PLEASE READ THE FOLLOWING INSTRUCTIONS BEFORE USE.

Actto-50A

DNH medtech

EN INSTRUCTIONS FOR USE

CONTENTS

HOW TO USE THE INSTRUCTIONS

1. Please carefully read the Instructions for the safety before using the product.
2. Please see troubleshooting guide in the event of a device failure.
3. It's highly recommended to carefully read the Instructions before use to be experienced with operation procedure and precautions without any problems.

PRECAUTIONS FOR SAFETY

⚠ **Please carefully read the Instructions before use**

- Do not use near flammable or combustible material to prevent source of potential fire or explosion.
- Do not disassemble or repair the product without permission. In case of any abnormal operation or malfunction, please stop using the product and contact our office.
- The replacement parts of the product have to be approved by our company. Warranty of the product will not be accepted in case of using different parts than those supplied by our company.
- This product may have influence on other electronic equipment and vise versa.
- Please keep the following Instructions.

⚠ **Please do not use the device with the following medical instrument or conditions because it may cause malfunction of the medical instrument. Please do not use together unless wise indicated by medical specialist.other**

⚠ **The risks resulting from neuromuscular stimulation that can occur, especially, with modes producing electrical arcs between ACTIVE ELECTRODE and tissue.**

Unless it is recommended by medical specialist

- The patient with electronic implanted medical device.
- The patient with life-support system including respirator.
- The patient with portable electronic medical device including ECG monitor.
- The patient with an electronic implanted device such as a cardiac pacemaker.

- Type of protection against electric shock: Class I equipment
- Degree of protection against electric shock: Type BF applied parts
- Protection against harmful ingress of water (footswitch): IPX8
- Use environment in an Oxygen Rich Environment: Not suitable
- Mode of operation: Operate 10 seconds and wait 30 seconds before repetition
- Operation temperature : 10~35 °C

SYMBOLS USED ON THE PRODUCT

CE 2460	CE marking with the identification number of the Notified Body (2460 for DNV, Norway) responsible for implementation of the conformity assessment procedures acc. to the MDD (93/42/EEC), Annex V.		
	Symbol for Type BF Applied Parts	SN	Serial no.
	General cautions		Protection earth ground
	Date of manufacture		Manufacturer
	Read the instructions		Follow for instructions for use
EC REP	Authorized representative in the European community		Crossed-out wheeled bin acc. to WEEE directive (2012/19/EU) for Warning-Disposal of waste products
	Alternating current		Follow for instructions for use
	Dangerous voltage		Temperature limitation
	Humidity limitation		Atmospheric pressure limitation
	Fragile, handle with care		Keep dry
	This way up		Recycling

⚠ Processing instructions according to EN ISO 17664

The product has to be cleaned, disinfected and sterilized according to these processing instructions before its first use as well as after every further use. Disinfection alone is not enough. Thorough disinfection and cleaning are decisive prerequisites for the effective sterilization. The processing should be started as early as possible, 2 hours after use, however, at the latest. During the processing, the product should not be unnecessarily exposed to wetness or humidity. Please also observe the legal regulations applicable in your country as well as the hygiene regulations of the medical practice and/or the hospital.

LIMITATIONS IN THE PROCESSING: The frequent processing has only minor effects on this product. The end of the product's useful life is mainly determined by wear and damage caused by use. In case of doubt, the products should always be sorted out and replaced early. The user alone is responsible for making the decision regarding repeated use of the product. If the product is used too frequently, the manufacturer does not accept any warranty for the function, performance and safety of the product. **PERSONAL PROTECTIVE EQUIPMENT:** For reasons of occupational safety and to minimize infections / cross infections, suitable personal protective equipment (protective clothes, protective gloves, etc.) has to be used during the entire

INSTRUCTIONS: INITIAL TREATMENT AT THE PLACE OF USE: Remove surface contamination using a disposable cloth / paper cloth when you are still at the place of use. Rinse the products with water (at least drinking water quality) 2 hours after the application at the latest. The drying of residues or contamiantion of any kind on the product has to be avoided. When using the product for the first time at the of use, do not use any aldehyde-containing or alcohol-containing agents as they mau cause protrin fixation. **PREPARATION BEFORE CLEANING:** Disassemble the product into its individual components. Visual inspection for damage and wear.

