

## SPECIFICȚIE TEHNICĂ COMPLETATĂ

Modelul: ARC-100; Ref. 900-100; Producător: BOWA-electronic GmbH; Țara: Germania.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină ofertantă de către autoritatea ofertantă
<p>Electrocoagulator Frecvența: cuprinsă între 300 KHz și 1 MHz</p> <p>Minim un canal de ieșire ce asigura conectarea piese de mana monopolar și bipolar sau doua canale separate pentru fiecare.</p> <p>Comutator de mână – Da Comutator de picior – Da Moduri de lucru: Tăiere monopolară, coagulare monopolară, coagulare bipolară</p> <p>Puterea minim 100 W pentru cele 3 moduri de lucru solicitate</p> <p>Ajustare putere 0-100 W cu vizualizare afișare putere setată</p> <p>Regimuri de coagulare minim necesar : Coagulare moderată, Coagulare forțată.</p> <p>Regimuri de tăiere minim necesar : Tăiere cu hemostază și fără hemostază sau Tăiere auto.</p> <p>Funcția de autotestare – Da;</p> <p>Indicatoare: Acustic si Vizual</p> <p>Electrosecuritate: Clasa de protecție I; Tip CF</p> <p>Garanție minim 24 luni. "Accesorii livrate:</p> <p>a. Comutator de picior tip pedală, tăiere/coagulare, lungimea firului de conectare minim 3m, 1 buc.</p> <p>b. Cablu de alimentare 220V, lungimea minim 4 m, 1 buc.</p> <p>c. Cablu pentru egalizare de potențial, lungime a firului minim 4m, 1 buc.</p> <p>d. Cablu pentru conectarea instrumentelor bipolare cu lungimea 3 m, cu adaptor sau conector „european flat plug” - 2 buc.</p> <p>e. Electrode neutru din cauciuc autoclavabil, cu lungimea cablului de minim 3 metri, cu sau fără cablu interconectare, cu adaptor sau conector de tip BOWA/Erbe ICC/Valleylab NON-REM/Conmed -2 buc.</p> <p>f. Piesă de mână autoclavabilă, lungimea cablului conector minim 4m, pentru electrozi cu pin conectori de diametru 4 mm, tip BOWA/Erbe International/ Valleylab/ Conmed – 3 buc.</p>	<p><b>DA</b> Electrocoagulator</p> <p><b>DA</b> Frecvența: 500 KHz este int re valorile de 300KHz si 1 MHz <b>pag. 40 din ARC 100 Operation Manual</b></p> <p><b>DA UN</b> canal de ieșire ce asigura conectarea piese de mana monopolar și bipolar. <b>pag. 21 din ARC 100 Operation Manual</b></p> <p>Comutator de mână – <b>DA PN 220-145</b> Comutator de picior – <b>DA PN 901-012</b></p> <p><b>DA</b> Moduri de lucru: Tăiere monopolară, coagulare monopolară, coagulare bipolară <b>pag. 20 din ARC 100 Operation Manual</b></p> <p><b>DA</b> Puterea 100 W pentru cele 3 moduri de lucru solicitate <b>pag. 41 din ARC 100 Operation Manual</b></p> <p><b>DA</b> Ajustare putere 0-100 W cu vizualizare afișare putere setată <b>pag. 4 din ARC 100 Operation Manual</b></p> <p><b>DA</b> Regimuri de coagulare minim necesar : Coagulare moderată, Coagulare forțată. <b>pag. 20 din ARC 100 Operation Manual</b></p> <p><b>DA</b> Regimuri de tăiere minim necesar : Tăiere cu hemostază și fără hemostază. <b>pag. 20 din ARC 100 Operation Manual</b></p> <p>Funcția de autotestare – <b>DA, pag. 28 din ARC 100 Operation Manual</b></p> <p><b>DA</b> Indicatoare: Acustic si Vizual <b>pag. 4, 15, 31, 33 din ARC 100 Operation Manual</b></p> <p><b>DA</b> Electrosecuritate: Clasa de protecție I; Tip CF <b>pag. 39 din ARC 100 Operation Manual</b></p> <p><b>DA</b> Garanție 24 luni. "Accesorii livrate:</p> <p>a. <b>DA</b> Comutator de picior tip pedală, tăiere/coagulare, lungimea firului de conectare 4m, 1 buc. <b>PN 901-012</b></p> <p>b. <b>DA</b> Cablu de alimentare 220V, lungimea 5m, 1 buc. <b>PN 900-911</b></p> <p>c. <b>DA</b> Cablu pentru egalizare de potențial, lungime a firului 5 m, 1 buc. <b>PN 900-031</b></p> <p>d. <b>DA</b> Cablu pentru conectarea instrumentelor bipolare cu lungimea 3 m, cu adaptor sau conector „european flat plug” - 2 buc. <b>PN 287-040 / 101-140/ 351-040/ 353-040</b></p> <p>e. <b>DA</b> Electrode neutru din cauciuc autoclavabil, cu lungimea cablului de 4.5 metri, cu sau fără cablu interconectare, cu adaptor sau conector de tip BOWA/Erbe ICC/Valleylab NON-REM/Conmed -2 buc. <b>PN 242-003 + 386-050.</b></p> <p>f. <b>DA</b> Piesă de mână autoclavabilă, lungimea cablului conector 4.5 m, pentru electrozi cu pin conectori de diametru 4 mm, tip BOWA/Erbe International/ Valleylab/ Conmed – 3 buc. <b>PN 220-145</b></p>

Anexa 13

- g. Prelungitor autoclavabil pentru electrozi , cu lungimea 160 – 180mm, compatibilă cu electrozi cu pin conectori de diametru 4 mm – 2 buc.
- h. Set vârfuri electrozi variați pentru electrod cu pin conectori de diametru 4 mm, care să includă obligatoriu vârf bilă drept, vârf cuțit drept și vârf spatulă drept - 1 set
- i. Troliu cu minim 4 roti, 2 blocabile, cu poliță adițională pentru păstrarea accesoriilor-1 buc.

Notă: Accesoriile trebuie să fie produse de același producător ca și dispozitivul. "

- g. **DA** Prelungitor autoclavabil pentru electrozi , cu lungimea 175mm, compatibilă cu electrozi cu pin conectori de diametru 4 mm – 2 buc. **PN 500-150**
- h. **DA** Set vârfuri electrozi variați pentru electrod cu pin conectori de diametru 4 mm, care să includă obligatoriu vârf bilă drept, vârf cuțit drept și vârf spatulă drept - 1 set **PN 500-000**

- i. **DA** Troliu cu minim 4 roti, 2 blocabile, cu poliță adițională pentru păstrarea accesoriilor-1 buc. **PN: 902-050**

Notă: Accesoriile trebuie să fie produse de același producător ca și dispozitivul. " **DA toate sint produse de un singur producator.**



## ARC CART with frontal basket, assembled

The flexible solution for mobile work stations

### Scope of delivery

Incl. 900-911, 902-022, 2 x 902-911, 902-912, 902-921, 902-100, Y-mains cable, assembly instructions

Product number: 902-050

Unit: 1 piece

Type: for ARC with basket

Reset selection

Inquiry

Description

Specification

Download

## ARC CART equipment trolley

The ARC CART is available in various equipment options and can be customised for all the needs of the operating theatre and outpatient applications. It has 4 casters, 2 of which have brakes, and a cable winding aid. The column contains a cable shaft and a cable strain relief for neat layout of mains cables. The base plates have guards and are optimised attachment of BOWA devices. Numerous attachments such as drawers, baskets and holders can be used to customise the trolley for specific requirements.



## Scope of delivery

Incl. 900-911, 902-022, 2 x 902-911, 902-912, 902-921, 902-100, Y-mains cable, assembly instructions

Do you still have any questions regarding the product?

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## Have you seen?



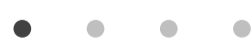
**ARC PLUS, unit for ARC 400 / 350 (REF 900-351)**  
The ARC PLUS for argon-assisted endo...  
1 piece



**ARC PLUS, unit for ARC 250 / 303**  
The ARC PLUS for argon-assisted endo...  
1 piece



**Electrosurgical unit ARC 400**  
Top quality monopolar and bipolar ele...  
1 piece



## Bipolar cable, BOWA forceps, for Martin, 4.5 m

### Bipolar connection cable for electrosurgery

- > Indelible laser marking for reliable identification
- > Ideal cleaning properties thanks to the round shape of the cable
- > Robust plug with kink protection and strain relief
- > Extreme durability for up to 300 reprocessing cycles
- > Special touch protection for bipolar forceps

### Scope of delivery

Incl. instructions for use

Product number: 287-040

Unit: 1 piece

Type of Forceps: BOWA MEDICAL

Device connection: 6/2 mm Martin

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Specification

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## BOWA MEDICAL RF cable for bipolar forceps

BOWA MEDICAL connecting cables for bipolar forceps are specially designed for the high demands of routine surgical procedures. The cables have excellent safety features, a high level of ergonomics and maximum durability (up to 300 reprocessing cycles).

For a safe connection to RF devices:

- Trip hazards are avoided: The cables are eye-catching with a striking, orange-coloured marking strip.
- Highly flexible and safe operation thanks to the supple, twist-free cable with soft sheathing
- Robust plug with kink protection and strain relief
- Easy handling thanks to finger recess pull-off aid
- Consistently secure plug-in behaviour thanks to stable spring contacts
- 2-component encapsulation with smooth surfaces for optimal sealing
- Safe identification and easy replacement thanks to indelible laser marking.

## Connection cable with ergonomically perfected plug

The plug connections of the RF cables consist of two different plastic surfaces. The part that is gripped for plugging has a soft and non-slip feel. The part that goes into the socket frequently and easily is smooth and tough. All plugs have an ergonomic recessed grip so that every movement is correct, even in stressful situations.

## Durable BOWA MEDICAL cables for reliable contact with the instrument

BOWA MEDICAL cables guarantee reliable contact with the instrument:

- Corrosion protection through silver-plated conductors and the use of components that have been tried and tested a million times
- Reliable contact connections through large-scale crimping technology
- Special touch protection for bipolar forceps
- Extreme durability thanks to glass-fibre-reinforced material for up to 300 reprocessing cycles
- Ideal cleaning features thanks to the round cable shape

## RF connection cable for all commercially available device types

The bipolar cables are available for forceps with a European flat connector or a US 2-pin. Cables with COMFORT function offer Plug'n'Play on the BOWA MEDICAL ARC generators with COMFORT function.

