HAGER WERKEN

hf SURG®

HF-surgery unit
User Manual

Index

Please carefully read this user manual!

Read completely this user manual and get familiar with the use and functions of the unit and all accessories, before you start using the device clinically.

Unless you do not follow the directives as instructed, the following problems may occur:

- Serious injuries to the patient
- Serious injuries to the operator or to the service personal
- Damage of malfunction of the unit or of the accessories

Intended Purpose

The high frequency device hf-Surg is used for surgical applications in soft tissue in dentistry and is suitable for the following applications: oral surgery such as cutting, removal of soft tissue. No essential performance features according to EN 6061-1 are assigned to the device.

Field of application

The area of application is professional dentistry facilities.

Modifications

The manufacturer has the right to modify the appearance and technical data because of new product developments.

The marks: **“WARNING“**, **“ATTENTION“** and **“REMARK“** contain important hints.

Responsibility of manufacturer

Warranty and liability by Hager & Werken GmbH & Co KG is given, if:

- installation and start of operation is done by own personal or by personal authorized by the manufacturer
- installation and safety measures comply with national norms and regulations
- the unit is used in accordance with the user manual
- no manipulations to the unit or to the accessories, if manufacturer does not agree.

Warranty

The hf Surg unit has a legal warranty of 12 months.

Explanations to the user manual

Important directives, especially for technical safety and security, are mentioned:

ATTENTION

This information advices to special service procedures or caution measures, which must be considered to avoid damage to the unit.

REMARK

This is general and special information to clarify important and helpful instructions.

In the use of radio frequency devices, the emission of radiation is natural and cannot be avoided.

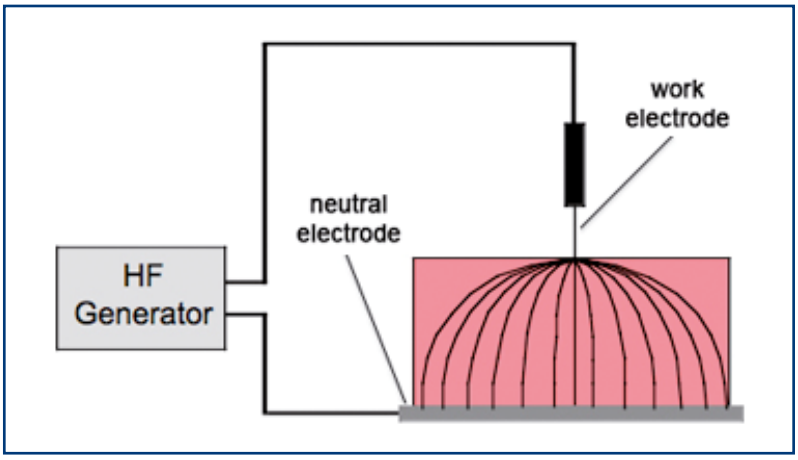
Interaction of radio frequency (HF)

If radio frequency is guided through very thin metal electrodes, a very large electro-magnetic power density is created in the tissue layer. The water is abruptly heated up in these cells which leads to cooking and rupture, respectively.
High-frequency current is used to protect the patient from electric shock.

THERMAL INTERACTION (MONOPOLAR)

CUTTING (CUT) / COAGULATION (COAG)

At monopolar cutting the radio frequency current is led from the device via a work electrode and a large neutral electrode back to the device. The current density at the treatment point is very high, but it is very low at the neutral electrode.
The electric current density leads to a fast and strong heating in tissue, which can be used for cutting and coagulation.



Technical Data

HF	frequency + power:	2,2 MHz, max. 50 W, load resistance 1000 Ohm
	method of operation	monopolar
	wave form	permanently / pulsed with ca. 80 %
Ambient temperature		+5 °C – +40 °C
Storage temperature		-20 °C – +70 °C
Humidity		Operating humidity: < 85%, non-condensing Storage humidity: < 90%, non-condensing
Air pressure		during storage : 500 hPa - 1080 hPa during operation : 700 hPa - 1080 hPa
Power supply		230 V AC, 50/60 Hz
Power consumption		max. 100 VA
Medical device classification		class IIb
Applicators	Hand piece	autoclavable
Safety		According to DIN EN ISO 6060-1
Electromagnetic compatibility		According to DIN EN ISO 6060-1-2
Safety hf surgery equipment		According to DIN EN ISO 60601-2-2

Cables

HF handpiece cable, yellow	Length 1.50m
HF neutral electrode cable	Length 1.50m
Foot switch cable	Length 2.50m
Power cable	Length 2.50m

Protection and safety provisions in the dental office for the use of the hf Surg device

The hf Surg device may only be put into operation after the instructions have been given by the operator and in compliance with the prescriptions and safety provisions.

