

Xtra Disposables – Important Safety Information

WARNINGS:

- The device must be used in accordance with the instructions for use provided in this manual.
- The device is intended to be used by professionally trained personnel.
- Do not use the device if it has been cracked, dropped or otherwise physically damaged.
- SORIN GROUP ITALIA is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Avoid any condition which may cause the blood temperature to exceed 37°C (98.6°F).
- Keep dry. Store at room temperature.
- Always apply and maintain a correct dose and accurate monitoring of the anticoagulant.
- For single use and for single patient use only: during use the device is in contact with human blood, body fluids, liquids or gases for the purpose of eventual infusion, administration or introduction into the body and due to its specific design it cannot be fully cleaned and disinfected at the end of use. Therefore, the reuse on other patients might cause cross contamination, infection and sepsis. In addition, the reuse increases the probability of product failure (integrity, functionality and clinical effectiveness).
- Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.
- The device must not undergo any further processing.
- Do not resterilize.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- The device must only be used if STERILE.
- The device contains phthalates. Considering the nature of body contact, the limited contact duration and the number of treatments per each patient; the amount of phthalates which might be released from the device do not raise specific concerns about residual risks. Further information is available on request from Sorin Group Italia.
- For further information and/or in case of complaint contact SORIN GROUP ITALIA or the authorized local representative.

CAUTIONS:

- For a detailed description of the circuits, refer to the user's manual of the SORIN GROUP ITALIA cell separator
- Refer to the cell separator user's manual for complete instructions on use of the device
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

For professional use. Please [click here](#) to find instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Consult your labeling.

Xtra Equipment – Important Safety Information

GENERAL WARNINGS:

- The use of operating or maintenance procedures other than those published by LivaNova (hereafter referred to as “the company”), or the use of accessory devices not recommended by the company may result in patient injury or loss of life. The company will not be responsible for patient safety or equipment performance if the procedures to operate, maintain, and calibrate the XTRA system are other than those specified by company. Persons performing the procedures must be appropriately trained and qualified. Any equipment modifications must be performed by qualified persons and be approved in writing by the company.
- All electrical installations must comply with all applicable local electrical codes and company specifications.
- Read the instructions carefully prior to use. Prior to use, this manual must be thoroughly read and understood by the personnel assigned to operate the system. Improper use may cause personal injury and damage to the equipment. Improper use, repair or modifications by unauthorized personnel may invalidate any warranty agreement. In XTRA displayed information and in these instructions for use, the meaning of “fatal alarm” expression is considered as equivalent to “fatal error”. The expression “fatal alarm” has been adopted because it is considered more familiar to the user, but, from regulatory point-of-view, it must be considered as “fatal error”. In a similar way, in XTRA displayed information and in these instructions for use, the meaning of “alarm” expression is considered as equivalent to “information signal”.
- The XTRA must be operated only by qualified personnel, trained in the use of the unit. Qualified and trained personnel ‘ means personnel capable of operating according to the directions and methods of use indicated in this manual.
- Check the product thoroughly on delivery. Transportation and subsequent handling may cause structural and functional damage to the unit.
- XTRA should be overhauled by authorized service technicians every 12 months.
- Disconnect the XTRA autotransfusion system from the power source prior to cleaning and maintenance.
- Do not use the XTRA in the presence of flammable agents because an explosion and/or fire may result.
- The availability of alarms does not relieve the operator of his or her obligation to carefully monitor the entire system during operation. Unattended processing can lead to the development of problems with the operation of the system and/or with the quality of the end product.
- Do not touch any moving parts of the centrifuge or pump. Injury may result.
- Besides making the unit not operational, hardware alarms also stop the vacuum pump.
- The American Association of Blood Banks recommends the following guidelines for expiration of salvaged blood¹:

Collection Type	Storage temperature	Time from the Start of Collection to Expiration	Time from Completion of Processing to Expiration	Special Conditions
Acute normovolemic hemodilution (whole blood)	Room temperature	8 hours	N/A	None
Acute normovolemic hemodilution (whole blood)	1-6°C	24 hours	N/A	Storage at 1-6°C shall begin within 8 hours of start of collection
Intraoperative blood recovery with processing	Room temperature	N/A	4 hours	None
Intraoperative blood recovery with processing	1-6°C (N/A if bacterial contamination is suspected)	24 hours	N/A	Storage at 1-6°C shall begin within 4 hours of completion of processing
Intraoperative blood recovery without processing	Room temperature	6 hours	N/A	None
Shed blood under postoperative or posttraumatic conditions with or without processing	N/A	6 hours	N/A	None
Combined Intraoperative and postoperative blood recovery with processing	Room temperature	Postoperatively processed units: 6 hours from the start of postoperative collection	Intraoperatively processed units: 4 hours	None
Red Blood cells prepared by apheresis and intended for transfusion	Room temperature	8 hours	N/A	None
Red Blood cells prepared by apheresis and intended for transfusion	1-6°C	24 hours	N/A	Storage at 1-6°C shall begin within 8 hours of collection

Table 1-1 Guidelines for Expiration of Salvaged Blood

- The American Association of Blood Banks recommends the following guidelines for expiration of Perioperative Autologous Non-Red-Cell Blood Products²:

Collection Type	Storage temperature	Expiration	Special Conditions
Platelet-rich plasma intended for transfusion	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area
Platelet-rich plasma intended for topical use	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area
Platelet-poor plasma intended for topical use	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area
Thrombin intended for topical use	Room temperature	Within 6 hours after component preparation (or not to exceed device manufacturer's recommendations)	Shall be used before the patient leaves the operating room or clinical procedure area

Table 1-2 Guidelines for Expiration of Perioperative Autologous Non-Red-Cell Blood Products

- To minimize blood cell trauma, LivaNova recommends that vacuum levels no higher than (in absolute value) 150 mmHg (20 kPa) be used when aspirating fluid from the surgical field.³

- Carefully observe the system for leaks before and during use. Leakage may result in loss of sterility or loss of blood and/or fluid. If leakage is observed before or during use, replace or retighten the leaking component as appropriate.
- To prevent interference with anticoagulation when using citrate anticoagulants, do not use wash solutions containing calcium. Only sterile 0.9% normal saline (injectable or approved for cell processing) should be used as a wash solution.
- Be sure that every bowl to be processed is adequately filled and packed before washing. Otherwise, the Wash cycle will be ineffective and the hematocrit will be low.
- Washed, packed red cells are depleted of clotting factors. Patients should be monitored for the presence of clotting abnormalities associated with the transfusion of large volumes of packed red blood cells without clotting factors. Physicians should be prepared to institute the appropriate therapy.
- Do not reinfuse the patient's blood from the primary RBC bag when it is connected to the XTRA autologous transfusion circuit. Reinfusion from the primary reinfusion bag connected to the circuit could lead to air embolism.
- To minimize the complications of particulate matter infusion and the risk of embolism, use of an in-line microaggregate filter on the patient reinfusion line is **STRONGLY RECOMMENDED**.
- Do not reinfuse under pressure (i.e., do not use a blood pressure cuff on the reinfusion bag) Reinfusion under pressure could lead to air embolism.
- To reduce risk of air embolism, remove all air from the primary reinfusion bag before handing the bag over for reinfusion.
- The physician ordering the use of this system and/or the surgeon operating the suction/collection wand shall use discretion in the collection of the following substances:

Potentially harmful substance	Effects	Recommended action in order of priority
Amniotic fluid	Soluble component contains proteolytic enzymes which could activate clotting. Squamous cells could cause pulmonary emboli	1. Do not aspirate into system
Fecal contamination	Sepsis	1. Do not aspirate into system 2. Aspiration may be necessary in emergency cases
Tumor cells	Potential risk of metastasis	1. Do not aspirate into system 2. Aspiration may be necessary in emergency cases 3. Irradiation of salvaged blood is always recommended
Clotting Adjuncts • Topical thrombin • Fibrin Glue Monofilament collagen	May activate clotting	1. Do not aspirate into system 2. Irrigate wound before resuming salvage
Microfibrillar Collagen (e.g. Avitene)	Causes platelet activation	Do not aspirate into system
Betadine	Reduces hemoglobin; seems to be a reversible effect. May cause hemolysis; may cause allergic reaction if patient is sensitive to iodine	1. Do not aspirate into system 2. Irrigate wound before resuming salvage 3. Thoroughly wash salvaged blood
Methylmethacrylate (fresh bone cement only)	Toxicity; heat produced hemolysis	1. Do not aspirate into system 2. Irrigate wound before resuming salvage
Gastric Fluids	Contains proteolytic enzymes; could activate clotting	1. Do not aspirate into system 2. Irrigate wound before resuming salvage 3. Thoroughly wash salvaged blood
Antibiotics not licensed for intravenous use	May be delivered in higher dose than normal concentrations; potential serious reactions (e.g. hypotension, shock).	1. Do not aspirate into system 2. Irrigate wound before resuming salvage
Epinephrine	May be delivered in higher than normal concentrations. Studies show that the catecholamines not removed. May cause severe hypertension	1. Do not aspirate into system 2. Irrigate wound before resuming salvage

Table 1-3 Suction/Collection Wand Substance Warnings

- The following substances that are not considered in the American Association of Blood Banks publication,⁴ should be added to the list:

Potentially harmful substance	Effects	Recommended action in order of priority
Smoke produced on the operative site by electro-surgical instrumentation	Carbonized particles may be aspirated from the field and directed inside the filter of the reservoir. The smoke aspirated could produce a brownish color on the vacuum line connected to the reservoir	Keep away the aspirator from the operative site during the use of electro-surgical instrumentation. Use evacuation systems to capture and filter surgical smoke to remove odor, particulates, and other potentially hazardous by-products of electro surgery procedures
Ceramic and metal debris released by prosthetics materials	Effect of darkened tissue or clots (blue/green/black) surrounding prosthesis unknown to systemic circulation	Do not aspirate into system

Table 1-4 Addendum to Suction/Collection Wand Substance Warnings

- Whole blood must be anticoagulated as it is collected into bags containing appropriate anticoagulant for plasma sequestration. Inadequate anticoagulation may result in clotting, interfering with the processing of the blood products.
- Non-red cell components (e.g., platelet rich/platelet poor plasma intended for transfusion and platelet rich/platelet poor plasma intended for topical application)

shall be used or applied before the patient leaves the operating room or clinical procedure area.⁵

- If plasma is being collected for transfusion, it must be transfused before the patient leaves the operating room or clinical procedure area.⁶
- Do not over anticoagulate collected blood. Plasma Sequestration has no Wash cycle to remove excess anticoagulant. A part of the anticoagulant used will be returned to the patient.
- Do not overfill PPP and PRP bags. Overfilling may cause back pressure that would cause fluid to fexit through the bowl seal.
- Do not reinfuse the PRP back to the patient if the XTRA fails to operate as intended.
- To reduce the possibility of air or particulate embolism, LivaNova STRONGLY RECOMMENDS the use of reinfusion protection devices, including microfilters, when infusing processed blood.
- Do not reinfuse under pressure (i.e., do not use a blood pressure cuff on the RBC or plasma/PRP bags). Reinfusion under pressure could lead to air embolism.
- Do not use solvents such as alcohol, ether, acetone, etc. to clean the equipment or the disposable circuits as contact of solvents with the plastic components may cause damage to the equipment or to the device. In addition to not using solvents, do not otherwise tamper with or alter the circuit's configuration.
- If the rotor of the roller pump has been removed to clean the upper panel, carry out the following operations to replace it correctly: open the lever, insert the rotor into its seat, turn it until aligns with the slot of the metal shaft and reposition the white lever into the slot.
- During the use and transportation of the unit, do not exceed the maximum loading capacity.
- The program parameters and the buffy-coat level are optimized according to the bowl size. At the end of the setup, verify that the bowl size automatically recognized by the machine (or manually selected) corresponds to the bowl size present in the disposable kit.
- In case of malfunction of the integrated vacuum pump, use an alternate vacuum source, i.e. the vacuum present in the operating room, possibly connected to a pressure regulator.
- Whenever the disposable kit is set to start a new case (or, if needed, substituted during the current case), make sure to conclude the setup by pressing LOAD PUMP; otherwise improper program parameters could be set, compromising performance.
- After Setup operations, verify that the size of the bowl used corresponds to that indicated on the display.
- The continuation of the current case by pressing RETAIN is under the full responsibility of the operator.
- The stand-by function stops the pump for several minutes, but not the centrifuge. Avoid any improper use. Do not activate the stand-by function for prolonged or repeated periods. Instead, press the Stop button and restart the case whenever needed.
- Improper use of RETAIN can lead to the risk of obtaining an inadequate blood product.
- XTRA is provided with an indicator which measures the Hct of the fluid entering and of the RBCs leaving the bowl. As this system is mainly intended to provide the user with a trending of Hct values, it is recommended that alternate means of measuring hematocrit be used when it is requested to evaluate the final hematocrit in the RBC bag. The same holds true also for volume, supernatant removal and waste line color monitoring features.
- The XTRA hematocrit sampling system has not been tested for all possible blood conditions. Conditions may exist which will result in hematocrit readings which differ

