User Manual

ELECTROSURGICAL UNIT

ICONIC IMAGE1

KAVANDISH SYSTEM

User Manual

Iconic

Image1

V3.3
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Preface

This User Manual and the device which is described have been only prepared for qualified medical professionals who have been trained for the particular technique and surgical procedure to be performed. This manual is designed only for using Iconic Image1, a product of Kavandish System Company. More technical information for authorized service personnel of this company and its authorized representatives is available in the Service Manual.

This manual covers following devices:

Iconic Image1

Made in IRAN
Printed in IRAN

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SZUTEST ISO 13485

MTIC INTERCERT CE 0068

Intended Use

Iconic family devices are electrosurgical generators used for cutting and coagulation of biological tissue in general and specialized surgery. The devices use HF (>100Khz) electrical current thermal effects for obtaining cutting and coagulation. Intended patient population can be of any age, weight or gender.

Conventions Used in this Manual

WARNING
Indicates a potentially hazardous situation which, if it is not avoided, it could result in death or serious injury.

CAUTION
Indicates a potentially hazardous situation which, if it is not avoided, it may result in medium or minor injury.

NOTICE
Indicates an operating tip, maintenance suggestion or a hazard which may damage the device.

Warranty

- This product is warranted for 24 months from the date of device delivery to the user. During this period any failure in the device due to defective parts or system error caused by manufacture will be fixed free of charge in the company.
- To receive the warranty card, please complete the yellow sheet related to warranty card request and post it to company at the earliest time (before sending it, note that it has been filled correctly and completely).
- Failure due to negligence in transportation or incorrect use of the product will not be covered by the warranty.
- During the warranty period, any repair must be carried out by Kavandish System Company or its authorized representatives; otherwise the warranty will be canceled.
- Accessories are not covered by the warranty and in case of damage must be replaced.
- Kavandish System Company agrees to repair and provide the spare parts for 10 years from the delivery date of the product.

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Chapter 1

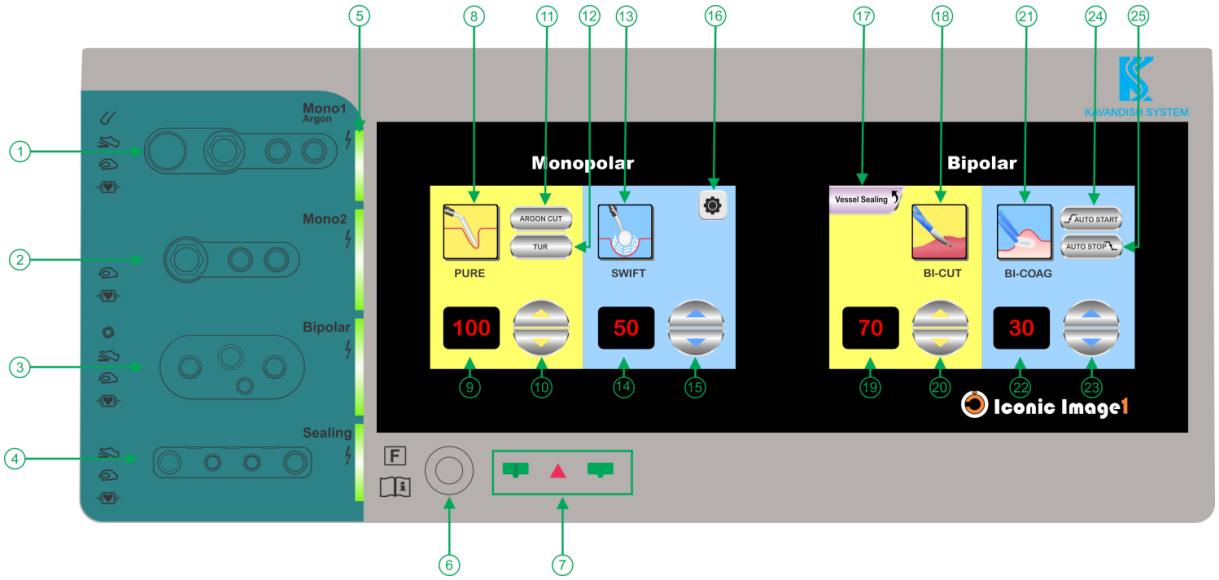
Overview and General Features

- Introduction
- Front Panel Features
- Back Panel Features
- Signs Used on Front and Back Panels

Introduction

Iconic Image1 electrosurgical generators are designed to provide Monopolar Cut, Monopolar ENDO-CUT (Papillotomy, Polypectomy), Monopolar Coagulation (Coag.), Bipolar Cut and Bipolar Coag. techniques for electrosurgery. This device provides the ability of Argon Plasma Coagulation (APC) and also equipped with the ability to coagulate large vessels (Vessel Sealing).

Front Panel Features



1. Monopolar1 instruments receptacle
2. Monopolar2 instruments receptacle
3. Bipolar instruments receptacle
4. Sealing instruments receptacle
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6. Single and dual plate receptacle (patient sheet)
7. Indicators of plate connection and related alarms

8. Selecting the default mode for Monopolar Cut
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23. Settings of power for Bipolar Coag
24. AUTO START activation
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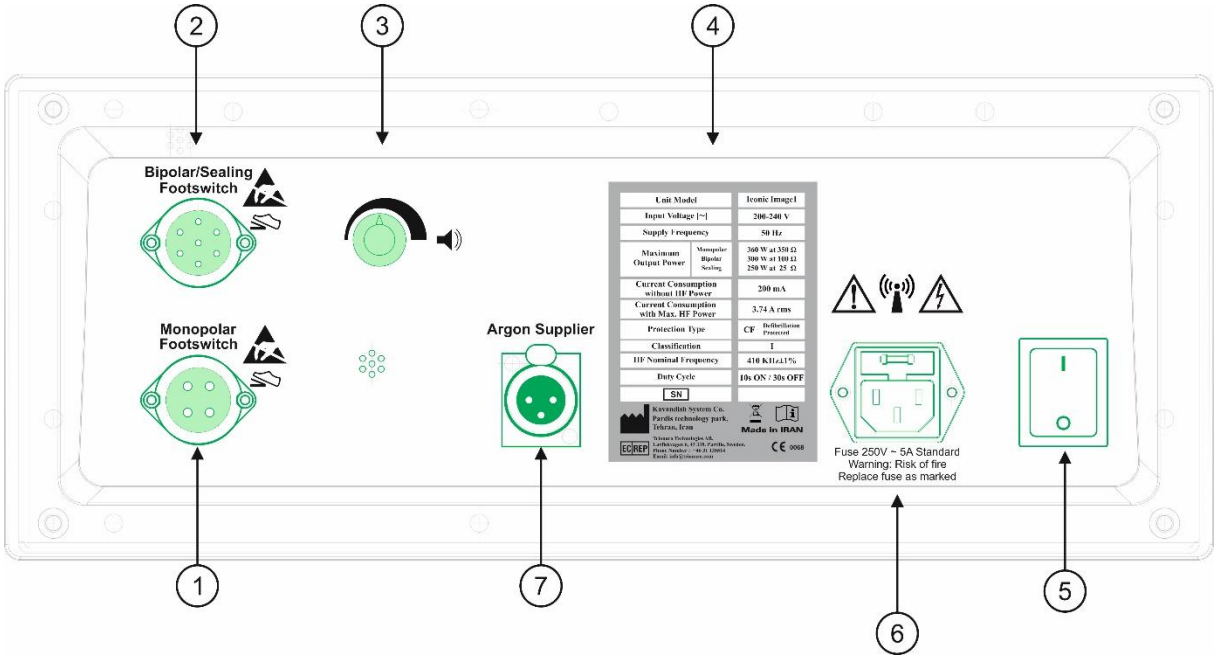
Back Panel Features



1. Monopolar footswitch receptacle for connecting a two-pedal footswitch
2. Bipolar/Sealing footswitch receptacle for connecting a two-pedal footswitch
3. Speaker volume control
4. Device identification label
5. Main (on/ off) power switch
6. Power cord receptacle and input fuse holder
7. APS1 argon supplier receptacle

Signs Used on Front and Back Panels

The degree of protection against electric shock is of Cardiac Floating (CF) type and low frequency leakage currents are negligible. Also the device is protected against high voltage due to defibrillator use for patient**.**

Adjacent output connector can be activated with hand switch

Adjacent output connector can be activated with footswitch

Adjacent output connector may be activated automatically, only through electrode contacting tissue, without pressing footswitch or hand switch.

Hazard of high voltage in the adjacent output connector

Adjacent connector can be used for TUR surgeries

Plate and other applied parts such as Monopolar, Bipolar and Sealing instruments are completely isolated from earth and supply mains outlet at both high and low frequencies.

Study the instruction manual.

This device is marked with the WEEE symbol according to Directive 2002/96/EC.

Devices marked with this symbol must be put into the separate waste collection for electrical and electronic devices. Please recycle where facilities exist.

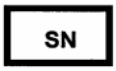
Check with your Local Authority or retailer for recycling advice **.**

Caution
Study all related sections in User Manual and or Service Manual before installation and operation of the device and or opening it for repair.

There is the possibility of electromagnetic interference on surrounding electronic units.

High voltages warning

Electrostatic discharge warning for connectors sensitive to electrostatic discharge and precautions should be made when working with them.



Device serial number

Manufacturer

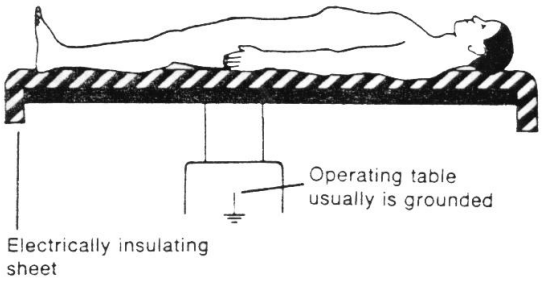
Authorized representative in the European Community

Chapter 2

General Warnings and Safety Notices

- Launching and Using the Device
- Fire Hazard
- Electromagnetic Interference
- Accessories
- Monopolar
- Bipolar
- Sealing
- After surgery
- Repairing or Servicing

Launching and Using the Device

WARNING
Study and follow all instructions and safety points provided with this manual.
Argon gas capability is supported by Iconic system using APS1 argon gas supplier device. For information regarding working principles of argon gas, advantages and its applications, APS1 installation and its connection to Iconic device, please refer to APS1 User Manual.
Check device performance in terms of appearance and safety alarms.
Electric shock hazard: use earthed outlets for connecting to supply mains.
In order to observe safety issues and avoid unwanted side effects, always use the lowest possible power which achieves the desired surgical effect. Of course in Continuous Argon and Pulsed Argon modes that the risk of gas embolism in lower power is increased, it's better to use higher powers.
Receptacles that are marked with electrostatic discharge warning symbol (IEC 60417-5134), are sensitive to electrostatic discharge and precautions should be made when working with them. Thus, make ensure of lack of electrostatic load accumulation, when connecting cables to these special connectors. Typically accumulated static load can be discharged from device body.
The patient's body shouldn't be in contact with metal components connected to the earth or with significant capacitance to the earth (for example, metal parts of the operating table, metal base of injection device, etc.) or with moist or wet fabrics. This may cause burn due to high frequency leakage current and high density of current on small surfaces (antistatic sheet is recommended).
Since the elastic surfaces on the surgery bed usually have small amount of electrical conductivity to prevent electrostatic load accumulation; therefore, they're not suitable for complete separation of the patient from the metal parts. Use dry, waterproof and thick plates for separating the patient from the operating bed and metal items, use moisture absorption towels to prevent fluids concentration under the patient. Place anti –static cloths between areas with heavy sweating and skin-to-skin contact area on the patient's torso. In addition, drain urine via a catheter.    Method of positioning patient on the operating table
Electrodes, monitoring equipment probes, irritant and imaging equipment can direct high frequency current leakage and therefore causes unwanted burn. Thus, when using high frequency electrosurgical device with these equipment; it's necessary that each electrode or monitoring probe be placed, if possible, far from surgical electrodes and patient plate and the minimum distance of 15 cm be observed between active electrode and ECG electrodes. Using needle electrodes is not allowed for monitoring and if you're forced to use this type of electrodes, separate cables of needle electrodes from the monitor during electrosurgical device activation. In any case it is recommended that high frequency current limiter monitoring systems is utilized.

WARNING
In order to reduce the risks of high frequency current leakage from unwanted directions, use the following measures: • As much as possible use low voltage modes, like Pure mode that has lower voltage than Blend mode and also Soft or Swift modes that have lower voltage than Spray mode. • Avoid keeping the device active in open circuit mode that active electrode is not in electrical contact with tissues.
In case you notice device output power is less than normal, check the following issues before increasing device power. • Make sure that the desired position on the device panel, footswitch or hand switches are correctly selected. • Do not put objects on the device. • In Monopolar technique, make sure of correct and complete plate connection. • Check cables and connectors connection to the device. • Clean electrodes tips completely from adhesives material.
If a failure occurs in the system, it is possible that device output power (in contrast with the selected power) increases.
If instruments are not used temporarily, keep them separate from surgery area and contacting with patient or conductive objects that are in contact with the patient. This prevents patient burn in case of unwanted device activation (due to accidental switch press).
Take the following steps to reduce the risks of minimally invasive surgery (such as laparoscopy) that sometimes burn occurs in the area not visible by the surgeon. • Check insulation quality and note that any crack, gap and ripple can be a sign of insulation weakness and a direction for current leakage. • Use minimum power and modes which uses minimum voltage. • Active the generator just when active electrode is contacted with tissue. • If active electrode is in the vicinity of metal parts or in contact with them, the generator should not be activated. • Use Bipolar method whenever it is possible. • If possible, use All metal cannula that external metal sheath covers all cannula system to reduce the possibility of leakage due to capacitated coupling.
Do not wind instruments and plate cables around metal objects; this can cause current leakage through metal objects and also high frequency induction in these objects causes them to hot up and create burn.
Use isolated ocular parts in cases such as endoscopy and TUR and note that because active electrode is in constant contact with tissues, any unwanted activation of the generator can cause burn in the active electrode contact with tissue.
Avoid coagulation as long as possible in the method that between active electrode and hemostat instrument, electric arc is established. In this method, first contact metal to metal and then activate the generator, this reduces unwanted shocks to surgeons
Neuromuscular stimulation and following inadvertent consequences such as spasms or muscle contractions may occur in modes with high output voltage such as spray mode due to low frequency harmonics in electric arc. The device has been designed to minimize such stimulations.
If alarm is heard from the device, check the device status and make sure of its correct operation condition before reusing it.
To minimize adhesive effects of active electrodes to tissues during coagulation, do not activate the generator before electrode contact with tissue and stop the current upon sufficient coagulation and keep the electrodes always cleans.

WARNING
Active electrodes may be hot due to electrical sparks and or contact with tissue during cutting and coagulation and their contact with other tissues can cause unwanted burn.
In cases the active electrode has constant contact with tissue even when the generator is not active, (eg. in endoscopy or TUR) more attention should be paid to visual and auditory signs of generator activation; and when there is no need to activate generators, for example during electrode take out from the patient's body, definitely set the output power displays in lack of output power mode or turn off the device.
In case generator is unwantedly activated and if electrodes are directly or indirectly through wet fabric or other conductor objects in contact with patient's body, it can cause burn. Unwanted generator activity can be due to accidental activation of ` device, generator is activated, the failure is due to the device. To avoid unwanted burns, never place active electrodes such that directly or through conductive objects or wet fabrics be in contact with patient.
Be careful in using of ESU in thin wall organs like intestine to avoid undesirable perforation. Set power as low as possible.
To prevent the staff's burn, avoid contact with patient during the activation of the ESU.
During activation, prevent patient body movement in the surgery site.

CAUTION
Some particles containing smoke and vapor are released in the environment due to surgery with electrosurgical device. The particles contain toxic chemicals, carbonized tissue, blood particles, bacteria and little amount of carbon dioxide. Therefore it is recommended to discharge the smoke by proper means and install suitable filters. Also the recommendations in this regard should be given to the operating room personnel and exhaust channels and open areas should not be used for smoke discharge. During surgery masks with high filtering effect with the lowest carbon particles inhalation must be used.

NOTICE
For ease in future follow-ups, register the device serial number in the patient's records.

Fire Hazard

WARNING
There is the risk of gases or flammable substances combustion when using electrosurgical device. Thus, avoid the flammable substances contact with electrodes of electrosurgical device.
Use of electrosurgery in o2 rich environments increases the risk of fire. Therefore, take measures to reduce the o2 concentration at the surgical site. Avoid enriched o2, n2o atmospheres near the surgical site.
If the surgery is performed in the region of the head and chest, do not use flammable anesthetics or oxidant gases such as nitrogen oxide (N2O) and oxygen. If use is unavoidable, you must extract the combustion-supporting gases before performing electrosurgery.
There is the risk of flammable solutions accumulation under the patient or body's dimples such as umbilicus and body cavities such as vagina. It's better to dry any liquid accumulated in these places before using the device.
Avoid flammable gases that are naturally produced and are accumulated in body cavities such as intestines. Extract the flammable endogenous gases in the gastrointestinal tract before performing electrosurgery or irrigate with co2.

WARNING
Some materials such as string, cotton and gauze when being saturated with oxygen, may be flamed when it come to contact with sparks produced in the normal use.
If flammable disinfectant materials (those which have alcohol base) are used, let them being evaporated before covering the patient and avoid flammable material contact with electric arc during surgery.

Electromagnetic Interference

WARNING
There is possibility of electromagnetic interference between electrosurgical device and adjacent electronic devices. Therefore, in case of observing unusual condition in adjacent devices, consider the above possibility and apply special measures of electromagnetic compatibility to solve the interferences.
In case interference occurs only when the generator is activate, then following steps can reduce the interference: • Reducing the device output power. • Using low-voltage modes, for example Pure mode instead of Blend mode or Soft or Swift modes instead of Spray mode. • Using Bipolar technique instead of Monopolar technique. • Increasing the distance of device and its external cables from the unit which is affected due to interference (such as monitor).
If patient has pace maker or other electronic devices implanted inside the body, there is risk of interference in their performance and even damaging them. In such cases, if you have to use electrosurgical device, take the following actions to reduce the risk: • Use Bipolar technique as much as possible. • Check cables and their connections and connection of plate to the patient carefully to prevent spark due to connections weakness. • Select the plate location such that it is close to the operation area and heart or pace marker should not be positioned between plate and operation area. • Definitely consult with cardiologist before the operation • Use reliable monitoring equipment and continuously pay attention to ECG signals. • Defibrillator should be always available.

NOTICE
Iconic needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the Iconic Service Manual and also this user manual.
Portable transmitters and RF telecommunication can affect the electrosurgical device operation.

Accessories

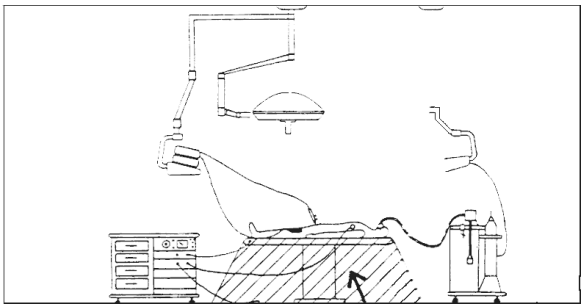
WARNING
Never use non-standard, poor quality, damaged and defective accessories and always make sure insulator of these devices is intact.

WARNING
Do not leave the electrodes of other equipment (such as monitor) on the patient body. They can create a path for leakage current and cause burning.
It is better that whenever accessory is replaced, the proper power level is adjusted again regarding to new accessory.
Using non-standard and defective accessories or using unauthorized accessories will be followed with the consequences listed below: • Unwanted generator activation • Generator break down • Injury or electric shock to the patient or surgery team • Inactivation of monitoring system of contact quality of plate to patient • Unwanted selection or mistake in surgical modes • Reducing or connecting and disconnecting output power • Electric shock or muscle nerves stimulation due to electric arc between two metals. • Electromagnetic interference in monitoring equipment (when the generator is activated) • Excessive high frequency current leakage
Never use accessories that their cable is rotted, tear or crushed or due to pressure or being coiled is deformed and sure that their pin is not broken.
Only use those instruments that can tolerate maximum output voltage (Vp) in each mode. For information regarding the maximum output voltage please refer to technical specifications chapter. In the related table maximum voltage is given as Vp-p= (2×Vp). Using instrument with rated voltage less than maximum output voltage may cause damage to the patient, operator or the instrument. It's essential that rated voltage of each instrument be provided from its manufacturer factory.
It is recommended to use the accessories whose length up to 3 m.
Note that disposable accessories should not be used several times.
If you are not confident in the compatibility of your accessories, please contact Kavandish System Company or its approved representatives for their compatibility status.
Monopolar instruments must be connected to Monopolar receptacles and Bipolar instruments to Bipolar receptacle and Sealing instruments to Sealing receptacles and never to be mismatched.
All accessories must be placed securely and without need to high pressure
Never use converters for connecting accessories to the generator.
Never connect two surgical devices to an output receptacle simultaneously, because this will cause that both devices be simultaneously activated and inactivated.
Always keep surgery electrodes clean. Necrotic tissue remaining on the electrodes increases the path resistance and reduces optimal performance. Also note that the electrodes can get hot at the time of device activation. Therefore, after inactivating the device, the electrodes shouldn't have any contact with patient's body.
Electrosurgical accessories should be positioned such that their unwanted contact with patient or with each other is avoided. Active electrodes that are not used should be kept separate from the patient. Also, cables connected to the surgical instruments are better to be placed in a direction that avoided contact with patient or any other conductive object so that the risk of unintended burn is reduced.

CAUTION
It's essential that placing and removing accessories connectors from the device are done slowly and gently and high pressure to cables and connectors should be avoided.

CAUTION
Avoid wrapping instrument cable tightly, with pressure, and also around the instrument; because this may cause cable deformation in the long run.

Footswitch

WARNING
It must be noted that footswitch should not be used in the region 25 cm from areas that are likely to leak flammable anesthetic materials. This area is known as Medical Zone which is shown in figure below.  The area that only protected switches from fire hazard can be used.
Use non-flammable substances for cleaning and disinfecting footswitch.

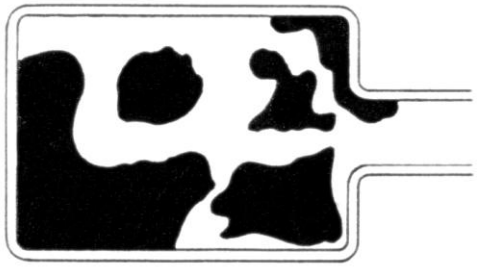
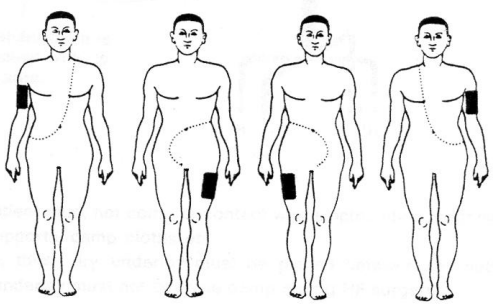
NOTICE
Never use footswitch cable for footswitch transportation
Avoid applying pressure to the cable connection to the footswitch.
Avoid wrapping cable around footswitch firmly and with pressure.

