Dear Ladies and Gentlemen,

We would like to thank you for the confidence you have shown in us and your choice of products from the company EMED. We are convinced that due to our solutions you will achieve the expected comfort of work, the maximum precision and safety. The present instructions have been prepared by an interdisciplinary team of experts in the fields of quality and safety, biomedical engineering and electronics. When they were elaborated the main objective was to facilitate your work by presenting information in the most friendly way. The most important notes are clearly marked and a large number of photographs makes it easier to understand the text. Each edition of the instructions is subject to strict control and we verify it and supervise it. We would be grateful for all your comments and suggestions so that we can still continue to meet your expectations as well as we can.

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Version 1.2, last update 2018.11.19

The present Instructions are based on a risk assessment and suitable for the levels of training, experience and education of the intended users. Before starting to use the Unit, become acquainted with the content of the Instructions for Use and keep them for reference in the future.

SYMBOLS USED IN THESE INSTRUCTIONS:

 **Important information**

 **What to do**

 **What not to do**

 **Warning**

Current version for devices with software version 0.02.S.03.05 or higher.

Contents

1 Introduction

1.1 ATOM smart accessories list

The table shows the standard accessories and documents attached with the ATOM smart electrosurgical unit.

Table 1. Standard equipment of the ATOM smart system.

No.	ITEM DESCRIPTION	QUANTITY
1	Power cable 4 m	1
2	Instructions for use	1
3	Unit operation log	1
4	Warranty certificate	1
5	Electrusurgical equipment safety guidelines	1

1.2 Intended use of the ATOM smart system

The ATOM smart unit is intended for cutting and coagulation in surgical procedures, particularly in:

- minor procedures of general and pediatric surgery (at outpatient clinics)
- dermatological procedures
- gynaecological procedures
- plastic and aesthetic surgery
- dental surgery procedures

The system is equipped with a CF (floating) output so that it can be used on the central nervous system and the heart.

1.3 Electrosurgery basics

Currently, electrosurgery is a technique used in nearly all kinds of surgical procedures. In order to use electrosurgery effectively, it is necessary to learn and understand it, and to apply the safety rules designed for maximum protection of both the surgeon and the patient.

An electrosurgical unit is a device that uses electricity to generate high-frequency (HF) alternating current. The thermal effect caused by the HF current flowing through the tissue is used for tissue cutting or coagulation. An electrosurgical unit generates alternating current of frequency higher than 300 kHz, so there is no risk of unintended effect of muscle and nerve electrolysis/stimulation.

Warning

When working with an electrosurgical unit generating high-frequency current, always remember the two fundamental rules:

- the current flows along all the available paths,
- the HF leakage current flows between two adjacent conductors even if they are separated from each other.

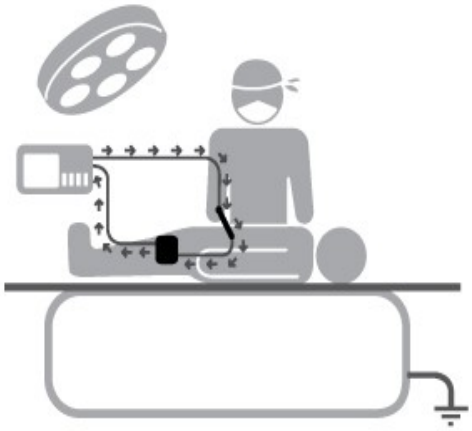


Figure 1: Monopolar operation.

Monopolar operation

In the monopolar mode, the HF current is delivered to the tissue by the active electrode. The cutting or coagulation effect results from the concentration of the high density HF current on the small surface of the active electrode. This causes an increase of temperature and water evaporation from the tissue in the direct vicinity of the active electrode and eventually results in haemostasis and arrest of bleeding, or cutting of the tissue.
Subsequently, the HF current flows to the neutral electrode where it is dispersed. In this way, the density of the HF current decreases and no unintended thermal effect occurs at the site of the neutral electrode application. From the neutral electrode the HF current returns to the unit.

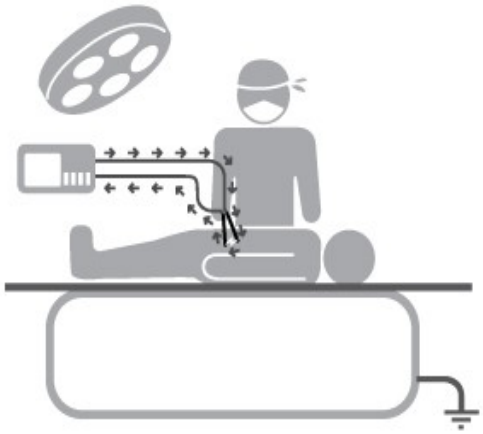


Figure 2: Bipolar operation.

Bipolar operation

When the system operates in the bipolar mode, the HF current flows between the two jaws of a bipolar instrument and concentrates exclusively on the small area located between them. In the bipolar mode the dangerous current flow through the patient's body to the neutral electrode does not occur, so the risk of burns occurring outside the immediate surgical area is minimised. Thus, the bipolar coagulation modes are safer than the monopolar modes and they are particularly recommended for procedures involving patients with cardiac pacemakers or for procedures performed on organs of a small cross-section area. In the bipolar mode, the neutral electrode is not required.

1.4 User

Warning

The electrosurgical system can only be used by persons with the authority to perform medical procedures and trained in the safety principles in electrosurgery, awarded a Certificate issued by EMED.

hologram

Training Certificate

Hereby EMED SP. Z O. O. SP. K. as a producer of electrosurgical units confirms that

Mr John Smith

is trained and qualified for Emed electrosurgical units in the scope of:

Product Use Training

Authorisation No.	502
Issuse date:	2013-10-28
Valid until:	2018-10-28

emed SP. Z O. O. SP. K.
05-816 OPACZ, ul. Ryżowa 69A
NIP 527-199-66-17
Nr KRS: 0000407548
tel. +48 (22) 723 08 00, fax. +48 (22) 723 00 81

Signature of EMED Training Center

EMED SP. Z O. O. SP. K. ul. Ryżowa 69A, 05-816 Opacz, tel. 22 723 08 00, fax 22 723 00 81, www.emed.pl, emed@emed.pl

The validity of the certificate expires after 5 years from the date of training. The certificate can be renewed after re-training. EMED is not responsible for monitoring the expiration dates of certificates.

1.5 Contraindications and possible side effects

What not to do

In all the cases of its use, the decision to apply electrosurgery should be taken by the person who performs a procedure, taking into account the possible benefits or adverse side effects.

Electrosurgery is not recommended for pregnant women and persons with:

- a cardiac pacemaker,
- stimulating electrodes,
- metal implants,
- arterial hypertension,
- mental disorders,
- renal insufficiency,
- blood coagulation disorders.

The factors listed above pose the risk of side effects. If necessary, the use of the bipolar method is recommended.

If you use the monopolar method, refer to section 7.2.4 "Neutral electrode application principles".

2 Protection measures and warnings

Warning

No modifications can be made to the unit without the manufacturer's authorisation. Modified units are not authorised by the manufacturer for further use.

Warning

The USB socket and the RS232 service socket can only be used for service purposes. Their use in any other manner can cause overload of the system.

Warning

When performing electrosurgical procedures, minimise the risk of burns by:

- using only the recommended accessories,
- constantly checking the cables for connecting the application electrodes, and in particular the condition of their insulation,
- correctly applying the neutral electrode (see Section "Neutral Electrode Monitoring")
- not allowing any fluids to enter between the silicone neutral electrode and the patient's body,
- preventing the patient from coming into contact with metal and grounding elements; in particular, the patient should be efficiently insulated from a grounded operation

table. For this purpose, a plastic film should be placed between the operating table and the surgical drapes on which the patient is positioned,

- not touching the patient's skin; in case it is necessary, dry gauze should be used as an insulator,
- not allowing the parts of the patient's body to come into contact with each other (for instance, the hand touching the thigh)
- the neutral electrode should be applied as close as possible to the procedure site, but not closer than 20 cm from the operating field.

Warning

When planning surgeries which cannot be safely completed in the event of basic electrosurgical system failure, a complete and ready-to-use substitute electrosurgical system should be prepared.

Warning

When performing procedures on patients connected to monitoring devices (ECG), remember to place the monitoring electrodes as far as possible from the electrosurgical electrode application site. Furthermore, it is recommended that monitoring devices equipped with protective systems against high-frequency currents should be used. Do not use needle electrodes for monitoring devices.

Warning

The application electrode cables should be connected so that:

- they do not touch the patient
- they are not intertwined with other cables

What not to do

The active electrode handle and active mono and bipolar electrodes cannot be put on the patient's body due to the risk of accidental activation and other risks. Moreover, the active electrodes become hot during operation. Take special precautions because accidentally touching tissues with a hot instrument can cause burns and perforation.

Warning

In order to reduce the risk of coagulation at unintended sites, the bipolar technique should be applied in procedures where high-frequency current could pass through body parts with a small cross-section.

What not to do

The output power setting should not be greater than necessary for performing a given procedure.

Warning

An error of an electrosurgical unit may result in an undesirable increase in output power and inadvertent damage to the patient's tissues. Annual technical inspection of the unit in an authorised manufacturer's service centre will minimise the risk of failure.

Warning

An evident drop in the output power, when the settings are normal, can mean:

- incorrect application of the neutral (silicone) electrode, damaged cables,
- residues of coagulated tissue on the instrument.

Check for the above situations before increasing the power.

Warning

Unclean electrodes can cause a deterioration in the quality of the unit. This especially applies to soft and bipolar coagulation. The active electrodes should be cleaned of residual tissues during the procedures.

Warning

The operation of the unit can have different effects on different tissues. In case of a sudden power drop, the neutral electrode application should be checked.

Important information

During the operations performed in the region of the thorax or the head it is recommended that the use of flammable anaesthetics or oxidising gases, such as nitrous oxide (N_2O) and oxygen, should be avoided, unless those agents are aspirated away. In order to remove gases and increase visibility during the operation, use of smoke-plume extraction is recommended, where removal is not possible in any other way

Warning

Use nonflammable disinfectants. Otherwise, they should be left to evaporate before the procedure. There is also a risk of pouring those agents under the body or into a body cavity. Should this happen, such flooded areas should be dried. A flammable agent can be set on fire by a spark occurring during normal system operation.

Warning

Sparks at the active electrode present the risk of setting bandages and metabolic gases on fire.

Warning

During a procedure, there is also a risk that a heart pacemaker can be damaged or its function can be interfered with during a procedure. In these cases, the bipolar technique should be used. If monopolar modes are necessary, the neutral electrode should be placed as far as possible from the pacemaker. The active electrode should not be used near the pacemaker. It is recommended that the current should be applied for a short time at short time intervals. Before using electrosurgery, consult an authorised representative for the heart pacemaker and a cardiac surgeon. Check the pacemaker thoroughly after the procedure. Use of electrosurgery systems on patients with heart pacemakers is not permitted under outpatient clinic conditions.

Warning

High-frequency leakage currents can cause burns at a distance from the electrode application site, if they are in contact with conductive elements.

Warning

The commonly-used "through-the-instrument" coagulation technique should only be applied when using properly insulated forceps. These are special forceps with insulated handles. **Surgical gloves do not sufficiently protect the operator from burns.**

Important information

When performing endoscopic procedures:

- maintain the active part of the electrode in the operator's field of vision to avoid accidental burns or coagulation at a random site
- avoid contact with the metal parts of the endoscope
- use a non-conductive cap on the endoscope eyepiece.

Important information

In designing electrosurgical generators, EMED paid special attention to the increasingly restrictive requirements regarding electromagnetic emissions. As a result, it selected solutions ensuring minimal emission levels to meet current and future requirements.
On-site measurements have confirmed that EMED-distributed generators ensure a high level of electromagnetic safety. Under typical work conditions, an 8-hour daily exposure field occurs at a distance of 5 to 15 cm from the working cables. Beyond 20-40 cm, the field falls below the maximum value without a time limit. Electromagnetic fields occur mainly around the cables and emission from the device itself is not significant.
When not activated, generators do not emit highfrequency power.
As the field distribution depends on the specific workplace, system placement and wiring, measurements must be performed individually. Your local Sanepid authority can determine the detailed distribution of the emission zones for you.

2.1 Symbols used in the instructions for use and placed on the device

The symbols applied conform to the Standards PN-EN-15223-1:2012 and PN-EN 60601-1:2011.

