CE 0483

LYSISTECH®

Radio Frequency Plasma Surgical System

User's Manual

Version 04

Table of Contents

Attention

This device has passed MDD 93/42/EEC.
It can generate and use RF energy. If not installed correctly, the device may interfere with surrounding devices. The interference can be tested by turning the device on and off. To correct it, please perform the following:

A. Change location of the device.
B. Move the device farther away from the device receiving the interference.
C. Connect the device to different electrical outlet or electro-circuit. Ask a service engineer for assistance.
D. Consult factory or service engineer for more help.

CAUTION: This device is restricted to sale by or on the order of a physician.

Section 1

System Application

1.1 General Configuration of System

This device is a radiofrequency plasma electrosurgical system with bipolar and multi polar functions. It is supposed for ablation, cutting, coagulation and hemostasis of human tissues.

There are two working modes, i.e. ABLATE for resection and ablation activated at Yellow control panel and Yellow foot pedal and COAG for coagulation and hemostasis activated at Blue control panel and Blue foot pedal. LED digital display of ABLATE value from 1-10 setting position and COAG value from 1-10 setting position. Time display is from 0-9, meaning 0-900ms, with +/-200ms error. Green light indicates power supply turned on. Accessories and single-use electrodes connected, it's green light and when unconnected it's red. Ablate and Coagulate can be adjusted using the Increase Key and Decrease Key. Press Increase or Decrease Key to increase or decrease the output value by one setting position.

A complete system mainly contain the components as follows:

1). A Generator, including 2 models: LARS600 andLARS700.
2). A Power Supply Cable.
3). A Foot Switch:AJ120. It has two working modes of ABLATE and COAG, each identified in different colors and working sounds.
4). A Treatment Cable(optional): AS130. It is reusable and supplied NON-STERILE, and is supposed for sterilization prior to use.
5). RF Plasma Surgical Electrodes, including various models, please refer to the User's Manual of the surgical electrodes for more details.
6). Flow Control Unit with cable (optional): AL100. It runs synchronously with the Generator. It can be turned on or off automatically when the Generator is activated or stopped.

Refer to the packing list for details.

1.2 Clinical Indication and Contraindication

1.2.1 Indication:

Indicated for cutting, excision, ablation, coagulation and hemostasis of soft tissues in surgical procedures. Usually, it is applicable for but not limited to ENT, Spinal, Orthopedics (Sports Medicine), Arthroscopic and Urology procedures, such as tonsillectomy, meniscectomy, lateral release, benign prostate hyperplasia, nucleoplasty, etc.

1.2.2 Contraindication:

Patients who are using heart pacemaker or pacemaker electrodes or the other electronic implants can't be treated by this device and should also not go near the device when being activated.

Refer to the User's Manual of Surgical Electrodes for more contraindications.

1.3 Features of RF Plasma Surgical System of Each Model:

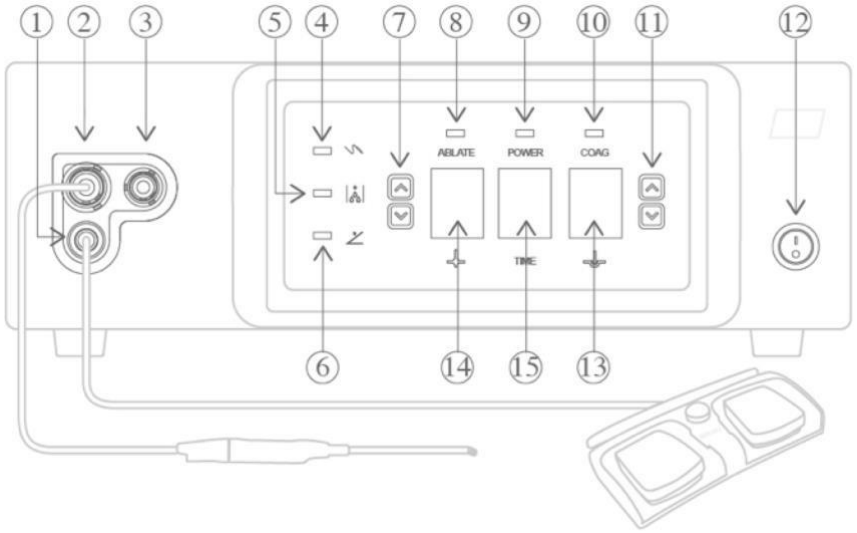
Model	Maximum Load Power of ABLATE (Bipolar Ablation & Cutting) (Error: + 20%)	Maximum Load Power of COAG (Bipolar Coagulation & Hemostasis) (Error: + 20%)	TIME CONTROL
LARS700	330W	60W	/
LARS600	330W	60W	0~900ms controllable

a) Push-button control panel makes it easier to use;
b) Special cutting electrode design to achieve fast and convenient cutting;
c) Precise time control from 0~900ms controllable. **Remark: this feature is only available for LARS600 models.**

Section 2

System Diagram

2.1 Connection Graph: Front View



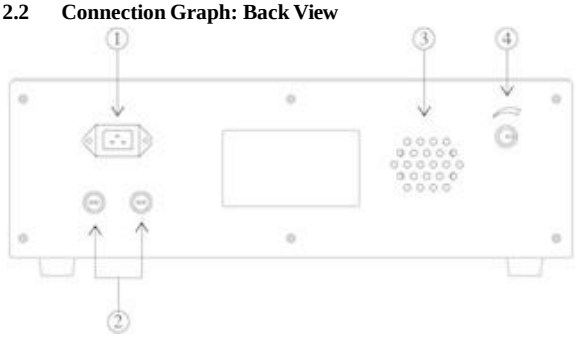
1. Socket for Foot Switch
2. Socket for Surgical Electrode
3. Socket for Saline Flow Control Unit (**Remark: no need to connect when the optional saline flow control unit is not supplied**)
4. Indicate the connection of surgical electrode
5. Indicate the connection of saline flow control unit
6. Indicate the connection of foot switch

7. ABLATE (PLA-CUT) Power Adjustment Switch

Increase Setting Key: Each press lifts one power setting level.

