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USER MANUAL

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USER MANUAL

VIO® 3

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Normal use

The VIO 3 can be combined with suitable Erbe units and modules (e.g. APC 3) and accessories. The VIO 3 may only be used in rooms used for medical purposes. The VIO 3 may only be used by medical professionals who have been trained in the use of the unit or combination of units on the basis of the User Manual.

Intended use

The VIO 3 is an electrosurgical unit for cutting and coagulation, as well as for vessel sealing. Thanks to its performance features, it offers universal applications.

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 equipment.

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.

Compliance with safety information

Working with medical equipment 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 equipment. Safety depends to a large extent on the training of medical personnel and correct operation of the equipment.

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

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
- Electric shock
- Fire / explosion
- Burns
- Risks due to incorrect use of the return electrode
- Defective unit
- Interference caused by the 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 equipment 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

NOTICE

Interference with the unit by portable and mobile HF communication devices (e.g. mobile phones, WLAN equipment)

Electromagnetic waves emitted by portable and mobile HF communication devices can effect the unit.

The unit may fail or not perform properly.

⇨ Please see the table "Recommended separation distances between portable and mobile HF communications equipment and the equipment" at the end of this User Manual.

NOTICE

Unsuitable temperature or level of humidity during operation

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

⇨ Operate the equipment 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 equipment, you will also find them in the Technical Data.

NOTICE

Unsuitable temperature or humidity in transit or storage

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

⇨ Transport and store the equipment 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 equipment, you will also find them in the Technical Data.

NOTICE

Insufficient acclimatization time, unsuitable temperature during acclimatization

If the device 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 device can sustain damage and fail.

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

NOTICE

Overheating of the device due to poor ventilation

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

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

NOTICE

Penetration of liquid into the device

The housing is not absolutely watertight. If liquid penetrates, the device can sustain damage and fail.

⇨ Make sure no liquid can penetrate the device.

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

Electric shock

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⚠ 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 / the equipment cart to a properly installed grounded power outlet.

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

⇨ Only use the Erbe power cord or an equivalent power cord for this purpose. The power cord must bear the applicable national test symbol.

⇨ 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

Incorrect line fuse, defective device

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

⇨ Blown line fuses may only be replaced by a competent technician. Only replacement fuses that have the same rating as the one specified on the unit's rating plate may be used.

⇨ When a fuse has been changed, the function of the unit must be verified. If the unit does not function properly or if there are any concerns, please contact Erbe.

⚠ WARNING

Connection of unit / equipment cart and power supply during cleaning and disinfection

Risk of electric shock to the medical personnel!

⇨ Switch off the device. Unplug the power cord of the device/equipment cart.

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.

⚠ DANGER

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 extract 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.

⚠ DANGER

Flammable endogenous gases in the gastrointestinal tract

Risk of explosion to the patient!

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

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⚠ DANGER

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 extract 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.

⇨ Before using argon plasma coagulation (APC) in the tracheobronchial system it is absolutely essential that you observe the specific safety information and instructions in the User Manual for the argon plasma unit!

⚠ 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 device / equipment cart

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 device.

⇨ 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 device 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 device in potentially explosive atmospheres.

Burns

⚠ WARNING

Damaged device, damaged accessories, modified device, and modified accessories

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

⇨ Check the device and accessories for damage every time before using them (e.g. footswitch, cords of instruments and the return electrode, equipment cart).

⇨ You must not use damaged equipment or damaged accessories. Replace defective accessories.

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

⇨ 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

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 operation due to sweat, blood, irrigation liquid, urine, etc., lay a waterproof plastic sheet under the drapes.

⚠ WARNING

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 surgical 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.

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⚠ WARNING

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.

⚠ 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.

⚠ CAUTION

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 device 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.

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⚠ 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!

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

⇨ 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

Activation time too long, effects too high

The longer the activation time of the unit and the higher the effect, the higher the risk of accidental tissue damage.

Risk of accidental tissue damage to the patient!

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

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

⇨ Set the effect as low as possible relative to the required surgical effect. However, an effect level that is too low can be dangerous, e.g. gas embolisms in connection with the APC (Argon Plasma Coagulation), because the plasma does not ignite at an effect level that is too low.

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

⇨ Check the instrument for soiling with insulating tissue remnants.

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

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

⚠ 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.

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⚠ WARNING

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

Risk of accidental tissue damage to the patient!

⇨ All users must be informed in good time of any change in maximum activation time. That is, before the user works with the modified maximum activation time for the first time.

⇨ The temperature at the return 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

Undesirable contact between the active instrument and metal objects in the patient's body

Contact with metal hemostats, etc.

Risk of burns to the patient!

⇨ Do not touch metal objects (e.g. implants) in the patient's body with the active instrument.

⚠ CAUTION

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

Risk of hand burns!

⇨ Such practice is not recommended. The risk of burns cannot be ruled out.

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⚠ CAUTION

The interconnections of the VIO 3 carry HF voltage when they are activated.

If you touch the interconnections during activation, you can suffer burns.

⇨ You may only remove the cap (1) (fig. below) if you install the VIO 3 on an APC 3.

⇨ Keep the cap in a safe place. If you disconnect the VIO 3 from the APC 3, you must replace the cap on the interconnections.

Fig. 1-1

Risks due to incorrect use of the return electrode

⚠ CAUTION

Non-compatible or non-split return electrode

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

When applying a non-split return electrode, the contact between return electrode and skin is not monitored. If contact between return electrode and skin is inadequate, the unit does not emit any visual or acoustic warning signal.

Risk of burns for the patient under the return electrode!

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

⇨ Use only suitable return electrodes.

⇨ When applying a non-split return electrode: Regularly check the return electrode for good skin contact.

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

⇨ Use only suitable return electrode cables.

⚠ WARNING

Positioning the return electrode above the heart

Risk of ventricular fibrillation and cardiac arrest for the patient!

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

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⚠ CAUTION

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.
- ⇨ Align the long edge of the return electrode (1) towards the surgical field. The current should flow from the instrument towards the long edge of the return electrode. See Fig. 1-2.
- ⇨ 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 device was activated frequently and for a long time.

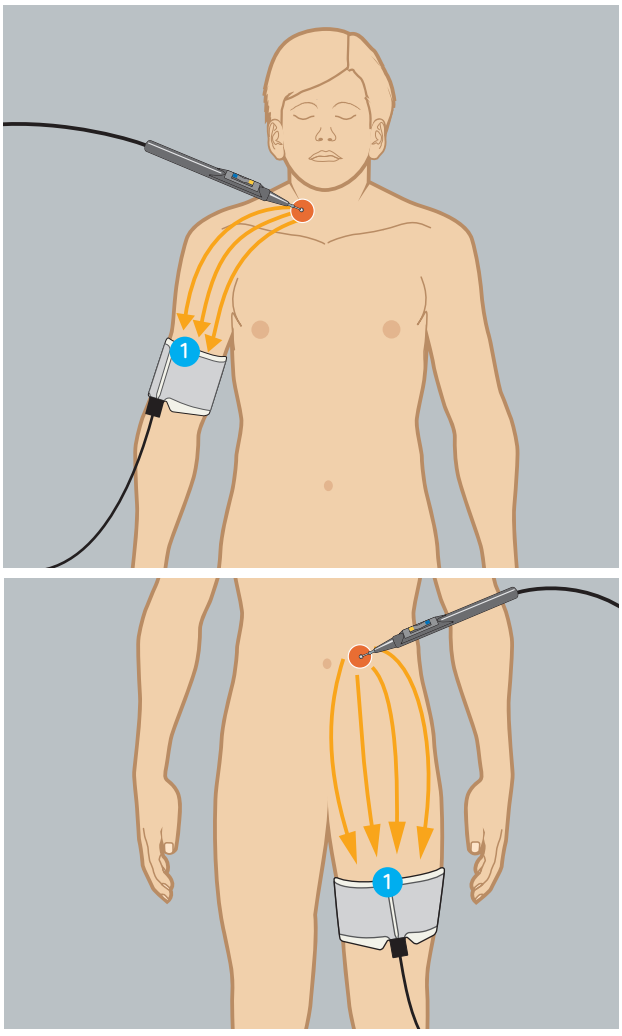

Fig. 1-2

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Defective unit

⚠ WARNING

Undesirable rise in output level due to failure of electrosurgical unit

Risk of accidental tissue damage to the patient!

⇨ The device shuts off independently.

⇨ To guard against a possible failure of the electrosurgical unit, have the device checked for safety 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 the device checked for safety at least once a year.

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

⚠ WARNING

Failure of display elements

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

Risk of injury or death for patients and medical staff!

⇨ You must not use the unit.

Interference caused by the unit

⚠ 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!

⇨ 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 return electrode near cardiac pacemakers, internal defibrillators, or other active implants.

NOTICE

Interference with electronic equipment due to the electrosurgical unit

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

The equipment may fail or not perform properly.

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

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

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⚠ 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 effect as low as possible relative to the required surgical effect.

NOTICE

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 device.

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 device.

NOTICE

Stacked devices

If you stack the device next to other equipment or with other equipment, the devices can affect each other.

The unit may fail or not perform properly.

