idi
imagediagnostics.com

ilex

Mobile Video Integration System



Operator Manual

For units using MSV2 video signal router

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

Made in the USA

L280-0975 REV G

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. The information provided in this manual may be updated at any time. Customers may access the most current IFU documentation online at www.imagediagnostics.com.

For technical assistance, call IDI at (978) 829-0009. Be prepared to give the complete model and serial number found on the data plate on the rear of the ilex base at the time of contact.

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

Made in the USA

This video integration device manufactured by Image Diagnostics, Inc. complies with applicable FDA performance standards contained in 21CFR at date of manufacture.

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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.



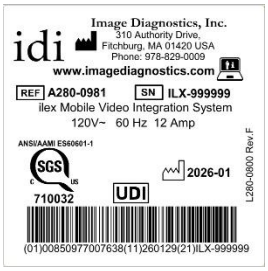
Read the Manual



SGS North America, Inc. Testing Service.



Alternating current.



Data plate with device serial tag.



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.



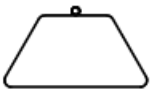
Electric Shock hazard. Information or instructions shown near this symbol must be adhered to in order to prevent a potentially hazardous situation which if not avoided, could result in death, personal injury or damage to the equipment.



Recyclable material, some material can be recycled rather than discarded



Emergency Stop Switch - Stops elevation motion.



Maximum allowable Weight Limits.



Protective Ground.
This is the common tie point between the AC cord ground, frame ground, and controller ground.



For safety and proper function of equipment, connect power cord to a properly grounded outlet.



Model of device.



Serial Number of device.



Date of manufacture of the device.



Location where device was manufactured.

2. Intended Use

Totally mobile solution for video display and image management. Configurable control of images from C-arm fluoroscopy, endoscopy, patient monitoring, etc

3. 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 system be familiar with the equipment operation, transport and all documentation supplied by IDI.

- The ilex system is intended to be used in typical clinical or research environments in accordance with national standards.
- When transporting the ilex system from room to room, it is imperative that the device be moved in the storage position which is with the monitor all the way down.
- When in use, the ilex system should be plugged into a medical grade electrical outlet.
- The ilex system 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.

4. Safety Hazards



CAUTION!
Do NOT store liquids above any electrical devices.



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!
Do NOT mount a display monitor weighing more than 96 LB (44 kg).



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



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



WARNING!
Connecting any electrical equipment to the socket outlets of the ilex system creates a new ME (Medical Electrical) Equipment unit possibly resulting in a reduced level of safety. Once this is done, the responsible organization must refer and comply to the standard IEC 60601-1.



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

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 system. Use special precautions regarding EMC when these carts are installed with any external accessories, maintained or operated adjacent or stacked with other equipment. EMC operating specifications for these tables can be located in the Specifications and Requirements section of this manual. 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:

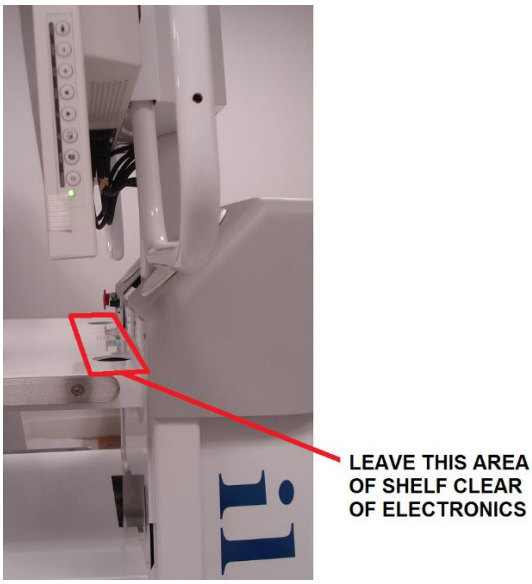
1. Verify that the equipment is the cause by turning the system off and on.
2. In the event of unintended motor actuation, immediately remove power to the equipment by engaging the E-stop switch.



5. Basic Setup Instructions

Electronics Installation

All electronic devices are to be installed according to their perspective manufacturer's user manuals.



When installing electronic accessories or placing other items on the top shelf, keep these items at least 2 inches (50mm) away from the vertical edge below the speakers (as shown above to allow room for the monitor when it is in the lowest position and to ensure easy access to controls.



Plugging a cauterization device into the internal power strip may cause the monitor to shut down temporarily. Plug a cauterization device into a separate wall outlet. A separate branch circuit may be needed.



Always position the cart in a way that the electrical outlet its power cord is plugged into can be easily accessed in the event that it needs to be disconnected quickly.



Use caution when raising or lowering monitor to prevent collision with personnel, walls, ceiling and other equipment.

