Model: ARC-303, Producator: Bowa, Tara: Germania

	Dispozitiv elect	ro-chirurgical (diaterm	ocoagulator caracteristici medii) cu	troliu	
Cod	280240				
Parametrul	Specificația				
Descriere	dispozitiv des		coagularea țesuturilor biologice în procesul actului chirurgical ză curenți electrici de frecvență înaltă		
				Confirmarea datelor tehnice	
Frecvența			cuprinsă înre 300 KHz și 1 MHz	da	
-	Monopolar		izolat	da 2 porturi	
	Comutator de r	nînă	da	da	
Canale de ieșire	Comutator de p	oicior	tip pedală dublă	da	
	Bipolar		da	da	
	1	Tăiere	≥ 300 W	da	
			≥ 300 Ohm	da	
	Monopolar	Coagulare	≥ 120 W	da	
			≥ 250 Ohm	da	
Moduri de lucru		Tăiere	≥ 120 W	da	
			≥ 250 Ohm	da	
	Bipolar	Coagulare	≥ 100 W	da	
			≥ 100 Ohm	da	
Regimuri de lucru preselectate	Blend, strong	soft, spray	minimum 5 regimuri	da	
Funcție de autotest	are		da	da	
Canal de ieșire inde			da	da	
	-		acustic	da	
Indicatoare			vizual	da	
Control volum sune	t		da	da	
		Accesorii			
Cablu pentru electro	od neutru reutiliz	abil, min. 2 metri	2 buc.	da	
Electrod neutru reu	tilizabil, tip adult		2 buc.	da	
Bisturiu electric cu o reutilizabil minim 10			2 buc.	da	
Lame reutilizabile p			10 buc.	da	
Electrod / pencetă l		zabil	1 buc.	da	
Cablu pentru electrod bipolar reutilizabil, min. 2 metri		1 buc.	da		
Pedală dublă		,	1 buc.	da	
	Să se indice mo	delul oferit	model	ARC CART	
	Mobil pe 4 roţi		da	da	
To a line	Minim 2 roți cu	frînă	da	da	
Troliu		/coș/poliță pentru	da	da	
	Mîner pentru tı	ransportare	da	da	
	willer pentru transportare				



Declaration of Conformity (DoC)

We

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz Strasse 4-10 72810 Gomaringen / Germany SRN manufacturer: **DE-MF-000007801**

declare in sole responsibility that the medical device(s)

Basic UDI-DI	4250350186084 4250350105429
CND	Z120109 ELECTROSURGERY INSTRUMENTS
Product code / REF	900-303
Device name	ARC 303
Product group(s)	PG14-5
Intended purpose	Electrosurgical equipment for cutting and coagulation of tissue

to which this declaration relates is classified as **risk class IIb**, according to the rules as set out in **Annex IX**, **chapter I and III** is in conformity with the following relevant European Union harmonization legislation:

Regulation (EU) 2017/745 relating to medical devices,

and that the device(s) is/are in conformity with the following standards and/or other normative documents

EN ISO 14971 / EN ISO 60601-1 / EN ISO 60601-2-2 / EN ISO 10993-1 / EN ISO 13485 / DIN EN 1041

and that the following Notified Body performed the intervention as described and issued the certificate

5	
Notified Body name	TUEV-SUED Product Service GmbH
Address	Ridlerstr. 65, 80339 München
Country	Germany
Identification number	0123
Description of intervention	Conformity assessment to Annex IX
Number certificate	G10 016316 0022 Rev. 00
Date certificate	2020-08-10
Duration and conditions of validity of the examination certificate	2025-08-09

Gomaringen, 2023-03-01

Head of Quality Management / Regulatory Affairs

BOWA MEDICAL BOWA-electronic GmbH & Co. KG Heinrich-Hertz-Strasse 4-10 72810 Gomaringen | Germany

Telefon +49 (0) 7072-6002-0 Telefax +49 (0) 7072-6002-33 info@bowa-medical.de | bowa-medical.de

Wolf-Rüdiger Fritz

Registergericht: Stuttgart HRA 381478 Geschäftsführer: Jens Kröber Martin Heinrich





Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Manufacturer:

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4-10 72810 Gomaringen GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713175396

 Valid from:
 2020-08-10

 Valid until:
 2025-08-09

Christoph Dicks

Issue date: 2020-08-10 Head of Certification/Notified Body



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Device Group:

Z120109 - ELECTROSURGERY INSTRUMENTS

Classification:

llb

Intended Purpose:

Generation of electrical power for monopolar and bipolar cutting

and coagulation on tissue structures in surgical operations

Device Group:

K020101 - ELECTROSURGICAL INSTRUMENTARY, MONO-

AND BIPOLAR, SINGLE-USE

Classification:

Ilb

Intended Purpose:

Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

K020102 - ELECTROSURGICAL PADS AND CABLES

Classification:

llb

Intended Purpose:

Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

K020480 - ARGON GAS SURGICAL DEVICES - ACCESSORIES

Classification:

IIb

Intended Purpose:

Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

L180201 - SCISSORS, "OPEN SKY" ELECTROSURGICAL,

REUSABLE

Classification:

Ilb

Intended Purpose:

Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

L180301 - HANDPIECES, "OPEN SKY" ELECTROSURGICAL,

REUSABLE

Classification:

llb

Intended Purpose:

Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

L180401 - FORCEPS, "OPEN SKY" ELECTROSURGICAL,

REUSABLE

Classification:

IIb

Intended Purpose:

Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

L180402 - FORCEPS, ELECTROSURGICAL ENDOTHERAPY,

REUSABLE

Page 2 of 3

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



0

ш



EU Quality Management System Certificate (MDR)

llb

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Classification:

Intended Purpose: Electrosurgical equipment for cutting and coagulation of tissue

Device Group: L180602 - ELECTRODES, ELECTROSURGICAL

ENDOTHERAPY, REUSABLE

Classification:

Intended Purpose: Electrosurgical equipment for cutting and coagulation of tissue

Device Group: K020401 - ARGON GAS SURGICAL INSTRUMENTARY,

SINGLE-USE

Classification:

Intended Purpose: Electrosurgical equipment for cutting and coagulation of tissue

Device Group: L180601 - ELECTRODES, "OPEN SKY" ELECTROSURGICAL,

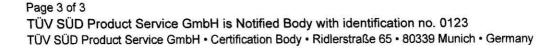
REUSABLE

Classification: IIb

Intended Purpose: Electrosurgical equipment for cutting and coagulation of tissue

The validity of this certificate depends on conditions and/or is limited to the following:

- none -









Product Service

Certificate

No. Q5 016316 0021 Rev. 02

Holder of Certificate: BOWA-electronic GmbH & Co. KG

> Heinrich-Hertz-Strasse 4-10 72810 Gomaringen **GERMANY**

Certification Mark:



Design and development, production and Scope of Certificate:

distribution of sterile and non-sterile medical devices:

Electrosurgical Units and Accessories, Argon Coagulation Units and Accessories,

Electrode Handles.

Active Electrodes and Instruments, Monopolar and Bipolar Forceps,

Endoscopic and Laparoscopic Instruments,

Instruments for Vessel Sealing,

Neutral Electrodes and

Bipolar Scissors

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 016316 0021 Rev. 02

Report No.: 713229570

Valid from: 2022-03-02 Valid until: 2025-03-01

Christoph Dicks Date. 2022-03-02

Head of Certification/Notified Body





Certificate

No. Q5 016316 0021 Rev. 02

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4-10, 72810 Gomaringen, GERMANY

Design and development, production and distribution of sterile

and non-sterile medical devices: Electrosurgical Units and Accessories, Argon Coagulation Units and Accessories,

Electrode Handles.

Active Electrodes and Instruments, Monopolar and Bipolar Forceps,

Endoscopic and Laparoscopic Instruments,

Instruments for Vessel Sealing and

Bipolar Scissors

Design and development and distribution of sterile

and non-sterile medical devices:

Neutral Electrodes

BOWA Polska Sp. zo. o.

Zlotkowo, ul. Obornicka 10, 62-002 Suchy Las, POLAND

Production of sterile and non-sterile medical devices:

Instruments for Vessel Sealing and

Neutral Electrodes

./.



Basic Electrosurgical Devices

ARC 250 / ARC 303

Top-level All-Rounders

Powerful basic devices for all fundamental electrosurgical functions with monopolar and bipolar instruments

for all medical fields

- for monopolar and bipolar instruments
- all fundamental electrosurgical functions
- Top level electrosurgical cutting and coagulation



















Excerpt from Programmes

- Standard: General and visceral surgery, cardiac and thorax surgery
- Resection:
 Gynaecology, urology
- Standard, Macro: Orthopaedics and accident surgery
- Micro:
 Paediatric surgery









Individually programmable

on 100 memory locations with individually definable programme names

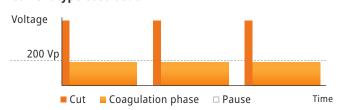
Intuitive, fast operation

via direct selection keys and the LCD display. Optional for a better overview: Cable holder and short instruction

Top programmes

- GastroCut option, particularly for delicate interventions in gastroenterology
- Resection is available for applications involving resectoscopes

Current type GastroCut



Connection sockets for instruments

2 monopolar sockets



1 bipolar socket



High-tech as standard

as all electrosurgical standard modes, AUTOSTART, EASY neutral electrode monitoring and ISSys monitoring system, are available

Reproducible tissue effects and safe power dosing

through the ARC CONTROL electric arc regulation

The Argon Workstation

for argon plasma coagulation (APC) and argon-assisted electrosurgery



ARC CART provides a highly mobile argon workstation with useful detailed solutions

Benefits of argon-assisted electrosurgery in surgery and gynaecology

- non-contact coagulation of parenchymal tissues, e. g. liver, without adhesion or bonding
- rapid coagulation of large surfaces
- free of carbonisation
- flexible, sustainable coagulation zone
- clear view due to fume-free coagulations
- very easy handling due to large ignition distance > 10 mm and simple ignition



Recommended basic accessories

Foot switch

Twin-pedal foot switch

with stirrup

REF

901-032

Twin-nedal foot switch

901-021

al foot switch

901-022

dal foot switch

901-011









802-033

SHE SHA smoke handle

REF



ARC 303 – SimCoag*

ARC 303 – simultaneous activation of two handles

In various applications in gynaecology, mastectomy, cardiac surgery, bypass, or trauma surgery, polytrauma, where there is a need to simultaneously apply electrosurgery at multiple sites in the patient.

Even the basic version of the ARC 303 offers this function providing considerable added value.



* not in ARC 250

TECHNICAL DATA

Type of insulation / classification	
Protection class according to EN 60601-1	I
Type of applied part according to EN 60601-1	CF
CE in accordance with 2017/745 EU (MDR)	CE 0123
Key data	
Key data Max. MONOPOLAR power ARC 250	250 W
•	250 W 300 W

Mains connection	
Power input in Standby mode	25 VA
Mains frequency	50/660 Hz
Max. power input at an HF output power of 300 Watt	500 VA
Connection for equipotential bonding	Yes
Dimensions and weight	

Dimensions and weight	
External dimensions width x height x depth (mm)	430 x 150 x 400
Weight	approx. 10 kg



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*

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Service packages

Adapted to your individual requirements



Devices on loan

Loan devices during repair or service



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Sustainable disposal of waste equipment

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Heinrich-Hertz-Strasse 4-10 72810 Gomaringen, Germany

Phone +49 7072 6002-0

bowa-medical.com info@bowa-medical.com

ARC 250 / ARC 303 Robust, reliable, convenient.

