

Biosealer CR 4 AA

including

**Bench Unit
Manual Handle
Ergonomic Handle MSH-III**

**User's Manual
and
Technical reference**

Ljungberg & Kögel AB

1. Important

This user's manual is written for the person responsible for the operation of Biosealer CR 4. The operational methods and routines are developed and tested to ensure a reliable, safe and effective operation of CR 4. It is important that the operator has studied and understood the contents of this manual before using CR 4.

Throughout this manual, CR4 means the same thing as CR4 AA.



- This instrument is a sealing equipment using radio frequency for welding and the electrical emission at the operating frequency 40.68 MHz is high. Make sure that other instruments and equipment near the sealing unit can withstand this emission.
- Never touch the electrodes with your fingers during the sealing process! This may cause burn damages!
- Ensure that the PVC tube is dry on the surface.



CR4 contains electronic components which are classified as dangerous for the environment and the equipment must be left to a recycling station when disposed.

2. Warranty

- 2.1. Ljungberg & Kögel AB, hereby guarantees the original buyer that Biosealer CR 4 is manufactured in a professional and quality manner, and will be free from all faults during a period of one year from the date of delivery from L&K.
- 2.2. The warranty includes equipment or components that prove to have faults during the warranty period. L&K will without cost for the customer, repair or replace the equipment that is faulty.
- 2.3. The warranty is not valid if the equipment has been repaired by anyone else than qualified personnel, approved by L&K.
- 2.4. The warranty is not valid if the equipment has been changed in any way that according to L&K:s opinion, affects the reliability or stability of the instrument.
- 2.5. The warranty is not valid when the serial number has been changed, crossed over or been removed, or if the fault has been caused by misuse or abnormal use.
- 2.6. In these cases L&K or L&K:s representative will inform the customer about the decision, and if wished by the client will repair the equipment for normal rate. An estimated price can be given on request.

Abelko Innovation is committed to develop high-quality equipment and technical services to all our customers. We welcome any inputs on technical issues that are encountered so that they can be resolved quickly and in the most appropriate manner. Please submit your comments/feedbacks through your local distributors or alternatively email us directly at info@abelko.se

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Rev history

2011-11-08 TI Ergonomic handle MSH3 included
 2011-11-28 TI Coiled cable Ergo Handle changed part number
 2011-12-08 TI Spare parts added 2-pole contact
 2012-11-09 JA Added Abelko Innovation commitment concerning technical feedback
 2012-12-13 JA Minor changes in the chapter layout
 2012-12-13 DC Partlist updated with 5.1
 2013-01-05 DC Type in DoC updated to Biosealer
 2014-04-17 DC Address in DoC updated, Added explanation that CR4 is the same as CR4 AA
 2014-05-07 DC RoHS added in DoC

4. Properties

- 4.1. **Model for continuous use.** Biosealer CR 4 is built for sealing PVC-tubes, especially blood bags tubes or sets for plasmaferes. CR 4 has a powerful HF-unit (high frequency), which makes it suitable both for routine procedures at donation rooms and repeated operations at preparation rooms without overheating.
- 4.2. **Bench Unit and Handle Unit.** The Power Unit can either be connected to a handle Unit and a Bench Unit or two Handle Units. Bench Unit automatically seals when a tube is in position. The Handle Unit is easy to move and therefore it is easy to reach the part of the tube which shall be sealed. Both units has a 1,9 m cable. The electrodes of the Handle Units are well protected by a plastic cover and are easy to clean.
- 4.3. **Wide and safe seal.** The high frequency HF gives a wide and safe seal of about 3mm with a marking in the middle for making it easier to pull the tubes apart.

5. Description

5.1. Power Unit



5.1.1. Connectors and indicators

HANDLE: BNC contact for HF output to Ergonomic Handle or Manual Handle

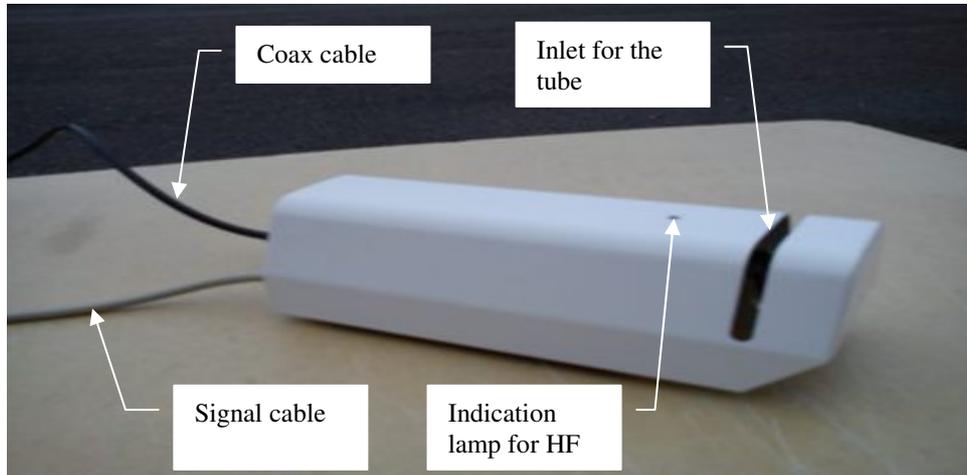
HANDLE/BENCH UNIT: BNC contact for HF output to Ergonomic or Manual Handle or a Bench Unit.