from Coulter Counter readings. For example, conditions which result in cellular changes (sickle cell anemia, high concentrations of anticoagulants which may cause red cell shrinkage, or the use of certain anticoagulants which may cause red cell volume expansion) or conditions outside of the applicable ranges may result in Hematocrit readings which differ from Coulter Counter readings.

- When releasing an IV pole or reservoir pole locking lever, the operator must always handle the pole manually; otherwise, there is a serious risk of injury.
- Do not open the lid in the event of a power failure if the centrifuge has not yet come to a stop (which may take between 50 and 90 seconds).
- In the event of excess heparin in collection reservoir due to inappropriate ratios, the salvaged blood may contain residual heparin.
- In the event of decreased patient antithrombin III levels if using heparin anti coagulation, consult the physician in order to provide alternate anticoagulation.
- When the XTRA or XVAC is used alone, the RS422 serial ports used to connect them must be covered and secured with a cap.
- The use of the Last Bowl function is recommended only to complete the case, with the following conditions: The reservoir is empty, no more blood is expected to be collected, and sufficient red cells in saline solution are available in the RBC bag to complete the Concentrate cycle.
- In case a partial bowl is washed, the hematocrit of the collected blood as well as the removal of waste components might be lower than expected.
- The maximum volume in the RBC bag is 1 liter. To avoid explosions, check the level inside the bag carefully before activating the Last Bowl function.
- The Last Bowl function automatically activates a second Empty phase at the end of the first Empty phase. Carefully monitor the air in the RBC bag in case of repeated activation of the Last Bowl function.
- The XTRA and XVAC should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the XTRA and XVAC should be observed to verify normal operation is occurring in the configuration in which they are used.
- In order to comply with "General Requirements for basic safety and essential performance of Medical electrical equipments" (IEC 60601-1, Rules preventing instability), it is requested that the waste bag not be filled with more than 9 liters of waste liquid.
- Use of protocols different from Post-op in postoperative contexts might expose the patient to risks of tissue damage due to high aspiration level of vacuum module and risks of blood return due to availability of the Return function.
- Use of the vacuum pump in INTRA mode while collecting blood postoperatively might expose the patient to risks of tissue damage.
- Transport should only be undertaken in a certain condition that is clearly described in Appendix D of this manual.
- In the event of large volumes of blood leaking or splashing inside the centrifuge well, the integrity of the centrifuge plate and centrifuge well gasket could be compromised. In this case please contact the authorized Services of your LivaNova branch or your local LivaNova representative.

Storage and Transporting Warnings:

- When not in use, the unit must be stored under the specified environment conditions in a dust-free place, covered with the protective cover supplied.
- When the unit is not in use, switch off the main switch, disconnect the plug from the socket and wind the power cord around the holders on the rear of the unit.
- The unit must be stored in a cool, dry and well ventilated place.

- When closing the lateral pins, ensure your fingers are external to the levers; otherwise you expose yourself to a serious risk of injury.

