Aesculap

Instructions for use/Technical description
Bipolar HF surgical device GN160
### Legend

1. Power OFF switch
2. Power ON switch
3. Indicator lamp power ON
4. Operating mode display (STANDARD or FORCED)
5. Display field (DOSIS or MALUS value)
6. Unit display (DOSIS or MALUS)
7. Indicator lamp HF-ON
8. Output socket HF-bipolar
9. Indicator ring (green, white or red)
10. Control knob (with pushbutton function)
11. Connection socket (foot switch)
12. Terminal (potential equalization)
13. Mains power input socket
14. Fuse holder (with 2 fuses)
15. Type plate

### Symbols on product and packages

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Caution, general warning symbol" /></td>
<td>Caution, see documentation supplied with the product</td>
</tr>
<tr>
<td><img src="image" alt="Follow the instructions for use" /></td>
<td>Follow the instructions for use</td>
</tr>
<tr>
<td><img src="image" alt="Foot switch" /></td>
<td>Foot switch</td>
</tr>
<tr>
<td><img src="image" alt="Type CF unit with defibrillation protection" /></td>
<td>Type CF unit with defibrillation protection</td>
</tr>
<tr>
<td><img src="image" alt="Potential equalization terminal" /></td>
<td>Potential equalization terminal</td>
</tr>
<tr>
<td><img src="image" alt="Fuse" /></td>
<td>Fuse</td>
</tr>
<tr>
<td><img src="image" alt="Alternating current" /></td>
<td>Alternating current</td>
</tr>
<tr>
<td><img src="image" alt="Non-ionizing radiation" /></td>
<td>Non-ionizing radiation</td>
</tr>
<tr>
<td><img src="image" alt="Labeling of electric and electronic devices according to directive 2002/96/EC (WEEE), see Chapter Disposal" /></td>
<td>Labeling of electric and electronic devices according to directive 2002/96/EC (WEEE), see Chapter Disposal</td>
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1. Safe handling

CAUTION
Federal law restricts this device to sale by or on order of a physician!

Note
The present instructions for use only describe the layout, function and operation of the HF surgical device GN160! A general description of the application of high-frequency electrosurgery can be found in the respective O.R. manuals and other relevant literature.

The present instructions for use are not suitable for instructing a beginner in high-frequency electrosurgery.

- Have the product and accessories operated and used only by persons who possess the requisite training, expertise or experience.
- Transport the product only in its original box.
- Clean the new product thoroughly, by hand, after removing its transport packaging and prior to its initial sterilization.
- Prior to use, check for proper condition and functioning of the product.
- Observe "Notes on Electromagnetic Compatibility (EMC)", see TA022130. The bipolar HF surgical device GN160 complies with all requirements acc. to CISPR 11 Class A.
- To prevent damage caused by improper setup or operation, and in order not to compromise warranty and manufacturer liability:
  - Use the product only according to these instructions for use.
  - Observe all safety information and maintenance advisories.
  - Only combine Aesculap products with each other.
  - Adhere to application instructions according to relevant norms.
- Regularly inspect the accessories. Check the electrode cables and endoscopic accessories for possible insulation damage.
- Keep the instructions for use accessible for the user.
- Always adhere to applicable standards.

1.1 Safe for use in conformance with IEC regulations

1.1.1 The operating environment

Risk of death by electric shock!
- Do not open the product.
- Only ever connect the product to power mains with equipment grounding conductor.

Danger of injury from burns and/or explosion from flammable gases! Sparks can occur even if the HF surgical device is used properly and according to its intended use.
- 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.
- Ensure that no combustible fluids accumulate under the patient or in body cavities (e.g. the vagina). Wipe off all fluids before using the HF surgical device.
- Ensure the absence of any endogenous, combustible gases.
- Check that oxygen-soaked materials (e.g. absorbent cotton or moss) are kept at a safe distance from the HF field, so that they cannot ignite.

Risk of interference with other devices!
Even during normal use, the HF surgical device creates electromagnetic fields that can interfere with other devices.
- Check that no electronic devices that could be subject to interference by electromagnetic fields are set up in the vicinity of the HF surgical device.
Danger due to inadequate preparation or faults in the HF surgical device:

- Check that the HF surgical device 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.

Risk of burns suffered by the patient due to inadvertent activation of the HF surgical device:

- In case of any inadvertent activation of the HF surgical device, switch off the device immediately at the mains power OFF switch.
- Always exercise particular care when operating the foot switch.

Risk of injury to the patient due to uncontrolled rise of the HF output voltage due to some fault in the HF surgical device:

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

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

- Check the mains power cord/protective ground connections.