Decrease Setting Key: Each press lowers one power setting level.
8. Indicate ABLATE (PLA-CUT) working
9. Indicate Power On
10. Indicate COAG (PLA-COAG) working
11. COAG (PLA-COAG) Power Adjustment Switch
Increase Setting Key: Each press lifts one power setting level.
Decrease Setting Key: Each press lowers one power setting level.
12. Power switch.
13. Display of COAG (PLA-COAG) selected power setting level.
14. Display of ABLATE (PLA-CUT) selected power setting level.
15. **Time Display: This control panel and feature are only available when the electrodes that have time setting are supplied and connected**.

2.2 Connection Graph: Back View



1. Power Cord Socket: Triple-wire Power Cord, only compatible with triple-wire power source with grounded wire.
2. Fuse Socket
3. Fan Outlet
4. Button to adjust sound volume

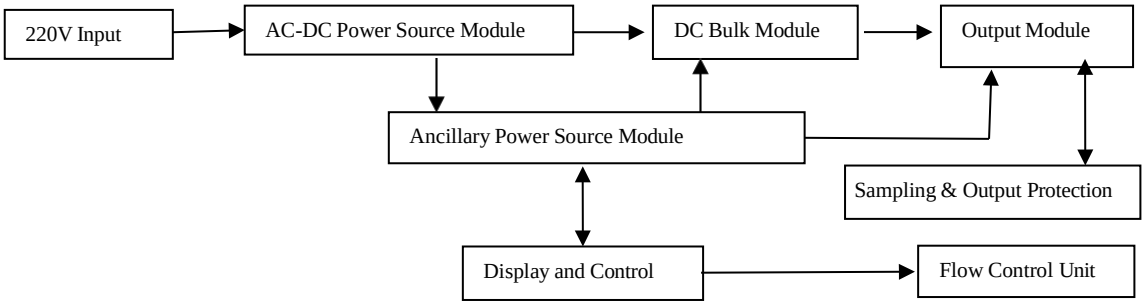
ATTN: The pictures shown in this User's Manual may differ from the real product. Refer to the real product for more detail.

2.3 Working Principles

2.3.2 How it Works:

The LARS600 and -700 RF Plasma Surgical System makes use of 100KHzradio frequency energy. The radio frequency electricity only flows between the working electrode and return electrode to generate local energy field. By the mode of plasma cutting and ablation function, it excites the electrolyte, usually normal saline, to generate a thin layer of plasma energy around the electrodes. The thin plasma layer consists of massive charged particles which can generate sufficient energy to break the organic molecular bonds within the tissue, and make the tissue rapidly dissolve at a relatively low temperature.

2.3.3 Drawing of Principle



Picture 1

The picture 1 shows the main structures of this device.

Signals are formed in the vibration unit and then output is realized in isolation via control side and power amplifier. Meanwhile, the detection circuit will inspect the output for sampling and then send feedback to the CPU control center. CPU will control accurately the output as per the preset power value. Each setting has the corresponding power range. Detection unit will monitor in real-time the impedance of the treatment part to judge the treatment degree.

Display part can show in real-time the treatment time, impedance change, power output value.

In key processing part, the operator can preset the power output, warning and impedance value and change the working models.

Treatment cable and electrodes are used to guide the power to the target tissues.

Sound display can display the treatment status during operation.

Section 3

Warnings, Cautions and Adverse Events

Below there are included the warnings and cautions during regular operation of this device. More warnings and cautions are available in the instructions for use supplied with electrodes.

3.1 Warnings:

3.1.1. Failure to follow all applicable instructions may result in serious surgical consequences.

3.1.2. FIRE HAZARD: Do not activate the working accessories close to or make contact with flammable materials like gauze or cloth covering, as it may potentially cause fire.

3.1.3. Electrosurgical accessories, when activated or hot from use, can cause a fire. Observe fire precautions at all times. Sparking and heating

associated with electro surgery may potentially cause fire.

3.1.4. After the electrosurgical current is switched off, accessory tips may remain hot enough to cause burns.

3.1.5. Do not activate or move surgical electrodes outside the field of vision as it may cause injury to the patients/users.

3.1.6. When connecting electrical equipment to the MSO effectively leads to creating a ME SYSTEM and the result can be a reduced level of safety. The electrosurgical current carried through other instruments or conductive objects may cause local burn to patients or operators.

3.1.7. Electrosurgical current may be generated in conductive objects by direct contact with the active electrode or by the active or return electrode being in close proximity to a conductive object.

3.1.8. If excessive use or excessive heating or physical forces causes damage to the surgical electrode tip, foreign body fragments may result, possibly requiring extended surgery for removal.

3.1.9. Electrical Shock Hazard: Do not connect wet accessories to the Generator.

3.1.10. Do not use non-conductive solutions (like sterile water, GW, air, gas, glycine, etc.) as medium. Use ONLY sterile conductive solutions like normal saline, Ringer lactate solution, etc.

