



Advancing Healthcare Worldwide®

iReceptal® Mini

Digital Surgical Suction System

220-240 VAC System REF iRS551-02

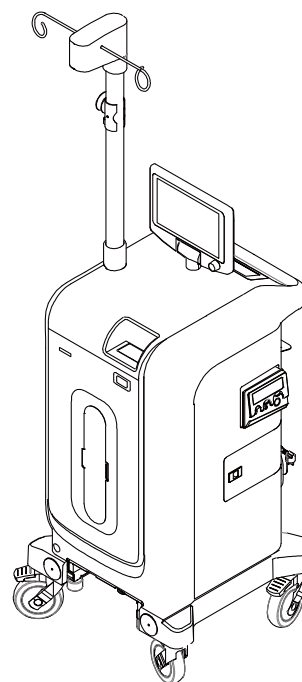
220-240 VAC System REF iRS552-02

Instructions For Use

220-240 VAC iReceptal Mini Rover, iRR551-02

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

R_x ONLY



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1 Important Information

1.1 Warnings

! WARNING:

HIGH SUCTION DEVICE

Only trained and experienced healthcare professionals may use this equipment.



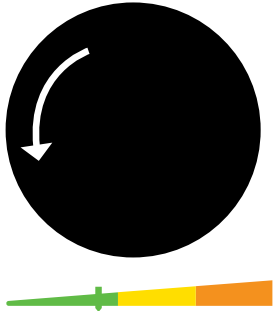
DO NOT connect directly to chest tubes.



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 RESULT IN 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

WARNING

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 Rover REF IRR552-01	220-240VAC iReceptal Docking Station	iRD502-02
Rover Model	Docking Station Accessory	REF
All Rovers	iReceptal 3 Docking Detergent Enzymatic Cleaner (Neutral (pH 7), non-corrosive, low-foam detergent.)	iRC003 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-inch connector	Commercially available
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 1/4 inch, 3/8 inch, or 7/8 inch connector	Commercially available

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 Rover REF iRR552-02	220-240VAC iReceptal Docking Station	iRD502-02
Docking Station Accessory		
All Rovers	iReceptal 3 Docking Detergent Enzymatic Cleaner (Neutral (pH 7), non-corrosive, low-foam detergent.)	iRC003 Commercially available
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-inch connector	Commercially available
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) 220-240VAC Rover REF iRR552-02(EI)	I	WDYX002
220-240VAC Rover REF iRR551-01(EG) 220-240VAC Rover REF iRR552-02(EG)	G	WDYX006
220-240VAC Rover REF iRR551-02EF 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	E/F	WDYX010

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 220-240VAC Rover REF iRR552-02SW	J	WDYX011
220-240VAC Rover REF iRR551-02DA 220-240VAC Rover REF iRR552-02DA	K	WDYX012

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

1.10.1 General Safety

WARNING

- 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 seen.
- 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.

1.10.2 Patient/Clinician Safety

WARNING

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.

WARNING

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.

WARNING

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.

⚠ WARNING

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

⚠ WARNING

ELECTROMAGNETIC INTERFERENCE HAZARD

1. 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.
2. 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.

⚠ WARNING

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.

1.10.4 Environmental 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 (docked), 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.

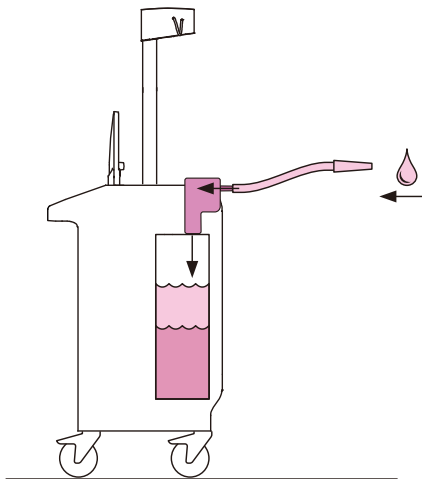


Figure 1 To collect Fluid Waste

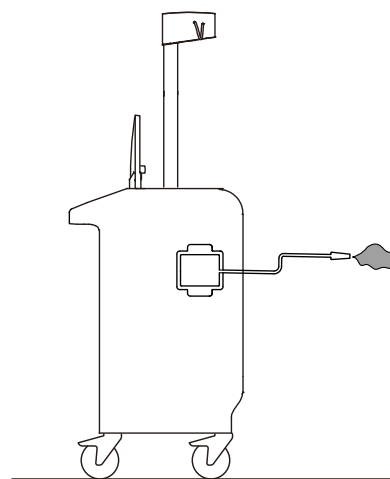


Figure 2 To Evacuate Surgical smoke

After collection, the rover is relocated and attached to the docked, which is typically installed in a healthcare facility waste disposal area. Once the rover is attached, the docked 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.

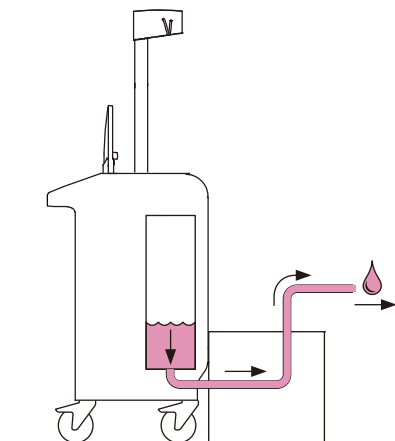


Figure 3 To Empty the Canister

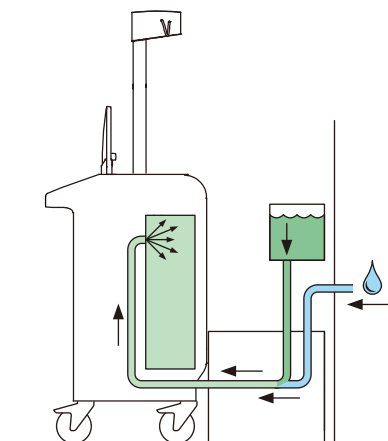


Figure 4 To Clean the Canister

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).

