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USER MANUAL

USER MANUAL

APC 2

CE 0124

Unit REF No. 10134-000

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Chapter 1
Safety Instructions

Intended use

APC 2 is an argon plasma coagulator for argon plasma coagulation (APC) with VIO electrosurgical units.

Combination with other equipment

You can combine this unit with matching Erbe equipment: e.g. VIO electrosurgical units, IES 2, EIP 2. You will then have a well-conceived, coordinated system.

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.

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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.

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

APC can only be performed with an APC 2 and a VIO electrosurgical unit. All the safety instructions for monopolar electrosurgery and additional safety instructions for APC apply.

You will find the additional safety instructions for APC in Chapter 2.

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
- Inadvertent tissue damage
- Risks due to incorrect use of the neutral 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 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

NOTICE

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.

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.

NOTICE

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.

⇨ 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.

NOTICE

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.

⇨ 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.

NOTICE

Penetration of liquid into the unit

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

⇨ Make sure no liquid can penetrate the unit.

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

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 / 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 power fuse, defective unit

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

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⇨ Blown power 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 Elektromedizin. You will find the addresses in the address list at the end of this User Manual.

⚠ WARNING

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

Risk of electric shock to the medical personnel!

⇨ Switch off the unit. Unplug the power cord of the unit / 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 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.

⚠ 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.

⇨ Or scavenge with argon.

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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 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 / 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 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.

⚠ 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.

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Burns

⚠ WARNING

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

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

- ⇨ Check the unit and accessories for damage every time before using them (e.g. footswitch, cords of instruments and the neutral electrode, 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.
- ⇨ 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 surgery 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 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.

⚠ 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.

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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.

⚠ 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 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!

⇨ 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.

⚠ WARNING

Power setting too high, ON time too long, effects too high

The higher the power setting the longer the ON 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!

⇨ Set power as low as possible relative to the required surgical effect. However, power settings that are too low can be dangerous, e.g. gas embolisms with the APC (Argon Plasma Coagulation).

⇨ 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.

⇨ Set effect as low as possible relative to the required surgical effect.

⇨ If you are unable to achieve a surgical effect with a power setting / ON time / effect level that is 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 neutral 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.

⚠ 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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⚠ 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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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.

Risks due to incorrect use of the neutral electrode

Please read the safety instructions in the User Manual for the VIO electrosurgical unit.

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.

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 and medical staff!

⇨ 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.

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NOTICE

Interference with electronic units due to the electrosurgical unit

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

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

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 unit.

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.

NOTICE

Stacked units

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

Units may fail or not function properly.

⇨ The unit may only be placed next to or stacked with VIO-series units.

⇨ If it is necessary to operate the unit near or stacked together with non-VIO-series units 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?

⚠ 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 the patient.

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)"*.

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⇨ 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.

Damage to the unit and accessories

NOTICE

Alcohol-based spray disinfectant for fast disinfection

With membrane keyboards and paint surfaces there is the risk of cracks. Propanol and ethanol will erode 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.

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.

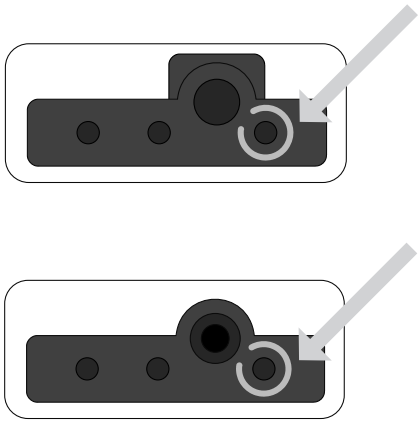

Fig. 1-1

NOTICE

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.

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

⇨ Instructions are available in the "Accessories" chapter of the VIO User Manuals.

Notes

Grounding

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

Use of a defibrillator

Note: The unit conforms to the requirements of Type CF and is protected against the effects of a defibrillator discharge.

Membrane keyboards

Note: If alcohol-based disinfectants are used on units with membrane keyboards, this remove the anti-glare finish. However, the user surfaces remain fully functional. This does not present a hazard.

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Chapter 2
Additional safety instructions for APC

The safety instructions are structured according to the following risks:

- Fire / explosion
- Burns
- Risks due to gas embolisms or excessive intraluminal gas pressure
- Risk of infection
- Risks due to the pressure gas bottle

Fire / explosion

⚠ DANGER

Hot tissue, combustible materials, and oxygen in the tracheobronchial system

Due to APC the tissue can become so hot that it can ignite combustible materials in the vicinity, e.g. due to hot particles flying around. Combustible materials are, for example, plastic insulation at the distal end of the bronchoscope or a tracheal tube.

However, ignition is only possible if a fire-supporting gas, e.g. oxygen, is present at the same time. This particularly applies to highly concentrated oxygen or pure oxygen.

Risk of burns to the patient!

⇨ Do not admit any oxygen to the tracheobronchial system directly before, and particularly during, APC. Do not admit any other combustible or fire-supporting gases (e.g. nitrous oxide) or combustible liquids either.

⇨ If APC is used for a lengthy period of time: Administer the oxygen required for patient ventilation and APC alternately.

⇨ The distal end of the APC applicator must always be in the field of view of the endoscope before and during activation of the argon plasma. Never activate the argon plasma without visual control.

⇨ Keep the argon plasma as far as possible away from combustible materials.

⚠ DANGER

Combustible gas mixture in the tracheobronchial system

Hemostasis and devitalization of tissue produce smoke. In conjunction with oxygen a highly combustible gas mixture develops.

Risk of burns to the patient!

⇨ Short activation pulses reduce development of the gas mixture.

⇨ Extract the gas mixture.

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⚠ 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.

⇨ Or scavenge with argon.

Burns

⚠ WARNING

An active APC electrode comes into contact with tissue during coagulation

There is a cutting effect and uncontrolled coagulation!

⇨ Do not touch tissue with an active APC electrode during coagulation.

⚠ WARNING

The activated APC applicator presses into tissue or against the organ wall

Risk of emphysemas / wall lesions!

⇨ Do not press the activated APC applicator into tissue or against the organ wall.

Risks due to gas embolisms or excessive intraluminal gas pressure

⚠ WARNING

The activated APC applicator is pointing at an open vessel, argon flow is too high, the power setting is too low

Risk of gas embolisms!

⇨ Do not point the APC applicator at open vessels.

⇨ Set argon flow as low as possible.

⇨ Do not press the activated APC applicator into tissue or against the organ wall.

⇨ Observe the Erbe recommended settings for the APC (power, mode).

⚠ WARNING

The argon introduced can not escape from body cavities

Risk of intraluminal pressure rise and distension! Risk of gas embolisms!

