

en

# Docon<sup>®</sup> 7

## Blood mixing scales

**Instructions for use**





**IMPORTANT**

READ CAREFULLY BEFORE USE

KEEP THESE INSTRUCTIONS FOR FUTURE CONSULTATION

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## General safety information

# 1 General safety information

## 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 also 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**

**Sealing handle:** Tissue burns can result due to incorrect use or if the sealing handle electrodes come into direct contact with tissue.



Stand - by



Serial number



Catalog number



Alternating current



Direct current



Return and disposal as per the WEEE Directive



USB host



RJ45 network connection



Consult instructions for use



Class II equipment

**General safety information**



The included lithium ion battery must be disposed of properly.



Compliant with ANSI/AAMI ES60601-1  
CAN/CSA 22.2 No. 60601-1-08

The rating plate is located below the tray.

**1.1.3 Symbols on the display**



A USB memory stick is connected



Docon 7 is connected to the power supply



Clamp open



Clamp closed



Battery operation + charge level display



Battery indicator while charging Akkuanzeige beim Laden



Scanner is connected



WLAN operation



Network operation



Docon 7 status indicator connected

**1.1.4 Symbols on the retail packaging**



Catalog number



Batch code



Serial number



## General safety information



Do not use if package is damaged



Stacking limit, do not store more than 4 packs high



Keep dry



Humidity, limitation



Temperature limit



Manufacturer



Date of manufacture (YYYY-MM-DD)



Total length



Caution



Fragile, handle with care



Top, store the right way up

**Rx ONLY**

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](http://www.moeller-medical.com/glossary-symbols)

## General safety information

### 1.2 Explanation of the format conventions employed

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

Font	Use
<b>Bold</b>	Buttons in instructions.
<i>Italics</i>	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 device 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 device is 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 old devices as per the German Electrical and Electronic Device Act (ElektroG).

### 1.4 Operator's obligation to exercise diligence

The operator is responsible for the proper operation of the medical device. In line with the German Medical Device Operator Ordinance (MPBetreibV), the user must perform a wide range of duties and also assume responsibility when handling medical devices within the framework of his activities.

Whenever the Docon 7 is handled and used, precise knowledge and compliance with these instructions for use is necessary. 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 7 may only be operated in rooms in which operating personnel who monitor the donation process are present for the entire course of continuous operation.

Performance and safety may be impaired if Original Equipment Manufacturer device parts are not used.

## General safety information

All work which requires tools must be performed by the manufacturer's technical service or parties authorised by the latter.

In environments in which the perfect functioning of the ground wire connection cannot be guaranteed, the Docon 7 must be battery-operated.

The user must not touch one or several device connections (USB, LAN and docking connection) of the Docon 7 and the donor at the same time!



The Docon 7 mobile and the sealing handle may be used in the vicinity of the donor.

The Docon 7 may be operated at a multiple portable socket which is approved as per 60601-1 with a maximum of 2 devices. Operation with more than 2 devices at such multiple sockets is not permitted as it cannot be ensured that the approved values for leakage current will not be exceeded (see EN 60601-1). In such cases, a separator, e.g. an isolation transformer approved for medical use, must be used.

Position the Docon 7 during normal donation operation so that the user is able to simply disconnect it from the power supply by pulling out the power cord.

The Docon 7 must not be changed.

No liquids must be allowed to penetrate the current-carrying parts of the device.

When cleaning, ensure that no cleaning agents are sprayed into the sockets.

Pull the plug out before cleaning the Docon 7.

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 7 to excessive heat or fire.

Do not subject the Docon 7 to major impacts.

If excessive heat, fumes or smoke are seen, immediately disconnect the Docon 7 from the power supply.

Do not extinguish the Docon 7 with water in the event of fire.



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 the donor is established

## General safety information

### 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.



No additional active device (device with its own power supply) may be connected to the USB interface of the Docon 7.

**Intended use**

## 2 Intended use

### 2.1 Proper use - intended use

The Docon 7 is a medical device and serves to mix the blood during a blood donation with the anticoagulant in the blood bag and to stop the blood supply once an adjustable volume has been reached. In addition, internal information on the donation as well as external data entered by the user can be collated and transferred to an EDP system.

Only those who fulfil the general criteria for blood donations are permitted to donate blood, e.g. "Guidelines for the Preparation of Blood and Blood Components and for the Use of Blood Components" and "Guide to the preparation, use and quality assurance of blood components".

### 2.2 Combination with other products



Blood bag systems are necessary to allow blood to be donated. The Docon 7 may only be operated with bag systems which satisfy all the statutory requirements made of blood bag systems.

Furthermore, the maximum capacity of the bag systems must not exceed 500 ml.

### 2.3 Essential performance features

The Docon 7 does not have any essential performance features.

### 3 Product description

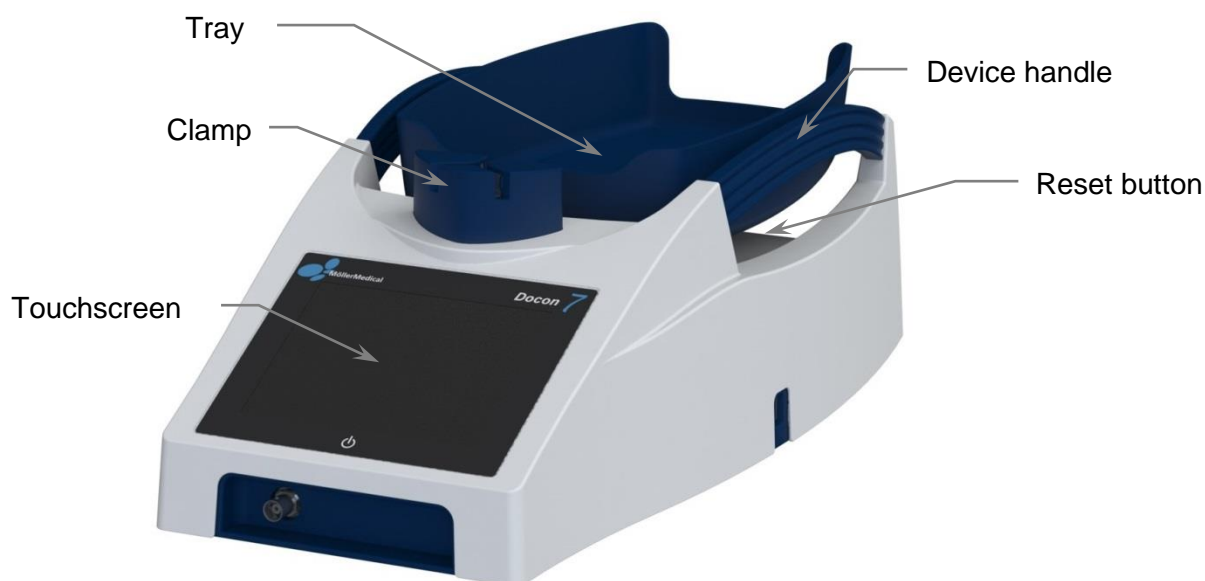


Figure 1: Docon 7

#### 3.1 Control elements

##### 3.1.1 Touchscreen

The user can input data into the Docon 7 via the touchscreen. To enter information either a finger or a suitable stylus can be used. To select a button on the screen, press on the touchscreen around the button applying gentle pressure.

##### 3.1.2 Reset button

If the Docon 7 stops functioning properly and no longer reacts to the usual inputs, press the Reset button. This can be found on the rear of the device to the left of the power plug socket. This resets the Docon 7 to its original state.

#### 3.2 Tray

The Docon 7 tray which is used to hold the bag system is secured on the swing carrier by a magnet. This detaches if overloaded which reduces the risk of the Docon 7 being damaged.

## Product description

### 3.3 Clamp

This serves to clamp off the blood removal tube when the final volume is reached.

The blood removal tube is inserted from the rear through the clamp. The tube can be run out to the right or left, depending on the position of the scales towards the donor bed.

Tube recognition is contact-free. As such, the sensor is not subject to mechanical wear.

Two-stage clamping of the tube ensures double security. After inserting the tube, the clamp automatically locks the tube inlet and both tube outlets to prevent the tube from inadvertently escaping. At the same time, the tube is directly clamped at the inlet (position 1).

The clamped tube inlet is released when donation commences, and the blood starts to flow (position 2).

The clamp remains locked during donation and switches to position 1 when the donation volume has been reached. Once the donation is complete, press the clamp button to unlock the clamp and remove the tube.



To guarantee maximum safety for donors, the clamp is closed immediately in the event of a power failure when operating with a 230 V network.

This can be countered if the device is fitted with a battery.

### 3.4 Device handles

The device handles have multiple functions. On the one hand, they serve to ensure simple handling and, on the other hand, to protect the tray from being knocked accidentally.

The handles thus provide a protective function for the weighing system in order to prevent incorrect measurements due to damages to mechanical components.

### 3.5 Accessories and options



Operation of the **Docon®7** with additional accessories such as transducers or cables, which are not defined for the intended use with the device, may result in increased electromagnetic emissions, reduced immunity to interference or faulty operation.

## Product description

### 3.5.1 Docon 7 mobile II LSC

The Docon 7 mobile is used to input barcodes during donation.

In order to ensure protection of the back, the Docon 7 can be operated using the scanner keyboard. The current status of the donation is also shown on the colour display and signal states are indicated by a flashing LED. The Docon 7 mobile includes a 1-D laser scanner.



Figure 2: Docon 7 mobile II LSC

### 3.5.2 Holder for Docon 7 mobile II LSC

Depending on the situation at hand, the following holders are available for the Docon 7 mobile II LSC:

- Table base
- Plug-in base
- Swan neck
- Table assembly system (for assembly on the Docon 7 table)

You can find order information on the options described above on *Page 66*.



## Product description

### 3.5.3 Docon 7 Basic Barcodereader

The Docon 7 Basic Barcode Reader can be used as an alternative to our Docon 7 mobile II LSC for the purposes of barcode scanning. It has the ability to scan a very large area, simplifying reading long barcodes from a shorter distance.



Figure 3: Docon 7 Basic Barcodereader

### 3.5.4 Docon 7 status indicator

The Docon 7 status indicator can be secured in a raised position to improve signal recognition (e.g. on the donor's bed). It can be fixed in place using either a magnet or clip. All signal states which the Docon 7 shows on its display are transferred as an optical signal to the light.

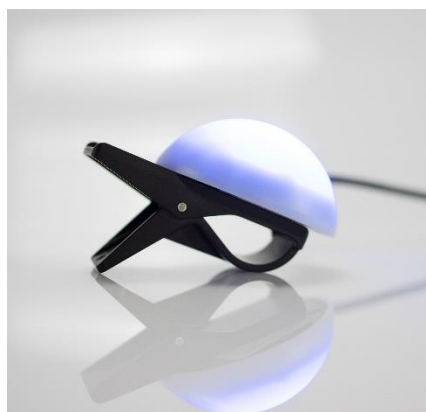


Figure 4: Docon 7 status indicator

## Product description

### 3.5.5 Docon 7 sealing option – sealing handle

The sealing 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. The sealing procedure can be documented in the data set.

Various PVC tubes with different diameters and wall thicknesses can be sealed. The sealing time is automatically adjusted for the tubes specified. The sealing process is indicated by a LED on the sealing handle (see *Sealing procedure* on page 19).



The sealing handle corresponds to the electrical safety requirements of a type B applied part as per EN 60601.

Only the original sealing handle may be connected to the Docon 7.



Only position the designated object between the electrodes of the Docon 7 sealing handle. See *Technical data* (page 59)

To achieve an optimal sealing result, only use tubes and bag systems which have been approved by the device manufacturer.

