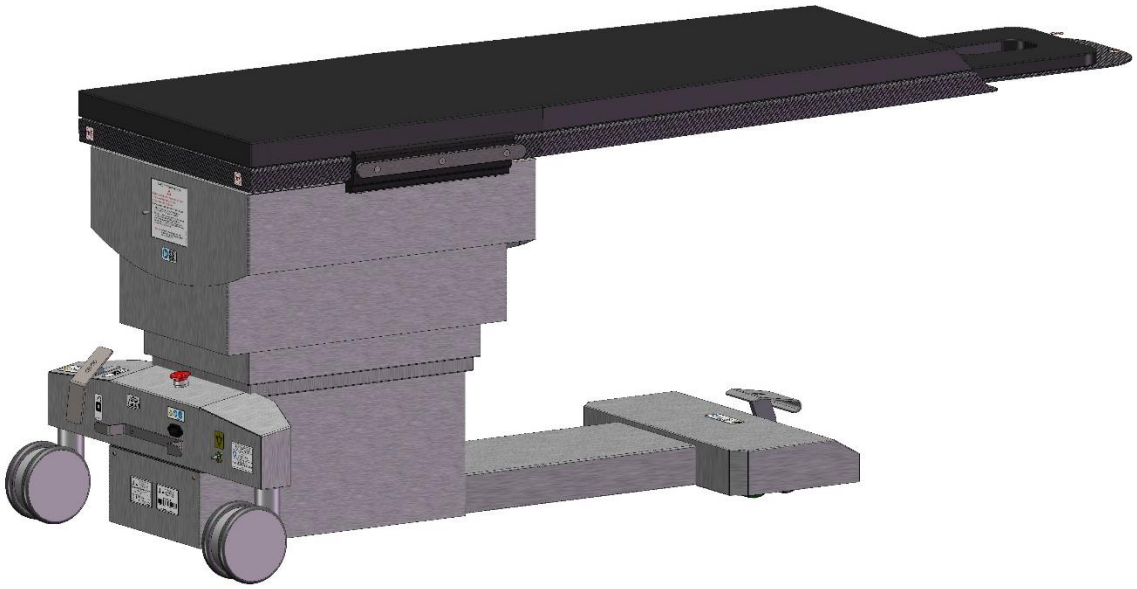
Aspect ISO-Drive

Mobile Imaging Table



User Manual

Made in the USA

CE

OVERVIEW

An Aspect ISO DRIVE along with any accessories shall be referred to in this manual as "this equipment." This manual is not intended as a substitute for certified training for the use of this equipment. The operation of this equipment should be limited to qualified medical personnel who have been trained in the use of medical equipment.

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

This equipment complies with applicable FDA performance standards contained in 21CFR at date of manufacture.

OWNER RESPONSIBILITIES

The owner of this equipment is responsible to ensure system compatibility, the qualifications of operators and maintenance personnel. Operators 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 equipment 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 this equipment. Operating practices and safety for this equipment are the sole responsibility of the owner and operators. Image Diagnostics, Inc. assumes no liability or responsibility for personal injury or damage resulting from misuse of this equipment.

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

CUSTOMER SUPPORT

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

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

Table of Contents

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.

Emergency Stop Pushbutton.

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.

Equipotential Terminal of the table which provides for a connection between the table and the equipotential bus bar of the facility.

Recyclable material.

There is the potential of exposure to harmful x-rays. Be sure to read and comply with all warnings.

Not made with natural rubber latex.

Not for Patient Transport. The Table should not be relocated with a patient on it nor should it be used to move a patient.

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

Patients must be loaded from the side of table. There is possible tilting or instability if patient is loaded onto the pedestal end of table or the imaging end of the table.

EC REP

European Authorized Representative:

Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

REF

Model of Table.

SN

Serial Number of Table.

Item complying to Type B applied part per IEC 60601-1.

Date of manufacture of the device.

Location where device was manufactured.

Alternating Current (AC).

CPR (Cardiopulmonary resuscitation)

This symbol denotes that the product contains electronic devices and cannot be disposed of with household waste. This product cannot be included in municipal waste and must be disposed or recycled according to local waste regulations.

CE

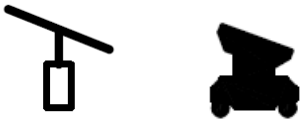
Indication of European Conformity for sale in the European Economic Area (EEA).

Elevate tabletop.

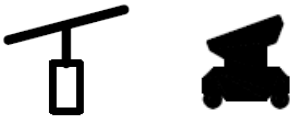
Lower tabletop.

Tilt tabletop's imaging end up (Trendelenburg).

Tilt tabletop's imaging end down (Trendelenburg).



Roll tabletop clockwise.



Roll tabletop counterclockwise.

2. INTENDED USE & ESSENTIAL PERFORMANCE

The *Aspect* IS0-Drive is a mobile multipurpose imaging table used by the professional healthcare industry for pain management, endoscopy, G.I. and general procedures. The table is used to support and position the patient as required by the medical procedures. It is a "C-arm" style table to allow radiological imaging equipment to be used in conjunction with the table. The table has backup battery power which should only be used temporarily for necessary function of the table if the external power supply is disrupted.

