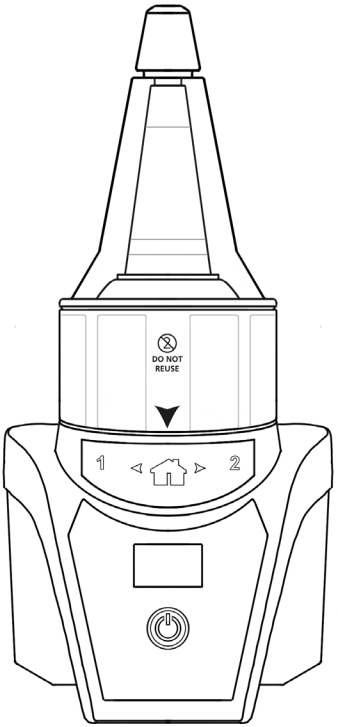
PEAK® Platelet Rich Plasma System

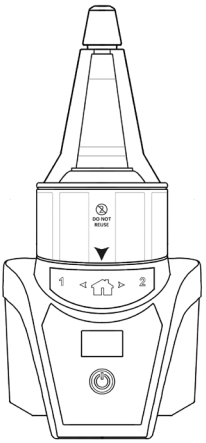


DePuy Synthes
MITEK SPORTS MEDICINE
COMPANIES OF Johnson & Johnson

30 mL Disposable Part No. 278001 60 mL Disposable Part No. 278002 Centrifuge Part No. 278010

PEAK® Platelet Rich Plasma System

Instructions for Use
(U.S.)



System Description

The PEAK® Platelet Rich Plasma System is a medical device designed for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood collected at the patient's point of care. The device consists of a reusable Centrifuge, a single-use Disposable Unit, accessories for drawing blood from the patient, and accessories for collecting the PRP. To prepare the PRP, a sample of the patient's blood is first combined with Anticoagulant Citrate Dextrose A Solution (ACD-A) to prevent coagulation during processing. The PRP is then separated from the anticoagulated whole blood within the Disposable Unit by centrifugation. Once the centrifugation is complete, the PRP is collected from the Disposable Unit for use by physicians in clinical procedures.

Indications for Use

The PEAK® PRP System is intended to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood collected at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Contraindications

- Any active infection
- Blood supply limitations and previous infections, which may retard healing
- Use in hemodynamically unstable or hypercoagulable patients

Possible Adverse Events

- Allergic and other reactions to device materials
- Damage to blood vessels, hemorrhage/bleeding, pain, erythema, bruising, swelling, hematoma, nerve damage, delayed wound healing and/or infection associated with blood draw

How Supplied

Disposable Unit Kit Contents 30 mL (Part Number 278001)
Disposable Unit Kit Contents 60 mL (Part Number 278002)

Component	Quantity in 30 mL Kit	Quantity in 60 mL Kit	Sterilization Method
Disposable Unit	1	1	Ethylene oxide
Adhesive Bandage	1	1	Ethylene oxide
Blood Collection Needle Set	2	2	Ethylene oxide
60 mL Syringe	N/A	1	Gamma radiation
30 mL Syringe	1	N/A	Gamma radiation
10 mL Syringe	1	1	E-Beam radiation
Cannula	2	2	Gamma radiation
Gauze Pad	2	2	Ethylene oxide or Gamma radiation
Syringe Tip Cap	2	2	Gamma radiation
18G x 1.5” Safety Needle	2	2	E-Beam radiation
ACD-A Anticoagulant	1	1	Steam
Patient Label	4	4	Non-sterile
Specimen Label	3	3	Non-sterile
Instructions for Use (IFU)	1	1	Non-sterile
Tourniquet	1	1	Non-sterile
Surgical Tape	1	1	Non-sterile

Note: The contents of the Disposable Unit Kit are for single use only.
Note: The ACD-A included in this kit is only for use with PEAK® PRP Systems manufactured by DSM Biomedical. Discard the unused portion.
Note: The materials used for the Disposable Unit, cannulas, syringes, the blood collection needle set, syringe tip caps, and needles consist of medical grade polymers, elastomers, and stainless steel. The kit contains standard accessories for blood draw site preparation. Refer to the vial label for ACD-A anticoagulant contents. All components within the Disposable Unit Kit are not made with natural rubber latex.

