Instructions for use

Cell Washer Centrifuge Hettich Rotolavit II and Rotolavit II-S

manufactured by

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1 Used terms and signs

Certain terms and symbols are used in this manual and on the device to warn you of possible dangers or to prevent injury or property damage. In order to avoid accidents and damage, you must strictly observe and follow these instructions. The terms and symbols are explained below.

1.1 Explanation of the terms used

DANGER	Indicates a hazard with a high level of risk which, if not avoided, will result in death or serious injury.
WARNING	Indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.

1.2 Explanation of the symbols used

Symbol on the device:
Attention, general hazard zone.
Before using the device, be sure to read the operating instructions and observe the safety-related information!

Symbol in this document:
Attention, general hazard zone.
This symbol indicates safety-relevant information and indicates potentially dangerous situations situations. Ignoring these instructions can lead to property damage.

Symbol in this document:
This symbol indicates important facts.

Symbol on the device and in this document:
Biohazard warning.

Symbol on the device and in this document:
Symbol for the separate collection of electrical and electronic equipment in accordance with WEEE.
The device belongs to group 8 (medical devices). Use in the countries of the European Union as well as in Norway and Switzerland.

Symbol in this document:
Disconnect the mains plug

Symbol in this document:
Wearing safety gloves

Symbol in this document:
Important or useful additional information

Attention! Read Instructions for use

2 Intended Use

The present device is a washing centrifuge intended for in-vitro diagnostic applications in accordance with Regulation (EU) 2017/746. The sample processing using the device and the corresponding inserts is carried out by filling it with a washing liquid and then shaking, centrifuging and decanting. The device itself is used for sample processing and not for sample analysis.

The following device types are available for this device:

Rotolavit II, Type 1008

These device types are used to wash erythrocytes for carrying out quick anti-human globulin tests (direct and indirect Coombs tests) in crossmatch, antibody screening and differentiation.
Leukocytes can be washed in the same way to prepare samples for tuberculosis testing. The device is intended exclusively for the applications mentioned and is only allowed to be used in closed clinical laboratories by medically trained specialists.

Rotolavit II-S, Type 1008-00S

This device type is used to wash blood or other cell-containing samples to prepare the flow cytometric analysis on a sample preparation system and flow cytometer. The process steps can be individually configured by the user and stored in the device. The configured process steps are processed automatically by the device. A wash-cycle may consist of several processes in which the samples are centrifuged, the supernatant decanted, and then each sample tube is filled with a physiological saline solution and mixed.

The device should only be used by trained medical personnel in clinical laboratories and used only for the stated purpose.

The life cycle of the device specified by the manufacturer is seven (7) years. The lifetime of some parts of the accessories is divergent and is specified in chapter 11.10 of this manual.
Any other use beyond this purpose, as well as non-observance of the intended use (see instructions in the operating instructions regarding transport, storage and execution of cleaning, inspection and maintenance work) is considered to be improper use. The company Hettich AG accepts no liability for any damage arising from this.

2.1 Versions

The device is available in different versions. Equipment or functions available exclusively for certain versions are marked at the relevant points in this manual. The functions described in this manual apply to firmware version 1.01.425 and higher.

2.2 Storage and handover of the operating instructions

This instruction manual belongs with the device and should always be stored where persons working on the device have access to it. It is the responsibility of the owner to ensure that persons who are working or will work on the device are informed as to the whereabouts of this operator manual. We recommend that it is always stored in a protected location close to the device. Make sure that the instruction manual is not damaged by fluid or humidity. If the device is sold on or transported and then set up again at a different location, the operator manual must go with it.

2.3 Responsibility of the owner

The owner:

- is responsible for the perfect condition and operation of the device according to the specifications.
- is responsible for ensuring that the people responsible for operation or service are qualified for these tasks, have been instructed accordingly and are familiar with these operating instructions.
- Must be familiar with applicable policies, requirements and safety regulations and train employees accordingly.
- is responsible for ensuring that unauthorized persons do not have access to the device.
- is responsible for ensuring that the maintenance plan is followed and that maintenance work is carried out with appropriate care (see Chapter 11).
- must, for example, ensure that the device and its operating environment are kept clean and tidy through appropriate instructions and inspections.
- is responsible for ensuring that operating personnel wear personal protective equipment (e.g. work clothing, protective gloves).
- must ensure that all qualifications such as Installation Qualification (IQ), Functional Qualification (OQ) and Process Qualification (PQ) are in place before starting work with this equipment.
- is responsible for regularly rinsing, cleaning and disinfecting the device - as described in Chapter 11- and for checking the required quality of the liquid used.
- ensures the protection of passwords and user settings (chapter 8.6.2).

2.4 Requirements for operating personnel

The device may only be operated and maintained by adults who have received appropriate training. Persons in training or to be trained on the device may only operate the device under the constant supervision of a person with experience. Repairs may only be carried out by qualified electricians who have been authorized by the manufacturer to carry out this work. In addition, the instructions contained in the separate service manual must be followed.

2.5 Modifications and conversions

The device must not be subjected to any unauthorized changes or modifications. The device may not be supplemented with components that have not been approved by the manufacturer. Unauthorized changes or modifications will result in the loss of validity of the EU declaration of conformity, meaning that the device may no longer be operated. The manufacturer is not liable for any damage, danger or injury of any kind resulting from unauthorized modifications, modifications or failure to comply with the provisions contained in this manual.

2.6 Warranty

No claim of warranty will be considered by the manufacturer unless **ALL** instructions in this manual have been followed. Especially the flow-sensor and the magnetic-valve are excluded from a warranty exchange if they are enriched with salt-crystals and this happens if the information in chapter 11 are not followed.

No claim of warranty will be considered by the manufacturer when an unauthorized modification is implemented or non-authorized parts are installed.

3 Safety instructions

No claim of warranty will be considered by the manufacturer unless ALL instructions in this manual have been followed.

Before using the centrifuge, read and follow the operating instructions. Only people who have read and understood the operating instructions may operate the device.

The centrifuge must be installed on a good, stable base. We suggest that no other critical device, like a balance, microscope or HPLC, is placed onto the same base.

The centrifuge must be set up in such a way that no containers with e. g. containing liquids can fall onto the centrifuge.

During centrifuge operation, according to EN / IEC 61010-2-020, no people, dangerous substances or objects may be present within a safety area of 300 mm around the centrifuge.

Rotors, hangers and accessories that show severe signs of corrosion or mechanical damage, or whose useful life has expired, may no longer be used.

The centrifuge may no longer be put into operation if the centrifuge chamber exhibits safety-related damage.

In centrifuges without temperature control, the centrifuge chamber may heat up if the room temperature is elevated and/or if the device is used frequently. A temperature-related change in the sample material cannot therefore be ruled out.

The centrifuge must not be used in potentially explosive areas.

The centrifuge should not be used with:

- flammable or explosive materials
- Materials that chemically react with each other with high energy are prohibited.

When working with hazardous substances (according to the Hazardous Substances Ordinance (GefStoffV)) such as solutions containing formaldehyde, suitable protective measures must be taken in accordance with local regulations, e.g. centrifuge under a ventilation hood.
When using such substances, they can be released into the air - especially during centrifugation and after opening the device.

In addition to the operating instructions and the binding regulations for accident prevention, the recognized technical rules for safe and professional work must also be observed. These operating instructions must be read together with the national environmental protection and safety regulations of the respective operating country.

The centrifuge is a state-of-the-art piece of equipment and is therefore very reliable. However, it can pose a danger to the user or third parties if it is not used by trained personnel, improperly or not as intended.

The centrifuge must not be moved or displaced during operation.

In the event of a malfunction or an emergency release, never reach into the still rotating rotor.

To avoid damage caused by condensation, when moving from a cold to a warm room, the centrifuge must warm up in the warm room for at least 24 hours before it can be connected to the mains.

Only the rotors and accessories approved by the manufacturer for this device may be used (see chapter “Rotors and Accessories”). Before using tube holders and reducers that are not listed in the “Rotors and Accessories” chapter, the user must check with the manufacturer whether they may be used. When centrifuging at maximum speed, the density of the substances or mixtures of substances must not exceed 1.2 kg/dm ^{3}.

The centrifuge may only be operated with an imbalance that is within acceptable limits
≤ 5g = pass and ≥10g = stop

When centrifuging dangerous substances or mixtures of substances that are toxic, radioactive or contaminated with pathogenic microorganisms, the user must take appropriate measures.

Repairs may only be carried out by personnel authorized by the manufacturer.

Only original spare parts and approved original accessories from the manufacturer may be used.

Components contaminated with blood (e.g. rotor, spin chamber) must be disposed of as hazardous waste for blood-contaminated materials after replacement.

The following safety regulations apply:
EN / IEC 61010-1 and EN / IEC 61010-2-020 as well as their national deviations.

The safety and reliability of the centrifuge are only guaranteed if:

- the centrifuge is operated in accordance with the operating instructions.
- The electrical installation at the installation site of the centrifuge meets the requirements of EN / IEC.
- The tests for device safety required in the respective countries, e.g. in Germany according to DGUV regulation 3 (DGUV Vorschrift 3), are carried out by an expert.

4 Behavior in case of malfunctions and irregularities

The device may only be operated in perfect condition. If the operator notices any irregularities, malfunctions or damage, they must immediately switch off the device and inform their supervisor.

For troubleshooting measures, see Chapter 12.

4.1 Residual risks

The device is built according to the state of the art and the recognized safety regulations. Improper use and handling can pose a risk to the life and limb of the user or third parties, or damage to the device or damage to property. The device is to be used exclusively for its intended purpose and only when it is in perfect safety condition.
Possible malfunctions that could impair safety must be eliminated immediately and the device taken out of operation until then.

In the event of serious incidents with the device, report them to the manufacturer or, if necessary, the responsible authority.

4.2 Switch off the device in an emergency

In an emergency, turn off the power switch on the rear wall and pull out the power plug. This means that all poles of the device are disconnected from the power supply.

4.3 Emergency release

In the event of a power failure, the lid cannot be opened. An emergency unlocking must be carried out manually.

For emergency unlocking, disconnect the centrifuge from the mains.

Only open the lid when the rotor is at a standstill.

Only the plastic unlocking pin supplied may be used for emergency unlocking.

- Switch off the mains switch (switch position “0”).
- Look through the window in the lid to make sure the rotor is stationary.
- Insert the unlocking pin horizontally into the hole. Push the unlocking pin in until the handle can be swiveled upwards when the pin is pushed in.
- Open the lid.
- An error appears on the display after switching on the centrifuge.

5 Technical data

Model	Rotolavite II	Rotolavit II-S
Type no.	1008-00	1008-00S
Base UDI-DI	07640173551008-0029	07640173551008-00S49
UDI-DI	07640173551003	07640173554004
GMDN	35901	35881
Class conform 2017/746 (EN)	Class A, according to Annex VIII, Rule 5	
External power supply	100-240V~ (single phase)	
Mains frequency	50-60Hz	
Device protection class	Protection class I	
Connected load	144 VA	
Current consumption	0.7 A (230 V~) or 6 A (24 V=)	
Power	150W	
Fuse	10A / 250VF	
Width	330mm	
Depth	480mm	
Height (lid closed)	280mm	
Height (lid opened)	580mm	
Weight	24.4kg	
Capacity (default)	12 x 5ml	
Capacity (optional)	24 x 5ml	
Speed / Radius	3500RPM / 105mm	
Relative centrifugal acceleration	1438 RZB	
Max. kinetic energy	250 Nm	
Max. allowable density	1.2kg/ ^{dm3}	
Max. filling tolerance	± 0.3ml @ 24-fold rotor / 3.5ml capacity	
Mandatory inspection (BGR 500)	No	
EMC	IEC61326-3-2 / FCC CFR47, Part 15, 2015 Edition, Class B	
Sound pressure level	62dB	
Ambient conditions Acc. EN / IEC61010-1 Ambient altitude	Not suitable for use in potentially explosive environments, indoors only up to 2000 m above sea level M.	
Ambient temperature	18°C to 30°C	
Humidity	20%RH to 80%RH / non-condensing	
Storage conditions	5°C to 50°C / max. 60%RH	
Storage battery	CR2032	

Table1

6 Unpacking the centrifuge

If the packaging arrives damaged, this must be confirmed by the transport company and the device must be specifically checked.

