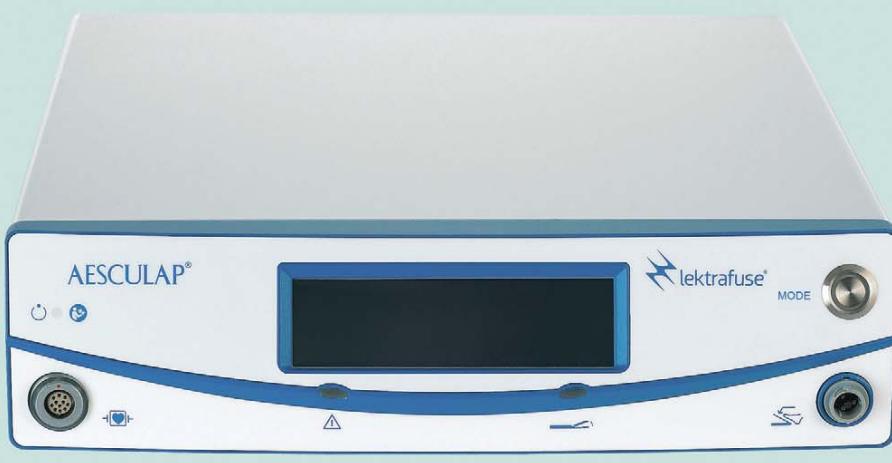


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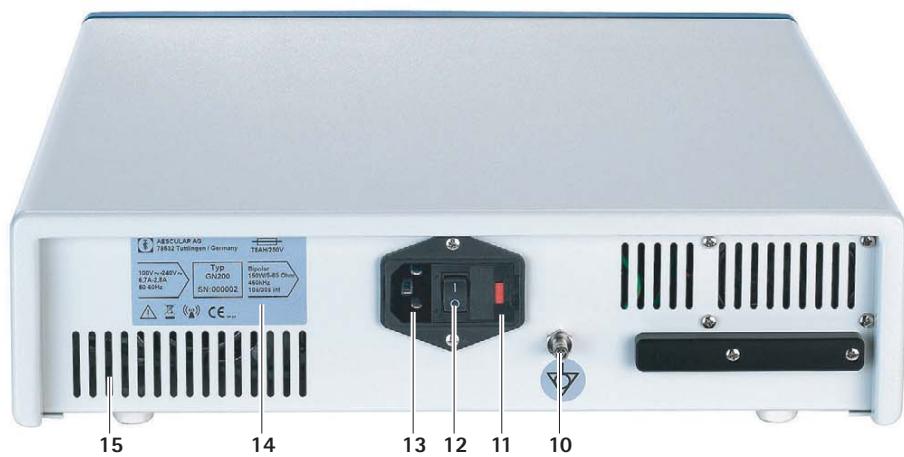
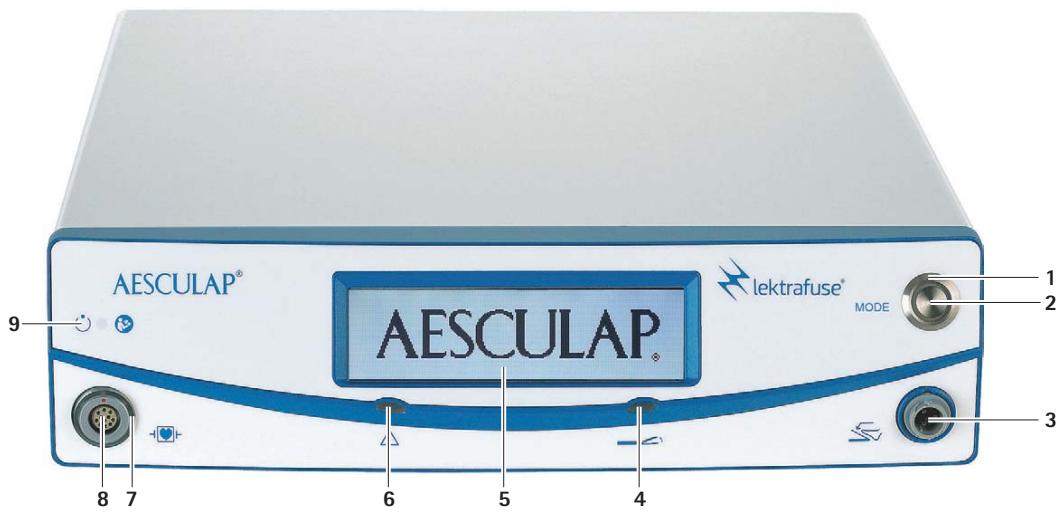


Aesculap Endoscopic Technology

Valid for units with software version 2.0 and higher

Instructions for use/Technical description

USA Lektafuse HF generator GN200



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Lektrafuse HF generator GN200

Legend

- 1 Signal lamp HF-ON (surrounding ring)
- 2 Operating mode selection button (MODE) (middle)
- 3 Connection socket (foot switch)
- 4 Signal lamp regrasp
- 5 Display
- 6 Signal lamp error
- 7 Signal ring instrument
- 8 Connection socket (instrument)
- 9 Indicator lamp power ON
- 10 Equipotential connector
- 11 Fuse holder (with 2 fuses)
- 12 OFF/ON switch
- 13 Mains power input socket
- 14 Type plate
- 15 Ventilation slots

Symbols on product and packages

	Caution Observe important safety information such as warnings and precautions in the instructions for use.
	Follow the instructions for use
	Marking of electric and electronic devices according to directive 2002/96/EC (WEEE), see Disposal
	Foot switch
	Regrasp
	Type CF applied part, defibrillation-protected
	Equipotentialization
	Fuse
	Non-ionizing radiation
	Alternating current
	Batch designation
	Serial number
	Order number
	Date of manufacture

