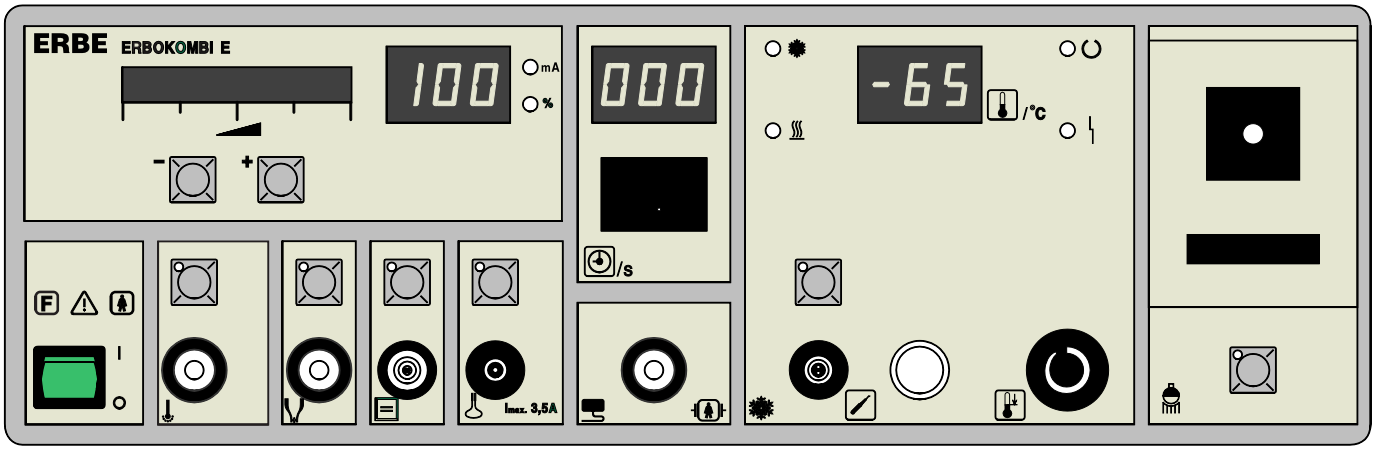
ERBOKOMBI E / OPHTHALMOTOM

Instruction Manual



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ERBE

ERBOKOMBI E / OPHTHALMOTOM

Instruction Manual

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It would be nice if this instruction manual contributed to easing your work and helped you utilize all the functions of your unit safely.

- It has been created by me in cooperation with developmental engineers and quality management with great care.
- Use of publishing software and digital photography have allowed the documentation team flexibility in design. Our objective: an attractive combination of text and photos.
- The translation of texts into your language is subject to strict quality control.
- The instruction manual is printed out digitally only when shipping out your unit. All information is up to date.

The ERBE documentation team would like to improve its products for you: I welcome your suggestions, criticism, questions, as well as any positive feedback.

ISO 9001
EN 46001

CE 0124

Instruction Manual Art. no. 80172-211
Erbokombi E Art. no. 10732-002
Ophthalmotom Art. no. 10738-002

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Printed in Germany
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CHAPTER 1

Intended use, safety instructions

Intended use

The *Erbokombi E* and the *Ophthalmotom* are equipment for ophthalmology. This equipment has the following functions:

- High-frequency monopolar current for coagulation of vessels, penetration, marking, and epilation.
- High-frequency bipolar current for coagulation of intraocular hemorrhages and for “pre”-coagulation with scleral incision, wet-field coagulation.
- Cathode-electrolysis for the performance of subretinal drainage, cauterization of the tear ducts.
- Electrocautery connection for coagulation of minor scleral hemorrhages.
- Cryosurgical module for the Erbokombi E. Cryotherapy of primary glaucoma, cryoretinopexy, cataract extraction, trichiasis, foreign body extraction.
- Cryo-preselection option on the Ophthalmotom.
- Cold light source for intraocular and transscleral illumination.

Explanation of the safety instructions

Make certain to read all safety instructions marked with an exclamation point before using the unit.

WARNING  The WARNING safety instruction indicates a danger which can result in personal injury.

CAUTION  The CAUTION safety instruction indicates a danger which can result in property damage.

ATTENTION The ATTENTION safety instruction indicates a danger which can cause functional failure of the unit.

ERBE equipment is safe and controllable

Safety of the procedure

With normal use and attention to the safety instructions, risks originating from this unit are controllable for users, patients, and the surroundings.

Your contribution to safety

Working with an electrical unit is always associated in principle with certain risks for the medical personnel and the patient. Risks cannot be completely excluded by constructive measures alone.

Safety of the unit

Safety is dependent to a high degree on factors which are under your control. The safety instructions in this chapter are concerned with these factors.

The unit conforms to all relevant, generally recognized rules of technology as well as the valid occupational safety and accident prevention regulations. This especially refers to electrical safety. An important component of the safety concept is the instruction manual.

If you combine this unit with other ERBE products intended for this purpose, you will have a well-designed, harmonized system.

WARNING ⚠

Only use accessories approved by ERBE Elektromedizin. If not, ERBE Elektromedizin assumes no responsibility.

Instruction manual, training of personnel

Who should read this instruction manual?

Everyone who prepares, adjusts, works with, dismantles, cleans or disinfects the unit and instrument set should read the unit instruction manual and the instructions for use for the instruments. Please pay particular attention to the safety instructions in every chapter.

Training

WARNING! The unit must only be used by persons who, under consideration of this instruction manual, have been trained in the proper handling.

Training may only be conducted by persons whose knowledge and practical experience qualify them to do so.

ERBE Elektromedizin GmbH assumes no liability for damage due to improper application.

Questions, criticism, suggestions?

If anything is unclear or if you have questions, please contact an ERBE employee or your local ERBE business office, the ERBE customer hotline, or the author of this instruction manual (publication details). We would be pleased to assist you and welcome your criticism and suggestions.

Protection against the risk of electrical shock

Inspection of the unit and accessories

WARNING! Inspect the unit and the accessories (e.g. instruments, pedals, cables, tubes) for damage before use. Never use a damaged unit or damaged accessories. Replace defective accessories. If the unit is damaged, please contact the Customer Service. For your safety and for that of your patient, never attempt to repair defective equipment or accessories. Any modification to the unit or accessories will exempt ERBE Elektromedizin from all liability.

Compare the supply voltage / supply frequency before connecting

WARNING! Compare whether the supply voltage and supply frequency of the unit agree with the values for the power supply. The supply voltage and supply frequency are indicated on the back of the unit and in the Technical Data. If in doubt, please contact the hospital technician.

Power cord, power outlet

WARNING! Only connect the power connection of the unit to a properly installed grounded socket using the power cord supplied by ERBE or one of at least equal quality. If you are using an equipment cart, this applies to the power cord on the equipment cart. The power cord must be labeled with the national test symbol.

WARNING! For reasons of safety, never use a multiple power outlet or an extension cord.

No wet hands!

WARNING! Never touch the plug or lines with wet hands.

Power fuse

WARNING! The unit is protected with power fuses. If one of these fuses burns out, the unit can only then be used again on a patient if it has been inspected previously by a qualified technician. Only replacement fuses with the values indicated on the unit's rating plate may be used.

Potential equalization

WARNING! Connect the potential equalization pin on the unit to the potential equalization in the operating room.

Disconnecting the unit from the power supply

WARNING! If you wish to disconnect the unit from the power supply, pull the plug from the wall outlet. Only then disconnect the connecting line from the unit.

Ambient, transport, and storage conditions

Risk of fire and explosion

WARNING! Electrosurgical equipment intentionally generates electric sparks between the active electrode and tissue. Electric sparks may also result within the unit. For this reason, electrosurgical equipment must never be used in potentially explosive areas. Considered potentially explosive is the area up to 20 cm above the floor and the area around and beneath the operating table, if inflammable or explosive cleaning agents, disinfectants, anesthetics etc are used. This also includes highly concentrated or even pure oxygen. High-frequency surgical equipment is normally installed outside the zone.