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, insert antistatic tissue between the patient and any metal parts. 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 of urine through a catheter.
- 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.
- Attach the electrodes of physiological monitoring devices without protective resistors or HF dampers as far away as possible from the HF electrodes. Do not use needle electrodes for intraoperative monitoring. Use monitoring systems fitted with devices to limit the HF current.

Arrange the wires and cables of monitoring devices in such a way that they do not touch 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.

Do not remove the hot electrode from the patient’s body immediately after cutting or coagulating.

Never put down HF instruments or 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.

Adjust the HF power output appropriately for the intended procedure, taking into account clinical experience and reference parameters.

Always set the power output of the HF surgical device to as low a level as possible for the intended procedure.

Should the output power appear insufficient with the usual settings, check that:

- the working electrodes are clean,
- all plug connections are properly in place.

For operations involving unavoidable, continuous contact between the electrodes and the patient (e.g. endoscopic procedures), press the power OFF switch at the HF surgical device immediately after any inadvertent activation of the electrode.

Adjust the acoustic warning, which signals the activation of the electrode, to such a level that it will always be heard without difficulty.
2. Product description

2.1 System components

<table>
<thead>
<tr>
<th>Designation</th>
<th>Art. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bipolar HF surgical device</td>
<td>GN160</td>
</tr>
<tr>
<td>Notes on electromagnetic compatibility (BMC)</td>
<td>TA022130</td>
</tr>
<tr>
<td>Instructions for use, bipolar HF surgical device GN160</td>
<td>TA022247</td>
</tr>
</tbody>
</table>

2.2 Components necessary for use

- Power cord
- Foot switch (single pedal)
- Bipolar connection cable
- Bipolar forceps

2.3 Intended use

Aesculap’s bipolar coagulator (GN160) is intended for use in surgery to generate electrical power for bipolar instruments. Bipolar coagulators are used in Neurosurgery, ENT surgery, Urology, Laparoscopy and Plastic Surgery.

2.4 Operating principle

The HF surgical device GN160 is fitted with a bipolar output socket that can provide HF currents for coagulation (optimized for forceps).

The HF surgical device can be activated only through a single-pedal foot switch (e.g. footswitch for operation from any angle, GN161), which is connected via a socket in the rear panel of the HF surgical device.

The output power is set directly by turning control knob 10, and is displayed in one of the two established units (DOSIS/MALIS; factory setting=DOSIS).

All other device parameters (e.g. operating mode, volume, etc.) and system information (software version, serial no., ...) are set and displayed via a submenu, which can be called up by pressing control knob 10.

The special function displays Operating mode 4 and Unit 6 are designed to be visible only while the respective special function is active. During normal operation, the display elements are hidden, contributing to the easy-to-use, uncluttered quality of the device controls.

The HF surgical device GN160 offers two operating modes, both with a setting range of 1–60 DOSIS (or 10–170 MALIS):

- The STANDARD operating mode (factory default) allows rapid coagulation throughout the entire power range, with limiting the output voltage by measuring the tissue resistance. This can have an effect on less tissue adhesion.

- The FORCED mode allows coagulation of the surrounding tissue.

The HF surgical device GN160 can also be combined with accessory devices (e.g. JET irrigation unit GN090).

2.5 Monitoring functions

Self-test

When switched on, the HF surgical device performs a self-test of the control elements, the acoustic warning signal, the microprocessor and the hardware functions.

Continuous test cycle during operation

During operation, safety–relevant functions and signals are monitored throughout a continuous test cycle. As soon as a critical error is detected, the HF surgical device terminates the HF activation.

The code number of the error is displayed in display field 5 and an acoustic warning signal may be issued, see Chapter Troubleshooting list.
2.6 Output graphs
Output power ($P_{out}$) as function of setting (DOSIS/MALIS):

- **Fig. 1** DOSIS
- **Fig. 2** MALIS

Power output may be expressed either in Watts (DOSIS) or MALIS units. A MALIS unit is a reference term used to provide a repeatable indication of the output power which avoids the implied exactness of watts terminology which cannot be obtained with a load that varies in impedance which is typical with electrosurgery.

The DOSIS is a 1 to 1 setting, which means that with a setting of 30 the output will be 30 Watts.

The MALIS setting allows a finer tuning from 0 to 170. Especially in the lower output power range a finer tuning is beneficial. For example a MALIS setting at 103 will deliver 30 Watts.

2.7 Adaptation curves
Operating modes STANDARD and FORCED: $P_{out} = f(R_l)$ (measured with original cable: $C_L = 175 \text{ pF}$)

- **Fig. 3** Operating mode STANDARD
- **Fig. 4** Operating mode FORCED
2.8 Maximum peak output voltage ($U_p$)

Note
The following graphs allow the user to judge whether the HF surgical device or its output setting is suitable for a given accessory (insulation rating).

