# *Instruction Manual*

# Radiocauter
# Altius HF 200W

CE **Nr. 1868**

**English**

Date: 13 Jan 2015

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## General considerations

The ALTIUSHF200W device has been created in order to give the medics and the medical institutions, both from the country and from abroad, a reliable alternative to the equipments that already exist on the market. Thus, by combining the latest technology from the electronic field with advanced software systems, MobilService managed to make a product which offers high standards of safety for the patients and excellent performances during the surgical procedures.

ALTIUS HF200W is the only radiocautery homologated and approved by CE, made in Romania, which uses high frequency, between 3,6 Mhz and 4.1 Mhz in monopolar mode, and 0.8 - 1.1 Mhz in bipolar mode. This fact reduces considerably the secondary effects on the tissue and which, combined with the unique systems of protection, it leads to safer surgical interventions with minor impact on the patients.

## Radiosurgery – the surgery of the future

The advantages of using radiosurgery:

- Due to the use of high frequency currents , there was a decreased postoperative pain and recovery of patients in a much shorter time than with classical interventions ( multiple studies conducted by American specialists ).
- Minor breakup of tissue caused by the heat
- In radiosurgery, the antenna type electrode can be used by placing it over clothes or in direct contact with the patient, as close as posssible to the place of intervention , thus it can be used easy in ambulatory surgery , neonatology and pediatrics.
- Surgical interventions in areas where access to a scalpel is often difficult, and also controlling coagulation.
- Precision and control of the interventions on the soft tissue

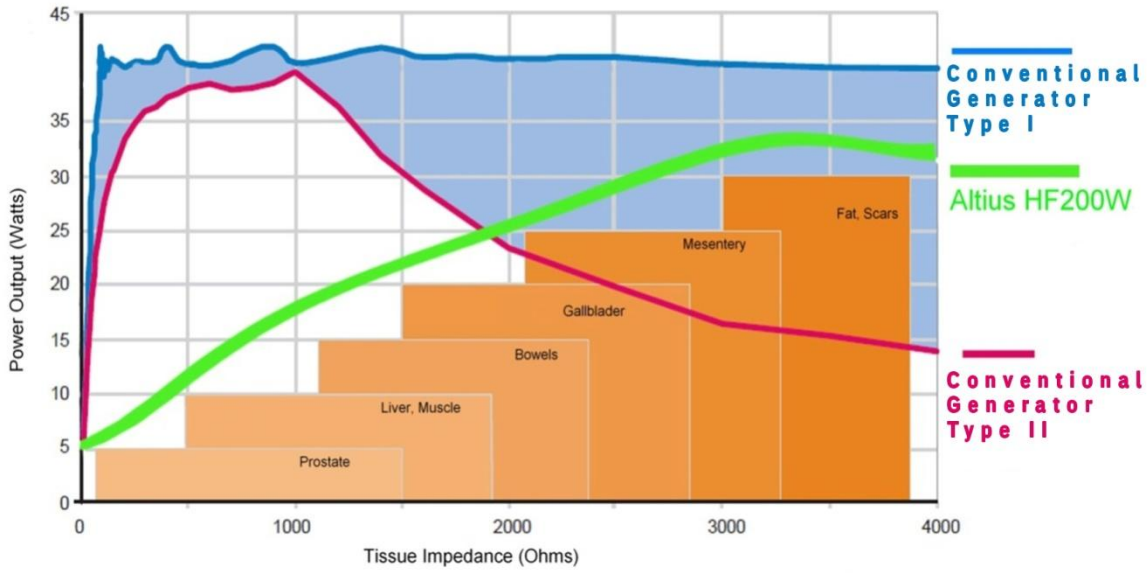



Figure no. 1 – Power variation chart depending on tissue impedance

# The advantages of using the ALTIUS HF 200W device

- ALTIUS has implemented a patented system to verify the connection to ground (patent no. 126244), leading to safer interventions with minimal negative impact on patients.
- In "bipolar coagulation" mode a delay can be programmed from 0.1 to 9.9 seconds which facilitates dual use as both anatomical forceps for handling tissue and as bipolar forceps for radiosurgery.

- Perfect control of the surgical cut depth is supplemented by a protection system that prevents tissue damage when you apply more pressure than necessary on the handpiece.
- Ability to work both in bipolar and monopolar mode without the need for additional manipulations for changing accessories.
- LCD color touchscreen display with the menu preset in the main international languages, with permanent display of working mode and accessories used.
- The device is compatible with a wide range of accessories used in both electrosurgery and in radiosurgery.
- Use under intensive work without stopping for a period greater than with traditional electrosurgical devices.
- Due to high working frequencies, antenna type neutral electrodes can be used with optimal efficiency.

## *1. The presentation of the electrosurgical generator.*


Figure no.2 – Radiosurgical System Altius HF200W

**The accessories that can be connected to the electrosurgical equipment are:**

- Simple and double footswitch (pedal);
- Bipolar cable and bipolar forceps;
- Hand piece (active electrode);
- Antenna or contact type neutral electrode.

ALTIUS HF200W is an electrosurgical equipment which operates in the following modes presented in the table below:

| **Monopolar mode:** | **Bipolar mode:** |
|---|---|
| - Cut; | - Bipolar Coagulation |
| - Cut-Coagulation; | - Bipolar Blend |
| - Coagulation; | |
| - Forced Coagulation | |

The unit have automatic control systems that monitor the internal parameters and detect the possible damages or errors occured. The operational parameters are constantly stored so that, every time the unit is switched on or the operative method is changed, the last utilized parameters are recalled. Control of the units is made via front panel touchscreen buttons. Power suply is achieved with a cable connected tot the rear panel of the unit.

## *2. The control panel, accesories and connection modes*

### *2.1 Control panel*

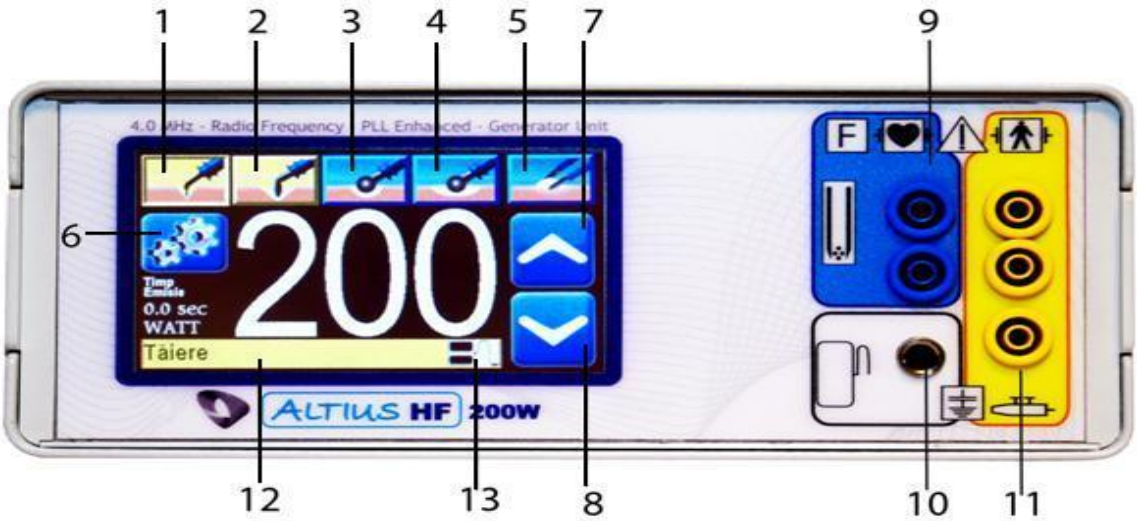



Figure no.3 – Control Panel

**Legendă:**

1. Cut Mode Selection (with cut mode selected).
2. Cut-Coagulation Selection Mode
3. Coagulation Selection Mode
4. Forced Coagulation Selection Mode
5. Bipolara Coagulation Selection Mode
6. Configuration Menu Selection
7. Increment Selection
8. Decrement Selection
9. Bipolar Mode Slot
10. Neutral electrode Slot
11. Monopolar Mode Slot
12. Selected Mode Display Bar
13. Neutral or antenna electrode display

### *2.2 Accesories*

The accessories used may be disposable or autoclavable at 134 ° C.

| | |
|---|---|
|  |  |
| Figure no.4 - Hand piece | Figure no.5 - Bipolar forceps |
| | |
|  |  |
| Figure no.6 - Bipolar blend forceps | Figure no.7 - Antenna type - neutral electrode |
| | |
|  |  |
| Figure no.8 - Neutral electrode (patient plate) and connecting cable | Figure no.9 - Double Footswitch (pedal) |

### *2.3 Monopolar Instrument Connector*

To function in **Monopolar** Mode the cable with three connectors of the hand piece is inserted in slot number 11 (figure no.3) and is required to insert the neutral electrode (patient plate) in slot number 10 (figure no.3).

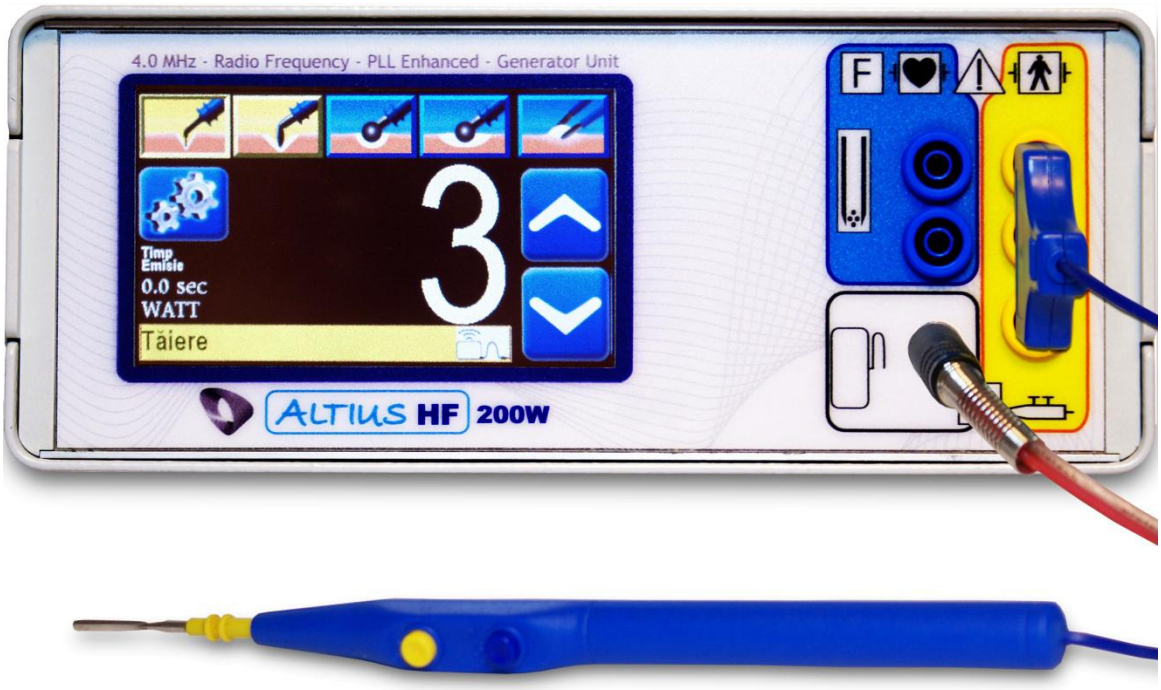



Figure no.10 – Monopolar Instrument Connection

In monopolar mode we recommend using specific tips for every surgical intervention type. The use of the adequate tips induces a small amount of energy into the tissue, thereby is obtained a high efficiency.

