Image Diagnostics, Inc.
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Fitchburg, MA 01420
United States of America

IDI Armboards
Instructions for Use



IDI Armboards:
IDI2000, IDI2005
IDI2006, IDI2007
IDI2008

Prior to using this or any other type of medical equipment with a patient, it is recommended that you read the *Instructions for Use* and familiarize yourself with the product.

- Read and understand all warnings in this manual and on the device itself prior to use with a patient.
- The symbol is intended to alert the user to important procedures or safety instructions regarding the use of this device.
- The symbol on the labels is intended to show when the IFU should be referenced for use.
- The techniques detailed in this manual are only manufacturer's suggestions. The final responsibility for patient care with respect to this device remains with the attending physician.
- Device function should be checked prior to each usage.
- This device should only be operated by trained personnel.
- All modifications, upgrades, or repairs must be performed by an authorized specialist.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the national competent authority where the user is located.

NEVER EXCEED THE WEIGHT CAPACITY AND LOAD DISTRIBUTON OF THE OPERATING ROOM TABLE

1 Instructions for Use:

1.1 Indication for Use:

These products are used in a variety of surgical procedures including, but not limited to gynecology, urology, laparoscopy, colorectal, general, and robotic surgery. These devices are capable of being used with a broad patient population as deemed appropriate by the caregiver or institution.

1.2 Intended Use:

These products are designed to position and support the patient in a variety of surgical procedures including, but not limited to gynecology, urology, laparoscopy, general and robotic surgery. These devices are intended to be used by healthcare professionals within the Operating Room setting.

1.3 Intended User and Patient Population:

Intended User: Surgeons, Nurses, Doctors, Physicians and/or Healthcare professionals involved in the intended procedure utilizing the device. Not intended for Lay persons.

Intended Populations: This device is intended to be used with patients that do not exceed the weight in the safe working load field specified in the product specification section 3.2.

1.4 Residual Risk:

This product complies with relevant performance, safety standards. However, device harm from misuse, device damage, function or mechanical hazards cannot be completely excluded. User is responsible to ensure device is securely attached and will operate in a safe manner.

2 Safety Considerations:

2.1 Safety hazard symbol notice:



DO NOT USE IF PRODUCT SHOWS VISIBLE DAMAGE.

2.2 Equipment Misuse:

Do not use the product if package is damaged or unintentionally opened before use. All modifications, upgrades, or repairs must be performed by an authorized specialist.

2.3 Safe Disposal:

Customers should adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories.

If in doubt, the user of the device shall first contact IDI Technical Support for guidance on safe disposal protocols.

2.4 Symbols:

Symbol Used	Description	Reference
MD	Indicates the device is a medical device	MDR 2017/745
	Indicates the medical device manufacturer	EN ISO 15223-1
SN	Indicates the manufacturer's serial number	EN ISO 15223-1
GTIN	Indicates the medical device Global Trade Item Number	21 CFR 830 MDR 2017/745
LOT	Indicates the manufacturer's lot code	EN ISO 15223-1
	Indicates the date when the medical device was manufactured	EN ISO 15223-1
REF	Indicates the manufacturer's catalogue number	EN ISO 15223-1
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions.	EN ISO 15223-1
LATEX	Indicates the device do not contain natural rubber or dry natural rubber latex	EN ISO 15223-1
EC REP	Indicates the authorized representative in the European Community	EN ISO 15223-1
CH REP	Indicates the authorized representative in Switzerland	EN ISO 15223-1
UK REP	Indicates the authorized representative in the United Kingdom	EN ISO 15223-1
UK CA	Indicates the Medical Device complies to REGULATION UK MDR 2002	UK MDR 2002
CE	Indicates the Medical Device complies to REGULATION (EU) 2017/745	MDR 2017/745
	Indicates a Warning	IEC 60601-1
	Indicates the need for the user to consult the instruction for use	EN ISO 15223-1

