



Special Medical Technology Co.Ltd.

# HF/RF Electrosurgery Unit

## SMT ESU 60 M (MONO)



### Operating Manual



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INDEMNITY AGREEMENT  
END USER REGISTRATION CARD  
DECLARATION OF CONFORMITY



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Device classification class: ..... **II b**

Device service life: ..... **7 years**

## 1. INTRODUCTION

In view of the continuously ongoing development, some of the device's characteristics and technical data may be changed without prior warning.

No part of this document may be photographed, reproduced or translated into another language without the written permission of the manufacturer.

In the event that technical assistance is required, contact the supplier.

It is very important that this manual is kept for future consultation.

### 1.1. Principles of safe use

Operation of all high-frequency (HF) or radio-frequency (RF) surgical devices brings certain risks and specific rules need to be observed to minimise these risks. In terms of transparency, we provide a general outline of these rules here and many of these rules are mentioned again further in the text.

**These instructions were compiled for your safety and for the safety of other persons therefore we request that you read them carefully before installing and using the device:**

1. An operator with a university medical degree is required to work with the electrosurgical device (HF/RF generator).
2. If other than the accessories (cables and instruments) supplied by the manufacturer are used, the manufacturer needs to be consulted to prevent incompatibility, dangerous operation and personal risk!

3. THE PATIENT may not come into contact with metal parts which are not earthed or have a greater capacity against earth (e.g. operating table, supports etc.). In these cases we recommend using antistatic bed linen.
4. If a high-frequency surgical device and monitoring instrument is used on a PATIENT simultaneously, the **monitoring electrodes** should be located as far as possible from the surgical electrodes. It is not recommended using needle monitoring electrodes.
5. The electrode feeds must be allocated in a way to exclude contact with the PATIENT or with other conductors.  
Temporarily unused active electrodes must be stored away from the PATIENT.
6. Combustible anaesthetics or oxidising gases, such as nitrous oxide (N<sub>2</sub>O) and oxygen, should not be used if these agents cannot be sucked away. Non-combustible substances should be used everywhere where possible. Combustible substances used for cleaning, disinfection or as solvents must be left to evaporate before applying high-frequency surgery. Some substances, such as cotton wool and gauze with absorbed oxygen, may ignite due to possible sparks during normal use of the device.
7. In patients with cardiostimulators or other active implants there may be a risk in view of the interference with the activity of the cardiostimulator or it may be damaged.
8. It must be expected that the disruption caused by the operation of the high-frequency surgical device may have a negative effect on the operation of other electronic equipment. If telecommunication or other equipment is disrupted, the user should take such precautions to remove the disruption.
9. At the time of activated output, the device could become a source of the disruption of electromagnetically sensitive devices located nearby. One of the possible precautions is to locate the HF/RF generator and the disrupted device as far apart from each other as possible.
10. Regular preventive checks of the device and its accessories are essential, with special attention payed to the condition of the insulation of the feeds of the active bipolar electrodes.
11. There should be no unqualified intervention with the device. Request all repairs and inspections from the manufacturer or authorised repair shop.

12. In order to minimise risks arising from a possible power cut, we recommend using the device in operating rooms with a backup supply of electricity, and we recommend feeding the device from an uninterruptable power supply (UPS) for outpatient use.
13. The device needs to be inspected by the manufacturer or authorised service centre for safety reasons at least once a year.

## **2. GENERAL INFORMATION**

In order to achieve the best results, it is important to understand the basics of electrosurgery and so we recommend that you read the following basic explanation carefully.

### **2.1. How high-frequency electrosurgery works**

The device's electrode concentrates HF (RF) energy to the required place. The HF (RF) current passes through the tissue painlessly, without shock and the sole effect is creating heat inside the tissue, moderate intensity of the current only in the place that comes in contact with the active electrode.

