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USER MANUAL

USER MANUAL

VIO® 50/100 C

MEDICAL - APPLIED CURRENT/ENERGY EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
AAMI ES60601-1:2005/(R)2012 and A1:2012/(R)2012 and A2:2021, CSA-C22.2 No. 60601-1 (Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14)
ANSI/AAMI/IEC 60601-2-2, CAN/CSA-C22.2 No. 60601-2-2
19NA

CE 0124

VIO 50 C: Art. No. 10140-550; VIO 100 C: Art. No. 10140-500

The information contained in this User Manual can be changed or expanded without prior notice and without obligation on the part of Erbe Elektromedizin GmbH.

The illustrations in this User Manual may differ in some details from your product.

Printed by Erbe Elektromedizin

Printed in Germany

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Chapter 1
General Instructions for Use

This User Manual describes the normal use of the unit.

Note: Report serious incidents with the product to your local dealer or Erbe. If you are a user in the European Union, also report incidents to the responsible authority in your Member State.

Intended Use / Indications for Use

The electrosurgical unit (ESU/Generator) model VIO 50 C/VIO 100 C with instruments and accessories is intended to deliver High Frequency (HF) current for cutting and/or coagulation of tissue.

Compatibility

The VIO 50 C/VIO 100 C can be combined with suitable instruments and accessories.

See the Accessories chapter for information on the compatibility of instruments and accessories.

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Intended Patient Population

No restrictions.

Contraindications

No known contraindications.

Side effects

Known side effects are:

neuromuscular stimulation.

Environment

For the intended use, the unit may only be operated in premises used for medical purposes.

Qualification of user

For the intended use, the unit may only be operated by medical professionals who have been trained in the use of the unit or combination of units on the basis of the User Manual.

Performance characteristics

Performance characteristics relating to the intended use are:

Provision of a defined HF power.

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Chapter 2
Safety Instructions

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Safety notations

⚠ DANGER

indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING

indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTICE

indicates a potentially hazardous situation which, if not avoided, may result in property damage.

Meaning of the note

"Note:"

Refers a) to manufacturer's information that relates directly or indirectly to the safety of people or protection of property. The information does not relate directly to a risk or dangerous situation.

Refers b) to manufacturer's information that is important or useful for operating or servicing the unit.

Who must read this User Manual?

Knowledge of the User Manual is absolutely essential for correct operation of the unit.

The User Manual must therefore be read by everyone who works with the unit.

Anyone who prepares, sets, disassembles, cleans and disinfects the unit must also read the User Manual.

Please pay particular attention to the safety instructions in each chapter.

Read the user manuals for all products that are used with the unit.

Compliance with safety information

Working with medical units is associated with certain risks to patients, medical personnel and the environment. Risks cannot be entirely eliminated by design measures alone.

Safety does not depend solely on the unit. Safety depends to a large extent on the training of medical personnel and correct operation of the unit.

The safety instructions in this chapter must be read, understood and applied by everyone who is working with the unit.

Structure of safety instructions

The safety instructions are structured according to the following risks:

- Operating errors and incorrect installation by persons without training
- Risks due to the environment
- Malfunctions to other equipment caused by the unit, malfunctions to the unit caused by other equipment
- Electric shock
- Fire / explosion
- Burns
- Risk of infection
- Inadvertent tissue damage
- Stimulation of nerves and muscles
- Risks due to incorrect use of the neutral electrode
- Defective unit
- Damage to the unit and accessories
- Notes

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Operating errors and incorrect installation by persons without training

⚠ WARNING

Operating errors and incorrect installation by persons without training

Persons without training can operate or install the unit incorrectly.

Risk of injury or death for patients and medical staff! Risk of damage to property.

⇨ The unit may only be used and installed by persons who have been trained on how to use and install it properly according to this User Manual.

⇨ Training may only be carried out by persons who are suitable on the basis of their knowledge and practical experience.

⇨ In the event of uncertainties or if you have any questions, please contact Erbe Elektromedizin. You will find the addresses in the address list at the end of this User Manual.

Risks due to the environment

⚠ WARNING

Unsuitable temperature or level of humidity during operation

If you operate the unit at an unsuitable temperature or level of humidity, it may sustain damage, fail, or not perform properly.

Risk of injury to patient and medical personnel!

⇨ Operate the unit at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

⇨ If other ambient conditions must be observed for operation of the unit, you will also find them in the Technical Data.

⚠ WARNING

Unsuitable temperature or humidity in transit or storage

If you transport or store the unit at an unsuitable temperature or level of humidity, it may sustain damage and fail.

Risk of injury to patient and medical personnel!

⇨ Transport and store the unit at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

⇨ If other ambient conditions must be observed for transport and storage of the unit, you will also find them in the Technical Data.

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NOTICE

Insufficient acclimatization time, unsuitable temperature during acclimatization

If the unit was stored or transported below or above a certain temperature, it will take a certain time and temperature to acclimatize.

If you do not observe the rules, the unit can sustain damage and fail.

⇨ Acclimatize the unit according to the rules in the Technical Data.

NOTICE

Overheating of the unit due to poor ventilation

If ventilation is poor, the unit can overheat, sustain damage, and fail.

⇨ Install the unit in such a way that there is an unobstructed circulation of air around the housing. Installation in confined wall recesses is prohibited.

⚠ WARNING

Penetration of fluid into the unit during operation or when cleaning the unit

Risk of electric shock to the medical personnel.

The unit may become damaged and fail.

⇨ Make sure no liquid can penetrate the unit.

⇨ Do not place vessels containing liquids on top of the unit.

⇨ If fluid has penetrated into the unit, take the unit out of operation immediately. You can only start using the unit again once it has been checked by a service technician.

Malfunctions to other equipment caused by the unit, malfunctions to the unit caused by other equipment

⚠ WARNING

Interference with electronic units due to the electrosurgical unit

The activated electrosurgical unit can affect the performance of electronic units by causing interference.

Risk of injury to patient and medical personnel.

The units may fail or not perform properly.

⇨ Position the electrosurgical unit, the cords of the instruments, and the cord of the neutral electrode as far away as possible from electronic units.

⇨ Position the cords as far away as possible from the cords of electronic units.

⚠ WARNING

Stacked units

If you place the unit next to or stack it with other units, the units may affect each other.

Risk of injury to patient and medical personnel.

Units may fail or not function properly.

⇨ Place the unit where possible only near Erbe units or stack the unit where possible only on Erbe units.

⇨ If it is necessary to operate the unit near or stacked together with units from other manufacturers, keep as much distance as possible between the units. Check whether the units are affecting each other: Are the units behaving unusually? Are faults occurring? If yes, increase the distance between the units.

⚠ WARNING

Use of non-approved EMC-relevant accessories

This can result in the increased emission of electromagnetic interference or reduce the electromagnetic immunity of the unit.

Risk of injury to patient and medical personnel.

Units may fail or not function properly.

⇨ Only use cable that is specified in the table *"EMC-relevant accessories"*, see chapter *"Notes on electromagnetic compatibility (EMC)"*.

⇨ If you are using accessories from other manufacturers, check whether the Erbe unit is interfering with other units or being affected by interference itself. You cannot use the unit if there is any interference.

⚠ WARNING

Interference with cardiac pacemakers, internal defibrillators, or other active implants

Activation of the electrosurgical unit may affect the performance of active implants or damage them.

Risk of injury or death for patients!

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⇨ In the case of patients having active implants, consult the manufacturer of the implant or the competent department of your hospital prior to performing surgery.

⇨ Do not position the neutral electrode near cardiac pacemakers, internal defibrillators, or other active implants.

⚠ WARNING

Interference with the unit from portable and mobile HF telecommunications units (e.g. mobile phones, WLAN units)

Electromagnetic waves emitted by portable and mobile HF telecommunications units may affect the unit.

Risk of injury to patient and medical personnel.

The unit may fail or not perform properly.

⇨ When using portable and mobile HF telecommunications units, including their accessories, there must be a distance of at least 30 cm between them and the unit and its cords.

Electric shock

⚠ WARNING

Defective grounded power outlet, power supply network without proper grounding, inferior-quality power cord, incorrect line voltage, multiple power outlets, extension cords

Risk of electric shock and other injuries to the patient and medical personnel! Risk of damage to property.

⇨ Connect the unit to a properly installed grounded outlet.

⇨ Only connect the unit to a power supply network with proper grounding.

⇨ Use the compatible Erbe power cord (see the *Accessories, Compatible power cords* chapter).

⇨ Check the power cord for damage. You must not use a damaged power cord.

⇨ The supply voltage must match the voltage specified on the unit's rating plate.

⇨ Do not use multiple power outlets.

⇨ Do not use extension cords.

⚠ WARNING

Damaged unit, damaged accessories, modified unit, and modified accessories

Risk of electric shock to the patient and medical personnel!

Risk of injury to patient and medical personnel!

Risk of burns to the patient and medical personnel!

Risk of material damage.

⇨ Check the unit and accessories for damage before each use (e.g. footswitch, instrument cables and cart).

⇨ You must not use a damaged unit or damaged accessories. Replace defective accessories.

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⇨ If the unit or cart is damaged, please contact our customer service.

⇨ Blown power fuses may only be replaced by a competent technician.

⇨ For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of Erbe Elektromedizin GmbH.

⚠ WARNING

Connection of unit and power supply during cleaning and disinfection

Risk of electric shock to the medical personnel!

⇨ Switch off the unit. Unplug the power plug of the unit.

⚠ WARNING

The user touches the patient and the connections on the unit at the same time.

Patient and medical staff may be put at risk by compensating currents.

Risk of injury to patient and medical staff. The unit can fail.

⇨ Do not touch the patient and the connections on the unit at the same time.

Fire / explosion

In electrosurgery electric sparks and arcs occur at the instrument. Flammable gases, vapors, and liquids can be set alight or caused to explode.

⚠ WARNING

Flammable anesthetics

Risk of explosion to the patient and medical personnel! Risk of damage to property.

⇨ Do not use flammable anesthetics when an operation is being performed on the head or thorax.

⇨ If use is unavoidable, you must evacuate the anesthetics before performing electrosurgery.

⚠ WARNING

Flammable gas mixture in TUR (Transurethral Resection) and TCR (Transcervical Endometrial Resection)

Hydrogen and oxygen can ascend into the roof of the bladder, the upper part of the prostate, and the upper part of the uterus. If you resect into this gas mixture, it could combust.

Risk of combustion to the patient!

⇨ Allow the gas mixture to escape through the resectoscope sheath.

⇨ Do not resect into the gas mixture.

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⚠ WARNING

Flammable endogenous gases in the gastrointestinal tract

Risk of explosion to the patient!

Risk of burns to the user.

⇨ Extract the gases before performing electrosurgery or irrigate with CO_2.

⚠ WARNING

Combustion-supporting gases, e.g. oxygen, nitrous oxide

The gases can accumulate in materials like cotton wool or gauze. The materials become highly flammable.

Risk of fire to the patient and medical personnel! Risk of damage to property.

⇨ Do not use combustion-supporting gases when an operation is being performed on the head or thorax.

⇨ If use is unavoidable, you must evacuate the combustion-supporting gases before performing electrosurgery.

⇨ Remove any jeopardized (e.g. cotton wool or gauze) materials before performing electrosurgery.

⇨ Check the oxygen-carrying tubes and connections for leaks.

⇨ Check the endotracheal tubes and their cuffs for leaks.

⚠ WARNING

Active or hot instruments in contact with combustible materials

Materials like gauze, swabs, and cloths can catch fire.

Risk of fire to the patient and medical personnel! Risk of damage to property.

⇨ Do not bring active or hot instruments into contact with combustible materials.

⇨ Put instruments down in a safe place: sterile, dry, non-conductive, and easy to see. Instruments that have been put down must not come into contact with the patient, medical personnel, or combustible materials.

⚠ WARNING

Flammable detergents and disinfectants, flammable solvents in adhesives used on the patient and on the unit

Risk of fire and explosion to the patient and medical personnel! Risk of damage to property.

⇨ Use products that are not flammable.

If the use of flammable products is unavoidable, proceed as follows:

⇨ Allow the products to evaporate completely before switching on the unit.

⇨ Check whether flammable liquids have accumulated under the patient, in body recesses such as the navel, or in body cavities such as the vagina. Remove any liquids before performing electrosurgery.

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⚠ WARNING

Ignition of anesthetics, skin cleansers, and disinfectants in potentially explosive atmospheres

If you place the unit in a potentially explosive atmosphere, anesthetics, skin cleansers, and disinfectants can ignite.

Risk of fire and explosion to the patient and medical personnel! Risk of damage to property.

⇨ Do not place the unit in potentially explosive atmospheres.

⚠ WARNING

Application of electrosurgery using an oxygen concentration in the tracheobronchial system that is too high

Risk of fire in the respiratory tract for the patient!

⇨ Reduce the oxygen supply below a critical threshold in accordance with therapeutic guidelines before activating the instrument in the tracheobronchial system.

Burns

⚠ WARNING

Damaged unit, damaged accessories, modified unit, and modified accessories

Risk of electric shock to the patient and medical personnel!

Risk of injury to patient and medical personnel!

Risk of burns to the patient and medical personnel!

Risk of material damage.

⇨ Check the unit and accessories for damage before each use (e.g. footswitch, instrument cables and cart).

⇨ You must not use a damaged unit or damaged accessories. Replace defective accessories.

⇨ If the unit or cart is damaged, please contact our customer service.

⇨ Blown power fuses may only be replaced by a competent technician.

⇨ For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of Erbe Elektromedizin GmbH.

⚠ WARNING

Using unsuitable accessories

Risk of injury to patient and medical personnel.

⇨ Observe the notes in the *Accessories* chapter.

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⚠ CAUTION

HF leakage current flows through metal parts

The patient must not have contact with electrically conductive objects. That includes metal parts of the operating table, for example. HF current can be discharged through points of contact accidentally (HF leakage current).

Risk of burns to the patient!

⇨ Position the patient on dry, antistatic drapes.

⇨ If the drapes can become wet during the surgery due to sweat, blood, irrigation liquid, urine, etc., lay a waterproof plastic sheet under the drapes.

⚠ CAUTION

The connecting cables (e.g., instrument cable, neutral electrode cable) are touching each other or the patient.

Risk of burns to the patient and medical personnel!

⇨ Do not place the connecting cables on the patient.

⇨ Place the connecting cables separate from each other.

⚠ CAUTION

HF leakage current flows through monitoring electrodes

HF current can be discharged through points of contact between the skin and monitoring electrodes accidentally (HF leakage current).

Risk of burns to the patient!

⇨ Position monitoring electrodes as far away as possible from the procedural field (area where electrosurgical instruments are used).

⇨ Do not use needle electrodes for monitoring during electrosurgery.

⇨ Where possible, use monitoring electrodes that contain devices to limit high-frequency current.

⚠ CAUTION

HF leakage current flows through skin-to-skin points of contact

HF current can be discharged through skin-to-skin points of contact accidentally (HF leakage current).

Risk of burns to the patient!

⇨ Prevent skin-to-skin points of contact. For example, lay dry gauze between the patient's arms and body.

⚠ CAUTION

HF leakage current flows through the skin of medical personnel

Risk of burns to the patient and medical personnel!

⇨ Do not come in contact with the patient while the surgeon is using an active electrosurgical instrument on the patient.

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⚠ WARNING

Unintentional activation of the instrument

Risk of burns to the patient and medical personnel!

⇨ Put instruments down in a safe place: sterile, dry, non-conductive, and easy to see. Instruments that have been put down must not come into contact with the patient, medical personnel, or combustible materials.

⇨ Instruments that have been put down must not come into contact with the patient, not even indirectly. An instrument can come into contact with the patient indirectly through electrically conductive objects or wet drapes, for example.

⚠ WARNING

Hot instruments

Even non-active instruments that are still hot can burn the patient or medical personnel.

⇨ Put instruments down in a safe place: sterile, dry, non-conductive, and easy to see. Instruments that have been put down must not come into contact with the patient, medical personnel, or combustible materials.

⇨ Instruments that have been put down must not come into contact with the patient, not even indirectly. An instrument can come into contact with the patient indirectly through electrically conductive objects or wet drapes, for example.

⚠ WARNING

Unintentional activation of the instrument during an endoscopic application

If the instrument is activated and remains activated during an endoscopic application, the patient can suffer burns when the instrument is removed.

All points that come into contact with the active part of the instrument are at risk. The cause of unintentional activation can be a fault in the footswitch or unit for example.

You will recognize unintentional activation from the continuous activation signal, even though you have released the footswitch.

Risk of burns to the patient!

⇨ Turn off the power switch on the electrosurgical unit immediately. Only then should the instrument be removed from the patient's body.

⚠ WARNING

Capacitive coupling between the cords of two instruments

When one instrument is activated, current can be transferred to the cord of another instrument (capacitive coupling).

The patient can suffer burns if the non-active but still live instrument has direct or indirect contact with the patient.

Risk of burns to the patient and medical personnel!

⇨ Lay the cords of instruments in such a way that they are as far apart as possible.

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⇨ Put instruments down in a safe place: sterile, dry, non-conductive, and easy to see.

⇨ Instruments that have been put down must not come into contact with the patient, medical personnel, or combustible materials.

⇨ Instruments that have been put down must not come into contact with the patient, not even indirectly. An instrument can come into contact with the patient indirectly through electrically conductive objects or wet drapes, for example.

⇨ Touch the tissue before activating the instrument.

⚠ WARNING

Capacitive coupling between the instrument and the hybrid trocar

When an instrument is activated, current can be transferred to the trocar without any contact (capacitive coupling).

Risk of burns to the patient and medical personnel!

⇨ Do not use hybrid trocars (i.e., a combination of metal and plastic) if you are using monopolar instruments.

⚠ WARNING

Unsuitable endoscopes, resectoscopes with electrosurgery

Risk of burns to the patient and medical personnel!

⇨ Use only endoscopes or resectoscopes that have been approved for electrosurgery.

⚠ WARNING

Power setting too high, ON time too long

The higher the power setting, the longer the ON time of the unit, the greater the risk of accidental tissue damage.

Risk of accidental tissue damage to the patient!

⇨ Set power as low as possible relative to the required surgical effect. If the required surgical effect is not achieved, increase the power.

⇨ Activate the unit for as short a time as possible relative to the required surgical effect.

⇨ The temperature at the neutral electrode site increases during long and continuous activations; therefore, ensure that the cooling phases between activations are sufficient.

⇨ If you are unable to achieve a surgical effect with a power setting / ON time that is sufficient judging from experience, this can be due to a problem with the electrosurgical unit or accessories:

⇨ Check the instrument regularly for soiling with insulating tissue remnants. Clean the instrument if it has become soiled.

⇨ Check the neutral electrode to make sure it is secure.

⇨ Check the connectors on all cords to make sure they are secure.

