English	Instructions for Use: IntraSpin

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BioHorizons Implant Systems Inc.
2300 Riverchase Center
Birmingham AL, 35244 USA
TOLL-FREE 888.246.8338
TEL 205.967.7880
FAX 205.870.0304
www.biohorizons.com

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Table of Contents

Table of Contents 2
1. INDICATIONS FOR USE 5
2. CONTRAINDICATIONS 5
3. PATIENT POPULATION 5
4. INTENDED USERS 5
5. WARNINGS AND PRECAUTIONS 5
6. INTRASPIN SYSTEM COMPONENTS 6
7. BRIEF CENTRIFUGE SETUP 7
8. BLOOD COLLECTION TUBES AND BLOOD COLLECTION SET CAUTIONS AND INSTRUCTIONS 7
8.1 VENIPUNCTURE TECHNIQUE AND BLOOD SAMPLE COLLECTION 8
9. L-PRF PREPARATION 9
10. FIBRIN MATRIX PREPARATION 9
10.1 XPRESSION BOX 9
10.2 PROTOCOL #1: L-PRF MEMBRANE 10
10.3 PROTOCOL #2: L-PRF PLUG 11
10.4 PROTOCOL #3: BIOMATERIAL/L-PRF MIXTURE 11
10.5 PROTOCOL #4: BIOMATERIAL/L-PRF MATRIX MIXTURE 11
10.6 PROTOCOL #5: BIOMATERIAL HYDRATION 11
11. TISSUE REGENERATION KIT CLEANING AND STERILIZATION 12
11.1 CLEANING STEPS: 12
11.2 STERILIZATION STEPS: 12
12. ABOUT OPERATING INSTRUCTIONS 13
12.1 USE OF OPERATING INSTRUCTIONS 13
12.2 COMMON SYMBOLS/MARKERS 13
13. SAFETY 14
13.1 INTENDED USE 14
13.2 NON-INTENDED USE 14
13.3 FORESEEABLE MISUSE 14
13.4 PERSONNEL REQUIREMENTS 14
13.4.1 REQUIRED QUALIFICATIONS 14
13.4.2 PERSONAL PROTECTIVED EQUIPMENT 14
13.5 OPERATOR'S RESPONSIBILITY 15
13.5.1 PROVIDE INFORMATION 15
13.5.2 PERSONNEL TRAINING 15
13.6 SAFETY INSTRUCTIONS 15
14. DEVICE OVERVIEW 17
14.1 TECHNICAL DATA 17
14.1.1 RATING PLATE 18
14.2 IMPORTANT SYMBOLS ON THE PACKAGING 19
14.3 IMPORTANT SYMBOLS ON THE DEVICE 19
14.4 OPERATING AND INDICATOR ELEMENTS 20

14.4.1 CONTROL PANEL 20
14.4.2 INDICATOR ELEMENTS 20
14.4.3 CONTROLS 20
14.5 ORIGINAL SPARE PARTS 21
14.6 SCOPE OF DELIVERY 21
14.7 RETURNS 21
15. TRANSPORT AND STORAGE 21
15.1 TRANSPORT AND STORAGE CONDITIONS 21
15.1.1 TRANSPORT CONDITIONS 21
15.1.2 STORAGE CONDITIONS 22
15.2 FASTENING THE TRANSPORT LOCK 22
16. COMMISSIONING 23
16.1 UNPACKING THE CENTRIFUGE 23
16.2 REMOVING THE TRANSPORT LOCK 23
16.3 SETTING UP AND CONNECTING THE CENTRIFUGE 24
16.3.1 SETTING UP THE CENTRIFUGE 24
16.3.2 CONNECTING THE CENTRIFUGE 24
16.4 SWITCHING THE CENTRIFUGE ON AND OFF 25
16.4.1 SWITCHING THE CENTRIFUGE ON 25
16.4.2 SWITCHING OFF THE CENTRIFUGE 25
17. OPERATION 25
17.1 OPENING AND CLOSING THE LID 25
17.1.1 OPENING THE LID 25
17.1.2 CLOSING THE LID 26
17.2 REMOVING AND INSTALLING THE ROTOR 26
17.2.1 REMOVING THE ROTOR 26
17.2.2 INSTALLING THE ROTOR 27
17.3 LOADING 27
17.3.1 FILLING CENTRIFUGE TUBES 27
17.3.2 LOADING THE ANGLE ROTORS 28
17.4 CENTRIFUGATION 28
17.4.1 CENTRIFUGATION IN CONTINUOUS OPERATION 28
17.4.2 CENTRIFUGATION WITH TIME PRESELECTION 28
17.4.3 SHORT-TIME CENTRIFUGATION 29
17.4.4 QUICK STOP FUNCTION 29
18. SOFTWARE OPERATION 29
18.1 CENTRIFUGATION PARAMETERS 29
18.1.1 INPUT WITH THE SELECT BUTTON 29
18.1.2 RUNTIME, T 31
18.1.3 SPEED, RPM 31
18.1.4 RELATIVE CENTRIFUGAL FORCE, RCF 31
18.1.5 RELATIVE CENTRIFUGAL FORCE (RCF) AND CENTRIFUGING RADIUS (RAD) 31

18.1.6 CENTRIFUGATION OF SUBSTANCES OR MIXTURES OF SUBSTANCES WITH A DENSITY HIGHER THAN 1.2 KG/DM³ 31
18.2 MACHINE MENU 32
18.2.1 QUERYING SYSTEM INFORMATION 32
18.2.2 CYCLE COUNTER 33
18.2.3 QUERYING OPERATING HOURS AND CENTRIFUGATION RUNS 33
18.2.4 AUDIBLE SIGNAL 34
18.2.5 VISUAL SIGNAL 34
18.2.6 AUTOMATIC UNLOCKING OF THE LID 35
18.2.7 INDICATOR BACKLIGHT 35
19. CLEANING AND CARE 35
19.1 OVERVIEW TABLE 35
19.2 INSTRUCTIONS FOR CLEANING AND DISINFECTION 36
19.3 CLEANING 36
19.3.1 CLEANING THE DEVICE 36
19.3.2 CLEANING THE ACCESSORIES 36
19.4 DISINFECTION 37
19.4.1 DISINFECTING THE DEVICE 37
19.4.2 DISINFECTING THE ACCESSORIES 37
19.4.3 AUTOCLAVING 37
19.5 MAINTENANCE 37
19.5.1 GREASING THE RUBBER SEAL OF THE CENTRIFUGE CHAMBER 37
19.5.2 CHECKING THE ACCESSORIES 38
19.5.3 CENTRIFUGE CHAMBER DAMAGE INSPECTION 38
19.5.4 GREASING THE MOTOR SHAFT 38
19.5.5 ACCESSORIES WITH A LIMITED SERVICE LIFE 38
20. TROUBLESHOOTING 38
20.1 FAULT DESCRIPTION 38
20.2 PERFORMING A MAINS RESET 39
20.3 EMERGENCY RELEASE 39
20.4 REPLACING THE MAINS INPUT FUSE 40
21. DISPOSAL 40
21.1 GENERAL INSTRUCTIONS 40
22. SYMBOLS AND DESCRIPTIONS 41

1. INDICATIONS FOR USE

The IntraSpin System is intended to be used for the safe and rapid preparation of autologous Leukocyte- and Platelet- Rich Fibrin (L-PRF) from a small sample of blood at the patient's point of care. The L-PRF is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. Observing all information in the Instructions for Use (IFU) is also a part of the intended use.

2. CONTRAINDICATIONS

The IntraSpin centrifuge is only meant for the purpose stated in the intended use of the device. Any other use of the device is considered non-intended. Use of the IntraSpin centrifuge is contraindicated in the presence of one or more of the following clinical situations:

- Patients with alcohol addiction or psychiatric disorders, blood dyscrasias, uncontrolled diabetes, hyperthyroidism, oral infections, malignancies or patients who have had myocardial infarction within the last 12 months.
- Patients with systemic diseases that compromise the immune system, such as AIDS, patients on medications that would compromise healing of an implant site, patients with a history of poor or noncompliance to oral hygiene procedures.
- Patients who are participating in anti-coagulant therapy.

3. PATIENT POPULATION

BioHorizons IntraSpin system is intended for use in skeletally mature, non-pediatric patients as long as the defined contraindications are nonapplicable.

4. INTENDED USERS

BioHorizons IntraSpin systems are only intended for use by licensed health care professionals, more specifically, BioHorizons IntraSpin systems are intended to be used by trained dentists and surgeons in a standard dental surgical setting, which may range from General Dentists' practice offices to Maxillofacial Surgical Operating Rooms. Use of these products requires specialized knowledge and experience. BioHorizons IntraSpin centrifuge is marked and labeled as a medical device (MD) and is Rx only.

5. WARNINGS AND PRECAUTIONS

- No claim of warranty will be considered by the manufacturer unless ALL instructions in this manual have been followed.
- This product is not authorized for sale in every market. Please consult with your local representative for additional information.
- The operating instructions are a part of the device. They must always be kept readily available. Instructions for use are available free of charge at http://ifu.biohorizons.com or in printed form upon request from BioHorizons or your local distributor. Additional technical information is available upon request from BioHorizons or may be viewed and/or downloaded at www.biohorizons.com. Contact BioHorizons Customer Care or your local representative with any questions you have regarding the IFU.
- Before operating the centrifuge system, the user must read and understand the operating instructions. Only personnel having read and understood the operating instructions are allowed to operate the device. 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 used. Meeting the country-specific requirements concerning occupational safety regarding the use of centrifuges at the workplaces is the responsibility of the user.
- This centrifuge is a state-of-the-art piece of equipment which is 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.
- Maintain the centrifuge in a location where ambient temperature and humidity are within the ranges provided in these instructions for use in section [→Technical Data]. If the centrifuge is repeatedly used, the centrifuging chamber may heat up. Allow time for the chamber to cool down.
- To avoid damage due to condensation, when switching from a cold to a warm room, the centrifuge must be allowed to warm

up for at least three (3) hours in the warm room before being connected to the electrical power. When switching from warm to cold, the centrifuge must be allowed to run for approximately thirty (30) minutes in the cold room.

