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Image Diagnostics, Inc.

Aspect100E

Mobile Imaging Table
Operator Manual

Made in the USA

Table of Contents

Linak documentation can be found at their web site: www.linak-us.com
Select “Products | User manuals” and click on “Actuators & Electronics”.

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

PRODUCT DATA

- Low attenuation carbon fiber tabletop (aluminum equivalency is less than 1mm)
- Locking swivel casters
- Low attenuation table pads
- Hand operator control is standard
- Optional foot operator control

INTRODUCTION

Overview

This manual pertains to the specified product only. It is intended for qualified medical personnel who have been trained in the use of medical equipment. It is not designed to replace or substitute for certified training in the application of this equipment.
Functional capabilities and operation of the equipment described herein which can be employed in a variety of diagnostic, therapeutic, and surgical applications. It is designed for use as either a fluoroscopic or radiographic table.

Owner Responsibilities

The owner 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 should only be installed in an area provided with the proper electrical power.

The owner 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 this 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 international 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, calibration instructions, 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 dataplate on the table base at the time of contact.

This X-ray component manufactured by Image Diagnostics, Inc. complies with applicable FDA performance standards contained in 21CFR at date of manufacture.

SYMBOLS AND DATA PLATE

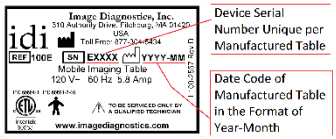
Intertek Testing Service

The system was tested and found to be in compliance with the requirements of all relevant directives and standards in effect within the European Union at the time of manufacture.

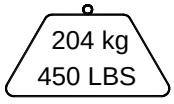
Attention! Consult accompanying documents.
Failure to follow these instructions can cause accidents resulting in serious personal injury or damage to equipment. CD ROMs containing file copies of all relevant drawings, BOMs, and documentation are included with this manual, one for general operators and one for the BIOMED department.

Type B equipment

Alternating current



Data Plate



Maximum Patient Weight

Equipotential Terminal (Featured on some models)
Indicates the Equipotential terminal of the table. Provides for a connection between the table and the equipotential bus bar of the facility.

Recycle
Some of the material can be recycled rather than discarded.

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

Do Not Sit
This label is found on parts that are not designed to support the sitting weight of a patient.

Not made with natural rubber latex

Single Use Item.

This symbol, when used in this manual, indicates the potential of exposure to harmful x-rays. Be sure to read and comply with all warnings.

European Authorized Representative

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

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.

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

SPECIFICATIONS

Mode of Operation:

For continuous operation with short time loading

Duty Cycle: 10% (6 min/hr)

Type of Equipment:

Class I Type B (as defined by IEC 60601-1, UL 60601-1,

EN 60601-1, CSA 601.1, IEC 60601-2-32:1994 and IEC 60601-2-46)

Type B protection against electrical shock

Complies with FDA standards

Electrical:

Supply Voltage: 120±5% Vac 60Hz or 230±10% Vac 50Hz

Duty Cycle: 10% (6 min/hr)

Current Rating: Less than 10 Amps

Internally Battery Powered

Environmental:

Operating Temperature Range: -10°C to +40°C

Operating Humidity Range: 30% to 75% relative humidity, noncondensing

Operating Pressure Range: 700hPa to 1060 hPa

Transport & Storage Temperature Range: -40°C to +60°C

Transport & Storage Humidity Range: 30% to 75% relative humidity, noncondensing

Transport & Storage Pressure Range: 500hPa to 1060 hPa

Rated IPX4 (Protected against splashing water)

Meets EMC requirements of EN 60601-2 (1993)

Tabletop:

The tabletop is made of carbon fiber and is certified to meet all the requirements of 21 CFR Subchapter J

ELECTROMAGNETIC COMPATIBILITY STATEMENT

This equipment may generate and use radio frequency energy. The equipment must be installed and used according to the manufacturer's instructions in order to avoid radio frequency interference.

If this equipment generates or receives interference:

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

- In the event of unintended motor actuation, immediately remove power to the equipment.

- Use only cables supplied by Image Diagnostics, Inc.

SETUP

Unpack

No special handling is required for unpacking this equipment at the site. Conventional shipping materials are used.