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1. Safe handling

- 3 **CAUTION**
- 4 **Federal law restricts this device to sale by or on order of a physician!**
- 5 **Note**
- 5 *These instructions for use only describe the set-up, function and operation of the Lektrafuse generator GN200 and is not suitable for initiating a beginner in high-frequency surgery.*
- 6 
DANGER
- 6 **Risk of injury to patients due to inappropriate application!**
- 6 ▶ The product and accessories should only be operated by qualified or trained and experienced personnel.
- 7 
WARNING
- 7 **Risk of injury and material damage due to inappropriate use of the product!**
- 7 ▶ Use the product only in accordance with the intended use.
- 8 
WARNING
- 8 **Risk of injury and material damage due to improper handling of the product!**
- 8 The Lektrafuse HF generator together with the accessories forms a system.
- 8 ▶ Follow the instructions for use of the Lektrafuse HF generator accessories.
- 8 ▶ Follow the instructions for use of all products used.
- 11 ■ General risk factors associated with surgical procedures are not described in this documentation.
- 13 ■ It is the operating surgeon's responsibility to ensure that the surgical procedure is performed correctly.
- 15 ■ The operating surgeon must have a thorough understanding of both the hands-on and conceptual aspects of the established operating techniques.
- 16 ▶ Transport the product only in its original box.
- 17 ▶ Prior to use, check that the product is in good working order.
- 17 ▶ Observe "Notes on Electromagnetic Compatibility (EMC)", see TA022130.
- 18 ▶ The Lektrafuse HF generator GN200 fulfills the requirements of CISPR 11, Class A.
- 18 ▶ To prevent damage caused by improper setup or operation, and in order not to compromise warranty and manufacturer liability:
- 19 - Use the product only according to these instructions for use.
- 19 - Follow the safety and maintenance instructions.
- 19 - Only combine Aesculap products with each other.
- 19 - Adhere to application instructions according to relevant norms, see Safe for use in conformance with IEC regulations.

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Lektrafuse HF generator GN200

- ▶ Inspect the accessories regularly: Electrode cables and endoscopic accessories, in particular, must be checked for possible damage to the insulation.
- ▶ Keep the instructions for use accessible for the user.
- ▶ Always adhere to applicable standards.

1.1 Safe for use in conformance with IEC regulations

The operating environment



DANGER

Risk of death by electric shock!

- ▶ Do not open the product.
- ▶ Only ever connect the product to power mains with equipment grounding conductor.



WARNING

Risk of injury from ignition or explosion of flammable gases! Sparks may occur when using the HF generator as directed.

- ▶ Do not use the device in explosion-hazard zones.
- ▶ When operating in the head or thoracic region, avoid using combustible anesthetics and accelerating gases (e.g. nitrous oxide or oxygen) or, when using such substances, ensure they are extracted from the region of operation.
- ▶ If possible, use incombustible cleaning and disinfecting agents.
- ▶ If combustible cleaning and disinfecting agents or solvents have to be used: Verify that such agents have evaporated prior to commencing HF surgery.
- ▶ Be sure that no inflammable liquids accumulate under the patient's body or in body cavities (e.g. the vagina). Before using the HF generator, wipe up all fluids.
- ▶ Ensure the absence of any endogenous, combustible gases.
- ▶ Check that oxygen-soaked materials (e.g. absorbent cotton or mull) are kept at a safe distance from the HF field, so that they cannot ignite.



CAUTION

Risk of interference with other devices!

HF generators create potentially harmful magnetic fields during normal use.

- ▶ Be sure that no electronic devices that could be damaged by an electromagnetic field are set up in the vicinity of the HF generator.



CAUTION

Restriction to view and/or side-effects due to the development of steam/smoke during HF surgery!

- ▶ If necessary, use smoke suction.

- ▶ Ensure that the device does not come in direct contact with the patient or in the sterile area respectively.
- ▶ Ensure that the user does not come into direct contact with the patient and HF generator at the same time.

Patient safety



DANGER

Danger to life from inadequate preparation or operational errors in the HF generator!

- ▶ Be sure that the HF generator is in perfect working order.
- ▶ Ensure that neither the foot switch nor the hand switch has been penetrated by conductive fluids (e.g. blood, amniotic fluid).
- ▶ Ensure there is no short circuit in the foot or hand switch cables.



DANGER

Risk of burns suffered by the patient due to inadvertent activation of the HF generator!

- ▶ Switch off the HF generator immediately using the power OFF/ON switch in the event that it is activated accidentally.
- ▶ Always exercise particular care when operating the foot switch.



DANGER

Risk of injury to the patient due to an unintended rise of the HF output voltage due to a fault in the HF generator!

- ▶ Stop using the HF surgical device as soon as it shows even the slightest anomaly.



WARNING

Risk of injury to patients/users due to defective power cord or missing protective ground connections!

- ▶ Check the mains power cord/protective ground connections.



WARNING

Danger of injuries due to muscle contraction, caused by stimulation of the nerves and muscles!

- ▶ Work with particular care on sensitive structures.

Always be sure to do the following:

- ▶ Position the patient in such a way that s/he is not in contact with any metal parts that are grounded or have a significant electric capacity against ground (e.g. operating table, fixtures). If necessary, interpose antistatic drape.
- ▶ Ensure that the patient will not be in contact with any damp cloths, drapes or bedding.
- ▶ Safeguard areas prone to strong perspiration against skin contact with the trunk of the patient's body by inserting antistatic tissue between such areas and the trunk.
- ▶ Siphon off urine with a catheter.
- ▶ For heart surgery, ground the HF generator via the potential equalization connection.
- ▶ For patients with cardiac pacemaker or other active implants, consult with the relevant medical specialist prior to applying HF surgery, so that irreparable damage to the pacemaker or implant can be avoided.
- ▶ If possible, remove from the vicinity of HF electrodes any electrodes from physiological monitoring devices that are not equipped with protective resistors or HF dampers.
- ▶ Do not use needle electrodes for intraoperative monitoring.
- ▶ Arrange the wires and cables of monitoring devices in such a way that they do not come in contact with the patient's skin.
- ▶ Keep the leads to the HF electrodes as short as possible, and arrange them in such a way that they do not touch the patient or any other wires or cables.
- ▶ Should the output power appear insufficient with the usual settings, check that:
 - the working electrodes are clean,
 - all plug connections are properly in place.
- ▶ Never lay active electrodes on or next to the patient.
- ▶ Put down active electrodes that are not needed at any particular moment, in such a way that they will not touch the patient.
- ▶ For operations involving unavoidable, continuous contact between the electrodes and the patient (e.g. endoscopic procedures), press the power OFF/ON switch **12** to switch off the HF generator immediately after any inadvertent activation of the electrode.
- ▶ Do not remove hot electrodes from the patient's body immediately after performing cutting or coagulation procedures.
- ▶ During operation of the generator, do not touch the electrodes on the instrument (on the upper or lower side) as the electrodes can heat up and this may lead to burns or injuries.
- ▶ With respect to the electric shock hazard, the Lektrafuse HF generator ^{^Wd eV T]Rd ZRz _ R_UdRw] d/bf Z^ V_ed` WR ej aV 47 UNgZVZ}
- ▶ The Lektrafuse HF generator is intended only for indoor operation and ^{d cRxVZ}

