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GB

Docon

User Manual

CE 1275

Manufacturer / Distributor

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Contents

1 General safety instructions

1.1 Precautionary duties of the operator

Each application of the unit is subject to precise knowledge of and compliance with these operating instructions. This manual does not replace the instructions of the user with those of the medical device consultant. This unit may only be used by personnel who have the necessary training or knowledge and experience. (German Medical Device Operator Ordinance)

The manufacturer can only be regarded as being responsible for the safety, reliability and serviceability of the unit if:

- assembly, upgrades, reconfiguration, changes or repairs are only carried out by personnel who have been authorised to do so by the manufacturer.
- the electrical installation of the room in question conforms to pertinent requirements and
- the unit is used in accordance with the user manual.
- the conditions specified in the technical data are observed.

Performance and safety may be impaired if unit components are utilised that do not conform to the original design of the manufacturer.
All work that requires the use of tools should be carried out by the technical service of the manufacturer or an authorised agent.
Liquid should be prevented from penetrating components conducting electrical power.

The *Docon* should be operated with batteries in environments where flawless functioning of the earthing conductor connection cannot be guaranteed.

The user should not simultaneously touch the unit connections at the rear of the *Docon* and the donor!

The *Docon* mobile module and the hand-held sealing tongs can be used in the vicinity of the patient.

The *Docon* should not be used with portable multiple socket outlets, as no assurance can be given that the permissible values for patient discharge current will not be exceeded (see EN 60601-1-1).

Additional equipment connected to the analog and digital interfaces of the unit should be proved to comply with its corresponding EN specifications ((e.g. EN 60950 for data processing equipment and EN 60601 for electromedical equipment). Anybody connecting additional equipment to the signal input or output module is a system configurer and responsible for ensuring that the valid system norm version EN 60601-1-1 is observed.
In the event of queries, please contact your distributor or the technical service of the manufacturer.
(MDD: 13.6c , IEC 601-1 : 6.8.2.c , 19.2.b , 19.2.2)

The manufacturer is under obligation to take back old units in compliance with the Electronic Equipment Act (ElektroG).

1.2 Explanation of the safety symbols

Important information in the operating manual is marked with symbols.
This information is a prerequisite to to exclude danger to the donor and the operating personnel, as well as to avoid damage or functional disturbances on the unit.

Caution! Important information

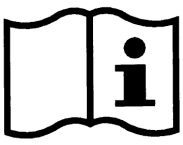
Caution! Risk to user - donor

Information - operating tip

Application component (type B)

Conformance according to MDD 93/42 EEC

Standby button to switch the unit on and off



The operating manual should be observed

Temperature limitation: the unit should be stored and operated within the specified temperature range.

Manufacturer

Identification symbol for electrical and electronic devices

2 Product Description

2.1 Correct use - intended purpose

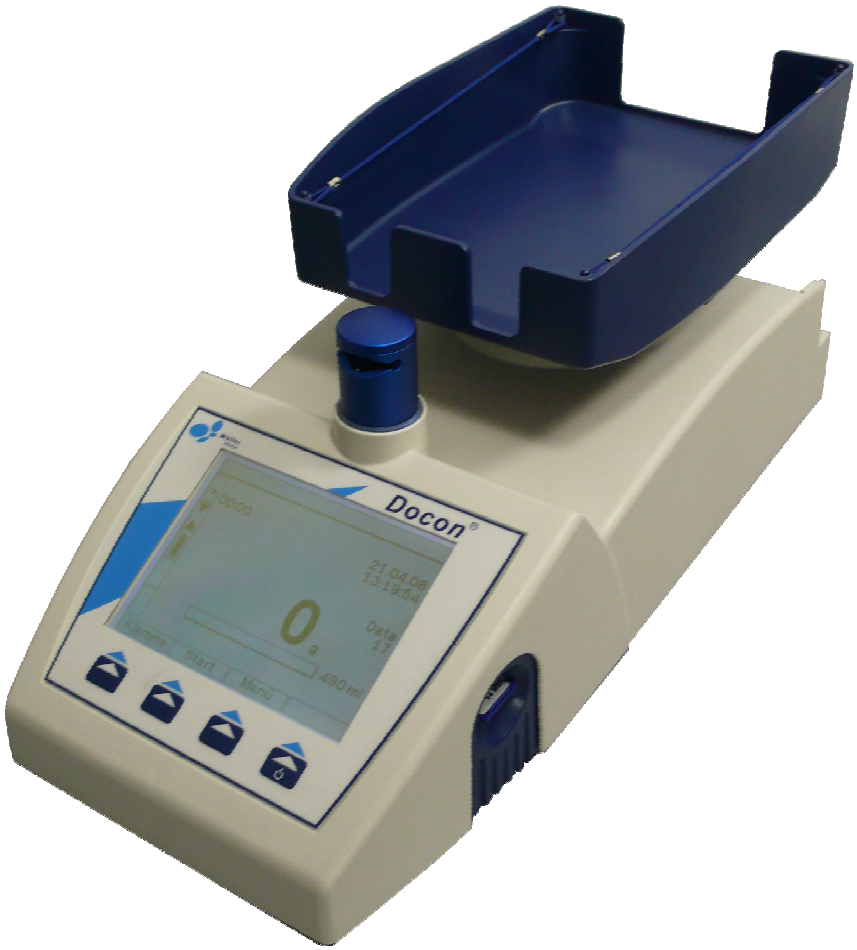
The ***Docon*** is a medical product that is used to mix blood with an anticoagulant in the blood bag during donation and to stop the flow of blood after a preconfigured volume has been collected. In addition, internal data on the collection as well as external data that is entered by the user is accumulated and sent to a data processing system.

Blood bag systems are required to collect the blood. The ***Docon*** should only be operated with blood bag systems that fulfil all statutory requirements for blood bag systems.
Furthermore, the empty weight of the bag systems should not exceed 1000 g.

Blood donations should only be obtained from persons who meet the generally valid criteria for blood donations (see for example the "Guide to the preparation, use and quality assurance of blood components").

2.2 Description of the unit

2.2.1 Design of the basic unit without accessories



2.3 Accessories and options

2.3.1 *Docon mobile*

The ***Docon mobile*** is used to enter barcodes into the ***Docon***.

2.3.2 Sealing option - sealing tongs

Docon Seal is an automatic sealing unit for sealing PVC catheters, particularly the collection tube to be sealed directly at the donor. This increases the safety on sealing the tube. The sealing processes can be documented in the data record.

The integrated sealing generator is linked to the Docon sealing tongs via a plug connection. Different PVC catheters with varying diameters and wall thicknesses can be sealed. The sealing time for the specified catheters is automatically adapted in this respect. The sealing process is indicated by an LED with three colours in the sealing tongs.

- Only the original sealing tongs should be connected to the ***Docon***.
- Do not position any other object than intended between the Docon sealing tongs electrodes. See technical data.

2.3.2.1 Sealing the collection tubes

- The sealing unit detects electromagnetic radiation emitted during sealing. Incorrect use or direct contact of tissue with the sealing tongs electrodes can lead to burning of tissue.

- The surface of the catheter should be dry and free of dirt or contaminants.
- The sealing process stops immediately as soon as pressure is no longer applied to the lever on the sealing tongs!
- No mechanical load should be applied to the catheter during sealing.
- In the case of several sealing operations on a single catheter, a distance of at least 10 mm must be maintained between consecutive sealings.
- The sealing quality of the sealing operation should be checked visually and periodically.

Sealing procedure

1. Insert the catheter in the recess of the sealing tongs. The green LED signals operational readiness.
2. Press the lever on the sealing tongs down to the stop. The LED changes from green to orange. Sealing starts automatically!
3. The LED changes from orange to green and sealing is terminated. The sealing tongs lever is opened and the catheter removed.

