Aquamantys Pump Generator™

USER GUIDE

SALIENT
SURGICAL TECHNOLOGIES

USER GUIDE

Software Version 1.11

SALIENT
SURGICAL TECHNOLOGIES

Foreword

The Aquamantys™ Pump Generator is for use only by qualified medical personnel properly trained in the use of electrosurgical equipment, technology and techniques. This manual is a guide for using the Aquamantys™ Pump Generator only. Additional technical information is available in the Instructions For Use which accompanies individual Aquamantys™ disposable bipolar devices which are designed to be used as a part of the Aquamantys™ System.

Precaution: *Federal (USA) Law restricts this device to sale, distribution and use by or on the order of a physician.*

Equipment covered in this manual:

Aquamantys™ Pump Generator

Supply	Nominal Voltage	Salient Model #
100V	50/60Hz	40-401-1
115V	50/60Hz	40-402-1
230V	50/60Hz	40-403-1
100V	50/60Hz	40-401-1R
115V	50/60Hz	40-402-1R
230V	50/60Hz	40-403-1R

CE 0123

For information call:

Salient Surgical Technologies, Inc.
180 International Drive
Portsmouth, NH 03801 USA
www.salientsurgical.com

Customer Service:
U.S. Telephone Numbers:
Tel: 866.777.9400
Fax: 866.222.0900

Outside the U.S.:
Tel: +1.603.742.1515
Fax: +1.603.742.1488
customerservice@salientsurgical.com

U.K. Telephone numbers:
Tel: 0808.101.1727
Fax: 0808.101.1726

EC REP

WMDE
Bergerweg 18
6085 AT Horn
The Netherlands
Tel: 0808.101.1727
Fax: 0808.101.1726

Table of Contents

List of Tables & Figures

Section 1

Introduction

This section contains information about:

- Indications for Use
- RF Power
- Simultaneous RF Power and Saline Delivery
- Saline Flow Rate Setting
- Priming

Indications for Use

The Aquamantys Bipolar Pump Generator is an electrosurgical generator with a rotary peristaltic pump which is for use only with Aquamantys single-use disposable bipolar devices for simultaneous delivery of radio-frequency (RF) energy with saline for hemostatic sealing of soft tissue and bone at the operative site. It is intended for, but not limited to, endoscopic and open abdominal, orthopaedic, spine, and thoracic surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization). The Aquamantys System is for use only by qualified medical personnel properly trained in the use of electrosurgical equipment, technology, and techniques.

Warnings: *The system is not intended for contraceptive tubal coagulation (permanent female sterilization).*

The system is not intended for cardiac or neurosurgical applications.

Do not activate the device unless saline is flowing and it is in contact with tissue to be treated.

If saline flow stops during the electrosurgical procedure, stop using the Aquamantys disposable bipolar device and attempt to resume saline flow. Ensure that the saline source is adequate and the saline delivery system is functioning properly. If unable to resume saline flow, discontinue use and return the device to Salient Surgical and use another Aquamantys disposable bipolar device or replace the Aquamantys Pump Generator.

Surgery should be performed by persons with adequate training and preparation. Personnel should fully understand the nature and use of RF before performing electrosurgical procedures to avoid the risks of shock and burn hazards to both the patient and the operator and damage to the instrumentation.

DO NOT use electrosurgery in the presence of flammable anesthetics or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents as fire could result.

Examine the Aquamantys disposable bipolar device before connecting it to the Aquamantys Pump Generator. After connecting the device, ensure that device and unit are functioning as intended.

The cable on the Aquamantys disposable bipolar device should be positioned in a way to avoid contact with the patient or other cables.

Consult the operating and user manuals for light sources and other ancillary devices for warnings, precautions, and instructions prior to their use with the Aquamantys System.

In the event that a high electrosurgical power setting is required, check all device connections, cables, and patient contacts before changing power settings. If all connections, cables, and patient contacts are fault-free, then increase power settings in small increments, checking carefully after each change.

Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the pump segment of the Aquamantys disposable bipolar device in the pump head while pump head rotor is turning. Prevent fingers or loose clothing from being caught in pump head rotors.

Use the Aquamantys System with caution in the presence of pacemakers, as electrosurgical equipment may cause interference with pacemakers or other active implants.

Precautions: *Read all warnings, precautions, and instructions provided with the Aquamantys Pump Generator before using.*

Read the warnings, precautions, and instructions provided with Aquamantys disposable bipolar devices before using. Specific instructions are not included in this manual.

Special care should be taken when using the Aquamantys System in the proximity of neural tissue.

It is recommended that physicians utilize pre-clinical training, review of pertinent literature, and other appropriate educational tools before attempting newer surgical procedures, such as endoscopic, laparoscopic, or thoracoscopic procedures.

Position the Aquamantys Pump Generator away from life supporting and/or monitoring systems to reduce/avoid interference with these systems.

If the RF-Surgical unit fails, an unwanted increase of the output power could be the result.

Features

- Simultaneous RF power and saline delivery
- Power settings from 20–200 watts
- Automatic settings for saline flow rate based on power setting
- Ability to select three different flow rate settings
- Convenient priming mode

RF Power

The Aquamantys Pump Generator delivers bipolar RF power with power settings in 5 watt increments in the range of 20 to 100 watts, and 10 watt increments in the range of 100 to 200 watts. At higher tissue resistances the unit senses the high resistance and reduces the RF power output, independent of the front panel setting, to a level which prevents arcing or cutting.

Simultaneous RF Power and Saline Delivery

The Aquamantys Pump Generator simultaneously delivers RF power and saline to an Aquamantys disposable bipolar device when the device is properly connected to the unit and the activation button on the device is depressed. The Pump Generator is for use only with Aquamantys single-use disposable bipolar devices.

Saline Flow Rate Setting

The saline flow rate setting is determined based on the power setting and the selection of one of three possible flow rate settings: Low, Medium, and High. The three possible saline flow rates for each power setting are preset automatically in order to provide the optimal saline flow for a given power setting.

Priming

The Aquamantys Pump Generator has a convenient one touch priming function which automatically primes the Aquamantys disposable bipolar device with saline prior to use after the device has been correctly connected to the unit. This function is activated by pressing the “START PRIME” button on the unit.

Precaution: *The “START PRIME” button activates and deactivates the timed priming cycle. Pressing the button a second time will immediately stop the priming cycle. Pressing the button a third time will reset the timer and restart the priming cycle from the beginning.*

Section 2

Controls, Indicators, and Receptacles

This section contains information about the front and rear panels, including all controls, indicators, receptacles, and the fuse drawer.

Figure 2-1. Front Panel

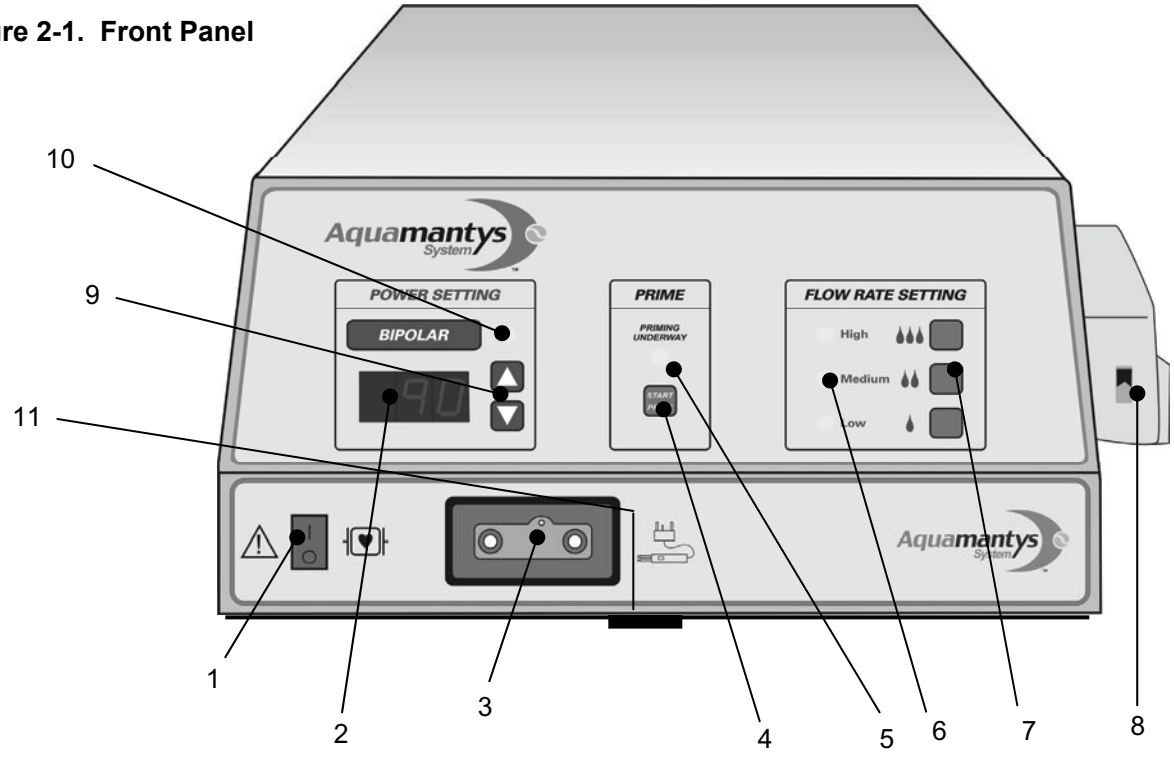
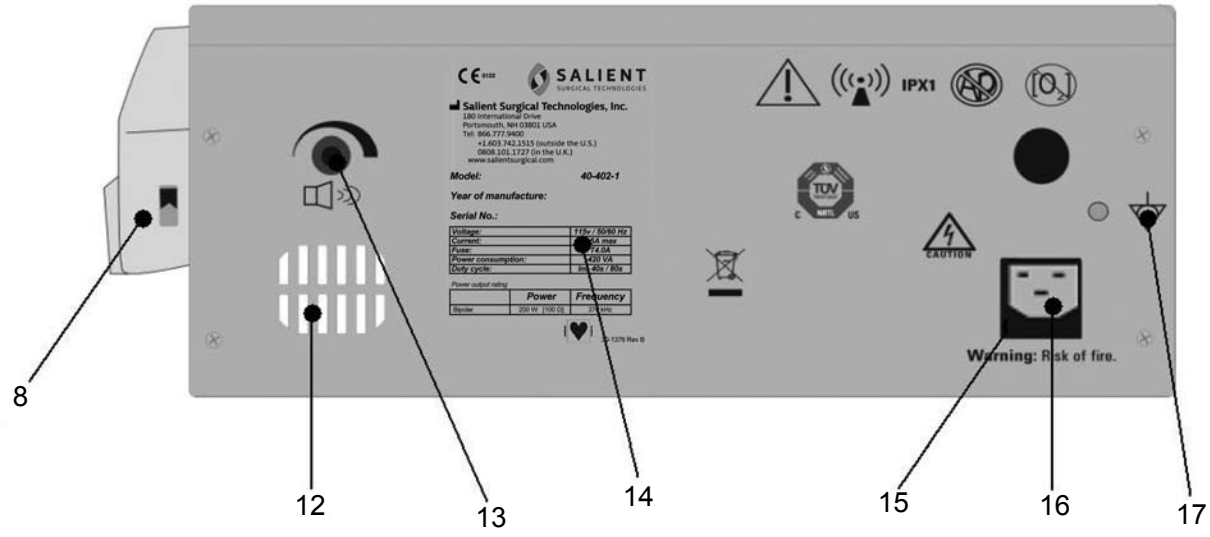


Figure 2-2. Rear Panel



1 Power On/Off Switch

The main power On/Off switch is located at the bottom left corner of the front panel on the Aquamantys Pump Generator.

The unit is switched on by pressing the top portion of the switch marked "|". The switch will be illuminated green when it is on.

The unit is switched off by pressing the bottom portion of the switch marked "O". It is recommended that the unit be switched off when it is not intended to be used for an extended period of time.

