en

Instructions for use

Docon® SealM
Docon® Seal

Mobile sealing unit

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP THESE INSTRUCTIONS FOR FUTURE CONSULTATION

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1 General Safety Instructions

1.1 Explanation of the safety symbols employed

In these instructions for use, important information is indicated visually. This information is essential for avoiding risks to the donor and operating personnel and avoiding damage to and malfunctioning of the device.

1.1.1 Symbols in the instructions for use

Caution

Information

1.1.2 Symbols on the device

Caution, hot surface
Docon Seal Handle: Tissue burns can result due to incorrect use or if the electrodes on the seal handle come into direct contact with tissue.

Refer to instruction manual/booklet

Catalog number

Medical device

Unique identifier of a medical device

Serial number

Manufacturer

Lithium ion battery

Return and disposal as per the WEEE Directive

Class II equipment

Conform ANSI/AAMI ES 60601-1
CAN/CSA 22.2 No. 60601-1-08

Alternating current

Direct current

The rating plate is located on the back of the device.

1.1.3 Symbols on the retail packaging

Catalog number

Medical device

Unique identifier of a medical device

Batch code

Serial number

Packaging unit

Keep dry

Humidity, limitation

General Safety Instructions

Temperature limitation

Fragile, handle with care

Manufacturer

Date of manufacture (YYYY-MM-DD)

Lithium ion battery

Return and disposal as per the WEEE Directive

Attention: Under US Federal law, this device may be only sold to a physician or ordered by a physician.

Further information on the symbols used can be found on our homepage: www.moeller-medical.com/glossary-symbols .

1.2 Explanation of the format conventions employed

In these instructions for use, different fonts are used to improve orientation

Font	Use
Bold	Buttons in instructions.
Italics	Device options, buttons and references to chapter and sections in the body text.

1.3 Manufacturer's responsibility

The manufacturer may only be regarded as responsible for the safety, reliability and suitability for use of the devices if:

- Assembly, expansions, resetting, changes and repairs are performed by individuals authorised by the manufacturer.
- The electrical installation in the room in question complies with the relevant requirements and regulations (e.g. VDE 0100, VDE 0107 or IEC specifications).
- The devices are used in accordance with the instructions for use and the country-specific regulations and national deviations are observed.
- The conditions stated in the technical data are observed.

The manufacturer undertakes to accept returned old devices according to the Electronic Equipment Act.

1.4 Operator's obligation to exercise diligence

The operator is responsible for the proper operation of the medical devices. In line with the German Medical Device Operator Ordinance, the user must perform a wide range of duties and assume responsibility when handling medical devices within the framework of his activities.
Whenever the Docon Seal series devices is handled and used, precise knowledge and compliance with these instructions for use is necessary.

General Safety Instructions

These instructions do not replace user training to be provided by the medical device consultant. The device may only be operated by persons with the necessary training or knowledge and experience.

The Docon Seal series devices are subject to special precautionary measures with respect to electromagnetic compatibility (EMC) and must be installed and operated in accordance with the EMC guidelines specified in Chapter 9.4. If one of the devices no longer seals properly due to a malfunction, the device must not be used any further and must be inspected by the technical service.

Performance and safety may be impaired if OEM device parts are not used. All work which requires tools must be performed by the manufacturer's technical service or parties authorised by the latter.

The user must not touch one or several device connections and the donor at the same time!
The Docon Seal Handle may be used in the vicinity of the donor.

While the Docon SealM is being charged on the power unit, no sealing processes are permitted. The device itself prevents this from happening.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or donor is established.

- Modification to the Docon Seal series devices is not permitted.
- No liquids must be allowed to penetrate the current-carrying parts of the device.
- When cleaning, ensure that no cleaning agent runs into the connector sockets.
- Remove the charger from the Docon SealM or the power cord from the Docon Seal before cleaning.
- Replace connecting cables of all kinds even if they are only slightly damaged; make sure not to roll over cables.
- Keep the cables away from heat sources. This prevents the isolation from melting which could cause a fire or an electric shock.

- Do not use force to push plugs into sockets.
- When removing plugs, do not pull on the cables. To remove if necessary, release the plug lock.
- Do not expose the Docon Seal series devices to excessive heat or fire.
- Do not subject the Docon Seal series devices to major impacts.
- If excessive heat, fumes or smoke are seen, immediately disconnect the Docon Seal series devices from the power supply.
- Do not extinguish the Docon Seal series devices with water in the event of fire.

1.5 Non-product-related additional equipment

Additional equipment which is connected to the analogue and digital device interfaces must demonstrably satisfy the relevant EN specifications (e.g. EN 60950 for data processing devices and EN 60601-1 for electromedical devices). Whoever connects additional devices to the signal input or output part, is the system configurer and thus responsible for ensuring that the valid version of the system standard EN 60601-1 is observed.
Should you have any queries, please contact your distributor or the manufacturer's technical service.

