



# 460 SERIES EXAMINATION TABLE INSTALLATION AND OPERATION MANUAL

SAVE THIS MANUAL FOR FUTURE USE.

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# 1 INTRODUCTION

Congratulations on your purchase of the Intensa 460 Series Examination Table. The following pages will provide you with important safety and operating instructions on the installation and operation of the Examination Table, as well as maintenance and warranty information. Read this manual carefully before operating your Examination Table and refer to it as often as needed. Consult your authorized distributor and / or healthcare professional with any questions or concerns regarding safe and effective techniques for operating your Examination Table.

This guide covers the use of the Intensa 460 Series Examination Table. Keep in mind that the basic safety procedures included in this manual are to be used as a guide only. You may find it necessary to develop your own unique methods for safely utilizing the Examination Table. Again, consult your healthcare professionals for their recommendations and never hesitate to ask for their assistance.

Upon receipt of the Examination Table, inspect it closely to ensure that nothing is damaged, there are no loose or broken parts, that all Examination Table parts are in the proper place, etc. Immediately replace any worn or broken components. Your Examination Table should receive maintenance on a regular schedule and should be inspected frequently for proper operation. Contact Intensa Tech Support at 1.336.884.4096 with any maintenance concerns.

Info: Before attempting to install the Examination Table, refer to the section titled "INSTALLATION" contained elsewhere in this manual. Contact Intensa Tech Support at 1.336.884.4096 or your Intensa authorized distributor if additional assistance is needed.

# **INTENDED USE**

The Intensa 460 Series Examination Table is intended to support patients during medical examinations. During these exams, medical professionals use adjusting mechanisms to manipulate and position the table to provide patient support and closer examination of a portion of or the entire patient.

# **Contraindications**

## 2 SAFETY PRECAUTIONS

IMPORTANT: Before installing or using Examination Table, read and then follow the following safety precautions and warnings. Failure to do so could result in serious personal injury or damage to your Examination Table.

Always consult your healthcare professional to determine safe methods most suitable for your individual abilities. Protect yourself, your attendant and Examination Table by having it serviced regularly. If you experience any malfunction, contact Intensa Tech Support at 1.336.884.4096 or your Intensa authorized distributor immediately, as a hazardous condition could result, causing personal injury or damage to your Examination Table.

Periodic inspection, adjustment and replacement of worn parts are necessary to provide years of excellent service. Refer to *CARE AND MAINTENANCE* section of this manual.

Maintenance MUST be performed by qualified personnel ONLY.

# Significance of safety statements

Note the following special statements, used throughout this manual, and their significance:

- ▲ NOTICE: Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in product or property damage.

Info: Provides application recommendations or other useful information to ensure that you get the most from your product.

# **WARNINGS**

- ⚠ WARNING: Important! Read and understand these instructions before assembling or using the Intensa 460 Series Examination Table. If you do not understand any part of these warnings, cautions or instructions, contact a healthcare professional for direction in the use of this product. If the Intensa 460 Series Examination Table is not properly assembled, personal injury and damage to the 460 could result.