Table 2. Symbols

	Defibrillation-proof type CF applied part		Non-Ionizing Radiation
	The generator output is floating (isolated) with respect to ground		Serial number
	Caution		Catalogue number
	Dangerous voltage		Equipotentiality
	Manufacturer		Conforms to Directive 93/42/EEC
	Operating instructions		The product may not be disposed of as normal domestic waste
	Follow instructions for use		LOT
	Follow instructions for use		Fragile
	Do not use if packaging is damaged		

3 Device appearance and construction

The generator casing is made of metal without ventilation holes. The front panel is made of plastic. The device can easily be cleaned with medical products dedicated disinfectants.

3.1 Front panel

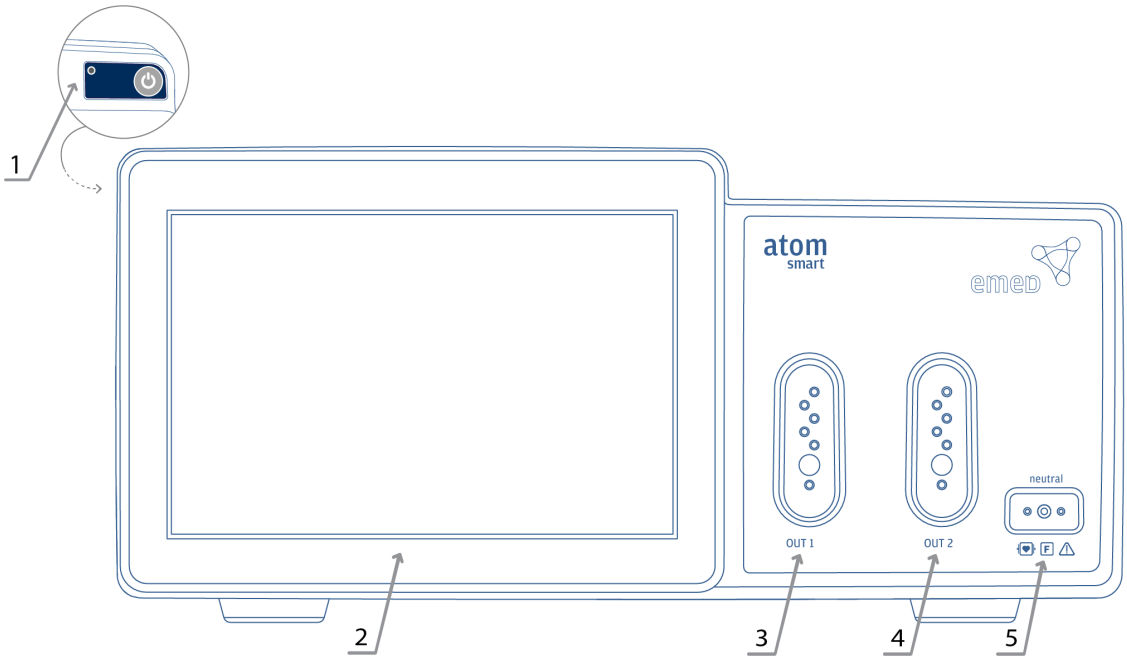


Figure 3. ATOM smart frontside view.

The front panel of the ENDO system contains the following items (Fig. 3):

- **(1)** standby button (on the back of the touch screen)
- **(2)** TFT screen with touch panel
- **(3)** universal SDS output (with instrument detection)
- **(4)** universal SDS output (with instrument detection)
- **(5)** neutral electrode socket

The settings or set levels of the system can be changed using the touch screen.

3.2 Back panel

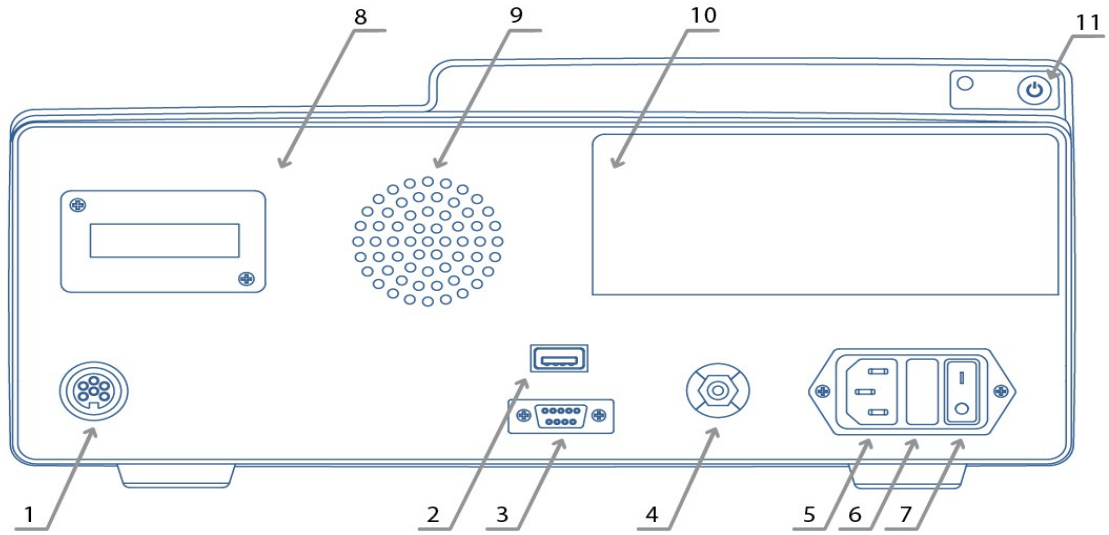


Figure 4. Back view of the ATOM smart system.

The back panel of the casing, as shown in Fig. 4, contains the following items:

- **(1)** universal footswitch socket
- **(2)** USB port
- **(3)** RS service port
- **(4)** additional grounding pin
- **(5)** power cable input
- **(6)** fuse socket
- **(7)** main power switch
- **(8)** wireless footswitch receiver module (as an option)
- **(9)** speaker
- **(10)** manufacturer's rating plate
- **(11)** standby button

3.3 Active panel

Warning

Before the first use of the system, the user should become acquainted with the effects of different settings by performing tests on fresh raw beef meat.

The system can show a screen with a general view where the selected modes and set levels for both outputs of the system can be seen.

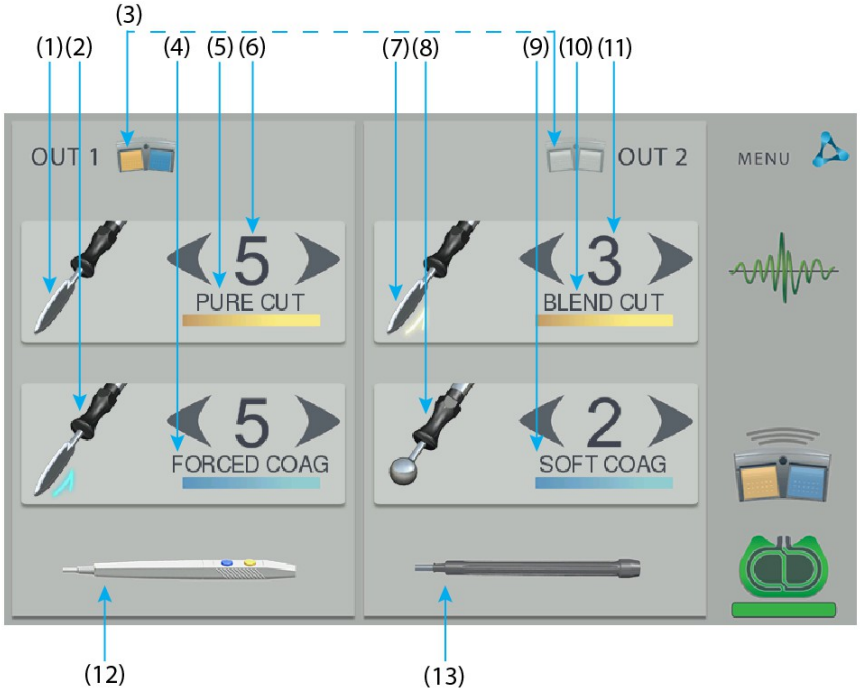


Figure 5. A general view of the panel.

A general view of the panel (Fig. 5) contains:

- **(1)** cutting mode icon for output OUT1 (section **7.4.1**)
- **(2)** coagulation mode icon for output OUT1 (section **7.4.2**)
- **(3)** footswitch control icon
- **(4,9)** name of the selected coagulation mode
- **(5,10)** name of the selected cutting mode
- **(6,11)** selected operation effect
- **(7)** cutting mode icon for output OUT2
- **(8)** coagulation mode icon for output OUT2
- **(12,13)** icon of the connected SDS instrument

4 Compatible and optional accessories

Important information

The EMED Company only allows the use of EMED accessories or those offered by the EMED Company.

In case of doubts concerning the compatibility and manner of connecting the accessories, please contact the producer or an authorised EMED distributor**.**

4.1 Compatible accessories

EMED offers high-quality accessories for operation with the ATOM smart system, which enable the performance of a variety of procedures in general surgery, vascular surgery, gynaecology, oncology and other fields.

The following SDS accessories manufactured by the company EMED should be plugged into the sockets situated on the front panel of the unit. Working end-pieces should be connected to the accessories (Fig. 3, item 3,4).

4.1.1 Neutral electrode cable

It should be connected to the **neutral electrode** socket made according to the USA standard (Fig. 11).

Figure 6. A disposable neutral electrode plug

For more information on the neutral electrode, see section 7.2 “Neutral electrode monitoring”.

4.1.2 Instrument cable for universal SDS sockets

The cables of instruments can be connected to sockets OUT1 and OUT2, which are universal ones with tool detection, manufactured in accordance with the 6-pin standard (SMART Device System) **(Fig. 11).**

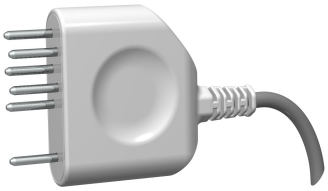


Figure 7. Universal SDS socket.

4.1.3 Neutral electrodes

Disposable neutral electrode EMED SAFE, hydrogel, split for adults (812-80H) and split for infants (812-83H).

4.1.4 Monopolar accessories

Monopolar electrode handle, catalogue No. 322-14S, 327-14S, 325-14S, 215-XXX, 218-XXX.

For monopolar electrode handle can be plugged monopolar electrodes with catalogue No 5XXXXX.
Full list of accessories is available in EMED catalogue.

4.1.5 Bipolar accessories

Bipolar cables, catalogue No. 351-XXS.

It is possible to connect bipolar pliers to cables, catalogue No 605-XXX.
Full list of accessories is available in EMED catalogue.

4.2 Optional accessories

4.2.1 Footswitch

The footswitch is connected to a socket located on the back wall of the system.

The manner of connecting the footswitch and the power cable is shown in Fig. 8, where the following elements are shown:

- **(1)** footswitch connection
- **(2)** connection of the power cable

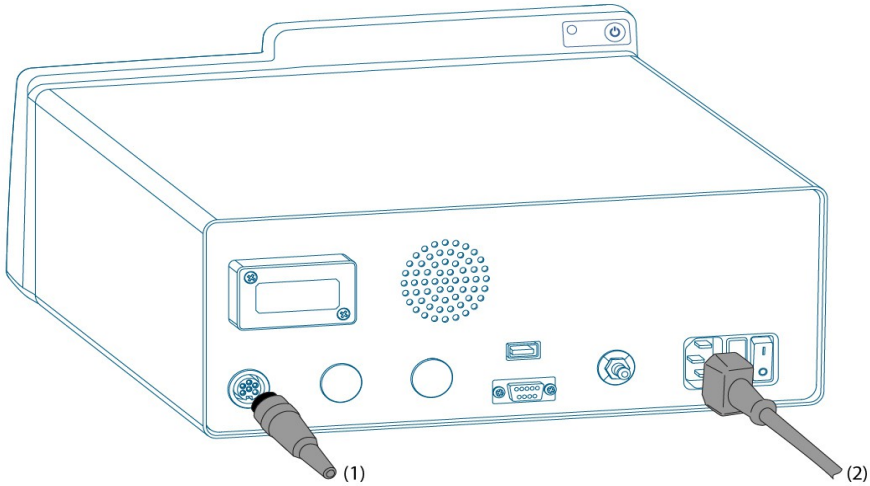


Figure 8. Manner of connecting the footswitches and the power cable.