- Before using the centrifuge, check the rotor for firm placement.
- A rotor or centrifuge accessory that shows traces of corrosion or mechanical damage should not be used and should be replaced as soon as possible. The rotor should not be used past its expiration date.
- The centrifuge may no longer be put into operation when the centrifuging chamber has safety-related damages.
- The centrifuge should be installed on a good, stable base.
- The centrifuge must not be moved or knocked during operation.
- When the centrifuge is running, no persons, dangerous substances or objects may be within the safety margin of three hundred (300) mm around the centrifuge.
- In case of fault or emergency release, never touch the rotor before it stops rotating.
- When centrifuging with maximum revolutions per minute the density of the materials or the material mixtures may not exceed 1.2 kg/dm^3.
- The centrifuge may only be operated when the balance is within the bounds of acceptability. If balance is not achieved, an error message will be displayed by the centrifuge to warn users.
- The centrifuge may not be operated in explosion-endangered areas.
- The centrifuge must not be used with inflammable or explosive materials or materials that react with one another producing energy.
- No biosafety systems are available for this centrifuge.
- The centrifuge must not be operated with highly corrosive substances which could impair the mechanical integrity of the rotor or accessories.
- Repairs must only be carried out by personnel authorized by the manufacturer.
- To ensure the highest level of clinical safety, the IntraSpin System devices with direct patient contact are manufactured with biocompatible materials.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the EU Member State in which the clinician and/or patient is established.

6. INTRASPIN SYSTEM COMPONENTS

Component	Quantity per System	Legal Manufacturer
IntraSpin Centrifuge including:	1	BioHorizons Implant Systems Inc. 2300 Riverchase Center, Birmingham, AL 35244 USA +1-205-967-7880
Power Cable	1	
Fuse	2	
Hex Hand Wrench	1	
Greiner Bio-One Tube 9ml Serum Clot activator, red cap (single use)	100	Greiner Bio-One North America Inc. 4238 Capital Drive, Monroe, NC 28110 USA +1-704-261-7800
Greiner Bio-One balancing tubes White Cap 9ml No additive	50	
Greiner Safety Blood Collection Set + Holder, 21G (single use)	24	
Latex Free Tourniquet	1	Propper Manufacturing 30-04 Skillman Ave., Long Island, NY 11101 USA +1-718-392-6650
Test Tube Rack	1	Heathrow Scientific LLC 620 Lakeview Pkwy, Vernon Hills, IL 60061 USA +1-847-816-5070
Tissue Regeneration Kit including:	1	BioHorizons Implant Systems Inc.

Component	Quantity per System	Legal Manufacturer
Surgical Curved Scissors	1	2300 Riverchase Center, Birmingham, AL 35244 USA +1-205-967-7880
Surgical tissue Forceps	1	
Round Stainless-Steel Bowl	1	
Rectangular Stainless-Steel Bowl	1	
Dual Biomaterial Carrier Spatula	1	
Dual Biomaterial Packer	1	
Xpression® Box	1	

Only verified compatible components for direct use with the IntraSpin centrifuge are recommended and warranted:

Compatible Part #	Description
455092	Tube 9ml Serum Clot activator, red cap (50 pcs)
455001	White Cap 9ml No additive blood collection tube (50 pcs)
BHEXZ (E613)	IntraSpin Hex key, 110v & 220v
BROTORZ (E3694)	IntraSpin Rotor, 100 v & 220v
BPOWER110Z (E1673)	IntraSpin Power Cord, 110v
BPOWER220Z (E1669)	IntraSpin Power Cord, 220v
BTUBEHOLDZ (E872 x 1)	IntraSpin Tube Holder Replacement
BFUSE110Z (E997)	IntraSpin Fuse 110v
BFUSE220Z (E891)	IntraSpin Fuse 220v

Refer to the following table for material(s) of devices with direct patient contact:

Compatible Part #	Description
Surgical Tissue Forceps	Stainless Steel (Iron, Chromium)
Dual Biomaterial Carrier Spatula	Stainless Steel (Iron, Chromium)
Dual Biomaterial Packer	Stainless Steel (Iron, Chromium)

7. BRIEF CENTRIFUGE SETUP

Remove and save transport bolts from bottom of centrifuge. Attach AC cable and plug into electrical outlet. Power centrifuge on by using the rocker switch on the back of the device. Select speed and time: Speed = 2700 RPM; Time = 12:00 minutes. Press *[START/PULSE]*. The centrifuge cover will open automatically at the end of each cycle. After the first procedure, the timing and speed are recorded in the centrifuge memory unless the settings are changed.

8. BLOOD COLLECTION TUBES AND BLOOD COLLECTION SET CAUTIONS AND INSTRUCTIONS

- Do not use tubes if foreign matter is present.
- Blood collection tubes must be allowed to fill completely.
- Handle all biological samples and blood collection “sharps” (e.g., needles, and blood collection sets) according to the policies and procedures of your facility.
- Do not bend the needle.
- Do not forcefully release or re-activate the needle safety mechanism after it has been activated.
- Obtain appropriate medical attention in the case of any exposure to biological samples (e.g., via puncture injury) due to the possible transmission of HIV (AIDS), viral hepatitis or other infectious diseases.

- Discard all blood collection “sharps” in approved biohazard containers.
- Transferring a sample from a syringe to a tube is not a recommended procedure.
- If blood is collected through an intravenous (IV) line, follow the policies and procedures of your institution to ensure that the line has been cleared of IV solution before beginning to fill the blood collection tubes.
- Blood clotting accelerant may appear white on the tube surface, which has no effect on the performance of the tubes. If any other discoloration or precipitates are present in the tube, it should not be used.
- Do not use the tubes after the expiration date.
- Store blood collection tubes at 4 - 25 °C (40 - 77 °F).
- Store blood collection set (needle and holder) at 4 - 36 °C (40 - 97 °F).
- Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the tube quality (i.e., vacuum loss, coloring, etc.).
- To prevent backflow, place the patient’s arm in a downward position, hold the tube with the cap up, release the tourniquet as soon as blood starts to flow into the tube, avoid tube contents coming in contact with cap or end of the needle during venipuncture.
- Be sure that the following materials are readily accessible before performing venipuncture: all necessary blood collection tubes, identified labels for positive patient identification of samples, blood collection needles and holders, alcohol swab for cleansing the puncture site, clean gauze, tourniquet, adhesive plaster or bandage, approved biohazard container. For protection against exposure to bloodborne pathogens, appropriate PPE (Personal Protective Equipment) is recommended (e.g., gloves, laboratory coat, goggles, etc.).

8.1 VENIPUNCTURE TECHNIQUE AND BLOOD SAMPLE COLLECTION

The blood collection must be made as quickly as possible since there is no anticoagulant in the collection tubes. The blood sample will begin to coagulate immediately. Wear gloves during venipuncture and when handling blood collection tubes to minimize exposure to hazards. Prior to the blood draw, wipe the top of the blood tube cap(s) with a disinfectant wipe of your choice. Remove the cover over the valve section of the needle. Prepare venipuncture site with an appropriate antiseptic. Do not palpate venipuncture area after cleansing. Place the patient’s arm in a downward position. Remove the needle cap. Perform the venipuncture with the arm downward and tube cap up. Immobilize the needle with tape when necessary. Push the blood collection tube into the holder and onto the needle valve puncturing the rubber diaphragm of the blood collection tube. Center the blood collection tubes in the holder when penetrating the cap to prevent sidewall penetration and subsequent premature vacuum loss. Remove the tourniquet as soon as blood appears in the blood collection tube. During the procedure, always hold the collection tube in place by pressing it with a thumb. This will ensure a complete vacuum draw. The blood collection tube will fill automatically. If no blood flows into collection tube or if blood flow ceases before an adequate specimen is collected, the following steps are suggested to complete a satisfactory collection:

- Push the blood collection tube forward to ensure the cap has been penetrated.
- Confirm the correct position of the needle in the vein.
- If blood still does not flow, remove and appropriately discard the collection tube. Obtain a new collection tube and push it into the holder.
- If the second collection tube does not draw, remove and appropriately discard the needle and the collection tube. Repeat the procedure.
- When the maximum volume fill line of the blood collection tube has been reached, gently remove it from the holder. Repeat with a second blood collection tube.

Gently invert each collection tube immediately upon removing from the holder. Do not shake the tubes filled with blood sample. Vigorous mixing may cause foaming or hemolysis. Insufficient mixing or delayed mixing in serum tubes may result in delayed clotting. Upon completion of blood sample collection, remove the needle from the vein. Activate the safety mechanism (safety shield) of the needle by pressing in both sides of the hub to engage the lock. Slide the safety mechanism backward until an audible click is heard. Do not recap the needle as this increases the risk of needle stick injury and blood exposure. Dispose of the used needle with holder using a suitable biohazard disposal container. Apply pressure to the puncture site with a dry sterile swab until the bleeding stops. If desired, apply a bandage once clotting has occurred. It is recommended that filled collection tubes be kept in an upright position. Once the second blood collection tube is full, remove it and place the first and second tubes into the centrifuge on opposite locations to counterbalance the rotor. Close the cover of the IntraSpin centrifuge and press the *[START/PULSE]* button to allow it to spin for twelve (12) minutes.