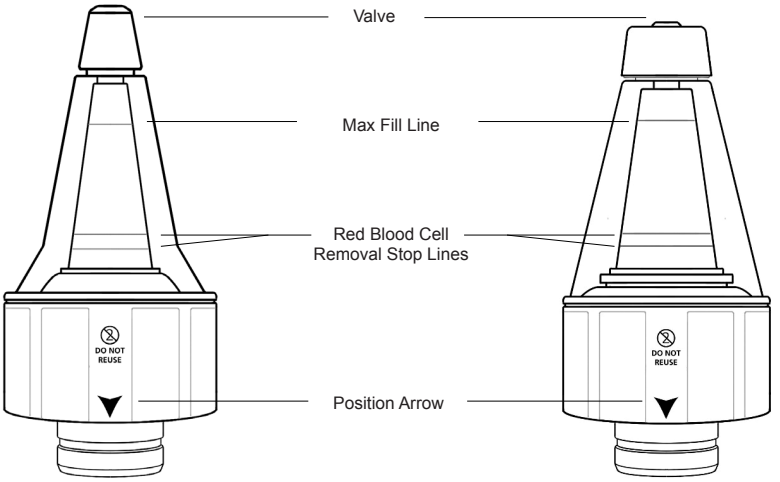


Figure 1a: 30 mL Disposable Unit

Figure 1b: 60 mL Disposable Unit

Centrifuge Kit Contents (Part Number 278010)

Component	Quantity	Sterilization Method
Centrifuge	1	Non-sterile
Power Supply (Elpac Power Systems, Model MWA065012A)	1	Non-sterile
Power Cord	1	Non-sterile

Note: The Centrifuge Kit components are reusable.

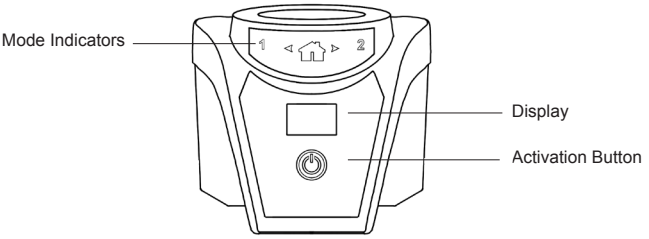


Figure 2: Centrifuge

Symbol	Name	Process Description
	Activation Button	• Start PRP production process • Deactivate Centrifuge (press & hold for 1 s)
	Home Position	• Initial 60 s centrifugation • Final PRP withdrawal
1	Position 1	• Red Blood Cell (RBC) Removal (visual control)
2	Position 2	• Platelet Poor Plasma Removal (automated 15 s countdown)

Warnings

- Failure to use this device in accordance with the Instructions for Use may result in device failure or compromised safety.
- Inspect product prior to use. Do not use sterile components if package is open or damaged.
- Inspect expiration date prior to use. Do not use Disposable Unit Kit components after expiration date.
- Do not reuse, reprocess or re-sterilize Disposable Unit Kit components as it may result in mechanical failure of the device and/or create a risk of contamination of the device, which could result in patient injury or illness.
- Centrifuge must only be used with the provided power supply and cord. Use of power supply or power cord other than those provided or specified by the manufacturer may result in increased electromagnetic emissions, decreased electromagnetic immunity, malfunction or compromised safety of the Centrifuge.
- To avoid risk of electric shock, this device must only be connected to a supply mains with protective earth.
- Do not use radio frequency identification (RFID) equipment within 4.5 feet of the Centrifuge.
- Do not replace components or otherwise modify the device, as these actions may result in malfunction or compromised safety.
- Do not operate device in oxygen rich environment.
- Use aseptic technique as applicable.
- Treat all body fluids using Universal Precautions for bloodborne pathogens.
- Use proper safety precautions to guard against needle stick injury.
- ACD-A anticoagulant and PRP prepared are not for intravenous infusion.
- Discard all Disposable Unit Kit components using acceptable disposal method for blood-contaminated products.
- PRP prepared with this device is not intended for transfusion.