2. Product description

2.1 Scope of supply

Designation	Art. no.
High frequency surgical device	GN200
Instructions for use	TA022414
Notes on Electromagnetic Compatibility	TA022130

2.2 Components required for operation

- Power cord
- Foot switch (optional)
- Caiman Instrument

2.3 Indications for Use

4RZA R_DMRj R_U 4fe EVTY_] Xj T_dZed ` WUMUZTReMu Sz`]Rc V|VTeC dFcxZTRj Z_dZd^ V_ed Z_eV_UMU Wc fdV Z_XV_VeRj dFcxVj R_U Xj_VT] XZT dFcxZTRj ac TVUFdV h YVdV]ZRz _ R_U UZgZz_ ` WgVdVjd Zd UvdvUZ EVY Z_daf^ V_ed TdVReV R dVrj Sj eV Raa]ZRz _ ` WSz`]Rc V|VTeC dFcxZTRj C7 V_Veqj /T RXf]ReZ_fi e` gRdtff]Rc dafTef dV/gVdVjdZ_eVca` dMu SVhW_ eV [Rh d` WeV UNgZVZ 2 Tf eeZ_X SJRUv Zd RTef ReV Wc eV UZgZz_ ` WZdfVZ

:_dZd^ V_ed %#T^ Z_ JV_XeY RdV Z_UZTReMu Wc` aV_aC TVUFdVdR_U Z_daf^ V_ed \$` T^ R_U %#T^ Z_ JV_XeY RdV Z_UZTReMu Wc`]RaRc dT aZT ac TVUFdVdZEVY Z_UZTReZ_d Wc fdV Z_TfUV XV_VdVj dFcxZTRj ac TVUFdVdZ_TfUZ_Xfc] XZTcgRdtff]Rc eV dRTZc R_U eV dRT dT aZTfc R_U Xj_VT] XZTRj ac TVUFdVd h YVdV]ZRz _ R_U UZgZz_ ` WgVdVjd Zd aVdWc` UZ EVdV ac TVUFdVd Z_TfUV gRZ_Rj Yj dVdVTe ^ Zd? ZdV_W_U a]ZRz _CT]VTe ^ j cRUYVdV j dZtS` h V] dVdVTe _cR_U `` aY` dTe ^ j` VTeZ` c R_j ac TVUFdVh YVdV gVdV]]ZRz _ /dVrj R_U Tf efteZdfV XcRdz_XcR_U UZdVTeZ_Zd aVdWc` UZ EVY UNgZVd TR_ SV fdM` _ gVdVjd fa e` R_U Z_TfUZ_X (^ R_U USf_UJvdRj]RcV Rdh Z] VdZ_eV [Rh d` WeV UNgZVd^ V_dZ

4RZA R_DMRj R_U 4fe EVTY_] Xj YRd _ e SW_dV h_ e` SV WNgZVd Vc eVdSRj dFcxZTRz _ ` cefSRj T RXf]ReZ _ Wc dVdZTRz _ ac TVUFdVdZ^ _ ` efdV eVdV dVdV Wc eVdV ac TVUFdVdZ

2.4 Operating principle

The Lektrafuse HF generator GN200 works on a micro-processor controlled basis and converts the voltage of the mains supply into a high-frequency alternating current for bipolar vessel sealing.

The sealing process is carried out via a closed control circuit. The sealing can be started and stopped via a button on the instrument or a foot switch.

The Lektrafuse HF generator GN200 has two operating modes:

- Standard mode: Pre-set operating mode
- Plus mode: Operating mode with increased energy output

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Lektrafuse HF generator GN200

2.5 Acoustic warning signal

Status	Acoustic warning signal	Notes
System failure	3 repetitions of: 1 long beep, 3 KHz, 1 beep, 2 KHz	Following each system failure, if identified (F001,...)
REGRASP error	3 repetitions of: 1 beep, 2 KHz, 1 beep, 3 KHz	Following each regrasp error, if identified
System error	3 beeps, 3 KHz	Following each failure report, if identified (E001,...)
System warning	3 beeps, 3 KHz	Following each warning, if identified
Start HF discharge	2 beeps, 480 Hz	When starting the HF discharge
HF discharge active	1 beep, 480 Hz ■ In Standard mode: Repetition with 1.8 Hz ■ In Plus mode: Repetition with 2.8 Hz	Continually during HF discharge
End of HF discharge	3 beeps, 530 Hz	When a sealing process has been successfully completed (no failure reports or errors)
Power up self-test	1 beep, 2 KHz	During the self-test, in order to check that the signal tone is functioning

2.6 Monitoring functions

Self-test

As soon as it is switched on, the unit performs a self-test of the control elements, the acoustic warning signal, the microprocessor and the hardware function. During this phase, the message "Performing Self-Test" appears in the display 5.