⇨ Check intraluminal gas pressure regularly.

⇨ Extract.

⇨ Introduce a decompression catheter if required.

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Risk of infection

⚠ WARNING

Contaminants are blown from the unit to the patient

Risk of infection!

⇨ Do not touch the APC socket.

Risks due to the pressure gas bottle

⚠ WARNING

Damage to the gas bottle or valve. Gas emerges at high pressure.

If the gas bottle has been weakened due to serious damage, this can lead to cracks in the wall of the gas bottle. Considerable stresses and strains occur at the cracks, causing the gas bottle to break open. Gas emerges at high pressure. The gas bottle is propelled like a rocket.

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

⇨ Do not apply force to gas bottles, gas bottle connectors, valves, or pressure regulators.

⇨ When transporting, storing, and using the gas bottle, prevent it from falling over and dropping by securing it with chains, hoops, or retaining straps.

⇨ Only transport gas bottles with the valve guard fitted: bottle cap or bottle collar.

⇨ Prevent the argon gas bottle from being heated by radiators or naked flames. The surface temperature must not exceed 50 °C.

NOTICE

Incorrect pressure regulator, incorrect pressure lines

The unit has a certain input pressure. You will find it in the Technical Data.

If you connect up the wrong pressure regulator or wrong pressure lines, the unit can be damaged.

⇨ Only connect argon gas bottles to the unit using the pressure regulator and pressure lines specified by Erbe.

⚠ DANGER

Wrong gas

The unit may only be operated with argon.

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

⇨ Check whether the gas bottle actually contains argon. Labels on the gas bottle must not be damaged or removed.

⇨ Use argon 4.8 (99.998% purity) or higher, e.g. argon 5.0.

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⚠ WARNING

Uncontrolled escape of argon

If the gas accumulates in air you are breathing, there is a risk of suffocation. Symptoms include drowsiness, rise in blood pressure, and respiratory distress. In an atmosphere of pure argon a person would fall unconscious immediately without any warning and suffocate.

⇨ When gas bottle valves are opened, there is a brief hissing sound. If the hiss continues for more than 2 seconds, there is a leak. The gas bottle must be closed again immediately. The unit may only be used when the leak has been stopped by a competent technician.

⇨ Make sure the connections of the pressure lines to the APC 2 are gastight. The same applies to the connection of the pressure regulator to the gas bottle.

⇨ Close the safety valves on the gas bottles after use.

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Chapter 3
Description of the Controls

Controls

The APC 2 itself represents a separate socket module within the VIO system as a whole. It must therefore only be used in connection with a VIO electrosurgical system, as the central controls are found there, including those for the APC 2. For operation of the APC 2 the following controls and options are thus basically available:

- the controls of the VIO electrosurgical system (see also relevant section)
- the controls on the sockets of the APC 2
- the footswitches for VIO.

Controls on the front panel

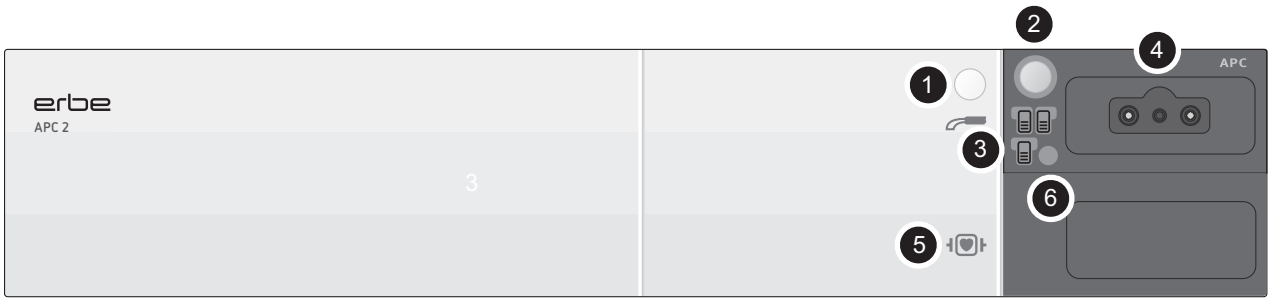

Fig. 3-1

(1) Purge button Before the instrument can be activated for the first time, it must first be purged with argon. The Purge button only functions for the socket whose Focus button is lit up.

In the service programs of the VIO system, a technician can make the appropriate setting according to whether the APC instrument is to be automatically purged with argon when it is connected to the APC socket.

(2) Focus button for APC socket If a Focus button next to the socket is pressed, the functions of the socket and the setting of the functions will be shown in the display.

(3) Footswitch indicator lights The footswitch symbol lights up when the respective footswitch is assigned to the socket.

(4) APC socket Plug the FiAPC connector of the instrument into this socket.

(5) CF icon The unit conforms to the requirements of Type CF (Cardiac Float) and is protected against the effects of a defibrillator discharge.

(6) ECB indicator light This light turns up red when there is no ECB connection between the APC and the electrosurgical unit.

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Controls on the back

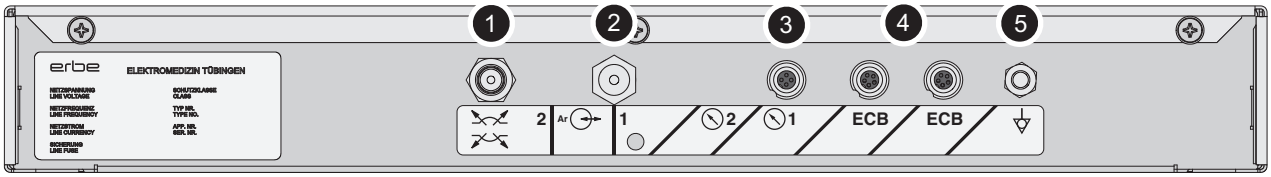

Fig. 3-2

(1) Purge pin see chapter Installation.

(2) Argon connection see chapter Installatio.

(3) High-pressure sensor see chapter Installation.

(4) ECB sockets The ECB (Erbe Communication Bus) enables communication between the electrosurgical unit and connected units.

(5) Potential equalization see chapter Installation.

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Chapter 4
Working with the APC 2 (in combination with a VIO from the D series)

Preparations for start-up

1. Make power connection, switch on unit, automatic performance test

The APC 2 can only be operated in conjunction with the electrosurgical unit! The power connection, startup and the automatic performance test are thus carried out jointly (automatically) on startup of the electrosurgical unit (see also relevant section).

2. Getting an overview: assignment of the active program for the APC 2

The window for operation of the APC 2 is accessed by pressing the Down button. In the display you can see a symbol for the Down button, and underneath, *APC* if an APC 2 is connected.: The Down button can be used to move to the *Directory* window of the APC 2. All other steps are exactly as for operation of the electrosurgical unit.