Moving and Positioning

Center Lock Pedal



Pedal Positions
Steer Float Lock

Caster Modes:

Total Lock: Step down on the right end of the caster brake pedal with the red dot to lock both the swivel and roll. Put the casters in this mode during use to prevent any horizontal movement of the unit.

Free Float: Position the pedal so that it is horizontal which will allow the casters to swivel and roll in any horizontal direction.

Steer Lock: Step down on the left end of the caster brake pedal with the green dot to lock the direction of the two casters closest to the pedal making steering easier when relocating the unit.



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



Move unit only with monitor fully lowered into transport position.



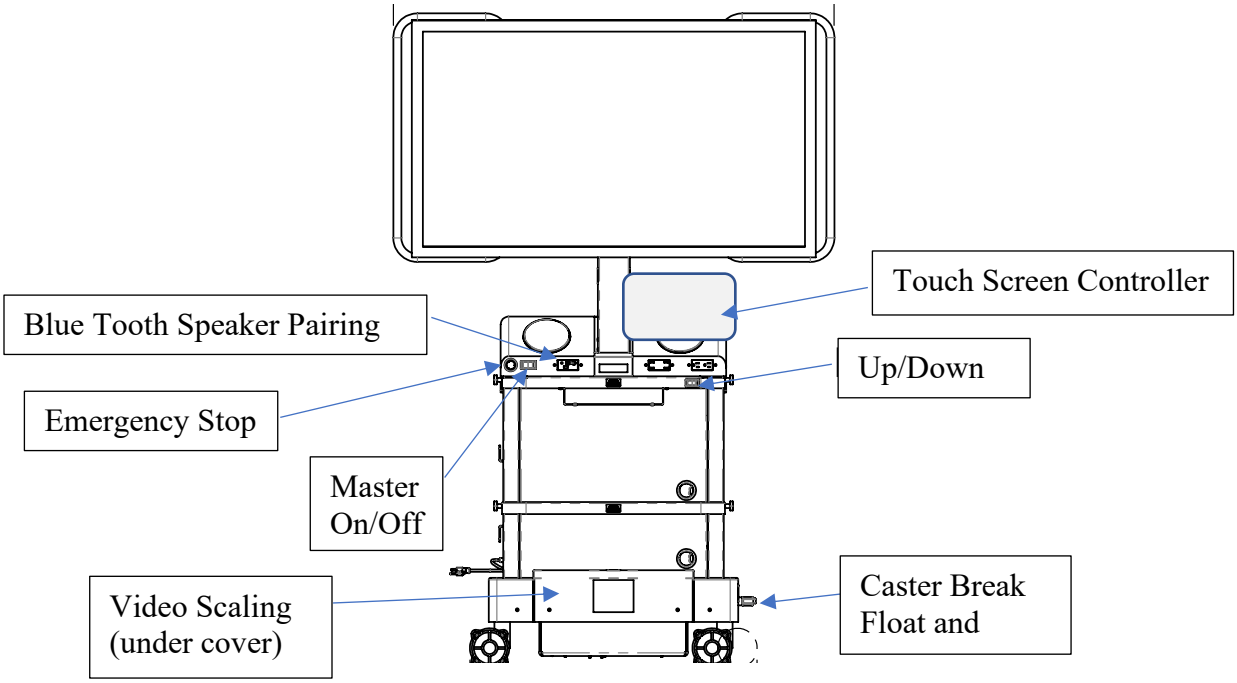
Casters must be in TOTAL LOCK while system is in use.



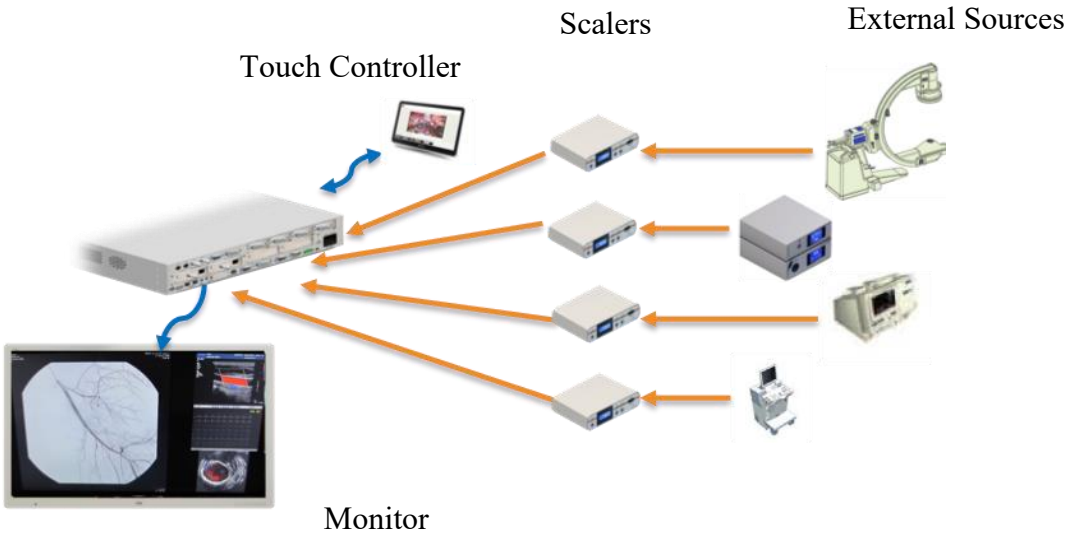
Do NOT move cart over cords or uneven, soft or sloping surfaces. Failure to comply may result in cart instability leading to equipment damage or personal injury.