SIGNAL CABLE: Signal output for controlling the Bench Unit electromagnet

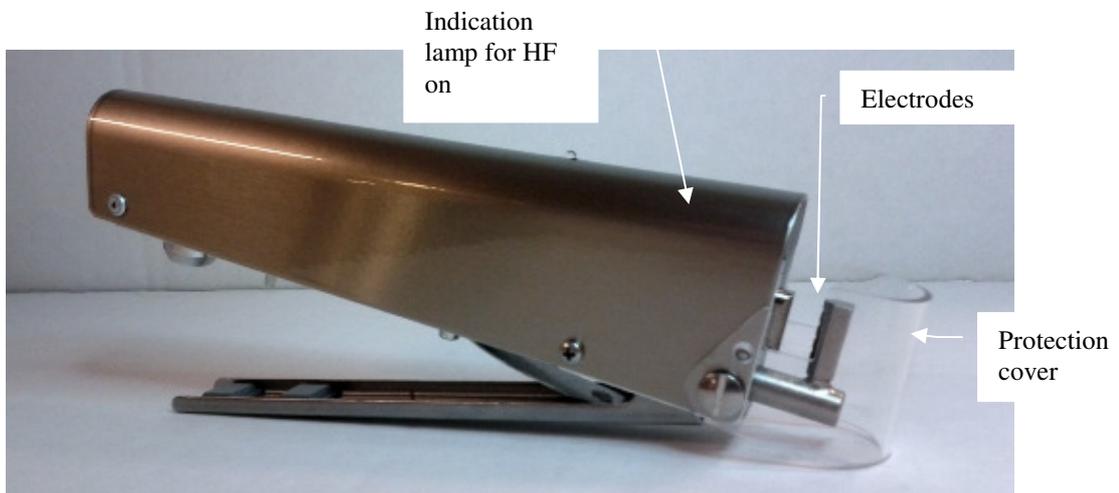
STATUS: BI-colour LED indicating power on (fixed green), sealing (blinking orange) or some error (blinking red).

TEMP ALARM: Red LED if HF generator is overheated.

5.2. Bench Unit



5.3. Handle Unit.



5.4. Ergonomic Sealing Handle (MSH-III)

- (1) **Sealing indication.** Is blinking blue during sealing process and turns to green when ready.
- (2) **Electrodes.** Transfers the high frequency energy to the PVC tube. The tube to be sealed must be placed between the electrodes.
- (3) **Protection cover.** Protects electrodes from damage and also prevent unintentional finger contact with electrodes.
- (4) **Coaxial cable**



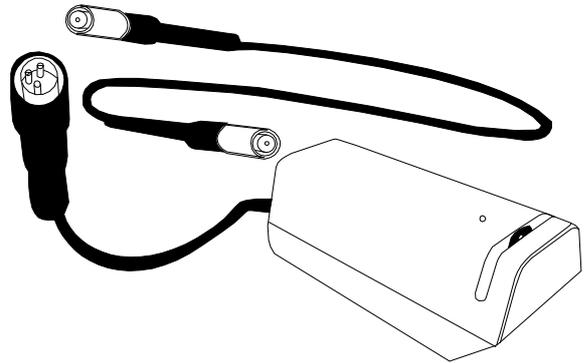
6. Operation with the Bench Unit



- Always turn the power off before you connect or disconnect a cable or both cables.
- Always use the coax cable that is delivered with the equipment. It is not allowed to extend the cable. If you need a longer cable, then order a longer cable, see spare parts list.

6.1. Connection of Bench Unit

- 6.1.1. Connect the Bench Unit to the HF-contact on the Power Unit with the coax cable.
- 6.1.2. Connect the signal cable from the Bench Unit to the signal contact on the Power Unit.



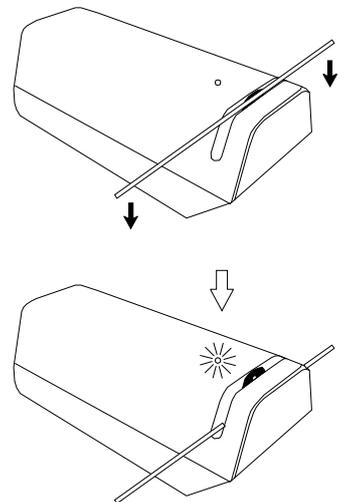
6.2. Sealing

- 6.2.1. Place the PVC-tube in the slot of the Bench Unit.
- 6.2.2. The sealing automatically starts, and the indication diodes are lit on the Power Unit and the Bench Unit.

Note !

Do not pull the PVC-tube when sealing.

- 6.2.3. The PVC-tube is sealed in appr. 1-2 sec. The electrodes automatically release the tube and the indication is switched off. CR4 is adjusted for tubes of 4-5 mm thickness. CR4 for tubes of up to 6,5 mm is on demand. See chapter 9 for sealing of other tubes.