Explosion-proof footswitch

WARNING! The footswitch must be suitable for operation within potentially explosive areas. Footswitches used in the operating room must have a watertight switch element.

Base

WARNING! Place the unit on a stable, level base. This must be able to bear a weight of at least 14 kg.

Operating conditions

ATTENTION: The unit should be operated at an ambient temperature between +10°C and +30°C. The relative humidity should be between 30% and 70%, noncondensing. If levels fall outside this tolerance range, the unit may malfunction.

Transport and storage conditions

ATTENTION: The unit can be transported and stored at a temperature between -40°C and +70°C. Extreme temperatures should be avoided, particularly in storage.

Acclimatization

ATTENTION: If the unit was stored or transported at temperatures below +10°C, and especially below 0°C, the unit requires approx. 4 hours to become acclimatized to ambient temperature.

Air circulation

ATTENTION: The unit must be set up in such a way that free air circulation around the housing in ensured. Setting up the unit in narrow corners or shelves is not permissible.

Protection from moisture

CAUTION! The housing is not completely tight. Make certain that no liquid penetrates into the unit. If liquid has penetrated into the unit, it can only be operated after inspection by the Customer Service.

Safety instructions for electrosurgical equipment

Unintentional thermal tissue damage

Electrosurgery is associated in principle with various risks for the patient, the personnel and the surroundings. In order to prevent these risks in practice, the surgeon and his/her assistants must recognize these risks and observe the appropriate rules for prevention of injuries. In the following, these risks and rules for prevention of injuries are presented.

Unintentional thermal tissue damage due to HF leakage currents

During electrosurgery, the patient unavoidably conducts high-frequency electrical current to ground potential. If the patient makes contact with electrically conductive objects during electrosurgery, a high-frequency electrical current can result at the contact point between the patient and this object, which in turn can cause thermal necroses. Not only objects made of metal are electrically conductive, but also wet cloths.

WARNING! The patient must be insulated against electrically conductive objects during electrosurgery. The black elastic table covers on operating tables demonstrate a certain electrical conductivity to divert electrical charges. Therefore they are never suitable for ensuring the required insulation of the patient against metal parts of the operating table. For this reason, an electrically insulating intermediate layer, for example dry cover cloths, must be laid between the patient and the black operating table cover during application of electrosurgery.

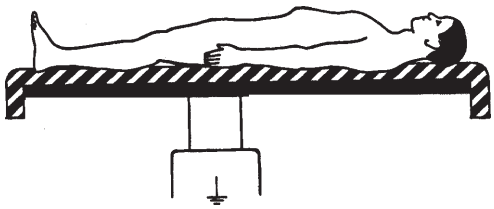


Fig: Insulated positioning of the patient on the operating table.

If it is possible for this intermediate layer to become wet during the operation, for example due to perspiration, irrigation liquid, urine etc., wetting of these intermediate layers must be prevented by a watertight sheet of plastic. Urine should be carried away via catheter.

Extremities lying against the trunk or skin-to-skin contact points should be insulated from one another by laying dry cover cloths between them.

WARNING! Do not apply ECG electrodes closer than 15 cm next to the operating field. Needle electrodes or injection cannulas should not be used as ECG electrodes during high-frequency surgery.

Unintentional activation of an HF generator

WARNING! Unintentional activation of an HF generator can lead to burns on the patient if the active electrode hereby touches the patient directly or indirectly through electrically conductive objects or wet cloths.

Unintentional activation of an HF generator can, for example, be caused by:

Unintentionally pressing a footswitch pedal

Unintentionally pressing a fingerswitch

Defective fingerswitches, footswitches or cables

Penetration of electrically conductive liquids (blood, amniotic fluid, urine, physiological saline solution, irrigation fluids etc.) into fingerswitches or footswitches.

Errors within the electrosurgical unit

WARNING! To prevent burns on the patient due to unintentional activation of a high-frequency generator, the following application rules should be heeded:

Never lay active electrodes onto or beside a patient in such a way that they can touch the patient directly or indirectly through electrically conductive objects or wet cloths.

The lines to the active electrodes should be positioned in such a way that they touch neither the patient nor other lines.

Always set the acoustic signal, which indicates the active status of the high-frequency generator, so that it can be easily heard.

In general, the bipolar coagulation technique should be applied in preference to the monopolar coagulation technique.

Unintentional thermal tissue damage

WARNING! Always make certain that the HF current does not flow through thin tissue structures or vessels with a small diameter.

Inappropriate or nonapplication of the neutral electrode

WARNING! With inappropriate or nonapplication of the neutral electrode, there is a large risk of thermal tissue damage both at the application point of the neutral electrode as well as to other areas on the patient's body.

The neutral electrode must be applied with its entire surface as closely and safely as possible to the operating field on the patient's body, on the upper arm during ophthalmology.

WARNING! The effective contact surface, i.e. the electrical conductive value between the neutral electrode and the patient must correspond to the HF capacity used, meaning the intensity of the HF current. Here the effective contact surface means the surface of the neutral electrode which has electrically conductive contact to the skin of the patient during high-frequency surgery.

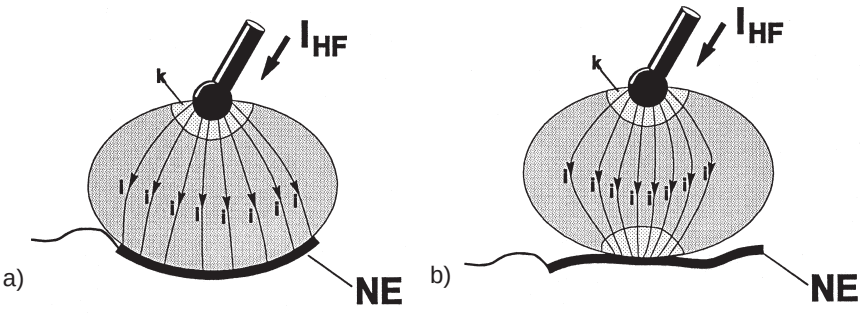


Fig: The neutral electrode must be applied at an appropriate location on the patient's skin using the entire contact surface available (a). If the neutral electrode has only partial contact to the patient's skin (b), there is a risk that burning will occur at this location.

Unsuitable or faulty accessories

WARNING! It must be ensured that only accessories in perfect condition are used for electrosurgery. Only accessories that are compatible or tested by the unit manufacturer must be used. This applies both to the active electrodes including cables and plugs, as well as to the neutral electrodes including cables and plugs.

WARNING! When using an instrument with electric insulation, it is necessary to be certain that these insulations are not overloaded and destroyed by overly high electric voltages. The electric output voltages for the electrosurgical unit are indicated for the various cutting and coagulation modes relative to the possible settings in this instruction manual. The electric strength of the instrument insulations can be found in the technical data for the instruments or, in case of doubt, it can be requested from the manufacturer of the respective instrument.

WARNING! All insulation for electrodes, electrode holders, cables, plugs etc. must be in perfect condition.

Risk of fire and explosion

WARNING! Make certain during electrosurgical operations that anesthetics, skin cleaning agents and disinfectants are nonflammable. If their use is unavoidable, they must have completely evaporated and the vapor must be removed from the area of spark formation before switching on the electrosurgical unit. No anesthetic procedures must be applied which require the use of highly concentrated or even pure oxygen.

Unintentional burns due to hot electrodes

WARNING! Coagulation electrodes become hot during coagulation procedures indirectly due to the heated tissue and due to the electric arc. Tissue can be unintentionally burnt immediately after coagulation procedures if electrodes which are still hot touch the tissue.

Electric shock

An electric shock may occur if the electrosurgical unit delivers a too heavy low-frequency current or if too heavy low-frequency current flows through the patient into the electrosurgical unit from another voltage source.

A known risk of electrosurgery is the unintentional electric stimulation of the patient's nerves and muscles. This stimulation can result from low-frequency electrical currents that are caused either by low-frequency current sources or due to electrical arcs between an active electrode and the patient's tissue.

