FRESENIUS KABI

CompoGuard *Advance*

Operating Instructions

Software Version: 01.00.xxx
Edition: 2/09.24
Part number: M715991

CE 0123

Manufacturer information

Manufacturer

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg
Germany

Phone: +49 (0) 6172 / 608-0

Central customer service

Fresenius HemoCare GmbH
Technical Service
Grüner Weg 10
61169 Friedberg
Germany

Phone: +49 (0) 6172 / 686-8469
Fax: +49 (0) 6172 / 686-8539

Local service

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Glossary

ABS	**A**crylonitrile **B**utadiene **S**tyrene
BIS	**B**lood **I**nformation **S**ystem
BSB	**B**lut**s**pende**b**ank (blood bank)
CGA	**C**ompo**G**uard ***A**dvance*
DB	**D**ata**B**ase
DMA	**D**onation**M**aster ***A**dvance*
E-Code	Hardware version code
HF	**H**igh **F**requency
IB	**I**nterface **b**oard
LED	**L**ight **E**mission **D**iode
MC	**M**otor **C**ontroller
MDR	**M**edical **D**evice **R**egulation
OS	**O**perating **S**ystem
PVC	**P**oly**V**inyl **C**hloride
REACH	**R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals
RoHS	**R**estriction **o**f **H**azardous **S**ubstances
S-Code	Software version code
Shore-A	Unit of hardness, predominantly for elastomers and elastic polymers
UDI	**U**nique **D**evice **I**dentifier
WPA2	**W**i-Fi **P**rotected **A**ccess 2 (security standard for wireless network)

1 Important information

1.1 How to Use the Operating Instructions

NOTE

The Operating Instructions:

- must be carefully studied before attempting to operate the device
- are part of the accompanying documents and are an integral part of the device
- must be kept in the immediate vicinity of the device and accessible to personnel at all times
- enable a safe and efficient operation of the device

It is imperative that all safety instructions are followed.

1.2 Symbols used in this document

1.2.1 Warning notices and safety instructions

WARNING

Warns about the risk of a hazard that has a medium probability of causing serious or fatal injuries.

- Proceed as follows to avoid risks.

CAUTION

Warns about the risk of a hazard that has a low probability of causing minor or moderate injuries.

- Proceed as follows to avoid risks.

1.2.2 Notes

NOTE

Warns about the risk of damage.

- Proceed as follows to avoid risks.

INFO

Includes information on how to use the device.

1.2.3 Procedure instructions

Procedure instructions comprising multiple parts are numbered.

1. Open the transport case using the side buckles and remove the lid.
2. Take the device out of the case.

➤ A dialogue box opens.

Single procedure instructions are bulleted.

- Clean the surfaces of the CompoGuard *Advance* with a soft, moist cloth and a neutral cleaning agent.

➤ The surfaces have been cleaned.

1.2.4 Keys/buttons and menu items

Keys, buttons and messages on the user interface are emphasized using formatting.

- Press the button **Start**.

The following information appears on the user interface in graphical form:

– Processing status
– Procedure instructions
– Error messages
– Test programs for service

1.2.5 Warning symbols

Shape: triangular
Background colour: yellow
Pictogram colour: black

1.2.6 Caution symbols

Shape: round
Background colour: white, red edge with red diagonal
Pictogram colour: black

1.2.7 Mandatory symbols

Shape: round
Background colour: blue
Pictogram colour: white

1.3 Intended Purpose

The CompoGuard *Advance* is intended for the donation of human blood and the mixing of the blood with the anticoagulant in blood bag systems.

1.4 Intended User

The system may only be operated under the supervision of personnel qualified and trained in the process of whole blood collection.

It must not be used by lay persons.

Minimum training requirements for operators are reading and understanding the instructions for use of the device and the user manual of the Donation Master software.

Further training of operators is based on the requirements of the appropriate state, federal, or national health regulating agencies, as well as institutional standard operating procedures (SOPs) for the individual blood collection center.

1.5 Intended Patient Population

The CompoGuard *Advance* is intended to be used with donors rather than patients. Donors should be selected based on the requirements of the appropriate state, federal, or national health regulating agencies, as well as institutional standard operating procedures (SOPs) for the individual blood collection center.

1.6 Indication

The CompoGuard *Advance* is indicated for the blood donation process with donors selected based on the requirements of the responsible local, federal or national health authorities as well as the standard operating procedures (SOPs) of the related blood donor center.

1.7 Clinical benefit

The CompoGuard *Advance* provides:

- regular mixing of the blood bag
- controlled termination of the blood donation
- weight monitoring of the blood bag

1.8 Contraindication

With the use of blood donation there is no known contraindication for the CompoGuard *Advance*.

1.9 Reporting of undesirable incidents

Any serious incident related to the device should be reported to the manufacturer and the responsible authorities in the EU member state where the user is based. The report should include, as a minimum, the device identifier, the part number, the serial number, the UDI code, the date the incident occurred and a description of the incident.

1.10 Classification according to Regulation (EU) 2017/745 on medical devices

The CompoGuard *Advance* is manufactured according to the state of the art and complies with EN 60601-1 (IEC 60601-1).

The device belongs to class IIa (according to regulation (EU) 2017/745 (MDR) as per rule 12).

1.11 Liability limitation

The manufacturer shall assume no liability in the following cases: non-compliant use of the device, non-compliance with the notes in the Operating Instructions, or opening of the device.

1.12 Copyright protection

1.13 Warranty

The purchaser’s warranty rights are governed by the applicable legal regulations. Non-compliant use voids all liability and warranty.

1.14 Guarantee

For guarantee refer to the respective sales contracts. Proper function of the system is guaranteed for the period specified in the sales contract.

Any use of the system which is not in accordance with its intended use will void any liability and warranty.

2 Safety

2.1 Personnel qualifications

The CompoGuard *Advance* may only be operated and used by persons possessing the appropriate knowledge and experience and training and/or instruction required.

2.2 Duties of the responsible organization

The responsible organization assumes the following responsibilities:

- Compliance with national or local installation, operation, use and maintenance regulations.
- Compliance with accident prevention regulations.
- Correct, safe condition of the CompoGuard *Advance* and operation as per the Operating Instructions.
- Permanent availability of the Operating Instructions.

2.3 Operator's responsibility

The parameters entered must be verified by the operator, i.e. the operator must check that the values entered are correct. If the verification reveals a deviation between the desired parameters and the parameters displayed, the setting must be corrected before activating the function.

The actual values displayed must be compared with the desired values specified!

2.4 Cybersecurity and security information

The security of your CompoGuard *Advance* is of the utmost importance. This chapter gives you an overview of the most important aspects of cybersecurity, as well as general safety guidelines for the use of this medical device.

2.4.1 Cybersecurity measures

The CompoGuard *Advance* uses cybersecurity measures to protect the integrity, availability and confidentiality of personal health data. However, it is important to follow some basic security practices:

Software updates

Make sure that the CompoGuard *Advance* is always supplied with the latest software updates. These updates can close security gaps and improve the performance of the device.

Firewall settings

If the CompoGuard *Advance* is connected to a network, check the firewall settings to block unauthorized access.

Encrypted connections

Only use encrypted connections to ensure that data is protected during transmission.

2.4.2 Behaviour in the event of faulty operation

The CompoGuard *Advance* should always be used under the supervision of a qualified user. Particularly in environments where sensitive medical information is processed, appropriate supervision by trained personnel is essential to minimize potential risks.

If any signs of a possible cyber-attack or faulty operation are noticed, follow the steps below:

Disconnection from the network

Disconnect the CompoGuard *Advance* from the network immediately to prevent the spread of attacks.

Notification of the manufacturer

Inform the manufacturer immediately of any deviations in operating behaviour or suspicious incidents.

Stop switch

Use the Stop switch, if available, to switch off the CompoGuard *Advance* immediately and minimize potential risks.

Your personal commitment to the safety of the CompoGuard *Advance* is critical. Here are some guidelines for supervision and responsibility:

Regular review

Check the device settings regularly to ensure that no unknown or unauthorized changes have been made.

Access restrictions

Restrict access to the device to authorized users and specialist personnel, e.g. by means of access controls.

Training and sensitization

Ensure that all users are adequately trained to recognize and report potential security risks.

By observing these cybersecurity measures and security guidelines, you make a significant contribution to protecting the integrity and confidentiality of your health data and ensuring the secure operation of the CompoGuard *Advance*.

2.4.3 Software updates

To ensure that the CompoGuard *Advance* always meets the latest security standards, it is essential to keep the software up to date. You can obtain information on this from your sales partner or our service department.

2.4.4 Physical security

Secure the CompoGuard *Advance* against physical access by unauthorized persons. Protect all interfaces, USB ports or other connection points to prevent tampering or unauthorized access.

2.4.5 Backup / Data backup

Backing up your data is crucial to ensure the smooth operation and integrity of your medical device. Regular backups play a key role in minimizing data loss and recovering from unforeseen events.

2.4.6 Measures implemented in the device

Encrypted Wi-Fi connection

To prevent unauthorized access to the medical device via the network, the Wi-Fi connection is secured by the WPA2 protocol ("Wi-Fi Protected Access 2"). This strong encryption ensures that data is protected during transmission in the network and that only authorized devices can establish a connection.

Fresenius USB stick for data backup

Only a dedicated USB stick from Fresenius is intended for data backup. The medical device recognizes this special USB stick by means of integrated hardware recognition. This ensures that only authorized storage devices can be used for data backup, which minimizes the risk of unauthorized data leakage or malware infection.

Access-protected order and result files

Order and result files that are temporarily stored by the medical device are protected by an access control system. Only authorized users with the appropriate permissions can access this sensitive data. This protects against unauthorized access and ensures that confidential patient data is stored securely.

2.4.7 Cybersecurity during decommissioning and disposal

Proper decommissioning and disposal of a medical device and its associated PC software are critical steps to ensure cybersecurity and minimize potential risks. The following measures should be considered during this process:

1. Data deletion and reset
   - Ensure that all sensitive data on the medical device and the associated software is deleted before decommissioning.
   - Reset the device to the factory settings to ensure that no confidential information is left behind.
2. Removal of access data
   - Deactivate all access data and user accounts on the medical device and the software to prevent unauthorized access.
   - Change passwords or deactivate access data that is linked to the device and the software.
3. Physical security of the device
   - Follow the manufacturer's instructions for safe physical disposal of the medical device.
   - If possible, remove storage media or other data carriers and destroy them in accordance with the data protection guidelines.
4. Deletion of software
   - Uninstall the software according to the manufacturer's instructions and ensure that all associated files and configurations are deleted.
   - Check whether it is necessary to return or deactivate licenses.
5. Documentation of disposal
   - Create precise documentation of the disposal process, including all safety measures taken.
   - Keep this documentation for an appropriate period of time in accordance with legal requirements.

6. Consideration of environmental aspects

- Dispose of the medical device and the software in compliance with environmental regulations and in consideration of recycling options.
- Find out about local regulations and standards for the environmentally friendly disposal of electronic devices.

7. Final report to the IT security managers

- Inform those responsible for IT security about the decommissioning and disposal. Provide relevant information about the security measures taken.

8. Staff training

- Train involved personnel on safe decommissioning and disposal to ensure that all required safety protocols are followed.

By following these steps during decommissioning and disposal, you will help to close potential security gaps and maintain the integrity of your cybersecurity. Always observe the applicable data protection provisions and regulations for the safe disposal of electronics.

2.4.8 Cybersecurity during service or repair by the manufacturer

In the event that the CompoGuard *Advance* is returned to the manufacturer for service or repair, it is essential that all personal data is deleted prior to shipment. Personal data may contain sensitive information such as patient data, medical reports or other confidential information that must be protected in accordance with applicable data protection regulations.

Before returning the device to the manufacturer, please carry out the following steps:

1. Back up all important data stored on the device to an external storage medium or secure network storage.
2. Delete all stored data that can be identified as personal or confidential information. This includes, but is not limited to, patient data, names, addresses, medical records and other information not intended for the public.
3. Check the device carefully to ensure that no personal data is left before sending it to the manufacturer for repair or service.
4. Failure to comply with these guidelines may result in data breaches and legal consequences. Please note that the manufacturer is not liable for the loss or disclosure of data that has not been properly backed up and deleted.

We thank you for your understanding and cooperation in complying with data protection regulations. If you have any questions about the secure handling of your data, please contact your data protection officer.

2.4.9 Further information

If you have any questions about cybersecurity, please contact your sales partner or service.

2.5 General safety notes

WARNING

Electrical hazard

Hazard due to damage to the device.

- Check the device for visible damage after unpacking.
- Never use damaged or defective devices and do not connect to power. Notify a service technician.

WARNING

Electrical hazard

Hazard due to incorrect use of the power connection.

- Connect and operate the device according to the information on the rating plate.
- Do not kink, crush or modify the power supply cord.
- Check the power supply cord for damage while connecting the device. Never use devices with damaged mains and power connection and do not connect to power. Notify a service technician.
- Disconnect the power plug to disconnect the device from the electricity supply. Never pull the power supply cord.

WARNING

Risk of infection

There is a risk of damage to the blood bag system due to improper use, malfunctions or damage to the device. If blood escapes, there is a risk of infection.

- In case of persistent malfunction and damage do not use the device.
- Inform Service.
- Wear protective gear and protective gloves to protect against the risk of infection.
- The device must only be used by trained personnel.

WARNING

Risk of injury

Device damage resulting in sharp edges and corners may cause a risk of injury to the operator.

- Check the device for visible damage after unpacking.
- Never use damaged or defective devices and do not connect to power. Notify a service technician.

WARNING

Risk of injury

There is a risk of trapping at the moving parts of the mixing tray during the taring and weighing process. Abrasion and minor crushing to the finger may occur.

- Do not reach into the moving tray.

WARNING

Risk of injury

There is a risk of trapping at the moving parts of the safety clamp on opening and closing. Abrasion and minor crushing to the finger may occur.

- Never touch the safety clamp during opening and closing.

WARNING

Hazard for the donor (blood loss)

If the device is not in correct working order or an incorrect or leaking bag system is used, there may be a hazard for the donor due to blood loss, if the required target volume for the whole blood donation is exceeded or the bag system is damaged.

- Monitor the volume of the donation and the health of the donor before, during and after the donation to detect possible problems at an early stage.
- Continuously check the state of the device and the bag system.

CAUTION

Risk of injury

Risk of burning at hot surfaces on the device due to damage or device malfunctions.

In case of device damage or hot device components and surfaces:

- Turn off the device and disconnect it from the power supply.
- Do not use the device and notify a service technician.

NOTE

The device sealing system uses radio frequency for sealing medical PVC tubing. The device meets the normative requirements in relation to electromagnetic compatibility (IEC 60601-1-2).

During the operation of the device, we recommend a minimum distance of 2 meters from other electrical medical equipment (e.g., heart pacemakers, insulin pumps).

NOTE

Electro magnetic irradiation may cause malfunctioning of the device.

- Maintain a distance of 0.3 m between the device (including accessories and cables) and HF communication equipment such as cell phones (including the related accessories such as the antenna cable, external antenna cables and external antennae).

NOTE

- In case of defective keypad or operating keys, switch off the device, disconnect it from power supply and notify a service technician.

INFO

- Do not use a sharp or hard object (e.g., pen, pointer, scissors, etc.) on the touchscreen.

2.6 Specific safety instructions

WARNING

Electrical hazard

Moisture in the device can cause an electric shock. To prevent electric short circuit and electric shock:

- For cleaning and disinfecting, turn off the device and disconnect it from the power source.
- Make sure that no fluids get into the inside of the device.
- Do not spray into the device or onto surfaces.
- If liquid (blood, blood components or cleaning agent) has entered the interior of the device, disconnect the power plug and notify a service technician.

WARNING

Risk of injury

Damaged battery packs may cause a risk of injury.

- Store battery packs within a temperature range from -20°C to +50°C.
- Protect battery packs from wet and humidity.
- Never short-circuit, reverse the polarity, open, modify or burn a battery pack.
- Check or exchange dropped battery packs by a service technician.
- Do not incinerate or heat battery packs above the permissible temperature. Otherwise explosive gases may escape and cause an explosion.

WARNING

Risk of infection

Improper cleaning and disinfection of the device may expose operators and donors to the risk of infection with pathogens.

- Always treat blood as potentially infected.
- Follow stipulated cleaning process (see chapter 8 on page 89).
- Wear protective clothing and safety gloves.

Safety instructions for the hand sealer

WARNING

Electrical hazard

The hand sealer electrodes are under electrical voltage during the sealing process.

- Never touch the electrodes while sealing.
- Never place electrically conductive material in the hand sealer or between the sealing electrodes.

WARNING

Risk of injury and device damage

The use of non-approved equipment may cause a risk of injury, as well as damage to the device. Electromagnetic emissions or reduced electromagnetic immunity may result in malfunctions and incorrect operation.

- Use only original equipment approved by the manufacturer.
- Use only original batteries and battery packs approved by the manufacturer.
- Use only original coaxial extension cables for the hand sealer.
- Do not use USB extension cables.

WARNING

Risk of injury

During the sealing process the electrodes may overheat and may cause a risk of burns.

Never touch the electrodes while sealing.

WARNING

Risk of infection

Improper handling or technical defect with the hand sealer may result in a risk of infection, caused by leakage/ spillage of the tubing content (blood) and temporary failure of the sealing function

- Never attempt to pull the tubing apart during the sealing process.
- Only seal the tubing specified in the Operating Instructions.
- Visually check seals for leaks.
- Wear protective gear and protective gloves to protect against the risk of infection.

2.7 Safety symbols

General warning symbol

Disconnect the power plug

Observe Operating Instructions

2.8 Symbols

The CE mark documents the manufacturer's declaration that the product complies with EC regulations applied by the manufacturer have been complied with.

The CompoGuard *Advance* reflects the latest state of technology and complies with the requirements of EN 60601-1 (IEC 60601-1). According to rule 12 of REGULATION (EU) 2017/745 on medical devices, the CompoGuard *Advance* is a class IIa device.

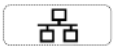
Recycling of electrical/electronic devices and components.

Radio frequency oscillator

Total weight

USB port

Date of manufacture



Network

UDI: Code consisting of:
UDI-DI (Device Identifier)
UDI-PI (Product Identifier)

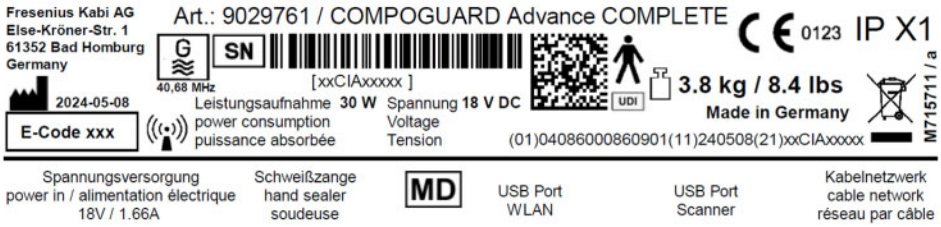
Serial number

Drip-proof

Medical Device

Application part type B

RoHS-compliant



The type label shown is only an example.

For the current data of the device, consult the device type label.

2.9 Protective equipment

Wear goggles

Wear gloves

Wear protective clothing

3 Specifications

3.1 General technical data

Dimensions of CompoGuard *Advance*

Height	16.5 cm
– incl. Gooseneck	16.5 cm + 40.00 cm
Width	22.5 cm
Depth	44.5 cm
Weight	
– Basic	3.6 kg
– Data	3.6 kg
– Complete	3.8 kg
Housing material	ABS (Acrylnitril-Butadien-Styrol)

Dimensions of the Transport Case

Height	28 cm
Width	29 cm
Depth	60.4 cm
Weight	3.4 kg
Housing material	Plastic, dyed throughout

Measurement Function Tolerances

Measuring range	1000 g
Measurement accuracy of target volume	
at 350-1000 g	≤1 %
at 100-350 g	±3.5 g

Operating Conditions

Operating temperature	+15 °C to +40 °C
Relative humidity	30 % to 70 %
Atmospheric pressure	700 hPa to 1060 hPa
Position of use	horizontal

Storage and Transport

Ambient temperature	-20 °C to +70 °C
Relative humidity	10 % to 80 %
Atmospheric pressure	500 hPa to 1060 hPa

Electrical safety

Requirement	Complies with the following requirements of the Medical Products Safety IEC 60601-1
Protection against electric shock	Protection category II
Protection against electric shock	Application part type B
Degree of protection against ingress of liquids	IPX1

Electrical Supply CompoGuard *Advance*

Voltage input	18 V DC ±5 %
Power consumption	5 W
Power consumption with battery charging	30 W (maximum 36 W)
RF frequency	40.68 MHz ±50 kHz
RF rated maximum output power	60 W
Input current	0.1 to 2 A
Battery pack	Lithium ions 14.4 V / 5900 mAh

Electrical supply Power supply unit

Voltage input	100-240 V AC
Nominal frequency	50 to 60 Hz
Input current	150 to 700 mA
Voltage output	18 V DC ±5
Output current	1.66 to 2 A

Electromagnetic compatibility

Requirement	Complies with the requirements of IEC 60601-1-2

Connectors

Power connection

Ethernet

USB

Validated tubing systems

Fresenius CompoFlow
Fresenius CompoFlex
Fresenius CompoSelect

Validated router

D-Link DIR-809

3.2 Guidance and Manufacturer's Declaration regarding electromagnetic compatibility (IEC 60601-1-2)

NOTE

Electro magnetic irradiation may cause malfunctioning of the device.