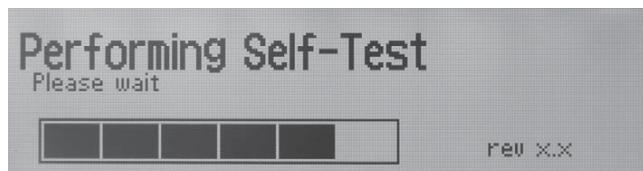


Fig. 1

Continuous test cycle during operation

During operation, safety-relevant functions and signals are monitored through a continuous test cycle. As soon as a critical error is detected, the HF generator terminates the HF activation. In display 5, the error number of the corresponding error is displayed and an acoustic warning signal is emitted, see Troubleshooting list.

2.7 Output power diagrams

Representation of the output power as a function of the load resistance.

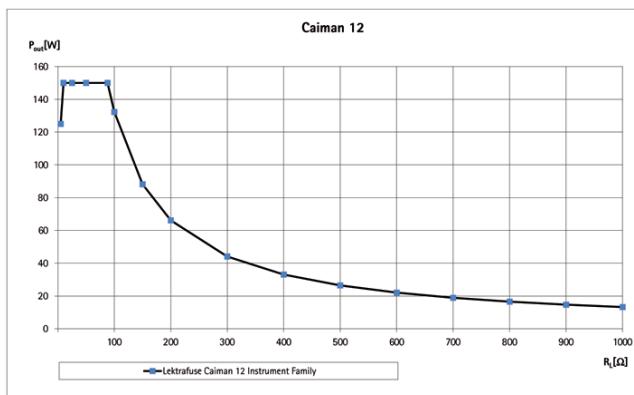


Fig. 2 Output power diagram Caiman 12 mm Seal & Cut instrument family

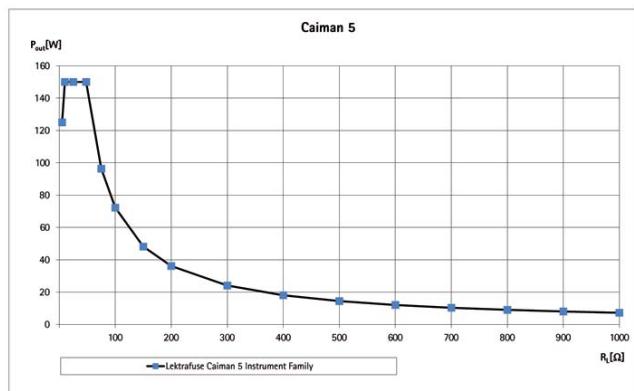


Fig. 3 Output power diagram Caiman 5 mm Seal & Cut instrument family

2.8 Maximum peak output voltage (U_p)

Note

The following data allow the user to judge whether the HF generator GN200 is suitable for a given accessory (insulation rating).



Risk of injury to patient or user caused by inadequate accessories (insulation rating)!
 ► Make certain that the accessory voltage rating specified in the product documentation is higher than maximum peak output voltage.

Maximum peak output voltage (U_p): 200 V

3. Preparation and setup

Non-compliance with the following instructions will preclude all responsibility and liability in this respect on the part of Aesculap.

- When setting up and operating the product, adhere to
 - national regulations for installation and operation,
 - national regulations on fire and explosion protection.

Note

For the safety of patients and users it is essential that the mains power cord and, especially, the protective earth connection are intact. In many cases defective or missing protective earth connections are not registered immediately.

- Connect the device via the potential equalization terminal at the rear panel of the device to the potential equalization system of the room used for medical purposes.

Note

The potential equalization lead can be ordered from the manufacturer as article no. GK535 (4 m length) or TA008205 (0.8 m length).

- In order to ensure sufficient ventilation and cooling of the HF generator, leave at least 10 cm to 15 cm of space around the HF generator.

3.1 First use



WARNING

Risk of injury and/or product malfunction due to incorrect operation of the electromedical system!
 ► Adhere to the instructions for use of any medical device.

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4. Working with the Lektrafuse HF generator GN200

4.1 System set-up

Connecting the accessories



DANGER

Risk of injury due to unapproved configuration using additional components!

- For all applied components, ensure that their classification matches that of the application component (e.g. Type BF or Type CF) of the respective device.

Combinations of accessories that are not mentioned in the present instructions for use may only be employed if they are specifically intended for the respective application, and if they do not compromise the performance and safety characteristics of the products.

Only CAIMAN instruments can be used in conjunction with the Lektrafuse HF generator GN200, see Accessories/Spare parts.

Connecting the power supply



DANGER

Risk of death from electric shock!

- Only connect the product to power mains with equipment grounding conductor.
- Set up the device in a way that switching it off using the power OFF/ON switch is possible and straightforward.
- Set up the device in a way that disconnecting the power cord is straightforwardly possible.

The voltage of the mains power supply must correspond to the voltage indicated on the type plate of the device.

The device is fitted with a universal power supply unit, which means that it automatically adapts to mains voltages ranging from 100 V to 240 V without having to switch between voltage ranges.

- Ensure that the device is switched off. If necessary, switch off with the power OFF/ON switch 12.
- Plug in the power cord in mains power input socket 13 in the rear panel of the HF surgical device.
- Plug in the mains plug at the building mains power socket.

Switching on the device

- Switch on the device with the power OFF/ON switch 12.

Indicator lamp power ON 9 is illuminated. The device performs a self-test, see Continuous test cycle during operation:

If no instrument is connected, the message "Attach Instrument" appears in the display 5 after the self-test. If the self-test fails, an error message is shown in the display 5.



Fig. 4

Connecting the foot switch

Connecting the foot switch GN201 is optional.

Both the foot switch plug and connection socket (foot switch) 3 have a dot marking. To connect the plug to the connection socket correctly, these markings must be aligned.



Fig. 5

- Align the foot switch plug and insert it into the foot switch connection socket **3** until it engages.

When the device and the foot switch have been successfully connected, the message "Footswitch attached" appears for 3 seconds in the display **5**.

Footswitch attached

Fig. 6

Note

Do not activate the foot switch continually during HF discharge. HF discharge is started and stopped by pressing once on the foot switch and then releasing.

Remove the foot switch

- Turn the locking ring counter-clockwise and withdraw the connecting plug at the same time
- The message "Footswitch removed" appears in the display **5** for 3 seconds.