Precautions

- Safety and effectiveness of the device for bone healing, hemostasis or other clinical use has not been established.
- User must be familiar with this device and the surgical procedure prior to use.
- Disposable Unit must be used with the PEAK® Centrifuge only.
- Centrifuge should not be used adjacent to or stacked with other equipment or potentially hazardous materials, and if adjacent or stacked use is necessary, the Centrifuge should be observed to verify normal operation.
- Position the Centrifuge so that the coupler on the power supply is accessible, as the coupler serves to disconnect power from the Centrifuge.
- Portable and mobile radio frequency (RF) communications equipment can affect Medical Electrical Equipment.
- The device must be operated on a level and stable surface.
- The Disposable Unit should remain in an upright orientation at all times to avoid a spill.
- Do not insert the cannula into the Disposable Unit during device operation (while the motor is activated).
- Do not attempt to detach the Disposable Unit from the Centrifuge during device operation (while the motor is activated).
- Use PRP within 4 hours after drawing blood from the patient.
- PRP should be stored within a sterile capped syringe until use. It should not be stored in the Disposable Unit.
- Do not process materials other than whole blood.
- Avoid liquid accumulation on the Centrifuge.
- For additional information on ACD-A anticoagulant refer to component label.
- Refer to Centrifuge Maintenance for recommended cleaning and maintenance instructions.

Instructions for Use

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.
Caution: Use aseptic technique as applicable.

Blood Draw (30 mL)

1. Prepare the blood draw site using the supplied accessories in accordance with facility protocol.
2. Attach a supplied 18 gauge needle to the supplied 30 mL syringe.
3. Withdraw 3 mL of the supplied ACD-A anticoagulant into the 30 mL syringe. Ensure ACD-A coats the entire inner surface of the syringe.
4. Remove the 18 gauge needle and connect the 30 mL syringe to the blood collection needle set.
5. Slowly draw 27 mL of the patient's blood into the 30 mL syringe (30 mL total volume).
6. Disconnect the blood collection needle set from the 30 mL syringe.
7. Attach a supplied syringe tip cap to the end of the 30 mL syringe.
8. Invert the 30 mL syringe several times to ensure adequate mixing of the blood and ACD-A anticoagulant.

Blood Draw (60 mL)

1. Prepare the blood draw site using the supplied accessories in accordance with facility protocol.
2. Attach a supplied 18 gauge needle to the supplied 60 mL syringe.
3. Withdraw 6 mL of the supplied ACD-A anticoagulant into the 60 mL syringe. Ensure ACD-A coats the entire inner surface of the syringe.
4. Remove the 18 gauge needle and connect the 60 mL syringe to the blood collection needle set.
5. Slowly draw 54 mL of the patient's blood into the 60 mL syringe (60 mL total volume).
6. Disconnect the blood collection needle set from the 60 mL syringe.
7. Attach a supplied syringe tip cap to the end of the 60 mL syringe.
8. Invert the 60 mL syringe several times to ensure adequate mixing of the blood and ACD-A anticoagulant.

Device Preparation (30 mL device shown in figures, actions are the same for 60 mL device)

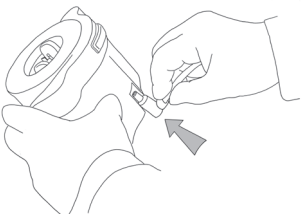


Figure 3

1. Place the Centrifuge on a level and stable surface.
2. Connect the power supply to the rear of the Centrifuge (Figure 3).
3. Connect power cord to power supply and the wall outlet.

Note: Confirm green light on the power supply is on, indicating power is being supplied to power supply.
Note: Upon providing power to the Centrifuge, the Centrifuge will display "- -" for 3 seconds.
Note: The Centrifuge will remain inactive until the Disposable Unit is attached.

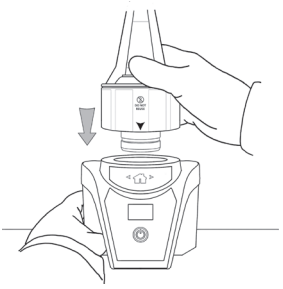


Figure 4

4. Attach the Disposable Unit to the Centrifuge; the Position Arrow on the Disposable Unit must be aligned with the Home Position on the Centrifuge (Figure 4).

Note: The Centrifuge will display "60" when the Disposable Unit is attached.

