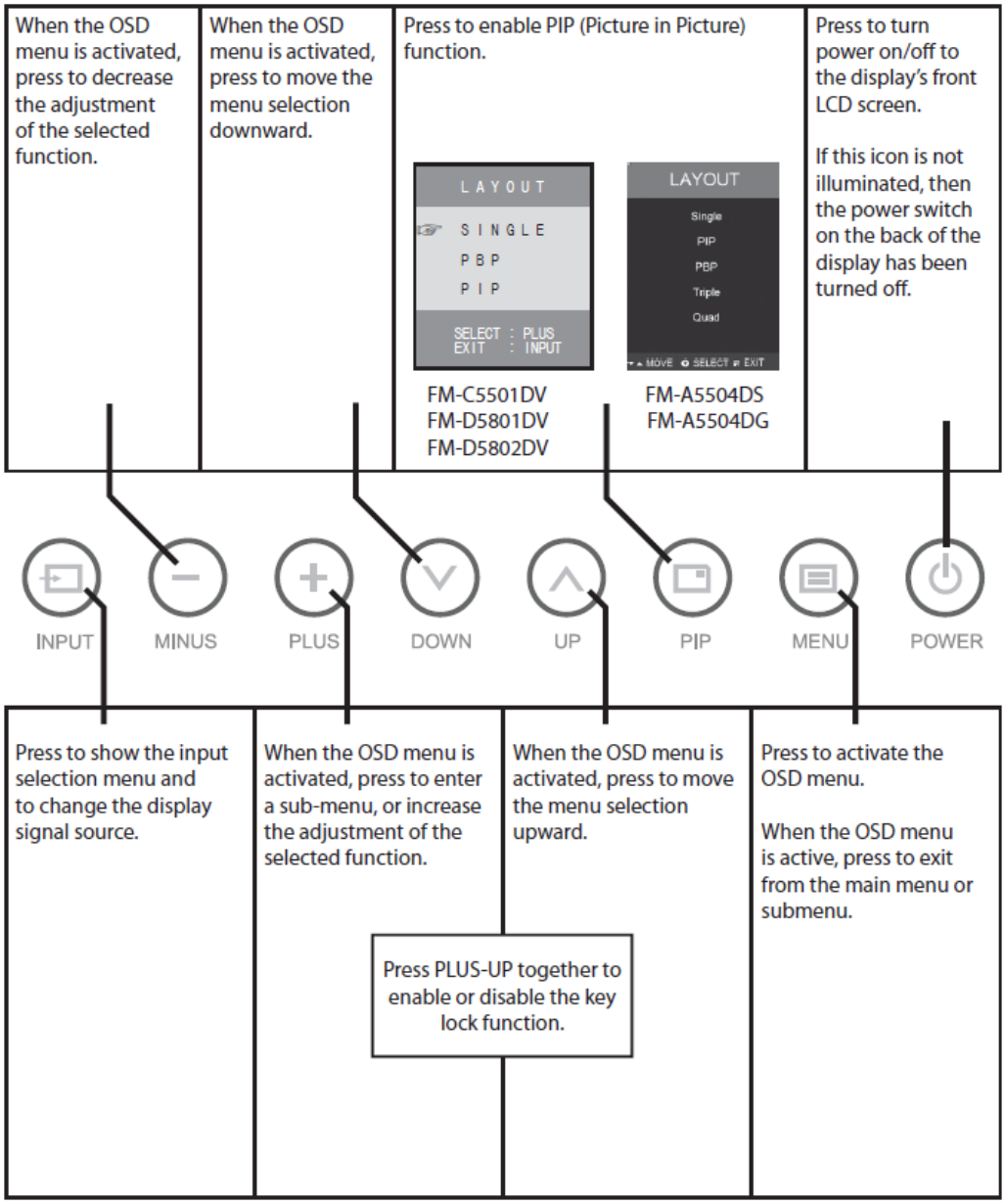
7. Monitor Setup

Monitor user manuals are provided with the ilex D when shipped from the manufacturer. To assist with determining which monitor is equipped, use the following criteria.

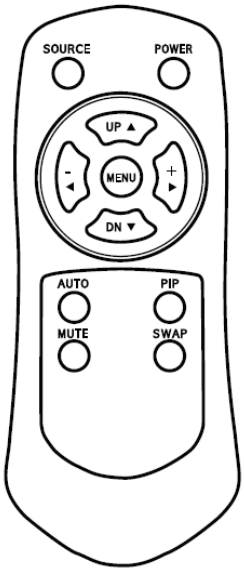
- FSN monitor will have menu buttons on the front bezel.
- Barco Monitor will have menu buttons on the right side of the screen.