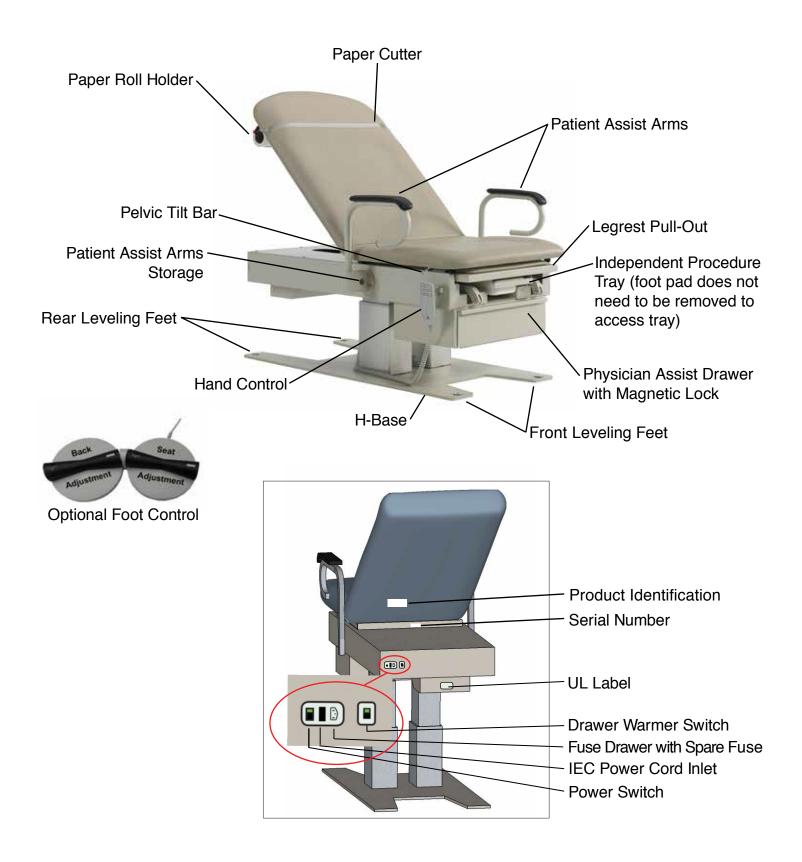
# **ELECTROMAGNETIC COMPATIBILITY (EMC) INFORMATION**

- ⚠ WARNING: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- ⚠ WARNING: Electronic equipment may be influenced by Radio Frequency (RFI). Caution should be exercised with regard to the use of portable communications in the area around such equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Intensa equipment including specified Intensa equipment cables. Degradation of the performance of the Intensa equipment could result.

- ⚠ WARNING: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is usually required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

# 3 FEATURES

# **EXAM TABLE COMPONENT IDENTIFICATION**



# 4 UNPACKING

# UNPACKING THE EXAM TABLE

- ▲ NOTICE: DO NOT use a knife or other sharp object to open packaging damage could occur to the exam table upholstery or surface.
- 1. Check for any obvious damage to the carton or its contents. If damage is evident, notify the carrier or your Intensa authorized distributor.
- 2. Carefully remove external strapping and boxing.
- 3. Carefully remove blocking from shipping pallet that secures exam table to pallet.
- ▲ NOTICE: DO NOT remove internal transport strapping from exam table until table is placed in final location; strapping will have labels denoting which straps should not be removed.
- 4. Once exam table is located in final position, remove internal transport strapping.
- 5. Carefully remove the exam table from the shipping pallet.

-

# 5 INSTALLATION

# **INSTALLATION ELECTRICAL REQUIREMENTS**

- **⚠ WARNING:** This table must only be connected to a mains supply with protective earth.

# **ELECTROMAGNETIC INTERFERENCE**

This product is designed and built to minimize electromagnetic interference with other devices. If interference is noticed:

- Remove interfering device from the room.
- · Plug exam table into an isolated circuit.

# **LEVELING THE EXAM TABLE**

Tools required: 3/8" hex key



- 1. Locate Leveling Screw Caps on H-Base Leveling Feet (4 Total) as shown at above left.
- 2. Remove all four Leveling Screw Caps by turning them counterclockwise. Leveling Screws will now be exposed, as shown at above center.
- 3. Adjust all four Leveling Screws, as shown at right above, by using a 3/8" hex key to turn them clockwise. STOP when each screw touches the floor.
- 4. Replace Leveling Screw Caps as shown at left above.

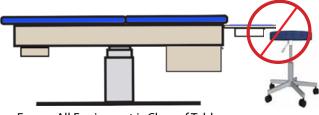
# 6 OPERATION

# **OPERATION SAFETY**

# **Exam Table Weight Capacity and Duty Cycle**

# **Personnel Clearance Safety**

# **Equipment Clearance Safety**



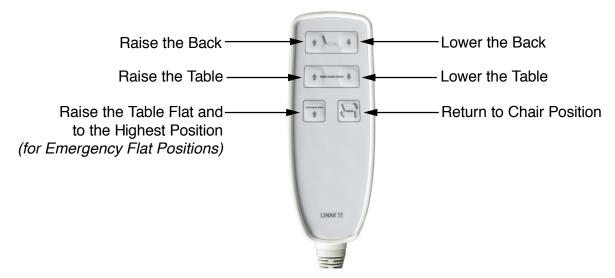
Ensure All Equipment is Clear of Table

- - Remove hand from hand control or remove foot from foot control.
  - 2. Unplug the exam table power cord, and
  - 3. Assist patient in getting off the table.