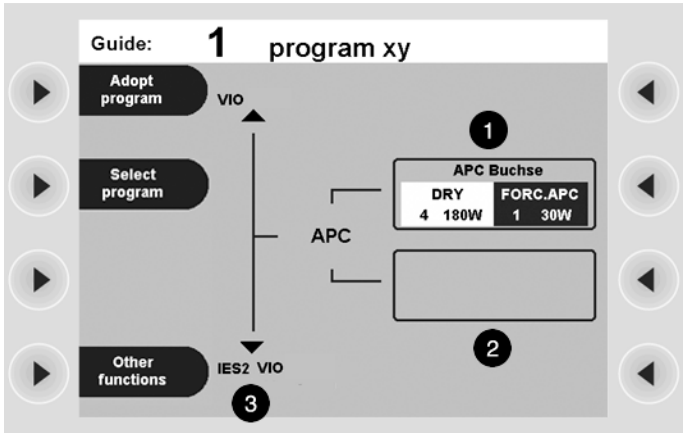

Fig. 4-1

3. Connecting the instrument

⚠ WARNING

Contaminants are blown from the unit to the patient

Risk of infection!

⇨ Do not touch the APC socket.

Connect an instrument to the APC socket.

Instrument detection

Erbe APC instruments possess an electronic identifier, i.e. the unit automatically detects the product and its specifications after the connection cable has been inserted and several default settings are executed automatically on the unit. In this case when the instrument connector is inserted in the VIO socket, the display shows the message: New instrument detected by system. When the connector is removed, the instrument is logged off and this is acknowledged by the message Instrument disconnected from the system.

Instrument detection of course does not prevent you from making your own preferred settings.

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Setup parameters on the APC 2

When working with the APC 2 you can select and set up various parameters. To do this you use the display and the controls of the VIO electrosurgical unit, which is already known to you. The availability of these parameters can be seen from the Focus View for the APC socket. However, this task is generally carried out for you by the instrument detection system of the Erbe APC instruments: certain values are stored electronically on the instrument and are preset automatically when the instrument is inserted in the socket of the unit.

Depending on the mode, the other parameters affect the coagulation result in completely different ways. It is therefore not possible to give simple rules of thumb for use.

Mode Here you can select a specific mode (FORCED APC, PRECISE APC, PULSED APC and possibly others). Modes vary according to their technical properties (voltage control etc.), which bring about different coagulation results.

Effect The effect is an indicator for the strength of the mode selected. This does not mean that with a higher effect the result will be greater in *every*regard. For example, although a higher effect results in faster coagulation of the tissue with FORCED APC, the coagulation depth is reduced as a consequence.

Flow With the flow, the rate of argon flow is set in litres per minute (l/min). Depending on the application, a lower flow rate (e.g. if there is a risk of argon being introduced into bodily cavities, gas embolisms) or a higher rate may be appropriate.

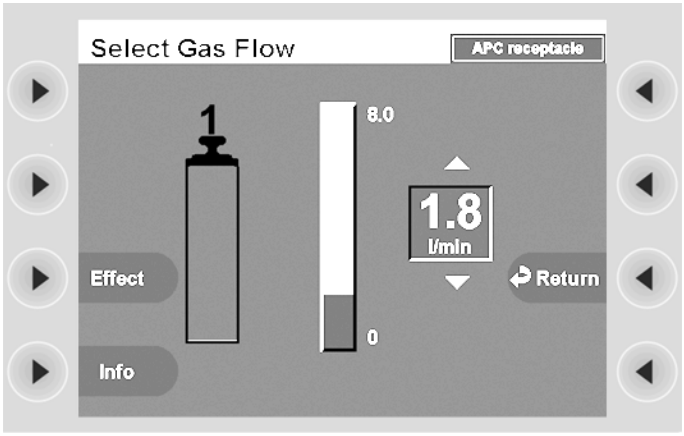

Fig. 4-2

Power The power setting allows you to preselect the maximum output applied to the tissue.

Purging the instrument with argon If you wish to purge the instrument with argon during surgery press the Purge button (1). The Purge button only refers to the socket whose Focus button is lit up. The instrument which you wish to purge must be connected to the socket with the illuminated Focus button.

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Chapter 5
Working with the APC 2 (in combination with a VIO from the S series)

Preparations for start-up

1. Make power connection, switch on unit, automatic performance test

The APC 2 can only be operated in conjunction with the electrosurgical unit! The power connection, startup and the automatic performance test are thus carried out jointly (automatically) on startup of the electrosurgical unit (see also relevant section).

2. Getting an overview: Assignment of the active program for the APC 2

When you press the focus button of the APC 2, the APC 2 settings of the active program are displayed on the base unit:

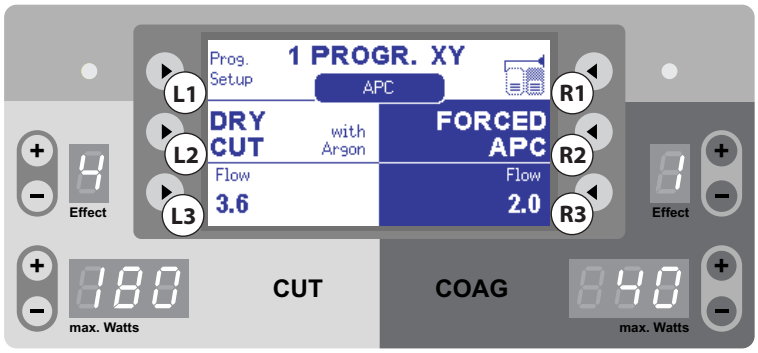

Fig. 5-1

You can modify the APC 2 settings in the same way as the settings of the base unit using the selection buttons (L1, L2, L3, R1, R2 and R3) and the plus/minus buttons of the base unit.

You can save modified parameters via the base unit in an existing or new program.

3. Connecting the instrument

⚠ WARNING

Contaminants are blown from the unit to the patient

Risk of infection!

⇨ Do not touch the APC socket.

Connect an instrument to the APC socket.

Instrument detection

Erbe APC instruments possess an electronic identifier, i.e. the unit automatically detects the product and its specifications after the connection cable has been inserted and several default settings are executed automatically on the unit. In this case when the instrument connector is inserted in the VIO socket, the display shows the message: "The connected instrument is ready for operation". When the connector is removed, the instrument is logged off, this is acknowledged by the message "An instrument has been disconnected"

Instrument detection, of course, does not prevent you from making your own preferred settings.

