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EIP 2

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MEDICAL – GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE
AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES60601-1 (2012)
CAN/CSA-C22.2 No. 60601-1:14
19NA

CE 0124

Device Art. No. 10325-000

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Chapter 1
Safety Instructions

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Intended Use

The EIP 2 is a tube pump for removing particles from the examination site. To this end, the EIP 2 pumps fluid into the examination site.

Combination with other equipment

You can combine this unit with other Erbe equipment: e.g. VIO electrosurgical units, APC 2, VEM 2, IES 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 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
- Defective unit
- Interference caused by the unit
- Too much or not enough irrigant
- Risk of infection
- Intraluminal pressure too high, suction of tissue, too little irrigation liquid
- Installation
- 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

⚠ 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.

NOTICE

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

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

The unit may fail or not perform properly.

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

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.

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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.

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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 / the equipment cart 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 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.

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⚠ 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.

Defective unit

⚠ 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.

⚠ WARNING

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

Risk of 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.

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Interference caused by the unit

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.

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

NOTICE

Stacked devices

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

The unit may fail or not function properly.

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

⇨ If it is necessary to operate the device near or stacked together with non-VIO-series equipment, keep as much distance as possible between the devices. Check whether the devices are affecting each other: Are the devices 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 device.

Risk of injury to the patient.

The unit may fail or not function properly.

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

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

Overdose or underdose of irrigation liquid

⚠ WARNING

Incorrect line voltage

If the device is operated outside of the permissible line voltage tolerances, it may fail or pump a flow of liquid that is different from what is indicated on the display. See also Electric Shock.

Risk of injury to the patient due to overdose or underdose of irrigation liquid!

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

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⚠ CAUTION

Use of a non-approved tubing set

EIP 2 can fail or pump a flow of liquid that is different from what is indicated on the display.

Risk of injury to the patient due to overdose or underdose of irrigation liquid!

⇨ Only use sterile Erbe tubing sets 20325-001, 20325-020, 20325-010, 20325-011.

⚠ CAUTION

Uncontrolled introduction of irrigation liquid

If the irrigation liquid is not introduced under control, cannot be discharged or is not suctioned off, pressure can build up in the area of application. This can damage the endoscope.

Risk of injury to the patient due to overdose or underdose of irrigation liquid!

⇨ In each case decide what irrigation flow and irrigation time are safe for the patient and endoscope.

⇨ Always start at a low irrigation flow setting.

⇨ In order to prevent an accidental overdose of irrigation liquid, the EIP 2 switches off automatically after 20 sec. of uninterrupted activation.

Risk of infection

⚠ WARNING

Non-approved irrigation liquid

If you use non-approved irrigation liquid, the material of Erbe tubing sets 20325-001, 20325-020, 20325-010, 20325-011 can be damaged.

If you do not use sterile irrigation liquid, there is a risk of infection for the patient!

⇨ Only use sterile physiological saline solution or sterile water.

⇨ The material compatibility of Erbe tubing sets 20325-001, 20325-020, 20325-010, 20325-011 was tested and confirmed with these irrigation liquids. If you use other irrigation liquids, you must verify material compatibility.

⇨ Only use sterile irrigation liquids.

⚠ WARNING

The tubing set and irrigation bottle are sterilized after use and reused

Risk of infection!

⇨ The tubing set and irrigation bottle must not be reused or sterilized.

⇨ Dispose of tubing set and irrigation bottle after use.

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⚠ WARNING

Non sterile tubing set

If the tubing set is non sterile, there is a risk of infection for the patient!

⇨ Use aseptic technique in the handling, set-up, and use of the tubing set

Intraluminal pressure too high

⚠ CAUTION

The irrigation bottle is emptied completely

If you empty the irrigation bottle completely, air will be drawn into the body of the patient. The air introduced cannot immediately escape from body cavities.

Risk of intraluminal pressure rise and distension.

⇨ Change the irrigation bottle before it is completely empty.

⚠ CAUTION

Irrigation tube not inserted properly

If you do not insert the tube properly, the pump draws instead of irrigating.

Risk to the patient of hematomas due to suction of tissue!

Restricted view for the surgeon. The pump can be damaged.

⇨ The arrow on the pump head cover indicates the direction of flow of the irrigation liquid. Insert the tube in the pump head, so that the puncturing spike points in the opposite direction of the arrow.

⚠ CAUTION

Irrigation tube kinked

Depending on how much you kink the irrigation tube, you will get either no irrigation liquid at all or less irrigation liquid than indicated on the display.

Restricted view for the surgeon. The pump can be damaged.

⇨ Do not kink the irrigation tube.

Installation

⚠ CAUTION

The device exceeds the load-bearing capacity of the surface underneath

Risk of injury due to the surface underneath collapsing.

⇨ Place the device on a stable, flat supporting surface. The latter must have a load-bearing capacity of at least 10 kg (22 lbs).

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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.

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: The equipment 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.

Footswitch Class AP, IPX8

Note: Erbe recommends the use of the Erbe footswitch No. 20325-000. It is suited for operation in the potentially explosive atmosphere of the operating room (Class AP). The footswitch is watertight (IPX8).

Close pump head cover before activation

Note: Activation of the EIP 2 is not possible with the pump head cover open. Close the pump head cover before activation.

If you open the pump head cover during activation, the EIP 2 switches off. Leave the pump head cover closed during activation.

Despite this safety precaution integrated into the design, never place your fingers in the pump head!

Pressure control

Note: If you use an Erbe tubing set 20325-001, 20325-020, 20325-010, or 20325-011, you can have a service technician switch on pressure control.

Function: If there is a hindrance in the irrigation tube (e.g. a kink in the tube, tapering of the irrigation channel), the pressure regulation limits the flow rate to approx. 60% of the maximum irrigation rate that can be set.

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Chapter 2
Description of the Controls

Controls on the front panel



Fig. 2-1

(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 could be easily disconnected from the power source.

(2) Icon: Caution, consult accompanying documents

In addition to the user manual, please observe all other documents provided with the device.

(3) (4) (5) Quick activation buttons

Quick setting of irrigation flow. You can program the buttons with an irrigation flow. Factory setting:

(3) 30% irrigation flow or approx. 150 ml/min

(4) 50% irrigation flow or approx. 8.45 fl oz/min

(5) 80% irrigation flow or approx. 13.53 fl oz/min

These irrigation flows only apply when using tubing sets 20325-001 or 20325-010. If you close the roller clamp of the tubing sets for irrigation forceps 20325-020 or 20325-011, the irrigation flow is reduced.

(6) Flow display

Display of irrigation flow in % of maximum possible irrigation flow. 100% is equivalent to an irrigation flow of approx. 500 ml/min.

(7) Up/Down adjustment buttons

Adjustment of irrigation flow.

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(8) Activation button Activate device.