# **460 EXAM TABLE HIGH-LOW OPERATION**

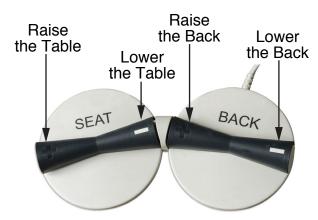
The exam table will stop once it reaches maximum or minimum height, whether operated with Hand Control Switch or Foot Control Switch.

# **Exam Table and Back Up and Down Using Hand Control**



**Hand Control Functions** 

# **Exam Table and Back Up and Down Using Foot Control**

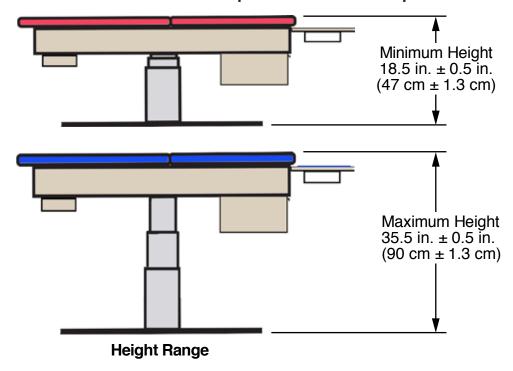


**Foot Control Functions** 

Info: The Foot Control will Not Control "Table Flat" or "Chair Position" Functions

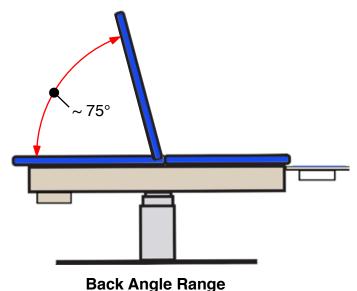
## **EXAM TABLE HEIGHT RANGE**

▲ NOTICE: This exam table is programmed with a limit switch. Once the table reaches its maximum height or minimum height, vertical movements of the table will stop. The bed height limit switch will activate if table requires more than 4 amps to raise.



# **EXAM TABLE BACK ANGLE RANGE**

⚠ WARNING: This exam table is maually operated. Once the back reaches its maximum angle or a horizontal position, the back will stop moving. When the back is lowered, ensure hands or other objects are clear from the downward motion area.



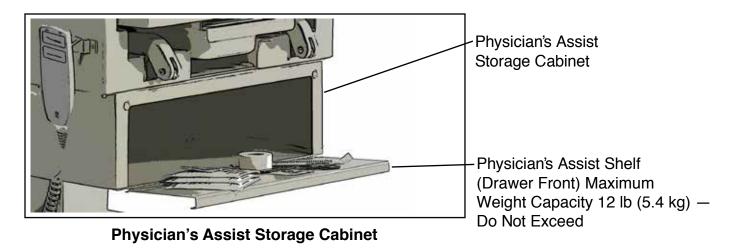
The exam table features a limited back angle of ~75° to accommodate heavier occupants comfortably, as shown above.

## PHYSICIAN'S ASSIST STORAGE CABINET

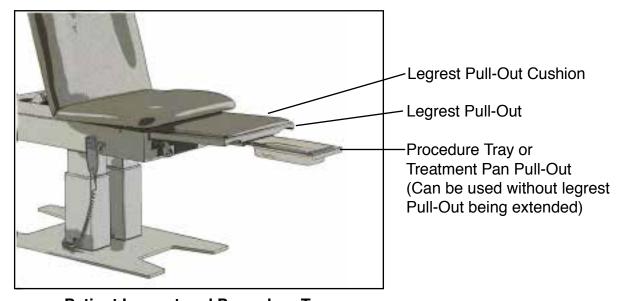
▲ NOTICE: The drawer front can be used as a shelf. The maximum weight that can be supported is 12 lb (5.4kg). The drawer front should not be lower than horizontal position; if drawer front is lower than horizontal postion, do not use drawer front as a shelf.

The Physician's Assist Storage Cabinet has the following features.