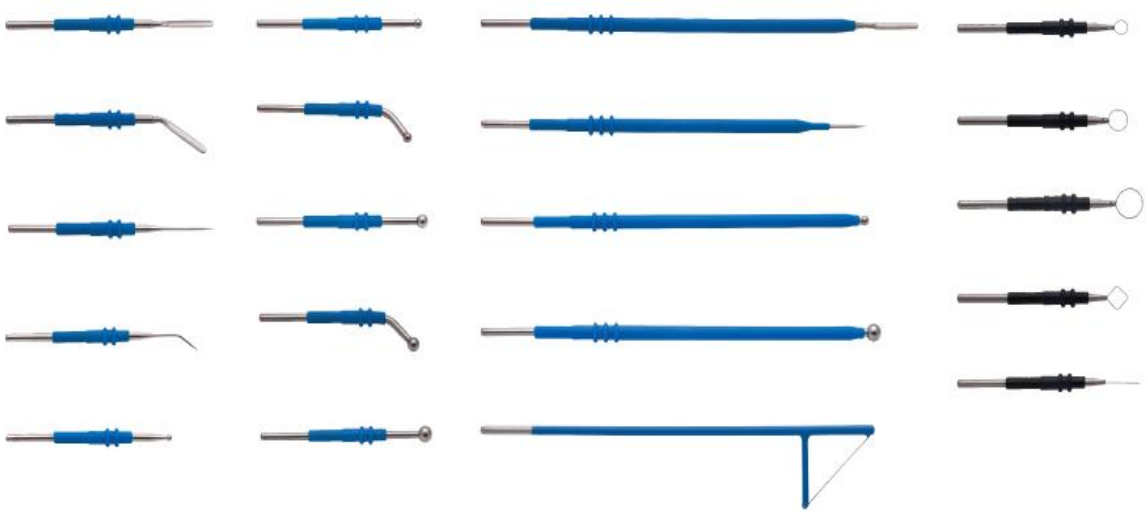


Figure no.11 – Tips for the **monopolar** instrument

### *2.4 Bipolar Instrument Connector*

To function in **Bipolar Coagulation Mode** the cable connector of the bipolar forceps must be inserted in slot number 9 (Figure no. 3 Control Panel). In this mode is not required to connect the neutral electrode.


Figure no.12 – **Bipolara Coagulation** Forceps Connection

Figure no.13 – Types of **Bipolar Coagulation** Forceps

### *2.5 Bipolar Blend Connector*

To function in **Bipolar Blend** Mode the cable connector of the bipolar forceps must be inserted in slot number 9 (Figure no. 3 Control Panel ). In this mode is not required to connect the neutral electrode.


Figure no.14 – **Bipolar Blend Forceps** Connection

Figure no.15 – Types of **Bipolar Blend Forceps**

### *2.6 Neutral Electrode Connector*

To function in monopolar mode the cable connector of the **neutral electrode (patient plate)** must be inserted in slot number 10 (Figure no. 3 Control Panel)


Figure no.16 – **Neutral Electrode** Connection

Antenna type electrode can be placed over clothes or in direct contact with the patient, as close as possible to the place of intervention, thus it can be used easy in ambulatory surgery , neonatology and pediatrics.

Figure no.17 – **Antenna** type Neutral Electrode

### *2.7 Footswitch (pedal) Connector*

The connection of the footswitch (pedal) is made by inserting the cable connector in the left slot from the rear panel (Figure no. 18). It can be used both with **a simple or a double footswitch.**

Conectarea accesoriului de tip **pedală** se face în conectorul de pe panoul din spate al aparatului, în partea stângă. Poate fi utilizată atât o **pedală simplă cât şi una dublă**.

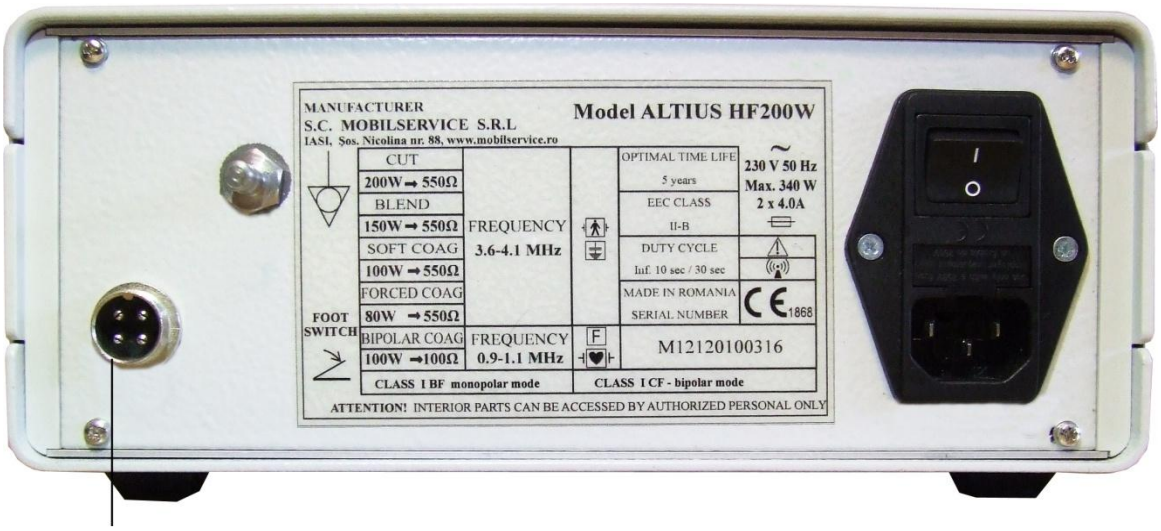



Figure no.18 – **Footswitch** Connection

### *2.8 Input connector with ON/OFF switch*

The connection of the input is made by inserting the cable connector into the right slot from the rear panel.

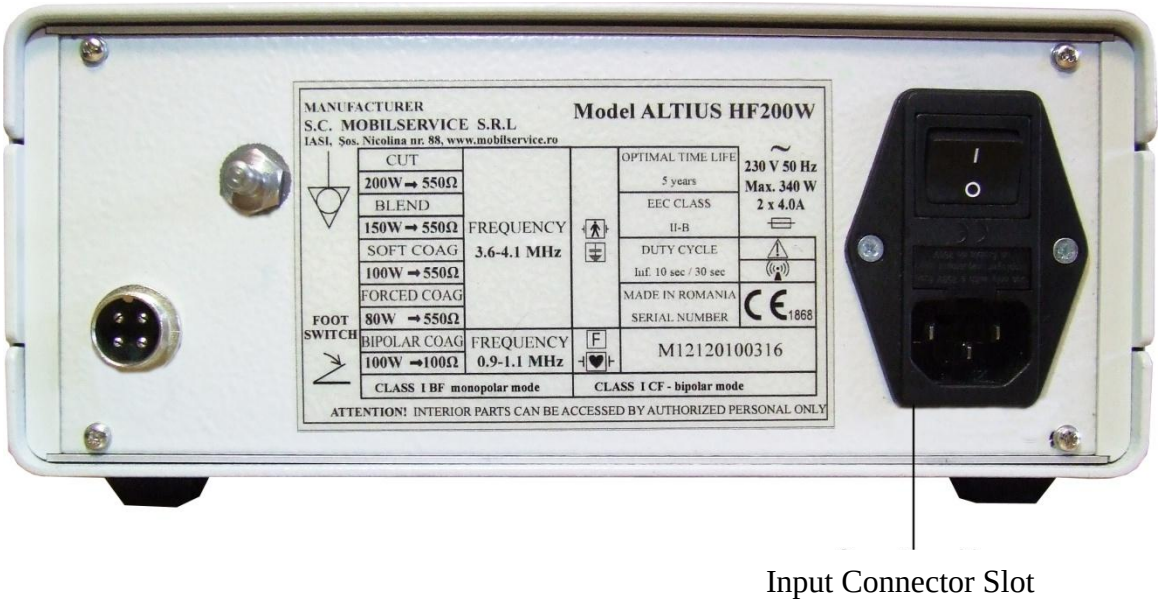



Figure no.19 – **Input Cable** Connection

# 3. Operating Modes

## 3.1 Monopolar Mode

**Monopolar cut** is the sectioning of the biologic tissue achieved by the high-density passage of high frequency current, which is concentrated at the point of the hand piece. The HF current, when it is applied through the active electrode, it creates such an intense molecular heat in the cells that cause explosion.

The cut effect is achieved by moving the electrode through the tissue and destroying the cells one by one. The movement of the electrode prevents the side propagation of the heat in the tissue, thus limiting the cells destruction.

The best HF current for cutting is the pure sine wave without modulation that provides a clean cut, with minor thermal effect. This effect can be precisely controlled and it can be safely used without damaging the bone tissue.

**Monopolar Coagulation** is the hemostasis of small blood vessels of the physical tissue through the passing of the HF current in correspondence of active electrode. The general current used is modulated. Depending on the current modulation, the quality of hemostasis and tissue destruction can be increased or deacreased.

## 3.2 Bipolar Mode (Bipolar Coagulation)

**Bipolar Coagulation** consists in the hemostasis of small blood vessels of the tissue between the two tips of the forceps. When the current density is reduced, the drying of the cellular surface is obtained, without deep penetration and its subsequent coagulation. It is required a gradual increase from a low intensity to achieve the desired effect of hemostasis between the two tips of forceps.

### 3.2.1 Bipolar Mode (Bipolar Blend)

**Bipolar Blend** is the blending of large diameter blood vessels with sizes between 1 and 5 mm using bipolar blend accessory ( Bipolar Blend forceps - Figure no.6 ) . The device is designed to work with any type of bipolar forceps for blending .

# 4. Commands for device use

## 4.1 Main menu

With button number 6 (Menu) is accesed the configuration menu from which we can:

- Bipolar mode menu
- Accesory type menu selection
- Volume/Brightness adjusting menu
- Language selection menu
- Info Menu

### 4.1.1 Bipolar mode menu

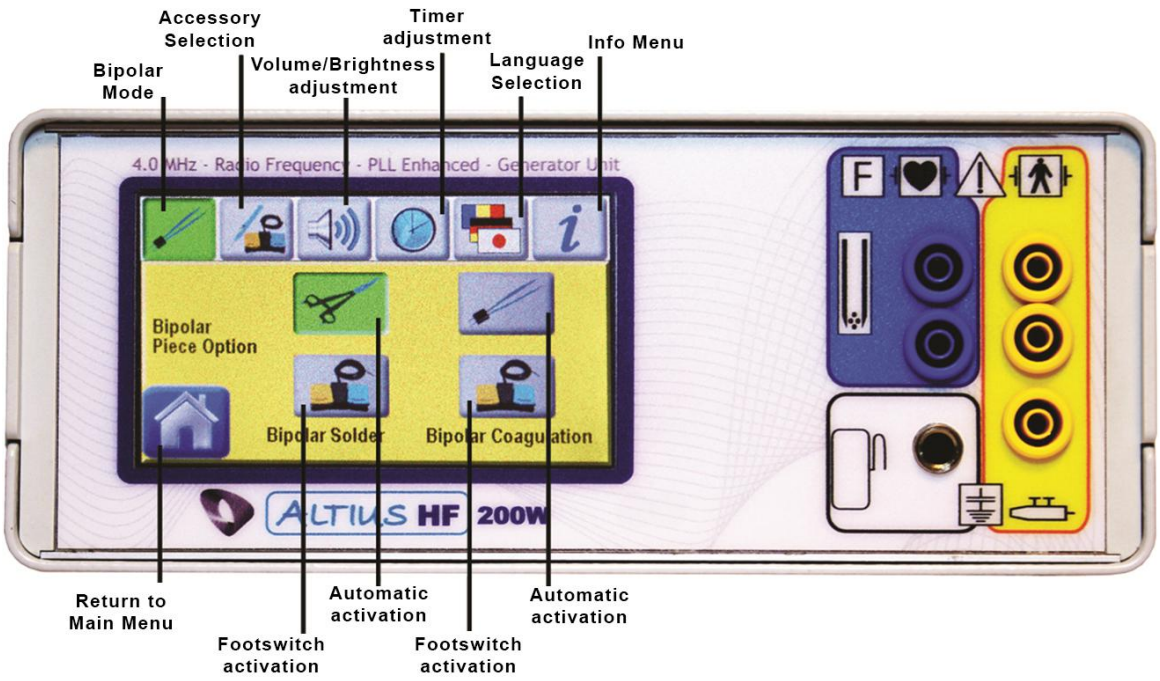



Figure no.20 – **Bipolar Mode** Menu

• Operation mode of **Bipolar Blend forceps** can be activated automatically by selecting from the menu the specific forceps, or from pedal in case of footswitch activation.