6. Instructions for Operation

System Components of the ilex



Electrical Components



Barco Monitor Controls

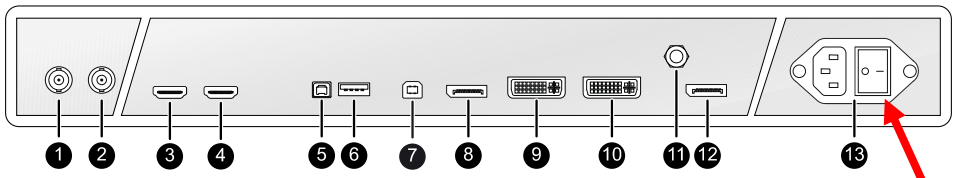


Image 2-3

View showing rear of Barco Monitor

1. SDI in
2. SDI out
3. HDMI2 2.0 in
4. HDMI1 2.0 in
5. +5 VDC – 2A power out
6. USB 2.0 type A interface
7. USB 2.0 micro-B interface
8. Main (Right) DisplayPort in
9. DVI-D in
10. DVI-D out
11. Potential Equalization pin (POAG)
12. 2nd (Left) DisplayPort in
13. 100-240 VAC (50-60 Hz) power in

On/Off Power Switch

To switch on/off your display:

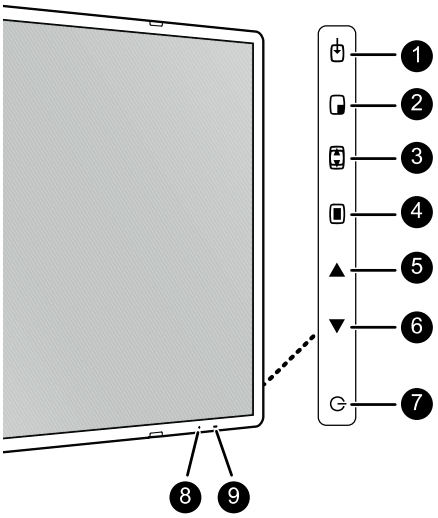


1. Power on/off your display using the mains switch located on the back of the display. While your display is on, press and hold the stand-by key for approximately 1 second to put the display in the stand-by mode.



2. While your display is in stand-by mode, press and hold the stand-by key for approximately 1 second to activate the display.

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)

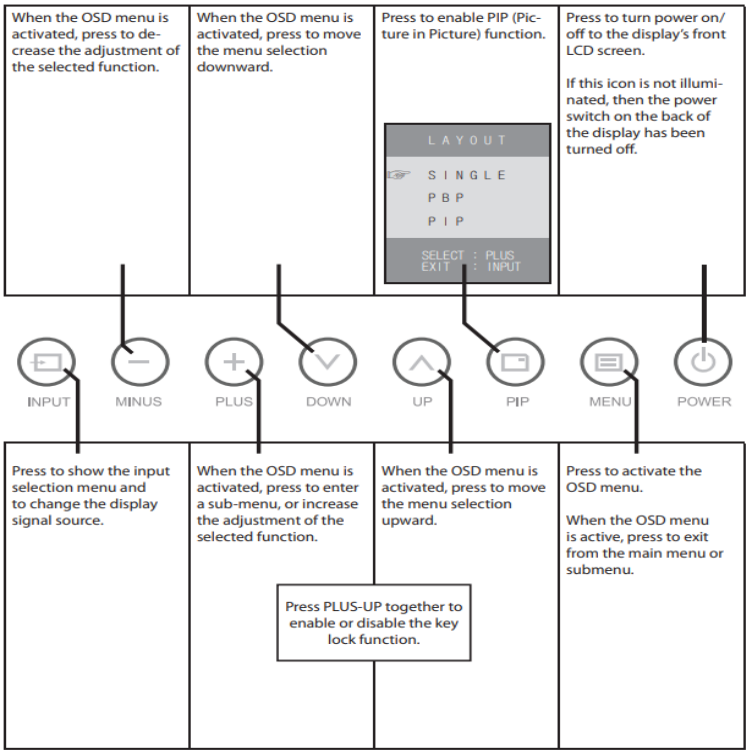
Please refer to Barco's User Guide accompanying the monitor for additional functionality and settings of the monitor.

