

# ENDO STRATUS™

## Irrigation Pump

### Instructions for Use – GI Endoscopy

MODEL: EGA-500

MODEL: EGA-500E

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# Instruction Manual

English

## Unpacking And Inspection

Upon receiving the ENDO STRATUS™ Irrigation Pump, ensure that the following items are contained in the shipping box:

- Base tray and Water Bottle Holder
- Operator's manual
- Foot Pedal
- Hardware to assemble base tray and Water Bottle Holder
- Power cord
- Pump Head



Read this manual thoroughly before proceeding with the operation of this equipment. The user manual is written at a level such that it can be understood by the intended users and is consistent with the education and training of users. These instructions should be stored and used for reference as needed. If there are any questions, please contact Customer Service - Service Department at 800-444-4729 / International: 01-782-594164.

## Introduction

### Definitions

Throughout this document the ENDO STRATUS Irrigation Pump may be referred to as "unit" or "device".

- mL/min – milliliters per minute (flow)
- kPa – kilo Pascal (pressure)
- VA – Volt Amps
- VAC – Volts Alternating Current (electrical potential)
- W – Watts
- Hz – Hertz (frequency)

### Indications For Use

- Federal (USA) law restricts this device to sale by or on the order of physician.
- The ENDO STRATUS Irrigation Pump is indicated for GI endoscopic irrigation with room temperature or warm water for use with washing catheters, integral GI endoscope water jet channels and GI endoscope working channels.
- The device contains a heated water bottle cradle that is intended to maintain a sterile water bottle for GI endoscopic irrigation at a maximum temperature set point of 37°C with a tolerance of  $\pm 3^{\circ}\text{C}$ .

### Contraindications

- The device should only be used for GI endoscopic procedures requiring irrigation of the gastrointestinal tract and should not be used for any other treatments or procedures.
- The device is not intended for use with or exposure to Magnetic Resonance Imaging (MRI) systems. Do not use the device in an environment where it could be exposed to MRI systems.

## Warnings And Cautions

### Signal Words



**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. It may also be used to alert against unsafe practices or potential equipment damage.

### Safety Symbols



Attention



Refer to operating instructions



**WARNING:**  
Dangerous voltage



Equipotentiality



Do not allow fingers to contact moving parts



Hot surface



MR unsafe

## Warnings

- A. To reduce risk of electrical shock, do not remove cover. Refer servicing to qualified service personnel.
- B. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth ground.
- C. The ENDO STRATUS™ Irrigation Pump is not suitable for use in the presence of a flammable anesthetic mixture with oxygen.
- D. The ENDO STRATUS Irrigation Pump shall be sold only by prescription for use by physicians/clinicians who are trained regarding the amount of water to use for irrigation and infusion.
- E. Always watch for abnormal flow rates and adjust the flow rate as necessary. If an unusual flow rate remains after adjustments have been made, then stop the procedure and investigate.
- F. Only qualified medical personnel in an acceptable medical facility should operate the ENDO STRATUS Irrigation Pump.
- G. The ENDO STRATUS Irrigation Pump should be connected to a properly grounded 120V receptacle marked "Hospital Grade" or "Hospital Only," otherwise grounding reliability cannot be achieved.
- H. Extreme precaution must be taken when handling liquids around electrical equipment. Do not operate the ENDO STRATUS Irrigation Pump if liquid has been spilled on the unit.
- I. The ENDO STRATUS Irrigation Pump should not be used adjacent to or stacked with other equipment other than another ENDO STRATUS device. Electromagnetic or other interference may occur between the ENDO STRATUS Irrigation Pump and other electronic devices. If stacked or adjacent use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- J. The ENDO STRATUS Irrigation Pump should only be used in conjunction with other equipment whose safety against leakage currents has been established.
- K. The instructions contained in the operating manuals of any equipment to be used in conjunction with the ENDO STRATUS Irrigation Pump must be followed to avoid any possible hazard from incompatibility.
- L. The instructions for use described in this manual must be followed. Otherwise, compromised safety, malfunction, injury to the operator and/or patient, or costly damage to the unit and other equipment may occur. Potential patient harms include pain, bloating, GI tract bleeding/irritation, perforation, infection, vagal reaction and headache.
- M. The ENDO STRATUS Irrigation Pump must be connected to an appropriate power source when loss of power source would result in an unacceptable risk.