2 RF Power Indicator

This indicator displays the power setting numerically in watts. Additionally, this indicator is used to display errors, in which case the display will show "**Err**" and blink alternately with a special error code number(s).

3 Aquamantys™ Disposable Bipolar Device Receptacle

This plug receptacle is used to connect a 3-pin plug of an Aquamantys disposable bipolar device to the Aquamantys Pump Generator.

4 Start Prime Button

This button activates and deactivates the timed priming cycle. Pressing this button once automatically primes the Aquamantys disposable bipolar device with saline prior to use. The pump will operate for a preset time period to prime the Aquamantys disposable bipolar device. After the time period is complete, the pump shuts off automatically.

Precautions: *Priming is required to avoid RF power activation without saline. The Aquamantys disposable bipolar device is primed when saline drips from both electrodes of the device. Failure to prime the device may result in RF power activation without saline. Activation without saline may result in charring or damage to the electrodes of the device leading to a decrease in the hemostatic effectiveness of the device.*

The "START PRIME" button activates and deactivates the timed priming cycle. Pressing the button a second time will immediately stop the priming cycle. Pressing the button a third time will reset the timer and restart the priming cycle from the beginning.

5 Priming Underway Indicator

This indicator will be illuminated during the priming cycle and turn off when the priming cycle is complete.

6 Flow Rate Setting Indicators

These indicators correspond to a saline flow rate setting of Low, Medium, or High. One of these three indicators will be illuminated when a saline flow rate setting is selected.

7 Flow Rate Setting Buttons

These buttons control the saline flow rate. Pressing one of these three buttons selects the flow rate setting of either Low, Medium, or High for each respective power setting. The Medium flow rate setting is automatically selected as the default setting if no setting is manually selected.

8 Saline Pump

This is a rotary peristaltic pump. A special pump segment is attached to the saline delivery tubing of each Aquamantys disposable bipolar device which is designed to operate with the pump. The pump segment is loaded into this Aquamantys Pump Generator pump head prior to operation of the device.

Warning: *Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the pump segment of the Aquamantys disposable bipolar device in the pump head while pump head rotor is turning. Prevent fingers or loose clothing from being caught in pump head rollers.*

Precaution: *Only the pump segment portion of the saline delivery tubing of the Aquamantys disposable bipolar device should be loaded into the pump head. Use of any other portion of the saline delivery tubing of the device or any other tubing in this pump may damage the saline delivery tubing and/or the pump. Incorrect insertion of the pump segment may also result in RF power activation without saline. Activation without saline may result in charring or damage to the electrodes of the device leading to a decrease in the hemostatic effectiveness of the device.*

9 RF Power Setting Buttons

These buttons control the RF power setting. Press the △ button to increase the RF power. Press the ▽ button to decrease the RF power.

10 RF Power Activation Indicator

This indicator will illuminate blue when RF power is activated.

11 Aquamantys™ Quick Reference Guide Pullout Tray

The Aquamantys Quick Reference Guide provides basic set-up and operating instructions and illustrations for the Aquamantys System.

12 Loudspeaker

13 Volume Control Knob

This knob controls the volume of the tone that will sound when the RF power is activated (RF power activation tone). To increase the volume of the RF power activation tone, turn the knob clockwise. To decrease the volume of the RF power activation tone, turn the knob counterclockwise. The tone cannot be silenced.

Warning: *Do not place adhesive tape or any other muffling device over the loudspeaker.*

14 Name Plate

This plate specifies the model number, serial number, nominal line voltages, frequency, current, and fuse rating information for the Aquamantys Pump Generator.

15 Fuse Drawer

This fuse drawer contains two fuses. Section 10 of this guide contains information for changing fuses.

16 Power Cord Receptacle

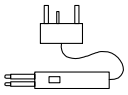
This plug receptacle is used to connect the main power cord to the Aquamantys Pump Generator. The power cord should only be connected to a source of power corresponding to that listed on the Name Plate.

17 Equipotential Grounding Lug Connector

This lug connector is used to connect the Aquamantys Pump Generator to earth ground.

Symbols

Several symbols appear on the Aquamantys™ Pump Generator front panel, rear panel, and pump head.

Symbol	Indicates	Symbol	Indicates
	**ATTENTION** –Consult accompanying documents.		This equipment intentionally supplies non-ionizing RF energy for physiologic effect.
	Defibrillation-Proof Type CF Applied Part		Volume control of RF power activation tone.
	**DANGER** – Explosion risk if used with flammable anesthetics.		Do not operate in oxygen-enriched environments.
	To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified personnel.		
		High 	High setting for saline flow rate
	Equipotential grounding lug	**Medium** 	Medium setting for saline flow rate
		Low 	Low setting for saline flow rate
	Bipolar Device		
	Caution: Moving Parts – Risk of Injury.		
	CE Mark		
		IPX1	This equipment has passed water ingress testing.
	TUV NRTL Mark		
			Activates/deactivates device priming sequence.
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner.		

Section 3

Patient and Operating Room Safety

It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

The Aquamantys Pump Generator is for use only by qualified medical personnel properly trained in the use of electrosurgical equipment, technology, and techniques.

Personnel should fully understand the nature and use of RF before performing electrosurgical procedures to avoid the risks of shock and burn hazards to both the patient and the operator and damage to the instrumentation.

It is recommended that physicians utilize pre-clinical training, review of pertinent literature, and other appropriate educational tools before attempting newer surgical procedures, such as endoscopic, laparoscopic, or thoracoscopic procedures.

General

Warnings: *Use the Aquamantys System with caution in the presence of pacemakers, as electrosurgical equipment may cause interference with pacemakers or other active implants.*

If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activations of ICDs.

Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Surgery should be performed by persons with adequate training and preparation. Personnel should fully understand the nature and use of RF before performing electrosurgical procedures to avoid the risks of shock and burn hazards to both the patient and the operator and damage to the instrumentation.

Physiological monitoring devices and their monitoring electrodes should be positioned away from the surgical site where the Aquamantys System will be utilized. Needle-type electrodes are not recommended for use on patients treated with the Aquamantys System.

Precautions: *Read all warnings, precautions, and instructions provided with the Aquamantys Pump Generator before using.*

Read the warnings, precautions, and instructions provided with Aquamantys disposable bipolar devices before using. Specific instructions are not included in this manual.

Always use the lowest RF power setting to achieve the desired surgical effect. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the power and the longer the power is applied, the greater the possibility of unintended thermal damage to tissue.

Do not attempt to alter device configurations or replace device components with nonstandard parts since this may result in decreased device performance, device malfunction, or patient injury.

Confirm Proper Connections

Warnings: *Before using any electrosurgical equipment confirm the following:*

The power cable on the Aquamantys disposable bipolar device is properly connected to the Aquamantys device receptacle on the front panel of the Aquamantys Pump Generator.

All electrical connections are tight, clean, and dry.

All fluid connections are secure.

Power Cords

Warnings: *Do not wrap power cords around metal objects. This may induce currents that could lead to shock, fire, or injury to the patient or surgical team. All power cords should be positioned in a way to avoid contact with the patient or other cables.*

Servicing

Warnings: ***Electric Shock Hazard*** *Do not remove the Pump Generator bottom cover. Removal of the bottom cover voids any warranty. Contact authorized personnel for service.*

Precautions: *The Aquamantys Pump Generator should only be serviced by a qualified personnel according to your hospital's capital equipment servicing guidelines. Salient Surgical recommends that the unit be verified and undergo a functional check by a qualified personnel on an annual basis.*

Before Surgery

Aquamantys Disposable Bipolar Devices are sterile, single-use devices which employ RF energy and saline irrigation for hemostatic sealing and coagulation. These devices are equipped with a dual electrode tip. Saline and electrical lines exit the opposite end of the handpiece from the dual electrode. The handpiece is equipped with an on/off button that simultaneously activates both RF power and saline flow. A saline fluid delivery line is provided with the device, and includes a section of pump tubing and drip chamber. The three-pin electrical connector is designed to be plugged into the Aquamantys Pump Generator.

Warnings: ***Electric Shock Hazard*** *Ensure that the device is correctly connected.*

Precautions: *Read the instructions, warnings, precautions, and instructions provided with the Aquamantys disposable bipolar devices before using. Specific instructions are not included in this manual.*

Always set the RF power to the lowest setting to achieve the desired surgical effect.

Inspect each device and cord for breaks, cracks, nicks, or other damage before every use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team.

Aquamantys™ Pump Generator

Warnings: ***Patient Safety*** *Use the Aquamantys Pump Generator only if the self-test has been successfully completed as described in the section entitled "Setting Up the Generator." Inaccurate power outputs may result if the unit is operated prior to completion of the self-test.*

Electrical Shock Hazard *Connect the Aquamantys Pump Generator power cord directly to a properly grounded receptacle which provides the appropriate electrical voltage and current.*

Fire Hazard *Do not use extension cords.*

Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the pump segment of the Aquamantys disposable bipolar devices in the pump head while the pump head rotor is turning. Fingers or loose clothing could be caught in the pump rollers.

Precautions: *Do not stack equipment on top of the Aquamantys Pump Generator or place the generator on top of electrical equipment. This may block access to the unit and not allow for proper ventilation.*

Provide as much distance as possible between the Aquamantys Pump Generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them

Nonfunction of the Aquamantys Pump Generator may cause interruption of surgery. A backup generator or alternative hemostatic techniques should always be available.

If required by your institution or applicable regulations, connect the generator's equipotential lug connector to earth ground using a suitable cable.

Connect the main power cord directly to a properly grounded receptacle which provides the appropriate electrical voltage and current. Otherwise, product damage may result.

Priming is required to avoid RF power activation without saline. The Aquamantys disposable bipolar device is primed when saline drips from both electrodes of the device. Failure to prime the device may result in RF power activation without saline. Activation without saline may result in charring or damage to the electrodes of the device leading to a decrease in the hemostatic effectiveness of the device.

During Surgery

Aquamantys™ Pump Generator Power Settings

Warnings: *Confirm the Aquamantys Pump Generator is set to the lowest RF power setting to achieve desired effect. Always use the lowest RF power setting to achieve the desired surgical effect.*

Precautions: *Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when a device is active.*

Aquamantys™ Disposable Bipolar Devices

Warnings: *Contact between the active electrodes and any metal will greatly increase current flow and can result in unintended, catastrophic burn injury.*

Fire Hazard *Do not place a device near or in contact with flammable materials. Electrosurgical devices that are activated can cause a fire. When not using the device, place it in a holster or in a clean, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.*

Aquamantys disposable bipolar devices are for use only with the Aquamantys Pump Generator. Use of these devices with other electrosurgical generators could result in injury to the patient or surgical team, or cause damage to the device and/or the generator.

Precautions: *Use of suction too close to the electrodes while the device is activated may remove saline flow that is needed for proper device function and result in activation without sufficient saline, which may char or damage the instrument.*

Do Not Use Other (Non-Aquamantys™) Devices

Warnings: *The Aquamantys Pump Generator is for use with Aquamantys disposable bipolar devices only. Refer to the Instructions For Use (IFU) which accompanies the device to confirm that it indicates that the device is compatible with the Aquamantys Pump Generator. A listing of Aquamantys Pump Generator compatible disposable bipolar devices is also included in Salient Surgical's Product Catalog. Use of non-Aquamantys devices could result in injury to the patient or surgical team, or cause damage to the device and/or the Pump Generator.*

After Surgery

Warnings: ***Electrical Shock Hazard*** *Always turn off and unplug the Aquamantys Pump Generator before cleaning.*

Precautions: *Do not clean the Aquamantys Pump Generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the unit. Use a mild cleaning solution or disinfectant with a damp cloth.*

Section 4
Before Surgery

This section contains information about preparing the Aquamantys Pump Generator for surgery.

Precautions: *Read all warnings, precautions, and instructions provided with the Aquamantys Pump Generator before using.*

Read the instructions, warnings, and precautions provided with Aquamantys disposable bipolar devices before using. Specific instructions are not included in this manual.