Contact your authorised BOWA medical devices consultant now.

support@bowa-medical.com



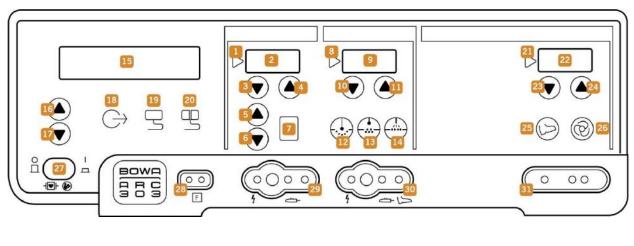
OPERATING MANUAL ELECTROSURGICAL UNIT

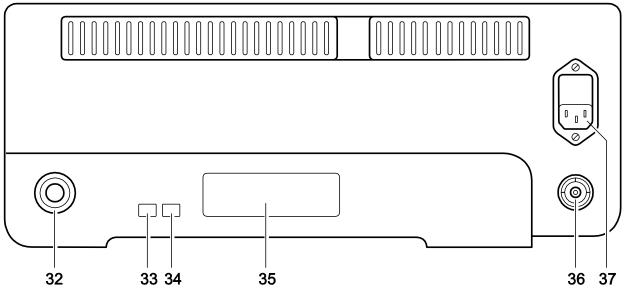














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0	n	0	n	n

14

_egena	
1	"Monopolar Cut" indicator arrow (yellow)
2	"Monopolar Cut" 7-segment display
3/4	Power limitation for monopolar cutting
5/6	Key for the degree of scabbing during monopolar cutting
7	"Monopolar Cut" blend factor indicator
	Blend settings 0–9
8	"Monopolar Coag" indicator arrow (blue)
9	"Monopolar Coag" 7-segment display
10/11	Power limitation for monopolar coagulation
12	Key/indicator for "Moderate Coagulation" current mode
13	Key/indicator for "Forced Coagulation" current mode

15 Indicator on main display: programs and information Current indicator on 2-line display

Key/indicator for "Spray Coagulation" current

- 16/17 Program key
- 18 Error status indicator
- 19 EASY monitoring for one-piece neutral electrode (EASY one-piece monitoring)
- 20 EASY monitoring for split neutral electrode (EASY split monitoring)
- 21 Indicator arrow for "Bipolar Coag" (blue) 22 "Bipolar Coag" 7-segment display 23/24 Power limitation for bipolar coagulation 25 Key/indicator for "Bipolar Output" FOOT SWITCH (socket connector 31) Only for bipolar coagulation! 26 Key/indicator for AUTOSTART "Bipolar Output" (socket connector 31) Only for bipolar coagulation!
- 27 On/off switch
- 28 Socket for the neutral electrode (NE)*
- 29 Socket connector for monopolar instruments with hand switch* (only for ARC 303)
- 30 Socket connector for monopolar instruments with hand or foot switch, Bovie connector or 4 mm monopolar endoscope connector, or 3-pin connector*
- 31 Socket connector for bipolar instruments with foot switch or AUTOSTART*
- Application part F according to IEC 60601-1

Back side of ARC 250/303

- 32 Socket connector for foot switch for sockets 30 and 31
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1. Using this operating manual

This operating manual is part of the device.

BOWA-electronic GmbH & Co. KG, referred to in the following simply as BOWA, assume no liability nor provide any warranty whatsoever for damage and consequential damages that arise due to non-compliance with the operating manual.

- ► Read the operating manual carefully and thoroughly before using this device.
- Store the operating manual in a safe place throughout the service life of the device.
- Keep the operating manual accessible to operating room personnel.
- Give the operating manual to each successive owner and/or user of this device.
- Always update the operating manual whenever you receive additional information from the manufacturer.

1.1. Revision index

Software version	Last revised	
from 2.33	2019/02	

1.2. Validity

This operating manual applies only to the devices designated on the title page.

1.3. Other applicable documents

Comply with other applicable documents in the appendix or in the other sections.

1.4. Icons and labeling

1.4.1. Structure of warning instructions



SIGNAL WORD

"Risk type, source and consequences there of" (Personal injury)!

Measure for risk prevention.



NOTE

"Risk type, source and consequences there of" (Property damage)!

Measure.



1.4.2. Risk levels in the warning instructions

Symbol	Risk level	Probability of occurrence	Consequences of non-compliance
	DANGER	Immediate risk	Death, serious injuries
	WARNING	Possible risk	Death, serious injuries
	CAUTION	Possible risk	Minor injuries
0	NOTE	Possible risk	Property damage

1.4.3. Tips

ĥ

Tips and additional information to facilitate tasks.

1.4.4. Other icons and labeling

Icon/Labeling	Meaning
\square	Prerequisite for an activity
>	Activity with one step
1. 2. 3.	Activity with several steps in a binding sequence
\$	Result of preceding activity
•	List (first level)
•	List (second level)
Emphasis	Emphasis
, see section xxx, page xxx	Cross reference
"Monopolar output" 29/30	Bold numbers (e.g. 29/30) refer to the schematic depiction of the ARC 250 / 303 and the associated legend see pages 6–7)



2. Intended use

2.1. Indications

Electrosurgical generators provide HF energy for the cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery in combination with electrosurgical accessories in different surgical disciplines.

2.2. Contraindications

Electrosurgical generators must not be used in direct contact with the heart, central nervous system or central circulatory system.

Do not use electrosurgical generators if their surgical techniques are contraindicated.

Do not employ electrosurgical generators if, in the opinion of an experienced doctor or according to the latest specialist literature, such use would endanger the patient, for example due to the patient's general condition or the presence of other contraindications.

ĵ

BOWA requires that the HF device is operated under the supervision of qualified and authorized personnel. The surgeon and medical staff must be trained in the fundamental principles, rules for use and risks of HF surgery and must be familiar with these in order to safely and reliably prevent putting patients, personnel and devices at risk.

ĥ

Any other use is neither intended nor proper and must be effectively prevented.



3. Safety

3.1. General safety instructions

- Ensure that no electronic devices that are subject to interference from electromagnetic fields are set up in the vicinity of the HF device.
- Observe the instructions on electromagnetic compatibility provided in section EMC, page 79.
- Always connect the HF device to a mains power system with a protective earth lead in order to prevent electric shock.

Additional devices that are connected to electrical medical devices must satisfy relevant IEC or ISO standards (e.g. IEC 60950 for data processing devices). Furthermore, all configurations must comply with the standardised requirements for medical systems (see IEC 60601-1-1 or Section 16 of the 3rd edition of IEC 60601-1 as relevant). Anyone who connects additional devices to electrical medical devices is automatically a system configurator and thus responsible for meeting standardised system requirements. Please note that local laws prevail over the aforementioned standard requirements. In case of questions, please contact your local dealer or Techical Service, see section Technical service, page 53.

ĵ

To protect personnel, BOWA recommends the use of a smoke evacuator to extract electrosurgical smoke, e.g. BOWA SHE SHA.

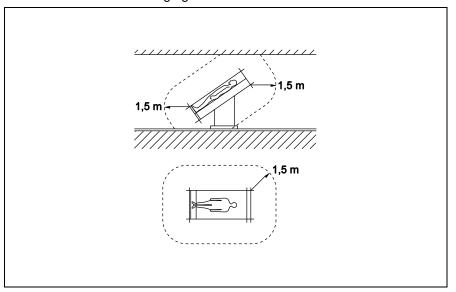


3.2. Personal safety instructions

3.2.1. Ambient conditions

Excessive leakage currents may create a risk of burns to the patient.

▶ Do not use the HF device in the immediate vicinity of the patient. Observe the minimum distances recommended by BOWA, as shown in the following figure.



3.2.2. Patients with pacemakers

Malfunctions or destruction of the pacemaker can endanger the life of the patient or result in irreversible injuries to the patient.

- In cases of patients with pacemakers, consult the cardiologist before carrying out HF surgery.
- Use bipolar HF methods.
- ▶ Move the HF neutral electrode close to the operating field.
- Set the demand pacemaker to a fixed frequency.
- Ensure that the pacemaker does not come into contact with the HF electrode.
- Keep a fully operational defibrillator handy.
- Carry out a postoperative pacemaker check.

3.2.3. Safe positioning of the patient

- Position the patient so that he is not touching any metal parts that are grounded or have considerable capacitance relative to ground (e.g. operating table brackets). Lay anti-static towels between the patient and the bedding.
- ▶ Ensure that the patient does not touch any wet towels or bedding.
- Place anti-static towels between areas of heavy sweating and skinto-skin contact on the patient's trunk.
- ► Ensure that you are using a suitable support surface in order to prevent pressure necrosis.



Drain urine via the catheter.

3.2.4. Correct connection of the HF device

- ▶ Always ground the HF device via the equipotential bonding. Also note the requirements of chapter 8.6.7 of ISO 60601-1 for medical electrical systems.
- Do not use any needle electrodes for monitoring.
- Attach electrodes of physiological monitoring devices without protective resistors or HF regulators as far as possible from the HF electrodes.
- Attach lines from monitoring devices so that they do not lie on the patient's skin.
- ► Keep the leads to the HF electrodes as short as possible and position them so that they do not touch the patient or other leads.
- Do not place any objects on the HF device.

3.2.5. Correct use of the HF device

Inadvertent activation in the non-visible area of the HF device can injure the patient.

- Activate the HF device only when the electrode is in your field of vision and you can quickly deactivate the HF device at all times.
- After inadvertent activation of the HF device, switch off the device immediately using the on/off switch.
- Pay particular attention whenever you use the foot switch or the manual switch.

Lack of preparation, errors in usage or faults in the HF device can cause damage to the HF device.

- Monitoring functions, page 22.
- ► Ensure that no conductive fluids (e.g. blood, amniotic fluid) have penetrated the foot switch or the manual switch.
- Ensure that the cables for the foot switch and manual switch are free from short circuits and broken leads.
- ► Ensure that the maximum cable length of each connected accessory and mains cable is no greater than 5 m.

3.2.6. Adjusting the settings of the HF device and use of the accessories

Setting the output power too high can injure the patient. Therefore, before you increase the output power, ensure that:

- the neutral electrode is correctly positioned,
- the working electrodes are clean,
- and the plug connections are all correct.



Setting the HF device correctly

- To prevent inadvertent (thermal) tissue damage during operations on body parts with small cross sections and in areas with high resistance (bones or joints), use the bipolar method in these areas.
- Set the acoustic signal that sounds when the electrode is activated so that it is always clearly audible.

Nerve and muscle irritations due to low-frequency currents!

In electrosurgical applications (particularly applications generating an arc), a part of the HF current is converted to a low-frequency current. This can trigger muscle spasms in patients.

► To minimize the risk of injury to the patient, set the power and effect as low as possible.

Correct usage of the accessories

- Use only insulated accessories.
- ► Check all electrodes for sharp edges and projecting parts before use.
- Use only electrodes that are free of defects and in good working order.
- Never place active electrodes on or near the patient.
- ▶ Do not remove hot electrodes from the patient's body directly after cutting or coagulation.
- ► Ensure that there is sufficient distance between the patient cables and the cables of the HF device.
- Do not run the patient cable across the patient.

3.3. Device-related safety instructions

Devices manufactured by BOWA are developed in accordance with the current state of technology and generally accepted safety rules. Despite this, risks to the life and health of the user or third parties and/or damage to the device and other objects can occur.

- ▶ Use only accessories approved by BOWA, see section Accessories and replacement parts, page 78).
- ▶ Use the device only when it is in free of technical defects and in good working order and only for the intended purpose, always remaining aware of safety requirements and risks while complying with this operating manual.
- ► Have malfunctions that can adversely affect safety (e.g. deviations from the permissible operating conditions) repaired without delay.
- Wipe down the HF device only with cleaning agents and disinfectants that are nationally approved for surface cleaning, see section Disinfection and cleaning, page 50.
- Never immerse the device in water or cleaning agents.
- Never boil the device and never disinfect it mechanically.
- Immediately drain any fluid that might have penetrated the device.

A malfunction can result in an undesired increase of the output power if the device is damaged or defective.



Certain devices or accessories can represent a hazard when used with low power settings. For example, there is a greater risk of a gas embolism in argon coagulation if the available HF power is too low to create an impenetrable eschar layer on the target tissue quickly.

