MEDORAH MEDITEK

UPSURGE™ ALPHA

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

UPSURGE™ ALPHA

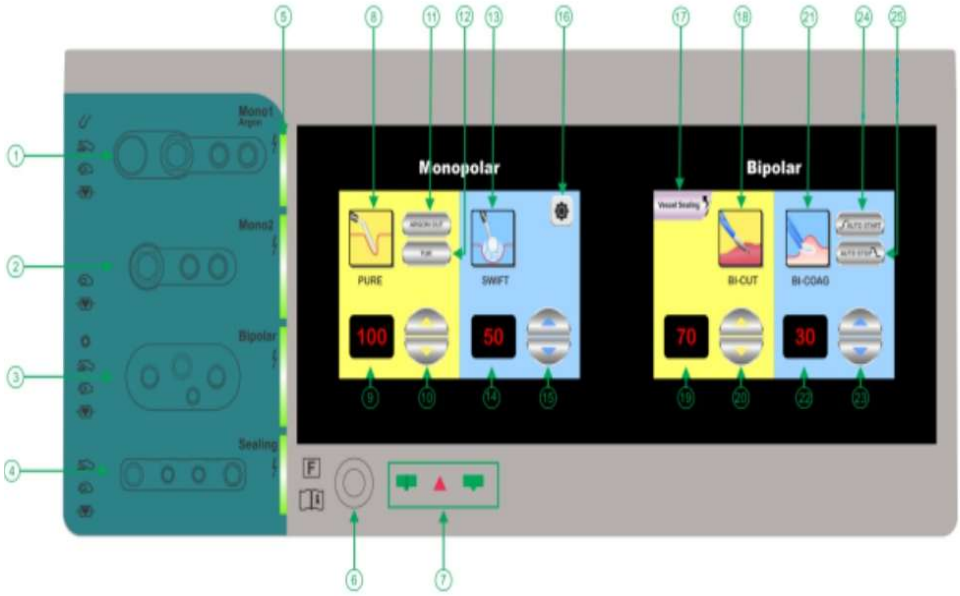
Intended Use / Indications for use

Intended use- UPSURGE™ Alpha are designed for cutting and coagulating biological tissue in both general and specialized surgeries. These devices utilize high-frequency (HF) electrical currents (>100 kHz) to achieve cutting and coagulation through thermal effects. They are suitable for patients of any age, weight, or gender.

Device Description

UPSURGE™ Alpha are engineered to deliver a range of techniques including Monopolar Cut, Monopolar ENDO-CUT (Papillotomy, Polypectomy), Monopolar Coagulation, Bipolar Cut, and Bipolar Coagulation. This device provides the ability of Argon Plasma Coagulation (APC) and also prepared with the ability to coagulate large vessels (Vessel Sealing).

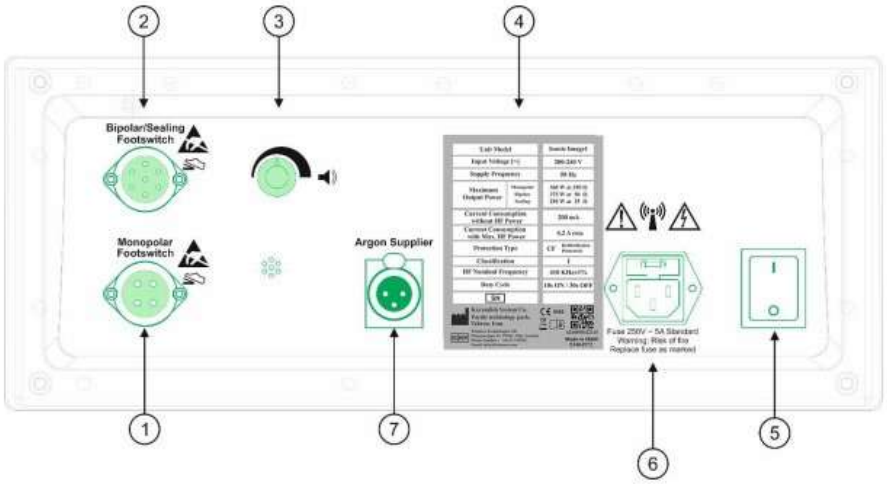
Front Panel Features



①	Monopolar1 instruments receptacle
②	Monopolar2 instruments receptacle
③	Bipolar instruments receptacle
④	Sealing instruments receptacle
⑤	LEDs that show the activation of output
⑥	Single and dual plate receptacle (patient sheet)
⑦	Indicators of plate connection and related alarms.
⑧	Selecting the default mode for Monopolar Cut
⑨	Display of power for Monopolar Cut

⑩	Settings of power for Monopolar Cut
⑪	ARGON CUT activation
⑫	TUR activation
⑬	Selecting the default mode for Monopolar Coag.
⑭	Display of power for Monopolar Coag
⑮	Settings of power for Monopolar Coag.
⑯	Setting pages
⑰	Vessel Sealing modes
⑱	Selecting the default mode for Bipolar Cut
⑲	Display of power for Bipolar Cut
⑳	Settings of power for Bipolar Cut
㉑	Selecting the default mode for Bipolar Coag
㉒	Display of power for Bipolar Coag
㉓	Settings of power for Bipolar Coag
㉔	AUTO START activation
㉕	AUTO STOP activation

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

Contraindications

- There are no known contraindications relating to safe application of the Generator.

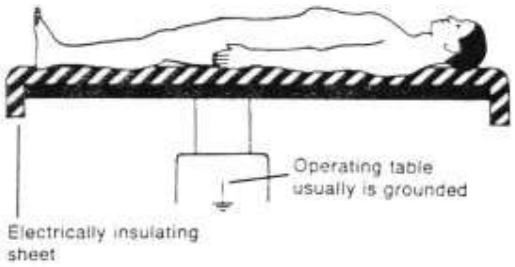
Warnings

Warnings: The entire User's Manual must be read thoroughly before using the device. It must be used by or under the supervision of a physician/s trained in the placement of stents. A detailed knowledge of the techniques, procedures and clinical applications and risks associated with the procedure is necessary before using the device.

Argon Gas Integration: The UPSURGE™ Alpha system supports argon gas functionality through the APS argon gas supply device. For detailed information on the principles, advantages, applications of argon gas, and the installation and connection of the APS to the Up-Surge device.
Device Performance Check: Regularly inspect the device for performance, focusing on its appearance and any safety alarms.

Electric shock hazard:

- **Use earthed** outlets for connecting to supply mains.
- **Use Minimal Power:** To ensure safety and minimize side effects, always use the lowest power level necessary to achieve the desired surgical effect. In Continuous Argon and Pulsed Argon modes, where lower power increases the risk of gas embolism, it is advisable to use higher power settings.
- **Electrostatic Discharge Precautions:** Receptacles marked with the electrostatic discharge warning symbol (IEC 60417-5134) are sensitive to electrostatic discharge. Ensure that there is no electrostatic charge build up when connecting cables to these connectors. Typically, accumulated static can be discharged from the device body.
- **Patient Contact Precautions:** Avoid direct contact between the patient and metal components connected to the earth, or those with significant capacitance to the earth (such as metal parts of the operating table or injection device), as well as moist or wet fabrics. This can cause burns due to high-frequency leakage currents and concentrated current on small surfaces. Use antistatic sheets to mitigate these risks.
- **Patient Separation:** Elastic surfaces on the operating table often have limited electrical conductivity and are not suitable for complete patient separation from metal parts. Instead, use dry, waterproof, and thick plates to separate the patient from the operating bed and metal items. Employ moisture-absorbing towels to prevent fluid accumulation under the patient. Place anti-static cloths between areas with heavy sweating and the patient's skin. Additionally, use a catheter to drain urine.



Method of positioning patient on the operating table

- **Avoid High-Frequency Current Leakage:** Electrodes, monitoring equipment probes, irritant devices, and imaging equipment can be affected by high-frequency current leakage, potentially causing burns. To minimize this risk, position each electrode or monitoring probe as far from the surgical electrodes and patient plate as possible. Maintain a minimum distance of 15 cm between the active surgical electrode and ECG electrodes.
- **Needle Electrodes Usage:** Needle electrodes should generally be avoided for monitoring during the use of high-frequency electrosurgical devices. If their use is unavoidable, ensure that the cables of needle electrodes are disconnected from the monitor while the electrosurgical device is active. It is highly recommended to utilize high-frequency current limiter monitoring systems to enhance safety.
- To minimize the risks of high-frequency current leakage from unintended directions, implement the following measures:

    . Use for low voltage settings whenever possible, such as Pure mode, which operates at a lower voltage than Blend mode, and Soft or Swift modes, which have lower voltages compared to Spray mode.
    . Avoid operating the device in open circuit mode where the active electrode is not in contact with tissues.

- If you find that the device's output power is lower than usual, check the following issues before increasing the power:

    . Verify that the correct settings are selected on the device panel, footswitch, or hand switches.
    . Ensure that no objects are obstructing or covering the device.
    . For Monopolar techniques, confirm that the plate is correctly and completely connected.
    . Inspect the cables and connectors for secure connections to the device.
    . Thoroughly clean the electrode tips to remove any adhesive residue.

- If a system failure occurs, the device's output power may increase beyond the selected setting.
- When instruments are not in use temporarily, keep them away from the surgical area and any items that are in contact with the patient. This helps prevent burns in the event of accidental device activation, such as an inadvertent switch press.
- To minimize the risks of burns in areas not visible during minimally invasive surgeries (such as laparoscopy), follow these steps:

    . Inspect the insulation quality carefully, noting that any cracks, gaps, or ripples could indicate insulation weakness and potential current leakage.
    . Utilize the lowest power settings and modes that operate at minimal voltage.
    . Activate the generator only when the active electrode is in contact with tissue.
    . Avoid activating the generator if the active electrode is near or in contact with metal parts.
    . Prefer the Bipolar method whenever possible.
    . Use an all-metal cannula, where the external metal sheath covers the entire cannula system, to reduce the risk of leakage due to capacitive coupling.

- Avoid wrapping instrument and plate cables around metal objects, as this can lead to current leakage through the metal and cause high-frequency induction, which may result in heating and burns.
- When performing procedures such as endoscopy or TUR, use isolated ocular parts. Since the active electrode is in constant contact with tissues, any unintended activation of the generator could cause burns at the electrode's tissue contact point.
- Minimize the use of coagulation techniques where an electric arc is established between the active electrode and hemostat instrument. To reduce the risk of accidental shocks to surgeons, ensure metal-to-metal contact is established before activating the generator.
- Neuromuscular stimulation, including spasms or muscle contractions, can occur in modes with high output voltage, such as spray mode, due to low-frequency harmonics in the electric arc. The device is designed to minimize such stimulations.
- If an alarm sounds from the device, check its status and ensure it is operating correctly before using it again.
- To reduce adhesive effects of active electrodes on tissues during coagulation:
  . Ensure the electrode is in contact with the tissue before activating the generator.
  . Stop the current as soon as coagulation is sufficient.
  . Keep electrodes clean at all times.
- Active electrodes may become hot due to electrical sparks or contact with tissue during cutting and coagulation, which can lead to unintended burns if they touch other tissues.
- When the active electrode is in constant contact with tissue, such as during endoscopy or TUR, pay close attention to both visual and auditory cues indicating generator activation. If the generator is not needed, for example, when removing the electrode from the patient, ensure the output power is set to "lack of output power" mode or turn off the device completely.
- Unintentional activation of the generator, especially if the electrodes are in contact with the patient's body directly or indirectly through wet fabrics or conductive objects, can cause burns. To avoid this, never place active electrodes where they might come into contact with the patient directly or through conductive materials.
- Exercise caution when using the ESU on thin-walled organs like the intestine to prevent perforation; set the power to the lowest effective level.
- To prevent burns to staff, avoid contact with the patient during ESU activation and ensure the patient remains still at the surgical 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.

Fire Hazard

- Using an electrosurgical device presents a risk of combustion when flammable gases or substances are present. To mitigate this risk, ensure that flammable substances do not come into contact with the electrodes of the electrosurgical device. In environments with high oxygen concentrations, such as those enriched with oxygen or nitrous oxide (N_2O), the risk of fire is increased. Therefore, measures should be taken to lower the oxygen concentration at the surgical site and avoid using oxygen-enriched or nitrous oxide environments near the area of surgery.
- For procedures involving the head or chest, avoid using flammable anaesthetics or oxidizing gases like nitrous oxide and oxygen. If their use is necessary, ensure that any combustion-supporting gases are thoroughly removed before performing electrosurgery.
- Additionally, be cautious of flammable solutions that may accumulate in body areas such as the umbilicus, body cavities like the vagina, or under the patient. It is advisable to dry any accumulated liquids in these areas before using the device. Also, take precautions to extract flammable endogenous gases from the gastrointestinal tract or irrigate with carbon dioxide (CO_2) prior to performing electrosurgery.
- Materials such as string, cotton, and gauze can ignite when saturated with oxygen if they come into contact with sparks produced during the normal use of an electrosurgical device. When using flammable disinfectants, particularly those with an alcohol base, allow them to fully evaporate before covering the patient. Additionally, ensure that these flammable materials do not come into contact with the electric arc during surgery to prevent potential ignition.

Electromagnetic Interference

- Electromagnetic interference between an electrosurgical device and nearby electronic devices can occur. If unusual conditions are observed in adjacent devices, consider this possibility and apply appropriate electromagnetic compatibility measures to address the interference.
- To reduce interference when the generator is active, take the following steps:
    - Lower the device's output power.
    - Use low-voltage modes, such as Pure mode instead of Blend mode, or Soft or Swift modes instead of Spray mode.
    - Use for Bipolar technique rather than Monopolar technique.
- Increase the distance between the device, its external cables, and the affected unit (e.g., monitor).
- If the patient has a pacemaker or other implanted electronic devices, there is a risk of interference or damage. To minimize this risk:
    - Use Bipolar technique whenever possible.
    - Carefully check the cables, their connections, and the connection of the plate to the patient to prevent sparks from weak connections.
    - Position the plate close to the operation area, ensuring that the heart or pacemaker is not between the plate and the operation site.
    - Consult with a cardiologist before the procedure.
    - Employ reliable monitoring equipment and continuously monitor ECG signals.

- Ensure a defibrillator is readily available.