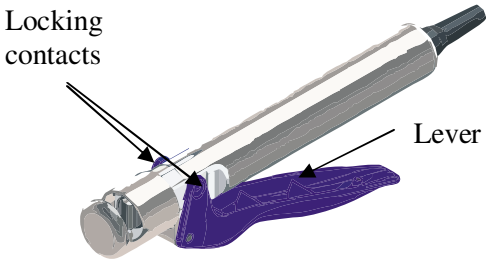
- A slowly flashing red LED indicates overheating of the system. The LED changes automatically to green if the sealing unit has cooled down and is ready again for operation.
- A rapidly flashing red LED always indicates that an error has occurred. Possible error sources may include dirty or damp electrodes (the same applies to the catheter), exceeded sealing time (max. 5s), inadequate Docon battery voltage (the Docon batteries should be changed from a battery charge of 50 %).

2.3.2.2 Cleaning the Docon sealing tongs

- **The Docon sealing tongs should always be disconnected for cleaning.**
- The Docon sealing tongs must be cleaned in the event of contact with blood. The user should wear suitable protective clothing for his or own safety during cleaning. A suitable disinfectant (generally isopropanol 70 %) is used for cleaning, being applied to the contaminated areas of the Docon sealing tongs for disinfection purposes. Sterilisation procedures such as autoclaving or use of ethylene oxide gas render the Docon welding tongs unusable. It should also be ensured that no liquids seep into the electronic component of the sealing tongs. Sharp objects should not be used for cleaning.

- General cleaning of the Docon sealing tongs should be realised once a month.

2.3.2.3 Dismantling of the Docon sealing tongs



Dismantling the sealing tongs

1. Press the lever until both electrodes just make contact with each other
2. Press in both locking contacts until a “click“ is audible (e.g.: use a pen or similar object).
3. push the electrode and lever forwards and remove.

Assembling the sealing tongs

1. Position the electrode with the lever on the sealing tongs, facing in the correct direction.
2. Slide on until a “click“ of both locking contacts is again audible.

- The Docon sealing tongs should be cleaned with a lint-free cloth and mild cleaning agent.
- The electrodes should be completely dry after cleaning.
- **Test sealings should be realised after the sealing tongs have been reassembled.**

2.3.3 Rechargeable batteries

The ***Docon*** is designed for operation with 2 rechargeable batteries. 2 batteries are always required simultaneously, as the internal unit voltage is 24 V.
The ***Docon*** has an integrated charging circuit which is suitable for recharging the batteries within 8-10 hours. Charging is signalled on the display as well as by a yellow LED at the rear of the unit next to the mains connection. This indicator is provided because the ***Docon*** can also be charged via an externally-accessible compartment in the case.

2.3.3.1 Battery charge indicator

The LED at the rear of the unit no longer illuminates if the batteries are flat. Charging is indicated by regular flashing. A fully-charged battery is indicated during mains operation by a short flash of the LED.

2.3.4 Holder for the *Docon mobile*

Different holders are available for the ***Docon mobile*** (table leg, plug-in foot, gooseneck,…).
This enables use of the ***Docon mobile*** corresponding to the respective operating situation.

2.3.5 *Docon poll*

The ***Docon poll*** transforms the serial PC signal into the radio signal which is used in the ***Docon*** radio network. In addition, operation is possible via the ***Docon poll*** of the ***Docon*** in a fixed network using RS485.

2.3.6 Transportation case

The compartment at the rear of the case is used to connect a mains cable to the ***Docon*** from the outside. This is used to charge the integrated batteries without having to remove the ***Docon*** or the batteries from the case.

The upper part of the case is placed on the floor with the handle on top during the blood donation, the lower part of the case with the Docon being then subsequently positioned on the upper part. This achieves an effective height for blood extraction.

2.3.7 Docon Card

Docon Card is a memory card with which data from the ***Docon*** can be transferred to a PC. A multimedia card (MMC) is used for this purpose. The Docon ***Card*** functions if firmware with the corresponding option is installed in the unit.
CAUTION: a memory card (MMC or SD) can only be used in the ***Docon*** if it is formatted with FAT 16!

2.4 Technical Data

Dimensions	(W*H*D) 205 x 215 x 460
Weight	approx. 3.3 kg without sealing option – without rechargeable batteries approx. 4.8 kg with 2 replaceable batteries
Minimum operating life	8 years
Wireless standard	IEEE 802.11b; 802.11g
Security	WEP/WPA2
Channel frequency range	2.412 – 2.484 GHz
PVC tube specification	2.5 – 5.0 mm outer diameter; 0.75 wall thickness
Sealing time	1- 6s
Sealing procedures	200/hour
Consecutive sealings	100

2.4.1 Electrical connection:

Voltage:	100 – 240 VAC
Current consumption:	0.35A - 0.15A
Tolerance range:	-10%, +10%
Frequency:	50 Hz – 60 Hz
Weighing range:	0 .. 999 g, 0 .. 999 ml, tare < 1000 g, accuracy ±5 g, ±5 ml
Data storage:	256 Kbytes for collection data, corresponds to approx. 1000 data records 1024 Kbytes for lists Memory for several languages

2.4.2 Operating conditions:

Temperature:	+10° C to +40° C
Humidity:	30 to 75 % rel. humidity

2.4.3 Transportation and storage conditions:

Temperature:	-10° C to +50° C
Humidity:	less than 90% rel. humidity
Protection class:	IP 20
Rechargeable battery:	lead gel battery 12V - 2.3 Ah with seal cap **Caution:** rechargeable batteries should be disposed of in accordance with regulations. **CAUTION:** the batteries should be removed from the unit if it is not used for a longer period of time!
Lithium battery:	The ***Docon*** is equipped with an internal lithium battery for the system clock. This should be disposed of in accordance with regulations at the end of its service life.

2.4.4 Technical safety checks:

The operator is obliged under regulations governing operators to have safety inspections conducted. These inspections should be conducted every 12 months and documented in the medical product logbook.

2.4.5 Article numbers:

		PC software	
Docon standard:	00 001 673	***Docon load***	00 001 996
Docon seal:	00 001 866	***Docon setup***	00 001 997
Docon WLan	00 003 420	***Docon com***	00 001 998
Docon WLan + seal	00 003 423	***Docon network***	00 001 999
Docon mobile II:	00 002 900		
Docon poll II	00 003 145		
Docon rechargeable battery:	00 001 863		
Transportation case large	00 002 037		
Transportation case small	00 002 689		

2.5 Start-up

2.5.1 Scope of delivery

Please ensure that the carton has been delivered to you in an undamaged condition.
Transportation damage should be reported immediately to the haulier.

The scope of delivery of the standard ***Docon*** package consists of :
1 x ***Docon*** (the unit itself) with weighing bowl for fitting
1 x mains cable
1 x user manual
2 x packaging inserts
1 x packaging carton

The following may be included in the scope of delivery, depending on the option involved:

2.5.1.1 *Docon* RF or WLan

Docon data

2.5.1.2 *Docon* seal

Docon seal, hand-held sealing tongs

2.5.1.3 *Docon* RF + seal

Docon RF + seal, hand-held sealing tongs

2.5.1.4 *Docon* WLan + seal

Docon WLan + seal, hand-held sealing tongs

2.5.1.5 *Docon* card

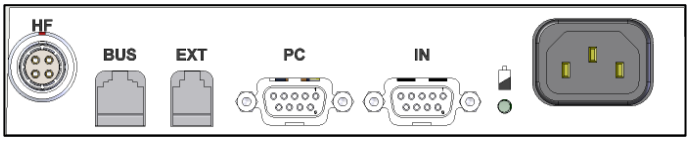
Docon (depending on the options, see above), memory card

We recommend that you retain the packaging
for any service work required and not dispose of it.

2.6 Connections

The ***Docon*** connections are located at the rear of the unit. They have the following function (from left to right).

Labelling	Function
HF	Connection for hand-held sealing tongs in case of ***Docon seal***. (***Docon seal*** only))
BUS	Connection to an RS 485 network.
EXT	External connection option for original accessories. No accessories are currently available for this interface.
PC	RS 232 connection to a PC. This interface is used to configure a single ***Docon*** or to read out data.
IN	RS 232 input interface for connecting the ***Docon mobile***.
	Battery charge indicator.



Ensure at all times that the connectors are fitted securely and use available securing options.

