

EBA 20 C

Operating Instructions
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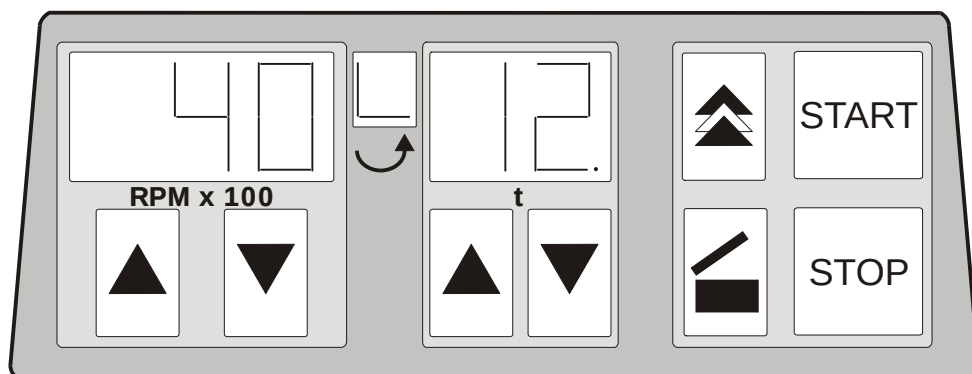


Fig. 1 EBA 20 C

Standards and regulations which apply to this device

The device is a high-end technical product. It is subject to extensive testing and certification procedures according to the following standards and regulations in their respectively valid version:

Electrical and mechanical safety for design and final testing:

Standard series: IEC 61010 (conform to standards of DIN EN 61010)

- IEC 61010-1 "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements" (Pollution Degree 2, Installation Category II)
- IEC 61010-2-010 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials" (applied to heated centrifuges only)
- IEC 61010-2-020 "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges"
- IEC 61010-2-101 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment"

Electromagnetic Compatibility:

- EN 61326-1 "Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements"

The EMC standard refers to the following generic standards:

Emission:

- | | |
|------------------------------------|------------------|
| • Conducted emission | EN 55011 Class B |
| • Radiated emission | EN 55011 Class B |
| • Harmonic current emissions | EN 61000-3-2 |
| • Voltage fluctuations and flicker | EN 61000-3-3 |

Immunity to...

- | | |
|--|---------------|
| • Electrostatic discharge | EN 61000-4-2 |
| • Electromagnetic fields | EN 61000-4-3 |
| • Electrical fast transients (Burst) | EN 61000-4-4 |
| • Surge | EN 61000-4-5 |
| • Conducted RF disturbances | EN 61000-4-6 |
| • Magnetic field | EN 61000-4-8 |
| • Voltage dips and short interruptions | EN 61000-4-11 |

Further partly applicable European directives:

- Machinery Directive 2006/42/EC
- EMC directive 2004/108/EC
- Low voltage directive 2006/95/EC

Applied medical device regulations outside Europe:

- **USA:** QSR, 21CFR 820 "CFR Title 21 - Food and Drugs: TITLE 21- FOOD AND DRUGS, CHAPTER I - FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES, SUBCHAPTER H - MEDICAL DEVICES, Part 820 QUALITY SYSTEM REGULATIONS"
- **Canada:** CMDR, SOR/98-282 "Medical Devices Regulations"

Certified quality management system according to

- ISO 9001 "Quality management systems – Requirements"
- ISO13485 "Medical devices - Quality management systems - Requirements for regulatory purposes"

Environmental management system according to

- ISO 14001 "Environmental management systems - Requirements with guidance for use"