If more than two tubes of blood are required, please follow this alternative procedure: After the first two tubes of blood are collected and gently inverted, immediately place them into the IntraSpin centrifuge, opposite from each other to ensure the centrifuge is properly balanced. Close the cover and press the *[START/PULSE]* button and allow the centrifuge to run while you collect the remaining tubes of blood. Press the *[STOP/OPEN]* button and allow the centrifuge to come to a full stop. The cover will pop open; immediately place the remaining tubes in the centrifuge opposite from each other to ensure proper balance and press the *[START/PULSE]* button to reset and complete recommended protocol.

Always place the tubes in pairs and place them in opposite positions to balance the centrifuge rotor. The tubes must always be balanced in the rotor before pressing the *[START/PULSE]* button or this may cause serious damage to the centrifuge, improper coagulation, and/or separation. If the tubes are not properly balanced, there will be too much vibration during centrifugation and a poor L-PRF fibrin clot will result.

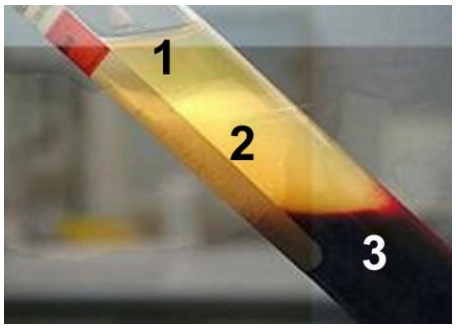
If you have an odd number of blood samples to centrifuge, then place a white cap balancing tube (e.g., 455001), filled with water to the indicated full line, opposite to the un-paired tube in the rotor. This will allow for proper balancing of the centrifuge.

Begin centrifugation immediately after collecting the blood samples. Delays affect the blood separation procedure and result in a poor L-PRF fibrin clot.

9. L-PRF PREPARATION

After centrifugation, three segments are visible:

1. Upper Segment = platelet poor plasma (PPP).
2. Middle Segment = fibrin clot: L-PRF.
3. Lower Segment = red blood cell clot.

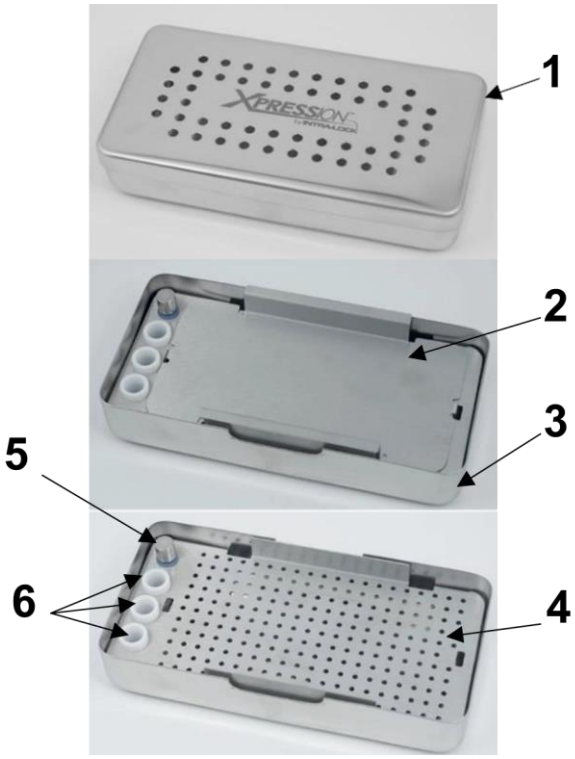


L-PRF fibrin membranes or plugs must be prepared relatively quickly: 0 - 15 minutes after centrifugation or the clot will shrink in volume by releasing the trapped serum. After centrifugation, remove the rubber stopper from each tube. Using the Surgical Tissue Forceps remove the L-PRF clot from the tube. Gently scrape the red blood cell clot from the L-PRF fibrin clot just below the union, using the Dual Biomaterial Carrier Spatula, so that only a minimal, residual amount of red blood cells are attached to L-PRF clot. Place the fibrin clot onto the Xpression Perforated Tray.

10. FIBRIN MATRIX PREPARATION

10.1 XPRESSION BOX

The Xpression Box enables the fabrication of fibrin membranes of constant thickness with ease. The exudate can be collected from the Xpression Collection Tray, underneath the Xpression Perforated Tray. The Xpression Box includes L-PRF plug fabrication cylinders and a piston to fabricate L-PRF plugs that easily fit post-extraction sockets.



1. Xpression Weighted Cover
2. Xpression Compression Plate
3. Xpression Collection Tray
4. Xpression Perforated Tray
5. Xpression Box Piston
6. Plug Fabrication Cylinders

Representative Xpression box components

10.2 PROTOCOL #1: L-PRF MEMBRANE

Place each of the fibrin clots on the Xpression Perforated Tray. Once all of the fibrin clots are placed, place the Xpression Compression Plate and Xpression Weighted Cover over the fibrin clots without exerting any pressure over the clots.

Allow the weight of the cover to slowly press down the fibrin clot while the exudate is filtered to the bottom of the tray. Do not apply pressure to the weighted cover. Gravitational force on the weighted cover will gently compress the clot and express the serum from the L-PRF clot without damaging the fibrin network.

Wait at least five (5) minutes before removing and using any fibrin membranes. Do not remove any fibrin membranes until actual time of use. The fibrin membranes should be used as quickly as possible but may remain in the Xpression Box for a period of two-and-a-half (2.5) to three (3) hours as long as they are re-hydrated with exudate (MLD601, R43069r).

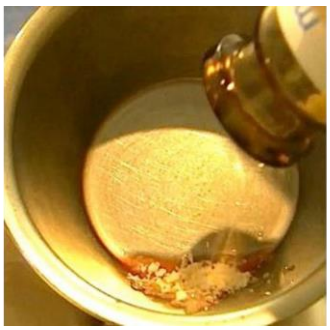
10.3 PROTOCOL #2: L-PRF PLUG

Place a fibrin clot inside the white plug fabrication cylinder. Use the piston to slowly press the clot inside the white L-PRF plug fabrication cylinder. Continue to press until the top edge of the piston is flush with the top edge of the white L-PRF plug fabrication cylinder. With this technique, one will be able to form a thick, round fibrin plug for the extraction socket. For a single tooth, one L-PRF plug may be sufficient. Pre molars may need two (2) L-PRF plugs, and three (3) L-PRF plugs may be needed for molars, depending on the size of the extraction socket and the size of the fibrin clot created.

The working properties of L-PRF provide a medium for use in combination with your biomaterial of preference. Utilizing any of the following mixing protocols, the biomaterial is captured in the fibrin matrix increasing its handling and biologic capacity.

10.4 PROTOCOL #3: BIOMATERIAL/L-PRF MIXTURE

To create a 'putty like' mixture that can be gently formed with the biomaterial instrument into the desired shape and thickness use the following protocol: Gently cut the L-PRF fibrin membrane into small pieces in a sterile dish with the Surgical Curved Scissors. Add the desired amount of bone graft material. Thoroughly mix the L-PRF and bone graft material. This mixture can be placed into defects using the Dual Biomaterial Carrier Spatula.

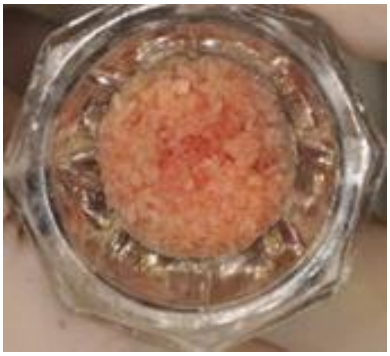




10.5 PROTOCOL #4: BIOMATERIAL/L-PRF MATRIX MIXTURE

Place the predetermined amount of bone graft material into a sterile bowl or tray. Dip the expressed LPRF membrane(s) or pieces of the L-PRF membrane into the graft material covering the entire surface area of the L-PRF membrane with graft material. Alternatively, the graft material may be sprinkled onto the L-PRF membrane covering the entire surface area with graft material. Note: A wetter L-PRF membrane may retain slightly more graft material than a dryer L-PRF membrane. The graft material should cling to the surface of the L-PRF, however, if desired, gently press the graft material onto the L-PRF membrane. The Surgical Tissue Forceps can be used to place this mixture into the defect.

10.6 PROTOCOL #5: BIOMATERIAL HYDRATION

Add the desired amount of bone graft material into a sterile bowl or tray. Utilize the exudate from the bottom of the Xpression Collection Tray to hydrate the graft material. Thoroughly mix the exudate and bone graft material. This mixture can be placed into defects using the Dual Biomaterial Carrier Spatula.



11. TISSUE REGENERATION KIT CLEANING AND STERILIZATION

The Tissue Regeneration Kit (including Xpression® Box, Surgical Curved Scissors, Surgical Tissue Forceps, Round Stainless-Steel Bowl, Rectangular Stainless-Steel Bowl, Dual Biomaterial Carrier Spatula, and Dual Biomaterial Packer) is NOT supplied sterile. Remove and discard any shipping material before initial cleaning and sterilization. Clean and sterilize the devices before each use. BioHorizons devices have not been validated for automated cleaning.

Disassemble the Xpression Box before each cleaning cycle. Remove the Xpression Compression Plate and the Xpression Perforated Tray from the Xpression Collection Tray. Remove the Piston from the Xpression Perforated Tray. The L-PRF plug fabrication cylinders and piston grommet are not intended to be removed from the Xpression Perforated Tray for cleaning and sterilization.

11.1 CLEANING STEPS:

1. Remove any visible debris from the Xpression Box, Surgical Curved Scissors, Surgical Tissue Forceps, Round Stainless-Steel Bowl, Rectangular Stainless-Steel Bowl, Dual Biomaterial Carrier Spatula, and Dual Biomaterial Packer using a soft-bristled brush dampened with a broad-spectrum cleaning detergent such as Hu-Friedy's Enzymax® or equivalent. Pay special attention to cracks, crevices, seams and hard to reach areas. Refer to the labeling of the detergent used for additional instructions for use.
2. Thoroughly rinse the devices under cold, running utility (tap) water.
3. Fully immerse the devices in the detergent solution and sonicate for ten (10) minutes.
4. Thoroughly rinse the devices under cold, running utility (tap) water.
5. Prepare a bath of Isopropyl Alcohol (70% IPA).
6. Immerse the devices in the isopropyl alcohol to remove any soap residue and minerals.
7. Dry the devices with a lint-free cloth and allow them to air dry.