Roll the table down a temporary ramp (if table is mobile) or lift off pallet with a forklift. When using a forklift, pad the forks to protect the paint. Lift from under the metal base. When rolling the table off the pallet by hand, use the metal rails attached to the tabletop (if table is equipped with accessory rails) to guide the table after releasing the caster brakes (if table is mobile).

Recycle or dispose of shipping material per local regulations.

Install

Mobile tables are equipped with four locking caster brakes. Unlock brakes while positioning.

Hand controls are standard with this table with foot controls as optional. The operator should become familiar with the controls before using.

The table operates on 110Vac (or 230Vac) or on internal battery backup. Swing the hinged cover open to find the power cord on some models. Plug the AC power cord into a properly grounded hospital grade outlet. The indicator on the control box with illuminate, however, depending on table model, this indicator light may not be visible without removing a cover.

During an AC failure, the table will automatically run on battery backup without any manual switching required. It is recommended that power be applied at all times, even when not in use, to keep a proper charge on the batteries and achieve maximum battery life. (Batteries are being charged during normal use).

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 Installation:

This equipment will need to be properly cleaned between patient use as it will inevitably come into contact with contaminants during procedures.

Review the SAFETY INSTRUCTIONS before operating table

SAFETY HAZARDS

Operators using this equipment should understand the safety issues, emergency procedures, and operating instructions provided.

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 send fax to (978) 829-0027.
Or call toll-free at (877) 304-5434.

SAFETY HAZARD ALERTS

Alert	Circumstances for 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.

WARNING!

If an antistatic path is required, use the equipment on an antistatic floor. Use only the tabletop pad (patient mattress) supplied with the table.

WARNING!

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

CAUTION

Secure power cord when in use so that it does not get entangled with other equipment and/or compromise the safety of the operator and/or staff.

CAUTION

Do not modify this equipment without authorization of the manufacturer.

SAFETY INSTRUCTIONS

This symbol, when found marked on the equipment means:
"Attention, consult accompanying documentation."

This manual should be accessible to all personnel installing, operating, or servicing this equipment.

Only a qualified technician may install or maintain this equipment.

Only qualified persons may operate this equipment.

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

WARNING!
Always safely position and secure patient on table

WARNING!
Do not exceed patient weight of 450 pounds (204kg)

CAUTION
Do not leave patient on table unattended

CAUTION
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 using power driven diagnostic equipment around table. Regular inspection of the tabletop is necessary for the safety of patient and operator.

CAUTION
Do not use table for patient transport.

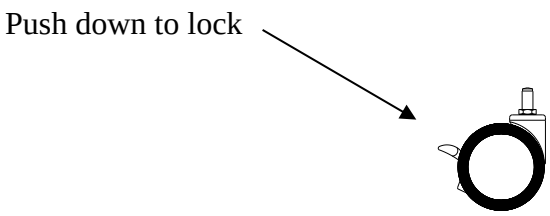
CAUTION
During operation, listen for any unusual sounds and watch for uneven operation.

CAUTION
Ensure that the tabletop does not contact other equipment as it moves.

CAUTION
Do not sit on the table top at the head 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.

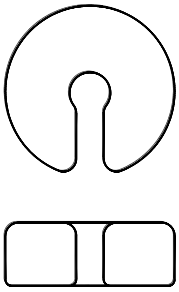
CAUTION
Secure wheel locks by depressing locks on all 4 wheels prior to patient usage and when table is not in motion. Disengage to reposition.



ACCESSORIES

CRESCENT FACE CUSHION *(supplied with some models)*

Use this pad for patient comfort when the patient will be positioned face down. Place a disposable cover over the pad.



