Electrosurgical Unit
ELECTROCOAGULATOR SMT

BM 170
BM 125
BM 100
BM 75

CE 1014

Instructions for Use

Content:

1. INTRODUCTION

Manufacturer:
Speciální Medicínská Technologie, s.r.o.
Zbraslavská 1113, 252 42, Jesenice, Czech Republic
Phone: +420 233 320 201
E-mail: smt-praha@smt-praha.com
URL: http://www.smt-praha.com

Class of medical device: **II b**

Device service life: **7 years**

(Date of the end of service life is on manufacturer´s label in format: yyyy-mm)
After the expiry service life, the manufacturer can extend the service life by one year (chapter 5.6.)

Please pay maximum attention to these Instructions for Use, carefully read it and **keep these instructions**.

We believe that you and your patients will be fully satisfied with our device.

Intended use:

The device is designed to cut and coagulate soft tissues in order to remove their pathological parts or stop bleeding.

Notice:

The device is not intended for the connection of applied type CF and should not be intended for direct use on the heart.

1.1. Warning:

Visual inspection of all parts of the device is required before each use of the device.

When the output power is activated the device may generate electromagnetic interference, which may affect the operation of other electrical devices.

The device can be operated only by persons who have been trained by the manufacturer or authorized person.

Don´t use device in present of flammable substances.

Use the device only to intended use.

Follow all instructions contained in Instructions for Use.

1.2. Contraindications

Presence of the metal implants in the presumed electric current path and presence the entire active implants when using the device in monopolar mode.
(In the case of use at patient with an active implant, it is necessary to consult with implant's manufacturer the implantation specialists).

1.3. Protection before electrosurgical smoke

During the electrosurgical operation is created electrosurgical smoke, which can have negative effects on health of medical staff. The smoke can be eliminated by using electrosurgical smoke evacuator to protect the health of staff.

2. GENERAL INFORMATION

2.1. How electrosurgery works

Electrosurgery works on principle of increase the heat during electric current flow. In place of contact with tissue is increased the heat proportional to the current density, that mean, that smaller tool surface (the electrodes) mean the higher the heat of tissue. The electric current passes into the body without pain and neuromuscular stimulations.

2.2. Main advantage of using electrosurgery

- Eliminate bleeding
- Exactly checking the size of the cut
- Reduce risk of post-operative infection
- Faster healing time
  Reduction of pain

2.3. Operation mode

2.3.1. Monopolar mode (MONO)

The monopolar mode has only one active electrode. The electric circle is closed by neutral electrode. On neutral electrode is electric current homogeneously dispersed and the heat of the tissue in contact with neutral electrode isn´t increased.

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2.3.2. Bipolar mode (BIPO)

The bipolar mode has two active electrodes most often in form of the forceps or peans. The electric current passes only between these two electrodes. Bipolar mode don´t needed the neutral electrode.

2.4. Operation output

2.4.1. Cut (CUT)

The Cut is created by sinus high frequency current flow, which causes increase the temperature into the cells over 100°C that destroyed the cells. It is used with slim electrosurgical electrodes like needles or loops.

2.4.2. Coagulation (COAG)

The Coagulation is created by modulate sinus output signal, which causes increase the temperature into the cells to 60°C, that causes to desiccation of cells and start haemostasis.
It is used with electrosurgical electrodes with bigger area like for example balls.

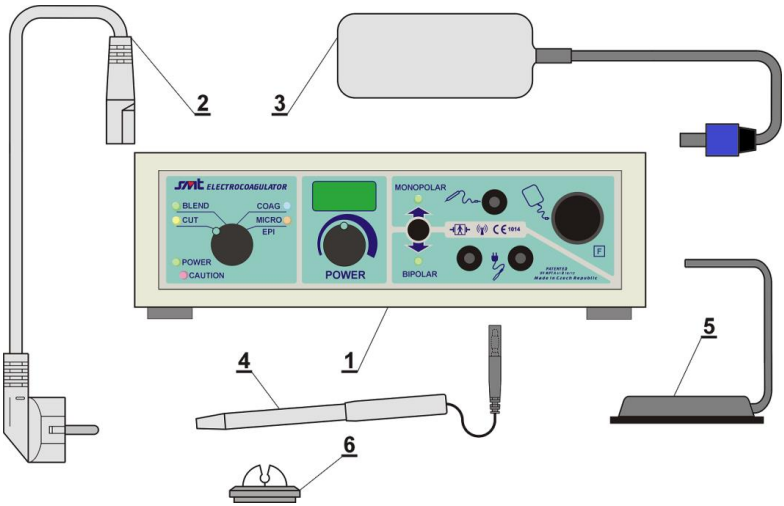
2.4.3. Blend cut (BLEND)

The Blend cut is combination of Cut and Coagulation.