FSN Monitor Controls



Controls on FSN Monitors are located either on the right side or the bottom of the monitor.

Touchscreen icons, located in bottom right corner of the LCD display, allows the user to make adjustments to various display parameters using the On Screen Display (OSD) system. Slightly touch any icon to activate all of the icons.



Please refer to FSN's User Guide accompanying the monitor for additional functionality and settings of the monitor.

Features

Maximum Number of Clinical Images Displayed

Up to 4

Video Inputs – Total of 5

4 DVI (possible)
1 SDI (possible)
1 VGA (possible)
4 HDMI® (possible)
2 DisplayPort™ (possible)
1 Direct PIP DVI (possible)

Video Output to monitor

1 HDMI 2.0

Max Resolution

3840x2160@60hz

4 Fixed Display Modes

Single, Side by Side, Quad, 1 Big 3 Over

4 Variable Custom Display Modes

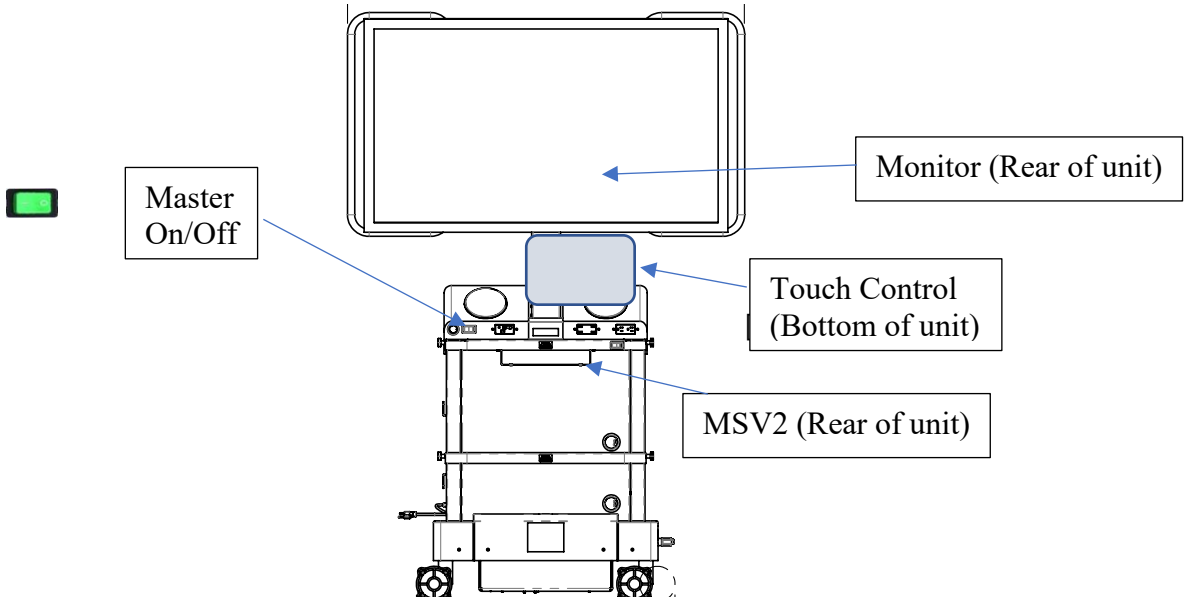
Programed 1 big 2 over, 1 big 2 over PIP, 1 top 2 bottom

Image Quality Options

Cropping image sizing, aspect lock, over lay, contrast, layout rotation and brightness adjustment

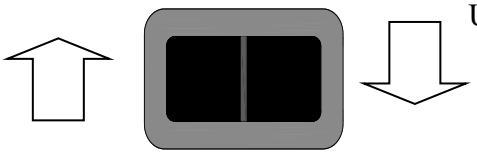
Power Switches

In the event power switches have been toggled "OFF", please use the following to turn power on to the different components. To power up the monitor there is a switch located on the rear of the monitor where video inputs are. To power up the MSV2 4k reach behind the tray on the top shelf on the right side of the box and there is a power on/off switch. The touchscreen monitor has a power button on the bottom of the unit, press and hold to turn on. Under normal use these buttons can stay in the "ON" position.





On/off Button, use the green toggle switch/thermal breaker to turn the system on and off and to reset the breaker.



Up/Down switch, use the monitor elevation toggle switch to adjust monitor height.



Maximum duty cycle of the actuator is 10% or 2 minutes of continuous use followed by 18 min. not in use. Exceeding this limit could damage the device and require replacement.