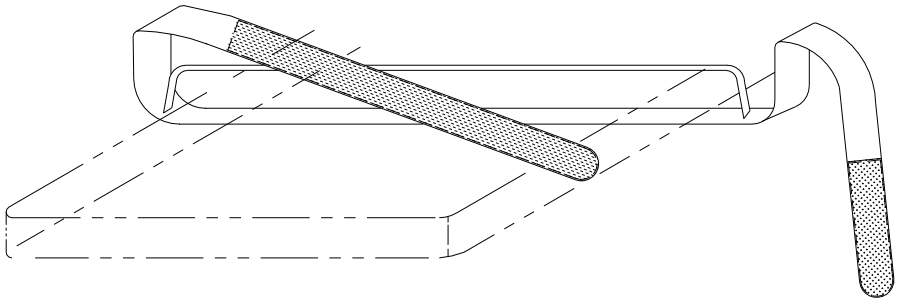
Crescent Face Cushion Head Pad

Part Number C000-0597

Disposable Covers

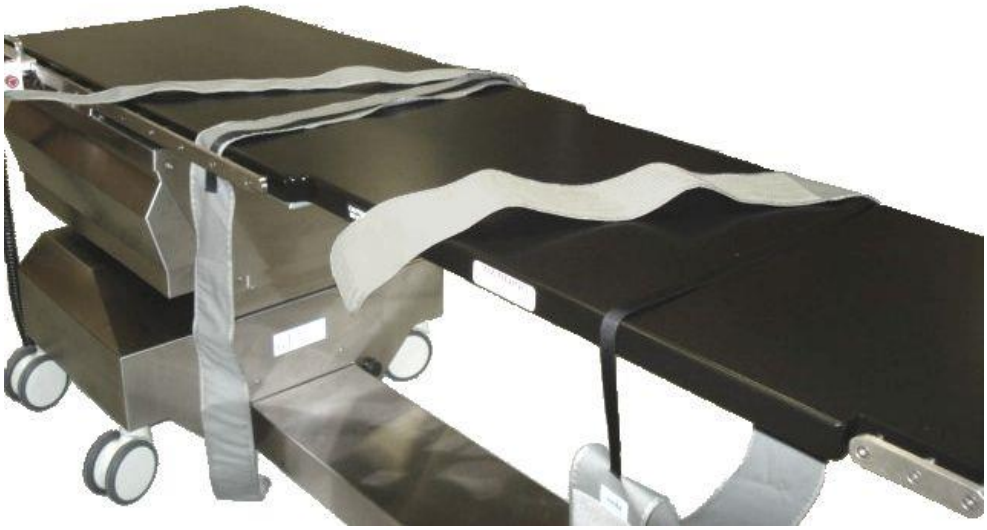
Part Number C000-0598 (box of 50)

PATIENT RESTRAINT STRAPS



SLIDE THE RESTRAINT STRAP OVER THE END OF THE TABLETOP
WITH THE SMALL RETAINING STRIP OVER THE TOP SURFACE OF THE TABLETOP.

PHOTO OF STRAP ARRANGEMENT:



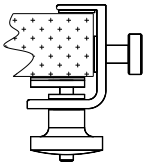
NOTE: Strap configuration shown above is recommended, however, patient restraint is a case-by-case condition. Please refer to the facility's policy on restraining a patient.

• Patient Restraint Strap Set (Standard)

Part Number C000-0328

Two straps, one 3" wide and one 5" wide, with hook & loop fasteners

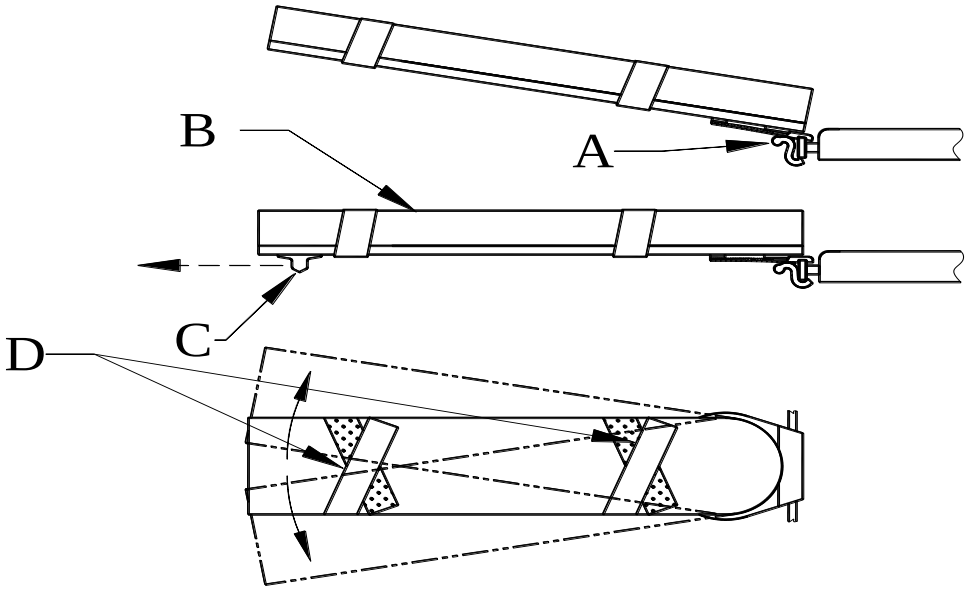
CLAMP-ON ACCESSORY RAIL AND ARMBOARD (OPTION)



