

Sigma 2-7 Sigma 2-7 IVD

from serial no. 157336



Operating Manual

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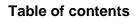




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1 General information

1.1 Importance of the operating manual

A fundamental requirement for the safe and trouble-free operation of the centrifuge is to be familiar with the fundamental safety instructions and all possible hazards.

The operating manual includes important information concerning the safe operation of the centrifuge.

This operating manual and, in particular, the notes on safety and hazards must be observed by all persons operating the centrifuge.

In addition, the local rules and regulations for the prevention of accidents must be complied with.

1.2 Intended use

The laboratory centrifuge is suitable for the separation of constituents of different densities in mixtures with a maximum density of 1.2 g/cm³.

The laboratory centrifuge that is marked with IVD is intended for human biological samples, including donated blood and tissue, in conjunction with diagnostic in-vitro applications. This means that it is a medical product in accordance with Regulation (EU) 2017/746 on in vitro diagnostica.

Only trained, specialised personnel are authorised to use the centrifuge in closed laboratories.

The intended use also includes:

- observation of all of the notes and instructions that are included in the operating manual and
- compliance with the inspection and maintenance instructions.

Sigma Laborzentrifugen GmbH cannot be held liable for:

- damage resulting from the improper use of the centrifuge not in line with its intended purpose,
- faulty results that are due to the incorrect or faulty procedures of the user.

1.3 Warranty and liability

The warranty and liability are subject to our "General Conditions" that were distributed to the operator upon the conclusion of the contract.

Warranty and liability claims are excluded if they are due to:

- · improper use.
- non-compliance with the safety instructions and hazard warnings in the operating manual.
- improper installation, start-up, operation, or maintenance of the centrifuge.

1 General information



1.4 Copyright

The copyright concerning the operating manual remains with Sigma Laborzentrifugen GmbH.

The operating manual is solely intended for the operator and their personnel. It includes instructions and information that must not be

- · duplicated,
- · distributed, or
- · communicated in any other way.

Non-compliance may be prosecuted under criminal law.

1.5 Standards and regulations

These operating instructions have been created in accordance with the relevant European standards and regulations (see chapter 11.5 - "EC declaration of conformity").

1.6 Scope of supply

The centrifuge comprises:

1 power cord with IEC C13 connector

1 socket wrench, size 4 (rotor)
 Part no. 930 050

1 socket wrench, size 6 (emergency release)
 Part no. 930 056

 1 tube (30 g) heavy-duty grease for loadbearing bolts

Part no. 71 401

Documentation:

Operating manual incl. EC declaration of conformity (see chapter 11.5 - "EC declaration of conformity")

Accessories

According to your order, our order confirmation, and your delivery note.



2 Layout and mode of operation

2.1 Layout of the centrifuge

2.1.1 Functional and operating elements

- 1 Lid
- 2 Display
- 3 User interface (see chapter 6.3.1 -"User interface")



Fig. 1: Total view of the centrifuge

- 4 Fuse holder
- 5 Mains power switch
- 6 Name plate (see chapter 2.1.2 -"Name plate")
- 7 Mains power input

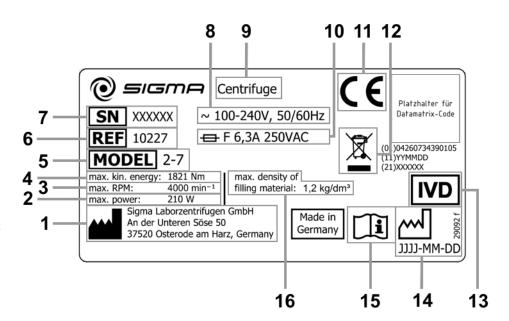


Fig. 2: Rear view of the centrifuge (example)



2.1.2 Name plate

- 1 Manufacturer
- 2 Power consumption
- 3 Max. speed
- 4 Max. kinetic energy
- 5 Product name
- 6 Part number
- 7 Serial number
- 8 Nominal voltage
- 9 Product designation
- 10 Input fuse
- 11 CE mark in compliance with the directive 2006/42/EC
- 12 Symbol for special disposal (see chapter 9 "Disposal")
- 13 IVD mark (if applicable)
- 14 Date of manufacture
- 15 Consult operating manual
- 16 Max. permissible density



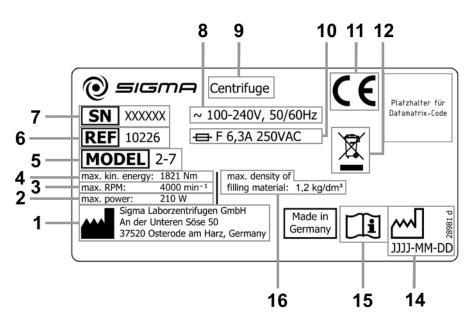


Fig. 3: Examples of name plates



2.2 Mode of operation

2.2.1 Centrifugation principle

Centrifugation is a process for the separation of heterogeneous mixtures of substances (suspensions, emulsions, or gas mixtures) into their components. The mixture of substances, which rotates on a circular path, is subject to centripetal acceleration that is several times greater than the gravitational acceleration.

Centrifuges use the mass inertia inside the rotor chamber for separating the substances. Due to their higher inertia, particles or media with a higher density travel outwards. In doing so, they displace the components with a lower density, which in turn travel towards the centre.

The centripetal acceleration of an object inside a centrifuge, as the effect of centripetal force, depends on the distance between the object and the axis of rotation as well as on the angular velocity. It increases linearly as a function of the distance with regard to the axis of rotation and quadratically as a function of the angular velocity. The bigger the radius in the rotor chamber is and the higher the speed is, the higher the centripetal acceleration is. However, the forces acting on the rotor also increase.

2.2.2 Area of application

Depending on the area of application of the centrifuge and also on the particle size, solids content, and volume throughput of the mixture of substances that is to be centrifuged, there are different types of centrifuges.

The areas of application go from household use as a salad spinner or honey separator up to specialised technical applications in the clinical, biological, or biochemical context:

- For numerous clinical examinations, cellular material must be separated from the liquid to be analysed. The normal separation process can be sped up considerably by using laboratory centrifuges.
- In the metal-working industry, centrifuges are used for separating oil from metal cuttings. Dairies use centrifuges in order to separate cow's milk into cream and low-fat milk.
- Particularly big centrifuges are used in the sugar industry for separating the syrup from the crystalline sugar.
- Ultracentrifuges are predominantly used in biology and biochemistry in order to isolate particles, e.g. viruses. They are specifically designed for high speeds up to 500,000 rpm. The rotor moves in a vacuum in order to avoid air friction.





2.2.2.1 Speed, radius, and relative centrifugal force

The acceleration g, which the samples are subject to, can be increased by increasing the radius in the rotor chamber and by increasing the speed. These three parameters are interdependent and linked with each other via the following formula:

Relative centrifugal force RCF = $11.18 \times 10^{-6} \times r \times n^2$

r = radius in cm n = speed in rpm RCF without any dimension

If two values are entered, the third value is determined by way of the stated formula. If, afterwards, the speed or the radius is changed, the resulting relative centrifugal force will be recalculated automatically by the control unit. If the RCF is changed, the speed will be adapted while the specified radius is maintained.

The speed-gravitational-field-diagram provides an overview of the relationship between speed, radius, and RCF (see chapter 11.2 - "Speed-gravitational-field-diagram").

2.2.2.2 **Density**

The laboratory centrifuge is suitable for the separation of constituents of different densities in mixtures with a maximum density of 1.2 g/cm³. All information concerning the speed of rotors and accessories refers to liquids with a density corresponding to this specification. If the density is above this value, the maximum permissible speed of the centrifuge must be reduced based on the following formula:

$$n = n_{max} x \sqrt{(1.2/\rho)}$$

 $\rho = density in g/cm^3$



3 Safety

3.1 Marking of the unit

The following symbols are used on this centrifuge:



On (Power)



Arrow indicating the direction of rotation



Off (Power)



Rotor loading information (see chapter 6.2.2.2 -"Installation of accessories")



Name plate (see chapter 2.1.2 - "Name plate")



CE mark in compliance with the directive 2006/42/EC



Do not dispose as part of domestic waste



Consult operating manual



Medical product in accordance with the regulation (EU) 2017/746



NRTL mark (only for the USA and Canada)



RCM mark (only for Australia)



China RoHS 2 mark (only for China)



California Proposition 65 mark (only for the USA)



Safety indications on the centrifuge must be kept readable at all times. If necessary, they must be replaced.



The marking varies depending on the version and country of destination of the centrifuge.



3.2 Explanation of the symbols and notes

In this operating manual, the following names and symbols to indicate hazards are used:



This symbol stands for a **direct** hazard to the life and health of persons.

Non-observance of these symbols <u>causes</u> serious health problems up to life-endangering injuries.



This symbol stands for a <u>direct</u> hazard to the life and health of persons due to electrical voltage.

Non-observance of these symbols <u>causes</u> serious health problems up to life-endangering injuries.



This symbol stands for a **potential** hazard to the life and health of persons.

Non-observance of these symbols <u>can</u> cause serious health problems up to life-endangering injuries.



This symbol indicates a potentially hazardous situation.

Non-observance of these notes can cause minor injuries or damage to property.



This symbol indicates important information.



3.3 Responsibility of the operator

The operator undertakes to authorise only trained, specialised personnel to work on the centrifuge (see chapter 3.4 - "Requirements concerning the personnel").

The areas of responsibility of the personnel concerning the operation, maintenance, and care of the unit must be clearly defined.

The safety-conscious work of the personnel in compliance with the operating manual and the relevant EC health and safety directives, and the national laws concerning health and safety and the prevention of accidents must be checked at regular intervals (e.g. every month).

Under the international rules for health and safety at work, the operator is obliged to:

- take measures in order to prevent danger to life or health during work.
- ensure that the centrifuges are used properly and entirely as intended (see chapter 1.2 "Intended use").
- take protective measures against fire and explosion when working with hazardous substances.
- take measures for the safe opening of the centrifuges.

The operator must perform a risk assessment concerning potential accidents in connection with the centrifuge and take design-related countermeasures, if necessary.

The operator must inform the users that any serious event which either directly or indirectly had, could have had or could have one of the following consequences must be reported to the manufacturer or competent authority:

- a) The death of a patient, user or other person,
- b) the temporary or permanent degradation of the health of a patient, user or other person,
- c) a serious risk to public health.

The centrifuge has to be maintained regularly (see chapter 8 - "Maintenance and service").