Footswitch removed

Fig. 7

Connecting the instrument

Only instruments of the CAIMAN Seal & Cut product family can be used in conjunction with the Lektrafuse HF generator GN200.

The instrument connector has an arrow marking and the connection socket **8** has a dot marking. To connect the plug to the connection socket correctly, these markings must be aligned.



Fig. 8

- Connect the instrument with the connection socket **8**.

The green signal ring **7** around the instrument connector lights up. The message "Ready to Seal" appears in the display **5**.

Ready to Seal	Standard
Press RF ON Button or Footswitch to start	Plus

Fig. 9

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Selecting the operating mode

The Lektrafuse HF generator has two operating modes for the sealing process. The selected operating mode will be retained until the HF generator is switched off. The operating mode can be changed during the procedure.

- Changing the operating mode: Press operating mode selection button (MODE) 2.
- Standard mode: Pre-set operating mode
- Plus mode: Operating mode with increased energy output

The operating mode is independent from the connected instrument. Changing or reconnecting the instrument does not change the operating mode.

The active operating mode is indicated in the display as follows:

- Border
- Bold font

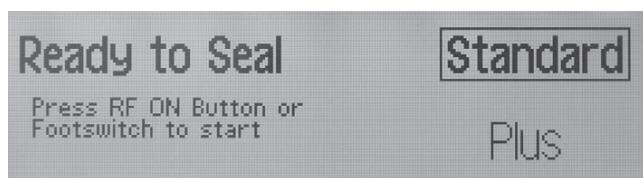


Fig. 10

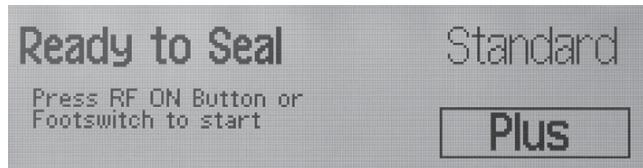


Fig. 11

Note

In case of a regrasp error, the active operating mode is not displayed. The active operating mode can be displayed by pressing the operating mode selection button (MODE) 2.

Note

The Plus mode can be distinguished from Standard mode by the higher frequency of the beep during HF discharge.

Shutting down

- Switch off the device with the power OFF/ON switch 12.
All the poles of the device are disconnected from the power supply.
- Withdraw mains cable.
The device is completely disconnected from the power supply.

4.2 Function checks

Prior to each use, carry out a functional test of the device:

- Check that the accessories have no visible damage.
- Prepare and set up the unit, see Preparation and setup.
- Check the functionality of the following elements, one after the other, in the following sequence:
 - Switch on the power OFF/ON switch 12; the power on signal lamp 9 lights up
 - Automatic self-test after each time the device is switched on: brief acoustic signal, all display elements light up briefly
 - Operating mode selection, see Selecting the operating mode
 - foot switch, see Connecting the foot switch
 - Instrument, see Connecting the instrument
 - Activation with instrument button and foot switch
 - Switch off the power OFF/ON switch 12

4.3 Safe operation



WARNING

Risk of injury and/or malfunction!

- Always carry out a function check prior to using the product.



WARNING

Risk of injury when using the product beyond the field of view!

- Apply the product only under visual control.

- Start the sealing process (HF discharge) by pressing the button on the instrument or foot switch once.

After completing the sealing process, the HF discharge is automatically stopped.

During sealing process, the message "Sealing in Progress" is shown on the display 5.

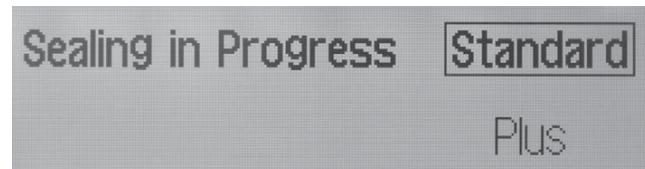


Fig. 12

To activate/deactivate device

- Switch on/switch off the device with the power OFF/ON switch 12.

Operating mode

The Lektrafuse HF generator GN200 automatically recognizes the connected instrument. The internal device settings are loaded. The user can choose between two operating modes.

Activating the HF current

- ▶ Be sure that the patient is prepared in such a way that the HF generator can be applied without any risk to the patient.
- ▶ Make sure that the required operating mode is selected.
- ▶ Ensure that the instrument and foot switch, if used, are correctly connected.
- ▶ Activate the HF generator via the hand switch or the foot switch.
- ▶ Do not activate the hand switch or foot switch continually during HF discharge.

Note

The vessel sealing process is started and ended by pressing the foot switch or hand switch on the instrument once. After completing the sealing process, the device stops the HF discharge automatically. The sealing process can be interrupted by pressing the button once more.

5. Validated reprocessing procedure

5.1 General safety instructions

Note

Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for sterile processing.

Note

For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of products.

Note

Mechanical reprocessing should be favored over manual cleaning as it gives better and more reliable results.

Note

Successful processing of this medical device can only be ensured if the processing method is first validated. The operator/sterile processing technician is responsible for this.

The recommended chemistry was used for validation.

Note

If there is no final sterilization, then a virucidal disinfectant must be used.

Note

For up-to-date information about reprocessing and material compatibility, see also the Aesculap Extranet at <https://extranet.bbraun.com>.

The validated steam sterilization procedure was carried out in the Aesculap sterile container system.

5.2 General information

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore the time interval between application and processing should not exceed 6 h; also, neither fixating pre-cleaning temperatures >45 °C nor fixating disinfecting agents (active ingredient: aldehydes/alcohols) should be used.

Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or to fading and the laser marking becoming unreadable visually or by machine for stainless steel.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfection and sterilization will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g. VAH or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' recommendations may be used for processing the product. All the chemical manufacturer's application specifications must be strictly observed. Failure to do so can result in the following problems:

- Optical changes of materials, e.g. fading or discoloration of titanium or aluminum. For aluminum, the application/process solution only needs to be of pH >8 to cause visible surface changes.
- Material damage such as corrosion, cracks, fracturing, premature aging or swelling.
- ▶ Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.
- ▶ Further detailed advice on hygienically safe and material-/value-preserving reprocessing can be found at www.a-k-i.org, link to Publications, Red Brochure – Proper maintenance of instruments.