When changing any batteries present, press the batteries lightly into the unit and raise them up at the rear. The batteries can then be removed from the ***Docon*** to the rear. When inserting batteries, push them into the unit with the logo on top. Press them gently downwards and they will click into place in the housing. The housing is sealed with plugs in units without batteries. These plugs should be removed if the unit is operated with rechargeable batteries.

Additional equipment connected to the analog and digital interfaces of the unit should be proved to comply with its corresponding EN specifications ((e.g. EN 60950 for data processing equipment and EN 60601 for electromedical equipment). Anybody connecting additional equipment to the signal input or output module is a system configurer and responsible for ensuring that the valid system norm version EN 60601-1-1 is observed.
In the event of queries, please contact your distributor or the technical service of the manufacturer.
(MDD: 13.6c , IEC 601-1 : 6.8.2.c , 19.2.b , 19.2.2)

2.7 Cleaning

The unit requires no maintenance on the part of the user. The disinfectants listed below should be used for cleaning. It is imperative that moisture and foreign bodies be prevented from penetrating the unit.

Disinfectant	Manufacturer
Terralin protect	Schülke & Mayr GmbH
Meliseptol	B.Braun Melsungen AG

The weighing bowl can be removed for cleaning by lifting it off directly upwards.

It is imperative to ensure that the narrow side with the two slots is fitted to the front when replacing the bowl. The weighing bowl can be fitted with ease if it is positioned correctly. Do not exert any force when fitting!

3 Description of the unit

3.1 Docon

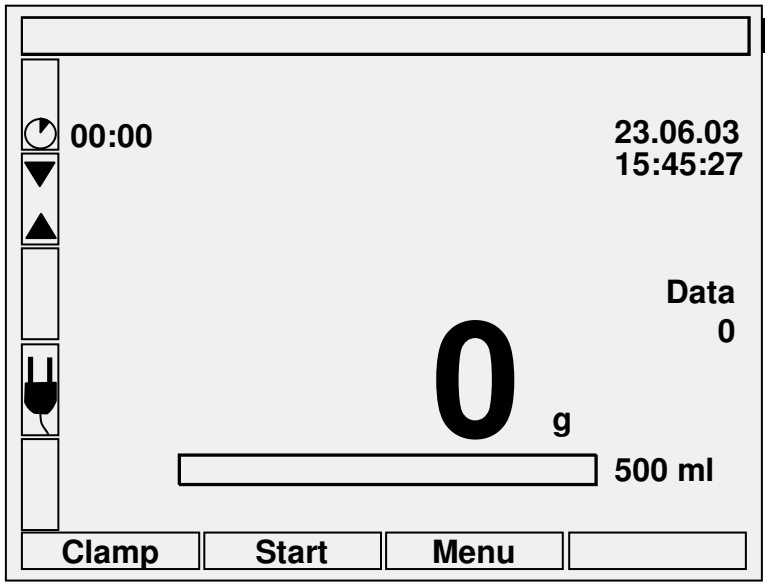
Press the Standby button to activate the ***Docon***. The button should be pressed somewhat longer if the unit is operated with rechargeable batteries. The ***Docon*** then conducts a self-test. The display shows the software version, the unit number and the manufacturer, the weighing bowl rocks once and the clamping device opens and closes once.
The zero point is then determined for the scale and the unit configured to the basic setting.

Control is realised using the 4 buttons under the display. The function of the individual buttons is indicated in the 4 fields on the display.

Individual fields on the margins of the display signal the varying status of the ***Docon***.

Symbol	Function
	Symbol for the duration of the current or last collection
	Clamping device opened, no tube detected
	Clamping device opened, tube detected
	Clamping device closed, tube detected
	Clamping device closed, no tube detected
	Battery, partially discharged, the symbol moves from bottom to top during charging
	Battery fully charged, during discharging and charging
	Mains voltage applied
	***Docon card*** memory card plugged in
	Memory card is being written! It should not be removed at the moment!

The display layout in the basic setting indicates the measured weight on the weighing bowl in grams in its centre.



Ensure when weighing a bag system for inspection purposes that the entire bag system is lying on the weighing bowl, the centre of gravity is in the middle of the bowl and the tubes are not lying anywhere where they could influence the weighing results.

3.2 Docon structure, mobile blood collection

It is necessary to position the ***Docon*** below the donor when collecting a blood donation with the ***Docon***. This is necessary because the blood only flows due to the difference in height between the donor and the ***Docon***. The height difference should be at least 20 cm.

The collected volume is checked relative to its weight. The user should ensure that the ***Docon*** is horizontal and cannot wobble to attain the specified accuracy. The bag system should be placed so that it lies entirely on the bowl and the tubes cannot falsify the results.

The user should check the accuracy of the weighing function with a reference weight the first time the ***Docon*** is set up or on setting up a mobile blood collection. A 500g weight is place in the middle of the weighing bowl for this purpose. The displayed value should lie between 495 g and 505g after the display has stopped changing. The ***Docon*** can no longer be used for blood collection until it has been checked by service personnel if the displayed value does not lie within these limits.

4 Description of use

4.1 Blood collection

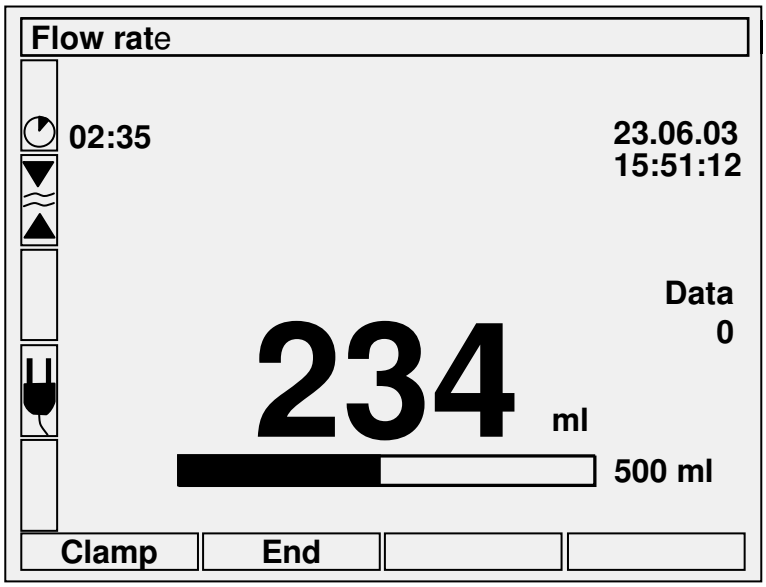
The ***Docon*** standard with the basic settings is suitable for blood collection without data acquisition. This is described below. For further options, please refer to the corresponding chapters.

4.1.1 Preparing a collection

The bag system should be placed on the weighing bowl before a blood collection is started. The collection tube is passed through the clamping device. Ensure that the bag lies entirely on the bowl and that the collection tube between the clamping device and the bowl is not under tension, even when the bowl tips backwards.
Finally, the clamp is closed by pressing the **Clamp** button. The clamping device is automatically closed with the **automatic clamping** option after the tube has been detected. The vein can now be punctured.

4.1.2 Blood collection

After the preparations are complete, collection is started by pressing the **Start** button. The ***Docon*** switches the display from **g** to **ml** and sets the volume and duration to 0. The clamping device is then automatically opened and the weighing bowl rocks to and fro twice. It then remains still for 2.5 seconds. The volume display is updated during this time and the flow checked to ensure it corresponds to the preset limits.