The HF (RF) current, passing through the tissue, creates molecular heat. Electrodes of various sizes are used in electrosurgery. In the bipolar method energy is concentrated with very high intensity on both working tips of the bipolar electrodes (usually the forceps). When this is applied to the tissue, the HF (RF) current creates such intensive molecular heat in each cell that it is possible to cut the tissue or coagulate (according to the output option CUT or COAG or mix of both - BLEND).

The main aim of good electrosurgical technique in general is to remove undesired tissue, stop bleeding without carbonisation of the surroundings, or to gain a precisely orientated and not destroyed sample of tissue for biological analysis and diagnosis. Some operating principles of electrosurgery need to be observed, to achieve a good result. Choose the optimum parameters. Choose the right mode for the chosen device. Remove all possible other conducting undesired diverters, including conducting fluids (e.g. disinfectants), out of reach of the electrodes and the patient.

The procedure may not be perfect if:

- Excessive power is used
- The power used is too small
- The moving through the tissue is too slow

- The procedure is repeated in the same area too soon  
Too small power results in the tissue fibres stick to the electrode and cause problems during further work.

A somewhat greater power may cause slight dehydration of the tissue surface at most without damaging it. If you choose the right operating output and performance of the device, you will achieve the desired result. It must be realised that the output CUT is without modulation, and therefore will reach a higher tissue temperature (over 100 °C). Water inside the cell boils and the cell bursts – it is destroyed for good. On the contrary, the output COAG has modulation – for the purpose of reducing the max. temperature of the water inside the cell (to 40-90 °C) and thereby coagulation (closing) the cell, not its destruction.

The device also contains the output BLEND which can be used to advantage where a combination of advantages is required of both outputs with partial destruction of the tissue.

A characteristic odour arises during electrosurgical procedures, which can be removed by central suction from the operated place. A suction unit is available or designed for this, holding a suction hose as close to the place of the procedure as possible. In the field of gynaecology, or proctology a speculla with a connector for the suction can be used during open surgery. It is constructed for this purpose. In endoscopic methods complex suction of the cavity, moreover for clearing the operating field, is available.

The manufacturer of this device also offers effective suction units which eliminate this sole disadvantage of all electrosurgical devices.

#### How to operate:

Firmly attach the neutral electrode to the patient. Remove all possible other conducting undesired diverters, including conducting fluids (such as disinfectants), out of reach of the electrodes and the patient. Move the device with the electrode continuously during the procedure to prevent heat accumulating in some part of the tissue.

- Too great a performance results in tissue dehydration and when moving the electrode in the tissue it is possible to observe sparks.
- Too low a performance results in tissue dehydration and tissue fibre, stick to the electrode and cause problems with their removal.
- Somewhat greater performance may cause slight tissue surface dehydration at most without damaging it with an adequate cutting movement, whereas too low a performance prevents the electrode from moving around the tissue.

## OPERATING OUTPUTS OF DEVICE ESU 60 M

### 2.2. Cutting

This is the separation of biological tissue with the passage of HF/RF current of high intensity concentrated in the cutting parts of the active electrode. When the HF/RF current is applied to the tissue with the aid of the active electrode, it creates intensive molecular heat in the cell which destroys the cell and separates the tissue.

The cutting effect is achieved by moving the tissue electrode and gradual cell destruction one after another. The continuous movement of the electrode prevents the lateral spread of heat in the tissue, thereby limits destruction of the number of cells to a minimum.

The most appropriate current for cutting is fully balanced and filtered HF (RF) current without any modulation. Such a current cuts very smoothly.

The following rules will help the operator to achieve a good cut however each user must follow his professional judgement as is always the case in practice.

- Move the electrode continuously without stopping.
- Activate the electrode just before contact with the tissue.
- Keep the electrode clean.

If the output performance is selected correctly, then:

- The electrode moves without resistance.
- No changes occur in the colour of the cut surface.
- Fibres from the tissue should not remain on the electrode.

### 2.3. Coagulation

This is hemostasis of small (blood) vessels of body tissue caused by the passage of the HF/RF current with the effect of active, most commonly spherical electrodes. If the current intensity is reduced and a large-scale electrode is used for the purpose of dispersing the energy over a greater area, this will cause the drying out of surface cells without deeper penetration and the onset of coagulation. The surface of such coagulated cells behaves like an insulating layer which prevents the penetration of heat arising with the subsequent application of the current to a greater depth.

