



maxium[®] electrosurgery unit with maxium[®] Beamer

Instructions for Use



Tested according to: UL 60601-1:2003 CAN/CSA C22.2 No. 601.1-M90



V. 8.0-EN (10.13)

Valid for software version V3.407 and hardware revision HW 06





Symbol explanation

<u> </u>	Observe safety-related information concerning this product
(3)	Observe Instructions for Use
7	Store in a dry places
Ţ	Fragile, avoid pressure and shaking
<u> </u>	Arrows pointing up, transport and store upright
夏	This product may not be disposed of as normal household garbage
C €0297	CE Mark
F qp	Connection for the neutral electrode. Neutral electrode insulated against ground (floating)
1	Symbol for classification of the unit as type CF: The unit is defibrillation-proof
4	CAUTION! High-voltage high-frequency currents
***	Manufacturer



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1 List of Abbreviations

Abbreviation	Name
EMC	Electromagnetic compatibility
G-grades	Gradation Levels
HF	High Frequency
LUP	Last Used Program
MABS	Martin Argon Beamer System
NE	Neutral electrode
PCS	Patient Control System
TUR	Transurethral Resection
W	Watt



2 Product Liability and Warranty

2.1 General Information

We thank you for having decided to buy a KLS Martin product. This product carries the CE mark, which means that it satisfies the essential requirements laid down in the EC Directive concerning medical devices.

We are the manufacturer of this product:

Gebrüder Martin GmbH & Co. KG

A company of the KLS Martin Group
KLS Martin Platz 1 · D-78532 Tuttlingen · Germany
Postfach 60 · D-78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
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2.2 Scope of Delivery

Electrosurgery unit:

- Maxium[®]
 - m-Version, item no. 80-042-00-04 or
 - i-Version, item no. 80-042-02-04 or
 - e-Version, item no. 80-042-04-04
- Mains cable, country-specific variant
- Instructions for Use, item no. 90-169-52-80
- Option: bipolar TUR, item no. 80-093-00-04
- Option: OR1 integration, item no. 80-093-01-04

Argon Beamer:

- Maxium[®] Beamer, item no. 80-044-00-04
- Connection cable, item no. 08-041-00-60
- Mounting kit

Equipment Cart:

- Maxium[®] Cart II, item no. 80-047-00-04
- Mains cable (installed)
- Basket (installed)
- Instructions for Use, item no. 90-329-58-10



2.3 Intended Use

2.3.1 Intended Use of the maxium®

The maxium® electrosurgery unit, hereinafter referred to as "the maxium®", comprises an HF generator and is used for electrosurgical cutting and coagulation of live human or animal tissue. To this purpose, electrical energy from the grid is converted into a high-frequency current which provides this surgical property. The maxium® provides the user with a large number of various currents individually optimized to meet differing surgical requirements.



Risk of injury by improper application!

Safe use of electrosurgery requires the user to be familiar with the technology and the applications.

With the maxium[®], Gebrüder Martin provides you with an electrosurgery unit that comprises state-of-the-art technology, also for the safety of the patient and the user.

The $maxium^{@}$ is equipped for monopolar and bipolar cutting and coagulation in micro- and macrosurgical operations.

The operational safety of the unit must be verified at regular intervals, see section 16 "Periodic Safety Checks (SC)", Seite 201.

If the device is not functionally reliable and/or safe to operate, it must be marked as such and withdrawn from service. A technical check is mandatory in any such case.

2.3.2 Intended Use of the maxium[®] Beamer

The maxium Beamer by KLS Martin is a gas flow control unit for generation of a defined gas flow in the range of 0-12 l/min which can be operated only in connection with the maxium and coagulation, individual gas flow rates can be selected. Gas and HF energy are combined in the patient-side part of the applicator. Only argon is used as a working gas. During electro-cutting, argon acts only as a shielding gas; during electro-coagulation, however, its use results in improved surface coagulation compared to conventional spray coagulation.



2.3.3 Instructions

The operator may use the device only if a function check has been performed before at the operating site by Gebrüder Martin or a person authorized by Gebrüder Martin. In addition, a responsible person designated by the operator must have been instructed in the proper handling, application, and operation as well as in permissible combinations with other medical units, objects and accessories. This responsible instructed person shall subsequently perform periodical training of the staff on behalf of the operator.

We recommend documenting the instruction sessions in a medical product log. A medicine product log is available from Gebrüder Martin.

2.4 Warranty

Our Standard Terms and Conditions of Sale effective at the time shall apply. Agreements diverging from these Standard Terms and Conditions do not restrict the legal rights of the buyer.

Any warranty exceeding the above provisions shall require a contractual form and shall exclude component-related vandalism, software updates and consumables.

Important Notices

The product may only be repaired by Gebrüder Martin or a qualified person or firm expressly authorized by Gebrüder Martin to perform such work.

If the repair is carried out by a person or firm specially authorized by Gebrüder Martin, the operator of the product is required to obtain from the repairer a certificate with details about the nature and scope of the repair work done. This certificate must show the date of the repair and the details of the person or firm carrying out the work and must be signed.

In all cases where a party other than the product manufacturer performed the work, repaired products must be additionally marked with the repairer's ID label.

Improper interventions or alterations performed by third parties during the period of limitation shall void any and all warranty claims. Unauthorized actions performed on the product shall invalidate any liability claims vis-à-vis Gebrüder Martin.

2.5 Inspection by User

Immediately upon receipt, the goods must be checked for completeness and potential damage in transit. Notice of any such damage must be given immediately.



2.6 Hotline

• Should you have any questions on how to handle the unit/product or question on its clinical application, please do not hesitate to contact the

Product Management

Tel: +49 7461 706-243 Fax: +49 7461 706-190

 Should you have any technical questions, please do not hesitate to turn to our Martin Service Center

Tel: +49 7461 706-343 Fax: +49 7461 706-408 E-Mail: service@klsmartin.com

• Should you have any questions concerning maintenance contracts or training courses, please contact our Technical Service Manager:

Tel: +49 74 61 706-332 E-Mail: service@klsmartin.com

NOTICE

To answer your technical questions as efficiently as possible, our service technicians will require the serial number of the product. Therefore, please have this number at hand when contacting our hotline. The serial number is to be found on the type plate, see section 6.1 "Overview", page 37.

2.7 Validity of these Instructions for Use

These instructions for use are valid from software version V3.400 and hardware status HW 06. If older hardware or software versions are used, it may be that functions described in this user manual are not available. Via the information provided on the starting screen, the maxium[®] indicates which version of the user manual matches the software version currently implemented. This ensures that it is always clear which software statuses are covered by these Instructions for Use.



3 Notices concerning this Document



Non-observance of this document can lead to serious or even lethal patient injury!

Improper handling and care as well as non-intended use can lead to premature wear and / or pose a risk to patients and users!

Be sure to read, understand and follow the instructions given below!

- Every user is required to read this document completely and follow them carefully.
- In particular, be sure to heed all cautions, warnings and danger notices.
- Keep this document accessible to users at all times.

3.1 Symbols Used in this Document

Throughout this document, important information (such as general or safety-related notices) is marked with the following symbols and signal words:



Danger of death or serious injury!

Indicates a situation which, if not avoided, **could** result in death or serious injury!



Danger of minor injury!

Non-compliance involves risk of bodily injury!

NOTICE

Risk of property damage!

Non-compliance may lead to property damage (loss of time, loss of data, machinery defects, etc.)!



4 Working Principles

4.1 Preface

High-frequency (HF) electricity has been known for more than a century. As early as the 1890s, Tesla, Nernst and d'Arsonval conducted first experiments into the physiological effects of currents with high frequencies and high voltages.

In 1904, Cook was the first to gather surgical experience with high-frequency electricity in the treatment of hypertrophic tonsils, removal of scars, and therapy of hemorrhoids and papillomata using sparks.

Since then, electrosurgery has definitely established itself in medicine, and modern therapy cannot be imagined without it.

With technology and medicine advancing, electrosurgery devices were likewise improved continuously. Apart from surgical qualities with HF energy, achieving maximum safety for patients, users and third parties has always been an essential criterion. Here enormous efforts were made to keep risks for these persons as low as possible.

KLS Martin has been one of these pioneers, producing ground-breaking technological innovations which are still in use today. More than 40 years of experience in medical HF technology speak for themselves.

Thus the maxium[®] electrosurgery unit by KLS Martin, too, has been developed and manufactured in accordance with the latest technological and medical findings. Special attention was paid to clarity, simplicity and lucidity for the safe handling of the maxium[®].

However, the user will be able to fully exploit the features of the maxium[®] by KLS Martin only if he or she is completely familiar with them. Below, the special handling features of this modern electrosurgery unit are described.

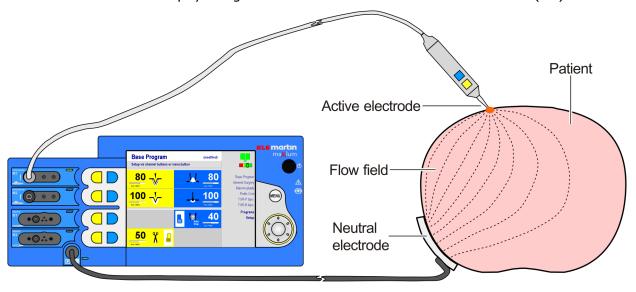
For any technical questions, please contact the Martin Service Center.



4.2 Monopolar application of HF energy

In monopolar application, the HF current is introduced into the operation field via an electrode on an electrode handle or other instrument. This so-called *active electrode* has a small surface. Thus at the transition point from the electrode to the patient, current density is high, resulting in the electrosurgical effect desired by the user. From this contact point, the current spreads radially. Its current density decreases rapidly with increasing distance from the contact point. This requires the anatomy of the contact point to allow formation of a radial current density distribution, also known as flow field.

For closing the circuit, the current delivered to the patient is collected again via an electrode applied to the patient's skin. This electrode has a large surface, so that the current density remains low and without physiological effect. It is called the *neutral electrode* (NE).



Between the active electrode and the neutral electrode, the current flowing through the patient forms a flow field, whose current density will at some distance from the contact point usually be so low that it exerts no adverse effect. However, a living organism does not constitute a homogeneous mass: Bones and cavities form insulating barriers, and the various tissue types exhibit differing electrical conductivities. Unintended concentrations of the current density may result. This is why the anatomical features of the operation field and its surroundings must be taken into account. Moreover, the current flowing through the patient produces a voltage drop which may cause of a whole host of unwanted side-effects. For further information, please refer to section 5 "Risk Minimization and Safety Measures", page 20.

The HF generator for monopolar applications is activated optionally via foot switch or finger switch on the surgical electrode handle.



4.2.1 Monopolar cutting

The high energy density on the surface of the active electrode leads to formation of a vapor layer between electrode and tissue, in which the physical processes take place which lead to dissection of the tissue. With specially designed electrodes, monopolar cutting, also known as electrotomy, allows shaping cuts which cannot be achieved with knives. In addition to the cutting currents, there are also such as effect coagulation simultaneously with the cutting and thus immediate hemostasis. The color yellow is used by convention for the identification of the currents for cutting.

4.2.2 Monopolar coagulation

Basically, two types of coagulation are to be distinguished. If the HF energy enters the tissue from the active electrode, heating it, this is called **contact coagulation**. The intended use is to stop major hemorrhages and denature tissue volumes.

Typical examples include hemostasis of bleeding from transected vessels by application of electricity directly to a hemostat. Denaturation of larger tissue surfaces is also known as *ablation*, of major tissue volumes as *desiccation*.

In the second type of coagulation, the energy enters the tissue not directly from the electrode, but by arcing through a vapor or air layer, due to high electrical voltage. Here the energy is converted essentially not in the tissue itself, but on its surface. Thus the purpose is hemostasis of superficial seeping hemorrhages. Coagulation currents of this type are called *spray coagulation* or *fulguration* and are particularly suited for superficial seeping hemorrhages. A special form of this type of coagulation is **surface coagulation** with ionized argon gas (argon beamer). With the maxium[®] Beamer, an accessory for providing and controlling the necessary argon gas flow is available.

The maxium[®] provides both types of currents for monopolar coagulation, as well as hybrid forms which combine the properties of both coagulation types. The color blue is used by convention for the identification of the currents for coagulations.



4.2.3 Neutral electrode

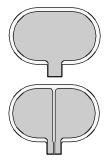
The current fed into the patient in monopolar application is returned to the unit by a largesurface electrode applied to the surface of the patient's skin. Such electrodes are available as reusable and as disposable electrodes.

The neutral electrodes consist of soft, electrically conductive plastic material which can easily adapt to the body contour.



The reusable neutral electrodes are equipped with a permanently attached cable. Contact with the body is established using elastic straps or bandages, or by the weight of the patient. The quality of the skin contact, however, is difficult to assess. In the case of split neutral electrodes, it can be monitored by the maxium[®].

Single-use neutral electrodes consist of a carrier made of soft plastic, onto which the actual electrode surfaces is applied as a metal foil. Upon this, an electrically conductive gel layer is applied, which establishes skin contact and attaches the electrode to the patient's skin. Connection to the maxium® is established via a reusable cable with connector clip. There are also disposable electrodes with permanently attached cable.



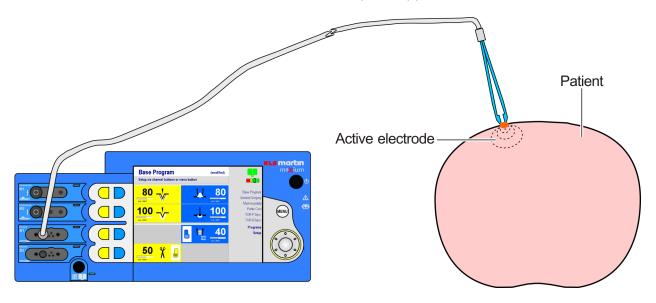
For two-piece disposable electrodes, the quality of the skin contact can be monitored by the maxium[®]. To this end, a low monitoring current is led from one side of the electrode via the patient to the other side.

The maxium[®] is capable of monitoring both non-split and split electrodes. The status of the neutral electrode (NE status) is shown in the upper right corner of the screen. In split electrodes, additionally the relative quality of the skin contact can be displayed.



4.3 Bipolar Application of HF Energy

In bipolar application, the current flows only between two electrodes in close spatial vicinity, which are connected to the HF generator with both poles. A flow field is formed which is essentially restricted to the contact zone of the two electrodes with the tissue. The depth of the effect is thus very limited. A neutral electrode is not required. The problems resulting from formation of an extensive flow field are avoided in bipolar application.



The maxium $^{(8)}$ allows activation of bipolar power via a foot switch or finger switch. In addition, the maxium $^{(8)}$ can be set up so that bipolar coagulation currents will be activated automatically also upon contact with the tissue.

4.3.1 Bipolar cutting

In contrast to monopolar cutting, in bipolar cutting the HF energy flows – as in bipolar coagulation – directly from one electrode to the nearby second electrode. A neutral electrode is not required. For bipolar cutting, an asymmetric electrode arrangement with a small electrode that performs the cutting and a larger electrode that acts as "local neutral electrode" is required.

4.3.2 Bipolar coagulation

In contrast to monopolar application, bipolar coagulation is exclusively pure contact coagulation. The electrode pair on the instrument is usually designed symmetrically.



4.3.3 Sealing using SealSafe® / SealSafe® IQ

The SealSafe® and SealSafe® IQ currents are special currents for the sealing of blood vessels and tissue layers. These currents were designed specifically for use with marClamp® and marSeal instruments. Here in comparison to traditional bipolar technology high power is used in conjunction with low voltage. The current has been optimized to exclude adhesion and carbonization of the tissue when used properly.

The special interplay of this particular HF current and the high pressure applied by the instrument will transform natural structure proteins such as collagen and elastin to create a permanently sealed zone. Here the special thing is that only the tissue between the electrodes is sealed. Lateral thermal tissue damage is limited to an absolute minimum. Effective sealing is possible without prior individual isolation / preparation.

The maxium[®] is able to continuously monitor the degree of sealing of the tissue using tissue impedance monitoring. Individual energy packets are sequentially emitted into the tissue in the form of high-frequency pulses, until the desired degree of sealing has been reached and the process is completed. With the SealSafe[®] IQ current, energy is continuously emitted during the process. The end of the sealing process is acoustically acknowledged by the maxium[®]. This shuts down the current automatically before carbonization of the tissue can occur.

The primary benefit of this method for the users consists in a significant reduction of clips and suture materials and significant time savings.

The maxium[®] offers two SealSafe[®] currents which can be used for a number of different surgical disciplines in combination with the instruments by KLS Martin:

- Current SealSafe® with marClamp® or marSeal instruments
- Current SealSafe® IQ with marClamp® IQ or marSeal IQ instruments

When using the IQ instruments, please note the following:

All IQ instruments have an instrument detection system. The maxium[®] will automatically provide the instrument inserted with the required current, with a factory-preset default power value. If a foot switch is required for activation, this will also be offered automatically.

If users prefer to work with a power setting other than the default value, this change of the power or the foot switch mapping can be regularly saved in the program used, i.e. the usual behavior of the program remains. Another difference is in the power display. For the SealSafe[®] IQ current, the power is selected in gradation stages (G-grades), for the SealSafe[®] current it is displayed in watts. These G-grades can be selected from G1 to G5, the switch-off impedance and sealing time increasing with increased G-grade.



4.3.4 Bipolar TUR

In contrast to classic monopolar TUR, where an electrically non-conductive irrigation fluid (sorbitol-mannitol-sugar solution) is used, for bipolar TUR an electrically conductive NaCl solution is used as irrigation fluid. The following instructions must be followed:

Use correct fluid (pre-warmed NaCl solution).
 Under no circumstances may unipolar TUR be performed with NaCl or bipolar TUR with sugar solution!

Bipolar → conductive NaCl solution

Monopolar \rightarrow non-conductive sorbitol-mannitol-sugar solution



Danger of burns!

Use of NaCl solution as irrigation fluid in monopolar application of HF power may cause burns of the rinsed area!

Avoid long activation times!
 In contrast to monopolar TUR which is performed with an electrically insulating irrigation fluid, in bipolar TUR energy flows continuously through the electrically conductive NaCl solution, as long as HF power is applied. The irrigation fluid is heated and may reach critical temperatures, especially in case of discontinuous irrigation.

The use of bipolar TUR currents is an option. In older units it can be retroactively activated via an unlock code. This must be entered into the input window of the **Service** menu. If this option is included in a new order, it is already enabled.



5 Risk Minimization and Safety Measures

AWARNING

Risk of serious injury in case of improper use!

Electrosurgery units comprise generators for high-frequency electrical energy, which can have high amperage and voltage by design. In order to avoid hazards to the patient, the operators and third parties, the procedure must be applied carefully. It is imperative to strictly observe and comply with all operating and safety instructions.

As the maxium[®] Beamer and other accessories will always be operated in combination with the maxium[®], all safety instructions for the maxium[®] also apply fully to the combination with the maxium[®] Beamer and any other accessories.

AWARNING

Possible malfunction of pacemakers and other active implants!

Electromagnetic interference from electrosurgical devices may disturb or completely block pacemakers or other active implants!

For further information, refer to section 5.5, page 31.

5.1 Risks from Stray Currents

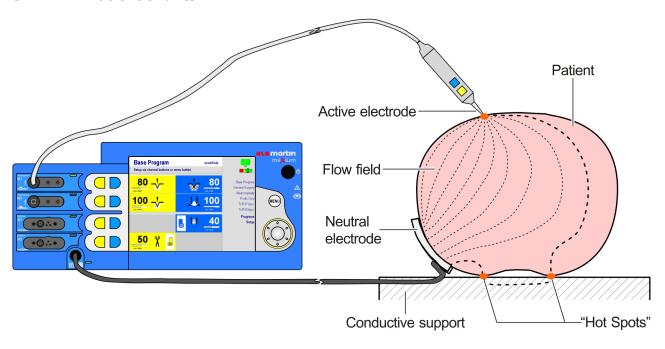
In the schematic representation of the flow of the current through the patient in section 4.2 "Monopolar application of HF energy", page 14, the HF energy entering the patient from the active electrode seems to always return directly to the neutral electrode. In practice, a part of the electricity takes detours where possible, and then HF currents will occur in positions where they are not expected to. Basically, here according to the nature of the danger three types of stray currents are to be distinguished:

- Currents via patient shunts
- High-frequency and low-frequency leakage currents
- Leakage currents through other medical devices

These currents are generally insignificant, as they amount only to a small fraction of the total electricity produced by the generator. If, however, they concentrate in small places on the body, burns may result.



5.1.1 Patient shunts



The spatial separation of operation field and neutral electrode causes a very extensive flow field to be formed. Here the currents do not necessarily all have to flow within the body. They may exit the body and re-enter it in another place before reaching the neutral electrode. Depending on where the neutral electrode is applied, such transitions may occur from the body to a conductive surface (operating table), from limbs to trunk or from one limb to another. If any contact point where the current leaves or enters the body is very small or poorly conductive (e.g., small finger on the thigh or on the operating table), then the current passing over may cause burns there. The decisive factor for burns by HF energy is the current density (current per area).

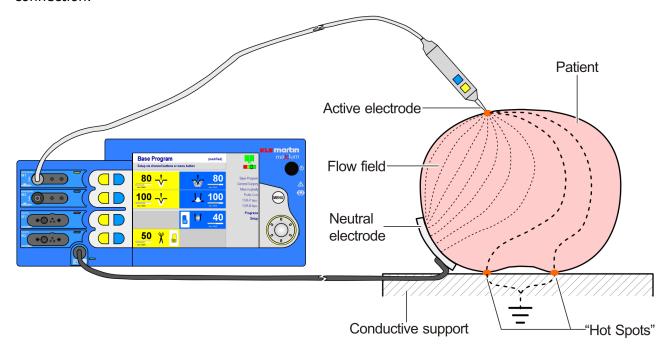
The risk of burns is particularly high where high-power monopolar cutting and contact coagulation currents are used, while it is very low in purely bipolar application.



5.1.2 High-frequency leakage currents

Wherever a circuit conducts high AC voltage against the ground, power may "leak", which is why this type of currents is also commonly known as leakage currents.

For an electrosurgery unit, that means that a small portion of the power fed into the patient by the active electrode will not flow back to the neutral electrode but rather be dissipated to the ground, whence it finds its way back to the generator via the mains cable or the bonding connection.



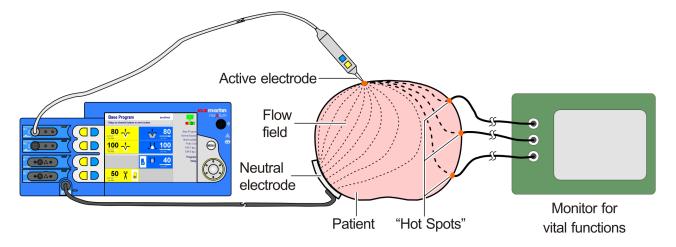
These currents are usually distributed over a large area; their current density is low and their physiological effect insignificant (unlike the interference effect on other electromedical units). This changes when such leakage currents are absorbed by the patient in concentrated form via a conductive connection to the ground. If the area for transition from the patient to this ground connection is small enough, then burns may result. Such a transition may also be formed between the patient and the user or a member of his team which is also grounded.

The risk of burns is particularly high where high voltage monopolar currents are used, and in particular with cutting currents and sparking coagulation currents. With the bipolar currents of the maxium[®], however, it is low.



5.1.3 Leakage currents to other medical devices

A special form of leakage currents are the leakage currents to other medical devices also connected to the patient. Although these units are not integrated into the circuit of the electrosurgery unit, a small portion of the HF energy flows as leakage current through the patient ports of these devices. If the connections (leads) have particularly small surfaces and permit larger currents, burns at the contact sites may result. Basically, not even a direct electrical connection to the patient is necessary. Even local proximity to the ground is sufficient (ground capacitance).



The risk of burns is particularly high where high voltage monopolar currents are used, and in particular with cutting currents and sparking coagulation currents. With the bipolar currents of the maxium[®], however, it is low.

5.1.4 Measures against risks from stray currents

In order to prevent formation of shunts for HF energy or concentrated leakage current paths, it is mandatory to comply with the following instructions when placing the patient on the operating table:

- Place the patient to be isolated from grounded metal parts. Particular care is required to ensure that the patient's limbs do not touch any metal structures either.
- Ensure the required high-frequency insulation against the operating table by a sufficient number of layers (insulating blankets). Since during the operation moisture, perspiration, etc. are to be expected, a waterproof foil must be used to prevent wetting of these layers which serve as high-frequency insulation.
- Fluid accumulation under the patient must be avoided under all circumstances. Use further dry cloth layers where appropriate.
- Keep areas with stronger perspiration, extremities touching the trunk or skin-on-skin contact apart from each other and dry (arm-trunk, leg-leg, breasts).



- Place the neutral electrode as close as possible to the operation field. For surgery on the trunk, the upper arms and upper legs are good application positions.
- The above requirements for insulation must also be fulfilled if the patient is repositioned during the operation.

To prevent high current densities by leakage currents to other medical devices, note the following:

- When simultaneously using electrosurgery and monitors on the same patient, use only such systems where possible leakage currents are reduced to non-hazardous strength by constructive measures, e.g. ECG monitors whose leads comprise protective resistors or HF reactors.
 - Do not use needle electrodes for monitoring their low surface and resulting high current density are a source of trouble.
 - Use the active electrode only at a distance of at least 15 cm from any ECG electrodes.
- Non-electrical medical units such as infusion cannulae or trocars may also cause a high
 density of leakage currents if they have an electrically conductive connection to the
 ground. Such a connection can also be formed by electrolytes such as sodium chloride
 solution.

5.2 Risks from Current Concentration

In the schematic representation of the flow of the current through the patient given in section 4.2 "Monopolar application of HF energy", page 14, the current density (field line density) of the HF energy entering the patient from the active electrode seems to decrease very quickly from the contact point of the active electrode, the HF current then flowing to the neutral electrode at low current density. In fact, the human body is an anatomically complex structure whose electrical conductivity is not homogeneous but heavily structured by anatomical features. As a result, locally the flow field may deviate strongly from the schematic diagram in section 4.2 "Monopolar application of HF energy", page 14. There is a risk of burns whenever due to the anatomical features of the operating field the currents either cannot dissipate or condense again. Basically, according to the nature of the danger two types of current condensations are to be distinguished here:

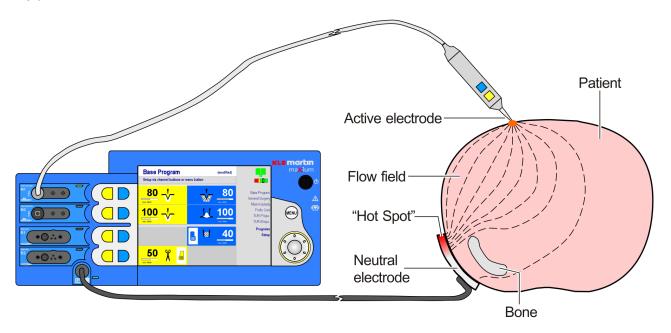
- Current condensation in the area of the neutral electrode
- Current condensation inside the body

Experience has shown that most incidents in connection with the use of electrosurgery result from this issue.

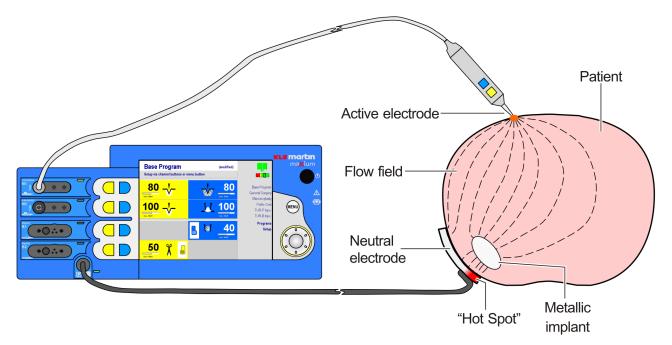


5.2.1 Current condensation in the area of the neutral electrode

Areas with low electrical conductivity in relation to the rest of the body and immediately under the neutral electrode can extremely distort the flow field by casting a "shadow" within the flow field.



The neutral electrode is then no longer able to absorb the power evenly over its entire surface. Areas of higher current density result, with a risk of burns.



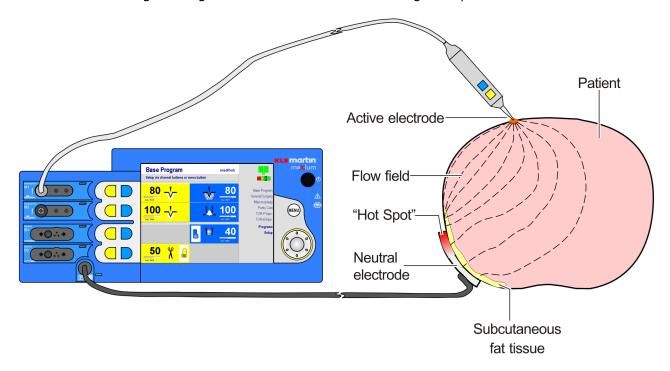
Conversely, metallic implants directly under the neutral electrode may act as a collecting lens for the current flowing to the neutral electrode. They cause current concentrations entailing a risk of burns.



The current concentration caused by the implant may lead to local overheating which presents an additional risk for the integrity of the implant itself.

Similarly, metal parts on or in the skin surface, such as rings, bracelets, chains, earrings, studs and body piercings may cause a focusing of the flow field on and under the surface of the skin.

The skin under the neutral electrode may itself be very heterogeneous, e.g. due to scars. The assumption of a smooth transition of the monopolar electricity from the patient to the neutral electrode is based on the notion that the skin to which the neutral electrode is applied covers a muscle layer with good conductivity in the electrosurgical sense. However, in the area of the upper limbs, which are a preferred application site for the neutral electrode, particular in obese patients there is actually a layer of fatty tissue with poor conductivity. As a result, under these conditions the current will return to a neutral electrode not from the depths of the tissue, but rather superficially from the direction of the operation field, with consequential current concentration along the edge of the neutral electrode facing the operation field.



The risk of burns under of the neutral electrode is particularly high if monopolar cutting or contact coagulation currents with particularly high power and longer duration are used (e.g. TUR-P, endometrium ablation).

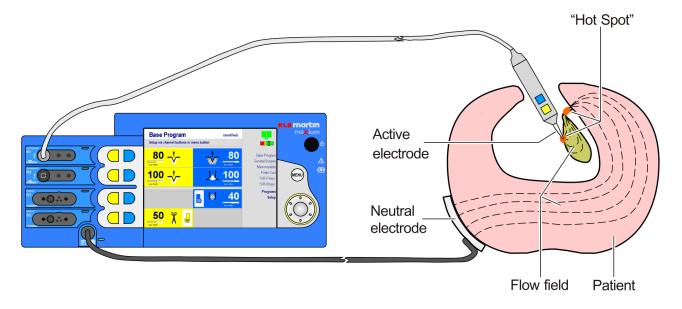
Do not use adhesive electrodes whose gel layer is injured, nor adhesive electrodes that have been detached. 2^{nd} or 3^{rd} degree burns might result.

The cable clip for the connection of the adhesive electrode must cover the gel-free connector straps so that they cannot come into contact with the patient. Make sure that the cable clip and the connector straps match.



5.2.2 Current condensation inside the body

Some anatomical structures are of filamentous nature (e.g. fallopian tubes) or connected to the body via filamentous structures (blood vessels, ducts). When monopolar HF energy is used, the effect of the current may have adverse effects along the entire length of a filamentous structure or affect the connection to the body off the actual operation field, causing coagulation in places where it is not desired.