To avoid damage, only unpack the device at the installation site. Check delivery for completeness using the delivery note. Check device for damage.

Do not lift by the front panel. Pay attention to the weight of the centrifuge, see chapter. 5(Technical data). Danger of cuts on the edges of the box when unpacking the device!

Lift the centrifuge with the required number of helpers on both sides and remove it from the box.

According to the laboratory equipment standard EN / IEC 61010-2-020, the building's electrical installation must be equipped with an emergency stop switch in order to be able to interrupt the power supply in the event of a fault. This emergency stop switch must be installed away from the centrifuge, preferably outside the centrifuge operating room or near the exit.

Before the centrifuge is connected to the power supply or the lid is opened using the emergency opening, carefully place the centrifuge on one side so that the three transport locking screws on the underside of the centrifuge can be removed using the included 6-point angled wrench. Carefully place the centrifuge back on its feet, connect the power supply correctly and put the centrifuge into operation and open the lid so that the transport lock of the supplied rotor, or the additional transport lock if delivered without a rotor, can be removed.

Position the centrifuge in a stable and level manner in a suitable place. During set-up, the required safety margin of 300 mm around the centrifuge is to be kept according to EN / IEC 61010-2-020.1 When the centrifuge is running, according to EN / IEC 61010-2-020, no persons, dangerous substances or objects may be within the safety margin of 300 mm around the centrifuge.

The centrifuge was packaged under non-sterile conditions.

If there are different delivery note details, damage or irregularities, do not use the device but inform the transport company and dealer first.

If possible, store transport materials and transport locks in a safe and dry place.

6.1 Storage after delivery

If storage is required after delivery of the device, check the packaging for external damage and, if necessary, inform the shipping company and dealer. For storage conditions see chap. 5(Technical data).

6.2 Installation after storage

If the storage conditions were outside the conditions specified for the operating environment, then the device, which is still unconnected, must first acclimate to the new environment for 24 hours.

6.3 Scope of delivery

1x power supply,
1x drain hose (∅14.3 mm) with connection, E4374,
1x filling hose (∅7.1 mm) with connection , E4373, inlet 1, with inlet pipe; for the physiological saline solution,
1x filling hose (∅7.1 mm) with connection ,
1x elbow (plastic), for the drain hose (for free- running drain), E4394,
1x power cable
1x release-pin, E2287,
1x hex L-key, hexagonal,

Depending on the order, the rotor(s) and the corresponding accessories are supplied in the appropriate number and design according to the delivery note.

6.4 Disposal of packaging material

The packaging material (cardboard, polyurethane foam, plastic bags and straps) must be disposed of in accordance with the waste disposal guidelines applicable in the respective country. If you have any further questions, please contact your local product dealer. We recommend keeping at least one set of the original packaging for transport purposes (chapter 6.5)

6.5 Transport

Keep the original packaging for later transport of the device. If the original packaging is no longer available for later transport, contact your local product dealer. The device as well as its motor and rotor must be protected during transport.

6.6 Labelling (name plate)

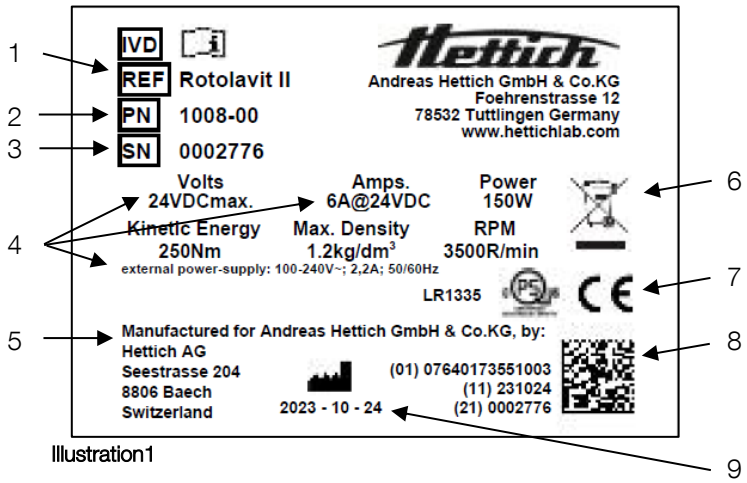


Illustration1

Legend:
1. Type designation
2. Part number
3. Serial number
4. Mains connection values
5. Manufacturer address
6. Disposal note
7. QPS certification, CE conformity
8. 2D data matrix
9. Date of manufacture

7 Installation of the cell washing centrifuge

7.1 Connections

1. Solution tube to the lid
2. Mounting bracket for the power-supply
3. Power switch
4. Ethernet interface
5. DC power input
6. Fuse, fuse holder
7. Inlet 1, saline
8. Inlet 2, reserve
9. Drain outlet

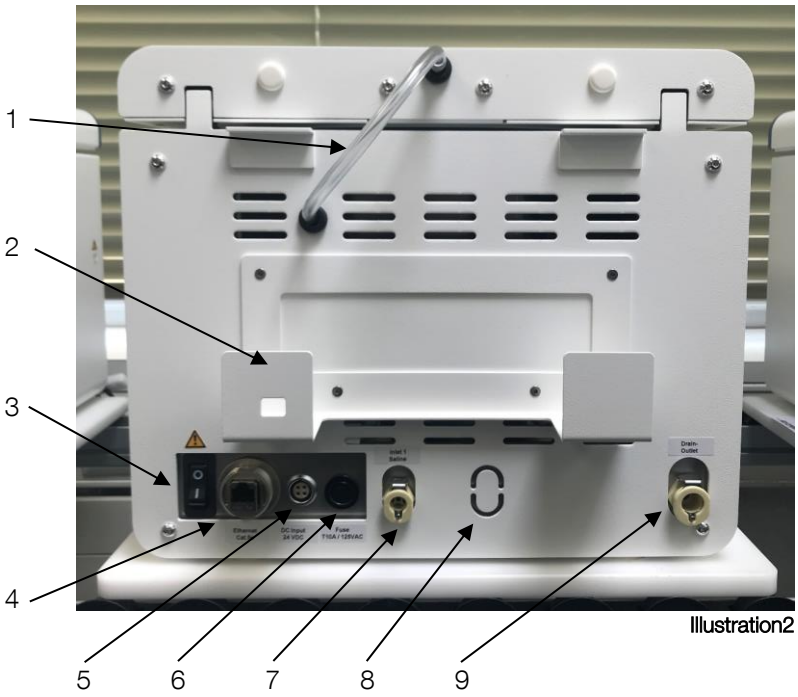


Illustration2

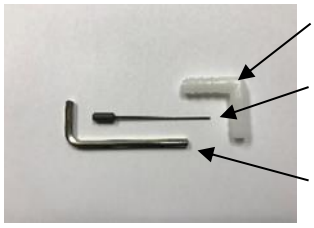
10 Emergency release hole (see chapter 0)

Illustration3

See the respective technical device data according to the device number in Table 1.

Only have the device installed by an authorized distributor.

7.2 Included supply

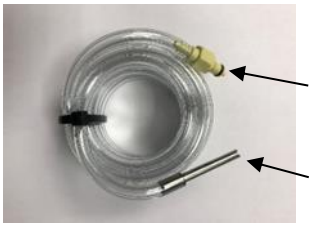


E4394, L-piece (elbow)

E2287, emergency release pin

Hex L-key

Illustration4

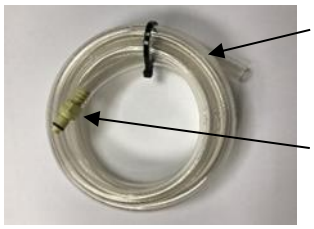


E4373, filling hose, Inlet 1, complete

E4261, input connection, input 1

E4258, intake pipe (single)

Illustration5



E4374, drain hose, waste, complete

E4259, drain connection (single)

Illustration6

E4251 / E4502, power supply

Illustration7

The L-piece (elbow) is for the drain hose. This ensures that the liquid drains and does not create a siphon. If liquid runs back into the device and fills the bowl, the device (motor) can be damaged.

Illustration8

Illustration9

7.3 First steps

Before starting installation, read chapter 3safety instructions.

Install the power supply into its holder on the back (see Illustration 2, item 2) and insert the plug into the DC voltage socket (Illustration 2, item 5). Connect the included power cord to the power adapter and then plug it into the power outlet.

For all electrical connections, observe the regulations of the respective country (in Germany, for example, provide an FI circuit breaker). When connecting, observe the connection and performance data noted on the device sticker and in the technical data. The electrical connection must be grounded via a protective conductor (PE).

Caution

Lay the power cable so that

- it is always accessible and within reach so that it can be disconnected from the network in the event of a fault
- no one can stumble over it
- There is no contact with solutions (water, salt solutions, etc.), mechanical components (shakers, mixing devices) or hot components (ovens or burners) .

Connect the filling hose to inlet 1 (Illustration 2, item 7) on the back and immerse the other end of the hose with the suction tube in the container with the saline solution.
If the filling hose is too short or if the container with the solution cannot be moved closer and a longer filling hose must be obtained (from the local appliance dealer), then the flushing and refilling programs must be checked for correct operation.
If the device has the optional inlet 2, then connect the filling hose 2 to the rear inlet 2 (Illustration 2, item 8) and immerse the other end of the hose with the suction pipe in the container with fluid solution 2.

Make sure that the ends of the hose and the container cannot be mixed up, otherwise all sample materials will be destroyed!

Connect the connection from the drain hose to the rear outlet (Illustration 2, item 9) and attach the other end of the hose to the hazardous waste container.

Make sure the drain hose runs flat on the surface and not as shown in Illustration 9 and Illustration 11. This will damage the device.

Clean and disinfect the device before first use.

