# Lot 9, anexa tehnica

# Rotofix 32 A, rotor 1418, 8 adaptoare 1647

# **DM000739303**, Rg04-000177

Parametri solicitati	Parametri oferiti
Centrifugă de laborator (32 tuburi)	Centrifugă de laborator (32 tuburi)
Cod 150930	Cod 150930
Descriere Centrifugele de laborator sunt destinate	Descriere Centrifugele de laborator sunt destinate
pentru a centrifuga sîngele.	pentru a centrifuga sîngele.
Parametrul Specificația	Parametrul Specificația
Viteza de rotație Minimală, rpm reglabilă	Viteza de rotație Minimală, rpm reglabilă
Maximală, rpm $\geq 3500$	Maximală, rpm 6000, 4000 cu rotorul 1418, inclus
	in set
Setări setarea vitezei	Setări setarea vitezei
Capacitatea Tipul tuburilor tuburi de 10 - 15 ml	Capacitatea Tipul tuburilor tuburi de 10 - 15 ml
Numărul de tuburi 32 unitati	Numărul de tuburi 32 unitati
Timer Diapazon minim de timp 1 - ≥60 min	Timer Diapazon minim de timp 1 - 99 min
Incrementarea ≤1 min	Incrementarea 1 min, manual, "enter tun time"
Securitatea Blocarea capacului în timpul lucrului	Securitatea Blocarea capacului în timpul lucrului
obligatoriu	obligatoriu
Indicatori Indicarori vizual și acustic obligatoriu	Indicatori Indicatori vizual și acustic - DA
Debalansare obligatoriu	Debalansare da
Pornire/oprire obligatoriu	Pornire/oprire da
Capac deschis obligatoriu	Capac deschis da
Display Digital obligatoriu	Display Digital da,
Nivelul de zgomot ≤ 65 dB obligatoriu	Nivelul de zgomot 52 dB
Fereastra, orificiu sau alt acces, necesar pentru	Fereastra, orificiu sau alt acces, necesar pentru
efectuarea procedurii de verificare periodica,	efectuarea procedurii de verificare periodica,
conform normelor si standartelor in vigoare	conform normelor si standartelor in vigoare
obligatoriu	obligatoriu





#### HIGHLIGHTS

- RPM: 500 6,000 min<sup>-1</sup>
  Adjustable in increments of 100
- max. RCF: 4,226
- max. capacity: 4 x 100 ml / 6 x 94 ml
- choice of 9 rotors
- easy operation with keypad
- 2 individual deceleration stages
- IVDR-conform according to regulation (EU) 2017/746

### FEATURES

- metal housing and lid
- viewing port in the lid
- one-hand lid lock
- lid dropping protection
- emergency lid lock release
- stainless steel chamber
- automatic rotor recognition
- brushless drive
- error display
- imbalance monitoring and switch-off
- control panel with actual values of all parameters
- auditory message after completion of the centrifugation run



# TECHNICAL DATA

RO	T	DF	IX	32	Α

voltage *)	208 – 240 V 1 ~
frequency	50 – 60 Hz
consumption	300 VA
emission, immunity	EN/IEC 61326-1, class B
max. capacity	4 x 100 ml / 6 x 94 ml
max. RPM	6,000 min <sup>-1</sup>
max. RCF	4,226
running time	1-99 min, ∞ continuous run, short cycle mode (impulse button)
dimesions (WxDxH)	366 x 430 x 257 mm
weight	approx. 23 kg
noise level	52 dB (A) with rotor 1628
Cat. No.	1206
100 – 127 V 1 ~ / 50 – 60 Hz *)	1206-01
emission, immunity	FCC class B

<sup>\*)</sup> Other voltages on request.

# - AVAILABLE ROTORS

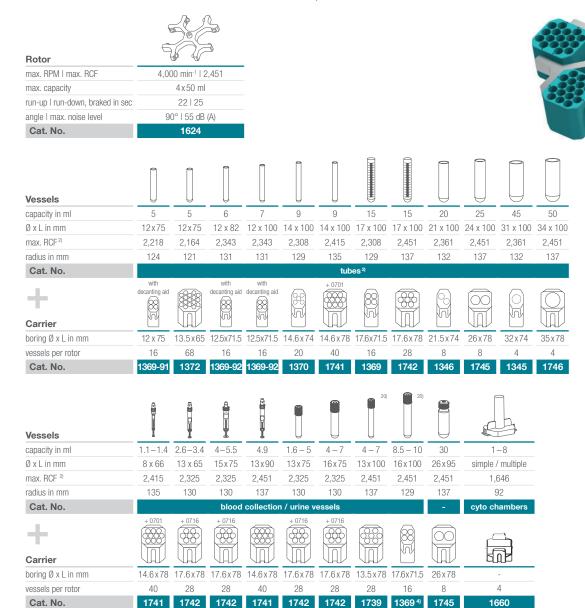
SWING-OUT ROTORS	angle	max. RPM	max. capacity	Cat. No.	page
swing-out rotor, 4-place	90°	4,000 min <sup>-1</sup>	4x100 ml	1624	3
swing-out rotor, 4-place	90°	4,000 min <sup>-1</sup>	4x100 ml	1324	6
swing-out rotor, 6-place	90°	4,000 min <sup>-1</sup>	6 x 50 ml	1619	8
swing-out rotor, 8-place	45°	4,000 min <sup>-1</sup>	8x50 ml	1617	8
swing-out rotor, 8-place	90°	4,000 min <sup>-1</sup>	8x15 ml	1611	9
swing-out rotor, 12-place	55° / 60° / 80°	4,000 min <sup>-1</sup>	12x15 ml	1628	9
ANGLE ROTORS					

#### **ANGLE ROTORS**

	angle rotor, 8-place	45°	4,000 min <sup>-1</sup>	8x50 ml	1418	10
	angle rotor, 6-place	35°	6,000 min <sup>-1</sup>	6x85 ml	1620A	11
0000	angle rotor, 12-place	35°	6,000 min <sup>-1</sup>	12x15 ml	1613	12

2





СҮТО

Cyto system available for this model. More information on page 180

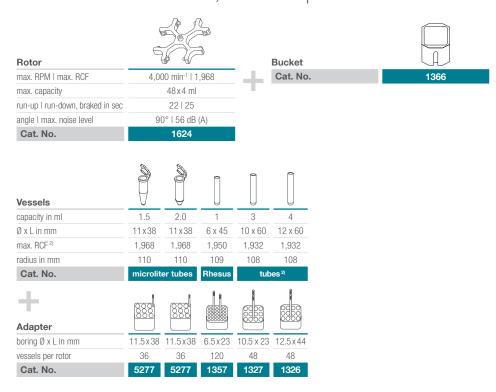
<sup>2)</sup> Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000.

Please remove the spacer.

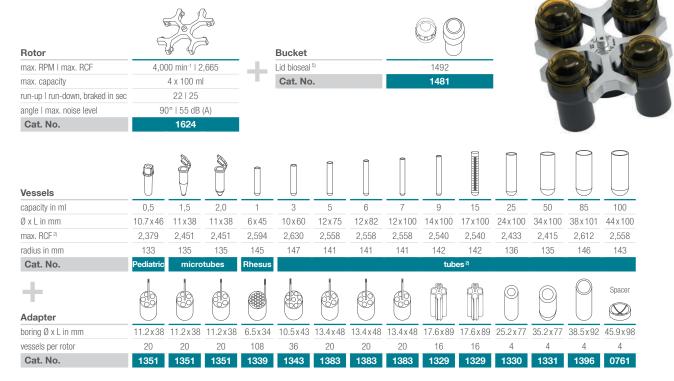
<sup>16)</sup> Packed in units of 10 pieces.

<sup>20)</sup> Vacutainers made of glass may not be used.



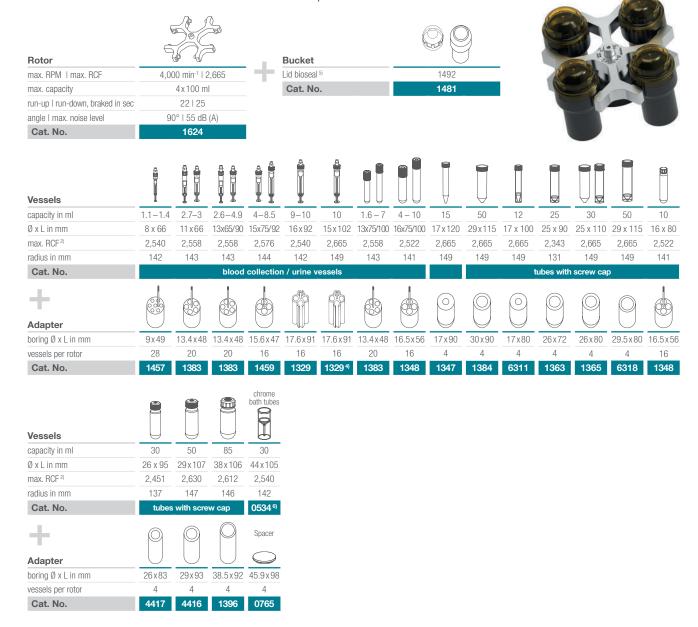






- 2) Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000.
- 5) Tested by TÜV in conformity with DIN EN 61010, section 2-020





<sup>2)</sup> Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000.

