idi

Image Diagnostics, Inc.

Aspect100HT

High-Tilt

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
- Low attenuation patient pad
- Tabletop: 61cm x 203cm (24in x 80in)
- Tilt: 0° (Horizontal) to 75°
- Height: 81cm (32in)
- Patient capacity: 238kg (525lbs)
- Locking swivel casters
- Foot operator control standard
- Emergency Stop Switch
- Equipotential Terminal
- Foot Rest
- Optional hand 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.

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. Pure Offices, Plato Close,
WARWICK CV34 6WE UK

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 wooden 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 with a hand control being an option. 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 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.

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 525 pounds (238kg)

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.

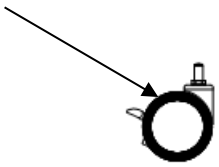
CAUTION
Ensure that the tabletop does not contact other equipment as it moves.

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.

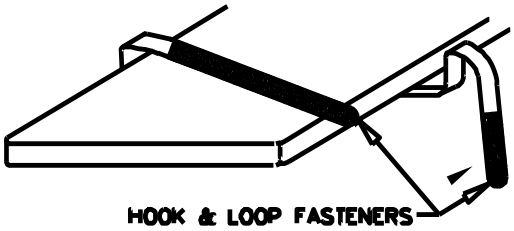
CAUTION
Secure wheel locks by depressing locks on all 4 wheels prior to patient usage and when table is not in motion. Disengage to reposition.

Push down to lock



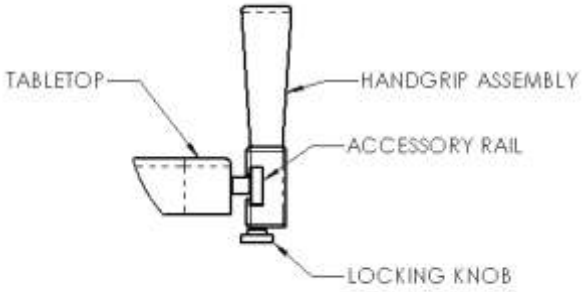
ACCESSORIES

- **PATIENT RESTRAINT STRAPS**



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

- **PATIENT HANDGRIP**



The patient handgrip can be quickly locked to the accessory rail in any position to suit the patient.

Patient Handgrip

Part Number A100-1711

(Order 2 for a complete pair)

WARNING!

25lbs (11kg) Maximum Load

Check that handgrip is tight before each use.

OPERATOR CONTROLS

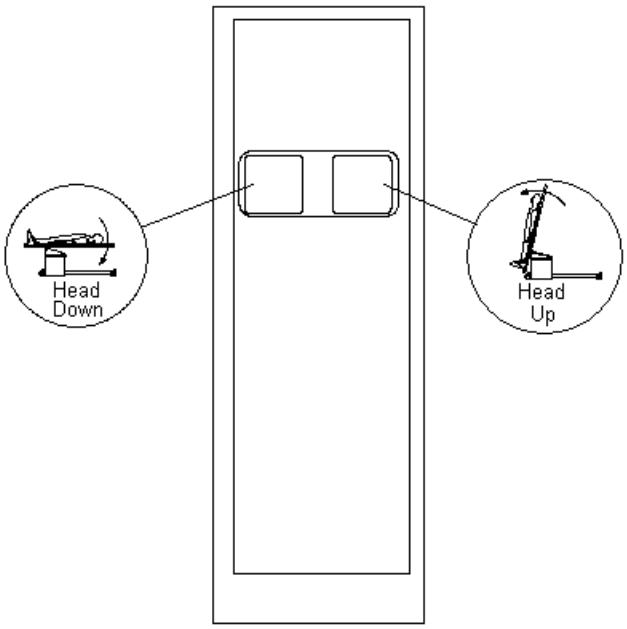
HAND CONTROL (OPTIONAL)

CAUTION

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

• Buttons control the tilt motion

To move the tabletop, press the appropriate button and hold until the desired position is reached.



Hand Control
Part Number: Handset K000-0041, Label D100-1824

Go to the Linak web site for disposal information.
The URL is listed on the table of contents page of this manual.