The ATOM smart system works with the following footswitches:

- wireless and with cable 1-button footswitch for cutting (nr ref. 100-304, 100-314),
- wireless and with cable 1-buttton footswitch for coagulation (nr ref. 100-305, 100-315),
- wired, 2-button (nr ref. 100-302),
- wireless and with cable, 2-buttton, MultiSwitch (nr ref. 100-303,100-313).

For more information about the connection of a wireless footswitch, see section 5.4.

4.2.2 Trolley

The trolley for the ATOM smart unit (Ref. No. 080-061) is equipped with wheels with a locking function. It has fixing pins preventing the unit from falling off and a case with shelves (Fig. 9).

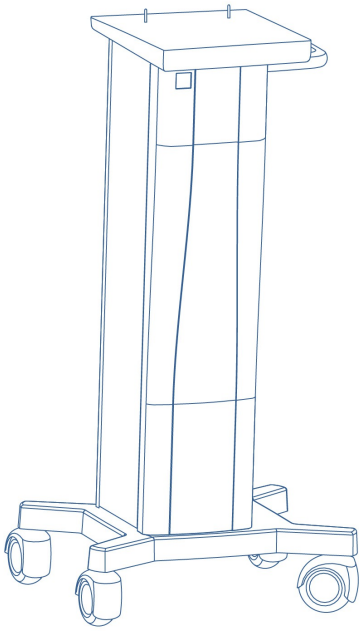


Figure 9. Trolley for ATOM smart.

5 Preparing the system for operation

In order to make the system ready to operate, connect the power cable and accessories.

Important information

Before starting to work, the user must become acquainted with the Instructions for Use and the Training Manual on "Electrosurgical Equipment Safety Guidelines

5.1 Connecting power cables

The power cable can only be plugged or unplugged when the system is off. The unit conforms to class I electric shock protection, and requires one phase power supply with outlets equipped with a grounding pin. The power supply socket is located on the back panel of the casing.

Warning

The system may only be connected to the mains with protective grounding, equipped with a residual current device (RCD).

The system does not need to be connected to an additional protective earth contact if it is connected to a grounded power socket. An additional protective earth contact serves to ground the system when an ungrounded power socket is used or at places where a shock protection system requires the connection of an additional protective earth contact.

After the system has been connected to the power supply, it is switched on with the STANDBY button located on the back of the screen. (Fig. 3, itme 1 and Fig. 4, item 11).

5.2 Connecting accessories for electrosurgical procedures

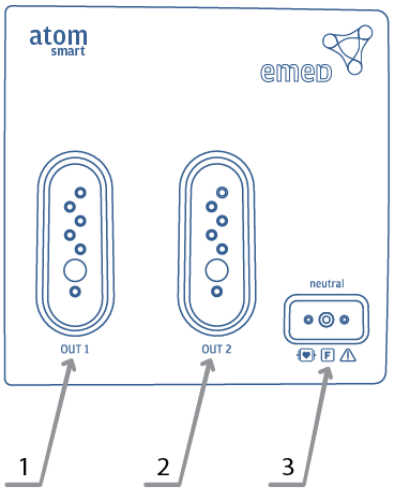


Figure 10. Sockets for connecting accessories

- **(1)** universal SDS output (with instrument detection)
- **(2)** universal SDS output (with instrument detection)
- **(3)** neutral electrode socket

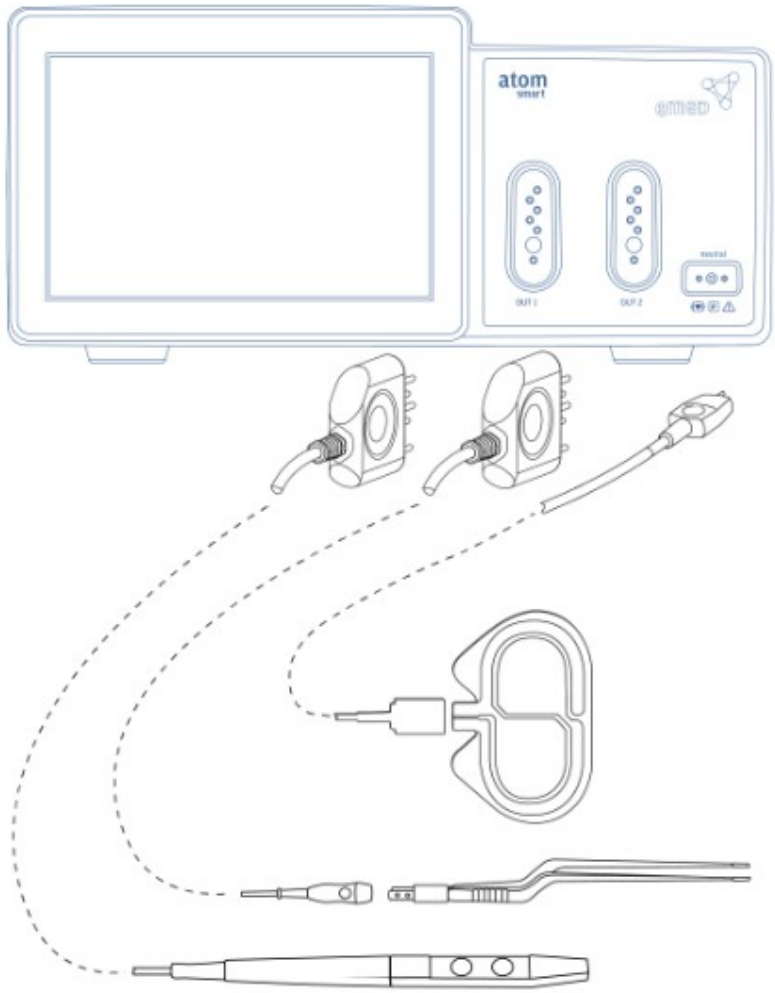


Figure 11. Manner of connecting accessories to the ATOM smart system.

5.3 Instrument detection

The universal sockets in the ATOM smart systems are equipped with an **instrument detection system – the SDS system**. It can detect and identify the connected instrument.

The detection system identifies the connected instrument and automatically recalls the default modes and setting. In case the parameters change, they will be saved and recalled for each subsequent connection of the instrument. At each stage of its operation, the system enables a quick recall of the default settings. SDS universal socket - supports basic and specialized modes monopolar and bipolar.

Fig. 13 contains data on the SDS instrument connected to the ENDO system.
Information on the instrument will be displayed on the screen after the instrument icon is touched (Fig. 12)

Figure 12. Icon of the connected SDS instrument.

The instrument data include:

- **(1)** catalogue number
- **(2)** instrument name

and the image of the connected instrument

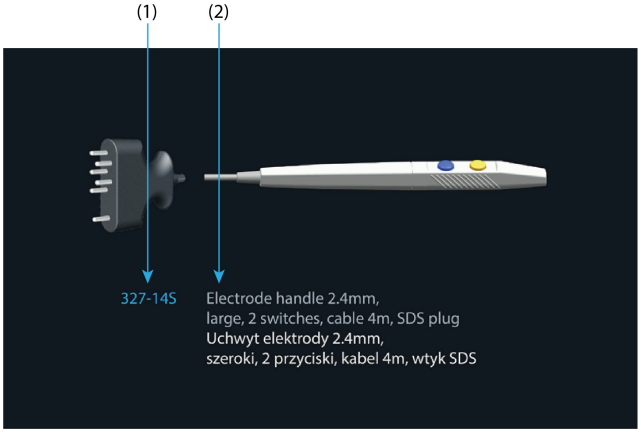


Figure 13. Information on the connected SDS instrument/ cable.

The operating mode and the settings can only be changed after the SDS instrument has been connected. In case that no instrument has been connected, the control panel is empty.

The following figure shows a list of available modes, which can be seen after the instrument has been connected to the SDS socket (Fig. 14).

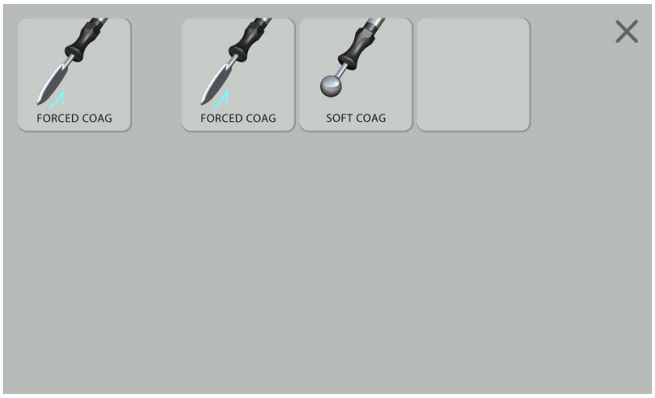


Figure 14. A list of available operating modes after the SDS has been connected.

In addition, the SDS instrument detection system enables the limitation of the maximum usable power for those instruments that need it. It is impossible to exceed the upper limit of the assigned power. This increases the safety of work and reduces the risk of damage to an instrument by using too high power settings.

5.4 Wireless footswitch receiver (optional)

The ATOM smart system can work with a wireless footswitch. A wireless footswitch transmits data using radio waves, eliminating in this way the number of unnecessary cables and enhancing the comfort of a procedure.

A wireless footswitch which works with the ATOM smart system is equipped with a receiver resembling an ordinary footswitch plug. It should be connected to the footswitch socket on the back of the system (Fig. 4, item 1). It is connected in the same way as the plug of the standard wired footswitch.

The ATOM smart unit monitors on a current basis the charge level of the battery of a wireless footswitch. In order to display information on the battery charge level, touch the footswitch icon.

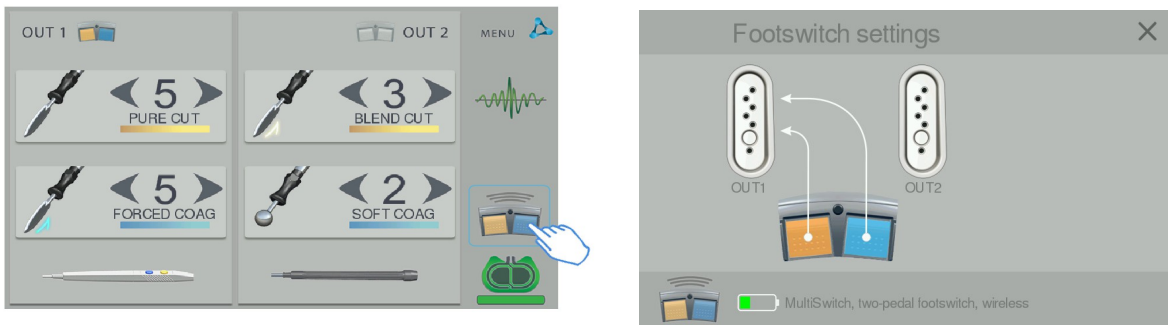
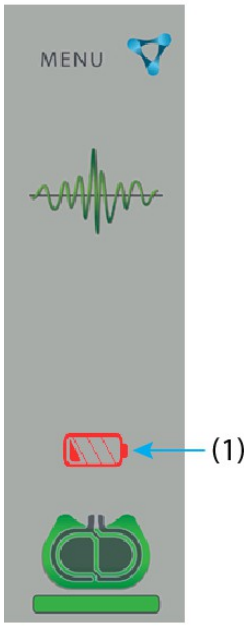


Figure. 15 Control settings of footswitch

In the case where a low battery charge level in the footswitch is detected (1), the following icon will appear on the screen.



- **(1)** A low battery charge in the footswitch

The alert status of the battery has been set at a level which enables the performance of procedures throughout the operating day. However, in order to ensure safety and to meet the need for the continuity of the operation, the battery should be charged immediately after the procedures scheduled for a given day have been completed

Important information

Additional information on a wireless footswitch can be found in the instructions for use of the footswitch.

6 Configuration

6.1 Software update

Important information

The users of the unit are unable to update the software themselves. To have it updated, they need to consult the authorised representative or the local distributor.

6.2 Switching the system on

To switch the system on, use the main power switch located on the back panel, then the stand-by button on the front panel. The start-up process takes a few seconds. During this time, an internal test of the system and the connected accessories is run. Accessories can be connected to a unit which has been switched on; of course, meeting the relevant safety requirements. In such a case, the possible start of the generator caused by incidental pressing on a button on a handle or footswitch should be prevented.