Note !

When sealing the PVC-tube on two or more places the distance between the seals must be more than 50 mm. Shorter distance may cause leakage.

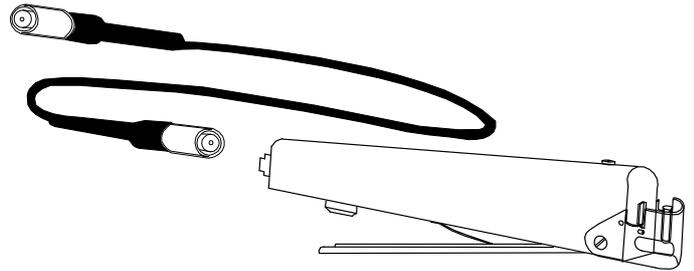
7. Operation with the Handle Unit



Always turn the power off before you connect or disconnect the coax cable.

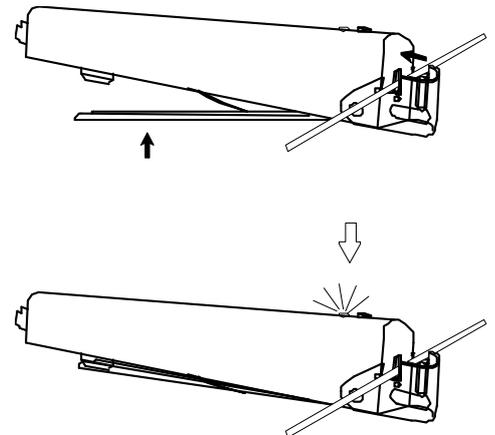
7.1. Connection of Handle Unit

- 7.1.1. Connect the Handle Unit to the HF-contact on the Power Unit with the coax cable.



7.2. Sealing

- 7.2.1. Place the PVC-tube in the slot of the Handle Unit.
- 7.2.2. Press the Handle Unit. The sealing indication on both the Power Unit and Handle Unit is lit.
- 7.2.3. The PVC-tube is sealed in appr. 1-2 sec. The PVC-tube is sealed in appr. 1 sec. Wait a short moment (0.5 sec) after the indication is turned off to let the seal cool down before releasing the tube. CR 4 is adjusted for PVC-tubes of 4-5 mm thickness. See chapter 9 for sealing other tubes.



Note !

When sealing the PVC-tube on two or more places the distance between the seals must be more than 50 mm. Shorter distance may cause leakage.

8. Operation with the Ergonomic Handle Unit



Always turn the power off before you connect or disconnect the coax cable.

8.1. Connection of Ergonomic Handle Unit MSH-III

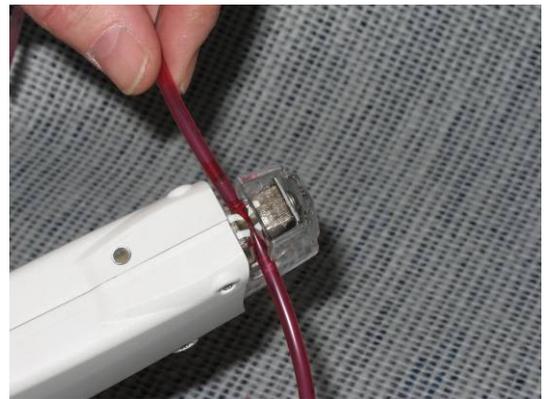
8.1.1. Connect the Handle Unit to the HF-contact on the Power Unit with the coax cable.

8.2. Sealing

8.2.1. Place the PVC-tube in the slot of the Handle Unit.

8.2.2. Press the Handle Unit. The sealing indication on the Handle Unit is blinking blue during seal process and turns to green when ready after about 1-2 sec.

8.2.3. CR 4 is adjusted for PVC-tubes of 4-5 mm thickness. See chapter 9 for sealing other tubes.



Note !

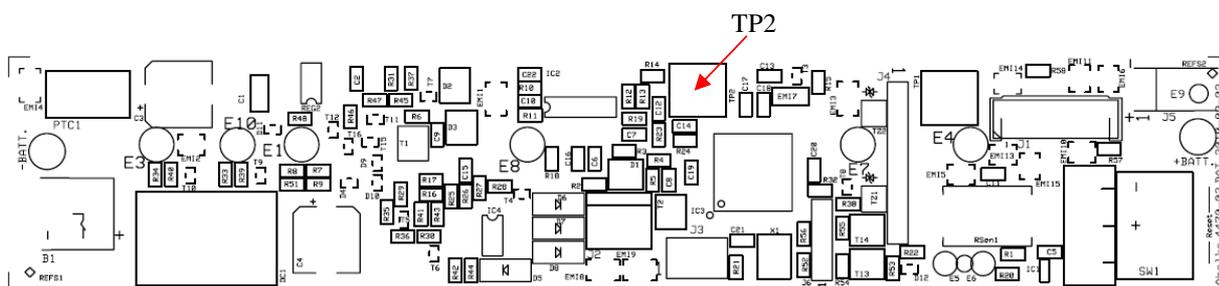
When sealing the PVC-tube on two or more places the distance between the seals must be more than 50 mm. Shorter distance may cause leakage.

