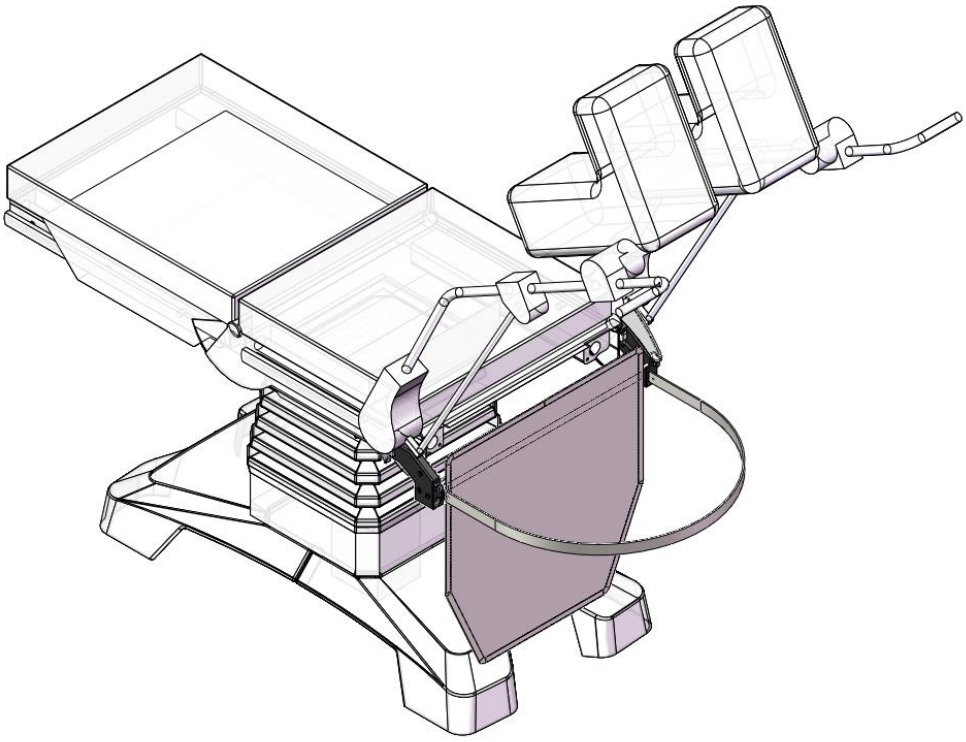
Urology Clamp Kit

Operator Manual

L100-3921 Rev A



ABOUT IMAGE DIAGNOSTICS, INC.

IDI is a leading manufacturer of specialized equipment and accessories for surgical and diagnostic imaging applications. Our company focus is on mobile equipment solutions for these applications, including C-arm compatible tables and mobile video display systems. IDI is headquartered in a modern 38,000 sq. ft. facility in Fitchburg, Massachusetts, USA, where IDI products are both designed and manufactured.

ORDER: sales@imagediagnostics.com
SUPPORT: techsupport@imagediagnostics.com
WEBSITE: https://imagediagnostics.com

+1-978-829-0009 (Press 1)
Monday through Friday
8am to 5pm, Eastern

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

OVERVIEW

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

The text of this manual was originally written, approved and published by the manufacturer in English.
This equipment complies with applicable FDA performance standards contained in 21CFR at date of manufacture.

OWNER RESPONSIBILITIES

The owner of this equipment is responsible for ensuring system compatibility, the qualifications of operators and maintenance personnel. Operators must be properly trained and have obtained credentials from the appropriate authorities.

This equipment must be installed onto Merivaara Smarter Practico operating tables or Image Diagnostics , Inc. The owner of this equipment is responsible for verifying continued compliance with all applicable regulations and standards. Consult local, state, federal and/or international agencies regarding specific requirements and regulations applicable to the use of this equipment.

Image Diagnostics, Inc. certifies only this equipment. Operating practices and safety for this equipment are the sole responsibility of the owner and operators. Image Diagnostics, Inc. assumes no liability or
responsibility for personal injury or damage resulting from misuse of this equipment.

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

CUSTOMER SUPPORT

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

For technical assistance, call IDI at (978) 829-0009 press 1. Be prepared to give the complete model and serial number found on the data plate on the equipment at the time of contact. Product Data

SYMBOL IDENTIFICATION

Attention! Consult accompanying documents.
Failure to follow these instructions could cause serious personal injury or damage to equipment.