The device irrigates as long as the button is pressed. After 20 sec. of continuous irrigation the device stops automatically for safety reasons.

(9) CF Symbol The device meets the requirements of Type CF and is protected against the effects of a defibrillator discharge.

(10) Direction arrow The arrow indicates the direction in which the irrigation liquid flows.

(11) Pump head cover With the pump head cover the pump head can be opened and closed for insertion of the tubing set.



Fig. 2-2

(12) Icon: Caution, consult accompanying documents In addition to the user manual, please observe all other documents provided with the device.

(13) Pump reel symbol Never place your fingers in the pump head!

(14) Applied parts

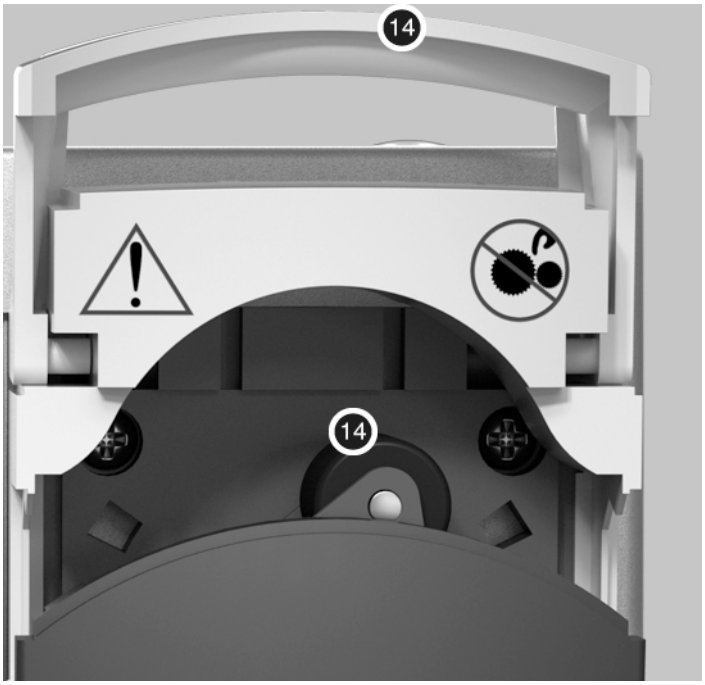


Fig. 2-3

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Controls on the back



Fig. 2-4

EIP 2 without ECB socket

(1) Footswitch socket

Erbe recommends the use of the Erbe footswitch No. 20325-000. It is suited for operation in the potentially explosive area of the operating room (Class AP). The footswitch is watertight (IPX8).

(2) Terminal for potential equalisation

Connect a potential equalization conductor, and attach this to the potential equalization system in the operating room. When using a CART designated by Erbe, connect the potential equalization cable to the potential equalization pin on the CART.

(3) Power supply / power fuses

The voltage of the power supply must agree with the voltage that is stated on the rating plate. Connect the device to a properly installed grounded power outlet. For this purpose only use the Erbe power cord or an equivalent power cord. The power cord must bear the national test symbol. If the device is installed on an Erbe CART, connect the power cord to the power outlet on the CART.

The device is protected by power fuses. If any of these fuses has blown, you may only use the device again on the patient when it has been tested by a competent technician. The rating plate on the device shows the ratings of the fuses. Only use replacement fuses that bear those ratings.

(4) Icon: Read the user manual

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

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Fig. 2-5

EIP 2 with ECB sockets

(5) ECB sockets ECB means Erbe Communication Bus. The ECB is used for communication between the electrosurgical unit and other equipment.

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Chapter 3
Use of irrigation bottle and tubing set

⚠ CAUTION

Use of a non-approved tubing set

EIP 2 can fail or pump a flow of liquid that is different from what is indicated on the display.

Risk of injury to the patient due to overdose or underdose of irrigation liquid!

⇨ Only use sterile Erbe tubing sets 20325-001, 20325-020, 20325-010, 20325-011.

⚠ WARNING

Non-approved irrigation liquid

If you use non-approved irrigation liquid, the material of Erbe tubing sets 20325-001, 20325-020, 20325-010, 20325-011 can be damaged.

If you do not use sterile irrigation liquid, there is a risk of infection for the patient!

⇨ Only use sterile physiological saline solution or sterile water.

⇨ The material compatibility of Erbe tubing sets 20325-001, 20325-020, 20325-010, 20325-011 was tested and confirmed with these irrigation liquids. If you use other irrigation liquids, you must verify material compatibility.

⇨ Only use sterile irrigation liquids.

Positioning the irrigation bottle, inserting the tubing set

⚠ WARNING

Non sterile tubing set

If the tubing set is non sterile, there is a risk of infection for the patient!

⇨ Use aseptic technique in the handling, set-up, and use of the tubing set

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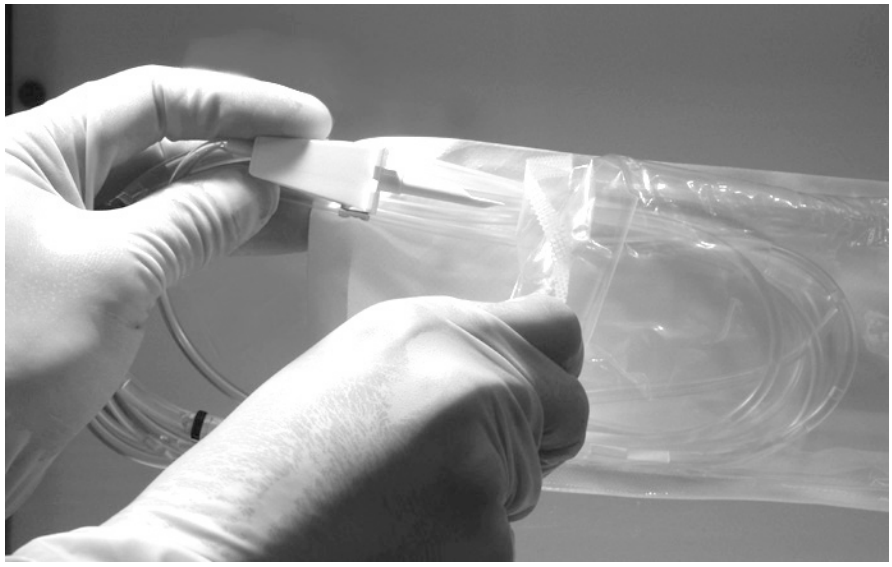


