

This unit is manufactured by ALSA APPARECCHI MEDICALI S.R.L., Via C. Bonazzi no. 16, 40013 Castel Maggiore (BO), Italy, that guarantees its safety, reliability and performances only if installation, recalibrations and repairs are carried out, using original spare parts, by personnel authorized by ALSA and if the unit is used in compliance with given instructions in an area that meets all the applicable IEC or CEI requirements.

The Manufacturer is at disposal to supply, if requested, the electric diagrams and any further information needed.

This manual must be kept where the unit is employed.

Please read this entire manual carefully to become familiar with each of the controls and features before making any attempt to use the equipment clinically and ask it again in case missing.

If any questions arise regarding the information contained in this manual according to specific needs, please contact the Manufacturer, directly or through the local distributor, before using the unit.

In accordance with the requirements of the European Directive for medical devices 93/42 CEE and with the procedures of Company Quality System for the after-sale control of the production, the users are pleased to inform the Manufacturer about every, even little, problem of this unit.

INTRODUCTION

In a biological tissue crossed by an electric current are shown the following effects.

1. Thermal: related to the specific resistance of the tissue, to the current density and to the length of the phenomenon
2. Faradic: due to the stimulus of the electrically excitable cells
3. Electrolytic: for which in the tissue positive ions are pushed towards negative pole and vice versa

By using high frequency alternating electric current are eliminated the last ones and it is utilized above all the thermal effect.

In fact, when an electric current having such characteristics flows with sufficient density the cellular liquid of the tissues, warms it rapidly and produces as follows:

- 1) Heating is so quick that the pressure of the vapour in the cells breaks their membranes causing their division (cut).
- 2) Heating is lower, so the liquid slowly evaporates allowing the coagulation of tissues (coagulation or haemostasis).
- 3) The phenomenon is a middle way between the two phenomena described above (cut with haemostasis).

The use of this kind of current presents also some risks and their reduction depends on the behaviour of the users:

- Undesired burns or charring
- Interferences on other units or implanted devices
- Little neuromuscular stimulations

Electrosurgical generators are designed to allow the controlled destruction of biological tissue and are inherently dangerous if operated improperly by not qualified users without respecting all instructions given by the Manufacturer to grant safety.

INSTRUCTIONS TO USE THE UNIT

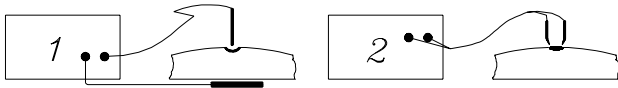
The EXCELL 200 MCDS can be used in the field of major or/and medium surgery for every kind of monopolar/bipolar cut or coagulation.

The apparatus are so suitable for:

- GYNAECOLOGY
- CARDIO-SURGERY
- ORTHOPAEDICS
- NEUROSURGERY
- DERMATOLOGY
- PLASTIC SURGERY
- O.R.L.
- UROLOGY
- MAXILLO-FACIAL SURGERY
- VASCULAR SURGERY
- GENERAL AND THORACIC SURGERY
- PAEDIATRIC SURGERY
- EMERGENCY SURGERY
- GASTROENTEROLOGY
- VETERINARY

WORKING AND ACTIVATION

1. **Monopolar working:** with active and neutral electrodes. In this case the current flows from the active electrode towards the neutral plate, therefore the phenomenon involves the area around the contact point of the active electrode.
2. **Bipolar working:** without neutral plate. In this case the current flows between the tips of the bipolar electrode, involving only the tissues in-between them.



Activation procedures:

All the monopolar and bipolar performances can be used independently but not together at the same time.

The first activation switch operated by the user automatically cuts-out the others, preventing errors.

By choosing the function coag. F "Fulguration" and "Spray" the two monopolar exits can be used at the same time (just pushing the pedal or hand activating control "blu – coag.") and the self-diagnosis system doesn't block the unit (see **Err ACE code in the *Automatic Control and Self-Test System* section).**

The device can be used, for monopolar applications, with one hand-switch handle and one with pedal switch.

The device can be used for bipolar coagulation as follows:

- a) with the pedal switch;
- b) with the automatic Start/Stop system (automatic micro-precise coagulation - MPA).

GENERAL PRECAUTIONS – *It is dangerous to ignore the following warnings:*

- 1 Each electro-surgical unit has its own specific features and therefore before using it, it is advisable to check its efficiency without relying on previous experience acquired on other devices. In any event, always start with very low powers to then reach that required according to the surgical requirements.
- 2 It is hazardous to use the device if the electrical system in the operating theatre fails to comply with safety standards in force.
Do not use "extension leads" for the power supply cable and if other equipment is used at the same time, request the technical department for its compatibility.
- 3 It is dangerous to use accessories not supplied by the manufacturer (they may not be suitable for the working voltages of the device, that are: approximately 7200 ppV for the monopolar performances and approximately 1100 ppV for the bipolar performances) or old accessories and those showing signs of wear. Always check these accessories before using them, especially if they are endoscopic accessories.
Bear in mind that:
 - worn or old active electrodes require the use of higher powers;
 - worn or old neutral electrodes are extremely dangerous as they could burn the patients;
 - disposable neutral plates must be used once only, following the instructions provided on the individual packs;
 - all worn or old accessories and cables are no longer perfectly efficient, they do not ensure perfect isolation and may run precariously to such an extent to cause the dangerous increase of the output powers.
- 4 Do not activate the device before the active electrode is touching the tissues, as electrical arcs may be created that burn them superficially, consequently preventing them to heal ideally.
- 5 Keep the active electrode clean, otherwise it could produce sparks or superficially burn the tissues. A dirty active electrode causes the reduction of the output power, as it is impossible to achieve a perfect contact with the tissues.
- 6 Remember that, even if these electro-surgical units comply with all the current standards force concerning electro-magnetic compatibility, their interference with other electro-medical equipment is quite normal.
- 7 Remember that, when operating on patients with pace-makers or other transplanted active devices, you may interfere with their efficiency (causing fibrillation etc.) or damage them (in these circumstances it is advisable to request specific professional advice from a cardiology unit for example).
- 8 Never use an electro-surgical unit in the presence of flammable anaesthetic gasses (i.e. oxygen and nitrogen protoxide etc.) especially if operating in cavities (chest, abdomen, trachea, head, etc.).
- 9 Do not use cleaning substances, disinfectants or flammable solvents, or at least carefully evaporate them before the operation. Always remove any remaining substances from hollow parts of the body or cavities (umbilicus, vagina, etc.) and from underneath the patient. Remember that while using the device, a spark may cause the endogenous gas (intestine) to explode or set fire to oxygen saturated material (cotton, gauze, etc.).
- 10 Always take metal objects off the patients: rings etc. and make sure that the patient is not touching any metal parts that are connected to earth or that may conduct electricity (table, supports, etc.) and isolate strongly secreting parts of the body and skin-to-skin contacts, using dry covers (i.e. between arm and body).
- 11 Always position any monitoring electrodes that are not specifically shielded as far away as possible from the electrodes of the electro-surgical units. Needle type or very small monitoring electrodes are inadvisable.
- 12 Use and position the neutral electrode as follows:
 - Make sure that it is perfectly efficient and choose an area of the body as near as possible to the area to be operated on (the ideal is a flabby part without hairs, where there are no protruding bones or uneven surfaces). Clean it, shave it and massage it to favour circulation.
 - Firmly fix the electrode without placing anything in-between, ensuring the best contact possible over the entire surface but without pressing too hard to avoid creating ischemic areas (maybe use conductive gels, etc.) and always make sure that the contact is constant, especially if the patient is moved or when liquids are poured.

13. The position of the neutral electrode with regard to the operating area creates a HF current route and any metal objects (prostheses, catheters, etc.) in that area may cause current concentrations that heat or even burn the adjacent tissue.
14. Position the cables of the electrodes so that they do not touch the patient or other wires.
While operating, position the unused active electrodes on isolating materials away from the patient.
15. Always use the lowest power possible. Bear this warning in mind when operating on patients for which smaller sized neutral plates are used (children or babies).
16. The insufficient performance of the equipment may depend on: faulty contact of the neutral plate, faulty connection or poor conditions of the active electrode. Check these factors before increasing the power.
17. Exploit the bipolar technique when operating on small portions of tissues or in cavities.
18. Keep to the advised operating times as far as possible and avoid time wasting short-circuits between electrodes.
19. Contact the Technical Department for the use of 'disposable' electrodes.
20. When you turn the device on, check all the settings before using it on the patient.
21. Remember that the inefficiency of the electro-surgical unit may cause an undesired power increase.

POSITIONING OF THE PATIENT AND USING OF NEUTRAL PLATE

When using an electro-surgical unit, it is **extremely important** that the patient is prepared and positioned on the operating table observing all the warnings (see. the *General Precautions* section) required to reduce all the potential risks as far as possible and bear in mind that, when the monopolar technique is exploited, all the high frequency current output on the patient via the active electrode must return to the device via the neutral plate.

Two serious consequences will be encountered if the neutral plate is positioned incorrectly, namely:

- 1) there is an uneven and/or insufficient contact between patient and neutral electrode and consequently the density of the current is increased between the contact points to the extent where the tissue will burn;
- 2) the power output by the device decreases and this may inappropriately induce you to increase it without need and dangerously.

SAFETY CIRCUIT OF THE NEUTRAL ELECTRODE

The neutral plate connection control circuit (**D** switches with red LED) operates in the two following manners:

- 1) With reusable or disposable standard electrodes (not split).
- 2) With disposable 'split' type electrodes that allow you to check also the quality of the contact between electrode and patient.
 - In the first case, the circuit controls if the cable of the neutral electrode is complete and correctly connected. If this is not the case, it stops the output power, tripping a luminous indicator (red LED lit continuously, 'Np Err' code indication) and also a buzzer (loud and intermittent).
 - In the second case, the circuit not only operates as described above but also controls if the electrode has an adequate contact with the patient's tissues, operating as follows:
 - a) When the contact is insufficient (roughly 80 % of the surface of an electrode for adults attached), the device works, automatically reducing the output powers to a maximum of 200 WRMS, if higher, with luminous indication (red flashing LED). **This condition always occurs when using neutral electrodes for children, guaranteeing major safety.**
 - b) When the contact is inadequate (roughly 30 % of the surface of an electrode for adults attached), the device works, completely stopping the output power, triggering the luminous indicator (red LED lit continuously, 'Np Error' code indication) and also the buzzer (loud and intermittent).