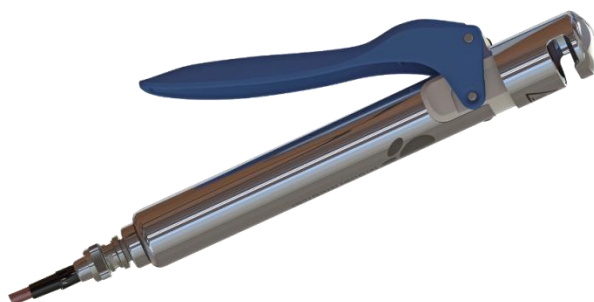


Figure 5: Sealing Handle for Docon 7

## Product description

### 3.5.5.1 Sealing of blood removal tubes



The integrated sealing unit emits electromagnetic radiation during sealing.

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

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 sealing 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.

### Sealing procedure

1. Place the tube in the recess on the sealing handle.
2. Press the sealing handle lever as far as it will go. The LED lights up and sealing starts automatically.
3. Sealing is complete once the LED on the sealing handle starts flashing.
4. Now open the sealing handle lever and remove the tube.

### 3.5.5.2 Cleaning the sealing handle

To rule out any risk to the user, pull the connecting cable out of the sealing handle before cleaning.

When cleaning, the user should wear appropriate protective clothing for his own protection.



Sterilisation methods such as autoclaving and ethylene oxide sterilisation render the Docon 7 sealing handle unusable.

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

Do not use sharp objects for cleaning.

To guarantee the functionality and safety of the sealing handle, it must be cleaned regularly. You will find a list of products tested for cleaning on *page 56*.



The Docon 7 sealing handle must always be cleaned after it has come in direct contact with blood.

The Docon 7 sealing handle should be cleaned thoroughly once per month.

## Product description

### Disassembly of the Docon 7 sealing handle

To clean the electrodes, firstly remove the blue lever and the electrode (see *Figure 6* to *Figure 9*).



Figure 6

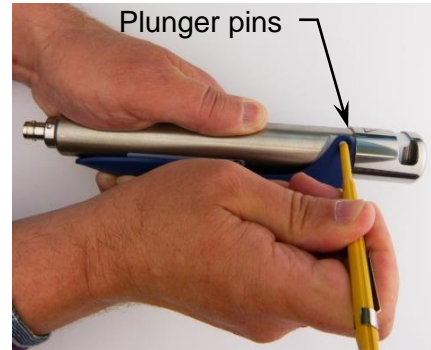


Figure 7

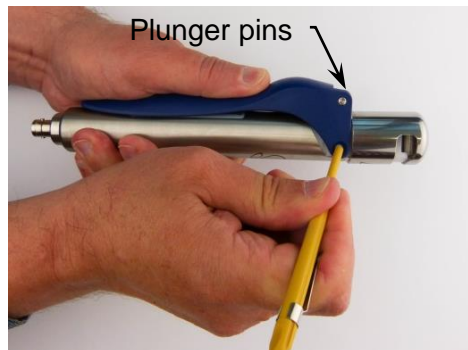


Figure 8



Figure 9

1. Press the lever as described in *Figure 6* 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 7* and *Figure 8*). Use a ballpoint pen or similar to push in the plunger pins.
3. Push the electrode and lever upward and remove (see *Figure 9*).

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.

## Product description

### Assembly of the handpiece and the lever with electrode after cleaning



Figure 10



Figure 11

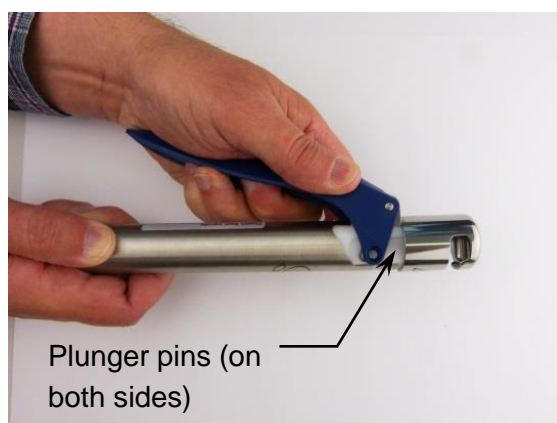


Figure 12

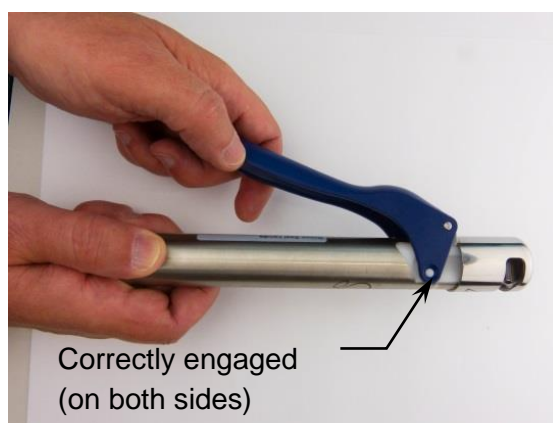


Figure 13

1. Place the lever with electrode on the handpiece and ensure that the lever is in the vicinity of the handpiece (see *Figure 10*).
2. Ensure that the electrode is positioned parallel with the fixed electrode and is aligned with the corresponding incision in the handpiece (see *Figure 11*).
3. Pull the lever with the electrode on the handpiece until both pins emit an audible "click" (see *Figure 12* and *Figure 13*).
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 sealing handle, perform a few trial sealing operations to test functionality.

## Product description

### 3.5.6 Docon 7 battery

Except in the case of mains operation, you can operate the Docon 7 with a battery (see *Figure 14*) in the battery compartment of the case. Given optimum conditions, up to 80 donations can be performed with a battery charge. Up to 50 donations are possible with a battery that is integrated in the Docon 7. The Docon 7 features an integrated charging circuit. Once you have connected the power cord to the device and put the batteries into their compartments as prescribed, the battery in the rear compartment of the case will be automatically charged. If the device only has an internal battery, only this battery will be charged.

Only original batteries may be used with the Docon 7. These batteries have been specially developed for use with the Docon 7 and satisfy the necessary requirements.



Risks can only be ruled out when the original batteries are used.

If not used for an extended period, the batteries are to be removed from the battery compartments in the case and stored in charged state. If the device has an internal battery, the device must be stored with the battery charged.

The batteries must be disposed of properly.

The batteries must not be disposed of as domestic waste.



Figure 14: Docon 7 battery

## Product description

### 3.5.6.1 Docon 7 during battery operation - internal battery

This version of the Docon 7 is only fitted with an internal (non-removable) battery. It does not have an external battery in the case.

This version is indicated by the additional symbol for lithium ion batteries on the rear of the device.



Figure 15: Identifying features for the internal battery

### 3.5.6.2 Docon 7 during battery operation - external battery

For this version, battery functionality of the Docon 7 is only ensured by the external battery in the transport case.

### 3.5.6.3 Battery charge display

Charging is signalled both on the display and via a LED on the rear of the device next to the mains connection. The LED on the rear is also visible when the Docon 7 is being charged via a compartment which can be externally accessed in the closed case. The LED shows the various operating modes via the two states, "On" and "Off".

LED	Operating modes	Battery
Off	Battery operation	Battery is being discharged
	Mains operation	Battery is fully charged
	Mains operation	No battery inserted
On	Mains operation	Battery is being charged

## Product description

### 3.5.7 Docon 7 transport case



Figure 16: Docon 7 transport case

The Docon 7 transport case performs two functions. Firstly, it serves to ensure safe transport of the Docon 7. Secondly, the top part of the case can be used as a platform for the bottom part of the case upon which the Docon 7 can be put in the necessary operating position.

The difference in height between the donor and the tray should be at least 20 cm.

Open the case for blood donation. Place the top part of the case on the floor. Then place the bottom part together with the Docon 7 on the top part.

The batteries in the transport case can only be exchanged when the case is open. Push the lateral spring clips on the battery compartments down slightly. The batteries are unlocked and are moved upward toward you. Now take these out of the case. To insert the batteries, slide them into the case with the logo pointing upward. Gently push the batteries inward to engage them in the intermediate base.

The rear battery compartment serves as an active compartment. The front compartment can be used for storing a possible spare battery so the battery can be quickly changed if required.

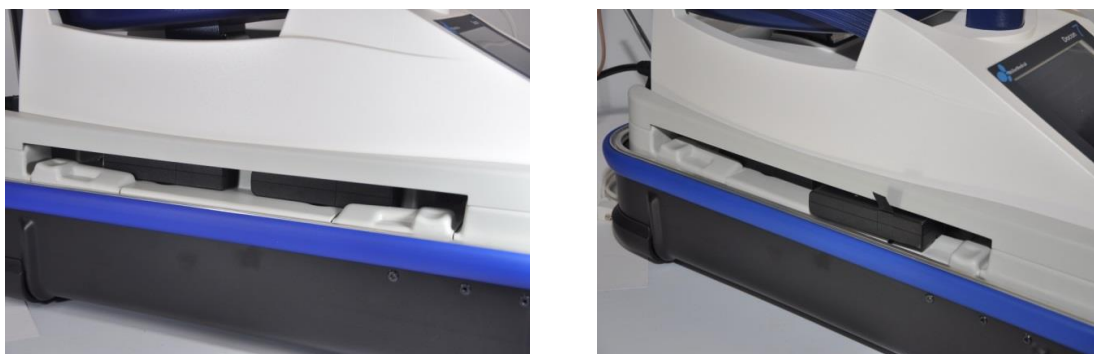


Figure 17: Docon 7 battery compartments



## Product description

To remove the mixing scales from the case, firstly unlock the black rotating lever on the front directly below the display (see *Figure 18*). Then gently lift up the front of the Docon 7 and pull it toward you out of the case tray.

To position the Docon 7 correctly in the case again, place it in a tilted position of approx. 30 degrees with the rear pointing down into the tray. Push the blue flap on the rear of the device into the designated recess (see *Figure 18* on the right). Finally, lower the front of the Docon 7 and lock the lever. The device is now ready for operation again.

The sliding compartment on the rear of the case allows the batteries to be charged whilst the case is closed. For this, open the rear sliding flap on the case and insert the power cord directly into the Docon 7 power socket.



Figure 18: Docon 7 case fixation

### 3.5.8 Docon 7 table

The table is mounted directly on the transport case. It serves as a storage place for donation utensils and also enables the Docon 7 mobile and the sealing handle to be placed in appropriate holders. For this you additionally require the scanner holder, table assembly system and tube holder.

To mount the table on the case, firstly insert the aluminium section into the duct on the bottom part of the case (see *Figure 19*). Now push the black clamp connection down to the case section and tighten by hand. Ensure that the projection on the connection is inserted correctly in the case section. Then place the table top on the aluminium section and also hand-tighten using the star-shaped knob.

**Product description**



**Figure 19: Docon 7 table**

**3.5.9 Docon 7 tube holder**

As described above, the tube holder is attached directly to the Docon 7 table. The sealing handle and blood tubes etc. can be safely stored in it.



**Figure 20: Docon 7 tube holder**

**3.5.10 Docon 7 stick**

The Docon 7 stick is a USB storage device with which data from the Docon 7 can be transmitted to a PC. It is not included in the scope of delivery.