Fig. 3-1

1. Open the packaging of the tubing set.

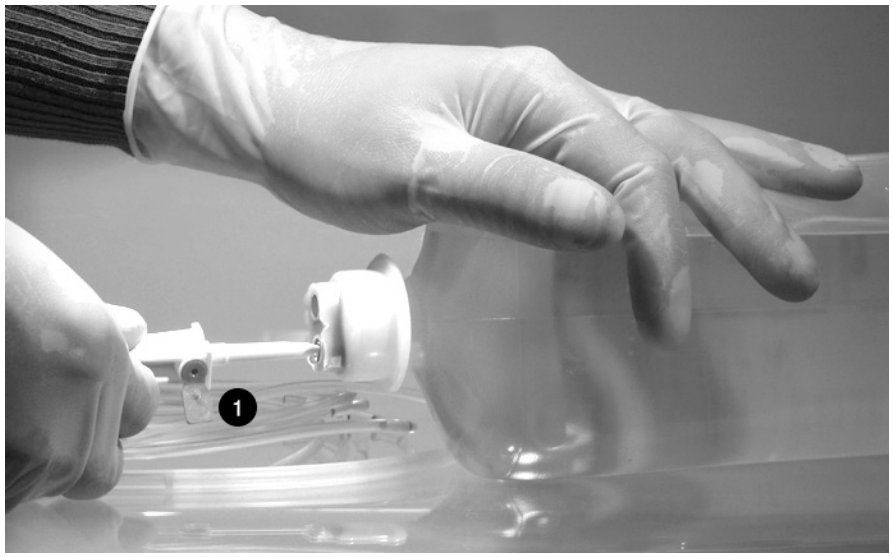


Fig. 3-2

2. Pierce the provided opening of the irrigation bottle. If you use a glass bottle, open the ventilation flap on the connector **(1)** for ventilation.

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Fig. 3-3

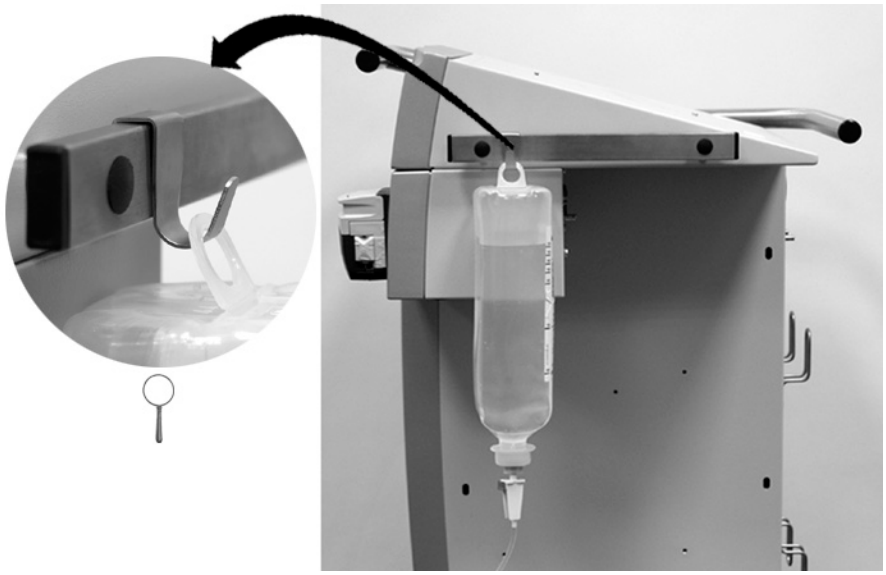


Fig. 3-4

3. Place the irrigation bottle in a suitable place near to the EIP 2. The irrigation bottle can also be hung up (e.g. on hook no. 20325-002). ATTENTION: Do not kink the irrigation tube.

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Fig. 3-5

4. Open the pump head cover.

⚠ CAUTION

Irrigation tube not inserted properly

If you do not insert the tube properly, the pump draws instead of irrigating.

Risk to the patient of hematomas due to suction of tissue!

Restricted view for the surgeon. The pump can be damaged.

⇨ The arrow on the pump head cover indicates the direction of flow of the irrigation liquid. Insert the tube in the pump head, so that the puncturing spike points in the opposite direction of the arrow.

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5. Place the soft peristaltic tube about midway over the pump rollers. The arrow on the pump head cover indicates the direction of flow of the irrigation liquid. Insert the tube in the pump head, so that the puncturing spike points in the opposite direction of the arrow. **(1)** to the patient. **(2)** to the irrigation bottle. ATTENTION: If you do not insert the tube properly, the pump does not irrigate.



Fig. 3-6

6. Close the pump closure lid.
7. Fill the tube with liquid by activating the pump.

8. Connect the Luer-Lock adapter of tubing set 20325-001 or tubing set 20325-010 to the irrigation connection of an endoscope. Connect the open end of the tube of tubing set 20325-020 or tubing set 20325-011 to the irrigation connection Ø 3 mm of irrigation forceps.

Removing the irrigation bottle and tubing set

Remove the irrigation bottle and tubing set as in the above procedure but in reverse order.

⚠ WARNING

The tubing set and irrigation bottle are sterilized after use and reused

Risk of infection!

⇨ The tubing set and irrigation bottle must not be reused or sterilized.

⇨ Dispose of tubing set and irrigation bottle after use.

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Chapter 4
Operation of the EIP 2 without VIO

Safety Instructions

⚠ CAUTION

Uncontrolled introduction of irrigation liquid

If the irrigation liquid is not introduced under control, cannot be discharged or is not suctioned off, pressure can build up in the area of application. This can damage the endoscope.

Risk of injury to the patient due to overdose or underdose of irrigation liquid!

⇨ In each case decide what irrigation flow and irrigation time are safe for the patient and endoscope.

⇨ Always start at a low irrigation flow setting.

⇨ In order to prevent an accidental overdose of irrigation liquid, the EIP 2 switches off automatically after 20 sec. of uninterrupted activation.

⚠ CAUTION

The irrigation bottle is emptied completely

If you empty the irrigation bottle completely, air will be drawn into the body of the patient. The air introduced cannot immediately escape from body cavities.

Risk of intraluminal pressure rise and distension.

⇨ Change the irrigation bottle before it is completely empty.

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Pressure control

Note: If you use an Erbe tubing set 20325-001, 20325-020, 20325-010, or 20325-011, you can have a service technician switch on pressure control.

Function: If there is a hindrance in the irrigation tube (e.g. a kink in the tube, tapering of the irrigation channel), the pressure regulation limits the flow rate to approx. 60% of the maximum irrigation rate that can be set.

Close pump head cover before activation

Note: Activation of the EIP 2 is not possible with the pump head cover open. Close the pump head cover before activation.

If you open the pump head cover during activation, the EIP 2 switches off. Leave the pump head cover closed during activation.

Despite this safety precaution integrated into the design, never place your fingers in the pump head!