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⚠ WARNING

Activation of the unit with no knowledge of active settings

If the user does not understand the active settings of the unit, he can cause the patient accidental tissue damage.

⇨ Check the active settings on the display of the unit, after: switching on the unit, connecting up an instrument, and changing the program.

⚠ WARNING

The user was not informed of a change in maximum ON time

Risk of accidental tissue damage to the patient!

⇨ All users must be informed of any change in maximum ON time at an early stage. That is, before the user works with the modified maximum ON time for the first time.

⇨ The temperature at the neutral electrode site increases during long and continuous activations; therefore, ensure that the cooling phases between activations are sufficient.

⚠ WARNING

Tissue structures / vessels with a cross-section that is small or becoming smaller

If monopolar HF current flows through parts of the body with a relatively small cross-section, there is a risk of unintentional coagulation for the patient!

⇨ If possible, use the bipolar coagulation technique.

⚠ WARNING

Activation signal not audible

You do not hear the signal when the electrosurgical unit is activated.

Risk of burns to the patient and medical personnel!

⇨ Adjust the activation signal so that it is clearly audible.

⚠ WARNING

Contact or too close proximity of the activated instrument to metal objects in or on the patient's body.

Risk of burns to the patient!

Metal implants may be damaged, e.g., hip arthroplasties.

⇨ Do not touch any metal objects, e.g., hemostats, hip arthroplasties, with the activated instrument.

⇨ Keep the activated instrument as far away as possible from metal objects, e.g., hemostats, hip arthroplasties.

⚠ WARNING

The unit does not shut off

The active instrument cannot be deactivated.

Risk of burns to the patient and medical personnel!

⇨ Press the power switch of the unit.

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⚠ WARNING

A hand-held metal instrument is touched with the active instrument (electrode)

Risk of hand burns!

⇨ Do not touch a hand-held metal instrument with the active instrument.

⚠ WARNING

The instrument is inserted into an activated socket. The instrument is inserted into an adapter or a cable that is connected to an activated socket.

Risk of burns to the patient and medical personnel!

⇨ Do not insert instruments into an activated socket.

⇨ Do not insert instruments into an adapter that is plugged into an activated socket.

⇨ Do not insert instruments into a cable that is plugged into an activated socket.

⚠ CAUTION

Activation of the unit during cleaning of an instrument

Risk of burns for the medical personnel!

⇨ Do not activate the unit while you are cleaning an instrument.

Risk of infection

⚠ WARNING

The unit is contaminated

Risk of infection to the patient and medical personnel.

⇨ Follow the instructions for cleaning and disinfecting the unit.

⚠ WARNING

Alternate use of disinfectant solutions based on different active ingredients

The agents may affect one another. The disinfection effect of the disinfectant solution may be weakened. Risk of infection to the patient and medical personnel.

The housing plastic may become brittle and break. A color reaction may occur with plastics.

⇨ Do not use these substances alternately.

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Inadvertent tissue damage

⚠ WARNING

Safety margin between the active instrument and sensitive tissue structures too narrow

Adjacent structures can be damaged by the thermal effect of electrosurgery.

⇨ Ensure that there is a sufficient safety margin between the active instrument and sensitive tissue structures (e.g. nerves, muscles).

⚠ CAUTION

Electrically conductive implants can redirect or concentrate current flow.

Risk of burns for the patient and possible damage to the implant.

⇨ In the case of patients wearing electrically conductive implants, consult the manufacturer of the implant or the relevant specialist department of your hospital prior to surgery.

⇨ Position the neutral electrode so that the implant is not located between the active electrode (monopolar instrument) and the neutral electrode.

Stimulation of nerves and muscles

⚠ WARNING

Low-frequency currents stimulate nerves and muscles (Neuromuscular Stimulation)

Low-frequency currents arise either due to low-frequency power sources or partial rectification of the HF current. Spasms or muscle contractions can occur.

Risk of injury to the patient.

⇨ Set power as low as possible relative to the required surgical effect. If the required surgical effect is not achieved, increase the power.

Risks due to incorrect use of the neutral electrode

⚠ WARNING

Non-compatible or single surface neutral electrode

When applying a non-compatible neutral electrode, it should be expected that monitoring the contact between neutral electrode and skin is faulty.

When applying a single surface neutral electrode, the contact between neutral electrode and skin is not monitored. If contact between neutral electrode and skin is inadequate, the unit does not emit any visual and acoustic signal.

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Risk of burns for the patient under the neutral electrode!

⇨ Check in the accompanying papers of the manufacturer whether the neutral electrode is suitable for the VIO unit used.

⇨ Use only suitable neutral electrodes.

⇨ When applying a single surface neutral electrode: Regularly check the neutral electrode for good skin contact.

⇨ Check in the accompanying papers of the manufacturer whether the neutral electrode cable is suitable for the neutral electrode used.

⇨ Use only suitable neutral electrode cables.

⚠ WARNING

Positioning the neutral electrode above the heart

Risk of cardiac arrhythmia for the patient due to function-related currents from neutral electrode monitoring!

⇨ Do not position the neutral electrode over the heart or in the region of the heart.

⚠ WARNING

Incorrect application of the neutral electrode

Risk of burns to the patient!

⇨ Apply the entire contact surface of the neutral electrode to a muscular part of the body with good blood circulation.

⇨ Apply the neutral electrode as close as possible to the surgical site.

⇨ Insert the contact tab of the neutral electrode completely into the connecting clamp. The contact tab must not touch the patient's skin. (For reusable cord with disposable pads only.)

⇨ Align the symmetry line of the neutral electrode towards the operating field. The current should flow from the active electrode (instrument) to the symmetry line of the neutral electrode.

⇨ Check the neutral electrode regularly for good contact with the patient's skin.

⇨ Check the neutral electrode especially when the patient has been repositioned and after surgical steps where the unit was activated frequently and for a long time.

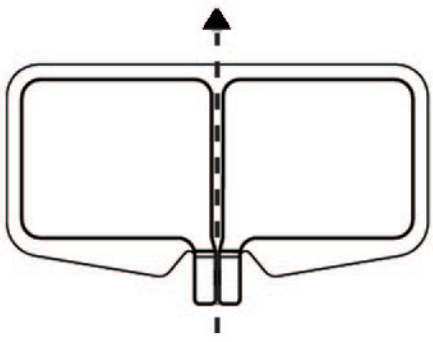

Fig. 2-1

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⚠ WARNING

Short circuit in the connecting cable or in the clip of a dual surface neutral electrode

If a short circuit occurs in the connecting cable or in the clamp of a dual surface neutral electrode, the unit can no longer monitor the contact with the patient's skin. You will not receive a warning if the electrode becomes detached from the skin.

Risk of burns to the patient!

⇨ To rule out the possibility of a short circuit in the connecting cable or in the clamp before using the unit, you can test the connecting cable. (See page 52.)

Defective unit

⚠ WARNING

Undesirable rise in output level due to failure of electrosurgical unit

Risk of accidental tissue damage to the patient!

⇨ The unit shuts off independently.

⇨ To guard against a possible failure of the electrosurgical unit, have a technical safety check carried out at least once a year.

⚠ WARNING

Technical safety checks not being done

Risk of injury or death for patients and medical staff! Risk of damage to property.

⇨ Have a technical safety check carried out on the unit at least once a year.

⇨ You must not use a unit that is not safe.

⚠ WARNING

Failure of display elements

If display elements fail, you can no longer operate the unit safely.

Risk of injury or death for patients and medical staff!

⇨ You must not use the unit.

Damage to the unit and accessories

⚠ WARNING

Electric load on instrument too high

The instrument can be damaged.

If the damaged area comes into contact with tissue, it can lead to unintentional coagulation.

⇨ Determine the electrical capacity of the instrument. It is either printed on the instrument or can be found in the User Manual. Compare the electrical capacity of the instrument with the maximum HF peak voltage of the required mode.

⇨ Instructions are available in the "Accessories" chapter.

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NOTICE

Mix-up of sockets on monopolar socket modules 20140-622, 20140-623

If the sockets are mixed up, the unit will be damaged.

⇨ If you use a connecting cable with a monopolar 4 mm dia. connector, you may only plug the connector into the socket with the blue ring. The correct socket is marked with an arrow on the illustration.

Fig. 2-2

⚠ WARNING

Very long activation cycles without cooling phases

The electrosurgical unit is designed and tested for a relative activation time of 25% (in accordance with IEC 60601-2-2). If you perform long activation phases without the appropriate cooling phases, there may be gradual heating under the neutral electrode or the unit may be damaged.

Risk of burns to the patient!

⇨ Keep to the 25 % relative ON time (see also Technical Data, Operating Mode), if you operate the unit for a lengthy period.

⚠ WARNING

Use of non-approved internal cables by Technical Service

This can result in the increased emission of electromagnetic waves or reduce the immunity of the unit.

Risk of injury to patient and medical personnel.

The unit may fail or not perform properly.

⇨ Technical Service may only use the internal cables that are listed in the service manual for the unit.

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Notes

Grounding

Note: Connect the grounding pin on the unit to the grounding system of the operating room using a grounding cable if required.

Use of a defibrillator

Note: All HF sockets and the neutral electrode socket (applied parts) meet Type CF requirements and are protected against the effects of defibrillator discharge.

Measures against smoke during electrosurgical interventions

Note: Erbe recommends using a smoke evacuation system, protective goggles, and a respirator.

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Chapter 3
Safety Features

Neutral electrode monitoring

The VIO 50 C/VIO 100 C is equipped with a neutral electrode monitoring system. The neutral electrode monitoring system monitors the electrical connection between the neutral electrode and the unit for single and dual surface neutral electrodes. The skin contact is also monitored for dual surface neutral electrodes.

To optimally utilize the unit's monitoring functions, Erbe recommends connecting a dual surface electrode, and in particular the Erbe NESSY Omega electrode. Apart from many other advantages, this electrode virtually eliminates any possibility of excessive heating of the tissue and skin at the edges of the electrode.

Monitoring the connection between neutral electrode and unit

If the connection between unit and neutral electrode is interrupted or if the contact tab for a neutral electrode with separate connecting cable is not fully inserted into the connection clamp, the neutral electrode indicator light illuminates red. The monopolar socket cannot be activated. A warning signal and error number is displayed when trying to activate the socket.

Monitoring the contact between skin and neutral electrode

The skin contact is only monitored for dual surface neutral electrodes.

If the contact between skin and neutral electrode is interrupted, the neutral electrode indicator light illuminates red. The monopolar socket cannot be activated. A warning signal and error number is displayed when trying to activate the socket.

Short circuit in the connecting cable or in the clip of a dual surface neutral electrode

If a short circuit occurs in the connecting cable or in the clamp of a dual surface neutral electrode, the unit can no longer monitor the contact with the patient's skin. You will not receive a warning if the electrode becomes detached from the skin.

To rule out the possibility of a short circuit in the connecting cable and in the clamp, you must test the connecting cable before use (see page 52).

Automatic monitoring of equipment output error

The unit is equipped with an automatic monitoring system for the HF output parameters. This system monitors any divergence between the actual value and the setpoint of the HF output parameters selected and emits warning signals or switches off the HF generator if the divergence is so great that the required quality of the respective effect (CUT or COAG) is no longer guaranteed. For the operating surgeon the display of any equipment output error allows him to immediately see, in the event of divergence or absence of the required effect, whether this defect has been caused by the unit. With the unit, any divergence of the HF output parameters from the HF output parameters actually selected can only be caused by loads with an excessively low resistance, e.g. too large coagulation electrodes, short circuit between active electrode and neutral electrode or by a defect in the unit.

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Automatic monitoring of the ON time

With proper use, a high-frequency generator is only briefly activated to carry out a cut or coagulation using a fingerswitch, pedal or AUTO START. This generally only takes a few seconds. A defect in the unit, in the accessories or in usage may cause the high-frequency generator to be switched on unintentionally. To prevent major damage being caused by accidental activation of a high-frequency generator the unit is equipped with a monitor which automatically monitors the ON time of the high-frequency generator.

When a predetermined maximum ON time is exceeded, the monitor emits a visual and acoustic signal and automatically switches off the HF generator. However, the HF generator can be switched back on at any time, resulting in renewed monitoring of the ON time. This prevents major damage being caused by the accidental activation of an HF generator for indefinitely long periods.

Custom adaptation of maximum ON time

In view of the risk of thermal tissue damage due to the accidental switch-on, a HF generator which has been switched on accidentally should be switched off again automatically, as far as possible immediately. As the unit cannot automatically distinguish between the intentional and accidental switch-on of a HF generator, the automatic switch-off of a HF generator should not take place too quickly as this would hinder the operating surgeon with cutting or coagulation. Setting of the ON time can only be carried out by a technician in the service programs.

⚠ WARNING

The user was not informed of a change in maximum ON time

Risk of accidental tissue damage to the patient!

⇨ All users must be informed of any change in maximum ON time at an early stage. That is, before the user works with the modified maximum ON time for the first time.

⇨ The temperature at the neutral electrode site increases during long and continuous activations; therefore, ensure that the cooling phases between activations are sufficient.

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Protection from operating errors

The unit is intuitive to use thanks to its well-conceived design.

All sockets of the applied part are arranged in the socket strip next to the front panel. These sockets are designed so that only connectors of the proper accessories can be inserted (provided that only the accessories supplied or recommended by the manufacturer of the unit are used).

You can connect a monopolar instrument and a bipolar instrument to the unit at the same time. However, for safety reasons they can only be activated alternately. HF voltage is only ever carried by one socket.

Whenever the power switch is switched on, an automatic test program is run inside the unit, designed to detect and signal the following defects in the operator controls of the unit and the connected accessories:

- If a button on the front panel has short-circuited due to an error or was pressed when the power switch was switched on, this error is indicated acoustically and by an error number after switching on the power switch.

- If a button on the electrode handle has short-circuited due to an error or has been bypassed at low resistance (e.g. due to moisture in the electrode handle) or was pressed while the power switch was switched on, this error is indicated acoustically and by an error number after switching on the power switch.
- If a contact of the footswitch has short-circuited due to an error or a pedal is jammed or a pedal was pressed while the power switch was switched on, the error is indicated acoustically and by an error number.

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Chapter 4
Accessories

Introduction

You can connect a number of instruments and neutral electrodes from different manufactures to the VIO.

Check Erbe instruments and instruments from other manufacturers for compatibility with the required CUT / COAG mode of the VIO before use. Instructions are available in this chapter.

Check the neutral electrodes from other manufacturers for compatibility with the VIO before use. Instructions are available in this chapter.

The following offers an overview of example accessories for each accessory category. A complete overview is available in the Erbe accessories catalog and on the Erbe website. We recommend the use of Erbe accessories.

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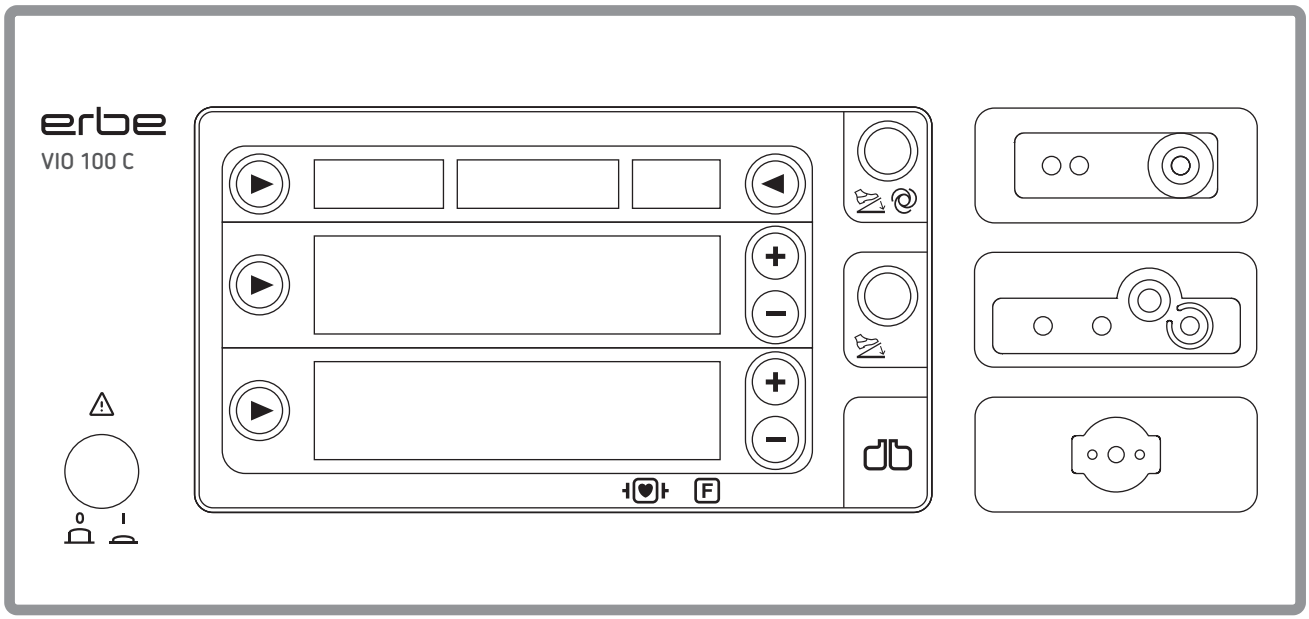
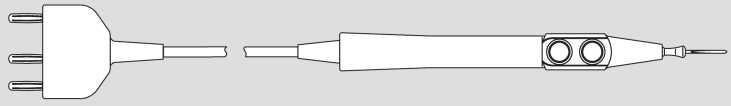
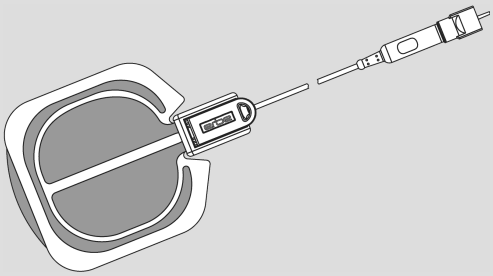
VIO 50 C/VIO 100 C – example accessories



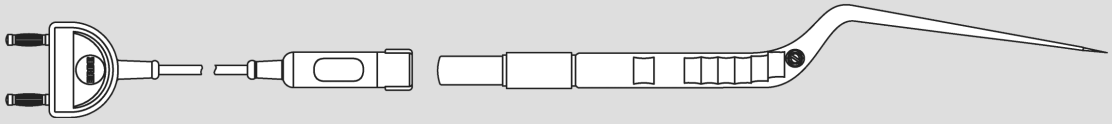
Monopolar electrosurgical pencils, monopolar electrodes



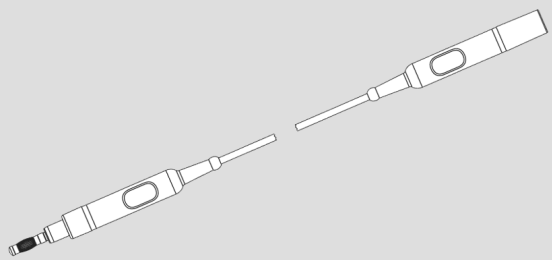
Neutral electrodes



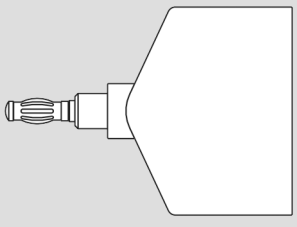
Bipolar instruments, bipolar forceps



Connecting cables



Adapters



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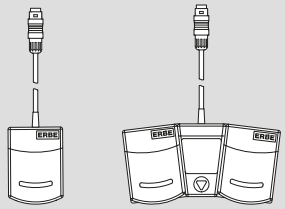
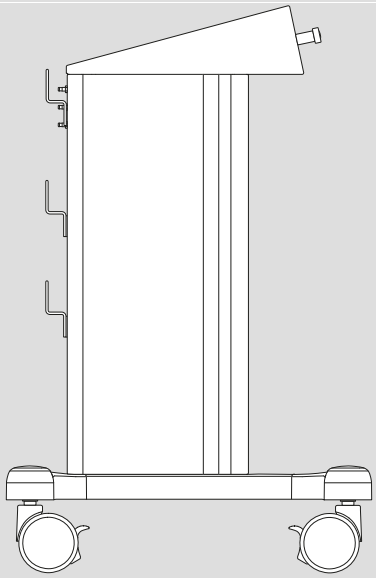
Accessories for units and modules





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Compatible instruments

You may only connect an instrument to the unit if the instrument's user manual indicates that the instrument is compatible with the unit.

