

Electrosurgical Unit

KENTAMED 1E



User Manual

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1. Introduction

1.1. Destination and fields of application

APPLICATION: *Minor and medium surgery*
DESTINATION: *Ideal for medical, dental and veterinary offices and clinics*

1.2. Functions

KENTAMED 1ME is an intelligent, microprocessor controlled electrosurgical unit. It characterizes functional completeness, reliable operation, operating comfort and increased patient's safety.

The unit has **100W maximal output power** and **5+1 operating modes**, allowing the surgeon to obtain a large spectrum of different tissue effects. The operating modes are separated in two groups (fields):

- Group I - the group of **cutting** modes (**Yellow** field), which includes:
 - **Pure CUT** - smooth cutting,
 - **Blended CUT** - cutting with increased degree of coagulation,
- Group II - the group of **coagulating** modes (**Blue** field), which includes:
 - **Contact COAG** - a standard coagulation,
 - **SPRAY COAG** – non-contact, sparking coagulation with superficial effect,
 - **Bipolar COAG** - bipolar and **Micro** bipolar coagulation

Each of these modes has independent power setting, shown by digital LED indications – one 3-digits indicator per each group. A digital memory stores the last power settings. The unit can be activated by two-button finger-switched handle or by twin footswitch. Overheating (**OH**) and Power failure (**PF**) sensors as well as **Neutral Electrode Monitoring System (NEMSY)** increase the patient's safety. A status monitor on the front panel indicates if some of the controlled parameters are out of the norm. If this happen, the control circuit immediately switches off the output power and generates a sound alarm.

1.3. Technical characteristics

KENTAMED 1E - Technical characteristics

	Maximal Output Power		Crest Factor
	Macro mode	micro mode	
Pure CUT	100W / 500 Ohms	-	1.5
Blended CUT	100W / 500 Ohms	-	2.1
Contact COAG	100W / 300 Ohms	-	3.0
SPRAY COAG	10W / 5000 Ohms	-	7.0
Bipolar COAG	80W / 100 Ohms	35W / 100 Ohms	1.5

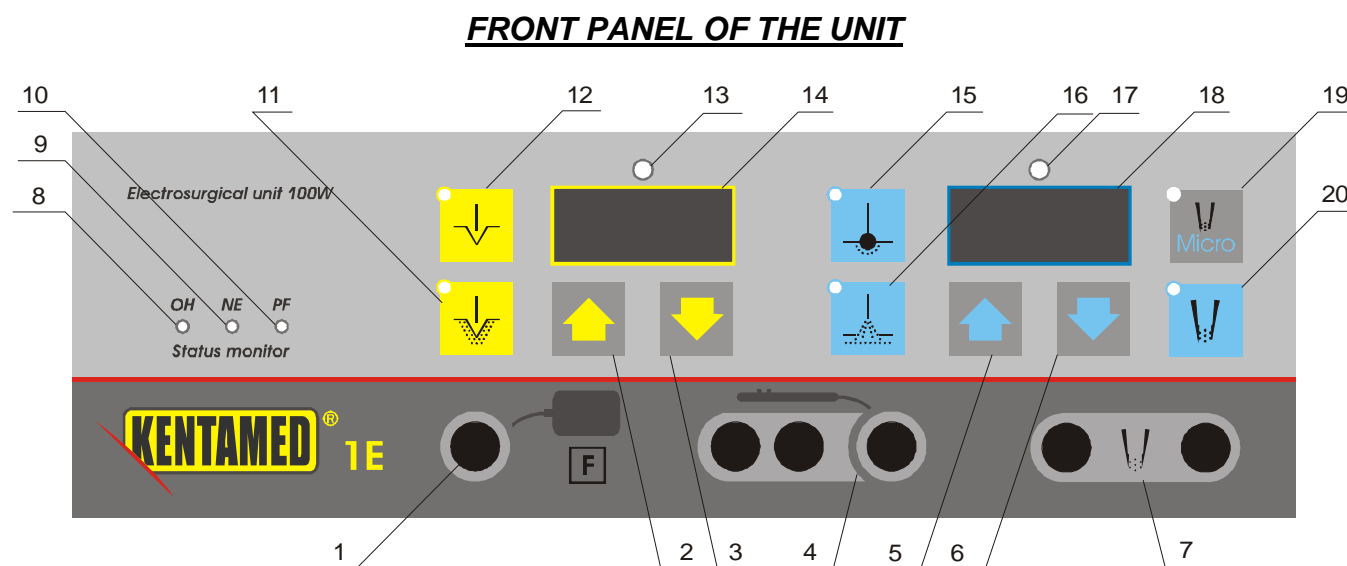
Working frequency [KHz]	500
Modulation frequency [KHz]	33
Patient safety	NEMSY (Neutral Electrode Safety System)
Activation	Twin footswitch and Hand Switched Pencil
Dimensions (W x D x H) in mm	255 x 215 x 85
Weight [kg]	5