Warning! Information or instructions shown near this symbol must be adhered to in order to prevent a potentially hazardous situation which if not avoided, could result in death, personal injury or damage to the equipment.

Recyclable material.

Not made with natural rubber latex.

Model of device

Serial Number of device.

Date of manufacture of the device.

Location where device was manufactured.

INTENDED USE & ESSENTIAL PERFORMANCE

The Uro kit device is intended to facilitate the mounting of drain bag, stirrups and a radiation shielding accessory to the Merivaara Smarter Practico OR table or Image Diagnostics, Inc. 100UC table, enabling its use in medical procedures. In most cases, medical and hybrid professionals can utilize the device in various procedures, including but not limited to Vascular, Ortho, Trauma, Spine, GI, Urology and OBL Cath labs.

Functional capabilities and operation of the equipment described herein can be employed in a variety of diagnostic, therapeutic, and surgical applications.

SAFETY HAZARDS

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

WARNING!

Do not modify this equipment without authorization of the manufacturer.

WARNING!

Do not attempt to service/perform maintenance while the ME Equipment is in use.

WARNING!

Do not exceed table weight capacity of 469.5lbs (213kg) on Merivaara Smarter Practico OR Table.

WARNING!

***Ensure the equipment is clamped to the device p*rior to starting procedure.**

CAUTION

Overtightening/over loosening of clamp might cause damage to the equipment.

CAUTION

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

CAUTION

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

CAUTION

When pairing leg holder stirrups with this equipment, use caution. The boot will drift if the clamp is not securely tightened.

CAUTION

When radiation shield (A610-0389) mounted onto the equipment, caution using the motorized leg extension on Merivaara Smarter Practico as it might cause permanent damage to the device.

CAUTION

When radiation shield (A610-0389) mounted onto the equipment, caution using the motorized leg extension on Merivaara Smarter Practico as it might cause permanent damage to the device.

CAUTION

Device has not been tested for use with HF Surgical equipment, cardiac defirbrillators, or cardiac defirbillators monitors.

CAUTION

Device Not for use in MR environment.

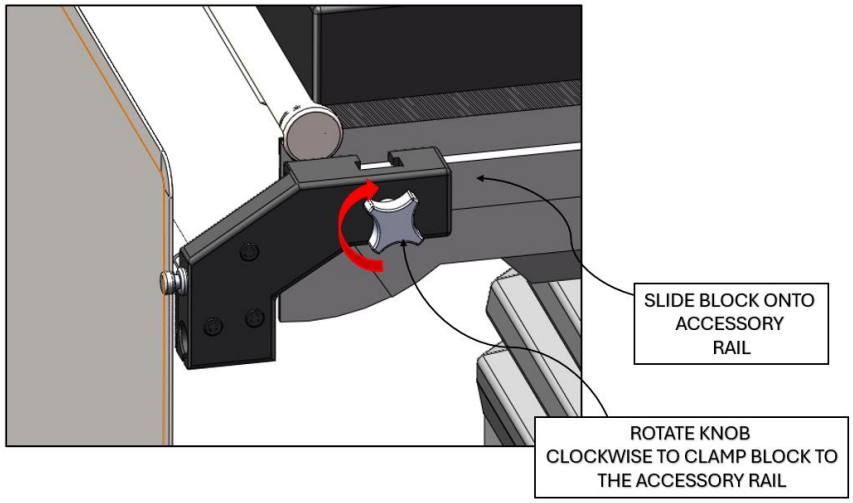
CAUTION

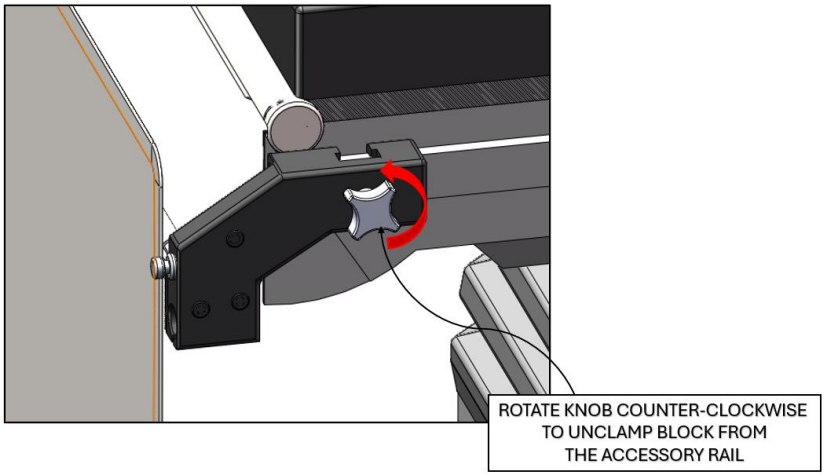
Device Not tested for use in Oxygen rich Environment