Quick Setup Instructions

If you are familiar with the Aquamantys Pump Generator, you may prefer to follow the quick setup instructions below. This information is also available in the **Aquamantys System Quick Reference Guide** printed on the pull out tray located below the front panel of the Pump Generator. If you are not familiar with the Aquamantys Pump Generator setup procedure, detailed setup instructions follow this section.

1. Ensure the power switch for the Aquamantys Pump Generator is in the off position by pressing the bottom portion of the power switch marked "O". Connect the unit's main power cord into the power cord receptacle on the rear panel.
2. Connect the Aquamantys Pump Generator main power cord directly into a properly grounded receptacle to provide the appropriate electrical voltage and current.
3. Turn the Aquamantys Pump Generator on by pressing the top portion of the power switch marked "|". Upon Pump Generator start-up, the unit will perform an automatic self-test. During the self-test, all front panel LEDs will illuminate momentarily and an audible tone test will sound. Wait for the self-test to be successfully completed before utilizing the unit.
4. Connect an Aquamantys disposable bipolar device to the Aquamantys Pump Generator by directly inserting the device into the plug receptacle on the front panel of the Pump Generator.
5. Load the pump segment portion of the Aquamantys device saline delivery tubing into the pump head and close the pump head. The black tubing connector on the pump segment should be positioned to the left side of the pump head and the white tubing connector should then be positioned to the right side of the pump head.
6. Using aseptic technique, remove the protective cover over the spike of the drip chamber at the end of the saline delivery tubing of the device and spike a bag of sterile saline (0.9%NaCl).
7. Select the RF power setting using the RF power setting buttons and RF power display.
8. Select the saline flow rate setting using the saline flow rate setting buttons and saline flow rate setting display.
9. Press the "START PRIME" button. The "Priming Underway" indicator will illuminate amber when priming is activated and thereafter shut off (darken) after priming. The System is now ready for use.

Setting Up the Aquamantys™ Pump Generator

Warnings: ***Electrical Shock Hazard*** *Connect the Aquamantys Pump Generator power cord to a properly grounded receptacle. Do not use power plug adapters.*

Fire Hazard *Do not use extension cords.*

Patient Safety *Use the Aquamantys Pump Generator only if the self-test has been completed as described in the "Setting up the Aquamantys Pump Generator" section of this guide. Using the unit prior to completion of the self-test may result in inaccurate power output.*

Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the pump segment of the Aquamantys device in the pump head while the pump head rotor is turning. Fingers or loose clothing could be caught in the pump rollers.

Precautions: *Do not stack equipment on top of the Aquamantys Pump Generator or place it on top of electrical equipment. These configurations are unstable and/or do not allow for proper ventilation.*

Provide as much distance as possible between the Aquamantys Pump Generator and other electronic equipment (such as monitors). When activated, the Aquamantys Pump Generator may cause interference with this equipment.

Failure to place the Aquamantys Pump Generator on a suitable table, cart, or surface may result in instability and increased risk for damage to the Pump Generator due to impact damage.

Nonfunction of the Aquamantys Pump Generator may cause interruption of surgery. A backup generator or alternative hemostatic techniques should always be available.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when a device is active.

If required by local codes, connect the Aquamantys Pump Generator to the hospital equalization connector with an equipotential cable.

Connect the power cord to a properly grounded receptacle having the correct voltage. Otherwise product damage may result.

1. Ensure the power switch for the Aquamantys Pump Generator is in the off position by pressing the bottom portion of the power switch marked "O".
2. Place the Aquamantys Pump Generator on an Aquamantys Cart. If you do not have an Aquamantys Cart, place the Aquamantys Pump Generator on a flat stable surface, such as a table or other suitable platform. Consult the procedures for your institution and applicable regulations.
3. Provide at least six inches of space around the sides and top of the Aquamantys Pump Generator for access to the controls, displays, and receptacles, and to provide for air cooling of the unit. The top, sides, and rear panel of the Pump Generator may become warm when the Aquamantys Pump Generator is used in a normal manner.
4. Connect the Aquamantys Pump Generator main power cord directly into the power cord receptacle on the rear panel.
5. Connect the Aquamantys Pump Generator main power cord directly into a properly grounded receptacle to provide the appropriate electrical voltage and current.
6. Turn the Aquamantys Pump Generator on by pressing the top portion of the power switch marked "|". Upon Pump Generator start-up, the unit will perform an automatic self-test. Prior to the self-test, the software version will be displayed. During the self-test, all front panel LEDs will illuminate momentarily and an audible test tone will sound.
7. After the automatic self-test is successfully completed (after about 6 seconds), the RF Power Indicator will display 20 watts.
8. If the automatic self-test is not successfully completed, an alarm will sound, the RF power output will be disabled, and an error code will be displayed in the RF Power Indicator. See the information below or refer to sections 7 and 8 of this User Guide if an error code appears.
9. If the display shows an alternating "**HP-**" and "**Err**" following the self-test, the self-test was executed while an Aquamantys disposable bipolar device was being activated. Simultaneous activation of the device during the self-test prevents the audio and visual indicators of the self-test from occurring. If this happens, release the button on the device.
10. If all LEDs do not illuminate or the audible test tone is not heard during the automatic self-test, turn the unit off and then turn the unit back on to cycle it through the self-test. If this does not resolve the problem, do not attempt to use the Aquamantys Pump Generator and refer to sections 7 and 8 of this User Guide.

Preparing for Surgery

Warnings: ***Electric Shock Hazard*** *Ensure that the device is correctly connected and that no metal is exposed.*

Precautions: *Read the instructions, warnings, and precautions provided with the electrosurgical device before using. Specific instructions are not included in this manual.*

Inspect the device and cord for breaks, cracks, nicks, or other damage before every use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team.

Set the RF power to the lowest setting before testing the device.

Connecting the Aquamantys™ Disposable Bipolar Device to the Aquamantys™ Pump Generator

1. Prepare the Aquamantys disposable bipolar device to be used for the procedure. Refer to the Instructions For Use provided with the device.
2. Connect the Aquamantys disposable bipolar device to the Aquamantys Pump Generator by directly inserting the plug of the device into the plug receptacle on the front panel of the Pump Generator (Figure 4-1).

Figure 4-1. Insert the device plug into the Aquamantys™ Pump Generator

Loading the Pump Segment Portion of the Aquamantys™ Disposable Bipolar Device into the Pump Head of the Aquamantys™ Pump Generator

Warning: *Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the pump segment of the Aquamantys disposable bipolar device in the pump head while the pump head rotor is turning. Fingers or loose clothing could be caught in the pump rollers.*

The saline delivery tubing of the Aquamantys disposable bipolar device includes a special pump segment portion designed to operate with the pump head of the Aquamantys Pump Generator.

The pump segment portion of the saline delivery tubing is located between a black tubing connector and a white tubing connector.

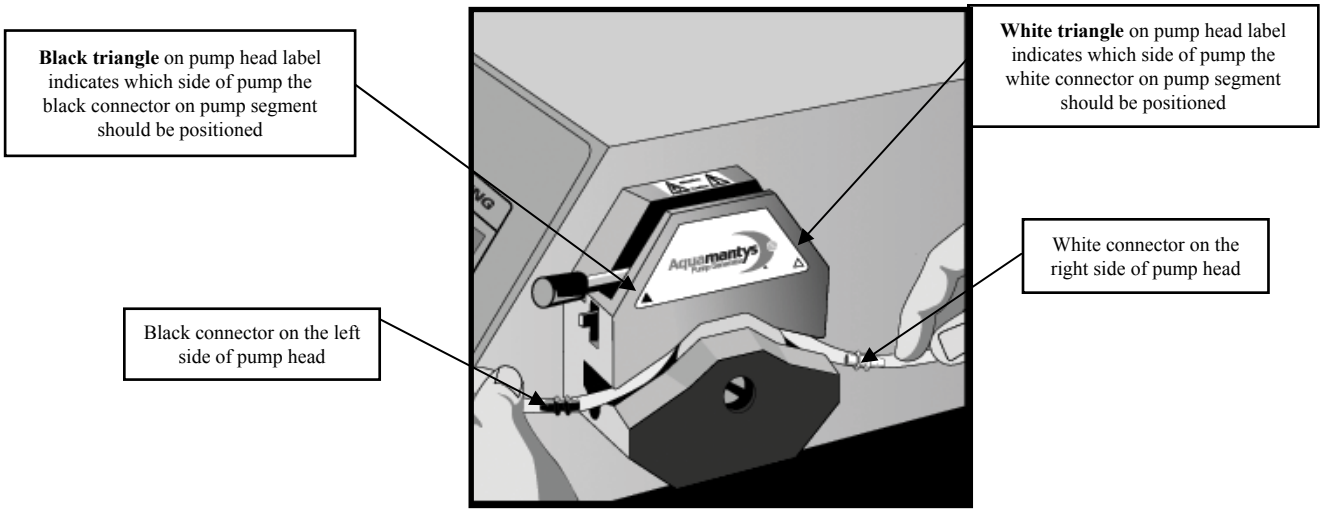
The pump head is located on the right side of the Aquamantys Pump Generator when looking at the unit from the front. It is best to position yourself facing the right side of the unit to load the pump segment portion of the Aquamantys disposable bipolar device into the pump head.

1. Use the black-tipped lever located on the right side of the pump head to open the pump head (Figure 4-2). Rotate the black-tipped lever 180° (degrees) counterclockwise from the right side of the pump head to the left side of the pump head. This action will raise the upper part of the pump head.

2. After locating the pump segment portion of the saline delivery tubing on the Aquamantys disposable bipolar device, place the pump segment portion of the saline delivery tubing into the pump head with the black tubing connector positioned to the left side of the pump head (i.e. closest to the front panel of the Aquamantys Pump Generator). The white tubing connector should then be positioned to the right side of the pump head (Figure 4-3).

Figure 4-2. Raising the pump head

Figure 4-3. Placing the pump segment portion of the saline delivery tubing into the pump head



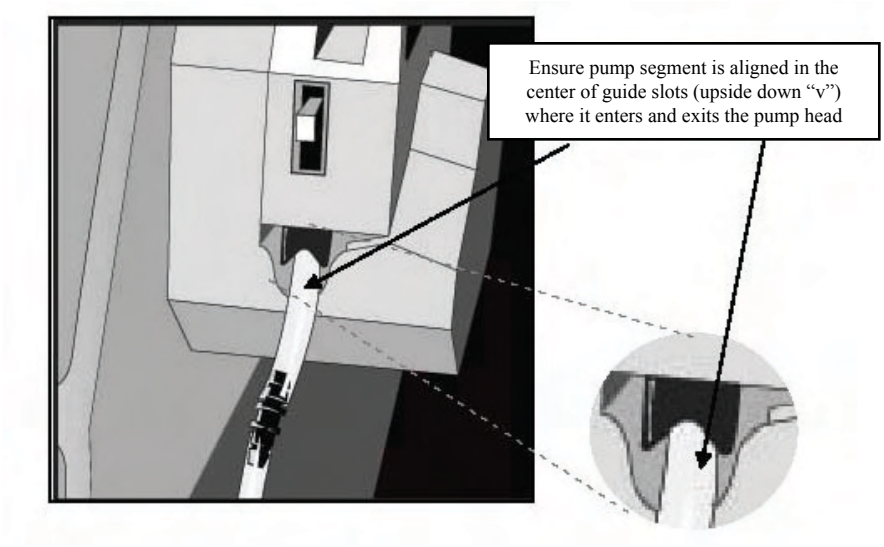
3. Use the black-tipped lever to close the pump head. Rotate the black-tipped lever 180° (degrees) clockwise from the left side of the pump head to the right side of the pump head. This action will lower the upper part of the pump head (Figure 4-4).