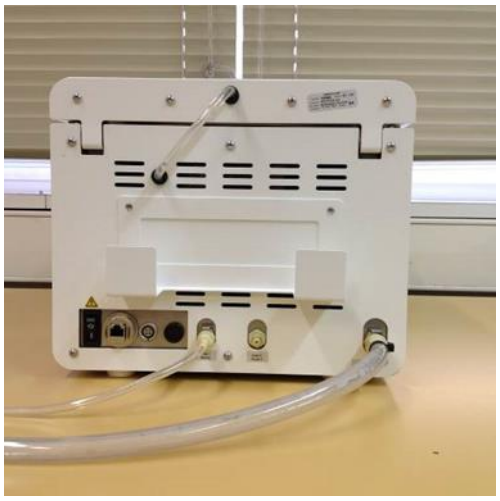
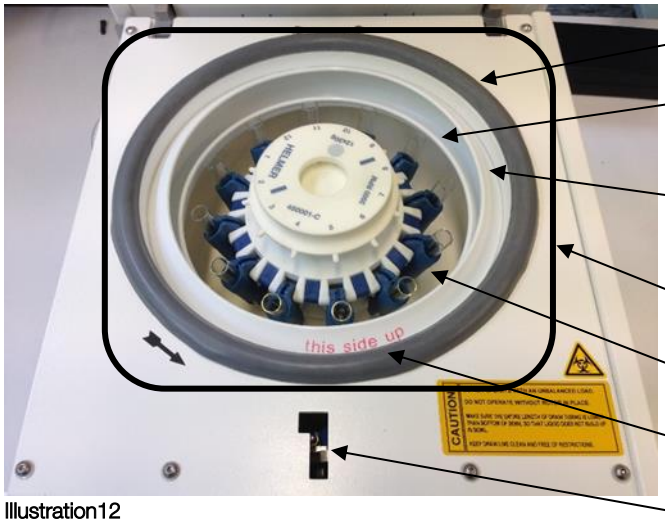


Illustration10

Illustration11



Seal

Splash guard receiver
(Caution! Do not press down too far)

Splash guard cap
(Caution! Do not press down too far)

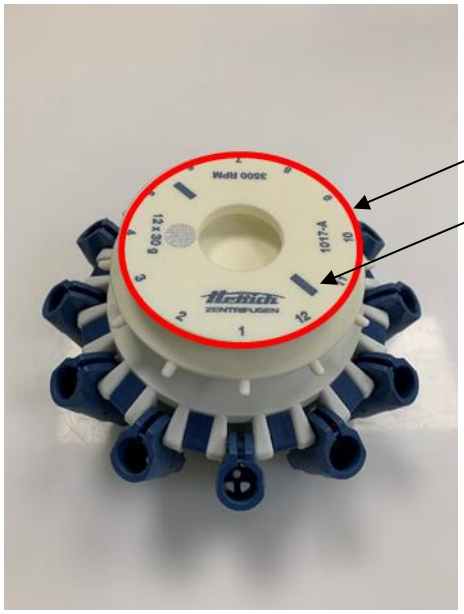
Centrifugation area

Bowl *(Material: ABS)*

Inscription (in red only in the picture)

Lid lock access hole

Illustration12



Handle for lifting the rotor

Marking for aligning the rotor

Illustration13

7.4 Start operation of the cell washing centrifuge

Switch on the mains switch (Illustration 2, item 3) (ON). The startup process takes approximately one minute.

When the main menu is displayed, press the lid opening button and open the lid (chapter 8.2, item 7), remove the transport lock from the top of the rotor and store it in a safe place.

7.5 Installing and removing the rotor

Either a 12-fold rotor or a 24-fold rotor can be used in the Rotolavit II and Rotolavit II-S. Both rotors can accommodate either 10 mm x 75 mm or 12 mm x 75 mm glass or plastic tubes. A rotor and its setup must be installed, see chap. 8.5System settings and chap. 10.1. The rotor type entry must be correct for the Rotolavit II to work correctly.

Installing the rotor:

1. Hold the rotor by the handle area (Illustration 13, No. 1) and place the rotor over the motor axis
2. Align the marks (Illustration 13, #2) on the top of the rotor with the slots on the motor axle
3. Lower the rotor onto the motor axis

If the rotor is incorrectly placed over the motor axis, the lid cannot be closed.

Removing the rotor:

1. Open the lid.
2. Grasp the rotor by the handle area and lift the rotor straight up

8 Operational settings

8.1 Overview menu navigation

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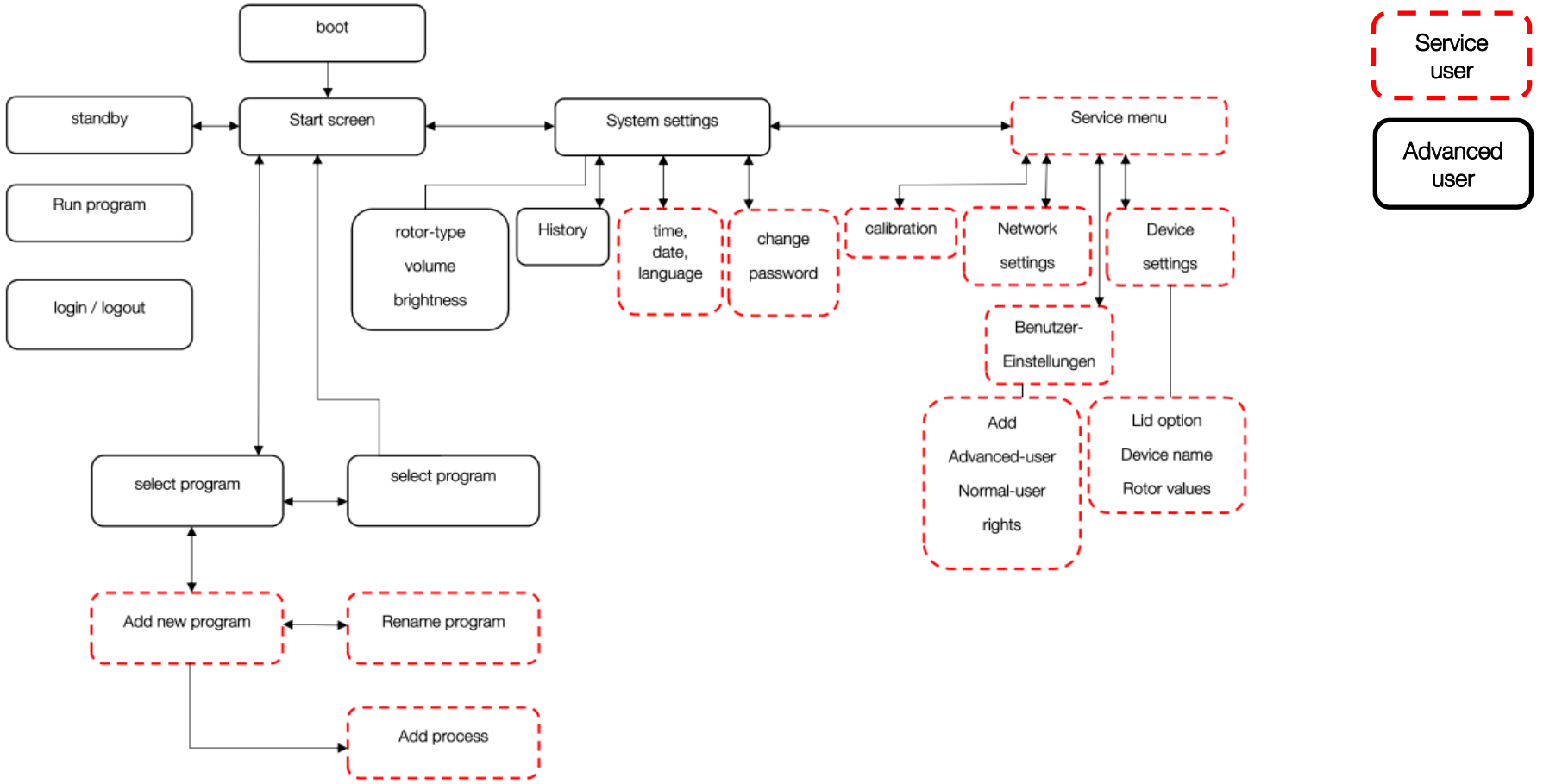
The operating settings for the device can be viewed and changed through the system settings menu.

Software version: 1.01.425



8.1.1 Password protection

Some operating functions are restricted for the "Normal User" level and some can be restricted (R) in the "User Settings" menu, see Chapter 8.6.2. However, the service user password is required for this. When delivered, the password for the advanced user (name can be changed) is “1008”. See also the following table:

If you have to be logged in with a password for an action, it will be marked with [Login].

Function for software	Normal user	Advanced user	Service user	Factory user
Select program	√ (R)	√	√	√
Start program	√ (R)	√	√	√
CHECK function	√ (R)	√	√	√
Cancel program	√ (R)	√	√	√
Add/change program		√	√	√
Select rotor type	√ (R)	√	√	√
Show history	√	√	√	√
Reset rotor operating time			√	√
Time and date settings		√	√	√
Adv. Change/Add/Delete Username			√	√
Adv. Change/add/delete user password			√	√
Calibrate filling volume			√	√
Change device settings				√
Change Password		√	√	

8.2 Start screen

1. Name of the program
2. Start program [Login]
3. Standby, black display
4. System and device settings
5. Login/Logout
6. Program selection
7. Unlock the lid

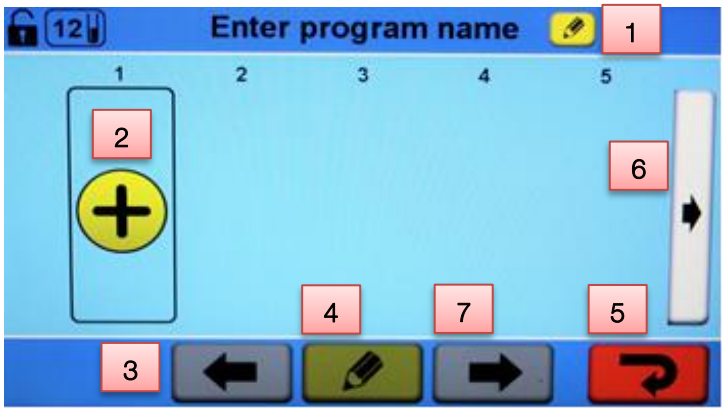
The service user can deprive the normal user of the ability to start a program.

8.3 Program selection

1. Existing programs
2. Add new program [Login]
3. Navigation through program list
4. Back to the start menu

The individual programs must be adapted or validated by the operator to the **customer-specific tubes.** The Rotolavit II, II-S has a memory capacity for a total of 24 programs including the two system programs flush 1 and refill pump 1.

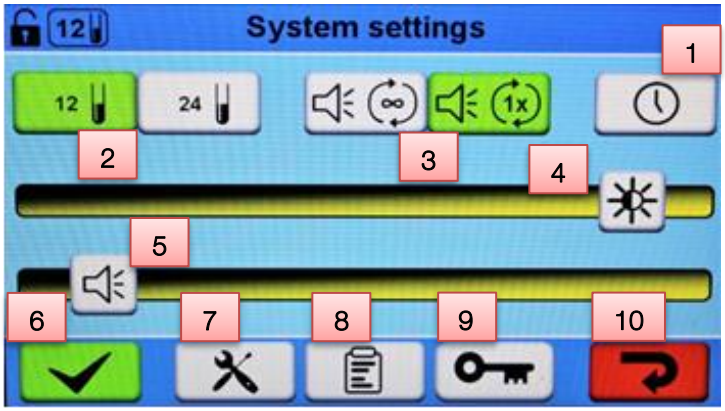
8.4 Add new program



1. Rename program [Login]
2. Add process step [Login]
3. Move selected process one step to the left [Login]
4. Edit process step [Login]
5. Back without saving [Login]
6. Next page with processes of the program [Login]
7. Move selected process one step to the right [Login]

8.5 System settings

It is necessary to enter the rotor type used (12-place or 24-place) to calculate the filling volume and it is only possible to enter the rotor type when the rotor has stopped.



