User Manual

Servotome

ACTEON

This document is an English translation of the original French version.
Reference J57210 version V10 and drawing number NE28FR010J

Contents

Foreword

The medical device that you are about to install and use in your practice is a medical device designed for professional use. It is therefore a key tool with which you will provide treatment within the context of your work.

To ensure optimum safety for yourself and your patients, comfort in your daily practice and to benefit fully from the technology of your medical device, please read the documentation provided carefully.

This document contains the following information:

- Documentation format
- Documentation archiving period
- Warnings concerning user and patient populations
- Treatment area
- Medical device usage interactions, contraindications and prohibitions
- Electromagnetic compatibility
- Disposal and recycling of the medical device
- Manufacturer responsibility
- Preparation of parts for sterilisation
- Detailed manual and automated instructions
- Information concerning conditioning for sterilisation
- Recommendations for the inspection of parts

Please refer to the User Manuals, Quick Start Guides and Quick Clean Guides for each medical device for information about the following:

- Unpacking and installing the medical device
- Using the medical device
- Monitoring and maintaining the medical device
- Technical specifications of the medical device

1 Documentation

This document contains the following information:

- Patient, practitioner and environment safety
- Installing your medical device in optimum conditions
- Identifying the manufacturer or the latter's representatives if necessary
- Indications for use
- Medical device description
- Installation of the medical device
- Medical device use
- Preparation for cleaning and disinfection of the medical device
- Monitoring and general maintenance of the medical device
- Maintenance to be performed by the user
- preparation for cleaning;
- medical device disinfection.

1.1 Associated documentation

This document must be used in association with the following documents:

Document title	References
Consulting electronic user instructions	J00007
Quick Start Servotome	I57211
Quick Clean Servotome	J57230
Warning sticker	J57234

> The Quick Start and Quick Clean documents are summaries created for your approval. The only binding instructions are the user manuals and regulatory documentation associated with the medical device.

1.2 Electronic documentation

The user instructions for your device are available in electronic format on the specified website and not in printed format. If the website is unavailable, try again later. You can also request a free printed copy of the user instructions within seven days via our website, by telephone or in writing.

The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file reader installed to read the electronic user instructions. It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories.

> Never use your device without first reading the user instructions.

The device user instructions can be consulted at the following addresses:www.ultradent.com and www.satelec.com.

When you receive your device, you are asked to print and/or to download all documents or sections of documents that you may need to refer to in the event of an emergency, if you are unable to connect to the internet or if your electronic display tool is not working (computer, tablet, etc.). We recommend that you visit the website regularly to consult and to download the latest version of your device's user instructions. Users are asked to keep documentation close at hand for reference when necessary.

All paper or electronic documentation relating to your medical device must be kept for the device’s entire service life. Keep the original documentation for your medical device and its accessories for future reference. When loaning out or selling the medical device, the documentation must be provided with it.

2 Warnings

2.1 Federal Law

> The indication below applies to the United States of America only.

The United States Federal Law restricts the use of this medical device in its territory to qualified, fit and certified dental health professionals (either directly or under their supervision).

2.2 Warning applicable to all countries in which the device is sold

> The information below is based on the requirements of standards to which the manufacturers of medical devices must adhere (as stated in standard IEC62366).

2.3 User population

This medical device must only be used by qualified dental health practitioners, fit and certified to perform their professional duties.

Users must know and comply with the rules of dental practice in compliance with knowledge acquired in the field and the key medical hygiene principles including cleaning, disinfection and sterilisation of medical devices.

The medical device can be used by any adult dental practitioner of any weight, age, height, gender and nationality.

The user must wear gloves.

The user is not the patient.

The user must not be prone to any of the following:

- visual impairments: any vision problems must be corrected by glasses or lenses.
- arm disability that may prevent the user from holding a handpiece;
- leg disability that may prevent use of a footswitch;
- hearing difficulties that could prevent the user hearing audible alarms depending on medical devices;
- difficulty memorizing or concentrating that could affect the setting of sequences or the performance of treatment protocols.

2.4 Specific user training

No specific training other than initial professional training is required to use this medical device.

The practitioner is responsible for performing clinical treatments and for dangers that may arise due to a lack of skill and/or training.

2.5 Patient population

This medical device is designed to be used with the following patient populations:

- Children,
- Teenagers,
- Adults,
- Old Age Pensioners.

This medical device can be used on any patient of any weight (except children), age, height, gender and nationality.

2.6 Patient population restriction

This medical device must not be used on the following patient populations:

- Infants,
- pregnant or breastfeeding women due to restrictions associated with the possible use of medical solutions such as anaesthetics;
- patients with medical issues,
- Patients allergic to some of the medical device components,
- patients with a clinical site not suitable for treatment,

- Patients who wear an implantable medical device such as a pacemaker, cochlear implants, vagus nerve stimulators.

The patient must be calm, relaxed, still, ideally lying flat on a dental chair.
The user is the only person who can decide whether or not to treat his/her patients.
Patients who have the items listed below must take additional precautions to prevent any risk of collateral injury:

- intraoral and perioral piercing;
- dental implants;
- dental crowns;
- metallic prostheses
- jewellery.

2.7 Parts of the body or types of tissues treated

Treatments must only be performed on the patient's oral environment.

2.8 Applied parts

Elements in direct contact with the patient	Electrode Electrode insulator
Part in indirect contact with the patient	Electrode holder cap

2.9 Essential performance

As stated in the applicable safety standard pertaining to electrical medical devices, The manufacturer has determined that the medical device did not manage essential performances.

2.10 Basic safety in normal use

The active part, the electrode holder and its electrode are in the practitioner's hand throughout the medical act.Being medically qualified, the practitioner is qualified to immediately detect any problem at the treatment site and to react accordingly.
The force applied to the electrode holder equipped with its electrode must be controlled by the practitioner according to good dental practices. Basic safety is ensured by the practitioner
It is advisable to have a spare medical device or an alternative means with which to perform the medical treatment in the event of device failure.

2.11 Normal usage conditions

The normal usage conditions are as follows:

- storage;
- installation;
- use;
- maintenance;
- disposal.

2.12 Service life

Because it is impossible to determine the maximum number of uses, we recommend changing the bracelet once the silicone is used and the metallic parts become visible.
Using the Servotome medical device with a defective bracelet may cause burns on the patient’s arm or loss of power in the device.

Because it is impossible to determine the maximum number of times the electrodes can be used (may depend on many parameters such as operating time, force exerted, wear, etc.), we recommend that you renew routinely used electrodes at least once a year.

2.13 Broken electrodes

An electrode is a medical device to which a mechanical force is applied to carry out dental treatments.
The electrodes have been developed to ensure safe use in association with the electrode holder SATELEC, a company of Acteon group in accordance with the power levels defined.
However, the tips may break depending on frequency of use, force exerted or by being dropped.
To reduce all risk, however minimal, we recommend the use of a suction device such as a non-metal saliva suction cannula. You should also encourage your patient to breathe through their nose.