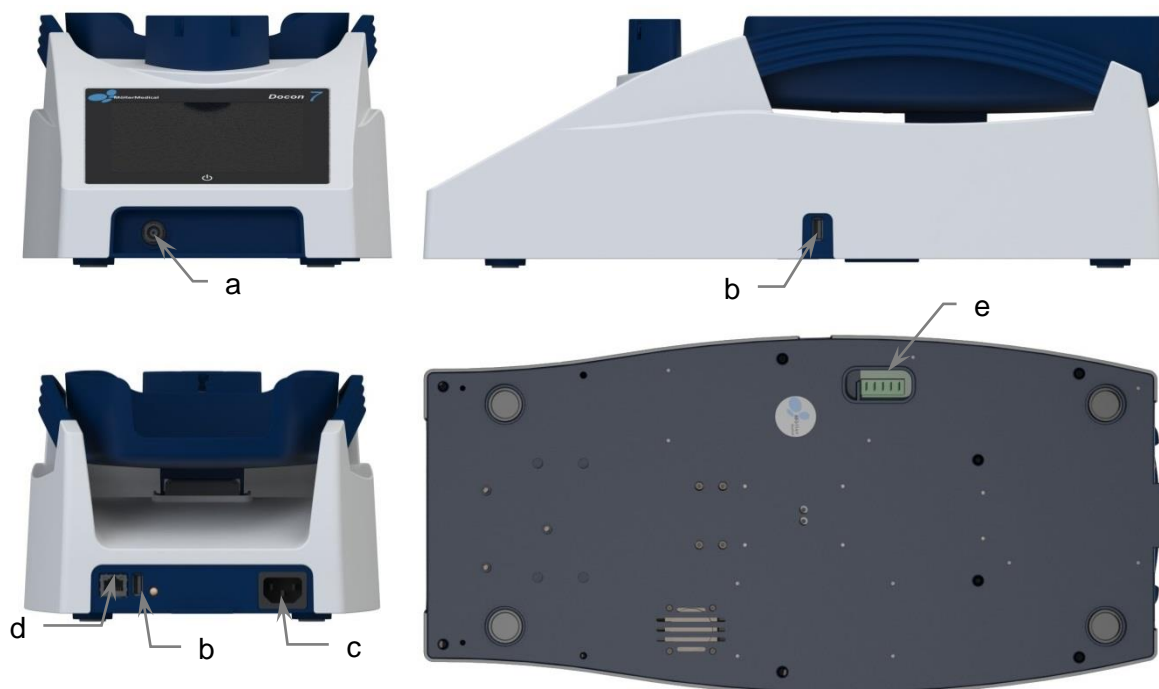
CAUTION: To allow the stick to be used in the Docon 7, it must be configured accordingly.



- Create a folder named "Docon" and a folder named data.
- Save the "Docon" folder on the storage medium and then drag the "data" file into the "Docon" folder.

## Product description

### 3.6 Connection options



**Figure 21: Connection options on the Docon 7.**

**a: BNC (sealing handle); b: USB; c: Power plug socket; d: Network; e: Docking connection**

The following connection options are available with the Docon 7 (see *Figure 21*):

a. BNC plug-in connector

- Sealing handle (only with Docon 7 with seal option)

b. 2 x USB

- Reading of donation data via the USB stick
- External barcode scanner
- LED status indicator

c. Power plug socket

- Socket for 3-pole type F power cord for connection to the power supply (the power cord must comply with IEC 60320)

d. Network

- RJ45 network connection for stationary mains operation

e. Docking connection for battery operation

## Product description

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 medical electrical devices). Whoever connects additional devices to the signal input or output part, is the system configurator and thus responsible for ensuring that the valid version of EN 60601-1 is observed.



When connecting a LAN network, a suitable hub approved for medical use or a galvanic isolation device approved for medical use is to be used.

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

### 3.7 User interface

The following section provides an overview of the Docon 7 user interface. Information on settings can be found as of *page 43*.

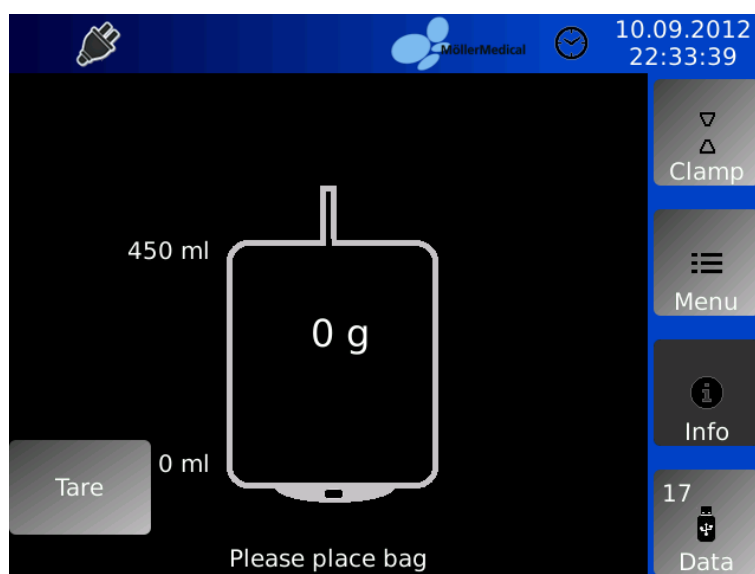


Figure 22: Basic setting display on the Docon 7

## Product description

### 3.7.1 Softkeys

You will find 4 control elements on the right-hand side. You can use these to call up various functions during the donation process.

Softkey	Function
Clamp	Manual opening and closing of the clamp
Menu	Access to the system menu
Info	Information on the current donation process
Data	Transmission of donation data to a USB medium

### 3.7.2 System state

The top part of the display provides information on the system state (connected devices, battery charge status etc.) as well as the donation time. The current time and date are also displayed. The symbols shown are explained on *page 8*.

#### Mains operation

If the Docon 7 is supplied with current via the power cord, the plug symbol confirms this operating mode.

#### Battery operation

The current charge level of the main battery is shown as a permanently coloured bar in the battery symbol and also as a percentage. The Docon 7 is suitable for network-independent (battery) operation.



If allowed to become completely discharged, this can result in permanent damage to the batteries and should thus be avoided.

### 3.7.3 Screen keyboard

If the screen keyboard is required to enter data in a field, it is automatically displayed. This corresponds to a standard computer keyboard and can be switched between alphabetic and numeric entries. The screen keyboard is only used in the system menu.

## 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. Check the Docon 7 for damage. 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 % relative humidity
weight incl. packaging:	6,4 kg
Dimensions of the Docon 7 with packaging:	Width x height x depth 585 mm x 370 mm x 380 mm

### 4.2 Unpack the device and check the scope of supply

The Docon 7 delivery comprises a cardboard box. 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 Docon 7 in its original packaging to prevent damage during transportation.

The **standard Docon 7 version** has the following scope of supply:

- 1 x Docon 7
- 1 x tray
- 1 x 3-pole type F power cord
- 1 x instructions for use

The Docon 7 scope of supply can vary depending on the device options which you have purchased.

#### Docon 7 seal option

- 1 x sealing handle

## Setup and commissioning

### Docon 7 optional internal battery

### WLAN option

### RFID option

## 4.3 Commission the Docon 7

Whenever the Docon 7 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.

To perform a blood donation with the Docon 7, position it below the donor. This is necessary as the blood can only flow if there is a difference in height between the donor and the Docon 7. The height difference should be at least 20 cm.

The donation volume is checked as a function of the weight. To achieve the stated accuracy, ensure that the Docon 7 is horizontal and does not wobble. Position the bag system so that it is completely on the tray and the measurement results cannot be falsified by tubes hanging over.

For mobile blood donations, place the upper part of the case on the floor then place the bottom part of the case with the Docon 7 on this upper part.

Once a day and after every change of location, the accuracy of the weighing function must be checked by using a reference weight.

When the Docon 7 is set up for the first time or when set up for mobile blood donation, the accuracy of the weighing function should be checked by using a reference weight. For this, place a 500 g weight in the middle of the tray. After the display stops varying, the value shown should be between **495 g** and **505 g**. If the value shown is not within these limits, the Docon 7 must be checked by the service team and may no longer be used for blood donations.

Please note the following points when setting up the Docon 7:



- Ensure that adequate space is maintained to other devices. The Docon 7 (incl. case installation height) requires a height of at least 550 mm and width of 270 mm.
- It must be guaranteed that the device can be easily disconnected from the mains (if used) by pulling the power cord.
- Accessories are to be connected so that any falsification of the measurement results due to cords on the tray can be ruled out.

## Setup and commissioning

### 4.3.1 Connect and switch on

After you have set up the device in the desired position, insert the power cord in the rear of the housing into the Docon 7. Insert the other end of the cord into a socket with a protective conductor. Note the voltage values stated on the rating plate. This is located on the rear of the device. If you wish to operate the device in battery mode, insert the battery in the rear compartment in the case's intermediate base.

To turn the Docon 7 on, touch the screen for 3 seconds. The Docon 7 then performs a self-test. The software version, device number and manufacturer are shown on the display. The tray swings once and the clamp opens and closes once. The weighing system then calibrates itself and the device is set to the basic setting.

### 4.3.2 Switch off

After completing a donation, turn the Docon 7 off as follows. Press anywhere on the touchscreen for longer than 2 seconds, then confirm by pressing **Shut Down** on the **dialogue window** that appears.

## 4.4 Operation with other devices



Never operate the Docon 7 directly (for distance see *chapter 4.7*) beside or in conjunction with other devices, as this could result in faulty operation. If operation in the proximity of or stacked with other equipment cannot be avoided, monitor the Docon 7 and other devices to verify specified normal operation.

## 4.5 Suitable operating environment

The Docon 7 is suitable for environments in the following areas:

- Home healthcare
  - Department stores, schools, lodgings (places of residence, nursing homes), hotels, guest houses and 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 Docon 7 is not approved for use in aircrafts or military applications. The appropriate EMC requirements for these environments have not been tested.



## Setup and commissioning

### 4.6 Operation in IT networks

The Docon 7 can exchange data with a PC using DMS software (see chapter 5.2) via the LAN or WLAN interface.

The Docon 7 can be connected to a standard LAN as per IEEE 802.3 or WLAN as per IEEE 802.11 2.4 GHz, see *chapter 3.6*.

Integration of the Docon 7 into an existing IT network that includes other devices is carried out at the risk of the operator. It may lead to previously unforeseeable risks for the patient, operator or third parties.

The operator must determine and assess these risks as per IEC 80001-1:2010.

The operator must reassess these risks in the event of changes to the IT network, such as adding or removing devices or IT components, or updating or upgrading devices in the IT network.

### 4.7 Use of RFID-tagged blood bag systems

By fitting the blood bag systems with RFID tags, the Docon 7 can read and write. To do so, passive UHF tags as per ISO/EIC 18000 must be attached to the bag system ("Smart Tags"), which communicate with the Docon 7 at a frequency of 13.56 MHz.

The RFID tag system is used to provide information and does not release the operator from checking the data via the printed label.

Only use tags of series IN410 made by LAB ID.

The use of non-verified tags is carried out at your own risk.

The Docon 7 can read and write up to three tags simultaneously.

The RFID tags are identified within the tray. Make sure that they are no more than 40 mm above the tray (also see *Figure 23*). If this distance is exceeded, it is no longer possible to reliably identify the tags.

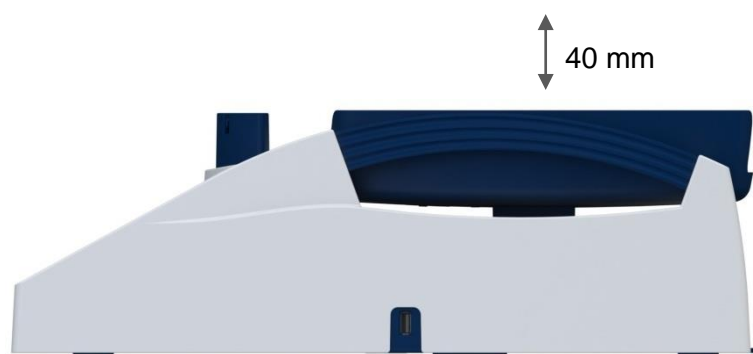


Figure 23: Maximum RFID tag position above the tray

## Setup and commissioning

If you operate several Docon 7s with RFID function simultaneously, make sure that the distance between them is not less than 15 cm so as to avoid interference between the devices.