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Setup parameters on the APC 2

When working with the APC 2 you can select and set up various parameters. To do this you use the display and the controls of the VIO electrosurgical unit, which is already known to you. The availability of these parameters can be seen from the Focus View for the APC socket. However, this task is generally carried out for you by the instrument detection system of the Erbe APC instruments: certain values are stored electronically on the instrument and are preset automatically when the instrument is inserted in the socket of the unit.

Depending on the mode, the other parameters affect the coagulation result in completely different ways. It is therefore not possible to give simple rules of thumb for use.

Mode

Using the L2 or R2 selection buttons, open the CUT mode or the COAG mode window to select a particular CUT or COAG mode. You have the choice between a "real" APC mode for Argon Plasma Coagulation (FORCED APC) and various modes for argon-enhanced cutting or coagulation. In the modes for argon-enhanced cutting or coagulation the argon gas reduces smoke formation, however, no argon plasma is produced.

Flow

Using the L3 or R3 selection buttons open the window for setting argon flow (unit: litres per minute). Depending on the application, a lower flow may be necessary (e.g. when there is a risk of argon blowing into bodily cavities, gas embolism), as may be a higher flow.

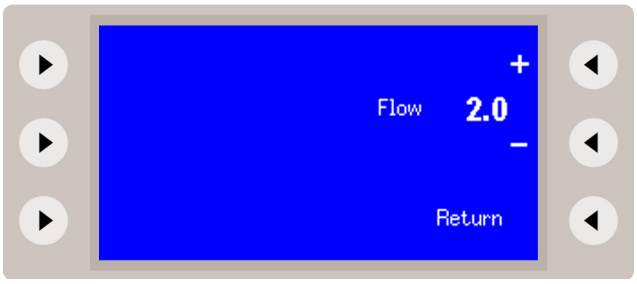

Fig. 5-2

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Effect

Set the effect using the plus/minus buttons next to the effect displays. The COAG effect influences the coagulation depth and coagulation speed in different ways depending on the COAG mode. For this, read the description of the selected mode in the User Manual for the VIO base unit. The CUT effect is a measurement of coagulation depth. As a rule, a higher CUT effect signifies a greater coagulation depth.

Fig. 5-3

Power limitation

Set the power limitation using the plus/minus buttons next to the watt displays. The power limitation sets the maximum power of the unit available in the selected CUT or COAG mode. The power limitation must not be confused with the actual power applied by the unit, which is regulated by the unit depending on the situation.

Fig. 5-4

Purging the instrument with argon

If you wish to purge the instrument with argon during surgery press the Purge button (1). The Purge button only refers to the socket whose Focus button is lit up. The in-

strument which you wish to purge must be connected to the socket with the illuminated Focus button.

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Chapter 6
Description of socket hardware

Socket combinations on the APC module

The APC module can accommodate two sockets. The following combinations are possible:

- One APC socket.
- Two APC sockets.
- One APC socket and one monopolar socket.
- One APC socket and one bipolar socket.
- One APC socket and one multifunctional socket. The multifunctional socket is only supported by the VIO 300 D.

The sockets of the VIO electrosurgical unit and the APC module must be regarded as one unit – as a socket strip of one and the same system.

You control the Cut and Coag functions of all the sockets via the Selection buttons and the display of the VIO electrosurgical unit (see the chapter *Tutorial* in the VIO User Manual).

If, for example, two or more monopolar sockets are installed in the VIO system's socket connector, these are counted from the top downwards. If you call up the monopolar sockets, you will see the designation *Monopolar socket 1*, *Monopolar socket 2* etc. in the *Cut/Coag Settings* window on the VIO system display.

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Purchasing further sockets

You can individually select the sockets of your electrosurgical unit when placing your order. After purchase it is possible to add further sockets or to replace existing sockets with others.

A socket unit consists of a front plate, socket insert and two holding clips. Installation in the electrosurgical unit is simple and can be carried out quickly by any technician authorized by Erbe.

FiAPC socket unit

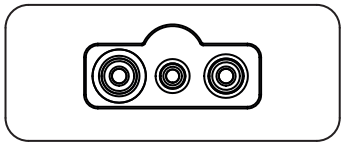

Fig. 6-1

REF No. 20134-651

Connectors supported

- FiAPC connector

Monopolar socket, bipolar socket, multifunctional socket

Read the chapter *Description of Socket Hardware* in the VIO User Manual for more information on these sockets.

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Chapter 7
Installation of the APC 2 and the Argon gas bottles

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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.

NOTICE

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.

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.

NOTICE

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.

⇨ 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.

NOTICE

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.

⇨ 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.

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.

NOTICE

Penetration of liquid into the unit

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

⇨ Make sure no liquid can penetrate the unit.

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

Electrical installation

Grounding

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

Installing the unit on an Erbe cart

Please read the User Manual for the cart concerned. There you will find instructions on how to secure the unit to the cart.

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Fixing argon gas bottles, connection of the working gas bottle, detachment of the working gas bottle on the VIO CART

1. Attach gas bottle pads

Fig. 7-1

Press the gas bottle pad (1) into the left-hand corner of the VIO CART. If you want to position a spare gas bottle in the right-hand corner, install a gas bottle pad there as well.

2. Insert fixing strap

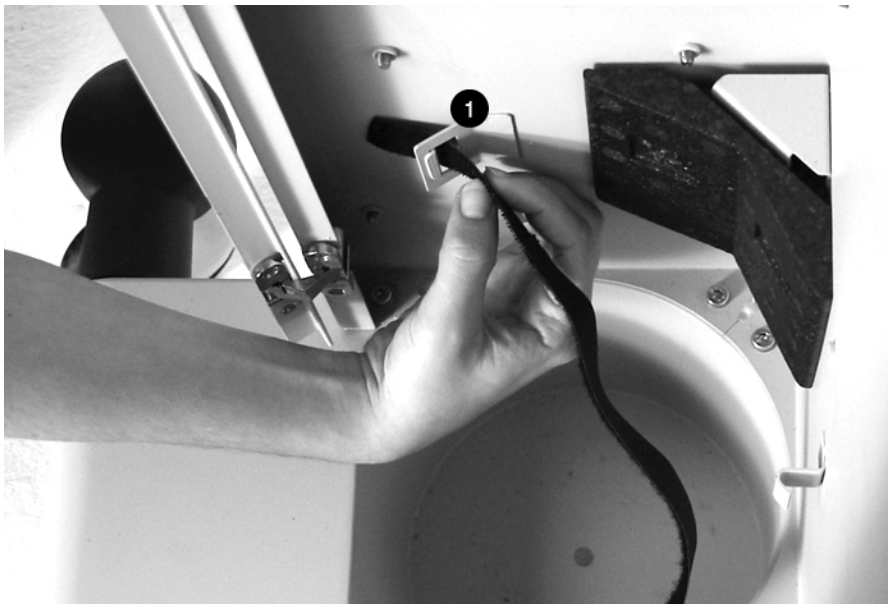

Fig. 7-2

Insert the fixing strap in the left-hand lug of the VIO CART (1). The fleecy side of the fixing strap must face outwards. If you want to position a spare gas bottle in the right-hand corner, insert a fixing strap there as well.

