

# iReceptal® Mini

# **Digital Surgical Suction System**

220-240 VAC System REF iRS551-02 220-240 VAC System REF iRS552-02

**Instructions For Use** 

220-240 VAC iReceptal Mini Rover, REF iRR551-02
220-240 VAC iReceptal Mini Rover (with IV Pole), REF iRR552-02

# R<sub>x</sub> ONLY



# **Contents**

| 1 | Imp  | ortant Ir       | nformation  | 5            |
|---|------|-----------------|---|--------------|
|   | 1.1  | Wa              | arnings   | 5            |
|   | 1.2  | Usi             | sing this Manual                                      | <del>(</del> |
|   |      | 1.2.1           | Conventions   | <del>(</del> |
|   |      | 1.2.2           | Contact Information                                   | <del>(</del> |
|   |      | 1.2             | 2.2.1 International Addresses                         | <del>6</del> |
|   | 1.3  | Int             | tended Purpose  | <del>(</del> |
|   | 1.4  | Coi             | ontraindications For Use                              | 7            |
|   | 1.5  | Int             | tended Users  | 7            |
|   | 1.6  | Int             | tended Patient  | 7            |
|   | 1.7  | For             | r Use With  | 7            |
|   | 1.8  | Acc             | cessories   | 8            |
|   | 1.9  | Do              | ocumentation  | g            |
|   | 1.10 | 0 Saf           | fety Directives                                       | g            |
|   |      | 1.10.1          | General Safety  | g            |
|   |      | 1.10.2          | Patient/Clinician Safety                              | 10           |
|   |      | 1.10.3          | Electrical Safety                                     | 11           |
|   |      | 1.10.4          | Environmental Safety                                  | 12           |
| 2 | Sys  | tem Over        | rview   | 13           |
|   | 2.1  | Sys             | stem Operation  | 13           |
|   | 2.2  | Sys             | stem Components and Interface                         | 14           |
|   | 2.3  | Sof             | ftware Interface                                      | 16           |
|   |      | 2.3.1           | Screens, Dialogs, and Drop-downs                      | 18           |
|   |      | 2.3             | 3.1.1 Main Display Control Screen Areas               | 18           |
|   |      | 2.3             | 3.1.2 Typical Settings Dialog Areas                   | 19           |
|   |      | 2.3             | 3.1.3 Typical Docking Mode Screen Areas               | 19           |
|   |      | 2.3             | 3.1.4 Typical Notification or Error Drop-down Areas   | 20           |
|   |      | 2.3             | 3.1.5 Secondary Control Panel Screen Areas (Rovering) | 20           |
|   |      | 2.3             | 3.1.6 Secondary Control Panel Screen Areas (Docking)  | 21           |
|   | 2.4  | De <sup>-</sup> | efinitions  | 21           |
|   |      | 2.4.1           | Main Control Panel Display Buttons                    | 21           |
|   |      | 2.4.2           | Secondary Control Panel Buttons                       | 24           |
|   |      | 2.4.3           | Suction Setting Colors                                | 24           |
|   |      | 2.4.4           | Message Area Colors                                   | 25           |
|   |      | 2.4.5           | Button Colors   | 25           |
|   |      | 2.4.6           | Disposable Manifold Symbol Colors                     | 25           |
|   |      | 2.4.7           | Canister Symbol Colors                                | 25           |
|   |      | 2.4.8           | Audible Event Indicators                              | 25           |
|   |      | 2.4.9           | Symbols   | 25           |
| 3 | Bef  | ore First       | Use   | 27           |
|   | 3.1  | То              | Unpack the Rover                                      | 27           |
|   | 3.2  | То              | Initially Dock the Rover                              | 28           |
|   |      |                 |   |              |

|   | 3.3  | To T       | Test the Rover  | 28 |
|---|------|------------|---|----|
|   |      | 3.3.1      | To Test Fluid Suction   | 28 |
|   |      | 3.3.2      | To Test Smoke Evacuation  | 29 |
|   |      | 3.3.3      | To Test the IV Pole Height Adjustment (optional)                  | 30 |
|   | 3.4  | To A       | Adjust the Rover Settings   | 30 |
| 4 | Bef  | ore the Pi | ocedure   | 32 |
|   | 4.1  | To S       | Setup the Rover   | 32 |
|   | 4.2  | To I       | nstall Disposable Components                                      | 33 |
|   |      | 4.2.1      | To Prepare For Fluid Suction                                      | 33 |
|   |      | 4.2.2      | To Prepare For Smoke Evacuation                                   | 34 |
|   |      | 4.2.3      | To Prepare the IV Pole (optional)                                 | 35 |
|   |      | 4.2.4      | To Prepare the Irrigation (optional)                              | 35 |
| 5 | Dur  | ing the Pr | ocedure   | 37 |
|   | 5.1  | To (       | Operate the Rover   | 37 |
|   |      | 5.1.1      | To Control Fluid Suction  | 37 |
|   |      | 5.1.2      | To Control Smoke Evacuation                                       | 38 |
|   |      | 5.1.3      | To Manage a Full Canister   | 39 |
|   |      | 5.1.4      | Monitoring irrigation fluid volumes (Adding fluid bag) (optional) | 40 |
| 6 | Afte | er the Pro | cedure  | 41 |
|   | 6.1  | To F       | Remove Disposable Components                                      | 41 |
|   |      | 6.1.1      | To Remove Fluid Suction Components                                | 41 |
|   |      | 6.1.2      | To Remove Smoke Evacuation Components                             | 42 |
|   |      | 6.1.3      | To Remove IV Pole Components (optional)                           | 42 |
|   | 6.2  | To S       | Shut Down and Relocate the Rover                                  | 43 |
|   |      | 6.2.1      | To Remove Power From the Rover                                    | 43 |
|   | 6.3  | To I       | Dock the Rover  | 44 |
|   |      | 6.3.1      | To Prepare the Docker   | 44 |
|   |      | 6.3.2      | To Perform a Docking Cycle  | 45 |
| 7 | Insp | ection ar  | nd Maintenance  | 47 |
|   | 7.1  | To I       | nspect the Equipment  | 47 |
|   | 7.2  | To F       | Replace the HEPA Filter   | 49 |
|   |      | 7.2.1      | To Install the Fluid Suction HEPA Filter                          | 49 |
|   |      | 7.2.2      | To Verify Proper Filter Installation                              | 50 |
|   |      | 7.2.3      | To Reset the Filter Timer   | 50 |
| 8 | Refe | erences    |   | 50 |
|   | 8.1  | Clea       | aning and Disinfection  | 50 |
|   | 8.2  | To \       | Nipe Down the Rover   | 51 |
|   | 8.3  | Sto        | rage and Handling   | 52 |
|   | 8.4  | Serv       | vice  | 52 |
|   | 8.5  | Disp       | oosal/Recycle   | 52 |
| 9 | Tro  | ubleshoot  | ting  | 53 |
|   | 9.1  | Rov        | er Troubleshooting  | 53 |
|   | 9.2  | Doc        | king Station Troubleshooting                                      | 55 |
|   | 9.3  | Tro        | ubleshooting Codes  | 56 |
|   |      |            |   |    |

| 10 | Specifications                | 58 |
|----|-------------------------------|----|
| 11 | Electromagnetic Compatibility | 61 |
| 12 | Glossary                      | 63 |
| 13 | Statement                     | 63 |

# 1 Important Information

## 1.1 Warnings

# **≜**WARNING:

#### **HIGH SUCTION DEVICE**

Only trained and experienced healthcare professionals may use this equipment.



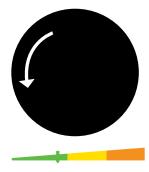
DO NOT connect directly to chest tubes.



DO NOT connect directly to tracheal tubes.



DO NOT connect to closed wound drains.



ALWAYS use the minimum suction setting required to achieve the desired clinical outcome.

#### FAILURE TO COMPLY COULD RESULTIN SERIOUS INJURY OR DEATH.

DO NOT remove any safety card from the equipment.

For more information, including safety information, or in-service training, contact your AMSINO sales representative or call iReceptal Customer Service

## 1.2 Using this Manual

This manual is the most comprehensive source of information for the safe, effective, and compliant use and/or maintenance of your product. This product is intended for use by trained and experienced healthcare professionals only. Read and understand this manual before using the product or any component compatible with the product. Contact Amsino for training as needed.

This manual is a permanent part of the product. Keep this manual for future reference.

#### 1.2.1 Conventions

The following conventions are used in this manual:

**WARNING:** A warning highlights a safety-related issue. ALWAYS comply with this information to prevent patient or healthcare staff injury.

**CAUTION:** A caution highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.

**NOTE:** A note supplements and/or clarifies procedural information.

## 1.2.2 Contact Information

For additional information, including safety information, or in-service training, contact your AMSINO sales representative or call AMSINO iReceptal Customer Service.

Note - The user and/or patient should report any serious product-related incident to both the manufacturer and the Competent Authority of the European Member State where the user and/or patient is established.

#### 1.2.2.1 International Addresses



Amsino International, Inc. 708 Corporate Center Drive Pomona, CA 91768, USA



Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands

# 1.3 Intended Purpose

The iReceptal Mini Digital Surgical Suction System is intended to be used in the operating room, pathology, surgical centers, and doctor's offices to collect and dispose of surgical fluid waste as well as collect smoke generated from electrocautery or laser devices.

## 1.4 Contraindications For Use

The iReceptal Mini Digital Surgical Suction System is contraindicated against:

- Connection directly to chest tubes.
- Connection to closed wound drainage systems.

### 1.5 Intended Users

Intended users of the iReceptal Mini Digital Surgical Suction System include clinical users such as surgeons, circulating nurses, scrub technicians/nurses, surgical assistants, anesthetists, endoscopists, and endoscopist technicians/nurses. Additionally, this manual is intended for other users such as in-service trainers, biomedical equipment technicians, and housekeeping staff.

## 1.6 Intended Patient

Intended patient of the iReceptal Mini Digital Surgical Suction System is the general patient population, including anyone subject to general surgery or procedures where surgical or procedural suction is used.

### 1.7 For Use With



The following components are required to be used with the equipment described in this manual to create a complete system: Components and accessories are sold separately.

| Rover Model                    | Docking Station                              | REF                    |
|--------------------------------|--|------------------------|
| 220-240VAC Rover REF iRR551-02 | 220-240VAC iReceptal Docking Station         | iRD502-02              |
| 220-240VAC Rover REF iRR552-01 |  |                        |
| Rover Model                    | Docking Station Accessory                    | REF                    |
| All Rovers                     | iReceptal 3 Docking Detergent                | iRC003                 |
|                                | Enzymatic Cleaner                            | Commercially available |
| Rover Model                    | Fluid Suction Filter                         | REF                    |
| All Rovers                     | Fluid Suction HEPA Filter (1 each)           | iRH500                 |
| Rover Model                    | Disposable Manifold                          | REF                    |
| All Rovers                     | Disposable Manifold                          | iRM500                 |
| Rover Model                    | Fluid Suction Tubing                         | REF                    |
| All Rovers                     | Medical grade fluid suction tubing with 3/8- | Commercially available |
|                                | inch connector                               |                        |
| Rover Model                    | Smoke Filter                                 | REF                    |
| All Rovers                     | Surgical Smoke Evacuate ULPA Filter          | iRF500                 |
| Rover Model                    | Smoke Tubing                                 | REF                    |
| All Rovers                     | Medical grade smoke evacuator tubing with a  | Commercially available |
|                                | 1/4 inch, 3/8 inch, or 7/8 inch connector    |                        |

NOTE: Smoke Evacuator tubing and other accessories are also required for a complete system. These components may not be sold by AMSINO. See the Contact Information section (page 6) for more information.

## 1.8 Accessories

This section describes system components that may be ordered to replace original equipment that is damaged, worn, or must be replaced. This section may also contain optional components used with the system.

The following AMSINO-approved accessories are sold separately:

| Rover Model                        | Description                                  | REF                    |  |  |
|------------------------------------|--|------------------------|--|--|
| Docking Station                    |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02     | 220-240VAC iReceptal Docking Station         | iRD502-02              |  |  |
| 220-240VAC Rover REF iRR552-02     |  |                        |  |  |
|                                    | Docking Station Accessory                    |                        |  |  |
| All Rovers                         | iReceptal 3 Docking Detergent                | iRC003                 |  |  |
|                                    | Fluid Suction Filter                         |                        |  |  |
| All Rovers                         | Fluid Suction HEPA Filter (1 each)           | iRH500                 |  |  |
|                                    | Disposable Manifold                          |                        |  |  |
| All Rovers                         | Disposable Manifold                          | iRM500                 |  |  |
|                                    | Fluid Suction Tubing                         |                        |  |  |
| All Rovers                         | Medical grade fluid suction tubing with 3/8- | Commercially available |  |  |
|                                    | inch connector                               |                        |  |  |
|                                    | Smoke Filter                                 |                        |  |  |
| All Rovers                         | Surgical Smoke Evacuate ULPA Filter          | iRF500                 |  |  |
|                                    | Power Cords                                  |                        |  |  |
| Rover Model                        | Plug Type Description                        | REF                    |  |  |
| 220-240VAC Rover REF iRR551-02(EI) | 1  | WDYX002                |  |  |
| 220-240VAC Rover REF iRR552-02(EI) |  |                        |  |  |
| 220-240VAC Rover REF iRR551-01(EG) | G  | WDYX006                |  |  |
| 220-240VAC Rover REF iRR552-02(EG) |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02EF   | E/F  | WDYX010                |  |  |
| 220-240VAC Rover REF iRR551-02FR   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02ES   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02DE   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02IT   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02PT   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02NL   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02SV   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02FI   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02NO   |  |                        |  |  |
| 220-240VAC Rover REF iRR551-02PL   |  |                        |  |  |
| 220-240VAC Rover REF iRR552-02EF   |  |                        |  |  |
| 220-240VAC Rover REF iRR552-02FR   |  |                        |  |  |
| 220-240VAC Rover REF iRR552-02ES   |  |                        |  |  |
| 220-240VAC Rover REF iRR552-02DE   |  |                        |  |  |
| 220-240VAC Rover REF iRR552-02IT   |  |                        |  |  |
| 220-240VAC Rover REF iRR552-02PT   |  |                        |  |  |
| 220-240VAC Rover REF iRR552-02NL   |  |                        |  |  |

| 220-240VAC Rover REF iRR552-02SV |   |         |
|----------------------------------|---|---------|
| 220-240VAC Rover REF iRR552-02FI |   |         |
| 220-240VAC Rover REF iRR552-02NO |   |         |
| 220-240VAC Rover REF iRR552-02PL |   |         |
| 220-240VAC Rover REF iRR551-02SW | J | WDYX011 |
| 220-240VAC Rover REF iRR552-02SW |   |         |
| 220-240VAC Rover REF iRR551-02DA | К | WDYX012 |
| 220-240VAC Rover REF iRR552-02DA |   |         |

NOTE: For a complete list of accessory information, contact your AMSINO sales representative or call AMSINO iReceptal Mini Digital Surgical Suction System Customer Service.