The supported instrument plugs are described in the chapter *Description of socket hardware*. If you have a compatible instrument whose plug does not fit, you can insert an adapter between the plug and the socket.

If you have an instrument without a cable, connect a suitable cable.

Please see the Erbe accessories catalog for adapters and cables.

Check compatibility of instrument and CUT / COAG mode

⚠ WARNING

Electric load on instrument too high

The instrument can be damaged.

If the damaged area comes into contact with tissue, it can lead to unintentional coagulation.

⇨ Determine the electrical capacity of the instrument. It is either printed on the instrument or can be found in the User Manual. Compare the electrical capacity of the instrument with the maximum HF peak voltage of the required mode.

⇨ Observe the following instructions.

1. Determine the electrical capacity of the instrument

The maximum electrical capacity of the instrument is indicated on the instrument or in the instrument's notes on use. The unit of measurement for electrical capacity is Vp. For example, an instrument can have a maximum electrical capacity of 4 kVp (4000 Vp). Another instrument can have a maximum electrical capacity of 800 Vp. You are not permitted to load the instrument beyond these values.

2. Compare electrical capacity of the instrument with the maximum HF peak voltage of the required mode

Example 1

You want to operate an instrument with a maximum electrical capacity of 4 kVp (4000 Vp) with the DRY CUT mode. You review the technical data of the DRY CUT mode.

HF voltage waveform	pulse-modulated sinusoidal alternating voltage
Rated frequency	540 kHz (at R_L = 500 Ω) ± 10 %
Crest factor	2.4 (at R_L = 500 Ω)
Rated load resistor	500 Ω
Max. HF peak voltage	900 Vp
HF power limitation	VIO 50 C: 1 watt to 50 watts in 1 watt steps VIO 100 C: 1 watt to 100 watts in 1 watt steps
Max. power output at rated load resistor	VIO 50 C: 50 watts ± 20 % VIO 100 C: 100 watts ± 20 %
Max. RMS current (maximum HF output current in normal use)	VIO 50 C: 200 mA VIO 100 C: 330 mA

In the table, you see the line "Max. HF peak voltage 900 Vp". The DRY CUT mode would then load the instrument with maximum 900 Vp. The instrument sustains 4 kVp (4000 Vp). The electrical capacity of the instrument (4000 Vp) is greater than the maximum HF peak voltage (900 Vp) of the DRY CUT mode. You may use the instrument with the DRY CUT mode.

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Example 2

You want to operate an instrument with a maximum electrical capacity of 800 Vp with the DRY CUT mode. You review the technical data of the DRY CUT mode.

HF voltage waveform	pulse-modulated sinusoidal alternating voltage
Rated frequency	540 kHz (at R_L = 500 Ω) ± 10 %
Crest factor	2.4 (at R_L = 500 Ω)
Rated load resistor	500 Ω
Max. HF peak voltage	900 Vp
HF power limitation	VIO 50 C: 1 watt to 50 watts in 1 watt steps VIO 100 C: 1 watt to 100 watts in 1 watt steps
Max. power output at rated load resistor	VIO 50 C: 50 watts ± 20 % VIO 100 C: 100 watts ± 20 %
Max. RMS current (maximum HF output current in normal use)	VIO 50 C: 200 mA VIO 100 C: 330 mA

In the table, you see the line "Max. HF peak voltage 900 Vp". The DRY CUT mode would then load the instrument with maximum 900 Vp. However, the instrument only sustains 800 Vp. The electrical capacity of the instrument (800 Vp) is less than the maximum HF peak voltage (900 Vp) of the DRY CUT mode. In this case, you may only use the instrument with a power limitation with a maximum HF peak voltage of 800 Vp. You determine the permissible power limitation as follows:

If the electrical capacity of the instrument is less than the maximum HF peak voltage of the mode, review the diagram labeled "U HF (Vp)" on the vertical axis and "Power HF max. (W)" on the horizontal axis.

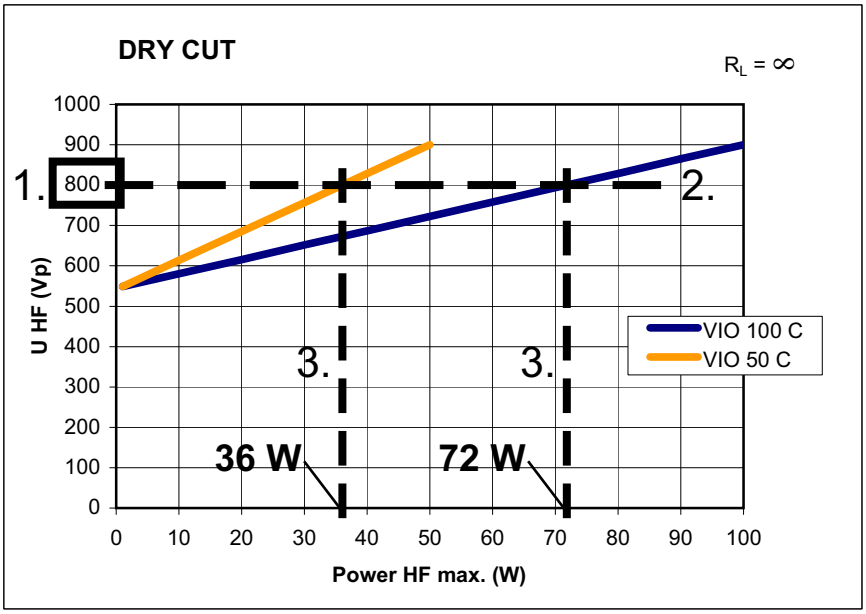

Fig. 4-1

The electrical capacity of the instrument in our example is 800 Vp.

1. Look for the value 800 Vp on the vertical axis.
2. Drag a horizontal line from this value.
3. Put a vertical line at the point at which the horizontal line cuts the curve for the VIO 50 C or VIO 100 C.

At the intersection of the vertical lines and the horizontal axis, you can read which maximum power limitation you can set on the VIO 50 C or on the VIO 100 C. In our example, you can set a maximum power limitation of 36 watts on the VIO 50 C, a maximum power limitation of 72 watts on the VIO 100 C. When selecting these power limitations, the instrument is loaded with max. 800 Vp.

In case of doubt, ask the manufacturer of the instrument. The telephone no. for the Erbe customer hotline is listed at the end of the User Manual.

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Compatible neutral electrodes

⚠ WARNING

Non-compatible or single surface neutral electrode

When applying a non-compatible neutral electrode, it should be expected that monitoring the contact between neutral electrode and skin is faulty.

When applying a single surface neutral electrode, the contact between neutral electrode and skin is not monitored. If contact between neutral electrode and skin is inadequate, the unit does not emit any visual and acoustic signal.

Risk of burns for the patient under the neutral electrode!

⇨ Check in the accompanying papers of the manufacturer whether the neutral electrode is suitable for the VIO unit used.

⇨ Use only suitable neutral electrodes.

⇨ When applying a single surface neutral electrode: Regularly check the neutral electrode for good skin contact.

⇨ Check in the accompanying papers of the manufacturer whether the neutral electrode cable is suitable for the neutral electrode used.

⇨ Use only suitable neutral electrode cables.

The supported neutral electrode plugs are described in the chapter *Description of socket hardware*.

If you have a neutral electrode without a cable, connect a suitable cable. Please see the Erbe accessories catalog.

The neutral electrode monitoring system of the VIO C monitors the electrical connection between the neutral electrode and the unit for single and dual surface neutral electrodes. The skin contact is also monitored for dual surface neutral electrodes.

All Erbe neutral electrodes are correctly monitored. When using third-party neutral electrodes, you must check in the accompanying papers of the manufacturer whether the neutral electrode is suitable for the VIO used.

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Compatible footswitches

You can connect only Erbe footswitches to the VIO. There are special footswitches for the VIO D / VIO S series and special footswitches for the VIO C series.

If you connect a footswitch, refer to the chapter *Controls on the back, Footswitch sockets*.

Compatible power cords

Use the following compatible Erbe power cords.

REF no. (supplied with the unit)	REF no. (spare part)	Length, amperage	Power plug Erbe designation	Power plug international designation
51704-037	52704-037	2.5 m, 10 A	303A	E+F
51704-038	52704-038	2.5 m, 10 A	404	G
51704-039	52704-039	4 m, 10 A	NEMA 5-15 P	B
51704-040	52704-040	2.5 m, 10 A	403	L
51704-042	52704-042	5 m, 10 A	303A	E+F
51704-043	52704-043	5 m, 10 A	404	G
51704-045	52704-045	5 m, 10 A	403	L
51704-046	52704-046	0.5 m, 10 A	303A	E+F
51704-050	52704-050	4 m, 10 A	PRC/3	I
51704-051	52704-051	4 m, 10 A	RA/3	I
51704-052	52704-052	4 m, 10 A	512	J
51704-053	52704-053	4 m, 10 A	DK3	K
51704-054	52704-054	4 m, 10 A	BR/3	N
51704-057	52704-055	5 m, 10 A	VII	E+F
51704-058	52704-058	5 m, 10 A	IL/3G	H
51704-075	52704-075	5 m, 10 A	I	I

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Chapter 5
Description of the Controls

Controls on the front panel

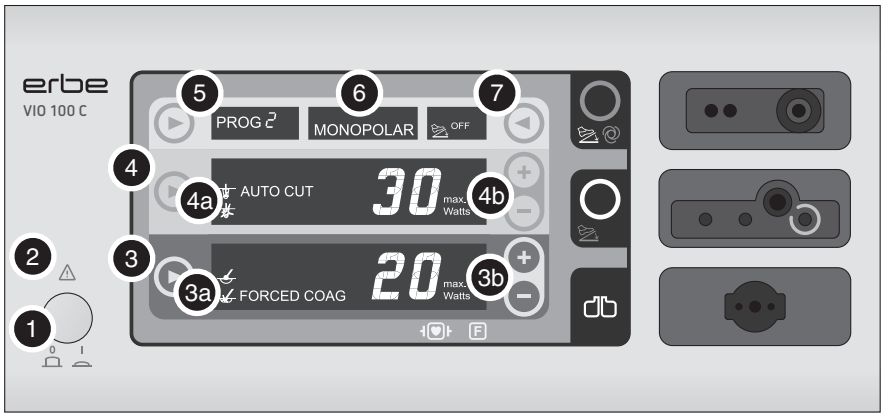

Fig. 5-1

(1) Power switch

Switches the unit on or off.

The unit is completely disconnected from the power supply when the power plug is pulled. Install the unit such that the power plug could be easily disconnected from the power source.

(2) Symbol "Caution"

Indicates that the safety instructions in the User Manual must be read before switching the unit on.

(3) COAG range of settings

(3a) Selection button and display for the COAG mode

(3b) Display and Plus/Minus buttons for adjusting the COAG power limitation

(4) CUT range of settings

(4a) Selection button and display for the CUT mode

(4b) Display and Plus/Minus buttons for adjusting the CUT power limitation

(5) Area for program selection

Selection button and display for the program.

(6) Focus display

Displays whether the monopolar or bipolar socket is currently in focus (selected). The settings of the socket currently in focus are always displayed.

(7) Area for selecting the activation type

Display and selection button for the activation type. Here you can assign the footswitches or AUTO START function to the socket currently in focus (AUTO START available for the bipolar socket of the VIO 100 C only).

Continued on the next page.

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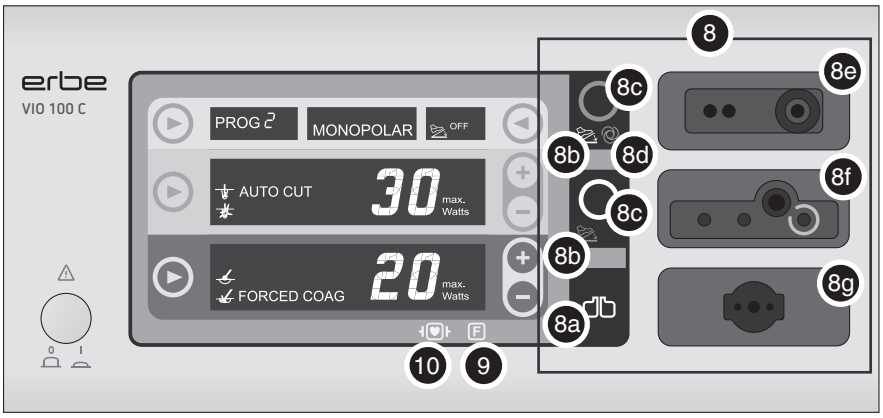

Fig. 5-2

(8) Socket area

(8a) Neutral electrode indicator light

Display green: The monopolar socket can be activated.

Display red: The monopolar socket cannot be activated.

(8b) Footswitch indicator light

If the connected footswitch is assigned to a socket, the corresponding footswitch indicator light illuminates.

(8c) Focus button

"Brings into focus" (selects) an instrument socket: The current settings of the socket in focus are displayed.

The socket currently in focus can be identified by the illuminated Focus button.

The button is yellow while the CUT current is activated; the button is blue while the COAG current is activated.

(8d) AUTO START indicator light

The AUTO START indicator light illuminates if the AUTO START function is assigned to the bipolar socket (available for the VIO 100 C only).

(8e) Bipolar socket

Socket for connecting a bipolar instrument.

(8f) Monopolar socket

Socket for connecting a monopolar instrument.

(8g) Neutral electrode socket

Socket for connecting a neutral electrode.

(9) Symbol "Protection from leakage currents"

The patient circuit is insulated against ground. The risk of leakage currents and thus the risk of burns is greatly reduced for the patient.

(10) Symbol "Defibrillation-proof type CF applied part"

All HF sockets and the neutral electrode socket (applied parts) meet Type CF requirements and are protected against the effects of defibrillator discharge.

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Controls on the back

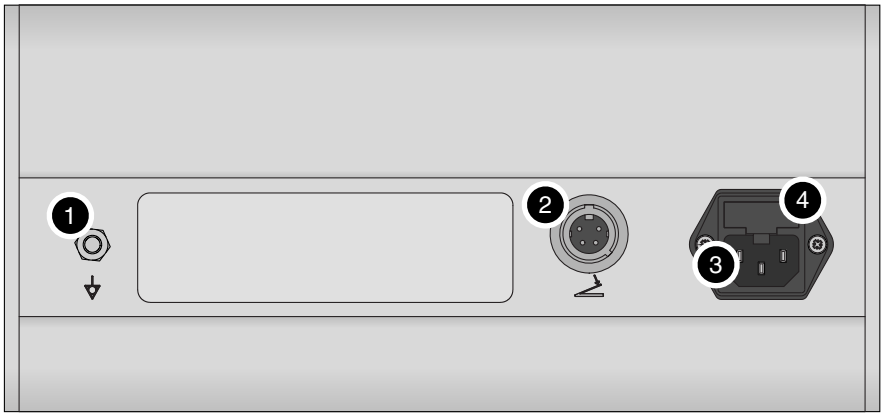

Fig. 5-3

(1) Grounding terminal The grounding terminal can be used to connect the unit to the grounding of the operating room as needed.

(2) Footswitch socket The one pedal or two pedal footswitch VIO C can be connected to the footswitch socket.

(3) Power connection The power connection is used to connect the unit to the power supply.

(4) Power fuses The unit is protected with power fuses.

Note: If one of these power fuses has blown, the unit may not be used on the patient again until it has been checked by a competent technician. The values of the power fuses are specified on the unit's rating plate. Only spare fuses with these values may be used.

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Chapter 6
Working with the electrosurgical unit

Re this chapter

Description based on a sample configuration

The unit sockets are available in various country-specific versions. In this regard, the sockets depicted are only examples of a configuration.

Contents of this chapter

This chapter starts with an overview of the options for setting the unit. See page 46.

A number of step instructions for different operating procedures then follow that you can perform with your unit, e.g. selecting a unit program or changing unit parameters. See page 50.

In the case of contents or special details described in another chapter or documents, reference will be made to the relevant source.

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Setting options for the unit

Programs and program-parameters

You can choose between 2 different programs on the VIO 50 C and between 4 different programs on the VIO 100 C.

The programs were programmed at the factory. They can be used for certain instruments or instrument combinations without having to make any changes to the program parameters (see page 47).

You can change and save the following settings within a program as required (see page 59):

- Socket in focus at program start: The socket in focus is the socket whose settings the unit currently displays.
- CUT and COAG modes: Cutting and coagulation modes
- CUT and COAG power limitations: The power limitation is a measure of the intensity of the coagulation for both the CUT and COAG modes. A higher power limitation means faster coagulation or a deeper coagulation zone during the same activation period. A power limitation as low as possible protects the patient and instrument from injury or damage.
- Assignment of the footswitch to one of the instrument sockets
- AUTO START function: Automatic activation of the COAG HF current of the bipolar socket (available for the VIO 100 C only)

In addition to the program parameters, it is possible to modify other general unit parameters:

Setup settings

The setup settings affect various display parameters of the unit, e.g. the volume of the tones. The user can change the settings (see page 62).

Service settings

Note: The service settings are inaccessible to the user. An Erbe service engineer can adjust/change the service settings based on your requirements.

Important service settings affecting operation of the unit include for example:

- Maximum ON time: Time period after which the unit automatically interrupts activation after sustained use (the unit can be reactivated at any time).