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

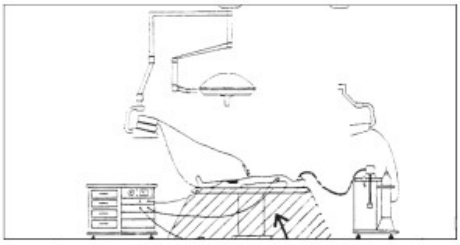
Accessories

- Never use non-standard, poor-quality, damaged, or defective accessories, and always ensure that the insulation of these devices is intact.
- Do not leave electrodes from other equipment, such as monitors, on the patient's body, as they can create a path for leakage current and potentially cause burns. When replacing accessories, adjust the power level appropriately for the new accessory to ensure safety and effectiveness.
- Using non-standard, defective, or unauthorized accessories can lead to several issues, including:
    - Unwanted activation of the generator
    - Generator breakdown
    - Injury or electric shock to the patient or surgical team
    - Malfunction of the monitoring system for plate contact quality
    - Incorrect selection or mistakes in surgical modes
    - Variations in output power or connection issues
    - Electric shock or nerve stimulation from electric arcs between metals
    - Electromagnetic interference with monitoring equipment
    - Excessive high-frequency current leakage
- Avoid using accessories with damaged, rotted, or deformed cables, and ensure that connectors are intact. Use only instruments that can tolerate the maximum output voltage specified in the technical specifications ($V_{p-p} = 2 \times V_p$). Using instruments with a lower rated voltage can cause damage. Verify the rated voltage with the manufacturer.
- Accessories should preferably be no longer than 3 meters and should not be reused if they are disposable. If there is any doubt about the compatibility of your accessories, contact Medorah Meditek Pvt Ltd or its approved representatives.
- Monopolar instruments must be connected to monopolar receptacles, bipolar instruments to bipolar receptacles, and sealing instruments to sealing receptacles to avoid mismatching. Accessories should be secured without excessive pressure, and converters should not be used to connect accessories to the generator.
- Never connect two surgical devices to the same output receptacle simultaneously, as this could cause both devices to activate and deactivate at the same time. Keep surgical electrodes clean to avoid increased resistance and reduced performance. After deactivating the device, ensure that the electrodes do not contact the patient's body, as they may be hot.
- Position electrosurgical accessories to prevent unwanted contact with the patient or each other. Keep unused active electrodes separate from the patient and route cables to avoid contact with the patient or other conductive objects, reducing the risk of unintended burns.

Caution: It is essential to handle the placement and removal of accessory connectors from the device slowly and gently, avoiding any high pressure on cables and connectors. Avoid wrapping instrument cables tightly or placing them under pressure, and refrain from wrapping them around the instrument. Such practices can lead to cable deformation over time.

Footswitch

- 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

- To prevent skin-to-skin contact, such as between the patient's arms, body, or thighs, use a towel or dry gauze. Ensure that areas of the patient's body prone to excessive sweating are kept dry to avoid contact with other body parts.
- Be aware that if two surgeons activate Monopolar1 and Monopolar2 outputs simultaneously in Spray mode, the output power is divided between the two surgical pencils. Consequently, connecting or disconnecting one Monopolar pencil can affect the output power of the other.

Plate

- Correct use and proper placement of the plate are crucial for the effective and safe application of Monopolar electrosurgery. Medorah Meditek Pvt Ltd recommends using dual plates to enhance patient safety. When using a single plate, the device will not monitor the contact quality between the plate and the patient.
- If using polymer plates, ensure they are silicon-based and of standard quality. Non-standard rubber plates from unknown brands can pose a risk of burns. Additionally, worn or old polymer plates may degrade over time and lose their effectiveness.
- Select the type and size of the plate according to the minimum surface area requirements specified on page 29 and based on the output power. Position the plate to ensure a suitable

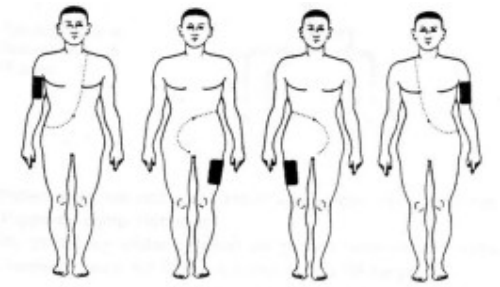
contact surface between the plate and the patient's skin. Inadequate or weak contact can reduce the effective contact surface area, potentially leading to burns due to increased current density in the contact area.

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.

- To enhance the electrical conductivity of the patient's skin where the neutral electrode is placed, clean and massage the area to improve blood circulation and shave any hair from the contact area. Avoid placing the plate over large hypodermic blood vessels, bones, or areas with typically poor blood circulation.
- For permanent plates, apply a uniform layer of conductive gel over the entire surface of the plate. Secure the plate in place with rubber bands and wrapping to ensure good contact with the patient's skin. Recheck the plate connection if the patient is moved.
- If gel is not used, ensure that fluids from bleeding, washing, disinfectants, or sweat do not reach the plate during surgery, as these can increase the risk of burns.
- Position the plate in an area with normal blood circulation (such as the upper arm or thigh) and as close to the operation site as possible. Ensure that the current path between the plate and the Monopolar active electrode is as short as possible and avoids passing through the heart and lungs.



- Never use water, salt water solutions, or wet fabrics to enhance contact between the plate and the patient. If electrically conductive parts are present inside the patient's body, position the plate so that these parts are not in the current path.
- Do not deform the patient's plate beyond the manufacturer's instructions, and ensure that it is not torn or damaged. Always verify that the cable insulation of the neutral electrode is intact.

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

Bipolar

- Given the advantages of the Bipolar technique, it is recommended to use it whenever feasible, especially in cases where the area of current flow in the body is small:
  - Reduced Burn Hazard: The Bipolar technique involves a smaller area of current effect, limited to the space between the two tips of the forceps. This requires lower output power and eliminates the need for a plate, significantly reducing the risk of burns compared to the Monopolar technique and minimizing the potential for unwanted coagulations.
  - Lower Electromagnetic Interference: Because the Bipolar technique uses a smaller current flow through the tissues and operates at lower output power, it poses a much lower risk of electromagnetic interference with electronic devices compared to the Monopolar technique.
- One issue with the Bipolar technique is tissue adhesion and blood clots on the tips of the forceps, which can lead to recurrent bleeding when removing the forceps from the tissue. To minimize these effects, follow these guidelines:
  - Avoid Early Activation: Do not enable the Bipolar generator before the electrode is in contact with the tissue. Early activation can cause tissue carbonization and adhesion. Use Auto Start mode with or without delay to ensure the generator is activated only after proper contact.
  - Limit Contact Time: Prolonged contact of the forceps with the tissue can lead to carbonization and sticking. Disable the generator once adequate coagulation is achieved, and avoid extending the coagulation process beyond its beneficial effect. Auto Stop mode is recommended to automatically end the process when sufficient coagulation is achieved.
  - Maintain Cleanliness: Keep the electrodes clean and thoroughly remove any tissue adhesion from previous use. This helps prevent interference during subsequent procedures.
  - Moisten Dry Tissue: If operating on dry tissues using the Bipolar technique, pre-moisten them with sterilized water or physiological saline solution to facilitate better performance and reduce adhesion.
- 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, the electrodes' surfaces can become covered with tissue fluids, which may dry and obstruct full electrical current flow through the electrodes. This can result in the surgeon perceiving a decrease in output power. To resolve this issue, clean the electrodes thoroughly after each coagulation to ensure optimal electrical contact and performance.

Sealing

- Do not use this technique until you have received proper training on the Sealing technique and are familiar with the associated surgical instruments. Using the device without adequate training can lead to adverse outcomes**.**
- The Sealing technique is not suitable for tubal sterilization or coagulation processes. For patients with specific vascular issues, such as atherosclerosis or aneurysmal vessels, ensure that seal positions are chosen on healthy vessels.
- Using the incorrect mode with a surgical instrument can result in inadequate seal quality or damage to tissue due to excessive heat. To ensure a reliable seal, the surgical instrument must be completely locked during the sealing process. Otherwise, the seal may be compromised.
- Tissue near the jaw hinge of the surgical instrument and outside the jaws will not be properly sealed, even if it appears white from the applied energy. Conductive fluids, such as blood or saline, in proximity to or in direct contact with the instrument can transfer heat and electrical energy to adjacent tissues. Therefore, dry the sealing area before starting the process.
- Ensure that surgical instruments are completely dry and fully connected to the generator. Be cautious, as the external surface of the instrument may become very hot after the process, potentially causing damage to other tissues.
- Do not activate the generator when the jaws of the instrument are near a metal tool, as this can result in ineffective energy transfer, potentially causing injury to the patient or operator. During the sealing process, the power level cannot be adjusted, so confirm the desired power level and mode settings before starting.
- If sparks are observed, immediately stop the surgery and inspect all generator and electrode connections. Metal-to-metal sparks can cause neuromuscular stimulation in the patient.
- For optimal seal quality, place vessels and their surrounding tissue within the jaws of the instrument to ensure a stronger seal. Avoid applying tension or mechanical pressure to vessels during the sealing process, as this can distort the vessel wall, leading to bleeding.
- Maintain cleanliness of the surgical instrument surfaces to ensure proper energy transfer and effective sealing. Frequent use of disposable surgical instruments can lead to tissue adhesion to the electrode, create electric arcs, and reduce seal quality.

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

After surgery

- 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.
- If you need to use flammable materials for cleaning and disinfecting the device, ensure that these materials are completely evaporated before turning the device back on.
- It is important to distinguish between burns caused by increased electric current density and other types of necrosis. Electric burns typically occur due to poor contact with metal objects or incomplete plate-to-patient contact. In contrast, pseudo-burns can result from other factors:
    - Chemical Burns: Prolonged contact with disinfectants can cause chemical burns, which should not be confused with burns from electric current density.
    - Pressure Injuries: Tissue necrosis can also occur from prolonged pressure during surgery or extended periods of immobility, such as during open heart surgery or in the ICU. Adequate care should be taken to avoid placing tissues under continuous pressure to ensure proper blood circulation.
- Unlike electrical burns, which manifest immediately or within an hour after surgery, pseudo-burns may only become apparent hours or even days later. Proper care and monitoring are essential to prevent and identify these types of injuries.

Notice:

- Penetration of liquids into the device can cause damage to it; Since there is the possibility of liquids penetrate 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

- Danger of electric shock: Never open the device case. Any modification or repair on device must be done by authorized service personnel from Medorah Meditek Pvt Ltd.

Precautions

- The Generator must be separated from other electrosurgical devices and their cords.
- Close proximity to the Generator and its cords to electrosurgical units that produce excessive RF current radiation could cause the Generator to change output power.
- Surgical electrode cords must be positioned to avoid contact with the patient or other leads. Temporarily unused active electrodes should be stored in a location that is isolated from the patient.
- Do not operate the Generator at temperatures below 50°F (10°C). Allow the Generator to warm up to at least 50°F (10°C) before use.

- Visually inspect the power cord, bipolar cord and Foot Pedal for damage prior to each use. Connect Foot Pedal, adjust Generator to desired power setting, and activate Foot Pedal to verify proper function. Replace accessories if necessary.
- Non-insulated bipolar forceps are not recommended for use with higher power settings. When higher power settings are employed, insulated bipolar forceps are recommended.
- Keep bipolar instrument tips clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning, as injury to operating personnel may result.
- The Generator is designed for use without a neutral electrode while operated in bipolar modes.
- The Generator does not generate waste.
- Disposable products used with the Generator must be disposed of in accordance with hospital procedures and regulations.
- Always position Generator so that the power cord can be easily unplugged from the rear panel. The output power should be set as low as is necessary to achieve the desired effect.
- Anyone who connects additional units to the input or output section thereby configures the system and is thus responsible for compliance with section IEC 60601-1:16.
- In order to be able to completely separate the unit from the grid in the event of danger, either the power socket of the unit or the outlet into which the mains cable is plugged should remain accessible.

Product Preparation:

1. **Inspect the Device**: After unpacking the device, thoroughly check the physical condition of both the device and its accessories. If you find any damage from transport or other causes, contact Medorah Meditek Pvt Ltd immediately. Provide details of the damage, the device serial number, and your address.

2. **Set Up the Device**: Place the device on a stable, flat surface that is free from vibrations to ensure proper operation.

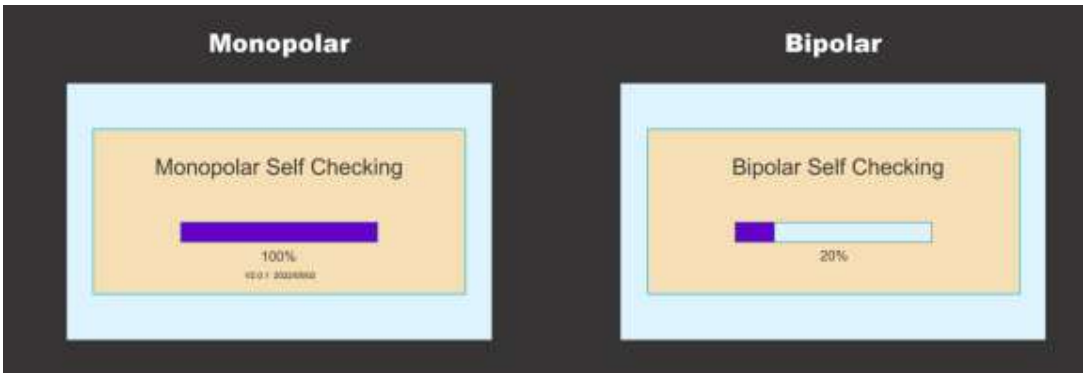
3. **Connect to Power**: Plug the device into an electric network with a voltage range of 200 V to 240 V using the provided power cable.

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

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

5. **Monitor Device Activation and Self-Checking**:

- **Self-Checking Process**: As the device powers on and performs its self-checking, observe the following:
- **Self-Checking Display**: The self-checking process is shown across multiple pages. The main page displays the progress of this process.
- **Monopolar and Bipolar Checks**: The self-checking sequence begins with Monopolar self-checking, which is displayed on the left side of the screen, and continues with Bipolar self-checking, shown on the right side.



- **Completion of Self-Checking**: After the self-checking process is complete:
- If no issues are detected, the screen will display the message: "No Errors Reported."
- If errors are found, the screen will show the message: "Error codes" the specific error codes. Refer to the alarm code tables in IFU of the UP-SURGE™ Alpha user manual for detailed information about the errors. Note that any modes associated with reported failures will not function correctly.
- **Final Message**: Once the self-checking process is complete and no errors are detected, a "Welcome" message will appear on the screen.
- After the self-checking process is complete, the default programs will be displayed on the screen. Press **OK** to enter the mode pages.
- During normal operation, if the plate is not connected to the device, "Er: PT" alarms will be triggered (refer to the Alarms section for more details).

Accessories

The following accessories are included with the UP-SURGE™ Alpha

1. Disposable Monopolar pencil
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

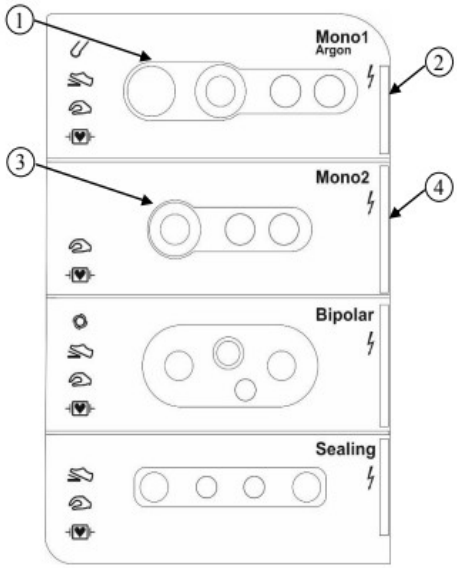
If you turn on the device for the first time, before using the device in the operating room, test the performance of the device using the following instruction:

1. Begin by powering on the device and observing the Self-Checking process. Once the device completes this process and enters normal operating condition, ensure that the mode adjustments and power settings are configured to the default conditions. The screen will then display the available modes, with default modes appearing first. These default modes are set with specific power levels and are generally the most useful. Selectable mode icons will be highlighted with a shadow, indicating their availability. Confirm that the displayed default modes meet your needs and verify that the device is ready for use according to its pre-set configurations.
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.
4. 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.
5. 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.
6. Change power levels in Monopolar Cut and Monopolar Coag. and by output activation, see the output power variation on the raw meat.
7. 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.
8. To enter the bipolar modes page, you must select Bipolar Surgery.
9. In Bipolar technique, by pressing Bipolar footswitch, apply the output on the raw meat through the instrument. Do this for both Bipolar Cut and Bipolar Coag. techniques and repeat it for different power levels.
10. 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.