3.1.11 Avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

3.1.12 See the appendix IV for electromagnetic compatibility warning.

3.2 Cautions:

3.2.1. Ensure that all package inserts, warnings, cautions, adverse events, and instructions for use are red and understood prior to using the device.

3.2.2. Safe and effective electrosurgical procedures are dependent not only on the equipment design, but also, to a large extent, on factors under the user's control. Only persons having adequate training and familiarity with electrosurgical procedures should perform procedures with this surgical system.

3.2.3. Before performing any procedures, consult medical literature relative to the techniques, complications and hazards.

3.2.4. Evaluate patients for predisposing medical problems that may be aggravated by the stress of surgery.

3.2.5. A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or generator grounding is not compromised.

3.2.6. When instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.

3.2.7. When not in use, remove the surgical electrodes from the surgical site and put away from metal objects. Surgical electrodes should remain separated from other electrosurgical equipment to avoid inadvertent electrical coupling between devices. Inadvertent activation may cause injury to patients or users or equipment damage.

3.2.8. Do not wrap the hand piece cable around metal objects; otherwise it may induce currents that could lead to shocks, fires, or injury to the patient or surgical personnel.

3.2.9. Do not use the electrode as a lever to enlarge surgical site or gain access to tissue which may result in bent or detached electrodes, damage to device and/or cracked spacer. The electrode is supposed for ablation and/or coagulation only, and not for mechanical displacement of tissue through applied force. This may result in bent or detached electrodes, damage to device and/or cracked spacer.

3.2.10. Do not allow fluid to contact any electrical connectors. Do not make any electrode, Generator or cable plugs contact any liquid during use.

3.2.11. Do not use the surgical electrode as a lever to enlarge surgical site or gain access to tissues.

3.2.12. Do not allow patient contact with grounded metal objects, e.g. the operating table frame or instrument table, to avoid potential shock. Grounding pads should not be used.

3.2.13. Do not contact metal objects with an activated electrode.

3.2.14. Do not user flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen.

3.2.15. Do not use flammable agents for cleaning and disinfection of Generator or cables.

3.2.16. As with other electrosurgical units, electrodes and cables can provide paths for high frequency current. Position cables to avoid contact with patient or other leads. Other electrical equipment may experience interference when positioned near this device.

3.2.17. High frequency electrosurgical equipment may adversely affect the operation of other electronic equipment.

3.2.18. Monitoring electrodes should be positioned as far as possible from the surgical electrodes when high frequency surgical equipment and physiological monitoring equipment are used simultaneously on a patient. Monitoring needle electrodes are not recommended.

3.2.19. Monitoring equipment incorporating high frequency current-limiting devices are recommended.

3.2.20. Do not open the cover of Generator and only qualified persons can do repair work.

3.2.21. Before each use, check that indicator lights and audio signals are functional. Make sure the power cable plug is properly connected to the Generator receptacle.

3.2.22. To avoid risk of fires, replace the fuse of Generator with the same type and rating.

3.2.23. The Generator malfunction may result in an unintended increase in output power value.

3.2.24. This surgical system is supposed to work as an independent unit, only to use the accessories from the manufacturer.

3.2.25 Do not touch the generator's fan and/or speaker while touching the patient.

3.2.26 Do not obstruct the exhaust fan.

3.2.27 Maintain the lowest generator power output setting necessary to achieve the desired tissue effect.

3.2.28 Confirm proper activation of the surgical electrode if a generator power output setting is chosen outside the selected and default settings.

3.3 Adverse Events

As a consequence of electrosurgery procedures, damages to the surrounding tissues through iatrogenic injury could occur.

3.4 Identification of Working and Alarming

3.4.1 **Working:** continuous single sound; working light is on, and the treatment function is activated with output.

3.4.2 **Alarming:** Discontinuous dual sound; working light is off, and no RF output.

Section 4

Unpacking, Installation and System Checks

4.1 Unpacking:

Please confirm that all components of the product are present and no inserts or packaging are missing. Should any damage or missing parts be registered, please keep all components together, including packaging and report the incident to the support team of the manufacturer.

4.2 Assembly and System Checks

4.2.1. Install the flow control unit. Connect the cable to the flow control unit and the socket at the Generator back.

4.2.2. Plug one end of the power supply cable into the socket at the rear of Generator, and plug the other end to the electrical outlet. If the power supply cable is not supplied together with the unit, to make sure it complies with appropriate electrical standards and be suitable for hospital use.

4.2.3. Press the power switch down at the Generator front and wait for 5 seconds.

4.2.4. Plug the foot switch into the socket at the front of Generator. The display light of foot switch should turn green.

4.2.5. Plug the treatment cable into the corresponding socket of the device. Prior to use, make sure the treatment cable is cleaned and disinfected, and the connection is dry.

4.2.6. Plug an electrode to the sterilized treatment cable. Plug the treatment cable to the socket at the front of the Generator. The display light of electrode turns green. If the electrode with integrated cable is used, plug the cable into the Generator socket, and no separate treatment cable is used.

CAUTION: DO NOT contact metal objects with an activated electrode.

CAUTION: DO NOT place active accessories near or in contact with flammable materials, e.g. gauze or surgical drapes.

CAUTION: Electrosurgical accessories, which are activated or hot from use, can cause a fire.

CAUTION: Accessory tips may remain hot enough to cause burns after the electrosurgical current is switched off.

CAUTION: Localized burns to the patient or user may result from electrosurgical current carried through other instruments and conductive objects.