Electrical Warnings:

- Before connecting the unit, check that the mains socket is supplied at the voltage and frequency shown on the label on the unit.
- Connect the unit to a mains socket of the same size as the plug used. Do not use adapters between plug and socket. Ensure that the mains socket is equipped with a grounding line and safety devices.
- For continued protection against risk of fire, replace fuses only with components of the same type and ratings.
- Electrical shock hazard. No user service able parts inside. For servicing refer to qualified personnel authorized only by the manufacturer.
- Never connect the plug to the mains socket with wet or damp hands. If liquids are poured onto the unit during use, turn off the power switch and remove the plug immediately, before drying the external panels.
- Always remove the plug from the socket by gripping it with the hand. Do not pull on the power cord.
- Ensure that the plug is secured to the machine by means of the metallic grid (see Figure 5-12) to prevent accidental unplugging.
- To prevent risk of electrical shock, do not use alternate power plugs or adapters that disconnect the green/yellow wire safety ground.
- The electrical installation must be in compliance with electrical safety regulations and according to voltage and current ratings specified on the labels on the back of the unit.
- The XTRA system must be always grounded via the hospital electrical power source according to the regulations in force in the country of use.
- Electrical safety features are contained in Appendix A: Safety Standards EN 60601-1-2 .
- The use of accessories and cables other than those provided by LivaNova may result in increased emissions or decreased immunity of the XTRA and XVAC devices.
- Accessories and cables provided by LivaNova may only be used with the XTRA and XVAC devices. The use with other equipment or system may result in increased emission or decreased immunity of that equipment or system.
- To prevent risk of electrical shock, shut OFF power and unplug the system from the electrical outlet before performing cleaning procedures.
- OPERATOR must not touch the relevant part and the PATIENT simultaneously:
 - accessible contacts of connectors;
 - contacts of fuse holders that are accessible during replacement of the fuse;
 - parts inside an ACCESS COVER that can be opened without the use of a TOOL, or where a TOOL is needed but the instructions for use instruct any OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER.
- Connecting electrical equipment to the integral multiple socket-outlet of XTRA effectively leads to creating an ME system, and can result in a reduced level of safety. Connecting of other devices (which is not allowed according to this user manual), must fulfill all requirements of the standard IEC 60601-1:Edition 3.1.
- The only way to separate the equipment from the supply mains on all poles simultaneously is by disconnecting the POWER CORD from the mains inlet plug. Do not position XTRA and XVAC in a way to make it difficult to disconnect the POWER CORD.

- To isolate XTRA and XVAC (if connected) electrically from the SUPPLY MAINS on all poles (Line and Neutral, PE conductor remains connected) simultaneously use the SUPPLY MAINS switch, Figure 3-2 in this manual.
- Connecting electrical equipment other than XVAC to the integral multiple socket-outlet of XTRA can result in a reduced level of safety.

General Precautions:

- The XTRA must be used only with XTRA disposables.
- Due to the possibility of operator exposure to blood borne pathogens (such as HIV, hepatitis viruses, bacteria, Cytomegalovirus, etc.) when handling extracorporeal blood circuits, adequate precautions should be taken at all times to prevent the exposure to and transmission of such agents.
- An adequate quantity of salvaged, viable, washed, packed red blood cells cannot always be predicted or depended upon in a blood salvage procedure. Physicians should be prepared to institute appropriate additional therapy if necessary.
- Use aseptic technique when installing disposables.
- Failure to maintain adequate anticoagulation during blood collection can cause excessive clotting in and possible clogging of the collection reservoir or centrifuge bowl.
- Incorrect assembly of the vacuum overflow trap or assembly using damaged components could allow an overflow to enter the machine and damage internal vacuum system parts.
- The operator is responsible for setting safe parameters for the custom protocols and for the factory protocols modified during a case.
- The XTRA will always start up with the Wakeup protocol as the Active protocol. Always verify the Active protocol prior to processing.
- Sterile 0.9% normal saline, USP (injectable or approved for cell processing) is typically used as a wash solution. Other solutions intended for intravenous use that have been approved by the FDA and have documentation available to show the component is safe may be used.⁷
- During the Wash cycle, pump speeds lower than those used in the preset XTRA protocols may decrease the wash quality.
- Inadequate washing of the packed red blood cells may lead to an excessive level of contaminants (e.g., anticoagulant, plasma free hemoglobin) in the processed blood.
- The clamp on the inlet port of the waste bag must be open during blood salvage processing.
- When clearing the line, stop the Empty cycle or manual cranking of the pump before air enters the primary reinfusion bag. Stop the Empty cycle by pressing the Empty or Stop buttons.
- Overfilling the reinfusion bag may cause it to rupture.
- Ignoring a full waste bag may cause back pressure from the waste bag that could result in fluid leakage around the bowl's rotating seal or waste fluid being returned to the centrifuge bowl.
- Do not completely empty the waste bag until the end of the case. If you empty the waste bag during the case, leave approximately one liter of fluid in the waste bag to prevent the possibility of vacuum being generated in the waste bag during the Empty cycle. Vacuum in the waste bag may prevent complete emptying of the bowl.
- The waste bag should be replaced with the equipment STOPPED (pump and centrifuge) and the bowl completely empty. This instruction does not apply if the replacement of the waste bag is done with a vented waste bag.