WARNING!
25lbs (11kg) Maximum Load

To install clamp to tabletop:

- Turn knob *counterclockwise* (as viewed from above) to open clamp enough to slip onto tabletop
- Turn knob *clockwise* to tighten clamp to tabletop



A – Push to open latch to install to accessory rail or remove from accessory rail

B – Armboard pad

C – Pull trigger to rotate armboard to desired position

D – Hook & loop patient straps

Clamp-on Rail Accessory Assembly #A100-1007 (Qty. 1, fits left or right side of table)

Armboard with Pad & 2 Straps #A310-056 (Qty. 1, fits left or right side of table)

Replacement Armboard Pad #A100-1655 (Qty. 1, fits left or right side of table)

Replacement Armboard Straps #C000-0455 (Pair, fits left or right side of table)

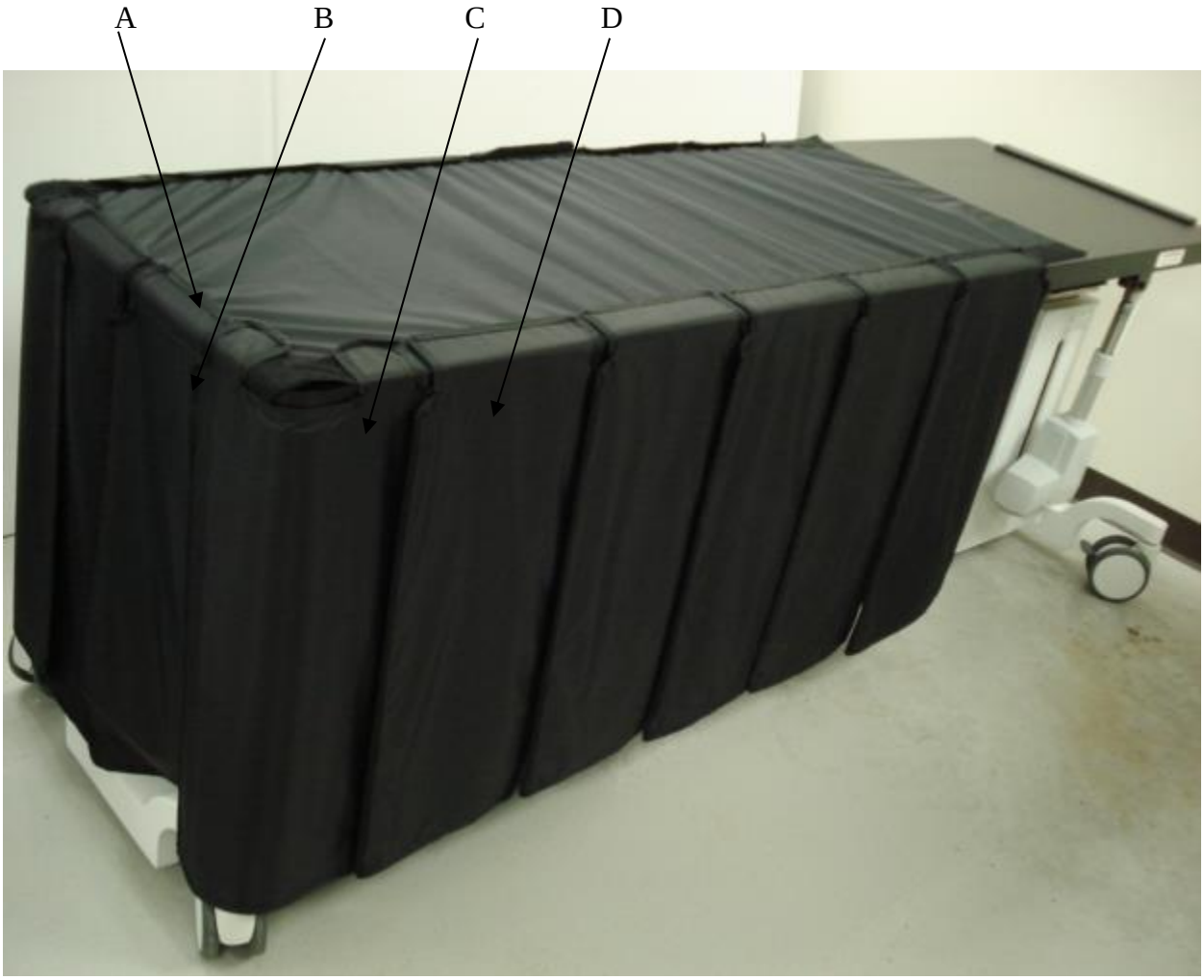
RADIATION SHIELDS, SADDLE STYLE (OPTIONAL)