11.2 STERILIZATION STEPS:

1. Place the Surgical Curved Scissors, Surgical Tissue Forceps, Round Stainless-Steel Bowl, Rectangular Stainless-Steel Bowl, Dual Biomaterial Carrier Spatula, Dual Biomaterial Packer and reassembled Xpression Box in FDA cleared sterilization bags or wraps.
2. Run through one of the following qualified sterilization cycles:

Sterilization Method	Temperature	Exposure Time	Minimum Drying Time
Pre-vacuum Steam (ANSI/AAMI ST79)	132 °C (270 °F)	4 minutes	20 - 30 minutes
Pre-vacuum Steam (UK DoH Health Technical Memorandum 01-01)	134 °C (273 °F)	3 minutes	20 - 30 minutes

WARNING
Improper cleaning may lead to inadequate sterilization.

- Failure to completely dry the Surgical Curved Scissors, Surgical Tissue Forceps, Round Stainless- Steel Bowl, Rectangular Stainless-Steel Bowl, Dual Biomaterial Carrier Spatula, Dual Biomaterial Packer and Xpression Box components during autoclaving may leave moisture and cause discoloration and oxidation.
- The use of hydrogen peroxide or other oxidizing agents will damage the surface of the devices.
- Periodic testing, cleaning, and calibration of the autoclave equipment is recommended to ensure the unit remains in proper working order.

12. ABOUT OPERATING INSTRUCTIONS

12.1 USE OF OPERATING INSTRUCTIONS

- Read this document carefully and in full before commencing initial operation of the device.
- Observe other enclosed instructions as necessary.
- This document constitutes part of the device and must be kept within easy reach.
- The most recently updated version of this document in the available languages can be found on the manufacturer's website at: https://ifu.biohorizons.com.

12.2 COMMON SYMBOLS/MARKERS

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

Symbol/Marker	Explanation
CAUTION	Cautions of which the user should be mindful
WARNING	Warnings which enable users to avoid dangers and hazards
DANGER	Possible risks, dangers and hazards with subsequent explanation
NOTICE	Important notices to user
IMPORTANT	Important informational text of which the user should take note
[→...]	Quick link to aid in document navigation

Symbol/Marker	Explanation
[Buttons]	Controls (for example: buttons, switches)
'Indicator'	Indicator elements (for example: signal lights, screen elements)

13. SAFETY

13.1 INTENDED USE

The centrifuge is used solely to separate substances or mixtures of substances with a density of no more than 1.2 kg/dm³.

The IntraSpin® centrifuge is designed for rapid and safe separation of autologous blood samples for the preparation of autologous platelet-rich fibrin (PRF). PRF is used to prepare fibrin matrices that can be mixed with autologous and/or allogeneic bone material prior to use in bone defect cases.

The centrifuge is only intended for the use referred to above. Intended use also includes the observation of all instructions in the IFU and compliance with the required inspection and maintenance intervals. Any other use or use beyond this is considered improper. BioHorizons Implant Systems Inc. shall not be liable for any damage arising from this.

The IFU is part of the product. The product is only intended for use in accordance with this IFU.

13.2 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 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.

13.3 FORESEEABLE MISUSE

- The manufacturer recommends using only accessories that it has approved for the intended purpose.
- Only operate the centrifuge under supervision.

13.4 PERSONNEL REQUIREMENTS

13.4.1 REQUIRED QUALIFICATIONS

The user has read the IFU in full and familiarized themselves with the device.

NOTICE
Damage to the device by unauthorized personnel

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

Trained users have been educated and trained in laboratory work, are able to carry out the work assigned to them, and to recognize and prevent potential hazards independently.

13.4.2 PERSONAL PROTECTIVED 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.

13.5 OPERATOR'S RESPONSIBILITY

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

Keep the IFU for future reference.

13.5.1 PROVIDE INFORMATION

- Following the instructions in this document will help:
  - To avoid dangerous situations.
  - To minimize 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 with the correct revision.
- Keep the user manual available at the place where the device is used.

13.5.2 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 instructions.

13.6 SAFETY INSTRUCTIONS

IMPORTANT
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 local 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 sample.

- 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).

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
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.

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.

14. DEVICE OVERVIEW

14.1 TECHNICAL DATA

Manufacturer	BioHorizons Implant Systems Inc. 2300 Riverchase Center, Birmingham, AL 35244, USA	
Model	IntraSpin®	IntraSpin®
Type	IS220Z	IS110Z
Mains voltage (10%)	200-240 V 1~	100-127 V 1~
Mains frequency	50-60 Hz	50-60 Hz
Power consumption	100 VA	100 VA
Power consumption	0.5 A	1.0 A
Max. capacity	8 x 15 ml	
Max. permissible density	1.2 kg/dm^3	
Max. speed	6000 RPM	
Max. acceleration	3461 RCF	
Max. kinetic energy	750 Nm	
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 (6561 ft) above sea level	
Ambient temperature	2 °C to 40 °C (35.6 °F to 104°F)	
Humidity	Maximum relative humidity 80% for temperatures up to 31 °C (87.8 °F), decreasing linearly to 50% relative humidity at 40 °C (104 °F)	
Overvoltage category 9IEC 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)	≤50 dB(A)
Dimensions:	
Width	261 mm (10.28 inches)
Depth	353 mm (13.90 inches)
Altitude	228 mm (8.98 inches)
Weight	Approx. 9 kg (19.84 lbs)

14.1.1 RATING PLATE

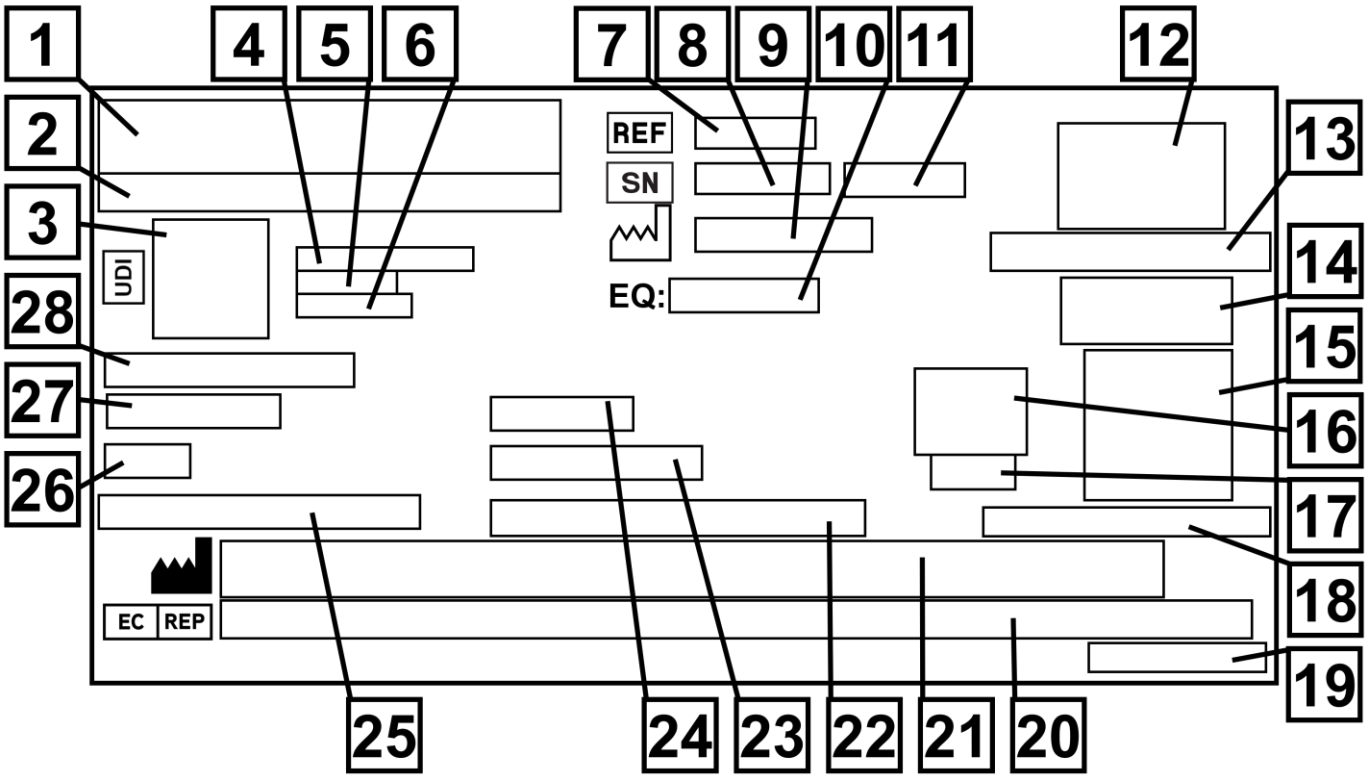
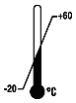


Figure 1: Rating plate

1. Brand logo
2. Item name
3. UDI 2D data matrix
4. Global Trade Item Number (GTIN)
5. Manufacturing date
6. Serial number
7. Item number
8. Serial number
9. Manufacturing date
10. Equipment number
11. Revision
12. Medical device symbols
13. Country of manufacture
14. Medical device symbols
15. QR code to navigate to IFU website
16. CE mark
17. Notified body number
18. IFU website URL

19. Label name and revision
20. EC representative name, address and phone number
21. Manufacturer name, address and phone number
22. Maximum permissible density
23. Maximum kinetic energy
24. Mains frequency
25. Maximum revolutions per minute (RPM)
26. Power consumption
27. Mains voltage
28. Centrifuge type

14.2 IMPORTANT SYMBOLS ON THE PACKAGING

Symbol	Explanation
	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 must be 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".
	TIME LIMIT, EXPIRATION DATE Rotor expiration date.