1. Time, date and language settings [Login]
2. Change rotor type [Login]
3. Beep at program end
4. Screen brightness
5. Volume beep
6. save Changes
7. Service menu [Login]
8. history
9. Edit password [Login]
10. Back without saving

8.5.1 History

1. One month forward or back
2. Back to system settings

Jump to the previous or next month. Days colored yellow contain saved data.

If the history date is far away from the current date, switch the device off using the main switch, wait 10 seconds and switch it on again. The next time you select the history, the current date will appear.

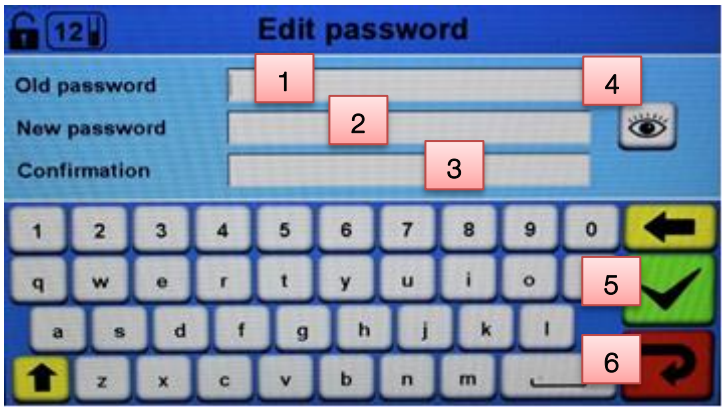
8.5.2 Language, date and time setting

Selection wheels for setting date, time and language [Login]

1. Accept changes
2. Discard changes and go back to system settings

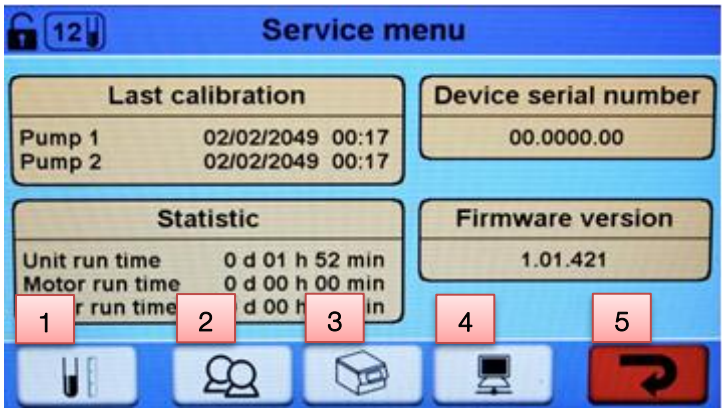
After changing the language, the device must be switched off using the main switch.

8.5.3 Edit password



1. Enter old password [Login]
2. Enter new password [Login]
3. Confirm new password [Login]
4. Show/hide passwords [Login]
5. Accept changes [Login]
6. Discard changes without saving [Login]

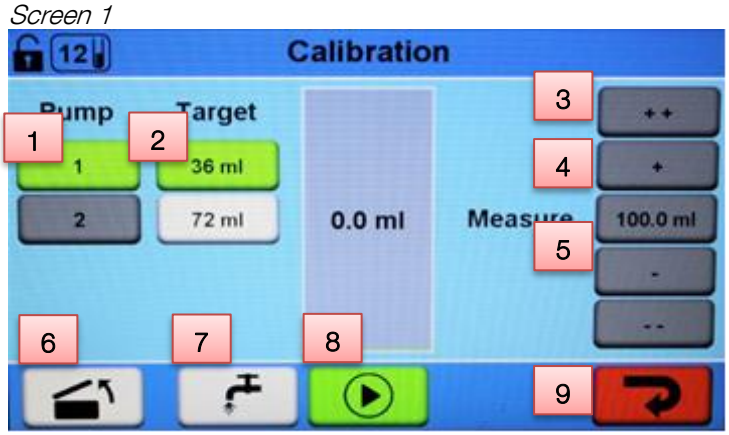
8.6 Service menu



1. Calibration [Login]
2. User Settings [Login]
3. Device settings [Login]
4. Network Settings [Login]
5. Back to system settings [Login]

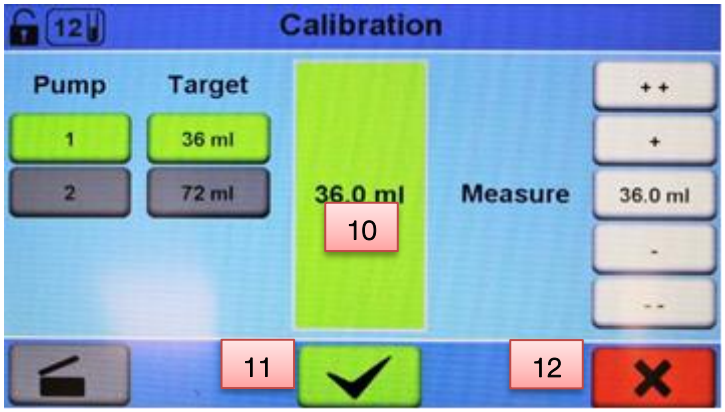
8.6.1 calibration

Screen 1



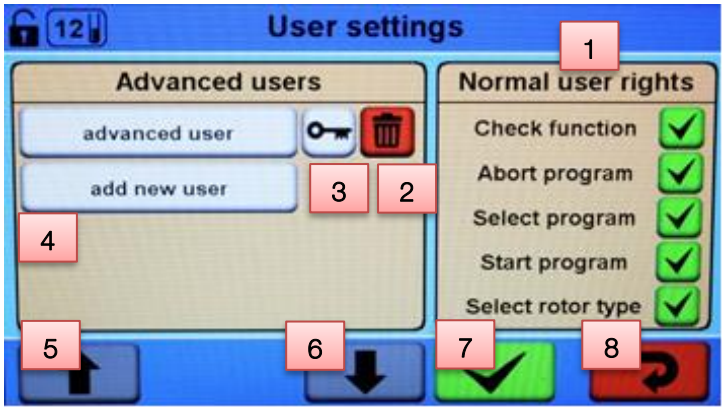
1. Select pump [Login]
2. Select target volume [Login]
3. Correction by 1ml [Login]
4. Correction by 0.1ml [Login]
5. Target measurement [Login]
6. Unlock cover [Login]
7. Operate the pump / pump liquid
8. Start calibration
9. Return to the service menu without calibrating

Screen 2



10. Show fill level [Login]
11. Accept and save calibration
12. Reject calibration

8.6.2 User Settings



1. Grant/deny user rights [Login]
2. Delete user [Login]
3. Set up password [Login]
4. Add new user [Login]
5. Up in user list [Login]
6. Down in user list [Login]
7. Save user [Login]
8. Back without saving [Login]

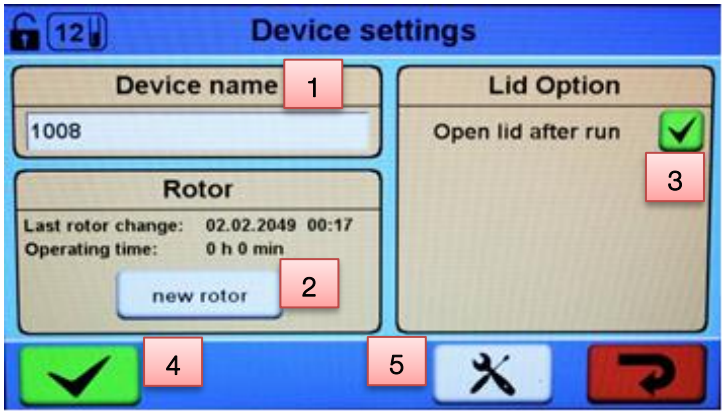
Only the “Service User” can generate new “Advanced Users” and restrict the user rights of the “Normal User” user (without login) accordingly, e.g. change the green check mark to a red “X” so that the “Normal User”. “ cannot select the “Check” function during a run.

The password for the “Advanced User” is “1008” and should be adjusted accordingly during commissioning.

The “Advanced User” has no access to the device settings and the calibration menu.

8.6.3 Device settings

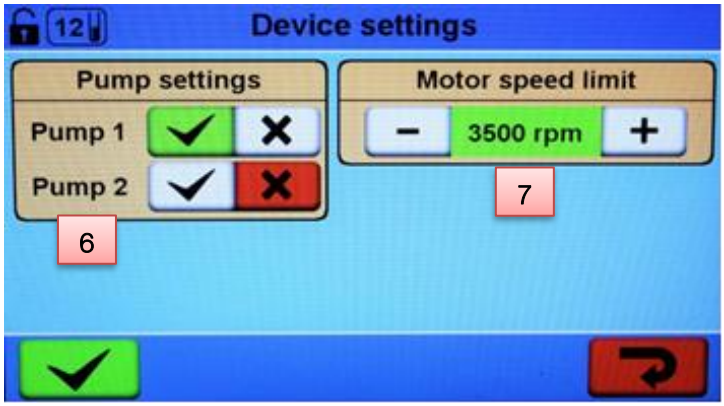
Screen 1



1. Change device name [Login]
2. Use new rotor [Login]
3. Open the lid at the end of a program [Login]
4. Save changes [Login]
5. To the second screen [Login]

The lid option should not be confused with the “CHECK” process. By activating, the lid is automatically unlocked every time a program is completed or an error message is received.

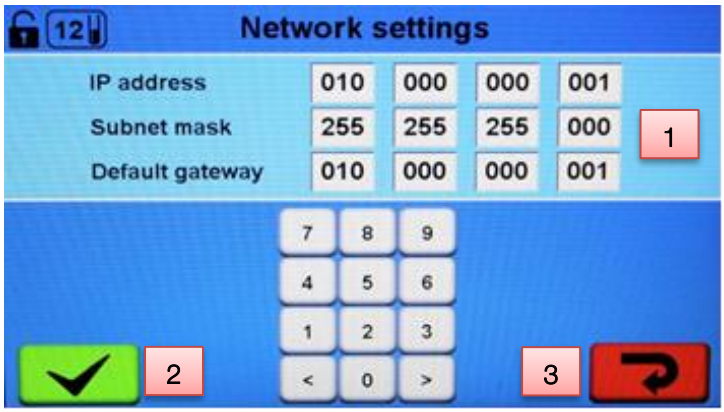
Screen 2



6. Activate / deactivate pumps [Login]
7. Define upper limit for engine speed [Login]

Factory setting: Pump 1 = activated, Pump 2 = deactivated, motor speed limit = 3500rpm, Device name = 1008 (or 1008 03), rotor = the date corresponds to the manufacturer's initial inspection

8.6.4 Network settings



1. Current network settings [Login]
2. Save changes [Login]
3. Back without saving [Login]

9 Programs

9.1 Validation

Validation of the device before use is strongly recommended, for example by the BCSH (=British committee for Standards in Hematology), the AABB (=American Association of Blood Banks), the guidelines for the collection of blood and blood components of the German Medical Association.

9.2 Start program

Start menu:

The currently loaded program is “decant”

To start, press “Start Program”.

1. Press the button to select another program

Select a program. To add a new program, see Chapter 8.4.

The individual programs must be adjusted by the operator to the customer-specific tube. When changing tubes, the program must be readjusted!

After selecting the program, the individual process steps are displayed.

Check the program and all settings!

Press to load the program.

The program name of the loaded program is now displayed.

To start click on “Start program” press.

The program will start and the current process will be highlighted.

Pressing “CHECK” causes the lid to automatically unlock after the current process has been completed.

