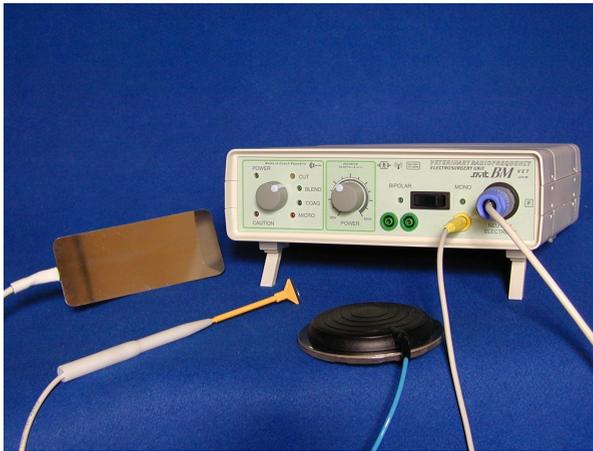


*Mark CE 0459 awarded*

*Certified by  
NB 0301 BVQI:*



# *VETERINARY RADIOFREQUENCY ELECTROSURGERY UNIT*



# ***S M T B M V E T***

## *Operating Instructions*



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***Class: II b***



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Indemnity agreement

End User Registration Card

## 1. INTRODUCTION

With regard to parallel running development of the device, some specifications and technical data subject to change without previous notice.

No part of the following document is permitted to be photographed, copied or translated into other languages without previous manufacturer's written agreement.

In case of need for an engineering assistance, please contact the supplier.

This manual must be kept for future possible consultation.

### 1.1. The Principles of the Safe Use

The operation of all high-frequency Electrosurgical instruments breeds certain risks, the minimization of which needs observing particular rules. We have presented the comprehensive list of these rules herein to ensure lucidity, although, many of them are repeatedly mentioned hereafter.

**These instructions were draft out for your safety and for the safety of other people. Before you begin installing and operating this unit, please read them carefully to be sure you get the best possible performance at highest possible safety:**

1. The qualification required for operating an Electrosurgery Unit must be at a university grade in a medical branch.
2. In case of using some other accessory than supplied by manufacturer (input cords, active and neutral electrodes), it's necessary to consult the manufacturer, so that the incompatibility and thus the dangerous operation may be prevented.
3. The neutral electrode has to be reliably and firmly connected up with the PATIENT's body with its contact surface as near as possible to the operation area.
4. The PATIENT must not come into contact with any metallic parts that are earthed or have high earth capacitance (e.g. surgical table, rests, and the like). When this is the case, we recommend using antistatic bed-clothes.
5. It's necessary to prevent any contact skin - skin (e.g. between an arm and a body of a PATIENT) by applying dry gauze.

6. If a high-frequency electrosurgical unit and a monitoring device are used at a PATIENT simultaneously, monitoring electrodes should be placed at the farthest possible distance from surgical electrodes. We don't recommend using needle monitoring electrodes. Anyhow, it's advisable to use monitoring systems with the limitation of high-frequency current.
7. The electrode input cords have to be placed in such a way that any contacts with the PATIENT's body or other electric conductors are prevented. The temporarily unused active electrodes have to be kept separately from the PATIENT.
8. At performing such surgical procedures when high-frequency current can flow through the parts of the patient's body with relatively small cross-sections, we recommend to use the bipolar technique to avoid the unintentional coagulation.
9. The output function has to be set at the minimum level for a **given elemental operation**.
10. The improperly used neutral electrode or its inconvenient or incorrect connection can cause demonstrably decreased output function or the system malfunction. The function of such Electrosurgical Unit isn't optimal even at standard operational conditions.
11. If a surgical operation is performed in the area close to chest or head, the use of combustible anesthetics or oxidizing gases (e.g. dinitrogen oxide /N<sub>2</sub>O/ and oxygen) must be avoided, unless the vapor drawing off is ensured. The incombustible substances have to be used wherever possible. The combustible substances, used for cleaning, disinfecting, or as a solvent, must evaporate off before the application of the high-frequency surgery. The accumulation of combustible substances under the PATIENT or in PATIENT's sinuses, e.g. abdomen or vagina, may be dangerous. Before using the Unit, the combustible substances have to be absorbed from these spaces by gauze. Pay close attention to the danger of inflammation of endogenous gases. The potential sparking can occur and cause the inflammation of some substances (e.g. absorbent cotton and gauze saturated with oxygen) even at normal application of the Unit. Patients with any active implantation are endangered by the eventual interference of the Electrosurgical Unit. Such implantation can be damaged as well. You must count on the interference, arising from the operation of high-frequency Electrosurgical Unit, which can negatively affect the operation of other electronic equipment. During an activated output function, this it could be a source of an interference for other devices, placed nearby and sensitive to