## Scope of delivery

Incl. instructions for use

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## Bipolar cable, BOWA forceps, COMFORT, 4.5 m

### Bipolar connection cable for electrosurgery

- > Indelible laser marking for reliable identification
- > Ideal cleaning properties thanks to the round shape of the cable
- > Robust plug with kink protection and strain relief
- > Extreme durability for up to 300 reprocessing cycles
- > Special touch protection for bipolar forceps

### Scope of delivery

Incl. instructions for use

Product number: 101-140

Unit: 1 piece

Type of Forceps: BOWA MEDICAL

Device connection: 3 pin BOWA COMFORT

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Inquiry



Specification

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## Scope of delivery

Incl. instructions for use

Do you still have any questions regarding the product?

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## Electrode container, 12 standard electrodes, shaft 4 mm

### Accessories related to electrodes and handles

#### Scope of delivery

Incl. lid, rack, instructions for use and 12 standard electrodes: 500-007, 500-009, 500-008, 500-011, 500-014, 500-015, 500-017, 500-018, 500-021, 500-022, 500-023, 500-126

Product number: 500-000

Unit: 1 piece

Accessories: Electrode container, 4 mm

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Inquiry

Description

Specification

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Size / Dimensions

4 mm

Total gross weight

365 G

Net weight

282 G

Electric strength

5700 Vp

Single-use / reusable

Reusable

Sterile / non-sterile

Non-sterile

Permissible combinations

Reusable handles 4 mm, 104-045, 110-045, 112-045, 120-145, 214-045, 215-045, 215-145, 220-145, 220-245, 322-045, 330-030

Packaging unit

PCS (1 PCS)

Scope of delivery

Incl. lid, rack, instructions for use and 12 standard electrodes: 500-007, 500-009, 500-008, 500-011, 500-014, 500-015, 500-017, 500-018, 500-021, 500-022, 500-023, 500-126

CE conformity marking

YES

Notified body

TÜV SÜD Product Service GmbH (0123)

EU medical device classification

IIb

Manufacturer

BOWA-electronic GmbH & Co. KG


Monopolar / bipolar / passive

Monopolar

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### Electrode extension, 175 mm, shaft 4 mm

Accessories related to electrodes and handles

Scope of delivery  
Incl. instructions for use  
Product number: 500-150  
Unit: 1 piece

Accessories: 172 mm electrode extension Ø 4 mm

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[Inquiry](#)

Description	Specification	Download
Size / Dimensions	4 mm	
Length	175 mm	
Total gross weight	60 G	
Net weight	8 G	
Electrode strength	5700 Vp	
Monopolar / bipolar / passive	Monopolar	
Single-use / reusable	Reusable	
Sterile / non-sterile	Non-sterile	
Cleaning / Disinfecting	Autoclave	
Preparation	75 cycles	
Permissible combinations	4 mm electrodes, Reusable handles 4 mm, 104-045, 110-045, 112-045, 120-145, 214-045, 215-045, 215-145, 220-145, 220-245, 322-045, 330-030	
Packaging unit	PCS (1 PCS)	
Scope of delivery	Incl. instructions for use	
CE conformity marking	YES	
Notified body	TÜV SÜD Product Service GmbH (0123)	
EU medical device classification	IIb	
Manufacturer	BOWA-electronic GmbH & Co. KG	

Do you still have any questions regarding the product?  
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## Equipotential bonding, 5 m

Equipotential bonding cables for BOWA devices and equipment trolleys

Product number: 900-031

Length: 5 m
▼

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Inquiry

Description

Specification

<b>Size / Dimensions</b>	5 m
<b>Total gross weight</b>	334 G
<b>Net unit weight</b>	329 G
<b>Sterile / non-sterile</b>	Non-sterile
<b>Disinfection</b>	Wipe disinfection
<b>Permissible combinations</b>	LG4, 900-000, 900-001, 900-100, 900-250, 900-303, 900-351, 900-400, 900-600, 902-050, 902-054, 902-055, 902-056, 902-070, 902-911, 950-001
<b>Packaging unit</b>	PCS (1 PCS)
<b>CE conformity marking</b>	NO
<b>EU medical device classification</b>	non-medical

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### Accessories

**ARC CART, connector PE-line**  
Individual adjustment options of the A...  
1 piece

### Have you seen?


**ARC PLUS, unit for ARC 250 / 303**  
The ARC PLUS for argon-assisted endo...  
1 piece

**Electrosurgical unit ARC 303**  
Powerful top-class electrosurgical cutti...  
1 piece

**Electrosurgical unit ARC 100**  
Electrosurgical device for outpatient a...  
1 piece







**JackKNIFE, 2 switches, shaft 4 mm, for 3-pin, cable 4.5 m**

Universal ergonomics in a modern design

Scope of delivery  
Incl. instructions for use  
Product number: 220-145  
Unit: 1 piece

Electrode receiver: 4 mm

Socket type: 3-pin International

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Description	Specification	Download
Size / Dimensions	155 mm	
Cable	4.5 m	
Total gross weight	198 G	
Net unit weight	143 G	
Electric strength	6000 Vp	
Monopolar / bipolar / passive	Monopolar	
Single-use / reusable	Mehrweg	
Sterile / non-sterile	Unsteril	
Cleaning / Disinfecting	Autoclave	
Preparation	200 cycles	
Connector type	3-pin International	
Permissible combinations	4 mm electrodes	
Packaging unit	PCS (1 PCS)	
Scope of delivery	Incl. instructions for use	
CE conformity marking	YES	
Notified body	TÜV SÜD Product Service GmbH (0123)	
EU medical device classification	IIb	
Manufacturer	BOWA-electronic GmbH & Co. KG	


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Have you seen?



**Electrodes, short**  
Reusable short electrodes for electrosurgery

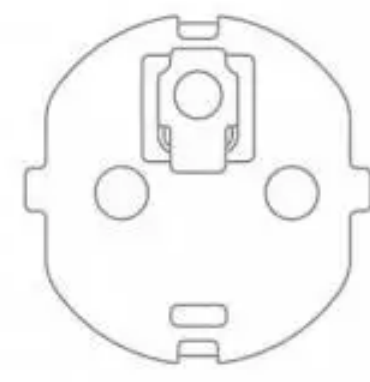


**LLETZ electrodes**  
Monopolar loop electrodes for conisation



**Electrodes, long**  
Reusable long electrodes for electrosurgery





## Mains cable, plug type F, 5 m

**BOWA ARC mains cable**

Product number: 900-911

Unit: 1 piece

Connector type: Type F

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[Inquiry](#)

Description **Specification**


Size / Dimensions	5 m
Total gross weight	476 G
Net unit weight	455 G
Sterile / non-sterile	Non-sterile
Preparation	Wipe disinfection
Connector type	Type F
Permissible combinations	LG4, 900-100, 900-250, 900-303, 900-351, 900-400, 900-600, 950-001
Packaging unit	PCS (1 PCS)
CE conformity marking	YES
EU medical device classification	non-medical

Do you still have any questions regarding the product?


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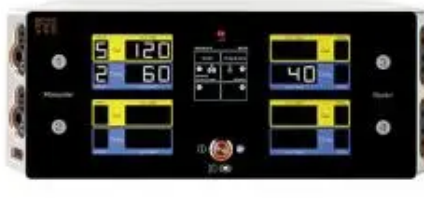
### Have you seen?




**Electrosurgical unit ARC 100**  
Electrosurgical device for outpat...  
1 piece



**Electrosurgical unit ARC 400**  
Top quality monopolar and bipo...  
1 piece



**Electrosurgical unit ARC 350**  
Touch-assisted universal system...  
1 piece



**SHE SHA smoke evacuation unit**  
A healthy working environment ...  
1 piece



ARC Electrosurgery

Instruments / Accessories

LOTUS ultrasonic surgery

Plasma surgery

Surgical smoke

Morcellation

## Rubber return plate, adults, 250 x 150 mm, international

Reusable neutral electrodes for simple procedures

Product number: 242-003

Unit: 1 piece

Use: Adults

Connection: International

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Description

Specification

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Size / Dimensions	375 cm <sup>2</sup>
Cable	0.5 m
Total gross weight	454 G
Net weight	279 G
Modality / bipolar / passive	Passive
Single-use / reusable	Reusable
Sterile / non-sterile	Non-sterile
Cleaning / Disinfecting	Autoclave
Preparation	75 cycles
Permissible combinations	194-075, 295-050, 385-050
Packaging unit	PCS (1 PCS)
CE conformity marking	YES
EU medical device classification	IIb
Manufacturer	BOWA-electronic GmbH & Co. KG
Note	non-split, for adults > 15 kg

Do you still have any questions regarding the product?

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## Single-pedal footswitch for ARC 100, cable 4m

### ARC 100 footswitch

Scope of delivery

Incl. instructions for use

Product number: 901-012

Unit: 1 piece



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Description

Specification

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Size / Dimensions	140 x 140 x 40 mm
Cable	4 m
Total gross weight	1000 G
Net unit weight	910 G
Sterile / non-sterile	Non-sterile
Preparation	Wipe disinfection
Permissible combinations	900-100
Packaging unit	PCS (1 PCS)
Scope of delivery	Incl. instructions for use
CE conformity marking	YES
Notified body	TÜV SÜD Product Service GmbH (0123)
EU medical device classification	I Ib
Manufacturer	BOWA-electronic GmbH & Co. KG

Do you still have any questions regarding the product?

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Have you seen?



### Electrosurgical unit ARC 100

Electrosurgical device for outpatient and mino...