Monopolar

WARNING
Prevent skin to skin contact (for example between arms, the patient's body or thighs). For that purpose a towel or dry gauze can be used. Also, the parts of patient's body that have excessive sweating and there is the possibility of having contact with other parts of the body, should be kept dry with a towel.
Note that if two surgeons activate Monopolar1 and Monopolar2 outputs simultaneously in Spray mode, output power is divided between the two surgical pens. So, power connection or disconnection in one Monopolar pen can affect on the other output power.

Plate

WARNING
Correct use and proper placement of plate is one of most important points in effective and safe use of Monopolar electrosurgery.
Kavandish System Company suggests using dual plates to increase patient safety. In case of single plate use, contact quality of plate with patient will not be monitored by the device.
In case of using polymer plates, definitely use silicon and standard types. Non-standard rubber plates with unknown brands can cause burn. Worn and old polymer plates will lose its quality over time

WARNING
Select kind and dimension of plate according to the table related to the minimum surface required for plate on page 29 and output power. And place the plate such that a suitable contact surface is established between itself and the patient's skin. If the effective contact surface is low due to weak and imperfect contact, it could cause burn resulting from current density increase in contact area.  Reduction of effective plate area ☐ Electrical current conductor area ■ An area that doesn't conduct electrical current since it has no contact with skin and because of being oxidized or contaminated with lipid particles has a weak conductivity.
Increase electrical conductivity of the skin of patient's body that neutral electrode is placed on it through cleaning, massaging to increase blood circulation in skin and shaving hair of contact area.
Avoid placing plate on hypodermic large blood vessels or bones or parts that blood circulation is usually weak.
In permanent plates, use proper gel uniformly on all plate surfaces. Fix plate position using rubber bands and wrapping band around it so inner surface of plate has good connection in patient skin and in case of moving the patient, check correct plate connection again.
If gel is not used, be careful that during surgery, any fluids or moisture due to bleeding, or washing or disinfectant liquids or patient's body sweat does not reach the plate. Due to penetration of those liquids to plate, may increase the possibility of burn in the area
All over the current conductive area from plate should be fixed, in an appropriate location that blood circulation in that area is normal (such as upper arm and thigh), in the closest area to the operation position. Such that direction of current flow between the plate and Monopolar active electrode be the short possible path and as much as possible does not pass through heart and lungs. 
Never use water, salt water solution or wet fabric for strengthening plate to patient contact.
In case electrically conductive parts are placed inside the patient's body, choose the plate location such that those parts are not in the current path.
Never deform patient's plate against the manufacturer's instruction and note that they're not torn or interrupted.
Always make sure that cable insulation of neutral electrode in intact.

NOTICE

It is recommended that plate position and patient's skin condition is recorded in patient document before plate placement.

Bipolar

WARNING

Based on advantages of Bipolar technique that are expressed below; it is recommended to use Bipolar techniques in all practical possible cases which the area of current flow in body is small.

- In Bipolar technique, due to the limited area of the current effect region which is small area between the two tips of forceps, it requires lower output power, and no need for plate. Therefore it has much less burn hazards than Monopolar technique and also prevents unwanted coagulations.
- In Bipolar technique, due to smaller current flow through tissues and lower output power, possibility of electromagnetic interference in electronic devices is much less than Monopolar technique.

One of Bipolar technique problems is tissues adhesion and blood clots on the two forceps' tips. This issue sometimes causes recurrent bleeding when removing forceps form the tissue. To minimize the effects of adhesion, please consider the following:

- If the system is enabled before electrode-tissue contact, the first spark between the electrode and the tissue can cause tissue carbonization and sticking tissue to the electrode. Thus as far as possible, do not enable Bipolar generator before electrode-tissue contact. For this purpose, use Auto Start mode with or without delay.
- Keeping forceps on the tissue for a long time can cause tissue carbonization which itself causes tissue to stick to the forceps. Therefore disable the generator once the sufficient coagulation is done. And avoid continuing coagulation process without having beneficial effect (It is suggested to use Auto Stop mode).
- Always keep electrodes clean and after each use completely remove effects of tissue adhesion due to the previous coagulation.
- If dry tissues are operated under Bipolar technique, moist them with sterilized water or physiological salt solution previously.

Whenever during Bipolar surgery, the electrode sticks to the tissue, before separating the electrode from the tissue deactivate the current and wait for a few seconds so that capillaries discharge and adjacent tissues reduce the adhesion effects. In more severe cases, sterilized water or physiological salt solution can be used.

If Auto Start mode is selected, necessary precautions should be made. Since if electrode contacts with the tissue, the generator will be automatically activated.

Ensure that no instruments are being cleaned when Auto Start is activated.

CAUTION

During coagulation, electrodes surface are covered with tissue fluids. While the fluids are being dried, it can prevent full electrical current flow through the electrodes surface and the surgeon feels the output power is low. This problem will be resolved by cleaning the electrode after each coagulating.

Sealing

WARNING

Do not use this technique so long you haven't learned how to use the device in Sealing technique and have not learned procedure of using related surgery instruments in this technique. Using the device without training could have adverse results.

WARNING
Using Sealing technique is not appropriate for tubal sterilization or tubal coagulation for sterilizing processes.
For patients with particular vascular problems such as atherosclerosis or aneurismal vessels, seal positions must be selected on healthy vessels.
Using the wrong mode when working with a surgical instrument causes either no sufficient reliability for seal quality or damage to the tissue due to excessive heat.
In order to apply the required mechanical pressure during sealing, surgical instrument must be completely locked. Otherwise, created seal will not be reliable.
Tissue close to the jaw hinge of surgical instrument and outside the two jaws will not be sealed (even if it turns white by applying energy).
Conductive fluids such as blood or saline in the vicinity or direct contact with surgical instrument can transfer heat and electrical energy to adjacent tissues. Thus, dry sealing area before starting the process.
Surgical instruments must be completely dry and fully connected to the generator
External surface of surgical instrument may be too hot after the end of the process. Be careful of contacting and damaging to other tissues.
Do not activate the generator when jaws of surgical instrument are adjacent to a metal tool. In this case it is possible that energy is not transferred to the tissue or the patient or doctor is being injured.
Note that during sealing process, the power level cannot be changed. Therefore before starting the process, be assured of the desired power level setting and the selected mode.
In case of observing any spark, immediately stop the surgery and check all connections of the generator and electrode. Metal to metal spark can cause patient neuromuscular stimulation.
To create a seal with good quality, It is better to place vessels with their surrounding tissue in the jaws of surgical instrument. Thus the created seal will show more strength.
During sealing process, the vessels should not be under tension or mechanical pressure. The reason is that in the condition that vessel wall begins to melt and change its condition, the slightest tension causes distortion and separation in wall structure which results in bleeding.
Cleanness of surgical instruments surface has an important role in proper and appropriate energy transfer to the tissue and completing sealing process.
Frequent use of disposable surgical instruments causes tissue adhesion to the electrode, creating electric arc, and reducing seal quality

NOTICE
If during Sealing technique activation, Monopolar technique activation is demanded. Monopolar will not be activated and Sealing continues.

After surgery

WARNING
Gently, open the communication cables from connectors.
Gently, separate the plate from the patient and see plate to patient contact area to investigate any possible injuries and burn.
If possible, for cleaning and disinfecting the device use non-flammable materials.

WARNING
In case you have to use flammable materials for cleaning and disinfecting the device, wait a while until these materials are completely evaporated, before turning the device on.
Sometimes, other factors rather than increase of electric current density cause necrosis. It should be noted that such factors should not be mistaken with burns caused by electric current density increase that only occur at patient connection with metal objects or incomplete plate to patient connection area. One of those pseudo burns is chemical burns which caused by prolonged tissue contact with disinfectants material. Another kind of those pseudo-burns is related to tissue being under pressure during surgery. Tissue necrosis may occur in patients who undergo surgery for a long period of time (such as open heart surgery or neurosurgery) or after they stayed in ICU under anesthesia or with no movement. To prevent such necrosis, adequate care must be taken to avoid placing patient's tissues under prolonged pressure which could prevent supplying proper blood to tissues. Also despite the burn caused by electrosurgical device which shows itself immediately or one hour after surgery, the signs of those pseudo-burns may show themselves hours or even days after surgery.

NOTICE
Penetration of liquids into the device can cause damage to it; Since there is the possibility of liquids penetration from its bottom side, observe necessary precautions during cleaning and disinfecting the device.
The expected service life of the device is 10 years. Do not dispose of this device in the unsorted municipal waste stream. It should be placed in separate waste collection for electrical and electronic devices. Always comply with the national regulations of the relevant country when disposing of or recycling the device or its components.

Repairing or Servicing

WARNING
Danger of electric shock: Never open the device case. Any modification or repair on device must be done by authorized service personnel from Kavandish System Company.

Chapter 3

Installation and Launching

- Before Launching
- Turning on the Device
- Checking the Device before Using in Operating Room

Before Launching

1. After opening the device package, please check the physical condition of device and its accessories. In case of damage due to transport or any other cause, please contact Kavandish System Company and notify failure type, device serial number, and your address.
2. Place the device on a fixed flat and without vibration surface.
3. Connect the device to electric network (200 V to 240 V) via power cable.

WARNING
To ensure compliance with safety issues and suitable earth for the device, use earthed outlets for connecting to supply mains.

NOTICE

Selecting a suitable location for the device can prevent system damage and injury.

Turning on the Device

1. Turn on the device using the main power switch (on the back panel).

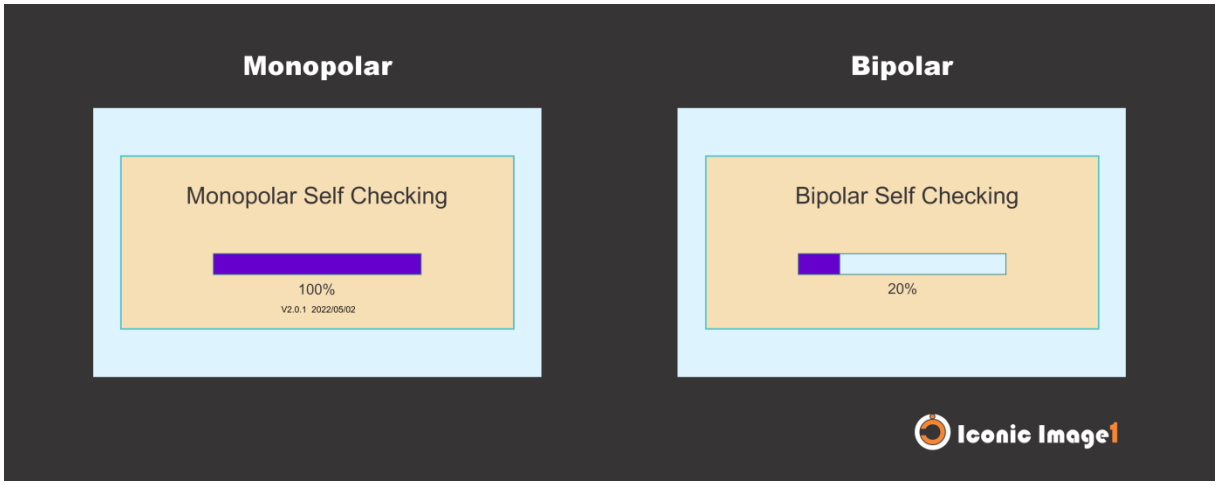
NOTICE

To avoid receiving any false errors, all accessories should be kept detached from the system at turn on time and during the self checking of the device.

2. Observe and check the following when the device is turning on and during self-checking (testing different parts of the device).

- Self-checking is displayed in several pages:

In this main page of self-checking, the progress of self-checking process is shown. It starts with Monopolar self-checking (left side) and continues by Bipolar self-checking (right side).



- If after complete checking, no problem is observed, the message of “No Errors Reported” will be displayed on the screen.
- If any errors are detected, the error codes will be displayed by this message: “Error codes are:”.

  In such case please refer to alarm code tables on chapter 8 of Iconic user manual, to find more information about types of error. Obviously, the modes in which failure has been reported will not operate correctly.
- Finally, “welcome to Image1” message will appear on the screen.

- Default programs will be displayed on the screen after self-checking. Press OK to enter the mode pages.

After starting normal operation, Er: PT alarms will be generated if the plate is not connected to the device (see Alarms section).

Accessories:
The accessories provided with the IMAGE1 device are as follows:
1. Disposable Monopolar pen
2. Disposable dual plate
3. Plate cable
4. Bipolar forceps open surgery 20 cm
5. Bipolar cable
6. Two channel pedal
7. Power cable

Checking the Device before Using in Operating Room

If you turn on the device for the first time, before using the device in the operating room, test the performance of the device using the following instruction:

1. First, turn on the device and observe Self Checking processes according to the previous section. After entering the normal operating condition, mode adjustment and power setting must be according to default condition. At this stage, the screen displays the selected modes.
   Firstly, default modes appear. Selectable modes icon have a shadow around them. It is assumed that the default pages display the selected modes, so each selected mode will eventually be placed on the default page.

   The default modes on the screens are more useful modes with specific powers.

NOTICE

"•" in power displays is the sign of not selecting power in the output.

2. Carefully check all device accessories including each technique instruments, plate and footswitches, if they are ok, connect them to the device.
3. If normal single plate is connected to the device; LED indicator of single plate connection must be on. If normal dual plate is connected to the device, and if it is completely contacted with tissue, LED indicator of dual plate connection must be on. Otherwise, alarm LED related to lack of proper plate connection will be on and corresponding alarm will be generated.
4. For activating Monopolar, put a piece of raw meat (or raw fruit, or a bar of soap or a piece of damp cloth) on the plate and by pressing hand switches on Monopolar instrument or corresponding footswitch, activate Monopolar Cut and Monopolar Coag. techniques and apply the output to the raw meat through Monopolar instrument. Each time by activating generator, the margin of the activated mode will get red and continuous sound of speaker will be heard. Simultaneously, information about selected technique and mode, generator activation type and alarm (if any) appears on the screen. Do this test for both Monopolar outputs.
5. Change power levels in Monopolar Cut and Monopolar Coag. and by output activation, see the output power variation on the raw meat.
6. There are two default modes on the Vessel Sealing page including Large Seal and Fine Seal. After selecting any of these modes and by pressing the finger switch on the Sealing instrument or by pressing the bipolar blue pedal, you can apply the output to the raw meat by the tool.
7. To enter the bipolar modes page, you must select Bipolar Surgery.
8. In Bipolar technique, by pressing hand switch on Bipolar instrument or corresponding footswitch, apply the output on the raw meat through the instrument. Do this for both Bipolar Cut and Bipolar Coag. techniques (by setting them through corresponding buttons) and repeat it for different power levels.

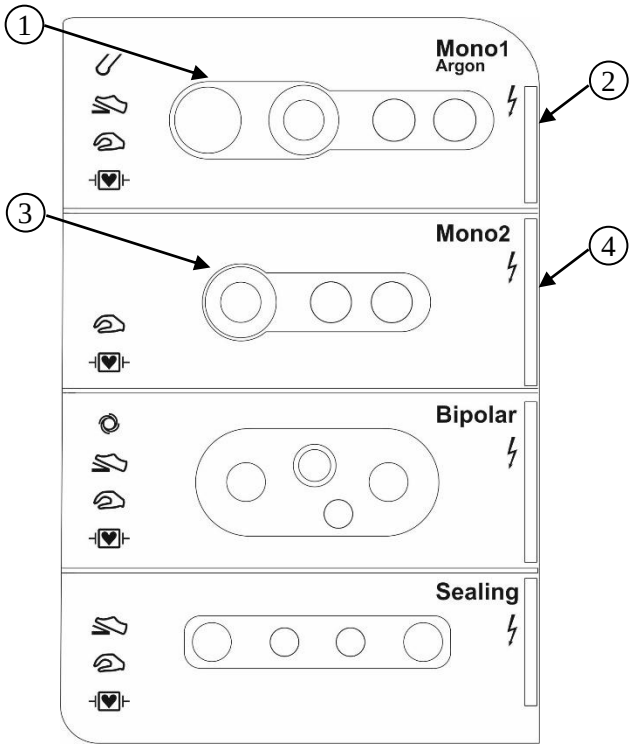
9. Select Auto Start mode for Bipolar Coag. technique and put Bipolar instrument on raw and damp meat. In this mode Bipolar generator automatically, with 0 to 2 seconds delay depending on the selected value (Setting → Adjustment → Auto Start Delay) is activated.

Chapter 4

Monopolar Technique

- Information Regarding Monopolar in Receptacles Module Section
- Monopolar Receptacles and their Accessories
- Patient Plate
- Footswitch
- Capability of Using Argon Gas
- Monopolar Cut Modes
- Monopolar Coag. Modes
- Power Level Changes in Monopolar
- Output Power Selection in Monopolar
- Important points in using ENDO-CUT technique
- Coagulation intensity changes in ENDO-CUT
- Method of Monopolar Cut Setting
- Method of Monopolar Coag. Setting
- Method of Using Monopolar

Information Regarding Monopolar in Receptacles Module Section



(1) Monopolar1 instruments receptacle

NOTICE

Use of output along with argon gas (in argon modes) is possible only via Monopolar1 receptacle

NOTICE

In most programs, Monopolar1 is activated with the pedal. Therefore, Monopolar instruments that do not have a hands-switch (such as TUR instruments) must be connected to this connector.

(2) Indicator of Monopolar generator activation and receiving output via Monopolar1 receptacle

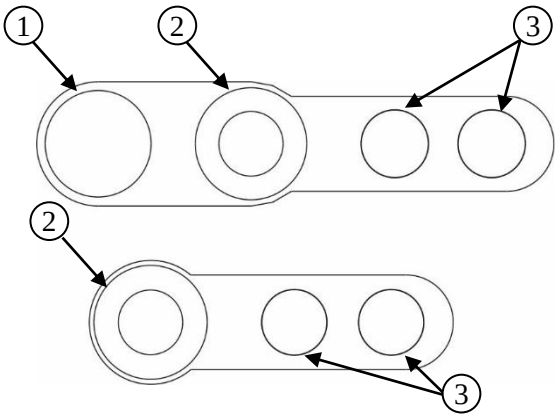
(3) Monopolar2 instruments receptacle

NOTICE

Monopolar2 is activated with a hands-switch. Only in program number 10 called APC-Endocut, this connector is activated with a pedal. In this program, you can connect Polypectomy Snare to Monopolar2 and argon probe to Monopolar1.

(4) Indicator of Monopolar generator activation and receiving output via Monopolar2 receptacle

Monopolar Receptacles and their Accessories



(1) 8 mm connector
(2) 4 mm coaxial connector
(3) 4 mm normal connectors

The high frequency main current path is from 8 mm connector and core of 4mm coaxial connector. 4mm normal connectors and 4 mm coaxial connector outer shield are used for hand switch connections.

Monopolar Instruments

WARNING
Kavandish System Company recommends only using Monopolar instruments within the device package which are approved by its quality control department or from the following companies: Bowa, Fiab, Martin, Tecno and Metko and Valleylab.

In the Iconic product, you can use various Monopolar instruments with variety of connectors. Specifications of those connectors are presented in below table.

Instrument Connector	**Activation Type**	**Iconic Monopolar connector**	**Description**
1-pin connector with 8 mm plug 	Footswitch	8 mm connector	In addition to Monopolar pen, this connector can also be found on devices such as endoscopy, laparoscopy and TUR
Connector with 4 mm coaxial plug (Martin type) 	Footswitch and hand switch	4 mm coaxial connector	--
1-pin connector with 4 mm normal plug 	Footswitch	Core of 4 mm coaxial connector	In addition to Monopolar pen, this connector can also be found on devices such as endoscopy, laparoscopy and TUR

3-pin connector 	Footswitch and hand switch	Core of 4 mm coaxial and 4mm normal connectors	--

WARNING

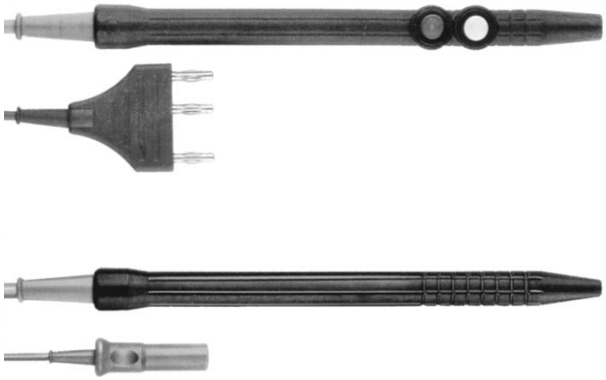
When Monopolar is active, all output connectors of the relevant Monopolar receptacles and pens connected to these connectors have voltage. Therefore necessary precautions should be made and never connect two pens to a Monopolar connector simultaneously.

NOTICE

Use auxiliary connectors just for 3-pin pens. 1-pin connector instruments should not be connected to those connectors. Such connection could damage the Monopolor receptacle.

Only Monopolar instruments which is connected to Monopolar1 receptacle can be activated by footswitch

Monopolar instruments are activated in two ways. Some instruments have hand switches which can be activated either this way or by footswitch. Other instruments don't have hand switch and can only be activated by footswitch.



Usually, there are two push buttons on Monopolar instruments using hands witches; the surgeon selects cutting mode by pressing yellow button which is closer to the tip and coagulation mode by pressing blue button.

WARNING
Note that cables and Monopolar pens must have sufficient insulation to withstand output voltage of device (according to maximum output voltage graphs). To ensure this, it's necessary to refer to documents associated with Monopolar pen. The importance of this issue is higher in high voltage modes like spray mode; in those modes, damage or weakness of cable and pen insulation can cause unwanted effects and burn.
Monopolar cable and pen are not repairable and in case of damage a new pen must be used.

Monopolar Electrodes

Various types of electrodes of different shapes and sizes are used as an active electrode in Monopolar surgery. Those electrodes are installed on Monoplar pens. Electrode installation and replacement are easily done and the surgeon can choose their intended appropriate direction by rotating each electrode.

Some types of electrodes such as knife electrodes are provided with the device which covers common surgical uses. However, the surgeon may use other types of active electrode which can be installed on Monopolar pen depending on their needed specific mode.

NOTICE

To prevent electrode damage, always use appropriate boxes for storage and transportation.

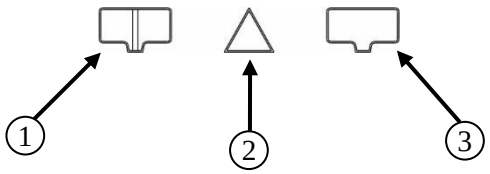
Patient Plate

In Monopolar technique, the current enters the patient body through Monopolar pen electrode, and returns back to the device through plate (neutral electrode). Plates are in different types of single and dual. Those types of plates can be connected to Iconic plate receptacle using 6.3 mm diameter connector.

WARNING

Kavandish System Company recommends only using plates within the device package which are approved by its quality control department or from the following companies: Bowa, Erbe, Fiab, Martin, Shuyou and valleylab.

Plate Indicators on the Panel



① Indicator of dual plate connection
② Indicator of plate alarms
③ Indicator of single plate connection

If a single plate is connected to the device, indicator of single plate connection and if a dual plate is connected to the device, indicator of dual plate connection turns on. If any alarm is detected related to plate (see alarm conditions on page 58), the indicator of plate alarms related to lack of appropriate connection turns on and the two indicators of plate connection turns off.