⇨ The device may only be stacked next to or with VIO series units.

⇨ If it is necessary to operate the device near other equipment or stacked together with other equipment, check whether the devices are affecting each other: Are the devices behaving unusually? Do errors occur?

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Damage to the unit and accessories

NOTICE

Alcohol-based spray disinfectant for fast disinfection

In the case of elastic molded parts and paint surfaces, there is a risk of formation of cracks. Propanol and ethanol will attack the surfaces.

⇨ Do not use these substances.

NOTICE

Alternate use of disinfectant solutions based on different active ingredients

A color reaction may occur with plastics.

⇨ Do not use these substances alternately.

⚠ CAUTION

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.

⚠ CAUTION

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 undertake long activation phases without the appropriate cooling breaks, gradual heating under the return electrode may occur, or the unit may sustain damage.

Risk of burns to the patient!

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

Notes

Grounding

Note: If necessary, the equipment can be connected to the external grounding system of the room with the grounding pin on the back of the unit and/or Cart using a connecting cable designed for this purpose. Affects of low frequency leakage currents due to a defective grounding system within the room may be eliminated through external grounding.

Use of a defibrillator

Note: All HF receptacles and the return electrode receptacle (applied parts) meet Type CF requirements and are protected against the effects of defibrillator discharge.

Using a smoke evacuator

Note: In order to evacuate the smoke that develops during electrosurgical procedures, Erbe recommends using a smoke evacuator.

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Chapter 2
Safety Features

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NESSY

What is NESSY?

Should you wish to activate the unit's monopolar mode, you have to connect a return electrode and apply it on the patient.

The unit is equipped with a Neutral Electrode Safety System (NESSY), which monitors the return electrode, warns of critical situations, and thus prevents burns. Observe the unit's optical and acoustic warning signals. Observe the error and advisory messages from return electrode monitoring.

Safety when connecting a split or non-split return electrode

You can connect a split or a non-split return electrode to the VIO 3. Erbe recommends connecting a split return electrode, as it offers enhanced safety with regard to burns.

When connecting a **split return electrode**, three safety-relevant properties are monitored:

- the connection to the VIO 3
- the contact to the patient's skin
- the application direction of the return electrode (NESSY symmetry monitoring)

When connecting a **non-split return electrode**, only one safety-relevant property is monitored:

- the connection to the VIO 3

Preferred return electrode type

In the VIO 3 *Protected settings*, you or an authorized person can set whether you wish to work with a split or non-split return electrode.

If you connect the preferred type of return electrode, you do not need to register the return electrode on the VIO 3.

If you connect another type of return electrode, VIO 3 asks you: *Which return electrode type have you just connected?* You then have to make the decision between a split or a non-split return electrode.

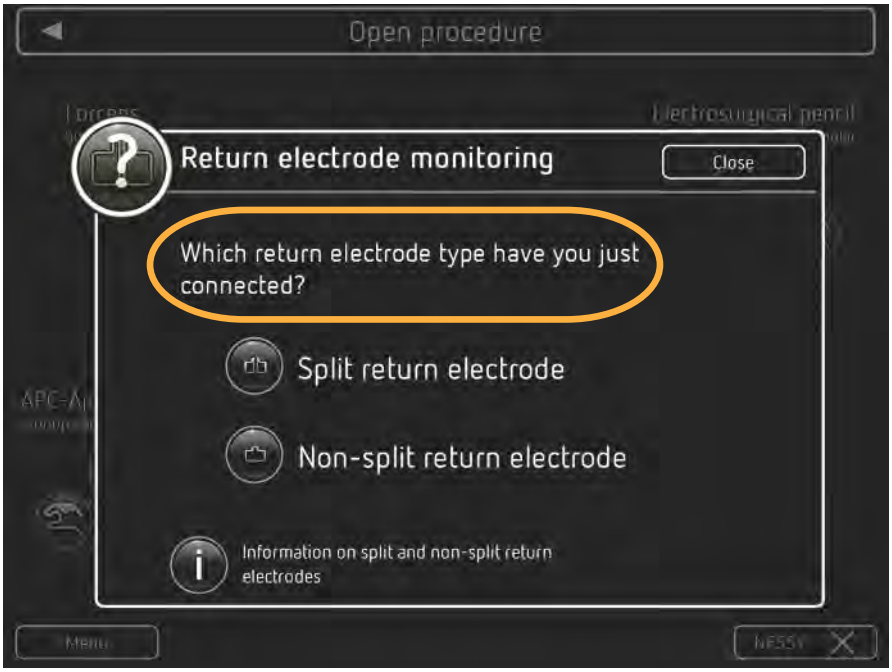

Fig. 2-1

Note: Make sure you actually register the return electrode on the VIO 3 that you connect. Otherwise, you cannot activate the monopolar modes.

Example: split return electrode:

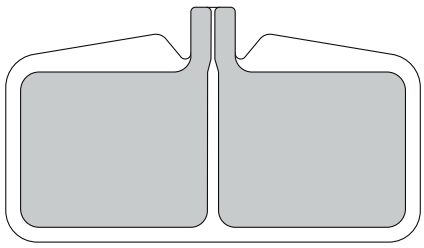

Fig. 2-2

Example: non-split return electrode:

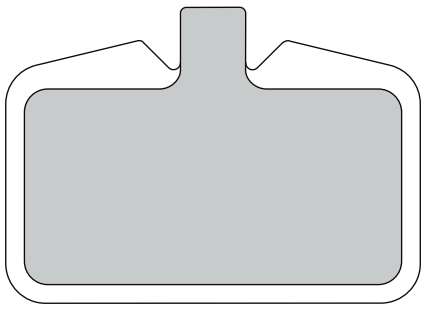

Fig. 2-3

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VIO 3 detects no return electrode

Fig. 2-4

If you switch on the VIO 3 and the unit detects no return electrode, the return electrode is crossed out on the screen. The frame of the return electrode socket is not lit.

Activation of the monopolar modes is not possible. If you need assistance, touch the *NESSY button*.

Possible cause	Action
No return electrode connected	Connect return electrode
Return electrode not applied to the skin	Apply return electrode to the skin
Cable damaged	Replace damaged cable
Contact strip is not correctly positioned in the connecting terminal	Insert the contact strip correctly into the connecting terminal
Connector is not correctly in the return electrode socket	Plug connector into the return electrode socket as far as it goes

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Split return electrode connected

Connection correct

Fig. 2-5

If you connect a split return electrode, the unit monitors:

- the connection to the VIO 3
- the contact to the patient's skin
- the application direction of the return electrode (NESSY symmetry monitoring)

The return electrode on the screen lights green; the frame of the return electrode socket lights green. The monopolar mode can be activated.

Connection critical, activation still possible

The return electrode on the screen lights green; the frame of the return electrode socket lights green. Activation of the monopolar modes is still possible. The return electrode monitoring alerts you with a reference to a critical situation.

➢ Check the return electrode as soon as possible.

Possible cause	Action
Return electrode has too little contact to the skin	The entire surface of the return electrode must be applied without creases; the skin must be free of oil, dry and free from hair.
The long edge of the return electrode does not point to the surgical field.	Align the long edge of the return electrode towards the surgical field
The return electrode does not support monitoring of the application direction of the return electrode (NESSY symmetry monitoring).	Connect a suitable return electrode

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Connection faulty, activation not possible

Fig. 2-6

The return electrode on the screen lights red; the frame of the return electrode socket lights red. Activation of the monopolar modes is not possible. You see a message on the screen.

➢ Check the return electrode immediately.

Fig. 2-7

An example for a message from return electrode monitoring is given in Fig. 2-7. In addition to the text, you see on the right a resistance display with resistance ranges. If the needle is in the gray or red range, you cannot activate monopolar modes.

Possible cause	Action
Cable damaged	Replace damaged cable
Non-split return electrode connected, but registered on the VIO 3 as a split return electrode	Connect split return electrode
Return electrode has too little contact to the skin	The entire surface of the return electrode must be applied without creases; the skin must be free of oil, dry and free from hair.
The long edge of the return electrode does not point to the surgical field.	Align the long edge of the return electrode towards the surgical field
The return electrode does not support monitoring of the application direction of the return electrode (NESSY symmetry monitoring).	Connect a suitable return electrode