electromagnetic field. A possible precaution is placing the electrocauter and an interferenced device far between.

12. The preventative inspections of the Unit and its accessory must be done regularly. It is important to pay special attention to the condition of insulation of the electrode input cords.

13. Any unprofessional encroaching up on the Unit must be avoided. Have all revisions, reconditions, and inspections carried out by the manufacturer or by the chartered service.

14. To minimize risks and consequences of possible power cut, we recommend using the Unit in operating theatres equipped with stand-by power distribution. At ambulatory applications the Unit should be fed from stand-by power supply (UPS).

15. Have the Electrosurgical system overhauled concerning the safety by the manufacturer or at the chartered service minimum once a year.

## **2. ELECTROSURGICAL SYSTEM SMT BM VET**

### **2.1. Control Unit**

The electrosurgery generator is a high-frequency high-powered oscillator. Its output current can be modulated to be suitable for the incision, coagulation and their combinations.

The operator can control the output function level in such a way that it fully complies with his needs. The output function is adjustable in the range of several stages ("Min. - Max."). The Unit can operate either in MONOPOLAR or in BIPOLAR mode. In each mode, it's possible to select the current for the incision, mixed incision, coagulation or micro-coagulation. And, also in each mode, the output function level can be increased or decreased from "Min." up to "Max." with the output function controller which is on the front panel.

### **Colour-Light Indicators**

Green	POWER SUPPLY - the Unit is on
Green	with position MONOPOLAR - BIPOLAR
Yellow	INCISION (CUT) - current of the output function is selected for the incision
Green	MIXED INCISION (BLEND) - current of the output function is selected for the mixed incision
Blue	COAG - current of the output function is selected for the coagulation
Orange	MICRO - the output function current is selected for the microcoagulation
Red	NEUTRAL ELECTRODE (alarm) - the system malfunction in the circuit of neutral electrode

### **2.2. Surgical Tool - Applicator**

An applicator holds the active electrode selected for a particular electrosurgery operation. This medical help is executed in accordance with the specialized medical treatments and recommendations mentioned above, in chapter 2. The most frequent applications are the incision by scalpel, loop electrode LOOP or needle electrode, and coagulation by ball electrode BALL. (All that supplied by manufacturer of this Electrosurgical Unit.)

The miniature applicator is a device which is very often used in micro-surgery. It is suitable for the micro-coagulation. This applicator holds a special needle that functions as an active electrode.

It's also possible to use tweezers - the bipolar mode.

### **2.3. Active Electrodes - Operating Instruments**

The active electrodes concentrate high-frequency current and apply it into tissue. According to their shape, they are intended especially for the incision or for the coagulation. The thin wire electrodes, straight or loop, are usually used for the incision. The loop electrodes are used for the tissue excision.

The ball electrodes are used for coagulation. Standardized chucking diameter of electrode shank is 2.4 mm. The electrode tip is partly sterilized by high-frequency energy, that destroys also germs accidentally occurring in the operation area. But most electrodes can be repeatedly sterilized by all conventional methods. Manufacturer recommends sterilization by steam - see Chapter 5.1.

## **2.4. Neutral (Patient) Electrode - the Contact Part**

The neutral electrode closes the circuit. It must be fastened reliably and with its entire contact surface to the patient body as near as possible to the operation area. It is usually a plate made of metal, conductive rubber, or plastic; dimensions are about 6 x 14 cm or larger.