- When cleaning the process air detector, red blood cell detector, Hct indicator, and waste line color indicator, do not use bleach, abrasive materials, or solvents, as they may damage the indicators. Use a mild detergent.
- Do not immerse the rotor in cleaning solution. Do not autoclave. Component damage may result.
- The fluid collected in the Centrifuge Well Collection may be biohazardous. Handle accordingly and dispose of the container according to hospital protocol.
- Prior to first use of the XTRA, electrical and operational checks should be performed according to hospital protocol and the company's recommendations.
- Report immediately to the responsible service personnel any of the following conditions. Do not use the XTRA until corrective action has been taken:
 - Damaged or worn power cord, plug or receptacle.
 - Switches that are loose or do not operate with a positive action.
 - A machine that has been subject to significant physical damage.
 - A machine that has given anyone an electrical shock while in use.
 - A machine that appears to be overheating.
- It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.
- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Store plasma products containing platelets at room temperature (20°C to 24°C) with continuous, gentle agitation.⁸
- Make sure that you attach both PRP bags included in the XTRA Sequestration Set. Because the XTRA does not alert you when a specified volume is collected, you must have sufficient bags available for the entire amount that can be collected.
- Air must be collected and be available to be returned to the centrifuge bowl during the Empty cycle. Otherwise, plasma may be accidentally drawn back into the centrifuge bowl. Ensure that the bag with the air remains attached to the bowl outlet tubing and OPEN during the Empty cycle.
- If using the waste bag for air management, the waste line should not be clamped until plasma starts to exit the bowl during plasma sequestration.
- Make sure that the waste line is unclamped before starting blood salvage processing.
- The physician ordering the collection of PRP shall use discretion when any of the following conditions exist:
 - Sepsis
 - Preoperative hematocrit less than 30%
 - Preoperative platelet count less than 195,000 per μ l
 - Hemodynamic instability
 - Prolonged clotting times
 - Recent use of anti-platelet drugs
 - Inability to maintain stable oncotic pressure
- When collecting PRP, LivaNova recommends the following precautions be taken to insure that the PRP product is not contaminated:
 - Use sterile techniques when setting up the XTRA disposables.
 - Thoroughly clean and disinfect the donation site.
 - Use sterile techniques whenever handling the PRP product.
 - Make sure to open a blood collection (plasma) bag flow path before closing the waste bag port. Failure to do so may result in fluid leaking from the centrifuge bowl seal.
- Any device connected to the RS232 port must comply with the applicable IEC standard for that device.
- In the event that a hematocrit value is desired and not obtained with the Hct Sampling System of the unit, use an alternate means of measuring hematocrit.