**WARNING**
- Risk of injury to patients or users 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 for the intended setting.

Maximum peak output voltage ($U_p$) as function of setting (DOSIS/MALIS):

- **Fig. 5**  DOSIS
- **Fig. 6**  MAUS
3. Preparation and setup

Non-compliance with these rules will result in complete exclusion of liability on the part of Aesculap.

- When setting up and operating the product, always observe:
  - national regulations for installation and operation,
  - national regulations on fire and explosion protection.
- Connect the HF surgical 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. G0538 (4 m length) or G0536 (0.6 m length).

3.1 Preparation

3.1.1 Stacking of units

The stacking provisions integrated in the device cover allows secure mounting of an accessory device (e.g. JET Irrigation unit GN090) on top of the HF surgical device GN160, see Fig. 7.

- Make certain the system is set up on a sufficiently stable support (e.g. a table, ceiling support, equipment cart, etc.).

Stacking of units fitted with stacking provisions

- Do not exceed a stack height of 475 mm.
- Remove the caps from stacking cones C.
- Unscrew the feet of the product that will be on top.
- Move stacking cones C to the correct mounting position by applying a screwdriver on locking screw B and turning it counterclockwise to the positive stop.
- Place the upper device on the one below it.
- Securing the device: Turn locking screw B clockwise to the positive stop.
- Slightly lift the units to check that they are safely connected to each other.
- Place the units in a stable position.

3.1.2 Moving stacks of units

- Always lift stacks from underneath the bottommost unit.

3.1.3 Dismantling stacks of devices

![Fig. 8 Dismantling stacks of devices](image)

Legend

- B Locking screw
- Apply a screwdriver on locking screw B and turn it counterclockwise to the positive stop.
- Remove the topmost device.
- Screw back on the feet of the device, either by hand or using a screwdriver.

![Fig. 7 Stacking of units](image)

Legend

- Accessory device, e.g. JET irrigation unit GN090
- B Locking screw
- C Stacking cone
4. Working with the HF surgical device GN160

4.1 System set-up

4.1.1 Connecting the accessories

Risk of injury due to unapproved configuration using additional components!
- For all applied components, ensure that their classification (e.g., Type BF or Type CF) matches the classification 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.

Any equipment connected at the interfaces must demonstrate the respective IEC standards (e.g., IEC 60601-1 for medical electrical equipment).

All configurations must comply with the system standard IEC/DIN EN 60601-1-1. The person connecting the devices is responsible for the configuration and must ensure that it complies with the system standard IEC/DIN EN 60601-1-1 or equivalent national standards.

The insulation of the accessories (e.g., HF cables, instruments) must be adequately rated for the maximum peak output voltage (see IEC 60601-2-2).
- Please contact your B. Braun/Aesculap Partner or Aesculap Technical Service, see Chapter Technical Service, with any inquiries in this respect.

4.1.2 Connecting the power supply and switching on the HF surgical device GN160

Risk of death by electric shock!
- Only ever connect the product to power mains with equipment grounding conductor.

The mains voltage must correspond to the voltage indicated on the type plate at the back of the unit.

The HF surgical device is fitted with a universal power adapter for mains voltages 100–120 V and 220–240 V.
- 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.

- Switch on the HF surgical device at power ON switch 2. Indicator lamp power ON 3 is illuminated. The HF surgical device performs a self-test.

On switching on the device for the first time, the basic factory default settings will be shown on the display at the end of the self-test, see Fig. 9.

Fig. 9 Factory default setting

On every further switch-on, the device settings last used prior to the most recent switch-off will be applied and displayed.

4.1.3 Connecting a single-pedal foot switch (e.g. GN161)

Both the foot switch plug and connection socket (foot switch) 12 carry an arrow marking. To connect the plug to the connection socket correctly, the two arrows must be aligned.

Fig. 10 Connecting the single-pedal foot switch (e.g. GN161)
- Plug in the foot switch plug in connection socket (foot switch) 11.
4.1.4 Connecting bipolar accessories

**WARNING**

- Make certain that not more than one patient cable is connected to the output socket.

**Note**
Connect the bipolar cable only after switching on the GN160!

The following plug types can be connected at output socket HF 8.

![Coax plug](image1)

**Fig. 11** Coax plug

![2-pin plug](image2)

**Fig. 12** 2-pin plug

**Note**
ICE/DIN EN 60601-2-2:2007 requires active plugs with more than one contact pin to be specified with fixed pin spacing. Loose (flying) leads are not allowed!

- Plug the bipolar cable in output socket HF 8.