Assistance on NESSY symmetry monitoring

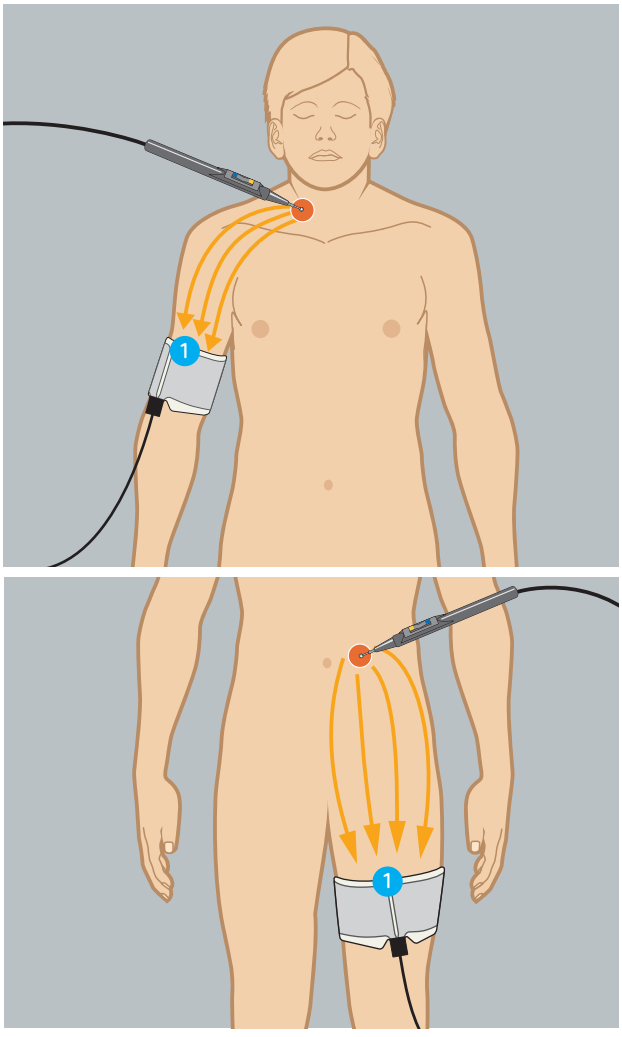

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Fig. 2-8

➢ Align the long side of the return electrode (1) towards the surgical field. The current should flow from the instrument towards the long edge of the return electrode.

Non-split return electrode connected

Connection correct

Fig. 2-9

If you connect a non-split return electrode, the unit monitors:

- the connection to the VIO 3

The return electrode on the screen lights green; the frame of the return electrode socket lights green. The monopolar mode can be activated.

Connection faulty, activation not possible

Fig. 2-10

The return electrode on the screen lights red; the frame of the return electrode socket lights red. Activation of the monopolar modes is not possible. You see a message on the screen.

Possible cause	Action
Cable damaged	Replace damaged cable

Note: When applying a non-split return electrode, the contact between the skin and the return electrode is not monitored! You will not receive a warning if the return electrode becomes detached from the skin and there is a danger of burns. The application direction of the return electrode is also not monitored. Erbe recommends the use of split return electrodes.

Neonatal monitoring

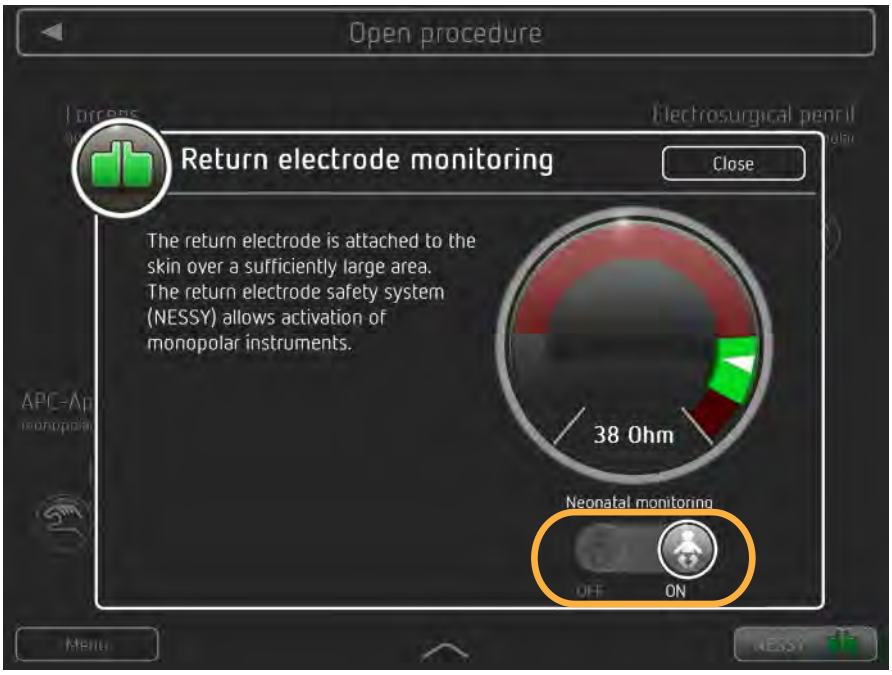

Fig. 2-11

When using a neonatal return electrode, you can activate neonatal monitoring. In critical situations you then see the following message on the screen:

"An elevated temperature is possible under the return electrode! Activate for as brief a period as possible. Reduce the effect setting if the situation permits."

To switch on the neonatal monitoring, proceed as follows:

1. Touch the *NESSY button* on the main screen.
2. Slide the neonatal monitoring switch to the *ON* position.

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Automatic monitoring of the HF output parameters electrical voltage and power

The unit is equipped with automatic monitoring of the HF output parameters (voltage and power). Deviations of the actual value[1] from the setpoint[2] are monitored. If the deviation is so great that the quality of the required CUT or COAG effect is no longer guaranteed, the unit switches off the HF generator and displays a message.

Automatic monitoring of the maximum activation time

With proper use, a HF generator is only briefly activated. A defect in the unit, in the accessories or a user's error may cause the HF generator to be activated unintentionally. To prevent major damage being caused, the activation time is automatically monitored.

The maximum activation time is saved in the unit's *Protected settings*. If the maximum activation time is exceeded, the unit generates an acoustic signal and displays a mes-

1. Actual value: Value actually specified by the unit.
2. Setpoint: Value the unit should specify.

sage. The HF generator is automatically switched off. The HF generator can be restarted at any time, resulting in renewed monitoring of the activation time. This prevents major damage being caused by accidental activation over indefinitely long periods.

Custom adaptation of the maximum activation time

Setting of the maximum activation time can only be carried out by an authorized person. The factory setting is 30 seconds.

⚠ WARNING

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

Risk of accidental tissue damage to the patient!

⇨ All users must be informed of a change in the maximum activation time, before the user works with the modified maximum activation 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.

Protection from operating errors

To prevent operating errors, the displays on the touchscreen are designed such that illogical or incomplete settings are automatically monitored and signalized.

All connection sockets in the application section are arranged in the socket strip next to the front panel. These connection 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 up to four instruments simultaneously to the unit. However, for safety reasons you can only activate one instrument. The twinCOAG mode is an exception to this.

Whenever the power switch is switched on, an automatic test program is run. The following errors are detected and are displayed with a message and indicated acoustically:

- The button on the electrode handle is short-circuited or bypassed at low resistance while you switch on at the power switch. The cause can be moisture in the electrode handle.
- The button on the electrode handle is pressed while you switch on at the power switch.
- The contact of a footswitch is short-circuited,a pedal is jammed or a pedal is pressed while you switch on at the power switch.

The message on the touchscreen of the VIO 3 tells you how to remedy the error.

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Chapter 3
Accessories

Introduction

You can connect a number of instruments and return electrodes from different manufactures to the VIO 3.

Check Erbe instruments and instruments from other manufacturers for compatibility with the required CUT / COAG mode of the VIO 3 before use. Instructions are available in this chapter.

Check the return electrodes from other manufacturers for compatibility with the VIO 3 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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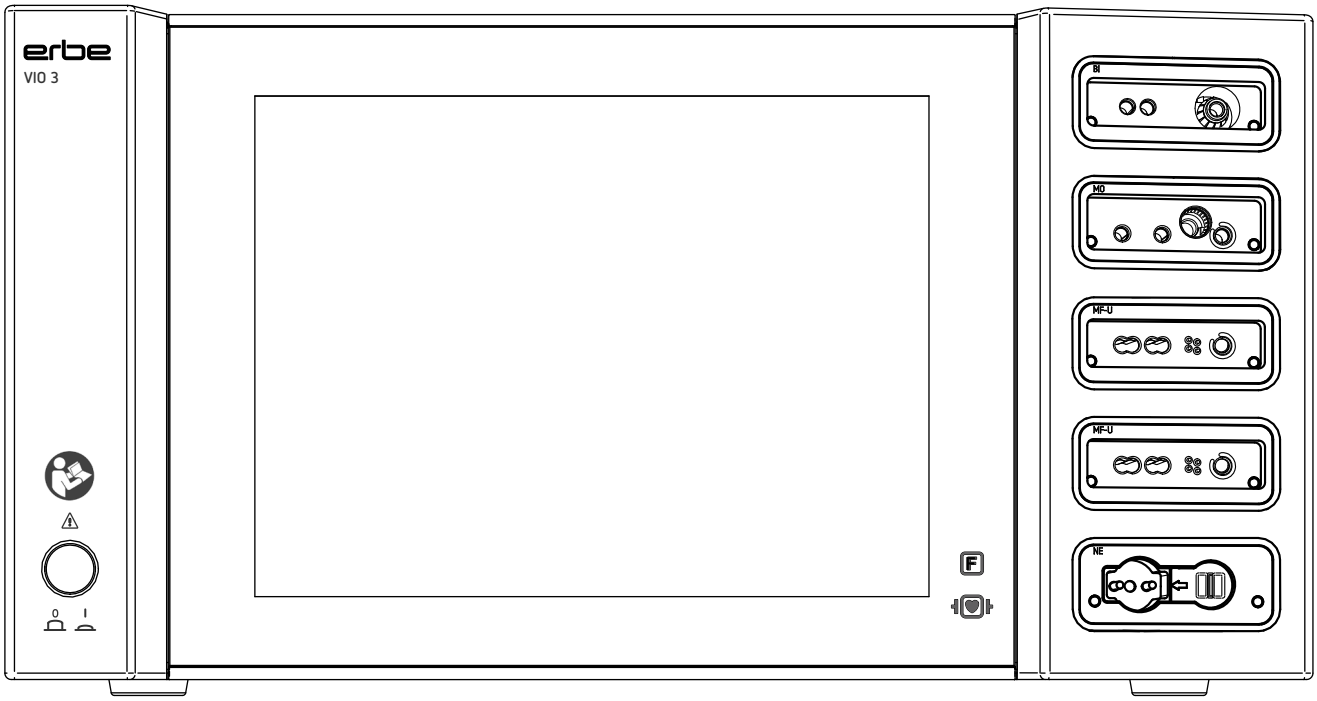
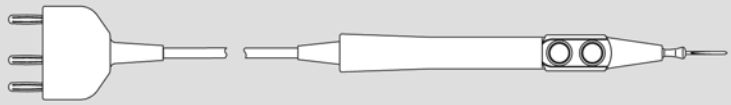
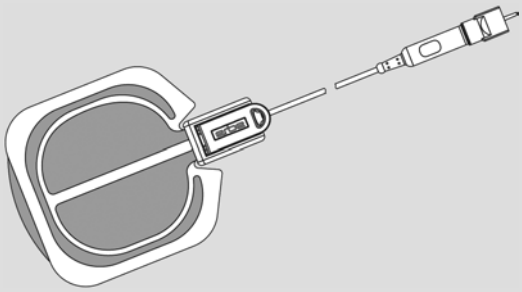
VIO 3 example accessories