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Factory unit settings

Programs and program-parameters

The programs were programmed at the factory. They can be used for certain instruments or instrument combinations without having to make any changes to the program parameters.

Program 1: "Bipolar with footswitch"

For using a bipolar instrument with footswitch activation. Example: Bipolar forceps.

A monopolar instrument with fingerswitch activation can also be used. Example: Handpiece with monopolar electrode.

Program 2: "Monopolar with fingerswitch"

For using a monopolar instrument with fingerswitch activation. Example: Handpiece with monopolar electrode.

A bipolar instrument with footswitch activation can also be used. Example: Bipolar forceps.

Program 3: "Bipolar with AUTO START"

Available for VIO 100 C only.

For using a bipolar instrument with AUTO START activation. Example: Bipolar forceps.

A monopolar instrument with footswitch activation can also be used. Example: Handpiece or LAP instrument.

Program 4: "Monopolar with footswitch"

Available for VIO 100 C only.

For using a monopolar instrument with footswitch activation. Example: Handpiece or LAP instrument.

A bipolar instrument with AUTO START activation can also be used. Example: Bipolar forceps.

Note: The applications described only apply as long as the factory settings for "Socket in focus at program start", "Footswitch assignment" or "AUTO START" have not be changed and thus correspond to the following table.

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Program parameters at a glance

The following settings are specified at the factory for the programs:

	Program 1	Program 2	Program 3 (VIO 100 C only)	Program 4 (VIO 100 C only)
Socket in focus at program start	Bipolar socket	Monopolar socket	Bipolar socket	Monopolar socket
Footswitch assignment	Bipolar socket		Monopolar socket	
AUTO START bipolar socket	VIO 50 C: not available VIO 100 C: not assigned		Assigned (active)	
COAG mode bipolar socket	BIPOLAR (= BIPOLAR SOFT COAG)			
COAG power limitation bipolar socket	30 watts			
CUT mode monopolar socket	AUTO CUT	DRY CUT	AUTO CUT	DRY CUT
CUT power limitation monopolar socket	40 watts	40 watts	40 watts	40 watts
COAG mode monopolar socket	SOFT COAG	FORCED COAG	SOFT COAG	FORCED COAG
COAG power limitation monopolar socket	30 watts	30 watts	30 watts	30 watts

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Resetting to factory settings

An Erbe service technician can reset the program parameters to the factory settings listed in the table above as required.

Important service settings

- Maximum ON time: 99 seconds

Checking the unit and accessories

⚠ WARNING

Damaged unit, damaged accessories, modified unit, and modified accessories

Risk of electric shock to the patient and medical personnel!

Risk of injury to patient and medical personnel!

Risk of burns to the patient and medical personnel!

Risk of material damage.

⇨ Check the unit and accessories for damage before each use (e.g. footswitch, instrument cables and cart).

⇨ You must not use a damaged unit or damaged accessories. Replace defective accessories.

⇨ If the unit or cart is damaged, please contact our customer service.

⇨ Blown power fuses may only be replaced by a competent technician.

⇨ For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of Erbe Elektromedizin GmbH.

Connect footswitch

Note: When connecting the footswitch, make sure that you insert the 4 pins on the plug of the connecting cable with the correct alignment into the corresponding contacts of the footswitch socket.

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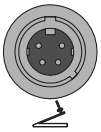


➢ Connect the one pedal or two pedal footswitch VIO C on the back of the unit to the footswitch socket.

Connect unit and switch on

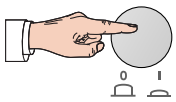
Make power connection

Note: Use the compatible Erbe power cord (see the *Accessories, Compatible power cords* chapter).

1. Check that the line voltage matches the voltage specified on the unit's rating plate.
2. Connect the unit to a properly installed grounded outlet.

Switch on unit

Note: When restarting, the unit always loads the program last used when the unit was switched off. The saved program settings are loaded. Any program changes not saved from the last time the unit was used are no longer available.



1. Use the power switch to switch the unit on and observe the display elements.
   The unit then carries out a self-test and checks all sockets. All display elements illuminate. After completing the self-test, the settings of the active program flash.

Note: If a display element does not illuminate during the self-test, the display element is defective. A unit with a defective display element must not be used.

2. Check the visible settings and confirm by pressing any button, e.g. selection button.

Select/switch program

➢ If you want to use program different than the program currently displayed, press the selection button next to the program display.

Connect monopolar/bipolar instruments

You can connect a monopolar instrument and a bipolar instrument to the unit at the same time. However, for safety reasons they can only be activated alternately. HF voltage is only ever carried by one socket.

Note: When using an instrument make sure you also observe the notes on use for the instrument.

⚠ WARNING

Electric load on instrument too high

The instrument can be damaged.

If the damaged area comes into contact with tissue, it can lead to unintentional coagulation.

⇨ Determine the electrical capacity of the instrument. It is either printed on the instrument or can be found in the User Manual. Compare the electrical capacity of the instrument with the maximum HF peak voltage of the required mode.

⇨ Instructions are available in the "Accessories" chapter.

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NOTICE

Mix-up of sockets on monopolar socket modules 20140-622, 20140-623

If the sockets are mixed up, the unit will be damaged.

⇨ If you use a connecting cable with a monopolar 4 mm dia. connector, you may only plug the connector into the socket with the blue ring. The correct socket is marked with an arrow on the illustration.

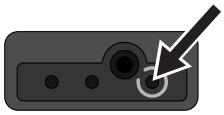

Fig. 6-1

"BI" 

1. Connect your bipolar instrument to the bipolar socket (top unit socket).

"MO" 

2. Connect your monopolar instrument to the monopolar socket (middle unit socket).

Connect neutral electrode

You always need a neutral electrode if you use a monopolar instrument.

You can connect a single surface or dual surface neutral electrode.

⚠ WARNING

Non-compatible or single surface neutral electrode

When applying a non-compatible neutral electrode, it should be expected that monitoring the contact between neutral electrode and skin is faulty.

When applying a single surface neutral electrode, the contact between neutral electrode and skin is not monitored. If contact between neutral electrode and skin is inadequate, the unit does not emit any visual and acoustic signal.

Risk of burns for the patient under the neutral electrode!

⇨ Check in the accompanying papers of the manufacturer whether the neutral electrode is suitable for the VIO unit used.

⇨ Use only suitable neutral electrodes.

⇨ When applying a single surface neutral electrode: Regularly check the neutral electrode for good skin contact.

⇨ Check in the accompanying papers of the manufacturer whether the neutral electrode cable is suitable for the neutral electrode used.

⇨ Use only suitable neutral electrode cables.

To optimally utilize the unit's monitoring functions, Erbe recommends connecting a dual surface electrode, and in particular the Erbe NESSY Omega electrode. Apart from many other advantages, this electrode virtually eliminates any possibility of excessive heating of the tissue and skin at the edges of the electrode.

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For a dual surface electrode: Connect connecting cable to the unit and test

⚠ WARNING

Short circuit in the connecting cable or in the clip of a dual surface neutral electrode

If a short circuit occurs in the connecting cable or in the clamp of a dual surface neutral electrode, the unit can no longer monitor the contact with the patient's skin. You will not receive a warning if the electrode becomes detached from the skin.

Risk of burns to the patient!

⇨ To rule out the possibility of a short circuit in the connecting cable and in the clamp before using the unit, test the connecting cable as described below.

The following requirements must be met for the test:

- For a neutral electrode without a permanent connecting cable: The cable must not be connected to the neutral electrode.
- For a neutral electrode with a permanent connecting cable: The neutral electrode must not be applied to the patient.

"NE" 

1. Plug the connecting cable into the neutral electrode socket (bottom unit socket).
2. Check the neutral electrode indicator light next to the neutral electrode socket.

Fig. 6-2

Note: The signal assignment described below (red = no short circuit; green = short circuit) is technically determined and correct.

If the neutral electrode indicator lamp is red, there is no short circuit. The cable may be used.

If the neutral electrode indicator lamp is green, there is a short circuit. The cable must not be used.

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For a single surface neutral electrode: Connect connecting cable to the unit

A short circuit test is not required / not available for a single surface neutral electrode.

"NE" 

➢ Plug the connecting cable into the neutral electrode socket (bottom unit socket).

Attach neutral electrode to patient

⚠ WARNING

Positioning the neutral electrode above the heart

Risk of cardiac arrhythmia for the patient due to function-related currents from neutral electrode monitoring!

⇨ Do not position the neutral electrode over the heart or in the region of the heart.

⚠ WARNING

Incorrect application of the neutral electrode

Risk of burns to the patient!

⇨ Apply the entire contact surface of the neutral electrode to a muscular part of the body with good blood circulation.

⇨ Apply the neutral electrode as close as possible to the surgical site.

⇨ Insert the contact tab of the neutral electrode completely into the connecting clamp. The contact tab must not touch the patient's skin. (For reusable cord with disposable pads only.)

⇨ Align the symmetry line of the neutral electrode towards the operating field. The current should flow from the active electrode (instrument) to the symmetry line of the neutral electrode.

⇨ Check the neutral electrode regularly for good contact with the patient's skin.

⇨ Check the neutral electrode especially when the patient has been repositioned and after surgical steps where the unit was activated frequently and for a long time.

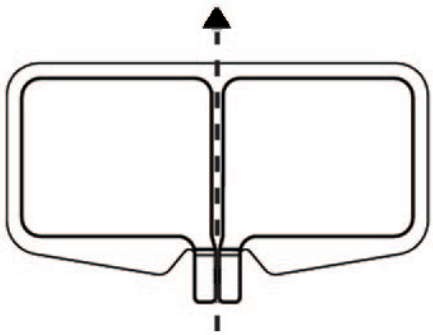

Fig. 6-3

1. Apply the neutral electrode to the patient.
2. For neutral electrodes without a permanent connecting cable: Connect the neutral electrode to the connecting cable.
3. Check the neutral electrode indicator light next to the neutral electrode socket.

Fig. 6-4

Display green: The monopolar socket can be activated.

Display red: The monopolar socket cannot be activated.

If you attempt to activate the monopolar socket when the indicator light is red, a tone sounds and the error number "2" is displayed.

Possible causes:

- Connection to unit interrupted
- Contact tab of electrode not completely inserted into connecting clamp
- Insufficient contact between skin and electrode (only monitored with dual surface electrode!)

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Rectify error

1. If the indicator light is red when a **single surface** neutral electrode is connected, check the first two of the sources of error above and remedy the error if necessary.
   If the indicator light is red when a **dual surface** neutral electrode is connected, check all of the sources of error above and remedy the error if necessary.
2. In case of doubt, remove the neutral electrode and check the condition of the skin (skin must be shaven and dry).
3. Dispose of the neutral electrode you removed and apply a new neutral electrode to the patient.

Monitor neutral electrode during use

If one of the errors above occurs again during use, the neutral electrode indicator light switches from green to red. If you attempt to activate the monopolar socket when the indicator light is red, a tone sounds and the error number "2" is displayed.

➢ Eliminate any error if necessary.

Check program settings

⚠ WARNING

Activation of the unit with no knowledge of active settings

If the user does not understand the active settings of the unit, he can cause the patient accidental tissue damage.

⇨ Check the active settings on the display of the unit, after: switching on the unit, connecting up an instrument, and changing the program.

Check assignment of the footswitch/AUTO START function

➢ Watch the indicator lights of the instrument sockets on your VIO.
Two examples are shown in the following illustration.

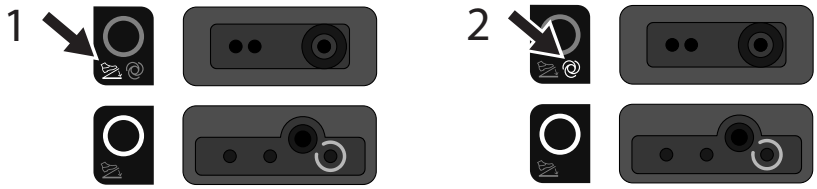

Fig. 6-5

Example 1	Example 2
The footswitch indicator light of the bipolar socket illuminates: The footswitch is assigned to the bipolar socket.	The AUTO START indicator light illuminates: The AUTO START function is assigned to the bipolar socket (available for the VIO 100 C only).
In this case, you activate the HF current of the bipolar socket with the footswitch.	The COAG current is automatically activated if you grasp tissue with the bipolar instrument.

How to assign the footswitch to a socket is described on page 60.

How to assign the AUTO START function to the bipolar socket is described on page 60.

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Check instrument socket settings

Focus View

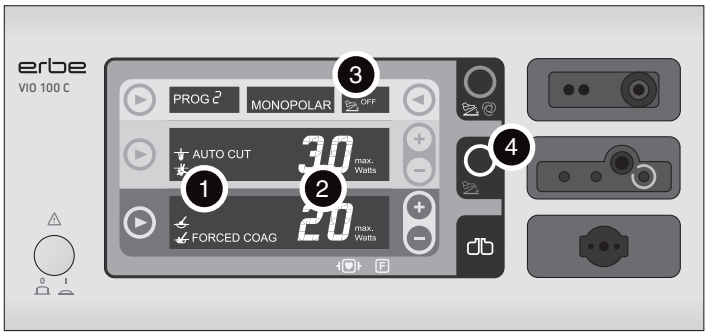


Fig. 6-6

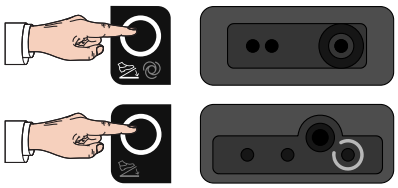
The VIO display always shows the settings of one socket only. The socket in focus (selected) can be identified by the illuminated focus button **(4)**. The following settings of the socket in focus are displayed:

- **(1)** CUT and COAG mode
- **(2)** CUT and COAG power limitation
- **(3)** Assignment of the footswitch or AUTO START function (AUTO START function available for the VIO 100 C only)

You can bring a socket into focus by pressing the Focus button of the socket or by activating an instrument connected to the socket.

CAUTION! If you activate an instrument, be careful not to touch any persons or objects!

Check the settings as follows:



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1. If you are using the bipolar socket: Bring the bipolar socket into focus and check the settings on the display.
2. If you are using the monopolar socket: Bring the monopolar socket into focus and check the settings on the display.

How to change the unit settings is described on page 59.

Using the unit (cutting/coagulation)

⚠ WARNING

Very long activation cycles without cooling phases

The electrosurgical unit is designed and tested for a relative activation time of 25% (in accordance with IEC 60601-2-2). If you perform long activation phases without the appropriate cooling phases, there may be gradual heating under the neutral electrode or the unit may be damaged.

Risk of burns to the patient!

⇨ Keep to the 25 % relative ON time (see also Technical Data, Operating Mode), if you operate the unit for a lengthy period.

An instrument switch, footswitch or the AUTO START function (available for the VIO 100 C only) can be used to activate the HF current.

Note: If you activate the HF current of a socket currently not in focus, the socket focus changes and the settings of the activated socket are displayed.

Use the footswitch to activate the HF current

Note: The footswitch is always used to activate the CUT or COAG current of the socket to which the footswitch is assigned. This even applies when the other socket is in focus before activation (the Focus button of the other socket is shining)!

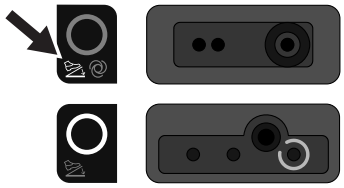

Fig. 6-7

Example (illustration above): The footswitch indicator light of the bipolar socket illuminates: The footswitch is assigned to the bipolar socket. In this case, you activate the HF current of the bipolar socket with the footswitch.

How to assign the footswitch to a socket is described on page 60.

➢ Press the CUT or COAG pedal of your footswitch.
A tone sounds and the Focus button of the activated socket lights up yellow or blue.
The CUT or COAG current is activated.

Use the fingerswitch to activate the HF current

Note: If you use an instrument with fingerswitch, you can activate the instrument independently of the current footswitch assignment using the fingerswitch.

➢ Press the CUT or COAG switch of your instrument.
A tone sounds and the Focus button of the activated socket lights up yellow or blue.
The CUT or COAG current is activated.

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Activating with AUTO START (available for the VIO 100 C only)

The AUTO START function is only available for the COAG current of the bipolar socket.

The AUTO START function causes the COAG current to activate automatically after you have used a bipolar instrument to grasp the tissue to be coagulated.

The power limitation level can be set to max. 50 watts.

You can use the AUTO START function if the AUTO START indicator light of the bipolar socket is illuminated.

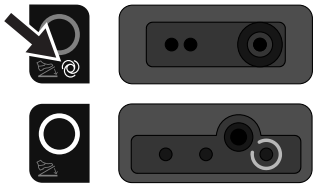

Fig. 6-8

How to assign the AUTO START function to the bipolar socket is described on page 60.

➢ Use the bipolar instrument to grasp the tissue to be coagulated.
The unit activates the COAG current automatically.

Activation of the COAG current ends when you open or remove the instrument from tissue.

Change power limitation

To optimize the coagulation results, it may be necessary to change the CUT or COAG power limitation during use.

The power limitation is a measure of the intensity of the coagulation for both the CUT and COAG modes. A higher power limitation means faster coagulation or a deeper coagulation zone during the same activation period.

A power limitation as low as possible protects the patient and instrument from injury or damage.

⚠ WARNING

Power setting too high, ON time too long

The higher the power setting, the longer the ON time of the unit, the greater the risk of accidental tissue damage.

Risk of accidental tissue damage to the patient!

⇨ Set power as low as possible relative to the required surgical effect. If the required surgical effect is not achieved, increase the power.

⇨ Activate the unit for as short a time as possible relative to the required surgical effect.

⇨ The temperature at the neutral electrode site increases during long and continuous activations; therefore, ensure that the cooling phases between activations are sufficient.

⇨ If you are unable to achieve a surgical effect with a power setting / ON time that is sufficient judging from experience, this can be due to a problem with the electrosurgical unit or accessories:

⇨ Check the instrument regularly for soiling with insulating tissue remnants. Clean the instrument if it has become soiled.

⇨ Check the neutral electrode to make sure it is secure.

⇨ Check the connectors on all cords to make sure they are secure.

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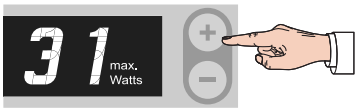
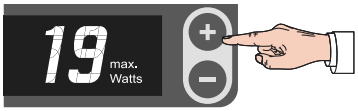


1. To change the CUT power limitation, press the Plus/Minus buttons next to the watt display in the CUT setting area.



2. To change the COAG power limitation, press the Plus/Minus buttons next to the watt display in the COAG setting area.

Clean unit

1. Clean the unit after each use (see chapter about cleaning on page 89).
2. Clean/disinfect and sterilize all reusable accessories and instruments according to the manufacturers' instructions.
3. Dispose of single-use parts in line with the local/national regulations and also the manufacturers' instructions where appropriate.

