LIFE 21® apheresis unit Warnings, precautions and troubleshooting

User Manual

Software version from 7.3



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Software version from 7.3

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Essential information

This user manual provides warnings, precautions, and troubleshooting advice for the use of the LIFE 21 apheresis unit (instrument) and its treatment-specific components. For details on the instrument as well as specific procedures, see the LIFE 21 user manuals issued for the respective matter.

In general, the TheraSorb® LIFE 21 therapeutic apheresis platform (LIFE 21 apheresis platform) is intended for professional operators in health care settings and should only be used by persons who have been trained by Miltenyi Biotec authorized personnel.

⚠ WARNING

Before putting the instrument into operation, the operator must read and understand the safety information, warnings, precautions, and instructions for proper operation provided in the LIFE 21 user manuals (including without limitation the safety information in chapter 3 "Important safety information" of the user manual LIFE 21 apheresis unit "General information – Instrument") and in any safety-related recommendations issued by Miltenyi Biotec. Pay special attention to all warnings displayed on the instrument or provided with consumables and accessories. Confirm all safety information, warnings, precautions, and instructions are observed at all times while the instrument is in operation.

Retain the user manuals for future reference. They should be kept accessible and readily available together with all other safety and operating documentation during the entire life cycle of the instrument for all personnel responsible for installation, operation, and maintenance.

Disregard of any instructions, warnings or cautions at any time can endanger patients, operator and others due to possible instrument damage or malfunction and may compromise the electrical, electronical, electromagnetic and mechanical safety. This might result in the risk of electrical shock, physical injuries, fluid imbalances or loss, vascular damage, hemolysis or embolism. Disregard also excludes the manufacturer from any liability.

If the operator is concerned about the safe use of the LIFE 21 apheresis platform or requires any information about the instrument and its consumables, contact the authorized local Miltenyi Biotec service provider or call the Miltenyi Biotec Technical Support.

IMPORTANT

Before using any products of the LIFE 21 apheresis platform for clinical treatments outside the European Economic Area, the regulatory approval of the products in your country must be confirmed.

Table of contents

1	**Introduction**	**9**
1.1	General information	9
2	**Glossary**	**11**
2.1	Graphical depiction	11
2.2	Glossary of symbols and terms	12
3	**Important safety information**	**13**
3.1	General warnings and precautions	13
3.2	General side effects and risks	14
3.2.1	Side effects	14
3.2.2	Risk associated with blood withdrawal and restitution	16
3.2.3	Balancing of liquids during treatment	17
3.2.4	Risks associated with cell loss	17
3.2.5	Risks associated with cell activation	18
3.2.6	Risks associated with plasma loss	18
3.2.7	Risks associated with plasma dilution	18
3.2.8	Risks associated with acidosis	19
3.2.9	Risks associated with electrolyte concentration	19
3.2.10	Risks associated with incorrect anticoagulation	20
4	**General recommendations and handling instructions**	**21**
4.1	Anticoagulation	21
4.1.1	Recommended dosage of the anticoagulant	22
4.1.2	Adaptation of ACD-A to blood ratio	22
4.2	Calcium substitution	23

4.3	Patient venous access	23
4.4	Interruption of a treatment	23
4.5	Abortion of a treatment	24
4.5.1	Immediate end of treatment	24
4.5.2	Premature end of treatment	24
4.6	Resuming a treatment	25
4.7	Touchscreen monitor remains dark	26
4.8	Manual bag exchange	27
4.9	Switch to Single or Double Needle mode during treatment	31
4.9.1	Switch to Single Needle mode	31
4.9.2	Switch to Double Needle mode	32
4.10	Notification "max. hematocrit, reduce TMP"	33

5 Alarm management 35

5.1	Visual alarm signal	36
5.2	Acoustic alarm signal	38
5.3	Alarm handling	38
5.3.1	Alarm screens with RESTART button	41
5.3.2	Alarm screen with CONFIRM button	42
5.3.3	Alarm screen with SHUTDOWN button	43

6 Troubleshooting 45

6.1	Leaking tubing set	46
6.1.1	Tubing set leakage during set-up	46
6.1.2	Leakage during treatment or reinfusion phase	47
6.2	Manual adsorber regeneration and preservation	48
6.2.1	Rinsing of adsorber pair with priming solution	49
6.2.2	Rinsing of adsorber with elution buffer	51
6.2.3	Preservation of adsorber pair with preservation buffer	53

6.3	Exchange of disk separator	53
6.4	Empty disk separator drip chamber	58
6.5	Noisy disk separator	58
6.6	Notification: no plasma flow	59
6.7	Removal of air from blood return line	60
6.8	Hemolytic plasma suspected	64
6.9	Blood leakage in disk separator suspected	67
6.10	Calibration of hemolysis sensor failed	70
6.10.1	Plasma line (yellow) from disk separator affected	71
6.10.2	Cell concentrate line (blue) from disk separator affected	72
6.10.3	Air in plasma line (yellow) from disk separator	73
6.10.4	Air in cell concentrate line (blue) from disk separator	74
6.11	External pressure sensor alarms	75
6.11.1	Hydrophobic filter at pressure line EX1 (red) wet	75
6.11.2	Hydrophobic filter at pressure line EX2 (blue) wet	78
6.11.3	Hydrophobic filter at pressure line EX3 (yellow) wet	81
6.11.4	Hydrophobic filter at pressure line EX4 (white) wet	85
6.11.5	Hydrophobic filter at pressure line to EX1 and/or to EX2 wet	89
6.12	Adsorber barcode cannot be scanned	93

7	**List of error codes**	**95**
7.1	Hardware errors (050–)	96
7.2	Software errors (100–)	97
7.3	Internal system errors (150–)	97
7.4	Handling errors (200-)	98
7.5	Door errors (250-)	99
7.6	Internal pressure sensor errors (300–)	100
7.7	Optical sensor errors (350–)	107
7.8	Sensor errors (400–)	110
7.9	External sensor errors (EX1-EX4; 450–)	111

7.10 Air detection errors (500–) 124
7.11 Tubing set-related errors (550–) 127
7.12 Internal monitoring errors (600–) 128

8 Legal notes 131
8.1 Limited warranty 131
8.2 Trademarks 132

1 Introduction

1.1 General information

This user manual provides warnings, precautions, and troubleshooting advice for the use of the LIFE 21 apheresis unit (instrument) and its treatment-specific components. For details on the instrument as well as specific procedures, see the LIFE 21 user manuals issued for the respective matter.

IMPORTANT

The screens presented in this manual are representative screens and may differ slightly from the screens presented on the instrument.

2
Glossary

2.1 Graphical depiction

The following section lists and explains the panels depicting the potential consequences of hazardous situations which can occur if instructions, warnings or precautions outlined are not followed.

⚠ WARNING

Indicates a hazard or hazardous situation which could result in death or persisting or life-threatening medical conditions, ailments, and injuries that require stationary medical intervention and observation.

⚠ CAUTION

Indicates a hazard or hazardous situation which could result in temporary and reversible medical conditions, ailments, and injuries that require ambulatory medical intervention and observation.

NOTICE

Indicates a hazardous situation which, if not avoided, could lead to property damage, but not to an injury.

IMPORTANT

Indicates other situations which may occur if particular instructions or information are not followed or observed.

2.2 Glossary of symbols and terms

An overview of symbols and terms is provided in the user manual “General information – Instrument” or in the appropriate package insert of the products used.

3

Important safety information

3.1 General warnings and precautions

Warnings and precautions regarding the instrument and its treatment-specific components in general are described in this chapter. To avoid potential risks and hazards associated with operating the instrument read the appropriate user manuals carefully. For the most current safety information, contact Miltenyi Biotec Technical Support.

⚠ WARNING

Risk of electrical shock, physical injuries, fluid imbalances or loss, vascular damage, hemolysis or embolism. Disregard of any instructions, warnings or cautions at any time can endanger patients, operator and others due to possible instrument damage or malfunction and may compromise the electrical, electronical, electromagnetic and mechanical safety. Disregard also excludes the manufacturer from any liability. Read, study, understand, and observe all safety information, warnings, precautions, and instructions provided by Miltenyi Biotec before using the instrument. Do not use or attempt to use the instrument unless an authorized Miltenyi Biotec instructor has trained the operator.

IMPORTANT

Any serious incident that has occurred in relation to this product should be reported to Miltenyi Biotec B.V. & Co. KG – using the contact information provided – and the competent authority of the member state in which the operator of this product is established and in which the patient has been treated.

3.2 General side effects and risks

3.2.1 Side effects

- Dizziness, headache, drop in blood pressure, peripheral paraesthesia, cardiac arrhythmias, complement activation, hypotension, prolonged bleeding or hematoma after treatment, bradycardia, allergic skin or mucosa reaction, edema, nausea/vomiting, puncture problems, thrombophlebitis, symptomatic hypocalcemia, muscle cramps, fever with shivering, and hemolysis have been described for all extracorporeal therapies.
- During the treatment, minor, unspecific loss of plasma protein and electrolytes occurs. This is caused by the plasma, which is lost to the waste every time an adsorber is regenerated. The loss of plasma constituents is equivalent to a plasma loss of about 2.5–12% after processing 1-fold the patient's plasma volume. Therefore, it is recommended to monitor blood chemistry before and after a treatment session.
- Anemia after repeated treatments requiring transfusion was observed in some cases of pediatric applications.
- Activation and elimination of thrombocytes is possible due to the method of plasma separation in the treatment. A decrease in platelet count of app. 15% was observed after treating 2-fold the patient's plasma volume. Therefore, it is recommended that blood control measures are carried out before and after the treatment.
- Heparin-induced thrombocytopenia and hemolysis can occur when heparin is solely used as an anticoagulant.
- Allergic reactions (e.g., skin or mucosa reaction, pruritus/itching, flush, urticaria, back pain, asthma, Quinke edema) cannot be excluded.
- For patients with progressive heart diseases, extracorporeal therapies may lead to an increase in angina pectoris or dyspnea due to the extracorporeal blood volume necessary for the treatment.
- A metabolic acidosis or itching cannot be excluded when the adsorbers are insufficiently neutralized. An increase in the pH of the blood within the normal range or metabolic alkalosis can occur with the use of citrate as anticoagulant. If hepatic citrate metabolism is impaired the use of citrate as anticoagulant may result in metabolic acidosis.
- Enhanced drop in blood pressure may occur when treating patients under ACE-inhibitor medication.
- Antibody medications (biologicals) given to the patient will be removed to a certain extent based on the principle of Ig apheresis as well.

- Interactions with medications, which are not antibodies or parts thereof have not been observed so far but cannot be completely excluded.
- Increased rate of infections (in case of immunoadsorption).
- In patients with a central venous access, cases of central line thromboses were described.
- Despite the use of particle filters in the plasma return line of the tubing set, ingress of particles less than 5 µm in diameter into the patient cannot be excluded. Cases of clinical problems due to particle uptake have never been described or suspected.
- Single cases were described with the following adverse events:
  - Perioral and acral paresthesia.
  - Dysgeusia.
  - Decrease of serum albumin.
  - Pneumonia, temporary disturbance in attention.
  - Short-term changes in electrolytes, creatinine, hemoglobin, liver function tests or fibrinogen levels are encountered. Immune system components may also be transiently affected, with increased leucocyte concentrations, and activation of the complement system.
  - Abdominal pain.

IMPORTANT

See package insert of the respective adsorber as well.

3.2.2 Risk associated with blood withdrawal and restitution

A venous access with incorrect shape or wrong dimensions (length and diameter) can lead to damage of blood cells by high suction forces and high blood flow rates. The sensors of the instrument constantly measure the withdrawal pressure and the pressure in the blood return line. When values outside the defined range are detected, the instrument will stop the treatment with an alarm message.

A possible risk of blood withdrawal and restitution is a leaking connection between the venous access tool and the tubing line. Typical consequences would result in a drop in blood withdrawal pressure and air bubbles appearing in the tubing line. This will lead to an alarm. The instrument will stop and wait until the problem has been fixed by the operator.

Potential harms for the patient are:

- Blood loss with the possibility of hypovolemia.
- Infection due to ingress of bacteria.

A potential harm for the operator is infection by contaminated blood (e.g., viral contamination).

Any pressure deviations outside the defined specifications can lead to:

- Vascular damage.
- Rupture of the venous wall with hematoma at the site of the venous access (blood restitution only).
- Inflammation of the surrounding tissue. The use of cannula with a small diameter can also lead to damage of the blood cells due to high pressure and high flow rates.

3.2.3 Balancing of liquids during treatment

During extracorporeal treatments it is mandatory to keep the homeostasis of the patient intact. Neither the concentration of the blood components (cells, proteins, electrolytes) nor the volume of the blood should vary too much. In case of an imbalance between the liquids withdrawn and the liquids returned to the patient, typical clinical side effects might be:

- hypotension or hypertension
- headache or faintness, vomiting, loss of consciousness
- electrolyte deficiency or increase in electrolyte concentration
- hypo- or hyperproteinemia
- hypo- or hypervolemia
- edema

Suitable tests to evaluate effects of homeostatic imbalance are blood pressure determination, assay of blood levels of sodium, potassium, calcium, and phosphate, protein concentration and hematocrit before and after apheresis.

3.2.4 Risks associated with cell loss

Platelet loss is a common phenomenon during apheresis. The range for a single treatment can be up to 40 percent.
Damage of red blood cells can also occur during extracorporeal treatment. Due to elevated pressure in the system and high flow rates, three areas have to be considered where red blood cell damage could occur:

- The tubing set which might harm the cells due to sharp edged plastic parts.
- The disk separator which exerts a g-force on the blood cells.
- The blood pumps which compress the tubing might also damage the blood cells.

As a sign of hemolysis, the decrease of haptoglobin concentration can be determined before and at the end of the treatment. The data available show that haptoglobin concentration usually drops by 5–50% but remains below the limit that clinically defines “hemolysis”. A clinically significant hemolysis will be detected by the safety system of the instrument. If visible hemolysis with reddish coloring of the plasma cannot be counteracted within a few minutes, stop the treatment and take appropriate measures.

3.2.5 Risks associated with cell activation

In addition to platelet loss, a second potential risk is an activation of platelets during passage through the disk separator with a resulting aggregation of platelets. Only minor activation of platelets has been observed in standard treatments with sufficient anticoagulation.

3.2.6 Risks associated with plasma loss

Clinical parameters of plasma loss comprise the appearance of edema, hypotension, and onset of arrhythmias in patients under treatment with anti-arrhythmic drugs. Typical laboratory parameters that demonstrate plasma loss are changes in hematocrit, total protein, albumin, coagulation factors, and decrease in blood level of albumin bound drugs like digoxin, carbamazepine, and others.

Plasma loss is a typical finding in adsorber treatment, since some plasma gets lost to waste in each plasma loading and regeneration cycle of one adsorber. Therefore, the maximum number of cycles has been limited to keep the loss of plasma at tolerable levels in patients.

3.2.7 Risks associated with plasma dilution

Plasma dilution can occur during adsorber treatments for two reasons:

- Anticoagulation is administered at a fixed anticoagulation:blood ratio (usually 1:18 to 1:35). Prior to regeneration of an adsorber, the plasma is displaced by priming solution and redirected to the patient. A dilution of the plasma by priming solution cannot be avoided technically. Plasma dilution can be estimated by comparing the hematocrit before and after each apheresis procedure. Data from experiences with adsorber treatments demonstrate that the decrease in hematocrit is usually less than 10% as is the decrease in potassium concentration. If the drop of albumin is more pronounced than the drop of hematocrit, a loss of protein is more probable than the dilution of the blood.
- Plasma dilution occurs on each adsorber cycle change. Plasma loaded on one adsorber is directed to a second adsorber during cross-over phase, but the separation between plasma and priming solution is never 100%, therefore an intake of NaCl into plasma occurs regularly.

3.2.8 Risks associated with acidosis

Acidosis of the patient can occur due to two reasons:

- Insufficient neutralization of the adsorber after regeneration by low pH (acidic) buffers.

  Signs of insufficient pH neutralization were observed in some patients and this phenomenon was attributed to insufficient neutralization by PBS (phosphate buffered saline) 10 mmol/L solution. Since the introduction of 30 mmol/L PBS no case of insufficient pH neutralization has been reported.

- Acidification by citric acid in the anticoagulation solution ACD-A (Acid-Citrate-Dextrose formulation A).

  ACD-A is taken up by the tissue, especially the muscles, and excreted by the kidney. A low pH of the urine is a sign for acid elimination. In a patient with normal kidney function, the elimination of acidic valences is not considered to be a clinical problem. For patients with impaired kidney function, or patients under intensive care conditions, the elimination of acidic valences might create clinical problems.

3.2.9 Risks associated with electrolyte concentration

During apheresis, a certain quantity of sodium chloride and phosphate enters the circulation. Calcium is bound by citric acid, which lowers the level of free calcium in the blood. In combination with dilution of blood, the levels of different electrolytes can change up to 10% (Na, K, Ca) and up to almost 30% for phosphate. The change of electrolyte concentration bears the risks for functional impairment of nervous system and muscles with symptoms such as paresthesia, heart arrhythmias, cramps, convulsions, and possible unconsciousness. To reduce the risks for such complications, the operator must:

- Check for clinical signs of electrolyte deficiencies.
- Monitor electrolyte levels before and after treatment.
- Substitute deficient levels of electrolytes during treatment orally or intravenously.

3.2.10 Risks associated with incorrect anticoagulation

Therapeutic apheresis requires constant anticoagulation of the blood of the patient in the extracorporeal circuit. The anticoagulation regimens used are mainly based on clinical experience. During apheresis, activation of the clotting and complement system can occur through contact of blood with the surfaces of the treatment-specific components.
An insufficient dose of anticoagulant can lead to occlusion of the extracorporeal circuit during the treatment. However, an exaggerated anticoagulation dosage increases the risk of bleeding for the patient.
ACD-A blocks several calcium-dependent activation steps of the coagulation and complement cascade by complexing with free ionized calcium. Citrate is metabolized in the liver with a half-life of 20 minutes, making this form of anticoagulation well controllable. In case of hepatic insufficiency, the degradation of citrate can lead to metabolic alkalosis and misdistribution of electrolytes. A typical consequence of citrate application is hypocalcemia with the following symptoms:

- paresthesia
- muscle cramps
- arrhythmias
- heart arrest

Heparin has a plasma half-life of less than 60 minutes, depending on the dosage. In case of one injection, the heparin level can be low after several hours and coagulation may occur.

4

General recommendations and handling instructions

⚠ WARNING

Risk of embolism, vascular damage, fluid loss or imbalance, hemolysis, bleeding or clotting, paresthesia and cardio-vascular irregularities. Neglect of the patient's condition or of messages and alarms from the instrument can endanger the patient's health or the pathogen removal. Make sure that the patient connected to the instrument never remains unattended during the treatment. Check for tubing set integrity regularly during the treatment.

4.1 Anticoagulation

To prevent blood or plasma coagulation in the extracorporeal circuit during the treatment, the blood must be anticoagulated. Anticoagulation should be individually adapted for each patient in accordance with the instructions of the attending physician. Recommended is a combination of the anticoagulants ACD-A and Heparin.

⚠ WARNING

Risk of bleeding or mineral imbalances and extracorporeal blood clotting. The instrument cannot monitor the connection of wrong or incorrectly concentrated anticoagulation solutions. Impaired anticoagulation in the extracorporeal fluid path may cause bleeding or mineral imbalances and extracorporeal blood clotting. If the patient experiences symptoms of hypocalcaemia (a risk if ACD-A is administered) countermeasures have to be taken (e.g., calcium administration). The patient must be informed about symptoms of physiological reactions to citrate.

IMPORTANT

If the recommended combination of anticoagulants is used, the instrument only distributes and monitors one anticoagulant. The second anticoagulant must be connected externally e.g., with an infusion pump.

4.1.1 Recommended dosage of the anticoagulant

ACD-A	An ACD-A:blood ratio of 1:18 is recommended and should only be lowered when clinically necessitated.
Heparin	A heparin bolus of 60 IU/kg body weight is recommended immediately before start of the treatment run, followed by a continuous heparin infusion at a rate of 20 IU/kg/hour.

⚠ CAUTION

Risk of thrombocytopenia and hemolysis. Clinical experience mainly with high molecular weight (HMV) heparin has shown intolerance in some patients. If the patient shows signs of intolerance against HMW heparin, like heparin-induced thrombocytopenia, and cannot be treated with ACD-A alone, the administration of low molecular weight (LMW) heparin should be considered.

4.1.2 Adaptation of ACD-A to blood ratio

The optimal ratio ACD-A:blood depends on the blood withdrawal flow. The lower the blood flow, the higher the ACD-A concentration should be.
For example, for a male patient with 70 kg body weight the ACD-A:blood ratio should be 1:18 when the blood flow is below approximately 60 mL/min. With higher blood flow rates, the ACD-A:blood ratio should be adapted (less ACD-A) proportionally.
Be aware that any interruption of the treatment will increase the risk of coagulation in the extracorporeal circuit. Therefore, the anticoagulation should be at the maximum tolerable level for the patient.

If only a single anticoagulant is used, the dosage should be adjusted (increased) accordingly to account for low blood flow to prevent coagulation in the extracorporeal fluid path.

4.2 Calcium substitution

Substitution of calcium is not generally recommended, but may be required for certain clinical conditions, such as low body weight (<60 kg), initially low blood calcium levels or history of cardiac arrhythmia. If a patient experiences clinical signs of a calcium deficiency during apheresis such as tingling of the lips, paresthesia, muscle cramps, oral or intravenous substitution of calcium may be indicated.
A dose of 2.5 mmol (5 mval) calcium e.g., in 100 mL NaCl (0.9%) is recommended for slow administration as a drip infusion or with a perfusor. Blood calcium levels should be closely monitored during and after calcium substitution.

4.3 Patient venous access

The connection of the patient to the extracorporeal circuit requires at least one vascular venous access and should be individually adapted for each patient in accordance with the instructions given by the attending physician. However, it is recommended to use cannulas of type 16 G (diameter 1.6 mm) for a peripheral venous access or via a Cimino-Brescia-Shunt. If required, a central venous access (e.g., Shaldon catheter) can be used as an alternative.

⚠ CAUTION

Risk of vascular damage. Dislocation of the needles can lead to vascular damage. Patient access must be carefully monitored to avoid dislocation of the needles. To avoid inflammation and sclerotization of punctured veins, inject heparin bolus into the venous access, if required.

4.4 Interruption of a treatment

It might be necessary to interrupt the treatment for a short period.

Operator action:

- Press **STOP**, on the treatment screen. All pumps of the instrument will be stopped.
- Press **Restart** to continue the treatment.

⚠ CAUTION

Risk of insufficient pathogen removal or treatment delays. Treatment interruptions can cause clotting in the extracorporeal fluid path of the system. Do not interrupt the treatment for longer than necessary.

4.5 Abortion of a treatment

Due to an error occurrence, it might be necessary to end the treatment immediately or prematurely.

4.5.1 Immediate end of treatment

This option allows the operator to abort a treatment at any time, without reinfusion of plasma to the patient and regeneration and preservation of the adsorber.

Operator action:

- Press **STOP** on the treatment screen. All pumps of the instrument will be stopped.
- Close clamps on blood withdrawal line (red) and blood return line (blue).
- Disconnect patient lines from the venous accesses of the patient.
- Shut down the instrument. If no shut down is possible switch off the instrument with the power switch on the rear of the instrument.
- For manual regeneration and preservation of the adsorber see section 6.2 “Manual adsorber regeneration and preservation”.

To resume the aborted treatment, see section 4.6 “Resuming a treatment”.

4.5.2 Premature end of treatment

This option allows the operator to abort a treatment at any time and to continue with the reinfusion of plasma to the patient and the regeneration and preservation of the adsorber. This option also allows the operator to abort the reinfusion and to continue with the regeneration and preservation of the adsorber.