- Prior to collecting any blood, prime the reservoir with approximately 200 ml of the anticoagulant solution.
- In the event of anticoagulant deficiency in collection reservoir due to inappropriate ratios, the salvaged blood may clot in the reservoir.
- Avoid use of Ringer's when using citrate anticoagulant as the simultaneous use of incompatible IV fluids may cause clotting in the system.
- Use only XTRA USB memory sticks.
- Be sure to properly place and hook the machine to the cart in order to avoid the danger of the machine falling.
- If the display shows incomprehensible and erroneous messages or messages different from those indicated in this manual, immediately stop the unit and contact LivaNova Technical Service.
- In the event of problems with the automatic removal of the lid opening lock: (a) do not attempt to force open the lid; (b) switching the machine off and on might resolve the problem; (c) if the problem persists, contact authorized technical service.
- The Waste bag must not be squeezed while treatment is being done and must have the space to fill up properly. If the bag is squeezed or cannot fill up properly because it is positioned near an obstacle (for example, a wall) a reflux toward the bowl or a back pressure might be created sufficient to cause the liquid to leak from the bowl seal.
- A failed or improper connection of the lines can lead to the risk of gas or liquids entering the circuit from the environment.
- Strictly adhere to these instructions for the installation of disposables to guarantee the proper execution of the treatment. In particular, be careful with the: (a) proper connection of the RBC bag to avoid leakage of red blood cells, (b) proper connection of the wash bag to guarantee proper washing, and (c) proper connection of the reservoir to allow access to the blood to be processed.
- In the event of problems with the automatic unloading of the pump circuit, open the lid of the centrifuge and manually remove the tubing of the pump circuit from the pump rotor: Rotate the pump rotor counterclockwise while extracting the tubing of the pump circuit.
- Always close the centrifuge lid before starting any function of the machine that uses the pump and/or centrifuge action to avoid the risk of touching any moving parts of the device.
- The use of phase buttons and, in general, modifications that alter the normal execution of protocols can create reductions of normal machine performance. It is the responsibility of the user to evaluate if and when these procedures can be performed.
- The availability of alarms does not relieve the operator of his or her obligation to carefully monitor the entire system during operation. Unattended processing can lead to the development of problems with the operation of the system and/or with the quality of the end product.
- During the execution of emergency protocols, the control that causes a warning of "Minimum wash quality wash might not be reached yet" is automatically disabled.
- The use of emergency protocols with the Rapid Transfer option produces an unwashed final collection in which the removal of contaminants is only possible through the 40- μ m filter in the reservoir. It is the full responsibility of the user to evaluate if the conditions exist to use emergency protocol with the Rapid Transfer option.
- The emergency protocols promote fast execution rather than the quality of the final product, which is reduced compared to that guaranteed by other predefined protocols. Their use is, therefore, reserved to situations in which there is a preponderant urgent need for blood regarding the concentration of RBC collected and

the wash quality. It is the full responsibility of the user to evaluate if the conditions exist to use said protocols.

- The use of emergency protocols with the No Wash option produces an unwashed final collection in which the removal of contaminants is only possible through the 40- μ m filter in the reservoir and the concentration of the Fill phase. It is the full responsibility of the user to evaluate if the conditions exist to use an emergency protocol with the No Wash option.
- Inadequate washing of concentrated red blood cells can lead to an excessive level of contaminants (i.e. anticoagulants and plasma free hemoglobin) in the treated blood.
- Use of the vacuum pump in INTRA mode while collecting blood postoperatively might expose the patient to risks of tissue damage.
- As soon as postoperative drainage operations are completed, the patient must be disconnected from the reservoir.
- The use of protocols different from POST-OP in postoperative contexts might expose the patient to risks of tissue damage due to high aspiration levels of vacuum module and risks of blood return due to availability of the return function.
- During setup and unloading the kit, the patient must not be connected to the reservoir through the drainage line.
- The deactivation of the RBC Detector is at the full responsibility of the doctor/operator who must carefully supervise the fill phase (or concentration) and manually touch the Wash button to start the washing phase (or Spill or Empty to start the phase of the same name during a sequestration protocol). A delayed procedure might lead to a loss of red blood cells or, in sequestration procedures to inadequate collections. An early procedure might lead to low quality collection.
- The repeated use of the Return function on the same red blood cells might lead to them being damaged and therefore to their loss.
- The Concentration function reprocesses already collected red blood cells subjecting them again to the mechanical action of the pump and the centrifuge. The repeated use of the Concentration function on the same red blood cells might lead to them being damaged and therefore to their loss.
- Any modification done on the acoustic signals can make the operator take longer to realize that the machine has made a warning.
- The deactivation of the alarms "RBC bag full" and/or "Waste bag full" is the responsibility of the user who must directly control the fill level of the bags.
- In the event of replacing a collection bag, verify that the new bags are properly connected and the manual clamps reopened before restarting the process in order to avoid problems of blood component leakage and circuit breaks.
- In the course of preoperative sequestration treatments, it is necessary to open and/or close some of the manual clamps along the lines. Erroneous execution of these procedures by the operator might lead to breakage of the disposable blood component leakage and inadequate collections.
- The use of the Prime IV function or repeated calibration phases of the HCT sensor can lead to a dilution of the collection (PPP/PRP).
- Always close the centrifuge lid before starting any function of the machine that uses the pump and/or centrifuge action to avoid the risk of touching moving parts of the device.
- Although it is possible to configure some of the acoustic notifications that the machine makes, any changes to the audible signals might cause the operator to take longer to realize the machine has made a notification.
- It is possible to temporarily deactivate some of the controls that the machine does. The operator can make use of this possibility, under his own responsibility, therefore directly managing those controls.
- At the end of installation verify that the bowl outlet is not crushed or obstructed.