DISINFECTION: MANUAL For the manual disinfection, please only use approved disinfectants wih tested effectiveness (CE mark, VAH-/DGHM-listed). Put the products / individual components into corresponding disinfection baths according to the disinfectant manufacturer's specifications. Ensure that the products are sufficiently covered and do not contact each other. The instructions for use of the disinfectant manufacturer must be strictly observed. Particularly the concentrations and contact times have to be observed. Application with the following agents is recommended: - Dürr Dental ID 213 instrument disinfection.

DESCRIPTION OF THE RECOMMENDED DISINFECTION PROCESS: Completion of proper cleaning preparation and manual cleaning. **Disinfection:** Insert the part of the instrument with patient contact into the strainer bowl. Hang the strainer bowl into the disinfection bath with disinfection solution. **Disinfectant:** ID 213, company Dürr Dental, concentration: 2 %. **Contact time:** 5 min. **Rinsing:** Rinse with water (at least drinking water quality) for 20 sec. **Drying:** Drying at room temperature. Make sure that the disinfectant is compatible with the products and cleaning agents that might be used. The pH of the disinfectant should lie between 5.5 and 8.5. Do not use organic solvents (e.g. alcohols, ether, ketones, petrol), oxidizing agents (e.g. peroxides), halogens (chlorine, iodine, bromine) or aromatic / hydrocarbons. Please observe thermal restrictions that might apply considering the disinfectant manufacturer's specifications.Afterwards, rinsing of the products / individual components with water (at least drinking water quality) for at least 20 seconds. Before further processing, the product must be free from any residues and dry. **Drying:** If you process the products manually, the products / individual components may be dried by blowin them off with filtered, oilfree compressd air according to DIN ISO 8573-1 (medical cleanliness class) or at room temperature.

CLEANING: MANUAL The manual cleaning should be completed in a water bath (at least drinking water quality) with the cleaning agent specified below using a brush below the water suface to achieve bothm sufficient cleaning of the products / individual components avoiding protein fixation, and to protect the environment from contamination with splash water. The duration should be based on the level of contamination of the product / individual component; it should, however, not be less than 1 minute. Afterwards, rinsing of the products / individual components with water (at least drinking water quality) for at least 20 seconds. **DESCRIPTION OF THE RECOMMENDED CLEANING PROCESS: Pre-cleaning:** Remove surface contamination using a disposable cloth. **Cleaning:** Insert the instrument into an instrument sieve (the sieve basket). Hang the instrument sieve (the sieve basket) into the cleaning bath with cleaning solution, remove contamination by means of cleaning brushes. **Cleaning tools:** Flexbrush brush, REF 605 254, Mirabrush, REF 605 260/61, Apply-Tips, REF 605 510**. Rinsing:** Rinse with water (at least drinking water quality) for 20 sec. **Drying:** Drying at room temperature. The manual cleaning should not exceed a temperature of 45 °C. It has to be ensured that visual contamination has been completely removed. If after the cleaning process, there is still contamination visible, the cleaning has to be repeated.

MAINTENANCE, CONTROL AND CHECK The product does not make special requirements on maintenance. Re-assemble disassembled products / individual components. You must always carry out a visual inspection for contamination, damage, wear and deformation before and after the individual work steps. Damaged or corroded products must no longer be used. If the product / individual component is not visibly clean, the entire processing has to be repeated or the product / individual component has to be properly disposed of.
A warning indicating failure of HF SURGICAL EQUIPMENT could result in an unintended increase of output power.

PACKAGING The product is to be packed in suitable and standardized transparent sterile packaging (sterilization bags) and sealed. Observe the instructions of the sterilization bag and sealing machine manufacturers as well as the current, normative requirements. Products / individual parts that have not been sterilized in bags must be used immediately.