INSTRUCTIONS FOR EQUIPMENT OPERATION

1.1CLAMP LOCKING AND UNLOCKING

Install the Uro block by sliding it on to the table's accessory rail. Each accessory has a left and right-hand side, orientation should match what is shown below. Secure it by rotating the knob clockwise to clamp either the block onto the rail or the stirrups onto the rail. For adjustment for removal, simply rotate the knob in the counterclockwise direction, allowing easy repositioning or detachment of stirrups or the block.





1.2 Installing Stirrups

WARNING!

***Ensure the equipment is clamped to the device p*rior to starting procedure.**

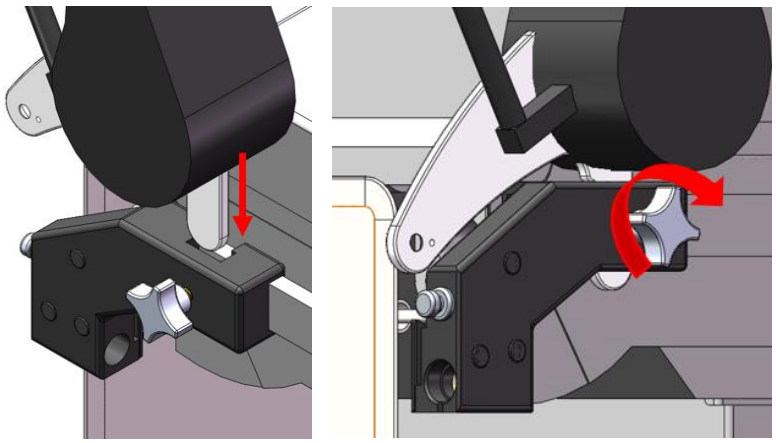
CAUTION

When pairing leg holder stirrups with this equipment, use caution. The boot will drift if the clamp is not securely tightened.

CAUTION

Overtightening/over loosening of clamp might cause damage to the equipment.

Insert the stirrup blade into the designated slot, then secure it by turning the knob clockwise. Once clamped, verify that both the block and stirrups are securely in place.



Rotate the knob counterclockwise for easy repositioning or detachment of stirrups.

PATIENT PREPARATION

2.1 Preparation for Patient Use

- New Installation: This equipment will need to be properly cleaned before patient use as it will inevitably come into contact with contaminants during shipping, unpacking, storage, and installation.
- After initial use, this equipment will need to be properly cleaned between uses with patients as it will inevitably come into contact with contaminants during procedures. Refer to the General Cleaning Section of this manual for cleaning instructions and approved cleaning substances.

2.2 Patient Loading

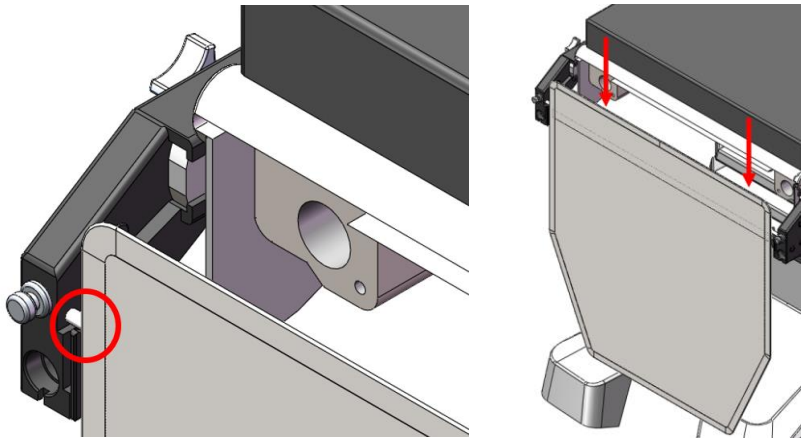
- Patient should be loaded per facilities procedures.

WARNING!

Ensure the equipment is clamped to the device before loading or unloading patient. Always safely position and secure patient.