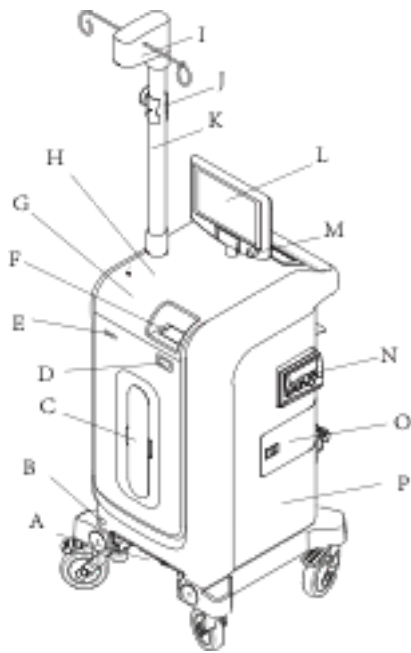


Figure 5 Rover Front View

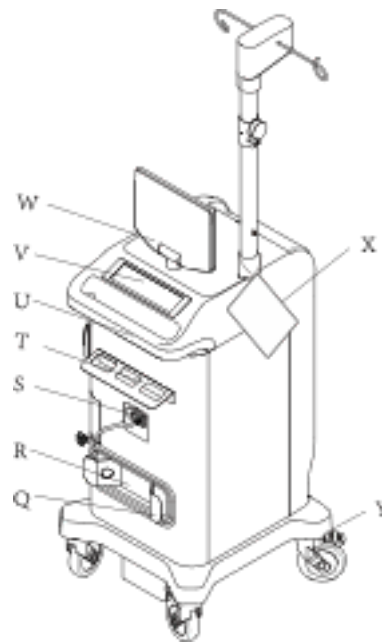



Figure 6 Rover Back View

A	<p>Docking Station Interface – Provides a sealed flow path for fluid waste transfer from the rover to the docker. Also provides fresh water and detergent transfer from the docker to the rover canister.</p> <p>Provides power to the rover from the docker.</p>	B	<p>Infrared Communication Window – Allows data transfer between the docker and rover during the docking procedure</p>
C	<p>11L (11-liter) Canister– Allows for the collection and containment of fluid waste. The canister receives fluid through an installed Disposable Manifold during collection. The canister contains a fluid level sensor to provide volume information to displays.</p>	D	<p>Eject Button— Facilitates the removal of the Disposable Manifold.</p>
E	<p>Suction Range Indicator– Provides color- coded visual information about the suction limit range setting.</p>	F	<p>Disposable Manifold Receptacle — Allows for the installation of a single-use, Disposable Manifold.</p>
G	<p>High Suction Device WARNING Label –</p> 	H	<p>Speaker – Located inside the rover; provides audible event indicators.</p>
I	<p>Scale with fluid bag hooks (optional) – Measures the weight of the irrigation fluid bags. The pole allows to hang max 12 L</p>	J	<p>Strain relief for fluid bag tubing (optional)– Ensures that no stress is put through the strained fluid bag tubing on the scale in the irrigation pole</p>
K	<p>Height Adjustable, Powered IV Pole with Hooks (optional) – This IV pole is capable of supporting four three-liter [3000 mL] fluid bag.</p>	L	<p>Control main display–Provides interface to start and stop suction via a touch-sensitive, color display. Important notification and status information are also provided. The display</p>

			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 (clockwise to increase, counterclockwise to decrease) the SUCTION LIMIT. The selection determines the maximum suction available.	N	Smoke Evacuator Filter Compartment – Allows for the installation and removal of a disposable smoke evacuator filter (not included) with an ULPA efficiency rating.
O	Fluid Suction Filter Compartment – Allows for the installation and removal of a disposable fluid suction filter. This filter (included) provides HEPA filtration of the air from the canister.	P	Vacuum Pump (not shown) – Creates suction for canister.
Q	Power Cord Bracket – Allows for the wrapping and storage of the supplied power cord.	R	Specification Label — Identifies the model, weight, compliance markings, and manufacturer information.
S	Power Switch — Used to turn the rover ON and OFF.	T	Disposable Manifold Holder — Store new, unused single-use, Disposable Manifolds.
U	Handle – Allows for relocation and positioning of the rover.	V	Secondary Control Panel –While roving, panel 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 including specimen collection.	X	Quick Reference Card (QRC) – Allows for quick access to warnings and troubleshooting information.
Y	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.