FSN Monitor

(from monitor's user guide, #FSN1995-10/2019), menu buttons on front panel of monitor.



Menu buttons are also available on the IR remote provided.



To change monitor layouts, press the PIP button. Hitting the PIP button multiple times will cycle the PIP layouts in this order Single, PIP (picture in picture), PBP (picture by picture), triple, and quad. Alternately press PIP button to show the on-screen menu, then press up or down to select desired layout, then press "+" button to activate the selected layout.

Layouts and source inputs are preset when shipped from IDI. However, it is possible to change source input for a different layout. To do this press the source button, and a green box will appear on screen. This activates the monitor window, if this is not the desired window to change the input, press the source button again and the green window will switch to the next screen window. Once the desired window has been selected, press the up and down arrows and select the desired input. To activate the input press the "+" button to lock in the desired input. These steps can be repeated to change inputs as desired. In cases when changing from DVI 1 to SDI 1, press the source button, get green box window in the correct location, scroll down to DVI 1, and press "-" button, which will switch to DVI 1, then press "+" to activate. This is the same process for all 4 DVI and SDI input channels.

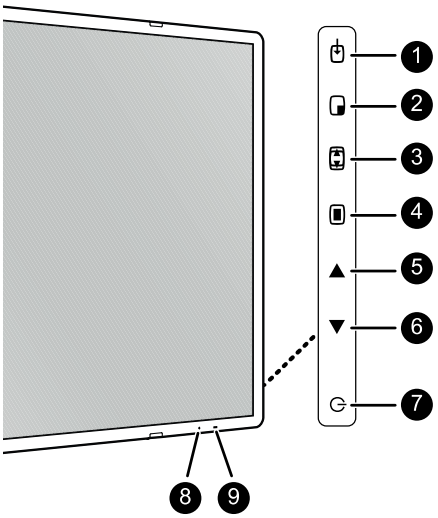
For example, if PBP is displayed with DVI 1 on the left and DVI 3 on the right, but user would like DVI 4 on the left and DVI 2 on the right. The user would click source and verify the green box is on the left-hand side of the screen. Press down until the on-screen menu is highlighting DVI 4, then press "+" to activate the input. The monitor will then put DVI 4 on the left-hand side of the monitor, and DVI 3 will remain on the right-hand side of the monitor. Then the user would hit source, press down until the on-screen menu highlights DVI 2, then press "+" button and the monitor will show DVI 4 on the left, and DVI 2 on the right. This process can be repeated as many times as required.

For additional features and options, please consult monitor operator guide, FSN1995-10/2019, or contact IDI for further assistance.

Barco Monitor

(from the monitor's User Guide #K5902133 (451920612483)-02)

View showing the front controls of the Barco Monitor



1. Input Selection Key
2. Scroll to Desired Page/Down Key
3. Image Zoom/Up Key
4. Brings up OSD Menu /Saves or Enter Key
5. Brightness -/Left Key
6. Enter Key/ Brightness Increase +
7. Stand-by Key
8. Power Mode LED
9. IR Remote (future)

The video input for the monitor should be already set from the factory. If the input is not showing up, press the input button on the side of the monitor to select the correct option.

In some cases, pressing key 7, bottom key, will turn on the monitor.

For any additional features of the monitor please consult user guide provided with the monitor or contact IDI for further assistance.

8. General Cleaning

Tools: Soft cloth and approved cleaner:

- 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. ™

Notes:

- For the cleaning of monitor or electrical equipment, please consult corresponding literature for these devices.
- NEVER use alcohol to clean the monitor.

Procedure:

1.1. Unplug the cart prior to the cleaning process.
1.2. Wipe clean the surfaces of the system with a diluted mixture of mild detergent (listed above) and water, using a soft cloth.
Use a soft cloth to dry any stainless-steel items.