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 for use as either a fluoroscopic or radiographic table. Available motions for the tabletops on these tables are in the vertical, Trendelenburg, and can roll in the lateral direction.

This table is intended for all patients that do not weigh more than the maximum allowable weight as labeled on the table itself. This table is also a reusable device. The conditions for reuse are that it functions properly based on the criteria stated in section 13.1 of this manual and that it has been cleaned per section 12 of this manual along with the protocols of the facility the device is being used in.

Personnel intended to operate the table are physicians, clinicians, nurses and assistants that are present for the procedures performed on the table. Those individuals must be qualified and trained to use the table according to the policies and procedures of the facility the table is being used in.

3. SAFETY INSTRUCTIONS

Review the SAFETY HAZARDS and OPERATING INSTRUCTIONS before operating table

- ✓ All persons using this equipment must fully understand its operation instructions, emergency procedures, capabilities including total range of motion and be aware of all potential safety hazards.
- ✓ This manual should be accessible to all personnel installing, operating, or servicing this equipment.
- ✓ Only a qualified technician may install or service this equipment.

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

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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

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

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 equipment 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.

WARNING!

If an antistatic path is required, use this equipment on an antistatic floor.
Use only the Patient Mattress Pad supplied with the table.

CAUTION

Do not leave patient unattended on table.

WARNING!
Safely position and secure patient onto table.
Do not exceed table weight capacity of 600 pounds (272kg).

CAUTION
When lying on the table, patient must be restrained at all times. The restraining straps are not intended to restrain an uncontrollable patient.

CAUTION
The carbon fiber top is subject to damage or possible damage from impact from other objects.
Take caution when moving the table or using power driven diagnostic equipment around table. Collisions with nearby equipment can cause equipment damage or patient harm. Regular inspection of the tabletop is necessary for the safety of patient and operator.

CAUTION
Do not use table for patient transport.

CAUTION
During operation of the table, if any unusual sounds and/or erratic movement is observed, immediately discontinue use of the table.

CAUTION
Do not place or store any containers or large items underneath the tabletop. As the tabletop is descending, contact with an obstruction may cause permanent damage to the table.

5. EMC (Electromagnetic Compatibility) STATEMENT

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment including this equipment. Use special precautions regarding EMC when these tables are installed, operated, and maintained. EMC operating specifications for these tables are in the SPECIFICATIONS section of this manual (Section 17).

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

WARNING: This equipment should not be used adjacent to or stacked with other medical electrical equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

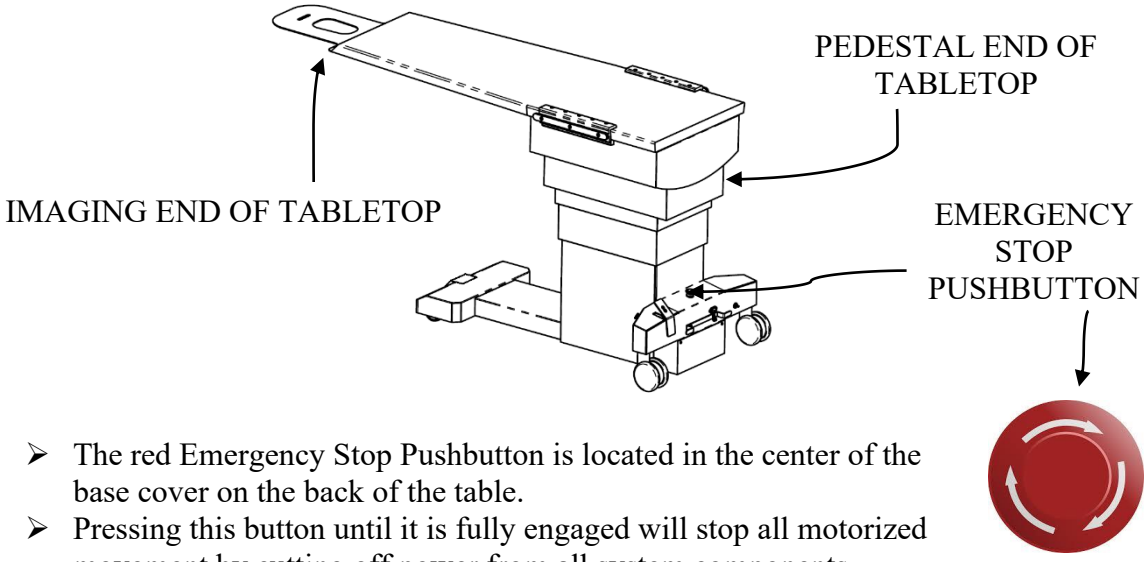
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment, including cables connected to the table. Otherwise, degradation of the performance of this equipment could result.