STERILIZATION Only tested steam vacuum autoclaves may be used. Make sure that during the sterilization of several different products / individual components, the autoclove is not overfilled and that the products / individual components do not contact each other. The following sterilization cycles may be completed: Steam sterilization, 134 °C, hold time 5 minutes or steam sterilization, 121 °C, hold time 15 minutes To dry the products / individual components, the drying cycle of the autoclave should be set. Use the autoclave manufacturer's instructions for use.

STORAGE To maintain the sterility, the products have to be stored in standardized sterilization bags at a dry, clean place until they are used. If the sterile packaging is damaged, the products must be processed once again before their use.

ADDITIONAL INFORMATION Mark the sterilized products according to the legal and national regulations. The recommended storage duration for sterile medical devices is described in standards DIN 58953-8 and depends on external influences and effects during storage, transport and handling. The user must ensure within the scope of their quality management system that specified processing cycles that migh apply (see Limitations in the processing) are not exceeded. The manufacturer and the competent authority of your member state shall be immediately notified all serious incidents occuring in connection with the product. For the disposal of the products, there are regionally different recommendations and regulations. Ask your competent disposal company for the current regulations in your region.

⚠ Cleaning and Sterilizations

HANDPIECE, NEUTRAL ELECTRODE, FOOTSWITCH, POWER CORD: Always clean after each use on patient. Remove the electrode from the handpiece for cleaning. The outer surface of the handpiece, neutral electrode, footswitch and power cord should be cleaned with antiseptic soap or solution; wipe with disinfectant and/or water. Electrodes and handpiece: Always disinfect, clean and sterilize after each use to prevent spreading germs and diseases to other patients. Saliva, blood, and other debris may be left on the electrode. To sterilize the electrodes and handpiece, wipe them thoroughly using a mild detergent. Rinse thoroughly and dry. Weld in the electrodes and handpiece, then steam sterilize at 134 °C, 15 minutes, 2.1kgf/㎠.

⚠ Cleaning and Sterilizations

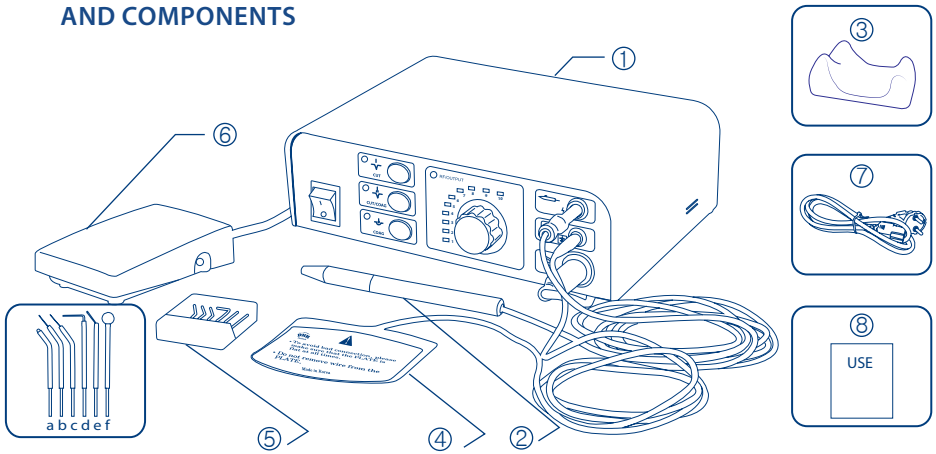
DEVICE. Since the device does not have direct contact with the patient, it can be cleaned by carefully wiping with alcohol. Avoid using disinfectants not specified for use with metal.

⚠ The device is used by medical specialists and dentists. In case of the following, DNHmedtech will not responsible for any loss which may result in the user's wrong use.