5.2.3 Measures against the risks posed by current accumulation

In order to minimize the risk of burns or other problems in the area of the neutral electrode, during application of the neutral electrode please mind the following:

- The neutral electrode must butt against the patient's body as close to the operation field as possible, reliably, and with its whole surface. For an operation field on the torso, the upper arms and thighs are good application sites.
- Secure contact of the neutral electrode must be ensured for the total duration of the high frequency application.
- When applying the neutral electrode to a limb, perfusion must not be affected. Particularly
 for longer operation times it must be made sure that the patient does not lie on the cable
 connection clip of the neutral electrode (risk of pressure necrosis).
- The current paths in the body should be as short as possible and run in the longitudinal or diagonal direction of the body, not across it, the latter particularly not on the chest. Any metal parts in or on the body should be removed if possible, insulated, or paid special attention to.
- After any repositioning of the patient, the neutral electrode and its connection must be controlled.
- Do not apply the neutral electrode above implants or other metal parts, nor above bone protrusions or scarred tissue. Clean, degrease and epilate the application area. For removal do not use substances (e.g. alcohol) that desiccate the skin.
- Do not use adhesive electrodes whose gel layer is injured, nor adhesive electrodes that have been detached. 2nd or 3rd degree burns might result. The cable clip for the connection of the adhesive electrode must cover the gel-free connector straps so that they cannot come into contact with the patient. Make sure that the cable clip and the connector straps match.
- For removal, detach the neutral electrode at the edge; do not pull at the cable or the connector strap. Quick removal of adhesive electrodes may hurt the skin.
- For work on filamentous structures use bipolar currents, if possible.



5.3 Risks from Arcing and Sparking

Under the intended conditions of usage, at the active electrode electric arcs or sparks (arcs of very short duration) are formed which are capable of igniting combustible material. The plasma beam of the argon beamer is also capable of this. This risk is considerably increased by the presence of medical oxygen, since in an oxygen-rich atmosphere combustive reactions are easier to ignite and more violent. Nitrous oxide, itself non-combustible, may work as a fire accelerant like oxygen.

Flammable substances in the operation area are:

Anesthetics

Flammable anesthetics such as ether form explosive mixtures with breathing air even at concentrations as low as those regularly used.

• Solvents in cleaning and disinfecting products

They are used before the actual surgery, so that the solvent will have evaporated from the skin. However, these substances may accumulate in depressions such as the navel or moisten the cover of the operating table and thus remain present for extended periods of time.

Wipes, cotton wool, gauze

Under normal atmosphere, these substances are not easily ignitable by arcs or sparks. However, cotton and products made of it are prone to adsorb oxygen, significantly increasing their flammability and the violence of the combustion.

Plastic hoses and films

Under a normal atmosphere, these substances are usually self-extinguishing and cannot be ignited by the arc at the active electrode. Under an oxygen-rich atmosphere, however, they are combustible, unless made of silicone or Teflon.

Endogenous gases

In the gastrointestinal tract, digestion produces gases comprising combustible components (hydrogen, methane). In case of opening of the gastro-intestinal tract by electrosurgery, inflammation and deflagration of these gases may result.

Pyrolysis and electrolysis gases

During electrosurgical cutting, thermal decomposition of the tissue lead to the formation of small amounts of pyrolysis gas. In surgery under liquid, there also occurs electrolysis of water due to the high voltage between active electrode and tissue. During interventions with long activation times such as TUR, these gases formed at low rates may accumulate to form bubbles. If the active electrode enters this gas bubble, deflagration may result.

In order to avoid fire and explosion hazards in the use of electrosurgery, the following rules must be observed:

- Use no ignitable anesthetics.
- Accumulations of combustible liquid under the patient, in depressions such as the navel or in body cavities such as the vagina must be removed before any electrosurgery unit may be used.



- In case of increased concentrations of oxygen and / or nitrous oxide in the area of the operation field, special care must be taken.
- Remove bubbles of pyrolysis and electrolysis gas in body cavities by appropriate irrigation to avoid formation of significant accumulations.

5.4 Risks from High Voltage



Danger of neuromuscular stimulation!

The application of a current with high voltage, and in particular of a monopolar high voltage coagulation current, may cause neuromuscular stimulation in the patient.

Electrosurgery units are designed to generate high electrical voltages. In particular, some monopolar coagulation currents, as well as the argon beamer coagulation, have especially high voltages of several thousand volts. Not every electrosurgical instrument is suitable for such high voltages. In particular endoscopic HF accessories, often of very delicate design, quickly reach their limits here. Therefore in section 11 "Currents, their Properties and Technical Data", page 102, the HF output voltages for all currents are specified as a function of the power setting. Make sure that the maximum voltage specified by the manufacturer of the accessory is not exceeded!

During hemostasis using HF energy via a compressor, in practice arcing of the surgical glove occurs frequently at the point where the compressor is held.

The high voltage coagulation currents may cause corona discharges between the supply cable of the active electrode and the skin of the patient or the surgeon, if the cable has direct contact with the skin. Slight burns may result.

In the maxium[®], the mains voltage is separated from the patient connections by two insulating barriers. These barriers may be bridged, however, if large quantities of liquid penetrate into the unit. Bedewing by transport of the unit from a very cold to a warm environment will also affect the insulation negatively.

For avoidance of risks associated with high electrical voltages, observe the following instructions:

- For endosurgical accessories, check that the current which the instrument is to be operated with has a voltage below the maximum approved for the instrument. For such instruments, the maxium[®] has special Endo currents with lower voltage.
- For HF coagulation, it is imperative to use insulated hemostatic compressors! Surgical gloves do not represent a defined insulation.



- The power supply cables to monopolar active electrodes must not be laid over the patient nor across the cables of other medical units attached to the patient.
- Set up the electrosurgery unit so that it cannot be sprayed or poured over with liquids. If any liquid has entered the unit, it must be taken out of operation. It may be put back into operation only after a safety inspection has been performed successfully.
- If the unit comes from a cold environment, first make sure that there is no condensation water contained in the unit. To this purpose, allow the unit to warm up in active state at least for half an hour.

5.5 Risks from Electromagnetic Interference

Radios, cell phones, or other emitters in the immediate vicinity of the unit may affect the safe operation of the same. For minimum distances from emitting devices, see Table 206 in section 15.4 "Guidelines and Manufacturer's Declaration on Electromagnetic Compatibility (EMC)", page 197.

Electrosurgery units with their high-frequency output voltages can be powerful sources of interference. Other electromedical units are primarily affected not by emission of electromagnetic waves, as is usually assumed, but, as described in section 5.1 "Risks from Stray Currents", page 20, by HF leakage currents which either spread via the power supply or are derived directly from the patient.

Monitors for vital signs may be affected in a particularly drastic manner. As these systems resume their normal work after the end of the HF current activation, these brief disturbances will usually be tolerated.

In case of active implants such as cardiac pacemakers there is always the danger of damage or alteration of the programming with unforeseeable consequences. Therefore, before electrosurgery on patients with pacemakers a cardiologist should be consulted, and the following rules must be observed:

- Such patients are to be monitored using suitable technology.
- A defibrillator as well as an external pacemaker should be kept ready for use.
- Select the lowest possible output power on the electrosurgery unit.
- Do not use the active electrode of the electrosurgery unit closer than 15 cm to the implant or its electrodes.
- Wherever possible, use bipolar technology.

If the maxium[®] causes interference with other units, contact the Martin Service Center, see section 2.6 "Hotline", page 11.



5.6 Risks from Pressure Vessels and Argon Gas Flow

5.6.1 Pressure vessels

Through their high internal pressure and weight, the cylinders in which argon is usually delivered form a potential source of danger. Toppling or falling cylinders may lead to serious accidents, in particular when the angle valve is struck off, resulting in uncontrolled pressure release. The safety and work guidelines for the transport, storage, and setting up of such pressure cylinders, which apply to the other medical gases as well, must be complied with.

Observe the following rules:

• Never transport cylinders without protective cap!

After removal, keep the protective cap at a designated place in the vicinity of the pressure cylinder. If the cylinder is set up on the maxium[®] Cart II, the cap can be placed in the intended location (recess) on the floor of the cart.

- Cylinders must be secured against toppling by suitable means!

 When the cylinder is set up in the maxium[®] Cart II, it can be secured with the belt provided for the purpose.
- Never open the angle valve if there is no pressure reducer connected!
- Use only argon as working gas!

The pressure reducer can be connected to other pressure cylinders for so-called special gases such as carbon dioxide as well! Make sure that the cylinder which the pressure reducer is to be connected to really does contain argon. Appropriate cylinders are labeled with a band reading "ARGON".

There are inert gas coagulation systems on the market which use helium as the working gas. This is not possible with the maxium[®] Beamer, since the gas flow regulation is calibrated for argon. When connecting to a helium cylinder, which is mechanically possible, the actual gas flow would be higher by several orders of magnitude than that displayed!

Use only a pressure reducer by KLS Martin!

The function and safety of the system are guaranteed only when a pressure reducer of KLS Martin is being used!

5.6.2 Embolisms and emphysema

Insufflation of gas into the operation field always entails the dangers of this gas being also blown into transected vessels. This leads to danger of gas embolism. Although argon, in contrast to air or oxygen, does not induce blood coagulation, argon gas bubbles in the arterial blood flow may, through the ramifications of the vessels which become finer and finer, reach a point where they obstruct the flow of blood and can stop it in the immediate environment. If the gas outlet at the tip of the applicator is placed directly upon the tissue, there is the danger of injecting argon into the underlying tissue (emphysema).



In tissue structures where a skin layer is located above a closed tissue layer or which several layers of skin overlay each other, argon may be insufflated between these layers, leading to separation of these layers and trapping of larger quantities of argon.

To prevent this, observe the following rules:

- Never place the gas outlet of the applicator directly onto the tissue! If the striking properties of the exiting beam are poor, then either select a higher output power setting at the maxium[®] electrosurgery unit or replace the applicator tip (burning down of the ignition electrode tip).
- Do not use the maxium® Beamer for hemostasis of larger transected vessels!

 Such bleeding cannot be controlled reliably with the purely superficially active maxium®

 Beamer and must be dressed with conventional monopolar or bipolar contact coagulation, using a hemostat if necessary.
- If possible, move the applicator so that it is not perpendicular to the tissue but rather forms an angle between 30° and 60°. This will allow for a clarification of the operation field and reduce the likelihood of argon penetration into the tissue.

5.6.3 Additional insufflation for endosurgical applications

Through the application of the maxium[®] Beamer, argon is blown into the operation field. If the operation field is located in a body cavity, then there is the danger that such gas insufflation leads to an unacceptably high increase of internal pressure if the gas cannot escape. In particular in laparoscopic surgery there is the risk of a collapse of the large venae cavae with the danger of circulatory failure if the insufflation pressure exceeds the diastolic pressure of the relevant blood vessel.

To prevent this, observe the following rules:

- **Select low gas flow rate!** Use endosurgical applicators working with low gas flow rates of no more than of 3 l/min.
- When using an insufflator, it must be equipped with a pressure monitoring unit that gives alarm in case of exceedance of a permitted limit value, alerting the user and enabling him to take measures for reduction of the pressure.
- When no insufflator is used, provide for discharge of the accumulating argon if there is the danger of a pressure increase by argon.

5.6.4 Contamination of the operation field

The cylinders for argon, the fittings attached to them and the valve block in the maxium $^{\$}$ Beamer with the connection for gas inlet and applicator comprise no parts that are suitable as a habitat for germs. But they are non-sterile and not intended to be sterilized either. If this is critical for an application, then there is the possibility of inserting a sterile filter for single use with a pore width of 0.2 μ m between the gas outlet of the unit and the sterilizable applicator. Such filters are available as accessories, see section 7.1.4 "Argon", page 53. These filters hold back germs that are larger than viruses.



5.6.5 Concentration of argon in the breathing air

Because of its inertness, argon – unlike carbon dioxide which is also used in medical technology – does not affect gas exchange in the lungs, but it can displace the respiratory air if the concentration becomes very high. In a normally ventilated room, under normal conditions of use of the maxium[®] Beamer no argon concentrations can form which entail danger of asphyxiation. Argon is a possible danger if it leaks in unventilated locations or pits. Since argon is heavier than air, it can accumulate on the ground if sufficient ventilation is not ensured.

5.7 Miscellaneous

5.7.1 Inadvertent emission of HF energy

Accidental pressing of an activation element, triggering of the automatic activation system or malfunctions of the unit or accessories may lead to uncontrolled activation of the generator. In order to minimize the resulting risks for patients and users, observe the following rules:

- Do not deposit electrosurgical instruments on the patient.
- Deselect the permanently connected foot switch or lift it from the floor when it is currently not required, see section 10.3.3 "Assignment of an activation source", page 76.
- If an activation sound is audible although no current has been intentionally activated, then there is a system malfunction. The **ON/OFF** key allows turning off the unit so that it cannot emit any energy.
 - The activation sound always accompanying activation of an HF current is an important safety element. Therefore it can be turned down, but not off. Taping over of the sound outlet or other measures to "muzzle" the unit constitute illegal manipulation of a safety device!
- In endosurgical application, the automatic activation system of the bipolar coagulation currents must not be switched on, since otherwise unwanted activation by accidental tissue contact or by unintended contact with the metallic trocar sleeve during placement of the electrosurgical instrument might occur. For this reason, in the case of the selection of a program comprising a bipolar current with automatic activation, attention is drawn to this fact. The user must then decide whether he or she wants to have the automatic activation in the program, otherwise it will automatically be shut off.



5.7.2 Combination with other devices

When combining the maxium[®] with electro-medical devices other than those specified in this manual or linking it to an integrated electromedical system, attention must be paid to the following points:

- Accessories to be connected to the analog and digital interfaces of the unit must demonstrably satisfy the applicable IEC specifications (e.g. IEC Standard 60950 for data processing units and IEC 60601-1 for electromedical equipment).
- Anyone who connects additional units to the input or output section thereby configures the system and is thus responsible for compliance with section 16 of IEC 60601-1.
- In case of questions, the Martin Service Center provides information, see section 2.6 "Hotline", page 11.

5.7.3 HF output power

The hazard potential of electrosurgery increases with the power applied. Therefore the following rules are to be observed:

- The HF output power should be selected as low as possible for the application in question, and not higher than necessary for the application in question. On the other hand, it should also be kept in mind that too lower power settings may also pose a risk, e.g. if due to insufficient power cutting is not achieved and local coagulation results where it is not desirable or even dangerous.
- Insufficient effect in case of normal settings may have the following causes, which are to be checked before increasing HF output power:
 - Poor contact of the neutral electrode with the patient's body
 - Poor contact in plug-in connections
 - Wires broken beneath the insulation
 - Encrusted electrodes
- A defect in the electrosurgery unit may cause undesirable increases in the HF output power.



5.7.4 Use of two electrosurgical devices on one patient

Basically, due to the increased risk of accidental burns by high-frequency currents two electrosurgical units should be used on one patient only if medical requirements necessitate this.

The following rules are to be observed in the concomitant operation of two electrosurgical devices:

- Only type CF electrosurgery units by KLS Martin may be used.
- Each unit that is operated in monopolar application requires a neutral electrode separately attached to the patient. It is mandatory to comply with the instructions for proper application of the neutral electrode.
- Exclusively bipolar application of a unit obviates the need for a separate neutral electrode for this unit.
- The expected current paths from each active electrode to the corresponding neutral electrode must not overlap or intersect. To this end, always place each neutral electrode in the immediate vicinity of the operation field.
- The total power of the simultaneously applied currents must not exceed 400 W.



6 Functions

6.1 Overview

The maxium[®] is a microprocessor-controlled high frequency surgery device according to the latest state of the art. It converts electrical energy from the grid into high-frequency AC power for monopolar and bipolar application.

In monopolar operation, the unit can be activated via finger switches on an electrode handle or via foot switches, in bipolar operation also by automatic functions (see section 9.7 "Automatic Functions of Bipolar Coagulation", page 70). Only one output port can be activated at one time, with the exception of the monopolar Duo coagulation currents.

In order to meet the different requirements of the global market, the maxium[®] is available in three variants with different connections for instruments:

- m-version (Martin)
 Module for accessories by KLS Martin
- i-version (International)
 Module for international accessories
- e-version (Erbe)
 Module for 5-mm accessories

These instrument connections are located on a socket module which can be replaced as a whole if necessary to convert the maxium[®] to a different connection system.



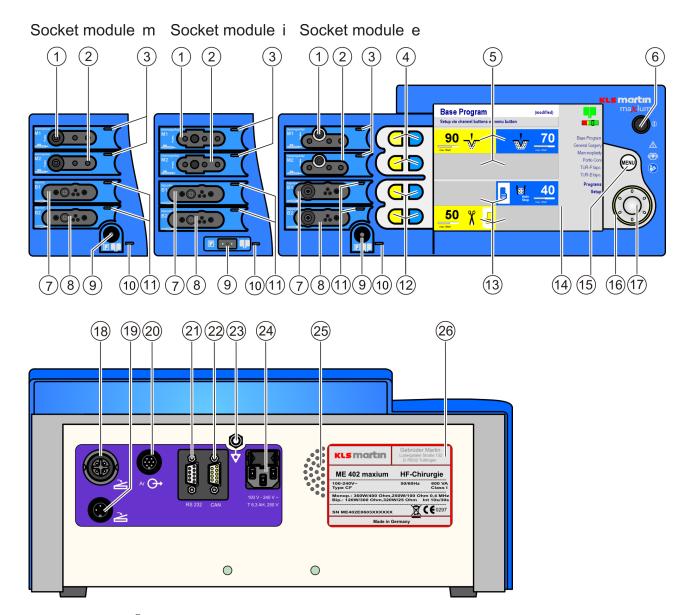


Fig. 6-1: maxium[®] with m, i and e socket modules

Symbols on maxium®: Refer to "Symbol explanation", page 2.



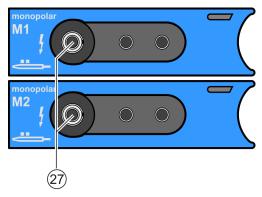
- 1 M1 Monopolar HF output port 1
- 2 M2 Monopolar HF output port 2
- 3 Activation indicators for HF output ports M1 and M2
- 4 Channel selector keys for HF output ports M1 and M2
- 5 Channel display Cutting / Coagulation for HF output ports M1 and M2
- 6 **ON/OFF** key
- 7 B1 Bipolar HF output port 1
- 8 B2 Bipolar HF output port 2
- 9 Socket for neutral electrode
- 10 Status indicator for neutral electrode
- 11 Activation indicators for HF output ports B1 and B2
- 12 Channel selector keys for HF output ports B1 and B2
- 13 Channel display Cutting/Coagulation for HF output ports B1 and B2
- 14 Screen
- 15 **MENU** key
- 16 Background light of the rotary switch
- 17 Rotary switch with central **ENTER** key
- 18 Connection for double-pedal foot switch
- 19 Connection for single-pedal foot switch
- 20 Connection for beamer
- 21 Connection for serial interface
- 22 Connection for CAN-BUS
- 23 Connection for bonding
- 24 Connection for mains cable
- 25 Speakers
- 26 Type plate



6.2 Connections on the Front

The maxium[®] by KLS Martin can be equipped with three different versions (m, i and e) of socket modules for the HF output ports, see section 6.1 "Overview", page 37.

6.2.1 Monopolar connections



In the socket module of the maxium[®] m-version, the sockets M1 and M2 are suitable for standard instruments by KLS Martin.

The following cables can be connected here:

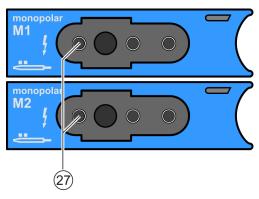
- Connecting cable with circular plug by KLS Martin
- Connecting cable with US 3-pin plug
- Instrument with a plain 4-mm connector (banana plug)

For this plug, use the left socket (27). Insertion into either of the neighboring control contacts will cause malfunction!



Risk of injury from unauthorized accessories!

On the aftermarket, there are connection cables for bipolar accessories available which can also be connected to the monopolar standard connector M1 or M2. For safety reasons such cables may not be used here!

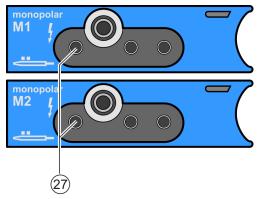


In the socket module of the maxium $^{\mbox{\tiny $\!\!\! (B)$}}$ i-version, the sockets M1 and M2 are suitable for the international standard.

The following cables can be connected here:

- Connector cable with 8-mm "Bovie Plug"
- Connecting cable with US 3-pin plug
- Instrument with a plain 4-mm plug for the left-hand connector socket (27, e.g. for a handle). Insertion into either of the neighboring control contacts will cause malfunction!





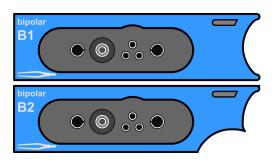
In the socket module of the maxium[®] e-version, the sockets M1 and M2 are suitable for instruments with 5-mm plug (coaxial circular connector with 5-mm inner conductor).

The following cables can be connected here:

- Connector cable with coaxial circular connector with 5-mm inner conductor
- Connecting cable with US 3-pin plug
- Instrument with a plain 4-mm plug for the left connector socket (27). Insertion into either of the neighboring control contacts will cause malfunction!

The activation indicators (3, Fig. 6-1) and (10, Fig. 6-1) of the sockets M1 and M2 are lit upon activation of the respective HF output port. According to the cutting or coagulation function, the activation signal on the enabled channel is lit yellow or blue.

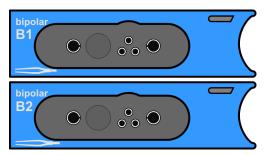
6.2.2 Bipolar connections



In the socket module of the maxium® m-version, the sockets B1 and B2 are suitable for standard instruments by KLS Martin and for special instruments. The sockets are equipped with a connector for small coaxial plugs for standard connection cables by KLS Martin and with 4-mm sockets for bipolar flat-pin plugs. In addition, both sockets are equipped with connections for multifunctional connection cables by KLS Martin and offer finger switch control and instrument detection.

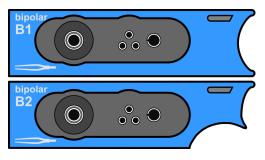
Using an external adapter, both output ports can be expanded so that two instruments for bipolar cutting and for bipolar coagulation can be connected at the same time and separately activated via a foot switch. Additionally, another instrument for coagulation with automatic activation can be connected to the other port.





In the socket module of the maxium® i-version, the sockets B1 and B2 are suitable for the international instrument standard and offer the same features. B1 and B2 are suitable for connection of bipolar connection cables with two individual 4-mm-connectors, as well as with US 2-pin-flat-pin plugs (e.g. for bipolar forceps, bipolar HF clamps or bipolar scissors).

In addition, both sockets are suitable for connection of a flat-pin plug with additional control contacts in order to operate finger switch activation and instrument detection.



In the socket module of the maxium® e-version, the sockets B1 and B2 offer the same features and are suitable for instruments with 12-mm coaxial connector (coaxial circular connector with internal 4-mm conductor).

They can also be used for US 2-flat connectors. In addition, both sockets are suitable for connection of a flat-pin plug with additional control contacts to control finger switch activation and instrument detection.

NOTICE

Into these sockets, monopolar instruments with 12-mm coaxial plugs or instrument cables with 4-mm plugs can also be inserted. These will then indicate no function; connecting them is not intended use!

Upon activation of the respective HF output port, the activation indicators (3, Fig. 6-1) and (11, Fig. 6-1) of the sockets B1 and B2 are lit yellow for cutting and blue for coagulation.



6.2.3 Neutral electrode connection



In the socket modules of the maxium[®] m- and e-version, the connection socket (9, Fig. 6-1) is suitable for connection of standard neutral electrode cables by KLS Martin with 6.3-mm jack plug.



In the socket module of the maxium[®] i-version, the connection socket (9, Fig. 6-1) is suitable for connection of the neutral electrode cable with symmetric (rectangular) plug according to US standard.



Risk of injury due to failure of power control!

Do not use the maxium® with reusable neutral electrodes of type TWIN-PAD!

Extensive neutral electrodes which are not in direct contact with the patient's skin (so-called capacitive neutral electrodes) limit or disable the control of the HF output power for some monopolar cutting currents. When using such neutral electrodes, note the instructions for the use of the respective cutting currents in section 11.1, page 102!

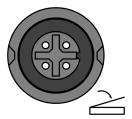


6.3 Connections on the Rear

6.3.1 Foot switch connections

Two foot switches can be connected to the maxium[®]:

- One double-pedal foot switch at the connection socket (18, Fig. 6-1),
- one single-pedal foot switch at the connection socket (19, Fig. 6-1).



At the connection socket (18, Fig. 6-1) for the double-pedal foot switch, in accordance with its intended purpose the yellow pedal is used for both monopolar and bipolar cutting and the blue pedal for monopolar and bipolar coagulation. The yellow pedal can be freely assigned to any cutting channel, the blue to any coagulation channel.



The additional connection of a further single-pedal foot switch (19, Fig. 6-1) allows activation of an instrument both in the monopolar (cutting / coagulation) and also in the bipolar area (cutting / coagulation). The pedal can be freely assigned to any cutting or coagulation channel.

NOTICE

The connection socket (18, Fig. 6-1) can also be used to connect the double-pedal foot switch item no. 80-821-04-04 and 80-825-30-04 by KLS Martin which are designed for bipolar operation of the ME 401/411 device series. Here only the blue pedal is unlocked for activation.

Assignment of the blue pedal of this double-pedal foot switch to a cutting mode is possible, but not the intended use in connection with the maxium[®]!

6.3.2 Interface for the maxium[®] Beamer

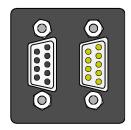


For connection of the maxium[®] Beamer, the socket (20, Fig. 6-1) is provided. This connection is used both for control of and power supply to the maxium[®] Beamer.





6.3.3 Serial interfaces



RS 232 CAN

On the maxium[®], two serial interfaces (21 und 22, Fig. 6-1) are available. The RS-232 (21, Fig. 6-1) is used for linking the maxium[®] to an integrated surgery system, as well as for service purposes such as copying the programs onto a PC or updating the operating software.

The CAN bus interface (22, Fig. 6-1) serves for linking to an integrated surgery system, as well as for the control of external accessories such as fume suction.

Accessories to be connected to the analog and digital interfaces of the unit must demonstrably satisfy the applicable IEC specifications (e.g. IEC Standard 60950 for data processing devices and IEC 60601-1 for electromedical equipment). Anyone who connects additional units to the input or output section thereby configures the system and is thus responsible for compliance with section 16 of IEC 60601-1. In case of any questions, contact the authorized dealer or the Martin Service Center.

6.3.4 Equipotential bonding connection



Equipotential bonding, aka potential equalization, is the conductive electrical connection of the casings of units to each other and the ground. It ensures that the units will always, even in case of an electric defect, have the same potential. Equipotential bonding is mandatory for certain operating rooms, e.g. those for intracardiac interventions. It can be established via the equipotential bonding connection (23, Fig. 6-1). The necessary connection cable is not included in the scope of delivery and can be purchased as item no. 80-260-50-04 if required.

6.3.5 Mains connection



100 V - 240 V~ T 6,3 AH, 250 V

The maxium $^{\otimes}$ is equipped with a wide-range power supply, so that the nominal value of the mains voltage can be from 100 V to 240 V without need for switching the network connection. The power connector (24, Fig. 6-1) also comprises the fuse protection of the unit with two fuses T 6.3 AH, 250 V.



6.4 Controls

For control of the maxium $^{\otimes}$, in addition to the **ON/OFF** (6, Fig. 6-1) key there are the channel selection keys (4 and 12, Fig. 6-1), the **MENU** key (15, Fig. 6-1) and the rotary switch with the central **ENTER** (17, Fig. 6-1) key.

6.4.1 ON/OFF key



After proper preparation and installation of the maxium[®] (see national installation and operation regulations and national rules for fire and explosion protection), in the designated areas the unit can be set into operational condition by pressing the **ON/OFF** key (6, Fig. 6-1).

The maxium[®] is set to display the last used program after each switching on. However, in the **Service** menu, the base program can be defined as autostart program (factory default, see section 10.6.9 "Service Menu", page 101).

NOTICE

If the automatic function of the bipolar coagulation **Auto Start** is to be used, for safety reasons it must be activated after each switching on of the maxium[®].

If any setting of the program which was active during the last switching off has been modified, there appears a notification that the program will be started with the default settings. This is done for safety reasons in order to alert the user to the fact that the settings of the program on the screen are not the same as during the last switching off.

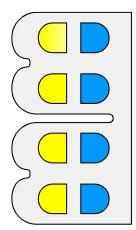
NOTICE

The ON/OFF key will not disconnect the unit from the grid!

To disconnect the unit from the grid, the plug of the connecting cable must be pulled – at the unit or from the outlet.



6.4.2 Channel selector keys



To each HF output socket a pair channel selection key (4 and 12, Fig. 6-1) is assigned which is used to select a channel for adjustment.

For further information, refer to section 10.2 "Selection and Deselection of Working Channels", page 73.

6.4.3 MENU key

Pressing the **MENU** key (15, Fig. 6-1) causes:



- appearance of a blue bar on the top entry of the list on the right hand side of the screen. This list consists of the Last Used Programs (LUPs) and the **Programs** and **Setup** menus.
- return to the main menu.

For further information, refer to section 10.4 "Navigation within the Programs and Functions of the maxium®", page 77.



6.4.4 Backlit rotary switch

The rotary switch (17, Fig. 6-1) is used for navigation within the programs and functions of the maxium[®]. For further information, see section 10.4 "Navigation within the Programs and Functions of the maxium[®]", page 77. The rotary switch can be turned to change the selection or modify a current parameter. Pressing its center has the effects of **ENTER**.

The color of its background light indicates the current status of the maxium[®].



No light

The maxium[®] will not respond to movements of the rotary switch. Pressing any of the channel selection keys or of the **MENU** key, as well as activation of a current, will change the background light, and the maxium[®] will respond to the rotary switch being moved. After a timeout adjustable in the **Setup** menu, the unit will automatically return to the state in which it does not react to the rotary switch. This is to prevent accidental change of parameters during phases in which the maxium[®] is not being actively used.



Yellow light

A cutting channel is selected or activated.

Turning the rotary switch changes the power or current or the associated foot switch in the field of the selected cutting channel. The variable parameter is marked on the screen with a red frame. The power of the cutting current can be changed during activation and immediately afterwards. **ENTER** dismisses the input mask.



Blue light

Turning the rotary switch changes the power or current selection or the associated foot switch in the field of the currently selected coagulation channel. The variable parameter is marked on the screen with a red frame. The power of the coagulation channel can be changed via the rotary switch both during activation and immediately afterwards. **ENTER** dismisses the input mask.



White Light

By pressing the **MENU** key, navigation in the menu on the right side of the screen is enabled. In this mode, the rotary switch moves the marking within the menu on the right side of the screen.



7 Accessories

NOTICE

Only accessories approved by the manufacturer or compatible accessories may be used.

7.1 maxium[®] Beamer

7.1.1 General Information

The maxium[®] Beamer is an accessory for the maxium[®] electrosurgery unit that serves to generate a defined gas flow in the range of 0 - 12 l/min.

The gas flow will be activated synchronously with the HF energy. For cutting and coagulation, individual gas flow rates can be selected. Argon gas and HF energy are combined in the patient section of the applicator. For flushing the applicator upon connection to the beamer with argon and displacing the remaining air therein, a gas flow without HF energy can be triggered via the **PURGE** key.

The easy ionization of the noble gas argon can be used in coagulation by directing the coagulation current in the form of an ionized gas jet (Argon Beam) onto the tissue surface, allowing this to coagulate in more targeted and more uniform fashion than with conventional spray coagulation.

During cutting, argon can flow around the cutting electrode as a shielding gas, displacing atmospheric oxygen and thereby reducing the formation of combustion products. In both cases the gas jet helps to clear the operation field by displacing existing liquids from the surface sideward and blowing off the smoke produced.

Argon is usually supplied from pressure cylinders with a filling pressure of 20 MPa (200 bar). This high pressure is reduced directly on the cylinder to 250 - 450 kPa (2.5 - 4.5 bar) and fed to the maxium[®] Beamer with this pressure.

Only the MABS pressure reducer described in section 7.1.3 "Gas supply", page 52, may be connected to the maxium® Beamer.

Alternatively, the maxium[®] Beamer may be connected to a central argon supply, if such a system is present and its operating pressure in the required range. To this purpose a special adapter hose will be necessary, which is available upon request as an optional extra.



Risk of injury due to excessive gas pressure!

A central argon gas supply must be equipped with an additional safety system to guard against unacceptably high pressure. It must be ensured that the inlet pressure at the gas inlet of the maxium[®] Beamer does not exceed a value of 600 kPa (6 bar)!