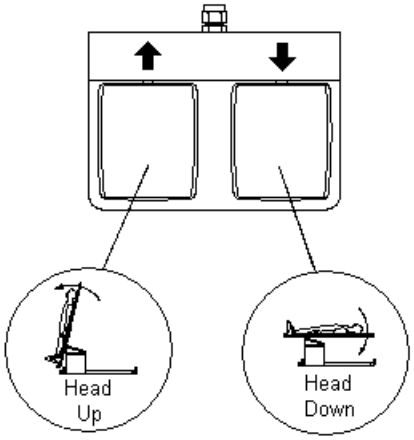
- **FOOT CONTROL** (OPTIONAL)

CAUTION

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

• The two pedals control the tilt motion

To move the tabletop, depress the appropriate pedal and hold until the desired position is reached.



Foot Control

Part Number A100-1823

Contact IDI Customer Service for individual components of foot control.

EMERGENCY STOP SWITCH

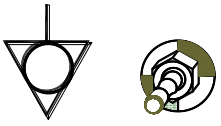
- The red emergency stop button is located on top of the control box
- Pressing this button down will stop all motor movement
- In the event that the hand or foot control malfunctions, the emergency stop control prohibits motion by removing power from all system components

- 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.***

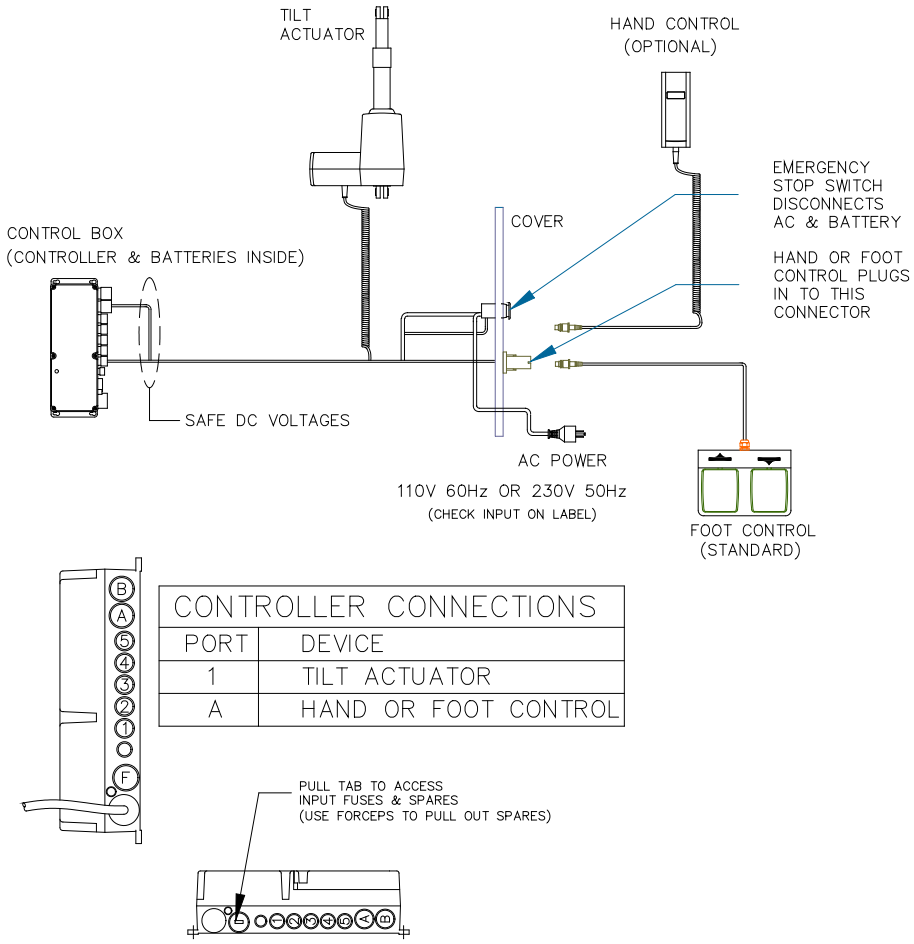
EQUIPOTENTIAL TERMINAL

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



Symbol Terminal

ELECTRIC SYSTEM



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

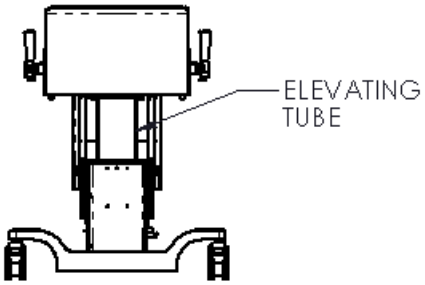
GENERAL CLEANING

CAUTION

After each procedure, the table should be carefully cleaned.