1. Do not tamper with device or any of its components.
2. For safety operation, confirm that the device is plugged into a three-wire grounded power source.
3. Do not use on patient with active implants such as pacemakers, cochlear or nerve stimulators.
4. Metal can conduct redio frequency energy just same as electricity. Remove partial dentures if it is removable and check the area arround fixed partial dentures. Metal restorations can conduct energy and cause burns and discomfort to the patient.
5. Be careful that metal restorations, bone or teeth do not come into contact with active electrodes. While transient contact is to be detrimental, extended contact may result in damage. All instruments used during device should be made of a non-conducting plastic material. Cotton rolls or gauze pads used in the patient's mouth should be kept from moist during operation. Skin-to-skin contact (for example between the arms and body of the patient) should be avoided by insertion of dry gauze for an example.
6. When high frequency surgical and physiological monitoring equipment are used simultaneously on the same patient, all monitoring equipment of electrodes should be placed as far as possible from the surgical electrode.
7. Position the cables to the surgical electrodes in such a way that contact with the patient or so that other leads can be avoided. Store electrodes out of reach the patient.

8. The neutral electrode (return electrode) must be used during all applications on the patient. The entire surface of the neutral electrode should be positioned flat (firm and non-conductive with clothing) behind the right shoulder of the clothed patient. This creates the largest possible contact surface
9. Do not place neutral electrode near the heart.
10. The use of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen should be avoided. Non-flammable agents should be used for cleaning or disinfecting. Solvents of adhesives is allowed to evaporate before the application. Some material may be ignited by sparks produced in normal use of the equipment (for example, cotton wool and gauze when saturable with oxygen). Gases within the device may be ignited. The device should be used after completely removing anesthetics or disinfections.
11. The lowest effective output setting could be achieved the best results.
12. The interference produced by the operation of the high frequency may adversely influence on the operation of other electrical equipment. In case of interference, de-energize or increase the distance between equipment. Connecting with a different power circuit may also reduce interference.
13. Regularly inspect the accessories, particularly the electrode sheaths and cables, to avoid possible insulation damage.
14. The electrode is composed with the tip (wire, loop, ball etc) and insulation part. The incision and coagulation have to be operated with tips of electrode. The electrode insulation part has a limited life expectancy and should be replaced regularly or exchanged according to the deterioration condition.
15. Be sure to use appropriate accessories supplied from DNHmedtech. Unauthorized cables and accessories may negative effect on EMC performance and safe operation.
16. Failure of the device or excessive electrical interference could result in an unintended power increase, decrease or activation. In case of electrical interference de-energize or increase the distance between equipment causing interference. Connecting to a different power circuit may also reduce interference
17. Recommended not to use the type of needle-shaped monitoring electrodes.
18. Electrical components may malfunction due to liquid ingress.

⚠ 1. DESCRIPTION OF PRODUCT AND COMPONENTS



No.	Name		Doc No.	QTY	Description
1	Device		ES-SET-50A	1	Electrosurgical Unit Monopolar
2	Handpiece (assembly)		ES-050-300	1	HF energy of the electrosurgery travels from the monopolar handpiece and electrode tip to neutral electrode.
3	Handpiece table		ES-050-304	1	Handpiece holder for resting
4	Neutral electrode (return electrode / assembly)		ES-050-301	1	HF energy of electrosurgery returns to return electrode.
5	Electrode tip	a	D15-45	1	Coagulation: Ball electrode Ø1.6 mm shaft 45° angled
		b	D01-45	1	Knife: Needle electrode 0.2mm straight shaft 45° angled, L 7.0 mm
		c	D03-45	1	Scoop: Wire loop electrode elongated 6 x 1.7 mm shaft 45° angled, wire 0.2 mm
		d	D12-90	1	Coagulation: Coagulation and fulguration electrode 0.5 mm 90° angled, L 10 mm
		e	D05-45	1	Scoop: Wire loop electrode elongated 6 x 1.7 mm, 45° angled, wire 0.2 mm
		f	D06-00	1	Scoop: Wire loop electrode Ø 4 mm straight, wire 0.2 mm
6	Footswitch(assembly)		ES-050-303	1	Determine the performance level
7	Power cord		ES-050-306	1	The AC main power supply
8	User manual		ES-050-307	1	Operation and instruction manual