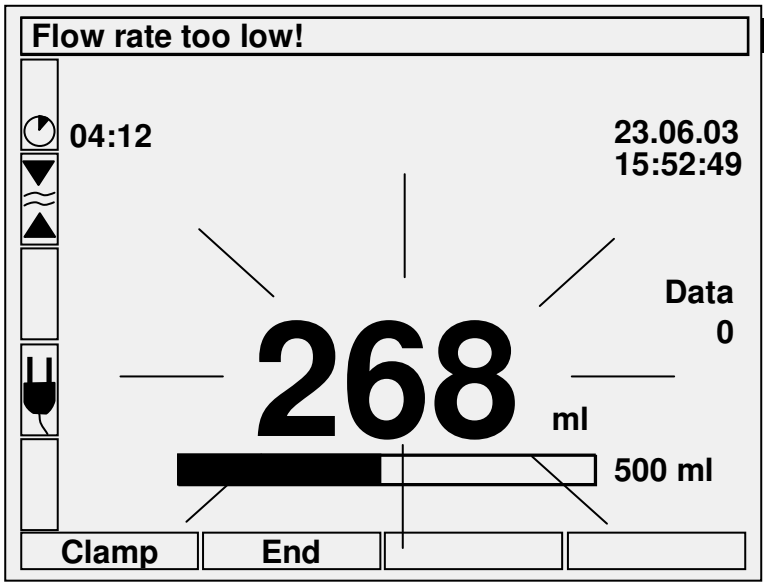


The rhythm between rocking and stationary is continued until the volume is 20 ml less than the preset final volume. The ***Docon*** stops rocking. A short acoustic signal indicates when this stationary limit is reached. The volume can be continuously monitored in the stationary condition to give a high collection accuracy.
When the preset volume is reached, the clamping device automatically closes, the **End** button flashes and an acoustic signal indicates that the final volume has been collected. The loudness of all acoustic signals can be adjusted independently to 4 different levels. The volume indicator on the display flashes so that it can be seen from a distance that this ***Docon*** requires the attention of a user. The ***Docon*** now continues to rock because the blood flow has stopped. The volume display is then updated during each stationary period.

4.1.3 Faults in the flow rate

The ***Docon*** can monitor the flow rate in ml per minute. It is also possible to show the current flow rate on the display. The flow rate is always measured during the stationary period, shortly before the weighing bowl starts to rock again.
The current flow rate is checked to ascertain whether it is too low or too high. The standard limit for a high flow rate is 200ml/min. If the value is larger, the message "**Flow rate too high!**" is displayed, the volume indicator flashes and an acoustic signal is generated.

The standard limit for a flow rate that is too low is 50ml/min. However, a signal is generated only when the flow rate is continuously lower than the limit value for a preset time (standard 45 seconds). It should be taken into account that this check only takes place once per stationary period.



The fault messages stop when the fault has been eliminated or the clamping device has been closed by pressing the **Clamp** button. The delay time for a flow rate that is too low thus begins from zero again.

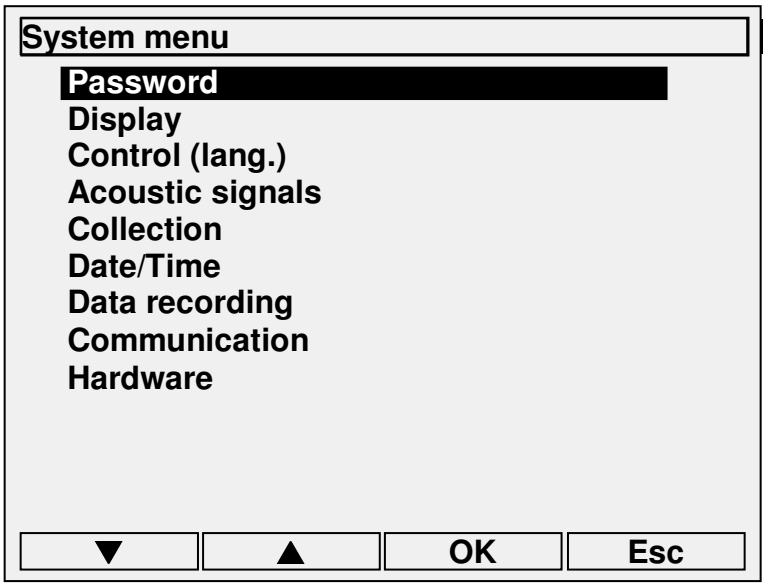
4.1.4 End of the blood collection

The ***Docon*** generates a visual and acoustic signal if the preset volume has been reached. The **End** button should then be pressed. The ***Docon*** then stops rocking. The display reverts to the basic setting again. The volume indicator returns to showing the weight. The display then shows the total weight of the stored blood including the bag system.
The user should then attend to the donor and safely seal the tube. The clamping device is then reopened by pressing the **Clamp** button so that the tube can be removed.

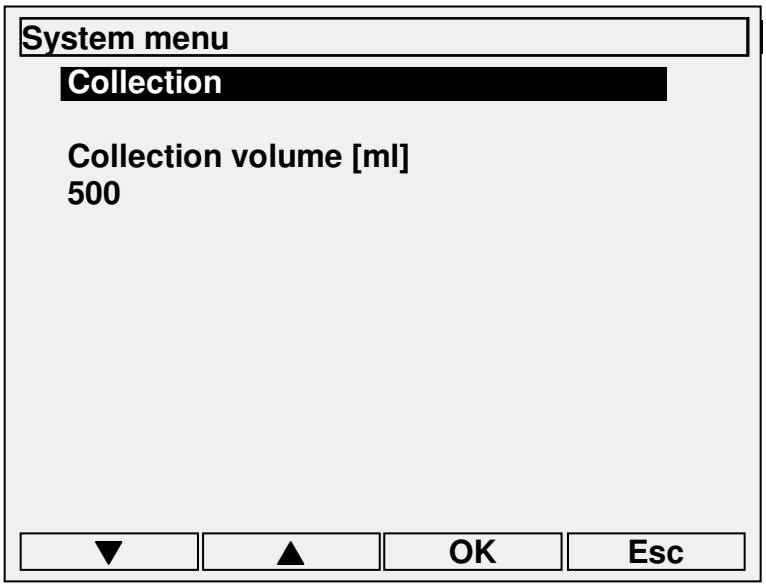
5 Configuration and optional extras

5.1 Configuration options on the unit, system menu

The unit has a system menu that can be called up by pressing the menu button. The menu appears as follows



The selection bar is moved with the ▼ and ▲ buttons. The corresponding submenu is called up by pressing the **OK** button. The submenus consist of several parameters that are displayed in sequence.



The next parameter is reached by pressing the OK button. Use the ▼ and ▲ buttons to change a value. If the changed value is not to be accepted, press the **Esc** button, or wait until the system menu is automatically closed. The time for automatic closing of the menu is adjustable.
To accept the changed value, press the **OK** button. The value briefly flashes as an indication that the value has been accepted. This value can be changed again by pressing the ▼ and ▲ buttons, or press **OK** to jump to the next parameter or press **Esc** to leave the submenu. After all parameters of a submenu have been called up, the display returns to the main menu. The main menu can also be closed by pressing **Esc** or by the timeout.

5.1.1 Display submenu

The settings for the display are configured in the display submenu.

Display contrast

Meaning: The display contrast is configured here. The value directly affects the display as it is changed, allowing the user to find the correct setting more easily. However, the value is only saved if the **OK** button is pressed.

Minimum value: 0
Maximum value: 31
Default value: 18

Display brightness

Meaning: The brightness of the display background lighting is configured here. The value directly affects the display as it is changed, allowing the user to find the correct setting more easily. However, the value is only saved if the **OK** button is pressed. Please note when operating the unit with rechargeable batteries that increased brightness leads to increased energy consumption.

Minimum value: 0
Maximum value: 6
Default value: 3

Timeout illumination [s]

Meaning: The background illumination switches off automatically after a preset time on completion of the last operation to save power. The parameter can be set to **OFF** if this function is not required.

Function off: OFF
Minimum value: 1
Maximum value: 600
Default value: 60

5.1.2 Control submenu

The Control submenu contains functions that relate to the behaviour of the unit with respect to the user.

Language

Meaning: This configures the display language

Values: ENGLISH
Default value: ENGLISH

Automatic clamping device

Meaning: When this option is activated, the clamping device automatically closes when the unit detects that the tube has been inserted while it is in the basic setting. This means that the **clamp** button need not be pressed.

Values: NO, YES
Default value: NO

Tube detection active

Meaning: Collection can only be started when tube detection is active if the clamping device is closed and a tube has been detected. In addition, an acoustic signal is generated if the tube has slipped out of the clamping device during collection. These two checks are dispensed with if this option is not available.