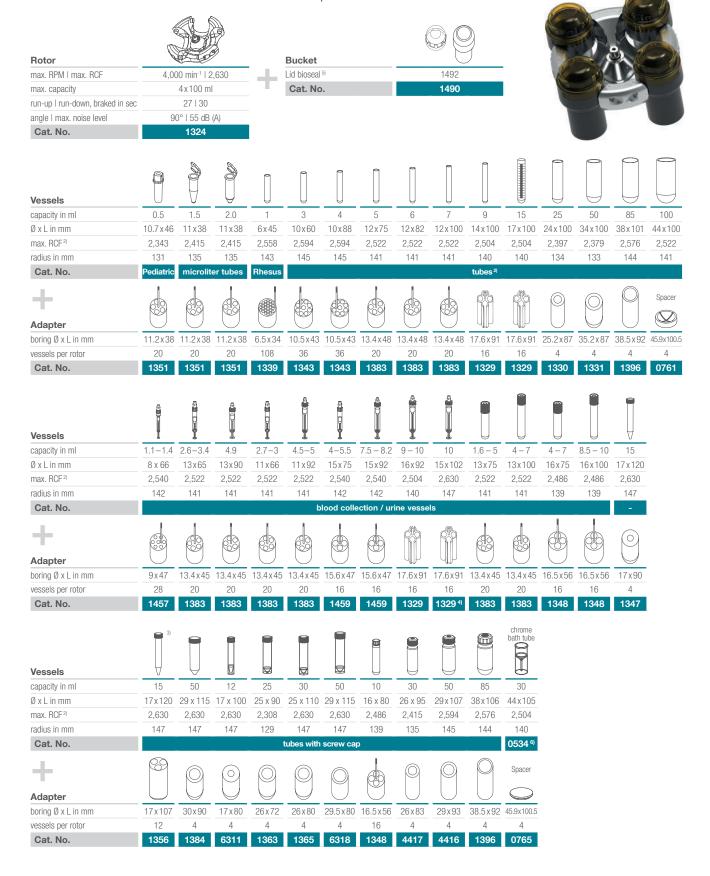
<sup>3)</sup> When using these tubes, bucket 1490 cannot be closed with lid 1492.

Please remove spacer.

<sup>5)</sup> Tested by TÜV in conformity with DIN EN 61010, section 2-020.

A rubber stopper for closing the tube for agitating or mixing is available under Cat. No. 0535. The tube may not be centrifuged with the stopper.



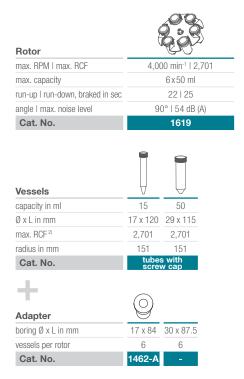




Rotor max. RPM   max. RCF max. capacity run-up   run-down, braked in sec angle Cat. No.	4,000 min <sup>-1</sup>   2,612 4x50 ml 27   30 90°   56 dB (A) 1324		4x50 ml aked in sec 27 l 30 90° l 56 dB (A)			1398								
Vessels capacity in ml Ø x L in mm max. RCF <sup>2</sup> radius in mm	5 12x75 2,486 139	6 12x82 2,486 139	7 12x100 2,486 139	9 14x100 2,522 141	15 17x100 2,522 141	2.6-3.4 13x65 2,486 139	2.7-3 11x66 2,486 139	4.5-5 11x92 2,486 139	4.9 13x90 2,486 139	9 – 10 16x92 2,522 141	10 15x102 2,522 141	1.6 – 5 13x75 2,486 139	4-7 13x100 2,486 139	4-7 16x75 2,397 134
Cat. No.			tubes 2)					b	lood colle	ection / ur	rine vesse	ls		
Adapter														+ 0716
boring Ø x L in mm	13.4x57.5	13.4x57.5	13.4x57.5	17.5 x 81	17.5 x 81	13.4x57.5	13.4x57.5	13.4x57.5	13.4x57.5	17.5 x 81	17.5x81	13.4x57.5	13.4x57.5	17.5 x 81
vessels per rotor  Cat. No.	20 <b>1486</b>	20 <b>1486</b>	20 <b>1486</b>	16 <b>1482A</b>	16 <b>1482A</b>	20 <b>1486</b>	20 <b>1486</b>	20 <b>1486</b>	20 <b>1486</b>	16 <b>1482A</b>	16 <b>1482A</b>	20 <b>1486</b>	20 <b>1486</b>	16 <b>1482A</b>
Vessels capacity in ml Ø x L in mm max. RCF 2) radius in mm Cat. No.	15 17 x 120 2,612 146	50 29 x 115 2,576 144 ubes with	12 17 x 100 2,522 141 screw ca	50 29 x 115 2,576 144										
Adapter boring Ø x L in mm vessels per rotor Cat. No.	17x100 16 1483A	30x98 4 1484	17.5x81 16 1482A	30x98 4 1484 4)										

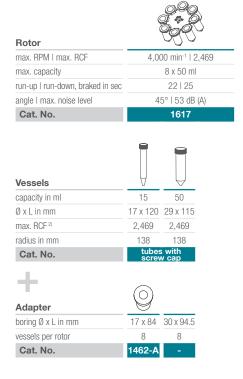
<sup>2)</sup> Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000. Please remove spacer.







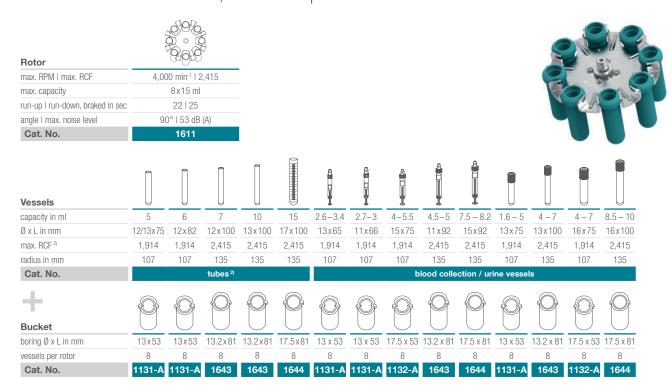
# - SWING-OUT ROTOR, 8-PLACE | 1617



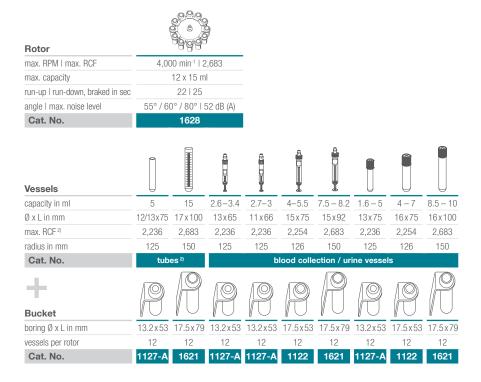


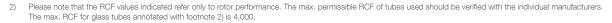
<sup>2)</sup> Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000.





# - SWING-OUT ROTOR, 12-PLACE | 1628







# - ANGLE ROTOR, 8-PLACE | 1418



Rotor	~U09
max. RPM I max. RCF	4,000 min <sup>-1</sup>   2,612
max. capacity	8 x 50 ml
run-up I run-down, braked in sec	36   43
angle I max. noise level	45°   53 dB (A)
Cat. No.	1418

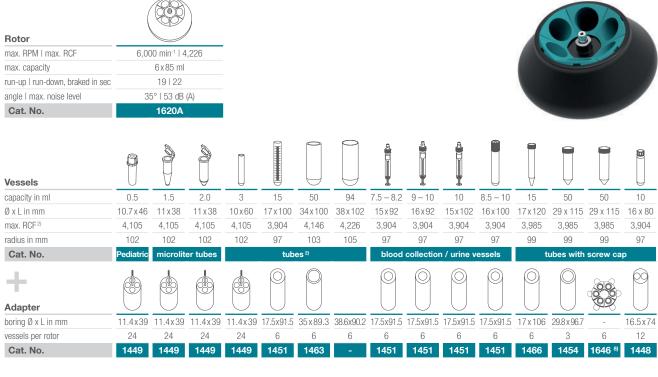


Vessels													
capacity in ml	5	12	1.1-1.4	2.6-3.4	2.7-3	9 – 10	1.6 – 5	15	50	15	50	50	
Ø x L in mm	12x75	17 x 100	8 x 66	13 x 65	11 x 66	16x92	13x75	17 x 120	29 x 115	17 x 100	29 x 115	29 x 107	
max. RCF <sup>2)</sup>	2,182	2,540	2,182	2,182	2,182	2,540	2,182	2,594	2,486	2,540	2,486	2,486	
radius in mm	122	142	122	122	122	142	122	145	139	142	139	139	
Cat. No.	tub	es <sup>2)</sup>	b	lood colle	ection / ur	ine vesse	ls	tubes with screw cap					
+	+ 1054-A	+ 0716	+ 1054-A	+ 1054-A	+ 1054-A	+ 0716	+ 1054-A	+ E2109	+ E2110-A	+ 0716			
Carrier													
boring Ø x L in mm	17.4x91	17.4x91	17.4x91	17.4x91	17.4x91	17.4x91	17.4 x 91	17.4x91	30.2 x 92	17.4x91	30.2x92	30.2 x 92	
3													
vessels per rotor	32	32	32	32	32	32	32	32	- 8	32	- 8	- 8	

<sup>2)</sup> Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000.



# - ANGLE ROTOR, 6-PLACE | 1620A



Vessels			
capacity in ml	30	50	85
Ø x L in mm	26 x 95	29 x 107	38 x 106
max. RCF 2)	3,824	4,025	4,226
radius in mm	95	100	105
Cat. No.	tubes	with scre	w cap
Adapter			
boring Ø x L in mm	26 x 85	29 x 92	38.6x90.2
vessels per rotor	6	6	6
Cat. No.	1447	1446	_

<sup>2)</sup> Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000.

<sup>8)</sup> Adapter (Set), 6-place: for conical 50 ml tubes with screw cap.