- Maintain a distance of 0.3 m between the device, its accessories as well as its cables and HF communication equipment such as cell phones (including the related accessories such as the antenna cable, external antenna cables and external antennae).

Electromagnetic emissions

Guidance and Manufacturer's Declaration - Electromagnetic emissions		
The CompoGuard *Advance* is intended for use in the electromagnetic environment specified below. The customer or the operator of the CompoGuard *Advance* should assure that it is used in such an environment.		
Emission tests	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The CompoGuard *Advance* must emit electromagnetic energy in order to perform its intended function. Adjacent electronic equipment may be affected.
RF emissions CISPR 11	Class A	The CompoGuard *Advance* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
RF emissions CISPR 11 (without sealing function)	Group 1	The CompoGuard *Advance* does not need to emit electromagnetic energy to perform its intended function.
RF emissions CISPR 11 (without sealing function)	Class B	In addition to the stated equipment class A, the CompoGuard *Advance* is also suitable for operation in residential environments.

NOTE

Due to its EMISSION characteristics, this device is suitable for use in industrial areas and hospitals (CISPR 11 class A). If the device is used in a residential environment (for which CISPR 11 class B is normally required), it may not provide appropriate protection for HF communication services.

- If necessary, mitigation measures are to be taken, e.g., changing the position or the alignment of the equipment.

NOTE

The radio modules used meet all common national standards.

- Make sure the radio module is not operated in countries where the standards are not met.

Electromagnetic immunity

Guidance and Manufacturer's Declaration - Electromagnetic immunity			
The CompoGuard *Advance* is intended for use in the electromagnetic environment specified below. The customer or the operator of the CompoGuard *Advance* should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electro static discharge (ESD) IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15 kV air	±8 kV contact ±2kV, ±4kV, ±8kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines 100kHz repetition frequency	±2 kV for power supply lines ±1 kV for input/output lines 100kHz repetition frequency	Mains power quality should be that of a typical commercial and/or hospital environment.
Surges IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to earth	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles at 0° 0% U_T; 250/300 cycles <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	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles at 0° 0% U_T; 250/300 cycles <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	Voltage dips can cause the device to switch off automatically. It is the operator's responsibility to put the device back into the required mode.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF	3 V_{eff} 150 kHz to 80 MHz 6 V in ISM frequency range between 0.15 and 80 MHz at 80 % AM and 1 kHz	3 V 6 V	Portable and mobile RF communications equipment should be used no closer to any part of the CompoGuard *Advance*, 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 150 kHz to <80 MHz

Disturbances IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V/m	d = 1.2 √P for 80 MHz to <800 MHz d = 2.3 √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, [a] should be less than the compliance level in each frequency range.[b]  Interference may occur in the vicinity of equipment marked with the following symbol:

<table>
<tr><td rowspan="8">High-frequency fields in the immediate vicinity of wireless communication devices
IEC 61000-4-3
Frequency and level according to table 9
IEC60601-1-2</td><td>Range
MHz</td><td>Level
V/m</td><td>Range
MHz</td><td>Level
V/m</td><td rowspan="8">Mains power quality should be that of a typical commercial and/or hospital environment.</td></tr>
<tr><td>380-390</td><td>27</td><td>380-390</td><td>27</td></tr>
<tr><td>430-470</td><td>28</td><td>430-470</td><td>28</td></tr>
<tr><td>704-787</td><td>9</td><td>704-787</td><td>9</td></tr>
<tr><td>800-960</td><td>28</td><td>800-960</td><td>28</td></tr>
<tr><td>1700-1990</td><td>28</td><td>1700-1990</td><td>28</td></tr>
<tr><td>2400-2570</td><td>28</td><td>2400-2570</td><td>28</td></tr>
<tr><td>5100-5800</td><td>9</td><td>5100-5800</td><td>9</td></tr>
<tr><td rowspan="5">Radiated fields in the close range - Fixed frequencies up to 30 MHz IEC 61000-4-39</td><td>Frequency
kHz</td><td>Level
A/m</td><td>Frequency
kHz</td><td>Level
A/m</td><td rowspan="5">Mains power quality should be that of a typical commercial and/or hospital environment.</td></tr>
<tr><td>30</td><td>8</td><td colspan="2">Not applicable</td></tr>
<tr><td>134.2</td><td>65</td><td>134.2</td><td>65</td></tr>
<tr><td>13560</td><td>7.5</td><td>13560</td><td>7.5</td></tr>
<tr><td colspan="6">Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. In case the field intensity measured on the site where the CompoGuard Advance is used exceeds the above-mentioned matching levels, it is recommended to monitor the CompoGuard Advance for detecting its intended function. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CompoGuard Advance.

bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF telecommunication devices and the CompoGuard *Advance*

Recommended separation distances between portable and mobile RF telecommunication devices and the CompoGuard *Advance*			
The CompoGuard *Advance* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Electromagnetic interference can be reduced or avoided if a minimum distance is maintained between portable and mobile HF telecommunication equipment (transmitters) and the CompoGuard *Advance*.			
Rated maximum output power of transmitter W	Separation distance d according to frequency of transmitter m		
	150 kHz to < 80 MHz d = 1.2 √P	80 MHz to < 800 MHz d = 1.2 √P	800 MHz to 2.5 GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.3	0.3	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

4 Installation and Operation

4.1 Brief description

The CompoGuard *Advance* is a mixer that mixes human blood with an anticoagulant in a bag system during the donation. A safety clamp stops the donation when the programmed volume is reached. The tube on the donation bag is sealed manually using an external hand-held sealing unit after the end of the donation.

The CompoGuard *Advance Complete* has an additional integrated sealing function for the tube after the end of the donation. The device models *Data* and *Complete* include additional functions that assist and optimize operation while drawing blood.

The CompoGuard *Advance* system reflects the latest state of technology and complies with the requirements of medical product safety IEC 60601-1.

Bag systems of other manufacturers

Bag systems from other manufacturers can also be used.

However, as no quality agreement exists between Fresenius Kabi and the manufacturers, we are unable to comment on the application of the bag systems produced by these companies.

For this reason, on startup of the CompoGuard *Advance*, every responsible organization is responsible for performing a verification with the bag systems used in its blood bank.

The following requirements must be met when using other bag systems:
- The total weight of the bag system and the donation must not exceed 1000 g.
- The bag system must fit into the tray without overlapping the tray.
- The tubing must fit into the line holder and the safety clamp.
- The tubing between the safety clamp and tray must be long enough to allow the scales to move freely.
- The safety clamp must securely clamp the tubing.
- The tubing must be HF weldable.

4.2 Design

INFO

In the following, the "Complete" model CompoGuard *Advance* is presented and described. The *Basic* and *Data* models comprise selected components of the device shown below.

4.2.1 Front side

Fig. 1 Front side

1 Gooseneck with control panel
2 Barcode scanner with scanner holder
3 Tray with filter holder
4 On/Off button
5 USB port (service and data exchange)
6 7" touchscreen for displaying the user interface
7 Safety clamp
8 Hand sealer
9 Optenna (optical antenna)

4.2.2 Back view

Fig. 2 Back side

1 Power supply connection

2 Hand sealer connection

3 USB port (WLAN stick)

4 USB port (scanner)

5 Port for network cable

INFO

- Turn and release the silver BNC connector on each end to disconnect the coaxial cable - do not pull the cable during this process.

4.2.3 USB ports

The following components can be connected to the rear USB ports as desired:

USB port - front

– Service

– Data exchange

USB port - rear

– Scanner (only for *Data* and *Complete*)

– WLAN (only for *Data* and *Complete*)

The USB sticks for service and data exchange are only compatible with the USB port on the front of the device. It cannot be plugged into either of the two rear ports. This also applies for the USB sticks Scanner and WLAN, which cannot be connected to the front of the device.

INFO

The USB port on the front of the device is intended to be used for service USB sticks and the exchange of data.

The USB ports on the rear are intended to be used for scanner and WLAN USB sticks.

4.3 Functional Description

1 Turn the device on

The device is switched on and automatically undertakes a system check (see chapter 6.3.1 on page 41). After the successful completion of the system check, the main menu (see chapter 6.3.2 on page 42) appears on the user interface.

The **Start** button (Fig. 11, Item 3) is pressed. The safety clamp opens. The tray swivels over its entire swivelling range and then remains tipped to the rear. This process ensures that sufficient tube length is available between the bag and the safety clamp during the mixing process.

The mixing tray now determines its empty weight and is zeroed.

2 Insert and secure bag system

The donation bag is placed in the tray on the device. Fix the filter using the filter holder. The tube is threaded through the device's safety clamp and secured. There are three positions of the safety clamp

- Open: The tube can be inserted or removed.
- Closed: The tube is clamped securely so that blood flow is not possible. It is not possible to insert or remove the tube.
- Donation open: The safety clamp is open to allow for blood flow into the donation bag, while ensuring the tube remains in place.

INFO

Make sure that the tubing is properly inserted in the safety clamp. The length of the tube should be selected such that it is not under tension between the tray and the safety clamp and it is also not trapped between the tray and housing.

INFO

The tray on the CompoGuard *Advance* is sufficiently large that there is space in the tray for up to 5 donation bags and filters.

3 Weighing and taring

The CompoGuard *Advance* determines the empty weight after the donation bag and filter are inserted. After the **Continue** button (Fig. 33, Item 5) is pressed, the empty weight of the tray is determined and the scale is set to zero.

When the donation starts, the tray moves. This movement mixes the blood donated to prevent coagulation.

The volume of blood in the donation bag is determined and monitored via the inlet flow rate and indicated on the user interface as per the donation program. The donation ends at the weight specified in the donation program.

If the weighing system detects an immediate weight gain or loss (±10 g) before the start of a blood donation, this is indicated by an acoustic signal and a message on the user interface. Once the correction has been made, a re-tare can be performed by pressing the **Start** button.

4 Donation

The operator and the donor are identified by reading the corresponding scancodes and communicated to the system. The necessary data can be read. The related area on the donor's arm is disinfected before inserting the needle. As soon as the flow of blood is ensured, the donation starts after the **Start** button is pressed. The safety clamp moves to the "Donation open" position. During the donation, the volume/weight of the donation bag is determined and the tray undertakes mixing movements.

On the LED display on the gooseneck, the donor can follow and change the progress of the donation (e.g., by making a fist and opening their hand again).

5 Donation end

Just before reaching the target volume or the maximum donation time, the device signals the end of the donation by means of a visual signal on the Optenna as well as an audible signal. After the target volume or the maximum donation time is reached, the safety clamp closes. The flow of blood into the donation bag is interrupted. The mixing tray continues to perform the mixing movements to ensure the donated blood is mixed.

6 Remove bag system

Press the **Open Clamp** button to release the donation bag. The safety clamp opens. The mixing movement of the tray is stopped and the tray remains in the horizontal position. Remove the donation bag. Seal the line set or separate it from the bag with the aid of the hand-held sealer (for the *Basic* and *Data* models with separate hand-held sealing unit, for the *Complete* model using the hand-held sealer). The **Continue** button is pressed to return to the main menu.

The operator removes the line set. Treat the venepuncture site on the donor's arm according to instructions issued by the blood bank.

7 Read out donation data

After the blood donation, the donation data is stored in the internal memory of the device. These can be read out via a USB stick. USB ports are available on the device for this purpose (Fig. 1, Item 5). The data is read automatically via a WLAN or LAN connection.

NOTE

The safety and integrity of the network to which both CompoGuard *Advance* and DonationMaster *Advance* are connected must be guaranteed.

- Only use trusted networks. To do this, select WPA2 as the encryption method.

INFO

It should be ensured that there is sufficient storage space on the USB stick. If this is not the case. In this case, the data set remains in the internal memory of the device.

The data stored in this way can be made available manually to the blood information system (BIS). The donation data from several CompoGuard *Advance* devices can be saved on a USB stick (see chapter 6.3.3.6 on page 52).

INFO

The USB stick must be removed immediately after data transfer. Otherwise the battery life will be greatly reduced.

5 Transportation and Start-up

5.1 Delivery and transportation of the device

The CompoGuard *Advance* and the transport case are each delivered separately in a package.

General external checks

- Check the outside of the CompoGuard *Advance* for possible damage in transit or other damage.

After delivery, do not unpack the device until it has adapted to the specified ambient conditions see Storage and Transport on page 15.

WARNING

Electrical hazard

Hazard due to damage to the device.

- Check the device for visible damages after unpacking.
- Never use damaged or defective devices and do not connect to power. Notify a service technician.

WARNING

Risk of injury

Falling parts and devices can result in a risk of injury.

- Transport the device with care in its original packaging or in the transport case.
- Carry the device only by the provided handles.
- Check if equipment is stored securely in the provided holders.

INFO

Never use the transport case to ship the device. Only use it as a transport aid for short distances.

INFO

The transport case allows easy and safe transportation of the device. The transport cases can be stored stacked.

5.1.1 Device Transportation

The CompoGuard *Advance* must always be transported packed in the transport case when being moved.

5.1.2 Unpacking the device from the transport case

1. Open the transport case using the side buckles and remove the lid.

Fig. 3 Open the transport case

2. Take the device out of the case.
3. Remove all additional equipment and cables from the transport case and connect to the CompoGuard *Advance*. Turn over the tray, push into the fastening provided and engage.

Fig. 4 Additional equipment in the transport case

INFO

The transport case (with or without cover) can be used as a stand for the CompoGuard *Advance* during operation.

Packing the CompoGuard *Advance* into the transport case for transportation is done in reverse order (7.2.6.1 Loading the transport case).

INFO

Incorrect transportation may damage the additional equipment.

- Never lift the CompoGuard *Advance* by the additional equipment.

5.2 Set-up and Installation

5.2.1 Preparatory work

Scope of delivery

- Before progressing to the initial start-up, check that all parts have been accounted for:

CompoGuard *Advance* - **Basic**

– Standard equipment
  1x AC adapter
  1x Operating Instructions

– Additional equipment available
  1x Gooseneck
  1x Transport case with/without charging function
  1x Battery pack
  1x Multi loader

CompoGuard *Advance* - **Data**

– Standard equipment
  1x AC adapter
  1x Gooseneck
  1x WLAN stick
  1x Operating Instructions

– Additional equipment available
  1x 1D/2D Barcode scanner
  1x Transport case with/without charging function
  1x Battery pack
  1x Multi loader
  1x USB stick DonationMaster *Advance* Software

CompoGuard *Advance* - **Complete**

– Standard equipment
  1x AC adapter
  1x Gooseneck
  1x Hand sealer
  1x Battery pack
  1x WLAN stick
  1x Operating Instructions

– Additional equipment available
  1x 1D/2D Barcode scanner
  1x Transport case with/without charging function
  1x Multi loader
  1x USB stick DonationMaster *Advance* Software

5.2.2 Start-up

INFO

In order to achieve a correct weighing result, the mixing tray must be free to move, i.e. it must not be obstructed by cables, etc.

- Place the CompoGuard *Advance* on a flat, vibration-free surface so that it cannot fall down. The connections on the back of the device should be easily accessible and free from electrical interference.
- The device should not be exposed to direct sunlight.

Placing the device on the transport case

The transport case (with or without cover) can be used as a stand for the CompoGuard *Advance*. This means that it is also available for transporting the device at any time.

- Close the empty transport case via the side buckles and turn it upside down.
- Place the transport case on a flat, vibration-free surface so that it cannot fall down. The connections on the back of the device should be easily accessible.
- Place the CompoGuard *Advance* on the transport case.

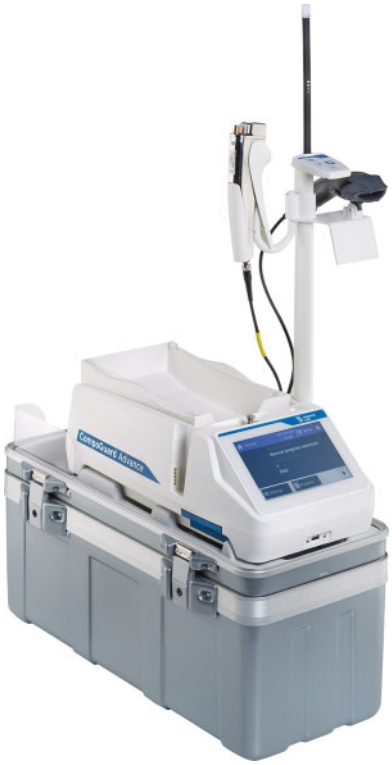


Fig. 5 Device on transport case

- Place the mixing tray on the weighing device of the machine. The mixing tray must be able to swing freely.
- Insert the gooseneck on the right or left side of the device into the recess provided.

Fig. 6 Attaching the gooseneck

- Attach the (optional) scanner holder to the gooseneck by clicking on it, then insert the barcode scanner into the scanner holder.
- Insert the (optional) hand sealer into the holder on the gooseneck.

5.2.3 Connection

WARNING

Electrical hazard

Hazard due to incorrect use of the power connection.

- Connect and operate the device according to the information on the rating plate.
- Do not kink, crush or modify the power supply cord.
- Check the power supply cord for damage while connecting the device. Never use devices with damaged mains and power connection and do not connect to power. Notify a service technician.
- Disconnect the power plug to disconnect the device from the electricity supply. Never pull the power supply cord.

- Connect the USB stick to the front USB port (Fig. 1, Item 5, page 24), the connection cable for the hand-held sealer (Fig. 2, Item 2) (optional) and/or other options to the rear USB ports (Fig. 2, Item 3 or 4).
- Plug the mains cable into the appropriate connector (Fig. 2, Item page 251) and connect the plug to a power supply.
- Plug the optional network cable into the Ethernet connector (Fig. 2, Item 5).
- Insert the (optional) battery pack into the battery slot on the left side of the CompoGuard *Advance* (Fig. 7). The battery pack is locked by a latch into the housing.

The battery pack is inserted correctly when its cap is aligned with the device housing and cannot be pulled or lifted out.

Fig. 7 Battery compartment on the device

INFO

The inserted battery pack is charged when the CompoGuard *Advance* is connected to the plug-in power supply. Charging is faster in standby mode than in operating mode.

INFO

A fully discharged battery requires up to 5 hours in the standby mode to charge.
For further information about the battery pack, see 7.2.4 Battery pack.

5.3 Initial Start-Up

Only trained, authorized personnel are permitted to undertake initial start-up.

A commissioning report must be kept for the initial commissioning of the device.

⚠ CAUTION

Hazard, deviating product volume

To ensure correct weighing result,

- the device must be operated in horizontal position
- Place all 4 feet of the device on a firm surface that is subjected only to limited vibration
- During calibrations and during the donation, there must not be any additional objects on the tray
- Do not trap anything between the tray and the housing. The tray must move freely, i.e. its movement may not be obstructed by cables.

NOTE

Before initial start-up the device must reach its operating temperature (15 °C up to 40 °C). Disregarding this instruction may cause malfunctioning of the device.

NOTE

Do not use the device close to other equipment or in a stack with other equipment. This situation could cause the device to operate incorrectly.

If, nevertheless, such use is necessary, the correct function of all equipment used must be confirmed.

- Press the **On/Off** key (Fig. 1, Item 4) for around 2 seconds to switch on the CompoGuard *Advance*.

➤ The CompoGuard *Advance* performs a system check.

➤ The screen page with the system check appears on the user interface. Information is displayed here (see 6.3.1 on page 41).

The device performs a function test:

– The safety clamp (Fig. 1, Item 7) opens and closes.

– The mixing tray (Fig. 1, Item 3) performs a mixing movement.

– An acoustic signal sounds to test the alarm signal transmitter.

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6 Operation

WARNING

Risk of injury

Device damages resulting in sharp edges and corners may cause a risk of injury to the operator.

- Check the device for visible damages after unpacking.
- Never use damaged or defective devices and do not connect to power. Notify a service technician.

WARNING

Electrical hazard

The hand sealer electrodes are under electrical voltage during the sealing.

- Never touch the electrodes while sealing.
- Never place electrically conductive material in the hand sealer or between the sealing electrodes.

WARNING

Risk of injury

During the sealing process the electrodes may overheat and may cause a risk of burns.

Never touch the electrodes during sealing.

WARNING

Risk of injury

There is a risk of trapping at the moving parts of the safety clamp on opening and closing. Abrasion and minor crushing to the finger may occur.

- Never touch the safety clamp during opening and closing.

For information about the interaction of CompoGuard *Advance* and DonationMaster *Advance*, see the DonationMaster *Advance* User Manual.

NOTE

The safety and integrity of the network to which both CompoGuard *Advance* and DonationMaster *Advance* are connected must be guaranteed.

- Only use trusted networks. To do this, select WPA2 as the encryption method.