## 1.9 Documentation

See the instructions for use supplied with each system component for important information.

| Instructions for Use                | REF       |  |
|-------------------------------------|-----------|--|
| iReceptal Docking Station           | iRD502-02 |  |
| Disposable Manifold                 | iRM500    |  |
| Fluid Suction HEPA Filter           | iRH500    |  |
| Surgical Smoke Evacuate ULPA Filter | iRF500    |  |

## 1.10 Safety Directives

## 1.10.1General Safety

#### **MARNING**

- Healthcare professionals should be thoroughly familiar with the instructions for use and the operation of this product prior to use.
- Healthcare professionals should be thoroughly familiar with the performance characteristics, and the indicated, contraindicated, and intended uses of this product. Contact your AMSINO sales representative or AMSINO iReceptal Customer Service for in-service training.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this
  equipment and the specific technique used for each patient. AMSINO, as a manufacturer, does not recommend
  surgical procedure or technique.
- DO NOT disassemble, modify, service, or repair any system component or accessory without the authorization of the manufacturer. Call AMSINO iReceptal Customer Service.
- Upon initial receipt and before each use, inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met. See the Inspection and Maintenance section (page 47) for inspection criteria.
- ALWAYS operate the equipment within the specified environmental condition values. See the Specifications section (page 58).
- The canister scale and fluid volume display are not diagnostic tools. DO NOT use the scale or fluid volume display to

determine the amount of fluid lost from or retained by the patient.

- DO NOT cover the device user interface with drapes or other objects. Make sure the user interface can be clearly
- TIPPING HAZARD DO NOT lean on the rover. Please pull the handle when cross the step, do not push the rover. Do NOT push the rover from the side.
- The use of ACCESSORIES other than those specified by AMSINO or sold by AMSINO as replacement parts for internal components, may result in increased emissions or decreased immunity of the iReceptal Mini Digital Surgical Suction System.

## 1.10.2Patient/Clinician Safety



#### HIGH SUCTION HAZARD: MAXIMUM = -540 mmHg/-72kPa

- The effectiveness of aspiration is dependent upon the intensity of the vacuum applied.
- ALWAYS use the minimum suction setting required to achieve the desired clinical outcome.
- ALWAYS follow your institution's guidelines for suction limits.
- The suction setting of the collection canister may be adjusted by using the suction control dial on the main control
  panel. Interruption and restoration of rover power while suction is ON, whether accidental or intentional, does not
  reset the suction limit range to zero. See ISO 10079-1: 2022, clause 7.2. Use caution when activating suction with a
  high suction limit range.

Death or serious injury can result from improper suction levels.

### **MARNING**

#### **INAPPROPRIATE CONNECTION HAZARDS**

- DO NOT connect directly to chest tubes.
- DO NOT connect to closed wound drains.
- DO NOT connect directly to tracheal tubes.
- NOT FOR USE as a suction source for: automatic intermittent suction applications, patient positioner devices and organ stabilizer/positioner devices.

Death or serious injury can result from inappropriate connections.

#### **MARNING**

#### INFECTION HAZARDS

- Always clean and disinfect the rover as indicated upon initial receipt and before each use.
- Always keep the rover outside the sterile field. The suction tubing with end-effector are used in the sterile field.
- Do not reuse, process, or repackage the non-sterile Disposable Manifold, a single patient use disposable device.
  - The Disposable Manifold may not withstand chemical, chemical vapor, or high temperature sterilization

processing.

- Design features may make cleaning difficult.
- Reuse may create a contamination risk and compromise structural integrity, resulting in operational failure during use.

Failure to comply may lead to infection or cross-infection and result in patient and/or healthcare staff injury.



#### **BLOODBORNE PATHOGEN HAZARD**

- The Bloodborne Pathogens Standard provided by the United States Occupational Safety and Health Association (US OSHA 29 CFR 1910.1030) requires those with employees having occupational exposure to potentially infectious materials to establish a written Exposure Control Plan. The Exposure Control Plan is designed to eliminate or minimize employee exposure through use of personal protective equipment (PPE), appropriate vaccinations (e.g. hepatitis B), and other control measures.
- Always wear PPE when operating or handling this equipment.
- Always leave suction tubing attached to the Disposable Manifold during use and disposal.
- Always close unused Disposable Manifold ports during use and disposal.
- Always follow the current local regulations and procedures governing biohazard waste to safely handle and dispose
  of surgical waste.

Failure to comply may cause infection and result in healthcare staff injury.

## 1.10.3 Electrical Safety



#### **ELECTROMAGNETIC INTERFERENCE HAZARD**

- Use only AMSINO-approved system components and accessories, unless otherwise specified. Using other electronic components and accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment
  like this system. Install and place this system into service according to the EMC information contained in this
  manual.
- 3. This equipment utilizes mobile RF communications equipment that can affect medical electrical equipment.
- 4. Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- 5. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
  - (1) This device may not cause harmful interference, and
  - (2) This device must accept any interference received, including interference that may cause undesired operation.
- 6. This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:
  - (1) this device may not cause interference, and

- (2) this device must accept any interference, including interference that may cause undesired operation of the device.
- 7. This equipment complies with FCC/IC RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.
- 8. Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.



#### **ELECTRICAL SHOCK HAZARD**

- 1. ALWAYS connect this equipment to a hospital-grade, facility power receptacle with protective earth (ground).
- 2. The power switch is used to disconnecting the device from the facility power. Do not position Rover so that disconnecting the device is difficult.
- 3. DO NOT touch or make contact with the rover and patient simultaneously.

Failure to comply may cause electrical shock and result in patient or healthcare staff injury.

### 1.10.4Environmental Safety

#### **≜** WARNING

#### MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT

• This product is MR unsafe. Do not use the product in an MRI environment. Operating the product outside the specified environmental conditions could result in death or serious injury.

#### **▲** WARNING

#### FIRE HAZARD

• DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen or nitrous oxide. Failure to comply may cause a fire and result in burn injury or property damage.

#### FLUID WASTE LEAKAGE HAZARD

• ALWAYS make sure rover power is ON when collecting fluid waste. The rover can only detect full canister if the rover is ON. If the rover is OFF, biohazard waste leakage or loss of suction can occur.

#### **CONTAMINATION HAZARD**

- Do not collect fluids from patients being treated with radioisotopes or hazardous chemical agents. Failure to comply may cause environmental contamination and result in injury.
- Always follow the current local recommendations and/or regulations governing environmental protection and the
  risks associated with recycling or disposing of the product at the end of its useful life. Failure to comply may cause
  environmental contamination and result in injury.

# 2 System Overview

## 2.1 System Operation

The Amsino iReceptal Mini Digital Surgical Suction System consists of the iReceptal Mini Rover (rover), the iReceptal Docking Station (docker), and supporting accessories.

The Amsino iReceptal Mini Rover (rover) is a reusable, non-sterile mobile unit that suctions and collects fluid waste and surgical smoke during a procedure. Suction is created to facilitate collection via an integrated vacuum pump. The rover also has a height-adjustable, powered IV pole.

During collection, fluid waste is suctioned from the surgical site through suction tubes connected to inlet port(s) of a disposable, non- sterile, single patient use Disposable Manifold (iRM500) installed in the rover. The Disposable Manifold (iRM500) facilitates the collection of surgical tissue and the removal of fluid waste (Figure 1). Once suctioned, the fluid waste is collected in the 11L canister of the rover. The canister design allows suction setting and fluid volume measurement capability. Fluid volume measurements are shown on the main control panel display and the secondary control panel display.

Disposable Manifold (iRM500) and suction tubing are single-use disposables and must be replaced between patients. However, it may not be necessary to empty the contents of the rover's collection canister.

If the rover display indicates sufficient fluid volume capacity in the canister, the rover may be used for another procedure before waste disposal. Adding fluid from a second procedure on top of the previous procedure is called fluid stacking.

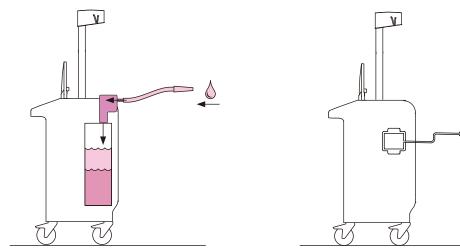


Figure 1 To collect Fluid Waste

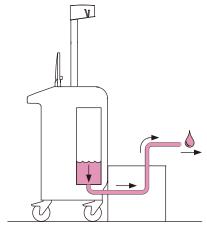
Figure 2 To Evacuate Surgical smoke

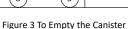
After collection, the rover is relocated and attached to the docker, which is typically installed in a healthcare facility waste disposal area. Once the rover is attached, the docker empties the rover's canister of fluid waste for subsequent disposal. Cleaning of the interior of the canister takes place immediately after the removal of fluid waste (Figure 3). The disposal of fluid waste and the cleaning of the rover canister is an automated, closed system process that minimizes exposure to blood borne pathogens.

The rover canister is rinsed with clean water and Docking Detergent to clean the canister of any residual fluid waste (Figure 4).

Surgical smoke may also be evacuated from the surgical site through smoke tubing connected to the Surgical Smoke Evacuate ULPA Filter (iRF500) installed in the rover. The surgical smoke is filtered inside the rover (Figure 2).

The rover can optionally be equipped with a height adjustable, motor operated irrigation pole, to hang irrigation fluid bags. Equipped in this way, the rover can display in real time the amount of fluids both irrigated from the pole and collected into Canister and report the possible loss of fluids within those amounts called liquid deficit. Monitoring of irrigation fluid is enabled when the irrigation pole is in place. The height of the IV pole may be adjusted by touching and holding buttons on the control screen.





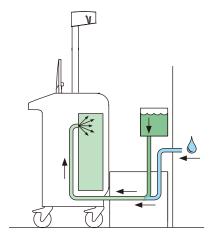
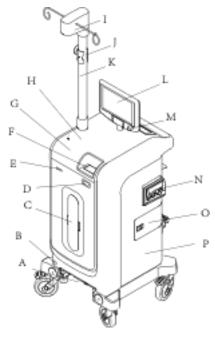


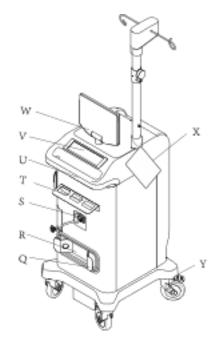
Figure 4 To Clean the Canister

# 2.2 System Components and Interface

A complete iReceptal Mini Digital Surgical Suction System consists of a rover with an installed fluid suction High Efficiency Particulate Air (HEPA) filter, a docker, and various single-use, disposable devices, including one Disposable Manifold per collection canister, and fluid suction tubing. A smoke evacuator Ultra Low Penetration Air (ULPA) filter and smoke evacuator tubing may also be required (Figure 5).

The user interface provides complete control over functionality and provides audible, visual, and tactile feedback of status. The user interface elements include one main display with touch capability, one suction control dial, one Disposable Manifold receptacle suction indicator and one Secondary Control Panel (Figure 5, and Figure 6).





|   | Figure 5 Rover Front View  |   | Figure 6 Rover Back View                         |  |
|---|--|---|--|--|
| Α | Docking Station Interface – Provides a sealed  | В | Infrared Communication Window – Allows data      |  |
|   | flow path for fluid waste transfer from the  |   | transfer between the docker and rover during     |  |
|   | rover to the docker. Also provides fresh water   |   | the docking procedure                            |  |
|   | and detergent transfer from the docker to the  |   |  |  |
|   | rover canister.  |   |  |  |
|   | Provides power to the rover from the docker.   |   |  |  |
| С | 11L (11-liter) Canister– Allows for the  | D | Eject Button— Facilitates the removal of the     |  |
|   | collection and containment of fluid waste. The   |   | Disposable Manifold.                             |  |
|   | canister receives fluid through an installed   |   |  |  |
|   | Disposable Manifold during collection. The   |   |  |  |
|   | canister contains a fluid level sensor to provide  |   |  |  |
|   | volume information to displays.  |   |  |  |
| Е | Suction Range Indicator – Provides color- coded  | F | Disposable Manifold Receptacle — Allows for      |  |
|   | visual information about the suction limit   |   | the installation of a single-use, Disposable     |  |
|   | range setting.   |   | Manifold.  |  |
| G | High Suction Device WARNING Label –  | Н | Speaker – Located inside the rover; provides     |  |
|   | WARNING  HIGH SUCTION DEVICE  DO NOT connect directly to chest tubes or other dosed vocard dates.  Falure to comply could result in serious injury or death. |   | audible event indicators.                        |  |
| I | Scale with fluid bag hooks (optional) – Measures   | J | Strain relief for fluid bag tubing (optional)–   |  |
|   | the weight of the irrigation fluid bags. The pole  |   | Ensures that no stress is put through the        |  |
|   | allows to hang max 12 L  |   | strained fluid bag tubing on the scale in the    |  |
|   |  |   | irrigation pole                                  |  |
| K | Height Adjustable, Powered IV Pole with Hooks  | L | Control main display–Provides interface to start |  |
|   | (optional) – This IV pole is capable of supporting   |   | and stop suction via a touch-sensitive, color    |  |
|   | four three-liter [3000 mL] fluid bag.  |   | display. Important notification and status       |  |
|   |  |   | information are also provided. The display       |  |

|   |   |   | swivels in a 360-degree fashion and pivots for   |
|---|---|---|--|
|   |   |   | ease of viewing from the surgical field or       |
|   |   |   | control panel.                                   |
| M | Suction Control Dial — Used to adjust                 | N | Smoke Evacuator Filter Compartment – Allows      |
|   | (clockwise to increase, counterclockwise to           |   | for the installation and removal of a disposable |
|   | decrease) the SUCTION LIMIT. The selection            |   | smoke evacuator filter (not included) with an    |
|   | determines the maximum suction available.             |   | ULPA efficiency rating.                          |
| 0 | Fluid Suction Filter Compartment – Allows for         | Р | Vacuum Pump (not shown) – Creates suction        |
|   | the installation and removal of a disposable          |   | for canister.                                    |
|   | fluid suction filter. This filter (included) provides |   |  |
|   | HEPA filtration of the air from the canister.         |   |  |
| Q | Power Cord Bracket – Allows for the wrapping          | R | Specification Label — Identifies the model,      |
|   | and storage of the supplied power cord.               |   | weight, compliance markings, and                 |
|   |   |   | manufacturer information.                        |
| S | Power Switch — Used to turn the rover ON and          | Т | Disposable Manifold Holder — Store new,          |
|   | OFF.  |   | unused single-use, Disposable Manifolds.         |
| U | Handle – Allows for relocation and positioning        | V | Secondary Control Panel –While roving, panel     |
|   | of the rover.   |   | displays fluid volume since last reset, almost   |
|   |   |   | full, and full indication. While docking, the    |
|   |   |   | panel provides buttons to select wash cycle      |
|   |   |   | options and displays wash cycle status. While    |
|   |   |   | roving or docking, panel displays error status   |
|   |   |   | information.                                     |
| W | Work Surface — Facilitates additional tasks           | Х | Quick Reference Card (QRC) – Allows for quick    |
|   | including specimen collection.                        |   | access to warnings and troubleshooting           |
|   |   |   | information.                                     |
| Υ | Casters (four) – Four swivel casters provide          |   |  |
|   | mobility for the rover to roll across a floor. The    |   |  |
|   | casters have locks to prevent unintended              |   |  |
|   | movement.   |   |  |
|   | •   |   | •  |

# 2.3 Software Interface

The main display control screen has a menu structure that provides access to the primary control functions.

