User Manual

ELECTROSURGICAL UNIT

MEG 2

KAVANDISH SYSTEM

www.kavandish.ir

KAVANDISH SYSTEM

Electrosurgical Generator

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Contents

CHAPTER 1

1 Controls and Symbols

1.1 To User

This operation manual is intended to serve as an aid in the proper setup, installation and operation of the unit. The additional technical information is available in the service manual. All essential details of the equipment and all action required on your part are clearly presented and explained. Only qualified physician should be using this equipment. Please carefully study this manual and keep on hand for quick reference.

1.1.1 Intended Use

Meg2 devices are electrosurgical generators used for cutting and coagulation of biological tissue and sealing the vessels in general and specialized surgery. The devices use HF (>100 KHz) electrical current thermal effects for obtaining cutting, coagulation and seal. Intended patient population can be of any age, weight or gender.

1.2 Some of the new advantages and features of the MEG2 electrosurgery

In conventional electrical surgery techniques, by using usual monopolar or bipolar instruments, vessels with a diameter of up to 2mm can be coagulated and for larger vessels, common vascular surgery procedures, such as tying or clips, should be used.

Now, by using vessel sealing system modes of MEG2, the ability to seal all vessels with a diameter of less than 7mm is provided. In this system, vessels or tissues containing vessels are placed between two jaws of a special surgical instrument and electrical current is applied to the tissue by following an intelligent and controlled algorithm. The device automatically detects reaching the optimum point and then stops generating energy and informs the surgeon of the sealing completion by using optical and audial alarms.

The advantages of using this system are:

- Significant reduction in the time of surgery and increasement of surgery speed, especially in cases where the surgeon access to the blood vessels is difficult
- Reducing of general patient bleeding during surgery and reducing the patient's hospitalization time after surgery
- Greater stamina of sealed vessels against hypertension than conventional bipolar and ultrasound methods
- Ease of use by the surgeon
- Ability to use this system in open and laparoscopic surgeries
- By applying intelligent algorithms of power and voltage control and feedback of tissue impedance changes, the optimum seal point is detected by the device and the output is cut off. Therefore, the carbonization, adhesion to tissue and thermal damage will be minimal.
- The use of vessel sealing system reduces damage caused by stitch needles, thus reducing the likelihood of transmission of hepatitis and AIDS.
- In the new method, collagen and elastin from the walls of the vessels and surrounding tissues are used to seal the vessels, so unlike previous methods, no external substances are used and the side effects of external substances remaining inside the patient's body are eliminated (complications such as the effect on future diagnostic imaging or unwanted infections).

1.3 Front Panel Operating Controls

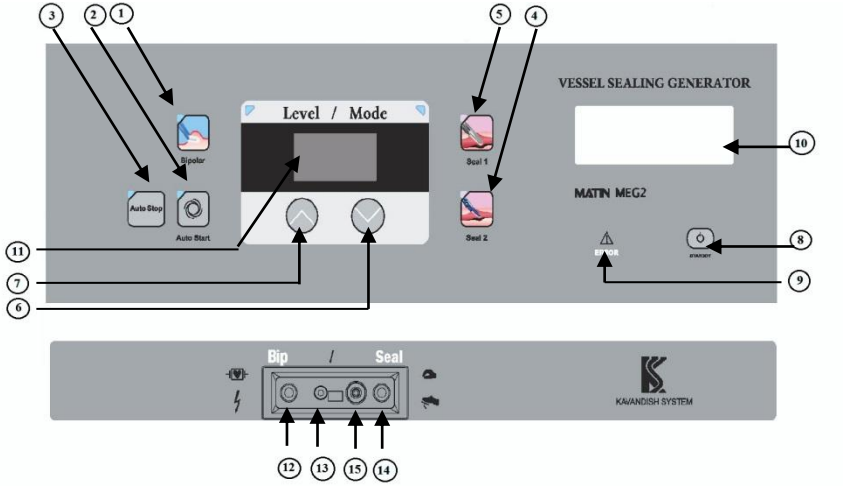


Figure 1: Front panel

1. This indicator light selects manual Bipolar Coagulation.
Bipolar output is activated only by pressing footswitch.
2. This pushbutton and indicator light selects auto-start mode with 0.5s delay for patient and operator safety. It is worth mentioning, the Auto Start mode will change to manual mode by pressing the footswitch.
Auto Start Bipolar coagulation: The bipolar output is activated after the two tips of forceps touch the tissue.
3. This pushbutton and indicator light selects Auto Stop mode for Bipolar coagulation.
If you want to stop coagulation at the time of optimum coagulation automatically in Bipolar Coag mode, you can choose Auto Stop mode. Consequently the equipment will measure electric resistance changes of the tissue which is under coagulation. When the tissue reaches to the optimum

coagulation stage (before carbonizing and desiccation of the tissue), the output will be terminated automatically and related audible alarm will be sounded. Moreover you should notice that Auto Stop mode is always activated in Vessel Sealing modes. So, pressing this button in these modes, do not make anything.

4. This pushbutton and indicator light selects vessel sealing/seal2 mode.

This mode is intended to be used for vessel sealing with special instruments mentioned in Table 5-1 in chapter 5.

5. This pushbutton and indicator light selects vessel sealing/seal1 mode.

This mode is intended to be used for vessel sealing with special instruments mentioned in Table 5-1 in chapter 5.

Warning:

In Meg2, the right mode of Vessel Sealing is chosen based on the surgical tool and by referring to the Table 5-1. Otherwise, the seal will not be reliable.

6. This pushbutton decreases Bipolar Coag. output power.

If you press buttons 6 and 7 one time or hold your finger on them, you will observe changes of the level on digital display 11. These changes are achieved in the form of separate steps in order that selecting the levels can be fulfilled more accurately.

Notice that from 0.1 to 1.0 level, the rate of level will change 0.1 step by 0.1 step, from 1.0 to 5.0 level it will change 0.2 by 0.2 step, from 5 to 10 level it will change 0.5 by 0.5 steps, from 10 to 20 level it will change step by step and from 20 to 100 level the changes will be two steps by two steps. Also the rate of chosen level is almost equal to output power and can be selected from the range of 0.1 w to nominal power.

7. This pushbutton increases the Bipolar Coag. output power.

8. This pushbutton places the equipment in the standby mode. In order to

activate standby mode, you should press this button and hold your finger on it 1 to 2 seconds. In this case the equipment will not run any command. Notice that whenever you exit from this mode, the unit will turn on and operate commands. In order to exit from the standby mode, press the button again and hold it 1 to 2 seconds (when the equipment is in the standby mode, all of previous saved data will be reserved in the unit memory and as soon as the unit exits from this mode, all of saved data will be displayed. However, electric current interruption will disappear all of the saved data).

9. This indicator light informs you that an error has been occurred because of an internal damage, or operator mistake. (refer to chapter 3 for more details)

10. LCD display which is used to display modes and messages.

11. This digital display indicates the Bipolar Coag. output power.

12, 13, 14. Connection place of vessel sealing accessory

12, 14. Connection place of common bipolar accessory

15. Bipolar forceps jack (for Martin & Berchtold Standard).

1.4 Rear Panel Operating Controls

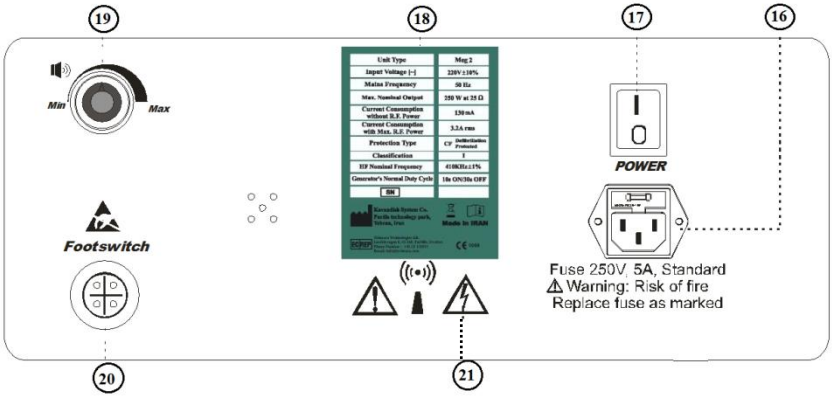


Figure 2: Rear panel

16. Line cord receptacle (200–240(VAC), 50Hz) and Input Fuse (5A/250V/S/5*20mm) place.

17. Main power switch.

18. Manufacturer's identification label.

19. Audio volume dial

Rotate the dial clockwise to increase volume and vice versa.

20. Pedal footswitch receptacle.

21. A warning sign which indicates possibility of electric shock due to direct contact with steel parts of connectors or internal circuits of the unit because high voltage exists in these parts.