5.3 Preparations at the place of use

- ▶ Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.
- ▶ Transport the dry product in a sealed waste container for cleaning and disinfection within 6 hours.

5.4 Preparation before cleaning

- ▶ Disconnect the unit from mains power.
- ▶ Remove accessories.

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5.5 Cleaning/disinfection

Product-specific safety instructions for the reprocessing procedure



DANGER

- Risk of electric shock and fire hazard!
- ▶ Unplug the device before cleaning.
 - ▶ Do not use flammable or explosive cleaning or disinfecting solutions.
 - ▶ Ensure that no fluids will penetrate the product.



CAUTION

- Damage to, or destruction of the product caused by mechanical cleaning/disinfection!
- ▶ Only clean and disinfect the product manually.
 - ▶ Do not sterilize the product under any circumstances.



CAUTION

- Damage to the product due to inappropriate cleaning/disinfecting agents!
- ▶ Only use cleaning/disinfecting agents approved for surface cleaning. Follow the manufacturer's instructions for the respective cleaning/disinfecting agent.



CAUTION

- Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!
- ▶ Use cleaning agents and disinfectants according to the manufacturer's instructions.
 - ▶ Observe specifications regarding concentration, temperature and exposure time.

Validated cleaning and disinfection procedure

Validated procedure	Special features	Reference
Wipe disinfection for electrical devices without sterilization	–	Chapter Wipe disinfection for electrical devices without sterilization

5.6 Wipe disinfection for electrical devices without sterilization

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Wipe disinfection	RT	≥1	-	-	Meliseptol HBV wipes 50 % Propan-1-ol

RT: Room temperature

Phase I

- ▶ Remove any visible residues with a disposable disinfectant wipe.
- ▶ Wipe all surfaces of the optically clean product with a fresh, disposable disinfectant wipe.
- ▶ Observe the specified application time (1 min minimum).

5.7 Inspection, maintenance and checks

- ▶ Inspect the product after each cleaning and disinfecting cycle to be sure it is: clean, functional, and undamaged.
- ▶ Set aside the product if it is damaged.
- ▶ Perform a safety inspection annually, see Maintenance.

5.8 Storage and transport



Damage to the product caused by switch-on too early after storage/transport at temperature below +10 °C (50 °F)!
▶ Allow the HF generator to acclimate at room temperature for about 1 hour.

- ▶ Transport the product only in its original box.
- ▶ For storage and transport conditions, see Ambient conditions.

6. Maintenance

No servicing is required for the Lektrafuse HF generator GN200.

Note

Maintenance must only be carried out by authorized personnel. If necessary, the circuit diagrams and the service manual, which contains all the necessary documents, are provided for this.

6.1 Safety inspection

- A safety inspection must be carried out annually. The person in charge of the inspection will document the inspection findings and measurement values according to the printed inspection protocol.
- ▶ Only have the product and its accessories inspected by persons who possess the requisite training, knowledge and experience and who are authorized to do so.
 - ▶ If there are significant deviations from the inspection protocol values, or if the prescribed maximum values are exceeded: Send in the device. For technical service, please contact your national B. Braun/Aesculap agency, see Technical Service.



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B BRAUN SHARING EXPERTISE		Inspection protocol – safety inspection		
TEST INTERVAL:	1 Year			
TYPE OF DEVICE:	Bipolar Electrosurgical Unit GN200			
MANUFACTURED BY:	Aesculap AG, Am Aesculap-Platz 78532 Tuttlingen/Germany			
RESPONSIBLE				
SN:	INVENTORY NO.:	ORGANIZATION:		
Measurement equipment:				
SCOPE OF INSPECTION			Verdict	
1.) VISUAL INSPECTION			PASS	FAIL
1.1	Inspection of power cable for visually detectable damage			
1.2	Inspection of foot switch for visually detectable damage			
1.3	Type plate still present and readable			
1.4	Check fuse links for prescribed values			
1.5	Overall condition of device: dirt, damage			
2.) ELECTRICAL INSPECTION			Measured value	Verdict Pass / Fail
2.1	Protective earth resistance incl. mains cable according IEC62353:2007		$R_{max} = 0,3 \Omega$ (at $\geq 0,2 A$)	
2.2	Earth leakage current according IEC60601-1*		N.C. $I_{max} = 0,50 mA$ S.F.C. $I_{max} = 1,00 mA$	
2.3	Enclosure leakage current/touch current according IEC60601-1*		N.C. $I_{max} = 0,10 mA$ S.F.C. $I_{max} = 0,50 mA$	
2.4	Patient leakage current according IEC60601-1*		N.C. $I_{max} = 0,01 mA$ S.F.C. $I_{max} = 0,05 mA$	
2.5	Equipment leakage current - alternative method according IEC62353:2007		$I_{max} = 1,00 mA$	
2.6	Applied part leakage current - alternative method according IEC62353:2007		$I_{max} = 0,05 mA$	
2.7	HF-leakage current bipolar according IEC60601-2-2:2009		$I_{max} = 122 mA$	
2.8	Insulation resistance according IEC62353:2007 (Preparation according Service Manual)		test voltage = 500 V DC	
2.8.1	Mains against HF output		$R_{min} = 7 M\Omega$	
2.8.2	Mains against housing		$R_{min} = 2 M\Omega$	
2.8.3	HF-output against housing		$R_{min} = 2 M\Omega$	
2.9	HF-output power measurement with induction-free resistor			
	Instrument	Channel	R_{load}	Rated value
	C5	1	50 Ω	145 Watt $\pm 20\%$
	C24/44	1	50 Ω	150 Watt $\pm 20\%$
		2	50 Ω	150 Watt $\pm 20\%$
2.10	DC resistance between the two HF output poles according IEC60601-2-2:2009 section 201.8.4.102		$R_{min} = 2 M\Omega$	
2.11	Function test according to instructions for use		Performed:	
TEST RESULT				
Deficiencies were determined, by which patient, user or other individuals can be endangered			No <input type="checkbox"/>	Yes <input type="checkbox"/>
<input type="checkbox"/> Repair		<input type="checkbox"/>	Next date of inspection	
Place/Date		Inspector/Signature	Responsible Organization	