3 System:

3.1 System Componets Identification:



1. Armboard Base
2. Armboard Pad
3. Rotation Release Handle
4. Side Rail Clamp Attachment
5. Rail Release Lever

3.2 Product Specification

Mechanical Specifications	Description
Product Dimensions	26" x 5.5" (L x W) *approx.* 66cm x 14cm
Material	Stainless Steel, Aluminum, Carbon Steel, Delrin, and Polycarbonate
Safe Working Load on the Device	• Armboard: 500 lbs. (227 kg) • Bariatric Armboard: 800 lbs. (363kg)
Overall Weight of Device	• Armboard: 4 lbs. (1.8 kg) • Bariatric Armboard: 5 lbs. (2.27kg)
Storage Specifications	**Description**
Storage Temperature	-20° F to 140° F (-29° C to +60° C)
Storage Relative Humidity Range	15% to 85%
Operating Temperature	This device is intended to be used in a controlled Operating Room environment.
Operating Relative Humidity Range	
Compatibility Specifications	**Description**
Compatible with:	Armboard Replacement Pads
Operating Room Table Compatibility	Compatible with the following surgical table rail styles: US, UK, EU, DEN, JP, based on clamp selection.

3.3 System Setup and Use:





3.4 Device Maintenance

Make sure that all labels are installed and can be read. Replace labels as necessary by using a plastic scraper to remove the label. Use an alcohol wipe to remove any adhesive residue.

Contact IDI, if you need to repair or replace the device contact us using the information from the contact details section.

3.5 Cleaning and Disinfection:

WARNING:

- After each use, clean the device as directed in this instruction for use.
- Do not submerge the device in liquid. Equipment damage can occur.
- Use caution in areas where liquid can get into the mechanism.
- Do not use bleach or products that contain bleach to clean the device. Injury or equipment damage can occur.
- Make sure that the device is dry before you store it or use it again.

Wipes:

- Wipes may contain up to 2% sodium hypochlorite.
- Wipes may contain benzalkonium chloride (< or = 0.6% conc.) and didecyl dimethyl ammonium chloride (up to 0.6% conc.)
- Wipes may contain benzalkonium chloride (up to 0.6% conc.), didecyl dimethyl ammonium chloride (up to 0.6% conc.) and may also contain polyhexamethylene biguanide (up to 0.6% conc.).

Sprays:

- Sprays may contain up to 2% sodium hypochlorite.
- Sprays may contain up to .2% benzalkonium chloride and up to 0.2% didecyl dimethyl ammonium chloride (quaternary ammonium chloride solution (QACs) and may also contain polyhexamethylene biguanide (up to 0.6% conc.).
- Sprays may contain up to 2% hydrogen peroxide.

Read the cleaning product's directions and follow the instructions on the label. Use caution in areas where fluid migration may occur:

Wipe device with a clean, dry cloth. Make certain the product is dry prior to reinstalling to avoid damage.

CAUTION: Damage may result if product is cleaned with caustic chemicals or harsh abrasives

ATTENTION: If any IDI product is damaged or appears to be functioning abnormally, discontinue use and contact IDI Customer Service at 1-978-829-0009.

4 Compliance with Medical Device Regulations:

CE This product is a non-invasive, Class I Medical Device and system is CE-marked according to Annex VIII, Rule 1, of the Medical Device Regulations (REGULATION (EU) 2017/745).

4.1 EC Authorized Representative:

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

4.2 Manufacturing Information:

Kyra Medical, Inc.
102 Otis St
Northborough, MA 01532 USA
888-611-KYRA (North America)
508-936-3550 (International)

4.3 UK Authorized Representative:

UK REP
Emergo Consulting (UK) Limited
c/o Cr360 - UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ
United Kingdom

4.4 EU Importer:

Kyra Medical Europe Limited
Office 2, 12A Lower Main St
Lucan Dublin
K78X5P8
Ireland

4.5 CH Authorized Representative:

CH REP
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

IFU 03-0183 (DOC-141) Ver. 2

Approved By:

(CO-223) IDI, Dornier, Diacor IFU Updates for CH-Rep

Description

03-0122 Rev J, DORNIER Stirrups IFU 03-0123 Rev J, IDI Stirrups IFU 03-0183 Rev G, IDI Armboards IFU 03-0207 Rev I, IDI Clamps IFU 03-0266 Rev I, DIACOR Stirrups IFU

Justification

Addition of CH-Rep

Assigned To:	Initiated By:	Priority:	Impact:
Sherrie DiMare	Sherrie DiMare	High	Major

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