Note. This circuit is inoperative in the *standby* function.

INITIAL CHECKS AND CONNECTION OF THE ACCESSORIES

Initial checks

1. Make sure that the power supply mains corresponds with the technical data (see technical data at back) and connect the device with the main ON/OFF (**H**) switch turned off.
(see also the *standby function* section).
2. Use the (**J**) plug for the possible equipotential connection.
3. Use the (**K**) potentiometer to set the acoustic indications (max. clockwise).
The alarm indications can't be adjusted.

Connecting monopolar accessories

1. Socket (**1**): pedal switch.
2. Socket (**2**): first hand-switch handle.
3. Socket (**3**): second with pedal switch.
4. Socket (**4**): neutral electrode.

Connecting bipolar accessories

1. Socket (**5**): cable for the bipolar electrodes (without particular polarity).

STANDBY FUNCTION

The device is provided with the *standby* function with the relative controls (**C**) and orange LED. This function ensures additional safety as:

1. The device is practically inactive and does not output power but allows all kind of adjustments to be made.
2. The device will not work even if any activation switch is pressed.

The device is always turned on in the *standby* mode (orange LED flashing) which must be disabled by pressing the relative key (orange LED off). This function may always be activated by the operators.

DATA STORING WHEN TURNING ON THE DEVICE

When turned off, the device stores the last adjustments exploited and calls them up when the device is turned on, with the following exceptions:

- a) it is always turned on in the *standby* mode (see. the *Standby function* section);
- b) it does not store the selection of the bipolar coagulation with automatic Start and Stop system (MPA) as this is prohibited by the safety standards for electro-surgical units. It sets itself in the bipolar coagulation function (MP).

RUNNING MEMORIES

The device stores (switches **B**) four complete running programs that may be called-up by pressing the relative key until the desired memory is selected (M_I, M_{II}, M_{III}, M_{IV}).

Proceed as follows to store:

1. Select the memory to be programmed using the relative key.
 2. Make all the desired adjustments (automatically saved) which however may be modified during use;
- When turned off, the device stores the last adjustments exploited (see the *Data storing when turning on* section).

THE IMPORTANCE OF THE CORRECT ADJUSTMENT OF THE POWERS

The correct adjustment of the output powers is fundamental and, considering that it is impossible to provide specific indications for each operation, as the adjustment also depends on the personal preferences of each operator, we are providing some indications to be observed to obtain the best results possible:

1. In each type of coagulation, the power must not be too high (sparks or undesired burning may be encountered) nor too low.
2. When using the cut, especially under liquid, the power must be such to avoid the tissues from even slightly sticking to the electrode. For example: if the electro-surgical unit cuts with a power of 100 W, but not perfectly, it must be gradually increased further by slightly increasing it by 10-15 W at a time.
3. When bipolar forceps are used, it proves useful to keep the tips damp with a physiological solution for example, in order to reduce the inevitable slight sticking phenomenon of the tissues.

USE AND ADJUSTMENT OF POWERS IN THE MONOPOLAR USE

PURE CUT (PC)

This function is used for all types of cut without coagulating effect.

Commands to be used (E):

1. Select the PC function using the S key and adjust the powers using the keys on the left-hand side of the S key.
2. The output, with specific acoustic and luminous indication (see *Technical characteristics*), is obtained by either pressing the pedal switch (left pedal, yellow symbol) or the yellow push button of the hand-switch handle.

Operational instructions, adjustments and electrodes

1. For open surgery or endoscopic surgery in a dry or wet field:

Use cutting electrodes (blade, needle, loop, etc.) starting with 30-40 W.

2. For endoscopic surgery under liquid (i.e. for TUR in urology):

Use specific cutting electrodes starting with 60-70 W when the tissues are softer (i.e. in the bladder), with 90-100 W when the tissues are harder (i.e. for TUR) and with 110-120 W when the tissues are even harder (i.e. for second TUR).

COAGULATING CUT I (BCI) AND II (BCII)

This function is used for all types of cut with a light coagulating effect (BCI) and medium coagulating effect (BCII).

Commands to be used (E):

1. Select the BCI and BCII function using the S key and adjust the powers using the keys on the left-hand side of the S key.
2. The output, with specific acoustic and luminous indication (see. *Technical characteristics*), is obtained by either pressing the pedal switch (left pedal, yellow symbol) or the yellow push button of the hand-switch handle.

Operational instructions, adjustments and electrodes

1. For open surgery or endoscopic surgery in dry or wet field:

Use cutting electrodes (blade, needle, loop, etc.) starting with 30-40 W.

2. For endoscopic surgery under liquid (i.e. for TUR in urology):

Use specific cutting electrodes starting with 60-70 W when the tissues are softer (i.e. in the bladder), with 90-100 W when the tissues are harder (i.e. for TUR) and with 110-120 W when the tissues are even harder (i.e. for second TUR).

COAGULATING CUT III (BCIII)

This function is used for all types of cut with a strong coagulating effect achieved by barely touching the tissues with the electrode.

Commands to be used (E):

1. Select the BC III function using the S key and adjust the powers using the keys on the left-hand side of the S key.
2. The output, with specific acoustic and luminous indication (see. *Technical characteristics*), is obtained either by pressing the pedal switch (left pedal, yellow symbol) or the yellow push button of the hand-switch handle.

Operational instructions, adjustments and electrodes:

1. For open surgery or endoscopic surgery in dry or wet field:

Use cutting electrodes (blade, needle, loop, etc.) starting with 25-35 W.

2. For endoscopic surgery under liquid:

It is not advised.

“PIN POINT, SOFT CONTACT” COAGULATION (PCS)

This function ensures a strong deep haemostatic effect and a good superficial one and is therefore advised for coagulations achieved using the forceps or surgical instruments and also for coagulations achieved by touching the tissues with the active electrode.

Commands to be used (F):

1. Select the PCS function using the S key and adjust the powers using the keys on the left-hand side of the S key.
2. The output, with specific acoustic and luminous indications (see *Technical characteristics*), is obtained either by pressing the pedal switch (right pedal, blue symbol) or the blue push button of the hand-switch handle.

Operational instructions, adjustments and electrodes

1. For open surgery or endoscopic surgery in dry or wet field:

Use coagulation electrodes (ball), cutting electrodes with good surface (blade), coagulation type isolated forceps and start with 40-50 W.

2. For endoscopic surgery under liquid:

Use coagulation electrodes or if this is impossible, cutting ones starting with 50-60 W when the tissues are softer (i.e. in the bladder), and 80-90 W when the tissues are harder (i.e. for the prostate).

AUTOMATIC” COAGULATION (A)

This function guarantees a similar effect to those of the PCS coagulation with more delicacy because the output is pulsed type (1/100s ON 1/100s OFF) and this allows to obtain, in a lot of surgical fields, the same results obtained using lower powers and, in laparoscopy, a remarkable reduction of smoke.

Commands to be used (F):

1. Select the A function using the keys on the left-hand side of the key S
2. The output, with specific acoustic and luminous indications (see *Technical Characteristics*), is obtained either by pressing the double pedal switch (right pedal, blue symbol) or the blue push button of the electrodes-holder handle with manual control

Operational instructions, adjustments and electrodes (for open surgery or endoscopic surgery in dry or wet field):

Use coagulation electrodes (ball electrodes), cutting electrodes with good surface (blade electrodes), coagulation isolated type forceps and start with 20-30 W.

“FULGURATION” COAGULATION (F)

This function guarantees a strong deep and superficial haemostatic effect and is therefore advisable both for coagulations achieved using forceps or surgical irons and also for coagulations achieved by directly barely touching the tissues with the active electrode.

Commands to be used (F):

1. Select the F function using the S key and adjust the powers using the keys on the left-hand side of the S key.
2. The output, with specific acoustic and luminous indication (see *Technical characteristics*), is obtained either by pressing the pedal switch (right pedal, blue symbol) or the blue push button of the hand-switch handle.

Operational instructions, adjustments and electrodes

1. For open surgery or endoscopic surgery in dry or wet field:

Use coagulation electrodes (ball), blade or needle electrodes, coagulation type isolated forceps and start with 40-50 W.

2. For endoscopic surgery under liquid:

Use coagulation electrodes or if this is impossible, the cutting type starting with 40-50 W when the tissues are softer (i.e. in the bladder) and 70-80 W when the tissues are harder (i.e. for the prostate).

“SPRAY” COAGULATION (SPR)

This function guarantees a good deep haemostatic effect and an extremely strong superficial effect and therefore, even if it may be used also for coagulations achieved using forceps or surgical instruments, it is especially advisable for coagulations achieved directly with the active electrode without touching the tissue.

Commands to be used (SPR):

1. Select the SPR function using the S key and adjust the powers using the keys on the left-hand side of the S key.
2. The output, with specific acoustic and luminous indication (see *Technical characteristics*), is obtained either by pressing the pedal switch (right pedal, blue symbol) or the blue push button of the hand-switch handle.

Operational instructions, adjustments and electrodes

1. For open surgery or endoscopic surgery in dry or wet field:

Use coagulation electrodes (ball), blade or needle electrodes, coagulation type isolated forceps and start with 30-40 W.

2. For endoscopic surgery under liquid:

Use coagulation electrodes or if this is impossible, the cutting type starting with 40-50 W both when the tissues are soft (i.e. in the bladder) and hard (i.e. for the prostate).

MONOPOLAR SETTING INSTRUCTIONS

OPEN SURGERY

Cut:

Use blend cut BC I or BC II starting with 40/50 W or BC III, starting with 30/40 W, if a cut with an extremely strong superficial coagulation capacity is desired (*spray* effect).