9. Adjustments

9.1. Change to manual timer

Note! This is an operation which must be done by an authorized technician. We do not recommend manual timer settings since this can lead to overheating the HF generator or the electro magnet in the Bench Unit. It should only be used when sealing very special tubes. If in doubt contact Ljungberg&Kögel before thi settings.

If you have hard sealed tubes that needs longer timer i.e. more time for the high frequency, you can disconnect the automatic state by turning the potentiometer TP2 on the timer PC board clockwise with a small screwdriver. Turning it more than 20% turns on the manual timer and the timer will be set from 2 to 10 sec. (potentiometer 20-100%). To be able to locate TP2 you have to lift off the cover by unscrewing the 4 screws on the side.



10. Maintenance

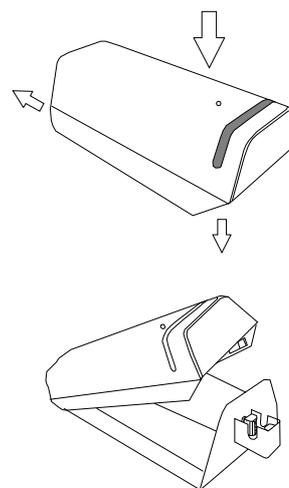


Always turn the power off before cleaning the electrodes !

10.1. Cleaning the electrodes.

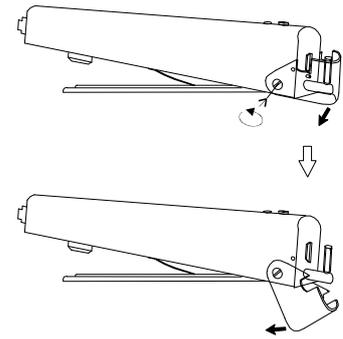
10.1.1. Bench Unit

- 10.1.1.1. Remove the coax-cable from the Bench Unit.
- 10.1.1.2. Press gently on top of the cover and pull the lever for the locking device on the backside. This will release the cover locking.
- 10.1.1.3. Lift the cover. Clean both electrodes with distilled water or alcohol.
- 10.1.1.4. Dry up the electrodes carefully with a soft and lint-free cloth.
- 10.1.1.5. Put the cover back in position by pressing the cover while pushing the locking device.
- 10.1.1.6. Replace the coax cable.



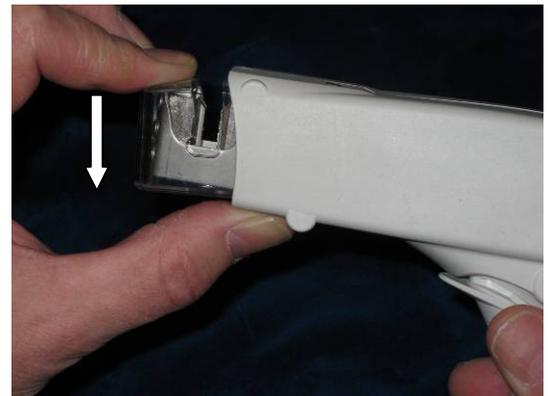
10.1.2. **Handle unit**

- 10.1.2.1. Remove the coax-cable from the handle unit.
- 10.1.2.2. Loosen a bit the two screws holding the protection cover and tilt it down.
- 10.1.2.3. Clean both electrodes with distilled water.
- 10.1.2.4. Dry up the electrodes carefully with a soft and lint-free cloth.
- 10.1.2.5. Tilt up the protection cover and fasten it with the two screws.
- 10.1.2.6. Replace the coax cable.

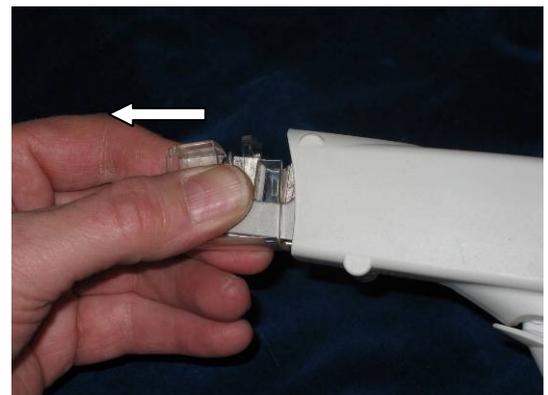


10.1.3. **Ergonomic Handle MSH-III**

- 10.1.3.1. Remove the coaxial cable from the handle unit
- 10.1.3.2. Remove the protective cover by first pressing the front down as shown in the figure.



- 10.1.3.3. Then pull the cover forwards.



- 10.1.3.4. Clean both electrodes with distilled water.
- 10.1.3.5. Dry up the electrodes carefully with a soft and lint-free cloth.
- 10.1.3.6. Replace the coax cable.

11. Technical description

CR 4 consists of a HF generator module operating at 40,68 MHz with a maximum output power of 100W. The HF generator (HFG-01) is a complete module mounted on the backside of CR 4 to achieve the best possible cooling. HFG-01 is provided with current, 24 V, from a 200W medical approved power supply.

Note!