This part of the electrosurgery set is very important. The International Safety Directives require the parallel monitoring of the safe fastening of the neutral electrode to patient body. If the neutral electrode is disconnected, or, if though one wire of the two-core input connection cord is broken and at the same time monopolar mode is selected, then the warning red light intermittently flickers and the panel sounds with the intermittent acoustic signal. The function is interrupted. This warning is also activated whenever the electric circuit of the neutral electrode is disconnected in the course of a surgical treatment. If a situation like this occurs, such electrode must be overhauled, and, if need be, replaced. The visual checking of all electrodes and their input connection cords is recommended before each operation.

Using neutral electrode is of vital importance for perfect execution of a surgical treatment with the minimum and safest possible amperage, and also for the due operation of the Unit. (An operation without neutral electrode requires the higher output function. Moreover, unless the neutral electrode is applied, many various effects, e.g. weight of the patient, conductivity of patient skin, and also the position of an operator, could affect the high-frequency impedance and thus influence the operation of the electrosurgical instrument and in that connection also the surgical treatment.)

The neutral electrode must be placed in such a way, that it forms the reliable compact contact with a part of the patient's body.

When you use the neutral electrode observing the Principles of the Safe Use (specified in Chapter 1.1.) is obligatory.

## **2.5. Foot-Operated Switch**

The foot-operated switch is pneumatic one, without any electric cords, therefore highly safe.

### 3. TECHNICAL DESCRIPTION AND BASIC SPECIFICATIONS

Type:.....	SMT BM VET
Supply voltage.....	230V/50Hz
No-load input.....	22 VA
<b>Output.....</b>	<b>120 W</b>
Working frequency.....	460,85 kHz
Insulation class .....	II ☐
Dimensions /mm/.....	260x250x80
Weight.....	4,5 kg
Power supply transformer Prim. 230V; sec.1=57V; 200 VA;	
sec. 2 = 16V;	
CSN EN 60601-1	

#### 3.1. The operation and storing of the Unit:

Ambient temperature .....	+10°C up to +40°C
Relative humidity.....	from 30% to 75%
Atmospheric pressure.....	from 700 kPa to 1060 kPa
Index of protection against an undesirable water penetration.....	protection IP 21

The Unit was certified by the procedure conformably to CSN EN 60601-1:1994, CSN EN 60601-2-2:1994, CSN EN 60601-1-2:1996, CSN EN 55011 Standards.

The Unit was internationally certified by the Directive 93/42 EEC, the way of ANNEX II and it is labeled with **MARK of Conformity CE 0459**.

Used symbols:

The Unit is type BF with protection against defibrillation discharge, the corresponding symbol on the Unit is .

The Unit operates with high-frequency energy with nonionizing radiation, the corresponding symbol is .

The Unit operates in MONOPOLAR (symbol ) and BIPOLAR (double jack for tweezers) modes.

The selected mode is activated by the switch-over (picture 1, no. 3).

The mode is unipolar or bipolar for all output functions.

Operational output functions ..... the incision (cut), mixed incision (blend), coagulation, micro-coagulation.

Technique of operation ..... the uninterrupted operation with intermittent loading (see chapter 4).

The instruction "ATTENTION, consult enclosed documentation", the corresponding symbol on the Unit is  $\triangle$ .

### 3.2. Operating Instrument Holder - Applicator

The essential accessory of the Unit is the basic applicator for monopolar application. The bipolar or monopolar tweezers can be bought extra for all systems BM.

### 3.3. Neutral Electrode

The insulated contact part of electrode type F, the corresponding symbol  $\boxed{F}$  on the instrument.

### 3.4. Pneumatic Foot Switch

Dimensions..... 109 mm

Length of the inlet tube.....ca 3 m

Weight.....0.25 kg

Foot-operated switch, the corresponding symbol  $\sphericalangle$  on the rear panel.

### 3.5. Electrodes and Accessory

The manufacturer supplies the electrodes in the assortment specified in Chapter 6. If you need to upgrade the assortment and purchase other accessory, please follow instructions in Article 2, Chapter 1.1.