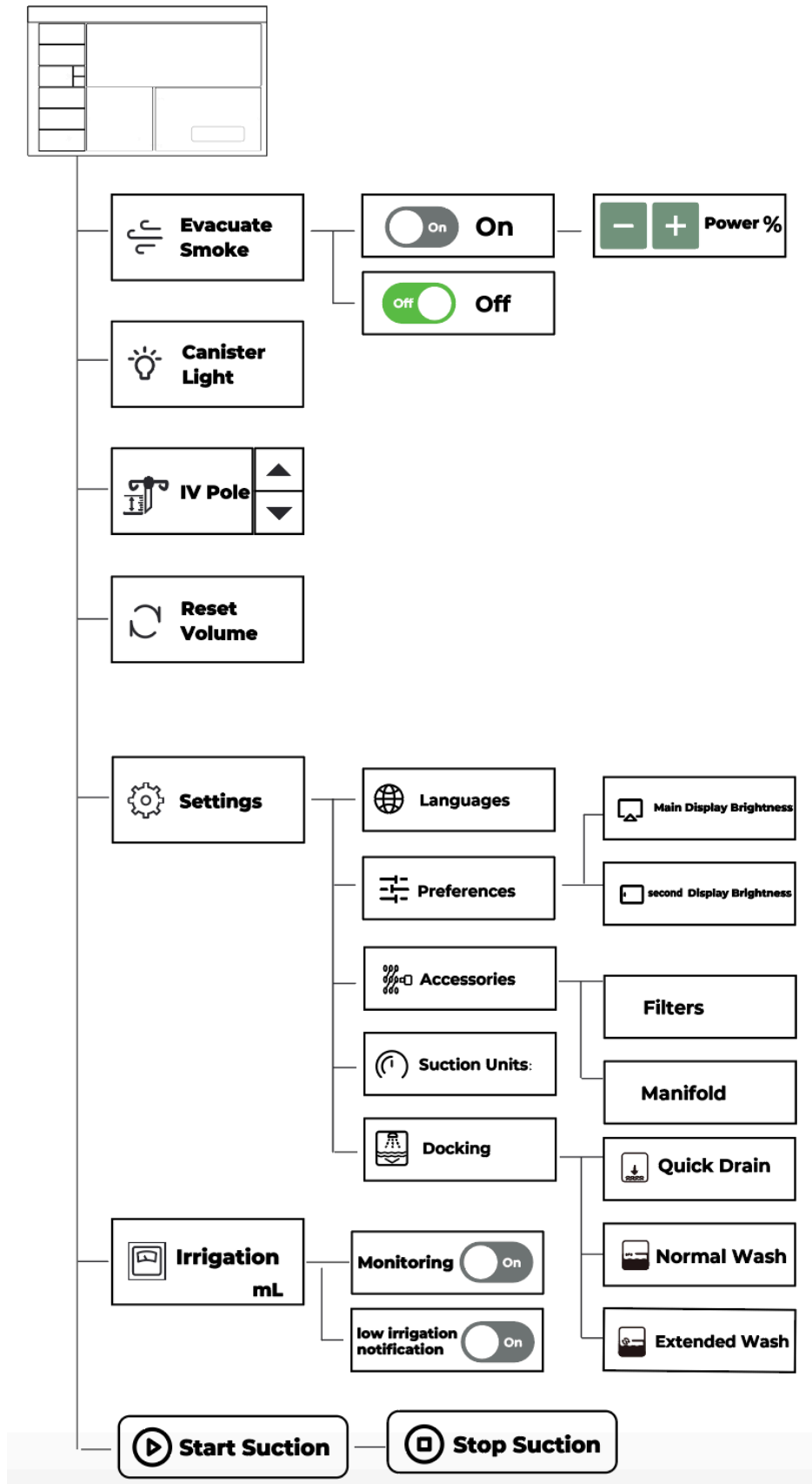


Figure 7 Control Screen Menu Structure

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

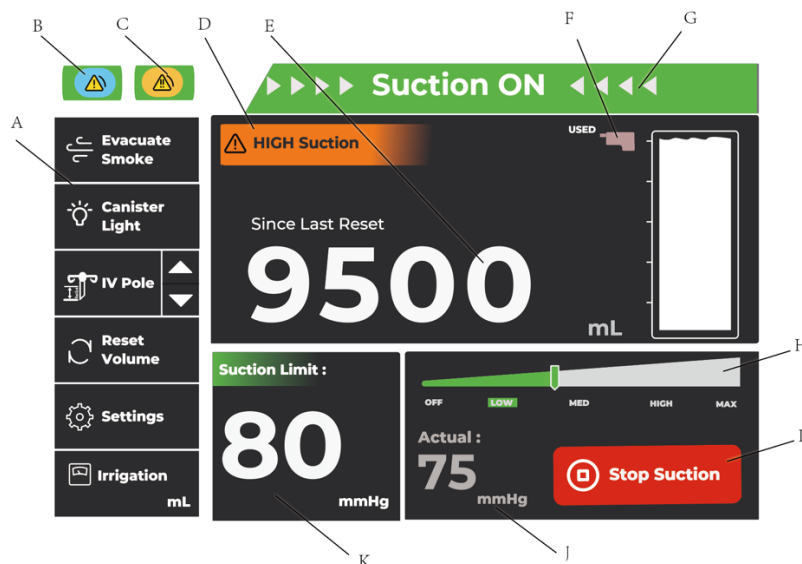


Figure 8 Roving Mode (Control) Screen

A	Control Menu Area – Provides buttons to control the primary functions of the rover.	B	Notification Message Area – Indicates when a low priority notification condition has occurred; touch to access the drop-down list and/or message.
C	Error Message Area – Indicates when a medium priority notification condition has occurred; touch to access the drop-down list and/or message.	D	Canister Information Area – Identifies the suction status of canister.
E	Fluid Volume Information Volume Area – Provides fluid volume information via a 11L canister symbol and a fluid volume reading. If the canister’ volume is reset, the words ‘since last reset’ will appear.	F	Disposable Manifold Indicator Area– Indicates the status of the Disposable Manifold installed in the receptacle. Status conditions include new or used.
G	Title Area – Indicates status, including system setup, suction ON and suction OFF.	H	Suction Gauge Area – Indicates the suction selected with the rotary suction control dial, including OFF, LOW, MEDium, HIGH, or MAXimum.
I	Suction Control Area– Provides a toggle button to control the presence or absence of fluid suction.	J	ACTUAL Suction Value Area – Indicates the actual suction value present in the canister. 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		

	the rotary suction control dial.
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2.3.1.2 Typical Settings Dialog Areas