Electric alternating current with a frequency above 300 kHz is unable to stimulate nerves and muscles.

WARNING! When using electrosurgery on electrically stimulable structures, contractions of the affected muscles must be taken into account.

Cardiac pacemakers

WARNING! For patients with implanted cardiac pacemakers or pacemaker electrodes, irreparable damage to the pacemaker and disturbance of the pacemaker function, which can lead to ventricular fibrilation, must be reckoned with.

Danger of explosion

WARNING! Electrosurgical units always generate sparks on the active electrode during operation. For this reason, it is necessary to make certain during interventions that anesthetics, degreasers and disinfectants are neither flammable nor explosive. They should at least have evaporated completely before switching on the high-frequency surgical unit and be removed from the area of spark formation. No anesthetic procedures should be applied in which concentrated oxygen is used.

Interference with other electronic equipment

CAUTION! Electrosurgical units normally generate high-frequency electrical voltages and currents which can interfere with other electronic equipment. When installing or arranging sensitive electronic equipment in the operating room, this problem should be taken into consideration. In principle, sensitive electronic equipment should be set up as far as possible from the electrosurgical unit and particularly from the cables providing the HF current. In addition, the cables providing HF current, which act like broadcast antennas, should not be unnecessarily long and should never be positioned parallel or too close to cables from sensitive electronic equipment.

Safety instructions for cauterization

Carbonization of tissue

WARNING! The cautery loop must not become too hot: The tissue may carbonize; the loop wears quickly and may burn through.

Select a maximum power setting at which the loop glows dark-red. To check this, look at the loop away from the bright operating room illumination.

Safety instructions for cathode-electrolysis

Burns caused by Cl_2 or HCl

WARNING! Neutral electrodes and hand cylinders must only be used together with a well-moistened sponge. If the sponge is not used, the patient may be burned by Cl_2 or HCl.

Burns caused by chlorine gas

WARNING! The neutral electrode and/or the hand cylinder must be connected to the red cable. The active electrode must be connected to the gray cable. If the polarity is incorrect, chlorine gas may form.

Unsatisfactory effect or pain

WARNING! When epilating the cilia, start at a setting of 1.5 mA and work your way up in 0.1 mA steps.

Cardiac pacemaker

WARNING! Before any application of the ERBE Kathalyse on patients with a cardiac pacemaker, the cardiologist responsible for this patient should be consulted in case of doubt in regard to risk for the patient.

Safety instructions for cryosurgery

Storage of the refrigerant

WARNING! Dry nitrous oxide (N_2O) in gas cylinders is recommended as a refrigerant, which are stored vertically and must be secured against falling over. The gas cylinders must be stored at room temperature, but never in the proximity of a heat source. Only then work with the unit when both the unit as well as the gas cylinder are at room temperature (18°C to 25°C). Room temperature that is too low can interfere with the freezing capacity since the gas pressure will then not reach the 40 bar value necessary for effective operation.

Valve protection

WARNING! Gas cylinders must only be transported with a protective cap or protective collar firmly attached.

Pressure line

WARNING! Gas cylinders must only be connected using pressure lines supplied by ERBE.

Use no force

WARNING! Never use any force on the cylinder and cylinder connection. Protect the gas cylinder from falling over or down during transport, storage and application by means of chains, brackets, and safety belts.

Cylinder pressure

WARNING! The cylinder pressure should be between 40 and 60 bar and must never exceed 60 bar. At a gas pressure of 60 bar plus (red field on the pressure gauge), the unit must not be operated. In this case, the gas cylinder must be closed and the unit separated from the gas cylinder. The overpressure can be released via the hand valve on the gas cylinder.

Damaged cylinders

WARNING! Damaged cylinders must not be used for operation. Label them. Immediately notify the gas supplier. Only use gas cylinders which conform to the respective national safety standards.

Use only N_2O / CO_2

WARNING! It is possible for a cylinder with dangerous contents to be connected to the gas inlet of the unit. Check the cylinders as to whether they also contain N_2O / CO_2: Labels must not be damaged or removed.

Uncontrolled release of gas

WARNING! When opening the cylinder valve, there is a brief hissing sound resulting from gas flowing into the tube. If this hissing continues for longer than 2 seconds after opening a cylinder, there is a leak. The gas cylinder must be reclosed immediately. The unit may only then be used once the leak has been repaired. Make certain that the pressure line is connected tightly to the unit. Skin or eye contact with released CO_2 causes freezing and severe eye injuries. Close the safety valve on the gas cylinder once application is over.

WARNING! High concentrations of CO_2 can cause suffocation. Symptoms include loss of mobility and unconsciousness. The victim is unaware of this. Risk of lethal injury! Low concentrations of CO_2 cause accelerated breathing and headache.

WARNING! N_2O has an anesthetic effect. High concentrations lead to unconsciousness - Risk of lethal injury! Skin or eye contact with released N_2O causes freezing and severe eye injury.

Long term injuries due to N_2O

WARNING! Frequent contact with N_2O can cause long term injury to your health. We recommend connecting the *Erbokombi E* to a gas disposal system using a waste gas hose.

WARNING! Never attempt

- to severely kink or compress the connecting tubes for the cryoprobes
- to bend the probe shank
- to work with liquid N_2O / CO_2
- to use cylinders with a riser
- to sterilize cryoprobes with dry heat
- to take apart the unit or probes without appropriate training

Size of the cryolesion

WARNING! During the freezing process, the tissue turns a white color. This tissue is necrotized and rejected. The size of the freezing lesion is an indication of the depth of freezing. The unit has no device for determining the size of the cryolesion. This requires freezing by sight or, with similar applications, by time.

Handling the probes

WARNING! Before a probe has completely thawed out, it must not be removed by twisting or pulling (except for vein stripping). A defrosted probe can be removed with minimal use of force. Never remove probes frozen in place with a twisting or pulling movement. The probe must not be pulled forcefully from the tissue. Bent or damaged probes must never be used.

CHAPTER 2

Description of application possibilities, description of the controls

Description of application possibilities

Erbokombi E and *Ophthalmotom* share the same design in function and operation. Only the *Ophthalmotom* has no cryomodule.

Monopolar coagulation

Monopolar coagulation current for coagulating vessels, penetration, marking and epilation.

Bipolar coagulation

Bipolar coagulation current for coagulating intraocular hemorrhages and for "pre"-coagulation for scleral incision.

Timer with time preselection for restricting coagulation time. In this way, pinpoint coagulations are possible, particularly for marking purposes.

Cathode-electrolysis (chemical coagulation)

Cathode-electrolysis for conducting subretinal drainage and cauterizing tear ducts.

Electrocautery

Electrocautery for coagulation of small scleral hemorrhages.

Cryosurgery

Cryosurgery for the *Erbokombi E*

Option of cryo-preselection for the *Ophthalmotom.*

The *Erbocryo AE* can be operated from the *Ophthalmotom* using the *Erbebus* interface with the Ophthalmotom footswitch.