1.5 The Explanation of Symbol Printed in Front and Rear Panel

The degree of protection against electric shock is CF type and LF leakage current is very low and is protected against high voltage due to defibrillator.	
The output connectors are marked with this sign can be activated by hand switching.	
The output connectors are marked with these signs can be activated by foot switching.	
The outputs are marked with this sign may be activated automatically after the electrode has come into contact with the tissue.	
Study the instruction manual before operating the equipment.	
Hazard of high voltage in the output connectors	
Study the instruction manual	
This device is marked with the WEEE symbol according to Directive 2002/96/EC. Devices marked with this symbol must be put into the separate waste collection for electrical and electronic devices. Please recycle where facilities exist. Check with your Local Authority or retailer for recycling advice.	
Warning Electrostatic discharge	
Unit serial number	
A warning sign which indicates the probable unit interference with operation of surrounding electronic units.	

CHAPTER 2

2 General Warnings and Cautions

2.1 General Warnings

- Read the user manual to know about the high frequency electrosurgery and its specific instructions. You can register the device serial number in the patient's documents for ease of follow-up.
- Always use the minimum required power and remember that extra increase of power increases the risk of burn.
- This device is not intended for use in areas subjected to explosion hazards because may arise ignition of flammable media.
- The unit can interfere with operation of surrounding electronic equipment.
- Please always clean and disinfect the unit with incombustible substances, otherwise let vaporize the applied flammable substances before operation.
- To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth
- Never use needle electrodes for monitoring and if you are obliged to use them, separate their cables from HF cables of electrosurgical unit.
- Monitoring equipment, stimulating or taking photography probes may leak HF current and cause accidental burn so isolate them from surgical electrode as far as possible.
- Observe 15-centimeter between electrode and ECG electrode when they are in use with HF unit simultaneously.
- If electrosurgical method used on patient having cardiac pacemaker or any other electronic devices, may lead to irreparable damage or electromagnetic interference with their operation so consult a cardiologist and take sufficient care before operation. Use monitoring system and keep on hand defibrillator.
- The flammable liquid may accumulate under patient or body cavities such as navel, vagina or bowel so before the operation remove liquid from these

areas.

- Put connecting cable of electrode in such a manner to avoid any contact with patient or any conductor In order to reduce the accidental burn hazards.
- Place the outputs and bipolar forceps in such a manner do not come into contact with the patient and each other inadvertently. Isolate the active electrode are not in use now from patient's body.
- Avoid wrapping instrument cable tightly, with pressure, and also around the instrument; because this may cause cable deformation in the long run.

- Use of electrosurgery in o2 rich environments increases the risk of fire. Therefore, take measures to reduce the o2 concentration at the surgical site. Avoid enriched o2, n2o atmospheres near the surgical site.

If the surgery is performed in the region of the head and chest, do not use flammable anesthetics or oxidant gases such as nitrogen oxide (N2O) and oxygen. If use is unavoidable, you must extract the combustion-supporting gases before performing electrosurgery.

- Do not leave the electrodes of other equipment (such as monitor) on the patient body. They can create a path for leakage current and cause burning.
- It is better that whenever accessory is replaced, the proper power level is adjusted again regarding to new accessory.
- Extract the flammable endogenous gases in the gastrointestinal tract before performing electrosurgery or irrigate with co2.
- The patient's body must not be allowed to come into contact with nearby electrically conductive objects (e.g. operating table, metal objects and wet towel). Since contact areas will generally be small in such cases, burn could arise from excessive current densities.
- Since elastic surface on operating table has a little electrical conduction are not suitable for isolation of patient from metal objects, thick dry electrically insulating pad thus be inserted between patient and the operating table and under any objects in use. Use absorbent towel to prevent the accumulation of liquid under patient.

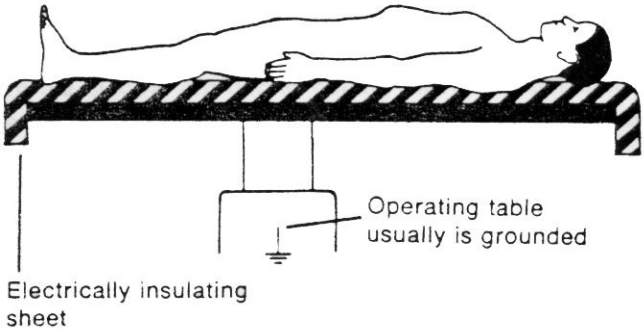


Figure3: Positioning of patient on the OR table

- Use monitoring system is equipped with HF current limit objects.
- Some material like cotton string and gauze when they are saturated with Oxygen may ignite from the sparking of the unit in ordinary use.
- In case you think that the output power rate is less than general situation, you may consider following items before increasing the output power of the unit.
- Utilize merely accessories which are compatible with unit and never use damaged or defective accessories. Always check them and get confident of the accuracy of their insulation.
- Notice that at the time of activating output of the unit, it can electronically interfere with operation of surrounding electronic equipment.
- Never connect simultaneously two surgery pens to one output connector because two pens will be activate and inactivate simultaneously.
- Take whole specific precaution of electromagnetic compatibility and those which have been mentioned in section 2.3 of this manual.
- Portable and RF telecommunication equipment may interfere with the operation of Meg2 electrosurgical generator electromagnetically.
- If any damage occurs in the unit, the output power rate may increases (in contrast with the selected level).
- Receptacles that are marked with electrostatic discharge warning symbol

(IEC 60417-5134), are sensitive to electrostatic discharge and precautions should be made when working with them. Thus, make ensure of lack of electrostatic load accumulation, when connecting cables to these special connectors. Typically accumulated static load can be discharged from device body.

- Some factors, except increase of current density, may cause Necrosis. For instance during long lasting surgery operation such as cardiac surgery or neurosurgery, some tissue which are under pressure (such as buttocks and back of the head) will get necrosis. Sometimes long lasting contact of the tissue with chemical and allergen materials (such as disinfectants) will cause necrosis. In the case of observing early symptoms of necrosis (like unusual skin pale) take necessary measures to remedy injured parts.

- If you think output power no longer is optimal, check to be certain everything is in proper working order before increasing the power level.
  - Is power level on panel properly set?
  - Are desired conditions on the front panel properly set?
  - Are cables and plugs firmly connected?
  - Is electrode cleaned?
- The unit should be operated with the compatible accessories (refer to chapter 6) and never apply defective and damaged accessories.

Warning:

associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than the maximum output voltage (Vp) of related surgical mode. For information regarding the maximum output voltage please refer to chapter Technical Characteristics page 69. In the related table maximum voltage is given as Vp-p= (2×Vp). Using instrument with rated voltage less than maximum output voltage may cause damage to the patient, operator or the instrument. It's essential that rated voltage of each instrument be provided from its manufacturer factory.

- All thermal instruments used in surgery produce smoke which potentially contains infective agents that may be hazardous to staff.

Dedicated smoke evacuators must be used and the filters recommendations. High filtration face masks should be worn in all procedures that produce surgical plume to minimize the inhalation of carbonaceous particles.

Warning:

Patient can also suffer burns due to inadvertent activation of the HF generators due to occurring any direct or indirect contact between electrode and patient through dampened cloth or any electrically conductive objects.

- In fact unintended activation of the generators can occur as follows:
  - ☞ If the footswitch inadvertently depressed
  - ☞ If there is a fault in one of the accessories cables
  - ☞ If the unit is defective
  - ☞ If the connection of footswitch or electrode to the unit causes an inadvertent activation, the defect arises from accessories.
- If the generators are activated without any connection of accessories to the unit, the unit will be defective.
- To prevent the accidental burn, never leave electrodes in manners that could result in direct or indirect contact through the mediation of electrically conductive objects or damp cloth.
- If active electrode remains in constant contact when the generator will not be triggered, pay more attention to the audible and optical signals due to activation of generators.
- Don't immerse bipolar electrode in the liquids.
- Don't put liquid containers on the device. Ingress of liquid may cause device damage.
- In status do not need any generator activation for example, when you withdraw the electrode from the patient's body, certainly put output power displays in minimum level or switch off the unit.
- The electrodes can become very hot during procedures, toughing or

electrical sparking which could result in accidental burn when they come in contact with the other tissue. However, in the Bipolar technique, the HF current area is limited to the tips of instrument, and then burn hazards are reduced in comparison with monopolar technique because the output power is very low.

- Be careful in using of ESU in thin wall organs like intestine to avoid undesirable perforation. Set power as low as possible.
- During activation, prevent patient body movement in the surgery site.

Warning:

In sensitive structures neuromuscular stimulation can occur leading to secondary risks like injury caused by muscle contractions.

Caution:

Note that active electrodes may become hot during Cut and Coag. due to electrical sparkles or contact with tissues, and their contact with other tissues can cause unwanted burn.