Operator action:

- Treatment abortion: Press **Menu**, **Cancel treatment (reinfusion)**
- Reinfusion abortion: **Press Menu, Cancel reinfusion**

4.6 Resuming a treatment

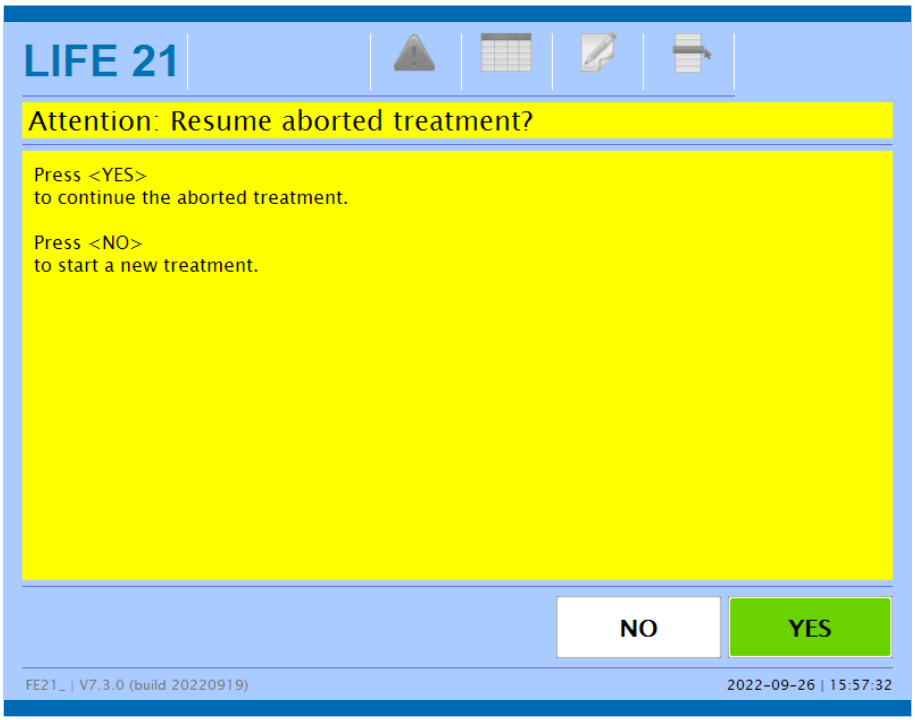
It is possible to resume the current treatment after the instrument had to be switched off.

Operator action:

- Switch on the instrument after waiting at least 60 seconds.
- Make sure that the patient chip card is in the chip card drive. In the “Treatment selection” screen, treatment mode should be selected automatically (if not, remove and re-insert patient chip card).
- Press OK to continue.
- Press OK to acknowledge the “Treatment-info” screen.
- Press YES to continue with an aborted treatment (see Screen 4.1).

IMPORTANT

If the last treatment module is not automatically selected as described above, the treatment cannot be restored. A new treatment session must be started.



Screen 4.1: Resuming an aborted treatment

4.7 Touchscreen monitor remains dark

Operator action:

- Shut down the instrument. If no shut down is possible switch off the instrument with the power switch on the rear of the instrument.
- Switch on the instrument after waiting at least 60 seconds.

IMPORTANT

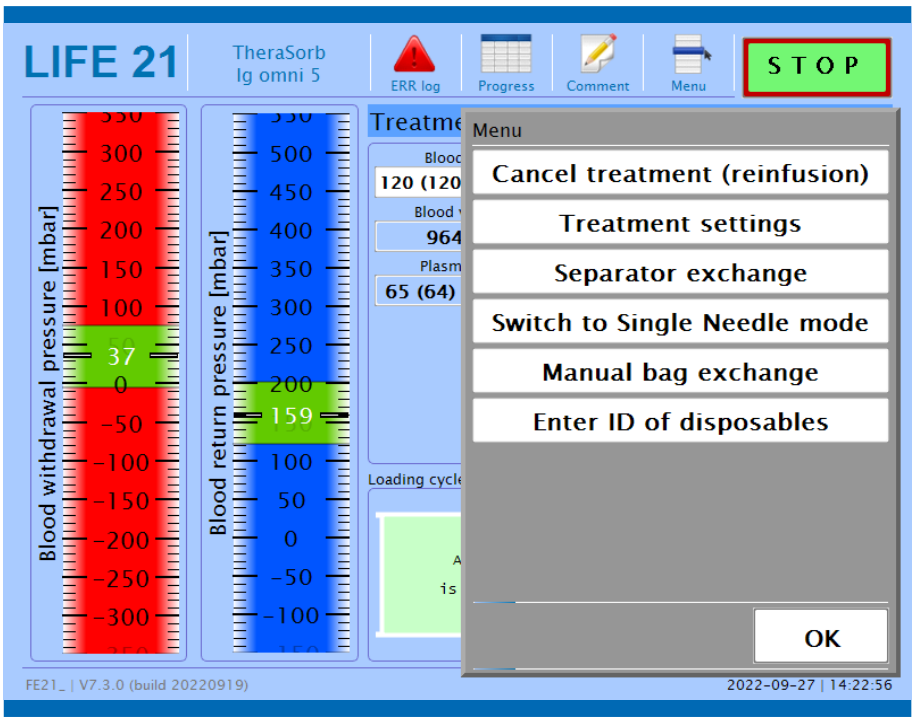
If the problem persists, contact Miltenyi Biotec Technical Support.

4.8 Manual bag exchange

During the treatment the residual volume and the remaining time before the next bag exchange is measured and shown in the **Next user action** field of the treatment screen. If the remaining time is below 1 minute the status line will turn yellow. If the bag is empty an alarm will be prompted, which shows a required operator action. Here, the exchange of the anticoagulation bag is described as an example.

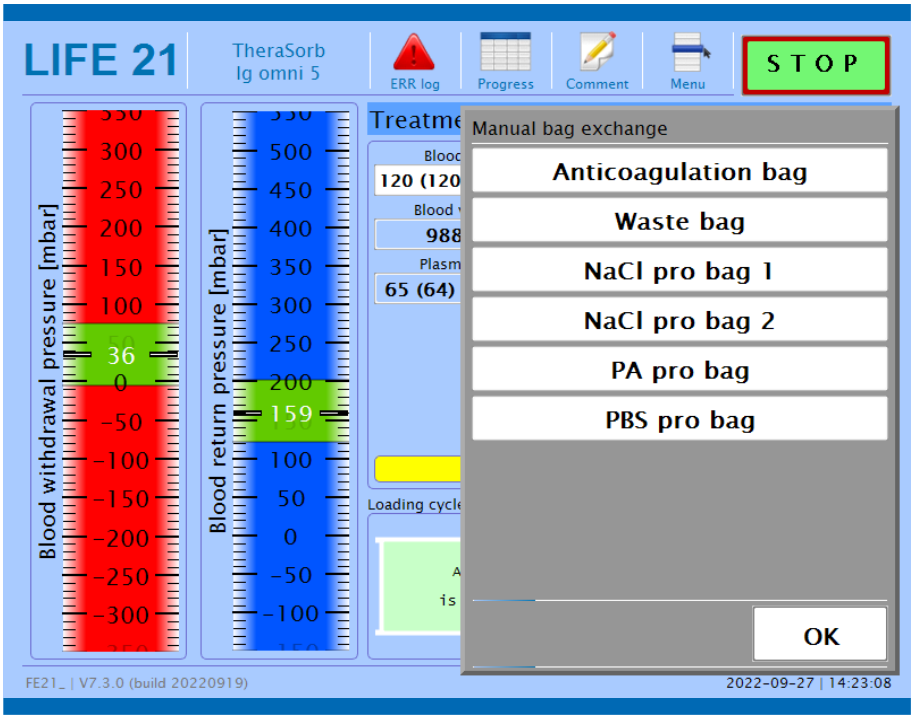
Operator action:

- Press **Menu** and select **Manual bag exchange**.
- Press **OK** to continue.



Screen 4.2: Select menu button to exchange a bag manually

- Select **Anticoagulation bag** and press **OK** to continue.

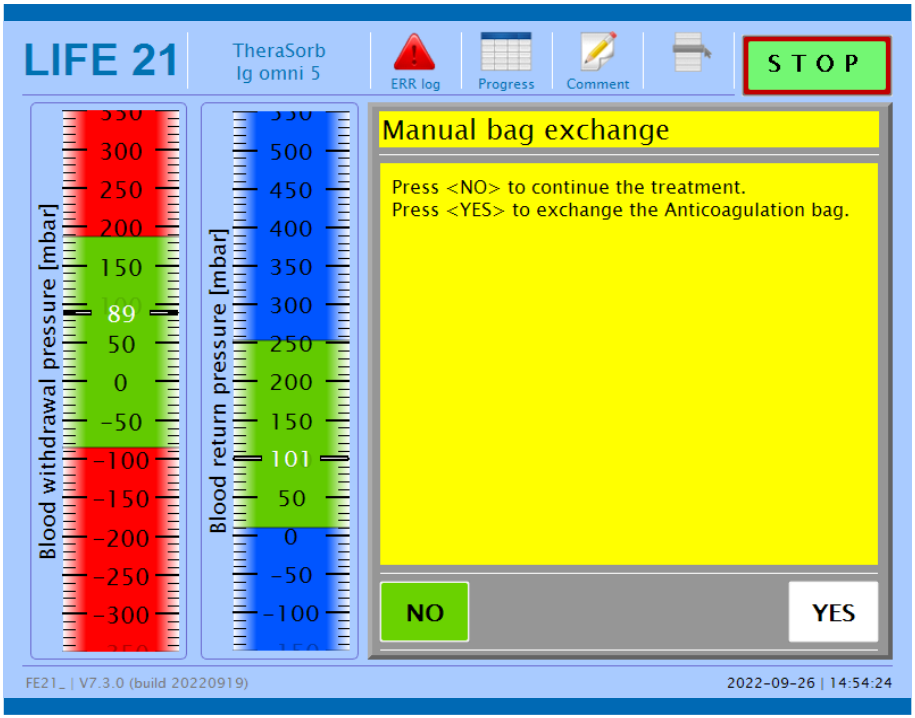


Screen 4.3: Select menu button to exchange anticoagulation bag

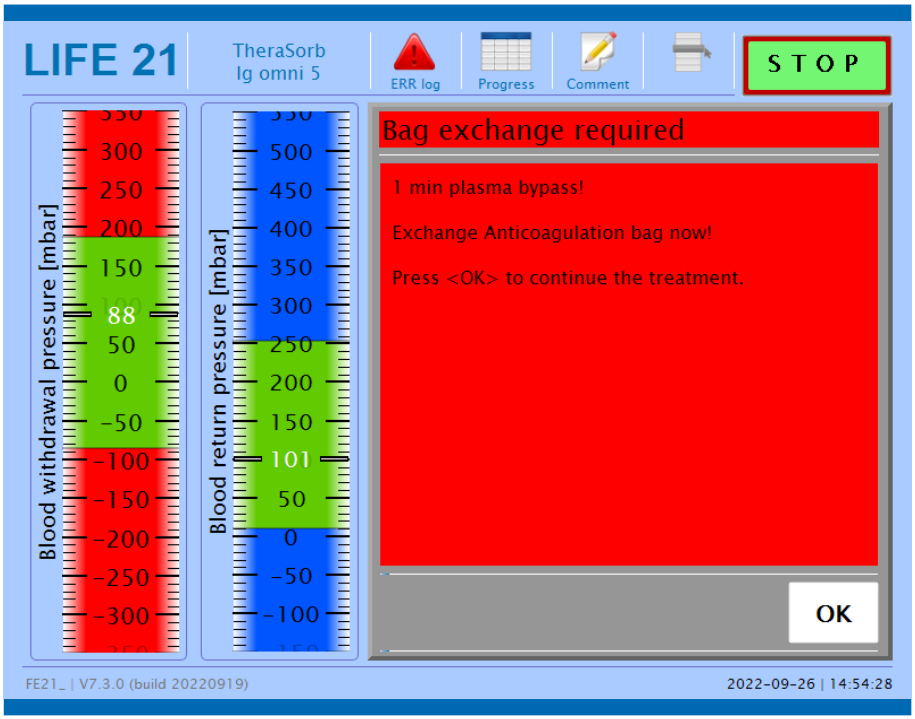
- Press **YES** to confirm the exchange of the bag (see Screen 4.4). An alarm screen is shown. Exchange the bag within one minute (see Screen 4.5). During this time the anticoagulant pump is stopped, and the treatment continues for one minute without anticoagulation. Once the standby time ends, an alarm is shown, and the operator is asked to continue the treatment.
- Press **OK** when the exchange of the anticoagulation bag is finished.

⚠ CAUTION

Risk of insufficient pathogen removal or treatment delays. The anticoagulation bag must be changed within the standby time given by the instrument to maintain anticoagulation and to prevent clotting. Change the anticoagulation bag within the standby time given by the instrument.

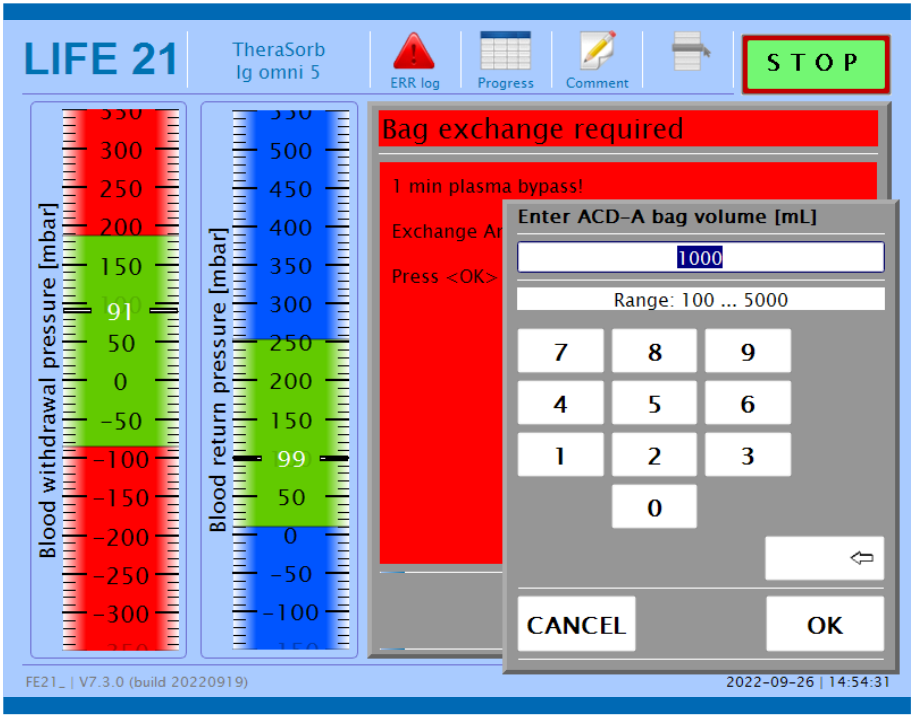


Screen 4.4: Confirmation of anticoagulation bag exchange



Screen 4.5: Alarm screen shows standby time of anticoagulation pump

- Enter the volume of the anticoagulant bag and press **OK** (see Screen 4.6).



Screen 4.6: Entry of anticoagulation bag volume

4.9 Switch to Single or Double Needle mode during treatment

4.9.1 Switch to Single Needle mode

During a treatment it might be necessary to switch the venous accesses of the patient from two accesses to one access.

Operator action:

- Select **Menu** on treatment status screen.
- Press **Switch to Single Needle mode** and confirm selection.
- Close the clamps of vascular patient accesses.
- Close the clamps in the blood return line (blue) and blood withdrawal line (red) of the tubing set.
- Disconnect the blood return line (blue) and blood withdrawal line (red) from vascular patient accesses.
- Connect the blood return line (blue) and blood withdrawal line (red) to a sterile Y-connector or equivalent adapter.
- Connect the Y-connector to the vascular patient access.
- Open the clamp on the vascular patient access.
- Open the clamps in the blood return line (blue) and blood withdrawal line (red) of the tubing set.
- Press **OK** to continue treatment in Single Needle mode.

⚠ CAUTION

Risk of cell loss. A 3-way stopcock is not equivalent to a Y-connector. Cells will be ruptured due to shear forces. Use only adapters that equals the function of a Y-connector.

4.9.2 Switch to Double Needle mode

During a treatment it might be necessary to switch the venous access of the patient from one to two accesses.

Operator action:

- Select **Menu** on the treatment status screen.
- Press **Switch to Double Needle mode**, confirm the selection, and wait until information screen for Double Needle mode is shown (current single needle cycle will be finished first).
- Close the clamp of the vascular patient access.
- Close the clamps in the blood return line (blue) and blood withdrawal line (red) of the tubing set.
- Disconnect the Y-connector or equivalent adapter from the vascular patient access.
- Remove the Y-connector or equivalent adapter from the blood return line (blue) and blood withdrawal line (red).
- Connect the blood return line (blue) and blood withdrawal line (red) to the vascular patient accesses.
- Open the clamps on the vascular patient accesses.
- Open the clamps in the blood return line (blue) and blood withdrawal line (red) of the tubing set.
- Press **OK** to continue treatment in Double Needle mode.

4.10 Notification "max. hematocrit, reduce TMP"

The hematocrit notification in the status line indicates an increased risk of cell damage in the separator due to a higher-than-normal density of the blood cells. In accordance with the notification, adjust the transmembrane pressure (TMP) value of the disk separator to reduce the density of the cells in the separator.

Operator action:

- Press **TMP** on the treatment screen.
- In the pop-up menu enter a value of 20 mbar below the current value for TMP.
- Press **OK** to confirm the changed value.

⚠ CAUTION

Risk of hemolysis or insufficient treatment (damage to the adsorber). The adsorber can be damaged by the hemolytic plasma. Carefully maintain control of the system to notice any hemolysis occurring.

IMPORTANT

The stepwise reduction of TMP can be repeated several times unless the plasma flow is too low to allow an acceptable treatment. The probability of reaching the maximum hematocrit in the disk separator depends on the hematocrit in the patient's blood and is most likely when that value is above 45%.

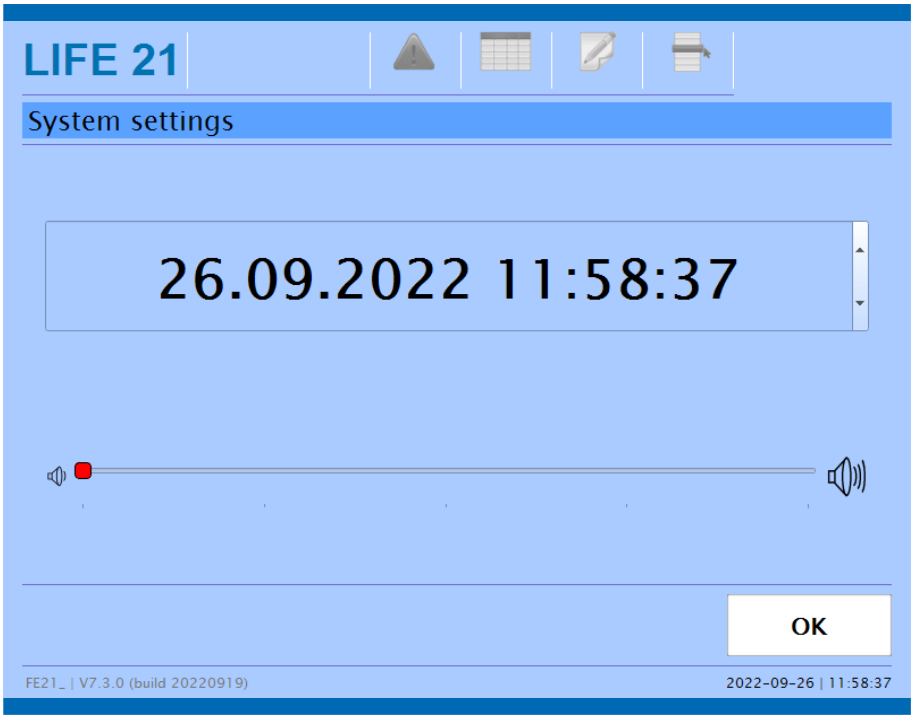
5
Alarm management

The instrument continuously monitors the functionality of its hardware as well as safety-related procedural specifications and limits, to protect both the patient and the operator. If an unsatisfactory functional state (system malfunction or component out of specification) or other hazardous situation (treatment parameter out of limit) is detected, an alarm is triggered. If an alarm is activated, the instrument stops all critical fluid paths immediately, so that patient safety is ensured.

IMPORTANT

The screens presented in this manual are representative screens and may differ slightly from the screens presented on the instrument.

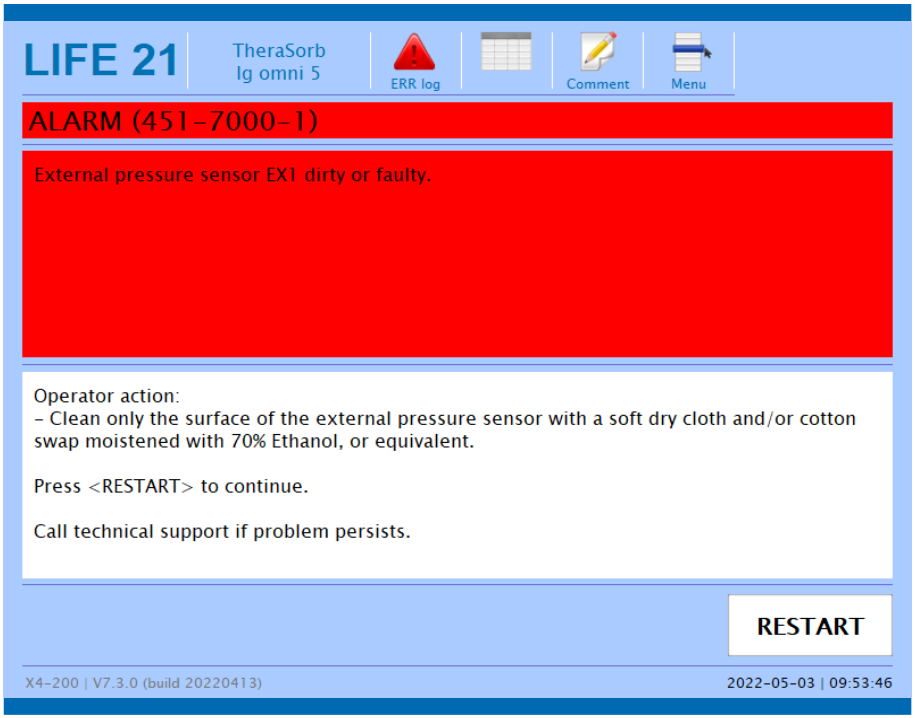
- The instrument generates only a single type of alarm, which concurrently utilizes both a visual and an escalating auditory alarm signal to notify the operator of a hazardous situation.
- Every alarm is also connected with the nurse call interface to activate any remotely connected alarm system.
- The alarm signals are preset and configured by the manufacturer and cannot be changed by the operator.
- The volume of the auditory signals can be adjusted at the beginning of a treatment within the preset thresholds. To adjust the volume press **Menu** followed by **System settings**. Move the controller to the desired position on the volume bar (see Screen 5.1).
- Except for the hemolysis and blood leak alarm the operator cannot permanently disable an alarm.



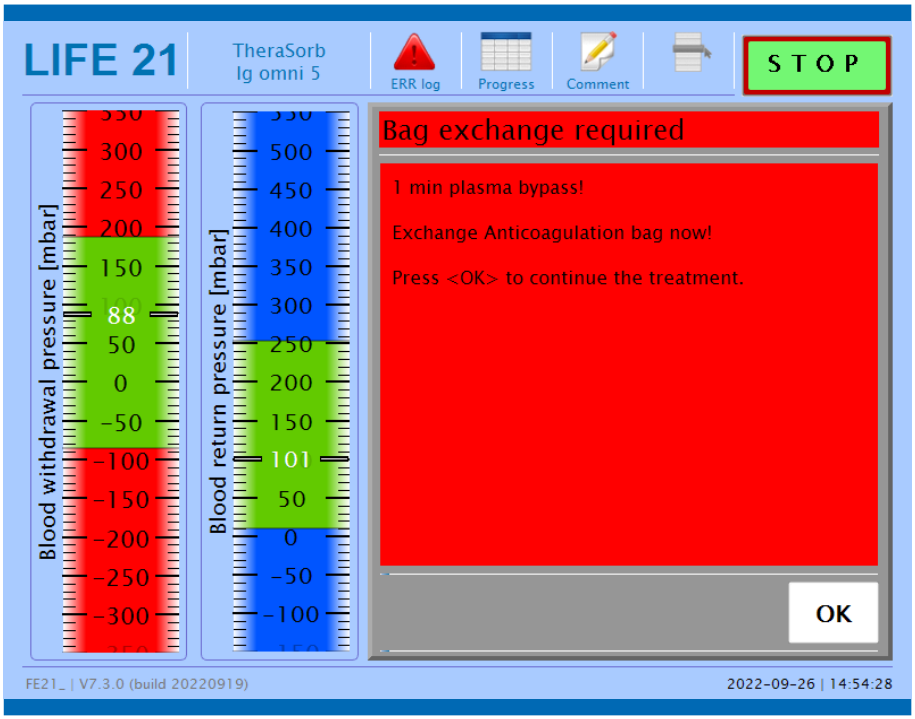
Screen 5.1: System settings

5.1 Visual alarm signal

The visual alarm signal consists of an alarm window, which changes its background color between red and white in an interval of 1 second. Depending on the individual alarm the alarm screen either overlays part of the current status screen (the blood removal and return pressure bars remain visible) or the complete screen (see Screen 5.2 and Screen 5.3).