Operation



Fig. 4-1

1. Switch the unit on at the power switch **(1)**. The output display **(6)** shows 0%.
2. Select an irrigation flow. Either press one of the quick activation buttons **(3) (4) (5).**
   Factory setting:
   (3) 30% irrigation flow or approx. 150 ml/min
   (**4**) 50% irrigation flow or approx. 250 ml/min
   (5) 80% irrigation flow or approx. 400 ml/min,
   or select an irrigation flow using the Up/Down buttons **(7)**.
   100% corresponds to an irrigation flow of approx. 500 ml/min.
   These irrigation flows only apply when using tubing sets 20325-001 or 20325-010. If you close the roller clamp of the tubing sets for irrigation forceps 20325-020 or 20325-011, the irrigation flow is reduced.
3. **(8)**Activate the EIP 2 with the footswitch or the activation button.

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Programming the quick activation buttons

You can program the quick activation buttons with an irrigation flow.

1. Select an irrigation flow with the Up / Down buttons **(7)**.
2. Press the quick activation button until you see a dot on the flow display **(6)** .

The drops on the quick activation buttons symbolize irrigation flows. When programming the quick activation buttons observe the following rules:

Irrigation flow on button < irrigation flow on button .

irrigation flow on button < irrigation flow on button .

If you do not observe the rules, the device will indicate operator control error L 1 . Your flow input will not be saved.

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Chapter 5
Operation of the EIP 2 in combination with a VIO from the D series

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Safety Instructions

⚠ CAUTION

Uncontrolled introduction of irrigation liquid

If the irrigation liquid is not introduced under control, cannot be discharged or is not suctioned off, pressure can build up in the area of application. This can damage the endoscope.

Risk of injury to the patient due to overdose or underdose of irrigation liquid!

⇨ In each case decide what irrigation flow and irrigation time are safe for the patient and endoscope.

⇨ Always start at a low irrigation flow setting.

⇨ In order to prevent an accidental overdose of irrigation liquid, the EIP 2 switches off automatically after 20 sec. of uninterrupted activation.

⚠ CAUTION

The irrigation bottle is emptied completely

If you empty the irrigation bottle completely, air will be drawn into the body of the patient. The air introduced cannot immediately escape from body cavities.

Risk of intraluminal pressure rise and distension.

⇨ Change the irrigation bottle before it is completely empty.

Pressure control

Note: If you use an Erbe tubing set 20325-001, 20325-020, 20325-010, or 20325-011, you can have a service technician switch on pressure control.

Function: If there is a hindrance in the irrigation tube (e.g. a kink in the tube, tapering of the irrigation channel), the pressure regulation limits the flow rate to approx. 60% of the maximum irrigation rate that can be set.

Close pump head cover before activation

Note: Activation of the EIP 2 is not possible with the pump head cover open. Close the pump head cover before activation.

If you open the pump head cover during activation, the EIP 2 switches off. Leave the pump head cover closed during activation.

Despite this safety precaution integrated into the design, never place your fingers in the pump head!

Extended activation relative to the EIP 2 stand-alone unit

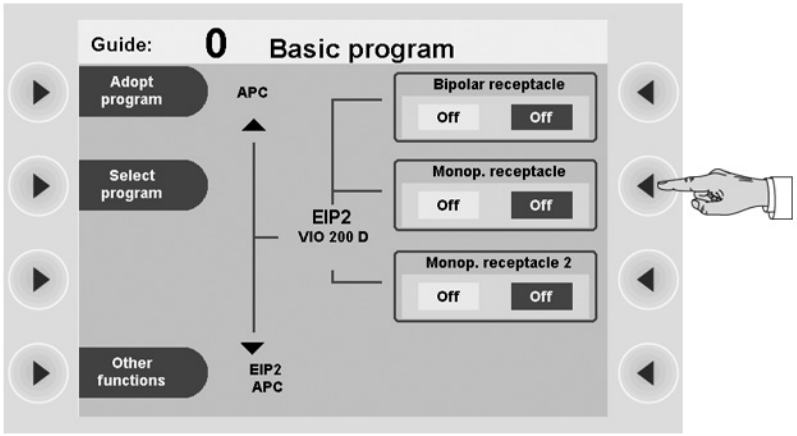
When the VIO electrosurgical unit is activated, the EIP 2 is switched on automatically for the duration of activation.

Prerequisites:

- The EIP 2 is connected to a VIO (from version 1.4.2) via the ECB interface (Erbe Communication Bus).
- You have selected a CUT irrigation flow / COAG irrigation flow on the display of the VIO.

Setting the EIP 2 on the VIO display

1. Switch on the VIO and the EIP 2.
2. Scroll in the window *Guide*with the Down button to access the *EIP 2 settings for VIO*.



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Fig. 5-1

3. You can set an irrigation flow for the CUT and COAG functions of each receptacle. Press the selection button next to the required receptacle, example: Monopolar receptacle.

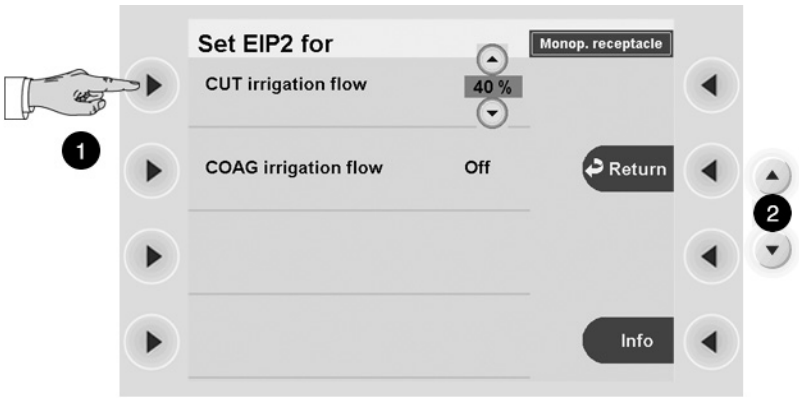


Fig. 5-2

4. Press the selection button**(1)** next to the menu item *Irrigation flow,* example *CUT irrigation flow*. Use the Up and Down buttons **(2)** to select an irrigation flow, example: 40%. Press the selection button next to the menu item *Back*.