The current which is normally used for coagulation is always blended and modulated and the depth of modulation then depends on the quality of tissue hemostasis. The deeper modulation of the HF/RF



current causes somewhat rougher, however more effective coagulation.

The following rules help the operator to achieve good coagulation however every user must follow their own professional judgement:

Select the appropriate size of the spherical electrode (BALL) or other appropriately shaped coagulating electrode.

Localise bleeding vessels.

Touch the bleeding vessels slightly before activating the electrode, press the foot switch.

Terminate the activation of the electrode as soon as the tissue goes pale to prevent unnecessary tissue destruction.

Keep the operating device sterile and clean.

Monopolar forceps, péan forceps or scissors can also be used for the coagulation. In such a case both lines of instruments is one – active electrode and another - bigger – passive electrode is the neutral electrode attached to the patient (as close to the place of the procedure as possible).

## **2.4. Blend**

In some cases it is advantageous to CUT and COAGULATE in one intervention, by one operating instrument. For these cases is the selection of the BLEND output suitable.

## **2.5. Merits of the use of electrosurgery**

Some of the basic merits of the use of electrosurgery are:

- Prevention or restriction of the loss of tissue.
- Prevention or restriction of bleeding makes it difficult for the doctor to see into the operating field when using a traditional instrument (scalpel).
- Prevention of bone damage. Provided that care is taken when carrying out the procedure with the electrode, the bone tissue is not affected by the electrosurgical procedure. The continuous movement of the electrode prevents heat accumulation.
- Quick and positive healing of healthy tissue with good generation and with little scarring of the tissue. The time required for healing does not differ from the time during a procedure performed with a traditional instrument (scalpel).
- Restriction of the pain of the procedure.

### **3. ELECTROSURGICAL UNIT ESU 60 M FEATURES**

#### **3.1. Control unit**

The electrosurgical generators is a high-frequency, highly efficient oscillator the current of which may be modulated if it is appropriate for cutting, coagulation and a combination of both.

The level of the output performance is managed by the operator so that it fully meets his needs. It is optional within the “Min” – “Max” range up to a max. performance of 60 W. The device allows work in the MONOPOLAR mode. The current can be chosen for cutting, for blended cutting or for coagulation.

##### **3.1.1. Lights signals**

Green MAINS – the device is switched on

Yellow CUT – output current for cutting

Green BLENDED CUT – output of the current for a blended cut

Blue COAG - output of the current for coagulation

Red .....

NEUTRAL ELECTRODE (alarm) – fault in the circuit of the neutral electrode

#### **3.2. Holder of the operating tool – applicator (ES pencil)**

The applicator holds the selected active electrode (operating tool) for the electrosurgical procedure. The applicator for monopolar use (2.4 mm) is supplied with the device as the basic accessory, com. 2, FIG 4.

Also the applicators diameter 1.6 mm or 0.8 mm can be supplied as optional access.

This procedure is carried out based on specialised medical procedures according to the recommendations in Chapter 2 above. The most common use is for cutting using a scalpel, LOOP or needle and coagulation with the aid of the BALL or flat electrode. (The manufacturer supplies any of these tools.) See 3.3.

#### **3.3. Active electrodes (operating tool)**

Active electrodes concentrate high-frequency (HF) or radio-frequency (RF) current and apply it to the tissue.

NOTE: High-frequency with a frequency of over about 200 KHz is not dangerous for living tissue unlike the current of the standard mains frequency of 50 Hz!

Depending on their shape electrodes are intended mostly for cutting or coagulation. Thin wire electrodes, straight or looped, are usually used for cutting. Tissue excision is carried out using loops.

