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Image Diagnostics, Inc.

Manufacturers of Quality Medical Products

Connexus



Setup & Operator Manual

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

Made in the USA

L280-0921 REV B

OVERVIEW

This manual pertains to the specified devices only and does not intended 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. The device is designed to transmit video signals to a secondary monitor for fluoroscopic or radiographic procedures.

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 or send fax to (978) 829-0027. Be prepared to give the complete model and serial number found on the data plate on the base of the Connexus box at the time of contact.

This video transmission 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.



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.



Presence of non-ionizing electromagnetic radiation.



Model of Connexus.



Serial Number of Connexus.



Date of manufacture of the device.



Location where device was manufactured.

2. INTENDED USE & ESSENTIAL PERFORMANCE

The Connexus video transmission system is used by the medical industry to transmit imaging from “C-arm” style radiological imaging equipment to a secondary monitor within the procedure room. With the unit permanently installed on the wall, video source cables will be directly inserted into this product. The source will be run through a signal converter (FSN DAU) and transmitted to the secondary monitor by a hardwired cable.

Connexus is non-sterile reusable device not intended for use in the sterile field. Connexus is not intended to be used in a MR environment. Connexus is not tested for use with high frequency surgical equipment, cardiac defibrillators, or cardiac defibrillator monitors. Connexus is also not designed to be used within the vicinity of diathermy equipment. Finally, this device is may not be used in connection with life support equipment. **Do NOT use Connexus in MR environment, or with cardiac defibrillators, or within the vicinity of diathermy equipment.**

3. SAFETY INSTRUCTIONS



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.

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 or Toll Free (877) 304-5434.
The fax number for IDI is (978) 829-0027.

4. SAFETY HAZARDS

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



WARNING!

This equipment has not been tested for use with high frequency surgical equipment, cardiac defibrillators, or cardiac defibrillator monitors. Use with such equipment may cause patient burns, explosion hazards or electrical shock to the patient or operator.



WARNING!

To avoid electric shock, plug the electrical power cord into a properly grounded hospital grade outlet!



WARNING!

This product may be used in conjunction with x-ray equipment. This constitutes potential exposure to harmful x-rays for both the patient and operator. Be sure to use proper radiation shielding.

5. PACKAGE CONTENTS

Contents

- Connexus Electronics Enclosure
- HDMI Cables (2x) with adapters for DVI and Displayport
- Sync on Green (SOG) Cables with BNC Connectors (2x)
- Connexus Installation Manual #L280-0920
- Connexus Setup & Operation Manual #L280-0921
- Installed items – see install guide L280-0920
 - Connexus in conjunction with:
 - Ilex32
 - Ilex55
 - Fixed monitor

6. PRECAUTIONS

- Always treat product with care and keep it in a clean and dust free environment
- Do not expose the product to liquid, moisture, or humidity
- Do not use the product in temperatures above 40°C when unit is operational
- Do not drop or throw the product
- Do not attempt to disassemble or modify the product. Only authorized personnel should perform service on the product
- Do not use different AC adapters
- Replace damaged equipment, if damage is found call IDI representative. Do not attempt to operate the system before thoroughly reading these instructions for use. For future reference, keep these documents in a convenient, easily accessible place.

7. SETUP INSTRUCTIONS

7.1. Installation

- For wall mounting instructions please see Connexus Installation Manual #L280-0920.



- External electrical power connection and disconnection is through the AC power cord and outlet. The Connexus unit will operate on 110 V~.

When external electrical power is applied to the box the internal power strip will illuminate, indicating the device is powered on. Look through the hole in the bottom of the unit to see if the amber light is powered up, if press the switch to turn on the power strip