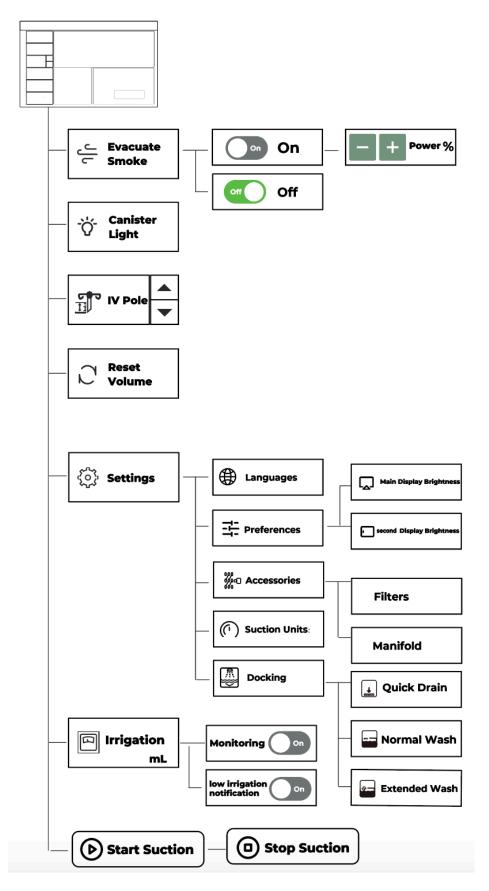


Figure 7 Control Screen Menu Structure

NOTE: The software version number appears in the upper right corner of the main display WARNING screen. Make sure the number on the screen matches the software version number on the cover of this instructions

for use. If not, contact your sales representative or call Customer Service to obtain the latest instructions for use manual. See Section "Contact Information" (Page6).

# 2.3.1 Screens, Dialogs, and Drop-downs

## 2.3.1.1 Main Display Control Screen Areas

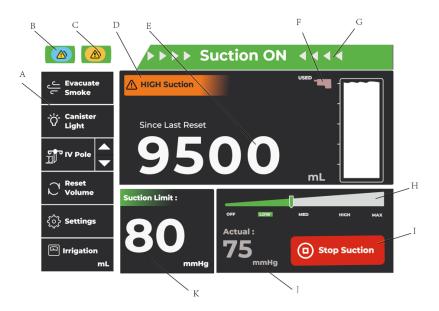


Figure 8 Roving Mode (Control) Screen

| Α | Control Menu Area – Provides buttons to         | В | Notification Message Area – Indicates when a      |
|---|---|---|---|
|   | control the primary functions of the rover.     |   | low priority notification condition has occurred; |
|   |   |   | touch to access the drop-down list and/or         |
|   |   |   | message.  |
| С | Error Message Area – Indicates when a           | D | Canister Information Area – Identifies the        |
|   | medium priority notification condition has      |   | suction status of canister.                       |
|   | occurred; touch to access the drop-down list    |   |   |
|   | and/or message.                                 |   |   |
| Ε | Fluid Volume Information Volume Area –          | F | Disposable Manifold Indicator Area– Indicates     |
|   | Provides fluid volume information via a 11L     |   | the status of the Disposable Manifold installed   |
|   | canister symbol and a fluid volume reading. If  |   | in the receptacle. Status conditions include      |
|   | the canister' volume is reset, the words 'since |   | new or used.                                      |
|   | last reset' will appear.                        |   |   |
| G | Title Area – Indicates status, including system | Н | Suction Gauge Area – Indicates the suction        |
|   | setup, suction ON and suction OFF.              |   | selected with the rotary suction control dial,    |
|   |   |   | including OFF, LOW, MEDium, HIGH, or              |
|   |   |   | MAXimum.  |
| 1 | Suction Control Area – Provides a toggle button | J | ACTUAL Suction Value Area – Indicates the         |
|   | to control the presence or absence of fluid     |   | actual suction value present in the canister.     |
|   | suction.  |   | The ACTUAL value may fluctuate and could be       |
|   |   |   | significantly lower than the suction LIMIT value. |
| K | Suction LIMIT Value Area – Indicates the        |   |   |
|   | selected suction limit value obtained by using  |   |   |

## 2.3.1.2 Typical Settings Dialog Areas

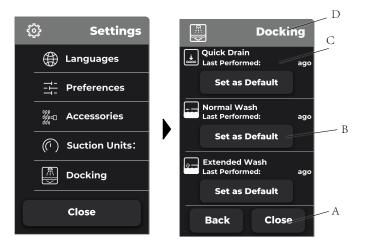


Figure 9– Typical Settings Dialog

| Α | Navigation Area – Provides buttons used to    | В | Options Area – Provides options that may be     |
|---|---|---|---|
|   | return to the SETTINGS dialog menu or control |   | adjusted, as well as default settings           |
|   | screen.                                       |   | information or life-cycle use information.      |
| С | Tab Selection Area – Provides selection tabs, | D | Title Area – Indicates the name of the settings |
|   | including FILTERS, DISPOSABLE MANIFOLDS,      |   | dialog, including DOCKING, ACCESSORIES, and     |
|   | and DISPLAYS.                                 |   | PREFERENCES.                                    |

## 2.3.1.3 Typical Docking Mode Screen Areas

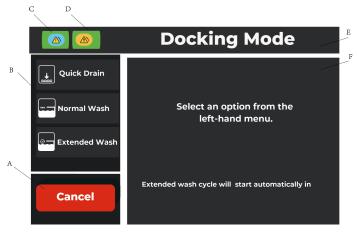


Figure 10 Docking Mode Screen

| Α | Control Menu Area – Provides buttons to        | В | Cycle Options Menu – Allows for the manual  |
|---|--|---|---|
|   | control the primary functions of the rover.    |   | selection of a cycle. Manual selection will |
|   | Cycle Control Area – Allows for most control   |   | override the default cycle setting.         |
|   | over cycle activity, including: ABORT TO QUICK |   |   |
|   | WASH, CANCEL, and RELEASE FROM DOCKer          |   |   |
|   | after cycle completion.                        |   |   |

| С | Notification Message Area – Indicates when a   | D | Error Message Area – Indicates when a          |
|---|--|---|--|
|   | low priority notification condition has        |   | medium notification condition has occurred;    |
|   | occurred; touch to access the drop-down list   |   | touch to access the drop-down list and/or      |
|   | and/or message.                                |   | message.                                       |
| E | Title Area – Indicates the name of the screen. | F | Status Area – Provides instruction, identifies |
|   |  |   | the type of cycle selected, and indicates the  |
|   |  |   | cycle status.                                  |

## 2.3.1.4 Typical Notification or Error Drop-down Areas

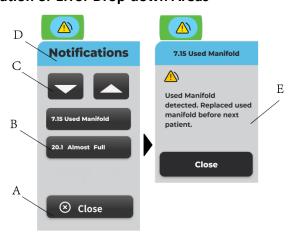


Figure 11 Notification Drop-down

| Α | Response Area – Provides a CLOSE button to       | В | List Area – Provides one or more notification |
|---|--|---|---|
|   | exit a notification or error drop-down.          |   | message or error message buttons. Each button |
|   |  |   | allows access to a specific message.          |
| С | Navigation Area – Provides UP and DOWN           | D | Title Area – Identifies the type of message   |
|   | buttons to scroll through a list of notification |   | displayed, either notification or error.      |
|   | message or error message buttons.                |   |   |
| E | Message Area – Provides specific notification    |   |   |
|   | or error message information.                    |   |   |

## 2.3.1.5 Secondary Control Panel Screen Areas (Rovering)



Figure 12 Secondary Control Panel Screen (rovering)

| Α | Suction Status Area – Indicates                  | В | ACTUAL Suction Value Area – Indicates the         |
|---|--|---|---|
|   | the suction status of a canister, including LOW, |   | actual suction value present in the canister. The |
|   | MEDium, HIGH, or NO suction                      |   | ACTUAL value may fluctuate and could be           |
|   |  |   | significantly lower than the suction LIMIT value. |
| С | Notification Message Indicator Area —            | D | Title Area – Indicates status, including system   |
|   | Indicates the notification status of the rover.  |   | setup, suction ON and suction OFF.                |
|   | Action may be required.                          |   |   |
| E | Disposable Manifold Indicator Area – Indicates   | F | Canister Information Area – Identifies the        |
|   | the status of the Disposable Manifold installed  |   | specific canister; also provides graphical        |
|   | in the receptacle. Status conditions include     |   | indication of total fluid volume collected via a  |
|   | new or used.                                     |   | 11L canister symbol and provides the fluid        |
|   |  |   | volume value in milliliters of the specific       |
|   |  |   | canister.   |

## 2.3.1.6 Secondary Control Panel Screen Areas (Docking)

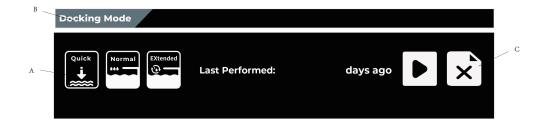


Figure 13 Secondary Control Panel Screen (docking)

|   | ,  |   | ,                                     |
|---|--|---|---------------------------------------|
| Α | Cycle Options Menu – Allows for the manual     | В | Title Area – Indicates working model. |
|   | selection of a cycle. Manual selection will    |   |                                       |
|   | override the default cycle setting.            |   |                                       |
| С | Wash Cycle Control Areas —Provides a button    |   |                                       |
|   | to abort an active wash cycle and an eject     |   |                                       |
|   | button to detach the rover from the docker     |   |                                       |
|   | after a complete wash cycle. For additional    |   |                                       |
|   | wash cycle option information, see To Dock the |   |                                       |
|   | Rover (page 44).                               |   |                                       |

# 2.4 Definitions

# 2.4.1 Main Control Panel Display Buttons

This table defines the function of each button that appears on the control screen.

| BUTTON | NAME | FUNCTION |
|--------|------|----------|
|        |      |          |

| c <mark>⊂ Evacuate</mark><br>⊂ Smoke | EVACUATE SMOKE                | Touch the button to access the EVACUATE SMOKE dialog; including OFF, ON, and the power level of smoke evacuation may also be adjusted.  When smoke evacuation is active, the smoke evacuation button displays the current smoke evacuation power level. |
|--------------------------------------|-------------------------------|---|
| Off                                  | OFF                           | Touch the toggle button to enable or disable the OFF mode of smoke evacuation/Irrigation fluid monitoring/ low irrigation fluid notification.   |
| On                                   | ON                            | Touch the toggle button to enable or disable the ON mode of smoke evacuation/Irrigation fluid monitoring/ low irrigation fluid notification.  |
| - +                                  | MINUS/DECREASE, PLUS/INCREASE | Touch the Plus and Minus sign button to decrease or increase power level of smoke evacuation.   |
| Canister Light                       | CANISTER LIGHT                | Touch the toggle button to turn ON or OFF the canister light. When canister light is active, the canister light button displayed in Green.  |
| Tip IV Pole                          | IV POLE                       | Touch the button to access the IV POLE HEIGHT SETTING dialog menu; including180cm、190cm、200cm、210cm、MAX and Min   |
|                                      | DOWN/DECREASE, UP/INCREASE    | Touch and hold the DOWN or UP arrow button to decrease or increase the height of the powered IV pole, respectively. These buttons may also be used to decrease or increase values or scroll down or up through a list of options.                       |
| Reset Volume                         | RESET VOLUMES                 | Touch to access the RESET VOLUME dialog and reset the canister fluid volume value to zero.  |
| 🗒 History                            | HISTORY                       | Touch to access the HISTORY data.   |
| ₹०⟩ Settings                         | SETTINGS                      | Touch the button to access the SETTINGS dialog menu with system options. Select and adjust the system settings, as required. See Section To Adjust the Rover Settings (page 30).  |
| Languages                            | LANGUAGES                     | Touch the button to access the LANGUAGES dialog menu with language options. Select the language, as required. This dialog menu will appear disabled if suction is ON.   |
| 다-<br>-는 Preferences                 | PREFERENCES                   | Touch the button to access the PREFERENCES dialog; including the DISPLAY status information and brightness control. The brightness of the Secondary Control Panel and main display may be increased or decreased as required.                           |
| <b>☆</b> - <b>☆</b> +                | DOWN/DECREASE,<br>UP/INCREASE | Touch the button to increased or decreased the brightness of the Secondary Control Panel and main display.  |
| <b>‰</b> -□ Accessories              | ACCESSORIES                   | Touch the button to access the ACCESSORIES dialog. Select the FILTERS tab or the DISPOSABLE MANIFOLDS tab, as required.   |
| C Reset hours                        | RESET HOURS                   | Touch the button to reset the hours of use associated with a newly installed filter to a zero value. ALWAYS reset the hours of use after the installation of a new fluid suction HEPA filter or a new Surgical Smoke Evacuate ULPA Filter.              |

| Suction Units:   | SUCTION UNITS                            | The Suction Units primary control function is for international customers.  |
|------------------|--|---|
| Docking          | DOCKING                                  | Touch the button to access the DOCKING dialog menu. Select a default cycle option to be performed automatically when the rover is connected to the docker.  |
| Set as Default   | SET AS DEFAULT                           | From the DOCKING dialog menu, touch the button to select the default cycle to be performed when the rover is connected to the docker. The selected button will gray out and indicate DEFAULT CYCLE.   |
| Irrigation mL    | IRRIGATION                               | Touch the button to access the Irrigation FLuid dialog; including turn on or turn off irrigation fluid monitoring, irrigation volume display, and turn on or turn off low irrigation fluid notification.  When irrigation fluid monitoring is active, the irrigation volume displays. |
| Start Suction    | START SUCTION                            | Touch the toggle button to start fluid suction.   |
| Stop Suction     | STOP SUCTION                             | Touch the toggle button to stop fluid suction.  |
| Close            | CLOSE / CLOSE<br>NOTIFICATION<br>MESSAGE | Touch the button to accept the responses of a dialog and exit or close a drop-down list.  |
| Back             | BACK                                     | Touch the button to exit and return to the previous screen.   |
| <b>⊘</b> Confirm | CONFIRM                                  | Touch the button to acknowledge understanding of important safety information or allow the performance of a critical and/or irreversible action.  |
|                  | CANCEL                                   | Touch the button to cancel the performance of a task or the responses to a dialog.  |
|                  | NOTIFICATION<br>MESSAGE<br>INDICATOR     | Touch to access notification message information. A drop- down list of one or more messages will appear. Touch the FORWARD button or the BACK button to scroll through the notification messages as required.   |
|                  | ERROR MESSAGE<br>INDICATOR               | Touch to access error message information. A drop-down list of one or more messages will appear. Touch the FORWARD button or the BACK button to scroll through the error messages as required.  |
| Quick Drain      | QUICK WASH                               | Touch the button to select the QUICK WASH cycle option. A cycle description and when the cycle was last performed are provided.   |
| Normal Wash      | NORMAL WASH                              | Touch the button to select the NORMAL WASH cycle option. A cycle description and when the cycle was last performed are provided.  |
| Extended Wash    | EXTENDED WASH                            | Touch the button to select the EXTENDED WASH cycle option. A cycle description and when the cycle was last performed are provided.  |
| Start            | START                                    | Touch the button to initiate the QUICK WASH cycle, the NORMAL WASH cycle, or the EXTENDED WASH cycle (Figure 36).   |

| Cancel               | CANCEL                   | Touch the button to stop docking and prepare the rover for release.  The RELEASE FROM DOCKer button will appear.   |
|----------------------|--------------------------|--|
| Abort to Quick Drain | ABORT TO QUICK<br>WASH   | Touch the button to interrupt the NORMAL WASH or EXTENDED WASH cycle and initiate the QUICK WASH cycle. This option is only available during the early stages of the NORMAL WASH cycle or EXTENDED WASH cycle. |
| Release From Dock    | RELEASE FROM<br>DOCK(er) | Touch the button, available after the cycle is complete or a cancellation, to disconnect the rover from the docker.  |