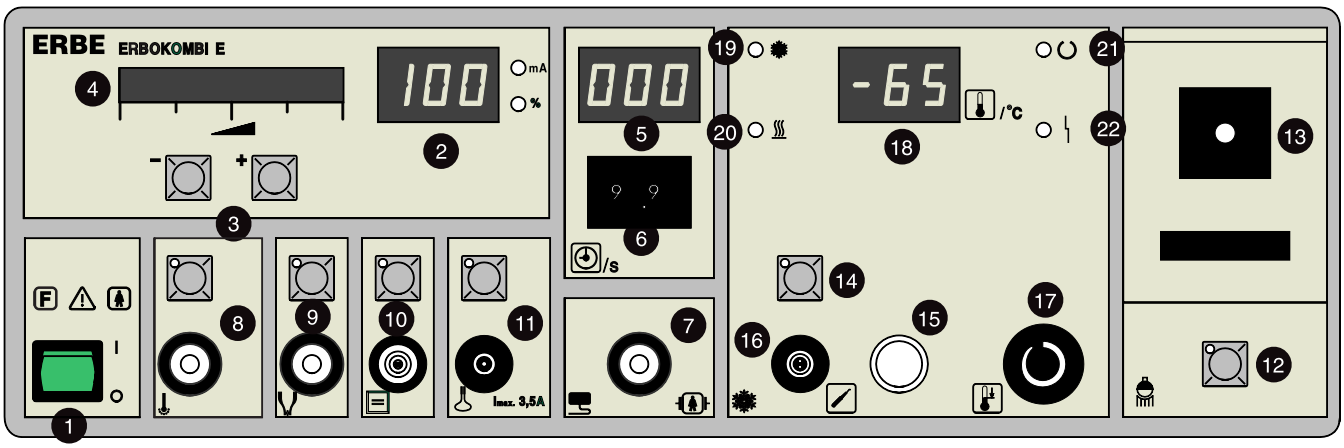
Cold light source

Cold light source for intraocular and transscleral illumination.

Activation concept

With the exception of the cold light source, all functions are locked out from one another so that only one function can be activated. HF monopolar is activated via the foot- or fingerswitch, HF bipolar, cathode-electrolysis and cryo are activated via the footswitch. Electrocautery is activated via the button on the electrode handle.

Description of the controls, Erbokombi E front panel



(1) Power switch

Unit ON / OFF. The green lamp on the power switch indicates operational readiness.

(2) Intensity display

The display indicates the selected intensity for *monopolar / bipolar coagulation, cautery* and *cathode-electrolysis*.

(3) Higher value + / lower value -

Monopolar / bipolar coagulation and *electrocautery* can be set in the *intensity display (2)* at a percentage of the maximum voltage of the unit. Adjust the current for *cathode-electrolysis* in mA. The unit stores the setting. When you switch back and forth between functions on the unit, the settings remain as long as the unit remains switched on.

While preselecting the intensity, the (4) *activation display* is also illuminated and goes out a few seconds after preselection of the intensity.

(4) Activation

The display is illuminated when you activate *monopolar / bipolar coagulation, electrocautery or cathode-electrolysis.* For *cathode-electrolysis*, the display also indicates how much power is currently being output.

(5) Activation time

Display of activation time for *monopolar / bipolar coagulation* in 1/10 seconds steps; for *cryo* in 1 second steps. When activating the foot- or fingerswitch again, the display is automatically reset to 0. For *cathode-electrolysis* and *cautery,* the display has no significance and is faded out.

(6) Time switch

Monopolar / bipolar coagulation can be time restricted using the timer. Preselection of coagulation time in 1/10 seconds to a maximum of 9.9 seconds. Once time has run out, activation is automatically ended. At the “0.0” second setting, no activation is possible.

(7) Connection for the neutral electrode

During *monopolar coagulation*, the neutral electrode must be connected both to the unit as well as to the patient.

(8) Monopolar coagulation

Once you have selected *monopolar coagulation* using the button, you can adjust the intensity using (3) *higher value + / lower value -*. Connect a handle for *monopolar coagulation* to the socket. Activate coagulation using the button (if provided) on the electrode handle or using the footswitch.

(9) Bipolar coagulation

Once you have selected *bipolar coagulation* using the button, you can adjust the intensity using (3) *higher value + / lower value -*. Both bipolar pincettes, bipolar pins, as well as intraocular electrodes can be connected to the socket. These are activated via the footswitch.

(10) Cathode-electrolysis

Once you have selected *cathode-electrolysis* using the button, you can adjust the current using (3) *higher value + / lower value -*.

The cable for cathode electrolysis is connected to the socket. Depending on the intervention, the handle and inactive electrodes can be polarized at the end of the cable by switching the banana plug. These are activated via the footswitch.

(11) Electrocautery

Once you have selected *electrocautery* using the button, you can adjust the voltage using (3) *higher value + / lower value -*.The electrode handle for electrocautery is connected to the socket. This is activated via the button on the handle.

(12) Cold light source ON / OFF

Switches the cold light module on and off.

(13) Connection for the fiber optic cable

The cold light source is equipped with a quick change device for halogen lamps. Interrupting an intervention because of a lamp change is not necessary.

(14) Cryo ON / OFF

Switches the cryo module on and off.

(15) Cryoprobe connection

Connect the gas-conducting part of the cryoprobe coupling to the socket.

(16) Temperature measurement connection

Connect the plug from the thermosensor of the cryoprobe to the socket. When using cryoprobes without thermosensors, such as cataract probes, the temperature display indicates approx. 0° C.

(17) Temperature setting

Using the knob, adjust the probe temperature during the freezing process. The probe temperature can be read from the *temperature display* (18).

(18) Temperature display

Indicates the temperature of the probe tip. When using cryoprobes without temperature sensors, the display indicates approx. 0° C.

(19) Freezing

Freezing activation display.

(20) Defrosting

When the footswitch is released, the *defrost* lamp is illuminated for approx. 6 seconds. During the defrost procedure, the probe is under pressure and must not be removed from the unit.

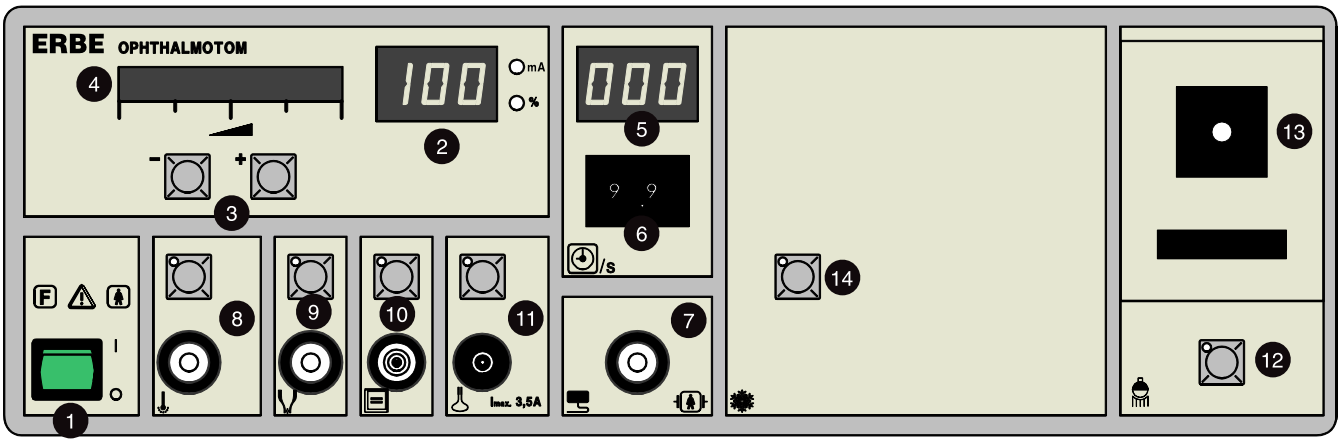
(21) Operational readiness

Once you have connected the cryoprobe, the lamp is illuminated. You can then start the freezing process.

(22) Low pressure

The lamp blinks if the pressure in the gas cylinder is too low. You can read the precise pressure on the back of the unit on the pressure gauge.

Description of the controls, Ophthalmotom front panel



(1) Power switch

Unit ON / OFF. The green lamp on the power switch indicates operational readiness.

(2) Intensity display

The display indicates the selected intensity for *monopolar / bipolar coagulation*, *cautery* and *cathode-electrolysis*.

(3) Higher value + / lower value -

Monopolar / bipolar coagulation and *electrocautery* can be set in the *intensity display (2)* at a percentage of the maximum voltage of the unit. Adjust the current for *cathode-electrolysis* in mA. The unit stores the setting. When you switch back and forth between functions on the unit, the settings remain as long as the unit remains switched on.