4.2.7. When electrode is connected, the power value is automatically goes to its default setting.

4.2.8. Prepare a glass of normal hospital-grade saline.

4.2.9. Use the default power value shown when the electrode is connected to Generator successfully.

4.2.10. Take care not to touch the surgical electrode tip. Press the yellow control pedal of Ablation function, and then put the electrode tip into the normal saline. Then an orange plasma light can be seen around the electrode tip and an audible sound can also be heard coming from the electrode tip. Press the blue control pedal of Coagulation function and then put the electrode tip into the normal saline. Bubbles should be seen around and audible sound can also be heard coming from the electrode tip.

Contact your customer service department for assistance if required.

Section 5

Instructions for Use

5.1 Requirement on Operators:

Operators should be experienced in electrosurgical techniques, and it is recommended that the users remain current with advances in electrosurgical procedures.

5.2 General System Operations

5.2.1 Foot Switch:

To activate the Generator functions. It has three functions as below:

5.2.1.1. Activation of ABLATE function: Press the yellow control pedal for ABLATE to activate the ABLATE mode.

5.2.1.2. Activation of COAG function: Press the blue control pedal for COAG to activate the COAG mode.

5.2.1.3 Press the ABLATE setting adjustment button to adjust the ablation voltage level on the Generator. Each time the ABLATE setting button is pressed, the ablation voltage level increases by one level up to the maximum setting point for each electrode type. Once the maximum level for the selected electrode has been reached, the Generator will cycle back to setting point 1.

5.2.2 Settings (Power Output Value) Adjustment

5.2.2.1.  To increase the settings (power output value for Ablate and Coagulate): press the up arrow to increase the voltage level of the corresponding mode. Each press will increase the output voltage by one level until reaching the highest of setting of 10.

5.2.2.2.  To reduce the settings (power output value for Ablate and Coagulate): press the down arrow to reduce the voltage level of the corresponding mode. Each press will reduce by one level until reaching the lowest level of setting of 1.

5.3 Voltage Output

The selected voltage output value of ABLATE and COAG is LED displayed in single numbers at the front control panel. The maximum voltage output is as follows:

Model	Maximum Load Power of ABLATE (Bipolar Ablation & Cutting) (W Error: + 20%)	Maximum Load Power of COAG (Bipolar Coagulation & Hemostasis) (W Error: + 20%)
LARS700	330W	60W
LARS600	330W	60W

Model	Maximum output peak voltage of ABLATE (Bipolar Ablation & Cutting) (Vp Error: + 10%)	Maximum output peak voltage of COAG (Bipolar Coagulation & Hemostasis) (Vp Error: + 10%)
LARS700	695Vp	280Vp
LARS600	695Vp	280Vp

NOTE: If a setting point is chosen outside of the selected, default range, proper activation of the electrode should be confirmed.

5.4 System Preparations:

Refer to the Assembly and System Check process as above. Prior to each use, inspect the complete system for possible damage to the Generator case and cables.

5.5 Electrode Selection:

Select the most suitable Electrode for different surgical procedure, to optimize a safe and effective surgical procedure.

NOTE: Initial and maximum setting points are suggested settings. Proper activation of the electrode should always be confirmed.

5.6 System Shut Down:

5.6.1. Press the power supply switch up, and wait for below 5 seconds until all lights at the Generator are off.

5.6.2. Disconnect the suction tubing if appropriate.

5.6.3. If using the reusable treatment cable, remove the electrode from treatment cable and unplug the cable from the Generator. Dispose of the electrode and prepare the treatment cable for sterilization and future use.

5.6.3. If the electrode with integrated cable is used, unplug the electrode from the Generator socket and dispose the single use electrode. Do not attempt to separate the electrodes from the cable component. Dispose of the electrode with integrated cable.

5.7 Transportation and Storage

5.7.1 Transportation

5.7.1.1. This device can be transported by automobile, by train, by ship and by air.

5.7.1.2. Before transportation, pack well, to avoid potential generator damage. Do not drop the box containing the generator. On the outer packing, ensure that the indicated markings of "Upwards", "Handle with Care", "Weather Proof" are on the box.

5.7.2 Storage

5.7.2.1. Temperature: -40℃～+70℃;

5.7.2.2. Relative humidity: 10-100%;

5.7.2.3. Atmospheric pressure: 500hPa～1060hPa

This device should be stored in a well-ventilated room without corrosive gas. The height above ground and the distance from wall should be above 30cm. Stack limit is 6 cases. Before being stored for a long time, it should be cleaned thoroughly for proper packing and storage. And it should also be taken out for power up every year, in order to avoid damage from moisture, mildew or even damage.

5.8 Regulations on Equipment Disposal

The device contains an integrated circuit, so it must be treated according to the local government regulations and policies for the scraping of electronic devices. All the accessories like electrodes and cables should be disposed of according to standard medical waste procedures of that country.

Section 6

Cleaning, Disinfection and Maintenance

A complete system includes the Generator and its accessories. Prior to use, please read carefully and follow strictly the user's manual provided by manufacturer in order to guarantee a correct operation.

6.1 Device Cleaning, Disinfection and Sterilization

6.1.1 Cleaning of Generator and Accessories

Do not pour cleanser or other liquid directly on the Generator and accessories. Use a piece of soft cloth and detergent/disinfectants to clean the surface, control panels, handles, cables, footswitch, flow control unit, etc., according to standard practices. The generator and accessories can not be immersed in any fluids/disinfectants and any other solution.