Coagulation:

Use:

- Coagulation F starting with 40/50 W for superficial or deep coagulations (using active electrode or forceps).
- Coagulation PCS starting with 40/50 W for deep coagulation using forceps.
- Coagulation SPR starting with 40/50 W for superficial coagulation (with active electrode) without contact.

LAPAROSCOPIC SURGERY

Cut:

See *Open surgery* above.

Coagulation (see above) with also coagulation A, starting with 40/50 W (helps to reduce smoking effect).

ENDOSCOPIC SURGERY

Cut:

Use pure cut P or BC I or BC II coagulation starting with 40/50 W.

Coagulation:

See *Open surgery* above.

ENDOSCOPIC SURGERY UNDER LIQUID (TUR, etc.)

Cut:

Use pure cut P starting with 70/80 W.

Coagulation:

Use coagulation F starting with 60/70 W or spray coagulation again starting with 60/70 W.

USE AND ADJUSTMENT OF POWERS IN THE BIPOLAR USE

“MICRO PRECISE” COAGULATION (MP)

This function guarantees extreme precision of the haemostatic effect, restricted to the tissues in-between the tips of the forceps.

Commands to be used (G):

1. Select the MP function using the S key and adjust the powers using the keys on the left-hand side of the S key.
2. The output, with specific acoustic and luminous indication (see *Technical characteristics*), is obtained by pressing the pedal switch BIP (right pedal, blue symbol).

Operational instructions, adjustments and electrodes

For surgery in dry and/or wet field:

Use the coagulation bipolar forceps with the following tip sizes:

- 0.5 mm – starting with 0.5-1 W;
- 1 mm – starting with 1-2 W;
- 2 mm – starting with 2-4 W.

AUTOMATIC “MICRO PRECISE” COAGULATION (MPA)

This function is identical to the “micro precise” coagulation function, but it is provided with automatic Start and Stop system and therefore does not require the pedal switch.

- *Safety standards state that the operators must intentionally select this function when the device is turned on and therefore it cannot be stored in the memory.*
- *When using this type of coagulation, the forceps must be placed on isolating material when they are not in use.*

Switches to be used (G) and (L at the back):

1. Select the MPA function using the S key and set the starting delay using the O switch (switch turned to the left: 1 second, switch turned to the right: 5 seconds).
2. Adjust the powers using the keys on the left-hand side of the S key. The function is activated automatically following the set delay when the tissue is touched and it stops automatically either when the tissues are coagulated or by removing the forceps from the tissue.

The output is indicated by means of specific acoustic and luminous indicators (see *Technical characteristics*).

For safety reasons the device also automatically stops following six seconds of use (if the forceps remain on the tissues, it starts again in the same manner following a stop time equal to the delay set for its starting).

“STANDARD MACRO” COAGULATION (SM)

This function guarantees a strong haemostatic effect and is advisable for laparoscopic surgery and for coagulating rather large tissue areas.

Commands to be used (G):

1. Select the SM function using the S key and adjust the powers using the keys on the left-hand side of the S key.
2. The output, with specific acoustic and luminous indication (see *Technical characteristics*), is obtained by pressing the pedal switch BIP (right pedal, blue symbol).

Operational instructions, adjustments and electrodes

For surgery in dry or wet field:

Use bipolar coagulation forceps with the following tip sizes:

- 1 mm – starting with 2-3 W;
- 2 mm – starting with 4-5 W;
- for laparoscopic surgery – starting with 10-15 W.

AUTOMATIC CONTROL AND SELF-TEST SYSTEM

The device is provided with a self-diagnosis system that intervenes automatically if it detects any abnormal running conditions that also include outputs higher than those set. It stops the device, triggering a loud intermittent buzzer and indication of the problem (see the *incorrect use codes – System fault codes* tables). The buzzer is not triggered only in the case of continuous activation for more than 30 seconds.

When the device is turned on this control system carries out a complete self-test cycle over the hardware and software (in fact, all the LED indicators and displays light up and the loudspeaker is enabled). If everything is efficient, this cycle ends with the device in the *standby* mode and the software program version is displayed for an instant.

If the system detects any problems, these are indicated as described above and the operator must either attempt to eliminate the relative causes if possible, or turn the device off and contact a technician for assistance.

When the device is running this control system checks the running efficiency of the device, including the output powers (7000 times per second), repeating the tests of some parameters that are crucial in order to guarantee its efficiency and safety every 45 minutes (in an activation interval).

In this case too, any problems possibly detected in the running efficiency of the device are indicated as described above in the *When the device is turned on* section.

Table: Incorrect use codes

The operators may attempt to eliminate the cause that tripped the self-test system when any of the problems listed below are encountered.

ERROR CODE	ERROR CAUSE
Displays flashing	The device is activated continuously for more than 30 seconds (don't press the activation switch for an instant and then press it again)
Err nP	Neutral plate not connected (see relative section). Not in <i>standby</i> mode.
Err Act	Activation error (2 activation switches pressed at the same time or wrong activation switch pressed compared to the functions selected on the control panel)
Err PEd	Only during initial self-test – Pedal switch pressed when the device was turned on
Err Hnd	Only during initial self-test – Manual switch pressed when the device was turned on
Err 21	Only during initial self-test – Key on control panel pressed when the device was turned on

The causes for which the automatic control system tripped with regard to the PEd err, Hnd err, 21err may not necessarily depend only on mistakes made by the operators, but may also depend on specific faults of the device and as such belong to the table indicated below.

Table: System fault codes

The operators must request technical assistance for all these problems, after having checked the indications and having turned the device off and on.

ERROR CODE	ERROR CAUSE
Err 1	General system error
Err 11C	Communication problems between the peripheral units
Err Ht1	High temperature problems in the RF section
Err Ht2	High temperature problems in the power supply section
Err uP2	Second microprocessor test
Err ALS	Microprocessor power supply control
Err nPC	Fault of the internal alarm circuit of the neutral plate
Err Ad2	Conversion problems in the analogue/digital converter of the second microprocessor
Err 9	Power supply control in the monopolar RF section
Err 10	Power supply control in the bipolar RF section
Err 11	RF modulation signal control
Err 12	Reading signal of the monopolar power control
Err 13	Reading signal of the monopolar power in the <i>spray</i> mode control
Err 14	Reading signal of the bipolar power control
Err 15	Problems with the internal RAM
Err 16	EPROM CRC control
Err 17	EEPROM data integrity control
Err 20	<i>Watchdog timer</i> of the first microprocessor control
Err 23	Problems in the auxiliary analogue/digital converter (available)
Err 25	System variables complementation error
Err 27	Problems in reading the effective output current
Err 28	Peak voltage reading problems
Err 30	Problems in the reference voltage of the neutral plate alarm circuit

TECHNICAL FEATURES

- Electronic generator according to the Safety Standards CEI EN 60601-2-2 (IEC 601-2-2 Ed. 1991)
- General mains switch and standby switch
- Monopolar and bipolar working frequency: 475 kHz
- Classification: Class I - type CF
- Output Circuit: "floating out", isolated from ground at high and low frequencies and protected against the use of the defibrillator
- Mains and absorption: 230 V ~ 50 Hz - 800 VA
- Mains Fuses: T 5 A
- Monopolar working with the possibility of connection at the same time of two handles (one with hand switch and one with pedal switch)
- Bipolar working by means of the pedal switch or (with specific setting) by automatic control of switching on and switching off according to the conditions of the tissue (impedance sensitive).
Typical values of working: 0-30 Ω = not-activated system; under 900 Ω = start; from 1000 to 1700 Ω = stop
Starting delay: adjustable from 2 s to 5 s
- Memorization System: 4 memories
- Setting: by push buttons (power indicated on the display in centesimal scale)
- Control Circuit: by double microprocessor
- Autocontrol and autodiagnosis circuit, with acoustic signal (very high, strong, intermittent) and visualization of the fault code
- Neutral electrode safety circuit with acoustic signal (very high, strong, intermittent), luminous signal (red) and visualization of the relative code
- Protection against liquids: common, not-protected casing
- Convection cooling without fan – Discontinuous running: 10s ON/30s OFF
- Useful life: 5 years
- Dimensions and weight: cm (LxDxH) 35x38x15 - Kg 15
- EMC compatibility - Directive 89/336/CEE: apparatus in accordance with cat. A.
- Supply cable: length 3 m, section 3x1 mm².

Performances, output maximum powers with relative load, maximum voltages peak to peak at vacuum, crest values, working acoustic and luminous signal

Monopolar performances:

Function	Maximum power	Load	Voltage p.p at vacuum	Crest values	Acoustic and luminous signals
Pure Cut: PC	280 WRMS	400 Ω	1530 V	1.6	Low sound – yellow light
Blend Cut 1: BCI	280 WRMS	400 Ω	2050 V	2.0	Low sound – yellow light
Blend Cut 2: BCII	280 WRMS	400 Ω	2500 V	2.3	Low sound – yellow light
Blend Cut 3: BCIII	120 WRMS	400 Ω	7200 V	7.1	Low sound – yellow light
Pin-point Coagulation, Contact, Soft: PCS	180 WRMS	400 Ω	2800 V	2.7	High sound – blue light
Coagulation Fulguration: F	130 WRMS	400 Ω	3750 V	5.3	High sound – blue light
Coagulation Spray: SPR	120 WRMS	400 Ω	7200 V	7.1	High sound – blue light
Coagulation Automatic: A	120 WRMS	400 Ω	2650 V	3.6	High sound – blue light

Bipolar Performances:

Function	Maximum power	Load	Voltage p.p at vacuum	Crest values	Acoustic and luminous signals
Coagulation Micro Precise: MP	60 WRMS	100 Ω	380 V	1.6	High signal – blue light
Coagulation Micro Precise Automatic: MPA	60 WRMS	100 Ω	380 V	1.6	High signal – blue light
Coagulation Standard Macro: SM	80 WRMS	100 Ω	450 V	1.8	High signal – blue light

CLEANING AND STERILISATION

1. Clean the unit by neutral soap solution taking great care because any liquid doesn't go inside and wipe it by dry cloth. Please note that the pedal switches can be cleaned both with neutral soap solution and using a cold, disinfectant solution (for example "Amuchina").
2. **Attention: at the moment of the sale the accessories are not sterile.** The electrodes-holder handle (MPE/E) and all active electrodes (from E1 to E39) are sterilizable both by autoclave (121°C for 20 minutes), and by cold solutions (for example "Amuchina"). The electrodes-holder handle (MPE/CMS) is sterilizable as the handle MPE/E, but only 100 times. The cable and the forceps for bicoagulation (CPB/E, PBC/C, PBC/R, PMC/C, PMC/R, PMC/CS, PMC/RS) are sterilizable both by autoclave (121°C for 20 minutes), and with cold solutions (for example "Amuchina"). The cable and the forceps for monopolar coagulation (CP/I, PMI/1, PMI/2) are sterilizable both by autoclave (121°C for 20 minutes), and with cold solutions (for example "Amuchina"). The neutral electrode (NP/A, with the relative cable CMS/E, or NP/GP or NP/GA) are sterilizable with cold solutions (for example "Amuchina"). During the sterilization do not bend too much the connection cables and wipe perfectly all the accessories' parts: the best is to centrifuge them.