Product Specification

1. **Monopolar in Receptacles Module Section**



① Monopolar1 instruments receptacle.

Notice: The use of output with argon gas (in argon modes) is exclusively possible through the Monopolar1 receptacle.

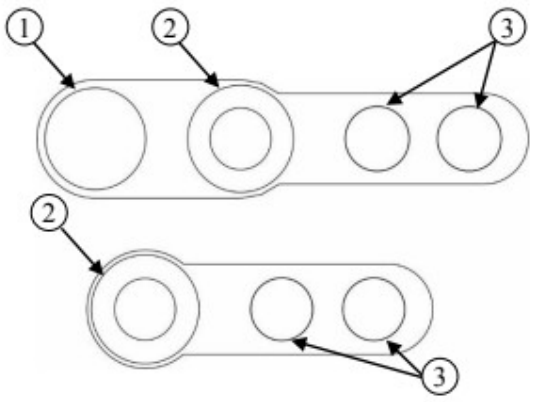
In most programs, Monopolar1 is activated with the pedal. Therefore, Monopolar instruments that do not have a hands-switch (such as TUR instruments) must be connected to this connector.

② Indicator of Monopolar generator activation and receiving output via Monopolar1 receptacle
③ Monopolar2 instruments receptacle

Notice: Monopolar2 is typically activated using a hand switch. However, in program number 10, known as APC-Endo-cut, this connector can also be activated with a pedal. In this specific program, you can connect a Polypectomy Snare to Monopolar2 and an argon probe to Monopolar1.

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

Monopolar Receptacles and their Accessories



①	8mm 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

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

Instrument Connector	Activation Type	UP-SURGE™ Alpha Monopolar connector	Description
1-pin connector with 8 mm plug 	Footswitch	8 mm connector	In addition to Monopolar pencil, 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 pencil, 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	--

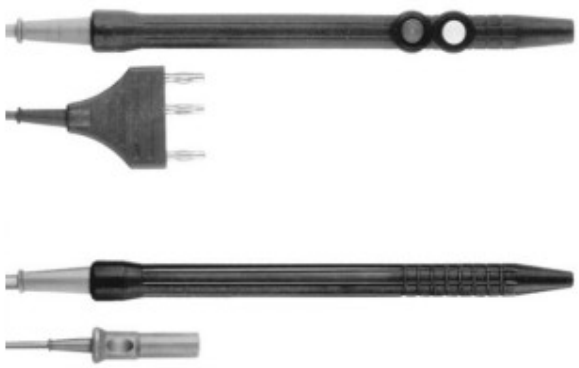
Warning: When Monopolar is active, all output connectors of the relevant Monopolar receptacles and pencils connected to these connectors have voltage. Therefore, necessary precautions should be made and never connect two pencils to a Monopolar connector simultaneously.

Notice: Use auxiliary connectors just for 3-pin pencils. 1-pin connector instruments should not be connected to those connectors. Such connection could damage the Monopolar receptacle. Only Monopolar instruments which is connected to Monopolar1 receptacle can be activated by footswitch.

Monopolar instruments can be activated in two different ways:

1. Hand Switch: Some instruments are equipped with hand switches, allowing activation either by manually pressing the switch or by using a footswitch.

2. Footswitch Only: Other instruments do not have a hand switch and can be activated solely through the footswitch.



Monopolar instruments that use hand switches typically feature two push buttons. The yellow button, located closer to the tip of the instrument, is used to select the cutting mode, while the blue button is used to select the coagulation mode.

Warning: Ensure that cables and Monopolar pencils have adequate insulation to withstand the device's output voltage, as specified in the maximum output voltage graphs. For verification, refer to the documentation associated with the Monopolar pencil. This is especially critical in high-voltage modes, such as spray mode, where any damage or weakness in the cable and pencil insulation can lead to unintended effects and burns. Monopolar cables and pencils are not repairable; if damaged, they must be replaced with new ones.

Monopolar Electrodes

In Monopolar surgery, various types of electrodes with different shapes and sizes are used as active electrodes and are mounted on Monopolar pencils. The installation and replacement of these electrodes are straightforward, allowing the surgeon to adjust their orientation by rotating each electrode as needed.

While the device typically includes common electrodes, such as knife electrodes, for general surgical use, surgeons may opt for other types of active electrodes that are compatible with the Monopolar pencil, depending on the specific mode required for their procedure.

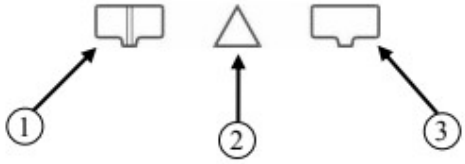
Notice: To prevent electrode damage, always use appropriate boxes for storage and transportation.

Patient Plate

In the Monopolar technique, the electrical current flows from the Monopolar pencil electrode into the patient's body and returns to the device via a plate (neutral electrode). Plates come in various types, including single and dual configurations. These plates connect to the UP-SURGE™ Alpha device using a 6.3 mm diameter connector.

Notice: Medorah Meditek Pvt Ltd using only plates that are included in the device package and approved by its quality control department, or those 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

When a single plate is connected to the device, the indicator for a single plate connection will light up. Conversely, if a dual plate is connected, the indicator for a dual plate connection will be illuminated. If an alarm related to the plate is the indicator for plate alarms will activate, signaling an issue with the connection. In this case, both indicators for plate connection will turn off.

Patient Plate Monitoring System

A reduction in the surface contact of the neutral electrode or a weak connection to the patient's body can increase current density, potentially causing burns at the contact site. To mitigate this risk, the device is equipped with a patient plate monitoring system that continuously measures plate resistance at a frequency of 100 kHz ±10 kHz, regardless of whether the generator is active

or inactive. This system assesses the quality of the plate's connection to the patient and identifies the plate type based on resistance measurements. The following scenarios may occur:

- Resistance Less than 25 Ohms: This indicates a single plate. In this case, the quality of the plate's connection to the patient cannot be monitored effectively.
- Resistance Between 25-150 Ohms: This indicates a dual plate, allowing the monitoring system to evaluate the quality of the plate's connection to the patient's body.

To assess the quality of the plate's connection to the patient, the device monitors not only the resistance but also changes in resistance. When resistance is within the range of 25-150 Ohms, the system evaluates both current resistance and any fluctuations in resistance to ensure stable contact quality. If the resistance increases by more than 50 percent compared to the minimum recorded resistance, the system detects this as a poor connection, triggering an alarm. Resistance changes are only analyzed when the Monopolar generator is inactive to avoid interference from generator noise. Since the generator's active periods are brief and changes in plate connection status are unlikely within such short times, this approach minimizes false alarms.

If resistance exceeds 150 Ohms, it indicates either a disconnection or poor connection quality between the plate and the patient's body or the device. In this scenario, the alarm system triggers a plate problem alarm.

The plate monitoring system is designed to automatically address these issues by:

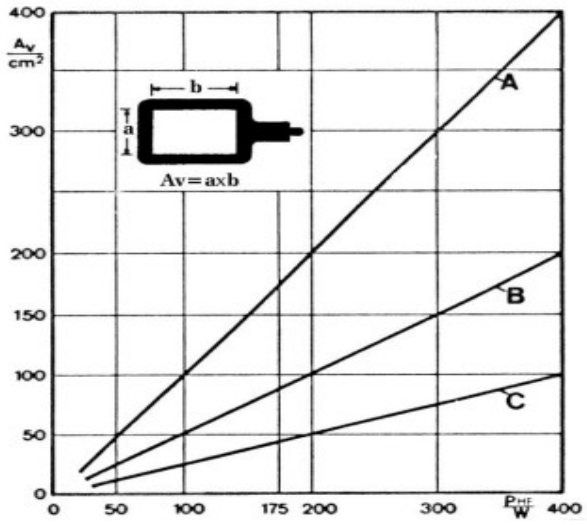
- Generating an alarm and preventing the Monopolar generator from activation if the plate is not connected to the device or if there is a damage in the cable or connector path.
- Checking the effective contact area when dual plates are used. If the contact area is insufficient, the system generates an alarm and prevents the generator from continuing operation.
- Monitoring for changes in plate connection quality when the Monopolar generator is inactive. Significant changes trigger an alarm, halting the generator's operation to prevent potential hazards.

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

To use the footswitch in Monopolar technique, connect the two-pedal footswitch to the Monopolar footswitch receptacle located on the back panel of the device. With this setup:

- Pressing the yellow pedal will activate the Monopolar Cut mode.
- Pressing the blue pedal will activate the Monopolar Coag mode.

The two-pedal footswitch included with the device facilitates control over these Monopolar functions during surgery.

Warning: Medorah Meditek Pvt Ltd only two-pedal footswitch within the device package which are approved by its quality control department.

Capability of Using Argon Gas

The UPSURGE™ Alpha device supports the use of argon gas for surgical procedures through the APS argon gas supplier device, specifically designed for this purpose. The APS controls and directs argon gas to the surgical probe, where it is ionized by applying a high voltage between the electrode tip and the tissue surface. This ionization creates a low-impedance path for electric current, forming an argon gas plasma that emits a distinctive blue light. While argon gas is primarily used for surface coagulation, it also has limited applications in cutting. The advantages of using argon gas in surgery include:

- Enhanced Control: Argon gas allows precise control over the energy application, reducing damage to adjacent tissues by controlling the argon ray.
- Reduced Electrode Adhesion: By maintaining a distance between the probe and the tissue surface, argon gas minimizes electrode adhesion.
- Decreased Odor and Smoke: The argon gas displaces oxygen at the surgical site, which reduces the production of odor and smoke.
- Efficient Coagulation: It enables rapid and uniform coagulation of tissue surfaces, typically ranging from 1 mm to 3 mm in depth.

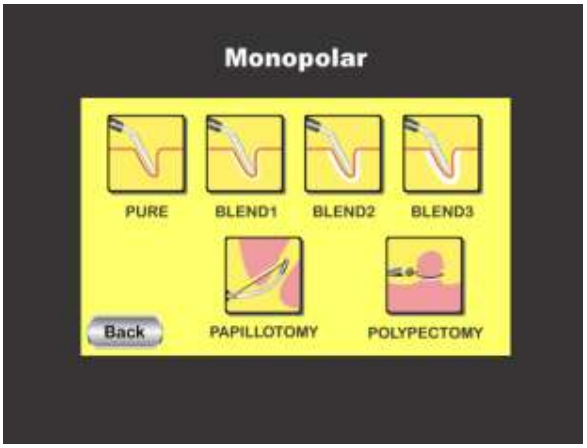
Overall, the use of argon gas with the UPSURGE™ Alpha device enhances surgical precision and safety by addressing several common challenges associated with traditional electrosurgical methods.

Warning: To utilize the argon gas capability with the UPSURGE™ Alpha device, the APS argon gas supplier device must be provided. For detailed information on how argon gas works, its benefits, and its applications, as well as guidance on APS installation, operation, and connection to the UPSURGE™ Alpha device, please refer to the APS User Manual.

Additionally, exercise caution when using the Argon Plasma Coagulation (APC) mode, especially with thin-walled tissues such as the cecum, to avoid the risk of perforation.

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



1. **Pure Mode**: This mode offers a clean and smooth cut with minimal coagulation of surrounding tissues. It ensures that damage to adjacent tissues during cutting is kept to a minimum.

2. **Blend Mode**: In this mode, cutting is combined with coagulation of tissues adjacent to the electrode. There are three degrees of Blend mode (Blend1, Blend2, Blend3) for controlling the depth of coagulation:

- Blend1: Provides minimal coagulation.
- Blend2: Offers moderate coagulation.
- Blend3: Results in the greatest degree of coagulation, making it suitable for cutting tissues with excessive bleeding or fat layers.

3. **Papillotomy Mode**: This mode involves pulsed tissue cutting and coagulation with specific timing. It allows the surgeon to control coagulation intensity and cutting speed. An additional beep sound signals tissue cutting, providing feedback on cutting speed and amount. This mode is optimal for needle electrodes and sphincters.

4. **Polypectomy Mode**: Similar to Papillotomy, but with adjusted pulse timing for optimizing wire snare or loop electrodes' direction. This mode is also optional and available upon request.

5. **TUR Mode**: Designed for surgeries in fluid environments, such as the bladder and prostate. It works in conjunction with one of the Blend modes (Pure, Blend1, Blend2, or Blend3) to enhance clinical effects in fluid operations.

6. **Argon Cut Mode**: This mode uses argon gas in combination with cutting. It is activated along with one of the Blend modes (Pure, Blend1, Blend2, or Blend3) to create clean cuts and smooth coagulation. This mode is suitable for cutting high-impedance tissues like cartilage. Refer to the APS1 User Manual for more details on using argon gas.

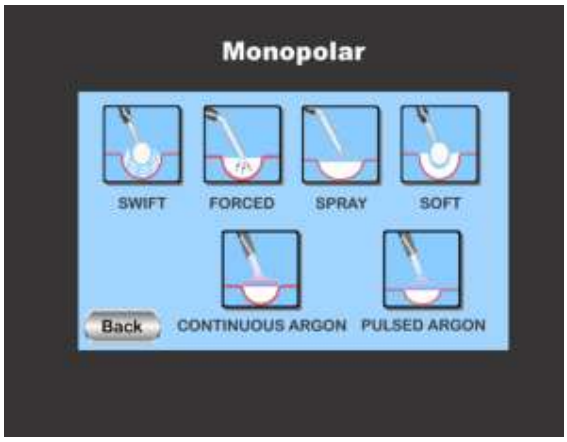
- The Monopolar Cut modes available via the default mode icon are Pure, Blend1, Blend2, and Blend3.

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



1. Swift Mode: This mode is designed for rapid coagulation of tissues using electrodes with larger cross sections, such as ball, plate electrodes, or forceps. The surgeon positions the forceps and contacts the active electrode to achieve quick coagulation.

2. Forced Mode: Ideal for deep tissue coagulation, this mode utilizes electrodes with smaller cross sections. It is suitable for penetrating coagulation where a more focused approach is required

3. Spray Mode: Spray mode allows for surface coagulation without direct contact between the electrode and the tissue. It features a more intense electric arc and is used for coagulating tissue surfaces with low depth. This mode is beneficial for minimizing cutting effects and tissue separation. Notably, both Monopolar1 and Monopolar2 outputs can be activated simultaneously in this mode, unlike others where Monopolar1 takes priority.

4. Soft Mode: Soft mode provides gentle coagulation without causing carbonization or adhesive effects on the electrode. It operates at a lower power compared to Swift, Forced, and Spray modes, making it suitable for delicate coagulation tasks.