- In the case of malfunction of the integrated vacuum pump, use an alternative vacuum source, i.e., the vacuum present in the operating room, possibly connected to a pressure regulator.
- There are numerous software and hardware features built into the XTRA that monitor the Hct sampling system performance, ensuring a reliable and accurate Hct reading. As with any measurement system, errors can occur and the results obtained may be in question. In the event that the user of this device questions the accuracy of the Hct reading, it is recommended that an alternate means of measuring hematocrit be used. The same holds true also for volume, supernatant removal and waste line color monitoring features.
- If the values regarding volumes, hematocrit, supernatant removal and waste color line are important for the patient, it will always be necessary to use other standard measurement instruments of the hospital.

Operating Conditions

Warning:

- Do not use the unit in the presence of inflammable anaesthetic gases. do not expose to heat sources. Avoid any operating situation where the blood may be exposed to temperatures exceeding 37°C (98.6°F).

Cautions:

- When the unit is operating, the following conditions must be met:
 - Room temperature: 10 - 35°C (50 - 95°F)
 - Relative humidity: 30 - 75%
 - Atmospheric pressure: 80 - 106 kPa
- Conditions that cause the unit to overheat when operating must be avoided.

References:

- 1 American Association of Blood Banks. Standards for Perioperative Autologous Blood Collection and Administration . 4th Edition. Bethesda, MD. 2010 Reference Standard 5.1.8A (Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Products).
- 2 American Association of Blood Banks. Standards for Perioperative Autologous Blood Collection and Administration . 3rd Edition. Bethesda, MD. 2007 Reference Standard 5.1.8 (Handling, Storage, Transportation).
- 3 Guidelines for blood recovery and reinfusion in surgery and trauma . Bethesda, MD; American Association of Blood Banks, 1997: 19-22.
- 4 Guidelines for blood recovery and reinfusion in surgery and trauma. Bethesda, MD; American Association of Blood Banks, 1997: 19-22
- 5 American Association of Blood Banks. Standards for Perioperative Autologous Blood Collection and Administration . 3rd Edition. Bethesda, MD. 2007 Reference Standard 5.1.8 (Handling, Storage, Transportation)
- 6 American Association of Blood Banks. Standards for Blood Banks and Transfusion Services. 18th ed. Bethesda, MD: American Association of Blood Banks, 1997.
- 7 American Association of Blood Banks. Standards for Perioperative Autologous Blood Collection and Administration . 3rd Edition. Bethesda, MD. 2007 Reference Standard 5.4.4 (Addition of Drugs and Solutions)



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8 American Association of Blood Banks. Standards for Blood Banks and Transfusion Services. 18th ed. Bethesda, MD: American Association of Blood Banks, 1997: G3.300.

For professional use. Please [click here](#) to find instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Consult your labeling.