**RenovaRP®**
*Paracentesis Management System*


# RenovaRP®
## Paracentesis Pump
## OPERATING MANUAL

# RenovaRP®

*Paracentesis Management System*

## SYMBOLS

Caution: In the United States of America, Federal law restricts this device to sale by, or on the order of, a physician.

Consult instruction for use (Consulter les instructions d'utilisation)

Warning (Avertissement)

Caution

Curtis Strauss NRTL mark

Potential for elecromagnetic interference

Fuse

Protective earth ground

Standby

Type B applied part (Partie appliquée de type B)

Temperature limits (Température limite)

Manufacturer (Manufacture)

Date of Manufacturer (Date de Manufacture)

Pinch point (Pincer)

Correct tubing placement to bag (Placement de tube correct au panier)

Alternating Current (Courant alternative)

SN Serial Number (Numero de serie)

REF Catalogue Number (Numero de catalogue)

## ABBREVIATIONS

| | |
|---|---|
| A | Amperes |
| Hz | Hertz |
| SN | Serial Number |
| V | Volts |

## INDICATIONS FOR USE

The GI Supply RenovaRP® Paracentesis Pump is intended as a peristaltic pump to remove ascitic fluid from the abdominal cavity in conjunction with the GI Supply RenovaRP Paracentesis Kit. The GI Supply RenovaRP Paracentesis Pump is intended to be used by medically trained healthcare professionals knowledgeable about paracentesis.

## CONTRAINDICATIONS

Paracentesis procedures should not be performed on patients with clinically apparent disseminating intravascular coagulation and oozing from needle sticks or primary fibrinolysis until bleed risk is reduced. Paracentesis should not be performed on patients with a massive ileus with bowel distension unless the procedure is image guided.

## ⚠ WARNINGS

- **CAUTION:** In the United States of America, Federal law restricts this device to sale by, or on the order of, a physician.
- This pump is not intended for infusion or dialysis procedures.
- **Avoid dangerous environments.** This is a class I, Type B device. It has no protection against the ingress of fluids. Electrical instruments designed to process liquids must be operated with extreme caution. If liquid comes in contact with internal electrical components or wiring, fire or electric shock may occur. Do not operate electrical equipment in a combustible atmosphere. Do not operate in an $O_2$ enriched environment. The pump is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- **Ground the equipment.** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- **Avoid potential electromagnetic interference.** If this product is used with EMI sensitive equipment, care should be taken to prevent possible interference.
- The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.
- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

## PRECAUTIONS

- Know your equipment. Read the manual carefully and learn the device's operation and limitations before use.
- **Use location:** Always place pump in a location where the power cord is easily accessible if disconnection of the device is required.
- **Avoid accidental start up.** Always make sure that the switch is in the standby position before plugging the pump into the proper outlet.
- **Disconnect instrument.** Always disconnect the instrument from the power source before servicing.
- **Maintain instrument with care.** Keep unit clean. Inspect the plug and cord before each use. Do not operate this device if there are signs of damage.
- **Leakage:** Although the system is closed, there is the potential for leakage to occur. Should leakage occur refer to the cleaning section of this manual for appropriate cleaning.
- **Proper Tube Loading:** All connections should be checked for tightening and tubing checked for pinching, twisting or stretching prior to starting pump.
- **Specification of the Applied Part:** The RenovaRP Tube Set found within the RenovaRP Paracentesis Kit is the Applied Part.

## DESCRIPTION

The GI Supply RenovaRP Paracentesis Pump is a portable, reusable peristaltic pump designed to remove ascitic fluid from the abdominal cavity in a manner that is both rapid and convenient. The pump is intended to be used in conjunction with the RenovaRP Paracentesis Kit and RenovaRP Fluid Drainage Bags.

An easily opened compartment is located on the front of the pump for positioning of the tubing; posts are located on each side of the pump for hanging the drainage bags. Operation of the pump is initiated with a control knob on the front panel. The pump requires no tools to load or remove the tubing and drainage bags.

## OPERATION

⚠ **CAUTION:** ONLY USE THE RenovaRP PARACENTESIS KIT WITH THE PUMP. USE OF OTHER PARACENTESIS KITS MAY RESULT IN INADEQUATE PUMP OPERATION AND FLUID REMOVAL.

⚠ **CAUTION:** CLINICIAN MUST USE PPE AND HANDLING PROCEDURES FOR BIOHAZARD WASTE ACCORDING TO FACILITY PROTOCOLS.