2.4.4. Microcoagulation (MICRO)

The Microcoagulation is the type of coagulation with decrease the output power for work close to very sensitive organ (like eyes) or for epilation.

3. ELECTROCOAGULATOR SMT SYSTEM



Parts of Electrocoagulator SMT BM:

1. Control Unit
2. Power cord
5. Footswitch

(BM 75 have footswitch without metal stand)

Compatible parts:

3. Neutral electrode with cable
4. Applicator with active electrode
6. Applicator holder
7. Bipolar forceps with cable

3.1. Control Unit

Control Unit is main part of Electrocoagulator SMT using like generator of high frequency electric current. Allows set one of 4 operation outputs (Cut, Coag, Blend, Micro) in both modes (Mono or Bipo).

Signalization:

Switch ON/OF	- *green LED near POWER is shining*
Switch MONO / BIPO	- *green LED near MONO/BIPO is shining*
Choose CUT output	- *yellow LED near CUT is blinking*
Active CUT output	- *yellow LED near CUT is shining*
Choose COAG output	- *blue LED near COAG is blinking*

Active COAG output	- *blue LED near COAG is shining*
Choose BLEND output	- *green LED near BLEND is blinking*
Active BLEND output	- *green LED near BLEND is shining*
Choose MICRO output	- *orange LED near MICRO is blinking*
Active MICRO output	- *orange LED near MICRO is shining*
Alarm of neutral electrode	- *red LEDs near CAUTION are blinking and accompanied by acoustic signalization*

3.2. Applicator (holder of operation electrode)

Applicator is used to connection of operation electrode to control unit in monopolar mode.

Designated accessories:
Applicator SMT 2.4..... REF 160 60
Applicator SMT 1.6..... REF 160 61

3.3. Operation electrode (Active)

Operation electrodes are used to targeting high frequency current to the tissue. They can have a lot parameters according the function.
The thin electrodes (Needles, Loops) are used for cutting the tissue and the electrodes with bigger size (Balls) are used for coagulation the tissue.

Designated accessories:
Monopolar electrode Ø2.4

3.4. Neutral electrode (NE)

Neutral electrode used to close electric circle in monopolar mode. Neutral electrodes are divided according to materials (Metallic, Silicone or Single-use) or according to the number of electric circle using for monitoring contact of neutral electrode with patient (REM).

In case using the neutral electrode with more than one electric circle (standard are two) is automatically monitored the quality of connection between the patient and the neutral electrode. That means if the neutral electrode isn´t connected to the patients (or is connected only small parts of electrode) the control unit blocks the output and start alarm. The neutral electrode with only one circle (without REM) haven´t this protection. **If you can use NE with REM system, contact the manufacturer of the electrosurgical unit first. This is necessary be inform about compatibility of unit and neutral electrode.**

Designated accessories:
Metal neutral electrode – flat ..... REF 160 62
Metal neutral electrode – circular ..... REF 160 65
Cable for silicone NE ..... REF 160 21
Cable for single use NE ..... REF F7903
Silicone neutral electrode ..... REF F7915
Single use neutral electrode – Adult ..... REF F7805
Single use neutral electrode – Pediatric ..... REF F7805P
Single use neutral electrode – Neonatal ..... REF F7805N

3.5. Bipolar accessories

Bipolar forceps, peans and scissors are used in bipolar mode.

Designated accessories:
Bipolar cable ..... REF 707-303
Bipolar forceps ..... European type of connection

3.6. Footswitch

Footswitch are used to activation all operation outputs in monopolar and bipolar mode. They work on pneumatic principle that means if the tube is bent, broken or loaded by heavy object the footswitch isn't function.

Designated accessories:
Footswitch ..... REF 160 70
Footswitch with metal stand ..... REF 160 75

4. GENERAL TECHNICAL PARAMETERS

4.1. General parameters

Input voltage ..... ~ 230 V, 50 Hz

Power consumption in load:
BM 170 ..... 250 VA
BM 125 ..... 190 VA
BM 100 ..... 140 VA
BM 75 ..... 105 VA

Power consumption in stand by ..... 27 VA

Maximal output power

[W]	Cut		Blend		Coag		Micro (EPI)	
	MONO	BIPO	MONO	BIPO	MONO	BIPO	MONO	BIPO
BM 170	170	170	140	140	140	140	60	60
BM 125	125	125	100	100	100	100	40	40
BM 100	100	100	85	80	85	80	36	32
BM 75	75	75	65	60	65	60	30	24