WARNING
The device must only be connected to a power supply with an earth wire in order to avoid the risk of an electric shock.
Check the cables, hand piece and electrodes as well as the foot pedal on visible damage before starting up the hf Surg device. Instruments with brittle or faulty insulation must not be used as they pose a danger of injury.
When operating the hf Surg device, unpredictable malfunctions might occur that could cause unwanted output power increase.

1. During operation, a minimum distance of c. 20 cm from any walls must be kept.
2. The NEUTRAL ELECTRODE should be reliably stuck to a correspondingly prepared suitable area of the PATIENT body with its entire surface, as defined by the PRODUCER.3. The PATIENT should not get in touch with any metal parts that are grounded or have a significant earth capacitance (e.g. operating table supports etc.).
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4. Skin-to-skin contacts (e.g. between the arms and the body of the PATIENT) should be avoided, e.g. by inserting dry gauze. The cable leading to the hf Surg device should neither touch the patient nor any other lines. Instruments which are temporarily not
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5. The output power should be set as low as possible for the corresponding purpose.
6. An obviously low output value or functional failure of the hf Surg device in usual operation can be caused by insufficient adherence of the NEUTRAL ELECTRODE or insufficient contact in its connections. In such case, the adherence of the NEUTRAL ELECTRODE and its connections should be checked before setting a higher output power.
7. The use of ignitable anesthetic agents or combustible gases like nitrous oxide (N_20) and oxygen should be avoided if a surgical intervention is executed in the head area, unless these substances are aspirated. If possible, non-ignitable ingredients should be used for cleaning and disinfection. Ignitable ingredients used as cleaning and disinfection agents or as solvents for adhesives should have evaporated before the use of the hf Surgery.
8. For patients with pacemakers or other active implants, there is a potential DANGER of disturbance of the pacemaker function or damage to the pacemaker. In case of doubt, an expert should be consulted.
9. The accessories must have a minimum accessory reference voltage of 500 V. Only use the original accessories contained in the delivery and offered by the producer to achieve maximum safety for the patient and the caregiver. The characteristics of the applied parts and conducts are adapted to the output power and output voltage of the device, so that a safe operation is ensured for all operation modes and settings.
10. The device must be disconnected from the power supply during cleaning.
11. Service and maintenance tasks may only be executed by authorized specialized personnel.
12. The radiation emitted by the hf Surg device during operation can interfere with the functionality of other electric devices. Computers, laptops and mobile phones should be kept away from the hf Surg device. Data on computers and laptops should be saved beforehand.
13. If any safety provisions and operating instructions contained in this manual are violated, any warranty and liability of the manufacturer is cancelled.
14. In operating rooms, the device may only be used with pedal switches with AP labeling.

Operator regulation

The device unit is classified as medical device unit class IIb (Europe). Thus all directions of the European operator regulation apply.

See MPBetreibV 2017:
§ 10: Operation and execution
§ 11: Technical controls
§ 12: Medical product documentation

Technical controls:
The user is committed to perform on a regular basis technical controls after the following specifications:
Period: every 24 months, starting with date of delivery and after each repair.

Covering:
Visual check of the unit and accessories - Check according to IEC 62353
- Protective earth resistance
- Alternate leakage current
- Alternate patient leakage current

Function check
- Main switch
- Switch CUT - CUT/COG with LEDs
- Uniformity of performance throughout the range of adjustment*

Measurement of radio frequency (HF) output power at a load of 1 kΩ:
- Output CUT (50W)
- Output COAG (45W)

All results of measurements must be documented according to DIN EN ISO 62353 concerning the first measured values.
If defects occur during the controls, the user is responsible to initiate repair.