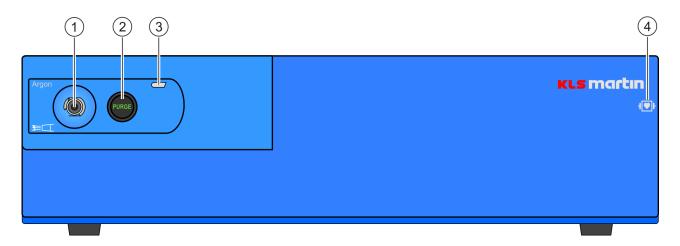


With its regulator, the maxium[®] Beamer controls the gas throughput so that at the patient end of the applicator the selected gas pressure will result. Different flow resistances of the applicators are automatically taken into account in the process and do not affect the value of the gas flow. This makes the maxium[®] Beamer suitable also for endosurgical applications, in which the applicators comprise particularly thin hoses.

The gas flow is activated synchronously with the HF current. Here the maxium[®], which also supplies power to the maxium[®] Beamer, activates the latter via the connecting cable.



7.1.2 Control and display elements, connections



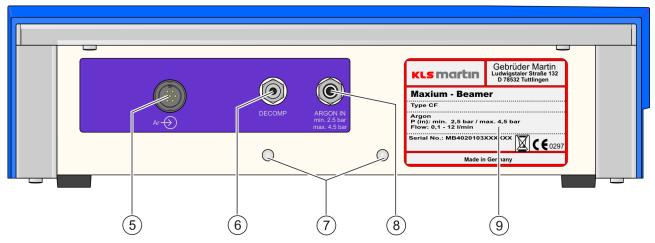


Fig. 7-1: maxium[®] Beamer

- 1 Gas outlet, Luer-lock connection for applicator
- 2 **PURGE** key for flushing the applicator with argon gas
- 3 Operating status indicator
- 4 Label for classification of the unit as type CF. The unit is defibrillation-proof.
- 5 Connector for connection to the maxium®
- 6 Decompression pin
- 7 Threaded connection for permanent installation
- 8 Connection of the argon gas supply
- 9 Type plate



7.1.3 Gas supply



ARGON IN min. 2,5 bar max. 4,5 bar

For the operation of the maxium[®] Beamer, the noble gas argon is needed. Argon is available in cylinders of various sizes with a nominal filling pressure of 200 bar. For installation on the maxium[®] Cart II, Gebrüder Martin recommends to use 5-liter cylinders with argon of quality 4.8 (purity higher than 99.998 %, see section 7.1.4 "Argon", page 53). Expanded to atmospheric pressure, these cylinders contain 1,000 liters of argon each, enough for approximately 3 – 6 hours of activation time (depending on the selected flow value). The connection is made at the inlet (8, Fig. 7-1) on the rear of the unit.



Fig. 7-1: MABS pressure reducer

When connected to a gas cylinder, the corresponding pressure reducer reduces the high pressure to 2.5 – 4.0 bar. Before connecting the pressure reducer to the cylinder, the latter must be set up safely. To this end, the workplace safety guidelines and procedures for handling pressure vessels must be complied with. When the maxium® Beamer is installed on the cart, the cylinder can be placed there and secured with a strap. Once the cylinder has been set up safely, remove the protective cap from the angle valve and screw on the pressure reducer.

Tighten the knurled screw only as far as manually possible without effort!

Only then open the angle valve of the cylinder (at least half a rotation in counter-clockwise direction). The pressure indicated on the gauge of the pressure reducer shows the filling level of the cylinder.

When the maxium $^{\rm @}$ Beamer is connected to a central gas supply, compliance with the inlet pressure of 2.5 – 4.5 bar must be ensured.

The hose installed on the pressure reducer has at its end a quick coupler which is snapped onto the gas connector pin of the maxium[®]. This quick coupler comprises a locking device which closes the outlet in case of separation from the gas connector pin so that no gas can escape. If the hose is already under pressure, then more force will be needed for snapping it on than under zero-pressure conditions, and during the snapping on a small amount of gas will escape. This is harmless.





Close the angle valve to replace the cylinder. For bleeding the pressure reductor,

- disconnect the quick coupler from the gas connector pin of the beamer and place it briefly on the decompression pin (6, Fig. 7-1),
- **DECOMP**
- alternatively leave the gas hose on the beamer and produce a gas stream by
 - activating the maxium[®] Beamer on the electrosurgery unit or
 - pressing the PURGE key on the maxium[®] Beamer.

Then unscrew the pressure reducer from the cylinder.

Never empty the cylinder completely!

At a residual pressure of 30 bar or less, the cylinder should be replaced. Pay attention to indicator on the maxium[®] screen!

If the system is not used for an extended period of time, close the valve on the pressure cylinder to avoid argon loss from the system while it is not used.



Risk of injury by use of improper pressure reducer!

The function and safety of the maxium® beamer are guaranteed only when a MABS pressure reducer by KLS Martin is being used!

7.1.4 Argon

The chemical element argon (atomic number 18) is a noble gas which accounts for 0.93 % of the atmospheric air and is obtained from the latter by liquefaction. As a noble gas, argon will not participate in chemical reactions (intrinsic chemical inertness). Therefore it is non-toxic, odorless, non-flammable, and non-corrosive, and in the plasma of the argon beams no decomposition products of argon can be formed. Its release into the ambient air, from which it has been obtained, causes no environmental problems.

Although in principle all noble gases are suitable for the operation of a beamer, the maxium[®] Beamer is designed to work with argon, since this gas is by far the cheapest and most easily available noble gas. Gebrüder Martin recommends the use of argon of quality 4.8 with a purity of more than 99.998 %. This purity is per se not required for the process of the maxium[®] Beamer. But only these high-purity gases primarily intended for analytics are filled into pressure cylinders which do not run in the same circulation as pressure cylinders for production and handicraft area, which may be very dirty. The use of a quality level higher than 4.8 is possible, but will not present any advantages.



Because of its inertness, argon – unlike carbon dioxide which is also used in medical technology – does not affect the gas exchange in the lungs, but it can displace the respiratory air if the concentration becomes very high and thus lead to asphyxiation. In a normally ventilated room, under normal conditions of use of the maxium[®] Beamer no argon concentrations can form which entail danger of asphyxiation. Argon is a possible hazard if it leaks in poorly ventilated locations or pits. Since argon is heavier than air, it can accumulate on the ground if sufficient ventilation is not ensured.

7.1.5 Connection of beamer instruments

The electrode handles for argon-supported cutting and / or coagulation have separate connections for the supply of HF energy and gas. The HF connector with its flat-pin plug (US 3-pin) is inserted into one of the monopolar output ports M1 or M2 of the maxium[®]. Activation is possible both via finger and foot switch. If an argon-supported current has already been selected, e.g. in the context of a program start, and is displayed on the screen, then the plug is to be inserted into the channel which the argon-supported current belongs to.



The gas supply at the electrode handle is part of a Luer-lock connection and to be connected to the socket (1, Fig. 7-1) on the front of the maxium® Beamer. In order to flush out any air present in the applicator, by pressing the **PURGE** key (2, Fig. 7-1) an argon gas flow can be initiated without activating the electrosurgery unit.

The components of the gas supply and the gas flow control inside the unit up to the outlet are non-sterile. For more protection against microbial contamination, there is the possibility of inserting a sterile single use filter (item no. 80-181-90-04) with a pore width of 0.2 μ m between the gas outlet of the unit and the sterilizable applicator, which will hold back potential germs (with the exception of viruses).

7.2 Instruments, Electrode Handles, Electrodes, Foot Switches and Cables for maxium[®] and maxium[®] Beamer

The maxium® as well as the maxium® Beamer may be used only with accessories, wear parts and single use articles whose safety of use has been demonstrated by a declaration of conformity. The use of uncertified accessories by other manufacturers may constitute a source of danger. In case of doubt, consult the manufacturer.

The accessories certified for electrosurgery units by KLS Martin can be taken from the accessories catalog of KLS Martin, which can be requested or directly downloaded from www.klsmartin.com.

Combinations of accessories which are not mentioned in these Instructions for Use may be used only if expressly designed for the intended application. Features and safety requirements must not be affected adversely.



7.3 Bipolar Port Expander

The maxium® electrosurgery unit (from HW 06 and software revision V3.394 on) allows connection of bipolar port expanders to the bipolar output ports B1 and / or B2, to each of which an instrument for bipolar cutting and an instrument for bipolar coagulation can then be connected.

Via the port expander, both instruments simultaneously use the same bipolar output port, but can be separately configured and enabled.

To this purpose, connect the cutting instrument to the yellow socket and the sealing / coagulation instrument to the blue socket of the port expander.

NOTICE

Upon activation of the respective HF output port, the activation indicators of the sockets B1 and B2 are lit yellow for cutting and blue for coagulation.

AWARNING

Danger of burns by uncontrolled activation of HF energy!

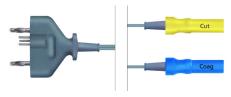
When the function "Bipolar Automatic" is active (automatic mode for bipolar coagulation), simple contact of the patient with the electrode can result in unintended HF activation. This can cause severe health risks for the patient.

When using the bipolar port expanders, it must be made sure that at any moment only one of the two instruments attached to the port expander is with its bipolar electrodes in contact with the patient. Since this cannot be reliably ensured in endoscopic use, the bipolar port expander must **not** be used in endoscopy.



The following figure shows three different port expanders suitable for all bipolar socket modules of the maxium[®] electrosurgery unit by KLS Martin (HW 06 and above).

The difference between the individual bipolar port expanders consists in the blue and yellow outlet sockets for the connection of the instruments.



Item no. 80-790-00-04

for all socket modules of the maxium®

Bipolar port expander version "Martin" for the connection of two instrumentation cables with an 8-mm coaxial plug (small coaxial plug for standard connection cables by KLS Martin).



Item no. 80-790-01-04

for all socket modules of the maxium®

Bipolar port expander, version "International" for connection of two instrumentation cables with US-2 flat-connectors.



Item no. 80-790-02-04

for all socket modules of the maxium®

Bipolar port expander, version "Erbe®" for connection of two bipolar instrument cables with 12-mm coax connectors (coaxial circular connector with 4-mm inner conductor).



	MICRO COAG	MICRO AUTO START	MICRO AUTO STOP	AUTO MICRO	SEALSAFE
	18	Auto Start	& Auto Stop	8 Auto Auto Start Stop	Seal Safe
BIPOL PURE CUT					
bipol.	Х	1)	X	1)	Х
BIPOL BLEND CUT bipol.	V	4)		4)	V
W.	X	1)	X	1)	X
FORFEX					
X	Х	1)	X	1)	Х

1) This feature is available for the maxium® electrosurgery unit from HW 06 and software version V3.398 on.

Older units must be retrofitted with this feature by a special software update to be performed at KLS Martin. Units with a serial number lower than ME402x060303048 will additionally require a hardware upgrade.

NOTICE

Bipolar instrument detection is not possible in connection with the bipolar port expander.



	MACRO COAG	MACRO AUTO START	MACRO AUTO STOP	AUTO MACRO	SEALSAFE
	*	Auto Start	Auto Stop	Auto Auto Start Stop	Seal Safe
BIPOL PURE CUT					
bipol.	Х	1)	X	1)	Х
BIPOL BLEND CUT					
bipol.	X	1)	0	1)	X
FORFEX					
X	Х	1)	Х	1)	Х

1) This feature is available for the maxium® electrosurgery unit from HW 06 and software version V3.398 on.

Older units must be retrofitted with this feature by a special software update to be performed at KLS Martin. Units with a serial number lower than ME402x060303048 will additionally require a hardware upgrade.

NOTICE

Bipolar instrument detection is not possible in connection with the bipolar port expander.



8 Installation of the maxium® and the maxium® Beamer

8.1 Standalone Installation of the maxium®

The maxium[®] is designed to be set up on a level surface such as a table or a shelf. For installation on an elevated or inclined tray, e.g. a ceiling-mounted supply unit, this should be equipped with the ball-head safety bolts, item no. 08-063-00-18, for which the maxium[®] has two receptacles in its base, preventing falling or slipping of the unit.

Connection to a power outlet is established with the supplied mains cable to be inserted into the mains port on the backside. The maxium $^{\$}$ can use any AC mains voltage in the nominal range of 100 – 240 V. Thus no special adaptation to the mains voltage at the installation is required.

If the maxium[®] is to be connected on-site to a grounded equipotential bonding network, then this can be done using the connection pin on the rear via the equipotential bonding cable, item no. 80-260-50-04. This cable is optional and not included in the scope of delivery of the maxium[®].

Usually, on the rear also a double-pedal switch will be connected. If required, in addition a small single-pedal switch can be connected.

After connection of the electrode cables, the maxium[®] is then ready for commissioning.



Risk of electric shock!

In order to avoid the risk of electric shock, this unit may be connected only to a grounded mains supply.

NOTICE

Risk of damage to property

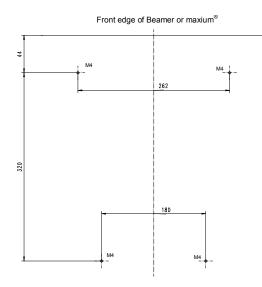
In order to be able to completely separate the unit from the grid in the event of danger, either the power socket of the unit or the outlet into which the mains cable is plugged in should remain accessible.

For the decommissioning of the unit, no special measures are necessary.



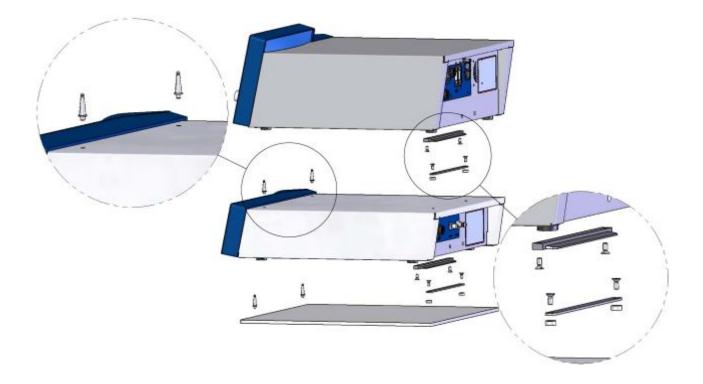
8.2 Installation of the maxium® with maxium® Beamer

Typically, the maxium[®] and maxium[®] Beamer system components are stacked one upon the other with the beamer below and connected to each other by ball-head safety bolts and two interlocking rails. This mounting kit is included in the scope of delivery of the maxium[®] Beamer. Prior to installation, the two ball-head safety bolts must be screwed into the top of the beamer. The bayonet-profile rail is screwed into the base of the maxium[®], with the pointed part to the rear.



The counterpart above on the casing of the beamer is already fitted in the factory. Control by the maxium[®] is done via a special cable which also supplies electrical power to the beamer. The connection cable from the maxium[®] Beamer to the maxium[®] is included in the scope of delivery of the maxium[®] Beamer.

For installation on an elevated or inclined tray, e.g. a ceiling-mounted supply unit, it is recommended to secure it not only with ball-head safety bolts but also with mounting brackets for mounting on a support arm system, item no. 08-022-00-18. It may be necessary to drill threads for the reception of these fasteners.





Perform the gas installation as follows:

- Set up the pressure vessel with the argon gas so that it is secured against toppling.
- Remove the protective cap and screw on the pressure reducer. Tighten the knurled screw of the pressure reducer only manually!
- Snap the hose of the pressure reducer onto the argon inlet at the rear of the beamer. If the angle valve of the pressure vessel is already open, then a bit of force is required, and a small amount of gas will escape in a loud hiss.

After turning the angle valve open by at least half a turn in counterclockwise direction, the system is ready for commissioning.



Risk of injury by use of improper pressure reducer!

Do not connect any pressure reducer to the maxium[®] Beamer other than that offered as a standard accessory by KLS Martin!



8.3 Installation on the maxium® Cart II



For accommodation of the complete system consisting of maxium[®] Beamer, maxium[®] electrosurgery unit, argon cylinders and the respective accessories in a self-contained unit, Gebrüder Martin recommends installation on the maxium[®] Cart II.

The maxium[®] electrosurgery unit and the maxium[®] Beamer are stacked one upon the other and connected to the maxium[®] Cart II using the same elements which also connect the maxium[®] and the maxium[®] Beamer to each other.

If the maxium[®] is to be set up on the maxium[®] Cart II alone, then the mounting rail included in the scope of delivery of the cart must be installed.



The lower part of the cart can safely accommodate a 5-liter argon cylinder. After inserting the pressure cylinder into the cart, screw on the pressure reducer. Turn the cylinder so that the pressure gauge on the pressure reducer is easy to read. Lead the hose to the beamer out through the lateral opening. The protective cap of the cylinder can be stored on the bottom of the cart next to the cylinder.

Lines for connection to a central argon gas supply are available upon request.

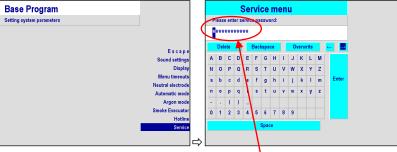


8.4 Integration of the maxium[®] into the Karl Storz OR1™ System

The option "OR1 Integration" allows linking the maxium[®] to the integrated surgery system $OR1^{TM}$ by Karl Storz.

This combination allows the user to operate the maxium[®] in the sterile area via the screen of the OR1 system. The screen can be used e.g. to start programs and modify power settings, currents or activation types. This option is enabled via an unlock code which must be entered into the input window of the **Service** menu. If this option is included in a new order, it is already unlocked by default.





Here enter the 12-digit code and confirm with **Enter**.

For integration of the maxium $^{\otimes}$ into the OR1 $^{\text{TM}}$, the following conditions must be met:

- Extra-cost option "Integration into OR1", item no. 80-093-01-04
- Presence of the OR1[™] system NEO by Karl Storz, version 20090001S411. This version number can be found on the startup screen of the OR1[™] or in the **About SCB** menu.





Display window of the menu About SCB with the exact software version

- Special hardware to be purchased from Karl Storz:
 - Interface Control Set, item no. 200 905-01, consisting of Interface Control, SCB-cable and mains cable.
 - maxium $^{\mathbb{B}}$ Module Set, item no. 200 912-90, consisting of $\mathsf{OR1}^{\mathsf{TM}}$ and RS232 serial cable for maxium $^{\mathbb{B}}$.



9 Commissioning of the maxium[®] and the maxium[®] Beamer

9.1 General Information

The maxium[®] may be used only by persons trained in the proper and safe use of the unit. The Instructions for Use are to be adhered to in instruction and application.

9.2 Switching on the maxium®



If the unit is correctly set up and connected to the power supply, it can be switched on by pressing the **ON/OFF** key. Before the maxium[®] is ready, it will perform a number of self-tests to identify any system errors. This takes some time. During this time, the startup screen is displayed. The progress bar at the bottom of the screen shows the status of the self-test.

After successful self-test, the display changes to the last used program.

If the unit was turned off after modifications to the program settings (indicated by the addition "modified" to the name of the file in the headline), the message "WARNING: Program is going to be reloaded, please confirm!" appears, and the program will be reset to the most recently saved settings.

This is done for safety reasons in order to alert the user to the fact that the settings of the newly loaded program are not the same as before. The user must confirm the program start by pressing **Confirm** or start the base program by pressing **Cancel**. If the last used program was the base program, upon selection of **Confirm** or **Cancel** the same will happen.

If the mains supply was interrupted without the unit being switched off before, a message "Restart after mains power interruption" will appear once the power supply is restored.

If the self-test is not passed, a message will appear in the status line of the screen, in case of serious errors together with an error number.



Typical messages during the self-test of the maxium[®] include the following:

• Self-test: XX switch engaged upon unit startup!

During self-test, the maxium[®] has received a signal from an activation element. Either an attempt to activate an HF current was made already during self-test, or the switch of some activation element is blocked. Possibly the cable of the foot switch, when it is not intended to be used, is wrapped around the foot switch so that a pedal is actuated. In case of doubt disconnect all accessories from the maxium[®] and switch the unit off and on again. If the message appears again, then there is a malfunction, and the unit must be taken out of operation.

Unplug bipolar instrument from B1/B2 during self-test!

During self-test, the maxium[®] registers that between the active electrodes of a bipolar instrument connected to output B1 or B2 there exists a contact which should not be there yet at that time. Unplug cable from the indicated output port B1 or B2. Either the maxium[®] continues the self-test, or it must be switched off and on again. If the message appears again, although no instrument is connected to the bipolar output, then there is a malfunction, and the unit must be taken out of operation.

For additional messages see section 13 "Messages", page 185.

During the self-test, the lights for indication of activation and NE status, as well as the background light of the rotary switch, will be lit in groups. They must all be visible, and the activation sounds must be audible.



9.3 Switching on the maxium[®] Beamer

The maxium[®] Beamer is fed and controlled by the maxium[®]. When switched on, independently of the maxium[®] it will perform a self-test, checking the functions of the gas flow control and the status of the argon gas supply.

If the active program of the maxium[®] does not comprise any argon-supported currents, after the self-test the beamer will change to a passive mode, its status light remaining dark. If the program comprises any argon-supported currents, after passing the self-test the status light will be lit green.

In case of an error the status light will be lit red, and the status line on the screen will show a message together with an error number.

Typical messages during the self-test of the maxium[®] Beamer are the following:

Argon Beamer Warning: Inlet pressure too low

The pressure measured at the gas inlet is too low to ensure the required gas flow at the end of the applicator under all operation conditions. Make sure that the argon gas supply from the pressure reducer is connected to the rear of the beamer, and the angle valve of the cylinder opened. If the gauge at the pressure reducer indicates a pressure of less than 10 bar, operation with the residual pressure is not expedient. The cylinder should never be completely emptied!

Argon Beamer E55-59: Offset failure

The pressure sensors of the maxium[®] Beamer are sensitive to temperature changes. In case of temperature changes, the temperatures of the individual components of the unit will adapt to the new temperature, but often with very different speeds. If components of the pressure sensors have different temperatures, the pressure sensors will yield output signals which are liable to incorrect interpretation. If a beamer is moved from a very cold to a warm environment, due to the resulting temperature gradient the self-test may not be passed. In this case, allow the maxium[®] Beamer to warm up for half an hour with the unit switched on. If the self-test is again not completed successfully, there is a malfunction.

For additional messages see section 13.5 "Messages from the Argon Beamer and the Fume Suction System", page 190.

9.3.1 Noise during operation

In intervals of a few minutes, the maxium[®] Beamer will check the calibration of the gas flow control. To this purpose, a small amount of gas is released into the inside of the beamer, and both the activity of the solenoid valves and the gas flow will be heard. This is not a malfunction of the beamer, but serves to ensure maintenance of the accuracy of the operating data.



9.4 Connection of the active electrodes

Active electrodes, their sockets and lines must be examined for defects of the insulation before being connected. Active electrodes with insulation defects present a risk for the patient and the surgeon.

If currents with high output voltage are to be used, it must be made sure that the accessories combined with the active electrode are up to the potential voltage. For each current, section 11 "Currents, their Properties and Technical Data", page 102, lists the voltages as function of the power settings.

If a monopolar instrument is to be connected to one of the M1 or M2 output ports with a simple cable with a 4-mm connector (banana plug), it must be made sure that this plug is always inserted into the leftmost single socket of the US 3-pin connector. In the version by KLS Martin, this is the inner conductor of the coaxial combo socket (see section 6.2.1 "Monopolar connections", page 40).

The lines to the active electrode should not be placed over the patient nor over patient lines of other electromedical units.

9.5 Connection of the neutral electrode

If a monopolar HF current is to be used, then a neutral electrode must be placed on the patient. Also in cases where bipolar application is intended but additional application of monopolar electricity is likely in case of complications, a neutral electrode should at least be kept ready.

9.5.1 Application of the neutral electrode

By overwhelming majority of troubles in the application of electrosurgery have to do with the neutral electrode. That is why it is worthwhile to pay special attention to this issue in daily routine.

For application of the neutral electrode, the following rules must be observed:

- The neutral electrode must butt against the patient's body as close to the operation field as possible, reliably, and with its whole surface. For an operation field on the torso, the upper arms and thighs are good application sites.
- Safe contact of the neutral electrode must be ensured for the whole duration of the HF
 application. When applying the neutral electrode to a limb, perfusion must not be affected.
 Particularly for longer operation times it must be made sure that the patient does not lie on
 the cable connection clip of the neutral electrode. Otherwise there is a danger of pressure
 necrosis.
- The current paths in the body should be as short as possible and run in the longitudinal or diagonal direction of the body, not across it, the latter particularly not on the chest. Any metal parts in or on the body should be removed if possible, insulated, or paid special attention to.



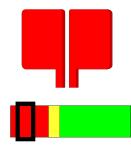
- After any repositioning of the patient, the neutral electrode and its connection must be con-trolled for proper attachment.
- For applications with high power and long activation times, such as TUR-P and endometrium ablation, it is strongly recommended to use split monitored adhesive electrodes.
- Do not apply the neutral electrode above implants or other metal parts, nor above bone protrusions or scarred tissue. If necessary, prepare the application site by cleaning and degreasing it; strong hair-growth is to be removed. For removal do not use substances (e.g. alcohol) that desiccate the skin.
- Do not use adhesive electrodes whose gel layer is injured, nor adhesive electrodes that have been detached. 2nd or 3rd degree burns might result. The cable clip for the connection of the adhesive electrode must cover the gel-free connector straps so that they cannot come into contact with the patient. Make sure that the cable clip and the connector straps match.
- For removal of the neutral electrode, do not pull at the cable or the connector strap. Quick removal of adhesive electrodes may hurt the skin.

An explanation for better understanding of these rules is provided in section 5.1 "Risks from Stray Currents", page 20, and in section 5.2 "Risks from Current Concentration", page 24.

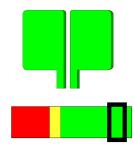
9.5.2 KLS Martin Patient Control System (PCS)

Correct application of the neutral electrode is of particular importance. The maxium[®] can be used both with single-piece and with split monitored electrodes.

The Patient Control System (PCS) by KLS Martin is a tried and tested system for monitoring the connection and body contact of neutral electrodes. The PCS automatically detects whether a connected neutral electrode is single-piece or divided; user input is not required.

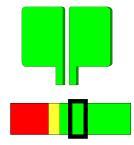


The status of the neutral electrode is indicated by a light next to the NE-connection socket as well as in the upper right corner of the screen. If no neutral electrode is connected, the light at the socket will be flashing red, while the screen shows the representation of a red split neutral electrode, below an indicator representing the application state of the neutral electrode as a variable signal. This indicator can be shut off if desired, see section 10.6.4 "Neutral electrode", page 91. In this condition no monopolar HF current can be activated. When an attempt is made to activate an HF current, an intermittent acoustic warning signal is sounded and a message displayed in the status line of the screen.



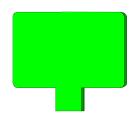
Upon connection of a split neutral electrode which adheres correctly to the patient's skin, after a short run-in the color of the status indicator light next to the NE-socket will change to green. The representation of the NE on the screen will change to green. The pointer of the indicator (black frame) is now in the green field. Now monopolar HF currents can be activated, too.





During the time in which the neutral electrode is applied to the skin of the patient, the PCS will monitor the resistance of the skin. The lowest measured resistance is used as reference for the contact quality and represents the rightmost position of the pointer. If the resistance measured between the two halves of the neutral electrode should increase again over the further course of the application, the pointer of the indicator will move leftward, signaling deterioration of the skin contact. This may be caused by loss of contact of the neutral electrode with the skin due to repositioning of the patient or drying up of a self-adhesive electrode (absorption of water through the skin) during very long operations.

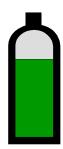
This permanent representation of contact changes is very helpful in the localization of contact problems with the neutral electrode. Sometimes, in the case of split electrodes after application of the electrode on the skin the NE alarm will not go out. If the pointer of the indicator slowly moves away from the left edge into the yellow field, the patient has a particularly high electrical resistance. This may be due to the age of the patient, his/her ethnic background or other reasons. Generally it is to be expected that in such a case the alarm will end with delay. If the pointer does not move, there is a probability of an interruption in the monitoring circuit, e.g. at the transition from the cable connection clip to the NE. Oscillations of the pointer indicate an unstable contact in the monitoring circuit, which will most likely be found in the area of the connector at the maxium[®] or in the vicinity of the cable connection clip.



Upon connection of a non-split reusable NE or adhesive NE for single use, the status light at the NE connection will turn green. On the screen, a non-split green NE without contact indicator will appear, since with such electrodes no patient contact supervision takes place. Section 10.6.4 "Neutral electrode", page 91, describes how to set up the maxium® so that it will accept only split, PCS-monitorable electrodes. If the maxium® is set up like this, then the NE status display will remain red upon connection of unsplit electrodes. The screen will show a red NE, and HF activation is not possible.



9.6 Argon Filling Level



If an argon beamer is connected to the maxium[®] and the current program comprises an argon current, the upper right corner of the screen will display a pressure cylinder with a filling level representing the argon reserve still available. While the argon in the pressurized cylinder form is not present in liquid form but as a compressed gas, representation of the available reserve in the form of a steadily dropping level is easier to understand and to present graphically than representation in the form of decreasing pressure.

The level indicator of the maxium[®] Beamer is based on a special feature of the MABS pressure reducer, not on measurement of the pressure on the input side of the pressure reducer. This is also why it will work only with the former and only if no argon gas flow is activated. During activation, the previously measured level will be frozen.

If the level indicator on the screen deviates strongly from the pressure gauge on the pressure reducer, the display should be re-calibrated, see the maxium[®] Service Manual. If in doubt, the display of the pressure gauge is authoritative.

9.7 Automatic Functions of Bipolar Coagulation

The bipolar coagulation currents can be used with automatic shut-off of the HF energy. The threshold at which the power is to be shut off can be set for each current, see section 10.6.5 "Parameters for coagulation automatics", page 92.

The bipolar coagulation currents Micro Coag and Macro Coag can also be activated automatically upon tissue contact of the instrument. A delay of the automatic activation of the HF current can be set in the menu **Automatic mode**, see section 10.6.5 "Parameters for coagulation automatics", page 92.

The automatic functions are assigned to currents by selection of the current from the list of coagulation currents. To this end, this list comprises the Micro Coag and Macro Coag currents four times each, according to the number of possible combinations with the two automatic functions:







Micro Coag and Macro Coag without automatic functions

The HF current is activated and deactivated by the user via the foot switch or, if present, finger switch. The automatic functions are disabled.





Micro Coag Auto Stop and Macro Coag Auto Stop

The HF current is activated by the user via the foot switch or, if present, finger switch. The HF current is switched off automatically after a preselected degree of coagulation has been reached. Premature withdrawal of the instrument from the tissue before the auto-stop function becomes active will also turn off the HF power.

For reactivation of the current, release the foot or finger switch and actuate it again.





Micro Coag Auto Start/Stop and Macro Coag Auto Start/Stop

HF power is activated upon tissue contact, if desired with pre-selected delay. The HF power is automatically turned off after a pre-selected degree of coagulation has been reached. Premature withdrawal of the instrument from the tissue before the auto-stop function becomes active will also turn off the HF power.

In order to activate the current again, briefly remove the instrument from the tissue and bring it into tissue contact again.





Micro Coag Auto Start and Macro Coag Auto Start

HF power is activated upon tissue contact, if desired with pre-selected delay. However, the HF current is not turned off before the instrument is removed from the tissue. The difference from the auto-start / auto-stop function is that the threshold for Auto Stop is very high, so that in normal coagulation it will be exceeded only when the tissue is released. For very fine forceps or very strongly desiccated tissue the current may be switched off even though the instrument still has tissue contact.

The bipolar currents SealSafe® and SealSafe® IQ also use the auto-stop function. Here it forms part of the intended use and cannot be deselected.

The sensor signal which controls the automatic functions in bipolar coagulation can be used to set the pitch of the activation sound. With a bit of familiarization, the user can thus follow the course of the coagulation process acoustically. This is useful in cases where visual control of the coagulation is impossible or only inadequately possible. The activation of this audio feedback function is described in section 10.6.1 "Sound settings", page 87.



9.7.1 Information about the limitations of the auto-start function



Danger of injury by burns!

In endoscopic surgery, do not use the auto-start function!

For technical reasons, a bipolar output cannot be associated with a cutting current and a coagulation current with auto-start function at the same time. Selection of a coagulation current with **Auto Start** will automatically deselect the parallel cutting channel, see also section 10.2 "Selection and Deselection of Working Channels", page 73. Conversely, selection of a cutting current will deselect the parallel coagulation channel, if a current with Auto Start is selected there. If the coagulation channel is selected again, then the original current appears without auto-start function.