2. Description of the unit

2.1. Basic components of the unit

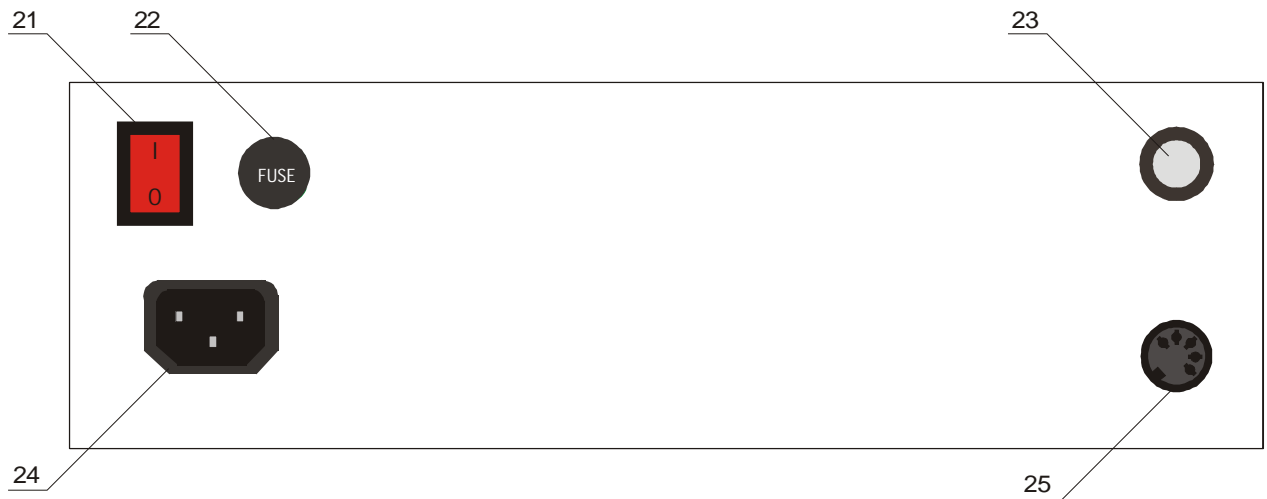
The basic components of the electrosurgical unit **KENTAMED 1ME** are a power supply module, a power generator and a control module. The unit is built in a plastic housing with a front panel and a rear panel and conveniently placed on it controls, indications and connectors for the accessories.

2.2. Controls, indications and connectors



1. Socket for the Neutral Electrode's cable.
2. Push-button for **increasing** the power setting for Pure and Blended CUT modes
3. Push-button for **decreasing** the power setting for Pure and Blended CUT modes
4. Sockets for active electrodes handles – as for Hand-switched as well as for foot-switched handles (pencils)
5. Push-button for **increasing** the power setting for Contact, SPRAY and Bipolar COAG modes
6. Push-button for **decreasing** the power setting for Contact, SPRAY and Bipolar COAG modes
7. Sockets for the bipolar accessories
8. Red LED indicating an Over Heating (OH) of a power module of the unit. If this happen the output power is immediately switching down and a sound alarm is generated. The normal work can continue after several minutes, when the power module of the unit comes to normal operating temperature.
9. Red LED indicating a Neutral Electrode contact failure (NE). If this happen the output power is immediately switching down and a sound alarm is generated. This indication is generated by NEMSY in some of the next situation:
 - a. When a bipolar (split) neutral electrode is used and it's contact with the patient's body is not sufficient
 - b. When the connector of the neutral electrode's cable (in cases of bipolar or monopolar NE) is damaged or not coupled to the socket 1
10. Red LED indicating a Power Failure (PF) in a situation when the output power exceeds the desired power setting. If this happen the output power is immediately switching down and a sound alarm is generated.
11. Push-button, selecting the **Blended CUT** mode – cutting with more haemostasis
12. Push-button, selecting the **Pure CUT** mode – a smooth cutting, similar to classic scalpel
13. Yellow LED indicating the activation of output power at pre-selected cutting operating mode
14. Digital display indicating the output power setting corresponding to pre-selected cutting operating mode
15. Push-button, selecting the **Contact COAG** – a standard monopolar coagulation
16. Push-button, selecting the **SPRAY COAG** – a superficial monopolar coagulation
17. Blue LED indicating the activation of output power at pre-selected **coagulating** operating mode
18. Digital display indicating the output power setting corresponding to pre-selected **coagulating** operating mode
19. Push-button, selecting the **Micro BICOAG** operating mode with possible power settings between 1 and 35W
20. Push-button, selecting the **BICOAG** operating mode with possible power settings between 1 and 80W