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3. Place the argon gas bottle in the VIO CART and fix in place

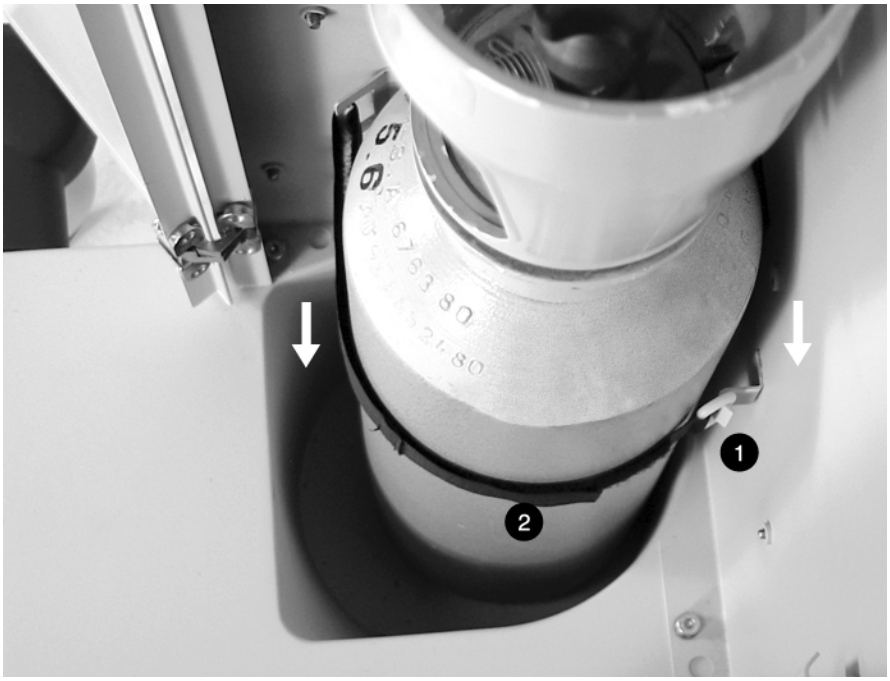

Fig. 7-3

Place the working gas bottle in the recess. Place the spare gas bottle - if installed - to the right of it.

Hook the fixing strap into the lug (1). Close the fixing strap (2) firmly. If you are using a spare gas bottle, proceed in the same manner.

4. Connect pressure reducer to working gas bottle

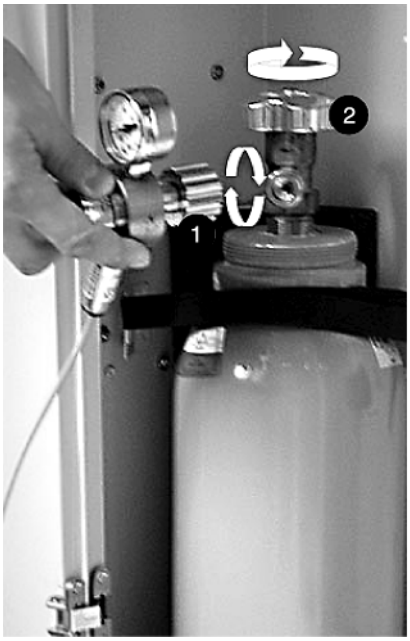

Fig. 7-4

Input pressure: (5 ± 2) x 10^5 Pa / 5 ± 2 bar.

For the country-specific gas bottles Erbe Elektromedizin offers the appropriate pressure reducer complete with pressure sensor. Information is available from Erbe or your distributor.

1. Remove the protective cap from the gas bottle (not with French gas bottles, for which the gas bottle collar is left in place). Remove the valve closure nut. Only

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turn the union nut (1) of the pressure reducer clockwise onto the gas bottle by hand. Do not use tools! To prevent any soiling of the valve connection, screw the pressure reducer onto the gas bottle at once.

2. Insert the pressure line and the line of the high-pressure sensor through the opening (3) above the argon gas bottle.

5. Connect the pressure line and the high-pressure sensor line

Fig. 7-5

1. Fit the connector of the pressure line (1) to the argon connection of the APC 2.
2. Fit the connector of the high-pressure sensor (2) to the sensor connection of the APC 2. Tighten the union nut by hand.
3. Open the gas bottle valve (2) without jerking by turning the handwheel counter-clockwise. After one full turn the gas bottle valve is opened completely.

6. Detach empty gas bottles

1. Close the gas bottle valve by turning the handwheel clockwise. It is possible that the gas bottle valve may be fairly stiff.
2. Remove the pressure line from the argon gas bottle connection of the APC 2.
3. Place the opening of the pressure line on the purge pin (3) of the APC 2 and press. There is still a residual amount of argon in the line. This now escapes with a loud hissing noise.
4. Remove the union nut of the pressure reducer turning anticlockwise by hand only and detach the pressure reducer.

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Fixing argon gas bottles, connection of the working gas bottle, detachment of the working gas bottle on the Universal Cart

1. Attach gas bottle pads

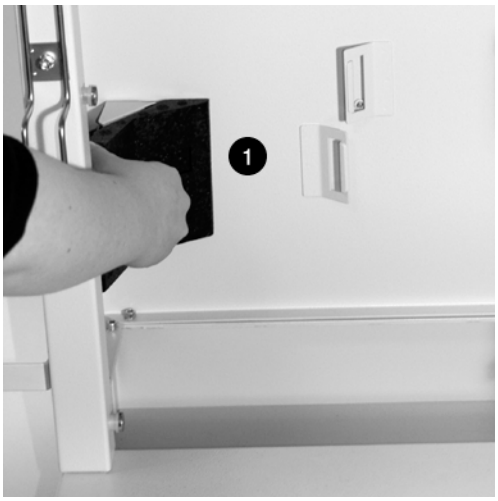

Fig. 7-6

Remove the door of the Universal Cart. Press the gas bottle pad (1) into the left-hand corner of the Universal Cart. If you want to position a spare gas bottle in the right-hand corner, install a gas bottle pad there as well.

2. Place argon gas bottle in the Universal Cart.

Place the working gas bottle in the left-hand corner. Place the spare gas bottle - if installed - to the right of it.