Precaution: *Do not peel saline delivery segment apart from the device cable before placing the pump segment in the pump head. Peeling the tubing first increases the potential for loading the pump segment in the reversed position.*

Figure 4-4. Lowering the pump head

4. At the locations where the tubing enters and exits the pump head, the upper (moving) part of the pump head includes black slotted tubing guides. Ensure that the pump segment portion of the saline delivery tubing is properly aligned in the pump head by inspecting where the tubing enters and exits the pump head. The pump segment must be centered in the guide slot of both tubing guides, with no pinching of the tubing. This is shown in Figure 4-5.

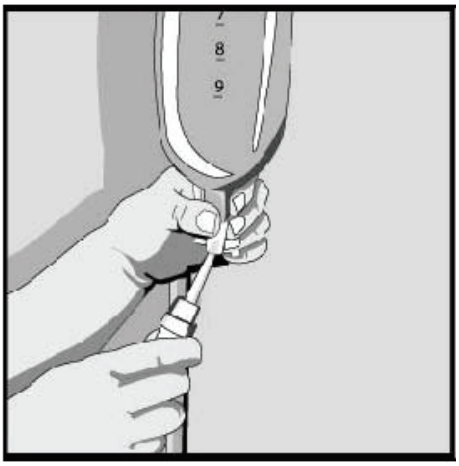
Figure 4-5. Proper alignment of the pump segment portion of the saline delivery tubing in the left and right guide slots of the tubing guides



Spiking the Saline Bag

1. Hang a bag of sterile saline (0.9% NaCl) solution on the Aquamantys Cart I.V. pole or another I.V. support which is in close proximity to the Aquamantys Pump Generator.
2. Remove the protective cover over the spike of the drip chamber at the end of the device's saline delivery tubing.
3. Using aseptic technique, spike the bag of sterile saline (0.9% NaCl) solution.
4. Squeeze the drip chamber once or twice to fill the drip chamber to a level of at least one-third full. This is shown below in Figure 4-6.

Figure 4-6. Spiking the saline bag



Priming the Aquamantys™ Disposable Bipolar Device

1. Press the “START PRIME” button as shown in Figure 4-7. This initiates priming of the Aquamantys disposable bipolar device with saline.

   The pump will operate for a preset time period to prime the Aquamantys device. The pump head speed is accelerated during the priming cycle compared to normal use.

   The Aquamantys device is primed when saline drips from both of the electrodes of the device. After the priming cycle is complete, the pump shuts off automatically.

   The “Priming Underway” indicator will illuminate amber when priming is activated and shut off (darken) after the priming cycle is complete.

Figure 4-7. Initiating Priming of the Aquamantys™ Disposable Bipolar Device

Precautions: *Always place the device into a holster or over a container to collect the saline that exits the electrodes as a result of the priming process. If excess saline is not collected, saline could drip on the patient, patient drapes, surgical instruments, or operating room surfaces.*

Lack of saline flow from both of the electrodes can result in a lack of tissue effect and may damage the electrodes during device activation. Use caution to avoid the following conditions that can result in lack of adequate saline flow from the device:

- *Pump segment portion of the saline delivery tubing loaded improperly into the pump head:*
  - *In the wrong direction. The black tubing connector should be to the left side of the pump head (i.e. closest to the front panel of the Aquamantys Pump Generator).*
  - *Pinched pump segment portion. Tubing not aligned in the center of the tubing guide slot.*
  - *Upper part of pump head not completely lowered onto the pump segment portion of the saline delivery tubing. The upper part of the pump head must be completely lowered all the way down (black lever rotated all the way to the right), so that the pump head can properly interact with the pump segment portion of the saline delivery tubing.*
  - *Pump segment not loaded into the pump head at all.*
- *Priming not completed:*
  - *“START PRIME” button not pressed.*
  - *“START PRIME” button pushed before the saline bag was spiked.*
  - *“START PRIME” button pressed a 2nd time prior to priming cycle being completed.*

The "START PRIME" button activates and deactivates the timed priming cycle. Pressing the button a second time will immediately stop the priming cycle. Pressing the button a third time will reset the timer and restart the priming cycle from the beginning.

Pressing the "START PRIME" button more than once will result in additional saline being delivered to the device. Always place the device into a holster or over a container to collect the saline that will exit the electrodes as a result of the priming process.

Keep fingers clear when lowering the pump head to avoid pinching fingers along with the pump segment.

Adjusting the RF Power Setting

Warnings: *Always use the lowest setting possible to achieve the desired tissue effect.*

1. Set the RF power (shown in Figure 4-8):

   - Press the △ button to increase the RF power.
   - Press the ▽ button to decrease the RF power.

The RF power changes in increments of 5 watts in the range of 20 to 100 watts, and in increments of 10 watts in the range of 100 to 200 watts. If either button is held down the setting will change slowly, then more rapidly. Release the button when the desired RF power setting is displayed. An alarm tone will sound when the power reaches 200 watts and when it is lowered to 20 watts.

The RF power setting cannot be adjusted while the Aquamantys disposable bipolar device is being activated.

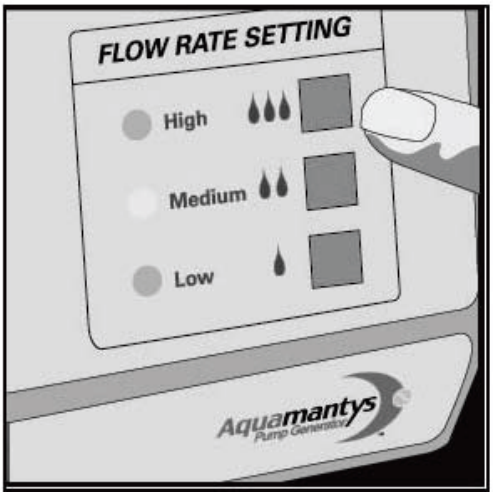
Figure 4-8. Adjusting the RF Power Setting

Adjusting the Saline Flow Rate

1. Adjust the saline flow rate setting by pressing the button next to the desired flow rate. This is shown in Figure 4-9. Flow rate options include:

   - High saline flow rate **High**
   - Medium saline flow rate **Medium**
   - Low saline flow rate **Low**

Figure 4-9. Adjusting the Saline Flow Rate



The three possible saline flow rates are preset for each given RF power setting. See Figure A-3 on page A-5 for more detailed information on the saline flow rates for each given RF power setting.

The saline flow rate setting cannot be adjusted while the Aquamantys disposable bipolar device is activated.

If a flow rate setting is not manually selected, the medium setting is selected as the default setting.

The Flow Rate Setting Indicator next to the selected flow rate will be illuminated amber to indicate the current flow rate setting.

Section 5

During Surgery

This section contains information about:

- Checking the Aquamantys Disposable Bipolar Device Connection
- Changing the RF Power Setting
- Changing the Saline Flow Rate Setting
- Activating the Aquamantys Disposable Bipolar Device
- Adjusting the Volume of RF Power Activation Tones
- Responding to Alarms

Precautions: *Read all warnings, precautions, and instructions provided with this Aquamantys Pump Generator before using.*

Read the warnings, precautions, and instructions provided with Aquamantys disposable bipolar devices before using. Specific instructions are not included in this manual.

Do not continuously activate the Aquamantys System for extended periods of time. Extended activation could potentially overheat the Pump Generator and increase risk of device malfunction or fire hazard.

Do not use the Aquamantys disposable bipolar device in an immersed setting (e.g. arthroscopic surgery). Use in an immersed setting could potentially overheat the Pump Generator and increase the risk of device malfunction or fire hazard.

Only activate the Aquamantys disposable bipolar device on tissue intended to be treated. Activation over another location may result in hot saline run-off onto unintended tissue, patient, patient drapes, hospital staff, and operating room surfaces.

Use caution to prevent inadvertent activation of the Aquamantys disposable bipolar device during the procedure. Inadvertent activation may result in injury to the patient or surgical team.

Checking the Aquamantys™ Disposable Bipolar Device Connection

Warnings: *Do not wrap device cords around metal objects. This may induce currents that could lead to shocks, fires, or injuries to the patient or surgical team.*

Precautions: *Inspect the Aquamantys disposable bipolar device and cord for breaks, cracks, nicks, or other damage before every use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team.*

Confirm that the Aquamantys disposable bipolar device is properly connected to the Aquamantys Pump Generator. Only one device can be connected at any one time.

Changing the RF Power Setting

Warnings: *Confirm proper power setting before proceeding with surgery. Use the lowest setting possible to achieve the desired tissue effect.*

Precautions: *Inspect the device and cord for breaks, cracks, nicks, or other damage before every use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team.*

Press the △ button to increase the RF power.
Press the ▽ button to decrease the RF power.

The RF power setting changes in increments of 5 watts in the range of 20 to 100 watts, and in increments of 10 watts in the range of 100 to 200 watts. If either button is held down the setting will change slowly, then more rapidly. Release the button when the desired RF power setting is displayed. An alarm tone will sound when the power reaches 200 watts and when it is lowered to 20 watts.

The RF power setting cannot be adjusted while the Aquamantys disposable bipolar device is being activated.

Changing the Saline Flow Rate Setting

Precautions: *Using the low flow rate setting at the high power setting may result in more steam production at the electrodes than with the medium or high flow rate settings, and may result in electrode charring or damage, with reduced hemostatic effectiveness.*

Set the saline flow rate setting by pressing the button next to the desired flow rate.
Flow rate options include:

- High saline flow rate **High** 
- Medium saline flow rate **Medium** 
- Low saline flow rate **Low** 

The three possible saline flow rates are preset for each given power setting. See Figure A-3 on page A-5 for more detailed information on the saline flow rates for each given power setting.

The saline flow rate setting cannot be adjusted while the Aquamantys disposable bipolar device is being activated.

The flow rate setting Indicator next to the selected flow rate will be illuminated amber to indicate the current flow rate setting.

Activating the Aquamantys™ System

Warnings: *Do not activate the Aquamantys disposable bipolar device when the electrodes are not in contact with the tissue to be treated. Activating off tissue may result in inadvertent tissue damage or user injury due to contact with hot saline.*

Precautions: *Use the Aquamantys disposable bipolar device only until the desired tissue effect is achieved.*

1. Press the activation button on the hand piece of the Aquamantys disposable bipolar device to simultaneously activate RF power and saline flow from the device.
2. Release the activation button on the hand piece of the Aquamantys disposable bipolar device to shut off both RF power and saline flow from the device.

Pressing the activation button on the Aquamantys disposable bipolar device will activate the Aquamantys Pump Generator. The RF Power Activation Indicator will illuminate blue and a continuous RF activation tone will sound to indicate the presence of RF power output.

At maximum output settings (200 Watts) and rated load conditions (100 Ohms) the Aquamantys Pump Generator may be safely operated for activation times of 40 seconds on, 80 seconds off, for 1 hour. With reduced power settings, the unit can be activated for greater durations without generating excess internal temperatures.

Adjusting the Volume of the Activation Tone

Precautions: *Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when a device is active.*

To change the volume of the RF power activation tone, turn the volume control knob on the rear panel of the Aquamantys Pump Generator:

- To increase the volume of the RF power activation tone, turn the knob clockwise.
- To decrease the volume of the RF power activation tone, turn the knob counterclockwise.
- The Pump Generator prevents this tone from being silenced.

Responding to Alarms

When the Aquamantys Pump Generator senses a malfunction, a series of alarm tones will sound and the RF power is disabled. Additionally, the RF Power Indicator will show "**Err**" and blink alternately with a special error code number(s).

1. Turn the Aquamantys Pump Generator off by pressing the bottom portion of the power switch marked "O".

2. After 10 seconds, switch the unit on by pressing the top portion of the power switch marked " | " and verify that the self-test is successfully completed. During the self-test, all front panel LEDs will illuminate momentarily and an audible tone test will sound.

If the automatic self-test is successfully completed (after about 6 seconds), the RF Power Activation Indicator will illuminate and the RF Power Indicator will display 20 watts.

If the automatic self-test is not successfully completed, an alarm will sound, the RF power output is disabled, and an error code is displayed in the RF Power Indicator. Do not attempt to use the Pump Generator and refer to section 8 of this guide.