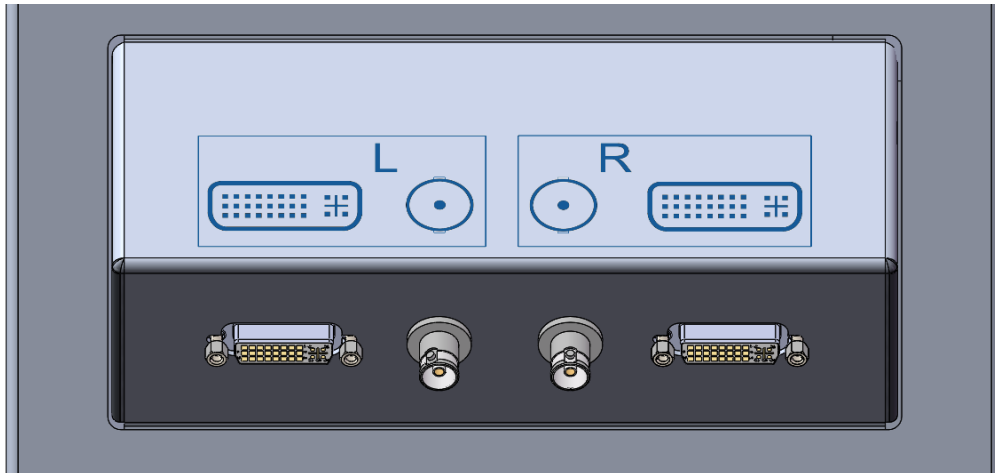
WARNING!
To avoid electric shock, plug the electrical power cord into a properly grounded hospital grade outlet!

- The electrical power outlet used should be visible and accessible to the user. The electrical power cord should be routed where it will not be subject to damage or be a tripping hazard.
- Check that the ground pin on the electrical cord plug is in good condition before each time that it is plugged in.

8. INSTRUCTIONS FOR OPERATION

The following instructions highlight features as well as demonstrate how the Connexus unit should be used. Please follow in sequential order for best results.

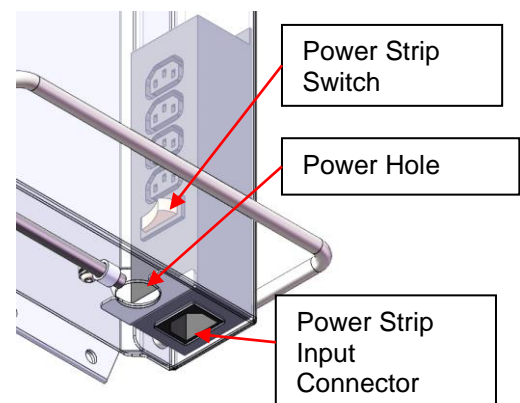
8.1. Video Panel



- Connexus is equipped with 4 video ports, 2 DVI and 2 SOG connector ports
- Only one source can be transmitted per L and R channel, either a DVI or SOG signal
- In the event two video sources are plugged into the same channel (L or R), the first source plugged in will be utilized
- Install video input cables into one of the ports on the video panel
- Video adapters allow for connection to DVI, HDMI, SOG, and DisplayPort
- Install video input cable into one of the ports on the video panel.
- Adapters are also provided to connect to DVI, Displayport, HDMI or SOG.

8.2. Powering up Connexus box

- To power up the Connexus box, plug a medical grade power cord with an IEC 320 C/14 connector into an appropriate hospital outlet.
- Verify the Connexus box is powered up by looking under the unit to see if the amber light is illuminated on the power strip
- If the Connexus box is not powered up, look under the unit and reach into the power hole with a finger and flip the power strip switch to the “ON” position. This will be indicated by an illuminated orange LED when power is on.
- Once the power strip is turned on it does not need to be turned off again.

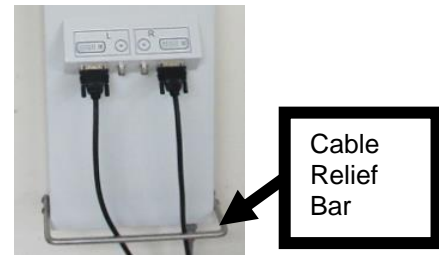


8.4. Connexus DVI ports

- There are two DVI outputs on the top of the Connexus enclosure
- Each port is marked, L for Left and R for Right. These also correspond to the Left and Right channel marked on the video panel
- Video signal input cables are to be connected into the video panel on the front of the Connexus enclosure
- DVI video signal output cables are to be connected into the top of the Connexus enclosure and routed to the designated monitor

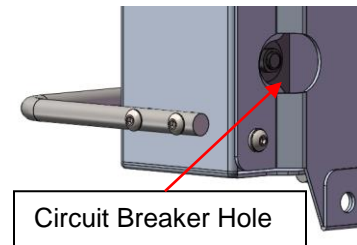
8.5. Cable Relief Bar

- Connexus is equipped with a cable relief bar to reduce the strain on cables
- Video cables should pass between the Connexus box and the inside of the bar when plugging in
- The cable relief bar also directs cables down towards the floor to reduce trip hazards as much as possible