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Change program settings

Program settings should only be made by knowledgeable personnel who are familiar with the functions of the unit in all details and are able to assess the effects of the settings selected.

Note: When setting the unit take note of the description of the CUT and COAG modes on page 69 ff.

1. Use the selection button next to the program display to choose the program you want to change.
2. Make the required changes for one or both sockets one after the other and save the settings (see the following sections).

The following describes changes to program settings using Program 2 as an example.

Focus socket

This socket has to be focused to change the settings for a specific socket.

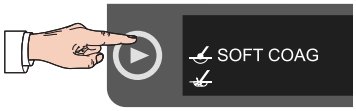
The unit always displays the settings of the socket currently in focus. The socket currently in focus can be identified by the illuminated Focus button.

➢ Press the Focus button of the socket for which you want to perform settings (e.g. the Focus button of the monopolar socket).
The selected socket is focused.
The current settings of the socket in focus are displayed.

Change mode

A description of the CUT and COAG modes can be found on page 69 ff.

1. To change the CUT mode, press the selection button next to the display of the CUT mode in the CUT setting area.



2. To change the COAG mode, press the selection button next to the display of the COAG mode in the COAG setting area.

Change power limitation

The power limitation is a measure of the intensity of the coagulation for both the CUT and COAG modes. A higher power limitation means faster coagulation or a deeper coagulation zone during the same activation period.

A power limitation as low as possible protects the patient and instrument from injury or damage.

⚠ WARNING

Power setting too high

The higher the power setting, the higher the risk of accidental tissue damage.

Risk of accidental tissue damage to the patient!

⇨ Set power as low as possible relative to the required surgical effect. If the required surgical effect is not achieved, increase the power.

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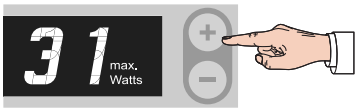
1. Make sure that the socket required is in focus and the mode required is set.



2. To change the CUT power limitation, press the Plus/Minus buttons next to the watt display in the CUT setting area.

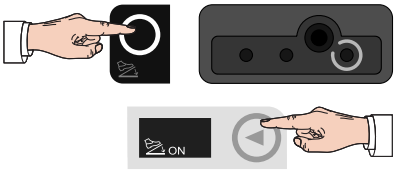
3. To change the COAG power limitation, press the Plus/Minus buttons next to the watt display in the COAG setting area.

Perform settings for the second socket

➢ Repeat the previous setting steps as required (starting from "Focus socket") for the second socket.

Assign the footswitch to the monopolar or bipolar socket

Note: You can only assign the footswitch to a socket if the socket is in focus.



1. Press the Focus button of the socket to which you want to assign the footswitch (e.g. the Focus button of the monopolar socket).

2. Use the selection button next to the display of the activation type to choose the "ON" setting.
   The footswitch indicator light of the socket in focus illuminates.

Fig. 6-9

Assign the AUTO START function to the bipolar socket (available for the VIO 100 C only)

The AUTO START function is only available for the COAG current of the bipolar socket.

Note: You can assign either the footswitch or the AUTO START function to the bipolar socket, but not both.

Note: You can only assign the footswitch to the bipolar socket if the bipolar socket is in focus.

1. Press the Focus button of the bipolar socket.

2. Use the selection button next to the display of the activation type to choose the "AUTO" setting.
   The AUTO START indicator light of the bipolar socket illuminates.

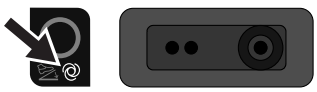


Fig. 6-10

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Determine the socket in focus at program start

Which socket is in focus at program start is determined in each program.

If you resave a program, the socket that was in focus when saving the program is in focus each time the program is started thereafter.

➢ Before saving the program, press the Focus button of the socket that should be in focus any time the program is called up in the future (e.g. the Focus button of the monopolar socket).

Save program settings

Note: Amended program settings are not accepted automatically but have to be saved manually.

➢ To save the changed settings in the active program, press the selection button next to the program display for approx. 3 seconds.

A progress indicator appears under the program name. A tick then confirms that the save process was successful.

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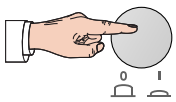
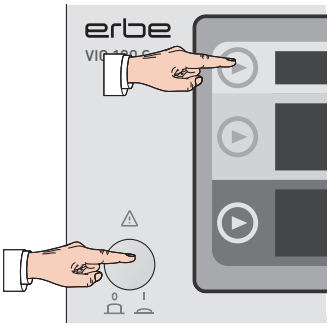
Change setup settings (signal volume, display brightness)



1. If your unit is on, use the power switch to turn the unit off.



2. Press and hold the top left selection button and turn the unit ON (again).
   Once you release the selection button, setup number "1" appears on the display.

Fig. 6-11

You can amend the following setup settings:

No.	Setup settings
1	Volume of the audible signal for CUT activation
2	Volume of the audible signal for COAG activation
3	Volume of the audible signal when pressing a unit button
4	Volume of the audible signal for error message (warning tone)
5	Display brightness

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3. Use the Plus/Minus buttons on the right next to the setup number to select the number of the setting you want to change (e.g. the "2" for the setup setting "Volume of the audible signal for COAG activation"; see table above).

4. Press the selection button on the left next to the setup number.
   A number appears at the bottom of the display. The number stands for the volume (or brightness) currently set.

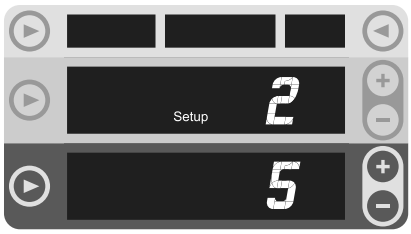


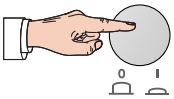
Fig. 6-12

5. Use the bottom right Plus/Minus buttons to select the required volume (or brightness).

6. To save the change setting, press the top left selection button for approx. 3 seconds.

   A progress indicator appears next to the selection button in the display segment. A tick then confirms that the save process was successful.

7. If you want to change other setup settings, repeat steps 3 to 6.



8. If you want to continue using the unit after making the settings, turn the unit off and then on again.

Change service settings

Note: The service settings are inaccessible to the user. An Erbe service engineer can adjust/change the service settings based on your requirements.

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Behavior when an error message appears

The VIO 50 C/VIO 100 C can identify various operating and system errors during operation. An error number is assigned to each error that appears on the display when the error occurs.

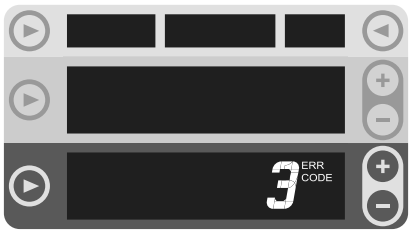

Fig. 6-13

A description of the messages and any action required can be found at the back of this User Manual on page 93.

In the event of a message being shown on the display proceed as follows:

1. Use the table on page 93 to check whether you can resolve or prevent the error.
2. If the error cannot be corrected by action described in this User Manual and/or recurs, Erbe Service should be informed.

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Chapter 7
Description of socket hardware

Sockets for different modes and instrument connectors

In this chapter the sockets are described from the aspect of their usage and compatibility with various instrument connectors.

Cutting and coagulation modes

Specific cutting and coagulation modes are allocated to the sockets. Via the monopolar socket you can thus activate AUTO CUT and SOFT COAG for example. If you require SOFT COAG for one of your applications, the monopolar socket is used.

Instrument compatibility

The VIO electrosurgical unit is sold all over the world. The standard instrument connectors vary from country to country. To ensure your instruments can be connected to the electrosurgical unit, the sockets are available in various designs.

Bipolar socket

Coagulation modes

Only the following mode is available for the bipolar socket:

- BIPOLAR (= BIPOLAR SOFT COAG)

Instrument compatibility

Socket module BI 8/4

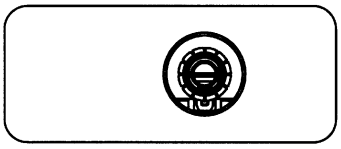

Fig. 7-1

REF No. 20140-610

The socket module is suitable for the following connectors: Bipolar connector based on Erbe standard. Rear contact ring dia. 8 mm, front contact ring dia. 4 mm.

Socket module BI 2 pin 22 – 28 – 8 / 4

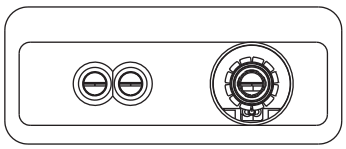

Fig. 7-2

REF No. 20140-613

You can connect ONE of the following connectors, as required: international bipolar connector with 2 pins (pin spacing 22 mm); international bipolar connector with 2 pins (pin spacing 28.5 mm); Erbe standard bipolar connector.

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Monopolar socket

Cutting and coagulation modes

The following modes are available for the monopolar socket:

- AUTO CUT
- DRY CUT
- SOFT COAG
- FORCED COAG

Instrument compatibility

Socket module MO 3-pin Bovie

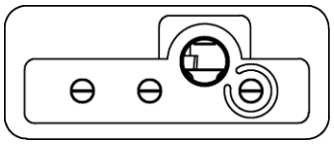

Fig. 7-3

REF No. 20140-622

You can connect ONE of the following connectors as required: a monopolar 3-pin connector; a Bovie connector; a monopolar connector dia. 4 mm to the input marked blue.

Socket module MO 3-pin 9 / 5

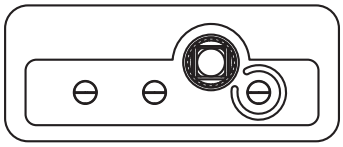

Fig. 7-4

REF No. 20140-623

You can connect ONE of the following connectors as required: a monopolar 3-pin connector; a monopolar socket based on Erbe standard; a monopolar connector dia. 4 mm to the input marked blue.

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Socket for neutral electrode

Function

The socket is used to connect a neutral electrode with monopolar modes.

Connector compatibility

Socket module NE 6

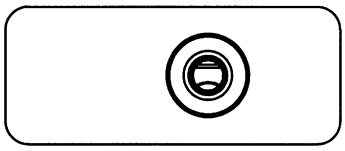

Fig. 7-5

REF No. 20140-640

The socket module is suitable for the following connectors: Erbe neutral electrode connector Ø 6.35 mm.

Socket module NE 6 and NE 2-pin

Fig. 7-6

REF No. 20140-642

You may connect ONE of the following plugs: Erbe neutral electrode plug with Ø 6.35 mm; neutral electrode plug with 2 pins. The socket is equipped with a slide switch that allows you to connect the plug with Ø 6.35 mm or the plug with 2 pins based on the position of the socket (see illustration above).

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Chapter 8
Monopolar Modes

AUTO CUT

Properties Reproducible, extremely tissue-sparing cuts, minimal to medium hemostasis.

Areas of use All cutting procedures in electrically conductive tissue: e.g. muscle tissue and vascular tissue. Dissections and cutting of fine structures.

Suitable electrodes Needle electrodes, knife electrodes, spatula electrodes.

Technical data

HF voltage waveform	unmodulated sinusoidal alternating voltage
Rated frequency	550 kHz (at R_L = 500 Ω) ± 10 %
Crest factor	1.6 (at R_L = 500 Ω)
Rated load resistor	500 Ω
Max. HF peak voltage	570 Vp
HF power limitation	VIO 50 C: 1 watt to 50 watts in 1 watt steps VIO 100 C: 1 watt to 100 watts in 1 watt steps
Max. power output at rated load resistor	VIO 50 C: 50 watts ± 20 % VIO 100 C: 100 watts ± 20 %
Max. RMS current (maximum HF output current in normal use)	VIO 50 C: 195 mA VIO 100 C: 224 mA

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Diagrams

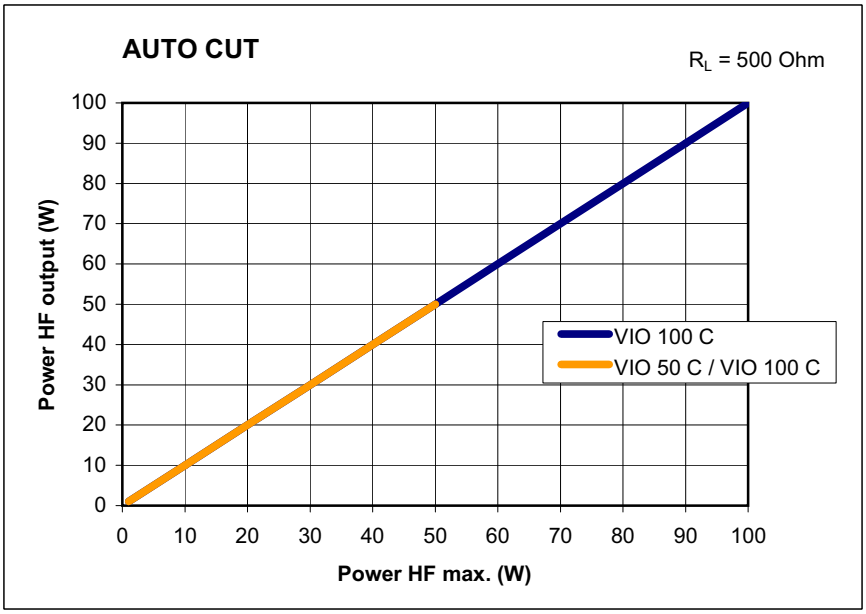

Fig. 8-1

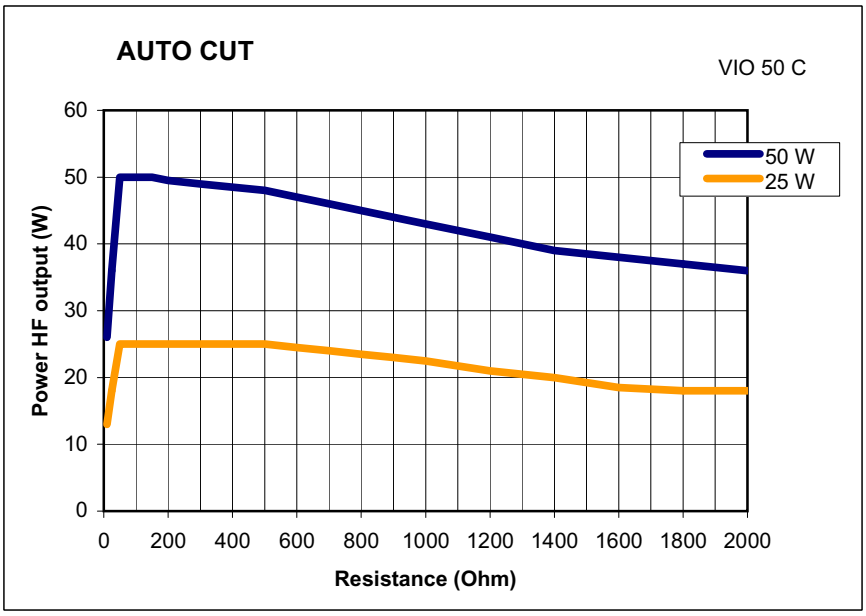

Fig. 8-2

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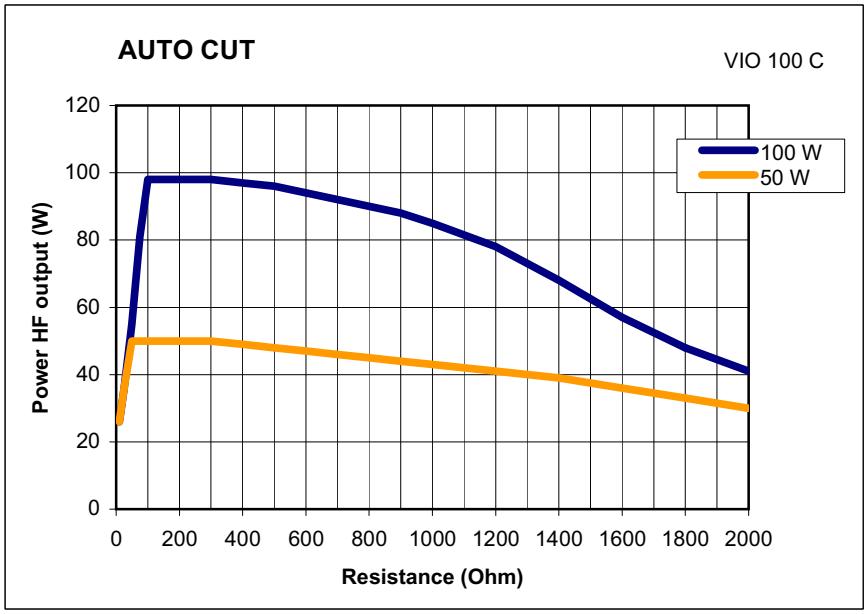

Fig. 8-3

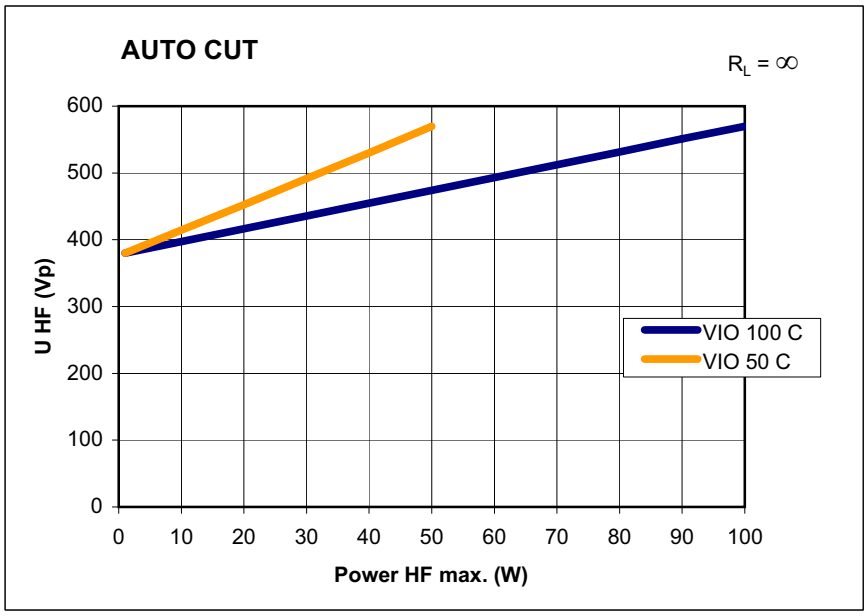

Fig. 8-4

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DRY CUT

Properties Intense hemostasis with somewhat slower cutting speed.

Areas of use All cutting procedures that require very good primary hemostasis during the cut and tolerate a somewhat slower cutting process.

Suitable electrodes Needle electrodes, knife electrodes, spatula electrodes.