2 Intended use

2.1 Proper use – intended purpose Docon Seal M

The Docon SealM is a medical device and is used for sealing the hoses during blood donation or when processing and storing blood bags and to facilitate simple disconnection. The device is transportable and can also be used to seal hoses attached to donors.
No form of use other than the intended use described here is permitted.

2.1.1 Proper use – intended purpose Docon Seal

The Docon Seal is a medical device and is used for sealing the tubes during blood donation, plasmapheresis or when processing and storing blood bags and to facilitate simple disconnection. The device can also be used to seal tubes attached to donors.
No form of use other than the intended use described here is permitted

The integrated sealing unit emits electromagnetic radiation during sealing.

Incorrect use or direct contact between the seal handle electrodes and tissue can result in tissue burns.

2.2 Combination with other products

Only use tubes which have been specified and approved by the device manufacturer.

2.3 Essential performance features

The Docon Seal series devices do not have any essential performance features.

3 Product description

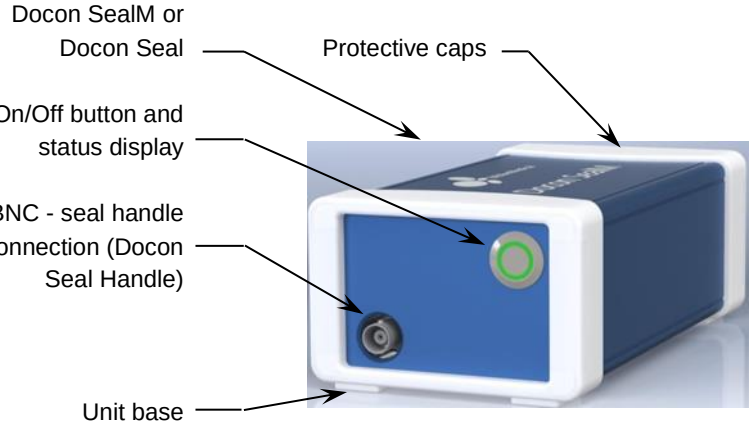

Figure 1: Docon SealM

3.1 Docon SealM, Docon Seal

The Docon Seal series devices supply the required HF energy through the BNC connection cable to the Docon Seal Handle. Up to 150 successive sealing processes can be carried out.

If the temperature of the seal generator exceeds a defined value as a result of successive operations, the unit shuts down. Sealing is then no longer possible.

The unit must now be allowed to cool down. The length of time needed to cool down depends on the ambient temperature and may take up to 20 minutes.

3.1.1 Integrated battery pack (Docon Seal M only)

The firmly integrated lithium-ion battery pack supplies the sealing unit with the energy it requires for up to 2000 sealing processes. The battery does not reach full capacity until after a few charge cycles.

If not in use for extended periods, the Docon SealM must be stored in a charged state.

See Storage conditions
After use, store the Docon Seal series devices in accordance with the hygiene regulations. Also note the storage conditions on *page **40.***

Due to its integrated battery pack, the device must be disposed of properly.

Batteries must not be disposed of as domestic waste. Physical properties mean that as the battery ages, its capacity drops, and it must be replaced with a new one. In this case, contact the manufacturer or your distributor.

3.2 On/Off button and status display

The Docon Seal series devices are switched on and off using the button on the front panel. This status display provides you with information about the operational and charge state of the devices.

3.3 Unit base

For tabletop operation, the Docon Seal series devices must be placed on the base provided.
This allows the heat generated during operation to be dissipated to the environment.

3.4 Protective caps

The rubber-like protective caps fitted to front and back protect the devices as well as the BNC seal handle connection against any impacts.

3.5 Connection options

The following connection options are available with the Docon SealM:

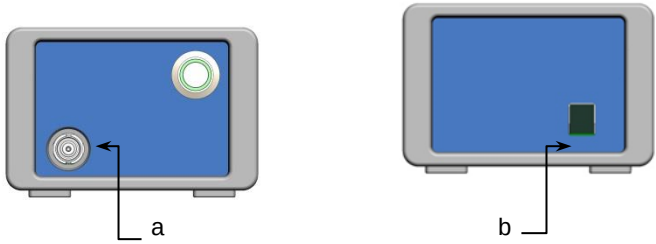

Figure 2: Connection options on the Docon SealM

a: BNC seal handle connection **b: charger socket**

The following connection options are available with the Docon Seal:

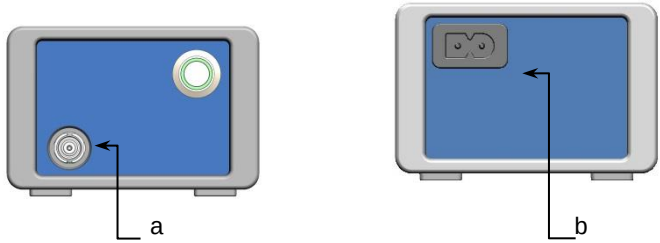

Figure 3: Connection options on the Docon Seal

a: BNC seal handle connection **c: mains connection**

3.5.1 BNC seal handle connection

The BNC socket (*Figure 2 and Figure 3, a*) serves to connect the BNC cable and the associated original Docon Seal Handle.