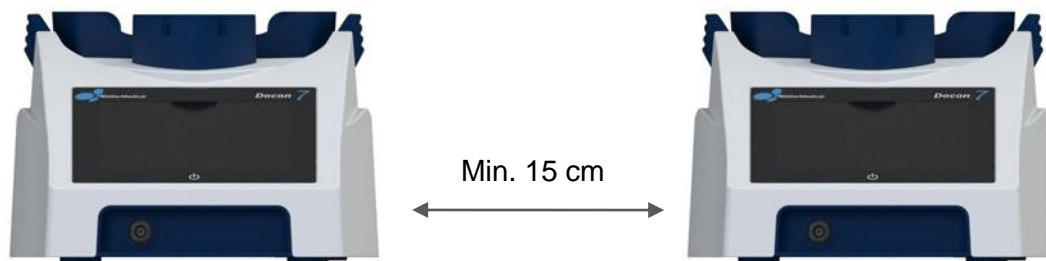


Figure 24: Minimum distance between two Docon 7s during RFID operation

### 4.7.1 Preparation of the blood bag system

Prior to using the RFID function on the Docon 7, the blood bag systems have to be provided with RFID tags.

To do this, attach tag 1 to the top of the **whole blood bag** as shown in *Figure 25*.

It must be positioned in the middle on the left and the RFID chip must be aligned with the inside of the system. This helps to prevent possible malfunctions from the downstream centrifugation process.

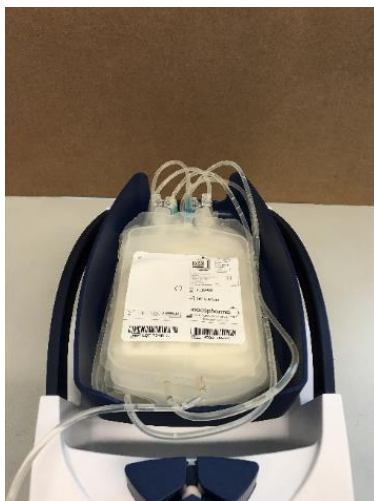


Figure 25: RFID tag position on top bag

Now attach tag 2 to the bottom of the **erythrocyte bag** as shown in *Figure 26*.

It must be positioned at the top on the right and the RFID chip must also be aligned with the inside of the system. This helps to prevent possible malfunctions from the downstream centrifugation process.

## Setup and commissioning



Figure 26: RFID tag position on middle bag

Finally attach tag 3 to the bottom of the **plasma bag** as shown in *Figure 27*.

It must be positioned at the bottom on the right and, again, the RFID chip must be aligned with the inside of the system. This helps to prevent possible malfunctions from the downstream centrifugation process.



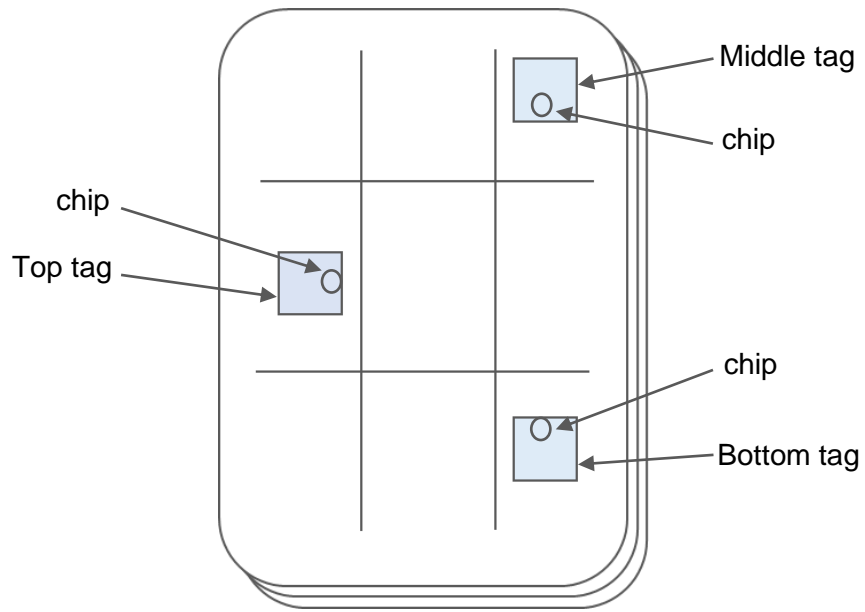
Figure 27: RFID tag position on bottom bag



When attaching the individual tags avoid overlapping >10%.

If you look at the blood bag system from above, then you can see the following sticker pattern.

**Setup and commissioning**



**Figure 28: RFID tag positions on the bag system**

## 5 Application and operation

### 5.1 Blood donation

With its basic settings with integrated standard setup, the Docon 7 standard is suitable for taking blood without recording data. This is described below. For other options please take the relevant chapters into account.

The standard donation process is such that the operator is exposed to the minimal possible risk of incorrect operation. The individual stages are described in detail step by step in the display.

The processes can be configured in line with the customer's requirements using PC software **DMS Docon**.

#### 5.1.1 Preparation for blood collection

Before the blood donation, place the bag system on the tray. Guide the blood removal tube from the rear through the clamp. Depending on which side of the mixing scales the donor bed is located, guide the tube to the left or right out of the clamp Y-piece.

All the bag must be on the tray. The blood removal tube must never be trapped between the clamp and tray, even if the tray is tilted backward.

The weight applied before the start of the donation must be less than 1300 g.

After the tube has been successfully recognised you will be requested to close the clamp. Close the clamp by pressing the **clamp softkey**.



With the automatic clamp option, the clamp is closed automatically once the tube has been recognised.

The vein can now be punctured.

#### 5.1.2 Start of blood collection

Press the **start** button to start donation. The Docon 7 then switches the display from g to ml and sets the volume and duration to 0. You can freely select how g and ml are displayed when adjusting the settings. The clamp is then automatically opened and the tray swings to and fro twice. It then remains still for 2.5 s. During this time, the volume display is updated and the inflow to the set limits is checked.

The swinging and resting cycles continue until the volume is 20 ml less than the set end volume. The Docon 7 then stops swinging. A brief signal sounds to indicate that the resting limit has been reached. In the resting state, the volume can be permanently monitored, and a high degree of accuracy can be achieved.

## Application and operation

Once the set volume has been reached, the clamp closes automatically. The dialogue field **Donation volume reached** appears and an acoustic signal sounds. The volume of the acoustic signals can be infinitely set using the system menu. The Docon 7 now swings to and fro again as there is no inflow. The volume display is updated each time the system comes to rest.

### 5.1.3 Display collection information

Press the **Info** button on the right-hand side of the screen in order to display information on the average blood flow and the current donation volume as a flow chart.

Press any position on the screen to return to the donation screen.

### 5.1.4 Inflow error messages

The Docon 7 can monitor inflow in ml per minute. The inflow is only measured when the system is resting, just before the tray starts to swing again.

It is monitored whether the inflow is too high or too low. The maximum inflow limit is set to 200 ml/min as standard. If the value is larger, the message "Inflow too high!" appears in an additional window which covers virtually the entire screen and an acoustic signal also sounds.

The standard value for excessively low inflow is 50 ml/min. However a signal is only emitted if the inflow is continuously below this limit value for a set period of time (standard 45 s).

The messages are automatically deactivated once the errors have been remedied or the info window has been confirmed. The delay period for an excessively low inflow then starts again.

## Application and operation

### Overview of signal status for *Inflow too low*

Physiological signal status	Measured inflow too low
Technical signal status	N/A
Signal limit	Inflow min. [ml/min] can be set by user
Signal state delay	2 +-1 [s]
Delay in signal generation (device display)	Duration of low flow [s] can be set by user
Delay in signal visualisation in the communication software	Dependent on Docon 7 connection to PC (with deactivated WLAN scan): WLAN: < 2 s
Signal	Audible / visible
Signal priority	High
Signal description on display	Inflow too low
Paused audio	No

### Overview of signal status for *Inflow too high*

Physiological signal status	Measured inflow too high
Technical signal status	N/A
Signal limit	Inflow max. [ml/min] can be set by user
Signal state delay	2 +-1 [s]
Delay in signal generation (device display)	Duration of high flow [s] can be set by user
Delay in signal visualisation in the communication software	Dependent on Docon 7 connection to PC (with deactivated WLAN scan): WLAN: < 2 s
Signal	Audible / visible
Signal priority	High
Signal description on display	Inflow too high
Paused audio	No

All changes to signal settings are saved permanently and automatically reset after the power supply has been interrupted.

## Application and operation

### 5.1.5 Cancel application

You can cancel the process prematurely at any time once the donation cycle has begun.

For this press the **Cancel** or **End** button.

### 5.1.6 End of blood collection

Once the set volume has been reached, this is signalled by the Docon 7 both visually and acoustically.

Now close the **Donation volume reached** dialogue window and press the **End** button.

After pressing the End button, the Docon 7 stops swinging.

Now seal the blood removal tube manually and attend to the donor.

Press the **Clamp** button to open this fully.

Remove the tube and the bag system in order to complete the donation process.

The display returns to the basic setting. The volume display is hidden and the weight display appears. The overall weight of the stored blood including the bag system is shown. You can freely select how g and ml are displayed when adjusting the settings.

The Docon 7 has once again been set to the basic setting and is ready for the next blood donation.



The volume/weight of the bag must be checked again after the donation has been completed.



## Application and operation

### 5.1.7 Docon 7 mobile II LSC

The Docon mobile II LSC serves as a barcode entry device for recording data with the Docon 7. In addition, it allows back-friendly operation of the device. The signal messages from the Docon 7 are also shown on the Docon 7 mobile II LSC. The Docon 7 mobile II LSC is operated using softkeys, i.e. buttons whose functions are described in the display.

Press the **Scan** button to use the integrated barcode scanner. The scanner is activated which is indicated by an emitted red laser line. Hold the scanner so that the red laser line can be seen on the barcode. Once it has been read in, a barcode is immediately displayed on the Docon 7 mobile II LSC and then shortly afterwards on the Docon 7.

The Docon 7 mobile II LSC corresponds with laser class 1.

When scanning, the distance between the barcode reader and the barcode should be between 10 and 40 cm.



The Docon 7 mobile II LSC is an independent device which communicates with the Docon 7. Accordingly, with the menu button on the Docon 7 mobile II LSC you can call up the Docon 7 mobile II LSC system menu and the menu button on the Docon 7 calls up the Docon 7 system menu.

The standby button on the Docon 7 mobile II LSC cannot be used to turn the Docon 7 on.

## 5.2 Data recording

### 5.2.1 DMS Docon

The DMS Docon PC software has been specially designed for data management of the Docon 7 and supports the following functions:

- Firmware updates
- Data management via WLAN manually and in online mode
- Bidirectional data transmission
- Creation, reading and writing of setup files

The software is available in the most diverse languages and is continuously being expanded. The latest revisions can be updated online. The handbook can be accessed after starting the program by pressing F1.

### 5.2.2 Record donation data

When recording donation data, the focus is on documenting a donation process in order to rule out mix-ups for example prior to the donation. With the setup program, the Docon 7 is a powerful tool for configuring data recording as required by the blood bank.