6.1 Switching the CompoGuard *Advance* on and off

6.1.1 Switching the device on

- Press the **On/Off** key at the top right of the CompoGuard *Advance* for around 2 seconds.
  The user interface appears after a boot sequence.
  The device performs a system check (self-test) and moves to its home position (see chapter 6.3.1 on page 41).
  During the system check, an attempt is made to establish a connection to the DonationMaster *Advance* software.
  After successful completion of the self-test, the CompoGuard *Advance* is ready for operation. The **On/Off** key lights up green.

6.1.2 Switching the device off

Before switching off the device, it must be in its home position waiting for another donation.

- Press the **On/Off** key at the top right of the CompoGuard *Advance* and keep pressed for at least 3 seconds.
  A page is displayed where you must confirm switch off. Normal switch off is not permitted during the donation. You must hold the **On/Off** key for at least 10 seconds to force switch off.

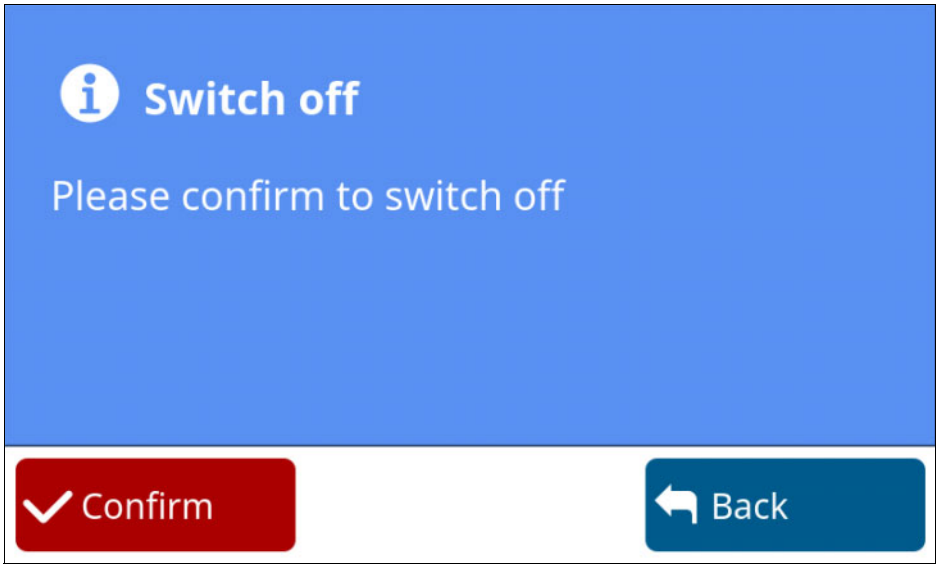


Fig. 8 Switching the device off

➤ Once the device is finally switched off, the LED beside the **On/Off** key extinguishes and the safety clamp is closed.

INFO

It is **not** permitted to switch off the CompoGuard *Advance* while a donation is in progress.

6.2 Operating of the CompoGuard *Advance*

The CompoGuard *Advance* is operated via the user interface on the device. This is a 7” LCD touch screen.

INFO

- Do not use a sharp or hard object (e.g. pen, pointer, scissors, etc.) on the touchscreen.

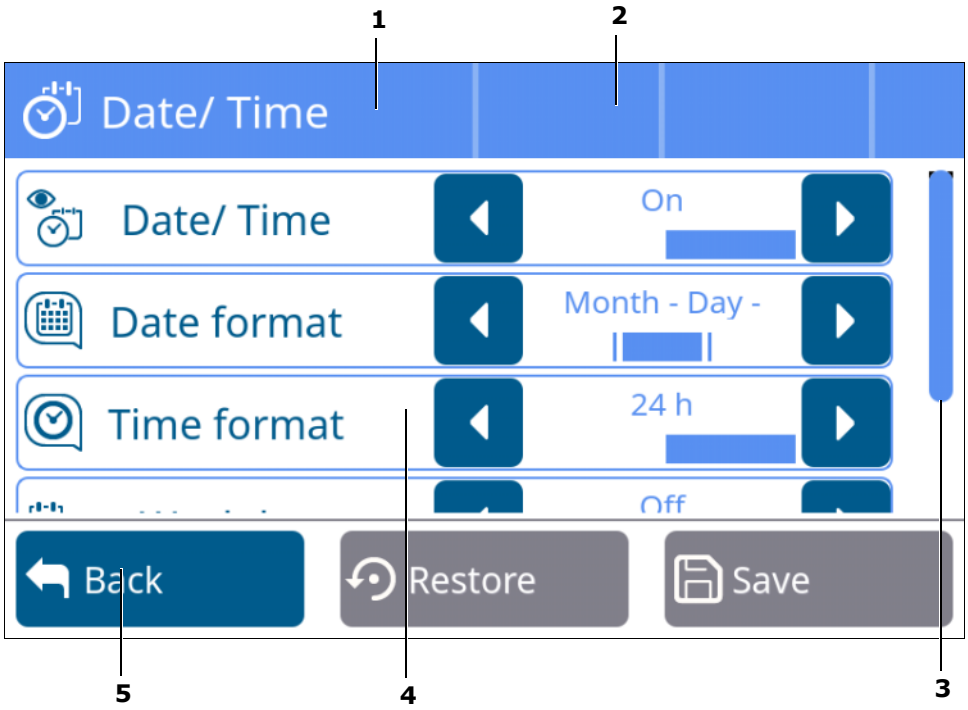


Fig. 9 Structure of the user interface

1 Menu bar

2 Indications, e.g., about the operation of the device (connected to the electricity supply or battery operation), the charge state of the battery

3 Indication that a menu consists of several “pages”

4 Display/input area (depending on the selected menu)

5 Buttons

The menu bar is permanently displayed in the upper area of the user interface. This is highlighted in light blue and cannot be selected directly. In addition to the currently selected menu, it shows the current date and time as well as the battery charge level (in %). If the device is connected to the mains via the mains plug, this is also indicated by a symbol.

There are several possible indications for the charge state of the device:

The device is connected to the electricity supply via the power plug. The battery is in the device and is charging. The battery is up to 25% charged.

The battery pack is supplying the device with electrical power. The battery is up to 55% charged.

The device is connected to the electricity supply via the power plug. The battery temperature is too high or low for charging.

There are several possible indications for the network state of the device:

Connection to the DonationMaster *Advance* established

Search for WLAN stick

Search for Ethernet cable connection

No network configured in the settings

Device is searching for the DonationMaster *Advance*. The DMA IP of the DonationMaster *Advance* is being used.

Device is searching for the DonationMaster *Advance*. A manually entered DMA IP is being used.

The network settings are incorrectly configured or the network is not accessible.

The network connection timed out. An incorrect network key was probably used.

Waiting for a network connection.

The device is in "CGA controlled" configuration mode.

Depending on the selected menu/submenu, parameters, display and/or input fields are shown in the middle section. Picture/symbol displays are also shown in the running program to assist the operator in carrying out the donation.
If a menu consists of several pages, the menu page can be scrolled manually via the user interface. Two dots are displayed on the right-hand side. Selecting the top item takes you to the first menu page (the item is then filled in). Selecting the lower item takes you to the last menu page (this item is then filled in).

Buttons are usually displayed in the lower area. These can be used either to execute functions or to select further menus. Selectable buttons are highlighted in dark blue. If a button is inactive and cannot be selected, it is greyed out.

The **Back** button always takes you back to the previous menu.

Use the **Restore** button to discard the settings made but not yet saved.

Use the **Save** button to save the settings made.

6.3 Description of the menus

After switching on the CompoGuard *Advance*, a short acoustic signal will sound, and a start-up screen will appear on the user interface showing the device name in white letters with a blue background. When the control is completely up, the text changes to blue and the background to white. After this boot process is completed, the device performs a self-test. The user interface shows the menu **Selftest**.

6.3.1 Selftest

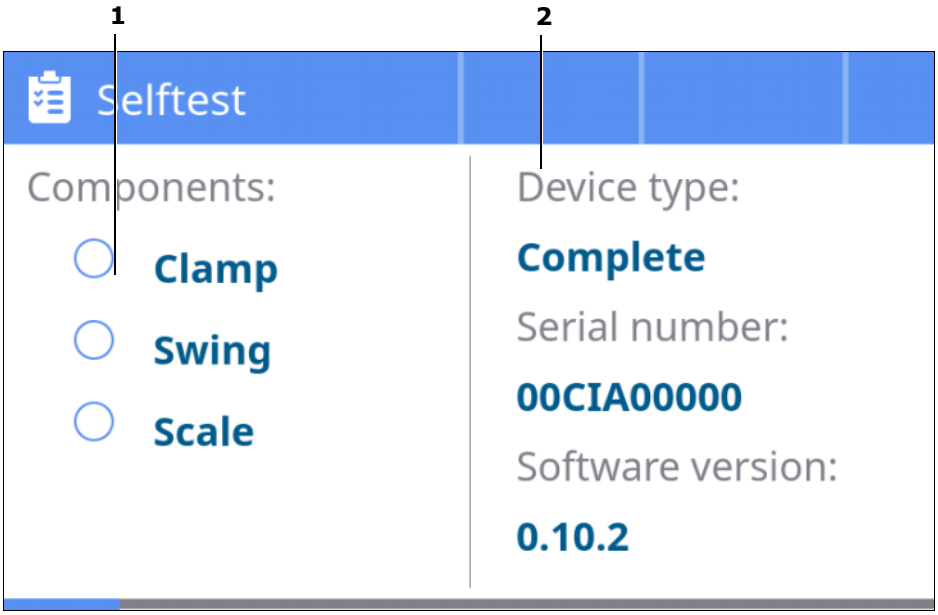


Fig. 10 Menu Selftest (here for example the device type Complete)

1 Status of the system components after the system check

2 Information on the device and the device software

On the right-hand side of the menu, information on the serial number of the device, the device type (Basic, Data or Complete) and the version of the associated device software are displayed.

All system components that are tested during the self-test are displayed on the left-hand side. The sequence shown corresponds to the test sequence.
- The safety clamp is moved to the "Open" and "Closed" positions.
- The tray undertakes a mixing movement.
- The weighing is checked.

During the test, a rotating circle symbol appears in front of the currently tested component. A check mark appears after the successful completion of the check. If the test is completed and was not successful, a cross symbol appears. The LED on the **On/Off** key flashes green during the self-test.

After completion of the self-test, the LED on the **On/Off** key lights up green. The main menu is displayed on the user interface.

6.3.2 Main menu

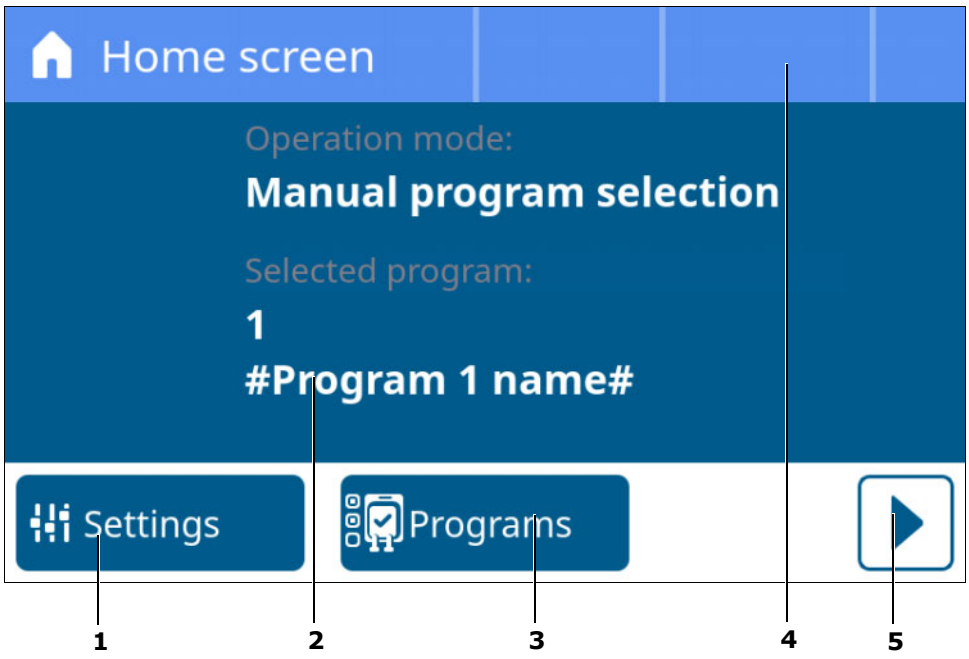


Fig. 11 Simplified main menu

1 Button for selecting the menu **Settings**

2 Display of the selected program and the pre-set operating mode

3 Button for selecting the **Programs**

4 Indication with connection to the DonationMaster *Advance* (not shown here)

5 **Start** button for starting the program

The main menu can be displayed in *simplified* or *advanced* mode (see 6.3.3.4 Submenu Display).

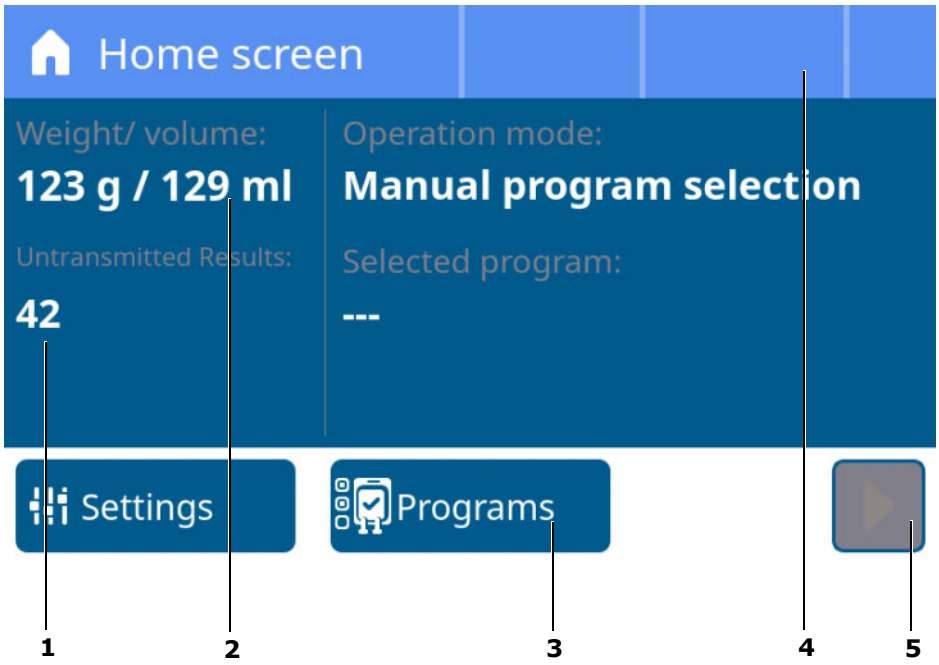


Fig. 12 Advanced main menu

1 Display of results that have not yet been transmitted via the network or USB stick

2 Display of the current weight and blood volume on the mixing tray

From the main menu, the **Settings** menu can be accessed. In this menu, all necessary settings for the user interface of the device software are made. You can also select the **Programs** menu to select the donation program to be used and loaded into the controller. Then start the donation using the **Start** button.

The **Programs** and **Start** buttons are dependent on the operation mode in which the CompoGuard *Advance* is operating (see chapter 6.4 on page 74).

6.3.3 Settings

The following submenus can be selected via this menu using the relevant button.

- In the main menu, press the **Settings** button (Fig. 11, Item 1).

➤ The **Settings** menu appears.

Depending on the configuration in DonationMaster *Advance*, the **Settings** menu can also be protected with an access pin.

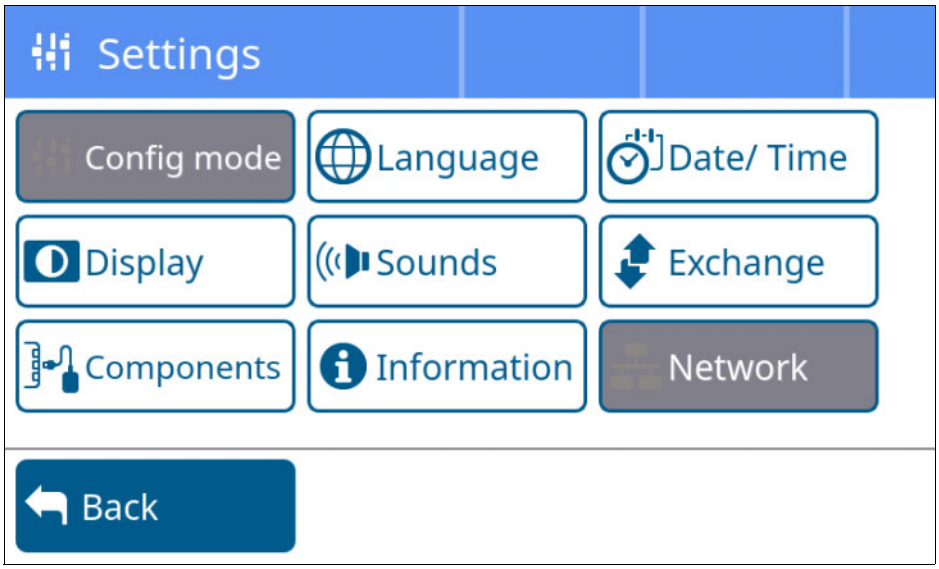


Fig. 13 Menu Settings

In these submenus, general settings for the user interface of the device are made. The selection is made directly via the corresponding button.

Some settings may not be available depending upon the device variant. In this situation, the buttons are greyed out.

You can only choose the following settings on the CompoGuard *Advance* Data and CompoGuard *Advance* Complete variants.

– **Config mode**
  You must be logged in as a user with appropriate authorization.

– **Network**
  The device must be connected to a network.

You can only select the following settings in the "CGA controlled" configuration mode.

– **Language**

– **Date/Time**

6.3.3.1 Submenu Config mode

Select the configuration mode on this submenu.

Fig. 14 Submenu Config mode

Here you can select whether the CompoGuard *Advance* is to be controlled using the general device configuration in DonationMaster *Advance* (**DMA** selected) via the device itself (**CGA** selected).

- Select Configuration mode.

➤ The button you selected has a colour background and is displayed with a check mark.

The configuration is loaded after you leave the menu by pressing the **Back** button.

6.3.3.2 Submenu Language

Select the user interface language on this submenu.

- In the menu **Settings** press the button **Language**.

➤ The **Language** menu appears.

Fig. 15 Submenu Language

- Press the button with the desired language.

➤ The button is displayed with a blue background and a check mark symbol.

After you select a new language, the **Save** button becomes active and the button is displayed with a colour background. Pressing the button loads the selected language and the indication automatically switches back to the **Settings** menu. The user interface is also automatically changed to the selected language.

6.3.3.3 Submenu Date/Time

In this submenu, the date and time as well as the display format can be set. The settings made here can also be found in specifications for backup files or logs.

- In the menu **Settings** press the button **Date/Time**.

➤ The submenu **Date/Time** appears.