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

If this equipment receives excessive electromagnetic interference, motion controls for the table may be slow or unresponsive to user inputs. In this event,

1. Verify the cause by turning nearby equipment off and retest motions. (Note: All motions will be slowed when operating on battery backup as compared to full AC power)
2. If this problem is not resolved, immediately remove power to the equipment by engaging the Emergency Stop Pushbutton as shown in section 6 of this manual.
3. Notify IDI customer service using the contact information in the section 18 of this manual.

6. EMERGENCY STOP PUSHBUTTON



- The red Emergency Stop Pushbutton is located in the center of the base cover on the back of the table.
- Pressing this button until it is fully engaged will stop all motorized movement by cutting off power from all system components.
- RESET: Restore the electrical functions by rotating the button a quarter turn.

7. SETUP INSTRUCTIONS

7.1. Setup

- Hand operated controls for the movement of the tabletop are included with the table. The operator should become familiar with the controls before using them.
- External electrical power connection and disconnection is through the AC power cord and outlet. The table will operate on 110 V~, 230 V~ or on internal battery backup power.

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.

- When the table is not connected to AC power, the table will automatically switch to backup battery mode. The table should only be used under backup battery power temporarily for necessary function if the external power supply is lost.
- It is recommended that AC power be applied for a minimum of 8 hours every day to keep a proper charge on the batteries and achieve maximum battery life. Batteries are constantly being charged during normal use when connected to AC power.

When the table is not in use and not connected to AC power, the Emergency Stop Pushbutton must be fully engaged to prevent the battery from being discharged and to safely power off the equipment.

8. INSTRUCTIONS FOR TABLE OPERATION

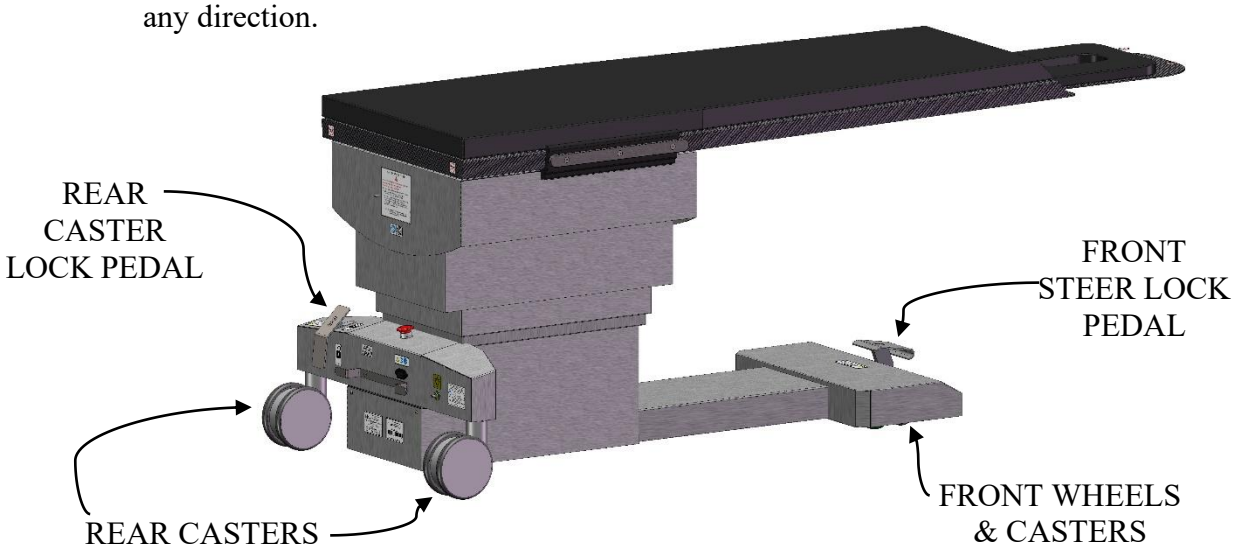
8.1. CASTER LOCKING AND UNLOCKING SETTINGS

The rear casters can be configured in a locking setting which totally locks all motion of the rear casters and an unlocked setting which allows the rear casters to swivel freely. The front wheels can be set to roll unidirectionally forwards and backwards or swivel freely.

WARNING!