Technical data

HF voltage waveform	pulse-modulated sinusoidal alternating voltage
Rated frequency	540 kHz (at R_L = 500 Ω) ± 10 %
Crest factor	2.4 (at R_L = 500 Ω)
Rated load resistor	500 Ω
Max. HF peak voltage	900 Vp
HF power limitation	VIO 50 C: 1 watt to 50 watts in 1 watt steps VIO 100 C: 1 watt to 100 watts in 1 watt steps
Max. power output at rated load resistor	VIO 50 C: 50 watts ± 20 % VIO 100 C: 100 watts ± 20 %
Max. RMS current (maximum HF output current in normal use)	VIO 50 C: 200 mA VIO 100 C: 330 mA

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Diagrams

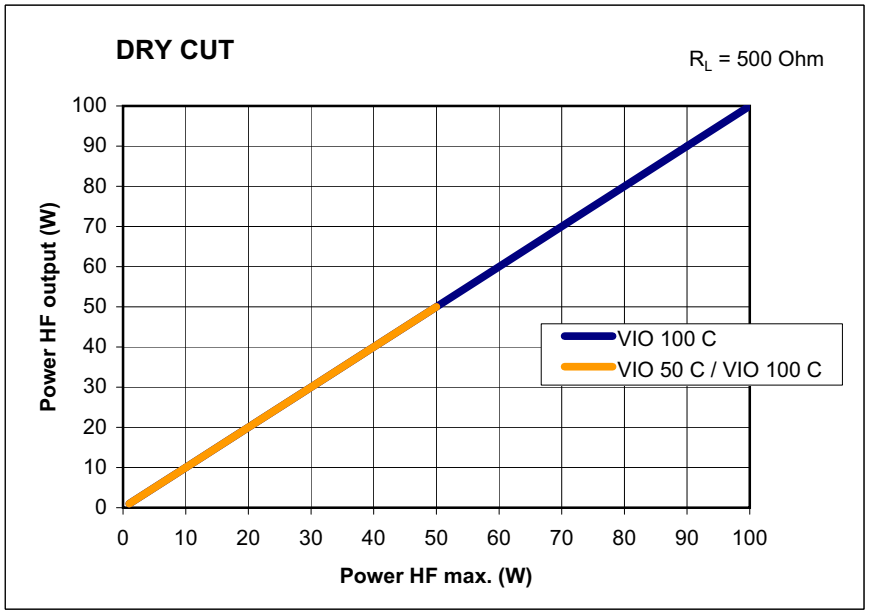

Fig. 8-5

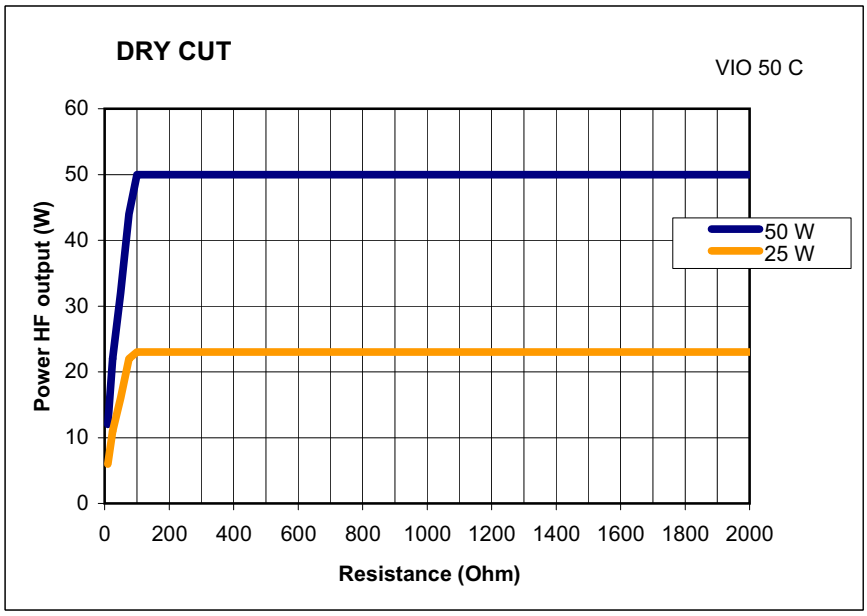

Fig. 8-6

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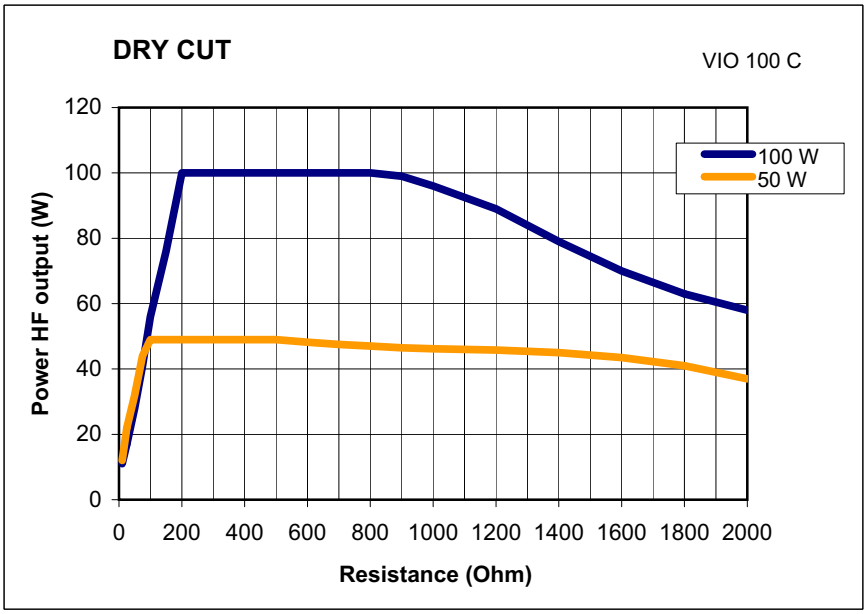

Fig. 8-7

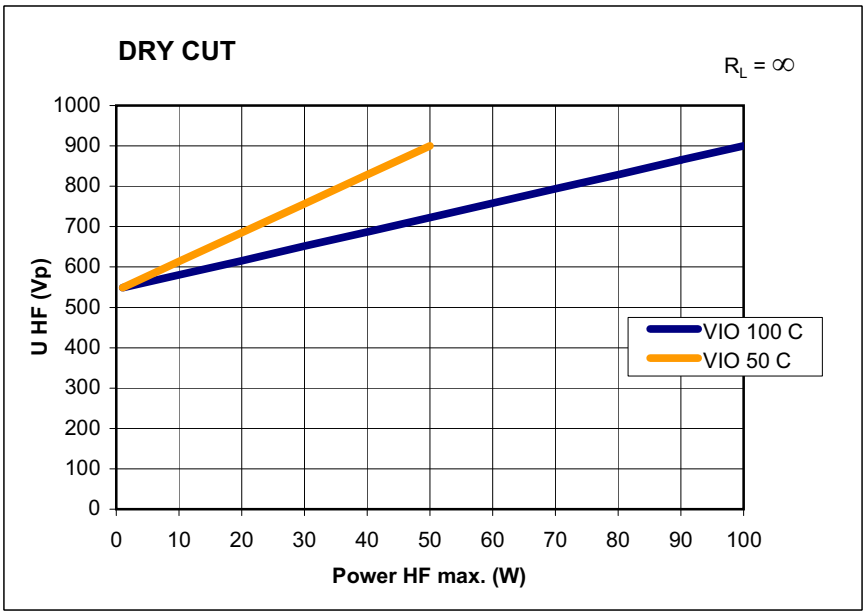

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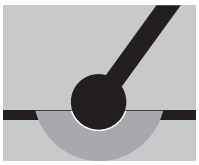
Fig. 8-8

SOFT COAG



Properties

There is no sparking which prevents carbonization of the tissue and reduces adhesion of the electrode to the tissue considerably.

Areas of use

All surgical procedures that call for safe, intense coagulation or in which adhesion of the electrode would have a negative effect on the coagulation process.

Suitable electrodes

Ball electrodes, knife electrodes, spatula electrodes.

Technical data

HF voltage waveform	unmodulated sinusoidal alternating voltage
Rated frequency	550 kHz (at R_L = 500 Ω) ± 10 %
Crest factor	1.5 (at R_L = 500 Ω)
Rated load resistor	100 Ω
Max. HF peak voltage	190 Vp
HF power limitation	VIO 50 C: 1 watt to 50 watts in 1 watt steps VIO 100 C: 1 watt to 80 watts in 1 watt steps
Max. power output at rated load resistor	VIO 50 C: 50 watts ± 20 % VIO 100 C: 80 watts ± 20 %
Max. RMS current (maximum HF output current in normal use)	VIO 50 C: 300 mA VIO 100 C: 400 mA

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Diagrams

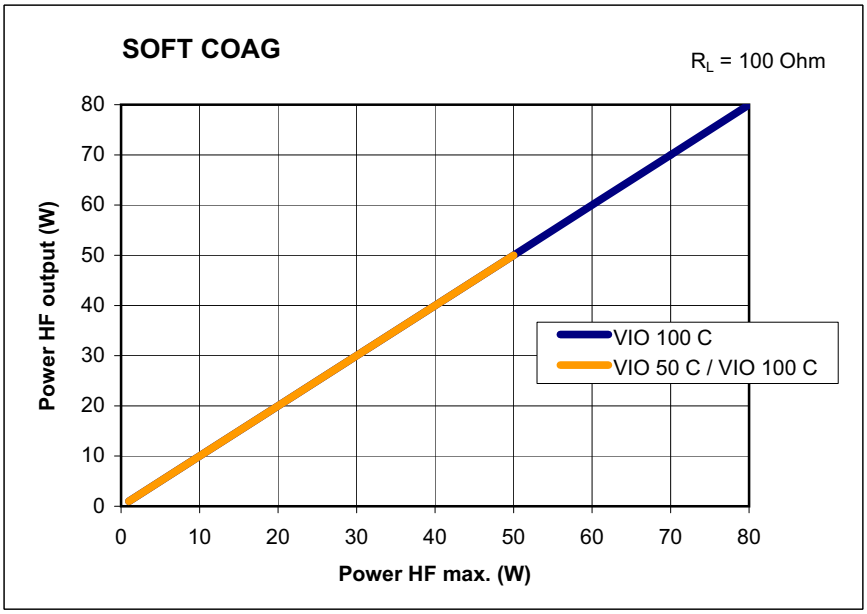

Fig. 8-9

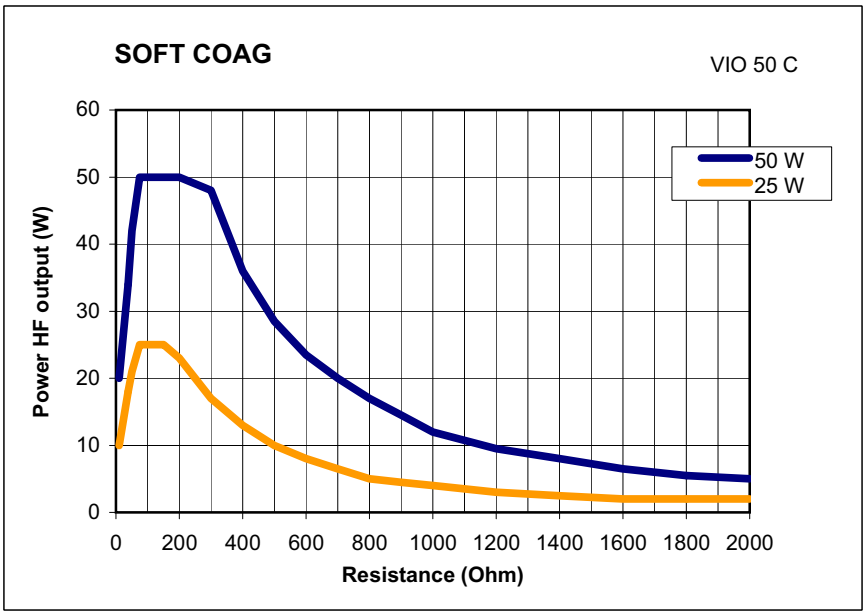

Fig. 8-10

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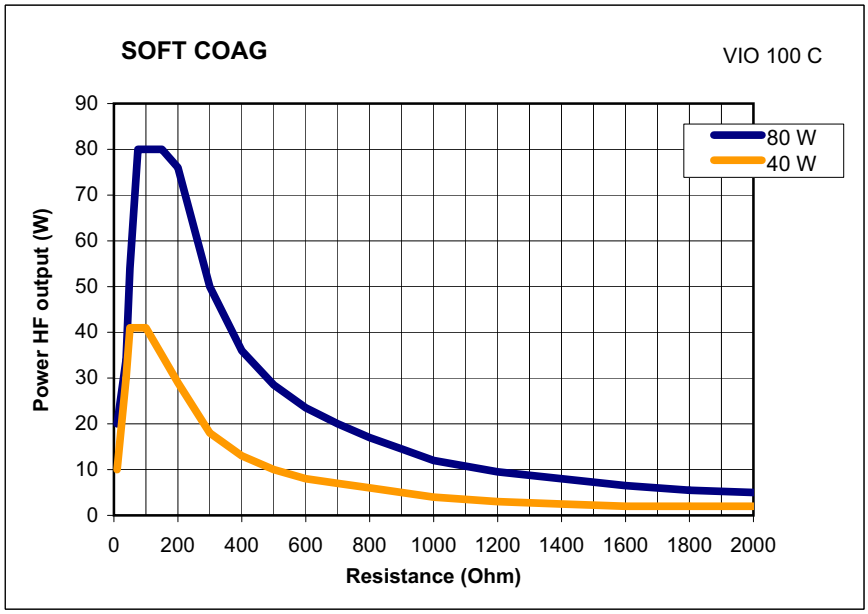

Fig. 8-11

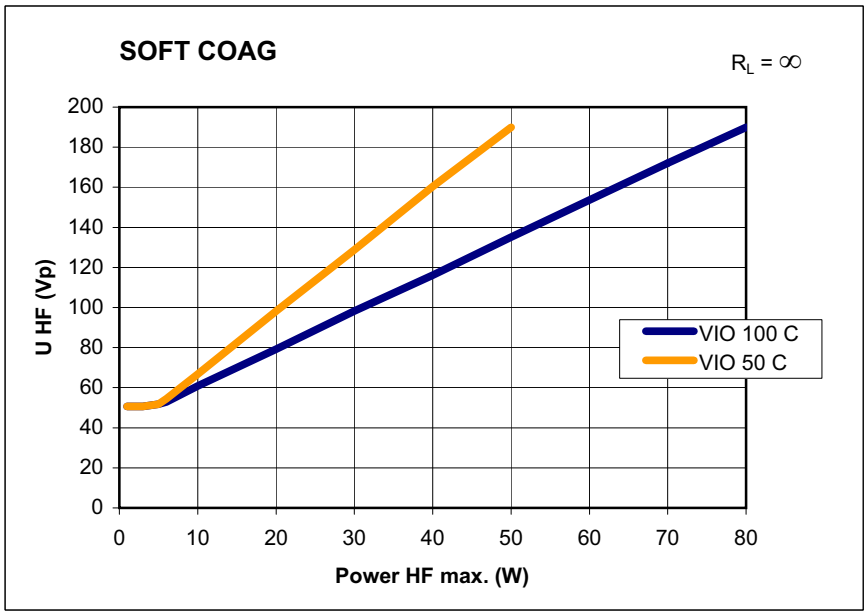

Fig. 8-12

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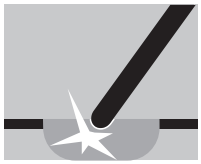
FORCED COAG



Properties Effective, fast standard coagulation with sparking.

Areas of use All surgical procedures that require fast and effective coagulation.

Suitable electrodes Ball electrodes, knife electrodes, spatula electrodes for contact coagulation. Insulated monopolar forceps for clamp coagulation.

Technical data

HF voltage waveform	pulse-modulated sinusoidal alternating voltage
Rated frequency	510 kHz (at R_L = 500 Ω) ± 10 %
Crest factor	5.0 (at R_L = 500 Ω)
Rated load resistor	500 Ω
Max. HF peak voltage	1300 Vp
HF power limitation	1 watt to 50 watts in 1 watt steps
Max. power output at rated load resistor	50 watts ± 20 %
Max. RMS current (maximum HF output current in normal use)	160 mA

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Diagrams

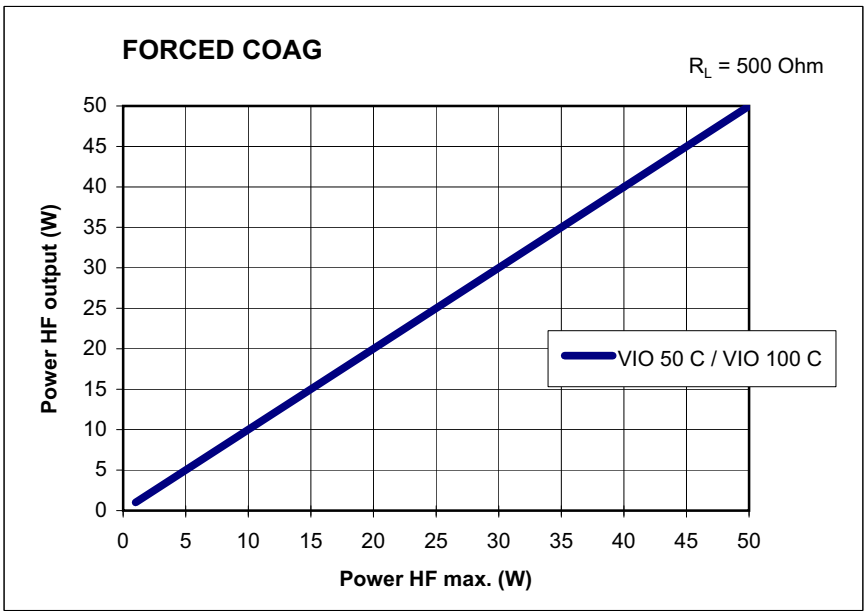

Fig. 8-13

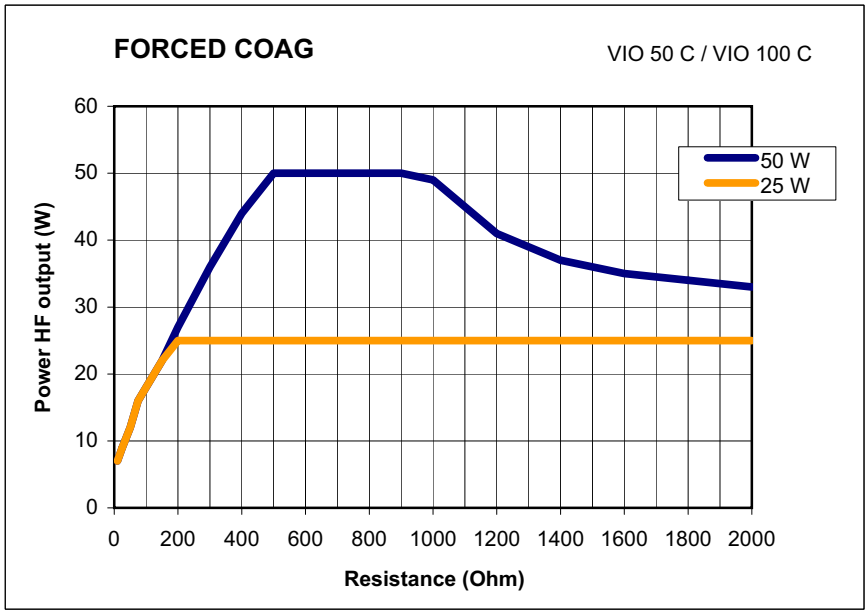

Fig. 8-14

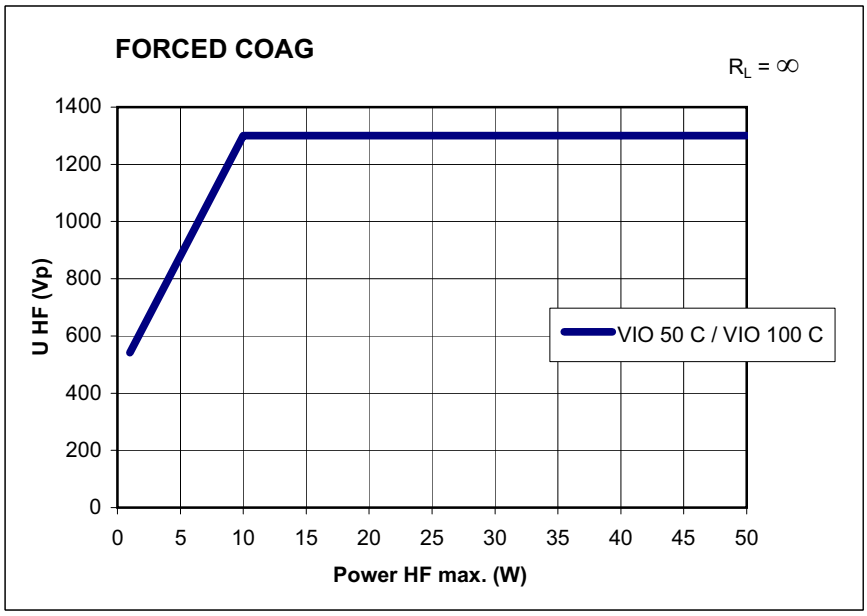

Fig. 8-15

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Chapter 9
Bipolar Modes

BIPOLAR (= BIPOLAR SOFT COAG)

Properties

There is no sparking which prevents carbonization of the tissue and reduces adhesion of the electrode to the tissue considerably.