14.3 IMPORTANT SYMBOLS ON THE DEVICE

IMPORTANT
The symbols and labels on the device must not be removed, covered or have anything pasted over them.

Symbol	Explanation
 **DANGER**	ATTENTION, GENERAL DANGER AREA. Possible risks, dangers and hazards with subsequent explanation
	Biohazard warning.

	DIRECTION OF ROTATION OF THE ROTOR The orientation of the arrow indicates the rotor's direction of rotation.
	DIRECTION OF ROTATION OF THE EMERGENCY RELEASE The orientation of the arrow indicates the emergency release's direction of rotation.
	SEPARATE COLLECTION OF ELECTRICAL AND ELECTRONIC EQUIPMENT Symbol used in accordance with Directive 2012/19/EU (WEEE). Use in European Union countries, Norway and Switzerland.

14.4 OPERATING AND INDICATOR ELEMENTS

14.4.1 CONTROL PANEL

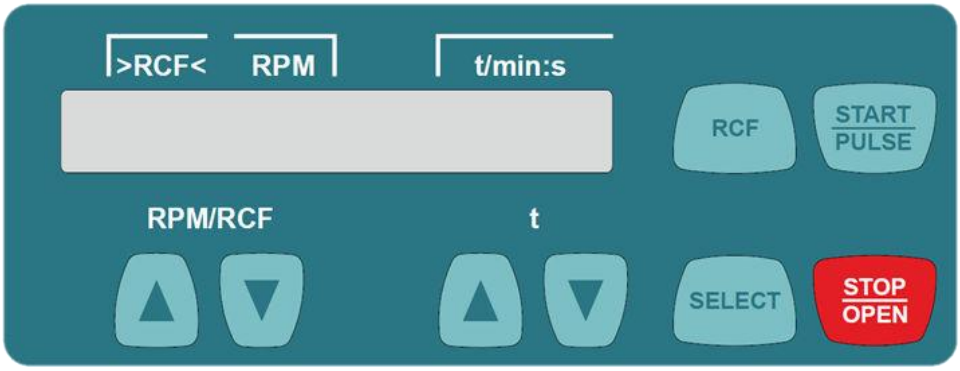


Figure 2: Control panel

14.4.2 INDICATOR ELEMENTS

Figure 3: 'Lid unlocked' indicator

- The indicator appears when the lid is unlocked

Figure 4: 'Lid locked' indicator

- The indicator appears when the lid is locked.

Figure 5: 'Rotation' indicator

- The indicator light rotates when the rotor is turning.

14.4.3 CONTROLS

Figure 6: *[Mains switch]* button

- Switch the device on and off.

Figure 7: *[RPM/RCF]* button

- Enter speed.
- The value changes at an increasing rate if the button is held down.

Figure 8: *[t]* button

- Enter runtime. Adjustable up to one (1) minute in 1-second increments and from one (1) minute in 1-minute increments.
- Enter the centrifugation parameters.
- The value changes at an increasing rate if the button is held down.

Figure 9: *[RCF]* button

- Toggle between RCF indicator and RPM indicator.
- Relative centrifugal force, RCF. The RCF is displayed in brackets > <.
- Speed, RPM.

Figure 10: *[SELECT]* button

- Selecting the individual parameters.
- Open 'MACHINE MENU'.
- Scroll forward in the menus.

Figure 11: [*START/PULSE]* button

- Start centrifugation run.
- Short-time centrifugation. The centrifugation run takes place as long as the button is being pressed.
- Open submenus.

Figure 12: *[STOP/OPEN]* button

- End the centrifugation run. The rotor ramps down to a stop at the pre-selected brake level.
- Pressing the button twice triggers the quick stop function.
- Unlock the lid.

14.5 ORIGINAL SPARE PARTS

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

14.6 SCOPE OF DELIVERY

The following accessories are supplied with the centrifuge:

- Two (2) fuse link
- One (1) hex key (SW5 x 100)
- One (1) Rotor
- One (1) power cable
- One (1) instruction sheet, transport lock

14.7 RETURNS

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 [→Transport and Storage] section.

15. TRANSPORT AND STORAGE

15.1 TRANSPORT AND STORAGE CONDITIONS

15.1.1 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 up the device up for at least three (3) hours in a warm room before connecting it to the electrical power.
  or
- When switching from a warm to cold room, the centrifuge must be allowed to run for approximately thirty (30) minutes in the cold room.

- Before transporting, fasten the transport lock and disconnect the device from the mains socket.
- The transport temperature must be between -20 °C (-4 °F) and +60 °C (140 °F).
- Humidity must not be condensing. Humidity must be between 10% and 80%.
- Be aware of the weight of the device.
- 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.

15.1.2 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 (-4 °F) and +60 °C (+140 °F).
- Humidity must not be condensing. Humidity must be between 10% and 80%.

15.2 FASTENING THE TRANSPORT LOCK

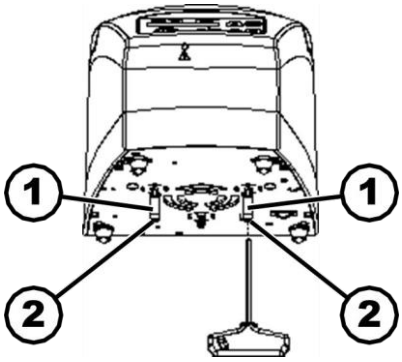


Figure 13: Transport lock

1. Space sleeve
2. Screw

Personnel: Trained user

- The lid is closed.
- The main cable is disconnected from the device.
  1. Tilt the device on its back.
  2. Insert two (2) spaced sleeves (1).
  3. Screw in two (2) screws (2).

16. COMMISSIONING

16.1 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 [→Technical Data] section.

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. Open the box at the top.
2. Remove the padding.
3. Remove the device and accessories by lifting them up out of the box.
4. Place the device on a stable and level surface.

16.2 REMOVING THE TRANSPORT LOCK

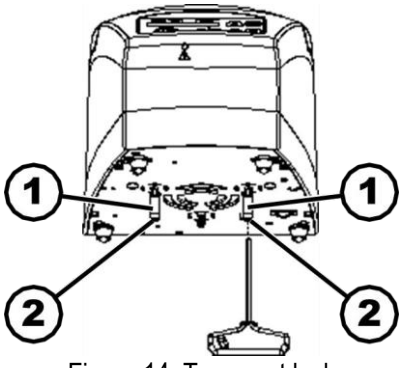


Figure 14: Transport lock

1. Space sleeve
2. Screw

Personnel: Trained user

- The lid is closed.
- The main cable is disconnected from the device.
  1. Tilt the device on its back.
  2. Unscrew two (2) screws (2).

3. Remove two (2) spacer sleeves (1).
4. Keep the screws and spacer sleeves in a safe place.

16.3 SETTING UP AND CONNECTING THE CENTRIFUGE

16.3.1 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 three hundred (300) mm (11.81 inches) around the centrifuge during a centrifugation run.
- A distance of three hundred (300) mm (11.81 inches) 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.

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 three hundred (300) mm (11.81 inches) around the device.
3. Comply with the ambient conditions in the technical data. See [→Technical Data] section.

16.3.2 CONNECTING THE CENTRIFUGE

NOTICE
Damage to the device by unauthorized personnel.

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

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 up the device up for at least three (3) hours in a warm room before connecting it to the electrical power.
  or
- When switching from a warm to cold room, the centrifuge must be allowed to run for approximately thirty (30) minutes in the cold room.

Personnel: Trained user

1. 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.

16.4 SWITCHING THE CENTRIFUGE ON AND OFF

16.4.1 SWITCHING THE CENTRIFUGE ON

Personnel: Trained user

1. Set the mains switch to *[I]*.
   The buttons flash, depending on the centrifuge type. The following indicators appear one after the other, depending on the centrifuge type:
   - The centrifuge model.
   - The machine type and program version.
   - The last centrifugation data used.
2. The lid opens.

16.4.2 SWITCHING OFF THE CENTRIFUGE

Personnel: Trained user

1. Set the mains switch to *[0]*.

17. OPERATION

17.1 OPENING AND CLOSING THE LID

17.1.1 OPENING THE LID

Personnel: Trained user

- The centrifuge is switched on.
- The rotor is stationary.
  1. Press the *[STOP/OPEN]* BUTTON.

- The lid unlocks by means of a motor
- The ‘Lid unlocked’ indicator appears.

17.1.2 CLOSING THE LID

CAUTION

Crushing hazard when closing the lid.

Dangers of fingers getting crushed when the closing motor pulls the lid against the seal.

- No parts of the operator's body should be in the hazard zone of the lid when closing the lid.
- To close the lid, press on the lid from above.

NOTICE

Damage to the device caused by the lid slamming.

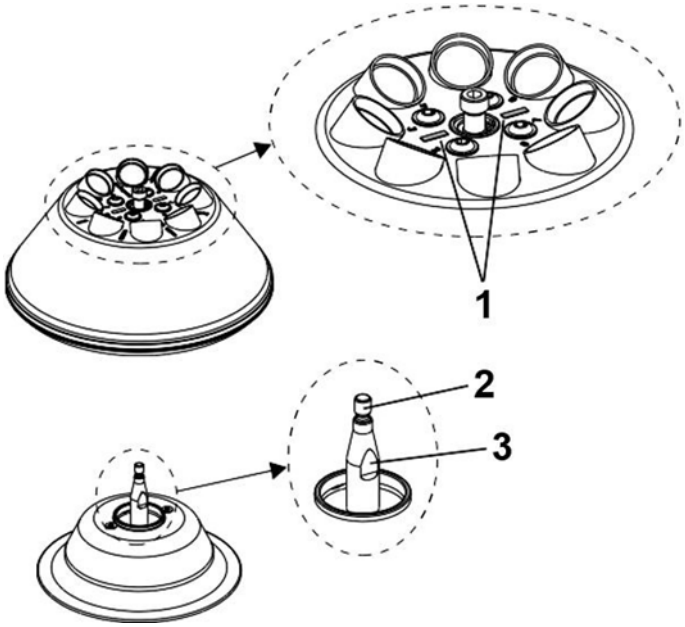
- Close the lid slowly.
- Do not slam the lid.