5. Continuous Argon Mode: This mode combines continuous electric current with Argon gas for tissue coagulation. It is effective for large area coagulation at high speed. Although Spray Mode is commonly used for surface coagulation, Continuous Argon Mode offers enhanced control and reduces the risk of damaging surrounding normal tissues due to the controlled argon gas environment. Refer to the APS1 User Manual for detailed information.

6. Pulsed Argon Mode:

Pulsed Argon Mode delivers electric current in pulses along with Argon gas, resulting in reduced energy application and lower coagulation compared to Continuous Argon Mode. It is ideal for procedures requiring lower argon power and minimized tissue destruction, making it suitable for laparoscopy and thin, sensitive tissues. For further details, consult the APS1 User Manual. These modes provide various options for coagulation, allowing the surgeon to choose the most appropriate method based on the surgical needs and tissue characteristics.

Notice: When utilizing Argon gas with the UPSURGE™ Alpha device, it's essential to remember that Argon gas can only be used through the Monopolar1 receptacle. Therefore, if you select either the Continuous Argon or Pulsed Argon mode and simultaneously need to activate the Monopolar2 receptacle, the system will automatically default to the Forced mode without Argon gas. To manage power settings and prevent sudden changes, if the pre-set power level for the Argon mode is set below 60, the device will limit the power for the Forced mode to a maximum of 80. This

restriction helps avoid abrupt power increases during mode transitions. Conversely, if the present power for the Argon mode is 60 or above, the Forced mode will operate with its independent power settings, ensuring a consistent and controlled power application.

Power Level Changes in Monopolar

In UP-SURGE™ Alpha, 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 for Monopolar techniques is crucial for achieving high-quality cutting and coagulation results. The optimal power setting is influenced by various factors, including the geometry of the active electrode, the surgeon's hand speed, the technique of electrode movement on the tissue, the tissue characteristics, and the selected current waveform. Although power selection often relies on the surgeon's experience and judgment, the following guidelines can aid in choosing the right power level:

- **In Pure Mode**: For smaller diameter electrodes, such as needle or lancet electrodes, it is advisable to use lower power settings. Conversely, for larger diameter electrodes, like knife electrodes, higher power settings should be employed to ensure effective cutting and coagulation.
- **For Fatty Tissues**: Cutting through fat requires higher power settings compared to other tissues due to the increased electrical resistance of fat tissue.
- **Electrode Cleanliness**: The presence of dried blood and tissue on electrodes can obstruct current flow, necessitating higher power levels. To avoid excessive power use, it is important to maintain clean electrodes to ensure optimal current transfer and performance.

Important points in using ENDO-CUT technique

1. Electrode Diameter and Cutting Efficiency: A thinner electrode wire diameter results in a more precise cut with reduced coagulation. This allows for more controlled incisions with less thermal spread to surrounding tissues.

2. Polyp Removal Considerations: When removing a polyp from tissue with a thinner wall, the risk of perforation is higher. Therefore, it is advisable to use a less aggressive coagulation setting to minimize the risk of damaging the tissue.

3. Pedal Usage and Coagulation: Releasing the pedal too quickly may prevent the device from entering the coagulation phase properly, which can increase the risk of bleeding. Ensure that the pedal is pressed long enough to complete both cutting and coagulation processes effectively.

4. Snare Handling: Avoid pulling the snare too forcefully in an attempt to accelerate the cutting process. This can increase the likelihood of bleeding. Instead, use a steady, controlled motion to minimize complications.

5. Snare Closure Force: Applying excessive force when closing the snare can cause it to penetrate too deeply into the tissue, increasing the contact area and reducing current density. This may delay tissue cutting and lead to excessive coagulation, which in turn heightens the risk of perforation. Aim to apply a balanced force when closing the snare.

6. Sphincterotomy Technique: To avoid excessive contact surface during sphincterotomy, insert only about one-third of the wire's front into the papilla. This helps in achieving a controlled and precise incision with minimal surrounding tissue damage.

7. Internal Gases Check: Before activating the device, ensure that no internal gases are present in the body, particularly if there is a risk of intestinal obstruction. Internal gases can affect the performance of the device and the outcome of the procedure.

Coagulation intensity and cutting speed changes in ENDO-CUT

By entering the settings page after touching the Cut Speed/Coag Effect icon, you can change the cutting speed and coagulation intensity.

Coagulation intensity in the Monopolar technique can be adjusted on the device screen across four levels. Each level increases the coagulation intensity: the higher the level selected, the greater the coagulation effect. For procedures where the risk and severity of bleeding are higher, opting for a higher coagulation level is advisable. However, it is important to be aware that increased coagulation also raises the risk of perforation. For tissues with a thinner wall, it is better to use lower coagulation levels to minimize the risk of excessive damage.

- Level 1 (L1): Very low coagulation
- Level 2 (L2): Low coagulation
- Level 3 (L3): Medium coagulation
- Level 4 (L4): High coagulation

Cutting speed can also be adjusted to three levels:

- Level 1: Slow (low cutting speed)

- Level 2: Medium (medium cutting speed)
- Level 3: Fast cut

To ensure proper functioning, it is recommended to test the snare tool on wet gauze before using it in the endoscope channel. The wet gauze should be placed on the plate to verify that the tool is operating correctly.

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.

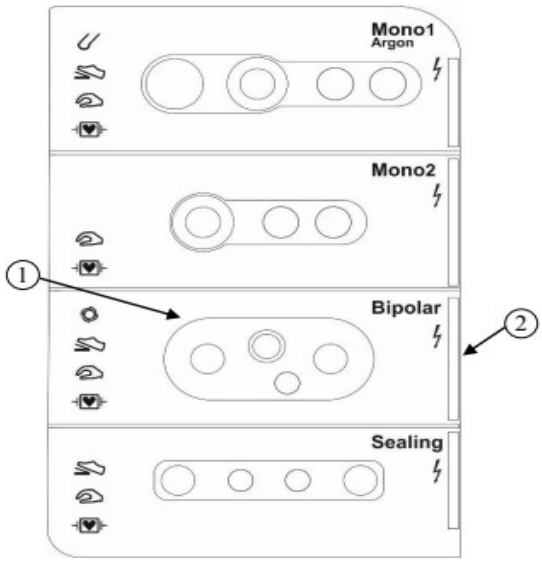
2. Power value of the current mode is displayed in Monopolar Coag. power display. Press the power set buttons to change the value. Power value will change one unit by each time you press on the buttons. To speed up power value change, keep your finger on the button.

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 are used, connect footswitch to Monopolar footswitch receptacle (on the back panel).
4. If modes along with argon are used, then setup APS and connect it to UP-SURGE™ Alpha.
Warning: For use of Argon gas advantage, use APS Argon gas supplier device in order to connect to Up-Surge device. For information regarding principle of working with Argon gas, its benefits and advantages, installation and launching of APS, and connection to Up-Surge please refer to APS device User Manual.

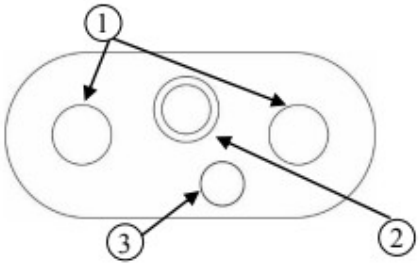
5. Settings of Monopolar can be done in setting section.
6. Place the surgical instrument on the tissue.
7. Press yellow hand switch or footswitch for Monopolar Cut activation and blue hand switch or footswitch for Monopolar Coag. activation. By Monopolar activation, LED indicator of Monopolar generator 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.

2. Bipolar Technique 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.

Notice: Medorah Meditek Pvt Ltd that only Bipolar instruments approved by its quality control department or from the following companies—Bowa, Fiab, Martin, Tecno, Metko, and Valleylab should be used with their device package.

In the UPSURGE™ Alpha device, you can use a range of Bipolar instruments with different types of connectors. The specifications for these connectors are detailed in the table below.

Instrument connector	Activation type	UP-SURGE™ Alpha Bipolar connector
2-pin connector 	Footswitch	4mm normal connectors
Twin connector 	Footswitch	4mm normal connectors
3-pin connector (American company type 	Footswitch	4mm normal connectors and 2.5 mm connector
Connector with 2mm coaxial plug (Martin type) 	Footswitch	2mm coaxial connector

Bipolar Coag. Forceps

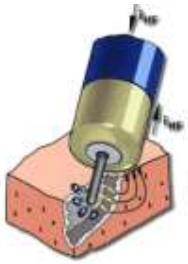
There are a variety of Bipolar forceps with various shapes and sizes which can be used for tissue coagulation.

In Bipolar forceps, the insulating material covers all areas except the two ends of the forceps. This design ensures that coagulation occurs only at the tips when they contact tissue, preventing unintended coagulation elsewhere on the forceps. Additionally, this insulation helps prevent irritation to the surgeon's hand when the 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, other instruments are used for Bipolar Cut, particularly in specialized surgeries. An example of such an instrument is shown in the following figure. This instrument features one polar that is a thin, needle-shaped electrode designed for precise tissue cutting, while the other polar is a metal cover that provides a path for the returning current.



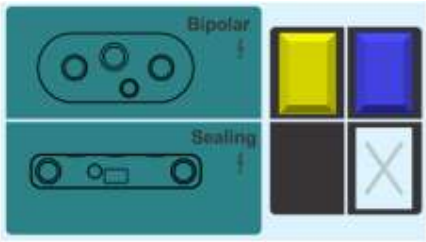
Footswitch

To operate the Bipolar technique using a footswitch, it is essential to connect a two-pedal footswitch to the Bipolar/Sealing footswitch receptacle on the back panel. In this setup, pressing the yellow footswitch will activate the Bipolar Cut modes, while pressing the blue footswitch will activate the Bipolar Coag/Sealing modes. The two-pedal footswitch that comes with the device is as follows:

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

In order to switch the blue pedal between Bipolar Coag and Sealing, there is an icon for setting the status of the pedal on the Seal page and on the Bipolar page.

By touching this icon, the device enters the bipolar pedal setting page.

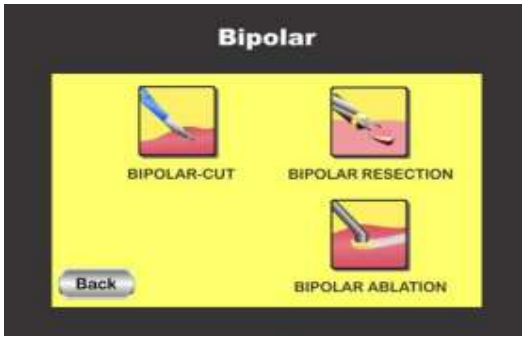


On this page you can assign the blue pedal to Sealing or Bipolar Coag and then touch Ok to finalize the changes.

Warning: Medorah Meditek Pvt Ltd 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.



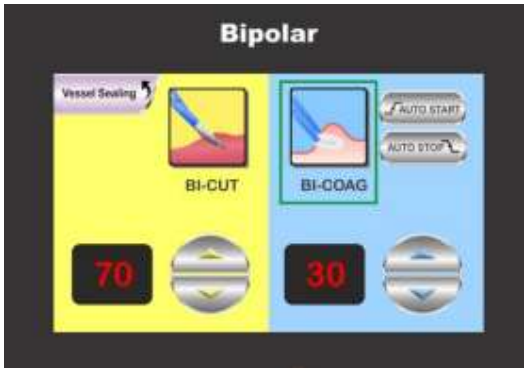
Bipolar Cut: This mode is designed for cutting tissue with a restricted current path, confined to the area between the blades of the scissors. This localized current path requires significantly less power than the Monopolar Cut technique, making it a safer option for the patient.

- **Bipolar TUR (Resection):** This technique is used for cutting tissues in a saline solution during Trans Urethral Resection procedures. Normal saline is required for effective operation. Start with a power setting of 70W for cutting and adjust if needed for optimal results. The yellow pedal activates the Bipolar Cut (BI-Cut) mode, while the blue pedal activates the Bipolar Coag/Sealing (BI-Coag) mode.

- **Bipolar Ablation**: This mode is designed for shaving tissues using specialized ablation tools in procedures such as arthroscopic surgery or tonsillectomy. It reduces heat by creating plasma in a normal saline environment, thereby minimizing thermal damage to surrounding tissues.

Bipolar TUR (Resection) and Bipolar Ablation are optional modes and are available upon customer request.

Bipolar Coag Modes



Bipolar Coag.: The Bipolar Coag. mode is designed for soft tissue coagulation without causing carbonization or adhesion of tissue to the electrode. The UP-SURGE™ Alpha device offers two features for this technique: Auto Start and Auto Stop.

Auto Start: This feature allows the generator to automatically activate the Bipolar Coag. mode with a delay after detecting tissue contact (when the two tips of the forceps touch the tissue). The delay can be set from 0 to 2 seconds in 0.1-second increments using the display screen. For instructions on setting the delay in Auto Start mode, please refer to the relevant section. Note that pressing the corresponding footswitch will immediately exit Auto Start mode.

Auto Stop: This feature provides automatic detection of optimal tissue coagulation, which is crucial since the time between achieving optimal coagulation and the onset of tissue carbonization is very short. When Auto Stop is activated, the generator will automatically deactivate once optimal coagulation is reached, enhancing precision and ease of use during surgery.

Power Level Changes in Bipolar

In the UPSURGE™ Alpha device, the Bipolar power levels are adjustable within different ranges, with varying steps for each range:

- Range 1:0 to 1 with a step of 0.1
- Range 2: 1 to 5 with a step of 0.2
- Range 3: 5 to 10 with a step of 0.5
- Range 4: 10 to 20 with a step of 1
- Range 5:20 to 100 with a step of 2
- Range 6:100 to 150 with a step of 5
- Range 7:150 to 200 with a step of 10 for Bipolar Cut and 5 for Bipolar Coag
- Range 8:200 to 350 with a step of 50 for Bipolar Cut

Output Power Selection in Bipolar

Here are the recommended considerations for selecting the appropriate power level in Bipolar Coagulation:

- Avoid Excessive Power: Using too much power can cause the electrode to stick to the tissue, leading to carbonization of the electrode surface and impeding current flow. For optimal coagulation, a clean tip and correctly set power level should allow complete coagulation within 1 to 5 seconds.
- Avoid Insufficient Power: If the power is set too low, coagulation will occur very slowly, which may be ineffective and inefficient.
- Manage High Power Levels: Selecting a high-power level can cause a rapid increase in tissue temperature, leading to increased vapor pressure within the tissue. This can result in tissue bursting and tearing.

Method of Bipolar Setting

1. **Setting Techniques**: To configure Bipolar Cut and Bipolar Coag. techniques, press the corresponding icon to access the subset modes.

2. **Auto Start and Auto Stop**: To activate Auto Start and Auto Stop conditions for Bipolar Coag., press the corresponding buttons until they turn green.

3. **Setting Auto Start Delay**: To adjust the Auto Start delay, press the "Setting" icon on the left screen, then select "Adjustment" (refer to the section on how to set the delay in Auto Start).

4. **Adjusting Power Value:** The power value for the current mode is shown on the power display. Press the power set buttons to change the value incrementally. To adjust the power value more quickly, hold down the button.