When the red emergency stop button is pushed in, elevation of the monitor is not allowed. **<u>Always</u> push the red emergency stop button when moving the ilex system to reduce the risk of damage to the unit**. Reset by rotating the button a quarter turn.

Switches

To use the speakers with an external audio device with Bluetooth® capability, perform the following steps:



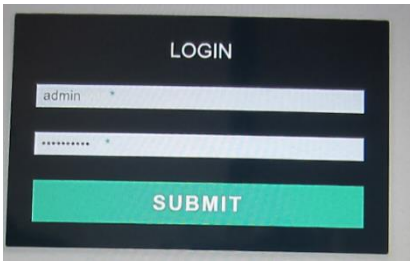
1. Ensure that the green toggle power switch is on and lit up.
2. On the cart's audio control panel, ensure that the "INPUT SELECT" switch is set to "BT."
3. Turn the power on to the Cart's audio system by turning the rotary Volume Control knob clockwise so that the red PWR light lights up.
4. If the system doesn't automatically sync, press in the white Volume Control knob button and hold it in for 3 seconds (or until the 'BT' Bluetooth® indicator light begins to blink. (You may also hear the system prompt say 'Power ON').
5. Turn on a Smart Device and locate a list all available Bluetooth devices. The Network Name will appear as 'PYLEUSA' on your Smart Device list. No password is required to connect, but if you are prompted, enter '0000' (4 zeroes).
6. As the Smart Device and the cart are synchronizing, the LED indicator light on the cart will blink progressively quicker and you will hear the system prompt 'Paring.'
7. When a successful connection is established, the LED indicator light on the cart will stay lit without blinking and you will hear the system prompt, 'Your device is connected', indicating that the unit is ready to transmit audio.

(Note: Audio Devices can also be connected to the Cart using cables that have a 3.5mm Aux Jack or a ¼in. Microphone Jack. Move the "Input Select" switch to the corresponding format and adjust the volume as desired.)

Navigating Video Output Menus on Tablet

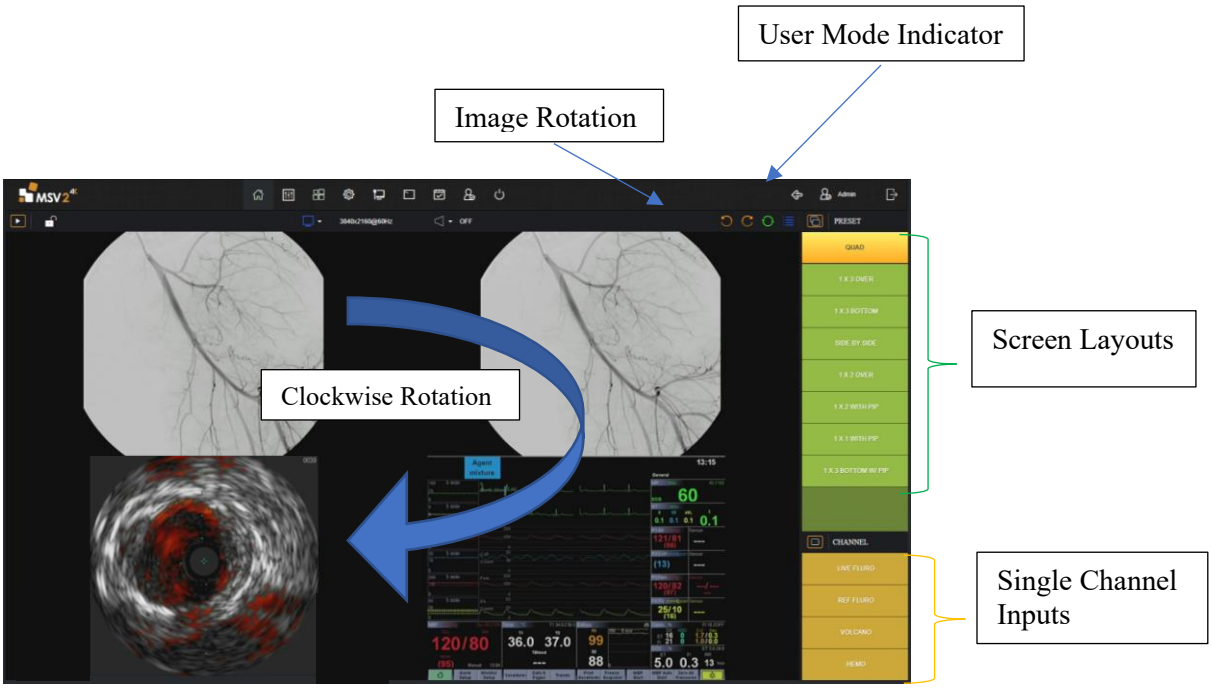
Verify that all cables are connected, and devices are powered on. Ilex power switch will illuminate green when powered up and will power up all devices.
Note: In the event the screen is blank preform a system check to see that all devices are powered up. The MSV2 4K will show LED lights on the front panel of the box itself. The monitor will bootup with a visual indicator on screen, as well as the buttons in lower right will light up. Touchscreen tablet will have a visual on-screen indicator.