Values: NO, YES
Default value: YES

Automatic start button

Meaning: Data acquisition commences prior to donation directly after the tube is inserted in the clamping device if the parameter is set to Yes. It is not necessary to press the start button. This parameter is not assigned a function if data acquisition does not occur.

Values: NO, YES
Default value: NO

Timeout menu [s]

Meaning: The system menu is closed in seconds after the preset time, regardless of the level or the parameter in which the entry is currently being realised. This discards any parameter that has not yet been imported with **Okay**. If this parameter is set to **OFF**, the system menu can only be closed by pressing the **Esc** button.

Function off: OFF
Minimum value: 10
Maximum value: 300
Default value: 30

Switch off after [min]

Meaning: Similar to timeout in the system menu, this parameter is used to preset the time after which the ***Docon*** should automatically switch off when the last operation is completed.
The bowl no longer rocks back into the starting position if the ***Docon*** switches off automatically.

Function off: OFF
Minimum value: 1
Maximum value: 300
Default value: 10

Display of current flow rate

Meaning: The current measured flow rate in ml/min is shown on the display above the current volume during collection. Please note that the flow rate is only measured once during each stationary period and can therefore not change in the intervening periods.

Values: NO, YES

Default value: NO

Automatic daylight saving time

Meaning: The ***Docon*** switches automatically between summer and winter time when the option is selected. However, the switch in time only ever occurs in the case of activation via battery or when the network link is established.
The function applies to Central Europe (i.e. daylight saving time begins on the last Sunday in March and ends on the last Sunday in October.

Values: NO, YES

Default value: YES

Validation imperative

Meaning: A validation should be realised for every activation which involves testing the Docon weighing function with a 500 g weight. The Docon cannot be utilised if the measured weight does not lie within 495 g and 505 g. The test is then repeated when the unit is reactivated.
The consequence of a positive test result is that the validation test is only repeated again on the next day. Where a second validation is required on the same day, the test can be initiated by pressing and holding down the left-hand button until the input prompt appears. However, the unit is not disabled by this voluntary validation.
CAUTION: The respective input chain should be configured with the setup program to enable use of this function.

Values: NO, YES

Default value: NO

Bag weight min [g]

Meaning: A donation can only commence when at least the min. configured weight is detected on the bowl. The weight should be min. 30 g less than an empty bag to avoid problems with differing empty bag weights.
This function generates an error message if the Docon is activated with a bag in position, as the empty bag is added to the bowl tare in this case.

Values: OFF, 1..500 g

Default value: OFF

Bowl tilted for [g]

Meaning: This function ensures that the bowl is tilted to the rear if an empty bag system is placed on the empty bowl prior to a donation. The maximum tube length for the collection tube from the bowl to the clamping device is available for this purpose. A useful reference value for this configuration is half the empty bag system.

Values: OFF, 30..500 g

Default value: OFF

Sealing always active?

Meaning: The sealing tongs of a Docon can be utilised for sealing at any time if this parameter is set to "yes". This is necessary where, in the case of two adjacent Docons, only one is equipped with a sealing tongs and the intention is to utilise the sealing tongs for both donor bays.
Sealing is only possible at certain points on an input chain if the parameter is set to "no". The sealing processes can also be documented in the data record at these positions.

Values: NO, YES

Default value: NO

Bowl tilted at end?

Meaning: The bowl is tilted forwards after pressing the End button if this option is activated. This facilitates removal of the bag system. This option is particularly advantageous if the Docon is positioned under a table.

Values: NO, YES

Default value: YES

Alarm for barcodes?

Meaning: The flow is not checked if a barcode inquiry occurs during the donation. The Docon operates as usual if the end of the input chain is reached or the volume for termination is exceeded by 10 seconds.
Flow monitoring occurs in the background if barcode alarms are active (yes). The input chain is interrupted and the alarm message output should an alarm condition arise. The interrupted input chain is then reactivated at the end of the donation.

Values: NO, YES

Default value: NO

Menu during donation?

Meaning: It is normally impossible to activate the menu during a donation, thus ensuring that parameters cannot be changed which could lead to inadvertent behaviour by the bowl. However, should menu activation be desirous, the menu button can be activated with this parameter.

Values: NO, YES

Default value: NO

Text on Docon mobile?

Meaning: Display of input prompts on the Docon mobile can be suppressed with this parameter.

Values: NO, YES

Default value: YES

Docon mobile cyclic?

Meaning: Cyclic output of the weight/volume on the Docon mobile can be suppressed with the NO setting.

Values: NO, YES

Default value: YES

5.1.3 Acoustic signals submenu

The ***Docon*** has various acoustic signals to alert the user to particular events or status conditions. Loudness can be altered at 4 levels, while the signal can also be switched off completely with the **OFF** setting.
When a new value is accepted, the signal is played so that the loudness can be checked immediately.

Signal: flow rate too low!

Meaning: An acoustic signal is generated when the flow rate is detected as being too low during collection. The signal can also be switched off. In this case, the signal only appears on the display.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 2

Signal: flow rate too high!

Meaning: An acoustic signal is generated when the flow rate is detected as being too high during collection. The loudness of this signal can be altered at 4 levels. The signal can also be switched off. In this case, the signal only appears on the display.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 2

Signal: end reached

Meaning: This signal is generated when the end of the collection is reached. It is immaterial whether the end is reached with respect to the final volume or the maximum collection time.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 3

Signal: battery warning

Meaning: This signal is generated if the voltage from the rechargeable battery is too low at the end of a collection. This means that the rechargeable battery should be changed.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 2

Signal: barcode error

Meaning: The barcode error signal is generated if a barcode is read in that is not permissible at this point.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 2

Signal: stationary period

Meaning: The ***Docon*** is designed to stop rocking 20 ml before the final volume is reached. A brief confirmation signal also sounds at this point in time, and its loudness can be configured here.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 2

Signal: tube detection

Meaning: This signal is generated if the tube detection option has been activated and a collection is

to be started without an inserted tube or if the tube is no longer detected during a collection.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 2

Signal: key touch

Meaning: Key actuation can also be indicated with brief confirmation signals. Their loudness can be configured here.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 2

Signal after switching on

Meaning: This signal is generated during the switch-on test to enable testing of acoustic signal generation.

Values: OFF, LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4
Default value: LEVEL 2

5.1.4 Collection submenu

The Collection submenu contains functions that relate to the realisation of a collection.

Collection volume [ml]

Meaning: This parameter is used to specify the collection volume in ml. The clamping device is closed and the end is signalled when this volume is reached.

Minimum value: 100
Maximum value: 750
Default value: 500

Duration collection max. [min]

Meaning: A blood donation can also be terminated when a maximum time has been reached. The message **Collection time reached** is then shown on the display. The **Clamp** button should be pressed if the collection is to be completed in spite of this message. Collection is then continued until the preset volume is reached.

Function off: OFF
Minimum value: 1
Maximum value: 20
Default value: 20

Duration until termination [min]

Meaning: A further donation duration can be configured here. However, the donation cannot be continued after this time is reached. The duration until termination selected should, of course, be longer if both final times are used.

Function off: OFF
Minimum value: 1
Maximum value: 30
Default value: OFF

Volume duration 1 [ml]

Meaning: If a volume is configured here, the parameter “Duration collection max. [min]“ only has one function if the volume configured here has already been reached.
This means that rapid donations with a particular minimum volume can be defined.

Function off: OFF
Minimum value: 1
Maximum value: 750
Default value: 20

Stationary period volume [ml]

Meaning: In order to obtain the most accurate final volume possible, the bowl is no longer rocked towards the end of a collection. This parameter is used to configure the number of millilitres before reaching the final volume when the bowl stops rocking.

Minimum value: 0
Maximum value: 750
Default value: 20

Flow rate min. [ml/min]

Meaning: This parameter is used to configure the limit for a flow rate that is too low. If the flow rate is less than this limit value over a certain length of time, which can also be preset, a corresponding message is generated for the user.