3.4. Safe handling (general instructions)

- ▶ Before each use of the device, check to ensure that it is functioning properly and is in good working order and connected properly.
- ▶ Observe the instructions for use with regard to standards, see section Risk levels in the warning instructions, page 9.
- Always observe and obey the acoustic signals or error indications during use, see section Error list, page 45.
- The device and accessories may be operated and used only by people who have the necessary training, knowledge and experience.
- ► Check the accessories regularly for damage to the isolation, for proper function, and the expiration date, especially the electrode cable, endoscopic accessories, and neutral electrodes.
- Do not place any instruments on the patients or on the devices.
- Ensure that no instruments are being cleaned when AUTOSTART is activated.
- Wear suitable gloves during operations.

3.4.1. Surgical environment: prevention of explosions/combustion

Sparks fly during proper use of the HF device.

- ▶ Do not use the HF device in areas where there is a risk of explosion.
- Do not use any flammable or explosive liquids.
- If display components fail, do not use the HF device any longer.
- Avoid using ignitable anesthetics and gases which support combustion (e.g. nitrous oxide, oxygen) during operations (e.g. in the head and thoracic regions).
- Wear suitable gloves during operations.
- Use exclusively non-flammable cleaning agents, disinfectants and solvents (for adhesives). If you use flammable cleaning agents, disinfectants or solvents, ensure that they have fully evaporated before using the HF surgical equipment.
- ► Ensure that no flammable liquids collect beneath the patient or in body cavities (e.g. the vagina). Suction and/or flush body cavities before activating the device.
- Wipe off all liquids before using the HF device.
- ▶ Ensure that no endogenous gases are present that could ignite.
- ► Ensure that all materials saturated with oxygen (e.g. cotton, gauze) are removed far enough from the HF environment that they cannot ignite.



3.4.2. Application of the neutral electrode

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Please read and comply with the notes about using the neutral electrode listed in the user manual as well as the information on the packaging of the neutral electrode.

In the monopolar HF method, the neutral electrode feeds the current introduced into the patient's body at the surgical site back to the HF device.

- ► To prevent a rise in temperature at the current emergence point, the following conditions must be ensured:
 - sufficiently large contact surface between the neutral electrode and the patient's body
 - high electrical conductivity between the neutral electrode and the patient's body
- ➤ To prevent the patient being burned by the neutral electrode, you must comply with the following conditions:
 - Select the application point for the neutral electrode so that the current paths between the active and neutral electrodes are as short as possible and run longitudinally or diagonally to the patient's body (because muscles are more conductive in the direction of the fibrils).

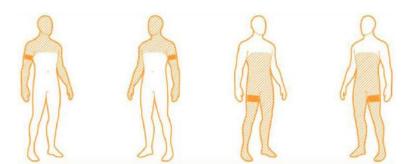


Figure 3-1: Application point of neutral electrode

- During surgery in the thoracic region, do not run the current path transversely across the patient's body and ensure that the patient's heart is never in the path of the current.
- Depending on the surgical site, apply the neutral electrode to the nearest upper arm or thigh if possible, but never closer than 20 cm.
- In the case of self-adhesive disposable electrodes, comply with any further manufacturer specifications regarding the point of application.
- Ensure that the application point is free of scar tissue, bony protuberances, surface hair and ECG electodes.
- Ensure that there are no implants (e.g. bone nails, bone plates, endoprostheses) in the current path.



- Ensure that no short circuits can occur at the neutral electrode connection.
- Avoid locations where fluids may collect.

Before applying the neutral electrode

- ▶ Shave the area where the neutral electrode will be applied.
- ► Clean the application site, but do not use any alcohol, as it dries out the skin and increases the transition resistance.
- If the patient has poor circulation, massage or brush the application site.
- Apply the neutral electrode using the entire contact surface. Secure reusable neutral electrodes with rubber bands or elastic ties so that they do not loosen or fall off when the patient moves. Ensure that the patient's circulation is not impaired (risk of necrosis).
- Never use wet towels or electropastes.
- ► Ensure that no liquids (e.g. cleaning fluids, disinfectants, blood, urine) get between the patient and the neutral electrode.
- Do not place the neutral electrode under the patient's buttocks or back.
- ► Ensure that there are no ECG electrodes in the current path of the HF device.

Example application using a disposable electrode

- ▶ Remove the protective film and attach the self-adhesive disposable electrode to the patient. Ensure that the long side of the disposable electrode faces the operation site and the electrode is fully in contact with the skin. This avoids excessive current concentration on the short side.
- Using both hands, press the self-adhesive disposable electrode firmly against the patient's skin.
- Clamp the electrode tab to the neutral electrode cable.
- After the operation, remove the disposable electrode carefully to avoid skin damage.

Use of a one-piece neutral electrode

► Check the one-piece neutral electrode during the surgery.

Use of a split neutral electrode

Apply the split neutral electrode correctly and without any additional objects, as the HF device does not recognize the bridging of the section surfaces by other objects.

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See chapter EASY neutral electrode monitoring (EASY monitoring), page 23, for additional information about monitoring the neutral electrode.



4. Functionality

The HF device is controlled by a microprocessor and converts the mains voltage into a high-frequency alternating current for monopolar or bipolar applications.

The "ARC Control" regulator reduces the output power to the minimum level necessary, depending on the tissue and its resistance.

4.1. Monopolar modes

In monopolar operation, the HF device has the following operating modes:

- "Cut" for cutting in low-resistance tissue
- "Moderate Coag" for contact coagulation
- "Forced Coag" for coagulation with light contact
- "Spray Coagulation" for contactless surface coagulation

Instruments can be connected to monopolar output (socket connector **29/30**).

4.1.1. "Cut" mode

In this mode a powerful HF current with a low crest factor is used for cutting in biological tissue. The maximum power is 250 W with the ARC 250, or 300 W with the ARC 303. The ARC CONTROL regulator quickly adjusts the output power to the minimum level necessary in response to variations in the tissue and changes in the cutting surface or cutting speed.

When setting the blend function between level 0 and 9, it is possible to set a variably adjustable degree of surface scabbing.

4.1.2. "Moderate Coag" mode

This mode is used in contact coagulation for stopping hemorrhagic oozing, hemostasis of larger tissue areas, and coagulation over smaller surfaces.



4.1.3. "Forced Coag" mode

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If you wish to change the settings for "Forced Coag" mode, see section Menu program 3 "Forced Coag Mode", page 40.

This mode is used for contact coagulation extending over a short distance in the tissue, preferably using electrodes with fine tips or small surfaces.

Three sub-modes are available in "Forced Coag" mode:

Mode	Characteristics	Application
Non Cutting	High coagulation rate Minimal cutting tendency	Requirements for good coagulation without cutting tissue
Mixed Mode	High coagulation rate Moderate cutting effect	All standard applications (factory setting)
Cutting Mode	Good hemostasis Outstanding cutting effect	Preparatory cutting with the blue key

The simultaneous activation of two monopolar connection ports makes it possible to use two manually controlled instruments at the same time. Handles with finger switches can be connected to connection ports **29/30**. The handles are activated with the "Coag" button on the handle. Both handles can be switched on or off independently of one another.

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The set power applies to both connection ports. The distribution of the power depends on the tissue structure and may change during the application.

4.1.4. "Spray Coagulation" mode

This mode is used for contactless surface coagulation via arcing.

This mode is used for hemostasis in parenchymal tissue or in poorly accessible crevices and in conjunction with argon coagulation.

The simultaneous activation of two monopolar connection ports makes it possible to use two manually controlled instruments at the same time. Handles with finger switches can be connected to connection ports **29/30**. The handles are activated with the "Coag" button on the handle. Both handles can be switched on or off independently of one another.

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The set power applies to both connection ports. The distribution of the power depends on the tissue structure and may change during the application.



4.1.5. "GastroCut" mode

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If you wish to change the settings for "GastroCut" mode, see section Menu program 3A "GastroCut-Modes", page 41.

This mode consists of a pulse sequence of cutting current and coagulation phase.

This mode is used for the removal of polyps or for making incisions in papillae. The following applies:

- Blend 0 = low coagulation rate
- Blend 9 = high coagulation rate

Three sub-modes are available in "GastroCut" mode:

Mode	Characteristics	Application
Slow	Cutting characteristics: Slower pulse sequence	Recommended for particularly intricate tasks
Medium	Cutting characteristics: Dynamic	Recommended for skilled users (default setting)
Fast	Cutting characteristics: Dynamic and fast pulse sequence	Recommended for experienced users in this specialist area



4.2. Bipolar modes

Special instruments are necessary in order to achieve optimal results using the bipolar method (particularly with minimally invasive surgery).

Advantages of the bipolar method:

- The required high-frequency output is only one-fourth of the output required for the monopolar method.
- It is not necessary to apply a neutral electrode to the patient, which eliminates the associated risks to the patient.

Instruments can be connected to the bipolar output (socket connector 31).

The AUTOSTART mode can be activated only for bipolar coagulation.

In the AUTOSTART mode, the coagulation current is automatically added after low-resistance tissue contact of the connected bipolar instruments. Thus activation using the foot switch is not necessary.

If an output operating in AUTOSTART mode is activated using the foot switch, AUTOSTART mode is deactivated and the foot switch signal is used.

This type of current can be used for bipolar cutting instruments.

This type of current is suitable for the application of bipolar scissors, e.g. BOWA BiZZER.

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To prevent activation problems in AUTOSTART mode, we recommend limiting the bipolar cable length to 4.5 meters or less.

Forceps

Under moist conditions the forceps may be released accidentally, for example by contact with blood. This can cause an undesirable increase in the duration of the surgical therapy.

When the forceps are set aside with AUTOSTART enabled, inadvertent activation with associated risk of injury may occur when the forceps are wiped with a moist cloth or come in contact with metallic components, such as other instruments.



4.3. Activation and alarm signals in monopolar and bipolar mode

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The activation and alarm signals are output at volume level 1. The minimum volume is level 1. The volume of the activation signal should be increased as necessary for use in relativey noisy surrouondings. The maximum volume is level 10. The alarm tone is not adjustable.

Mode	Indicator in menu program	Frequency (Hz)	Signal type
Monopolar Cut	Sound Level 1	500	Continuous sound
Monopolar Coag	Sound Level 2	420	Continuous sound
Bipolar Coag	Sound Level 3	340	Continuous sound
Sim Coag	_	800	Continuous sound
GastroCut end	_	_	Pulsating alternating sound
Alarm	_	1000	Intermittent

4.4. Emergency shutoff

The HF device can be switched off at any time by using on/off switch 27 for emergency shutoff.

4.5. Monitoring functions

4.5.1. Self-test

When the HF device is switched on, it runs a self-test that checks the operating elements, acoustic signal, microprocessor and hardware for proper operation. If errors occur, see section Detecting and correcting faults, page 45.

4.5.2. Cyclical test during operation

During operation, safety-relevant functions and signals are tested cyclically. If errors are detected, the HF generator will shut itself off. An error message appears on the display. For further information, see section Detecting and correcting faults, page 45.

4.6. ARC Control technology

The "ARC Control" regulator takes varying cutting surfaces and cutting speeds into account, detects differences in tissue and the resulting changes in resistance, and adjusts the output power to the minimum level necessary under actual conditions.



4.7. Neutral electrode monitoring

Always use the largest possible electrode when attaching a neutral electrode.

4.7.1. General information

BOWA recommends using split neutral electrodes, since only this type of electrode allows the HF device to detect detachment of the neutral electrode if this occurs.

Monitoring of the neutral electrode minimizes the risk of burns at the site where the neutral electrode is attached.

Two types of neutral electrodes can be monitored:

- One-piece neutral electrodes
- Split neutral electrodes.

The split neutral electrodes are shown on display **20**, and the one-piece neutral electrodes are shown on display **19**, see chapter Error Display in EASY monitoring, page 49.

4.7.2. EASY neutral electrode monitoring (EASY monitoring)

The EASY monitoring system measures changes in resistance between the patient and the high-frequency surgery device both before and during HF activation. If required, it requests personnel to intervene via an optical and acoustic alarm. For this purpose, a split neutral electrode with corresponding contact surfaces and suitable transition resistances which is attached to the patient according to the manufacturer's instructions is required. The EASY system does not monitor partial currents in the two contact pads of the split neutral electrode.