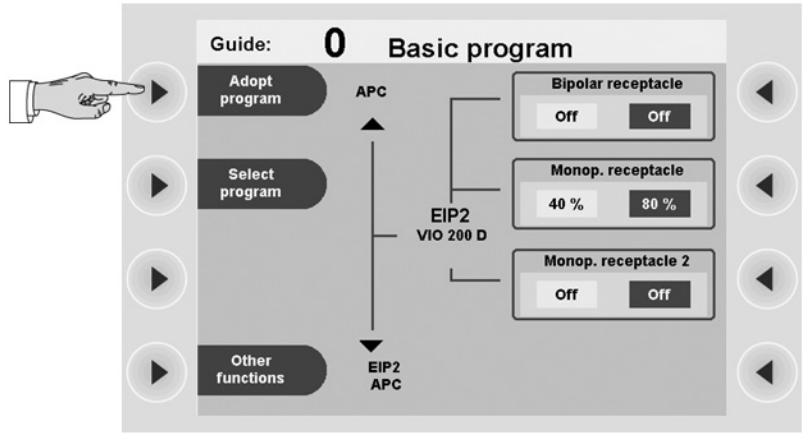


Fig. 5-3

5. In the window *Guide* call up other receptacles or press the selection button next to the menu item *Adopt program*.

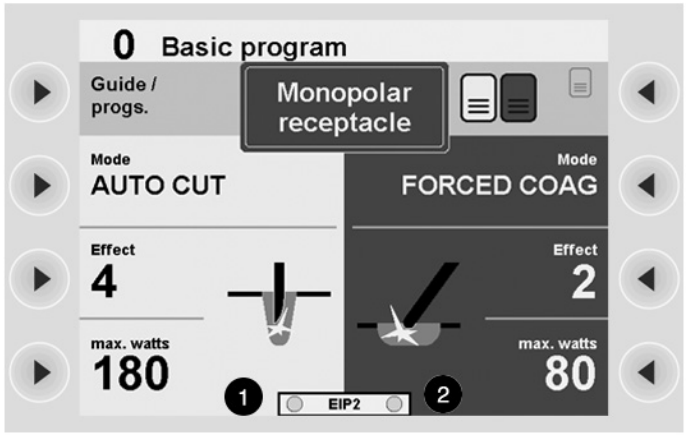


Fig. 5-4

In the window *Cut / Coag Settings* you will see from the two green dots **(1) (2)** on the EIP 2 display that the EIP 2 will be activated automatically when CUT and COAG are activated.

Irrigation flow on the display of the EIP 2

The display of the EIP 2 always indicates the irrigation flow that was called up last. If, for example, you have activated CUT with 40% irrigation flow, the display will indicate 40%.

Activation of the EIP 2 without activation of the VIO D

If the irrigation flow upon activation of the VIO D is not sufficient for you, you can also activate the EIP 2 on its own.

Connect a footswitch to the EIP 2. Activate the EIP 2 with the footswitch.

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Chapter 6
Operation of the EIP 2 in combination with a VIO from the S series

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Safety Instructions

⚠ CAUTION

Uncontrolled introduction of irrigation liquid

If the irrigation liquid is not introduced under control, cannot be discharged or is not suctioned off, pressure can build up in the area of application. This can damage the endoscope.

Risk of injury to the patient due to overdose or underdose of irrigation liquid!

⇨ In each case decide what irrigation flow and irrigation time are safe for the patient and endoscope.

⇨ Always start at a low irrigation flow setting.

⇨ In order to prevent an accidental overdose of irrigation liquid, the EIP 2 switches off automatically after 20 sec. of uninterrupted activation.

⚠ CAUTION

The irrigation bottle is emptied completely

If you empty the irrigation bottle completely, air will be drawn into the body of the patient. The air introduced cannot immediately escape from body cavities.

Risk of intraluminal pressure rise and distension.

⇨ Change the irrigation bottle before it is completely empty.

Pressure control

Note: If you use an Erbe tubing set 20325-001, 20325-020, 20325-010, or 20325-011, you can have a service technician switch on pressure control.

Function: If there is a hindrance in the irrigation tube (e.g. a kink in the tube, tapering of the irrigation channel), the pressure regulation limits the flow rate to approx. 60% of the maximum irrigation rate that can be set.

Close pump head cover before activation

Note: Activation of the EIP 2 is not possible with the pump head cover open. Close the pump head cover before activation.

If you open the pump head cover during activation, the EIP 2 switches off. Leave the pump head cover closed during activation.

Despite this safety precaution integrated into the design, never place your fingers in the pump head!

Extended activation relative to the EIP 2 stand-alone unit

When the VIO electrosurgical unit is activated, the EIP 2 is switched on automatically for the duration of activation.

Prerequisites:

- The EIP 2 is connected to a VIO (from version 1.1.0) via the ECB interface (Erbe Communication Bus).
- The irrigation function was activated via the VIO.

Functions/setting options of the EIP 2

In combination with a VIO from the S series the EIP 2 provides you with the following setting options:

Activation/deactivation of the irrigation function

If the irrigation function has been activated, the EIP 2 starts the irrigation process automatically when the HF current is activated via the VIO.

You can activate the irrigation function for CUT HF current and COAG HF current for each HF receptacle separately. This applies to all the HF receptacles on the VIO and all the HF receptacles on add-on modules (e.g. APC 2).

Example: If you have activated the COAG irrigation function for the first Monopolar receptacle on the VIO, irrigation starts automatically when you activate COAG HF current via the first Monopolar receptacle on the VIO.

As required you can, in addition, also start irrigation manually on the EIP 2 using the activation button or the footswitch.

CUT irrigation flow

CUT irrigation flow is the irrigation flow during activation of the CUT HF current of the VIO. You can select a value between 20% and 100%. 100% is equivalent to an irrigation flow of approx. 500 ml/min.

COAG irrigation flow

COAG irrigation flow is the irrigation flow during activation of the COAG HF current of the VIO. You can select a value between 20% and 100%. 100% is equivalent to an irrigation flow of approx. 500 ml/min.

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Important aspects when setting the EIP 2

This chapter draws your attention to special aspects when setting the EIP 2 parameters. The procedure for setting the individual parameters is described in the following chapters in the form of step-by-step instructions.

If you operate the EIP 2 in combination with a VIO from the S series, bear in mind the following aspects when setting the EIP 2 parameters:

Activation/deactivation of the irrigation function via the VIO

Activation/deactivation of the irrigation function is set using the user interface of the VIO.

The settings for activation/deactivation of the irrigation function can be saved in the VIO programs.

Setting the irrigation flows via the EIP 2

You can only set CUT and COAG irrigation flow using the controls on the EIP 2, not the user interface of the VIO.

The irrigation flows are stored in the VIO and (assuming the relevant irrigation function is activated) if the relevant HF current is activated, they are sent to the EIP 2, where

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they take effect (irrespective of the value that is displayed on the EIP 2 before activation!).

The irrigation flows must be changed with the VIO switched on and connected or else the values changed on the EIP 2 will be overwritten again by the VIO at the next activation of HF-current.

The irrigation flows are stored globally in the VIO. As opposed to activation/deactivation of the irrigation function the irrigation flows can therefore not be saved in the VIO programs (as is possible with the VIO from the D series for example).

Switching on the VIO system and EIP 2

Switching on the VIO system

1. Use the power switch to switch the unit on and observe the display elements.

The unit then carries out a performance test and checks all the receptacles. Connected units and footswitches are detected. All display elements light up. The version number of the unit software appears on the display.