## 4. INSTALLATION

The uninterrupted operation of the Unit is possible at supposed minimum usual resistance of the operated tissue 100 Ohms. The technical limits of the Unit are defined by the following technique of operation:

INTERRUPTED OPERATION - 180/30 (180 sec operation / 30 sec interruption)

For the installation of the Unit, select a place which is stable, sheltered from heat radiation and direct sunshine. First, insert the power cord into the coupler plug on the rear panel of control unit, then, plug it in the properly installed socket of electrical system.

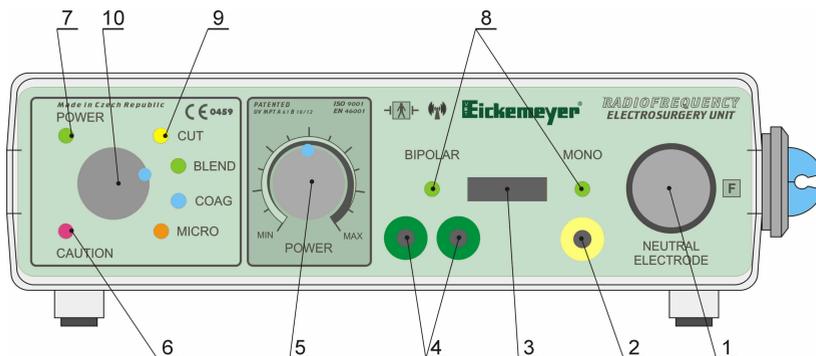
The small hose of the pneumatic foot-operated switch put in the connector on the rear panel (the connection has to be hermetically sealed).

Switch on the power-supply switch on the rear panel - the indication by light signal (picture 1, no. 7). Select the required mode by the MONOPOLAR - BIPOLAR mode switch (picture 1, no. 3), the switch position is indicated by the light signal (picture 1, no. 8). Then insert the electrode connection cords into respective jacks pursuant to the picture of the front panel (picture 1). Insert the connection cord of the neutral electrode into the respective coupler plug, then move the blue collar clockwise round a slight amount till you feel, that the connector snaps down into the coupler plug. When disconnecting the neutral electrode always pull the grey collar back to you, and move round a slight amount contrariwise. Select the operating output function with the change-over switch (picture 1, no. 10). Adjust the estimate of the required output function by the output function controller (picture 1, no. 5).

The activation of the output function is indicated by the respective light signal (picture 1, no. 9) and simultaneous uninterrupted acoustic signal.

The taking out of the neutral electrode at monopolar mode causes the activation of intermittent acoustic alarm and of red light signal (picture 1, no. 6). In this case, however, this phenomenon doesn't indicate malfunction, but checks the right function of the monitor circuit of neutral electrode.

**Picture 1 - THE FRONT PANEL OF CONTROL UNIT**



Legend:

- 1 - coupler plug for the attachment of the neutral electrode
- 2 - jack for the monopolar electrode
- 3 - MONOPOLAR / BIPOLAR mode switch
- 4 - two plugs for a bipolar instrument (tweezers)
- 5 - output function regulator unit of intensity
- 6 - red light signal - malfunction in the area of the neutral electrode
- 7 - green light signal - power-supply is switched on
- 8 - signals indicating the position of the M/B mode switch
- 9 - signals indicating the output functions
- 10 - change-over switch of the output functions

## 5. MAINTENANCE

The Electrosurgical Set doesn't require any special maintenance, except usual cleanup of all parts. Have any repairing performed by the manufacturer or the chartered service.

### 5.1. Sterilization

The sterilization of all parts which are in contact with patient body - electrode holders, patient neutral electrode, and also surgical electrode - can be done in autoclave, or by subjecting to formaldehyde or ethylene-oxide. The **producer** of this device **recommends** the sterilization in **autoclave**. The sterilization of the electrodes (LOOP, BALL, scalpel, needle) can be also done by hot air, up to temperature 150°C. After each

sterilization, it is necessary to do the preventative visual inspection of all connection cords of operating electrode holder and neutral electrode.

## **5.2. Cleaning**

The surface of the control unit case can be wiped with a damp gauze with addition of a usual detergent. However, do not allow washing solution to get inside.