The min. pad area of the electrode must be set to 110 cm² for the "Resection" program and the "Moderate Coagulation" mode.



4.8. Foot switch

In addition to the manual switch, the foot switch can be used to activate various operating modes.

A foot switch can be connected to socket connector **32**. The HF device automatically detects whether a foot switch is connected.

The following foot switch systems can be connected to the HF device:

Article No.	Designation
901-011	Single-pedal foot switch with pushbutton (SP+)
901-021	Double-pedal foot switch (DP)
901-031	Double-pedal foot switch with pushbutton (DP+)
901-032	Double-pedal foot switch with pushbutton and clip (DP+)

4.9. Memory functions

The generators in the ARC family allow the parameter settings of all programs to be stored.

To do this, set parameters such as output, blend factor, coagulation mode and foot switch assignment and then store them by pressing the AUTOSTART key **26** and keeping it pressed. This storage procedure only stores the current program.

The individual device settings and entered settings can be retrieved with the press of a button, see section Basic program settings, page 34.

The saved values will be stored even when the device is switched off.



5. Description

5.1. Icons on the device

Symbol	Designation
2	Foot switch connector
F	Neutral electrode isolated from ground for HF
⊣● ⊢	CF-type device with defibrillation protection
$\stackrel{\diamond}{\downarrow}$	Equipotential bonding
	Fuse
~	Alternating current
~	On/off switch
((<u>*</u>))	During activation (of the HF device) RF energy in the radio frequency range 9 kHz to 400 GHz is applied, which produces electromagnetic radiation.
4	Labeling of electrical and electronic devices in accordance with Directive 2002/96/EC (WEEE), see Disposal
	Identification of (active) HF output; caution: dangerous electrical voltage!
	Manufacturer
سا	Date of manufacture
③	Comply with the user manual
	Foot switch
<u>—</u>	Finger switch
⊕⊕→→	AUTOSTART
⊕	Fiber-optic signal input
Θ	Fiber-optic signal output
Ronly	Caution: May only be sold and prescribed by doctors. For the attending doctor only.
REF	Product number
SN	Serial number
(€ ₀₁₂₃	CE mark and number of notified body This product complies with the essential requirements of the Medical Device Directive 93/42/EEC.



5.1.1. Rating label

The device has been configured with the correspondingly required voltage range in accordance with its authorisation and is delivered with the respective type plate.

Mains voltage: 100-127 V~ / 220-240 V~

Input current: 10 A@100 V / 4 A

8 A@127 V

Power fuse: 2x T 10 AH 250 V / 2x T 5 AH 250 V

5.2. Scope of delivery

You'll find detailed information on the scope of delivery in the current catalogs.

5.3. Components required for operation

- Power cable
- Foot switch
- Neutral electrode
- Electrode handle for monopolar applications with finger keys or activation via foot switch
- Working electrode
- Connection cable

5.4. Operating conditions

Temperature: +10 °C to +40 °C

Relative humidity: 30% to 75%, non-condensing

Atmospheric pressure: 700 hPal to 1060 hPa

Max. operating altitude: 3000 m a.s.l.



6. Preparation

6.1. Setting up the HF device





When the HF device is used as intended, electromagnetic fields are generated. This can affect other devices.

 Ensure that no electronic devices are set up in the vicinity of the HF device.



WARNING

Shock hazard!

Always connect the HF device to a mains power system with a protective earth lead in order to prevent electric shock.



▲ DANGER

Risk of burns to patients due to excessive leakage current!

Do not place the HF device in the immediate vicinity of the patient, see section Ambient conditions, page 12.

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HF devices may be used only in rooms used for medical purposes that meet the requirements of DIN VDE 0100-710.

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If the HF device was previously stored or transported at temperatures below +10 °C, it will take approximately three hours to adjust to room temperature.

- Observe and comply with the operating conditions, see chapter Operating conditions, page 26
- 2. Place the HF device on one of the following platforms:
 - a table,
 - an equipment trolley,
 - a console suspended from a ceiling support or wallmounted brackets.
 - if necessary, position the HF generator on the additional device ARC PLUS

Except for the additional device ARC PLUS, do not place any other devices on the HF device

3. Set up the HF device with sufficient clearance to other electronic devices, see section EMC, page 79.



- 4. Position the HF device with the front of the device facing the patient/surgeon.
- 5. Do not place any other objects on or above the HF device.
- 6. Do not set up the HF device on other devices.
- 7. Connect the power cable.

6.2. Switching on the HF device

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Do not use the HF device if the indicator elements are not working. For error correction, see section Detecting and correcting faults, page 45.

- 1. Switch the HF device on using the on/off switch 27.
- The HF device carries out a self-test: all indicator elements light up and blink alternately with the display.

All modes that can be set in the menu programs are displayed alternately. For more information about the setting options, see section Menu programs, page 39.

- Check whether all the indicators (2, 7, 9, 12, 13, 14, 15, 22, 25, 26) and LEDs (1, 8, 18, 19, 20, 21) on the front panel light up and flash alternately with the display.
- 3. Press any key to end the self-test.
- The HF device is ready for operation.
- The parameters of the most recently selected program appear on the display.

A self-test is carried out if the device is switched off for longer than 15 to 20 seconds after being used. The default parameters of the most recently selected program subsequently appear.



6.3. Connecting instruments

- ▶ Before connecting instruments, ensure that the following conditions are met:
 - Combinations of accessories not mentioned in the operating manual may be used only if they are explicitly designed for the intended use. Performance features as well as safety requirements must always be taken into account.
 - The insulation of the accessories (e.g. HF cables, instruments) must be sufficient for the maximum output peak voltage (see IEC 60601-2-2 and IEC 60601-2-18).
 - Do not use accessories with defective insulation.

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In order to arrange and protect all cables connected to the HF device, use the pull-out cable guide on the left underside of the device.

6.3.1. Instruments for monopolar applications

- 1. Plug the neutral electrode cable into the socket for the neutral electrode **28**.
- Check EASY monitoring for a one-piece neutral electrode 19 or EASY monitoring for a split neutral electrode 20 to ensure that it corresponds to the type of neutral electrode connected.
- Connect the electrode handpiece to the active socket connector 29/30.

– or –

With accessories lacking finger buttons: connect a foot switch to socket connector **32**, and connect the monopolar connection cable to the Bovie jack on connection port **30**.

- or -

Connect the monopolar cable for endoscopy to the socket connector for monopolar instruments **30** (left).

6.3.2. Instruments for bipolar applications

- 1. Connect the bipolar cable with the instrument, e.g. the tweezers.
- 2. Connect the bipolar cable to the active socket connector 31.
- 3. For bipolar use without AUTOSTART, connect a foot switch to socket connector **32**.

- or -

For bipolar use with AUTOSTART, press the AUTOSTART key 26.

Once the contact is closed, the application starts after the configured response time.

6.3.3. Connecting the foot switch

Connect the desired foot switch to the foot switch socket connector 32.



Standard arrangement:

Single-pedal foot switch \rightarrow monopolar coagulation (with ARC 303 connection port **30**).

Double-pedal foot switch → cutting and monopolar coagulation.

6.3.4. Assigning a foot switch output

 Press the extra button on the dual foot pedal swiitch (e.g. for "Bipolar Output" 31).

– or –

Key/indicator for "Foot Switch" 25.

- The "Bipolar Foot Switch" indicator **25** will light up and an alternating acoustic signal will be emitted for acoustic confirmation of the switchover process. The blue foot switch pedal is now activated for bipolar coagulation.
- 2. Press the key/display for AUTOSTART **26** for longer than 5 seconds.
- The configured HF parameters will be saved and the symbol -> appears on the display or main display 15.



6.4. Functional test

6.4.1. Autotest function

The HF device automatically carries out a self-test after being switched on and a cyclical test during operation. If errors occur, see section Detecting and correcting faults, page 45.

6.4.2. Functional test execution

Perform the following functional test before putting the device into service:

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The accessories must be designed for the indicated maximum voltage.

- 1. Connect the neutral electrode and attach it to the patient's arm.
- The EASY neutral electrode indicator 19/20 changes to green.
- 2. Remove the neutral electrode.
- The indicator **18** changes to red, acoustic signals sound, and the EASY neutral electrode monitoring indicator **19/20** goes dark.
- 3. Press the surfaces of the neutral electrode against each other.
- The EASY neutral electrode monitoring indicator **19/20** changes back to green.

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The neutral electrode used for this test may not later be used for an operation.

- Connect a monopolar HF handpiece to a monopolar socket connector 29/30 and use the hand and foot switches to individually activate "Cut" and "Coag".
- 5. Check the settings on the display.
- 6. Now change to the bipolar output and connect bipolar tweezers.
- Press the key/display for AUTOSTART 26 again and use the foot switch to activate the bipolar output. Check the settings and indicators in the bipolar section.
- 8. Press the key/display for AUTOSTART **26** again and use the foot switch to activate the bipolar output. Check the settings and indicators in the bipolar section.

6.4.3. Actions in case of problems

Proceed as follows in case of functional problems:

- 1. Immediately disconnect the patient from the HF device.
- 2. Inspect the HF device and perform a functional test.



- 3. Report incidents and near-accidents to the German Federal Institute for Medications and Medical Products in accordance with Section 3 of the German Ordinance on the Installation, Operation and Use of Medical Products (MPBetreibV). Observe the provisions of the in-house reporting system in this regard.
- Contact the service center, see section Technical service, page 53.

6.4.4. **EASY** neutral electrode electrode monitoring (EASY monitoring)



NOTE



Risk of incorrect application of the neutral electrode!

Ensure compliance with the specifications for correct application of the neutral electrode with regard to size, adhesive properties and full-surface contact of the complete electrode.

The following functions can be tested for split and one-piece neutral electrodes:

Actual status	Output	Measure
Cable for one-piece or split neutral electrode not connected	Indicators for EASY monitoring of split neutral electrode 20 or EASY monitoring of one-piece neutral electrode 19 do not light up	Plug in the cable for the one-piece or split neutral electrode.
Only the cable for the one- piece or split neutral electrode is connected	Indicators for EASY monitoring of split neutral electrode 20 or EASY monitoring of one-piece neutral electrode 19 light up	Check the cable for a short circuit.
Cable with split neutral electrode plugged in but not attached to patient.	Indicators for EASY monitoring of split neutral electrode 20 or EASY monitoring of one-piece neutral electrode 19 light up	Check whether the electrode is correctly attached to the cable connection.
The cable for the split or one- piece neutral electrode is plugged in and attached to the patient.	The indicators for EASY monitoring of the split neutral electrode 20 or EASY monitoring of the one-piece neutral electrode 19 light up green, but the type of neutral electrode is not correctly detected.	Based on the assessment of benefit and harm, decide whether you should activate the HF device.



7. Operation

7.1. Program overview

An overview of the programs that can be executed with the HF device is displayed below.

Program number	Program name	ARC 250	ARC 303
0	Standard	X	X
1	Macro	X	X
2	Micro	X	Х
3	Resection	X	Х
4	Argon	GastroCut option	GastroCut option
5	Argon-Flex	GastroCut option	GastroCut option
6	Gastro LOOP	GastroCut option	GastroCut option
7	Gastro KNIFE	GastroCut option	GastroCut option

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The data about settings, points of application, application duration, and the application of instruments are based on clinical practice. However, these are only basic guidelines which must be tested and approved for suitability by the operator. Depending on the individual conditions, it may be necessary to deviate from the specified data. Medicine is continuously evolving and growing due to R&D and clinical practice. These developments may also make deviations from the specified data necessary.

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All programs have basic settings, e.g. operating language, sound or display and memory options, which can be changed for individual applications, see section
Menu programs, page 39.



7.2. Basic program settings

7.2.1. Calling up a program

Call up each of the selectable programs with the following procedure:

- 1. Press the program key **16/17** repeatedly until the corresponding program is shown on the display.
- 2. Connect the instrruments, see section Connecting instruments, page 29.