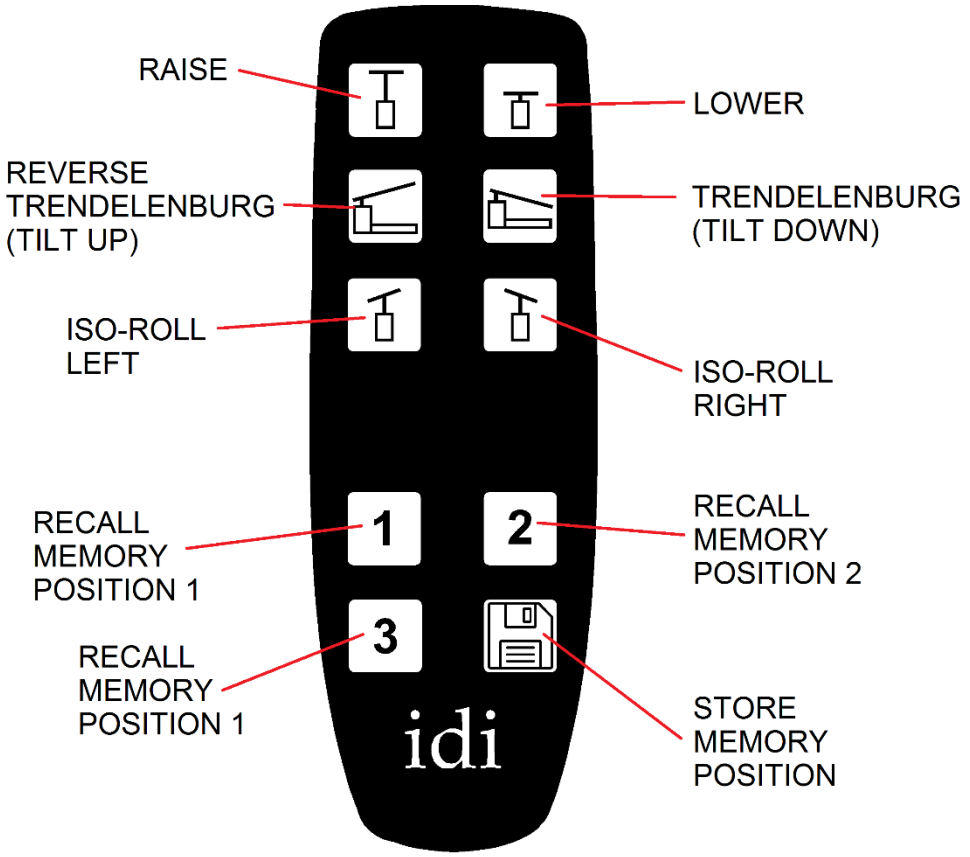
Before loading a patient onto the table, always set the base caster pedals in BOTH the front AND the rear to their "LOCK" positions. Failure to do so could result in death or serious injury.

- The Table is in the "LOCK" setting when the Rear Caster Lock Pedal is pushed forward on the **TOP** half until it is fully engaged and when the Front Steer Lock Pedal is pushed **DOWN**. The Rear Casters will be totally locked and will not roll in any direction. **Always lock all casters in this way before loading the patient onto the table.**
- The table is in the "UNLOCK" setting when the Rear Caster Lock Pedal is pushed down on the **BOTTOM** half until it is fully engaged and when the Front Steer Lock Pedal is pulled **UP** to disengage the unidirectional wheels and engage the free swiveling casters. The Rear and Front Casters will be allowed to roll and swivel in any direction.



8.2. TABLE MOTION CONTROLS

WARNING!
The Handset Control is always active when connected to a powered-up table.



- When using the Handset Control shown above, each button must be held down to get continuous motion of the tabletop. Motions will stop as soon as the button is released.
- To store the current position of the table to a memory location press “Store Memory Position” then the desired recall button; 1, 2, or 3.
- To recall a memory position, hold the desired recall button continuously until the table motion stops.

9. PATIENT PREPARATION

9.1. Preparation for Patient Use

- New Installation: This equipment will need to be properly cleaned before patient use as it will inevitably come into contact with contaminants during shipping, unpacking, storage, and installation.

- After initial use, this equipment will need to be properly cleaned between uses with patients as it will inevitably come into contact with contaminants during procedures. Refer to section 13 of this manual for cleaning instructions and approved cleaning substances.

9.2. Patient Loading

CAUTION
If the tabletop is struck hard enough, it may slide to reduce damage to the carbon fiber top.

WARNING!
Before loading a patient onto the table, always set the base caster pedals in BOTH the front AND the rear to their "LOCK" positions. Failure to do so could result in death or serious injury.

- Patients must be loaded from the side of table. There is a possibility of tilting, instability and/or tipping if patient is loaded onto the pedestal end or the imaging end of the table.

- To reduce potential motion during patient transfers with larger patients, move the tabletop lateral (side to side) in the direction the patient will be moving until the limit of the tabletop travel is reached, release the Panhandle Tabletop Float Break to re-engage the break and then transfer the patient onto the Table.

9.3. Preparation for Performing CPR

- Return table to level position and lower table position to a comfortable height before performing CPR on a patient.

10. STANDARD ACCESSORIES

10.1. Patient Mattress Pad for Tabletop.

The Patient Mattress Pad is held in place by hook and loop fasteners. To remove the pad, simply pull pad up gently to remove. Replacement pads are supplied with new self-adhesive fasteners installed and new adhesive backed mating pieces for the tabletop. Peel off old fasteners from Tabletop. Peel off the protective paper and carefully put new pad into position. Apply pressure to complete installation.

Note: Pad complies with California Technical Bulletin 117.