## Caution

- A. If emergency or abnormal function occurs, immediately turn OFF the power to the unit.
- B. Field-servicing of the ENDO STRATUS Irrigation Pump is limited to the replacement of the power cords, Water Bottle Holder and heater assemblies, Pump Heads, Foot Pedals and fuses.
- C. Remove power from the device before initiating any field servicing of the replacement parts.
- D. There are no user serviceable parts inside the ENDO STRATUS Irrigation Pump unit. Repairs to the ENDO STRATUS Irrigation Pump should only be performed by qualified service personnel.
- E. Do not use the device if the enclosure is damaged or enclosure integrity has been compromised.
- F. Do not attempt to operate the device before reading and understanding all sections of this manual.
- G. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in *Electromagnetic Compatibility Information*.
- H. Portable and mobile Radio Frequency (RF) communications equipment can affect medical electrical equipment. Do not expose the device to sources of electromagnetic interference such as CT equipment, diathermy equipment, cellular phones, RFID tags and metal detectors.

## Product Features

- Built-in water bottle warmer maintains water at up to 37°C with an allowable tolerance of  $\pm 3^\circ\text{C}$ .
- Prime feature runs pump for 20 seconds with automatic timer.
- Includes side water bottle clip for traditional Water Bottle Holder.
- Safety feature prevents pump from running when Pump Head is open.
- Robust motor design for consistent performance.
- Water Bottle Holder is angled for easier access to water bottle and tubing.

## Theory Of Operation

The ENDO STRATUS Irrigation Pump works by turning a peristaltic-roller-type Pump Head to move liquid through a tube set and into a GI endoscope system. The Pump Head will not operate if the Pump Head is open, and will cease to operate if the Pump Head is opened while the motor is activated.

The unit incorporates a Prime feature which allows the unit to operate for a pre-set period of time. This feature can be canceled while in progress by pressing the Foot Pedal.

The water bottle warmer is intended to maintain the warmth of the water in a sterile water bottle that has been pre-warmed. It is controlled by dual temperature sensors for redundancy and safety. There is a heating element integrated into the Water Bottle Holder which then radiates heat through the bottle and into the water. The temperature of the Water Bottle Holder is maintained at a maximum of  $37^\circ\text{C} \pm 3^\circ\text{C}$ .

# Technical Specifications

## Electrical Specifications

Input Voltage:	100-240 VAC
Input Frequency:	50-60 Hz
Power Consumption:	110 VA
Fuse Rating:	M10AL250V Medium-acting, 10 amp, low-breaking capacity, 250 volt Replace fuses only with those of same type and rating
Certifications:	IEC-60601-1, IEC-60601-1-2, IEC-60601-2-18
Classification:	Class 1 Type B
Water Bottle Warmer:	20W resistive element with dual temperature sensors.
IP Rating (Ingress Protection):	IP24



**WARNING: Grounding reliability can only be achieved when connected to a receptacle marked "Hospital Grade".**

## Mechanical Specifications

### Physical Dimensions:

• Height	4 3/4" inches	121 mm
• Width	7 3/4" inches	197 mm
• Depth	13 3/4" inches	349 mm
• Weight	10.5 pounds	4.8 kg

### Flow Rates:

• Auxiliary Water Channel	0-300 ml/min*
• Biopsy Channel	0-650 ml/min*

\*These values are approximate and are based on an average flow obtained with three different manufacturer's GI endoscopes with biopsy channel diameters ranging from 2.8 mm - 4.2 mm and auxiliary water channel diameters ranging from 0.8mm - 1.0 mm. User results may vary depending on scope used, channel size and working channel length.