Particularly in endoscopy the auto-start function carries the risk of burns and coagulation necroses due to unnoticed and unintended automatic activation of HF energy in the placement of endoscopic instruments. For this reason, the auto-start function of the maxium[®] is equipped with some restrictions which are intended to exclude inadvertent activation of this function as far as possible:

- In none of the factory-preset programs an auto-start function is enabled. This is to ensure that users not yet familiar with this feature cannot be exposed to a risk of uncontrolled HF emission which they are unaware of. If a user wants to deliberately use a current with auto-start function, he/she can manually select it and save the program under a new name, see section 10.5.4 "Saving a program under a new name", page 81.
- Selection of a program comprising a current with auto-start function invokes a confirmation dialog asking the user to confirm or reject the auto-start function. In case of rejection the auto-start function will be disabled upon loading of the program. A current with **Auto Start/Stop** is then changed e.g. to one with Auto Stop. The same dialog appears if the maxium[®] is set so that upon startup the last used program will appear and the settings of this program comprise a current with auto-start function.



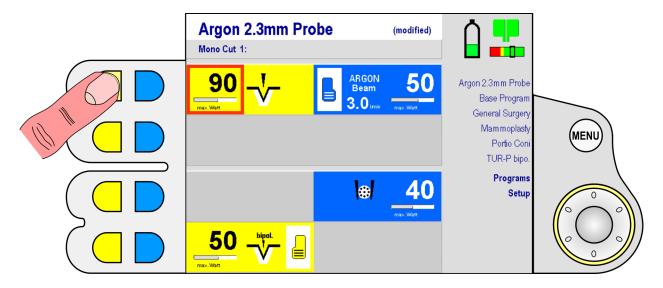
10 Using the maxium®

10.1 General Information

To each instrument connection, on the screen a cutting channel as a yellow field and a coagulation channel as a blue field are assigned. Each of these channel fields is associated with a channel selection key to the left of the screen. All settings of the unit for daily clinical operation are adjusted using these eight channel keys and the rotary switch. Further adjustments which will generally be made only once for the intended workplace and rarely changed, are available in the **Setup** and **Service** menus, see section 10.6.9 "Service Menu", page 101. In daily routine, the parameters of the unit for a specific application are selected quickly and easily using pre-defined programs, which can then be modified or extended on a case-by-case basis as needed.

10.2 Selection and Deselection of Working Channels

After pressing a channel selection key, a red frame will mark the power setting of the corresponding channel. Continued pressing of the channel selection key will move the red frame onto the current, thence – with argon currents – to the argon gas flow, thence to the setup field for the foot switch, and thence back to the power settings. The value currently marked with the red frame can be changed via the rotary switch. The background of the rotary switch is lit yellow when a cutting channel is enabled, and blue for a coagulation channel.

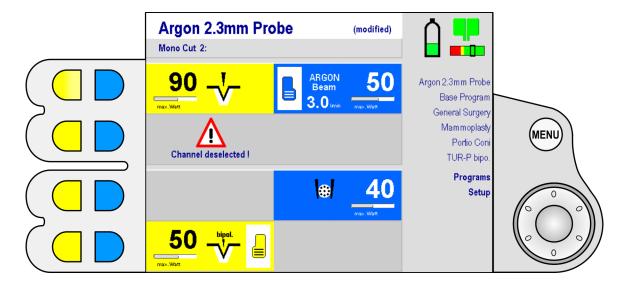


The duration for which the red frame remains there without further user action can be set in the **Menu timeout** menu. The factory default setting is 5 minutes. For further information, refer to section 10.6.3 "Setting of time frames", page 90. This is to prevent the unattended unit from accepting unintended changes to the settings, e.g. when cleaning during work breaks.



In order to improve the clarity of the screen layout, channels not required for the current application can be deselected. To this purpose, press the corresponding channel selection key for at least one second. The channel display of the corresponding channel disappears from the screen. Thus up to seven of the eight channels can be deselected. This approach is especially recommended when working with programs that are tailored to very specific applications.

- Deselection of an HF output port that is not used makes it much clearer to which of the two HF output ports an instrument for a specific application is to be connected (in the example: to the upper of the two monopolar HF output ports).
- Deselection of the HF output port that is not used clarifies which of the two channels is to be used (in the example: coagulation instead of cutting for HF output port Bipolar 1).



When attempting to activate a deselected channel with its activation source, the gray channel will display a message, accompanied by an intermittent acoustic signal. The HF current itself is disabled. To use the deselected channel again, briefly press the corresponding channel selection key to select it.

10.3 Setting the Values for the Working Channels

The channel fields are used for

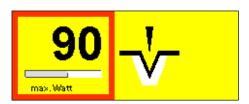
- selecting the HF output power, page 75,
- selecting the current, page 75,
- selecting the activation source, page 76,
- in the case of argon-supported currents also for setting the gas flow, page 75.



10.3.1 Selecting the HF output power

After selecting the desired channel, the red frame marks the power setting. The power can now be set via the rotary switch. In contrast to other settings, the power setting will change immediately, without confirmation by pressing **ENTER**.

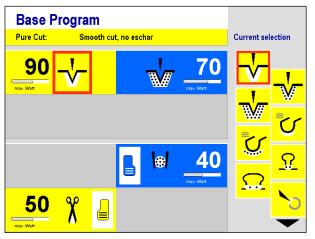
Upon activation of an HF current, the red frame jumps to the power value in the associated channel. This allows direct selection of the power setting without using the channel selection key. The HF output power is the only value which can be adjusted during activation as well. If so desired, this can be shut off in the **Service** menu.



Below the number for the power setting there is a horizontal bar indicating the power relative to its maximum value. This indicator is not linear.

10.3.2 Selecting a current

After selecting the desired channel, the red frame marks the power setting. By pressing the channel selector again, the red frame moves a step towards the center of the screen to the position of the current associated with this channel. At the same time, on the right side of the screen a **menu** with the currents available for this channel opens. A red frame indicates the current previously set in the channel field. The rotary switch can now be used to scroll through these currents, the color of the frame changing to black as soon as it is no longer on the current still selected in the channel field.



ENTER accepts the desired current, replacing the previous selection. The system returns to the menu interface.

For argon-supported currents, in addition to the current a gas flow must be selected as well. By pressing the channel selection key again, the red frame jumps to the numerical value in the input field for the current. Change the value with the rotary switch and press **ENTER**. The value will be accepted, and the red frame disappears.

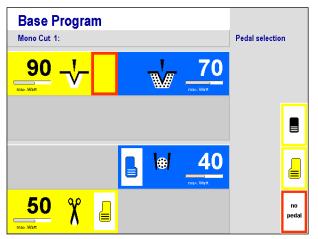
By pressing the **MENU** key, the operation can be canceled at any time. The software will return to the menu. Activation of HF power during the setting will likewise cancel the operation, since availability of the HF energy for the surgeon enjoys higher priority than adjustment of device parameters.



10.3.3 Assignment of an activation source

The maxium[®] can be activated via finger switches on the instrument, via foot switches, and for bipolar coagulation currents also automatically. While each finger switch is always unambiguously assigned to the channel to which its instrument is connected, foot switches must first be assigned to a channel by the user.

Two foot switches can be connected to the maxium[®], a double-pedal foot switch with a yellow pedal for cutting and a blue pedal for coagulation, as well as a single-pedal foot switch with a neutral black pedal.



After pressing a channel selection key, the red frame will mark the power setting of the corresponding channel. Continued pressing of the channel selection key moves the red frame first onto the current and then to the setup field for the foot switch. At the same time, on the right edge of the screen a selection menu for the foot switch opens, with a red frame highlighting the current selection for this channel. The rotary switch moves this frame through the selection, with the frame color changing when the frame is no longer on the current selection for this channel.

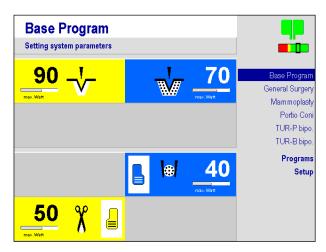
The following are offered: The standard double-pedal foot switch, the single-pedal foot switch and the possibility of explicit deselection of a foot switch (display **no pedal**). If instruments with finger switches are used, this deselection is useful to exclude risks from unintentional actuation of the foot switch.

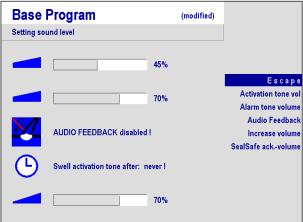
ENTER applies the selected setting. The red frame disappears, and the maxium[®] returns to normal mode. If during selection a foot switch was associated, it will disappears at the same time from the channel to which it had been previously assigned.

By pressing the **MENU** key, the operation can be canceled at any time. The software will return to the menu. Activation of HF power during the setting will likewise cancel the operation, since availability of the HF energy for the surgeon enjoys higher priority than adjustment of device parameters.



10.4 Navigation within the Programs and Functions of the maxium®





The maxium[®] starts up with the main menu.

When the **MENU** key is pressed, a blue bar appears at the top entry of the list on the right hand side of the screen.

The top six entries of this list represent the last used programs in their chronological order of use. The two bottom entries comprise the **Programs** and **Setup** menus.

The rotary switch is used to move the blue bar up and down through the list of the programs and functions. If it is on an entry, the latter can be accepted by **ENTER**. If the selected entry is a program, this will then be installed. If it is a menu comprising other functions, these will appear.

Selection of the entry **Back** in the menu levels causes return to the next higher level. Pressing the **MENU** key will return to the main menu.



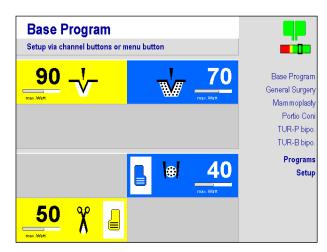
10.5 Working with Programs

Setting each channel parameter before the operation is time-consuming due to the variety of options and carries the risk of operating errors. Therefore, such settings, called programs, will be saved under a name in the unit. Up to 100 such programs can be stored in the maxium[®]. By factory default, there are already some programs saved which are denoted with applications for which they are particularly suitable. The operator can use, modify and save or delete these programs or create custom programs.

10.5.1 Base program

By default, the maxium[®] starts up with the base program.

The settings of the base program can be changed, like those of every other program. In case of a deviation from the basic setting, the addition "modified" will appear behind the name in the status line on the screen. This modification, however, cannot be saved in the base program. If the modifications are to be saved permanently, then the modified program must be saved under a new name, see section 10.5.4 "Saving a program under a new name", page 81.

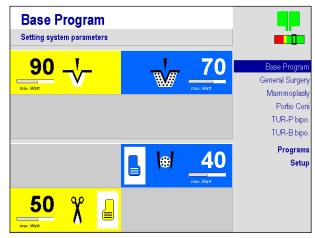


The base program cannot be deleted. The name "Base program" cannot be used for other programs.

With the function **Start with base progr.**, the **Service** menu offers the option of setting up the unit so that upon start-up the base program appears, rather than the last-used program. Here the settings of the base program can be changed as well, if this is explicitly desired. The procedure is described in the maxium[®] Service Manual.



10.5.2 Selecting Programs





There are two ways to select and activate a program stored in the unit:

- via the list of recently used programs
- via the **Programs** menu

Selection via the list of recently used programs:

- Press the MENU key.
- Highlight the desired program and press ENTER.

The settings of the program will be installed. This process takes about 2 seconds, during which the unit will not react to further input. The process is shown by a clock icon at the top of the screen.

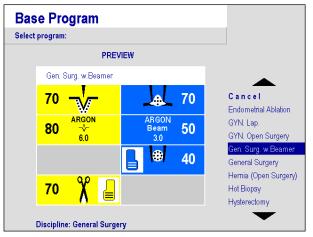
Selection via the **Programs** menu:

- Press the **MENU** key.
- Highlight the **Programs** menu and press **ENTER**.
- In the menu Management of userdefined programs, highlight the function Select program and press ENTER.

On the right side of the screen there appears the list of all programs in alphabetical order, on the left a simplified representation of the channel fields with the settings for this program.

The rotary switch can be used to scroll through the list of programs. If the blue bar is on an entry, the corresponding preview of the channel fields will appear to the left.



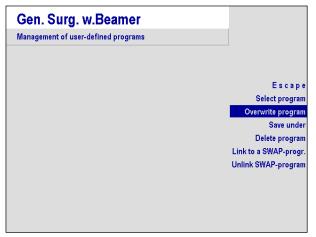


 To install a program, highlight it and press ENTER.

The display changes to the main menu.

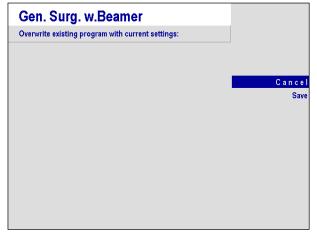
- To exit the menu without installation of the program,
 - highlight the function Cancel and press the ENTER key or
 - press the MENU key.

10.5.3 Saving modified programs



Changes made to a program can be made permanent.

- Press the MENU key.
- Highlight the **Programs** menu and press **ENTER**.
- In the menu Management of userdefined programs, highlight the function Overwrite program and press ENTER.

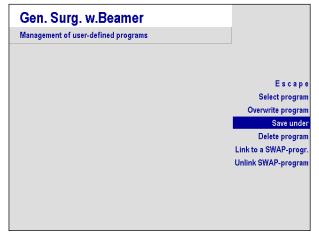


- To save the changes, highlight Save in the subsequent dialog and press ENTER.
- To exit the menu without saving the changes, highlight the function Cancel and press ENTER.

The base program and programs with the "padlock" icon can be neither deleted nor overwritten. Changes can only be saved under a different program name, see section 10.5.4 "Saving a program under a new name", page 81.

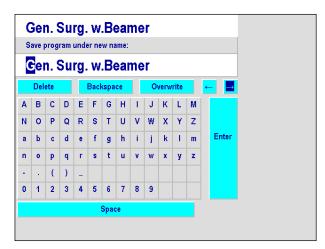


10.5.4 Saving a program under a new name



If a setting is to be saved as an independent program, this setting must be given a new name.

- Press the MENU key.
- Highlight the **Programs** menu and press
 FNTFR
- In the menu Management of userdefined programs, highlight the function Save under and press ENTER.



A text editor will appear. This consists of a line of text for the new program name to be generated and key fields for alphanumeric characters and functions.

Navigate to the individual key fields by rotating the switch. These fields are selected by pressing **ENTER**.

The text line initially comprises the name of the program under which the setting which is now to be stored under a new name has been generated. The first character is shown in inverse video.

This inverse display marks the position of a cursor as in a word processing program.

The **arrow fields** (\leftarrow and \rightarrow) move the cursor within the text line. If further key fields are available, you can scroll to those using the **arrow fields** (\uparrow and \downarrow).

Delete deletes the character under the cursor. The following characters are moved one position to the left.



Backspace deletes the character to the left of the cursor. The cursor and the subsequent characters move one position to the left.



The **Overwrite** key field changes the input mode upon being clicked and indicates it by its content. In **overwrite** mode, the character under the cursor is going to be replaced by the selected alphanumeric character. In **insert** mode, the selected character is going to be placed in front of the character under the cursor, moving the following characters to the right.

The length of the name is limited by the length of the text line. Characters which exceed the visible length will be truncated. The name "Base program" is not available as name for a custom program.

Enter closes the text input. The software returns to the next higher menu level.

The operation can be canceled at any time by pressing the **MENU** key.

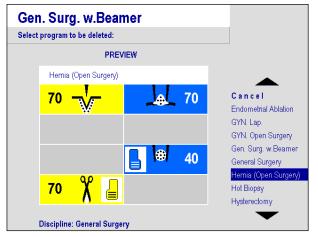
10.5.5 Deleting programs



Deleting obsolete programs provides a better overview of those which are still in use.

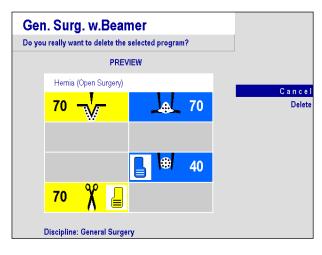
To delete a program, proceed as follows:

- Press the MENU key.
- Highlight the **Programs** menu and press **ENTER**.
- In the menu Management of userdefined programs, highlight the function Delete program and press ENTER.



- To delete a program, highlight it and press ENTER.
- To save the changes, highlight **Delete** in the following dialog and press **ENTER**.





- To exit the menu without deleting the program,
 - highlight the function Cancel and press the ENTER key or
 - press the **MENU** key.
- To exit the menu without saving the changes, highlight the function Cancel and press ENTER.

The base program and programs with the "padlock" icon can be neither deleted nor overwritten. Changes can only be saved under a different program name, see section 10.5.4 "Saving a program under a new name", page 81.

10.5.6 **SWAP** mode

The SWAP mode allows switching to and fro between two pre-set programs by using the foot switch or the finger switch on electrode handle.

This new function allows the operator to use different settings during the operation, without the need for switching to be made by a non-sterile person directly at the maxium[®]. It is useful where there is a need to change any settings of the unit in the course of a surgery.

Switching from a user program to the associated parallel program is possible by using the special double-pedal foot switch with SWAP mode (item no. 80-821-03-04) or by simultaneously activating both finger switches of any two-key electrode handle. This function cannot be used with electrode handles in which the two keys are combined into a rocker switch.



Fig. 10-1: Double-pedal foot switch with SWAP Mode

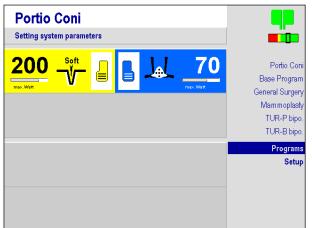


Fig. 10-2: Electrode handle with 2 keys



The maxium® confirms the switching by a multiple acoustic signal.

For using the SWAP mode, the following conditions must be created:



First, for the active program a SWAP program must be defined.

To this purpose, an already existing program can be used, otherwise first a program must be generated and saved, for which purpose usually the program will be used which it is to be assigned to afterwards.



The name of this SWAP program should reflect the link with the initial program.

The assignment is made via the **MENU** key under **Programs / Link to a SWAP prog.**

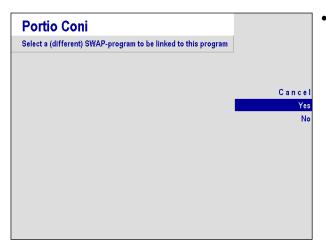
- Highlight the menu **Programs** with the rotary switch and press **ENTER**.
- Select function Link to a SWAP prog.



The preview window with the existing programs will appear.

 Highlight the desired program with the rotary switch and press ENTER.





Confirm the linking of the two programs with **Yes**, or decline with **No**.



On the screen, the active program is now prefixed with an **A**.

The linked program becomes visible on the screen as the active program (preceded by a **B**) upon pressing the additional key on the double-pedal foot switch with SWAP mode or pressing both activation keys of the electrode handle.



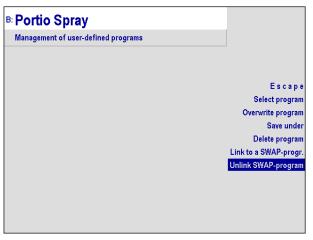
 For linking another program with the active program, another program must be assigned as described above.

The link to the previous program will be deleted automatically, since each program can be linked to only one other.





An existing link to another program is indicated in the preview with the note "Swap Partner: ...".



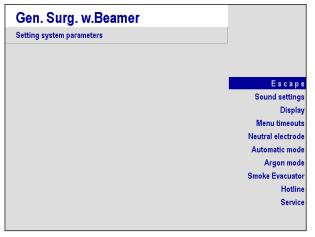
 For unlinking a SWAP connection, select the function **Unlink SWAP program** and reconfirm with **YES**.

10.6 The Setup Menu

In the **Setup** menu, various unit and service settings can be made:

- Sound settings (section 10.6.1 "Sound settings", page 87)
- Screen (section 10.6.2 "Screen Settings", page 89)
- Menu timeout (section 10.6.3 "Setting of time frames", page 90)
- Neutral electrode (section 10.6.4 "Neutral electrode", page 91)
- Automatic mode (section 10.6.5 "Parameters for coagulation automatics", page 92)
- Fume suction system (section 10.6.7 "Use of the marVAC® fume suction system with the maxium®", page 94)
- Hotline (section 10.6.8 "Hotline", page 100)
- Service (section 10.6.9 "Service Menu", page 101)





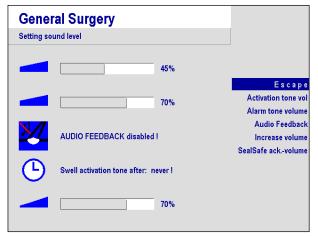
Some settings will affect the current program only (**local settings**). Others will affect all programs (**global settings**).

Whereas global settings are saved automatically, changes to local settings are considered temporary modifications which will be lost when the power is turned off. If local setting are to be preserved, they must be saved manually with the program, see section 10.5.3 "Saving modified programs", page 80. As the base program cannot be saved after changes, changes to the base program will always be temporary.

10.6.1 Sound settings

In this menu, the volume of activation and alarm tones can be set, and the audio feedback function can be enabled and disabled. These settings are global.

The function **Activation tone** serves to adjust the volume of the sound which indicates activation of an HF current. The sound itself is audible, so that the volume can be adjusted to an acceptable value. The display shows a bar and the relative value in percent. As the sound has a safety function, it cannot be turned down arbitrarily. The applicable standard IEC 60601-2-2 prescribes a minimum of 40 dB(A). For this reason, reduction of the volume to less than 40 % is not possible. The factory default setting is 40 %.



The function **Alarm tone** allows adjusting the volume of the sound heard upon attempting activation with the NE-alarm activated. The sound itself is audible, so that the volume can be adjusted to an acceptable value which should be higher than that of the activation sound. The display shows a bar and the relative value in percent. As the sound has a safety function, it cannot be turned down arbitrarily. The applicable standard IEC 60601-2-2 prescribes a minimum of 65 dB(A).

For this reason, reduction of the volume to less than 65 % is not possible. The factory default setting is 65 %.



Audio Feedback provides acoustic feedback about the course of a bipolar coagulation. The pitch of the activation sound is controlled by the electrical resistance of the tissue between the two electrodes of a bipolar instrument, which first decreases over the course of the coagulation and then strongly increases as the end of the coagulation approaches. In those cases where visual inspection of the coagulation is not possible, for example because the bipolar electrodes are below the tissue surface, as in nasal turbinate coagulation, the user will thus receive a feedback about the course of the coagulation process.



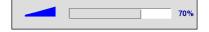
The function can be switched on and off via the rotary switch. By default, the function is switched off; upon switching on, it acts locally on the bipolar coagulation currents of the current program. The current program then appears in the main menu with the addition "Modified".

If this setting is to be preserved, it must be stored, see section 10.5.3 "Saving modified programs", page 80.



The maxium® electrosurgery unit is equipped with an automatic sound level increase function that increases the activation sound after a preset period of time. Options: 15, 30, 60 seconds, or Never.

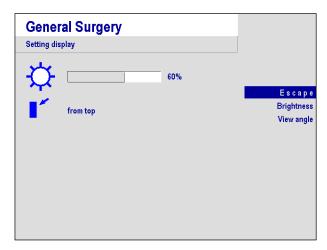
This function can serve to acoustically alert the user to unintentional activation of the HF current and thus to avoid possible burns.



The **SealSafe volume** function can be used to change the confirmation sound after completion of bipolar vessel sealing using the SealSafe[®] or SealSafe[®] IQ currents.



10.6.2 Screen Settings

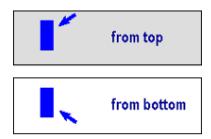


In the **Screen** menu the brightness of the screen can be adjusted to adapt it to the prevailing viewing direction. These settings are global.

With the function **Brightness**, brightness of the screen can be set to a minimum value of 35 - 100 %. The change will take effect immediately, so that an acceptable brightness level can be set directly. The factory default setting is 60 %.

It is to be taken into account that the lifetime of the lamps which illuminate the screen will decrease disproportionately at high brightness values.

A special feature of the screen used in the maxium[®] is the change of the screen contrast if the screen is looked at from below.

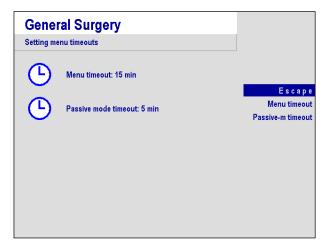


If the unit is installed on a ceiling-mounted supply unit above eye level, switching the angle by selecting the function **View angle** and pressing the rotary switch is recommended to compensate for the contrast shift.

The factory default setting is view **from above**.



10.6.3 Setting of time frames (Menu timeout)



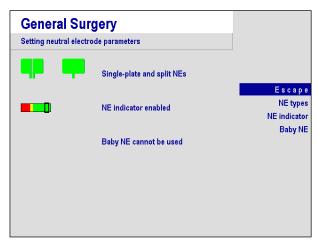
This menu is for the global definition of time frames for the operation of the unit.

The **Menu timeout** function determines the time after which the software automatically leaves a menu level and returns to the main menu. The smallest selectable time amounts to 10 seconds; it can be extended to up to 1 hour in several steps. A confirmation within a menu will always reset the time; exiting a menu via **Back** or pressing the **MENU** key remains unaffected thereby.

The **Passive-mode timeout** function defines how long the maxium[®] will remain responsive to input in the channel fields, i.e., how long the red frame will remain there. This time can be varied in several steps between 2 seconds and 1 hour. Any change to a setting will reset the time, as will actuation of a channel selection key or activation of an HF output.



10.6.4 Neutral electrode



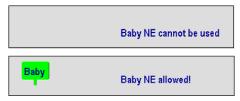
In this menu, restrictions or permissions for certain features of neutral electrodes can be set.

Upon selection of the function **NE types** it can be determined whether the unit is to allow operation with single-piece as well as with twopiece electrodes or with two-piece electrodes only.

The global default setting provides for operation with both electrode types.

Via the function **NE Indicator** the display for the patient contact of a split NE which appears in the upper right corner of the screen can be switched off if this is desired in the interest of clarity. This setting is global, too.

The indicator is turned on by default.



The function **Baby NE** allows the use especially of small-area neutral electrodes for neonates and infants.

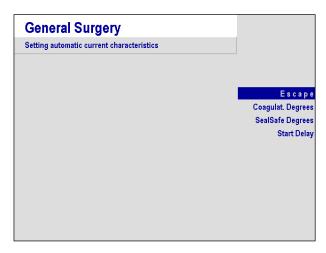
The settings of these electrodes are subject to some restrictions.

The adjustable HF output power is limited for monopolar currents. All bipolar currents with the exception of the bipolar TUR-currents are fully available. When the Baby NE has been chosen, only appropriate currents can be selected. A red text message in the status line on the screen informs about this. This setting is local, since it is useful only for pediatric purposes. One of the factory-preset programs is equipped with this setting.

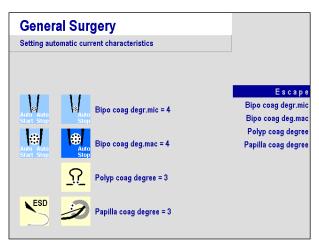


10.6.5 Parameters for coagulation automatics

The bipolar coagulation currents offer the option of automatic shut-off of the HF current after reaching a pre-defined degree of coagulation. The bipolar Macro Coag and Micro Coag currents also offer the option of automatic activation of the HF current upon tissue contact. In addition, here the coagulation degrees of the special monopolar currents for endoscopy can be set. These settings are local settings.

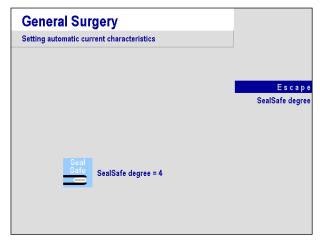


Selection of the function **Automatic mode** will display a menu either for adjustment of the degree of coagulation to shut down the HF power or the setting of the starting time delay.



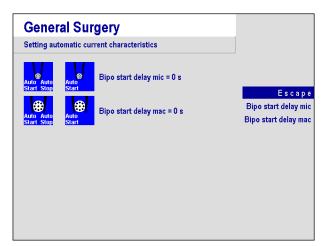
Selection of the function **Coagulation Degrees** will display a menu for selection of the desired current and the degree of coagulation to be achieved with a gradation from 1 to 9 (for the Polyp and Papilla currents from 1 to 5), where 9 (or 5) represents the highest degree of tissue desiccation.





Selection of the function **SealSafe grade** allows selecting the degree of coagulation to be achieved with the SealSafe current from 1 to 9. With increased value, the desiccation of the tissue and thus the shut-down behavior of the sealing process increases.

A prerequisite for a current to be selected is its presence in the currently selected program (currents not on the surface are shown in faded letters) in the main menu; otherwise a message is displayed in the status line of the screen. If two identical currents are present in the program, then the setting will apply to both. The factory default setting for all currents is the value of 4.



For the currents with auto-start function, selection of the function **Start delay** allows definition of a delay of the activation of the HF energy after tissue contact in several steps from 0 to 5 seconds. Here the factory default setting is 0 for both types of currents.

10.6.6 Argon mode

This menu can be used to define whether the argon currents and the functions of the maxium[®] are to be displayed in the menu levels even if no maxium[®] Beamer is connected. If the argon mode is not activated, in some of the menus some functions will be eliminated, making the menus easier to read. Thus the currents with argon beamer are not displayed in the list of selectable currents if beamer operation is deselected. If a maxium[®] Beamer is connected to the unit, then argon mode will be activated automatically. By default, the unit is set not to display the beamer-relevant functions if no beamer is connected. This is a global setting which, however, does not apply to the base program, where the beamer parameters will always be displayed. There, deactivation of beamer operation causes only a temporary hiding until the unit is turned off and on again.



10.6.7 Use of the marVAC® fume suction system with the maxium®

NOTICE

Additionally please note the Instructions for Use of the marVAC® fume suction system.

During vaporization of human and animal tissue of electrosurgical equipment, smoke and vapor constituents are formed. This smoke typically consists of water vapor, aerosols and organic gases.

The marVAC® fume suction system draws in the smoke released. The air is purified by a high-performance air filter (in accordance with the ULPA standard) and fed back into the room air.

The cleaning of the air includes removal of harmful components such as aerosols, which are held back with the help of an ULPA high-performance filter, and organic gases, which may cause unpleasant odors.

There is the option of feeding the extracted air into a central operating room suction system.

The suction parameters of the marVAC® fume suction system can be set via the user interface of the maxium® electrosurgery unit. To this purpose, the version of the maxium® must be at least HW 06 and software V3.398. For connection, the MCB connection cable (item no. 80 091 01-04) is required.

Connection of the marVAC® fume suction system to the maxium®:

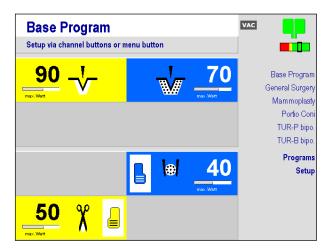


 Plug the MCB connection cable (item no. 80-091-01-04) into the MCB (Martin Communication Bus) connection socket on the rear of the marVAC[®] fume suction system.



• Connect the other end of the MCB connection cable to the CAN (CAN bus interface) connector socket on the rear of the maxium[®].





Turn on marVAC[®] und maxium[®].

If the two units are correctly linked, on the screen of the maxium $^{\otimes}$ there appears the icon **VAC** at the top of the screen.

10.6.7.1 The parameters of the marVAC® fume suction system

The marVAC[®] fume suction system can be run with the power settings **Standby suction** and **Active suction**. Both parameters can be provided with a rundown time.

NOTICE

Possible damage to the unit!

This fume suction system must not be used for removing liquids. Aspiration of liquids may damage the unit.

Note the Instructions for Use of the marVAC $^{\tiny{(\! R \!)}}$ fume suction system.

Active Suction

The parameter **Active suction** determines the desired suction power during the activation of the maxium[®]. The value is specified in %. This parameter can also be disabled if desired. Then the surgical suction of the marVAC[®] cannot be activated until the parameter is enabled again.

Rundown time for Active Suction

The Active suction will continue to run for the selected rundown time after deactivation. The rundown time can be set to up to 30 seconds, in increments of 1 second.

Standby Suction

With the parameter **Standby suction** the desired suction power during breaks can be selected. The value is specified in %.