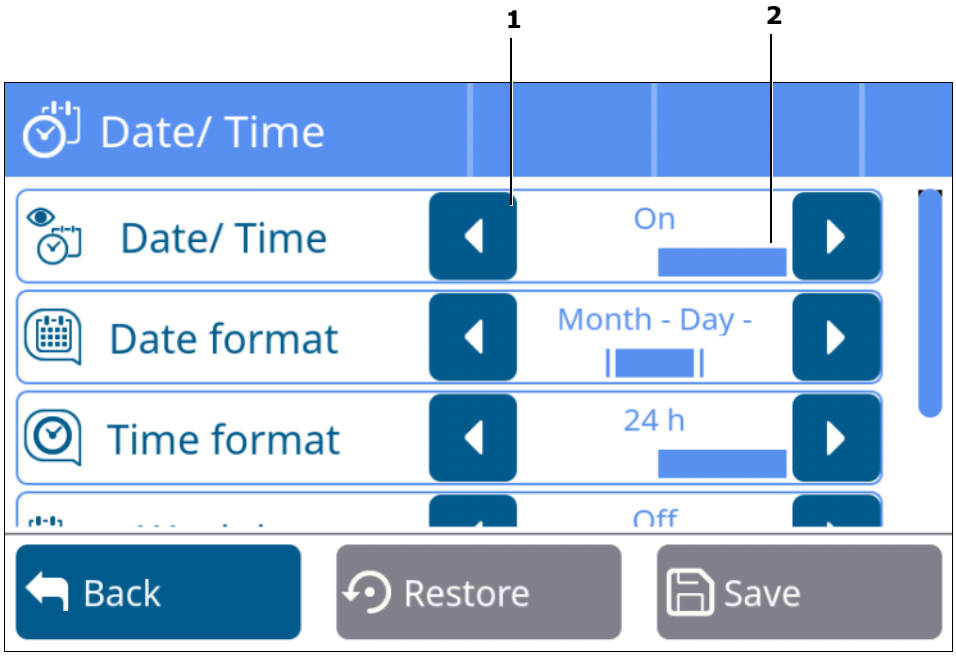


Fig. 16 Submenu Date/Time

1 Toggle (arrow) button, each to the right or left

2 Display of the selected setting

Displaying Date/Time

The toggle buttons can be used to set whether the date and time should be displayed in the menu bar. Choose between:
– On
– Off

Date format

The toggle buttons can be used to set the format in which the date is to be displayed. Choose between:
– Day/Month/Year
– Month/Day/Year
– Year/Month/Day

Time format

The toggle buttons can be used to set the format in which the date is to be displayed. Choose between:
– 12h
– 24h

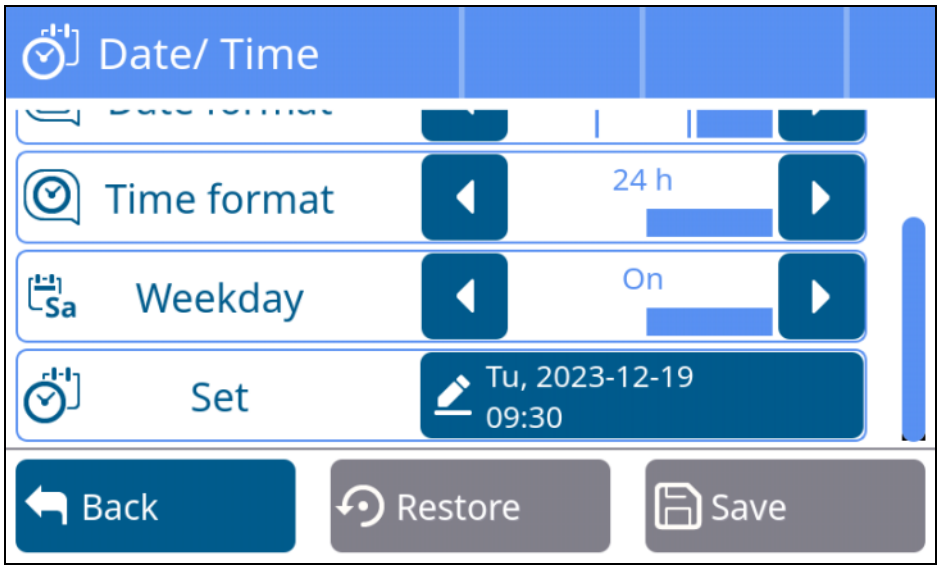


Fig. 17 Setting Date/Time

Weekday

The toggle buttons can be used to set whether or not the day of the week should also be displayed in the menu bar. Choose between:
- On
- Off

Set

Pressing this button opens another menu page.

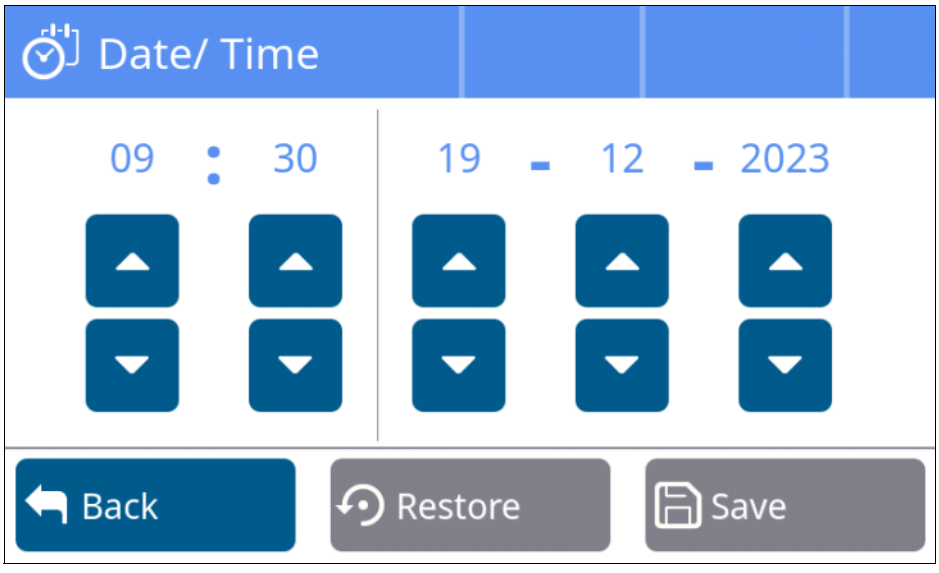


Fig. 18 Setting Date/Time

Here, the time can be set in the left area and the date in the right area using the toggle buttons. The setting depends on the previously selected time and date formats.

By pressing the **Save** button, the settings made are loaded and the indication automatically returns to the **Settings** menu.

INFO

If the CompoGuard *Advance* is connected to the DonationMaster *Advance*, the device will automatically synchronize with the settings in the DonationMaster *Advance*.

6.3.3.4 Submenu Display

In this submenu, the brightness of the user interface can be set.

Fig. 19 Adjusting the brightness

Brightness

A brightness between 10% and 100% can be selected via the toggle buttons. Each time one of the arrow buttons are pressed, the brightness increases or reduces by 10%. The setting is indicated by a percentage bar and as a value.

Main menu

The **Main menu** button can be used to switch between simple and advanced mode for the main menu (see 6.3.2 Main menu).

6.3.3.5 Submenu Sounds

In this submenu, settings can be made for acoustic signals, e.g., for alarm signals, donor signals, etc.

Fig. 20 Adjusting the acoustic signals

Use the arrow buttons to select settings here. Depending upon the device's features, the parameter may not be accessible. In the "DMA controlled" configuration mode, only the device volume can be adjusted. All other parameters are specified by the DonationMaster *Advance*.

Speaker Volume

A volume between 10% and 100% can be selected via the toggle buttons. Each time one of the arrow buttons are pressed, the volume increases or reduces by 10%. The setting is indicated by a percentage bar and as a value.

Button sound

Use the arrow buttons to set whether an audible signal is to sound when a key or a button is pressed. Choose between:
– On
– Off

Donation results

Use the arrow buttons to set whether an audible signal is to sound at the start of a donation. Choose between:
– On
– Off

Selftest completed

Use the arrow buttons to set whether an audible signal is to sound at the start of the selftest. Choose between:
– On
– Off

Low battery capacity

Use the arrow buttons to set whether an audible signal is to sound when a battery charge state of less than 10% is reached. Choose between:
– On
– Off

This option can only be selected on the *Basic* and *Data* models with the battery pack extra.

Before donation end

Use the arrow buttons to set whether an audible signal is to sound shortly before the stipulated donation time or fill volume is reached. Choose between:
– On
– Off

Donation end

Use the arrow buttons to set whether an audible signal is to sound when the stipulated donation time or fill volume is reached. Choose between:
– On
– Off

Ready to scan

Use the arrow buttons to set whether an audible signal is to sound when the device is ready to scan. Choose between:
– On
– Off

This option can only be selected on the *Data* (with additional equipment) and *Complete* models.

Successful scan

Use the arrow buttons to set whether an audible signal is to sound if a valid scancode is scanned. Choose between:
– On
– Off

This option can only be selected on the *Data* (with additional equipment) and *Complete* models.

Failed scan

Use the arrow buttons to set whether an audible signal is to sound if an invalid scancode is scanned. Choose between:
– On
– Off

This option can only be selected on the *Data* (with additional equipment) and *Complete* models.

Daily QC

Use the arrow buttons to set whether an audible signal is to sound during a daily start check. Choose between:
– On
– Off

This option can only be selected if the daily start check is active in DonationMaster *Advance*.

Ready to seal

Use the arrow buttons to set whether an audible signal is to sound when the device is ready to seal. Choose between:
– On
– Off

This option can only be selected on the *Data* (with additional equipment) and *Complete* models.

Successful seal

Use the arrow buttons to set whether an audible signal is to sound after successful sealing with the sealing unit. Choose between:
– On
– Off

This option is only available for the model *Complete*.

Failed seal

Use the arrow buttons to set whether an audible signal is to sound after unsuccessful sealing using the sealing unit. Choose between:
– On
– Off

This option is only available for the model *Complete*.

6.3.3.6 Submenu Exchange

You can exchange donation data via the USB interface on this submenu. Device data can be exported and device settings can be imported.

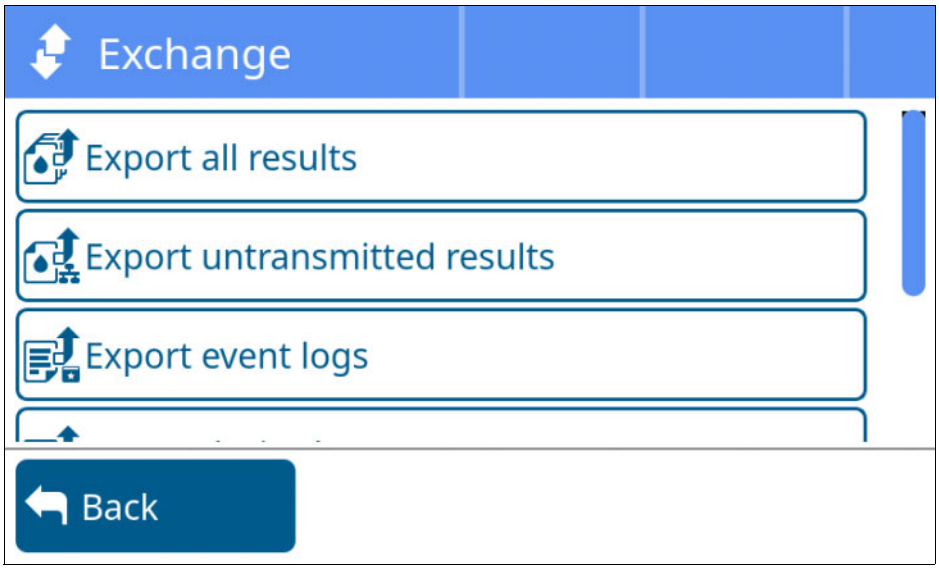


Fig. 21 Submenu Data exchange

- Press the **Export all results** button.

➤ A further menu page appears.

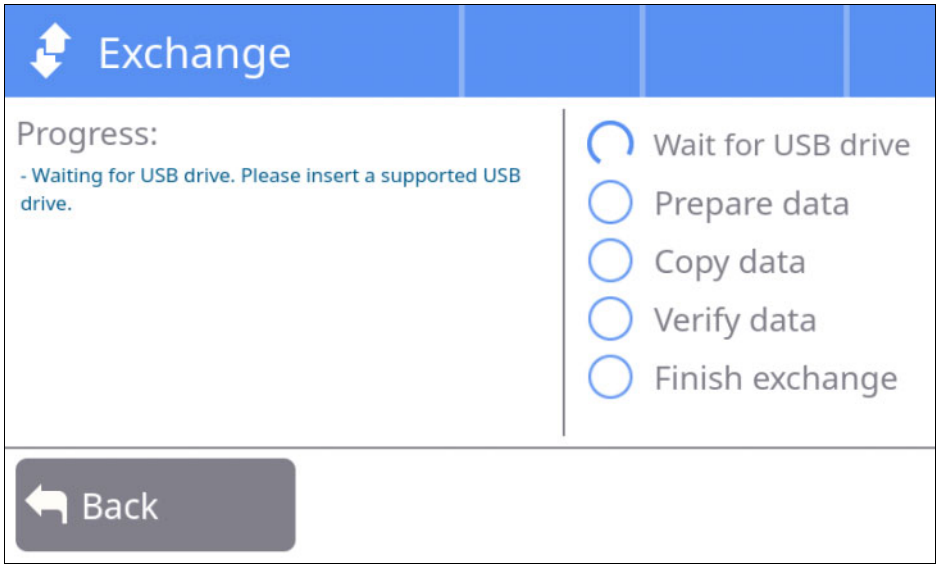


Fig. 22 Testing the USB stick

- Insert a compatible USB stick in the front of the device (Fig. 1, Item 5). The **Start** button is displayed.

NOTE

You must ensure that the USB sticks used for the device have FAT32 format.

The device checks the USB stick before the export. The data export starts if the check is successful.

In the right-hand area of the page, the respective steps are listed and are indicated by a rotating circle symbol while they are being "executed". If the "execution" was successful, a tick symbol appears.

At the same time, information on the current status is listed in the left-hand area of the page during "execution".

All data sets with results in the device's internal memory are saved on the USB stick and deleted from the device's internal memory.

Importing the donation data from the USB stick into the DonationMaster *Advance* software is possible.

Prerequisites for writing the donation data from the device to the USB stick are:

- the donation is finished
- the device is in standby mode
- the safety clamp is closed
- a data set is available
- sufficient space is available
- the device is not connected to DonationMaster *Advance*

Once the export is completed, a corresponding message appears on the user interface. You can now remove the USB stick.

If the data export was completed successfully, the **Back** button becomes active. Pressing this button returns the display to the **Settings** menu.

6.3.3.7 Submenu Information

Information about the device, e.g., the serial number, the device type, as well as the version of the software for the user interface is displayed on this submenu.

Fig. 23 Submenu Information

Use the **Service** button to select the **Service** submenu. Only trained service personnel can open this submenu.

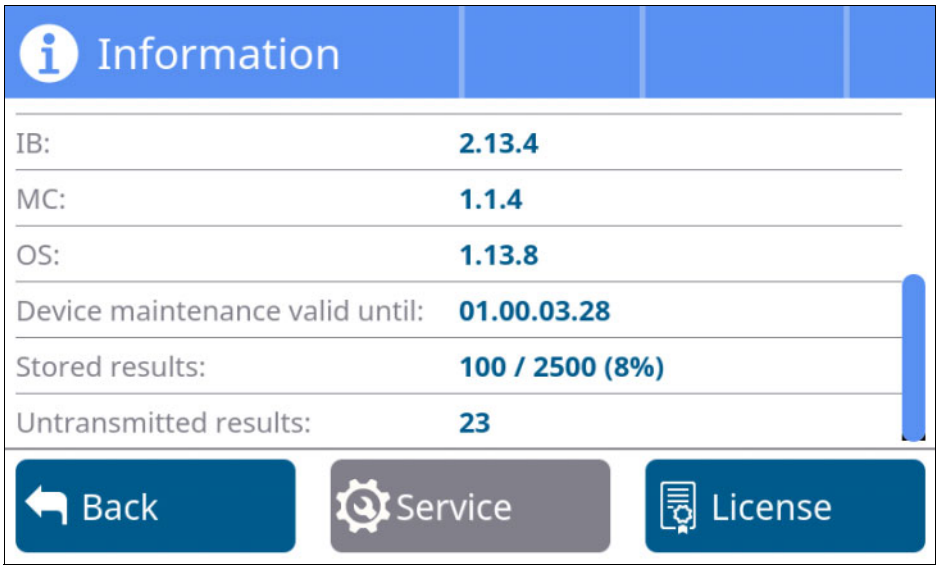


Fig. 24 Submenu Information

Via the **License** button all used software licenses, etc. are be displayed in the menu **License**.

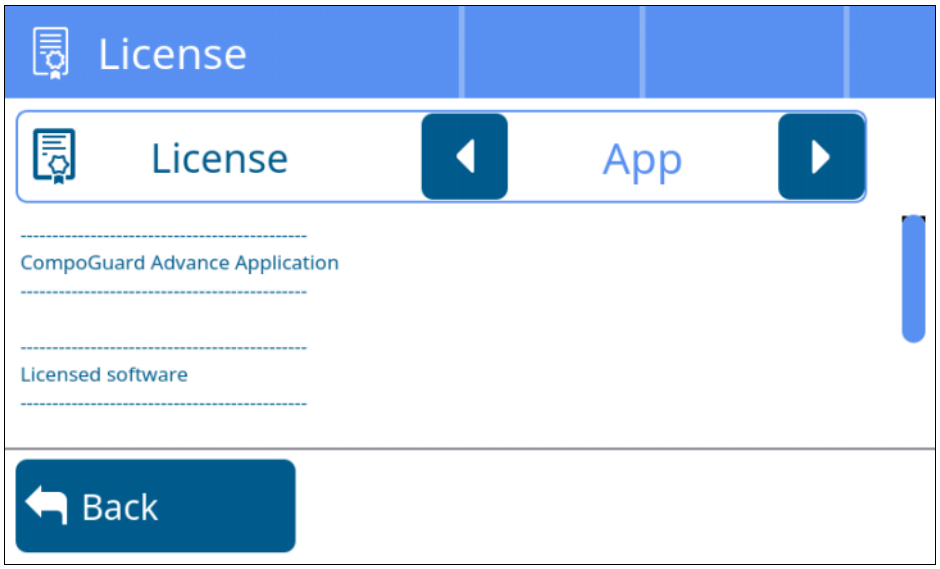


Fig. 25 Submenu License

The **Back** button returns the display to the menu **Settings**.

6.3.3.8 Submenu Network

In this submenu all settings for implementing the device into a network are made.

After you open this submenu, a dialogue box is displayed where you must enter the access PIN.

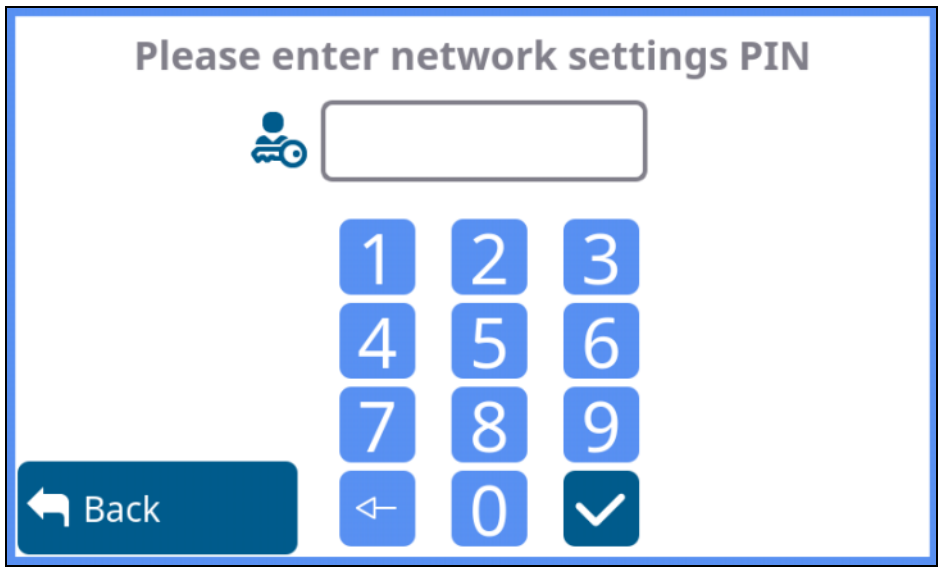


Fig. 26 PIN entry

The first time the network settings are accessed:

- Enter *1111* as the PIN using the keyboard on the user interface.
  You should change the pin the first time you access the settings.
- Accept your entry using the check mark button.

➤ The menu **Network** appears.

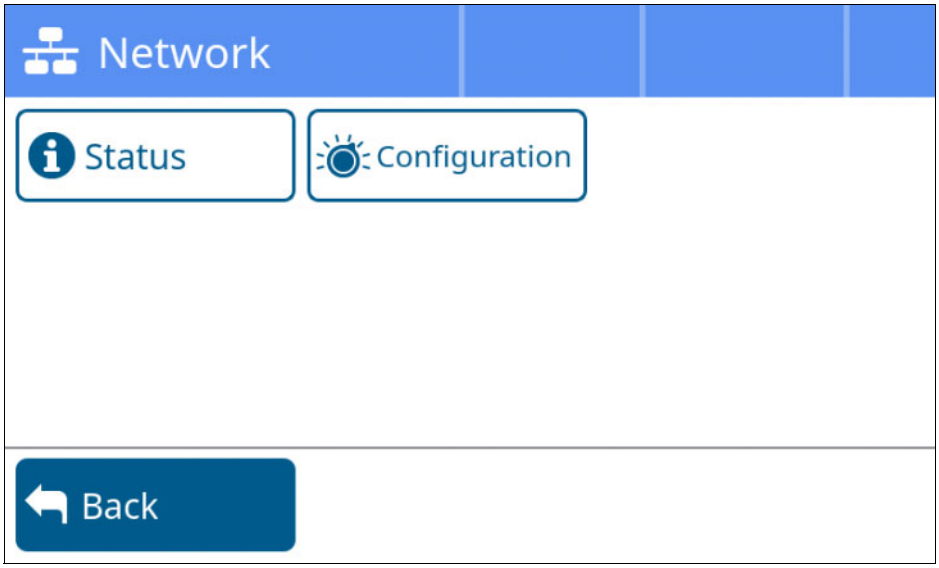


Fig. 27 Submenu Network

Use the **Status** button to access information about the current device network settings on the following pages.