CAUTION

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



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

• 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.

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

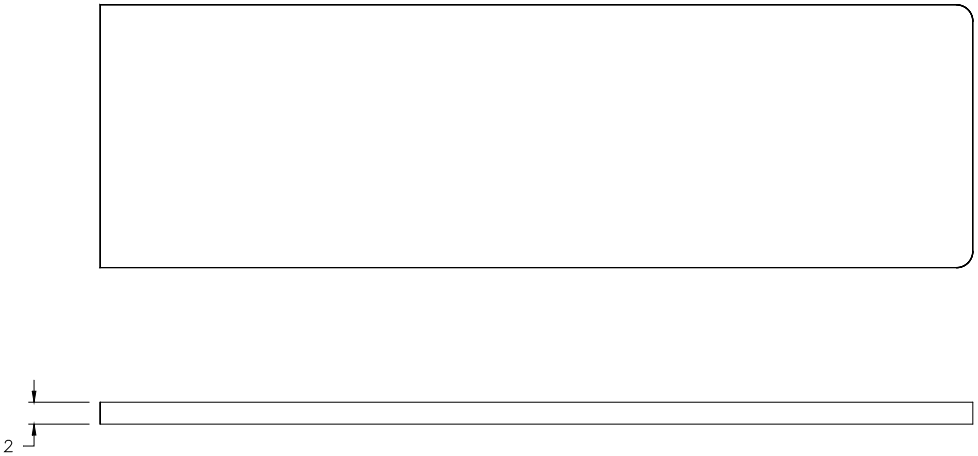
These are easily replaced by the operator.

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

• 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).



Tabletop Pad 2.5 cm x 61 cm x 203 cm (1” x 24” x 80”)

Part Number X100-1649

Optional Tabletop Pad with Hood 5cm x 61 cm x 203 cm (2” X 24” x 80”) with hood.

Part Number X100-2008

Not made with natural rubber latex

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

Image Diagnostics, Inc. Aspect Imaging Tables Official Product Warranty for USA & Canada

1. Scope and Duration of Warranty: Image Diagnostics, Inc. (IDI) warrants, to the original Purchaser only, that the Covered Products conform to the manufacturer's published specifications and are free from defects in material or workmanship. The warranty period will commence on the date of delivery. The duration of the warranty ("Warranty Period") is 36 months on parts and 12 months on labor, except for accessories, hand controls, foot controls, casters, table top pads, batteries, power cords and electrical cords for hand and/or foot controls, which have a warranty period of 12 months for both parts and labor[1]. If Purchaser discovers within this Warranty Period a failure of the Covered Products to conform to specifications or a defect in material or workmanship, Purchaser must promptly notify IDI by calling IDI Customer Service at 877-304-5434 during normal business hours: Monday through Friday, 8:00 a.m. through 5:00 p.m., Eastern Time, excluding holidays. IDI's warranty obligations will apply only to such notifications made during the warranty period and will not apply to notifications made after warranty expiration.

2. Exclusive Product Warranty Remedies: If Purchaser promptly notifies IDI of Purchaser's warranty claim and makes the Covered Product available for service, IDI will, at IDI's option, either repair, adjust or replace (with new or exchange replacement parts) the non-conforming Covered Product or parts of the Covered Product Replaced parts will become the property of IDI. The warranty period for any Covered Product furnished to the customer as a warranty remedy will be the remaining portion of the warranty period applicable to the repaired or replaced Covered Product All warranty service will be performed by an IDI's authorized service representatives. During normal business hours, Warranty service will be performed without charge. If Purchaser requests warranty service, the service visit will be scheduled at a mutually acceptable time. If Purchaser refuses to make the Product available for service upon arrival of the IDI service representative, the Purchaser will be responsible for payment of service travel time and expenses and all time on site that the service representative is required to wait for access to the Product, whether or not the service is completed. These charges will be billed at IDI's prevailing service rates. If Purchaser requests Warranty service outside of normal business hours it will be provided at IDI's prevailing "after-hours" service rates and will be subject to availability of service personnel.