# - ANGLE ROTOR, 12-PLACE | 1613





Vessels													
capacity in ml	0.5	4	5	6	15	1.1-1.4	2.6-3.4	2.7-3	4.5-5	4.9	7.5 – 8.2	9 – 10	10
Ø x L in mm	10.7 x 46	10x88	12/13x75	12x82	17 x 100	8 x 66	13x65	11 x 66	11 x 92	13 x 90	15 x 92	16x92	15 x 102
max. RCF <sup>2)</sup>	2,777	3,502	3,300	3,300	4,146	3,300	3,300	3,300	4,146	4,146	4,146	4,146	4,146
radius in mm	69	87	82	82	103	82	82	82	103	103	103	103	103
Cat. No.	Pediatric		tub	es <sup>2)</sup>				blood	collection	ı / urine v	essels		
+	Pediatric	9	tube	es ²				blood	collection	n / urine v	ressels		
Adapter													
+		11.5x67.5	13.5x60	13.5x60	17.7x88	13.5 x 60	13.5x60	13.5x60	17.7 x 88	17.7x88	17.7x88	17.7x88	17.7x88
Adapter		11.5x67.5 12			17.7x88 12	13.5 x 60 12						17.7x88 12	17.7x88 12

Vessels		0)		
capacity in ml	1.6 – 5	8	8.5 – 10	15
Ø x L in mm	13x75	16 x 125	16x100	17x120
max. RCF 2)	3,300	4.146	4,146	4,146
radius in mm	82	103	103	103
Cat. No.	blood	collection vessels	/ urine	-
Adapter				
boring Ø x L in mm	13.5 x 60	17,7x88	17.7x88	17.7 x 88
vessels per rotor	12	6	12	6
Cat. No.	1054-A			

Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers.

The max. RCF for glass tubes annotated with footnote 2) is 4,000.



# - CERTIFICATIONS / REGISTRATIONS



Product certification: | Product registration:



Company certifications:



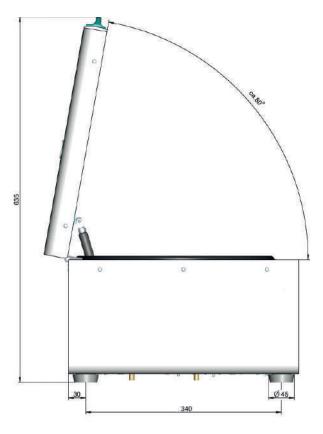




# - DIMENSIONS









# Operating instructions

**ROTOFIX 32 A** 



Translation of the original operating instructions

AB1206en Rev.: 17 / 01.2024 1 / 39



©2023 – All rights reserved

Andreas Hettich GmbH & Co. KG

Föhrenstrasse 12

D-78532 Tuttlingen, Germany

Telephone: +49 (0)7461 705-0

Fax: +49 (0)7461 705-1125

Email: info@hettichlab.com, service@hettichlab.com

Internet: www.hettichlab.com

2 / 39 Rev.: 17 / 01.2024 AB1206en



# Table of contents

1	Α	bout	this document	5
	1.1	Use	of this document	5
	1.2	Ger	nder reference	5
	1.3	Syn	nbols and labels in this document	5
2	S	afety	/	5
	2.1	Inte	nded use	5
	2.2	Pers	sonnel requirements	6
	2.3	Оре	erator's responsibility	7
	2.4	Safe	ety instructions	7
3	D	evice	overview	9
	3.1	Tecl	hnical data	9
	3.2	Euro	opean registration	11
	3.3	lmp	ortant labels on the packaging	12
	3.4	lmp	ortant labels on the device	12
	3.5	Оре	erating and indicator elements	13
	3.	.5.1	Control	13
	3.	5.2	Indicator elements	13
	3.	.5.3	Controls	14
	3.6	Orio	ginal spare parts	14
	3.7	Sco	ppe of delivery	14
	3.8	Ret	urns	15
4	Ti	ransp	oort and storage	15
	4.1	Trar	nsport and storage conditions	15
	4.2	Fas	tening the transport lock	16
5	C	omn	nissioning	17
	5.1	Unp	packing the centrifuge	17
	5.2	Ren	noving the transport lock	17
	5.3	Sett	ting up and connecting the centrifuge	18
	5.4	Swi	tching the centrifuge on and off	20
6	С	)pera	tion	20
	6.1	Оре	ening and closing the lid	20
	6.2	Ren	noving and installing the rotor	20
	6.3	Inse	erting and removing buckets	22
	6.4	Inse	erting and removing adapters	23
	6.5	Loa	ding	24
	6.6	Оре	ening and closing the biosafety system	26
	6.	.6.1	Explanation	26
	6.	.6.2	Lid with screw cap	26
	6.7	Cer	ntrifugation	26
		.7.1	Centrifugation in continuous operation	26
	6.	7.2	Centrifugation with time preselection	27
			Short-time centrifugation	27



7	S	oftwa	are o	peration	28
	7.1	Cen	trifuç	gation parameters	28
	7.	1.1	Set	the brake level	28
	7.	1.2	Rela	ative centrifugal force, RCF	28
	7.	1.3		ntrifugation of substances or mixtures of substances a density higher than 1.2 kg/dm³	28
	7.	1.4	Cer	ntrifuging radius	29
	7.2	Roto	or de	etection	29
	7.3	Mac	hine	Menu	29
	7.	3.1	Aud	lible signal	29
		7.3.	1.1	General	29
		7.3.	1.2	Setting an audible signal	30
8	С	leani	ng a	nd care	30
	8.1	Ove	rviev	v table	30
	8.2	Instr	ructio	ons for cleaning and disinfection	31
	8.3	Clea	aning	J	31
	8.4	Disir	nfect	ion	32
	8.5	Mair	ntena	ance	33
9	Ti	oubl	esho	ooting	34
	9.1	Faul	t des	scription	34
	9.2	Perf	ormi	ng a MAINS RESET	35
	9.3	Eme	erger	ncy release	35
	9.4	Rep	lacin	g the mains input fuse	36
10	) D	ispos	sal		37
	10.1	Gen	eral	instructions	37
11	l In	dex.			39

Rev.: 17 / 01.2024



#### 1 About this document

#### 1.1 Use of this document

- Read this document carefully and in full before commencing initial operation of the device.
  - Observe other enclosed instruction sheets where necessary.
- This document constitutes part of the device and must be kept within easy reach.
- This document must be included if the device is passed on to a third party.
- The most recently updated version of this document in the available languages can be found on the manufacturer's website at: https:// www.hettichlab.com/de/download-center/

#### 1.2 Gender reference

The employed masculine or feminine language form is to facilitate reading. In the spirit of equal treatment, corresponding terms apply in principle to all genders and do not imply any valuation.

### 1.3 Symbols and labels in this document

#### General symbols

The following markers are used in this document to highlight instructions, results, listings, references and other elements:

Marker	Explanation
1	Step-by-step instructions
-	Results of action steps
<b>#</b>	References to sections of the document and other applicable documents
•	Listings without a fixed order
[Buttons]	Controls (for example: buttons, switches)
'Indicator'	Indicator elements (for example: signal lights, screen elements)

# 2 Safety

# 2.1 Intended use

Intended use

The centrifuge **ROTOFIX 32 A** is an in vitro diagnostic medical device in accordance with the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746. The device is used for centrifugation as well as enrichment of sample material of human origin for subsequent further processing for diagnostic purposes. The user can set each of the variable physical parameters within the limits set by the device.

AB1206en Rev.: 17 / 01.2024 5 / 39



The centrifuge may only be used by qualified personnel in closed laboratories. The centrifuge is only intended for the use referred to above. Intended use also includes observing all instructions in the user manual and compliance with inspection and maintenance. Any other use or use beyond this is considered improper. Andreas Hettich GmbH & Co. KG shall not be liable for any damage arising from this.

#### Non-intended use

- The centrifuge is not suitable for use in explosive or radioactive, or biologically or chemically-contaminated atmospheres.
- The user must take appropriate actions when centrifuging hazardous substances or mixtures of substances that are toxic, radioactive or contaminated with pathogenic microorganisms.
  - The manufacturer generally recommends using only centrifuge tubes with special screw caps designed for use with hazardous substances. Use sealable centrifuge tubes with a biosafety system for materials of risk groups 3 and 4.
- The manufacturer does not recommend centrifugation of flammable or explosive materials.
- The manufacturer does not recommend centrifugation of materials that react chemically with one another with high activation energy.

#### Foreseeable misuse

The manufacturer recommends using only accessories approved that it has approved for the intended purpose.

Only operate the centrifuge under supervision.

### 2.2 Personnel requirements

#### Required qualifications

The user has read the Operating Manual in full and familiarised themselves with the device.



#### NOTICE

#### Damage to the device by unauthorised personnel



Tampering with and modifications to devices by unauthorised persons are at the operating organisation's own risk and will result in the loss of all warranty and liability claims.

#### Trained user

The user has been educated and trained in laboratory work and is able to carry out the work assigned to them, and to recognise and prevent potential hazards independently.

#### Personal protective equipment

Lack of personal protective equipment or unsuitable personal protective equipment increases the risk of impaired health and injury.

- Only use personal protective equipment that is in proper condition.
- Only use personal protective equipment that is adapted to the person (correct size, for example).
- Observe instructions on other protective equipment for specific activities.



### 2.3 Operator's responsibility



Follow the instructions in this document for proper and safe use of the device.

Keep the user manual for future reference.

#### Provide information

- Following the instructions in this document will help:
  - To avoid dangerous situations.
  - To minimise repair costs and downtime.
  - To increase the reliability and service life of the device.
- The operator is responsible for compliance with company regulations, standards and national laws.
- Note and keep the revision of the document separate from the document. If lost, the document can be replaced in the correct revision.
- Keep the user manual available at the place where the device is used.
- Pass the user manual on to the buyer when the device is sold.

#### Personnel training

Lack of knowledge when working with the device may result in serious injury or death.

Instruct personnel on their tasks and the associated risks in accordance with the instruction.

## 2.4 Safety instructions



#### Reporting serious incidents and notifiable incidents

In the event of serious incidents or notifiable incidents involving the device or its accessories, these must be reported to the manufacturer and, where applicable, to the competent authority where the user and/or the patient is registered.