REAR PANEL OF THE UNIT



21. Power ON/OFF switch (I = ON, 0 = OFF)
22. Socket for safety fuse 2.5A / 220V
23. Potentiometer for acoustic signal volume adjustment.
24. Socket for the mains power cable
25. Socket for two-sections footswitch coupling

2.3. Instruments and accessories

The most used accessories are:

- Mains power cable
- Twin footswitch with yellow and blue sections respectively for cutting and coagulation
- Finger-switched handpiece for active monopolar electrodes
- A set of different monopolar electrodes for cutting and coagulation. A Neutral Electrode with a cable for it. The unit can work with a simple plate neutral electrode as well as with a split plate neutral electrode. The use of split neutral electrode provides maximal safety for the patient thanks of the **Neutral Electrode Monitoring System (NEMSY)**.
- Bipolar forceps with an European coupling
- Other bipolar electrodes / with an European coupling /
- Silicon bipolar cable with a socket for bipolar forceps and bipolar electrodes. The other side of this cable ends with two “banana” jacks for coupling to the ESU (sockets 7 of the front panel).

3. Method of operation

3.1. Installation

- The unit is placed on a specially selected place in the Operating Room (OR) so it can be accessible to the people, who are responsible for setting the working modes and the necessary output power during the operation. In the same time the distance to the operating field must provide the surgeon and his assistants enough operating space, having in mind that the patient cables are with 3 meters length typically.
- The footswitch must be placed on the floor in the suitable for the surgeon place.

- The electrical installation of the OR must be in perfect condition.

3.2. Connecting of the accessories to the unit

- Check if the power switch 21 is in position “0” – off. Connect consecutively the mains power cable to the socket 24 of the rear panel and to the mains power socket on the wall of OR.
- Connect the cable of the footswitch to the socket 25 on rear panel.
- Connect the 6mm jack connector of the neutral electrode cable to the socket 1 on the front panel. This connector is identical for the cables of both mono-polar and bipolar (split) neutral electrodes.
- Connect the three-banana connector (type Valleylab) of the finger-switch electrode handle to the socket 4 on the front panel. If you use a foot-switch electrode handle, connect the banana to the right socket of the group sockets 4.
- Connect the bananas of the bipolar silicone cable to the sockets 7 on the front panel.

3.3. Switching ON/OFF the unit

The unit can be switched-on by turning the power switch 21 in position “I”. All LED indicators on the front panel, including all segments of the digital indicators 14 and 18 must go on for a second. This is an initial LED-test, allowing the operator to see if all indicators are working properly. After the initial test is finishing, all indicators must go out, except some indicators:

- In the “yellow” field for cutting modes:
 - The LED on the push-button (11 or 12), corresponding to the pre-selected operating mode
 - The digital indicator in the yellow window, showing the power setting for the pre-selected operating mode.
- In the “blue” field for coagulating modes:
 - The LED on the push-button (15, 16, 19 and/or 20), corresponding to the pre-selected operating mode. Note that when the Micro bipolar mode is pre-selected, two LED’s are switched – on the buttons 19 and 20.
 - The digital indicator in the blue window, showing the power setting for the pre-selected operating mode.

You can switch-off the unit by turning the power switch 13 in position “0”.

3.4. Setting the operation mode

- You can select the desired operating mode by pushing the corresponding push-button, after which the corresponding button-indicator is switching on.
- For each of the group modes, described in 1.2. the surgeon selects the desired working mode. So he must push one of the buttons 11 and 12 for cutting (group I) and one of the buttons 15, 16, 19 and 20 for coagulation (group II).
- Preliminary selected is that working mode, whose button-indicator is switched on.
- It is not possible to select two or more working modes of the same group simultaneously (an exception is the **Micro BICOAG** mode, which is a *sub-mode* of **BICOAG**)

3.5. Activation of the output

Only one of the preliminary selected working modes can be activated in a single moment. Pushing a button of the finger-switch handle or pressing some section of the twin footswitch can make the activation.