Personnel: Trained user

1. Close the lid and press the front edge of the lid down gently.
   - The lid locks using a motor.
   - The 'Lid locked' indicator appears.

17.2 REMOVING AND INSTALLING THE ROTOR

17.2.1 REMOVING THE ROTOR



1. Marker bar
2. Motor shaft
3. Surfaces

Figure 15: Rotor installation and removal

Personnel: Trained user

1. Open the lid.
2. Loosen the clamping nut using the supplied IntraSpin Hex Key (BHEXZ [E613]).
    - 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.

17.2.2 INSTALLING THE ROTOR

Personnel: Trained user

- The lid is open.

1. Clean the motor shaft (2) and rotor hole.
2. Lightly grease the motor shaft (2). See [→Instructions for Cleaning and Disinfection] section.
3. Place the rotor vertically on the motor shaft (2).
   The two marker bars (1) on the rotor must be parallel to the two surfaces (3) on the motor shaft.
4. Hand-tighten the rotor clamping nut using the supplied IntraSpin Hex Key (BHEXZ [E613]).
5. Check that the rotor is firmly seated.
6. A test run must be performed if a different rotor has been installed.
   For the test run, the adjustment weight supplied (7g) must be placed in a rotor location and a centrifugation run with a runtime of one (1) minute must be performed at a speed of 6000 RPM.
    - The drive must not switch off.

IMPORTANT
The adjustment weight must be removed from the rotor location again before the next centrifugation run.

17.3 LOADING

17.3.1 FILLING CENTRIFUGE TUBES

WARNING
Risk of injury from contaminated sample material.

Contaminated sample material escapes from the sample tube during centrifugation.

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.

Personnel: Trained user

1. Open the lid.
    - 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.

17.3.2 LOADING THE ANGLE ROTORS

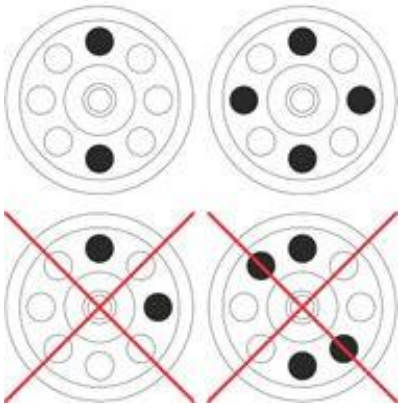


Figure 16: Loading the angle rotors

- 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.

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.

17.4 CENTRIFUGATION

17.4.1 CENTRIFUGATION IN CONTINUOUS OPERATION

Personnel: Trained user

1. If required: Press the *[RCF]* button to select the RPM indicator.
    - The parameter RCF (‘>RCF<’) or RPM (‘RPM’) is displayed. Press the *[RCF]* button to toggle between the two parameters.
2. Enter the desired speed (RPM) or relative centrifugal force (RCF).
3. Set the parameters t/min and t/sec to zero (0).
    - '----' is displayed.
4. Press the *[START/PULSE]* button.
    - The centrifugation run starts.
    - The timing starts at '0:00'.
    - The rotor speed or the resulting RCF value and the elapsed time are displayed during the centrifugation run.
5. Press the *[STOP/OPEN]* button to cancel the centrifugation run.
    - Ramp-down takes place with the set brake level. The brake level is displayed.
    - When the rotor is at a standstill, the lid opens, an audible signal sounds and the remaining number of run cycles (centrifugation runs) is displayed.

17.4.2 CENTRIFUGATION WITH TIME PRESELECTION

Personnel: Trained user

1. If required: Press the *[RCF]* button to select the RPM indicator.
    - The parameter RCF (‘>RCF<’) or RPM (‘RPM’) is displayed. Press the *[RCF]* button to toggle between the two parameters.
2. Enter the desired speed (RPM) or relative centrifugal force (RCF).
3. Set the parameters t/min and t/sec to the desired value.
4. Press the *[START/PULSE]* button.
    - The centrifugation run is started.

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

5. Press the *[STOP/OPEN]* button to cancel the centrifugation run or wait for the centrifugation time to elapse.
    - Ramp-down takes place with the set brake level. The brake level is displayed.
    - When the rotor is at a standstill, the lid opens, an audible signal sounds and the remaining number of run cycles (centrifugation runs) is displayed.

17.4.3 SHORT-TIME CENTRIFUGATION

Personnel: Trained user

1. If required: Press the *[RCF]* button to select the RPM indicator.
    - The parameter RCF (‘>RCF<’) or RPM (‘RPM’) is displayed. Press the *[RCF]* button to toggle between the two parameters.
2. Enter the desired centrifugation parameters.
3. Press and hold the *[START/PULSE]* button.
    - The centrifugation run starts.
    - The timing starts at ‘0:00’.
    - The rotor speed or the resulting RCF value and the elapsed time are displayed during the centrifugation run.
4. Release the *[START/PULSE]* button to end the centrifugation run.
    - Ramp-down takes place with the set brake level. The brake level is displayed.
    - When the rotor is at a standstill, the lid opens, an audible signal sounds and the remaining number of run cycles (centrifugation runs) is displayed.

17.4.4 QUICK STOP FUNCTION

Personnel: Trained user

1. Press the *[STOP/OPEN]* button twice.
    - Ramp-down with brake level "fast" (shortest ramp-down time) is displayed and executed.

18. SOFTWARE OPERATION

18.1 CENTRIFUGATION PARAMETERS

18.1.1 INPUT WITH THE SELECT BUTTON

IMPORTANT
The number of centrifugation parameters that can be set differs depending on whether the RPM indicator or the RCF indicator is selected.

This section describes input of the centrifugation parameters with the RPM indicator and RCF indicator selected, one after the other.

IMPORTANT
The display returns to the previous values if no button is pressed for eight (8) seconds after parameter selection or during parameter entry. The parameters must then be entered again.

18.1.1.1 RPM INDICATOR

1. If required: Press the *[RCF]* button to select the RPM indicator.
    - Press the *[RCF]* button to toggle between the two parameters RPM (‘RPM’) and RCF (‘>RCF<’).
2. Press the *[SELECT]* button.

- Runtime in ‘t/min’ is displayed.

3. Use the *[t]* buttons to set the desired value.
    - Adjustable from one (1) to ninety-nine (99) minutes in 1-minute increments.
    - The parameters t/min and t/sec must be set to zero (0) to set continuous operation.
    - '----' is displayed.
4. Press the *[SELECT]* button.
    - Runtime in ‘t/sec’ is displayed.
5. Use the *[t]* buttons to set the desired value.
    - Adjustable from one (1) to fifty-nine (59) seconds in 1-second increments.
    - The parameters t/min and t/sec must be set to zero (0) to set continuous operation.
    - '----' is displayed.
6. Press the *[SELECT]* button.
    - Speed ‘RPM’ is displayed.
7. Use the *[t]* buttons to set the desired value.
    - A numerical value from two hundred (200) RPM to the maximum rotor speed can be set.
    - Adjustable in 100-RPM increments.
8. Press the *[SELECT]* button.
    - The DEC brake level is displayed:
    - Fast: short ramp-down time
    - Slow: long ramp-down time
9. Use the *[t]* buttons to set the desired value.
10. Press the *[START/PULSE]* button.
    - The settings are stored.

18.1.1.2 RCF INDICATOR

1. If required: Press the *[RCF]* button to select the RPM indicator.
    - Press the *[RCF]* button to toggle between the two parameters RPM (‘RPM’) and RCF (‘>RCF<’).
2. Press the *[SELECT]* button.
    - Runtime in ‘t/min’ is displayed.
3. Use the *[t]* buttons to set the desired value.
    - Adjustable from one (1) to ninety-nine (99) minutes in 1-minute increments.
    - The parameters t/min and t/sec must be set to zero (0) to set continuous operation.
    - '----' is displayed.
4. Press the *[SELECT]* button.
    - Runtime in ‘t/sec’ is displayed.
5. Use the *[t]* buttons to set the desired value.
    - Adjustable from one (1) to fifty-nine (59) seconds in 1-second increments.
    - The parameters t/min and t/sec must be set to zero (0) to set continuous operation.
    - '----' is displayed.
6. Press the *[SELECT]* button.
    - Centrifuging radius ‘RAD/mm’ is displayed.
7. Use the *[t]* buttons to set the desired value.
    - A numerical value from ten (10) mm to two hundred fifty (250) mm can be set.
    - Adjustable in 1-millimeter increments.
8. Press the *[SELECT]* button.
    - Relative centrifugal force ‘RCF’ is displayed.
9. Use the *[t]* buttons to set the desired value.
    - A numerical value can be set that gives a speed between two hundred (200) RPM and the maximum rotor speed.
    - Adjustable in 100-RPM increments.
10. Press the *[SELECT]* button.
    - The DEC brake level is displayed:
    - Fast: short ramp-down time
    - Slow: long ramp-down time
11. Use the *[t]* buttons to set the desired value.

12. Press the *[START/PULSE]* button.
    - The settings are stored.

18.1.2 RUNTIME, T

1. Use the *[t]* buttons to set the desired value.
    - The value is set up to one (1) minute in 1-second increments.
    - Adjustable from one (1) to ninety-nine (99) minutes and one (1) to fifty-nine (59) seconds.
2. The parameters t/min and t/sec must be set to zero (0) to set continuous operation.
    - '----' is displayed.