⚠ 2. APPEARANCE AND STRUCTURE

1. EXTERIOR PHOTOS

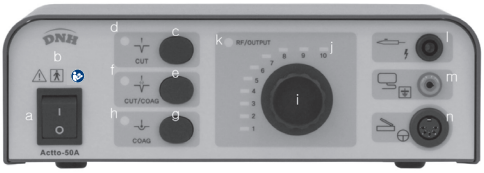
1) FRONT VIEW

2) REAR VIEW

3) SIDE VIEW (RIGHT)

(LEFT)

2. DETAILED DESCRIPTION OF THE PART



THE FRONT

a) Power switch: Main power on or off
b) Power lamp: When power switch is on, light turns green.
c) Function (CUT) switch: Initially when power switch is on, start function "CUT", by pressing button.
d) Function (CUT) lamp: If "CUT" is selected, the yellow light is on.
e) Function (CUT/COAG): Selected function by pressing button
f) Function (CUT/COAG) lamp: If "CUT/COAG" is selected, the yellow light is on.
g) Function (COAG) switch: Selected function by pressing button
h) Function (COAG) lamp: If "COAG" is selected, the blue light is on.
i) Power rotary switch: Select output power level (1-10).
j) Power level lamp: Power levels are displayed cumulatively of green lights by power rotary switch
k) RF/Output lamp: The orange light is on when the output is operated by footswitch.
l) Handpiece socket
m) Return electrode (neutral electrode) socket
n) Footswitch socket

THE REAR

a) AC power inlet: Connect AC power cord
b) Fuse cartridge: Main fuses (250V, F2.5AH x2)
c) Volume: Tuning of the tone, when operated.
d) Label

3. DIMENSION AND WEIGHT

1) Dimension of device: approx. (W) 265 x 180 x 89 mm 2) Weight of deivce (only): approx. 3.5 kg 3) Dimension and weight of component

Name	Appearance	Dimension	Weight
Handpiece		Handle length: 15 cm Wire: 200 cm	50 g
Neutral eletrode (return electrode)		Width: 9cm Height: 9cm Wire: 200cm	50 g
Electrode set		Length: 45mm	6 g
Footswitch		Width: 7 cm Height: 3 cm Length: 10 cm Wire: 200 cm	290 g
Power Cord		150 cm	210 g

4. COMPOSITION AND FEATURES OF THE PRODUCT

1) Product composition: The device is used to generate high frequency for cutting and coagulation of tissue. It is composed of active electrode (Handpiece), return electrode (neutral electrode), electrode, foot switch and the AC power cord supplying the main power.
2) Product characteristic:
   a) Characteristic : The device using generated high frequency energy is able to cut and coagulate tissue with focused heat energy at the active electrode-tip. It has three output modes: 'CUT', 'CUT&COAG' and 'COAG'. The intensity of these modes and output levels can be adjusted by the operator in accordance with purpose of treatment.
   b) Operation principle: The high frequency energy is generated at the main device, it is returned to electrode through the patient's body placed on the patient's back. At this time high frequency energy is created at the electrode and hyper-thermal energy is placed at the treatment area. Depending on the intended use, the output energy of device may be either partially or fully rectified. A fully rectified output is appropriate for cutting, while coagulation is achieved with a partially rectified output.
   c) The electrical specification - The rated frequency : 50/60Hz - Power consumption : 220VA
      - The rated voltage: AC 220-230V
   d) The protection type and degree for the electric shock: the first class equipment, BF type equipment.
   e) The safety device
      - The power transformer is blocked by the fuses inside equipment when an over current is detected.
      - The output and power levels are controlled by output level switch and foot switch in accordance with treatment purpose. And operatior or staff can check all device conditions such as function lamps ("CUT": yellow, CUT/COAG": yellow, "COAG": blue), output power level lamp (green) and operation lamp ("RF/OUTPUT": orange)
      - The device emits a tone while the output is energized.