## Application and operation

A donation with data recording differs from a donation without data recording in that mostly before and after the donation, barcodes need to be read in. The precise barcodes and the requirements which they need to satisfy in order to be accepted are specified by the user by programming with the DMS software.

### 5.2.3 Save donation data

If the Docon 7 works with data recording, every donation is documented with a data set in the device. The structure of the data sets is also specified by the user with the setup program. Only those fields which are actually required are saved.

On conclusion of a donation the data is saved in an internal memory.

### 5.2.4 Transmit donation data

The data can be read out using a LAN or WLAN interface from a PC via DMS Docon. Alternatively, the data can be read out with an USB stick.

For this, insert a configured USB stick in one of the USB sockets as described on *page 26*.

Once the stick is inserted, its symbol is activated in the display and data can be transferred.

Now press the **Data** button to transfer the donation data.

The data counter goes back to zero after a successful transmission.

### 5.2.5 Process data

In order to make the EDP data available to the blood bank, the PC program **DMS Docon** is also used. When connected via an interface, the program handles communication with the devices. The data is then saved in ASCII format with clear file names.

The memory sticks are also read out with this program. The sticks can be read with standard Windows programs but conversion to the ASCII format and specification of the file names is done with the PC software.

The individual data sets are separated by line breaks in the files, the individual fields by tabs. This means the files can be directly loaded into Excel for example.

## 5.3 Storage conditions

After use, store the Docon 7 in accordance with the hygiene regulations. Also note the storage conditions on *page 57* and Technical data 59.

## Settings

### 6 Settings

#### 6.1 Setting options on the device, system menu

Press the **Menu** button to open the Docon 7 system menu.



**Figure 29: System menu display on the Docon 7**

1. Press one of the available buttons to open the corresponding submenu and make settings there.
2. Make your settings and confirm by pressing **Accept** to save the parameters and return to the system menu.
3. Only press **Cancel** if you wish to return to the system menu without saving the settings.
4. Press the **Back** button to exit the system menu.



Please note that the system menu can only be accessed if the Docon 7 is set in the basic setting.

General: You can freely select the colours and symbols for the system menu.

## Settings

### 6.1.1 Password submenu

There are 3 password levels to process the system menu.

Depending on the password entered, various menu items are either available or blocked.

**Default value:** Depending on the level 0, 101 or 202

**Minimum value:** Not specified, only text box is shown here

**Maximum value:** Not specified, only text box is shown here

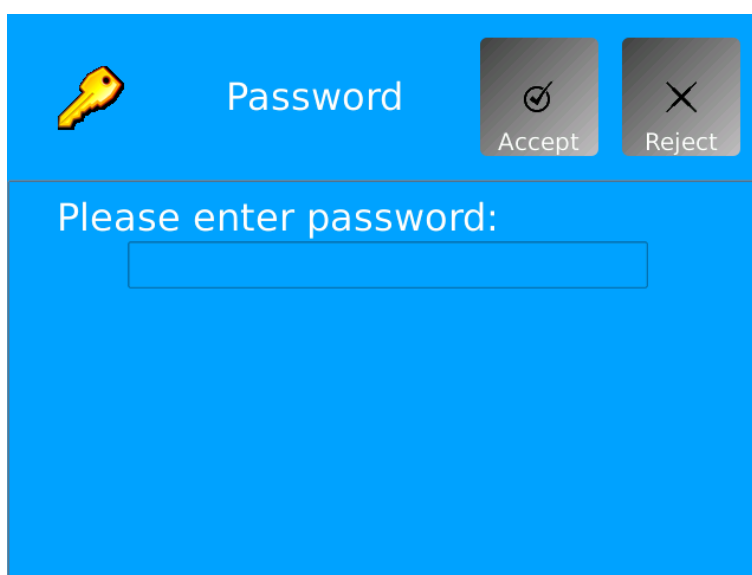


Figure 30: Password submenu display on the Docon 7

1. Press the **Password** button to open the setting area.
2. Click on the field below the prompt to call up the screen keyboard.
3. Enter the specified password directly via the screen keyboard and then confirm by pressing **OK**.

The display then switches back to the system menu view and the corresponding buttons are enabled.

Code level 0	Lowest-level authorisation with activation of menu items Password – Options – Validation – Display and Info
Code level 1	Medium-level authorisation with additional activation of the menu items Energy – Language – Region and Donation
Code level 2	Maximum authorisation with additional activation of the menu item Communication

## Settings

### 6.1.2 Options submenu

The relevant device options can be imported with this setting.

Option 1: WLAN

Option 2: Sealer

Option 3: Scanner

Option 4: RFID

Active options are indicated by a green checkmark, inactive ones by a red cross.

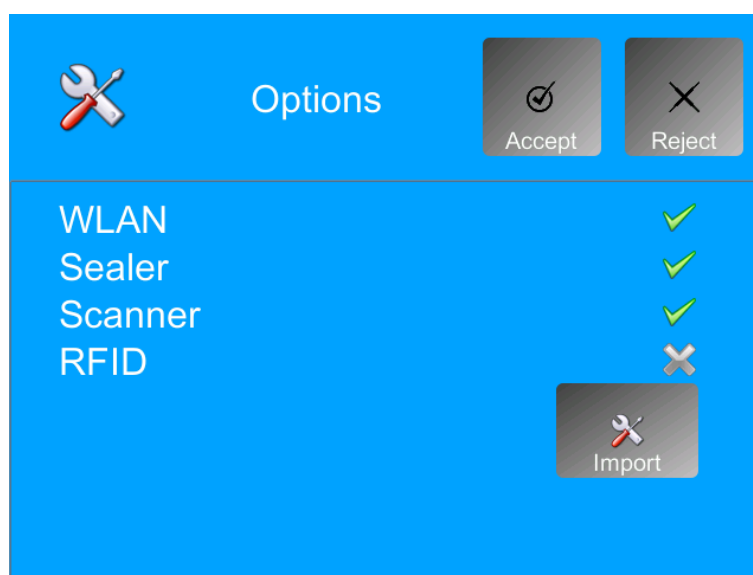


Figure 31: Options submenu display on the Docon 7

#### Load KEYS from the USB:

1. Save the file which contains the registration key on an USB stick.
2. Connect the USB stick to a free USB connection on the Docon 7.
3. Press the **Options** button.

Now press the **Import** button. The Docon 7 imports the keys saved on the stick and then switches back to the system menu.

4. Call up the **Options** submenu again to check that the options have been loaded correctly.

## Settings

### 6.1.3 Display submenu

#### 6.1.3.1 Brightness



Please note that operation with batteries implies greater brightness and higher power consumption.

The minimum display brightness is limited to a minimum value to ensure that the Docon 7 can be operated whatever the setting is.

The display brightness is set in this submenu. The brightness setting changes immediately when you alter the value to enable you to easily find the correct setting.

**Default value:** 100 %

**Minimum value:** 0 %

**Maximum value:** 100 %

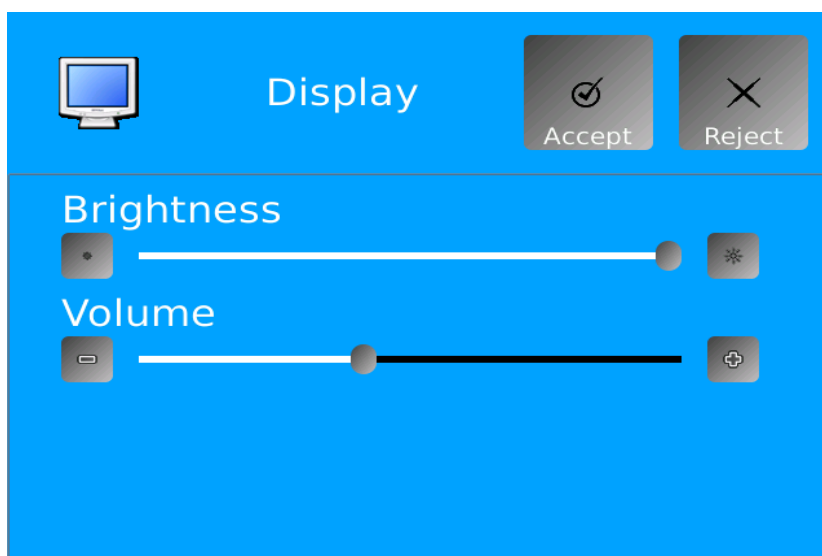


Figure 32: Display submenu on the Docon 7

1. Press the **Display** button.
2. Regulate the display brightness using the slider or the +/- buttons.
3. Press **Accept** to confirm and save the settings.

#### 6.1.3.2 Volume

The volume of the audio signals can also be set in the display submenu.

The changed setting is played back directly when you alter the value to enable you to easily find the correct setting.

## Settings

**Default value:** 50 %

**Minimum value:** 0 %

**Maximum value:** 100 %

1. Press the **Display** button.
2. Regulate the volume of the audio signals using the slider or the +/- buttons.
3. Press **Accept** to confirm and save the settings.

### 6.1.4 Energy submenu

Different energy saving measures can be defined here.

#### 6.1.4.1 Switch off the display's background lighting

Activate this setting to automatically switch off the background lighting after a set period of time. If this function is not desired, set the parameter to **Never power off display**.

**Default value:** Always on

**Minimum value:** Background lighting always on

**Maximum value:** Switches off after 15 mins

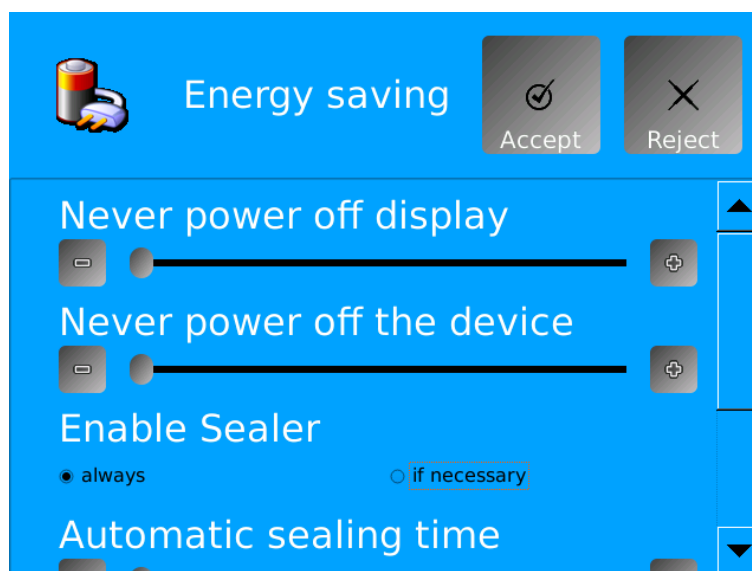


Figure 33: Energy submenu display on the Docon 7

1. Press the **Energy** button.
2. Regulate the switch-off time for the background lighting using the slider or the +/- buttons.
3. Press **Accept** to confirm and save the settings.

## Settings



After switching off the background lighting, touch the display briefly to turn it on again.

### 6.1.4.2 Switch off the Docon 7

With this setting, you define the switch-off time for the Docon 7 if it is not operated. If this function is not desired, set the parameter to **Never power off the device**.

**Default value:** Device always on

**Minimum value:** Device always on

**Maximum value:** Switches off after 60 mins

1. Press the **Energy** button.
2. Regulate the device's switch-off time using the slider or the **+/-** buttons.
3. Press **Accept** to confirm and save the settings.



You can achieve maximum energy savings by switching the device off. However, when the device is switched on again, you must allow for a start-up time of approx. 45 seconds.

### 6.1.4.3 Enable Sealer

You specify here whether the sealing function is always active or only switched on when necessary within the setup.

