Aspect100T

Mobile Fluoroscopic Table
User Manual

Made in the USA

CE

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
- Low attenuation patient pad
- Standard Tabletop: 61cm x 203cm (24in x 80in)
- Imaging area: 61cm x 157cm (24in. x 62in.)
- Trendelenburg: ±15°
- Height range: 71cm to 101cm (28in to 40in)
- Patient capacity: 204kg (450lbs)
- Table weight: ~147kg (~325lbs)
- Locking swivel casters
- Low attenuation table pads
- Hand operator controls standard
- Accessories

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. 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

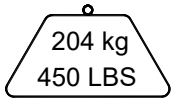
The system was tested and found to be in compliance with the requirements of all relevant directives and standards in effect within the European Union at the time of manufacture.

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.

Emergency Stop Button

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.

INTENDED USE & ESSENTIAL PERFORMANCE

The *Aspect* 100T is a mobile imaging table used by the medical industry for GI and interventional pain management procedures including the option of using radiology. They are designed to be used in a professional healthcare environment in conjunction with "C-arm" style radiological imaging equipment. 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. Tabletop motion for this table are in the vertical and Trendelenburg directions.

These tables are intended for all patients that do not weigh more than the maximum allowable weight as labeled on the table itself. These tables are also reusable devices. The conditions for reuse are that they function properly based on the criteria stated in the maintenance section (page 22) of this manual and that it has been cleaned per the cleaning section (page 20) 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.

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.

To remove the table from the shipping pallet, roll the table down a temporary ramp 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, grip the handles attached to the tabletop to guide the table after releasing the caster brakes.

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. Plug the power cord into a properly grounded hospital grade outlet. The green indicator will illuminate. The green indicator can be seen through the port in the large side cover.

The outlet used should be visible and accessible to the user. The cord should be routed where it will not be subject to damage or be a hazard. Check that the power cord ground pin is in good condition. Check that the cord ground wire is securely connected to the ground stud inside the unit.

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).

Where the integrity of the external protective earth conductor is in doubt, this equipment shall be operated from its internal electrical power source by unplugging the power cord from the mains.

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.

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.

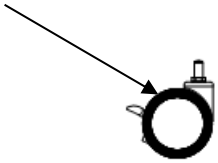
CAUTION

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.

Push down to lock



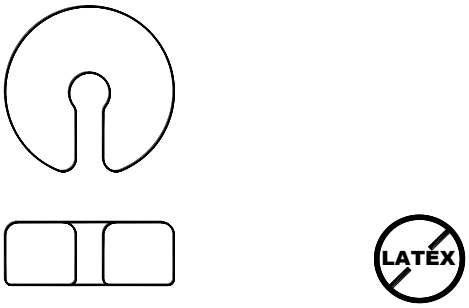
NOTICE

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

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**

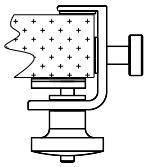
NOTE: Strap configuration shown above is recommended, however, patient restraint is a case-by-case condition. Please refer to the facility's policy on restraining a patient.