1 piece

OPERATING MANUAL  
ELECTROSURGICAL UNIT

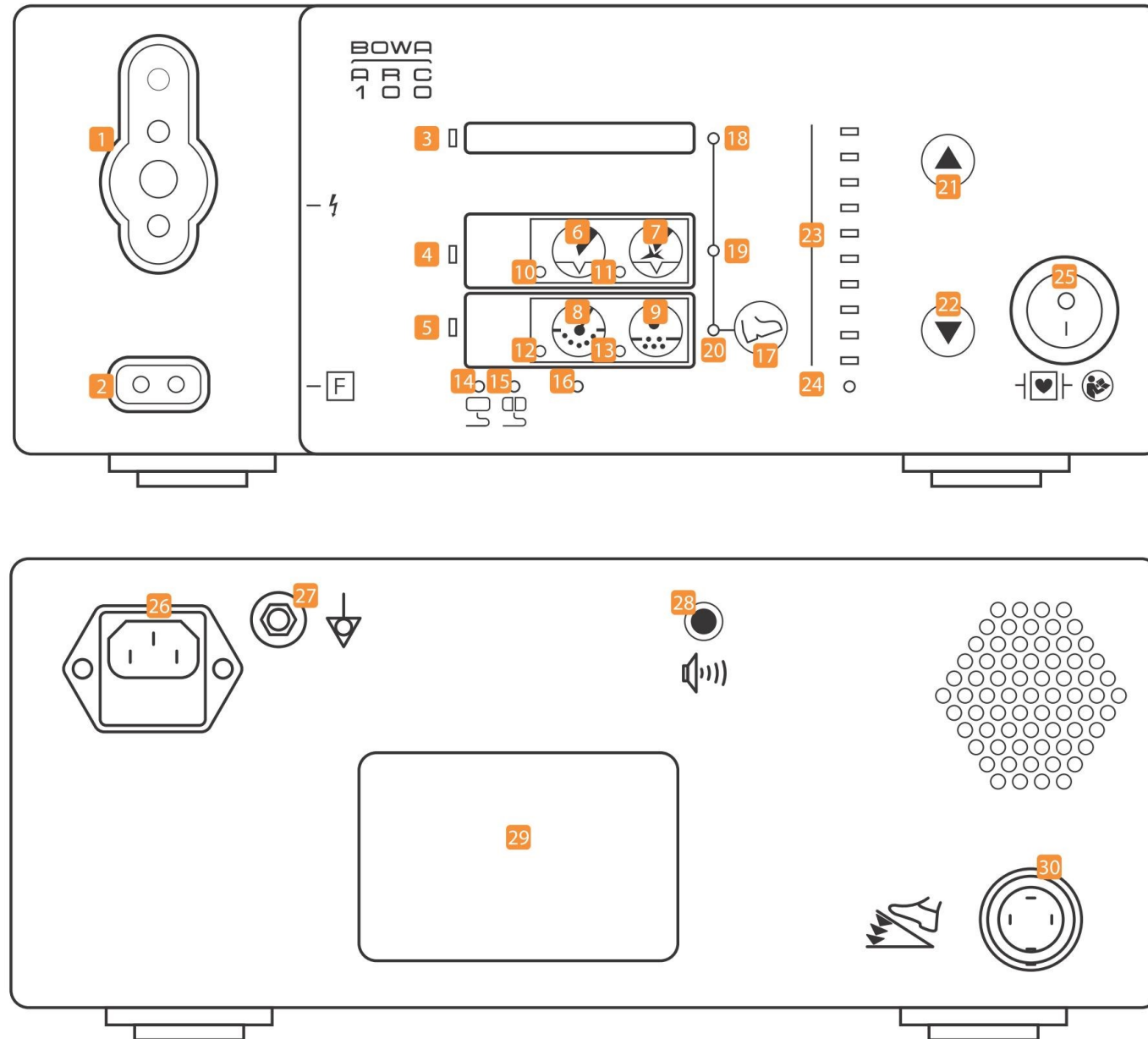


**BOWA**  
ARC  
1000





Legend



**Front of ARC 100**

- 1 Multifunction connection socket for monopolar instruments with hand or foot switch or bipolar instruments with foot switch \*
- 2 Socket for the neutral electrode (NE) \*
- 3 Activation indicator for bipolar coagulation (blue)
- 4 Activation indicator for monopolar cutting (yellow)
- 5 Activation indicator for monopolar coagulation (blue)
- 6 Key for "Pure" monopolar cutting current
- 7 Key for "Dry" monopolar cutting current
- 8 Key for "Moderate" monopolar coagulation current
- 9 Key for "Forced" monopolar coagulation current
- 10 Indicator for "Pure" monopolar cutting current
- 11 Indicator for "Dry" monopolar cutting current
- 12 Indicator for "Moderate" monopolar coagulation current
- 13 Indicator for "Forced" monopolar coagulation current
- 14 Neutral electrode monitoring, non-split
- 15 EASY neutral electrode monitoring, split
- 16 Indicator for EASY neutral electrode "Alarm" fault status
- 17 Key for foot switch assignment
- 18 Indicator for foot switched bipolar coagulation
- 19 Indicator for foot switched monopolar cutting
- 20 Indicator for foot switched monopolar coagulation
- 21/22 Keys for adjusting the power limitation
- 23 Power limitation indicator
- 24 Indicator for "Error" fault status
- 25 On/off switch

**Rear of ARC 100**

- 26 IEC chassis-mount power connector
- 27 Connection for equipotential bonding
- 28 Knob to adjust volume
- 29 Rating label
- 30 Connection socket for foot switch

\* Applied part of Type F according to IEC 60601-1



**Table of contents**

<b>Legend</b> .....	<b>4</b>
<b>1. Using this operating manual</b> .....	<b>8</b>
1.1. Revision index .....	8
1.2. Scope of validity .....	8
1.3. Other applicable documents .....	8
1.4. Symbols and notation .....	9
1.4.1. Structure of warning instructions .....	9
1.4.2. Hazard levels of warning instructions .....	9
1.4.3. Tips .....	9
1.4.4. Other symbols and notation .....	10
<b>2. Safety</b> .....	<b>11</b>
2.1. Intended use .....	11
2.2. General safety instructions .....	12
2.3. Personal safety instructions .....	13
2.3.1. Ambient conditions .....	13
2.3.2. Patients with pacemakers .....	13
2.3.3. Safe positioning of the patient .....	14
2.3.4. Correct connection of the HF device .....	14
2.3.5. Correct use of the HF device .....	14
2.3.6. Adjusting the settings of the HF device and use of the accessories .....	15
2.4. Device-related safety instructions .....	16
2.5. Safe handling (general instructions) .....	16
2.5.1. Surgical environment: Prevention of explosions and ignition .....	17
2.5.2. Application of the neutral electrode .....	17
<b>3. Functionality</b> .....	<b>20</b>
3.1. Monopolar modes .....	20
3.2. Bipolar mode .....	20
3.3. Monopolar/bipolar multifunction socket .....	21
3.4. Connection socket for neutral electrode .....	21
3.5. Activation and alarm signals in monopolar and bipolar mode .....	21
3.6. Emergency stop .....	22
3.7. Monitoring functions .....	22
3.7.1. Self-test .....	22

3.7.2.	Cyclical test during operation .....	22
3.8.	Neutral electrode monitoring.....	22
3.8.1.	General information .....	22
3.8.2.	EASY neutral electrode monitoring (EASY monitoring) .....	23
3.9.	Foot switches .....	23
<b>4.</b>	<b>Description.....</b>	<b>24</b>
4.1.	Symbols on the device.....	24
4.1.1.	Rating label.....	24
4.2.	Scope of delivery .....	25
4.3.	Components required for operation .....	25
4.4.	Operating conditions .....	25
<b>5.</b>	<b>Preparation.....</b>	<b>26</b>
5.1.	Setting up the HF device.....	26
5.2.	Switching on the HF device .....	27
5.3.	Connecting instruments .....	27
5.3.1.	Instruments for monopolar applications .....	27
5.3.2.	Instruments for bipolar applications.....	27
5.3.3.	Connecting the foot switch .....	28
5.3.4.	Assigning a foot switch output.....	28
5.4.	Functional test.....	28
5.4.1.	Autotest function.....	28
5.4.2.	Functional test execution.....	28
5.4.3.	Actions in case of problems.....	29
5.4.4.	EASY neutral electrode monitoring (EASY monitoring) .....	29
<b>6.</b>	<b>Operation.....</b>	<b>30</b>
6.1.	Mode overview .....	30
6.2.	Basic settings .....	31
6.2.1.	Selecting the mode .....	31
6.2.2.	Setting power levels .....	31
6.2.3.	Changing the volume.....	31
6.3.	Mode descriptions.....	31
6.3.1.	Monopolar cutting, "Pure".....	31
6.3.2.	Monopolar cutting, "Dry".....	31
6.3.3.	Monopolar coagulation, "Moderate" .....	32
6.3.4.	Monopolar coagulation, "Forced" .....	32

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6.3.5.	Bipolar coagulation .....	32
<b>7.</b>	<b>Detecting and correcting faults .....</b>	<b>33</b>
7.1.	System errors.....	33
7.1.1.	Error list .....	33
7.2.	Fault indications for EASY monitoring .....	34
<b>8.</b>	<b>Cleaning .....</b>	<b>35</b>
8.1.	Preparation of the accessories .....	35
8.2.	Disinfection and cleaning .....	35
<b>9.</b>	<b>Maintenance and repair .....</b>	<b>36</b>
9.1.	Maintenance .....	36
9.1.1.	Safety inspection .....	36
9.2.	Repairs.....	37
9.3.	Technical service .....	38
<b>10.</b>	<b>Storage .....</b>	<b>38</b>
<b>11.</b>	<b>Technical specifications .....</b>	<b>39</b>
11.1.	Technical data for ARC 100.....	39
11.2.	Power, voltage and current charts .....	42
<b>12.</b>	<b>Accessories and replacement parts.....</b>	<b>47</b>
<b>13.</b>	<b>EMC.....</b>	<b>47</b>
13.1.	Guidelines and manufacturer's declaration in accordance with DIN EN 60601-1-2, para. 6.8.3.201.....	47
<b>14.</b>	<b>Disposal.....</b>	<b>51</b>

# 1. Using this operating manual

This operating manual is part of the product.

BOWA-electronic GmbH & Co. KG, referred to in the following simply as BOWA, assume no liability nor provide any warranty whatsoever for any damage or consequential damages arising from 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 theatre 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
1.0	2014/12

## 1.2. Scope of validity

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

## 1.3. Other applicable documents

- ▶ Comply with other applicable documents mentioned in the appendix or in the other sections.
- ▶ Provided in addition to this operating manual is an introductory video; see accompanying CD.

## 1.4. Symbols and notation

### 1.4.1. Structure of warning instructions



#### **SIGNAL WORD**

Type, source and consequences of the risk (personal injury)!

- ▶ Measure for avoiding the risk.







#### **NOTE**

Type, source and consequences of the risk (property damage)!

- ▶ Measure.

### 1.4.2. Hazard levels of warning instructions

Symbol	Hazard level	Probability of occurrence	Consequences of non-compliance
	<b>DANGER</b>	Immediate risk	Death or serious injuries
	<b>WARNING</b>	Possible risk	Death or serious injuries
	<b>CAUTION</b>	Possible risk	Minor injuries
	<b>NOTE</b>	Possible risk	Property damage

### 1.4.3. Tips



Tips and additional information for easier working.