**Default value:** Always on

**Minimum value:** Always on

**Maximum value:** If necessary

1. Press the **Energy** button.
2. Make the desired setting by clicking on the relevant option.
3. Press **Accept** to confirm and save the setting.



## Settings

### 6.1.5 Language submenu

Define the desired language setting here.

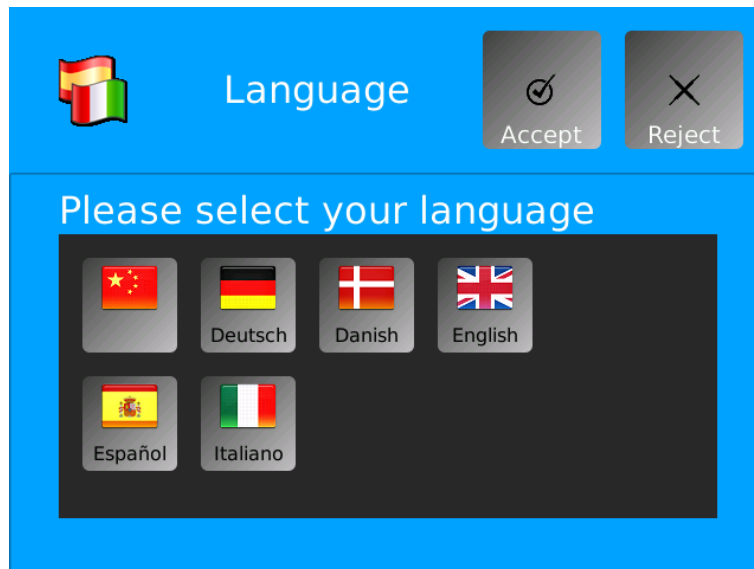


Figure 34: Language submenu display on the Docon 7

1. Press the **Language** button.
2. Make the desired setting by clicking on the relevant flag.
3. Press **Accept** to confirm and save the setting.



The button of the currently used language setting is highlighted blue.

## Settings

### 6.1.6 Locale submenu

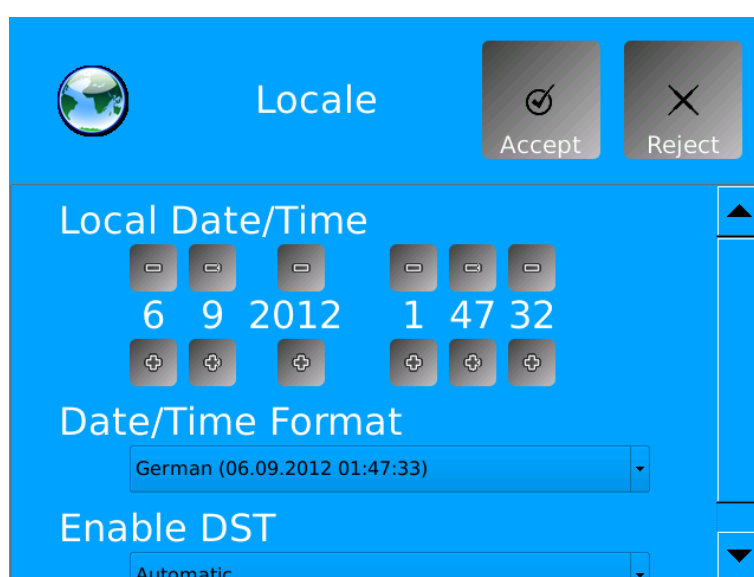
In this submenu the system clock of the Docon 7 can be set. The correct time is important for recording data.

The date and time format for visualisation in the donation screen are also specified here.

Furthermore, you can activate automatic switch over from summer to winter time.



This function is valid for Central Europe, i.e. summer time starts on the last Sunday in March and ends on the last Sunday in October.



**Figure 35: Locale submenu display on the Docon 7**

1. Press the **Locale** button.
2. Make the desired settings.
  - Date and time  
Set the correct date and time using the + and – buttons.
  - Date/time format  
Press the arrow on the right-hand side of the window to open the drop-down menu and select one of the available date formats.
  - Activate summer time  
Press the arrow on the right-hand side of the window to open the drop-down menu to activate or switch off the automatic summer time function.
3. Press **Accept** to confirm and save the settings.

## Settings

### 6.1.7 Donation submenu

This function is used to load one of the setups saved in the device. Up to three different setup configurations can be saved in this submenu. The setup is created by the manufacturer or an authorised partner. Both customer-specific and graphic adaptations can be made.

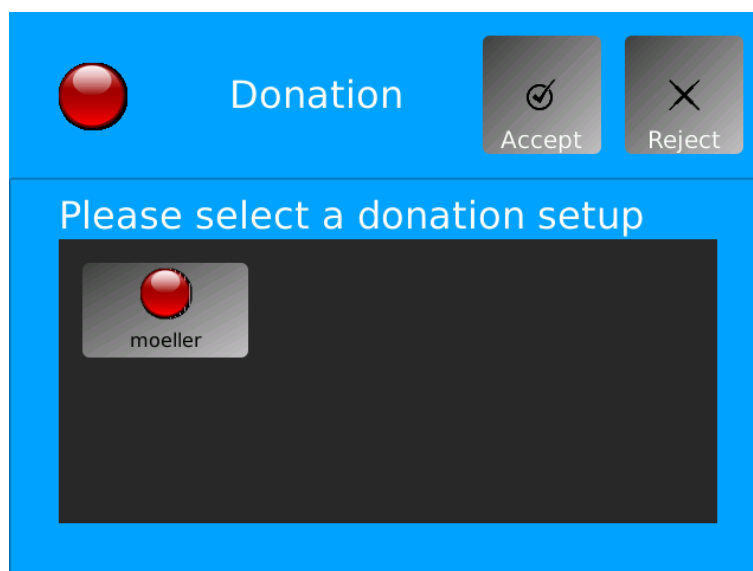


Figure 36: Donation submenu display on the Docon 7

1. Press the **Donation** button.
2. Select one of the desired setups by touching the relevant button.
3. Press **Accept** to confirm and save the setting.

### 6.1.8 Communication submenu

The Docon 7 includes various communication options for data transmission to the PC and for data recording via input devices such as the Docon 7 mobile II.

The Docon 7 distinguishes between two interfaces. The interface to the PC (LAN) serves to transfer data to a PC. In addition, data can also be transmitted via WLAN.



You can switch off the LAN and WLAN interfaces in this menu item (if they are not required) in order to increase the battery life.

The USB interfaces serve to enter data, such as barcodes.

Detailed descriptions on interface configuration can be found in the **DMS Docon** online documentation.

**Settings**

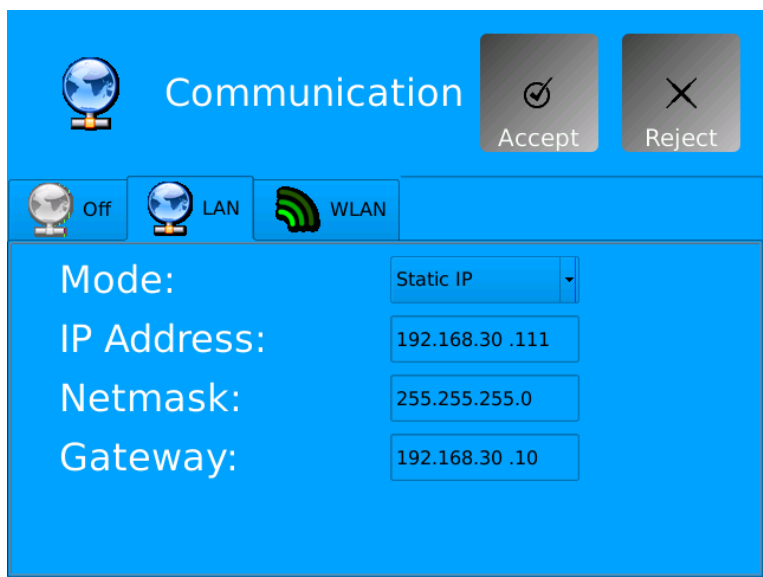


Figure 37: Communication submenu display on the Docon 7

### 6.1.9 Validation submenu

This function enables the 500 g validation of the Docon 7 to be repeated or checked. An internal data set is saved for each validation process, this documents the date/time, serial number and weight.

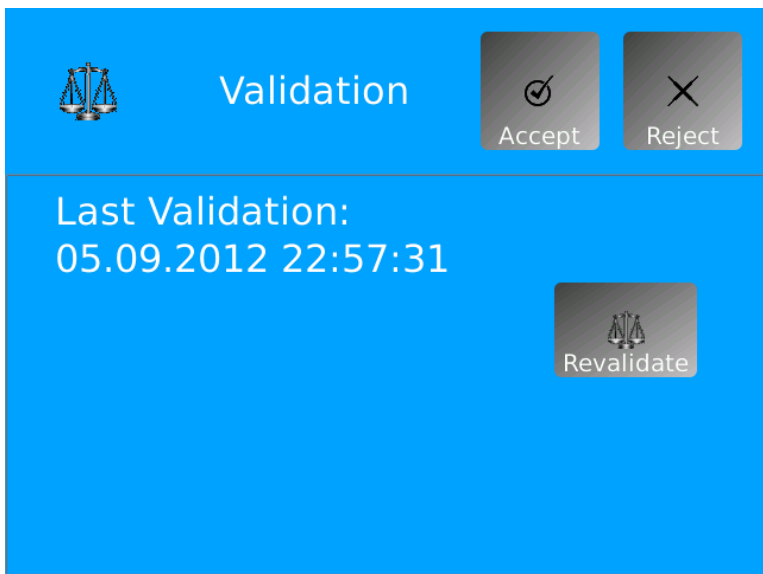


Figure 38: Validation submenu display on the Docon7

Press the **Revalidate** button to go to your normal validation screen.

### 6.1.10 Info submenu

Get an overview of the serial number, firmware and setup version, MAC address and date of the next safety check for the Docon 7.

## Settings

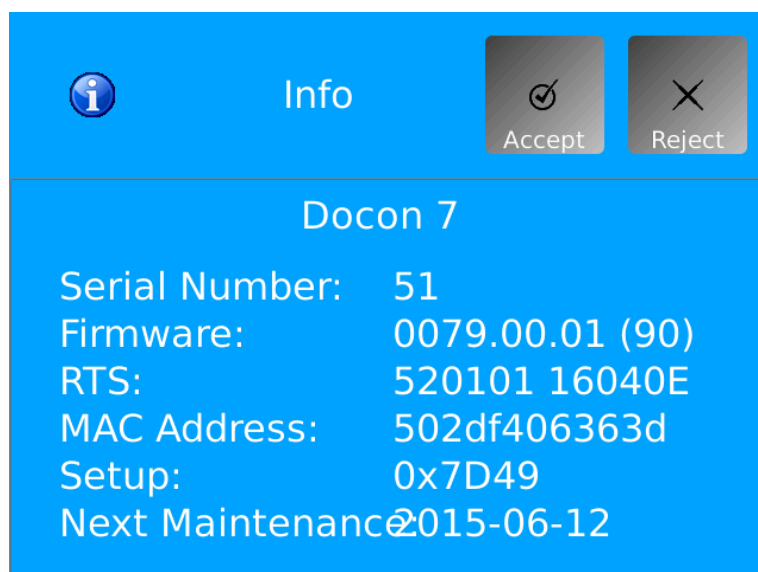


Figure 39: Info submenu display on the Docon 7

1. Press the **Info** button.
2. Exit the submenu by pressing the **Cancel** button.

## 6.2 Remediating of errors

A number of errors are listed in this chapter which could occur in connection with Docon 7. Several possible solutions are given for each error. The solutions proposed should be executed in the order provided until the fault is remedied. The Docon 7 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 service team.