#### **DANGER**

Risk of contamination for the user due to inadequate cleaning or failure to observe the cleaning instructions.

- Observe cleaning instructions.
- Wear personal protective equipment when cleaning the device
- Observe laboratory regulations (e.g. TRBAs, the German Protection against Infection Act, hygiene plan) for handling biological agents.



#### **DANGER**

Fire and explosion hazard due to hazardous substances in samples.

- Observe relevant regulations and directives for handling chemicals and hazardous substances.
- Do not use aggressive chemicals (for example: dangerous, corrosive extraction agents such as chloroform, strong acids).

AB1206en Rev.: 17 / 01.2024 7 / 39





#### WARNING

Dangers due to insufficient maintenance or maintenance not carried out on time.

- Follow maintenance intervals.
- Check the device for visible damage or defects.
   If any visible damage or defects are present, take the device out of service and inform a service technician.





#### **WARNING**

Risk of electric shock due to ingress of water or other liquids.

- Protect the device against external liquids.
- Do not pour any liquids into the interior of the device.
- Transport using original transport packaging.





#### **WARNING**

# Contamination with hazardous substances and substance mixtures!

Observe the following actions for substances and substance mixtures that are toxic, radioactive and/or contaminated with pathogenic microorganisms:

- As a rule, use only centrifuge tubes with special screw caps for hazardous substances.
- Use sealable centrifuge tubes with a biosafety system for materials of risk groups 3 and 4.
- If no biosafety system is used, the device is not microbiologically tight in the sense of standard EN / IEC 61010-2-020.
- Contact the manufacturer if necessary.



#### **WARNING**

Risk of injury and damage to the device due to a loose rotor.

- The driver of the rotor shaft must be correctly seated in the groove of the rotor when mounting the rotor.
- Hand-tighten the nut securing the rotor.
- Check that the rotor is firmly seated.
- Follow maintenance intervals.



#### **CAUTION**

#### Risk of injury due to rotating rotor

Long hair and items of clothing can get caught on the rotor if the rotor is moved manually.

- Tie long hair back.
- Do not allow garments to hang in the centrifuging chamber.

8 / 39 Rev.: 17 / 01.2024 AB1206en





#### NOTICE

Damage to the device electronics due to incorrect voltage or frequency at the device circuit breaker.

 Operate the device with the correct mains voltage and mains frequency.

The value can be found in the technical data and on the rating plate.



#### **NOTICE**

Damage to the device and samples due to premature program termination.

Premature program termination is caused by power failure, switching off during the program or pulling out the mains plug.

- Do not switch off the device while the program is running.
- Do not trigger the emergency release on the device while the program is running.
- Do not pull out the mains plug while the program is running.

#### 3 Device overview

#### 3.1 Technical data

Manufacturer	Andreas Hettich GmbH & Co. KG, D-78532 Tuttlingen		
Model	ROTOFIX 32 A		
Type	1206 1206-34	1206-01 1206-33	
Mains voltage (±10%)	208-240 V 1~	100-127 V 1~	
Mains frequency	50-60 Hz	50-60 Hz	
power consumption	300 VA	300 VA	
Power consumption	1.4 A	3.0 A	
max. capacity	4 x 100 ml / 32 x 15 ml		
max. permissible density	1.2 kg/dm³		
max. speed (RPM)	6000		
max. acceleration (RCF)	4226		
max. kinetic energy	3160 Nm		

AB1206en Rev.: 17 / 01.2024 9 / 39



Obligation to perform checks (DGUV Rules 100-500) (valid only in Germany)	No					
Ambient conditions (EN / IEC 61010-1):						
Installation site	indoors only					
Altitude	up to 2000 m above sea level					
Ambient temperature	2 °C to 40 °C					
Humidity	maximum relative humidity 80% for temperatures up to 31 °C, decreasing linearly to 50% relative humidity at 40 °C.					
Overvoltage category (IEC 60364-4-443)	II					
Pollution level	2					
Device protection class	I not suitable for use in potentially explosive atmospheres.					
EMC:						
Emitted EM interference, EM interference immunity	EN / IEC 61326-1 Class B	FCC Class B				
Noise level (rotor-dependent)	≤57 dB(A)					
Dimensions:						
Width	366 mm					
Depth	430 mm					
Altitude	257 mm					
Weight	approx. 23 kg					

10 / 39 Rev.: 17 / 01.2024 AB1206en



#### Rating plate

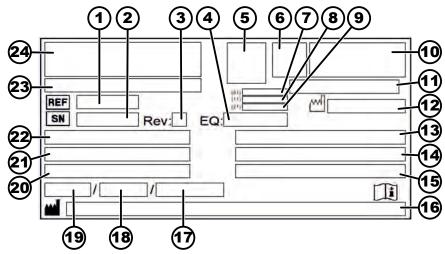


Fig. 1: Rating plate

- 1 Item number
- 2 Serial number
- 3 Revision
- 4 Equipment number
- 5 Data matrix code
- 6 any labelling indicating whether medical device or in vitro diagnostic medical device
- 7 Global Trade Item Number (GTIN)
- 8 Date of manufacture
- 9 Serial number
- 10 any EAC mark, CE mark
- 11 Country of manufacture
- 12 Date of manufacture
- 13 Mains frequency
- 14 Maximum kinetic energy
- 15 Maximum permissible density
- 16 Manufacturer's address
- 17 any Coolant circuit pressure
- 18 any Coolant capacity
- 19 any Coolant type
- 20 Revs per minute
- 21 Performance values
- 22 Mains voltage
- 23 any Device designation
- 24 Manufacturer's logo

# 3.2 European registration

**Device conformity** 

Device conformity according to EU directives.



Single Registration Number SRN: DE-MF-000010680

AB1206en Rev.: 17 / 01.2024 11 / 39



#### Basic-UDI-DI

Basic-UDI-DI	Device assignment
040506740100129P	ROTOFIX 32 A (in vitro diagnostic medical device)

# 3.3 Important labels on the packaging



#### TOP

This is the correct upright position of the shipping container for transport and/or storage.



#### FRAGILE GOODS

The contents of the shipping container are fragile, so it must be handled with care.



#### PROTECT FROM MOISTURE

The shipping container must not be exposed to rain and kept in a dry environment.



### TEMPERATURE LIMITATION

The shipping container must be stored, transported and handled within the indicated temperature range (-20 °C to +60 °C).



#### **HUMIDITY LIMITATION**

The shipping container must be stored, transported and handled within the indicated humidity range (10% to 80%).



#### STACK LIMITATION BASED ON QUANTITY

Maximum number of identical packages that may be stacked on the lowest package, "n" standing for the number of packages allowed. The lowest package is not included in "n".

### 3.4 Important labels on the device



The signs on the device must not be removed or covered, or have anything pasted over them.





Attention, general danger area.

Ensure you read the instructions for commissioning and operation and observe the safety instructions before using the device.



Biohazard warning.



Direction of rotation of the rotor.

The orientation of the arrow indicates the rotor's direction of rotation.



Symbol for the separate collection of electrical and electronic equipment, in accordance with Directive 2012/19/EU (WEEE).

Use in European Union countries, Norway and Switzerland.

### 3.5 Operating and indicator elements

#### 3.5.1 Control

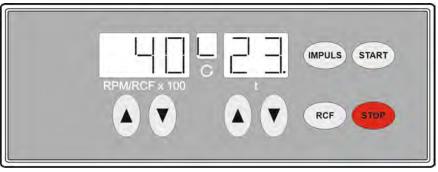


Fig. 2: Control

#### 3.5.2 Indicator elements

Fig. 3: 'Lid closed' indicator

- The indicator appears when the lid is closed.
- If the 'Lid closed' and 'Lid open' indicators flash alternately, further operation of the centrifuge is only possible after opening the lid once.
- The indicator appears when the lid is open.





Fig. 5: 'Rotation' indicator

■ The indicator light rotates when the rotor is turning.

AB1206en Rev.: 17 / 01.2024 13 / 39



#### 3.5.3 Controls



Fig. 6: [Mains switch]



Fig. 7: [IMPULSE] button



Fig. 8: [RCF] button



Fig. 9: [START] button



Fig. 10: [STOP] button

#### RPM/RCFx100





Fig. 11: [RPM/RCFx100] button



Fig. 12: [t] button

- Switch the device on and off.
- Short-time centrifugation. The centrifugation run takes place as long as the button is being pressed.
- Display the brake level and centrifuging radius.
- Relative centrifugal force, parameter RCF.
   The relative centrifugal force (RCF) is displayed for as long as the button is pressed.
- Start centrifugation run.
- End the centrifugation run.

The rotor ramps down to a stop at the preselected brake level.

- Save the brake level and centrifuging radius.
- A numerical value from 500 RPM to the maximum rotor speed can be set.

Adjustable in increments of 100 (RPM = displayed value x 100).

Display the brake level and centrifuging radius.

#### Enter runtime.

#### Adjustable from 1 to 99 minutes in 1 minute increments.

Centrifuging radius.

Input in centimetres. Adjustable from 5 to 16 centimetres, in 1 centimetre increments.

Brake level 0 or 1.

Level 1 = short ramp-down time

Level 0 = long ramp-down time.

# 3.6 Original spare parts

Use only original spare parts from the manufacturer and approved accessories.

### 3.7 Scope of delivery

The following accessories are supplied with the centrifuge:

- 1 Release pin
- 1 hex key (SW5 x 100)
- 1 grease for the trunnions

Rev.: 17 / 01.2024



- 1 power cable
- 2 Fuse links
- 1 user manual
- 1 instruction sheet, transport lock

Rotors and the corresponding accessories are supplied depending on the order.

#### 3.8 Returns

An original Return Material Authorisation (RMA) form from the manufacturer must always be requested for a return. Secure and reliable acceptance and booking in of the goods with the manufacturer is not possible without an original RMA form from the manufacturer. The Return Material Authorisation (RMA) form contains a Declaration of No Objection (UBE), which must be completed in full and enclosed with the return.