ENVIRONMENTAL AND ATMOSPHERIC CONDITIONS OF USE, TRANSPORT AND PRESERVATION

The unit must be used in an area with the following environmental conditions:

Temperature (°C): +10 ÷ +40 Humidity: 30% ÷ 75% Pressure (hPa): 700 ÷ 1060

The unit must be used and transported in the area of use as follows:

- not less than 30 cm. from walls or objects that can obstruct the cooling areas
- in a horizontal position, on a trolley or on a bearing surface (under the base there're 2 screwed points for the relative fixing)

When the unit is not used, it must be kept in a dry place, not too much dusty, and take due care because on it is not poured any liquid.

The transport and storage conditions are:

Temperature (°C): -40 ÷ +70 Humidity: 10% ÷ 95% Pressure (hPa): 500 ÷ 1060

For the shipment of the unit we suggest to use the original packing or make a new one that can guarantee the same reliability.

MAINTENANCE

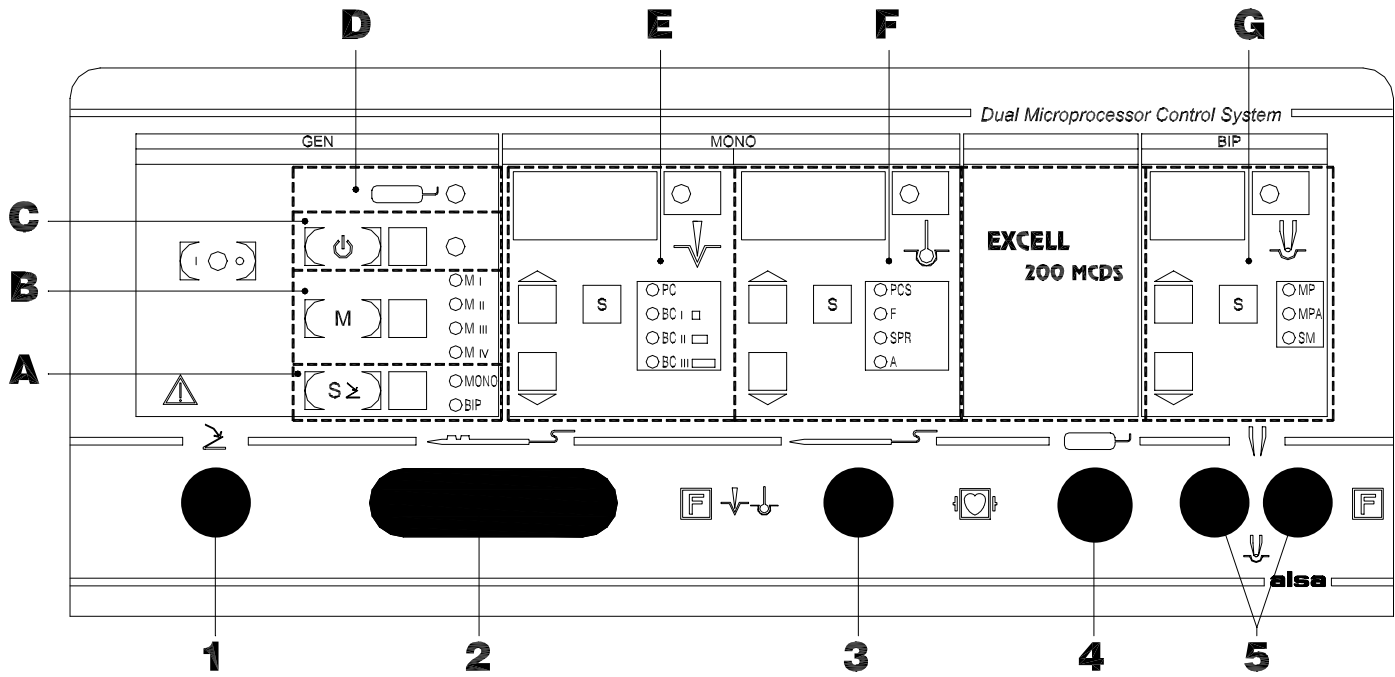
The unit must be regularly checked (yearly at least) from qualified staff, better from the Manufacturer, always checking perfect conditions of the accessories, otherwise their use is dangerous (for example broken cables, dirty electrodes, and so on).

This check should confirm, at least, all the technical data of the original testing document accompanying the unit.











DISPOSAL

The unit and its accessories must be used only for purposes specified in this manual.




The final disposal must respect every specific National Rule, with a special care to the accessories (above all to active electrodes or/and neutral plates) because they get in touch with the tissues of the patients (they must be sterilized).








CONTROLS AND SYMBOLS

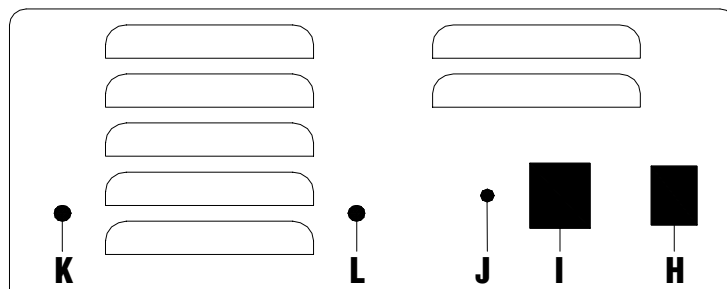
- 1: Connection pedal switchsymbol: 
- 2: Monopolar hand-switch handle connectionsymbol: 
- 3: Monopolar foot-switch handle connectionsymbol: 
- 4: Neutral plate connection..... symbol: 
- 5: Bipolar electrode connection symbol: 
- A: Pedal switch selection (monopolar or bipolar)
- B: Memories control
- C: Standby switch (orange signal)..... symbol: 
- D: Neutral plate safety circuit (red signal)..... symbol: 
- E: Monopolar cut setting section (yellow signal).....symbol: 
- F: Monopolar coagulation controls (blue signal) symbol: 
- G: Bipolar coagulation setting (blue signal)symbol: 