Method of Using Bipolar

1. **Connect Instruments:** Attach the desired surgical instrument to the Bipolar receptacle located on the front panel.
2. **Connect Footswitch:** If using a footswitch, plug it into the Bipolar/Sealing footswitch receptacle on the back panel.
3. **Set Bipolar Parameters:** Configure the Bipolar settings as described in the related section (see the previous section).
4. **Position Instrument:** Place the surgical instrument onto the tissue.
5. **Activate Bipolar Mode:** To activate Bipolar mode, press the footswitch. If Auto Start is enabled, Bipolar Coag. will automatically activate when the instrument contacts the tissue. Activation is indicated by a red shadow around the selected icon and a continuous speaker sound. Maintain pressure on the footswitch to continue cutting or coagulating.
6. **Deactivate Generator:** Release pressure on the footswitch to stop generator activation. If Auto Stop is enabled, the generator will automatically deactivate once optimal coagulation is detected. An auditory and visual "Coag Complete" signal will notify the user (refer to the “information conditions” section for details).

3. Sealing Technique Features

In traditional surgical methods, vessels up to 2 mm in diameter can be coagulated with conventional Monopolar or Bipolar instruments. For larger vessels, techniques such as tying or using clips are typically employed. However, with the advanced sealing modes available, vessels

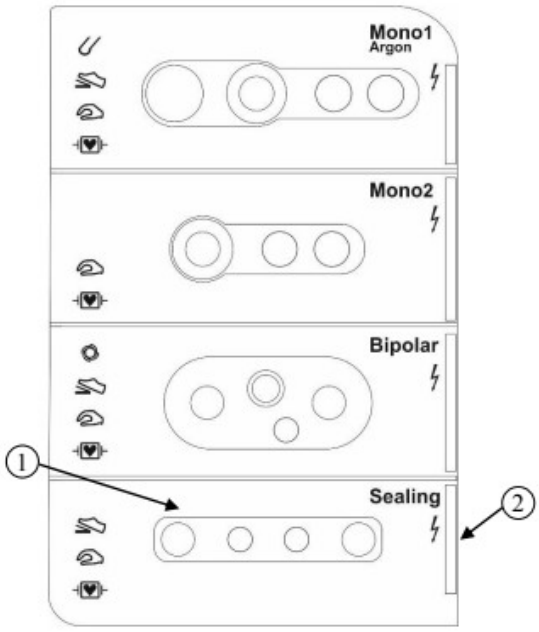
up to 7 mm in diameter can now be effectively sealed. In this advanced technique, vessels or tissues containing vessels are placed between the jaws of a specialized surgical instrument. An intelligent algorithm controls the application of electrical current to the tissue. The combination of applied energy and mechanical pressure from the instrument melts the elastin and collagen in the vessel walls, causing them to merge. This process enables natural sealing of the vessels without the need for additional surgical tools like stitches or clips. The device automatically detects the optimal sealing point and stops energy application when this is achieved. It then notifies the surgeon of the completion of the sealing process using visual and auditory signals (see the "information conditions" section for details).

Sealing Technique Advantages

The advanced sealing technique offers several advantages:

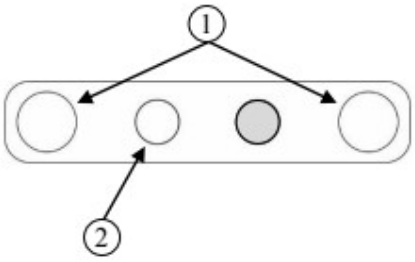
- Enhanced Coagulation Capability: Effective for vessels up to 7 mm in diameter.
- Reduced Surgery Time: Speeds up the procedure, particularly in areas with difficult access to blood vessels.
- Lower Bleeding Rates: Decreases overall bleeding during surgery.
- Increased Vessel Strength: Provides stronger sealing against blood pressure increases compared to conventional Bipolar and ultrasound methods.
- Surgeon Comfort: Improves ease of use and comfort for the surgeon.
- Versatility: Applicable in both open and laparoscopic surgeries.
- Optimal Coagulation Detection: Minimizes carbonization, tissue sticking, and thermal damage.
- Reduced Risk of Infection: Decreases complications related to suture needles, lowering the risk of transmitting hepatitis and HIV.
- No Foreign Substances: Avoids complications associated with leaving foreign materials in the body, such as effects on future diagnostic radiology or unwanted infections.

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 Change of performance

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

Sealing Instruments

It 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	Urology Colorectal General surgery Gynecology
LS2110 , LS2111 	Large Seal	Footswitch and hand switch	open	

LS3090 , LS3092 	Large Seal	Footswitch and hand switch	open	
LS3110 , LS3112 	Large Seal	Footswitch and hand switch	open	
Bowa – Tissueseal 	Large Seal	Footswitch and hand switch	open	
LF4318 , LF4418 	Large Seal	Footswitch and hand switch	open	Urology Colorectal General surgery Gynecology
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 Oophorectomy Splenectomy
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 and hand switch	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
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

Sealing instruments come in two types based on their activation methods. Some instruments feature a hand switch that allows activation either through the hand switch or the footswitch.

These instruments use a 3-pin connector that connects to both the 4 mm and 2.5 mm connectors of the Sealing receptacle. On the other hand, some instruments lack a hand switch and can only be activated by the footswitch. These instruments are equipped with a 2-pin connector that connects solely to the 4 mm connectors.

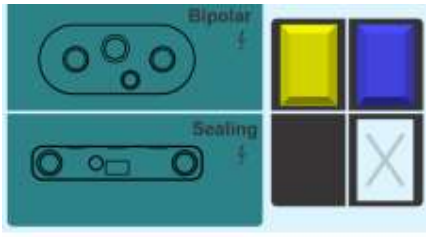
Warning: In Sealing technique, if a surgical instrument which is not listed in the above table is used, there will not be enough reliability for seal quality.

Footswitch

To use the footswitch for the Sealing technique, you must connect a two-pedal footswitch to the Bipolar/Sealing footswitch receptacle on the back panel. When connected, pressing the blue footswitch will activate the Bipolar Coag/Sealing modes. The two-pedal footswitch provided with the device is configured as follows:

In order to switch the blue pedal between Bipolar Coag and Sealing, there is an icon for setting the status of the pedal on the Seal page and on the Bipolar page.

By touching this icon, the device enters the bipolar pedal setting page.



On this page you can assign the blue pedal to Sealing or Bipolar Coag and then touch Ok to finalize the changes.

Sealing Modes

In the UPSURGE™ Alpha device, the Sealing technique is suitable for coagulating vessels with diameters up to 7 mm and offers two modes: Large Seal and Fine Seal. Each Sealing surgical instrument compatible with the device is designed for one of these modes:

- **Large Seal:** This mode is intended for surgical instruments with a larger contact surface with the tissue. It provides more energy to ensure that vessels are completely sealed.
- **Fine Seal:** This mode is meant for surgical instruments with a smaller contact surface with the tissue. It delivers less energy, sufficient for sealing vessels effectively with a more targeted approach.

Auto-start

If Auto Start is selected on the Bipolar screen, the icon will turn green. In this mode, you can simultaneously use the bipolar forceps. When the forceps contact the tissue, the sealing screen will automatically switch to the bipolar screen, and the BI COAG mode will be activated with the pre-set power level.

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. Adjusting Sealing Technique: Select either the Large Seal or Fine Seal mode based on the surgical instruments being used.

1. Power Adjustment Restriction: In Large Seal and Fine Seal modes, the user cannot change the power level manually, as the device intelligently adjusts the output power to suit the selected mode.

Method of Using Sealing

1. **Connect Surgical Instrument:** Attach the desired surgical instrument to the Sealing receptacle on the front panel.
2. **Connect Footswitch:** If using a footswitch, plug it into the Bipolar/Sealing footswitch receptacle on the back panel.
3. **Prepare Instrument:** Grab the tissue with the surgical instrument and press the instrument handle until you hear a locking sound, indicating that the instrument is securely locked.

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. **Activate Sealing:** To activate the Sealing and apply energy to the tissue (if one of its modes has been selected), press the instrument's hand switch or the corresponding footswitch. When Sealing is activated, the Sealing icon will display a red margin, and a continuous speaker sound will be heard. Keep the device active until the Sealing process is complete. The device will automatically detect the end of the Sealing process and provide a visual and auditory "Seal Complete" signal to notify you. The device will then stop activation (refer to the “information conditions” section for details).
5. **Address Regrasp Alarm:** If a Regrasp alarm occurs (see the “alarm conditions” section), it indicates that the Sealing process is not complete. Reactivate Sealing and reapply energy to the tissue. If the Regrasp condition persists, consult the related table to diagnose the issue and 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.

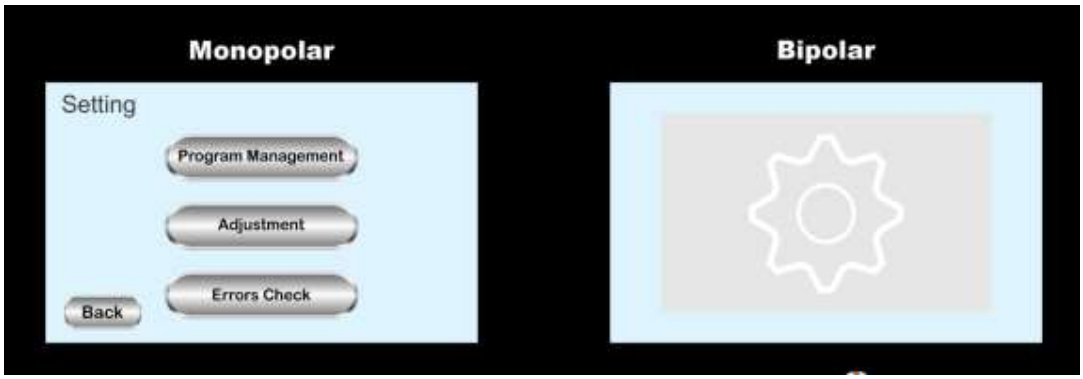
4. Setting

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 the UPSURGE™ Alpha device, you can store up to 30 programs, each including various modes and power settings for different surgeries. These predetermined settings allow for quick adjustments between different surgical procedures. The company has already saved 10 settings for various surgeries, which include specific operation modes and power levels. The default cutting mode is yellow, and the default coagulation mode is blue, as detailed in the table below.

PROG#	Program	Monopolar Cut	Monopolar Coag	Bipolar/ Sealing	
30	Bipolar / Sealing	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 Cut - 30
6	Laparoscopy	Blend2-30	Forced -30	Large Seal	
7	Mastectomy	Blend2-30	Spray -60	Bipolar Cut - 30	Bipolar Cut - 30
8	Microsurgery (Neurosurgery) (Spine)	Blend2-30	Spray -20	Bipolar Cut - 30	Bipolar Cut - 30
9	APC - ablation or High hemostasis in open surgery	Blend2-30	Bipolar Cut - 30	Large Seal	
10	APC - Endo, medium hemostasis for GI-Bleeding	Polypectomy-L2	Bipolar Cut - 30	Bipolar Cut - 30	Bipolar Cut - 30

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

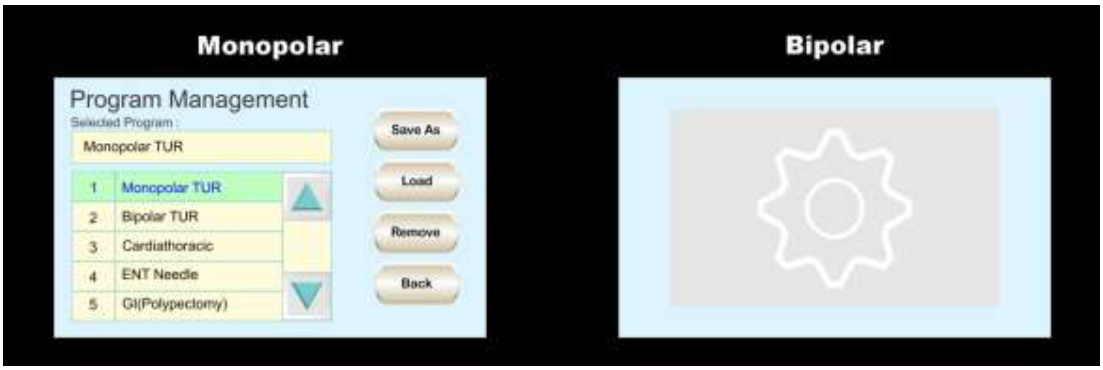
How to Enter the Program Management Pages

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.



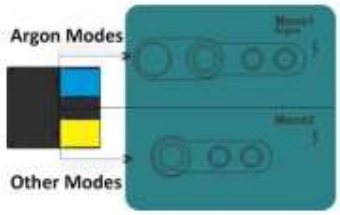
5. Select “Save As” to save the program and you will be taken to a new page. Each character can be selected from English letters or numbers from 0 to 9. Select “Back” to return to the Setting.

Save and Load a program

- Save a program by the user- Users can save custom settings, including specific modes and power levels for particular surgeries, into the device memory. To do this, first apply the desired settings on the device. Next, click “Save As” and select a name for the program. Finally, click “Save” to store the settings.
- Load a presets program by the user- Different settings, each tailored for specific surgeries, are saved on the device. To select and load one of these programs, use the scrolls to navigate through the list and choose the desired program. Then, click “Load” to activate the selected settings.

APC Endo Cut program for endoscopic surgery (program 10)

In Argon Endo mode, the output activation varies based on the selected mode. If Pulsed Argon or Continuous Argon modes are chosen, pressing the blue pedal activates the Mono1 output (ARGON connector). Conversely, for argon-free modes, such as Pure, Blend, or Forced, pressing the yellow pedal for cutting or the blue pedal for coagulation activates the Mono2 output.



Therefore, as illustrated in the figure, you can use the blue pedal for Argon Plasma Coagulation (APC) on Mono1 and the yellow pedal for simple cutting (such as polypectomy) on Mono2 simultaneously.

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

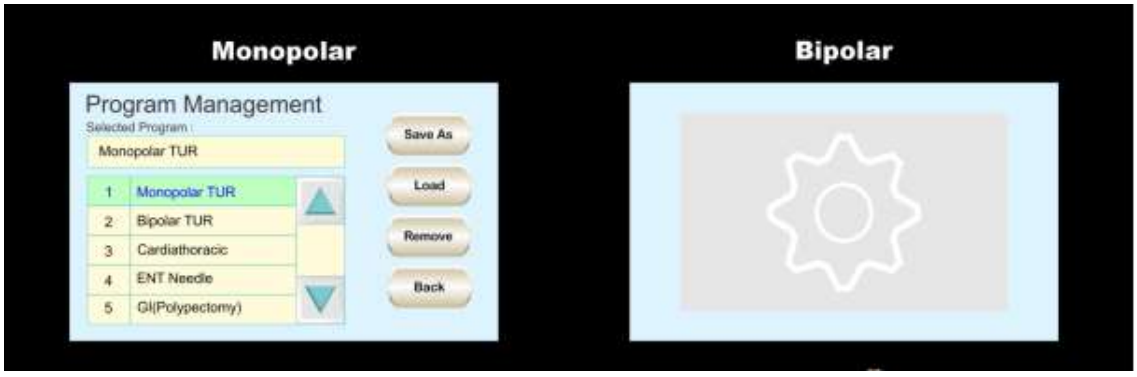
How to Set Delay Time in Auto Start of Bipolar Coag. Mode

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”.