If the device and/or accessories are returned to the manufacturer, the complete return shipment must be cleaned and decontaminated by the sender. If returns are not cleaned and/or decontaminated or are insufficiently cleaned and/or decontaminated, this will be performed by the manufacturer and charged to the sender.

The original transport locks must be attached for return shipment, see 

→ Chapter 4 'Transport and storage' on page 15. The device must be shipped in its original packaging.

# 4 Transport and storage

### 4.1 Transport and storage conditions

Transport conditions



#### NOTICE

Damage to the device due to failure to use the transport locks.

Secure the transport locks before transporting the device.



#### NOTICE

Damage to the device due to condensation.

There is a risk of condensation forming on electrical components when component surfaces are cold and the surrounding air is warmer. The condensation that forms may cause a short circuit and/or destroy electronics.

- Warm the device up for at least 3 hours in a warm room before connecting it to the mains.
  - or
- Warm up for 30 minutes in a cold room.
- Before transporting, fasten the transport lock and disconnect the device from the mains socket.
- The transport temperature must be between -20 °C and +60 °C.
- Humidity must not be condensing. Humidity must be between 10% and 80%.
- Be aware of the weight of the device.

AB1206en Rev.: 17 / 01.2024 15 / 39



- When transporting using a transport aid (e.g., a pallet truck), the transport aid must be able to carry at least 1.6 times the transport weight of the device.
- Secure the device to prevent it tipping over and falling down during transport.
- Never transport the device sideways or upside down.

#### Storage conditions

- The device must be stored in the original packaging.
- Only store the device in dry rooms.
- The storage temperature must be between -20 °C and +60 °C.
- Humidity must not be condensing. Humidity must be between 10% and 80%.

## 4.2 Fastening the transport lock

#### Personnel:

Trained user

The lid is closed.

The mains cable is disconnected from the device.

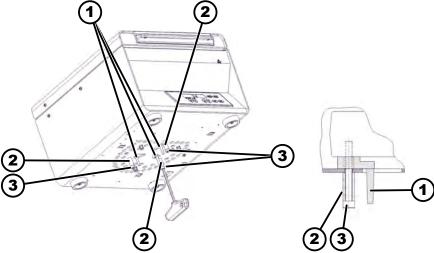


Fig. 13: Transport lock

- 1 Transport lock
- 2 Spacer sleeves
- 3 Screws
- 1. Tilt the device on the back of the device.
- 2. Insert 3 transport locks (1).
- **3.**  $\triangleright$  Screw in 3 screws (3) with spacer sleeves (2).



## 5 Commissioning

# 5.1 Unpacking the centrifuge



#### **CAUTION**

Danger of crushing due to parts falling out of the transport packaging.

- Keep the device balanced during the unpacking process.
- Only open the packaging at the points provided for this purpose.



#### **CAUTION**

Risk of injury from lifting heavy loads.

- Provide an adequate number of helpers.
- Note the weight. See → Chapter 3.1 'Technical data' on page 9.



#### NOTICE

Damage to the device due to improper lifting.

 Do not lift the centrifuge by the control panel or the control panel holder.

#### Personnel:

- Trained user
- 1. If present: Remove the packaging tapes.
- 2. Lift the box up and remove the padding.
- 3. Remove the accessories and store them safely.
- 4. Place the device on a stable and level surface.

### 5.2 Removing the transport lock

#### Personnel:

Trained user

The lid is closed.

The mains cable is disconnected from the device.

AB1206en Rev.: 17 / 01.2024 17 / 39



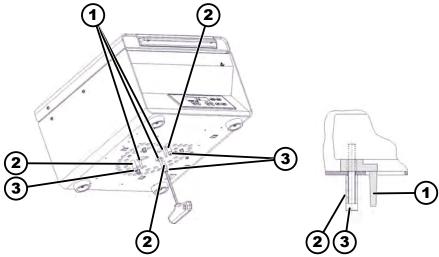


Fig. 14: Transport lock

- 1 Transport lock
- 2 Spacer sleeves
- 3 Screws
- 1. Tilt the device on the back of the device.
- **2.** Unscrew 3 screws (3) with spacer sleeves (2).
- 3. Remove 3 transport locks (1) and store them safely.
- **4.** Keep the screws, spacer sleeves and transport lock in a safe place.

# 5.3 Setting up and connecting the centrifuge

Setting up the centrifuge



#### **WARNING**

Risk of injury due to failing to maintain a sufficient distance to the centrifuge.

- As per EN / IEC 61010-2-020, no persons, hazardous materials or objects may be present within a safety zone of 300 mm around the centrifuge during a centrifugation run.
- A distance of **300 mm** from the ventilation slots and ventilation openings of the centrifuge must be maintained.



#### CAUTION

Risk of crushing and damage to the device due to it falling down because of vibration-induced position alterations.

- Place the device on a stable and level surface.
- Select the installation surface dependent on the weight of the device.

18 / 39 Rev.: 17 / 01.2024 AB1206en





#### NOTICE

Damage to the samples and the device if the ambient temperature exceeds or falls below the respective maximum/minimum permissible ambient temperature.

- Comply with the maximum and minimum permissible ambient temperatures for installation of the device.
- Do not place the device next to a heat source.
- Do not expose the device to direct sunlight.
- Do not expose the device to frost.

#### Personnel:

- Trained user
- 1. Place the device on a stable and level surface.
- 2. Maintain a distance of 300 mm around the device.
- 3. Comply with the ambient conditions in the technical data (→ Chapter 3.1 'Technical data' on page 9).

#### Connecting the centrifuge



#### **NOTICE**

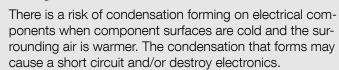
#### Damage to the device by unauthorised personnel

Tampering with and modifications to devices by unauthorised persons are at the operating organisation's own risk and will result in the loss of all warranty and liability claims.



#### **NOTICE**

#### Damage to the device due to condensation.



- Warm the device up for at least 3 hours in a warm room before connecting it to the mains.
  - or
- Warm up for 30 minutes in a cold room.

#### Personnel:

- Trained user
- A type B residual current circuit breaker must be used if the device is additionally protected with a residual current circuit breaker in the building installation.

When using a different type, the residual current circuit breaker may either not switch off the unit if there is a fault on the unit, or it may switch off the unit even though there is no fault on the unit.

- 2. Check whether the mains voltage matches the specification on the rating plate.
- 3. Connect the device to a standard mains socket using the mains cable.

AB1206en Rev.: 17 / 01.2024 19 / 39



### 5.4 Switching the centrifuge on and off.

Switching the centrifuge on

Personnel:

- Trained user
- \_\_\_\_ Set the mains switch to [/].
  - → The buttons flash, depending on the centrifuge type. The last centrifugation data used is displayed.

Switching off the centrifuge

The rotor is stationary.

Set the mains switch to [0].

# 6 Operation

### 6.1 Opening and closing the lid

Opening the lid

Personnel:

Trained user

The centrifuge is switched on.

The rotor is stationary.

- 1. Swivel the handle strip on the lid upwards.
  - → The 'Lid open' indicator appears.
- 2. Deen the lid.

Closing the lid



#### **NOTICE**

Damage to the device caused by the lid slamming.

- Close the lid slowly.
- Do not slam the lid.

#### Personnel:

- Trained user
- Close the lid and swivel the handle strip downwards
  - → The 'Lid closed' indicator appears.

### 6.2 Removing and installing the rotor

Removing the rotor with a clamping nut

Personnel:

Trained user

20 / 39 Rev.: 17 / 01.2024 AB1206en



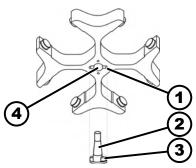


Fig. 15: Rotor installation and removal

- 1 Groove
- 2 Motor shaft
- 3 Driver
- 4 Hole

- 1. Open the lid.
- 2. Loosen the rotor clamping nut using the supplied spanner.
  - → After passing the working point for lifting the rotor, the rotor detaches from the cone of the motor shaft (2).
- 3. Turn the clamping nut until the rotor can be lifted off the motor shaft.
- 4. Remove the rotor.

# Installing the rotor with a clamping nut

#### Personnel:

Trained user

The lid is open.

- 1. Clean the motor shaft (2) and rotor hole (4).
- 2. Lightly grease the motor shaft (2), see → Chapter 8.2 'Instructions for cleaning and disinfection' on page 31.
- Place the rotor vertically on the motor shaft (2).The driver (3) of the motor shaft must be in the groove (1) of the rotor. The orientation of the groove is marked on the rotor.
- **4.** ightharpoonup Hand-tighten the rotor clamping nut using the supplied spanner.
- 5. Check that the rotor is firmly seated.

# Removing the rotor without a clamping nut

#### Removing the rotor

#### Personnel:

Trained user

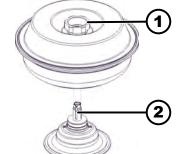


Fig. 16: Rotor installation and removal

- 1 Rotary handle
- 2 Hub

Hold the rotor by the rotary handle (1) of the lid and lift it off the hub (2).

AB1206en Rev.: 17 / 01.2024 21 / 39



#### Removing the hub

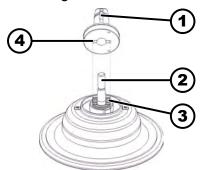


Fig. 17: Hub installation and removal

- 1 Hub
- 2 Motor shaft
- 3 Driver
- 4 Groove

# Installing the rotor without a clamping nut

Installing the hub

### Personnel:

- Trained user
- 1. Den the lid.

1. Deen the lid.

3. Remove the hub.

2. Unscrew the clamping nut.

- 2.  $\triangleright$  Clean the motor shaft (2) and rotor hole.
- 3. Lightly grease the motor shaft (2), see → Chapter 8.2 'Instructions for cleaning and disinfection' on page 31.