18.1.3 SPEED, RPM

1. If required: Press the *[RCF]* button to select the RPM indicator.
    - Press the *[RCF]* button to toggle between the two parameters RPM ('RPM') and RCF ('>RCF<').
2. Use the *[RPM/RCF]* buttons to set the desired value.
    - A numerical value from two hundred (200) RPM to the maximum rotor speed can be set.
    - Adjustable in 100-RPM increments.

18.1.4 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 center of the axis of rotation to the bottom of the tube

18.1.5 RELATIVE CENTRIFUGAL FORCE (RCF) AND CENTRIFUGING RADIUS (RAD)

The relative centrifugal force (RCF) is dependent on the centrifuging radius (RAD). After entering the RCF, check that the correct centrifuging radius is set.

1. If required: Press the *[RCF]* button to select the RPM indicator.
    - Press the *[RCF]* button to toggle between the two parameters RPM ('RPM') and RCF ('>RCF<').
2. Use the *[RPM/RCF]* buttons to set the desired value.
    - A numerical value can be set that gives a speed between two hundred (200) RPM and the maximum rotor speed.
    - Adjustable in 100-RPM increments.
    - The centrifuging radius (RAD) is displayed during setting.
3. If required: Use the *[t]* buttons to set the desired centrifuging radius.
    - A numerical value from ten (10) mm to two hundred fifty (250) mm can be set.
    - Adjustable in 1-millimeter increments.

18.1.6 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:

$$Reduced\ Speed\ (n_{red}) = \sqrt{\frac{1.2\ \left(\frac{kg}{dm^3}\right)}{Greater\ Density\ \left[\frac{kg}{dm^3}\right]}} * Maximum\ Speed\ [RPM]$$

For example, Maximum speed = 4000 RPM, density = 1.6 kg/dm³:

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

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:

$$Reduced\ Speed\ (n_{red}) = \sqrt{\frac{Maximum\ Load\ [g]}{Actual\ Load\ [g]}} * Maximum\ Speed\ [RPM]$$

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

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

Please contact the manufacturer if you are not sure.

18.2 MACHINE MENU

18.2.1 QUERYING SYSTEM INFORMATION

The following system information can be queried:

- Centrifuge model
- Centrifuge program version
- Centrifuge type number
- Date of manufacture of the centrifuge
- Centrifuge serial number
- Frequency converter type
- Program version for the frequency inverter

The rotor is stationary.

1. Press and hold the *[SELECT]* button.
   - '*MACHINE MENU*' is displayed after eight (8) seconds.
2. Press the *[SELECT]* button.
   - '-> Info' is displayed.
3. Press the *[START/PULSE]* button.
   - The centrifuge model is displayed.
4. Press the *[SELECT]* button.
   - The centrifuge program version 'CP FW=' is displayed.
5. Press the *[SELECT]* button.
   - The centrifuge type number 'Type#1:' is displayed.
6. Press the *[SELECT]* button.
   - The continuation of the centrifuge type number 'Type#2:' is displayed.
7. Press the *[SELECT]* button.
   - The date of manufacture 'Date:' of the centrifuge is displayed.
8. Press the *[SELECT]* button.
   - The centrifuge serial number 'Serial#:' is displayed.
9. Press the *[SELECT]* button.

- The type of frequency converter ‘FC type’ of the centrifuge is displayed.

10. Press the *[SELECT]* button.
    - The program version of the frequency converter ‘FC FW=’ of the centrifuge is displayed.
11. Press the *[STOP/OPEN]* button twice to exit the ‘-> Info’ menu or press the *[STOP/OPEN]* button three (3) times to exit the ’*MACHINE MENU*’.

18.2.2 CYCLE COUNTER

The centrifuge is equipped with a cycle counter. The cycle counter counts the run cycles (centrifugation cycles). The remaining number of run cycles (centrifugation runs) is displayed briefly after each centrifugation run.

If the maximum permissible number of rotor run cycles (50,000) entered is exceeded, ‘Cycles passed’ is displayed after each start of a centrifugation run. The centrifugation run must be restarted. The rotor must be replaced with a new one.

IMPORTANT
The rotor has a period of use of fifty thousand (50,000) cycles or five (5) years, whichever comes first.

Once the rotor has been replaced, the cycle counter must be reset to ‘0’.

18.2.2.1 RESETTING THE CYCLE COUNTER

The cycle counter must be reset to ‘0’ after installing a new rotor.

1. Press and hold the *[SELECT]* button.
    - ‘*MACHINE MENU*’ is displayed after eight (8) seconds.
2. Press the *[SELECT]* button repeatedly until ‘-> Time & Cycles’ is displayed.
3. Press the *[START/PULSE]* button.
4. Press the *[SELECT]* button repeatedly until ‘Cyc sum=...’ is displayed.
5. Press the *[RCF]* button.
6. Press the *[t ▼]* button.
    - The number of run cycles completed is reset to ‘0’.
7. Press the *[START/PULSE]* button.
    - ‘Store cycles...’ is displayed.
8. Press the *[STOP/OPEN]* button twice to exit the ‘-> Time & Cycles’ menu or press the *[STOP/OPEN]* button three (3) times to exit the ‘*MACHINE MENU*’.

18.2.3 QUERYING OPERATING HOURS AND CENTRIFUGATION RUNS

The operating hours are divided into internal and external operating hours.

- Internal operating hours: Total time for which the device has been switched on.
- External operating hours: Total time of centrifugation runs to date.

The rotor is stationary.

1. Press and hold the *[SELECT]* button.
    - ‘*MACHINE MENU*’ is displayed after eight (8) seconds.
2. Press the *[SELECT]* button repeatedly until ‘-> Time & Cycles’ is displayed.
3. Press the *[START/PULSE]* button.
    - ‘TimeExt=’ is displayed.
    - TimeExt: External operating hours.
4. Press the *[SELECT]* button.
    - ‘TimeInt=’ is displayed.
    - TimeInt: Internal operating hours.
5. Press the *[SELECT]* button.
    - ‘Starts=’ is displayed.

- Starts: Number of all centrifugation runs.

6. Press the *[STOP/OPEN]* button twice to exit the '->; Time & Cycles' menu or press the *[STOP/OPEN*] button three (3) times to exit the '*MACHINE MENU*'.

18.2.4 AUDIBLE SIGNAL

18.2.4.1 GENERAL

The audible signal sounds:

- 2-second interval: after a problem occurs
- 30-second interval: after completion of the centrifuge run and rotor standstill
- Opening the lid or pressing any button stops the audible signal.

18.2.4.2 SETTING AN AUDIBLE SIGNAL

1. Press and hold the *[SELECT]* button.
    - '*MACHINE MENU*' is displayed after eight (8) seconds.
2. Press the *[SELECT]* button repeatedly until '-> Settings' is displayed.
3. Press the *[START/PULSE]* button.
    - 'End beep = on' or 'End beep = off' is displayed.
4. Use the *[t]* buttons to set 'off' or 'on'.
    - Off: Audible signal after completion of the centrifugation run is disabled.
    - On: Audible signal after completion of the centrifugation run is enabled.
5. Press the *[SELECT]* button.
    - 'Error beep = on' or 'Error beep = off' is displayed.
6. Use the *[t]* buttons to set 'off' or 'on'.
    - Off: Audible signal after the occurrence of a malfunction is disabled.
    - On: Audible signal after the occurrence of a malfunction is enabled.
7. Press the *[SELECT]* button.
    - 'Beep volume = min', 'Beep volume = mid' or 'Beep volume = max' are displayed.
8. Use the [t] buttons to set 'min', 'mid' or 'max'.
    - Min: The volume of the audible signal is set to low.
    - Mid: The volume of the audible signal is set to medium.
    - Max: The volume of the audible signal is set to loud.
9. Press the *[START/PULSE]* button.
    - The setting is stored.
    - 'Store Settings...' is displayed briefly.
    - '-> Settings' is then displayed.
10. Press the *[STOP/OPEN]* button once to exit the '-> Settings' menu or press the *[STOP/OPEN]* button twice to exit the '*MACHINE MENU*'.

18.2.5 VISUAL SIGNAL

The indicator backlight flashes as a visual signal after the centrifugation run is finished.

18.2.5.1 SWITCHING ON AND OFF

1. Press and hold the *[SELECT]* button.
    - '*MACHINE MENU*' is displayed after eight (8) seconds.
2. Press the *[SELECT]* button repeatedly until '-> Settings' is displayed.
3. Press the *[START/PULSE]* button.
    - 'End beep = on' or 'End beep = off' is displayed.
4. Press the *[SELECT]* button repeatedly until 'End blinking=off' or 'End blinking =on' is displayed.
5. Use the *[t]* buttons to set 'off' or 'on'.
    - Off: Backlight does not flash.
    - On: Backlight flashes.
6. Press the *[START/PULSE]* button.

- The setting is stored.
- ‘Store Settings...’ is displayed briefly.
- ‘-> Settings’ is then displayed.

7. Press the *[STOP/OPEN]* button once to exit the ‘-> Settings’ menu or press the *[STOP/OPEN]* button twice to exit the ‘*MACHINE MENU*’.

18.2.6 AUTOMATIC UNLOCKING OF THE LID

Setting whether the lid unlocks automatically after the centrifugation run.

The rotor is stationary.