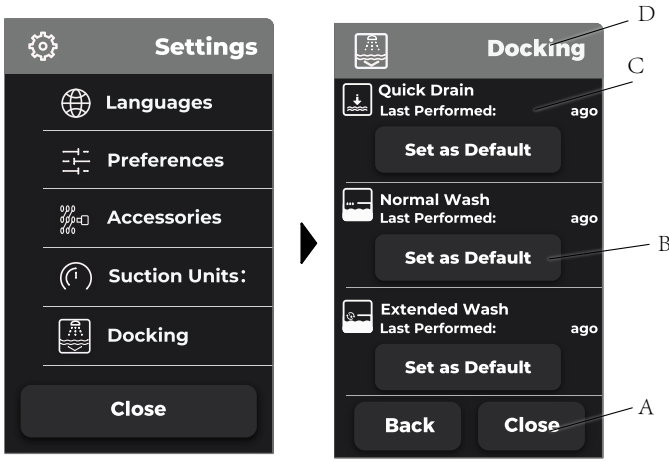


Figure 9– Typical Settings Dialog

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

2.3.1.3 Typical Docking Mode Screen Areas

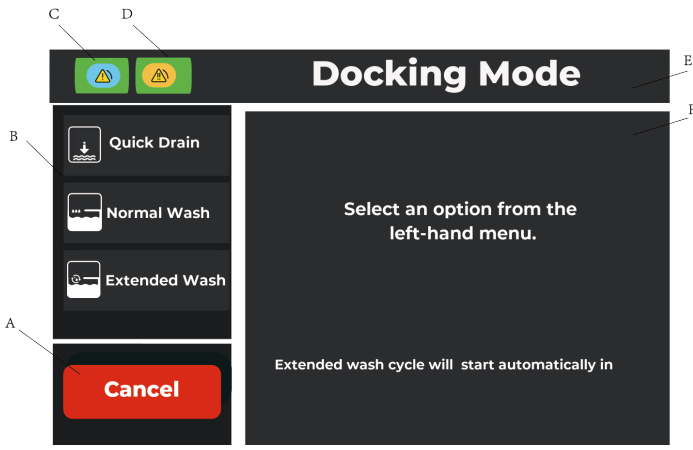


Figure 10 Docking Mode Screen

A	Control Menu Area – Provides buttons to control the primary functions of the rover. Cycle Control Area – Allows for most control over cycle activity, including: ABORT TO QUICK WASH, CANCEL, and RELEASE FROM DOCKER after cycle completion.	B	Cycle Options Menu – Allows for the manual selection of a cycle. Manual selection will override the default cycle setting.
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C	Notification Message Area – Indicates when a low priority notification condition has occurred; touch to access the drop-down list and/or message.	D	Error Message Area – Indicates when a medium notification condition has occurred; touch to access the drop-down list and/or 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

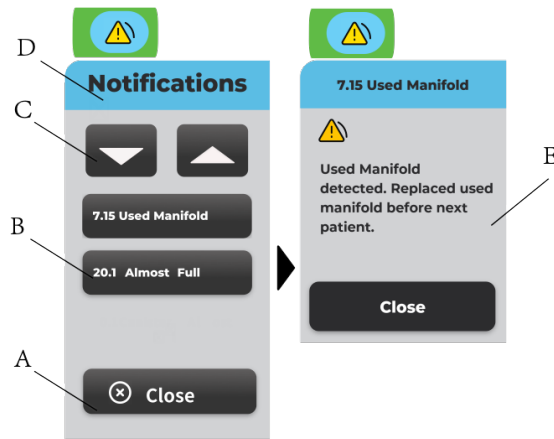


Figure 11 Notification Drop-down

A	Response Area – Provides a CLOSE button to exit a notification or error drop-down.	B	List Area – Provides one or more notification message or error message buttons. Each button allows access to a specific message.
C	Navigation Area – Provides UP and DOWN buttons to scroll through a list of notification message or error message buttons.	D	Title Area – Identifies the type of message displayed, either notification or error.
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)

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

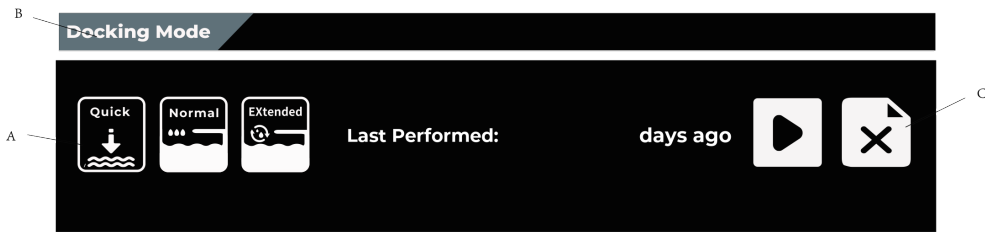


Figure 13 Secondary Control Panel Screen (docking)





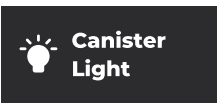




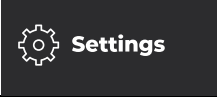





A	Cycle Options Menu – Allows for the manual selection of a cycle. Manual selection will override the default cycle setting.	B	Title Area – Indicates working model.
C	Wash Cycle Control Areas —Provides a button to abort an active wash cycle and an eject button to detach the rover from the docker after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

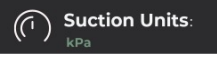













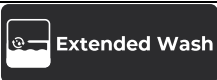

2.4 Definitions




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
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	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	Touch the toggle button to enable or disable the OFF mode of smoke evacuation/Irrigation fluid monitoring/ low irrigation fluid notification.
	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	Touch the toggle button to turn ON or OFF the canister light. When canister light is active, the canister light button displayed in Green.
	IV POLE	Touch the button to access the IV POLE HEIGHT SETTING dialog menu; including 180cm、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 VOLUMES	Touch to access the RESET VOLUME dialog and reset the canister fluid volume value to zero.
	HISTORY	Touch to access the HISTORY data.
	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	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.
	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.
	DOWN/DECREASE, UP/INCREASE	Touch the button to increased or decreased the brightness of the Secondary Control Panel and main display.
	ACCESSORIES	Touch the button to access the ACCESSORIES dialog. Select the FILTERS tab or the DISPOSABLE MANIFOLDS tab, as required.
	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	The Suction Units primary control function is for international customers.
	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	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	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	Touch the toggle button to start fluid suction.
	STOP SUCTION	Touch the toggle button to stop fluid suction.
	CLOSE / CLOSE NOTIFICATION MESSAGE	Touch the button to accept the responses of a dialog and exit or close a drop-down list.
	BACK	Touch the button to exit and return to the previous screen.
	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 MESSAGE 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 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 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	Touch the button to select the NORMAL WASH cycle option. A cycle description and when the cycle was last performed are provided.
	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	Touch the button to initiate the QUICK WASH cycle, the NORMAL WASH cycle, or the EXTENDED WASH cycle (Figure 36).