Monitor Cleaning Only

Precautions

- Take care not to damage or scratch the front filter or LCD panel.
- Be careful with rings or other jewelry that can touch the front filter
- Do not apply pressure on the front filter or LCD panel.
- Do not apply or spray liquid directly to the front filter, panel or cabinet as excess liquid may cause damage to internal electronics. Instead, apply the liquid to the cleaning cloth.
- Follow your hospital or clinical institution protocol for the handling of blood and body fluids.
- The display is not disinfected or packed in sterile environment.
- Follow your hospital protocol in case the display needs to be disinfected prior to installation.
- The following products are tested and approved:
  - Misty Clear Lemon 10 Disinfectant
  - Bohle glass cleaner
  - Zep Heavy-duty glass & all surface cleaner
  - Klear Screen
  - Screen TFT (Kontakt Chemie)
  - Incidin Foam (Ecolab)
  - Microzid
  - Mild detergent
  - Isopropyl alcohol with concentration < 5%
  - Household bleach (generic sodium hypochlorite, solutions of 5.25% sodium hypochlorite diluted with water between 1:10 and 1:100)

DO NOT USE: (see next page for list)

DO NOT USE:

- Alcohol/solvents at higher concentration > 5%
- Strong alkalis lye
- Strong solvents
- Acid
- Detergents with fluoride
- Detergents with ammonia
- Detergents with abrasives
- Steel wool
- Sponge with abrasives
- Steel blades
- Cloth with steel thread

Cart Chassis Cleaning

Proceed as follows:

1. Clean the chassis using a soft cotton cloth, lightly moistened with a recognized cleaning product for medical equipment.
2. Repeat with water only.
3. Wipe dry with a dry cloth.
4. Cabinet has been tested for resistance to the following products:
    - Virex Ready-to-use Disinfectant Cleaner
    - Misty Clear Lemon 10 Disinfectant
    - Bohle glass cleaner
    - Zep Heavy-duty glass & all surface cleaner
    - Klear Screen
    - Screen TFT (Kontakt Chemie)
    - Incidin Foam (Ecolab)
    - Microzid
    - Mild detergent
    - Isopropyl alcohol with concentration < 5%
    - Household bleach (generic sodium hypochlorite, solutions of 5.25% sodium hypochlorite diluted with water between 1:10 and 1:100)
    - Precise Hospital Foam Cleaner Disinfect

9. Service & Repair

On this device there is no serviceable parts.

For repairs or replacement of components, please contact Image Diagnostics for Service and Repair at (978) 829-0009.

10. Maintenance

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 (Prior to use)	***Inspect all external cables, and casters.*** ***Replace damaged cables promptly.***

11. Disposal of Components



The ilex D is constructed mostly of steel, aluminum and copper which are easily recycled. Some components can be disassembled before recycling.

COMPONENT	ITEM	RECYCLING GROUP
Chassis	Column and base	Metal (Steel and Aluminum)
Casters	Locking caster	Metal Plastic
Cables	Windings	Copper

12. Specifications

Mode of Operation

- For continuous use

Type of Equipment:

- Class I (as defined by IEC 60601-1, 3rd Edition)
- Monitor is 60601 listed
- Monitor stand tested to applicable 60601 standards

Electrical:

- Supply Voltage: Per monitor, see monitor manual

Environmental:

- Operating Temperature Range: +32°F to +95°F (0°C to +35°C)
- Operating Humidity Range: 10% to 85% relative humidity, noncondensing.
- Operating Pressure Range: 700 hPa to 1060 hPa.
- Transport & Storage Temperature Range: -4°F to +140°F (-20°C to +60°C).
- Transport & Storage Humidity Range: 20% to 80% relative humidity, noncondensing.
- Transport & Storage Pressure Range: 700 hPa to 1060 hPa.
- **NOT suitable for oxygen rich environment**

Product features included with Ilex D:

- Individual cables for monitor power and video input.
- Detachable AC power cord.

Physical Characteristics:

- Steel Frame with height adjustable monitor
- 35 5/8” (90.64cm) wide x 29 1/2” (74.8cm) deep footprint of the base.
- The height of the unit from the floor to the top of the monitor bar is 64 1/4” (163.1cm) at its lowest elevated position and up to 84 1/4” (214cm) at its highest elevated position.

Typical Positions of Operator during use:

- To move the cart, the operator may stand in front or to the rear of the device and push on the handles.
- For transporting cart, the casters can be placed in the lock or unlock position.

13. ME Equipment and Systems

For RF data on monitor please contact Image Diagnostics, please have ilex D serial number ready for faster assistance. The serial number plaque is located on lower side of the upper column assembly.

14. 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.