Function off: OFF
Minimum value: 1
Maximum value: 100
Default value: 50

Flow rate max. [ml/min]

Meaning: This parameter is used to configure the limit for a flow rate that is too high. If the flow rate is greater than this limit value, a message is generated for the user.

Function off: OFF
Minimum value: 1
Maximum value: 1000
Default value: 200

Neg. flow alarm [ml/min]

Meaning: A "Negative flow" alarm is generated as soon as the current flow drops below the configured limit value. This should then be confirmed by the user to deactivate the signal again.

Function off: OFF
Minimum value: -2
Maximum value: -100
Default value: -5

Duration of low flow rate [s]

Meaning: This is used to configure the delay after which the message **Flow rate too low** is generated. The flow rate should be lower than the limit value (**flow rate min. [ml/min]**) for this entire preset period. The time is reset again as soon as it is higher and the duration should be reached again.
Please note that the flow rate is only measured once during each stationary period, and only then can the corresponding messages change.

Minimum value: 10
Maximum value: 200
Default value: 45

Collection rocking frequency

Meaning: The scale normally rocks twice duration donation and then remains stationary for 2.5 seconds for measurement. It should be noted that, in the event of the number of rocking motions changing, the entire time relationship also alters, particularly the stationary period volume prior to reaching the final volume.

Minimum value: 2
Maximum value: 10
Default value: 2

Bowl tilted during collection

Meaning: The bowl is designed to remain stationary tilted at the rear during blood donation. It remains stationary in the horizontal when "NO" is selected. The bowl then tilts slowly to the rear of its own accord if the bag is full. However, this only has a minor influence on measurement accuracy.

Values: NO, YES
Default value: YES

Volume indication at end?

Meaning: The unit does not switch automatically to the weight display at the end of the blood donation when this option is selected. The volume remains on the display until the bag system is removed from the bowl.

Values: NO, YES
Default value: YES

Rocking during BC collection?

Meaning: It is possible to select whether the scale rocks or not in the case of a barcode inquiry.

Values: NO, YES
Default value: YES

Clamping interval

Meaning: The clamping device is closed when the collection is completed. This stops the blood flow through the tube. The tube clamp can be automatically reopened in intervals to prevent blood from coagulating in the tube before the user can complete the collection and remove the tube. This allows blood to flow in the tube and into the bag.
The times for opening and closing of the clamping device can be preset.
Please note that the interval clamping function means that the final volume configured is no longer correct.

Values: NO, YES
Default value: NO

Interval volume [ml]

Meaning: As explained under the interval clamping parameter, this function means that the preset final volume is exceeded. This parameter is used to configure the volume of additional millilitres which may flow into the bag before the clamping device remains closed.

Minimum value: 0
Maximum value: 100
Default value: 10

Interval shut [s]

Meaning: This parameter indicates the time that the clamping device remains closed during interval clamping. This value is configured in seconds.

Minimum value: 10
Maximum value: 120
Default value: 45

Interval open [s]

Meaning: This parameter indicates the time that the clamping device remains open during interval

clamping. This value is configured in seconds.

Minimum value: 1
Maximum value: 10
Default value: 3

Spec. weight of blood [g/ml]

Meaning: The specific weight of the blood can be adapted within certain limits.

Minimum value: 1.000
Maximum value: 1.100
Default value: 1.053

5.1.5 Date / Time submenu

The ***Docon*** system clock can be configured in this submenu. The correct time is important for data logging.

Year

Meaning: Setting for the current year

Minimum value: 2001
Maximum value: 2099
Default value: 2003

Month

Meaning: Setting for the current month

Minimum value: 1
Maximum value: 12
Default value: 1

Day

Meaning: Setting for the current day

Minimum value: 1
Maximum value: 31, depending on the month configured
Default value: 1

Hour

Meaning: Setting for the current hour

Minimum value: 0
Maximum value: 23
Default value: 0

Minute

Meaning: Setting for the current minute

Minimum value: 0
Maximum value: 59
Default value: 0

Second

Meaning: Setting for the current second

Minimum value: 0
Maximum value: 59
Default value: 0

5.1.6 Data recording submenu

Data acquisition is activated in the Data format menu. This setting is only effective if the ***Docon*** is equipped with the "**data**" software option.

Rescue data MMC?

Meaning: Inputting "YES" copies the entire ring memory to the memory card. The parameter then switches automatically to "NO" again when this is completed.

Values: NO, YES
Default value: NO

Data recording

Meaning: This option is used to switch data acquisition on and off during collection. The configuration for data acquisition itself cannot be realised on the unit, but only with the setup program.

Values: NO, YES
Default value: NO

Volume barcode start

Meaning: The input sequence is activated during collection when the configured volume is reached if this function is active.

Function off: OFF
Minimum value: 0
Maximum value: 400
Default value: 20

Volume barcode stop

Meaning: The input chain is terminated during collection when the configured volume is reached if this function is active. A complete polling of the chain is then realised in this case after collection is completed. Termination only occurs if the volume is exceeded for 10 seconds. This enables the application of labels to the bags during polling (to give an example), and this can lead to a brief increase in weight.

Function off: OFF
Minimum value: 0
Maximum value: 400
Default value: 200

Insert chain before tube?

Meaning: A control chain is activated with this option by pressing the Start button prior to inserting the tube. This means that barcodes can be recorded prior to inserting the tube or user instructions output.

Values: NO, YES
Default value: NO

5.1.7 Communication submenu

The ***Docon*** has a variety of communication options for data transfer to the PC and data acquisition via input devices such as the ***Docon mobile***.
The ***Docon*** distinguishes between two interfaces. The interface to the PC is used to transfer data to a PC. Wireless communication also takes place via this interface. The other interface is used for inputs, for example barcodes.
Both interfaces have several more communication options (e.g. RS 232, RS 485, wireless, ...). The baud rate can be configured separately for each of these communication channels.

Com. channel PC

Meaning: The input channel for communication to the PC is configured here.

Values: RS 232, RS 485, WIRELESS, WLan
Default value: RS 232

Baud rate PC RS 232

Meaning: The baud rate (bits per second) for data transfer via the RS 232 interface to the PC is configured here. The RS 232 connection is a single connection, therefore only one ***Docon*** can be connected to the PC at any one time.

Values: 2,400, 4,800, 9,600, 19,200, 38,400, 57,600
Default value: 38.400

Baud rate PC RS 485

Meaning: The baud rate for data transfer via the RS 485 interface to the PC is configured here. The RS 485 can be used for a stationary network. A PC can therefore be connected to several ***Docon*** units.

Values: 2,400, 4,800, 9,600, 19,200, 38,400, 57,600
Default value: 38.400

Baud rate PC wireless/WLan

Meaning: The baud rate for data transfer via the wireless interface to the PC is configured here. A wireless network can also be built up in which several ***Docon*** units are "connected" to one PC.
Please note that the ***Docon*** only has one interface for wireless or WLan transmission. The baud rate configurations for WLan should be set to 57600.

Values: 2,400, 4,800, 9,600, 19,200, 38,400, 57,600
Default value: 38.400

Protocol PC

Meaning: The protocol for the PC is configured here. This parameter should be set to polling for

software version 01.01.

Values: POLLING
Default value: POLLING

Com. channel input

Meaning: The input channel for communication with an input device, e.g. ***Docon mobile***, is configured here.
It is also possible to select the connector to the PC as an input interface. This is realised via the setting **232 PC**.

Values: RS 232, 232 PC
Default value: RS 232

Baud rate input RS 232

Meaning: The baud rate (bits per second) for data transfer via the RS 232 interface to the input device is configured here.

Values: 2,400, 4,800, 9,600, 19,200, 38,400, 57,600
Default value: 9.600

Baud rate input 232 PC

Meaning: The baud rate (bits per second) for data transfer via the RS 232 interface to the input device is configured here.

Values: 2,400, 4,800, 9,600, 19,200, 38,400, 57,600
Default value: 9.600

Protocol input

Meaning: The protocol for the input device should be at MOBILE 02 for the ***Docon mobile*** with the black/white display and MOBILE 01 for the ***Docon mobile*** with the colour display.