Patient Plate Monitoring System

Reduction of surface contact of neutral electrode or its weak connection to patient body can increase current density and thus may cause burn on contact place. This device is equipped with patient plate monitoring system and thus reduces the burns caused by inappropriate plate connection to patient body.
Patient plate monitoring system permanently (both in active and inactive state of generator) measures plate resistance with 100kHz±10kHz frequency. Based on plate resistance, plate type and its connection quality to body are determined. Therefore, the following three cases may occur:

- If resistance is less than 25 Ohms, it will be detected as a single plate. In this case, because of using a single plate, quality of plate connection to patient cannot be investigated.
- If resistance is between 25-150 Ohms, it will be detected as a dual plate and monitoring system is able

to investigate the quality of plate connection to patient. In this case resistance changes are also calculated in addition to resistance in order to investigate changes in quality of plate connection to patient. And if the measured resistance at any time increases more than 50 percent relative to the minimum measured resistance, a poor connection quality is considered and the alarm of plate problem is generated by alarm system. Of course resistance changes are only investigated in the inactivity state of Monopolar due to because of possible impact of generator noise on plate circuits. Generator active state is short and the probability of changes in the plate connection status in short times is too small.

- If the resistance is higher than 150 Ohms, Then either the plate connection to body or device is not established, or the connection quality is low. In this case, the alarm system generates plate problem alarm.

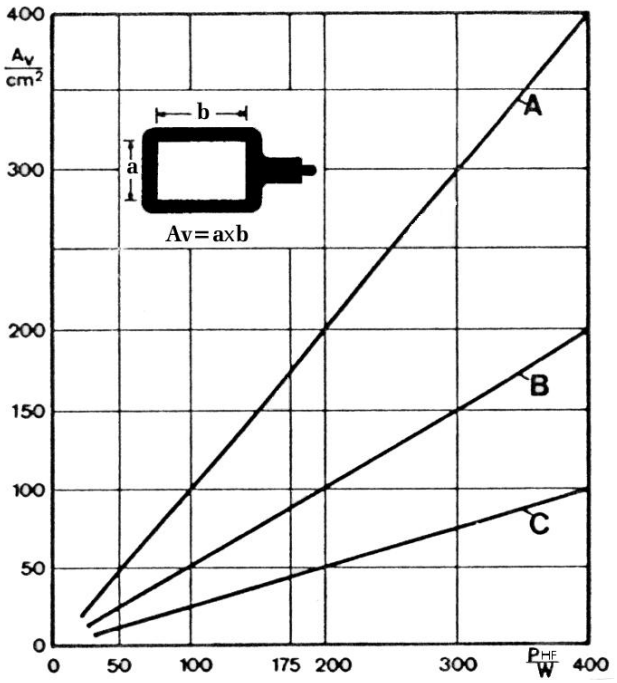
Consequently, plate monitoring system is able to detect the inappropriateness of plate condition and automatically take the following actions:

- If the plate is not connected to the device or any damage occurs in the cable and plate connector path to the device which disconnects the connection path; appropriate alarm is generated and prevented from activation or operation continuation of the Monopolar generator.
- If dual plates are used, the appropriate plate connection to patient is investigated and if the effective contact area is not enough, the suitable alarm is generated and prevented from activation or operation continuation of the Monopolar generator.
- If dual plates are used and Monopolar generator is inactive, changes in plate connection to patient are investigated and if those changes are higher than adequate level, the suitable alarm is generated and prevented from Monopolar generator operation.

WARNING
In dual plates, its effective contact area to patient body is of great importance and if there is any problem in the quality of plate connection to patient body, the device will sense it and generates the alarm.
Using dual plates extensively reduces unwanted burns in plate location.

Material and Dimension Selection of Patient Plate

Choosing material and dimension of patient plate depends on the used output power. In the following figure the minimum required surface area for different types of plates is shown.



A: patient plate is made of silicon rubber.
B: patient plate is made of stainless steel without using electrical current conductor gels.
C: patient plate is made of flexible metal plate with using electrical current conductor gels or disposable plates having current conductor gels or sticky gels.

WARNING
For patient safety, it is necessary to use the minimum required contact surface area for patient plate based on the maximum output power used on each patient.

Footswitch

In order to use footswitch in Monopolar technique, it is necessary to connect a two-pedal footswitch to the Monopolar footswitch receptacle on the back panel. In this case, by pressing yellow pedal, Monopolar Cut and by pressing blue pedal, Monopolar Coag. will be activated.
The two-pedal footswitch provided with the device is as follows:

WARNING
Kavandish System Company recommends only two-pedal footswitch within the device package which are approved by its quality control department.

Capability of Using Argon Gas

Capability of using argon gas for surgery has been provided in Iconic device. For this purpose, APS1 argon gas supplier device has been designed and made for Iconic support. APS1 is responsible for controlling and argon gas directing to the surgical probe. Argon gas exiting from the tip of the surgical probe, by placing high voltage between the electrode tip and tissue surface, argon gas is ionized and direct path with low impedance for electric current passing is created as argon gas plasma. The ionized gas flow in this case will have brightness with special blue light. Generally argon system is used for both coagulation and cutting. However argon application is very limited in cutting and its main application is surface coagulation. Argon gas used in surgery has many advantages, some of which include:

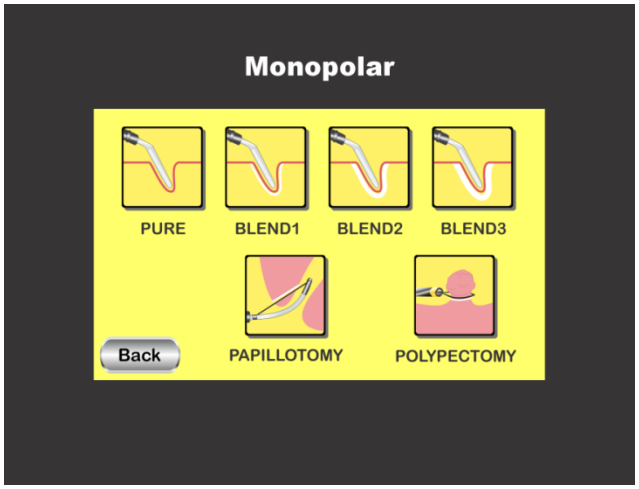
- The ability to control argon ray and therefore controlling energy position apply and reducing adjacent tissue damage.
- Reducing electrode adhesion to the tissue due to probe distance from tissue surface
- Reducing odor and smoke surgery due to removing oxygen from surgery position
- The possibility of tissue surface coagulation (between 1 mm to 3 mm) with high speed and in aboard and uniform surface

WARNING
For using argon gas capability, provide APS1 argon gas supplier device for supporting Iconic device and for information on principles of argon gas working, its advantages and applications, APS1 installation and launching and connecting it to Iconic refer to the User Manual of APS1 device.
Be careful about the risk of perforation when using APC in thin-walled tissues such as cecum.

Monopolar Cut Modes

Monopolar Cut modes that are displayed by pressing the default mode icon and entering the mode selection page are:

PURE, BLEND1, BLEND2, BLEND3, PAPILLOTOMY, POLYPECTOMY



Pure: This mode provides pure and smooth cut with minimum coagulation in surrounding tissues. In this mode damage to the surrounding tissues during cutting is minimal.

Blend: In this mode in addition to cutting, the tissues adjacent to electrode will be coagulated. 3 blend degrees exist for controlling coagulation depth of adjacent tissues during cutting. By increasing the blend degree from Blend1 to Blend3, the rate of coagulation of adjacent tissues will be greater. In Blend3 tissues adjacent to cutting area will be more coagulated than other cut modes. As a result, this degree is suitable for cutting tissues with excessive bleeding and tissues with fat layers.

- **Papillotomy:** In this mode, tissue cutting and coagulation are performed in pulses with a specific timing and according to tissue conditions. As a result, coagulation intensity and cutting speed will be under the surgeon's control. In addition, in this mode, the device intelligently detects the tissue cut and at the same time, with the sound of an additional beep, the tissue cutting will be notified to the surgeon. In this way, the surgeon will get more information about the speed and amount of tissue cut and safety will be improved during the surgery. This mode is used for needle electrodes and sphincters.
- **Polypectomy:** The description of this mode is similar to the description of Papillotomy, except pulse timing that has been changed to optimize the direction of wire snare or loop electrodes.

- **Papillotomy and Polypectomy are optional modes and are available upon customer request.**

TUR: This mode has been prepared for surgery in fluid environments such as bladder and prostate. It will be activated along with one of the optional modes of Pure, Blend1, Blend2 and Blend3 as a complementary mode to create clinical effects of those four modes in fluid environment operation.

Argon Cut: This mode has been prepared for cutting tissues along with argon gas. It will be activated along with one of the optional modes of Pure, Blend1, Blend2 and Blend3 as a complementary mode to create clinical effects of those four modes with argon gas. Using argon gas with cutting creates a clean cut along with smooth coagulation for the surgeon. The mode can be used for cutting tissues with high impedances such as cartilage (please refer to User Manual of APS1)

- Monopolar Cut modes which are shown by pressing default mode icon and entering mode page are: Pure, Blend1, Blend2, Blend3

Notice

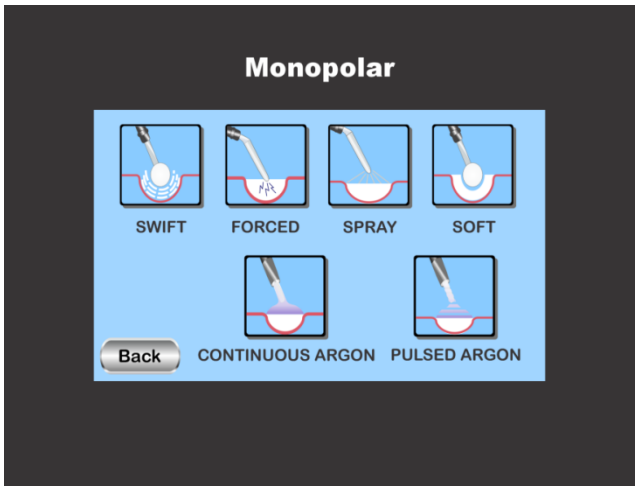
Since Argon gas can only be used via Monopolar1 receptacle, in case the Argon Cut is selected but needs to use Monopolar2 receptacle, then the selected output is activated as complimentary mode (one of Pure, Blend1, Blend2, and Blend3 modes) without Argon gas.

Each one of Monopolar Cut modes (PURE, BLEND1, BLEND2, BLEND3) can be activated with Argon Cut and TUR that are existed on default page and the inside of these two icons turn to green by selecting.

Notice

After activation, an orange shadow and a red border will display around the mode icon to alert the user. Since the device is activated there is no possibility of touching the screen or changing the power or selecting the mode.

Monopolar Coag. Modes



Swift: This mode is used for rapid coagulation of tissues using electrodes with relatively large cross section such as ball, plate electrodes or forceps (the surgeon takes the position with forceps and contacts the active electrode to it).

Forced: This mode is used for deep coagulation of tissues using electrodes with small cross section.

Spray: This mode is used for coagulation of tissues surfaces with low depth without contacting the electrode with tissue. The main feature of this mode compared to others is its more electric arc intensity and the possibility of coagulation by the use of electric arc without direct contact of electrode with tissue. This mode is appropriate for minimizing the effects of cutting and tissue separation. If this mode is selected, the two Monopolar1 and Monopolar2 outputs can be activated simultaneously; whereas in other modes in the case of demand for activating two Monopolar outputs, priority is given to Monopolar1 and Monopolar2 will not have output.

Soft: This mode is used for soft coagulation of tissues without carbonization and adhesive effects of tissue to electrode. In this mode, the output power is lower than the three previous modes.

Continuous Argon: This mode is the most popular and practical method for electrosurgery using Argon. In this mode continuous electric current along with Argon gas is applied to tissue. In general, this mode is applied for cases which continuous coagulation is needed in a large area with high speed. The common mode for coagulation of tissue surface is Spray Mode. But due to lack of control in accidental movement of electric arc, there is possibility of damaging the normal tissues in surrounding coagulation area. While using Argon gas helps to remedy the above problem (please refer to APS1 device User Manual).

Pulsed Argon: In this mode, the electric current is applied to tissue in form of pulse along with Argon gas. This mode compare to the previous one, the energy applied to tissue is reduced and creates lower coagulation. In general, the pulse is used when low argon gas power and depth is needed. Therefore, the tissue destruction (creating whole or tear in tissue) is minimized. This mode mostly used in laparoscopy and for thin and sensitive tissues (please refer to APS1 device User Manual).

Notice

Since Argon gas can only be used via Monopolar1 receptacle, in case one of Continuous Argon or Pulsed Argon modes selected, but the activity from Monopolar2 receptacle is requested, then the output would be activated according to Forced mode without Argon gas. In this case regarding patient's safety, if the adjusted power for Forced mode is more than adjusted power for argon mode, Forced mode will be activated with the argon mode power.

Power Level Changes in Monopolar

In Iconic, Monopolar adjustable power level is divided into different ranges. Step of power level changes in various ranges is different:

- Range 1: from 0 to 50 with step1
- Range 2: from 50 to102 with step 2
- Range 3: from 105 to 200 with step 5
- Range 4: from 200 to the end with step 10

Output Power Selection in Monopolar

Selecting the appropriate output power value in Monopolar technique is one of the most important effective factors in cutting and coagulation quality. Optimal power value depends on different factors such as geometry of the used active electrode, speed of surgeon's hand, the way of electrode movement on tissue, tissue characteristics, and selected current waveform.
Although power selection completely depends on surgeon's experiences and opinion; but following considerations are recommended for appropriate power selection:

- In Pure mode, in the case of using needle or lancet electrodes which have small diameter, lower powers and with larger diameter electrode such as knife electrodes, higher powers should be used.
- In fat tissues cut, the selected power must be greater than for other tissues cut due to the increased electrical resistance of those tissues.
- Since there are layers of dried blood and tissues on surfaces of dirty electrodes, which prevents sufficient current flow, there is a need to select excessive power. To prevent using excessive power; it is necessary to keep the surface of active electrodes clean.

Important points in using ENDO-CUT technique

1. The thinner the diameter of the electrode wire, the greater the cut and the less coagulation.
2. If the polyp is on the tissue with less wall thickness, the risk of perforation is higher and less coagulation surface should be used.
3. If the pedal is released immediately and not kept long enough, the device will not enter the coagulation phase and the possibility of bleeding will increase.
4. Do not pull the snare. Pulling the Snare with the goal of achieving a faster cut increases the likelihood of bleeding.
5. Closing the snare with excessive force causes the snare dipping into the tissue, increasing the contact area of the snare and decreasing the current density. In these conditions, the onset of tissue cut may be delayed and excessive coagulation may occur. Excessive coagulation increases the likelihood of perforation. Try to close the snare with a balanced force.
6. To prevent problems caused by excessive contact surface between sphincterotomy and tissue, insert only one-third of front of the cut wire into the papilla.
7. Before activating the device, make sure that there are no internal gases in the body, especially in case of intestinal obstruction possibility.

Coagulation intensity changes in ENDO-CUT

Adjustable changes for each mode in ENDO-CUT are 4 levels, which can be adjusted on the screen with the power up and down keys. In ENDO-CUT, increasing and decreasing the surface does not have a significant effect on the cutting speed, but rather affects the coagulation intensity. The higher the level selected, the higher the coagulation intensity. Therefore, it is recommended to use the higher level when the probability and severity of bleeding is higher. Note, that more coagulation also increases the likelihood of perforation.
Due to the greater coagulation depth at higher levels, it is recommended to use lower levels where the tissue wall thickness is low.

- Level 1: L1 (with very low coagulation)
- Level 2: L2 (low coagulation)
- Level 3: L3 (medium coagulation)
- Level 4: L4 (high coagulation)

To be sure, you can check the snare tool on the wet gauze before entering to the endoscope channel. (Wet gauze should be placed on the plate)

Method of Monopolar Cut Setting

1. For setting Monopolar Cut technique on each of Pure, Blend1, Blend2, Blend3, Papillotomy and Polypectomy, press the default mode icon on main page and then select the desired mode.
2. If TUR or Argon Cut mode is selected, for complementary modes among Pure, Blend1, Blend2 and Blend3, press the default icon on the main page to select the desired mode.
3. Power value of the current mode is displayed in Monopolar Cut power display. Press the power set buttons to change the value. Power value will change one unit by each time you press on the buttons. To speed up power value change, keep your finger on the button.

Method of Monopolar Coag. Setting

1. For setting Monopolar Coag. technique on each of Swift, Forced, Spray, Soft, Continuous Argon, press the default mode on the main page and then select the desired mode.

2. Power value of the current mode is displayed in Monopolar Coag. power display. Press the power set buttons to change the value. Power value will change one unit by each time you press on the buttons. To speed up power value change, keep your finger on the button.

Method of Using Monopolar

1. Connect the desired plate to the plate receptacle (on the front panel).
2. Connect the desired surgical instruments to the Monopolar receptacle (on the front panel).
3. If footswitches is used, connect footswitch to Monopolar footswitch receptacle (on the back panel).
4. If modes along with argon are used, then setup APS1 and connect it to Iconic.

WARNING
For use of Argon gas advantage, use APS1 Argon gas supplier device in order to connect to Iconic device. For information regarding principle of working with Argon gas, its benefits and advantages, installation and launching of APS1, and connection to Iconic please refer to APS1 device User Manual.

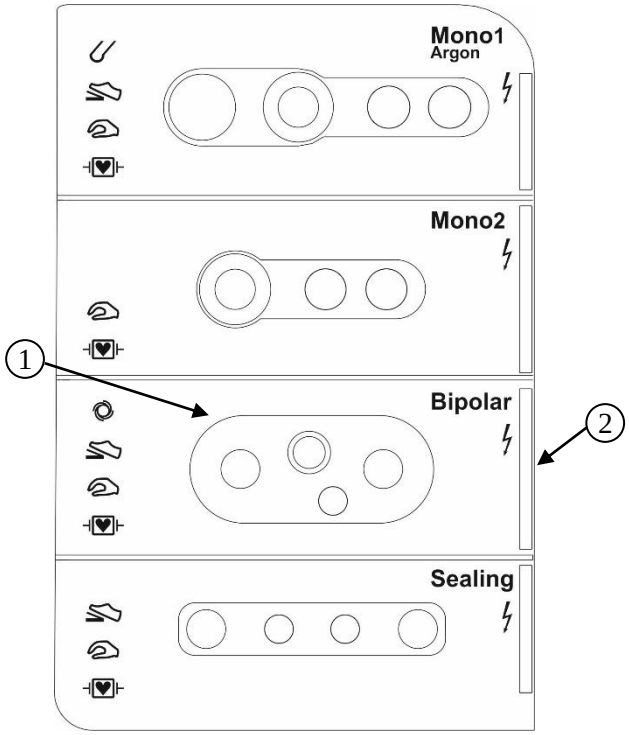
5. Settings of Monopolar can be done in setting section. (please refer to the previous two sections).
6. Place the surgical instrument on the tissue.
7. Press yellow hand switch or footswitch for Monopolar Cut activation and blue hand switch or footswitch for Monopolar Coag. activation. By Monopolar activation, LED indicator of Monopolar generator activation (related to the Monopolar Cut or Monopolar Coag.) will be on and continuous speaker sound is heard. To proceed with cut or coagulation keep the generator active.
8. Stop generator activation after the desired cutting or coagulation by removing the pressure on hand switch or footswitch.

Chapter 5

Bipolar Technique

- Information Regarding Bipolar in Receptacles Module Section
- Bipolar Receptacle and its Accessories
- Footswitch
- Bipolar Cut Modes
- Bipolar Coag Modes
- Power Level Changes in Bipolar
- Output Power Selection in Bipolar
- Method of Bipolar Setting
- Method of Using Bipolar

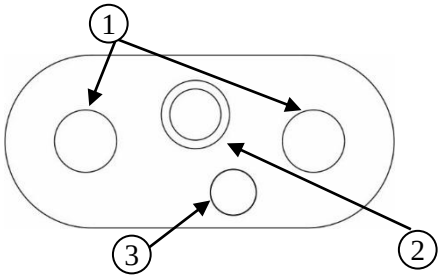
Information Regarding Bipolar in Receptacles Module Section



(1) Bipolar instruments receptacle

(2) Indicator of Bipolar generator activation and receiving output via corresponding connector

Bipolar Receptacle and its Accessories



(1) 4 mm normal connectors with 30 mm distance from each other

(2) 2 mm coaxial connector

(3) 2.5 mm connector

The high frequency main current path is from 4 mm normal connectors and 2mm coaxial connector. 2.5mm connector is used for hand switch connections.

Bipolar Instruments

WARNING
Kavandish System Company recommends only using Bipolar instruments within the device package which are approved by its quality control department or from the following companies: Bowa, Fiab, Martin, Tecno, Metko and Valleylab.

In the Iconic device, there is the possibility of using various Bipolar instruments having a variety of connectors. Specifications of those connectors are presented in below table.

Instrument connector	Activation type	Iconic Bipolar connector
2-pin connector 	Footswitch	4 mm normal connectors
Twin connector 	Footswitch	4 mm normal connectors
3-pin connector (American company type) 	Footswitch and hand switch	4 mm normal connectors and 2.5 mm connector
Connector with 2mm coaxial plug (Martin type) 	Footswitch	2 mm coaxial connector

Bipolar Coag. Forceps

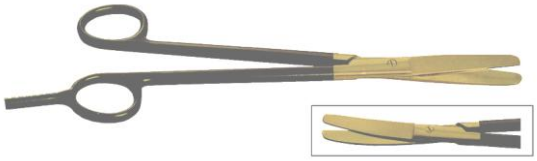
There are a variety of Bipolar forceps with various shapes and sizes which can be used for tissue coagulation.

In Bipolar forceps, except the two ends of forceps, the rest of areas are covered with insulating material. Thus, coagulation doesn't occur in other areas except the forceps tips when contacting with the tissue. Also it will not cause surgeon's hand irritation when Bipolar output is activated.

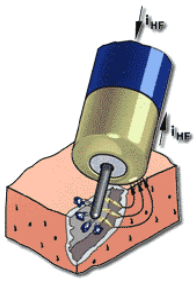
Notice

Do not tightly press forceps or open its tips, because it will damage the coating of forceps insulation

Bipolar Cut Scissors

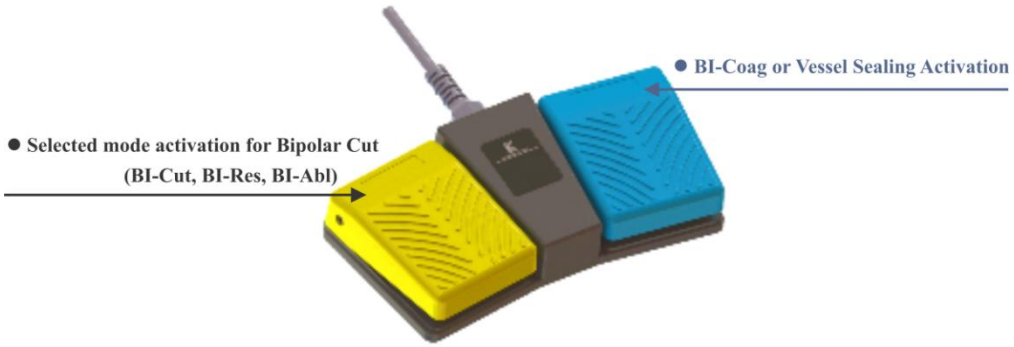


In addition to scissors, some other instruments are used for Bipolar Cut. Those instruments are used in special surgeries. An example of such instruments is shown in the following figure. In this instrument, one of the polar is a thin needle-shape electrode, which is suitable for tissue cut and the other polar is a metal cover to provide the returning current path.