### 1. LOAD TUBING

- Position control knob to Standby Mode.
- ⚠ **CAUTION:** BE SURE PUMP DRIVE IS IN STANDBY MODE ( ⏻ ) BEFORE LOADING TUBING. SERIOUS INJURY MAY RESULT IF FINGERS ARE INSERTED INTO THE PUMP ROTOR DURING OPERATION. PUMP IS IN STANDBY MODE WHEN PLUGGED IN AND CONTROL KNOB TURNED TO THE STANDYBY POSTION. GREEN LED WILL NOT BE ILLUMINATED.
- Lift the flip top track until fully open.
- Remove the pump tubing from the RenovaRP Paracentesis Kit and fit section of large diameter tubing across the pumphead rotor.

⚠ **CAUTION:** ENSURE THAT THE SECTION OF TUBING LEADING FROM THE PATIENT ENTERS THE LEFT SIDE OF THE PUMPHEAD AND EXITS ON THE RIGHT SIDE TO THE DRAINAGE BAGS. (See Figure 1)

- Lower the flip top track ensuring that the tubing is fitted correctly between the rollers and track and that there is no pinching of the tubing by the tube clamps. The tubing must lie naturally againsts the track and must not be twisted or stretched.
- Press the T shaped stopcock assembly into the recessed area of the handle.
- Place a RenovaRP Fluid Drainage Bag on the posts located on each side of the pump and attach the bags to the stopcock assembly. (See Figure 2)

**FIGURE 1**

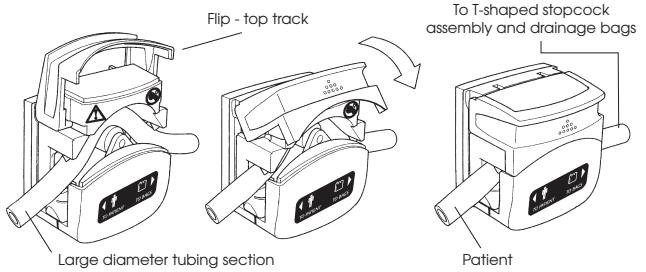
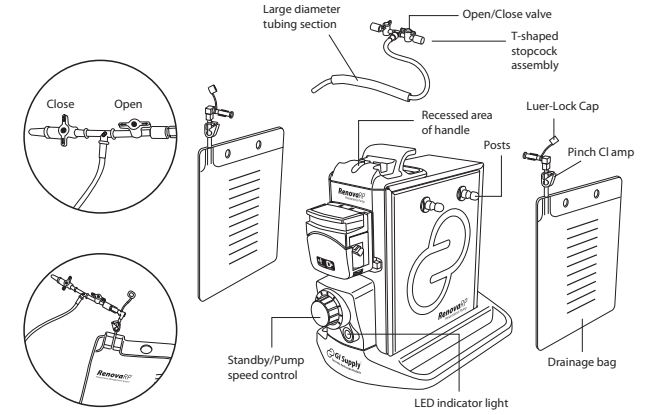



**FIGURE 2**




## 2. START PUMP

- With the control knob in the standby ⏻ position, ensure the power cord is plugged into the device and the grounding plug is inserted into the proper grounding type receptacle.
- Ensure that the RenovaRP Tube Set is attached to the catheter.
- Ensure that the T shaped stopcock in the handle recess is OPEN for flow to ONE of the drainage bags and is CLOSED for flow to the second bag.
- Ensure that the drainage bag clamp is in the OPEN position.
- Set the pump to the desired speed output using the control knob which is calibrated to provide speed control within 0 to 100% of maximum speed. The green LED will illuminate when the unit is operating and out of the standby ⏻ position.
- The control knob may be adjusted to a achieve desired flow rate.

## 3. CHANGE DRAINAGE BAGS

- When the drainage bag is full of fluid, open the stopcock to the empty drainage bag. As the second bag begins to fill, close the stopcock of the full bag.
- Close the clamp on the tubing to the full bag and detach the bag from the tubing assembly.
- Replace filled bag with another empty bag and redirect fluid as needed.

## 4. COMPLETION OF THE PROCEDURE

- At the completion of the procedure, ensure the control knob is turned to standby.
- Ensure both sides of the T shaped stopcock are closed. Close the clamp on the tubing to the full bag and detach the bag from the tube set.
- Remove the used tubing and drainage bags. Dispose of according to facility protocol for biohazard waste.

**Guidance and manufacturer's declaration –electromagnetic immunity**

**The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.**

| IMMUNITY TEST | IEC 60601 test level | Compliance Level | Electromagnetic environment-guidance |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3Vrms 150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | Recommended separation distance: $d=1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) and according to the transmitter manufacturer and d is the recommended separation distance in meters(m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] "should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: ((•)) |

**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**

[a] **Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.**

[b] **Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m**

**Recommended separation distances between portable and mobile RF communications equipment and the product**

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

| Rated maximum output power of transmitter | Separation distance according to frequency of transmitter | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d=1.2\sqrt{P}$ | 80 MHz to 800 MHz $d=1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d=2.3\sqrt{P}$ |
| 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 to 800 MHz, the separation distance for the higher frequency range applies.**

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

All medical electronic devices, including this product, must conform to the requirements of IEC 60601-1-2. Precautions, adherences to the EMC guideline information provided in this manual and verification of all medical devices in simultaneous operation are required to ensure the electromagnetic compatibility and co-existence of all other medical devices prior to any procedure.