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Contents

1	Use according to specification	6
2	Remaining risks	6
3	Technical specifications	6
4	Notes on safety	7
5	Symbol meanings	8
6	Delivery checklist	8
7	Initial operation	9
8	Opening and closing the lid.....	9
8.1	Opening the lid	9
8.2	Closing the lid	9
9	Loading the rotor.....	9
10	Control and display elements	10
10.1	Symbols on the control panel.....	10
10.2	Keys and setting options	10
11	Centrifugation	10
12	Relative centrifugal force (RCF)	11
13	Emergency release	11
14	Maintenance and servicing.....	12
14.1	Centrifuge (housing, lid and centrifuging chamber).....	12
14.1.1	Surface cleaning and care	12
14.1.2	Surface disinfection.....	12
14.1.3	Removal of radioactive contaminants	12
14.2	Rotor and accessories	13
14.3	Rotors and accessories with limited service lives	13
14.4	Autoclaving	13
14.5	Cell separation containers.....	13
15	Faults	14
16	Change mains input fuses	15
17	Returning Devices	15
18	Disposal	15
19	Anhang / Appendix	16
19.1	Rotor und Zubehör / Rotor and accessories	16

1 Use according to specification

The centrifuge serves solely for separating human blood or bone marrow into its liquid (blood plasma) and solid (erythrocytes, leukocytes) components in cell separation containers manufactured by Stryker Orthobiologics with the help of a specially designed rotor.

The centrifuge is only meant for this purpose.

Another use or one which goes beyond this, is considered to be non-intended. The company Andreas Hettich GmbH & Co. KG is not liable for damage resulting from this.

Observing all information in the operating instructions and complying with the measures described therein is also a part of the intended use.

2 Remaining risks

The device is built according to the state-of-the-art and the recognized safety regulations. If used and handled improperly, there could be life-threatening danger to the user or third parties, or the device could be impaired or there could be other property damage. The device is only to be used for its intended purpose and only when it is in safe working condition.

Malfunctions which could affect safety must be corrected immediately.

3 Technical specifications

Manufacturer	Andreas Hettich GmbH & Co. KG D-78532 Tuttlingen
Model	EBA 20 C
Type	2002-01C
Mains voltage ($\pm 10\%$)	100 - 120 V 1~
Mains frequency	50 - 60 Hz
Connected load	100 VA
Current consumption	0.8 A
Max. capacity	2 x cell separation containers, each filled to capacity (approximately 10 ml of blood or bone marrow)
Allowed density	1.2 kg/dm ³
Speed (RPM)	4000
Force (RCF)	1574
Kinetic energy	850 Nm
Obligatory inspection (BGR 500)	no
Ambient conditions (EN / IEC 61010-1) – Set-up site – Altitude – Ambient temperature – Humidity – Excess-voltage category (IEC 60364-4-443) – Pollution degree	Indoors only Up to 2000 m above sea level 2°C to 40°C Maximum relative humidity 80% for temperatures up to 31°C, linearly decreasing to 50% relative humidity at 40°C. II 2
Device protection class	I
Not suitable for use in explosion-endangered areas.	
EMC – Emitted interference, - Interference immunity	FCC Class B
Noise level (dependent on rotor)	≤ 63 dB(A)
Dimensions – Width – Depth – Height	230 mm 304 mm 216 mm
Weight	approx. 4 kg

4 Notes on safety



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



- The centrifuge should be installed on a good, stable base.
- Before using the centrifuge absolutely check the rotor for firm placement.
- When the centrifuge is running, according to EN / IEC 61010-2-020, no persons, dangerous substances or objects may be within the safety margin of 300 mm around the centrifuge.
- Rotors, suspensions and accessories that possess traces of corrosion or mechanical damage or if their term of use has expired may not be used any longer.
- The centrifuge may no longer be put into operation when the centrifuging chamber has safety-related damages.
- For centrifuges without temperature control, when the room temperature is increased and/or if the device is frequently used, the centrifuging chamber could be heated up. Therefore, it can't be ruled out that the sample material might be changed due to the temperature.