2.3 RADIATION SHIELD

Radiation shield: A610-0389 (0.5mm Pb Eq) Install by dropping rod into the notches located in drain bag blocks. For proper Cleaning of shielding material, refer to General Cleaning Section.



WARNING!

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

Leg extensions on Merivaara Smarter Practico: When radiation shield (A610-0XXX) is mounted onto the equipment, caution using the motorized leg extensions as it might cause permanent damage to the device.

CAUTION

When radiation shield (A610-0389)is mounted onto the equipment, caution using the motorized leg extension on Merivaara Smarter Practico as it might cause permanent damage to the device.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L
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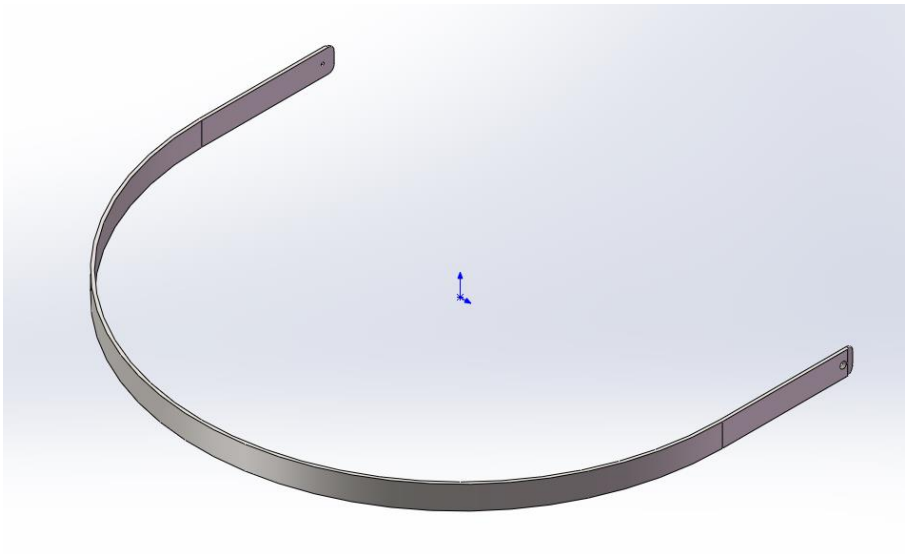
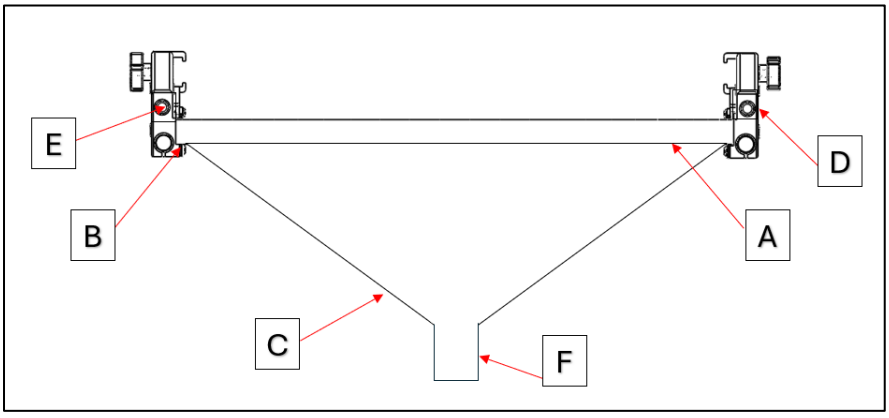
2.4 Drain bag Assembly

2.4.1 Uro Drain bag Assembly with Plastic Hoop

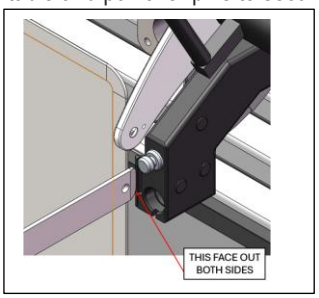




Drain bag hoop: Z100-3359
Do not throw away hoop, this is a reusable part

Installation:

1. Uro Drain bag with plastic hoop: C000-0593 (sterile) / C000-1111 (non-sterile) are intended for one time use collection of bodily fluid.
2. Slide each end of drain bag support hoop (A) into drain bag block slots (B) until internal spring pin engages. Make sure hoop face with angle faces outward on both sides when inserting.
3. Drop drain bag body (C) through hoop, while pulling drain bag edge hood over hoop's outer edge.
4. Grasp tab strips (D) of drain bag. Align holes with pins (E) on end of table and pull over pins to secure.
5. Connect hose (F) to collection system.