6.3 Menu content

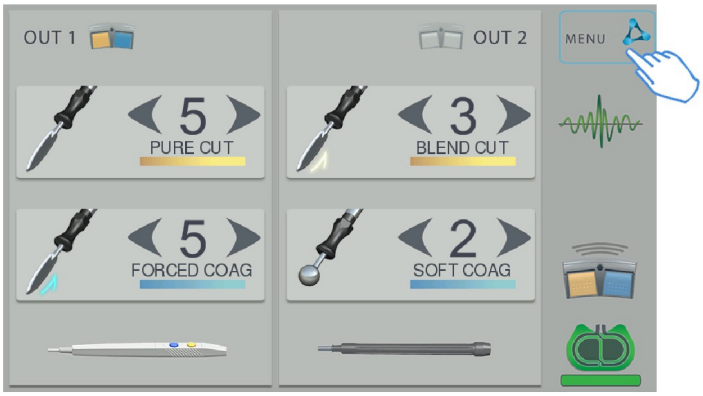


Figure 16. Menu.

By selecting the Menu button on the main panel, the following tools can be used:

- **(1)** Screen brightness
- **(2)** Unit
- **(3)** Volume
- **(4)** Language
- **(5)** Modes
- **(6)** Contact

The screen of the settings of individual functions can be entered by clicking on one of the following icons.

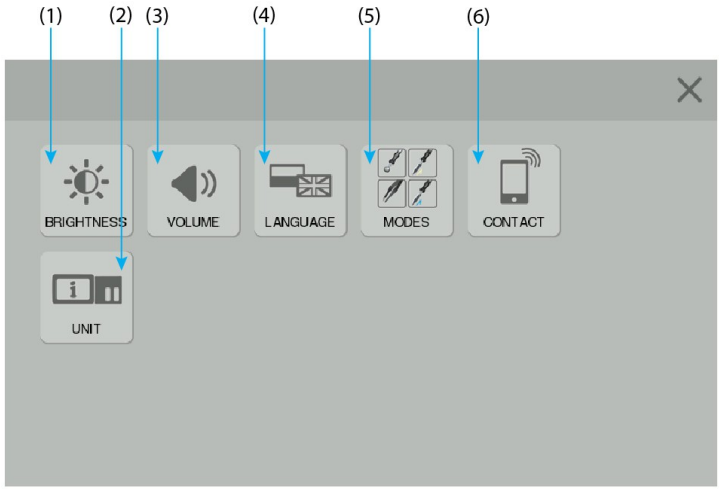


Figure 17. Menu

6.4 Screen brightness change

The ATOM smart system offers an option to adjust screen brightness. To adjust brightness, touch the screen brightness icon and increase or decrease screen brightness as required using the arrows

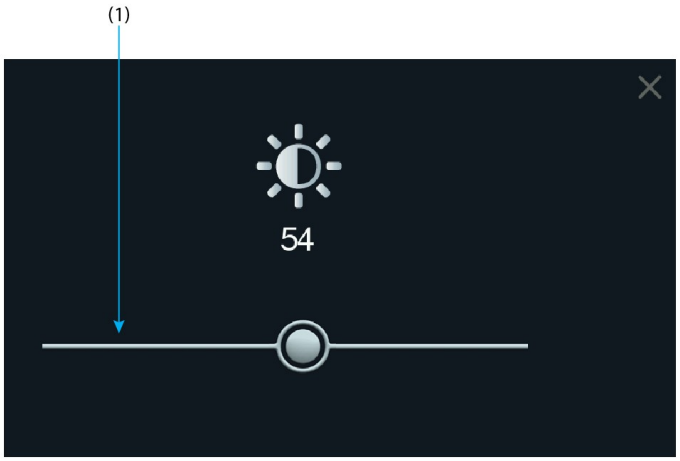


Figure 18 Volume adjustment.

6.5 Volume adjustment

The volume of acoustic activation signals can be adjusted by the user. To decrease/increase the sound volume, move the slider tab.

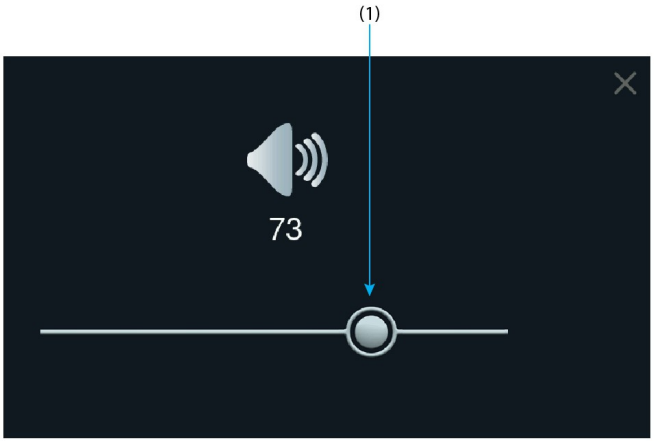


Figure 19. Volume adjustment.

Important information

For safety reasons, when working with an electrosurgical unit, it is not possible to completely mute the acoustic signals. The alarm sounds always remain at the same volume level, regardless of volume adjustments.

6.6 Change of text and message language

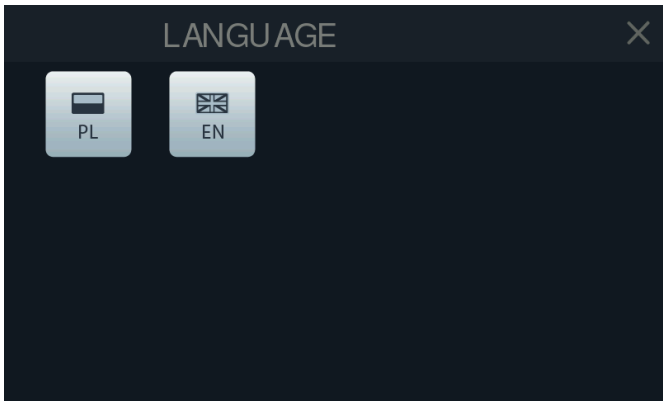


Figure 20. Language selection for texts and messages.

The ATOM smart system offers an option of selecting the language for texts and messages which appear on the touch panel of the system. To change the language, click the field with the selected language version. Depending on the system version, the language versions may differ. However, there are always two basic versions, i.e. Polish and English.

6.7 Modes

The user can switch off unused operating modes. By clicking the icon of the mode to be switched off, the mode icon field is faded to grey. The mode will not be visible on the panel of modes available to the SDS instrument. To restore the switched-off mode, press the dimmed mode icon field to activate it. The possibility of switching off unused modes improves the comfort of operation.

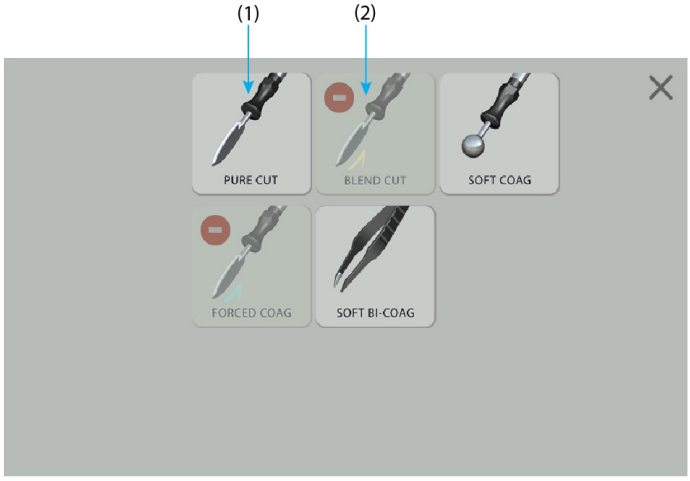


Figure 21 Modes.

- **(1)** active mode
- **(2)** inactive mode (off)

6.8 Contact

This icon contains contact details for the manufacturer's or authorized distributor's place of business.

Figure 22 Contact.

6.9 Unit

The "Unit" icon contains information including: the software version, hardware version, license, and serial number of the unit.

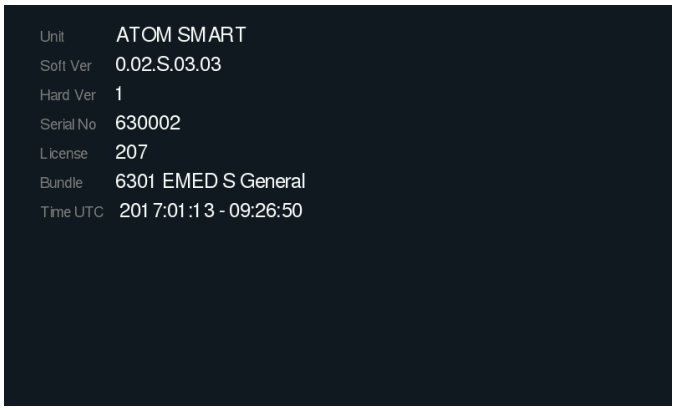


Figure 23. Unit.

7 System operation and surgical procedures

7.1 Methods of operating modes activation

Operating modes can be activated:

- using the buttons in the monopolar electrode handle,
  using the footswitch,

7.1.1 Activation by electrode handle button

To activate the system using the monopolar handle, connect a handle with two buttons (cutting and coagulation).

The output, to which the instrument is plugged, is activated. The activation parameters correspond to those that have been set on the control panel. The yellow button activates monopolar cutting modes, while the blue one activates monopolar coagulation modes.

7.1.2 Activation from the footswitch

Using the switch connected to a socket on the back of the unit, the cutting and coagulation modes can be activated at both outputs of the unit. The activation is implemented at the output which has been indicated by using the output selection button, controlled by a footswitch.

Assignment of the footswitch buttons

After the footswitch has been switched on, the system will identify the type of the switch which has been connected and will display the relevant icon on the side bar of the screen.

In the case where a two-button footswitch has been connected, the system enables any assignment of the footswitch buttons to sockets OUT1 or OUT2. After the footswitch icon has been pressed, the footswitch settings screen will be displayed. The buttons can be assigned to any socket of the system by pressing the cutting or coagulation button icons. The arrows indicate to which socket a button has been assigned.

Figure 24. Footswitch control settings.

footswitch-based control: the activation of the cutting and coagulation modes for output OUT1

footswitch-based control: the activation of the cutting modes for output OUT1, the coagulation button is inactive for output OUT1.

footswitch-based control: the activation of the coagulation modes for output OUT2, cutting button is inactive for output OUT2.

footswitch- based control: the footswitch is inactive f or output OUT2

7.2 Monopolar surgery

7.2.1 Monitoring of the application of split disposable neutral electrodes

In the monopolar operating mode, the system requires a neutral electrode to be connected.

ATOM smart is equipped with a neutral electrode application monitoring system, referred to as NEM (Neutral Electrode Monitor). The NEM System installed in EMED devices is designed for use with EMED SAFE disposable split neutral hydrogel electrodes with catalogue numbers 812-80H and 812-83H. Only these neutral electrodes are compatible with the NEM (Neutral Electrode Monitor) System.

In the monopolar operating mode, the unit monitors the correct connection of the cables of the neutral electrode. When disposable electrodes are used the message indicating the correct application of the neutral electrode is shown on the display. This is illustrated by the red colour on the progress bar under the icon of the electrode which must change its colour to green.

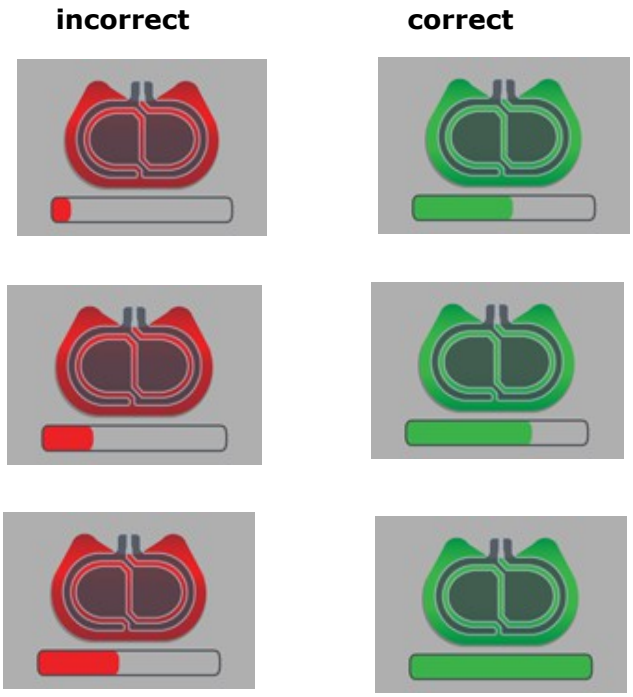


Figure 25 Monitoring of the application of split disposable neutral electrodes.