3.5.2 Charger socket Docon SealM (*Figure 2, b*)

The internal battery is charged via the charger socket *(Figure 2b)* with the help of the relevant original charger device.

3.5.3 Mains connection Docon Seal (*Figure 3, c*)

The Docon Seal is connected to the mains via the mains connection socket (*Figure 3,* c) using the original mains connection cable.

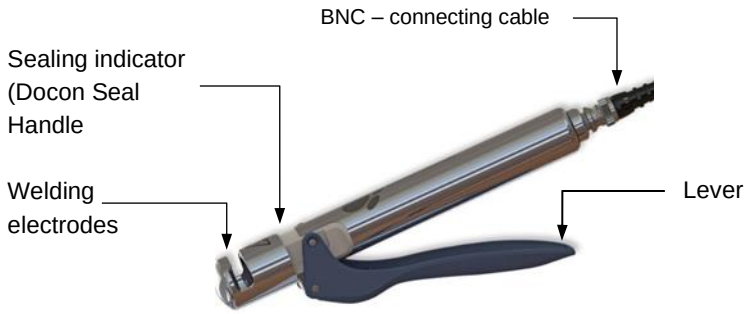

Figure 4: (Docon Seal Handle)

3.6 Seal handle

The Docon Seal Handle is an automated sealing unit used to seal PVC tubes, particularly the blood removal tube directly attached to the donor. This ensures greater safety when sealing the tube.

Various PVC tubes with different diameters and wall thicknesses can be sealed. The sealing time is automatically adjusted for the tubes specified.

3.7 Welding electrodes

The hose to be sealed is positioned between the welding electrodes (*see Application and operation
, page 25*).

3.8 Lever

The welding process is initiated by pressing the lever (*see Application and operation
, page 25*).

3.9 Docon Seal Handle

The sealing process is indicated by an LED on the seal handle (*see Application and operation on page 25*).

3.10 BNC connecting cable

The BNC connecting cable links the Docon Seal Handle to the Docon SealM and transmits HF energy.

The seal handle complies with the electrical safety requirements of a type B applied part as per EN 60601.

Only the original seal handle may be connected to the Docon Seal series devices.

Only position the designated object between the electrodes of the Docon Seal Handle. *(see Appendix , page 39).*

To achieve an optimum sealing result, only use tubes which have been approved by the device manufacturer.

Additional equipment which is connected to the analogue and digital device interfaces must demonstrably satisfy the relevant EN specifications (e.g. EN 60950 for data processing devices and EN 60601 for medical electrical devices). Whoever connects additional devices to the signal input or output part, is the system configurer and thus responsible for ensuring that the valid version of EN 60601-1 is observed.

Should you have any queries, please contact your distributor or the manufacturer's technical service.

3.11 Accessories

3.11.1 Charger and adapter

Figure 5: Charger

Use the adapter to adapt the charger to the country-specific power supply (socket). Use the charger to charge the Docon SealM battery (*see Connecting and charging the Docon SealM battery , page 22).*

3.11.1.1 Overview of charger signal statuses

As well as the display on the Docon SealM, the charger has its own signal indicator. This signal display can indicate green and orange statuses. The following table provides you with an overview.

Status	Colour	LED
Operating mode, ready for operation	Green	Lit
Operating mode, charging	Orange	Lit
Operating mode, charged to at least 65%	Yellow	Lit
Operating mode, charging complete (battery fully charged)	Green	Lit

3.11.2 Transport case

Figure 6: Transport case

The device components are safely stored and transported in the transport case. Any adapters not required can remain in the case.

3.11.3 Mains cable

Use the country-specific power cable to connect the Docon Seal device to the power supply (power outlet). Use the power cable to power the Docon Seal.

4 Setup and commissioning

Ensure that the box is not damaged when delivered to you. The forwarder must be notified immediately of any transport damage. Investigate the device for any damages. Should the product show signs of defects, it must not be used, and the supplier is to be notified immediately.

4.1 Transport and storage information

Temperature:	-20°C to +50°C
Humidity:	Less than 90% rel. humidity
Weight incl. packaging	2400g
Dimensions of the Docon SealM and Docon Seal with packaging:	Width x height x depth 340 mm x 80 mm x 300 mm

4.2 Unpacking the device and checking the scope of supply

The delivery of a device of the Docon Seal series comprises a cardboard box and a transport case. When unpacking ensure that no parts remain in the packaging.

It is recommended to use the packaging for possible service requests and not to dispose of it.

Only send the devices in its original transport case and its associated packaging to prevent transport damage.