3. Thread the lashing strap

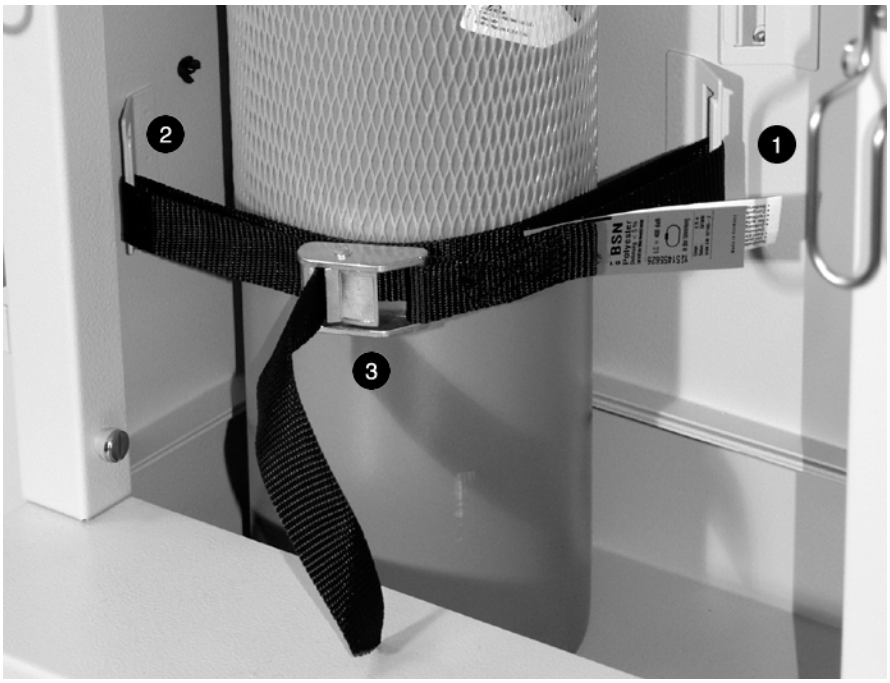

Fig. 7-7

Thread the lashing strap through the lower middle lug (1) and through the left-hand lug (2). The buckle (3) must be on the outer side.

If you have positioned a spare gas bottle in the right-hand corner, thread a lashing strap there as well.

Tighten the lashing strap. Attach the door again.

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4. Connect pressure reducer to working gas bottle

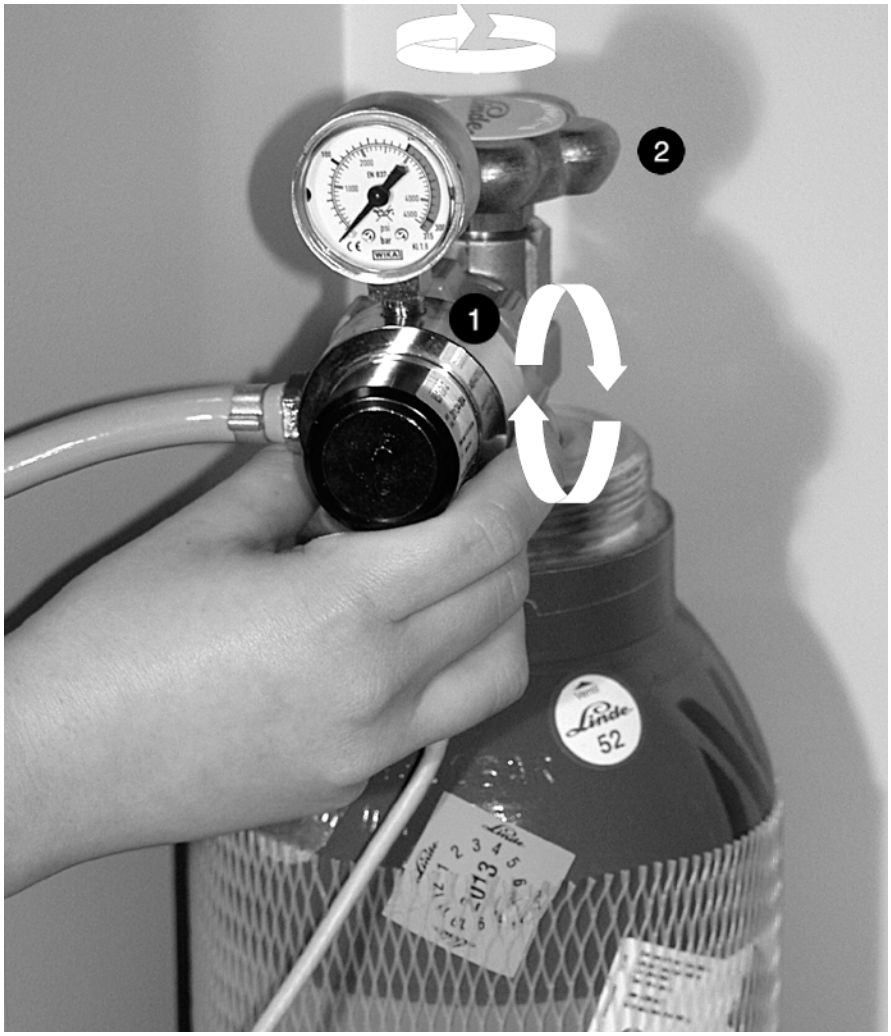

Fig. 7-8

Input pressure: (5 ± 2) x 10^5 Pa / 5 ± 2 bar.

For the country-specific gas bottles Erbe Elektromedizin offers the appropriate pressure reducer complete with pressure sensor. Information is available from Erbe or your distributor.

Remove the protective cap from the gas bottle (not with French gas bottles, for which the gas bottle collar is left in place). Remove the valve closure nut. Screw the union nut (1) of the pressure reducer onto the gas bottle (clockwise) by hand only. Do not use tools! To prevent any soiling of the valve connection, screw the pressure reducer onto the gas bottle at once.

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5. Connect the pressure line and the high-pressure sensor line

Fig. 7-9

1. Fit the connector of the pressure line (1) to the argon connection of the APC 2.
2. Fit the connector of the high-pressure sensor (2) to the sensor connection of the APC 2. Tighten the union nut by hand.
3. Open the gas bottle valve (2) without jerking by turning the handwheel counter-clockwise. After one full turn the gas bottle valve is opened completely.