Footswitch

To use footswitch in Bipolar technique, it is essential to connect a two-pedal footswitch to Bipolar/Sealing footswitch receptacle on the back panel. In this case, by pressing the yellow footswitch, the Bipolar Cut modes and by pressing the blue footswitch, the Bipolar Coag/Sealing modes will be activated. The two-pedal footswitch provided with the device is as follows:



Notice

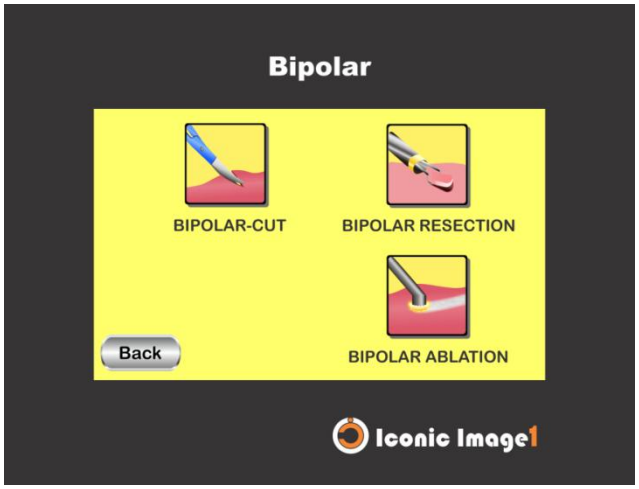
If the device activation request is created on the Bipolar screen by the Vessel Sealing handswitch, the Bipolar screen will change to the Sealing screen and the selected Seal mode will be activated.

WARNING

Kavandish System Company recommends only using two-pedal footswitch within the device package which are approved by its quality control department.

Bipolar Cut Modes

Bipolar Cut, Bipolar Resection and Bipolar Ablation are displayed by pressing the BI-Cut icon.

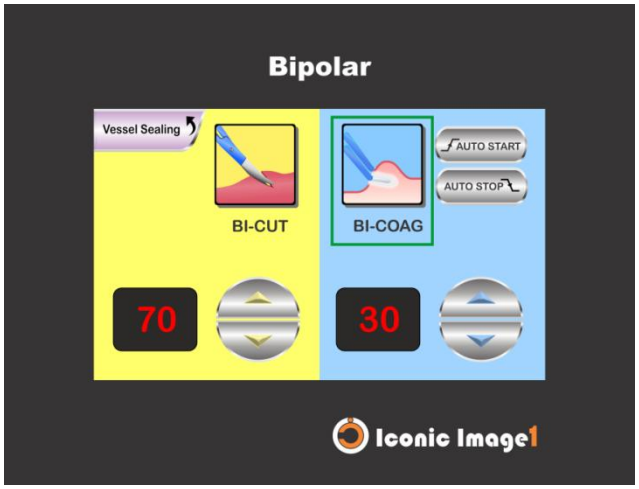


Bipolar Cut: This mode is used for tissue cutting with limited current path. In this mode current path is limited to part of the tissue between the blades of scissors. Therefore, a dramatically less power is needed compared with Monopolar Cut technique. Consequently, this technique is safer for patient.

- **Bipolar TUR (Resection):** Bipolar TUR is used to cut tissues in saline solution in TransUrethral Resection. In Bipolar Resection technique, it is necessary to use normal saline. It is recommended to start with 70W for cutting and increase the power if the cutting is not done well. BI-Cut is activated by yellow pedal and BI-Coag is activated by blue pedal.

- **Bipolar Ablation:** This mode is used to shave tissues with special ablation tools in Arthroscopic surgery or Tonsillectomy. In this mode, by creating plasma in a normal saline environment, the amount of heat is reduced and the lateral damage to the surrounding tissues will be less.
- **Bipolar TUR (Resection) and Bipolar Ablation are optional modes and are available upon customer request.**

Bipolar Coag Modes



Bipolar Coag.: Bipolar Coag. mode provides soft tissue coagulation without carbonization and tissue adhesive effect to electrode. In Iconic, the possibility of selecting Auto Start and Auto Stop are provided for this technique.

Auto Start: In this mode the possibility of automatically activating generator in Bipolar Coag. has been provided. If Auto Start is activated, generator will automatically be activated with a certain delay after sensing the tissue (contacting two tips of forceps with tissue). The delay value can be set from 0 to 2 seconds with 0.1 second intervals. Delay setting can be done by display screen. To learn how to set delay in Auto Start of Bipolar Coag. mode please refer to the related section.
It should be mentioned that if the corresponding hand switch or footswitch are pressed; Bipolar Coag. will immediately be out of Auto Start mode.

Auto Stop: In this mode, automatic detection of optimal tissue coagulation is provided. In surgery, interval time between optimal coagulation and start of tissue carbonization is about few tenths of a second which makes the coagulation process control difficult by the surgeon. In case Auto Stop is activated, the generator is automatically deactivated when achieving the optimum coagulation, therefore more accuracy and ease in process is achieved.

Power Level Changes in Bipolar

In Iconic, Bipolar adjustable power level is divided into different ranges. Step of power level changes in various ranges is different:

- Range 1: from 0 to 1 with step 0.1
- Range 2: from 1 to 5 with step 0.2
- Range 3: from 5 to 10 with step 0.5
- Range 4: from 10 to 20 with step 1
- Range 5: from 20 to 100 with step 2
- Range 6: from 100 to 200 with step 5
- Range 7: from 200 to 300 with step 10

Output Power Selection in Bipolar

The following considerations are recommended for selecting the suitable power;

- In Bipolar Coag., selecting excessive output power causes sticking of electrode to tissue, carbonizing of electrode surface, and preventing from current flow. If the tip of the forceps is clean and power is selected optimally, then complete coagulation is done within 1 to 5 seconds.
- In Bipolar Coag., if the power is selected less than the required value, coagulation is done very slowly.
- In Bipolar Coag., if the selected power is high, the tissue temperature rises rapidly which may lead to increased vapor pressure within the tissue and thus bursting and tearing the tissue.

Method of Bipolar Setting

1. For setting Bipolar Cut and Bipolar Coag. techniques, press the corresponding icon to enter the subset modes.
2. For selecting Auto Start and Auto Stop Bipolar Coag. conditions; press the corresponding buttons to turn green.
3. If you need to set Auto Start delay, press Setting icon  on left screen and then press Adjustment (refer to" how to set delay in Auto Start" section).
4. Power value of the current mode is displayed in power display. Press the power set buttons to change the value. Power value will change one unit by each time you press on the buttons. To speed up power value change, keep your finger on the button.

Method of Using Bipolar

1. Connect the desired surgical instrument to the Bipolar receptacle (on the front panel).
2. If footswitch is used, connect the footswitch to the specific Bipolar/Sealing footswitch receptacle (on the back panel).
3. Perform Bipolar setting in the related section (see the previous section).
4. Place the surgical instrument on the tissue.
5. To activate Bipolar (if one of its mode is selected), press the hand switch or footswitch (in case Auto Start has been selected, Bipolar Coag. will automatically be activated). By Bipolar activation, a red shadow around the selected icon is appeared and continuous speaker sound is heard. To proceed with cut or coagulation keep the generator active.
6. Stop generator activation after the desired cutting or coagulation by removing the pressure on hand switch or footswitch (if Auto Stop has been selected, the generator will automatically detect the tissue coagulation and Bipolar Coag. is disabled. In this condition, the visual and auditory Coag Complete information signal is generated to notify the user (please refer to "information conditions" section).

Chapter 6

Sealing Technique

- Sealing Technique Features
- Sealing Technique Advantages
- Information Regarding Sealing in Receptacles Module Section
- Sealing Receptacle and its Accessories
- Sealing Modes
- Output Power Selection in Sealing
- Regrasp
- Method of Sealing Setting
- Method of Using Sealing

Sealing Technique Features

In conventional surgical techniques, vessels with a maximum diameter of 2 mm can be coagulated by using conventional Monopolar or Bipolar instrument and for larger vessels, conventional vascular surgery such as tying or clips can be used. Now by using different modes of Seal, coagulability of all vessels with a diameter of less than 7 mm has been provided.

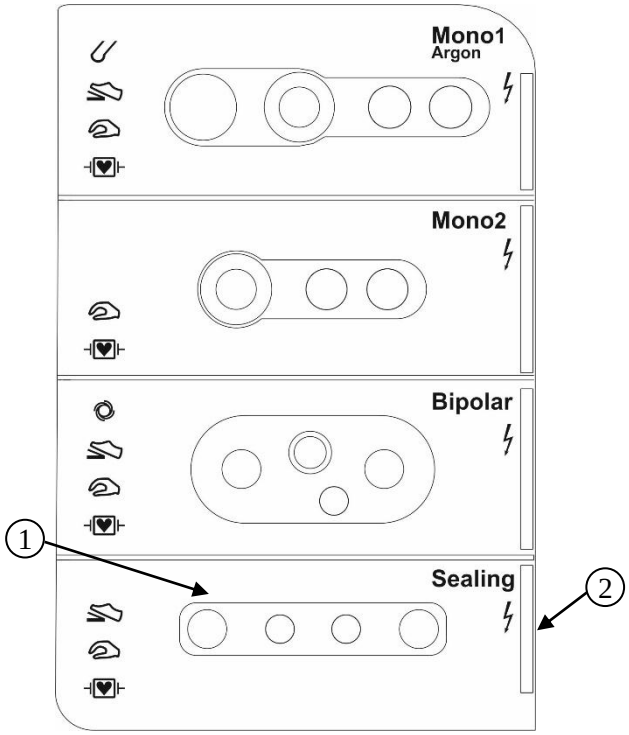
In this technique, vessels or tissues containing vessels place in the two jaws of a special surgical instrument and based on an intelligent algorithm electric current is applied to the tissue following. Applying determined energy along with mechanical pressure by surgical instrument causes melting elastin and collagen in the vessel wall consequently merging the vessel walls. Therefore, without the need of surgical instruments such as stitches or clips; a natural Sealing will occur in the vessels. In this technique the device automatically detect the optimum sealing point and then stops energy application and informs the surgeon about the seal process completion by using visual and auditory signals (please refer to "information conditions" section).

In conventional surgical techniques, vessels with a maximum diameter of 2 mm can be coagulated using conventional Monopolar or Bipolar methods and for larger vessels, conventional vascular surgery such as tying or clips can be used. Now using different modes of seal, the capability of coagulating all vessels with diameter of up to 7 mm has been provided.

Sealing Technique Advantages

- Capability of coagulation of all vessels with diameter up to 7 mm diameter
- Significant reduction in surgery time and increase of surgeon speed especially where access to blood vessels is difficult.
- Reduction in general bleeding rate of patient during surgery
- Increase of sealed vessel strength against blood pressure increase in comparison with conventional Bipolar and ultrasound methods.
- Surgeon's comfort in using this technique
- Capability of using this technique in open and laparoscopic surgeries
- Optimum coagulation point detection therefore minimum amount of carbonization, tissue sticking and thermal damage.
- Reducing damages due to suture needles and thus reducing the risk of transmitting hepatitis and HIV
- No use of foreign substances in the body and thus, not producing complication caused by leaving foreign substances in the patient body (postoperative complications such as effects of future diagnostic radiology or unwanted infections)

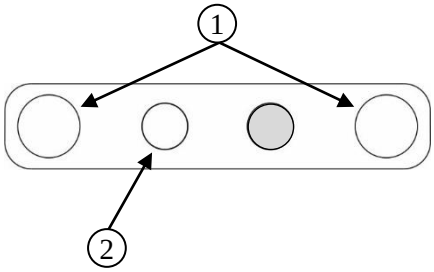
Information Regarding Sealing in Receptacles Module Section



(1) Sealing instruments receptacle

(2) Indicator of Sealing generator activation and receiving output via the corresponding connector.

Sealing Receptacle and its Accessories



(1) 4 mm normal connectors

(2) 2.5 mm connector

The high frequency main current path is from 4 mm connectors. 2.5 mm connector is used for hand switch connections.

Sealing Instruments

Iconic is just compatible with certain types of Sealing surgical instruments made by American Company. The specifications of these instruments are given in the table below.

Instrument type	Mode	Activation type	Surgery type	Some of surgical applications
Atlas (LS1037) 	Large Seal	Footswitch and hand switch	laparoscopy	Adhesiolysis- Appendectomy Colectomy- Gastric Bypass Nissen fundoplication Lap- Assisted vaginal hysterectomy Adrenalectomy- gastrectomy Splenectomy- slapingo Oophorectomy- Nephrectomy
Atlas (LS1020) 	Large Seal	Footswitch and hand switch	open	Adhesiolysis Abdominal hysterectomy Gastric Bypass Colon Resection Colectomy Radical prostatectomy Gastrectomy splenectomy Nephrectomy Slapingo - Oophorectomy
LS2110 , LS2111 	Large Seal	Footswitch	open	
LS3090 , LS3092 	Large Seal	Footswitch and hand switch	open	
LS3110 , LS3112 	Large Seal	Footswitch and hand switch	open	
Bowa – Tissueseal 	Large Seal	Footswitch	open	
LF4318 , LF4418 	Large Seal	Footswitch and hand switch	open	Urology Colorectal General surgery Gynecology

Instrument type	Mode	Activation type	Surgery type	Some of surgical applications
LF1623 , LF1723 , LF1823, LF1923 	Fine Seal	Footswitch and hand switch	open	Abdominal hysterectomy Gastric bypass Colon resection Cystectomy Radical prostatectomy Gastrectomy Salpingo-oophorectomy
LF1637 , LF 1737 , LF1837 , LF1937 	Fine Seal	Footswitch and hand switch	laparoscopy	Adhesiolysis , Adrenalectomy Colectomy , Gastrectomy Gastric bypass Laparoscopic hysterectomy Nephrectomy Nissen fundoplication OophorectomySplenectomy
LF1644 , LF1744 , LF1844 , LF1944 	Fine Seal	Footswitch and hand switch	laparoscopy	Adhesiolysis , Colectomy Laparoscopic hysterectomy Nephrectomy Oophorectomy Roux-en-Y gastric bypass Sleeve gastrectomy Splenectomy
LS1200 	Fine Seal	Footswitch	open	Throidectomy Neck Dissection Parotidectomy Other general surgery procedures
BZ4212 , BZ4212A 	Fine Seal	Footswitch and hand switch	open	Tonsillectomy Throidectomy Neck Dissection Parotidectomy
LS1500 	Fine Seal	Footswitch and hand switch	laparoscopy	Adhesiolysis- colectomy Gastric bypass Nissen fundoplication Adrenalectomy- gastrectomy Splenectomy Slapingo- Oophorectomy Nephrectomy

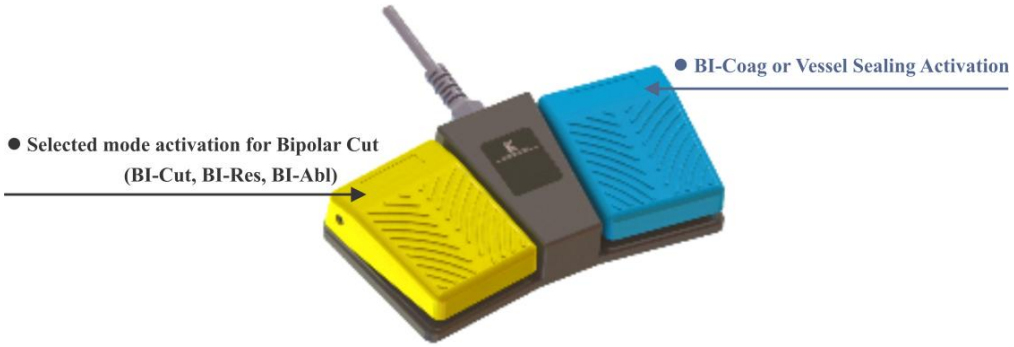
Instrument type	Mode	Activation type	Surgery type	Some of surgical applications
Bowa Ligator 	Fine Seal	Footswitch and hand switch	laparoscopy	Adhesiolysis- colectomy Nissen fundoplication Adrenalectomy- gastrectomy Splenectomy Slapingo- Oophorectomy Nephrectomy
LS1520, LF1520 	Fine Seal	Footswitch and hand switch	open	Cystectomy Nephrectomy Prostatectomy Open colectomy Axillary dissection Hemorrhoidectomy Liver resection Gynecological procedures
LF1212, 1212A, LF2019 	Fine Seal	Footswitch and hand switch	open	Ear,Nose and Throat (ENT) General Plastic/Reconstructive Urologic Thoracic

In terms of activation, Sealing instruments are of two types. Some instruments have hand switch which can be activated both by hand switch and footswitch. Some other ones don't have hand switch and can be only activated by footswitch. Connector of instrument with hand switch has 3 pins and connects to 4 mm connectors and 2.5 mm connector of Sealing receptacle. Connector of instrument that can be activated only with footswitch has 2 pins and connects to 4 mm connectors

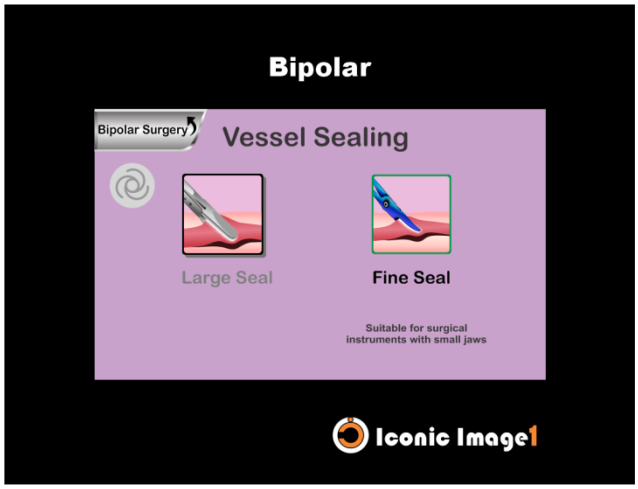
WARNING
In Sealing technique, if a surgical instrument which is not listed in the above table is used, there will not be enough reliability for seal quality.

Footswitch

To use footswitch in Sealing technique, it is essential to connect a two-pedal footswitch to Bipolar/Sealing footswitch receptacle on the back panel. In this case, by pressing the blue footswitch, the Bipolar Coag/Sealing modes will be activated. The two-pedal footswitch provided with the device is as follows:



Sealing Modes



In Iconic, Sealing technique is suitable for coagulating all vessels with a diameter up to 7 mm. This technique has two modes of Large Seal and Fine Seal. For each Sealing surgical instrument compatible with the device, one of those two modes is appropriate.

Large Seal: This mode is designed for a variety of surgical instruments which have more contact surface with the tissue and more energy is required that vessels be completely sealed.

Fine Seal: This mode is designed for a variety of surgical instruments which have less contact surface with the tissue and less energy is required that vessels be completely sealed.

Autostart

If the Autostart is selected on the Bipolar screen, this icon will turn to green. In this situation, it is also possible to use the bipolar forceps at the same time. This means that when the bipolar contacts the tissue, the sealing screen will change to the bipolar screen and the BI COAG mode will be activated with the preset power.

Setting the output power in Sealing

In this device, the output power in Sealing mode is intelligently adjusted by the device and there is no need to adjust the power by the user.

Regrasp

When the generator successfully completes the Sealing process, the informative signal of Seal Complete will be generated (see information conditions section). But if for any reason the generator could not succeed the seal, Regrasp alarm is generated (see alarm conditions section). Causes of Regrasp conditions and solutions of fixing the problem are provided in “Additional information related to alarms and information signals” table.

Method of Sealing Setting

1- To adjust the sealing technique, select the Large Seal or Fine Seal mode based on the surgical instruments.
2- In Large Seal and Fine Seal modes, it is not possible for the user to change the power because the

device will intelligently adjust the output power.

Method of Using Sealing

1. Connect the desired surgical instrument to Sealing receptacle (on the front panel)
2. If footswitch is used, connect footswitch to the specific Bipolar/ Sealing footswitch receptacle (on the back panel).
3. Grab the tissue with surgical instrument and press the instrument handle until you assured the instrument is locked. The sound of instrument locking can be heard while pressing.

WARNING
By locking surgical instrument, the suitable mechanical pressure for Sealing is provided. If the instrument is not locked while applying energy, there would not be enough reliability for Sealing quality
During sealing, do not apply extra force to the lever to ensure proper operation. If the lever does not open, open it by pushing forward from the handle.

4. To activate the Sealing and apply of energy to tissue (if one of its mode has been selected), press on instrument hand switch or corresponding footswitch. By Sealing activation, Sealing icon gets a red margin and continuous sound of speaker is heard. Keep the device active until the end of Sealing process. To proceed with cut or coagulation keep the generator active. The device detects the completion of Sealing process automatically; visual and auditory Seal Complete information signal is generated to notify the user (refer to information conditions section) and device activation stops.

5. If Regrasp alarm is generated (See alarm conditions section), Sealing process is not complete. Therefore activate the Sealing again and apply energy to tissue. If Regrasp condition is repeated, refer to the related table. After checking the cause, follow the appropriate solution.

WARNING
If you remove the pressure on hand switch or footswitch before Seal Complete announcement. Seal process is not complete and device generates Regrasp alarm. In this condition, there is not enough reliability for Sealing quality and Sealing process should be repeated.

Chapter 7

Setting

- Setting
- Programm management Pages
- How to enter the program management pages
- Save and load a program
- APC Endo Cut program for endoscopic surgery (program 10)
- How to Set Delay Time in Auto Start of Bipolar Coag. Mode
- How to Set Display Brightness

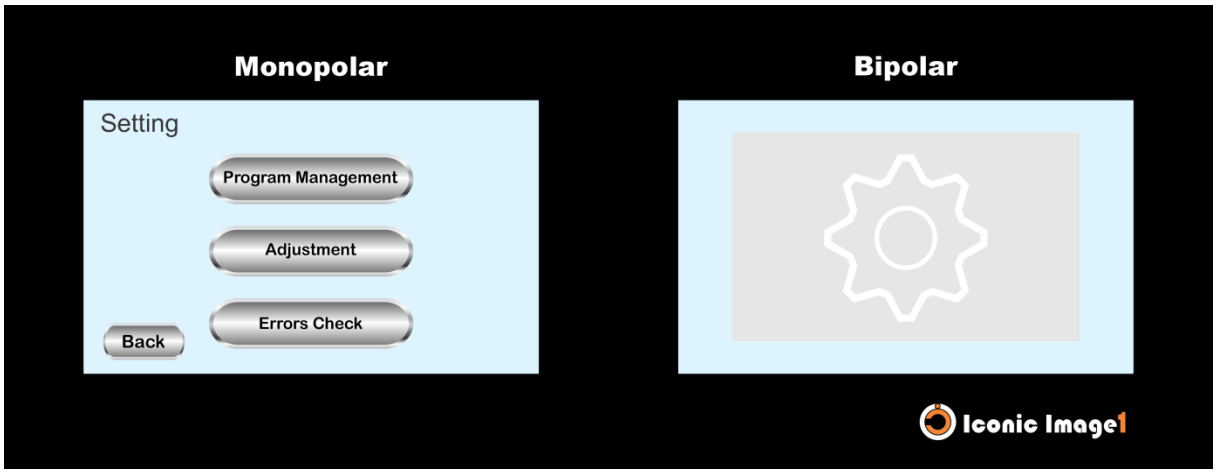
Setting

Enter the setting pages by pressing the Setting Icon.