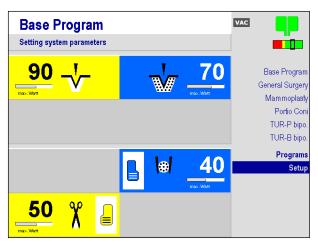
LAP Mode*

The **LAP mode** is designed specifically for use in laparoscopic applications. The parameters for suction are automatically limited (no **Standby suction**, limitation of the **Active suction**). A special valve in the fume suction system closes the extraction channel completely, preventing gas loss in the operation field. Furthermore, appropriate parameters must be selected on the insufflator; refer to the operating instructions of the insufflator. Activity of the **LAP mode** is indicated on the screen.

In laparoscopic application of the fume suction system, always keep in mind that the extraction volume needs to be compensated by the insufflator. For this reason, the lowest possible active suction should be selected.

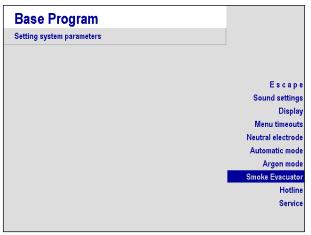
* This function is available only with unit variants offering an **LAP mode**, item no. 80-061-00-04/-10.

10.6.7.2 Setting the parameters via the maxium®



You can activate the parameters of the fume suction for the channels which are not deselected. In the example shown on the left, it would thus not be possible to select extraction parameters for B1/Cutting and B2/Coagulation.

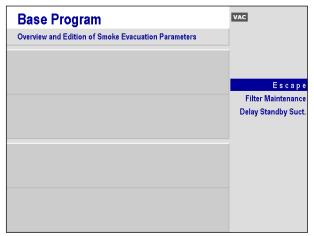
- Press the MENU key.
- Highlight the Setup menu and press ENTER.



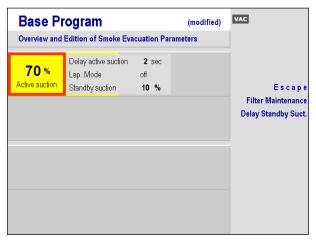
 In the Setting system parameters menu, highlight the function Smoke evacuator and press ENTER.

The menu **Overview and Edition of Smoke Evacuation Parameters** appears, in which the parameters for the fume suction system can be set.





The parameters for **Delay active suction**, **LAP mode** and **Standby suction** can be selected per output port only. The Parameter **Active suction** can be set separately for cutting and coagulation currents.



The suction parameters of the fume suction system are assigned to the respective output port of the electrosurgery unit. In order to be able to modify parameters, or to activate parameters for an output port, the respective **channel selection key** (yellow for cutting currents, blue for coagulation currents) must be pressed.

 For adaptation of parameters Active suction for Cutting, press the yellow channel selection key.

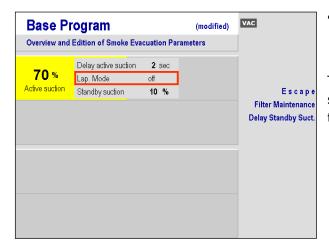
The value which can be modified is marked with a red frame. The rotary switch allows changing the parameter accordingly.

 In order to set the rundown time in seconds, press the channel selection key again.

The rundown time can now be changed in steps of 1 second using the rotary switch.

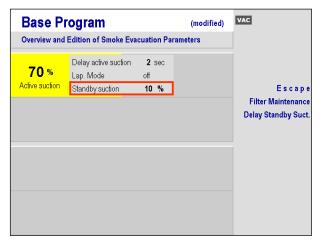






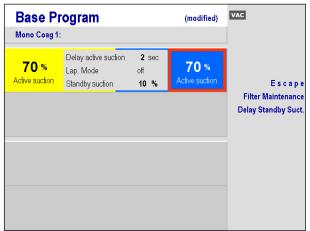
 To activate or deactivate the LAP mode with the rotary switch, press the channel selection key again.

This requires the connected marVAC[®] fume suction system to offer a **LAP mode**. Otherwise the field will be skipped.



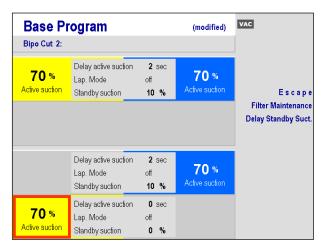
 In order to change the parameter Standby suction, press the channel selection key again.

The parameters can be changed accordingly using the rotary switch.



• Use the same approach also for a coagulation current (**blue**).



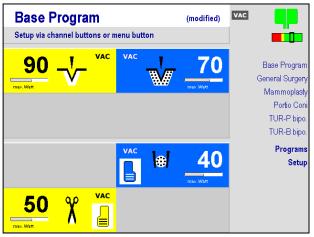


 Press the respective channel selection to activate the suction parameters at the output of the electrosurgery units.

By pressing and holding down the channel selector key for a longer time, the parameters can be deactivated: The parameter display will be cleared. Pressing the channel selector again will reactivate the deactivated parameters.

Please note that the communication of the two units is bidirectional, i.e. the parameters changed on the maxium[®] will be automatically transferred the marVAC[®] fume suction system and displayed on the screen.

Conversely, in case of a change of parameters on the control panel of the marVAC[®] fume suction system the active program in the maxium[®] will be changed.



In the main menu, the assignment of the fume suction system is now indicated by the marking **VAC** on the respective channel.



10.6.7.3 Saving the modified user prE-Mailsogram

The adjusted parameters of the fume suction system can be saved in the respective user program of the maxium[®], either by **Overwrite program** or by **Save program as**.

10.6.8 Hotline

Under **Hotline**, contact information for direct help in case of questions about or problems with the maxium[®] can be found.



10.6.9 Service Menu

The **Service** menu provides access to the functions which are not needed in the clinical operation of the maxium[®]. They are therefore accessible for technicians and service only. This includes, inter alia, the following functions:

- Selection of the user interface language: The texts of the menus, functions, and fields, as well as the messages in the status line, can be displayed in various national languages.
- Unit status: Display of the hardware and software configuration, detection of peripherals, display of the activation and error log.
- Surgical disciplines:
 - Selection of various surgical disciplines such as general surgery, urology, gynecology, cardiopulmonary surgery and gastroenterology.
 - Program discipline: Programs can be subsequently assigned to other surgical disciplines.
- Unit settings:
 - Setting of the limitation of the output voltage, change the order of the activation sounds, change of the sequence of Polyp or Papilla currents.
 - Changing the rotational direction of the rotary switch
 - Selecting from among a number of sound themes
 - Timing of Endo currents: Decide whether Endo currents begin or end with a pulse.
- Program settings: Locking and unlocking of programs; special use of the base program; reset to factory default settings.
- Beamer parameters: Setting of the alarm threshold and other argon-related parameters.
- Calibration: Adjustment of parameters to the device hardware.
- Updating the maxium[®]: Manual update of the firmware if Plug & Play fails.

Since custom settings can be deleted irreversibly (e.g. Reset to factory defaults will delete all personal user settings) in this menu, it is password-protected. Details are described in the Service Manual for the maxium[®] by KLS Martin. For details, please consult the maxium[®] service manual by KLS Martin.



11 Currents, their Properties and Technical Data

11.1 Monopolar Cutting Currents



Pure Cut

Pure Cut is a cutting current with a low proportion of coagulation. Since the edges of the cut are coagulated only weakly, a low hemostatic effect results. A so-called "clean cut" results, which comes most closely to the classic scalpel cut and favors wound healing.

This current is equipped with a cutting effect regulation adapted to the power settings and varying commensurately with them. Thus always consistent cutting results are achieved, independent of cutting depth. The delivered power will usually be well below the selected power level, which is to be understood only as setting with power reserve. However, the selected power will never be exceeded.

This current can be used universally wherever tissue-conserving work with large-surface active electrodes is to be done.



Risk of injury due to failure of power control!

The output power of the Pure Cut current can be set to up to 360 W. At a power of more than 150 W, the risks of burns described in section 5.1, 5.2 and 5.3 will increase. The safety measures described therein shall be applied with increased diligence.

When using large-surface capacitive neutral electrodes that do not have direct contact to the patient's body, the cutting effect regulation will not work. The result is that the selected power is delivered to the patient in full.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 700 V.



Technical Data

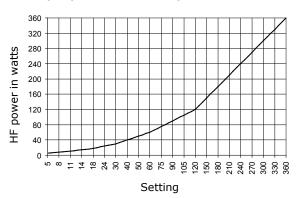
Power setting range: 5 - 360 W at 400Ω

 $\begin{array}{ll} \text{Max. periodic HF output voltage:} & 700 \text{ V}_{\text{S}} \\ \\ \text{Fundamental frequency:} & 403 \text{ kHz} \end{array}$

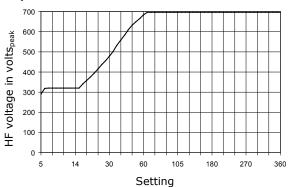
Crest factor at 400 Ω : 1.5

Output curves

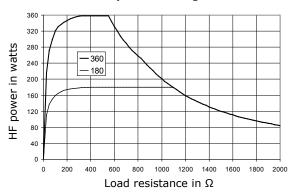
Output power versus set power



Repetitive peak output voltage versus set power



Output power versus resistance at 50 % and 100 % of max. power setting







Blend Cut

Blend Cut is a cutting current with a moderate proportion of eschar formation. The wound edges are simultaneously coagulated during cutting, coagulating the extensive bleeding from transected capillaries immediately during cutting. This is not possible when using a scalpel for cutting. However, the effect has disadvantageous effects on wound healing in comparison to the Pure Cut current.

Depending on the selected power, this is kept constant over a wide application range in order to ensure a reproducible surgical result.

The Blend Cut current can be used universally wherever extensive active electrodes are to be used and a certain hemostasis effect immediately during cutting is expected. For needle electrodes or electrodes with wire loops, this current is less suitable. With such electrodes, hemostasis is achieved more easily with contact-free coagulation.



Risk of injury from excessive power!

The output power of the Blend Cut current can be set to up to 250 W. At a power of more than 150 W, the risks of burns described in section 5.1, 5.2 and 5.3 will increase. The safety measures described therein shall be applied with increased diligence.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 900 V.



Technical Data

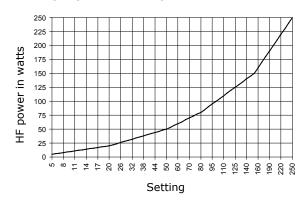
Power setting range: 5 - 250 W at 400Ω

Max. periodic HF output voltage: 900 V_{S} Fundamental frequency: 403 kHz

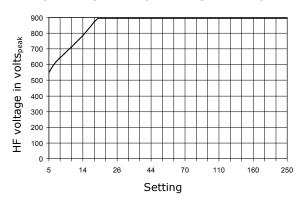
Crest factor at 400 Ω :

Output curves

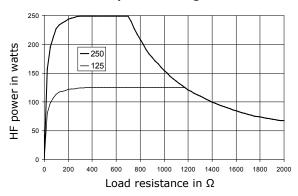
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power versus resistance at 50 % and 100 % of max. power setting







Super Blend

Super Blend is a cutting current with a proportion of eschar formation than Blend Cut. The wound edges are simultaneously coagulated during cutting, coagulating the extensive bleeding from transected capillaries immediately during cutting. This is not possible when using a scalpel for cutting. The effect on wound healing, however, is less advantageous; for this reason, this current is predestined for certain types of resections.

Depending on the selected power, this is kept constant over a wide application range in order to ensure a reproducible surgical result.

This current can be used universally wherever extensive active electrodes are to be used and pronounced hemostasis immediately during cutting is expected. For needle electrodes, the power setting should be lower than the power preset upon activation of the current. For electrodes with wire loops, this current is less suitable.



Risk of injury from excessive power!

The output voltage of the Super Blend current is higher than that of the cutting currents with lower hemostasis. This will increase the risks of burns described in section 5.1, 5.2 and 5.3. The safety measures described therein shall be applied with increased diligence.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 2,100 V.



Technical Data

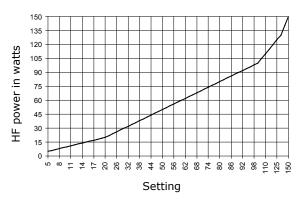
Power setting range: 5 - 150 W at 400Ω

 $\begin{array}{ll} \text{Max. periodic HF output voltage:} & 2,100 \text{ V}_{\text{S}} \\ \\ \text{Fundamental frequency:} & 735 \text{ kHz} \end{array}$

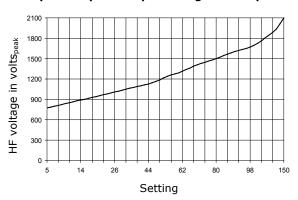
Crest factor at 400 Ω : 3.7

Output curves

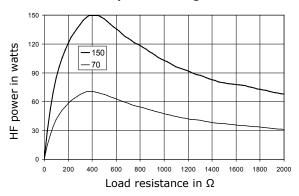
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power versus resistance at 50 % and 100 % of max. power setting







Uro Pure Cut

When cutting under irrigation fluid, the basic conditions differ fundamentally from those of open-surgery. Uro Pure Cut takes this into account and provides a cutting current with low hemostasis specifically for urology in TUR-P or TUR-B applications.

This current is equipped with a cutting effect regulation adapted to the power settings and varying commensurately with them. Thus always consistent cutting results are achieved, independent of cutting depth. The delivered power will usually be well below the selected power level, which is to be understood only as setting with power reserve. However, the selected power will never be exceeded.

This current is specially designed for resection under liquid. For resection under open-surgery conditions, the other cutting currents (Pure Cut, Soft Cut) are better suited.



Risk of injury from excessive power!

The output power of the Uro Pure Cut current can be set to up to 360 W. At a power of more than 150 W, the risks of burns described in section 5.1, 5.2 and 5.3 will increase. The safety measures described therein shall be applied with increased diligence.

When using large-surface capacitive neutral electrodes that do not have direct contact to the patient's body, the cutting effect regulation will not work. The result is that the selected power is delivered to the patient in full.

Attention is drawn in particular to the danger of formation of pyrolysis and electrolysis gases, which may accumulate upon cutting within body cavities such as the bladder or the uterus. These gases can form explosive mixtures, leading to danger of deflagrations which may result in ruptures if such accumulations are permitted to occur and electrosurgery is used in the area of such an accumulation. For further information, refer to section 5.3, page 29.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 1,000 V.



Risk of injury due to mix-up of irrigation fluid!

Make sure you use non-conductive irrigation fluid, see section 4.3.4, page 19.

When using saline or any other conductive solution, there is no cutting effect, and application of RF energy may cause severe local burns.



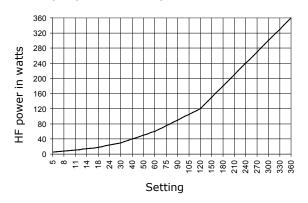
Power setting range: 5 - 360 W at 600Ω

Max. periodic HF output voltage: $1,000 \ V_S$ Fundamental frequency: $403 \ kHz$

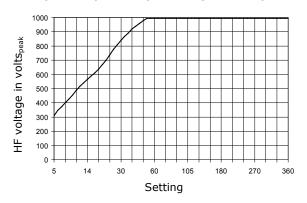
Crest factor at 600 Ω :

Output curves

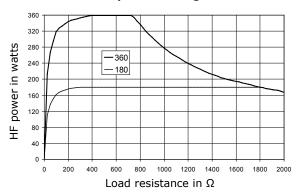
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power versus resistance at 50 % and 100 % of max. power setting







Uro Blend Cut

When cutting under irrigation fluid, the basic conditions differ fundamentally from those of opensurgery. Uro Blend Cut takes this into account and provides a cutting current with concomitant hemostasis for applications such as TUR-P or TUR-B in urology or endometrium ablation.

Depending on the selected power, this is kept constant over a wide application range in order to ensure a reproducible surgical result.

This current is specially designed for resection under liquid. For resection under open-surgery conditions, the other cutting currents (Blend Pure Cut, Super Blend) are better suited.



Risk of injury from excessive power!

The output power of the Uro Blend Cut current can be set to up to 320 W. At a power of more than 150 W, the risks of burns described in section 5.1, 5.2 and 5.3 will increase. The safety measures described there shall be applied with increased diligence.

Attention is drawn in particular to the danger of formation of pyrolysis and electrolysis gases, which may accumulate upon cutting within body cavities such as the bladder or the uterus. These gases can form explosive mixtures, leading to danger of deflagrations which may result in ruptures if such accumulations are permitted to occur and electrosurgery is used in the area of such an accumulation. For further information, refer to section 5.3, page 29.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 1,200 V.



Risk of injury due to mix-up of irrigation fluid!

Make sure you use non-conductive irrigation fluid, see section 4.3.4, page 19.

When using saline or any other conductive solution, there is no cutting effect, and application of RF energy may cause severe local burns.



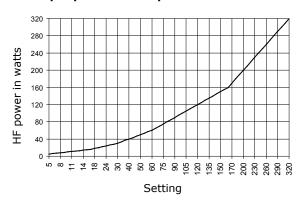
Power setting range: 5 - 320 W at 600Ω

 $\begin{tabular}{lll} Max. periodic HF output voltage: & 1,200 V_S \\ Fundamental frequency: & 347 kHz \\ \end{tabular}$

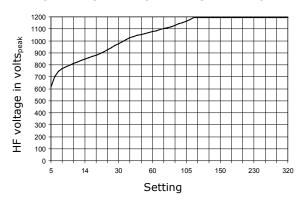
Crest factor at 600 Ω : 1.9

Output curves

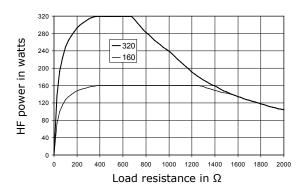
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power versus resistance at 50 % and 100 % of max. power setting







Polyp I

Polyp I is an application-specific current for polypectomy. It is a hybrid current, automatically alternating between cutting and coagulation. It is used for low-bleeding treatment of small or pedunculate polyps using a polypectomy wire loop.

Activation of the Polyp I current starts the cycle with a coagulation phase followed by a very short cutting phase. If desired, this sequence can be changed in the **Service** menu (see the maxium[®] Service Manual). Its purpose is to first iteratively coagulate a polyp at its stem. The subsequent cutting phase causes the resection loop to cut into this pre-coagulated area without bleeding.

This process is repeated periodically until the separation of the polyp, with the correct matching of selected power and tension on the resection loop being decisive for the optimization of a polypectomy that is to be performed as bloodless as possible.

The Polyp I current has an automatic cutting effect regulation in combination with the selection of a power level. This achieves consistent cutting results for each power level. Readjustment of the power level alters the cutting effects.

Although the coagulation phase accounts for the major time share, this current is listed as a cutting current, since its purpose is the resection of polyps.



Risk of injury from excessive current density!

When removing polyps from the intestinal wall, application of HF energy poses the risk of local coagulation necroses by excessive current density, see section 5.2.2, page 27.

It must be ensured that the parts that make up the active electrode of the instrument do not come into contact with other metallic instruments. Transiently the cutting pulses have a high power output.

During pulsed cutting, the yellow foot switch pedal must be kept pressed for the entire duration of the activation. **Do not actuate the pedal repeatedly!**

Active accessories to be used with this current must be able to withstand an HF voltage of at least 600 V.



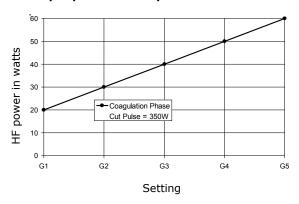
Max. output power (Cut phase): 350 W at 400 Ω

Max. output power (Coag Phase): 60 W at 100 Ω

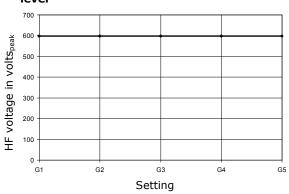
Max. periodic HF output voltage: 600 V_{S} Fundamental frequency 403 kHz

Output curves

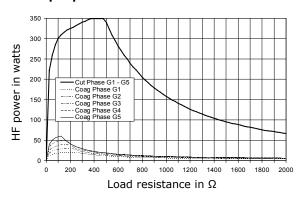
Output power vs. set power



Repetitive peak output voltage vs. set power level



Output power* vs. resistance at G1 to G5



^{*} Cutting power within the short pulse; deviates strongly from the average value





Polyp II

Polyp II is an application-specific current for polypectomy. It is a hybrid current, automatically alternating between cutting and coagulation. It is used for low-bleeding resection of flat-based, sessile polyps using a polypectomy wire loop. Mucosectomy by the piecemeal technique can also be performed advantageously with this current.

Activation of the Polyp II current starts the cycle with a coagulation phase followed by a very short cutting phase. If desired, this sequence can be changed in the **Service** menu (see the maxium[®] Service Manual). Its purpose is to first iteratively coagulate a polyp at its base. The subsequent cutting phase causes the resection loop to cut into this pre-coagulated area without bleeding. This process is repeated periodically until the separation of the polyp, with the correct matching of selected power and tension on the resection loop being decisive for the optimization of a polypectomy that is to be performed as bloodless as possible.

The Polyp II current has an automatic cutting effect regulation in combination with the selection of a power level. This achieves consistent cutting results for each power level. Readjustment of the power level alters the cutting effects.

Although the coagulation phase accounts for the major time share, this current is listed as a cutting current, since its purpose is the resection of polyps.



Risk of injury from excessive current density!

When removing polyps from the intestinal wall, application of HF energy poses the risk of local coagulation necroses by excessive current density, see section 5.2.2, page 27.

It must be ensured that the parts that make up the active electrode of the instrument do not come into contact with other metallic instruments. Transiently the cutting pulses have a high power output.

During pulsed cutting, the yellow foot switch pedal must be kept pressed for the entire duration of the activation. **Do not actuate the pedal repeatedly!**

Active accessories to be used with this current must be able to withstand an HF voltage of at least 600 V.



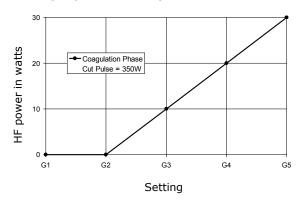
Max. output power (Cut phase): 350 W at 400 Ω

Max. output power (Coag Phase): 30 W at 200 Ω

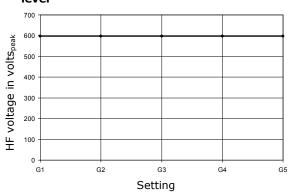
Max. periodic HF output voltage: 600 V_{S} Fundamental frequency: 403 kHz

Output curves

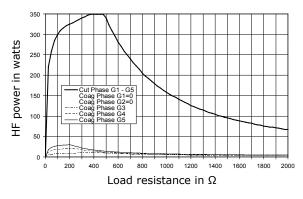
Output power vs. set power level G1 to G5



Repetitive peak output voltage vs. set power level



Output power* vs. resistance at G1 to G5



^{*} Cutting power within the short pulse; deviates strongly from the average value





Papilla I

Papilla I is an application-specific current for papillotomy. It is used for low-bleeding incision using a fistulotome or needle knife.

This papillotomy current dispenses with an additional coagulation current portion; therefore the process begins with a pause followed by the cutting pulse. If desired, this sequence can be changed in the **Service** menu (see the maxium[®] Service Manual). Here the degree of coagulation is based solely on the thermal relaxation of the tissue in the cutting intervals. It is the current of choice when fistulotomes or needle knifes are to be used.

This current has an automatic cutting effect regulation in combination with the selection of a power level. This achieves consistent cutting results for each power level. Readjustment of the power level alters the cutting effect.



Danger of injury by operating errors!

It must be made sure that the parts that make up the active electrode of the fistulotome or needle knife do not come into contact with other metal instruments, especially not with the edge of the endoscope from whose working channel the fistulotome or needle knife exits.

During pulsed cutting, the yellow foot switch pedal must be kept pressed for the entire duration of the activation. **Do not actuate the pedal repeatedly!**

Active accessories to be used with this current must be able to withstand an HF voltage of at least 560 V.

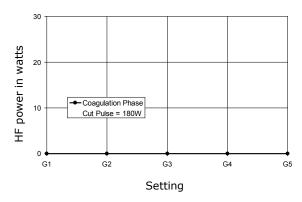


Max. output power (Cut phase): 180 W at 400 Ω

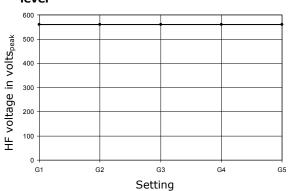
Max. periodic HF output voltage: 560 V_{S} Fundamental frequency: 403 kHz

Output curves

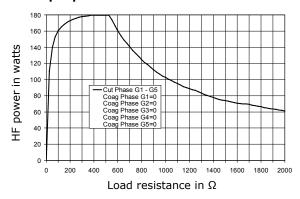
Output power vs. set power level G1 to G5



Repetitive peak output voltage vs. set power level



Output power* vs. resistance at G1 to G5



* Cutting power within the short pulse; deviates strongly from the average value





Papilla II

Papilla II is an application-specific current for papillotomy. It is a hybrid current, automatically alternating between cutting and coagulation. It is used for low-bleeding incision using a papillotome. If wire coil papillotomes are used, or if increased bleeding is expected, this papillotomy current can be selected. Here – as in polypectomy – a special coagulation phase is followed by a cutting pulse. If desired, this sequence can be changed in the **Service** menu (see the maxium[®] Service Manual).

This current has an automatic cutting effect regulation in combination with the selection of a power level. This achieves consistent cutting results for each power level. Readjustment of the power level alters the cutting effect.



Danger of injury by operating errors!

It must be made sure that the parts that make up the active electrode of the papillotome do not come into contact with other metal instruments, especially not with the edge of the endoscope from whose working channel the papillotome exits.

During pulsed cutting, the yellow foot switch pedal must be kept pressed for the entire duration of the activation. **Do not actuate the pedal repeatedly!**

Active accessories to be used with this current must be able to withstand an HF voltage of at least 560 V.



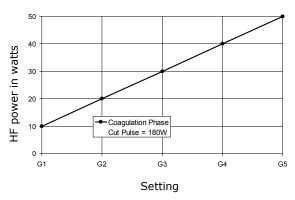
Max. output power (Cut phase): 180 W at 400 Ω

Max. output power (Coag Phase): 50 W at 150 Ω

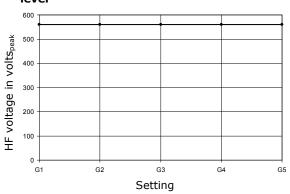
Max. periodic HF output voltage: 560 V_{S} Fundamental frequency: 403 kHz

Output curves

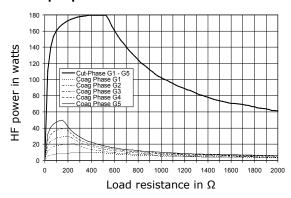
Output power vs. set power level G1 to G5



Repetitive peak output voltage vs. set power



Output power* vs. resistance at G1 to G5



^{*} Cutting power within the short pulse; deviates strongly from the average value





Papilla III

Papilla III is an application-specific current for papillotomy. It is used for low-bleeding incision using a papillotome. This papillotomy current dispenses with an additional coagulation current portion; therefore the process begins with a pause followed by the cutting pulse. If desired, this sequence can be changed in the **Service** menu (see the maxium[®] Service Manual). Here the degree of coagulation is based solely on the thermal relaxation of the tissue in the cutting intervals. It is the current of choice if monofilamentous wire coil papillotomes are to be used and only minimal coagulation is desired.

This current has an automatic cutting effect regulation in combination with the selection of a power level. This achieves consistent cutting results for each power level. Readjustment of the power level alters the cutting effect.



Danger of injury by operating errors!

It must be made sure that the parts that make up the active electrode of the papillotome do not come into contact with other metal instruments, especially not with the edge of the endoscope from whose working channel the papillotome exits.

During pulsed cutting, the yellow foot switch pedal must be kept pressed for the entire duration of the activation. **Do not actuate the pedal repeatedly!**

Active accessories to be used with this current must be able to withstand an HF voltage of at least 560 V.



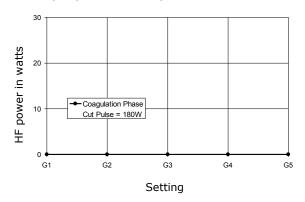
Max. output power (Cut phase): 180 W at 400 Ω

Max. output power (Coag Phase): 50 W at 150 Ω

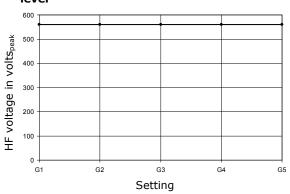
Max. periodic HF output voltage: 560 V_{S} Fundamental frequency: 403 kHz

Output curves

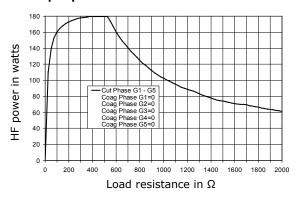
Output power vs. set power level G1 to G5



Repetitive peak output voltage vs. set power level



Output power* vs. resistance at G1 to G5



^{*} Cutting power within the short pulse; deviates strongly from the average value





ESD

ESD is an application-specific current for endoscopic submucosa dissection. It is a hybrid current, automatically alternating between cutting and coagulation. It is used for low-bleeding dissection of the submucosa using a needle knife. Here – as in polypectomy – a special coagulation phase is followed by a cutting pulse. If desired, this sequence can be changed in the **Service** menu (see the maxium[®] Service Manual).

The current is similar to the Papilla II current, but the intermittent pulse sequence is much faster.

This current has an automatic cutting effect regulation in combination with the selection of a power level. This achieves consistent cutting results for each power level. Readjustment of the power level alters the cutting effect.



Danger of injury by operating errors!

It must be made sure that the parts that make up the active electrode of the needle knife do not come into contact with other metal instruments, especially not with the edge of the endoscope from whose working channel the needle knife exits.

During pulsed cutting, the yellow foot switch pedal must be kept pressed for the entire duration of the activation. **Do not actuate the pedal repeatedly!**

Active accessories to be used with this current must be able to withstand an HF voltage of at least 560 V.



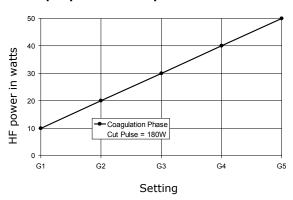
Max. output power (Cut phase): 180 W at 400 Ω

Max. output power (Coag Phase): 50 W at 150 Ω

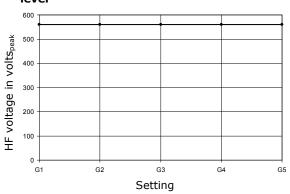
Max. periodic HF output voltage: 560 V_{S} Fundamental frequency: 403 kHz

Output curves

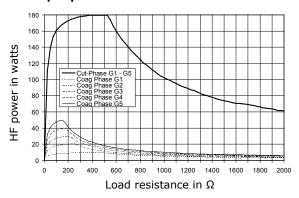
Output power vs. set power level G1 to G5



Repetitive peak output voltage vs. set power



Output power* vs. resistance at G1 to G5



^{*} Cutting power within the short pulse; deviates strongly from the average value





Soft Cut

Soft Cut offers precise and smooth cutting specifically for the use of applicators with wires as active electrode, such as fine wire loops or needle electrodes. Thus this current causes only minimal injury to the tissue edge. The hemostatic effect is weak.

The Soft Cut current is equipped with a cutting effect regulation which is constant over the power adjustment range. This achieves a consistent cutting result independent of cutting depth and power selected. The power actually delivered will usually be well below the selected power level, which is to be understood only as setting with power reserve. However, the selected power will never be exceeded.

Soft Cut can be used for the work with electrode arrangements such as needle or with wire loop electrodes, as well as for portio conisation with wire loop electrodes. The high power reserve allows serving all applications where a cutting current with low hemostasis is demanded.



Risk of injury from excessive power!

The output power of the Soft Cut current can be set to up to 360 W. At a power of more than 150 W, the risks of burns described in section 5.1, 5.2 and 5.3 will increase. The safety measures described therein shall be applied with increased diligence.

When using large-surface capacitive neutral electrodes that do not have direct contact to the patient's body, the cutting effect regulation will not work. The result is that the selected power is delivered to the patient in full. Therefore, the use of Soft Cut in connection with capacitive neutral electrodes is strongly discouraged.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 650 V.