4.2 Function checks

Factory settings display:

![Display](image3)

**Operating mode:** Standard
**Unit:** D005

**Note**
Every subsequent switch-on of the HF surgical device is followed by the display of the last device settings applied prior to the most recent switch-off.
Any changed settings applied during the function test are saved immediately.

Any device settings other than the factory settings must be noted down before the function test is continued!
If in doubt, we recommend restoring the factory settings.

- Check the device for correct functioning prior to every use.
- Check that the accessories do not show any visible damage.
- Prepare and set up the HF surgical device, see Chapter Preparation and setup.
- Connect the device to mains power, see Chapter System set-up.
- Check the functionality of the following elements, one after the other, in the following sequence:

<table>
<thead>
<tr>
<th>User action</th>
<th>Device reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Press power ON switch 2.</td>
<td>Indicator lamp power ON 3 is illuminated. The HF surgical device performs a self-test, accompanied by an acoustic signal. All display elements are activated in rapid sequence. <strong>Sequence:</strong> 1. Display Operating mode (FORCED) 4 2. All segments of display field 5 (as running light) 3. Display Unit (MALUS) 6 4. Indicator lamp HF-ON 7 5. Indicator ring (green) 9 6. Indicator ring (white) 9 7. Indicator ring (red) 9 An acoustic signal confirms that the self-test is complete and the device ready for operation Indicator ring 9 is illuminated green after completion of the self-test. The most recent device settings applied prior to the last switch-off are displayed.</td>
</tr>
<tr>
<td>User action</td>
<td>Device reaction</td>
</tr>
<tr>
<td>-------------</td>
<td>----------------</td>
</tr>
<tr>
<td>2. Turn control knob 10 clockwise.</td>
<td>The parameter value displayed in display field 5 is increased.</td>
</tr>
<tr>
<td>3. Turn control knob 10 counterclockwise.</td>
<td>The parameter value displayed in display field 5 is decreased.</td>
</tr>
<tr>
<td>4. Press control knob 10 (&gt;2 s).</td>
<td>Indicator ring 9 is illuminated white. Display of selected operating mode in display field 5 Operating mode STANDARD <strong>SED</strong> Operating mode FORCED</td>
</tr>
<tr>
<td>5. Press control knob 10 again (&gt;2 s).</td>
<td>The submenu is quit. Indicator ring 9 is illuminated green. Display of most recent setting in display field 5</td>
</tr>
<tr>
<td>6. Plug in the single-pedal foot switch plug in connection socket (foot switch) 11.</td>
<td>No device reaction. If the HF surgical device is activated at this stage, the foot switch is defective!</td>
</tr>
<tr>
<td>7. Press the single-pedal foot switch.</td>
<td>The HF surgical device is activated. Indicator ring 9 turns off. Indicator lamp HF-ON 7 illuminated. If there is no device reaction at this stage, there can be a fault either in the HF surgical device or in the foot switch. Repeat the test with another foot switch, see Chapter Troubleshooting List.</td>
</tr>
<tr>
<td>8. Press power OFF switch 1.</td>
<td>Indicator lamp power ON 3 turns off.</td>
</tr>
</tbody>
</table>

### 4.3 Safe operation

**WARNING**

- Risk of injury and/or malfunction!
  - Always carry out a function check before using the product.

- Risk of injury when applying the product outside the field of view!
  - Apply the product only under visual control.

#### 4.3.1 Switching on/off the HF surgical device

- To switch on the HF surgical device: Press power ON switch 2.
- To switch off the HF surgical device: Press power OFF switch 1.

#### 4.3.2 Setting a DOSIS or MALIS value

The DOSIS or MALIS value is set via control knob 10 and displayed in display field 5.

Slow rotation of control knob 10 allows selecting any possible setting; quick rotation allows going through the entire setting range by only a few turns.

For both operating modes (STANDARD/FORCED), DOSIS settings of 1–60 or MALIS settings of 10–170 can be selected.

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> In case of device reactions other than those intended: Do not use the HF surgical device and contact Technical Service, see Chapter Technical Service.
The possible setting range and graduation depend on the unit selected (DOSIS or MAUS):

<table>
<thead>
<tr>
<th>Display unit</th>
<th>Setting range</th>
<th>Graduation</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOSIS</td>
<td>1.0–10.0</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>10.0–30.0</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>30–60</td>
<td>1</td>
</tr>
<tr>
<td>MAUS</td>
<td>10–170</td>
<td>1</td>
</tr>
</tbody>
</table>

Note
The precision of the setting meets the requirements of IEC 60601-2-21

Note
At the start of the setting process, the HF surgical device issues a short acoustic signal, alerting the user to the impending change of the DOSIS or MAUS setting. In this way it is ensured that the user will be aware of any inadvertent change of the setting!