- **Patient Restraint Strap Set (Standard)**

  Part Number A100-3731

  Two straps, one pad

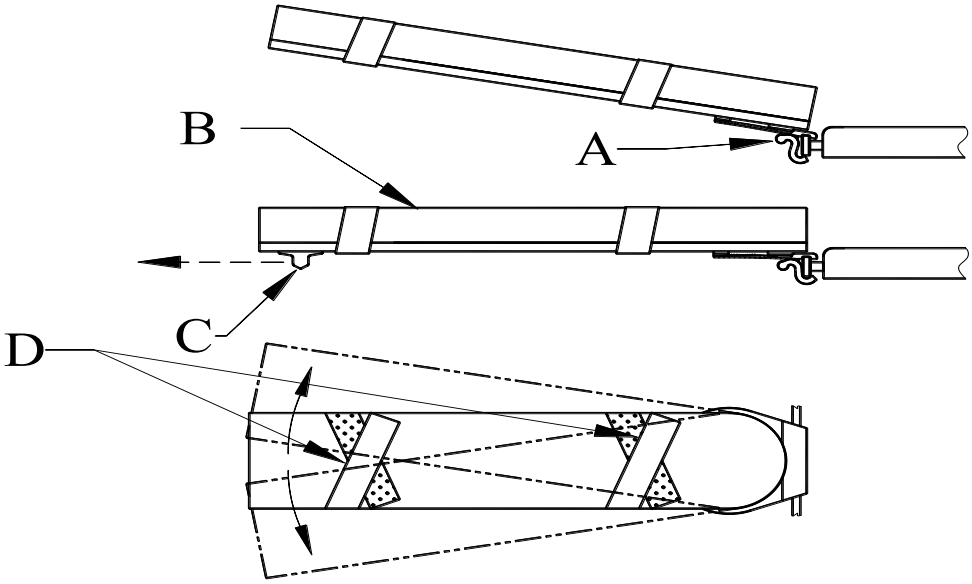
- **CLAMP-ON ACCESSORY RAIL AND ARMBOARD (OPTION)**



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.

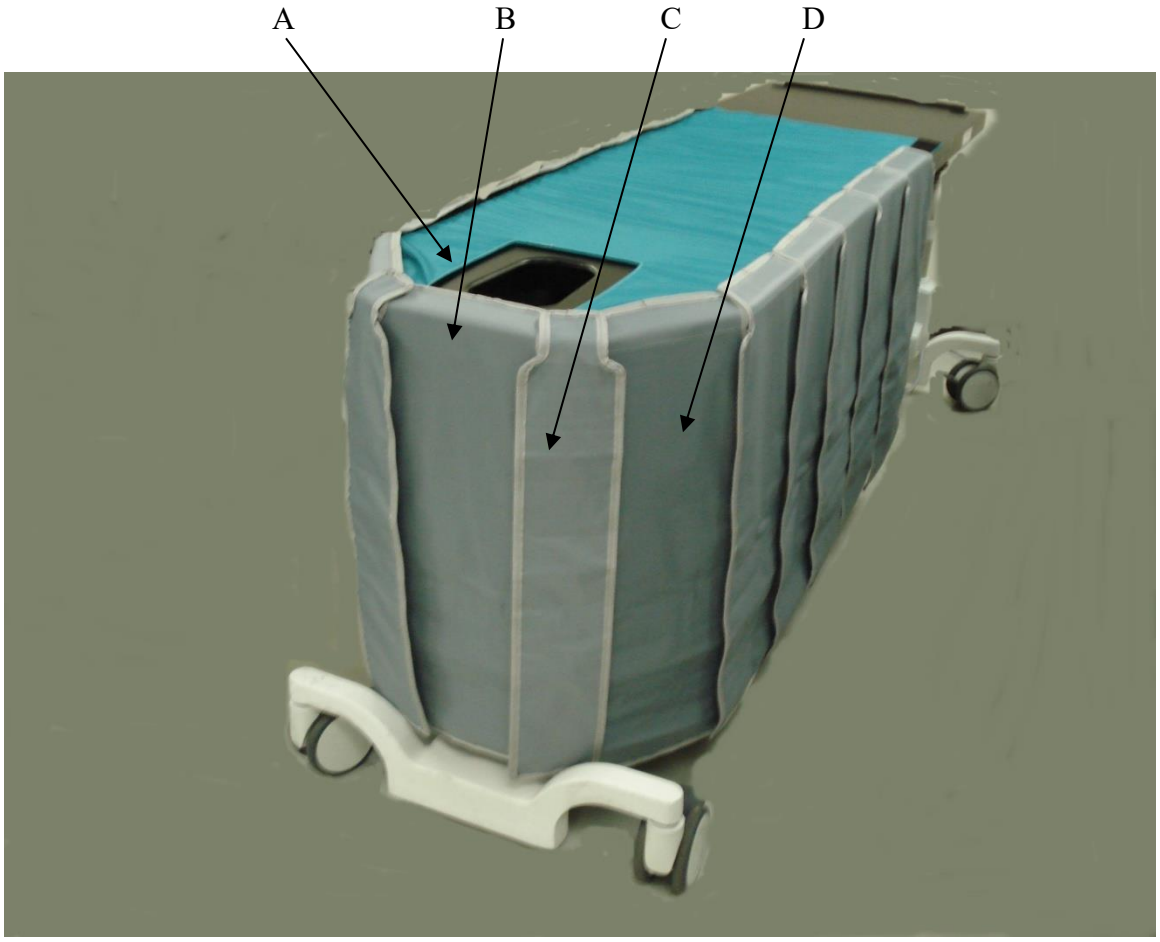
Step D: Finish by attaching five 11" panels along the side of the tabletop.