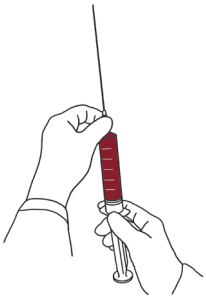


Figure 5

5. Remove the syringe tip cap from the syringe and attach a supplied cannula (Figure 5).

   Caution: Avoid contact with the tubular portion of the cannula to prevent contamination.

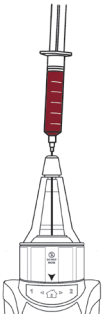


Figure 6

6. Insert the cannula into the valve on top of the Disposable Unit (Figure 6).

   Caution: Do not insert the cannula into the Disposable Unit during device operation (while the motor is activated).

7. Slowly dispense the blood (30 mL or 60 mL total volume).

   Caution: Do not overfill the Disposable Unit.
   When the 30 mL device is filled with 30 mL, the fluid level should be well below the Max Fill Line.
   When the 60 mL device is filled with 60 mL, the fluid level should be just below the max Fill Line.

8. Remove the cannula from the Disposable Unit prior to device activation.

   Caution: To avoid spillage, aspirate residual blood from the cannula into the syringe prior to cannula removal.

Device Operation

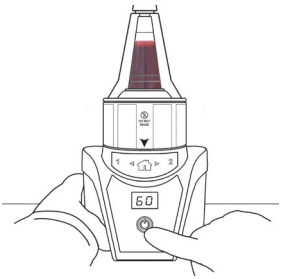


Figure 7

1. Initiate centrifugation by pressing the Activation Button ⏻ (Figure 7).

   Note: The device may be deactivated at any time by pressing and holding the Activation Button ⏻ for 1 second.
   Caution: The device must be operated on a level and stable surface.
   Caution: Do not attempt to detach the Disposable Unit from the Centrifuge during device operation (while the motor is activated).

2. Wait while the device completes the 60-second centrifugation mode.

   Note: The display will count down from 60 to 0.
   Note: A border between the red blood cell and plasma sections of the blood will become visible.
   Note: The device will continue operating (while the motor is activated) during subsequent steps.
   Caution: The user must monitor the device closely for approximately 20 seconds during the red blood cell removal steps (Steps 3 and 4).

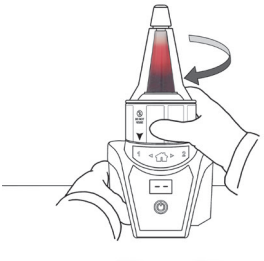


Figure 8

3. Following the 60-second countdown, rotate the Disposable Unit ▼ to Position 1 to start the red blood cell removal mode (Figure 8).

   Note: The border between the red blood cell and plasma sections of the blood will begin to move downward.

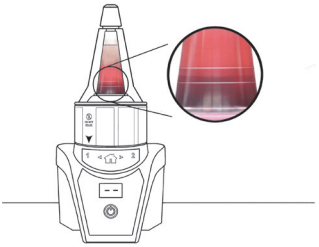


Figure 9

4. To stop the red blood cell removal mode, rotate the Disposable Unit ▼ to the Home Position ⌂ when the border between the red blood cell and plasma sections of the blood is between the red blood cell removal stop lines (two horizontal markings) on the Disposable Unit (Figure 9).

   Note: The red blood cell removal mode should take approximately 20 seconds.

   Caution: Stopping the red blood cell removal mode too early (above the upper red blood cell removal stop line) will result in lower platelet concentration. In this case, the user may rotate the Disposable Unit ▼ back to Position 1 for further red blood cell removal.

   Caution: Stopping the red blood cell removal mode too late (below the lower red blood cell removal stop line) will result in lower platelet concentration.

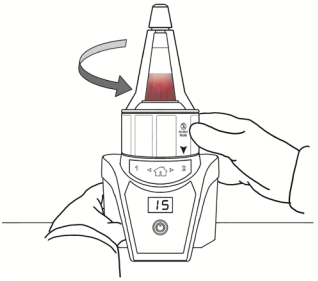


Figure 10

5. Rotate the Disposable Unit ▼ to Position 2 to start the plasma removal mode (Figure 10).
6. Wait while the device completes the 15-second plasma removal mode.

   Note: The display will count down from 15 to 0.