The scope of delivery of the **standard versions of Docon SealM and Docon Seal** include the following:

- 1 x Docon SealM or Docon Seal
- 1 x Docon Seal Handle
- 1 x BNC connecting cable
- 1 x charger (Docon Seal M only)
- 1 x power cable (Docon Seal only)
- 1 x instructions for use
- 1 x transport case

4.3 Commissioning the Docon SealM

Whenever the Docon SealM is handled and used, precise knowledge and compliance with these instructions for use is necessary. These instructions do not replace user training. The device may only be used by specialist staff.

4.3.1 Connecting and charging the Docon SealM battery

Fully charge the Docon SealM before initial commissioning.

The charge process can take up to 4.5 hours.

1. Set up the device in the desired position with the base facing downwards.
2. Select the right adapter for your socket.
3. Plug the adapter into the power unit until it clicks into place.
4. Plug the charger connector on the back of the housing into the Docon SealM.
5. Plug the charger into a socket. Note the voltage values stated on the charger. The internal battery on the Docon SealM is now charging and the LED on the On/Off switch flashes orange.
6. The LED on the On/Off switch lights up green as soon as the battery has been charged sufficiently. Now the device can be disconnected from the charger cable.

4.3.2 Connecting the seal handle

1. Connect the BNC connecting cable to the seal handle and secure by turning it clockwise.
2. Connect the other end of the cable to the Docon SealM and, once again, secure by turning it clockwise.

4.3.3 Switching on

To switch on the Docon SealM, press the On/Off switch on the front of the device.

4.3.4 Switching off

After completing the sealing processes, turn off the Docon SealM by pressing the On/Off switch.

4.4 Commissioning the Docon Seal

Whenever the Docon Seal is handled and used, precise knowledge and compliance with these instructions for use is necessary. These instructions do not replace user training. The device may only be used by specialist staff.

4.4.1 Connecting and commissioning the Docon Seal

1. Set up the device in the desired position with the base facing downwards.
2. Connect the power cable on the back of the housing to the Docon Seal power socket.
3. Insert the power cable into a socket.
4. Turn on the Docon Seal by pressing the on/off button.
5. The LED of the on/off switch lights green.

Further steps as described in *Chapters* 4.3.2 to 4.3.4.

4.5 Overview of button signal statuses

Status	Colour	LED
Ready for operation	Green	Lit
Remaining capacity of battery 10-30% (Docon SealM only)	Green	Flashing
Residual capacity of battery <10% (Docon SealM only)	Orange	Flashing
Error status or BATTERY empty	Orange	Lit
Charging (Docon SealM only)	Orange	Flashing
Charging complete (battery fully charged) (Docon SealM only)	Green	Lit

4.6 Suitable operating environments Docon Seal / SealM

The Docon Seal / SealM is suitable for environments in the following areas:

- Home-based health care

  Department stores, schools, lodgings (places of residence, nursing homes), hotels, guest houses and stationary vehicles, provided that the devices are not connected to the vehicle's DC power supply

- Professional healthcare facilities with specific requirements

  Clinics (rooms in A+E, hospital rooms, intensive care, operating theatres, except for in the proximity of active facilities of RF surgery devices or outside of the RF-shielded room for magnetic resonance imaging, first aid facilities).

The devices of the Docon Seal series cannot be used in combination with electrosurgical devices.

5 Application and operation

5.1 The sealing process

1. Place the tube to be sealed in the recess on the seal handle.
2. Press the seal handle lever as far as it will go. The LED on the seal handle lights up and sealing starts automatically.
3. Sealing is complete once the LED on the seal handle starts flashing.
4. Now open the seal handle lever and remove the tube.
5. Check the welding seam is sealed. If leaks appear in the welding seam, repeat the sealing process 10 mm to the left or right beside the welding seam already created.
6. After correctly performing the sealing process, disconnect the hose by pulling apart the welded seam. To do this, simply pull the hose sections apart, i.e. by pulling the left and right sides of the welded seam in opposite directions.

If the LED on the seal handle flashes rapidly instead of slowly after the sealing process, this indicates that the operation was insufficient (*see Overview of signal statuses on Docon Seal Handle, page 26*).

Possible causes: soiled hoses or dampness. In this case, repeat the sealing process on a clean and dry place.

5.1.1 Overview of signal statuses on Docon Seal Handle

Status	Colour	LED
Sealing	Orange	Lit
Sealing complete	Orange	Flashing
Sealing defective	Orange	Flashing rapidly
Short circuit detected	Orange	Flashing rapidly
Ready for sealing	Orange	Switched off

Make sure that the surface of the tube, at the point where the seal is to be made, is dry and free of dirt.

Sealing stops immediately when you release the seal handle lever.

The tube must not be subjected to mechanical loading during sealing.

If a tube is sealed in several places, there must be a minimum distance of 10 mm between each sealed point.

Check the quality of the seals visually and periodically.

5.2 Storage conditions

After use, store the Docon Seal series devices in accordance with the hygiene regulations. Also note the storage conditions on *page 40.*

5.3 Battery care when storing the Docon SealM

If the device is stored or not used for a period of 6 months, the battery should be at least 65% charged at the time of storage. The state of charge can be read off the display on the charger. The LED on the charger must display at least the colour yellow. If the LED lights up orange, continue charging the unit.