2.14 Warnings specific to electrosurgical medical devices

> The following information is from the normalization requirements which the manufacturers of medical devices for high-frequency surgery are subject to (in the sense of the IEC60601-2-2 standard).

- The whole surface of the bracelet (neutral electrode) must be securely fastened to the patient's right wrist. The bracelet must be adjusted to remain in direct contact with the patient's skin. The patient must not have skin lesions.
- The patient should never come into contact with earthed or grounded metal parts or parts with a high capacitance (e.g. operating table, supports, suction cannula, etc.).
- Skin-to-skin contact (e.g. between the patient's arms and body) must be avoided, for example by placing a dry gauze between them.
- Contact between the patient's skin and that of the practitioner must be avoided.
- If the device is used simultaneously with physiological monitoring devices and the medical device on the same patient, the monitoring electrodes should be placed as far away as possible from the surgical electrodes.
- Needle-type monitoring electrodes are not recommended. In all cases, monitoring systems with high-frequency current limiting are recommended.
- Surgical electrode cables must be positioned so that all contact with the patient or with other conductors is avoided.
- Active electrodes that are temporarily not being used must be kept well away from the patient.
- During surgical procedures in which the high-frequency current could flow through relatively thin parts of the body, the use of bipolar techniques may be desirable to avoid accidental damage to tissue.
- The selected output power must be the lowest possible for the required purpose.
- A low output power or malfunction of a high-frequency electrosurgical medical device at the normal operating settings may be due to an incorrectly fitted conductive bracelet (neutral electrode) or a bad contact in its connections. In this case, check that the neutral electrode and its connections are correctly fitted before selecting a higher power output.
- All use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen during the surgical operation must be avoided, unless these agents are evacuated by suction.
- Non-flammable agents must be used for cleaning and disinfection, where possible.
- The flammable products used for cleaning and disinfection or as adhesive solvents must be allowed to evaporate before beginning high-frequency surgery.
- There is a risk of buildup of flammable solutions under the patient or in the depressions or cavities of his/her body.
- Some materials like cotton wool or gauze may, when saturated with oxygen, be ignited by the sparks produced during the normal use of high-frequency electrosurgical medical devices.
- The interference produced by a high-frequency electrosurgical medical device may disrupt the operation of other electronic equipment.
- The operator must regularly check the accessories.
- In particular, the electrode cords and accessories must be checked.

- The failure of a high-frequency electrosurgical medical device may result in an accidental increase in the output power.
- The medical device must be used in combination with a surgical suction system to reduce the propagation of smoke.
- In some cases, electric arcs between the electrode and the clinical site may induce neuromuscular stimulation. This may result in injuries caused by involuntary and uncontrolled movements.

3 Required information

3.1 Indication for use

This medical device is used for the incision and coagulation of soft gingival tissue.
It is used in conjunction with a bracelet (neutral electrode) and an electrode holder which can be fitted with a wide range of monopolar incision or coagulation electrodes using high-frequency electrical energy.

3.2 Operating principle

The medical device converts the low voltage electrical energy into high-frequency electrical energy which flows through the patient's body between the active electrode fixed to the electrode holder and a bracelet (neutral electrode) in contact with the patient.
The high-frequency electrical energy density at the end of the active electrode produces the desired effect, incision or coagulation.

3.3 Connecting and disconnecting accessories during use

> Do not connect or disconnect cords or the electrode holder when the medical device is on and the pedal is pressed down.

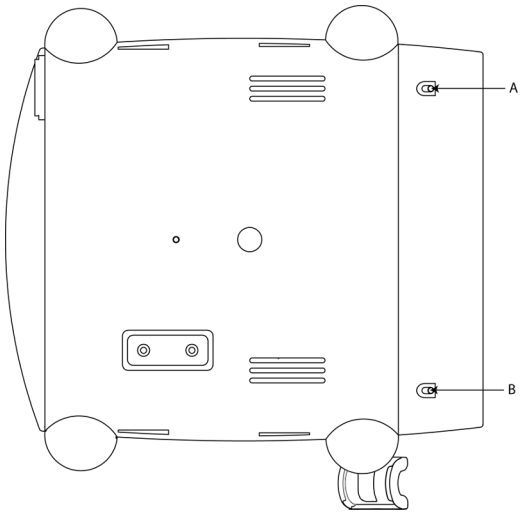
> Do not tighten or loosen the electrodes when the electrode holder is activated.

3.4 Repairing or modifying the medical device

Contact the supplier of your device. Using the services of an unapproved repairer could render your device dangerous for you and your patients.
Do not repair or modify the device without seeking the prior permission of SATELEC, a company of Acteon group.
If the device is modified or repaired, specific checks and tests must be carried out to ensure that the medical device is still safe to use.
In the event of doubt, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team:
`www.acteongroup.com`
`satelec@acteongroup.com`

> SATELEC, a company of Acteon group, at the request of technical personnel working for the network of approved dealers, will provide any information required to repair defective parts on which they may perform repairs.

3.5 Warranty



The screws marked A and B must never be unscrewed by the user. Unscrewing these screws will void the warranty for the medical device.

3.6 Latest document update

10/2017

3.7 Date of first CE marking

2013

4 Interactions, contraindications, prohibitions

This includes information relating to the interactions, contraindications and prohibited operations known by the manufacturer on the date on which this document was written.

4.1 Contraindications

The medical device must not be used in the presence of unruly, emotional or excessively nervous patients.
The medical device must not be used in the following cases:

- Incomplete anaesthesia
- delicate surgery (mucoperiosteal surgery, grafts);
- Very fragile tissue
- Ignorance of the theory of electrosurgery
- Lack of practice on anatomical parts
- Insufficient knowledge of the patient or his/her general condition
- Presence of metallic surgical equipment implanted on the patient especially on the high-frequency current conduction path

4.2 Interference with other medical devices

The medical device presents potential risks due to the emission of electromagnetic fields. Interferences may occur when the system is used on patients fitted with implantable medical devices such as a pacemaker, deep brain stimulator or vagus nerve stimulator.

It may in particular cause malfunction of all types of active implanted device:

- before using this medical device, check whether patients and practitioners are fitted with a device of this type (active or inactive);
- explain the situation;
- weigh up the benefits versus the risks and contact your patient's cardiologist or another qualified health professional prior to starting treatment;
- keep this system away from implantable devices;
- apply suitable emergency measures and act fast if the patient shows signs of being unwell.

> Symptoms such as an increased heart beat, irregular pulse or dizziness may indicate a malfunction of a pacemaker or an implantable defibrillator.

The medical device is not designed to withstand electrical defibrillation shocks.