* The listed allowable values comply with the requirements of the IEC60601-1:1988+A1:1991+A2:1995 and IEC60601-1:2005

Fig. 13 Inspection protocol form Safety inspection

7. Troubleshooting list

7.1 Regrasp error

A regrasp error, i.e. potentially insufficient sealing of the vessels, is displayed as follows:

- Unambiguous sound sequence and interruption of the sound sequence of HF operation, also stops HF discharge
- The yellow regrasp error light **4** on the front side of the HF generator lights up
- Warning message in the display **5** on the front side of the HF generator

Regrasp error message	Significance	Remedy
REGRASP INDICATOR – OPEN Visually check seal – Manually cut - Clean jaws OR Regrasp thicker tissue	Check the vessel sealing. Contact areas of the jaw part must be covered with dried vessel residue or bodily fluids. - or - The gripped bundle of tissue is too thin	Clean contact areas with sterile water and a sponge Grip a thicker tissue bundle
REGRASP INDICATOR – SHORT Visually check seal – Manually cut Check for metal or occlusion in jaw Remove excess fluids	There is metal (e.g. staples) or other foreign material between the electrodes in the jaw part	Open and check jaw part Remove any foreign material Remove excess suction fluids in the operating area
REGRASP INDICATOR – TIME Visually check seal – Reseal as needed Seal cycle interrupted Seal endpoint not reached	HF generator has reached its maximum sealing time and has not ascertained any complete seal - or - The user has ended HF discharge during sealing	Check the quality of the seal

Procedure if a regrasp error occurs:

- Do not cut the vessel.
 - Open the instrument.
 - Check the sealed vessel.
- When correct hemostasis has occurred:
- Cut the vessel manually with surgical scissors.
- When hemostasis has not occurred in the correct way:
- Place the instrument on the vessel again and lock it in place.
- Start additional HF cycle.
 - If the additional HF cycle leads to a normal seal, the vessel can be cut, and the instrument can be opened and removed.
 - If a regrasp error occurs again, do not cut the vessel, open the instrument and manually cut the sealed vessel with surgical scissors. When so doing, ensure that the hemostasis is correct.

Note

The regrasp error must not be confirmed. Activating the hand switch or foot switch will start the next sealing process immediately.

Note

In case of a regrasp error, the active operating mode is not displayed. The active operating mode can be displayed by pressing the operating mode selection button (MODE) **2**.



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7.2 Warnings

A warning is indicated as follows:

- Individual tone (different from a failure, an error or normal HF operation)
- Warning message in the display **5** on the front side of the HF generator

Warning message	Significance	Remedy
Generator Cooling Please Wait	generator temperature too high	Check the airflow around the generator
Generator Too Cold Please Wait	Generator must first warm up	Do not switch off the generator whilst it is warming up

7.3 Error reports

An error is indicated as follows:

- Unambiguous tone sequence (different from a failure or normal HF operation)
- Failure message in the display **5** on the front side of the HF generator

Error code	Error report	Significance	Remedy
E001	ERROR E001 Instrument HF activation button error Release Instrument RF-ON Button Remove and reattach instrument	Instrument "HF activation" button is pressed while the instrument is connected to the HF generator	Release the "HF activation" button Remove instrument and reconnect it
E002	ERROR E002 Instrument Error Remove and reattach OR Remove and replace instrument	HF generator cannot find instrument - or - Instrument is defective and must be replaced	Remove instrument and reconnect it - or - Replace instrument
E003	ERROR E003 Footswitch Error Release footswitch Remove and reattach footswitch	Foot switch is pressed while the foot switch is connected to the HF generator	Release foot switch Remove foot switch and reconnect it

7.4 Failure messages

A failure is indicated as follows:

- Clear sound sequence (as necessary, may interrupt the sound of the HF discharge)
- The red error light **6** on the front side of the HF generator lights up
- Error message in the display **5** on the front side of the HF generator

Note

If the failure occurs during HF discharge, the vessel sealing may be incomplete or insufficient.

In order to ensure that sufficient hemostasis has been achieved, follow the procedure for regrasp errors, see Regrasp error.

Note

If the failure continues after turning the device off and on again twice, contact your national B. Braun/Aesculap agency, see Technical Service.

Failure code	Cause	Remedy
F001	Software error on the HF generator	Switch off HF generator, wait 5 s, switch HF generator on
F002	Dosage error of HF generator	Switch off HF generator, wait 5 s, switch HF generator on
F003	Hardware error	Switch off HF generator, wait 5 s, switch HF generator on
F004	Internal communication error of the HF generator	Switch off HF generator, wait 5 s, switch HF generator on
F005	Overheating of HF generator	Switch off HF generator and leave to cool down Check the air stream around the generator
F006	Error in the operating mode selection button (MODE) 2 (activated when switching on)	Switch off HF generator, wait 5 s, release operating mode selection button (MODE) 2 , switch HF generator on
F007	Error with HF energy output	Switch off HF generator, wait 5 s, switch HF generator on
F008	Fault: HF outside the calibration	Switch off HF generator, wait 5 s, switch HF generator on
F009	Fault: Internal power supply	Switch off HF generator, wait 5 s, switch HF generator on

7.5 Problem solving

Finding	Remedy
HF generator does not switch on	Ensure that the power cord has been correctly plugged into the power supply 13 of the HF generator. Ensure that the power cord is connected to a functioning power source. Ensure that the power OFF/ON switch 12 of the HF generator is in the power ON position. Check the fuse in the fuse box and replace if necessary, see Fuse replacement. If the error continues, replace power cord.
The device is switched on, but no displays are illuminated and the self-test is not being carried out	Switch off HF generator, wait 5 s, switch HF generator on again. If the error continues, contact your national B. Braun/Aesculap agency, see Technical Service.
Self-test fails	Switch off HF generator, wait 5 s, switch HF generator on again. If the error continues, contact your national B. Braun/Aesculap agency, see Technical Service.
HF generator is active (power ON signal lamp 9 lights up), and accessories are connected, but there is no HF discharge	Verify that the required foot switch (if used) is properly connected and plugged in. Ensure that the Caiman Seal & Cut Instrument is correctly connected and plugged in (green ring 1 is lit up). In order to start the HF discharge, activate the button on the instrument or the foot switch. If the error continues, replace Caiman instrument.