Errors	Solution
<p>No functionality, the display is off.</p> <p>or</p> <p>The Docon 7 cannot be turned on.</p>	<ul style="list-style-type: none"> <li>• Start the Docon 7 by pressing the touchscreen for at least 3 seconds.</li> <li>• Check the power supply (mains or battery operation)</li> <li>• Switch multiple sockets on.</li> <li>• If the Docon 7 is battery-operated, check that the batteries are sufficiently charged.</li> <li>• Check the supply lines.</li> </ul>

## Settings

Errors	Solution
The touchscreen can no longer be operated.	If you are wearing gloves, remove these and try to operate the Docon 7 again via the touchscreen.  or Start the Docon 7 by pulling out/removing the power cord or battery and then inserting again. Should this not bring about a change, the device must be checked by the service team.
The wrong fields are selected when entering data via the touchscreen.	In this case, the device must be checked by the service team.
Problems when recording data.	Check the settings in the setup program.
Error due to moisture in the plug connection.	Remove all plugs from the device and allow the connections to dry.
The device signals a recurring signal with a fixed frequency.	Start the Docon 7 by pulling out/removing the power cord or battery and then inserting again. Should this not bring about a change, the device must be checked by the service team.



The Docon 7 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.

## Settings

### 6.3 Service

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



Whenever the **Docon®7** is returned, a suitable disinfection process must be carried out in order to rule out the possible risk of infection.

Consumables must be disposed of as per the hygiene guidelines.

#### Manufacturer:

##### **Möller Medical GmbH**

Wasserkuppenstrasse 29-31  
36043 Fulda, Germany

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



##### **Service**

Telephone: +49 (0) 661 94195 - 500  
Fax: +49 (0) 661 94195 - 850  
E-Mail: [service@moeller-medical.com](mailto:service@moeller-medical.com)

#### Distributor:

## 7 Care

### 7.1 Cleaning and disinfection



No humidity must be allowed to enter into the device.

Before cleaning and disinfecting the device surfaces, disconnect the mains plug.

Use a lint-free, soft cloth for cleaning and disinfecting.

Wipe the device to clean and disinfect it. Immersing or spraying the device may lead to hazards.

Start the cleaning process using a cloth dampened with mild soap solution or 70% isopropanol solution.

After cleaning, disinfect the surfaces of the Docon 7 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 disinfectants have completely evaporated before using the Docon 7.

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

The tray can be removed for cleaning by pulling it upward.

### 7.2 Maintenance

#### 7.2.1 Safety check

A safety check as per the German Medical Devices Operator Ordinance must be performed at least every 12 months. Only use the Docon 7 if the device is functioning safely and safe to operate. Otherwise it must be repaired immediately by the service team.

#### 7.2.2 Service documents

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



## Care

### 7.3 Transport

The Docon 7 may only be transported as per the transport conditions (see technical data on *page 59*). A transport case is available as an accessory for mobile use and day-to-day transport. Inside this case, the Docon 7 is protected from external damage (see *Docon 7 transport case on page 24*).

If the Docon 7 is sent to the service team, it must be packed in its original packaging as this provides the best possible protection from external damage.



Please note that the Docon 7 is an electromechanical device. It must not be thrown. If condensation forms after the device is transported in the cold and set in a warm room, the Docon 7 must not be switched on until the condensation water has evaporated. Please note in particular any water on the battery contacts and the sealing handle. The warm-up and cool-down phases relate to a room temperature of 20°C.

Transport temperature	Warm up / Cool down Phase
- 20 °C	2.5 hours with a closed case
- 20 °C	2 hours with an open case
50 °C	1.5 hours with an open case

### 7.4 Battery care when storing the Docon 7



If the device is stored or not used for a period of 2 months, the battery should be charged to 65% at the time of storage. The state of charge can be read off the display when the Docon 7 is switched on.

After not being used for 2 months, the battery must be recharged to 65%. The state of charge can be read off the display when the Docon 7 is switched on.

### 7.5 Disposal

#### Docon 7 and accessories



This device includes 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.

## 8 Device options

To expand the functional spectrum of the Docon 7, various useful device options and upgrades can be purchased. These are:

1. WLAN option
  - Wireless transfer of donor data (also possible online).
2. Seal option
  - Sealing of the blood removal tube directly at the donor's bed.
3. Optional internal battery
4. RFID option

If required, the desired device options can be activated on your Docon 7 with a valid key and a corresponding hardware update can be performed. In this case, please consult the manufacturer or your distributor (see *page 55*).

## Notes

## 9 Notes

### 9.1 Technical data

<b>General data</b>	
Order number REF:	00003700 - 1xxx / 2xxx 1xxx shows the versions of the standard device. 2xxx shows the versions of the sealing device. 3xxx shows the versions of the RFID device.
Docon 7 dimensions	Length x width x height 458 mm x 222 mm x 152 mm
Weight [kg]:	2.9 - 3.1 kg
Minimum operating life:	10 years
<b>Electrical connection</b>	
Voltage:	100 – 240 VAC (alternating current)
Frequency:	50 – 60 Hz
Current consumption:	1.10 – 0.46 A
Power consumption	110 VA
Current consumption, seal version	1.75 – 0.73 A
Power consumption, seal version	175 VA
Protection class:	II
Type of protection:	IP 20
Lithium button cell:	The Docon 7 features an internal button cell for the real-time clock. This must be disposed of as per the regulations at the end of its service life.
Total weighing range	0 g - 1,900 g, 0 ml - 1,792 ml (blood)
Weighing range before donation begins	0 g - 1,300 g
Weighing tolerance:	± 5 g, ± 5 ml (blood)
Reading accuracy	1 g
Memory:	1 GB internal
<b>Transport and storage information</b>	
Temperature:	-20°C to +50°C
Humidity:	less than 90% relative humidity
Weight with packaging:	6.4 kg
Packaging dimensions:	Width x height x depth 585 mm x 370 mm x 380 mm
Air pressure:	700 – 1050 hPa
<b>Operating conditions:</b>	
Temperature:	+10 °C to +40 °C
Humidity:	30% to 75% relative humidity
Air pressure:	790 – 1050 hPa
Operating altitude:	< 3000 m
<b>Sound level:</b>	
Signal sound pressure level:	73.5 dB(A) +/- 3.5 dB(A)
Noise level of the blood mixing scale during routine use (without pending alarms)	52,1 dB(A) +/- 0,2 dB(A)
<b>Communication:</b>	
Wireless Standard:	IEEE 802.11b; 80211g; 80211n
Security:	WPA2
Frequency range:	2,412 - 2,484 GHz

**Notes****Sealing:**

PVC tube specification:	4.0 - 6.0 mm outside dia.; 0.75 mm wall thickness
Sealing times:	1 - 1.5 s
Sealing procedures:	30/hour
Successive sealing procedures:	5

**External battery:**

Type:	Lithium ion battery
Voltage:	22.2 V
Capacity:	4500 mAh
Energy:	99.9 Wh

**Internal battery:**

Type:	Lithium ion battery
Voltage:	22.2 V
Capacity:	3000 mAh
Energy:	66,6 Wh

## Notes

## 9.2 Electromagnetic emissions

The Docon 7 is intended for the use in the electromagnetic environment as specified below. The customer and/or operator of the Docon 7 should ensure that the Docon 7 is used in an electromagnetic environment as described below.

### 9.2.1 Docon 7 Standard

Measurement of electromagnetic interference	Compliance	Electromagnetic environment - guidelines
RF electromagnetic interference acc. to CISPR 11	Group 1	To satisfy its intended function, the Docon 7 has to emit electromagnetic energy. Electronic devices in the vicinity could be influenced.
RF electromagnetic interference acc. to CISPR 11	Class B	For areas of application, see <i>chapter 4.5</i>
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Complies	

### 9.2.2 Docon 7 Seal

Measurement of electromagnetic interference	Compliance	Electromagnetic environment - guidelines
RF electromagnetic interference acc. to CISPR 11	Group 2	To satisfy its intended function, the Docon 7 must emit electromagnetic energy. Electronic devices in the vicinity could be influenced.
RF electromagnetic interference acc. to CISPR 11	Class B	For areas of application, see <i>chapter 4.5</i>
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Complies	

## Notes

The Docon 7 with seal option intentionally uses RF energy to seal tubes at a frequency of 40.66 - 40.70 MHz. In this frequency range, the device has an effective radiated power of <math><150\text{ dB}\mu\text{V}</math>. This radiated power level can interfere with devices located near the Docon 7 with seal option.

If abnormal performance is observed on other adjacent devices, additional measures may be necessary, such as reorienting or relocating the Docon 7.

### 9.2.3 Docon 7 RFID

Measurement of electromagnetic interference	Compliance	Electromagnetic environment - guidelines
RF electromagnetic interference acc. to CISPR 11	Group 1	To satisfy its intended function, the Docon 7 has to emit electromagnetic energy. Electronic devices in the vicinity could be influenced.
RF electromagnetic interference acc. to CISPR 11	Class B	For areas of application, see <i>chapter 4.5</i>
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Complies	

The RFID reader integrated in the Docon 7 has the following electromagnetic properties:

<b>Modulation</b>	Amplitude shift keying (ASK) 100% according to standard ISO 15693
<b>Frequency</b>	13,56 MHz
<b>Effective radiated power (ERP)</b>	831,8 nW

## Notes

### 9.2.4 Docon 7 WLAN option

The WLAN module integrated in the Docon 7 has the following electromagnetic properties:

<b>Modulation</b>	802.11b: DSSS (DBPSK, DQPSK, CCK) 802.11g: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11n: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11a: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11ac: OFDM (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM)
<b>Frequency</b>	IEEE 802.11 ac/a/b/g/n ISM band: 2,412 GHz~2,484 GHz, 5,150 GHz~5,850 GHz

#### Effective radiated power (ERP)

Frequency range (MHz)	IEEE standard 802.11	Effective radiated power (ERP)
2400-2483,5	b	89,536 mW
2400-2483,5	g	93,541 mW
2400-2483,5	n(HT20)	94,842 mW
2400-2483,5	n(HT20)	98,175 mW
5150-5250	a	187,499 mW
5250-5350	a	88,92 mW
5470-5725	a	85,507 mW
5150-5250	n(HT20)	178,649 mW
5250-5350	n(HT20)	100,000 mW
5470-5725	n(HT20)	99,816 mW
5150-5250	n(HT40)	158,125 mW
5250-5350	n(HT40)	99,312 mW
5470-5725	n(HT40)	98,401 mW

## Notes

## 9.3 Electromagnetic immunity

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment / guidelines
Electrostatic discharge (ESD) IEC61000-4-2	Docon 7 Standard and Docon 7 RFID and Docon 7 Seal  ±8 kV contact discharge ±15 kV air discharge	Docon 7 Standard and Docon 7 RFID and Docon 7 Seal  ±8 kV contact discharge ±15 kV air discharge	Floors should be from wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast transient electric disturbance/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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 cycles 70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles < 5 % $U_T$ (> 95% dip in $U_T$ ) for 5 sec	< 5 % $U_T$ (> 95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles < 5 % $U_T$ (> 95% dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Docon 7 Standard and Docon 7 RFID And Docon 7 Seal  30 A/m	Docon 7 Standard and Docon 7 RFID And Docon 7 Seal  30 A/m	Power frequency magnetic fields should be acc. to the typical values of a commercial or hospital environment.

Note:  $U_T$  is the AC mains voltage prior to application of the test level.