Spherical electrodes (BALLS) are mainly used for coagulation. The normalised gripping 2.4 mm diameter of the electrode stem is used above all. The cutting end of the electrode is partly sterilised by HF (RF) energy which destroys organisms which could occur in this area. However most electrodes can be repeatedly sterilised using all conventional methods. The manufacturer recommends sterilisation by steam – see further Chapters.

### **3.4. Neutral electrode**

The neutral electrode closes the circuit of the NF current. It must therefore be fastened firmly along its entire area to the patient's organism, as close to the working field as possible. Usually this is a metal or conducting silicon board of about 6x14 cm or bigger. It can also be a single-use conducting plastic (dispersal) material.

This part of the electrosurgical set is very important and the international safety directive requires that its safe attachment to the patient must be continuously monitored. If this electrode is not attached to the device or if even one conductor of the double feed cable interrupted, and therefore the electric circuit is not closed, controlling the integrity of the feed conductors of neutral electrodes, the warning red light on the back panel (left) flashes and the sound signal sounds repeatedly. The function of the device is interrupted. This warning is activated even with a break in the control electric circuit of the neutral electrode which controls the integrity of the feeds to the neutral electrode during the operating procedure. If such a situation arises, these electrodes must be inspected. The visual control of the electrode and its feeds are recommended before each operation.

The use of neutral electrode is of fundamental importance for a precise surgical procedure with the smallest and safest possible current.

The neutral electrode must be placed so that some part of the patient's body forms a firm, reliable and electric conducting contact with it, without any separating pads (gauze).

The principles in Chapter 1.1 must be followed when applying neutral electrode. The basic operating electrode supplied by the manufacturer with this device is a multiuse stainless steel electrode. As required it is possible to supply a neutral silicon electrode.

However when using the electrode it needs to undergo repeated inspection to check its electric conductivity, at least once every 6 months because silicon electrodes lose their conductivity in time. The service life of silicon neutral electrodes is limited to a period of 12 months. Once this period expires, the silicon electrode must be replaced with a new one.

Simple and cheap neutral electrodes with conducting gel, usually self-adhesive, are intended for single use. Feeds to these electrodes are checked by the above described electric circuit and its interruption is indicated, just as in previous types, visually and acoustically on the control unit panel, with the current automatic interruption of the device's function. The use of single-use self-adhesive neutral electrodes is a full alternative. Despite a neutral electrode, the current circuit is closed so it must be reliably attached for conductivity! With a bad connection a patient could be burnt in the place of the neutral electrode, or even in a different place (e.g. there where an unwanted conducting connection arises, e.g. conducting disinfectant which is absorbed into the cushion under the patient!)

The neutral electrode set is insulated as its insulation complies with type F which complies with mark **F** on the device. The neutral electrode stainless steel is supplied with the device as its basic accessories com. 3, FIG 4.

## 4. TECHNICAL DESCRIPTION, BASIC TECHNICAL PARAMETERS

### 4.1. Control unit

Feed voltage ..... 230V~/50Hz (or as ordered)

Maximum input:

Cut	85 VA	at impedance of	500 Ω
Blended cut	75 VA	at impedance of	500 Ω
Coagulation	75 VA	at impedance of	500 Ω