- In cases such as endoscopy, note that because the active electrode has permanent contact with tissues, any unwanted activation of the generator can cause burn in active electrode contact site. Put the output power on minimum or turn off the device when there is no need to activate the generator for a long time.
- Avoid coagulation in a way that causes electric arc between active electrode and hemostat tool. In these cases, firstly contact active electrode and hemostat tool then activate the generator. This will reduce the unwanted shocks to surgeons.
- If any alarm is heard from the device, check the device and make sure about the accuracy of its performance before reusing it and record the type of alarm in the patient's documents.
- To reduce the risks of high frequency leakage current through

unwanted paths, avoid keeping the device active in open circuit status, where the active electrode has no electrical contact with tissues.

- Do the following steps to reduce the risks of Minimally Invasive Surgery procedures (such as laparoscopy) that sometimes cause burns out of sight:
  - Check the quality of the insulators carefully and note that any cracks and roughness can be a sign of insulators weakness and can be a pathway for leakage.
  - Use minimum power and modes with minimum voltages.
  - Activate the HF generator only when the active electrode is in contact with the tissue.
  - If the active electrode is in the vicinity or contact of electrically conductive parts, the generator should not be activated.
  - If possible, use all metal cannula, which the outer cannula system covered by metal entirely, to reduce the risk of leakage due to capacitive coupling.
- Postoperative care:
  - At the end of the surgery, turn off the device immediately and zero mechanical volumes on the device.
  - Open the cables from the connectors gently and never pull the wires to remove them from the device.

2.2 The Procedures Minimize Adherence Effect in Bipolar technique:

The bipolar technique offers the following benefits compared to the monopolar technique:

1. ***The applied HF current is smaller.***
2. ***No neutral electrode is used.***
3. ***HF current flows between both identical tips electrode.***

4. ***Hazards of unintentionally burning patient are negligibly small.***
5. ***prevents form unpredictable and unwanted coagulation.***
6. ***Possibility of the electromagnetic interference with other electronic is drastically low.***

Therefore, the bipolar operative technique should be preferred whenever it can be used.

In bipolar technique, one or more of the following complications could arise:

☛ Sticking tissues and clots to the tips of forceps sometimes caused to reopen the blood vessels when the forceps are withdrawn so the instrument should be kept clean at all times.

☛ Setting the output power more than you need or remaining the forceps on tissues at long time could be result in carbonizing the tissues and lead to adhesion of the tissue.

☛ On the other hand, if the unit is activated before keeping electrode in contact with tissue, the initial sparking between electrode and tissue will cause either to carbonize the tissue or to adhere the tissue to the electrode.

- To minimize the adhesion effects of active electrodes to tissues during coagulation, do not activate the generator before contacting the electrode with tissue, and cut off the HF current as soon as sufficient coagulation is done and keep the electrodes clean at all times.
- In Auto start system, impedance between two electrodes is constantly detected. Whenever the tissue is positioned between two poles, the system will automatically be activated after a 0.5 seconds delay.
- Switch off the HF-current as soon as sufficient coagulation has been formed.
- Do not continue coagulation does not have any intended surgical effect.
- Always keep electrode clean and completely remove the tissue residues from electrode.
- Moisten the dry tissue to be coagulated with sterile water or with

corporeal salt solution.

- If the tissue is adhered to the electrode during bipolar operation, switch off the HF current and withdraw the electrode then wait a minute to reduce the adherence through capillaries and adjacent tissues secretion.
- To coagulate the tissue keep electrode in contact with the tissue for a brief period after the HF current is switched off. In fact, fluid flows from capillaries and adjacent tissues will soften and dissolve adhering matter at the contact surface. Use sterile water or corporeal salt solution in such intensive cases.
- Always clean the electrode after every use because the tissues fluids cover the electrode surface. Remaining such fluids on electrode conduct the current slightly, so the surgeon thinks that output power is low.
- In case generator is unwantedly activated and if electrodes are directly or indirectly through wet fabric or other conductor objects in contact with patient's body, it can cause burn. Unwanted generator activity can be due to accidental activation of pedal or hand switches or a failure in cable of accessories or the device itself; if connecting pedal or pen to device causes unwanted device activation, the failure is due to accessories, and if without connecting them to the device, generator is activated, the failure is due to the device. To avoid unwanted burns, never place active electrodes such that directly or through electrically conductive objects or wet fabrics be in contact with patient.
- In cases the active electrode has constant contact with tissue even when the generator is not active, (eg. in endoscopy or TUR) more attention should be paid to visual and auditory signs of generator activation; and when there is no need to activate generators, for example during electrode take out from the patient's body, definitely set the output power displays in lack of output power mode or turn off the device.

2.3 Electromagnetic Interference

Warning:

Interference produced by the HF surgical equipment may adversely influence the operation of adjacent electronic instruments.

If you see abnormal situation in the adjacent equipment, note that it can be because of the action of the HF surgical equipment.

If you realize that the interference only occurs when the generator is active, use following guidelines to reduce interference:

1- Use the lowest appropriate power setting

2- Keep the electrosurgical equipment and accessories away from the susceptible equipment.

For patients with cardiac pacemakers or other active implants, interference may occur, and even they can be damaged.

When use of electrosurgical equipment is urgent in patients with cardiac pacemakers, use following guidelines to reduce the risk:

1- Consult a cardiologist and take sufficient care before operation.

2- Ensure that there is good continuous ECG monitoring during the electrosurgical procedure.

3-Ensure that a defibrillator is in hand at all times.

Warning:

Iconic needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the Iconic Service Manual and also this user manual.

CHAPTER 3

3 Important Remarks on the Operation of Electrosurgical Unit Meg2

3.1 Installation and Operating Instructions

Remove all packing materials. Thoroughly check all accessories and any appearance items of the product for probable damages. In the case of any damage(s) due to shipping or any other reason, please notify defects or damages to kavandish system engineering company and send your address with the serial number of the unit.

Connect the power – supply cord into an electric outlet. Notice that the power- supply source should be 220V ± 10%. Then turn on the equipment with the main power switch (17), located at the unit rear panel.

Warning:

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

The front panel should switch on and then the system starts to operate self-checking process. This process begins with checking LCD display and 7-segment displays by turning them on. Then modes will be checked and their related indicator lights will be turned on. At the end of self-checking process, in case of detecting technical problem, this message should appear on the LCD display (Figure 4).

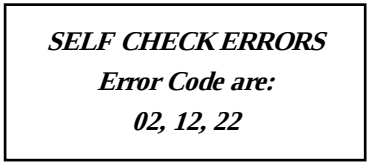


Figure 4

In case the reported errors were not under your consideration (in your select mode), you would press any key to activate the system (explanation about

error codes is prepared in pages 28). It should be mentioned that activation of those modes which are listed in the error report is not free of problem.
If self-checking process was achieved successfully and No error detected in the system, this message should appear on the LCD display (Figure 5):

Figure 5

Then you will observe this message on the LCD display: “Welcome to MEG2” (Figure 6).

Figure 6

At this stage all data which have been saved in the memory, will appear and flash on LCD display. Then you may press any key to choose normal mode and make the system ready to operate normally.

If you are switching on the unit for the first time, you should conduct an operational check of the device before utilizing the unit in operating room. Perform checking process according to the following instructions:
Self – checking process should end up without any interruption. Finally select modes should appear on LCD display.

Digital display 11 should indicate the power rate which have been set default.

Note:

Appearing this position ((----)) on display, indicates that the rate of output power has not been selected.

Check all accessories, pedal footswitch and Bipolar pen connectors accurately. Connect them to the unit if they are in proper condition.

Set the digital display 11 by pressing pushbuttons 6, 7. Place Bipolar forceps against row meat and then activate the HF output by depressing the foot switch. Whenever you activate generator, a running sound related to the select mode should be audible.

Press push button 2 to set Bipolar generator to Auto mode. Place two tips of forceps on a raw and wet meat. The Bipolar generator should be switched automatically and activate after a 0.5 second delay. Now press pushbuttons 1, 4 or 5 to set the generator to Bipolar Coag., seal 1 or seal 2. In this position the generator should not become activate automatically after placing two tips of forceps on the raw meat.

9) Press pushbuttons 6 and 7 in Bipolar mode to observe the changes of the level on digital display 11. Place Bipolar output against raw meat and activate it by depressing footswitch or automatically in order to observe changes of the output power.

The operator shall notify any problem or defect or dissatisfaction related to the operation of the unit (after performing checking process) or packing or shipping the product or even recycling the product (at the end of its service life) and also any suggestion to improve product's quality, to Kavandish system company, department of post- sales services with the serial number and address.

3.2 Introduction and operation of LCD display pages

The Meg2 unit is equipped with LCD display which makes the operator familiar with the situation of the unit. The LCD will display select mode, warning messages and the type of accessory which used for activation (Hand switch or Foot switch).