#### 1.4.4. Other symbols and notation

Symbol or notation	Meaning
<input checked="" type="checkbox"/>	Prerequisite for an activity
▶	Activity with one step
1. 2. 3.	Activity with several steps in strict sequence
↳	Result of preceding activity
•	List (first level)
•	List (second level)
<b>Emphasis</b>	Emphasis
...; see Section xxx, page xxx	Cross reference
... "On/off switch" <b>25</b>	Bolded numbers (here: <b>25</b> ) refer to a schematic diagram of the ARC 100 and the respective legend (page 4)

## 2. Safety

### 2.1. Intended use

The HF device is intended exclusively for the generation of electrical power for monopolar cutting or monopolar and bipolar coagulation in surgical operations.

It is used in the following areas:

- General surgery
- Paediatric surgery
- Gynaecology
- Hand surgery
- Neurosurgery (not on the central nervous system)
- Dermatology
- Plastic surgery
- Oral and maxillofacial surgery
- Dentistry
- ENT

Do not use the HF device if, in the opinion of an experienced physician or according to current professional literature, such use would endanger the patient, due for example to the general condition of the patient, or if other contraindications are present.



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, staff and equipment at risk.



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

---

## 2.2. 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.
- ▶ Please comply with the instructions on electromagnetic compatibility (EMC); see Section EMC, page 47.
- ▶ 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 demonstrably satisfy the 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 medical electrical devices is perforce a system configurator and therefore responsible for meeting standardised system requirements. Please note that local laws prevail over the aforementioned standard requirements. For further advice, please contact your local specialist retailer or our technical service; see Section Technical service, page 38.



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

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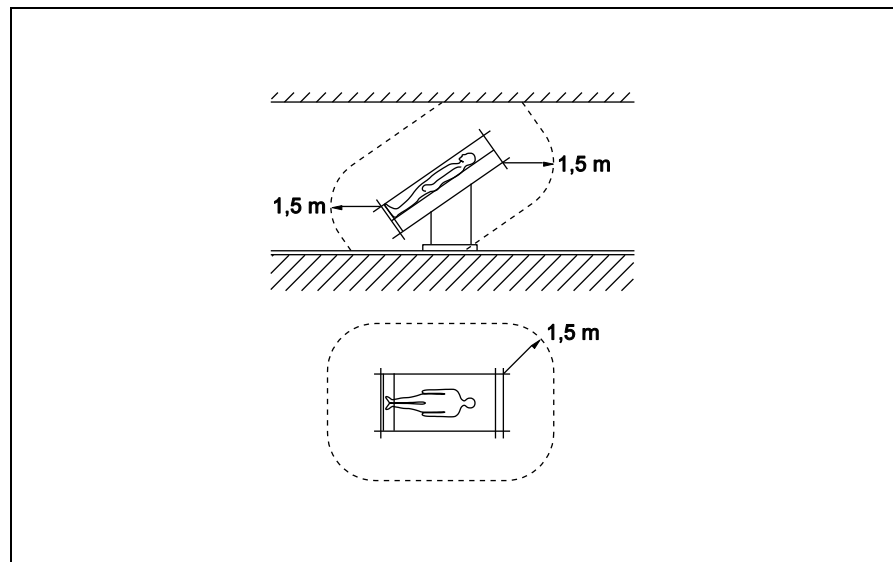


## 2.3. Personal safety instructions

### 2.3.1. Ambient conditions

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

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



### 2.3.2. Patients with pacemakers

Malfunction 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 when possible.
- ▶ 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 within reach.
- ▶ Carry out a postoperative pacemaker check.

### 2.3.3. Safe positioning of the patient

- ▶ Position the patient so that the patient is not touching any metal parts that are grounded or have considerable capacitance relative to ground (e.g. operating table brackets). If necessary, place 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 skin-to-skin contact on the patient's trunk.
- ▶ Ensure a suitable support surface in order to prevent pressure necrosis.
- ▶ Drain urine via the catheter.

### 2.3.4. Correct connection of the HF device

- ▶ Always ground the HF device via the equipotential bonding. Also observe the requirements in Section 8 of ISO 60601-1 regarding 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.

### 2.3.5. 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.

- ▶ Use the automatic monitoring functions to ensure that the HF device works properly without errors. For information on the automatic test functions, see Section 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.

### 2.3.6. 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 stimulation by low-frequency currents.

In HF surgical applications (especially applications in which an arc is formed) part of the HF current is converted into a low-frequency current. This current can trigger muscle contractions in patients.

- ▶ To minimise the risk of patient injury, 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.

## 2.4. 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 other parties and/or damage to the device and other objects can occur.

- ▶ Use only accessories that are approved by BOWA; see Section Accessories and replacement parts, page 47.
- ▶ Use the device only if it is free from 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 35.
- ▶ Never immerse the device in water or cleaning agents.
- ▶ Never boil the device and never disinfect it mechanically.
- ▶ Immediately drain any fluid that may have penetrated the device.

If the device is damaged, a malfunction may cause an undesirable increase in output power.

## 2.5. 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.
- ▶ Comply with the instructions for use as specified by the standard; see Section Error list, page 33.
- ▶ Pay attention to and comply with the acoustic signals and error indicators of the HF device during use; see Section Error list, page 33.
- ▶ The device and accessories may be operated and used only by persons who have the necessary training, knowledge and experience.
- ▶ Regularly inspect the accessories, especially electrode cables, endoscopic accessories and neutral electrodes, for proper operation, damage to the insulation, and expiration date.
- ▶ Do not place any instruments on the patients or on the devices.
- ▶ Wear suitable gloves during surgery.

### 2.5.1. Surgical environment: Prevention of explosions and ignition

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.
- ▶ During surgery in regions such as the head or thorax, avoid using ignitable anaesthetics and gases which support combustion (e.g. nitrous oxide or oxygen) or suck them away.
- ▶ Wear suitable gloves during surgery.
- ▶ Use only 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 or gauze) are kept far enough away from the HF environment that they cannot ignite.

### 2.5.2. Application of the neutral electrode



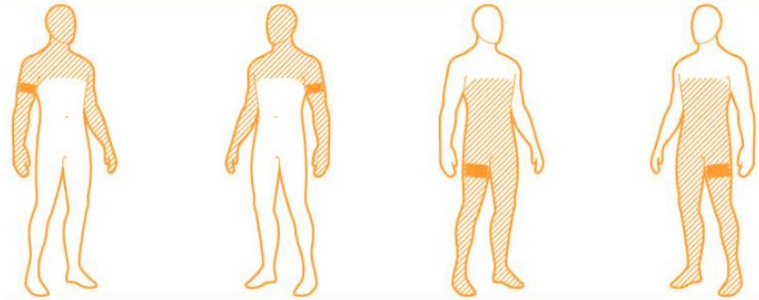
Observe the instructions for use of the neutral electrode in the operating instructions and the instructions on the packaging of the neutral electrode.

---

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 2-1: Application site for the 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 electrodes.
- 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 sites where liquids can collect.

**Before applying the neutral electrode**

- ▶ Shave the area where the neutral electrode will be applied.
- ▶ Clean the application site, and do not use alcohol, as this dries out the skin and increases contact resistance.
- ▶ In case of 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 prevents the current density from becoming excessive at the short edge.
- ▶ 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.



For monitoring of the neutral electrode, see Section EASY neutral electrode monitoring (EASY monitoring), page 23.

---

## 3. 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.

For descriptions of the individual modes and their areas of application as well as appropriate instruments, see Section Mode descriptions, page 31.

### 3.1. Monopolar modes

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

- "Pure" for cutting in low-resistance tissue
- "Dry" for cutting with strong haemostasis
- "Moderate" for contact coagulation
- "Forced" for coagulation with light contact

Instruments can be connected to the multifunction socket **1**.

### 3.2. Bipolar mode



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

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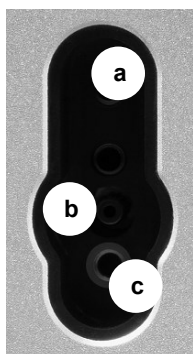
Advantages of the bipolar method:

- 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 multifunction socket **1**.



### 3.3. Monopolar/bipolar multifunction socket



- a** BOWA multifunction (monopolar and bipolar) 3-Pin US type (monopolar)
- b** Martin (bipolar)
- c** 4 mm (monopolar, foot switched)

The multifunction socket **1** allows the connection of a monopolar instrument with hand or foot switching, or a bipolar instrument with foot switching.

The BOWA multifunction cable REF 220-345 for ARC 100 combines a monopolar handpiece and the connecting cable for bipolar forceps in one connection.

### 3.4. Connection socket for neutral electrode



- US-type neutral
- Applied part of Type F according to IEC 60601-1

The neutral electrode connector socket is suitable for neutral electrode plugs with two sockets.

### 3.5. Activation and alarm signals in monopolar and bipolar mode



The volume of the activation signal should be increased as necessary by turning the knob **28** for use in relatively noisy surroundings. The alarm sound and the startup melody cannot be changed.

Mode	Frequency (Hz)	Signal type
Monopolar Cut	635	Continuous sound
Monopolar Coag	475	Continuous sound
Bipolar Coag	505	Continuous sound
Alarm	-	Beep sound

### 3.6. Emergency stop

The HF device can be switched off at any time by using the on/off switch **25** as an emergency stop.

### 3.7. Monitoring functions

#### 3.7.1. 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 33.

#### 3.7.2. 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 code will be indicated using the power display. For further information, see Section Detecting and correcting faults, page 33.

### 3.8. Neutral electrode monitoring



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

---

#### 3.8.1. 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:

- Non-split neutral electrodes
- Split neutral electrodes.

The split neutral electrodes are shown on indicator **15**, and the one-piece neutral electrodes are shown on indicator **14**; see Section Fault indications for EASY monitoring, page 34.

### 3.8.2. 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 the currents in the individual sections of split neutral electrodes.

### 3.9. Foot switches

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















The foot switches are connected to socket connector **30**.

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

Article No.	Designation
901-012	Single pedal foot switch

## 4. Description

### 4.1. Symbols on the device

Symbol	Designation
	Foot switch connection
	Neutral electrode at HF insulated from ground
	CF-type device with defibrillation protection
	Potential equalization connection
	On/off switch
	HF energy in the range of 9 kHz to 400 GHz is used when the HF device is activated. This energy generates electromagnetic radiation.
	Labelling 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
	Date of manufacture
	Observe operating instructions
	Foot switch
	Volume adjustment range
	Volume control

#### 4.1.1. Rating label



Figure 4-1: ARC 100 rating label

## 4.2. Scope of delivery

- ARC 100
- Power cable
- CD including training video
- Operating instructions

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

## 4.3. Components required for operation

- Power cable

### Monopolar accessories:

- Monopolar connecting cable
- Monopolar instrument
- Neutral electrode
- Connecting cable for neutral electrode

### Bipolar accessories:

- Bipolar connecting cable
- Bipolar instrument

- and / or-

- Foot switch

## 4.4. Operating conditions

Temperature:	+10 °C to +40 °C
Relative humidity:	30% to 75%, non-condensing
Atmospheric pressure:	700 hPa to 1060 hPa
Maximum operating altitude:	3600 m AMSL

## 5. Preparation

### 5.1. Setting up the HF device



#### NOTE

**Electromagnetic fields are generated during normal use of the HF device. This can adversely affect other devices.**

- ▶ Ensure that no electronic devices are placed in the vicinity of the HF device.