6.1.2 Cleaning and Sterilization of Treatment Cable

The treatment cable is supplied NON-STERILE. It is reusable if cleaned and sterilized prior to each use. The cables hould not be cleaned and immersed in water or any other solution, otherwise the cable might not function properly. Wipe clean with a soft cloth and mild detergent like absolute alcohol as needed. Sterilize the clean treatment cable by the recommended sterilization method as below:

Sterilized by EO (Ethylene Oxide)

NO	Item	Setting
1	Preheat Temperature	40±5°C
2	Preheat Time	2h
3	Vacuumed Pressure	-18Kpa
4	Vacuumed Time	5min
5	Sterilization Temperature	50±5°C
6	Sterilization Humidity	40-80%
7	Sterilization Pressure	-18--10Kpa
8	Oxirane Dosage	9kg
9	Administration timing of drug	40min
10	Sterilization Time	8h
11	Level of Ventilating vacuum	2.0 kPA±0.2 kPa
12	Ventilation times and time in sterilization cabinet	3times 15min
13	Ventilation Time	1h

NOTE: The recommended sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated. Make sure the cable is thoroughly dry before use. Wet cable may damage the cable and generator. Damaged treatment cable should not be used.

6. 1. 3Surgical Electrodes

All surgical electrodes are strictly for single use, and supplied sterile. DO NOT clean, resterilize, or reuse the electrode as this may result in product malfunction, failure, or patient injury, which may also expose the patient to the risk of transmitting infectious diseases. Please refer to the instructions for use of the electrodes. The manufacturer is not responsible in any case or accidents related to the reuse and sterilization of the surgical electrodes. The surgical electrodes are sterilized with ETO (ethylene oxide).

6.2 Maintenance

6.2.1 Maintenance of Generator

Generator should be placed in a dry environment. There must be at least 50CM space between the Generator rear end and the wall. The ventilation openings on both sides can not be blocked, to ensure the system has proper ventilation. Two minutes before the operation, switch on the power switch of the Generator in order to warm up the system. The generator should be connected to an appropriately grounded electrical outlet to ensure security. Before the procedure begins, ensure power supply cables, handle and electrodes have a good connection.

6.2.2 Maintenance of Treatment Cable

To insert the cable correctly, always hold the cable connection. Do not insert or remove the cable from the cable line.

6.2.3 Maintenance of Surgical Electrodes

When in use, if soft tissue remnants stick to the electrode tip use a piece of wet gauze to wipe the electrode tip. Do not use sharp tools to clean the electrode tip. Do not use or continue to use the electrode if the insulation of the electrode tip is damaged. Connect and disconnect the electrode cable at the connection end and not the cable line.

Section 7

System Troubleshooting

7.1 On-site Inspection

7.1.1. Connect power supply as per standard procedures.

7.1.2. Connect the electrode, cables and foot switch, and ensure the display lights are working well.

7.1.3. Obtain a cup of conductive medium, e.g. Normal Saline, and activate the power output switch by pressing the yellow pedal (ABLATE MODE). Place the bipolar RF plasma electrode tip into the normal saline. If the orange RF plasma light can be seen around the electrode tip and the normal working sound can be heard (i.e. continual single sound), it shows the device is working normally.

7.2 Troubleshooting Guide

Troubles	Trouble Symptoms	Trouble Check and Removal
No Power Supply	No display at the control panel.	1. Check whether the power supply voltage is 220V±22V or not; 2. Check whether Power Supply Cable damaged or not; 3. Check whether fuse damaged or not.
No Power Output	After the Generator is started up successfully for a while, there is still no change found at the surgical electrode tip.	1. Check whether the surgical electrode tip is dipped into the saline. 2. Confirm the successful connection of electrode, cables and foot switch. 3. Test by using a new cable or new electrode or new foot switch to make sure all the accessories have no problem. 4. If the accessories are tested to have no problem, the problem is due to the over-low power output of the Generator. Contact our company representative for troubleshooting.

Steps for changing fuse:

1. Turn off the Power Switch and disconnect from main power, plug slotted screw into the slotted bolt on the lid of fuse, turn 90 degree anticlockwise, and then the lid on the fuse can be removed.
2. Remove the fuse lid, and remove the damaged fuse.
3. Plug a new fuse of the same specification into the fuse housing, making sure it is installed firmly.
4. Put the lid in the lid socket, plug slotted screw into the slotted bolt on the lid of fuse and turn 90 degree clockwise. Ensure the fuse lid is locked correctly.

Attention: Only qualified technicians trained and authorized by the manufacturer can arrange repair and maintenance of the device. Failure to comply with this requirement will forfeit customer's right to receive any further related service by the manufacturer.