If the display shows an alternating "**HP-"** and "**Err"** following the self-test, the self-test was executed while an Aquamantys disposable bipolar device was being activated. Simultaneous activation of the device during the self-test prevents the audio and visual indicators of the self-test from occurring. If this happens, release the button on the device.

If all LEDs do not illuminate or the audible tone test is not heard during the automatic self-test, turn the unit off and then turn the unit back on to cycle it through the self test. If this does not resolve the problem, do not attempt to use the Aquamantys Pump Generator and refer to section 8 of this guide.

If you are unable to correct the malfunction, use a backup generator or traditional hemostatic techniques to complete the surgical procedure. Contact Biomedical Engineering Department or a Salient Surgical Customer Service representative (866.777.9400 in the U.S., 0808.101.1727 in the U.K., +1.603.742.1515 outside the U.S.) for further assistance.

Section 6

After Surgery

This section contains information about:

- Disposing of the Aquamantys Bipolar Device
- Preparing the Aquamantys Pump Generator for Reuse
- Transportation and Storing the Aquamantys Pump Generator

Disposing of the Aquamantys™ Bipolar Device

1. Turn the Aquamantys Pump Generator off by pressing the bottom portion of the power switch marked "O".
2. Firmly knot the saline delivery tubing between the drip chamber and the pump segment.
3. Open the pump head and remove the Aquamantys disposable bipolar device pump segment portion of the saline delivery tubing.
4. Remove the used saline bag from I.V. pole.
5. Disconnect the Aquamantys disposable bipolar device from the Pump Generator.
6. Dispose of the Aquamantys device and used saline bag according to the procedures for your institution.

Precautions: *The Aquamantys disposable bipolar device and the saline bag will contain unused saline following use of the device. Take precautions to prevent the unused saline from flowing onto operating room surfaces by placing hand piece into waste receptacle prior to opening pump head and removing device pump segment.*

Preparing the Aquamantys™ Pump Generator for Reuse

Warnings: ***Electric Shock Hazard*** *Always turn off and unplug the unit before cleaning.*

Precautions: *Do not clean the unit with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the unit.*

1. Turn the Aquamantys Pump Generator off by pressing the bottom portion of the power switch marked "O".
2. Unplug the main power cord from the wall outlet and receptacle on the Pump Generator.
3. Thoroughly wipe all surfaces of the unit and power cord with a damp cloth using a mild cleaning solution or disinfectant. Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. The unit should not be sterilized.

Transportation and Storage of the Aquamantys™ Pump Generator

Care should be taken when transporting the Aquamantys Pump Generator prior to and after use to prevent impact damage to the unit. The unit should be transported on the Aquamantys Cart or a suitable alternative. Consult the procedures for your institution and applicable regulations.

If the unit is stored at a temperature outside its normal operating range of 50° to 104° F (10° to 40° C), allow it to stabilize at room temperature prior to use.

The unit can be stored indefinitely. However, if you store it longer than one year, you must perform specific checkout procedures, including functional verification before use. Refer to section 10 of this guide.

Do not store the Aquamantys Pump Generator on its side or end. This may cause damage to the unit.

Precautions: *Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner by a certified disposal company.*

Section 7

Troubleshooting

This section contains information about:

- General Troubleshooting Guidelines
- Troubleshooting Malfunctions
- Responding to Alarms

General Troubleshooting Guidelines

If the Aquamantys Pump Generator malfunctions, first check for obvious conditions that may have caused the problem:

- Check the unit for visible signs of physical damage.
- Make sure the fuse drawer is tightly closed.
- Verify that all cords are connected and attached properly.

Troubleshooting Malfunctions

If a solution is not readily apparent, use the table below to help identify and correct specific malfunctions. After you troubleshoot the malfunction, verify that the unit completes the self-test as described in Section 4.

Figure 7-1. Troubleshooting

Situation	Possible Cause	Solution
No power	No power cord.	Use power cord shipped with Aquamantys Pump Generator or contact Salient Surgical Customer Service to obtain new power cord.
	Wrong power cord utilized.	Use power cord shipped with Aquamantys Pump Generator or contact Salient Surgical Customer Service to obtain new power cord.
	Faulty wall outlet.	Insert power cord into a functioning wall outlet.
	Fuse drawer is open or fuses are blown.	Close the fuse drawer. Replace the blown fuse(s). Refer to section 10.
	Wrong fuse.	Use fuse listed in section 10 of this guide. Correct fuse is also listed on back panel of the unit.
	Unit not turned on.	Switch unit on using the power switch located on the front panel of the unit.
	Insufficient insertion of device plug into receptacle.	Ensure Aquamantys disposable bipolar device is fully inserted into device plug receptacle.
	Insufficient insertion of power cord into unit or wall jack.	Ensure power cord is fully inserted into back of unit and wall jack.
	Damaged Aquamantys Pump Generator power cord.	Contact Salient Surgical Customer Service to obtain a new power cord.
	Damaged Aquamantys disposable bipolar device power cord.	Do not use device. Return the device to Salient Surgical and use new device.
No saline when device activated	Pump tubing segment not inserted correctly into pump head.	Remove pump tubing segment from pump head and reinsert correctly as indicated in User Guide.
	Saline bag positioned on side or upside down.	Ensure saline bag is positioned right side up.
	Pump head not closed.	Close the pump head prior to use.
	No saline source.	Ensure spike at end of device tubing set is correctly inserted into a 250 ml or larger I.V. bag of sodium chloride solution (0.9%NaCl).
	Priming cycle not completed.	Press “START PRIME” button once and ensure priming cycle completes and saline drips from both electrodes of the device.
	Priming button on unit pressed before the saline bag was spiked.	Press “START PRIME” button once and ensure priming cycle completes and saline drips from both electrodes of the device.
	Inadequate supply of saline.	Replace used bag of sodium chloride solution (0.9%NaCl) with a new bag.

Situation	Possible Cause	Solution
No saline when device activated (continued)	Pump tubing segment inserted in reverse orientation.	Ensure black connector on the Aquamantys disposable bipolar device pump tubing segment is oriented to the left side of the pump head and the white connector to the right side of the pump head when pump tubing segment is inserted.
	Saline line kinked/compressed/occluded.	Ensure Aquamantys disposable bipolar device pump segment is properly aligned in the pump head. Ensure saline line is not kinked, compressed, or occluded by operating room equipment, instruments, or personnel.
	Non-Aquamantys bipolar device connected to Pump Generator.	Ensure device connected to Pump Generator is an Aquamantys device (Aquamantys logo on the side of the device). If incorrect device is being utilized, discard and utilize correct Aquamantys disposable bipolar device.
	All saline slots in either electrodes of the Aquamantys disposable bipolar device clogged by tissue or coagulated blood.	Clean device electrodes with gauze. Ensure precautions are taken to avoid inadvertent device activation when cleaning device electrodes. If this does not correct the problem, discontinue use and return device to Salient Surgical and use new device.
	Aquamantys disposable bipolar device pump is jammed by pump segment connector which has inadvertently entered into pump head.	Ensure pump segment is aligned in the center of guide slots (upside down “v”) where it enters and exits the pump head.
	Source of normal saline is a non-vented glass bottle.	Open vent cap on Aquamantys disposable bipolar device drip chamber.
Incorrect saline flow when device activated	Pump tubing segment not inserted correctly into pump head.	Remove pump tubing segment from pump head and reinsert correctly as indicated in User Guide.
	Saline bag height below pump head.	Ensure saline bag is positioned at a height above the pump head.
	Saline delivery tubing inserted into pump head instead of pump tubing segment.	Ensure black connector on the Aquamantys disposable bipolar device pump tubing segment is oriented to the left side of the pump head and the white connector to the right side of the pump head when pump tubing segment is inserted.
	Air bubbles in line due to incorrect priming technique.	Press “START PRIME” button once to reprime the device in order to remove air bubbles.
	Saline line kinked or compressed.	Ensure Aquamantys disposable bipolar device pump segment is properly aligned in the pump head. Ensure saline line is not kinked, compressed, or occluded by OR equipment, instruments, or personnel.
	Incorrect (non-Aquamantys) disposable device utilized.	Ensure device connected to Pump Generator is an Aquamantys device (Aquamantys logo on the side of the device). If incorrect device is being utilized, discard and utilize correct Aquamantys disposable bipolar device.
	One or more of the saline slots in either of the electrodes of Aquamantys disposable bipolar device clogged by tissue or coagulated blood.	Clean device electrodes with gauze. Ensure precautions are taken to avoid inadvertent device activation when cleaning device electrode. If this does not correct the problem, return device to Salient Surgical and use new device.
	Aquamantys disposable bipolar device pump segment is not inserted into pump head.	Insert pump tubing segment into pump head as shown in User Guide.

Situation	Possible Cause	Solution
Generator doesn't work	Pump Generator damaged.	Contact Biomedical Engineering Department or a Salient representative for assistance. Use a backup Pump Generator or traditional hemostatic techniques to complete the surgical procedure if repairs cannot be made prior to the scheduled surgical procedure.
	Pump Generator did not receive a scheduled safety check.	Contact Biomedical Engineering Department or a Salient representative for assistance. Use a backup Pump Generator or traditional hemostatic techniques to complete the surgical procedure if repairs cannot be made prior to the scheduled surgical procedure. See section 10 of this guide for maintenance schedule.
	Pump Generator plugged into an inappropriate wall outlet (e.g. not protected against ground fault, etc.).	Plug Pump Generator into an appropriate wall outlet prior to use.
Unit is on, but did not complete self-test.	Software or internal component malfunction.	Turn off, and then turn on the unit. If the error code reappears: • Record the error code number and refer to *Responding to Alarms* in this section. • Use a backup Pump Generator or traditional hemostatic techniques to complete the surgical procedure.
Unit is on and disposable device is activated, but unit does not deliver output.	Power setting is too low.	Increase the power. Refer to Section 5, *Changing the RF Power Setting.* Use the lowest possible power setting needed to obtain the desired surgical effect.
	Malfunctioning Aquamantys disposable bipolar device or improper device connection.	Turn off the unit. Check the device connection. If device continues to malfunction, replace device and contact Salient Surgical to report device malfunction.
	A malfunction condition exists.	Check the power display for an error code. Note the code number and refer to *Responding to Alarms* in this section.
Interference with other device only when the unit is activated.	Metal-to-metal sparking.	Check all connections to the unit and device.
	Electrically inconsistent ground wires in the operating room.	Verify that all ground wires are as short as possible and go to the same grounded metal.
Continuous monitor interference.	Faulty chassis-to-ground connections.	Check and correct the chassis ground connections for the monitor and for the unit.
	Monitor responding to radiated frequencies.	Check other electrical equipment in the room for defective grounds. If not resolved, contact Biomedical Engineering Department to check with the monitor manufacturer.
Abnormal neuromuscular stimulation *(Stop surgery immediately)*	Metal-to-metal sparking.	Check all connections to the unit and devices.