7.2.2. Changing the program

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The preconfigured programs can be selected from 0 to 7. The parameters of the preconfigured programs can be changed, and the new parameters can be saved. Only the specific types of current cannot be changed. To change the parameters, make settings such as power level, blend factor, coagulation mode and foot switch assignment and then store them by pressing the AUTOSTART key **26** and keeping it pressed.

Programs 8 to 99 are fully user configurable. These programs output standard types of current.

You can change the following factory settings:

Select cutting settings

Press the power limitation key for monopolar cutting 3 or 4.

Set blend factor

- 1. Press key 5 or 6 for the monopolar scabbing level.
- 2. Set the blend factor from 1 to 9, or to 0 for coagulation-free cutting.

Select current type for coagulation current

1. Press key/display 12 for "Moderate Coagulation" current

– or –

Press key/display 13 for "Forced Coagulation" current

- or -

Press key/display 14 for "Spray Coagulation" current

Set the power limit for the monopolar coagulation current using the keys for power limitation for monopolar coagulation 10/11.

- or -

1. Set the power limit for the bipolar coagulation current using the keys for power limitation for bipolar coagulation **23/24**.



7.3. Program descriptions

The following recommended settings for standard programs are based on empirical values and must be verified in each individual case by the surgeon.

7.3.1. Program 0 "Standard"

This program is used for monopolar/bipolar cutting and coagulation in standard applications.

7.3.2. Program 1 "Macro"

This program is used in plastic surgery of the hand and maxillofacial region.

7.3.3. Program 2 "Micro"

This program is used in the lower output range with fine electrodes for microscopic tissue structures.

7.3.4. Program 3 "Resection"

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- Both cutting and coagulation are possible with monopolar operation.
- Use the socket connector for monopolar instruments 29/30 for monopolar Resection/TUR.
- Only the Standard coagulation current is available at the "Bipolar Output" 31.

This program is used for underwater cutting during transurethral and transvaginal resection and vaporisation on prostata, bladder, and uterus.

In this program, the resection snare is used for cutting and coagulation. Arc control technology generates the cutting effect with simultaneously minimized output power.

ARC control facilitates immediate cutting and prevents adhesion of the electrodes.

- The key/display for "Monopolar Output" **29/30** and "Bipolar Output" **31** are preconfigured.
- Connect the monopolar resectoscope to the "Monopolar Output" 29/30.



7.3.5. Program 4 "Argon" (only with GastroCut option)

In this program, open surgical interventions are carried out with the additional device ARC PLUS for argon electrocoagulation. When suitable instruments are connected, argon coagulation can be carried out with rigid electrodes and argon cutting.

- 1. Connect the additional device ARC PLUS.
- Connect the argon handpiece with the rigid probes to the ARC PLUS.
- 3. Connect the surgical handpiece to the HF device.

7.3.6. Program 5 "Argon-Flex" (only with GastroCut option)

This program is used in argon electrosurgery with ARC PLUS.

In this program, surgical interventions are carried out with endoscopic use of flexible probes with the additional device ARC PLUS for argon electrocoagulation.

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The connection port **29** has no function in the "Argon-Flex" program.

- ☑ The key/display "Monopolar Output" **30** is preconfigured.
- Connect the additional device ARC PLUS.
- 2. Connect the flexible probes to "Monopolar Output" **30** of the HF device.

7.3.7. Program 6 "Gastro LOOP" (only with GastroCut option)

This program is used in gastroenterology.

In this program, polypectomy snares are used for cutting and coagulation.

Arc control technology generates the cutting effect with simultaneously minimized output power.

ARC control facilitates immediate cutting and prevents adhesion of the electrodes.

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The degree of coagulation increases with an increasing blend factor.

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The connection port **29** has no function with the programs "Gastro LOOP" and "Gastro KNIFE".



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Three modes are available in this program: fast (approximately 3 cutting pulses per second), medium (approximately 1.6 cutting pulses per second) and slow (approximately 1 cutting pulse per second).

For more information on "GastroCut" mode, see section "GastroCut" mode, page 20.

- ☑ The key/display "Monopolar Output" 30 is preconfigured.
- 1. Connect the polypectomy snares to the socket for "Monopolar Output" **30** (use an adapter if necessary).
- 2. Connect the foot switch to the HF device.
- Activate the HF current via the yellow key of the foot switch for cutting.
 - or -

Activate the HF current via the blue key of the foot switch for coagulation.

- 4. Set the coagulation level using the keys for scabbing level **5/6**.
- Press keys 3 and 4 to switch between: slow (non-accelerated) GastroCut Pol; dynamic (medium speed; default) GastroCut Pol; fast dynamic (accelerated) GastroCut Pol.
- In the case of hemorrhages:
 Press the key/display for "Forced Coagulation" current 13 or use a clip.
- If necessary, remove the polypectomy snares and connect the argon probe and the ARC PLUS argon unit.
- 8. Press the key/display for "Spray Coagulation" current" 14.
- 9. Press the blue key of the foot switch for coagulation.

7.3.8. Program 7 "Gastro KNIFE" (only with GastroCut option)

This program is used in gastroenterology. Papillotomes and endoscopic resection instruments are used for cutting and coagulation.

ARC control technology generates the cutting effect with simultaneously minimized output power.

ARC control facilitates immediate cutting and prevents adhesion of the electrodes.

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The connection port **29** has no function with the programs "Gastro LOOP" and "Gastro KNIFE".



Three modes are available in this program: fast (approximately 2.5 cutting pulses per second), medium (approximately 1.8 cutting pulses per second) and slow (approximately 1.4 cutting pulses per second).

For more information on "GastroCut" mode, see section "GastroCut" mode, page 20.

- ☑ The key/display "Monopolar Output" 30 is preconfigured.
- 1. Connect the papillotome to the socket for "Monopolar Output" **30** (use an adapter if necessary).
- Connect the foot switch to the HF device.
- 3. Activate the HF current via the yellow key of the foot switch for cutting.

– or –

Activate the HF current via the blue key of the foot switch for coagulation.

- 4. Set the coagulation level using the keys for scabbing level **5/6**.
- Press keys 3 and 4 to switch between: slow "Gastro KNIFE" (non-accelerated), dynamic " Gastro KNIFE" (medium speed; default) and fast dynamic " Gastro KNIFE" (accelerated).
- 6. In the case of hemorrhages:

 Press the key/display for "Forced Coagulation" current **13** or use a clip.
- 7. If necessary, remove the papillotome and connect the argon probe and the ARC PLUS argon unit.
- 8. Press the key/display for "Spray Coagulation" current" 14.
- 9. Press the blue key of the foot switch for coagulation.



7.4. Menu programs

The menu programs are standard programs for specifying basic parameters, such as the operating language, sound, display and memory options of the main programs.

7.4.1. Overview

The following menus are available:

- Menu program 1 "Set Language"
- Menu program 2 "Sound Level"
- Menu program 3 "Forced Coag Mode"
- Menu program 3A "GastroCut-Modes"
- Menu program 4 "Show Prev Inf-No"
- Menu program 5 "Hide Fix Prog"
- Menu program 6 "AutoStart Delay"
- Menu program 7 "Edit Prog Names"
- Menu program 8 "Restore Programs"
- Menu program 9 "Panel Check"

Selecting a menu program

- When switching on the device, simultaneously press the on/off switch 27 and the program selection switch 17 to see the list of menu programs.
- The current software version is displayed on the display/main display **15**.
- 2. Press the menu selection switch **16** to select a menu program.
- 3. Press the power limitation key for monopolar cutting **4** to launch the selected program.

Exiting a menu program

Press the power limitation key for monopolar cutting 3 to return to the list of menu programs.

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When the HF device is switched off, the new settings will be saved automatically.



7.4.2. Menu program 1 "Set Language"

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The language of the menu programs is English and cannot be changed.

Use menu program "Set Language" to set the language for the standard programs (language codes D = Deutsch; E = English; F = Français; I = Italiano; S = Español; T = Türk; P = Polski).

- 1. Press the power limitation key for monopolar cutting 4.
- 2. Press the key for scabbing level **5/6** to select the appropriate language.
- 3. Press the power limitation key for monopolar cutting **3** to return to the menu programs.

After the front panel test has been run after the device is switched on, the selected language is shown by the language code letter on the "Bipolar Coag" display 22.

7.4.3. Menu program 2 "Sound Level"

Use "Sound Level" to set the volume of the individual activation signals.

- 1. Press the power limitation key for monopolar cutting 4.
- 2. Press the key for scabbing level **5/6** to change the volume.
- 3. Press the power limitation key for monopolar cutting **11** to select the next acoustic signal.
- 4. Press the power limitation key for monopolar cutting **3** to return to the menu programs.

7.4.4. Menu program 3 "Forced Coag Mode"

Use "Forced Coag Mode" to set the cutting and coagulation parameters of the "Forced Coag" current.

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For more information on "Forced Coag" mode see section "Forced Coag" mode, page 19.

- 1. Press the power limitation key for monopolar cutting 4.
- 2. Press the key for scabbing level **5/6** to change the forced coagulation mode.
- 3. Press the power limitation key for monopolar cutting **3** to return to the menu programs.



7.4.5. Menu program 3A "GastroCut-Modes"

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For more information on "GastroCut-Modes", see section "GastroCut" mode, page 20.

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You can configure a control tone for each cutting pulse in the "GastroCut" program. This setting can only be made in the Service program, and it applies to both "Gastro LOOP" and "Gastro KNIFE".

Changing the cutting speed for "Gastro LOOP"

- 1. Press the power limitation key for monopolar cutting 4.
- Press the key for scabbing level 5/6 to swicth between slow "Gastro LOOP" (non-accelerated), dynamic " Gastro LOOP" (medium speed; default), and fast dynamic " Gastro LOOP" (accelerated).
- 3. Press the power limitation key for monopolar cutting **3** to return to the menu programs.

Changing the cutting speed for "GastroCut Pap"

- 1. Press the power limitation key for monopolar cutting 4.
- Press the key for monopolar coagulation 10/11 to swicth between slow "Gastro KNIFE" (non-accelerated), dynamic " Gastro KNIFE" (medium speed; default), and fast dynamic " Gastro KNIFE" (accelerated).
- 3. Press the power limitation key for monopolar cutting **3** to return to the menu programs.

Enabling or disabling the control tone for cutting pulses

- 1. Press the power limitation key for monopolar cutting 4.
- 2. Press the key for power limitation bipolar coagulation **23/24** to enable or disable the control tone for cutting pulses.
- 3. Press the power limitation key for monopolar cutting **3** to return to the menu programs.



7.4.6. Menu program 4 "Show Prev Inf-No"

The errors saved in the HF device are called up in the "Show Prev Inf-No" menu program.

- 1. Press the power limitation key for monopolar cutting 4.
- 2. Press the key for scabbing level **5/6** to call up individual errors.
- The error number will appear on the main display 15.
- Press the key/display for AUTOSTART 26 to call up the last 10 errors.
- The error number will appear on the main display 15.
- 4. Press the power limitation key for monopolar cutting **3** to return to the menu programs.

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See the service manual for additional information on menu program 6.

7.4.7. Menu program 5 "Hide Fix Prog"

The "Hide Fix Prog" menu program hides standard programs that are not required.

- 1. Press the power limitation key for monopolar cutting **4**.
- 2. Press the power limitation key for bipolar coagulation **24** to display all standard programs.
- The message "All FixPgm active" appears on the display/main display 15.
- 3. Press the power limitation key for bipolar coagulation **23** to hide all standard programs.
- The message "No FixPgm active" appears on the display/main display **15**.

– or –

Press the key/display for AUTOSTART **26** to show or hide individual standard programs.

- 4. Press program key **16/17** to browse the standard programs.
- 5. Press the power limitation key for monopolar coagulation **10** to hide the standard program.

- or -

Press the power limitation key for monopolar coagulation **11** to show the standard program.

6. Press the power limitation key for monopolar cutting **3** to return to the menu programs.



7.4.8. Menu program 6 "Autostart Delay"

Use menu program "Autostart Delay" to change the delay time in AUTOSTART mode.