**CAUTION: The ENDO STRATUS™ Irrigation Pump is intended for use only by physicians/clinicians who are trained regarding the amount of water to use for irrigation and infusion during GI endoscopic procedures.**

## Environmental Requirements

• Operating Temperature:	16° to 24°C (+61° to 75°F)
• Operating Relative Humidity:	30% to 75% non-condensing
• Operating Pressure:	70 kPa-106 kPa_(10.2 PSI -15.4 PSI)

## Accessory Items



Note: The ENDO STRATUS™ Irrigation Pump EGA-500 is intended to be used only with the specific models of compatible tubing sets, connectors and accessories identified in the table below and/or officially recommended by Medivators. Use of the device with accessories not identified in the table below or officially recommended by Medivators may result in incompatibility and/or the risk of cross-contamination and infection transmission.

Category / Type	Description	Order Number
Irrigation Tubing	ENDOGATOR™ Irrigation Tubing For Use With EGA-500	100130 (24 Hr Use)
	ENDOGATOR Irrigation Tubing For Use With EGA-500E	100130U (24 Hr Use)
	ENDOGATOR™ Hybrid Tubing For OLYMPUS® 140/160/180/190 Series GI Endoscopes For Use With EGA-500	100609 (24 Hr Use)
	ENDOGATOR Hybrid Tubing For OLYMPUS 140/160/180/190 Series GI Endoscopes For Use With EGA-500E	100609S (24 Hr Use)
Connectors / Valves / Adapters	ENDOGATOR™ Single Patient Use Auxiliary Water Jet Connector For OLYMPUS GI Endoscopes	100241 (Single Patient Use)
	ENDOGATOR Single Patient Use Auxiliary Water Jet Connector For PENTAX® GI Endoscopes	100242 (Single Patient Use)
	Adapter For Connecting ENDOGATOR Tubing To FUJIFILM™ 530 Series GI Endoscopes	100141 (Single Patient Use)
	Backflow Valve	100126 (Single Patient Use)
	Biopsy Irrigation Channel Tubing	100135 (Single Patient Use)
	ENDOGATOR™ Channel Adapter	100136 (Single Patient Use)
	DEFENDO™ Y-OPSY™ Irrigator For OLYMPUS GI Endoscopes	100303 (Single Patient Use)

## Replacement Parts

Use of replacement parts and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

EGA-500		EGA-500E	
Item	Order Number	Item	Order Number
Power Cord	EGA-7014	Power Cord (UK)	EGA-7022
		Power Cord (EU)	EGA-7017
		Power Cord (AUS)	EGA-7021
Water Bottle Holder and Warmer Assembly	EGA-7010	Water Bottle Holder and Warmer Assembly	EGA-7010
Pump Head	EGA-7016	Pump Head	EGA-7016
Foot Pedal	47049-942	Foot Pedal	47049-942

## Front Panel Controls/Connections



Note: All status indicator lights will be green during normal operation.

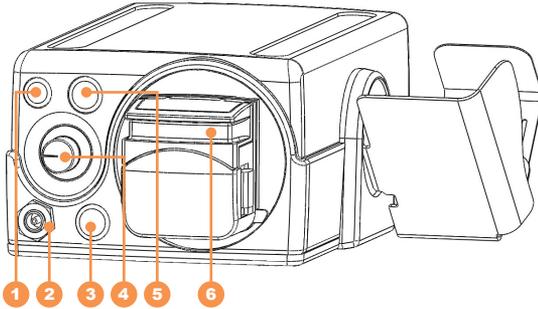


Figure 1: Front panel. The appearance of your device may differ slightly from picture shown above.