Table of warning concepts which are displayed by codes in Self-Checking:

code	Code concept
01	Voltage increase in auto-bi-coag power supply.
02	Output power decrease in auto-bi-coag generator.
11	Voltage increase in bi-manual power-supply.
12	Output power decrease in bi-manual generator.
21	Voltage increase in seal2 power-supply.
22	Output power decrease in seal2 generator.
31	Voltage increase in seal1 power-supply.
32	Output power decrease in seal1 generator.

CHAPTER 4

4 Recommendations for power setting in Bipolar Surgery

Warning:

Remember that, selecting power rate more than the required rate can cause an increase of probable dangers and side effects.

Mostly suitable power in this technique is between 25 and 50Watt.

Setting too high power result in adhering electrode to the tissue would certainly produce superficial carbonization, so the current is not delivered. If you clean the tips of forceps and set the optimum power, complete coagulation will form during 1 to 5 seconds.

Setting the power too high can lead to increase the vapor pressure within tissue originating from sharp rises in temperature that are sufficient to produce sudden rupture or explosion of tissue. However, setting the power too low can be subjected to forming coagulation very slowly.

CHAPTER 5

5 The Vessel Sealing System

The Vessel Sealing System, a new technique presented along with electrosurgery, is used worldwide by surgeons. Using an intelligent microprocessor system, the device applies a controlled amount of the RF current to tissues and vessels. By applying the needed amount of energy and mechanical pressure, the collagen and elastin are melted, sealing the vessel naturally, without the usual stitches, clips… used in surgeries.

5.1 Advantages

☛Complex algorithms of power and voltage control, which process the feedback received from the impedance of the tissue, detect the optimum seal point and the device automatically turns off. Thus, carbonization, sticking to the tissue, and thermal damage is minimized.

☛In case of increase in blood pressure, sealed arteries can bear up to three times systolic pressure. This is comparable to the pressure that a vessel sealed through usual surgical procedures (stitches …) can stand, and it is considerably more than what vessels sealed using the conventional bipolar or ultrasonic systems could bear.

☛This system seals any vessel with 7mm of diameters or less.

☛The Vessel Sealing System noticeably reduces the time of the surgery and the patient's blood loss.

☛Using the specially designed tools, the system could be used in both open and laparoscopic surgeries.

☛Using the Vessel sealing system reduces needle stick injuries, lowering the probability of transmission of Hepatitis and HIV.

Warning:

The Vessel Sealing System is not useful for Tubal sterilization or Tubal coagulation for sterilization processes.

Warning:

In patients with certain types of vascular pathology (atherosclerosis, aneurismal vessels), unaffected vessels must be chosen to be sealed.

5.2 Tools Used for Vessel Sealing

In Meg 2, Vessel Sealing is only possible when special tools designed for Vessel Sealing are used. The tools that could be used with Meg 2 are shown in Table 5-1.

Table 5-1 Tools used for vessel sealing

Instrument type	Mode	Surgery type	Some of surgical applications
LS1037 	Seal1	laparoscopy	Adhesiolysis- Appendectomy Colectomy- Gastric Bypass Nissen fundoplication Lap- Assisted vaginal hysterectomy Adrenalectomy- gastrectomy Splenectomy- slapingo Oophorectomy- Nephrectomy

Instrument type	Mode	Surgery type	Some of surgical applications
LS1020 	Seal1	open	Adhesiolysis Abdominal hysterectomy Gastric Bypass Colon Resection Colectomy Radical prostatectomy Gastrectomy splenectomy Nephrectomy Slapingo-Oophorectomy
LS2110 , LS2111 	Seal1	open	
LS3090 , S3092 	Seal1	open	
LS3110 , LS3112 	Seal1	open	
Bowa – Tissueseal 	Seal1	open	Adhesiolysis Abdominal hysterectomy Gastric Bypass Colon Resection Colectomy Radical prostatectomy Gastrectomy splenectomy Nephrectomy Slapingo - Oophorectomy

Instrument type	Mode	Surgery type	Some of surgical applications
LF4318 , LF4418 	Seal1	open	Urology Colorectal General surgery Gynecology
LF1623 , LF1723 , LF1823, LF1923 	Seal2	open	Abdominal hysterectomy Gastric bypass Colon resection Cystectomy Radical prostatectomy Gastrectomy Salpingo-oophorectomy
LF1637 , LF 1737 , LF1837 , LF1937 	Seal2	laparoscopy	Adhesiolysis , Adrenalectomy Colectomy , Gastrectomy Gastric bypass Laparoscopic hysterectomy Nephrectomy Nissen fundoplication OophorectomySplenectomy

Instrument type	Mode	Surgery type	Some of surgical applications
LF1644 , LF1744 , LF1844 , LF1944 	Seal2	laparoscopy	Adhesiolysis , Colectomy Laparoscopic hysterectomy Nephrectomy Oophorectomy Roux-en-Y gastric bypass Sleeve gastrectomy Splenectomy
LS1200 	Seal2	open	Throidectomy Tonsillectomy Neck Dissection Parotidectomy Other general surgery procedures
BZ4212 , BZ4212A 	Seal2	open	Tonsillectomy Throidectomy Neck Dissection Parotidectomy
LS1500 	Seal2	laparoscopy	Adhesiolysis- colectomy Gastric bypass Nissen fundoplication Adrenalectomy-gastrectomy Splenectomy Slapingo- Oophorectomy Nephrectomy

Instrument type	Mode	Surgery type	Some of surgical applications
Bowa – Ligator (laparoscopic) 	Seal2	laparoscopy	
LS1520, LF1520 	Seal2	open	Cystectomy Nephrectomy Prostatectomy Open colectomy Axillary dissection Hemorrhoidectomy Liver resection Gynecological procedures
LF1212, 1212A, LF2019 	Seal2	open	Ear,Nose and Throat (ENT) General Plastic/Reconstructive Urologic Thoracic

Warning:

☛ If tools other than what is mentioned in Table 5-1 are used, the seal will not be reliable.

Warning:

☛As mentioned in Table 5-1, the modes of seal 1 or seal 2 must be chosen according to the selected surgical tool. Otherwise, the quality of the seal will not be reliable and there will be a chance of thermal damage to the tissue.

5.3 Using the Vessel Sealing System

5.3.1 The Right Mode

The vessel sealing system can be used in two different modes of seal 1 and seal 2.

The mode seal 1 is used in cases where tools are in touch with a larger surface of the tissue and more energy is needed to be applied. The shaft diameter of these tools is often is 10mm.

The mode seal 2 is employed for cases where tools are in touch with a smaller surface of the tissue and less energy is needed to be applied. The shaft diameter of these tools is often is 5mm.

Therefore, it is recommended that use seal1 when utilizing seal tool with 10mm shaft diameter, and use seal2 when utilizing the seal tool with 5mm shaft diameter.

To use the vessel sealing system of the device, choose the right mode by pressing either seal1 or seal 2.

Warning:

☞ Choosing the wrong mode for the surgical tool you have selected, leads to an unreliable seal or a considerable raise of surgical injuries.

☞ Using the usual bipolar mode is not allowed for Vessel Sealing. This would result in an unreliable seal.

Attention:

Vessel Sealing mode operates smartly. It means this mode applies sufficient power to tissue for sealing based on tissue impedance assessment. Therefore, power adjustment is not required in seal1 and seal2.

5.3.2 Grasping the Tissue with the tool

Take the tissue with the tool and press the handle, as you do so you will hear the tool become locked.

Caution:

When the tool is locked, there is enough mechanical pressure for the seal. If the tool is not locked while applying energy, the seal will not be reliable.

5.3.3 Applying Energy to the Tissue

Activate vessel sealing system by pressing the hand switch or the pedal (in double footswitch, press blue pedal). Keep pressing until you hear two short beeps and you see the message *seal complete*. In case you see the message *regrasp* on the device, the seal is incomplete and you will need to apply energy to the tissue again. In case the message *regrasp* was repeated, refer to

Table 5-2 to find the reason.

Warning:

If you stop activation before hearing two short beeps and before you see the message *seal complete*, the seal will be incomplete and the device will show the message *regrasp*. In this case, the seal is not reliable and you need to repeat the process.

5.4 Warnings and Messages about the Vessel Sealing System

The LCD screen shows two messages about the Vessel Sealing System:

☞ ***Seal complete*****:** When the device identifies the seal as complete;

☞ ***Regrasp*****:** When the seal is not complete, due to any reason;

To find the reason why the device is showing the message *Regrasp* refer to Table 5-2.