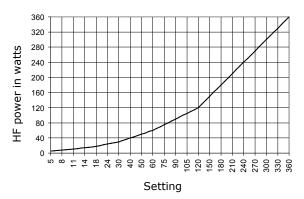
Power setting range: 5 - 360 W at 400Ω

Max. periodic HF output voltage: 650 V_{S} Fundamental frequency: 403 kHz

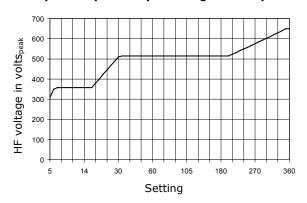
Crest factor at 400 Ω :

Output curves

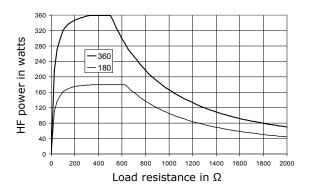
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Argon Cut

The Argon Cut current corresponds to the Pure Cut current with additional application of argon. Under an argon gas atmosphere, this current supports a cutting which causes even less eschar formation than Pure Cut. The argon gas displaces the oxygen in the thermally induced cutting channel, strongly reducing tissue carbonization. Such cutting under inert gas produces less combustion products with proportionally lower release of smoke. In addition to the electrical parameters, after selection of this cutting current the argon gas flow of the maxium[®] Beamer can also be easily adjusted via the user interface of the maxium[®].

Argon Cut is equipped with a cutting effect regulation adapted to the power settings and varying commensurately with them. Thus always consistent cutting results are achieved, independent of cutting depth. The delivered power will usually be well below the selected power level, which is to be understood only as setting with power reserve. However, the selected power will never be exceeded.

This current can be used universally wherever tissue-conserving work with large-surface active electrodes is to be done.



Risk of injury from excessive power!

The output power of the Argon Cut current can be set to up to 360 W. At a power of more than 150 W, the risks of burns described in section 5.1, 5.2 and 5.3 will increase. The safety measures described therein shall be applied with increased diligence. The argon beam increases the risk of the ignition of flammable substances, see section 5.3, page 29.

When using large-surface capacitive neutral electrodes that do not have direct contact to the patient's body, the cutting effect regulation will not work. The result is that the selected power is delivered to the patient in full.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 700 V.



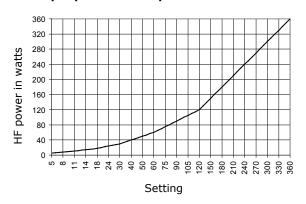
Power setting range: 5 - 360 W at 400Ω

Max. periodic HF output voltage: 700 V_{S} Fundamental frequency: 403 kHz

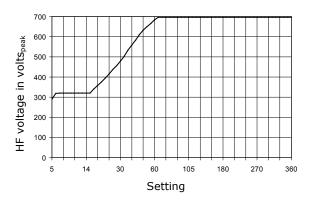
Crest factor at 400 Ω : 1.5

Output curves

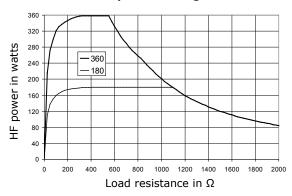
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting





11.2 Monopolar Coagulation Currents



Clamp Coag

The "gentle" Clamp Coag coagulation current is preferably applied indirectly via surgical instruments (e.g. hemostat, surgical forceps) for hemostasis. The needle, knife or lancet electrode of the electrode handle is brought into contact with the surgical instrument for activation (recommendation: first bring the active electrode into contact with the surgical instrument, only then start HF activation). Application is also possible directly via ball or paddle electrodes of the electrode handle. The current penetrates deep into the tissue, resulting in volume coagulation. The user himself determines the degree of coagulation by the duration of the activation.

Basically, under the condition that the same amount of HF energy is required the following apply:

- Low penetration:
 Short application time and correspondingly high HF output power
- Deep penetration:
 Long application time and correspondingly low HF output power

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Risk of injury from excessive power!

In case of indirect application via a hand-held instrument, this should be insulated so as not to expose the surgeon to the HF voltage transmitted directly from the active electrode to the instrument. Despite common practice it must be kept in mind that the surgical glove is no defined electrical insulation, and arcing may occur.

The output power of the Clamp Coag current can be set to up to 250 W. At a power of more than 150 W, the risks of burns described in section 5.1 and 5.2 will increase. The safety measures described therein shall be applied with increased diligence.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 850 V.



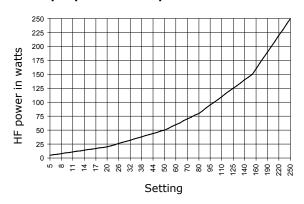
Power setting range: 5 - 250 W at 200Ω

Max. periodic HF output voltage: 850 V_{S} Fundamental frequency: 403 kHz

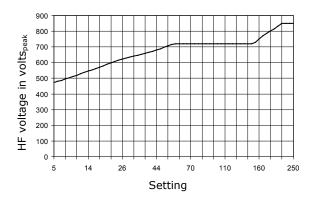
Crest factor at 200 Ω :

Output curves

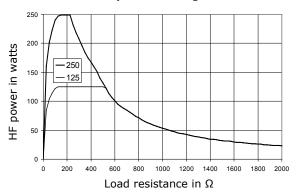
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Forced Clamp

In comparison to the Clamp Coag current, the forced coagulation current Forced Clamp effects coagulation more quickly. The application technique is the same as for Clamp Coag. If the instrument or electrode is only slightly in contact with the tissue, by design some sparking between the tissue and the electrode will be observed. Thus the tissue at the point of contact will be strongly desiccated; slight tissue carbonization will take place. Due to quickly occurring coagulation, the effective depth is limited.

Basically, under the condition that the same amount of HF energy is required the following apply:

- Low penetration:
 Short application time and correspondingly high HF output power
- Deep penetration:
 Long application time and correspondingly low HF output power



Danger of injury by operating errors!

In case of indirect application via a hand-held instrument, this should be insulated so as not to expose the surgeon to the HF voltage transmitted directly from the active electrode to the instrument. Despite common practice it must be kept in mind that the surgical glove is no defined electrical insulation, and arcing may occur.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 1,200 V.



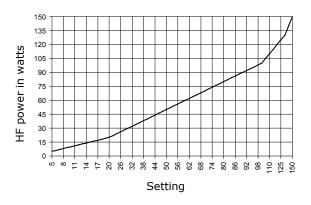
Power setting range: 5 - 150 W at 400Ω

Max. periodic HF output voltage: $1,200 \text{ V}_S$ Fundamental frequency: 735 kHz

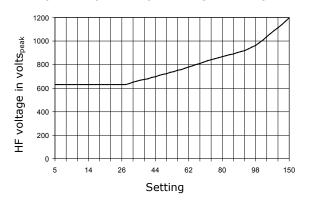
Crest factor at 400 Ω : 3.7

Output curves

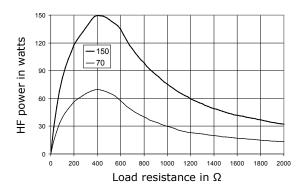
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Forced Prep

In comparison to the Forced Clamp current, the forced coagulation current Forced Prep effects coagulation more quickly. This makes this current suitable for preparation, since despite its dominant coagulation it has an effective cutting power. If the instrument or electrode is only slightly in contact with the tissue, by design sparking between the tissue and the electrode will be observed. Thus the tissue at the point of contact will be strongly desiccated; slight tissue carbonization will take place. Due to quickly occurring coagulation, the effective depth is limited

Basically, under the condition that the same amount of HF energy is required the following apply:

- Low penetration:
 Short application time and correspondingly high HF output power
- Deep penetration:
 Long application time and correspondingly low HF output power

Activation is done via the blue switches (finger or foot).



Danger of injury by operating errors!

In case of indirect application via a hand-held instrument, this should be insulated so as not to expose the surgeon to the HF voltage transmitted directly from the active electrode to the instrument. It must be kept in mind that the surgical glove is no defined electrical insulation for this current, and arcing is indeed likely.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 2,100 V.



Output power setting range (sum of both outputs): 5 - 150 W at 400 Ω

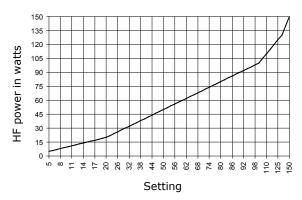
Max. periodic HF output voltage: 2,100 V_S

Fundamental frequency: 735 kHz

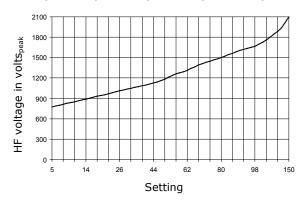
Crest factor at 400 Ω :

Output curves

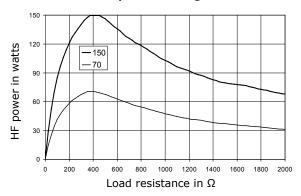
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Contact Coag

The "gentle" Contact Coag coagulation current is preferably applied indirectly via surgical instruments (e.g. hemostat, surgical forceps) for hemostasis. The needle, knife or lancet electrode of the electrode handle is brought into contact with the surgical instrument for activation. Application is also possible directly via ball or paddle electrodes of the electrode handle. The current penetrates deep into the tissue, resulting in volume coagulation. The user himself determines the degree of coagulation by the duration of the activation.

Basically, under the condition that the same amount of HF energy is required the following apply:

- Low penetration:
 Short application time and correspondingly high HF output power
- Deep penetration:
 Long application time and correspondingly low HF output power



Risk of injury from excessive power!

In case of indirect application via a hand-held instrument, this should be insulated so as not to expose the surgeon to the HF voltage transmitted directly from the active electrode to the instrument. Despite common practice it must be kept in mind that the surgical glove is no defined electrical insulation, and arcing may occur.

The output power of the Contact Coag current can be set to up to 250 W. At a power of more than 150 W, the risks of burns described in section 5.1 and 5.2 will increase. The safety measures described therein shall be applied with increased diligence.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 650 V.



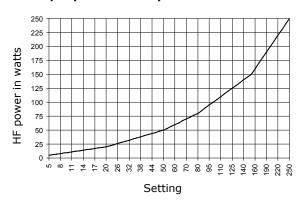
Power setting range: 5 - 250 W at 100Ω

Max. periodic HF output voltage: 650 V_{S} Fundamental frequency: 403 kHz

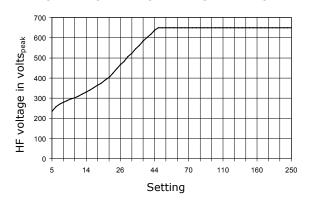
Crest factor at 100 Ω : 3.3

Output curves

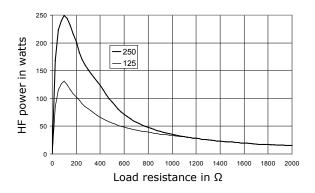
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Forced Coag

In comparison to the Contact Coag current, the forced coagulation current Forced Coag effects coagulation more quickly. The application technique is the same as for the Contact Coag current. If the instrument or electrode is only slightly in contact with the tissue, by design some sparking between the tissue and the electrode will be observed. Thus the tissue at the point of contact will be strongly desiccated; slight tissue carbonization will take place. Due to quickly occurring coagulation, the effective depth is limited.

Forced Coag is very similar to the Forced Clamp coagulation current, differing from it mainly by a higher output voltage. For indirect application via a surgical instrument, the current Forced Clamp should therefore be used, if possible.

Basically, under the condition that the same amount of HF energy is required the following apply:

- Low penetration:
 Short application time and correspondingly high HF output power
- Deep penetration:
 Long application time and correspondingly low HF output power

Forced Coag can be used like a non-contact coagulation current for purely superficial coagulation, too.



Risk of injury by insufficient insulation!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 2,400 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

In case of indirect application via a hand-held instrument, this should be insulated so as not to expose the surgeon to the HF voltage transmitted directly from the active electrode to the instrument. Despite common practice it must be kept in mind that the surgical glove is no defined electrical insulation, and arcing may occur, especially as this current already has a significantly higher voltage.



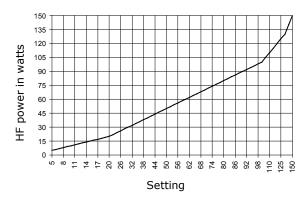
Power setting range: 5 - 150 W at 400Ω

Max. periodic HF output voltage: $2,400 \text{ V}_S$ Fundamental frequency: 735 kHz

Crest factor at 400 Ω : 5.4

Output curves

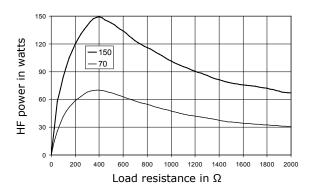
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Uro Coag

Uro Coag is a specialized coagulation current for use under liquids in combination with resectoscope loops. Similar to surface coagulation (see section 4.2.2 "Monopolar coagulation", page 15), here the HF energy is directed into the tissue without or only with slight tissue contact. In this process, the energy independently finds its way to the source of the hemorrhage through the blood, which is more conductive than the non-conductive irrigation fluid (monopolar work, sorbitol-mannitol-sugar solution). The quality of the current prevents "sinking in" of the electrode loop into the tissue upon tissue contact.



Danger of injury by ruptures!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 2,500 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

Attention is drawn in particular to the danger of the formation of pyrolysis and electrolysis gases, which may accumulate upon application of HF energy in fluid in body cavities such as the bladder or the uterus. These gases can form explosive mixtures, leading to danger of deflagrations which may result in ruptures if such accumulations are permitted to occur and electrosurgery is used in the area of such an accumulation. For further information, refer to section 5.3, page 29.



Risk of injury due to mix-up of irrigation fluid!

Make sure you use non-conductive irrigation fluid, see section 4.3.4, page 19.

When using saline or any other conductive solution, coagulation is very poor, and application of RF energy may cause severe local burns.



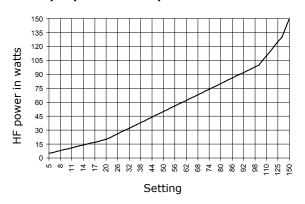
Power setting range: 5 - 150 W at 600Ω

Max. periodic HF output voltage: $2,500 \text{ V}_{\text{S}}$ Fundamental frequency: 961 kHz

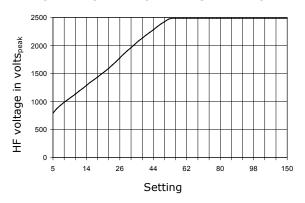
Crest factor at 600 Ω : 5.7 – 4.4 depending on settings

Output curves

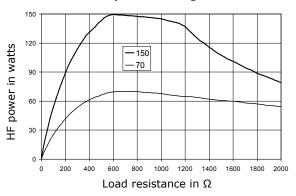
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Forced Uro Coag

Forced Uro Coag is a specialized coagulation current for TUR applications which, compared to the Uro Coag current, is even less prone to cause the loop electrode to sink in upon tissue contact during the coagulation process. This current, however, places increased insulation requirements on the resectoscope. In addition, bubble formation in the irrigation fluid during energy transmission into the tissue is slightly higher than with Uro Coag.



Risk of injury from unauthorized accessories!

It must be made sure that the electrosurgical accessories to be used are suitable for the occurring voltage. See technical data on the following page and safety instructions in section 5.4, page 30.



Danger of injury by ruptures!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 2,500 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

Attention is drawn in particular to the danger of the formation of pyrolysis and electrolysis gases, which may accumulate upon application of HF energy in fluid in body cavities such as the bladder or the uterus. These gases can form explosive mixtures, leading to danger of deflagrations which may result in ruptures if such accumulations are permitted to occur and electrosurgery is used in the area of such an accumulation. For further information, refer to section 5.3, page 29.



Risk of injury due to mix-up of irrigation fluid!

Make sure you use non-conductive irrigation fluid, see section 4.3.4, page 19.

When using saline or any other conductive solution, coagulation is very poor, and application of RF energy may cause severe local burns.



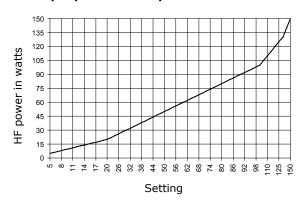
Power setting range: 5 - 150 W at 600Ω

Max. periodic HF output voltage: $2,500 \text{ V}_S$ Fundamental frequency: 961 kHz

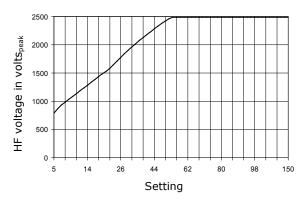
Crest factor at 600 Ω : 5.7

Output curves

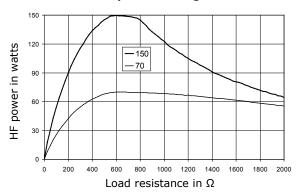
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Spray

Spray is a high-voltage coagulation current for non-contact surface coagulation with very low depth and carbonization. The current is expediently used for hemostasis in thoracic surgery (hemostasis on the sternum) or parenchyma tissue surgery.

For contact coagulation, this current is less well suited. If a coagulation current is required that can be used both for contact and for surface coagulation, then the Forced Coag current should be selected.



Danger of injury by sparking!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 8,000 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

Because of the extremely high voltage, this current should not be used in endoscopy. For this application, there is the Endo Spray current with significantly lower voltage.

The powerful sparking may cause ignition of combustible substances or mixtures of substances, see section 5.3, page 29.

Do not use this current for indirect contact coagulation via surgical instruments. There is great danger of arcing.



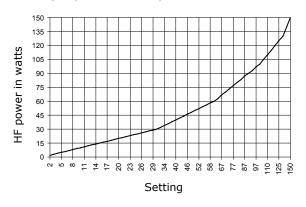
Power setting range: 2 - 150 W at 600Ω

Max. periodic HF output voltage: $8,000 \text{ V}_S$ Fundamental frequency: 833 kHz

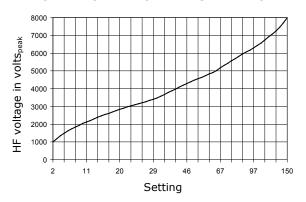
Crest factor at 600 Ω : 9.0

Output curves

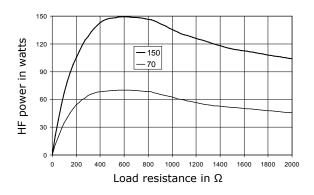
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Air Beam

Air Beam is a high-voltage coagulation current for non-contact surface coagulation using low-penetration sparks. This current allows keeping an extremely large distance between electrode and tissue during application. This applies from the lowest power settings with threshold thermal effect up to the maximum power of 150 W. The purging action of the resulting energy-air flow (spray performance) comes very close to that of an argon beamer ("air beamer").

For contact coagulation, this current is not suitable. If a coagulation current is required that can be used both for contact and for surface coagulation, then the Forced Coag current should be selected.

In the lower and intermediate power range, this current causes whistling noises of not insignificant volume, which may be irritating. This is a physically-caused side effect. All non-contact coagulation currents generate noises, but usually these are in the ultrasound frequency range beyond the perception of the human ear. With increasing power the frequency likewise increases until it is no longer noticeable.



Danger of injury by sparking!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 8,000 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

Because of the extremely high voltage, this current should not be used in endoscopy. For this application, there is the Endo Spray current with significantly lower voltage.

The powerful sparking may cause ignition of combustible substances or mixtures of substances, see section 5.3, page 29.

Do not use this current for indirect contact coagulation via a surgical instrument. There is great danger of arcing.



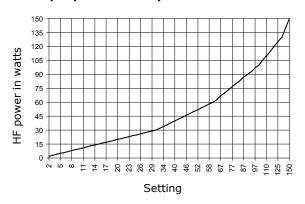
Power setting range: 2 - 150 W at 600Ω

Max. periodic HF output voltage: $8,000 \text{ V}_{\text{S}}$ Fundamental frequency: 833 kHz

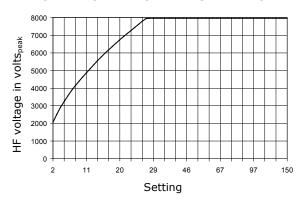
Crest factor at 600 Ω : 20 – 9.0 depending on settings

Output curves

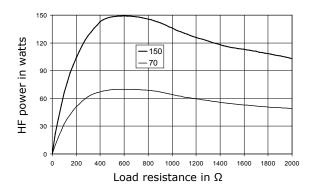
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Endo Spray

Endo Spray is a "gentle" spray current for endoscopically applied surface coagulation. The Endo Spray takes into account the fact that for reasons of design the dielectric strength of endoscopic instruments will generally be lower. This current also allows for the fact, inherent in the application, that in endoscopy leakage currents pose a greater problem.



Danger of injury by sparking!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 4,000 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

The powerful sparking may cause ignition of combustible substances or mixtures of substances, see section 5.3, page 29.

Do not use this current for indirect contact coagulation via a surgical instrument. There is great danger of arcing.



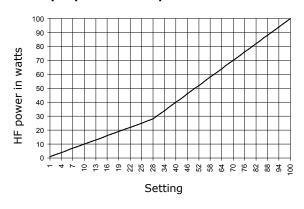
Power setting range: 1 - 100 W at 500 Ω

Max. periodic HF output voltage: $4,000 \text{ V}_{\text{S}}$ Fundamental frequency: 833 kHz

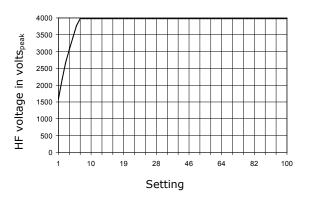
Crest factor at 500 Ω : 18 – 5.4 depending on settings

Output curves

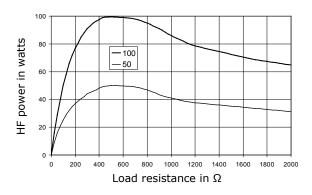
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Duo Prep

If two monopolar patient circuits can be activated simultaneously via independent hand or foot switches, the selected power of the generator feeding the circuits can be split between the two channels. The corresponding technical standard (IEC 60601-2-2) provides this possibility only for coagulation currents allowing contact-free application. To a certain extent such coagulation currents can also be used for tissue preparation.

Duo Prep qualitatively corresponds to the Forced Prep current, with the difference that in addition to individual activation there is also the aforementioned simultaneous activation of the monopolar outputs M1 and M2 possible. This current can be used specifically in cases where one patient is to be operated upon at two different surgical locations at the same time, for example in cardiac surgery (preparation of the crural vein with a low coagulation component and simultaneous preparation of the mammaria in the thoracic area). Activation is done via the blue switches (finger or foot).

If this current is selected for either of the coagulation channels of the M1 or M2 output ports, it will appear also on the parallel channel of the other output port. The power is set to the same value for both channels; upon change of the power of one channel, the value of the other will change to reflect this. If the current of one channel is switched off or replaced by any other, the parallel channel will switch to "single version" Forced Prep.

In case of individual activation of the currents, they behave like the Forced Prep current. In case of synchronous activation, the power is split between the two outputs. Reasonable splitting of the power that allows for simultaneous will, however, work only in non-contact mode.



Risk of injury from inadequate insulation!

In case of indirect application via a hand-held instrument, this should be insulated so as not to expose the surgeon to the HF voltage transmitted directly from the active electrode to the instrument. It must be kept in mind that the surgical glove is no defined electrical insulation for this current, and arcing is indeed likely.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 2,100 V.





Risk of injury from excessive power!

The output power of the active electrodes may change during use, due to switching on or off of the parallel patient output port or unbalanced and varying application conditions!

Technical Data

Output power setting range (sum of both outputs): 5 - 150 W at 400Ω

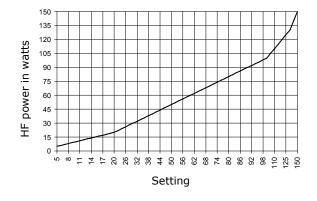
Max. periodic HF output voltage: 2,100 V_S

Fundamental frequency: 735 kHz

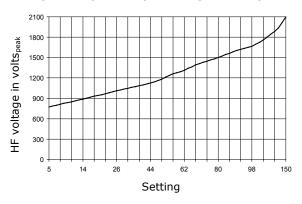
Crest factor at 400 Ω : 3.7

Output curves

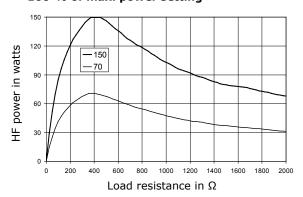
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Duo Spray

If two monopolar patient circuits can be activated simultaneously via independent hand or foot switches, the selected power of the generator feeding the circuits can be split between the two channels. The corresponding technical standard (IEC 60601-2-2) provides this possibility only for coagulation currents allowing contact-free application. To a certain extent such coagulation currents can also be used for tissue preparation.

Duo spray qualitatively corresponds to the Spray current with the difference that in addition to individual activation also simultaneous activation of the monopolar outputs M1 and M2 is possible. This type can be used specifically in cases where one patient is to be operated upon at two different locations at the same time, for example in cardiac surgery (preparation of the crural vein with a very strong coagulation component and simultaneous preparation of the mammaria in the thoracic area). Activation is done via the blue switches (finger or foot).

If this current is selected for either of the coagulation channels of the M1 or M2 outputs, it will appear also on the parallel channel of the other output port. The power is set to the same value for both channels; upon change of the power of one channel, the value of the other will change to reflect this. If the current of one channel is switched off or replaced by any other, the parallel channel will switch to "single version" Spray.

In case of individual activation of the currents, these behave like the Spray current. In case of synchronous activation, the power is split between the two outputs. Reasonable splitting of the power that allows for simultaneous will, however, work only in non-contact mode.



Danger of injury by sparking!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 8,000 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

The powerful sparking may cause ignition of combustible substances or mixtures of substances, see section 5.3, page 29.

Do not use this current for indirect contact coagulation via a surgical instrument. There is great danger of arcing.





Risk of injury from excessive power!

The output powers of the active electrodes may change during use due to switching on or off of the parallel patient output port or unbalanced and varying application conditions!

Technical Data

Output power setting range (sum of both outputs): 2 - 150 W at 600 Ω

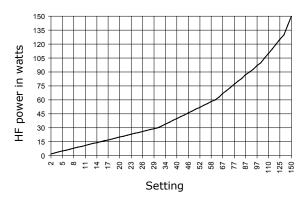
Max. periodic HF output voltage: 8,000 V_S

Fundamental frequency: 833 kHz

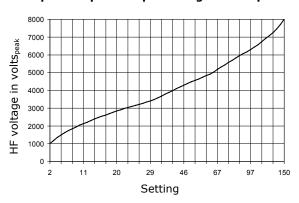
Crest factor at 600 Ω :

Output curves

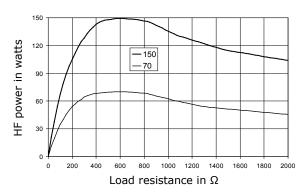
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Argon Beam

Argon Beam is a current for surface coagulation by ionized argon gas for use in open surgery. For use of this current, a maxium[®] Beamer and an MABS applicator are required. If this current is selected and a maxium[®] Beamer connected, the argon gas flow can also be

If this current is selected and a maxium[®] Beamer connected, the argon gas flow can also be selected directly via the user interface of the maxium[®]. The argon gas flow is adjustable from 0.1 – 12 l/min. This current is characterized by its outstanding striking properties and large application distance.

This current can be selected if a maxium[®] Beamer is connected.



Risk of injury from excessive voltage!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 8000 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

Because of the extremely high voltage, this current should not be used in endoscopy. For this application, there is the Argon Endo current with significantly lower voltage.

As electrosurgical accessories, use only the MABS applicators provided by KLS Martin.

The argon beam may cause ignition of combustible substances or mixtures of substances, see section 5.3, page 29.



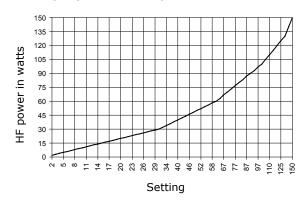
Power setting range: 2 - 150 W at 600Ω

Max. periodic HF output voltage: $8,000 \text{ V}_S$ Fundamental frequency: 833 kHz

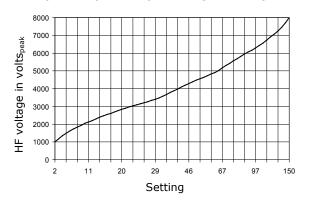
Crest factor at 600 Ω : 9.0

Output curves

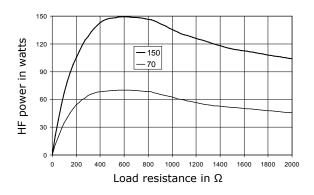
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Endo Argon

Endo Argon is a current for surface coagulation by ionized argon gas for use in endoscopy. For use of this current, a maxium[®] Beamer and an MABS applicator are required. If this current is selected and a maxium[®] Beamer connected, the argon gas flow can also be selected directly via the user interface of the maxium[®].

Endo Argon is tailored to the needs of endoscopic applications. In endoscopic applications it is difficult for the user to maintain a constant distance between the applicator and the tissue. Endo Argon compensates for "distance fluctuations" and prevents a collapse of the argon beam over a wide range. The striking properties of this current are particularly noteworthy.

This current can be selected if a maxium[®] Beamer is connected.



Risk of injury from excessive voltage!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 4,000 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

As electrosurgical accessories, use only the MABS applicators provided by KLS Martin.

The argon beam may cause ignition of combustible substances or mixtures of substances, see section 5.3, page 29.



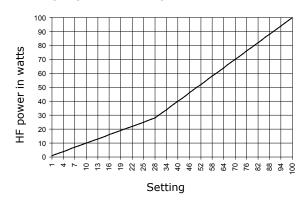
Power setting range: 1 - 100 W at 500 Ω

Max. periodic HF output voltage: $4,000 \text{ V}_{\text{S}}$ Fundamental frequency: 833 kHz

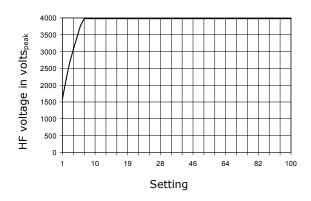
Crest factor at 500 Ω : 18 – 5.4 depending on settings

Output curves

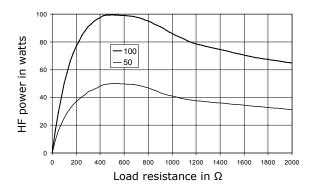
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Pulsed Argon I

Pulsed Argon II

The two currents Pulsed Argon I and Pulsed Argon II correspond to the Pulsed Argon current, with the difference that the HF is emitted not continuously, but in pulsed fashion.

Two currents with different pulse repetition intervals are offered. While Pulsed Argon I provides, through longer pulse intervals, better controllability of the coagulation result at the cost of more time required, Pulsed Argon II allows working faster with shorter pulse intervals.

During argon application, the bright glow of the argon plasma prevents assessment of the thermally induced tissue changes. In order to be able to dose the energy input into the tissue, the user must therefore interrupt the HF output in the conventional manner using a control unit (e.g. foot switch).

The pulsed Argon mode now allows the user to assess the tissue changes in the pulse intervals and continue the application until the desired tissue effect has been reached. The portioned energy input into the tissue which is automated via the Pulse Mode thus supports the so-called "Spot Technique".



Risk of injury from excessive voltage!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 4000 V in order to be able to use the full power. Otherwise the power may be increased only until the output voltage reaches the maximum operating voltage of the accessories, see curve on the next page.

For the special risks posed by high electrical voltages, see section 5.4, page 30.

As electrosurgical accessories, use only the MABS applicators provided by KLS Martin.

The argon beam may cause ignition of combustible substances or mixtures of substances, see section 5.4, page 30.



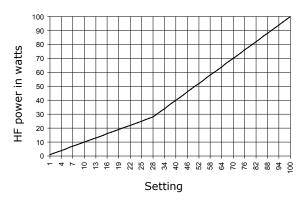
Power setting range: 1 - 100 W at 500 Ω

Max. periodic HF output voltage: $4,000 \text{ V}_{\text{S}}$ Fundamental frequency: 833 kHz

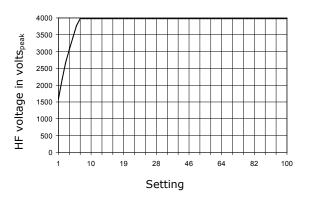
Crest factor at 500 Ω^* : 18 – 5.4 depending on settings

Output curves

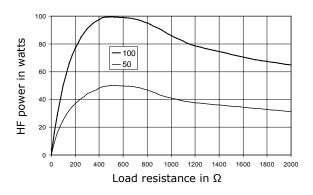
Output power* vs. set power



Repetitive peak output voltage vs. set power



Output power* vs. resistance at 50 % and 100 % of max. power setting



* Within the pulse



11.3 Bipolar Cutting Currents



Bipol Pure Cut

The Bipol Pure Cut current offers the safety benefits of bipolar technology for tissue dissection as well. No stray currents, no leakage currents and no need for a neutral electrode – these are the prime benefits. Bipol Pure Cut provides a smooth cut with a low degree of eschar formation and low hemostasis effect.