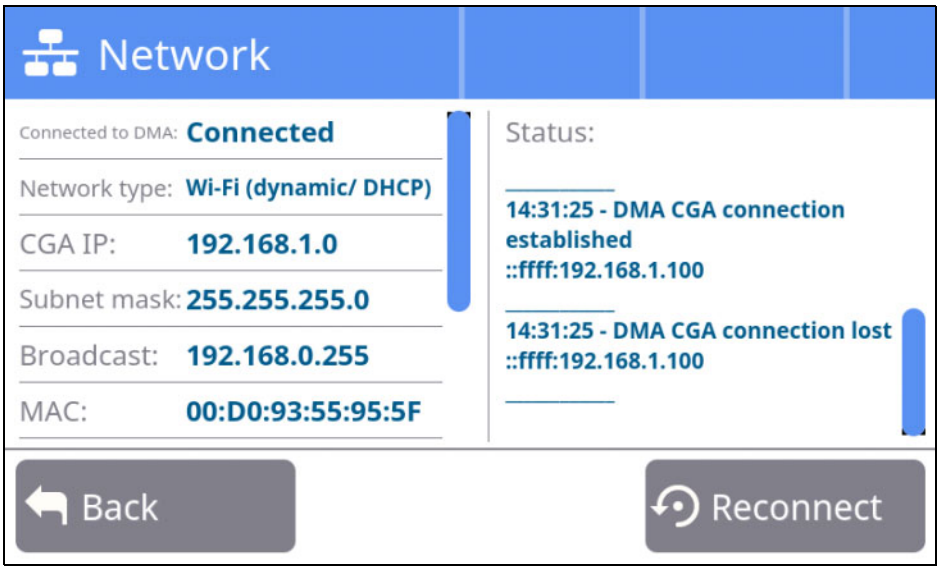


Fig. 28 Submenu Network - Status

Use the **Configuration** button to configure the device's network settings.

Fig. 29 Submenu Network - Configuration

The settings you can specify include:

- The network type (e.g., WLAN or LAN)
- The IP address for the network in which the device is to be integrated.
- The SSID

After making changes, press the **Save** button to apply the changes.

The **Back** button returns the display to the menu **Settings**.

6.3.3.9 Submenu Components

The components Scale, Scanner and Sealer can be used in this submenu. This allows them to be checked for functionality, for example.

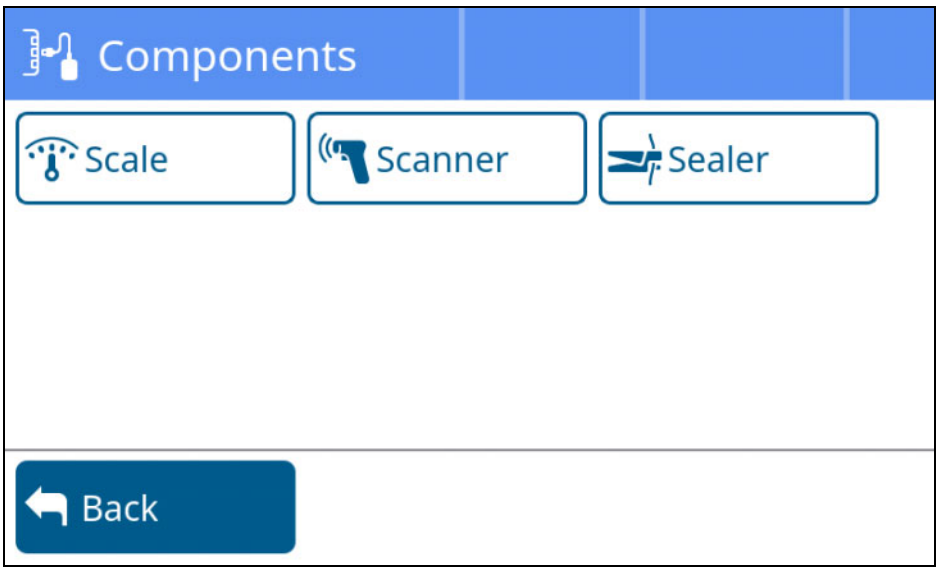


Fig. 30 Submenu Components

6.3.4 Program selection

The **Programs** menu lists all the donation programs available for the CompoGuard *Advance*.

INFO

You can only prepare and/or delete programs using DonationMaster *Advance* (on this topic see the User Manual).

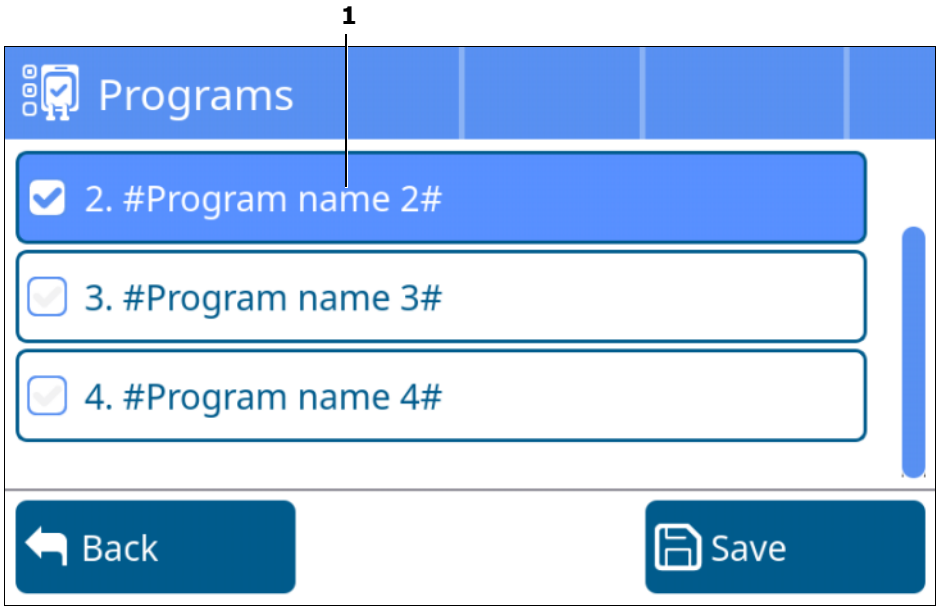


Fig. 31 Menu Program selection

1 List of selectable donation programs

- In the main menu press the **Programs** button (Fig. 11, Item 3).

➤ The menu **Programs** appears.

- Select a donation program and press the **Save** button.

➤ The selected program button changes background colour and is displayed with a check mark.

After leaving the menu by pressing the **Back** button, the donation program is loaded and displayed in the main menu (Fig. 11, Item 2).

6.3.5 Starting the program

In this menu the previously selected donation program (see chapter 6.3.4 on page 59) is started. Prompts are displayed with all the necessary work steps in the form of both graphics and text.

- In the main menu press the **Start** button (Fig. 11, Item 5).

➤ A test movement of the tray is started. This is to ensure that the mixing tray is free to move.

After the successful conclusion of the test phase, the tray stops in the position tilted toward the rear of the device. This ensures that the maximum tube length from the clamp to the outermost deflection of the mixing tray is provided when the donation bag is inserted later.

If the test phase has not been completed successfully after the stipulated time has elapsed, this situation is indicated by a yellow border on the user interface.

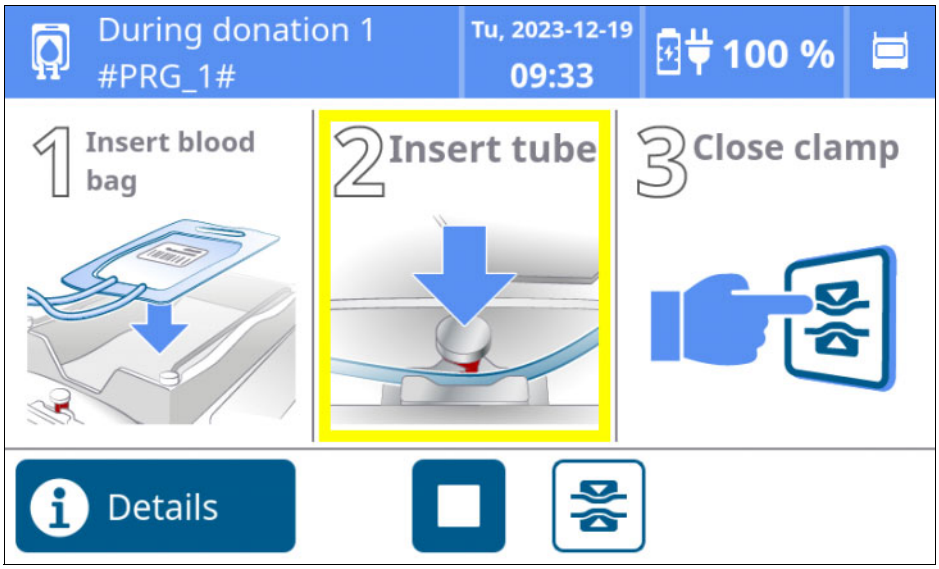


Fig. 32 Error indication during a work step

The functions for operating the device are explained in the following illustration.

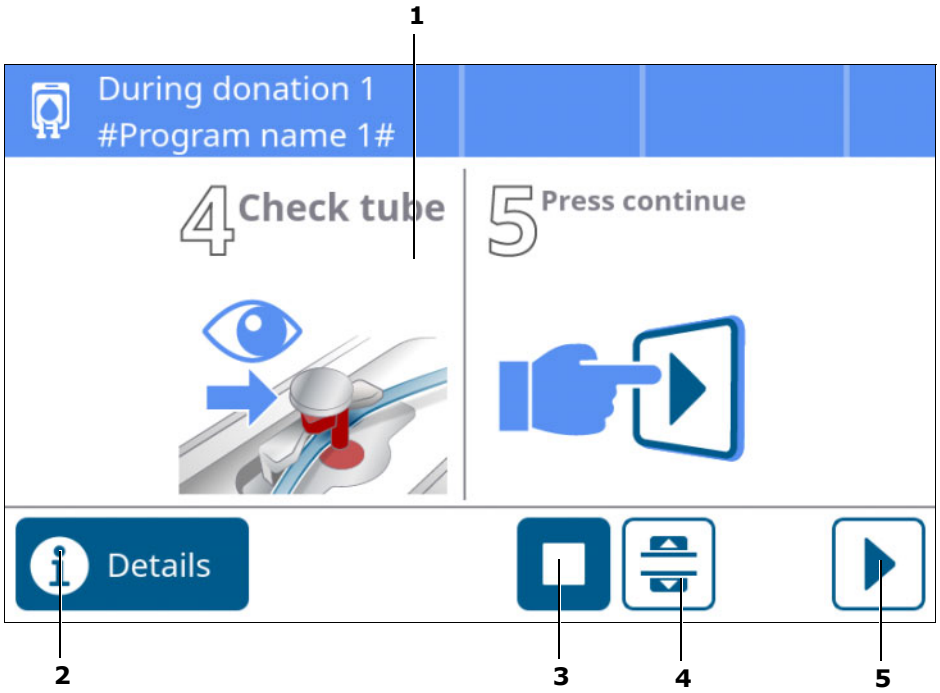


Fig. 33 Donation menu - (during the donation)

1 Depiction of work step instructions in the correct sequence

2 Button **Details**

3 Button **Stop**

4 Button **Close/Open clamp**

5 Button **Continue**

INFO

The displays in the **Donation** menu depend on the selected program step. Further displays can be shown in addition to the steps described below. If a program step includes, for example, the scanning of a scancode, this is also shown symbolically on the user interface in the specified sequence.

The **Details** menu consists of three sections divided into:

- Before the donation
- During the donation
- After the donation

It is possible to view, at any time, through the menu page, which additional steps (e.g., scan scancode, seal tube, etc.) are necessary due to the selected donation program. This page can be selected from any other menu page in the **Donation** menu.

- For this purpose, press the **Details** button (Fig. 33, Item 2).

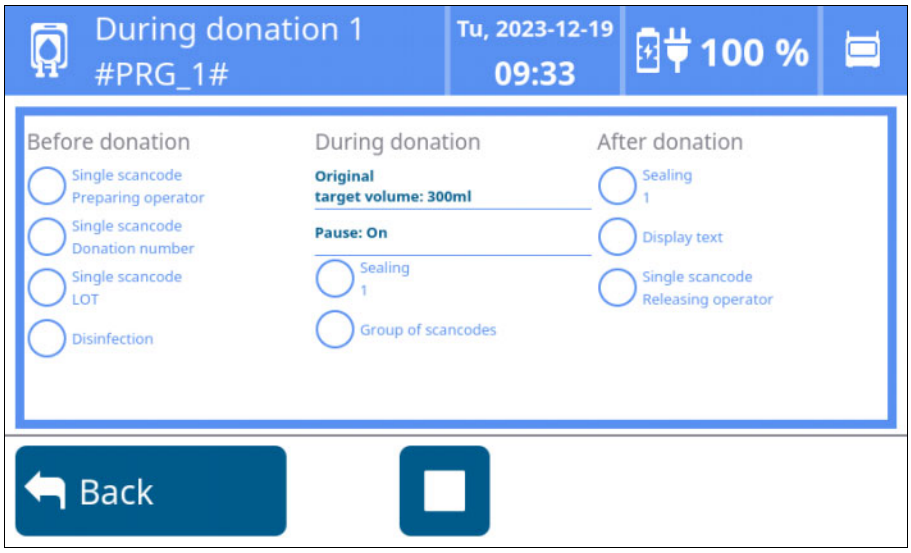


Fig. 34 Information about donation program selected

- Press the **Back** button to return to the previous page.
  The display returns automatically to the previous page after 5 seconds.

● Before the donation

The work steps before the donation are displayed and depicted symbolically on these two pages.

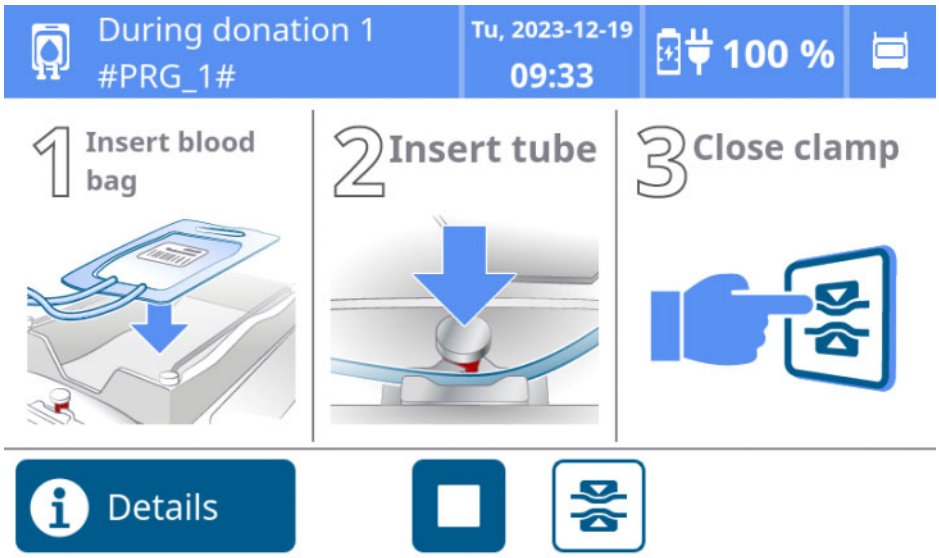


Fig. 35 Sequence before the donation - steps 1-3

1 Insert blood bag

- Place the empty donation bag in the mixing tray.
- If the bag system is equipped with a filter, secure the filter using one of the filter holders on the side of the mixing tray.

2 Insert tube

- Insert the tube into the safety clamp.

3 Close clamp

- Press the **Close clamp** button (Fig. 33, Item 4).

INFO

The tube can only be clamped by pressing the button and not via the instruction on the user interface.

➤ The safety clamp closes and clamps the tube securely. The **Close clamp** button changes to **Open clamp**. The indication on the user interface changes to the next page.

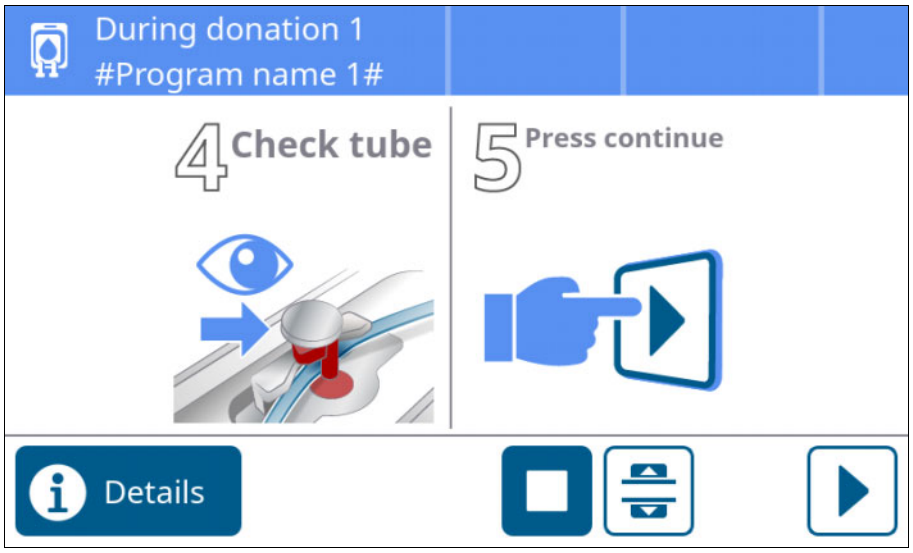


Fig. 36 Sequence before the donation - steps 4-5

4 Check tube

- Check the clamping of the tube for correct fit.

5 Press continue

- Press the **Continue** button to continue the donation program.

If the device detects an error during the work steps, the program step with the error appears with a yellow border after pressing the **Continue** button.

If, for example, the tube was not clamped properly, the safety clamp moves to the open position and the button becomes active again.

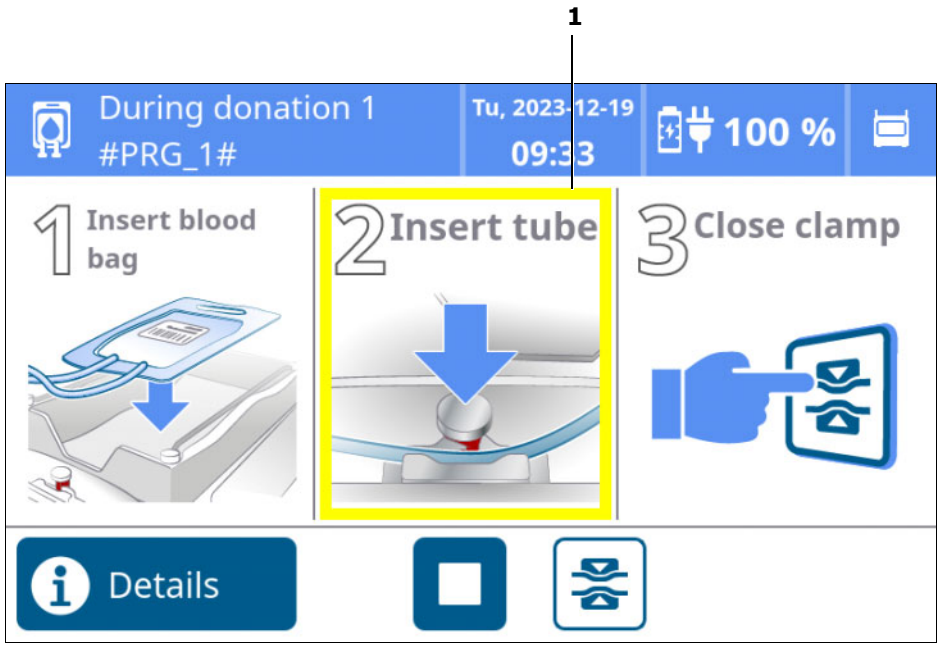


Fig. 37 Donation menu - example error message

1 Error display

INFO

The program can only be continued if all program steps have been carried out correctly before the donation.

After correctly inserting the bag system and clamping the tube, press the **Continue** button to display the **During donation** page.