10.2. Head Positioning Pads.

Four Head Positioning Pads are provided with the ISO-Drive's unique tapered top, these are held in place by hook and loop fasteners. To remove the pad, simply pull pad up gently to remove. Replacement pads are supplied with new self-adhesive fasteners installed and new adhesive backed mating pieces for the tabletop, when replacing Head Positioners peel off old fasteners from Tabletop. Peel off the protective paper and carefully put new pad into position. Apply pressure to complete installation. When changing Head Positioners, it isn't necessary to replace the mating fastener on the tabletop

- 1" Thick positioner with facial opening

- Full height positioner with facial opening

- Wedge positioner with facial opening

- Full height positioner without facial opening

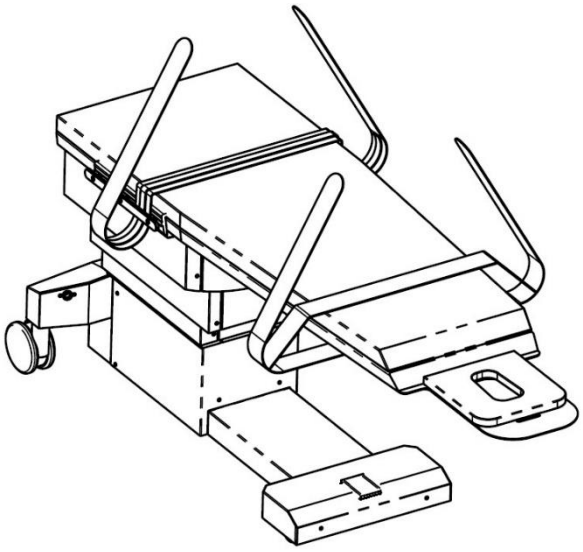
Note: Positioning pads comply with California Technical Bulletin 117.

10.3. Patient Restraint Straps.

WARNING!

Strap configuration is recommended; however, patient restraint is a case-by-case condition. Please refer to the facility's policy on restraining a patient.

The Patient Restraint Straps can be used in two different ways depending on where the strap is to be located along the length of the Tabletop. If the strap is to be used on the end of the table that has the two long accessory rails, then the whole strap drapes over the Table Top, hangs down between the rails and the tabletop and wrapped over the outside of the rails to meet over the top of the table. If the strap is to be used along the rest of the tabletop, slide the strap over the end of the table with the thin part of the strap over the Tabletop and the thicker part under the tabletop. The ends of the strap meet over the top of the table and connect with hook and loop fasteners.



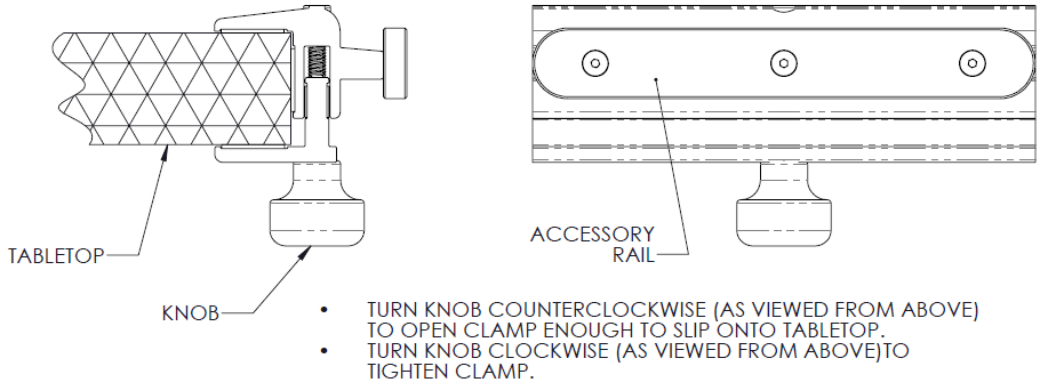
10.4. Arm Comfort Strap.

A strap is provided to rest the arms of the patient for their comfort. This strap is passed through the slot at the head end of the tabletop, exposed beyond the Head Positioner, using the hook and loop to size the strap appropriately the patient can rest their arms either above or below the facial recess of the tabletop.

11. ADD-ON ACCESSORIES

11.1. Clamp-on Accessory Rail #A100-1007

Fits on left or right side of table. 6” length. (European version with 10mm x 25mm metric rail is available).

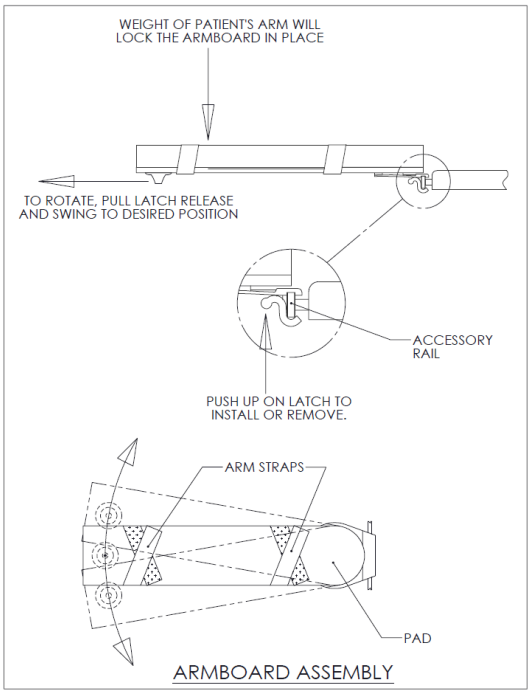


11.2. Vascular Access Arm Board (VAB) #A100-2244

One-piece, extra wide carbon fiber arm board for vascular access and fistula application procedures. Mounts to table by laying across the width of the tabletop underneath the Patient Mattress Pad and uses a hook pin to hold in place. Includes arm board, pad, and restraint strap.