- Before the initial operation of your centrifuge you should read and pay attention to the operating instructions. Only personnel that has read and understood the operating instructions are allowed to operate the device.
- Along with the operating instructions and the legal regulations on accident prevention, you should also follow the recognised professional regulations for working in a safe and professional manner. These operating instructions should be read in conjunction with any other instructions concerning accident prevention and environmental protection based on the national regulations of the country where the device is to be used.
- This centrifuge is a state-of-the-art piece of equipment which is extremely safe to operate. However, it can lead to danger for users or others if used by untrained staff, in an inappropriate way or for a purpose other than that it was designed for.
- The centrifuge must not be moved or knocked during operation.
- In case of fault or emergency release, never touch the rotor before it has stopped turning.
- To avoid damage due to condensate, when changing from a cold to a warm room the centrifuge must either heat up for at least 3 hours in the warm room before being connected to the mains, or run hot for 30 minutes in the cold room.
- Only the rotor and the accessories approved by the manufacturer for this device may be used (see section "Anhang/Appendix, Rotor und Zubehör/Rotor and accessories"). Before centrifuge vessels are used which are not listed in the chapter "Anhang/Appendix, Rotor und Zubehör/Rotor and accessories ", the user must make sure they can be used by asking the manufacturer.
- It is only permitted to centrifuge blood or bone marrow in cell separation containers manufactured by Stryker Orthobiologics.
- The centrifuge rotor may only be loaded in accordance with the chapter "Loading the rotor".
- The centrifuge may only be operated when the balance is within the bounds of acceptability.
- The centrifuge may not be operated in explosion-endangered areas.
- The centrifuge must not be used with:
 - inflammable or explosive materials
 - materials that react with one another producing a lot of energy.
- The centrifuge must not be operated with highly corrosive substances which could impair the mechanical integrity of rotors, hangers and accessories.
- Rotors, hangers and accessories that show clear signs of corrosion or mechanical damage should no longer be used.
- Repairs must only be carried out by personnel authorised to do so by the manufacturer.
- Only original spare parts and original accessories licensed by the Andreas Hettich GmbH & Co. KG company are allowed to be utilised.

- Carbon brush change must be carried out by authorised and qualified personnel.
- The following safety regulations apply:
EN / IEC 61010-1 and EN / IEC 61010-2-020 as well as their national deviations..
- The safe operation and reliability of the centrifuge can only be guaranteed if:
 - the centrifuge is operated in accordance with the operating instructions,
 - the electrical installation on the site where the centrifuge is installed conforms to the demands of EN / IEC stipulations.
 - the tests for device safety required in the respective countries, e.g. in Germany in acc. with BGV A1 and BGR 500, are carried out by an expert.

5 Symbol meanings



Symbol on the device:

Attention, general hazard area.

Before using the device, make sure you read the operating instructions and observe the safety information!



Symbol in this document:

Attention, general hazard area.

This symbol refers to safety relevant warnings and indicates possibly dangerous situations.

The non-adherence to these warnings can lead to material damage and injury to personal.



Symbol on the device and in this document:

Beware of biohazard.



Symbol on the device:

Equipotential: Connector (PE connector) for potential equalization (only for centrifuge with PE connector).



Symbol in this document:

This symbol refers to important circumstances.



Symbol on the device and in this document:

Symbol for the separate collection of electric and electronic devices according to the guideline 2002/96/EG (WEEE). The device belongs to Group 8 (medical devices).

Applies in the countries of the European Union, as well as in Norway and Switzerland.

6 Delivery checklist

The following items and accessories are delivered with the centrifuge:

- 1 Connecting cable
- 2 Fuses
- 1 Notes on moving the equipment safely
- 1 Operating instructions
- 1 Counter-weight (is required for centrifugation of an individual cell separation container)
- 2 Carbon brushes



Carbon brush change must be carried out by authorised and qualified personnel.

The model EBA 20 C is supplied complete with angle-rotor (2-times).

7 Initial operation

- Position the centrifuge in a stable and level manner in a suitable place. During set-up, the required safety margin of 300 mm around the centrifuge is to be kept according to EN / IEC 61010-2-020.