4.3 Using accessories not supplied by the manufacturer

The medical device was designed and developed with its accessories to guarantee maximum safety and performance. The use of accessories from another source could put you and your patients at risk and could damage your medical device.
Do not try to connect accessories not provided by SATELEC, a company of Acteon group to your medical device connector(s) or to the handpiece.
Even if the manufacturer or dealer of your accessory claims full compatibility with SATELEC, a company of Acteon group equipment, it is advisable to exercise caution with regards to the origin and safety of the product offered. Look out in particular for lack of information, information in a foreign language, very attractive prices, suspect appearance, mediocre quality or premature wear. If necessary, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team.
The medical device is designed to be used with a SATELEC, a company of Acteon group bracelet, and electrode holder and electrodes. Use of neutral electrode bracelets, electrode holders or electrodes made by other manufacturers will incur serious risks to the patient and the practitioner.

4.4 Prohibited uses

- Never cover the medical device and/or obstruct the air inlets.
- Do not immerse or use outdoors.
- Do not place the medical device next to a source of heat or in direct sunlight.
- Do not expose the medical device to water spray or mist.
- Do not use the medical device in an AP or APG gas-filled atmosphere.

The medical device is not designed to operate near a source of ionising radiation.

A hot/cold temperature contrast can cause condensation to form in the medical device, which may be dangerous. If the medical device needs to be moved from a cold place to a warm place, do not use the device immediately. Wait until it reaches room temperature.

The medical device may not be stored or used outside the temperature, atmospheric pressure and humidity ranges recommended in the User Manual supplied with your medical device.

Only use the medical device for the purpose for which it has been designed.

Do not short-circuit the charging base spring loaded contacts or the battery. Do not burn the battery as this may cause an explosion.

4.5 Assembly and disassembly

Unless otherwise indicated in the instructions specific to your medical device:

- Control devices are not designed to be removed or disassembled.
- Access doors and/or flaps are not designed to be removed or disassembled.

5 Unpacking the medical device

When you receive your medical device, check for any damage that may have occurred during transportation.
If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.
If you have any questions or requirements, contact your supplier.
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If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.
If you have any questions or requirements, contact your supplier.
The medical device includes the following items:

- a control unit;
- a control footswitch;
- an electrode holder and its cord;
- a mains cord with ground conductor;
- a cord with bracelet (neutral electrode);
- a box of electrodes;
- a Quick Start guide for the medical device [I57211]
- a Quick Clean guide for the medical device [J57230]
- a warning about the bracelet [J57234].

6 Installing the medical device

Place the medical device in the position that is suitable for your activity.

The medical device must be placed on a secure and flat surface or a surface with a maximum slope of five degrees.

Check that the cords do not hinder the movement or free circulation of anyone.

Adjust the position of your medical device to correspond to your angle of vision and the characteristics of your workstation, e.g. lighting or distance between the user and the medical device.

Ensure that your medical device is readily accessible. The disconnecting devices - the switch and the power plug - must be easy to access.

Do not install your medical device near or on another device.

6.1 Fixing the medical device to a non-removable support

After its initial installation, the medical device is not designed to be moved. The medical device must be fixed to ensure that it cannot be removed or moved without the use of a tool.

6.2 Install cords

Never wind the electrode holder cord around the medical device.

Make sure that it is not possible to wheel over or walk on the different cords.

The cord attached to its handpiece must be easily accessible. Make sure that the cord is slack during use.

> Do not put the medical device cords in a cable cover or a cable tray.

6.3 Installing the control pedal

The control pedal must be positioned near the feet of the operator and must be readily accessible.

7 Connect the medical device

7.1 Connecting the medical device to the electrical network

> Have your medical device connected to the mains power by an approved dental installation technician.

Switch the medical device OFF (position O) and check that the mains voltage is compatible with that indicated on the medical device or its mains adapter. Next, connect the cord to the wall socket in compliance with the standards in force in the country of use.

A different voltage would cause damage to the medical device and could injure the patient and the user. Any variation in the electrical network voltage or electromagnetic field that is non-compliant with the limits in force, could interfere with the medical device's operation.

Medical devices equipped with a protective earth must be connected to a supply network equipped with a protective earth.

> Do not plug the medical device into an extension lead and do not put the mains cord in a cable cover or cable tray.

> If when using the medical device, a power outage can create an unacceptable risk, the user and the installer must ensure that the medical device is connected to an appropriate power source such as an uninterruptable power supply.

8 Dispensing a treatment

8.1 Accessory usage conditions

The accessories of the Servotome must be cleaned, disinfected and sterilised prior to each use.

Refer to the cleaning, disinfection and sterilisation instructions for accessories listed in the chapter *Clean and disinfect the medical device page 31*.

8.2 Pre-use test

Before using the medical device for the first time, it is essential to carry out tests on anatomical parts (pieces of meat - ideally, a piece of beef heart, chicken breast, etc.) to determine how they react to incision and to help adopt the right clinical procedure (electrode movement speed). Do not hesitate to repeat these exercises as many times as necessary.

The accessories used on animal parts must not be reused on human patients.

Before using the medical device for the first time, it is essential that all the equipment is maintained and/or sterilised using the procedures defined in the chapter chapter *Clean and disinfect the medical device page 31*.

8.3 First use

> Keep the footswitch well away to prevent accidentally activating it during the following phases.

- Switch the ON/OFF switch to ON position (I);
- the green light  on the front face lights up;
- The medical device is now ON and ready for use.

8.3.1 Using the medical device

> Do not check the presence of the high-frequency current by creating electric arcs on metal parts, this will damage the medical device.

- Adjust the incision and coagulation power using the  and  control knobs.

> This adjustment must be made before the surgical procedure otherwise there is a risk of burns or undesirable effects.

- Move the footswitch close to your foot.
- Position the electrode on the clinical site.
- Press the footswitch.

The incision or coagulation effect is then obtained.

The yellow indicator lamp lights up and the buzzer sounds. The indicator goes off as soon as the pressure on the footswitch is released.

8.4 Switching off the medical device

> Keep the pedal well away to prevent accidentally activating it during the following phases.

- Set the medical to minimum power using the  button;
- Set the medical device's master switch to "O" OFF position;
- remove the bracelet from the patient;
- Disconnect the lead medical device's bracelet;
- disconnect the electrode holder from its cord;
- remove the electrode from the electrode holder;
- Disconnect the electrode holder cord from the medical device.

At the end of each working day or before a long absence, the medical device must be switched OFF.

When not in use, or in storage or before a long absence, disconnect the medical device from the mains power supply.

- Set the medical device's master switch to "O" OFF position;
- Take hold of the cord plug, hold the wall socket and disconnect the medical device.

9 Medical device description

9.1 Control unit

The top of the control unit comprises the following control items:

- indicator lamps;
- incision and power control knobs.

The front of the control unit comprises the connector for the electrode holder cord.

The right side of the unit comprises the electrode holder rest.

The following items are on the rear of the unit:

- a connector for the bracelet (neutral electrode);
- a footswitch connector;
- a mains switch;
- fuse housing;
- a mains connector.