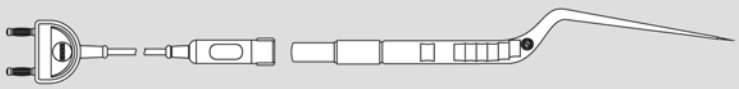
Monopolar electrosurgical pencils, monopolar electrodes



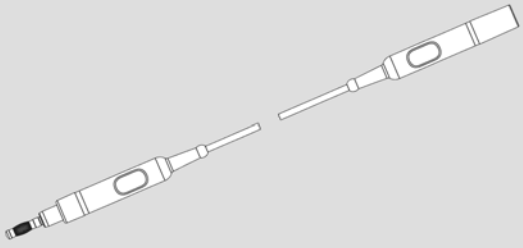
Patient plates



Bipolar instruments, bipolar forceps



Connecting cables for electrosurgery



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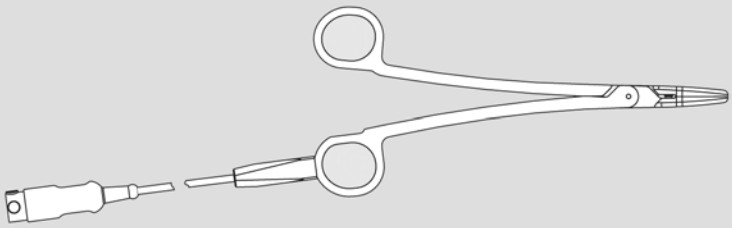
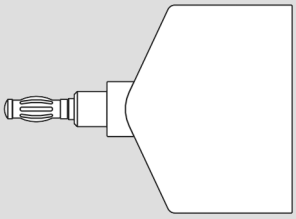
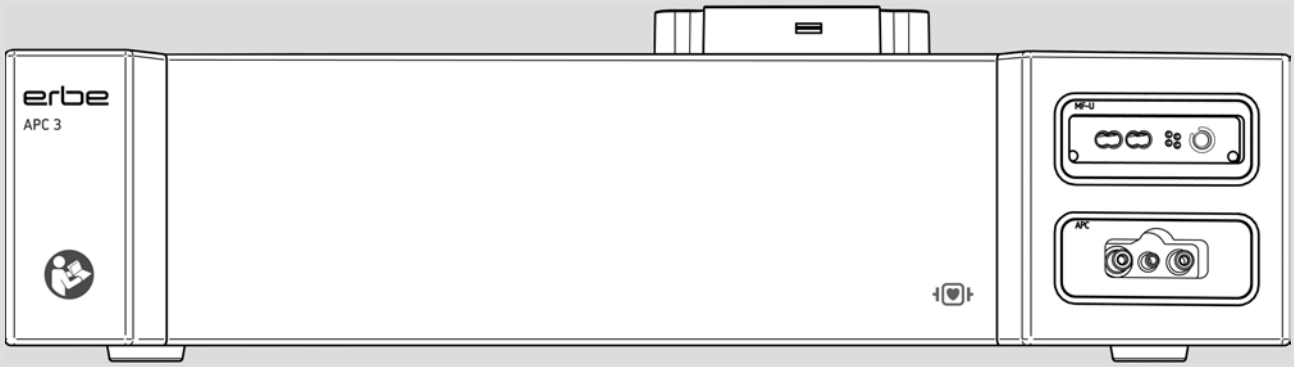
BiClamp and BiClamp LAP forceps



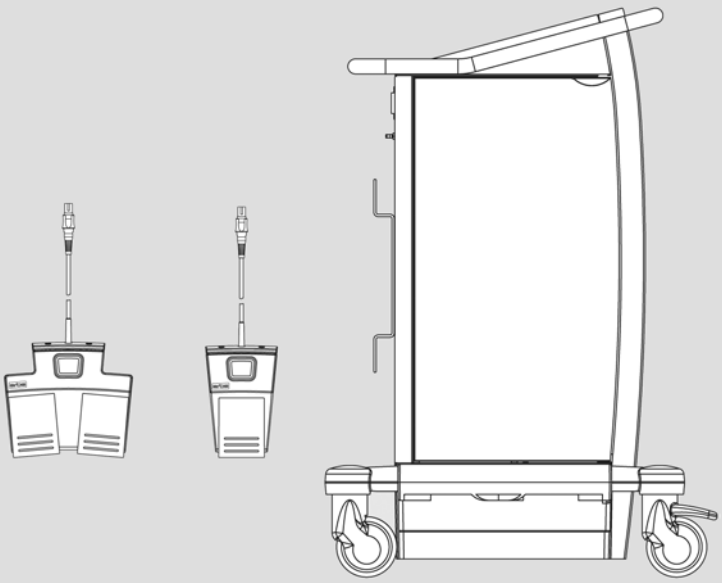
Adapters for electrosurgery



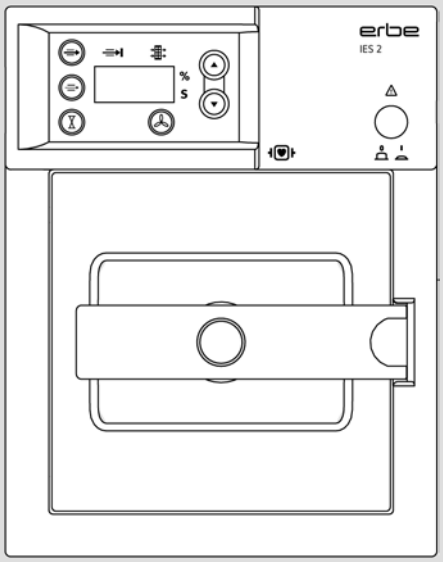
APC 3 (unit for argon-plasma coagulation)



Accessories for ESU and modules



IES 2 (smoke evacuation)



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Use of APC instruments

You can only connect Erbe APC instruments with an integrated filter to the APC socket of the APC 3. You can only set the mode, effect and argon flow within a specified range wit these instruments.

Check compatibility of instrument and CUT / COAG mode with the help of the Upmax display

⚠ CAUTION

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 users manuals of the instruments. The unit of measurement for electrical capacity is Vp. For example, an instrument can have a maximum electrical capacity of 5 kVp (5000 Vp). Another instrument can have a maximum electrical capacity of 500 Vp. You are not permitted to load the instrument beyond these values.

Example

You wish to operate an instrument that has a maximum electrical capacity of 500 Vp. You wish to operate an instrument in autoCUT mode with effect 5.5. See the display *max. voltage* in the CUT effect window.

2. Call up the CUT effect window

1. If the instrument symbol for the required instrument is not highlighted, touch the relevant instrument symbol.
2. Touch the CUT effect display.

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Fig. 3-1

The autoCUT mode with effect 5.5 would burden the instrument with a peak voltage of 550 Vp. You must not operate the instrument with effect 5.5 in autoCUT mode. The electrical capacity of the instrument (500 Vp) is lower than the maximum HF peak voltage (550 Vp) of the autoCUT mode with effect 5.5.

➢ Reduce the effect. Touch the minus button until the HF peak voltage is equal to or less than 500 Vp.