Note: If a display element does not light up during the self-test, this display element is defective (exception: the Focus button of the return electrode does not light up as this Focus button does not have an LED). A unit with a defective display element must not be used.

Switching on the EIP 2

1. Switch on the EIP 2 at the power switch. The EIP 2 performs a self-test. All the displays light up.

Activating/deactivating the irrigation function

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Prerequisite: The EIP 2 and the VIO are switched on and connected to one another.

Note: You can activate the CUT irrigation function and/or the COAG irrigation function for all the HF receptacles on the VIO and for all the HF receptacles on add-on modules with HF receptacles (e.g. APC 2) separately.

Selecting a program

1. On the VIO select the program from which you want to change the settings for activation of the irrigation function.

Focus receptacle

1. Press the Focus button for the desired receptacle. The CUT/COAG window for the selected receptacle is displayed.



Fig. 6-1

There are 2 check boxes in the lower part of the display. If a check box is ticked, it means the CUT/COAG irrigation function is activated. In the illustration both irrigation functions are deactivated (no ticks).

Activating/deactivating the CUT irrigation function

1. Press Selection button L3. The activation window of the CUT irrigation function is displayed.



Fig. 6-2

2. Press Selection button R2. A tick appears in the check box on the right-hand side of the display. The CUT irrigation function is activated.



Fig. 6-3

3. Return to the CUT/COAG window with Selection button R3. A tick appears in the left-hand check box in the CUT/COAG window.



Fig. 6-4

Note: The irrigation function can be deactivated in a similar way to activation. In deactivation the relevant ticks are removed from the check boxes again.

Activating the COAG irrigation function

1. In the CUT/COAG window press Selection button R3. The activation window of the COAG irrigation function is displayed.



Fig. 6-5

2. Press Selection button L2. A tick appears in the check box. The COAG irrigation function is activated.

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Fig. 6-6

3. Return to the CUT/COAG window with Selection button R3. A tick appears in the right-hand check box in the CUT/COAG window.



Fig. 6-7

In the illustration the CUT and COAG irrigation functions of the first Monopolar receptacle are activated (there is a tick in each of the two check boxes).

Note: The irrigation function can be deactivated in a similar way to activation. In deactivation the relevant ticks are removed from the check boxes again.

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Performing settings for other receptacles

1. If required, repeat the settings for other HF receptacles.

Saving the settings in a program

1. If desired, save the settings in an existing program in the VIO (e.g. in the active program) or use the settings to create a new program (see VIO User Manual).

Setting irrigation flows on the EIP 2

Prerequisite: The EIP 2 and the VIO are switched on and connected to one another.

Setting CUT irrigation flow

Note: *CUT irrigation flow* can only be set after prior activation of the CUT HF current of a receptacle with the CUT irrigation function activated. If you set irrigation flow on the EIP 2 without previously activating CUT HF current, this changed setting will be overwritten again by the setting stored in the VIO the next time HF current is activated.

1. For a receptacle with activated CUT irrigation function, activate CUT HF current briefly on the VIO. The EIP 2 shows the current setting of *CUT irrigation flow*.
2. On the EIP 2 use the quick activation buttons or the Up / Down adjustment buttons to change *CUT irrigation flow*. As soon as you change irrigation flow, the settings window for *CUT irrigation flow* appears on the display of the VIO. The displayed value for *CUT irrigation flow* changes simultaneously with the display of the value on the EIP 2.

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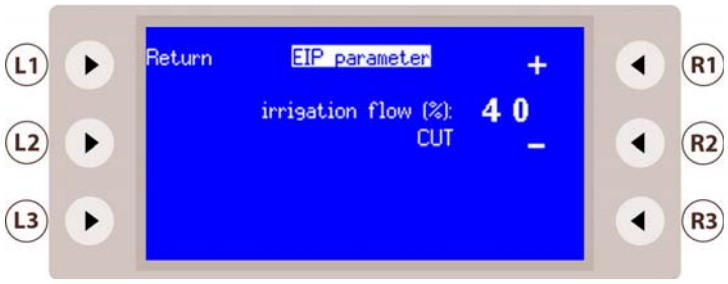


Fig. 6-8

Setting COAG irrigation flow

Note: *COAG irrigation flow* can only be set after prior activation of the COAG HF current of a receptacle with the COAG irrigation function activated. If you set irrigation flow on the EIP 2 without previously activating COAG HF current, this changed setting will be overwritten again by the setting stored in the VIO the next time HF current is activated.

1. For a receptacle with activated COAG irrigation function, activate COAG HF current briefly on the VIO. The EIP 2 shows the current setting of *COAG irrigation flow*.
2. On the EIP 2 use the quick activation buttons or the Up / Down adjustment buttons to change *COAG irrigation flow*. As soon as you change irrigation flow, the settings window for *COAG irrigation flow* appears on the display of the VIO. The displayed value for *COAG irrigation flow* changes simultaneously with the display of the value on the EIP 2.

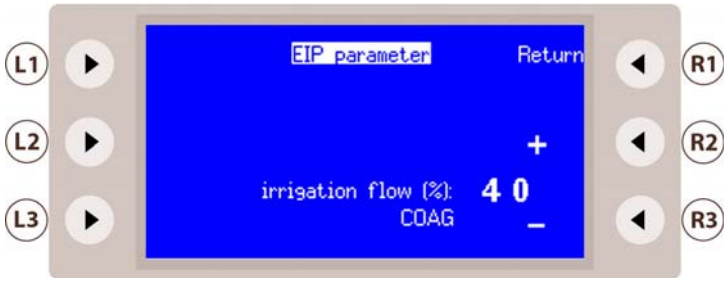


Fig. 6-9

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Checking the settings

Note: The EIP 2 applies the irrigation flow setting stored in the VIO when HF current is activated (provided the relevant irrigation function has been activated). For this reason it is generally advisable to check the current settings before using the EIP 2. This applies particularly if you have just connected the EIP 2 to a VIO for the first time. If you are not sure what irrigation flows will take effect during use, proceed as described below.

Prerequisite: The EIP 2 and the VIO are switched on and connected to one another.

1. For a receptacle with activated CUT irrigation function, activate CUT HF current briefly on the VIO. The EIP 2 shows the current setting of *CUT irrigation flow*.
2. For a receptacle with activated COAG irrigation function, activate COAG HF current briefly on the VIO. The EIP 2 shows the current setting of *COAG irrigation flow*.
3. Change the current settings if required (see previous chapter).

Using the EIP 2 (irrigation)

Prerequisite: The EIP 2 and the VIO are switched on and connected to one another.

1. Activate the electrosurgical unit. Provided the relevant irrigation function is activated, the EIP 2 will irrigate for as long as you activate the electrosurgical unit. If you activate the electrosurgical unit continuously for more than 20 seconds, the EIP 2 switches off automatically after 20 seconds.