After not being used for 6 months, the battery must be recharged to reach a charge state of at least 65%. The state of charge can be read off the display on the charger. The LED on the charger must display at least the colour yellow. If the LED lights up orange, continue charging the unit.

5.4 Energy-saving mode

The Docon Seal / Docon SealM features an energy-saving mode that switches the device off automatically 45 minutes after the last welding operation. This energy-saving mode is activated as standard upon delivery.

The energy-saving mode can be switched on and off.

It is only possible to switch between energy-saving mode and continuous operation with a fully charged battery (Docon SealM only) and without a charger connected (Docon SealM only).
Proceed as follows:

1. Before switching modes, charge the device until the status LED on the device and the LED on the charger are lit up green (Docon SealM only).
2. Remove the charger from the Docon SealM (Docon SealM only).

3. Then press the On/Off button for at least 7 seconds. After this time, the Docon Seal / Docon SealM device switches to the configuration menu where you can switch from or to the energy-saving mode. This is indicated by a change in the colour of the status LED. Depending on which mode is set – energy-saving or continuous operation – the status LED either flashes orange or is permanently lit orange.
4. Press the On/Off button twice in succession. The speed with which the button is pressed is irrelevant. This switches between energy-saving mode and continuous operation. The modes are displayed as follows:

Colour	**LED**	**Mode**
Orange	Lit	Continuous operation
Orange	Flashing	Energy-saving mode

   You can switch between the modes as often as you like if you are in the menu.

5. To save the set mode permanently and exit the configuration menu, press the On/Off button for at least 7 seconds. The Docon Seal / Docon SealM device switches back to normal operation. This is indicated by the change in colour of the status LED. The status LED is permanently lit green after exiting the menu. The set mode is retained even after restarting the device. You can check the currently set mode at any time by carrying out steps 3 to 5 after restarting the device.

When the Docon Seal / Docon SealM device is in the configuration menu, it is not possible to perform welding operations.

Application and operation

When the Docon Seal / Docon SealM device is in continuous operation, it monitors the current charge status of the integrated battery (Docon SealM only). If the battery's remaining capacity is below 10%, the device switches off (Docon SealM only). Even after restarting and subsequently checking the battery charge, the device will automatically switch off again if the battery capacity is below 10%.

In this case, connect the charger to charge the Docon SealM fully and restore operational readiness.

6 Remedying of errors

A number of errors are listed in this chapter which could occur in connection with the Docon Seal series devices.

Several possible solutions are given for each error. The suggestions should be performed in the order given until the error is remedied. The devices must always be turned off when connecting and disconnecting plug connections. Should these suggestions not help to remedy the error, the defect must be resolved by the Möller Medical GmbH service team.

Errors	Solution
The Docon SealM cannot be turned on.	• Charge the Docon SealM.
The Docon Seal cannot be turned on.	• Check the correct plug connection of the power cable to the mains input socket and the socket.
The Docon Seal Handle does not work properly.	• Check the charge state of the Docon SealM and charge it again if necessary. • Check that the BNC cable is connected properly. • Ensure that the welding electrodes are clean and are free of moisture. • Connect a different seal handle to your device.

Remedying of errors

Errors	Solution
The Docon SealM will not charge.	• Check the connection to the charger. The displays on the charger and Docon SealM must light up or flash orange. • If the displays fail to light up or flash: Check the charger and socket or use a different charger. • Recharge the Docon SealM.
If the energy-saving mode will not switch on or off	• Make sure that the battery is fully charged (Docon SealM). • Make sure that the Docon SealM is disconnected from the charger once the battery is fully charged. • Make sure that the device is connected to the mains (Docon Seal only).
Error due to moisture in the plug connection.	Remove all plugs from the device and the seal handle and allow the connections to dry.
Damaged, illegible inscriptions or labels	Please contact the manufacturer ‘s service centre or your local distributor.

Should you be unable to remedy the error, please contact your **Möller Medical GmbH** service team or distributor.

7 Service

The Docon Seal series devices must not be opened by users. Service measures may only be performed by service teams who have received appropriate training from the manufacturer.

Only send cleaned and disinfected devices to the service team.

When returning a device of the Docon Seal series, ensure that the device is appropriately disinfected to avoid the risk of infection.

Consumables must be disposed of as per the hygiene guidelines.

Manufacturer:

Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda, Germany

Telefone: +49 (0) 661/94 19 5 – 0
Fax: +49 (0) 661/94 19 5 – 850
Web: www.moeller-medical.com
E-Mail: info@moeller-medical.com

Service
Telefone: +49 (0) 661 94195 - 500
Fax: +49 (0) 661 94195 - 850
E-Mail: service@moeller-medical.com

Distributor:

8 Care

8.1 Cleaning and disinfection the devices

To rule out any risk to the user, pull all connecting cables out of the device before cleaning.