Section 8

System Specifications

8.1 Technical Specifications

8.1.1 Treatment Cable:

Length ----------3m;

Cleaning/Sterilization Method ---------- EtO (Ethylene Oxide);

8.1.2 Generator:

RMS Current ---------- 5Amp Maximum;

Voltage ---------- 110-242VAC;

Frequency ---------- 50Hz;

Fuse Type ---------- RF1-20-5A;

Cleaning Method ---------- surface clean with disinfectant;

8.1.3 Power Output

General Frequency ---------- 100KHz;

Voltage Range ---------- 0-310Vrms@100khz;

Maximum Output Power ---------- 400W/250Ω;

Working Temperature ---------- 10-40℃;

8.1.4 Dimension of Generator:

Largest Weight ---------- 12KGS;

Height ---------- 13CM;

Width ----------40CM;

Length ----------40CM;

8.1.5 Foot Switch:

Cable Length ---------- 4.5m;

Cleaning Method ---------- Anhydrous Ethanol;

8.1.6 Transportation and Operation:

Operation Environment

Ambient Temperature	10-40℃
Relative Humidity	30~75%
Air Pressure	700-1060hpa

Environment of storage and transportation

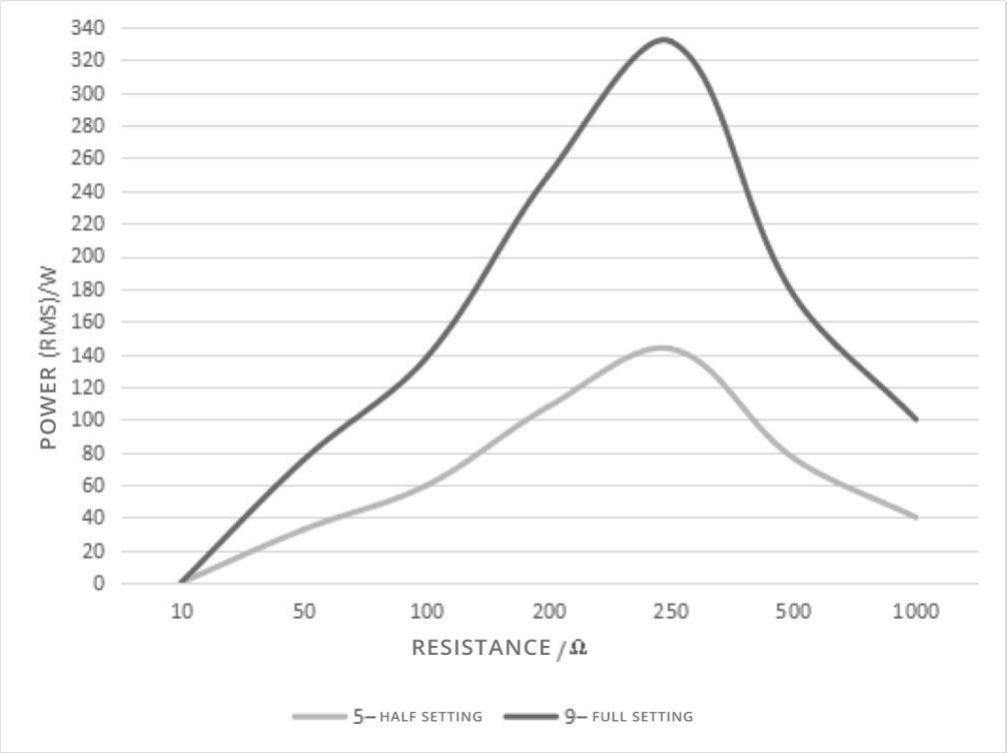
Ambient Temperature	-40-70℃

Relative Humidity	10~100%
Air Pressure	500-1060hpa

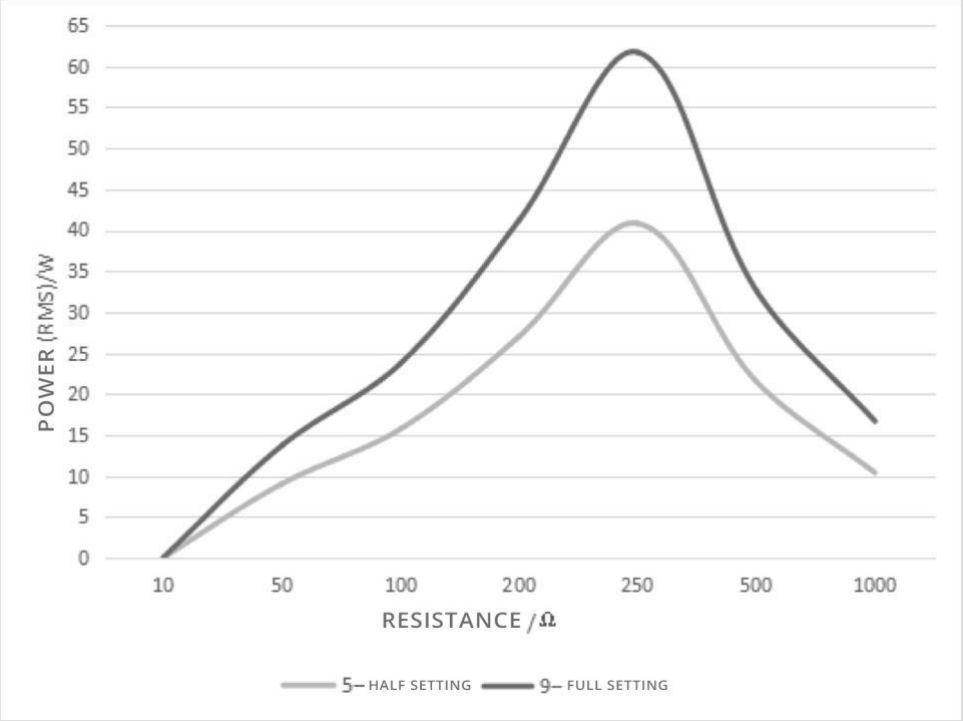
8.2 Output Graph

8.2.1 Power Output Graph

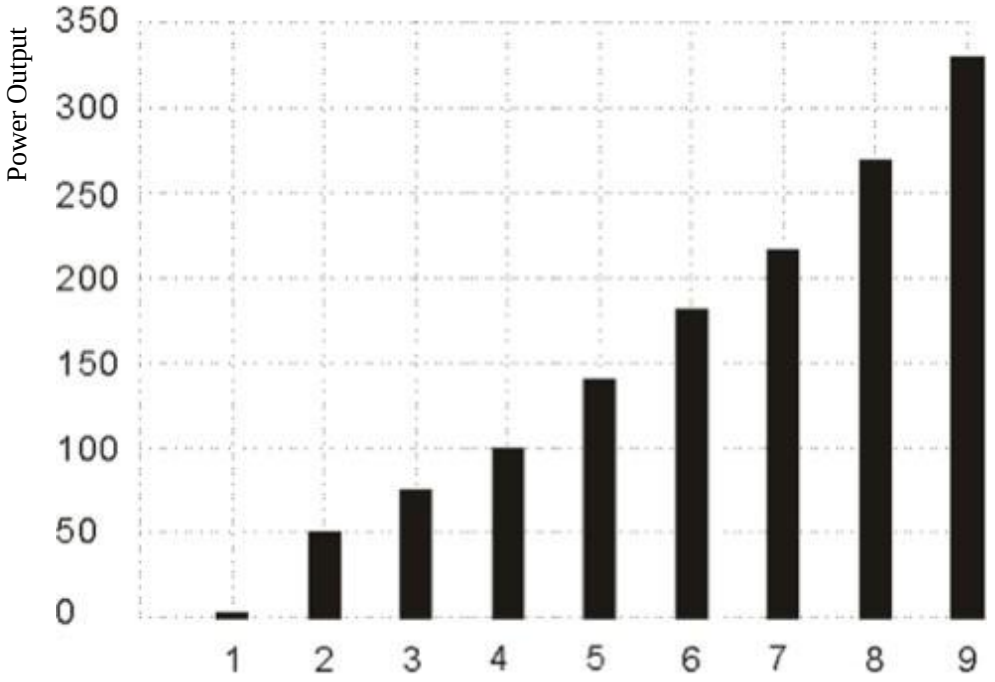
LARS700/LARS600ABLATE (Bipolar Ablation and Cutting) Mode: Relationship between Power and Load Resistance



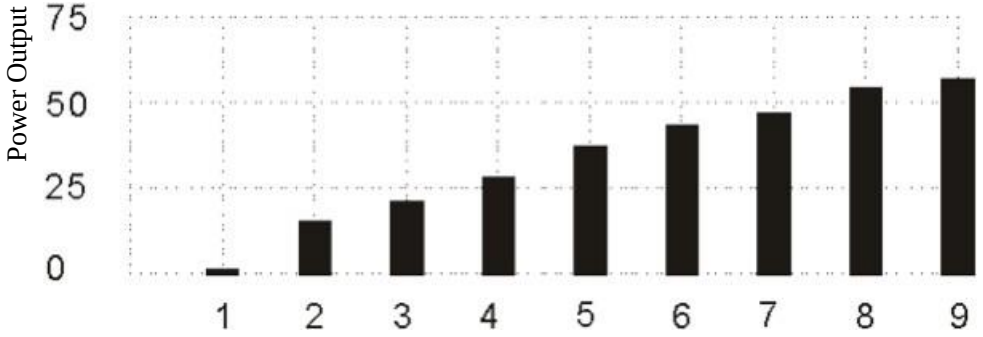
LARS700/LARS600COAG (Bipolar Coagulation and Hemostasis) Mode: Relationship between Power and Load Resistance



LARS700/LARS600ABLATE (Bipolar Ablation and Cutting) Mode: Relationship between the Setting Value under 250Ohm Load and the Actual Output



LARS700/LARS600COAG (Bipolar Coagulation and Hemostasis) Mode: Relationship between the Setting Value under 250Ohm Load and the Actual Output



8.3 System Classification

As per the regulations of EN 60601-1:2006 /AC:2010:, this device is classified as below:

8.3.1. Class I Type BF as per shock proof classification