# **2.4.2 Secondary Control Panel Buttons**

| BUTTON   | NAME          | FUNCTION   |
|----------|---------------|--|
|          | START         | Touch the button to initiate the QUICK WASH cycle, the NORMAL WASH cycle, or the EXTENDED WASH cycle (Figure 36).  |
|          | EJECT         | Touch to disengage and release the rover from the docker after completion of a wash cycle.   |
| ×        | ABORT         | Touch the button to interrupt the NORMAL WASH or EXTENDED WASH cycle and initiate the QUICK WASH cycle. This option is only available during the early stages of the NORMAL WASH cycle or EXTENDED WASH cycle. |
| Quick    | QUICK WASH    | Touch the button to select the QUICK WASH cycle option. A cycle description and when the cycle was last performed are provided.  |
| Normal   | NORMAL WASH   | Touch the button to select the NORMAL WASH cycle option. A cycle description and when the cycle was last performed are provided.   |
| EXtended | EXTENDED WASH | Touch the button to select the EXTENDED WASH cycle option. A cycle description and when the cycle was last performed are provided.   |

# 2.4.3 Suction Setting Colors

| COLOR            | SUCTION LIMIT | RANGE   |  |
|------------------|---------------|---|--|
| Orange - Maximum |               | 540mmHg/72kPa                                   |  |
|                  | High          | 460 mmHg $\sim$ 540mmHg $/$ 60 kPa $\sim$ 72kPa |  |
| Yellow- Green    | Medium        | 80 mmHg $\sim$ 460 mmHg/ 10.5 kPa $\sim$ 60kPa  |  |
| Green-           | Low           | 50mmHg $\sim$ 75mmHg/ 7 kPa $\sim$ 10 kPa       |  |
| Grey-            | Off           | 0   |  |

# 2.4.4 Message Area Colors

| COLOR  | DEFINITION                             |
|--------|--|
| Blue   | Indicates LOW PRIORITY notification    |
| Yellow | Indicates MEDIUM PRIORITY notification |

## 2.4.5 Button Colors

| COLOR | DEFINITION   |
|-------|--|
| Green | Indicates a START or CONFIRM condition or function |
| Red   | Indicates a STOP function                          |

# 2.4.6 Disposable Manifold Symbol Colors

| COLOR | DEFINITION                         |
|-------|------------------------------------|
| White | Indicates NEW Disposable Manifold  |
| Pink  | Indicates USED Disposable Manifold |

# 2.4.7 Canister Symbol Colors

| COLOR  | DEFINITION                               |
|--------|--|
| White  | Indicates fluid volume SINCE last reset  |
| Grey   | Indicates fluid volume BEFORE last reset |
| Blue   | Indicates fluid volume ALMOST FULL       |
| Yellow | Indicates fluid volume FULL              |

## 2.4.8 Audible Event Indicators

| TYPE          | INDICATION          | TRIGGER                             |
|---------------|---------------------|-------------------------------------|
| Button Touch  | Click Tone          | Main display button actuation       |
| Task Complete | Ding tone           | Valid Disposable Manifold installed |
|               |                     | successfully or docking complete    |
| Notification  | Two declining tones | Any LOW PRIORITY Notification       |
| Error         | Three slow tones    | Any MEDIUM PRIORITY Notification or |
|               |                     | Canister full                       |

# 2.4.9 Symbols

The following symbols appear on the device and/or its labeling. For more information, see "Technical specifications"

| Symbol | Description | Symbol | Description |
|--------|-------------|--------|-------------|
|--------|-------------|--------|-------------|

| Symbols           | Symbols on device                 |            |  |  |
|-------------------|-----------------------------------|------------|--|--|
| r   7             | ON (POWER) ; IEC 60417- 5007      |            | SECONDARY CONTROL PANEL SCREEN   |  |
|                   | OFF (POWER)                       |            | MAIN TOUCH SCREEN  |  |
|                   | POWERED IV POLE HEIGHT ADJUSTMENT | 7          | DISPOSABLE MANIFOLD  |  |
|                   | DOWN/DECREASE                     | 1  1       | SOUND (VOLUME)   |  |
|                   | UP/INCREASE                       |            | 11 L CANISTER  |  |
| JJ                | EVACUATE SMOKE                    |            | DOCKING  |  |
|                   | DOWN/DECREASE                     | <u></u>    | QUICK WASH   |  |
| +                 | UP/INCREASE                       |            | NORMAL WASH  |  |
|                   | ON (SMOKE EVACUATOR)              | <u></u>    | EXTENDED WASH  |  |
|                   | OFF (SMOKE EVACUATOR)             | г т<br>    | ALTERNATING CURRENT  |  |
| $\mathcal{C}$     | RESET VOLUME                      |            | DIRECT CURRENT   |  |
| -Öʻ-              | CANISTER LIGHT                    |            | TYPE CF APPLIED PART   |  |
| £025              | SETTINGS                          |            | GENERAL WARNING SIGN (yellow); ISO 7010-W001   |  |
| [3]               | IRRAGATION VOLUME                 |            | LOW PRIORITY NOTIFICATION  |  |
| <b>(b)</b>        | START SUCTION                     |            | MEDIUM PRIORITY NOTIFICATION   |  |
| <b>•</b>          | STOP SUCTION                      | <b>(3)</b> | REFER TO INSTRUCTION MANUAL/<br>BOOKLET (blue); ISO 7010-M002  |  |
|                   | LANGUAGES                         |            | PROTECTIVE EARTH (GROUND)  |  |
| 井                 | PREFERENCES                       | (((•))     | NON-IONIZING ELECTROMAGNETIC RADIATION   |  |
| -<br>099□<br>099□ | ACCESSORIES                       | (          | SMOKE FILTER COMPARTMENT   |  |
| (1)               | SUCTION UNITS                     | IP22       | Degree of protection against ingress of water. The device has an IP22 degree of protection against liquids (drip-proof). |  |
| <b>©</b>          | DRAIN IN PROGRESS                 | •          | STEAM DRAIN IN PROGRESS  |  |

| 50°C                             | QUICK WASH TEMPERATURE DISPLAY IN CANISTER  EXTENDED WASH TEMPERATURE | 50°C                          | NORMAL WASH TEMPERATURE DISPLAY IN CANISTER         |
|----------------------------------|---|-------------------------------|---|
| 50°C                             | DISPLAY IN CANISTER   |                               |   |
| Symbols                          | on consumables  | Symbols on exterior packaging |   |
| []i                              | Consult instructions for use  |                               | Fragile – handle with care                          |
| 2                                | Do not reuse  |                               | This end up   |
| LOT                              | Batch code  |                               | Keep dry  |
| À                                | Caution   | <b>*</b>                      | Keep away from sunlight                             |
|                                  | Latex free  |                               |   |
| DEHP<br>DEHP-FREE                | DEHP free   |                               |   |
| Transport and storage conditions |   | Operating conditions          |   |
|                                  | Temperature limit: -20°C ~+40 °C; ; ISO 7000-0632                     |                               | Temperature limit: 10°C ~+40 °C                     |
| <b>%</b>                         | Humidity limitation: 10% ~75%   | [%]                           | Humidity limitation: 30% ~75%                       |
|                                  | Atmospheric pressure limitation: 500 hPa ~ 1060 hPa                   |                               | Atmospheric pressure limitation: 700 hPa ~ 1060 hPa |

# 3 Before First Use

# 3.1 To Unpack the Rover



**LIFT HAZARD:** -ALWAYS have more than one person unpack and move this equipment from the shipping pallet. See the Specifications section (page 58). for rover weight. Failure to comply may result in personal injury.

Upon initial receipt, inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met.

1. Remove the exterior packaging materials from the rover and recycle the material as required.

- 2. Using at least two people, remove the rover from the shipping pallet.
- 3. Inspect the rover and components for damage. If damage is apparent, DO NOT use the equipment.
- 4. Make sure all of the components are supplied with the rover. Some components may vary based on market requirements.

## 3.2 To Initially Dock the Rover

Before the rover may be tested and placed into use, initial docking is required. Initial docking will add prefill fluid to the canister. Failure to comply will result in prefill errors and prevent the rover from operating properly.

See the To Dock the Rover section (page 44).to perform initial docking of the rover.

### 3.3 To Test the Rover

## 3.3.1 To Test Fluid Suction

- 1. Connect the rover to a hospital-grade electrical wall outlet using the supplied power cord.
- 2. Push the power switch to the ON position.
- 3. Read the WARNING message on the control screen, touch the ACKNOWLEDGE button to confirm understanding and access the on-screen controls. (Figure 14).



Figure 14 To Connect Power

Note - A SET UP SYSTEM screen appears after confirmation of the safety information. A valid Disposable Manifold must be inserted into the Disposable Manifold receptacle to enable suction control.

If the Disposable Manifold is valid and inserted correctly, a SYSTEM READY indication will occur, a Disposable Manifold. indicator will illuminate white (NEW) or pink (USED), and suction control will be

- enabled (START SUCTION button enabled).
- 4. Insert a new (valid) Disposable Manifold into the Disposable Manifold receptacle. Confirm on screen that the Disposable Manifold is new and unused.
- 5. Make sure the Disposable Manifold is fully inserted and locked into place. Make sure all the inlet ports of the Disposable Manifold are closed.
- Touch the START SUCTION button. Make sure the vacuum pump starts. If not, see the Troubleshooting Section (page 30).
- 7. Adjust the manual suction control dial to the maximum suction level.
- 8. Make sure the actual suction value changes as indicated on the main control screen and reaches a suction level of at least 513 mm-Hg. If not, see Troubleshooting.
- 9. Discard the Disposable Manifold used for testing purposes.



Figure 15 To Test Fluid Suction

#### 3.3.2 To Test Smoke Evacuation

NOTE: Make sure a smoke evacuator filter is installed in the rover before testing smoke evacuation. See the section for use with (page 7). See the instructions for use supplied with the smoke evacuator filter for installation information.

The rover monitors the use and life expectancy of the smoke evacuator filter. DO NOT relocate the smoke evacuator filter after initial installation into the rover.

- 1. Touch the EVACUATE SMOKE button. The EVACUATE SMOKE dialog will appear.
- 2. While in the ON mode, touch the PLUS/INCREASE, MINUS/DECREASE buttons to increase or decrease the smoke evacuator power setting, as required.
- Verify smoke evacuation power can be adjusted correctly. If not, see Section Troubleshooting (page 53).



Figure 16 To Test Smoke Evacuation

## 3.3.3 To Test the IV Pole Height Adjustment (optional)

#### Note:

IV Pole is enabled when an irrigation pole is installed.

From the control screen menu, touch and hold the IV Pole UP and DOWN arrow buttons to raise and lower the IV pole, respectively or select the desired height. Make sure the height of the IV pole increases and decreases correctly. If not, see Section Troubleshooting (page 53).

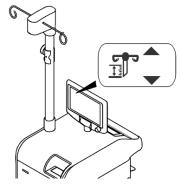


Figure 17 To Test IV Pole

# 3.4 To Adjust the Rover Settings

#### Note

- Make sure the rover has been initially prefilled, tested, and powered up.
- See Features Software Menu (page 16).
- 1. From the main control screen, touch the SETTINGS button. The SETTINGS dialog menu will appear (Figure 18).
- 2. From the SETTINGS dialog menu, touch the desired SETTINGS button, which includes LANGUAGES, PREFERENCES, ACCESSORIES, SUCTION UNITS or DOCKING.

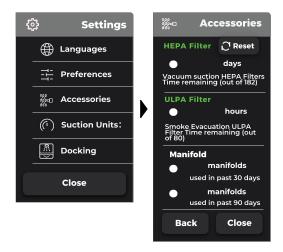


Figure 18 Settings Menu Dialog

### **Settings Options**

| Menu          |                         | Options           |
|---------------|-------------------------|-------------------|
| LANGUAGES     |                         | 简体中文,English      |
| PREFERENCES   | Main Display brightness | Increase/Decrease |
|               | Secondary Control Panel | Increase/Decrease |
|               | brightness              |                   |
| ACCESSORIES   | Filters                 | Reset Hours       |
|               | Disposable Manifolds    | Not Applicable    |
| SUCTION UNITS |                         | kPa, mmHg         |
| DOCKING       | Quick Wash              | Set as Default    |
|               | Normal Wash             | Default Cycle     |
|               | Extended Wash           | Set as Default    |

- 3. From the selected SETTINGS dialog menu, touch the desired setting option. Make the appropriate adjustment or selection as required.
- 4. Touch the CLOSE button or CONFIRM button to accept the adjustment or selection and exit. Touch the BACK button to cancel any adjustment or selection and exit.
- 5. After adjusting and/or selecting options, push power switch to OFF, disconnect the rover from facility power, and wrap the power cord around the power cord bracket.

# 4 Before the Procedure

# 4.1 To Setup the Rover

#### **.** WARNINGS:

- Upon initial receipt and before each use, inspect each component for damage. DO NOT use any equipment if
  damage is apparent or the inspection criteria are not met. See the Inspection and Maintenance section (page 47)
  for inspection criteria. DO NOT use the rover until it has been tested properly to ensure functionality. See the To
  Test the Rover section (page 28).
- ALWAYS clean the equipment as indicated upon initial receipt and before each use.
- DO NOT place the rover within the sterile field. Failure to comply may cause infection and result in patient or healthcare staff injury.

#### **CAUTIONS:**

- DO NOT clamp or attach any accessory onto the pole or base of the powered IV pole assembly.
- ALWAYS use the correct power cord configuration. Configurations will vary based on local requirements.

#### NOTES:

- DO NOT use the rover until the docker has been installed and tested properly to ensure functionality. See the instructions for use supplied with the docker.
- Before first use, initial docking is required. Initial docking will add prefill fluid to the canister. See To Dock the Rover (page 44). Failure to comply will result in prefill errors and prevent the rover from operating properly.
- The volume of the initial prefill fluid in the canister is accounted for in the fluid level value indicated on the display.