While preselecting the intensity, the (4) *activation display* is also illuminated and goes out a few seconds after preselection of the intensity.

(4) Activation

The display is illuminated when you activate *monopolar / bipolar coagulation, electrocautery or cathode-electrolysis.* For *cathode-electrolysis*, the display also indicates how much power is currently being output.

(5) Activation time

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Monopolar / bipolar coagulation can be time restricted using the timer. Preselection of coagulation time in 1/10 seconds to a maximum of 9.9 seconds. Once time has run out, activation is automatically ended. At the “0.0” second setting, no activation is possible.

(7) Connection for the neutral electrode

During *monopolar coagulation,* the neutral electrode must be connected both to the unit as well as to the patient.

(8) Monopolar coagulation

Once you have selected *monopolar coagulation* using the button, you can adjust the intensity using (3) *higher value + / lower value -*. Connect a handle for *monopolar coagulation* to the socket. Activate coagulation using the button (if provided) on the electrode handle or using the footswitch.

(9) Bipolar coagulation

Once you have selected *bipolar coagulation* using the button, you can adjust the intensity using (3) *higher value + / lower value -*. Both bipolar pincettes, bipolar pins, as well as intraocular electrodes can be connected to the socket. These are activated via the footswitch.

(10) Cathode-electrolysis

Once you have selected *cathode-electrolysis* using the button, you can adjust the current using (3) *higher value + / lower value -*.

The cable for cathode electrolysis is connected to the socket. Depending on the intervention, the handle and inactive electrodes can be polarized at the end of the cable by switching the banana plug. These are activated via the footswitch.

(11) Electrocautery

Once you have selected *electrocautery* using the button, you can adjust the voltage using (3) *higher value + / lower value -*.The electrode handle for electrocautery is connected to the socket. This is activated via the button on the handle.

(12) Cold light source ON / OFF

Switches the cold light module on and off.

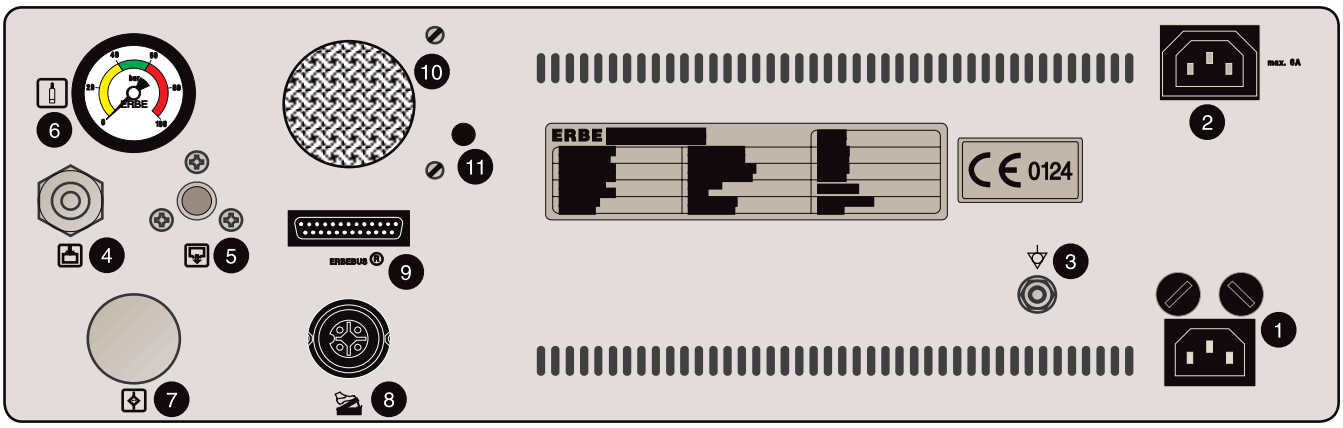
(13) Connection for the fiber optic cable

The cold light source is equipped with a quick change device for halogen lamps. Interrupting an intervention because of a lamp change is not necessary.

(14) Cryo ON / OFF

If an *Erbocryo AE* is connected to the Ophthalmotom, it is selected using this button.

Description of the controls, Erbokombi E Back



(1) Power connection / power fuses

Using only the power cord supplied by ERBE or one of at least equal quality, connect the power connection of the unit to a correctly installed grounded outlet. If you are using an equipment cart, this applies to the power cord on the equipment cart. The power cord must be labeled with a national test symbol.

WARNING! For reasons of safety, never use multiple power outlets or extension cords.

WARNING! Never touch the plug or lines with wet hands.

WARNING! The unit is protected with power fuses. If one of these fuses burns out, the unit can only then be used again on a patient if it has previously been tested by a trained technician. Only replacement fuses with the values indicated on the unit's rating plate can be used.

(2) Power outlet

You can connect other ERBE equipment with a max. power consumption of 6 A to this socket. The socket is not fuse-protected.

(3) Connection for potential equalization

Connect the potential equalization pin on the unit to the potential equalization in the operating room.

(4) Gas inlet

Connection for the gas tube for N_2O / CO_2 - (gas supply for the cryo unit)

(5) Gas outlet

Connection for the waste gas tube. You can connect this either to the gas disposal system or direct the gas out of the operating room.

(6) Pressure gauge

On the pressure gauge, you can see the pressure in the gas cylinder. The pressure should be between 40 and 60 bar.

(7) Gas filter

The filter cartridge should be replaced after gas consumption of 40 - 50 kg (approx. 6 gas cylinders).

(8) Footswitch connection

You can connect a footswitch to this socket. Using the pedal, you can activate *monopolar* and *bipolar coagulation, cathode-electrolysis* and *cryosurgery*.

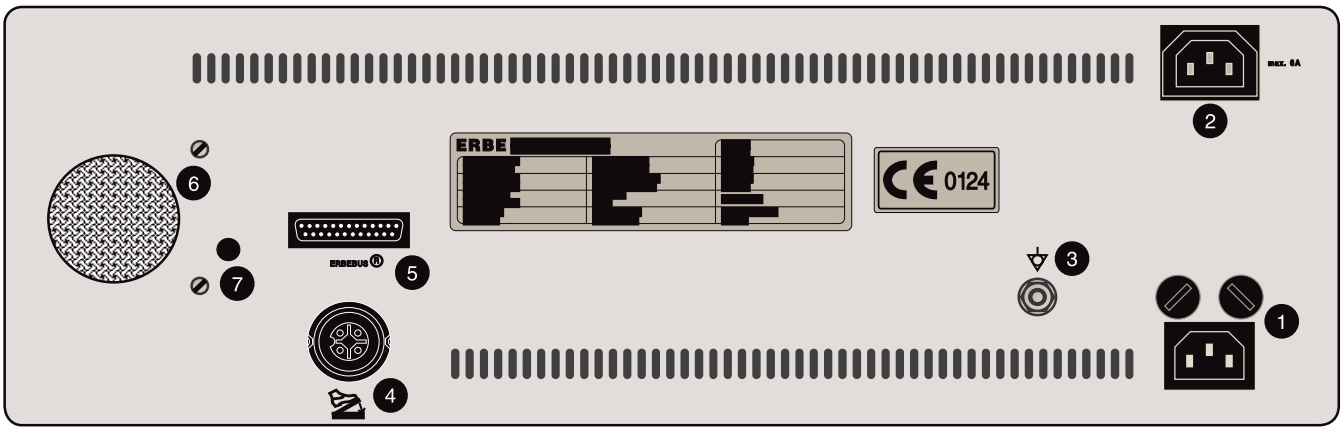
(9) Erbebus

The *Erbebus* is an interface system. Using it, you can join various equipment from the ERBE program to one another. Depending on the combination and preselection, you can operate the equipment using just one footswitch.

(10) Speaker For reproducing acoustic signals.

(11) Volume setting Volume setting for the acoustic signals with the help of a screwdriver.