8.3.2. Class I device as per counter-shock protection type

8.3.3. Type BF as per counter-shock protection degree

8.3.4. As per water damage protection classification, the footswitch can meet the water-proof structure requirement of Term 44.6 of EN60601-2-2:2009+A11:2011.

8.3.5. It is not recommended to use the device when flammable anesthetic agents are being used.

8.3.6. Operation mode: continuous operation in intermittent loading.

Section 9

Customer Service

9.1 Warranty Terms

From the shipment date to the original purchaser, the warranty of the generator is a period of 12 months and the warranty of the footswitch is a period of 180 days and warranty of treatment cable is a period of 90 days. During warranty, if any parts or accessories have problem caused by defective materials or defective technique, we will replace or repair them for free.

9.2 Product Complaints

Any complaints or comments about the system quality, reliability or durability of this product should be directed to Customer Service or an authorized representative. Contact Customer Service for an authorized representative for a return authorization.

9.3 Manufacturer's Obligations

9.3.1 The manufacturer is in charge ofAny products that fail to meet the product standard requirements.

9.3.2 The manufacturer shall take responsibility for patients/user injury, and property damages other than defective device itself, caused by the product defects, but the following circumstances are not included. The manufacturer has no liability for the following circumstances:

❖ No defects or problems found when the products delivered to the original purchaser.

❖The customer or user fails to read and understand the user's manual and instructions or failure to follow the relevant indications therein.

❖ Patients/user injury and property damages caused by inappropriate transportation, installation, operation, repair or storage, as well as the user's failure to follow the Warnings and Cautions provided by manufacturer.