Screen 5.2: Representative alarm screen with red background



Screen 5.3: Representative partial alarm screen during treatment

5.2 Acoustic alarm signal

The primary acoustic alarm signal is sounded by the internal speakers of the touchscreen monitor. If an alarm screen is not acknowledged within 2 minutes, the buzzer at the rear side of the instrument will give an escalated acoustic alarm signal.

IMPORTANT

To pause the primary internal and secondary external audio alarm signal for a period of 2 minutes touch the red field on the alarm screen or the yellow bar on the instruction screen. The management of an alarm and its consequences depend on the respective origin of the alarm.
Technical details about the audio and visual alarm system can be found in the LIFE 21 apheresis unit user manual "General information – Instrument".

5.3 Alarm handling

The visual alarm signal ("alarm" screen) shows the error code line on top (see Figure 5.1).
The error code consists of three numbers separated by a hyphen:

- A three-digit number (category 1) which reflects the cause of the error.
- A four-digit number (category 2) which reflects the process state.
- A service info number (category 3) which can consist of up to six number blocks.

The first number (category 1) of an alarm screen is needed for locating the error description in the chapter 7 "List of error codes". For filing a customer complaint, the complete error code is required. Therefore, write down the error code before the respective alarm is acknowledged.

⚠ CAUTION

Risk of insufficient removal of pathogens. Confirmation of frequently repeated identical alarms without identification and removal of the underlying cause might result in a termination of the treatment phase. Damage resulting from inadequate management of repeated alarms is excluded from any liability of the manufacturer. Always remove the underlying cause of the alarm.

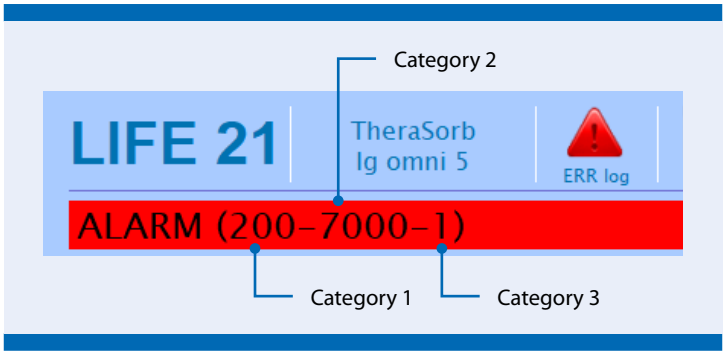


Figure 5.1: Category assignment of error code

The info field with the error description and the instruction field with information for operator action assigned to the specific alarm are shown in Figure 5.2.

- Press the white field or arrow to maximize and show the complete operator actions.
- If applicable, use the scroll bar to scroll through the complete text of the instruction field (see Figure 5.3).

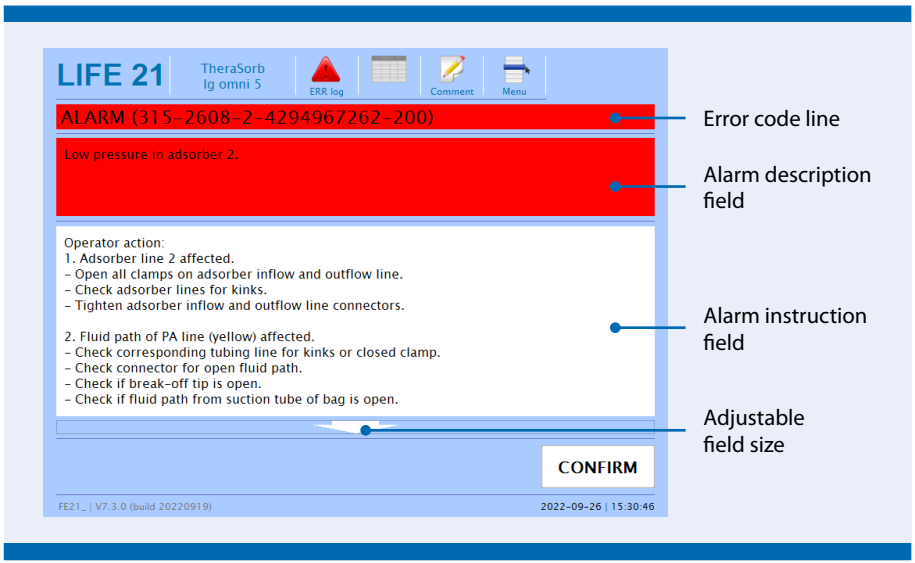


Figure 5.2: Composition of alarm screen

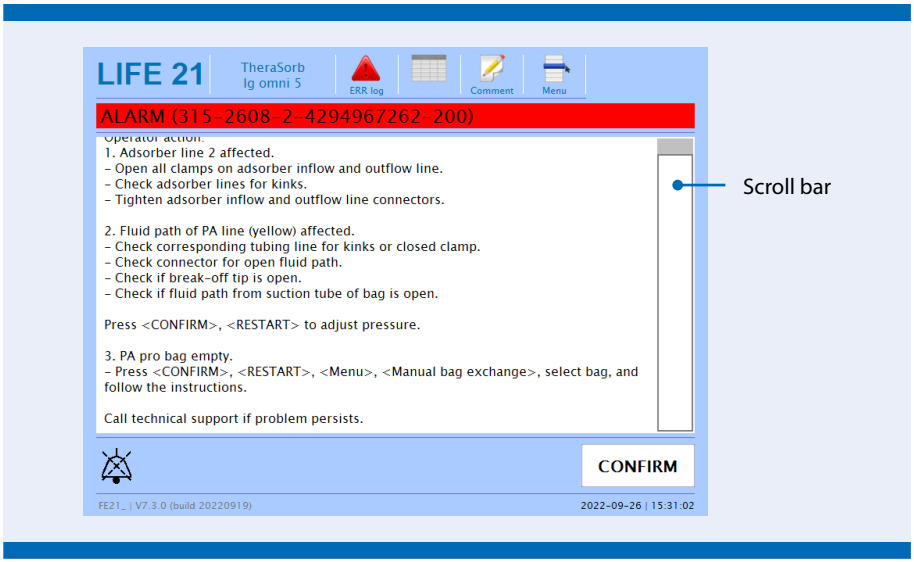


Figure 5.3: Use of scroll bar function

Each error code is assigned to one of the twelve category 1 definitions as shown in Table 5.1. In addition, each alarm is assigned to an alarm priority (high, medium or low).
A list of all alarms sorted by category 1 including priority can be found in chapter 7 “List of error codes”.

Category 1	Definition
050 –	Hardware errors
100 –	Software errors
150 –	Internal system errors
200 –	Handling errors
250 –	Door sensor errors
300 –	Internal pressure sensor errors
350 –	Optical sensor errors
400 –	Sensor errors
450 –	External sensor errors (EX1-EX4)
500 –	Air detection errors
550 –	Tubing set-related errors
600 –	Internal monitoring errors

Table 5.1: Category 1 error code definition

IMPORTANT

Serious errors with impact on the operational safety of the instrument cannot be suppressed or ignored by acknowledgement and restart. In this case, the treatment cannot be continued. Contact Miltenyi Biotec Technical Support.

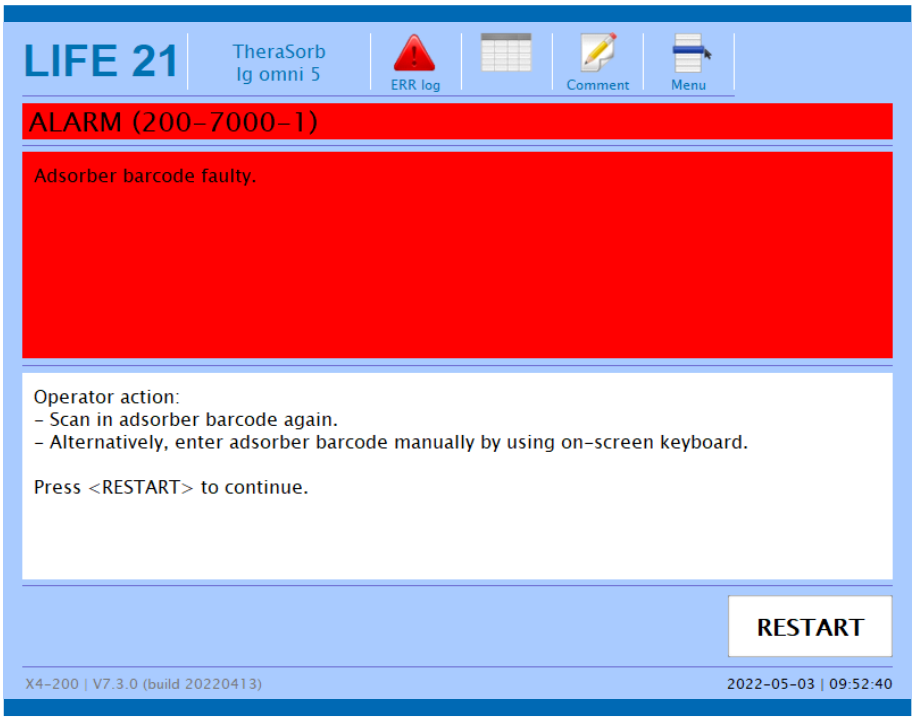
Alarms will be repeated until the underlying cause for the alarm has been solved by the operator.
Only alarm situations that could endanger the patient will cause an interruption of the treatment by stopping all pumps. Otherwise, only pumps related to the underlying cause will be interrupted for the alarm period.

⚠ CAUTION

Risk of insufficient removal of pathogens or treatment delays. Prolonged interruption of treatment may affect anticoagulation effectiveness and cause clotting of the extracorporeal fluid path. Immediately acknowledge any alarm which might interrupt the treatment.

5.3.1 Alarm screens with RESTART button

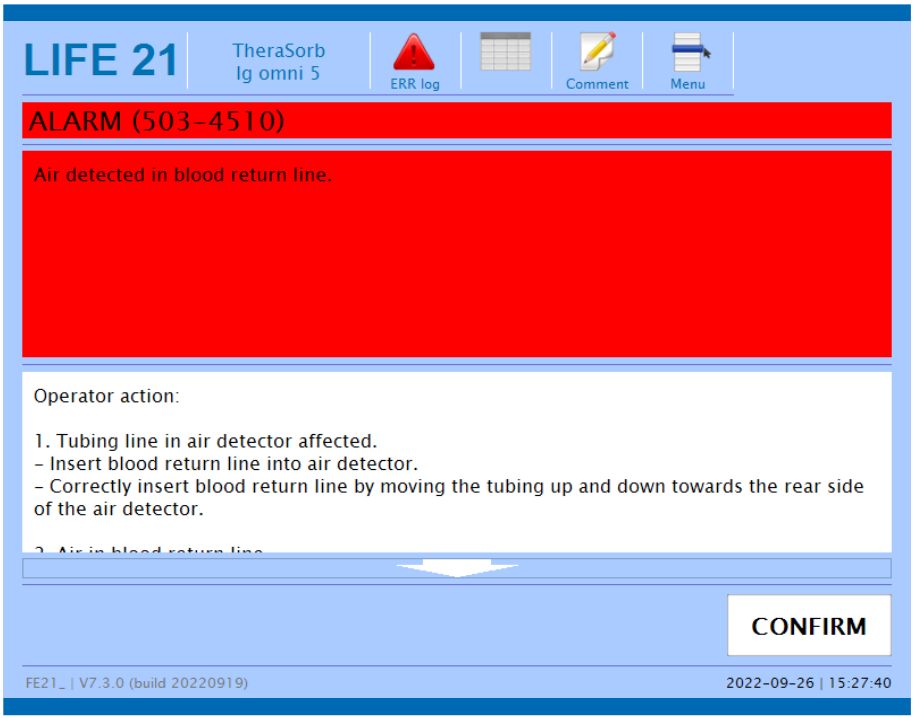
- Press **RESTART** on the alarm screen. The treatment will be continued if the alarm cause has been resolved.



Screen 5.4: Representative alarm screen with RESTART button

5.3.2 Alarm screen with CONFIRM button

- Press **CONFIRM** on the alarm screen after the required operator action has been performed (see Screen 5.5).



Screen 5.5: Representative alarm screen with CONFIRM button

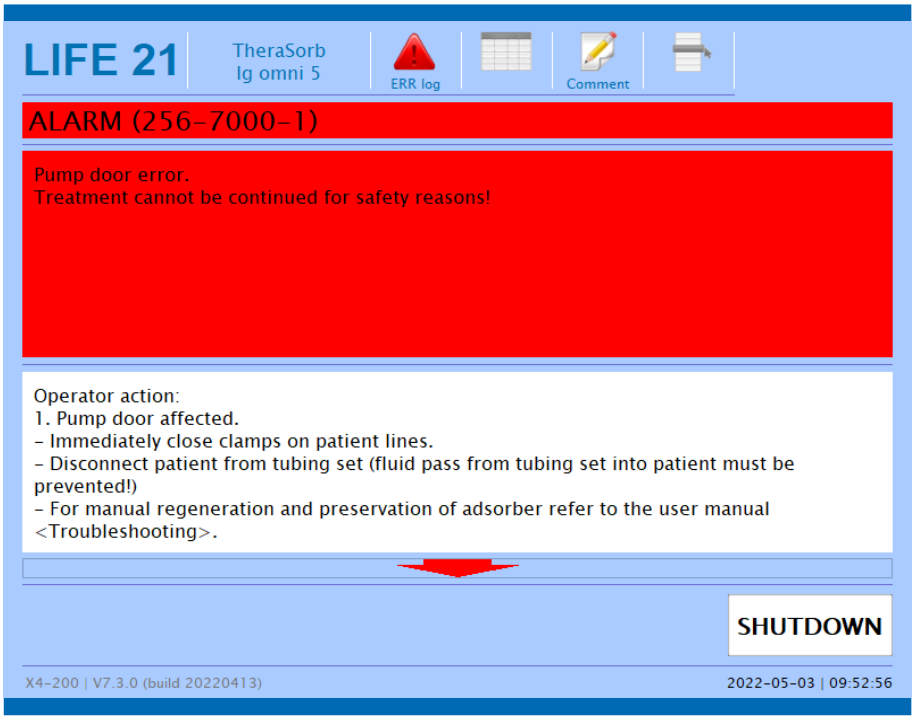
Treatment is not automatically continued. Instead, the alarm screen is closed and the "Treatment Status" screen or information screens will be shown. If required, change parameters to prevent re-occurrence of the alarm, e.g., reduction of blood flow, change of patient pressure limits.

- To continue the treatment press **RESTART**.

  If the treatment is not restarted within 60 seconds after initial acknowledgement, the alarm screen is shown again.

5.3.3 Alarm screen with SHUTDOWN button

- Immediately follow the instructions on the Screen 5.6.
- Press **SHUTDOWN** to initiate system shutdown.
- If no shut down is possible switch off the instrument with the power switch on the rear of the instrument as soon as the switch-off screen is displayed.
- Call Miltenyi Biotec Technical Support and submit the error code.



Screen 5.6: Representative alarm screen with **SHUTDOWN** button

6 Troubleshooting

In this chapter the most common alarm situations are described with their underlying causes and step-by-step information on how to rectify the fault condition. If an error cannot be corrected, inform the Miltenyi Biotec Technical Support. Note the complete error code from the screen for easier identification of the problem.

⚠ CAUTION

Risk of contamination. Any open part of the extracorporeal fluid path may cause contamination. If the correction of an alarm/error requires the opening of any part of the extracorporeal fluid path, this can cause contamination. Observe adequate hygienic measures for aseptic handling. Keep the exposure time for the patient to a minimum.

For filing a complaint submit the customer complaint form with all pertinent information to:

+49 3996 158-258
+49 3996 158-222
macstec@miltenyibiotec.de

Visit www.miltenyibiotec.com for local Miltenyi Biotec Technical Support contact information.

6.1 Leaking tubing set

If a tubing set leaking occurs, the procedure must be aborted irrespective of the treatment phase (preparation, treatment, or reinfusion).

⚠ WARNING

Risk of electrical shock. Ingress of liquids can cause electrical shortage. Do not use the instrument if liquids have penetrated the interior of the LIFE 21 apheresis unit. The instrument should not be used until a Miltenyi Biotec service engineer has inspected it.

6.1.1 Tubing set leakage during set-up

Operator action:

- Press STOP to stop the pumps.
- Close all clamps on lines of the tubing set.
- If adsorber have already been connected to the tubing set: disconnect adsorber inlet and outlet lines from adsorber and close the lines.
- Connect sterile stop caps (spare parts) to adsorber inlet and outlet connectors.
- Shut down the instrument. If no shut down is possible switch off the instrument with the power switch on the rear of the instrument.
- Switch on the instrument after waiting at least 60 seconds.
- Make sure that the patient chip card is in the chip card drive. In the “Treatment selection” screen, treatment mode should be selected automatically (if not, remove and reinsert patient chip card).
- Press OK to continue.
- Press OK to acknowledge the “Treatment-info” screen.
- Press NO to start a new treatment. The instrument will start the self-test routines and the pump door will be opened.
- Remove the tubing set and all other disposables from the instrument.
- Close the pump door and press RESTART on the alarm screen (pump door open) and follow further instructions.

6.1.2 Leakage during treatment or reinfusion phase

Operator action:

- Press **STOP** to stop the pumps.
- Close the patient lines (blood withdrawal and blood return line) immediately.
- Disconnect the patient from the patient lines.
- Close all clamps on the lines of the tubing set.
- Disconnect the adsorber inlet and outlet lines from the adsorber.
- Connect sterile stop caps (spare parts) to the adsorber inlet and outlet connectors.
- Shut down the instrument. If no shut down is possible switch off the instrument with the power switch on the rear of the instrument.
- Switch on the instrument after waiting at least 60 seconds.
- Make sure that the patient chip card is in the chip card drive. In the “Treatment selection” screen, treatment mode should be selected automatically (if not, remove and re-insert patient chip card).
- Press **OK** to continue.
- Press **OK** to acknowledge the “Treatment-info” screen.
- Press **NO** to start a new treatment. The instrument will start the self-test routines and the pump door will be opened.
- Remove tubing set and all other disposables from the instrument.
- Close the pump door. Press **RESTART** on the alarm screen (pump door open) and follow further instructions.

Before re-using the adsorber for the new treatment or storing the adsorbers after the cancellation of the treatment, manually regenerate and preserve the adsorbers (for details see section 6.2 “Manual adsorber regeneration and preservation”).

6.2 Manual adsorber regeneration and preservation

In case of an unexpected cancellation of the treatment, manually regenerate and preserve the adsorber pair.
Each adsorber may contain some amount of plasma and the interruption of the fluid circulation through each adsorber may cause coagulation of the plasma. Therefore, it is critical to start the manual regeneration and preservation of the adsorber pair as soon as possible.
The procedure comprises of three steps:

- Rinsing of both adsorber with priming solution (plasma is washed out).
- Rinsing of both adsorber with elution buffer (adsorber are regenerated).
- Preservation of both adsorber with preservation buffer.

The following materials/solutions specified for the respective treatment are required:

- priming solution (approx. 200 mL per 50 mL adsorber volume, approx. 500 mL per 100 mL adsorber volume or approx. 600 mL per 200 mL adsorber volume)
- elution buffer (approx. 500 mL per 50 mL adsorber volume, approx. 1,000 mL per 100 mL adsorber volume or approx. 2,000 mL per 200 mL adsorber volume)
- preservation buffer (500 mL per 50 mL adsorber volume or 1,000 mL per 100/200 mL adsorber volume)
- two infusion lines (spike/male Luer Lock)
- two 3-way stopcocks
- two Luer Lock extension lines (female/male Luer Lock e.g., Heidelberger extension line)
- two Luer Lock extension lines (waste line, female/male or male/male Luer Lock)
- two infusion lines (vented spike/male Luer Lock)
- four sterile syringes (50 mL)
- one waste container

6.2.1 Rinsing of adsorber pair with priming solution

Operator action:

Step 1 (Rinsing of adsorber with priming solution)

1. Hang the priming solution bag on the infusion stand of the instrument.

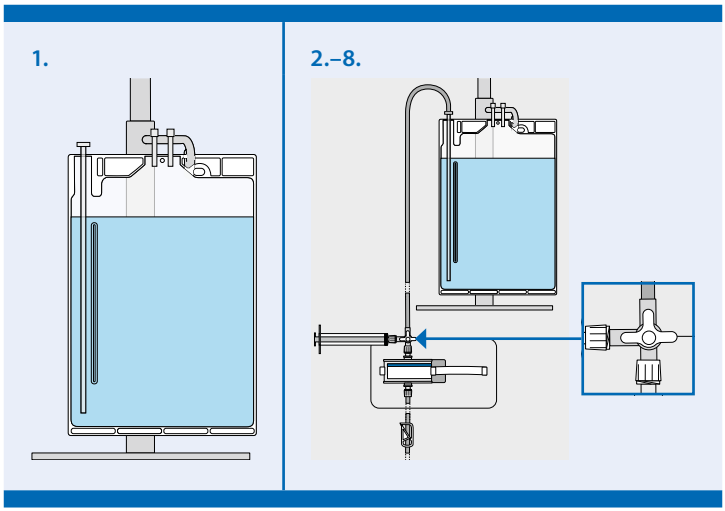


Figure 6.1: Step 1–8 from subsection 6.2.1

Step 2–8 (Rinsing of adsorber with priming solution)

2. Connect a 3-way stopcock to the adsorber inlet.
3. Connect an infusion line (spike) and a sterile syringe (50 mL) to the 3-way stopcock.
4. Connect the Luer Lock extension line (waste line) to the adsorber outlet.
5. Position the end of the waste line in a waste container.
6. Close the clamp on the waste line.
7. Connect the infusion line (spike) of the adsorber inlet to the priming solution bag.
8. Turn the 3-way stopcock to open the line to the priming solution bag and syringe. Make sure that the path to the adsorber is closed.

Step 9 (Rinsing of adsorber with priming solution)

9. Aspirate air into the syringe to create a vacuum.

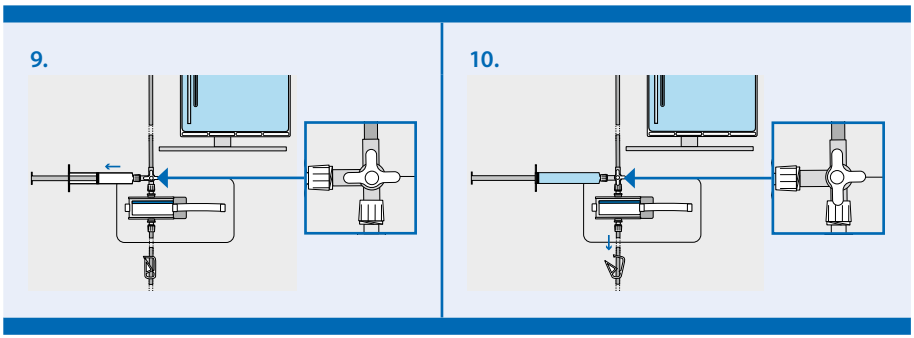


Figure 6.2: Step 9-10 from subsection 6.2.1

Step 10 (Rinsing of adsorber with priming solution)

10. Turn the 3-way stopcock to open the line between the priming solution line and the adsorber inlet. Make sure that the lateral exit to the syringe is closed and the waste line is open.

Step 11–15 (Rinsing of adsorber with priming solution)

11. Start rinsing by gravity (approximately 200 mL per 50 mL adsorber volume, approx. 500 mL per 100 mL adsorber volume or approx. 600 mL per 200 mL adsorber volume).