When the centrifuge is running, according to EN / IEC 61010-2-020, no persons, dangerous substances or objects may be within the safety margin of 300 mm around the centrifuge. Substances can be discharged through the ventilation opening on the rear side of the centrifuge. The device is to be placed in such a way that the air stream is not directed towards people.

- Do not place any object in front of the ventiduct. Keep a ventilation area of 300 mm around the ventiduct.
- Centrifuge with PE connector:
If required, connect the PE connector at the back of the device with an additional medical potential equalization system.
- Check whether the mains voltage tallies with the statement on the type plate.
- Connect the centrifuge with the connection cable to a standard mains socket. For connection ratings refer to Chapter "Technical specifications".
- Turn on the mains switch. Switch position "I".
The last used centrifuge data will be displayed.
- Open the lid.
- Remove the transportation safety device in the centrifuge, see sheet "Transportation safety device".

8 Opening and closing the lid

8.1 Opening the lid



The lid can only be opened when the centrifuge is switched on and the rotor is at rest. If it cannot be opened under these circumstances, see the section on "Emergency release".

- Press the key  and open the lid. The symbol "L" (lid open) illuminates in the rotation indicator .

8.2 Closing the lid



Do not bang the lid shut.

- Place the lid and press the lid grip down slightly. The symbol "—" (lid closed) illuminates in the rotation indicator .

9 Loading the rotor

- Check the rotor for firm seating.
- Load both rotor positions equally. During centrifugation of only one cell separation container, the opposite rotor position must be loaded with the supplied counter-weight, and the cell separation container must be loaded with the maximum filling quantity as specified by Stryker Orthobiologics.
- The weight of the permitted filling quantity is specified on the rotor. This weight must not be exceeded.
- Always fill the cell separation containers outside of the centrifuge. Observe the specifications of the manufacturer of the cell separation containers.
- The maximum filling amount of the cell separation containers as specified by the manufacturer must not be exceeded.
- To keep the weight differences within the cell separation containers as low as possible maintain an even filling height within the containers.

10 Control and display elements

See figure on page 2.

Fig. 1: Display and control panel

10.1 Symbols on the control panel



Rotation indicator. The rotation indicator lights up and rotates anticlockwise while the rotor is turning.

When the rotor is stationary, the status of the lid is displayed by symbols in the rotation indicator:

Symbol  : Lid open

Symbol  : Lid closed

Operator errors and occurring faults are indicated on the display (see Chapter "Faults").

10.2 Keys and setting options



- Start centrifugation run.



- End centrifugation run.



- Unlock the lid.

RPM x 100

t



- These keys have no function.

11 Centrifugation



When the centrifuge is running, according to EN / IEC 61010-2-020, no persons, dangerous substances or objects may be within the safety margin of 300 mm around the centrifuge.



If the permissible weight difference is exceeded within the rotor loading, the drive switches off during the run-up time, and error -3- is displayed (see chapter "Faults").

The centrifugation run can be interrupted at any time by pressing the key **STOP**.

After a centrifugation run, the display flashes until the cover is opened or a key is pressed.

The speed and running time are permanently set and cannot be changed.

- Switch on the mains switch (switch position "I").
- Load the rotor and close the centrifuge cover.
- Press the key **START**. The rotation indicator  appears while the rotor is turning.



The time is displayed in minutes. The last minute is counted down in seconds.
When the time is displayed in minutes, a point flashes next to the number.

- After expiry of the time or if the centrifugation run is interrupted by pressing the key **STOP**, the rotor is braked to a standstill.

During the centrifugation run the rotor speed and the remaining time are displayed.

12 Relative centrifugal force (RCF)

The relative centrifugal force (RCF) is given as a multiple of the acceleration of gravity (g). It is a unit-free value and serves to compare the separation and sedimentation performance.