5. SUMMARY OF EQUIPMENT APPLICATION SPECIFICATION

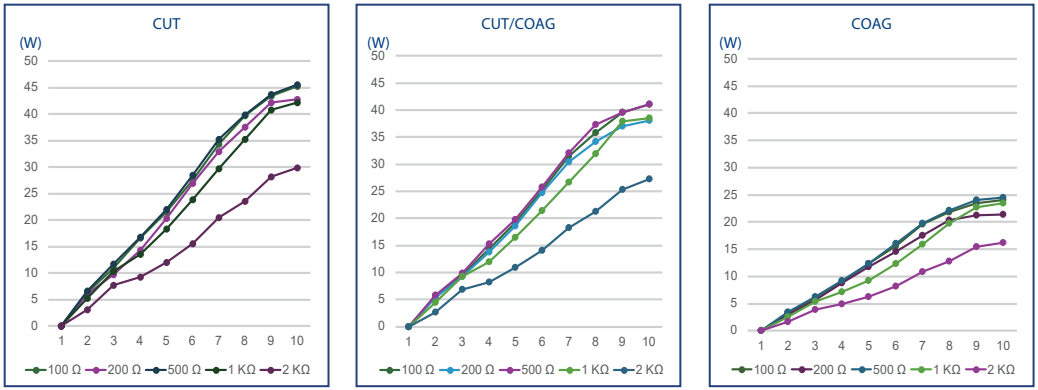
1) Medical purpose. Electrosurgical unit, monopolar type Actto-50A is a high frequency electrosurgical system, intended to cut and coagulation tissue by the radio frequency energy, focusing the heat energy at the small and active electrode.
2) Applied part of body or type of tissue interacted with
   a) Treatment site: teeth areas
   b) Condition: intact teeth areas within oral orifice
3) Applied part; Electrode
4) Intended USER
   a) Language understanding: - language as specified in the operation manual
   b) Experience: - no special experience needed - no maximum
   c) Permissible impairments:
      - mild reading vision impairment or vision corrected tolog MAR 0.2 (6/10 or 20/32);
      - one arm/hand system capable of guiding and holding device;
      - average degree of aging-related short term memory impairment;
      - impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz
5) Environment
   a) General: - hospital, intended for professional use only;
      - indoor use only;
   b) Conditions of visibility:
      - Ambient luminance 100-500 lux
      - Viewing distance 20 cm to 1 metre
      - Viewing angle: normal to the scale ± 20°
   c) Physical
      - temperature range: 10 °C to 35 °C
      - relative humidity range: 30 % to 75 %
      - Atmospheric pressure range: 70 to 106 kPa
      - background sound pressure level: <70 dB(A) in the range of 100 Hz - 8 kHz
   d) Frequency of use: - unlimited; but 10s On and 30s Off
   e) Mobility: - transportable; but placed on the table during use

⚠ 3. PERFORMANCE

1. PERFORMANCE

1) Protection type and level for electric shock : Class1 Equipment, Type BF Applied Part
2) The power supply device - Input voltage and power consumption AC 220-230V, 50/60 Hz, 220VA
   - Power transformer output voltage : 83V, 7V
3) The output a) Normal operating frequency : hf Surg Plus (1.2 MHz ± 10 %) b) Coagulation modulation wave shape : Square wave
   c) Maximum output power (Output impedance : 500Ω)
   - CUT : 50W ± 20 % - CUT/COAG : 40W ± 20 % - COAG : 30W ± 20 %
   d) Maximum HF output (Output impedance : 500Ω)
   - Voltage (rms) : CUT (158 V), CUT/COAG (145 V), COAG (122 V)
   - Current (rms) : CUT (315 mA), CUT/COAG (297 mA), COAG (227 mA)
   e) Rated accessory voltage - Handpiece : 600 Vpeak - Return electrode (neutral electrode): 600 Vpeak