3. What Is Not Covered Bv This Warranty: IDI does not warrant (i) any Product or part not sold by IDI or its authorized representatives, (ii) defects caused by failure to provide a suitable installation environment for the Covered Product (iii) damage caused by use of the Covered Product for purposes other than those for which it was designed, (iv) damage caused by disasters such as fire, flood, wind, earthquake, lightning or other natural disasters, (v) damage caused by unauthorized attachments or modification, (vi) abuse or misuse by the Purchaser or its personnel, or (vii) other causes beyond IDI's control. Product damage or failures not covered by this warranty may include, but are not limited to, failure to adhere to instructions provided in the Product Operator Instructions.

4. Products not Covered bv This Warranty: The warranties set forth herein do not cover the following Products: (i) consumable items, including but not limited to drapes, (ii) used or refurbished equipment, (iii) Products serviced by anyone other than IDI or its authorized representatives during the Warranty Period.

5. Disclaimer of Warranty: THE FOREGOING WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

6. Limitation of Remedies: In no case shall IDI or its affiliates and representatives be liable for any special, incidental or consequential damages based upon breach of warranty, breach of contract, negligence, strict tort or any other legal theory. Such damages include, but are not limited to, loss of profits, loss of savings or revenue, loss of use of the Covered Products or any associated equipment, cost of capital, cost of any substitute equipment, facilities or services, downtime, the claims of third parties including customers and injury to property. This limitation does not apply to damages caused by breach of the warranty of title and patent or copyright infringement or to claims for personal injury.

7. No Other Warranties: Unless modified in writing and signed by both parties, this Warranty is understood to be the complete and exclusive product warranty agreement between the parties, superseding all prior agreements, oral or written, and all other communications between the parties relating to the subject matter of this Warranty. Except for an authorized IDI corporate officer, no IDI employee or IDI representative or any other party is authorized to make any warranty in addition to those made in this Agreement.

8. Warranty Terms Subject to Change: IDI reserves the right to modify the terms and conditions of its Official Warranty from time to time. The warranty terms and conditions, and IDI's obligations under such, will be determined based on the prevailing version of IDI's Official Warranty in effect at the date of purchase order.

[1] Certain parts subject to frequent wear and tear and misuse are limited to 12 months warranty as defined in Article 1 above.

Image Diagnostics, Inc.
Aspect Imaging Tables Official Product Warranty
for Tables Installed Outside the USA & Canada

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2. Exclusive Product Warranty Remedies: If Purchaser promptly notifies IDI of Purchaser's warranty claim, IDI will, at IDI's option, provide a replacement of the non-conforming Covered Product or parts of the Covered Product with either new or exchange replacement parts. Replaced parts will become the property of IDI. The warranty period for any Covered Product furnished to the customer as a warranty remedy will be the remaining portion of the warranty period applicable to the repaired or replaced Covered Product. All warranty service labor will be the responsibility of the Purchaser (Dealer).

3. What Is Not Covered By This Warranty: IDI does not warrant (i) any Product or part not sold by IDI or its authorized Distributors or representatives, (ii) defects caused by failure to provide a suitable installation environment for the Covered Product, (iii) damage caused by use of the Covered Product for purposes other than those for which it was designed, (iv) damage caused by disasters such as fire, flood, wind, earthquake, lightning or other natural disasters, (v) damage caused by unauthorized attachments or modification, (vi) abuse or misuse by the Purchaser or its personnel, or (vii) other causes beyond IDI's control. Product damage or failures not covered by this warranty may include, but are not limited to, failure to adhere to instructions provided in the Product Operator Instructions.

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5. Disclaimer of Warranty: THE FOREGOING WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

6. Limitation of Remedies: In no case shall IDI or its affiliates and representatives be liable for any special, incidental or consequential damages based upon breach of warranty, breach of contract, negligence, strict tort or any other legal theory. Such damages include, but are not limited to, loss of profits, loss of savings or revenue, loss of use of the Covered Products or any associated equipment, cost of capital, cost of any substitute equipment, facilities or services, downtime, the claims of third parties including customers and injury to property. This limitation does not apply to damages caused by breach of the warranty of title and patent or copyright infringement or to claims for personal injury.

7. No Other Warranties: Unless modified in writing and signed by both parties, this Warranty is understood to be the complete and exclusive product warranty agreement between the parties, superseding all prior agreements, oral or written, and all other communications between the parties relating to the subject matter of this Warranty. Except for an authorized IDI corporate officer, no IDI employee or IDI representative or any other party is authorized to make any warranty in addition to those made in this Agreement.

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