Table 5-2 What may cause the message Regrasp

Regrasp situation	**Possible cause**	**Solution**
Regrasp ---------- Energy Stopped	Seal activity demand was stopped.	For seal modes, after activating device, don't stop applying energy until device displays "Seal Complete" message.
Regrasp ----------	Low current at the start of sealing.	Check the connections. There is a possibility of disconnection in

Low Current 0		connectors or cables and possibility of accessory breakdown. Also, if the tissue is not in the handpiece's jaws, this alarm is displayed.
Regrasp ---------- Low Current 1	Low current in energy applying phase during seal process.	Check the connections. There is a possibility of disconnection of connectors or cables and possibility of accessory breakdown.
Regrasp ---------- Low Current 2	Low current in impedance control phase during seal process.	Check the connections. There is a possibility of disconnection in connectors or cables and possibility of accessory breakdown.
Regrasp ---------- High Current 1	No tissue response to electrical current during Seal process. Despite high current flow, desired response is not observed in tissue. There is a possibility of instrument failure or short circuit between the two jaws of surgical instrument.	Without cutting the tissue, open the jaws and grasp the tissue again. If the error repeats, replace the surgical instrument.
Regrasp ---------- High Current 2	Detecting short circuit in impedance control phase during Seal activity. Despite high current flow, desired response is not observed in tissue. There is a possibility of instrument failure	Without cutting the tissue, open the jaws and grasp the tissue again. If the error repeats, replace the surgical instrument.

	or short circuit between the two jaws of surgical instrument.	
Regrasp ---------- Time Over	No complete tissue response observed at the specified time. Maybe the tissue taken by surgical instruments is too thick. Maybe there is accumulation of blood and fluids around the jaws of surgical instruments.	Without cutting the tissue, open the jaws, drain blood and fluids around the jaws and grasp the tissue again.
Regrasp ---------- High Power	Unallowable output power. Possibility of device failure.	Stop using the device. To check and fix the problem, send the device to the manufacturer.
Regrasp ---------- Unexpecte d Change	Unexpected response in tissue. Much change is observed in the electrical impedance of the tissue.	Without cutting the tissue, open the jaws and grasp the tissue again.
Seal complete	Successful Seal process completion	The signal is just informative and no action is needed.

5.5 Points about Using the Vessel Sealing System

1. Do not use the Vessel Sealing System before being trained or you will face unintended consequences.
2. In Meg2, the right mode of Vessel Sealing is chosen based on the surgical tool and by referring to the Table 5-1. Otherwise, the seal will not be reliable.
3. The tool must be dry and completely connected to the generator.
4. For a reliable seal, the tool must be completely locked so that the needed amount of mechanical pressure could be applied to the tissue.
5. Any part of the tissue out of the instrument's jaws or near the joint of the instrument will not be sealed, even if it turns white while applying energy.
6. When the process is over, the surfaces of the tool become hot. Be careful not to burn other tissue parts by accidentally touching it.
7. Do not activate the generator if the tool's jaws is in touch with any metal object. In such cases, the energy may not be transferred to the tissue, or the patient/physician may burn.
8. Before starting the process, dry the seal zone. If the tools become in contact with conductive fluids (blood or saline) heat or energy may be carried on to adjacent tissues.
9. As you can not change the setting during the sealing process, confirm the power and mode before starting.
10. Soak the tools in an enzymatic cleaning agent such as Enzol or Klenzyme and scrub the entire surface with a soft brush. All the surface and the holes of the tools must be cleaned of blood and tissue. Then rinse with water and dry with a soft cloth. It is important

that the tools be clean to insure proper energy transmission and to complete the seal process.

11. In case you observe any sparking, stop the surgery at once and check all the connections of the device. A metal to metal sparking could cause neuromuscular stimulation on the patient.

12. The vessel should be grasped together with its surrounding tissue, and not in isolation, by the tool's jaws. This will lead to a more reliable seal.

13. Through the sealing process, the vessel must not be under tension or mechanical pressure. The vessel is so weak during the transitional phase that it is torn by the slightest tension and will start bleeding.

14. Reusing the disposable tools will make the tissue stick to the electrodes and cause an electric arc, thus the seal will not be reliable.

15. The connection point of the conventional bipolar tools and the Vessel Sealing tools are the same in Meg 2. However, these two modes are different considering software and algorithms of applying energy.

16. Two surgical tools must not be connected to the bipolar/vessel sealing output at the same time, or they will be activated and deactivated together.

17. MEG2 device in the bipolar Coag. mode only becomes activated by footswitch which supplied with device. In the case of using double footswitch, bipolar Coag. mode only becomes activated by pressing the blue pedal.

CHAPTER 6

6 Accessories

6.1 The Accessories of Unit

The following accessories are included in the MATIN Meg2 packaging according to the customer's order:

1. ***footswitch***
2. ***Bipolar forceps with connecting cables.***
3. ***Tools used for vessel sealing.***

Warning:

Use only original accessories recommended by kavandish.
In case of doubt ask the kavandish or its representative to certify compatibility.
Utilizing non-standard or defective accessories or using accessories other than those allowed by Kavandish may cause following consequences:
- Inadvertent generator activation.
- Injury or electrical shock to the patient or surgical team.
- Unintended surgical effects.
- Low or intermittent ESU power output.
- Abnormal neuromuscular stimulation because of metal-to-metal arcing or sparking.
- Monitor interference when ESU is activated.
- Excessive HF current leakage.
- Generator malfunctions.

It is recommended to use the accessories whose length up to 3 m.

Warning:

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

All accessories must fit securely without forcing the accessory into the port. Do not use any accessory that does not connect properly, or that has cuts, nicks, or other visible signs of wear.

Fix the connectors and plugs of accessories gently to the unit and don't put any extra pressure on cables and plugs.

Warning:

Don't use accessory adaptors which are not approved by Kavandish System Co.

It is recommended to use the accessories whose length up to 3 m.

6.1.1 Footswitch

The footswitch receptacle accepts four-pin self-retaining plug and is compatible only with Kavandish, Erbe footswitch. The receptacle can be firmly screwed to the footswitch plug.

Figure 7: footswitch receptacle

The footswitch supplied with MEG2 is single footswitch which manufactured by Kavandish System Co. and is designed and produced in accordance with international standards IEC60601-1 and IEC60601-2-2. The construction of the footswitch has been protected against spillage and ingress of liquids.

Figure 8: Single footswitch

If double footswitch is used, device output is only activated by pressing blue pedal.

Figure 9: Double Footswitch

- Do not transport it with the cable. Avoid any pressure to the connection. Do not lay the cable in loop. Do not wind the cable around pedal firmly.
- In the event of using the non-AP pedals, do not clean and disinfect them with the explosive substance. Do not use in Medical Zone, i.e. 25-centimeter site where the leakage of combustible anesthetic gases may occur. Medical Zone is shown in figure 10.

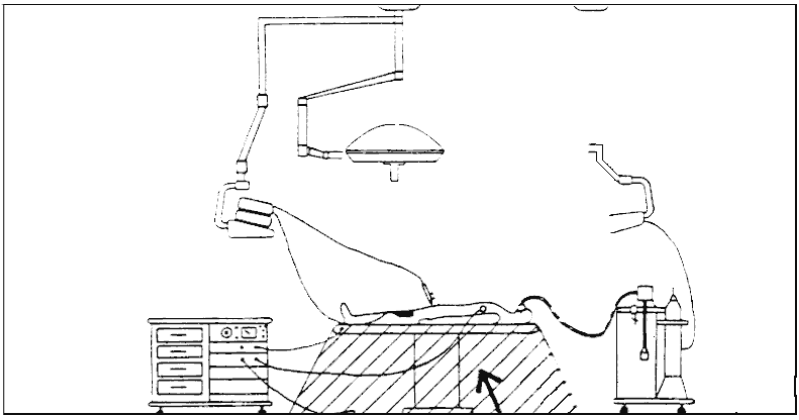


Figure 10: Location that only AP footswitches can be used

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

6.1.2 Bipolar accessories

There are various types of bipolar accessories in shapes and dimensions well suited to coagulation the tissues.

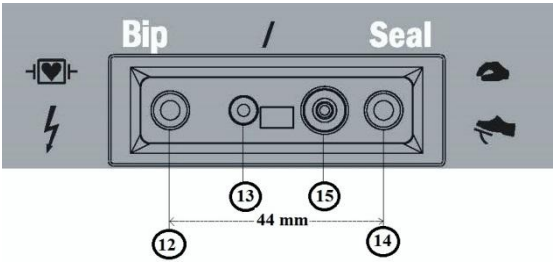


Figure 11: Bipolar and Seal connector

The Bipolar receptacle only accepts following types of cables:

1- Bipolar cable with shrouded Martin type connector.(15)

2- Bipolar cable with international connectors with two pins Ø 4mm. (12, 14)
Kavandish only recommends accessories for conventional Bipolar from following companies:
Bowa, Martin, Tecno, Berchtold, Metko, Valleylab

Warning:

In Meg 2, Vessel Sealing is only possible when special tools designed for Vessel Sealing are used. The tools that could be used with Meg 2 are shown in Table 5-1. If tools other than what is mentioned in Table 5-1 are used, the seal will not be reliable.