No load input ..... 5 VA




Working output (CUT-at impedance 500-1500 Ω) ..... 60 W

Max. output (CUT-at impedance 850 Ω) ..... 68 W


Working frequency (controlled by crystal) ..... 460.85 kHz

Class II insulation ..... symbol 

Dimensions ..... 260 x 160 x 80 mm

Weight ..... 2.25 kg  
Mains transformer ..... Talema Plzeň  
Type 52643; Prim. 230V, sec. 1 = 45V, sec. 2 = 16V; 100 VA;  
EN 60 601-1  
Operation and storage of device: surrounding temperature .....  
.....+10°C (+50°F) to + 40°C (104°F)  
Relat. humidity..... from 30% to 75%  
Atm. Pressure ..... from 700 to 1060 kPa  
Level of protection against unwanted water seepage cover .....IP21  
EMC – The device was checked for electromagnetic compatibility  
according to international standard EN 60 601-1-2.  
Output data: The device is BF type with protection against  
defibrillating discharge which complies with the mark on the unit .  
The unit uses high-frequency energy with non-ionising radiation as  
marked by symbol..... .  
Operating output ..... cut, blended cut, coagulation  
Method of operation .....  
.....constant operation with interrupted load (see Chapter 5)  
The information “ATTENTION, read the accompanying  
documentation” complies with the marking on the device.....   
The maximum peak output voltage of unloaded circuit is achieved in  
the mode BLEND, of 1140 V<sub>šp-šp</sub>.  
The device does not contain and does not use any dangerous  
substances.

## 4.2. Special - Highly Safe - Pneumatic Foot Switch

Dimensions ..... diameter 70 mm  
Length of feed hose ..... cca 3 m  
Weight ..... 0.25 kg  
Foot switch complies with this marking on the back panel ..... 

## 5. PUTTING INTO OPERATION

In order to determine the technical limits the following method of  
**operation** is defined:

### INTERRUPTED.

Practically – in usual medical practice - the device can work  
continuously.

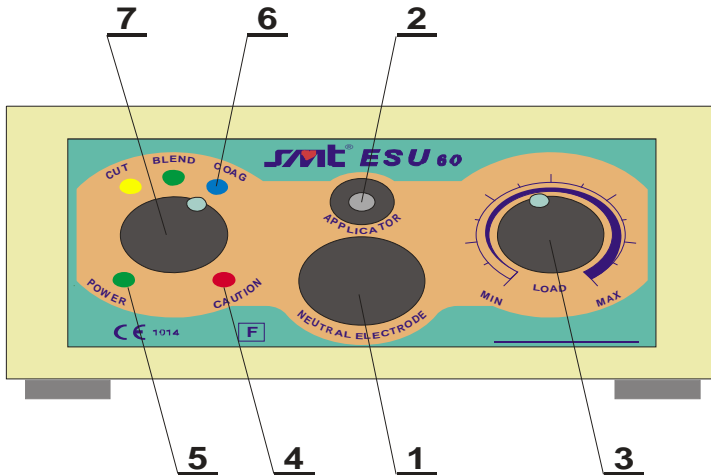
Place the device in a stable place where there is no blazing heat or  
direct sunrays. Slide the mains cable firstly into the back panel of the

control unit (com.2, FIG. 2), then connect to a properly installed electric mains socket.

Slide the flexible tube of the foot pneumatic switch into the opening on the back panel (com.1, FIG. 2).

Switch on the mains switch on the back of the panel (com.3, FIG. 2) – light warning signal (com.5, FIG. 1). Slide the instrument cable into the relevant connection as seen in the figure of the front panel (com. 2, FIG. 1). Select the operating output with the function switch (com.7, FIG. 1). Set the preliminary value of the power with the intensity regulator (com.3, FIG. 1).

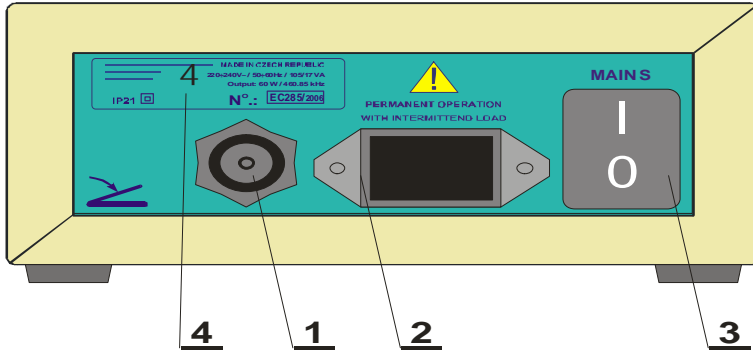
Now the “Operating Process” may begin by pressing the foot switch. The relevant light signal lights up to indicate that the preselected operating output is activated (com.6, FIG. 1) while a continuous acoustic signal sounds out.