Components that are not in a perfect state must be replaced immediately.



3.4 Requirements concerning the personnel



Risk of injury if the personnel are not sufficiently qualified

If unqualified personnel perform work on the centrifuge or are present in the danger zone of the centrifuge, hazards result that can cause serious injuries and considerable damage to property.

- Ensure that all the tasks are performed by personnel with the corresponding qualifications.
- Ensure that unqualified personnel stay clear of the danger zones.



Risk of fatal injury to unauthorised persons due to hazards in the danger zone or work area

Unauthorised persons who do not fulfil the requirements described herein are not aware of the hazards in the work area. This is why there is a risk of serious or even fatal injuries for unauthorised persons.

- Ensure that unauthorised persons stay clear of the danger zone and work area.
- If in doubt, address these persons and instruct them to leave the danger zone and work area.
- Interrupt any running work if unauthorised persons are present in the danger zone or work area.

This manual uses the following personnel qualifications for various areas of activity:

Qualified electrician

Due to their special training, knowledge, experience and familiarity with the relevant standards and regulations, qualified electricians are in the position to perform work on electrical systems and to autonomously identify and prevent possible hazards.

Qualified electricians have been specifically trained for the environment in which they work and they are familiar with all the relevant standards and regulations.

Qualified electricians must fulfil the requirements as set out in the applicable legal provisions concerning the prevention of accidents.

Specialised personnel

Due to their special training, knowledge, experience and familiarity with the relevant regulations, specialised personnel are in the position to perform any tasks assigned to them and to autonomously identify and prevent possible hazards.

Operating personnel

Only trained, specialised personnel are authorised to operate the unit. The persons operating the unit must

- be familiar with the fundamental health, safety, and accident prevention regulations,
- have read and understood this operating manual, in particular the safety sections and warning notes, and confirmed this with their signature,
- have been instructed in the operation and maintenance of this centrifuge.



The operating personnel must ensure that any serious event which either directly or indirectly had, could have had or could have one of the following consequences will be reported to the manufacturer or competent authority:

- a) The death of a patient, user or other person,
- b) the temporary or permanent degradation of the health of a patient, user or other person,
- c) a serious risk to public health.

3.5 Informal safety instructions

- This operating manual is a part of the product.
- The operating manual must be kept at the location of use of the centrifuge. Ensure that it is accessible at all times.
- The operating manual must be handed over to any subsequent owner or operator of the centrifuge.
- Any changes, additions or updates received must be added to the operating manual.
- In addition to the operating manual, the general and local rules and regulations concerning the prevention of accidents and the protection of the environment must also be supplied.
- Safety and danger indications on the centrifuge must be kept readable at all times. If necessary, they must be replaced.



3.6 Safety instructions

3.6.1 Electrical safety

As protection against electric shock, the centrifuge is equipped with an earthed mains power cable and connector. To ensure the effectiveness of this safety feature, the following must be ensured:



- Ensure that the wall socket is properly wired and grounded.
- Check that the mains voltage agrees with the nominal voltage listed on the name plate.
- Ensure that the mains power cable is intact prior to using the centrifuge. Damaged or faulty mains power cables must be replaced immediately.
- Do not place vessels containing liquid on the centrifuge lid or within the safety distance of 30 cm around the centrifuge. Spilled liquids may get into the centrifuge and damage electrical or mechanical components.
- Service tasks or repairs of the electrical system for which the housing needs to be removed must only be carried out by authorised specialist personnel.
- Inspect the electrical equipment of the unit regularly. Defects such as loose or burnt cables must be eliminated immediately.
- Following the completion of any type of repair or service, the authorised specialist personnel must perform final inspection and testing in compliance with the relevant standards (see chapter 8.3 -"Service").

3.6.2 Mechanical safety

In order to ensure the safe operation of the centrifuge, observe the following:



- Do not open the lid when the rotor is in motion!
- Do not reach into the rotor chamber when the rotor is in motion!
- Do not use the centrifuge if it was installed incorrectly.
- Do not use the centrifuge without panels.
- Do not use the centrifuge if the rotors and inserts show signs of corrosion or other defects.
- Only use the centrifuge with rotors and accessories that have been approved by the manufacturer. In case of doubt, contact the manufacturer (see chapter 7.3 - "Service contact").
- Do not hold your fingers between the lid and the housing when closing the lid. Risk of crushing!
- Defective lid relieving devices could cause the centrifuge lid to fall (contact the service department, if necessary). Risk of crushing!
- Do not hit or move the centrifuge during its operation.
- Do not lean against or rest on the centrifuge during its operation.





- Do not spin any substances that could damage the material of the rotors and buckets of the centrifuge in any way. Highly corrosive substances, for example, damage the material and affect the mechanical strength of the rotors and buckets.
- Stop the centrifuge immediately in the event of a malfunction. Eliminate the malfunction (see chapter 7 "Malfunctions and error correction") or inform the service department of the manufacturer (see chapter 7.3 "Service contact").
- Ensure that all repairs are performed only by authorised and specialised personnel.
- Prior to any start-up, check the centrifuge, rotor, and accessories for signs of damage that can be discerned from the outside. Special attention must be paid to all of the rubber parts (e.g. motor cover, lid seal, and adapters) in terms of visible structural changes. Defective parts must be replaced immediately.
- Open the centrifuge when it is not in use so that moisture can evaporate.

3.6.3 Fire prevention



- Do not spin explosive or inflammable substances.
- Do not use the centrifuge within hazardous locations.

3.6.4 Chemical and biological safety

If pathogenic, toxic, or radioactive samples are intended to be used in the centrifuge, it is in the responsibility of the user to ensure that all necessary safety regulations, guidelines, precautions, and practices are adhered to accordingly.



- Infectious, toxic, pathogenic, and radioactive substances may only be used in special, certified containment systems with a bio-seal in order to prevent the material from being released.
- Take suitable precautions for your own safety if there is a risk of toxic, radioactive, or pathogenic contamination
- Materials that chemically react with each other with a high level of energy are prohibited.



- Keep informed about local measures to avoid harmful emissions (depending on the substances to be centrifuged).
- Protective clothing is not required for the operation of the centrifuge.
 The materials to be centrifuged may, however, require special safety
 measures (e.g. centrifugation of infectious, toxic, radioactive, or
 pathogenic substances).



3.6.5 Safety instructions for centrifugation

For safe operation, observe the following before starting the centrifuge:



- Ensure that the centrifuge was set up properly (see chapter 5 "Set-up and connection").
- Keep a safety range of at least 30 cm free around the centrifuge as well as with regard to walls and other devices.
- Do not store any dangerous goods in the centrifuge area.
- Do not stay in the safety area longer than what is absolutely necessary for the operation of the centrifuge.
- Only use the centrifuge with rotors and accessories that have been approved by the manufacturer. We explicitly warn against the use of equipment of poor quality. Breaking glass or bursting vessels can cause dangerous imbalances at high speeds.
- Ensure that the rotor and buckets are correctly fitted(see chapter 6.2.2.1 " Installation of a rotor").
- Observe the instructions on the installation of accessories (see chapter 6.2.2.2 - "Installation of accessories").
- The rotor must be loaded in a rotationally symmetrical manner at equal weights.
- If liquids with a density > 1.2 g/cm³ are used, reduce the speed (see chapter 2.2.2.2 "Density").
- Do not use the centrifuge if the rotor is loaded asymmetrically.
- Do not use the centrifuge with tubes that are excessively long.

3.6.6 Resistance of plastics

Chemical influences have a strong effect on the polymeric chains of plastics, and, therefore, on their physical properties. Plastic parts can be damaged if solvents, acids, or alkaline solutions are used.



Refer to the resistance data (see chapter 11.4 - "Resistance data")!



3.6.7 Safety of rotors and accessories

3.6.7.1 Marking of rotors and accessories

Marking of the service life of rotors and accessories

see chapter 3.6.7.2 - "Service life (for centrifuges according to Machinery Directive)" and chapter 3.6.7.3 - "Service life (for centrifuges according to the IVD regulation)"

Marking of rotors with Sigma "Comfort" rotor coating

see chapter 3.6.7.4 - "Service life of the "Sigma Comfort" rotor coating"

3.6.7.2 Service life (for centrifuges according to Machinery Directive)

The rotors and accessories have a limited service life.



- Perform regular checks (at least once per month) for safety reasons!
- Pay special attention to changes, such as corrosion, cracks, material abrasion, etc.
- After 10 years, they must be inspected by the manufacturer.
- After 50,000 cycles, the rotor must be scrapped for reasons of safety.
- If other data concerning the service life are engraved on the rotor or bucket, these data shall apply accordingly. For example, a bucket with the engraving "max. cycles = 15000" has a service life of 15,000 cycles, and a rotor with the engraving "Exp. date 01/27" must be scrapped in January 2027 at the latest (see figure).
- If a specification concerning the maximum number of cycles and a specification concerning the service life (i.e. a date) are provided, the specification that occurs first shall apply.





Fig. 4: Different service life - engraving on the bucket/rotor



 Refer to the table of the service life of rotors and accessories (see chapter 11.3 - " Table of the service life of rotors and accessories ")!



3.6.7.3 Service life (for centrifuges according to the IVD regulation)

Centrifuge

The service life of the centrifuge depends on several factors, e.g. the type and frequency of use, the area of application and the performance of service and maintenance tasks.

- The centrifuge has an expected service life of 10 years if all of the specified maintenance intervals are observed and all of the necessary maintenance tasks are performed without delay (see chapter 8.3 -"Service"). Non-compliance will shorten the service life of the centrifuge accordingly.
- The availability of spare parts can no longer be guaranteed after 10 years from the date of manufacture of the centrifuge.

Rotors and accessories

The rotors and accessories have a limited service life.



- Perform regular checks (at least once per month) for safety reasons!
- Pay special attention to changes, such as corrosion, cracks, material abrasion, etc.
- The rotors and accessories must be put out of service after 10 years.

 Any use after this period may be permissible in individual cases after an inspection performed by the manufacturer.
- After 50,000 cycles, the rotor must be scrapped for reasons of safety.
- If other data concerning the service life are engraved on the rotor or bucket, these data shall apply accordingly. For example, a bucket with the engraving "max. cycles = 10,000" has a service life of 10,000 cycles, and a rotor with the engraving "Exp. date 01/27" must be scrapped in January 2027 at the latest (see figure below).
- If a specification concerning the maximum number of cycles **and** a specification concerning the service life (i.e. a date) are provided, the specification that occurs first shall apply.