12. Disconnect infusion line (spike) from the adsorber inlet and leave the waste line on the adsorber outlet.

13. Disconnect syringe from 3-way stopcock

14. Continue with subsection 6.2.2.

15. Handle the second adsorber the same way as described above.

6.2.2 Rinsing of adsorber with elution buffer

Operator action:

Step 1 (Rinsing of adsorber with elution buffer)

1. Hang the elution buffer bag on the infusion stand of the instrument.

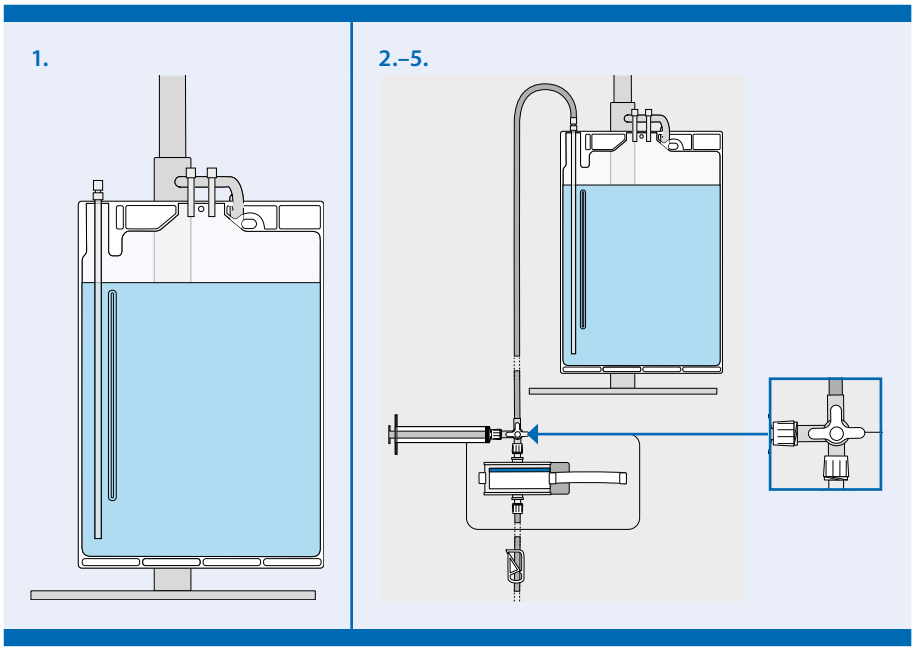


Figure 6.3: Step 1–5 from subsection 6.2.2

Step 2–5 (Rinsing of adsorber with elution buffer)

2. Connect a Luer Lock extension line (female/male Luer lock, e.g., Heidelberger extension line) and a sterile syringe (50 mL) to the 3-way stopcock.
3. Close the clamp on the waste line.
4. Connect the Luer Lock extension line of the adsorber inlet to the elution buffer bag.
5. Turn the 3-way stopcock to open the line to the elution buffer bag and syringe. Make sure that the path to the adsorber is closed.

Step 6 (Rinsing of adsorber with elution buffer)

6. Aspirate air into the syringe to create a vacuum.

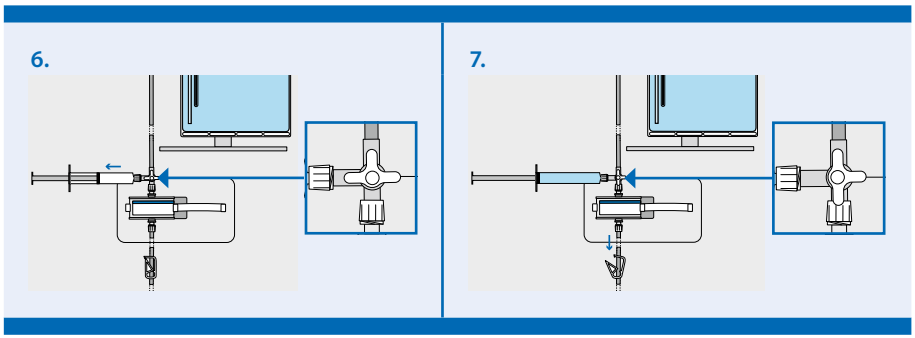


Figure 6.4: Step 6–7 from subsection 6.2.2

Step 7 (Rinsing of adsorber with elution buffer)

7. Turn the 3-way stopcock to open the line between the elution buffer line and the adsorber inlet. Make sure that the lateral exit to the syringe is closed and the waste line is open.

Step 8–13 (Rinsing of adsorber with elution buffer)

8. Start rinsing by gravity (approx. 500 mL per 50 mL adsorber volume, approx. 1,000 mL per 100 mL adsorber volume or approx. 2,000 mL per 200 mL adsorber volume).
9. Close the clamp on waste line.
10. Disconnect the Luer Lock extension line from the adsorber inlet.
11. Disconnect the 3-way stopcock with syringe from the adsorber inlet.
12. Continue with subsection 6.2.3.
13. Handle the second adsorber the same way as described above.

6.2.3 Preservation of adsorber pair with preservation buffer

Operator action:

- Hang one or two preservation buffer bottle(s) on the infusion stand.
- Close all clamps on the infusion line(s) with vented spike(s).
- Connect the vented spike(s) to the preservation buffer bottle(s).
- Open the ventilation caps on the vented spike(s).
- Connect the infusion line(s) to each adsorber inlet.
- Open the clamps on infusion line(s) and waste line(s).
- Start rinsing by gravity and rinse each adsorber with 500 mL per 50 mL or 1,000 mL per 100/200 mL adsorber volume).
- Remove the infusion line(s) and waste line(s) close each adsorber inlet and outlet with sterile stop caps (spare parts).
- Shake each adsorber vigorously before storage.
- Store the adsorber pair clicked into the adsorber holder at +2 °C to +8 °C (+36 °F to +46 °F) in the refrigerator.

6.3 Exchange of disk separator

A disk separator replacement might need to be performed for the following reasons:

- ruptured membrane of the disk separator
- hemolysis
- inefficient or no plasma flow

The following components are needed to replace the disk separator:

- one disk separator TheraSorb - DS 100 (spare part)
- one NaCl bag, for infusion (min. 250 mL)
- one infusion set (drip line)
- three tubing clamps
- one container for fluid collection (e.g., kidney bowl)

Operator action:

Step 1 (Exchange of disk separator)

1. Disconnect the separator pressure lines from EX3 (yellow) and EX4 (white).

Step 2 (Exchange of disk separator)

2. Clamp off all three separator-side lines (red, blue, yellow).

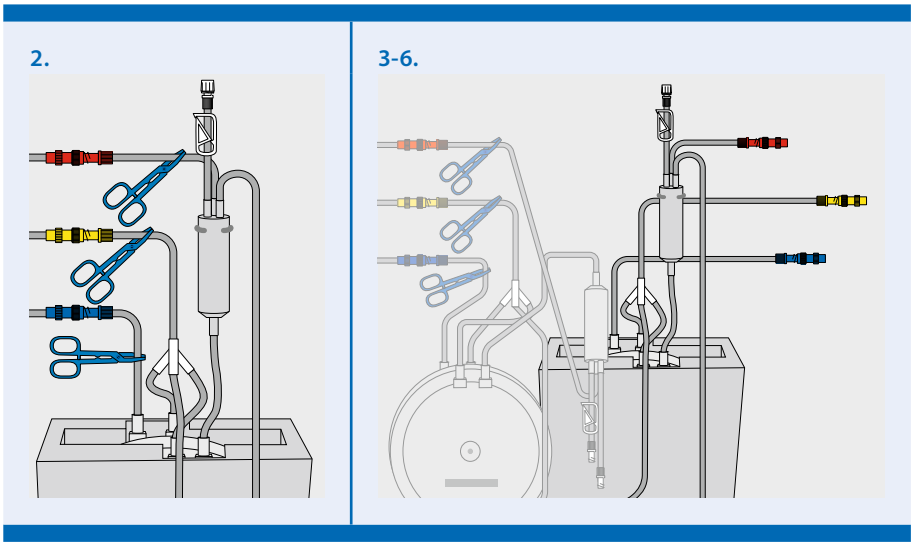


Figure 6.5: Step 2-6 from section 6.3

Step 3–6 (Exchange of disk separator)

3. Leave the separator-side lines connected to the tubing set and remove the disk separator from the separator drive.
4. Insert the new disk separator into the separator drive with labeling onwards.
5. Click the separator drip chamber into the holder.
6. Close the clamp on the separator drip chamber service line.

Step 7 (Exchange of disk separator)

7. Connect the pressure lines of the new disk separator to EX3 (yellow) and EX4 (white). Carefully tighten the connections to the external pressure sensors EX3 and EX4 and hydrophobic filters. Do not overtighten!

Step 8–11 (Exchange of disk separator)

8. Connect the infusion set to the NaCl bag.
9. Connect the red line of the new disk separator to the infusion set.
10. Connect a hydrophobic filter to the service line of the separator.
11. Place a kidney bowl underneath the blue and yellow separator lines to collect spilled fluid.

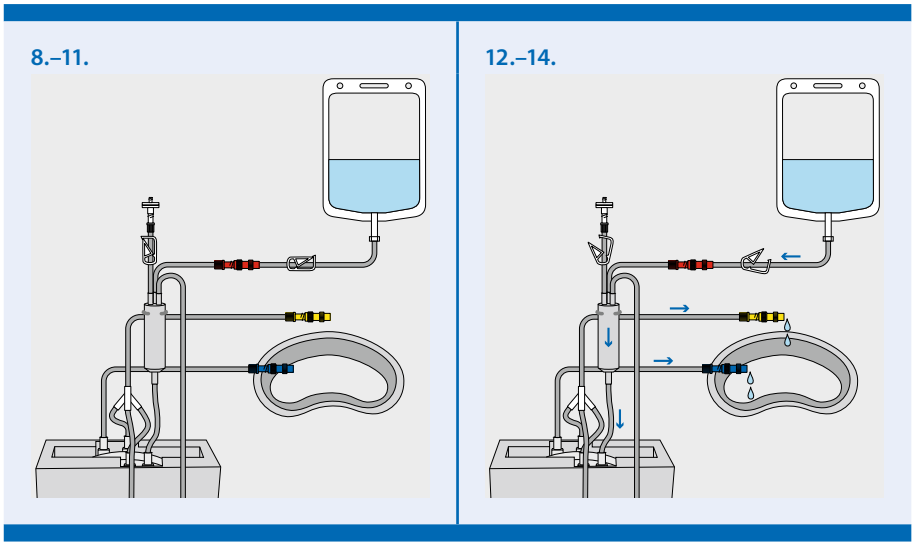


Figure 6.6: Step 8–14 from section 6.3

Step 12–14 (Exchange of disk separator)

12. Open the clamp on the infusion set and disk separator service line.
13. After the drip chamber is filled close the clamp on the disk separator service line.
14. Continue the filling of the separator until the blue and yellow separator lines are filled completely.

Step 15–16 (Exchange of disk separator)

15. Close the clamp on the infusion set.

16. Disconnect the old disk separator-side lines (first blue, second yellow, third red) one after the other and replace with the new disk separator-side lines in the same order.

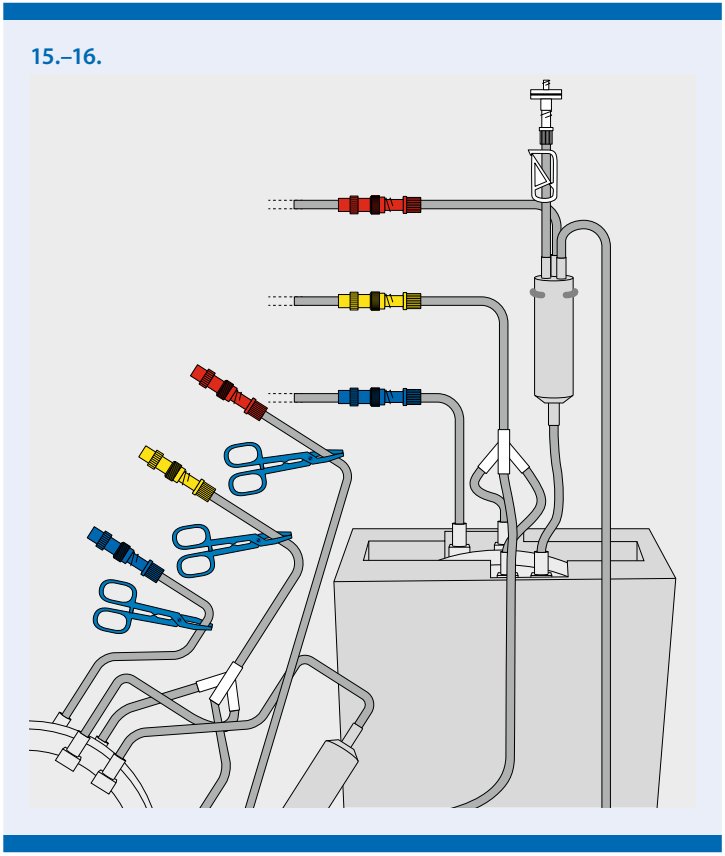


Figure 6.7: Step 15–16 from section 6.3

Step 17–18 (Exchange of disk separator)

17. Check if drip chamber and lines to the disk separator are filled with fluid.

18. Press **OK** to continue treatment.

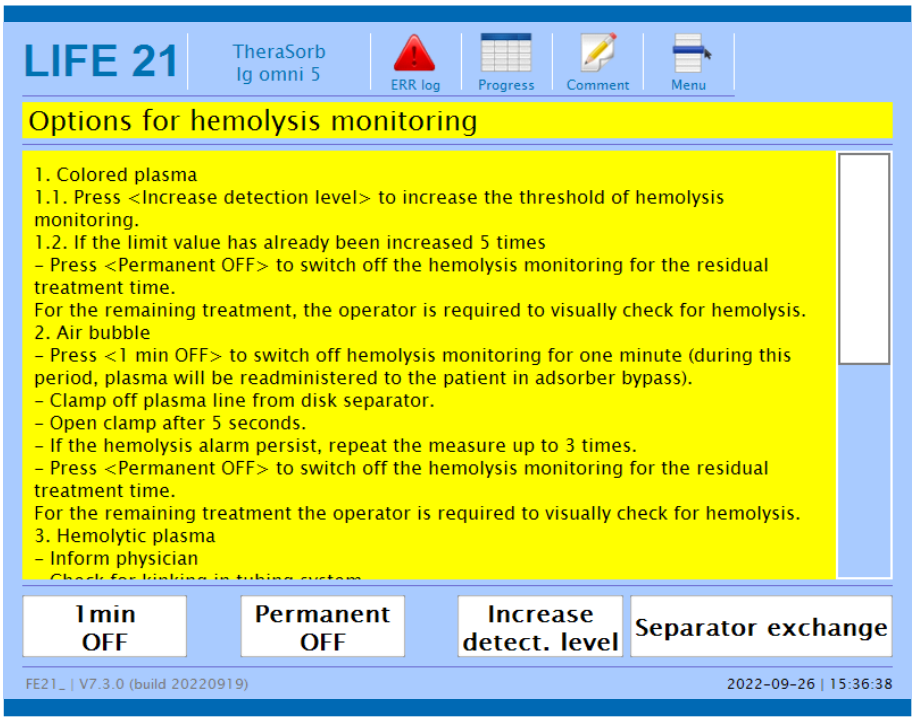
⚠ WARNING

Risk of blood leakage. Rupture of the plasma filter membrane causes a blood leak. Negative pressure can rupture the membrane in the disk separator. Make sure that the drip chamber is filled with liquid. Do not deaerate the disk separator via aspiration with a syringe. Never prime the disk separator outside of the separator drive.

After continuation of the process the new disk separator is filled with blood first. Priming solution is infused into the patient. During this period no plasma is separated. After the pumps restart, another blood leak or hemolysis alarm may be set off. This is attributable to residual hemoglobin in the tubing segment in front of the hemolysis sensor and requires a 1min suppressing of the blood leakage detection (see Screen 6.1).

Operator action:

- To suppress the hemolysis alarm for one minute press **1 min OFF**.



Screen 6.1: Options for hemolysis monitoring

6.4 Empty disk separator drip chamber

A completely air-filled disk separator drip chamber might lead to air entry into the disk separator. This can reduce separation efficiency and might lead to unspecific alarms.

Operator action:

- Attach a sterile syringe to the service line.
- Open the clamp in the service line. The service line should automatically deaerate into the syringe.
- If not, carefully aspirate air with the syringe.
- Close the clamp in the service line and remove syringe.

⚠ WARNING

Risk of blood leakage. Rupture of the plasma filter membrane causes a blood leak. If the separator drip chamber runs dry, attach a sterile syringe to the service line. Then start the treatment again and carefully aspirate air with the syringe. Close the clamp in the service line after completing the aspiration.

6.5 Noisy disk separator

Air in the disk separator might be the underlying cause when the disk separator emits noises during set-up or treatment.

Operator action:

- Press **TMP** on the treatment screen.
- Write down the value for the TMP.
- Enter “0” mbar as a value.
- Press **OK** to confirm the changed value.
- Lift the disk separator 3 cm out of separator drive and slightly turn it towards the right side until the blood cell line (blue) is in a vertical position to allow for the release of the air into the venous drip chamber.
- Position the disk separator correctly back into the separator drive.
- Press **TMP** on the treatment screen.
- Enter the written down value for TMP.
- Press **OK** to confirm the new value.

6.6 Notification: no plasma flow

If no plasma flow occurs, a periodic acoustical signal is set off. Additionally, a notice is shown on the status line of the treatment screen.

Operator action:

- Check that **TMP** is set above “0”.
- Check the disk separator lines for kinks.
- Check if the hydrophobic filter at the external pressure sensors EX3 or EX4 is wet. If the filters are wet see subsection 6.11.3 and subsection 6.11.4, respectively.
- Press **TMP** on the treatment screen.
- Write down the value set for TMP before entering “0” mbar.
- Press **OK** to confirm the changed value.
- Wait until the TMP has been reduced to “0”.
- Press **TMP** on the treatment screen.
- Enter “40” mbar as a value.
- Press **OK** to confirm the changed value.
- Wait for 10 seconds and watch for plasma flow.
- Increase the TMP value stepwise until the above noted TMP value has been reached.
- If there is still no plasma, the disk separator must be exchanged (see section 6.2 “Manual adsorber regeneration and preservation”).

6.7 Removal of air from blood return line

If air is suspected in the blood return line, the air must be removed before the air detector alarm is confirmed and the treatment is continued.

⚠ WARNING

Risk of embolism. Air in the blood return line, especially at a point beyond the air detector, can enter the patient's circulatory system and cause air embolism. Remove the air from the tubing segment as described.

Operator action:

Step 1–3 (Removal of air from blood return line)

1. Connect a sterile syringe filled with 10 mL NaCl to the lateral exit of the blood return line.
2. Close the patient access.
3. Turn the 3-way stopcock of the blood return line to open the lateral exit.

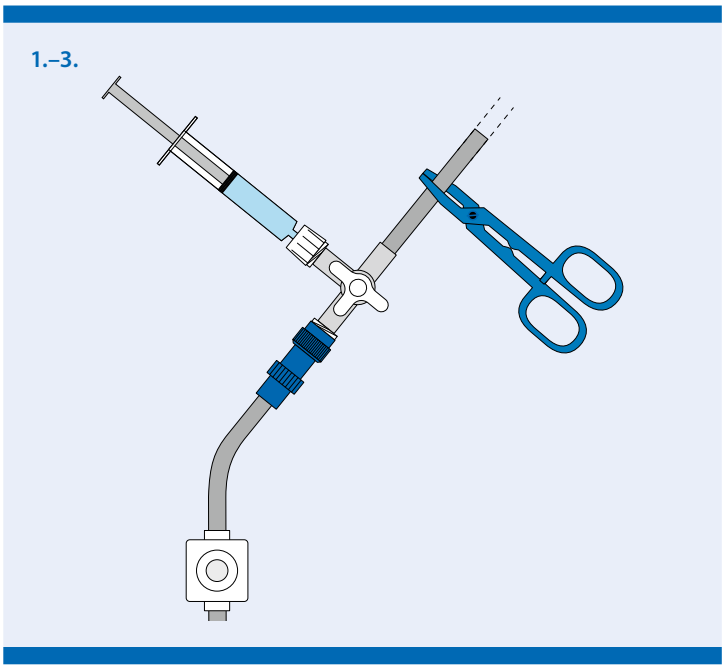


Figure 6.8: Step 1–3 from section 6.7

Step 4–5 (Removal of air from blood return line)

4. Close the clamp on the venous drip chamber service line.
5. Remove the hydrophobic filter on the venous drip chamber.

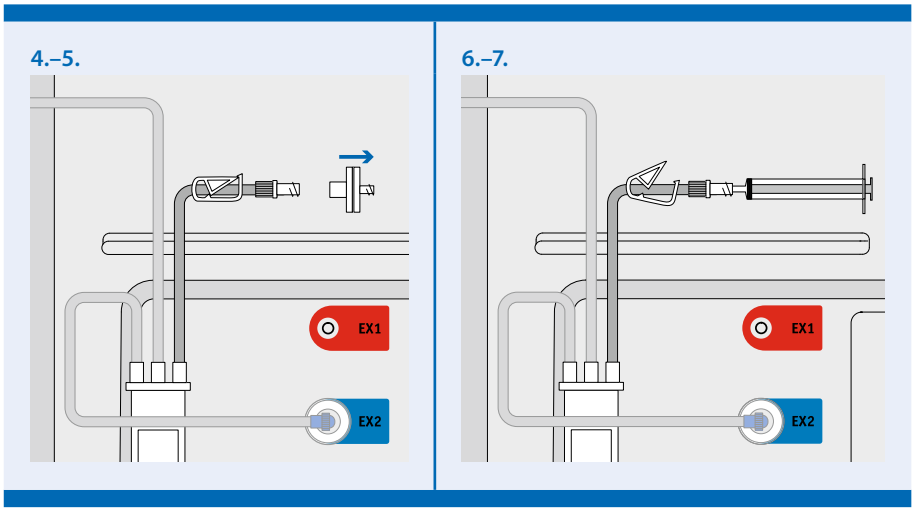


Figure 6.9: Step 4–7 from section 6.7

Step 6–7 (Removal of air from blood return line)

6. Connect an empty 10 mL sterile syringe to the venous drip chamber service line.
7. Open the clamp on the venous drip chamber service line.

Step 8 (Removal of air from blood return line)

8. Carefully administer NaCl solution into the blood return line until the venous drip chamber is filled.

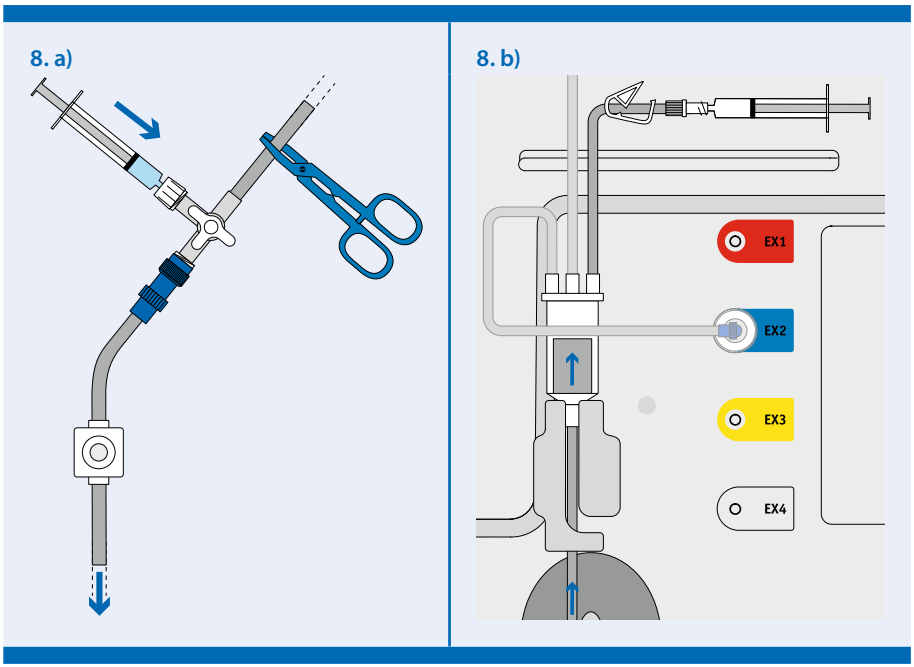


Figure 6.10: Step 8 from section 6.7

Step 9 (Removal of air from blood return line)

9. Close the clamp at the venous drip chamber service line.

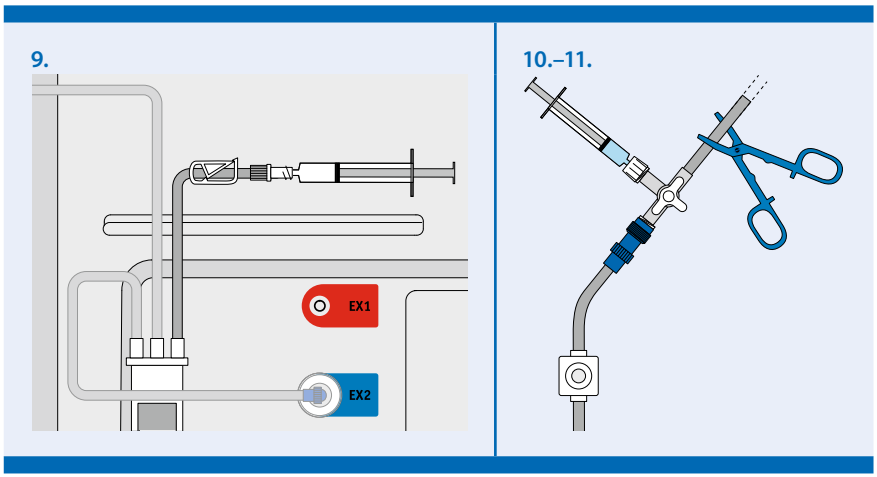


Figure 6.11: Step 9–11 from section 6.7

Step 10–11 (Removal of air from blood return line)

10. Turn the 3-way stopcock of the blood return line to close the lateral exit.

11. Open the patient access.

Step 12 (Removal of air from blood return line)

12. Press **CONFIRM**, **RESTART** and process at least 100 mL of blood volume without further alarms before the syringes are removed. After removal, close the lateral exit and venous drip chamber service line with a sterile cap.