#### WARNING

**Shock hazard**

- ▶ Always connect the HF device to a grounded power distribution system in order to prevent electric shock.



#### DANGER

**Risk of burns to patients due to excessive leakage current**

- ▶ Locate the HF device outside the immediate vicinity of the patient; see Section Ambient conditions, page 13.



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



If the HF device was previously stored or transported at temperatures below +10 °C or at a relative humidity above 75%, non-condensing, it will take approximately three hours to adjust to room temperature.

1. Observe the specified operating conditions; see Section Operating conditions, page 25.
2. Place the HF device on one of the following platforms:
  - a table,
  - an equipment trolley;
  - a console suspended from a ceiling support or wall-mounted brackets.
  - Do not place any device on the HF device.
3. Place the HF device a sufficient distance away from other electronic equipment; see Section EMC, page 47.
4. Position the HF device with the front of the device facing the patient and surgeon.
5. Do not place any other objects on or above the HF device.
6. Do not place the HF device on top of other devices.

7. Connect the power cord.

## 5.2. Switching on the HF device



Do not use the HF device if the display components are not working. See Section Detecting and correcting faults, page 33 for troubleshooting instructions.

1. Switch the HF device on using the on/off switch **25**.
  - ↳ The HF device carries out a self-test: all indicator lamps light up.
2. Check that all LEDs (**3, 4, 5, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 23, 24**) on the front panel light up.
  - ↳ The HF device is ready for operation.
  - ↳ The parameters for the most recently selected program appear on the front panel.

## 5.3. 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.

### 5.3.1. Instruments for monopolar applications

1. Plug the neutral electrode cable into the socket for the neutral electrode **2**.
2. Check monitoring for a non-split neutral electrode **14** or EASY monitoring for a split neutral electrode **15** to ensure that it corresponds to the type of neutral electrode connected.
3. Connect the electrode handpiece to the active connector socket **1**.  
– or –  
For accessories without finger sensors: Connect the foot switch to the connector socket **30**. Connect the monopolar connection cable with a 3-pin or 4 mm plug to connector socket **1**.

### 5.3.2. Instruments for bipolar applications

1. Connect the bipolar cable with the instrument, e.g. the forceps.
2. Connect the bipolar cable to the active connector socket **1**.
3. For bipolar use, connect the foot switch to the connector socket **30**.

### 5.3.3. Connecting the foot switch

- ▶ Connect the desired foot switch to the foot switch connector socket **30**.

### 5.3.4. Assigning a foot switch output

1. Press the button for "Foot switch" **17** repeatedly in order to assign the foot switch to the desired current type.
- ↪ When indicator **18** lights up, the foot switch is assigned to bipolar coagulation; indicator lamp **19** is for monopolar cutting and indicator **20** is for monopolar coagulation.

## 5.4. Functional test

### 5.4.1. 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 33.

### 5.4.2. Functional test execution

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

1. Connect a split single-use neutral electrode and attach it to the patient's arm.
  - ↪ The EASY neutral electrode indicator **15** changes to green.
2. Remove the neutral electrode.
  - ↪ The indicator **16** changes to red, and the EASY neutral electrode monitoring indicator **15** goes dark.
3. Press the surfaces of the neutral electrode against each other.
  - ↪ The EASY neutral electrode monitoring indicator **15** changes back to green.



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

---

4. Connect a monopolar HF handpiece to the multifunction socket **1** and use the hand and foot switches to individually activate "Cut" and "Coag".
5. Check the settings on the display.
6. Connect a bipolar forceps to the multifunction socket **1** and activate coagulation on a piece of wet gauze using the foot switch.



### 5.4.3. 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.
4. Contact our technical service; see Section Technical service, page 38.

### 5.4.4. EASY neutral 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 monitoring of non-split neutral electrode <b>14</b> or EASY monitoring of split neutral electrode <b>15</b> 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 monitoring of non-split neutral electrode <b>14</b> or EASY monitoring of split neutral electrode <b>15</b> light up	▶ Check the cable for a short circuit.
Cable with split neutral electrode plugged in but not attached to patient.	Indicators for monitoring of non-split neutral electrode <b>14</b> or EASY monitoring of split neutral electrode <b>15</b> 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 monitoring of the non-split neutral electrode <b>14</b> or EASY monitoring of the split neutral electrode <b>15</b> 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.

## 6. Operation

### 6.1. Mode overview

An overview of the modes that can be employed with the HF device is shown below.

Mode icon	Designation
	Monopolar cutting - Pure
	Monopolar cutting - Dry
	Monopolar coagulation - Moderate
	Monopolar coagulation - Forced
-	Bipolar coagulation



The data about points of application and the use of instruments is 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.

Please contact the medical product consultants authorized by BOWA regarding recommendations for settings.

## 6.2. Basic settings

### 6.2.1. Selecting the mode

Use the following procedure to call up the selectable current types:

1. For monopolar cutting or coagulation press the corresponding button/display **6/7/8/9**.  
 ↳ The corresponding LED **10/11/12/13** lights up.
2. Connect the instruments; see Section Connecting instruments, page 27.

### 6.2.2. Setting power levels

Ten power levels are available for each mode.

1. Press the keys **21/22** to raise or to lower the power.  
 ↳ The number of lit LEDs **23** indicates the current power level.

### 6.2.3. Changing the volume

1. Turn the knob **28** on the rear of the device to adjust the volume.

## 6.3. Mode descriptions

The following recommendations are based on empirical values and must be verified in each individual case by the surgeon.

### 6.3.1. Monopolar cutting, "Pure"

In this mode a high-performance HF current with a low crest factor is used for cutting biological tissue.

#### Application areas

Cutting tissue with low electrical resistance, such as muscle tissue or vascular tissue.  
 Cutting or preparing fine structures.

#### Suitable instruments

- Needle electrodes
- Knife electrodes
- Spatula electrodes
- Sling electrodes

### 6.3.2. Monopolar cutting, "Dry"

This mode is used for monopolar dry cutting. A large, controlled arc is generated, which allows significantly deeper coagulation to be obtained.

#### Application areas

Operations in which pronounced haemostases are needed during the cutting process.

Cardiac surgery and blood coagulation in retracting blood vessels in the sternum region.

**Suitable instruments**

- Knife electrodes
- Spatula electrodes
- Ribbon snare electrodes

### **6.3.3. Monopolar coagulation, "Moderate"**

This mode is used in contact coagulation for stopping haemorrhagic oozing, haemostasis of larger tissue areas, and coagulation over smaller surfaces. Carbonisation of the tissue is prevented and adhesion of the electrode to the tissue is greatly reduced. A greater coagulation depth is achieved in comparison to the other coagulation modes.

**Application areas**

Coagulation with high penetration, little adhesion of the electrode to the tissue.

**Suitable instruments**

- Electrodes with large contact area, e.g. ball-type electrodes

### **6.3.4. Monopolar coagulation, "Forced"**

This mode is used for contact coagulation extending only over a small area of the tissue, preferably with small surfaces and fine electrodes. A high degree of coagulation with moderate cutting tendency is achieved.

**Application areas**

Rapid coagulation with low penetration and moderate cutting tendency.

**Suitable instruments**

- Knife electrodes
- Spatula electrodes
- Isolated monopolar forceps

### **6.3.5. Bipolar coagulation**

This mode is employed for arc-less contact coagulation when using forceps. The use of a neutral electrode is not necessary.

**Application areas**

Bipolar coagulation

**Suitable instruments**

- Bipolar forceps
- Bipolar scissors

## 7. Detecting and correcting faults

Two types of faults can occur:

- System errors
- EASY monitoring faults

### 7.1. System errors

If a system error should occur, the fault status indicator **24** will light up red. The combination with the lit display **23** indicates the corresponding error.

#### 7.1.1. Error list

##### Errors not listed

- ▶ Please contact the service centre in the event of errors that do not appear in the error list; see Section Technical service, page 38.
- ▶ 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 fault indications

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

- ▶ Please contact the service centre if the suggested corrective measure does not eliminate the error; see Section Technical service, page 38.

Errors are signalled with a lit Error LED **24** and Power LED **23**:

LED code	Cause	Corrective measures
<b>1</b>	EASY neutral electrode fault	Check the neutral electrode and the neutral electrode cable.
<b>2</b>	The YELLOW button on the finger switch is in an actuated state when switching on the unit.	Switch on the device using the on/off switch <b>25</b> and do not actuate any other operating elements at the same time. If the problem persists, replace the connected instrument and/or the foot switch.
<b>3</b>	The GREEN button on the finger switch or the pedal on the foot switch is in an actuated state when switching on the unit.	Switch on the device using the on/off switch <b>25</b> and do not actuate any other operating elements at the same time. If the problem persists, replace the connected instrument and/or the foot switch.
<b>4</b>	Key on the front panel pressed when switching on the unit	Switch on the device using the on/off switch <b>25</b> and do not actuate any other operating elements at the same time.
<b>5-10</b>	Internal fault	Restart the device. If the error should recur, please contact our technical service.

## 7.2. Fault indications for EASY monitoring

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

Easy monitoring 15	Cause	Indicator	Corrective measures
Switches from green to continuous red	When the monopolar current is activated, a significant problem occurs  Marked increase in the resistance Depending on the indication, there may be heating under the neutral electrode	An acoustic signal sounds. The Easy indicator 16 lights up red.	<ul style="list-style-type: none"> <li>▶ Check the neutral electrode and the neutral electrode cable; see Section Neutral electrode monitoring, page 22.</li> <li>▶ Check the neutral electrode cable for proper connection and external damage.</li> </ul>
	Loosened electrode	The Easy indicator <b>16</b> lights up red.  The device electronics switch the output socket <b>1</b> off.	<ul style="list-style-type: none"> <li>▶ Correct the position of the neutral electrode. In the case of continuing error messages, replace the neutral electrode.</li> </ul>

## 8. Cleaning

### 8.1. Preparation of the accessories

- ▶ Prepare the accessories (e.g. surgical handpieces, instruments, active electrodes, neutral electrodes and cables) as described in the corresponding operating manuals.
- ▶ Check the accessories before and after use for damage and ensure that they are working properly.