6. Detach empty gas bottles

1. Close the gas bottle valve by turning the handwheel clockwise. It is possible that the gas bottle valve may be fairly stiff.
2. Remove the pressure line from the argon gas bottle connection of the APC 2.
3. Place the opening of the pressure line on the purge pin (3) of the APC 2 and press. There is still a residual amount of argon in the line. This now escapes with a loud hissing noise.
4. Remove the union nut of the pressure reducer turning anticlockwise by hand only and detach the pressure reducer.

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Risks due to the pressure gas bottle

⚠ WARNING

Damage to the gas bottle or valve. Gas emerges at high pressure.

If the gas bottle has been weakened due to serious damage, this can lead to cracks in the wall of the gas bottle. Considerable stresses and strains occur at the cracks, causing the gas bottle to break open. Gas emerges at high pressure. The gas bottle is propelled like a rocket.

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

⇨ Do not apply force to gas bottles, gas bottle connectors, valves, or pressure regulators.

⇨ When transporting, storing, and using the gas bottle, prevent it from falling over and dropping by securing it with chains, hoops, or retaining straps.

⇨ Only transport gas bottles with the valve guard fitted: bottle cap or bottle collar.

⇨ Prevent the argon gas bottle from being heated by radiators or naked flames. The surface temperature must not exceed 50 °C.

NOTICE

Incorrect pressure regulator, incorrect pressure lines

The unit has a certain input pressure. You will find it in the Technical Data.

If you connect up the wrong pressure regulator or wrong pressure lines, the unit can be damaged.

⇨ Only connect argon gas bottles to the unit using the pressure regulator and pressure lines specified by Erbe.

⚠ DANGER

Wrong gas

The unit may only be operated with argon.

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

⇨ Check whether the gas bottle actually contains argon. Labels on the gas bottle must not be damaged or removed.

⇨ Use argon 4.8 (99.998% purity) or higher, e.g. argon 5.0.

⚠ WARNING

Uncontrolled escape of argon

If the gas accumulates in air you are breathing, there is a risk of suffocation. Symptoms include drowsiness, rise in blood pressure, and respiratory distress. In an atmosphere of pure argon a person would fall unconscious immediately without any warning and suffocate.

⇨ When gas bottle valves are opened, there is a brief hissing sound. If the hiss continues for more than 2 seconds, there is a leak. The gas bottle must be closed again immediately. The unit may only be used when the leak has been stopped by a competent technician.

⇨ Make sure the connections of the pressure lines to the APC 2 are gastight. The same applies to the connection of the pressure regulator to the gas bottle.

⇨ Close the safety valves on the gas bottles after use.

Refilling the working gas bottle

Argon gas bottles can be refilled by your Erbe subsidiary or your gas dealer.

Return argon gas bottles with slight overpressure, i.e. not completely empty. This ensures that no foreign substances can enter the gas bottle.

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Chapter 8
Cleaning and disinfection

Wipe disinfection

For cleaning and disinfecting the surfaces of the unit or of the cart, Erbe recommends a wipe disinfection. Use only disinfectant which complies with the relevant national standards.

Instructions for cleaning and disinfection

Mix the disinfectant in the concentration specified by the manufacturer.

Clean surfaces contaminated with blood before using the disinfectant; otherwise it may be less effective.

Wipe the surfaces. Make sure the surfaces are treated uniformly. Comply with the action time of the disinfectant specified by the manufacturer.

Safety Instructions

⚠ WARNING

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

Risk of electric shock to the medical personnel!

⇨ Switch off the unit. Unplug the power cord of the unit / cart.

⚠ WARNING

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

Penetration of liquid into the unit

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

⇨ Make sure no liquid can penetrate the unit.

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

NOTICE

Alcohol-based spray disinfectant for fast disinfection

With membrane keyboards and paint surfaces there is the risk of cracks. Propanol and ethanol will erode 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.

Membrane keyboards

Note: If alcohol-based disinfectants are used on units with membrane keyboards, this remove the anti-glare finish. However, the user surfaces remain fully functional. This does not present a hazard.

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Chapter 9
Status Messages, Error Messages

An error message consists of an error code and an error text. The display of the VIO system shows two different types of error messages.

a) Error messages that prompt you to take action and remedy the error. You will find these error messages in the table.

b) Error messages that prompt you to inform Technical Service. These error messages are not listed individually in the User Manual because the error texts of the relevant error codes are constantly repeated. The error texts are:

- Activation has been stopped. Activate again. If the display shows this error number repeatedly, please inform Technical Service.
- Minor deviation from the system parameters. If the display shows this note repeatedly, please inform Technical Service.

Status Messages	
B-86	APC socket 1 is ready for operation.
B-8A	APC socket 2 is ready for operation.
B-8C	APC 2 is ready for operation.

Error Messages	
B-87	APC socket 1 fault. Restart VIO. If fault cannot be remedied, inform Technical Service.
B-8B	APC socket 2 fault. Restart VIO. If fault cannot be remedied, inform Technical Service.
B-8D	APC 2 disconnected from system.
B-B4	Purging APC instrument.
A-02	The APC setup parameters are incomplete or invalid.
A-10	Gas supply faulty. Underpressure on central gas supply line. Please inform hospital maintenance. Or the gas cylinder is empty. Please change gas cylinder.
A-11	Gas supply faulty. Overpressure on central gas supply line. Please inform hospital maintenance.
A-40	Flow insufficient. The instrument is blocked. The gas flow is not suitable for the instrument.
A-85	Instrument detection fault. Please do not use APC instrument; have it checked.
A-86	The APC tube is possibly blocked.
A-90	Gas cylinder 1 will soon be empty. Please change the gas cylinder.

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Chapter 10
General Technical Data

Connections	
Low voltage	via VIO electrosurgical unit
HF	via VIO electrosurgical unit
Terminal for potential equalisation	yes

Gas specification	
Type of gas	Argon
Argon minimum purity	Argon 4.8 (99.998% purity) or higher, e.g. argon 5.0.
Density (relative; air = 1)	1.38
Critical temperature	−122 °C
Color	Colorless gas
Odor	No warning by smell
Concentration of explosion limit (vol. % in air)	Non-combustible
Special risks	Heat/fire can result in an increase in pressure causing the pressure gas bottle to explode! Gas in high concentrations can be suffocating!

Gas-specific unit data			
Input pressure	$(5 \pm 2) \times 10^5$ Pa	5 ± 2 bar	72.5 ± 29 psi
Max. discharge pressure	$2 \times 10^5 \pm 4 \times 10^4$ Pa	2 ± 0.4 bar	29 ± 5.8 psi
Variable gas flow	0.1 - 8 l/min limited by the instrument attached, adjustable in 0.1 l increments		
Tolerance of the rated flow	(in range 0.2 - 5 l/min) ± 20 %		
Purging flow	Depending on the instrument (corresponds to the setpoint flow of the instrument which is currently connected)		
Purging time	3 sec.		
If you use a gas bottle, the residual volume display is activated at	7×10^5 Pa	7 bar	101.5 psi
Residual volume display	VIO display		
Residual pressure display	Pressure gauge		
The APC 2 switches off when the input pressure is	$< 3 \times 10^5$ Pa	< 3 bar	<43.5 psi

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Dimensions and weight	
Width x height x depth	410 x 80 x 370 mm
Weight	4.8 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%, noncondensing

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	IIb
Type as per EN 60 601-1	CF

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Chapter 11
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 the patient.