6.8 Hemolytic plasma suspected

A hemolysis alarm interrupts the treatment if reddish colored plasma in the separator´s plasma line is detected. Possible causes could be:

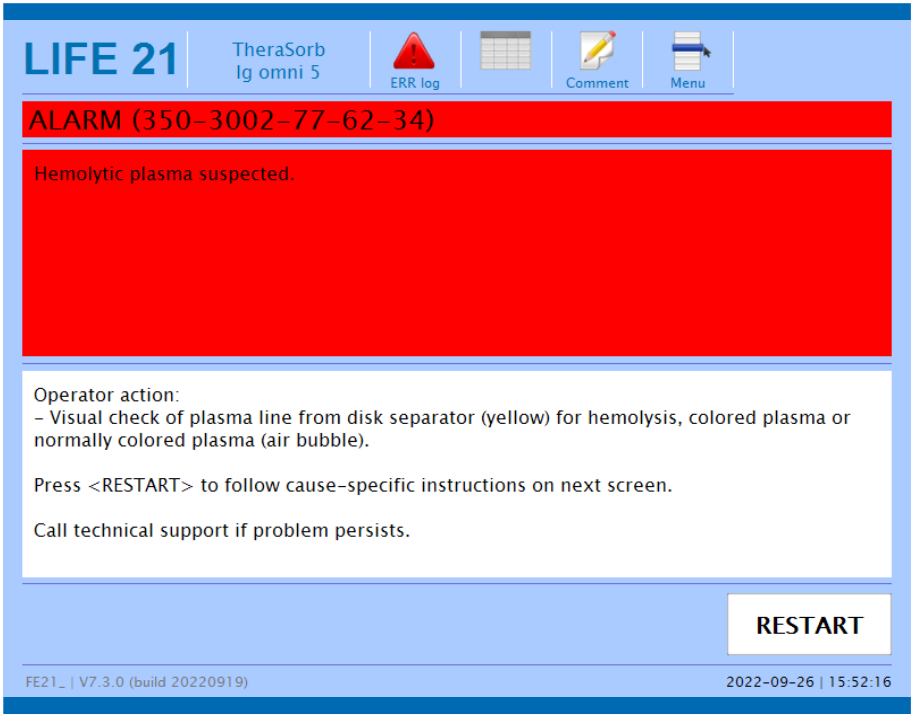
- hemolysis
- lipemic plasma (high triglycerides)
- high bilirubin
- dark plasma
- air bubbles at hemolysis sensor

IMPORTANT

Only the color of the plasma is detected, not the presence of free hemoglobin. Therefore, first identify the underlying cause for the color change.

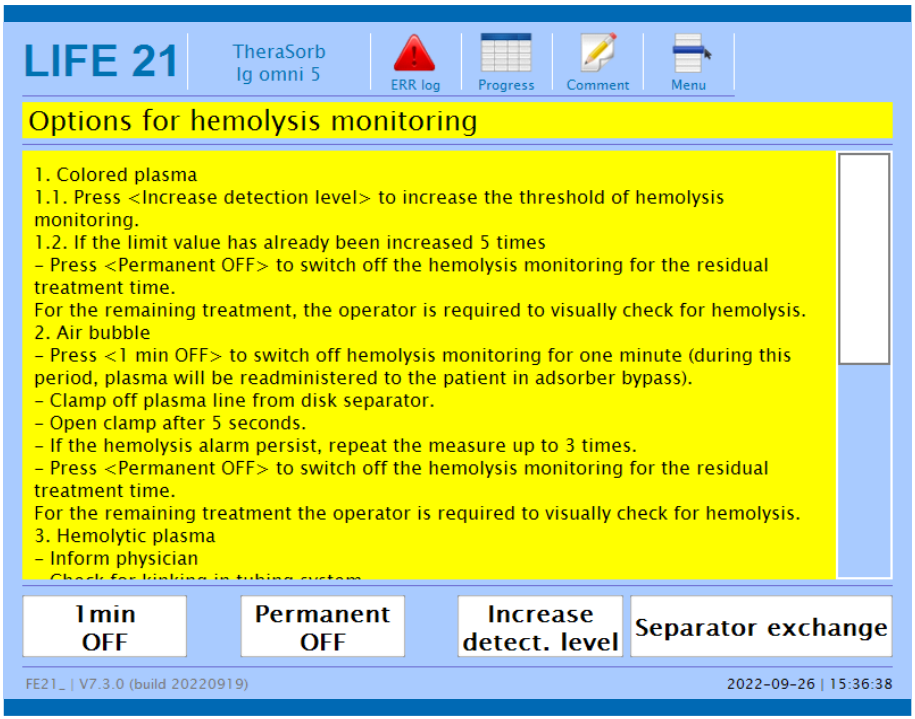
Operator action:

- Observe the instructions given on the Screen 6.2.
- The complete error code shown on the screen should be noted for later reference.

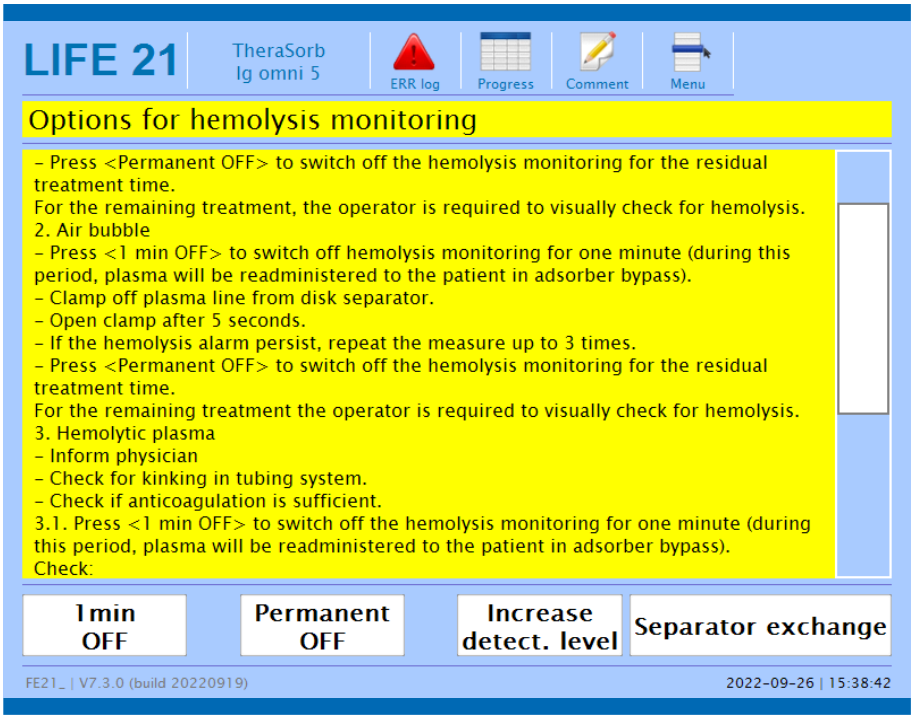


Screen 6.2: Representative hemolysis alarm screen

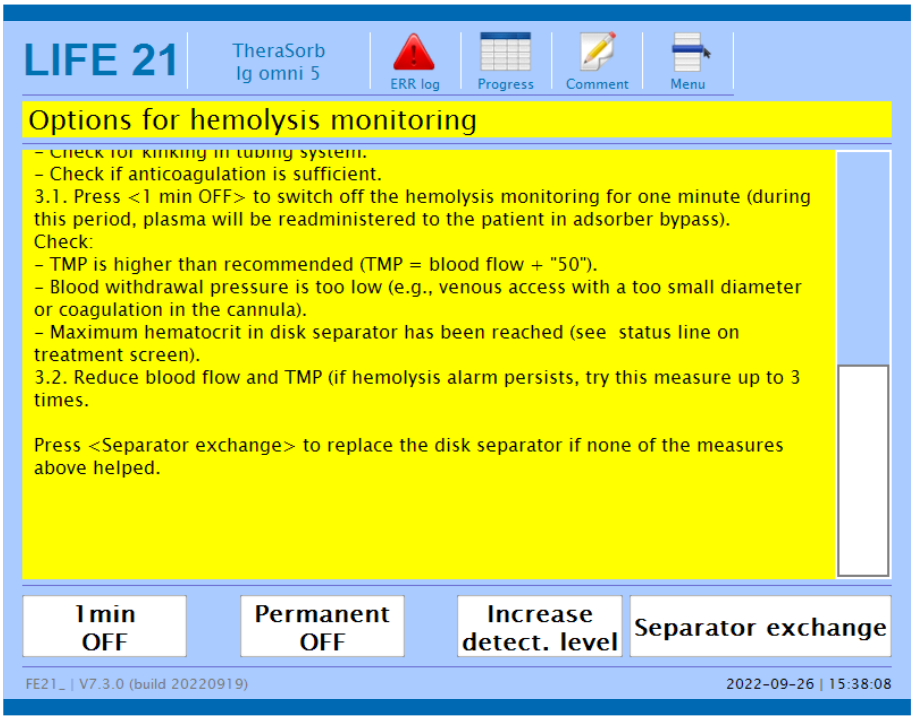
- After the visual check has been completed, press **RESTART** to get cause-specific instructions (see Screen 6.3, Screen 6.4, and Screen 6.5).



Screen 6.3: Options (1.–2.) for hemolysis monitoring



Screen 6.4: Options (2.–3.) for hemolysis monitoring



Screen 6.5: Options (3.1.–3.2.) for hemolysis monitoring

IMPORTANT

When the option **1 min OFF** *has been chosen, the separated plasma is redelivered to the patient via the bypass pump for the duration of 1 minute without being passed over the active plasma loaded adsorber. The remaining time of suspension of hemolysis detection is displayed in the right third of the treatment screen.*

If the hemolysis alarm is completely deactivated, no further control of the plasma color for hemolysis is performed by the system. No alarm will be set off if a further hemolysis occurs or plasma becomes reddishly colored. In therapeutic plasma exchange (TPE), hemolytic plasma will be discarded into the waste bag. Free hemoglobin will thus be removed and replaced with hemoglobin-free solutions. In adsorption treatments, hemolytic plasma will be passed over the active plasma-loaded adsorber and may damage the adsorber. It is therefore of utmost importance to observe the color of the plasma carefully to detect any further increases or persistence of the hemolysis.

⚠ CAUTION

Risk of hemolysis or insufficient treatment (damage to the adsorber). The adsorber can be damaged by the hemolytic plasma. Carefully maintain control of the system to notice any hemolysis occurring.

6.9 Blood leakage in disk separator suspected

A blood leak alarm interrupts the treatment if dark red colored plasma in the separator´s plasma line is detected. Possible causes could be:

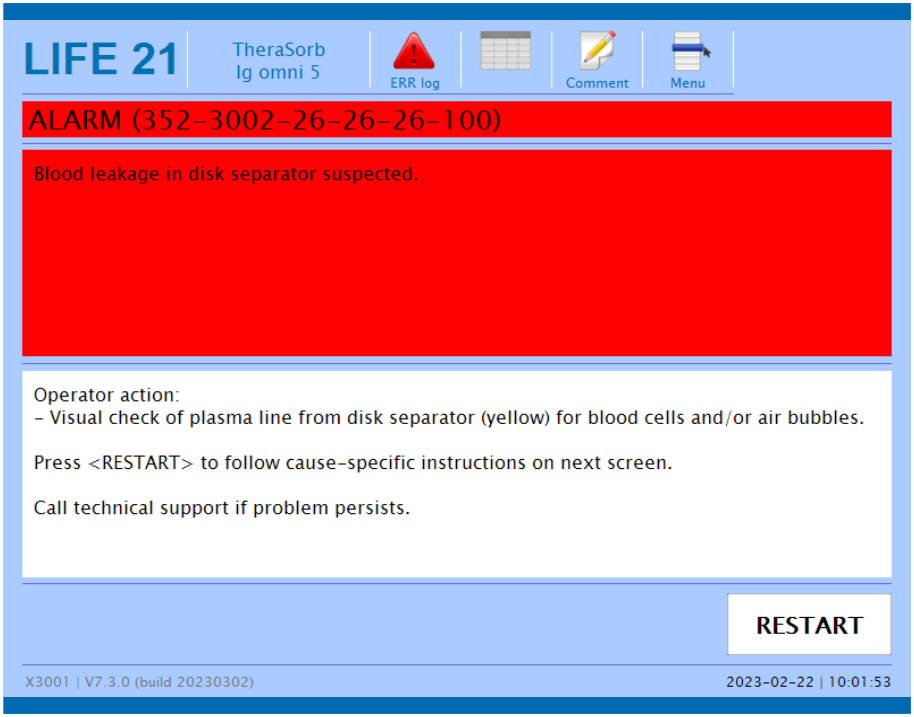
- membrane rupture of the disk separator
- air bubbles at hemolysis sensor

IMPORTANT

Only the color of the plasma is detected, not the presence of red blood cells. Therefore, first identify the underlying cause for the color change.

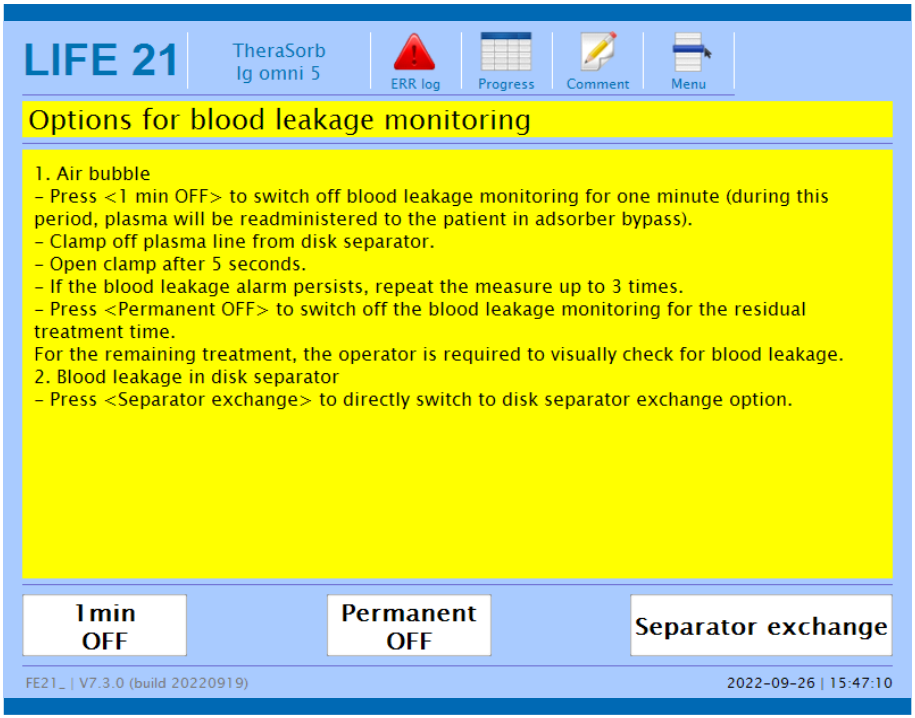
Operator action:

- Observe the instructions given on the Screen 6.6.
- The complete error code shown on the screen should be noted for later reference.



Screen 6.6: Representative blood leakage alarm screen

- After the visual check has been completed, press **RESTART** to get cause-specific instructions (see Screen 6.7).



Screen 6.7: Options for blood leakage monitoring

⚠ WARNING

Risk of blood leakage. If the blood leak control is completely deactivated, no further control of the plasma color is performed by the system. No alarm will be set off if a further blood leak occurs. Therefore, maintain control of the system to notice any blood leakage occurring.

6.10 Calibration of hemolysis sensor failed

After the completion of the priming procedure, the hemolysis sensors 9 and 10 are calibrated. An alarm is shown if the calibration has failed.
The complete error code shown on the screen should be noted for later reference.

The underlying cause for the alarm could be:

- Plasma line (yellow) from disk separator affected.
- Cell concentrate line (blue) from disk separator affected.
- Air in plasma line (yellow) from disk separator.
- Air in cell concentrate line (blue) from disk separator.

6.10.1 Plasma line (yellow) from disk separator affected

Operator action:

Step 1 (Plasma line [yellow] from disk separator affected)

1. Clamp off the plasma line from the disk separator.

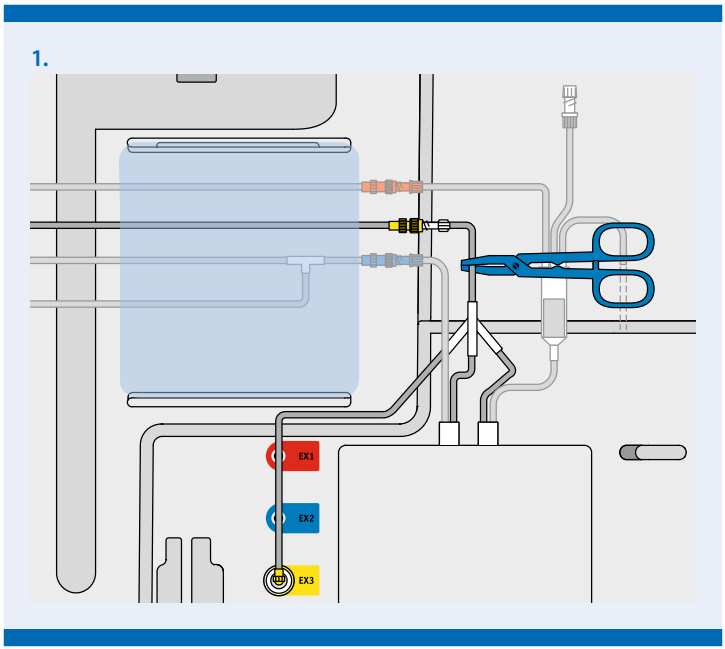


Figure 6.12: Step 1 from subsection 6.10.1

Step 2–4 (Plasma line [yellow] from disk separator affected)

2. Press **RESTART** to start the pumps.
3. Open the clamp after 5 seconds.
4. Repeat measures up to 3 times.

6.10.2 Cell concentrate line (blue) from disk separator affected

Operator action:

Step 1 (Cell concentrate line [blue] from disk separator affected)

1. Clamp off the cell concentrate line from the disk separator.

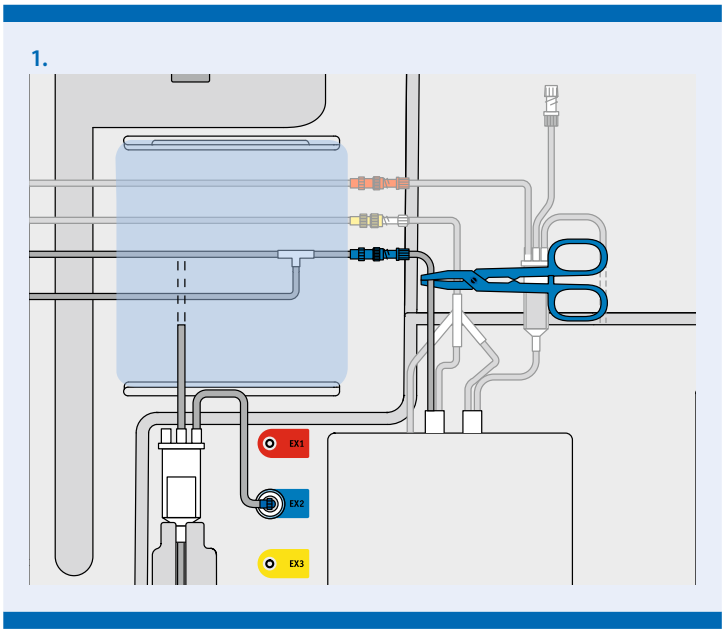


Figure 6.13: Step 1 from subsection 6.10.2

Step 2–4 (Cell concentrate line [blue] from disk separator affected)

2. Press **RESTART** to start pumps.
3. Open the clamp after 5 seconds.
4. Repeat measures up to 3 times.

If the problem persists, continue with the following measures described in subsection 6.10.3 and 6.10.4.

6.10.3 Air in plasma line (yellow) from disk separator

Operator action:

Step 1 (Air in plasma line [yellow] from disk separator affected)

1. Clamp off the plasma line underneath the yellow connector.

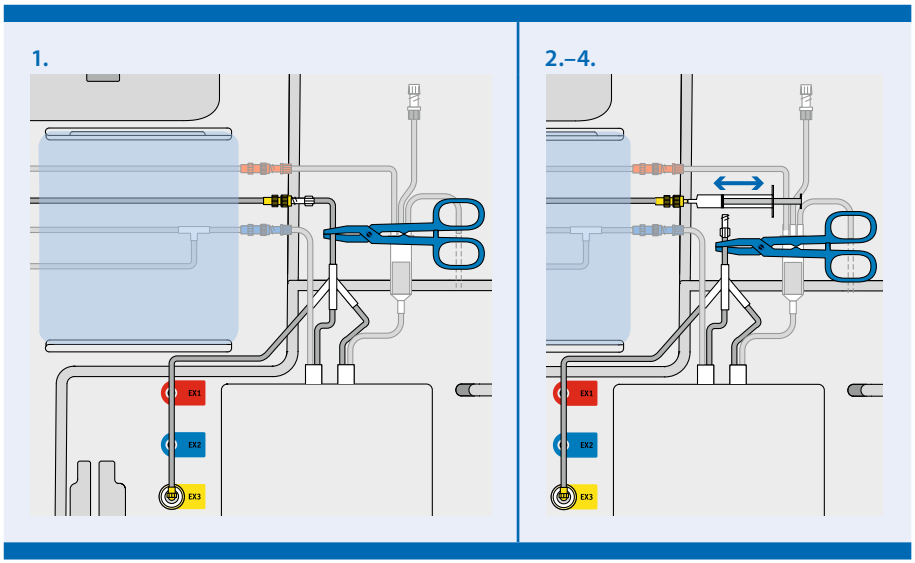


Figure 6.14: Step 1–4 from subsection 6.10.3

Step 2–4 (Air in plasma line [yellow] from disk separator affected)

2. Open the connector.
3. Connect a 5 mL sterile syringe to the plasma line (yellow) descending from the tubing set carrier.
4. Carefully move the plunger several times up and down.

Step 5–6 (Air in plasma line [yellow] from disk separator affected)

5. Remove the sterile syringe and reconnect the plasma line.
6. Press RESTART to start the pumps.

6.10.4 Air in cell concentrate line (blue) from disk separator

Operator action:

Step 1 (Air in cell concentrate line [blue] from disk separator affected)

1. Clamp off the plasma line underneath the blue connector.

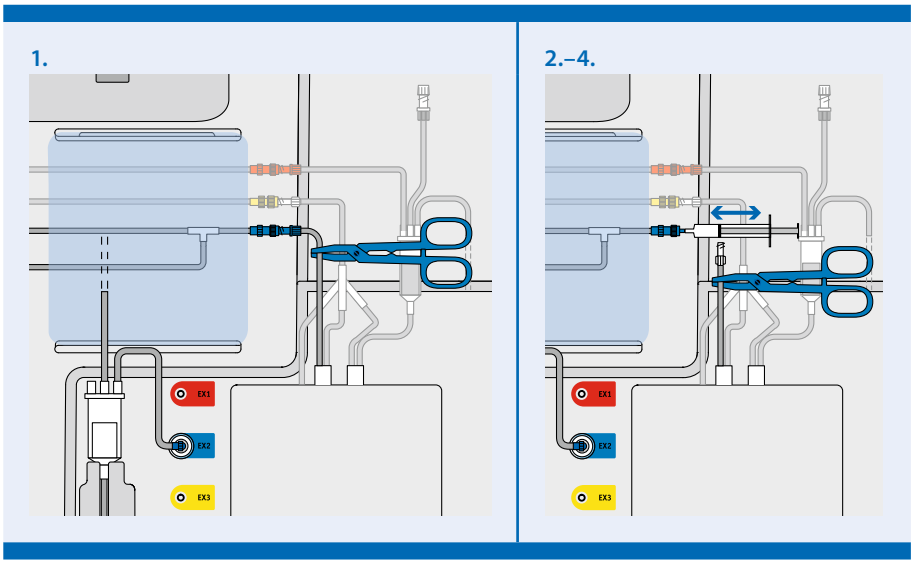


Figure 6.15: Step 1–4 from subsection 6.10.4

Step 2–4 (Air in cell concentrate line [blue] from disk separator affected)

2. Open the connector.
3. Connect a 5 mL sterile syringe to the plasma line (blue) descending from the tubing set carrier.
4. Carefully move the plunger several times up and down.