• Operation mode of Bipolar Coagulation forceps can be activated automatically by selecting from the menu the specific forceps, or from pedal in case of footswitch activation.

### 4.1.2 Accesory type menu selection.

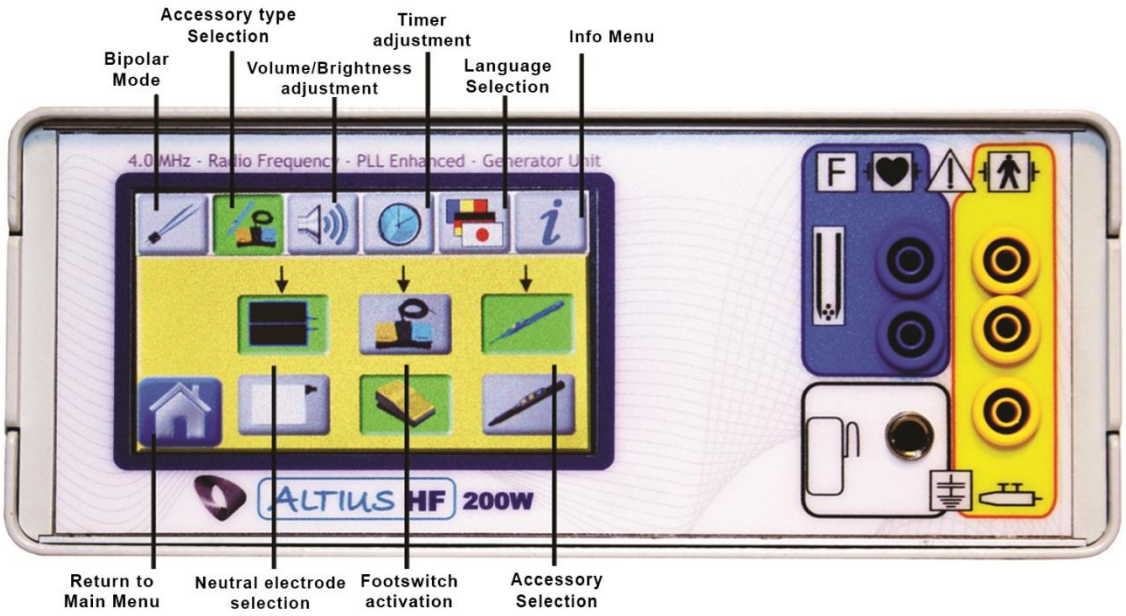



Figure no.21 – Accessories Selection Menu

Neutral Electrode Selection:

The equipment allows the use of both **contact neutral electrode** and the **antenna type contact neutral electrode.**

**The antenna type neutral electrode** is recommended to be used both in ambulatory and neonatology surgery because it doesn't require direct contact with the patient and powers used are not very high. The placement of the antenna type neutral electrode is recommended to be as close as possible to the intervation area.

**The contact type neutral electrode** is recommended in surgical procedures involving the use of high power work . For a correct placement of the contact electrode is essential to read the chapter 7.1.

Footswitch selection:

The device can be set to work both with simple or double footswitch. In case of double footswitch selection, the yellow pedal is specific for the first two modes, **Cut and Cut-Coagulation,** and the blue one to **Coagulation, Forced Coagulation, Bipolar Coagulation and Bipolar Blend.**

In case of monopolar mode selection (**Cut or Cut Coagulation**) followed by the yellow pedal, the device saves the current operation mode.

In case of **Coagulation, Forced Coagulation or Bipolar Coagulation/ Bipolar Blend** modes followed by blue pedal, the device saves the current operation mode.

In case of simple footswitch selection, this is specific to the selected mode, both in monopolar or bipolar mode.

**Hand piece** selection:

The device can be set to work with a hand piece with two or three buttons.

In case the two button hand piece is selected, the yellow button is referring to first two modes (**Cut and Cut Coagulation)** and the blue one to the remaining monopolar modes (**Coagulation and Forced Coagulation).**

In case the three button hand piece is selected, the first yellow button is referring to the **Cut** mode, the second yellow button to the **Cut Coagulation**, and the blue one to the remaining two monopolar modes: **Coagulation and Forced Coagulation.**

### 4.1.3 Volume/Brightness adjusting menu.

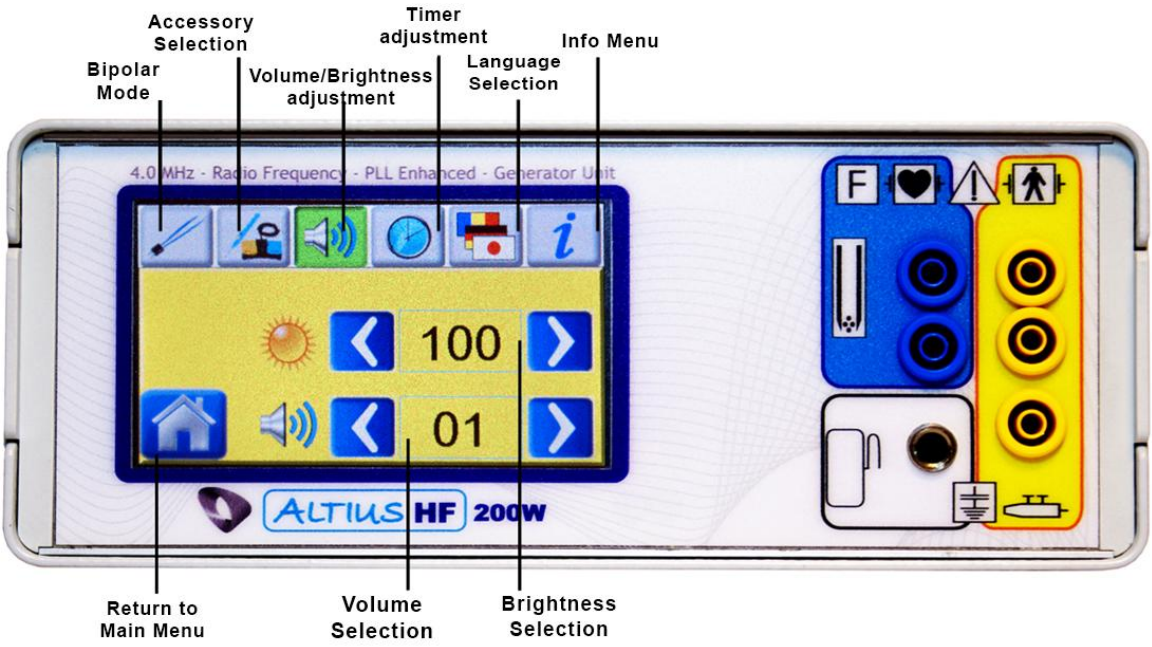



Figure no.22 – **Volume/Brightness** Adjusting menu

- For adjusting the brightness of the LCD screen you need to tap the left/right arrow key until you get the desired light intensity.
- For adjusting the volume you need to tap the left/right arrow key until you get the desired loudness.

### 4.1.4 Timer adjusting menu.

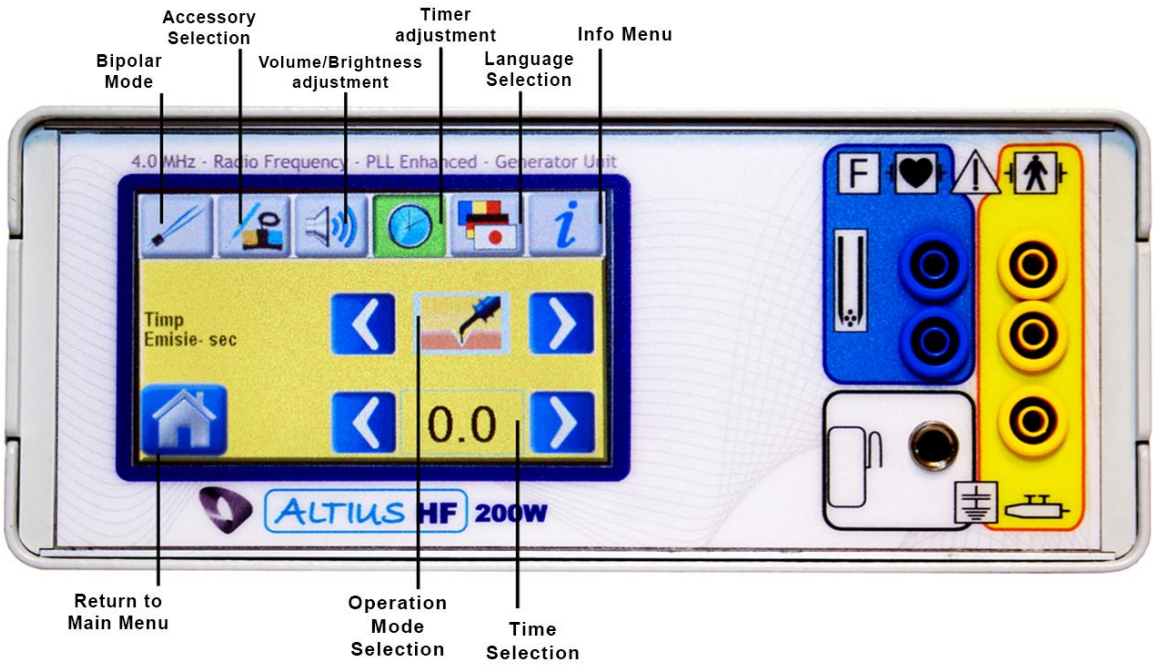



Figure no.23 – **Emission time** adjusting menu

The **emission time** (from 0.1 to 9.9 seconds) can be set for every mode with the help of the left/right arrow key (time selection).

Emission time is the period selected by the user in which the bipolar forceps or the hand piece is active. It is used mainly in microsurgical interventions. If the emission time is not set (0.0) the device operates continuously for 30 seconds (in all modes) and the is followed by a warning bleep and the power is stopped until a new activation.

The delay time (from 0.1 to 9.9 seconds) can be set only for **Bipolar Blend** and **Bipolar Coagulation.**

For **Bipolar Coagulation**, the delay time is represented by the period of time in which the bipolar forceps can be used as anatomical forceps for exploring tissue. After this period the bipolar forceps becomes active. If the delay time is set to 0, the bipolar forceps becomes activ when both tips are in contact with the tissue.

For Bipolar Blend, delay time is used for keeping the procedure active, after the blend is finished, for a selected period of time. This ensures that the blend was succesfuly made.