### 8.2. Disinfection and cleaning



#### **NOTE**

**Incorrect use of the HF device can cause damage to the unit**

- ▶ Never sterilize the ARC 100 HF device. Instead, clean or disinfect it.



#### **WARNING**

**Risk of electric shock and fire!**

- ▶ Unplug the power cable before cleaning the device.
- ▶ For surface cleaning, use approved cleaning agents and/or disinfectants according to the manufacturer's instructions.
- ▶ Ensure that no liquid penetrates the device.

1. Apply the cleaning agent and disinfectant.
2. 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.

## 9. Maintenance and repair

### 9.1. Maintenance

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#### **DANGER**

##### **Infection hazard**

- ▶ To avoid spreading germs and infections, disinfect the surface of the device and pack it in addition to the shipping packaging before it leaves the hospital or surgical practice.
- 

- ▶ Check the device, the device trolley and the accessories (e.g. foot switch, cable) after each use for damage or defects. In particular, ensure 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. Consult the appropriate service manual for additional technical information.

#### 9.1.1. 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 centre; see Section Technical service, page 38.



## 9.2. 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 centre 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 have been carried out only by persons authorised by BOWA to do this work.
- 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.

– or –

- ▶ Describe the repairs to be made.

### 9.3. Technical service

Contact the following service centre 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](mailto:service@bowa.de)

or visit our website:

[www.bowa-medical.com](http://www.bowa-medical.com)

## 10. Storage

- ▶ If you store the HF device longer than one year, pay particular attention to the indicators of the automatic function tests; see Section Functional test, page 28.
- ▶ 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: -10 °C to +60 °C
- Relative humidity 10 % to 85 %, non-condensing
- Atmospheric pressure: 500 hPa to 1060 hPa

## 11. Technical specifications

### 11.1. Technical data for ARC 100

Insulation type / Classification	
EMC	IEC 60601-1-2: 2007
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 + A1:2013 IEC 60601-1-2: 2007, IEC 60601-2-2: 2009, IEC 60601-1-6:2010 IEC 60529:1989 + A1:1999 IEC 62304:2006 IEC 62366:2007 ISO 14971: 2007, ISO 13485: 2003 + Cor.1: 2009
Classification according to EC Directive 93/42/EEC	IIb

Power connection	
Power consumption in standby mode (100 V)	14 VA
Power consumption in standby mode (230 V)	30 VA
Line frequency	50/60 Hz
Maximum power consumption with 100 W HF output power	160 VA
Connection for potential equalisation line	Yes

Voltage range 100 - 260 V	
Input voltage range	100 V to 260 V
Current consumption in standby mode (100 V)	140 mA
Current consumption in standby mode (230 V)	130 mA
Current consumption at maximum HF output (100 V)	1.6 A
Current consumption at maximum HF output (230 V)	0.7 A
Mains fuses	2 x T3,15 A 250V

Dimensions and weight	
External dimensions: width x height x depth (mm)	280 x 114 x 310
Weight	Approx. 5.6 kg

<b>Monitoring of the neutral electrode</b>	
EASY: Electrode Application System	√
Indicator for non-split or split electrode on the front panel	√
Warning signal in the event of risk under the neutral electrode	Visual, acoustic
Warning indicator on the front panel	√

<b>Safety features</b>	
<b>ISSys</b> : Integrated Safety System	√
Self-test	√
Continuous status indication on the front panel	√
Display of operating errors on the front panel	√
Display of system errors on the front panel	√

<b>Service support</b>	
Service support via ISSys	√

<b>Cooling</b>	
Convection	√

<b>Duty factor</b>	
Intermittent	10 sec / 30 sec (on/off)

<b>Characteristics</b>	
Max. CUT power	100 W (at 500 Ω)
Max. COAG power	100 W (at 100 Ω)
Output frequency	500 kHz
Sockets	1x monopolar/bipolar multifunctional socket, monopolar with foot switch and finger switch, bipolar with foot switch
Connection for foot switch	1x
Scope of delivery	Incl. User manual, mains cable

<b>Compatibility</b>	
Permitted combination	Foot switch (REF 901-012)

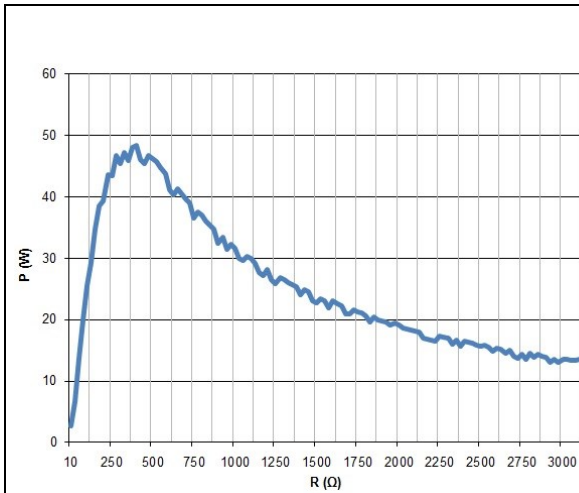
<b>Conditions of operation, transport and storage</b>	<b>Operation</b>	<b>Transport and storage</b>
Temperature	+10°C to +40°C	-10°C to +60°C
Relative humidity	30 to 75%, non-condensing	10 to 85%, non-condensing
Atmospheric pressure	700 to 1060 hPa	500 to 1060 hPa
Operating altitude (max.)	3600 m above sea level	

## Current types

Description	Form of HF voltage	Max. Power output		Peak voltage
		Level	Power range	
<b>Monopolar Modes Cutting</b>				
Pure	Sinusoidal constant	1	10 W - 100 W	300 Vp
		2		480 Vp
		3		600 Vp
		4		730 Vp
		5		810 Vp
		6		950 Vp
		7		1100 Vp
		8		1200 Vp
		9		1260 Vp
		10		1380 Vp
Dry	Sinusoidal modulated	1	10 W - 100 W	390 Vp
		2		635 Vp
		3		775 Vp
		4		940 Vp
		5		1100 Vp
		6		1200 Vp
		7		1250 Vp
		8		1350 Vp
		9		1440 Vp
		10		1500 Vp
<b>Monopolar Modes Coagulation</b>				
Moderate	Sinusoidal constant	1	10 W - 100 W	150 Vp
		2		190 Vp
		3		250 Vp
		4		295 Vp
		5		317 Vp
		6		360 Vp
		7		370 Vp
		8		100 Vp
		9		420 Vp
		10		440 Vp
Forced	Sinusoidal modulated	1	10 W - 100 W	720 Vp
		2		1040 Vp
		3		1200 Vp
		4		1380 Vp
		5		1500 Vp
		6		1680 Vp
		7		1760 Vp
		8		1890 Vp
		9		2210 Vp
		10		2340 Vp
<b>Bipolar Mode Coagulation</b>				
Bipolar	Sinusoidal constant	1	10 W - 100 W	117 Vp
		2		158 Vp
		3		195 Vp
		4		227 Vp
		5		246 Vp
		6		270 Vp
		7		290 Vp
		8		315 Vp
		9		335 Vp
		10		346 Vp

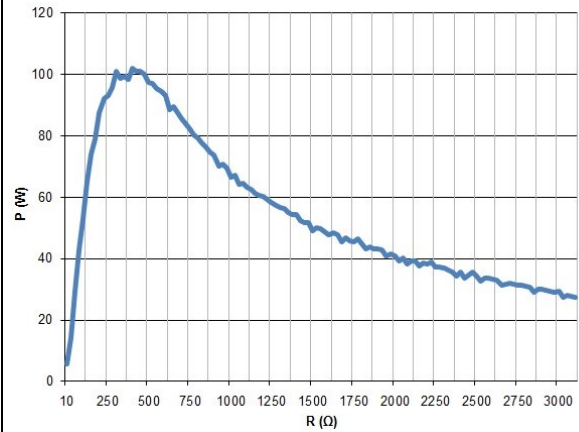
## 11.2. Power, voltage and current charts

### Monopolar cutting – Pure



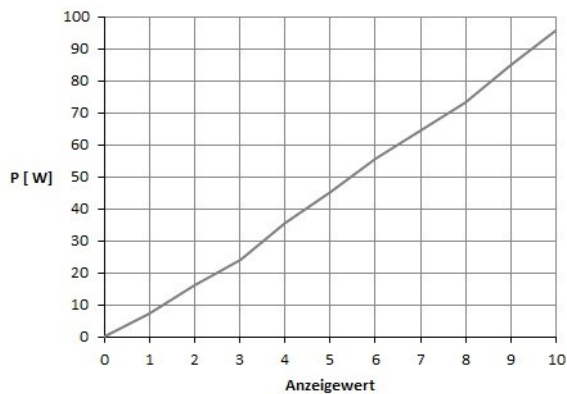
Values measured using non-inductive resistors

- Graph of output power P [W] as a function of the load resistance R [Ω] for the "Monopolar Cutting Pure" setting = 50 W



Values measured using non-inductive resistors

- Graph of output power P [W] as a function of the load resistance R [Ω] for the "Monopolar Cutting Pure" setting = 100 W