- 1. Press the power limitation key for monopolar cutting 4.
- 2. Press the power limitation key for monopolar coagulation **10/11** to adjust the start-up delay in 50 ms increments (from 50 to 2500 ms).
- 3. Press the power limitation key for monopolar cutting **3** to return to the menu programs.

7.4.9. Menu program 7 "Edit Prog Names"

Use the menu program "Edit Prog Names" to edit the text shown on the display/main display for user-defined programs.

Press the power limitation key for monopolar cutting 4.

Editing text in the display/main display

- 1. Press the program key **16/17** to select the program to be edited.
- 2. Press the key/display **12** for moderate coagulation in order to enable editing mode.
- Both EASY indicators 19/20 will light up.
- 3. Press the key for scabbing level 5 or 6 to select a letter or number.
- 4. Press the power limitation key for monopolar coagulation **10/11** to toggle between upper and lower case.
- 5. Press the power limitation key for monopolar cutting **4** to select the next letter or character.
- 6. Press the power limitation key for monopolar cutting **3** to delete the last letter or character.
- 7. Press the key/display for AUTOSTART **26** to save entered names.
- 8. Press the power limitation key for monopolar cutting **3** to return to the menu programs.

Deleting the text in the display/main display

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All HF parameters of the deleted programs will also be deleted.

- Press the power limitation key for bipolar coagulation 23 and the key/display for AUTOSTART 26 to delete the entire text entry for the selected program.
 - or –
- Press the power limitation key for bipolar coagulation 24 and the key/display for AUTOSTART 26 to delete all entries in the freely selectable HF programs (8–99).
- 3. Press the power limitation key for monopolar cutting **3** to return to the menu programs.



7.4.10. Menu program 8 "Restore Programs"

Menu program "Restore Programs" resets all modified parameters of standard programs in the HF device to the factory default settings.

- 1. Press the power limitation key for monopolar cutting **4** to reset the standard programs (0-7).
- 2. Press the key/display for AUTOSTART **26** to confirm the reset.
- After the restoration procedure has been completed, the program automatically returns to the menu programs.

7.4.11. Menu program 9 "Panel Check"

Menu program "Panel Check" activates all illuminated indicators and displays on the control panel.

- Press the power limitation key for monopolar cutting 4 to activate all lighting components.
- 2. Press the power limitation key for monopolar cutting **3** to return to the menu programs.



8. Detecting and correcting faults

Two types of faults can occur:

- system faults
- EASY monitoring faults

8.1. System errors

When a system error occurs, the error indicator **18** lights up red. "INF" appears on the "Monopolar Cut" display **2**, and a one- to three-digit error code appears on the "Monopolar Coag" display **9**.

8.1.1. Error list

Errors not listed

- ► Contact the service center in case of errors not shown in the error list, see section Technical service, page 53.
- ▶ If the expected change in the tissue does not occur and no error message appears, check the parameters and the accessory connections.

Visual and acoustic signals indicating errors

The error messages are accompanied by visual and acoustic signals. Furthermore, the generator cancels activation if certain errors occur and the system is reset.

Optical and acoustic signals:

Signals	Designation
\hookrightarrow	"Output error" indicator lights up red
InF	Display and storage of the message number
₫ ;	Acoustic warning signal sounds

System events:

System events	Designation
RESET	System reset
	Generator cancels activation

Contact the service center if the suggested corrective measure does not eliminate the error, see section Technical service, page 53.



Error no. (INF)	Signals/ System events	Cause	Corrective measures
1	\hookrightarrow	Defective cable or output set too low	Check/Replace the cable.Set the output higher.
2	⊖ • InF □	Defective cable or output set too low	 Check/Replace the cable. Set the output higher.
6	⊖ • InF •	Internal error	Restart the device. If the error recurs, contact the service center.
11	⊖ • InF	Constant power is output at a constant resistance over a longer period.	Check the connection and the accessories.
22	⊖ • InF •	Internal error	Restart the device. If the error recurs, contact the service center.
40	☐ ☐ InF ☐	Additional device ARC PLUS not connected / not switched on / offline	 Switch the additional device ARC PLUS on. Check the connection to the interface.
43	⊖ InF ∰	Key on front panel pressed when switching on the unit	Switch on the device with the on/off switch 27 while taking care not to press any other key at the same time.
44	⊖ InF ∰	Finger or foot switch activation is pending when the device is switched on	Switch on the device with the on/off switch 27 while taking care not to press any other key at the same time.
45	⊖ • InF □(÷	Both keys of the handpiece have been actuated at the same time	Press only one key of the handpiece at a time.
46	⊖ • InF □	Both pedals of the double-pedal foot switch have been activated simultaneously	Activate only one pedal of the double-pedal foot switch.



Error no. (INF)	Signals/ System events	Cause	Corrective measures
47		No power set for the activated output	Set the power for the activated output.
49	○→ •• InF □(÷	Connection socket activated via finger and foot switches At the end of activation a different activation signal is pending for the same socket	Activate the output via the finger or foot switch one after the other.
61	⊖ • InF ⊕	Tissue contact is already pending upon activation of the AUTOSTART mode	Remove the instrument from the tissue and re-activate AUTOSTART.
90	⊖ • InF •	Papillotome or snare is not applied	Apply the papillotome or the snare.
91	⊖ • InF •	Instrument for GastroCut application defective or short circuit	Replace the Gastro instrument.Select a new point of application.
92	☐ ☐ InF ☐ ☐	Excessive low-resistance activation (e.g. in saline)	Ensure that the instrument has sufficient contact with the tissue for coagulation or cutting before activating the device.
100-104	☐ ☐ InF ☐ ☐	EASY neutral electrode error	Check the neutral electrode and the neutral electrode cable, see section Neutral electrode monitoring, page 23.
146	☐ ☐ InF ☐	Internal error	Restart the device. If the error recurs, contact the service center.
147	☐ ☐ InF ☐ ☐	Internal error	Restart the device. If the error recurs, contact the service center.



Error no. (INF)	Signals/ System events	Cause	Corrective measures
149	⊕ InF H	 3-pin plug of the handpiece has been inserted incorrectly Handpiece possibly defective Monopolar 4-mm connecting cable plugged into the right-hand monopolar output socket 29/30 	 Check the handpiece. Replace the handpiece. Plug the 4-mm connecting cable into the left-hand 4-mm monopolar output socket 29/30.
150 – 255		Internal error	Restart the device. If the error recurs, contact the service center.



8.2. Error Display in EASY monitoring

When working with a split neutral electrode, the following errors may occur:

EASY monitoring 20	Cause	Indicator	Corrective measures
Blinks yellow	Significant increase in resistance Heat may develop under the neutral electrode depending on indication	_	Application need not be terminated.
Switches from green to continuous red	When the monopolar current is activated, a significant problem occurs	An acoustic signal sounds. A corresponding "INF - xxx" message appears on the "Monopolar Cut" 7-segment display 2 and the "Monopolar Coag" 7-segment display 9.	 Check the neutral electrode and the neutral electrode cable, see section Neutral electrode monitoring, page 23 Check the neutral electrode cable for proper contact and external damage.
	Loosening electrode	An acoustic signal sounds. A corresponding "INF – xxx" message appears. The device disables the monopolar outputs to sockets 29/30 and 31.	Correct the position of the neutral electrode. In the case of continuing error messages, replace the neutral electrode.



Preparation 9.

9.1. Disinfection and cleaning



NOTE

Incorrect handling of the HF device can cause damage to the unit!

Never sterilize the ARC 250 / 303 device. Instead, clean or disinfect it.

WARNING

Risk of electric shock and fire!



- Unplug the power connection before cleaning the device.
- For cleaning surfaces, use the approved cleaning agents/disinfectants only as specified by the manufacturer.
- Ensure that no liquid penetrates the device.
- Ensure that the AUTOSTART function is deactivated.
- Apply the cleaning agent and disinfectant. 1.
- Wipe the agent off with a sponge moistened with clean water or with a cloth.
- 3. Dry the device using a clean, lint-free cloth.



10. Maintenance and repair

10.1. Maintenance

♠ DANGER



Infection hazard!

- Carry out a surface disinfection and wrap the device in addition to the shipping packaging material before allowing the device to leave the hospital or office to avoid spreading germs and infections.
- Check the device, the device trolley and the accessories (e.g. foot switch, cable) after each use for damage or defects. In particular, make sure that the insulation is intact on all cables.
- Do not use any damaged device, damaged device trolley or damaged accessories.
- Replace defective accessories immediately.
- Have the safety inspection for the device performed once a year. Please consult and comply with the respective service instructions for additional technical information.

10.1.1. Safety inspection

Safety inspections must be performed once a year.

- The device and accessories may be inspected only by persons who have the required training, knowledge or experience and who can perform the inspection independently.
- With regard to the safety inspection, you must comply with the country-specific rules and regulations.

The inspector documents the inspection results and measured values corresponding to the printed inspection protocol.

In the case of severe deviations from the values of the attached final acceptance report, or if the specified maximum values were exceeded:

Send the HF device to the service center, see section Technical service, page 53.



10.2. Repairs



NOTE



You can damage the HF device by doing your own repairs and modifications of medical equipment!

- If a repair is necessary, have it done only by the service center specified below.
- Never carry out any repairs yourself.

BOWA is liable for safety, reliability and performance of the HF device under the following conditions:

- full compliance with all instructions regarding the installation and proper use for the intended purpose contained in this operating manual was maintained.
- changes, repairs, new settings and similar procedures were carried out only by persons authorized to do this work by BOWA.
- the electrical installations in the relevant room meet the local requirements and statutory provisions.

Fast and satisfactory repairs can only be guaranteed when all required data have been supplied in full.

The following information is required for returning the device:

- complete address
- model number
- serial number
- software version
- Describe the problem, the appropriate application and the accessories used.

Describe the repairs to be made.



10.3. Technical service

Contact the following service center for maintenance and repair work:

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4-10

72810 Gomaringen, Germany

Phone +49 (0) 7072-6002-0

Fax +49 (0) 7072-6002-33

E-Mail service@bowa.de

or visit our website:

www.bowa-medical.com

11. Storage

- ▶ If you store the HF device for longer that one year, pay specific attention to the indicators during automatic functional testing, see section Functional test, page 31.
- Clean the HF device thoroughly before you put it into storage.
- Store the HF device in a clean, dry place in accordance with the storage conditions.