Situation	Possible Cause	Solution
Ineffective hemostasis	Power setting too low.	Increase the power. Refer to Section 5, *Changing the RF Power Setting.* Use the lowest possible power setting needed to obtain the desired surgical effect.
	Tissue under-treated. Tissue not treated long enough to result in a reduction in intraoperative or postoperative blood loss.	See Aquamantys disposable bipolar device Instructions For Use and/or device treatment guides for treatment recommendations.
	Wrong fluid used for device irrigation.	Only utilize sterile bag of sodium chloride solution (0.9%NaCl) with the Aquamantys System.
	Electrode(s) of Aquamantys disposable bipolar device clogged by tissue or coagulated blood.	Clean device electrodes with gauze. Ensure precautions are taken to avoid inadvertent device activation when cleaning device electrodes. If this does not correct the problem, return device to Salient and use new device.
	Excessive blood, fluid or saline in surgical field where device is being utilized.	Utilize appropriate suction to remove blood, fluid and/or saline. See Aquamantys disposable bipolar device instructions for use and/or device treatment guides for treatment recommendations.
Unintended tissue effect	Power setting too high.	Decrease the power. Refer to Section 5, *Changing the RF Power Setting.*
	Tissue over-treated.	See Aquamantys disposable bipolar device Instructions For Use and/or device treatment guides for treatment recommendations.
	Non-Aquamantys bipolar device utilized.	Ensure device connected to Pump Generator is an Aquamantys device (Aquamantys logo on the side of the device). If incorrect device is being utilized, discard and utilize correct Aquamantys disposable bipolar device.
Excessive saline	Saline flow rate setting too high.	Decrease saline flow rate. Refer to Section 5, *Changing the Saline Flow Rate Setting.*
	Excess saline resulting from priming cycle.	Place the device into a holster or over a container to collect the saline that will exit the electrodes as a result of the priming process.
	2nd (or more) activation of priming cycle.	Place the device into a holster or over a container to collect the saline that will exit the electrodes as a result of the priming process.
	Off tissue device activation.	Only activate the Aquamantys disposable bipolar device on/over tissue intended to be treated. Activation over another location may result in hot saline run-off onto unintended tissue, patient, patient drapes, hospital staff, and operating room surfaces.
	Saline delivery tubing inserted into pump head instead of pump tubing segment.	Ensure black connector on the Aquamantys disposable bipolar device pump segment is oriented to the left side of the pump head and the white connector to the right side of the pump head when pump tubing segment is inserted.
	Pump head disengaged following procedure prior to firmly knotting the saline delivery tubing between the drip chamber and the pump segment on the device.	The Aquamantys disposable bipolar device and the saline bag will contain unused saline following use of the device. Firmly knot the saline delivery tubing between the drip chamber and the pump segment on the device prior to opening the pump head.
Error codes	Error codes appear.	Turn power off for a minimum of 10 seconds, turn power back on. If error code still displays, contact Salient Surgical.

If problem persists after applying the appropriate solution indicated in this table, use a backup pump generator or traditional hemostatic techniques to complete the surgical procedure. Contact Salient Surgical Customer Service for assistance, refer to section 10 of this guide (Returning the Aquamantys™ Pump Generator for Service).

Section 8

Error Codes and Error Handling

The Aquamantys Pump Generator self-test, which is executed immediately following power up, comprises several phases. The first phase covers the internal RAM and the MPU0 watchdog test. The second phase tests the major computer hardware components (microcontroller). The third phase tests the NV-RAM and the separate RFGEN modules for potential errors. Portions of this self-test are repeated in the background during normal use (see “Checked During Use?” column of Error Code Description Table).

If an error is detected, the respective test is repeated at least once in order to exclude sporadic deviations. If the deviation remains, the self-test aborts, an error message is generated, and the unit enters the safe state. The safe state disables all functions of the pump generator until the error condition is cleared.

Error display during the self-test

While in the safe state following the detection of a self-test error, the power setting display will repeatedly sequence through three displays. The first display is “**Err**”, followed by the error number, followed by the measured value.

Table 8-1. Error Display

Display Description	Display format
Err	Err
Error Code Number	XXX
Measured value	XXX

Error handling

As a first response to an error indication, it is recommended to turn the power off to the unit, wait for approximately 10 seconds, and then turn it on again to repeat the self-test.

Table 8-2. Error Code Descriptions

Error No.	Brief description	Checked During Use?	Remarks
001	CRC check error		
002	RAM test error		
003	CRC check error	YES	
004	Watchdog error		
005	Local I²C BUS errors (EEPROM)	YES	
006	Controller I²C BUS error	YES	
007	µController defective	YES	
008	Software inconsistency	YES	
009	Heat sink MP1	YES	**Note 1**
010	Heat sink MP2	YES	**Note 1**
011	Case temperature	YES	**Note 1**
013	Int. A/D converter, reference voltage and analog multiplexer	YES	
014	Ground	YES	
015	High power supply 0 V test		
016	High power supply watchdog test		
017	Power supply enable test		
018	Power down test		
019	High power supply error U test		
020	High power supply error I test		
023	MPU1 self-test error	YES	**Note 2**
026	Power level 2 error		
027	Power level 3 error		
028	Power level 4 error		
029	Power level 5 error		
030	Power level 6 error		
032	RF enable error		
033	Current level 0 error		
034	Current level 1 error		
035	Watchdog reset	YES	
036	Excess output: power	YES	
037	Faulty variable contents	YES	
038	Mutual time monitoring of MPUs	YES	
039	Power supply voltage exceeds tolerances	YES	
040	Power supply current exceeds tolerances	YES	
041	Oscillator frequency exceeds tolerances	YES	
042	Pump voltage exceeds tolerances	YES	**Note 3**
043	Pump current below tolerances	YES	**Note 3**
044	Pump current exceeds tolerances	YES	**Note 4**
045	Power down capacitor test		
046	Power failure occurred	YES	
047	Command error	YES	

Error Code Notes:

1) Check (listen) for proper blower operation. Ensure that the recommended duty cycle (40 secs on/80 secs off) is observed.

2) Error code 023 (MPU1 error) has its own subset of error conditions. See MPU1 Error section below.

3) Check proper functioning of pump motor.

4) First insure pump head rotor is not jammed and then check proper functioning of pump motor.

MPU1 Error Codes:

When an error code 023 is encountered during the self-tests described in the table above, the display sequence is reallocated for a subset of error codes specific to MPU1 errors. The power setting display will still repeatedly sequence through three displays, but the first display is "**Err**", followed by 023 to indicate the primary error number, followed by the unique MPU1 error code.

Table 8-3. MPU1 Error Display

Display Description	Display format
Err	Err
Primary Error Code	023
MPU1 Error Code	XXX

Table 8-4. MPU1 Error Code Description

Error No.	Brief Description	Checked During Use?
023 / 001	CRC check error	
023 / 002	RAM test error	
023 / 003	CRC check error	
023 / 004	Watchdog error	
023 / 005	Local I²C BUS errors (EEPROM)	
023 / 006	Controller I²C BUS error	
023 / 007	μController defective	
023 / 008	Software inconsistency	
023 / 009	+5 V AD converter or reference voltage error	
023 / 010	+15V error	
023 / 011	-15V error	
023 / 012	Ground, AD converter error	
023 / 013	Relay test	
023 / 014	Mutual time monitoring of MPUs	
023 / 020	Power watch and power compensation error	
023 / 042	Temperature outside of tolerance	
023 / 043	Handpiece detection test, open test sense line, negative pulse	
023 / 044	Handpiece detection test, open test sense line, positive pulse	
023 / 045	Handpiece detection test, diode test line, negative pulse	
023 / 046	Handpiece detection test, diode test line, positive pulse	
023 / 050	Command error	

Section 9

Testing and Servicing Safety

Warnings: ***Shock Hazards****:*

Contact a Salient Surgical service professional for all assembly operations, readjustments, modifications or repairs. Routine maintenance and functional verification can be performed by a qualified biomedical technician as set forth in section 10 (Routine Maintenance).

The Aquamantys Pump Generator power cord must be connected to a properly grounded receptacle during normal use or testing.

Burn Hazards*:*

High frequency, high voltage signals are present on the output circuit when activated. These signals can cause severe burns. Extreme caution must be used when testing or troubleshooting the output of the pump generator.

Load resistors used to test the output of the pump generator will become extremely hot. Use extreme caution to avoid any contact. All load resistors must be properly mounted and isolated from any flammable materials.

The Aquamantys Pump Generator power cord must be connected to a properly grounded receptacle during normal use or testing. Do not use extension cords or adapter plugs.

Precautions: *All warnings and precautions accompanying the Aquamantys Pump Generator should be read and understood prior to attempting any testing or servicing of the unit.*

When performing accuracy measurements, keep all leads as short as possible and keep leads away from metallic surfaces.

Observe stated duty cycle when testing or servicing unit. The Aquamantys Pump Generator is not intended for continuous activation for extended periods of time.

Section 10
Maintenance and Repair

This section contains information about:

- Routine maintenance
- Returning the Aquamantys™ Pump Generator for service

Responsibility of the Manufacturer

Salient Surgical is responsible for the safety, reliability, and performance of the Aquamantys Pump Generator only under the following circumstances:

- Installation and setup procedures in this manual are followed.
- Assembly operation, readjustments, modifications, or repairs are carried out by persons authorized by Salient Surgical Technologies, Inc.
- The Pump Generator is connected to electrical wiring which complies with local codes and regulatory requirements.
- The equipment is used in accordance with the Aquamantys System instructions for use.

For warranty information, refer to the Warranty at the end of this guide.

Routine Maintenance

Recommended Periodic Functional Verification

The Aquamantys Pump Generator should be periodically checked for functionality and performance according to your hospital's equipment servicing guidelines. Salient Surgical recommends that the unit's calibration be verified and a safety check be performed by a qualified biomedical technician on an annual basis as outlined below.

Recommended Functional Verification Procedure

The verification and functional check should include:

- Protective earth conductor test
- Earth leakage current measurement
- Housing leakage current measurement
- Patient leakage current measurement
- RF leakage current measurement at maximum power with no-load
- Output power accuracy verification
- Peristaltic pump test (function, flow rate accuracy)
- Test of visual indicators
- Test of alarm tone and volume control function
- Power cord inspection (for damage)
- Fuse check

Recommended test equipment:

- Safety tester for medical units as per IEC #60601
- RF power meter for RF surgery systems
- Stopwatch

Leakage currents and protective earth conductor test

The following connections should be established according to the safety tester's instructions:

- Male end of Aquamantys Pump Generator's power cord into the safety tester mains socket.
- Aquamantys' equipotential bonding terminal (see section 2, item #17 for location) to safety tester respective terminal.
- Aquamantys' bipolar output sockets to safety tester applied part terminals.

Perform leakage and PE conductor tests per the safety tester instructions. The following limits must be complied with in accordance with IEC #60601 (Class I, Type CF device):

Table 10-1. Leakage Current and PE Conductor Limits

Measured Characteristic	Maximum Value
PE conductor impedance	0.2 Ω
Earth leakage current, normal condition	500 µA
Earth leakage current, single fault condition	1000 µA
Housing leakage current, normal condition	100 µA
Housing leakage current, single fault condition	500 µA
Patient AC leakage current, normal condition	10 µA
Patient DC leakage current, normal condition	10 µA
Patient AC leakage current, single fault condition	50 µA
Patient DC leakage current, single fault condition	50 µA

RF leakage current

The RF leakage current may be measured with the safety tester used in the previous leakage tests if that function is available. If not, it may be directly measured with a high frequency current sensing coil (i.e.: Pearson Electronics model #4100), a precision voltmeter and a noninductive 200 Ω load resistor.

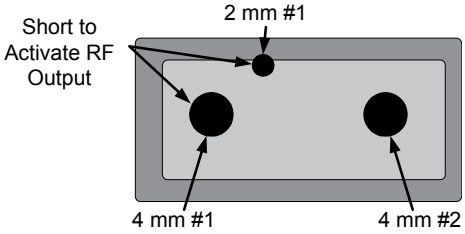
The RF leakage is the current which flows from one side of the Aquamantys bipolar output socket through 200 Ω to the Aquamantys equipotential bonding terminal. During this measurement, the RF output must be active at the maximum power setting (200 watts). Both outputs of the bipolar output socket (4mm connector #1 and 4mm connector #2) should each be tested one at a time. The RF leakage current should not exceed 100 mA.

In the absence of an Aquamantys bipolar disposable device, the Aquamantys Pump Generator bipolar RF output may be manually activated by ***carefully*** shorting the 2mm banana style connector #1 to 4mm banana style connector #1 as shown in the following figure 10-1.

Warnings: *High frequency, high voltage signals are present on the output circuit when activated.* ***These signals can cause severe burns.*** *Extreme caution must be used when testing or troubleshooting the output of the pump generator.*

When 2mm connector #1 is shorted to 4mm connector #1, the Aquamantys bipolar RF output will be active from 4mm connector #1 to 4mm connector #2.