Fig. 5: Different service life - engraving on the bucket/rotor



• Refer to the table of the service life of rotors and accessories (see chapter 11.3 - " Table of the service life of rotors and accessories ")!



3.6.7.4 Service life of the "Sigma Comfort" rotor coating Marking

All "Comfort" coated swing-out rotors have a "C" shown after their number. These rotors do not need to be greased during the service life of the coating.

- 1 Marking indicating the "Sigma Comfort" rotor coating
- 2 Load-bearing bolt



Fig. 6: Marking of a rotor with "Comfort" coating (example)



A list of the available rotors with a "Comfort" rotor coating as well as information about the service life of the coating can be found in the "Sigma Comfort rotor coating" document that comes supplied with every rotor having a "Comfort" rotor coating.



It is not permissible to combine "Comfort" coated rotors with buckets or carriers with a cleanroom coating.

Service life

The service life of the coating varies and depends on the degree of utilisation of the rotor. Tests have shown a service life of 7,000 to 40,000 cycles. The service life of the "Comfort" rotor coating can be increased by way of specific measures:

The following factors have an influence on the service life:

- Speed/load:
 - The service life of the coating can be increased by a factor of 3.5 if the speed or load is decreased by approximately 15%. In case of a load decrease by 20%, the service life increases approximately by a factor of 5.5.
- Temperature:
 - The service life of the coating decreases by approximately 30% at lower temperatures (approximately 4°C) compared to room temperature (approximately 20°C).
- · Use of buckets:
 - The buckets and rotor form a joint unit. For the coating to reach the maximum possible service life, ensure to always use the same set of buckets and to always install the individual buckets in their specific position within the rotor.



Cleaning frequency:
 Regular cleaning of the accessories is indispensable. The more
 frequently the rotor needs to be cleaned, the shorter the service life of
 the coating will be.



Traces of use on the black coating do not affect the anti-friction properties (see the following illustration).



Fig. 7: Load-bearing bolt with traces of use - no greasing required

End of the service life of the "Comfort" rotor coating

When the coating has worn off nearly completely and the metallic surface of the load-bearing bolt becomes visible (see the following illustration), the anti-friction effect decreases. As a result, the buckets will swing out irregularly, thereby potentially resulting in unwanted imbalance.

- From this moment on, the rotor must be used with greased load-bearing bolts (heavy-duty grease for load-bearing bolts, ref. no. 71401) until it reaches the end of its service life.
- Mark the rotor accordingly to prevent it from being used without grease on the load-bearing bolts.



Fig. 8: Load-bearing bolt with completely worn-off anti-friction coating - greasing required



3.7 Safety devices

3.7.1 Lid lock device

The centrifuge can only be started when the lid is properly closed. The electrical lock must be locked. The lid can only be opened when the rotor has stopped. If the lid is opened by way of the emergency release system during operation, the centrifuge will immediately switch off and decelerate brakeless. If the lid is open, the drive is completely separated from the mains power supply, i.e. the centrifuge cannot be started (see chapter 7.1.1 - "Emergency lid release").

3.7.2 Standstill monitoring system

Opening of the centrifuge lid is only possible if the rotor is at a standstill. This standstill is checked by the microprocessor.

3.7.3 System check

An internal system check monitors the data transfer and sensor signals with regard to plausibility. The system continuously performs a self-check and identifies malfunctions. Malfunctions are indicated by error messages with a number in the speed/rcf display (see chapter 7.2 - "Table of error codes").

3.7.4 Earth conductor check

An earth conductor check can be carried out by authorised and specialised personnel using a suitable measuring instrument. Please contact the Sigma service department (see chapter 7.3 - "Service contact").

3.8 Measures in the event of hazards and accidents



- If an emergency arises, switch off the centrifuge immediately!
- If in doubt, call the emergency doctor!

3.9 Remaining hazards

The centrifuge was built in accordance with the state of the art and in compliance with the generally recognized safety rules. However, danger to life and limb of the operator, or of third parties, or impairments of the unit or other material assets cannot be completely excluded when the unit is being used.

- Use the unit only for the purpose that it was originally intended for (see chapter 1.2 "Intended use").
- Use the unit only if it is in a perfect running state.
- Immediately eliminate any problems that can affect safety.



4 Storage and transport

4.1 Dimensions and weight

	Sigma 2-7, Sigma 2-7 Cyto, Sigma 2-7 IVD
Height:	293 mm
Height with open lid:	643 mm
Width:	378 mm
Depth:	535 mm
Weight:	23 kg

4.2 Storage conditions

The centrifuge can be stored in its original packaging for up to a year.

- Store the centrifuge only in dry rooms.
- The permissible storage temperature is between -20°C and +60°C.
- If you would like to store it for more than one year, or if you intend to ship it overseas, please contact the manufacturer.

4.3 Notes on transport

 When lifting the centrifuge, always reach under the centrifuge from the side.



The centrifuge weighs approx. 23 kg!

• For transport use suitable packaging and, if at all possible, the original packaging (see chapter 4.4 - "Packaging").



4.4 Packaging

The centrifuge is packaged in a cardboard box.

- Open the box.
- Take out the box containing the accessories.
- Remove the upper foam element.
- Lift the centrifuge out of the cardboard box. When lifting the centrifuge, always reach under the centrifuge from the side.



The centrifuge weighs approx. 23 kg!

Retain the packaging for any possible future transport of the centrifuge.

4.5 Transport safety device

The centrifuge is not equipped with a transport safety device.



5 Set-up and connection

5.1 Installation site

Operate the centrifuge only in closed and dry rooms.

All the energy supplied to the centrifuge is converted into heat and emitted to the ambient air.

- · Ensure sufficient ventilation.
- Keep a safety range of at least 30 cm free around the centrifuge as well as with regard to walls or other devices so that the vents in the machine remain unobstructed and fully effective.
- Do not subject the centrifuge to thermal stress, e.g. by positioning it near heat generators.
- Avoid direct sunlight (UV radiation).
- The table must be stable and have a solid, even surface.
- Attention: During transport from cold to warmer places, condensational water will collect inside the centrifuge. It is important to allow sufficient time for drying (min. 24 h) before the centrifuge can be used again.

5.2 Power supply

5.2.1 Type of connection



The operating voltage on the name plate must correspond to the local supply voltage!



The mains power plug is an isolating device which is why it must be accessible at all times.

Sigma centrifuges are units of protection class I. The centrifuges of this model series have a three-wire power cord with an IEC C13 connector.



The removable power cord must not be longer than 3 m!

The power cord must not be replaced with a power cord of inadequate rating!



5.2.2 Customer-provided fuses

Typically, the centrifuge must be protected with 16 Amp B fuses that are to be provided by the customer.



To ensure safe disconnection in the event of a fault, an AC/DC-sensitive RCD (residual current device) must be integrated in the wiring system of the building.



6 Using the centrifuge

6.1 Initial start-up



 Before the initial start-up, please ensure that your centrifuge is properly set up and installed (see chapter 5 - "Set-up and connection").

6.2 Switching the centrifuge on

Press the mains power switch.

The display then illuminates. The centrifuge is ready for operation.

6.2.1 Opening and closing the lid

The lid can be opened if the centrifuge is at a standstill.

Press the lid key in order to open the lid.

The centrifuge cannot be started if the lid is opened.

 To close, press with both hands slightly on the lid until the lid lock is locked.



Do not place your fingers between the lid and the housing when closing the lid. Risk of crushing!



6.2.2 Installation of rotors and accessories

6.2.2.1 Installation of a rotor

- Open the centrifuge lid by pressing the lid key.
- Loosen the rotor tie-down screw by turning it anti-clockwise, but do not remove it.
- Lower the rotor with its central bore straight down onto the motor shaft.
- Tighten the rotor tie-down screw clockwise with the supplied rotor wrench with 3 Nm. In doing so, hold the rotor at its outer rim.
- Follow the safety instructions and hazard warnings (see chapter 3 "Safety")!



Once a day or after 20 cycles, the rotor tie-down screw must be loosened by some turns, and the rotor must be lifted and fastened again. This ensures a proper connection between the rotor and the motor shaft.



Rotors can be used without a cover. This leads, however, to higher levels of noise and temperatures when running.

Removing a rotor

Loosen the rotor tie-down screw anti-clockwise and remove the rotor.



6.2.2.2 Installation of accessories

- Only use inserts that are suitable for the rotor.
- All buckets of the swing-out rotor need to be installed when spinning.
- Always load the axial symmetrical inserts/buckets of the rotors with the same accessories and fill to avoid imbalance.

Centrifugation with different tube sizes

Working with different tube sizes is possible. In this case, however, it is very important that axial symmetrical inserts are identical (see figure).

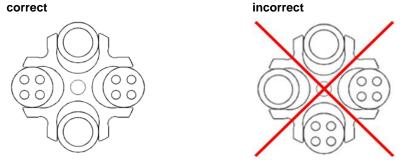


Fig. 9: Permissible and impermissible loading of a swing-out rotor with different tube sizes (example illustration)

Centrifugation with low capacity

- Install the tubes axial symmetrically so that the buckets and their inserts are loaded evenly.
- It is not permissible to load angle rotors on only one axis.

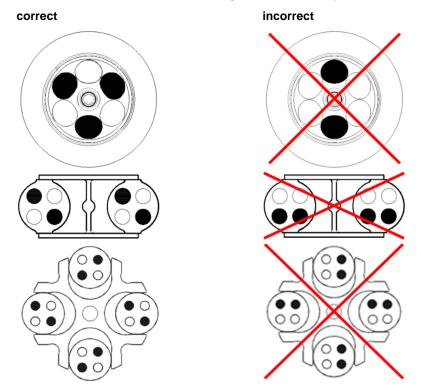


Fig. 10: Permissible and impermissible loading of an angle rotor and a swing-out rotor (example illustrations)





Pay attention to the marking of the centrifuge (see the illustration below)! Safety indications on the centrifuge must be kept readable at all times. If necessary, they must be replaced.

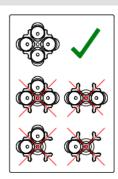


Fig. 11: Safety indication on the centrifuge: Loading of a swing-out rotor

6.2.2.3 Adapters

In order to ensure easy handling, even if vessels of various sizes are used, carrier systems were developed.