Sterilisation methods such as autoclaving and ethylene oxide sterilisation render the devices of the Docon Seal series unusable.

Do not use sharp objects for cleaning.

No humidity must be allowed to enter the device. Therefore, spray disinfectants must not be used directly on the device.

Lint-free, soft tissues are to be used for wipe-down disinfection and cleaning.

Clean using a cloth dampened with mild soap solution or 70% isopropane solution.

After cleaning, disinfect the surfaces of device with a pH-neutral, approved detergent-alcohol based disinfectant with up to 70% alcohol (e.g. Propan-1-ol, recommended disinfectant: Meliseptol®). During disinfection, follow the instructions of the disinfectant manufacturer.

Ensure that the cleaning agents and disinfecting agents have completely evaporated before using the device.

Visual inspection: The sockets of all connections and plugs of the cables to be connected must be free of all types of dirt.

8.2 Cleaning the Docon Seal Handle

To rule out any risk to the user, pull the connecting cable out of the Docon Seal Handle before cleaning.

Sterilisation methods such as autoclaving and ethylene oxide sterilisation render the Docon Seal Handle unusable.

Make sure that no liquids flow into the electronic components of the seal handle.

Do not use sharp objects for cleaning.

To guarantee the functionality and safety of the seal handle, it must be cleaned regularly. You will find a list of products tested for cleaning on *page 33*

The seal handle must always be cleaned after it has come in direct contact with blood.

The seal handle should be cleaning thoroughly once per day.

Disassembly of the Docon Seal Handle

To clean the electrodes, first remove the blue lever and the electrode (see *Figure 7* to *Figure* 10).

Figure 7

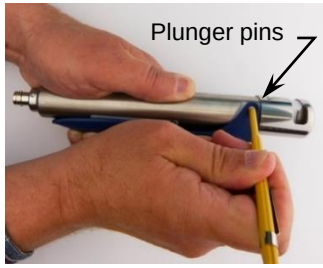

Figure 8

Care

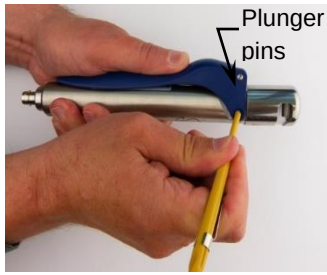

Figure 9

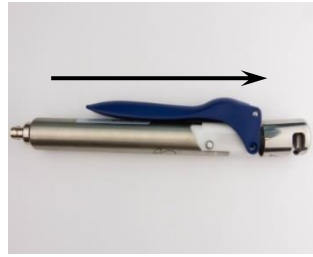

Figure 10

1. Press the lever as described in *Figure 7* against the handpiece until the two electrodes in the handle head come into contact.
2. Press the plunger pins in on both sides until an audible "click" is heard *(see Figure 8* and *Figure 9)*. Use a ballpoint pen or similar to push in the plunger pins.
3. Push the electrode and lever upward and remove them *(see Figure* 10).

The round handpiece and electrodes should be cleaned with a lint-free cloth.

The removed lever with electrode can be washed under running water.

Dry all parts carefully. Ensure that the electrodes are completely dry to avoid spark discharge.

Care

Assembly of the handpiece and lever with electrode after cleaning

Figure 11

Figure 12

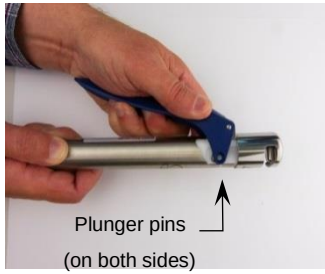

Figure 13

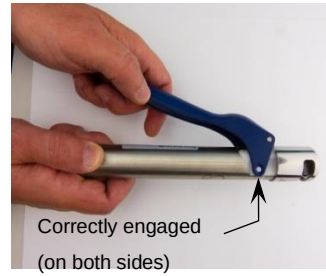

Figure 14

1. Place the lever with electrode on the handpiece and ensure that the lever is in the vicinity of the handpiece *(see Figure 11).*
2. Ensure that the electrode is positioned parallel with the fixed electrode and is aligned with the corresponding incision in the handpiece *(see Figure 12).*
3. Pull the lever with the electrode on the handpiece until both pins emit an audible "click" *(see Figure 13 and Figure* 14*).*
4. Press the lever twice and make sure that the electrodes move uniformly and are not loose.

After cleaning, check the electrodes for signs of mechanical damage and wear. Never use damaged parts!

After assembly of the seal handle, perform a few trial sealing processes to test functionality.

8.3 Maintenance

8.3.1 Safety check

A safety check as per the German Medical Devices Operator Ordinance (MPBetreibV) must be performed at least every 12 months. It ensures that the basic safety and the electromagnetic characteristics of the device are maintained during the expected lifetime of the device. Only use the Docon SealM/Docon Seal if the devices are functioning safely and/or are safe to operate. Otherwise, they must be repaired immediately by the service team.