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.

NOTICE

Stacked units

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

Units may fail or not function properly.

⇨ The unit may only be placed next to or stacked with VIO-series units.

⇨ If it is necessary to operate the unit near or stacked together with non-VIO-series units 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?

NOTICE

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.

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.

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 unit.

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.

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 A	The properties of this unit in terms of its emissions mean it can only be used in medical facilities that are connected to supply systems specifically provided for that purpose (usually supplied via isolating transformers). For domestic use (for which class B is usually required as per CISPR 11), this unit may not offer adequate protection against radio services. The user may need to take corrective measures such as relocating or reorienting the unit.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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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.
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**
Grounding cable (POAG)	10 m
ECB cable	15 cm
Monopolar connecting cable	5 m [b]
Bipolar connecting cable	5 m [b]
Multifunction cable	4 m [b]
APC cable	6 m
Pressure sensor cable	75 cm

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, 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 12
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 in accordance with IEC 60601-1 Section 18
- Testing the leakage current in accordance with IEC 60601-1 Section 19
- General performance testing
- Functional testing of all the unit's operating and control elements
- Testing the monitoring equipment
- Gas flow measurement
- Performance testing of the gas bottle valve, performance testing of the pressure regulator
- Pressure line testing

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.

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.

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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 13
Accessories

Introduction

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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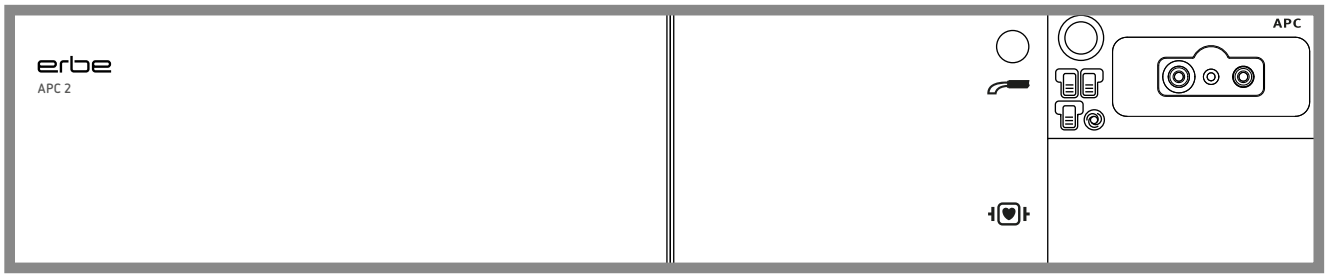
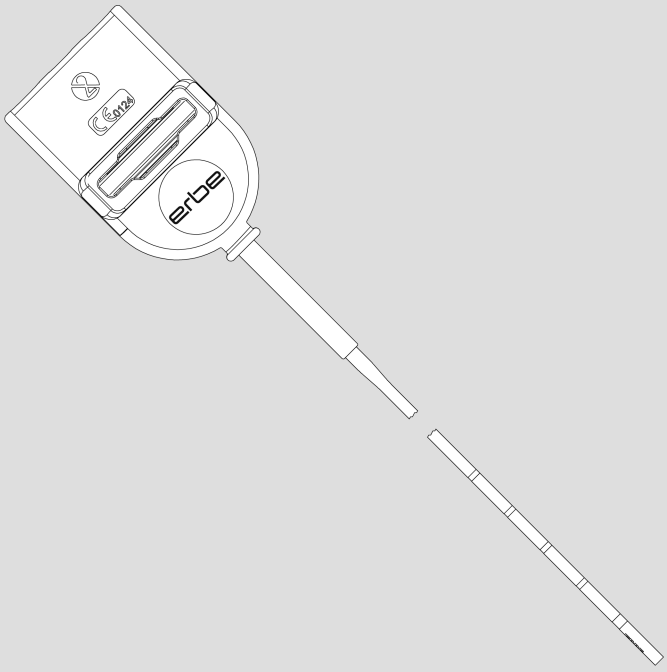
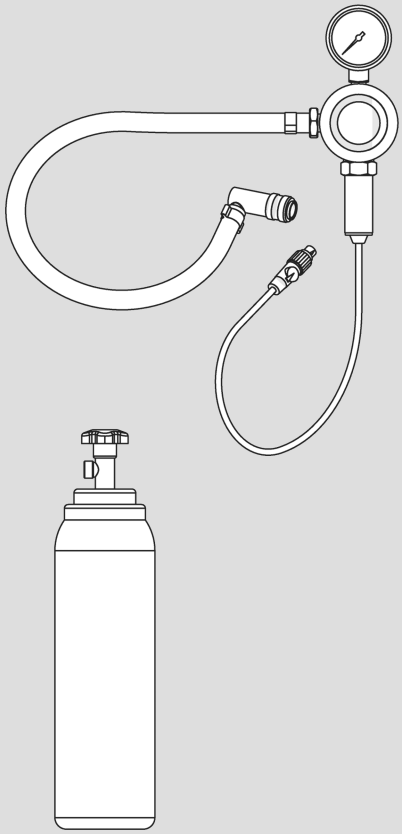
APC 2 example accessories



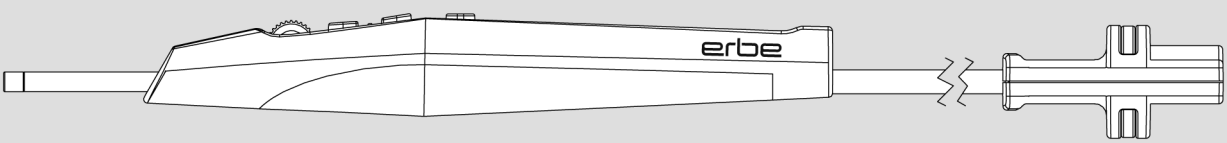
Instruments for the APC



Accessories for subsystems



Accessories for the APC



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Chapter 14
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.
REF	Catalogue number
SN	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
	Foot switch
ECB	Erbe Communication Bus Used to exchange data between Erbe units.

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Symbol	Explanation
	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
	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.
	European conformity marking
	Medical device

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