Areas of use

All surgical procedures that require safe coagulation with bipolar instruments.

AUTO START

Available for the VIO 100 C only.

You can assign the AUTO START function to the bipolar socket – and thus the BIPOLAR SOFT COAG mode – in the area for selecting the activation type.

The AUTO START function causes the COAG current to activate automatically after you have used a bipolar instrument to grasp the tissue to be coagulated.

Suitable electrodes

Bipolar instruments, e.g. bipolar forceps.

Technical data

HF voltage waveform	unmodulated sinusoidal alternating voltage
Rated frequency	550 kHz (at R_L = 500 Ω) ± 10 %
Crest factor	1.5 (at R_L = 500 Ω)
Rated load resistor	100 Ω
Max. HF peak voltage	190 Vp
HF power limitation	VIO 50 C: 1 watt to 50 watts in 1 watt steps VIO 100 C: 1 watt to 80 watts in 1 watt steps
Max. power output at rated load resistor	VIO 50 C: 50 watts ± 20 % VIO 100 C: 80 watts ± 20 %

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Diagrams

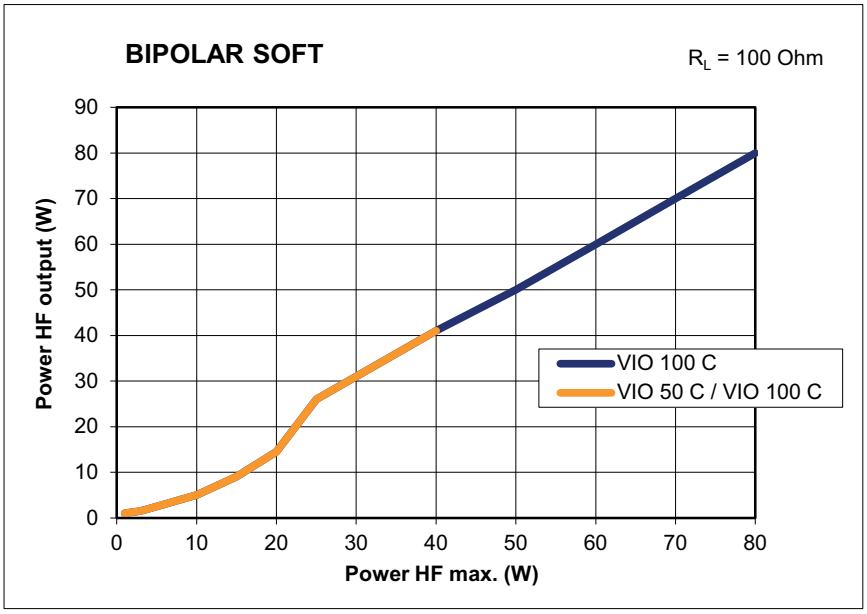

Fig. 9-1

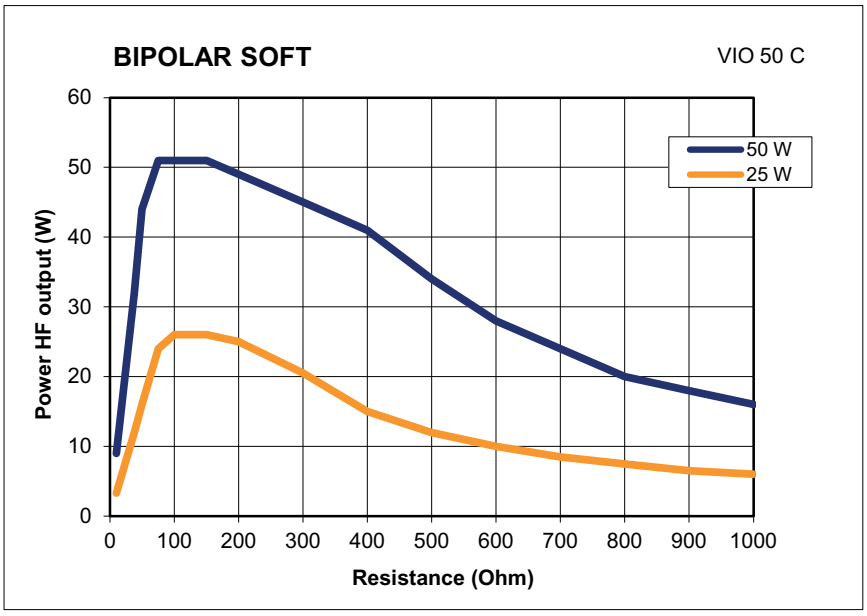

Fig. 9-2

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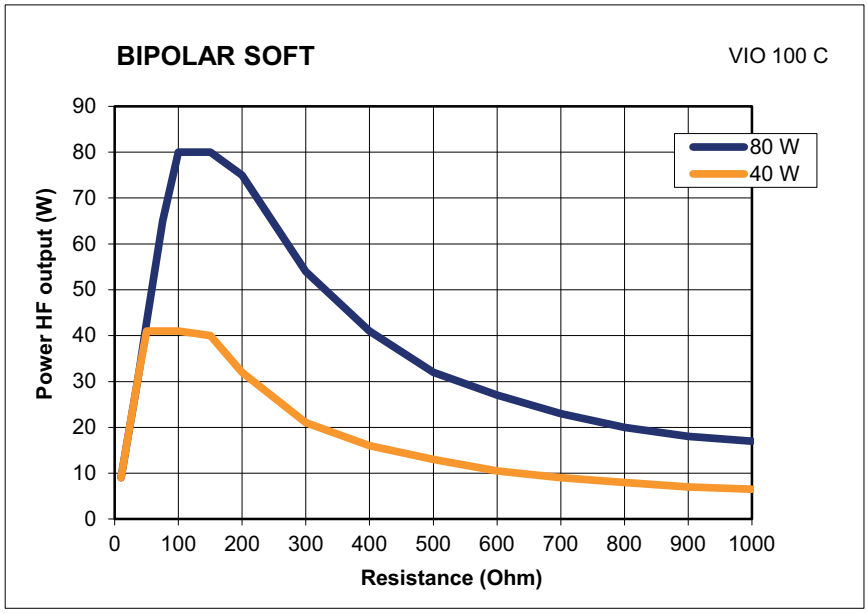

Fig. 9-3

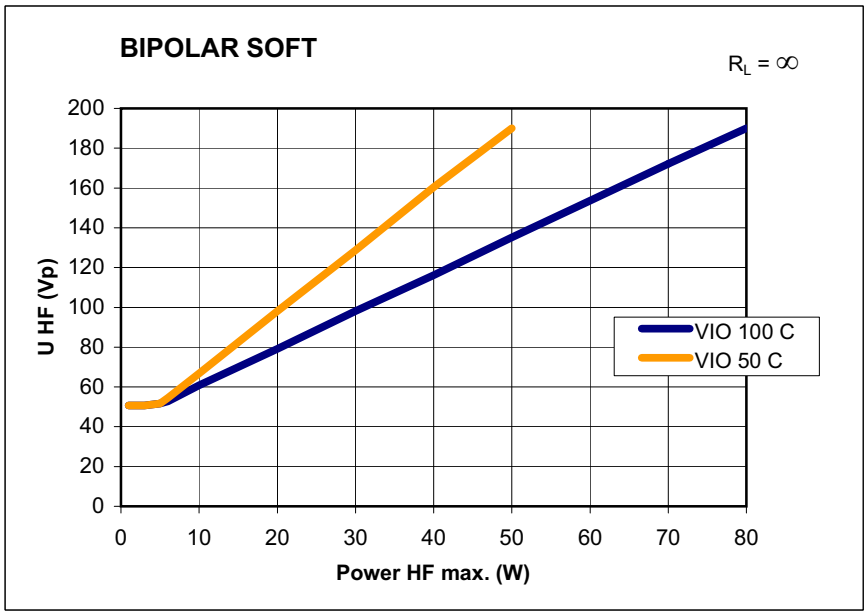

Fig. 9-4

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Chapter 10
Installation

Safety Instructions

Ambient conditions

⚠ WARNING

Ignition of anesthetics, skin cleansers, and disinfectants in potentially explosive atmospheres

If you place the unit in a potentially explosive atmosphere, anesthetics, skin cleansers, and disinfectants can ignite.

Risk of fire and explosion to the patient and medical personnel! Risk of damage to property.

⇨ Do not place the unit in potentially explosive atmospheres.

⚠ WARNING

Interference with the unit from portable and mobile HF telecommunications units (e.g. mobile phones, WLAN units)

Electromagnetic waves emitted by portable and mobile HF telecommunications units may affect the unit.

Risk of injury to patient and medical personnel.

The unit may fail or not perform properly.

⇨ When using portable and mobile HF telecommunications units, including their accessories, there must be a distance of at least 30 cm between them and the unit and its cords.

⚠ WARNING

Unsuitable temperature or level of humidity during operation

If you operate the unit at an unsuitable temperature or level of humidity, it may sustain damage, fail, or not perform properly.

Risk of injury to patient and medical personnel!

⇨ Operate the unit at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

⇨ If other ambient conditions must be observed for operation of the unit, you will also find them in the Technical Data.

⚠ WARNING

Unsuitable temperature or humidity in transit or storage

If you transport or store the unit at an unsuitable temperature or level of humidity, it may sustain damage and fail.

Risk of injury to patient and medical personnel!

⇨ Transport and store the unit at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

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⇨ If other ambient conditions must be observed for transport and storage of the unit, you will also find them in the Technical Data.

NOTICE

Insufficient acclimatization time, unsuitable temperature during acclimatization

If the unit was stored or transported below or above a certain temperature, it will take a certain time and temperature to acclimatize.

If you do not observe the rules, the unit can sustain damage and fail.

⇨ Acclimatize the unit according to the rules in the Technical Data.

NOTICE

Overheating of the unit due to poor ventilation

If ventilation is poor, the unit can overheat, sustain damage, and fail.

⇨ Install the unit in such a way that there is an unobstructed circulation of air around the housing. Installation in confined wall recesses is prohibited.

⚠ WARNING

Penetration of fluid into the unit during operation or when cleaning the unit

Risk of electric shock to the medical personnel.

The unit may become damaged and fail.

⇨ Make sure no liquid can penetrate the unit.

⇨ Do not place vessels containing liquids on top of the unit.

⇨ If fluid has penetrated into the unit, take the unit out of operation immediately. You can only start using the unit again once it has been checked by a service technician.

Electrical installation

⚠ WARNING

Defective grounded power outlet, power supply network without proper grounding, inferior-quality power cord, incorrect line voltage, multiple power outlets, extension cords

Risk of electric shock and other injuries to the patient and medical personnel! Risk of damage to property.

⇨ Connect the unit to a properly installed grounded outlet.

⇨ Only connect the unit to a power supply network with proper grounding.

⇨ Use the compatible Erbe power cord (see the *Accessories, Compatible power cords* chapter).

⇨ Check the power cord for damage. You must not use a damaged power cord.

⇨ The supply voltage must match the voltage specified on the unit's rating plate.

⇨ Do not use multiple power outlets.

⇨ Do not use extension cords.

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⚠ WARNING

Damaged unit, damaged accessories, modified unit, and modified accessories

Risk of electric shock to the patient and medical personnel!

Risk of injury to patient and medical personnel!

Risk of burns to the patient and medical personnel!

Risk of material damage.

- ⇨ Check the unit and accessories for damage before each use (e.g. footswitch, instrument cables and cart).
- ⇨ You must not use a damaged unit or damaged accessories. Replace defective accessories.
- ⇨ If the unit or cart is damaged, please contact our customer service.
- ⇨ Blown power fuses may only be replaced by a competent technician.
- ⇨ For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of Erbe Elektromedizin GmbH.

Access to the power cord

Note: Install the unit such that the power cord could be easily disconnected from the power source.

Installing the unit on a SystemCarrier compact

The installation is described in the assembly instructions for the SystemCarrier compact/compact plus.

Set up and install unit

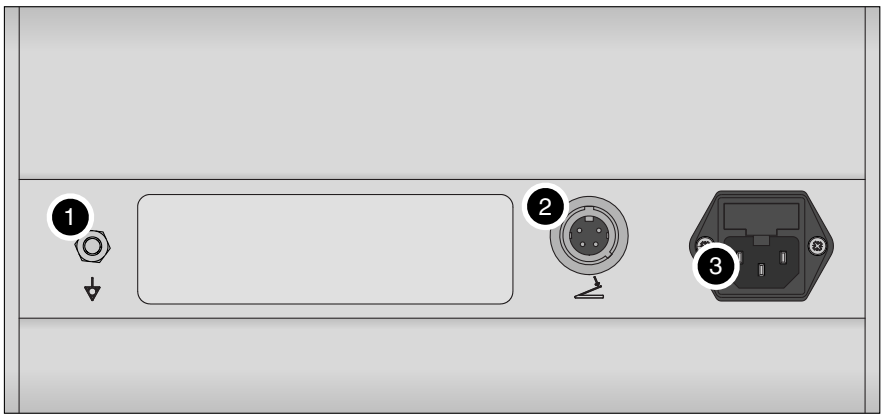

Fig. 10-1

1. Connect as required the grounding terminal pin (1) through a grounding cable with the grounding system of the operating room.
2. Make a power connection to a power socket through the power connector (3).

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Note: When connecting the footswitch, make sure that you insert the 4 pins on the plug of the connecting cable with the correct alignment into the corresponding contacts of the footswitch socket.

3. Connect the one pedal or two pedal footswitch VIO C to the footswitch socket (2).

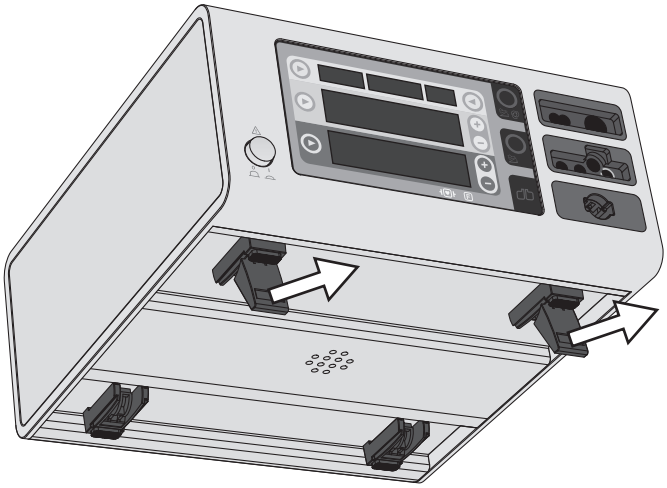

Fig. 10-2

4. Fold out the setting feet as required.

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Chapter 11
Cleaning and disinfection

Safety Instructions

⚠ WARNING

The unit is contaminated

Risk of infection to the patient and medical personnel.

⇨ Follow the instructions for cleaning and disinfecting the unit.

⚠ WARNING

Alternate use of disinfectant solutions based on different active ingredients

The agents may affect one another. The disinfection effect of the disinfectant solution may be weakened. Risk of infection to the patient and medical personnel.

The housing plastic may become brittle and break. A color reaction may occur with plastics.

⇨ Do not use these substances alternately.

⚠ WARNING

Connection of unit and power supply during cleaning and disinfection

Risk of electric shock to the medical personnel!

⇨ Switch off the unit. Unplug the power plug of the unit.

⚠ WARNING

Flammable detergents and disinfectants, flammable solvents in adhesives used on the patient and on the unit

Risk of fire and explosion to the patient and medical personnel! Risk of damage to property.

⇨ Use products that are not flammable.

If the use of flammable products is unavoidable, proceed as follows:

⇨ Allow the products to evaporate completely before switching on the unit.

⇨ Check whether flammable liquids have accumulated under the patient, in body recesses such as the navel, or in body cavities such as the vagina. Remove any liquids before performing electrosurgery.

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⚠ WARNING

Penetration of fluid into the unit during operation or when cleaning the unit

Risk of electric shock to the medical personnel.

The unit may become damaged and fail.

⇨ Make sure no liquid can penetrate the unit.

⇨ Do not place vessels containing liquids on top of the unit.

⇨ If fluid has penetrated into the unit, take the unit out of operation immediately. You can only start using the unit again once it has been checked by a service technician.