- The customer or user fails to comply with the written request from the manufacturer related to the product performance, improvement or change.
- Patients/user injury and property damages caused due to the product modifications or alterations which are not directed by the manufacturer.
- Patients/user injury and property damages caused due to the customer's or user's negligence, recklessness or intentional wrongdoing of the product.

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Section 10

For signs and symbols please see the following table:

	Manufacturer
	Authorized Representative in the European community.
	Indicates the date after which the medical device is not to be used.
	Indicates the date when the medical device was manufactured.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates a medical device that has been sterilized using ethylene oxide.
	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	Do not resterilize
	Do not use if package is damaged
	Type BF
	Indicates cable connection
	Indicates saline flow control connection
	Indicates foot switch connection
	Indicates to increase the settingpoint
	Indicates to decrease the setting point
	Non-ionizing radiation
	The product cannot be together with household garbage discarded, it must be sent to the appropriate facilities for recovery and recycling.
	Please see the instruction manual
	See Package Inserts, User's Manual and Instructions for Use
	PLA-CUT: Ablation function
	PLA-COAG: Coagulation function
	CE mark and identification number of Notified Party. The product meets the essential requirements of the Medical Device Directive 93/42/EEC.
	Keep dry
	Keep away from sunlight

Appendix 1:

Radio Frequency Plasma Surgical System
Indications for Use

Pre-operative Preparation:

1. Connection:
1) Connect thepower cord to the power socket on the backside.
2) Connect the footswitch to the front side of Generator. Pay attention to the socket position.
3) If separate surgical electrode is used, the treatment cable is required. Connect the treatment cable to the front side of Generator. Pay attention to the socket position.
4) Connect suitable Electrode in accordance with the surgical procedure requirement.
2. Starting up the Device
1) Connect the power cord to an appropriately grounded electrical outlet.
2) Turn on the power switch, and wait for 2 minutes.
3.Choose the mode (PLA-CUT for ABLATE or PLA-COAG for COAGULATION) that is needed for the surgery.
4. Use normal saline of medical use when normal saline is required.

During-operative Instructions:

1. The surgeons can adjust the suitable power settings for relevant functions accordingly.
2. If some residual is attached on the Electrode tip when treating one patient, wipe it off by using gauze with medical alcohol immerse. Any other subjects are not recommended to use for wiping the tip.

Post-operative Instructions:

1. System shut down: Press the power supply switch up, and wait for below 5 seconds until all lights at the Generator are off.
2. Remove the plug from the wall.
3. Remove the electrode from treatment cable if separate surgical electrode is used, and unplug the cable from the Generator. If surgical electrode with integrated cable is used, unplug the cable from the Generator.
4.Dispose of the SINGLE USE electrodes, and if the reusable treatment cable is used, clean and sterilize the cable for future use.

Appendix II:

Installation of Flow Control Unit with Cable (optional)

1. The Front Side of the Flow Control Unit

2. Fix the control unit on the IV stand by the screw on the back of the Flow Control Unit

3. Connect one end of the flow control unit cable to the socket at the front side of Generator, and another end of the cable connected to the socket on the back of the saline flow control unit. Make sure the correct direction to connect the cable. After successful connection, turn on the power supply switch on the saline flow control unit.

4. After turned on, the power light on the front of flow control unit turns green, and the flow control valve opens, where the saline flow tubing can be inserted.

5. Insert the saline flow tubing inside the flow control valve and turn off the switch on the saline flow control unit.

6. Open the valve on the flow control tubing, and the saline will flow out. During procedures, the flow control unit can be acti vated together with the Generator by the footswitch.

Appendix III:

The Environmental Protection

The European RoHS (on to ban the use of certain hazardous substances in electrical and electronic equipment directive) related information。

Part name	Toxic and harmful substances or elements					
	Pb	Hg	Cd	Cr VI	PBB	PBDE
PCB	×	○	○	○	○	○
The power adapter	×	○	○	○	○	○
The power cord	×	○	○	○	○	○
The connector	×	○	○	○	○	○
Machinery parts- shaft, roller	×	○	○	○	○	○
Mechanical parts – motors	×	○	○	○	○	○
Mechanical parts – others	×	○	○	○	○	○

○ :It said components in all of the toxic or harmful substances in the same quality of a material is lower than the limit stipulated.
×:It said parts at least one kind of toxic or harmful substances in the same quality of a material is higher than the concentration limit stipulated.
This product conforms to the EU Directive 2011/65/EU (regulations on restrictions on the use of certain hazardous substances)

To dispose the device, equipment subparts, and any related accessories, the user should contact the manufacturer for receiving guidelines on proper disposal procedures.

Appendix IV:

ELECTROMAGNETIC COMPATIBILITY (EMC)

This equipment has been tested and found to comply with the limits for:

EN 60601-1-2:2007 Medical Electrical Equipment-Part1-2:General Requirements for Safety and essential performance-Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.

1. These limits are designed to provide reasonable protection against harmful electromagnetic or other interference in most installations. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful electromagnetic or other interference, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the LARS unit
- Increase the separation between the LARS unit and the affected equipment.
- Connect the non-medical system equipment into an outlet on a circuit different from that to which the unit is connected.
- Consult the dealer or experienced technical personal for help.

WARNING! Changes or modifications not expressly approved by LYSISTECH could void the user's authority to operate the equipment.

TABLES OF GUIDANCE AND DECLARATION REGARDING ELECTROMAGNETIC IMMUNITY