  Foam does not affect this fluid level value.
- ALWAYS close unused Disposable Manifold ports and remove or clamp unused tubing to maintain optimal suction levels.
- If the suction limit is in the high suction range, the rover will provide an audible and visual indication of this condition. See Table High Suction Visual and Audible Indicators.
- 1. Position the rover on a flat surface and in a convenient location within the operating room environment.
- 2. Lock the rover's two rear casters to prevent unintended rover movement.
- 3. Orient the position of the Main Control Screen for optimal viewing.
- 4. Open the canister viewing doors from side of the rover to allow viewing of the contents, if desired.
- 5. Connect the rover to a hospital-grade electrical wall outlet using the supplied power cord.
- 6. Push the power switch to the ON position.



Figure 19 To Connect Power

Read and acknowledge the warning messages on the main control screen. Touch the CONFIRM button to
acknowledge understanding and access the on-screen controls. A SET UP SYSTEM screen will appear.

## 4.2 To Install Disposable Components

#### NOTE:

- The fluid suction tubing and suction accessory are applied parts.
- If the Disposable Manifold is valid and installed correctly, a 'task complete' audible indicator will occur, the Disposable Manifold suction indicator will illuminate white or pink, and the START SUCTION button will be enabled.

## 4.2.1 To Prepare For Fluid Suction

## WARNINGS:

- Both the Disposable Manifold and suction tube are subject to contamination and are for single use.
- Both the Disposable Manifold and suction tube are for single patient use only. Do not reuse, process, service, modify, or repackage a single use device.
  - The single-use device may not withstand chemical, chemical vapor, or high temperature sterilization processing.
  - Design features may make cleaning difficult.
  - Reuse may create a contamination risk and compromise structural integrity, resulting in operational failure during use.

Failure to comply may lead to infection or cross-infection and result in patient and/or healthcare staff injury.

- Before use, inspect each disposable component for damage. Do not use any equipment if damage is apparent.
- Do not use a Disposable Manifold that has been dropped or mishandled. Failure to comply may cause leakage and result in patient and/or healthcare staff injury.
- Do not remove the suction tubing from the Disposable Manifold ports during use and at shutdown. Always leave the suction tubing attached to the Disposable Manifold ports after installation.
- Do not use a Y-connector to add more than one suction line to each port. Failure to comply may cause cross-

- contamination and result in patient injury.
- 1. Align the Disposable Manifold tabs and insert a new (valid) Disposable Manifold into the Disposable Manifold receptacle. Push the Disposable Manifold straight into the receptacle until a click is heard (Figure 20). Confirm the new Disposable Manifold symbol (white) appears on the main control screen and a confirmation sound occurs.
- 2. Obtain new sterile suction tubing.
- 3. Connect the suction tubing to the appropriate Disposable Manifold port(s). ALWAYS close unused Disposable Manifold ports.
- 4. Attach a fluid suction accessory to the end of the suction tubing, if required.
- 5. From the control screen, touch the RESET VOLUME button to reset the fluid volume valuer to zero milliliters, if required. A CONFIRM dialog will appear.

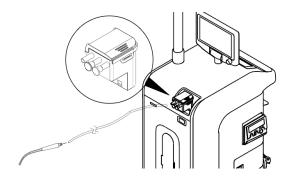


Figure 20 To Prepare for Fluid Suction

## 4.2.2 To Prepare For Smoke Evacuation

#### NOTES:

- Make sure a smoke evacuator filter is installed in the rover before using smoke evacuation. See the for use with section (page 7). See the instructions for use supplied with the smoke evacuator filter for installation information.
- The smoke evacuator tubing and optional smoke evacuator attachment are applied parts.
- 1. Install the smoke evacuator tubing to the smoke evacuator filter (Figure 21).
- 2. Attach a smoke evacuator accessory to the end of the smoke tubing, if desired.
- 3. Adjust smoke evacuator power as required.

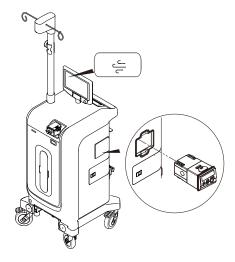


Figure 21 To Prepare for Smoke Evacuation

## 4.2.3 To Prepare the IV Pole (optional)

- Hang one irrigation bag on each IV pole hook, if an IV Pole is installed. The maximum volume allowed per hook is 6000 milliliters.
- From the control screen menu, touch and hold the IV pole UP arrow button or select the desired height (e.g., 190 cm) to raise the fluid bag(s) to the desired height and the pole will automatically rise to the preset position and securely lock in place.

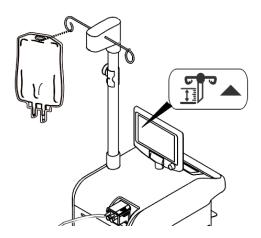


Figure 22 To Use the IV Pole

# 4.2.4 To Prepare the Irrigation (optional)

### NOTES:

- Monitoring of irrigation fluid volume is enabled when an irrigation pole is in place. The volume measurement of irrigated fluid is available when an irrigation pole is installed.
- If irrigation bags are removed from irrigation pole hooks (e.g. for reposition), removed volume may be counted and displayed as irrigated liquid.
- Use strain relief to ensure that nothing weighs down the irrigation bag tubing. Excessive pull may result in inaccurate irrigation and liquid deficit values.

#### **WARNINGS:**

- Fluid monitoring is composed of an irrigation and a collection scale system including canister and irrigation pole. Fluid monitoring is not a diagnostic tool.
- Use strain relief to ensure that nothing weighs down the irrigation bag tubing. Excessive pull may result in inaccurate irrigation and liquid deficit values.
- To obtain accurate fluid monitoring values, do not add fluid bags weighing less than 1 kg on the hooks. Minimize any interference with fluid bags and tubes on the pole once the surgery has started. During the surgery, do not remove any bags, empty or full, once placed on the hooks. Any weight removed from the hook is counted as irrigated fluid.
- To obtain a reliable liquid deficit volume, fluid from all sources must be collected in the device.
- The maximum irrigation volume on the pole is 12 L. Use irrigation pole only for irrigation fluid bags.
- The liquid deficit is calculated by subtracting the collected volume measurement from the irrigated volume and displays the difference on the screen. When the collected volume is larger than the irrigated volume, the display numerical field is dashed with "-".
- Liquid deficit volume is not a diagnostic tool. Estimating the fluid volume remaining in the patient is the responsibility of the physician.
- 1. Hang the fluid bag on the irrigation pole hook. The maximum volume allowed simultaneously is 12 L.
- 2. Open the clamp on the fluid bag tubing to fill the tube(s).
- 3. When the irrigation bag tubing is filled, close the clamp.
- 4. Fix the irrigation bag tubing in the strain relief.
- 5. From the control screen menu, touch and hold the IV pole UP arrow button to raise the fluid bag(s) to the desired height. Height adjustment is also available from the IV pole dialog, which height shown in the measurement scale is from the ground to the lower edge of the fluid bag hook.
- 6. Monitor the volume of irrigation fluid by Activating the irrigation fluid monitoring from Irrigation button on the left side of control screen as needed.

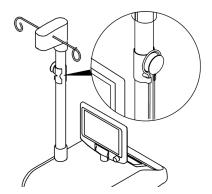


Figure 23 To Prepare the Irrigation (optional)

# **5 During the Procedure**

### 5.1 To Operate the Rover

#### **!** WARNINGS:

- HIGH SUCTION DEVICE [MAX = -540 mmHg/ -72kPa]
- The effectiveness of aspiration is dependent upon the intensity of the vacuum applied.
- ALWAYS use the minimum suction setting required to achieve the desired clinical outcome.
- ALWAYS follow your institution's guidelines for suction limits.
- DO NOT connect directly to chest tubes.
- DO NOT connect to closed wound drains.
- DO NOT connect directly to tracheal tubes.
- NOT FOR USE as a suction source for:
  - Intermittent suction applications
  - Patient positioner devices
  - Organ stabilizer/positioner devices

Death or serious injury can result from improper suction levels.

- The collection canister scale, top display, and main display are not diagnostic tools. DO NOT use the scale or
  either display to determine the amount of fluid lost from or retained by the patient.
- ALWAYS make sure rover power is ON when collecting fluid waste. The rover can only detect full canister if the
  rover power is ON. If the rover power is OFF, fluid waste leakage can occur.

#### NOTES:

- This equipment provides an adjustable suction limit of 50 to 540 mm-Hg [7 72 kPa] measured with all Disposable Manifold inlet ports closed.
- Make sure the rover has been properly prepared for operation. See Section before first use (page 27).
- To reset the fluid level value to zero, touch the RESET VOLUME button on the control screen menu. Canister fluid level value will reset to a zero value.
- To view the saved data in the history, touch the history button below the reset button.
- The suction limit range of each collection canister may be adjusted by the appropriate suction control dial on the control panel. Interruption and restoration of rover power, whether accidental or intentional, does not reset the suction setting to zero.

#### **5.1.1 To Control Fluid Suction**

NOTE: See the High Suction Visual and Audible Indicators Table for important condition, indication, and action

information.

- 1. While viewing the suction gauge on the main display, turn the suction control dial to the level of suction required (Figure 24).
- 2. Touch the START SUCTION button to start fluid suction.
- 3. Turn the suction control dial to adjust the suction limit during the procedure as required.
- 4. Adjust the location of the suction end effector at the surgical site as required.
- 5. Suction the fluid from the surgical site at various suction limit values or intervals as required.



Figure 24 To Start and Adjust Fluid Suction

#### Note:

Always use the minimum suction limit required to achieve the desired clinical outcome.

After suction has started, the STOP SUCTION button may be touched to stop fluid suction.

#### **High Suction Indicator**

| SUCTION CONDITION  | INDICATION  | ACTION                                     |
|--|---|--|
| HIGH suction limit RANGE: the suction setting selected is equal to or greater than 460 mm-Hg [60 kPa]. | Two declining tones; orange HIGH suction banner appears for appropriate canister on the Secondary Control Panel and main display; suction range indicator illuminates orange for associated canister. | Determine whether a high range is desired. |

#### 5.1.2 To Control Smoke Evacuation

**CAUTION:** DO NOT use the smoke evacuator to evacuate or suction surgical fluid. Excessive amounts of fluid pulled into the smoke evacuator may cause equipment damage.

# 5.1.3 To Manage a Full Canister

#### **Fluid Volume Indicators**

| CONDITION                         | INDICATION                             | ACTION                       |  |
|-----------------------------------|--|------------------------------|--|
| CANISTER ALMOST FULL – The        | Two declining tones; ALMOST FULL       | Prepare to switch to an      |  |
| fluid volume level is near full   | notification drop-down appears on      | alternate suction source.    |  |
| capacity. Fluid suction will soon | main display; blue ALMOST FULL         |                              |  |
| stop in the full canister.        | banner appears on display; canister    |                              |  |
|                                   | icon appears blue on both displays     |                              |  |
|                                   | (Figure 25 and Figure 26).             |                              |  |
|                                   |  |                              |  |
| CANISTER FULL – The fluid         | Three slow tones occur continuously;   | Switch to an alternate       |  |
| volume level is at full capacity. | FULL WARNING drop-down appears on      | suction source               |  |
| Fluid suction has stopped in the  | the main display; yellow SUCTION       |                              |  |
| full canister.                    | STOPPED banner appears on main         |                              |  |
|                                   | display; yellow FULL banner appears    | Dock the rover to dispose of |  |
|                                   | on display; canister icon appears      | waste. See Section To Dock   |  |
|                                   | yellow on both displays (Figure 27 and | the Rover (page 44).         |  |
|                                   | Figure 28).                            |                              |  |

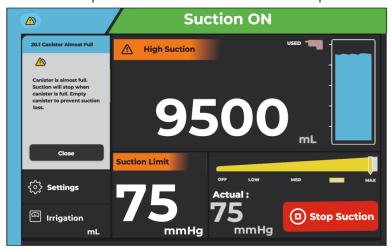


Figure 25 Almost Full Canister Condition (Main Control Panel Display)



Figure 26 Almost Full Canister Condition (Secondary Control Panel Display)



Figure 27 Full Canister Condition (Main Control Panel Display)



Figure 28 Full Canister Condition (Secondary Control Panel Display)

#### NOTES:

- If the rover display indicates sufficient fluid volume capacity in the canister, the rover may be used for another surgical procedure before waste disposal. Adding fluid from a second procedure on top of the previous procedure is called fluid stacking.
- Before each procedure, touch the RESET VOLUME button to reset the procedure fluid volume readout. After the
  fluid volume is reset, the rover will display the amount of fluid, if any, the rover has collected since the last
  procedure.
- 1. Monitor the volume of fluid captured in the rover canister. See Fluid Volume Conditions and Indicators.
- 2. If the canister is full, shut down the rover for docking. See Section To Remove Disposable Components (page 41) and Section To Shut Down and Relocate the Rover (page 43). Dock the rover to empty the full canister. See Section To Dock the Rover (page 44).

## 5.1.4 Monitoring irrigation fluid volumes (Adding fluid bag) (optional)

It is not necessary to stop the procedure when adding a bag.

#### **WARNINGS:**

- Leave empty fluid bags hanging on the pole hooks to maintain accurate irrigation and liquid deficit values.
- Time any contact with fluid bags, with the ongoing procedure to minimize influence on accuracy of fluid volume measurement.
- DO NOT REMOVE ANY BAGS (EMPTY OR FULL) ONCE PLACED ON THE HOOKS. Any weight removed from the hook is counted as irrigated fluid. Minimize any interactions with fluid bags and tubes on the poles once the L11424 Rev. B. ENG

surgery has started. Irrigation values are frozen during the interference even though measurement is ongoing. Values are updated once interference ends.

- 1. Hang the bag on one of the hooks. The device automatically recognizes the addition of a bag.
- 2. Spike the bag.
- 3. Clamp the empty bag and unclamp the new bag.
- 4. Wait for the bag to stop moving. During movement, the irrigation reading is not updated.

# **6** After the Procedure

### **6.1 To Remove Disposable Components**



#### **BLOODBORNE PATHOGEN HAZARD:**

- ALWAYS wear personal protective equipment (PPE) when operating or handling this equipment.
- ALWAYS leave tubing attached to the Disposable Manifold and close unused ports during disposal.
- ALWAYS follow local regulations regarding proper handling and disposal of biohazard waste.

Failure to comply may cause infection and result in healthcare staff injury.

#### **NOTES:**

- Although the disposable, single-use Disposable Manifold and suction tubing must be replaced between patients, it may not be necessary to empty the contents of the rover's collection canister.
- If sufficient fluid volume capacity exists in the canister, the rover may be used for additional surgical procedures.

## **6.1.1 To Remove Fluid Suction Components**

- 1. With suction active, gather the suction tubing toward the Disposable Manifold port to purge the tubing of fluid waste. DO NOT remove any attached suction tubing from the Disposable Manifold.
- 2. Turn the suction control dial to zero.
- 3. Touch the STOP SUCTION button on the main control screen to stop fluid suction (Figure 29).



Figure 29 Stop the Suction

- 4. Push the EJECT button to remove the Disposable Manifold from the receptacle (Figure 31). Maintain the Disposable Manifold in a horizontal orientation.
- 5. Pull the Disposable Manifold with the attached suction tubing out of the receptacle to fully remove the Disposable Manifold from the rover (Figure 31).