4) Output power diagrams (control setting)



⚠ 4. HOW TO OPERATE OR USE

1. PREPARATIONS BEFORE USE

1) Read the instruction manual to get used to operation and precautions before use.
2) Check all components.
3) Before connecting AC power supply, check that the power switch is in the "Off" position.
4) Place the device in a location where it will not be potentially explosive atmospheres because electrical spark may occur within the device.
5) Do not leave the device in wet location.
6) Check if the component (handpiece, return electrode - hereinafter referred to as neutral electrode -, foot switch) are connected correctly.
7) When necessary, clean and sterilize electrode sheath by a gravity steam sterilization at 134 °C for 15 minutes.
8) Insert the appropriate electrode into the handpiece holder and secure it in the handpiece by turning it clockwise. Check the tightness of the electrode by gently pulling it. It has to be impossible to turn the electrode or to drag it out of the shaft. Make sure that the coated part of the electrode (metal part) is completely inside the handpiece. No metal parts of the shaft should be visible outside of the head of the hand piece. Otherwise, you pose a risk of injury to you and your patients. notice: Only the approved original electrodes must be used. These electrodes are adapted to the handpieces and devices.

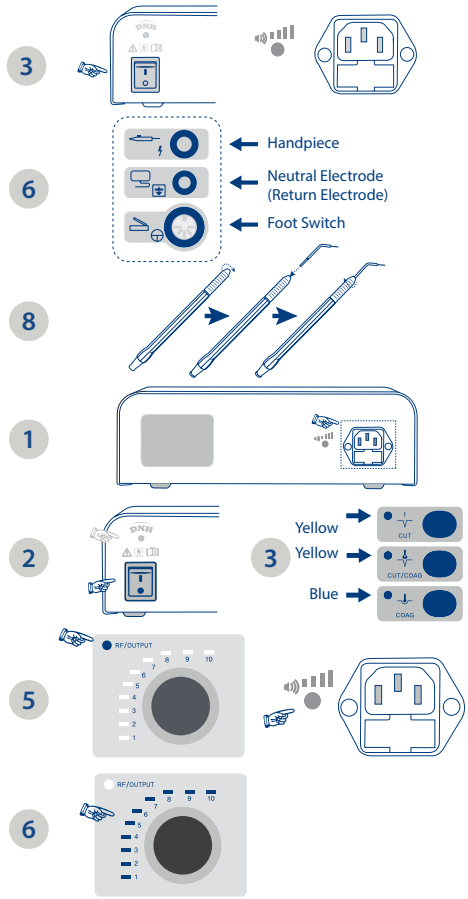
2. HOW TO USE

1) Connect AC Power cord to power inlet at the back of device. And connect the plug to a grounded power outlet. (The appliance coupler shall be placed to be easily accessible.)
2) Turn the power switch on ("I"), and check power lamp is on(green).
3) Select the functions ("CUT","CUT/COAG","COAG") by pressing the button, and check display lamp.
4) Fasten the neutral electrode on patient's back.
   Notice: When operating the electrosurgical unit, it must always be worked with the connected neutral electrode to ensure optimal, consistent performance.
5) Before applying the electrode to patient tissue, check the normal operation by the OUTPUT lamp (orange) and the acoustic tone by pressing the footswitch. Adjust volume of the alarm.
6) Set output power level by power rotary switch and check of green lights.
7) The lowest output set is effective for the best results. If the electrodes affected on electrical resistance, the set level is too low. Increase the level until there is no resistance when cutting, no sparking, and no discoloration along the incision; the active electrode glides smoothly through the tissue without resistance at your working speed. This is the lowest effective level.

⚠ Application of NEUTRAL ELECTRODE and its connections to be checked before selecting a higher output power

8) Operating time is repeated at 30 seconds intervals over the following 10 seconds.
9) Position cables to surgical in such a way that they are contacted with the patient or other leads. Store active electrodes out of reach the patient.

Note: After reading instruction, practicing on raw and lean beef can help the dentist acquire the necessary skills to achieve superior clinical results.