The cleaning of electrodes can be analogous to the cleaning of the control unit case. In addition to this, before the sterilization, they must be cleaned also mechanically and sufficiently rinsed with running water.

## **5.3. Troubleshooting and Reparations**

- If the electrode isn't effective enough, though the light signal lights up and the uninterrupted acoustic signal is on after pressing-down the foot-operated switch, then recheck, whether the electrode is connected properly, and, whether the intensity of high-frequency current is adjusted correctly.
- In case, when after switching on the Unit and pressing down the foot-operated switch the electrode doesn't respond to it, and neither light nor acoustic signal function is on, even after checking carefully insertions of all connections, then the failure can be in the circuits of the control unit. In that case, you must contact a chartered service or directly the manufacturer.

## **5.4. Preventative Inspections**

The preventative inspections of the Electrosurgery Control Unit must be carried out minimum once a year, and of connection cords and parts contacting patient body minimum once a half-year. The instrument and the contacting parts with cords must be checked visually after each sterilization (using above recommended technique).

The preventative revisions of the Operating Instruments and Accessories safety are obligatory once a year. This must be carried out by the manufacturer or at the chartered service.

## **5.5. Guarantee**

The manufacturer guarantees that there will be no failure in the function of the Electrosurgery Unit for a period of 24 months from the date of installation. The manufacturer will repair the system free of charge during the guarantee period. The manufacturer shall not be held responsible for any damages to the system or improper performance of the



system if the damage was caused by improper operation of the unit by the end user.

## **5.6. Instructions for the Realization of Guarantee Repair**

Forward or transport personally the Unit, duly packed (preferably in the original covering), with the enclosed Indemnity Agreement and description of the failure, to the address of manufacturer, or, after the previous telephonic agreement with manufacturer, to the address of the nearest relevant service organization.

## **6. TESTING ACCORDING TO STANDARDS**

Since the SMT's Electrosurgical Units were tested by the Czech chartered person No. 201 and by the European Notified Body, it is marked with the **EURO Mark of Conformity CE**. The Units were tested according to standards IEC 601-1 (The Electric Medical Instruments - The General Requirements on Safety) and IEC 601-2-2 (The Electric Medical Instruments - The Special Requirements on Safety of the High-Frequency Surgical Instruments) and was granted the certificates No. 5.001382-00 and B-30-00568/00 under the Council **Directive 93/42 EEC** of the EU Community. Chosen Conformance route was **Annex II**. Notified Body was BVQI 0301 (England) till October 2002. From November 2002 it is the new Notified Body G-MED (France) 0459 **MARK** of Conformity **CE 0459**.

## **7. ELECTROSURGICAL UNIT AND SUPPLIED ACCESSORY**

### **7.1. The basic accessory:**

- 1 - control unit with the applicator holder**
- 2 - applicator**
- 3 - neutral electrode (stainless steel)**
- 4 - foot-operated switch**
- 5 - power cord**
- 6 - active electrode (6 pieces)**

**Operating Instructions (incl. Indemnity Agreement and End User Registration Card)  
Covering**



**7.2. The additional accessory:**

- 1 - large selection of coagulation and resection electrodes and microcoagulation needles
- 2 - applicator for microcoagulation (with connection cord)
- 3 - tweezers for bipolar application
- 4 - connection cord for tweezers for bipolar application

## **INDEMNITY AGREEMENT**

**Product: RADIOFREQUENCY ELECTROSURGERY UNIT**

**Type: SMT BM VET**

**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 month 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, whose address is in heading.
- 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:



## END USER REGISTRATION CARD

**PRODUCT: RADIOFREQUENCY ELECTROSURGERY UNIT**

**TYPE: SMT BM VET**

Serial number:

Sales clerk:

User:

Name:

Organization:

Address:

Telephone:

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., Papírenská 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 13 485:2003 our firm conforms and the user of medical technology must be acquainted with.

Please, when we will send you a Form “Feed Back”, be so kind and fill it and send back to our address. You will so help us in further development of the product.

Thank You very much for your cooperation.  
**Special Medical Technology, Ltd. Co.**