➢ Turn control knob 10 clockwise or counterclockwise to set the intended DOSIS or MAUS value.

4.3.3 Navigation in the submenu
The submenu allows the following settings and display of system information:
- Settings
  - Operating mode (STANDARD/FORCED)
  - Noise
  - Unit (DOSIS/MAUS)
- System information
  - Last error event
  - Software version
  - Serial number

Note
The HF surgical device cannot be activated while the submenu is active!

➢ To call up the submenu: Press control knob 10 for some time (>2 s).
  The first submenu item (Operating mode) is displayed.
➢ To call up the next submenu item: Briefly press control knob 10 (<2 s).
  The next submenu item is called up.
➢ To quit the submenu: Press control knob 10 for some time (>2 s).
  The setting for the displayed submenu item is applied.
If no input via the control knob is applied through a period of 30 s, the setting of the displayed submenu item is applied and the submenu is quit automatically.

Setting the operating mode
➢ To select an operating mode: Press control knob 10 for some time (>2 s).
The following display appears in display field 5:
  - In operating mode STANDARD
  - In operating mode FORCED
➢ To set an operating mode: Turn control knob 10.
The following display appears in display field 5:
  - In operating mode STANDARD

Display Operating mode 4 is not visible.

The following display appears in display field 5:
  - In operating mode FORCED

Display Operating mode 4 is illuminated.
➢ To apply the setting: Briefly press control knob 10 (<2 s).
  The next submenu item is called up.
➢ To quit the submenu: Press control knob 10 for some time (>2 s).
  The setting for the displayed submenu item is applied.

Adjusting the volume
The signal volume of the HF surgical device can be adjusted to any of 9 volume levels.
➢ To select an operating mode: Press control knob 10 for some time (>2 s).
  The first submenu item (Operating mode) is displayed.
➢ Repeatedly, briefly (<2 s) press control knob 10 until submenu item (Volume) is displayed.
The following display appears in display field 5 (SP for speaker) and the actual volume level setting (1–9):

An acoustic signal is issued at the currently set volume.
➢ To adjust the volume: Turn control knob 10.
  The actual volume level is displayed and an acoustic signal is issued at the actual volume.
➢ To adopt the setting: Briefly press control knob 10 (<2 s).
  The next submenu item is called up.
➢ To quit the submenu: Briefly press control knob 10 (<2 s).
  The setting for the displayed submenu item is applied.
  - or -
➢ To quit the submenu without adopting the setting: Press control knob 10 for some time (>2 s) or wait for 30 s.
Selecting the unit (DOSIS/MALIS)

➢ To select the unit: Press control knob 10 for some time (>2 s).
  The submenu item (Operating mode) is displayed.
➢ Repeatedly, briefly (<2 s) press control knob 10 until submenu item
  Unit (Unit) is displayed.

As long as the unit DOSIS is selected, the Unit display 6 is hidden.
If the unit MALIS is selected, display Unit 6 is illuminated.
➢ To select the unit: Turn control knob 10.
➢ To adopt the setting: Briefly press control knob 10 (<2 s).
  The next submenu item is called up.
➢ To quit the submenu: Press control knob 10 briefly (<2 s) or wait for
  30 s.
  The setting for the displayed submenu item is applied.

Displaying the last error event

Note
For detailed error descriptions, see Chapter Troubleshooting list!
➢ To call up the submenu: Press control knob 10 for some time (>2 s).
  The first submenu item (Operating mode) is displayed.
➢ Repeatedly, briefly (<2 s) press control knob 10 until submenu item
  (Last error event) is displayed.
  The following display appears in display field 5 (E for error and the
  respective error code):

➢ To switch to another submenu item: Briefly press control knob 10
  (<2 s).
  The next submenu item is called up.
➢ To quit the submenu: Press control knob 10 briefly (<2 s) or wait for
  30 s.

Displaying the software version

➢ Press control knob 10 for some time (>2 s).
  The submenu item (Operating mode) is displayed.
➢ Repeatedly, briefly (<2 s) press control knob 10 until submenu item
  (Software version) is displayed.
  The following marquee display appears in display field 5 (SOF for soft-
  ware), followed by an underscore and the three-digit version number):

➢ To switch to another submenu item: Briefly press control knob 10
  (<2 s).
  The next submenu item is called up.
➢ To quit the submenu: Press control knob 10 briefly (<2 s) or wait for
  30 s.