No.	Name	Description
1	On/Off Push Button	Turns main power ON or OFF to the unit.
2	Foot Pedal Connection	
3	Prime Button	When pressed, pump will run for a period of 20 seconds. The cycle can be canceled at any time by either pressing the Foot Pedal or Prime button again. See <i>Setup and Operation</i> for full explanation.
4	Pump Flow Control	The Flow Control knob is a continuous variable Flow Control that has settings between 0-100% flow. The lowest knob setting corresponds to no flow while the max Flow Control setting represents 100% flow. It contains bracketed visual iterations to represent flow magnitude in increasing increments of approximately 10%, however the Flow Control knob response is not entirely linear. Incremental Flow Control knob increases between 50-100% have a larger impact on flow rate response as compared to incremental changes between 0-50%. Flow Rates:           Auxiliary Water Channel       0-300 ml/min* Biopsy Channel                       0-650 ml/min*
5	Water Bottle Warmer On/Off	Push to turn Water Warmer ON or OFF.
6	Pump Head	Refer to <i>Setup and Operation</i> for assembly instructions.

\*These values are approximate and are based on an average flow obtained with three different manufacturer's GI endoscopes with biopsy channel diameters ranging from 2.8 mm-4.2 mm and auxiliary water channel diameters ranging from 0.8 mm-1.0mm. User results may vary depending on scope used, channel size and working channel length.



**CAUTION:** The ENDO STRATUS™ Irrigation Pump is intended for use only by physicians/clinicians who are trained regarding the amount of water to use for irrigation and infusion during GI endoscopic procedures.

## Rear Panel Connections

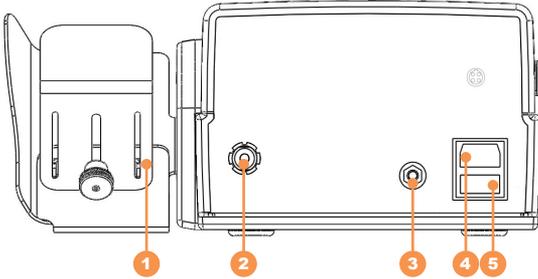


Figure 2: Rear panel. The appearance of your device may differ slightly from picture shown above.

No.	Name	Description
1	Water Bottle Holder and Warmer	The Water Bottle Holder contains the heating element and an integral hold-down bracket to secure the water bottle in place.
2	Water Bottle Warmer Connection	Power connection for water bottle warmer.
3	Equipotentiality (Earth Ground)	
4	AC Power Connection	AC power input 100-240 VAC, 50-60HZ.
5	Fuse Receptacle	



**WARNING: Use only the Hospital Grade power line cord supplied with this unit. Connect only to a power receptacle marked as Hospital Grade.**

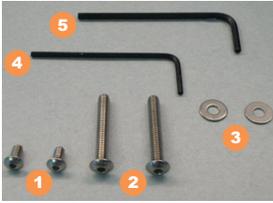


**WARNING: Replace Fuse Receptacle only with type and rating marked M10AL250V.**

# Setup And Operation

## Initial Setup

1. Before beginning, visually inspect the exterior of the ENDO STRATUS™ Irrigation Pump for any signs of damage.
2. Install the Pump Head onto the device by aligning the flat shaft on the front of the device with the slotted hole in the Pump Head and rotate the Pump Head until it locks in place.
3. Assemble the Water Bottle Holder and Warmer Assembly in the following manner:
  - A. The following supplies are necessary and can be found in a bag attached to the Water Bottle Holder:



No.	Name	Description
1	Short Screws	Two (2) screws.
2	Long Screws	Two (2) screws.
3	Washers	
4	Small Hex Key	
5	Large Hex Key	

- B. Attach the Water Bottle Holder to the base tray using the (2) small screws, washers and small hex key.



- C. Place the ENDO STRATUS Irrigation Pump on the base tray and install the (2) long screws using the large hex key.



- D. Adjust the Water Bottle Hold-Down Bracket to fit the water bottles used by your facility. This is done by loosening the nut on the back and sliding the bracket up or down so it contacts the water bottle and then re-tightening the nut.
4. Plug the Water Warmer Cable into the receptacle marked "Water Warmer" on the back of the unit.
  5. Place the ENDO STRATUS Irrigation Pump on a flat surface such as an endoscope accessory cart or other suitable working surface.
  6. Before connecting the power cord to the Hospital Grade wall receptacle, make sure the power is OFF to the device, and no accessories are connected.
  7. Connect the power cord to the back of the device.