9.2 Light indicator

9.2.1 Indicator lamp ON

 This yellow indicator remains lit as long as the footswitch is pressed and indicates the presence of the high-frequency current. Note that a buzzer sounds, an audible signal meeting current standards, when the footswitch is being pressed. The volume is not adjustable.

9.2.2 Indicator ON

 This indicator is green; it lights up when the medical device's ON/OFF switch is in "I" position (ON).

9.3 Adjusts the power

9.3.1 Control knobs

The medical device is controlled by adjusting the power and coagulation control knobs.

Incision power settings  .

Adjusts the incision power from the minimum value to the maximum value.

At maximum power (setting 10), the power delivered is 30 W approx.; however, it depends on the operating conditions and the patient's histological variables.

Coagulation settings  .

- Value 1: Minimum coagulation.
- Value10: Maximum coagulation.

9.4 Air inlets

Air inlets ensure correct ventilation of the control unit. Leave them uncovered to allow air to circulate.

9.5 Control pedal

The ON/OFF type footswitch is used by the practitioner to operate the medical device. The footswitch connector connects the medical device to the control footswitch.

Pressing the footswitch automatically activates high frequencies.

The control footswitch equipped with its cord can be disconnected. Its weight and antislip pad ensure good stability.

Pressing the control footswitch activates the medical device's high-frequency output. For greater safety, the footswitch can be fixed to the medical device by two attachment screws present on the footswitch cord connector.

9.6 Switch

The mains switch is used to switch on (position I) or to stop (position O) the medical device.

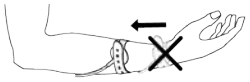
9.7 Bracelet

The medical device's bracelet connector is used to connect the medical device to the bracelet cord.

This neutral electrode must be installed in accordance with the following criteria:

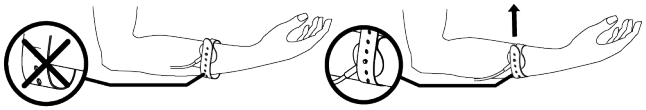
- Remove all metal objects that are in direct contact with the patient's skin in the current's path: piercings, jewellery or other.
- Put the bracelet on the patient's right arm, opposite the heart, so that the current is diverted toward the electrode by the patient's right side.

> Please do not put the bracelet too close to the wrist, because the bones prevent the proper conductivity of the bracelet.



- Adjust the bracelet so that its entire surface is in contact with the patient's arm.
- Check that the bracelet is well attached and does not move.

> You can use the electrically conductive gel to promote the contact between the bracelet and the patient's arm.



9.8 Electrode holder connector

Connect one end of the electrode holder cord to the front face connector, then connect the electrode holder to the other end of the cord.

Only SATELEC, a company of Acteon group electrode holders can be connected to the medical device. The connector on the front face is designed to receive the electrode holder cord connector.

> Do not connect/disconnect the electrode holder cord when the medical device is switched ON and the footswitch is pressed.

The electrode holder rest can be cleaned with a wipe and must be removed for sterilisation.

9.9 Installing an electrode

Do not use the electrode if the plastic sheath looks damaged (splits, holes, etc.) or is missing. If damaged or missing, replace the electrode.

- unscrew the electrode holder cap by a few turns;
- insert the electrode appropriate for the surgical procedure;
- push the electrode as far in as possible. the insulating plastic must be firmly against the end of the cap and no metal must protrude beyond the electrode holder cap;
- screw the electrode holder cap to secure the electrode in place.

It is essential to push the electrode well in so that no metal part is visible between the electrode holder cap and the electrode's plastic sheath. Any visible part would cause the current to flow and result in a painful incision in the wrong area of the patient's mouth.

Replace the electrode holder if it no longer holds the electrode tightly.

> Do not touch the electrode when the footswitch is pressed.

9.9.1 Choosing an electrode

The blue electrodes (diameter 0.22 mm) are for incision only.

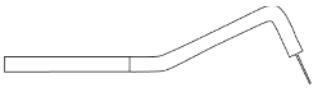
The yellow electrodes (diameter 0.40 mm) are for coagulation incision only.

The white electrodes (diameter 0.22 mm) are for excision only.

The red electrodes (diameters 1mm, 2.5mm and 3.2mm) are for fulguration and coagulation only.

The medical device can be used with a wide range of electrodes.

Adjust the medical device for the electrode used, as indicated in the settings table.

		
	6 - 8	3 - 4
	6 - 8	3 - 4
	6 - 8	3 - 4
	5 - 7	1 - 3

9.10 Fuse recess

The recess holds two fuses designed to protect the medical device in the event of overvoltage or an internal fault.
Please read the instructions listed in the chapter *Replacing the fuses page 35*

10 Disinfection and sterilising

The table below lists the elements of the medical device and their treatment methods.

Element	Wipes	Water + brush, bottle-brush, sandpaper	Ultrasonic tank	Drying + placing in a bag	Autoclave
Electrode	X	X	X	X	X
Electrode holder cap	X	X	X	X	X
Electrode holder	X	X	X	X	X
Bracelet	X	-	-	-	-
Unit	X	-	-	-	-
Cords	X	-	-	-	-
Footswitch	X	-	-	-	-

In all cases, the local regulations in force relating to the cleaning, disinfection and sterilisation protocols for accessories take precedence over the information provided by SATELEC, a company of Acteon group.

10.1 Clean and disinfect the medical device

The medical device must be in OFF or O stop position during cleaning and disinfecting procedures.

> Avoid using cleaning and disinfection products that contain flammable agents.

Otherwise, ensure that the product has completely evaporated or that there is no fuel left on the medical device and its accessories before switching it on.

> Do not use an abrasive product to clean the medical device.

> Never apply sprays directly to the medical device to clean it. Always spray the product onto a wipe, then clean the medical device.

The medical device's control unit, electrode holder cord and control pedal must be cleaned and disinfected daily. The following cleaning and disinfection products can be used:

- alkaline disinfectant products;
- dental surgery disinfectant wipes, SEPTOL™ type WIPES.

10.2 Cleaning, disinfecting and sterilising accessories

10.2.1 Cleaning the bracelet and its cord

The bracelet and its cord must be cleaned and disinfected with disinfectant wipes.

10.2.2 Cleaning electrodes and the electrode holder

- Do not use steel wool or abrasive cleaners.
- Avoid solutions containing iodine or with a high chlorine content.
- The pH of the detergents/disinfectants must be between 7 and 11.
- The cleaning method for electrodes and the electrode holder recommended by SATELEC, a company of Acteon group is manual or automatic.
- All devices must be carefully cleaned and then undergo a final sterilisation before use.
- The sterilization parameters are only valid for correctly cleaned devices.
- The electrodes require special attention during cleaning.

During automatic cleaning, the electrodes must be placed on suitable instrument holders or in small baskets to prevent them from being damaged during washing.

It is the responsibility of the end user to ensure that all equipment used to recondition SATELEC devices is properly installed, validated, maintained and calibrated.