Once tablet and MSV2 has powered up a login screen should appear on the tablet, as shown to the right. Touch the submit to log into the program. If there is an error or the MSV2 has not loaded fully, please restart the tablet by pressing and holding the white power button on the bottom of the tablet. Upon restarting the login screen should re appear. The program should look similar to the image at the bottom of the page.



On the right side of the screen each of the preset layouts is displayed (Quad, 1x3, 1x2 etc). Touch each of the layouts until the desired layout is reached. To get a full screen of 1 of the channel inputs select one of the four channel inputs in the lower panel on the right side of the screen.

Basic Layout navigation is done in the "Guest" mode of the system. Changing or programing of the layout format is available only in the "Administrator" mode which is defined in the installation manual. In the upper corner of the screen there is a red, yellow and green set of arrows. When pressed the screens will rotate, clockwise, or counterclockwise. **The green arrow will reset the screens to the default position.**

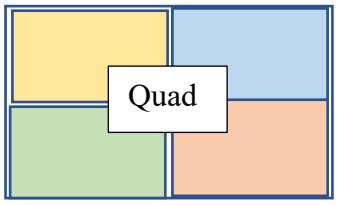


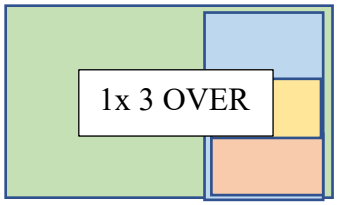
Note: video screens will be slightly different depending on video inputs.

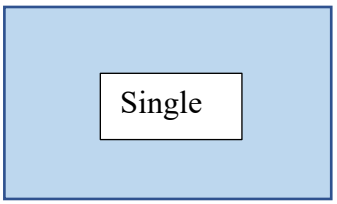
Ilex Typical Layouts

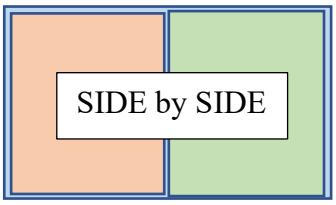
Layouts can be customized in the Administration section of the Operating Guide. The Most common layouts have been programed onto your system. The Clinical image can be directed to a location by illuminating the image and dropping it into the layout location (some optimization maybe required).

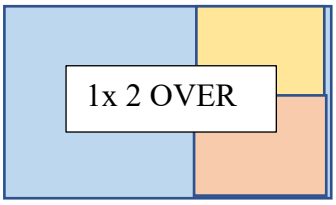
Typical Layout Examples:

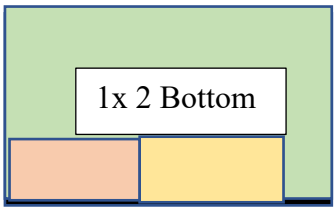


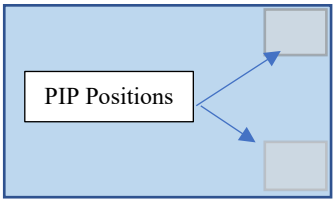












Your system has ghosted PIP positions that will allow for a Cell phone timer clock be ported into the system

StableCable™ cable management system

IDI's StableCable cable management system keeps external video signal cables firmly locked in place to prevent their terminations from being pulled out of the panel on the unit. It also tucks the external cables neatly along the back of the ilex neatly out of the way. The StableCable is located on the back of the ilex just below the external cable ports. Instructions on how to use the system is as follows:

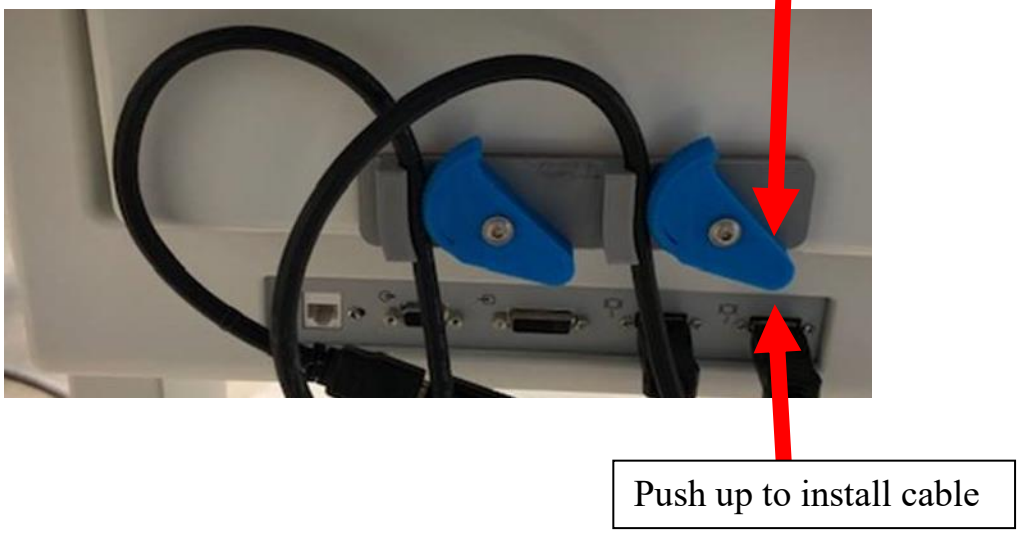


Operating Instructions to insert cable:

1. Press downward on blue cam's tapered end to allow room to seat cable in groove of grey base.
2. Lay cable into groove.
3. Push upward on blue cam's tapered end gently until teeth of blue cam is pressing against cable.
4. Grab cable hanging down below StableCable and gently pull down until blue cam is snug against cable.

Operating Instructions to remove cable:

1. Push downward on blue cam's tapered end until cam is clear of cable.
2. Remove cable from groove of grey base.



7. Batteries

The ilex system is designed to be used when powered with a hospital grade AC outlet. Battery backup to elevate the monitor is available for emergency or transportation only. When AC power is applied, the actuator backup battery will begin charging until the battery reaches full capacity at which time, the charging will taper off. If the unit loses AC power, the monitor elevation function will automatically switch to battery back-up mode. An audible tone is sounded when using an operator control function if the battery charge is low.

Batteries are located inside the base and can be accessed from the front of the unit.



WARNING

Actuator Batteries are ***not*** automatically maintained to original maximum charge requiring periodic testing and replacement if necessary.



CAUTION

Batteries are not to be changed by the operator. Refer to authorized technician.

Local procedures may be in place for proper disposal or recycling of batteries.

For more information about batteries, such as battery life, production codes and disposal, see the Linak® website.

Battery Part Number K000-0379

Note: The battery will not charge if the system is not plugged in or the green toggle switch/thermal breaker is off.

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 shelf equipment, please consult corresponding literature for these devices.
- NEVER use alcohol to clean the monitor.

Procedure:

1.1. Unplug the ilex system 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.
1.3. To clean speaker grilles, simply pull off and wash.



Large Monitor Cleaning FSN monitors only

Products FM-C5501DV, FM-A5502DC, FM-D5801DV, For Barco Tablet and Barco monitor see next section

Precautions

- Before cleaning, switch the display in stand-by position to prevent the control touch panel from being activated inadvertently by sweeping over the front filter. In stand-by position the touch panel cannot be activated by just sweeping over them. To switch the display on again, you must press the stand-by key again.
- 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 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.

- Front Filter
- Proceed as follows:
    - 1. Remove dust with a dry, lint-free, non-abrasive soft cotton cloth.
    - 2. Remove fingerprints or grease using a lint-free, non-abrasive soft cotton cloth that is lightly moistened with plain water or a mild commercial glass cleaning product suited for coated glass surfaces.
    - 3. Gently wipe dry with a dry cloth.
- 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:

- 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

Cabinet

Proceed as follows:

1. Clean the cabinet 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

Large Monitor Cleaning Barco Only

Cleaning Instructions

- Be sure to unplug the power cord from the mains when cleaning your LCD monitor.
- Take care not to scratch the front surface with any hard or abrasive material.
- Dust, finger marks, grease etc. can be removed with a soft damp cloth (a small amount of mild detergent can be used on the damp cloth).
- Wipe off water drop immediately.

Possible cleaning solutions

- 250 ppm chlorine solution
- NaCI solution 0.9% – Sodim chloride 00-236
- Bacillol AF
- 1.6 percent aqueous ammonia
- Cidex® (2.4 percent glutaraldehyde solution)
- Sodium hypochlorite (bleach) 10 percent
- "Green soap" (USP)
- Like Cleansafe® optical cleaning liquid
- Isopropanol
- Haemosol solution (1% in 1 liter water)
- Chlorehexidine 0,5% in 70% Ethanol

Teguar Tablet cleaning

WARNING: Unplug the power cable from the mains power input before cleaning the display.
CAUTION: Take care not to damage or scratch the front glass or LCD. Be careful with rings or other jewelry and do **NOT** apply excessive pressure on the front glass or LCD.
CAUTION: Do **NOT** apply or spray liquid directly to the display as excess liquid may cause damage to internal electronics. Instead, apply the liquid to a cleaning cloth.

To clean the display

Clean the display using a sponge, cleaning cloth or soft tissue, lightly moistened with a recognized cleaning product for medical equipment. Read and follow all label instructions on the cleaning product. In case of doubt about a certain cleaning product, use plain water.