- Dimensions, W x D x H: 20 in. x 12 in. x 6 in. (50.8 cm x 30.5 cm x 15.2 cm)
- Opening, W x H: 18 in. x 5 in. (45.7 cm x 12.7 cm)
- Usable Shelf Space, W x D: 18 1/2 in. x 5 in. (47 cm x 12.7 cm)
- Magnetic Lock with 18 in. (45.7 cm) continuous hinge for extra shelf support



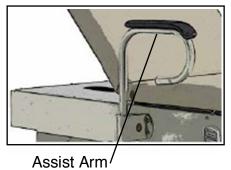
# PATIENT LEGREST AND PROCEDURE TRAY

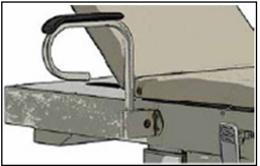


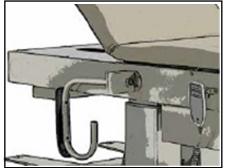
**Patient Legrest and Procedure Tray** 

The Legrest Pull-Out, shown above, is located under the seat portion of the table cushion and can be extended 16 in. (41 cm). The Procedure Tray or Treatment Pan can be extended up to 13 in. (33 cm) and can be used independently of the Legrest Pull-Out — the Legrest Pull-Out cushion need not be removed to access the Procedure Tray.

## PATIENT ASSIST ARM







**Forward Assist Arm Position** 

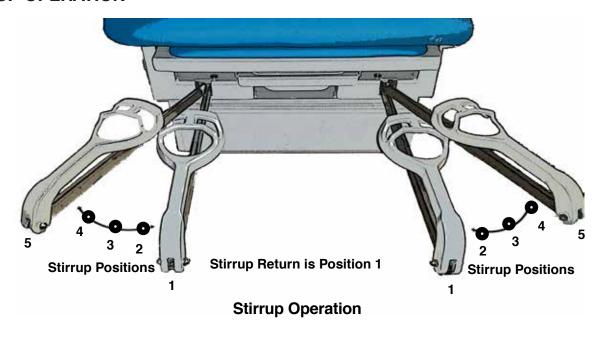
**Outward Assist Arm Position** 

**Rear Assist Arm Position** 

Refer to pictures above.

- Forward position is the normal Patient Assist Arm use position.
- Outward Position: Rotate Assist Arms 90 degrees outward by raising arms and turning them to outward position. To return to forward position, rotate arms forward into brackets.
- Assist Arm Storage: Rotate Assist Arms to rear position or totally remove and store them in side holes.

# STIRRUP OPERATION



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- 1. Pull Stirrup straight out and unfold heel portion.
- 2. To move stirrups left and right, lift slightly and move to desired location as shown above.
- 3. Press down to lock stirrup into one of the available five positions as shown above.

# **PELVIC TILT OPERATION**





**Pelvic Tilt Down Position** 

**Pelvic Tilt Up Position** 

- 1. Lift seat portion of upholstery to raise and lower pelvic tilt.
- 2. Once pelvic tilt is in desired position, lower the seat.

# 7 TROUBLESHOOTING

If you have a problem with your Intensa exam table, contact Intensa Tech Support at 1.336.884.4096 for further information. Do not attempt to repair components or parts on your exam table, as this may invalidate your warranty or cause further problems that may result in patient injury. Stop using your exam table immediately if it is not functioning correctly.

⚠ WARNING: If you experience a problem with your exam table and are unable to service it yourself, contact Intensa Tech Support at 1.336.884.4096.

# 8 MAINTENANCE

- ▲ NOTICE POSSIBLE EQUIPMENT DAMAGE HAZARD: Steam cleaning and pressure washing of exam table is not recommended and may void warranty.

Info: For more detailed information, please contact GF Health Products, Inc. at 1.336.884.4096.

# **CLEANING**

- ▲ NOTICE: DO NOT wash Examination Table under water pressure or steam clean.
- ▲ NOTICE: Cleaning solvents, dyes or sharp objects can damage upholstery. Promptly remove any excess fluids and rinse surface with clean water and wipe surface dry. Clean your upholstered top weekly. For basic cleaning use mild soap and water, rinse thoroughly and wipe surface dry.

Perform the following cleaning procedures as scheduled:

Component	Cleaning Procedure	Schedule	Cleaning Agent *	Special Notes
Pads	Wipe with damp cloth to remove any foreign material	After each use	Routine hospital grade disinfectants, soap and water	Use only medium strength cleaners Do not steam clean or pressure wash
Exam table	Wipe with damp cloth to remove any foreign material	After each use	Routine hospital grade disinfectants, soap and water	Lubricate pivot points after cleaning
Electrical components	Wipe external surfaces ONLY with damp cloth to remove any foreign material	After each use	Routine hospital grade disinfectants, soap and water	Use only medium strength cleaners