Removal:

1. Pull plastic tab strips (D) off support pins (E).
2. Pull out drain bag support.

Drain Bag Hoop Storage:

1. Drain Bag Hoop may be stored in its regular use configuration with both ends in drain bag block slots, with internal spring pins locking hoop in position.
2. Alternatively, Drain bag hoops may be laid flat or hung vertically with a mounting pin through the hole in the end of the hoop.
3. If slight deformation occurs, hoop may be laid flat or hung vertically for 24 hours. In some cases, the hoop will relax back to its flattened state. If the hoop does not return to its relaxed state or if hoop appears to have any structurally effecting deformation, hoop should be discarded and a replacement one should be ordered.

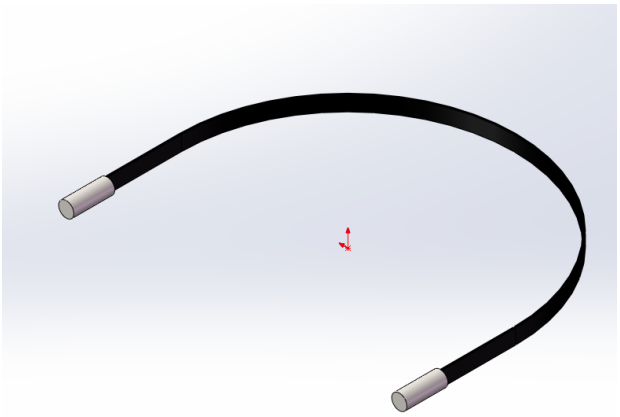
Not made with natural rubber latex.

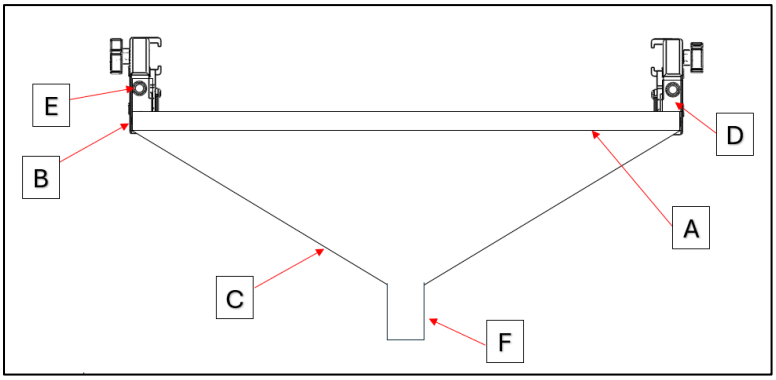
Dispose soiled drain bags per local procedures

CAUTION!

Do not leave drain bag support hoop fully pressed into drain bag blocks for more than 1 hr. Excessive bends for prolonged time can lead to permanent hoop deformation.

2.4.2 Uro Drain bag with Drain bag Hoop

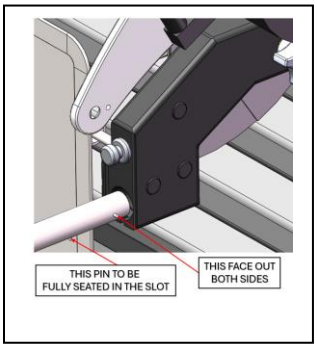




Drainbag Hoop: C000-0595

Installation:

1. Slide each end of drain bag support hoop (A) into drain bag block slots (B) until spring pin on drain bag hoop engages. Make sure the hoop face with the spring pin outward on both sides when inserting and the pin at the bottom should be seated the slot.
2. Drop drain bag body (C) through hoop, while pulling drain bag edge hood over hoop's outer edge.
3. Grasp tab strips (D) of drain bag. Align holes with pins (E) on end of table and pull over pins to secure.
4. Connect hose (F) to collection system.



Removal:

1. Pull plastic tab strips (D) off support pins (E).
2. Pull out drain bag support.
3. Do not throw away drain hoop, this is reusable component for the drain bag assembly

Drain Bag Hoop Storage:

1. Drain Bag Hoop may be stored in its regular use configuration with both ends in drain bag block slots, with spring pins on hoop locked in position with the block.

Not made with natural rubber latex.

Dispose soiled drain bags per local procedures

CAUTION!