Values: MOBILE 01, MOBILE 02
Default value: MOBILE 01

Transportation protomobile

Meaning: This parameter relates to the protocol between ***Docon*** and ***Docon mobile***. This parameter should be set to YES to utilise the RFID options.

Values: NO, YES
Default value: NO

Scanner PC interf.?

Meaning: The parameter should be set to YES if a standard barcode scanner is to be connected to the PC interface. CAUTION: an internal hardware modification is necessary for this purpose.

Values: NO, YES
Default value: NO

System menu to MMC?

Meaning: The system menu settings are written to a configuration file on the memory card if YES is selected here. This can then be transmitted again to any ***Docon*** during startup. Existing files are written over.
ATTACH functions in the same manner, but the information is attached to an existing file. This can be utilised if the data acquisition configuration has already been saved to the card with DoconSetup. The system menu settings can then be supplemented in this manner.
The parameter is automatically set to NO again after this action.

Values: NO, YES, ATTACH

Default value: NO

5.1.8 Password submenu

There are 3 password levels for system menu editing.
Various menu items are either enabled or disabled, depending on the password entered. Passwords for these levels can be specified here.

Enter password

Meaning: A password can be input here to enable further menu levels. The password input remains valid until the menu is exited again or another password is entered.
CAUTION: the display is reset to 0 again each time a password is entered. This does not indicate whether the password was correct or incorrect.

Minimum value: 0

Maximum value: 29999

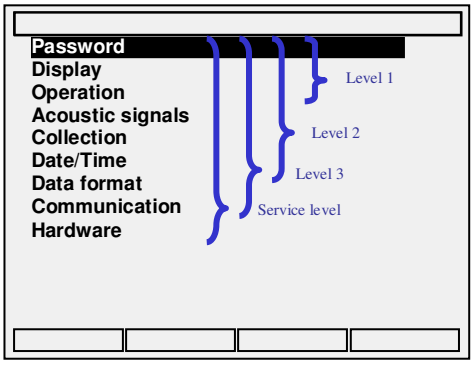
Default value: 101, 202 or 303, depending on the level

System Menu code inquiry

Meaning: Menu enabling levels are determined here.
Value 1 indicates that level 1 is available when the system menu is activated (i.e. the password, display and control entries). A valid password for a higher level should be input for Password to blend in further levels. However, this enabling is only maintained as long as one stays in the system menu.
Only the Password submenu is available for value 0.

Values: 0..4

Default value: 3



Code level 1

Meaning: Authorisation code with the lowest priority. The user can only edit the Operation and

Display submenus with this authorisation.

Minimum value: 0
Maximum value: 29999
Default value: 101

Code level 2

Meaning: Authorisation code with medium priority. The user can only edit the Acoustic signals, Collection and Date / Time submenus with this authorisation.

Minimum value: 0
Maximum value: 29999
Default value: 202

Code level 3

Meaning: Authorisation code with the highest priority. The Communication and Data Format submenus can also be edited with this authorisation.

Minimum value: 0
Maximum value: 29999
Default value: 303

5.2 Configuration with the setup program

The setup program is used to configure data acquisition to an extremely comprehensive degree. The user can configure both the structure of the data records as well as polling and comparisons of individual fields on the unit.

5.2.1 Basic structure of the setup program

A data record description should be generated as an initial step in the setup program. This specifies which fields should be transmitted in which sequence to the PC. The size of the individual fields is also specified. This data record description only refers to the data processing evaluation and has no influence on whether an individual field is filled by the ***Docon*** or contains a barcode.

The control structure then specifies how the fields in the data record description are to be filled. The fields can be filled with internal information from the unit (e.g. the date and time or the preset final volume). Information can also be entered via the ***Docon mobile*** scanner. It is also possible to configure whether a comparison of the input (barcode) should be conducted before it is accepted in this structure.
The assignment of the buttons (soft keys) during a barcode inquiry can also be freely specified by the user in this area.
Since the setup program allows the user (administrator) to avail of many options, this person is responsible for ensuring that the system configured by him/her functions according to plan and that it also guarantees safe blood collection.
A test protocol should therefore be generated after changing the set-up configuration that confirms that the changes lead to the desired result.

5.3 Acquisition of collection data

Acquisition of collection data involves the documentation of a donation collection and the exclusion of, for example, mistaken identities prior to collection.

The ***Docon*** setup program provides a powerful tool for data acquisition configuration to ensure it conforms to the requirements of the individual blood bank.
The sequence of a collection with data acquisition differs from one without data acquisition in that barcodes are usually read in before and after blood collection. The user specifies the individual barcodes and the conditions that should be fulfilled for their acceptance in the setup program.

5.3.1 Storage of collection data

Each collection is documented by one data record in the unit if the ***Docon*** operates with data acquisition. The structure of the data records is also specified by the user in the setup program. Only those fields which are necessary are saved.
The data is saved in an internal ring memory when collection is completed. The ring memory has a capacity of approx. 250 Kbytes. It can therefore accommodate approx. 1000 data records. The exact number depends on the configuration realised by the user.

5.3.2 Data transfer

The data can be read out again from a PC via an interface. Possible interface options include RS 232, RS 485, wireless and WLan (see also System menu).
A further option also enables reading out of data via the ***Docon card*** memory card. The symbol for the card is shown on the right-hand side of the display if the memory card has been inserted. The "**Card**" function is displayed for the right-hand button if collection data is also contained in the ring memory (collection counter greater than zero). The menu for the card is displayed if this button is pressed.

If the OK button is pressed for the "**Write data to card ?**" message, current collection data can be transferred to the memory card. An exclamation mark "!" is displayed during writing in the card symbol which indicates that the card should not be removed during the writing process. The collection counter simultaneously counts down.

CAUTION: The standby button does not react if a card is inserted and the memory contains data records. The data should either be transferred first, or the card should be removed.

5.3.3 Rescuing data

The data is written into an internal ring memory. This means that data that has been read is not deleted, but only overwritten after the ring memory has been filled once. Approx. 1000 data records can thus be restored in the event of data being lost (e.g. through loss of a memory card).
This function can be selected in the Data format submenu of the System menu. A memory card should be plugged into the ***Docon*** for this purpose and "Yes" selected for the "Rescue data MMC?" parameter. The entire ring memory is written to the card in this case. Several seconds are required for this purpose, due to the large quantity of data involved.
The ***Docon*** only attempts to read data records out of the ring memory. The percentage indicator is not updated while the start of a data record is being searched for. This can occur in new units that have not yet stored a sufficient number of data records.

5.3.4 Data processing

The PC program ***Docon com*** is used to make data available to the computer processing department of the blood bank. The program takes over communication with the devices in the case of connection via an interface. The data is then stored in ASCII format under clearly-defined file names.
The memory cards are also read out with the ***Docon com*** program. Although the memory cards can be read by standard programs running under Windows, the conversion to ASCII format and determination of file names is realised in the PC software.

Individual data records within the files are separated by line breaks, with individual fields being separated by tabs. This means that files can be exported directly (e.g. into Excel).

5.3.5 Structure of the file names

File start with a configurable identifier in order to generate clearly-defined files names. This can be used, for example, for different teams if they read out their units themselves. The use of date and time ensures that no name appears twice.

5.3.5.1 Example:

Identifier	Year	Month	Day	Hour	Minute	Second	Identifier
Team1	2004	01	12	13	47	22	.txt

5.4 Docon mobile

The ***Docon mobile*** is the input module for the ***Docon*** with data acquisition. It is not only used to read in barcodes in this context, but can also be utilised to simultaneously operate the ***Docon*** . Since the ***Docon mobile*** is a hand-held module, it is unnecessary to bend over each time to operate the ***Docon***.
The ***Docon*** message signals are also signalled on the ***Docon mobile*** .

The ***Docon mobile*** display is structured in the same manner as the ***Docon*** display. Control is also realised here via soft keys (i.e. keys whose function is shown on the display).