- **24X80 Straight Tabletop Shield**
  Part Number: A610-096

INSTALLATION INSTRUCTIONS FOR 24" SADDLE STYLE RADIATION SCATTER SHIELD
(0.5mm PbEq)

Note: Individual shields have hook fasteners that are engaged into the loop fasteners of the saddle. Overlap shields as shown.

Step A: Place the saddle with the loop fastener side "up" on the tabletop. The adhesive dots may be applied to hold the saddle in place.



Step B: Attach two 8 1/2" panels at the end of the tabletop centered as shown.

Step C: Attach two 13" panels so they wrap around the corners.

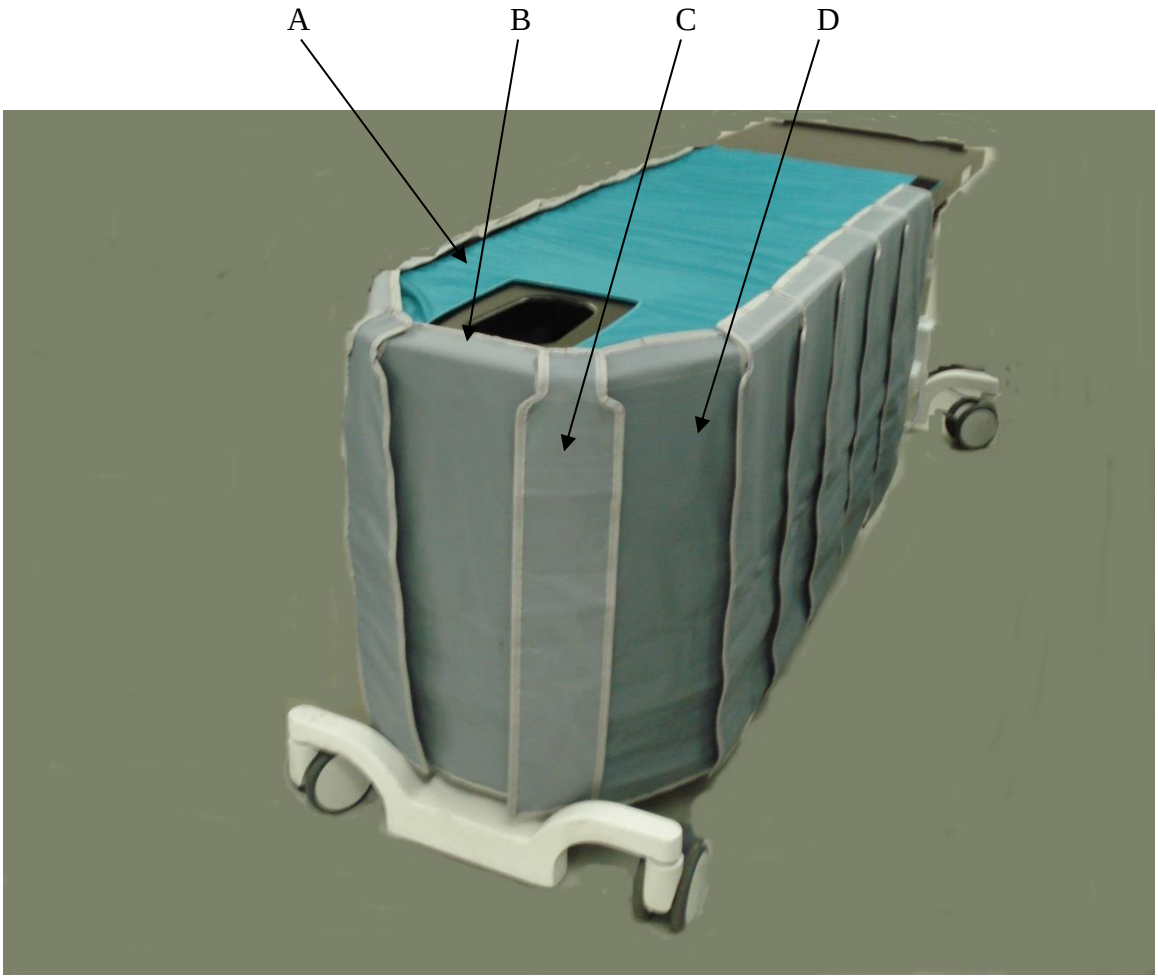
Step D: Finish by attaching five 11" panels along the side of the tabletop.