- **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.

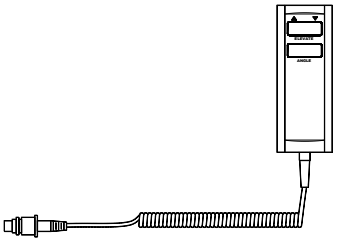
OPERATOR CONTROLS

HAND CONTROL

CAUTION

Always check that the patient is secure before activating any table motion

- Top pair of buttons moves tabletop up and down
- Bottom pair of buttons controls the Trendelenburg motion



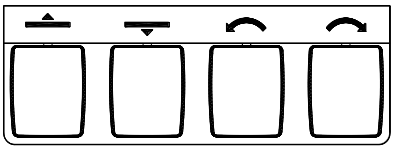
Hand Control

Part Number K000-0054 plus label D100-731

- **FOOT CONTROL** (OPTIONAL)

CAUTION

Always check that the patient is secure before activating any table motion



- The pair of pedals on the left move the tabletop up and down
- The pair of pedals on the right control the Trendelenburg motion

Foot Control

Part Number A100-500 (contact IDI for individual replacement parts)

EMERGENCY STOP SWITCH

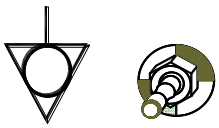
- The red emergency stop button is located on top of the control box
- Pressing this button down will stop all motor movement
- In the event that the hand or foot control malfunctions, the emergency stop control prohibits motion by removing power from all system components

- ACTIVATE: Engage the emergency stop mode by pushing the button down
- RESET: Restore the electrical functions by rotating the button a quarter turn

Note: ***The battery will not charge if the emergency stop switch is pushed down.***