### 4.1.5 Language selection menu.

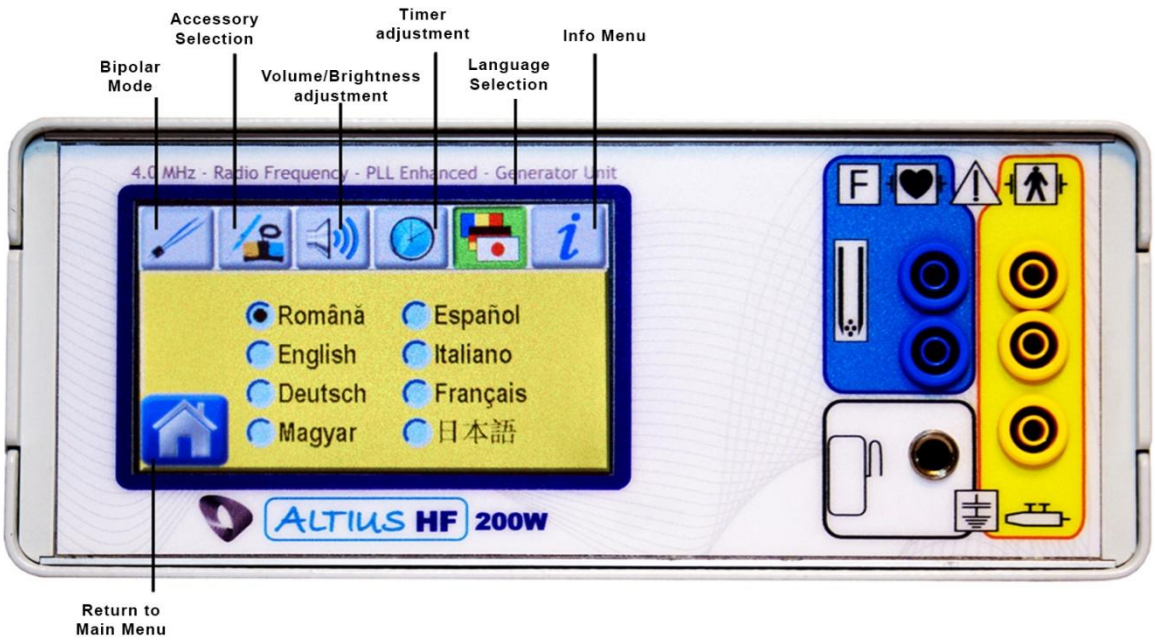



Figure no.24 – **Language** selection menu.

Select the radio button corresponding to the desired language.

### 4.1.6 Info menu

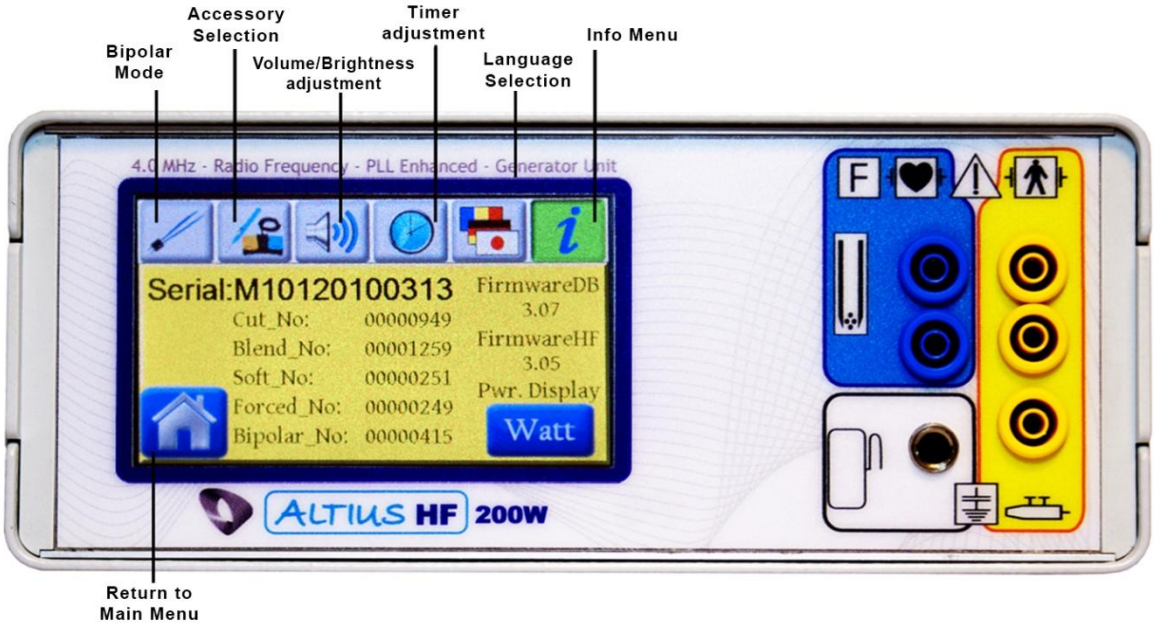



Figure no.25 – **Info** menu

In the info menu can be viewed: device's serial number, number of actions on every mode, software and firmware version.

Also it can be specified how values are displayed on the screen. If the button from bottom right of the screen is pressed and on is surface is displayed Watt, then the selectable values are displayed in watts (**Cut** 3-200W, **Cut Coagulation** 3-160W, **Coagulation** 3-120W, **Forced Coagulation** 3-100W, **Bipolar Coagulation** 1-100W, **Bipolar Blend** 20-100W).

If the button is pressed again and on his surface is displayed "%", then the selectable values are displayed as a percentage from 1-100 % for every mode (for example **Cut** 200W - 100%, 3W - 1%; **Bipolar Cut** 100W-100%, 1W-1%)

## *4.2 Operation Modes for Monopolar.*

Four operation modes are defined:

- Cut Mode
- Cut-Coagulation Mode
- Coagulation Mode
- Forced Coagulation Mode

### 4.2.1 Cut Mode

When the device is opened, on the screen it is displayed the working mode which has been previously set. When Cut Mode is selected, it highlights by emphasizing the frame symbolizing the button pressed.

To select the working values (power mode) the UP and Down keys are used, which are marked with the numbers 7 and 8.

After the value of power is established, the user can pass to the sectioning of body tissue by using the yellow button from the active electrode (hand piece) or by using the yellow footswitch.

### 4.2.2 Cut-Coagulation Mode (60% Cut and 40% Coagulation).

Cut-coagulation mode operation is achieved by selecting the corresponding symbol.

When Cut-Coagulation Mode is selected, it highlights by emphasizing the frame symbolizing the button pressed. To select the values of work (power mode) use the Up and Down buttons, marked with the numbers 7 and 8.

After the value of power is established, the user can pass to the sectioning of body tissue by using the yellow button from the active electrode (hand piece) or by using the yellow footswitch.

### 4.2.3 Coagulation Mode (Cut 40% / Coagulation 60%)

Coagulation mode operation is achieved by selecting the corresponding symbol.

When Coagulation Mode is selected, it highlights by emphasizing the frame symbolizing the button pressed. To select the values of work (power mode) use the Up and Down buttons, marked with the numbers 7 and 8.

After the value of power is established, the user can pass to the sectioning of body tissue by using the blue button from the active electrode (hand piece) or by using the blue footswitch.

### 4.2.4 Forced-Coagulation Mode (Cut 10% and Coagulation 90%)

Forced Coagulation mode operation is achieved by selecting the corresponding symbol.

When Forced-Coagulation Mode is selected, it highlights by emphasizing the frame symbolizing the button pressed. To select the values of work (power mode) use the Up and Down buttons, marked with the numbers 7 and 8.

After the value of power is established, the user can pass to the sectioning of body tissue by using the blue button from the active electrode (hand piece) or by using the blue footswitch.

## *4.3 Operation Modes for Bipolar.*

**Two operation modes are defined:**

- **Bipolar Coagulation**
- **Bipolar Blend**

### 4.3.1 Bipolar Coagulation

Bipolar Coagulation mode operation is achieved by selecting the corresponding symbol.

When Bipolar Coagulation Mode is selected, it highlights by emphasizing the frame symbolizing the button pressed.

Right above where the operation mode is show, the bipolar forceps will pe displayed (as shown in picture from left).

To select the values of work (power mode) use the Up and Down buttons, marked with the numbers 7 and 8.

After the value of power is established, the user can pass to the sectioning of body tissue by using the blue footswitch in manual mode or by using only the bipolar forceps in automatic mode.

### 4.3.2 Bipolar Blend

Bipolar Blend mode operation is achieved by selecting the corresponding symbol.

When Bipolar Blend Mode is selected, it highlights by emphasizing the frame symbolizing the button pressed.

Right above where the operation mode is show, the bipolar forceps for the bipolar blend will pe displayed (as shown in picture from left).

To select the values of work (power mode) use the Up and Down buttons, marked with the numbers 7 and 8.

After the value of power is established, the user can pass to the blending of the blood vessels by using the blue footswitch in manual mode or by using only the forceps in automatic mode.

## 5. Application areas

Using the high-frequency surgical equipment is intented only to specialized medical staff. The device is intended for using in the following application areas:

- General Surgery
- Otorhinolaryngology
- Cardiovascular Surgery
- Pediatric Surgery
- Urology
- Orthopedics
- Chirurgie BMF
- Plastic Surgery
- Neurosurgery
- Dermatology
- Ginecology
- Stomatology
- Veterinary medicine

### *5.1 General Surgery – Advantages:*

- doesn't severly injure tissue, neither mechanically (as with scalpel), neither with heat (as with electrocautery or laser), because it generates small amount of heat;
- excludes wound infection (doesn't rankle) due to the effect of the "sterilization";
- ability to cut without pressure, leading to interventions on very thin or "mobile" tissue (for example eyelid or ear lobe);
- body regeneration after interventions is made much faster and is more "aesthetic" (no hard scars);
- the small amount of heat formed in the tissue when the radio waves are passing, doesn't affect the tissue, it remains unchanged, which is very important for the biopsy

### *5.2 Plastic and Reconstructive Surgery – Advantages:*

- low heat and minimum injure of the lateral tissue leads to a faster healing;
- decreased postoperative pain with aesthetic results superior to laser, electrosurgery or scalpel;
- adaptability of special electrodes;
- dissection of tissue without causing burns;
- low risc of infection or hematoma;
- the time allocated to surgical procedures is reduced;
- minimal maintanance cost;
- wide range of procedures;

### *5.3 Dermatology – Advantages:*

- by using only the antenna type neutral electrode the intervention costs are reduced (by eliminating disposable or autoclavable electrodes)
- using the antenna type electrode doesn't require direct contact with the patient and so the small procedures are made faster;
- body regeneration after interventions is made much faster and is more "aesthetic" (results superior to laser, electrosurgery or scalpel);
- minimal injure of the tissue means a minimal inflammation and a better and faster healing of the wound;
- minimize the edema and the inflammation;
- decreased postoperative pain;
- wide range of procedures;

### *5.4 Ginecology – Advantages:*

- using the antenna type electrode doesn't require direct contact with the patient and so the small procedures are made faster;
- the tissue for the biopsy sampling remains almost unchanged, so the accuracy of the sample is very good
- minimize the edema and the inflammation, fast healing;
- perfect surgical cuts;
- low risc of infection or hematoma;
- reduces postoperative discomfort and treatments;
- clean surgical field with maximum visibility.

### *5.5 ORL/ Otorhinolaryngology – Advantages:*

- using the antenna type electrode doesn't require direct contact with the patient and so the small procedures are made faster and cheaper;
- using bipolar accessories ( Bayonet RF turbine) specific to procedures involving high frequency ;
- minimal injure of the tissue means a minimal inflammation and a better and faster healing of the wound;
- decreased posperative pain - radisurgery causes less trauma;
- is a safer method than electrosurgery, radiosurgery involves a minimum of safety measures.