- Load the opposite adapters with the same number of vessels and with the same weights in order to avoid imbalance.
- If all of the compartments of a carrier are not used, the buckets must be loaded evenly. Loading the edges of a bucket only is not permissible.

6.2.2.4 Vessels

General

- Load the vessels outside of the centrifuge. Liquids in the bores of the rotor cause corrosion.
- Fill the vessels carefully and arrange them according to their weight. Imbalances result in the excessive wear of the bearings.
- After the centrifugation, remove the vessels carefully in order to prevent the samples from mixing.
- Follow the safety instructions and hazard warnings (see chapter 3 -"Safety")!

Glass vessels

- When using glass vessels, the maximum value of 4,000 x g must not be exceeded (except special high-strength glass vessels; please refer to the information provided by the manufacturer).
- When inserting 100 ml glass tubes (part no. 15100) into the buckets, a rubber cushion (part no. 16051) is mandatory.



If the glass tubes (part no. 15100) are used without a rubber cushion, they may break!



6.3 Control System "Spincontrol Basic"

6.3.1 User interface

- 1 Display
- 2 Set key
- 3 Program key
- 4 Arrow keys
- 5 Lid key
- 6 Start/Stop key
- 7 Quick run key



Fig. 12: User interface (example)

The centrifuge is started directly via the user interface. When the centrifuge is switched on, all segments will be illuminated for a short time. It is now ready for operation.

6.3.2 Display

The centrifuge display has the following display fields:

- Field for deceleration curves, run mode, and programs
- 2 Speed / RCF field
- 3 Time field
- 4 Field for rotor selection

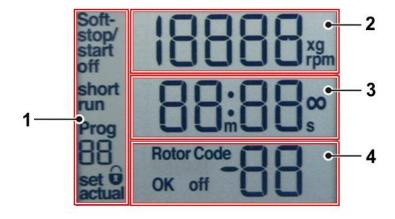


Fig. 13: Display, completely illuminated



6.3.3 Starting a centrifugation run

The centrifuge is ready for operation when the mains power switch is on and the lid is closed.

Press the start/stop key in order to start a centrifugation run.

During the centrifugation run, "actual" will be displayed in the lower left-hand area of the display.

In addition, a blue LED in the base area of the centrifuge lights up. It goes out when the centrifuge is at a standstill.

6.3.4 Interrupting a centrifugation run

 Press the start/stop key in order to interrupt a centrifugation run. The centrifugation run will be terminated prematurely.

6.3.5 Interrupting a deceleration process

• Press the start/stop key during a deceleration process in order to interrupt it and to restart the centrifuge.

6.3.6 Speed / Relative centrifugal force (RCF)

The RCF value is determined by the rotor geometry and speed. The RCF and speed values, therefore, depend on each other. If one of the two values is entered, the other value will be set automatically.

- To enter a value, press the Set button repeatedly until the corresponding unit and the word "set" flash in the lower left-hand area of the display.
- Select the desired speed or RCF value via the arrow keys.

The data will be saved in the following situations:

- When a centrifugation run is started.
- After approx. 20 seconds if no other button is pressed during this time.

During operation, you can switch from the speed value to the RCF value and vice versa via the arrow keys.

6.3.6.1 Changing the speed/RCF value during centrifugation

The preselected speed or RCF value can be changed during centrifugation.

- Press the set key repeatedly until the desired unit flashes on the display.
- Change the speed or RCF value by pressing the arrow keys. The parameters will take effect immediately.



6.3.7 Runtime

The preselected total runtime is displayed in the lower line of the display. During centrifugation, the remaining runtime is displayed. The runtime of the centrifuge can be set at one-second-intervals up to 99 minutes and 59 seconds.

- To enter a value, press the Set button repeatedly until the corresponding unit and the word "set" flash in the lower left-hand area of the display.
- Select the desired runtime by pressing the arrow keys.

The data will be saved in the following situations:

- When a centrifugation run is started.
- After approx. 20 seconds if no other button is pressed during this time.

6.3.7.1 Changing the runtime during centrifugation

The preselected runtime can be changed during centrifugation.

- Press the "set" key repeatedly until the time unit flashes on the display.
- Change the desired runtime by pressing the arrow keys. The parameters will be accepted immediately.



If the centrifugation time is changed during the run, the centrifuge will run for the entire new time and will disregard the previous runtime that has already elapsed.

6.3.7.2 Short run

During the short run, the centrifuge accelerates at maximum power until the maximum speed is reached.

· Keep the quick run key pressed during the short run.

The message "short run" and the duration of the short run are displayed. When the quick run key is released, the centrifuge decelerates at maximum power to a standstill.

After the short run, the lid unlocks automatically and the program that was set beforehand is displayed again.

6.3.7.3 Continuous run

During the continuous run, the runtime of the centrifuge is unlimited and must be stopped manually. The centrifuge accelerates during the continuous run until the set speed is reached.

- To start the continuous run, press the set key until the time unit flashes on the display.
- Press the down-key (arrow key) until the display switches from "00:10" to "--:--".



After 99 min 59 sec, any additional runtime will no longer be displayed, but the centrifugation will continue.

- To stop a continuous run, press the start/stop key. The centrifugation will end.
- Enter a runtime. The centrifugation will end after this time.

6.3.8 Rotor selection

In the factory settings, a rotor is already preselected, depending on the centrifuge version. If another rotor is used, the configuration must be adapted accordingly so that the prescribed maximum speed can be reached and the correct RCF value can be indicated.

- To select a rotor, press and hold the Set button until the rotor selection screen is displayed. Then, release the Set button.
- Use the arrow buttons to select the ID number (code) of the rotor that is used from the table (see below):
- Press the set key to confirm the input.

The RCF value will be adjusted automatically to the selected rotor.



The rotor selection will be saved under the corresponding program number.

Code	Rotor / bucket
1	11037
2	11071 with 13299
3	11071 with 13296
4	12072
5	12073
6	11123 with 13223 (Not certified for Sigma 2-7 IVD!)



6.3.9 Softstart and softstop function

The softstart function is used to extend the acceleration time, whereas the softstop function is used to extend the deceleration time. The current combination is shown on the display.

- To activate the softstart and softstop functions, press the set key repeatedly until "Soft-stop/start" flashes in the upper left part of the display.
- Press the arrow keys until "Soft-stop/start on" is displayed. The softstart and softstop functions are now activated.
- Press the arrow key until "Soft stop on" is displayed. Only the softstop function will be active and the centrifuge will start at normal speed.
- Press the arrow key until "Soft off" is displayed. The softstart and softstop functions are now deactivated.

The data will be accepted immediately and saved after approx. 20 seconds.

You can also change the settings as described above during a centrifugation run.

6.3.10 Automatic lid opening function

The automatic lid opening function ensures that the lid opens when the rotor has stopped. In the factory settings, the automatic lid opening function is activated.

- To deactivate the automatic lid opening function, press and hold the Set button.
- Press the upper arrow button 5 times and then release the Set button.

The automatic lid opening function is deactivated.

 Proceed in the same manner in order to activate the automatic lid opening function.

6.3.11 Start delay ("Clotting time")

This function has been specially developed for laboraties that use serum tubes with a so-called clot activator. For this application, the samples must be at rest for a defined time prior to the actual centrifugation. This time is referred to as the "clotting time".

The start delay function can be used to start the entire centrifugation process, including the clotting time, following the insertion of the samples without any further inputs.

After the programmed delay has elapsed, the centrifuge will start automatically with the preset parameters.

In the factory settings, this function is deactivated.

- To deactivate the function, press and hold the Set button.
- Press the upper arrow button 4 times and then release the Set button.
- Select the desired delay by way of the arrow buttons.
- Press the Set button in order to confirm the selection.

The selected delay is activated. During the set start delay, the word "clot" is displayed and the blue LED flashes slowly. When the actual centrifugation process starts, the LED lights continuously.



 To deactivate the delay function, proceed as described above and select the value 0.

6.3.12 Sound signal

This function provides a sound signal that is issued at the end of a centrifugation run, in the event of an imbalance, or when an error message is displayed. In the factory settings, the sound signal is activated.

- To deactivate the sound signal, press and hold the Set button.
- Press the upper arrow button 2 times and then release the Set button.

The sound signal is deactivated.

Proceed in the same manner in order to activate the sound signal.

6.3.13 Button signal

This function provides a sound signal that is issued whenever a button is pressed. In the factory settings, the button signal is activated.

- To deactivate the button signal, press and hold the Set button.
- Press the upper arrow button 6 times and then release the Set button. The button signal is deactivated.
- Proceed in the same manner in order to activate the button signal.

6.3.14 Button lock

In order to prevent any unauthorised use of the centrifuge, its buttons can be locked. In the factory settings, the button lock is deactivated.

 To activate the button lock, press the Start/Stop button 3 times while the lid is open. When pressing it the third time, hold it until the lock symbol is displayed.

The button lock is activated. The Start/Stop button, lid button, and arrow buttons for selecting the indication of the speed or RCF value remain active even if the button lock is active.

• Proceed in the same manner in order to deactivate the button lock.



6.3.15 Programs

Program is are used to save or load certain recurrent settings of the centrifuge. 10 different programs can be saved and called up.

6.3.15.1 Saving the current settings

- Press the program key. Then, select a program number by pressing the arrow keys. The display "Prog - - " will now flash.
- · Select the correct rotor.
- Press the set key repeatedly until the corresponding unit flashes on the display. Select the desired parameters.
- In order to save the data, start the centrifuge or press the set key repeatedly until the indication "Prog -" stops flashing.



Program numbers that are already occupied will be overwritten with the current data.

6.3.15.2 Calling up stored programs

- Press the program key. Then, select a program number by pressing the arrow keys. The display "Prog - - " will now flash.
- · Ensure that the correct rotor is installed.
- In order to save the data, start the centrifuge or press the set key repeatedly until the indication "Prog - -" stops flashing.

6.4 Switching the centrifuge off

- Open the centrifuge when it is not in use so that moisture can evaporate.
- Switch the centrifuge off by pressing the mains power switch.



7 Malfunctions and error correction

7.1 General malfunctions

Malfunctions are indicated by error messages with a number in the speed/RCF display. In addition, the blue LED flashes rapidly.

In the event of a fatal error (e.g. a defective lid lock), a certain safety time will be counted down on the display. During this time, "ERR" and "SAFE" flash alternately on the display. When the time is up, "OFF" will be displayed.



Do not switch the centrifuge off until "OFF" is displayed! This is necessary in order to ensure that the rotor is at a complete standstill.