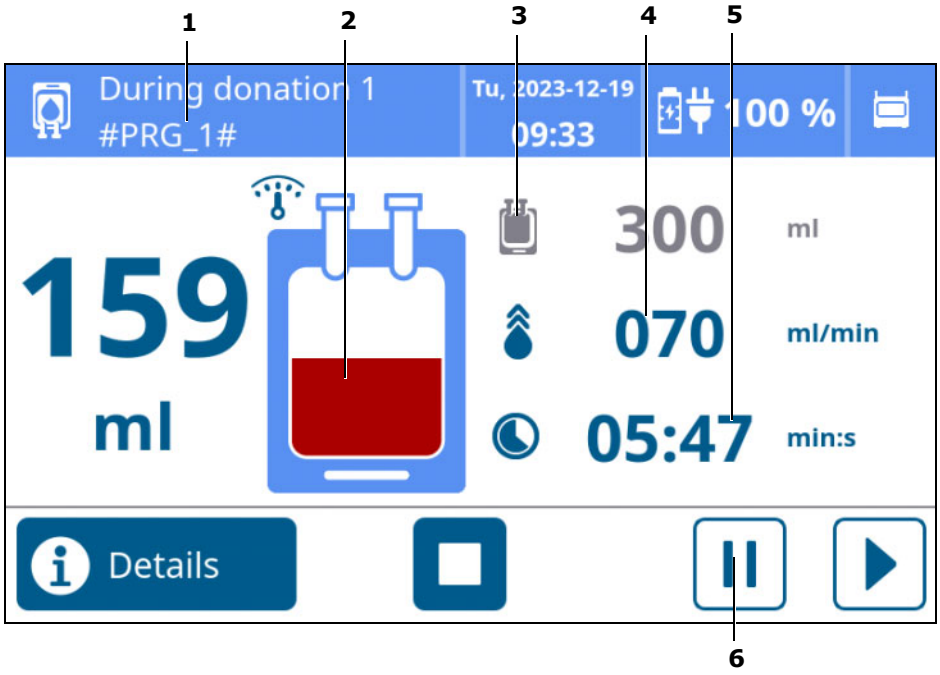


Fig. 38 Donation program menu - During donation

1 Indication of the donation program selected

2 Donation bag graphic with current fill volume in milliliters and as fill level in the blood bag

3 Indication of the target volume from the donation program in milliliters

4 Indication of the flow rate in milliliters per minute

5 Indication of the duration of the donation, including donation pauses, in minutes and seconds

6 Button **Pause**

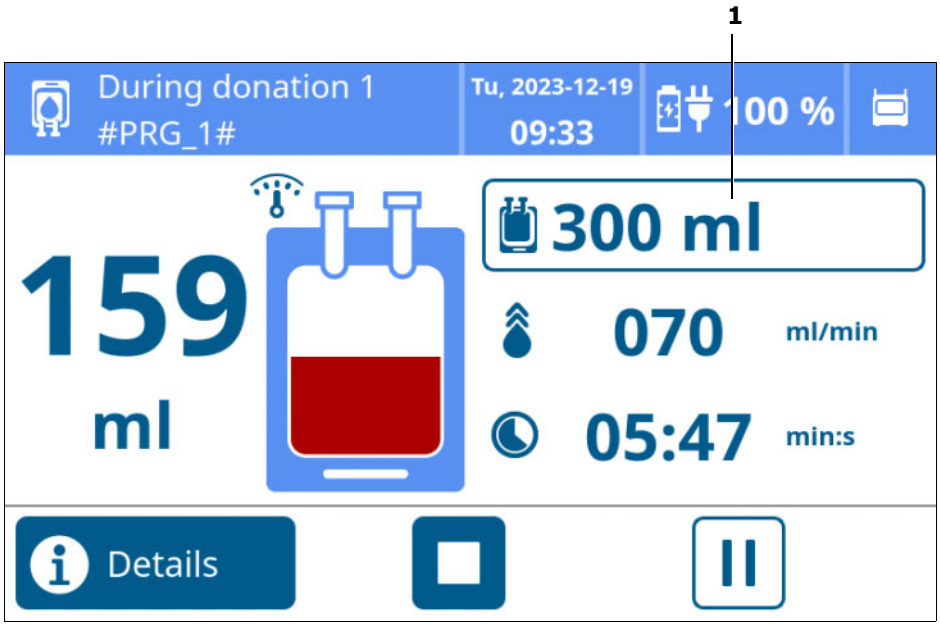


Fig. 39 Donation menu - during the donation (start)

1 Target volume, can be changed

If the indication for the target volume has a colour background (not shown), the target volume can be changed.

This option must be specified in the donation program.

- Press the display area for the target volume.

A menu for changing the target volume appears.

Fig. 40 Donation menu - changing the target volume

- Use the arrow buttons to change the value.
- Press the **Save** button to save the change.
- Press the **Back** button.

➤ The display changes back to the previous page. The new target volume is displayed.

● During the donation

Start the donation process

- Press the **Start** button.

➤ The tray undertakes a short mixing movement.
The safety clamp opens and the donation starts immediately.

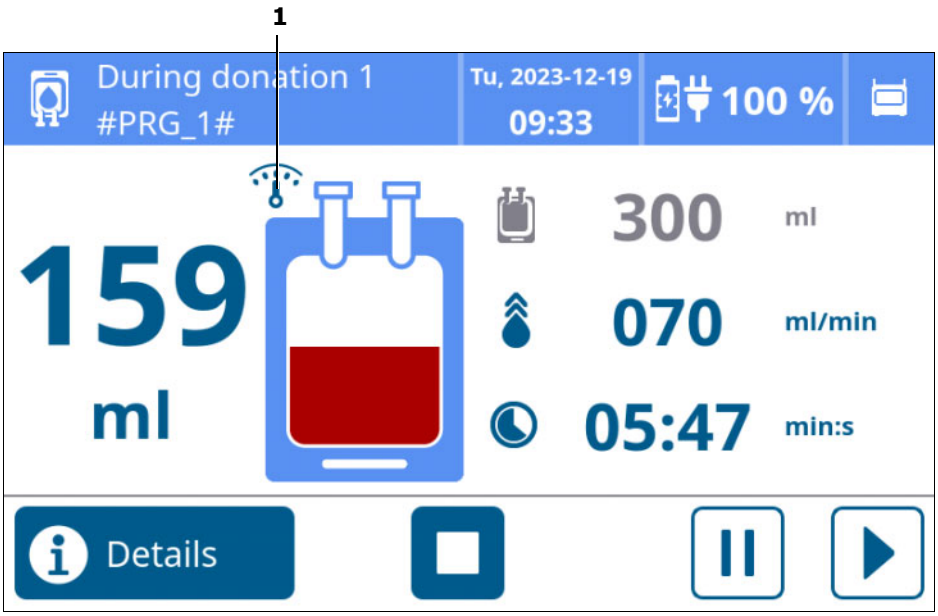


Fig. 41 Donation program menu - Donation started

Changing symbols appear at the top left beside the graphic depiction of the bag (Fig. 41, Item 1). These provide an additional indication of the current state of the tray.

Possible states are listed in the following.

Indicates that the bag is stationary at the start of the donation and is waiting for blood. (Waiting time before first mixing movement - can be configured in DonationMaster *Advance*.)

Indicates mixing movements after the start of the donation - can be configured in DonationMaster *Advance*.

Indicates that the bag is stationary and is waiting for blood.

Indicates that bag mixing is currently in progress.

Indicates that bag weighing is currently in progress.

During the donation, the mixing tray performs regular mixing movements.

Pause donation

If the donation program includes a pause as a program step, the **Pause** button becomes active on the user interface. It is possible to trigger the pause manually via the button if this is requested by the program.

- Press the **Pause** button.

➤ The safety clamp closes.

- To end the pause, press the **Start** button.

➤ The safety clamp is opened.

Or there is an automatic pause during donation if requested by the program. The safety clamp closes and opens automatically.

The donation continues.

Stop donation

If a donation has to be stopped, this is done via the **Stop** button.

- Press the **Stop** button.

➤ A prompt appears.

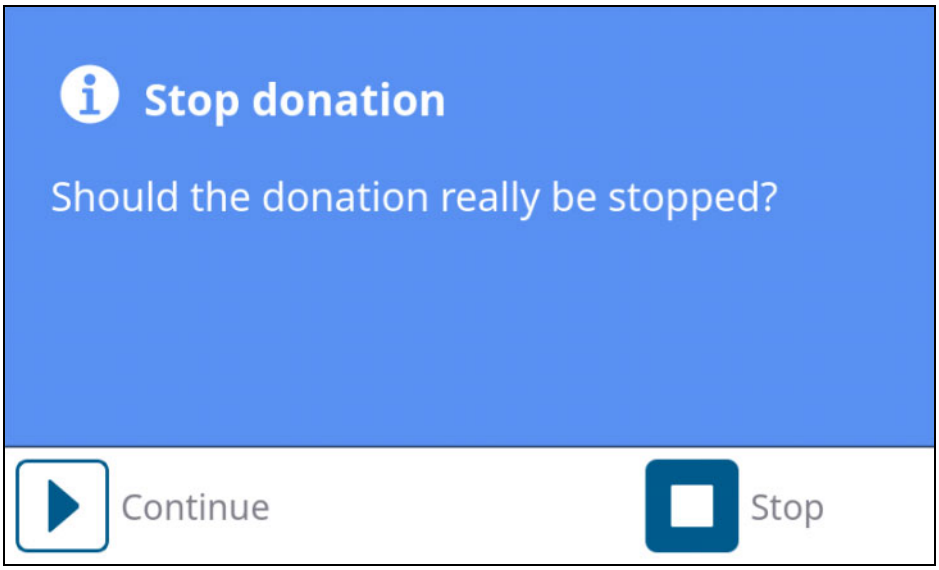


Fig. 42 Prompt to end the donation

- Press the **Stop** button to stop the donation.

➤ The safety clamp closes. The donation cannot be continued and has come to an end (see **After the donation** on page 72).

- Press the **Continue** button to continue the donation.

➤ The display changes back to the previous menu.

Notes during the donation

During the donation process, various conditions may occur. These conditions are displayed in the bag symbol and through a change of background colour. The corresponding parameter is also displayed with a colour background. Acoustic signals can be muted using the **Mute** button.

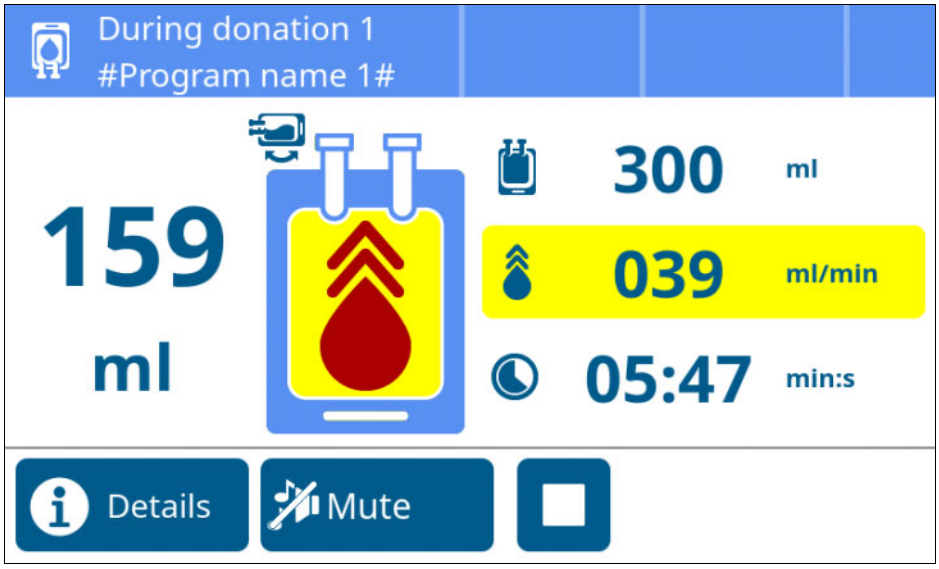
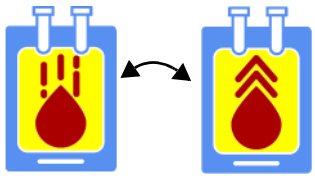


Fig. 43 Presentation of indications during the donation (example only)

The following are possible conditions for blood flow.

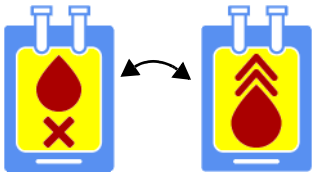


High blood flow rate:

The animation switches back and forth between the two representations. If this message is displayed, the blood flow is too fast (> 20 mL/min).

- A visual display appears at the gooseneck.
- The safety clamp closes.
- The mixing movement continues.

After checking the cause, the safety clamp must be actively opened, using the **Open clamp** button.



Low blood flow rate:

The animation switches back and forth between the two representations. If this message is displayed, the blood flow is too slow (< 20 mL/min) or there is no blood flow.

- A visual display appears at the gooseneck.
- The safety clamp remains open.
- The mixing movement continues.

The alarm automatically disappears once the desired flow rate has been achieved.

Weight jump:

The animation switches back and forth between the representations. If this message is displayed, a sudden increase in weight has been detected. (For example, something has fallen into the mixing tray).

This parameter can be configured in DonationMaster *Advance*.

Weight drop:

The animation switches back and forth between the representations. If this message is displayed, a sudden weight loss has been detected. (For example, the bag is taken out of the mixing tray).

This parameter can be configured in DonationMaster *Advance*.

Preliminary flow alarm:

The animation switches back and forth between the representations. If this indication appears, a preliminary flow rate alarm has been triggered. It is indicated to the donor that the donor can increase the low flow rate by making a fist.

– A visual display appears at the gooseneck.

A further indication appears shortly before the end of the donation:

Just before reaching the target volume or the maximum donation time, an audible signal sounds and the volume of blood (Fig. 44) or the donation time (Fig. 45) is displayed with a yellow background on the user interface.

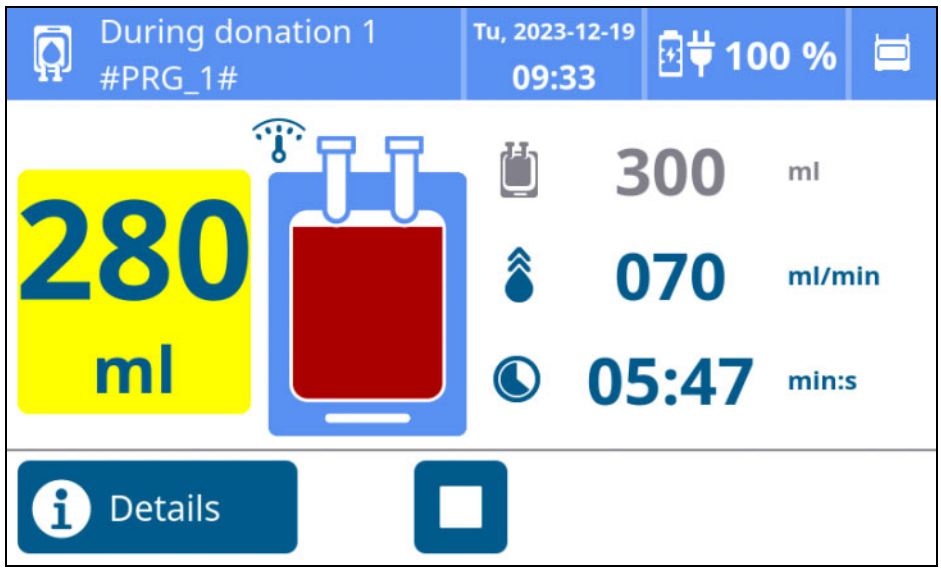


Fig. 44 Indication just before reaching the target volume

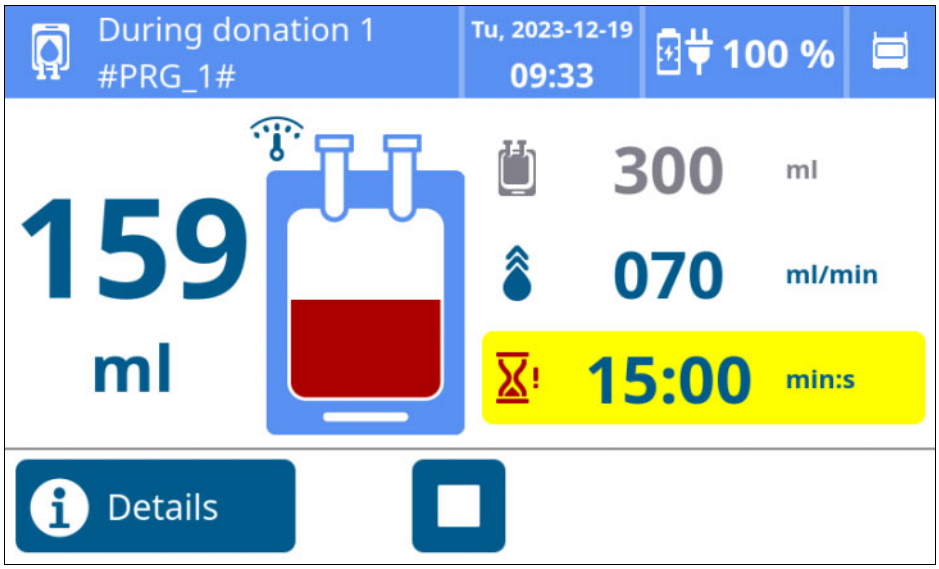


Fig. 45 Indication just before the donation time elapses

Just before the end of the donation, the tray no longer undertakes any mixing movement to achieve the highest possible accuracy while measuring the volume of blood.

Once the target volume or the maximum donation time is reached, the safety clamp closes automatically. The tray now undertakes mixing movements again. Depending on the setting, an acoustic signal can also be triggered at the end of the donation.

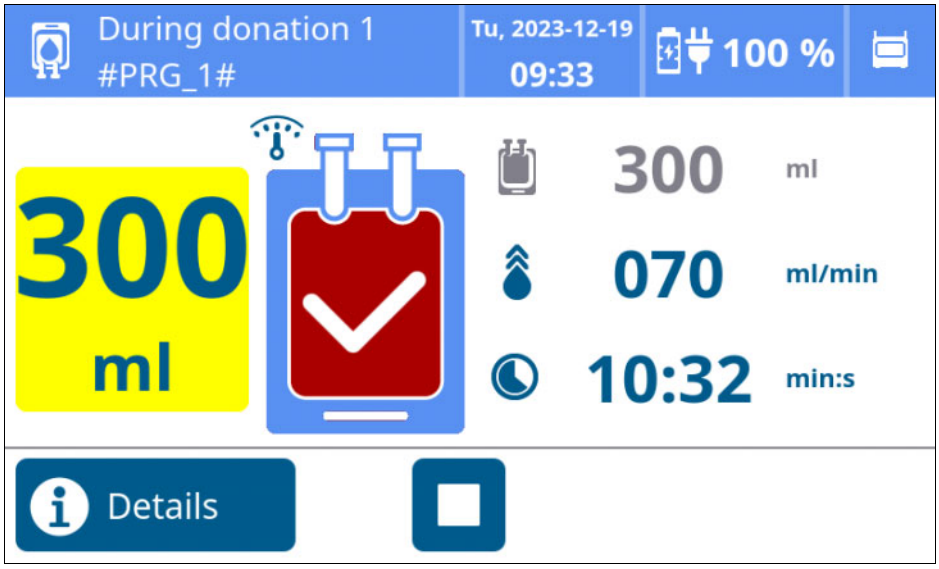


Fig. 46 End of the donation reached

- Press the **Continue** button.

➤ The indication changes to the next page (after the donation).

After the donation

The work step sequence, following a donation, are described here.

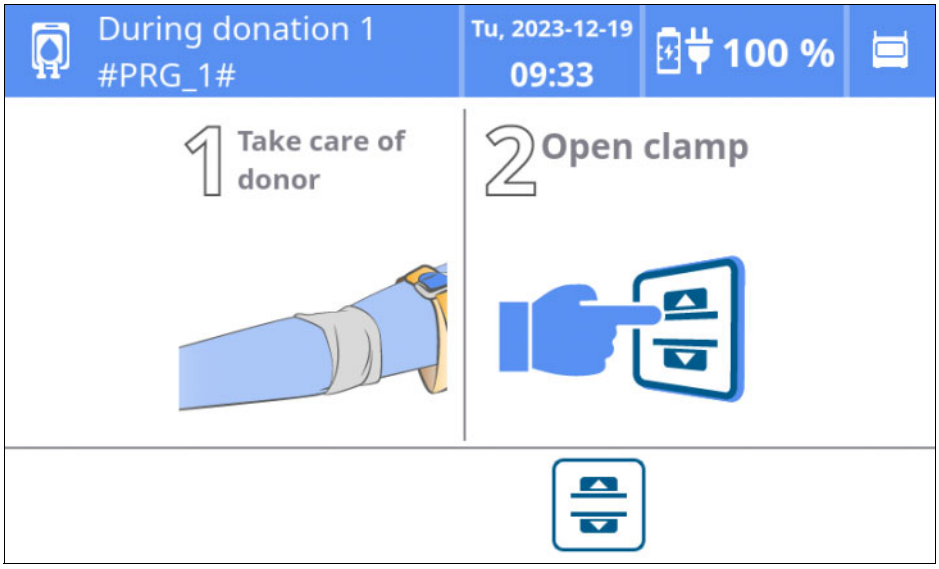


Fig. 47 Sequence after the donation

1 Take care of donor

- Disconnect the line set from the donor as per the instructions issued by the blood bank and treat the venepuncture site.
- Seal the line using the hand-held sealer (with model CompoGuard *Advance* Complete). If using the CompoGuard *Advance* Basic or CompoGuard *Advance* Data models, a separate hand-held sealer may be used.

2 Open clamp

- Press the **Open clamp** button.

➤ The safety clamp opens and releases the tube.

INFO

The tube can only be released by pressing the button and not through the representation on the user interface.

By combining the CompoGuard *Advance* safety clamp and the sealing, air can be prevented from entering the primary blood bag.

