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Image Diagnostics, Inc.

Aspect100US

Gyn/Fertility Mobile Imaging Table
Operator Manual



Made in the USA

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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
- Tabletop: 61 cm x 117 cm (24 in x 46 in)
- Imaging area: 61 cm x 117 cm (24 in x 31 in)
- Height range: 66 cm to 101 cm (26 in to 38 in)
- Patient capacity: 204 kg (450 lbs)
- Table weight: ~177 kg (~390 lbs)
- Locking swivel casters
- Low attenuation table pads
- 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

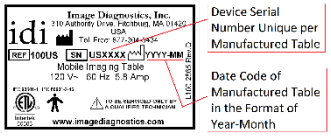
Intertek Testing Service

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.

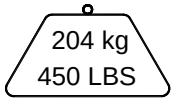
Attention! Consult accompanying documents.
Failure to follow these instructions can cause accidents resulting in serious personal injury or damage to equipment. CD ROMs containing file copies of all relevant drawings, BOMs, and documentation are included with this manual, one for general operators and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



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

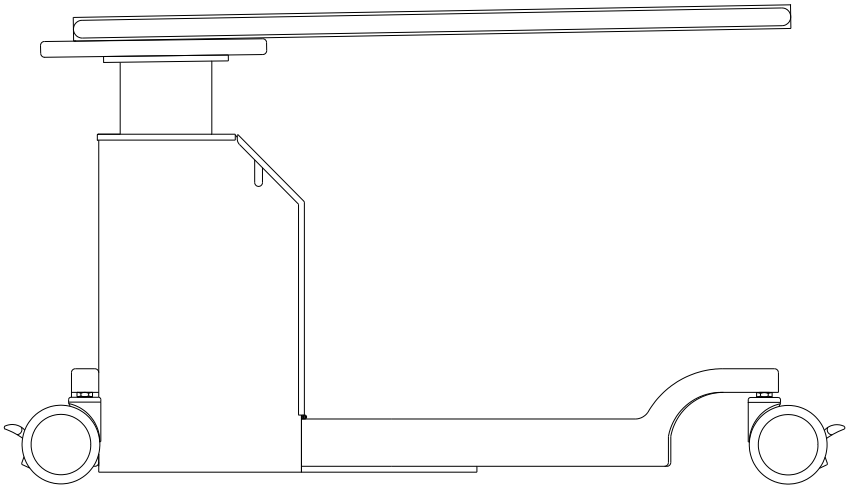
This equipment may generate and use radio frequency energy. The equipment must be installed and used according to the manufacturer's instructions in order to avoid radio frequency interference.

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.

To remove the table from the shipping pallet, first remove the shipping brackets that secure the table to the wooded pallet using a ½" wrench. Then 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, use the long metal rails 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.

Foot controls are standard with this table. 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 green indicator on the control box with illuminate, however, the hinged cover will need to be opened to see the green indicator.

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 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
If using legholder stirrups with this table, use caution. The boot will drift if the clamp is not securely tightened. Note: there is a left and a right boot.



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.

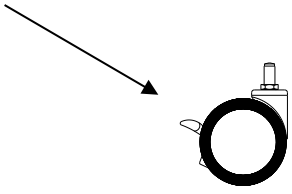


CAUTION
Do not sit at the head of the table.



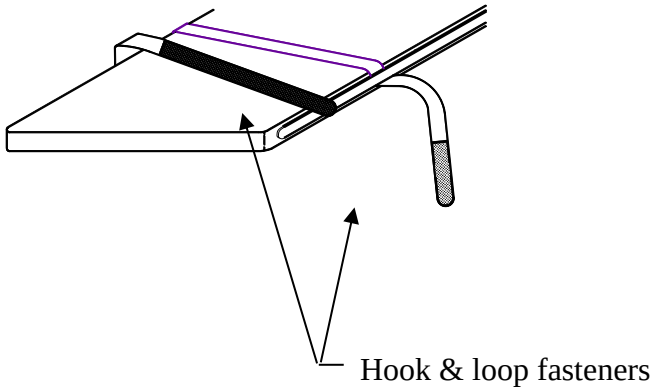
CAUTION
Secure wheel locks by depressing locks on all 4 wheels prior to patient usage and when table is not in motion. Disengage to reposition.