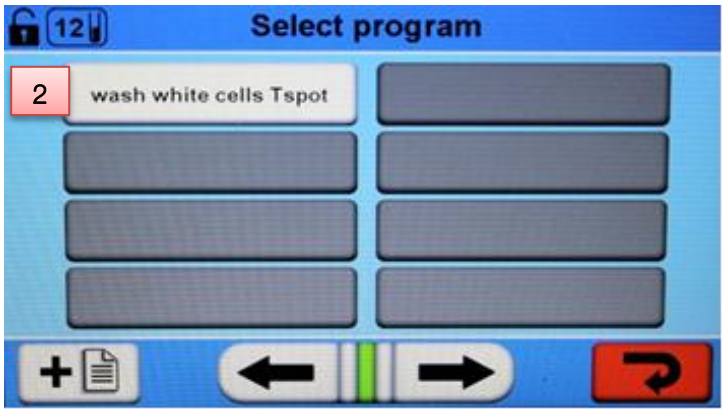
9.3 Stop running program

To cancel the current program, press “STOP”.

 press to confirm

 press to cancel

9.4 Pre-installed programs



1. Pre-installed system programs

2. Pre-installed user programs for device type 1008-00

Pre-installed user programs for device type 1008-00S:

-cell recovery
-immunophenotyping

9.4.1 flush

This pre-installed system program is specifically designed for flushing the external and internal tubing system to flush the tubing system with deionized or distilled water after routine to prevent salt crystals from forming.

This program does not have bubble detection to ensure that the system does not trigger an error message during the flushing process.

Before the routine, the tubing system must be flushed with saline.
If this program is deleted, only a specialist can restore it.

9.4.2 refill pump

This pre-installed system program was designed specifically for refilling the external and internal hose system in order to remove any air bubbles contained in the hose system without turning the rotor.

This program does not have bubble detection to ensure that the system does not trigger an error message during the flushing process.

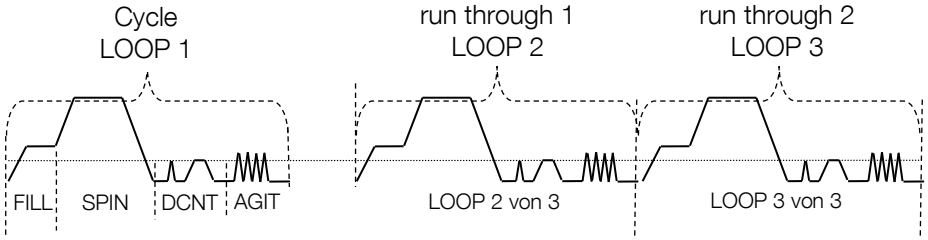
If this program is deleted, only a specialist can restore it.

9.4.3 wash redcells 3 5ml 3x (wash erythrocytes, 3.5 ml, 3 x)

Below is a visualization of the pre-installed program as an example:

The process values are as follows:

- FILL 3.5ml 1100rpm (fill with 3. 5ml at 1100rpm)
- SPIN 20sec 3500rpm (acceleration 800rpm/s), braking 1000rpm/s)
- DECANT 390rpm (decant at 390rpm)
- AGIT 15x (15 shakes)
- LOOP 3x (two more runs, i.e., a total of 3 washing cycles)



9.4.4 agit and spin

The process values are as follows:

- AGIT 15x (15 shakes)
- SPIN 20sec 3500rpm (acceleration 800rpm/s), braking 1000rpm/s)

9.4.5 decant

The process values are as follows:

- DECANT 390 rpm (decant at 390rpm)

9.4.6 spin 20sec 3500 rpm

The process values are as follows:

- SPIN 20sec 3500rpm (acceleration 800rpm/s), braking 1000rpm/s)

9.4.7 susp 3 5ml spin 20sec (centrifuge 3.5ml suspension for 20sec)

The process values are as follows:

- FILL 3.5ml 1100rpm (fill 3. 5ml at 1100rpm)
- SPIN 20sec 3500rpm (acceleration 800rpm/s), braking 1000rpm/s)

9.4.8 wash 3 5ml 3x and anti (3.5 ml wash, 3 x, plus antihuman globulin test)

The process values are as follows:

- FILL 3.5ml 1100rpm (fill 3.5ml at 1100rpm)
- SPIN 20sec 3500rpm (acceleration 800rpm/s, braking 1000rpm/s)
- DECANT 390rpm (decant at 390rpm)
- AGIT 15x (15 shakes)
- LOOP 3x (two more runs)
- CHECK Pause (to add the antihuman globulin manually)
- SPIN 20sec 3500rpm (acceleration 800rpm/s, braking 1000rpm/s)

9.4.9 wash white cells Tspot (wash leukocytes, Tspot)

The process values are as follows:

- FILL 2.5ml 900rpm (fill 2. 5ml at 900rpm)
- SPIN 7min 2260rpm (acceleration 800rpm/s, braking 1000rpm/s)
- DECANT 370rpm (decant at 370rpm)
- AGIT 100x (100 shakes)
- LOOP 2x (only 1 more run)

9.4.10 cell recovery (only for device type 1008-00S)

The process values are as follows:

- FILL 2.0ml 1100rpm (fill 2.0ml at 1100rpm)
- SPIN 4min 2260rpm (acceleration 800rpm/s, braking 1000rpm/s)
- DECANT 370rpm (decant at 370rpm)
- AGIT 50x (50 shakes)
- LOOP 2x (only 1 more run)
- FILL 2.6ml 1100rpm (fill 2. 6ml at 1100rpm)

9.4.11 immunophenotyping (only for device type 1008-00S)

The process values are as follows:

- FILL 1.5ml 1100rpm (fill 1.5ml at 1100rpm)
- SPIN 5min 1850rpm (acceleration 800rpm/s, braking 1000rpm/s)
- DOWN 1100rpm
- DECANT 370rpm (decant at 370rpm)
- AGIT 15x (15 shakes)
- LOOP 2x (only 1 more run)
- FILL 0.5ml 1100rpm (fill 0.5ml at 1100rpm)

9.5 Process descriptions

9.5.1 Basic process

A program can contain a maximum of 20 different processes, but only one LOOP process. A program can be started with any process except LOOP or CHECK processes, whereby the LOOP process can only occur once in the program.

9.5.2 FILL 1 process

Fill the physiological saline solution directly into the tubes via the distributor of the rotating rotor to obtain a good resuspension of the cells.

A speed range from 0 rpm to 2500 rpm is available for this.

The filling volume to be set per tube is between
0.1 ml and 10 ml.

The default value is 3.5 ml at 1100rpm.

The best result is achieved for both rotor types at a speed of 1100 rpm.
The device calculates the complete volume for the preselected rotor independently.

If the volume is not at the desired value, it is recommended to recalibrate the pump.

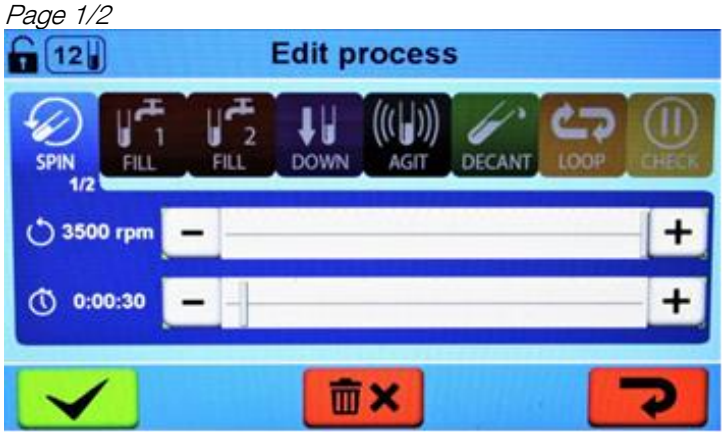
If the solution is distributed unevenly across the tubes, it may be that the rotor outlet nozzles are clogged or that the device is on an uneven surface.

9.5.3 DOWN process

Down:
A speed range from 0 rpm to 3500 rpm is available for this. The selectable time period is between 0s and 20s. The default value is 5s with a 2000 rpm centrifugation run to centrifuge the drops remaining on the wall of the tube to the bottom of the tube.

9.5.4 SPIN process

Page 1/2



Sedimentation:
A speed range from 0 rpm to 3500 rpm is available for this. The selectable time period is between 1s and two hours (0:00:01 to 2:00:00). The default value is 30 seconds at 3500 rpm (0:00:30)

The erythrocytes are sedimented at a selectable speed. The set time only expires after the set speed has been reached. After the time has elapsed, rapid braking occurs to prevent resuspension of the pellet.

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To change sides, 1/2 or 2/2, press and hold on the SPIN symbol.

The default acceleration value is 800 rpm/s.

The default deceleration value is 1000 rpm/s.

Operation with an endless SPIN process is not possible.

If a longer, single SPIN process is required, this can be achieved by adding a LOOP process for the desired period of time up to a maximum of 200 hours. (with multiple processes up to 3800 hours).

A gentler acceleration or deceleration is recommended if the samples are lost during decantation despite speed limitation. The lower the rpm/s, the gentler the acceleration and braking.

9.5.5 DECANT process

Decanting:
A speed range from 0 rpm to 1500 rpm is available for this.

The supernatant is decanted at a selectable speed. For decanting, the direction of rotor rotation is reversed to the normal direction of rotation, whereby the solution is decanted.

The default value is 370 rpm.

The correct speed must be determined based on the tubes used in order to achieve the best possible decantation results: Differences in the format (e.g. 10 mm or 12 mm inner tube diameter) and material (e.g. differences in surface tension for tubes made of glass or plastic) of the tubes have an effect to the optimal speed.

If the decantation speed (DECANT) is too high, the washed cells may also be decanted! However, if the decanting speed is too low, then too little liquid may be decanted from the tubes, which will cause the tubes to be overfilled during the next FILL process!

9.5.6 AGIT process

Shake:
Selection of the number of shaking movements (between 0 and 500 movements).

The default value is 15x.

Quick, short movements of the rotor and tube holder separate the pellet again for the subsequent washing cycle.

9.5.7 LOOP process

Rerun.
This process causes at least one previous process to be run again.

The number of reruns (LOOPS) can be between 1 and 100 repetitions.

The default value is 3x.

After completion of the previous process, all previous processes are repeated with the set number minus 1.

If the previous process was a two-hour centrifugation process (SPIN) for which a one-time repetition (LOOP 2 x) was set, then the program will repeat the centrifugation process once plus a period of 2 hours, causing the device to centrifuge for four hours.

After the LOOP process, any other process (except a LOOP) can be added, that is, a cell wash with two cycles instead of three can be programmed with a decantation process with a speed of approximately 320 rpm. With this lower speed, not all of the liquid is decanted and a small amount of liquid remains in the tubes. If the same process is added after the LOOP process, but the speed of the decantation process is set to 370 rpm, this will empty the tubes of the solution.

9.5.8 CHECK process

Check, pause:
This process requires at least one other process to precede it. After completing the previous process, the program pauses and the lid is opened. The operator can check the samples or add other liquids using a pipette.

The program continues after the lid is closed.

If the previous processes are a washing cycle and anti-human globulin serum could be added during the check process (CHECK), then the following processes are required: AGIT process or SPIN process.