Figure 12: Conventional Bipolar Forceps

Bipolar forceps are covered by insulating material except its two tips. During connection to the tissue, the coagulation does not occur except in tips of forceps areas, and also does not cause the surgeon's hand burn when the bipolar output is activated. Bipolar cable connection place is at the end of the forceps.
Avoid applying too much pressure to the forceps, or opening the jaws,

because it damages the insulator covers on the forceps. Avoid wrapping the bipolar cable strongly and with pressure, as this will change the shape of the cable in the long time.

CHAPTER 7

7 Alarm System

There are some conditions in the equipment that need user consideration; these conditions are categorized in alarm and information groups. In case of these conditions, visual and auditory signals (by LCD, LED, 7-segment and speaker) will be generated by the system. All signals generators will be activated by the system turning on. So user could be assured of alarm system function. In order for the visual and auditory signals to be perceived by the user (except LCD), a maximum of 3m distance between user and equipment is recommended. A maximum of 2m distance is suitable for LCD checking.

7.1 Alarm conditions:

Alarm conditions are listed and described in Table 7-1.

7.1.1 Alarm conditions group:

Alarm conditions are categorized into two groups based on reason of external cause.

1) Technical:
   Event happened in the equipment or its accessories.

2) Functional
   Event happened in the interaction between equipment and operator/patient while using the equipment.

An alarm condition may be occurred because of different technical or functional reasons. For this kind of alarms, the phrase of “Technical-Functional” is mentioned in Table 7-1.

7.1.2 Alarm conditions priority:

Alarm conditions are assigned into two priorities based on severity of their harm on patient, operator, or equipment.

These two priorities are named “Medium” and “Low” based on IEC 60601-1-8 standard.

1) Medium Priority:

Due to serious harm probability in medium priority alarms, the generator will be stopped and cannot satisfy user requests. This could have some potential harm. Thus, immediate response of user is necessary to resolve the problem.

By occurrence of a medium priority alarm, a message related to the alarm that started with “Fail:” will be displayed on LCD. Also, ERROR LED starts blinking and an auditory signal with frequency of 985 Hz will be generated by a speaker.

The pattern and characteristics of these visual and auditory signals are as follows:

- LED:
  Pattern: Continuously flashes on (600 ms) and off (250 ms).
  Color: Red

- Auditory signal:
  Pattern: Three subsequent pieces of sound, overall named a burst, which is repeated every 4s. In each burst, speaker will be turned on and off every 250 ms.

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

2) Low priority:

Due to slight harm probability in low priority alarms, changing the equipment status (e.g. generator inactivation) is not needed immediately. But user should be aware to show the necessary reaction to the alarm condition in proper time. Also, during system

activation in this condition, a lower auditory noise (because of the lower priority) will be generated.

By occurrence of a low priority alarm, a message related to the alarm that started with "ER:" will be displayed on LCD. Also, ERROR LED starts blinking and auditory signal with frequency of 985 Hz will be generated by the speaker. The pattern and characteristics of these visual and auditory signals are as follows:

- LED:
  Pattern: Continuously flashes on and off.
  Color: Red

- Auditory signal:
  Pattern: Speaker will be on and off twice with 150 ms interval.

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

7.1.3 Alarm signals generation ranking:

By occurrence of low and medium priority alarm conditions simultaneously, alarm signals will be generated only for medium priority alarm conditions. Also, by occurrence of the same priority alarms, all related messages will be displayed on LCD.

Table 7-1 Alarms

NO.	Event	Message on LCD	Group	Priority	Effect on generator	Save in the memory
1	Voltage increase in internal power supply more than a specified value	**Fail: OV**	Technical	Medium	Stopping activation	✓
2	Decrease in output power of HF generator less than a permitted value	**Er: FE**	Technical	Low	---	✓
3	Non-stop activation of generator for 30 seconds	**Fail: Time Out**	Functional	Medium	Stopping activation	×
4	Non-stop activation of generator for 10 seconds	**Er: TO**	Functional	Low	---	×
5	Regrasp	**Fail: Regrasp**	Functional	Medium	Stopping activation *	×
6	Activation request at the time of conventional start of system when it was in Standby or Self-Checking mode or Setting bipolar to Auto Coag. when bipolar electrode is on tissue	**Er: IR**	Technical-Functional	Low	Avoidance of activation the generator that causes this alarm	×
7	System memory failure	**Er: ME**	Technical	Low	---**	✓
8	Internal system boards disconnection when the generator active or an activation request received	**Fail: Connector**	Technical	Medium	Stopping or avoidance of activation	✓

9	Internal system boards disconnection when no activation request presents	**Er: CN**	Technical	Low	---	✓

* Please refer to Table 5-2 and f description

** Please refer to following description

Table (5-1) description:

1) **"Regrasp" Alarm**

The situations leading to this alarm are given in Table 5-2. With the occurrence of this alarm, in addition to the usual signals (ERROR LED and message on the LCD), the 7 segments also blink with a frequency of approximately 0.83 Hz and a working cycle of 50% (600ms (on), 600ms (off)).

When demand is met, the last burst of the speaker is completed and the sound will be stopped, but the rest of the signals continue. If the Regrasp alarm is sounded by meeting demand, the speaker will only sound for one burst.

The Regrasp alarm continues until the next vessel sealing request. However, with any activity request, or detection of any alarm or information conditions, generation of all alarm signals except blinking of the 7 segments will be interrupted.

This means exiting the alarm condition and stopping all visual and auditory signals except the 7 segments, which means the end of the Regrasp alarm. Also, by selecting any of the bipolar modes, blinking of the 7 segments is stopped and by selecting one of the vessel sealing modes again, they start blinking again.

2) "System memory failure":

Each time system settings are saved in the memory, the settings and stored values are compared. Any inequality causes the alarm of "System memory failure". By any request for activation, this alarm will be stopped.

7.2 Information conditions:

In addition to alarm conditions, there may be other conditions that need operator consideration although they don't harm patient or operator. These conditions are called information condition and include use errors (when there is no harm for patient or operator) and any new happenings that occur during normal use of equipment (e.g. generator activation). Information conditions are listed and described in Table 7-2.

7.2.1 Information signals characteristics:

Information signals during generator activation are different from the ones generated when the system is not active.

Generator has an exclusive page on LCD to show its activation. This page includes settings details of the technique being activated. During generator activation, LED dedicated to the activated mode will be on and a continuous auditory signal will be generated by a speaker with adjustable sound level (50dBA-70dBA from 1m).

- Generated sound frequencies during Bipolar Coag. and vessel sealing activation: 470 Hz

By occurrence of the other information conditions, a related message will be displayed on LCD. In some conditions (item 2 in Table 7-2) the related 7-segments will start blinking as well. In addition, an auditory signal will be generated by a speaker with adjustable sound level (50dBA-70dBA from 1m).

- 7-segments blinking pattern:

7-segments will flash on and off every 350 ms.

- Auditory signal generation pattern:

Speaker will turn on and off twice, with 350 ms timing.

7.2.2 Information signals ranking in compare with alarm signals:

By simultaneous occurrence of information and alarm conditions, only alarm message(s) will be displayed on LCD, while other information and alarms signals are generated. However, information messages related to user requests (Item 2, 4 and 5 in Table 7-2) will be given priority to be displayed on LCD until the request presents.

Table 7-2 Information conditions

No.	Event	Message on LCD	Effect on generator
1	Generator activation	Exclusive page	---
2	Starting with p=0 or power decreasing to 0 during activation	P=0	Stopping or avoidance of activation
3	Setting bipolar to Auto Coag. when bipolar electrode is not on tissue	Auto Bip.	---
4	Detecting optimum coagulation of the tissue in Auto Stop	Coag Complete	Stopping activation
5	Detecting optimum Seal in Vessel Sealing modes	Seal Complete	Stopping activation

CHAPTER 8

8 Post-Sales Support and Warranty

8.1 Routine Maintenance and Inspections

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

8.2 Cleaning and Disinfecting of the Unit

- Install the unit in proper site to avoid any damage to the unit.
- Place the device on a fixed flat and with no vibration surface.
- This unit is not intended to use in areas subject to explosive substance hazards and infected liquid.
- The device's surface should be cleaned and disinfected with incombustible substances.
- Do not allow any liquid enter the unit.
- Do not use flammable or explosive liquids. If you have to clean and disinfect the unit with them, make certain that all combustible substances have been vaporized from the operating room.
- Withdraw or insert the accessories plugs smoothly to increase the service life of them.