- Eliminate the source of the problem (see tables below).
- Acknowledge the error messages with the lid key.

Type of error	Possible reason	Correction			
No indication on the display	No power in the mains supply	Check fuse in the mains supply			
	Power cord is not plugged in	Plug in power cord correctly			
	Mains power switch off	Switch mains power switch on			
	Lid is not closed correctly	Close the lid			
Centrifuge cannot be started: The set speed value is displayed in an	Several possible causes	Power off/on. If the error occurs again, contact service			
unchanged manner	The lid lock is not closed correctly	Open and close lid. If the error occurs again, contact service			
Centrifuge decelerates during operation and displays an error from 1 to 18 after powering on	Several possible causes	Power off/on. If the error occurs again, contact service			
Centrifuge decelerates during operation and displays error 19 after powering on	Several possible causes	Acknowledge by pressing the lid key			
Lid cannot be opened	Lid locks have not released	Unlock the lid manually (see chapter 7.1.1 - "Emergency lid release")and contact service			
	Lid seal sticks	Clean the lid seal and apply talcum powder			
Temperature value cannot be reached (only for refrigerated centrifuges)	Condenser dirty	Contact service			



7.1.1 Emergency lid release

In the event of a power failure, it is possible to manually open the centrifuge lid.

- Switch off the mains power switch and disconnect the power cord from the socket.
- Remove the plug (see figure, item 1) from the front panel, e.g. with a screwdriver.



Fig. 14: Position of the opening for the emergency lid release

 Insert the supplied hexagon socket key horizontally into the hole and turn it anti-clockwise to the stop. The lid lock will then audibly unlock.



Fig. 15: Manual release of the lid lock

• Then, reinsert the plug.



Do not unlock or open the lid unless the rotor is at a standstill.

If the lid is opened via the emergency lid release system during a centrifuge run, the centrifuge will be switched off immediately and decelerate in an unbraked manner.



7.2 Table of error codes

_			
Error no.	Kind of error	Measures	Note
1-9	System error	Allow to slow downPower off/on	All these errors stop the centrifuge or cause it to decelerate brakeless
10-19	Speedometer error	Allow to slow downPower off/on	
20-29	Motor error	Power offEnsure ventilation	
30-39	EEPROM error	Allow to slow downPower off/on	With error 34, 35, and 36, the centrifuge will stop; with error 37 and 38 only an error message will be given
40-45	Temperature error (only for refrigerated centrifuges)	 Allow to slow down Power off Allow to cool down Provide better ventilation (only air-cooled centrifuges) Provide sufficient water throughput (only water-cooled centrifuges) 	
46-49	Imbalance error (only for centrifuges with imbalance monitoring system)	Allow to slow downPower offEliminate the imbalance	
50-59	Lid error	 Press lid key Close lid Remove foreign matter from the opening of the lid lock device 	With error 50 and 51, the centrifuge will stop
60-69	Process error	Allow to slow downPower off/on	With error 60, the message "power failure during run"will be displayed, with error 61, the message "stop after power on" will be displayed
70-79	Communication error	Allow to slow downPower off/on	
80-89	Parameter error	Power offAllow to cool downProvide for better ventilation	With error 83, error message only
90-99	Other errors	 Check connections Provide sufficient water throughput (only water-cooled centrifuges) 	



If it is impossible to eliminate the errors, contact the service!



7.3 Service contact

In the event of queries, malfunctions, or spare part enquiries:

From Germany:

Contact

Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode (Germany) Tel. +49 (0) 55 22 / 50 07-44 44 E-mail: support.lab@sigma-zentrifugen.de

Outside Germany:

Contact our agency in your country. All agencies are listed at $\underline{www.sigma-zentrifugen.de} \rightarrow [Sales Partners]$



 If you would like to utilise our service, please state the type of your centrifuge and its serial number.



8 Maintenance and service

The centrifuge, rotor, and accessories are subject to high mechanical stress. Thorough maintenance performed by the user extends the service life and prevents premature failure.



If corrosion or other damage occurs due to improper care, the manufacturer cannot be held liable or subject to any warranty claims.

- Use soap water or other water-soluble, mild cleaning agents with a pH value between 6 and 8 for cleaning the centrifuge and accessories (see also chapter 8.2 "Sterilisation and disinfection of the rotor chamber and accessories").
- · Avoid corrosive and aggressive substances.
- · Do not use solvents.
- Do not use agents with abrasive particles.
- Do not expose the centrifuge and rotors to intensive UV radiation or thermal stress (e.g. by heat generators).

8.1 Maintenance

8.1.1 Centrifuge

- Unplug the mains power plug before cleaning.
- Carefully remove all liquids, including water and particularly all the solvents, acids, and alkaline solutions from the rotor chamber using a cloth in order to avoid damage to the motor bearings.
- If the centrifuge has been contaminated with toxic, radioactive, or pathogenic substances, clean the rotor chamber immediately with a suitable decontamination agent (depending on the type of contamination).



Take suitable precautions for your own safety if there is a risk of toxic, radioactive, or pathogenic contamination.

 After every cleaning process, grease the motor shaft slightly with a small amount of heavy-duty grease for load-bearing bolts (part no. 71401) and distribute the grease with a cloth so that it forms a thin layer.



8.1.2 Accessories



For the care of the accessories, special safety measures must be considered as these are measures that will ensure operational safety at the same time!

- Immediately rinse off the rotor, buckets, or accessories under running
 water if they have come into contact with any liquids that may cause
 corrosion. Use a brush for test tubes in order to clean the bores of angle
 rotors. Turn the rotor upside down and allow it to dry completely.
- Clean the accessories outside the centrifuge once a week or preferably after each use. Adapters should be removed, cleaned and dried.



Do not clean the accessories in a dishwasher!

Cleaning in a dishwasher removes the anodised coating; the result is cracking in areas that are subject to stress.

- If the rotors or accessories have been contaminated with toxic, radioactive, or pathogenic substances, clean them immediately with a suitable decontamination agent (depending on the type of contamination). Take suitable precautions for your own safety if there is a risk of toxic, radioactive, or pathogenic contamination.
- Dry the accessories with a soft cloth or in a drying chamber at approx. 50°C.

8.1.2.1 Plastic accessories

The chemical resistance of plastic decreases with rising temperatures (see chapter 11.4 - "Resistance data").

• If solvents, acids, or alkaline solutions have been used, clean the plastic accessories thoroughly.



Plastic accessories must not be greased!



8.1.3 Rotors, buckets and carriers

Rotors, buckets and carriers are produced with the highest precision, in order to withstand the permanent high stress from high gravitational fields. Chemical reactions as well as stress-corrosion (combination of oscillating pressure and chemical reaction) can affect or destroy the metals. Barely detectable cracks on the surface can expand and weaken the material without any visible signs.

- Check the material regularly (at least once a month) for
 - cracks
 - visible damage of the surface
 - pressure marks
 - signs of corrosion
 - other changes.
- Check the bores of the rotors and multiple carriers.
- Replace any damaged components immediately for your own safety.
- After every cleaning process, grease the rotor tie-down screw slightly with a small amount of heavy-duty grease for load-bearing bolts (part no. 71401) and distribute the grease with a cloth so that it forms a thin layer.

8.1.3.1 Load-bearing bolts of the swing-out rotor

Use of plastic buckets



The load-bearing bolts of the rotor must not be greased if plastic buckets are used!

Use of aluminium buckets

Rotors with Sigma "Comfort" rotor coating



The load-bearing bolts of some types of swing-out rotors have an antifriction coating. This coating prevents friction between the buckets and bolts.

The bolts do not require any greasing during the service life of the coating (see chapter 3.6.7.4 - "Service life of the "Sigma Comfort" rotor coating")!

All "Comfort" coated swing-out rotors have a "C" shown after their number (see chapter 3.6.7.1 - "Marking of rotors and accessories").



A list of the available rotors with a "Comfort" rotor coating as well as information about the service life of the coating can be found in the "Sigma Comfort rotor coating" document that comes supplied with every rotor that has anti-friction coating.







It is not permissible to combine "Comfort" coated rotors with buckets or carriers with a cleanroom coating.

Rotors without "Sigma Comfort" rotor coating

The load-bearing bolts of rotors that do not (or no longer) have anti-friction coating must be greased. This is the only way to ensure a uniform swing-out motion of the buckets and, therefore, the smooth operation of the centrifuge. Load-bearing bolts that are insufficiently greased may cause the centrifuge to stop due to an imbalance.

- Clean the load-bearing bolts and bucket groove in order to remove the old grease.
- Apply a small amount of heavy-duty grease for load-bearing bolts (ref. no. 71401, see the following picture) to both load-bearing bolts of a bucket.



Fig. 16: Sufficient quantity of grease for one bolt

- Install the bucket and swing it manually back and forth once in order to distribute the grease.
- Repeat this process with all the other buckets.



8.1.4 Glass breakage



In the case of glass breakage, immediately remove all glass particles (e.g. with a vacuum cleaner). Replace the rubber cushions since even thorough cleaning will not remove all glass particles.

Glass particles will damage the surface coating (e.g. anodising) of the buckets, which will then lead to corrosion.

Glass particles in the rubber cushions of the buckets will cause glass breakage again.

Glass particles on the pivot bearing of the load- bearing bolts prevent the buckets and carriers from swinging evenly, which will cause an imbalance.

Glass particles in the rotor chamber will cause metal abrasion due to the strong air circulation. This metal dust will not only pollute the rotor chamber, rotor, and materials to be centrifuged but also damage the surfaces of the accessories, rotors, and rotor chamber.

In order to completely remove the glass particles and metal dust from the rotor chamber:

- Grease the upper third of the rotor chamber with e.g. Vaseline.
- Then, let the rotor rotate for a few minutes at a moderate speed (approx. 2000 rpm). The glass and metal particles will now collect at the greased part.
- Remove the grease with the glass and metal particles with a cloth.
- If necessary, repeat this procedure.

8.2 Sterilisation and disinfection of the rotor chamber and accessories

- Use commercially-available disinfectants such as, for example, Sagrotan®, Buraton®, or Terralin® (available at chemist's shops or drugstores).
- The centrifuge and the accessories consist of various materials. A
 possible incompatibility must be considered.
- Before using cleaning or decontamination agents that were not recommended by us, contact the manufacturer to ensure that such a procedure will not damage the centrifuge.
- For autoclaving, consider the continuous heat resistance of the individual materials (see chapter 8.2.1 "Autoclaving").