* Note for the user: the sound that can be heard during the operation of the HF changes its tone color with the operating mode (CUT or CUT/COAG), and the volume with the power setting. It is recommended that the user should check the regularity of the power output once in a while by turning the power knob from minimum to maximum with activated output and simultaneously checks if the signal has any dropouts. When changing the operating mode, the tone color must change a little bit. If dropouts or no difference between CUT and CUT/COAG can be heard, the device must be sent to the maintenance service.

Preparation for commissioning

- Before the hf Surg device is put into operation, it should be held at room temperature for a longer time (min. 30 minutes) to avoid the formation of condensation.

Commissioning

1. Insert the device plug on the back into the corresponding socket (n° 2) and the power plug into the power socket and connect the pedal switch (n° 3). Push the main switch (n° 1) of the device to the right, and one of the small yellow lamps on the front (n° 5 or 6) will turn on. Now, the device is ready for operation.

   The small lamps in the yellow labeling field show the selected wave type:
   yellow light above (n° 5) – cutting shaft
   yellow light below [n° 6) – cutting/coagulation shaft
   By pushing the switch (n° 4), the wave type can be selected.
2. On the front part, connect the handpiece to the yellow socket

3. Connect the neutral electrode to the socket provided for that purpose (n° 3).

4. Put the desired electrode on the handpiece.

5. Check the intensity regulator (n° 1) and adjust it if required.

6. Activate the pedal switch, the pure tone typical of the set wave type can be heard.

Important notice:

Always activate the electrode by pushing the pedal switch before touching the tissue when you want to cut or cut/coagulate.

Lockout after use

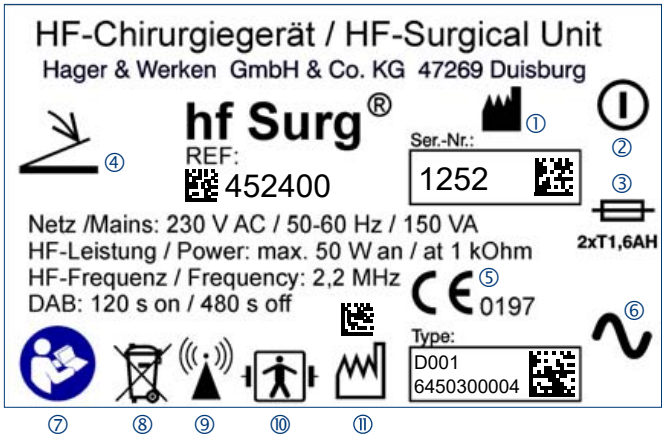
1. Place the hand piece into the instrument holder

2. Remove the electrode and reprocess it accordingly

3. Switch off the device to position 0, using main switch 1 (back).

Label

At the back side of the unit:

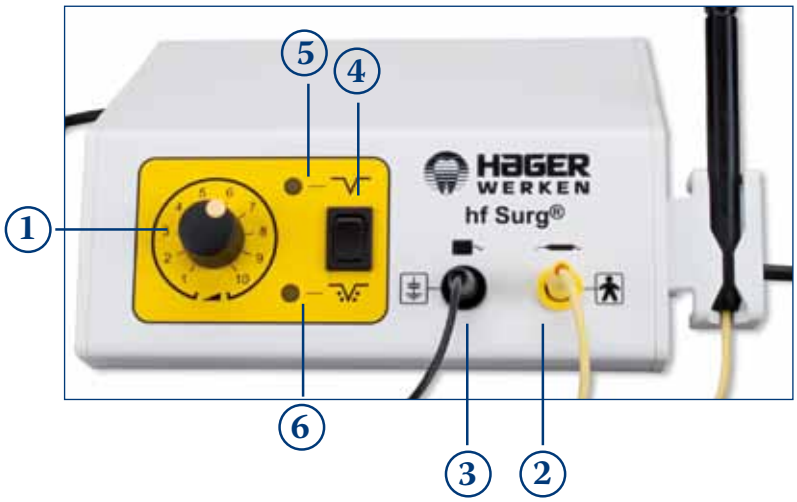


Explanations

① Manufacturer
② On / Off
③ Mains fuse
④ Foot cotrol
⑤ CE mark
⑥ Alternating current
⑦ Follow the instructions for use
⑧ Disposal
⑨ Non-ionizing radiation
⑩ Defibrillation-protected application part
⑪ Date of construction