Note: As required you can, in addition, also activate irrigation manually on the EIP 2 using the activation button or the footswitch. In this case the irrigation flow value that takes effect on the EIP 2 is the one that was last sent to the EIP 2 by the VIO.

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Chapter 7
Operating the EIP 2 in combination with a VIO 3 from V 1.1.x

Safety Instructions

⚠ CAUTION

Uncontrolled introduction of irrigation liquid

If the irrigation liquid is not introduced under control, cannot be discharged or is not suctioned off, pressure can build up in the area of application. This can damage the endoscope.

Risk of injury to the patient due to overdose or underdose of irrigation liquid!

⇨ In each case decide what irrigation flow and irrigation time are safe for the patient and endoscope.

⇨ Always start at a low irrigation flow setting.

⇨ In order to prevent an accidental overdose of irrigation liquid, the EIP 2 switches off automatically after 20 sec. of uninterrupted activation.

⚠ CAUTION

The irrigation bottle is emptied completely

If you empty the irrigation bottle completely, air will be drawn into the body of the patient. The air introduced cannot immediately escape from body cavities.

Risk of intraluminal pressure rise and distension.

⇨ Change the irrigation bottle before it is completely empty.

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Pressure control

Note: If you use an Erbe tubing set 20325-001, 20325-020, 20325-010, or 20325-011, you can have a service technician switch on pressure control.

Function: If there is a hindrance in the irrigation tube (e.g. a kink in the tube, tapering of the irrigation channel), the pressure regulation limits the flow rate to approx. 60% of the maximum irrigation rate that can be set.

Close pump head cover before activation

Note: Activation of the EIP 2 is not possible with the pump head cover open. Close the pump head cover before activation.

If you open the pump head cover during activation, the EIP 2 switches off. Leave the pump head cover closed during activation.

Despite this safety precaution integrated into the design, never place your fingers in the pump head!

Switching on the VIO 3, EIP 2

Switching on a VIO 3 unit

Use the power switch to switch on the unit. The unit carries out a self-test and tests all sockets. Connected units and footswitches are detected. All socket frames light up. You see the version number of the software on the screen.

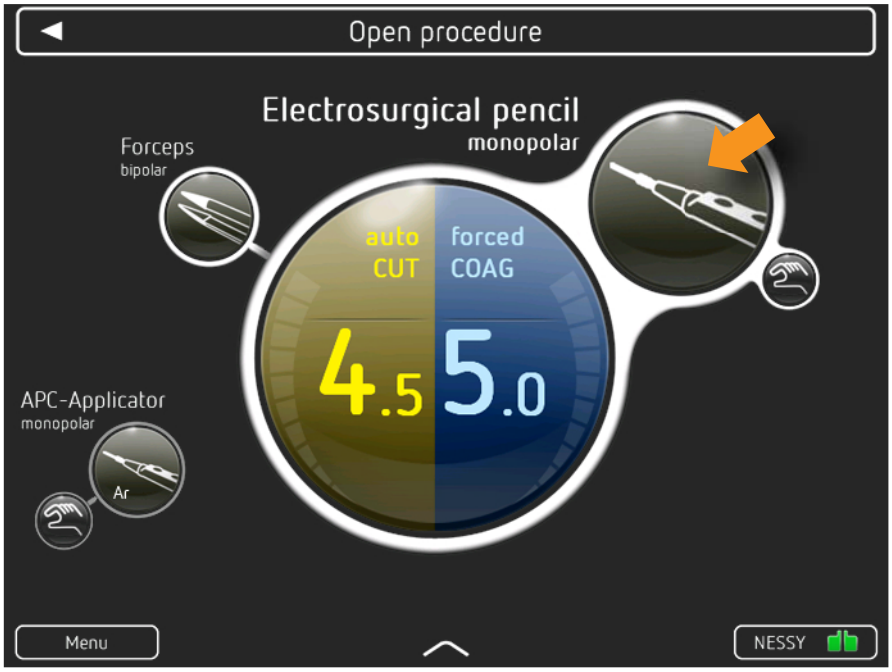
Switching on the EIP 2

Use the power switch to switch on the EIP 2. The power display shows 0%.

Switching on the EIP irrigation pump for an instrument

The following section provides an example using the operating steps for the monopolar electrode handle. Repeat the operating steps for each required instrument.

1. Switch to the VIO 3 main screen.
2. If the instrument symbol for the required instrument is not highlighted, touch the corresponding instrument symbol.



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Fig. 7-1

3. Touch the highlighted instrument symbol.

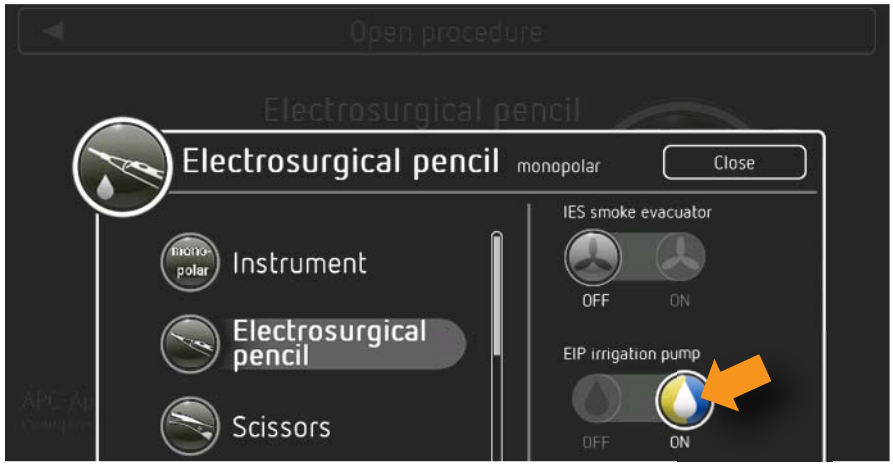


Fig. 7-2

4. The instrument menu opens. Switch on the *EIP irrigation pump* on the VIO 3's touchscreen.
5. *Close* the instrument menu.



Fig. 7-3

The irrigation symbol in the instrument symbol shows that the *EIP irrigation pump* starts automatically when the instrument is activated.

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Operation



Fig. 7-4

1. Select an irrigation flow. Either press one of the quick activation buttons **(3) (4) (5).**
   Factory setting:
   (3) 30% irrigation flow or approx. 150 ml/min
   (**4**) 50% irrigation flow or approx. 250 ml/min
   (5) 80% irrigation flow or approx. 400 ml/min,
   or select an irrigation flow using the Up/Down buttons **(7)**.
   100% corresponds to an irrigation flow of approx. 500 ml/min.
   These irrigation flows only apply when using tubing sets 20325-001 or 20325-010. If you close the roller clamp of the tubing sets for irrigation forceps 20325-020 or 20325-011, the irrigation flow is reduced.
2. **(8)**Activate the EIP 2 with the footswitch or the activation button.