The EMC tables below are provided for your reference.

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The product 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 B | The product is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:<br><br>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the product or shielding thelocation. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration –electromagnetic immunity | | | |
|---|---|---|---|
| The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment. | | | |
| IMMUNITY TEST | IEC 60601 test level | Compliance Level | Electromagnetic environment-guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | +6kV contact<br>+8kV air | +6kV contact<br>+8kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electrical fast transient/burst IEC 61000-4-4 | +2kV for power supply lines | +2kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment |
| Surge IEC 61000-4-5 | +1kV lines to line<br>+2kV line to earth | +1kV lines to line<br>+2kV line to earth | Mains power quality should be that of a typical commercial or hospital environment |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% UT (>95% dip in UT) For 0,5 cycle<br>40% UT (60% dip in UT) For 5 cycles<br>70% UT (30% dip in UT) For 25 cycles<br><5% UT (>95% dip in UT) for 5 s | <5% UT (>95% dip in UT) For 0,5 cycle<br>40% UT (60% dip in UT) For 5 cycles<br>70% UT (30% dip in UT) For 25 cycles<br><5% UT (>95% dip in UT) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power source. |
| Power frequency 50/60 Hz) magnetic field | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Note UT is the AC mains voltage prior to application of the test level. | | | |

## CLEANING

⚠ **CAUTION:** USE OF AN UNAPPROVED CLEANING SOLUTION OR METHOD MAY RESULT IN DAMAGE TO THE PUMP. USE ONLY APPROVED PRODUCTS AND FOLLOW THE GUIDELINES BELOW.

The RenovaRP® Paracentesis Pump housing and tubing track may be cleaned with commonly used solutions, such as:

- Isopropyl alcohol
- Mild detergent and warm water

Unplug the pump before cleaning. Use sterilization wipes or spray the cleaning agent on a soft wipe, paper towel, or equivalent material. Do not use excessive amounts of fluid or spray fluid directly on any part of the pump. After cleaning, dry the pump with a soft cloth to remove any cleaning residues.

Do not apply cleaning solutions to the electrical connections. Do not sterilize the pump.

⚠ **CAUTION:** DO NOT SUBMERGE THE PUMP IN FLUID.

If a spill does occur, the control knob should be turned to standby and the instrument disconnected from the power source before cleaning. Any spillage into the base can be cleaned by removing the 4 screws located on the underside of the base using a hex or flat head screw driver. Additional disinfection of the pump should be performed per institutional guidelines. Following disinfection, replace the base and securely tighten all 4 screws to the underside of the base. It is recommended that a drop of medium strength thread locker be added to each of the screws before re-inserting.

## MAINTENANCE

The speed control circuit has solid-state components which do not require service. An excessive load on the system may, however, cause a fuse to blow. An indication of this would be that with power applied to the drive and the control knob turned on, the power indicator LED does not light. If this condition does occur, fuses are located on the back of the pump housing. If found defective replace with a fuse of the same type and rating (5x20mm, F2.5A250V). This information is printed on the back of the unit.

## STORAGE AND OPERATION

Store and operate the pump at room temperature in a clean environment away from high humidity.

## SERVICE AND REPAIR

⚠ **WARNING:** No modification of this equipment is allowed.

Operation of the RenovaRP Paracentesis Pump for removal of ascitic fluid from the abdomen requires no installation and no routine service. Information on replacement parts and servicing may be obtained by contacting GI Supply at 1-800-451-5797. Items returned must be authorized by GI Supply.

The expected service life of the pump is 7-10 years. Disposal of the RenovaRP Paracentesis Pump should be done in accordance with institution guidelines for equipment.

## SPECIFICATIONS

**Physical Specifications**
**Dimensions:** 13 x 9 x 13 in (33 x 23 x 33cm)
Weight: 8.5lbs (3.9kg)

**Functional Specifications**
**Power Specifications:**
Input current: 2.5A
Input Voltage: 100- 230V~
Input Frequency: 50/60Hz
Power Cord: Hospital Grade power cord

**IEC 60601-1 General Requirements for Safety**
This device is BV approved WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1:2003/CAN/CSA C22.2 No. 60601-1-08

This device meets the requirements of EN-60601-1: 2005+A1:2012 so as to conform to the Medical Device Directive 93/42/EEC and 2007/47/EC (general safety information)

This product complies to the above standards only when used with the supplied accessories.

**Manufactured by:** GI Supply® Specialty Endoscopic Products
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