* Disinfecting and Cleaning Upholstery - ALWAYS follow manufacturer's recommended dilution			
Disinfectants	Phenolic disinfectants are the best choice for vinyl		
for vinyl products	Properly diluted quaternaries are also acceptable for vinyl		
products	Quaternary / Isopropyl disinfectants ARE NOT recommended for vinyl		
Disinfectants	Quaternary disinfectants are recommended for urethane		
for urethane products	Quaternary / Isopropyl disinfectants are recommended for urethane		
products	Phenolics SHOULD BE AVOIDED on urethane		
Disinfectants for all products	All fabrics may be cleaned with a 1:10 dilution of household bleaches containing 5.25% sodium hypochlorite as recommended by the Centers for Disease Control in Atlanta, Georgia; there is no harmful effect on the fabric		
	Disinfectants applied at full concentration or in highly concentrated solutions will decrease the useful life of fabric		
	lodophor-type disinfectants used on fabric may result in staining		
* Disinfecting and Cleaning Upholstery continued			

Soils or Stains	Use neutral soapsuds and lukewarm water; DO NOT use harsh cleansers, solvents or detergents
Hard-To- Clean Spots	Use standard household / vinyl cleansers and a soft bristle brush on troublesome spots or stains; presoak heavy, dried-on soil
Laundering	Laundering Vinyl-laminated, Polyurethane-coated, or Rubber-coated fabric IS NOT recommended; laundering may substantially decrease the useful life of the fabric

# **MAINTENANCE**

Have a qualified service technician perform the following maintenance as scheduled:

Maintenance Procedure	Materials / Action Required	Schedule
Inspect all mechanical functions for good operation	If replacement is needed, contact GF Health Products, Inc. at 1.336.884.4096	
Examine power cord for wear and function	Examine for external wear, cuts, or wear. If replacement is needed, contact GF Health Products, Inc. at 1.336.884.4096	Every 3 months
Inspect all fasteners to ensure proper fit, position and tightness (including nuts, bolts, etc.)	Proper size wrench and screwdriver	
Lubricate all moving and sliding parts and hinge points	Lubricating oil, light-duty grease, wax stick lubricant or Never-Seez lubricant	
Inspect all surfaces and remove any sharp or burred areas; apply touch-up paint where required	Metal file, proper color paint (specify color when ordering)	

#### **STORAGE**

Store the repackaged Examination Table in a dry area.

#### **DISPOSAL**

This product may contain substances that could be harmful to the environment if disposed of in places (landfills) that are not appropriate according to local legislation.

At the end of this product's useful life, dispose of it in accordance with local requirements, or contact the manufacturer for advice. Recycle this product through your recycling facility or dispose of it in accordance with local regulations.

We recommend disassembling and dividing the equipment and components into different waste groups such as: metal, cable, electronic, recoverable resource and plastic for recycling or combustion. Most plastic components are provided with a plastic types code and fiber content to aid sorting of plastic parts.

# 9 CERTIFICATION

# **10 SPECIFICATIONS**

Exam Table Load Rat	ing (Evenly Distributed)	600 lb (272 kg)
	imum Weight Capacity	50 lb (23 kg)
	aximum Weight Capacity	100 lb (46 kg)
Table Height Range		18.5" to 35.5" ± .5" (47 cm to 90 cm ± 1.3 cm)
Back Angle Range		0° to ~75°
<b>Upholstered Top Size</b>	• (W x L)	27 in. x 60 in. (69 cm x 152 cm)
<b>Upholstered Leg Sup</b>	port Pad Size (W x L)	18 in. x 19.5 in. (46 cm x 49.5 cm)
COM (Customer's Ow	n Material) Requirements	3 yd. (2.74 m)
Overall Exam Table L	ength	60 in. (152 cm)
Overall Exam Table L	ength with Leg Extension	73 in. (185 cm)
Drawer Size	3 Pass Through Drawers (W x L x D)	18 in. x 20.5 in. x 4 in. (46 cm x 52 cm x 10 cm)
	2 Storage Drawers (W x L x D)	17 in. x 17.5 in. x 4 in. (43 cm x 44 cm x 10 cm)
Electrical Requirements	Models 460, 460-AA, 460-DW, 460-DW-AA, 460-DW-PS-AA, 460-FL, 460-FS, 460-PS, 460-PS-AA, and 460-PS-DW	115-250 VAC Drawer warmer (two ea) 120-240 VAC
Power Cord Length (from table)		90 in. (229 cm)
	Specifications	300V / 18AWG/ 3 Conductor / SJT Jacket with Hospital Grade Plug or Detachable Power Cord
Control Box Fuse Rat	ting	4 Amp / 250 VAC Fast Blow
Foot Switch Ingress	Against Liquid	IPX-6
<b>Drawer Warmer (option</b>	onal) temperature	Will heat area approximately 97°-99°
Paper Roll Sizes (W x	Roll Diameter)	18 in. x 3 in. (46 cm x 8 cm)
		19 in. x 3 in. (48 cm x 8 cm)
		21 in. x 3 in. (53 cm x 8 cm)
Transport and	Temperature Range	-20°F to 150°F (-29°C to 66°C)
Storage Conditions	Relative Humidity	10% to 90%
Operating	Temperature Range	65°F to 85°F (18°C to 29°C)
Conditions	Relative Humidity	10% to 90%
Fuses		10 Amp / 250 VAC Fast Blow