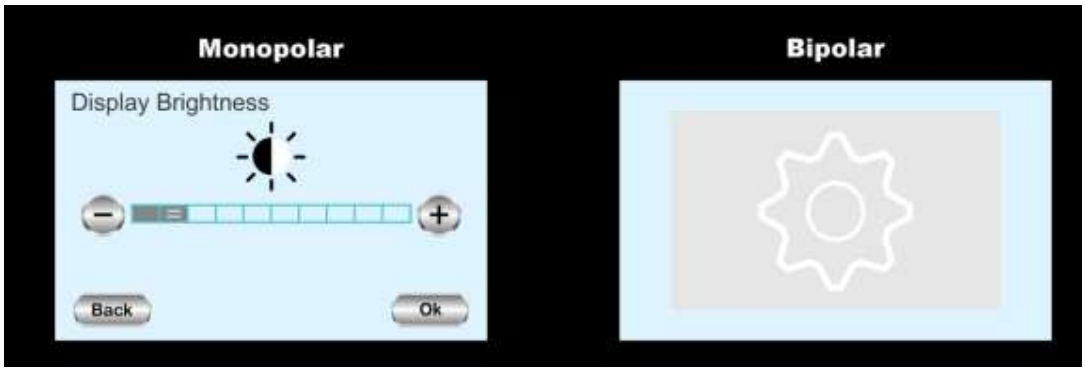
How to Set Display Brightness

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.



5. Alarm System 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	Stop Activity Or prohibition 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	Fail: LC	Technical	Medium	Stop of activity	✓

Monopolar activation more than the permitted value					
Continuous operation of the equipment for 60 seconds	Fail: Time Out	Functional	Medium	Stop of activity	×
Continuous operation of the equipment for more than 30 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	Prohibition 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	Stop Activity or prohibition 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	Prohibition of activity	×

Failure in Patient Plate Condition Alarm

This alarm is triggered under two conditions:

1. **Plate Connection Failure:** This occurs due to issues such as the disconnection of the plate connector or its cable in a single plate setup, or the disconnection of the plate connector or return cable in a dual plate setup. It can also result from poor plate contact with the patient's body, complete disconnection, or significant resistance variations between the two parts of the plate. Note that resistance variations are not monitored during Monopolar activation due to potential interference from generator noise on the plate circuits.
2. **Circuit Failure of Patient Plate Monitoring:** This indicates an error in the transmission circuit of the dual plate connection to the control system. When such a failure occurs, the alarm code is recorded in memory and investigated only when the generator is inactive. If a Monopolar technique is requested after this alarm, the equipment will not activate, and a "Fail: plate" alarm will be generated.

System Memory Failure Alarm

Each time system settings are written to memory, the stored values are validated against the intended settings. If there is a discrepancy, a "system memory failure" alarm is triggered. This alarm condition ends when the system operation is requested**.**

Alarm Conditions Group

Alarm conditions are categorized into two groups based on their external causes and where they occur:

- **Technical:** These alarms are triggered by issues within the equipment or its accessories.
- **Functional:** These alarms arise from problems in the interaction between the equipment and the operator or patient during use.

Various technical or functional reasons can cause alarms. The alarm condition table (refer to the “alarm conditions” section on page 60) specifies whether each alarm is categorized under "technical" or "functional" in the group section.

Alarm Conditions Priority

Alarm conditions are categorized into two priorities based on their potential impact on the patient, operator, or equipment, as defined by the IEC60601-1-8 standard:

- **Medium Priority:** Alarms with medium priority indicate a potential for serious injury. When such an alarm occurs, the generator activity is halted, and the equipment will not function as expected. This situation could pose a significant hazard, so a prompt response from the user is crucial to resolve the issue. Medium priority alarms are displayed with an orange background.
- **Low Priority:** Alarms with low priority are associated with minor potential damages that do not require an immediate change in the equipment's operation status, such as stopping the generator. However, the user should still address the alarm in a timely manner.

During continuous operation, low priority alarms generate less auditory noise due to their lower urgency. Low priority alarms are displayed with a grey background.

Alarm Signals

When an alarm condition is detected, the system generates visual and auditory signals through displays, LEDs, and buzzers. All these signalling mechanisms are activated when the equipment is turned on, ensuring that the alarm system is functioning properly. For optimal perception of these signals, it is recommended that the user be within a maximum distance of 3 meters from the equipment. For checking the display, a distance of up to 1.5 meters is deemed suitable.

Alarm Signals Characteristics with Medium Priority

When a medium priority alarm occurs, a red background message is displayed on the screen. Additionally, the ERROR LED or plate LED (depending on the alarm) starts flashing in a specific pattern, and an auditory signal is generated by a buzzer with a sound level of 79 dBA (measured at 1 meter) and a frequency of 2300 Hz. The LED flashing pattern consists of continuous on (600 ms) and off (250 ms) intervals. The auditory signal follows a pattern of three successive bursts, repeated every 4 seconds, with each burst comprising the buzzer turning on and off every 250 ms. If the medium priority alarm condition is resolved, all alarm signals will cease, although if a burst is in progress, it will continue until completion.

For low priority alarms, a message starting with "Er:" is displayed on the screen. The ERROR LED or plate LED (depending on the alarm) remains continuously lit in red. The auditory signal is emitted by a buzzer with the same specifications (79 dBA and 2300 Hz frequency) and follows a pattern where the buzzer turns on and off twice with 150 ms intervals. When the low priority alarm condition is resolved, all alarm signals will stop immediately.

Regrasp Alarm Signals Characteristics

When this alarm occurs, the usual signals are activated, including the ERROR LED, buzzer, and a message displayed on the screen. After the alarm is addressed, the last burst of the buzzer will complete its cycle and stop, but the other signals will persist. If a Regrasp alarm is triggered and then the demand is removed, the buzzer will sound only one burst. The Regrasp alarm will continue until the Sealing request is repeated. However, any new activation request or detection of an alarm or information condition will terminate all alarm signals. Thus, the end of all visual and auditory signals signifies the conclusion of the Regrasp alarm**.**

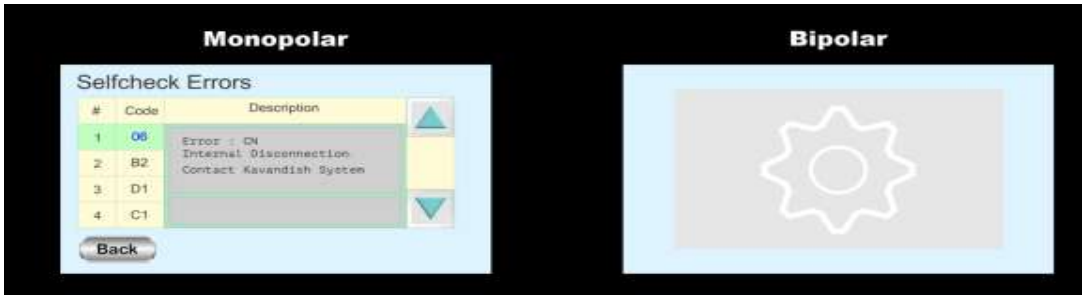
Alarm Signals Generation Ranking

With occurrence of alarm conditions with medium and low priority simultaneously, alarm signals are 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 alarm types, only technical alarms indicating equipment failure are stored in memory as codes, allowing for the identification of system issues if needed. The memory can retain information for up to 10 alarms, meaning it always holds details about the most recent 10 alarms. This stored data persists even when the equipment is turned on or off, or if power is disconnected.

Each alarm code consists of two characters: the right character denotes the type of alarm condition, while the left character indicates the mode in which the alarm occurred. The tables below provide the character designations for alarm condition types and modes.

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	

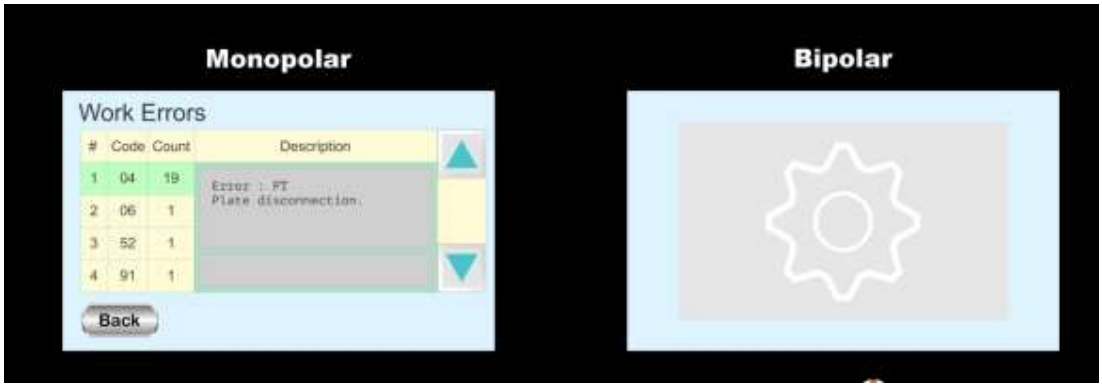
	Polypectomy	
4	Swift	Monopolar Coag
	Forced	
5	Spray	
6	Soft	
7	Continuous Argon	
8	Pulsed Argon	
9	Bipolar Cut	Bipolar Cut
A	Bipolar Resection	
	Bipolar Ablation	
B	Auto Start	Bipolar coag.
	Manual	
C	Large Seal	Sealing
D	Fine Seal	Sealing

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, there are other situations that, while not harmful to the patient or operator, still require user attention. These are referred to as information conditions. Information conditions may involve equipment usage errors that do not pose immediate harm or new events such as generator activation during normal equipment operation. The table below lists the various information conditions along with their corresponding descriptions.

Events	Message on the	Impact on activity

	display screen	
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 of activity
Simultaneous activation request of Monoploar Cut and Monopolar Coag.	Unacceptable Request	Deny the permission of activity
Set the Bipolar Coagulation on Auto start when the pencil 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

When information conditions are detected, the system generates visual and auditory signals through the display, LED, and speaker. Information signals related to generator activation are distinct from those for other information conditions. During generator activation, a dedicated page on the display provides technical information about the activation. LEDs corresponding to the activated technique will be lit, and a continuous auditory signal is emitted by a speaker with an adjustable sound level ranging from 50 dBA to 70 dBA at a 1-meter distance.
During the activation of each technique, the system generates specific sound frequencies:

- **Monopolar Cut:** 680 Hz
- **Monopolar Coag:** 520 Hz
- **Monopolar Coag1 and Coag2 simultaneously:** 470 Hz
- **Bipolar Cut:** 610 Hz
- **Bipolar Coag. and Sealing:** 470 Hz

For other information conditions, the display will show a term related to the condition. In some cases, such as with "P=0" and "Unacceptable Request," the corresponding 7-segment display will start to flash. An auditory signal will also be emitted by the speaker, with an adjustable sound level ranging from 50 dBA to 70 dBA at a 1-meter distance.

The **7-segment flashing pattern** involves the segments turning on and off with a 350 ms interval, while the **auditory signal generation pattern** consists of the speaker turning on and off twice consecutively, also with a 350 ms interval.

Information Signals Rank in Comparison with Alarm Signals

When both information and alarm conditions occur simultaneously, the system typically displays the message related to the alarm condition on the screen. Despite this, all relevant information and alarm signals will be generated. However, messages related to information conditions that pertain to user requests—such as "P=0," "Unacceptable Request," "Coag Complete," and "Seal

Complete"—take priority over alarm condition messages. These priority messages will remain displayed until the user resolves the corresponding request.

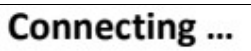
Additional information related to alarms and information signals

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.
	Error : Regrasp - High Current 1 No tissue response to electrical energy during seal process and not entering the impedance control phase. 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.
	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.
	Error: Regrasp - Unexpected Change Unusual change in tissue response observed. Without cutting the tissue, open the jaws and grasp the tissue again.
	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.
	Error: Regrasp-Energy Stopped In Seal modes do not stop applying energy until "seal complete" is announced.

	Error: Connector Activation while internal disconnection detected. Contact Kavandish System.
	Error: Extra Power Extra power at generator output. Contact Kavandish System.
	Error: Heat Factor 1 System over heat. Do not reactivate generator repeatedly in high power. Allow cooling.
	Error: Heat Factor 2 Pre-Overheat at plate. Do not activate generator continuously at high power. Allow plate cooling.
	Error: Heat Factor 3 Overheat at plate. Do not activate generator continuously at high power. Allow plate cooling.
	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: FE Loss of output power.Contact Kavandish System.
	Error: TO Pre-timeout. Do not activate generator for a long time continuously.
	Error: ME System memory failure. Contact Kavandish System.
	Error: CN Internal Disconnection. Contact Kavandish System.
	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 Simultaneous activation request of Cutting and Coagulation.
	Coag Complete Bipolar coag completed
	Seal Complete Sealing Completed
	A malfunction has been observed between the displays and the device. Wait a few seconds to reconnect.

6. Manufacture Responsibility

Medorah Meditek Pvt Ltd guarantees the safety and performance of the device only if the following instructions are adhered to:

Installation and Launching: The device must be installed and launched according to the procedures outlined in this User Manual.

Usage: The device should be used in strict accordance with the instructions provided in this User Manual.

Modifications and Repairs: Any modifications or repairs must be carried out exclusively by authorized service personnel from Medorah Meditek Pvt Ltd or its designated representatives.

Routine Maintenance

It is recommended to have the device's calibration, overall safety, and performance condition checked annually. We suggest sending the device to Medorah Meditek Pvt Ltd or one of its authorized representatives for these checks. Upon completion, you will receive a qualitative control report and a safety standard test card with your unit**.**

Safety Checks

Safety checks are conducted to ensure that the device meets the required safety and performance standards. These checks include:

- **Visual Inspection:** Assessing the device for any visible signs of damage or wear.
- **Impedance Between Receptacles:** Measuring impedance to ensure proper function.
- **Bipolar and Monopolar Output RF Leakage:** Testing for radiofrequency leakage in accordance with IEC 60601-2-2.
- **Line Frequency Current Leakage:** Measuring current leakage at 50-60 Hz as per IEC 60601-1.
- **Plate and Tissue Sensor Auxiliary Current Test:** Verifying current levels related to plate and tissue sensors in accordance with IEC 60601-1.
- **Grounded Conductor Test:** Checking the grounded conductor according to IEC 60601-1.
- **Input Current Consumption:** Measuring the current consumption of the device.

- **Output HF Power Measurements:** Assessing the high-frequency output power of the device.

These tests can be performed without removing the sealed enclosure of the device. If any defects or failures are detected during these checks, the device should be promptly returned to Medorah –Meditek Pvt Ltd or an authorized representative for examination and repair. Do not attempt to open the enclosure or modify the device yourself.

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.

Warning: 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 Medorah Meditek Pvt Ltd.

7. Technical Specifications

Dimensions and Weight

Width	40 cm
Depth	44 cm
Height	17 cm
Weight	9 kg

Input Power

Mains voltage	220V ± 10% , 50HZ (110 V ± 10% , 50/60HZ)*
Maximum power consumption	920 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	4.2 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 Dual plate	 Less than 25 Ohms 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

The duty cycle of the device is designed to ensure its safe operation and longevity under maximum load conditions. Specifically, the device operates on a (10 s/30 s) active and inactive cycle when delivering its maximum output power to a nominal load or a load with resistance less than the nominal value. This means that the generator should be active for 10 seconds, followed by a 30-second cooling period where the generator remains off.