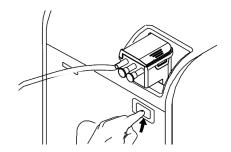


Figure 30 Remove the Disposable Manifold

6. Maintaining the Disposable Manifold in a horizontal orientation, properly dispose of the used Disposable Manifold and attached suction tubing (Figure 31).

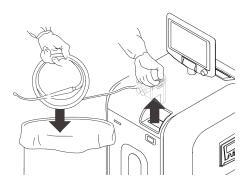


Figure 31 To Remove Disposable Manifold and Tubing

## **6.1.2 To Remove Smoke Evacuation Components**

- 1. From the control screen, touch the EVACUATE SMOKE button. From the EVACUATE SMOKE dialog, touch the OFF button to stop smoke evacuation.
- Gather the smoke evacuator tubing with any connected attachments toward the smoke evacuator filter. Remove the tubing and any connected attachment from the smoke evacuator filter (Figure 32).
- 3. Properly dispose of the used smoke evacuator tubing and any connected attachment.

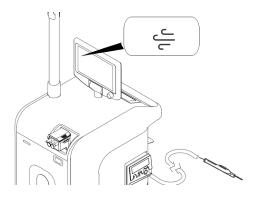


Figure 32 To Remove Smoke Evacuation Components

## **6.1.3 To Remove IV Pole Components (optional)**

1. From the main control screen menu, touch and hold the IV pole DOWN button to lower the fluid bag(s).

2. Remove all fluid bag(s) from the IV pole hooks.

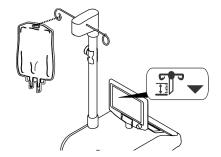


Figure 33 To Remove IV Pole Components

#### 6.2 To Shut Down and Relocate the Rover

#### 6.2.1 To Remove Power From the Rover

#### Note

- Always use the rover handle when repositioning or relocating the rover.
- If the rover is full or the rover will not be used for two hours, dock the rover to dispose of the collected fluid waste in the canister.
- The rover is not required to be connected to facility power when not in use.
- 1. Push the power switch to the OFF position (Figure 34).
- 2. Disconnect the power cord of the rover from facility electrical power. Wrap the power cord around the cord bracket.
- 3. Using the handles, close the canister viewing doors to conceal the canister contents as required.
- 4. Unlock the four casters of the rover and relocate the rover as required.
- 5. If Canister is full or the rover contains fluid waste and will not be used within two hours, relocate the rover to the docker using the rover handle. See Section To Dock the Rover (page 44).
- 6. If the canister is not full and the rover will be used within two hours, relocate the rover to the desired location using the rover handle.
- 7. Clean and disinfect the rover after every surgical procedure. See the Cleaning and disinfection section (page 50).

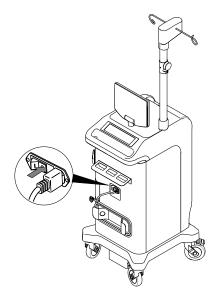


Figure 34 To Remove Power

#### 6.3 To Dock the Rover



#### **PINCH POINT HAZARD**

 ALWAYS keep hands out and away from the mating surfaces of the rover and docker during the docking procedure to avoid a pinch point hazard.

#### **BLOODBORNE PATHOGEN HAZARD**

- ALWAYS wear personal protective equipment (PPE) when operating or handling this equipment.
- ALWAYS follow local regulations regarding proper handling and disposal of biohazard waste.

Failure to comply may cause infection and result in healthcare staff injury.

#### NOTES:

- Canister is subject to contamination and should be cleaned and disinfected by Docking to the Docker after each use.
- Use the docker to empty the rover canister of fluid waste and perform a wash cycle. Prefill fluid will remain inside
  the canister after the wash cycle is complete. Prefill contains a specified amount of detergent for initiating the
  breakdown of fluid waste collected during rover use. After completing the wash cycle, the rover is ready for use or
  storage.
- Before docking the rover, always allow the docker to initiate for at least 60 seconds after applying power to the docker.
- The docker provides power to the rover during the docking process.
- DO NOT lock the rover casters while the rover is connected to the docker.

### 6.3.1 To Prepare the Docker

1. Make sure the power switch is in the ON position and illuminated.

2. Make sure the bottle of Detergent is connected and has detergent to perform a wash cycle (Figure 35).

**NOTE:** The end of the inlet tube must be located at the bottom of the detergent bottle. See the instructions for use supplied with the detergent bottle.

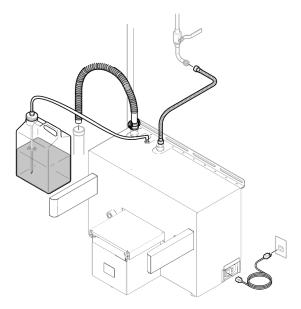


Figure 35 To Prepare the Docker

## 6.3.2 To Perform a Docking Cycle

**NOTE:** The default cycle will start within 15 seconds, automatically, unless another option is manually selected from the DOCKING MODE screen menu. See Table Docking Cycle Options.

Push the rover toward the docker and between the guides until the rover and docker attach automatically (Figure 36). Make sure the strike plates of the rover engage with the electromagnets of the docker. Make sure the rover is not plugged in during the wash cycle, the docker provides power to the rover during the docking process. Do not lock the casters. The DOCKING MODE screen will appear.

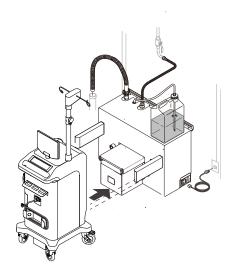


Figure 36 To Perform a Wash Cycle

 Press one of three timed wash cycle buttons from the main control display (Figure 37) or the secondary control display (Figure 38) and touch the START button to initiate the selected cycle. See Wash Cycle Options. If no option is selected, the default wash cycle will run.

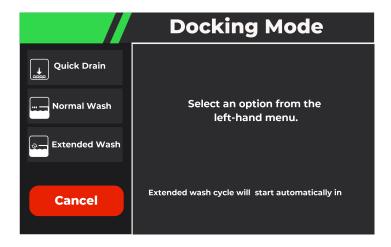


Figure 37 Initial Docking (main control display)

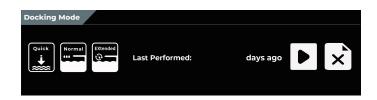


Figure 38 Initial Docking (secondary control display)

NOTE: During the cycle a 'progress' message will appear on the screen, followed by a 'completed' message. I

3. After the cycle is complete, touch the RELEASE FROM DOCK button to release the rover from the docker (Figure 39 and Figure 40). Pull the rover away from the docker.



Figure 39 RELEASE FROM DOCK button on the Main display



Figure 40 RELEASE FROM DOCK button on the Secondary display

4. Visually inspect the canister for any remaining soil. If soil remains, an Extended Wash cycle is available to provide a more thorough cleaning of the canister.

#### NOTES:

- 1. During the first rover docking procedure, the information on the main display may appear inconsistent. The procedure may also take a few more minutes than specified in Table Docking Cycle Options. Both conditions are normal and temporary.
- To exit the NORMAL WASH or EXTENDED WASH cycle, touch the ABORT TO QUICK WASH button (Figure 41 and Figure 42) to perform a QUICK WASH cycle. After the QUICK WASH cycle is complete, touch the RELEASE FROM DOCK(er) button to disconnect the rover from the docker.



Figure 41 ABORT TO QUICK WASH button on the Main display



Figure 42 ABORT TO QUICK WASH button on the Secondary display

#### **Wash Cycle Options**

| CYCLES        | DESCRIPTION   | TIME (approx.)   |
|---------------|---|------------------|
| Wash          | Cycle drains the contents of Canister, applies detergent to | 5 to 7 minutes   |
|               | the interior walls of Canister, and rinses the detergent    |                  |
|               | with water. More rinse cycles occur.                        |                  |
| Quick Wash    | Cycle drains the contents of Canister, applies detergent to | 2 to 4 minutes   |
|               | the interior walls of Canister, and rinses the detergent    |                  |
|               | with water. Fewer rinse cycles occur.                       |                  |
| Extended Wash | Cycle drains the contents of Canister, applies detergent to | 45 to 55 minutes |
|               | the interior walls of Canister, and rinses the detergent    |                  |
|               | with water. Intermittent periods of soaking occur during    |                  |
|               | the cycle.  |                  |

NOTE: If this is the initial docking of the rover, make sure the rover is tested before use. See the To Test the Rover section (page 28).

# 7 Inspection and Maintenance

## 7.1 To Inspect the Equipment

#### **MARNINGS:**

- Upon initial receipt and before each use, inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met.
- Always comply with the inspection interval to ensure the safe and effective use of the equipment.
- Do not disassemble, modify, or repair this product without the authorization of the manufacturer. Call AMSINO iReceptal Customer Service.

#### NOTES:

- Only biomedical equipment technicians trained and experienced in the maintenance of this reusable medical device should install and maintain this equipment.
- Maintenance documentation for this equipment is available upon request to Amsino-authorized service personnel only.

- For service, contact your AMSINO sales representative or call AMSINO iReceptal Customer Service.
- Routine and careful inspection of the equipment is the best method for determining the service life of the
  equipment. See Inspection Criteria and Actions.

Table - Inspection Schedule and Criteria

| INTERVAL   | INSPECTION CRITERIA   | ACTION  |
|--|---|---|
| Before initial use                                       | Inspect equipment for damage or missing components and for proper operation.  | If damage is apparent, replace the equipment. See the for use with section (page 7).  |
|  | Make sure the rover and docker operate as a system properly.  | See the following sections: To Dock the Rover (page 44), To Test the Rover (page 28), and To Adjust the Rover Settings (30).  |
| Before each use and after each cleaning and disinfection | Inspect equipment for damage or missing components.  Inspect for corrosion, discoloration, pitting, cracked materials, or         | If damage is apparent, replace the equipment. See the for use with section (page 7).  |
|  | unacceptable deterioration on any external surfaces, including labels and product markings.  Inspect the canister exterior, smoke |   |
|  | evacuator filter cover, and infrared communication window for cracks or damage.   |   |
|  | Inspect all of the casters and make sure the locks function properly.   |   |
|  | Inspect the power cord for cuts and the power cord plug for bent pins.  |   |
|  | Inspect the power cord receptacle for bent pins or bent contacts.   |   |
|  | Inspect the infrared communication window for any dirt or debris.   | Thoroughly remove any dirt or debris on the infrared communication window. See Section Cleaning and Disinfection (page 50).   |
| Six months   | Inspect the replacement date on the label of the fluid suction filter. The fluid suction filter life is 500 hours.                | Replace the fluid suction filter every six months or as indicated on the main display. See Section For Use With (7) and the instructions for use supplied with the filter.        |
|  | Inspect the replacement date on the label of the smoke evacuator filter. The smoke evacuator filter life is 80 hours.             | Replace the smoke evacuator filter every six months or as indicated on the main display. See Section For Use With (page 7) and the instructions for use supplied with the filter. |

NOTE: If any component must be discarded, see the Disposal/Recycle section (page 52).

### 7.2 To Replace the HEPA Filter

#### **MARNINGS:**

#### **BLOODBORNE PATHOGEN HAZARD**

- The Bloodborne Pathogens Standard provided by the United States Occupational Safety and Health Administration
  (US OSHA 29 CFR 1910.1030) requires those employers with employees having occupational exposure to potentially
  infectious materials to establish a written Exposure Control Plan. The Exposure Control Plan is designed to eliminate
  or minimize employee exposure through use of personal protective equipment (PPE), appropriate vaccinations (for
  example, hepatitis B), and other control measures
- Always wear PPE when operating or handling this equipment.
- Always leave suction tubing attached to the Disposable Manifold during use and disposal.
- Always close unused Disposable Manifold ports during use and disposal.
- Always follow local regulations regarding proper handling and disposal of biohazard waste.

Failure to comply may cause infection and result in healthcare staff injury.

#### **MARNINGS:**

Do not touch the filter media. The media filters the air evacuated from fluid collection canister of the rover before the air is vented. Failure to comply may cause media damage and result in patient and/or healthcare staff injury.

#### 7.2.1 To Install the Fluid Suction HEPA Filter

#### **NOTES:**

- Replace the filter every six months or as indicated on the main control panel display of the rover. Failure to comply
  will result in the reduction of fluid suction or an increase in odor.
- The filter life is 500 hours. The rover calculates filter usage time automatically. Always reset the filter timer after the filter is replaced.
- 1. Make sure the rover power switch is OFF.
- 2. Unlock and Open the filter cover. (Figure 43).

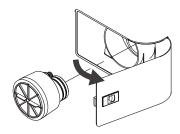


Figure 43 Remove and Replace the Filter

- 3. Remove and properly dispose of the used HEPA filter.
- 4. Obtain a new HEPA filter. See For Use With
- 5. Mark the replacement date on the label of the new HEPA filter.

- 6. Install the new HEPA filter into the filter compartment.
- 7. Install the filter cover over the filter compartment; close the filter cover and lock it in place.

### 7.2.2 To Verify Proper Filter Installation

- 1. Connect the rover power cord to facility power.
- 2. Press the rover power switch to the ON position.
- 3. Read the safety information on the control panel display. Based on the configuration of the rover, select OK or CONFIRM on the control panel.
- 4. Insert a Disposable Manifold into the Disposable Manifold receptacle.
- 5. Make sure all the inlet ports of the Disposable Manifold are closed.
- 6. Touch the START SUCTION button.
- 7. Adjust the manual suction control dial to the maximum suction level.
- 8. Verify the actual suction value changes as indicated on the main control panel display and reaches a suction level of at least 513 mm-Hg.

**Note** - If a suction level of at least 513 mm-Hg is NOT reached, reposition the filter. See To Replace the HEPA Filter (Page 49). If the suction level is still NOT reached, contact service.

9. Discard the Disposable Manifold used for testing purposes.

#### 7.2.3 To Reset the Filter Timer

- 1. Access the SETTINGS menu. Select the ACCESSORIES dialog and the FILTERS tab.
- 2. Touch RESET HOURS button to reset the hours to zero; close the dialog.

# 8 References

## 8.1 Cleaning and Disinfection

▲ WARNING: ALWAYS clean the equipment as indicated upon initial receipt and before each use. Failure to comply may cause infection and result in patient or healthcare staff injury.

#### **CAUTIONS:**

- External surfaces of the rover is subject to contamination and should be cleaned and disinfected after each use, please refer to section 8.2
- DO NOT immerse any system component in liquid. DO NOT allow liquids or moisture to enter any electrical connection.
- DO NOT sterilize any system component.
- DO NOT use solvents, lubricants, or other chemicals, including glutaraldehyde or similar chemical cleaners, unless

otherwise specified.

• Do not use unapproved disinfectants. Failure to comply may cause system damage.