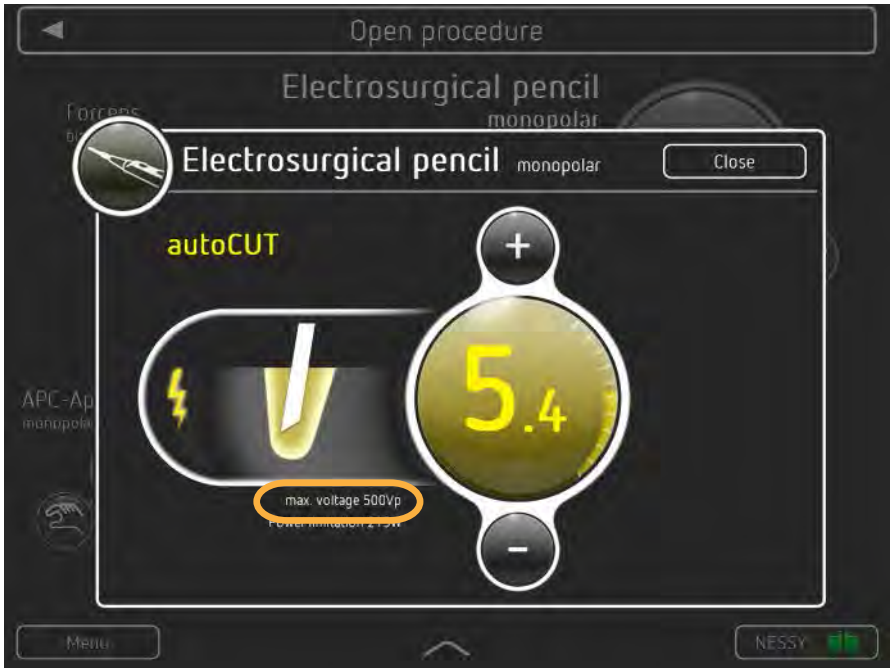

Fig. 3-2

The HF peak voltage (500 Vp) of the autoCUT mode with effect 5.4 is the same as the electrical capacity of the instrument (500 Vp). You may work with this setting.

In the same way, you can test the compatibility of the instrument and COAG mode. Touch the COAG effect display for this purpose.

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Check compatibility of the return electrode

⚠ CAUTION

Non-compatible or non-split return electrode

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

When applying a non-split return electrode, the contact between return electrode and skin is not monitored. If contact between return electrode and skin is inadequate, the unit does not emit any visual or acoustic warning signal.

Risk of burns for the patient under the return electrode!

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

⇨ Use only suitable return electrodes.

⇨ When applying a non-split return electrode: Regularly check the return electrode for good skin contact.

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

⇨ Use only suitable return electrode cables.

Depending on the return electrode (non-split or split), the Neutral Electrode Safety System (NESSY) of the Erbe VIO and compatible return electrodes monitors various parameters:

- The unit / return electrode connection
- The skin / return electrode contact
- The application direction of the return electrode

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Familiarize yourself in the chapter Safety Devices which individual parameters are monitored. When using non-split return electrodes, the skin / return electrode contact is not monitored.

When using third-party return electrodes, you must check in the accompanying papers of the manufacturer whether the return electrode is suitable for the VIO used.

Compatible footswitches

You can only connect Erbe footswitches to the VIO 3. There is no footswitch for the VIO 3 series.

Chapter 4
Description of the Controls

Controls on the front panel

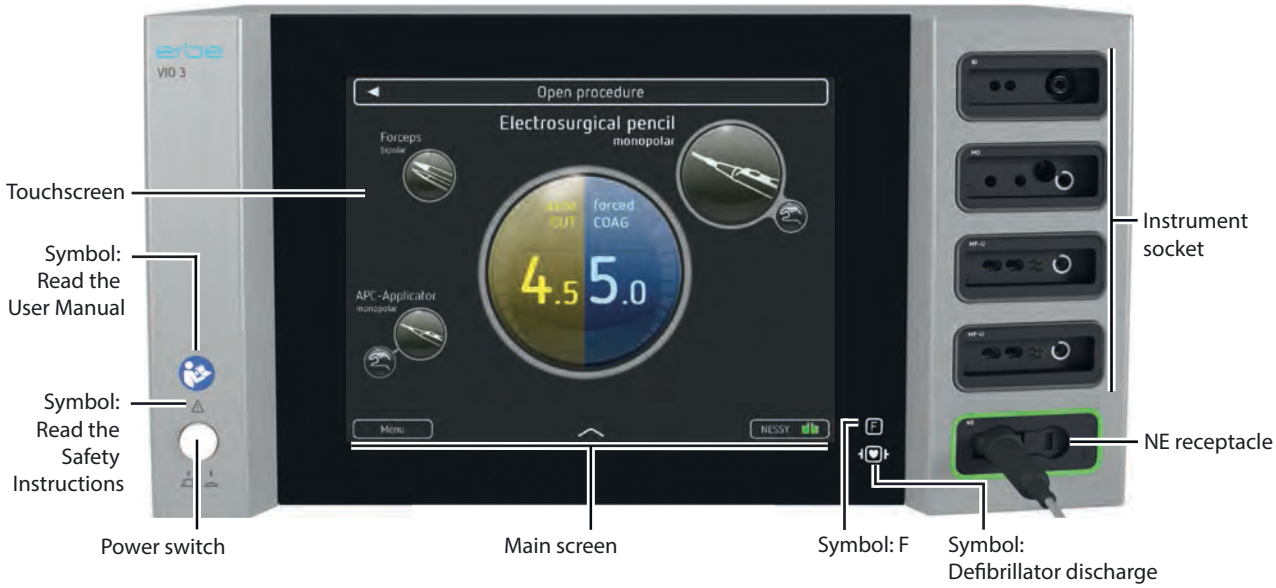

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Fig. 4-1

Power switch

Unit on / off. The unit is only fully disconnected from the power supply once the power cord is pulled out. Install the device such that the power cord can be pulled out without problems.

Main screen

On the main screen you see all information and controls necessary for operating the unit during an operation.

The main screen is the control center of the VIO 3. On this screen you can select the instruments , set the instruments, monitor the return electrode and call up other screens.

"F" icon

The symbol designates a constructional safety measure. The patient circuit is insulated from ground. The danger of leakage currents and therefore the danger of burns is substantially reduced for the patient.

Icon: defibrillator discharge

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

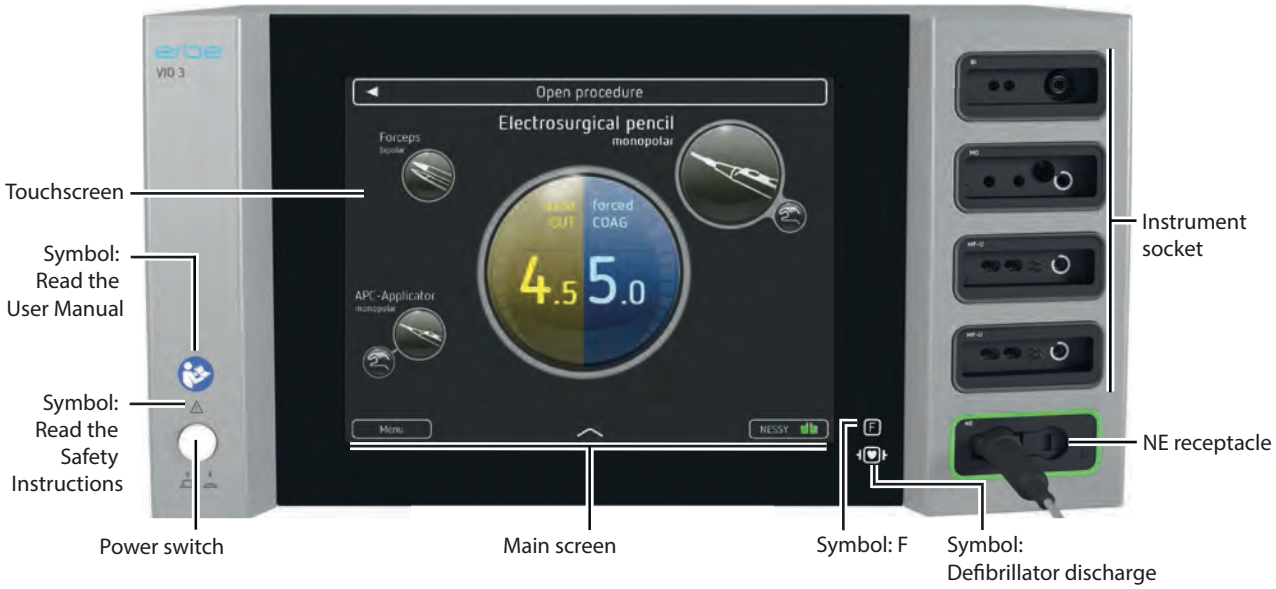

Fig. 4-2

Return electrode socket

Should you wish to activate the unit's monopolar mode, you have to connect a return electrode and apply it on the patient.

Instrument sockets

Connect HF instruments at these sockets.

Touchscreen

Touch-sensitive screen to set the VIO 3. The controls on the touchscreen change dependent on the task currently undertaken. User your fingers to control the VIO 3.

Icon: read the user manual

Read the user manual before switching on and using the unit.