These values are calculated using the formula below:

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

RCF = relative centrifugal force

RPM = rotational speed (revolutions per minute)

r = centrifugal radius in mm = distance from the centre of the turning axis to the bottom of the centrifuge.
For more on the centrifugal radius see the chapter "Anhang/Appendix, Rotoren und Zubehör/Rotors and accessories".



The relative centrifugal force (RCF) stands in relation to the revolutions per minute and the centrifugal radius.

13 Emergency release

The lid cannot be opened during power failure. An emergency release has to be executed by hand.



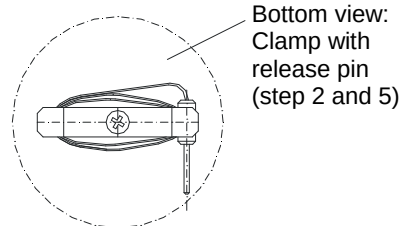
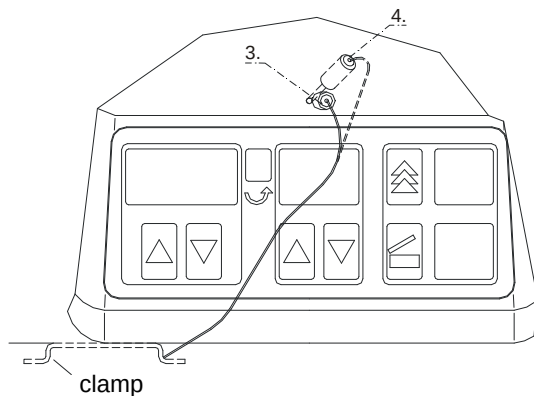
For emergency release disconnect the centrifuge from the mains.

Open the lid only during rotor standstill.

Only the plastic release pin attached at the bottom of the centrifuge may be used for emergency release.

The release pin is fixed with a clamp at the bottom of the centrifuge and tied to it with a plastic cord.

1. Switch off the mains switch (switch position "0").
2. Pull out the release pin and uncoil the cord, see drawing.
3. Insert the release pin horizontally into the hole located in the middle of the front panel, see drawing.
4. Push the release pin to the right, then up to a 45° position. Pull the lid upwards at the same time to unlock, see drawing.
5. Pull the release pin out and recoil the cord around the clamp. Re-fasten the release pin as shown below.



Bottom view:
Clamp with
release pin
(step 2 and 5)

14 Maintenance and servicing



The device can be contaminated.



Pull the mains plug before cleaning.

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

- Centrifuges, rotors and accessories must not be cleaned in rinsing machines.
- They may only be cleaned by hand and disinfected with liquids.
- The water temperature must be between 20 – 25°C.
- Only detergents/disinfectants may be used which:
 - have a pH between 5 - 8
 - do not contain caustic alkalis, peroxides, chlorine compounds, acids and alkaline solutions
- In order to prevent appearances of corrosion through cleaning agents or disinfectants, the application guide from the manufacturer of the cleaning agent or disinfectant are absolutely to be heeded.

14.1 Centrifuge (housing, lid and centrifuging chamber)

14.1.1 Surface cleaning and care

- Clean the centrifuge housing and the centrifuging chamber regularly, using soap or a mild detergent and a damp cloth if required. For one thing, this services purposes of hygiene, and it also prevents corrosion through adhering impurities.
- Ingredients of suitable detergents:
soap, anionic tensides, non-ionic tensides.
- After using detergents, remove the detergent residue by wiping with a damp cloth.
- The surfaces must be dried immediately after cleaning.
- In the event of condensation water formation, dry the centrifugal chamber by wiping out with an absorbent cloth.
- The centrifuging chamber is to be checked for damage once a year.



If damage is found which is relevant to safety, the centrifuge may no longer be put into operation. In this case, notify Customer Service.