Do not leave drain bag support hoop fully pressed into drain bag blocks for more than 1 hr. Excessive bends for prolonged time can lead to permanent hoop deformation.

2.5 List of Consumables

- **Vinyl Urology Table Covers: C000-0645** Box of 20
- **Uro Drain Bags with Hose** Sterile: **C000-0593** non-sterile: **C000-1111** Box of 20
- **Uro Drain bag Plastic Support Hoop: Z100-3359** Qty of 1 Each
- **Uro Drain bag Hoop: C000-0595** Qty of 1 Each
- **Uro Collection Unit:** 5 gal/18.9 L: **C000-0612** Box of 10
- **Uro Collection Unit:** 4 gal/15 L: **C000-1307** Box of 10

GENERAL CLEANING

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

APPROVED AND TESTED DISINFECTANT CLEANERS FOR EQUIPMENT:

- Sodium hypochlorite (generic household bleach) in solution of 5.25% sodium hypochlorite diluted between 1:10 and 1:100 with water.
- Alcohol (generic).
- Envirocide ® Disinfectant and Cleaner.

APPROVED AND TESTED DISINFECTANT CLEANER FOR RADIATION SHIELD:

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

APPROVED AND TESTED GENERAL-PURPOSE CLEANERS:

- Simple Green ™ cleaner.

CLEANING STEPS FOR CLAMP:

a) Detach Uro blocks from the accessory rail.
b) Wipe off any excess fluids with a water dampened cloth or sponge.
g) Clean the blocks and accessories using an approved cleaner listed above.
k) Gently rub with a soft, clean cloth until dry.

CLEANING STEPS FOR RADIATION SHIELD:

a) Remove the section from the Uro assembly and lay it flat before using the recommended cleaner in an adequately ventilated area.
b) Apply approved cleaner to one side at a time and allow to stand a few minutes.
c) Scrub with a soft bristle scrub brush. Do not let the solution dry before rinsing.
d) Rinse with water and a damp cloth.
e) Scrub and rinse again, if necessary.
f) Allow shield to fully dry before reinstalling.

MAINTENANCE SERVICE AND REPAIR

All maintenance procedures should be done by an experienced and qualified technician with demonstrated knowledge and skills (electrical and mechanical) in the service of medical equipment. Never attempt to service/repair while the ME Equipment is in use.

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

3.1. RECOMMENDED PERIODIC PERFORMANCE CHECKS

Daily	• Inspect clamping mechanism. Damaged hardware must be replaced promptly. Replacement must be performed only by a qualified service technician. • Inspect radiation shield slot. Ensure there is no debris in the designated slot to drop the shield.
Weekly	• Inspect drain bag hoop operation by sliding and removing hoops. • Clean the designated hole for the drain bag hoop. • Inspect the spring plunger on the drain bag hoop.
Semi-annually	• Inspect all labels and ensure that they can be read.
Annually	• Inspect set screw on the knob and inspect bolt responsible for clamping mechanism.

3.2. SERVICE & REPAIR STATEMENT

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

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

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

DISPOSAL OF COMPONENTS

The Equipment is made up of mostly aluminum parts, Steel and Brass which are easily recycled. It is recommended that some components be disassembled before disposal for recycling. The table below lists components

COMPONENT	ITEM	RECYCLING GROUP
Block	All components of block	Metal (Steel, Aluminum & Brass) Plastic
Drain Bag Hoop	Z100-3359 C000-0593	Plastic (Delrin) Metal (Steel)

PRODUCT DATA

Patient capacity:	
Merivaara Smarter Practico	~213kg (~469.5lbs)
Equipment:	
Equipment Weight (Each block)	~0.61kg (~1.35lbs)
Dimensions (Each block)	6 X 1 3/8" X 4 ¼" [L X W X H]

SPECIFICATIONS

Type of Equipment:

- This equipment is classified as a class I Medical device, and is noninvasive per FDA guidelines. Product code is HXD.

Environmental:

- Operating Temperature Range: -10°C to +40°C.
- Operating Humidity Range: 30% to 75% relative humidity, noncondensing.
- Operating Pressure Range: 700 hPa to 1060 hPa.
- Transport & Storage Temperature Range: -40°C to +60°C.
- Transport & Storage Humidity Range: 30% to 75% relative humidity, noncondensing.
- Transport & Storage Pressure Range: 500 hPa to 1060 hPa.

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)