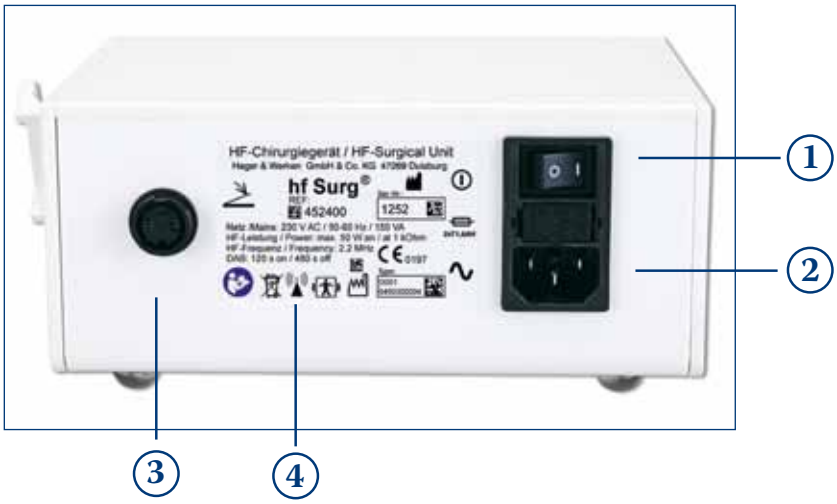
Unit Front

1. Controller
2. Output HF CUT
3. Neutral electrode
4. Switch cut or cut/coag
5. LED Cut
6. LED Cut/COAG



Unit Back

1. ON/OFF switch
2. 2230 V Power supply with fuses
3. Footswitch
4. Label



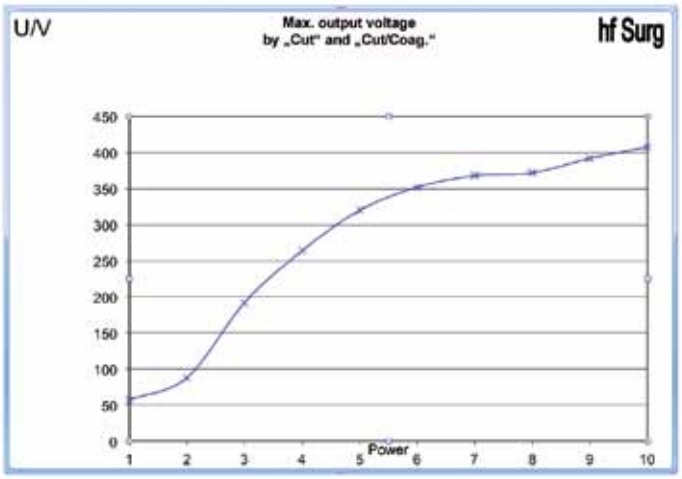
Standard hand piece

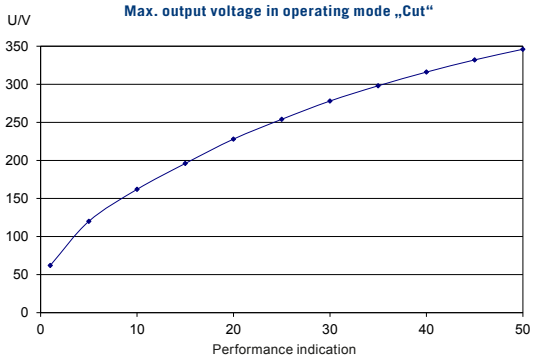
HF-electrode CUT

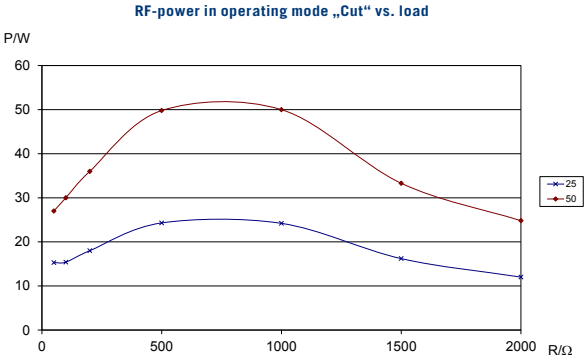
Neutral electrode

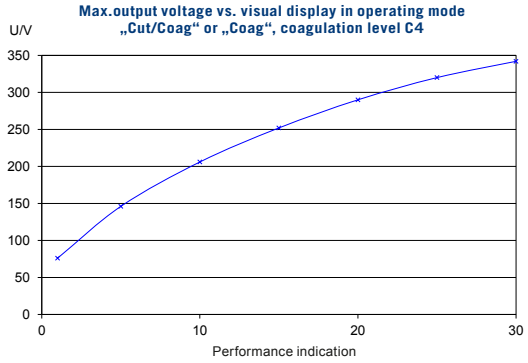
Precision of power setting radio frequency (HF)

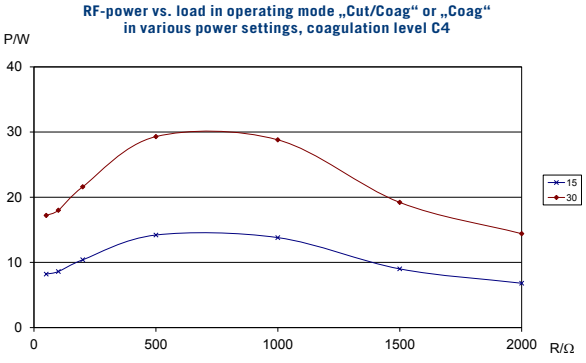
The power of the radio frequency generator depends on the tissue specific resistance and can vary within limits. The specified 50 W are in accordance with a specific resistance of 1 kΩ. The settings of the radiofrequency will be displayed without the measuring unit [W] and will be scaled in accordance with the graph.











Selection of the correct radio frequency (HF) mode

ATTENTION

All surgical applications with radio frequency need local or block anaesthesia. Make sure the tissue is moist.

Cutting - CUT MODE

This mode – with a permanent power flow – is best rated for clean cuts in tissue without coagulation. In this mode cutting is with marginal heat and little hemostasis and can be used near to bones or to the periost tissue to avoid shrinking processes of the tissue.
Histological examinations can be done in this mode as well.

Hint: Activate the electrode by pressing the foot switch before touching the tissue. Then a regular cut will be produced from the beginning.

Cutting / Coagulation - CUT / COAG MODE

This mode allows the precise cutting and simultaneous coagulation of the cut surface. Clinically the coagulation zone is marginal, but allows an effective hemostasis, does not disturb the primarily wound healing and disappears spontaneous after the wound is healed. These cuts do not need suturing, thus this mode is very effective in cosmetic surgery.

Hint: Activate the electrode by pressing the foot switch before touching the tissue. Then a regular cut will be produced from the beginning.

Neutral electrode = NE

When operating the HF mode, it must always be worked with the connected NE. This ensures an optimal power during use.
The NE must be placed between the back of the patient and the treatment chair, as close as possible to the head..

Practical exercise on a beef model

Prepare the device for operation and folow the steps mentioned below.

1. Select a piece of fresh, lean beef. Veal is not suitable, because itdoes not change color when cut with an electrode. Because of its cell structure pork is also not suited. Wait until the beef has obtainedroom temperature.

Make sure that the meat is placed on the plugged-in neutralelectrode. If this is not the case the waves cannot derivate and, consequently you cannot proceed with the exercise.