11.3. Quick Release Rail Mount Arm Board #A310-056 (requires Clamp-on Accessory Rail)

Radiolucent materials. Includes arm board, pad and restraint straps. (European version for 10mm x 25mm metric rail size is available)

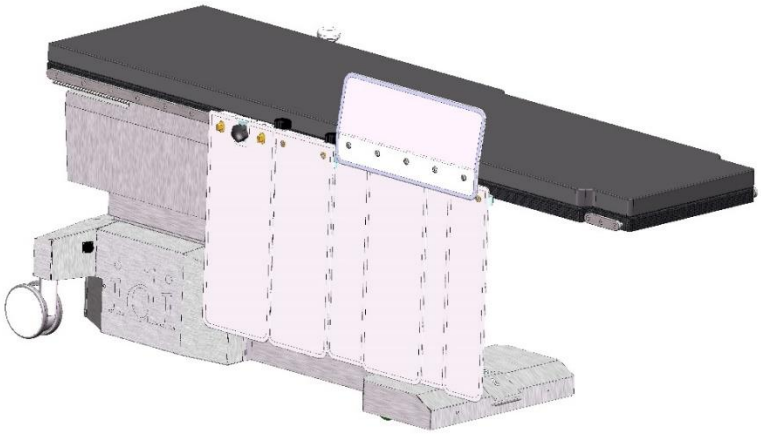


11.4. Arm Board, Shoulder Mount #A310-059

Carbon fiber base. Mounts to table by sliding under Patient Mattress Pad. Includes padded arm board and restraint strap.

11.5. Articulating Radiation Shield #A610-051

Articulating with removable upper panel. Panels are lead-free. Can be used on either side of table. Mounts to both the accessory rail and the tabletop by clamp.



11.6. Clamp-on Radiation Shield #A610-080

Fixed shield with integrated clamp system. Panels are lead-free. Can be used on either side of table. Clamps to the tabletop sides. Snap-on upper section above level of tabletop is removable. Shown mounted on Aspect 100RT, similar mounting on Iso-Drive.

12. GENERAL CLEANING

After each medical procedure, the table should be properly cleaned. Do not use harsh abrasives, solvents, sprays, or corrosive agents. Some accessories may come with individual cleaning instructions.

APPROVED AND TESTED DISINFECTANT CLEANERS FOR TABLE:

- 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 DISINFECTANT CLEANER FOR RADIATION SHIELD:

- Scrubbles® (Infab Corporation)
  https://www.infabcorp.com/apron-cleaning/

APPROVED AND TESTED GENERAL PURPOSE CLEANERS:

- Simple Green ™ cleaner.

CLEANING STEPS FOR TABLE:

a) Move the tabletop to a level horizontal position.
b) Lower the tabletop to its lowest position.
c) Disconnect the table from the AC power outlet and press the Emergency Stop Pushbutton.
d) Power cord, Handset Control and Foot Control cords must be plugged in at the table base to protect the inside of the connectors from debris.
e) Remove all pads and accessories.
f) Wipe off any excess fluids with a water dampened cloth or sponge.
g) Clean the Tabletop and accessories using an approved cleaner listed above.
h) Clean all pads according to the instructions attached to the pad.
i) Clean the table frame, castors, and base with Simple Green ™ cleaner.
j) Thoroughly rinse Patient Mattress Pad, Tabletop and Accessory Rails with water.
k) Gently rub with a soft clean cloth until dry.

CLEANING STEPS FOR RADIATION SHIELD:

a) Lift off the upper section and lay it flat before using the recommended cleaner in an adequately ventilated area.
b) Apply approved cleaner to one side at a time and allow to stand a few minutes.
c) Scrub with a soft bristle scrub brush. Do not let the solution dry before rinsing.
d) Rinse with water and a damp cloth.
e) Scrub and rinse again, if necessary.
f) Remove the main section of the Radiation Shield and clean in the same manner.
g) Attach Radiation Shield back onto Tabletop.
h) Install upper panel of Radiation Shield.

13. MAINTENANCE, SERVICE & REPAIR

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

- ✓ This individual must have access to this manual and the proper tools.
- ✓ Lubrication of this device is *not* required.

13.1. RECOMMENDED PERIODIC PERFORMANCE CHECKS

Daily	Inspect all external cables, controls, and the tabletop for wear and damage. Damaged cables must be replaced promptly. The *Aspect ISO-Drive* uses a medical grade power cord which is not user serviceable. Replacement must be performed only by a qualified service technician.
Weekly	• Check battery operation by disconnecting the AC power and running the tabletop up and down. • Run the tabletop through its full range of motions to help keep the actuators from sticking or freezing up.
Quarterly	Battery must be charged every 3 months only while in storage.
Semi-annually	Inspect carbon fiber tabletop.