	CANCEL	Touch the button to stop docking and prepare the rover for release. The RELEASE FROM DOCKER button will appear.
	ABORT TO QUICK 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(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 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	Touch the button to select the NORMAL WASH cycle option. A cycle description and when the cycle was last performed are provided.
	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 ~ 540mmHg/ 60 kPa ~ 72kPa
Yellow- Green	Medium	80 mmHg ~ 460 mmHg/ 10.5 kPa ~ 60kPa
Green-	Low	50mmHg ~ 75mmHg/ 7 kPa ~ 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 on device			
	ON (POWER) ; IEC 60417- 5007		SECONDARY CONTROL PANEL SCREEN
	OFF (POWER)		MAIN TOUCH SCREEN
	POWERED IV POLE HEIGHT ADJUSTMENT		DISPOSABLE MANIFOLD
	DOWN/DECREASE		SOUND (VOLUME)
	UP/INCREASE		11 L CANISTER
	EVACUATE SMOKE		DOCKING
	DOWN/DECREASE		QUICK WASH
	UP/INCREASE		NORMAL WASH
	ON (SMOKE EVACUATOR)		EXTENDED WASH
	OFF (SMOKE EVACUATOR)		ALTERNATING CURRENT
	RESET VOLUME		DIRECT CURRENT
	CANISTER LIGHT		TYPE CF APPLIED PART
	SETTINGS		GENERAL WARNING SIGN (yellow); ISO 7010-W001
	IRRIGATION VOLUME		LOW PRIORITY NOTIFICATION
	START SUCTION		MEDIUM PRIORITY NOTIFICATION
	STOP SUCTION		REFER TO INSTRUCTION MANUAL/ BOOKLET (blue); ISO 7010-M002
	LANGUAGES		PROTECTIVE EARTH (GROUND)
	PREFERENCES		NON-IONIZING ELECTROMAGNETIC RADIATION
	ACCESSORIES		SMOKE FILTER COMPARTMENT
	SUCTION UNITS	IP22	Degree of protection against ingress of water. The device has an IP22 degree of protection against liquids (drip-proof).
	DRAIN IN PROGRESS		STEAM DRAIN IN PROGRESS

	QUICK WASH TEMPERATURE DISPLAY IN CANISTER		NORMAL WASH TEMPERATURE DISPLAY IN CANISTER
	EXTENDED WASH TEMPERATURE DISPLAY IN CANISTER		
Symbols on consumables		Symbols on exterior packaging	
	Consult instructions for use		Fragile – handle with care
	Do not reuse		This end up
	Batch code		Keep dry
	Caution		Keep away from sunlight
	Latex free		
	DEHP free		
Transport and storage conditions		Operating conditions	
	Temperature limit: -20°C ~+40 °C; ; ISO 7000-0632		Temperature limit: 10°C ~+40 °C
	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

 WARNING:

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.
6. 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.

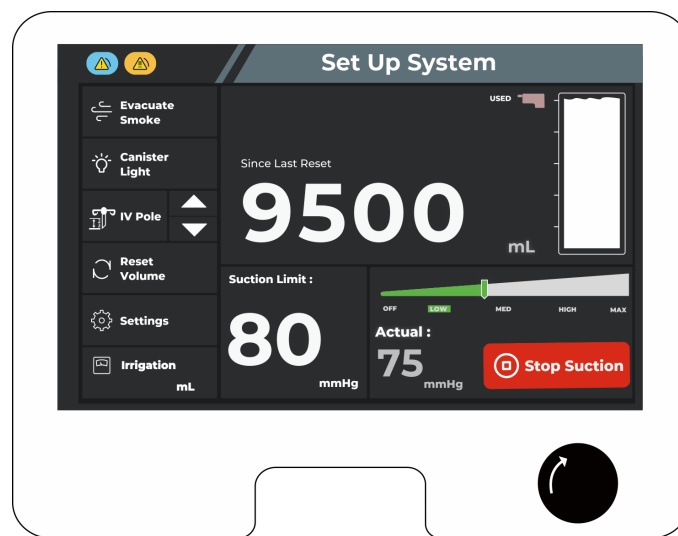


Figure 15 To Test Fluid Suction

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.
3. Verify smoke evacuation power can be adjusted correctly. If not, see Section Troubleshooting (page 53).

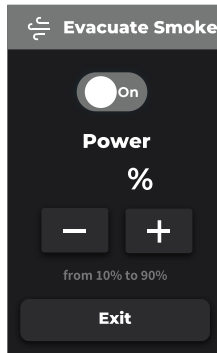


Figure 16 To Test Smoke Evacuation

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).

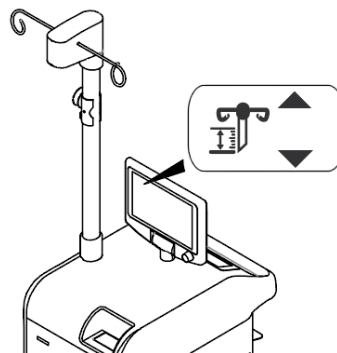


Figure 17 To Test IV Pole

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.

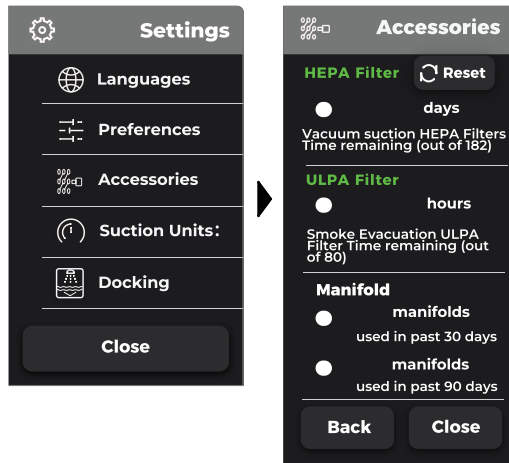


Figure 18 Settings Menu Dialog

Settings Options

Menu		Options
LANGUAGES		简体中文, English
PREFERENCES	Main Display brightness	Increase/Decrease
	Secondary Control Panel brightness	Increase/Decrease
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

- From the selected SETTINGS dialog menu, touch the desired setting option. Make the appropriate adjustment or selection as required.
- 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.
- 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.