Displaying the serial number

➢ Press control knob 10 for some time (>2 s).
  The submenu item (Operating mode) is displayed.
➢ Repeatedly, briefly (<2 s) press control knob 10 until submenu item
  (Serial number) is displayed.
  The following marquee display appears in display field 5 (Sn for serial
  number, followed by an underscore and the four-digit device serial
  number):

➢ To quit the submenu: Briefly press control knob 10 (<2 s).
  - or -
➢ Press control knob 10 for some time (>2 s) or wait for 30 s.

4.3.4 Activating the HF current

➢ Ensure that the patient is prepared in such a way that the HF surgical
  device can be operated safely.
➢ Verify that the required accessories are properly connected and
  plugged in.
➢ Check that all settings of the HF surgical device are appropriate for the
  intended application.
➢ Press the foot switch.
  Indicator lamp HF-ON 7 will be illuminated for the duration of the
  activation.

Note
The activation period is limited to a maximum of 120 s, meaning: after
120 s of continuous activation, the HF current is deactivated automatic.
To alert the user to the automatic deactivation, the activation signal
volume will rise, during the last 60 s, from the selected volume setting to
maximum volume.
5. Validated processing procedure

5.3 Cleaning/Disinfecting

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

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

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.

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

5.1 General notes

Encrusted or fixed residues from surgery can make the cleaning process more difficult or ineffective, and can cause corrosion of stainless steels. To avoid this, the time interval between application and processing should not exceed 6 h, and neither fixating pre-cleaning temperatures >45 °C nor any fixating disinfecting agents (active ingredients: aldehyde, alcohol) be used.

Only use process chemicals that have been tested and approved (e.g. VAH/DBH or FDA approval or CE mark) and which are compatible with the product’s materials according to the chemical manufacturers’ recommendations. All process parameters specified by the chemical’s manufacturer, such as temperatures, concentrations and exposure times, must be strictly observed. Failure to do so can result in the following problems:

- Optical deterioration, e.g. fading or discoloration of titanium or aluminum surfaces. For aluminum, pH >6 in the application/process solution can already cause visible surface changes.
- Material damage, e.g. corrosion, cracks, fracturing, premature aging or swelling.
- Do not use process chemicals that cause stress cracking or brittleness of plastic materials.

For further detailed advice on hygienically safe and material-/value-preserving reprocessing, see www.a-k-i.org

5.2 Preparations at the place of use

- Remove visible surgical residues as completely as possible, using a lint-free wet wipe.
5.4 Manual cleaning/disinfecting

5.4.1 Wipe disinfection for electrical devices not to be sterilized

<table>
<thead>
<tr>
<th>Stage</th>
<th>Step</th>
<th>T [°C/°F]</th>
<th>t [min]</th>
<th>Conc. [%]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Wipe disinfection</td>
<td>RT</td>
<td>≥1</td>
<td>-</td>
<td>-</td>
<td>Melspectol HBV wipes</td>
</tr>
</tbody>
</table>

RT: Room temperature

Stage I

- Remove any visible residues with a single-use disinfecting wipe.
- Wipe all surfaces of the optically clean product with a new, disposable disinfecting wipe.
- Observe the specified application time (1 minute minimum).

5.5 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.

5.6 Storage and transport

⚠️ CAUTION Damage to the product caused by switch-on too early after storage/transport at temperature below +10 °C (50 °F):

- Allow the HF surgical device to acclimate at room temperature for about 3 hours.

- Transport the product only in its original box.
- For storage and transport conditions, see Chapter Technical specifications.

6. Maintenance

The HF surgical device GN180 is a maintenance-free product.

6.1 Safety inspection

A safety inspection must be carried out annually.

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.

- The person in charge of the inspection will document the inspection findings and measurements according to the printed inspection protocol, see Fig. 13.
- In case of significant deviations from the values specified in the inspection protocol, or if any specified maximum values are exceeded: Send the HF surgical device back to the manufacturer, see Chapter Technical Service.
# Bipolar HF surgical device GN160