Step 5–7 (Air in cell concentrate line [blue] from disk separator affected)

5. Remove the sterile syringe and reconnect the plasma line (blue).
6. Remove the clamp from the plasma line.
7. Press **RESTART** to start the pumps.

If the error persists, a new treatment must be started.

6.11 External pressure sensor alarms

The external pressure sensors (EX1–EX4) are located between the air detector and the separator drive.
If the blood withdrawal flow is higher than 15 mL/min the pressure at all external sensors EX1–EX4 is monitored for continuous pressure fluctuation. A lack of pressure fluctuation can occur due to wet hydrophobic filters or blocked tubing lines. The following subsections describe the exchange of a wet hydrophobic filter in detail.

⚠ WARNING

Risk of vascular damage, cell loss and hemolysis. A blocked filter prevents correct measurement of the pressure limits within the plasma separator and the patient lines. Observe blood return and withdrawal line when they are open to the patient.

6.11.1 Hydrophobic filter at pressure line EX1 (red) wet

Operator action:

Step 1–2 (Hydrophobic filter at pressure line EX1 [red] wet)

1. Turn the 3-way stopcock of the blood withdrawal line to open the lateral exit.
2. Connect a 5 mL sterile syringe to the lateral exit.

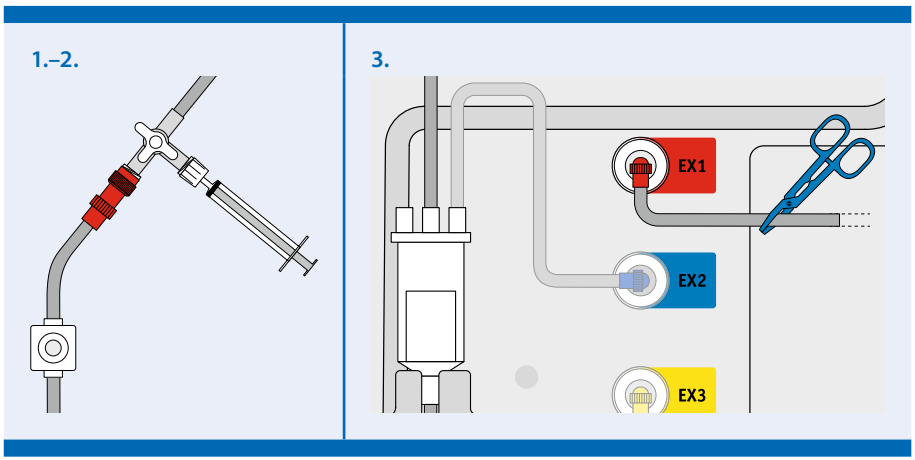


Figure 6.16: Step 1–3 from subsection 6.11.1

Step 3 (Hydrophobic filter at pressure line EX1 [red] wet)

3. Clamp off the pressure line to EX1.

Step 4 (Hydrophobic filter at pressure line EX1 [red] wet)

4. Connect an air-filled 5 mL sterile syringe to the hydrophobic filter of pressure line.

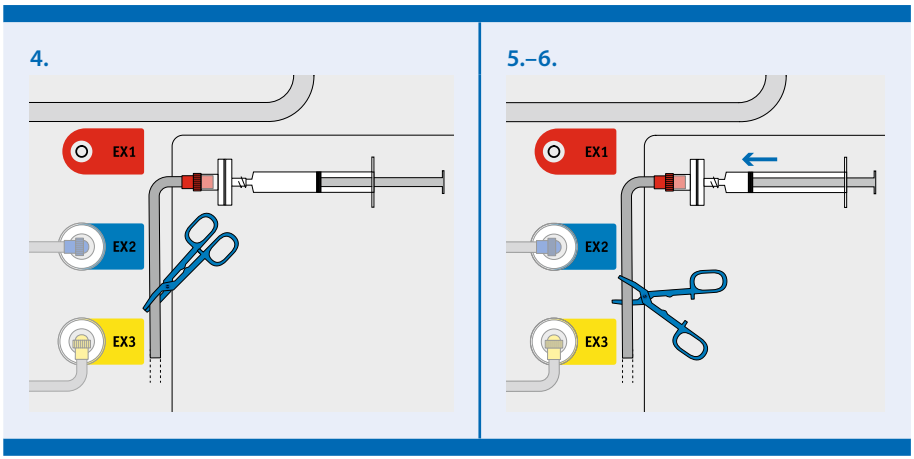


Figure 6.17: Step 4–6 from subsection 6.11.1

Step 5–6 (Hydrophobic filter at pressure line EX1 [red] wet)

5. Open the clamp on the pressure line.
6. Carefully press air into the pressure line.

Step 7–11 (Hydrophobic filter at pressure line EX1 [red] wet)

7. Clamp off the pressure line and remove the sterile syringe.
8. Exchange the hydrophobic filter with a spare part.
9. Reconnect the pressure line to EX1 (red).
10. Remove the clamp from the pressure line.
11. Close the lateral exit on the blood withdrawal line and remove the sterile syringe.

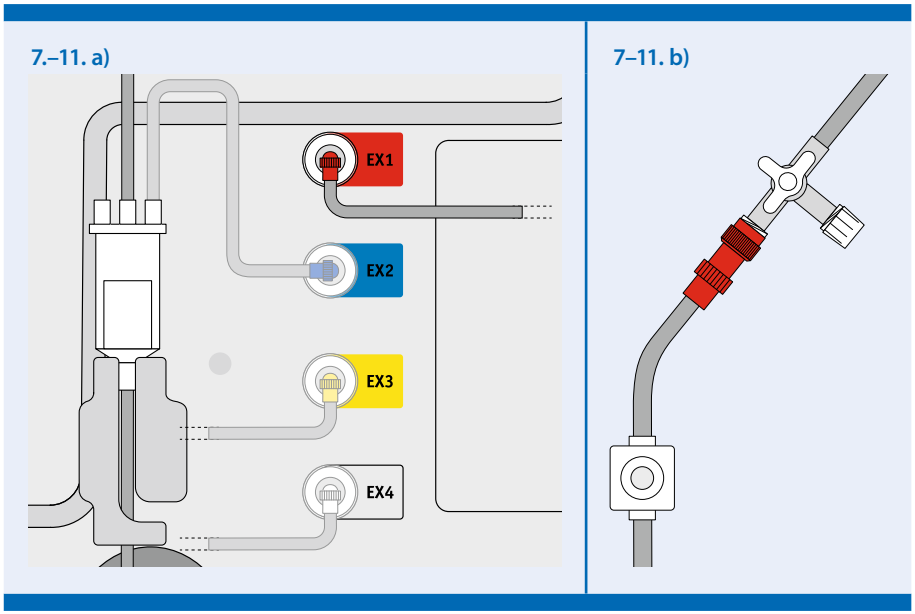


Figure 6.18: Step 7–11 from subsection 6.11.1

6.11.2 Hydrophobic filter at pressure line EX2 (blue) wet

Operator action:

Step 1 (Hydrophobic filter at pressure line EX2 [blue] wet)

1. Clamp off the blood return line underneath the venous drip chamber.

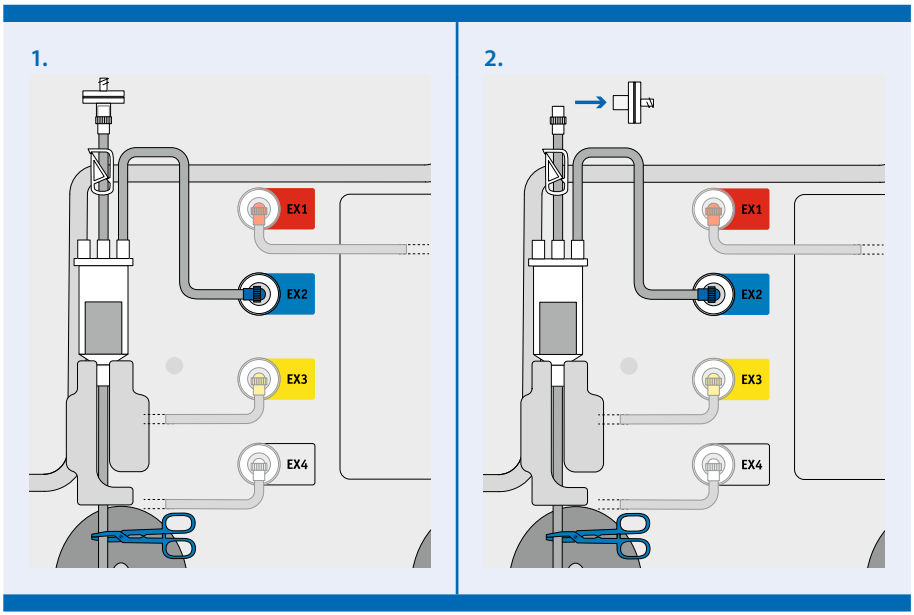


Figure 6.19: Step 1-2 from subsection 6.11.2

Step 2 (Hydrophobic filter at pressure line EX2 [blue] wet)

2. Remove the hydrophobic filter from the venous drip chamber service line.

Step 3–5 (Hydrophobic filter at pressure line EX2 [blue] wet)

3. Connect a 5 mL sterile syringe to the service line.
4. Open the clamp on the service line.
5. Clamp off the pressure line to EX2.

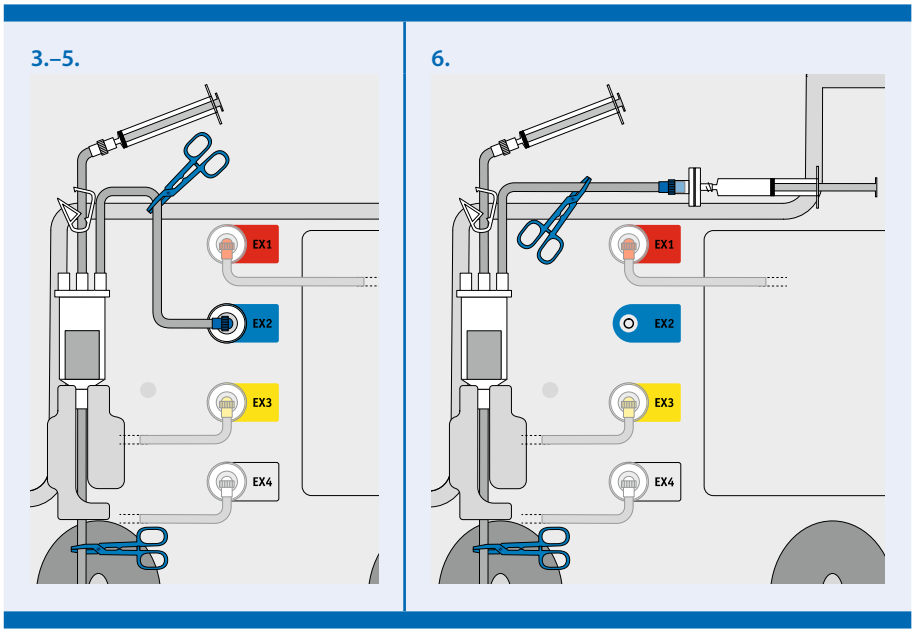


Figure 6.20: Step 3–6 from subsection 6.11.2

Step 6 (Hydrophobic filter at pressure line EX2 [blue] wet)

6. Connect an air-filled 5 mL sterile syringe to the hydrophobic filter of the pressure line.

Step 7–8 (Hydrophobic filter at pressure line EX2 [blue] wet)

7. Open the clamp on the pressure line.
8. Carefully press air into the pressure line.

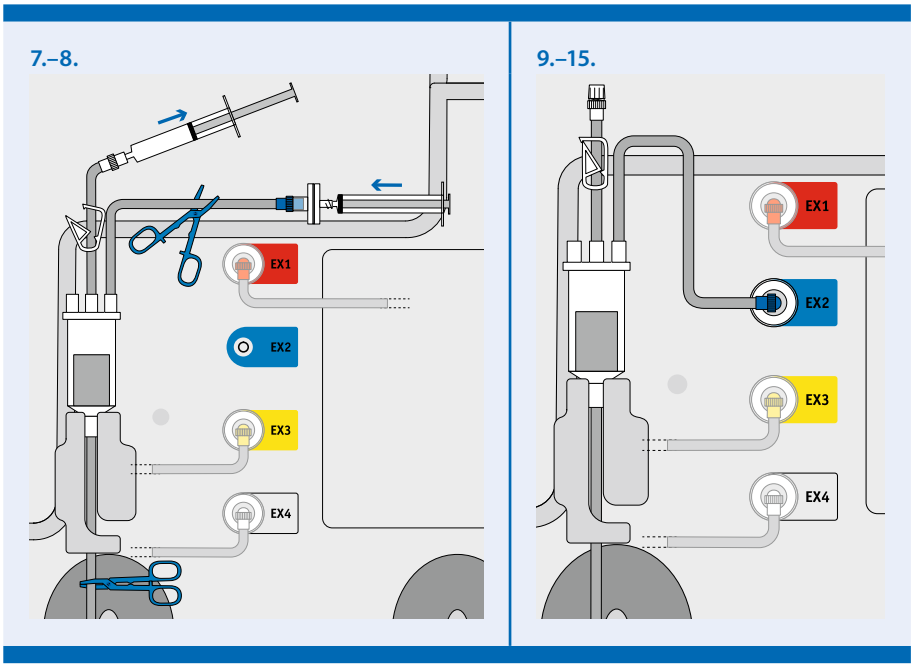


Figure 6.21: Step 7–15 from subsection 6.11.2

Step 9–15 (Hydrophobic filter at pressure line EX2 [blue] wet)

9. Clamp off the pressure line and remove the sterile syringe.
10. Exchange the hydrophobic filter with a spare part.
11. Reconnect the pressure line to EX2.
12. Remove the clamp from the pressure line.
13. Close the clamp on the venous drip chamber service line.
14. Remove the sterile syringe from the service line and close the line with a cap.
15. Remove the clamp from the blood return line underneath the venous drip chamber.

6.11.3 Hydrophobic filter at pressure line EX3 (yellow) wet

Operator action:

Step 1–2 (Hydrophobic filter at pressure line EX3 [yellow] wet)

1. Clamp off both plasma lines coming directly out of the disk separator.
2. Clamp off the disk separator plasma line underneath the yellow connector.

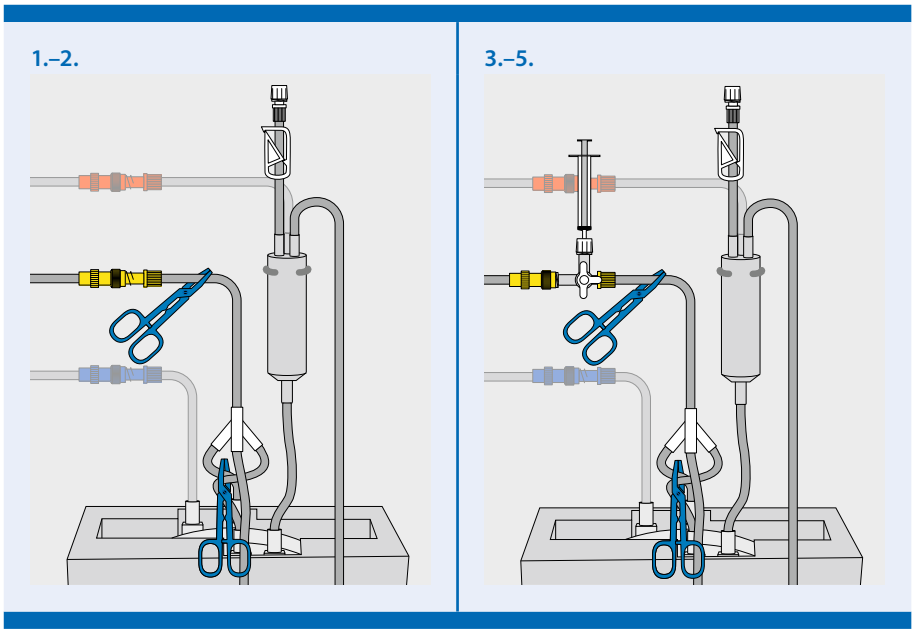


Figure 6.22: Step 1–5 from subsection 6.11.3

Step 3–5 (Hydrophobic filter at pressure line EX3 [yellow] wet)

3. Connect a 3-way stopcock in between the yellow connectors.
4. Connect a 5 mL sterile syringe to the lateral exit of the 3-way stopcock.
5. Open the 3-way stopcock to enable free flow of fluid from the disk separator plasma line to the sterile syringe.

Step 6 (Hydrophobic filter at pressure line EX3 [yellow] wet)

6. Remove the clamp on the disk separator plasma line underneath the yellow connector.

Step 7 (Hydrophobic filter at pressure line EX3 [yellow] wet)

7. Clamp off the pressure line to EX3.

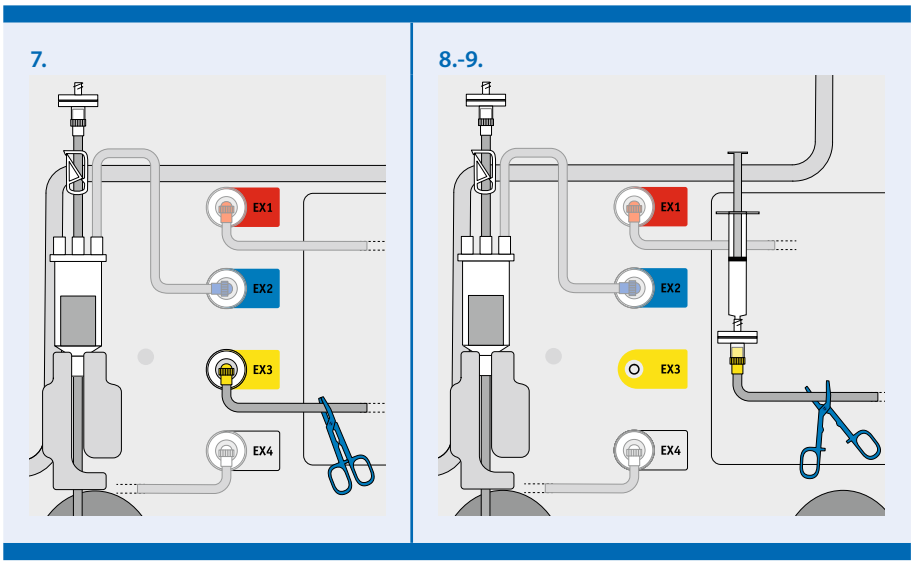


Figure 6.23: Step 7–9 from subsection 6.11.3

Step 8–9 (Hydrophobic filter at pressure line EX3 [yellow] wet)

8. Connect an air-filled 5 mL sterile syringe to the hydrophobic filter of the pressure line.

9. Open the clamp on the pressure line.

Step 10 (Hydrophobic filter at pressure line EX3 [yellow] wet)

10. Carefully press air into the pressure line.

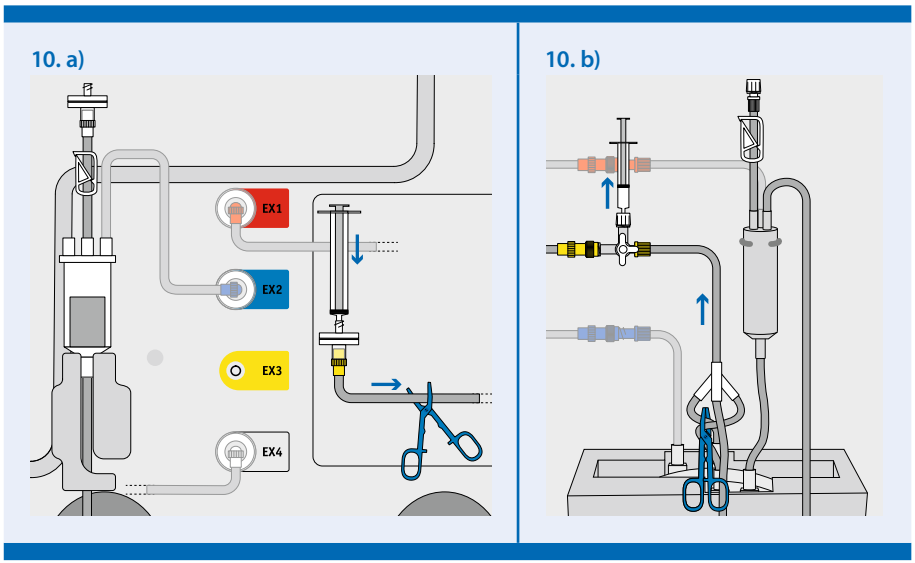


Figure 6.24: Step 10 from subsection 6.11.3

Step 11–14 (Hydrophobic filter at pressure line EX3 [yellow] wet)

11. Clamp off the pressure line and remove the sterile syringe.
12. Exchange the hydrophobic filter with a spare part.
13. Reconnect the pressure line to EX3 (yellow).
14. Remove the clamp from the pressure line.

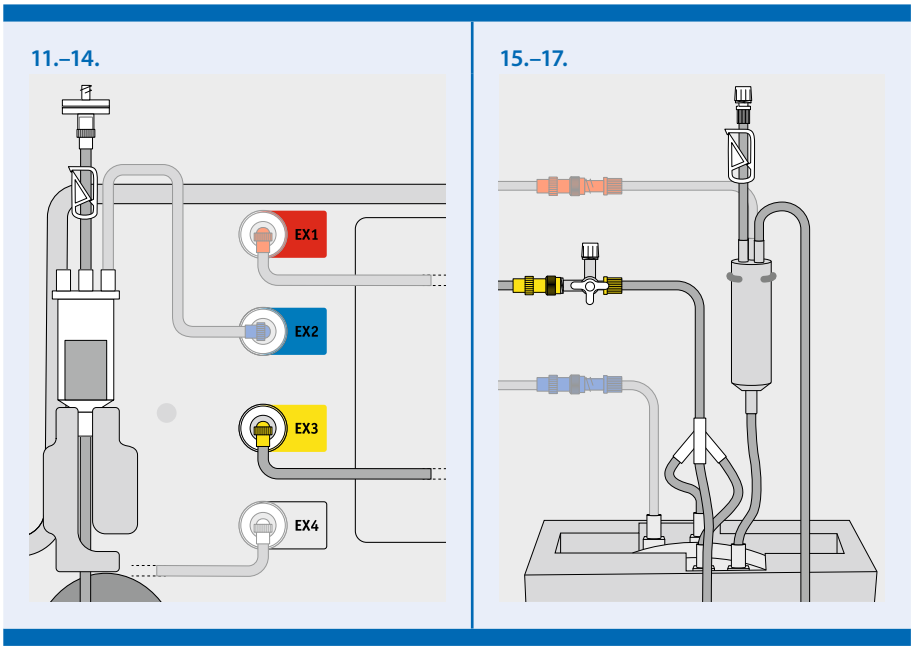


Figure 6.25: Step 11–17 from subsection 6.11.3

Step 15–17 (Hydrophobic filter at pressure line EX3 [yellow] wet)

15. Rotate the 3-way stopcock to close the lateral exit. The fluid-pass through plasma line opens.
16. Remove the sterile syringe from the 3-way stopcock and close the lateral exit with a cap.
17. Remove the clamp at both plasma lines coming directly out of the disk separator.

6.11.4 Hydrophobic filter at pressure line EX4 (white) wet

Operator action:

Step 1–4 (Hydrophobic filter at pressure line EX4 [white] wet)

1. Remove the cap from the disk separator drip chamber service line.
2. Connect a 5 mL sterile syringe to the service line.
3. Open the clamp on the service line.
4. Clamp off the line underneath the separator drip chamber.