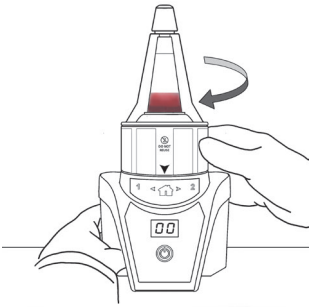


Figure 11

7. Following the 15-second countdown, rotate the Disposable Unit to the Home Position (Figure 11). The device will automatically deactivate.

Platelet Rich Plasma Removal

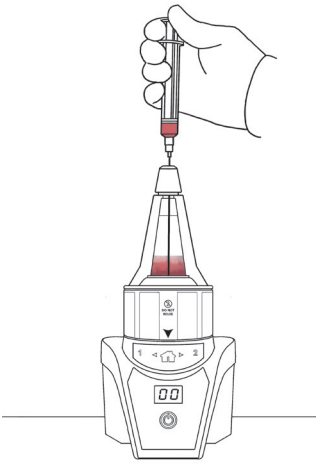


Figure 12

1. Attach a supplied sterile cannula to the supplied 10 mL syringe.

   Caution: Avoid contact with the tubular portion of the cannula to prevent contamination.

2. Insert the cannula into the valve on top of the Disposable Unit until the tip of the cannula reaches the bottom center of the Disposable Unit's inner chamber (Figure 12).

   Caution: Do not insert the cannula into the Disposable Unit during device operation (while the motor is activated).

3. Slowly withdraw the PRP (approximately 3 mL or 6 mL).

   Caution: To avoid spillage, aspirate residual PRP from the cannula into the 10 mL syringe prior to cannula removal.

4. Detach the cannula from the 10 mL syringe.

   Note: Attach a provided sterile syringe tip cap to the end of the 10 mL syringe if the PRP is not used immediately.

5. The PRP is ready for use.

Disposable Unit Disposal

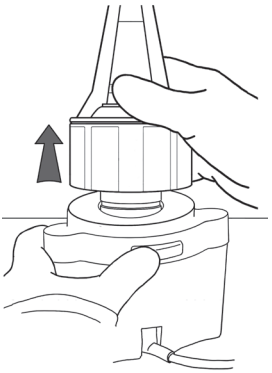


Figure 13

1. Detach the Disposable Unit by pressing the release button on the rear of the Centrifuge and lifting the Disposable Unit (Figure 13).

   Caution: Maintain the Disposable Unit upright, as tilting may result in a spill.

2. Dispose of the Disposable Unit and accessories according to facility protocol.

Troubleshooting

Note: The device may be deactivated at any time by pressing and holding the Activation Button for 1 second.
Note: Rotate the Disposable Unit to the Home Position if an error code is observed during device operation.

Condition	Error Code	Possible Cause(s)	Recommended Action(s)
Disposable Unit does not attach to Centrifuge.	NA	• Misalignment of Disposable Unit coupling and Centrifuge coupling.	• Remove the Disposable Unit and attempt to reattach. • If necessary, use new Disposable Unit.
Centrifuge does not power on.	NA	• Power supply is not connected to Centrifuge.	• Inspect power supply connection at rear base of Centrifuge.
		• Power cord is not connected to power supply or wall outlet.	• Inspect power cord connection to power supply and wall outlet.
		• Defective Centrifuge.	• Call for service.
Centrifuge does not detect attached Disposable Unit.	NA	• Disposable Unit is attached backwards.	• Remove the Disposable Unit, rotate 180° and reattach.
	NA	• Defective Disposable Unit.	• Replace Disposable Unit.
	NA	• Defective Centrifuge.	• Call for service.
Disposable Unit placement error.	E0	• Disposable Unit improperly attached to Centrifuge.	• Remove the Disposable Unit and attempt to reattach.
Power failure.	E1	• Loss of mains power during device operation (motor activated).	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage. • If Disposable Unit was removed during power outage, wait 15 s (or depress Activation Button for 2 s) to clear error code.
		• Power supply disconnected from Centrifuge during device operation (motor activated).	
		• Power cord disconnected from power supply or wall outlet during device operation (motor activated).	
Procedure aborted prior to completion of procedure.	E2	• Activation button depressed for 1 s during device operation (motor activated).	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage.
Disposable Unit removed during device operation.	E3	• Disposable Unit removed during device operation (motor activated).	• Discard Disposable Unit. Do not use PRP. • Wait 15 s (or depress Activation Button for 2 s) to clear error code.
		• Centrifuge release latch depressed while rotating Disposable Unit.	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage. • Wait 15 s (or depress Activation Button for 2 s) to clear error code. • Avoid depressing Centrifuge release latch while rotating Disposable Unit.
Prolonged procedure duration.	E4	• Device operates for > 4 min in centrifugation mode.	• Remove and discard Disposable Unit. Do not use PRP.
		• Device operates for > 2 min (cumulative) in RBC removal mode.	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP.
		• Device operates for > 3 min (cumulative) in idle mode (between RBC removal mode and plasma removal mode).	• Remove and discard Disposable Unit. Do not use PRP.
		• Device operates for > 2 min in plasma removal mode.	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage.
Incorrect operational sequence.	E5	• Disposable Unit rotated to Position 1 during centrifuge mode (without allowing the 60-second centrifuge mode to finish).	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage. • Refer to Instructions for Use for proper operational sequence.
		• Disposable Unit rotated to Position 2 during centrifuge mode (without first rotating to Position 1 to perform RBC removal).	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage. • Refer to Instructions for Use for proper operational sequence.
		• Disposable Unit rotated to Home Position during plasma removal mode (without allowing the 15-second plasma removal mode to finish).	• Remove and discard Disposable Unit. Do not use PRP. • Refer to Instructions for Use for proper operational sequence.