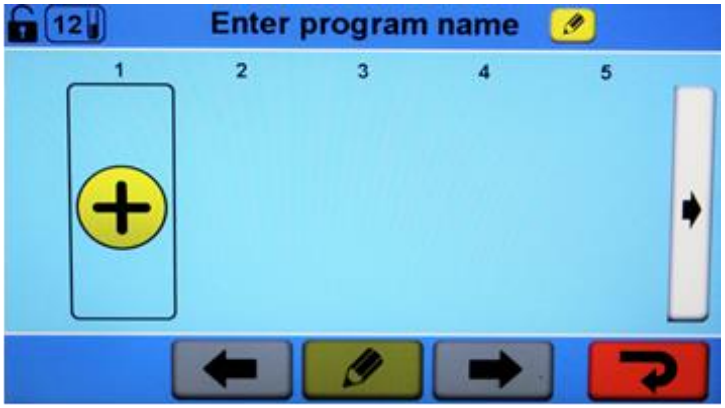
9.6 Add new program

Select the symbols shown on the right:

- To the program list:

Only with login as an authorized user [Login]

- Add a new program:

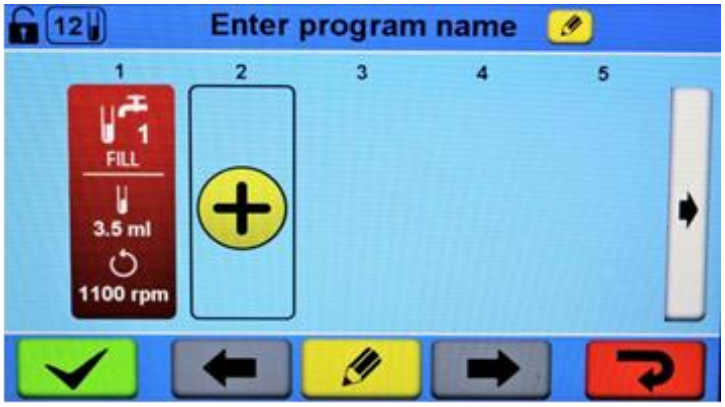


- Edit program name (in the header):

- Add the first process:

The first process in this example is: “FILL 1”

- Select the “FILL 1” symbol
- The filling capacity and the speed during filling can be entered in the bar below.
- Confirm FILL-1 process with:



- Add another process:

For this example, add the process “SPIN”.

- Select the “SPIN” symbol
- The speed and duration of the process can be entered in the bar below. The acceleration and braking bar can be seen on page 2/2 with:

- Confirm SPIN process with:

- Add more processes with:

- By selecting a process, the process can be moved to the previous process position
- Move the process one step forward to the left:

- Move process one step to the right:

- To edit a process, select (in footer):

- Save with:

- Processes 6-10, 11-15 and 16-20 can be called up using the following right (forward) or left (back) symbols.

Each program must be verified with at least 12 samples using a 12-fold rotor and equivalently 24 samples using a 24-fold rotor and compared to another device or method.

When changing the tubes (different size / different material / type no longer available), all programs used must be checked.

10 Settings

10.1 Enter the rotor type

To calculate the filling volume, you must enter the type of rotor used (12x or 24x). Entering the rotor type is only possible when the rotor is at a standstill.

Adjust settings:

- Call up system settings (start menu, chapter 8.2, item 4)
- Change the currently used rotor type (12-fold or 24-fold) (chapter 8.5, item 2)
- Save the setting and go back to the start menu using the “Save changes” button (chapter 8.5, item 6).

10.2 Calibrate filling volume

- Call up system settings (start menu, chapter 8.2, item 4)
- Call up the service menu (system settings, chapter 8.5, item 7)
- Call up calibration (service menu, chapter 8.6, item 1)
- Open the lid (chapter 8.6.1, item 6)
- Check that the target of 36 ml for using a 50 ml graduated cylinder is colored green (according to DIN/EN/ISO 4788). The same must apply to the target of 72 ml when using a 100 ml cylinder.
- Remove the rotor, hold a container under the injection pipe, press the button for “Activate pump” (section 8.6.1, item 7) and make sure that there are no air bubbles in the solution hose on the back of the lid (Illustration 2, item 1).
- Hold a cylinder under the injection pipe located on the inside of the cover and press the “Start calibration” button (chapter 8.6.1, item 8).
- the reading value of the cylinder with the target measurement (chapter 8.6.1, item 10) using the “+” or buttons. “–” (decimal separator 0.1 ml) or with the buttons “++” or “– –” (decimal separator 1 ml).
- Either confirm the calibration (chapter 8.6.1, item 11) or reject it (chapter 8.6.1, item 12)
- If a calibration change was necessary, the calibration must be checked again.
- Complete the process with the “Back to service menu” button (chapter 8.6.1, item 9)

It is recommended to check the calibration:

- Weekly, for the first five weeks after installation
- Before validation
- After maintenance work

10.3 Acoustic signal

The following acoustic signals are programmed:

- every two seconds when a fault occurs
- every ten seconds after the centrifugation run has ended and the rotor has stopped
- Opening the lid or pressing any button will stop the acoustic signal.
- The signal after the program has ended can be activated or deactivated as follows when the rotor is at a standstill:
  - To adjust the volume, call up the start menu and press the system settings button (chapter 8.2, item 4).
  - Use the slider in the bar (chapter 8.5, item 5) to adjust the volume (deactivate acoustic signal = slider all the way to the left)
  - Select the preferred audible signal to sound at the end of the program (a single beep or a continuous 10 s interval for 1 hour)
  - with the “Save changes” button (chapter 8.5, item 6).

If a program completion or alarm signal sounds, the standby mode is only activated after 60 minutes (not after 10 minutes, as is normal) and the display only darkens after 10 minutes (not after 5 minutes, as is normal).

10.4 Relative centrifugal acceleration (RZB)

The relative centrifugal acceleration (RZB) is given as a multiple of the acceleration due to gravity (g). It is a dimensionless quantity and is used to compare the separation and sedimentation performance.

The calculation is carried out according to the following formula:

$$RZB = \left(\frac{RPM}{1000}\right)^2 \times r \times 1{,}118 \quad \Rightarrow \quad RPM = \sqrt{\frac{RZB}{r \times 1{,}118}} \times 1000$$

RZB Relative centrifugal acceleration
RPM speed (revolutions per minute)
r centrifugation radius in mm = distance from the center of the axis of rotation to the bottom of the centrifugation vessel (see Chapter 16.1, rotors and accessories).

The relative centrifugal acceleration (RZB) depends on the speed and the centrifugation radius.

10.5 Operating hours query

Call up system settings (start menu, chapter 8.2, item 4),
Call up the service menu (system settings, chapter 8.5, item 7),

11 Maintenance and service work

The device may be contaminated

Unplug the power cord before cleaning.

For safety reasons, you must wear gloves and a respiratory mask when cleaning the equipment used for blood processing.

Before any other cleaning or decontamination process other than that recommended by the manufacturer is applied, the user has to check with the manufacturer that the planned process does not damage the device.

- Centrifuges, rotors and accessories must not be cleaned in rinsing machines.
- Only hand cleaning and liquid disinfection may be carried out.
- The water temperature must be 20 °C to 25 °C (68°F – 77°F).
- Only cleaning or disinfecting agents may be used that:
  – have a pH value between 5 and 8
  – Does not contain caustic alkalis, peroxides, chlorine compounds, acids and alkalis.
- In order to avoid signs of corrosion caused by cleaning or disinfecting agents, it is essential to follow the specific application instructions provided by the respective manufacturer.
- Certain preservatives in azide-free saline solutions can damage the plastic components in the device after long-term exposure. Regular cleaning prevents salt deposits and extends the life of these components.

11.1 Centrifuge

- The following actions must be carried out daily:
  - Check the hoses and their connections. The hoses must not be torn or blocked and must be securely connected. Don't forget to also check the solution hose to the lid (Illustration 2, Item 1). The used saline solution must be able to flow freely through the drain hose.
  - The spin room must be clean and free of dried salt crystals and other deposits. Clean the spin chamber, the splash guard holder and the splash guard cap with a damp cloth or sponge. The splash guard holder and the sealing ring can be removed from the spin chamber for cleaning (see Chapter 11.4, “Removing the splash guard holder and splash guard cap”).
  - Check the filling volume of the saline solution in the container
  - The system must be flushed with distilled water to avoid the formation of salt crystals (see Chapter 11.5, “Flushing the system with deionized or distilled water”).
- It is important to keep the hoses clean and free of dried salt crystals and other deposits.
- The system must be cleaned regularly (see Chapter 11.6, “Cleaning the system with cleaning solution”). Cleaning is recommended at least once a week.
- Clean the centrifuge housing and the spin chamber regularly and, if necessary, clean with soap or a mild detergent and a damp cloth. On the one hand, this serves hygiene and it prevents corrosion caused by contamination.
- Ingredients of suitable cleaning agents: soap, anionic surfactants, non-ionic surfactants.
- After using cleaning agents, remove any cleaning agent residue by wiping with a damp cloth.
- The surfaces must be dried immediately after cleaning.
- After each cleaning, lightly rub the rubber seal of the spin chamber with talcum powder or a rubber care product.
- Surface disinfection:
  - If infectious material gets into the spin room, it must be disinfected immediately.
  - Ingredients of suitable disinfectants: ethanol, n-propanol, isopropyl alcohol, glutaraldehyde, quaternary ammonium compounds.
  - After using disinfectants, remove any disinfectant residue by wiping with a damp cloth.
  - The surfaces must be dried immediately after disinfection.
- Removing radioactive contaminants:
  - The agent must be specifically designed to remove radioactive contaminants.
  - Ingredients of suitable agents for removing radioactive contaminants: Anionic surfactants, non-ionic surfactants, polyhydrogenated ethanol.
  - After removing the radioactive contamination, remove the remaining agent by wiping with a damp cloth.
  - The surfaces must be dried immediately after the radioactive contamination has been removed.
- The spin room must be checked for damage annually and after glass breaks.


Caution

If safety-relevant damage is discovered, the centrifuge may no longer be put into operation. In this case, customer service must be notified.

11.2 Rotor

- The rotor must be kept clean and free of dried salt crystals and other deposits.
- Either soak the rotor in warm, distilled water or let the water flow directly from above into the rotor for a few minutes. The water must flow out of all injectors.
- If the injectors are clogged, insert the plastic pin provided into the injectors and carefully push it back and forth until the nozzles are free again.
- To prevent corrosion and material changes, the rotors and accessories must be cleaned regularly with soap or a mild cleaning agent and a damp cloth. Cleaning is recommended at least once a week. Dirt must be removed immediately. Ingredients of suitable cleaning agents: soap, anionic surfactants, non-ionic surfactants.
- After using cleaning agents, remove any cleaning agent residue by rinsing with water (only outside the centrifuge) or wiping with a damp cloth.
- The rotors and accessories must be dried immediately after cleaning.
- Disinfection:
  - If infectious material gets on the rotors or accessories, appropriate disinfection must be carried out.
  - Ingredients of suitable disinfectants:
    Glutaraldehyde, propanol, ethylhexanol, anionic surfactants, corrosion inhibitors.
  - After using disinfectants, remove the disinfectant residue by rinsing with water (only outside the centrifuge) or wiping with a damp cloth.
  - The rotors and accessories must be dried immediately after disinfection.
  - Removing radioactive contaminants:
  - The agent must be specifically designed to remove radioactive contaminants.
  - Ingredients of suitable agents for removing radioactive contamination:
  - Anionic surfactants, non-ionic surfactants, polyhydrogenated ethanol.
  - After removing the radioactive contamination, remove the remaining agent by rinsing with water (only outside the centrifuge) or wiping with a damp cloth.
  - The rotors and accessories must be dried immediately after removing radioactive contamination.
  - Check the rotor monthly for corrosion damage.