## Aesculap

**Inspection protocol (Safety inspection)**

<table>
<thead>
<tr>
<th>SCOPE OF INSPECTION</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. VISUAL INSPECTION</strong></td>
<td></td>
</tr>
<tr>
<td>1.1 Inspection of power cable for visually detectable damage</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>1.2 Inspection of foot pedal for visually detectable damage</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>1.3 Inspection of cauterization cable for visible signs of damage; check the fitting of the plug connector</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>1.4 Rating plate present and readable</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>1.5 Test to ensure device achieves default values</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>1.6 Overall condition of device: Dirt, damage</td>
<td>Satisfactory</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>2. ELECTRICAL INSPECTION</strong></th>
<th>Measured value</th>
<th>OK/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 LF ground leakage current s.f.o. according to DIN EN 60601-1</td>
<td>$I_{m} = 1$ mA</td>
<td></td>
</tr>
<tr>
<td>2.2 LF patient leakage current s.f.o. to DIN EN 60601-1</td>
<td>$I_{m} = 0.05$ mA</td>
<td></td>
</tr>
<tr>
<td>2.3 LF substitute patient leakage current with mains voltage at the application unit acc. to VDE 0751-1</td>
<td>$I_{m} = 55$ mA</td>
<td></td>
</tr>
<tr>
<td>2.4 LF leakage current booster DIN EN 60601-2-2</td>
<td>$I_{m} = 0.05$ mA</td>
<td></td>
</tr>
<tr>
<td>2.5 Insulation resistance</td>
<td>Test voltage = 500 V DC</td>
<td></td>
</tr>
<tr>
<td>2.6.1 Mains against HF output</td>
<td>$R_{m} = 7$ MΩ</td>
<td>Yes</td>
</tr>
<tr>
<td>2.6.2 Mains against housing</td>
<td>$R_{m} = 2$ MΩ</td>
<td>Yes</td>
</tr>
<tr>
<td>2.6.3 HF output against housing</td>
<td>$R_{m} = 2$ MΩ</td>
<td>Yes</td>
</tr>
<tr>
<td>2.7 Ground wire resistance incl. power cord acc. to VDE 0751-1</td>
<td>$0.3$ Ω at ±0.2 A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>2.8 HF output with insulation-free resistance</strong></th>
<th>Rated value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF output</td>
<td>Operational mode</td>
</tr>
<tr>
<td>Bipolar</td>
<td>STANDARD</td>
</tr>
<tr>
<td>FORCED</td>
<td>80</td>
</tr>
</tbody>
</table>

2.9 DC resistance between the two HF output poles, DIN EN 60601-2-2, section 5.8.106.

2.10 Function test according to instructions for use

<table>
<thead>
<tr>
<th>Performed by</th>
<th>Inspector</th>
<th>Operator</th>
</tr>
</thead>
</table>

---

Fig. 13
7. Troubleshooting list

In case of error, the letter E (for error) with the respective error code is displayed in display field 5.

Indicator ring 9 is illuminated red, at the same time.

<table>
<thead>
<tr>
<th>Malfunction</th>
<th>Finding</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
</table>
| 1           | Switch-on self-test foot switch activated | Foot switch pressed during switch-on, or foot switch defective | Release or unplug the foot switch
Contact Araculap Technical Service |
| 2           | Switch-on self-test control knob | Control knob pressed during switch-on, or control knob defective | Release the control knob
Contact Araculap Technical Service |
| 3           | Control knob pushbutton function | Control knob kept pressed for too long; control knob defective | Release the control knob
Contact Araculap Technical Service |
| 4           | Time limit exceeded | HF activation time limit exceeded | Release the foot switch |
| 10–99       | Internal error | Internal device fault/error | Switch the HF surgical device off and on again
Contact Araculap Technical Service |
| 90–99       | Adjustment | Missing adjustment | Contact Araculap Technical Service |

7.1 Changing fuses

Risk of death by electric shock!

➤ Unplug the unit before changing the fuses!

<table>
<thead>
<tr>
<th>Specified fuse sets</th>
<th>TA020005 (x2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designation acc. to IEC 60127–1</td>
<td>1 2.5 A, 250 V</td>
</tr>
<tr>
<td>Form factor</td>
<td>5 x 20 mm</td>
</tr>
<tr>
<td>Current rating</td>
<td>2.5 A</td>
</tr>
<tr>
<td>Breaking capacity</td>
<td>1 500 A at 250 V/50–60 Hz, cos ϕ = 0.7–0.8 (H)</td>
</tr>
<tr>
<td>Time–Current characteristic</td>
<td>Time lag (T)</td>
</tr>
</tbody>
</table>

Fig. 14
Legend

A Latch nose
B Fuse sets
C Fuse holder
➤ Push down latch nose A at fuse holder C and unlock the fuse holder.
➤ Remove fuse holder C.
➤ Replace both fuse sets B.
➤ Insert fuse holder C so that it clicks into its proper position.
8. Technical Service

Risk of injury and/or malfunction!
> Do not modify the product.