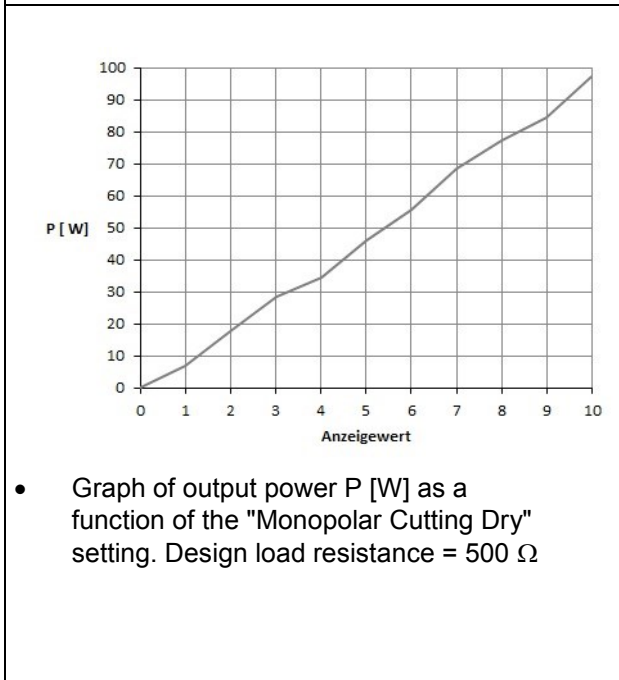
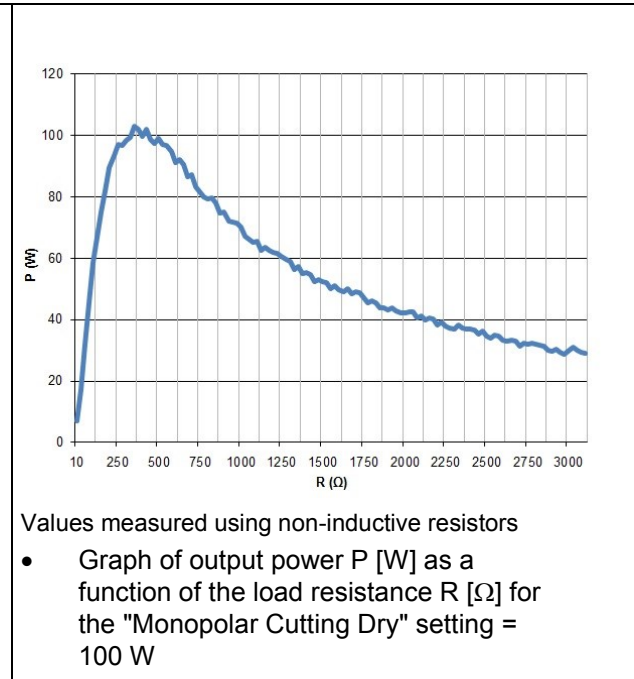
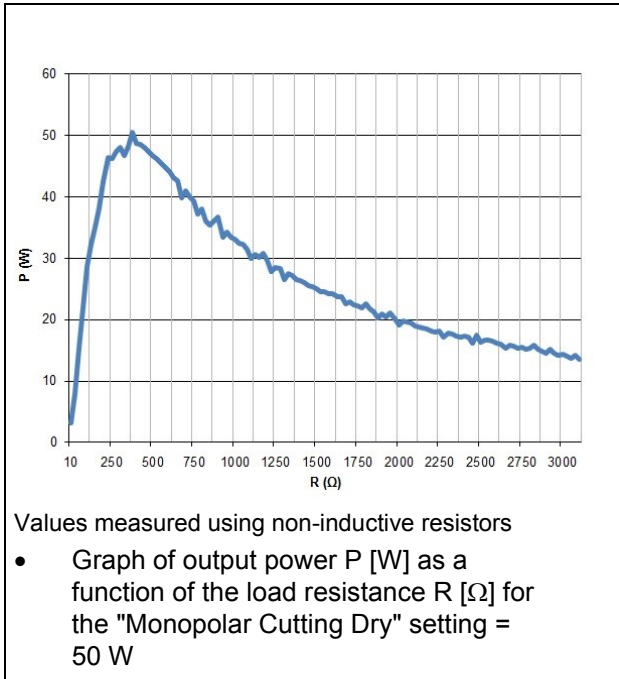


- Graph of output power P [W] as a function of the "Monopolar Cutting Pure" setting. Design load resistance = 500 Ω

Level	U (Vp)
1	300
2	480
3	600
4	730
5	810
6	950
7	1100
8	1200
9	1260
10	1380

- Table of HF output voltage U [Vp] as a function of the "Monopolar Cutting Pure" setting (no load)

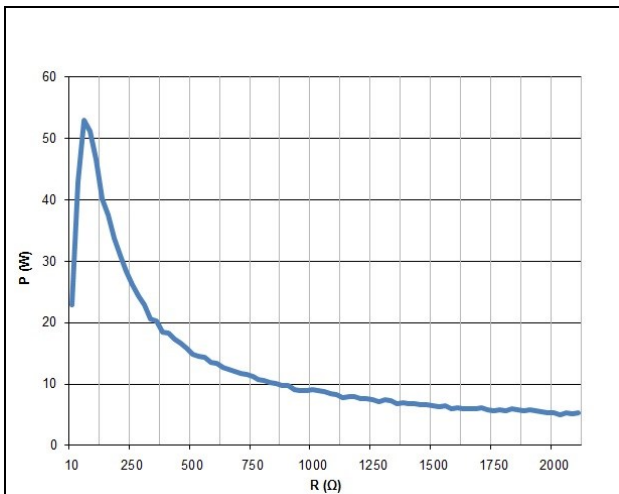
**Monopolar cutting – Dry**



Level	U (Vp)
1	390
2	635
3	775
4	940
5	1100
6	1200
7	1250
8	1350
9	1440
10	1500

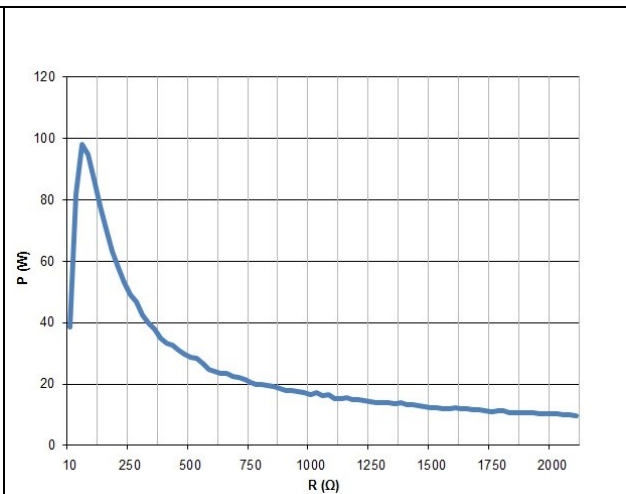
- Table of HF output voltage U [Vp] as a function of the "Monopolar Cutting Dry" setting (no load)

**Monopolar coagulation – Moderate**



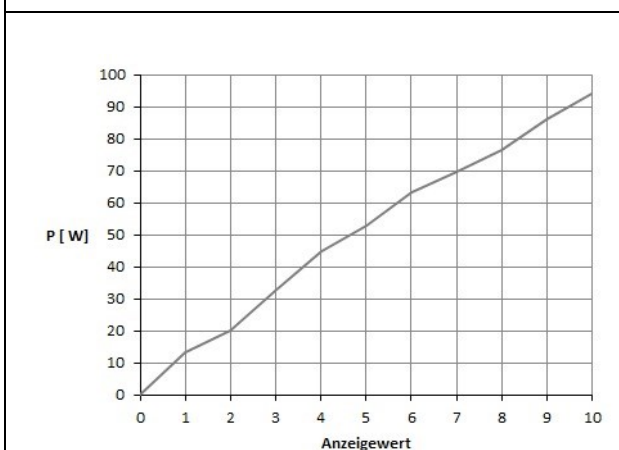
Values measured using non-inductive resistors

- Graph of output power P [W] as a function of the load resistance R [Ω] for the "Monopolar Coagulation Moderate" setting = 50 W



Values measured using non-inductive resistors

- Graph of output power P [W] as a function of the load resistance R [Ω] for the "Monopolar Coagulation Moderate" setting = 100 W



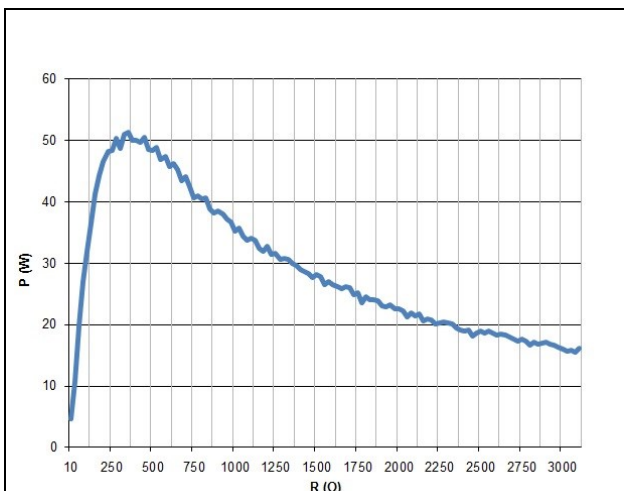
- Graph of output power P [W] as a function of the "Monopolar Coagulation Moderate" setting. Design load resistance = 100 Ω

Level	U (Vp)
1	150
2	190
3	250
4	295
5	317
6	360
7	370
8	400
9	420
10	440

- Table of HF output voltage U [Vp] as a function of the "Monopolar Coagulation Moderate" setting (no load)

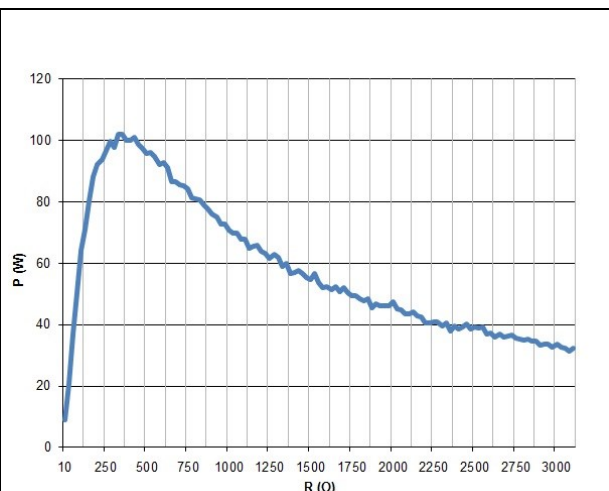


**Monopolar coagulation – Forced**



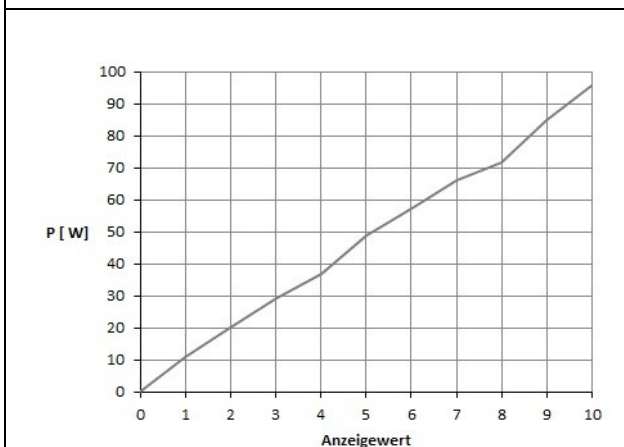
Values measured using non-inductive resistors

- Graph of output power P [W] as a function of the load resistance R [Ω] for the "Monopolar Coagulation Forced" setting = 50 W