Storage conditions:

• Temperature: -20 °C to +50 °C

Relative humidity
 0% to 75 %, non-condensing

• Atmospheric pressure: 500 hPa to 1060 hPa



12. Technical specifications

12.1. Technical specifications of ARC 250 and ARC 303 HF devices

Insulation type / Classification	
EMC	IEC 60601-1-2: 2014
Level of protection provided by the housing	IP 21
Protection class according to EN 60601-1	I
Type of application component as specified in EN 60601-1	CF
Compliance with standards	IEC 60601-1: 2005 + Cor.1 (2006) + Cor. 2 (2007) + A1: 2012 IEC60601-2-2:2017 IEC 60601-1-2: 2014, IEC 60601-2-2: 2009, ISO 14971: 2007, ISO 13485: 2003 + Cor.1_2009
Classification as per EC Directive 93/42/EEC	Ilb

Power connection	
Power consumption in standby mode	65 VA
Line frequency	50/60 Hz
Maximum power consumption with 300 W HF output power	930 VA
Connection for potential equalization line	Yes

Voltage range: 220 V – 240 V	
Input voltage range	120 V to 240 V
Current consumption in standby mode	0,29 A
Current consumption at maximum HF output	4,0 A
Mains fuses	2 x 5 AH T

Voltage range: 100 V – 127 V	
Input voltage range	100 V to 127 V
Current consumption in standby mode	0,45 A
Current consumption at maximum HF output	7,1 A
Mains fuses	2 x 10 AH T



Dimensions and weight	
External dimensions: width x height x depth (mm)	430 x 150 x 400
Weight	Approx. 10 kg

Programs	
Number of programs in the device	100
Standard programs, factory set	\checkmark
Individually programmable	\checkmark
Program number and information shown on the display	V

Monitoring of the neutral electrode	
EASY: Electrode Application System	\checkmark
Indicator for one-piece or split electrode on the front panel	$\sqrt{}$
Transition resistance between the individual surfaces (CQM) of split neutral elecrodes shown on the display	V
Lead resistance shown on the display when using a one-piece neutral electrode (CM continuity monitor)	$\sqrt{}$
Maximum resistance between the sections of split electrodes (CQM)	999 Ω
Maximum allowable resistance between the sections of split electrodes	220 Ω
Warning signal in the case of risk under the neutral electrode	Visual, acoustic
Warning indicator as a text on the display:	\checkmark

Safety features	
ISSys: Integrated Safety System	\checkmark
Continuous monitoring of the HF leakage current with error messages	V
Monitoring of the dosage, error message on the display	$\sqrt{}$
Continuous self-test	\checkmark
Continuous status indication on the display	√
Display of operating errors on the display	√
Display of system errors on the display	√



Documentation	
Recording and storage of data in the device	\checkmark
Error statuses	$\sqrt{}$
Operating errors	\checkmark
Retrieval of this data via the display	√

Communication	
External interface for communication with the ARC PLUS	$\sqrt{}$
External PC interface using BOWA software	
Service support using BOWA software	

Service support	
Service support integrated in the device via service programs	√
Service support via ISSys	$\sqrt{}$

Cooling	
Convection	$\sqrt{}$
Temperature-controlled fan	

Duty factor	
Intermittent	10 s / 30 s (on/off)



\$20	-			Monopolar cutting "Gastro yes ye	Mode: Slow	Monopolar cutting "Gastro yes ye LOOP" Mode: Medium	ing "Gastro yes	LOOP" Mode: Fast	Monopolar cutting "Gastro yes ye KNIFE"	cutting "Gastro yes	Mode: Medium	Monopolar cutting "Gastro yes ye KNIFE" Mode: Fast	Monopolar "Moderate Contact Coagulation"	
ARC control	 =			yes sinusoidal, modulated		yes sinusoidal, modulated	yes sinusoidal,	modulated	yes sinusoidal, modulated	yes sinusoidal, modulated		yes sinusoidal, modulated	sinusoidal	
Nominal frequency	330 KHZ			330 KHZ		330 KHZ	330 KHz		330 KHZ	330 KHz		330 KHZ	330 KHZ	
əbeijo _n yeəd [.] xeW	950 Vp for "Monopolar Cut"	570 Vp for "MicroCUT/MacroCUT"		d∧ 008		dv 008	800 Vp		800 Vp	dv 008		d∧ 008	190 Vp for "Standard"	150 Vp for "Micro Moderate Coag"
Display of output, 7-segment display	3 places	2 places		10 places		10 levels	10 levels		10 levels	10 levels		10 levels	3 places	2 places
Max. Dower or the state of the	250 W (ARC 250) 300 W (ARC 303)	30 W for "MicroCUT"	75 W for "MacroCUT"										120 W	30 W for "Micro Moderate Contact Coagulation"
HF power limitation	1 to 300 W, adjustable in 1 W steps	1 to 30 W, adjustable in 1 W steps	1 to 75 W, adjustable in 1 W steps										1 to 120 W, adjustable in 1 W steps	1 to 30 W, adjustable in 1 W steps
Accuracy of HF power	± 20 %							_				_ =	± 20 %	
Effect setting	10 levels		▼	10 1 levels	Ac	10 1 levels Ad	┺	levels Ac	10 1 levels Act	10 1 levels	Ac	10 1 levels Ad		4 4
s _{IndinO}	1, type 3 pin + Bovie	Activation with finger switch and foot switch	ARC 303: +1 type 3 pin with finger switch	1, type 3 pin, 4 mm + Bovie	Activation only with foot switch	1, type 3 pin, 4 mm + Bovie Activation only with foot switch	1, type 3 pin, 4 mm + Bovie	Activation only with foot switch	1, type 3 pin, 4 mm + Bovie Activation only with foot switch	1, type 3 pin, 4 mm + Bovie	Activation only with foot switch	1, type 3 pin, 4 mm + Bovie Activation only with foot switch	1, type 3 pin + Bovie	Activation with finger switch and foot switch ARC 303: +1 type 3 pin with
Max. output current	2,0 A												1,5 A	0,8 A



Max. output current	0,7 A	0,7 A	0,7 A	0,4 A		0,4 A		0,8 A		0,4 A				1,5 A	
sindino	1, type 3 pin 0 + Bovie		with linger switch and foot switch	ARC 303: +1 type 3 pin with 0 finger switch		0	Activation only with foot switch	1, type 3 pin 0 + Bovie	Activation		ARC 303: +1 type 3 pin with finger switch	1, type 3 pin + Bovie	Activation only with foot switch Activation with finger switch	1, type 2 pin 1 Activation with foot switch	Activation with AUTO STABT
Effect setting				_			⋖						4		
Accuracy of HF power	± 20 %							± 20 %				± 20 %		± 20 %	
HF power limitation	1 to 75 W, adjustable in 1 W stens	1 to 120 W,	adjustable in 1 W steps	1 to 30 W,	1 W steps		1 to 50 W, adjustable in 1 W steps	1 to 120 W, adjustable in	1 W steps	1 to 30 W, adjustable in	1 W steps	1 to 120 W, adjustable in 1 W steps		1 to 120 W, adjustable in 1 W stens	1 to 50 W, adjustable in
Max. power output	75 W	120 W		30 W			50 W	120 W		30 W		120 W		120 W	30 W
Display of output, Authority o	2 places	3 places		2 places				3 places		2 places		3 places		3 places	2 places
əβejlo∧ ¥eəd :xeW	1 660 Vp for "Cutting Mode"	3 180 Vp	Tor "Mixed Coag Mode" 4 770 Vp for "Non Cutting Mode"	1 020 Vp for "Micro Cutting Mode"	2 610 Vp for "Micro Mixed Mode"	4 000 Vp for "Micro Non Cutting Mode"	3 700 Vp for "GastroCUT Forced COAG"	4 600 Vp for "Spay COAG"		3 450 Vp for "Micro Spray Coagulation"		4 600 Vp for program Argon-Flex "Spray COAG I"	3 840 Vp for program Argon "Spray COAG II"	175 Vp for "Standard COAG"	140 Vp for "Micro Bipolar Coag"
Vominal frequency	1 MHz	<u> </u>			<u> </u>	<u> </u>		1 MHz				1 MHz		330 KHz	
Form of HF Voltage	pulse, odulated							pulse, modulated				pulse, modulated		sinusoidal 3	
ARC CONTO															
8000 80000	oolar "Forced lation"							Monopolar "Spray Coagulation"				Monopolar "Argon Plasma Coagulation"		Bipolar "Contact Coagulation"	



12.2. Power, voltage and current charts

Setting	Programme				
Monopolar CUT	0, 3-4, 8-99				
## 100	300 250 Effect 0 Effect 1 Effect 2 Effect 3 Effect 3 Effect 4 Effect 5 Effect 5 Effect 5 Effect 5 Effect 6 Effect 7 R [ohm] Effect 8 Effect 9				
Measurement at ohmic resistances, without light arc generation in ARC 250 Output power P [W] as a function of the load resistance R [Ω] with the "Monopolar Cut" setting = 125 W	 Measurement at ohmic resistances, with previous light arc generation in ARC 250 Output power P [W] as a function of the load resistance R [Ω] with the "Monopolar Cut" setting = 250 W 				
## 100	300 250 200 Effect 0 Effect 1 Effect 2 Effect 3 Effect 3 Effect 4 Effect 5 Effect 5 Effect 6 Effect 7 Res Ohm Effect 8 Effect 9				
 Values measured on ohmic resistances without arc formation for ARC 303 Output power P [W] as a function of the load resistance R [Ω] with the "Monopolar Cut" setting = 150 W 	 Values measured on ohmic resistances without arc formation for ARC 303 Output power P [W] as a function of the load resistance R [Ω] with the "Monopolar Cut" setting = 300 W 				



Setting Monopolar CUT

Programme 0, 3-4, 8-99

Effect	Output power P [W]
0	78
1	78
2	99
3	122
4	122
5	122
6	114
7	116
8	116
9	116

Effect	Output power P [W]
0	78
1	78
2	98
3	122
4	122
5	122
6	147
7	147
8	176
9	176

Measurement at 2,000 $\Omega,$ with previous light arc generation in ARC 250 $\,$

 Output power P [W] versus effect setting with the "Monopolar Cut" setting = 125 W

"Effect 0–9" (load resistance 2,000 Ω)

Measurement at 2,000 $\Omega,$ with previous light arc generation in ARC 250 $\,$

 Output power P [W] versus effect setting with the "Monopolar Cut" setting
 = 250 W

"Effect 0–9" (load resistance 2,000 Ω)

Effect	Output Power P [W]
0	77
1	77
2	98
3	121
4	121
5	121
6	146
7	146
8	138
9	138

Effect	Output Power P [W]
0	77
1	77
2	97
3	120
4	121
5	121
6	146
7	146
8	174
9	174

Values measured on 2000 Ω with prior arc formation for ARC 303 $\,$

 Output power P [W] versus effect setting with the "Monopolar Cut" setting = 150 W

"Effect 0–9" (load resistance 2,000 Ω)

Values measured on 2000 Ω with prior arc formation for ARC 303 $\,$

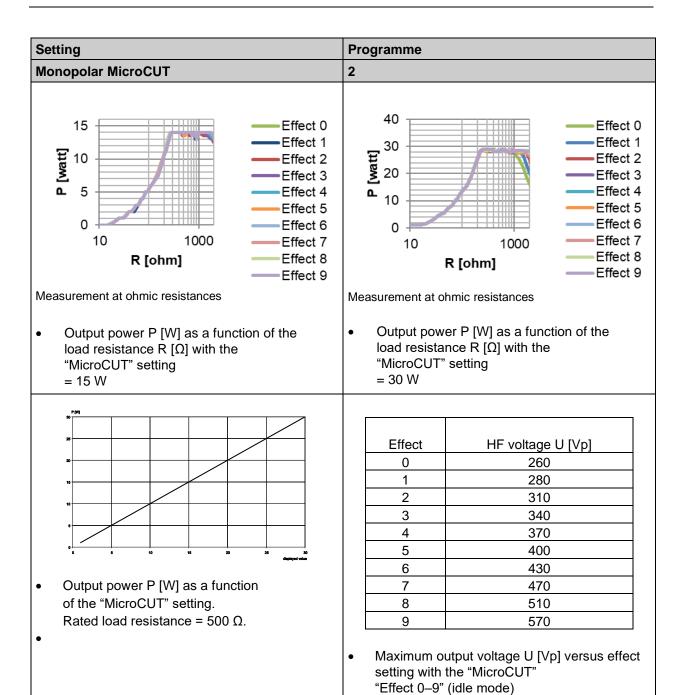
 Output power P [W] versus effect setting with the "Monopolar Cut" setting = 300 W

"Effect 0–9" (load resistance 2,000 Ω)



Setting	Programme
Monopolar CUT	0, 3-4, 8-99
Output power P [W] as a function of the "Monopolar Cut" setting. Rated load resistance = 500 Ω	Effect HF voltage U [Vp] 0 590 1 590 2 680 3 760 4 760 5 760 6 880 7 880 8 950 9 950 • Maximum output voltage U [Vp] versus effect setting with the "Monopolar Cut" "Effect 0–9" (idle mode)

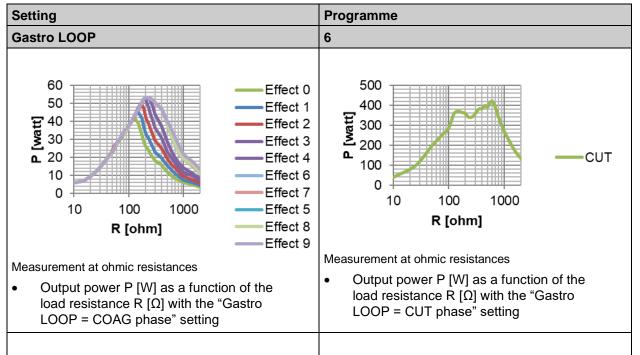






Setting	Programme
Monopolar MacroCUT	1
## 20	Effect 0 Effect 1 Effect 2 Effect 3 Effect 4 Effect 5 Effect 5 Effect 6 R [ohm] Effect 9
Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Monopolar MacroCUT" setting = 38 W	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Monopolar MacroCUT" setting = 75 W
Measurement at ohmic resistances • Output power P [W] as a function of the "Monopolar MacroCUT" setting. Rated load resistance = 500 Ω •	Effect HF voltage [Vp] 0 260 1 280 2 310 3 340 4 370 5 400 6 430 7 470 8 510 9 570 • Maximum output voltage U [Vp] versus effect setting with the "Monopolar MacroCUT" "Effect 0–9" (idle mode)





Effect	Coag share in W	Cut share in W
0	36	370
1	36	370
2	36	370
3	36	370
4	36	370
5	36	370
6	36	370
7	36	370
8	36	370
9	36	370

•	Output power P [W] versus effect setting with "Gastro LOOP". Rated load
	resistance:
	Coag 75 Ω, Cut 500 Ω

Effect	HF voltage [Vp]
0	800
1	800
2	800
3	800
4	800
5	800
6	800
7	800
8	800
9	800

Output voltage U [Vp] versus effect setting with the "Gastro LOOP". "Effect 0–9" (idle mode)



The short-term peak power exceeds 400 W, but this is permissible because the mean value over 1 second is below 400 W.