Rotors and accessories must no longer be used if there are signs of wear or corrosion, such as cracks in the material.

11.3 Autoclaving

The system must be cleaned and disinfected regularly (see Chapter 11.6“ Clean system with cleaning solution”). The device components and accessories are not suitable for autoclaving.

11.4 Remove splash guard holder and splash guard cap

The splash guard holder and splash guard cap can be removed from the boiler (Illustration 12) and the spin chamber (Illustration 12) for cleaning.

Remove splash guard holder and splash guard cap:
- Remove the splash protection cap (Illustration 12) from the boiler.
- Fold up the seal (Illustration 12) and remove the splash guard holder (Illustration 12) from the spin chamber.

Install splash guard holder and splash guard cap:
- Carefully fold up the seal (Illustration 12) located at the rear of the centrifugal chamber and guide the splash guard holder under the seal (Illustration 12).
  The drain opening of the splash guard holder must be above the drain opening in the bowl.
- Carefully fold the sealing ring up around the splash guard mount and carefully press the splash guard mount down. The splash guard holder must be located below the sealing ring.
- Place the splash guard cap (Illustration 12) on the splash guard holder so that the label “This side up” is legible (Illustration 12, in red)

11.5 Flush system with deionized or distilled water

- Remove the filling tube (solution 1) from the container with the physiological saline solution and insert it into the glass flask with the deionized or distilled water
- Start the system-program “flush”
- Remove the filling tube from the glass flask and reinsert it into the container with the saline solution
- Open the lid and dry the spin chamber

Leave the deionized or distilled water in the system until the next wash cycle is started to protect the system from crystallized salt crystals.

Before starting other programs, it is essential to first flush the system with the flushing program to avoid destroying the samples.

With the use of the optional 3-way valve (RL.S800), there is no need to change the filling tube. Further details Chapter 16.2.

11.6 Clean system with cleaning solution

- Prepare approximately 400 ml of a 0.5% sodium hypochlorite cleaning solution in a beaker and prepare some deionized or distilled water in a glass flask.
- Remove the saline solution tube (Solution 1) from the saline container and insert it into the beaker containing the 0.5% sodium hypochlorite cleaning solution
- Start the “flush” system program
- Wait 5 minutes
- Remove the saline solution tube from the beaker and insert it into the glass flask containing the deionized or distilled water
- Start the “flush” system program
- Open the lid and dry the spin chamber
- Remove the saline solution tube from the glass flask and insert it into the container containing the saline solution
- Start the “flush” system program
- Carry out a filling volume calibration as described in Chap. 10.2(“Calibrate the filling volume”).
- Remove the saline tube from the saline container and insert it into the glass flask containing deionized or distilled water
- Start the “flush” system program

- Leave the deionized or distilled water in the system until the next wash cycle is started. It is therefore essential that you first flush the system with the flushing program before running another program!

With the use of the optional 3-way valve (RL.S800), there is no need to change the filling tube. Further details Chapter 16.2.

11.7 Broken glass

If glass breaks, glass splinters and spilled centrifuged material must be carefully removed from the centrifugation chamber and from the tube holders.

The spilled centrifuged material may be infectious material, which is why the area must be disinfected immediately.

Before removing the glass splinters, first close the drain opening of the bowl (e.g. with a stopper, eraser or some cellulose) so that no glass splinters can get into the drain opening and block the drain connection on the back of the device (Illustration 2, item 9).

Before resuming operations

- Inspect the boiler for scratches. If available, have the boiler replaced by a service technician (contact your local appliance dealer).
- Replace tube holders from broken tubes. Check the rotor and its tube holder for scratches and check that the rotor is functioning correctly. If there are scratches or malfunctions, replace the rotor.

Never use tubes that

- fell on the floor
- have cracks in the glass

11.8 Repairs

Repairs and periodic maintenance work on the device (which requires opening the housing) are reserved ONLY for technicians authorized by the manufacturer. For repairs, ONLY use original parts certified by the manufacturer.

11.9 Rotor crash

In the event of a rotor crash, be sure to contact the manufacturer or local equipment dealer immediately for further instructions before touching the device or its components.

If contact is not possible, then take photos of the device from different angles, introduce a disinfectant into the device and disinfect the surroundings, but refrain from any further action!

11.10 Maintenance schedule

Recommended minimum requirements. The regulations applicable to the respective company or the respective conditions may require that certain maintenance items be carried out more frequently and / or exclusively by authorized service technicians.

Task	frequency			
	daily	weekly	monthly	yearly
Inspect the tubing and drain and clear obstructions if necessary	X			
Inspect the tubing connections and secure them if necessary	X			
Flush the system with deionized or distilled water	X			
Clean and dry the interior after normal usage to prevent corrosion and contamination	X			
Flush the system with cleaning solution		X		
Clean the fill ports on the rotor		X		
Check the saline volume setting and calibrate it if necessary. Frequency varies by length of service		X		
Check the rotor speed and calibrate it if necessary				X
Inspect the rotor for wear, corrosion, and damage Replace the rotor if these conditions exist			X	
Inspect the tube holders for wear and damage Replace tube holders if they are worn or damaged, or after they have been in use for two years			X	
Clean the exterior		X		
Replace the supply-/drain tubing and internal tubing				X
Replace the tube holder inserts for 10 mm x 75 mm tubes				X

Manufacturer recommendation:

- Replace tube holder every two years
- Replace rotor (including tube holder) every four years

If applicable, please follow the instructions on the rotor and comply with them.

12 Malfunctions and errors

12.1 Operation error

Disturbance	Caused	remedy
Incomplete wash cycle	• A 24-place rotor is being used, even though a 12-place rotor has been set as the rotor type. • The filling volume is set too low. • The injection nozzles are blocked.	• Check the rotor parameter in the system settings. • Check the volume (ml) and speed from the FILL-process in the used program. • Clean the injection nozzles.
Pellet does not form on the base of used tube	• The revolutions per minute during the centrifugation run for the agglutination test are too low. • The tube holders are left hanging in the decantation position • Wrong tube type	• Check the spin process from the used program. • Check the rotor functions. • Check if the used tube is the same as during the program validation
No pellet/pellet too small	• A 12-place rotor is being used, even though a 24-place rotor has been set as the rotor type. • The filling volume is set too high. • Wrong tube type	• Check the rotor parameter in the program. • Check the saline (ml) parameter in the program. • Check if the used tube is the same as during the program-validation.
The liquid is not decanted.	• The rotor mechanism is defective. • The revolutions per minute during the DECANT-process are too low.	• Check the rotor functions • Check the DECANT-process from the used program.
Noise during centrifugation	• Rotor brushes against splash guard	• Do not push the splash guard down too far.
Uneven distribution of liquid in the tubes	• Injection nozzles on rotor clogged • Device placed on an uneven surface.	• Clean injection nozzles • Place the device on a flat surface.

If the filling volume difference exceeds a tolerance of 15% compared to the setting, check the filling opening of the rotor and clean or replace it if necessary.

12.2 Error codes

Error Code	Error Name	Description	Possible reasons
0	No error	Program was successful, no error has occurred	
1	Running	Program is still running, so far no error has been detected (should never be visible in history)	
Motor error			
10	Motor startup error	Motor could not be started (no speed could be detected)	• Motor is blocked • Motor cable connection problem • Motor power supply problem
11	Motor acceleration error	Motor could not accelerate within tolerance (motor was too slow)	• Wrong rotor type selected • Mechanical friction too big
12	Motor acceleration error	Motor could not accelerate within tolerance (motor was too fast)	• Wrong rotor type selected
13	Motor speed error	Motor could not hold the desired speed (motor was too slow)	• Wrong rotor type selected Maximum of motor speed limit too high (4000 rpm can maybe not been hold) • Motor speed control does not work as intended • Motor speed reading failure
14	Motor speed error	Motor could not hold the desired speed (motor was too fast)	• Motor speed control does not work as intended • Motor speed reading failure
15	Motor brake error	Motor could not slow down within tolerance	• Wrong rotor type selected
16	Motor internal error	Motor has signalized an error	• Motor blocked • Motor over temperature • Motor power supply error
17	Motor power supply	The 24 V of the motor supply is not available	• Lid is detected as open
Fluid injection system error			
20	Pump error	Pump was not able to pump the desired amount of liquid	• Pipe blocked • Pump not working • Flow sensor not working
21	Liquid container empty	Not enough liquid available or air is in the pipe	• Liquid container empty • Air in the pipe • Flow sensor problem
Lid error			
30	Lid blocked	Open or check button was pressed, but the lid could not be opened.	• Lid mechanically blocked
31	Unlocking failed	Open or “CHECK” button was pressed, but the lock could not be unlocked.	• Motor was still rotating at the time the command for unlocking was received • Problem with the lock
32	Unexpected unlocking	Lid was opened without a request.	• Emergency unlocking was used

33	Lid detection failure	Lid sensor has detected an opening of the lid, but the lock sensor still signalizes the lock is closed	• Wrong lid detection of the lid sensor • Wrong lock detection of the lock sensor
System error			
40	Program reading error	It was not possible to read the complete program.	• Program file is corrupted • Not enough dynamic memory was available
41	Image loading failed	Not all images could be loaded	• An image is missing on the flash • An image on the flash is corrupted
42	EEPROM-error	Loading data from EEPROM failed. (reading not possible or checksum for the data is incorrect)	• EEPROM not initialized (login of a service user needed) • Communication failure
Miscellaneous			
50	Unknown	An error has occurred, but the kind of the error could not be identified	• Unexpected behavior
51	Program interrupted	A running program was interrupted	• Power interrupted during a running program.
52	Program aborted by user	The program was aborted by the user	• User has aborted the program
53	Imbalance	The program was stopped because of an imbalance of the rotor	• Rotor was not loaded symmetrically • Positioning of the imbalance sensor not correct

Screen freeze:
If the display is “frozen” (= device not in standby mode and no reaction when touching the darkened screen), perform a power reset.

Perform MAINS RESET:

- Switch off the main switch (Illustration 2, item 3) (“0” position).
- Wait at least 10s and turn the main switch back on (position “1”).
- Call up the last device run in the history, note the error code and report it to the local device support.

Warning

Before opening the lid, use the release pin (chapter 4.3) to check whether the rotor is at a standstill through the sight glass.

If the lid does not close: Check whether the lid latch access hole (Illustration 12) is blocked by a small object. If this is the case, contact local device support.

12.3 Change fuse

Unscrew the screw cap of the fuse holder (Illustration 2, item 6) by turning it 1/8 of the way counterclockwise and pull it out with the fuse. Replace the defective fuse element and screw the new element with the screw cap into the fuse holder by turning it in clockwise direction.

Warning

Turn off the power switch and disconnect the power plug of the power supply from the mains!

Only fuse elements of type T10A/125VAC (6.3 x 32 mm) with UL and CSA approval (order no. UC.E114) as well as screw caps for 6.3 x 32 mm fuse holders (order no. UC.E104) or fuse elements of type T10AA/250VAC (5.0 x 20 mm) with UL and CSA approval (order no. UC.E118) as well as screw caps for 5.0 x 20 mm fuse holders (order no. UC.E116) use.

13 Return of devices/device components

Warning

If the device, some parts of it or its accessories are returned to Hettich AG or the local supplier, to provide protection for people, the environment and materials, it must be decontaminated and cleaned before shipment, a declaration should be attached to the device or parts.