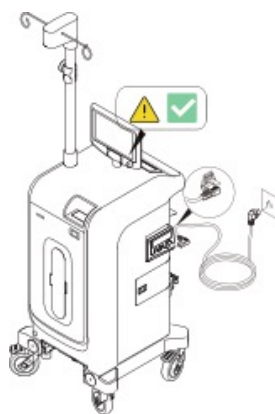


Figure 19 To Connect Power

7. 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 value to zero milliliters, if required. A CONFIRM dialog will appear.

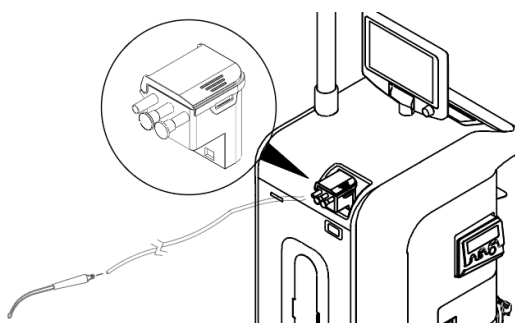


Figure 20 To Prepare for Fluid Suction

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.

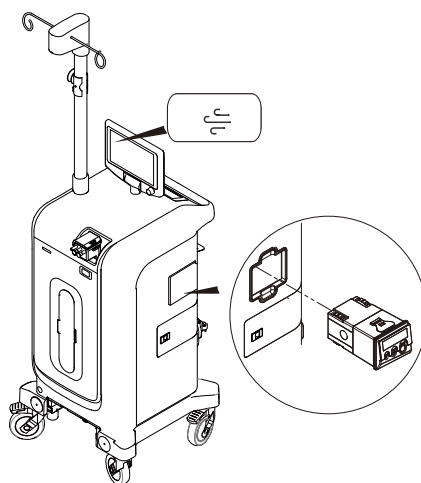


Figure 21 To Prepare for Smoke Evacuation

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.

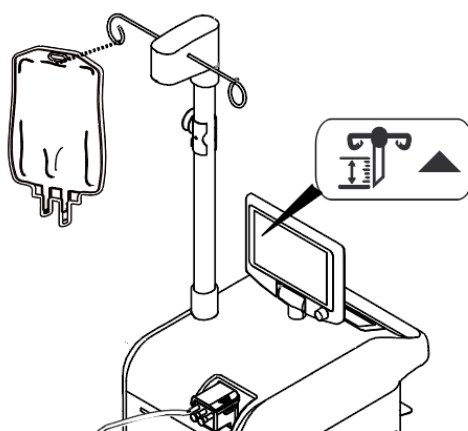


Figure 22 To Use the IV Pole

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.

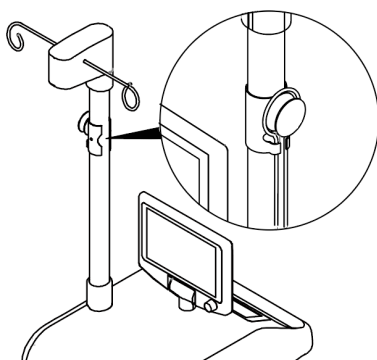


Figure 23 To Prepare the Irrigation (optional)

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.

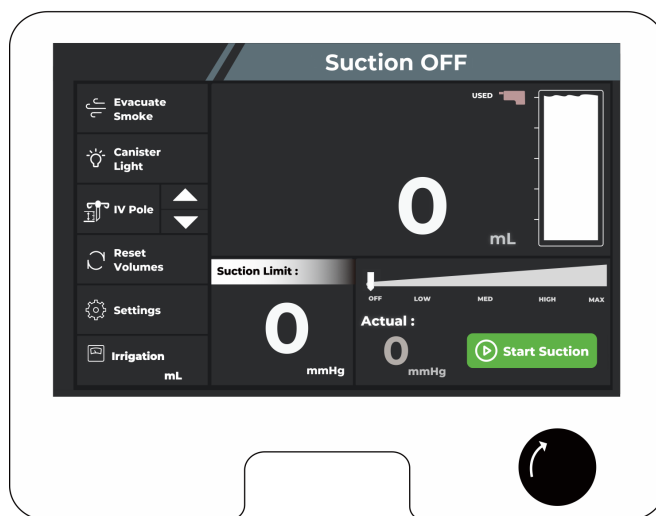


Figure 24 To Start and Adjust Fluid Suction

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.

See Section To Test Smoke Evacuation (page 29) to control smoke evacuation.

5.1.3 To Manage a Full Canister

Fluid Volume Indicators

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

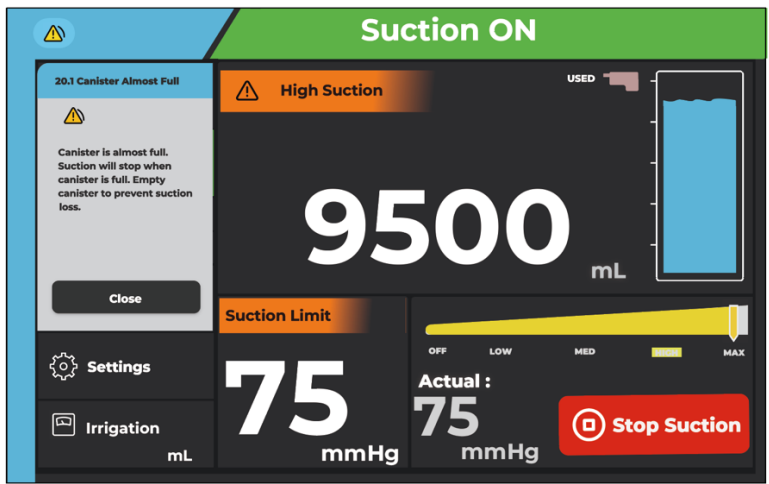


Figure 25 Almost Full Canister Condition (Main Control Panel Display)