Bellow actions can be done by the user through these pages.

Icon name	Action
Program Management	Save/ Load/ Remove a program.
Adjustment	Setting the Auto start delay/ Display Brightness
Errors Check	Observing saved errors in the device

Touching each of these icons displays their subsets on the screen. These menus enable the user to make selections related to the title of the icon being touched. Each time you press the icons, they get a green border.



Program Management Pages

In Iconic, the possibility of storing 30 programs, including various modes and powers setting for different surgeries, is provided. Those predetermined settings provide the possibility of rapid changes in different surgeries. 10 settings for different surgeries have already saved by the company. The list of those settings, related surgeries, operation modes, and powers are given in table below.
Default cutting modes are yellow and default coagulation modes are blue in bellow table.

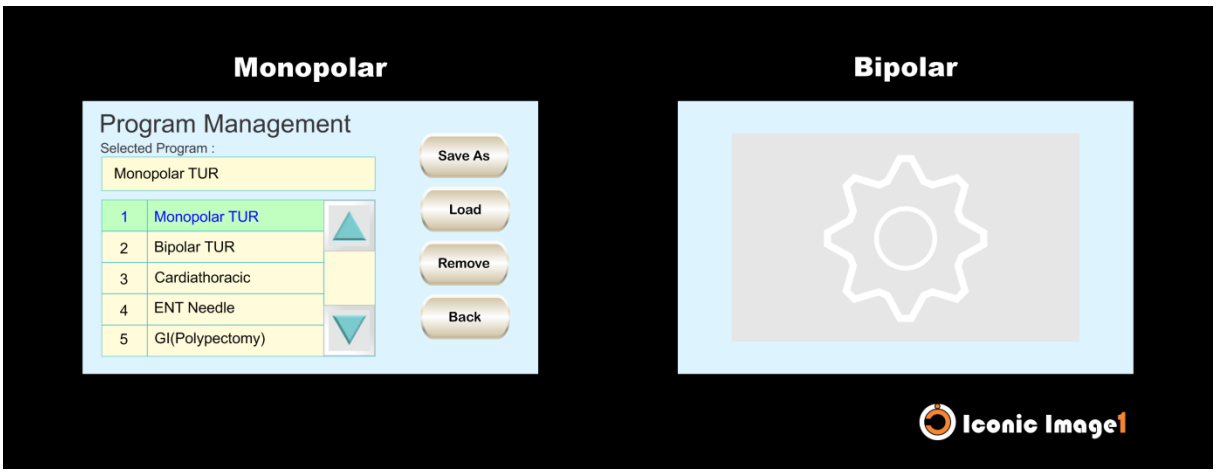
PROG #	Program	Monopolar Cut	Monopolar Coag	Bipolar / Sealing	
30	Default Program	Blend2-60	Spray -40	Large Seal	
1	Monopolar TUR	Blend2-100	Soft-100	Bipolar Cut - 50	Bipolar Coag- 30
2	Bipolar TUR	Blend2-60	Soft -80	Bipolar TUR-70	Bipolar Coag- 30
3	Cardiothoracic (Sternum)	Blend2-60	Spray -60	Large Seal	
4	ENT (T&A) Needle	Blend2-30	Forced -30	Fine Seal	
5	GI (Polypectomy)	Blend2-30	Forced -30	Bipolar Cut - 30	Bipolar Coag- 30
6	Laparoscopy	Blend2-30	Forced -30	Large Seal	
7	Mastectomy	Blend2-30	Spray -60	Bipolar Cut - 30	Bipolar Coag- 30
8	Microsurgery (Neurosurgery) (Spine)	Blend2-30	Spray -20	Bipolar Cut - 30	Bipolar Coag- 30

9	APC - ablation or High hemostasis in open surgery	Blend2-30	Continuous Argon -60	Large Seal	
10	APC - Endo, medium hemostasis for GI-Bleeding	Polypectomy-L2	Pulsed Argon -30	Bipolar Cut - 30	Bipolar Coag-30

The surgeon can save/remove and load a program through the Program Management→ Save / Load / Remove when it is necessary.

How to Enter the Program Management Pages

1. First, press the Setting icon to enter the setting page.
2. Select the Program Management option.
3. You can Save / Load / Remove an intended program.
4. Press Back to return.



5. Select "Save As" to save the program and you will be taken to a new page. Each character can be selected from English letters or numbers from 0 to 9. Select "Back" to return to the Setting.

Save and Load a program

Save a program by the user

Through these pages, the user can save the default settings in the device memory, which include a special mode and power for a special surgery. To do this, first apply your desired settings on the device. Then click "Save As". Select the program name and click "Save" at the end.

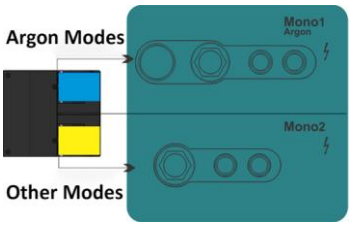
Load a presets program by the user

Different settings with different names are saved on the device to perform special surgeries. To select and load any of these programs, first select the program you want by moving up and down scrolls and then click "Load".

APC Endo Cut program for endoscopic surgery (program 10)

In Argon Endo mode, if one of the Pulsed Argon or Continuous Argon modes is selected, pressing the blue pedal activates the Mono1 output (ARGON connector). But in argon-free modes such as Pure, Blend, Forced, etc., pressing the pedal related to that mode (yellow for cutting and blue for coagulation) activates the Mono2 output.

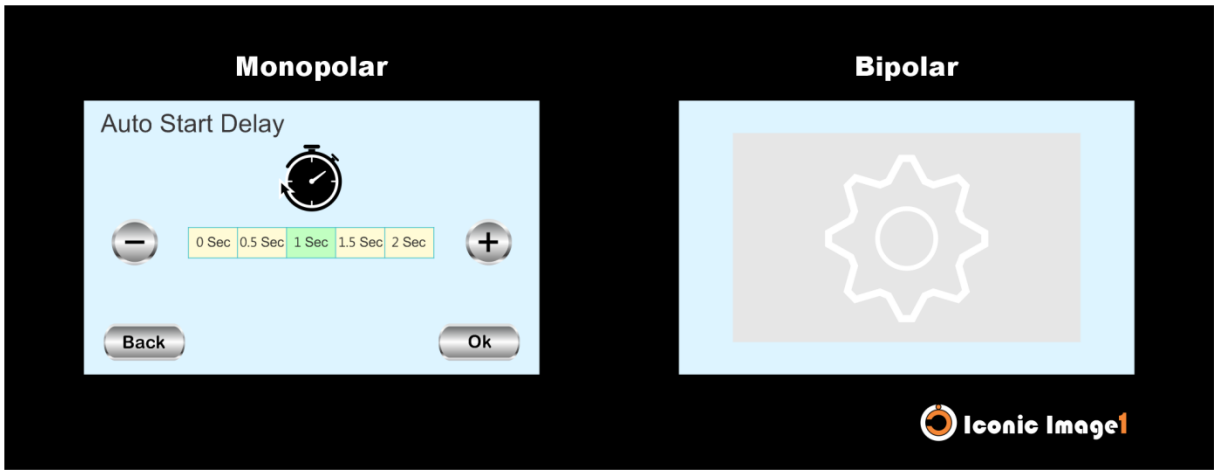
Therefore, according to the figure, you can use the blue pedal for APC on Mono1 and the yellow pedal for simple cutting (polypectomy) on Mono2 at the same time.



In APC Endocut, connect the Snare interface cable to Mono2 output and insert the snare into the endoscope. Set the device on one of the cutting modes such as Papillotomy , Polypectomy, and press the yellow pedal.

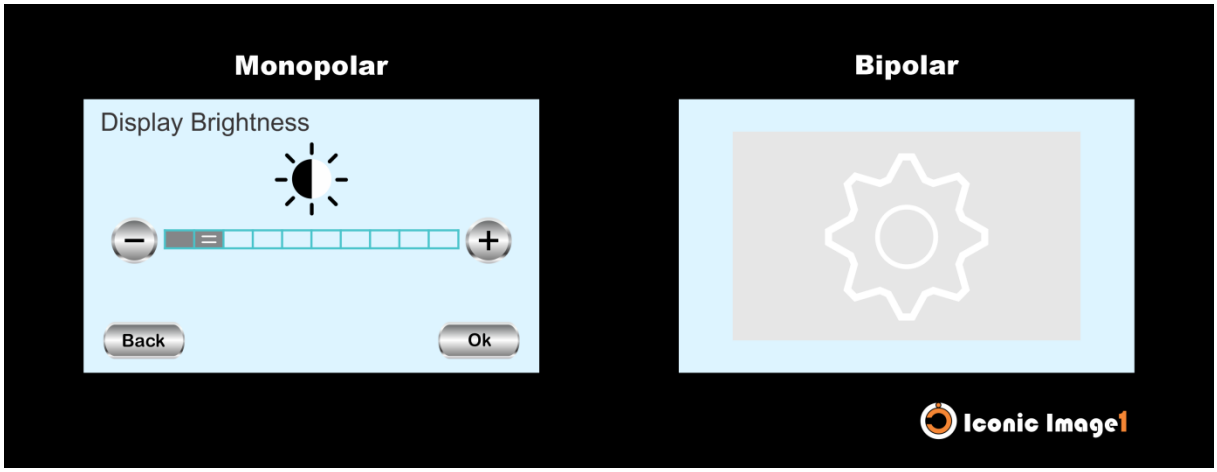
How to Set Delay Time in Auto Start of Bipolar Coag. Mode

1. First enter to the Setting page.
2. Select Adjustment.
3. Select Auto Start Delay.
4. Set the delay time on desired value using Inc+ and Dec- icons then press “Ok”. Select the “Back” to return to the “Setting”.



How to Set Display Brightness

1. First, enter to the Setting page.
2. Select Adjustment.
3. Select Display Brightness
4. Set Display Brightness using Inc+ and Dec- icons then press “Ok”. Select the “Back” to return to the Setting.



Chapter 8

Alarm System

- Alarm Conditions
- Failure in Patient Plate Condition Alarm
- Alarm Signals
- Information Conditions
- Additional information related to alarms and information signals

Alarm Conditions

Device alarm conditions with relevant specifications are provided in the following table.

Event	Message on the display	Group	Priority	Impact on the activity	Log (in memory)
Failure in patient plate condition during Monopolar activation and or request	**Fail: Plate**	Technical/ Functional	Medium	Deny the permission or stop of Monopolar activity	✓*
Failure in patient plate condition while no request for Monopolar activation	**Er: PT**	Technical/ Functional	Low	--	✓*
Voltage increase in internal power supply more than the determined value	**Fail: OV**	Technical	Medium	Stop of activity	✓
Decrease in output power of HF generator below the permitted value	**Er: FE**	Technical	Low	--	✓
Increase of leakage current in Monopolar activation more than the permitted value	**Fail: LC**	Technical	Medium	Stop of activity	✓
Continuous operation of the equipment for 30 seconds	**Fail: Time Out**	Functional	Medium	Stop of activity	×
Continuous operation of the equipment for more than 10 seconds	**Er: TO**	Functional	Low	--	×
Regrasp**	**Fail: Regrasp**	Functional	Medium	Stop of activity	×
Activation request during normal start of the system, when it was in Standby or Self-Checking mode, or Setting Bipolar to Auto Start Coagulation when the electrode is on tissue	**Er: IR**	Technical/ Functional	Low	Deny the permission of activity of the generator that caused the alarm	×
System memory failure	**Er: ME**	Technical	Low	--	✓
Disconnection between system internal boards during the request for system activation	**Fail: Connector**	Technical	Medium	Deny the permission or stop of activity	✓
Disconnection between system internal boards when no activation request presents	**Er: CN**	Technical	Low	--	✓
Increase in output power of generator more than a permitted value, during activation	**Fail: Extra Power**	Technical	Medium	Stop of activity	✓
Instability and fluctuation in input signals	**Er: IN**	Technical	Medium	Deny the permission of activity	×

*Only in circuit failure of patient plate monitoring, this alarm is recorded in memory.
**See table of additional description related to alarms and information signals.

Failure in Patient Plate Condition Alarm

This alarm is generated in two conditions:

- **Plate connection failure**: This failure is occurred due to disconnection of plate connector or its cable in single plate and for dual plate is due to disconnection of plate connector or its return cable, poor quality of plate connection to the patient's body, full disconnection of plate to patient's body or large variations in resistance between the two parts of plate. Naturally, resistance variation is not checked in Monopolar activation due to possible effects of generator noise on plate circuits.
- **Circuit failure of patient plate monitoring:** This failure means that there is error in transmission circuit of dual plate connection condition to the control system. In case of such failure, the relevant alarm code is recorded in the memory. This error is only investigated when the generator is inactive phase. But subsequent to this alarm, in case of a request for activation of Monopolar technique, the equipment will not be activated and "Fail: plate" alarm is generated.

System Memory Failure Alarm

By each time writing system settings in memory, the validation of the stored values in the memory with those settings are checked, and their inequality causes "system memory failure" alarm. By any demand for system operation, "system memory failure" alarm condition ends.

Alarm Conditions Group

Based on the external cause of event and its occurrence part, alarm conditions are divided into two groups.

- Technical
  The event occurs in the equipment or its accessories.
- Functional
  The event happened in the interaction between equipment and operator/patient while using the equipment

An alarm may occur due to various technical or functional reasons. In alarm condition table (see alarm conditions section on page 58) in front of those alarm conditions in group section, technical/ functional term has been mentioned.

Alarm Conditions Priority

Two priorities have been assigned to alarm conditions based on the amount of harm that can have for the patient, operator or the equipment. Those two priorities are called "medium" and "low" based on the IEC60601-1-8 standard.

- **Medium priority**
  At the time of alarm conditions with medium priority, due to possibility of serious injury, generator activity is stopped and the equipment cannot meet the user expectation. This issue itself could have potential hazard. Thus, quick response of user is needed to fix the problem. Medium priority alarm is displayed with orange background.
- **Low priority**
  At the time of alarm conditions with this priority, possible damages are so mild that does not require urgent need to change the equipment operation status (such as generator inactivation). But, the user should be aware of such a condition so proper response is provided to the relevant alarm condition in appropriate time. Also, in this case that the equipment is in continuous operation, less auditory noise (due to less urgency of low priority) is generated. Low priority alarm is displayed with gray background.

Alarm Signals

By detecting of alarm conditions, visual and auditory signals (through displays, LED, Buzzer) are generated in the system. All means of generating those signals are activated (by turning on the equipment). So the user can be confident of alarm system functionality. In order to perceive the visual and

auditory signals by user, maximum of 3 m distance between user and equipment is recommended. The maximum distance of 1.5 m is suitable for display checking.

Alarm Signals Characteristics with Medium Priority

By occurrence of an alarm with medium priority, a message with red background is shown on the screen. Also, ERROR LED or plate LED (based on the alarm) starts to flash and auditory signal is generated according to a certain pattern by a buzzer with 79 dBA sound level (from 1m distance) and 2300 Hz frequency.

- **LEDs flashing pattern**
  Continuously flashes on (600 ms) and off (250 ms).
- **Auditory signal generation pattern**

Three subsequent sounds, which is generally called burst is repeated every 4s. In each burst, buzzer is turned on and off every 250 ms.

If the medium priority alarm condition no longer exists, all generated alarm signals will cease. Only if the burst of auditory signal is not yet completed, the signal will be continued until the end of the burst.

Alarm Signals Characteristics with Low Priority

By occurrence of an alarm with low priority, a term associated with alarm condition which starts with "Er:" world is displayed on the screen. Also, ERROR LED or plate LED (based on the alarm) is on in red color and auditory signal is generated according to a certain pattern by a buzzer with 79 dBA sound level (from 1m distance) and 2300 Hz frequency.

- **LEDs flashing pattern**
  They turn on continuously
- **Auditory signal generation pattern**
  Buzzer turns on and off twice continuously with 150 ms intervals.

If the low priority alarm condition no longer exists, all alarm signals will cease.

Regrasp Alarm Signals Characteristics

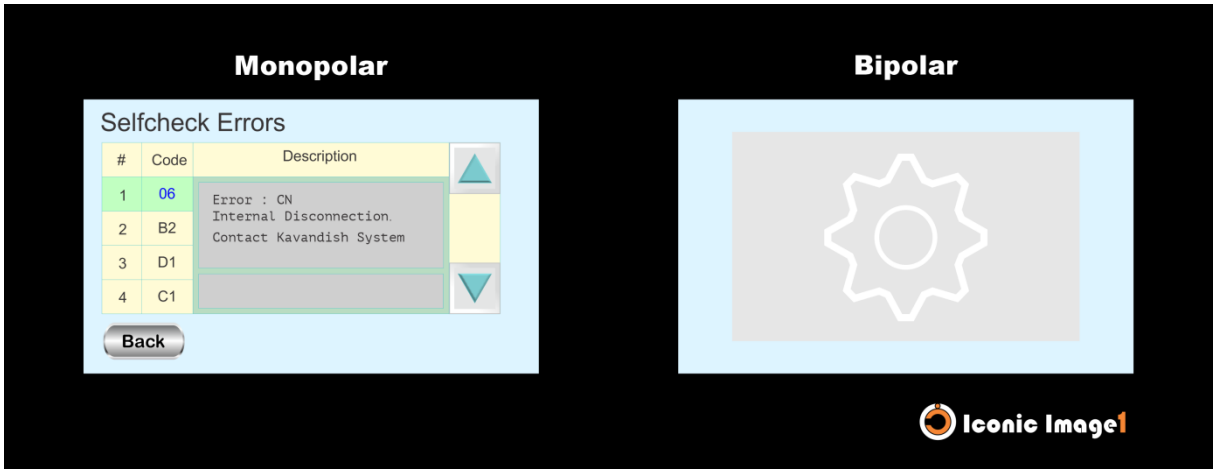
By occurrence of this alarm, usual signals (ERROR LED, buzzer, message on display) are happen. By demand removal, the last buzzer burst is completed and its sound is discontinued, but the other signals continue. If Regrasp alarm has been created with demand removal, buzzer will only ring for one burst.
Regrasp alarm continues until the request for Sealing is repeated. Of course, with each activation request or detecting of each alarm or information condition, all alarm signals are discontinued. This means exist of alarm mode. In another word, ending all visual and auditory signals means Regrasp alarm is finished.

Alarm Signals Generation Ranking

With occurrence of alarm conditions with medium and low priority simultaneously, alarm signals is generated only for alarm with medium priority. Meanwhile, with occurrence of alarm with the same priority, all relevant terms are displayed on the screen.

Alarm Logging System in the Memory

1. First, enter to the Setting page.
2. Select Error Check.
3. Select the Self Check Error.
4. Alarms will be appeared in a page with their codes.



Among all alarms, only technical alarms that indicate equipment failure are stored in memory as code; so, in case it is needed, system problems can be determined. The memory has the capacity to store 10 alarms, meaning that always the information of the last 10 alarms is stored in the memory. The content of this memory does not disappear by equipment turning on/off or power disconnection.
The code associated with each alarm is consisted of two characters. The right character is related to alarm condition type and the left character is related to the mode that in which this alarm has occurred. Characters related to alarm condition type and mode types that alarm has occurred (during their operation) are given in the following tables.

Alarm condition type	Right character of the code
Voltage increase in internal power supply more than the specified value	1
Decrease in output power of HF generator less than the permitted value	2
Increase of leakage current in Monopolar activation more than the permitted value	3
Problem in patient plate condition due to Circuit failure of patient plate monitoring	4
Increase in output power of generator more than the permitted value, during activation	5
Disconnection between system internal boards	7
System memory failure	1

Left character	Mode	Technique
0	---	Not active
1	Pure	Monopolar Cut
2	Blend1	
	Blend2	
	Blend3	
3	Papillotomy	
	Polypectomy	
4	Swift	Monopolar Coag
	Forced	
5	Spray	
6	Soft	
7	Continuous Argon	
8	Pulsed Argon	
9	Bipolar Cut	Bipolar Cut
A	Bipolar Resection	
	Bipolar Ablation	

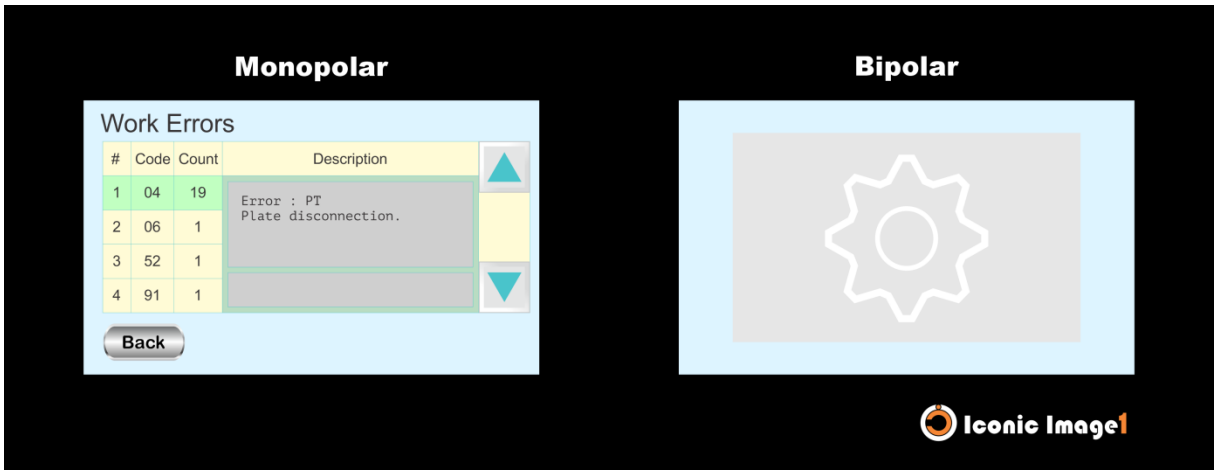
B	Auto Start	Bipolar Coag.
	Manual	
C	Large Seal	Sealing
D	Fine Seal	

Work Errors

If some alarms are generated while working with the device, the corresponding alarm code is stored in memory (see alarm code tables).

Work Error Codes displaying, created during device operation (Work Errors)

1. First, enter to the Setting page.
2. Select Error Check.
3. Select the Work Errors. Alarms will be appeared in a page with their codes.



NOTICE

In the Work Errors section, only the code for alarms that occurred while working with the device appears and errors related to Self-Checking mode are not displayed here.

Information Conditions

In addition to alarm conditions, other conditions also occur that although they are not harmless to the patient or operator, but they require user attention. Those conditions are called information condition. They include error of equipment use (when it is not harmless to the patient or operator) and new event (such as generator activation) that occurs in normal use of the equipment. The equipment information conditions with the corresponding description are given in table below.