Symbol: Read the safety instructions

When reading the User Manual, pay special attention to the safety instructions.

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VIO 3 main screen

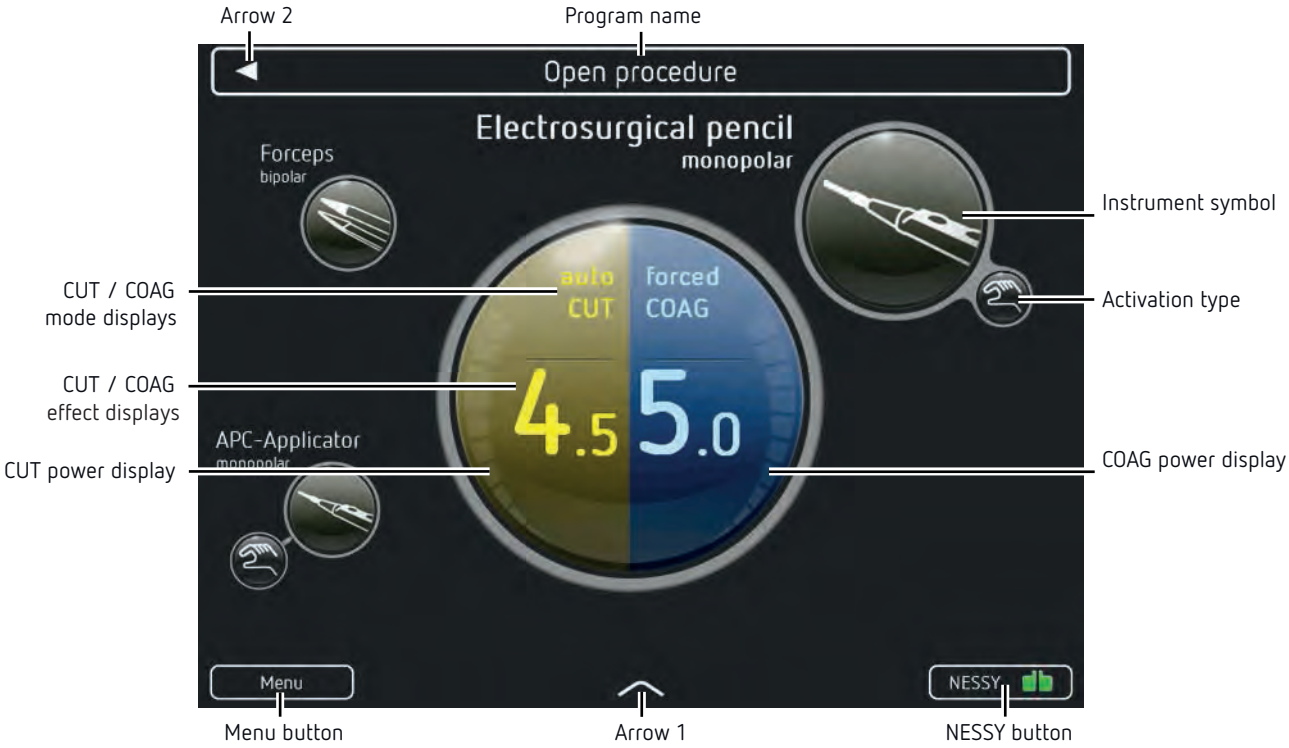

Fig. 4-3

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On the main screen you see the symbols of the instruments stored in the program. A series of further controls are also visible.

If you touch an instrument symbol, connect or activate the corresponding instrument, the instrument symbol is highlighted (Example: monopolar electrode handle). In addition to information on the allocated activation type, you then obtain information on:

- CUT mode / COAG mode
- CUT effect / COAG effect
- Power output for CUT / COAG and progress display for sealing in the thermoSEAL mode

Only if the instrument symbol is highlighted, can you change the instrument mode and effect.

Menu button

If you touch the menu button you call up a menu to adapt a large number of unit settings. These settings are explained in detail in the next chapter.

Arrow 1

If you touch Arrow 1, you call up the 'Assign activation type' field. Using symbols you can assign footswitches, AUTO START and AUTO STOP to the instruments.

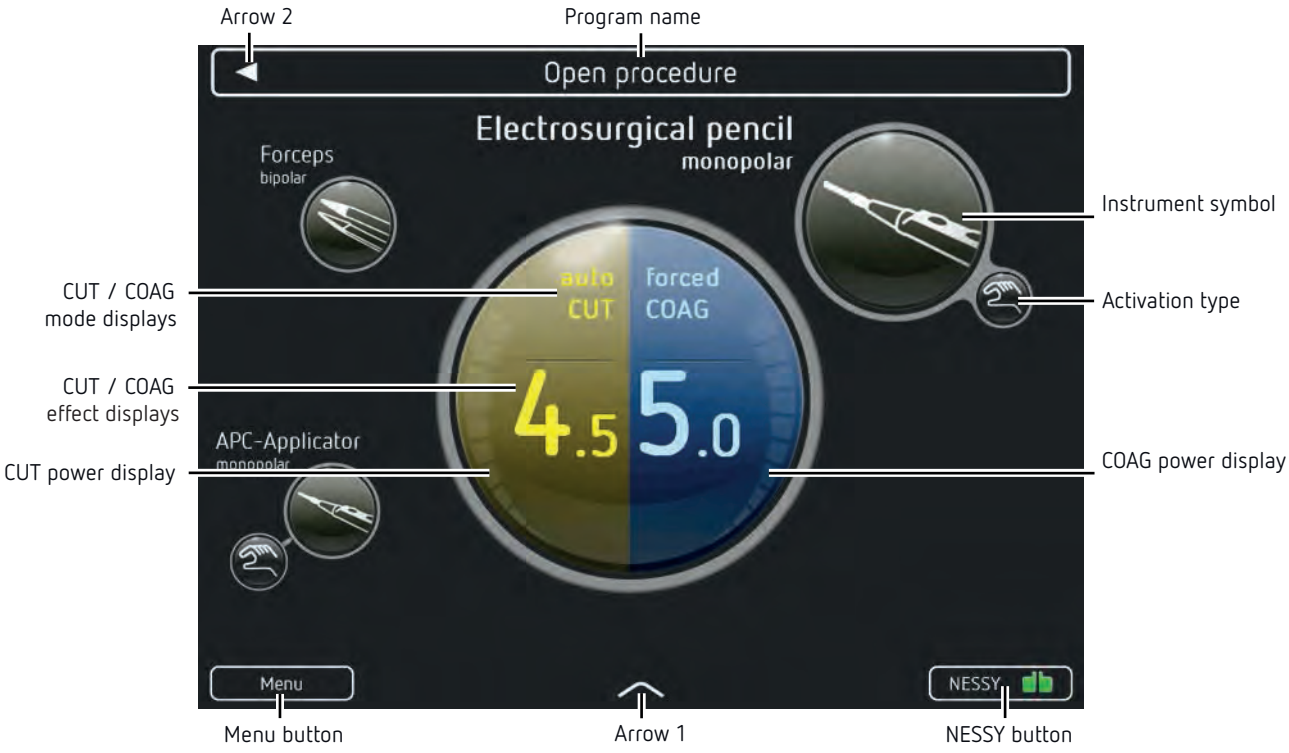

Fig. 4-4

NESSY button

The return electrode symbol provides information on what return electrode you have connected: split or non-split. If the return electrode symbol is green, you can activate monopolar modes. If the return electrode symbol is red, you cannot activate monopolar modes.

If you touch the NESSY button, you call up the 'return electrode monitoring' window. Here you receive information about the status of the return electrode. You can also switch the neonatal monitoring on and off.

CUT and COAG power display

The segments of the CUT and COAG power displays show you whether and how much power is output.

In the thermoSEAL mode, the display is a progress display for sealing.

Activation type

Shows the activation types assigned to the instrument.

Instrument symbol

The instrument symbols show the instruments in the program. If you connect an instrument which is not stored in the program, the unit displays an additional instrument symbol.

If an instrument is connected to the unit, there is a connection between the instrument symbol and the mode/effect displays. The outer circle of the instrument symbol is highlighted white. No instrument is connected in the above fig.

If you touch an instrument symbol, you see the set modes and effects for the instrument in the mode and effect displays.