#### **Recommended Equipment and Materials**

- Personal Protective Equipment (PPE) as recommended by the disinfectant supplier (minimum: gown, gloves, face/eye shield)
- Soft, lint-free cloth
- United States Environmental Protection Agency (US EPA) registered disinfectant with a claim for activity against
  Hepatitis B. The following disinfectants have been validated for use on the exterior surfaces of the AMSINO
  iReceptal digital surgical suciton System: Surface disinfectant decontaminant cleaner CaviCide® (EPA Reg. #46781-6)

### 8.2 To Wipe Down the Rover

- 1. Wipe all external surfaces of the rover with a soft, lint-free cloth moistened with a non-abrasive, hospital disinfectant (Surface disinfectant decontaminant cleaner CaviCide®). Pay particular attention to highlighted critical areas such as the handle, control panel, communication window, and Manifold receptacles about one minutes(Figure 44).
- 2. Upon the removal of visible, gross soil, use a clean cloth moistened with disinfectant and wipe all surfaces. Surfaces must remain visibly wet at room temperature for at least the minimum time specified in the instructions for use supplied by disinfectant manufacturer.
- 3. Remove any excess disinfectant solution using a soft, lint-free cloth moistened with water if required by the instructions supplied by the disinfectant manufacturer.
- 4. Inspect the rover. See Section Inspection and Maintenance (page 47).
- 5. Refill the Disposable Manifold holder with new, unused Disposable Manifolds, as required. See Section For Use With (page 7)for ordering information.
- 6. If the rover will be used again, use the rover handle to push and relocate the rover. If the rover will no longer be used, use the rover handle to push and relocate the rover to a storage area. See Section Storage and Handling (page 52).

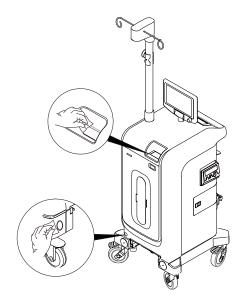


Figure 44 To wipe down the rover

### 8.3 Storage and Handling

#### **CAUTIONS:**

- ALWAYS store and transport the equipment within the specified environmental condition values throughout its useful life. See the Specifications section (page 58).
- ALWAYS call AMSINO iReceptal Customer Service before transporting or storing this equipment in freezing
  conditions. Failure to comply will cause the expansion of frozen internal fluid to damage the equipment.

**NOTE:** The rover does not have to be connected to facility power when not in use.

#### 8.4 Service

#### **WARNING:**

- Do not disassemble, modify, or repair this product without the authorization of the manufacturer if liquids or solids have been drawn into the vacuum pump.
- Do not disassemble, modify, or repair this product without the authorization of the manufacturer. Contact Amsino for service.
- ALWAYS process (clean, disinfect) all potentially contaminated equipment BEFORE contacting Amsino for service. Amsino will not service any potentially contaminated equipment.

#### Note:

- Maintenance documentation for this product is available upon request to Amsino -authorized service personnel only.
- For service information, contact Amsino Customer Service.
- Make sure you have the serial number of your Amsino product available when calling Amsino Customer Service or Technical Support. Include the serial number in all written communication.

## 8.5 Disposal/Recycle

**MARNINGS:** 

#### **BLOODBORNE PATHOGEN AND CONTAMINATION HAZARDS**

- ALWAYS follow local regulations for safe handling, recycling, and disposal of biohazardous fluid waste and iReceptal digital surgical suction equipment.
- Call AMSINO iReceptal Customer Service for rover decontamination procedures.

Failure to comply may cause environmental contamination or infection and result in personal injury.



In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) as amended product should be collected separately for recycling. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information. Ensure infected equipment is decontaminated prior to recycling.

Collect batteries separately for recycling per European Community Batteries Directive.

No Mercury: <0.0001% of Battery Weight

# 9 Troubleshooting

## 9.1 Rover Troubleshooting

NOTE: For service, contact your AMSINO sales representative or call AMSINO iReceptal Customer Service.

| SYMPTOM                        | POTENTIAL CAUSE                       | CORRECTIVE ACTION                           |
|--------------------------------|---------------------------------------|---|
| Rover Operation                |                                       |   |
| The rover does not power up    | Power cord is not connected or is not | Connect the power cord or make sure the     |
| and the power switch is in the | connected securely.                   | power cord is connected securely.           |
| ON position.                   |                                       |   |
| The rover does not recognize a | Disposable Manifold is altered or     | Replace the Disposable Manifold. See        |
| Disposable Manifold.           | damaged.                              | Section For Use With (page 7) and the       |
|                                |                                       | instructions for use supplied with the      |
|                                |                                       | Disposable Manifold.                        |
| No vacuum pump action after    | Canister is full and an error occurs. | Dock the rover.                             |
| the SUCTION BUTTON is          | The rover is damaged.                 | Remove the rover from use. Contact          |
| touched.                       |                                       | AMSINO iReceptal Customer Service.          |
| The rover's fluid suction is   | Disposable Manifold is not installed  | Insert the Disposable Manifold to make sure |
| weak or insufficient.          | correctly.                            | it is locked in place.                      |
|                                | Unused Disposable Manifold ports are  | Close all unused Disposable Manifold ports  |
|                                | open.                                 | of each canister.                           |
|                                | Suction tubing connection is not      | Make sure all suction tubing connections    |
|                                | secure.                               | are secure.                                 |
|                                | Unused suction tubing is not          | Clamp any suction tubing not in use.        |
|                                | clamped.                              |   |
|                                | Suction tubing is blocked or          | Clear or replace the suction tubing.        |
|                                | damaged.                              |   |
|                                | Suction accessory is blocked or       | Clear or replace the suction accessory.     |
|                                | damaged.                              |   |

|                                   | T                                     |  |
|-----------------------------------|---------------------------------------|--|
|                                   | Suction tubing is too long or has a   | Use shorter length or larger diameter          |
|                                   | narrow diameter.                      | suction tubing.                                |
|                                   | Disposable Manifold is clogged or     | Replace the Disposable Manifold. See for       |
|                                   | damaged.                              | use with section (page 7). See the             |
|                                   |                                       | instructions for use supplied with the         |
|                                   |                                       | Disposable Manifold.                           |
|                                   | The SUCTION control dials are         | Turn the suction control dials to adjust the   |
|                                   | adjusted too low.                     | suction limit to the proper level.             |
|                                   | The fluid suction filter requires     | Replace the fluid suction filter. See Section  |
|                                   | replacement.                          | For Use With (page 7) and the instructions     |
|                                   | ·                                     | for use supplied with the filter.              |
|                                   | The rover is damaged.                 | Remove the rover from use. Contact             |
|                                   | - The series as a series general      | AMSINO iReceptal Customer Service.             |
| The rover's suction capability is | The rover is damaged.                 | Remove the rover from use. Contact             |
| lost.                             | The rover is dumaged.                 | AMSINO iReceptal Customer Service.             |
| 1031.                             | An Error has occurred.                | See Section Troubleshooting Codes              |
|                                   | All Ellor has occurred.               |  |
| A C11                             | T. G.: L: Ch                          | (page 56).                                     |
| A filter error appears on the     | The fluid suction filter has exceeded | Replace the HEPA fluid suction filter. See     |
| main display.                     | its useful life.                      | for use with section (page 7). See the         |
|                                   |                                       | instructions for use supplied with the filter. |
|                                   | The smoke evacuator filter has        | Replace the smoke evacuator filter. See for    |
|                                   | exceeded its useful life.             | use with section (page 7). See the             |
|                                   |                                       | instructions for use supplied with the filter. |
| The rover is releasing a strong   | The fluid suction filter has exceeded | Replace the smoke evacuator filter. See for    |
| odor.                             | its useful life.                      | use with section (page 7). See the             |
|                                   |                                       | instructions for use supplied with the filter. |
|                                   | The docker does not dispense          | See Section Docking Station Operation          |
|                                   | detergent during the cleaning cycle.  | (page 44). and Section Troubleshooting         |
|                                   |                                       | Codes (page56).                                |
|                                   | The canister require special          | Remove the rover from use. Contact             |
|                                   | additional cleaning.                  | AMSINO iReceptal Customer Service. See         |
|                                   |                                       | Section Contact Information (page6).           |
| The smoke evacuator fails to      | The smoke evacuator is damaged.       | Remove the rover from use. Contact             |
| operate after activation          | _                                     | AMSINO iReceptal Customer Service.             |
| (EVACUATE SMOKE BUTTON is         |                                       |  |
| Taped).                           |                                       |  |
| A smoke evacuator error           | The smoke evacuator filter is not     | Install the smoke evacuator filter correctly.  |
| appears on the user interface     | installed, installed incorrectly, or  | See the instructions for use supplied with     |
| display.                          | damaged.                              | filter.  |
|                                   | The smoke evacuator is damaged.       | Remove the rover from use. Contact             |
|                                   | Sinone evacuator is dumuged.          | AMSINO iReceptal Customer Service.             |
| IV polo hoight cannot be          | IV polo is supporting too much        | *  |
| IV pole height cannot be          | IV pole is supporting too much        | Remove excessive weight from IV pole.          |
| adjusted to its maximum           | weight.                               | Paragraphic Control                            |
| height.                           | The IV pole is bent, kinked, or       | Remove the rover from use. Contact             |
|                                   | pinched.                              | AMSINO iReceptal Customer Service.             |

| Sporadic electrical interference | Electrical noise is present. | Turn off all the electrical equipment not in |
|----------------------------------|------------------------------|--|
| is experienced.                  |                              | use in the room.                             |
|                                  |                              | Relocate the electrical equipment to         |
|                                  |                              | maximize the distance between the            |
|                                  |                              | equipment. Increase spatial distance.        |
|                                  |                              | Connect the electrical equipment into        |
|                                  |                              | different hospital-grade facility power      |
|                                  |                              | receptacles with protective earth (ground).  |

# 9.2 Docking Station Troubleshooting

| PROBLEM                             | POTENTIAL CAUSE                      | CORRECTIVE ACTION                        |
|-------------------------------------|--------------------------------------|--|
| Docking Operation                   |                                      |  |
| The rover will not dock or an error | The docker power cord is not         | Make sure the docker power cord is       |
| has occurred during docking.        | connected or is loosely connected.   | connected securely.                      |
|                                     | The docker power switch is in the    | Make sure the power switch is in the     |
|                                     | OFF position.                        | ON position and illuminated.             |
|                                     |                                      | If power switch is OFF, Tap the power    |
|                                     |                                      | switch to the ON position. Wait 60       |
|                                     |                                      | seconds. Dock the rover.                 |
|                                     | The docker power switch is in the ON | Make sure facility power is provided     |
|                                     | position, but not illuminated.       | to the wall receptacle.                  |
|                                     |                                      | If facility power is OFF, apply facility |
|                                     |                                      | power to the docker. Wait 60             |
|                                     |                                      | seconds. Dock the rover.                 |
|                                     | The rover is not completely          | Push the rover forward enough to         |
|                                     | connected to the docker.             | complete a docker-rover interface        |
|                                     |                                      | connection.                              |
|                                     | Communication between the rover      | Remove the dirt or debris from the       |
|                                     | and docker is interrupted because    | rover's infrared communication           |
|                                     | the infrared communication window    | window. See Section Cleaning and         |
|                                     | is either dirty or obstructed.       | Disinfection (page 50). Dock the         |
|                                     |                                      | rover.                                   |
|                                     |                                      | Remove any obstruction from the          |
|                                     |                                      | docker's infrared communication          |
|                                     |                                      | windows. Make sure there are no          |
|                                     |                                      | tubes, hoses, or towels covering the     |
|                                     |                                      | docker's infrared communication          |
|                                     |                                      | windows. Dock the rover.                 |
|                                     | The docker is not receiving facility | Make sure the water inlet hose is        |
|                                     | water.                               | connected correctly. Make sure the       |
|                                     |                                      | facility water supply valve is open.     |
|                                     |                                      | Dock the rover.                          |
|                                     | The docker requires a power reset.   | Remove power, then apply power to        |
|                                     |                                      | the docker. Wait 60 seconds. Dock        |
|                                     |                                      | the rover.                               |

|   | 1                                       |                                       |
|---|---|---------------------------------------|
|   | If the problem persists, the docker     | Contact AMSINO iReceptal Customer     |
|   | may be damaged.                         | Service.                              |
| Prefill fluid remains inside the rover  | The presence of prefill is normal. This | No action is required.                |
| canister after a cycle is complete.     | water and detergent solution (prefill)  |                                       |
|   | initiates the breakdown of fluid        |                                       |
|   | waste collected during the rover's      |                                       |
|   | next use.                               |                                       |
| The docker does not dispense            | The bottle of detergent is empty.       | Replace the bottle of the detergent.  |
| detergent during the cleaning cycle.    |   | See for use with section (page 7).    |
|   |   | Make sure the detergent inlet tube is |
|   | The end of the detergent inlet tube is  | routed through the tube stiffener and |
|   | not immersed in the detergent.          | the end of the tube reaches the       |
|   |   | bottom of the detergent bottle.       |
|   | The detergent inlet tube is not         | Securely connect the detergent inlet  |
|   | connected securely to the detergent     | tube to the detergent inlet port of   |
|   | inlet port of the docker.               | the docker.                           |
|   | If the problem persists, the docker     | Contact AMSINO iReceptal Customer     |
|   | may be damaged.                         | Service.                              |
| The rover canister is not clean after a | The bottle of detergent is empty.       | Replace the bottle of the detergent.  |
| cleaning cycle.                         |   |                                       |
| An error occurs while the rover is      | The fluid connectors prevent the        | Remove power, apply power to the      |
| docked and the rover cannot be          | removal of the rover from the docker.   | docker. Wait 10 seconds.              |
| removed from the docker.                |   | Pull the rover away from the docker.  |
|   |   | Wait 60 seconds. Dock the rover.      |
|   | If the problem persists, the fluid      | Contact AMSINO iReceptal Customer     |
|   | connectors may be damaged.              | Service.                              |
| The rover cannot be removed from        | The four casters are locked.            | Make sure the four casters are        |
| docker.                                 |   | unlocked. The casters do not need to  |
|   |   | be locked when the rover is docked.   |
|   |   | Pull the rover away from the docker.  |
|   | The operator failed to acknowledge      | From the DOCKING MODE screen,         |
|   | the docking cycle is complete.          | touch the RELEASE FROM DOCK(er)       |
|   |   | button to disconnect the rover from   |
|   |   | the docker.                           |

# 9.3 Troubleshooting Codes

#### NOTE:

- A low or medium priority notification message may appear in the notification or error message area on the control screen, respectively. Touch the indicator area to access the drop-down list and/or message.
- For service, contact your AMSINO sales representative or call AMSINO iReceptal Customer Service.