Description of the controls, Ophthalmotom back



(1) Power connection / power fuses Using only the power cord supplied by ERBE or one of at least equal quality, connect the power connection of the unit to a correctly installed grounded outlet. If you are using an equipment cart, this applies to the power cord on the equipment cart. The power cord must be equipped with a national test symbol.

WARNING! For reasons of safety, never use multiple power outlets or extension cords.

WARNING! Never touch the plug or lines with wet hands.

WARNING! The unit is protected with power fuses. If one of these fuses burns out, the unit can only then be used again on a patient if it has previously been tested by a trained technician. Only replacement fuses with the values indicated on the unit's rating plate can be used.

(2) Power outlet You can connect other ERBE equipment with a max. power consumption of 6 A to this socket. The socket is not fuse-protected.

(3) Connection for potential equalization Connect the potential equalization pin on the unit to the potential equalization in the operating room.

(4) Footswitch connection You can connect a footswitch to this socket. Using the pedal, you can activate *monopolar* and *bipolar coagulation, cathode-analysis* and *cryosurgery*.

(5) Erbebus The *Erbebus* is an interface system. Using it, you can join various equipment from the ERBE program to one another. Depending on the combination and preselection, you can operate the equipment using just one footswitch.

(6) Speaker For reproducing acoustic signals.

(7) Volume setting Volume setting for the acoustic signals with the help of a screwdriver.

CHAPTER 3

Installation

Initial operation

Before delivery, the functions and safety of the unit are tested. To ensure that the unit also functions safely after transport and installation at the operators' location, it must only then be put into operation if:

1. it has been subjected to a performance test at the operating site, and
2. the party responsible for operating the unit has been trained by the manufacturer or supplier in handling the unit by means of the instruction manuals.

Ambient conditions

No operation in potentially explosive zones

WARNING ⚠

High-frequency surgical equipment intentionally generates electric sparks between the active electrode and tissue. Electric sparks may also result within the unit. For this reason, high-frequency surgical equipment must never be used in potentially explosive areas. Considered potentially explosive is the area up to 20 cm above the floor and the area around and beneath the operating table, if flammable or explosive cleaning agents, disinfectants, anesthetics etc. are used. This also includes highly concentrated or even pure oxygen. High-frequency surgical equipment is normally installed outside the zone designated as potentially explosive.

Explosion-proof footswitch

The footswitch must be suitable for operation within potentially explosive areas. Footswitches used in the operating room must have a watertight switch element.

Base

Place the unit on a stable, level base. This must be able to bear a weight of at least 14 kg.

Operating conditions

ATTENTION

The unit should be operated at an ambient temperature between +10°C and +30°C. The relative humidity should be between 30% and 70%, noncondensing. If levels fall outside this tolerance range, the unit may malfunction.

Acclimatization

If the unit was stored or transported at temperatures below +10°C, and especially below 0°C, the unit requires approx. 4 hours to become acclimatized to ambient temperature.

Air circulation

The unit must be set up in such a way that free air circulation around the housing is ensured. Setting up the unit in narrow corners or shelves is not permissible.

Protection from moisture

CAUTION! The housing is not completely tight. Make certain that no liquid penetrates into the unit. If liquid has penetrated into the unit, it can only be operated after inspection by the Customer Service.

Electrical installation

Inspection of the unit and accessories

Inspect the unit and the accessories (e.g. instruments, pedals, cables, tubes) for damage before use. Never use a damaged unit or damaged accessories. Replace defective accessories. If the unit is damaged, please contact the Customer Service. For your safety and for that of your patient, never attempt to repair defective equipment or accessories. Any modification to the unit or accessories will exempt ERBE Elektromedizin from all liability.

Compare the supply voltage / supply frequency before connecting

Compare whether the supply voltage and supply frequency of the unit agree with the values for the power supply. The supply voltage and supply frequency are indicated on the back of the unit and in the Technical Data. If in doubt, please contact the hospital technician.

Power cord, power outlet

Only connect the power connection of the unit to a properly installed grounded socket using the power cable supplied by ERBE or one of at least equal quality. If you are using an equipment cart, this applies to the power cable on the equipment cart. The power cord must be labeled with the national test symbol.

For reasons of safety, never use a multiple power outlet or an extension cord.

No wet hands!

Never touch the plug or lines with wet hands.

Power fuse

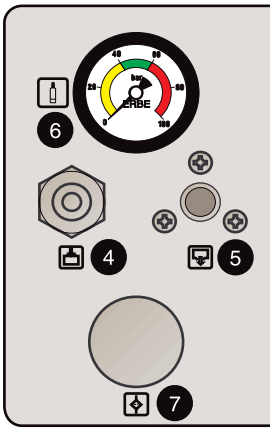
The unit is protected with power fuses. If one of these fuses burns out, the unit can only then be used again on a patient if it has been inspected previously by a qualified technician. Only replacement fuses with the values indicated on the unit's rating plate may be used.

Potential equalization

Connect the potential equalization pin on the unit to the potential equalization in the operating room.

Disconnecting the unit from the power supply

If you wish to disconnect the unit from the power supply, pull the plug from the wall outlet. Only then disconnect the connecting line from the unit.



Installation of the gas cylinder for the Erbokombi E

Proceed as follows, particularly for initial operation of the unit or after replacement of the gas cylinder:

- Briefly open the safety valve on the gas cylinder to blow out any dirt.
- Connect the pressure line to the gas cylinder. Connect the pressure line to the gas inlet (4) on the *Erbokombi E*. Open the safety valve on the gas cylinder.
- Switch on the unit.
- Connect the cryoprobe to the socket (15).
- Press the footswitch for several seconds so that the probe is blown out.
- Release the footswitch to defrost.

- Activate the footswitch again and listen to the sound produced by gas within each of the cryoprobes. With correct operation of the probe and with pure gas, the sound is regular.
- We recommend connecting the gas outlet (5) on the *Erbokombi E* to the gas disposal system using a waste gas hose.

Installation of the filter cartridge

The filter cartridge in the *gas filter* (7) should be replaced after gas consumption of 40 - 50 kg (approx. 6 gas cylinders).

To do this, the gas filter must be opened by turning counterclockwise under pressure-free conditions (pressure gauge 0 bar). Insert the new filter cartridge (No. 20410-008) and screw the cover back on.

WARNING ⚠

Cylinder pressure

WARNING! The cylinder pressure should be between 40 and 60 bar and must never exceed 60 bar. At a gas pressure of 60 bar plus (red field on the pressure gauge), the unit must not be operated. In this case, the gas cylinder must be closed and the unit separated from the gas cylinder. The overpressure can be released via the hand valve on the gas cylinder. Check the pressure gauge (6) on the rear of the Erbokombi E.

Use only N_2O / CO_2

It is possible for a cylinder with dangerous contents to be connected to the gas input of the unit. Check the cylinders as to whether they also contain N_2O / CO_2. Labels must not be damaged or removed.

Uncontrolled release of gas

When opening the cylinder valve, there is a brief hissing sound resulting from gas flowing into the tube. If this hissing continues for longer than 2 seconds after opening a cylinder, there is a leak. The gas cylinder must be reclosed immediately. The unit may only then be used after the leak has been repaired. Make certain that the pressure line is connected tightly to the unit. Close the safety valve on the gas cylinder once application is over.

High concentrations of CO_2 can cause suffocation. Symptoms include loss of mobility and unconsciousness. The victim is unaware of this. Risk of lethal injury! Low concentrations of CO_2 cause accelerated breathing and headache. Skin or eye contact with released CO_2 causes freezing and severe eye injuries.

N_2O has an anesthetic effect. High concentrations lead to unconsciousness - risk of lethal injury! Skin or eye contact with released N_2O causes freezing and severe eye injuries.

Long term injuries due to N_2O

Frequent contact with N_2O can cause long term injury to your health. We recommend connecting the *Erbokombi E* to a gas disposal system using a waste gas hose.