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

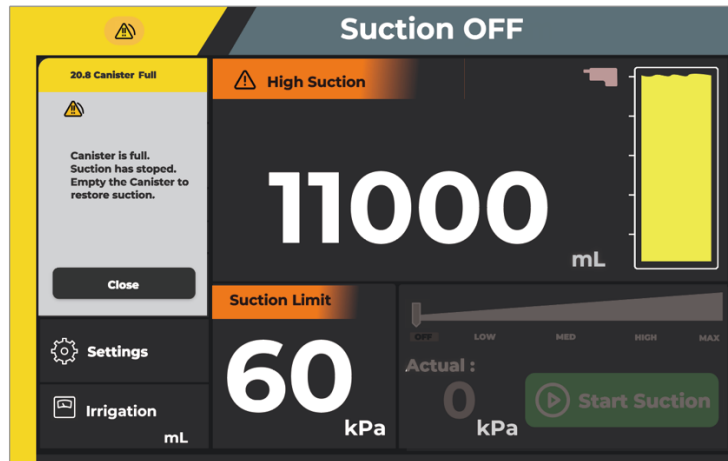


Figure 27 Full Canister Condition (Main Control Panel Display)



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

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

⚠ WARNING:

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).

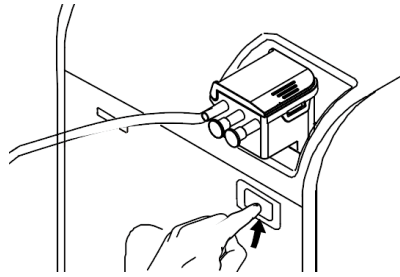


Figure 30 Remove the Disposable Manifold

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

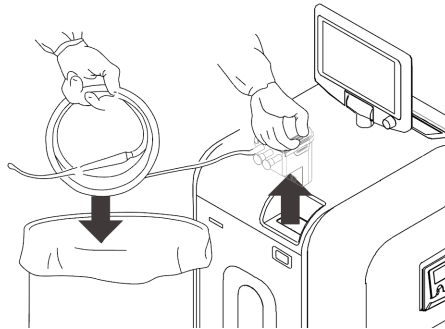


Figure 31 To Remove Disposable Manifold and Tubing

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.
2. 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.

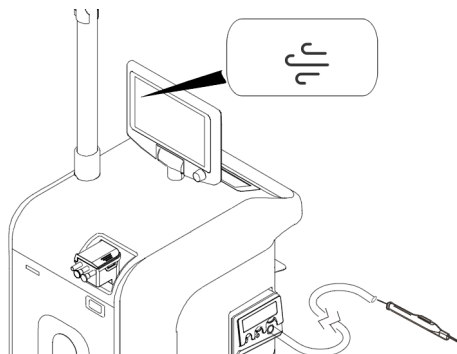


Figure 32 To Remove Smoke Evacuation Components

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.

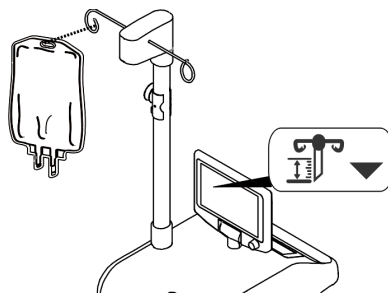


Figure 33 To Remove IV Pole Components

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).

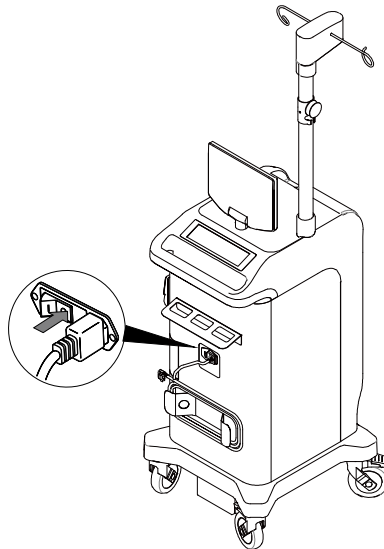


Figure 34 To Remove Power

6.3 To Dock the Rover

⚠ WARNINGS:

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.

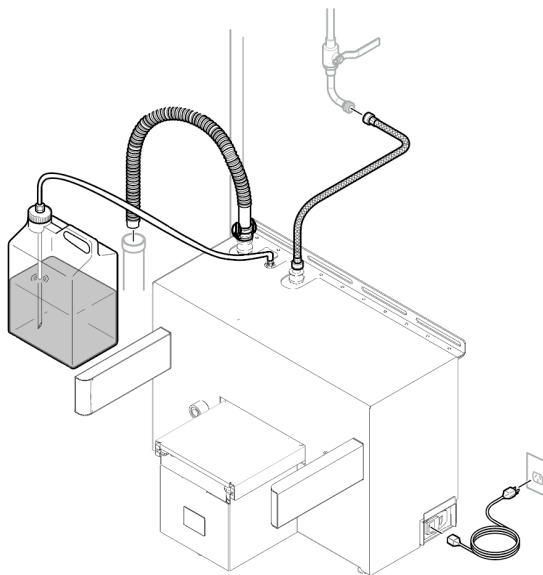


Figure 35 To Prepare the Docker

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.

1. 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.

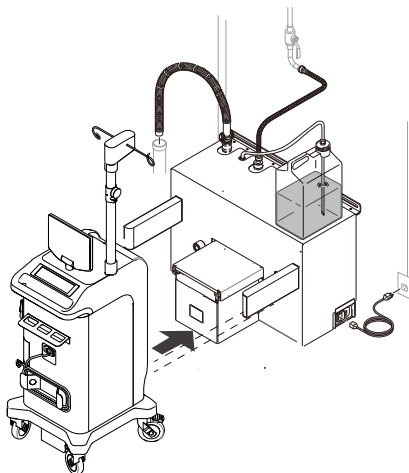


Figure 36 To Perform a Wash Cycle

2. 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.