- Possible Cleaning Solutions:Mild soap-and-water solution
- Clorox Disinfecting Wipes
- Clorox Healthcare Bleach Germicidal Wipes
- Clorox Commercial Solutions Hydrogen Peroxide Cleaner Disinfectant Wipes
- Lonza Disinfectant Wipes

- Lysol Brand Clean & Fresh Multi Surface Cleaner (20% cleaner solution to water ratio
- Purell Professional Surface Disinfectant Wipes
- Sani-Cloth Prime Germicidal Disposable Wipes
-

• Like Cleansafe® optical cleaning liquid

Do not use following products:

- Alcohol/solvents at higher concentration > 70%
- Methyl or Ethyl > 35%
- Thinner or Benzine
- Strong alkali lyes
- Strong solvents
- Acids
- Detergents with fluoride
- Detergents with ammonia at concentration > 1.6%
- Abrasive cleaners
- Detergents with abrasives
- Steel wool
- Sponges with abrasives
- Steel blades
- Cloth with steel threads
- 409

9. Service & Repair

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, castors and controls for wear and damage. Replace damaged cables promptly.***

Semi-annually	***Check battery operation by disconnecting the AC power and running the Monitor up and down.***
Annually	***Inspect movement of the monitor to ensure that it is smooth and continuous. Inspect monitor mounting hardware for loose fasteners.***

11. Disposal of Components



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

COMPONENT	ITEM	RECYCLING GROUP
Actuator	Spindle and Motor Housing	Metal (Steel and Copper) Plastic
	Cable	Copper
Control Box	PC Board	Electronic
	Plastic Housing	Plastic
	Cable	Copper
	Transformer	Copper
	Batteries	Lead Acid Batteries
Isolation Transformer	Windings	Copper

12. Specifications

Mode of Operation

- For continuous use

Type of Equipment:

- Class I (as defined by IEC 60601-1, 3rd Edition
- CENELEC EN 60601-1
- ANSI/AAMI ES60601-1
- IEC60601-1 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 50 Hz (1800VA).
- Current Rating: Less than 12 Amps @ 120 Vac or 7 Amps @ 230 Vac
- Isolation transformer limits leakage current to 50µ
- Isolation transformer is certified to meet Medical Safety Standards ANSI/AAMI ES60601-1

Environmental:

- Operating Temperature Range: 50°F to 95°F (10°C to 35°C)
- Operating Humidity Range: 20% to 80% 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**
- **NOT suitable for flammable anesthetic mixtures**

Product features included with ilex system:

- Thermal protector AC input module
- Medical grade outlet strip for Monitor & Ancillary power.
- Individual cables for monitor power and video input.
- 10.1" medical touch screen interface
- Detachable 20 foot (6m) AC power cord.
- Battery backup for monitor positioning any time.

Physical Characteristics:

- Steel Frame with telescoping steel square tube supporting a 55" or 58" LED monitor.
- 31" (78.75cm) wide x 29" (73.66cm) deep footprint of the base.
- The height of the unit from the floor to the top of the monitor is 72" (18.4cm) at its lowest elevated position and up to 92" (235cm) at its highest elevated position.

Typical Positions of Operator during use:

- In front or side of the cart to operate elevating monitor, accessing the shelves and operating any of the controls located on the front panel.
- On the side of the cart that has the Caster Lock Pedals when transporting cart or locking/unlocking caster functions.

13. ME Equipment and Systems

Table 1 per 5.2.2.1.c of IEC 60601-1-2: 2007 for CISPR 11 ME Equipment and ME Systems.

Guidance and manufacturer's declaration –electromagnetic emissions		
The ilex system is intended for use in the electromagnetic environment specified below. The customer or the user of the ilex system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance.
RF emissions CISPR 11	Group 1	The ilex system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ilex system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2 per 5.2.2.1.f of IEC 60601-1-2: 2007.

Guidance and manufacturer's declaration –electromagnetic immunity			
The ilex system is intended for use in the electromagnetic environment specified below. The customer or the user of the ilex system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ilex system requires continued operation during power mains interruptions, it is recommended that the ilex system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	3 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 4 per 5.2.2.2 of IEC 60601-1-2: 2007.

Guidance and manufacturer's declaration –electromagnetic immunity

The ilex system is intended for use in the electromagnetic environment specified below. The customer or the user of the ilex system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	[V_1] V	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	[V_2] V	$d = \left[\frac{3.5}{V_2}\right]\sqrt{P}$
			$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	[E_1] V/m	$d = \left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ilex system is used exceeds the applicable RF compliance level above, the ilex system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ilex system.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ILEX system

The ilex system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ilex system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ilex system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.79	3.79	7.27
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.