The Docon 7 Standard, Docon 7 RFID and Docon 7 Seal versions fulfil all the test levels according to IEC 60601-1-2 edition 4 (table 4 to 9).




## Notes



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 7 indicated by the manufacturer. Non-observance may result in a reduction of the device's performance.

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

Electromagnetic immunity test /standard	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment / guidelines
Conducted RF acc. to IEC 61000-4-6	Docon 7 Standard and Docon 7 RFID Docon 7 Seal  3 V <sub>rms</sub> 150 kHz to 30 MHz  6 V <sub>rms</sub> in ISM and amateur radio frequency bands between 150 kHz and 80 MHz	3 V <sub>rms</sub>   6 V <sub>rms</sub>	Portable and mobile RF communications equipment should be used no closer to any part of the Docon 7, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a)</sup> should be less than the compliance level in each frequency range <sup>b)</sup> . Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF acc. to IEC 61000-4-3	Docon 7 Standard Docon 7 RFID Docon 7 Seal  10V/m 80 MHz to 2.7 GHz  Table 9 of IEC 60601-1-2 Ed.4	Docon 7 Standard Docon 7 RFID Docon 7 Seal  10V/m  Table 9 of IEC 60601-1-2 Ed.4	

## Notes

Note:

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.

<sup>a)</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, 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 7 is used exceeds the applicable RF compliance level above, the Docon 7 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Docon 7.

<sup>b)</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

### 9.4 Recommended separation distances

See *chapter 9.3*

### 9.5 Accessories

#### Procurement options for accessories:

#### From Möller Medical GmbH or your direct distributor



Please keep the Docon 7 serial number to hand when ordering device options.

The key to activate the device options can only be used on the device stated when ordering and is only valid for 30 days. If the key is not transferred to the device during this period, it is no longer accepted.

#### Article numbers and device options for Docon 7

Docon 7 Standard	Article Number 00003700
Docon 7 WLAN Option	Article Number 00003676
Docon 7 Seal Option	Article Number 00003674
Docon 7 RFID modification kit	Article Number 92016029
Docon 7 mobile II LSC	Article Number 00003739
Docon 7 Status Indicator	Article Number 00003717
Docon 7 Transport Case	Article Number 00003673
Docon 7 Lithium Ion Battery	Article Number 93005614
Docon 7 Table for Transport Case	Article Number 00003672

**Notes**

Docon 7 Tube holder	Article Number 00003551
Docon 7 Scanner Holder II Table Assembly System	Article Number 00002901
Docon 7 Scanner Holder II Base	Article Number 00003056
Docon 7 Scanner Holder II with swan neck	Article Number 00003054
Docon 7 Scanner Holder II plug-in	Article Number 00003057
Docon 7 int. Battery Option	Article Number 00003803
Docon 7 Barcodereader Basic	Article Number 00003916
Docon 7 Transport Case Advanced	Article Number 00003862
Docon 7 Transport Case Basic	Article Number 00003919
Docon 7 Transport Case Basic +	Article Number 00003818
Docon 7 WALN Router	Article Number 00003855
Docon 7 Scanner Cradle with swan neck, short	Article Number 00003055

**Medizinproduktebuch Docon 7 (§7 MP BetriebV)**

## 10 Medizinproduktebuch Docon 7 (§7 MP BetriebV)

### Allgemeine Angaben zur Gerätefamilie

**Betreiberadresse (Stempel):**


**Gerätebezeichnung:**

Docon 7

**Standort:**

--

**Produkte- / Geräteart:**

Blutmischwaage Docon 7
------------------------

**Nummer nach Nomenklatur (DIMDI):**

--

**Kenn-Nr. der benannten Stelle:**

0482 (MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
---

**Zuordnung zu den Anlagen der MPBetriebV:**

MP nach Anlage 1	<input type="checkbox"/> ja <input checked="" type="checkbox"/> nein
------------------	---

MP nach Anlage 2	<input type="checkbox"/> ja <input checked="" type="checkbox"/> nein
------------------	---

**Hersteller nach §7 MPG:**

Möller Medical GmbH
Wasserkuppenstr. 29-31
D-36043 Fulda
Tel.: +49 661 94195-0
www.moeller-medical.com


**Technische Daten:**

<input checked="" type="checkbox"/> Medizinprodukt mit Messfunktion
---

Anwendungstyp (IEC 601): kein AW.-Teil
Schutzklasse: II

**Zubehör:**

<input type="checkbox"/> Docon 7 mobile II LSC	<input type="checkbox"/> Akku
<input type="checkbox"/> Scanner	<input type="checkbox"/> Tubeholder
<input type="checkbox"/> Docon 7 Schweißzange	<input type="checkbox"/> Tisch
<input type="checkbox"/> Transportkoffer	<input type="checkbox"/> Statusmelder

**Softwareausstattung:**

<input type="checkbox"/> Standard	<input type="checkbox"/> Scan
<input type="checkbox"/> Seal	<input type="checkbox"/> WLAN

## Medizinproduktebuch Docon 7 (§7 MP BetreibV)

### Bestehende Verträge (falls vorhanden) zur Durchführung der

<input checked="" type="checkbox"/> Sicherheitstechnische Kontrollen	
- alle 12 Monate	
Firma:	

### Verantwortlicher des Betreibers

<input type="checkbox"/> Beauftragung eines für den Betrieb des Medizinproduktes Verantwortlichen durch den Betreiber.		
Am: _____		
Datum	Name/Unterschrift des Beauftragten	Tel.-Nr. des Beauftragten

### Dokumente

Aufbewahrungsort der Gebrauchsanweisung:
--

### Einweisung des Verantwortlichen

<input type="checkbox"/> <b>Einweisung der/des vom Betreiber Beauftragten (Anwender) durch den Hersteller/Lieferant</b> für baugleiches Medizinprodukt unter Berücksichtigung der Zweckbestimmung, des verwendeten Zubehörs, der Kombination mit anderen Produkten anhand der Gebrauchsanweisung und der sicherheitsbezogenen Informationen.	
Am: _____	
Datum	Name / Institut / Unterschrift Beauftragter (Anwender)
Am: _____	
Datum	Name / Firma / Unterschrift des Einweisenden

**Medizinproduktebuch Docon 7 (§7 MP BetreibV)**

Gerätebezeichnung:	Docon 7
Seriennummer:	

**Meldung über Vorkommnisse**

**Ursache / Art**

Im Medizinproduktebuch sind folgende Vorkommnisse einzutragen:

**F-** Funktionsstörung  
**B-** Wiederholte gleichartige Bedienungsfehler  
**Ä-** Änderung der Merkmale oder Leistungen  
**U-** Unsachgemäßheit der Kennzeichnung oder der Gebrauchsanweisung

**Folgen**

Bei einer der hier aufgeführten Folgen muss eine Meldung an das BfArM erfolgen.

**zum Tod** **zur schwerwiegenden Verschlechterung des Gesundheitszustands**  
**T-** geführt hat **V-** geführt hat  
**mT-** geführt hätte **mV-** geführt hätte

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM):

Kurt-Georg-Kiesinger-Allee 3  
 53175 Bonn

Telefon: +49-(0)228-99 307 - 0  
 Telefax: +49-(0)228-99 307 - 5207

durchgeführt am Vorgangs-Nr.	Ursache / Art des Vorkommnisses (F, B, Ä, U) + Gerätenummer!	Beschreibung des Vorkommnisses eingeleitete, sicherstellende Maßnahmen <sup>1)</sup>	festgestellt von	Folge des Vorkommnisses (T, mT, V, mV)	gemeldet an BfArM durch Betreiber oder Anwender <sup>2)</sup>
					<input type="checkbox"/> ja <input type="checkbox"/> nein
Datum			Name		Datum
Uhrzeit			Unterschrift		Unterschrift
Vorg.-Nr.					<input type="checkbox"/> ja <input type="checkbox"/> nein
Datum			Name		Datum
Uhrzeit			Unterschrift		Unterschrift
Vorg.-Nr.					<input type="checkbox"/> ja <input type="checkbox"/> nein
Datum			Name		Datum
Uhrzeit			Unterschrift		Unterschrift
Vorg.-Nr.					<input type="checkbox"/> ja <input type="checkbox"/> nein
Datum			Name		Datum
Uhrzeit			Unterschrift		Unterschrift
Vorg.-Nr.					<input type="checkbox"/> ja <input type="checkbox"/> nein
Datum			Name		Datum
Uhrzeit			Unterschrift		Unterschrift
Vorg.-Nr.					<input type="checkbox"/> ja <input type="checkbox"/> nein
Datum			Name		Datum
Uhrzeit			Unterschrift		Unterschrift
Vorg.-Nr.					<input type="checkbox"/> ja <input type="checkbox"/> nein
Datum			Name		Datum
Uhrzeit			Unterschrift		Unterschrift
Vorg.-Nr.					<input type="checkbox"/> ja <input type="checkbox"/> nein
Datum			Name		Datum
Uhrzeit			Unterschrift		Unterschrift
Vorg.-Nr.					<input type="checkbox"/> ja <input type="checkbox"/> nein

<sup>1)</sup> Als sicherstellende Maßnahme wird die Hinzuziehung eines unabhängigen Sachverständigen empfohlen.

<sup>2)</sup> Meldeformular nach DIMDI verwenden.

## Medizinproduktebuch Docon 7 (§7 MP BetreibV)

Gerätebezeichnung:	Docon 7
Seriennummer:	

### Sicherheitsrelevante Erstmesswerte nach IEC 62353

Schutzleiterwiderstand:	$\Omega$	Ableitstrom vom Anwendungsteil, Ersatzmessung:	$\mu\text{A}$
Geräteableitstrom, Ersatz:	$\mu\text{A}$	Ableitstrom vom Anwendungsteil Netz am AW, direkt:	$\mu\text{A}$

### Funktionsprüfung / Inbetriebnahme am Betriebsort

Am:

Datum

Name / Institut / Unterschrift

### Sicherheitstechnische Kontrollen

durchgeführt am Vorgangs-Nr.	STK durchgeführt durch	Nr. des Prüfprotokolls	Ergebnis			nächste Kontrolle MM/JJ
			keine Mängel	keine sicherheits-erheblichen Mängel	Wartung/ Instandsetzung erforderlich	
	Anschrift Firma / Institution:					
Datum		Name Durchführender:				
Vorg.-Nr.						
	Anschrift Firma / Institution:					
Datum		Name Durchführender:				
Vorg.-Nr.						
	Anschrift Firma / Institution:					
Datum		Name Durchführender:				
Vorg.-Nr.						
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**Medizinproduktebuch Docon 7 (§7 MP BetreibV)**

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<p><b>Weitere Instandhaltungsmaßnahmen</b></p> <p><b>Bestehender Instandhaltungsvertrag</b></p>	<p>I = Inspektion, Feststellung des Ist-Zustands                  W = Wartung, Bewahrung des Soll-Zustands                  R = Reparatur, Wiederherstellung des Soll-Zustands</p>
Art des Vertrages: <input style="width: 100%;" type="text"/>	Kosten: <input style="width: 100%;" type="text"/>
Vertragsnummer: <input style="width: 100%;" type="text"/>	Kündigungsfrist: <input style="width: 100%;" type="text"/>
Laufzeit des Vertrages: <input style="width: 100%;" type="text"/>	Leistungsumfang, Notizen: <input style="width: 100%;" type="text"/>

durchgeführt am Vorgangs-Nr.	Maßnahme durchgeführt durch	Art (I, W, R)	Nummer des Serviceberichts	Bemerkungen / Maßnahmen
	Anschrift Firma / Institution:			
Datum		Name Durchführender:		
Vorg.-Nr.				
	Anschrift Firma / Institution:			
Datum		Name Durchführender:		
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