#### Table – Error Codes and Messages, Alarm Priorities, and Actions

| Code Message | Priority | Action |
|--------------|----------|--------|
|--------------|----------|--------|

| 0.X          | System error   | Error (medium)     | Call service   |
|--------------|--|--------------------|--|
| 1.1          | Memory Error   | Notification (low) | Setting options, including brightness and the default docking cycle require resetting. See To Adjust the Settings  |
| 1.2          | Memory Error   | Notification (low) | Collected data erased. This includes Disposable Manifolds used, filter hours, and last docking cycle.  |
| 1.X          | Memory Error   | Error (medium)     | Call service   |
| 3.0          | Vacuum Error   | Error (medium)     | Call service   |
| 3.1          | Vacuum Error   | Error (medium)     | Call service   |
| 4.0          | HEPA Filter Expired  | Notification (low) | Replace fluid suction HEPA filter; reset filter life counter. See To<br>Replace the HEPA Filter  |
| 4.1          | Surgical Smoke Evacuate ULPA Filter Expired                | Notification (low) | Replace smoke evac Surgical Smoke Evacuate ULPA Filter   |
| 5.0/5.1/5.2  | Disposable Manifold Error                                  | Error (medium)     | Call service   |
| 7.11         | Disposable Manifold Error                                  | Notification (low) | Install New Disposable Manifold  |
| 7.15         | Used Disposable Manifold                                   | Notification (low) | Install new Disposable Manifold before performing the next   |
| 10.1         | Level Sensor Error   | Error (medium)     | Call service   |
| 15.0         | Smoke Evac Error   | Notification (low) | Call service   |
| 15.2         | No Smoke Evac Filter                                       | Notification (low) | Install New smoke evac Surgical Smoke Evacuate ULPA Filter   |
| 15.3         | Smoke evac Surgical Smoke<br>Evacuate ULPA Filter about to | Notification (low) | Replace smoke Surgical Smoke Evacuate ULPA Filter after the Filter Expired   |
| 17.1         | Vacuum Error   | Error (medium)     | Call service   |
| 20.1         | CANISTER Almost Full                                       | Notification (low) | Prepare to use an alternate source of suction, or empty the canister of fluid waste to prevent the loss of suction. suction will stop when the canister is full. |
| 20.5         | Canister Full  | Error (medium)     | Use an alternate source of suction, or empty the canister to restore   |
|              | Docking Error  | Error (medium)     | Remove the rover from the docker. Cycle docker power. Wait 60 seconds; try docking the rover again.  |
|              | Offload Error  | Error (medium)     | Uninstall the Disposable Manifold; try docking the rover again   |
|              | Offload Error  | Error (medium)     | Call service   |
| 20. <i>X</i> | Prefill Error  | Error (medium)     | Make sure facility water is supplied to the docker; dock the rover again.  |
|              | Coupling Error   | Error (medium)     | Call service   |
|              | Dock Incomplete  | Notification (low) | Remove the rover from the docker. Cycle docker power. Wait 60 seconds; try docking the rover again.  |
|              | Docker Not Ready   | Error (medium)     | Remove the rover from the docker. Cycle docker power. Wait 60 seconds; try docking the rover again.  |

| Need To Dock  Notification (low)  Dock the rover; the used rover has not been docked in 48 hours. |
|---|
|---|

# 10 Specifications

TABLE 1. Rover specifications

|                            | TABLE 1. NOVEL SPECIFICA   |  |  |
|----------------------------|--|--|--|
| REF                        | iRR551-02 iRR552-02  |  |  |
| Electrical Power           | 220-240V~, 50/60 Hz, 3.4 A, single phase;  |  |  |
| Requirements:              | 24 V =, 5 A during docking procedure,  |  |  |
|                            | rover receives power from docker   |  |  |
|                            | REF iRD502-02  |  |  |
| Power inlet module:        | Power switch with 250V fuses on neutral a  | and line connection                          |  |
| European Conformity:       | <b>(€</b> <sub>0123</sub>  |  |  |
| Dimensions                 | Width: 54cm  | Width: 54cm                                  |  |
|                            | Height: 111.5cm  | Height: 220cm                                |  |
|                            | Depth: 57.5 cm   | (with IV pole up); 175cm (with IV pole down) |  |
|                            |  | Depth: 57.5 cm                               |  |
|                            |  |  |  |
|                            |  |  |  |
| Mode of Operation          | Continuous   |  |  |
| Volume                     | 11-liter capacity (11-liter canister)  |  |  |
|                            | Note- The canister has increment marks of 100 mL.  |  |  |
| Volume Overfill Protection | the rover contains automatic overfill p  | rotection through volume measurement and a   |  |
|                            | mechanical shutoff valve. When the collection canister is full, suction will cease and the rover |  |  |
|                            | must be docked to dispose of the waste and resume suction operation.                             |  |  |
| Mass                       | 87kg —collection empty   | 90kg —collection empty                       |  |
|                            | 98kg —collection full  | 101kg —collection full                       |  |
| Ingress Protection (IP):   | IP22   |  |  |
| Equipment Type:            | Type CF Applied Part   |  |  |
| Equipment Classification:  | Class I Medical Electrical (ME) Equipment  |  |  |
| Pollution Degree           | 2  |  |  |
| Environmental Conditions:  | Operation:   |  |  |
|                            | Temperature Limitation: 10°C ~ 40 °C   |  |  |
|                            | Humidity Limitation: 30% ~ 75%   |  |  |
|                            | Atmospheric Pressure Limitation: 70kPa ~ 106kPa  |  |  |
|                            | Storage and Transportation (before initial use):   |  |  |
|                            | Temperature Limitation: -20°C ~ 40 °C  |  |  |
|                            | Humidity Limitation: 10% ~ 75%   |  |  |
|                            | Atmospheric Pressure Limitation: 50kPa ~ 106kPa  |  |  |
|                            | Storage and Transportation (after initial use):  |  |  |
|                            | Temperature Limitation: 10°C ~ 40 °C   |  |  |
|                            | Humidity Limitation: 10% ~ 75%   |  |  |

|                             | Atmospheric Pressure Limitation: 50kPa ~ 106kPa   |  |  |
|-----------------------------|---|--|--|
| Installation location       | < 3,000 m above sea level. Usage not allowed in oxygen-rich or explosion- hazard                    |  |  |
|                             | environment.  12 000 mL or 6000 mL per IV pole book: for example four three-liter (6000 mL) IV bags |  |  |
| IV Pole Capacity:           | 12,000 mL or 6000 mL per IV pole hook; for example four three-liter (6000 mL) IV bags               |  |  |
| Light Emitting Diode (LED)  | WARNING: INVISIBLE LED RADIATION  |  |  |
| Classification (infrared    | DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS CLASS 1M LED PRODUCT — Viewing                        |  |  |
| communication windows):     | the laser output with certain optical instruments (for example, eye loupes, magnifiers and          |  |  |
|                             | microscopes) within a distance of 100 mm may pose an eye hazard.                                    |  |  |
| Ground Type:                | Protective Earth (ground); when connected to facility power   |  |  |
| Lifetime                    | Eight-years   |  |  |
|                             | Suction   |  |  |
| Suction Limit range         | 50 to 540 mmHg; measured with all ports closed  |  |  |
| 1                           | <b>Note</b> - Suction limits remain adjustable in increments of 5 mm-Hg for settings between 50 to  |  |  |
|                             | 120mm-Hg. Suction limits increment at 20 mm-Hg for settings over 120 mm-Hg.                         |  |  |
| Suction Tube Connection     | Inner diameter: >6.0mm  |  |  |
| Suction performance         | High vacuum/high flow   |  |  |
| category                    |   |  |  |
| Vacuum Measurement          | 0~-90kpa  |  |  |
| range                       |   |  |  |
| Vacuum Measurement          | ± 5% of full scale  |  |  |
| Accuracy:                   |   |  |  |
| Display resolution          | 0.1kPa/1mmHg.   |  |  |
|                             | Fluid collection  |  |  |
| Digital Display range       | 0 12,000mL  |  |  |
| Measurement accuracy        | 11-liter canister, ±50ml  |  |  |
|                             | NOTE: Volume measurements specified do not account for fluid evaporation or an inclined             |  |  |
|                             | plane of operation that exceeds the specified range.  |  |  |
| Inclined plane of operation | ±2.5 degrees  |  |  |
|                             |   |  |  |
|                             | Smoke evacuation  |  |  |
| Maximum Smoke Evacuator     | Standard Hose I.D. Flow Rates   |  |  |
| Flow Setting                | 22mm (7/8"). 707LPM (25CFM)   |  |  |
|                             | 9.5mm (3/8"). 130LPM (4.6CFM)   |  |  |
|                             | 6.4mm (1/4"). 60LPM (2.1CFM)  |  |  |
|                             | NOTE: The specified flow rates were obtained using smoke tubing with a 1.8m length. Actual          |  |  |
|                             | flow rates may vary depending on the length and diameter of the smoke tubing used.                  |  |  |
| Smoke evacuation tube       | 6.4mm, 9.5mm, 22mm  |  |  |
| connection                  |   |  |  |
|                             |   |  |  |

TABLE 2. Consumables specifications

| Single-patient Disposable Manifold                   |                                      |  |  |
|--|--------------------------------------|--|--|
| Shelf life 3 years from manufacturing                |                                      |  |  |
| Storage Conditions Keep dry, Keep away from sunlight |                                      |  |  |
| Surgical Smoke Evacuate ULPA Filter                  |                                      |  |  |
| Shelf life   | nelf life 3 years from manufacturing |  |  |
| Storage Conditions Keep dry, Keep away from sunlight |                                      |  |  |

# 11 Electromagnetic Compatibility

### Guidance and Manufacturer's Declaration

Below cables information are provided for EMC reference.

| Cable         | Max. cable length,<br>Shielded/unshielded |            | Number | Cable classification |
|---------------|---|------------|--------|----------------------|
| AC Power Line | 4.5m                                      | Unshielded | 1 Set  | AC Power             |

#### Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2 Edition 4.1 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The equipment with no ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally".
- The use of accessories, transducers 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.
- WARNING: 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 this product, including
  cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment
  could result."
- WARNING: If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.
- STATEMENT: For the purpose of its operation, the equipment has wireless communication function, operating frequency is13.56MHz, RF Module is ASK (Amplitude Shift Keying), and ERP is 14dBm.

### **EMI Compliance Table (Table 1)**

Table 1 - Emission

| Phenomenon   | Compliance                   | Electromagnetic environment                  |
|--------------|------------------------------|--|
| RF emissions | CISPR 11<br>Group 1, Class A | Professional healthcare facility environment |

| Harmonic distortion              | N/A | Professional healthcare facility environment |
|----------------------------------|-----|--|
| Voltage fluctuations and flicker | N/A | Professional healthcare facility environment |

NOTE 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 normally 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 re-orienting the equipment.

### **EMS Compliance Table (Table 2-4)**

**Table 2 - Enclosure Port** 

| Dhanamanan  | Basic EMC standard   | Immunity test levels   |
|---|----------------------|--|
| Phenomenon  | basic Eivic standard | Professional healthcare facility environment   |
| Electrostatic   | IEC 61000-4-2        | ±8 kV contact  |
| Discharge   | 12001000 12          | ±2kV, ±4kV, ±8kV, ±15kV air  |
|   |                      | 3V/m   |
| Radiated RF EM field  | IEC 61000-4-3        | 80MHz-2.7GHz   |
|   |                      | 80% AM at 1kHz   |
| Proximity fields from<br>RF wireless<br>communications<br>equipment | IEC 61000-4-3        | Refer to table 3   |
| Rated power frequency magnetic fields                               | IEC 61000-4-8        | 30A/m<br>50Hz or 60Hz  |
| Proximity fields  | IEC 61000-4-39       | 134,2 kHz Pulse modulation 2,1kHz, 65 A/m<br>13,56 MHz Pulse modulation 50kHz, 7,5 A/m |

Table 3 – Proximity fields from RF wireless communications equipment

| Test frequency | Band      | Immunity test levels                         |
|----------------|-----------|--|
| (MHz)          | (MHz)     | Professional healthcare facility environment |
| 385            | 380-390   | Pulse modulation 18Hz, 27V/m                 |
| 450            | 430-470   | FM, ±5kHz deviation, 1kHz sine, 28V/m        |
| 710            |           |  |
| 745            | 704-787   | Pulse modulation 217Hz, 9V/m                 |
| 780            |           |  |
| 810            |           |  |
| 870            | 800-960   | Pulse modulation 18Hz, 28V/m                 |
| 930            |           |  |
| 1720           |           |  |
| 1845           | 1700-1990 | Pulse modulation 217Hz, 28V/m                |
| 1970           |           |  |
| 2450           | 2400-2570 | Pulse modulation 217Hz, 28V/m                |

| 5240 |           |                              |
|------|-----------|------------------------------|
| 5500 | 5100-5800 | Pulse modulation 217Hz, 9V/m |
| 5785 |           |                              |

Table 4 - Input a.c. power Port

| Phenomenon            | Basic EMC standard    | Immunity test levels                             |
|-----------------------|-----------------------|--|
| Phenomenon            | Dasic Elvic Stalluaru | Professional healthcare facility environment     |
| Electrical fast       | IEC 61000-4-4         | ±2 kV  |
| transients/burst      | ILC 01000-4-4         | 100kHz repetition frequency                      |
| Surges                | IEC 61000-4-5         | ±0.5 kV, ±1 kV                                   |
| Line-to-line          | 10000-4-5             | ±0.3 kV, ±1 kV                                   |
| Surges                | IEC 61000-4-5         | ±0.5 kV, ±1 kV, ±2 kV                            |
| Line-to-ground        | ILC 01000-4-3         | 10.3 kV, 11 kV, 12 kV                            |
| Conducted             |                       | 3V, 0.15MHz-80MHz                                |
| disturbances induced  | IEC 61000-4-6         | 6V in ISM bands between 0.15MHz and 80MHz        |
| by RF fields          |                       | 80%AM at 1kHz                                    |
|                       |                       | 0% U <sub>T</sub> ; 0.5 cycle                    |
|                       | IEC 61000-4-11        | At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º |
| Voltage dips          |                       | 0% U <sub>T</sub> ; 1 cycle                      |
|                       |                       | and  |
|                       |                       | 70% U <sub>T</sub> ; 25/30 cycles                |
|                       |                       | Single phase: at 0º                              |
| Voltage interruptions | IEC 61000-4-11        | 0% U <sub>T;</sub> 250/300 cycles                |

# 12 Glossary

Applied part: a component of an electrical medical device that comes into physical contact with the patient during normal use is perform its function. The fluid suction tubing and suction accessory are applied parts. The smoke evacuator tubing and optional smoke evacuator attachment are applied parts.

# 13 Statement

Working Principle of Wireless communication function (RFID 13.56 MHz)

Operating Frequency Band:

Frequency RFID operates at 13.56 MHz, utilizing electromagnetic induction coupling (not electromagnetic wave propagation).

Energy Transfer:

The reader (Rover) emits an alternating magnetic field through its antenna coil.

The passive tag (Tag) receives energy via its inductive coil and rectifies it to power the chip.

**Data Communication Process:** 

Uplink (Reader  $\rightarrow$  Tag): Commands are transmitted using amplitude-shift keying (ASK) or phase-shift keying (PSK) modulation.

Downlink (Tag  $\rightarrow$  Reader): The tag changes the load state of its coil through (load modulation), generating an induced signal in the reader's antenna to achieve data return.

#### **Identification Process:**

- 1 The Rover emits a 13.56 MHz magnetic field and broadcasts a "card search" command.
- 2 The RFID tag enters the magnetic field, is activated, and responds.
- 3 Communication is established between the Rover and the tag, completing UID reading.
- 4 The Rover identifies the Disposable Manifold type or status based on the tag information.