Values measured using non-inductive resistors

- Graph of output power P [W] as a function of the load resistance R [Ω] for the "Monopolar Coagulation Forced" setting = 100 W

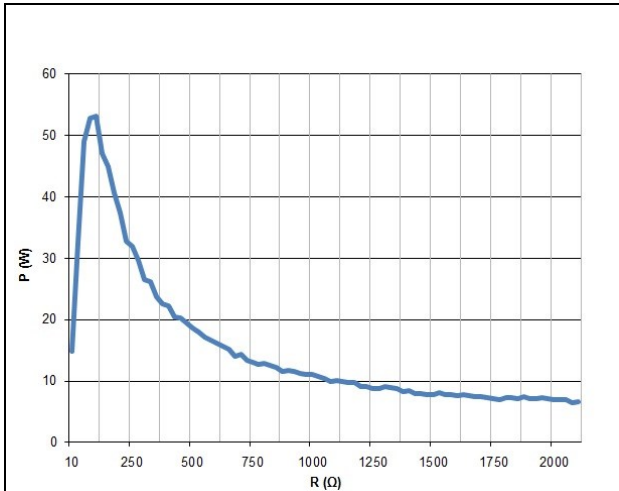


- Graph of output power P [W] as a function of the "Monopolar Coagulation Forced" setting. Design load resistance = 500 Ω

Level	U (Vp)
1	720
2	1040
3	1200
4	1380
5	1500
6	1680
7	1760
8	1890
9	2210
10	2340

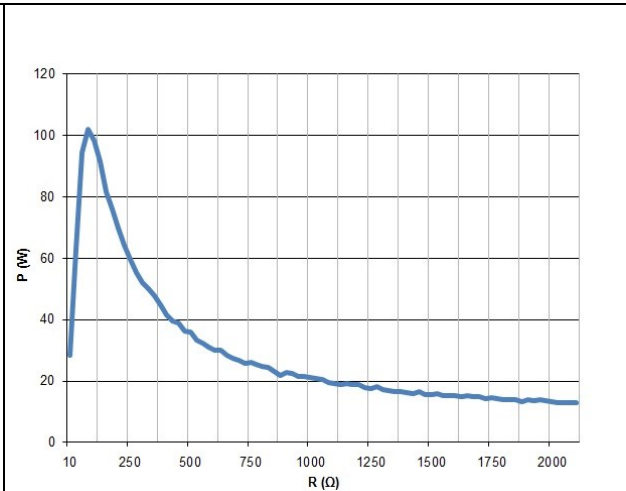
- Table of HF output voltage U [Vp] as a function of the "Monopolar Coagulation Forced" setting (no load)

**Bipolar coagulation**



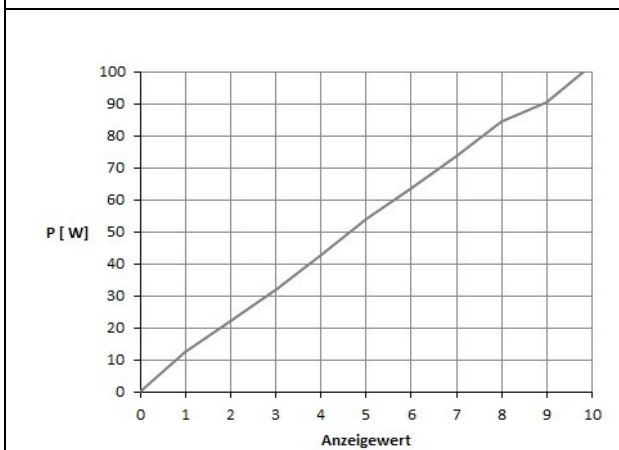
Values measured using non-inductive resistors

- Graph of output power P [W] as a function of the load resistance R [Ω] for the "Bipolar Coagulation" setting = 50 W



Values measured using non-inductive resistors

- Graph of output power P [W] as a function of the load resistance R [Ω] for the "Bipolar Coagulation" setting = 100 W



- Graph of output power P [W] as a function of the "Bipolar Coagulation" setting. Design load resistance = 100 Ω

Level	U (Vp)
1	117
2	158
3	195
4	227
5	246
6	270
7	290
8	315
9	335
10	346

- Table of HF output voltage U [Vp] as a function of the "Bipolar Coagulation" setting (no load)

## 12. Accessories and replacement parts

The BOWA multifunction cable REF 220-345 is optimally suited to the operation of a monopolar handpiece and bipolar forceps on the ARC 100 because both connectors are combined in one plug.

Original BOWA accessories are suitable for use with devices in the ARC and ARC PLUS families. 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 catalogue.

## 13. EMC

### 13.1. Guidelines and manufacturer's declaration in accordance with DIN EN 60601-1-2, para. 6.8.3.201

<b>Electromagnetic interference (IEC 60601-1-2, Table 201)</b>		
The ARC 100 is intended for operation in an electromagnetic environment as described below. The customer or user of the ARC 100 should ensure that it is operated in such an environment.		
<b>Interference measurements</b>	<b>Conformity</b>	<b>Electromagnetic environment guideline</b>
HF emissions as specified in CISPR 11	Group 1	The ARC 100 must emit electromagnetic energy in order to perform its intended functions. Nearby electronic devices may be affected.
HF emissions as specified in CISPR 11	Class B	The ARC 100 is suitable for use in facilities other than living areas and those connected directly to the public power supply network, which also supplies buildings used for residential purposes.
Emission of harmonics as specified in IEC 61000-3-2	Class B	
Emission of voltage fluctuations or flicker as specified in IEC 61000-3-3	Conforms	

<b>Electromagnetic immunity (IEC 60601-1-2, Table 202)</b>			
The ARC 100 is intended for operation in the electromagnetic environment described below. The customer or user of the ARC 100 should ensure that it is operated in such an environment.			
<b>Tests for resistance to interference</b>	<b>IEC 60601 test level</b>	<b>Conformity level</b>	<b>Electromagnetic environment guidelines</b>
Electrostatic discharge (ESD) according to <b>IEC 61000-4-2</b>	± 6 kV contact discharge	± 6 kV contact discharge	Floors should be made of wood or cement or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
	± 8 kV air discharge	± 8 kV air discharge	
Fast transient electrical interference (bursts as per IEC 61000-4-4)	± 2 kV for power supply lines	± 2 kV for power supply lines	The quality of the mains power should correspond to that of a typical business or hospital environment.
	± 1 kV for input and output lines	± 1 kV for input and output lines	
Surges as per IEC 61000-4-5	± 1 kV voltage outer conductor-outer conductor	± 1 kV voltage outer conductor-outer conductor	The quality of the mains power should correspond to that of a typical business or hospital environment.
	± 2 kV voltage outer conductor to ground	± 2 kV voltage outer conductor to ground	
Voltage collapses, brief interruptions and fluctuations in the power supply as per IEC 61000-4-11	< 5% $U_T$ for ½ period (> 95% dropout) 40 % $U_T$ for 5 periods (60 % dropout) 70% $U_T$ for 25 periods (30% dropout) < 5% $U_T$ for 5 s (> 95% dropout)	< 5% $U_T$ for ½ period (> 95% dropout) 40 % $U_T$ for 5 periods (60 % dropout) 70% $U_T$ for 25 periods (30% dropout) < 5% $U_T$ for 5 s (> 95% dropout)	The quality of the mains power should correspond to that of a typical business or hospital environment. If the user of the ARC 100 requires it to continue operating even in the presence of power interruptions, it is recommended that the ARC 100 be supplied from an uninterruptible power supply or a battery.
Note: $U_T$ is the AC supply voltage prior to the application of the test level.			

<b>Electromagnetic immunity (IEC 60601-1-2, Table 204)</b>			
The ARC 100 is intended for operation in the electromagnetic environment described below. The customer or user of the ARC 100 should ensure that it is operated in such an environment.			
<b>Tests for resistance to interference</b>	<b>IEC 60601 test level</b>	<b>Conformity level</b>	<b>Electromagnetic environment guidelines</b>
Conducted HF interference as per IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V	Portable and mobile wireless devices should not be used within the recommended protective working clearance from the ARC 100 and its cables, which is calculated using the equation corresponding to the relevant transmission frequency. <b>Recommended protective distance:</b> $d = 0.35 \times \sqrt{P}$ $d = 0.35 \times \sqrt{P}$ for 80 MHz to 800 GHz $d = 0.7 \times \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the nominal transmitter output in watts (W) specified by the transmitter manufacturer and d is the recommended protective distance in meters (m). The field strength of stationary transmitters as determined by on-site measurements <sup>a</sup> should be lower than the compliance level <sup>b</sup> at all frequencies. Interference is possible in the vicinity of devices that bear the following symbol. 
Radiated HF interference as per IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
Note 1	The higher frequency range applies in case of 80 MHz and 800 MHz.		
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and people.		
a	Field strengths from stationary transmitters such as base stations for wireless telephones and land mobile radios, amateur radio, AM and FM radio broadcasting and TV broadcasting cannot be predicted theoretically with accuracy. A study of the electromagnetic phenomena at the location should be done to determine the electromagnetic environment resulting from stationary transmitters. If the measured field strength at the location where the ARC 100 is being used exceeds the aforementioned compliance level, the ARC 100 should be monitored to verify that it is functioning properly. If unusual performance characteristics are observed, additional measures may be necessary, such as repositioning or relocation of the ARC 100.		
b	The field strength should be lower than 10 V/m over the frequency range of 150 kHz to 80 MHz.		

**Recommended protective working clearances between portable and mobile HF telecommunications devices and the ARC 100 (IEC 60601-1-2, Table 206)**

The ARC 100 is designed for operation in an electromagnetic environment in which HF interference is monitored. The customer or user of the ARC 100 can help to prevent electromagnetic interference by complying with the minimum clearance between portable and mobile HF telecommunication devices (transmitters) and the ARC 100. These clearances may vary depending on the output power of the relevant communication device as specified below.

Nominal transmitter output (W)	Protective distance (m) depending on transmission frequency		
	150 kHz to 80 MHz $d = 0.35 \times \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \times \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \times \sqrt{P}$
0.01	0.035	0.035	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0


For transmitters whose maximum nominal output is not specified in the table above, the recommended protective distance  $d$  in meters (m) can be determined using the equation in the corresponding column, where  $P$  is the maximum nominal output power of the transmitter in watts (W) as specified by the transmitter manufacturer.

Note 1	The higher frequency range applies in case of 80 MHz and 800 MHz.
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and people.

## 14. Disposal



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

Symbol	Designation
	<p>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.</p>

- ▶ If you have any questions regarding the disposal of the device, please contact our technical service; see Section Technical service, page 38.

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