Figure 10-1 Aquamantys™ Bipolar Output Socket; RF Output Activation



RF Output Power Accuracy Verification

Warnings: *Load resistors used to test the output of the Aquamantys Pump Generator will become extremely hot. Use extreme caution to avoid any contact. All load resistors must be properly mounted and isolated from any flammable materials.*

Precautions: *The RF power meter must have a current rating of at least 2.5 $A_{rms.}$*
Do not test the Aquamantys Pump Generator with a load of less than 50 ohms on the output – RF currents in excess of 2.5 amps rms will occur.

It is preferable that these measurements be performed using an electrosurgical tester which is intended for this purpose, however it is possible to perform this testing manually if required. The manual method is achieved with a high frequency current sensing coil (i.e.: Pearson Electronics model #4100), a precision voltmeter and 200W noninductive load resistors of appropriate resistive values. The delivered power will be calculated as I^2R. Also, manual RF output activation as described above will be required.

The RF output should be tested at both 100 watt and 200 watt settings with the output loaded at 50 ohms, 100 ohms and 150 ohms. At 50 ohm and 100 ohm loads, the measured RF output power should be equal to the set power ±20%. At the 150 ohm load, the measured RF power should be less than that measured at 100 ohms. The object is to compare the measured output power for any given load to the output power vs. resistance curve in the Technical Specifications section of this manual, applying a tolerance of ±20%.

Adjusting the RF Power Setting

Press the △ button to increase the RF power and press the ▽ button to decrease the RF power (Figure 10-2).

The RF power setting changes in increments of 5 watts in the range of 20 to 100 watts, and in increments of 10 watts in the range of 100 to 200 watts. Release the button when the desired RF power setting is displayed. An alarm tone will sound when the power reaches 200 watts and when it is lowered to 20 watts. The RF power setting cannot be adjusted while the unit is being activated.

Figure 10-2. Adjusting the RF Power Setting

Peristaltic pump test (function, flow rate accuracy)

Warnings: *Always close the pump head prior to activating pump motor. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Prevent fingers or loose clothing from being caught in pump head rotors.*

Verifying Proper Position of Pump Segment Guides

- The Pump Segment Guides have been retrofitted with an insert to prevent inadvertent adjustment of the Pump Segment Guides. This insert is intended to maintain the correct position of the Pump Segment Guides between the 2 and 5 position.
- In the event that there is no guide tab adjustment clip present, another clip can be obtained from Salient Surgical Technologies, Inc. Please contact Salient Surgical Customer Service (866.777.9400 in the U.S., 0808.101.1727 in the U.K., +1.603.742.1515 outside U.S.) for a replacement clip.
- If it is essential that the Pump Generator be used prior to obtaining a replacement clip, ensure that the Pump Segment Guides are located between the 2 and 5 position and that the pump segment tubing is loaded correctly. Refer to the User Guide, Generator Tray Quick Reference Guide for correct pump segment loading instructions.

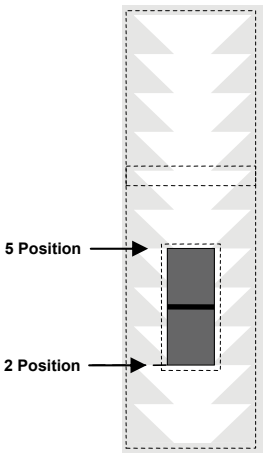


Figure 10-3.
Guide Alignment

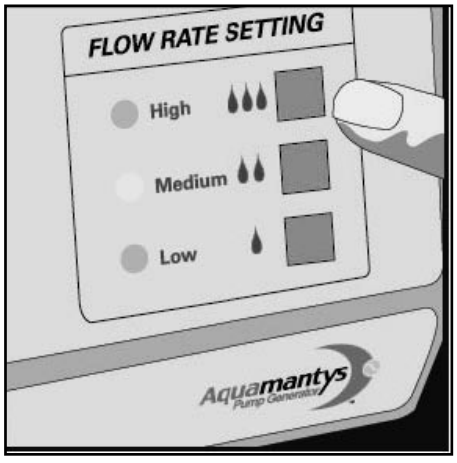
Adjusting Flow Rate Setting

The saline flow rate setting is adjusted by pressing the button next to the desired flow rate (Figure 10-4). Flow rate options include:

- High saline flow rate **High**
- Medium saline flow rate **Medium**
- Low saline flow rate **Low**

The Flow Rate Setting Indicator next to the selected flow rate will be illuminated amber to indicate the current flow rate setting. If a flow rate setting is not manually selected, the medium setting is selected as the default setting. The saline flow rate setting cannot be adjusted while the unit is being activated.

Figure 10-4. Adjusting the Flow Rate Setting



Verifying Proper Pump Head Rotation Rate

- If it is open, close the pump head by moving and locking the pump lever down toward the rear of the pump generator.
- Remove the black rubber plug on the pump face which covers the pump shaft.
- Mark a visual reference point near the outer circumference of the slotted end of the pump shaft using a felt tip marker or other means.
- Set the Aquamantys Pump Generator power output to 200 watts and the flow rate to low.
- Following the directions in the sections above, manually activate the Aquamantys RF output.
- Watching your reference marker on the slotted end of the pump shaft, observe that the pump shaft rotates essentially evenly without binding or stalling.
- Continuing to monitor your reference marker and, using a stopwatch as a timer, count the number of complete revolutions of the pump shaft in a period of 15 seconds. Repeat for medium and high flow settings.

Specifications:

Table 10-2. Flow Rate vs Pump Shaft Revolutions Limits

Flow Rate Setting	Min Revs / 15 sec	Max Revs / 15 sec
Low	17	23
Medium	22	30
High	27	36

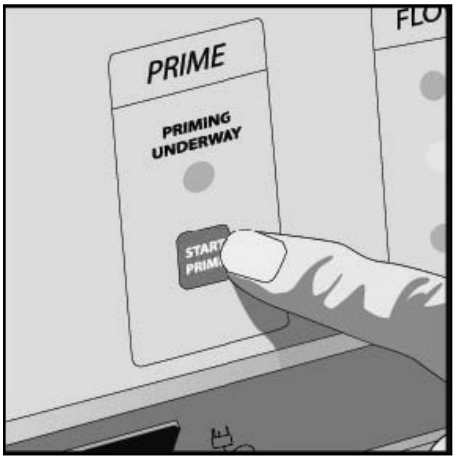
The flow rate regresses to zero mL/min in a linear fashion, so there is no need to verify the flow rate at lower power settings.

Verifying Flow Rate Accuracy of Priming Function

The flow rate accuracy of the priming function should also be verified as follows:

- Monitor the reference mark on the pump shaft as above and, using a stopwatch as a timer, press the prime switch (Figure 10-5) to initiate the priming process. Count the number of complete revolutions of the pump shaft in a period of 15 seconds. There should be between 31 and 42 revolutions in 15 seconds.

Figure 10-5. Initiating the Priming Sequence



The “START PRIME” button activates and deactivates the timed priming cycle. Pressing the button a second time will immediately stop the priming cycle. Pressing the button a third time will reset the timer and restart the priming cycle from the beginning.

Test of visual indicators

During the power-up self-test of the Aquamantys Pump Generator, verify that all visual indicators illuminate.

Test of alarm tone and volume control function

Using manual procedure described in the RF Leakage Current section, activate the bipolar output of the pump generator. Verify that there is an audible activation tone. Also verify that the volume of that tone can be adjusted (but not turned down to an inaudible range) with the volume control on the rear panel of the pump generator.

Power cord inspection

Inspect the power cord for any signs of exposed wires, cracks, frayed edges, or connector damage. Check the power cord each time you use the unit or at intervals recommended by your institution. Replace the power cord with an appropriate hospital grade replacement if any of these conditions or other evidence of damage exists.

Replacement power cords may be ordered from Salient Surgical Customer Service (866.777.9400 in the U.S., 0808.101.1727 in the U.K., +1.603.742.1515 outside U.S.).

Fuse check

An internal component malfunction can damage the fuses. You may need to replace the fuses if the unit stops functioning, even though it is receiving power from a wall outlet

Warnings: ***Shock Hazard.*** *Turn off and unplug pump generator prior to accessing the fuse holder.*

Check the rating of the fuses in the line filter on the rear of the Aquamantys Pump Generator for correct ratings. To do so, unplug the power cord from the generator. Using a flat bladed screwdriver, eject the fuse holder out of the line filter, remove the microfuses and check for correct rating:

Table 10-3. Fuse Ratings

Aquamantys™ type	Operating voltage	Fuse rating
40-401-1	100 V	T5.0 A
40-402-1	115 V	T4.0 A
40-403-1	230 V	T2.0 A
40-401-1R	100 V	T5.0 A
40-402-1R	115 V	T4.0 A
40-403-1R	230 V	T2.0 A

If necessary, replace the fuses with UL-certified (EN60127) fuses of the correct rating.

Returning the Aquamantys™ Pump Generator for Service

Before you return the unit, call your Salient Surgical representative for assistance.

If you are instructed to send the unit to Salient Surgical, first obtain a Return Goods Authorization Number and then ship the unit to Salient Surgical for service.

The unit should be cleaned prior to shipping and shipped in appropriate packaging which protects the unit from damage (see below).

Step 1 – Obtain a Return Goods Authorization Number

Call the Salient Surgical's Customer Service at 866.777.9400 (+1.603.742.1515 outside the U.S., 0808.101.1727 in the U.K.) to obtain a Return Goods Authorization Number. Have the following information ready when you call:

- Hospital / clinic name / customer number
- Telephone number
- Department, street address, city, state or province (if applicable), zip/postal code, and country if outside the U.S.
- Model number
- Serial number
- Description of the problem
- Type of repair to be done (if known)

Step 2 – Clean the Unit

Warnings: *Electric Shock Hazard Always turn off and unplug the unit before cleaning.*

Precautions: *Do not clean the unit with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the unit.*

1. Turn off the unit, and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the unit and power cord with a damp cloth using a mild cleaning solution or disinfectant. Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. The unit cannot be sterilized.

Step 3 – Ship the Unit

1. Attach a tag to the unit that includes the Return Goods Authorization Number and the information (hospital, phone number, etc.) listed in Step 1 – Obtain a Return Goods Authorization Number.
2. Be sure the unit is completely dry before you pack it for shipment. Package it in its original shipping container, if available. If the original shipping container is not available, contact Salient Surgical Customer Service at 866.777.9400 (outside U.S. +1.603.742.1515, in the U.K. 0808.101.1727).

Follow the shipping instructions provided while obtaining the Return Goods Authorization number.

Appendix A

Technical Specifications

Performance Characteristics

General

Output Configuration	Isolated output
Cooling	Internal fan, natural convection on outside of chassis
Display	Three (3) digital seven-segment displays: 0.55 inches (1.4 cm) each

Dimensions and Weight

Width	12.2 inches (31.0 cm)
Depth	15.2 inches (38.5 cm)
Height	5.9 inches (15.0 cm)
Weight	31.5 lbs (14.3 kg)

Operating Parameters

Ambient temperature range	50° to 104° F (10° to 40° C)
Relative humidity	15% – 85%, non-condensing
Air pressure	524 – 795 mmHg (700 to 1060 hPa)

Transport and Storage

Ambient temperature range	-29° to 149° F (-34° to 65°C)

Duty Cycle

At maximum output settings (200 Watts) and rated load conditions (100 Ohms) the unit may be safely operated for activation times of 40 seconds on, 80 seconds off, for 1 hour. With reduced power settings, you can activate the unit for greater durations without generating excess internal temperatures.

Internal Memory

During power failures, this unit has short time storage of the adjusted values. If the power fails for less than 10 seconds, the unit will restore the last adjusted working parameters.

Audio Volume

The audio volume level and frequencies of the activation tone and alarm tones meet the requirements of IEC60601-2-2:2006.