13.2. SERVICE & REPAIR STATEMENT

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

13.3. REINITIALIZE ACTUATOR CONTROLLER

If it is necessary to reinitialize the actuator controller, indications described in section 13. Troubleshooting, follow these procedures

To clear errors press and hold the Trendelenburg Up and Trendelenburg Down buttons simultaneously for 15 seconds, release and wait for 15 seconds.

To reinitialize the actuators, press and hold the Elevate Up and Elevate Down buttons for 15 seconds, release and wait 15 seconds, then press the Trendelenburg Down button to fully retract Trendelenburg to the down position. This will move slower than normal which is correct. Wait 15 seconds and full function is restored.

14. TROUBLESHOOTING

Note: The motion of the Tabletop is fully controlled by user interface with switches, buttons. In the event of a loss of these motions it is expected that the Tabletop will remain stationary without any unwanted movement.

Problem/Symptom	Possible Cause	Remedy
1. Table controls are not functioning.	1. No Power. 2. Battery is depleted. 3. Emergency Stop Pushbutton engaged. 4. Control connection. 5. Electromagnetic Interference. 6. Actuators uncalibrated.	1. Check electrical outlet. 2. Connect to AC Power. 3. Reset Emergency Stop Pushbutton. 4. Service Controller connections. 5. Refer to Section 5 of this manual. 6. Reinitialize Actuator Controller with Handset Control. (Section 13.3)
2. Table does not elevate.	1. No Power. 2. Battery is depleted. 3. Emergency Stop Pushbutton engaged. 4. Hand Control Failure. 5. Control connection. 6. Actuator(s) uncalibrated. 7. Actuator Failure.	1. Check electrical outlet. 2. Connect to AC Power 3. Reset Emergency Stop Pushbutton. 4. Replace Hand Control. 5. Service Control connections. 6. Reinitialize Actuator Controller with Handheld Control. (Section 13.3) 7. Replace Elevate Actuator.
3. Trendelenburg motion does not operate.	1. No Power. 2. Battery is depleted. 3. Emergency Stop Pushbutton engaged. 4. Hand Control Failure. 5. Control connection. 6. Actuator(s) uncalibrated. 7. Actuator Failure.	1. Check electrical outlet. 2. Connect to AC Power. 3. Reset Emergency Stop Pushbutton. 4. Replace Hand Control. 5. Service Control connections. 6. Reinitialize Actuator Controller with Handheld Control. (Section 13.3) 7. Replace Trendelenburg Actuator(s).

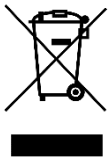
Problem/Symptom	Possible Cause	Remedy
4. ISO-Centric Roll does not operate.	1. No Power. 2. Battery is depleted. 3. Emergency Stop Pushbutton engaged. 4. Hand Control Failure. 5. Control connection. 6. Actuator(s) uncalibrated. 7. Actuator Failure.	1. Check electrical outlet. 2. Connect to AC Power 3. Reset Emergency Stop Pushbutton. 4. Replace Hand Control. 5. Service Control connections. 6. Reinitialize Actuator Controller with Handheld Control. (Section 12.3) 7. Replace ISO-Roll Actuator.
5. No response to Handset.	1. No Power. 2. Battery is depleted. 3. Emergency Stop Pushbutton engaged. 4. Handset Control Cable damaged. 5. Actuator(s) uncalibrated. 6. Device Failure.	1. Check electrical outlet. 2. Connect to AC Power. 3. Reset Emergency Stop Pushbutton. 5. Reinitialize Actuator Controller with Handset Control. (Section 12.3) 6. Replace faulty device.
6. Elevate, Trendelenburg and ISO-Roll slow or unexpected movement.	1. Running on Battery Power. 2. Actuator(s) uncalibrated.	1. Connect to AC Power. 2. Reinitialize Actuator Controller with Handset Control. (Section 12.3)

15. DISPOSAL OF COMPONENTS

IDI medical tables are 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
Actuators	Spindle and Motor Housing Cable	Metal (Steel and Copper) Plastic Copper
Control Box	PC Board Plastic Housing Cable Transformer Battery	Electronic Plastic Copper Copper Li-Ion Battery
Hand Controls	PC Board Housing Cable	Electronic Plastic Copper
Table Base	Frame Casters Covers	Metal (Steel) Plastic and Steel Stainless Steel

Electronic waste and batteries



Electronic components and devices must be disposed of according to local waste regulations. The symbol (left) denotes that the product contains electronic devices and cannot be disposed of with household waste. This product cannot be included in municipal waste and must be disposed or recycled according to local waste regulations.

16. PRODUCT DATA

Tabletop	Low attenuation carbon fiber tabletop and pad.
Tabletop surface	61cm x 155 cm (24 in x 84 in) standard.
Imaging range along table length	172.7 cm (58 in)
Trendelenburg (tilt)	Approx. ±12°
ISO-centric roll	Approx. ±12°
Tabletop height range:	81.3 cm to 111.3 cm (32 in to 44 in) without pad.
Patient capacity	272 kg (600 lbs.) without tabletop extensions.
Emergency Stop Pushbutton.	
Multi-caster/2 Position Multi-lock system: Total Lock, Steer.	
Handset motion control standard.	
Backup battery power.	