Maximal output voltage (peak-peak) ..... 1490 V

Required voltage on monopolar accessories ..... 4000 V
Required voltage on bipolar accessories ..... 1500 V

Output frequency ..... 460.85 kHz

Dimension of Control Unit ..... 290 x 250 x 80 mm
Height of Control Unit ..... 3.5 kg
Length of power cable ..... 2 m

Transformer ..... Prim. = 230V
..... sec. 1 = 57V / 3A (45V / 2A in type 75 MB)
..... sec. 2 = 16V / 0.5A

Operating conditions:

Temperature  ..... 10°C to 40°C

Relative humidity  .....30% to 75%

Atmospheric pressure  .....700 kPa to 1060 kPa

Storage conditions:

Temperature  .....-10°C to 70°C

Isolation class ..... II - symbol 
IP code ..... IP 21
Applied parts type (HF accessories) ..... Defibrillation-proof BF 
Type of ESU .....Isolation type 
Recovery time after defibrillator shock .....15 s

The device can be used in continuous load.

Rated load in monopolar .....500 Ω
Rated load in bipolar .....100 Ω

4.2. Request about Electromagnetic Compatibility (EMC)

The device is source of electromagnetic interference..... 

Caution: Device malfunction may cause increases the output power.

Caution: It is important to avoid using the device next to or with other devices, because it may cause malfunctions. If such use is required, the instruments should be monitored to verify that they are functioning normally.

Caution: If using cables, which it isn´t specified by the manufacturer, electromagnetic compatibility and interference may be impaired.

The maximal lengths of cables are above this chapter (Chapter 3.2, 3.4, 3.5 and 4.1).

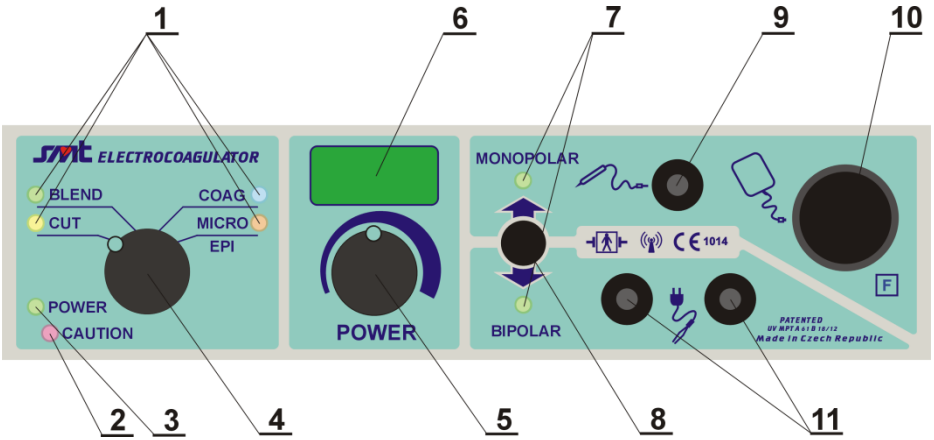
Caution: Portable RF communication devices (including terminal devices such as antenna cables and external antennas) should not be used more than 30 cm (12 inches) from any part of the electrosurgical device, including cables specified by the manufacturer. Otherwise, this device may have malfunctions.

Note: The emission characteristics of this device make it suitable for use in industrial areas and hospitals (Class A according to CISPR 11). If used this device in residential environments (normally requiring Class B under CISPR 11), may not provide adequate protection for high frequency communication services. The user may need to use mitigating steps such as relocating or changing the orientation of the device.

Warning for use in patients with active implants:
Use caution when using in patients with active implants.
Always consult using with implant device manufacturer and a specialist doctor.
Always prefer bipolar mode.
Never touch the implanted device directly with the active electrode (forceps).
For implantable cardioverter-defibrillators (ICD), ESU activation can cause unwanted false activations - therefore prior consultation with the implant manufacturer is necessary.