NOTICE

For bipolar cutting, special bipolar instruments with asymmetric electrode design are necessary. The commonly used forceps for bipolar coagulation are unsuitable for bipolar cutting.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 350 V.



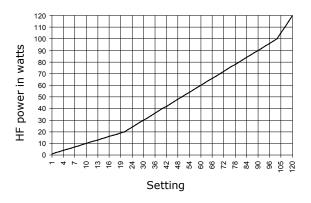
Power setting range: 1 - 120 W at 300 Ω

 $\begin{array}{ll} \text{Max. periodic HF output voltage:} & 350 \text{ V}_{\text{S}} \\ \\ \text{Fundamental frequency:} & 357 \text{ kHz} \end{array}$

Crest factor at 300 Ω : 1.7

Output curves

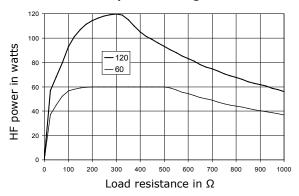
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Bipol Blend Cut

As for the monopolar cutting currents, for the bipolar cutting currents the maxium[®] also provides different hemostasis effects associated with the cutting. The Bipol Blend Cut current achieves a higher degree of eschar formation in the cutting channel than Bipol Pure Cut and thus stronger hemostasis.

NOTICE

For bipolar cutting, special bipolar instruments with asymmetric electrode design are necessary. The commonly used forceps for bipolar coagulation are unsuitable for bipolar cutting.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 500 V.



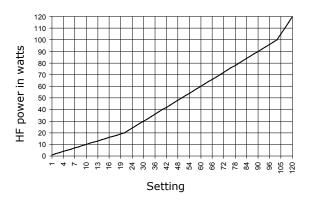
Power setting range: 1 - 120 W at 300 Ω

 $\begin{tabular}{lll} Max. periodic HF output voltage: & 500 V_S \\ \\ Fundamental frequency: & 357 kHz \\ \end{tabular}$

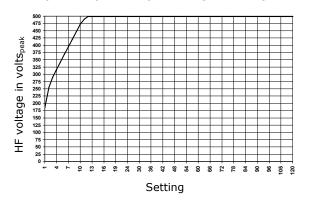
Crest factor at 300 Ω : 2.2

Output curves

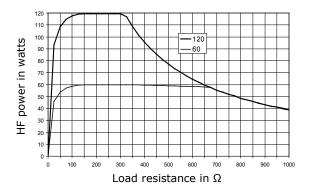
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Forfex

The Forfex bipolar cutting current supports mechanical cutting using scissors. The tissue between the two blades is coagulated by the Forfex current during cutting. Forfex is specifically designed for bipolar scissors, i.e. the mechanical blades of the scissors are maximally conserved by the Forfex current. This results in a long service life of the blades.

In addition to tissue coagulation synchronously with cutting, contact coagulation can also be performed, in which the slightly opened blades touch the location to be coagulated in a flat or point-shaped manner.

NOTICE

Bipolar scissors must not be used with the Bipol Pure Cut or Bipol Blend Cut currents. These currents would quickly blunt the scissors.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 180 V.



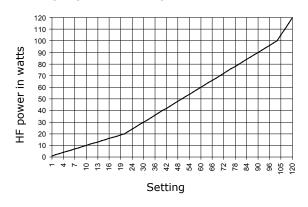
Power setting range: 1 - 120 W at 50 Ω

Max. periodic HF output voltage: $180 \ V_S$ Fundamental frequency: $481 \ kHz$

Crest factor at 50 Ω :

Output curves

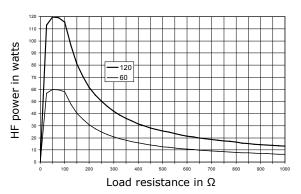
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Uro Bip Pure Cut - with Booster

The bipolar, unmodulated Uro Bip Pure Cut current with booster pulse for the initial support of the cutting process provides a high resection rate during TUR. Uro Bip Pure Cut is therefore particularly suited for TUR-P applications. The booster pulse allows to start cutting without having to press the wire loop of the electrode onto the tissue. It is sufficient to slightly touch the tissue with the electrode. Trimming cuts can also be carried out easily.

The first cut, supported by a sequence of booster pulses (up to 10 booster pulses in rapid succession), is performed within the first second after pressing the foot switch pedal. Within this time span, the electrode must have tissue contact. Otherwise the generator will automatically prevent further energy input into the tissue. A signal sounds. In this case the process must be restarted.

Since this cutting process takes place under saline, which is electrically very conductive, for maintenance of the plasma sheath a minimum electrical power must be present. This is ensured by the selection of the cutting level (G-grades G1 to G5).

The booster pulse builds up the plasma sheath around the wire loop.

NOTICE

Use of the Uro Bip Pure Cut current results in a longer service life of the wire loop than with the use of the Blend Cut current described below.



Danger of injury by operating errors!

In TUR-B-applications, the booster pulse may lead to contraction of the adductors, since the nervus obturatorius is stimulated. This applies in particular to resections in the immediate vicinity of this nerve. In cases where no such stimulation may take place, no current with booster pulse may be used!

Although the initial energy input ends after 10 booster pulses if no plasma sheath has formed, there is no time limit if the plasma disappears again afterwards. As long as the Blend Cut cutting current is enabled, by pressing the foot switch pedal energy is transmitted into the NaCl irrigation fluid and / or the tissue. Therefore, extensive, permanent activation times (e.g. > 5 - 10 s) should be avoided, if no plasma is visible! Continuous irrigation is also necessary!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 450 V.



NOTICE

Make sure you use saline as irrigation fluid. When using any non-conductive irrigation fluid, there will be no cutting effect.

Technical Data

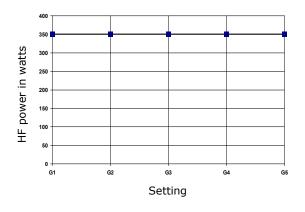
Maximum continuous output power: 350 W at 100 Ω

Max. periodic HF output voltage: 450 V_{S} Fundamental frequency: 379 kHz

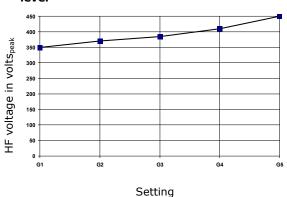
Crest factor at 100 Ω : 1.8

Output curves

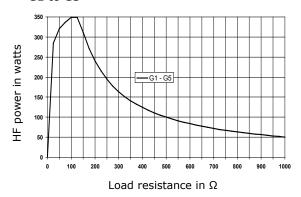
Maximum output power vs. set power level



Repetitive peak output voltage vs. set power level



Output power vs. resistance at power levels G1 to G5







Uro Bip Pure Cut – without Booster

The bipolar, modulated Uro GDP Blend Cut current without booster pulse is especially well suited for TUR-B applications. Stimulation of the nerve obturatorius is not to be expected with this current. Booster pulses are not necessary if smaller TUR loop sizes are used. However, the initial cutting result is slightly decreased.

The first cut must be performed within the first 3 seconds after pressing the foot switch pedal. Within this time span, the electrode must have tissue contact. If this is not the case, no plasma sheath can be formed around the loop, and the generator will automatically suppress further energy input into the tissue. A signal sounds. In this case the process must be restarted.

Since this cutting process takes place under saline, which is electrically very conductive, for maintenance of the plasma sheath a minimum electrical power must be present. This is ensured by the selection of the cutting level (G-grades G1 to G5).



Danger of injury by operating errors!

Although the initial energy supply ends after 3 booster pulses if no plasma sheath has formed, there is no time limit if the plasma then disappears again. As long as the Pure Cut cutting current is active, by pressing the foot switch pedal energy is transmitted into the NaCl irrigation fluid and / or the tissue. The irrigation fluid may be strongly heated. Therefore, extensive, permanent activation times (e.g. > 5 - 10 s) should be avoided, if no plasma is visible! Continuous irrigation is also necessary!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 450 V.

NOTICE

Make sure you use saline as irrigation fluid. When using any non-conductive irrigation fluid, there will be no cutting effect.



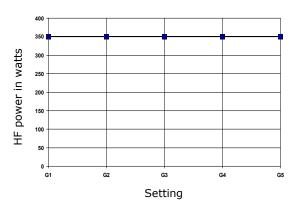
Maximum continuous output power: 350 W at 100 Ω

Max. periodic HF output voltage: 450 V_{S} Fundamental frequency: 379 kHz

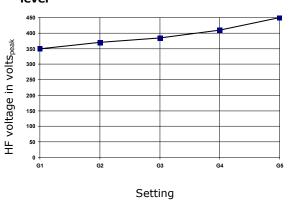
Crest factor at 100 Ω : 1.8

Output curves

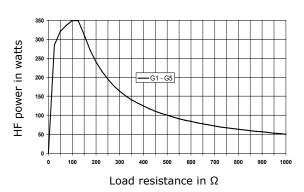
Maximum output power vs. set power level



Repetitive peak output voltage vs. set power level



Output power vs. resistance at power levels G1 to G5







Uro Bip Blend Cut - with Booster

The bipolar, modulated Uro Blend Pure Cut current with booster pulse for the initial support of the cutting process provides a high resection rate during TUR. Uro Bip Blend Cut is therefore particularly well suited for TUR-P applications. The booster pulse allows to start cutting without having to press the wire loop of the electrode onto the tissue. It is sufficient to slightly touch the tissue with the electrode. Trimming cuts can also be carried out easily.

The first cut, supported by a sequence of booster pulses (up to 10 booster pulses in rapid succession), is performed within the first second after pressing the foot switch pedal. Within this time span, the electrode must have tissue contact. Otherwise the generator will automatically prevent further energy input into the tissue. A signal sounds. In this case the process must be restarted.

The Uro Bip Blend Cut resection current offers stronger hemostatic effects during the cutting. Thanks to the characteristics of the current, there is little wear of the wire loop during the cutting process. The degree of wear of the electrode is higher with the Blend Cut than with the Pure Cut resection current. Therefore a reduced service life of the electrode loop is to be expected if this current is used.

Since this cutting process takes place under saline, which is electrically very conductive, for maintenance of the plasma sheath a minimum electrical power must be present. This is ensured by the selection of the cutting level (G-grades G1 to G5).

The booster pulse builds up the plasma sheath around the wire loop.



Danger of injury by operating errors!

In TUR-B-applications, the booster pulse may lead to contraction of the adductors, since the nervus obturatorius is stimulated. This applies in particular to resections in the immediate vicinity of this nerve. In cases where no such stimulation may take place, no current with booster pulse may be used!

Although the initial energy input ends after 10 booster pulses if no plasma sheath has formed, there is no time limit if the plasma disappears again afterwards. As long as the Blend Cut cutting current is enabled, by pressing the foot switch pedal energy is transmitted into the NaCl irrigation fluid and / or the tissue. Therefore, extensive, permanent activation times (e.g. > 5 - 10 s) should be avoided, if no plasma is visible! Continuous irrigation is also necessary!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 460 V.



NOTICE

Make sure you use saline as irrigation fluid. When using any non-conductive irrigation fluid, there will be no cutting effect.

Technical Data

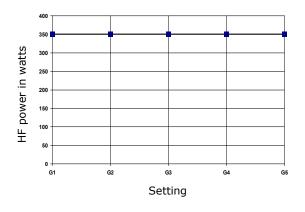
Maximum continuous output power: 350 W at 100 Ω

Max. periodic HF output voltage: 460 V_{S} Fundamental frequency: 379 kHz

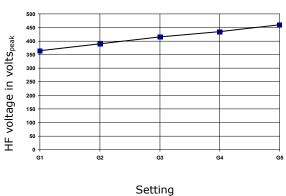
Crest factor at 100 Ω : 2.3

Output curves

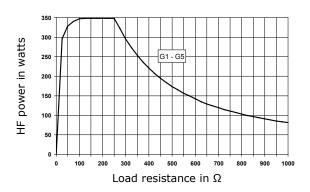
Maximum output power vs. set power level



Repetitive peak output voltage vs. set power level



Output power vs. resistance at power levels G1 to G5







Uro Bip Blend Cut - without Booster

The bipolar, modulated Uro Bip Blend Cut current without booster pulse is especially well suited for TUR-B applications. With this current, stimulation of the nerve obturatorius is not to be expected. Booster pulses are not necessary if smaller TUR loop sizes are used. The initial cutting result is slightly reduced, however, especially if the Blend Cut current is used.

The first cut must be performed within the first 3 seconds after pressing the foot switch pedal. Within this time span, the electrode must have tissue contact. If this is not the case, no plasma sheath can be formed around the loop, and the generator will automatically suppress further energy input into the tissue. A signal sounds. In this case the process must be restarted.

Since this cutting process takes place under saline, which is electrically very conductive, for maintenance of the plasma sheath a minimum electrical power must be present. This is ensured by the selection of the cutting level (G-grades G1 to G5).



Danger of injury by operating errors!

Although the initial energy supply ends after 3 booster pulses if no plasma sheath has formed, there is no time limit if the plasma then disappears again. As long as the cutting current Blend Cut is enabled, by pressing the foot switch pedal energy is transmitted into the NaCl irrigation fluid and / or the tissue. The irrigation fluid may be strongly heated. Therefore, extensive, permanent activation times (e.g. > 5 - 10 s) should be avoided, if no plasma is visible! Continuous irrigation is also necessary!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 460 V.

NOTICE

Make sure you use saline as irrigation fluid. When using any non-conductive irrigation fluid, there will be no cutting effect.



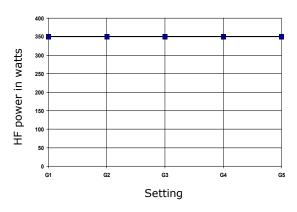
Maximum continuous output power: 350 W at 50 Ω

Max. periodic HF output voltage: 460 V_{S} Fundamental frequency: 379 kHz

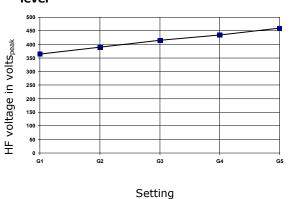
Crest factor at 100Ω : 2.3

Output curves

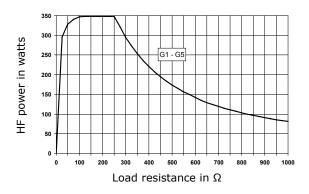
Maximum output power vs. set power level



Repetitive peak output voltage vs. set power level



Output power vs. resistance at power levels G1 to G5





11.4 Bipolar Coagulation Currents



Micro Coag



Micro Auto Stop



Micro Auto Start



Auto Micro

Bipolar coagulation currents for bipolar microsurgical instruments.

The Micro Coag current is available without automatics, with automatic start, with automatic stop, or with both automatic functions. For further information, refer to section 9.7 "Automatic Functions of Bipolar Coagulation", page 70. This currents takes into account the tissue- and instrument-specific circumstances of microsurgical applications. Voltage, current, and impedance matching will be automatically adapted to the respective situation.

The start delay for **Auto Start** and the coagulation degree for **Auto Stop** can be selected in the **Setup** menu, see section 10.6.5 "Parameters for coagulation automatics", page 92.



Danger of injury by operating errors!

The auto-start function must not be used in endoscopy. For safety reasons, currents with auto-start function are subject to some restrictions. For further information, refer to section 9.7, page 70, and section 5.7.1, page 34.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 160 V.



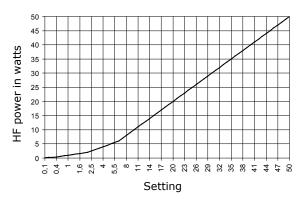
Power setting range: 0.1 - 50 W at 100Ω

Max. periodic HF output voltage: 160 V_{S} Fundamental frequency: 403 kHz

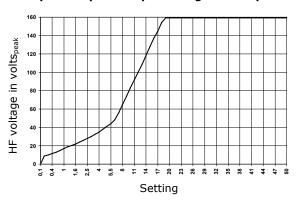
Crest factor at 50 Ω :

Output curves

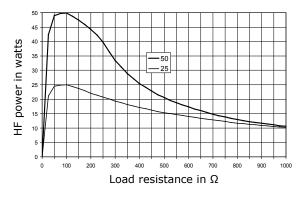
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Macro Coag



Macro Auto Stop



Macro Auto Start



Auto Macro

Macro Coag is a standard current for open surgery and laparoscopy with bipolar forceps. Macro Coag can be selected without automatics, with automatic start, with automatic stop or with both automatic functions; for further information, refer to section 9.7 "Automatic Functions of Bipolar Coagulation", page 70. The current is designed for relatively large-area forceps and operates, inter alia, the so-called jaw-insert Hirsch forceps, the Maryland dissector or the Kleppinger electrode. HF voltage adaptation to the typically used instruments largely prevents tissue carbonization and adhesion of coagulated tissue to forceps branches. The user determines the degree of coagulation primarily by the time of activation via the foot switch.

Basically, under the condition that the same amount of HF energy is required the following apply:

- Low penetration:
 Short application time and correspondingly high HF output power
- Deep penetration:
 Long application time and correspondingly low HF output power

The start delay for Auto Start and the coagulation degree for Auto Stop can be selected in the **Setup** menu, see section 10.6.5 "Parameters for coagulation automatics", page 92.



Danger of injury by operating errors!

The auto-start function must not be used in endoscopy. For safety reasons, currents with auto-start function are subject to some restrictions. For further information, refer to section 9.7, page 70, and section 5.7.1, page 34.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 180 V.



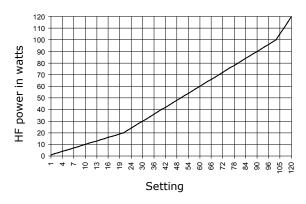
Power setting range: 1 - 120 W at 50 Ω

Max. periodic HF output voltage: $180 \ V_S$ Fundamental frequency: $481 \ kHz$

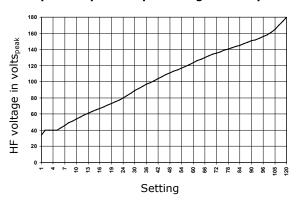
Crest factor at 50 Ω :

Output curves

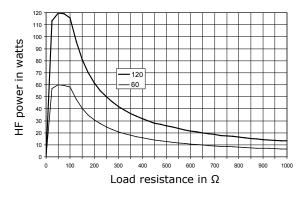
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting







Neptun



Neptun Auto Start

Neptun is a bipolar type of current for fluid-assisted HF coagulation (EHT method = electrohydrothermosation).

Preferentially, isotonic saline solution is fed to the instrument tip through the flushing channel(s) of a bipolar instrument and dropwise applied to the tissue to be coagulated. When the electrodes come into contact with the tissue, only a small amount of HF current flows through the tissue itself; the larger amount of HF energy heats the electrically conductive saline solution. The coagulation effect is based on the liquid thus caused to boil. The resulting temperature is limited to the boiling temperature of water (approx. $100\,^{\circ}\text{C}$), which avoids carbonation of the tissue. A large amount of energy is used for the vaporization of flushing liquid. Thus an output of $120\,-\,180$ watts must be set for the generator, depending on the supplied amount of liquid and the selected electrode size.

This method has been tried and tested particularly in the field of parenchyma surgery (liver, spleen, kidney). However, it can also be beneficial in other applications in visceral surgery or neurosurgery.

The supply of liquid before coagulation allows the origin of the bleeding to be localized more easily. Bleeding tissue is not carbonated and the traumatized wound area is smaller.

No coagulated tissue can stick to the active HF electrode, and therefore the inherent risk of initiating secondary bleedings is avoided.

This type of current can also be applied without supply of liquid. In this case, the generator output must be adjusted to 40 - 60 watts.

NOTICE

Risk of property damage!

When putting the instrument down in auto-start mode, ensure that the instrument tip does not come into contact with a cloth soaked in liquid.



Risk of injury!

- For laparoscopic / endoscopic applications, the instrument may not be used in auto-start mode.
- Arcing can occur in case of bipolar electrodes arranged in relative close vicinity. Arcing
 can occur especially when lifting up the instrument while a current or the generator is
 active and there is no contact to tissue / liquid.



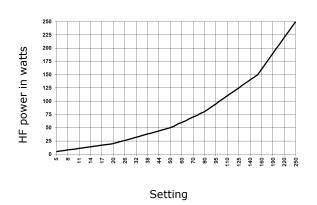
Power setting range: 5 - 250 W at 50Ω

Max. periodic HF output voltage: $235 V_s$ Fundamental frequency: 481 kHz

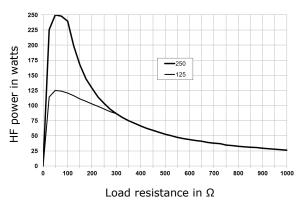
Crest factor at 50 Ω : 1.8

Output curves

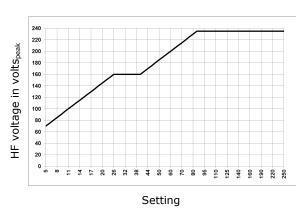
Output power vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting



Repetitive peak output voltage vs. set power







SealSafe

SealSafe $^{\$}$ is a bipolar current for laparoscopic and open-surgery sealing of vessels and tissue bundles. The method is described in section 4.3.3 "Sealing using SealSafe $^{\$}$ ", page 18, in general terms.

A marSeal instrument or a bipolar clamp of the marClamp[®] series is to be used. marSeal instruments allow central cutting of the sealing area and can be used in laparascopy and open surgery. marClamp[®] is a series of bipolar clamps which likewise provide the necessary defined pressure like the marSeal instruments. The SealSafe[®] method has been tested and approved only with the instruments listed above.

NOTICE

This current is designed specifically for the marSeal and marClamp[®] instruments, and reproducible sealing results are therefore guaranteed only with these.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 180 V.



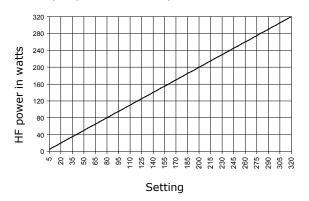
Power setting range: 5 - 320 W at 25Ω

Max. periodic HF output voltage: 180 V_{S} Fundamental frequency: 521 kHz

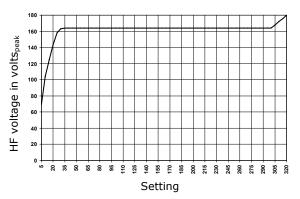
Crest factor* at 25 Ω : 1.9

Output curves

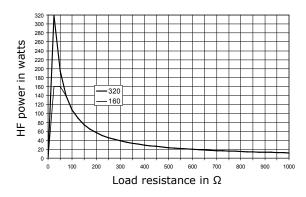
Output power* vs. set power



Repetitive peak output voltage vs. set power



Output power* vs. resistance at 50 % and 100 % of max. power setting



* Within the activation phase





SealSafe[®] IQ

SealSafe[®] IQ is a bipolar current for laparoscopic and open-surgery sealing of vessels and tissue bundles. The method and the handling of these instruments are described in section 4.3.3 "Sealing using SealSafe[®] / SealSafe[®] IQ", page 18, in general terms.

For this current, a marClamp[®] IQ or a marSeal IQ-instrument is required.

marSeal instruments allow central cutting of the sealing area and can be used in laparascopy and open surgery. marClamp[®] IQ is a series of bipolar clamps which likewise provide the necessary defined pressure like the marSeal IQ instruments. The SealSafe[®] IQ method has been tested and approved only with the instruments listed above.

NOTICE

This current is designed specifically for the marSeal IQ and marClamp[®] IQ instruments, and reproducible sealing results are therefore guaranteed only with these.

Active accessories to be used with this current must be able to withstand an HF voltage of at least 200 V.



Technical Data

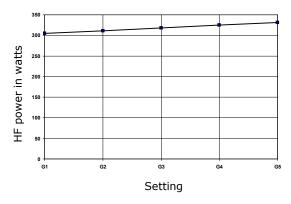
Power setting range: 5 - 320 W at 25Ω

 $\begin{array}{ll} \text{Max. periodic HF output voltage:} & 200 \text{ V}_{\text{S}} \\ \\ \text{Fundamental frequency:} & 521 \text{ kHz} \end{array}$

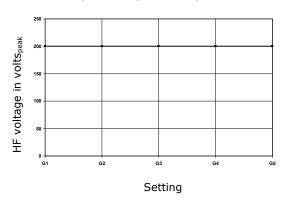
Crest factor* at 25 Ω : 1.9

Output curves

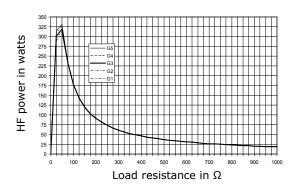
Output power* vs. set power



Peak output voltage vs. set power



Output power* vs. resistance



* Within the activation phase





Bipol TUR Coag

This current is non-modulated with limitation of the output voltage for avoidance of spark formation between electrode and tissue. In contrast to the "contactless" currents which are used by default for monopolar TUR-applications, Bipol TUR Coag is a genuine contact current. For hemostasis applications, the bleeding tissue must be touched directly with the electrode loop as long as the HF current is active. If the electrode has no contact with the tissue, the entire energy flows into the NaCl solution. This causes no hemostasis, but only heats the irrigation fluid. The Bipol TUR coagulation current offers a maximum output power of 120 W. We recommend 120 W for TUR-P and about 100 W for TUR-B applications.

The specific contact coagulation, where the electrode loop is used not just for a point-to-point contact but moved repeatedly over a wider tissue area, causes deposition of a "tissue layer" on the surface of the electrode loop. As such layers have insulating effects, they may even prevent further energy transmission into the tissue. In such cases, it helps to immerse the wire loop into the saline solution without tissue contact and briefly activate the cutting current. The cutting current will remove such layers immediately.



Danger of injury by operating errors!

As long as the Bipol TUR coagulation current is enabled, by pressing the foot switch pedal energy is transmitted into the NaCl irrigation fluid and / or the tissue. The irrigation fluid may be strongly heated. Therefore, extensive, permanent activation times (e.g. > 5 - 10 s) should be avoided, if no plasma is visible! Continuous irrigation is also necessary!

Active accessories to be used with this current must be able to withstand an HF voltage of at least 140 V.

NOTICE

Make sure you use saline as irrigation fluid. When using any non-conductive irrigation fluid, there will be no cutting effect.



Technical Data

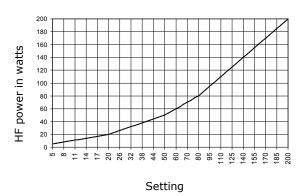
Power setting range: 5 - 200 W at 25Ω

Max. periodic HF output voltage: $140 \ V_S$ Fundamental frequency: $521 \ kHz$

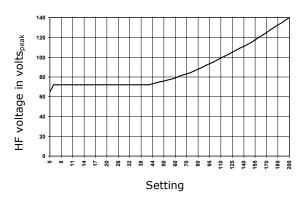
Crest factor at 25 Ω : 1.9

Output curves

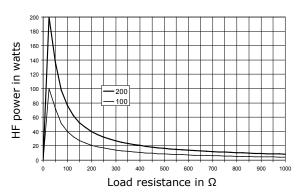
Output power vs. set power



Repetitive peak output voltage vs. set power



Output power vs. resistance at 50 % and 100 % of max. power setting





12 Cleaning and Disinfection

The responsibility for cleaning and disinfection lies with the operator/user of the product. Be sure to observe your local cleaning and hygiene regulations!



Danger of serious injury when using defective accessories!

Using a unit that is not in perfect working order or using defective accessories can pose a hazard to patients or users and compromise the proper functioning of the device.

- Be sure to maintain the unit and its accessories in perfect operating condition.
- Perform a visual inspection and check the system for insulation damage, cleanliness and integrity.
- A unit or accessories found to be unfit for use must be withdrawn from service.
- Never sterilize the unit!
- Always disconnect the unit from the supply before cleaning and disinfecting it.
- No liquid must be allowed to enter the unit. Therefore clean and disinfect it with care. Do not use sprays!
- Never clean the unit with abrasive cleaners, disinfectants or solvents that could scratch the housing or damage the device in other ways.
- For surface cleaning and surface disinfection, use the procedure recommended by your hospital or use another nationally recognized and approved method.
- When disinfecting accessories (by surface disinfection or immersion), be sure to observe
 the instructions of the manufacturer of the disinfectant regarding material compatibility,
 dosage and exposure time.
- Accessories not suitable for sterilization, such as the foot switch, must be cleaned with a disinfecting detergent.
- All disinfectant residues must be completely removed before putting the unit in operation.
- If accessories must be disinfected or sterilized, be sure to observe the respective Instructions for Use.



13 Messages of the Unit

The top line of the screen text can display texts indicating operating or error conditions. Below, the messages are explained which help the user to determine the current status of the unit or perform to troubleshooting. All other messages are described in the maxium[®] Service Manual.

13.1 Messages during Self-Test

After switching on, the unit displays the startup screen. If the unit remains in the starting phase and any of the following messages appears, then proceed as described.

Message	Description
Self-test: "Cut" foot switch engaged upon startup! Self-test: "Coag" foot switch engaged upon startup! Self-test: Universal foot switch engaged upon startup! Self-test: Backup foot switch engaged upon startup!	The unit expects that during the self-test no activation element is engaged. If during self-test is a foot switch is actuated, the unit will notice this. Check whether the cable is wrapped around the foot switch so that the pedal is actuated. Turn the unit off and then on again. If the message appears again, disconnect the foot switch from the unit and turn the latter off and on again. If the self-test is now completed successfully, the circuit of the instrument is shorted, otherwise there is a malfunction.
Self-test: "Cut" finger switch before startup! (Cable?) Self-test: "Coag" finger switch before startup! (Cable?)	The unit expects that during the self-test no activation element is engaged. If during the self-test is a finger switch is actuated, the unit will notice this. Turn the unit off and then on again. If the message appears again, disconnect the instrument from the unit and turn the latter off and on again. If the self-test is now completed successfully, the circuit of the instrument is shorted, otherwise there is a malfunction.
Self-test: Pressed or stuck key during system start!	The unit expects that during the self-test no activation element is engaged, otherwise the self-test will end with an error. Turn the unit off and then on again. If the self-test is again not completed successfully, there is a malfunction.
Self-test: Rotary switch active during system start!	The unit expects that during the self-test no control element is engaged. The unit detects the movement of the rotary switch during the self-test. Turn the unit off and then on again. If the self-test is again not completed successfully, there is a malfunction.



Message	Description
Unplug bipolar instrument from B1 during self-test!	The unit expects that during the self-test there is no tissue contact. If during the self-test tissue contact is established with the instrument connected on P1/P2, which may already
Unplug bipolar instrument from B2 during self-test!	with the instrument connected on B1/B2, which may already be positioned on or in the patient, the unit will notice this.
	Disconnect the instrument from port B1/B2.
	If the unit continues the self-test, then connect the instrument again. Check whether tissue contact is really plausible or whether there is rather a short circuit within the instrument. If the unit remains in self-test mode and does not proceed beyond it after switching off and on again either, then there is a malfunction in the unit.
Restart after interruption of mains power	The appearance of this message during self-test informs the user that the unit has been disconnected from the grid without having been regular turned off at the power switch before, and is now starting up again after return of the grid power. Here it will not go directly into operation readiness but enter a standby mode, and the user will be prompted to confirm or correct the default settings of the loaded program. This is to prevent the settings of the unit from being changed by a temporary power failure without the user noticing.



13.2 Messages in Case of Activation Errors

If upon actuation of a foot switch, a finger switch on the instrument or, in case of a bipolar coagulation current with automatic activation upon tissue contact, no activation of the HF current takes place and instead one of the messages listed below appears, then carry out the measures described.

First assign double foot switch CUT to a channel!

First assign double foot switch COAG to a channel!

First assign a channel to the single foot switch!

This channel must be selected first: No activation!

Conflicting activation actions \rightarrow HF interrupted!

Connection error on monopolar channel M1: Please swap the connections!

Connection error on monopolar channel M2: Please swap the connections!