### *5.6 Orthopedics – Advantages:*

- using the **Bipolar Blend** mode in major interventions with specific accessories for sealing big blood vessels;
- decreased intervention time;
- wide range of procedures;
- enough power for any type of intervention;

# 6. Patient and operating roomsafety measures

## 6.1 Generalities

The efficient and safe usage of electrosurgery is in the hands of the user. There is, under no circumstance, a replacement for highly-qualified medical personnel. The instructions that come together with this equipment must be read, understood and respected.

Electrosurgery has been safely used in numerous procedures. Before beginning any surgical procedure, the surgeon must: be prepared for the respective technique and for the surgical procedure that follows after it; he must be familiarized with the specialized medical vocabulary connected to this procedure and also with the possible complications that may appear; to be familiarized both with the risks and advantages of the respective procedure.

**Warning**

Use this electrosurgical equipment only if you are prepared to use it in the particular procedures. The use of this type of equipment by unprepared medical personnel has had as a result the serious accidental injury of patients, including the perforation of intestines and the irreversible accidental destruction of tissue.

This equipment is destined to be used only by highly-authorized personnel and authorized doctors.

Always use the lowest output necessary power to obtain the surgical effect desired.

The monopolar and bipolar foceps must be used only for a limited time, in order to minimize accidental burns.

Pediatric applications and procedures done on anatomic structures of small proportion could require small values of the working power.

The higher the flow of electric current and the longer the required time, the higher the possibility to take place thermal accidental damage of tissue is higher, especially during the its application on small structures.

Use carefully the electrosurgical procedures in the presence of intern and extern pacemakers. The interference (jamming) created during the use of the electrosurgical unities can make devices, such as cardiac stimulators (pacemakers), become asynchronous or it can block them entirely.

Please refer to the pacemaker's manufacturer or to the Cardiology Unit for further information, when you use the electrosurgical device on the patients.

**Warning**

This equipment may produce physiological effects.

Read the instructions and the warnings that come together with the electrosurgical accessories before the medical procedure.

### *6.2 Fire / Explosions*

**Warning**

Explosion hazard: don't use electrosurgery near the flammable anaesthetics.

Fire/explosion hazard: The following substances will lead to the risk of fire and explosion in the operating room:

- Flammable substances (alcohol-based agents used to disinfect (clean) the skin and infusions (tinctures) )
- Natural flammable gases which can gather in the body's cavities, like the intestines.
- Oxygen-rich atmosphere
- Oxidizing agents (like the atmosphere that contains nitrogen protoxide)

Sparks and heating combined with electrosurgery can become a source of inflammation. Always respect the rules of fire prevention. When using electrosurgery in the same room with these substances or gases, avoid their accumulation in the area where these electrosurgical procedures are done.

### *6.3 Fire hazard at the connections of oxygens circuits*

**Warning**

Fire/explosion hazard: Make sure that all the connections of the oxygen circuits don't have leaks, before and during the electrosurgical procedures.

Make sure that the endotracheal tubes are without leaks and that the gasket (gland) is perfectly airtight to avoid oxygen leaks. The atmosphere rich in oxygen can create fires and burns on the patients

### *6.4 Electrosurgical smoke*

**Warning**

Studies have shown that the smoke produced during the electrosurgical procedures represents a possible hazard for the medical personnel. These studies recommend the use of surgical masks, as well as proper ventilation through a smoke evacuation device or through other ways rezultat în urma procedurilor radiochirugicale.

### *6.5 Prevention of accidental burns*

**Warning**

Avoid contact between the patient and the metallic elements connected to ground or metal parts of the operating table because it may cause severe burns.

**Warning**

Electrodes and probes used with monitoring, stimulation and imaging devices (or similar equipment) can provide a path for high frequency current even if the electrodes or probes are isolated at 50-60 Hz, isolated and/or battery operated.

To reduce the risk of an inadvertent electrosurgical burn at the electrode or probe site, place the electrode and/or probe as far away as possible from the electrosurgical site and/or patient's neutral electrode.

Protective impedances (resistors or RF factors) installed in the monitoring leads may reduce the risk of such burns. Consult the hospital biomedical engineer for further information.

Do not use needles as monitoring electrodes during the electrosurgical procedures. Inadvertent electrosurgical burns may result.

In some circumstances, it exists the possibility for alternate site burns at points of skin (e.g. between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the patient's neutral electrode.

To reduce the potential for alternate site burns, do one or more of the following:

- Avoid skin-to-skin contact points, such as fingers touching leg or knee touching knee when positioning the patient
- Place insulation, such as dry gauze or towel, between contact points to ensure that contact does not occur
- Position the patient's neutral electrode to provide a direct current route between surgical site and the neutral electrode which avoids skin-to-skin contact areas
- Place patient neutral electrodes according to the manufacture's instructions
- The risk of such burns is higher if the neutral electrode is damaged.

### *6.6 Insurance of proper connections*

**Warning**

Examine all the accessories and connections from the electrosurgical generator before using it. Make sure that all the accessories are functioning properly. Incorrect connections may result in sparks, electric arcs, accessory damaging or unwanted surgical effects.

### *6.7 Repair*

**Warning**

Electric shock hazard: Do not take the lid off. Consult the qualified personnel for the service activities.

Note: Consult the service manual for the maintenance recommendations and for the electric and functional check procedures.

### *6.8 Additional warnings*

**Warning**

Malfunction risk of devices . The occurrence of errors during operation: It is recommended cables and wires separation, visual inspection of cable and wire insulation by the user. Maintain a maximum distance possible between the site where the RF signal is applied and the sensors or the cables connected to the monitoring equipment.

**Warning**

Risk of occurrence of measurement errors at monitoring : It is recommended the usage of electrocautery minimum power output to obtain the desired surgical effect.

**Warning**

Risk of permanent disability of the medical devices : It is recommended the usage of electrocautery minimum power output. We recommend keeping a maximum possible distance between the active parts of electrocautery and other medical devices .

**Warning**

Risk of causing severe burns to the patient: use of electrosurgery is not indicated on patients with implantable electrical stimulators . We recommend placing a neutral electrode at a minimum distance possible from the active electrode. It is recommended immediate interruption of the electrosurgical intervation in case of electromagnetic interference phenomena.

It is recommended the usage of electrocautery minimum power.

**Warning**

Risk of damage transient/ reset/ permanent disability of the medical devices: use of electrosurgery is not indicated on patients with implantable electrical stimulators. We recommend placing a neutral electrode at a minimum distance possible from the active electrode. It is recommended immediate interruption of the electrosurgical intervation in case of electromagnetic interference phenomena.

It is recommended the usage of electrocautery minimum power.

**Warning**

Risk of occurrence of errors in software / hardware : It is recommended immediate interruption of device use and shutdown. We recommend the request of troubleshooting service.

## *7. Safety measures before surgical procedure*

### *7.1 The neutral electrode intended for the patient.*

The safe use of monopolar electrosurgery requires a correct placement of the neutral electrode designed for the patient. (Figure no.26)

***The operation areas are dependent on the neutral electrode's placement***

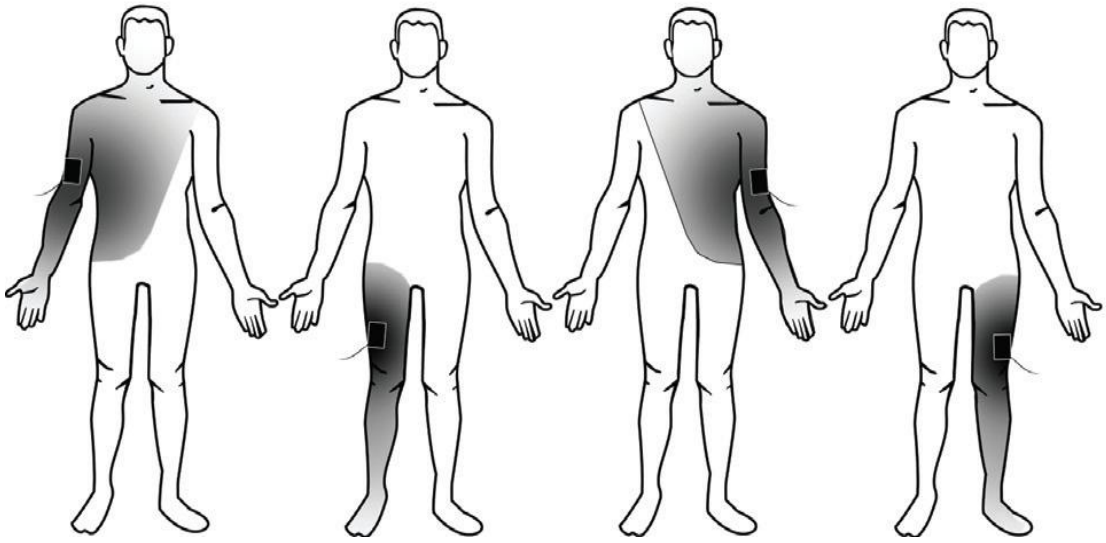


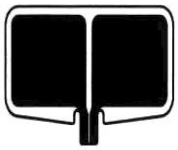
Figure no.26 – Neutral electrode placement

To avoid the electrosurgical burns respect all the instructions about the exact placement and use of this neutral electrode (return electrode). Don't cut the neutral electrode (return electrode) designed for the patient in order to make it smaller. The patient may suffer burns caused by the current's high intensity.

Altius HF200W detects the electrical connection between the unit and the neutral electrode and correct placement of the neutral electrode on the patient.

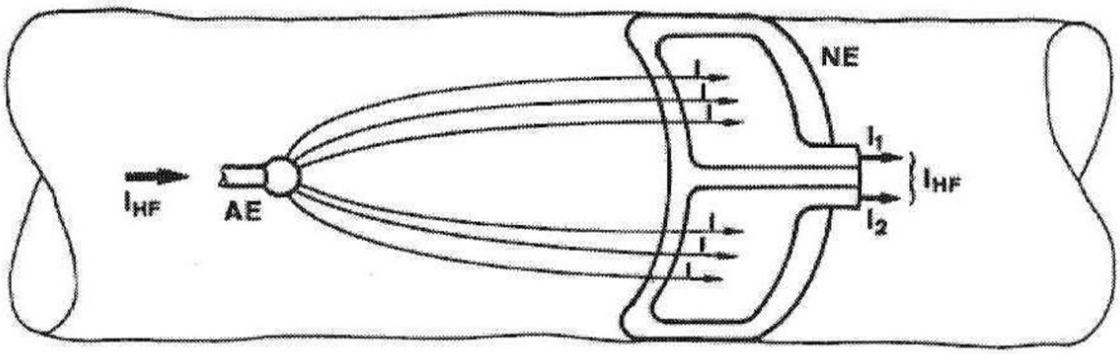
When neutral electrodes are used only with one contact surface, the system is monitoring only the electrical connection between the unit and neutral electrode.

If the connection is interrupted , a beep followed by a warning on the screen is alerting the absence or the interruption of the neutral electrode and the monopolar mode can not be enabled.

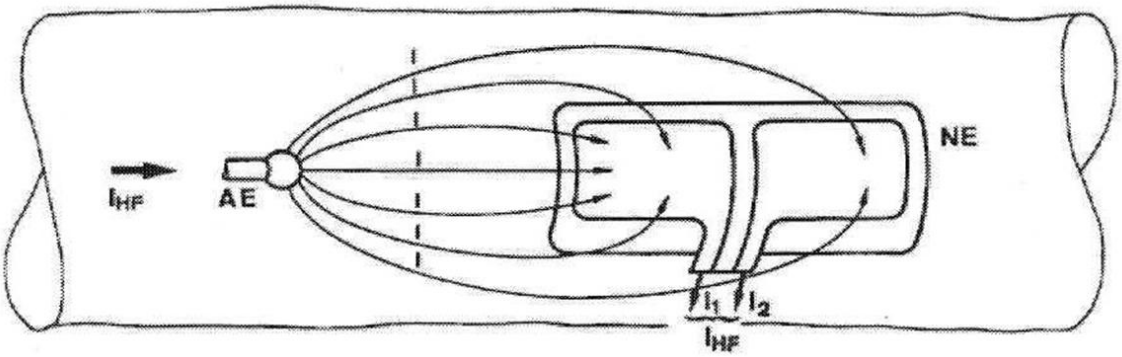


When using neutral electrodes with two contact surfaces not only electrical connection is monitored, but also the placement of the neutral electrode on the patient. In this case, the electrical conductivity between the two contact surfaces of the neutral electrode and the skin of the patient is measured automatically and in case of imperfect contact the device alerts the user to fix the issue (repositioning).