→ After passing the working point for lifting the rotor, the hub (1)

detaches from the cone of the motor (2).

- Place the hub (1) vertically on the motor shaft (2).

  The driver (3) of the motor shaft must be in the groove (4) of the hub.

  Check that the hub is firmly seated.
- 5. Hand-tighten the clamping nut of the hub using the supplied hex key.
- **6.** Check that the hub is firmly seated.
- 1. Clean the hub (2).
- 2.  $\blacktriangleright$  Lift the rotor by the rotary handle and place it vertically on the hub (2).
- **3.** Push the rotor down as far as it will go.

#### 6.3 Inserting and removing buckets

#### Inserting buckets

Installing the rotor



#### NOTICE

Damage to the device due to imbalances caused by incorrect loading of the rotor.

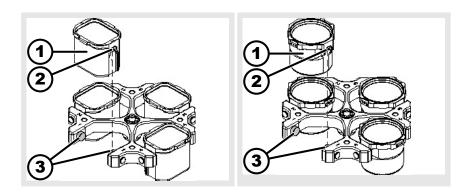
 Load all swing-out rotor locations with the same buckets.



Buckets marked with the number of the rotor location may only be used there.

Buckets marked with a set number may only be used together.





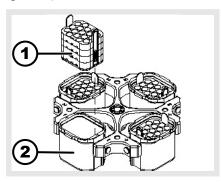
- 1. Check that the rotor is firmly seated.
- 2. Grease the trunnions (3).
- 3. Insert the bucket (1) into the rotor from above. The trunnions (3) must be in the grooves (2).
- 4. Push the bucket (1) down as far as it will go.

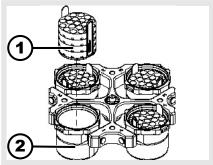
Removing the bucket

▶ Pull the bucket (1) vertically upwards out of the rotor.

# 6.4 Inserting and removing adapters

Inserting





the adapter

Insert the adapter (1) vertically into the bucket (2) from above.

removing

Remove the adapter (1) vertically upwards out of the bucket (2).

## Adapter with positioning pin

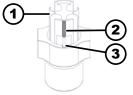


Fig. 18: Adapter with positioning pin

- 1 Inserting
- 2 Positioning pin
- 3 Inserting

the groove

Insert the adapter (1) into the bucket

The positioning pin (2) must be in the groove (3) of the bucket.

AB1206en Rev.: 17 / 01.2024 23 / 39



#### removing

# 6.5 Loading Filling centrifuge tubes

Remove the adapter (1) vertically upwards out of the bucket.



#### **WARNING**

#### Risk of injury from contaminated sample material.

Contaminated sample material escapes from the sample tube during centrifugation.

- Use centrifuge tubes with special screw caps for hazardous substances.
- For risk group 3 and 4 materials, use a biosafety system in addition to the sealable centrifuge tubes (see WHO's 'Laboratory Biosafety Manual').



#### **NOTICE**

Damage to the device due to highly corrosive substances.

Highly corrosive substances may impair the mechanical strength of rotors, buckets and accessories.

- Do not centrifuge highly corrosive substances.



Standard glass centrifuge tubes can be loaded up to RCF 4000 (DIN 58970 part 2).

#### Personnel:

- Trained user
- Fill centrifuge tubes outside the centrifuge.

The maximum capacity of the centrifuge tubes specified by the manufacturer must not be exceeded.

With angle rotors, the centrifuge tubes must only be filled to the extent that no liquid can be ejected from the tubes during the centrifugation run.

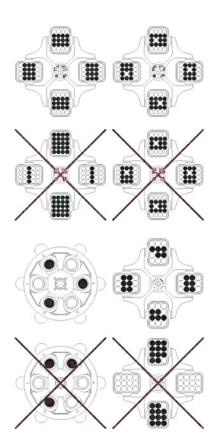
It must be ensured that there is a uniform fill level in the tubes in order to keep the weight differences in the centrifuge tubes as low as possible.

#### Loading swing-out rotors

#### Personnel:

Trained user





- 1. Check that the rotor is firmly seated.
- 2. The centrifuge tubes must be distributed symmetrically across all rotor locations.

The weight of the permissible filling capacity is indicated on each rotor. The weight must not be exceeded.

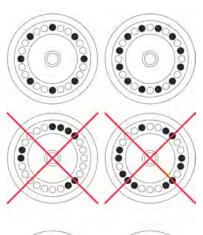
No liquid must be allowed to enter the buckets and the centrifuging chamber when loading the buckets and swinging them out during the centrifugation run.

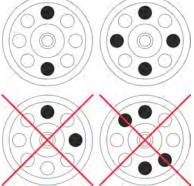
For containers with rubber inserts, there must always be the same number of rubber inserts under the centrifuge tubes.

All rotor locations must be filled with the same buckets. Certain buckets are marked with the number of the rotor location. The buckets must only be inserted in the corresponding rotor location.

Buckets marked with a set number (for example S001/4) must only be used in the set.

#### Loading the angle rotors





#### Personnel:

- Trained user
- 1. Check that the rotor is firmly seated.
- 2. The centrifuge tubes must be distributed evenly over all locations on the rotor

No liquid must be allowed to enter the rotor and the centrifuging chamber when loading the rotor.

With rotors, the centrifuge tubes must only be filled to the extent that no liquid can be ejected from the tubes during the centrifugation run.

The weight of the permissible filling capacity is indicated on each rotor. The weight must not be exceeded.

AB1206en Rev.: 17 / 01.2024 25 / 39



# 6.6 Opening and closing the biosafety system

#### 6.6.1 Explanation

The user must take appropriate actions when centrifuging hazardous substances or mixtures of substances that are toxic, radioactive or contaminated with pathogenic microorganisms.

Centrifuge tubes with special screw caps for hazardous substances must always be used.

For materials of risk group 3 and 4, a biosafety system must be used in addition to the sealable centrifuge tubes (see the World Health Organisation's "Laboratory Biosafety Manual").

In a biosafety system, a bioseal (sealing ring) prevents droplets and aerosols from escaping.

If the bucket of a biosafety system is used without the lid, the sealing ring must be removed from the bucket to prevent damage to the sealing ring during the centrifugation run.

Damaged biosafety systems are no longer microbiologically tight.

If no biosafety system is used, a centrifuge is not microbiologically tight in the sense of the EN / IEC 61010-2-020 standard.

## Storage of biosafety systems

Biosafety systems must only be stored with the lid open to avoid damage to the sealing rings during storage.

## 6.6.2 Lid with screw cap

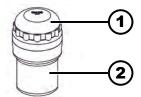


Fig. 19: Biosafety system

- 1 Lid
- 2 Bucket

#### Closing

- **1.**  $\triangleright$  Place the lid (1) centrally on the bucket (2).
- 2. Turn the lid (1) clockwise until it is tightly closed.

#### Opening

- 1. Turn the lid (1) anticlockwise until it is open.
- 2. Remove the lid (1) from the bucket (2).

# 6.7 Centrifugation

# 6.7.1 Centrifugation in continuous operation

#### Personnel:

- Trained user
- 1. Use the [RPM/RCF x 100] buttons to set the desired speed.
- 2. Use the [t] buttons to set the time to zero.
  - → "--" is displayed.



- 3. Press the [START] button.
  - → The centrifugation run is started.

The 'Rotation' indicator light rotates while the rotor is turning.

Timing starts at 0. The first minute is counted up in seconds, then the time is displayed in minutes. A dot flashes next to the number if the time is displayed in minutes.

The rotor speed or the resulting RCF value and the elapsed time are displayed during the centrifugation run.

**4.** Press the [STOP] button to cancel the centrifugation run.

Ramp-down takes place with the set brake level. The brake level is displayed.

An audible signal sounds when the rotor comes to a standstill.

# 6.7.2 Centrifugation with time preselection

#### Personnel:

- Trained user
- 1. Use the [RPM/RCF x 100] buttons to set the desired speed.
- 2. Use the /t/ buttons to set the desired time.
- 3. Press the [START] button.
  - → The centrifugation run is started.

The 'Rotation' indicator light rotates while the rotor is turning.

The time is displayed in minutes. The last minute is counted down in seconds. A dot flashes next to the number if the time is displayed in minutes.

The rotor speed or the resulting RCF value and the remaining time are displayed during the centrifugation run.

4. Ramp-down takes place with the selected brake level after the time has elapsed or if the centrifugation run is cancelled by pressing the *|STOP|* button.

An audible signal sounds when the rotor comes to a standstill.

## 6.7.3 Short-time centrifugation

#### Personnel:

- Trained user
- 1. Use the [RPM/RCF x 100] buttons to set the desired speed.
- 2. Press and hold the [IMPULSE] button.
  - → The centrifugation run is started.

The 'Rotation' indicator light rotates while the rotor is turning.

Timing starts at 0. The first minute is counted up in seconds, then the time is displayed in minutes. A dot flashes next to the number if the time is displayed in minutes.

The rotor speed and the elapsed time are displayed during the centrifugation run.

- 3. Release the [IMPULSE] button to end the centrifugation run.
  - ➡ Ramp-down takes place with the set brake level. The brake level is displayed.

An audible signal sounds when the rotor comes to a standstill.

AB1206en Rev.: 17 / 01.2024 27 / 39



# 7 Software operation

# 7.1 Centrifugation parameters

#### 7.1.1 Set the brake level

1. Switch off the mains switch.

2. Press and hold down the ▲ [RPM/RCF x 100] button and the [IMPULSE] button simultaneously.

3. Switch on the mains switch and release the buttons.

Press the ▲ [RPM/RCF x 100] button repeatedly until the speed indicator shows the machine version and the time indicator shows the brake level set (and/or '0' or '1').

The machine version is set ex works and cannot be changed.

The machine version is set ex works and cannot be changed.

4. Use the [t] buttons to set the desired brake level.

Level 1 = short ramp-down time. Level 0 = long ramp-down time.