Push down to lock



ACCESSORIES

- **PATIENT RESTRAINT STRAPS**



Patient Restraint Strap Set
Part Number C000-0571
(Two straps 3” wide)

- **STIRRUPS**



Stirrups
Part Number C000-0745 (pair)

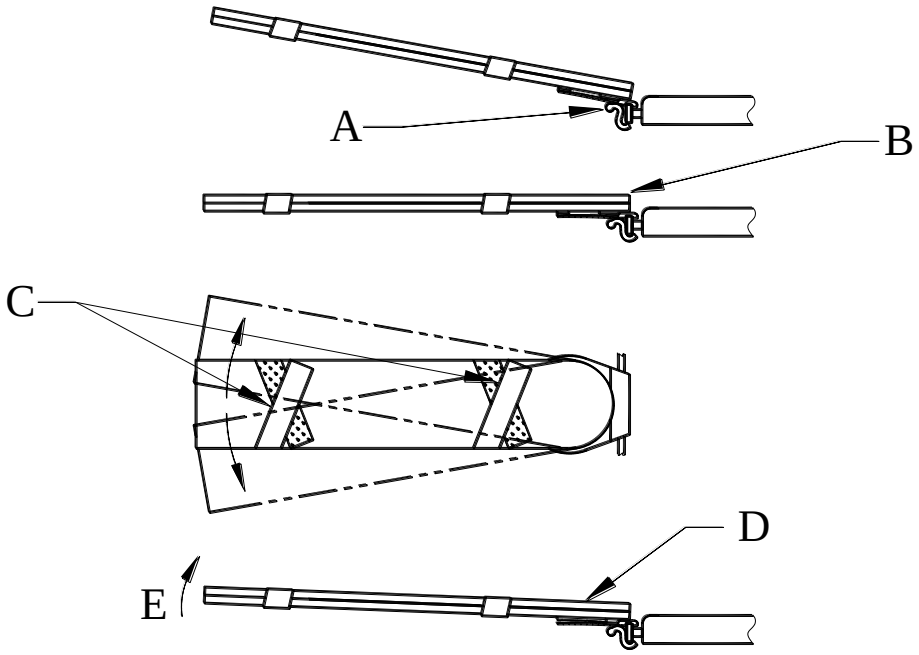
Accessory Clamps (to mount stirrups to accessory rail)
Part Numbert C000-0746 (order qty 2)

- **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 or remove

B – Patient's arm weight locks unit in place

C – Patient hook & loop arm straps

D – Pad

E – To rotate, lift end of armboard and move to desired location

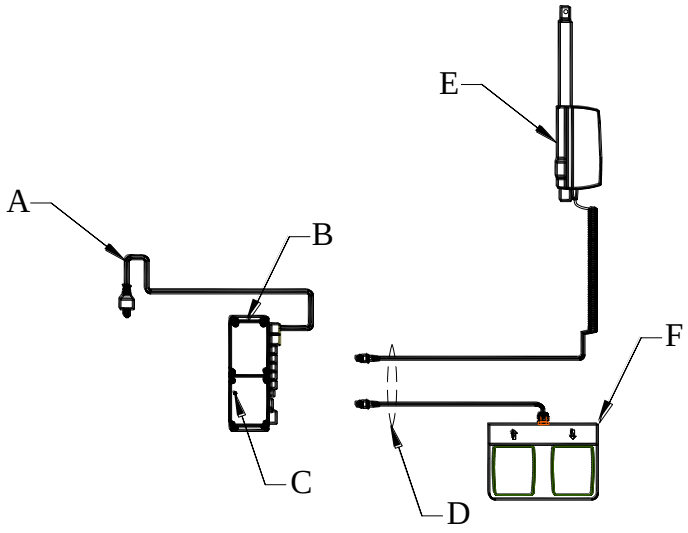
Armboard with Pad & 2 Straps #A310-057 (Qty. 1, fits left or right side of table)

Replacement Armboard Pad #A100-1073 (Qty. 1, fits left or right side of table)

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

LATEX

ELECTRIC SYSTEM



A – AC Power Cord

B – Control Box (controller, batteries and battery fuse inside)

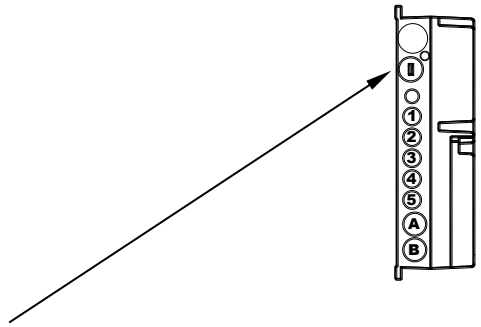
C – Power On Indicator

D – Safe DC Voltages

E – Elevating Actuator

F – Foot Control

CONTROLLER CONNECTIONS



Pull tab to access input fuses and spares

(use forceps to pull out spares)

PORT	DEVICE
1	ACTUATOR
A	FOOT CONTROL

BATTERY FUNCTION

When the AC power cord is plugged into the wall, the battery will be charging until the battery reaches full capacity. When it does, the charging will taper off. If the power at the outlet goes out, or the power cord is unplugged, the table will automatically switch to battery back-up mode.



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.

• 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).



Not made with natural rubber latex

- Tabletop Pad Part Number X100-1687
- Power Cord Part Number K000-0105
  To replace, pull cord straight out from control box.
  Power Cord (120V) Contact IDI Customer Service for other voltages

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.