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7.6 User maintenance

- In case of error, follow the instructions in the display and note the error code.
- If the error continues after following the instructions in the display, contact your national B. Braun/Aesculap agency, see Technical Service.

7.7 Fuse replacement



Risk of death by electric shock!

- Unplug the device before changing the fuses!

Specified fuses: 2 units Aesculap art. no. TA021404:

G fuse link, time lag (T) 8 A, breaking capacity H (1 500 A)

- Use a small screwdriver to release the clip on the fuse holder 11 and tilt up cover.
- Use a small screwdriver to release the fuse holder 11 and pull it out.
- Replace both fuses.
- Reinsert the fuse holder 11.
- Close the cover.

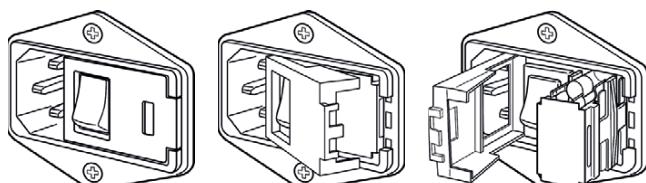


Fig. 14

Note

If the fuses burn out frequently, the device is faulty and should be repaired, see Technical Service.

8. Technical Service



Danger to life of patients and users if the product malfunctions and/or protective measures fail or are not used!

- Do not perform any servicing or maintenance work under any circumstances while the product is being used on a patient.
- Do not modify the product.

- For service and repairs, please contact your national B. Braun/Aesculap agency.

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service addresses

Aesculap Technischer Service
Am Aesculap-Platz
78532 Tuttlingen / Germany
Phone: +49 (7461) 95 -1601
Fax: +49 (7461) 14 -939

E-Mail: ats@aeculap.de
Or in the US:

Aesculap Inc.
Attn. Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood
MO, 63042 USA
Aesculap Repair Hotline
Phone: +1 (800) 214 -3392
Fax: +1 (314) 895 -4420

Other service addresses can be obtained from the address indicated above.

9. Accessories/Spare parts

Art. no.	Designation
TA021404	Fuse
-	Caiman 5 instrument family
-	Caiman 12 instrument family
GN201	Foot switch

Note

Other accessories, applied parts and replacement parts are described in Aesculap brochure C-304-81 and C-902-02

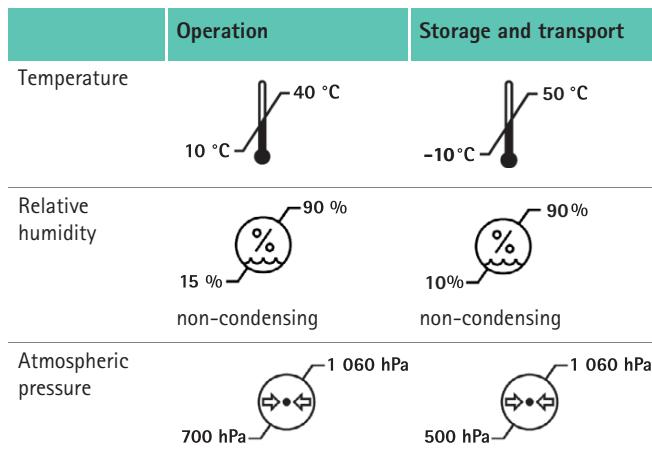
10. Technical data

Classification acc. to Directive 93/42/EEC

Art. no.	Designation	Class
GN200	High frequency surgical device	IIb

Mains voltage ranges (Current intake)	100V~240 V~ (6.7 A~2.8 A)
Frequency	50~60 Hz
Protection class (acc. to IEC / DIN EN 60601-1)	I
Foot switch circuit	ignition-safe acc. to IEC/DIN EN 60601, approved for use in "medical environment"
Output power	2 x 150 W on 50 Ohm
Device protection	T8 AH/250 V
Time-Current characteristic	T (Time lag) H (1 500 A)
Breaking capacity	5 mm x 20 mm
Construction	
HF operating frequency	460 kHz ± 1 %, Quasi-Sinus
Operating mode	Int 10 s/30 s
Weight	8.1 kg
Dimensions (L x W x H)	400 mm x 355 mm x 100 mm
Application part type acc. to IEC/DIN 60601-1	CF
Recovery time of the defibrillation-protected output	0 seconds
CISPR11	Class A
EMC	IEC/DIN EN 60601-1-2
Conforming to standard	IEC/DIN EN 60601-1 IEC/DIN EN 60601-2-2

10.1 Ambient conditions



Note

The atmospheric pressure of 700 hPa corresponds to a maximum operating altitude of 3 000 m.

Note

After transporting or storing at temperature outside the operating temperature range, leave the HF generator for one hour before use so that it can reach room temperature.

11. Disposal

Note

The user institution is obliged to process the product before its disposal, see Validated reprocessing procedure.



Adhere to national regulations when disposing of or recycling the product, its components and its packaging! The recycling pass can be downloaded from the Extranet as a PDF document under the respective article number. (The recycling pass includes disassembling instructions for the product, as well as information for proper disposal of components harmful to the environment.) Products carrying this symbol are subject to separate collection of electrical and electronic devices. Within the European Union, disposal is taken care of by the manufacturer as a free-of-charge service.

- Detailed information concerning the disposal of the product is available through your national B. Braun/Aesculap agency, see Technical Service.

12. Distributor in the US/Contact in Canada for product information and complaints

Aesculap Inc.

3773 Corporate Parkway
Center Valley, PA, 18034,
USA

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