Whenever possible, a washer/disinfector should be used for the electrodes and electrode holder. Prevent the overloading of wash baskets for ultrasonic cleaning or cleaning in a washer/disinfector.

10.2.3 Cleaning/sterilisation cycle limits

Repeated conditioning cycles that include ultrasonic cleaning, manual or automatic washing and sterilisation have a minimal effect on the electrodes and electrode holder.

End of service life is normally determined by wear and damage due to use.

- Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.
- Cover the devices with a soft lint-free cloth dampened with purified water to prevent blood and/or debris from drying.

10.2.4 Containment and transportation

Soiled devices must be transported separately from non-contaminated devices to avoid contamination.

10.2.5 Preparation for pre-disinfection/cleaning

It is advisable to recondition devices as soon as possible after use.

> Medical devices must be reconditioned within two hours of use.

Unscrew the electrode after each use and before cleaning.

10.3 Pre-disinfection and cleaning – Manual method

> Equipment: soft brush, soft lint-free swab, lint-free cloth, alkaline cleaner, ultrasonic cleaner.

Minimum duration of step	Cleaning instructions
1 minute	Rinse the soiled device under cold running water. Use a soft-bristled brush, a swab or a lint-free cloth to remove most of the contamination.
10 minutes	Immerse the medical device in a freshly prepared alkaline cleaning solution at about pH 11 for at least ten minutes. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations.
1 minute	Rinse the device under cold running water
4 minutes	Manually wash the device in a freshly prepared alkaline cleaning solution. Use a soft brush to remove soiling and debris, paying particular attention to the end of the electrode (metal part and intersection between the metal part and the sheath)
1 minute 30 seconds	Rinse the medical device in deionised or purified water
	Visually inspect the medical device. Repeat this procedure until the medical device is visibly clean. Perform a final rinse of the device using distilled or purified water. Dry the medical device using a soft lint-free cloth or medical grade clean compressed air

10.4 Pre-disinfection and cleaning – Automated method

> The manual pre-disinfection/pre-cleaning method must be performed prior to the automatic cleaning.

> Equipment: soft brush, soft lint-free swab, lint-free cloth, alkaline cleaner, ultrasonic cleaner.

Minimum duration of step	Cleaning instructions
1 minute	Rinse the soiled device under cold running water. Use a soft-bristled brush, a swab or a lint-free cloth to remove most of the contamination.

Minimum duration of step	Cleaning instructions
5 minutes	Immerse the medical device in a freshly prepared alkaline cleaning solution at about pH 11 for at least five minutes. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations.
1 minute	Rinse the device under cold running water
4 minutes	Manually wash the device in a freshly prepared alkaline cleaning solution. Use a soft brush to remove soiling and debris, paying particular attention to the end of the electrode (metal part and intersection between the metal part and the sheath)
1 minute 30 seconds	Rinse the medical device in deionised or purified water
	Visually inspect the medical device. Repeat this procedure until the medical device is visibly clean. Perform a final rinse of the device using distilled or purified water. Dry the medical device using a soft lint-free cloth or medical grade clean compressed air

10.5 Cleaning, automated method

Step	Minimum duration	Cleaning instructions
Pre-washing	2 minutes	Cold tap water
Washing	10 minutes	Warm tap water (40°C). Use an alkaline cleaning solution
Neutralisation	2 minutes	Warm tap water (40°C), with neutraliser if necessary.
Rinsing	2 minutes	Distilled or purified water, hotter than 40°C
Drying	40 minutes	At a temperature of 73°C.

10.6 Sterilisation

Unless otherwise specified, non-sterile products can be resterilised using validated steam sterilisation methods (ISO 17665 or national standards). SATELEC, a company of Acteon group recommends the following:

Sterilisation exposure time	Sterilisation exposure temperature	Drying time
3 to 18 minutes	134 °C	at least 15 minutes

> Saturated steam sterilisation with pre-vacuum

The drying times vary from 15 to 60 minutes according to the following criteria:

- the type of packaging material, such as a sterile barrier system or rigid reusable containers;
- steam quality;
- device materials;
- total mass;
- steriliser performance;
- usual practices for the geographical area;
- varying cool-down times.

> The manufacturer accepts no responsibility for sterilisation procedures performed by the end user or the customer that are not performed according to the manufacturer’s recommendations.

10.7 Inspection

- Devices must be inspected to check that no contamination remains, that they are not corroded, dulled, discoloured or damaged.
- Before conditioning and sterilising the cleaned devices, check they are clean, undamaged and function properly.
- Damaged devices must be discarded, they must not be lubricated.

10.8 Packaging

Use suitable packaging or a rigid reusable container for sterilisation; the sterile barrier system must comply with ISO standard 11607. Prevent any contact between devices and other objects that could damage their surface or the sterile barrier system.

10.9 Storage

Storage conditions are printed on the packaging label. Packaged products should be stored in a clean, dry environment, protected from direct sunlight, pests, humidity and extreme temperatures. Use products in the order in which they are received First in, First out, taking into account the expiry date indicated on the label.

11 Monitoring and routine maintenance

The only preventive maintenance the medical device requires is:

- Monitoring of accessories
- Routine cleaning, disinfection and sterilisation
- Cleaning

In application of the French Decree of 5 December 2001 and of the corresponding Order of 3 March 2003 relating to the obligation of maintenance and quality inspection of medical devices, the operator, who must ensure that the applicable maintenance operations are carried out, should refer to and apply the maintenance operations routinely encountered for high-frequency surgical devices.

Monitor the cleanliness of the air inlets on the control unit to prevent any heating.

Check the condition of the silicone in the bracelet, and ensure that it is not cracked or damaged so as to prevent burns on the patient's arms.

Check the condition of the electrodes, and ensure that they do not easily sink into the electrode holder without forcing.

Before and after use, check the medical device and its accessories entirely for any problems. This is necessary to detect any electrical isolation fault or damage. If necessary, replace damaged parts.

11.1 Thermal cutout

The operating cycle is as follows:

- 5 x 10-second operating cycles;
- 30-second stop;
- 10-minute stand-by.

> A thermal cutout is activated if the unit is used intensively.

11.2 Corrective Maintenance

In the event of faulty operation, the following corrective maintenance actions may be performed by the user.

11.2.1 Replacing the fuses

The medical device is protected by two fuses in the mains connector.

To replace the fuses, perform the following operations:

1. Stop the medical device (position O).
2. Disconnect the mains cord from the electrical network.
3. Disconnect the mains cord from the mains connector.
4. Insert the tip of a flathead screwdriver into the notch on top of the fuse holder to release it.
5. Remove the used fuses.
6. Replace the used fuses with fuses of the same type and same rating.
7. Place the fuse holder in its recess by pushing it until you hear a click that confirms it is in the correct position.
8. Connect the mains cord to the connector.
9. Connect the mains cord to the electrical network.