# 11 LIMITED WARRANTY

#### SCOPE OF WARRANTY

Intensa, Inc. ("Intensa") warrants to the original purchaser only that it will replace or repair components, at Intensa's sole discretion, that are defective in material or workmanship under normal use and service. All warranties are conditioned upon the proper use of the products strictly in accordance with good commercial practice and applicable Intensa instructions and manuals, including proper use and maintenance. To the extent that a third party warrants a component, Intensa conveys all of its rights under that warranty to the original purchaser, to the extent permitted.

This limited warranty shall only apply to defects that are reported in accordance with the provisions set forth in this warranty document, within the applicable warranty period and which, upon examination by Intensa or its authorized representative, prove to be a warranty item. (See Obtaining Warranty Service below) This limited warranty is not transferable.

Within the guidelines set forth in this document, the warranted components and time periods are set forth below:

#### **EXAMINATION TABLE COMPONENTS**

Base:	5 years
Mechanical Components:	3 years
Electronic Components:	2 years
Original and Replacement Upholstered Tops 1	
Replacement Parts +:	90 days

- \* Labor is not included in the warranty.
- Upholstery is only warranted on material supplied by Intensa.
- † The warranty period is as designated above. If a part is replaced under warranty, the original warranty period will not be affected. All other replacement parts will be subject to the warranty period specified.

The applicable warranty period shall commence from date of shipment to the original customer, unless there is an expiration date on the component in which case the warranty shall expire on the earlier of warranty period or the expiration date.

#### **OBTAINING WARRANTY SERVICE**

This limited warranty shall only apply to defects that are reported to the Distributor from whom the Customer purchased the product within the applicable warranty period. If there is not a Distributor, you must contact Intensa directly by calling 1.336.884.4096, or by e-mailing a request to intensa@grahamfield.com. Specific directions will be provided by the Customer Service Representative. Failure to abide by the specific directions will result in denial of the warranty claim.

#### **EXCLUSIONS**

The warranty does not cover and Intensa shall not be liable for the following:

- 1) Defects, damage, or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, tampering or failure to seek and obtain repair or replacement in a timely manner;
- Products which are not installed, used, or properly cleaned and maintained as required in the official manual for the applicable product;
- 3) Products considered to be of a non-durable nature including, but not limited to: filters, fuses, gaskets, lubricants, and charts;
- 4) Accessories or parts not provided by Intensa;
- 5) Matching of color, grain or texture except to commercially acceptable standards;
- 6) Changes in color caused by natural or artificial light:
- 7) Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing, in advance, by Intensa;
- 8) Any labor or shipping charges incurred in the replacement part installation or repair;
- 9) Costs and expenses of regular maintenance and cleaning; and
- 10) Representations and warranties made by any person or entity other than Intensa.

## ENTIRE WARRANTY, EXCLUSIVE REMEDY AND CONSEQUENTIAL DAMAGES DISCLAIMER

THIS WARRANTY IS INTENSA'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. INTENSA MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IF ANY MODEL OR SAMPLE WAS SHOWN TO THE CUSTOMER, SUCH MODEL OR SAMPLE WAS USED MERELY TO ILLUSTRATE THE GENERAL TYPE AND QUALITY OF THE PRODUCT AND NOT TO REPRESENT THAT THE PRODUCT WOULD NECESSARILY CONFORM TO THE MODEL OR SAMPLE IN ALL RESPECTS. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF THE DEFECTIVE PARTS. INTENSA SHALL NOT BE LIABLE FOR AND HEREBY DISCLAIMS ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO: DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, COVER, OR EMPLOYEE OR INDEPENDENT CONTRACTOR WAGES, PAYMENTS AND BENEFITS. CERTAIN STATES MAY CONFER ADDITIONAL RIGHTS REGARDING WARRANTIES AND IN THOSE STATES INTENSA'S LIABILITY AND THE LIABILITY OF INTENSA'S SUPPLIERS, SHALL BE LIMITED TO THE FULLEST EXTENT PERMITTED BY LAW.