Due to regulations of maximum emission (radiation) at other frequencies than 40,68 MHz the HFG-01 module is soldered up and shall be regarded as a component. It can not and it is not allowed to be adjusted or repaired by anyone else than the manufacturer. In the event of malfunction of HFG-01 it must be sent to the manufacturer for repair.



The voltage that occurs during sealing may cause burn damages if someone touches the hot electrode during the sealing process. Therefore it is absolutely necessary to turn off the power before cleaning or service of the Handle Unit or Bench Unit.

11.1. Sealing Function

The sealing function is controlled by the timer board mounted on the HFG. The timer board consists of a microprocessor which governs all functions. When the Handle Unit is pressed, or when a tube is placed in the Bench Unit the connection from the central conductor in the coax cable to ground is released and a DC-voltage of 5 V is supplied from the timer board.

This voltage is recognized by the microprocessor on the timer board. The processor first checks if there is any leakage of current between the electrodes, if so this indicates damp on the tube. The limit is set to 6 μ A. If the value exceeds this limit, the seal is cancelled and an indication is given by the diode STATUS which is flashing red indicating "Moist on tube". There will also be an audible warning signal. This means that the tube is damp and that there is a risk for sparking and leakage.

If no damp is found the HF generator is turned on. The microprocessor has an automatic sensing algorithm which turns off the HFG when the seal is finished. After this there is a cooling period of 500 ms to let the seal cool down and then the seal is completed and the Status diode and the lamp on the handle are turned green and the indication on the Bench Unit is turned off and the electromagnet releases the tube.

The temperature of the HFG is measured with a termistor mounted on the rear part and if the temperature exceeds an alarm set level of 75 °C the start of sealing is cancelled and the red diode "Temp Alarm" is blinking.

If the electrodes are shortened during sealing the HF-generator immediately is stopped.

12. Trouble shooting



Do not adjust the electrodes by yourself. They can be damaged by erroneous performed adjustment.

Sealing does not start and the diode "Status" is not blinking when the handle is pressed.	<ul style="list-style-type: none"> • Test another handle. • Change the coax cable
The diode "Status" is blinking orange but not the lamp on the handle or the Bench Unit.	<ul style="list-style-type: none"> • Test another handle. • Test another Bench Unit • Change the coax cable • Change the HF-generator. (Only for service personnel).
The diode "Temp Alarm" is lit and sealing does not start.	<ul style="list-style-type: none"> • The HF-generator is overheated. Let it cool down until the alarm is turned off.
The diode "Status" flashes red and sealing does not start.	<ul style="list-style-type: none"> • The tube is damp, dry it.
Sparks appear by the electrodes during sealing.	<ul style="list-style-type: none"> • This can happen if the electrodes are overheated due to too many seals in a short time. Let the electrodes cool down.
Sparks appear by the electrodes during sealing.	<ul style="list-style-type: none"> • If there has been a leakage and flashes have created carbon particles on the electrodes, these particles must be removed completely before sealing can continue.
Sparks appear by the electrodes during sealing.	<ul style="list-style-type: none"> • It can indicate that the electrodes are not parallel. Contact service personnel.
The seal is done but with bad quality, leakage may appear.	<ul style="list-style-type: none"> • Check that the coax cable is the right type, the length must be 1.9 m for the Bench Unit and the Manual Handle. The Ergonomic Handle must have the coiled cable. <i>Note! The cables must not be shortened or lengthened.</i>
Short-circuit is shown on display or Status is blinking red during a seal, blue lamp is turned off.	<ul style="list-style-type: none"> • The electrodes are getting hot and the tubes melts easier which may cause the electrodes to shorten during sealing. Let the electrodes cool down by pausing for 10-15 minutes.

13. Technical data

13.1. Power Unit

Voltage demands:	90-250 VAC 50/60 Hz
Power consumption:	200 VA
Net fuses:	2x T 3,15A L 250V
Internal fuses:	Protection for high current, type PTC
Frequency:	40,68 MHz crystal controlled
Output HF power:	100W/50Ω maximum power
Seal time:	Automatic or manually adjustable 2-10 sec
Dimensions:	290x205x85 mm (LxWxH)
Weight:	2.1 Kg
Rel. Humidity incl. storage and transport:	10-95% not condensing
Working temperature:	10-40 °C
Storage- and transportation temperature:	-40- +70 °C
Operation:	Recommended max 1 seal each 3rd sec during continuous use or max 150 seals in sequence and after that 15 minutes rest.

Protective classification: Protection against electrical shock: Class I type B. 