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Programming the quick activation buttons

You can program the quick activation buttons with an irrigation flow.

1. Select an irrigation flow with the Up / Down buttons **(7)**.
2. Press the quick activation button until you see a dot on the flow display **(6)** .

The drops on the quick activation buttons symbolize irrigation flows. When programming the quick activation buttons observe the following rules:

Irrigation flow on button < irrigation flow on button .

irrigation flow on button < irrigation flow on button .

If you do not observe the rules, the device will indicate operator control error L 1 . Your flow input will not be saved.

Chapter 8
Installation

Ambient conditions

⚠ 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.

NOTICE

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

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

The unit may fail or not perform properly.

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

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.

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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.

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Electrical installation

⚠ WARNING

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

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

⇨ Connect the unit / the equipment cart 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 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.

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⚠ 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

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.

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Access to the power cord

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

Grounding

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

Installing the unit on an Erbe equipment cart

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

Installation of the EIP 2 as a stand-alone unit

Make connections at the rear of the EIP 2



Fig. 8-1

- Connector footswitch **(1)** .
- Connect potentially equalization cable **(2)** .
- Connect power cord **(3)** to a power outlet.

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Chapter 9
Cleaning and Disinfection

Wipe disinfection

For cleaning and disinfecting the surfaces of the unit or of the equipment 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 / 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.

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.

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.

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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 10
Error messages

Error	Possible cause	Remedy
Time out error. The set value flashes and the pump is deactivated.	You have exceeded the activation time of t < 20 s.	End activation. Then reactivate the pump.
The pump cover symbol (on the left in the display) flashes. The pump cannot be activated or the already activated pump is deactivated.	1. The pump cover was not closed before activating the pump. 2. The pump cover was opened whilst the pump was activated.	Close the pump cover.
Operating error L 1	You are attempting to program a quick activation button with either a too high or too low irrigation flow value.	The drops on the quick activation buttons represent the irrigation flows. When programming, please observe the following rules: Irrigation flow on button < Irrigation flow on button Irrigation flow on button < Irrigation flow on button
Either E 1, E 2, E 3, E 4 or E 5 is displayed	Error in the interior of the unit.	This error cannot be remedied by the user. Please inform Technical Service.

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Chapter 11
Technical Data

Power supply for devices with 230 V			
Nominal line voltage	Line current	Power fuse	Nominal line frequency
230 V ± 10%	200 mA	T 0.2 A	50 / 60 Hz
Power input in Standby Mode		5 W	
Power input at max. irrigation flow		20 W	
Potential equalization terminal		Yes	

Power supply for devices with 120 V			
Nominal line voltage	Line current	Power fuse	Nominal line frequency
120 V ± 10%	400 mA	T 0.4 A	50 / 60 Hz
Power input in Standby Mode		3 W	
Power input at max. irrigation flow		20 W	
Potential equalization terminal		Yes	

Power supply for devices with 100 V			
Nominal line voltage	Line current	Power fuse	Nominal line frequency
100 V ± 10 %	315 mA	T 0.315 A	50 / 60 Hz
Power input in Standby Mode		3 W	
Power input at max. irrigation flow		20 W	
Potential equalization terminal		Yes	

Operating mode	
Continuous duty	Yes

Dimensions and weight	
Width x height x depth	205 x 125 x 170 mm (without pump head)
Width x height x depth	205 x 125 x 210 mm (with pump head)
Weight	3 kg

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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	II a
Protection class as per EN 60 601-1	I
Type as per EN 60 601-1	CF

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Chapter 12
Information on electromagnetic compatibility (EMC)

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

⚠ 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 device.

Risk of injury to the patient.

The unit may fail or not function properly.

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

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

NOTICE

Stacked devices

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

The unit may fail or not function properly.

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

⇨ If it is necessary to operate the device near or stacked together with non-VIO-series equipment, keep as much distance as possible between the devices. Check whether the devices are affecting each other: Are the devices behaving unusually? Are faults occurring?

NOTICE

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

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

The unit may fail or not perform properly.

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

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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.

Guidance and manufacturer's declaration - electromagnetic emissions

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

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

Guidance and manufacturer's declaration - electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment 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 equipment requires continued operation during power mains interruptions, it is recommended that the equipment 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)	

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Guidance and manufacturer's declaration - electromagnetic immunity			
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.

Guidance and manufacturer's declaration - electromagnetic immunity			
The equipment is intended for use in the electromagnetic environment specified below. The user of the equipment 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]
	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	Interference may occur in the vicinity of equipment marked with the following symbol. 
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 equipment, 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 device is used exceeds the abovementioned compliance level, the device 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 device.

Electromagnetic immunity against high-frequency wireless communication devices 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

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Electromagnetic immunity against high-frequency wireless communication devices as per IEC 61000-4-3			
5100 - 5800	5240, 5500, 5785	Pulse [a] (217 Hz)	9

Note: A **minimum safety distance of 30 cm** should be maintained between the device and portable HF telecommunications equipment that transmits in the stated frequency band. This includes mobile phones, WLAN and RFID, and Bluetooth devices. Failure to comply may lead to a reduction in the device's performance features.

Interference may occur in the vicinity of equipment 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 device must not exceed the lengths specified below.

EMC-relevant accessories [a]	
Name	**Maximum cable length**
Power cord	5 m
Grounding cable (POAG)	10 m
ECB cable	45 cm
Footswitch cable	3 m

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

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Operating environment

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

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

- distance between the device and the electrosurgical unit. In this user manual, refer to the safety instruction *Stacked devices*.
- Distances between the device and the electrosurgical unit's cords.
- Distances between the device's cords and the electrosurgical unit's cords.

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

Essential performance features

The device does not have any essential performance features within the meaning of IEC 60601-1.

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Chapter 13
Maintenance, Customer Service, Warranty, Disposal

Maintenance

Modifications and repairs

Modifications and repairs must not impair the safety of the equipment or equipment 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 equipment 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 device the following technical safety checks have been stipulated:

- Check on labels and User Manual
- Visual inspection of device and accessories for damage
- Inspection of electrical safety in accordance with EN 60 601-1
- Protective lead inspection
- Leakage current test
- Performance test on all switches and signal lamps on the device
- Inspection of the shutdown sensor when pump lid is open

The results of the safety checks must be documented.

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

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Customer service

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

Warranty

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

Disposal



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

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

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

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Chapter 14
Symbols

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

Symbol	Explanation
	Caution, consult accompanying documents
	Catalogue number
	Serial number
	Manufacturer
	Date of manufacture
	Keep away from sunlight
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Quantity (x)
	Follow instructions for use
	Warning; Electricity
	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.
	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

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