If the device operates at less than maximum output power or with a load that has higher resistance than the nominal load, it may be possible to increase the duty cycle. This adjustment allows the device to function with a longer active period or shorter inactive period, depending on the load conditions and power settings.

Output Characteristics

Monopolar Cut

Mode	Maximum output voltage (VP-P)	Maximum output current (A)	Heating Factor (A2 s)	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

Monopolar Coag.

Mode	Maximum output voltage (VP-P)	Maximum output current (A)	Heating Factor (A2 s)	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 (VP-P)	Maximum output current (A)	Crest Factor**	Maximum output power (Watts)	Rated load (Ohms)
Bipolar Cut	1280	2.5	2.4	100	1oo

*Bipolar Resection (TUR)	1090	4.4	1.5 to 5.5 ***	375	50
*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	A*	50

*Optional Modes

Sealing

Mode	**Maximum output voltage (VP-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	250	25

*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

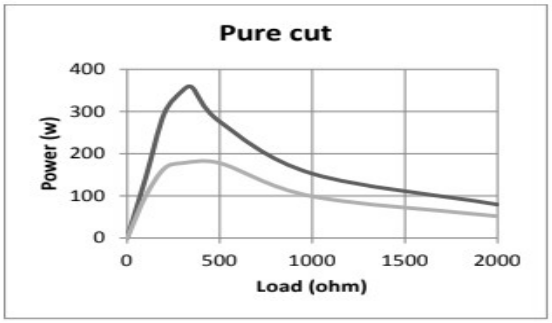
Standards
UPSURGE™ Alpha device meets all relevant clauses of IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2 standards.

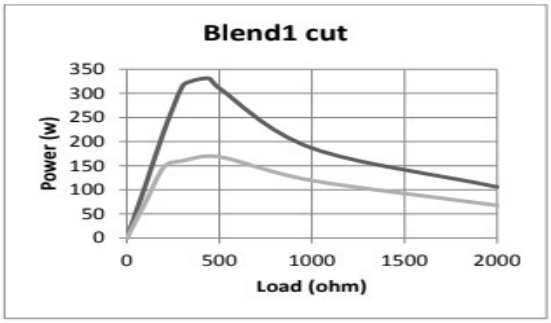
Drip Proof (IEC 60601-2-2)
UPSURGE™ Alpha enclosure is constructed so that in case of liquid spillage in normal use, the safety and performance does not adversely affect.

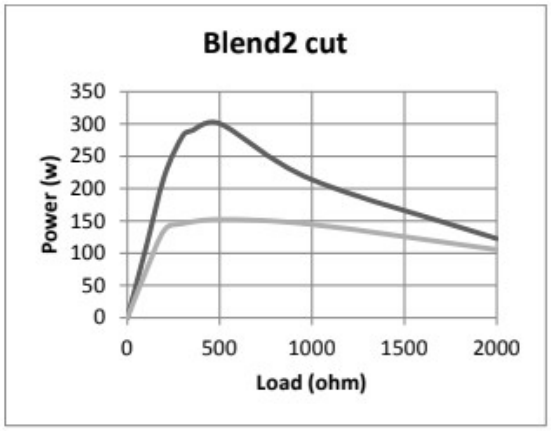
IEC Classification

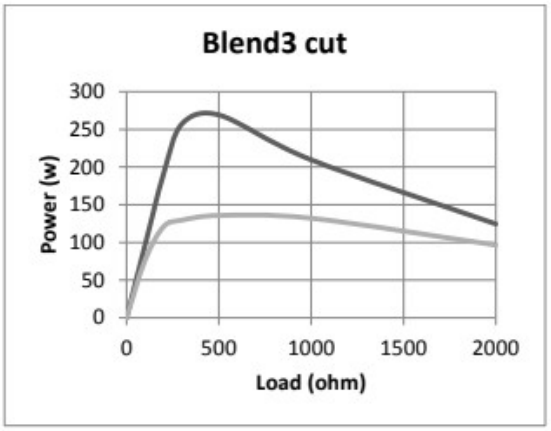
Protection class	I
Type of output	CF (Cardiac Floating)
Type of patient circuit	Floating Output

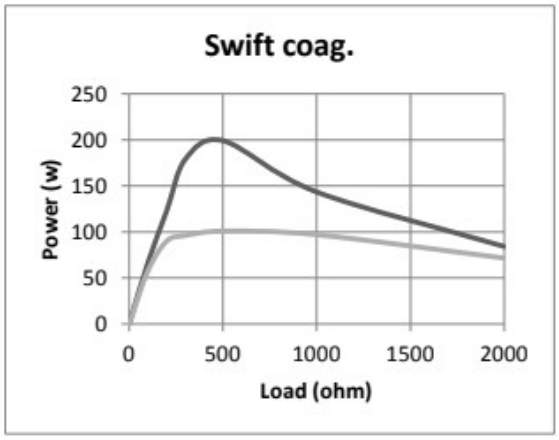
Maximum Output Power Graphs versus Load Resistance Storage
In these graphs, power level is constant and load value varies. The graphs have been drawn for the two cases of maximum power and half of maximum power in each mode.

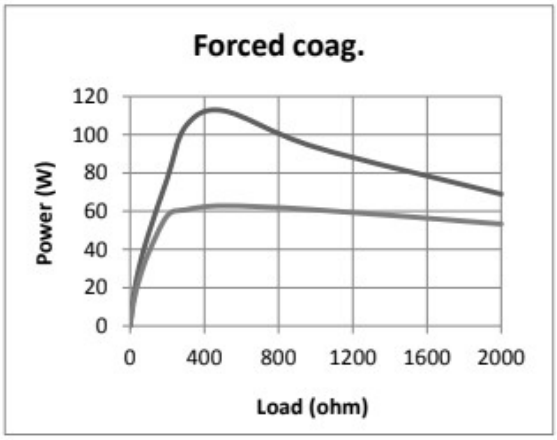

Pure cut
Power (w)
400
300
200
100
0
0
500
1000
1500
2000
Load (ohm)

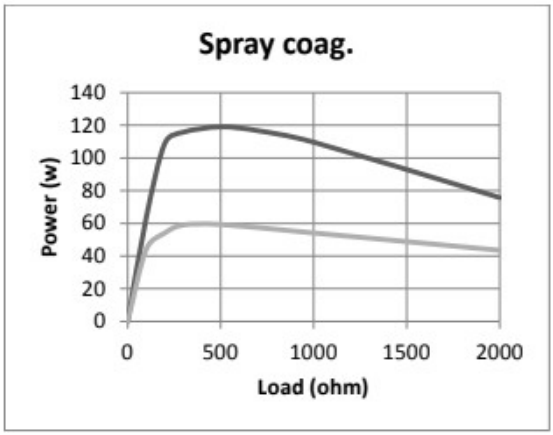

Blend1 cut
Power (w)
350
300
250
200
150
100
50
0
0
500
1000
1500
2000
Load (ohm)

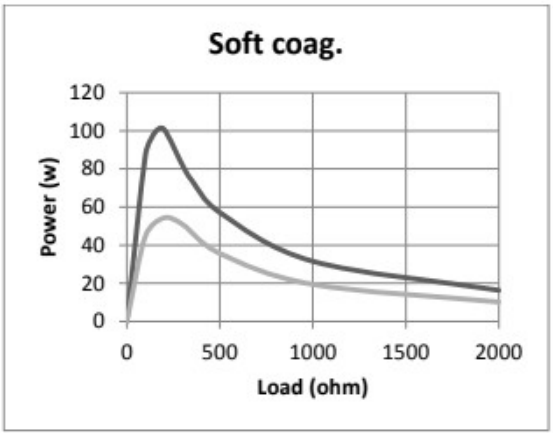

Blend2 cut
Power (w)
350
300
250
200
150
100
50
0
0
500
1000
1500
2000
Load (ohm)

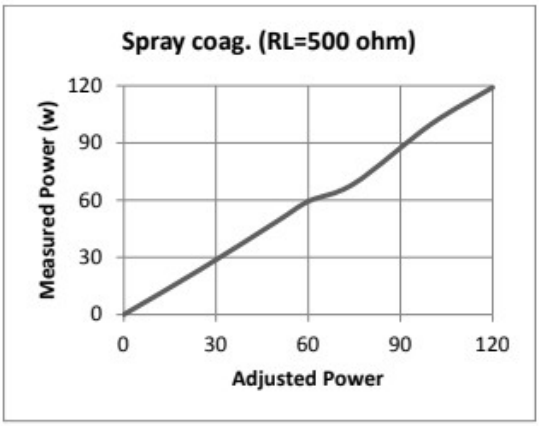

Blend3 cut
Power (w)
300
250
200
150
100
50
0
0
500
1000
1500
2000
Load (ohm)

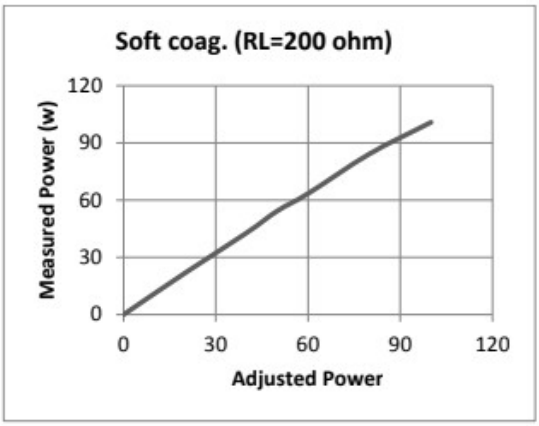

Swift coag.
Power (w)
250
200
150
100
50
0
0
500
1000
1500
2000
Load (ohm)

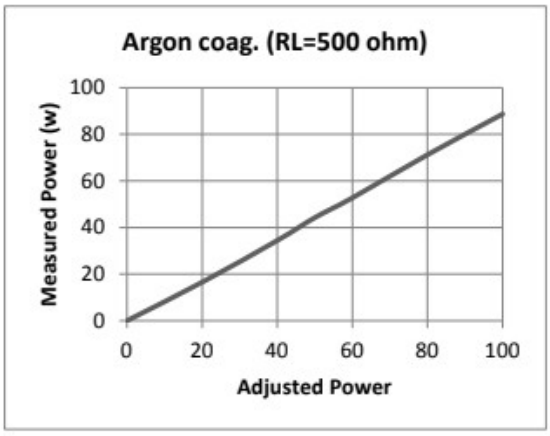

Forced coag.
Power (W)
120
100
80
60
40
20
0
0
400
800
1200
1600
2000
Load (ohm)


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

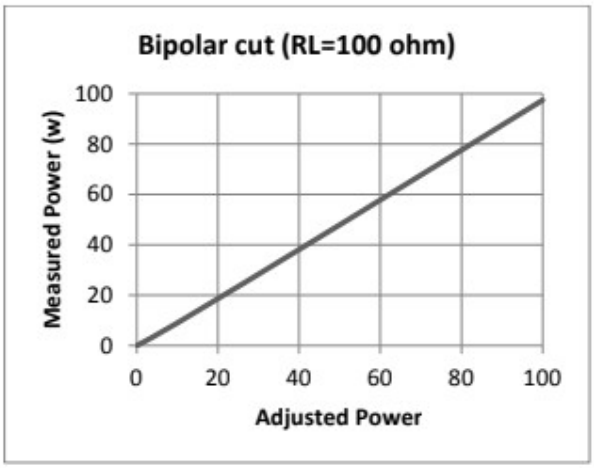

Soft coag.
Power (w)
120
100
80
60
40
20
0
0
500
1000
1500
2000
Load (ohm)

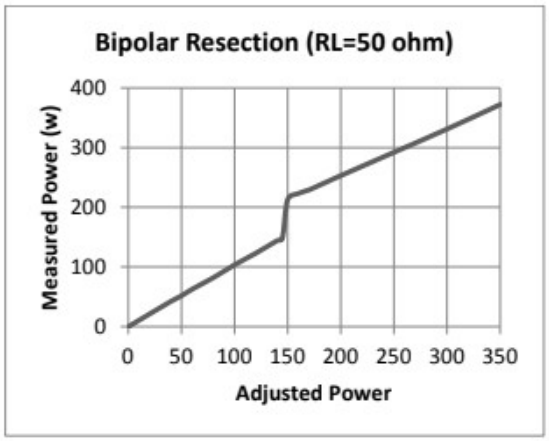

Spray coag. (RL=500 ohm)
Measured Power (w)
120
90
60
30
0
0
30
60
90
120
Adjusted Power

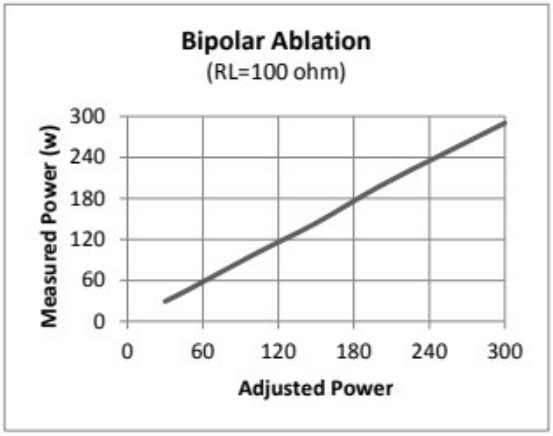

Soft coag. (RL=200 ohm)
Measured Power (w)
120
90
60
30
0
0
30
60
90
120
Adjusted Power

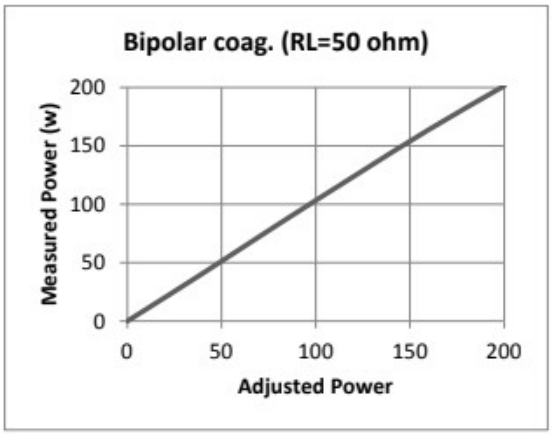

Argon coag. (RL=500 ohm)
Measured Power (w)
100
80
60
40
20
0
0
20
40
60
80
100
Adjusted Power

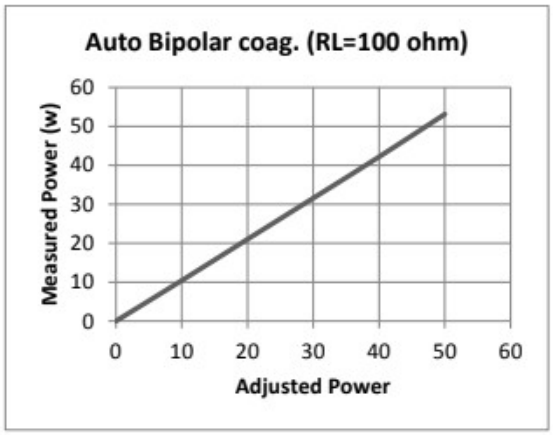

Pulsed Argon coag. (RL=500 ohm)
Measured Power (w)
50
40
30
20
10
0
0
10
20
30
40
50
Adjusted Power