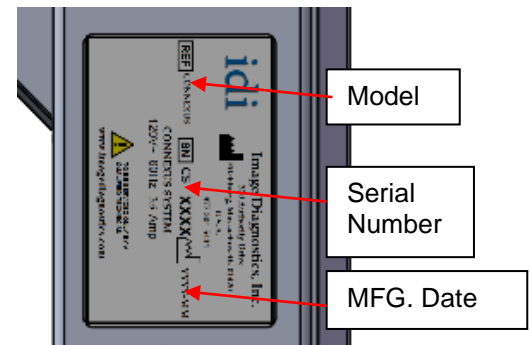
8.6. Power surge

- In the event of a power surge, the power strip has a resettable circuit breaker built into it. To access the breaker, locate the bottom right side of the unit about 2 inches from the bottom and reach your finger between the wall and the back of the Connexus box. Once you feel an opening, press the button just inside the opening to reset the power strip.
- To verify the power strip is powered look at the bottom of the Connexus unit and into the power hole to see that the orange LED on the power strip is illuminated.



8.7. Serial Number and Part Number

- For reference and troubleshooting, please have the serial number and part number ready. The identification label can be found on the right side of the Connexus box.



9. GENERAL CLEANING

Connexus is NOT intended to be used in the sterile field. After each week, the Connexus unit should be properly cleaned. Do not use harsh abrasives, solvents, sprays, or corrosive agents. If fluid or other contaminants make contact with the Connexus unit, it should be properly cleaned at the end of the procedure.

APPROVED AND TESTED DISINFECTANT CLEANERS FOR CONNEXUS:

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

APPROVED AND TESTED GENERAL-PURPOSE CLEANERS:

- Simple Green ™ cleaner.

CLEANING STEPS FOR CONNEXUS:

- Disconnect the unit from the AC power outlet.
- Wipe off any excess fluids with a water dampened cloth or sponge.
- Clean the Connexus using an approved cleaner listed above.
- Clean the Connexus box with Simple Green ™ cleaner.
- Gently rub with a soft clean cloth until dry.

10. 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.

10.1. Recommended Periodic Performance Checks

Daily	Inspect all external cables, and video ports, for wear and damage. Damaged cables must be replaced promptly. The <i>Connexus</i> uses a medical grade power cord which is not user serviceable. Replacement must be performed only by a qualified service technician.
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10.2. Service & Repair Statement

Only qualified personnel should perform repairs on this equipment. Please read this entire document before performing any diagnostics or repairs. 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.

11. TROUBLESHOOTING

Please see table below for other troubleshooting issues

Problem/Symptom	Possible Cause	Remedy
1. Video is not showing up on monitor	1. No Power to Connexus enclosure 2. Video source is unplugged 3. Monitor is using wrong input source	1. Check electrical outlet. Verify power strip is turned on 2. Check to make sure video cables are fully inserted at all connections 3. Verify correct input source is being used on monitor

12. DISPOSAL OF COMPONENTS



IDI Connexus is made up of mostly steel, copper and aluminum parts which are easily recycled. It is recommended that some components be disassembled before disposal for recycling. The table below lists components typically found in IDI products but varies with model and options.

COMPONENT	ITEM	RECYCLING GROUP
Connexus Box	Housing Cables Relief Bar	Aluminum Copper. Stainless Steel
Cables	Cables	Copper

13. PRODUCT DATA

Connexus Wall Mounted Unit	Aluminum box with Aluminum and steel components inside
Direct Connexus Wall Mounted Unit	10.5" W x 48.5" H x 5.75" D

14. SPECIFICATIONS

Mode of Operation

- For continuous use

Type of Equipment:

- Class II (as defined by IEC 60601-1, UL 60601-1, EN 60601-1)

Electrical:

- Supply Voltage: 120±5% Vac 60Hz
- Current Rating: Less than 10 Amps.

Environmental:

- Operating Temperature Range: 32°F to 122°F (0°C to 50°C).
- Operating Humidity Range: 10% 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.

15. WARRANTY

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

Connexus will have a 5-year life cycle with 1-year warranty on parts.



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



Or call IDI at (978) 829-0009 or Toll Free (877) 304-5434.
The fax number for IDI is (978) 829-0027.