Events	Message on the display screen	Impact on activity
Generator activation	**Change of mode icon color**	--
Starting with zero power or decrease of power to zero value during activation	**P=0**	Deny the permission or stop of activity
Simultaneous activation request of Monoploar Cut and Monopolar Coag. or request for Sealing activation while one of Bipolar modes is selected or request for Bipolar mode activation while one of Sealing modes is already selected .	**Unacceptable Request**	Deny the permission of activity
Set the Bipolar Coagulation on Auto start when the pen is not on the tissue	**Change of Auto Start icon color**	--
Detecting optimum coagulation of the tissue in Auto Stop mode	**Coag Complete**	Stop of activity
Detecting optimum Seal in the Sealing mode	**Seal Complete**	Stop of activity

Information Signals Characteristics

With detecting of information conditions, visual and auditory signals (through display, LED and speaker) are generated by the system.
Information signals corresponding to generator activation are different from other information conditions. The generator has a specified page on display which is displayed with its activation. This page includes technical information that is activated. During generator activation, LEDs corresponding to the activated technique are on and auditory signal is generated continuously by a speaker with adjustable sound level (50 dBA to 70 dBA from 1 m distance).

- **The sound frequencies generated during each technique activation**
  Monopolar Cut: 680 Hz
  Monopolar Coag: 520 Hz
  Monopolar Coag1 and Monopolar Coag2 activation simultaneously: 470 Hz
  Bipolar Cut: 610 Hz
  Bipolar Coag. and Sealing: 470 Hz

With occurrence of other information conditions, a term associated with it is displayed on the display. In some of those conditions (including P=0 and Unacceptable Request) the corresponding 7-segment also start to flash. Also, auditory signal is generated (according to a certain pattern) by the speaker with adjustable sound level (50 dBA to 70 dBA from 1m distance).

- **7-segment flashing pattern**
  7-segments turn on and off with 350 ms interval.
- **Auditory signal generation pattern**
  The speaker turns on and off twice consecutively with 350 ms interval.

Information Signals Rank in Comparison with Alarm Signals

In case of information and alarm conditions simultaneously, usually the message related to alarm condition(s) is displayed on the screen (But other corresponding information and alarm signals are generated). However, display message related to information conditions corresponding to the user request (including P=0, Unacceptable Request, Coag Complete and Seal Complete) as long as the request is not resolved those messages have priority to those messages related to alarm conditions.

Additional information related to alarms and information signals

A message appears on the screen when any alarm or information signal is generated. Touching that message will provide additional information on the screen for the user.

Alarm/Information Signals	Description
	Connect the plate. Ensure that patient electrode firmly and completely contacts the skin.
	Patient plate Loosening. Ensure that patient electrode firmly and completely contacts the skin.
	Failure in REM function. Contact KAVANDISH SYSTEM.
	Error: LC Increased leakage current. Contact Kavandish System.
	Error: OV Over voltage at internal power supply. Contact Kavandish System.
	Error: Time Out Activation timeout. Do not activate generator for a long time continuously.
	Error: Instability Instability in signals detected. Contact Kavandish System.
	Error : Regrasp - Low Current 0 Low current at the start of sealing. Check instrument connections. There is a possibility of disconnection of connectors or wires. Check tissue is grasped by surgical instrument jaws
	Error : Regrasp - Low Current 1 Low current during seal process. Check instrument connections. There is a possibility of disconnection of connector or wires. Don’t open instrument jaws until “seal complete” is announced.
	Error : Regrasp - Low Current 2 Low current during final seal process. Check instrument connections. There is a possibility of disconnection of connectors or wires. Don’t open instrument jaws until “seal complete” is announced.
	Error: Regrasp - High Power Stop using the device. To check and fix the problem, send the device to the manufacturer.

Regrasp	Error : Regrasp - High Current 1 No tissue response to electrical energy during seal process. There is a possibility of instrument failure or short circuit between the two jaws of surgical instrument. Without cutting the tissue, open the jaws and grasp the tissue again. If the error repeats, replace the surgical instrument.
Regrasp	Error : Regrasp-High Current 2 No tissue response to electrical energy during seal process. There is a possibility of instrument failure or short circuit between the two jaws of surgical instrument. Without cutting the tissue, open the jaws and grasp the tissue again. If the error repeats, replace the surgical instrument.
Regrasp	Error: Regrasp - Unexpected Change Unusual change in tissue response observed. Without cutting the tissue, open the jaws and grasp the tissue again.
Regrasp	Error: Regrasp - Time Over No complete tissue response observed at the specified time. Maybe the tissue taken by surgical instruments is too thick. Maybe there is accumulation of blood and fluids around the jaws of surgical instruments. Without cutting the tissue, open the jaws drain blood and fluids around the jaws and grasp the tissue again.
Regrasp	Error: Regrasp-Energy Stopped In Seal modes do not stop applying energy until “seal complete” is announced.
Fail: Connector	Error: Connector Activation while internal disconnection detected. Contact Kavandish System.
Fail: Extra Power	Error: Extra Power Extra power at generator output. Contact Kavandish System.
Fail: Heat Factor	Error: Heat Factor 1 System over heat. Do not reactivate generator repeatedly in high power. Allow cooling.
Fail: Heat Factor	Error: Heat Factor 2 Pre-Overheat at plate. Do not activate generator continuously at high power. Allow plate cooling.
Fail: Heat Factor	Error: Heat Factor 3 Overheat at plate. Do not activate generator continuously at high power. Allow plate cooling.
Er:PT	Connect the plate. Ensure that patient electrode firmly and completely contacts the skin. Patient plate Loosening. Ensure that patient
	Electrode firmly and completely contacts the skin.
	Failure in REM function. Contact KAVANDISH SYSTEM.
Er: FE	Error: FE Loss of output power.Contact Kavandish System.
Er: TO	Error: TO Pre-timeout. Do not activate generator for a long time continuously.
Er: ME	Error: ME System memory failure. Contact Kavandish System.
Er: CN	Error: CN Internal Disconnection. Contact Kavandish System.
Er:IN	Error : IN Instability in signals detected. Contact Kavandish System.

	Error: Zero power. Increase the power.
	Error: IR Irregular activation request. Tissue sensed whiles selecting Autostart!
	Error: IR Irregular activation request. Check footswitch/handswitches not remained in pressed condition.
	Error: Unacceptable Request Mismatch between selected mode and activation request by handswitch/footswitch.
	Error: Unacceptable Request Tissue contact detected at Bipolar. Select Autostart for activation.
	Coag Complete Bipolar coag completed
	Seal Complete Sealing Completed
Connecting …	A malfunction has been observed between the displays and the device. Wait a few seconds to reconnect.

Chapter 9

Maintenance and Repair

- Manufacture Responsibility
- Routine Maintenance
- Safety Checks
- Cleaning and Disinfecting
- After Sales Service

Manufacture Responsibility

Kavandish System Company can only accept the safety and device performance if below instructions are followed;

- The installation and launching of the device is done according to this User Manual.
- Device is used in accordance with the instructions of this User Manual.
- Any modifications or repairs can only be done by authorized service personnel of Kavandish System Company or its authorized representatives.

Routine Maintenance

It is recommended to check the device calibration and overall safety and performance condition of the system once a year. Therefore we suggest you to send the device to Kavandish System Company or one of its authorized representatives for calibration and safety checks and receive qualitative control results and safety standard test card along with your unit.

Safety Checks

Safety checks are performed to define whether the device's condition regarding safety and performance is in accordance with defined technical status. These checks include the following:

- Visual inspection
- Impedance between Receptacles
- Bipolar and Monopolar Output RF Leakage (according to IEC 60601-2-2)
- Line Frequency (50-60 Hz) Current Leakage (according to IEC 60601-1)
- Plate and Tissue Sensor Auxiliary Current Test (according to IEC 60601-1)
- Grounded conductor test (according to IEC 60601-1)
- Input current consumption
- Output HF Power measurements

These tests can be performed without removing the sealed enclosure of device. In case test results show any defect or failure in device performance, the device should be immediately returned to Kavandish System Company or one of its authorized representatives for examination and fixing. Do not attempt to open the enclosure or modify the device.

Cleaning and Disinfecting

Turn off the device and remove the cable from power outlet before any cleaning. Then clean all surfaces of the unit gently using a moistened cloth and cleanser or mild disinfectant solution.

WARNING
Use nonflammable material for cleaning and disinfecting. If you are forced to use flammable materials wait a while until those materials are completely evaporated before you turn on the device.

NOTICE

Penetration of liquids into the device can cause damage to it; since there is the possibility of liquids penetration from its borders and bottom side, observe necessary precautions during cleaning and disinfecting the device.

- Do not spill disinfectant on the device and do not spray directly.
- Do not use a rough cloth to avoid scratching the screen. Also, avoid putting too much hand pressure on the screen, and if you have ring in your hand that may scratch the screen, take the necessary care.
- Do not use alcohol above 70% and undiluted bleach, ammonia and acidic solutions containing fluoride.
- Wipe the plates with a suitable cloth and allow it to dry.

Cleaning Accessories

For cleaning and disinfecting of each accessory, follow the available instructions in related packaging.

After Sales Service

One of the important feature and essential advantages of this device compare to similar ones is its fast and excellent after sales support and services.
This product is warranted for 24 months from delivery date. During this time any defect due to defective parts, workmanship or manufacturer's fault will be resolved free of charge in the company. Also the company guarantees to provide its services in terms of repair, spare part, and support for 10 years.

NOTICE

Dear customer, in case of any problem and dissatisfaction regarding our product, packaging, delivery, or recycling of the unit (after its life time) or in case of any suggestion that may help us improving our service and product quality, please contact our after sales support department in Kavandish System Company.

Chapter 10

Technical Specifications

- Dimensions and Weight
- Input Power
- Operating Parameters
- Transport and Storage Parameters
- Internal Memory
- Displays
- Generator Activation Tone
- Alarm Tone
- Current Consumption
- High Frequency Leakage Current
- Low Frequency Leakage Current
- Patient Plate Monitoring System
- Duty Cycle
- Output Characteristics
- Standards
- Drip Proof (IEC 60601-2-2)
- IEC Classification
- Maximum Output Power Graphs versus Load Resistance
- Output Power Graphs versus Adjusted Power Level
- Maximum Output Voltage Graphs versus Adjusted Power Level

Dimensions and Weight

Width	40 cm
Depth	44 cm
Height	17 cm
Weight	۹ kg

Input Power

Mains voltage	220V ± 10% , 50HZ (110 V ± 10% , 50/60HZ)*
Maximum power consumption	800 VA
Fuse	Standard-5*20mm 5 A - 250 V AC (or 10 A)*

*Depends on customer request

Operating Parameters

Temperature	+10°C to +40°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 mbars to 1060 mbars

Transport and Storage Parameters

Temperature	-20°C to +65°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	500 mbars to 1060 mbars

Internal Memory

Storage capacity	2048 b

Displays

Displays	Two displays (64.8*108mm) for setting modes and memories and displaying alarms and messages

Condition of visibility

- The range of environment lighting: natural light (Touch Screen Transparency - Capacitive Touch: 90%)

- Distance to see the screen which shows the power: the maximum distance from display 1.5 meters.

- General insight distance: 20 cm to 50 cm
- Display Viewing Angles

Above Center	70 Degrees
Below Center	50 Degrees
Left of Center	70 Degrees
Right of Center	70 Degrees

-Display Viewing Direction
12 o'clock Display (Optimal viewing is from above when in Landscape/Wide mode)

Generator Activation Tone

Volume (adjustable)	50 dBA to 70 dBA (from 1 m distance)
Frequency	• Monopolar Cut: 680 Hz • Monopolar Coag.: 520 Hz • Mono Coag1 and Mono Coag2 (simultaneously): 470 Hz • Bipolar Cut: 610 Hz • Bipolar Coag.: 470 Hz • Sealing: 470 Hz
Duration	Continuous during generator activation

Alarm Tone

Volume (non-adjustable)	79 dBA (from 1 m distance)
Frequency	2300 Hz
Duration	• Alarm with medium priority: one burst includes 3 consecutive tones with 250 ms intervals repeated every 4 s • Alarm with low priority: 2 consecutive tone with 150 ms intervals

Current Consumption

Without R.F. power	200 mA
With maximum R.F. Power	3.74 A(rms)

High Frequency Leakage Current

Monopolar	Less than 150 mA
Bipolar	Less than 20 mA
Sealing	Less than 20 mA

Low Frequency Leakage Current

Normal condition*	Less than 10 µA
Single fault condition*	Less than 50 µA

* If all patient terminals are tied together

Patient Plate Monitoring System

Measurement frequency	100 kHz ± 10 kHz
Acceptable resistance ranges	
Single plate	Less than 25 Ohms
Dual plate	25 Ohms to 150 Ohms
Alarm occurs	- If the measured resistance is outside the acceptance range - In case of dual plate connection, if the measured resistance at any time increases more than 50 percent relative to the minimum measured resistance

Duty Cycle

Duty Cycle of the device, while the maximum output power in the nominal load (or a load with the resistance of less than nominal load), is utilized, has been established based on (10 s/30 s) active and inactive cycle. It means that after every 10 second operation of the unit generator, the generator should get switch off and remain 30 second in that position. In case that output power is less than maximum rate (or a load with the electric resistance of more than nominal load is utilized); it may be possible to increase the duty cycle of the unit.

Output Characteristics•

Monopolar Cut

Mode	Maximum output voltage (V_{P-P})	Maximum output current (A)	Heating Factor (A^2s)	Crest Factor**	Maximum output power (Watts)	Rated load (Ohms)
Pure	1420	1.3	44.1	1.5	360	350
Blend1	2725	1.1	33.6	2	330	450
Blend2	3325	1.1	35.9	2.5	300	500
Blend3	3700	1.1	34.9	2.8	270	500
*Papillotomy	1260	0.5	5.7	1.5	360	200
*Polypectomy	1150	0.4	5.3	1.5	360	200

*Optional Modes

Monopolar Coag.

Mode	Maximum output voltage (V_{P-P})	Maximum output current (A)	Heating Factor (A^2s)	Crest Factor**	Maximum output power (Watts)	Rated load (Ohms)
Swift	3600	1.0	27.7	3.3	200	500
Forced	3600	0.9	26.4	4.5	120	500
Spray	5250	0.8	19.1	5.5 to 7.5***	120	500
Soft	660	1.1	34.3	1.5	100	200
Continuous Argon	8100	0.7	17.7	7 to 9***	100	500
Pulsed Argon	10200	0.7	14.5	10 to 16***	50	500

Bipolar

Mode	Maximum output voltage (V_{P-P})	Maximum output current (A)	Crest Factor**	Maximum output power (Watts)	Rated load (Ohms)
Bipolar Cut	1280	2.5	2.4	100	100
*Bipolar Resection (TUR)	1450	4.1	1.5 to 2.4 ***	300	100
*Bipolar Ablation	1450	4.1	1.5 to 2.4 ***	300	100
Bipolar Coag.	365	2.2	1.5	200	50
Auto Start Bipolar Coag.	360	1.8	1.5	٨٠	50

*Optional Modes

Sealing

Mode	Maximum output voltage (V_{P-P})	Maximum output current (A)	Crest Factor**	Maximum output power (Watts)	Rated load (Ohms)
Large Seal	375	4.2	1.5	250	25
Fine Seal	375	4	1.5	235	25

•Nominal Frequency is 410kHz±1kHz.

*Optional Modes
**Crest Factor is a measurement of waveform which increases by increasing waveform coagulation capabilities and is calculated from the following equation:
C.F = Vpeak / Vrms.
***According to power adjustment

Standards

Iconic device meets all relevant clauses of IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2 standards.

Drip Proof (IEC 60601-2-2)

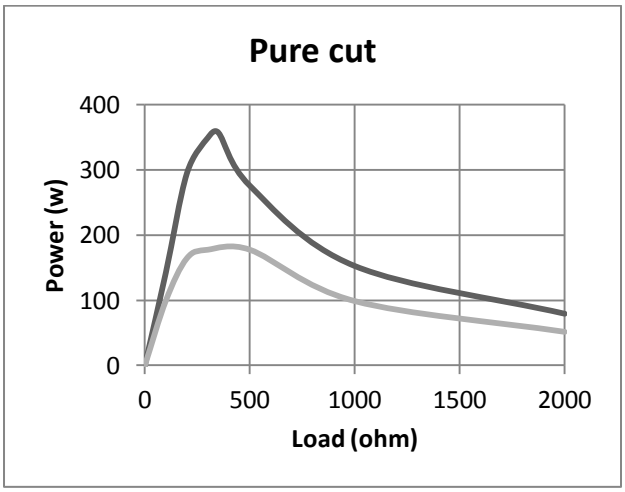
Iconic enclosure is constructed so that in case of liquid spillage in normal use, the safety and performance does not adversely affect.

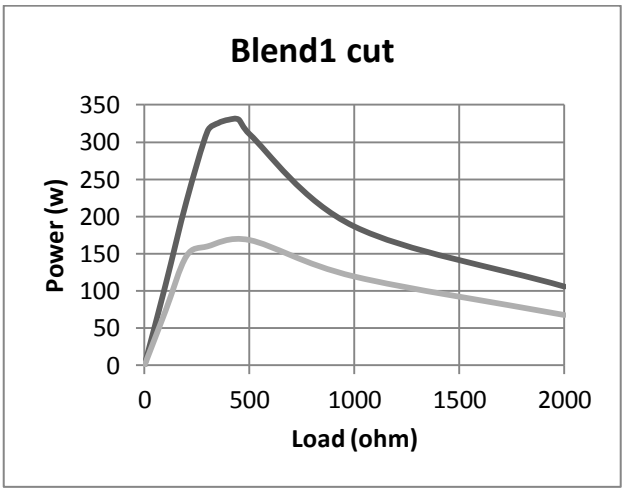
IEC Classification

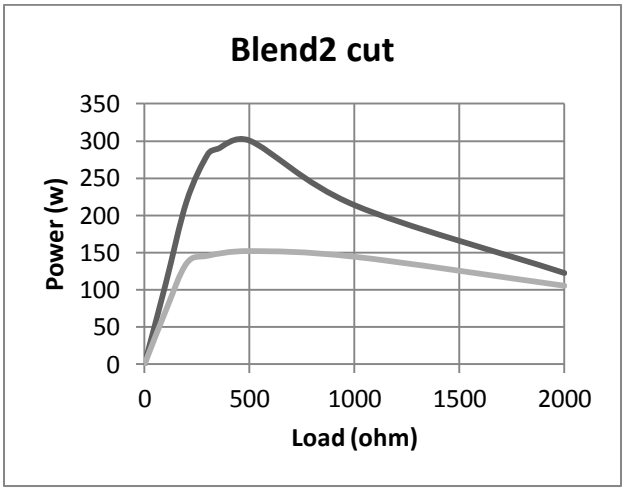
Protection class	I
Type of output	CF (Cardiac Floating)
Type of patient circuit	Floating Output

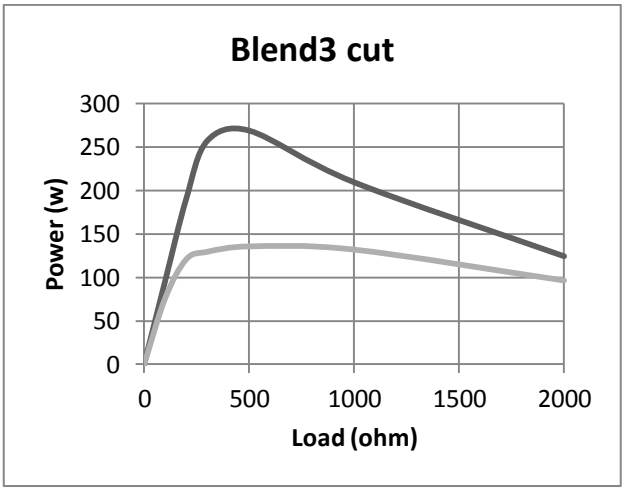
Maximum Output Power Graphs versus Load Resistance

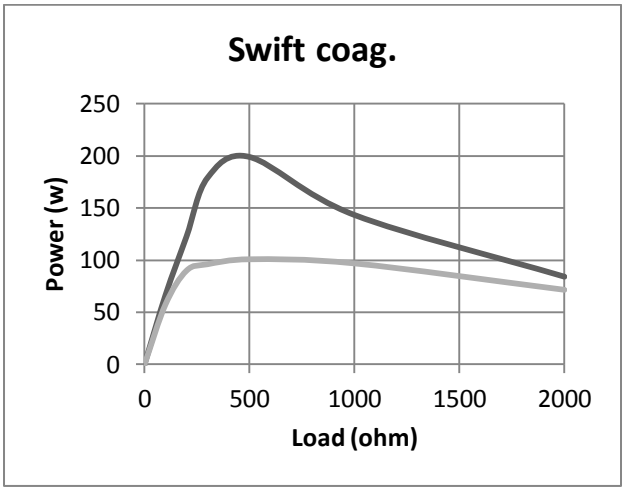
In these graphs, power level is constant and load value varies. The graphs have been drawn for the two cases of maximum power and half of maximum power in each mode.