2. Insert the electrode of your choice (Multi Tip, loop, diamon,d etc.) into the hand piece.
3. Turn the intensity control dial to 8.
4. Push the toggle switch to **Cut**
5. Activate the foot switch
6. Make several incisions of different lengths and depths with even, brushing movements. Then take the energy from the electrode and look at the result. You will notice that the intensity adjustment wastoo high, which caused sparks and remarkable discoloration alongthe cutting line.
7. Reduce the intensity setting to 1. You will notice that the electrode will either cut only if it is dragged and pulled through the meat, or does not cut at all. If a cut is possible at all, bits and pieces of meat will get caught on the electrode.
8. Repeat the above described process with slightly increased settings, until you reach the point at which discolorations and visible discharges of sparks no longer appear. The tip of the electrode should not encounter resistance. The cut should be precisely even, without the occurrence of a discharge of sparks and without the necessity to drag the electrode. Continue with your endeavors by executing slow, intermediate and faster cuts for each particular setting in order to achieve the necessary expertise and confidence you will need for the surgery of your patients.
9. Turn the toggle switch to cut with simultaneous coagulation and repeat the exercises. You will see that cuts with the slightly modified wave require a higher setting than when the fully filtered wave is used. This is normal and should be taken into consideration for the later work on the patient.

Application examples: HF

HF CUT & CUT COAG				
PRG No.	**Program**	**Power (Watt)**	**Coagulation grade**	**Indications & remarks**
1	CUT	ca. 28	6	(filtered wave) - sulcus dilatation - gingivectomy - internal gingivectomy - open curetage - tumor resection - lap preparation - vestibulum plastic - excision
3	CUT	ca. 22	5	
2	CUT COAG	ca. 22	6	(slightly modulated or non filtered wave) - gingivoplastic - exposure of teeth, stubs, approximal steps or crown edges - removal of hyperplasia for ablation of tissue if simultaneous coagulation is requested with the cut (Attention: 10% loss of tissue about 24 h post operatively due to extended lateral heat) Use only if distance to bone or periost is sufficient!
4	CUT COAG	ca. 17	7	

Environment-directive

Please adhere to the EU Directive 2012/19/EU on the disposal of electronic and electric devices:

The device must not be disposed of with household waste.
At the end of the device's operating life, the user is legally bound to return the device to the point of sale or to any of the public collecting points that have been set up for this purpose.

Conditioning advice for hand pieces of hf Surg (DIN ISO 17664:2004)

General indications:

- Only use cleaning and disinfection agents that have been checked and authorized by the competent national boards (disinfection agent list of the VAH, RKI list or DHGM list). In case of mechanical cleaning and disinfection, it has to be assured that the disinfector's efficacy is approved (e.g. DHGM- or FDA approval or a CE mark according to EN ISO 15883).
- The handpiece can be sterilized together with the cable in the autoclave in the foil sterilization pouch (e.g. steriCLIN heat seal bag).
- Only the handpiece head is suitable for mechanical cleaning and disinfection.

Limitation of reprocessing:

Frequent reprocessing has only got a small impact on this instrument. The instrument shelf life is mainly determined by wear and damage by use.

Place of handling:	Clean surface with a disposable cloth or paper towel.
Storage and transport:	No special requirements
Preparations for cleaning:	Disassemble product into its components (see separate user manual for electrode)
Cleaning:	Only use suitable cleansers, carefully following the instructions of the respective manufacturer. No mechanical cleaning. Keep away from running water.

Disinfection:	Only use suitable disinfecting solutions, carefully following the instructions of the respective manufacturer. No mechanical disinfection. Keep away from running water.
Maintenance:	No special requirements.
Packaging:	Standardized packing material for sterilisation can be used.
Sterilisation:	Vapor sterilisation at 134 °C for 5 minutes at 2 bar overpressure.
Control/Functional Check:	Sight check on damages, wear, deformation.
Storage:	No special requirements.

The a.m. instructions have been validated as SUITABLE for preparation of a medical device and its re-use by the medical device manufacturer. It is the reprocessor's responsibility that the actual reprocessing achieves the required results with the equipment and materials applied and personnel involved in the reprocessing site. Normally, validation and routine control are necessary. Furthermore, the reprocessor should evaluate any deviation from the provided instructions regarding efficiency and possible adverse consequences.

Scope of Delivery

hf Surg - REF 452 400

HF set of instruments:		HF hand piece Yellow 1,50 m	REF 452 423
Cutting electrode No. 40 Multi-Tip	REF 452 402	Neutral electrode	REF 452 421
Cutting electrode No. 2	REF 452 404	Foot pedal	
Cutting electrode No. 15	REF 452 407	User manual	
Cutting electrode No. 13	REF 452 411	Medical product journal	

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