12 Identifying incorrect operation

In the event of incorrect operation, refer to the tables below to quickly identify and repair the non-complex parts of the medical device.

If the incorrect operation is not described in the tables below, please contact your supplier or the customer service team at SATELEC, a company of Acteon group.

Do not use the medical device if it appears to be damaged or faulty. Isolate the medical device and make sure that it cannot be used.

> The medical device will need to be sent away for repair.

12.1 Not working

Symptoms: the medical device is not working

Possible causes	Solutions
No electrical current	Contact your electrician
Mains switch in position O	Set the mains switch to position I
Faulty connection between the mains cord and the electrical wall socket	Connect the mains cord to the electrical wall socket
Faulty connection between the mains cord and the mains connector	Connect the mains cord to the mains connector
Mains fuses in the mains connector not working	Replace the mains fuses with fuses of the same type and rating
Internal fuse not working	Return to the Customer Service team

> The internal fuse (ref. FU1 on the printed circuit board) cannot be accessed by the user.

12.2 Indicators or buzzer not working

Symptoms: The green indicator lamp lights up, but the yellow indicator does not and the buzzer does not work.

Possible causes	Solutions
Footswitch cord not properly connected	Push the footswitch cord plug firmly in
Faulty footswitch	Replace the footswitch or contact the dealer
Medical device thermal cut-out	Wait for the medical device to cool down

Symptoms: The indicator lamps come on and the buzzer is working but there is no high-frequency current.

Possible causes	Solutions
Electrode holder cord not properly connected	Check both ends of the electrode holder cord, on the medical device and on the electrode holder
Bracelet connector not properly connected	Check the bracelet connector
Other possibilities	Contact the Acteon Customer Service team

12.3 The electrode is not working or is working incorrectly

Symptoms: The electrode incises with difficulty or is not incising at all.

Possible causes	Solutions
Intensive use. Thermal cut-out activated	Allow the medical device to cool down
Neutral electrode (bracelet) in the wrong position	Check that the whole surface of the neutral electrode (bracelet) is in contact with the patient
Soiled electrode	Switch the medical device to "O" (OFF). Clean the electrode

Possible causes	Solutions
Electrode moving too fast	Reduce electrode movement speed
Inappropriate electrode	Select the appropriate electrode for the operating procedure
Worn electrode	Replace the electrode

Symptoms: The electrode sticks to the biological tissue.

Possible causes	Solutions
Power set too low	Increase power up to the incision threshold. Exceeding the threshold serves no purpose
Inappropriate electrode	Select the appropriate electrode for the operating procedure

Symptoms: The electrode incises but there are sparks.

Possible causes	Solutions
Incision power set too high	Reduce the incision power down to the incision threshold. Exceeding the threshold serves no purpose

13 Electromagnetic compatibility

> All the information below is based on the requirements of standards to which the manufacturers of electrical medical devices must adhere (as stated in standard IEC60601-1-2).

The medical device complies with the electromagnetic compatibility standards in force. However, the user must make sure that any electromagnetic interference does not create an additional risk, such as those created by radiofrequency transmitters, or other electronic devices.

This chapter contains the information required for you to install and use your medical device in optimum conditions in terms of electromagnetic compatibility.

The different medical device cords must be kept away from each other.

Some types of mobile telecommunication devices such as mobile phones may interfere with the medical device. The separation distances recommended in this chapter MUST be complied with.

The medical device must not be used near another device or placed on top of it. If this cannot be avoided, correct operation of the device in operating conditions must be checked prior to use.

The use of accessories other than those specified or sold by SATELEC, a company of Acteon group as replacement parts, may increase the transmission or reduce the immunity of the medical device.

13.1 Cable length

Cables and accessories	Maximum length	Test type	In compliance with:
Cables/Cords	< 3 m	RF emission	CISPR 11, Class B
		Harmonic current emission	IEC61000-3-2
		Voltage fluctuation and flickers	IEC61000-3-3
		Electrostatic discharge immunity	IEC61000-4-2
		Radiated immunity – Electromagnetic fields	IEC61000-4-3
		Electrical fast transient/burst immunity	IEC61000-4-4
		Surge immunity	IEC61000-4-5
		Immunity to conducted disturbances, induced by radiofrequency fields	IEC61000-4-6
		Radiated immunity - Magnetic fields	IEC61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11

13.2 Recommended separation distances

The medical device is designed to be used in an electromagnetic environment in which interferences caused by radiofrequency radiation are controlled.

The user or installer of the medical device may help to prevent electromagnetic interference by maintaining a minimum distance, depending on the maximum power of the handheld and mobile radiofrequency transmission equipment (transmitters), between the medical device and the equipment as recommended in the table below.

	Separation distance in metres (m) determined by transmitter frequency		
Max. nominal power of the transmitter in Watts	From 150 kHz to 80 Mhz d = 1.2 √P	From 80 MHz to 800 MHz d = 1.2 √P	From 800 MHz to 2.5 GHz d = 2.3 √P
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m
With regards to transmitters for which the maximum power is not listed above, the recommended separation distance (d) in metres (m) can be estimated by using the equation applicable to the transmitter frequency where (P) is the maximum power of the transmitter in watts (W) according to the manufacturer.			

Note 1: At 80 MHz and 800 MHz, the highest frequency range applies.

Note 2: These specifications may not be applicable in all situations.

The electromagnetic propagation is reduced by the absorption and reflection of structures, objects and people.

13.3 Electromagnetic emissions

The medical device is designed for use in the electromagnetic environment described in the table below. The user and/or installer must ensure that the medical device is used in the environment described below.

Emission test	Conformity	Electromagnetic environment - comments
RF emission (CISPR 11)	Group 1	The medical device uses radiofrequency energy for its internal operation. Consequently, its radiofrequency emissions are very low and are not likely to create any interference with other nearby equipment.
RF emission (CISPR 11)	Class B	The medical device is suitable for use in all establishments, including domestic and those directly connected to the low voltage energy supply public network supplying buildings used for domestic purposes.
Harmonic current emission (IEC61000-3-2)	Class A	
Voltage fluctuation and flickers (IEC61000-3-3)	Conforming	

13.4 Magnetic and electromagnetic immunity

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level in accordance with IEC60601	Conformity level	Electromagnetic environment / comments
Electrostatic discharge (ESD) (IEC61000-4-2)	± 6 kV contact ± 8 kV in the air	± 6 kV contact ± 8 kV in the air	Floors must be wood, concrete, cement or tiled. If floors are covered with synthetic materials (carpet, etc.), the relative humidity must be 30% minimum.
Electrical fast transient (IEC61000-4-4)	± 2 kV for electricity supply lines ± 1 kV for signal ports	± 2 kV for electricity supply lines	The quality of the electricity supply must be equivalent to that of a typical commercial environment or hospital establishment (hospital, clinic).
Surge (IEC61000-4-5)	± 1 kV in differential mode ± 2 kV in common mode	± 1 kV in differential mode ± 2 kV in common mode	The quality of the electricity supply must be equivalent to that of a typical commercial environment or a hospital.