1. Press and hold the *[SELECT]* button.
   - ‘*MACHINE MENU*’ is displayed after eight (8) seconds.
2. Press the *[SELECT]* button repeatedly until ‘-> Settings’ is displayed.
3. Press the *[START/PULSE]* button.
   - ‘End beep = on’ or ‘End beep = off’ is displayed.
4. Press the *[SELECT]* button repeatedly until ‘Lid AutoOpen=off’ or ‘Lid AutoOpen=on’ is displayed.
5. Use the *[t]* buttons to set ‘off’ or ‘on’.
   - Off: Lid does not unlock automatically.
   - On: Lid unlocks automatically.
6. Press the *[START/PULSE]* button.
   - The setting is stored.
   - ‘Store Settings...’ is displayed briefly.
   - ‘-> Settings’ is then displayed.
7. Press the *[STOP/OPEN]* button once to exit the ‘-> Settings’ menu or press the *[STOP/OPEN]* button twice to exit the ‘*MACHINE MENU*’.

18.2.7 INDICATOR BACKLIGHT

The indicator backlight can be switched off after two (2) minutes to save energy.

The rotor is stationary.

1. Press and hold the *[SELECT]* button.
   - ‘*MACHINE MENU*’ is displayed after eight (8) seconds.
2. Press the *[SELECT]* button repeatedly until ‘-> Settings’ is displayed.
3. Press the *[START/PULSE]* button.
   - ‘End beep = on’ or ‘End beep = off’ is displayed.
4. Press the *[SELECT]* button repeatedly until ‘Power save=off’ or ‘Power save=on’ is displayed.
5. Use the *[t]* buttons to set ‘off’ or ‘on’.
   - Off: Backlight is switched off.
   - On: Backlight is switched on.

19. CLEANING AND CARE

19.1 OVERVIEW TABLE

Section	Task to Execute	If Required	Daily	Weekly	Annually
19	Cleaning and Care				
19.3	[→Cleaning]				
19.3.1	[→Cleaning the Device]		X		
19.3.2	[→Cleaning Accessories]			X	
19.4	[→Disinfection]				
19.4.1	[→Disinfecting the Device]	X			

Section	Task to Execute	If Required	Daily	Weekly	Annually
19.4.2	[→Disinfecting the Accessories]	X			
19.5	[→Maintenance]				
19.5.1	[→Greasing the Rubber Seal of the Centrifuging Chamber]			X	
19.5.2	[→Checking the Accessories]			X	
19.5.3	[→Centrifuging Chamber Damage Inspection]				X
19.5.4	[→Greasing the Motor Shaft]				X
19.5.5	[→Accessories with a Limited Service Life]	X			

19.2 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 local 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:

- Use a broad spectrum disinfecting agent such as Bacillol® AF per the manufacturer's recommendations. Refer to the legal manufacturer's instruction for use of the disinfecting agent.
- Surface disinfectant (not disinfectant for hands or instruments)
- pH: 6 – 8
- Non-corrosive

19.3 CLEANING

19.3.1 CLEANING THE DEVICE

1. Open 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.

19.3.2 CLEANING THE ACCESSORIES

1. Clean the accessories using the detergent and a damp cloth.
2. Remove any detergent residues with a damp cloth after using detergents.
3. 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.

19.4 DISINFECTION

IMPORTANT
Disinfection must always be preceded by cleaning the components concerned. See [→Cleaning] section.

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

19.4.1 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. Open 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.

19.4.2 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.

19.4.3 AUTOCLAVING

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

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

NOTICE
Damage to the device due to autoclaving.

- Do not autoclave the rotor more than ten (10) times. The rotor must then be replaced.

The rotor may be autoclaved at 121 °C (250 °F) for twenty (20) minutes.

19.5 MAINTENANCE

19.5.1 GREASING THE RUBBER SEAL OF THE CENTRIFUGE CHAMBER

1. Rub the sealing ring lightly with a rubber care product.

19.5.2 CHECKING THE ACCESSORIES

1. The accessories shall be checked for wear and corrosion damage.
2. Check that the rotor is firmly seated.

19.5.3 CENTRIFUGE CHAMBER DAMAGE INSPECTION

1. Check the centrifuging chamber for damage.

19.5.4 GREASING THE MOTOR SHAFT

1. Remove accessories.
2. Clean the motor shaft.
3. Remove any detergent residues with a damp cloth after using detergents.
4. Grease the motor shaft with Hettich Tubenfett 4051 or equivalent. Refer to legal manufacturer's instructions for use of grease.
5. Excess grease in the centrifuging chamber must be removed.

19.5.5 ACCESSORIES WITH A LIMITED SERVICE LIFE

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 them has been reached.

- The maximum permissible number of run cycles or the expiry date can be seen on the accessories.
- The centrifuge is equipped with a cycle counter.

20. TROUBLESHOOTING

20.1 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 [→Ratings Plate] of the centrifuge.

* Error number does not appear on the display.

Fault Description	Cause	Remedy
No display	No power. Mains input fuses defective.	• Check the supply voltage. • Check mains input fuses. • The mains switch is in switch position *[I]*.
IMBALANCE	The rotor is unevenly loaded.	• Open the lid. • Check the loading of the rotor. • Repeat the centrifugation run.
MAINS INTER 11, MAINS INTERRUPT	Loss of mains power during the centrifugation run. The centrifugation run was not completed.	• Open the lid. • Press the *[START/PULSE]* button. • If required, repeat the centrifugation run.
TACHO - ERROR 1, 2	Speed pulse failure.	• Perform a MAINS RESET.
LID ERROR 4.1 - 4.127	Lid lock error.	• Perform a MAINS RESET.
OVERSPEED 5	Overspeed.	• Perform a MAINS RESET.
VERSION - ERROR 12	Wrong centrifuge model detected. Error/defect in electronics.	• Perform a MAINS RESET.
UNDER SPEED 13	Underspeed.	• Perform a MAINS RESET.
CTRL - ERROR 25.1 - 25.2	Error/defect in electronics.	• Perform a MAINS RESET.
CRC ERROR 27.1	Error/defect in electronics.	• Perform a MAINS RESET.
COM ERROR 31 - 36	Error/defects in electronics.	• Perform a MAINS RESET.

Fault Description	Cause	Remedy
FC ERROR 60, 61.1 - 61.21, 61.64 - 61.142	Error/defects in electronics.	• Perform a MAINS RESET.
FC ERROR 61.23	Speed measurement error.	• Do not switch off the device while 'Rotation' is displayed. • Perform a MAINS RESET if 'Lid locked' is displayed.
TACHO ERR 61.22	Speed measurement error	• Do not switch off the device while 'Rotation' is displayed. • Perform a MAINS RESET if 'Lid locked' is displayed.
FC ERROR 61.153	Error/defect in electronics.	• Perform a MAINS RESET. • Open the lid. • Check the loading of the rotor. • Repeat the centrifugation run.
The left half of the display lights up.	-	• Notify customer service

20.2 PERFORMING A MAINS RESET

1. Set the mains switch to *[0]*.
2. Wait ten (10) seconds.
3. Set the mains switch to *[I]*.

20.3 EMERGENCY RELEASE

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

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.

1. Hole

Figure 17: Emergency release

Personnel: Trained user

1. Look through the window in the lid to ensure that the rotor is stationary.

2. Insert the hex key horizontally into the hole (1) and turn anticlockwise until the lid opens.
3. Remove the hex key from the hole (1).

20.4 REPLACING THE MAINS INPUT FUSE

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.

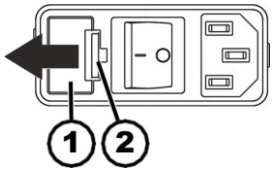


Figure 18: Mains input fuse

1. Fuse holder
2. Snap lock

Personnel: Trained user

- 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. 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	Type	Fuse	Order no.
IntraSpin®	IS220Z	T 1.6 AH/250 V	BFUSE220Z
IntraSpin®	IS110Z	T 3.15 AH/250 V	BFUSE110Z

21. DISPOSAL

21.1 GENERAL INSTRUCTIONS

IMPORTANT

The device can be disposed of via the manufacturer.

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

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

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)

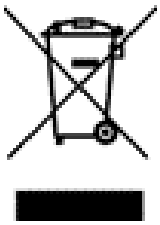


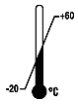
Figure 19: Household waste ban

- 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.

22. SYMBOLS AND DESCRIPTIONS

The symbols table below is for reference only. Refer to product packaging label for applicable symbols.

Symbol	Symbol Description
	Caution
	Electronic instructions for use
	Manufacturer
CE	BioHorizons products carrying the European Conformity (CE) mark fulfill the requirements of the Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC or the Medical Devices Regulation 2017/745. The CE mark is valid only if it is also printed on the product label. The four digit number accompanying the CE mark on applicable devices corresponds to the assigned EU Notified body.
REF	Reference/ article number
LOT	Lot/ batch number
UDI	Unique Device Identifier
	Do not re-use

Symbol	Symbol Description
	Do not re-sterilize
	Use-by-date
STERILE R	Sterile by gamma irradiation
	Date of manufacture
Rx Only	Caution: U.S. Federal law restricts these devices for sale, distribution and use by, or on the order of, a dentist or physician
EC REP	European Union Authorized Representative
	Do not use if package is damaged. Discard device and package.
MD	Medical Device
Non-Sterile	Non-sterile
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system
	Home
	Magnetic resonance warning: Device is MR conditional
UK RP	United Kingdom Responsible Person
	Keep dry. The shipping container must not be exposed to rain and kept in a dry environment.
	Fragile; handle with care.
	Temperature limitation. The shipping container must be stored, transported and handled within the indicated temperature range (-20 °C to +60 °C).
	This way up.
	Humidity limitation. The shipping container must be stored, transported and handled within the indicated humidity range (10% to 80%).
	Warning; Biological hazard.
	Warning: Electrical shock hazard.
	Warning: Crushing hazard.
	Separate collection of electric and electronic devices

Symbol	Symbol Description
Accessory	Accessory to a medical device as defined by the European Medical Device Regulation 2017/745 and the US FDA.
	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".
	Time limit or expiration data. Rotor expiration date.

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