The device must be equipped with a transport lock for return shipping.

To return the device or device components via local device dealers, a return shipping number (RMA) must be requested.

We reserve the right to refuse contaminated devices or accessories.

Any costs incurred for cleaning and disinfection measures will be invoiced to the customer.

14 Storage

The device may only be stored under the following conditions:

- Storage in a closed, dust-free room in accordance with the storage conditions specified in the technical data (Chapter 5, Table 1).
- Frost free
- not connected to the power supply
- If the storage period is longer than 12 months, it's recommended to remove the battery on the controller-board.

Warning

Before storing the device, it must be decontaminated and cleaned to protect people, the environment and property. It is recommended that a note be affixed to the device indicating the date, signature and cleaning/disinfecting solution used.

15 Disposal

Warning

Before disposing of the device, it must be decontaminated and cleaned to protect people, the environment and property. When disposing of the device, all relevant legal regulations must be observed. It is recommended that a note be affixed to the device indicating the date, signature and cleaning/disinfecting solution used.

When disposing of the device, the relevant legal regulations must be observed.

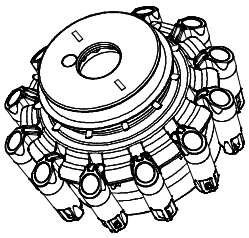
According to WEEE, all devices delivered after August 13, 2005 may no longer be disposed of with household or industrial waste. The device belongs to group 8 (medical devices) and is assigned to the business-to-business area.

The crossed-out trash can symbol indicates that the device must not be disposed of with household waste. The disposal regulations of individual EU countries may vary. If necessary, please contact the relevant authority or your supplier for further information on device disposal. The main board of the device is equipped with a lithium battery. This must be removed before the device is disposed of and disposed of in accordance with the legal regulations of the operating country.

Note for Germany:
The device must not be disposed of at public or municipal waste collection points or recycling points. If necessary, contact the relevant authority or your supplier for further information on device disposal.

16 Appendix

16.1 Rotors and accessories

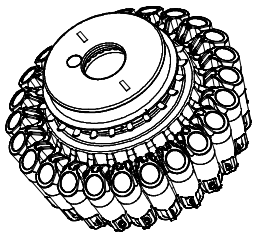
1017-A (for 1008-00) SM1012-A (for 1008-00S)		E2197					
Decant Rotor 12-Places  ∠ 45°							
		Adapter					
		1019 [1]					
							
		Tubes					
							
Capacity:	ml	3	5				
Dimensions / ∅ x L:	mm	10 x 75	12 x 75				
Number p. rotor		12	12				
Speed:	RPM (U/min)	3500 [2]					
RZB / RCF:		1438					
Radius:	mm	105					

[1] 1019 = reduction, set of 12 pieces
[2] max. speed 3500 rpm / 1438RCF => Consult the manufacturer/supplier of the tubes

The rotor for device type 1008-00S has the article number SM1012-A (without reductions)

All tests carried out by Hettich AG were carried out with the following tubes:

Glass 12x75mm, Haslab, 9270106 and 10x75mm Haslab, 9270105 and 10.5x75mm, Milian, 041-VR-10575-75.

1018-A (for 1008-00) SM1024-A (for 1008-00S)		E2197					
Dekantierrotor 24-fach / Decant Rotor 24-Places  ∠ 45°							
		Adapter					
		1019 [1]					
							
		Tubes					
							
Capacity:	ml	3	5				
Dimensions ∅ x L:	mm	10 x 75	12 x 75				
Number p. rotor:		24	24				
Speed:	RPM (U/min)	3500 [2]					
RZB / RCF:		1438					
Radius:	mm	105					

[1] 1019 = reduction, set of 12 pieces
[2] max. speed 3500 rpm / 1438RCF => Consult the manufacturer/supplier of the tubes

The rotor for device type 1008-00S has the article number SM1012-A (without reductions)

All tests carried out by Hettich AG were carried out with the following tubes:

Glass 12x75mm, Haslab, 9270106 and 10x75mm Haslab, 9270105 and 10.5x75mm, Milian, 041-VR-10575-75.

16.2 3-way valve

The 3-way valve (accessory no. RL.S800) is an optional switch between two liquids, e.g. saline solution and cleaning solution/distilled water, so that the tubes for the saline solution and cleaning solution do not have to be changed.

When switching between the two fluids, there may be air in the system. Therefore, the 3-way valve can only be operated with the two system programs (Flush and Refill pump).

It is recommended to use the "Refill pump" system program to remove air from the system. The duration can be adjusted as required.

If required, when the air is out of the system, the "Flush" system program can be used.

It is crucial that the suction tubes are completely submerged in the liquid tanks and that no air is being sucked in. Too much air in the system could result in an error message.

Make sure that the cleaning solution is completely removed from the system after cleaning before continuing with further work.

When installing in accordance with the separate installation instructions, ensure that all tube connections are tight.

16.3 Spare Parts

The following quantities are based on a recommendation from the manufacturer.

Item number	Description	> 5 devices	> 25 devices
E4259	plug, waste, for waste tube	X	
E4261	plug, Input 1, for saline tube	X	
E4260	Push-in plug, for emergency-release hole		X
E4258	weight for suction tube, INOX	X	
E4394	elbow nozzle, for drain-hose	X	
E4373	fill-hose, inlet 1, complete	X1	
E4374	waste-hose, drain-outlet, with connector	X1	
E4375	internal tube-set for periodic maintenance		X2
E2287-01	emergency-release pin		

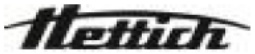
1 = Must be replaced after a rental or demo.

2 = Should be replaced after a rental or demo.

17 Revision history

Rev.	superseded version	Revision description	Date
1.0	01 - 06	Template, Contents, desc. of preloaded programs	23.05.2017
1.1	1.0	Correction p/n from accessories, implementation of Document History	24.05.2017
1.2	1.1	Edit chapter 12, 13, new CE-declaration and correction of typing errors	04.06.2017
1.3	1.2	Edit chapter 12, new header	07.06.2017
1.4	1.3	Editing formatting and adding the actual declaration of conformity	04.09.2017
1.5	1.4	Editing of writing and orthographic errors	30.11.2017
1.6	1.5	Editing the address from the manufacturer	01.12.2017
1.7	1.6	Editing the LOOP-process	01.12.2017
1.8	1.7	Editing of orthographic errors, preinstalled programs, notes on safety, use according to the specifications and unpacking the centrifuge	22.01.2018
1.9	1.8	Description from the preinstalled programs, DECANT max value, error 15	16.08.2018
2.0	1.9	tech. data (Noise), chapter password protection inserted, CE declaration renewed	08.01.2019
2.1	2.0	Edit chapter 2. Paragraph two, 2.1 software-version, edit chapter 8.1 overview, edit chapter 8.5.2 language, date and time settings, edit chapter 9.3.3 to 9.3.9 acceleration and braking presetting, edit chapter 9.4.5 SPIN-process	11.03.2019
2.2	2.1	Add. of the type 1008-00S, Chap. 2 best use, Chap. 5 tech. data, Chap. 6.3 Article number and added pictures, , Chap. 7.1.1 added, Chap. 9.3, 9.3.10 & 9.3.11 Program and Rotor added for device 1008-00S, Document history adapted	07.11.2019
2.3	2.2	Cha. 12.5 and 12.1 fixed typing errors, revision of the document history	02.12.2019
2.4	2.3	adjusted footer, Date p. 2, Cha. 3 typing errors fixed, line inserted in chap. 7.2 (orthography), access rights corrected in Chap. 8.2 and 8.5.2, translation errors corrected in Chap. 8.3, 8.5 and 8.6.2, font adapted to CI in Chap. 8.6.1 and the following chapter relocated to the next page, numbers implemented in pictures for better understanding in chap. 9.3, translation error corrected in chap. 9.4.5 and moved to the following page, added to the article number table and the reduction note expanded for better comprehensibility	31.01.2020
2.5	2.4	Revision status corrected in footer, typing error fixed (all chapters), layout adapted (entire document), all images and tables inserted in EN and updated according to the latest software 421, image captions and descriptions, image references adjusted (entire document) chap. 5 Technical data, sound pressure level changed from 49 to 62dB, chap. 16.2 inserted (from service manual), Fig.7.6 (rotor) inserted, chap. 8.1 Overview menu navigation new picture inserted in DE, chap. 8.6.3 Lid option explained and extra picture inserted, 9.4.6 DECANT new wording, 10.2 Calibration changed from monthly to weekly, sentence positions and spellings changed (all chapters) Chap. 15 Remove storage battery inserted, chap. 16.1 Added information regarding glass tubes, removed operator-manual from list in Cha. 6.3	09.06.2020

2.6	2.5	Removed everything about type 1008-03 from the entire instruction manual. Chapter 12.1, removed chapter reference to 10.2 Chapter 2.1 & 8.1, 8.1.1, inserted firmware version 1.01.424 Chapter 5, filling tolerance inserted and 12V car battery removed Chapter 8.3, inserted information about storage capacity of 24 programs Chapter 6, information that centrifuge was packaged under non-sterile conditions inserted Chapter 6.6 incl. picture added, marking (Nameplate) Title of cover sheet changed	02.12.2021
2.7	2.6	Chapter 2, resp. cleaning removed and replaced tuberculosis or tumor tests by tuberculosis tests Chapter 9.1 added Chapter 9.4.2, Results replaced by centrifugation results Chapter 9.4.6, Results replaced by decanting results Chapter 11, Centrifugation of materials or mixtures of materials with a density higher than 1.2 kg / dm3 removed Chapter 15.1, old tubes replaced by the newly tested tubes	21.01.2022
2.8	2.7	Chapter 9.5.1, section reworded Chapter 4.1, section reworded and added information regarding serious incidents	22.02.2022
2.9	2.8	Document name changed Total page inserted in footer and revision increased EC Declaration of Conformity removed Chapter 1.2, reference to exact guideline removed Chapter 14.1, reference to exact guideline removed Chapter 5, table-layout and base UDI-DI, class and Buffer battery inserted Chapter 8.1, red graphics frames formatted Chapter 8.1.1, symbol inserted, font changed to bold Chapter 9.6, Info about Login inserted	31.05.2022
2.10	2.9	Chapter 7.3, Added No. 1 & 2 to fig. 7.6 Chapter 7.5, wording changed Pos. 1&2 to No. 1&2 Chapter 8.4, changed wording at 3. and added 7.	20.06.2022
2.11	2.10	New Software 425 Chapter 5, Technical data: GMDN and Base UDI-DI added Chapter 9.5.3, FILL 2 process removed Chapter10.2, Calibrate fill volume: Wording of calibration check adjusted and recommended weekly check only five weeks after installation Chapter 10.4, Reference to chapter "Rotors and accessories" corrected Chapter 11.10, Maintenance schedule - " supply-/drain tubing " supplemented with "internal tubing".	21.04.2023
2.12	2.11	Chapter 1.1, information with DANGER, WARNING and CAUTION supplemented and shown in the complete document. Chapter 4, Added additional safety instructions Chapter 12.1, noise during centrifugation and uneven filling added Chapter 15, New Disposal. Subsequent chapters increased accordingly. Chapter 16.2, 3-way valve added as an accessory. Image captions renumbered where already present. Minor adjustments throughout the document. EC-REP and UK-REP added on the last page.	01.01.2024



EC REP

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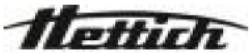

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