Activation Tone

Frequency (nominal) 940 Hz

Alarm Tone

Frequency (nominal) 349, 415, 524, 698 Hz

Leakage Currents

See IEC test record

LEDs

All LEDs inside the Aquamantys are CLASS 1 LED PRODUCT according to EN60825-1.

Input Power

The nominal mains voltage is factory selected. Refer to the rear panel markings for correct mains voltage.

Nominal V_{RMS}	Minimum V_{RMS}	Maximum V_{RMS}	Max Current A_{RMS}	Fuse Rating	Type of fuse
100	90	110	4.00	T5.0A	5x20mm, Glass fine fuse
115	104	127	3.50	T4.0A	5x20mm, Glass fine fuse
230	207	253	1.85	T2.0A	5x20mm, Glass fine fuse

Mains line frequency (nominal): 50/60 Hz

Maximum power consumption: 420 VA

Mains cable: 3-conductor hospital grade

Standards and IEC Classifications

ATTENTION

Consult accompanying documents.

To reduce the risk of electric shock, do not remove the cover.
Refer servicing to qualified service personnel.

DANGER

Explosion risk if used with flammable anesthetics.

Class I Equipment

Accessible conductive parts cannot become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor.

Type CF Equipment / Defibrillator Proof

This unit provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type CF isolated (floating) output.

IPX1

Drip Proof

This unit enclosure is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which, when wet, are likely to affect adversely the safety of the unit.

Electromagnetic Compatibility

The Aquamantys Pump Generator meets the electromagnetic compatibility requirements of IEC60601-1-2:2001.

Immunity Test	**IEC (60)601-1-2:2001 Test Level**
Conducted emission *DIN EN 55011, FCC Part 18, Class B, consumer class*	150 kHz – 30 MHz
Radiated emission *DIN EN 55011, FCC Part 18, Class B, non consumer class*	30 MHz – 1 GHz
Electrostatic discharge *DIN EN 61000-4-2*	± 6 kV Contact discharge ± 8 kV Air discharge
Immunity to electromagnetic fields *DIN EN 61000-4-3*	10 V/m 80 – 2500 MHz
Immunity to conducted fast transients *DIN EN 61000-4-4*	Burst: ± 2 kV power mains ± 1 kV signallines
Immunity to conducted slow transients *DIN EN 61000-4-5*	Surge 1.2/50µs: ± 2 kV unsym/± 1 kV sym power mains
Immunity to conducted disturbances Induced by RF-fields *DIN EN 61000-4-6*	10 Vrms 150 kHz – 80 MHz power mains / signallines
Voltage dips, short interruptions *DIN EN 61000-4-11*	Complies
Harmonic current emission *DIN EN 61000-3-2, class A*	Complies
Voltage fluctuation and flicker *DIN EN 61000-3-3*	Complies

Output Characteristics

Maximum Pump Generator Output

Mode	Maximum Open Circuit Voltage V_{pp} (V_p)	Maximum Short Circuit Current A_{rms}	Maximum Power Setting Watts	Crest Factor
Bipolar	650 (325)	3.2	200	1.5

RF Output

Output Power 20 to 200 watts

Adjustable Power Increments 5 watts, from 20 to 100 watts
10 watts, from 100 to 200 watts

Load Range 50 to 110 ohms

Rated Load 100 ohms

Output Waveform

Bipolar 370 kHz sinusoid

Saline Flow Rate

Priming Flow Rate 36 mL/min

Priming Time 41 seconds

Flow Rate 0.5 to 36 mL/min, depending on power setting and flow rate setting.

All specifications are valid for software version 1.11 and below.

All specifications are nominal and subject to change without notice.

Figure A-1. Output Voltage vs. Power Setting

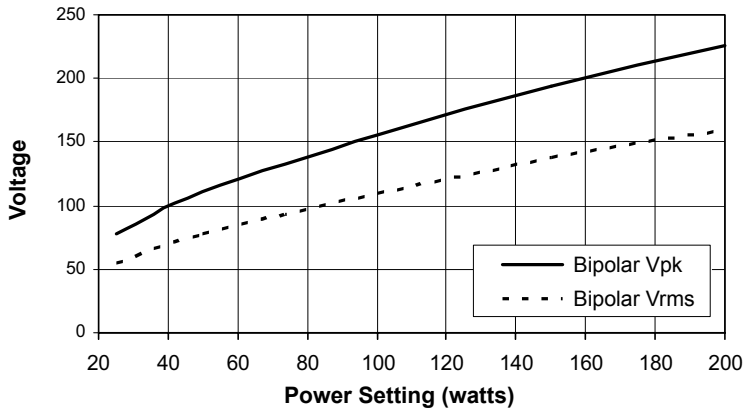


Figure A-2. Output Power vs. Resistance

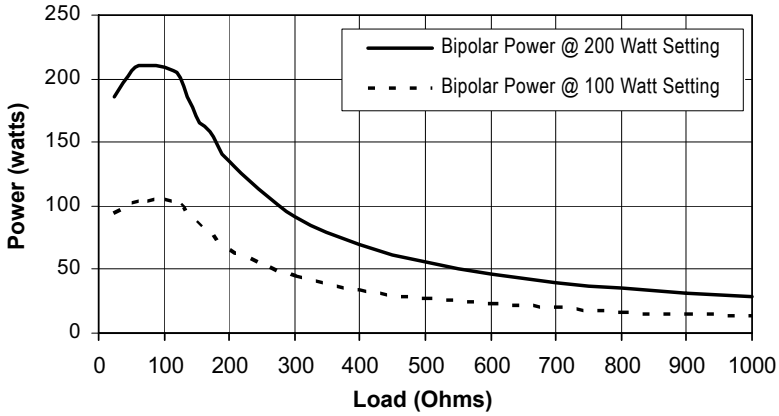


Figure A-3. Saline Flow Rate vs. Power Setting

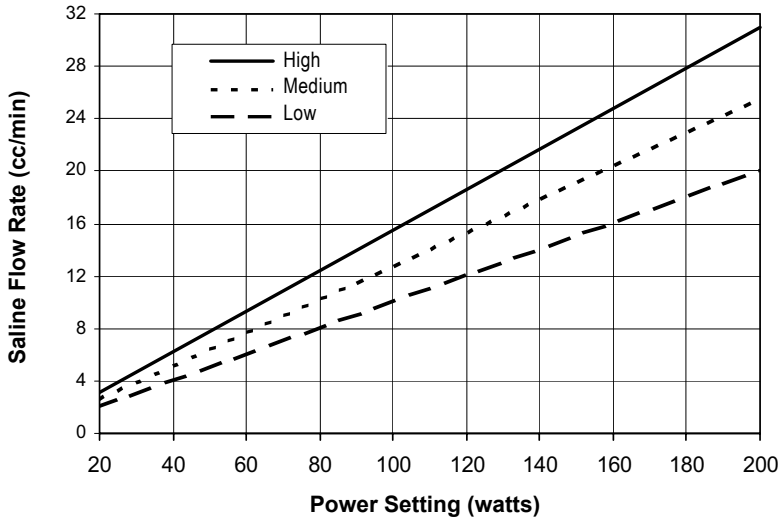
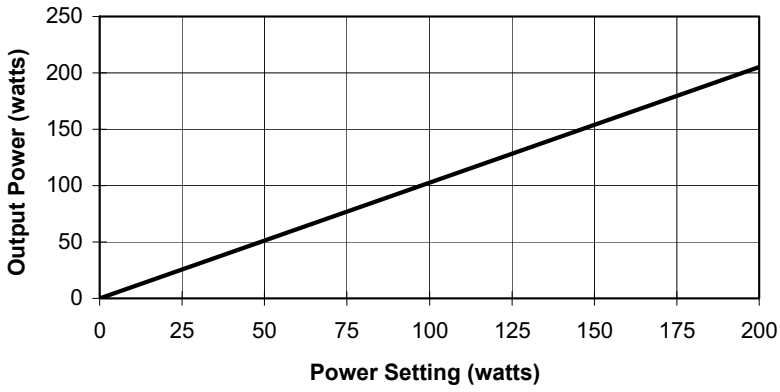


Figure A-4. Power Setting Characteristics at Rated Load



Accessories Aquamantys™ System Power Cords

Part #	Region	Voltage	Length	Connectors
30-501-1	North America	115V	12 feet	IEC 60320-C13 to NEMA 5-15
30-502-1	Europe	230V	4.5 m	IEC 60320-C13 to Europlug CEE 7/7
30-503-1	Japan	100V	4.5 m	IEC 60320-C13 to JIS 8303
30-504-1	United Kingdom	230V	4.5 m	IEC 60320-C13 to BS 1363

Appendix B

New Unit Warranty

LIMITED EXPRESS WARRANTY

For one (1) year from the date of shipment from Salient Surgical Technologies, Inc., if an Aquamantys Pump Generator or Cart is found, to Salient's satisfaction, to be inoperable during normal and proper use in accordance with applicable instructions, Salient Surgical Technologies, Inc. will repair or replace the product, at its sole option, provided the product is returned, freight prepaid, in accordance with all return packaging and shipping instructions. A product repaired or replaced under this warranty will be warranted for the remainder of the original warranty period.

SALIENT SURGICAL TECHNOLOGIES, INC. MAKES NO OTHER WARRANTIES WITH RESPECT TO THE PRODUCT AND EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER. IN NO EVENT SHALL SALIENT SURGICAL TECHNOLOGIES, INC. BE LIABLE FOR ANY CONSEQUENTIAL DAMAGES.

THE ABOVE WARRANTY IS VOID ON ANY PRODUCT WHICH HAS BEEN MODIFIED OR REPAIRED OTHER THAN BY SALIENT OR AN AUTHORIZED REPRESENTATIVE, IMPROPERLY INSTALLED, USED, MAINTAINED, OR STORED, OR SUBJECT TO ABUSE, MISUSE, NEGLECT, OR ACCIDENT. SALIENT IS NOT RESPONSIBLE FOR DAMAGE
OR ANY OTHER LOSS DURING RETURN SHIPMENT.

Refurbished Unit Warranty

PLEASE NOTE

For the refurbished Aquamantys Pump Generators, Model numbers 40-401-1R, 40-402-1R and the 40-403-1R the Limited Express Warranty described below replaces and voids the New Unit Limited Express Warranty found above.

LIMITED EXPRESS WARRANTY

For six (6) months from the date of shipment from Salient, if a refurbished Aquamantys Pump Generator is found, to Salient's satisfaction, to be inoperable during normal and proper use in accordance with applicable instructions, Salient Surgical Technologies, Inc. will repair or replace the product, at its sole option, provided the product is returned, freight prepaid, in accordance with all return packaging and shipping instructions. A product repaired or replaced under this warranty will be warranted for the remainder of the original warranty period.

SALIENT SURGICAL TECHNOLOGIES, INC. MAKES NO OTHER WARRANTIES WITH RESPECT TO THE PRODUCT AND EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER. IN NO EVENT SHALL SALIENT SURGICAL TECHNOLOGIES, INC. BE LIABLE FOR ANY CONSEQUENTIAL DAMAGES.

THE ABOVE WARRANTY IS VOID ON ANY PRODUCT WHICH HAS BEEN MODIFIED OR REPAIRED OTHER THAN BY SALIENT OR AN AUTHORIZED REPRESENTATIVE, IMPROPERLY INSTALLED, USED, MAINTAINED OR STORED, OR SUBJECT TO ABUSE, MISUSE, NEGLECT OR ACCIDENT. SALIENT IS NOT RESPONSIBLE FOR DAMAGE
OR ANY OTHER LOSS DURING RETURN SHIPMENT.

This page intentionally left blank.

Salient Surgical Technologies, Inc.
180 International Drive
Portsmouth, NH 03801
USA
www.salientsurgical.com

Customer Service:
Tel: 866.777.9400
Fax: 866.222.0900

Outside the U.S.:
+1.603.742.1515
+1.603.742.1488

U.K. Telephone numbers:
Tel: 0808.101.1727
Fax: 0808.101.1726

70-10-1358 Rev A