Condition	Error Code	Possible Cause(s)	Recommended Action(s)
	E6	• Prior to device operation (motor not activated), Disposable Unit is rotated to Position 1 or Position 2 for an excessive duration.	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage. • Refer to Instructions for Use for proper operational sequence.
		• Following device operation (motor not activated), Disposable Unit is rotated to Position 1 or Position 2 for an excessive duration.	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage. • Refer to Instructions for Use for proper operational sequence.
		• Following power interruption, Disposable Unit is in Position 1 or Position 2 when power restored to Centrifuge.	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Inspect Centrifuge for spillage. • Refer to Instructions for Use for proper operational sequence.
	A1	• Disposable Unit is rotated to Position 1 or Position 2 prior to device operation (motor not activated).	• Rotate Disposable Unit to Home Position. • Refer to Instructions for Use for proper operational sequence.
		• Disposable Unit is rotated to Position 1 or Position 2 following device operation (motor not activated).	• Rotate Disposable Unit to Home Position. • Refer to Instructions for Use for proper operational sequence.
Brake error.	A2	• Centrifuge brake mechanism is not functioning properly.	• Call for service.
Fuse error.	A3	• Centrifuge fuse not functioning.	• Call for service.
Disposable Unit does not attach to Centrifuge.	A4	• Disposable Unit latch mechanism is not functioning properly.	• Remove the Disposable Unit and attempt to reattach. • If necessary, use new Disposable Unit.
		• Centrifuge latch mechanism is not functioning properly.	• Remove the Disposable Unit and attempt to reattach. • If necessary, call for service.
Spillage from Disposable Unit	NA	• Excessive tilting of the Disposable Unit.	• Operate device on a level and stable surface. • Maintain the Disposable Unit in upright orientation.
		• Disposable Unit overfilled (volume exceeded max fill line).	• Do not exceed max fill line.
		• Disposable Unit rotated to Position 1 or Position 2 while attached to Centrifuge and motor not activated.	• Do not rotate Disposable Unit to Position 1 or Position 2 while Centrifuge and motor deactivated.
		• Reuse of Disposable Unit (overflow of internal liquid effluent container).	• Rotate Disposable Unit to Home Position, remove and discard Disposable Unit. Do not use PRP. • Disposable Unit is for single use only.
Vibration during operation.	NA	• Imbalance or misalignment of rotating component(s).	• Secure the Centrifuge (by hand). • If necessary, deactivate the Centrifuge by depressing the Activation Button for 1 s, remove and discard Disposable Unit. Do not use PRP. • Call for service if Centrifuge exhibits excessive or persistent vibration.
Centrifuge moves during operation.	NA	• Accumulation of dust or debris on underside of Centrifuge (loss of friction).	• Secure the Centrifuge (by hand). • If necessary, deactivate the Centrifuge by depressing the Activation Button for 1 s, remove and discard Disposable Unit. Do not use PRP. • Clean underside of Centrifuge in accordance with cleaning procedure. • Call for service if Centrifuge exhibits excessive or persistent vibration.