**FIG. 1** - Front control unit panel

Legend:

1. neutral electrode socket
2. active electrode socket
3. regulator of intensity (W)
4. red light signal indicating bad connection of neutral electrode
5. green signal indicating that the mains is switched on
6. function signal (operating outputs indicator)
7. function switch (operating outputs selector)



**FIG. 2 - Back control unit panel**

Legend:

- 1- pneumatic foot switch connector
- 2- mains cable socket
- 3- mains switch
- 4- production label

### **5.1. Maintenance instructions**

The high-frequency unit does not require any special maintenance besides standard cleaning of all parts. Any repairs must be ordered with the supplier, authorised repair shop or with the very manufacturer.

### **5.2. Sterilisation**

An autoclave, formaldehyde or ethylene oxide can be used to sterilise cables and operating instruments designed by the manufacturer for sterilisation. Hot air at a temperature of 160 °C can also be used to sterilise the actual reusable forceps. A preventive visual inspection of the cables and forceps (or other instruments) is required after each sterilisation.

### **5.3. Cleaning**

The surface of the control unit box can be wiped with damp gauze containing standard detergent, however make sure the washing solution does not get into any opening. The mains cable plug must be removed from the socket (when being wiped). The operating tools and the cable can be cleaned in a similar way as the control unit. Moreover, the active (non-insulated) part of the operating instrument

must be well cleaned mechanically and adequately rinsed in running water.

#### **5.4. Removal of faults, repairs, SERVICE**

If the instrument does not work and the function light signal lights up after the foot switch is pressed down and the continuous sound signal is activated, check whether the forceps are correctly connected and if the high-frequency current intensity is properly set.

In case the instrument is not responding after the unit is switched on and the foot switch pressed down, the function control light is not lit up and the signal does not sound even after carefully checking that all the connectors are in place, the fault may be in the circuits of the control unit. In such a case you need to contact your supplier, service organisation or the manufacturer directly.

#### **5.5. Service centre: Preventive checks**

Preventive checks need to be carried out as the law requires at least once every 12 months, additional parts and the cables once every 6 months. In case of sterilisation (in the above recommended way) run a visual check of the instrument and any other additional part with the cable after each sterilisation.

Preventive safety inspections at the manufacturer or the authorised service centre must be carried out once a year. During each inspection the HF (RF) output of the device must be measured at each power degree and each operating output.

#### **5.6. Guarantee**

The manufacturer provides a 24-month guarantee from the date of sale for the correct and faultless function of the unit. During this guarantee period the manufacturer will ensure free repair if the product was not damaged by bad handling, an unprofessional procedure or due to non-observance of the instructions contained in this manual.

##### **5.6.1. Instructions for guarantee repairs**


Send the properly wrapped up unit and accessory – if possible in its original packaging - (or transport in person) with the attached certificate of guarantee and a description of the fault to the address of the supplier or manufacturer, or upon a telephone agreement with the manufacturer, to the address of the nearest relevant service organisation.



## 5.7. Free post-guarantee service

Besides a guarantee, the manufacturer also provides an additional two-year free service provided that the legal requirements of regular technical inspections by the manufacturer are carried out. This service does not apply to normal wear and tear, to damage from unprofessional intervention, mechanical damage (e.g. the unit falling) or to the accessories which are consumer material.

## 5.8. Unit disposal

The ES unit must be disposed of in accordance with valid legislative standards and regulations . The manufacturer is registered under the legislative requirements at the Ministry of Environment under registration number 00794/05-ECZ and is obliged to accept the unit for liquidation.

## 6. THE FULFILMENT OF LEGISLATIVE REQUIREMENTS

The conformity was reviewed with the product. The manufacturer declares at its own responsibility exclusively that the product fulfils basic requirements stated in Annex 1 of Regulations of the Czech Government No. 336/2004 Coll. (93/42/EEC) in the relevant valid readings.