14.1.2 Surface disinfection

- If infectious materials penetrates into the centrifugal chamber this is to be disinfected immediately.
- Ingredients of suitable disinfectants:
ethanol, n-propanol, isopropyl alcohol, glutardialdehyde, quaternary ammonium compounds.
- After using disinfectants, remove the disinfectant residue by wiping with a damp cloth.
- The surfaces must be dried immediately after disinfecting.

14.1.3 Removal of radioactive contaminants

- The agent must be specifically labelled as being an agent for removing radioactive contaminants.
- Ingredients of suitable agents for removing radioactive contaminants:
anionic tensides, non-ionic tensides, polyhydrated ethanol.
- After removing the radioactive contaminants, remove the agent residue by wiping with a damp cloth.
- The surfaces must be dried directly after removing the radioactive contaminants.

14.2 Rotor and accessories



For safety reasons, the rotor may not be dismantled.

- To avoid corrosion and changes to the materials, the rotor and accessories have to be cleaned regularly with soap or a mild cleaning agent and a moist cloth. Cleaning is recommended at least once a week. Contaminants must be removed immediately.
- If the rotor or accessories are contaminated by pathogenic or radioactive material, appropriate cleaning must be carried out.
- Ingredients of suitable detergents:
soap, anionic tensides, non-ionic tensides.
- Ingredients of suitable disinfectants:
glutaraldehyde, propanol, ethyl hexanol, anionic tensides, corrosion inhibitors.
- Ingredients of suitable agents for removing radioactive contaminants:
anionic tensides, non-ionic tensides, polyhydrated ethanol.
- The rotor and accessories have to be dried immediately after cleaning.
- The rotor and accessories have to be checked monthly for wear and tear and damage due to corrosion.



The rotor and accessories must no longer be used if they show signs of wear or corrosion.

- Check the firm seating of the rotor on a weekly basis.

14.3 Rotors and accessories with limited service lives

The use of certain rotors, hangers and accessory parts is limited by time.

These are marked with the maximum permitted number of operating cycles or with an expiration date and the maximum permitted number of operating cycles or just with the expiration date; e.g.:

- "usable until end of month/year: 10/2014"
- "max. cycles: 50000".



For safety reasons, rotors, hangers and accessory parts may no longer be used if either the indicated maximum number of operating cycles or the indicated expiration date has been reached.

14.4 Autoclaving



The rotor and accessories must not be autoclaved.

14.5 Cell separation containers

- With leakage or breakage of cell separation containers, all broken container parts and leaked centrifugation material must be completely removed.



Remaining container parts can cause further container breakage!

- Disinfection is to be performed immediately.

15 Faults

If the fault cannot be eliminated with the help of the fault table, please inform Customer Service.

Please specify the type of centrifuge and the serial number. Both numbers can be found on the name plate of the centrifuge.



Perform a MAINS RESET:

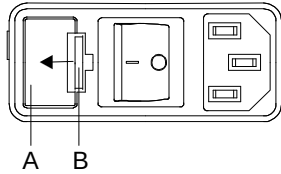
- Switch off the mains switch (switch position "0").
- Wait at least 10 seconds and then switch on the mains switch again (switch position "I").

Fault	Display	Cause of fault	Remedy
No display	---	No voltage Mains input fuses defective.	- Check distribution voltage. - Check mains power input fuse, refer to Chapter "Change mains input fuse". - Mains switch ON.
Tacho error	- 1 -	Failure of speed impulses during operation.	- The device may not be switched off as long as the rotation display  is lit up and rotating. Wait until the "" icon (lid closed) appears in the rotation display (after about 100 seconds) and then run a "POWER RESET".
System reset	- 2 -	Power failure during the centrifugation run. (The centrifugation run was not finished.)	- When stationary, open lid and press  key. - Repeat the centrifugation run if necessary.
Balance error	- 3 -	The rotor is unevenly loaded.	- Open lid when rotor is stationary. - Check the loading of the rotor, see chapter "Loading the rotor". - Repeat the centrifugation run.
Communication	- 4 -	Fault in control unit or power unit.	- Perform a MAINS RESET when the rotor has been stationary.
Overload	- 5 -	Motor or motor control defective.	- Perform a MAINS RESET when the rotor has been stationary.
Overspeed	- 7 -	Fault in the power unit.	- Perform a MAINS RESET when the rotor has been stationary
Lid error	- d -	Error in lid locking or lid closure.	- Perform a MAINS RESET when the rotor has been stationary.