Immunity test	Test level in accordance with IEC60601	Conformity level	Electromagnetic environment / comments
Magnetic field at 50 Hz/60 Hz (IEC61000-4-8)	3A/m	3A/m	The magnetic field intensity must be equal to the level found in a typical commercial or hospital environment.
Voltage dip, short interruption and voltage variation (IEC 61000-4-11)	< 5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 250 cycles	< 5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) For 250 cycles	The quality of the network supply must be equal to that of a typical commercial or hospital environment. If the use of the system requires continuous operation during mains power outages, it is advisable to supply the medical device using a separate current source (UPS, etc.).

13.5 Electromagnetic immunity, handheld radiofrequency equipment

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level	Conformity level	Electromagnetic environment - comments
Handheld and mobile radiofrequency communication devices must not be used near the medical device (including cables) at a distance below that recommended and calculated according to the frequency and power of the transmitter.			
Radiated radiofrequency electromagnetic fields (IEC61000-4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 2.3 √ P 800 MHz to 2.5 GHz Where (P) is the maximum nominal power of the transmitter in Watts (W) according to the manufacturer specifications and (d) is the minimum recommended separation distance in metres (m).
Radiofrequency conducted disturbance (IEC61000-4-6)	3 V/m 150KHz to 80MHz	3 V/m	d = 1.2 √ P 80 MHz to 800 MHz Recommended separation distance: d = 1.2 √P
The electromagnetic field intensity of fixed radiofrequency transmitters, as determined by an electromagnetic environment measurement (a), must be less than the conformity level for each frequency range (b). Interference may occur near equipment marked with the following symbol: 			

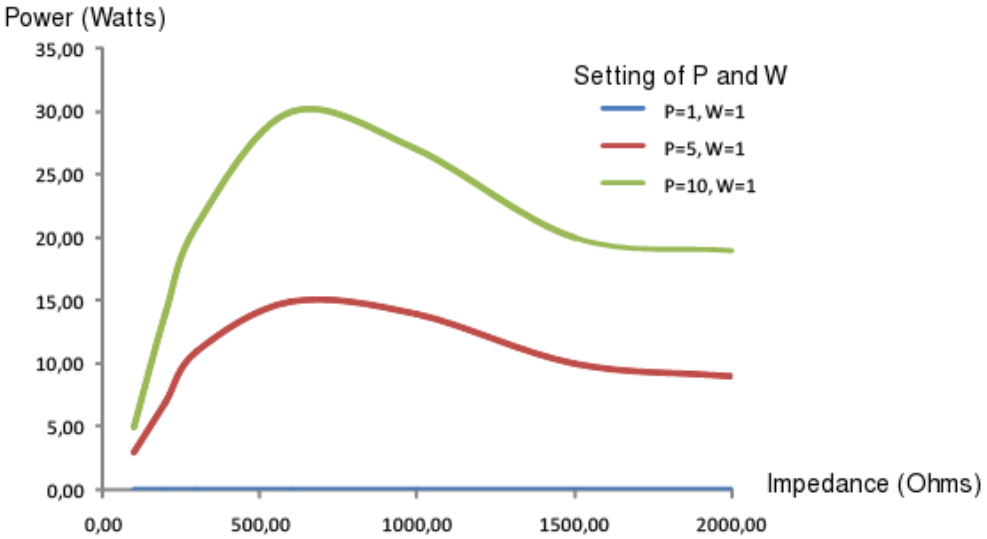
Note 1: At 80 MHz and 800 MHz, the highest frequency range applies.

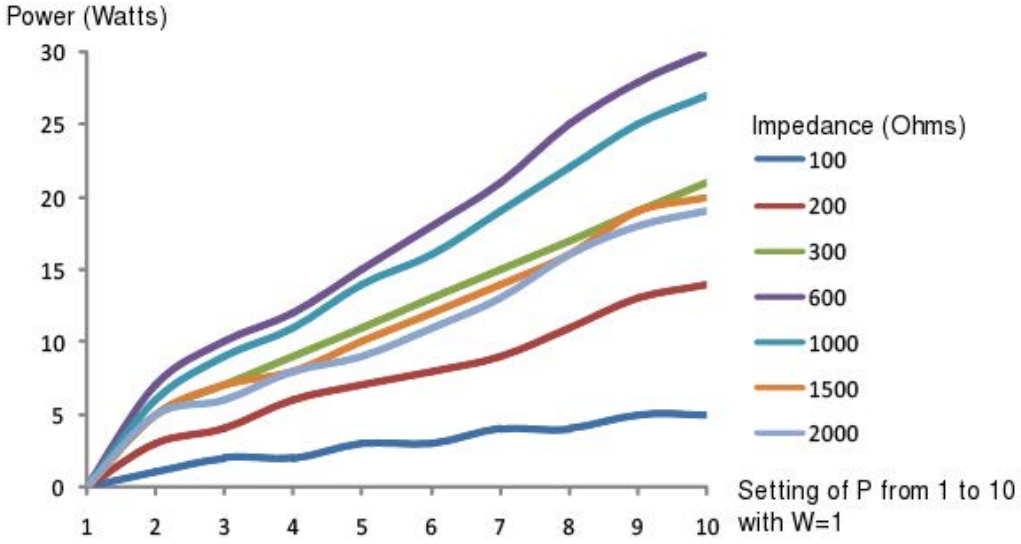
Note 2: These specifications may not be applicable in all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

(a) The electromagnetic field intensity of fixed radiofrequency transmitters, such as base stations for portable phones (mobiles / wireless), mobile radios, radio amateurs, AM/FM radio transmissions and TV transmissions cannot be determined accurately by the theory.
To assess the electromagnetic environment caused by fixed radiofrequency transmitters, an electromagnetic environment measurement must be taken. If the measured intensity of the radiofrequency field in the product's immediate use environment exceeds the radiofrequency conformity level specified above, it is necessary to test product performance to check this complies with specifications. If abnormal performance is observed, additional measures may be necessary, such as changing the direction of or moving the product.
(b) In the 150 kHz to 80 MHz frequency range, the electromagnetic fields must be less than 3 V/m.