- **22X80 Facial Cutout Tabletop Shield**
  Part Number: A610-092

INSTALLATION INSTRUCTIONS FOR 22" SADDLE STYLE RADIATION SCATTER SHIELD (0.5mm PbEq)

Note: Individual shields have hook fasteners that are engaged into the loop fasteners of the saddle. Overlap shields as shown.

Step A: Place the saddle with the loop fastener side "up" on the tabletop. The adhesive dots may be applied to hold the saddle in place.



Step B: Attach one 11" panel at the end of the tabletop centered as shown.

Step C: Attach two 5" panels so they wrap around the corners.

Step D: Finish by attaching six 11" panels along each side of the tabletop.

(Continued on next page)

WARNING!

Radiation shields require careful handling and periodic testing for safe use.
Test upon receipt and at regular intervals to insure shielding integrity. Test procedure and schedule to be the responsibility of the appropriate department of the facility where used.

IDI imaging tables are designed to provide excellent fluoroscopic imaging access with mobile C-arms. Whenever the table is used for procedures involving the use of a mobile C-arm, or any other equipment that produces ionizing radiation, all radiation safety standards and precautions should be applied, including but not limited to proper use of X-ray protective shielding for patients, operators and support personnel.

OPERATOR CONTROLS

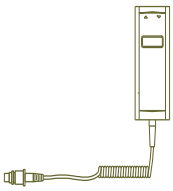
Table operates on 120 Vac or 240 Vac (as noted on dataplate) and incorporates 24Vdc battery backup.

It is recommended that power be applied at all times, even when not in use to keep a proper charge on the batteries and achieve maximum battery life.

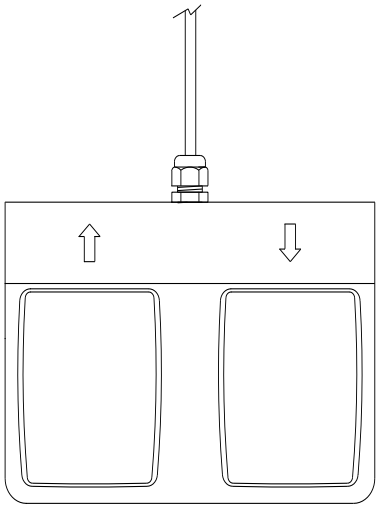
If power to table has been absent for an extended period of time, battery will need to be recharged. The battery is sealed and requires no other maintenance.

There is two (2) types of operator controls available:

- Remote (hand pendant control)
- Foot Control (placed on floor, movable)



• HAND CONTROL
This device is used by the operator to move the tabletop by depressing and holding the appropriate
button until the patient or tabletop is in the desired position.



- FOOT CONTROL *(Optional)*

This device is used by the operator to move the tabletop by depressing and holding the appropriate

button until the patient or tabletop is in the desired position.

TABLETOP MOTIONS

△ UP Depressing and maintaining the UP button on the remote, or UP foot switch, or toggling the panhandle rocker switch to the UP position causes upward tabletop motion until the upper limit is reached.