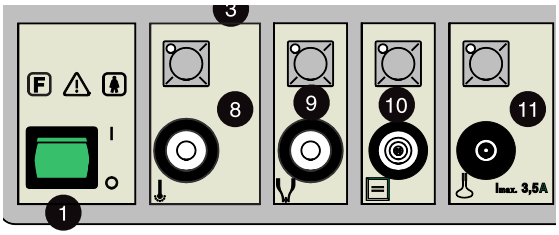
CHAPTER 4

Working with the Erbokombi E, Ophthalmotom

Erbokombi E and *Ophthalmotom* share the same design in function and operation.

Only the *Ophthalmotom* has no cryomodule.

Preparing the unit and accessories



Unit ON

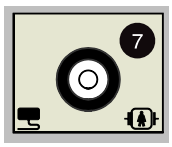
- Switch the unit on.

Connecting the footswitch

- Connect the footswitch to the back of the unit (socket 8).

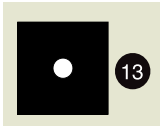
Connecting instruments

- Connect all instruments that you require (sockets 8 - 11, 15, 16).



Neutral electrode for monopolar coagulation

- If you wish to perform *monopolar coagulation*, connect the neutral electrode (socket 7) and apply this to the patient. Please pay attention to the safety instructions in Chapter 1.



Cold light source

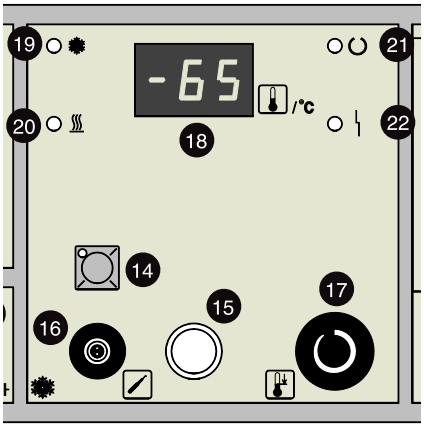
- If you wish to use the cold light source, connect the fiber optic cable to the *cold light source* (13).

Preparation of the cryomodule

- If you wish to work with the *cryomodule*, open the cylinder valve on the gas cylinder. Please first read the safety instructions in Chapter 1 and the installation instructions for the gas cylinder, the gas filter and the waste gas hose in Chapter 3.

WARNING

The cylinder pressure should be between 40 and 60 bar and must never exceed 60 bar. At a gas pressure of 60 bar plus (red field on the pressure gauge), the unit must not be operated. In this case, the gas cylinder must be closed and the unit separated from the gas cylinder. The overpressure can be released via the hand valve on the gas cylinder. Check the *pressure gauge* (6) on the back of the *Erbokombi E*.

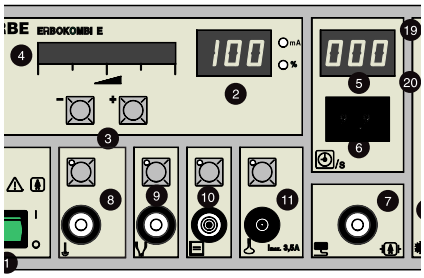


- Switch on the *cryomodule* using the button (14).
- Insert the cryoprobe plug into the socket (15). Screw tight. The *operational readiness* lamp (21) is illuminated.
- When taking apart the unit later: Wait a few seconds before unplugging the probe until the gas has dissipated. Then unscrew the knurled ring and carefully pull out the plug. Never pull by the cable.
- Connect the *thermosensor* plug to socket (16). The red marks must be in alignment.
- All cryoprobes are available without temperature measurement as well. If these are connected to the unit, the temperature display (18) indicates 0°C.

Operation of the individual functions

The unit stores the selected intensity settings. If you switch back and forth between functions on the unit, the intensity settings are retained.

Monopolar coagulation



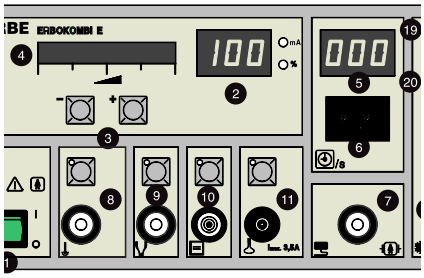
Once you have selected *monopolar coagulation* (8) with the button, you can set the intensity using (3) *higher value + / lower value -*. The intensity is indicated in % of the maximum intensity in the display (2). The *activation display* (4) is briefly illuminated when selecting the intensity.

You can limit the time for *monopolar coagulation* using the *timer* (6). Preselection of the coagulation time is possible in 1/10 second steps up to a max. 9.9 seconds. Once time has run out, the activation is automatically ended.

Activate coagulation using the button (if provided) on the electrode handle or with the footswitch. The *activation display* (4) is illuminated.

The display (5) indicates the *activation time* in 1/10 second steps. When the foot or fingerswitch is activated again, the display is automatically reset to 0.

Bipolar coagulation



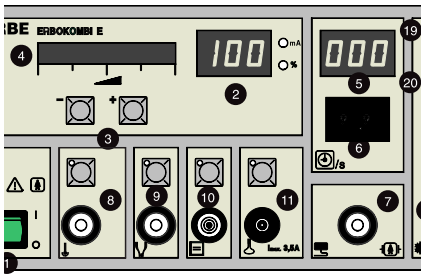
Once you have selected *bipolar coagulation* (9) with the button, you can set the intensity using (3) *higher value + / lower value -*. The intensity is indicated in % of the maximum intensity in the display (2). The *activation display* (4) is briefly illuminated when selecting the intensity.

You can limit the time for *bipolar coagulation* using the *timer* (6). Preselection of the coagulation time is possible in 1/10 second steps up to a max. 9.9 seconds. Once a time has run out, the activation is automatically ended.

Activate coagulation using the footswitch. The *activation display* (4) is illuminated.

The display (5) indicates the *activation time* in 1/10 second steps. When the footswitch is activated again, the display is automatically reset to 0.

Cathode-electrolysis



Once you have selected *cathode-electrolysis* (10) with the button, you can set the intensity using (3) *higher value + / lower value -*. The intensity is indicated in % of the maximum intensity in the display (2). The *activation display* (4) is briefly illuminated when selecting the intensity.

Place the flat electrode on the patient or place the hand cylinder in the patient's hand. The flat electrode or the hand cylinder are connected using the red conductive cable.

WARNING

Neutral electrodes and hand cylinders must only be used together with a well-moistened sponge. If the sponge is not used, the patient may be burned by Cl_2 or HCl.

Connect the epilation handle 20718-024 or the handle 20718-021 with the proper electrodes to the connecting socket for the gray conductive cable.

Activate *cathode-electrolysis* using the footswitch. The *activation display* (4) is illuminated and indicates how much power is currently being emitted.

Epilating the cilia

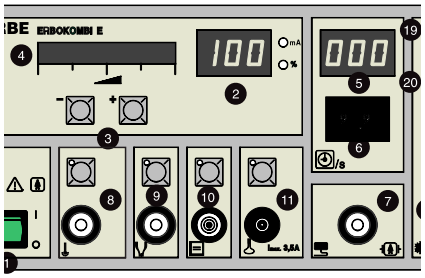
Set an output current of approx. 1.5 mA. If the 1.5 mA current is not enough, you can increase this in 0.1 mA steps. The current must never be so high that it triggers an unpleasant feeling of pain.

Drainage of subretinal fluid

Set an output current of approx. 1.4 mA.

WARNING

Before any application of the ERBE Kathalyse on patients with a cardiac pacemaker, the cardiologist responsible for this patient should be consulted in case of doubt in regard to risk for the patient.



Electrocautery

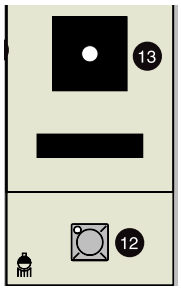
Once you have selected *electrocautery* (11) with the button, you can set the intensity using (3) *higher value + / lower value -*. The voltage is indicated in % of the maximum intensity in the display (2). The *activation display* (4) is briefly illuminated when selecting the intensity.