13.2. Bench Unit

Dimensions:	150 (L) x 60 (W) x 73(H) mm
Weight:	0.9 Kg
Length of cable:	1.9 m (4.3 or 9.1 m is available as option)

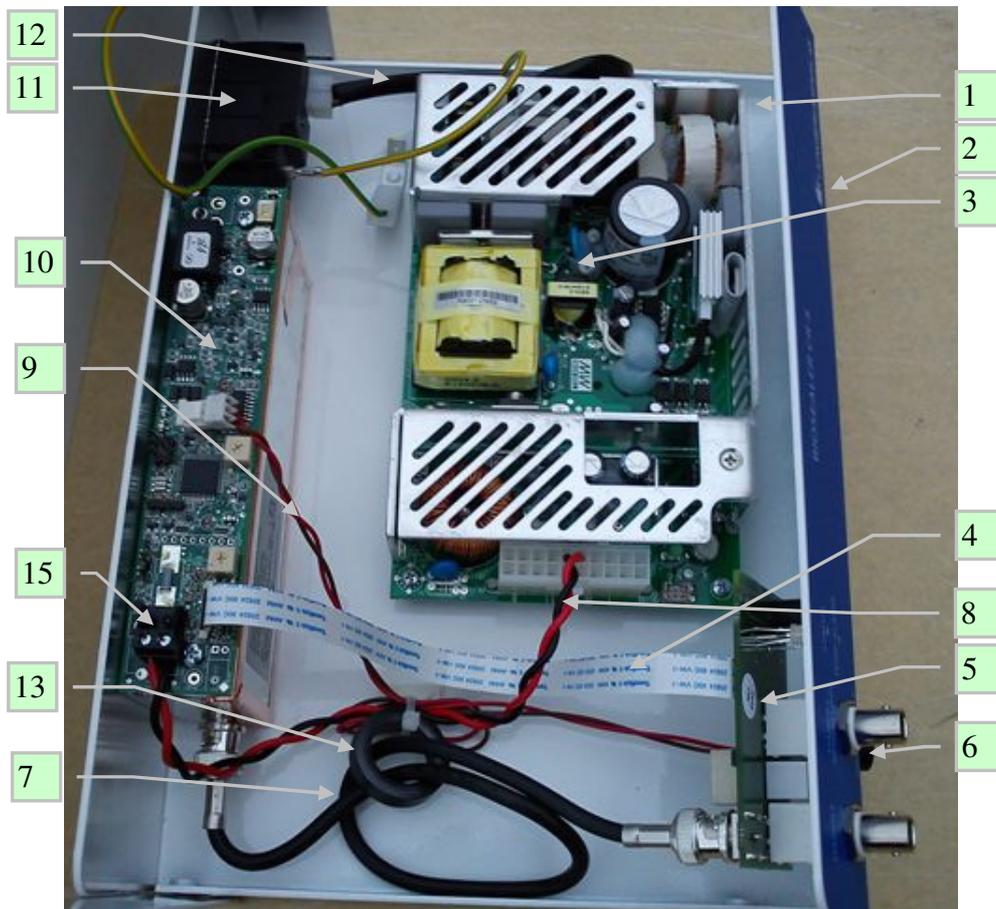
13.3. Handle Unit

Dimensions:	206 (L) x 27 (W) x 35 (H) mm
Weight:	0.3 kg
Length of cable:	1.9 m (4.3 or 9.1 m cable is available as option)

13.4. Ergonomic Handle Unit

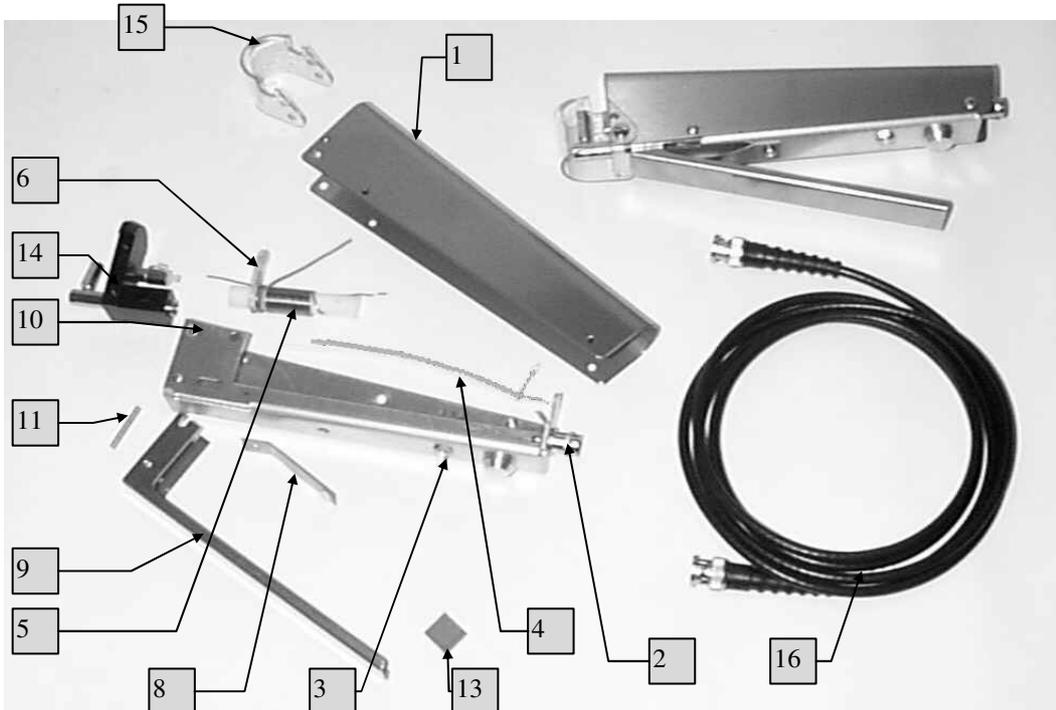
Dimensions:	180 (L) x 35 (W) x 145 (H) mm
Weight:	0.220 kg
Length of cable:	Straight cable 1.74m