8.3.2 Service documents

The service documents required to maintain the device can be requested from the manufacturer's authorised service partners.

8.4 Transport

The Docon Seal series devices may only be transported as per the transport conditions *(see Appendix on page 39).* For daily transport, the scope of delivery includes a transport case. Inside this case. The devices are protected from external damage.
If a device of the Docon Seal series is sent to the service team, it must be packed in its original packaging as this provides the device with the best possible protection from external damage.

Care

Please note that the Docon Seal series devices are electromechanical devices. They must not be thrown. If condensation forms after the devices are transported in the cold and set in a warm room, the devices must not be switched on until the condensation water has evaporated. Please note in particular any water on the connection sockets and the seal handle. The warm-up and cool-down phases relate to a room temperature of 20°C.

Transport temperature	Warm-up / cool-down phase without case
- 20 °C	90 minutes
50 °C	30 minutes

8.5 Disposal

Docon Seal series devices and accessories

These devices include materials which must be disposed of in an environmentally friendly manner. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE2) applies to this device. This device thus bears the symbol with a crossed-out bin on the rating plate.

Return devices and batteries which are no longer used to Möller Medical GmbH. This ensures that they will be disposed of in accordance with the national versions of the WEEE Directive.

9 Appendix

9.1 Technical data

General data	
REF Docon SealM	00003681
REF Docon Seal	00003900
Dimensions of Docon SealM and Docon Seal	Length x width x height 185 mm x 94 mm x 61 mm
Weight [kg]:	900 g (excluding the seal handle)
Electrical connection charger / Docon SealM input	
Voltage:	100-240 V AC
Frequency:	50-60 Hz
Current consumption:	0.6 A
Input	25.2 V DC, 2 A
Protection class:	II
Type of protection:	IP 20
Electrical connection of Docon Seal	
Voltage	100 - 240 VAC (alternating current)
Frequency:	50 - 60 Hz
Current consumption:	1.7-0.71 A
Power consumption	170 VA
Type of protection:	IP 20
Sealing	
PVC tube specification:	4.0 - 6.0 mm external Ø; 0.75 mm wall thickness
Filler media:	Air / 0.9% NaCl solution / whole blood / blood components
Sealing times:	1 - 5 s

Appendix

Docon SealM Successive sealing procedures: For ambient temperature:	150 +10 °C to +40 °C
Sealing processes / battery charge:	up to 2000
Docon Seal Successive sealing procedures For ambient temperature	300 (at 25 °C) 150 (at +10 °C to +35 °C) 120 (at +35 °C to +40 °C)
Docon SealM battery:	
Type:	Lithium ion battery
Voltage:	22.2 V
Capacity:	3000 mAh
Energy:	66.6 Wh
Transport and storage information	
Temperature:	-20°C to +50°C
Humidity:	less than 90% relative humidity
Weight with packaging:	2400g
Packaging dimensions:	Width x height x depth 340 mm x 80 mm x 300 mm
Air pressure:	700 – 1050 hPa
Operating conditions:	
Temperature:	+10°C to +40°C
Humidity: Air pressure: Operating altitude:	30 % to 75 % relative humidity 700 – 1050 hPa < 3000 m
Device service life	8 years

Appendix

9.2 Electromagnetic emissions

The Docon Seal series devices are intended for use in the electromagnetic environment specified below. The customer or operator of the devices should ensure that it is being operated in an environment such as this.

The use of different lines to the approved BNC line (*see Accessories, page 59)* could increase emission levels, or reduce the interference resistance of the Docon Seal series.

When used in the intended manner, the Docon Seal series devices use HF energy to seal hoses at a frequency of 40.66-40.70 MHz. Due to this specified HF energy, the devices of the Docon Seal series can interfere with adjacent devices. This radiated emissions level can interfere with devices located near the Docon Seal series devices. If abnormal performance is observed on other adjacent devices, additional measures may be necessary, such as reorienting or relocating the Docon SealM.

9.2.1 Docon SealM

Measurement of electromagnetic interference	**Compliance**	**Electromagnetic environment - guidelines**
RF electromagnetic interference acc. to CISPR 11	Group 2	The Docon SealM must emit electromagnetic energy to ensure that it performs its intended function. Electronic devices in the vicinity could be influenced.
RF electromagnetic interference acc. to CISPR 11	Class B	Application area see *Chapter 4.6*
Harmonic emissions acc. to IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Not applicable	

9.2.2 Docon Seal

Measurement of electromagnetic interference	Compliance	Electromagnetic environment - guidelines
RF electromagnetic interference acc. to CISPR 11	Group 2	The Docon Seal must emit electromagnetic energy to ensure that it performs its intended function. Electronic devices in the vicinity could be influenced.
RF electromagnetic interference acc. to CISPR 11	Class B	Application area see *Chapter 4.6*
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Complies	

9.3 Electromagnetic immunity

The Docon Seal series devices are intended for use in the electromagnetic environment specified below. The customer or operator of these devices should ensure that they are operated in an environment such as this.