The **Scan** button should be pressed to activate the integrated barcode scanner. The scanner is then activated, this being indicated by the red light. The scanner should be held so that the red light can be seen on the desired barcode. The barcode scanner reads at a distance of approx. 10cm and 20cm between the housing and the barcode.
The barcode entered is immediately displayed on the ***Docon mobile*** and, after a short delay, on the ***Docon***.

The ***Docon mobile*** is an independent module that communicates with the ***Docon***. The **Menu** button on the ***Docon mobile*** is therefore used to call up the ***Docon mobile*** system menu, whereas the **Menu** button on the ***Docon*** calls up the ***Docon*** system menu.
The standby ⏻ button on the ***Docon mobile*** cannot be used to activate the ***Docon***.

5.5 *Docon* RF

Docon RF is a ***Docon*** equipped with wireless data transfer.

5.6 Docon WLan

Docon WLan is a donation controller designed for WLan transmission of the data recorded. This enables the creation of a network of several blood mixing scales to transmit data to the PC or record the status of the donation in online mode.

The Docon is already preconfigured for a WLan network.

SSID	Docon_Wlan
Encryption type	WPA2-PSK/TKIP
Password	moedoconv1019
Network type	Infrastructure (DHCP – client)
	TCP/IP is automatically sourced from the ACCESS point

- An access point is required to realise WLan on a PC! A preconfigured access point can be purchased from the responsible distributor.
- A longer blood mixing scale battery life is achieved by deactivating WLan in battery mode. The connection is deactivated by selecting "OFF", RS 232 or RS 485 in the communication channel menu.
- Standard WLan network settings can be edited. Please contact the responsible service centre in this respect.

5.7 *Docon* poll

The ***Docon poll*** ensures the physical realisation of RS 232 to wireless or RS 485.

6 Transportation

The ***Docon*** should only be transported in accordance with the transportation conditions specified in the technical data. A transportation case is available as an accessory for mobile deployment and daily transportation. This case protects the ***Docon*** against external damage (see also Transportation case).
Should the ***Docon*** be returned for service, it should be sent in the original packaging, as this best protects the ***Docon*** against damage caused by external influences.

Please note that the ***Docon*** is an electromechanical device. It should not be thrown. Condensation can form after transportation in the cold and setting up in a warm room, and the ***Docon*** can only be activated after this condensation has evaporated.

7 Help in the event of malfunctions

In the event of faults, please check whether all connections are firmly connected to the ***Docon***. If operating with rechargeable batteries, please check that they are adequately charged.
Please check the settings in the system menu if individual functions are not realised as expected.

Please check the settings in the setup program in the event of problems relating to data acquisition.

The ***Docon*** should not be opened by the user. Service work should only be realised by service centres whose personnel have been trained on the ***Docon*** by the manufacturer.

Please contact your distributor or an authorised service centre should more complicated malfunctions occur.

Units should be cleaned and disinfected before being sent for servicing.

8 Service centre

The ***Docon*** is a medical product. Servicing should therefore only be realised by personnel who have been trained by the manufacturer with regard to the technology and safety functions of the ***Docon***.

Manufacturer:

Möller Medical GmbH

Wasserkuppenstr. 29-31
D-36043 Fulda

Tel.: +49 (0) 661 / 9 41 95-0
Fax: +49 (0) 661 / 9 41 95-90

http://www.moeller-medical.com
e-mail: info@moeller-medical.com

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Robert-Bosch-Strasse 11
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Service: +49 (0) 162 / 2326182

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9 Appendix

Electromagnetic emissions

The ***Docon*** is suitable for operation in the specified electromagnetic environment. The customer and/or operator of the ***Docon*** should ensure that he or she uses the ***Docon*** in an electromagnetic environment fitting the description below.

Measurement of emitted interference	**Conformance**	**Guidelines for electromagnetic environment**
High-frequency interference emission conforming to CISPR 11	Group 2	The Docon should transmit electromagnetic energy to fulfil its intended function. Electronic devices located in the near vicinity may be influenced.
High-frequency interference emission conforming to CISPR 11	Class B	The Docon is suitable for operation in residential environments directly connected to a low voltage supply network which (also) supplies the residential building.
Harmonic emittance acc. to IEC 61000-3-2	Not applicable	
Voltage fluctuation/flicker emittance acc. to IEC 61000-3-3	Not applicable	

Electromagnetic immunity

Resistance test	**IEC 60601 - testing level**	**Compliance level**	**Electromagnetic environment / Guidelines**
Discharging of static electricity (ESD) IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should consist of wood or concrete or should be fitted with ceramic tiles. If the floor is fitted with a synthetic material, relative humidity must be at least 30 %.
Rapid transient electrical interference variable/Bursts IEC 61000-4-4	±2 kV for power lines ±1 kV for input and output lines	±2 kV for power lines ±1 kV for input and output lines	The quality of supply voltage should conform to that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±1 kV normal mode voltage ±2 kV common mode voltage	±1 kV normal mode voltage ±2 kV common mode voltage	The quality of supply voltage should conform to that of a typical commercial or hospital environment.
Voltage dips, brief interruptions and fluctuations of supply voltage IEC 61000-4-11	< 5 % U_T (> 95 % dip of U_T) for 1/2 period 40 % U_T (60 % dip of U_T) for 5 periods 70 % U_T (30 % dip of U_T) for 25 periods < 5 % U_T (> 95 % dip of U_T) for 5 seconds	< 5 % U_T (> 95 % dip of U_T) for 1/2 period 40 % U_T (60 % dip of U_T) for 5 periods 70 % U_T (30 % dip of U_T) for 25 periods < 5 % U_T (> 95 % dip of U_T) for 5 seconds	The quality of supply voltage should conform to that of a typical commercial or hospital environment. We recommend an uninterrupted power supply or battery for operators of the product demanding continuous function even during an interrupted power supply.
Magnetic field of the supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the supply frequency should conform to the typical values found in commercial or hospital environments.
Comment: U_T is the AC supply voltage prior to application of the testing level.			

Electromagnetic immunity for devices that are not life-sustaining

Resistance test/Standard	IEC 60601-testing level	Compliance level	Electromagnetic environment / Guidelines
Derived HF disturbance variable acc. to IEC 61000-4-6 Radiated HF-resistance acc. to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 3 V/m	Portable and mobile radio equipment should not be used at a distance to the ***Docon***, including cables, less than the recommended safety distance calculated with the equation relevant to the transmission frequency. **Recommended safety distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the nominal transmitter power in Watt (W) acc. to transmitter manufacturer stipulations and d is the recommended safety distance in meters (m). According to an on-site[a)] examination, the field intensity of stationary radio transmitters should be lower than the correlation level[b)]. Disturbances may occur in the environment of devices carrying the following symbol. 

Notes:
COMMENT 1: The higher frequency range applies at 80 MHz and 800 MHz.

COMMENT 2: These guidelines may not be applicable in all cases. The spreading of electromagnetic variables is influenced by the absorption and reflection of the building, objects and people.

[a)] The field intensity of stationary emitters such as base stations of radio telephones and mobile terrestrial radio systems, amateur radio stations and AM and FM radio and television transmitters cannot, theoretically, be accurately determined in advance. To determine the electromagnetic environment in terms of the stationary emitter, a study of the site should be considered. In the event of the measured field intensity at the location in which the Docon is used exceeding the above conformance level, the Docon should be monitored to verify correct function. Additional measures may be necessary if unusual performance characteristics are observed (e.g. altered alignment or another ***Docon*** location).

[b)] The field intensity across the frequency range from 150 kHz to 80 MHz should be lower than 3 V/m.

Recommended safety distances

Recommended safety distance between portable and mobile HF telecommunication equipment and the *Docon*			
The Docon is designed for operation in an electromagnetic environment in which high-frequency interference variables are monitored. The customer or user of the ***Docon*** can thus help to avoid electromagnetic malfunctions by maintaining the minimum distance between portable and mobile HF telecommunication equipment (emitters) and the ***Docon***, relative to the output of the communication device as specified below.			
Capacity transmitter performance (W)	**Safety distance relative to transmission frequency (m)**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23