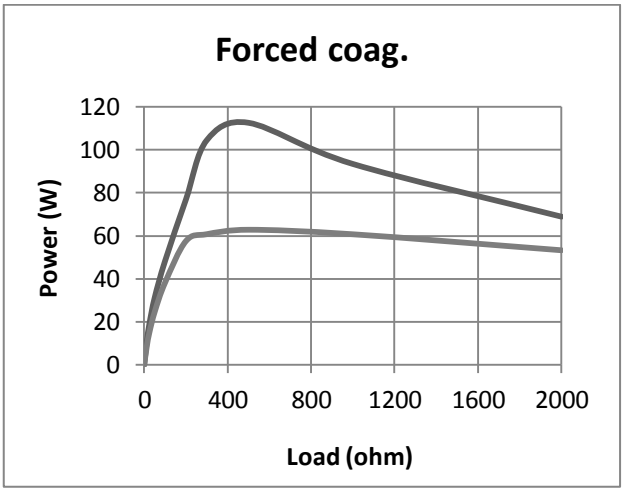


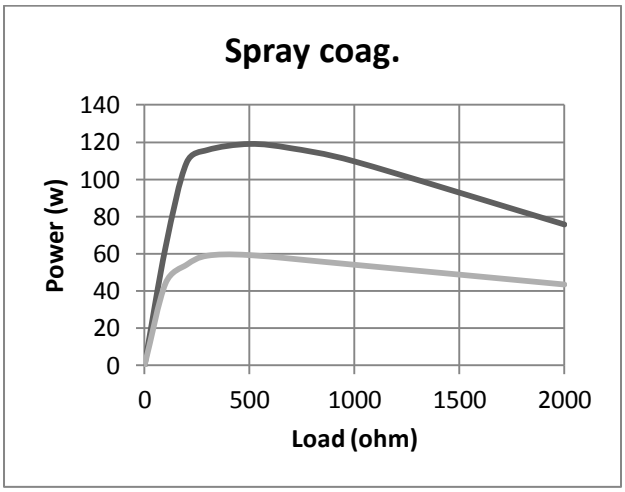


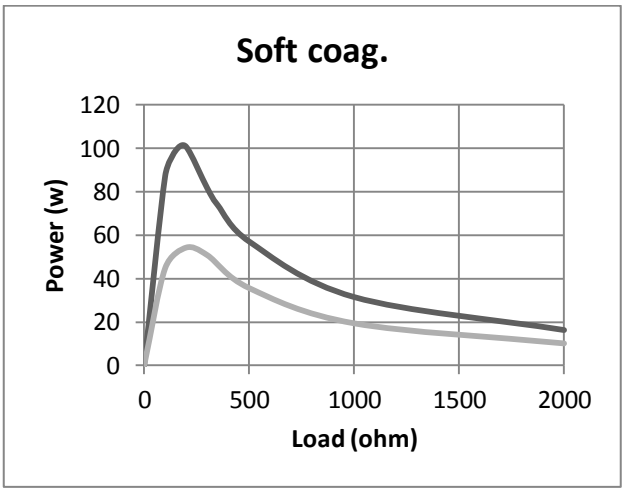

Blend2 cut
Power (w)
350
300
250
200
150
100
50
0
0
500
1000
1500
2000
Load (ohm)

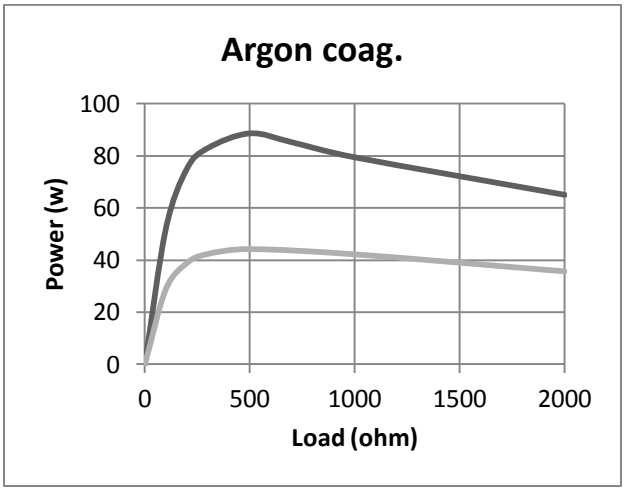

Blend3 cut
Power (w)
300
250
200
150
100
50
0
0
500
1000
1500
2000
Load (ohm)

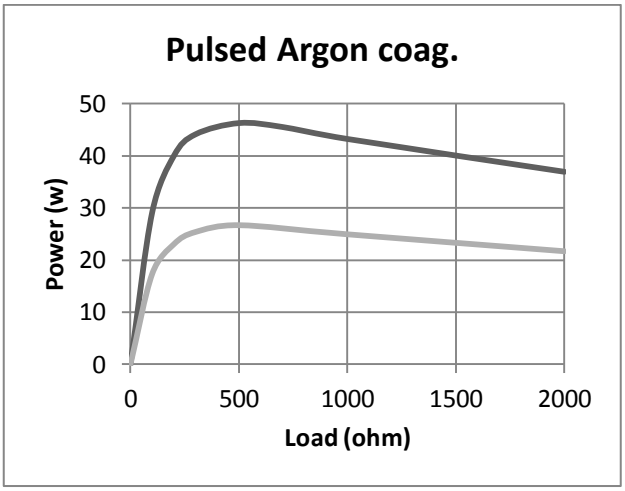

Swift coag.
Power (w)
250
200
150
100
50
0
0
500
1000
1500
2000
Load (ohm)


Forced coag.
Power (W)
120
100
80
60
40
20
0
0
400
800
1200
1600
2000
Load (ohm)

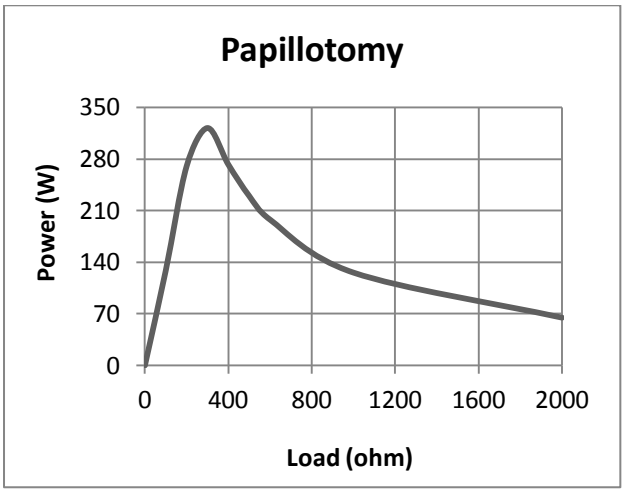

Spray coag.
Power (w)
140
120
100
80
60
40
20
0
0
500
1000
1500
2000
Load (ohm)

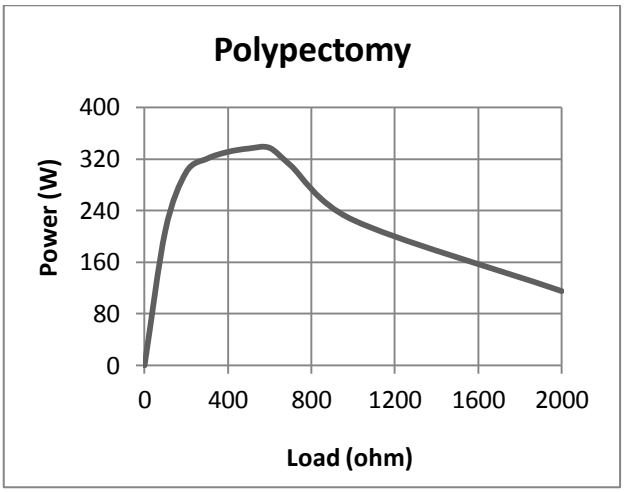

Soft coag.
Power (w)
120
100
80
60
40
20
0
0
500
1000
1500
2000
Load (ohm)

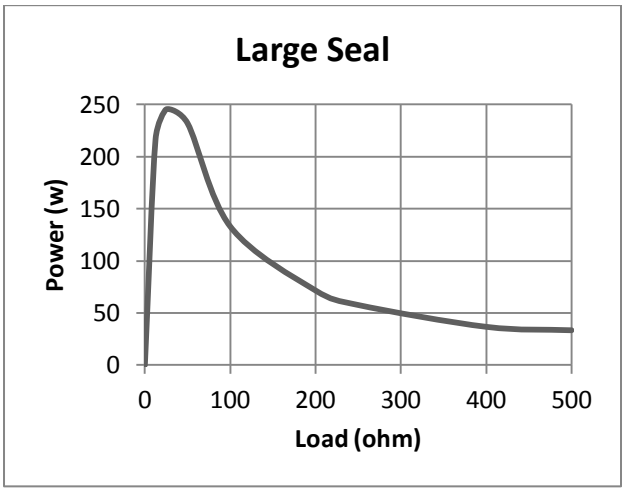


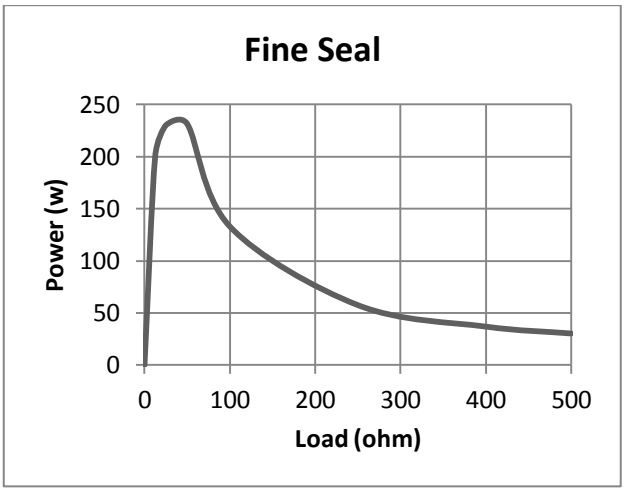


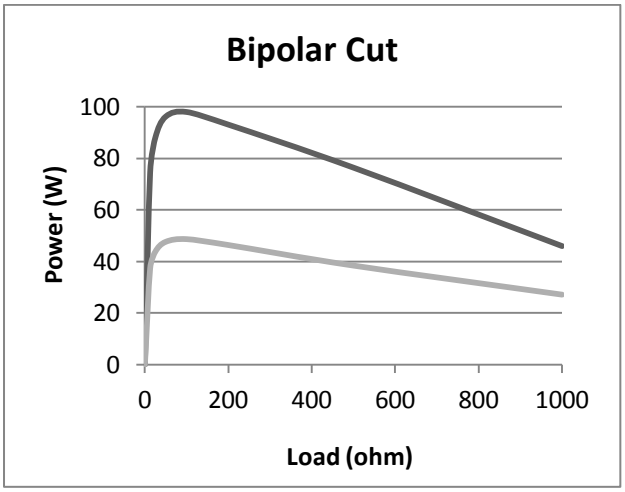
For Endo-Cut modes (Papillotomy and Polypectomy), the diagram of the maximum output power in the cutting phase, in terms of load, is as follows:

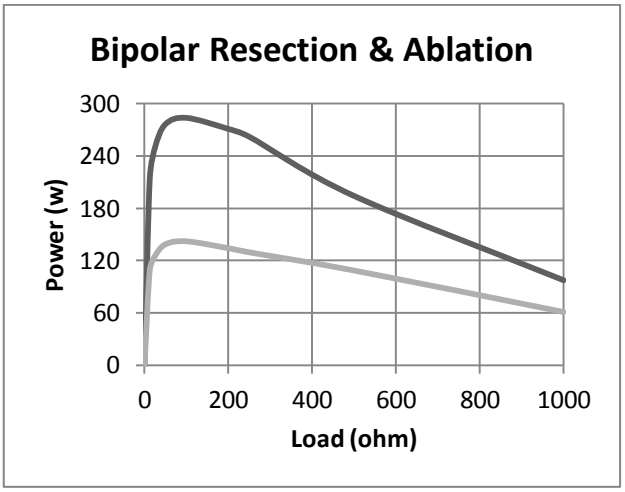


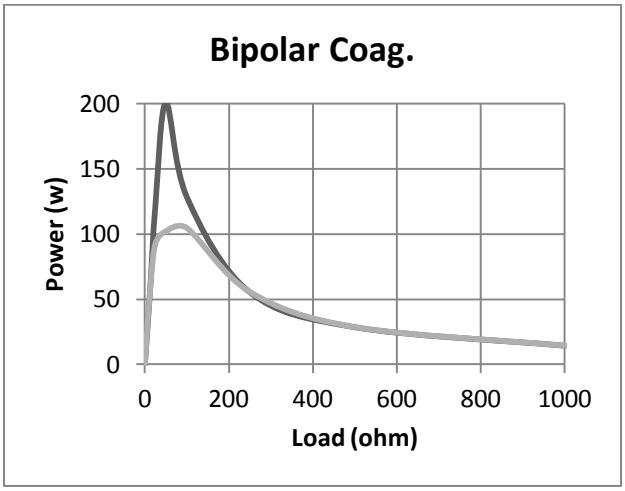


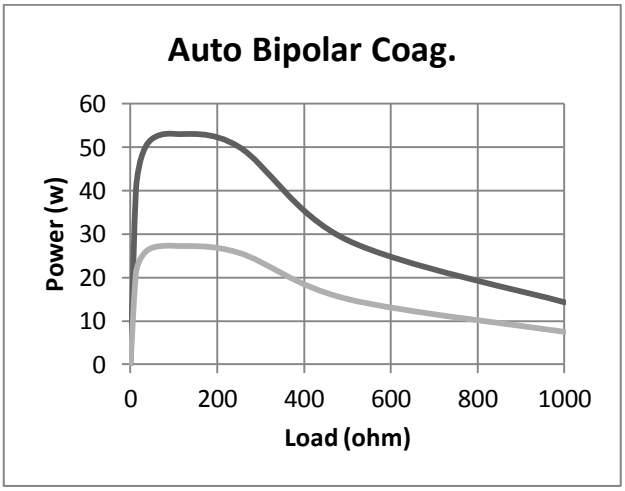





Bipolar Cut
Power (W)
100
80
60
40
20
0
0
200
400
600
800
1000
Load (ohm)

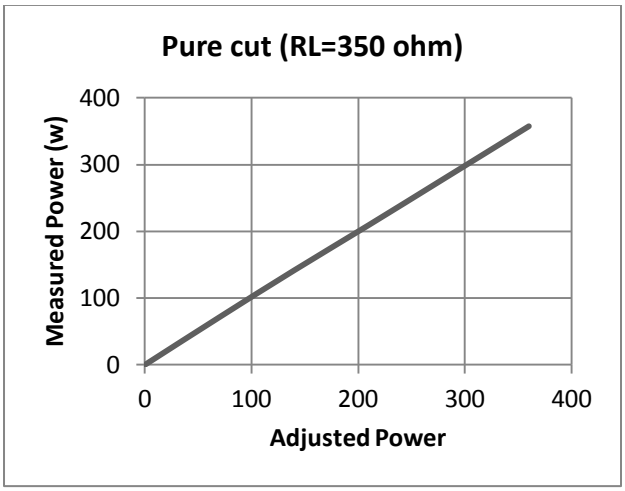

Bipolar Resection & Ablation
Power (w)
300
240
180
120
60
0
0
200
400
600
800
1000
Load (ohm)

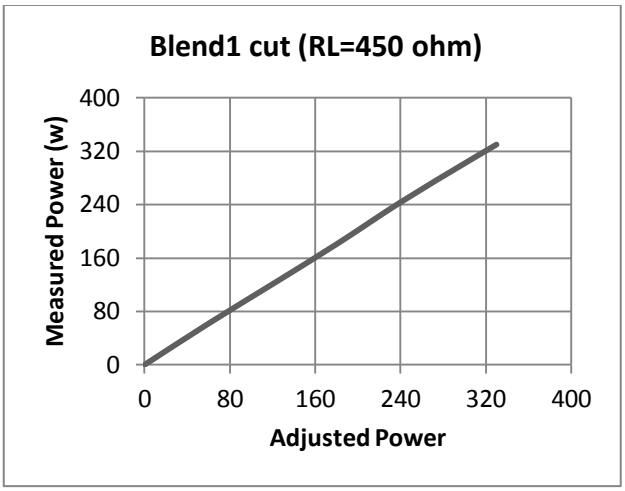

Bipolar Coag.
Power (w)
200
150
100
50
0
0
200
400
600
800
1000
Load (ohm)

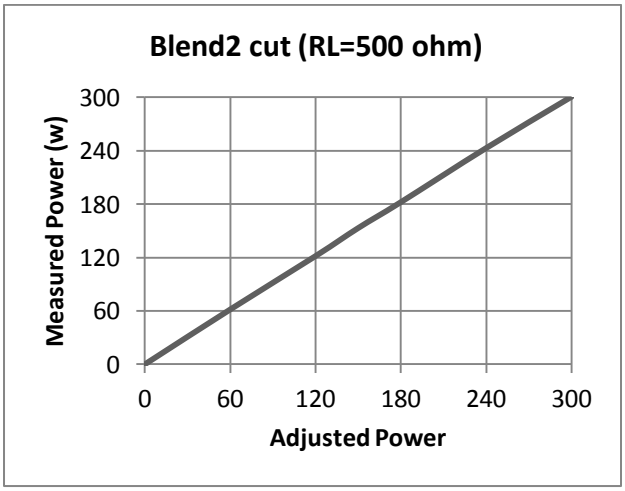

Auto Bipolar Coag.
Power (w)
60
50
40
30
20
10
0
0
200
400
600
800
1000
Load (ohm)

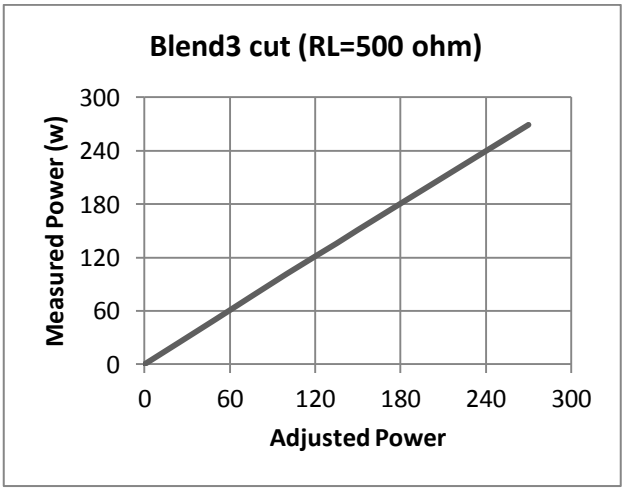
Output Power Graphs versus Adjusted Power Level

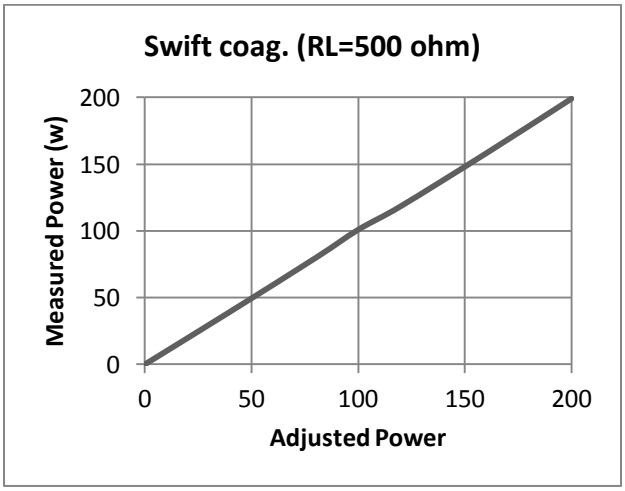
In these graphs, load is constant and power level varies from minimum to maximum.

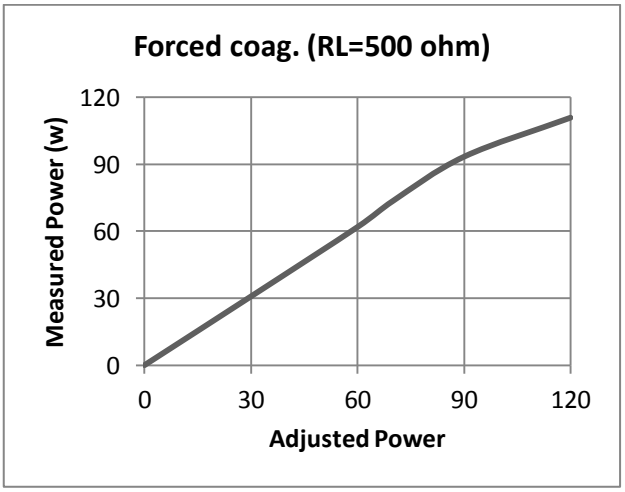


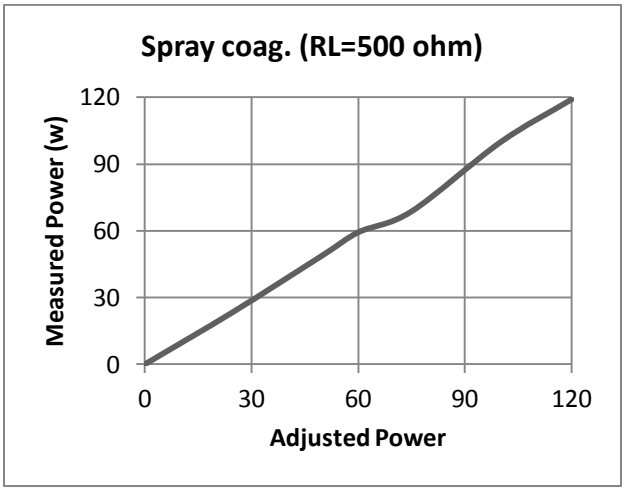


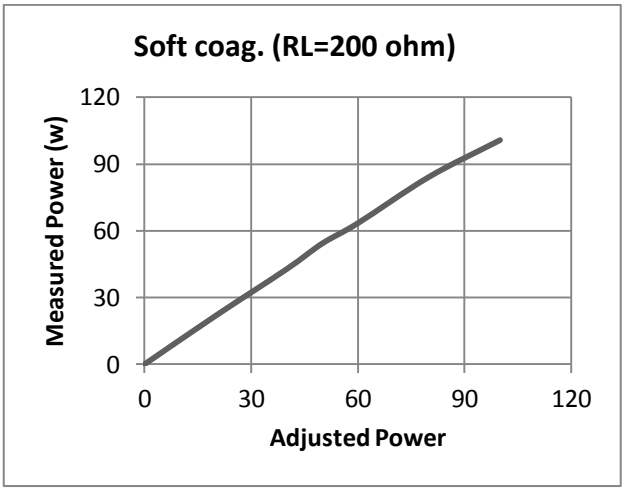


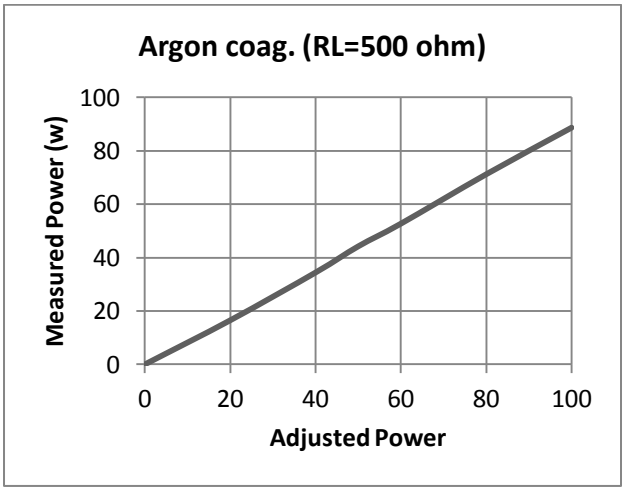


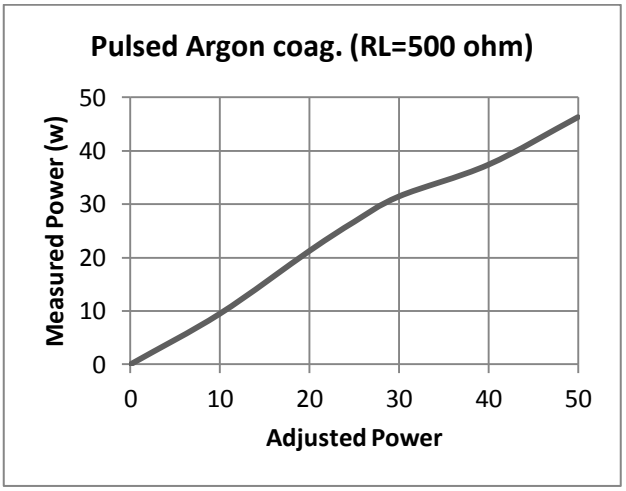


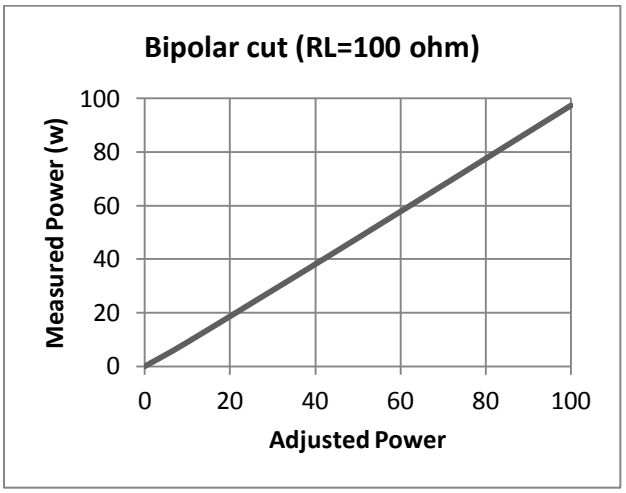


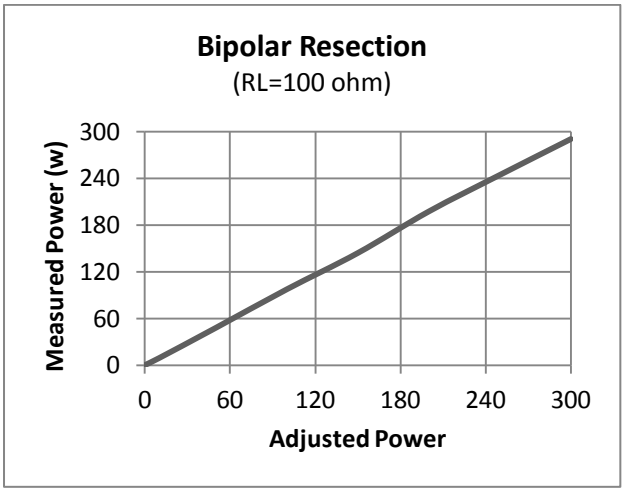

Spray coag. (RL=500 ohm)
Measured Power (w)
120
90
60
30
0
0
30
60
90
120
Adjusted Power