If system activation is attempted in the case of an incorrect application of the split neutral electrode, an error message will be displayed on the screen:

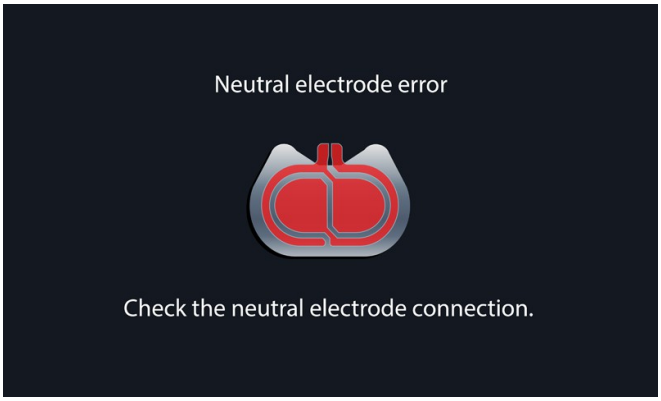


Figure 26. The neutral electrode is incorrectly connected or not connected at all.

An important advantage of the split neutral electrode monitoring system is that the monitoring is performed on a continuous basis, also during the operation of the generator. The neutral control monitoring system does not affect the operation in the bipolar mode.

Only the use of disposable split neutral hydrogel electrodes with an EMED SAFE belt, enabling the equal distribution of high-frequency current on the entire electrode surface, in combination with the NEM system, guarantees the continuous monitoring of neutral electrode adhesion and ensures the maximum patient safety during the procedure.

Important information

The only disposable neutral electrodes approved by the manufacturer for use with the NEM safety system are the electrodes with catalogue number 812-80H for adult patients and children and electrodes 812-83H for infants.

Neutral electrodes other than those mentioned above may not ensure proper operation with the NEM neutral electrode safety system.

The manufacturer is not responsible for the use of EMED electrosurgical devices with neutral electrodes other than those mentioned above, or for any incidents resulting from such use.

Selection of the neutral electrode type

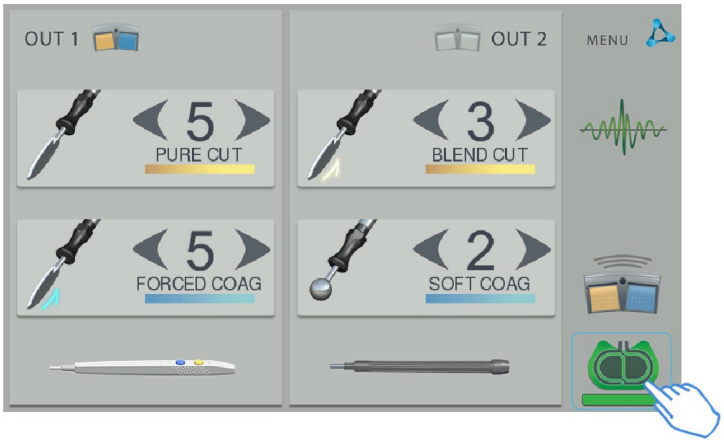


Figure 27. Selection of the neutral electrode type.

After the neutral electrode icon has been touched, the selection screen will appear. It contains bitmaps and the reference numbers of neutral electrodes authorised for use. At present, the selected electrode type is illuminated.

- **(1)** 812-80H - Disposable neutral electrode, split for adults and children >5kg
- **(2)** 812-83H - Disposable neutral electrode, split for infants <5kg
-

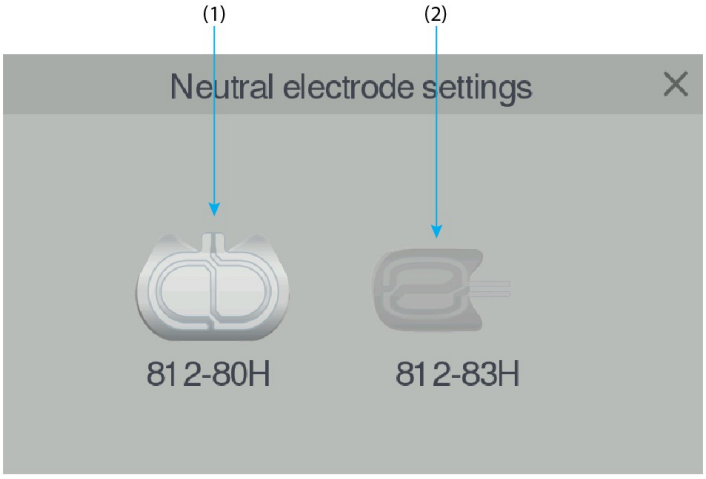


Figure 28 Selection of the neutral electrode.

Important information

For safety purposes, the selection of electrode 812-83H for infants will automatically limit the output power in the monopolar circuit to 150W.

7.2.2 Split disposable electrodes

What not to do

- The neutral electrode cannot be modified in any way.
- Once attached, the electrode should not be transferred to another location.
- Never use electrodes after their expiry date.
- **Do not use force to remove the electrode. It should be detached carefully.**

What to do

- Before applying a disposable neutral electrode, dry the application site very carefully.
- When using alcohol-based disinfectants, wait for the alcohol to evaporate.
- When using disposable electrodes, always check their expiry date.
- A disposable electrode can only be used once.
- The neutral electrodes are supplied in closed sachets. After a package has been opened an electrode must be used within 15 days. After that time, the conductive substance dries out and does not ensure sufficient conduction.
- Disposable electrodes should be applied carefully.
- If it is necessary to attach the electrode at a different location, use a new electrode.
- Check the neutral electrode application and the connected cables every time the patient's position has been changed.
- Protect the neutral electrodes against wetting during the procedure.

7.2.3 Non-split reusable electrodes

What not to do

When performing surgical procedures:

- **which require high power settings**
- **which present a risk of flooding of the neutral electrode with liquids;**
- **where the staff are not able to monitor the neutral electrode application;**

USE OF REUSABLE NEUTRAL ELECTRODES IS NOT RECOMMENDED.

What not to do

REUSABLE ELECTRODES ARE NOT PERMITTED FOR INFANTS AND CHILDEN BELOW 5 KG BODY WEIGHT.

The operator bears the full responsibility for the application of a reusable electrode on a child.

Important information

When using one-piece silicone electrodes, the surgical team is fully responsible for their correct application. Therefore, take special care to correctly place the neutral electrode to avoid burns at its application site during the procedure. Application of a one-piece neutral electrode should be monitored throughout the entire procedure.
Before applying a neutral electrode, read the instructions supplied by its manufacturer.

Warning

A one-piece reusable neutral (silicone) electrode **does not enable** monitoring of its application by the system, i.e. monitoring of its adhesion to the patient's body. Only a correct electrode connection to the system is monitored**.**

ATTENTION: Depending on ATOM smart configuration, some devices may not work with silicon rechargeable neutral electrodes.

What not to do

- The neutral electrode should never be wet or wrapped with anything.
- Do not spread additional conductive gels on the surface of the neutral electrode.
- When disconnecting the neutral electrode, never do so by pulling the cable.
- **Do not, under any circumstances, try to repair the neutral electrode yourself.**

What to do

- Examine the condition of the electrode and the connection cable before use. Do not use electrodes with visible surface defects or damaged insulation.
- The reusable silicone electrode should be attached with a special tape for neutral electrode fixing to prevent it from moving.
- Prevent fluid intrusion between the electrode and the patient's body.
- Reusable neutral electrodes should be disinfected before use (see section "System and accessories maintenance").

Warning

Remember that a silicone electrode loses its conductive properties as active substances are rinsed out from the rubber. Such an electrode increases the risk of burns. Therefore, not only the system but also the reusable electrodes should be subject to regular inspections.

Always read the manufacturer's instructions before applying a neutral electrode.

ALWAYS observe the manufacturer's instructions on the package of the neutral electrode.

7.2.4 Neutral electrode application principles

What not to do

- Do not apply the electrode on scar tissue, cuts or scratches.
- Do not apply the electrode in areas that are concave, bony or include protrusions.
- Do not apply the electrode on excessively hairy skin – shave the application area, if necessary.
- Do not use at sites with excessive fatty tissue, e.g. the abdomen or buttocks.
- Do not apply the neutral electrode over implants.
- Do not apply on the calf.
- Do not apply on the tattoos.
- When disconnecting the neutral electrode, never do so by pulling the cable.

The neutral electrode cannot touch any conductive elements, e.g. metal parts of the table.

What not to do

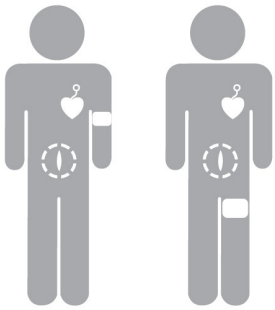
Monopolar procedures are not recommended for patients with metal elements in the body, especially dental braces. Before the application of a neutral electrode remove jewellery from the patient.

What to do

- The neutral electrode should be applied so as to adhere to the patient's body with its entire surface.
- The neutral electrode should be applied on clean and dry skin.
- The neutral electrode should be applied on smooth, well vascularised areas, without skin folds, for instance on the upper arm or thigh.
- The electrode should be placed in the vicinity of the operative field but at least 20 cm from it.
- When applying the neutral electrode make sure that its longer side faces the operative field.

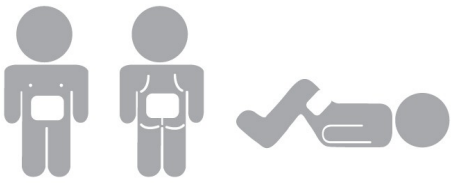
DISPOSABLE NEUTRAL HYDROGEL ELECTRODE APPLICATION SITES

Incorrect Correct



Correct sites of the neutral electrode application in patients with a cardiac pacemaker.

Correct sites of neutral electrode application in adult patients.



Correct sites of neutral electrode application in a child.

7.3 Operating mode selection

After the instrument has been connected to the SDS socket the system will automatically recall the operating modes suggested for a given instrument. In order to change the mode, touch the panel corresponding to the output to which the instrument is connected. After the icon of the cutting or coagulation mode has been touched a list of all the operating modes available for the instrument will appear. Select the required operating mode and confirm the selection by touching the selected mode again (Fig. 29, item 1).

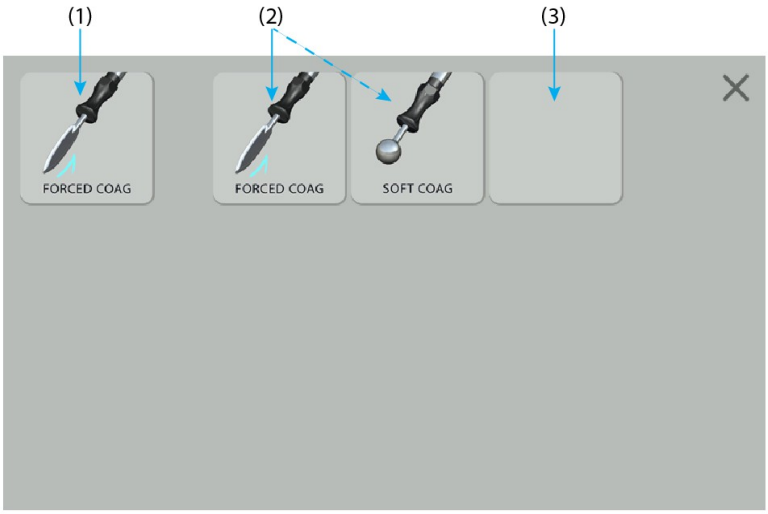


Figure 29. Operating mode selection.

- **(1)** icon of the currently selected cutting mode
- **(2)** available coagulation modes
- **(3)** inactive mode

In order to change the effect of the selected operating mode, use the arrows situated at the icon of the currently selected mode. The arrow pointing to the left decreases the effect, whereas the arrow pointing to the right increases the effect (Fig. 30, item 1).