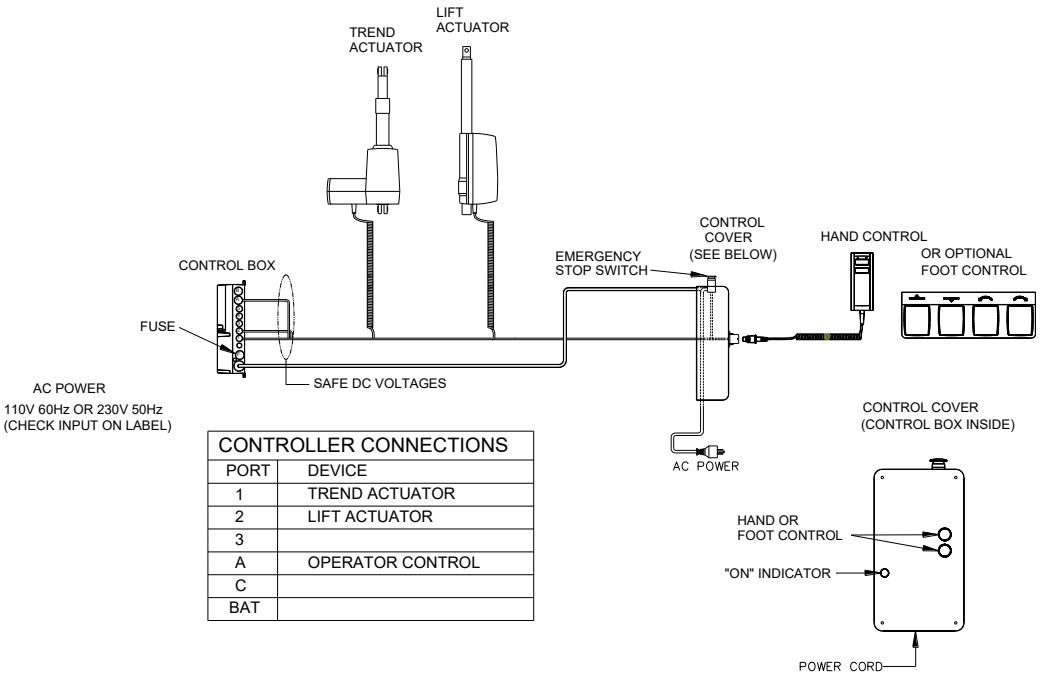
EQUIPOTENTIAL TERMINAL

The Equipotential terminal provides a connection point between equipment and a potential equalization busbar.



Symbol Terminal

ELECTRIC SYSTEM



CONTROLLER CONNECTIONS	
PORT	DEVICE
1	TREND ACTUATOR
2	LIFT ACTUATOR
3	
A	OPERATOR CONTROL
C	
BAT	

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.

Note: ***The battery will not charge if the emergency stop switch is pushed down.***

An audible tone is sounded when using an operator control function if the battery charge is low.

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

CAUTION

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 radiation shield.

• 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

APPROVED AND TESTED GENERAL PURPOSE CLEANERS

• Simple Green ™ cleaner

CLEANING STEPS

1. Move the tabletop into the horizontal position.
2. Lower the tabletop to the lowest position.
3. Power cord, hand control and foot control cords must be plugged in to protect the sockets.
4. Remove all pads and accessories.
5. Wipe off any access fluids with a water dampened cloth or sponge.
6. Clean the accessories, tabletop, and pads using approved cleaners.
7. Clean the table frame, castors, and base with Simple Green ™ cleaner.
8. Thoroughly rinse tabletop pad with water.
9. 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.

CLEANING THE OPTIONAL RADIATION SHIELD

CAUTION

Observe cleaning product cautions found on product labels.

After each procedure, the radiation shield should be carefully cleaned.

CLEANING STEPS

1) **Remove the panel sections and lay flat before using the recommended cleaner in an adequately ventilated area.**
2) **Apply to one side at a time and allow to stand a few minutes.**
3) **Scrub with a soft bristle scrub brush. Do not let the solution dry before rinsing.**
4) **Rinse with water and a damp cloth.**
5) **Scrub and rinse again, if necessary.**
6) **Remove the main section of the radiation shield and clean in the same manner.**
7) **Place main section of shield back on tabletop.**
8) **Install individual panel sections.**

APPROVED AND TESTED DISINFECTANT CLEANER:

- **Scrubbles® (Infab Corporation)**
  www.infab.org/catalog/apron_options_and_accessories.htm

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.

See also previous sections for operator hand and foot controls, armboard pads and protective covers.

- **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 2” x 24” x 80” Tabletop Pad Part Number X100-1742

Optional 2” x 28” x 80” Tabletop Pad Part Number X100-2083

Optional 2” x 22” x 80” Tabletop Pad with Facial Cutout Part Number X100-1757

Not made with natural rubber latex

TROUBLE-SHOOTING

SYMPTOM	POSSIBLE CAUSE	ACTION
No motor sound And/or movement	Power cord not plugged in No power at the receptacle	Connect power cord 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.