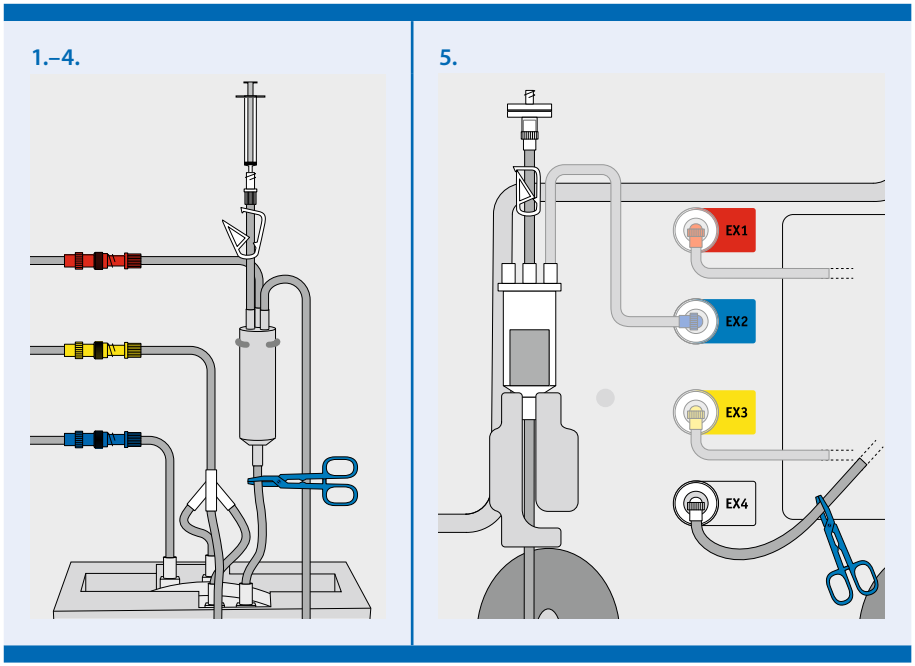


Figure 6.26: Step 1–5 from subsection 6.11.4

Step 5 (Hydrophobic filter at pressure line EX4 [white] wet)

5. Clamp off the pressure line to EX4.

Step 6 (Hydrophobic filter at pressure line EX4 [white] wet)

6. Connect an air-filled 5 mL sterile syringe to the hydrophobic filter of the pressure line.

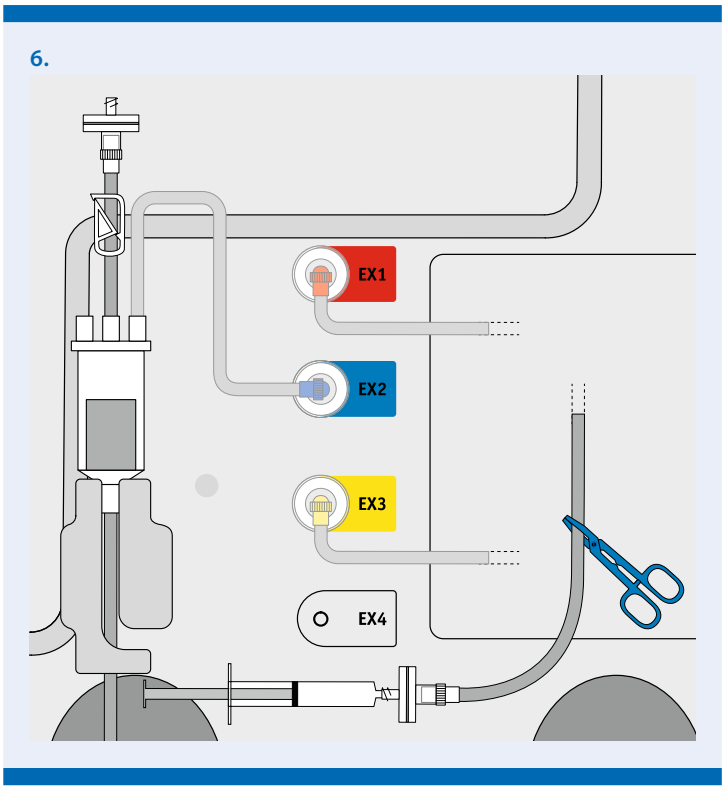


Figure 6.27: Step 6 from subsection 6.11.4

Step 7–8 (Hydrophobic filter at pressure line EX4 [white] wet)

7. Open the clamp on the pressure line.

8. Carefully press air into the pressure line.

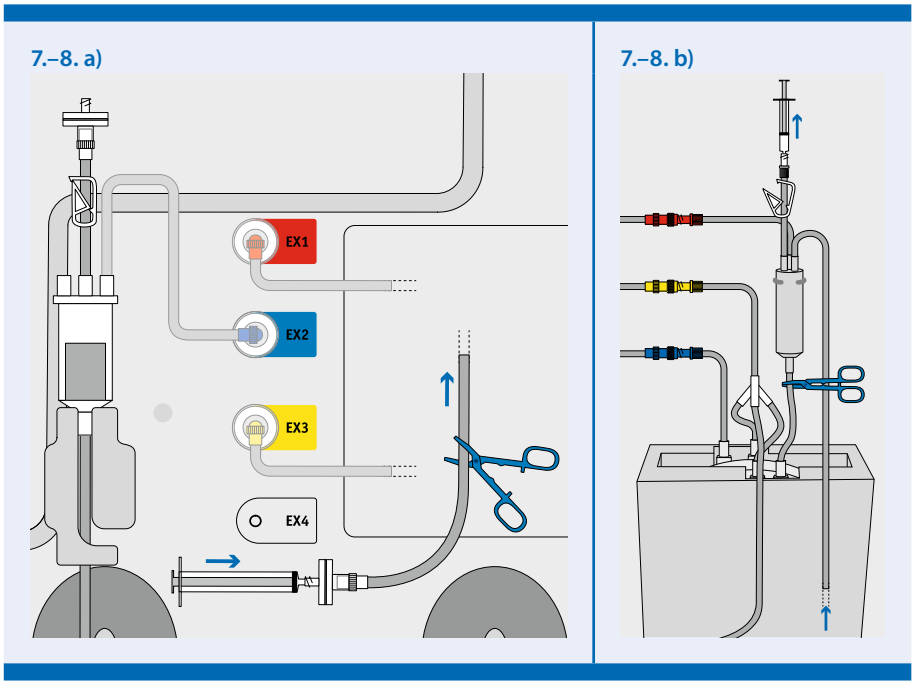


Figure 6.28: Step 7-8 from subsection 6.11.4

Step 9–12 (Hydrophobic filter at pressure line EX4 [white] wet)

9. Clamp off the pressure line and remove the sterile syringe.
10. Exchange the hydrophobic filter with a spare part.
11. Reconnect the pressure line to EX4 (white).
12. Remove the clamp from the pressure line.

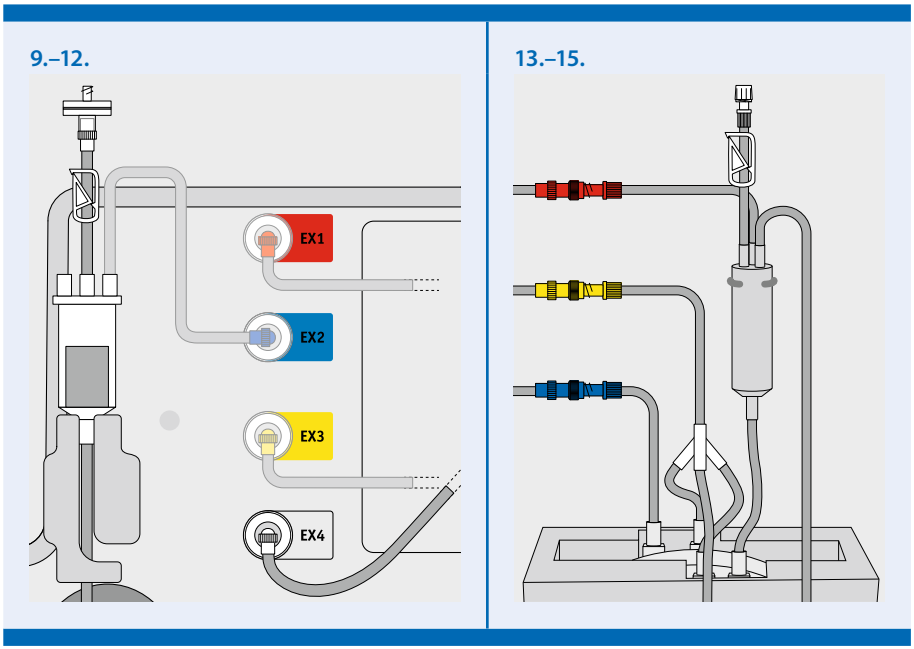


Figure 6.29: Step 9–15 from subsection 6.11.4

Step 13–15 (Hydrophobic filter at pressure line EX4 [white] wet)

13. Close the clamp on the separator drip chamber service line.
14. Remove the sterile syringe from the service line and close the line with a cap.
15. Remove the clamp from the line underneath the separator drip chamber.

6.11.5 Hydrophobic filter at pressure line to EX1 and/or to EX2 wet

This error occurs only during the preparation of the instrument.

Operator action:

Step 1–2 (Hydrophobic filter at pressure line EX1 and/or to EX2 wet)

1. Rotate the 3-way stopcock of the blood withdrawal line to open the lateral exit.
2. Connect a 5 mL sterile syringe to the lateral exit.

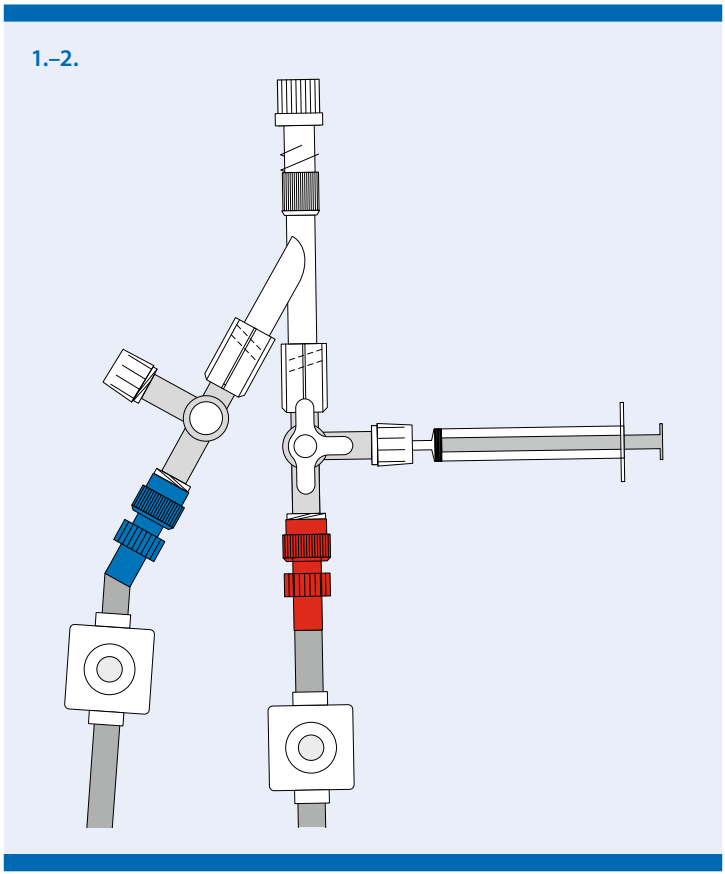


Figure 6.30: Step 1–2 from subsection 6.11.5

Step 3 (Hydrophobic filter at pressure line EX1 and/or to EX2 wet)

3. Clamp off the pressure line to EX1 and/or to EX2.

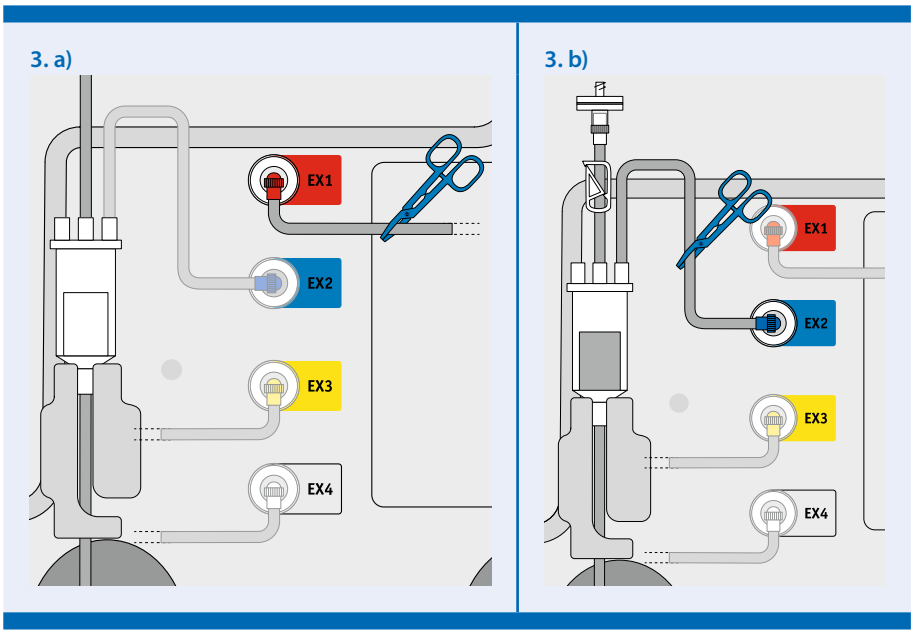


Figure 6.31: Step 3 from subsection 6.11.5

Step 4 (Hydrophobic filter at pressure line EX1 and/or to EX2 wet)

4. Connect an air-filled 5 mL sterile syringe to the hydrophobic filter of the pressure line to EX1 and/or to EX2.

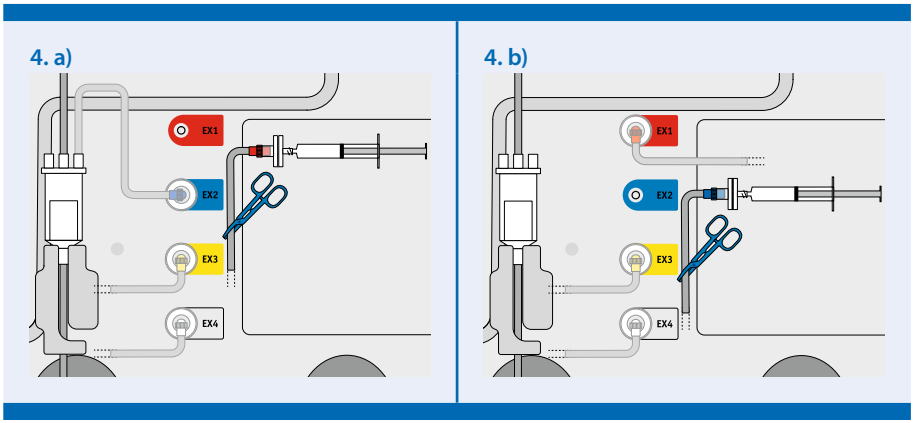


Figure 6.32: Step 4 from subsection 6.11.5

Step 5–6 (Hydrophobic filter at pressure line EX1 and/or to EX2 wet)

5. Open the clamp on the pressure lines to EX1 and/or to EX2.
6. Carefully press air into the pressure line to EX1 and/or to EX2.

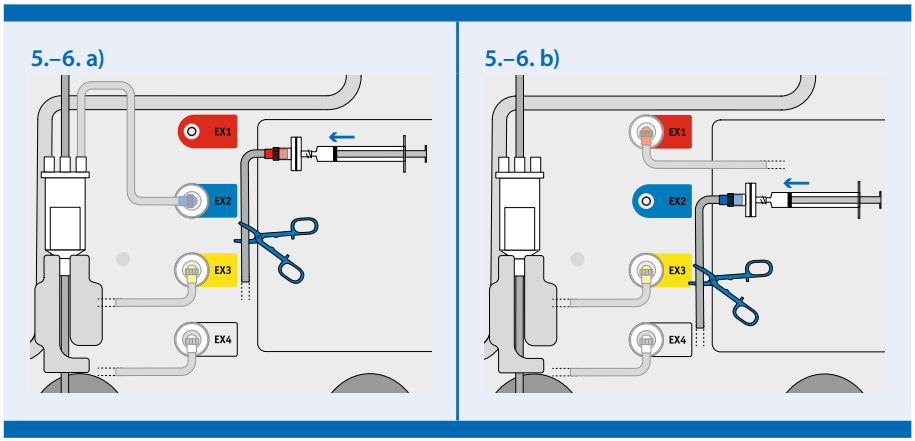


Figure 6.33: Step 5 from subsection 6.11.5

Step 7–11 (Hydrophobic filter at pressure line EX1 and/or to EX2 wet)

7. Clamp off the pressure line to EX1 and/or to EX2 and remove the sterile syringe.
8. Exchange the hydrophobic filter with a spare part.
9. Reconnect the pressure line to EX1 (red) and/or to EX2 (blue).
10. Remove the clamp from the pressure line to EX1 and/or to EX2.
11. Close the lateral exit on the blood withdrawal line and remove the sterile syringe.

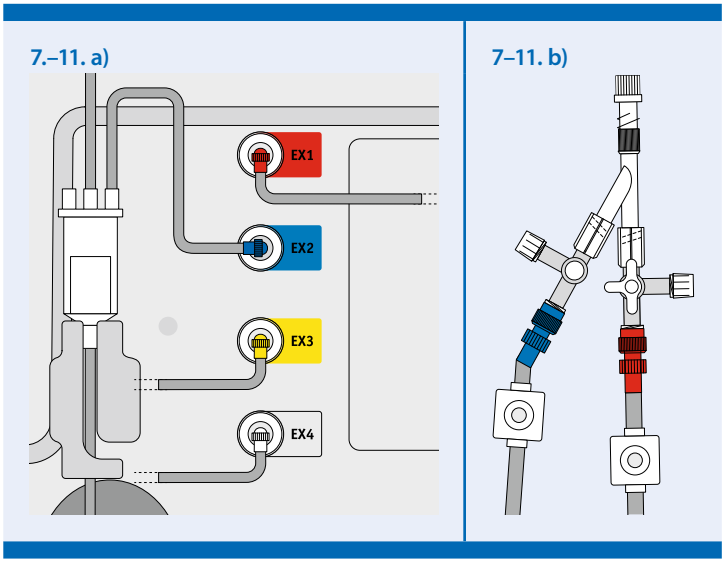


Figure 6.34: Step 7–11 from subsection 6.11.5

6.12 Adsorber barcode cannot be scanned

Scanning of the adsorber barcode is an integral part of the LIFE 21 safety system to prevent patient assignment errors. If the adsorber barcodes cannot be scanned, it might be due to a faulty barcode reader or an unreadable barcode label (smeared or covered by moisture film). In both cases, the barcode must be entered manually.

Operator action:
Use the keyboard on the touchscreen to enter the barcode located on the bottom of the adsorber housing. The barcode must be entered without any spaces in-between.

⚠ CAUTION

Risk of cross-contamination. Patient/adsorber pair assignment errors can cause cross-contamination. The operator must ensure that the adsorber and the patient match each other if the adsorber codes are to be entered manually. Manual data entry of adsorber codes is only an exception and should not become a routine handling procedure.

7 List of error codes

The error codes are sorted according to the category 1 error code definition. In the error definition [value] is used as a placeholder for variable information.

IMPORTANT

Always note the complete error code before performing an operator action. The error code will not be displayed during the subsequent actions.

If the error cannot be remedied with the instructions provided, call Miltenyi Biotec Technical Support and submit the error code.

7.1 Hardware errors (050–)

Error definition	Instruction for operator action	Alarm priority
Category 1, 050–061		
Internal error.	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	low
Category 1, 062		
Power failure Instrument is running on battery power!	1. Power connection affected. • Reinstall power connection. • Press RESTART to continue. If power failure persists, consider: 2. Set-up: Treatment cannot be continued. If manual regeneration and preservation of adsorber is required see section 6.2 “Manual adsorber regeneration and preservation”. 3. Treatment/Reinfusion: Battery power limited. • Press RESTART to continue. 3.1 Treatment: • If the remaining treatment (including reinfusion) persists longer than 15 minutes, press Menu, Cancel treatment (reinfusion) to initiate premature end of treatment. 3.2 Reinfusion: • Finish reinfusion in battery mode. • For manual regeneration and preservation of adsorber see section 6.2 “Manual adsorber regeneration and preservation”. 4. Treatment/Reinfusion: Battery power sufficient. • If the remaining treatment (including reinfusion) persists shorter than 15 minutes, press RESTART to finish treatment on battery mode. • For manual regeneration and preservation of adsorber see section 6.2 “Manual adsorber regeneration and preservation”. 5. Preservation: • For manual regeneration and preservation of adsorber see section 6.2 “Manual adsorber regeneration and preservation”.	low
Category 1, 063		
Battery empty Treatment cannot be continued if power failure occurs.	• Let the instrument switched on for at least 60 min before starting a treatment to allow the batteries to be loaded. • Press RESTART to continue.	low
Category 1, 064–066		
Power supply error	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	low

Error definition	Instruction for operator action	Alarm priority
Category 1, 067		
Internal error.	• Press RESTART to continue.	low
Category 1, 068		
Internal error. Treatment cannot be started.	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	low
Category 1, 069		
Disk separator test failed.	1. Disk separator not inserted correctly. • Check correct insertion of the disk separator and repeat the test. 2. Disk separator inserted correctly. • Disk separator is faulty. • Exchange disk separator and repeat the test. Press RESTART to continue.	low
Category 1, 070		
Disk separator error	• Press RESTART followed by Menu, Separator exchange, and follow the instructions. For details see section 6.3 “Exchange of disk separator”.	low

Table 7.1: Category 1 Hardware errors

7.2 Software errors (100–)

Error definition	Instruction for operator action	Alarm priority
Category 1, 100–102		
Internal error	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	low

Table 7.2: Category 1 Software errors

7.3 Internal system errors (150–)

Error description	Instruction for operator action	Alarm priority
Category 1, 150–153		
Internal error	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 154		
Access error to patient chip card.	• Remove and reinsert patient chip card or use new (empty) patient chip card. • Press RESTART to continue the treatment.	low
Category 1, 155		
Internal error.	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	low
Category 1, 156		
Internal error. Treatment cannot be continued for safety reasons!	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	low
Category 1, 157		
Protocol transfer to TheraSorb USB stick failed.	• Remove and reinsert TheraSorb USB stick. • Press RESTART to continue.	low
Category 1, 158		
Touchscreen error	1. Temporary touchscreen problem. • Try to press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown. • After 1 minute, switch on the instrument and restart the aborted treatment. 2. Permanent touchscreen problem. • Switch off the instrument on the rear panel. • After 1 minute, switch on the instrument and restart the aborted treatment.	medium

Table 7.3: Category 1 Internal system errors

7.4 Handling errors (200-)

Error definition	Instruction for operator action	Alarm priority
Category 1, 200		
Adsorber barcode faulty.	• Scan in adsorber barcode again. • Alternatively, enter adsorber barcode manually by using on-screen keyboard. • Press RESTART to continue.	medium

Error definition	Instruction for operator action	Alarm priority
Category 1, 201		
Adsorber expired. Expiry date: [value]	• Use a new adsorber pair.	medium
Category 1, 202		
Maximum operating time of the adsorber since initial use has been reached.	• Press RESTART to continue.	low
Category 1, 203		
Faulty PINCode: [value] no additional treatment has been activated.	• Enter correct PIN code. • Press RESTART to continue.	low
Category 1, 206		
Exchange of [value] not confirmed.	• Press RESTART to follow the instructions and to confirm bag exchange.	low
Category 1, 207		
Time exceeded for disk separator exchange.	• Exchange disk separator immediately to avoid coagulation in extracorporeal blood and plasma circuit. For details see section 6.3 “Exchange of disk separator”. • Press RESTART to show screen for disk separator exchange and follow instructions.	low

Table 7.4: Category 1 Handling errors

7.5 Door errors (250-)

Error description	Instruction for operator action	Alarm priority
Category 1, 250		
Pump door error.	• Check for correctly closed pump door. • Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 251		
Pump door did not open.	• Press RESTART to continue. • If problem persists, press Menu, Shutdown system, follow the instructions, and call Miltenyi Biotec Technical Support.	low
Category 1, 252		
Upper pump door lock opened.	• Close door at upper pump lock. • Press RESTART to continue.	low
Category 1, 253		
Lower pump door lock opened.	• Close door at lower pump lock. • Press RESTART to continue.	low
Category 1, 254		
Pump door open.	• Close pump door without pump cassette inserted. • Press RESTART to continue.	low
Category 1, 255–256		
Pump door error. Treatment cannot be continued for safety reasons!	1. Pump door affected. • Immediately close clamps on patient lines. • Disconnect patient from tubing set (fluid pass from tubing set into patient must be prevented!) • For manual regeneration and preservation of adsorber see section 6.2 “Manual adsorber regeneration and preservation”. • Press SHUTDOWN to initiate system shutdown.	medium