3. PRACTICAL EXERCISE ON A BEEF MODEL

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

1) Select a piece of fresh, lean beef. Veal is not suitable, because it does not change color when cut with an electrode. Because of its cell structure pork is also not suited. Wait until the beef has obtained room temperature. Note: Make sure that the meat is placed on the plugged-in neutral electrode. If this is not the case the waves cannot derivate and, consequently cannot proceed with the exercise.
2) Insert the electrode of your choice (Knife tip, loop) into the hand piece.
3) Turn the intensity control (power) dial to 10
4) Push the function button to "CUT"
5) Activate the foot switch
6) Make serverak incision of different lengths and depths with even, burshing movements. Then take the energe from the electrode and look at the result. You will notice that the intensity adjustment was too high, which caused sparks and remarkable discoloration along the cutting line.
7) Reduce the intensity setting to 1 (or low power). 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 particluar setting in order to achieve the necessary expertise and confidence you will need for the surgery of your patients.
9) Turn the function 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 take into consideration for the later work on the patient.

⚠ 5. STORAGE AND MAINTENANCE AFTER USE

1. HOW TO STORE AND MAINTAIN THE PRODUCT AFTER USE

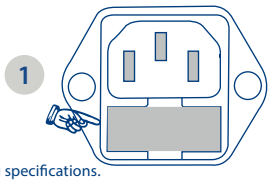
1) After using the device, the power switch should be disconnected.
2) When storing the accessories (Power cord, Handpiece, Neutral electrode, Footswitch, Electrode) separate them from the device, do not force it and check the disconnected cables are not twisted. Especially, keep neutral electrode (return electrode) packaged with wire and plate at all times.
3) Do not place ME equipment in a position that makes it difficult to operate the disconnecting device.
4) If necessary, clean and sterilize electrode sheath by a gravity steam sterilizing at 134 °C for 15 minutes.
5) The device should be kept clean for next use. Wipe the exterior surface with a soft cloth and some neutral detergent.
6) The product should be stored at the place:
   - In a dry condition
   - Away form direct sunshine, dust, salt or sulfur which may have negative effect on surrounding environment.

	Atmospheric pressure	Temperature	Humidity
condition	70 to 106 kPa	+10 to +35 °C	30 to 75 %

- Storage and transportation –20 to +60 °C, 15 to 93 % RH, 50 to 106 kPa

2. TROUBLESHOOTING

1) In the event of power failure, check the power cord, connection (plug and socket) and fuses.
2) If the temperature is not controlled, check the instruction manual.
3) If there is no output power under normal conditions (RF lamp on: orange, BEEP on), check the connection with handpiece and neutral electrode (return electrode).



3. OPERATOR REGULATION

The device unit is classified as medical device unit class IIb (Europe).
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, COAG with LEDs - Uniformity of performance throughout the range of adjustment

Measurement of radio frequency (HF) output power at a load of 500Ω:
- Output: CUT (50 W ± 20 %), CUT/COAG (40 W ± 20 %), COAG (30 W ± 20 %)

All results of measurements must be documented according to DIN EN ISO 62363 concerning the first measured values. If defects occur during the controls, the user is responsible to initiate repair.

4. SERVICE

If requested, circuit diagrams, components part lists, descriptions, calibration instructions or other information is provided for service activity of the equipment from DNHmedtech Co.

5. DISPOSAL OF WASTE PRODUCTS

When the crossed-out wheeled bin symbol is attached to a product, it means the product is followed by the European Directive 2012/19/EU. All electrical and electronic products should be disposed of separately to designated collection facilities of the municipal waste appointed by the local government or authorities.
The correct disposal of old appliance will help to prevent potential negative consequences for the environment and human health. For more detailed information about disposal of waste products, please contact the local authorities or waste disposal service.
Note: Please contact the supplier or the head office for inquiries.

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WEEE NR. DE21760541
MD
CE 2460

DNH-UM-001 Rev6 (2024-10)