14 Technical specifications of the medical device

14.1 Characteristic curves





14.2 Electrode summary table

Model	Illustration	Model	Illustration
I22S		I40S	
I22CA		I40CA	
TR22T		FC10N	

TR22R		FC25B	
TR22L		FC32B	

14.3 Identification

Manufacturer	SATELEC, a company of Acteon group
Name of the medical device	Servotome

14.4 Control unit

Width	250 mm
Height	110 mm
Depth	240 mm
Weight	1200 g
Ingress protection rating	IPX0

14.5 Generator

Supply voltage	115 VAC / 230 VAC
Power supply frequency	50 Hz / 60 Hz
Power consumption	170 VA to 230 VAC
Power output	30 W
Output voltage	650 V PP - P = 10, W = 1
Characteristic impedance	600 Ω
Output impedance range	100 Ω to 2 kΩ
Output frequency	1.2 MHz +/- 0.2 MHz
High-frequency output type	Floating (isolated from ground)
Power setting range	Less than 1 W to 30 W
Operating mode	5 cycles (10 sec. ON / 30 sec. OFF + 10 min stand-by)
Electrical rating	I
Internal fuse not accessible to the user	F1: 5 mm - T 500 mAL 250 VAC
Fuse (mains connector) - 115 V	5 mm x 20 mm / T 2 AL 250 VAC type FST - SCHURTER AG
Fuse (mains connector) - 230 V	5 mm x 20 mm / T 1.25 AL 250 VAC type FST - SCHURTER AG
Type of leakage currents	LF

14.6 Adjusts the power

Incision setting (relative units)	1 - 10
Coagulation setting (relative units)	1 - 10

14.7 Length of cords

Electrode holder cord	>2,000 mm
Bracelet cord	>2,000 mm

Control pedal cord	2 500 mm +/- 50 mm

14.8 Footswitch

Width	72 mm
Height	30 mm
Length	104 mm
Weight	155 g
Ingress protection rating	IPX1

14.9 Environmental characteristics

Ambient operating temperature	10 to +30°C
Storage temperature	0 to +50°C
Operating RH	30% to 75 %
Storage RH	10% to 100 %, including condensation
Atmospheric storage pressure	Between 500 hPa and 1060 hPa
Atmospheric operating pressure	Between 800 hPa and 1060 hPa
Maximum operating altitude	Equal to or less than 2000 metres

14.10 Environmental restrictions

Usage premises	Usable in all medical premises. The medical device must not be used in an operating theatre or outdoors.
Use in gas-filled atmosphere	The medical device is not designed for use in a type AP or APG gas-filled atmosphere or in the presence of anaesthetic gases.
Immersion	The console must not be immersed.
Immersion	The handpiece must not be immersed.

14.11 Main performance characteristics

High-frequency electrical energy frequency.

Electrical power.

Characteristic impedance.

Surface of electrodes.

15 Regulations and standards

15.1 Applicable standards and regulations

This medical device complies with the essential requirements of European Directive 93/42/EEC. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.
This equipment is designed and developed in compliance with the Electrical Safety standard IEC60601-1 in force.

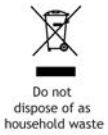
15.2 Medical class of the device

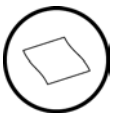
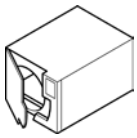
Class of medical device: IIb according to 93/42/EEC directive

15.3 Symbols

Symbol	Meaning
	Footswitch
O	Switching off (OFF)
I	Switching on (ON)
	Incision
	Coagulation
	High-frequency current light indicator
	Neutral electrode, bracelet
	Always wear safety goggles
	Always wear protective gloves
	Refer to the supporting documentation
	Consult the User Manual
	The accompanying documentation is available in electronic format
	Pressure limit

Symbol	Meaning
	Temperature limit
	Humidity limit
	Packaging unit
	Fragile, handle with care
	Store in a dry place
	Do not use the medical device if the patient or practitioner are fitted with an implantable device
	Do not use the medical device if the patient is wearing jewellery
	Do not use the medical device if the patient is fitted with a medical hearing aid device
	Do not use the medical device if the patient is wearing piercings
	Do not use the medical device if the patient is wearing a metallic medical prosthesis
	Do not use the medical device if the patient is wearing a medical device for deep brain stimulation
	Do not use the medical device if the patient is wearing a medical device for vagus nerve stimulation
	Biohazard
	Sterilisation at 134°C in an autoclave
	Sterilisation at 132°C in an autoclave

Symbol	Meaning
	Washer-disinfector for thermal disinfection
	Patient circuit isolated from ground (earth) at high frequency
	Type LF part in contact
I	Class 1
	Alternating current
	Electromagnetic interference
	CE marking
	CE marking
YYYY 	Year of manufacture
	Manufacturer
	Do not dispose of as household waste
	Recycle your lamps and professional electrical equipment with Récylum
Rx Only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.
IPX1	**IP**: ingress protection ratings procured by a range **X**: no ingress of protection rating claim against the penetration of solids **1**: protects against the vertical falls of drops of water
IPX0	**IP**: ingress protection ratings procured by a range **X**: no ingress of protection rating claim against the penetration of solids **0**: no protection against the penetration of liquids
SN	Serial Number
PN	Packaging Number
	Use a soft brush for cleaning

	Use a lint-free cloth for cleaning
	Use an ultrasonic tank for cleaning.
	Use a swab for cleaning
	Use an alcohol disinfectant wipe for pre-disinfection and cleaning.
	Clean under running water
	Use a pre-vacuum air autoclave for sterilisation

15.4 Manufacturer identification

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CE 0459
CE Marking

15.4.1 Manufacturer responsibility

The manufacturer shall under no circumstances be liable in the following cases:

- Non-compliance with manufacturer recommendations
- Maintenance or repair procedures performed by people who are unauthorised by the manufacturer.
- Use on an electrical fixture that is not compliant with regulations in force.
- Use of the device for purposes other than those specified in this manual.
- Use of accessories or handpiece not supplied by SATELEC, a company of Acteon group .
- Non-compliance with the instructions contained in this document.

> Note: the manufacturer reserves the right to modify the medical device and any documentation without notice.

15.5 Branch addresses

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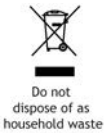
15.6 Disposal and recycling

As an item of Electrical and Electronic Equipment, the medical device must be disposed of via a specialist collection, removal, recycling or destruction channel. This applies in particular to the European market, in reference to Directive 2002/96/EC dated 27/01/2003.

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or the Acteon head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapter *Branch addresses page 51*.



The indication below applies to France only.

In compliance with the provisions of the French Environment Code relating to the disposal of electronic and electrical equipment waste or WEEE (Decree no. 2012-617 dated 2 May 2012), our Company fulfils its obligations to reclaim and dispose of its electrical and electronic equipment through the means established by the approved organisation Récylum, NOR approval: DEVP1427651A.

As a manufacturer, our Company is listed in the National Register of Producers kept by the ADEME (French Environment and Energy Management Agency). Professionals buying our products directly from the distribution chain are responsible for passing on this information about our established recycling methods to the end user.

In addition, the buyer agrees to take back our brand's devices at the end of their service life and to transfer them to one of the collection centres set up by Récylum for recycling (see list of collection centres on the site `http://www.recylum.com/`).

If necessary, Récylum can come and collect these devices from you free of charge once the quantity of devices has reached a certain level in the pallets-containers with which you are provided to store this waste.

An accessory that has reached the end of its service life must be disposed of in infectious clinical waste containers.

A medical device that has reached the end of its service life must be disposed of in infectious clinical waste containers.

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