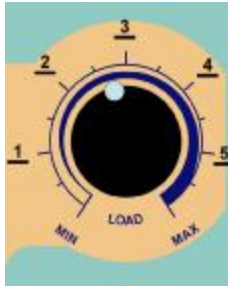
For the review were used these harmonised standards in a valid reading:

- EN ISO 13485
- EN 60601-1
- EN 60601-1-2
- EN 60601-2-2

The examination of the conformity was carried out in participation of the Authoritative person – Notified Body No. 1014.

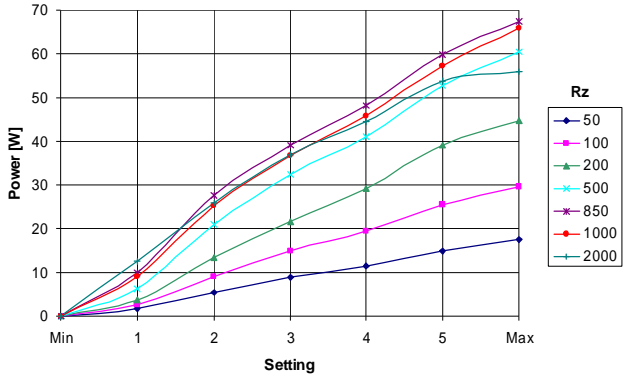
The Manufacturer issued a Declaration of Conformity on this matter.

## 7. PERFORMANCE CHARACTERISTICS

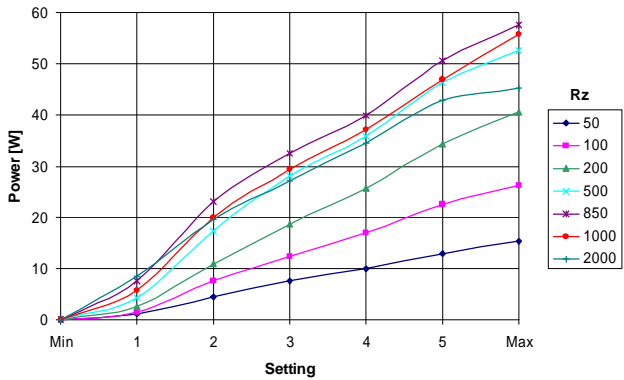


**FIG. 3 - Situating power setting values**

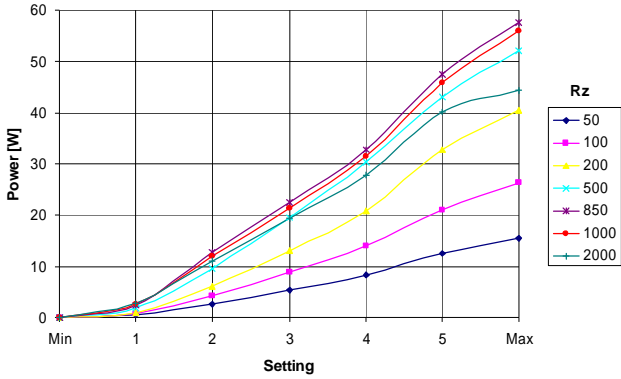
Maximum performance values are achieved at an impedance of 850  $\Omega$ .