5. Press the [STOP] button to save the settings.

# 7.1.2 Relative centrifugal force, RCF

The relative centrifugal force RCF is dependent on the speed and the centrifuging radius.

The relative centrifugal force RCF is stated as a multiple of the acceleration due to gravity (g).

The relative centrifugal force RCF is a dimensionless numerical value and is used to compare the separation and sedimentation performance.

$$RCF = \left(\frac{RPM}{1000}\right)^2 * r * 1,118$$

$$RPM = \sqrt{\frac{RCF}{r * 1,118}} * 1000$$

RCF = Relative Centrifugal Force

RPM = speed

r = centrifuging radius in mm = distance from the centre of the axis of rotation to the bottom of the centrifuge tube.

# Display of the relative centrifugal force (RCF)

1. Press and hold the [RCF] button during the centrifugation run.

➡ Relative centrifugal force (RCF) is displayed.

2. Release the [RCF] button.

→ The speed is displayed.

# 7.1.3 Centrifugation of substances or mixtures of substances with a density higher than 1.2 kg/dm³

The density of the substances or mixtures of substances must not exceed 1.2 kg/dm³ during centrifugation at maximum speed. The speed must be reduced for substances or substance mixtures with a higher density. The permissible speed can be calculated using the following formula:



$$\mbox{Reduced speed } (n_{red}) = \sqrt{\frac{1,2}{\mbox{Greater density [kg/dm^3]}}} * \mbox{maximum speed [RPM]}$$

For example: Maximum speed 4000 RPM, density 1.6 kg/dm<sup>3</sup>

$$n_{red} = \sqrt{\frac{1.2 ({\rm kg/dm^3})}{1.6 ({\rm kg/dm^3})}} * 4000 \; {\rm RPM} = 3464 \; {\rm RPM}$$

If, in exceptional cases, the maximum load indicated on the bucket is exceeded, the speed must also be reduced. The permissible speed can be calculated using the following formula:

$$\text{Reduced speed } (n_{red}) = \sqrt{\frac{\text{maximum load [g]}}{\text{actual load [g]}}} * \text{maximum speed [RPM]}$$

For example: Maximum speed 4000 RPM, maximum load 300 g, actual load 350 g

$$n_{red} = \sqrt{\frac{300 \text{ g}}{350 \text{ g}}} * 4000 \text{ RPM} = 3703 \text{ RPM}$$

Please contact the manufacturer if you are not sure.

# 7.1.4 Centrifuging radius

The centrifuging radius must be entered in centimetres.

- 1. Switch off the mains switch.
- Press and hold down the ▲ [RPM/RCF x 100] button and the [IMPULSE] button simultaneously.
- 3. Switch on the mains switch and release the buttons.
- 4. Press the ▲ [RPM/RCF x 100] button repeatedly until the centrifuging radius and 'rd' are displayed.
- 5. Use the [t] buttons to set the desired centrifuging radius.
- 6. ▶ Press the [STOP] button to save the settings.

#### 7.2 Rotor detection

- Rotor detection is performed after starting a centrifugation run.
- If the rotor has been changed, the centrifugation run is cancelled after rotor detection. The rotor code (red) is displayed.
- If the maximum speed of the rotor used is less than the set speed, the speed is limited to the maximum rotor speed.

# 7.3 Machine Menu

#### 7.3.1 Audible signal

#### 7.3.1.1 General

The audible signal sounds:

- after a problem occurs in the 2 s interval.
- after completion of the centrifugation run and rotor standstill in the interval.

Opening the lid or pressing any button stops the audible signal.

AB1206en Rev.: 17 / 01.2024 29 / 39



## 7.3.1.2 Setting an audible signal

- 1. Switch off the mains switch.
- Press and hold down the ▲ [RPM/RCF x 100] button and the [IMPULSE] button simultaneously.
- 3. Switch on the mains switch and release the buttons.
- 4. ▶ Press the ▲ [RPM/RCF x 100] button repeatedly until 'BEL 1' or 'BEL 0' is displayed.
- 5. Use the [t] buttons beneath the time indicator to set '0' or '1'.
  - 0 = audible signal disabled.
  - 1 = audible signal enabled.
- 6. Press the [STOP] button to save the settings.

# 8 Cleaning and care

# 8.1 Overview table

Chap.	Task to execute	if required	daily	weekly	Annually	Page
8	Cleaning and care					30
8.3	Cleaning					31
8.3	Cleaning the device		Χ			31
8.3	Cleaning biosafety systems			Χ		31
8.3	Cleaning accessories			Χ		32
8.4	Disinfection					32
8.4	Disinfecting the device	Χ				32
8.4	Disinfecting the accessories	Χ				32
8.5	Maintenance					33
8.5	Greasing the rubber seal of the centrifuging chamber			X		33
8.5	Greasing the rubber seal of the biosafety system			Χ		33
8.5	Trunnion greasing			Χ		33
8.5	Checking the accessories			Χ		33
8.5	Checking the biosafety system			Χ		33
8.5	Centrifuging chamber damage inspection				Χ	33
8.5	Greasing the motor shaft				Χ	33
8.5	Accessories with a limited service life	Χ				33

30 / 39 Rev.: 17 / 01.2024 AB1206en



Chap.	Task to execute	if required	daily	weekly	Annually	Page
8.5	Replacing centrifuge tubes	X				34

# 8.2 Instructions for cleaning and disinfection



#### **DANGER**

Risk of contamination for the user due to inadequate cleaning or failure to observe the cleaning instructions.

- Observe cleaning instructions.
- Wear personal protective equipment when cleaning the device.
- Observe laboratory regulations (e.g. TRBAs, the German Protection against Infection Act, hygiene plan) for handling biological agents.
- The device and its accessories must not be cleaned in dishwashers.
- Only perform hand cleaning and liquid disinfection.
- The water temperature must not exceed 25 °C.
- To prevent any corrosion due to use of detergents or disinfectants, it is essential to follow the special application instructions provided by the manufacturers of the detergent or disinfectant.

#### Disinfectant:

- Surface disinfectant (not disinfectant for hands or instruments)
- Ethanol as the sole active substance.

Do not use an ethanol-propanol mixture to disinfect the viewing window in the lid of the device.

- Concentration not less than 30%
- pH: 6 8
- Non-corrosive

# 8.3 Cleaning Cleaning the device

- 1. Deen the lid.
- 2. Switch off the device and disconnect it from the power supply.
- 3. Remove accessories.
- 4. Clean the centrifuge housing and the centrifuging chamber with soap or a mild detergent and a damp cloth.
- **5.** Remove any detergent residues with a damp cloth after using detergents.
- **6.** The surfaces must be dried immediately after cleaning.
- 7. Dry the centrifuging chamber with an absorbent cloth if condensation forms.

#### Cleaning biosafety systems

- 1. Clean the biosafety system using the detergent and a damp cloth.
- 2. Remove any detergent residues with a damp cloth after using detergents.

AB1206en Rev.: 17 / 01.2024 31 / 39



Dry the accessories immediately after cleaning using a lint-free cloth and oil-free compressed air. Dry all cavities completely using oil-free compressed air.

#### Cleaning accessories

- 1. Clean the accessories using the detergent and a damp cloth.
- **2.** Remove any detergent residues with a damp cloth after using detergents.
- 2. Dry the accessories immediately after cleaning using a lint-free cloth and oil-free compressed air. Dry all cavities completely using oil-free compressed air.

#### 8.4 Disinfection



Disinfection must always be preceded by cleaning the components concerned.

See → Chapter 8.3 'Cleaning' on page 31



Disinfectant concentration and application time according to the manufacturer's instructions.

#### Disinfecting the device



#### CAUTION

Risk of injury due to ingress of water or other liquids.

- Protect the device against external liquids.
- Do not disinfect the device using spray.
- 1. Den the lid.
- 2. Switch off the device and disconnect it from the power supply.
- 3. Remove accessories.
- 4. Clean the housing and centrifuging chamber using disinfectant.
- **5.** Remove any disinfectant residues with a damp cloth after using disinfectants.
- 6. ▶ The surfaces must be dried immediately after cleaning.

#### Disinfecting the accessories

- 1. Disinfect the accessories using the disinfectant.
- 2. Wet all cavities with bubble-free disinfectant.
- 3. Remove the disinfectant residues or leave them to dry after using disinfectants.

#### Autoclaving

The following accessories may be autoclaved at 121 °C / 250 °F (20 min):

- Swing-out rotors
- Aluminium angle rotors

Rev.: 17 / 01.2024

- Metal buckets
- Lid with bioseal
- Inserting

No statement can be made about the resulting degree of sterility.

The lids of the rotors and bucket must be removed before autoclaving.



Accessories with a limited

service life

Autoclaving accelerates the ageing of materials. It may cause changes in colour. After autoclaving, the rotors and accessories are to be visually inspected for damage and any damaged parts are to be replaced immediately.

The sealing ring in question is to be replaced if there are signs of cracking, embrittlement or wear. For lids with non-replaceable sealing rings, the whole lid must be replaced.

The sealing rings must be replaced after autoclaving to ensure the tightness of the biosafety systems.

# 8.5 Maintenance Greasing the rubber seal of ▶ Rub the sealing ring lightly with a rubber care product. the centrifuging chamber Greasing the rubber seal of ▶ Rub the sealing ring lightly with a rubber care product. the biosafety system Trunnion greasing 1. Remove accessories. 2. Clean the trunnions. 3. Remove any detergent residues with a damp cloth after using deter-**4.** Grease the trunnions and suspension with Hettich Tubenfett 4051. 5. Excess grease in the centrifuging chamber must be removed. Checking the accessories 1. The accessories shall be checked for wear and corrosion damage. 2. Let Check that the rotor is firmly seated. Checking the biosafety 1. Visually check all parts of the biosafety system for damage. system 2. Check the correct installation position of the sealing ring(s) of the biosafety system. 3. Replace the damaged parts of the biosafety system. 4. Replace the sealing ring in question immediately if there are signs of cracking, embrittlement or wear. For lids with non-replaceable sealing rings, the whole lid must be replaced. Centrifuging chamber damage Check the centrifuging chamber for damage. inspection Greasing the motor shaft 1. Remove accessories. 2. Clean the motor shaft. 3. Remove any detergent residues with a damp cloth after using deter-4. Grease the motor shaft with Hettich Tubenfett 4051. 5. Excess grease in the centrifuging chamber must be removed.