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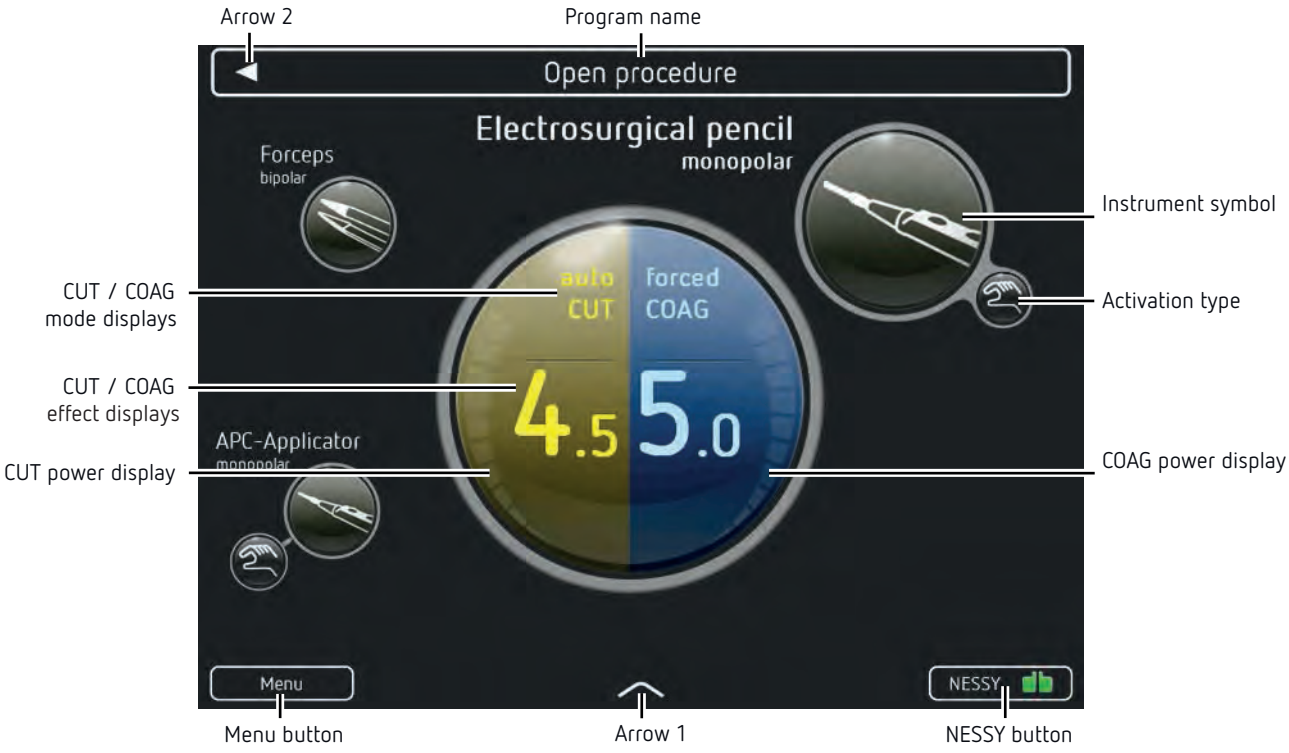

Fig. 4-5

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Program name

Name of the selected program.

Arrow 2

If you touch Arrow 2, you call up the program list.

CUT and COAG mode displays

Displays the CUT and COAG mode for the selected instrument. If you touch the display, you call up the window to change the mode.

CUT and COAG effect displays

Displays the CUT and COAG effect for the selected instrument. If you touch the display, you call up the window to change the effect.

Controls on the back

Fig. 4-6

Footswitch sockets

You connect a two-pedal and a one-pedal footswitch to these sockets. The combinations of two two-pedal footswitches or two one-pedal footswitches are not possible.

ECB sockets (Erbe Communication Bus)

These sockets serve to connect other units with the VIO 3.

Grounding terminal connection

If necessary, connect the grounding pin of the unit to the grounding system of the operating room using a grounding cable.

Power connection

Connect the unit to a properly installed grounded power outlet. Only use the provided power cord for this purpose. The power cord must bear the national test symbol.

Optionally, you can connect a power cord with V lock. The unit plug locks into the power connection of the VIO 3 and cannot loosen on its own.

Power fuses

The unit is protected with power fuses. 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 5
Working with VIO 3

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Make power connection

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

➢ Connect the unit to a properly installed grounded power outlet. Only use the Erbe power cord or an equivalent power cord for this purpose. The power cord must bear the national test symbol. If the unit is installed on the VIO CART, make the power connection with the power cord of the VIO CART.

Switching on, self-test

➢ Use the power switch to switch the unit on. The unit then carries out a self-test and tests all sockets. The units and footswitches connected are detected. All socket frames are lit. You see the version number of the software on the display.

In the unit's *Further settings* you can set which start screen you wish to start with after the self-test:

- *Program group list*,
  e.g. with the program groups Gynecology, General surgery
- Last used *Program list*,
  e.g. the Gynecology program list with the programs Open Procedure, Laparoscopic Procedure
- *FocusView* from the last used program
  = main screen of the unit with symbols of the instruments stored in the program and further controls

Although this setting is freely accessible, it should only be changed in coordination with all those who use the unit.

These instructions start with the *Program group list*.

Selecting the program

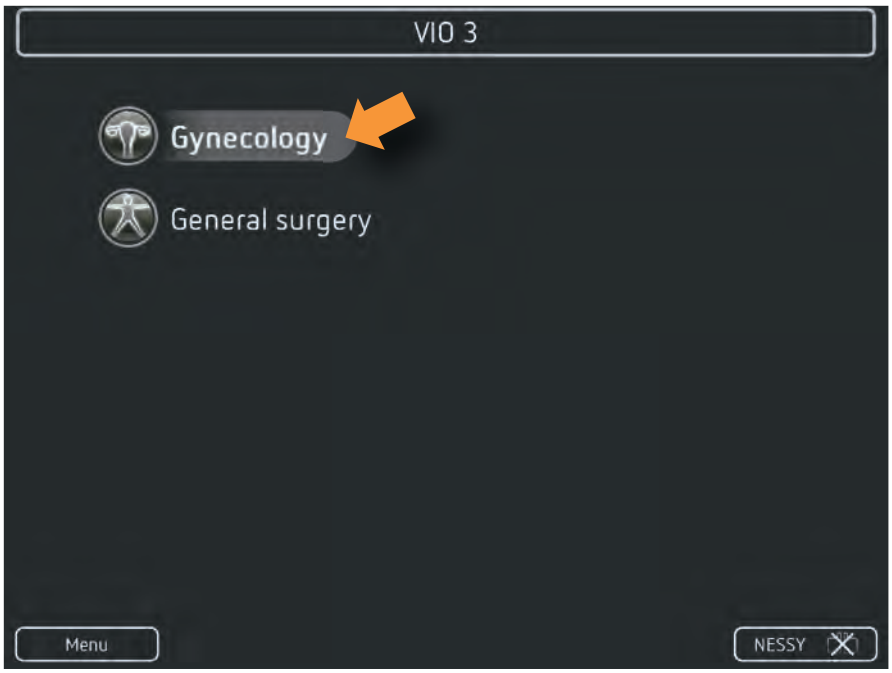

Fig. 5-1

1. Select a program group. Example: *Gynecology*

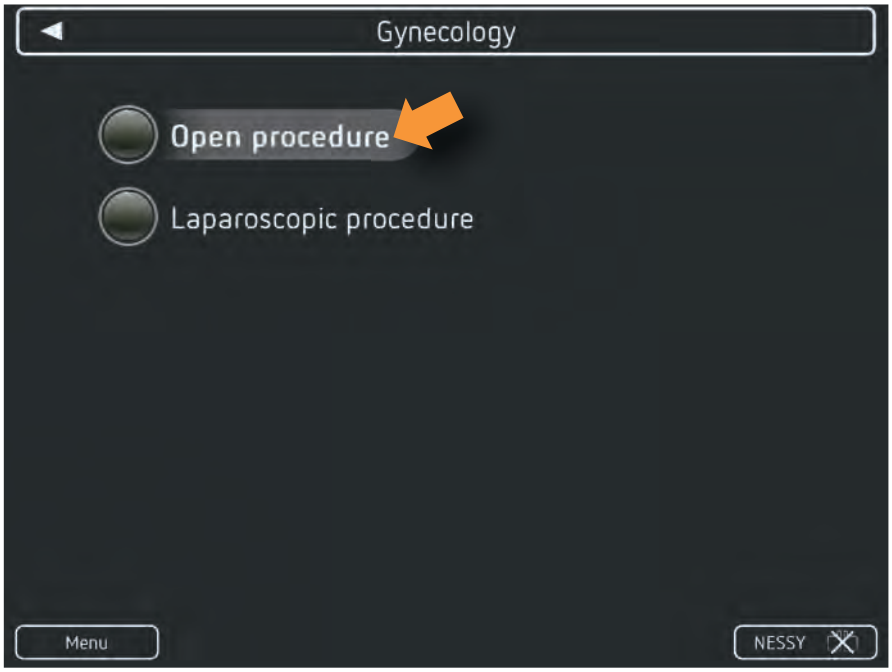

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Fig. 5-2

2. Select a program. Example: *Open Procedure*

Connecting return electrode, applying it on the patient

Fig. 5-3

1. Apply the return electrode on the patient.
2. Connect the return electrode cable to the return electrode socket.

Note: Under certain circumstances, the VIO 3 may ask you: *Which return electrode type have you just connected?* You then have to make the decision between a split or a non-split return electrode.

Make sure you actually connect the return electrode to the VIO 3 you register. Otherwise, you cannot activate the monopolar modes.

Check return electrode

Fig. 5-4

If you have connected the return electrode correctly, the return electrode on the screen lights green and the frame of the return electrode socket also lights green. The monopolar mode can be activated.

If the return electrode lights red or is crossed out, the frame of the return electrode socket lights red or is not lit, touch the NESSY button to obtain assistance.