Caution: Instrument has tissue contact, no activation!

Bipolar instrument has tissue contact...

No activation due to error of the neutral electrode!

Single-piece NE is prohibited by Setup, hence NE error!

The actuated foot switch has not been assigned to any channel of the current program yet.

Assignment the foot switch as described in section 10.3.3, page 76.

If upon actuation of a foot switch no effect on the instrument is perceptible although the activation sound is heard, then verify that the foot switch is assigned to the desired channel.

There was an attempt to activate a deselected channel. Is activability is intended, first the channel must be selected by pressing the channel selection key so that its settings appear on the screen, see section 10.2, page 73.

Both pedals of the foot switch were actuated at the same time. Simultaneous activation of both finger switches of a monopolar instrument triggers the SWAP mode.

A monopolar instrument was activated via foot switch, which is connected to the port output M1 or M2 via a single 4-mm connector. This plug is not connected to the leftmost 4-mm socket but to one of the sockets on its right, see section 6.2.1, page 40.

Unplug the 4-mm connector and insert it into the leftmost socket; for the m-version this is the inner conductor of the 13-mm coaxial socket.

This message appears when on a bipolar channel a coagulation current with auto-start function is selected while the instrument already has tissue contact. Automatic activation upon tissue contact is possible only after the instrument has been separated from the tissue and brought into contact again.

The bipolar auto-start / auto-stop function shows this message after activation has been stopped automatically. For reactivation, tissue contact must be interrupted and established again.

It was attempted to activate a monopolar current although the neutral electrode monitor shows no correct attachment and the status light next to the socket flashes red, see section 9.5, page 67.

The unit has detected connection of a single-piece neutral electrode, although this in not permissible in accordance with the change of the setting in the **Setup** menu. Activation of monopolar power is not possible in this fashion. If the unit is to be used (again) with single-piece electrodes, the setting must be reverted in the Setup menu, see section 10.6.4, page 91.



13.3 Input Feedback

The $maxium^{\$}$ will not accept illegal input or settings. A message will appear. In order to resolve the conflict, proceed as described in the table.

Message	Description
Currently no matching current is selected in the main menu!	In the menu for the parameters of the coagulation automatic (see section 10.6.5, page 92), an attempt was made to change a parameter for a current which does not exist on the main level, so that logical mapping of the parameter is not possible.
Current disabled because of 4 kVp voltage limitation (Setup)	An attempt was made to select a monopolar current with a maximum HF output voltage of more than 4,000 V which was excluded by a setting in the Service menu. For changing this, see the maxium [®] Service Manual.
This current is not available for Baby NE	An attempt was made to select a monopolar current excluded by the setting "Baby NE" in the Setup menu, see section 10.6.4, page 91.
Single-piece NE is prohibited by Setup, hence NE error!	The unit has detected connection of a single-piece neutral electrode, although this in not permissible in accordance with the change of the setting in the Setup menu. Activation of monopolar power is not possible in this fashion. If the unit is to be used (again) with single-piece electrodes, the setting must be reverted in the Setup menu, see section 10.6.4, page 91.
The incompatible current on the same output port was disabled	The alternating activation of bipolar cutting current and bipolar coagulation current with automatic function on the same output is not possible. Either current can be selected. Selection of one current will, however, automatically lead to deselection of the other.
This channel is not available due to the configuration.	A bipolar instrument with instrument detection is connected to the output port of this channel. This prevents the automatically selected channel from being deselected, and selection of the other channel is rejected.
The current does not match this instrument type	A bipolar instrument with instrument detection is connected to the output port of this channel. This prevents the automatically selected channel from being replaced by another, and selection of the other channel is rejected.



13.4 Messages in Connection with Programs

The $maxium^{\$}$ will not accept illegal input or settings. A message will appear. In order to resolve the conflict, proceed as described in the table.

Message	Description	
The base program cannot be overwritten! The base program cannot be deleted!	The base program is designed as an immutable program to serve as the basis for own programs which can then be saved under their own names.	
The sace program cannot be deficient.	In the Service menu it is possible to change the settings of the base program, see the maxium [®] Service Manual.	
Program name already exists! Overwrite?	This query is intended to prevent the user from accidentally overwriting a program.	
Program memory full, first delete a program!	Up to 100 programs can be stored in the maxium [®] . This message indicates that the capacity of the memory has been reached. It is necessary to delete programs first before new ones can be stored.	
Current program may not be its own SWAP partner	An attempt was made to establish a SWAP connection of a program with itself. Such a connection is pointless. Possibly adaptation of the parameters of one of the programs was forgotten.	
A locked program cannot be deleted. A locked program cannot be overwritten.	Before a program can be changed or deleted, it must be unlocked. This can be done only via the Service menu, see the maxium [®] Service Manual.	
Program name already exists in one of the foreign languages!	If for a new program a name is selected which already exists as a program name in another language, a logical problem may arise, which is why such names are not allowed.	



13.5 Messages from the Argon Beamer and the Fume Suction System

The MB 402 argon beamer and the marVAC $^{\rm @}$ fume suction system can display malfunctions and status messages on the screen of the ME 402.

Message	Description
Argon Beamer warning: Underdosage	Argon gas flow lower than specified. May be due to a constricted hose or a too high set-point value for a small hose.
Argon Beamer warning: Argon inlet pressure too low	The inlet pressure at the gas inlet of the MB 402 is too low. Possibly opening the angle valve at the gas cylinder has been forgotten, or the cylinder may be empty, which can be read on the gauge of the pressure reducer.
Argon Beamer warning: Obstruction	No or only very low argon gas flow. May be due to a kinked hose or, for applicators with a very small outlet, obstruction of the nozzle by encrustrations.
Argon Beamer warning: Argon cylinder empty	Replace cylinder, the required residual pressure for replacement of the cylinder is reached. The pressurized cylinder must not be emptied completely.
Argon Beamer warning: Low argon reserve	This warning appears if the residual pressure of the gas cylinder drops below 30 bar. It is intended to inform the user that the argon reserve is running low.
Argon Beamer E52: Inlet pressure too high!	The pressure at the gas inlet of the MB 402 is higher than 4.5 bar.
	If the unit is supplied via a MABS pressure reducer, the reason for the failure may be warming of the gas volume trapped in the pressure reducer. Disconnect hose from the pressure reducer to the MB 402 and reconnect it to allow some gas to escape. If the pressure is still too high, then there is the pressure reducer is malfunctioning.
	In case of central gas supply, the working pressure may be too high. In this case, an intermediary pressure reducer must be used.
Argon Beamer E75: Purge key during power-on test!	During the self-test, the Purge key on the MB 402 was actuated. Turn the device combination off and then on again. If the message appears again, then the MB 402 is malfunctioning.
The fume filter is missing or not properly inserted!	The marVAC® fume suction system reports absence or improper seating of the filter. Check that the filter is present and fully inserted.
Argon Beamer E55-59: Offset failure	The pressure sensors of the maxium [®] Beamer are sensitive to temperature changes. If the beamer is moved from a very cold to a warm environment, due to the resulting temperature gradient the self-test may not be passed. Allow the maxium [®] Beamer to warm up for half an hour with
	the unit switched on. If the self-test is again not completed successfully, there is a malfunction.



13.6 System Errors

Below, a number of messages are listed which the user can take care of on his own if necessary.

Message	Description
Overtemperature: Power output interrupted!	The HF generator is overheated from high power output over a longer period and needs a few minutes to cool down. As soon as the text message disappears, re-activation is possible. If this message is displayed after moderate power output a well, the unit should be checked.
B1: Unknown bipol instrument connected! Code: xx B2: Unknown bipol instrument connected! Code: xx	The bipolar instrument detection reads an unknown instrument code and cannot support this instrument. It may be a new instrument which is not known to the installed software yet. In this case a software update will be necessary. If it is an instrument which was always detected before, then connect the instrument to the other Bipolar Output. If it is detected correctly there, then there is a malfunction in the unit, otherwise the instrument itself is defective.
Error 285: Board scan failed – please restart system!	There was an error in the detection of the hardware configuration during self-test. Turn the unit off and then on again. If the message appears again, then there is a malfunction in the unit.
Error 298: Unit massively too cold, please switch off for 1 h!	The unit is or was located in a cold environment. If is set up in a much warmer environment, then there is the risk of condensation inside the unit and thus an electrical safety risk. The unit may be put back into operation only after the condensate has been completely evaporated.



14 Replacement Parts and Accessories

Name	Item no.
maxium [®] , m-Version	80-042-00-04
maxium [®] , i-Version	80-042-02-04
maxium [®] , e-Version	80-042-04-04
Instructions for Use for maxium®	90-169-52-80
Bipolar TUR	80-093-00-04
maxium [®] Beamer	80-044-00-04
Connecting cables from the maxium® Beamer to the maxium®	08-041-00-60
Maxium® Cart II	80-047-00-04
Instructions for Use for maxium® Cart II	90-329-58-10
double-pedal foot switch	80-821-04-04
double-pedal foot switch	80-825-30-04
double-pedal foot switch with SWAP mode	80-821-03-04
Connecting cable with potential equalization	80-260-50-04
Micro filter	80-181-90-04
Bipolar port expander, m-version	80-790-00-04
Bipolar port expander, i-version	80-790-01-04
Bipolar port expander, e-version	80-790-02-04
Ball stud	08-063-00-18
Mounting bracket for mounting on support arm system	08-022-00-18
Integration OR1 [™]	80-093-01-04
Interface Control Set by Karl Storz	200 905-01
maxium Module Set by Karl Storz	200 912-90
MCB connection cable	80-091-01-04
MarVAC® fume suction system with LAP mode	80-061-00-04/-10



15 Technical Specification

15.1 Technical Specifications of the maxium®

The maxium® is a microprocessor-controlled electrosurgery unit for interdisciplinary use. The maxium® conforms to the latest state of the art and offers a high degree of safety.

The maxium® is characterized, among other things, by the following features:

- Ergonomically designed user interface ("Quick Step" control)
- Clear 8.4" screen
- 99 individual memory slots + 1 base program
- More than 40 currents for all disciplines
- High cost-efficiency
- Coverage of all disciplines with a single unit configuration
- Two monopolar and two bipolar output ports
- Monopolar arc-free cutting up to max. 360 W
- Bipolar cutting with bipolar marCut[®] scissors and Forfex current
- Bipolar coagulation with automatic functions
- PCS Patient Control System with NE indicator guarantees NE monitoring with top safety standard
- Function Baby NE for safe work in infant surgery
- Various socket modules (m-, i-, e-version)
- "Night View" socket illumination
- Argon plasma coagulation with maxium® Beamer
- Combination with maxium® Cart II for equipment
- Future-oriented system, updatable and upgradeable
- Fractionated currents for endoscopy
- Bipolar SealSafe® and SealSafe® IQ Vessel Sealing System for applications in endoscopy and open surgery
- Currents for bipolar TUR (option)
- Integration into the intelligent operation system OR1[™] NEO by Karl Storz (option)
- SWAP mode Program change using double-pedal foot switch with SWAP mode or electrode handle with 2 finger switches
- Connection of encoded instruments (IQ-Plug and Play)
- Bidirectional communication with the marVAC® fume suction system
- Connection of 4 bipolar instruments using bipolar port expanders



15.2 Technical Data for maxium®

Description	maxium [®] Data		
Mains connection	100 - 240 V ± 10 %; 50 / 60 Hz		
Mains power	max. 6.3 A		
Mains fuse	6.3 A		
Power consumption	without HF output 40 VA at maximum output power 600 VA		
Output power	Maximum cutting power 360 W Maximum coagulation power 320 W		
Protection class	I		
Classification acc. to Medical Devices Act	II b		
Leakage currents LF and HF	according to IEC 60601-1 and I	EC 60601-2-2	
Type (Application Part)	CF; defibrillation-proof		
Operating mode	Intermittent INT 10 s / 30 s cor	r. to 25 % du	ty factor
Unit fuses	2 × T 6.3 AH, 250 V, Type G 5 × 20 mm		
Signal level	HF display: 55 dB(A); adjustable 45 – 60 dB Alarm: 65 dB(A)		
Weight	8.3 kg		
Radio interference suppression	The maxium [®] meets the requirements of IEC 60601-1-2 also in conjunction with the argon beamer, but with the restrictions pursuant to IEC 60601-2-2 Section 202.6.1 only during operation readiness.		
Dimensions	Width 390 mm Height 182 mm Depth 435 mm		
Environmental conditions for transport and storage	Ambient temperature $-25 ^{\circ}\text{C}$ to $+70 ^{\circ}\text{C}$ (-13 $^{\circ}\text{F}$ to $+158 ^{\circ}\text{F}$) Relative humidity $10 - 100 ^{\circ}\text{M}$ Air pressure $500 - 1,060 \text{hPa}$, ,
Environmental conditions for operation	Ambient temperature Relative humidity Air pressure	+10 °C to +6 30 - 75 % 700 - 1,060	40°C (50°F to +104°F) hPa
C € 0297	Compliant with 93/42/EEC		

The technical data for the individual currents are to be found in the description of the individual currents in section 11 "Currents, their Properties and Technical Data", page 102.



When the baby neutral electrode is selected, only the following currents with the maximum powers listed are permitted:

Monopolar cutting currents	Monopolar coagulation currents	
Pure Cut up to 30 W	Contact Coag up to 30 W	
Soft Cut up to 30 W	Clamp Coag up to 30 W	
Blend Cut up to 30 W	Forced Clamp up to 30 W	
Super Blend up to 30 W	Forced Coag up to 30 W	
	Forced Prep up to 30 W	
	Endo Spray up to 30 W	
	Endo Argon up to 30 W	



15.3 Technical Data for maxium[®] Beamer

Description	maxium® Data		
Power supply	via the maxium [®]		
Argon supply	Only approved for MABS pressure reducer.		
Fuse	M1.6A, internal		
Power consumption	max. 40 W		
Protection class	I		
Classification acc. to Medical Devices Act	пь		
Argon gas flow for CUT	0.1 - 12 l/min ± 20 %, can	be switched off by setting to 0.0 I/min	
Argon gas flow for COAG	0.1 - 12 l/min ± 20 %, can	be switched off by setting to 0.0 I/min	
Leakage currents LF and HF	In accordance with IEC 601, Part 1 (to be tested together with the HF generator of the maxium®)		
Type (Application Part)	CF; defibrillation-proof		
Operating mode	INT 10s/30s		
Weight	3.5 kg		
Radio interference suppression	See section 15.2. The maxium [®] meets the requirements of IEC 60601-1-2 also in conjunction with the argon beamer, but with the restrictions pursuant to IEC 60601-2-2 Section 202.6.1.		
Dimensions	Width Height Depth	390 mm 108 mm (without ball-head safety bolt) 435 mm	
Environmental conditions for transport and storage	Ambient temperature Relative humidity Air pressure	-25 °C to +70 °C (-13 °F to +158 °F) 10 - 100 % 500 - 1,060 hPa	
Environmental conditions for operation	Ambient temperature Relative humidity Air pressure	+10 °C to +40 °C (50 °F to +104 °F) 30 - 75 % 700 - 1,060 hPa	
C€ 0287	Compliant with 93/42/EEC		



15.4 Guidelines and Manufacturer's Declaration on Electromagnetic Compatibility (EMC)

Guidelines and manufacturer's declaration in accordance with IEC 60601-1-2 section 6.8.3.201 (a) (3) Table 201: Electromagnetic emission

The device ME 402 maxium® with or without ME 402 maxium® Beamer is designed for use in an electromagnetic environment as specified below. The user must ensure that it is operated in such an environment.

Immunity tests	Compliance level	Electromagnetic environment – Guidelines
HF emissions according to EN 55011	Group 2	The device must emit electromagnetic energy in order to fulfill its intended function. Nearby electronic units may be affected.
HF emissions according to EN 55011	Class B	The requirements of the class are complied with only in operation readiness without activation of HF energy!
Emission of harmonics according to IEC 61000-3-2	Class A	The device is suitable for use in any facilities, including residential areas and such as are directly
Emissions of voltage fluctuations / flicker according to IEC 61000-3-3	Complies	connected to the normal public supply network for residential buildings.



Guidelines and manufacturer's declaration in accordance with IEC 60601-1-2 section 6.8.3.201 (a) (3) Table 201: Electromagnetic emission

The device is designed for use in the electromagnetic environment specified below. The user of the device must ensure that it is operated in such an environment.

Interference immunity tests	Test level according to IEC 60601	Compliance level	Electromagnetic environment – Guidelines
Electrostatic discharge according to IEC 61000-4-2	± 6kV contact discharge ± 8kV air discharge	± 6kV contact discharge ± 8kV air discharge	Floors should be of wood or concrete or covered with ceramic tiles. If the floor is fitted with synthetic material, relative humidity must be at least 30 %.
Electrical fast transient/bursts according to IEC 61000-4-4	± 2kV for power lines ± 1kV for input and output lines	± 2kV for power lines ± 1kV for input and output lines	The quality of the supply voltage should correspond to that of a normal commercial or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV symmetrical voltage ± 2 kV asymmetrical voltage	± 1 kV symmetrical voltage ± 2 kV asymmetrical voltage	The quality of the supply voltage should correspond to that of a normal commercial or hospital environment.
Voltage dips, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	<5 % U_T (>95% drop of U_T) for $\frac{1}{2}$ period 40 % U_T (60 % drop of U_T) for 5 periods 70 % U_T (30 % drop of U_T) for 25 periods <5 % U_T (>95 % drop of U_T) for 5 seconds	$0\% U_{T}$ $(100\% drop of U_{T})$ for ½ period $40\% U_{T}$ $(60\% drop of U_{T})$ for 5 periods $70\% U_{T}$ $(30\% drop of U_{T})$ for 25 periods $0\% U_{T}$ $(100\% drop of U_{T})$ for 5 seconds	The quality of the supply voltage should conform to that of a normal commercial or hospital environment. If during activation of HF output energy perceptible problems with the power supply should occur, it is recommended to feed the device via an uninterruptible power supply.
Magnetic field at supply frequency (50 / 60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should conform to the typical values as found in industrial or hospital environments.
NOTE: U_T is the mains voltage prior to application of the test level.			



Guidelines and manufacturer's declaration in accordance with IEC 60601-1-2 section 6.8.3.201 (b) Table 204: Electromagnetic Interference Immunity

The device is designed for use in the electromagnetic environment specified below. The user of the device must ensure that it is operated in such an environment.

Interference immunity tests	Test level according to IEC 60601	Compliance level	Electromagnetic environment – Guidelines	
			Portable and mobile radio equipment should not be used at a lower distance to the device (including the leads) than the recommended working clearance resulting from the emitterspecific equation.	
			Recommended working clearance:	
			$d = 1.17\sqrt{P}$	
Conducted HF disturbances according to IEC 61000-4-6 Radiated HF disturbances according to IEC 61000-4-3	3 V _{eff} 150 kHz - 80 MHz 3 V/m 80 MHz - 2.5 GHz	3 V _{eff} 150 kHz – 80 MHz 3 V/m 80 MHz – 2.5 GHz	$d=1.17\sqrt{P}$ For 80 MHz to 800 MHz $d=2.33\sqrt{P}$ For 800 MHz to 2.5 GHz where P is the nominal power of the emitter in watts (W) in accordance with the information by the manufacturer of the emitter and d is the recommended working clearance in meters (m). At all frequencies, the field strength of stationary radio emitters determined on-site ^a should be below the compliance level. In the vicinity of devices carrying the following symbol, interference is possible.	
NOTE 1:.	At 80 MHz and 800 MHz, the higher frequency range applies			
NOTE 2:	These guidelines may not be applicable in all cases. Electromagnetic propagation is influenced by absorption and reflection by and on buildings, objects, and people.			

^a The field strengths of stationary transmitters, such as base stations for phones and mobile land radios units, amateur radio units, AM and FM radio stations and television channels, cannot be predicted precisely by theory. For analysis of the electromagnetic environment with regard to stationary transmitters, a site examination should be considered. If the field strength measured at the site where the device is used exceeds the aforementioned compliance level, the unit must be observed with respect to its proper function. Unusual operating behavior may necessitate extra measures, e.g. a change of orientation or another location of the device.

^b Over the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.



Recommended working clearance between portable and mobile telecommunication devices and the KLS Martin ME 402 maxium[®] with or without ME 402 maxium[®] Beamer in accordance with IEC 60601-1-2 section 6.8.3.201 (b), Table 206

The device is designed for the area in an electromagnetic environment where the HF disturbances are controlled. The user of the device can contribute to avoidance of electromagnetic interferences by maintaining the minimum distance between portable and mobile HF telecommunication equipment (emitters) and the unit – depending on the output power of the communication device, as specified below.

	Working clearance as function of transmission frequency (in m)				
Nominal power of the emitter W	$150 \text{ kHz} - 80 \text{ MHz}$ $d = 1.17\sqrt{P}$	80 MHz – 800 MHz $d = 1.17\sqrt{P}$	800 MHz – 2.5 GHz $d = 2.33\sqrt{P}$		
0.01	0.12	0.12	0.23		
0.1	0.37	0.37	0.74		
1	1.17	1.17	2.33		
10	3.7	3.7	7.4		
100	11.7	11.7	23.3		

For emitters whose maximum power rating is not specified in the table above, the recommended working clearance d in meters (m) can be determined using the equation that belongs to the respective column, where P is the maximum rated output of the emitter in watts (W) according to the manufacturer of the emitter.

NOTE 1:	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2:	These guidelines may not be applicable in all cases. Electromagnetic propagation is influenced by absorption and reflection by and on buildings, objects, and people.



16 Periodic Safety Checks (SC)

At least every 24 months the system (maxium[®], maxium[®] with maxium[®] Beamer) must be subjected to the following controls to be performed by people who, by virtue of their training, knowledge and experience gained from practical activities are able to properly perform such safety checks and not obliged to adhere to instructions with regard to such control activities. If the maxium[®] is equipped with a maxium[®] Beamer, this shall be inspected during the control of the maxium[®], too. A suitable protocol form can be requested from the Martin Service Center.

A: Visual inspections and function checks.

- Readability of type plate and markings.
 The information on the type plates of the maxium[®] and, if applicable, maxium[®] Beamer, as well as the labels on the rear side of the units, in particular those indicating the nominal value for the fuses of the units in the power cable connection, must be clearly legible.
 On the maxium[®] Beamer, the indication of the permissible pressure range at the gas inlet must be clearly legible.
- The instructions for use must be available in a version suitable for the unit. Updated instructions for use can be obtained from the Martin Service Center.
- The software version number VX.xxx shown on the startup screen upon switching on of the unit is to be entered into the protocol sheet. Note messages during the self-test.
- Check that both background lights of the display are in working order (uniform illumination of the field of view). Clear rendering of the icons and correct reproduction of the colors blue and yellow must be verified.
- Visual inspection of all ports on the unit.
 - Check the HF sockets M1, M2, B1 and B2 for visible damage.
 - Check sockets for foot switches, equipotential grounding connection and socket for maxium[®] Beamer on the rear for damage and tight fit.
 - Pull the mains cable out of the socket on the unit and test the connection socket for damage and tight fit.
 - On the maxium[®] Beamer, check connection socket for the connection cable to the maxium[®] for damage and tight fit.
 - Check gas inlet, decompression pin and grounding connection for tight fit.
 - Check the gas outlet on the front for damage and tight fit.
- Check the cables of all reusable accessories used with the unit for damage to the insulation and the connector plug, especially in the area of the particularly strained ends.



- Check the operation of the membrane keys on the front when the unit is turned on.
 Upon actuation of a channel selection key, the red frame must jump to the power selection field of this channel, if the channel is selected. If no channel has been selected, selection of the channel follows. Check all eight channel selector keys. After pressing the MENU key, a blue bar must appear on the first entry of the list on the right side of the screen.
- Check the operation of the rotary switch and its background light.
 Upon selection of a cutting channel, the background light must turn yellow; upon selection of a coagulation channel, blue. Upon actuation of the MENU key, the background light must turn white.
 - Check by turning the rotary switch that the power level on the selected channel is adjustable.
 - By pressing the rotary switch, check that the axial pressure switch function (axial click) snaps into place with the usual effort and the function is executed (red frame disappears again).
- Function check of activation, activation lamps and activation sound.
 - Disable NE alarm with jumper plug,
 - connect electrode handle to M1 and M2 and
 - press the two finger switches.

HF energy must be activatable. The activation lights assigned to the outputs M1 or M2 must be lit in the color of the activated current – yellow or blue –, and the activation sound must be audible.

- For combo connections, test the alternative accessories, if any are used.
- Connect double-pedal foot switch to the large foot switch socket and check whether
 the channels assigned on the screen are activated upon actuation of the yellow and the
 blue pedal; if necessary, assign foot switch pedals first.
- Connect single-pedal foot switch to the small foot switch socket and check whether any previously assigned channel is activated.
- Connect bipolar test cable successively to the bipolar output ports B1 and B2.
- On both channels, select a coagulation current with auto-start function and set to minimum power.
- Check whether a bipolar coagulation current is activated in case of short circuiting of the banana plugs and deactivated upon opening of the contact.
- Connect bipolar test adapter to output port B2 and check finger switch activation.



- Check the function of the neutral electrode monitoring. When the NE socket is open, the screen must show the symbol of a split red neutral electrode, with the pointer of the NE indicator (may have to be activated via the menu first, see section 10.6.4 "Neutral electrode", page 91) on the left end. Upon activation of a monopolar channel (electrode handle at M1 or M2), the intermittent NE alarm is sounded in a clearly audible manner.
 - Insert jumper plug.
 On the screen, the symbol of a green single-piece NE must appear, the NE indicator disappears.
 - Insert test connector with 270 Ω resistor. The pointer of the NE indicator must be in the yellow field.
- In the presence of a maxium[®] Beamer, first switch off the maxium[®], disconnect any argon gas supply connection from the maxium[®] Beamer and then switch on the unit again. The base program appears on the screen without argon current (select base program if necessary). The indicator on the beamer must remain dark. On one of the monopolar channels, select an argon-supported current. The indicator on the beamer must switch to red. The unit may first have to be set up for operation with the maxium[®] Beamer by selecting the function **Argon mode**. When connecting the gas supply to the gas inlet, the self-test must begin, after whose completion the indicator will change to green.
- Check pressure reducer and connecting hose to the unit for leaks.
- Pressing the key **PURGE** must activate a gas flow without HF current for 3 seconds to displace the air from the applicator.
- Function check of activation and activation lamps of the beamer.

 On the maxium[®], select one argon-supported cutting current and one coagulation current each and consecutively activate both. Upon activation, the indicator on the beamer must be lit yellow or blue according to the activated current.
- Function check of the steadily argon gas flow at the beamer. Usually a flow measuring unit calibrated for Argon will not be available. As the gas flow, however, is adjusted by the user not according to the figures measured but according to the visible surgical result, control of the continuous adjustability of the gas flow is sufficient. Connect argon applicator to the beamer, not to the electrosurgery unit! Via the foot switch, activate an argon-supported current at the flow rates of 0.3 l/min, 1 l/min, 3 l/min and 10 l/min, in this order. Ascertain by the sound of the blowing noise that the gas flow increases at each higher stage.

B. Measurement of the output data

Measure the HF output power for some exemplary currents.



C. Safety measurements according to IEC 60601-1

These measurements are often carried out using an automated safety tester. During the automatic test sequence, the supply voltage is turned on and off again several times. After a power failure of up to 4 seconds, the maxium[®] will start again after return of the supply voltage; after longer breaks, it will remain switched off. This is to be taken into account in case of automated testing; it may be necessary to carry out the test procedure manually.

For the periodic safety checks, the following measurements should be carried out according to IEC 60601-1:

• Measurement of the ground conductor resistance between the ground conductor contact of the appliance inlet and the equipotential grounding pin on the maxium $^{\text{®}}$. According to IEC 60601-1 section 8.6.4, this value must not exceed 0.1 Ω .

Earth Leakage Current

Normal condition

Measurement of the current in the protective grounding conductor of the mains cable without error simulation. This value must not exceed $1.5\times$ the value of the initially measured value according to the factory testing sheet which accompanies the unit, and it must also comply with the absolute upper limit of 500 μ A according to IEC 60601-1.

Single fault condition

Measurement of the current in the protective grounding conductor of the mains cable during simulation of an interruption of the near-ground phase N (causes the unit to switch off). This value must not exceed 1.5× the value of the initially measured value according to the factory testing sheet which accompanies the unit, and it must also comply with the absolute upper limit of 1,000 μA according to IEC 60601-1. Its value amounts to 2× the ground leakage current in the normal case.

Touch current

Normal condition

Measurement of the current that flows from the equipotential grounding connection of the maxium $^{\circledR}$ to the ground. Since this current path forms a parallel path to the protective grounding conductor, its value is normally very low and also undefined, since it depends on the undefined ratio of the partial ground resistances. Its value must not exceed the absolute upper limit of 100 μ A.

Single fault condition ground conductor

Corresponds to the value of the ground leaking current under normal conditions, since now the measurement path takes over the function of the ground conductor. Up to 1.5× the initially measured value, but according to IEC 60601-1 with an absolute maximum of 500 μ A.



Single fault condition mains

Measurement of the current that flows from the equipotential grounding connection of the maxium $^{\circledR}$ to the ground when the near-ground phase N is interrupted (causes the unit to turn off). Since this current path forms a parallel path to the protective grounding conductor, its value is normally very low and also undefined, since it depends on the undefined ratio of the partial ground resistances. Its value must not exceed the absolute upper limit of 500 μA .

Patient leakage current

Normal condition

Measurement of the current from the instrument connections M1, M2, B1, B2 and NE to the ground in non-activated condition. To this purpose, multiple ports can be connected in parallel. However, if this leads to indication of a value that exceeds the upper limit of $10~\mu A$ according to IEC 60601-1, the connections must be measured individually, and the highest value is to be logged. A short circuit of the bipolar output ports B1 or B2 leads to a message during self-test. Use measuring cables that are connected only to one pole of the B1 or B2 output ports, or perform this measurement manually after completion of the self-test, where, however, no current with auto-start function may be selected.

Single fault condition PE conductor

Measurement of the current from the instrument connections M1, M2, B1, B2 and NE in non-activated condition to the ground, with the protective conductor interrupted. The absolute upper limit according to IEC 60601-1 is 50 μ A. The same applies as described under "Patient leakage current, Normal condition".

Single fault condition voltage on the applied part

Measurement of the current from the instrument connections M1, M2, B1, B2 and NE in non-activated condition after grounding, where ground-related mains voltage is externally applied to the connectors of the maxium[®] through the measurement device! The absolute upper limit according to IEC 60601-1 is 50 μ A. The same applies as described under "Patient leakage current, Normal condition".

NOTICE

Performance of the safety check must be entered into the equipment log, and the results are to be documented!



17 Environment-Relevant Information

17.1 Packaging

Of course, Gebrüder Martin will take back all the packaging upon request. Whenever possible, parts of the packaging will be reused.

If this offer is not made use of, the packaging may be disposed of into the paper and domestic waste.

17.2 Environmentally Sound Device Operations

During regular cutting and coagulation of tissue, combustion products are formed that should not be inhaled over a longer period or for a longer time. For removal of such combustion products, a fume suction system such as the marVAC® can be used, see section 10.6.7 "Use of the marVAC® fume suction system with the maxium®", page 94.

During regular use of the unit, no pollutants other than these combustion products will be formed.

In the interest of low-energy use, we recommend switching off the unit during longer treatment breaks.

If disposable articles are used during treatment, we point out that these may be disposed of via domestic or problematic waste only after careful cleaning, disinfection and possibly sterilization. Infected sharp parts of disposable instruments shall be treated according to the applicable regulations like other "sharps" (needles, cannulae and scalpels – by disposal via germ-tight and puncture-resistant containers).

17.3 Disposal of the Product

When the unit was designed, composite materials were avoided wherever possible. Thanks to this design concept the unit can be mostly recycled at the end of its life time. We also offer you to take back the unit and to dispose of it correctly.

The national regulations for waste disposal must be complied with!



Marking of Electrical and Electronic Equipment (EEE) in accordance with Directive No 2002/96/EC (WEEE) or the German Electrical and Electronic Equipment Act (Elektround Elektronikgerätegesetz – "ElektroG")

The icon on the product or on its packaging indicates that this product must not be disposed of as normal household waste.

Instructions for Use maxium® electrosurgery unit with maxium® Beamer



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