AB1206en Rev.: 17 / 01.2024 33 / 39

them has been reached.

The use of certain accessories is time-limited. For safety reasons, the

accessories must no longer be used when either the maximum number of permissible run cycles marked on them or the expiry date marked on



The maximum permissible number of run cycles or the expiry date can be seen on the accessories.

#### Replacing centrifuge tubes



#### CAUTION

#### Risk of injury from broken glass.

Broken glass may cause glass splinters and contaminated liquids to be found inside the centrifuge.

- Wear cut-resistant gloves.
- Wear protective goggles and a face mask.

Broken parts of the tube, glass splinters and spilled centrifuge material must be removed completely in the event of leakage or if a centrifuge tube breaks. Glass splinters that are not removed will cause further glass breakage.

The rubber inserts and the plastic sleeves of the rotors must be replaced after a glass breakage.

Disinfection must be carried out if the material is infectious.

# 9 Troubleshooting

# 9.1 Fault description

Customer service must be notified if the fault cannot be rectified based on the fault table. State the centrifuge type and serial number. Both numbers can be seen on the type plate of the centrifuge.

Fault description	Cause	Remedy
no display	No power. Mains input fuses defective.	<ul><li>Check the supply voltage.</li><li>Check the mains input fuse.</li><li>Set the mains switch to [I].</li></ul>
-1-	Tacho error. Speed pulse failure.	The device must not be switched off while the 'Rotation' indicator is lit up and rotating. Wait until the 'Lid closed' symbol is displayed (after approx. 100 seconds) and then perform a MAINS RESET.
-2-	Loss of mains power during the centrifugation run. The centrifugation run was not completed.	<ul> <li>Open the lid and press the [START] button.</li> <li>If required: Repeat the centrifugation run.</li> </ul>
-3-	Imbalance. The rotor is unevenly loaded.	<ul><li>Open the lid.</li><li>Check the loading of the rotor.</li><li>Repeat the centrifugation run.</li></ul>
-4-	Communication. Error in the control section or power section.	Perform a MAINS RESET.
-5-	Overload. Motor or motor control defective.	Perform a MAINS RESET.

34 / 39 Rev.: 17 / 01.2024 AB1206en



Fault description	Cause	Remedy
-6-	Overvoltage. Mains voltage outside tolerances.	<ul><li>Perform a MAINS RESET.</li><li>Check the mains voltage.</li></ul>
-7-	Overspeed. Error in the power section.	Perform a MAINS RESET.
-8-	Undervoltage. Mains voltage outside tolerances.	<ul><li>Perform a MAINS RESET.</li><li>Check the mains voltage.</li></ul>
-9-	Overtemperature. Overtemperature switch in the motor has tripped.	<ul><li>Open the lid using the emergency release.</li><li>Let the motor cool down.</li></ul>
Version Error	Wrong machine version set. The control section skips to the Settings menu.	<ul> <li>Use the [t] buttons to set the number 7.</li> <li>Press the [STOP] button to save the settings.</li> <li>Perform a MAINS RESET.</li> </ul>
no speed indicator. Machine version set in the time indicator.	Version Error. Wrong machine version set. The control section skips to the Settings menu.	<ul> <li>Use the [t] buttons to set the number 7.</li> <li>Press the [STOP] button to save the settings.</li> <li>Perform a MAINS RESET.</li> </ul>
-C-	Controller watchdog. Error in the power section.	Perform a MAINS RESET.
-d-	Lid lock error.	Perform a MAINS RESET.
-E-	Short circuit in the control section / power section.	Perform a MAINS RESET.
-F-	No rotor detection when starting. No rotor inserted or defective tacho.	Perform a MAINS RESET.
rot	A new rotor has been detected.	Press the [START] button.
ments light up.	-	Notify customer service.

# 9.2 Performing a MAINS RESET

- 1. Set the mains switch to [0].
- 2. Wait 10 seconds.
- 3. Set the mains switch to [/].

# 9.3 Emergency release

The lid cannot be unlocked by the motor in the event of a power failure. Emergency unlocking by hand must be performed.

AB1206en Rev.: 17 / 01.2024 35 / 39





# **WARNING**

Risk of electric shock due to maintenance and servicing work on live device.

 Disconnect the device from the mains before carrying out repairs and maintenance.



#### **WARNING**

Danger of cutting and crushing due to moving rotor.

- Do not open the lid until the rotor has stopped.

#### Personnel:

Trained user

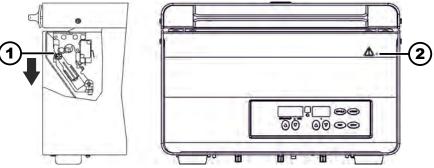


Fig. 20: Emergency release

- 1 Release pin
- 2 Hole
- **1.** Look through the window in the lid to ensure that the rotor is stationary.
- 2. Insert the release pin (1) horizontally into the hole (2). Push it in until the handle strip can be swivelled upwards when the pin is pressed down.
- 3. Open the lid.

# 9.4 Replacing the mains input fuse



# **MARNING**

Risk of electric shock due to maintenance and servicing work on live device.

 Disconnect the device from the mains before carrying out repairs and maintenance.

#### Personnel:

Trained user



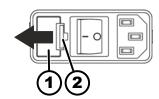


Fig. 21: Mains input fuse

- 1 Fuse holder
- 2 Snap lock

The mains fuses are located next to the mains switch.

The mains switch is in switch position [O]

- 1. Disconnect the mains cable from the device plug.
- 2.  $\triangleright$  Press the snap lock (2) against the fuse holder (1) and pull it out.
- 3. Replace the defective mains input fuses.
  Only use fuses with the nominal value specified for the type: see the table below.
- **4.** Push in the fuse holder (1) until the snap lock engages.
- 5. Reconnect the device to the mains.

Model	Туре	Fuse	Order no.
ROTOFIX 32 A	1206, 1206-34	T 3.15 AH/250 V	E997
ROTOFIX 32 A	1206-01, 1206-33	T 5 AH/250 V	E914

# 10 Disposal

# 10.1 General instructions



#### The device can be disposed of via the manufacturer.

A Return Material Authorisation (RMA) form must always be requested for a return.

If necessary, contact the Technical Service Department of the manufacturer:

- Andreas Hettich GmbH & Co. KG
- Föhrenstraße 12
- 78532 Tuttlingen, Germany
- Phone: +49 7461 705 1400
- E-Mail: service@hettichlab.com



# **WARNING**

Risk of pollution and contamination for people and the environment.

When disposing of the centrifuge, people and the environment may be polluted or contaminated by incorrect or improper disposal.

 Removal and disposal may be carried out only by a trained and authorized service personnel.

The device is intended for the commercial sector ("Business to Business" - B2B).

According to Directive 2012/19/EU, the devices may no longer be disposed of with household waste.

The appliances are assigned to the following groups according to the Stiftung Elektro-Altgeräte Register (EAR (German foundation under civil law)):

Group 5 (small appliances)

AB1206en Rev.: 17 / 01.2024 37 / 39





Fig. 22: Household waste ban

The crossed-out wheelie bin symbol indicates that the device must not be disposed of with household waste. Regulations governing disposal of such devices may differ in individual countries. If necessary, contact the supplier.

38 / 39 Rev.: 17 / 01.2024 AB1206en



I I Index	IVI
A	MAINS RESET
Accessories	Maintenance
biosafety systems	Intervals30
disinfection	N
the rotor	Non-intended use
with limited service life	0
Audible signal	
Autoclaving	Operator's responsibility
C	P
Care	·
Intervals	Personal protective equipment
Centrifugation	Personnel qualifications
in continuous operation	Personnel training
with higher substance density	
with time preselection	R
Centrifuging chamber inspection	Rating plate
Checking	Relative centrifugal force
the biosafety system	RCF
Cleaning	Removing the rotor
biosafety systems	Replacing
Cleaning and disinfection	centrifuge tubes
Instructions	Return
Connecting the centrifuge	Rotor detection
Continuous operation	S
D	
Device	Safety instructions
biosafety systems	Setting up the centrifuge
disinfection	Short-term centrifugation
Disinfection	Spare parts
Disposal	Storage conditions
E	Switching off
Error messages	Switching the unit on
F	Symbols 5
Footoning	Т
Fastening removal	Transport condition
the transport lock	Troubleshooting
Filling	Trunnion
Foreseeable misuse	greasing33
G	U
General safety instructions	Unpacking
Greasing	
the rubber seal	
1	
Intended use	
L	
Labels	
on the device	
on the packaging	
Lid	
the lid	
Loading	

Rev.: 17 / 01.2024

# Certificate

# mdc medical device certification GmbH

certifies that



# Andreas Hettich GmbH & Co. KG Föhrenstraße 12 78532 Tuttlingen Germany

for the scope

Design, development, manufacturing, distribution and servicing of laboratory centrifuges for IVD applications and general laboratory use, centrifuges for separation of blood components for transfusion purposes and microbiological incubators for IVD applications and general laboratory use

has introduced and applies a

# **Quality Management System**

The mdc audit has proven that this quality management system meets all requirements of the following standard

# **EN ISO 13485**

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from 2022-10-25
Valid until 2025-10-24
Registration no. D1459300003
Report no. P21-01967-222238
Stuttgart 2022-10-25

Head of Certification Body





Internet: http://www.mdc-ce.de