If the neutral electrode was not correctly placed, high-frequency current may be higher on one of the contact surfaces of the neutral electrode which can cause burns.




Neutral electrode placed correctly




Neutral electrode placed incorrectly

Figure no.27 – Different placement situations of the neutral electrode.

**Warning**

Any radiosurgery device can cause serious burns to the patient if the placement of the neutral electrode on the inervention area is not strictly observed.

**Warning**

Do not use an neutral electrode for the patient if you are using only bipolar accessories.

Otherwise, it is possible that the electrosurgical effect will not be narrowed on the tissue between the bipolar electrodes.

### *7.2 Generator installation*

**Warning**

**Electric shock hazard:** Connect the generator's electric cable at an outlet correctly grounded. Don't use adaptors for it.

**Fire hazard:** Don't use improvisations.

***The generator's installation:***

Follow these steps when installing the generator (pay attention to the warning mentioned above):

- Make sure that the generator is switched off by pushing the input switch on "OFF" (O).
- Place the generator on a plain and stable surface, like, for example, a table. For more details consult the procedures of your institutions or the local codes.
- Leave, at least, 10 inches around and above the generator for ventilation. Usually, the front surface, the sides and the rear panel are hot when the generator is being used for a long period of time.
- Wire the generator's electric cable into the input connector from the rear panel.
- Connect the generator's electric cable into a grounded outlet.

### *7.3 Electric configuration of the generator*

**Warning**

Verify the proper configuration of the radiosurgical generator before starting any intervention. Use the lowest power level to achieve the desired effect.

Do not increase the power without first checking the neutral electrode hand piece for the patient and their connections .

Use hand piece only in the minimum interval necessary for obtaining the desired surgical effect and to reduce the risk of burns.

This is especially true for pediatric patients and newborns or for any patient for which is required the use of small tools .

**Warning**

If you do not know the correct configuration , adjust the radiosurgical generator at very low intensity and increase power carefully to get the desired effect.

## *7.4 Verifying the neutral electrode intended for the patient*

**Warning**

To avoid patient burns, make sure that the neutral electrode is in stern contact with the skin. After the patient is repositioned and during the procedures that imply long activation periods periodically verify the electrodes.

When the level of power is amplified or when repositioning the patient, verify whether the neutral electrode (patient plate) is properly placed and verify the connection cables continuity.

## *7.5 Bipolar tool (bipolar forceps)*

Do not activate the generator only when forceps are in contact with the patient. If used concurrent with monopolar mode, bipolar forceps should not be in contact with the patient.

## *7.6 Monopolar tool (Hand piece)*

**Warning**

The contact of the active electrode (hand holder) with the metallic objects will amplify the flow of electric current and may cause undesirable surgical effects. When using electrosurgery, avoid the patient's direct contact with metallic objects connected to the ground (e.g. the frame of surgical table, the table for instruments). If this is not possible during some procedures (e.g. those which are used as supports for un-insulated head), use the maximum of caution for the patient's safety:

- Use the lowest electric level to obtain the desired effect. Place the neutral electrode designed for the patient as close as possible to the surgical area.
- If it is possible, place dry gauze between the patient and the ground-fixed object.
- Constantly monitor the contact points.

### *7.7 Active accessories*

**Warning**

The electrosurgical accessories which are activated or hot, because of intense use, may cause fires. Don't place them near/or in contact with flammable materials (like gauze). Use a support to sustain the electrodes and similar accessories, by keeping them away from the patients, the medical personnel and the flammable materials.

If you activate simultaneously the suction with the electrosurgical current, the electric arc phenomenon may be amplified at the point of the electrode; burns of some tissues may appear; or the medical personnel may be affected by burns and electric shocks.

When you aren't using the active accessories, keep them in a recipient or in a clean, dry non-conductive area, which can be easily observed. The accidental contact with the patient may cause burns.

### *7.8 Accessories connection check*

**Warning**

Make sure that all the accessories are correctly connected at the generator. When using multiple accessories don't mix the cables.

Don't twist or knot the cables.

# 8. Performing the connections and programming the functions.

## 8.1 Selecting the operation modes

Program the power levels at minimal set-up before testing an accessory. În When the device is turned on it will display the previously used mode. The selection of the monopolar/bipolar mode is done by activating the corresponding button.

When the mode is selected, it highlights by emphasizing the frame symbolizing the button pressed.

## 8.2 Connections for monopolar surgery

Follow the instructions that came together with the electrosurgical accessories for a good use and connection.

This generator's connectors are designed to accept only one instrument. Don't try to connect more than one instrument to a single connector.

The cable from the active electrode (hand piece) is connected to the connector with the number 11 from the front panel, which is presented in figure no.28

Figure no.28 – **Monopolar** accessory slot

Before each use, check all the accessories and cables (especially the reusable accessories and cables) and make sure that these aren't broken or defect.

If so, don't use them. Otherwise, the medical personnel and the patient may be hurt or electrocuted.

### *8.3 Set-up for monopolar surgery*

Set the electric levels on the lowest possible programming before testing an accessory.

The device's menu contains four functioning modes that can be selected.

In monopolar mode the four modes of functioning are the following:

**Cut**

When the mode is selected, it highlights by emphasizing the frame symbolizing the button pressed, and on the screen is displayed **"Cut"** message and a picture of the neutral electrode used.

**Cut-Coagulation**

When the mode is selected, it highlights by emphasizing the frame symbolizing the button pressed, and on the screen is displayed **"Cut-Coagulation"** message and a picture of the neutral electrode used.

**Coagulation**

When the mode is selected, it highlights by emphasizing the frame symbolizing the button pressed, and on the screen is displayed **"Coagulation"** message and a picture of the neutral electrode used.

**Forced-Coagulation**

When the mode is selected, it highlights by emphasizing the frame symbolizing the button pressed, and on the screen is displayed **"Forced-Coagulation"** message and a picture of the neutral electrode used.

### *8.4 Connections for bipolar surgery*

**Warning**

Electric shock hazard:

- Don't connect damp accessories to the generator.
- Make sure that all the accessories and adaptors are correctly connected and that no metal object exists on the operating surface.

Don't apply the active electrode if you use only bipolar accessories. Otherwise, it is possible that the electrosurgical effect may extend outside the area existent between the bipolar electrodes.

The cable from the bipolar forceps is introduced in the connector from the front panel with number 9 and presented in figure no. 29.

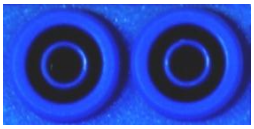


Figure no.29 – **Bipolar** accessory slot

### *8.5 Set-up for bipolar surgery*

Set the electric levels on the lowest possible programming before testing an accessory.

The device's menu contains two functioning modes that can be selected:

**Bipolar Coagulation**
When the mode is selected, it highlights by emphasizing the frame symbolizing the button pressed, and on the screen is displayed **"Bipolar Coagulation"** message and a picture of the bipolar forceps.

**Lipire Bipolară**
When the mode is selected, it highlights by emphasizing the frame symbolizing the button pressed, and on the screen is displayed **"Bipolar Blend"** message and a picture of the bipolar blend forceps.

### *8.6 Set-up of output power*

Program the power levels at minimum configuration before testing an accessory. After selecting the functioning mode, the output power is adjusted with the Up and Down keys, that have the numbers 7 and 8 (Figure no. 3).

| | | | |
|---|---|---|---|
| **Maximum levels of power:** | - Cut | **200** | **W** |
| | - Cut Coagulation | **150** | **W** |
| | - Coagulation | **100** | **W** |
| | - Forced Coagulation | **80** | **W** |
| | - Bipolar Coagulation | **100** | **W** |
| | - Bipolar Blend | **100** | **W** |

| | | | |
|---|---|---|---|
| **Minimal levels of power:** | - Cut | **3** | **W** |
| | - Cut Coagulation | **3** | **W** |
| | - Coagulation | **3** | **W** |
| | - Forced Coagulation | **3** | **W** |
| | - Bipolar Coagulation | **1** | **W** |
| | - Bipolar Blend | **1** | **W** |

### *8.7 Activity indicators*

| Operation Mode | Manual Switching | Pedal Switching | Activity Indicator |
|---|---|---|---|
| **Bipolar** | Close tightly the forcep's tips. | After you have selected one of two modes, press the blue pedal. | - specific tone of the mode;<br>- the bipolar indicator highlights by emphasizing the frame symbolizing the button pressed and the display bar (see figure no.3, element no. 12) is changing the background colour from blue to green. |
| **Monopolar** | Press the Cut or Coag button (Cut/Coagulation) | Press the yellow pedal for cut and cut-coagulation or the blue pedal for coagulation. | - specific tone of the mode;<br>- the cut indicator highlights by emphasizing the frame symbolizing the button pressed and the display bar (see figure no.3, element no. 12) is changing the background colour from yellow to green. |

### *8.8 The simultaneous use of two generators*

Two simultaneous generators (and two neutral electrodes) can be used on the same patient, only if both are insulated and earth connected.

Use of disposable neutral electrodes with REM is recommended.

### *8.9 Cardiac pacemakers*

**Warning**

Electromagnetic interference may occur, when using the electrosurgical devices, with the stimulator signal or the stimulator itself can be damaged.

Please refer to the pacemaker's manufacturer or to the Cardiology Unit for further information when these electrosurgical facilities are applied to the patients who use pacemakers.

If the patient has an internal cardiac defibrillator (ICD), contact the manufacturer for instructions before performing electrosurgical procedures.

Electrosurgery may induce multiple activations of these devices. To avoid interference with the pacemakers, place the neutral electrode (patient border) very close to the operating zone.

Make sure that the current which flows from the operating zone to the neutral electrode isn't near the heart or the area where the pacemaker is placed.

## *9. During the operation*

### *9.1 Changing the operation mode*

Verify the selected mode together with the surgeon. Don't change the mode while the generator is activated. In monopolar mode, the selection of the desired mode is done both from frontal panel and from hand piece (yellow only for **Cut, Cut-Coagulation** and blue for the remaining monopolar modes).

In bipolar mode, the change of the mode is done by selecting the desired mode and the by pressing the blue footswitch (or when both forcep's tips are touching each other if **auto** mode is activated), it highlights by emphasizing the frame symbolizing the button pressed.

When changing the operating modes, the power set-up is the one selected at the device's last use (the last selected value is memorized).

### *9.2 Selecting and changing the power set-up*

**Warning**

Verify is the generator's set-up is correct before proceeding with the surgery. Use the lowest power level to obtain the desired effect.

Don't amplify the power level without first checking the active electrode and the neutral one designed for the patient, as well as their connections. Use the active electrode or the forceps only during the minimum interval necessary to reduce the risk of burns.

Confirm the power set-up for the selected mode together with the surgeon. Don't change the power set-up when the generator is activated. To amplify the power of the selected mode press the button with the up-pointed arrow (see figure no.3, element 7). To reduce the power level press the button with the down-pointed arrow (see figure no.3, element 8).

To acquire either a maximum or a minimum level of the set-up press both the up-pointed arrow (see figure no.3, element 7) and the down-pointed arrow buttons (see figure 3, element 8). At first, the set-up will modify slowly, one unit at a time, then faster, from 10 to 10 units. Release the button when you achieve the desired value.