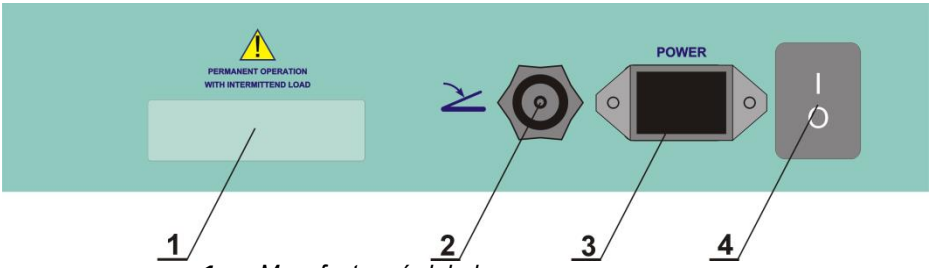
5. USE, OPERATION AND MAINTENANCE

5.1. Description of front panel



1. *Signalization of operation output*
2. *Signalization of problem with NE*
3. *Signalization switch ON/OFF*
4. *Switcher of operation outputs*
5. *Regulator of output power*
6. *Display*
7. *Signalization of active mode*
8. *Switch to switching mode*
9. *Socket to connect applicator*
10. *Socket to connect NE*
11. *Sockets to connect bipolar forceps*

5.2. Description of back panel



1. *Manufacturer´s label*
2. *Connector to connect footswitch*
3. *Socket to connect power cable*
4. *Power switcher*

5.3. Before use

Caution: All accessories are supplied by the manufacturer non-sterile and non-cleaned unless on the accessory packaging isn´t specifies otherwise. Prior to first use, it is necessary to clean and sterilize according to this Instructions for Use (5.5).

1. Place the device in a stable place where isn´t radiant heat or direct sunlight. Be careful not to clog the ventilation hole in the lower right corner of the control unit.

2. Connect the power cord (3. - 2) into the appropriate connector (5.2.3) and plug the other end of the cable to a power socket (230 V / 50 Hz).

3. Attach the free end of the pneumatic footswitch (3. - 5) to the pin (center tube) of the pneumatic connector (5.2 - 2) and push the hose as far as possible into the pin. Checking the correct operation is a characteristic click when the pneumatic switch is pressed.

4. Connect other accessories according to the medical operation.

In case using monopolar mode:

a) Connect the applicator (3. - 4) into the appropriate connector (5.1. - 9) on front panel of the control unit.

b) Put the connector of neutral electrode (3. - 3) into the socket (5.1. - 10) on front panel of the control unit. After turning it in, rotate it until you hear a click.

c) Put the neutral electrode on tissue of the patient. The neutral electrode must be connecting with patient all over the surface.

d) Rotate counterclockwise the front part of the applicator, loosen the applicator collet, insert the operation electrode and tighten the collet by turning the front part clockwise.

In case using bipolar mode:

a) Connect the fork of bipolar cable to the connector on the front panel of control unit (5.1. - 11).

b) To the second end of the bipolar cable put bipolar forceps, pean or other bipolar accessories.

5. Switch on the device by switcher (5.2. - 4) on the front side of control unit.

6. Pushing the button (5.1. - 8) choice the mode.

7. By switcher of the operation outputs (5.1. - 4) choice the operation output.

8. By Regulator o the output power (5.1. - 5) set the output power.

9. The output power activate by pressing the footswitch.

5.4. Use

Caution: The neutral electrode must be connecting with patient all over the surface for all operation time.

Caution: Set the output power must be on minimal possible level necessary to procedure. In case of a sudden noticeable drop in power, first check the path of the electrical current, including the connection of neutral electrode to the patient and the purity of the active electrode. If every is ok, than you can increase the power.

Caution: Use other accessories than is supplied by the manufacturer must be consulted with the manufacturer before use.

Caution: For procedures where the electrical current flows through small areas, bipolar mode should be used. It is also desirable to avoid skin-skin contact, which could result a change in the path of the electrical current.

Caution: If are used monitor or measuring electrodes (EKG) is necessary then this electrodes were situated as far as possible from electrosurgical electrodes.

Caution: Electrosurgical cables should be situated as far as possible from control unit and should not form loops around metal objects. Temporarily deposed electrodes must be separated from the patient.

Caution: Don´t use flammable substances. Watch out for disinfection on alcoholic base and medical gas (N_2O and oxygen).

Caution: Consultation with specialists is necessary in patients with active implants.

Caution: If an adverse event is suspected, minimize the negative effects of this event and inform the manufacturer without delay.

5.5. Re-Use

5.5.1. Cleaning

The control unit, the pneumatic footswitch and the power cable can be cleaned using conventional disinfectants. When are cleaning, make sure that the disinfection solution didn´t leak into the connectors or ventilator.

5.6. Removing typical malfunctions

- If the control unit can´t switch on by switcher on back side, check the correct connection the power cable to the socket.

- In case if the control unit don´t respond for press the footswitch, check that the tube isn´t bent, broken or loaded by heavy object and is correct push on the pin of the switcher (you can hear a characteristic click when the pneumatic switch is pressed).