NOTICE:

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

8.3 Post- Sales Support

Kavandish supports all post- sales services perfectly.

MATIN Meg2 provides a full 24 months warranty against defect due to defective parts, workmanship or manufacturer's fault. If the product should become defective within the warranty period will be repaired or replaced free of charge at Kavandish's discretion.

Note:

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.

8.4 Warranty

- Receive the warranty registration card that should be filled correctly and completely.
- The warranty provisions do not cover failure due to shipment, and misuse.
- The warranty provisions do not apply where the unit has been serviced by a person not authorized by us or serviced with non-approved parts.
- The warranty provisions do not cover the accessory failure, so replace defective part with a new one.
- We agree to repair and provide the spare parts for 10 years as of delivery to the customer.

CHAPTER 9

9 Technical Characteristics

9.1 Technical Specification:

9.1.1 Mains requirements:

Mains voltage: 200_{Vac} – 240_{Vac} 50Hz
Maximum Current Consumption: 3.2 A(rms)
Main fuses: 5A/250V (AC) Standard.

9.1.2 Environment condition for transport and storage

Temperature: 0C ~ +40C
Relative Humidity: 10% ~ 90% without Condensation
Atmospheric pressure: 500mbar ~ 1060mbar

9.1.3 Safety features:

Basic construction: in accordance with IEC60601-1 & IEC60601-2-2
Protection class: I

9.1.4 Type of output: CF (Cardiac Floating)

9.1.5 Switching of Neutral Electrode: Floating output

9.1.6 HF leakage current

Less than 20mA

9.1.7 LF leakage current

Normal condition <10μA
Single fault condition <50μA

9.1.8 Dosage rate control:

Automatic and permanent check of output power

9.1.9 Activation time control:

Acoustic & visual alarm after 30 seconds & shutting down after 60 seconds

9.1.10 Self-check:

Malfunctions are detected and recorded as coded message (most recent 10 messages)

9.1.11 Communication between user and machine:

- Visual and audible Indicators for activation (please refer to section 7.2.1)
- Digital 7-seg for output power
- 4×20 character STN LCD for monitoring modes, errors and messages

9.1.12 Bipolar coagulation and vessel sealing system:

- Coagulation with anti-sticking effect without tissue carbonization
- Hand switch and Foot switch activation for vessel sealing system.
- Foot switch and auto start (tissue sensor) activation for conventional Bipolar.
- Auto Stop mode for conventional Bipolar coagulation

9.1.13 Auto Stop mode:

In surgery, generally carbonizing the tissue occurs about a few tenths of second after reaching the optimum coagulation point. So controlling coagulation process would be a difficult task for the surgeon. In order to fulfill this process more comfortably and accurately, the unit has been equipped with a micro control system which is able to disconnect H.F generator automatically at the time of reaching the optimum coagulation, through utilizing automatic control facilities and processing changes of the tissue density and electric resistance.

9.1.14 Vessel sealing Mode:

The Vessel Sealing System, a new technique presented along with electrical surgery, is used worldwide by surgeons. Using an intelligent microprocessor system, the device applies a controlled amount of the RF current to tissues and vessels. By applying the energy and mechanical pressure, the collagen and elastin are melted, sealing the vessel naturally, without the usual stitches, clips… used in surgeries.

In this mode, by applying intelligent algorithms for controlling power and voltage, and establishing feedback from tissue impedance changes, the optimum seal point is detected by the device and the output is cut off, so the amount of carbonization, adhesion to tissue and thermal damage will be minimal.

Sealed vessels are resistant to hypertension, up to several times the systolic pressure. This resistance to pressure is equivalent to conventional vascular surgery procedures such as stitch and is much more than conventional ultrasound and bipolar methods.

By this system, all vessels with a diameter of less than 7mm can be sealed.

Seal 1 and Seal 2 modes can be selected based on the type of Vessel Sealing tools (see section 5 for more information about differences between these two modes).

By using special tools, this system can be used in open surgery or laparoscopic surgery.

9.1.15 Compatibility of accessories connectors:

➢Vessel Sealing receptacle complies with Valleylab and Bowa connectors. (For more information, please refer to Table 5-1

➢Bipolar receptacle complies with following types of connectors: Metko,

Martin, Tecno, Fiab, Berchtold, Bowa, Valleylab

➢The footswitch receptacle accepts four-pin self-retaining plug and complies with Kavandish and Erbe

9.1.16 Continuous operation of the unit:

The type of operation situation of the unit is continuous operation with short – time loading. (Generator's normal duty cycle: 10s ON / 30s OFF)

Warning:

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

Caution:

This unit is not equipped with the water proof system but the enclosure is constructed so that liquid spillage in normal use does not wet components which, when wetted, are likely to affect adversely the safety of the Meg2

9.1.17 Output characteristics:

Nominal frequency: 410 KHz ± 1%
Modulation frequency: 25KHz

9.1.18 Technical Specifications Table

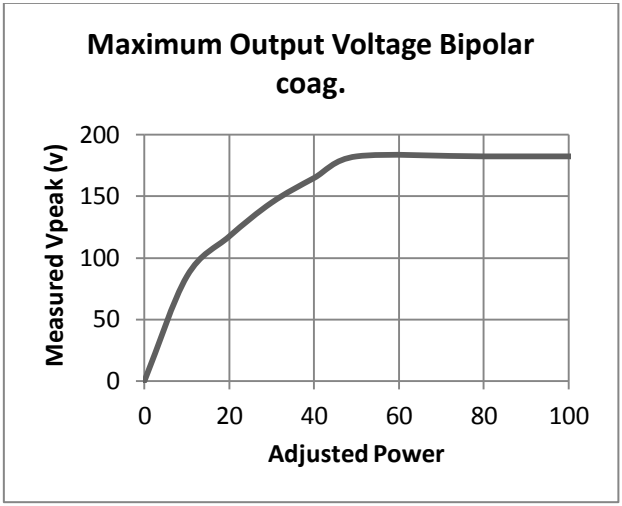
Technical Data	
Mains Voltage	***200V~240V (50 -60 HZ)***
Protection class	***I***
Type of output	***CF***
Leakage LF and HF Currents	***In accordance with IEC 60601-2-2***
Nominal frequency	***410 KHZ***
Current Consumption Without R.F. Power	***130 mA***
Current Consumption With Max. R.F. Power	***3.2 A (rms)***
Dimensions & Weight	
Weight	***6.80 Kg***
Height	***159 mm***
Width	***371 mm***
Depth	***465 mm***

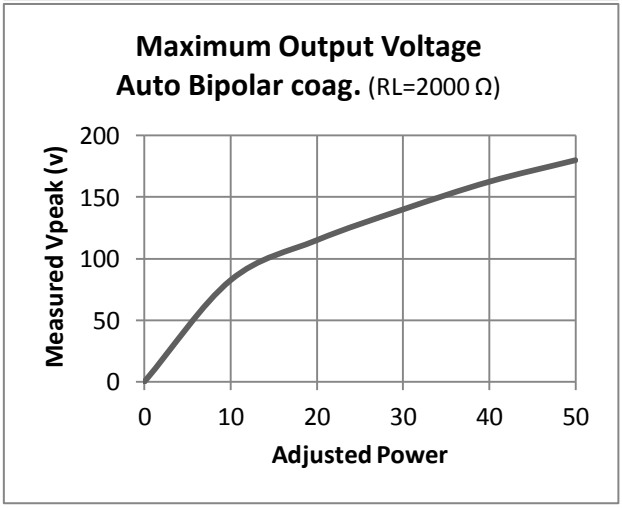
Mode	**Maximum output voltage** (V_{P-P})	**Maximum output current (A)**	**Crest Factor***	**Maximum output power (Watts)**	**Rated load (Ohms)**
Bipolar Coag.	370	2.4	1.5	100	100
Auto Start Bipolar Coag.	360	1.8	1.5	50	100
Seal1	375	4.2	1.5	250	25
Seal2	375	4.0	1.5	250	25

* 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.

9.2 Maximum output voltage graphs of MEG2:

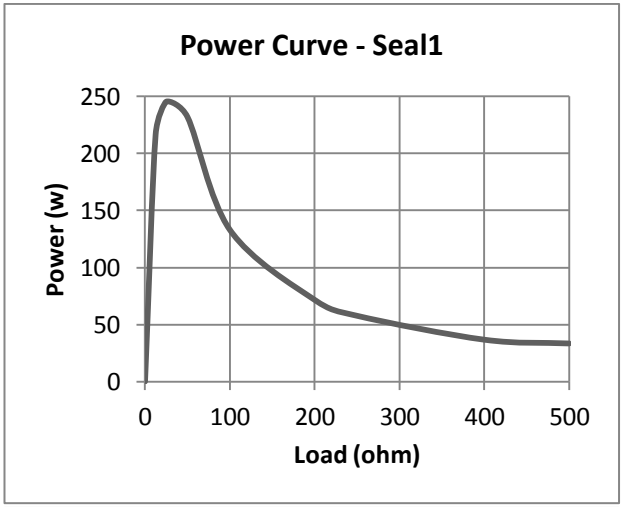
The following curved graphs indicate the maximum peak voltage of each mode.