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



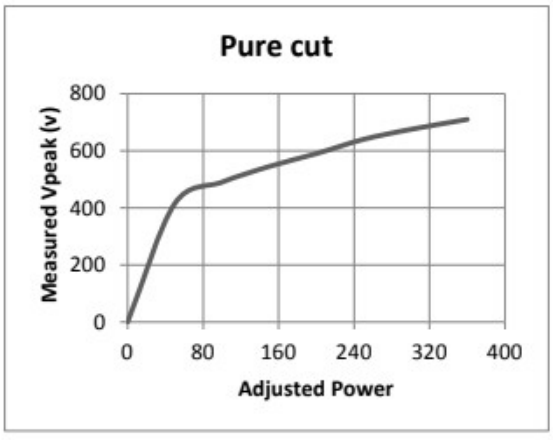


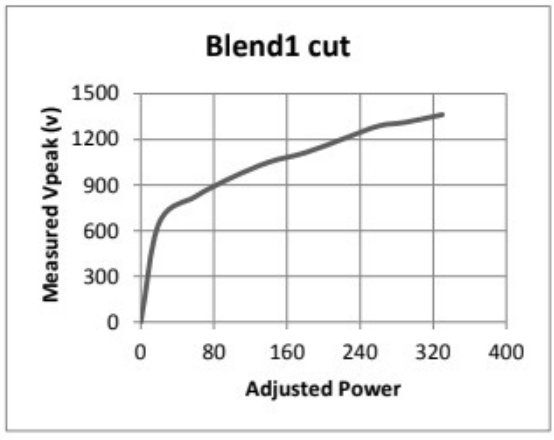


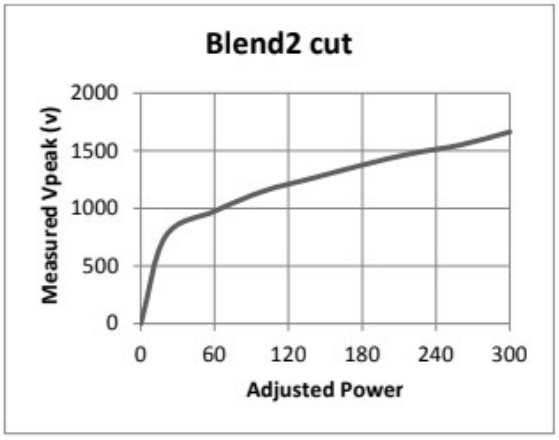


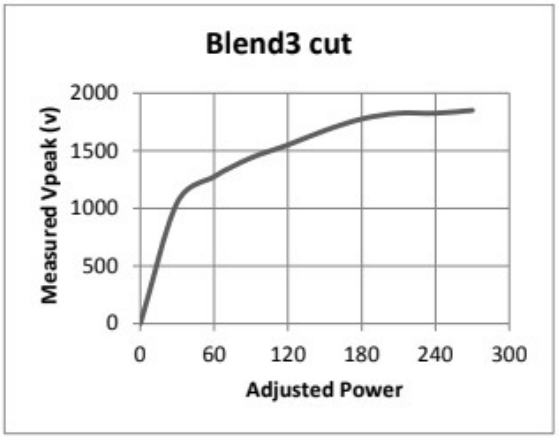
Maximum Output Voltage Graphs versus Adjusted Power Level

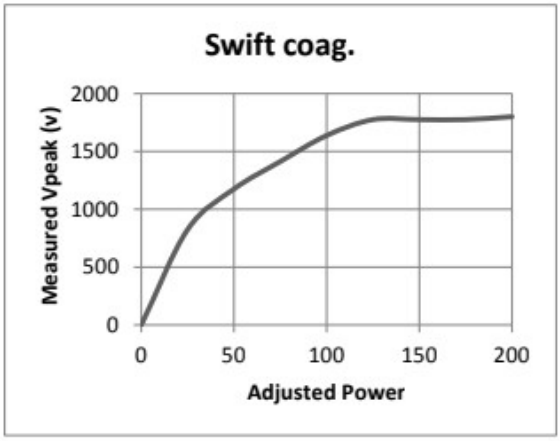
In these graphs, output voltages are measured in open circuit condition in different power levels**.**

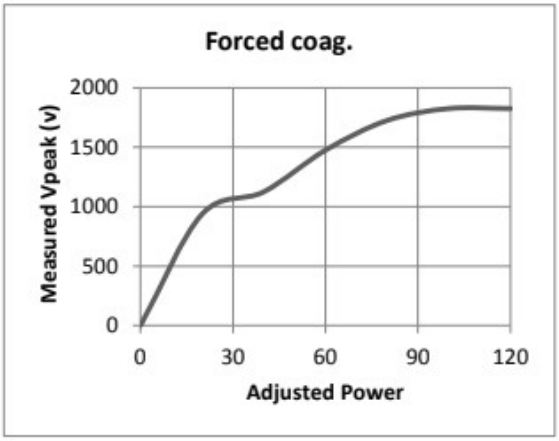


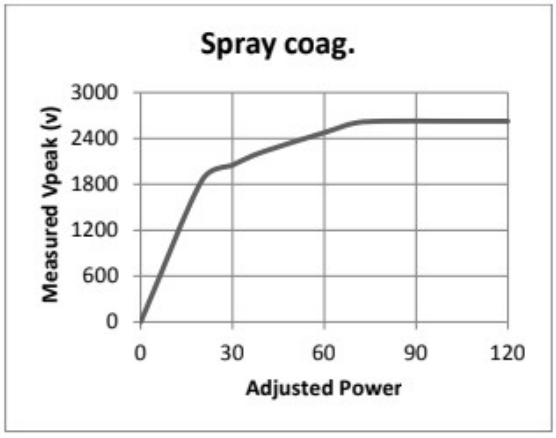


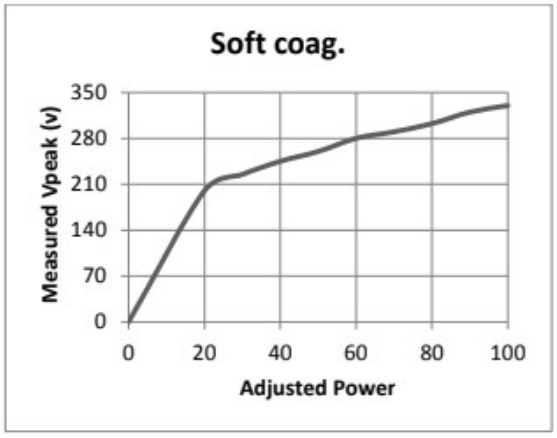

Blend2 cut
Measured Vpeak (v)
2000
1500
1000
500
0
0
60
120
180
240
300
Adjusted Power

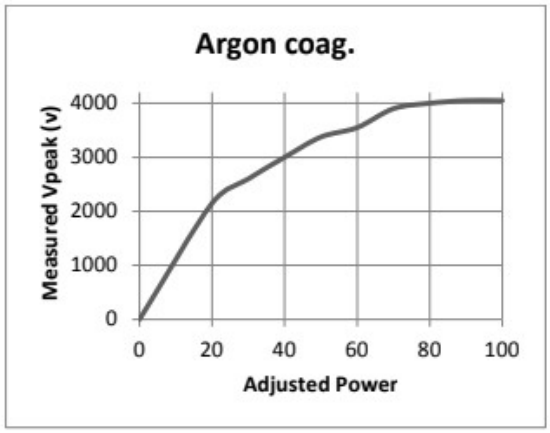

Blend3 cut
Measured Vpeak (v)
2000
1500
1000
500
0
0
60
120
180
240
300
Adjusted Power

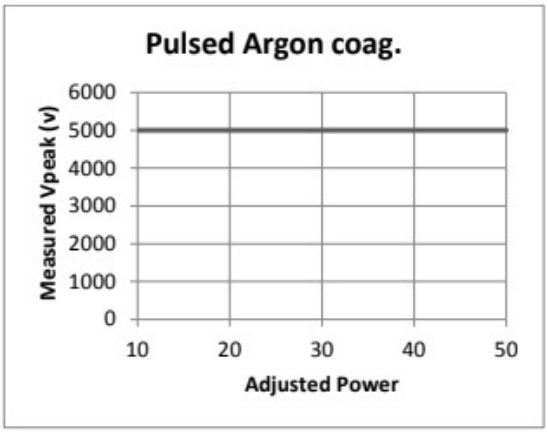

Swift coag.
Measured Vpeak (v)
2000
1500
1000
500
0
0
50
100
150
200
Adjusted Power

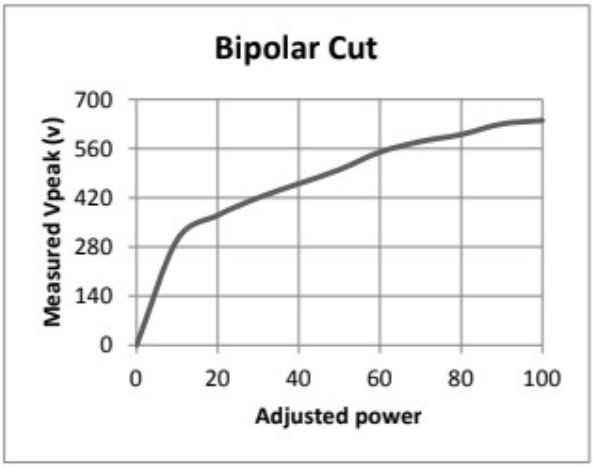

Forced coag.
Measured Vpeak (v)
2000
1500
1000
500
0
0
30
60
90
120
Adjusted Power

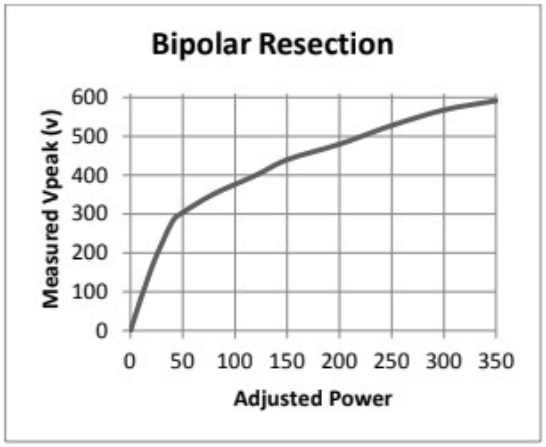

Spray coag.
Measured Vpeak (v)
3000
2400
1800
1200
600
0
0
30
60
90
120
Adjusted Power

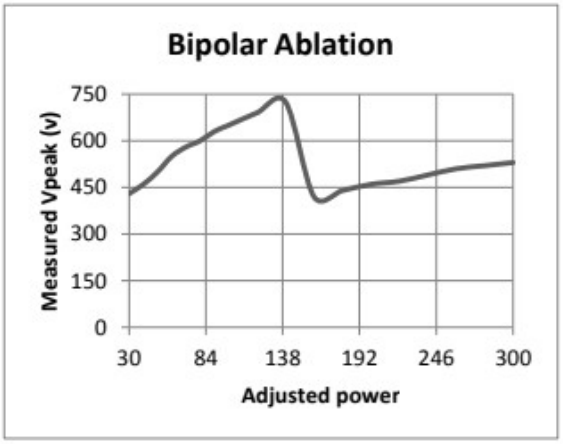

Soft coag.
Measured Vpeak (v)
350
280
210
140
70
0
0
20
40
60
80
100
Adjusted Power

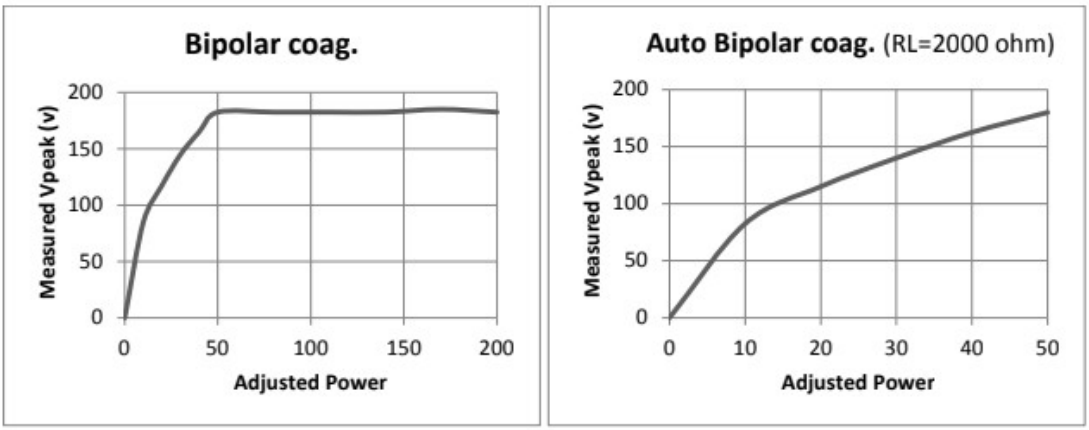

Argon coag.
Measured Vpeak (v)
4000
3000
2000
1000
0
0
20
40
60
80
100
Adjusted Power


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)
600
500
400
300
200
100
0
0
50
100
150
200
250
300
350
Adjusted Power


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



The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.

8. EMC Manual Tables

Guidance and manufacturer's declaration - electromagnetic emissions		
The UPSURGE™ Alpha is intended for use in the electromagnetic environment specified below. The customer or the user of the UP-SURGE™ Alpha should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The UPSURGE™, 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 UP-SURGE™ Alpha 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 UP-SURGE™ Alpha is intended for use in the electromagnetic environment specified below. The customer or the user of the UP-SURGE™ Alpha 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	Surge IEC 61000-4-5	±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 UP-SURGE™ Alpha quires continued operation during power mains interruptions, it is recommended that the UP-SURGE™ Alpha be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic

IEC 61000-4-8			fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTICE: UT is the A.C mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The UPSURGE™ Alpha is intended for use in the electromagnetic environment specified below. The customer or the user of the UPSURGE™ Alpha 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 UPSURGE™ Alpha, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \sqrt{p}$ $d = 1.2 \sqrt{p}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 2.3\sqrt{p}$ 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 UPSURGE™ Alpha is used exceeds the applicable RF compliance level above, the UPSURGE™ Alpha should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UPSURGE™ Alpha.
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 UP-SURGE™ Alpha

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

Change of Performance

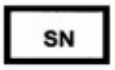
If a device's performance is changed or the intended purpose is lost, the further actions shall be taken according to medical specialist's decision considering clinical condition of patients.

Storage

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

Explanation of Symbols

	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,		Study the instruction manual.

	Bipolar and Sealing instruments are completely isolated from earth and supply mains outlet at both high and low frequencies.		
	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

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly

arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

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Mfd. By: Medorah Meditek Pvt. Ltd.

353, Udyog Vihar, Phase-IV, Gurugram, Haryana-122015 (INDIA)

Phone: 0124-4712471 | E-mail: info@medorah.com

www.medorah.com

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