## Pre-Procedure Setup

1. Place the Foot Pedal on the floor and insert the Foot Pedal cord into the designated front panel receptacle.
2. Insert a water bottle containing sterile water into the Water Bottle Holder.



**CAUTION: Use of irrigation fluid other than sterile water can pose an infection risk to patients.**

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Adjust the hold-down bracket by loosening the knob, lowering the bracket until it contacts the top of the bottle and then tightening the adjusting screw. After initial setup, if the same size and type of bottle is used, it should require no further adjustment.

3. Open a sterile pouch of the 100130 ENDOGATOR™ Irrigation Tubing or 100609 ENDOGATOR™ Hybrid Tubing. Read and follow its instructions for use.



**CAUTION: The ENDO STRATUS™ Irrigation Pump EGA-500 and EGA-500E is intended to be used only with specific models of compatible tubing sets, connectors and accessories identified in the table in *Technical Specifications* or officially recommended by Medivators. Use of the device with accessories not identified in the accessories table or officially recommended by Medivators may result in incompatibility and/or the risk of cross contamination and infection transmission.**

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4. Connect the tubing to the water bottle.
5. Open the Pump Head and place the tubing into the Pump Head rollers so that the water flow will be from right-to-left facing the pump.



Note: The device is equipped with a safety feature so that the pump will not operate if the Pump Head is open.

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6. Turn the Flow Rate Indicator to its lowest speed and turn the unit ON.
7. Perform the following procedure to ensure the tubing is fully filled with sterile water each time before connecting to a GI endoscope.
  - A. Direct the end of the tube into a receptacle capable of catching expelled water.
  - B. Depress the foot switch and turn up the Flow Rate Adjustment to the desired level based on the irrigation connection to the GI endoscope.



Note: The Prime function allows the user to perform this feature with the assistance of an automatic timer in lieu of pressing the Foot Pedal. Pressing the Prime button will run the pump for a period of 20 seconds. If at any time the Prime cycle needs to be stopped the button can be pressed again, or the Foot Pedal can be pressed.

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**CAUTION: The Prime function is not intended to be a definite means of fully priming the tubing. It is the responsibility of the end user to ensure the tubing and GI endoscope channel are fully filled with water before proceeding.**

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8. When priming is complete, attach the Irrigation Tube Set to the GI endoscope using the proper adapter for the endoscope model and endoscope channel (see *Technical Specifications* for a complete list of irrigation tubing and adaptors for various GI endoscopes).
9. The ENDO STRATUS™ Irrigation Pump is now ready to use.



**CAUTION: Never allow the sterile water bottle to empty completely to avoid air entering the irrigation tubing.**

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## Water Pre-Warming

1. The ENDO STRATUS™ Irrigation Pump has an integral water warming system that can maintain the temperature of the water at up to  $37 \pm 3^\circ\text{C}$ .



Note: The system is not intended to raise the temperature of the water; therefore pre-warming of the water bottle is required.

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2. Place sterile water bottle in a fluid warming oven set to  $37^\circ\text{C}$  for at least 2 hours until the water has been warmed to at least  $37^\circ\text{C} \pm 3^\circ\text{C}$ . Do not exceed this temperature. If warm water is not desired, turn the Water Warmer on the pump OFF and place a bottle of room temperature sterile water on the Water Bottle Holder.



**CAUTION: Excessively high water temperatures may result in patient hyperthermia, scalding and increased bleeding. Excessive volumes of cold water may result in patient hypothermia.**

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Note: If the Water Warmer has been enabled and has exceeded the upper temperature set point limit, the Water Warmer's switch indicator light will turn blue and the warmer will automatically shut off. If the switch indicator light is flashing blue, ensure the Water Warmer Cable is plugged into the back of the unit. If it is connected and the light is flashing, this may indicate a problem with the unit. Contact Customer Service at 800-444-4729.