### *9.3 Low level maintenance modes of power set-up*

The smaller the active electrode, the bigger the density of the current transmitted to the tissue, and, at the same time, the lesser amount of power needed to produce the same surgical effect. For example, the needle electrode will require a smaller level of power to make the cuts than the blade electrode.

The level of power necessary to produce the surgical desired effect depends on: the doctor's technique; on the selected mode; on the dimensions of the active electrode.

A low level reduces the quantity of power transmitted to the patient, minimizes the requisition of the active electrode and it helps to protect both the doctors and the patients against accidental burns and electric shocks.

### *9.4 Typical power set-ups*

Use the following list of configuration set-ups for various surgical procedures.

If you don't know the correct set-ups, adjust the electrosurgical generator at minimum emission power and increase gradually the level of power until you obtain the desired effect:

| **Power** | **Surgical procedure** |
|---|---|
| 10-50W | Dermatology<br>Oral surgery<br>Plastic surgery |

| | |
|---|---|
| | Neurosurgery |
| 50-100 W | Head and neck surgery |
| | General surgery |
| | Thoracic surgery (routine) |
| | Vascular surgery (major) |
| 50-200 W | Orthopedics |
| | Cancer extirpation surgery, mastectomy |

### *9.5 Activation tones volume adjustment*

**Warning**

The activation sound can be adusted from "Volume/Brightness Adjustment" menu. Don't turn off the activation sound. The activation tone warns the medical personnel when the accessory is active.

### *9.6 Possible alarms*

#### 9.6.1 Alert for lack of grounding (earth connection)

When connecting the device at the input with electric energy, the device will indicate the lack of ground connection (or if it is damaged) by displaying on the screen the message:

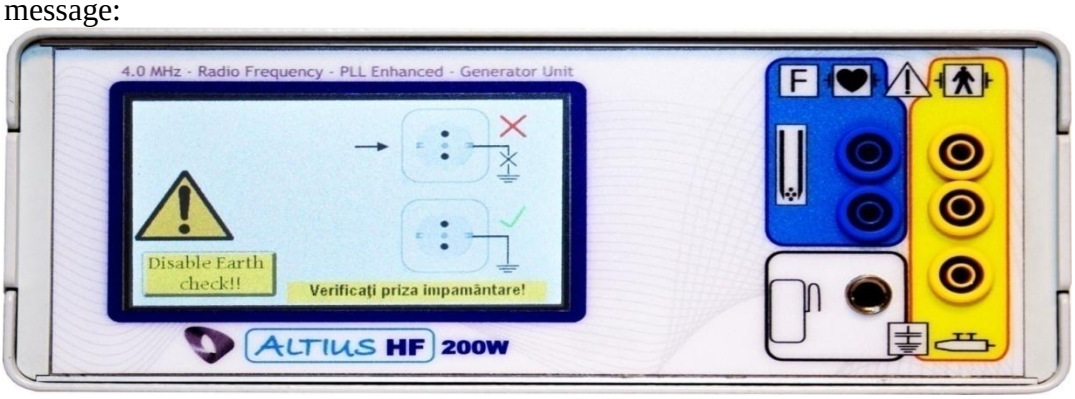



Figure no.30 – Lack of ground connection (according to patent nr.126244)

**Advice:**

If the operating room is equipped with equipotential power system then press button "Disable Earth check !!" and the unit will operate normally.

### 9.6.2 Alert for neutral electrode (patient plate).

The functioning between the two modes (monopolar-bipolar) is different. For the bipolar coagulation the device will function even if the patient plate (neutral electrode) is declutched.

If in the monopolar mode the neutral electrode is missing or the connection cable is damaged, the device will not function and will display the following message on the screen (figure no. 31):

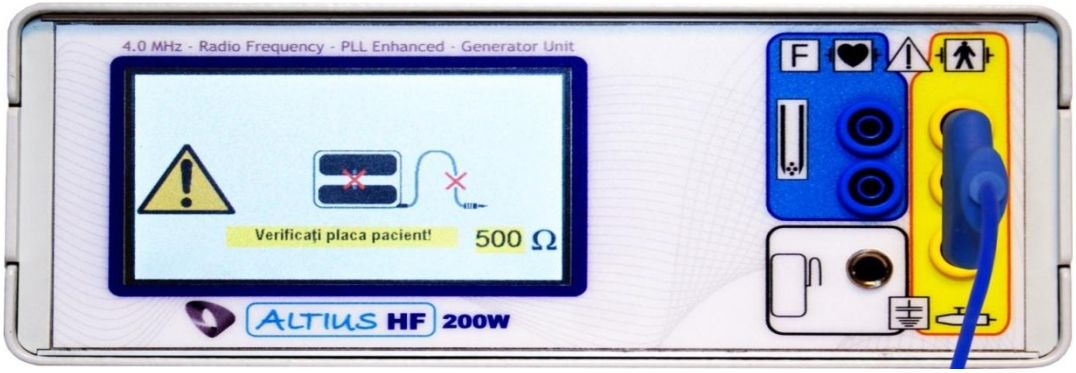



Figure no.31 – **Neutral electrode** (patient plate) alert.

### 9.6.3 Alert of internal malfunctions

This type of alerts occure when internal malfunctions of the device exists.

When this alerts occur, the generator no longer emits, and on the screen is displayed the error code.


Figure no.32 – Alert on possible malfunctions

A list of error codes with their meaning is provided in the table below:

| Number of error code | Error meaning |
|---|---|
| 01 | Internal malfunction |
| 02 | Dangerous internal voltages |
| 03 | Dangerous voltages |
| 04 | Invalid accessories |

In this case you should contact the service department to correct the problem .

## *10. After the surgical intervention*

### *10.1 Preparing the generator for re-usage*

**Warning**

Don’t re-use and don’t sterilize the accessories labeled as “disposable” or “single use only”.

Nu refolosiţi şi nu sterilizaţi accesoriile etichetate "disposable" sau "single use only" (de unică folosinţă).

- Disable the generator;
- Disconnect the cable from the electrical network;
- Declutch (switch off) all the accessories and remove the neutral electrode (patient plate) from the front panel
- If the accessory is *single use only*, dispose of it according to the procedures of your institution.
- If the accessory is re-usable, clean it and sterilize it according to the manufacturer’s instructions.

- Switch off and store the used switch pedal.
- Wipe all the generator's surfaces, as well as the electric cable with a mild cleanser or with a damp cloth. Respect the procedures approved by your institution or use an approved control procedure. Don't allow liquids to get into the housing. The generator cannot be sterilized

Note: Don't use chemical products to clean the generator, neither abrasive cleansers nor other materials that may scratch the panels or damage the generator.

### *10.2 The generator's storage*

- The generator can be stored for an unlimited period of time. In case of its storage for more than a year, subject it to checking procedures before using it again.

- If the generator is stored at a temperature that exceeds its normal limits of functioning (from -20ºC to +40ºC) let it get accustomed to the temperature of the room before using it.

## *11. Possible problems*

### *11.1 General indications for problem solving*

If the generator is damaged, look for the obvious conditions that could have caused the problem.

- Visible signs of physical damage on the generator.
- Check if the fuse department is tightly closed.
- Check if all the cables are properly connected.
- If the damage persists, it is possible that generator mat require repair. Contact the service department.
- When there is an system alert, an alarm sounds and the screen is displaying the message related to the alert.
- The generator is disabled until the issue is fixed.

## *11.2 Actions taken in case of alert condition (lack of the neutral electrode)*

Necessary steps:

- Make sure that the patient's neutral electrode has its cable properly connected at the generator.
- Inspect the cable and the cable's connection at the neutral electrode. If you find proofs of excessive use, breaks or other visible damage replace the neutral electrode and/or the cable.

## *11.3 Action taken in case of alert for lack of grounding*

- when connecting the device at the electric energy input net it will point out if the earth connection outlet is missing or is damaged.

- if the operating room is equipped with equipotential power system then press button "Disable Earth check !!" and the unit will operate normally.

## *11.4 Correcting defects*

If you couldn't find any fast solution, please use the table below to identify and fix the specific malfunctions.

| **Problems** | **Possible cause** | **Solution** |
|---|---|---|
| Abnormal neuromuscular stimulation (stop the operation immediately) | Metal-metal spark | Check all the connections to the generator, the neutral electrode and the active electrode |
| | It can take place during the coagulation | Use a low power level |
| | Abnormal drainage currents of 50-60 Hz | Consult the biomedical enginery department or contact the MobilService representative |
| The generator doesn't respond when it is activated | The electric cable is declutched or the outlet is damaged | Check the electric cable's connection (at the generator and the outlet). Connect the cable at a functional outlet |
| | Electric cable is damaged | Replace it |
| | Electric cable is damaged or the fuses are burnt. | Close the fuse compartment. Replace the burnt fuses. |
| | The internal parts damage | Use an extra generator. Consult the biomedical enginery department or contact a MobilService representative |

| Problems | Possible cause | Solution |
|---|---|---|
| The generator is activated, but the display isn't on | The software's damage | Disable and then reactivate the generator |
| | The internal part's damage | Use an extra generator. Consult the biomedical enginery department or contact a MobilService representative MobilService |
| The generator and the accessory is active, but the generator doesn't supply with energy. | The pedal or the manually switched tool is damaged | Disable the generator. Check and correct all the accessories' connections. |
| | The power level is too low | Amplify the level of power. Consult the chapter **"Changing the power set-up".** |
| | Possible alarm | Verify the message displayed and try to remedy the damage. |
| | Internal parts damage | Use an extra generator. Consult the biomedical enginery department or contact a MobilService representative |
| Continuous interference on the display | Improper grounding of the housing | Check and remedy the display's and the generator's proper grounding of the housing. Check the grounding of the other electric equipments from the room. |
| | The electric equipment is grounded at different objects instead of being all earth connected. The generator can respond to voltage differences between the grounded objects | Connect all the electric equipments in line in the same place. Contact the biomedical enginery department or contact the MobilService representative |
| | Damaged display | Replace the display |
| Interference with other parts only when the generator is activated. | Metal-metal spark | Check all the connections to the generator, the neutral electrode and the active electrode |
| | The grounding wires from the operating room are ellectrically inconsistent. | The biomedical enginery department must contact the display's manufacturer. |
| Interference with the pacemaker. | On-off connections or metal-metal spark | Check the connections of the active electrode's cable and of the neutral electrode's cable. It may be necessary to re-set the pacemaker. |
| | The current, transmitted from the active electrode to the return one during the monopolar electrosurgery, flows too close to the pacemaker | Check the bipolar instruments, if possible. If you must use a monopolar instrument, place the return electrode as close as possible to the operating area. Make sure that the current flow, from the operating area to the patient's neutral electrode, isn't near the heart or the area where the pacemaker is implemented. Always monitor patients with pacemaker during the operation and keep and extra |

| Problems | Possible cause | Solution |
|---|---|---|
| | | defibrillator.<br>Contact the pacemaker's manufacturer or the Cardiology Unit for further information when you use the electrosurgical instruments on the patients with pacemakers. |
| Activation of the intern cardiac defibrillator (ICD) | The ICD is activated by the electrosurgical generator. | Stop the procedure and contact the ICD's manufacturer for instructions. |

# *12. Maintenance and reparation*

## *12.1 The manufacturer's responsibility*

**MobilService** is responsible for the safety, reliability and generator's performance only in the following situations:

- The installing and assembly procedures are respected
- The assembly procedure, re-adjustment, modification or repairs are done only by authorized personnel
- The room's wiring (where the generator is installed) respects the local norms, like the practical SR ENs.
- The equipment is used in accordance with the instructions
- For further warranty information, follow the Warranty annex, found at the end of this book.