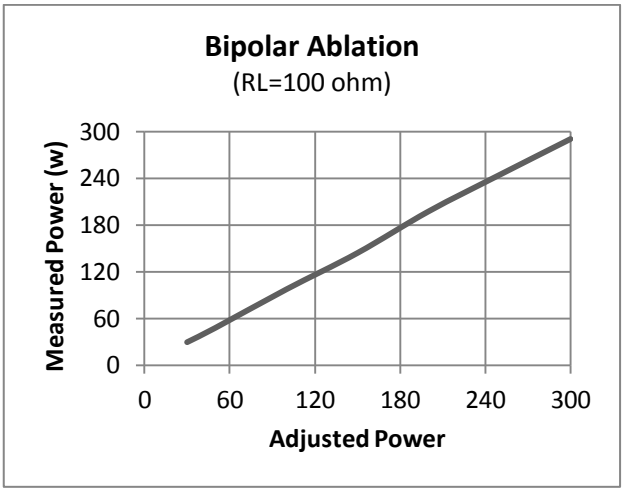

Soft coag. (RL=200 ohm)
Measured Power (w)
120
90
60
30
0
0
30
60
90
120
Adjusted Power

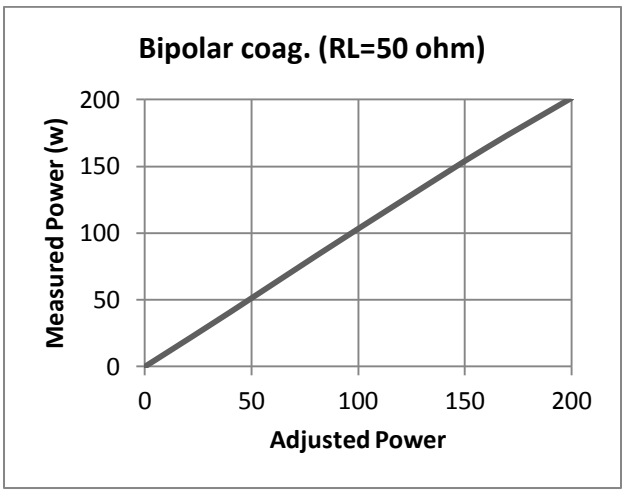

Argon coag. (RL=500 ohm)
Measured Power (w)
100
80
60
40
20
0
0
20
40
60
80
100
Adjusted Power

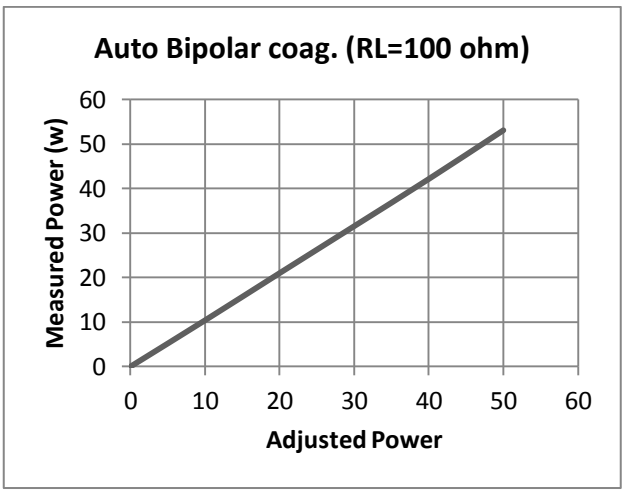

Pulsed Argon coag. (RL=500 ohm)
Measured Power (w)
50
40
30
20
10
0
0
10
20
30
40
50
Adjusted Power


Bipolar cut (RL=100 ohm)
Measured Power (w)
100
80
60
40
20
0
0
20
40
60
80
100
Adjusted Power



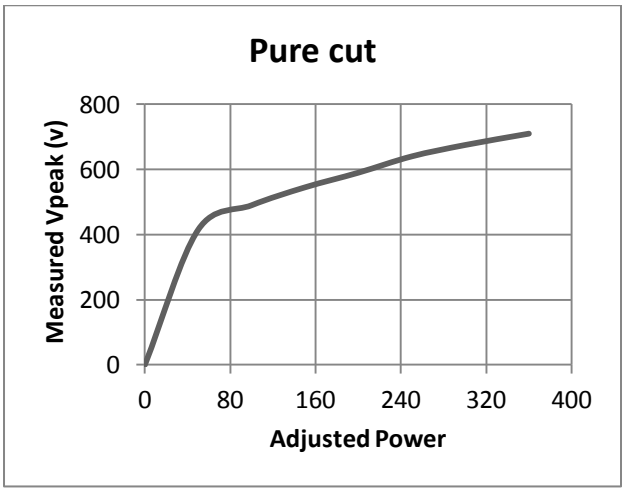


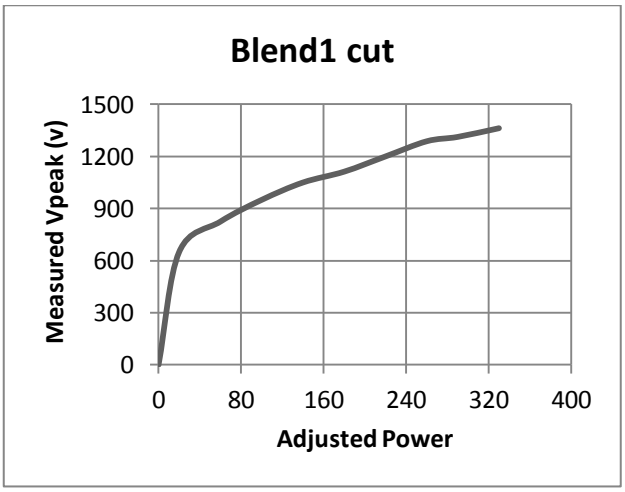


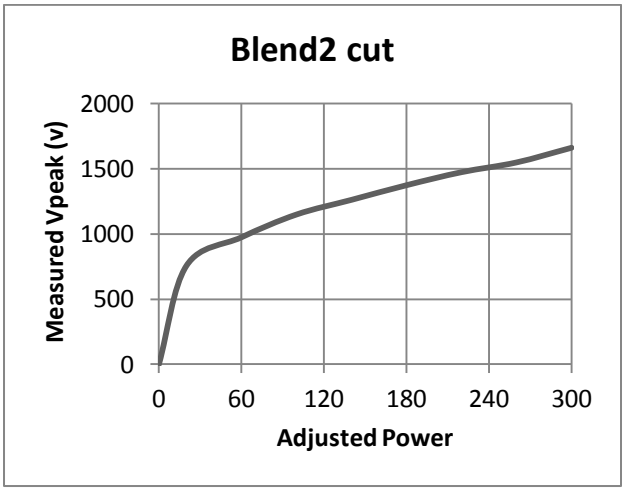


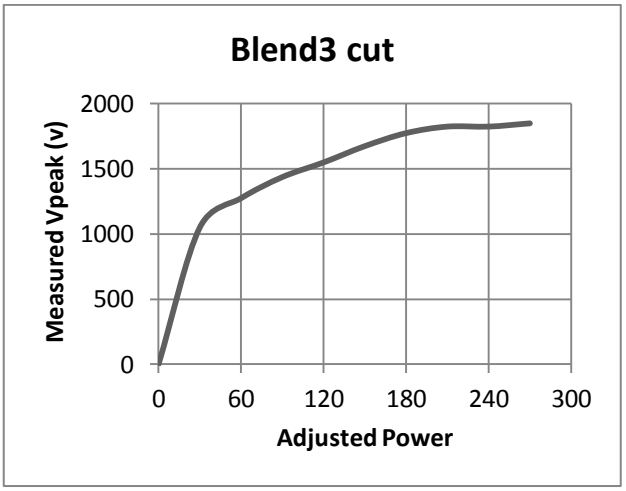
Maximum Output Voltage Graphs versus Adjusted Power Level

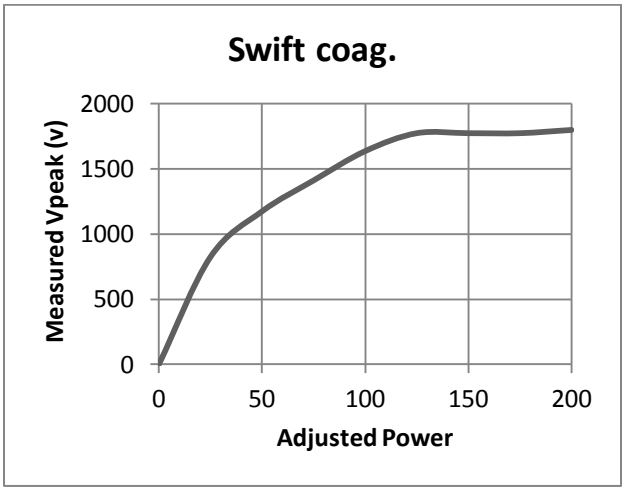
In these graphs, output voltages are measured in open circuit condition in different power levels.

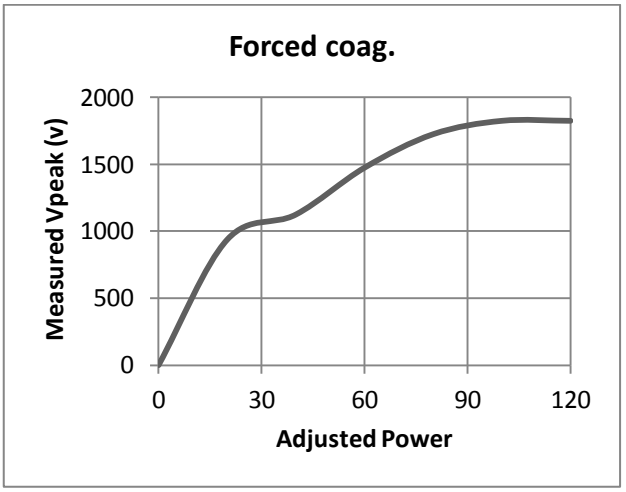


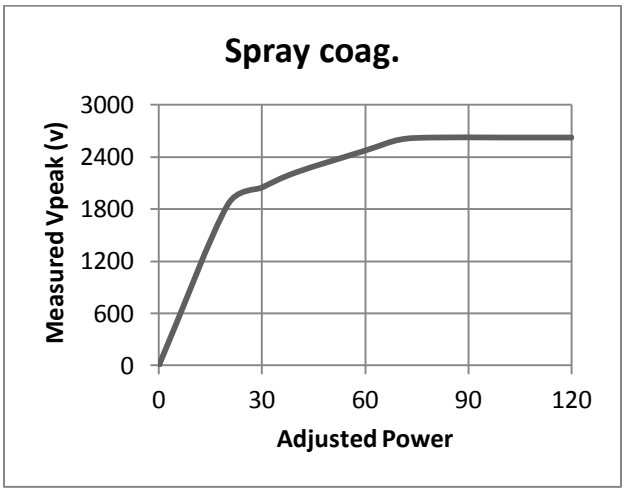


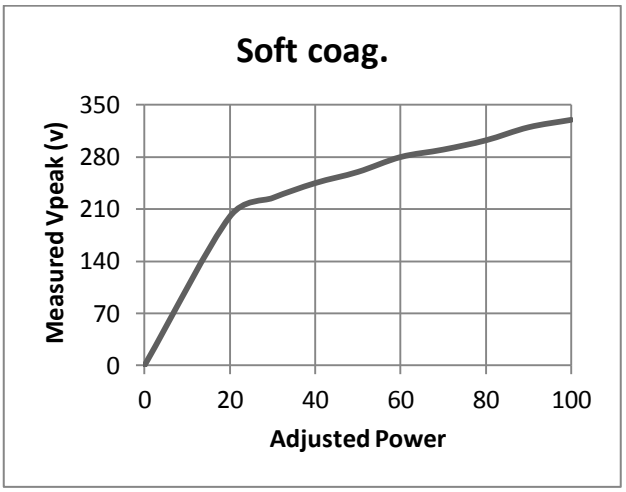

Blend2 cut
Measured Vpeak (v)
2000
1500
1000
500
0
0
60
120
180
240
300
Adjusted Power

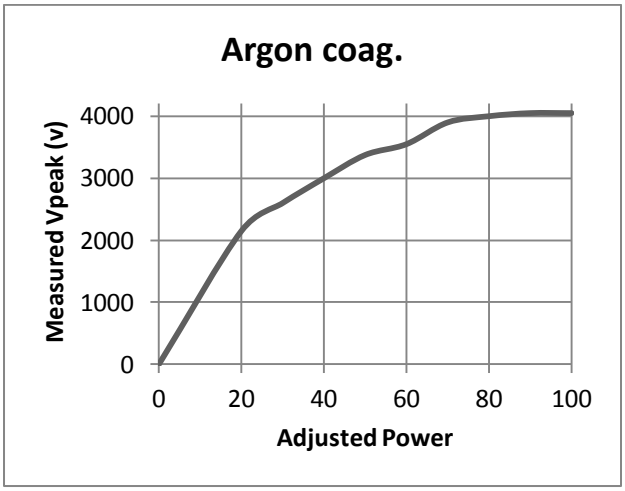

Blend3 cut
Measured Vpeak (v)
2000
1500
1000
500
0
0
60
120
180
240
300
Adjusted Power

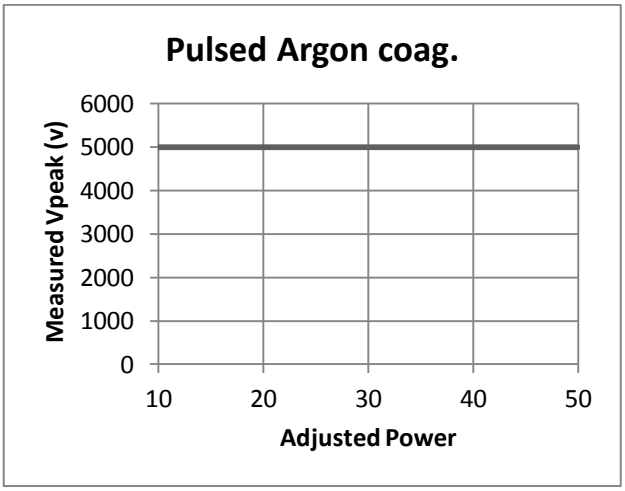

Swift coag.
Measured Vpeak (v)
2000
1500
1000
500
0
0
50
100
150
200
Adjusted Power

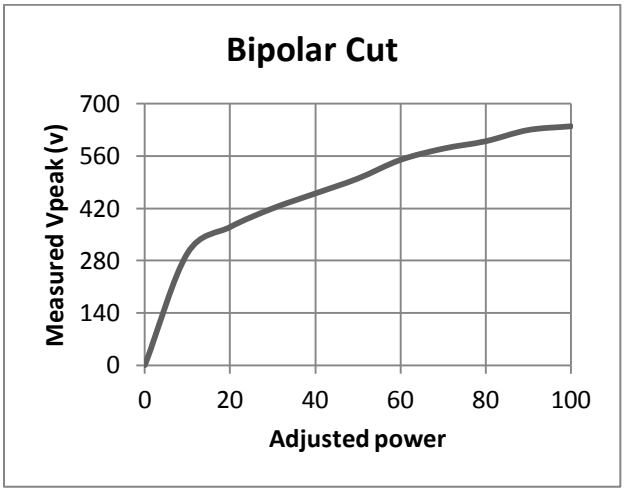

Forced coag.
Measured Vpeak (v)
2000
1500
1000
500
0
0
30
60
90
120
Adjusted Power

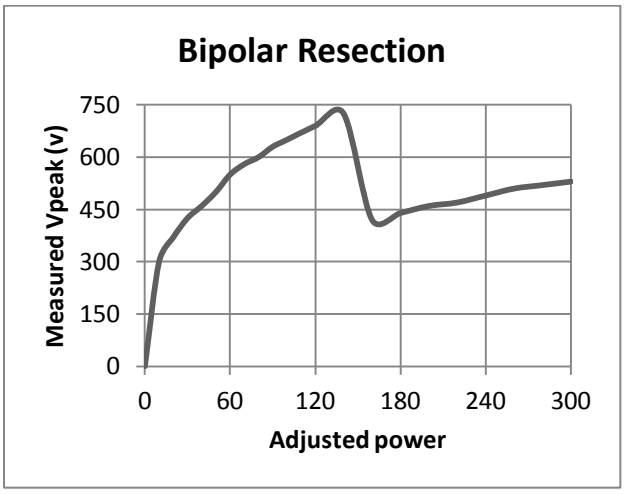

Spray coag.
Measured Vpeak (v)
3000
2400
1800
1200
600
0
0
30
60
90
120
Adjusted Power

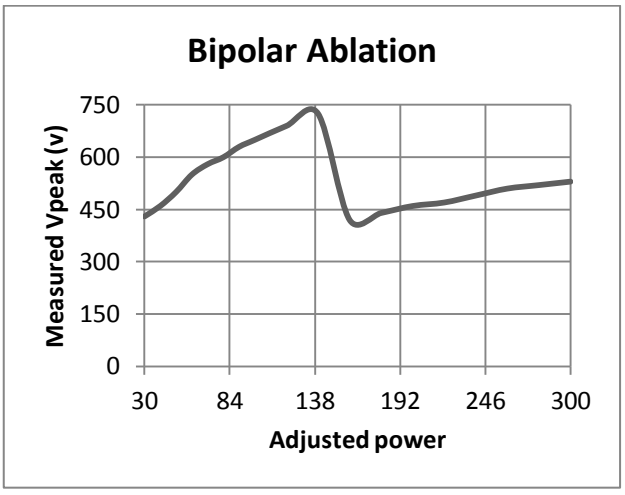

Soft coag.
Measured Vpeak (v)
350
280
210
140
70
0
0
20
40
60
80
100
Adjusted Power

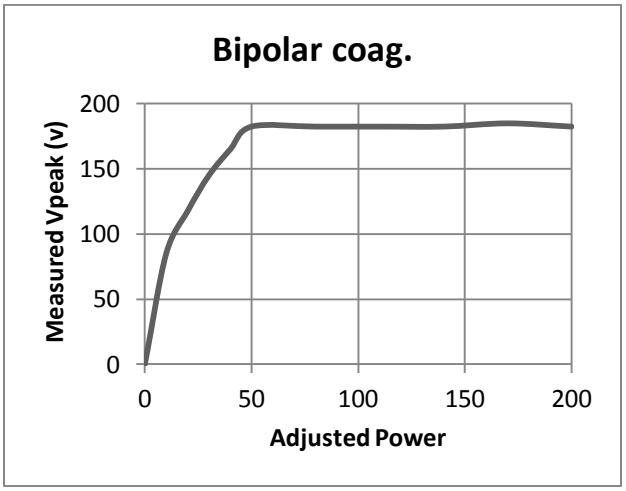

Argon coag.
Measured Vpeak (v)
4000
3000
2000
1000
0
0
20
40
60
80
100
Adjusted Power

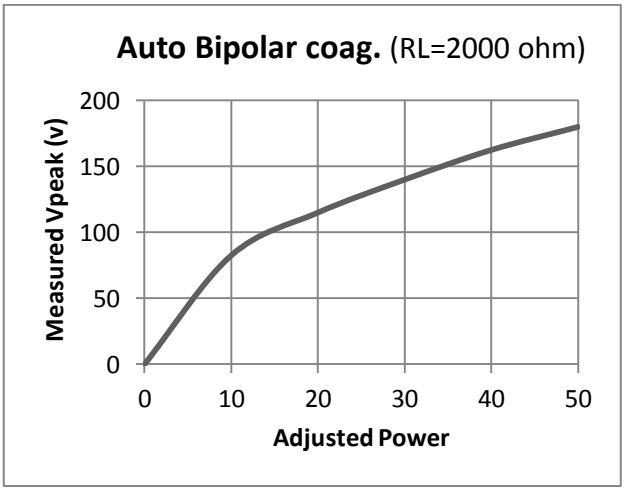

Pulsed Argon coag.
Measured Vpeak (v)
6000
5000
4000
3000
2000
1000
0
10
20
30
40
50
Adjusted Power


Bipolar Cut
Measured Vpeak (v)
700
560
420
280
140
0
0
20
40
60
80
100
Adjusted power


Bipolar Resection
Measured Vpeak (v)
750
600
450
300
150
0
0
60
120
180
240
300
Adjusted power


Bipolar Ablation
Measured Vpeak (v)
750
600
450
300
150
0
30
84
138
192
246
300
Adjusted power


Bipolar coag.
Measured Vpeak (v)
200
150
100
50
0
0
50
100
150
200
Adjusted Power


Auto Bipolar coag. (RL=2000 ohm)
Measured Vpeak (v)
200
150
100
50
0
0
10
20
30
40
50
Adjusted Power

Chapter 11

EMC Manual Tables

Guidance and manufacturer's declaration - electromagnetic emissions		
The Iconic is intended for use in the electromagnetic environment specified below. The customer or the user of the Iconic should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The Iconic, when the output switch is activated must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Group 1	The Iconic, when the output switch is not activated uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The electrosurgical equipment is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Iconic, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Iconic is used exceeds the applicable RF compliance level above, the Iconic should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Iconic.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Iconic

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{p}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{p}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{p}$
0.01	0.12m	0.12m	0.23m
0.1	0.38m	0.38m	0.74m
1	1.2m	1.2m	2.3m
10	3.8m	3.8m	7.4m
100	12m	12m	23m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object a d people.

Annex1: contents of packaging

The following accessories are included in Iconic family packaging according to the customer's order:

Item	Quantity
Iconic device	1
Single use patient plate PLACOM Pre-gelled electrosurgical Plates Comepa Industries	10
Plate cable NIPAK Company	2
Main power cable	1
Single pedal footswitch	1
Two pedal footswitch Trademark: SUNS REF: FS-82-SP	1
User manual	1
General tips label (for top of device)	1
Only For IS410S and Image1	
Single use Monopolar instrument M.A. Arain & Brothers REF: 231-014-3	2
Reusable Bipolar cable Metko co. REF : ESU-BP/BA LOT : 16003	1
Bipolar forceps Tecno co.	1

ICONIC IMAGE1

For General Surgery

- Advanced user interface design

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