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**CAUTION: Read and become familiar with all manufacturer's instructions on warming ovens and water bottles regarding maximum fluid temperatures. Never exceed  $40^\circ\text{C}$  during water pre-warming.**

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**CAUTION: Never use a microwave oven to warm a water bottle as this could heat the water to a dangerously high temperature or could result in uneven warming.**

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**CAUTION: The surface of the water bottle warmer may be hot to the touch.**

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## Operation

1. Water flow is initiated by pressing the Foot Pedal and releasing when no longer desired.
2. If more water flow is required, increase the Flow Control setting on the front panel. Refer to *Front Panel Controls/Connections* for flow rates.



Note: The device is equipped with a safety feature so that the pump will not operate if the Pump Head is open.

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**CAUTION: The physician must assess the condition of the patient and use clinical judgment to set the flow rate from the pump to a suitable level to avoid patient trauma. The Flow Control should always be set at the lowest setting at the start of the procedure and be increased incrementally to a level commensurate with the clinical condition of the patient and the degree of irrigation required. Excessive water pressure may result in damage or injury to patient including perforation of patient anatomy.**

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## Shutdown

1. Press the power button to turn the unit OFF. The light should extinguish.
2. If the warming element has been activated, press the power button for the warmer to turn OFF. The blue light should extinguish.
3. After the procedures are complete for the day, remove the tubing from the Pump Head and discard the tubing and water bottle.



Note: ENDOGATOR™ Irrigation tubing may be used for 24 hours.

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# Care and Maintenance

## Cleaning

- Before cleaning ensure the power to the unit is turned OFF and the electrical cord unplugged.
- The outside surface of the ENDO STRATUS™ Irrigation Pump can be cleaned with a damp cloth, 70% isopropyl alcohol solution, or a 10% bleach with water solution as often as deemed necessary.
- Do not use abrasive or harsh cleaners.
- Do not allow liquid to enter the unit.
- To disinfect the outside surface, use a mild disinfectant according to the manufacturer's instructions.
- Do not sterilize the unit by any means.

## Maintenance

### Pump Head Maintenance

If liquids are spilled onto the Pump Head, it should be removed and cleaned with a mild detergent. Remove any tubing from the Pump Head prior to removal for cleaning.

The same cleaning procedure should be used to limit the build-up of dust (which can become electrostatically charged and/or heated by friction).

### Servicing

The unit is not user serviceable. Please contact Customer Service and obtain a Return Material Authorization (RMA) number. The RMA number must accompany all units and paperwork for proper service or warranty work.

### Limited Warranty

Subject to the terms below, Medivators Inc. (the "Company") warrants that its products (the "Products") will conform to the Company's written specifications (where applicable) and will be free from defects in material and workmanship under normal use and service for the following periods (the "Warranty Period"):

- Endoscope reprocessors and associated equipment, and Irrigation Pumps: fifteen (15) months from date of shipment from the Company or one (1) year from the date of installation, whichever occurs first.
- Consumables, accessories, and Product service parts, including, but not limited to, endoscope hook-ups, filters, printers, printer supplies, test strips, accessory bags, and service parts for products: ninety (90) days from the date of installation or one-hundred-and-twenty (120) days from the date of shipment, whichever occurs first.
- Disposable Products: warranted for single use. The Warranty Period will not in any case exceed the expiration date on the Product label.

The warranty does not cover, and the Company will have no warranty obligation whatsoever with respect to, any damage to a Product caused by or associated with: (i) external causes, including without limitation, accident, vandalism, acts-of-God, power failure or electric power surges, (ii) abuse, misuse or neglect of the Product by the customer or use of unauthorized third party filters or other consumables and accessories, (iii) usage not in accordance with product instructions, (iv) the customer's failure to perform required preventive maintenance, or (v) servicing or repair not authorized by the Company.

### Limitation of Remedy

The warranty obligation of the Company hereunder is limited to (at its option) (i) the repair or replacement of the defective Products or any parts it deems defective, or (ii) a refund of the purchase price. This will be customer's exclusive remedy for a covered defect.