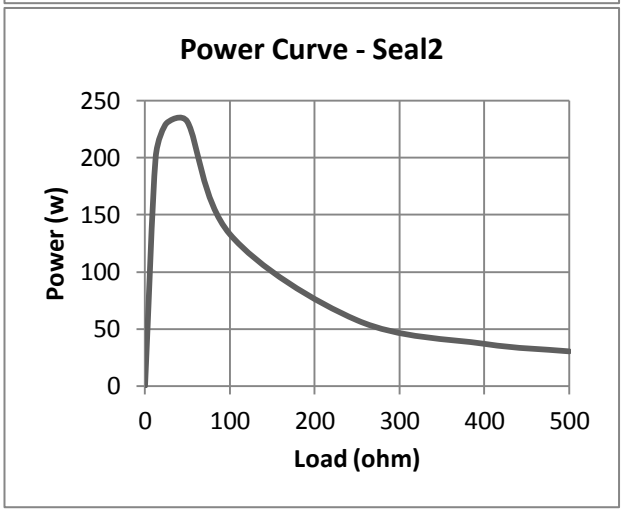


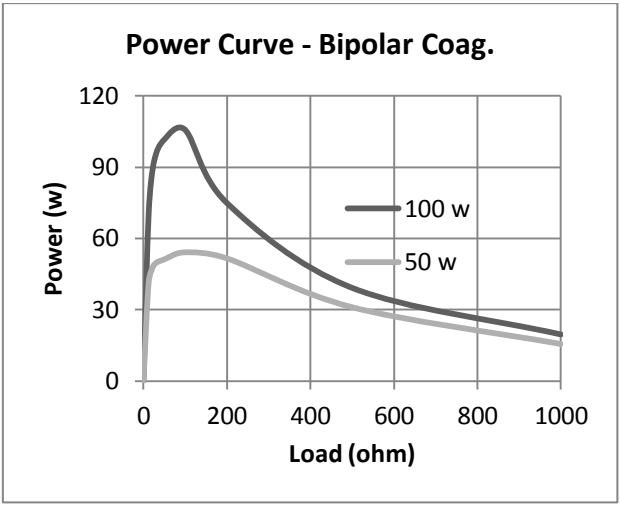


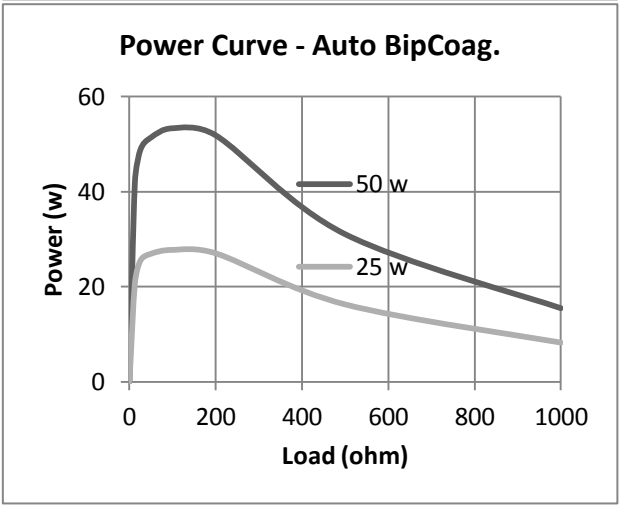
9.3 Typical output Power graphs of MEG2:

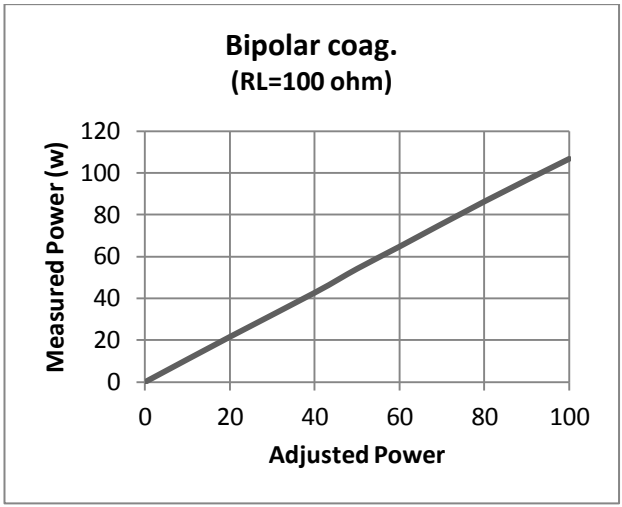
The following curved graphs indicate typical output Power graphs of MEG2.

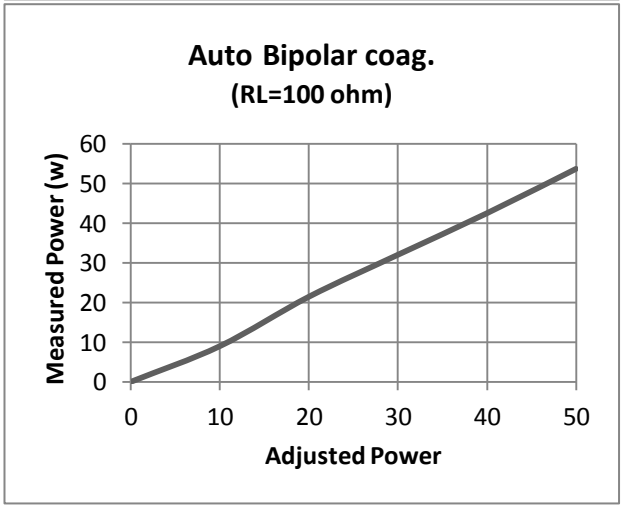





Power Curve - Bipolar Coag.
120
90
60
30
0
Power (w)
100 w
50 w
0
200
400
600
800
1000
Load (ohm)


Power Curve - Auto BipCoag.
60
40
20
0
Power (w)
50 w
25 w
0
200
400
600
800
1000
Load (ohm)


Bipolar coag.
(RL=100 ohm)
Measured Power (w)
120
100
80
60
40
20
0
0
20
40
60
80
100
Adjusted Power


Auto Bipolar coag.
(RL=100 ohm)
Measured Power (w)
60
50
40
30
20
10
0
0
10
20
30
40
50
Adjusted Power

CHAPTER 10

10 EMC Compliance

Electrical Emission

The device fulfills:

CISPR 11 Class A (2009+ A1): Radiated and conducted emission
IEC 61000-3-2 (2005+ A1+A2): Harmonic current emission
IEC 61000-3-3 (2013): Voltage fluctuations and flicker

Electrical Immunity

The device fulfills:

IEC 61000-4-2 (2008): Immunity to electrostatic discharge

Test level ±8 kV contact discharge ±2, ±4, ±8 and ±15 kV air discharge.

IEC 61000-4-3 (2006 + A1 + A2): Immunity to radiated electromagnetic fields in the frequency range 80 MHz – 2.7 GHz

Test levels: 3V/m with 80 % AM @ 1kHz

IEC 60601-1-2:2014: Table 9 (up to 28 V/m pulse modulation at frequencies in ISM bands)

IEC 61000-4-4 (2012): Immunity to fast transients/burst

Test levels on AC Power input port: AC input/output power input port ± 2,0 kV, Signal lines: 1Kv

IEC 61000-4-5 (2006): Surge immunity test

Test levels on AC Power input port: AC Power input port, ±0,5 kV and ±1,0 kV differential mode, 2,0 kV line to ground.

IEC 61000-4-6 (2014): Immunity to conducted disturbances in the frequency range 0,15 – 80 MHz

Test levels on AC Power input port: 6 Vrms with 80 % AM @ 1KHz.

IEC 61000-4-8 (2009): Immunity to power frequency magnetic fields

Test level: 30 A/m, 50 Hz and 60 Hz

IEC 61000-4-11 (2004): Voltage Dips and Interruptions

Test levels on AC Power input port:

According to 60601-1-2, table 4-13:

95 % for ½ cycle positive and negative half period.

95% for one period.

30 % for 25 cycles.

95 % for 5 sec.

Annex: contents of packaging

The following accessories are included in the MATIN Meg2 packaging according to the customer's order:

Item	Quantity
Reusable Bipolar cable	1
Bipolar forceps	1
Main power cable	1
Single pedal footswitch	1
Product instruction CD	1
User manual	1
General tips label (for top of device)	1

MEG2

Conventional Electrosurgery & Vessel Sealing System

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