Please contact us if you have any queries (see chapter 7.3 - "Service contact").



If dangerous materials (e.g. infectious and pathogenic substances) are used, the centrifuge and accessories must be disinfected.



8.2.1 Autoclaving

The service life of the accessories essentially depends on the frequency of autoclaving and use.

- Replace the accessories immediately when the parts show changes in colour or structure or in the occurrence of leaks etc.
- During autoclaving, the caps of the tubes must not be screwed on in order to avoid the deformation of the tubes.



It cannot be excluded that plastic parts, e.g. lids or carriers, may deform during autoclaving.

Category	Type of accessory	Material abbreviation	121 °C 20 min	134 °C 20 min	Remarks
Rotors and lids	Aluminium rotors	AL	yes	yes	
	Polypropylen rotors	PP	no	no	
	Polycarbonate lids for angle rotors	PC	no	no	
	Polyallomer lids for angle rotors	PA	no	no	
	Polysulfone lids for angle rotors	PSU	yes	yes	100 cycles max.
Buckets and caps	Aluminium buckets	AL	yes	yes	
	Polyamide buckets	PA	no	no	13035, 13296, 13299
	Polyphenylsulfone caps	PPSU	yes	yes	100 cycles max.
	Polysulfone caps	PSU	yes	yes	100 cycles max.
Adapters	Polyallomer carriers	PA	no	no	
	Polycarbonate carriers	PC	no	no	
	Polypropylene carriers	PP	no	no	
Tubes	Stainless steel tubes and bottles		yes	no	
	Glass tubes		yes	yes	
	Polyethylene tubes	PE	no	no	
	Polyflor tubes	PF	yes	yes	100 cycles max.
	Polycarbonate tubes	PC	no	no	
	Polypropylene copolymer tubes	PPCO	yes	no	20 cycles max.
	Polystyrene tubes	PS	no	no	
Additional equipment	Stainless-steel balance weight for blood-bag systems		yes	no	



8.3 Service



In the event of service work that requires the removal of the panels, there is a risk of electric shock or mechanical injury.

- Only authorised specialist personnel is authorised to perform this service work.
- Following the completion of any type of service, the authorised and specialised personnel must perform final inspection and testing in compliance with the relevant standards.

The centrifuge is subject to high mechanical stress. In order to be able to withstand this high level of stress, high-quality components were used during the production of the centrifuge. Nevertheless, wear cannot be excluded and it may not be visible from the outside. Especially the rubber parts that are – among other things – part of the motor suspension, are subject to ageing.

This is why we recommend having the centrifuge checked by the manufacturer during an inspection once per year in the operating state and once every three years in the dismantled state. Motor damping elements must be replaced after three years.

Repairs, changes, and repeat tests

After repairs, changes, and in the event of repeat tests, a qualified electrician must perform a test of the electrical safety (in accordance with DIN EN 61010-1).

The specified test in accordance with DGUV V3, DIN EN 61010-1 must be performed for centrifuges made by Sigma. The test is considered as passed if the specified limits are complied with.

A measurement in accordance with VDE 0701-0702 leads to higher values, which is due to a different measurement method. If the limit values are also complied with in this case, the test is also considered as passed. If the limit values are exceeded, a test in accordance with DIN EN 61010-1 is mandatory.

Information and appointments:

In Germany:

Contact Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode (Germany) Tel. +49 (0) 55 22 / 50 07-44 44

E-mail: support.lab@sigma-zentrifugen.de





Outside Germany:

Contact our agency in your country. All agencies are listed at www.sigma-zentrifugen.de → [Sales Partners]



 If you would like to utilise our service, please state the type of your centrifuge and its serial number.



8.4 Return of defective centrifuges or parts

Although we exercise great care during the production of our products, it may be necessary to return a unit or accessory to the manufacturer. In order to ensure the quick and economical processing of returns of centrifuges, spare parts, or accessories, we require complete and extensive information concerning the process. Please fill in the following forms completely, sign them, enclose them with the return package, and send them together with the product to:

Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode (Germany)

1. Declaration of decontamination

As a certified company and due to the legal regulations for the protection of our employees and of the environment, we are obliged to certify the harmlessness of all incoming goods. For this purpose, we require a declaration of decontamination.

- The form must be filled in completely and signed by authorised and specialised personnel only.
- Affix the original form in a clearly visible manner to the outside of the packaging.



We will return the part/unit if no declaration of decontamination is provided!

2. Form for the return of defective parts

This form is for the product-related data. They facilitate the assignment, and they enable the quick processing of the return. If several parts are returned together in one packaging, please enclose a separate problem description for every defective part.

• A detailed problem description is necessary in order to perform the repair quickly and economically.



If the form does not include a description of the malfunction, neither a refund nor a credit note can be issued. In this case, we reserve the right to return the part/unit to you at your expense.

 Upon request, we will prepare and submit to you a cost estimate prior to performing the repair. Please confirm such cost estimate within 14 days. If the cost estimate has still not been confirmed after 4 weeks, we will return the defective part/unit. Please note that you must bear the incurred costs.



8 Maintenance and service



The defective part/unit must be packaged in a transport-safe manner. Please use the original packaging for the unit, if at all possible. If the product is dispatched to us in unsuitable packaging, you will be charged the cost for returning it to you in new packaging.

The forms can be downloaded online from $\underline{\text{www.sigma-zentrifugen.de}} \rightarrow [\text{Service}] \rightarrow [\text{Overhaul and repair}].$



9 Disposal

9.1 Disposal of the centrifuge



In accordance with the directive 2012/19/EU, SIGMA centrifuges are marked with the symbol shown to the left. This symbol means that it is not permissible to dispose of the unit among household waste.

- You can return these centrifuges free of cost to Sigma Laborzentrifugen GmbH.
- Ensure that the unit is decontaminated. Fill in a declaration of decontamination (see chapter 8.4 - "Return of defective centrifuges or parts").
- Comply with any other applicable local rules and regulations.

9.2 Disposal of the packaging

- Use the packaging to return the centrifuge for disposal or
- dispose of the packaging, after having separated the individual materials.
- Comply with all local rules and regulations.



10 Technical data

Manufacturer:	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode Sigma (Germany)						
Type:	Sigma 2-7	Sigma 2-7 IVD					
Order no.:	10226	10227					
Connection requirements Electrical connection: Protection class: IP code: Max. power consumption (W): Input fuse (AF):	see name plate I 20 210 (at 100-240 V / 50 6.3 (at 220-240 V / 50	•					
Performance data Max. speed (rpm): Max. capacity (ml): Max. gravitational field (x g): Max. kinetic energy (Nm):	4,000 450 (30 x 15 ml) 2,540 1,821						
Other parameters Time range:	10 sec – 99 min 59 se short run, continuous						
Physical data Height (mm): Height with opened lid (mm): Width (mm): Depth (mm): Weight (kg): Noise level (db(A)):	293 643 378 525 23 55 (at max. speed)						

10.1 Ambient conditions

- The figures are valid for an ambient temperature of +23°C and a nominal voltage ± 10 %.
- · For indoor use only.
- Maximum altitude 2,000 m above sea level.
- Allowable ambient temperature +5°C to +40°C.
- Max. permissible relative humidity 80% from 5°C to 31°C, with a linear decrease to 50% relative humidity at 40°C.
- Pollution degree 2.

10.2 Technical documentation

For environmental reasons, the comprehensive technical documentation of the centrifuge (e.g. circuit diagrams) and the safety data sheets of the manufacturers of refrigerants and lubricants are not attached to this documentation.

You can order these documents from our service department.



11.1 Range of accessories

The complete list of accessories can be downloaded from www.sigma-zentrifugen.de.

11.1.1 Rotor radii

The information in the accessories table concerning the radius refers to the values of the respective rotor as shown below. The radius calculation is described in chapter 2.2.2.1 - "Speed, radius, and relative centrifugal force".

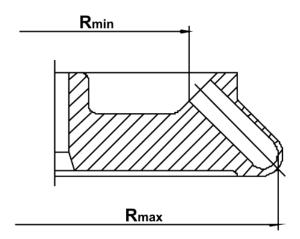


Fig. 17: Minimum and maximum radius of an angle rotor

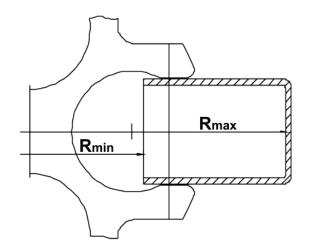


Fig. 18: Minimum and maximum radius of a swing-out rotor



11.2 Speed-gravitational-field-diagram

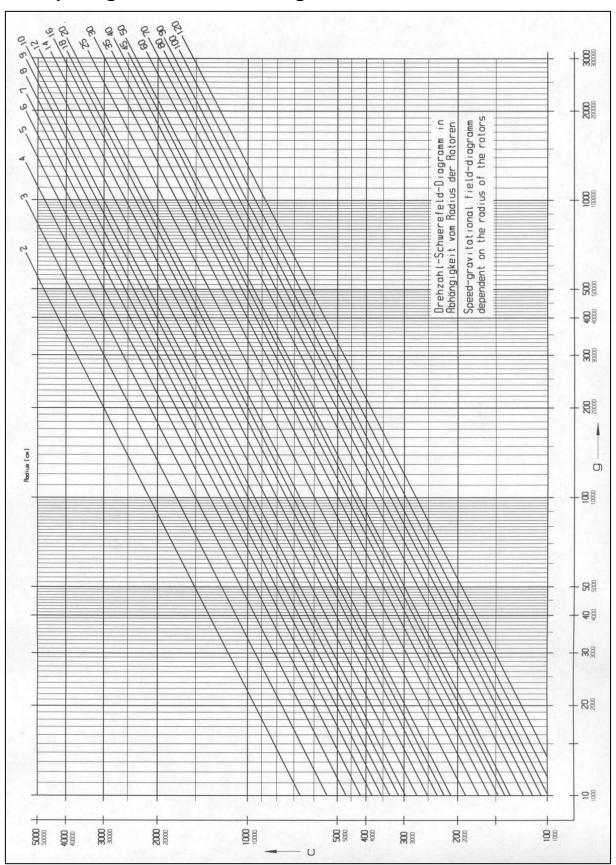


Fig. 19: Speed-gravitational-field-diagram



11.3 Table of the service life of rotors and accessories

- The rotors and accessories must be put out of service after 10 years. Any use after this period may be permissible in individual cases after an inspection performed by the manufacturer.
- If a specification concerning the maximum number of cycles **and** a specification concerning the service life (i.e. a date) are provided, the specification that occurs first shall apply.
- After 50,000 cycles, rotors must be scrapped for safety reasons.