▽ DOWN Depressing and maintaining the DOWN button on the remote, or DOWN footswitch, or toggling the panhandle rocker switch to the DOWN position causes downward tabletop motion until the lower limit is reached.

BATTERY FUNCTION *(Motorized tables)*

When AC power is applied, the battery will begin charging until the battery reaches full capacity. When it does, the charging will taper off. If the power goes out, the table 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.

• Battery (12V/2.9Ah) Part Number K000-0022 (Replace in pairs)
Battery compartment is part of the control box. Tool required to access batteries: T20 torx driver.

Local procedures may be in place for proper disposal or recycling.
For more information about batteries, such as battery life, production codes and disposal go to the Linak web site for disposal information.
Select "Products|User Manuals" and click on "Actuators & Electronics".
Linak documentation can be found at their web site: www.linak.com

GENERAL CLEANING

After each procedure, the table should be carefully cleaned

The disinfectant cleaners and cleaning steps on this page apply to all the parts of the table, except the lift column.

• Clean tabletop, pads, accessories, and painted surfaces with a clean cloth dampened with an approved cleaner (see list below).

Do not use abrasives, solvents, sprays, or corrosive agents.

APPROVED AND TESTED DISINFECTANT CLEANERS

• 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

CLEANING STEPS

1. Lower the tabletop to the lowest position.
2. Power cord must be plugged in to protect the socket.
3. Remove any accessories.
4. Wipe off any access fluids with a water dampened cloth or sponge.
5. Clean any accessories, tabletop and frame using an approved cleaner.
6. Thoroughly rinse tabletop pad with water.
7. Gently rub with a soft clean cloth to dry.

CAUTION

Avoid cleaning or getting cleaning solutions on elevating tube if possible.

If noise or uneven motion occurs when the table top is moving up or down, extend and clean the lifting tube with a soft clean cloth.

MAINTENANCE

"Qualified Technician"

- All maintenance procedures should be done by an experienced technician with demonstrated knowledge and skills (electrical and mechanical) relative to this type of equipment.

- This individual must have access to this manual and the proper tools.

ROUTINE MAINTENANCE

- Lubrication is *not* required however powdered graphite may be used on the lifting tube.

PERIODIC PERFORMANCE CHECKS

- Semiannually perform functional inspections of carbon fiber tabletop, support frame, and the elevating tube.

- Daily inspect all external cables, controls, and the tabletop for wear and damage. Replace damaged cables promptly.

- Weekly check battery operation by disconnecting the AC power and running the tabletop up and down.
  Check daily if table is routinely used without being attached to mains.

USER REPLACEMENT ITEMS

These are easily replaced by the operator.

• Standard Tabletop Pad

Pads are held in place by hook and loop fasteners. Simply pull pad up gently to remove. New replacement pads are supplied with new self-adhesive fasteners installed and new mating pieces for the tabletop. Peel off old fasteners from tabletop. Peel off the protective paper and carefully place new pad into position. Apply pressure to complete installation.

Note: Pads comply to California Technical Bulletin 117 as well as Underwriters Laboratories 94 (UL94).

Standard Tabletop Pad Part Number X100-1742

Not made with natural rubber latex

TROUBLE-SHOOTING

SYMPTOM	POSSIBLE CAUSE	ACTION
No motor sound And/or movement	Power cord not plugged in	Connect power cord
	No power at the receptacle	Check appropriate circuit breaker
	A missing or loose connection at the control box	Inspect wires and connections
	A blown fuse	Change fuse with same rating
	A damaged wire	Repair or replace wire
	Emergency stop button activated	Twist & pull up

For other symptoms, consult field service or linak website for actuator (motor) and controller**.** Website is www.linak-s.com

For other symptoms, consult field service.

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
Actuator	Spindle and Motor Housing Cable	Metal (Steel and Copper) Plastic Copper
Control Box	PC Board Plastic Housing Cable Transformer Batteries	Electronic Plastic Copper Copper Lead Acid Batteries
Hand Control	PC Board Housing Cable	Electronic Plastic Copper
Foot Control	PC Board Metal Housing Cable	Electronic Steel and Aluminum Copper
Table Base	Frame Casters	Metal (Steel) Plastic and Steel

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