9.3.1 Docon SealM

Immunity test	IEC 60601 - testing level	Compliance level	Electromagnetic environment - guidelines
Discharge of static electricity (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields of the supply frequency should conform with the typical values found in commercial or hospital environments.
Notes: U_T is the AC mains voltage prior to application of the test level.			

Appendix

The Docon SealM is intended for use in the electromagnetic environment specified below. The customer or operator should ensure that the Docon SealM is used in an environment such as this.

Electro-magnetic immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Radiated RF dis-turbances acc. to IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed.4	10V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed.4	Recommended separation distance: Portable RF communications equip-ment (radio devices) (including their accessories such as antenna cables and external antennas) should not be used closer than 30 cm (or 12 inches) from the parts and cables of the Do-con Seal indicated by the manufacturer. Non-ob-servance may result in a reduction of the device's performance. 
NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propa-gation is affected by absorption and reflection by structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellu-lar/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electro-magnetic site survey should be considered. If the measured field strength in the location in which the Docon SealM is used exceeds the applicable RF compliance level above, the Docon SealM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Docon SealM. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Appendix

The following measurements were not performed because the scope of delivery included an approved charger that has already passed these tests:

- Electrical fast transients/bursts acc. to IEC 61000-4-4
- Surges IEC 61000-4-5
- Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11
- Conducted RF acc. to IEC 61000-4-6

The Docon SealM satisfies all test levels in accordance with IEC 60601-1-2 Edition 4 (table 4 to 9).

9.3.2 Docon Seal

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Surge voltages (surges) IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment.
Surge voltages (surges) IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment.

Appendix

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5/6 cycles 70 % U_T (30 % dip in U_T) for 25/30 cycles	< 5 % U_T (> 95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5/6 cycles 70 % U_T (30 % dip in U_T) for 25/30 cycles	The quality of the supply voltage should be comparable to that for a typical shop or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	30 A/m at 50 Hz	30 A/m at 50 Hz	Magnetic fields of the supply frequency should conform with the typical values found in commercial or hospital environments.
Note: U_T is the AC mains voltage before applying the test levels.			

The requirements for use in aviation, transportation and military fields have not been considered as they have not been tested.

Appendix

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF acc. to IEC 61000 -4-6	3 Veff 150 kHz to 30 MHz 6 Veff in ISM and amateur radio frequency bands between 150 kHz and 80 MHz	3 Veff 150 kHz to 30 MHz 6 Veff in ISM and amateur radio frequency bands between 150 kHz and 80 MHz	Recommended separation distance: Portable RF communications equipment (radio devices) (including their accessories such as antenna cables and external antennas) should not be used closer than 30 cm (or 12 inches) from the parts and cables of the Docon Seal indicated by the manufacturer. Non-observance may result in a reduction of the device's performance. 
Radiated HF disturbance value acc. to IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed.4	10V/m 80 MHz to 2.7 GHz Table 9 of IEC 60601-1-2 Ed.4	
Notes: NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Docon Seal is used exceeds the applicable RF compliance level above, the Docon Seal should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Docon Seal. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

The Docon Seal satisfies all test levels in accordance with IEC 60601-1-2 Edition 4 (table 4 to 9).

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9.4 Recommended separation distances

Never operate the Docon Seal series devices immediately beside or in conjunction with other devices. If operation in the proximity of or stacked with other equipment cannot be avoided, monitor the Docon Seal series devices to verify specified normal operation.

9.4.1 Docon SealM

See *Chapter 9.3.1*

9.4.2 Docon Seal

See *Chapter 9.3.2*

9.5 Accessories

Procurement options for accessories:

From Möller Medical GmbH or your direct distributor

Docon SealM item numbers and accessories

Docon SealM	00003681
Docon SealM (control unit)	92014152
Docon Seal Handle	92013574
BNC connecting cable, length 1.8 m	93005638
Docon SealM transport case	93005938
Docon SealM charger	93005948 (without power adapter)
Docon SealM power adapter, EU	93005981
Docon SealM power adapter, UK	93005985

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Docon SealM power adapter, US	93005986
Docon SealM power adapter, AU	93005989
Instructions for use, EN Docon SealM / Docon Seal	9306028

Docon Seal item numbers and accessories

Docon Seal	00003900
Docon Seal Handle	92013574
BNC connecting cable, length 1.8 m	93005638
Docon Seal mains cable UK	93006855
Docon Seal mains cable US	93006767
Docon Seal mains cable EU	93006854
Instructions for Use Docon SealM / Docon Seal	9306028

Do not operate the Docon Seal Handle accessories or the BNC connecting cable with devices or systems other than those of the Docon Seal series as this would increase emission levels or could even impair the interference resistance of the other devices and systems.

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(REF) 93006028

Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda, Germany

Telefone: +49 (0) 661/94 19 5 – 0
Fax: +49 (0) 661/94 19 5 – 850
Web: www.moeller-medical.com
E-Mail: info@moeller-medical.com