Rotor / bucket	Cycles	Service life ("Exp.Date")	Suitable for centrifuge	Remarks
9100	35,000		4-5KL, 4-16S, 4-16KS, 4-16KHS, 6-16S, 6-16HS, 6-16KS, 6-16KHS	
9366	15,000		4-5KL, 4-16S, 4-16KS, 4-16KHS, 6-16S, 6-16HS, 6-16KS, 6-16KHS	
11805	15,000	10 years	8KS, 8KBS	
11806		10 years	8KS, 8KBS	
12082		7 years	1-14, 1-14K	
12084		7 years	1-14, 1-14K	
12092		5 years	1-14, 1-14K	
12094		5 years	1-14, 1-14K	
12096		5 years	1-14, 1-14K	
12097		5 years	1-14, 1-14K	
12134		5 years	1-16, 1-16K	
12135		5 years	1-16, 1-16K	
12137		5 years	1-16, 1-16K	
12505	30,000		8KS	
12600		7 years	6-16S, 6-16HS, 6-16KS, 6-16KHS	
13035			2-7	Do not grease the load-bearing bolts of the rotor
13218	20,000		4-5KL, 4-16S, 4-16KS, 4-16KHS, 6-16S, 6-16HS, 6-16KS, 6-16KHS	
13221	10,000		4-16S, 4-16KS, 4-16KHS, 6-16S, 6-16HS, 6-16KS, 6-16KHS	
13296	35,000	5 years	2-7, 2-16KL, 2-16KHL	Do not grease the load-bearing bolts of the rotor
13299		5 years	2-7, 2-7 Cyto, 2-16P, 2-16KL, 2-16KHL, 3-30KS, 3-30KHS	Do not grease the load-bearing bolts of the rotor
13625	20,000		6-16S, 6-16HS, 6-16KS, 6-16KHS	
13635	25,000		6-16S, 6-16HS, 6-16KS, 6-16KHS	
13650	20,000		6-16S, 6-16HS, 6-16KS, 6-16KHS	
13845	20,000		8KS	
13850	10,000	10 years	8KS	
13860	15,000	10 years	8KBS	



11.4 Resistance data



The data refer to resistance at 20°C.

- no data 1 resistant 2 practically resistant 3 partially resistant 4 not resistant		Concentration	High Density Polyethylene	Polyamide	Polycarbonate	Polyoxymethylene	Polypropylene	Polysulfone	Polyvinyl chloride, hard	Polyvinyl chloride, soft	Polytetrafluorethylene	Acrylonitrile-butadiene-caoutchouc	Aluminium
Medium	Formula	[%]	HDPE	PA	PC	POM	Ь	PSU	PVC	PVC	PTFE	NBR	AL
Acetaldehyde	C ₂ H ₄ O	40	3	2	4	2	3	4	4	-	1	4	1
Acetamide	C ₂ H ₅ NO	saturated	1	1	4	1	1	4	4	-	1	-	1
Acetone	C ₃ H ₆ O	100	1	1	4	1	1	4	4	-	1	4	1
Acrylonitrile	C_3H_3N	100	1	1	4	3	3	4	4	4	1	4	1
Allyl alcohol	C ₃ H ₆ O	96	1	3	3	2	2	2	2	4	1	1	1
Aluminium chloride	AICI ₃	saturated	1	3	2	4	1	-	1	-	1	1	4
Aluminium sulfate	Al ₂ (SO ₄) ₃	10	1	1	1	3	1	1	1	1	1	1	1
Ammonium chloride	(NH ₄)Cl	aqueous	1	1	1	2	1	1	1	1	1	1	3
Ammonium hydroxide	$NH_3 + H_2O$	30	1	3	4	1	1	2	1	-	1	-	1
Aniline	C ₆ H ₇ N	100	1	3	4	1	2	4	4	4	1	4	1
Anisole	C ₇ H ₈ O	100	3	4	4	1	4	4	2	-	1	4	1
Antimony trichloride	SbCl ₃	90	1	4	1	4	1	-	1	-	1	-	4
Benzaldehyde	C ₇ H ₆ O	100	1	3	4	1	1	3	4	4	1	4	1
Benzene	C ₆ H ₆	100	3	2	4	1	3	4	4	-	1	4	1
Boric acid	H ₃ BO ₃	aqueous	1	3	1	2	1	-	-	-	1	1	1
Butyl acrylate	C ₇ H ₁₂ O ₂	100	1	2	4	2	3	4	4	4	1	-	1
Butyl alcohol, normal	C ₄ H ₁₀ O	100	1	1	2	1	1	2	2	4	1	1	1
Calcium chloride	CaCl ₂	alcoholic	1	4	2	3	1	-	-	4	1	1	3
Carbon disulfide	CS ₂	100	4	3	4	2	4	4	4	4	1	3	1
Carbon tetrachloride (TETRA)	CCI ₄	100	4	4	4	2	4	4	4	4	1	3	1
Chlorine	Cl ₂	100	4	4	4	4	4	4	4	4	1	-	3
Chlorine water	Cl ₂ x H ₂ O		3	4	4	4	3	-	3	3	1	-	4
Chlorobenzene	C ₆ H ₅ CI	100	3	4	4	1	3	4	4	4	1	4	1
Chloroform	CHCl ₃	100	3	3	4	4	3	4	4	4	1	4	3



												ppen	
- no data 1 resistant 2 practically resistant 3 partially resistant 4 not resistant		Concentration	High Density Polyethylene	Polyamide	Polycarbonate	Polyoxymethylene	Polypropylene	Polysulfone	Polyvinyl chloride, hard	Polyvinyl chloride, soft	Polytetrafluorethylene	Acrylonitrile-butadiene- caoutchouc	Aluminium
Medium	Formula	[%]	HDPE	PA	PC	POM	a	PSU	PVC	PVC	PTFE	NBR	AL
Chromic acid	CrO ₃	10	1	4	2	4	1	4	1	-	1	4	1
Chromic potassium sulphate	KCr(SO ₄) ₂ x 12H ₂ O	saturated	1	2	1	3	1	-	1	-	1	-	3
Citric acid	C ₆ H ₈ O ₇	10	1	1	1	2	1	1	1	1	1	1	1
Citric acid	C ₆ H ₈ O ₇	50	1	3	1	2	1	-	-	-	1	1	1
Copper sulphate	CuSO ₄ x 5H ₂ O	10	1	1	1	1	1	1	1	1	1	1	4
Cyclohexanol	C ₆ H ₁₂ O	100	1	1	3	1	1	1	1	4	1	2	1
Decane	C ₁₀ H ₂₂	100	-	1	2	1	3	-	-	-	1	2	1
Diaminoethane	C ₂ H ₈ N ₂	100	1	1	3	1	1	-	3	4	1	1	1
Diesel fuel	_	100	1	1	3	1	1	-	1	3	1	1	1
Dimethyl formamide (DMF)	C ₃ D ₇ NO	100	1	1	4	1	1	4	3	-	1	3	1
Dimethyl sulfoxide (DMSO)	C ₂ H ₆ SO	100	1	2	4	1	1	4	4	-	1	-	1
Dimethylaniline	C ₈ H ₁₁ N	100	-	3	4	2	4	-	-	-	1	-	1
Dioxane	C ₄ H ₈ O ₂	100	2	1	4	1	3	2	3	4	1	3	1
Dipropylene glycol (mono)methyl ether	C ₄ H ₁₀ O	100	3	1	4	1	4	4	4	4	1	-	1
Ethyl acetate	C ₄ H ₈ O ₂	100	1	1	4	1	1	4	4	4	1	4	1
Ethylene chloride	C ₂ H ₄ Cl ₂	100	3	3	4	1	3	4	4	4	1	-	1
Ferrous chloride	FeCl ₂	saturated	1	3	1	3	1	1	1	1	1	-	4
Formaldehyde solution	CH ₂ O	30	1	3	1	1	1	-	-	-	1	2	1
Formic acid	CH ₂ O ₂	100	1	4	3	4	1	3	3	1	1	2	1
Furfural	$C_5H_4O_2$	100	1	3	3	2	4	-	-	-	1	4	1
Gasoline	C ₅ H ₁₂ - C ₁₂ H ₂₆	100	2	1	3	1	3	3	2	-	1	1	1
Glycerol	C ₃ H ₈ O ₃	100	1	1	3	1	1	1	1	2	1	1	1
Heptane, normal	C ₇ H ₁₆	100	2	1	1	1	2	1	2	4	1	1	1
Hexane, n-	C ₆ H ₁₄	100	2	1	2	1	2	1	2	4	1	1	1
Hydrogen chloride	HCI	5	1	4	1	4	1	1	1	-	1	2	4
Hydrogen chloride	HCI	concentrated	1	4	4	4	1	1	2	3	1	4	4
Hydrogen peroxide	H ₂ O ₂	3	1	3	1	1	1	1	1	-	1	3	3
Hydrogen peroxide	H ₂ O ₂	30	1	4	1	4	1	1	1	-	1	3	3
Hydrogen sulphide	H ₂ S	10	1	1	1	1	1	1	1	3	1	3	1
lodine, tincture of	l ₂		1	4	3	1	1	-	4	4	1	1	1