The warranties contained herein, together with Intensa's current Terms and Conditions, contain all the representations and warranties with respect to the subject matter of this document, and supersede all prior negotiations, agreements and understandings with respect thereto. The recipient of this document hereby acknowledges and represents that it has not relied on any representation, assertion, guarantee, warranty, collateral contract or other assurance, except those set out in this document. For additional information on this product or this warranty, please contact an Intensa Customer Service Representative.

#### NOTES

- Additional terms and conditions may apply. See Intensa's General Terms and Conditions on its website and the specific warranties, which may accompany the specific product.
- 2) Freight claims must be notated on the appropriate shipping documents and must be made with immediacy. International, federal and state regulations govern specific requirements for freight claims. Failure to abide by those regulations may result in a denial of the freight claim. Intensa will assist you in filing the freight claim.
- 3) Claims for any short shipment must be made within three (3) days of the invoice date.

# 12 KEY TO SYMBOLS

The following symbols are used on Intensa product labels.

Symbol	Meaning	
	Protective Earth	
<u></u>	Earth Ground	
$\wedge$	General Warning Sign	
A	Shock Hazard	
c Limb us Intertek	ETL	
EC REP	European Authorized Representative	
	Disconnect before Service	
MD	Medical Device	
	Manufacturer	
Ť	Keep Dry	

Symbol	Meaning	
Y	Fragile, Handle with Care	
X	Electrical and Electronic Equipment	
Consult Instructions for Use		
$\triangle$	Caution	
4	Pinch Point	
UDI	Unique Device Identifier	
11	Shipping Orientation	
	Maximum Weight Capacity 600 lb (272 kg) Evenly Distributed	
(° · · · )	Duty Cycle -10% - 2 minutes of use / 18 Minutes of non-use or downtime	

# 13 APPENDIX

# 13.1 GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC EMISSIONS

The Intensa 460 Series Examination Table is intended for use in the electromagnetic environment specified below. The customer or the user of the Intensa 460 Series Examination Table should assure that it is used in such an environment.

<b>Emissions Test</b>	Compliance	Electromagnetic Environment — Guidance
RF emissions CISPR 11	Group 1	The Intensa 460 Series Examination Table uses RF energy only for its internal function.
RF emissions CISPR 11	Class A	Therefore, its RF emission is very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The Intensa 460 Series Examination Table is suitable for use in all establishments other than
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

#### 13.2 ENCLOSURE PORT<sup>1</sup>

	Basic EMC standard or test method	IMMUNITY TEST LEVELS	
Phenomenon		Professional healthcare facility environment	
ELECTROSTATIC	IEC 61000-4-2	± 8 kV contact	
DISCHARGE		± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM	IEC 61000-4-3	3 V/m <sup>f)</sup>	
fields <sup>a)</sup>		80 MHz – 2,7 GHz <sup>b)</sup>	
		80 % AM at 1 kHz <sup>c)</sup>	
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 9.3.	
RATED power frequency magnetic fields d) e)	IEC 61000-4-8	30 A/m <sup>g)</sup>	
magnetic fields 27 27		50 Hz or 60 Hz	

a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.

b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).

f) Before modulation is applied.