17. SPECIFICATIONS

Mode of Operation

- For continuous use with short time loading.
- Duty Cycle: 10% (2 min on/18 min off).

Type of Equipment:

- Class II Type B applied part (as defined by IEC 60601-1, UL 60601-1, EN 60601-1, CAN/CSA 601.1-M90, IEC 60601-2-46:1998.
- Type B protection against electrical shock as the applied part is the table surface.

Electrical:

- Supply Voltage: 120±5% Vac 60Hz or 230±5% Vac 50Hz.
- Duty Cycle: 10% (2 min on/18 min off).
- Current Rating: Less than 10 Amps.
- Battery Backup Power.

Environmental:

- Operating Temperature Range: +5°C to +40°C.
- Operating Humidity Range: 30% to 75% relative humidity, noncondensing.
- Operating Pressure Range: 700 hPa to 1060 hPa.
- Transport & Storage Temperature Range: -10°C to +40°C.
- Transport & Storage Humidity Range: 30% to 75% relative humidity, noncondensing.
- Transport & Storage Pressure Range: 500 hPa to 1060 hPa.
- Rated IPX4 (Protected against splashing water).
- Meets EMC requirements of IEC 60601-1-2:2007.

Tabletop:

- The tabletop is made of carbon fiber and meets all the requirements of FDA CFR Title 21, Chapter 1, Subchapter J.

Guidance and Manufacturer's Declaration- Emissions, All Equipment and Systems:
Table 1 This equipment is intended for use in the electromagnetic environment specified below. The customer or user of this equipment should ensure that it is used in such an environment.

Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	This equipment use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	This equipment is suitable for use in the professional healthcare facility environment.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration- Immunity, All Equipment and Systems:

Table 2

This equipment is intended for use in the electromagnetic environment specified below.

The customer or user of this equipment should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
ESD EN/IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV at 100 kHz repetition frequency for AC Mains ±1kV at 100kHz repetition frequency for Signal I/O parts Port	±2kV Mains ±1kV I/Os	Main power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±0.5kV, ±1kV Line to Line ±0.5kV, ±1kV, ±2kV Line to Ground	±0.5 kV, ±1 kV Line to Line ±0.5kV, ±1kV, ±2 kV Line to Ground	Main power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	0 % *UT*; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % *UT*; 25/30 cycles for 50 Hz and 60Hz, respectively Single phase: at 0° 0 % *UT*; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	0 % *UT*; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % *UT*; 25/30 cycles for 50 Hz and 60Hz, respectively Single phase: at 0° 0 % *UT*; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	Main power quality should be that of a typical commercial or hospital environment. If the user of this equipment requires continued operation during power mains interruptions, it is recommended that this equipment be powered from an uninterruptible power supply or battery.
Power Frequency IEC 61000-4-8 Magnetic Field EN/IEC 61000-4-8	30A/m, 50Hz or 60Hz	30A/m, 50Hz or 60Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration Emissions, Equipment and Systems that are NOT Life-Supporting

Table 3

This equipment is intended for use in the electromagnetic environment specified below.

The customer or user of this equipment should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF EN/IEC 61000-4-6	AC Mains: 3V, 0.15MHz – 80MHz 6V in ISM band between 0.15MHz and 80MHz 80%AM at 1KHz [see table 5 of IEC 60601-1-2] SIP/SOPS: 3V, 0.15MHz – 80MHz 6V in ISM band between 0.15MHz and 80MHz 80%AM at 1kHz [see table 5 of IEC 60601-1-2]	AC Mains: 3V, 0.15MHz – 80MHz 6V in ISM band between 0.15MHz and 80MHz 80%AM at 1KHz [see table 5 of IEC 60601-1-2] SIP/SOPS: 3V, 0.15MHz – 80MHz 6V in ISM band between 0.15MHz and 80MHz 80%AM at 1kHz [see table 5 of IEC 60601-1-2]	Portable and mobile communications equipment should be separated from this equipment by no less than the distances calculated/listed below: D=(3.5/3)(Sqrt P) D=(3.5/3)(Sqrt P) 80 to 800 MHz D=(7/3)(Sqrt P) 800 MHz to 2.7 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF EN/IEC 61000-4-3	3V/m 80MHz to 2.7GHz 80%AM at 1kHz	3V/m 80% AM	

Recommended Separation Distances between portable and mobile RF Communication Equipment and this equipment.
Equipment and Systems that are NOT Life-Supporting.

Recommended Separations from this equipment is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of this equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and this equipment as recommended below, according to the maximum output power of the Communications Equipment.

Table 4

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz D=(3.5/3)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/3)(Sqrt P)	Separation (m) 800MHz to 2.5GHz D=(7/3)(Sqrt P)
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

18. 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.