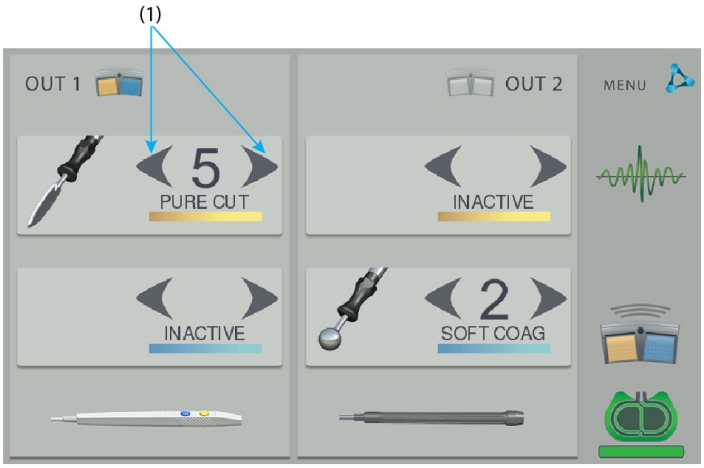


Figure 30 Changing the effect of the operation.

Important information

Two modes can always be seen on the control panel: one cutting mode and one coagulation mode. If a procedure is performed using only one operating mode (cutting or coagulation), for safety purposes it is recommended that the inactive status should be conferred to the other mode. The inactive status protects against accidental activation of the mode.

The inactive status is set by selecting an empty mode icon from the list of modes (Fig. 29, item 3). In such a case, the INACTIVE mode status appears on the control panel and it is impossible to activate a given type of mode.

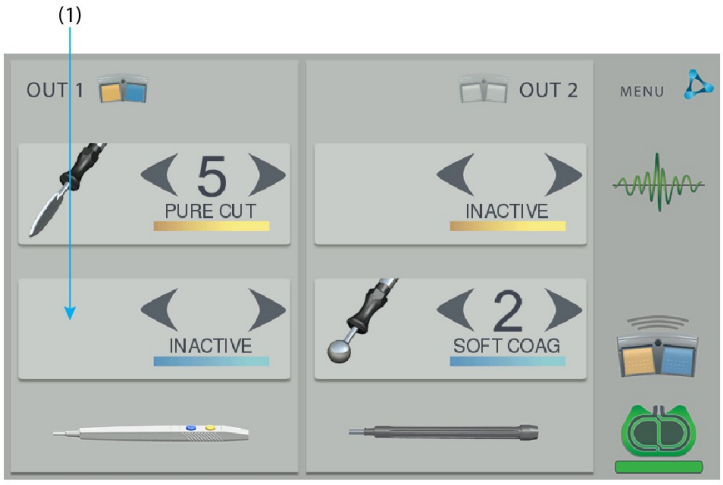


Figure 31 Inactive monopolar coagulation mode.

7.4 Modes

7.4.1 Monopolar cutting

The ATOM smart system is equipped with the following monopolar cutting modes:

PURE CUT Monopolar pure cutting

Cutting with a minimum margin of haemostasis, which is least harmful to the issue. It is applied in cases where there is no need for additional suppression of bleeding. Effects 1 and 2, with a power limit of 50 W.

Instruments: monopolar electrodes, e.g.: knife, loop, needle

BLEND CUT Monopolar cutting with haemostasis

Cutting with an enhanced margin of coagulation of the cut tissue. It strongly suppresses bleeding and has a stronger thermal impact on the tissue.

Instruments: monopolar electrodes, e.g.: knife, needle, loop.

Before starting the cutting, select the level and the type of the desired effect. The type and parameters of monopolar cutting are set in the upper bar of the control bar.

Important information

In the cutting mode, the system is activated using the yellow button in the electrode handle, or the yellow button of the footswitch.

7.4.2 Monopolar coagulation

The ATOM smart system is equipped with the following monopolar coagulation modes:

SOFT COAG Soft monopolar coagulation

Soft contact coagulation. It ensures deep coagulation without tissue carbonisation. As a rule, it is performed with a ball electrode.

Instruments: monopolar electrodes, e.g.: ball, spatula.

FORCED COAG Forced monopolar coagulation
A traditional type if coagulation intended for quick haemostasis of the bleeding tissue. It causes superficial carbonisation.
Instruments: monopolar electrodes, e.g.: knife, spatula, lancet, ball.

Important information

In monopolar coagulation mode, the system is activated using the blue button in the electrode handle, or the blue button of the footswitch.

7.4.3 Bipolar coagulation

The ATOM smart system is equipped with the following bipolar coagulation modes:

SOFT BI-COAG Low-voltage bipolar contact coagulation. In this mode, the current flows between the electrode tips and no passive electrode is required. Typically used for closing individual medium-sized blood vessels.
Instruments: bipolar forceps, bipolar needle electrodes, bipolar laparoscopic instruments.

Important information

Bipolar coagulation is activated using the blue button of the footswitch.

7.5 Channeling effect

Warning

In procedures where high-frequency current might flow through body parts with a small transverse diameter or through other pedicles (e.g. ovary-Fallopian tube, testes, gallbladder) there is a risk that the high-frequency current will cumulate in the narrowest place. This may lead to unwanted heat generation (burns) and tissue necrosis in a spot that is distant from the operating field. This phenomenon is known as the channelling effect. The bipolar mode should be employed in such cases, since it minimises the risk of coagulation in unwanted locations.

Examples of locations where the channelling effect may occur:

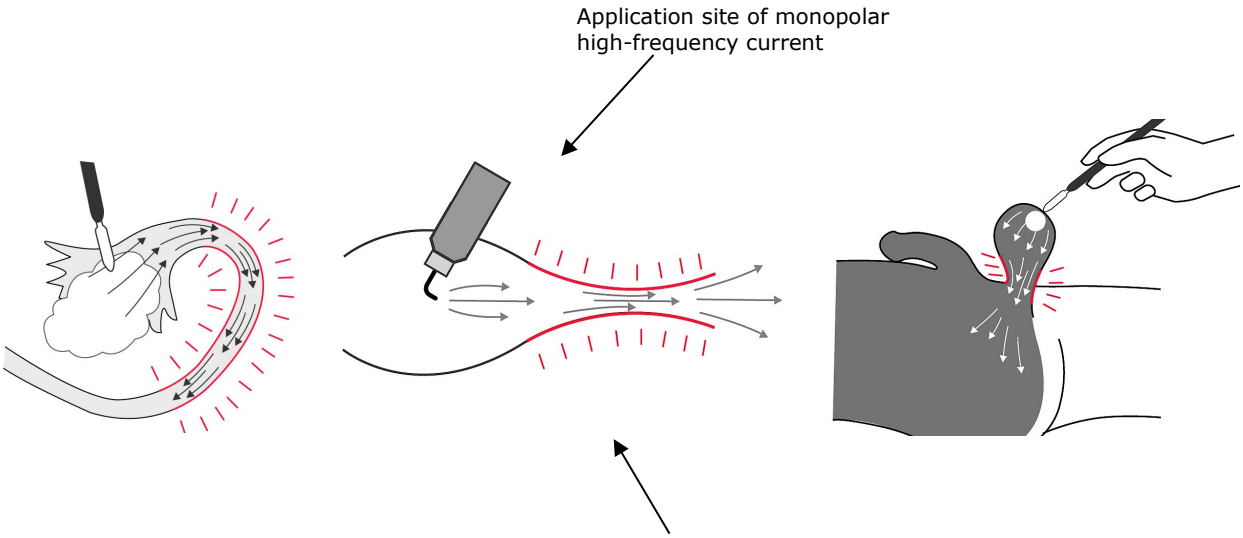


Figure 32. Channeling effect.

7.6 Power monitor

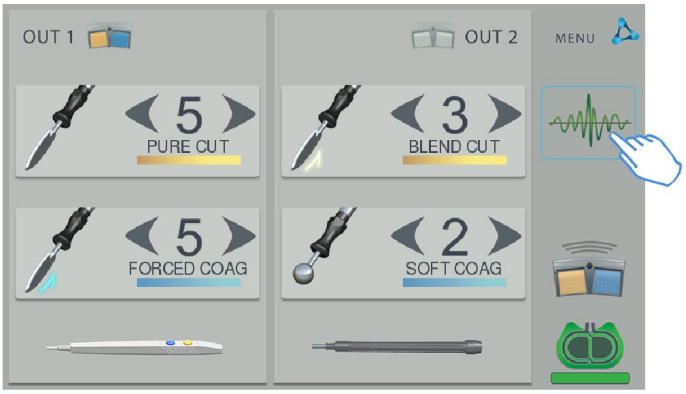


Figure 33 Power monitor.

ATOM smart uses a sophisticated measurement system, which continuously checks the output parameters in real-time and immediately changes the output power to match the varying conditions in the operation area.

The effect parameter is used to determine the real effect to be achieved on the tissue. The power is selected automatically.

The ATOM smart system is equipped with a power monitor, which shows the instantaneous power curve and the average power level after the cutting or coagulation process has been completed.

The following figure shows an example of power measurement. The last 15 seconds of the activation time are saved, taking its interruptions into account.

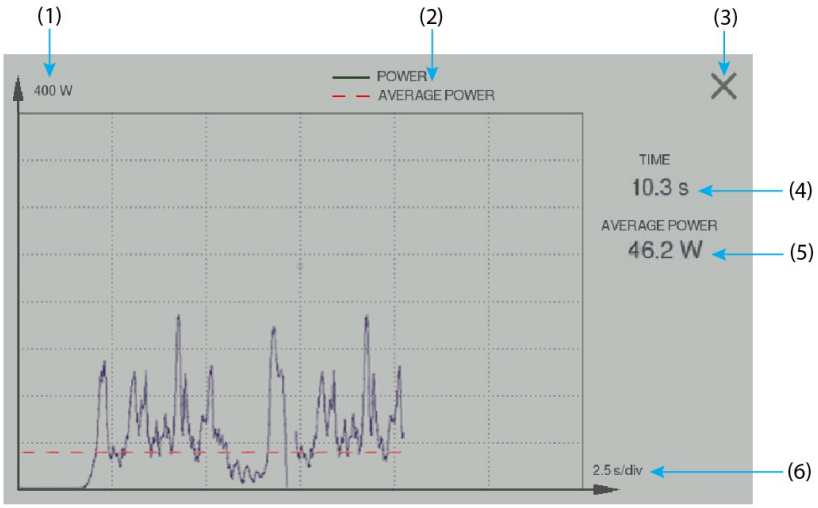


Figure 34 Power measurement in the course of the activation.

The plot maps the instantaneous power level, while the application time and the average output power level are shown on the side of the plot.

- **(1)** vertical axis of the plot showing the power measured
- **(2)** description of the functions imaged by the plot
- **(3)** exit from the panel
- **(4)** activation time
- **(5)** average power
- **(6)** horizontal axis of the plot showing the activation time

Warning

The power monitoring feature is not available during the activation.

7.7 System overload control

The system has work time restrictions, which protect it from overloading (OVERLOAD). The restrictions depend on the power settings and the type of procedure. In the extreme conditions, overload control allows at least 10 seconds of work after 30 seconds of rest.

The system overload is signalled by an acoustic signal and a message "System cooling". The system forces an interruption in the procedure until the indicator turns off (about 30 seconds).

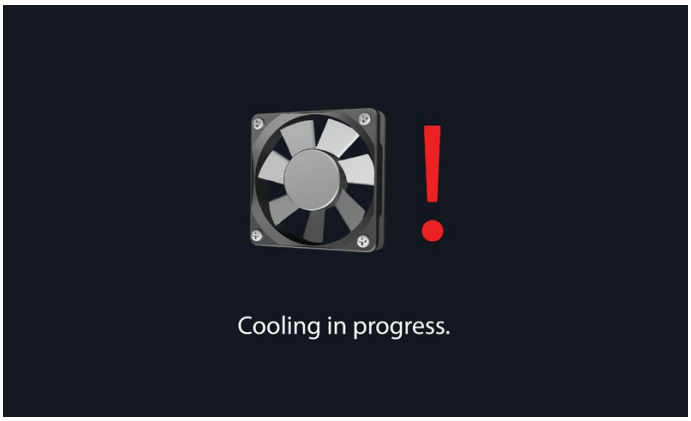


Figure 35 Message: System cooling.

Warning

Do not restrict system cooling during its operation. It means that the system cannot be covered with anything during its operation. If the system rests on a shelf, ensure that there is at least 2 cm of clearance above the device.

Failure to ensure the appropriate cooling conditions will cause the overheating to occur earlier and to last longer.

Do not put any objects on the device. Due to the risk of flooding, the system should be installed above and at a distance from fluids and irrigation conduits.