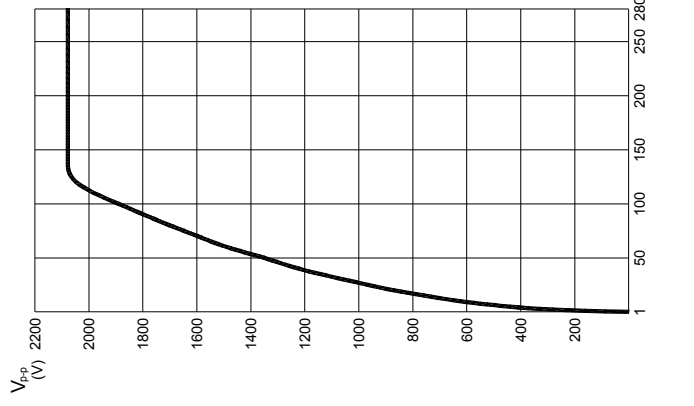
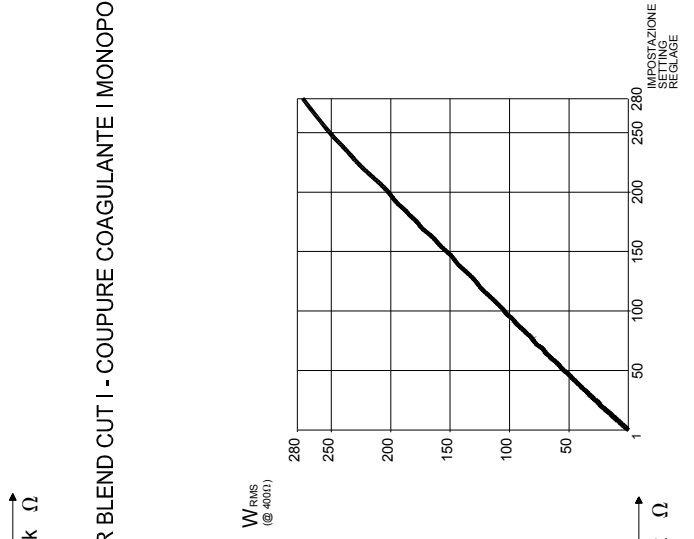
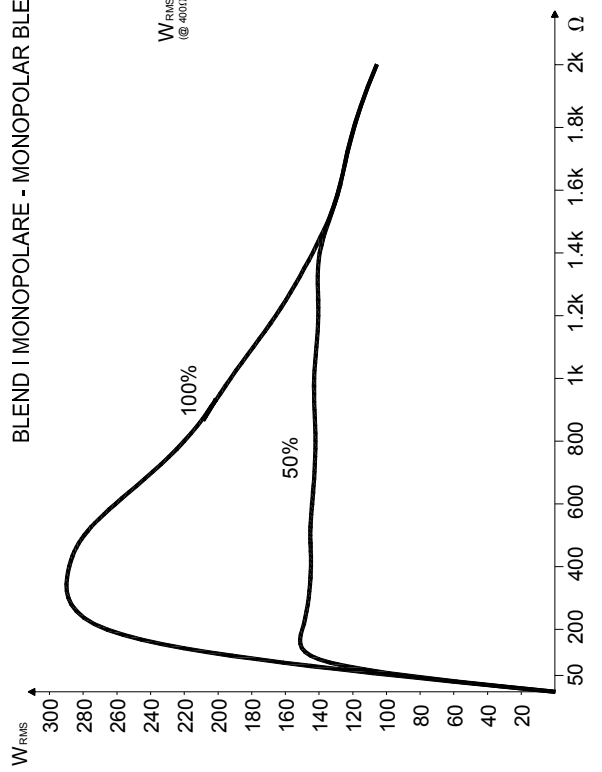
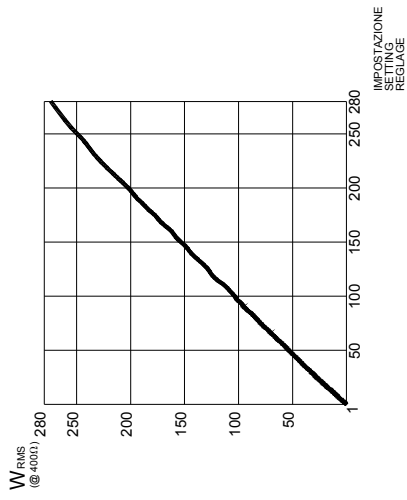
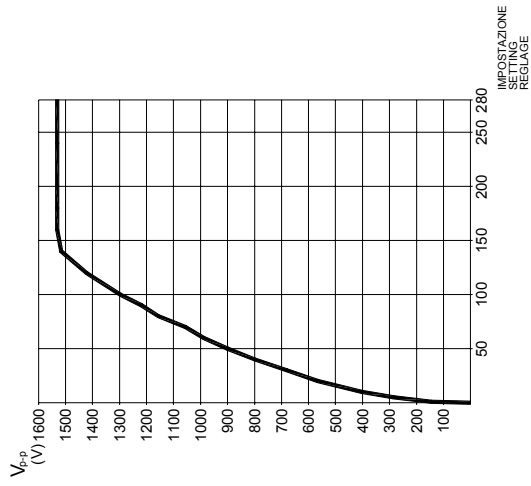
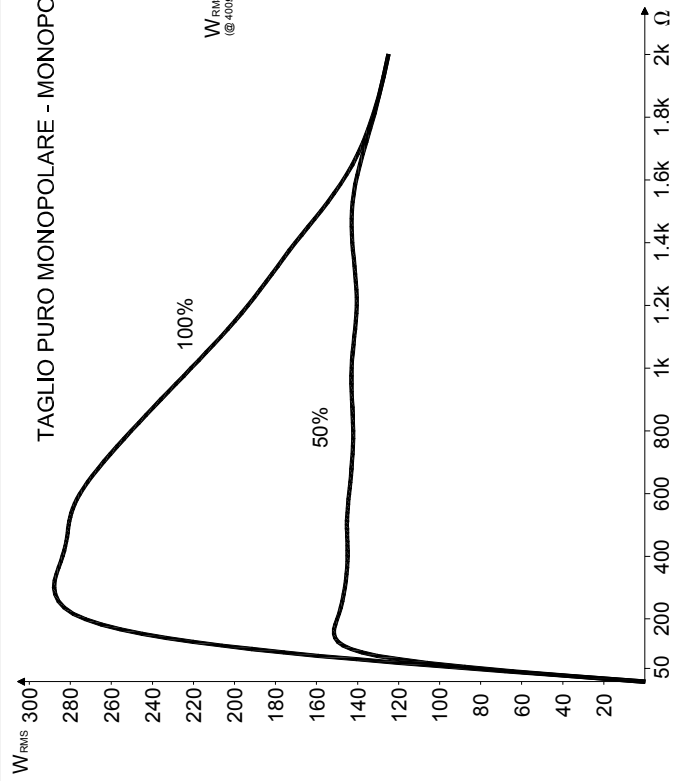
On the back

- H: Mains switch..... symbol:  Switching on  Switching off
- I: Power entry module with double fuse-holder
- J: Equipotential connection symbol: 
- K: Working acoustic sounds adjustment (not adjustable alarms)
- L: Setting of the bipolar coagulation automatic start delay

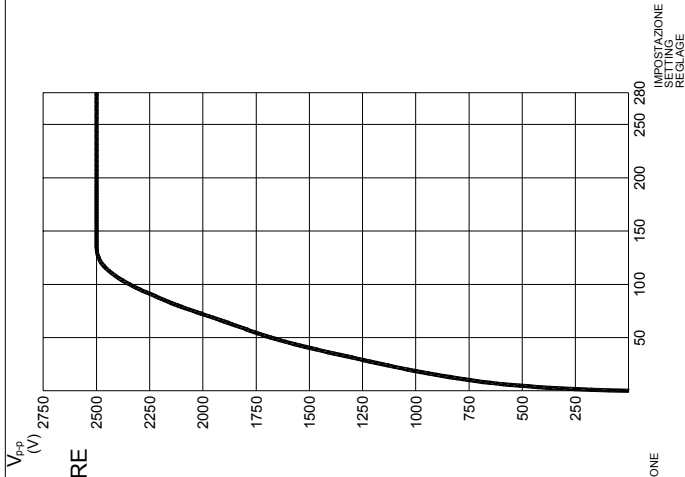
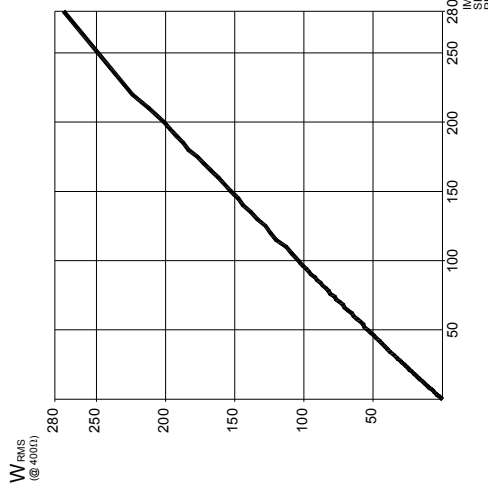
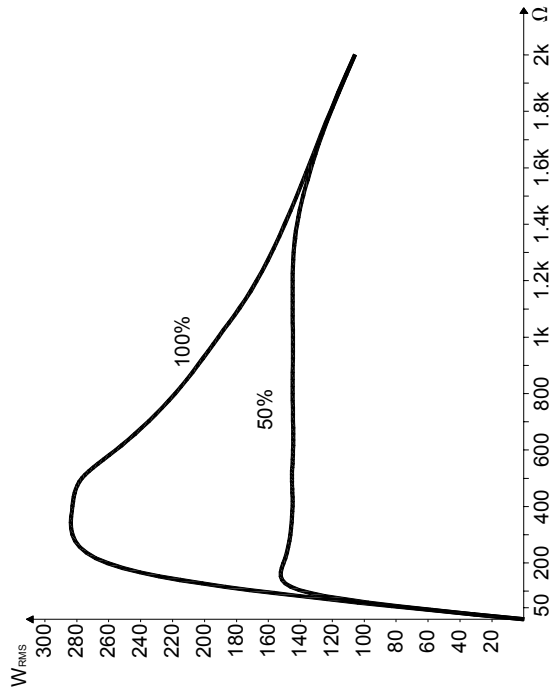
  Apparatus of class I type CF protected against the effect of the defibrillator (according to IEC 601-1) - Output circuit floating, insulated from hearth at high and low frequencies. This kind of unit is indicated for direct heart application.

 Hearth protection (inside)  Alternating current  Be careful: read the annexed documentation

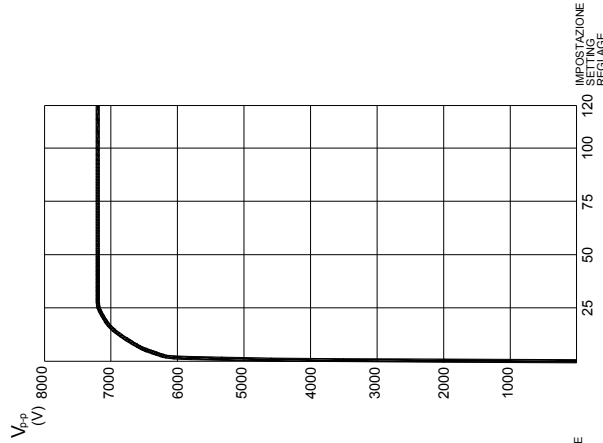
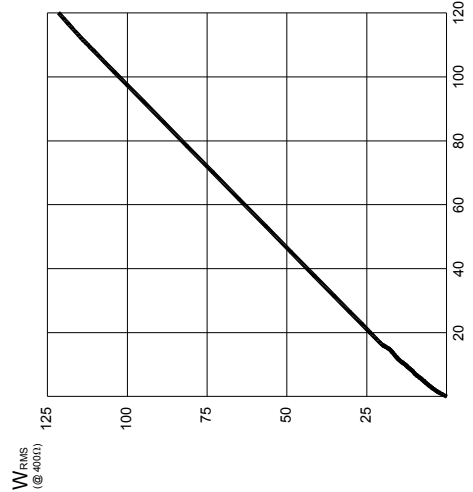
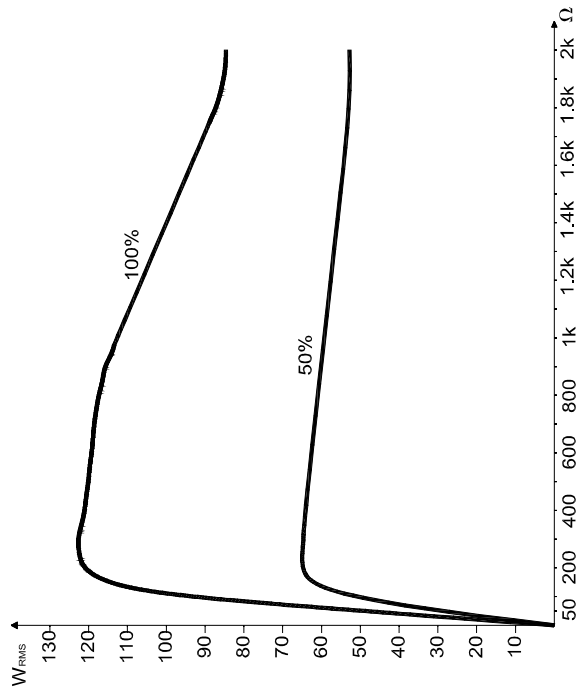