Centrifuge Maintenance

Cleaning and disinfection procedure:

Clean/disinfect the exterior surfaces of Centrifuge using a pre-wet 70% isopropyl alcohol wipe. Wipe the entire surface for 1 minute and let dry for 30 seconds. Repeat with a new wipe twice more or until no visible soil remains on the Centrifuge.

WARNING: Avoid liquid accumulation on the Centrifuge. Do not immerse. Do not autoclave.

Maintenance procedure:

Contact the distributor for Centrifuge service. Do not replace components or otherwise modify the Centrifuge, as these actions may result in malfunction or compromised safety of the Centrifuge.

Transport & Storage

The Disposable Unit Kit and the Centrifuge Kit should be transported in an ambient temperature range of -18°C to 55°C (0°F to 131°F), a relative humidity range of 5% to 100%, and an atmospheric pressure range of 59.5 kPa to 106.0 kPa.

The Disposable Unit Kit and the Centrifuge Kit should be stored in a dry location away from extreme environmental conditions. The Disposable Unit Kit must be stored in the original unopened packaging.

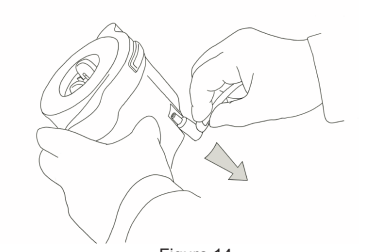


Figure 14

Before storing, unplug Centrifuge from the outlet, then disconnect the power supply from the rear as shown in Figure 14.

When disconnecting the power supply, be certain to grasp the connector and not the cord.

WARNING: Do not wrap cords around Centrifuge. Avoid excessive bending and pulling of the power cord.

Environmental Conditions

The Centrifuge should be operated in an ambient temperature range of 10°C to 40°C (50°F to 104°F), a relative humidity range of 30% to 75%, and an atmospheric pressure range of 70.0 kPa to 106.0 kPa.

The Centrifuge requires an input voltage of 100 – 240 V AC at 50 – 60 Hz.

Technical Information

Device is classified as Class I, IPX0, for Continuous Operation.

The Centrifuge needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Instructions for Use document and applicable labeling.

The following tables provide electromagnetic compatibility information about the Centrifuge.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Centrifuge is intended for use in the electromagnetic environment specified below. The customer or the user of the Centrifuge should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Centrifuge uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Centrifuge is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Centrifuge or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Centrifuge is intended for use in the electromagnetic environment specified below. The customer or the user of the Centrifuge should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition frequency	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° < 5% U_T (> 95% dip in U_T) for 1.0 cycle 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° < 5% U_T (> 95% dip in U_T) for 1.0 cycle 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the Centrifuge requires continued operation during power mains interruptions, it is recommended that the Centrifuge be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

			Portable and mobile RF communications equipment should be used no closer to any part of the Centrifuge, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands 150 kHz to 80 MHz	3 Vrms	**Recommended separation distance** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=1.2\sqrt{P}$ 800 MHz to 2.3 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See “Recommended test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment”		Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of quipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Centrifuge is used exceeds the applicable RF compliance level above, the Centrifuge should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Centrifuge.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

Recommended test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850 LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to archive the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME MYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Explanation of symbols on packaging labeling

LOT	Lot number		Non-pyrogenic
REF	Catalog number		Do not resterilize
STERILE	Sterile	NON STERILE	Non-sterile
STERILE R	Sterilized using irradiation	STERILE EO	Sterilized using ethylene oxide
	Refer to instruction manual/ booklet	STERILE	Sterilized using steam or dry heat
	Consult Instructions for Use		Do not use if package is damaged
	Do not re-use		Upper limit of temperature
	Use-by date	Rx Only	**Caution**: Federal law (U.S.) restricts this device to sale by or on the order of a physician
	Manufacturer	TÜVRheinland c US	Classified by TÜV Rheinland to be in compliance with ANSI / AAMI ES60601-1:2005+A2, CAN/CSA-C22.2 No. 60601-1-8
	Caution		

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