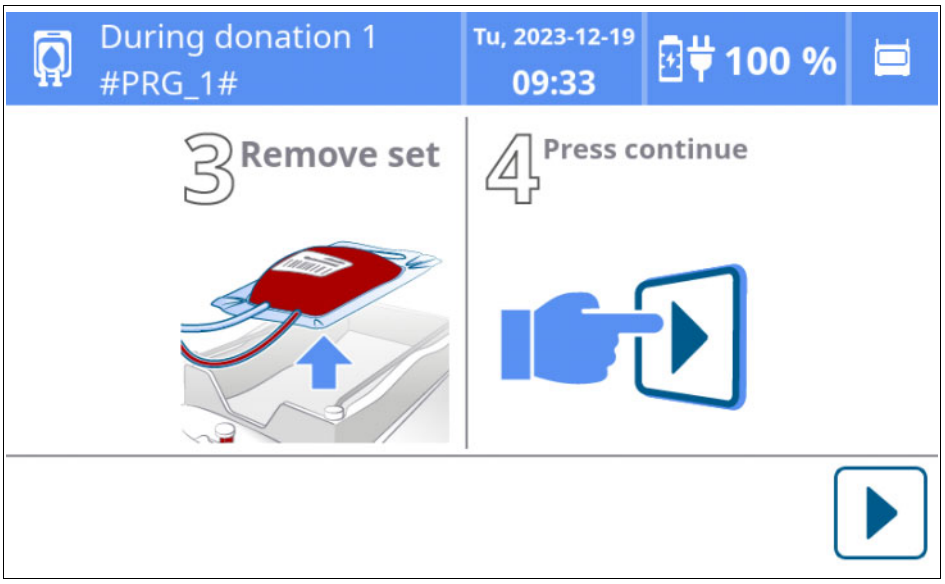


Fig. 48 Sequence after the donation - 2

3 Remove bag and tube

- Remove the donation bag and the tube from the tray.

4 Press continue

- Press the **Continue** button.

➤ The donation is finished. The main menu (Fig. 11) appears.

6.3.6 Interruption of donation due to power failure/unresponsive device

If the system stops responding during the donation, it is possible to complete the donation after a restart.

The tube can be sealed, depending on the device model. The clamp can be opened using the button, and the bag system can be removed.

The current progress during the donation is saved and sent to DonationMaster *Advance* in the DMA mode.

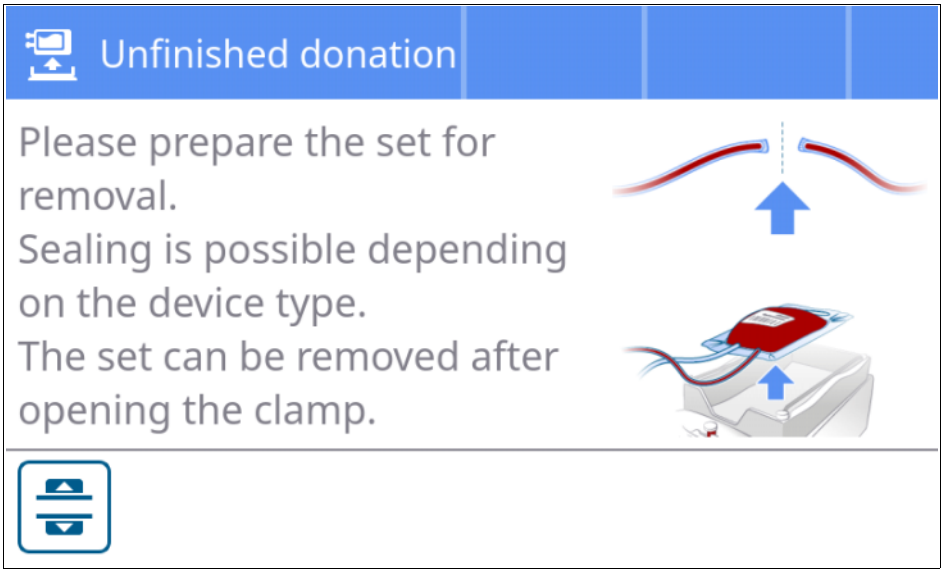


Fig. 49 Indication of an unfinished donation

6.4 Donation with DonationMaster *Advance*

INFO

The software DonationMaster *Advance* provides additional donation functions with the CompoGuard *Advance*.

In combination with the software DonationMaster *Advance*, functions additional to the settings described above on the CompoGuard *Advance* are possible. These additional functions can be activated without the need to make extensive settings on the device.

The donation programs executed by the CompoGuard *Advance* are prepared in DonationMaster *Advance* and transferred to the device (can be automatic or manual) as soon as the device is integrated into the DonationMaster *Advance* network. The donation programs include all the necessary steps to be taken before, during and after a donation. These can be, among others, scancode scans, seals and labelling.

NOTE

A disconnection during data transfer between the device and DonationMaster *Advance* can result in a risk of data loss.

- Do not disconnect the connection during data transfer.

NOTE

The donation processes programmed have been tested to achieve the desired results. Changing donation parameters can change the donation time and affect the quality of the donation. Changes are made at the sole risk of the operator.

E.g., the sequence of the individual steps is defined in the donation program. It is thus possible to provide an automatic pause to interrupt the mixing movements of the mixing tray during the donation and to be able to label the donation bag (see **Pause donation** on page 68).

The operating mode is also set by DonationMaster *Advance*. The operating mode determines how the donation programs are selected in CompoGuard *Advance*. This is displayed in the main menu (Fig. 11, Item 2) of the device.

Operation mode: Manual

In this operation mode, the donation program must be selected manually. The programs are not transferred automatically from DonationMaster *Advance* to the device.

Only one program can be selected from the pre-set programs; these programs differ in the parameters, program steps and blood bag systems (double or triple). It is not possible to select more than one program at a time.

The procedure for donation is as previously described. The individual work steps depend on the specifications in the selected donation programs.

A start scan can be scanned to automatically select a donation program.

7 Equipment

WARNING

Risk of injury and device damages

The use of non-approved equipment may cause a risk of injury to the patient and operator, as well device damages. Electromagnetic emissions or reduced electromagnetic immunity may result in malfunctions and incorrect operation.

- Use only original equipment approved by the manufacturer.
- Use only original batteries and battery packs approved by the manufacturer.
- Use only original coaxial extension cables for the hand sealer.
- Do not use USB extension cables.

Only the manufacturer or trained personnel (technician) are permitted to undertake assembly, expansion, adjustment, modification or repair.

7.1 Scope of delivery

7.1.1 Overview of Models

Three models of the CompoGuard *Advance* are available.

CompoGuard *Advance* Basic

The *Basic* model includes the basic equipment.

CompoGuard *Advance* Data

The *Data* model is also equipped with the gooseneck (see 7.2.1 Gooseneck) and a WLAN stick.

CompoGuard *Advance* Complete

The *Complete* model includes the features of the *Basic* and *Data* and is also equipped with the hand-held sealing unit (see 7.2.3 Hand sealer with hand sealer generator) and the battery pack (see 7.2.4 Battery pack).

7.1.2 AC adapter

The plug-in power supply device is part of the scope of delivery.

7.2 Additional equipment

WARNING

Any additional equipment connected to the device's analogue or digital interfaces must comply with the applicable EN standards (e.g., EN IEC 62368-1 for data processing equipment and EN 60601-1 (IEC 60601-1) for electro-medical equipment).

The connection of additional equipment to the signal input or output component affects the system configuration and anyone connecting additional equipment is therefore responsible for compliance with the system standard EN 60601-1-1 (IEC 60601-1-1).

The additional equipment listed in these instructions for use are approved within the framework of the CE conformity assessment procedure.

7.2.1 Gooseneck

The gooseneck can be obtained as additional equipment from Fresenius Kabi. The gooseneck allows for the use of basic functions on a raised control panel making operation easier to reach and preventing unnecessary stooping. Important information about the donation process is displayed visually to the operator and the donor.

For the models CompoGuard *Advance Data* and *Complete* the gooseneck is part of the basic scope of delivery.

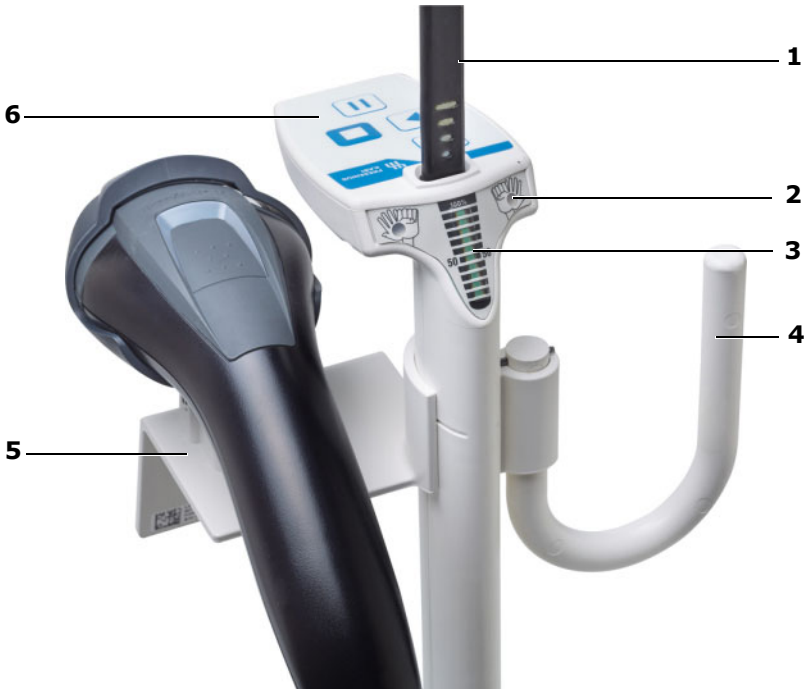


Fig. 50 Gooseneck components

1 Optenna/elevated alarm indicator

2 Preliminary flow alarm

3 Donor display (for the donor)

4 Holder for the hand sealer

5 Scanner holder

6 Raised control panel

The holders are used to attach the (optional) hand sealer and the (optional) 1D/2D barcode scanner. Data can be scanned even with the scanner fitted in the holder.

The Optenna can be extended progressively between the two marks and has an alarm indicator which can be seen from a distance.

INFO

Do not draw the Optenna out of the gooseneck beyond the lower marking.

If the Optenna is drawn out of the gooseneck, squeeze the springs (Fig. 51, Item 1) on the lower part of the optenna when reinserting it. As the Optenna and the holder in the gooseneck are conically shaped, ensure that the correct orientation is chosen.

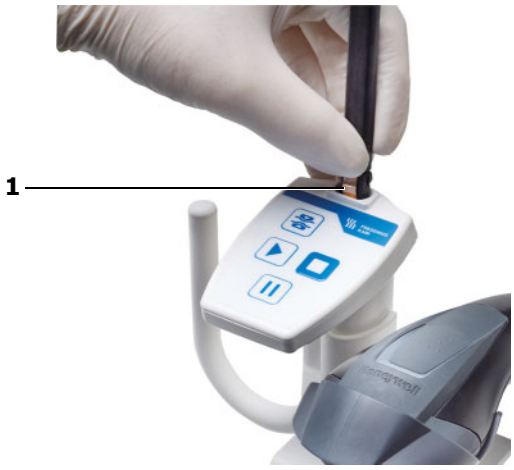


Fig. 51 Inserting the optenna

The donor display shows the donor the progress during the donation with a bar-graph in percent. Furthermore, a flow pre-alarm is indicated to the donor by flashing 2 red LEDs. This alarm can be counteracted by the donor repeatedly clenching and opening their fist, thus increasing the blood flow.

The raised control panel corresponds to the donation-relevant keys of the CompoGuard *Advance*. It allows operation in a standing or sitting position without stooping.

7.2.2 Barcode scanner

The barcode scanner can be obtained as optional equipment from Fresenius Kabi. The 1D/2D barcode scanner is programmed as standard for direct use with the CompoGuard *Advance*. This is used to read in scancodes.

The barcode scanner option is specifically configured for use with the CompoGuard *Advance*. The barcode scanner is provided for scanning various scancodes used for documentation and checks.

The barcode scanner must be connected to the USB connector on the CompoGuard *Advance*.

The 1D/2D barcode scanner connected is activated when you switch on the CompoGuard *Advance*.

The scanner is provided with an auto-sense function. This function enables the operator to scan and document a scancode with minimal handling.

INFO

You will find detailed information about the auto-sense function in the related addendum with the scanner settings.

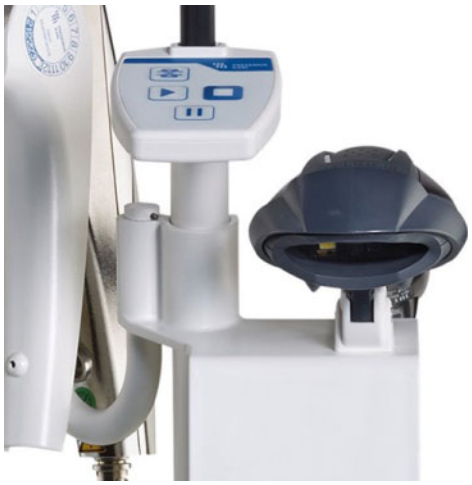


Fig. 52 Scanning with the 1D/2D barcode scanner

Initialization process:

If the scanner no longer functions correctly, it can be re-initialized with the aid of the scancode initialization diagram supplied with the scanner. The exact procedure for initialisation must be carried out according to the description supplied with the scancode initialisation plan.

7.2.3 Hand sealer with hand sealer generator

WARNING

Electrical hazard

The hand sealer electrodes are under electrical voltage during the sealing process.

- Never touch the electrodes on the hand-held sealer during the sealing process.
- Never place electrically conductive material in the hand sealer or between the sealing electrodes.

WARNING

Risk of infection

Improper handling or technical defect with the hand sealer may result in risk of infection caused by leakage/spillage of the tubing content (blood) and temporary failure of the sealing function.

- Never attempt to pull the tubing apart during the sealing process.
- Only seal the tubing specified in the Operating Instructions.
- Visually check seals for leaks.
- Wear protective gear and protective gloves to protect against the risk of infection.

NOTE

The device sealing system uses radio frequency for sealing medical PVC tubing. The device meets the normative requirements in relation to electromagnetic compatibility (IEC 60601-1-2).

During the operation of the device, we recommend a minimum distance of 2 meters from other electrical medical equipment (e.g., heart pacemakers, insulin pumps).

The hand-held sealer is included with the CompoGuard *Advance Complete* model and can be used with this device.

The hand sealer with hand sealer generator uses radio frequency AC to seal medical PVC-based tubing with an outer diameter from 3.2 to 4.6 mm and a maximum wall thickness of 0.75 mm. The material hardness is allowed to be between 65 and 75 Shore A.

Dry tubing if damp before sealing.

The temperature of the tubes to be sealed must be within the operating temperature range (15-40°C). See Operating Conditions on page 15 of the CompoGuard *Advance*.

The sealing generator is incorporated in the CompoGuard *Advance*. The hand-held sealer is connected to the rear of the CompoGuard *Advance* using a radio frequency cable.

On activating the hand-held sealer a sealing action is triggered that transfers the radio-frequency energy to the electrodes causing the PVC material between the electrodes to melt and to form the seal.

The hand sealer is supplied with energy from the battery pack (see 7.2.4 Battery pack).

INFO

Use of the sealing generator with hand sealer requires the battery pack. Safety instructions for the hand sealer (see page 11).

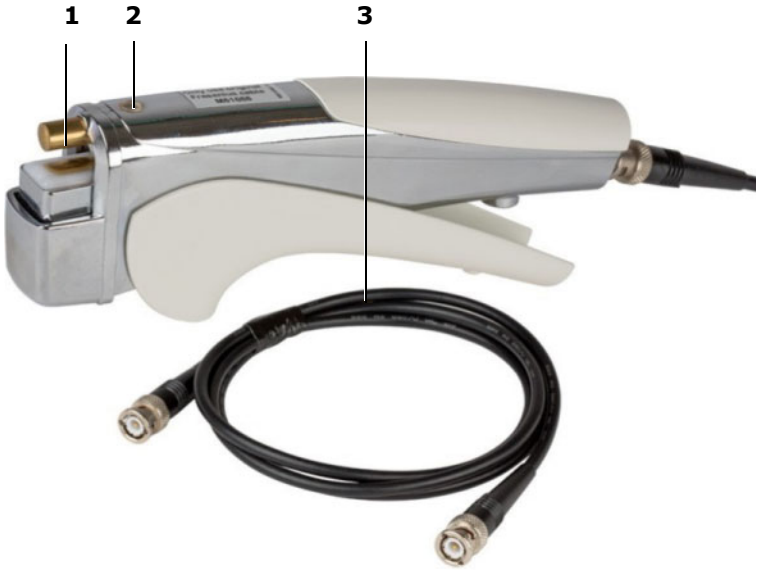


Fig. 53 Hand sealer

1 Sealing electrodes

2 Sealing indicator (LED indicator) during the sealing process

3 Exchangeable cable

- Connect the exchangeable cable (Fig. 53, Item 3) with the hand sealer and the hand sealer HF connection (Fig. 2, Item 2) to the rear of the CompoGuard *Advance*. The connectors are put together and closed by turning them clockwise.
- To seal, place the tube to be sealed between the electrodes (Fig. 53, Item 1).

INFO

Ensure that the tubing is completely between the sealing electrodes.

The hand-held sealer is designed for use with both hands.

- Press the hand sealer together.

➤ If the pressure exerted is high enough, a circuit is triggered in the hand sealer, thus starting the sealing process.

On the top, the LED indicator (Fig. 53, Item 2) of the hand sealer lights up during the sealing process. The sealing process is not completed until the indicator light is turned off.

- **After** the indicator light is turned off, count to 1 and then open the hand-held sealer.

The sealing produces two sealed surfaces and a seam that permits separation of the tube exactly in the centre of the seal.

If the sealing is undertaken as described in these Operating Instructions, consistently high-quality sealing with a reliable depth will be ensured.

Both right-handed and left-handed operators can use the hand-held sealing unit. Furthermore, the hand-held sealing unit was developed with a small, slender handle for ease of use.

INFO

The CompoGuard *Advance* sealing system is not designed for extremely high sealing performance.

- Use for a maximum of 10 seals per minute.

The hand sealer has a built-in alarm that is sounded in the event of sparking. Sparking may occur if the tubing is wet on the outside or when a seal leaks.

The alarm indicates that the seal should be checked and the tubing should be sealed again.

7.2.4 Battery pack

The battery pack can be purchased as optional equipment from Fresenius Kabi. For the model CompoGuard *Advance* Complete, the battery pack is part of the basic scope of delivery.

WARNING

Risk of injury

Damaged battery packs may cause a risk of injury.

- Store battery packs within a temperature range from -20°C to +50°C.
- Protect battery packs from wet and humidity.
- Never short-circuit, reverse the polarity, open, modify or burn a battery pack.
- Check dropped battery packs by a service technician.
- Do not incinerate or heat battery packs above the permissible temperature, otherwise explosive gases may escape and cause an explosion.

INFO

- Only charge battery packs in CompoGuard *Advance* or in the external multi-charger provided.
  If the battery is fully discharged, the battery pack takes approx. 4:15 hours to charge.
  The intended operating time of the device in the standby mode is at least 25 hours with the battery pack.

The battery pack is intended as a mobile power supply unit for the CompoGuard *Advance*.

The battery pack is designed as an exchangeable battery system.

If the battery pack is fully charged and in good condition with the energy-saving function active, the CompoGuard *Advance* can be used for up to 100 donations (depending upon device variant) during a continuous donation process. During extended standby times, if the battery pack is aged or the energy-saving function is deactivated, the number of donations with a fully charged battery pack is reduced.

In mobile donation operation, the use of an external multi-charger for battery packs (see 7.2.5 Multi-charger) is recommended.

- Collect the battery packs at the end of the donation operation to recharge them in the battery pack multi-charger.

The battery pack can also be charged inside the device via the transport case with charging option, which is available as an optional extra.

The battery pack is designed for at least 300 charge/discharge cycles. If there is a significant loss of capacity, it must be replaced and disposed of properly (see chapter 11 Environmental compatibility and disposal).

Charge indicator on the battery pack

On the front of the battery pack there is a display field that indicates the charge state of the battery pack. Up to 5 charge bars are displayed digitally. The number of charge bars displayed changes depending upon the charge state.

During the discharging of the battery pack:

Charge bars	Charge state, discharging	Charge state, charging
5	≥ 80%	≥ 80% (5 flashing)
4	≥ 60%	≥ 60% (4 flashing)
3	≥ 40%	≥ 40% (3 flashing)
2	≥ 20%	≥ 20% (2 flashing)
1	< 20%	≥ 0% (1 flashing)
1 flashing	≤ 10%	

If the battery is in the mode for protection against deep discharge:

- Completely disconnect CompoGuard *Advance* from the supply of electrical power (remove battery and disconnect power supply unit)
- Connect the battery
- Do not switch on the CompoGuard *Advance*
- Connect power supply unit

Important Instructions regarding the use of the battery pack

INFO

- During transport in an aircraft, only charge the battery pack to a maximum of 30% of its rated capacity and transport it separately from the CompoGuard *Advance*.
- The maximum storage period for the battery pack is 6 months. The battery pack should be charged every 6 months if not used.
- If the battery pack is not used for an extended period (> 1 week), only charge to a maximum of two thirds of the rated capacity.
- Observe the general instructions and regulations for handling lithium battery cells.

The battery pack option consists of battery cells with lithium-ion technology.

– A special feature of these battery cells is their resistance to high current required for the sealing option.

– The best way to care for the battery pack is to use it continuously. Optimal use is between 20% and 80%.

– Discharged battery packs must always be recharged immediately.

– The best operating temperature range for the battery pack is between 15 °C and 25 °C. For storage it is possible to deviate from this range.