- The yellow button of the finger-switch handle or the yellow section of the twin footswitch activates the preliminary selected working mode of a group I (one of the cutting modes). A corresponding sound and the indicator 13 are switched on till the button (footswitch) is pressed.
- The blue section of the foot-switch can activate any of the preliminary selected coagulating modes of a group II. The blue button of the finger-switched pencil activates only the preliminary selected monopolar coagulating modes. A corresponding sound and the indicator 17 are switched on till the button (footswitch) is pressed.

The preliminary selected working mode can be activated and the pre-settled output power can be delivered to the patient's tissue pressing the footswitch or finger-switch (button on the electrode handle). Switching on the corresponding LED indicator (13 or 17) as well as corresponding sound (different for every operating mode) accompanies the activation of the output power. The output power will be activated as long as the footswitch or finger-switch (button) will be pushed. If Over Heating, NE Connection Failure or Power Failure is occurred during the activation of output, the output power is automatically switched off; the corresponding LED indicator (OH, NE or PF) and a sound alarm are switched on as is described above (see p. 2.2).

3.6. Neutral electrode placement

The purpose of the neutral electrode is to close the circuit of the high frequency current passing through the active electrode and a patient's tissue back to the unit. The next rules must follow up when the NE is attached to the patient's body:

- Place the NE as close as possible to the operating field to minimize the rout of the HF current through the patient's body;
- Select a good vascularized tissue for NE placement to ensure relative good electrical conductivity;
- Ensure a maximal contact surface and direct contact between the NE and the patient's body. If the contact surface is not enough, thermal injuries can be occurred.
- In the case when is necessary to place the NE on a hairy surface, shave the hairs first or put enough quantity of electro-conductive gel (for example ECG gel) between the NE and the patient's body to ensure the electrical contact;
- Ensure enough contact pressure between the NE and patient's body:
 - By use of elastic belt, pressing the NE to the body;
 - By placing the NE under the seat of the patient, counting on the patient's weight;
- In the veterinary medicine also can use a rectal neutral electrode with suitable diameter and length, counting on the natural elasticity of the rectum as well as on it good contact conductivity;
- When a self-sticking disposable NE is used, the contact quality is guaranteed by the conductive function of the sticking gel, covering the NE. Check the expiration date of the NE before use;
- When a split NE electrode is used, it is necessary to place it so the dividing line between the contacts half's show the operating field. The aim is to ensure equal conditions for the HF current for passing to each of the half's.

3.7. Output power setting

The maximal output power can be settled separately for each operating mode using the push buttons 2 and 3 for the cutting modes or 5 and 6 for coagulating modes. You must have in mind the next:

- Every single and short push of the button 2 or 5 will increase the settled maximal output power with a single step of 1W. Respectively every single and short push of the button 3 or 6 will decrease the settled maximal output power with a single step of 1W. This can be observed in the digital displays 14 or 18 on the front panel of the unit.
- If you keep pushing the buttons longer than 1 sec., a sequence of 1W-steps will be made in the direction, corresponding to the pushed button. The longer you push the button, the more steps of 1W will count out the digital display. The changes will stop after depressing the button, or after reaching the minimal- or respectively maximal possible setting. The range of possible output power settings for the different modes is as follows:
 - For **Pure CUT** – from 1W to 100W;
 - For **Blended CUT** - from 1W to 100W;
 - For **Contact COAG** - from 1W to 100W;
 - For **SPRAY COAG** - from 1W to 10W;
 - For **BICOAG** – from 1W to 80W;
 - For **Micro BICOAG** – from 1W to 35W.
- The individual power setting for each operating mode is stored in a digital memory.
- Even when you switch off the unit and will switching it on again after a long time, the digital display will show the last settings for each mode.
- You can make many changes of the power setting – the digital memory will store the last one.
- During the real operation the output power is changed automatically depending of the actual electrical resistance of the tissue between the active and neutral electrodes. This dependency is analyzed by so called Power Distribution Test (see the diagrams on fig.1 – fig.3). When the surgeon makes the output power setting, in fact he sets the maximal output power, which the unit can give at the characteristic tissue resistance (at about 500 Ohms, 300 Ohms or 100 Ohms for the different working modes of the model KENTAMED 1E).