16 Change mains input fuses



Switch off the mains switch and separate the device from the mains!



The fuse holder (A) with the mains input fuses is located next to the mains switch.

- Remove the connecting cable from the machine plug socket.
- Press the snap-fit (B) against the fuse holder (A) and remove.
- Exchange defective mains input fuses.



Only use fuses with the rating defined for the type. See the following table.

- Reinsert the fuse holder until the snap-fit clicks shut.
- Reconnect the device to the mains supply.

Model	Type	Fuse	Order no.
EBA 20 C	2002-01C	T 3,15 AH/250V	E997

17 Returning Devices



Before returning the device, a transport securing device has to be installed.

If the device or its accessories are returned to Andreas Hettich GmbH & Co. KG, in order to provide protection for people, the environment and materials, it has to be decontaminated and cleaned before being shipped.

We reserve the right to refuse contaminated devices or accessories.

Costs incurred for cleaning and disinfection are to be charged to the customer.

We ask for your understanding in this matter.

18 Disposal

Before disposal, the device must be decontaminated and cleaned to protect people, the environment and property.

When you are disposing of the device, the respective statutory rules must be observed.

Pursuant to guideline 2002/96/EC (WEEE), all devices supplied after August 13, 2005 may not be disposed as part of domestic waste. The device belongs to group 8 (medical devices) and is categorized in the business-to-business field.

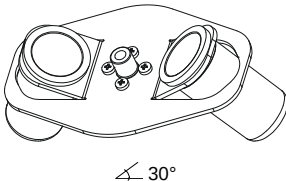
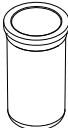
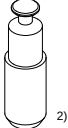
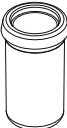
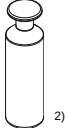


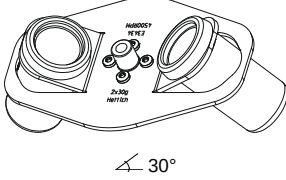
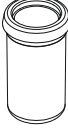
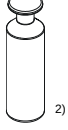
The icon of the crossed-out trash can shows that the device may not be disposed as part of domestic waste.

The waste disposal guidelines of the individual EC countries might vary. If necessary, contact your supplier.

19 Anhang / Appendix

19.1 Rotor und Zubehör / Rotor and accessories

E1824									
		E1823	E1822	E3435	E3436				
Angle rotor 2-times  $\angle 30^\circ$			 2)		 2)				
		CellPaker		VitaPrep Plasma Separator					
									
Capacity	ml	10		10					
Dimensions $\varnothing \times L$	mm	---		---					
Number p. rotor		2		2					
Speed	RPM	4000		4000					
RCF		1574		1574					
Radius	mm	88		88					
 (97%)	sec	8		8					
 1	sec	12		12					
 0	sec	22		22					
Sample temp. rise	K ¹⁾	7		7					

E3434									
		E3435	E3436						
Angle rotor 2-times  $\angle 30^\circ$			 2)						
		VitaPrep Plasma Separator							
									
Capacity	ml	10							
Dimensions $\varnothing \times L$	mm	---							
Number p. rotor		2							
Speed	RPM	4000							
RCF		1574							
Radius	mm	88							
 (97%)	sec	8							
 1	sec	12							
 0	sec	22							
Sample temp. rise	K ¹⁾	7							

1) Sample temp. rise during maximum speed and 1 hour running time

2) Counter-weight, used for centrifugation of only one cell separation container, see chapter "Loading the rotor".

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