14. Spare parts list Power Unit



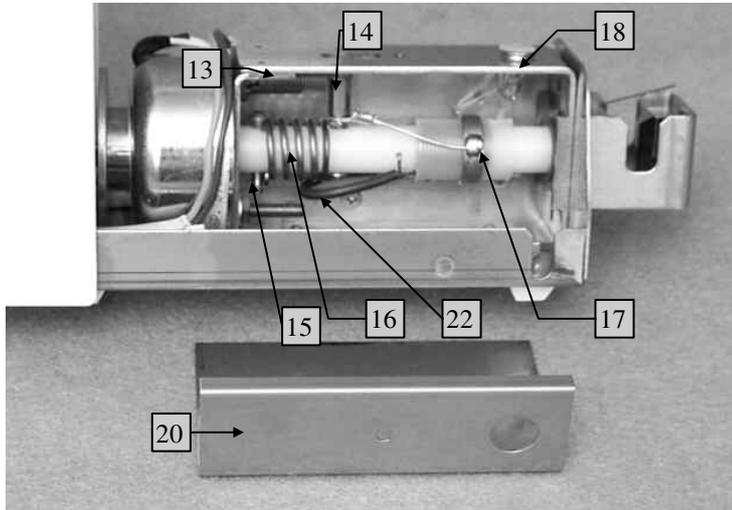
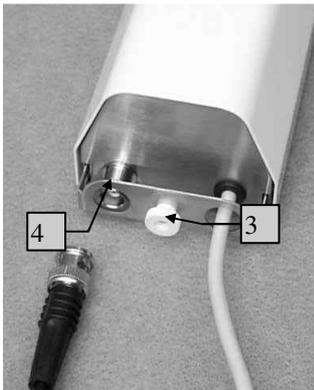
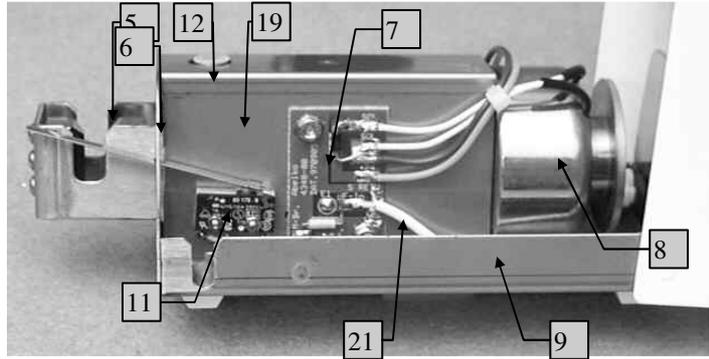
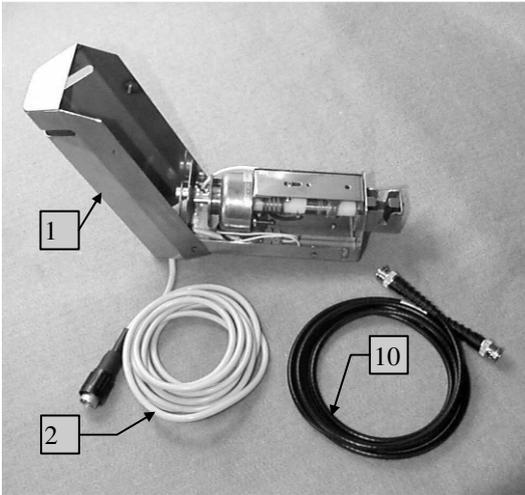
9-50401-00	Bottom plate (chassis)	9-50408-00	24V power contact incl cable
9-50402-00	Rubber feet x 4 (Not in picture)	9-50409-00	Bench unit internal signal cable
9-50403-00	Power supply 200W	9-50410-00	HF generator incl. timer board
9-50404-00	20-pole FFC cable	9-50411-00	Mains inlet
9-50405-00	Front board CR5	9-50412-00	Mains internal cable
9-50406-00	Signal contact bench unit	9-50413-00	Ferrite core \varnothing 29mm
9-50407-00	Internal coax cable	9-50414-00	Cover (Not in picture)
		9-50415-00	2-pole input power contact