7.8 Turning the system off

After a procedure has been completed switch off the unit with a standby button (by holding it for about 1 second) (Fig. 3, item 1) and, subsequently, with the mains switch and remove the plug from the mains socket. After the unit has been switched off disconnect the electrodes and scissors from cables and, subsequently, disconnect the cables of electrodes from the unit.

8 System and accessories maintenance

CLEANING

ATOM smart has been designed to ensure easier-than-ever operation and to keep the system clean in relation to its versatile applications in electrosurgical procedures.

As the system casing is made of metal without any ventilation holes, it can be cleaned using disinfectants, while the touch panel can be cleaned using alcohol-based disinfectants.

Clean the system without allowing any fluid to enter inside the device.

STERILISATION

Important information

Sterilisation should be adapted to the supplier's recommendations for a specific accessory. The supplied accessories, unless otherwise noted, **are not sterile and require sterilisation before they can be used.**

Unless otherwise marked, the offered electrosurgical accessories may be steam sterilized at up to 134°C and a pressure of 2 Bar. When using different accessories, please observe the manufacturer's recommendations.

Important information

Before reusable instruments are washed and sterilised it is necessary to read the sterilisation instructions provided by the manufacturer.

9 Errors and messages

9.1 General guidelines for troubleshooting

If the unit does not operate correctly, first check:

- whether the accessories have been connected correctly and have not been damaged;
- signs of physical damage to the unit;
- the connection of cables;
- the messages displayed on the touchscreen.

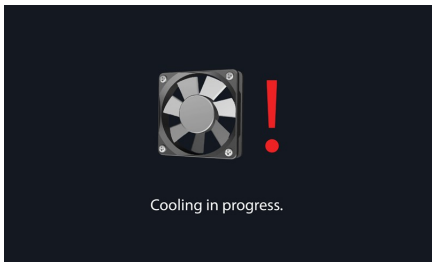
9.2 List of errors and message

Below is a list of errors and messages that may appear on the system panel.
Some messages must be acknowledged by selecting the checkbox:

UNIT ERROR 505

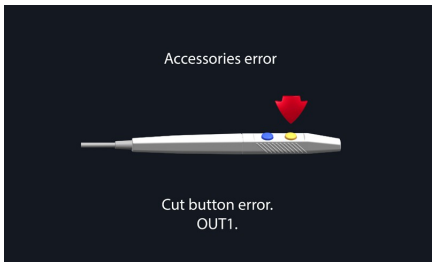
The system has locked for safety reasons. Follow the instructions.

SYSTEM COOLING



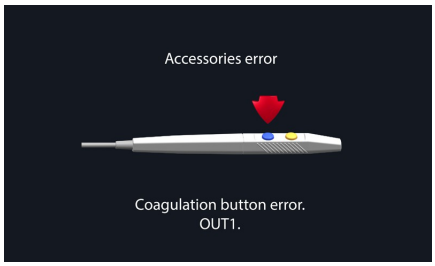
The system is cooled (section 7.7)

CUT BUTTON FAILURE



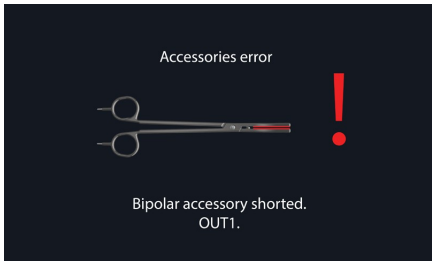
The cutting button in the handle may be damaged. Connect another handle.

COAGULATION BUTTON FAILURE



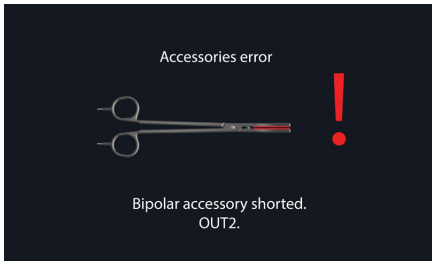
The coagulation button in the handle may be damaged. Connect another handle.

BIPOLAR ACCESSORY ERROR



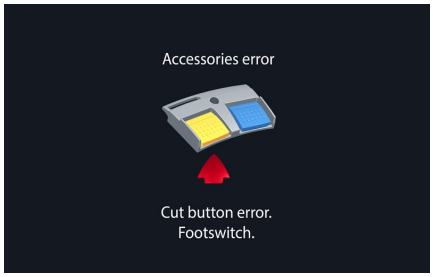
A closed bipolar instrument connected to output OUT1. Unclasp the tips of the bipolar instrument. If the unit continues to display an error an instrument in good working condition should be connected.

BIPOLAR ACCESSORY ERROR



A closed bipolar instrument connected to output OUT2. Unclasp the tips of the bipolar instrument. If the unit continues to display an error an instrument in good working condition should be connected.

FOOTSWITCH ERROR



The footswitch button is shorted. Release the footswitch. If the message continues to appear, the cutting button in the footswitch is damaged. Connect a footswitch in good working condition.

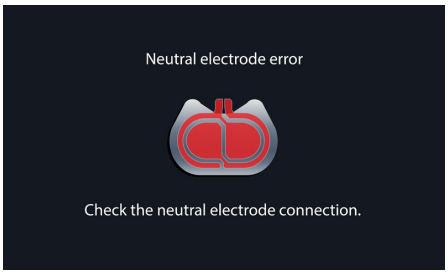
FOOTSWITCH ERROR

The footswitch button is shorted. Release the footswitch. If the message continues to appear, the coagulation button in the footswitch is damaged. Connect a footswitch in good working condition.

FOOTSWITCH ERROR

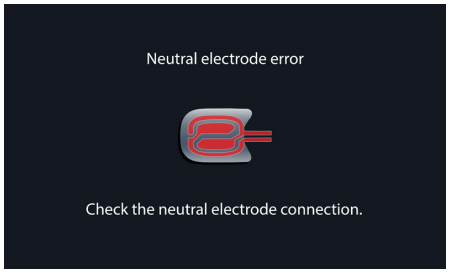
The footswitch button is shorted. Release the footswitch. If the message continues to appear, the MultiSwitch button in the footswitch is damaged. Connect a footswitch in good working condition.

NEUTRAL ELECTRODE APPLICATION



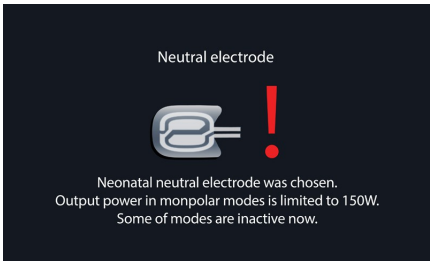
Check the neutral electrode connection. For additional information, see sections 7.2.1

NEUTRAL ELECTRODE FOR INFANTS APPLICATION



Check the neutral electrode connection. For additional information, see sections 7.2.1

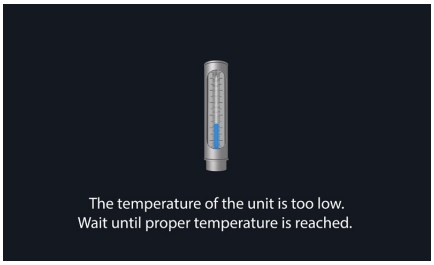
POWER LIMITATION FOR CONNECTION OF AN ELECTRODE FOR INFANTS



DISPOSABLE NON-SPLIT NEUTRAL ELECTRODE

UNSUPPORTED INSTRUMENT

TOO LOW TEMPERATURE



10 ATOM smart unit technical specifications

Table 4. Shortcuts

SHORTCUTS	EXPLICATION
m	meter
mm	milimeter
kg	kilogramme
dB	decibel
s	second
Hz	hertz
Pa	pascal
VA	voltamper
V	volt
W	watt
°C	degree Celsius

(the list of available modes can differ depending on the system version)

Table 4. ATOM smart technical specifications

GENERAL INFORMATION	
Cooling	Radiator
Volume	40-88 dB
Display	TFT
Connector	Connector DE-9 (interface RS232), USB-A, socket Footswitch (6-pin connector), 2 socket SDS, socket neutral elektrode, socket power supply C14, socket argon gas, socket argon sensor
Type of work	Itermittent 25% working time (10 s worku, 30 s interruption)
POWER SUPPLY	
Power supply	220-240 V ±10% or optionally 110-120 V ±10%
Frequency	50/60 Hz
Rated power consumption	600 VA

SAFETY CONDITIONS:	
Electric shock protection:	
Class	I
Degree	CF
Risk class (according 42/93/EEC)	IIb
Degree of protection	IP2X
Low frequency leakage currents	according to EN 60601-1
High-frequency leakage currents	according to EN 60601-2-2
Generator operation frequency	333 kHz
Fuses	Delayed: 8 A/250 V (unit 230 V) or 16 A/250 V (unit 110 V)
Defibrillation impulse resistance	according to EN 60601-1
NEUTRAL ELECTRODE APPLICATION CONTROL SYSTEM	
Optical indication	7 levels
POWER OUTPUT IN THE MONOPOLAR CIRCUIT - CUTTING	MAX 200 W
PURE CUT Monopolar pure cutting	9 effects
BLEND CUT Monopolar cutting with haemostasis	9 effects
POWER OUTPUT IN THE MONOPOLAR CIRCUIT - COAGULATION	MAX 200 W
FORCED COAG Forced monopolar coagulation	9 effects
SOFT COAG Soft monopolar coagulation	9 effects
POWER OUTPUT IN THE BIPOLAR CIRCUIT - COAGULATION	MAX 120 W
SOFT BI-COAG Soft bipolar coagulation	9 effects
DIMENSIONS AND WEIGHT	
Length	385 mm
Height	141 mm
Width	305 mm
Weight	5 kg
WORKING LIFE	10 years

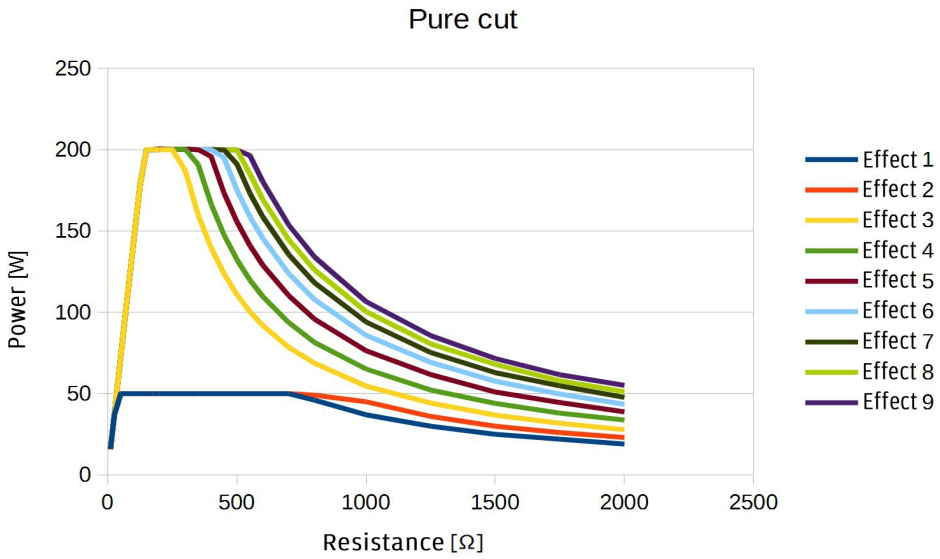
Important information

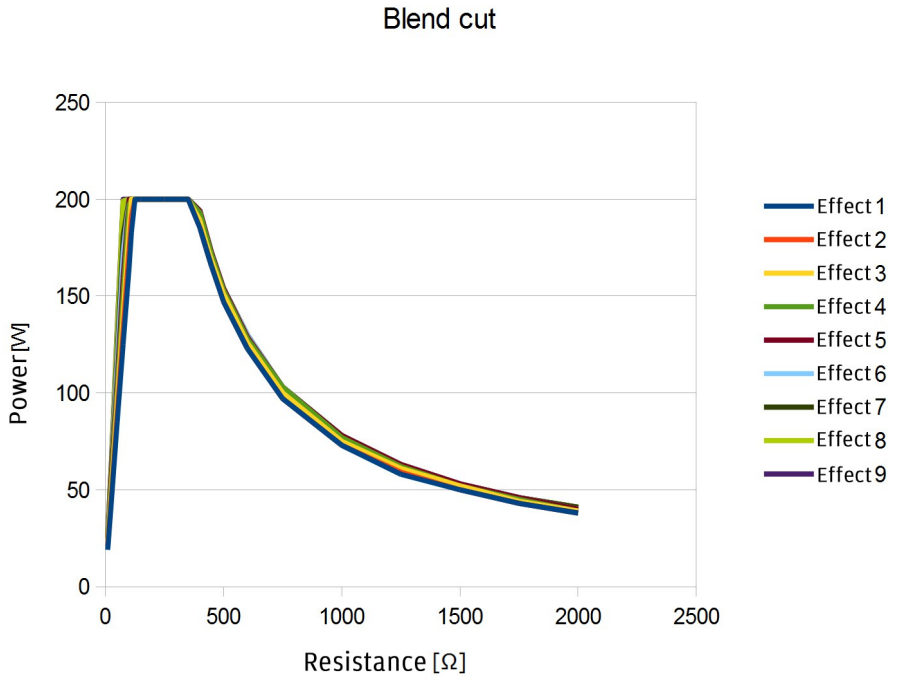
The technical specifications listed in the table may change as our products develop