In order to recover under the warranty, the customer must notify the Company in the state (if in the U.S.A.) or the country of installation, of the defect (describing the problem in reasonable detail) prior to the expiration of the Warranty Period and within thirty (30) days of discovery of the defect. Upon receiving the Company's official "Returned Material Authorization" (RMA), the customer must promptly return the defective part or Product to the Company (or the service center indicated on the RMA), freight and insurance prepaid. The Company will not be responsible for any damage during shipment.

### Warranty Disclaimer

THE WARRANTY ABOVE IS THE COMPANY'S ENTIRE WARRANTY OBLIGATION TO THE PURCHASER OF PRODUCTS. IT IS IN LIEU OF ALL OTHER WARRANTIES OF THE COMPANY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND THE COMPANY DOES NOT REPRESENT OR WARRANT THAT ANY PRODUCT WILL MEET CUSTOMER'S REQUIREMENTS. THE COMPANY'S RESPONSIBILITY FOR DEFECTS IN A PRODUCT IS LIMITED SOLELY TO REPAIR, REPLACEMENT OR REFUND OF THE PURCHASE PRICE AS SET FORTH IN THIS WARRANTY STATEMENT. TO THE EXTENT PERMITTED BY LAW, THE COMPANY SHALL NOT, UNDER ANY CIRCUMSTANCES, BE LIABLE TO CUSTOMER FOR CONSEQUENTIAL, INCIDENTAL, INDIRECT, PUNITIVE OR SPECIAL DAMAGES OR LOSSES, INCLUDING WITHOUT LIMITATION, DAMAGES ARISING OUT OF OR IN CONNECTION WITH ANY MALFUNCTIONS, DELAYS, LOSS OF PROFIT, INTERRUPTION OF SERVICE, OR LOSS OF BUSINESS OR ANTICIPATORY PROFITS, EVEN IF THE COMPANY HAS BEEN APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING.

This Warranty gives the customer of Products specific legal rights, and customers may also have other rights which vary from jurisdiction to jurisdiction.

In no event shall the Company's liability exceed the original purchase price of the covered Product.

No representative or agent of the Company has any authority to bind the Company to any other representation or warranty with respect to the Products, and the customer accepts the Products subject to all of the terms above.

### Disposal

No special care is needed when disposing of the device.

# Electromagnetic Compatibility (EMC) Information

**Table 1: Guidance and Manufacturer's Declaration - Electromagnetic Emissions for All ME Equipment and ME Systems**

Guidance and Manufacturer's Declaration - Emissions		
The EGA-500/EGA-500E is intended for use in the electromagnetic environment specified below. The customer or user of the EGA-500/EGA-500E should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The EGA-500/EGA-500E uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

**Table 2: Guidance and Manufacturer's Declaration - Electromagnetic Immunity for All ME Equipment and ME Systems**

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The EGA-500/EGA-500E is intended for use in the electromagnetic environment specified below. The customer or user of the EGA-500/EGA-500E should ensure that it is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD EN/IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout EN/IEC 61000-4-11	0% UT; 0.5 Cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0% UT; 1 Cycle 70% UT; 25 Cycles Single Phase at 0°  0% UT; 250 Cycles	0% UT; 0.5 Cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0% UT; 1 Cycle 70% UT; 25 Cycles Single Phase at 0°  0% UT; 250 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EGA-500/EGA-500E requires continued operation during power mains interruptions, it is recommended that the EGA-500E be powered from an uninterruptible power supply or battery.
Conducted RF EN/IEC 61000-4-6	3 Vrms 0.15 - 80MHz and 6 Vrms in ISM bands 0.15 - 80MHz	3 Vrms 0.15 - 80MHz and 6 Vrms in ISM bands 0.15 - 80MHz	Mains power quality should be that of a typical commercial or hospital environment.
Radiated RF EN/IEC 61000-4-3	6 V/m 80MHz - 2.7GHz	6 V/m 80MHz - 2.7GHz	The proximity fields met the minimum requirement of <i>Section 8.10</i> of IEC 60101-1-2

**Table 3: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the EGA-501/EGA-501E**

Recommended Separation Distances
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 EGA-501/EGA-501E, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## Trademarking / Legal Statements

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