15. Spare parts list Handle Unit



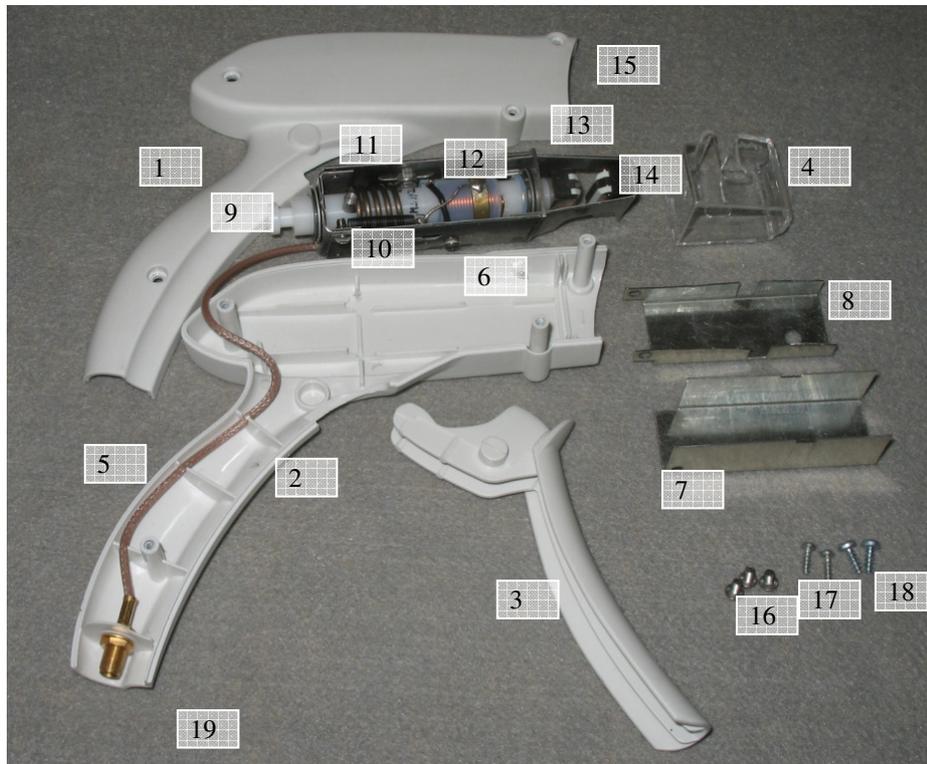
9-32401-00	Cover
9-32402-00	BNC chassis female contact
9-32403-00	Switch mom close
9-32404-00	Internal coax cable
9-32405-00	Coil incl. delrin core and dim glowing lamp
9-32406-00	Dim glowing lamp
9-32408-00	Plate spring
9-32409-00	Handle
9-32410-00	Chassis
9-32411-00	Pin
9-32413-00	Rubber tile
9-32414-00	Electrode house complete
9-32415-00	Electrode cover
9-32416-19	Coax cable 1.9m
9-32416-42	Coax cable 4.2m
9-32416-91	Coax cable 9.1m

16. Spare parts list Bench Unit



9-33401-00	Cover	9-33411-00	Micro switch
9-33402-00	Signal cable	9-33412-00	Welding house chassis complete
9-33403-00	Locking device	9-33413-00	Pull back spring
9-33404-00	Chassis BNC contact	9-33414-00	Steering pin complete
9-33405-00	Hot moving electrode	9-33415-00	Pin compl. with cases and locking nut
9-33406-00	Fixed electrode	9-33416-00	Clamp spring
9-33407-00	Circuit board for connections	9-33417-00	Piston complete incl. coil and dim glowing lamp
9-33408-00	Solenoid	9-33418-00	Dim glowing lamp
9-33409-00	Chassis	9-33419-00	Welding house cover, micro switch side
9-33410-19	Coax cable 1.9m	9-33420-00	Welding house cover
9-33410-42	Coax cable 4.2m	9-33421-00	Coax cable internal
9-33410-91	Coax cable 9.1m	9-33422-00	HF-cable flexible

17. Spare parts list Ergonomic Sealing Handle MSH-III



9-35401-00	Right cover	9-35411-00	Pushing spring
9-35402-00	Left cover	9-35412-00	Piston complete incl. coil
9-35403-00	Handle	9-35413-00	Moving electrode
9-35404-00	Protection cover	9-35414-00	Fixed electrode
9-35405-00	Internal coax cable with SMA contact	9-34515-00	PC board complete incl. micro switch (Not in picture)
9-35405-01	Washer for SMA contact		
9-35406-00	Indicator lens	9-34516-00	3 Socket head cap screw for screen plates
9-35407-00	Screen plate bottom	9-35417-00	Screw Torx T25x8
9-35408-00	Screen plate top	9-35418-00	Screw Torx T30x8
9-35409-00	Pushing knob	9-35419-16	Coax cable coiled, BNC-SMA 175cm (Not in picture)
9-35410-00	Pull back spring		

MDD Declaration

DECLARATION OF CONFORMITY

according to the
Medical Devices Directive 93/42/EEC
and
RoHS directive, 2011/65/EU

STANDARDS TO WHICH CONFORMITY IS DECLARED:

EN 60 601-1 Safety

EN 60 601-1-2 EMC

Including: EN 55011 Kl B, EN 61000-4-2, EN 61000-4-3, EN 61000-4-4, EN 61000-4-5

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Telephone: +46 042-139860

Telefax: +46 042-132181

Type of Equipment: Biosealer

Model: CR4 AA

Product class: Class 1



I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive and Standards.

Date of issue: 7 May 2014

A handwritten signature in black ink, appearing to read 'Tommy Lundström', is written over a horizontal line.

/ Tommy Lundström

Position/title: President

Ljungberg & Kögel AB