This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT OR ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

# 13.3 ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT 1

Test frequency	Band <sup>a)</sup>	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power	Distance	IMMUNITY TEST LEVEL
(MHz)	(MHz)			(W)	(m)	(V/m)
385	380 –390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine	2	0,3	28
710			Pulse	0,2	0,3	9
745	704 – 787	LTE Band 13, 17	modulation <sup>b)</sup> 0,2 217 Hz			
780						
810		GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18 Hz	2	0,3	28
870	800 – 960					
930						
1 720		GSM 1800; CDMA 1900; GSM 1900;	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
1 845	1 700 –					
1 970	1 990	DECT; LTE Band 1, 3, 4, 25; UMTS				
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
5 240		WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0,2	0,3	9
5 500	5 100 – 5 800					
5 785						

## 13.4 INPUT AC POWER PORT 1

	Basic EMC standard	IMMUNITY TEST LEVELS	
Phenomenon		Professional healthcare facility environment	
Electrical fast transients /	IEC 61000-4-4	± 2 kV	
bursts a) i) o)		100 kHz repetition frequency	
Surges a) b) j) o)	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Line-to-line			
Surges a) b) j) k) o)	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Line-to-ground			
Conducted disturbances	IEC 61000-4-6	3 V <sup>m)</sup>	
induced by RF fields c) d) o)		0,15 MHz – 80 MHz	
		6 V <sup>m)</sup> in ISM bands between 0,15 MHz and 80 MHz <sup>n)</sup>	
		80 % AM at 1 kHz <sup>e)</sup>	
Voltage dips <sup>f) p) r)</sup>	IEC 61000-4-11	0 % <i>U</i> <sub>T</sub> ; 0,5 cycle <sup>g)</sup>	
		At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <sup>q)</sup>	
		0 % <i>U</i> <sub>T</sub> ; 1 cycle	
		and	
		70 % U <sub>T</sub> ; 25/30 cycles <sup>h)</sup>	
		Single phase: at 0°	
Voltage interruptions f) i) o) r)	IEC 61000-4-11	0 % U <sub>T</sub> ; 250/300 cycle <sup>h)</sup>	

- a) The test may be performed at any one power input voltage within the ME EQUIPMENT OR ME SYSTEM RATED voltage range. If the ME EQUIPMENT OR ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.
- b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.
- <sup>c)</sup> Calibration for current injection clamps shall be performed in a 150  $\Omega$  system.
- d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.
- 9) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.
- h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
- i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

# 13.4 CONTINUED

- ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).
- k) Not applicable to Class II ME EQUIPMENT and ME SYSTEMS.
- Direct coupling shall be used.
- m) r.m.s., before modulation is applied.
- n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
- o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.
- p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.
- q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
- r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range. See Table 1 Note c) for examples calculations.

# 13.5 PATIENT COUPLING PORT 1

	Basic EMC standard	IMMUNITY TEST LEVELS	
Phenomenon		Professional healthcare facility environment	
ELECTROSTATIC DISCHARGE <sup>C)</sup>	IEC 61000-4-2	± 8 kV contact	
		± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Conducted disturbances induced by RF fields <sup>a)</sup>	IEC 61000-4-6	3 V <sup>b)</sup> 0,15 MHz – 80 MHz 6 V <sup>b)</sup> in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	

- a) The following apply:
  - All PATIENT-COUPLED cables shall be tested, either individually or bundled
  - PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
  - No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
  - Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
  - Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
  - If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
  - The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
- b) r.m.s., before modulation is applied
- C) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

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## 13.6 SIGNAL INPUT / OUTPUT PARTS PORT 1

	Paris FMC	IMMUNITY TEST LEVELS	
Phenomenon	Basic EMC standard	Professional healthcare facility environment	
ELECTROSTATIC DISCHARGE <sup>e)</sup>	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Electrical fast transients / bursts b) f)	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency	
Surges Line-to-ground <sup>a)</sup>	IEC 61000-4-5	± 2 kV	
Conducted disturbances induced by RF fields b) d) g)	IEC 61000-4-6	3 V h) 0,15 MHz - 80 MHz 6 V h) in ISM bands between 0,15 MHz and 80 MHz i) 80 % AM at 1 kHz c)	

- a) This test applies only to output lines intended to connect directly to outdoor cables.
- b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- <sup>d)</sup> Calibration for current injection clamps shall be performed in a 150  $\Omega$  system.
- e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.
- f) Capacitive coupling shall be used.
- g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- h) r.m.s., before modulation is applied.
- The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

# 13.7 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND INTENSA 460 SERIES EXAMINATION TABLE

The Intensa 460 Series Examination Table is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Intensa 460 Series Examination Table can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Intensa 460 Series Examination Table as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)				
power of transmitter (W)	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.7 GHz d = 2.3√P		
0,01	0.12	0.12	0.23		
0,1	0.38	0.38	0.73		
1	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

# 13.8 NOTES TO SECTIONS 13.2 - 13.7

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Lubrication 17