Setting			Progran	nme		
Gastro KNIFE		7				
Gastro KNIFE			1			
30 25 25 120 15 10 5 0	100 1000 R [ohm]	Effect 0 Effect 1 Effect 2 Effect 3 Effect 4 Effect 5 Effect 6 Effect 7 Effect 8	50 40 30 20 10	00 - 10 - 10 - 10	00 1000 ohm]	— CUT
Measurement at	ohmic resistances		Measurer	ment at ohmic r	esistances	
load resist	wer P [W] as a fur tance R [Ω] with th COAG phase" sett	ne "Gastro	load		W] as a function of R [Ω] with the "Gastrase" setting	
Effect	Coag share in W	Cut share in W		Effect	HF voltage [Vp]	
0	11	390		0	800	
1	20	390		1	800	
2	22	390		2	800	4
3	22	390		3	800	
4	22	390		4	800	
5	22	390		5	800	-
6	22	390		6 7	800	-
7	22	390			800	\dashv
8	22	390		8	800 800	\dashv
9	22	390		<u>9</u>	000	_

Output power P [W] versus effect setting with "Gastro KNIFE". Rated load resistance:

Coag 75 Ω , Cut 500 Ω

	6	800
	7	800
	8	800
	9	800
utput voltage U [Vp] versus effect		
tting with the "Gastro KNIFE".		

Ou setting with the "Gastro Kr "Effect 0-9" (idle mode)

The short-term peak power exceeds 400 W, but this is permissible because the mean value over 1 second is below 400 W.



Setting	Programme	
Moderate COAG Standard	0-1, 3-4, 6-99	
60 50 10 10 10 10 10 10 10 10 10 1	120 100 100 100 100 100 100 100	
 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Moderate COAG Standard" setting = 60 W 	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Moderate COAG Standard" setting = 120 W 	
Output power P [W] as a function of the "Moderate COAG Standard" setting. Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Moderate COAG Standard" (idle mode)	



Setting	Programme
Micro Moderate COAG	2
20 15 10 10 10 100 1000 R [ohm]	30 25 25 15 10 10 10 10 10 10 10 10 10 10 R [ohm]
 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Micro Moderate COAG Standard" setting = 15 W 	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Micro Moderate COAG Standard" setting = 30 W
Output power P [W] as a function of the "Micro Moderate COAG Standard" setting. Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Micro Moderate COAG" (idle mode)



Setting	Programme
Forced COAG Non Cutting	0-1, 3-4, 6-99
80 60 20 0 10 100 1000 R [ohm]	120 100 100 100 100 100 100 100
Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Non Cutting" setting = 60 W	Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Non Cutting" setting = 120 W
Output power P [W] as a function of the "Forced COAG Non Cutting" setting Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Forced COAG Non Cutting" (idle mode)



Setting	Programme
Forced COAG Cutting	0-1, 3-4, 6-99
40 30 20 10 10 10 100 1000 R [ohm]	80 60 40 20 0 10 100 1000 R [ohm]
Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Cutting" setting = 38 W	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Cutting" setting = 75 W
Output power P [W] as a function of the "Forced COAG Cutting" setting Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Forced COAG Cutting" (idle mode)



Setting	Programme
Forced COAG Mixed	0-1, 3-4, 6-99
80 60 20 0 10 100 1000 R [ohm]	150 100 100 100 100 1000 1000 1000 1000
Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Mixed" setting = 60 W	Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Mixed" setting = 120 W
Output power P [W] as a function of the "Forced COAG Mixed" setting Rated load resistance = 500 Ω • Output power P [W] as a function of the "Forced COAG Mixed" setting Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Forced COAG Mixed" (idle mode).



Setting	Programme		
Forced COAG Micro Cutting	2		
15 THE 10 10 10 100 1000 R [ohm]	30 25 25 20 15 10 10 5 0 10 100 1000 R [ohm]		
Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Micro Cutting" setting = 15 W	Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Micro Cutting" setting = 30 W		
Output power P [W] as a function of the "Forced COAG Micro Cutting" setting Rated load resistance = 500 Ω Output power P [W] as a function of the "Forced COAG Micro Cutting" setting Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Forced COAG Micro Cutting" (idle mode)		



Setting	Programme	
Forced COAG Micro Non Cutting	2	
20 15 15 10 5 0 10 100 1000 R [ohm]	40 30 20 10 10 10 10 10 100 1000 R [ohm]	
Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Micro Non Cutting" setting = 15 W	Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Micro Non Cutting" setting = 30 W	
Output power P [W] as a function of the "Forced COAG Micro Non Cutting" setting Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Forced COAG Micro Non Cutting" (idle mode)	



Setting	Programme		
Forced COAG Micro Mixed	2		
20 15 10 10 5 0 10 100 1000 R [ohm]	40 30 20 10 10 10 10 10 100 1000 R [ohm]		
 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Micro Mixed" setting = 15 W 	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Forced COAG Micro Mixed" setting = 30 W 		
Output power P [W] as a function of the "Forced COAG Micro Mixed" setting Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Forced COAG Micro Mixed" (idle mode)		



Setting	Programme		
Micro Spray COAG	2		
20 15 15 10 5 0 10 100 1000 R [ohm]	40 30 20 10 10 10 10 100 1000 R [ohm]		
 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Micro Spray COAG" setting = 15 W 	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Micro Spray COAG" setting = 30 W 		
Output power P [W] as a function of the "Micro Spray COAG" setting. Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Micro Spray COAG" (idle mode)		



Setting	Programme	
Spray COAG	0, 1, 3, 8-99 (without ARC Plus)	
Argon Flex Spray COAG I	5-7 (with ARC Plus)	
Argon Spray Open COAG II	4	
80 60 40 20 0 10 1000 R [ohm]	150 E 100 50 0 10 1000 R [ohm]	
Measurement at ohmic resistances • Output power P [W] as a function of the load resistance R [Ω] with the "Spray COAG", "Argon Flex Spray COAG I" and "Argon Spray Open COAG II" setting = 60 W	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Spray COAG", "Argon Flex Spray COAG I" and "Argon Spray Open COAG II" setting = 120W 	
Output power P [W] as a function of the "Spray COAG", "Argon Flex Spray COAG I" and "Argon Spray Open COAG II" setting. Rated load resistance = 500 Ω	Maximum output voltage U [Vp] versus power setting with "Spray COAG" (idle mode).	
Maximum output voltage U [Vp] versus power setting with "Argon Flex Spray COAG I" (idle mode).	Maximum output voltage U [Vp] versus power setting with "Argon Spray COAG II" (idle mode)	



Setting	Programme		
Bipolar COAG	0, 1, 3-99		
80 60 40 20 0 10 100 1000 R [ohm]	150 150 10 100 1000 R [ohm]		
 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Bipolar COAG" setting = 60 W 	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Bipolar COAG" setting = 120 W 		
 Output power P [W] as a function of the "Bipolar COAG" setting. Rated load resistance = 75 Ω 	Maximum output voltage U [Vp] versus power setting with "Bipolar COAG" (idle mode)		



Setting	Programme	
Bipolar Micro COAG	2	
20 15 10 10 10 100 1000 R [Ohm]	40 30 20 0 10 10 10 100 1000 R [Ohm]	
 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Bipolar Micro COAG" setting = 15 W 	 Measurement at ohmic resistances Output power P [W] as a function of the load resistance R [Ω] with the "Bipolar Micro COAG" setting = 30 W 	
 Output power P [W] as a function of the "Bipolar Micro COAG" setting. Rated load resistance = 75 Ω 	Maximum output voltage U [Vp] versus power setting with "Bipolar Micro COAG" (idle mode).	



13. Accessories and replacement parts

Original BOWA accessories are suitable for use with the ARC Series and ARC PLUS devices. When using accessories made by other manufacturers, the user must ensure that they are designed for and compatible with the maximum HF peak voltage of the HF device.

For the use and correct preparation of the autoclavable devices, compliance with the relevant instruction manuals accompanying these devices is required.

Detailed information on accessories and replacement parts is available in the current accessories catalog.



14. EMC

- Medical electrical devices are subject to special precautionary measures with regard to EMC and must be installed and commissioned in accordance with the EMC specifications in this operating manual.
- Portable and mobile RF communication devices can interfere with medical electronic equipment and should not be used at distances of less than 30 cm from the HF surgical device.
- ► The HF device must not be set up immediately adjacent to or stacked together with other electrical equipment. Should it prove necessary to use the HF device alongside or stacked together with other devices, its normal operation in the employed configuration must be monitored.
- Using accessories and cables in ways other than described can result in higher emission levels or reduced interference immunity.
- This HF device is exclusively intended for use by medical professionals. This HF device can cause radio interference or affect the operation of devices in its immediate vicinity. It may prove necessary to implement suitable corrective measures such as reorienting or repositioning the HF device or screening.

14.1. Guidelines and manufacturer's declaration in accordance with IEC 60601-1-2:2014

Electromagnetic immunity (IEC 60601-1-2, Table 1)

The ARC 250 / ARC 303 is suitable for operation in professional healthcare facilities.

The client or user of the ARC 250 / ARC 303 should make sure that this device is only operated in such environments. With regard to the interference immunity test levels in accordance with IEC 60601-1-2, Table 4 - 9, the values specified in the standard apply for operation in professional healthcare facilities.

Electromagnetic disturbances (IEC 60601-1-2, Table 1)

The ARC 250 / ARC 303 is intended to be used in an electromagnetic environment as set out below. The client or user of the ARC 250 / ARC 303 should make sure that this device is only operated in such environments.

Emissions Test	Compliance	Guideline on electromagnetic environment
RF emissions as per CISPR 11	Group 2	The ARC 250/ARC 303 must emit electromagnetic energy in order to perform its intended functionality. This may have an impact on adjacent electronic devices.
RF emissions as per CISPR 11	Class B	The ARC 250/ARC 303 is suitable for use in other
Harmonic emission pursuant to IEC 61000-3-2	Class A	facilities than domestic settings and others connected directly to the public distribution network, which also supplies residential buildings.
Emission of voltage fluctuations / flicker pursuant to IEC 61000-3-3	Compatible	which also supplies residential buildings.



15. Disposal

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Always comply with the national regulations of the relevant country when disposing of or recycling the device or its components.

Symbol	Designation
	A device marked with this symbol must be put into the separate waste collection for electrical and electronic devices. Disposal is carried out free of charge by the manufacturer within the European Union.

▶ If you have any questions regarding product disposal, contact the service center, see section Technical service, page 53.



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CE marked according to Medical Device 93/42/EWG