Activate electrocautery using the footswitch. The *activation display* (4) is illuminated.

WARNING

The cautery loop must not become too hot: The tissue may carbonize; the loop wears quickly and may burn through.

Select a maximum power setting at which the loop glows dark-red. To check this, look at the loop away from bright operating room illumination.

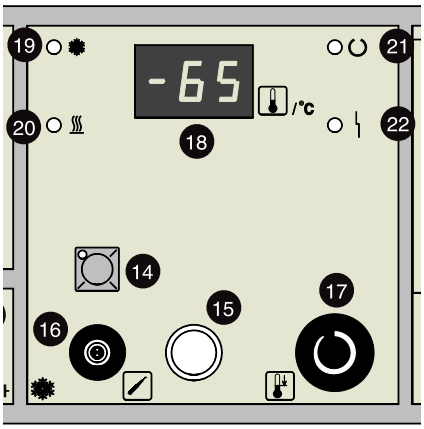


Cold light

Switch the *cold light* on using button (12).

Should the cold light source fail, pull the cold light source from its housing. Rotate the lamp socket 180°. Reinsert the cold light source into the housing.

WARNING ⚠ The cold light source is hot. Use caution when touching the lamp base.



Cryomodule

Read all safety instructions regarding work with N_2O / CO_2 in Chapter 1.

Switch on the *cryomodule* using the button (14).

Press the footswitch. The probe freezes. The *freeze* (19) lamp is illuminated.

During the freezing process, you can set the temperature using the *knob* (17). You can adjust the temperature infinitely from -20°C to -70°C. The max. temperature is dependent on the gas used.

You can control the temperature in the *temperature display* (18).

The activation time can be read from display (5). The activation time is given in one second intervals. When activating the foot- or fingerswitch again, the display is automatically reset to 0.

WARNING ⚠ During the freezing process, the tissue turns a white color. This tissue is necrotized and rejected. The size of the freezing lesion in an indication of the depth of freezing. The unit has no device for determining the size of the cryolesion. This requires freezing by sight or, with similar applications, by time.

To defrost, release the footswitch. The *defrost* (20) lamp is illuminated. After a defrost time of approx. 6 seconds, the pressure is automatically released from the probe.

WARNING ⚠ Before a probe has completely thawed out, it must not be removed by twisting or pulling (except for vein stripping). A defrosted probe can be removed with minimal use of force. Never remove probes frozen in place with a twisting or pulling movement. The probe must not be pulled forcefully from the tissue. Bent or damaged probes must never be used.

NOTE: Make certain that the module with which you wish to work is also switched on to prevent interference.

Performance test on the cryomodule

We recommend a performance test before every operation.

1. Connect the footswitch.
2. Switch on the unit.
3. Open the gas cylinder.
4. Check the correct operating pressure on the pressure gauge.
5. Make certain that no gas is leaking from the gas connection.
6. Connect a cryoprobe according to the description.
7. Press the footswitch to check whether the probe freezes. Check the leak-tightness and freezing performance by immersing the probe tip in sterile water.
8. Release the footswitch to check whether the probe defrosts.

The probe is automatically free of pressure approx. 6 seconds after defrosting.

CHAPTER 5

Cleaning, disinfection

Cleaning and disinfection of the unit

The unit housing should only be cleaned and disinfected with nonflammable and nonexplosive agents. Make certain here that no moisture penetrates into the unit.

We recommend a spray or wipe-down disinfection. However, the information from the disinfectant manufacturer absolutely must be observed here.

WARNING ⚠

If cleaning or disinfection of the unit with flammable or explosive agents is unavoidable, this must have completely evaporated from the unit before switching on the unit.

CHAPTER 6

Maintenance, Care, Disposal

Maintenance

Maintenance of the unit includes preventive and corrective measures. The safety checks represent preventive measures, while changes and repairs are corrective measures.

Through regular maintenance of the unit, proper functioning and safety are guaranteed at least until the next maintenance date. All maintenance must be documented in the logbook.

Changes and repairs

Changes and repairs must not reduce the safety of the unit for the patient, the user and the surroundings. For this reason, changes and repairs to the unit must only be performed by the manufacturer or by persons expressly authorized to do this by him.

If unauthorized persons perform improper changes or repairs to the unit, the manufacturer assumes no liability. Additionally in this case, the guarantee claim becomes void.

Safety checks performed by a service technician authorized by ERBE

The unit must be subjected to an annual safety check. Safety checks concern in particular:

- Visual inspection of the perfect condition of the unit and accessories
- Inspection of the grounded conductor
- Inspection of the insulation
- Inspection of the leakage current
- Equipment performance check
- Checking the activation of HF power using the ON button of the fingerswitch
- Checking the activation of HF power using the footswitch
- Checking the HF power
- Measurement of power consumption with and without a load
- Current measurement during cathode-electrolysis
- Leakage test (only on *Erbokombi E*)

Effective protection of the unit

Effective protection of the unit from damage also includes, in addition to proper operation and maintenance, the safe setup of the unit. This includes, in addition to safe fixation of the unit to its base, its protection from moisture, contamination and contact with flammable or explosive substances. To ensure good radiation of unit heat resulting from operation, air circulation around the cooling fans and the heat sink must not be impeded.

Disposal of the unit

The unit can be disposed of at the end of its useful life as standard electronic scrap.

CHAPTER 7

Customer service and guarantee

Customer service

If you are interested in a service contract, please contact ERBE Elektromedizin or an authorized retailer.

If you have questions, please contact an ERBE employee or your local branch office. We would be glad to help you.

Conditions of guarantee

Shipping damages

The unit and accessories must be immediately examined upon receipt for defects and shipping damage. Claims for damage compensation in this regard are only considered valid if the Seller or Shipping Agent is immediately notified. A damage report must be filled out.

Unit guarantee

The term of guarantee for the unit is 1 year, for accessory parts 6 months, calculated from the date of delivery. A claim of guarantee can only be made when the properly completed guarantee certificate is presented.

The scope of the guarantee encompasses no-cost repair of the unit, provided the damage was caused by a material or manufacturing error. Other claims, particularly claims of damage compensation, are excluded.

Repair must only be performed by ERBE, one of our representatives, or by an authorized retailer. The claim of guarantee becomes void if improper changes or repairs were made.

Through guarantee performances, the guarantee is neither extended nor renewed.

CHAPTER 8

Technical Data

Technical data

Supply voltage	230 V ± 10%, 50 Hz
Power input	max. 280 W
Power consumption	max. 1.2 A
Power fuse	T 2 A
Equipment power outlet	Connection for equipment with a max. power consumption of 6 A
HF power output *monopolar coagulation:* *bipolar coagulation:*	 40 W at 250 ohms ± 20% 40 W at 75 ohms ± 20%
Rated frequency *monopolar:* *bipolar:*	 2.2 mHz 2.2 mHz
Power setting *monopolar:* *bipolar:*	 infinite from 0% to 100% infinite from 0% to 100%
Switching of the neutral electrode	Floating output
Acoustic signals *HF surgery:* *Cautery:* *Start message:* *Error:*	 Continuous tone Soft continuous tone Triple tone Modulated tone
Visual signals	13 signal lamps (LED)
Cooling	Convection (cold light source with fan)
Cathode-electrolysis	0 ... 20 mA direct current ± 0.2 mA
Electrocautery	Pulse-width modulated direct current 0 ... 3.5 A
Cold light	150 W
Housing	W x H x D = 474 x 165 x 330 mm
Weight *Erbokombi E:* *Ophthalmotom:*	 13.3 kg 11.5 kg
Type in accordance with EN 60 601-1	BF
Protection class in accordance with EN 60 601-1	I
Classification according to EC Directive 93/42/EEC	II b
Ambient conditions for transport and storage of the unit	-40°C to +70°C Relative humidity 30% to 95%, noncondensing
Ambient conditions for operation of the unit	+10°C to +30°C Relative humidity 30% to 70%, noncondensing