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

Note: 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 Tuttingen (Germany)
Phone: +49 7461 95-1601
Fax: +49 7461 14-939
E-mail: ats@aesculap.de

Or in the US:
Aesculap Inc.
Attn. Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood, MO 63042
Aesculap Repair Hotline
Phone: +1 800 214-3392
Fax: +1 314 885-4420

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

9. Accessories/Spare parts

9.2 Potential equalization cable

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
<th>Length (in m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GK535</td>
<td>Potential equalization cable</td>
<td>4</td>
</tr>
<tr>
<td>GK536</td>
<td>Potential equalization cable</td>
<td>0.6</td>
</tr>
</tbody>
</table>

9.3 Foot switches

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>GN161</td>
<td>Single-pedal foot switch (round)</td>
</tr>
<tr>
<td>GK226</td>
<td>Single-pedal foot switch</td>
</tr>
</tbody>
</table>

9.4 Bipolar connection cables (device-side, Aesculap)

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
<th>Length (in m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GN073</td>
<td>with Aesculap flat connector</td>
<td>4</td>
</tr>
<tr>
<td>GN074</td>
<td>with Aesculap round-pin connector</td>
<td>4</td>
</tr>
<tr>
<td>GN076</td>
<td>with Euro plug, flat</td>
<td>4</td>
</tr>
</tbody>
</table>

9.5 Bipolar forceps

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GL427R</td>
<td>BiProtect – with insulated tips</td>
<td>0.7</td>
</tr>
<tr>
<td>GL427R</td>
<td>BiProtect – with insulated tips</td>
<td>1.0</td>
</tr>
<tr>
<td>GL447R</td>
<td>BiProtect – with insulated tips</td>
<td>1.3</td>
</tr>
</tbody>
</table>

Note
Information concerning other accessories and spare parts is available on request and can be found in Aesculap brochure C-304-81.

9.6 Spare parts

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>TA021539</td>
<td>Fuse</td>
</tr>
<tr>
<td>TA022130</td>
<td>Notes on electromagnetic compatibility (EMC)</td>
</tr>
</tbody>
</table>

Note
Information on other accessories and replacement parts is available on request and can be found in Aesculap brochure C-304-81.
10. Technical specifications

Classification acc. to Directive 93/42/EEC

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>GN160</td>
<td>Bipolar HF surgical device</td>
<td>IIb</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>GN160</td>
</tr>
<tr>
<td>Mains voltage range (Current intake)</td>
<td>100–120 V~ (1.0–0.81 A) / 220–240 V~ (0.44–0.41 A)</td>
</tr>
<tr>
<td>AC frequency</td>
<td>50–60 Hz</td>
</tr>
<tr>
<td>Safety rating (acc. to IEC/DIN EN 60601-1)</td>
<td>I</td>
</tr>
<tr>
<td>Protection type acc. to IEC 60529</td>
<td>IP31</td>
</tr>
<tr>
<td>Foot switch circuitry</td>
<td>Ignition-safe acc. to IEC 60601, approved for use in &quot;medical environment&quot;</td>
</tr>
<tr>
<td>Output power</td>
<td>STANDARD: 60 W at 75 Ohms / FORCED: 60 W at 100 Ohms</td>
</tr>
<tr>
<td>Output frequency</td>
<td>346 kHz</td>
</tr>
<tr>
<td>Operating mode</td>
<td>Int 10 s / 20 s</td>
</tr>
<tr>
<td>Device fuse</td>
<td>T 2.5 A H, 250 V</td>
</tr>
<tr>
<td>Breaking capacity</td>
<td>1 500 A at 250 V/50–60 Hz, cos φ = 0.7–0.8 (H)</td>
</tr>
<tr>
<td>Form factor</td>
<td>5 x 20 mm</td>
</tr>
<tr>
<td>Time-Current characteristic</td>
<td>Time lag (T)</td>
</tr>
<tr>
<td>Weight</td>
<td>6 kg</td>
</tr>
<tr>
<td>Dimensions (L x W x H)</td>
<td>305 mm x 135 mm x 325 mm</td>
</tr>
<tr>
<td>Applied part</td>
<td>Type OF</td>
</tr>
<tr>
<td>EMC</td>
<td>IEC/DIN EN 60601-1 / CISPR11 Class A</td>
</tr>
<tr>
<td>Conforming to standard</td>
<td>IEC/DIN EN 60601-1 / IEC/DIN EN 60601-2-2</td>
</tr>
</tbody>
</table>

10.1 Ambient conditions

<table>
<thead>
<tr>
<th></th>
<th>Operation</th>
<th>Transport and storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>10 °C / 40 °C</td>
<td>-10 °C / 50 °C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>75 % / 30 %</td>
<td>10 % / 90 %</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>700 hPa / 1 060 hPa</td>
<td>500 hPa / 1 060 hPa</td>
</tr>
</tbody>
</table>

11. Disposal

Note
The user institution is obliged to process the product before its disposal, see Chapter Validated processing 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 electric and electronic devices. Within the European Union, disposal is taken care of by the manufacturer as a free-of-charge service.

Please contact your national B. Braun/Aesculap agency if you have any questions concerning the disposal of the product, see Chapter 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