- If is activated the alarm of the neutral electrode and neutral electrode is connect to the socket on front side of the control unit:
    1. Check that the plug of the neutral electrode is correct connects to the socket. The connector is on bayonet base. When is connect you can hear characteristic click.
    2. If you using the neutral electrode with more than one electric circle, you must connect this electrode on the patient first.
    3. Try change the neutral electrode.

- If after the activation the output power (the light and acustic signalization work well) is no effect on the tissue:
    1. In case if you using the monopolar mode, check the connection the neutral electrode on the patient.
    2. Check, that you have set higher output power than zero.
    3. Check the accessory cables for mechanical damage.

In other case please contact the service.

5.7. Services

Speciální Medicínská Technologie, s.r.o *Zbraslavská 1113, 252 42, Jesenice, Czech Republic, EU*

Phone: +420 233 320 201, E-mail: obchod@smt-praha.com *www.smt-praha.com*

5.7.1. Periodic control

Periodic safety and technical inspection must be performed at least once a year (but it also depends on country regulations). The control may be performed by authorized service facility or manufacturer. Contact the manufacturer for information about authorized service facility.

5.7.2. Extension of service life

After the expiry service life, the manufacturer can extend the service life by one year, when is the control didn´t revealed safety or function malfunction.

5.7.3. Repair

All repairs will be carried out exclusively by the manufacturer or authorized service facility.

5.8. Disposal

The device must be disposal of in accordance with applicable laws and regulations. Disposal is provided by the manufacturer free of charge.

6. GUARANTEE

The manufacturer guarantees that there will be no failure in the function of the device for a period of 24 months from the date of sell. The manufacturer will repair the device free of charge during the guarantee period. The manufacturer shall not be held responsible for any damages to the device if the damage was caused by damaged by misuse, improper treatment or not following this Instruction for Use and the guarantee conditions. The warranty does not apply to accessories.

In case when the control will be provide at the manufacturer, the manufacturer guarantees an extension of the warranty on the selected parts for another three years.

The selected parts are:

- Complete main board
- Complete display board
- Transformer
- Pneumatic switcher

7. LEGAL REGULATION

The conformity was reviewed according to Regulations of the Czech Government No. 54/2015 Coll. (93/42/EEC) and was issued the Declaration of Conformity. The examination of the conformity was carried out in participation of the Notified Body No. 1014 – Electrotechnical Testing Institute (EZU) - Pod Lisem 129, Prague 8, 171 02.

No materials prohibited by Directive 2011/65 / EU have been used to produce the SMT BM Electrocoagulator and not contain active substances, human blood derivatives, phthalates, or any other similar substances.

8. USED LABELS

 Manufac-turer	 Atmospher-ic pressure	 Isolated electric circle
 Service life	 General warning	 Defibrilla-tion-proof applied parts BF
 Serial number	 CE Mark	 Applied parts BF
 Catalog number	 On / Off STAND-BY mode	 The device contains RF trans-mitter. May interfere with other electrical equipment.
 Tempera-ture	 Device with double iso-lation	 Footswitch connector
 Relative humidity	IP21 Protection level IP21: Protects against the intrusion of small ob-jects (12.5x12.5 mm) and dripping water (1mm / s)	 Read the instructions for use!

(Used labels are according to EN 60601-1 and ISO 15223-1)

9. INDEMNITY AGREEMENT

Product: ELECTOCOAGULATOR SMT

Type:

BM 75 BM 100 BM 125 BM 170

Serial number:

Date of sale:

Stamp and signature of expedition:

Guarantee Condition:

a) At observing Instructions for Use 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 manufacturer.
d) The free of charge repair within the guarantee period isn´t valid for the accessories (electrodes and cables).
e) Free repairs after the default warranty are applied only to selected parts of the device (Chapter 6). The manufacturer warrants this warranty for a period of 3 years from the end of the two years warranty period, only in case when all the conditions in these Instructions for Use are met and was doing the periodic control with the manufacturer. Free repairs after the two year warranty period do not include shipping costs.
f) The guarantee period will be extended for a term of the guarantee repair.
G) The Indemnity Agreement is “The Certificate of the Quality and Completeness of the Product”.

10. END USER REGISTRATION CARD

We will pleasure if we you fill this Registration Card and send it (in scan form) on e-mail address: obchod@smt-praha.com

Type: **Serial Number:**

User:

Address:

Contact (phone or e-mail):

Suggestions for improvements

Please share your impressions from this device that we can continue to improve it as effectively as possible.

Functionality:

Design (Looks):

Equipment (Accessories):

Thank you for completing this Registration Card and we look forward for future cooperation.

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