Selecting a suitable cleaning and disinfection agent

The following categories of cleaning agents and disinfectants should not cause any damage to the surfaces of unit / cart when used properly:

- Alcohol-based agents
- Agents based on guanidine
- Agents based on active oxygen-based per compounds
- Agents based on peracetic acid
- Chlorine-based agent with up to 3% bleach

Frequent use of the abovementioned agents may cause harmless discoloration to surfaces.

Do not use a cleaning and disinfection agent containing the following substances:

- Sodium hydroxide, strong organic acids, and strong oxidizing agents

These substances may attack metal parts due to their corrosive effect.

- Quaternary ammonium cations, phenolic compounds (e.g., phenoxyethanol)
- Solvents and benzine

These substances cause damage to plastics.

Supplies

- Ready-for-use wipes with a cleaning agent or disinfectant solution.

or

- Low-lint single-use wipes moistened before cleaning or disinfection with a suitable product.

Use different wipes for cleaning and disinfecting.

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Cleaning

Use only cleaning agents that comply with relevant national standards. Observe the manufacturer's specifications for the cleaning agent, particularly regarding material compatibility. If you use different products for cleaning and disinfection, the products must be compatible with each other.

1. Prepare the cleaning agent solution in a concentration specified by the manufacturer. Moisten low-lint single-use wipes with the cleaning agent solution.
2. Or use ready-for-use cleaning wipes with a cleaning agent solution.
3. Clean all visible contamination (e.g., blood) off the surfaces. Residual contamination may reduce the effectiveness of the subsequent disinfection.
4. Visually inspect all surfaces after cleaning. If you find any residual contamination, repeat cleaning until all contamination has been removed.

Note: If you cannot carry out a full clean, do not carry out a wipe disinfection. Do not use the unit or the cart. Contact Technical Service.

Disinfection

Use only disinfectants that comply with relevant national standards. Comply with the manufacturer's specifications for the disinfectant, particularly regarding material compatibility. If you use different products for cleaning and disinfection, the products must be compatible with each other.

1. Mix the disinfectant in a concentration specified by the manufacturer. Moisten low-lint single-use wipes with the disinfectant solution.
2. Or use ready-for-use disinfectant wipes with a disinfectant solution.
3. Wipe the surfaces thoroughly.
4. Ensure that the surfaces are completely wetted.
5. Leave the disinfectant to work as specified by the manufacturer (exposure time).
6. Keep the surfaces wet throughout the entire exposure time.
7. Visually inspect the surfaces for any damage after disinfection.

Note: If the surfaces are damaged, do not use the unit or the cart. Contact Technical Service.

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Validated procedure for cleaning and disinfection

Cleaning

Clean with mikrozid universal wipes premium, Schülke & Mayr GmbH, Norderstedt, Germany. Clean all visible contamination (e.g., blood) off the surfaces. Residual contamination may reduce the effectiveness of the subsequent disinfection.

Disinfection

Disinfect with mikrozid universal wipes premium, Schülke & Mayr GmbH, Norderstedt, Germany. Leave the disinfection solution to work for one minute, making sure it is visibly wetted.

Erbe recommends this processing procedure. Other equivalent procedures are possible. The user must ensure that the procedures used are suitable by means of suitable measures (e.g., validation, routine monitoring, check of material compatibility).

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Chapter 12
Error messages

The VIO 50 C/VIO 100 C can identify various operating and system errors during operation. An error number is assigned to each error that appears on the display when the error occurs.

Operating error messages

The user can normally eliminate or prevent an operating error with simple measures.

No.	Description	Action
1	The unit was activated longer than the maximum ON time set. Activation has been stopped automatically.	Reactivate the unit.
2	The connection between the neutral electrode and the unit is interrupted or the dual surface neutral electrode has insufficient contact with the skin.	Check the connection to the unit. If errors occur despite the correct connection, check the skin contact (see page 54).
3	The unit was activated without confirming the visible settings.	Use any button to confirm the visible settings. Reactivate the unit.
4	The CUT power limitation of the activated mode is set to 0 watts (display: --). **Note:** The text "max. Watts" flashes on the display of the CUT power limitation during and after the error message.	Set CUT power limitation to a value greater than 0 watts.
5	The COAG power limitation of the activated mode is set to 0 watts (display: --). **Note:** The text "max. Watts" flashes on the display of the COAG power limitation during and after the error message.	Set COAG power limitation to a value greater than 0 watts.
6	The unit was activated while a button on the front panel was pressed.	Only activate the unit when no button is pressed. Complete changes to unit settings before activating the unit.
8	2 switches (footswitch and/or instrument switch) have been pressed simultaneously.	Only press one switch.
9	The footswitch is not assigned to any socket. **Note:** The footswitch symbol and the text "OFF" flashes on the display of the activation type during and after the error message.	Assign footswitch to required socket (see page 60).

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No.	Description	Action
19	When the AUTO START function was assigned to the bipolar socket, there was electrically conductive contact between the electrodes of the connected bipolar instruments. The error may occur, for example, when the electrodes have direct contact or when the instrument is set on a conductive subsurface.	Avoid conductive contact between the electrodes when assigning the AUTO START function.
20 to 23	A footswitch or fingerswitch was pressed during start-up.	Do not press any footswitch or fingerswitch during start-up.
24 to 33	A button was pressed during start-up. The messages can also appear if the keyboard is defective.	Do not press any button during start-up. Switch unit off and back on. If the error persists, inform the Erbe service department.

System error messages

No.	Description	Action
43	System error. The message also occurs if the unit temperature lies outside the temperature range permissible for operation.	If necessary acclimatize the unit according to the specifications in the Technical Data. Switch unit off and back on. If the error persists, inform the Erbe service department.
60	The unit uses non-calibrated defaults for certain HF parameters. Tissue effects may deviate from the usual.	Switch unit off and back on. If the error persists, inform the Erbe service department. **Note:** With increased attention, an ongoing operation may continue to the end despite the error.
61	The neutral electrode monitoring system uses non-calibrated defaults for certain HF parameters. The sensitivity of the neutral electrode monitoring system is increased.	Switch unit off and back on. If the error persists, inform the Erbe service department. **Note:** With increased attention, an ongoing operation may continue to the end despite the error.
62	Customized programs and unit settings (e.g. maximum ON time) are no longer available. The unit uses the factory settings instead.	Switch unit off and back on. If the error persists, inform the Erbe service department. **Note:** With increased attention, an ongoing operation may continue to the end despite the error. **CAUTION!** Before continuing an ongoing operation, check the program settings provided by the unit and adjust if necessary.
Other	System error.	Switch unit off and back on. If the error persists, inform the Erbe service department.

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Chapter 13
General Technical Data

Power connection	
Rated supply voltage	100 V to 240 V (± 10 %)
Rated supply frequency	50 / 60 Hz
Line current	Max. 2.0 A
Power input in standby mode	< 15 watts
Power input with max. HF output	190 watts / 200 VA
Terminal for grounding (potential equalization)	Yes
Power fuses	T 4 A H / 250 V

Operating mode	
Intermittent operation	Duty cycle 25% (10 s ON / 30 s OFF)

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Output frequency	
Frequency	380 kHz, RL = ∞

Dimensions and weight	
Width x height x depth	280 x 135 x 300 mm
Weight	4.0 kg

Ambient conditions for transport and storage of unit	
Temperature	-40 °C to + 70 °C
Relative humidity	10% – 95%

Ambient conditions for operation of unit	
Temperature	+10 °C to +40 °C
Relative humidity	15% – 80%, non-condensing
Air pressure	54 kPa – 106 kPa
Maximum operating altitude	5000 m above sea level

Acclimatizing
If the unit has been stored or transported at temperatures below +10 °C or above +40 °C, the unit will require approx. 3 hours to acclimatize at room temperature.

Standards	
Classification according to EC Directive 93/42/EEC	II b
Classification according to Regulation (EU) 2017/745	II b
Protection class as per EN 60 601-1	I
Type as per EN 60 601-1	Defibrillation-proof type CF applied part

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Chapter 14
Notes on electromagnetic compatibility (EMC)

Where EMC is concerned, medical electrical units are subject to special safety measures and must be installed and commissioned according to the EMC notes stated herein.

Guidelines for avoiding, recognizing and rectifying unwanted electromagnetic effects on other units or systems, which are the result of operating the VIO system.

When VIO electrosurgical units are activated, disturbance of other units or systems in the immediate vicinity can occur. This can be recognized as, for example, image artifacts in imaging units or unusual fluctuations in measured value displays.

Such disturbances from an activated electrosurgical unit can be reduced by placing it further away and/or carrying out suitable shielding measures on the equipment or system experiencing disturbance.

When the VIO electrosurgical unit is in the non-activated state, interference with other units in the immediate vicinity does not occur.

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⚠ WARNING

Use of non-approved EMC-relevant accessories

This can result in the increased emission of electromagnetic interference or reduce the electromagnetic immunity of the unit.

Risk of injury to patient and medical personnel.

Units may fail or not function properly.

⇨ Only use cable that is specified in the table *"EMC-relevant accessories"*, see chapter *"Notes on electromagnetic compatibility (EMC)"*.

⇨ If you are using accessories from other manufacturers, check whether the Erbe unit is interfering with other units or being affected by interference itself. You cannot use the unit if there is any interference.

⚠ WARNING

Stacked units

If you place the unit next to or stack it with other units, the units may affect each other.

Risk of injury to patient and medical personnel.

Units may fail or not function properly.

⇨ Place the unit where possible only near Erbe units or stack the unit where possible only on Erbe units.

⇨ If it is necessary to operate the unit near or stacked together with units from other manufacturers, keep as much distance as possible between the units. Check whether the units are affecting each other: Are the units behaving unusually? Are faults occurring? If yes, increase the distance between the units.

⚠ WARNING

Interference with the unit from portable and mobile HF telecommunications units (e.g. mobile phones, WLAN units)

Electromagnetic waves emitted by portable and mobile HF telecommunications units may affect the unit.

Risk of injury to patient and medical personnel.

The unit may fail or not perform properly.

⇨ When using portable and mobile HF telecommunications units, including their accessories, there must be a distance of at least 30 cm between them and the unit and its cords.

⚠ WARNING

Use of non-approved internal cables by Technical Service

This can result in the increased emission of electromagnetic waves or reduce the immunity of the unit.

Risk of injury to patient and medical personnel.

The unit may fail or not perform properly.

⇨ Technical Service may only use the internal cables that are listed in the service manual for the unit.

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Guidance and manufacturer's declaration - electromagnetic emissions

The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
HF emissions CISPR 11	Group 1	In stand-by operation, the unit uses HF energy only for its internal function.
	Group 2	In the active state, the unit emits HF energy to the patient.
HF emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should ensure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Discharge of static electricity (ESD) in accordance with IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor should be made from wood or concrete or be covered with ceramic tiles. If the floor is covered with non-conductive synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short-term interruptions and voltage fluctuations on power supply input lines as per IEC 61000-4-11	0% U_T for 0.5 cycle, at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_T for 1 cycle, single-phase at 0 degrees 70% U_T for 25/30 cycles, single-phase at 0 degrees	0% U_T for 0.5 cycle, at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_T for 1 cycle, single-phase at 0 degrees 70% U_T for 25/30 cycles, single-phase at 0 degrees	Mains power quality should be that of a typical commercial or hospital environment. If the user of the unit requires continued operation during power mains interruptions, it is recommended that the unit be powered from an uninterruptible power supply or a battery.
Voltage monitoring as per IEC 61000-4-11	0% U_T for 250/300 cycles (50/60 Hz)	0% U_T for 250/300 cycles (50/60 Hz)	
Power frequency (50/60 Hz) magnetic field as per IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields as per IEC 61000-4-39	Test frequency 30 kHz Modulation CW Test level 8 A/m	Test frequency 30 kHz Modulation CW Test level 8 A/m	The strength of magnetic alternating fields should not exceed the values typically found in domestic environments.
	Test frequency 134,2 kHz Pulse modulation 2,1 kHz Test level 65 A/m Test frequency 13,56 MHz Pulse modulation 50 kHz Test level 7,5 A/m	Test frequency 134,2 kHz Pulse modulation 2,1 kHz Test level 65 A/m Test frequency 13,56 MHz Pulse modulation 50 kHz Test level 7,5 A/m	The strength of alternating magnetic fields should not exceed levels characteristic in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration - electromagnetic immunity

The unit is intended for use in the electromagnetic environment specified below. The user of the unit should ensure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted HF disturbances as per IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff} 150 kHz to 80 MHz	The field strengths of fixed transmitters, as determined by an electromagnetic site survey should be below the compliance level in each frequency range. [b)] Interference may occur in the vicinity of units marked with the following symbol. 
	6 V_{eff} [a)] in ISM frequency bands 150 kHz to 80 MHz	6 V_{eff} [a)] in ISM frequency bands 150 kHz to 80 MHz	
Radiated high-frequency electromagnetic fields as per IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	

Note: These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a)
The ISM bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.7 MHz.

b)
The field strengths of fixed transmitters, such as base stations for radio (cellular/cordless) telephones and terrestrial radio units, amateur radio stations, AM and FM radio and TV channels cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with regard to fixed transmitters, a site inspection should be considered. If the field strength measured at the site where the unit is used exceeds the abovementioned compliance level, the unit must be monitored to ensure it is functioning properly. In the event of any unusual operating behavior, additional measures may be required, such as changing the orientation or location of the unit.

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Electromagnetic immunity against high-frequency wireless communication units as per IEC 61000-4-3

Frequency band (MHz)	Test frequency (MHz)	Modulation	Compliance level (V/m)
380 - 390	385	Pulse [a)] (18 Hz)	27
430 - 470	450	FM ± 5 kHz deviation or pulse [a)] (18 Hz)	28
704 - 778	710, 745, 780	Pulse [a)] (217 Hz)	9
800 - 960	810, 870, 930	Pulse [a)] (18 Hz)	28
1700 - 1990	1720, 1845, 1970	Pulse [a)] (217 Hz)	28
2400 - 2570	2450	Pulse [a)] (217 Hz)	28
5100 - 5800	5240, 5500, 5785	Pulse [a)] (217 Hz)	9

Electromagnetic immunity against high-frequency wireless communication units as per IEC 61000-4-3
Note: A **minimum safety distance of 30 cm** should be maintained between the unit and portable HF telecommunications units that transmits in the stated frequency band. This includes mobile phones, WLAN and RFID, and Bluetooth units. Failure to comply may lead to a reduction in the unit's performance features. Interference may occur in the vicinity of units marked with the following symbol. 
a) The pulse modulation is defined as a square-wave signal with a 50% duty factor.

The cables / cords used on the unit must not exceed the lengths specified below.

EMC-relevant accessories [a]	
Name	**Maximum cable length**
Power cord	5 m
Grounding cable (POAG)	10 m
Footswitch cable	5 m
Monopolar connecting cable	5 m [b]
Bipolar connecting cable	5 m [b]
Neutral electrode cable	5 m [b]

a) EMC-relevant accessories refers to the cable specified. The cable can affect the unit's electromagnetic interference or the electromagnetic immunity of the unit.

b) When connecting Erbe instruments and neutral electrodes, the overall cord length increases by max. 0.5 m.

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Operating environment

For the intended use, the unit may only be operated in premises used for medical purposes.

The unit may be operated in the vicinity of an electrosurgical unit. The safety instructions for the unit and the electrosurgical unit must be observed. Please read the safety instructions on the following subjects in particular:

- distance between the unit and the electrosurgical unit. In this User Manual, refer to the safety instruction *Stacked units*.
- Distances between the unit and the electrosurgical unit's cords.
- Distances between the unit's cords and the electrosurgical unit's cords.

Position the units and cords so that they are as far apart as possible.

Essential performance characteristics

The unit does not have any essential performance features within the meaning of IEC 60601-2-2.

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Chapter 15
Maintenance, Customer Service, Warranty, Disposal

Maintenance

Modifications and repairs

Modifications and repairs must not impair the safety of the unit or cart and accessories for the patient, user and the environment. This condition is met when changes to the structural and functional characteristics are not detrimental to safety.

Authorized persons

Modifications and repairs may only be undertaken by Erbe or by persons expressly authorized by Erbe. Erbe accepts no liability if modifications and repairs to the unit or accessories are made by unauthorized persons. This will also invalidate the warranty.

Technical safety checks

The technical safety checks determine whether the safety and operational readiness of the unit or the cart and accessories conform to a defined technical required status. Technical safety checks must be performed at least once a year.

What technical safety checks must be performed?

For this unit the following technical safety checks have been stipulated:

- Checking of labels and User Manual
- Visual inspection of unit and accessories for damage
- Testing the grounded conductor as per IEC 62353
- Leakage current testing as per IEC 62353
- Functional testing of all the unit's operating and control elements
- Testing the monitoring equipment
- Measurement of DC resistance
- Testing footswitch and fingerswitch activation
- Testing the automatic start mode (for VIO 100 C only)
- Measurement of the output power in the CUT and COAG operating modes

The results of the technical safety checks must be documented.

If during the technical safety checks any defects are found which might endanger patients, staff or third parties, the unit may not be operated until the defects have been remedied by competent service technicians.

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Customer service

If you are interested in a maintenance contract, please contact Erbe Elektromedizin in Germany, or your local contact in other countries. This may be an Erbe subsidiary, an Erbe representative or a distributor.

Warranty

The General Terms and Conditions or the conditions of the purchase contract apply.

Disposal

Your product bears a crossed-out garbage can icon (see picture). Meaning: In all EU countries this product must be disposed of separately in accordance with the national laws implementing EU Directive 2012/19/EU of 07/04/2012, WEEE.

In non-EU countries the local regulations must be observed.

If you have any questions about disposal of the product, please contact Erbe Elektromedizin or your local distributor.

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Chapter 16
Symbols

Individual details of the symbols in this chapter may deviate from your product. Not all symbols may necessarily appear on your unit or its packaging.

Symbol	Explanation
	Caution: Before switching the unit on or performing another action related to the unit, read the safety instructions in the User Manual.
	Consult instructions for use
	Catalogue number
	Serial number
	Manufacturer
	Date of manufacture
	Keep away from sunlight
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Quantity (x)
	Follow instructions for use
	Warning; Electricity
	General warning sign

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Symbol	Explanation
	Foot switch
ECB	Erbe Communication Bus Used to exchange data between Erbe units.
	Equipotentiality Refers to the grounding terminal.
	Off, On
	Defibrillation-proof type CF applied part The applied parts of the unit (e.g. instrument sockets) are protected against the effects of defibrillator discharge.
	Computer network Refers to the computer network itself or the network connections.
	Input
	Air inlet
	Air outlet
F	HF isolated patient circuit The danger of leakage currents and therefore the danger of burns is substantially reduced for the patient.
	Non-ionizing electromagnetic radiation A unit that bears this symbol does not transmit ionizing electromagnetic radiation. Interference may occur in the vicinity of the unit.
	The product must be disposed of separately.
CE	European conformity marking
MD	Medical device

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