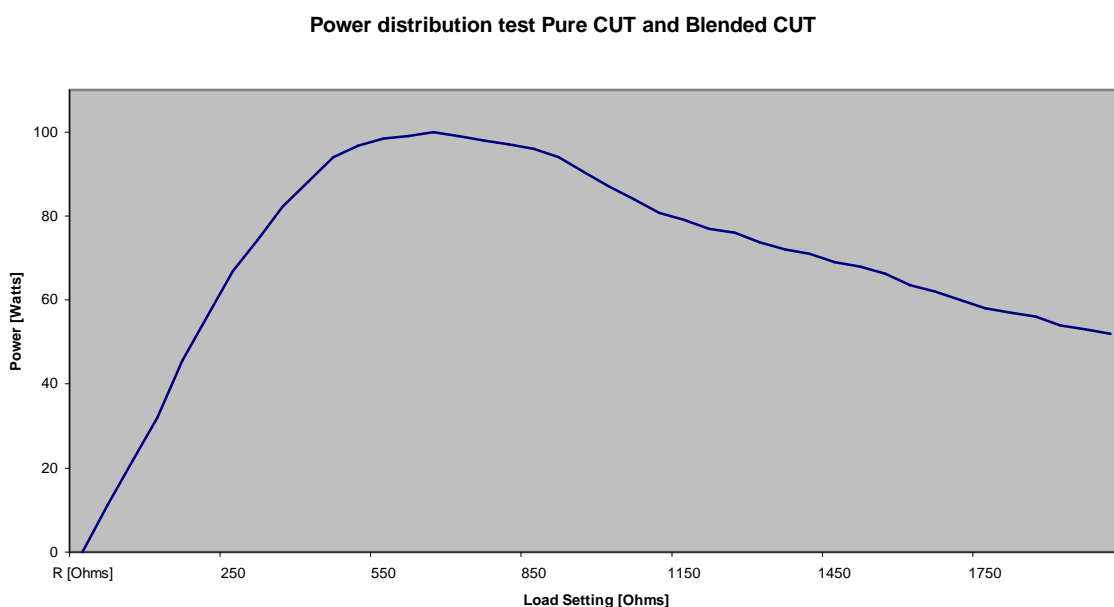


Fig.1

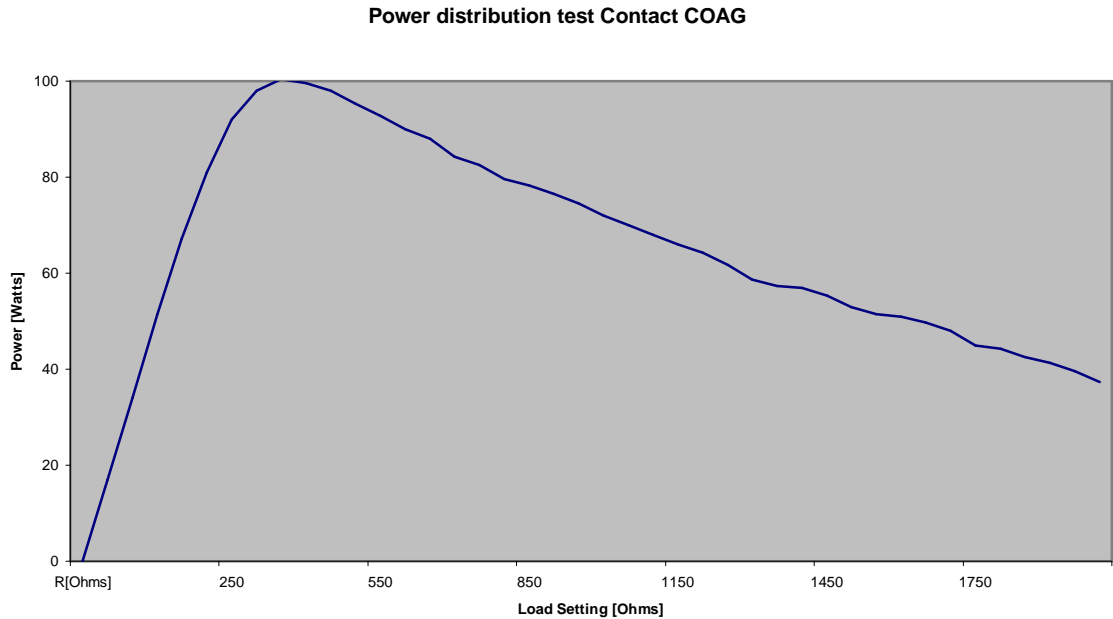


Fig.2

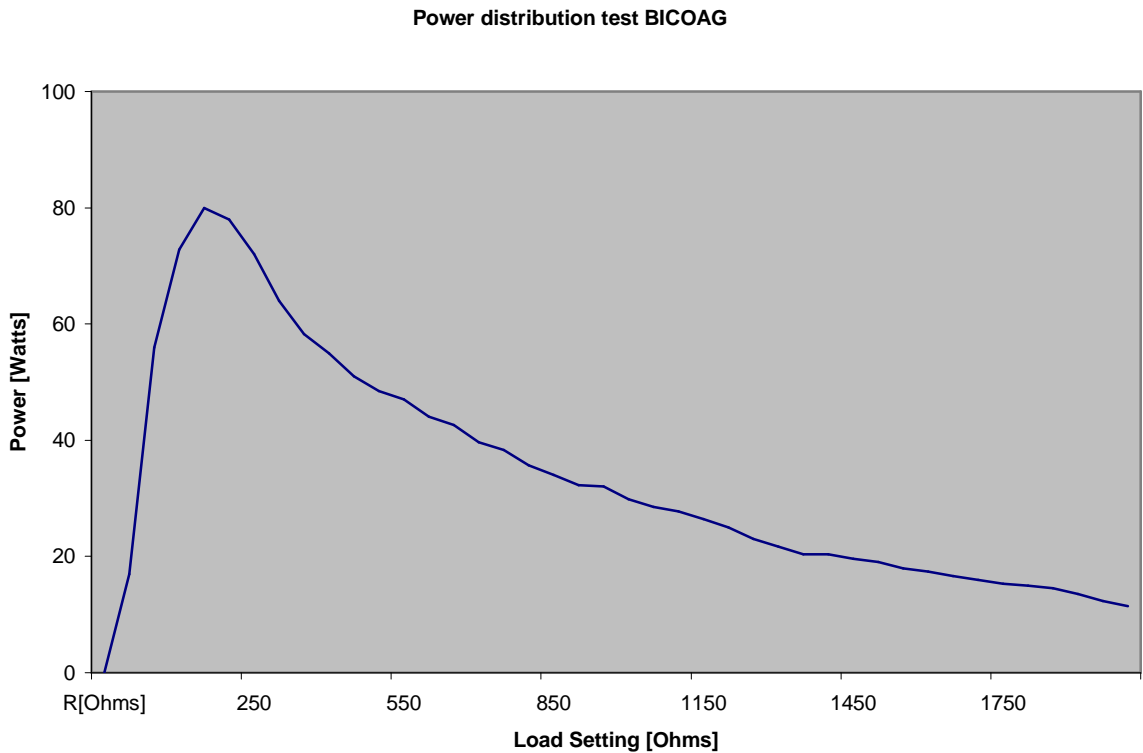


Fig.3.

3.8. Acoustic signal volume adjustment

When the footswitch is pressed, an acoustic signal is generated (different for the different modes).

- At normal work of the unit the volume of the acoustic signal can be adjusted by potentiometer 23 on the rear panel.
- At an overheating of the unit (OH), Neutral Electrode Contact failure (NE) or at output power failure (PF) a special acoustic signal is generated. Its volume can't be adjusted.

3.9. Cleaning the unit and the accessories

- **Cleaning the corpus of the unit** – it is recommended to use a soft material (tampon, gauze, etc.) and a cleaning liquid, such as ethyl alcohol etc., which would not damage the superficial coverage of the corpus. It is absolutely undesirable the penetration of a cleaning liquid inside the unit, because it can provoke an electrical damage of the electronic modules. That's why the tampon or the gauze must be only lightly damped.
- **Cleaning the footswitch, neutral electrode, electrode handle and the patient cables** – this can be made by the above-mentioned method. To enlarge the life of the cables and to avoid its damage do not bend it in immediate vicinity of the connectors. If it is necessary to wind the cable, leave a larger loop near the connector and the handle.
- **Cleaning the active electrodes and the bipolar forceps** – before the sterilization as well as periodically during the operations it must be cleaned by the carbonized tissue and blood, adhered to the metallic surface during the cutting and coagulation. Use gauze and suitable solvents such as ethyl alcohol, de-ionized water etc.

3.10. Sterilization

Follow up the instructions for the different accessories.

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