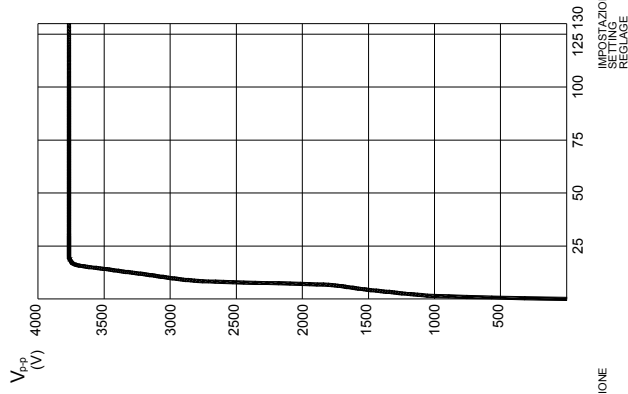
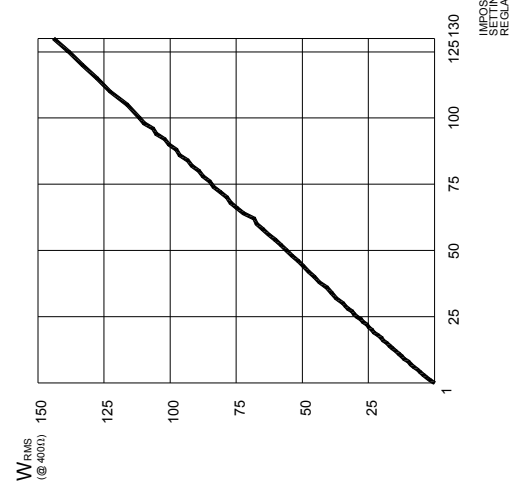
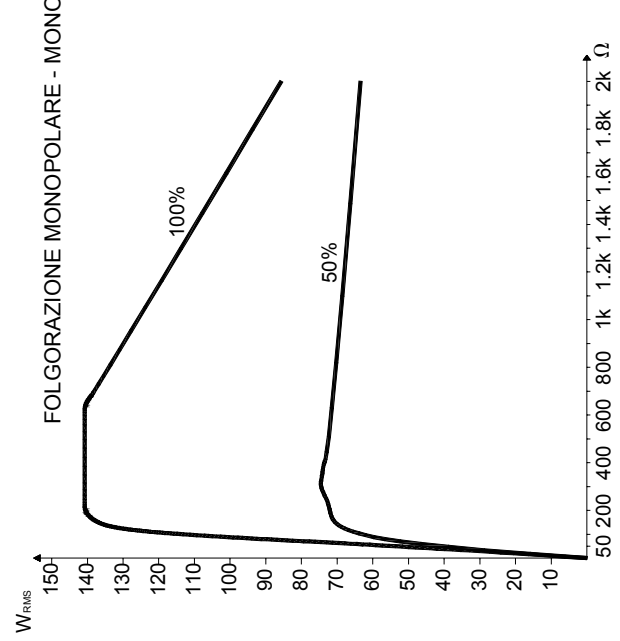
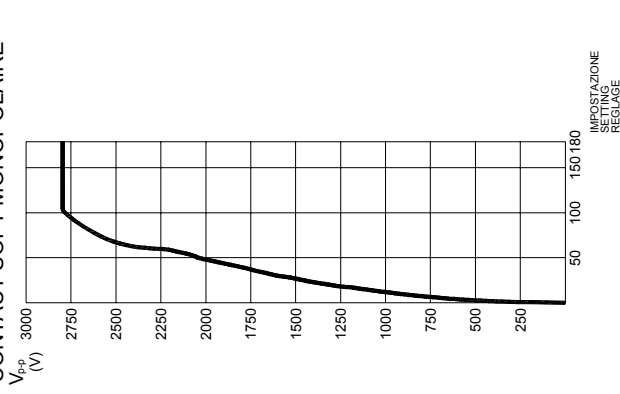
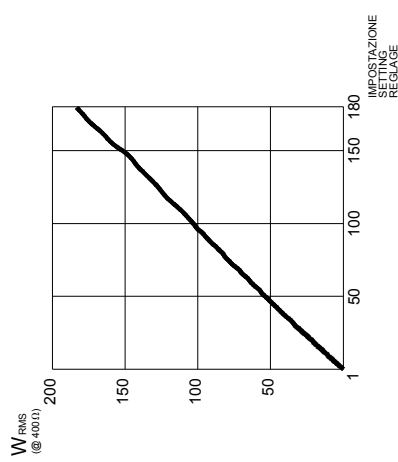
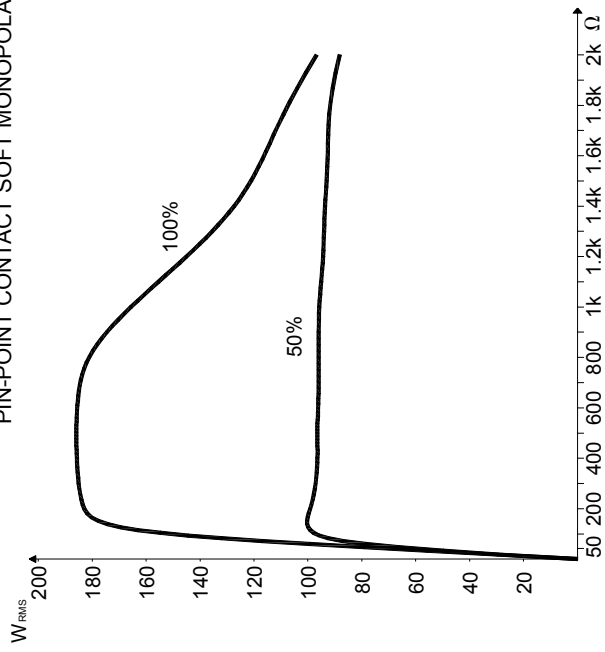
BLEND II MONOPOLARE - MONOPOLAR BLEND CUT II - COUPEURE COAGULANTE II MONOPOLAIRE



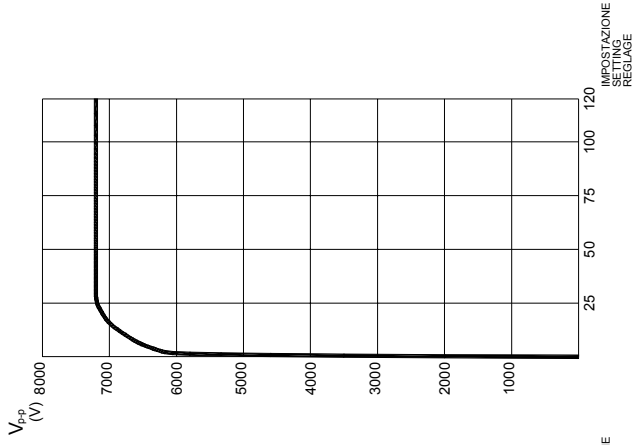
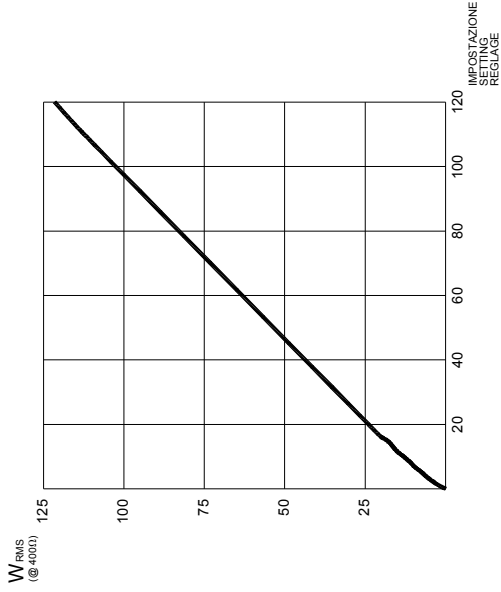
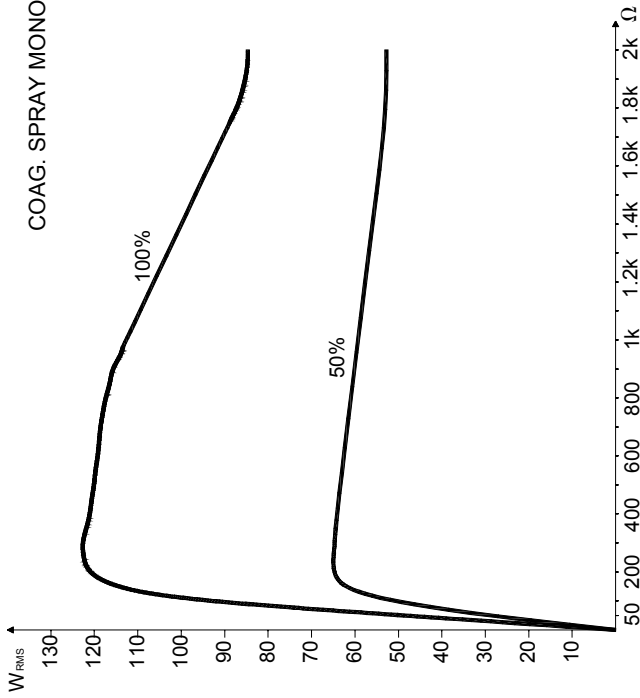
BLEND III MONOPOLARE - MONOPOLAR BLEND CUT III - COUPEURE COAGULANTE III MONOPOLAIRE