## *12.2 Recurrent maintenance*

**Note:** Contact MobilService maintenance recommendations and for the electric and functional checking procedures.

**When must you verify or repair the generator?**

MobilService recommends that the generator be verified by authorized personnel, at least twice a year. This check-up must include the generator's calibration.

**When must you verify or replace the electric cable?**

Verify the electric cable every time you use the generator or at the intervals recommended by your institution. Replace the electric cable if there are exposed circuits, breaks, shredded borders or damaged connectors.

**When must you replace the fuse?**

An intern damaged part or a surge of the electrical net may damage the fuses. If the generator stops from functioning you must replace the fuses, even if the generator has a voltage input.

### *12.3 Generator warranty return service*

Before returning the generator, contact the authorized representative. If you are told to repair the generator, first obtain a return authorization number. Then, clean the generator and return it to be repaired.

**Step 1 Obtain a return authorization number**

Contact the authorized representative. Prepare the following information:

- The name of the hospital/clinic/ the patient's number
- The phone number
- The department/address, city, postal code
- The number of the model
- Serial number
- Description of problem

**Step 2 – Clean the generator**
*Respect the recommendations and warnings from 10.1*

**Step 3 – The generator's delivery**

A. Attach a label to the generator, which must contain: the return authorization number and information (about the hospital, telephone number)
B. Make sure that the generator is properly cleaned before packing it and delivering it in its box.
C. Assure the generator's postpaid delivery at the MobilService headquarters.

# Annex A

## *A.1 Characteristics of functioning*

All the values of specification are nominal and subjected to changes that may take place without further notice. In this chapter, the word "typical" refers to a value of specification which varies between ± 20% from the value expressed at the room's temperature (25ºC) and a nominal input voltage.

| | |
|---|---|
| Output set-up | Insulated output in bipolar mode; un-insulated output versus load in alternative current in monopolar mode. |
| Cooling | Ventilation outlets on inferior panel, ventilator. |
| Display | LCD 128/64 pixels |
| Montage | Altius HF200W can be installed on a stable surface, or optionally it can be delivered with a removable support to upgrade the ergonomic level when using the device |

## *A.2 Dimensions and weight*

| | |
|---|---|
| Width | 234,5 mm |
| Depth | 280 mm |
| Vertical height | 101 mm |
| Weight | <3.5kg ± 5% |

## *A.3 Operating paramaters.*

| | |
|---|---|
| Electric cable: | connector with 3 pins, approved locally |
| Input voltage: | 200-240Vac/100-110Vac |
| Line network frequency range (nominal): | 50-60Hz |
| Fuses: | 2xT4 A |
| Ambient temperature: | from 10° to 40° C |
| Relative humidity: | from 30% to 75%, without sweat |
| Atmospheric pressure: | from 700 to l060 milibars |

**Heating time:** If it is transported or stored at temperatures outside the operating temperature, the device must remain inactive for at least an hour until it reaches the room's temperature.

## *A.4 Transport and storage*

| | |
|---|---|
| Ambient temperature: | from 10% to 80%, sweat |
| Relative humidity: | from - 20° to 40°C |
| Atmospheric pressure: | from 500 to 1600 milibars |

Storage duration: No matter how long it is the storage duration, the additional procedures that allow the device to function are completely forbidden, by way of exception being the default revisions.

## *A.5 Functioning modes*

At maximum levels of power and in case of nominal values (Clean Cut – 200W, value 200-300 ohmi) the generator can be activated from 10 to 10 seconds (activated), from 30 to 30 seconds (disabled), for an hour.

## *A.6 Audio volume*

The audio levels listed below are the activation tones (bipolar, cut and coagulation)and the alert tones are at 1 meter distance one from the other. The alert tones respect the requirements of the IEC 60601-2-2 standard.

### A.6.1 RF activation tones

Pe toată durata activării generatorului acesta emite un ton specific în funcţie de modul de lucru (vezi tabelul de mai jos). Volumul tonului de activare este reglabil în gama 45 - 65 dB.

| **Mod de lucru:** | **Frequency tone for activating the generator** |
|---|---|
| Cut: | 860 Hz ± 10% |
| Cut Coagulation: | 1055 Hz ± 10% |
| Coagulation: | 1260 Hz ± 10% |
| Bipolar Coagulation (Micro): | 1420 Hz ± 10% |
| Bipolar Coagulation: | 1635 Hz ± 10% |

### A.6.2 Alarm tone

| | |
|---|---|
| Volume (not adjustable): | > 65 dB |
| Frequency: | 1500 Hz ± 10% intermittent |
| Duration: | from 250 to 500 ms |

### *A.7 Output characteristics*

The device's nominal frequency is of ~ 3,6 - 4,1 Mhz, with an IF sinusoid (sine wave) current or pulse modulated and for bipolar mode 0,6 - 1,1Mhz.

Maximum output for the bipolar and monopolar modes:

| Mode | | P-P voltage opened circuit (max) | Nominal value (max) | Power (max) | Top factors |
|---|---|---|---|---|---|
| Bipolar | Bipolar | 500 | 100Ω | 100 W | 1,5 |
| | Blend | 500 | 100Ω | 100W | 1.5 |
| Monopolar | Cut | 1410 | 550 Ω | 200 W | 1.5 |
| | Cut - Coagulation | 1980 | 550 Ω | 150 W | 2.5 - 2.9 |
| | Coagulation | 2160 | 550 Ω | 100 W | 2.6 – 4.2 |
| | Forced Coagulation | 2200 | 550 Ω | 80 W | 2.8 – 4.8 |

In figure no.33 is presented the chart representing the features on power variations depending on the load resistance.

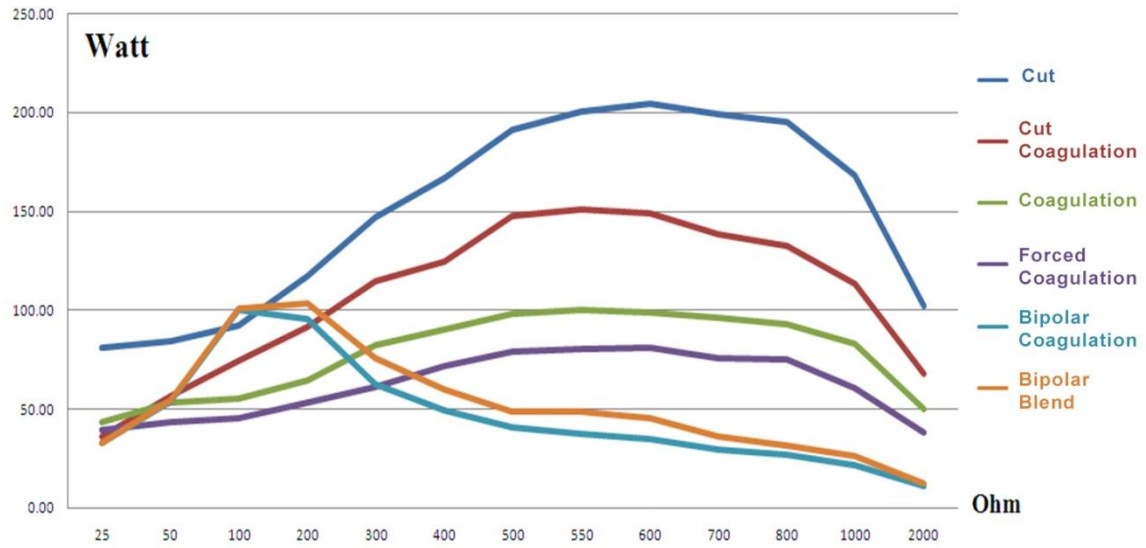



Figure no.33 - Power variations depending on the load resistance chart

### *A.8 IEC standards and classifications*

**Attention!**

**Danger!**

**Symbol used with a HF ISOLATED PATIENT CIRCUIT.**

**Symbol used with an EARTH REFERENCED PATIENT CIRCUIT.**

**CF type equipment protected against defibrillation shocks.**

**BF type equipment protected against defibrillation shocks.**

**Non-ionizing radiation.**

Explosion hazard, only if it used with flammable anaesthetics. To reduce the electroshock hazard don't take the case off. Contact the authorized service personnel.

**Equipment class I (60601-1) +A1+A2+A3: 2001**

The conductor accessible parts can't be activated in case of damage of the main insulation because of the way in which these are connected to the grounding conductor.

**Equipment class I CF (60601-1:2012) defibrillator protection for the bipolar mode**

The Altius HF 200W generator has a high degree of protection against electric shock, especially against the allowed leakage currents. It contains a CF output insulation and it can be used for procedures on or near the heart.

The neutral electrode's top for the Altius HF 200W is protected against the defibrillator's discharge, according to **SR EN 60601-2-2:2009**.

The equipment corresponds to the **SR EN 60601-1-4:2002** standard, regarding the general requirements for the programmable electronic systems.

The equipment corresponds to the **SRNE 980:2008** standard regarding the graphic symbols used for the device's labeling.

**Relatively water-proof (60601-2-2:2009)**

The generator's case is built so as the liquid spilled during the proper use may not affect the electric insulation or other components that may affect the generator's safety.

**Electromagnetic interference**

The Altius HF 200W generator functions without interference when it is placed on or under an electrosurgical generator. The generator reduces the electromagnetic interference of the video equipment used in the operating room.

**Electromagnetic compatibility (SR EN 60601-1-2:2007 şi SR EN 60601-2-2:2009)**

The Altius HF200W generator respects the SR EN 60601-1-2 and IEC 60601-2-2 specifications and the IEC 60601-2-2 that refer to the electromagnetic compatibility.

# Annex B

## B.1 Warranty conditions

The product's warranty is of 24 months from the moment in which it is purchased.

The product benefits from warranty and service only if the installation, manipulation and transportation rules are respected exactly as it is mentioned in the manual.

The producer guarantees for the components used in the manufacturing process, against manufacturing and material defects, during the period specified above, from the moment in which the product is purchased.

During the warranty period the producer reserves the right to repair or replace the damaged accessories.

## B.2 The supplier's liabilities

During the warranty period the supplier has the following liabilities:

- The profiling, the expertise, the montage/disabling, repair or free replacement of the damaged accessories, at the headquarters' Service Department, from Monday to Friday (9 a.m. – 5 p.m.)
- If, after the expertise, the Service Department finds out that the damage intervened even though all the rules have been properly respected, it will solve the problem in 10 working days from the moment in which it has been noticed.
- If, due to objective reasons (some parts may not be found) the damage cannot be solved in 10 days, the supplier will replace it with another one (equivalent to the old one). The warranty period will not suffer changes.
- The warranty period starts at the moment of the purchase and it extends with the time necessary for the repair of damage. The extension of the warranty period is listed in the warranty certificate.
- The profiling and the repair of damaged parts are done at the MobilService headquarters.
- These repair operations can also be done at the client (on the client's expense).

### *B.3 The customer's liabilities*

- To respect the manipulation, transportation, storage, exploitation and maintenance conditions from the contract.
- Any kind of change (montage, disabling of accessories) of the products delivered by the MobilService will be done only by authorized personnel. Failure of the customer to respect the conditions mentioned leads to the withdrawal of the product warranty;

- In case of complaints, the client must come to MobilService SRL, with the damaged products in their original manufacturing packaging, together with the warranty certificate and the invoice.
- The supplier ensures against payment the products' maintenance and repair outside the warranty period, for a period of 5 years based on a post-warranty contract.

### *B.4 Delivery and Reception of product*

Delivery and Reception of product is done at the supplier's headquarters. Product's reception is done based on the invoice emitted by supplier and on the warranty certificate. The good functioning and the integrity of the product will be approved and after explained to the customer.