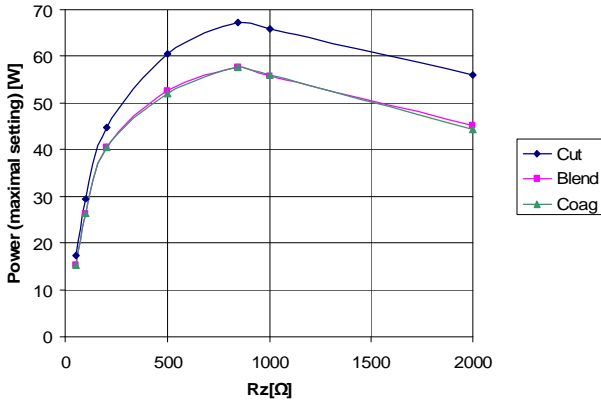
**Graph 1 - Cut**



**Graph 2 - Blend**



**Graph 3 - Coagulation**



**Graph 4 - Dependence of input power on load**

## 8. DEVICE WITH BASIC ACCESSORIES (INCLUDED)

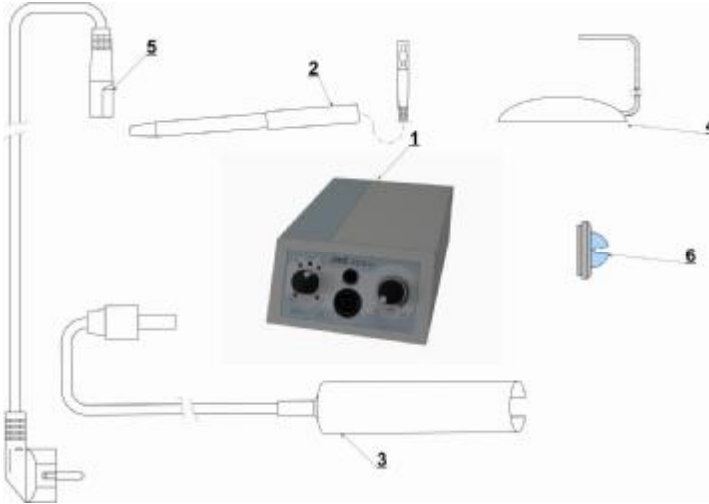


FIG. 4

### 8.1. Accessories included:

- 1- control unit
  - 2- instrument with cable
  - 3- neutral electrode (flat or circle)
  - 4- foot switch
  - 5- line cord
  - 6- instrument holder
- user manual with certificate of warranty, declaration of conformity and registration card  
packing



## **INDEMNITY AGREEMENT**

**Product:**

**ELECTROCAUTER - ELECTROSURGERY UNIT**

**TYPE: SMT ESU 60 M**

**Serial number:**

**Date of sale:**

**Stamp and signature of expedition:**

### **Guarantee Conditions:**

- a) At observing Operating Instructions the manufacturer guarantees that the product shall have characteristics assessed by the relevant technical conditions and standards for the duration of 24 months from the date of sale.
- b) In case of failure in function of the product, not caused by the end user or by an inevitable event within the guarantee period, the product will be repaired free of charge.
- c) The free of charge repair within the guarantee period will be done after the presentation of the Indemnity Agreement by an accredited service or by manufacturer.
- d) The guarantee period shall be extended for a term of the guarantee repair.
- e) The Indemnity Agreement is at the same time "The Certificate of the Quality and Completeness of the Product".



## RECORDS OF REPAIRS

Date of reception:

Description of malfunction:

Completion date:

\_\_\_\_\_  
Signature and stamp of the service:

Date of reception:

Description of malfunction:

Completion date:

\_\_\_\_\_  
Signature and stamp of the service:

Date of reception:

Description of malfunction:

Completion date:

\_\_\_\_\_  
Signature and stamp of the service:

Date of reception:

Description of malfunction:

Completion date:

\_\_\_\_\_  
Signature and stamp of the service:



END USER REGISTRATION CARD

**PRODUCT: ELECTROSURGERY SYSTEM SMT**

**TYPE: SMT ESU 60 M**

Serial number:

Sales clerk:

User:

Name:

Organization:

Address:

Phone:

Fax:

Herewith I confirm that I have got acquainted with the Operating Instructions and with the Guarantee Conditions and I will observe them.

Date:

Signature:

Dear customers,

Will you tear this registration card out and forward it to the address:

Special Medical Technology Ltd., Papirenska 114/5, 160 00, Prague 6, Czech Republic

The objective of this registration is, partly, to improve the quality of services our firm offers to its customers, and, partly, to observe strict requirements of standards ISO 9001, ISO 13485 and EEC 93/42 our firm conforms and the user of medical technology must be acquainted with.

Thank You







## **Special Medical Technology Co. Ltd.**

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**N 00146.01**

**[www.smt-praha.com](http://www.smt-praha.com)**

**The last revision and issue of this Operating Instructions 10/15/2012**