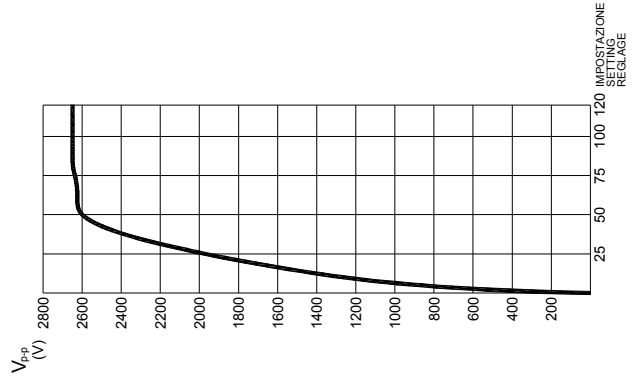
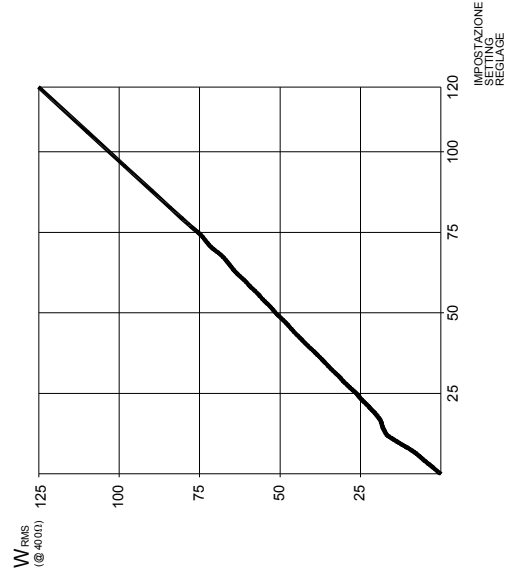
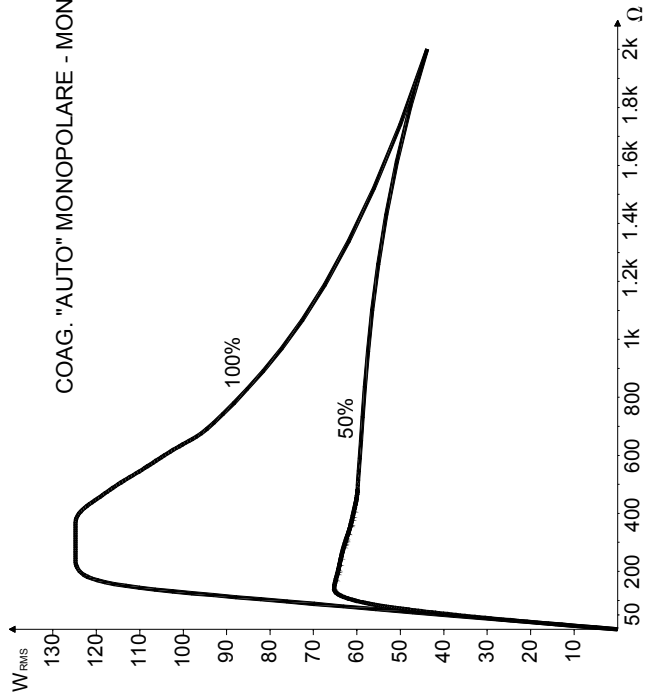
PIN-POINT CONTACT SOFT MONOPOLARE - MONOPOLAR PIN-POINT CONTACT SOFT - PIN-POINT CONTACT SOFT MONOPOLAIRE



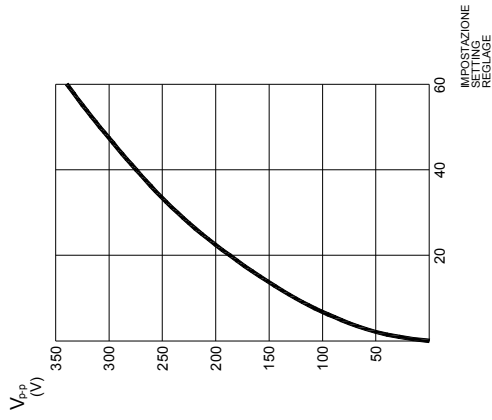
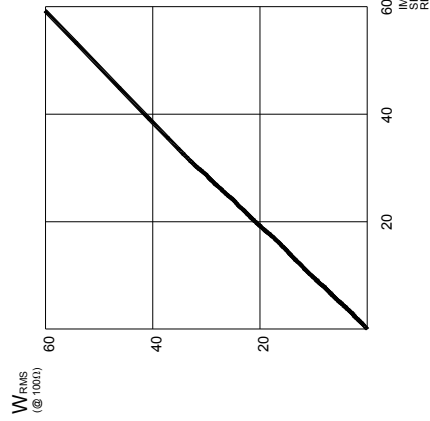
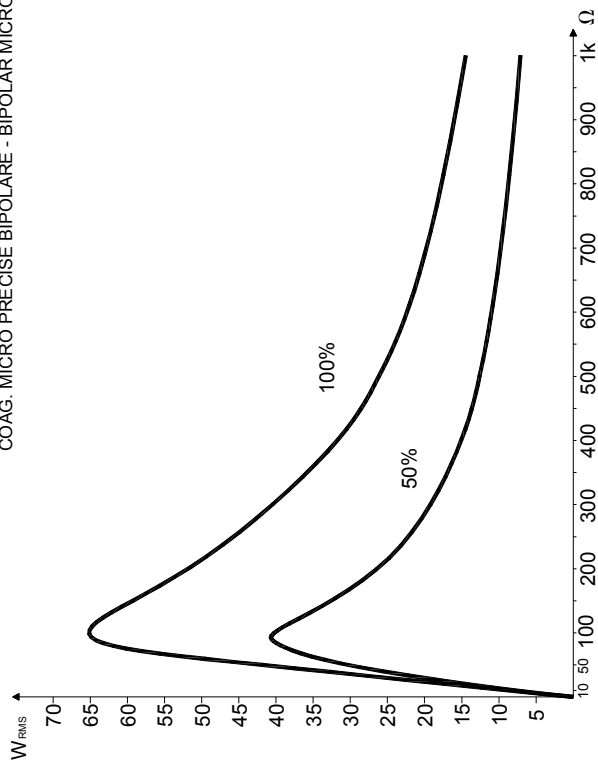
COAG. SPRAY MONOPOLARE - MONOPOLAR SPRAY - SPRAY MONOPOLAIRE



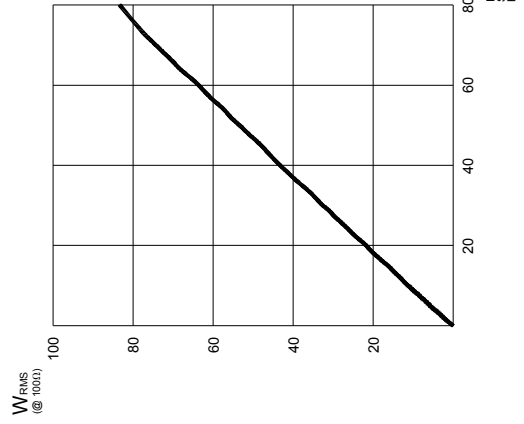
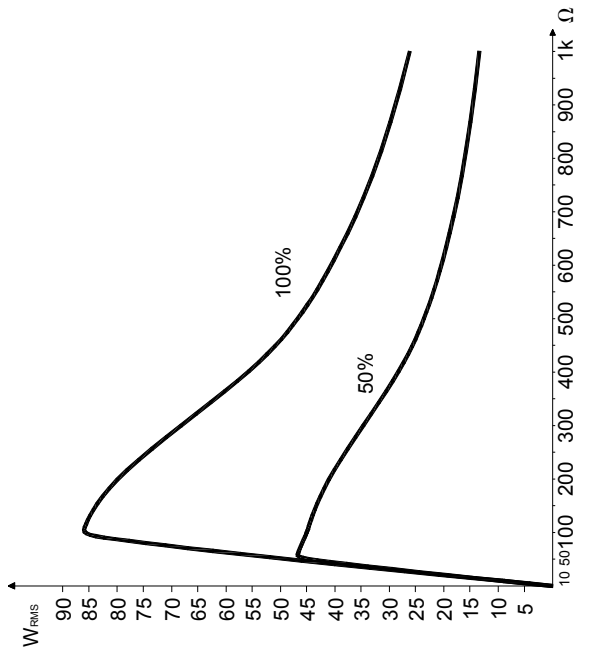
COAG. "AUTO" MONOPOLARE - MONOPOLAR "AUTO" COAG - "AUTO" COAG MONOPOLAIRE



COAG. MICRO PRECISE BIPOLARE - BIPOLAR MICRO PRECISE COAG. - COAGULATION MICRO PRECISE BIPOLAIRE



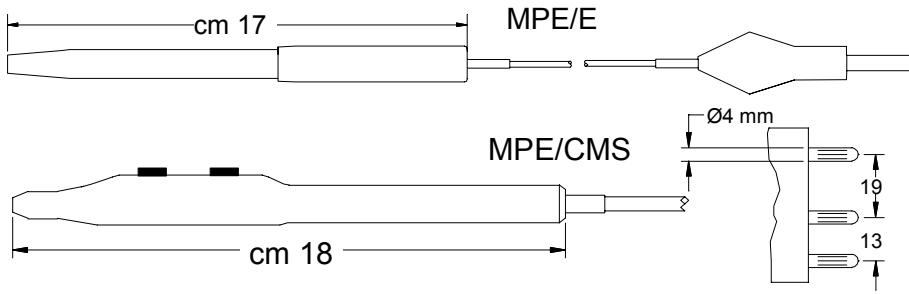
COAG. STANDARD MACRO BIPOLARE - BIPOLAR STANDARD MACRO COAG. - COAGULATION STANDARD MACRO BIPOLAIRE



ELECTRODES-HOLDER HANDLES

MPE/E - electrodes-holder handle with cable l. 3,5 m.