- П Аррения													
- no data 1 resistant 2 practically resistant 3 partially resistant 4 not resistant		Concentration	High Density Polyethylene	Polyamide	Polycarbonate	Polyoxymethylene	Polypropylene	Polysulfone	Polyvinyl chloride, hard	Polyvinyl chloride, soft	Polytetrafluorethylene	Acrylonitrile-butadiene- caoutchouc	Aluminium
Medium	Formula	[%]	HDPE	PA	PC	POM	&	PSU	PVC	PVC	PTFE	NBR	AL
Isopropyl alcohol	C ₃ H ₈ O	100	1	1	1	1	1	1	1	4	1	-	2
Lactic acid	C ₃ H ₆ O ₃	3	1	3	1	2	1	1	2	-	1	1	1
Magnesium chloride	MgCl ₂	10	1	1	1	1	1	1	1	1	1	1	1
Mercuric chloride	HgCl ₂	10	1	4	1	3	1	1	1	1	1	1	4
Mercury	Hg	100	1	1	1	1	1	1	1	3	1	1	3
Methyl acetate	C ₃ H ₆ O ₂	100	1	1	4	2	1	-	4	4	1	-	1
Methyl alcohol	CH ₄ O	100	1	2	4	1	1	3	1	3	1	2	1
Methyl benzene	C ₇ H ₈	100	3	1	4	1	3	4	4	4	1	4	1
Methyl ethyl ketone (MEK)	C ₄ H ₈ O	100	1	1	4	1	1	4	4	4	1	4	1
Methylene chloride	CH ₂ Cl ₂	100	4	3	4	3	3	4	4	4	1	-	1
Mineral oil	_	100	1	1	1	1	1	1	1	-	1	1	1
Nitric acid	HNO ₃	10	1	4	1	4	1	1	1	-	1	4	3
Nitric acid	HNO ₃	100	4	4	4	4	4	-	4	-	1	4	1
Nitrobenzene	C ₆ H ₅ NO ₂	100	3	4	4	3	2	4	4	4	1	4	1
Oleic acid	C ₁₈ H ₃₄ O ₂	100	1	1	1	2	1	-	1	-	1	3	1
Oxalic acid	C ₂ H ₂ O ₄ x 2H ₂ O	100	1	3	1	4	1	1	1	1	1	2	1
Ozone	O ₃	100	3	4	1	4	3	1	1	-	1	4	2
Petroleum	_	100	1	1	3	1	1	1	1	3	1	1	1
Phenol	C ₆ H ₆ O	10	1	4	4	4	1	4	1	3	1	3	1
Phenol	C ₆ H ₆ O	100	2	4	4	4	1	3	4	3	1	3	1
Phosphoric acid	H ₃ PO ₄	20	1	4	2	4	1	-	-	-	1	2	4
Phosphorus pentachloride	PCI ₅	100	-	4	4	4	1	-	4	4	1	-	1
Potassium hydrogen carbonate	CHKO₃	saturated	1	1	2	1	1	-	-	-	1	-	4
Potassium hydroxide	KOH	30	1	1	4	3	1	1	1	1	1	-	4
Potassium hydroxide	KOH	50	1	1	4	3	1	1	1	1	1	-	4
Potassium nitrate	KNO ₃	10	1	1	1	1	1	-	-	-	1	1	1
Potassium permanganate	KMnO ₄	100	1	4	1	1	1	-	1	-	1	3	1
Pyridine	C ₅ H ₅ N	100	1	1	4	1	3	4	4	4	1	4	1
Resorcinol	C ₆ H ₆ O ₂	5	1	4	2	3	1	4	2	-	1	-	2
Silver nitrate	AgNO ₃	100	1	1	1	1	1	1	1	1	1	2	4



 no data 1 resistant 2 practically resistant 3 partially resistant 4 not resistant 		Concentration	High Density Polyethylene	Polyamide	Polycarbonate	Polyoxymethylene	Polypropylene	Polysulfone	Polyvinyl chloride, hard	Polyvinyl chloride, soft	Polytetrafluorethylene	Acrylonitrile-butadiene- caoutchouc	Aluminium
Medium	Formula	[%]	HDPE	PA	PC	POM	PP PP	PSU	PVC	PVC	PTFE	NBR	AL
Sodium bisulphite	NaHSO₃	10	1	1	2	4	1	-	-	-	1	1	1
Sodium carbonate	Na ₂ CO ₃	10	1	1	1	1	1	-	-	-	1	-	3
Sodium chloride	NaCl	30	1	1	1	1	1	1	1	1	1	1	3
Sodium hydroxide	NaOH	30	1	1	4	1	1	1	1	1	1	2	4
Sodium hydroxide	NaOH	50	1	1	4	1	1	1	1	-	1	2	4
Sodium sulfate	Na ₂ SO ₄	10	1	1	1	1	1	1	1	1	1	1	1
Spirits	C ₂ H ₆ O	96	1	1	1	1	1	1	1	3	1	-	1
Styrene	C ₈ H ₈	100	4	1	4	1	3	-	4	4	1	4	1
Sulphuric acid	H ₂ SO ₄	6	1	4	1	4	1	1	1	-	1	2	3
Sulphuric acid	H ₂ SO ₄	fuming	4	4	4	4	4	4	4	4	1	4	3
Tallow	_	100	1	1	1	1	1	-	1	1	1	1	1
Tetrahydrofuran (THF)	C ₄ H ₈ O	100	3	1	4	1	3	4	4	4	1	3	1
Tetrahydronaphthalene	C ₁₀ H ₁₂	100	3	1	4	1	4	4	4	4	1	-	1
Thionyl chloride	Cl ₂ SO	100	4	4	4	2	4	4	4	4	1	-	3
Tin chloride	SnCl ₂	10	1	4	2	2	1	-	-	-	1	1	4
Transformer oil	_	100	1	1	3	3	1	1	1	-	1	1	1
Trichloroethane	C ₂ H ₃ Cl ₃	100	3	3	4	2	4	4	4	4	1	4	4
Urea	CH ₄ N ₂ O	10	1	1	1	1	1	-	-	-	1	1	1
Urine	_	100	1	1	1	1	1	-	1	1	1	-	2
Vinegar	C ₂ H ₄ O ₂	10	1	4	1	1	1	1	1	1	1	2	1
Vinegar	C ₂ H ₄ O ₂	90	1	4	4	4	1	3	1	4	1	-	1
Wax	_	100	-	1	1		1	-	-	-	1	-	1
Wines	_	100	1	1	1	2	1	1	1	1	1	-	4
Xylene	C ₈ H ₁₀	100	3	1	4	1	4	4	4	4	1	4	1





11.5 EC declaration of conformity



EC - DECLARATION OF CONFORMITY

The product named hereinafter was developed, designed, and manufactured in compliance with the relevant, fundamental safety and health requirements of the listed EC directives and norms. In the event of modifications that were not authorised by us or if the product is used in a manner that is not in line with the intended purpose, this declaration will be rendered void.

Product designation:	Laboratory centrifuge
Product name:	Sigma 2-7 Sigma 2-7 Cyto
Order number:	10226 10228
Directives:	2006/42/EC Machinery Directive 2014/35/EU Low Voltage Directive 2014/30/EU EMC Directive (EU) 2015/863 RoHS Directive
Normes:	EN 61010-2-020:2017 EN IEC 61326-1:2021

Sigma Laborzentrifugen GmbH

An der Unteren Söse 50 37520 Osterode Germany Authorised representative for CE matters: Eckhard Tödteberg

Osterode, 2024-12-04

Managing Director

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EC – DECLARATION OF CONFORMITY

Product designation:	Laboratory centrifuge
Product name:	Sigma 2-7 IVD
Part number:	10227
Basic UDI as referred to in Part C of Annex VI:	426073439IVD01001JQCJ4
Manufacturer:	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode Germany
Single Registration Number (SRN):	DE-MF-000009414

As the manufacturer of the unit(s), we assume full responsibility and hereby declare that the product(s) mentioned hereinabove comply with the requirements as set out in the following regulation(s)/directive(s).

Regulations:	(EU) 2017/746	Regulation on in vitro diagnostica
Directives:	(EU) 2015/863	RoHS directive
Risk class in accordance with Annex VIII	Class A	
Osterode, 2024-04-25		

Michael Souder
Managing Director

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11.6 Declaration of conformity – China RoHS 2



DECLARATION OF CONFORMITY

China RoHS 2 (Administrative Measures for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products)

Laboratory centrifuge models: Sigma 1-14, 1-14K, 1-7, 1-16, 1-16K, 2-7, 2-16P, 2-16KL,2-16KHL, 3-16L, 3-16KL, 3-18KS, 3-18KHS, 3-30KS, 3-30KHS, 4-5L, 4-5KL; 4-5KRL, 4-16S, 4-16KS, 4-16KHS, 6-16S, 6-16HS, 6-16KS, 6-16KHS, 8KS, 8KBS

Sigma Laborzentrifugen GmbH has made reasonable effort to avoid the use of hazardous substances in the products it manufactures (laboratory centrifuges).

A Product Conformity Assessment (PCA) was performed in order to determine whether the concentration of harmful substances in all homogeneous materials of the component parts is above or below the MCV limit (Maximum Concentration Value limit) as defined in GB/T 26572:

Mercury and its compounds: 0.1 % Cadmium (Cd) and its compounds: 0.01 %

Lead (Pb) and its compounds: 0.1 % Hexavalent chromium (Cr (VI)) and its compounds: 0.1 %

Polybrominated biphenyls (PBB): 0.1 % Polybrominated diphenyl ethers (PBDE): 0.1 %

	Table 1: N	表1 产 lame and conten	品中有害物质的 at of hazardous s		e product	
部件名称 Component	有害物质 Hazardous substance					
part (PCA)	铅 Lead (Pb)	汞 Mercury (Hg)	镉 Cadmium (Cd)	六价铬 Hexavalent Chromium (Cr (VI))	多溴联苯 Poly- brominated biphenyls (PBB)	多溴二苯醚 Polybromi- nated diphenyl ethers (PBDE)
Electronic PCB, cables	X ¹⁾	0	0	0	0	0
Display	0	0	0	O	0	0
Housing	X ²⁾	0	0	0	0	0
Base, metal, accessories	X ²⁾	0	0	O	0	0
			据SJ/T 11364的规 nade according to			

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- O: 表示该有害物质在该部件所有均质材料中的含量均在GB/T 26572规定的限量要求以下。 Indicates that the content of the harmful substance in all homogeneous materials of the component part is below the limit as defined in GB/T 26572.)
- X: 表示该有害物质至少在该部件的某一均质材料中的含量超出GB/T 26572规定的限量要求。(企业可在此处,根据实际情况对上表打"X"的技术原因进行进一步说明。) Indicates that the content of the harmful substance in at least one homogeneous material of the component part exceeds the limit as defined in GB/T 26752. (Contact the manufacturer for further technical information according to the actual situation.)
- 1) Contains parts in compliance with exemptions 6c, 7c.l, 7c.ll and 37 of 2011/65/EU RoHS.
- ²⁾ Contains parts in compliance with exemptions 6a, 6b and 6c of 2011/65/EU RoHS.

Apart from the exemptions given in this table, none of the substances listed above have been intentionally added to the product or metallic coatings.

Sigma Laborzentrifugen GmbH

An der Unteren Söse 50 37520 Osterode Germany

Osterode, 2024-04-25

M. Weigoni, Director of Procurement

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