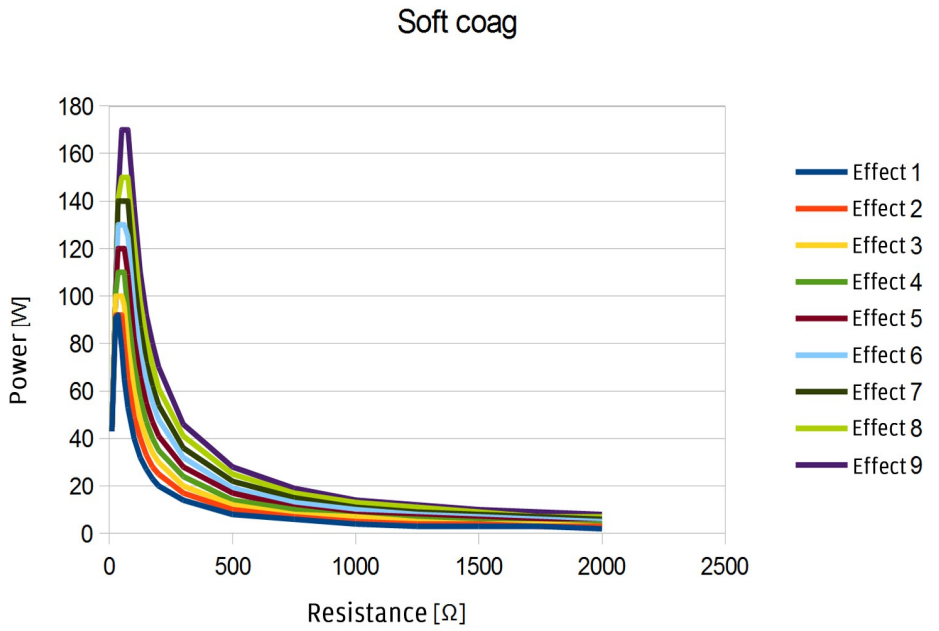
11 Power diagrams

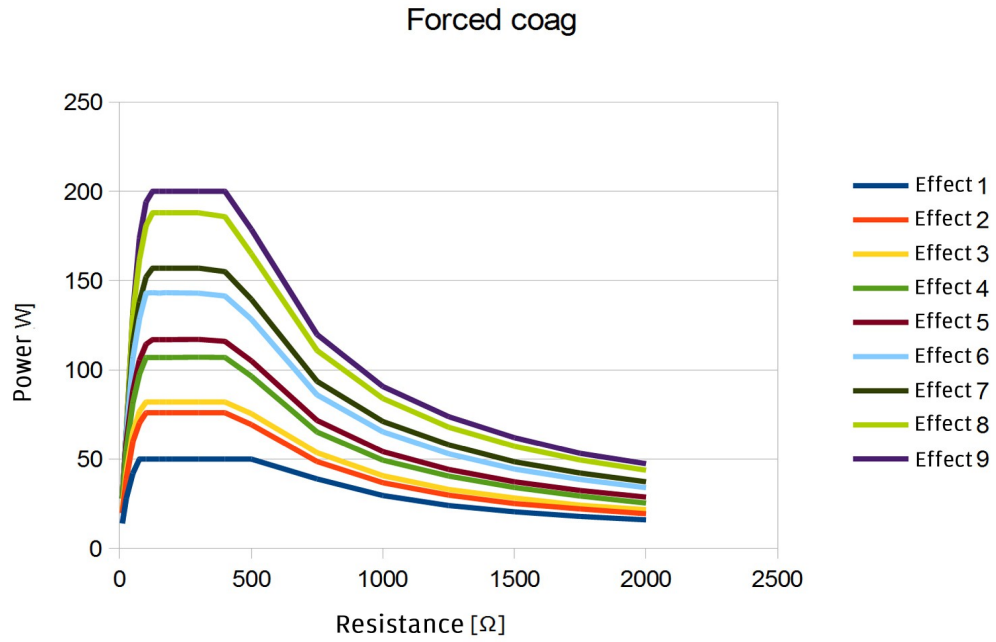
Table 6. Modes

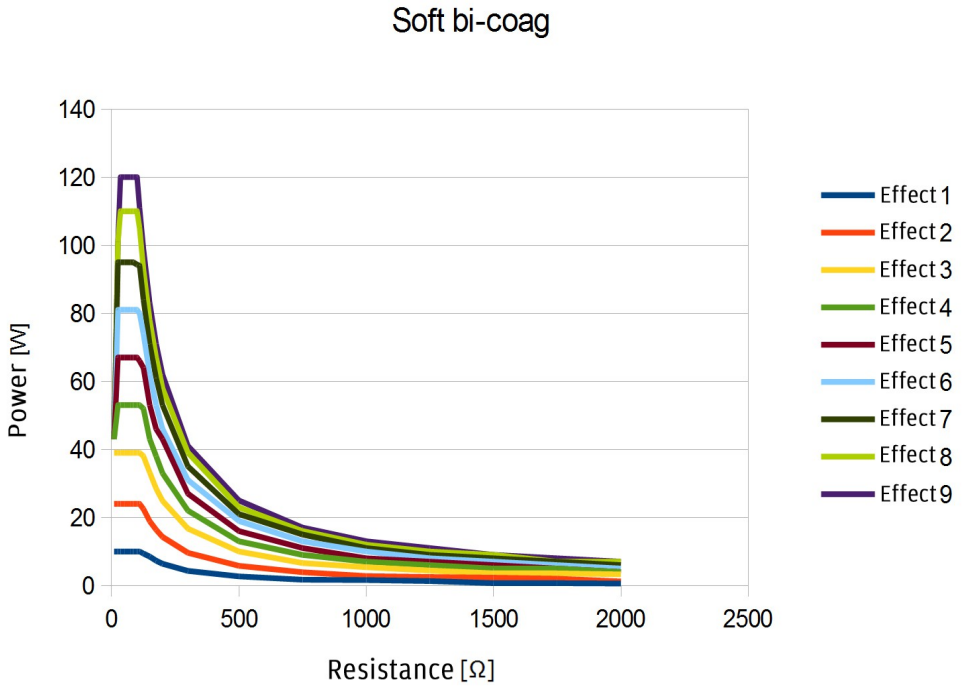
MODES	MAX. VOLTAGE [Vp]
Pure Cut	460
Blend Cut	650
Soft Coag	170
Forced Coag	680
Soft Bi-Coag	170




Blend cut
250
200
150
100
50
0
Power [W]
0
500
1000
1500
2000
2500
Resistance [Ω]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9


Soft coag
180
160
140
120
100
80
60
40
20
0
Power [W]
0
500
1000
1500
2000
2500
Resistance [Ω]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9


Forced coag
250
200
150
100
50
0
Power W]
0
500
1000
1500
2000
2500
Resistance [Ω]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9


Soft bi-coag
140
120
100
80
60
40
20
0
Power [W]
0
500
1000
1500
2000
2500
Resistance [Ω]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9

12 Environmental requirements

12.1 System transport and storage

Please adhere to standard safety measures when transporting the system. During transport, the system must be protected against mechanical damage and moisture.

If the system has been transported for a long time, it should be allowed to reach room temperature before it is started.

All components should be carefully unpacked and checked for transport damage. Any damage should immediately be reported to the manufacturer or authorized representative.

Table 7. System transport and storage.

	Transport and storage	Operation
Temperature	−20°C to 50°C	10°C to 40°C
Relative humidity	10 – 90%	10 – 90%
Pressure	700 – 1060 hPa	700 – 1060 hPa

12.2 Influence with other devices

Warning

The device is immune to electromagnetic interference not exceeding the permitted thresholds. Keep as much distance as possible between the device and other electronic equipment. The electrosurgical unit may cause interference with other electronic equipment.

12.3 Electromagnetic emissions

Table 8. Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The ATOM smart is intended for use in the electromagnetic environment specified below. The customer or the user of the ATOM smart should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	When ATOM smart is not activated, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The ATOM smart is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Emisja harmonicznych IEC 61000-3-2	Class A	
Wahania napięcia / migotanie emisji IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
ATOM smart is intended for use in the electromagnetic environment specified below. The customer or the user of the ATOM smart should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tie. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations in power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If it is necessary to continue the operation during mains power interruptions, it is recommended that the ATOM smart is powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE 1: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
ATOM smart is intended for use in the electromagnetic environment specified below. The customer or the user of the ATOM smart should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the ATOM smart, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	$3V_{RMS}$ 150 kHz to 80 MHz	$3V_{RMS}$	D = 1.2 $\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/m	D = 1.2 $\sqrt{P}$ 80MHz to 800MHz d = 2.3 $\sqrt{P}$ 800MHz to 2.5GHz
			Where *P* is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and *d* is the recommended separation distance in metres [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and ATOM smart

ATOM smart is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of ATOM smart can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and ATOM smart as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz d = 1,2 $\sqrt{P}$	80 MHz to 800 MHz d = 1,2 $\sqrt{P}$	800 MHz to 2,5 GHz d = 2,3 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distance *d* in meters [m] can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

13 Technical inspection, warranty and service

After each procedure, inspect the condition of power cables, electrodes and the footswitch. After connecting the system to a power supply, an autotest of the device and the connected accessories is performed. If an error pops up on the display, an appropriate error message is displayed (see section 9.2) and an alarm is sounded.

MECHANICAL FAILURES

In the case of damage to the sockets, switches, casing or film keyboard, or if the device is dropped, contact an authorised service before further use.

The manufacturer's authorised service can perform a more detailed technical inspection.

SERVICE

The electrosurgical unit is a device classified in the highest used risk class of a medical device, i.e. class Iib.

It means that all the companies which perform the installation, inspection, calibration or repair of these devices must have the required competence confirmed by authorisation of the manufacturer of the medical device.

Important information

A periodical inspection is required once a year. The manufacturer only permits the use of systems which an up-to-date inspection has been performed by an authorised service.

Important information

The Declaration of Conformity supplied by the manufacturer does not cover devices the maintenance, services or repairs of which are carried out by unauthorised services.

Important information

The manufacturer does not anticipate any calibrations or repairs of the electrosurgical system to be performed by the user, with the exception of power and mode settings.

Warning

Fuses can only be replaced by an authorised service of the manufacturer

The user is obliged to perform technical inspections recommended by the manufacturer, which should be performed by a service authorised by the manufacturer. If this condition is fulfilled, the manufacturer remains responsible for device safety. If the user does not adhere to the manufacturer's instructions and the required inspections are not performed, then, according to the laws, the responsibility is transferred to the user.

In order to ensure the correct operation of the device, the installation and staff training should be performed by an authorised representative of EMED. Each participant of such training receives a certificate which entitles him/her to use EMED electrosurgical units. These procedures are obligatory.

More information on the authorised services may be obtained from the manufacturer.

Service:

EMED SP. Z O. O. SP. K., 05-816 Opacz Kolonia, Ryżowa 69A

Tel. +48 (22) 723 08 00

e-mail: support@emed.pl

- limited warranty
- repairs in service
- obligatory reviews

14 Environmental protection guidelines

Since the transposition of Directive 2002/96/EU into the national law the following rules have been binding:

- Electric and electronic equipment must not be disposed of together with household waste.
- The user is obliged to dispose of a broken or redundant electrical or electronic device at a dedicated collection point, put it in a special container, or possibly return it to the seller.

The details are set forth in the relevant national laws. This obligation is indicated on the product packaging or in the manual in the form of a crossed-out waste bin. By sorting waste for recycling, you help to protect the natural environment.

(01) 5 9077632 98871 2 (10) 01.2