– Never short-circuit or reverse the polarity of battery packs. Do not open, modify or burn a battery pack.

- Battery packs must not be dropped or exposed to impacts.
- Battery packs must be protected from extreme temperatures, moisture and humidity.

INFO

The warranty and the right to replacement does not extend to damage or premature wear caused by a failure to observe the instructions.

The warranty period for battery packs is half a year.

Using a non-standard battery pack

If a battery pack is used that was not procured from Fresenius Kabi, it is not possible to use device functions with the battery pack. In this situation, an error message appears on the display.

The device is switched off and is **not** supplied from the electricity supply:

- The red LED illuminates after switching on the device
- There is a short error BEEP (lower-pitched sound)
- The CompoGuard *Advance* does not start

The device is switched off and is supplied from the electricity supply:

- The blue LED illuminates after switching on the device
- There is a short BEEP
- the CompoGuard *Advance* starts
- The sealing function cannot be used

7.2.5 Multi-charger

The multi-charger can be purchased as optional equipment from Fresenius Kabi.

The multi-charger is provided as an external charging unit for up to four battery packs. The charging time is approx. 3:30 hours.

For more detailed information refer to the Multi-charger Operating Instructions.

Fig. 54 Multi-charger as additional equipment

7.2.6 Transport case

The transport case can be obtained as additional equipment from Fresenius Kabi.

The cases are made of extremely robust plastic, having a relatively low weight.

Fig. 55 Transport case as additional equipment

The transport case is designed for stacking several transport cases on top of each other.

The central handle is convenient to use and provides stability.

The case has locks and latches for securing the housing and protecting the device.

The case has inserts for the device and all additional equipment.

The case can be used as a stand (with or without cover) to obtain the best possible action due to gravity while collecting the blood donation.

The case has a shield to prevent the trapping of cables.

7.2.6.1 Loading the transport case

The transport case should be loaded in the manner described to ensure the safe transport of the CompoGuard *Advance* and the related equipment.

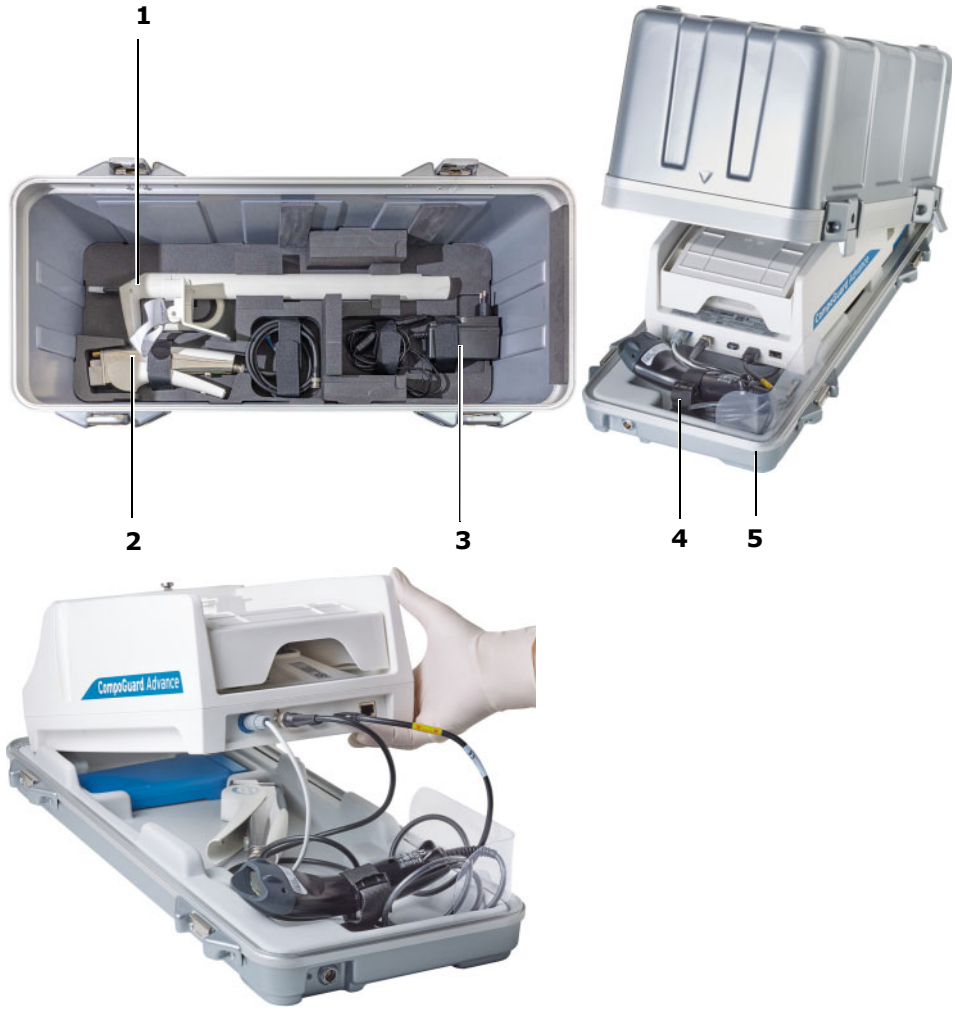


Fig. 56 Loading transport case

- Remove the tray from the CompoGuard *Advance* (8.2 Clean the mixing tray).
- Put the CompoGuard *Advance* on the bottom part (Fig. 56, Item 5) of the case and place the tray upside-down on the device.
- Stow the scanner, as shown, between the device and the protective cover and fix using the fastening strap (Fig. 56, Item 4).
  Other additional equipment, for example the battery, can be stowed under the CompoGuard *Advance*.
- Insert the gooseneck (Fig. 56, Item 1), the hand-held sealer (Fig. 56, Item 2) and the power supply unit (Fig. 56, Item 3) in the top part of the case as shown in the figure.
  Optionally, the hand-held sealer can also be stowed in the bottom part.
- Place the case top from the rear of the CompoGuard *Advance* onto the case bottom (Fig. 56, Item 5).
  When closing the transport case, ensure that the two marker arrows point to each other.
- Then close the four buckles.

7.2.6.2 Transport case with charging function

The transport case with charging function can be obtained as additional equipment from Fresenius Kabi.

This transport case has a charging function as an extension for charging the battery pack when the case is closed.

For this purpose, there is a socket on the back of the case into which the plug of the power supply unit can be inserted.

Fig. 57 Transport case with charging function as additional equipment

Connect the adapter cable inside the case to the AC adapter connector of the CompoGuard *Advance*.

The case with charging option has an LED indicator in the area of the connector plug.

– The indicator lights up red as long as the battery is being charged.

– The display changes to green at the end of charging.

– If the indicator does not light up, the transport case is not connected to the power supply connector or is not connected to the device.

  This layout has the advantage that it is not necessary to unpack the equipment at the end of the day to charge the batteries.

7.2.7 DonationMaster *Advance*

The software program can be obtained as additional equipment from Fresenius Kabi.

The DonationMaster *Advance* software program is used to configure and record the donation data of the CompoGuard *Advance* devices connected in a network and as a link to a blood bank information system.

Please reference the DonationMaster *Advance* User Manual for more details.

7.3 Part numbers

Part no.:	Description
9029741	CompoGuard *Advance* Basic
9029751	CompoGuard *Advance* Data
9029761	CompoGuard *Advance* Complete
9029771	DonationMaster *Advance*
9029951	DonationMaster *Advance* (US/AUS/KR)
9029841	Gooseneck
9027021	Hand sealer
9027041	Coaxial cable for hand-held sealer
9029791	1D/2D barcode scanner
9029831	Battery pack
9029491	Multi loader
9029811	Transport case
9029821	Transport case with charging function
9029851	USB stick
M657981SP	Filter holder
9029781	WLAN stick (EU/US/CA/BR/JP)
9029881	WLAN stick (RoW)
M723511SP	Power supply
M723631SP	Adapter for power supply (EU)
M723641SP	Adapter for power supply (UK)
M723651SP	Adapter for power supply (US/JP)
M723661SP	Adapter for power supply (AUS)

8 Cleaning and Disinfection

While cleaning the CompoGuard *Advance*, always wear personal protective equipment and switch off the device. While switching on the device, make sure there is no moisture residue on the display. Moisture residue can cause incorrect operation.

WARNING

Electrical hazard

Moisture in the device can cause an electric shock. To prevent electric short circuit and electric shock:

- For cleaning and disinfecting, turn off the device and disconnect it from power source.
- Make sure that no fluids get into the inside of the device.
- Do not spray into the device or onto surfaces.
- If liquid (blood, blood components or cleaning agent) has entered in the interior of the device, disconnect the power plug and notify a service technician.

WARNING

Risk of infection

Improper cleaning and disinfection of the device may cause an infection with pathogens of operator and donor.

- Treat the processed blood always as being potentially infected.
- Follow stipulated cleaning process (see chapter 8 on page 89).
- Wear protective clothing and safety gloves.

WARNING

Risk of injury and device damages

The use of non-approved cleaning and disinfection agents may cause a risk of injury, as well device damages.

- Only use the following disinfectants for cleaning and disinfection: 70% ethanol; 1% bleach; ammonium chloride.
- Do not use abrasive and corrosive agents or products that dissolve plastics and lubricants.
- Wear protective clothing and safety gloves.

8.1 Cleaning the surfaces

- Clean the surface of the CompoGuard *Advance* using a soft cloth moistened with the recommended cleaning agents.

➤ The surfaces have been cleaned.

8.2 Clean the mixing tray

The mixing tray can be removed from CompoGuard *Advance* to clean it.

- Push the release lever (Fig. 58) upwards and pull the mixing tray backwards out of the guide.
- Rinse off the tray under running warm water and, optionally, use a recommended cleaning agent.
  Before being fitted, the tray must be completely dry.
- Replace the mixing tray in the guide on the CompoGuard *Advance* and push it forward until it is locked again.

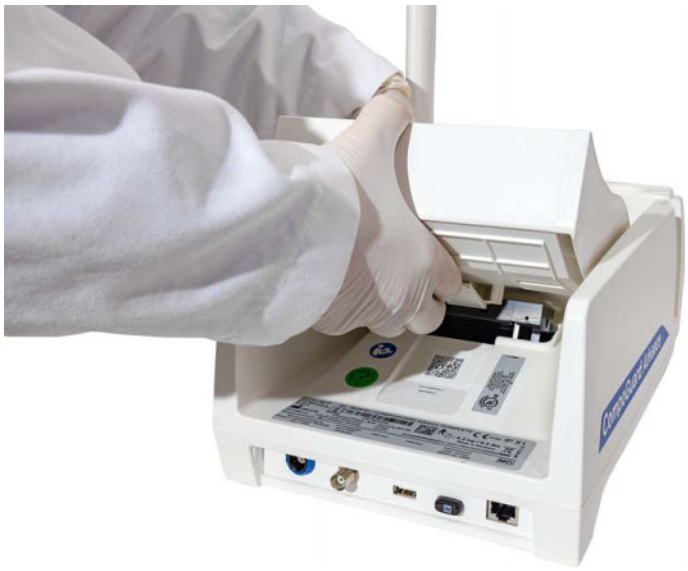


Fig. 58 Cleaning the mixing tray

8.3 Cleaning optional hand sealer

INFO

Depending upon the degree of soiling, the hand sealer can be cleaned in the assembled or disassembled state.

- Disconnect the hand sealer from the exchangeable cable.

Cleaning in assembled state

- Hold the hand sealer so that the sealing opening is visible and clean it with a cotton swab soaked in alcohol.
- Dry the cleaned surfaces with a new clean cotton swab.

Cleaning in disassembled state

- Using your right hand, hold the hand sealer in a horizontal position and close sealing head.

Fig. 59 Hand sealer

- Firmly close the movable sealing head by pushing with your middle finger (Fig. 60, Item 1), while exerting a counter-pressure on the hand sealer with your thumb (Fig. 60, Item 2).

Fig. 60 Hand sealer - loosen Handle

- This action will disengage the handle (Fig. 60, Item 3).

- Put down the hand sealer.
  The handle must be in the position shown in the illustration.

Fig. 61 Hand sealer - position of the handle

- Push the sealing head upwards with your thumb (Fig. 62, Item 1), while exerting a counter-pressure on the hand-held sealer with your index finger (Fig. 62, Item 2), slightly tilt and remove the sealing head by pulling it to the front (Fig. 62, Item 3).

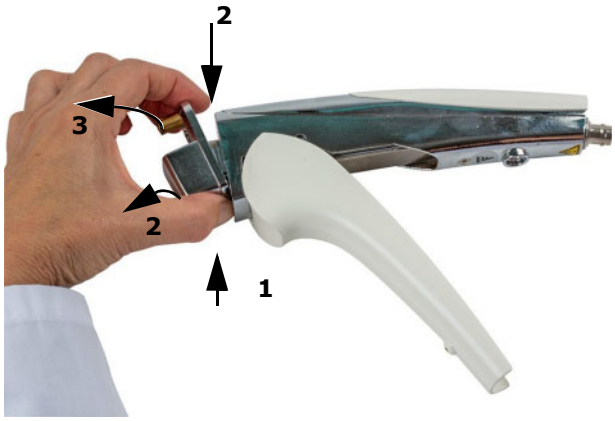


Fig. 62 Hand sealer - remove sealing head

- Remove the leaf spring (Fig. 63, Item 1) by pulling it to the front.
- Remove the handle.

Fig. 63 Hand sealer - remove leaf spring

- Clean the individual parts of the disassembled hand sealer with a cloth or cotton swab soaked in alcohol.
- Dry the cleaned parts with a clean cloth before reassembly.

Before assembling the hand sealer, lubricate the following movable parts using Vaseline:

- Leaf spring near the bolt
- Bar in the handle
- Hand sealer enclosure on all sliding parts

▪ Put down the hand sealer.
The handle must be in the position shown in the illustration.

Fig. 64 Hand sealer - after cleaning

INFO

You must **not** grease the electrodes.

Assembly is done in reverse order:

▪ Fully insert the leaf spring into the hand sealer (Fig. 65, Item 1).

Fig. 65 Hand sealer - insert leaf spring

▪ Place the sealing head onto the hand sealer (Fig. 66, Item 1).

▪ Close the handle (Fig. 66, Item 2).

➤ The handle will click into place.

Fig. 66 Hand sealer - insert sealing head

- For checking purposes, activate the hand sealer 2 to 3 times.

➤ The sealing head must close and open smoothly.

- After cleaning, connect the exchangeable cable to the hand sealer and CompoGuard *Advance*.

The hand sealer is again ready for operation.

9 Maintenance

Maintenance must be performed by authorised and trained service personnel or an authorised Fresenius Kabi service technician only.

The only exception to this is checking the weight display on the device.

The maintenance measures must be carried out once a year or after the service message pops up on the user interface.

A service message generally appears after a freely configurable number of blood donations or after one year.

- Please contact a customer service center authorized by Fresenius Kabi within one month or within the next freely configurable number of blood donations.

INFO

We generally recommend a maintenance agreement to prevent expensive repair work and to ensure an optimum service life of the device.

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10 Troubleshooting

10.1 Use of blood products if malfunctions occur

INFO

If, during the donation process, malfunctions occur on the CompoGuard *Advance*, the bag system or other malfunctions occur (e.g., power failure), the responsible transfusion physician must decide whether the blood donated can be used.

If the CompoGuard *Advance* detects an error, an error message will appear on the user interface. The CompoGuard *Advance* categorizes errors into two classes.

– Messages with a yellow background

– Messages with a black background

NOTE

If error messages with a black screen background persists or reoccur immediately after restart or frequently during use:

- Turn off the device and disconnect it from power supply.
- Do not use the device and notify a service technician.

These system errors cannot be corrected by the user.

10.2 Messages with a yellow background

Malfunctions that can be rectified by the operator are indicated by a yellow background on the display. The donation is also not interrupted if such a malfunction occurs. These malfunctions can be rectified while the donation is in progress.

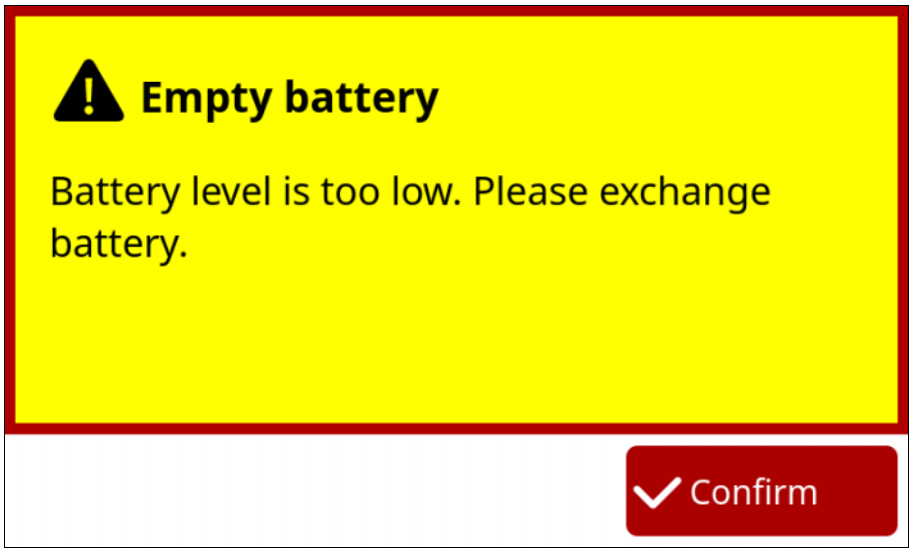

Fig. 67 Example error message (yellow background)

An error message consists of a symbol and the error message text. This text states the cause of the error and the possible work steps to rectify the error.

- After the rectification of the error, press the **Confirm** button.

➤ The message disappears and the last menu displayed appears.

10.3 Messages with a black background

Malfunctions that cannot be rectified by the operator are indicated by a black background on the display.

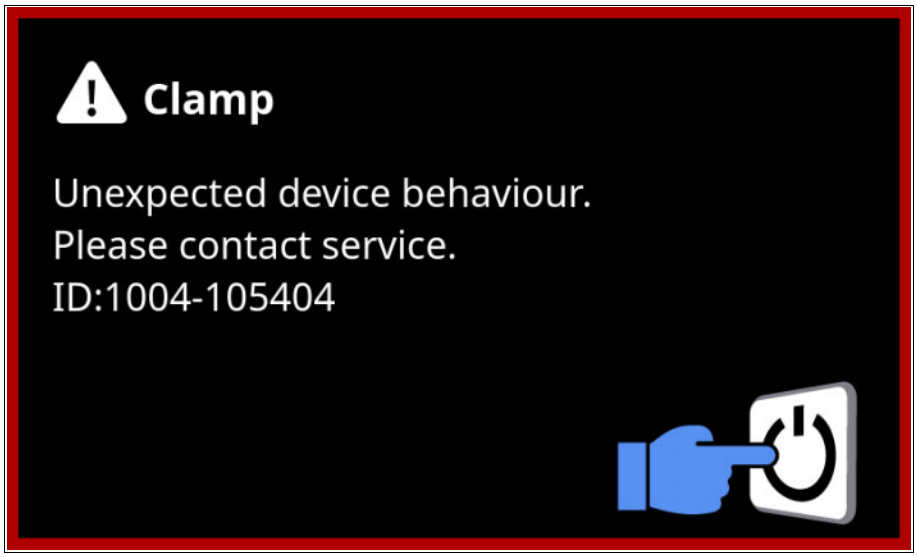

Fig. 68 Example error message (black background)

An error message consists of an error-related warning symbol and an error text.

If these error messages are displayed, switch off the CompoGuard *Advance*, take it out of use and inform your local service center.

11 Environmental compatibility and disposal

Only environmentally compatible and recyclable materials have been used for the manufacture of the CompoGuard *Advance* and the consumables. The materials used meet the requirements of EU Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS 2) and Regulation (EC) No. 1907/2006 (REACH Regulation) concerning the Registration, Evaluation, Authorization and Restriction of Chemicals.

The CompoGuard *Advance* is withdrawn in EU Member States in accordance with EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment. The applicable legal regulations must be observed.

The CompoGuard *Advance* and the consumables are generally considered to be contaminated and must therefore be sufficiently disinfected by the responsible organization as specified by the manufacturer.

WARNING

Danger for the environment

Improper disposal of batteries and battery packs may cause a risk to the environment.

- Dispose batteries and battery packs according to the respective regulations.
- Never throw batteries and battery packs into fire or dispose with ordinary domestic refuse.

Electronic boards can be disposed of in accordance with EU Directive 2012/19/EU on waste electrical and electronic equipment. Dispose of installed batteries in accordance with regulations.

WARNING

Danger for the environment

Improper disposal of electronic scrap may cause a risk to the environment.

- Dispose of the appliance in the EU in accordance with EU Directive 2012/19/EU on waste electrical and electronic equipment.
- The national statutory regulations are to be observed.
- Further information regarding disposal is available by the manufacturer.

Further information regarding disposal is available on request.

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12 Notes on the use of Free Software

You will find information about free software on the **Information** (6.3.3.7 Submenu Information) submenu in **License** (Fig. 25).

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