Read detailed information on the function of the return electrode in the *Safety Devices* chapter. Here you also find assistance for various error situations.

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Fig. 5-5

If a return electrode error arises during the operation, e.g. too little contact with the patient's skin, a window for return electrode monitoring opens with a message.

An example for a message from return electrode monitoring is given in Fig. 5-5. In addition to the text, you see on the right a resistance display with resistance ranges. If the needle is in the gray or red range, you cannot activate monopolar modes.

Connecting the first instrument

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Connecting the instrument with the aid of the pin configuration

Each instrument has a pin configuration showing the type and separations of the plug-in contacts. Each socket has a pin configuration showing the type and separations of the socket inputs. The pin configuration of the instrument and the socket must match.

1. Determine whether the instrument is monopolar or bipolar.
   Monopolar instruments can be connected to monopolar sockets, multifunctional sockets and MF-U sockets. Bipolar instruments can be connected to bipolar sockets, multifunctional sockets and MF-U sockets. APC instruments must be connected to the APC sockets.
2. Consult the pin configuration of the instrument and socket.
3. Connect the instrument to the socket with suitable pin configuration.

If you plug the instrument into the wrong socket, the unit displays a message. Then you cannot activate the unit.

Connecting the instrument with the aid of the VIO 3

Fig. 5-6

1. Touch the instrument symbol. Example: *Forceps bipolar*

Fig. 5-7

The outer circle of the instrument symbol is flashing. The instrument symbol is highlighted.

Fig. 5-8

2. Connect the instrument to the socket with flashing socket frame.

Connecting a second instrument

➢ Connect a second instrument. Example: *Electrode handle monopolar*

Fig. 5-9

After plugging in the instrument, the socket frame lights white. The instrument symbol of the instrument is highlighted on the main screen.

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Meaning of the instrument symbols in different displays

Fig. 5-10

If you touch an instrument symbol, connect or activate the corresponding instrument, the instrument symbol is highlighted (Example: monopolar electrode handle). In addition to information on the allocated activation type, you then obtain information on:

- CUT mode / COAG mode
- CUT effect / COAG effect
- Power output for CUT / COAG and progress display for sealing in the thermoSEAL mode

Only if the instrument symbol is highlighted, can you change the instrument mode and effect.

The monopolar electrode handle (1) has just been plugged, activated or the corresponding instrument symbol touched:

- The instrument symbol is highlighted in size.
- The outer circle of the instrument symbol is white.
- The instrument symbol is closely connected to the mode and effect displays.

You can check and change the instrument mode and effect in this display.

The bipolar forceps are connected to the unit (2):

- The outer circle of the instrument symbol is white.
- The instrument symbol is connected to the mode and effect displays with a thin line.

The APC applicator is not connected to the unit (3):

- The outer circle of the instrument symbol is grayed out.
- The instrument symbol is not connected to the mode and effect displays.

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Connecting an instrument which is not stored in the program

If required, you can connect instruments which are not stored in the program. The unit then displays an additional instrument symbol on the main screen. Under certain circumstances, a window with an instrument list may open.

➢ Select the instrument in the instrument list.

Note: The instrument additionally connected is not saved in the program. After switching off the unit, it no longer exists.

You can only save modified programs if you have access to the unit's *Protected settings*. See section: *Overwrite modified program or save as a new program*.

Checking program settings

In order to check the mode and effect settings of an instrument, the instrument symbol has to be highlighted.

➢ Prior to activation of instruments, check the program settings. You have to know which instrument you are activating with which activation type and which mode and effect settings.

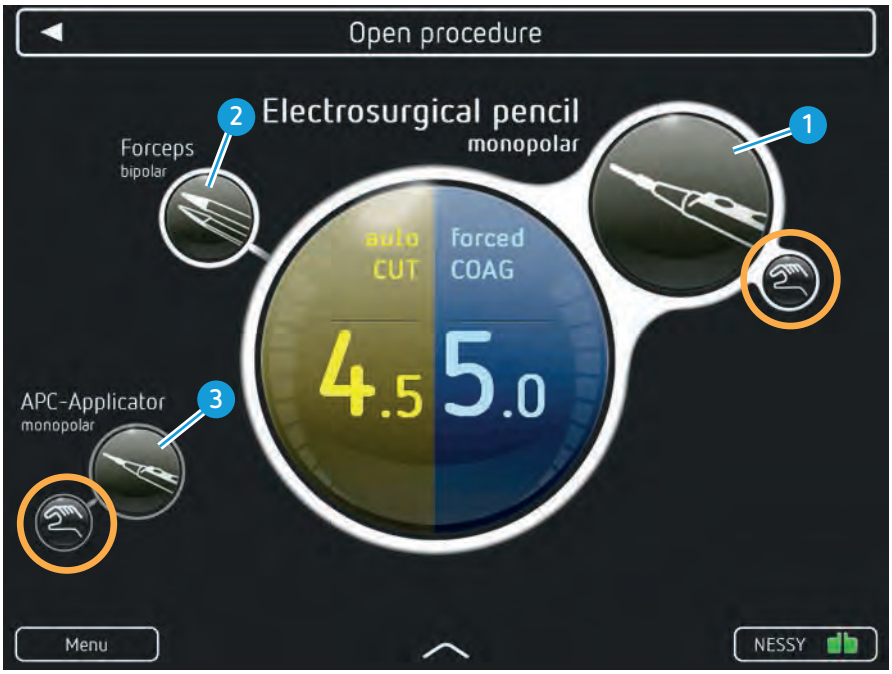

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Fig. 5-11

In the main screen you see at a glance which instruments are connected and which activation type is assigned to them:

In the *Open procedure* example program, a monopolar electrode handle (1) and bipolar forceps (2) are connected.

- The monopolar electrode handle (1) can be activated with the finger switch.
- The bipolar forceps (2) are not assigned any activation type. They cannot be activated.
- The APC applicator (3) is not connected. It could be activated with the finger switch.

In the *Open procedure* example program the instrument symbol for the monopolar electrode handle (1) is touched. You would activate the instrument with the following settings:

- autoCut, effect 4.5
- forcedCoag, effect 5.0

Changing mode and effect

Changing mode

1. If the instrument symbol for the required instrument is not highlighted, touch the relevant instrument symbol.
2. Touch the CUT or COAG mode display.

Fig. 5-12

3. A window with an mode list opens. The active mode is highlighted gray (Example: forcedCOAG). Touch the required mode.

Changing effect

1. If the instrument symbol for the required instrument is not highlighted, touch the relevant instrument symbol.
2. Touch the CUT or COAG effect display.

Fig. 5-13

3. A window with an effect display opens (Example: forced COAG, effect 5.0). Select the required effect with the + / - buttons.
4. Close the window.

Note: While you change the effect, the operating surgeon cannot activate the unit for several seconds.

Note: The changes are not stored in the program. After switching off the unit, they no longer exist.

You can only save modified programs if you have access to the unit's *Protected settings*. See section: *Overwrite modified program or save as a new program*.

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Assigning activation type

➢ Touch the arrow on the lower edge of the main screen (Arrow 1).

Fig. 5-14

The *Assign activation type* field opens. The field contains symbols for the activation types two-pedal footswitch, one-pedal footswitch, AUTO START, AUTO STOP.

Meaning of the symbols in different displays

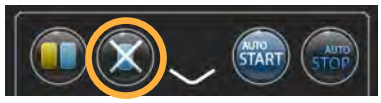

Fig. 5-15

If a footswitch is not connected, the corresponding symbol is crossed out.

Fig. 5-16

If the *"Assignment of two pedal footswitch"* is permitted in the *Protected Settings* you also see two symbols: CUT Pedal and COAG Pedal of the two-pedal footswitch.

Fig. 5-17

If the instruments stored in the program do not permit AUTO START or AUTO STOP, the corresponding symbol is grayed out.

If the *"Use of AUTO START"* is blocked in the *Protected settings* , the corresponding symbol is grayed out.

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Assigning activation type

Fig. 5-18

1. Touch a symbol. Example: Two-pedal footswitch
   You see docking points on all instruments, which allow the selected activation type.
2. Drag the symbol to the docking point of the required instrument.
   In the 'Assign activation type' field, the field is grayed out after assignment.

You can also drag symbols from one instrument to another.

Note: The changes are not stored in the program. After switching off the unit, they no longer exist.

You can only save modified programs if you have access to the unit's *Protected settings*. See section: *Overwrite modified program or save as a new program*.

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Activating VIO 3

⚠ 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.

Fig. 5-19

You can activate all instruments to which an activation type is assigned.

➢ Operate the finger switch, footswitch or use AUTO START. Example: The monopolar electrode handle is activated in COAG mode.

The outer circle of the mode and effect displays and the outer circle of the instrument symbol lights up blue with COAG activation, yellow with CUT activation.

The segments of the CUT and COAG power displays (1) (2) show you whether and how much power is output.

In the thermoSEAL mode, the display is a progress display for sealing.

Fig. 5-20

The socket frame of the activated instrument symbol lights up blue with COAG activation, yellow with CUT activation.

You hear an activation sound.

Note: You can also activate instruments whose settings you do not see. You should be sure which settings you activate.

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