MPE/CMS - hand switch handle, sterilizable 100 times.



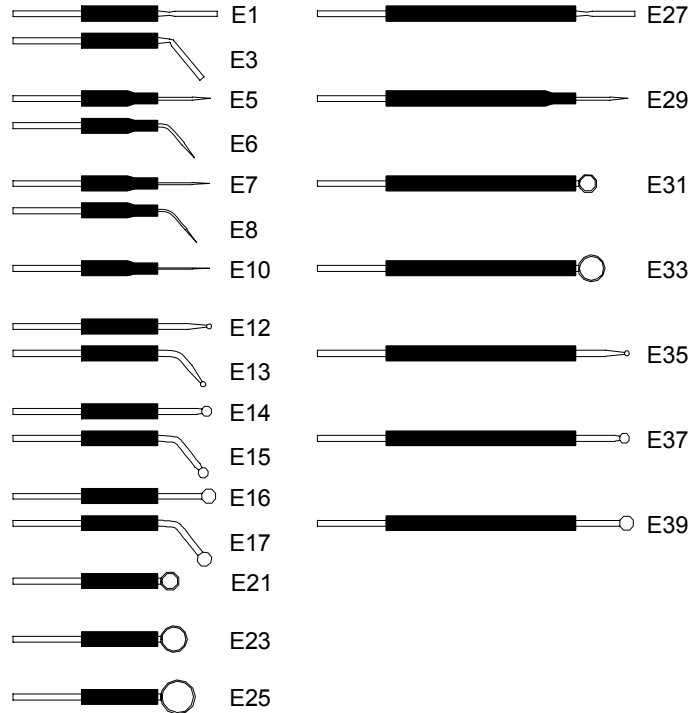
ACTIVE ELECTRODES

Short type: length mm 70

- E1- knife electrode – straight type
- E3- knife electrode – bent type
- E5- thick needle electrode – straight type
- E6- thick needle electrode – bent type
- E7- thin needle electrode – straight type
- E8- thin needle electrode – bent type
- E10-very fine needle electrode – straight type
- E12- ball electrode – straight type (diam. 2,5 mm)
- E13- ball electrode – bent type (diam. 2,5 mm)
- E14- ball electrode – straight type (diam. 4 mm)
- E15- ball electrode – bent type (diam. 4 mm)
- E16- ball electrode – straight type (diam. 6 mm)
- E17- ball electrode – bent type (diam. 6 mm)
- E21- loop electrode (diam. 5 mm)
- E23- loop electrode (diam. 10 mm)
- E25- loop electrode (diam. 15 mm).

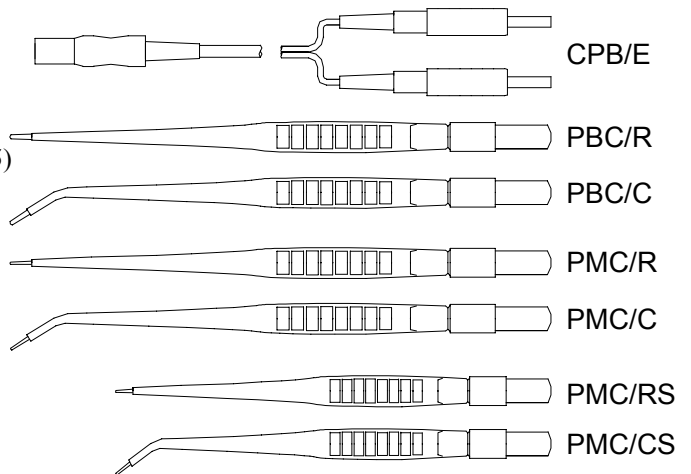
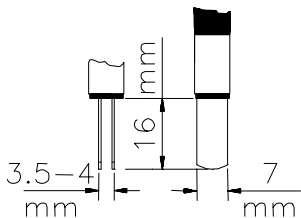
Long-type: length mm 100

- E27- knife type
- E29- needle electrode
- E31- loop electrode (diam. 5 mm)
- E33- loop electrode (diam. 10 mm)
- E35- ball electrode (diam. 2,5 mm)
- E37- ball electrode (diam. 4 mm)
- E39- ball electrode (diam. 6 mm).



ACCESSORIES FOR BICOAGULATION AND MICROBICOAGULATION

- CPB/E connection cable for bipolar forceps (3 m)
- PBC/R insulated forceps - straight type (tips mm 2 – l. mm 200)
- PBC/C insulated forceps - bent type (tips mm 2 – l. mm 200)
- PMC/R insulated forceps - straight type (tips mm 1 – l. mm 200)
- PMC/C insulated forceps - bent type (tips mm 1 – l. mm 200)
- PMC/RS insulated forceps - straight type (tips mm 0,5 – l. mm 165)
- PMC/CS insulated forceps - bent type (tips mm 0,5 – l. mm 165)



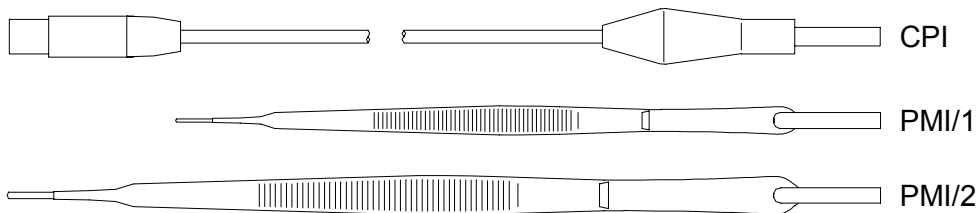
INSULATED FORCEPS FOR MONOPOLAR COAGULATION

ATTENTION: use them only for coagulation with max 2800 V.p.p. “Pin-Point Contact Soft (PCS) and Auto (A)”.

CPI Connection cable for monopolar forceps (3,5 m)

PMI/1 Straight insulated forceps (tips 1 mm)

PMI/2 Straight insulated forceps (tips 2 mm)

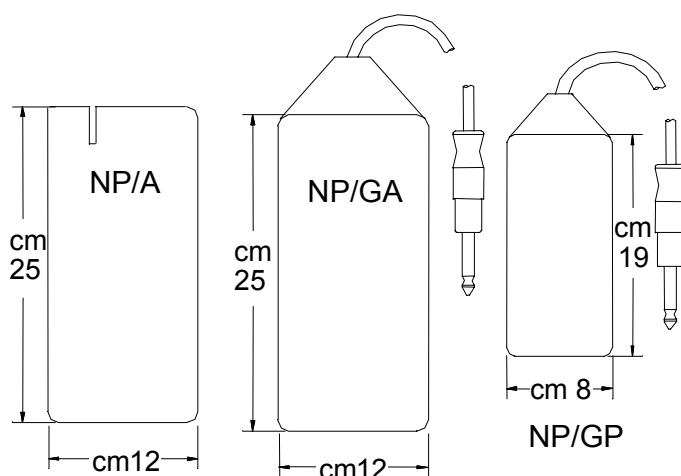


NEUTRAL ELECTRODES

NP/A: stainless steel neutral electrode for adult, cable l. 2,5 m

NP/GA: neutral electrode made of flexible conductive rubber, adult type cable l. 2,5 m

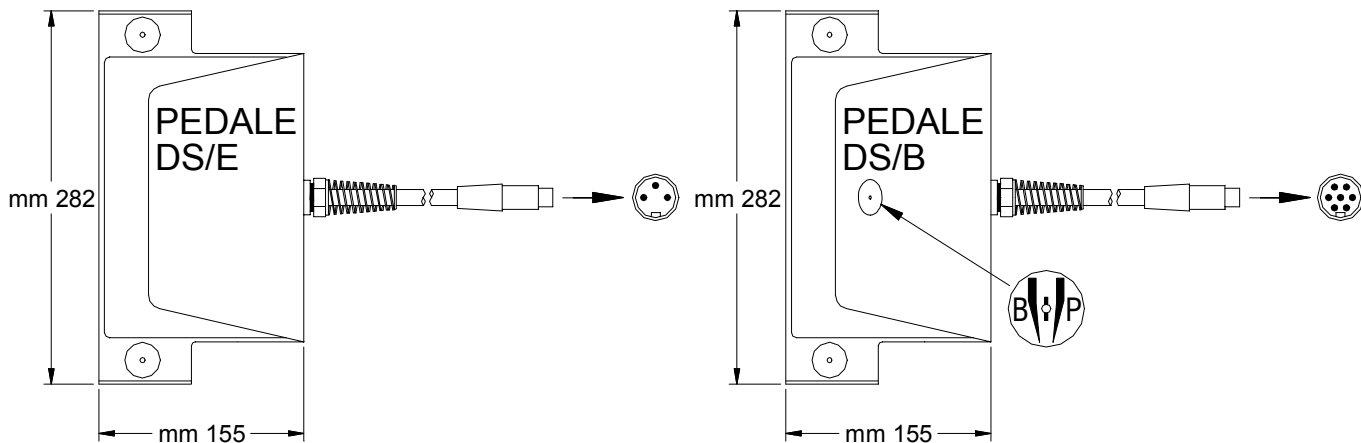
NP/GP: neutral electrode made of flexible conductive rubber, paediatric type, cable l. 2,5 m



FOOT PEDAL SWITCHES

DS/E: pedal switch

DS/B: pedal switch only for bipolar performances



DISPOSABLE NEUTRAL ELECTRODES

CMS/E: Connection cable length 2,5 m

EIP/DA: Neutral electrode adult type (not split), 134 cm²

EIP/DP: Neutral electrode paediatric type (not split), 72 cm²

EIP/SA: Neutral electrode adult type (“split”), 128 cm²

EIP/SP: Neutral electrode paediatric type (“split”), 71 cm²