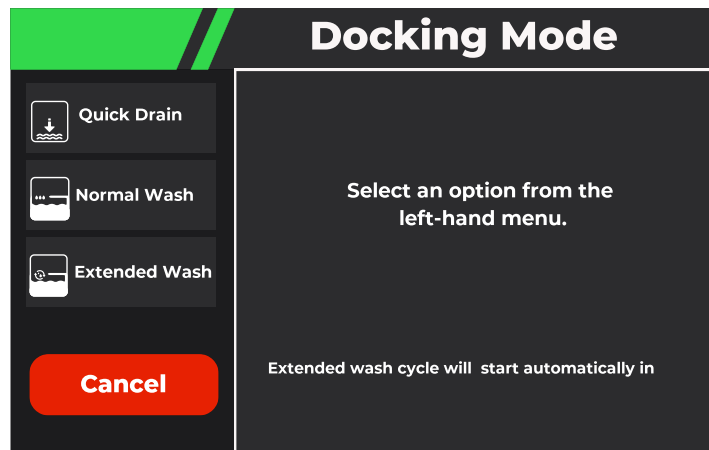


Figure 37 Initial Docking (main control display)

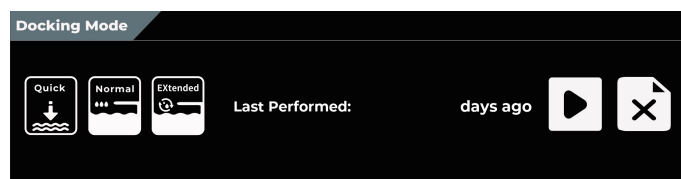


Figure 38 Initial Docking (secondary control display)

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.
2. 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.

Abort to Quick Drain

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

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

⚠ 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.
- 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.	If damage is apparent, replace the equipment. See the for use with section (page 7).
	Inspect for corrosion, discoloration, pitting, cracked materials, or 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

⚠ WARNINGS:

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.

⚠ WARNINGS:

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).

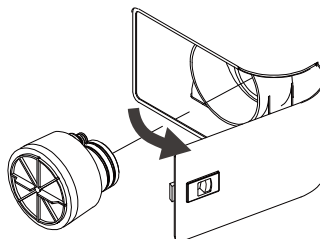


Figure 43 Remove and Replace the Filter

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 suction 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).

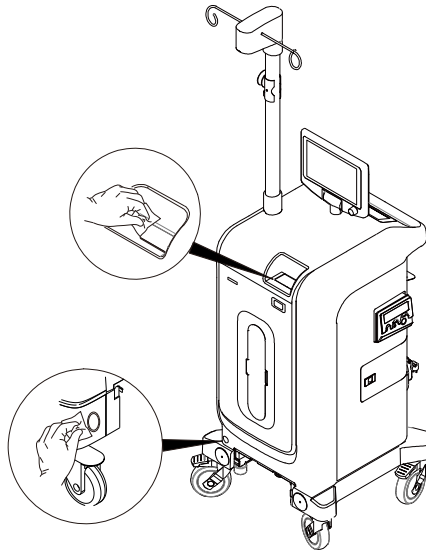


Figure 44 To wipe down the rover

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

⚠ WARNINGS:

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

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

Sporadic electrical interference is experienced.	Electrical noise is present.	Turn off all the electrical equipment not in 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 has occurred during docking.	The docker power cord is not connected or is loosely connected.	Make sure the docker power cord is connected securely.
	The docker power switch is in the OFF position.	Make sure the power switch is in the 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 position, but not illuminated.	Make sure facility power is provided 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 connected to the docker.	Push the rover forward enough to complete a docker-rover interface connection.
	Communication between the rover and docker is interrupted because the infrared communication window is either dirty or obstructed.	Remove the dirt or debris from the rover's infrared communication window. See Section Cleaning and 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 water.	Make sure the water inlet hose is 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.

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

TABLE 1. Rover specifications

REF	iRR551-02	iRR552-02
Electrical Power Requirements:	220-240V~, 50/60 Hz, 3.4 A, single phase; 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 and line connection	
European Conformity:		
Dimensions	Width: 54cm Height: 111.5cm Depth: 57.5 cm	Width: 54cm Height: 220cm (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 protection 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 98kg —collection full	90kg —collection empty 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:	<p>Operation:</p> <p>Temperature Limitation: 10°C ~ 40 °C</p> <p>Humidity Limitation: 30% ~ 75%</p> <p>Atmospheric Pressure Limitation: 70kPa ~ 106kPa</p> <p>Storage and Transportation (before initial use):</p> <p>Temperature Limitation: -20°C ~ 40 °C</p> <p>Humidity Limitation: 10% ~ 75%</p> <p>Atmospheric Pressure Limitation: 50kPa ~ 106kPa</p> <p>Storage and Transportation (after initial use):</p> <p>Temperature Limitation: 10°C ~ 40 °C</p> <p>Humidity Limitation: 10% ~ 75%</p>	


	Atmospheric Pressure Limitation: 50kPa ~ 106kPa	
Installation location	< 3,000 m above sea level. Usage not allowed in oxygen-rich or explosion- hazard environment.	
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) Classification (infrared communication windows):	WARNING: INVISIBLE LED RADIATION DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS CLASS 1M LED PRODUCT — Viewing 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 Note - 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 category	High vacuum/high flow	
Vacuum Measurement range	0~-90kpa	
Vacuum Measurement Accuracy:	± 5% of full scale	
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 Flow Setting	Standard Hose I.D.	Flow Rates
	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 connection	6.4mm, 9.5mm, 22mm	

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	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, 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 is 13.56MHz, 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 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

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

Table 3 – Proximity fields from RF wireless communications equipment

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

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

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T ; 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 → Tag): Commands are transmitted using amplitude-shift keying (ASK) or phase-shift keying (PSK) modulation.

Downlink (Tag → 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.