Table 7.5: Category 1 Door errors

7.6 Internal pressure sensor errors (300–)

Error description	Instruction for operator action	Alarm priority
Category 1, 300		
High pressure in waste line.	1. Fluid path of waste line affected. • Check corresponding tubing line for kinks or closed clamps. • Check connector for open fluid path. • Press RESTART to continue. 2. Waste bag full. • Press RESTART, Menu, Manual bag exchange, Waste, and follow the instructions. For details see section 4.8 “Manual bag exchange”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 301		
Internal pressure sensor [value] from top faulty.	1. Sensor is dirty. • Remove tubing from sensor. • Carefully clean pressure sensor without force with a soft dry cloth and/or cotton swap. • Reinsert tubing into sensor. • Close pump door. 2. Correct position of tubing. • Remove and reinsert tubing from sensor. • Close pump door. Press RESTART to continue.	low
Category 1, 302		
No tubing set detected at sensor [value] from top.	• Remove pump cassette. • Carefully clean pressure sensor without force with a soft dry cloth and/or cotton swap. • Reinsert pump cassette. • Close pump door. • Press RESTART to continue.	low
Category 1, 303		
Low pressure in anticoagulation line.	• Check anticoagulation tubing line for kinks or closed clamps. • Check spike connection to bag. • Press and release pillow of anticoagulation line for deaeration. • Press RESTART to continue.	low
Category 1, 304		
High pressure at pressure sensor [value] from top.	1. High pressure in adsorber lines (sensor ID 4, 5, 11, and 13): • Adsorber inflow or outflow line clamped off. • Particle filter clogged. Exchange particle filter. 2. All other sensor IDs: • Tubing line clamped off. • Faulty connection in tubing line. Press RESTART to continue.	low
Category 1, 305		
Pressure generation in adsorber lines failed.	• Check if adsorber lines are tightly connected. • Check if adsorber lines are interchanged. • If adsorber were connected too early, the treatment must be aborted. • Press RESTART and choose option.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 306		
Pressure reduction in adsorber line [value] failed.	1. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors need to be tightened or reconnected underneath the deaeration/particle filter (line 1 with 1 and 2 with 2). • Press RESTART to continue.	low
Category 1, 308		
Pressure generation in adsorber line [value] failed.	1. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to 1 and 2 to 2). 2. Adsorber connection faulty. • Check assignment of inflow and outflow lines to adsorber. Press RESTART to continue.	low
Category 1, 310		
Filling of SN chamber failed.	1. Fluid path of NaCl line(s) (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Check if fluid path from suction tube of bag(s) is open. 2. Pressure line to EX4 (white) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 3. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 3.1 for detailed instructions on filter exchange. Press RESTART to continue. 3.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 313		
Low pressure in anticoagulation line.	1. Fluid path of anticoagulation line affected. • Check corresponding tubing line for kinks or closed clamps. • Check connector for open fluid path. Make sure that cap of vented spike is closed. • Press and release pillow of anticoagulation line for deaeration. 2. Anticoagulation bag empty. • Press CONFIRM, RESTART, Menu, Manual bag exchange, Anticoagulation, and follow the instructions. For details see section 4.8 "Manual bag exchange". Press CONFIRM, RESTART to continue.	low
Category 1, 314		
Low pressure in adsorber [value].	1. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Tighten adsorber inflow and outflow line connectors. • Press CONFIRM, RESTART to adjust pressure.	low
Category 1, 315		
Low pressure in adsorber [value].	1. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Tighten adsorber inflow and outflow line connectors. 2. Fluid path of PA line (yellow) affected. • Check corresponding tubing line for kinks or closed clamp. • Check connector for open fluid path. • Check if break-off tip is open. • Check if fluid path from suction tube of bag is open. Press CONFIRM, RESTART to adjust pressure. 3. PA pro bag empty. • Press CONFIRM, RESTART, Menu, Manual bag exchange, select bag, and follow the instructions. For details see section 4.8 "Manual bag exchange".	low

Error description	Instruction for operator action	Alarm priority
Category 1, 316		
Low pressure in adsorber [value].	1. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Tighten adsorber inflow and outflow line connectors. 2. Fluid path of PBS line (black) affected. • Check corresponding tubing line for kinks or closed clamp. • Check connector for open fluid path. • Check if break-off tip is open. • Check if fluid path from suction tube of bag is open. Press CONFIRM, RESTART to adjust pressure. 3. PBS pro bag empty. • Press CONFIRM, RESTART, Menu, Manual bag exchange, select bag, and follow the instructions. For details see section 4.8 “Manual bag exchange”.	low
Category 1, 317		
Low pressure in adsorber [value].	1. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Tighten adsorber inflow and outflow line connectors. 2. Fluid path of NaCl lines (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Check if fluid path from suction tube of bag(s) is open. Press CONFIRM and/or RESTART to adjust pressure. 3. Treatment: NaCl pro bag empty. • Press CONFIRM, RESTART, Menu, Manual bag exchange, select bag, and follow the instructions. For details see section 4.8 “Manual bag exchange”.	low
Category 1, 318		
Low pressure in adsorber [value].	1. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Tighten adsorber inflow and outflow line connectors. 2. Fluid path of PBS-Azide lines (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Open ventilation port(s) on spike connector(s). Press RESTART to adjust pressure.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 319		
High pressure in adsorber [value].	1. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to adsorber 1 and line 2 to adsorber 2). 2. Deaeration/particle filter affected. • Exchange filter with spare part. 3. Adsorber affected • Flow resistance might be too high, call Miltenyi Biotec Technical Support. Press CONFIRM and/or RESTART to continue.	low
Category 1, 320		
Low pressure in adsorber.	1. Adsorber lines [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to 1 and 2 to 2). • Press RESTART to continue. 2. Sensor affected. • Press RESTART to continue.	low
Category 1, 321		
Adsorber connection faulty.	1. Adsorber [value] not connected. • Press RESTART and connect adsorber [value] according to instructions on screen. 2. Adsorber line [value] affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to adsorber 1 and line 2 to adsorber 2). • Press RESTART to continue.	low
Category 1, 322		
Faulty assignment of adsorber inflow/outflow lines to adsorber detected.	• Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to adsorber 1 and line 2 to adsorber 2). • Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 323		
Filling of SN chambers failed.	• Press RESTART to continue. If error persists, the current treatment cannot be continued in Single Needle mode. • Press RESTART, Menu, Double Needle to continue the treatment in Double Needle mode, if possible. For details see subsection 4.9.1 “Switch to Single Needle mode”.	low
Category 1, 324		
High pressure on particle filter.	1. Particle filter affected. • Clamp off cell concentrate line (blue) of disk separator. • Exchange particle filter with spare part. • Remove clamp from tubing line. 2. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) (mind color code). 3. Pressure line to EX4 (white) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 4. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 4.1 for detailed instructions on filter exchange. Press CONFIRM, RESTART to continue. 4.1. Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low
Category 1, 325		
Leak test failed.	1. Adsorber lines affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to 1 and 2 to 2). 2. Adsorber pair prematurely connected. • Disconnect adsorber pair from tubing set. • Interconnect adsorber inflow line and outflow line underneath the deaeration/particle filter (line 1 with 1 and 2 with 2). Press RESTART to continue. If error persists, a new treatment must be started.	low

Table 7.6: Category 1 Internal pressure sensor errors

7.7 Optical sensor errors (350–)

Error description	Instruction for operator action	Alarm priority
Category 1, 350		
Hemolytic plasma suspected.	• Visual check of plasma line from disk separator (yellow) for hemolysis, colored plasma or normally colored plasma (air bubble). For details see section 6.8 “Hemolytic plasma suspected”. • Press RESTART to follow cause-specific instructions on next screen.	low
Category 1, 351		
Hemolytic plasma suspected.	• Visual check of plasma line from disk separator (yellow) for colored plasma, normally colored plasma (air bubbles) or hemolysis. For details see section 6.8 “Hemolytic plasma suspected”. • Press RESTART to follow cause-specific instructions on next screen.	low
Category 1, 352		
Blood leakage in disk separator suspected.	• Visual check of plasma line from disk separator (yellow) for blood cells and/or air bubbles. For details see section 6.9 “Blood leakage in disk separator suspected”. • Press RESTART to follow cause-specific instructions on next screen.	low
Category 1, 353		
Problem in outflow line of adsorber [value].	1. Adsorber line affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to adsorber 1 and line 2 to adsorber 2). 2. Deaeration/particle filter blocked. • Exchange filter. Press RESTART to continue.	low
Category 1, 355		
Suction test for [value] failed.	1. Fluid path of [value] affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • If present, check if break off tip is opened. • Check if fluid path from suction tube of bag(s) is opened. • Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 357		
Calibration of hemolysis sensor failed.	1. Plasma line (yellow) from disk separator affected. • For details see subsection 6.10.1 “Plasma line (yellow) from disk separator affected”. 2. Cell concentrate line (blue) from disk separator affected. • For details see subsection 6.10.2 “Cell concentrate line (blue) from disk separator affected”. • If problem persists, continue with the following measures: 3. Air in plasma line (yellow) from disk separator. • For details see subsection 6.10.3 “Air in plasma line (yellow) from disk separator”. 4. Air in cell concentrate line (blue) from disk separator. • For details see subsection 6.10.4 “Air in cell concentrate line (blue) from disk separator”. If error persists, a new treatment must be started.	low
Category 1, 358		
Priming of patient line failed.	1. Fluid path of NaCl line(s) (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Check if fluid path from suction tube of bag(s) is open. 2. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) (mind color code). Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 359		
Priming of tubing set failed.	1. Fluid path of NaCl line(s) (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Check if fluid path from suction tube of bag(s) is open. 2. Patient lines affected. • Turn 3-way stopcock of blood withdrawal and blood return line to close fluid path completely. 3. Venous drip chamber service line affected. • Tighten or install a hydrophobic filter at the end of the service line. 4. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) (mind color code). 5. Pressure line to EX1 (red), to EX3 (yellow), and to EX4 (white) affected. • Check if pressure lines were correctly connected to external sensors (mind color code). • Check pressure lines to external sensors for kinks or closed clamps. • Carefully tighten connections to external sensors and hydrophobic filters. Do not overtighten! 6. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 6.1 for detailed instructions on filter exchange. 7. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 7.1 for detailed instructions on filter exchange. 8. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 8.1 for detailed instructions on filter exchange. Press **RESTART** to continue. 6.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”. 7.1 Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”. 8.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 360		
Adsorber installation too early.	1. Adsorber lines affected. • Open all clamps on adsorber inflow and outflow line. • Check adsorber lines for kinks. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to 1 and 2 to 2). 2. Adsorber pair prematurely connected. • Disconnect adsorber pair from tubing set. • Interconnect adsorber inflow line and outflow line underneath the deaeration/particle filter (line 1 to 1 and 2 to 2). Press RESTART to continue. If error persists, a new treatment must be started.	medium

Table 7.7: Category 1 Optical sensor errors

7.8 Sensor errors (400–)

Error description	Instruction for operator action	Alarm priority
Category 1, 400		
Installed pump cassette detected.	1. Pump cassette installed. • Remove pump cassette. 2. Sensor [value] from top dirty. • Clean optical sensor with soft dry cloth and/or cotton swap moistened with 70% Ethanol, or equivalent. • Carefully clean pressure sensor with soft dry cloth and/or cotton swap. • Close pump door. Press RESTART to continue.	low
Category 1, 401		
Internal sensor [value] from top faulty or ambient light too bright.	• Change instrument position to avoid direct, bright incidence of light. • Press RESTART to continue.	low
Category 1, 402		
Internal sensor [value] from top dirty or faulty.	• Clean optical sensor with soft dry cloth and/or cotton swap moistened with 70% Ethanol, or equivalent. • Carefully clean pressure sensor with soft dry cloth and/or cotton swap. • Close pump door. • Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 403		
Suction test for anticoagulation solution failed.	1. Fluid path of anticoagulation line affected. • Check corresponding tubing line for kinks or closed clamps. • Check connector to bag for open fluid path. • Press and release pillow of anticoagulation line for deaeration. 2. Patient lines affected. • Open clamps on patient lines to enable free flow of fluid. 3. Pressure lines to EX1 (red) and/or to EX2 (blue) affected. • Check if pressure line was correctly connected to EX1 and/or to EX2 (mind color code). • Check pressure line to EX1 and/or to EX2 for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 4. Hydrophobic filter at pressure line to EX1 and/or to EX2 wet. • For details see subsection 6.11.5 “Hydrophobic filter at pressure line to EX1 and/or to EX2 wet”. • Press RESTART to continue.	low

Table 7.8: Category 1 Sensor errors

7.9 External sensor errors (EX1-EX4; 450–)

Error description	Instruction for operator action	Alarm priority
Category 1, 450–451		
External pressure sensor EX[value] dirty or faulty.	• Clean only the surface of the external pressure sensor with a soft dry cloth and/or cotton swap moistened with 70% Ethanol, or equivalent. • Press RESTART to continue.	low
Category 1, 452		
Problem at external sensor EX1 (red) and/or EX2 (blue).	1. Pressure line to EX1 (red) and/or to EX2 (blue) affected. • Check if pressure line was correctly connected to EX1 and/or to EX2 (mind color code). • Check pressure line to EX1 and/or to EX2 for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 2. Hydrophobic filter at pressure line to EX1 and/or to EX2 wet. • For details see subsection 6.11.5 “Hydrophobic filter at pressure line to EX1 and/or to EX2 wet”. Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 453		
Problem at external sensor EX3 (yellow) and/or EX4 (white).	1. Pressure line to EX3 (yellow) and/or to EX4 (white) affected. • Check if pressure line was correctly connected to EX3 and/or to EX4 (mind color code). • Check pressure line to EX3 and/or to EX4 for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 2. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 2.1 for detailed instructions on filter exchange. 3. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 3.1 for detailed instructions on filter exchange. Press RESTART to continue. 2.1 Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”. 3.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low
Category 1, 454		
Pressure test of patient lines failed.	1. Venous drip chamber service line open. • Close clamp on service line. 2. Patient lines affected. • Turn 3-way stopcock of blood withdrawal and blood return line to close fluid path completely. • Pressure line to EX1 (red) and/or to EX2 (blue) affected. • Check if pressure line was correctly connected to EX1 and/or to EX2 (mind color code). • Check pressure line to EX1 and/or to EX2 for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 455		
Pressure test failed.	1. Patient lines affected. • Turn 3-way stopcock of blood withdrawal and blood return line to close fluid path completely. 2. Venous drip chamber service line affected. • Close clamp on venous drip chamber service line. • Tighten or install a hydrophobic filter at the end of the service line. 3. Pressure line to EX1 (red), to EX2 (blue) affected. • Check if pressure lines were correctly connected to external sensors (mind color code). • Check pressure lines to external sensors for kinks or closed clamps. • Carefully tighten connections to external sensors and hydrophobic filters. Do not overtighten! 4. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 4.1 for detailed instructions on filter exchange. 5. Hydrophobic filter at pressure line to EX2 (blue) wet. • Check if filter is wet. See 5.1 for detailed instructions on filter exchange. Press RESTART to continue. 4.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”. 5.1 Instructions for filter exchange (EX2, blue). • For details see subsection 6.11.2 “Hydrophobic filter at pressure line EX2 (blue) wet”.	low
Category 1, 456		
No pressure on external sensors EX3 (yellow) and/or EX4 (white).	1. Disk separator drip chamber service line affected. • Close clamp on disk separator drip chamber service line. • Tighten connectors of disk separator lines. 2. Pressure line to EX3 (yellow) and/or to EX4 (white) affected. • Check if pressure line was correctly connected to EX3 and/or to EX4 (mind color code). • Check pressure line to EX3 and/or to EX4 for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 457		
High pressure on external sensor EX[value].	1. Venous drip chamber service line closed. • Open clamp on service line. 2. Patient lines affected. • Open clamps on patient lines. 3. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) (mind color code). 4. Pressure line to EX1 (red), to EX2 (blue), to EX3 (yellow), and to EX4 (white) affected. • Check if pressure lines were correctly connected to external sensors (mind color code). • Check pressure lines to external sensors for kinks or closed clamps. • Carefully tighten connections to external sensors and hydrophobic filters. Do not overtighten! 5. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 5.1 for detailed instructions on filter exchange. 6. Hydrophobic filter at pressure line to EX2 (blue) wet. • Check if filter is wet. See 6.1 for detailed instructions on filter exchange. 7. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 7.1 for detailed instructions on filter exchange. 8. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 8.1 for detailed instructions on filter exchange. Press RESTART to continue. 5.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”. 6.1 Instructions for filter exchange (EX2, blue). • For details see subsection 6.11.2 “Hydrophobic filter at pressure line EX2 (blue) wet”. 7.1 Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”. 8.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 458		
Priming of tubing set failed.	1. Fluid path of NaCl line(s) (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Check if fluid path from suction tube of bag(s) is open. 2. Patient lines affected. • Turn 3-way stopcock of blood withdrawal and blood return line to close fluid path completely. 3. Venous drip chamber service line affected. • Tighten or install a hydrophobic filter at the end of the service line. 4. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) for open fluid path (mind color code). 5. Pressure line to EX1 (red), to EX3 (yellow), and to EX4 (white) affected. • Check if pressure lines were correctly connected to external sensors (mind color code). • Check pressure lines to external sensors for kinks or closed clamps. • Carefully tighten connections to external sensors and hydrophobic filters. Do not overtighten! 6. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 6.1 for detailed instructions on filter exchange. 7. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 7.1 for detailed instructions on filter exchange. 8. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 8.1 for detailed instructions on filter exchange. Press **RESTART** to continue. 6.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”. 7.1 Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”. 8.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 459		
Pressure release failed.	1. Patient lines affected. • Turn 3-way stopcock of blood withdrawal and blood return line to close fluid path completely. 2. Venous drip chamber service line affected. • Tighten or install a hydrophobic filter at the end of the service line. 3. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) (mind color code). 4. Pressure line to EX1 (red), to EX3 (yellow), and to EX4 (white) affected. • Check if pressure lines were correctly connected to external sensors (mind color code). • Check pressure lines to external sensors for kinks or closed clamps. • Carefully tighten connections to external sensors and hydrophobic filters. Do not overtighten! 5. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 5.1 for detailed instructions on filter exchange. 6. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 6.1 for detailed instructions on filter exchange. 7. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 7.1 for detailed instructions on filter exchange. Press RESTART to continue. 5.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”. 6.1 Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”. 7.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 460		
TMP limit value exceeded.	1. Pressure line to EX3 (yellow) and/or to EX4 (white) affected. • Check if pressure line was correctly connected to EX3 and/or to EX4 (mind color code). • Check pressure line to EX3 and/or to EX4 for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 2. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 2.1 for detailed instructions on filter exchange. 3. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 3.1 for detailed instructions on filter exchange. 4. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) (mind color code). 5. Disk separator affected. • Press **CONFIRM**, **RESTART**, **Menu**, **Separator exchange**, and follow the instructions. For details see section 6.3 “Exchange of disk separator”. Press **CONFIRM**, **RESTART** to continue. 2.1. Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”. 3.1. Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low
Category 1, 461		
Blood withdrawal pressure too low.	1. Patient connection affected. • Reduce blood withdrawal flow. • Check the connection of the blood withdrawal line to the patient. • Fluid path of blood withdrawal line needs to be opened. • Check the vascular access of the patient. 2. Pressure limits too narrow • Spread pressure limits. 3. Pressure line to EX1 (red) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 4. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 4.1 for detailed instructions on filter exchange. • Press **CONFIRM** and adapt blood flow and/or pressure limit. • Then press **RESTART** to continue. 4.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 462		
Blood withdrawal pressure too high.	1. Patient connection affected. • Check the connection of the blood withdrawal line to the patient. • Fluid path of blood withdrawal line must be opened. • Check the vascular access of the patient. 2. Pressure limits too narrow. • Spread pressure limits. 3. Pressure line to EX1 (red) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 4. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 4.1 for detailed instructions on filter exchange. Press CONFIRM and adapt blood flow and/or pressure limit. Then press RESTART to continue. 4.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”.	low
Category 1, 463		
Blood return pressure too low.	1. Patient connection affected. • Check the vascular access of the patient. • Increase blood withdrawal flow. • Check connection of the blood return line to the patient. • Fluid path of patient line must be opened. 2. Blood return pressure of patient below zero. • Adjust patient’s bed to a level above the level of the external sensors EX1 to EX4. 3. Pressure limits too narrow. • Spread pressure limits. 4. Pressure line to EX2 (blue) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 5. Hydrophobic filter at pressure line to EX2 (blue) wet. • Check if filter is wet. See 5.1 for detailed instructions on filter exchange. Press CONFIRM and adapt blood flow and/or pressure limit. Then press RESTART to continue. 5.1 Instructions for filter exchange (EX2, blue). • For details see subsection 6.11.2 “Hydrophobic filter at pressure line EX2 (blue) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 464		
Blood return pressure too high.	1. Patient connection affected. • Check the vascular access of the patient. • Reduce blood withdrawal flow. • Check connection of the blood return line to the patient. • Fluid path of blood return line needs to be opened. 2. Pressure limits too narrow. • Spread pressure limits. 3. Pressure line to EX2 (blue) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 4. Hydrophobic filter at pressure line to EX2 (blue) wet. • Check if filter is wet. See 4.1 for detailed instructions on filter exchange. 5. Venous drip chamber affected. • Check if venous drip chamber mesh is permeable. If mesh is clotted, treatment must be canceled. • Disconnect patient from blood withdrawal and blood return line. • Call Miltenyi Biotec Technical Support for further steps. Press CONFIRM and adapt blood flow and/or pressure limit. Then press RESTART to continue. 4.1 Instructions for filter exchange (EX2, blue). • For details see subsection 6.11.2 “Hydrophobic filter at pressure line EX2 (blue) wet”.	low
Category 1, 465		
Problem at external sensor EX1 (red).	1. Pressure line to EX1 (red) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 2. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 2.1 for detailed instructions on filter exchange. Press CONFIRM, RESTART to continue. 2.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 466		
Problem at external sensor EX2 (blue).	1. Pressure line to EX2 (blue) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 2. Hydrophobic filter at pressure line to EX2 (blue) wet. • Check if filter is wet. See 2.1 for detailed instructions on filter exchange. Press CONFIRM, RESTART to continue. 2.1 Instructions for filter exchange (EX2, blue). • For details see subsection 6.11.2 “Hydrophobic filter at pressure line EX2 (blue) wet”.	low
Category 1, 467		
Problem at external sensor EX3 (yellow).	1. Pressure line to EX3 (yellow) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 2. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 2.1 for detailed instructions on filter exchange. Press CONFIRM, RESTART to continue. 2.1 Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”.	low
Category 1, 468		
Problem at external sensor EX4 (white).	1. Pressure line to EX4 (white) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 2. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 2.1 for detailed instructions on filter exchange. Press CONFIRM, RESTART to continue. 2.1. Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 469		
Pressure loss at external sensor EX4 (white).	1. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) (mind color code). 2. Tubing lines of tubing set affected. • Check tubing set for leakage. • Tighten connector(s). 3. Separator drip chamber service line affected. • Close clamp on separator drip chamber service line. 4. Pressure line to EX4 (white) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 5. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 5.1 for detailed instructions on filter exchange. Press RESTART to continue. 5.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	high
Category 1, 470		
Pressure loss at external sensor EX4 (white).	1. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s) (mind color code). 2. Tubing lines of tubing set affected. • Check tubing set for leakage. • Tighten connector(s). 3. Separator drip chamber service line affected. • Close clamp on separator drip chamber service line. 4. Pressure line to EX4 (white) affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 5. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 5.1 for detailed instructions on filter exchange. Press RESTART to continue. 5.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	high

Error description	Instruction for operator action	Alarm priority
Category 1, 471		
High pressure at external sensor EX4 (white).	1. Tubing lines of disk separator affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Tighten connector(s). 2. Connection to EX4 (white) affected. • Open clamp on pressure line to EX4. • Check if pressure line was correctly connected to EX4 (mind color code). • Carefully tighten Luer Lock connection. Do not overtight. 3. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 3.1 for detailed instructions on filter exchange. 4. Disk separator affected. • Press CONFIRM, RESTART, Menu, Separator exchange, and follow the instructions. For details see section 6.3 “Exchange of disk separator”. Press CONFIRM, RESTART to continue. 3.1. Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low
Category 1, 472		
Pressure test failed.	1. Patient lines affected. • Turn 3-way stopcock of blood withdrawal and blood return line to close fluid path completely. 2. Pressure line to EX1 (red), to EX2 (blue) affected. • Check if pressure lines were correctly connected to external sensors (mind color code). • Check pressure lines to external sensors for kinks or closed clamps. • Carefully tighten connections to external sensors and hydrophobic filters. Do not overtighten! 3. Hydrophobic filter at pressure line to EX1 (red) wet. • Check if filter is wet. See 3.1 for detailed instructions on filter exchange. 4. Hydrophobic filter at pressure line to EX2 (blue) wet. • Check if filter is wet. See 4.1 for detailed instructions on filter exchange. Press RESTART to continue. If error persists, a new treatment must be started. 3.1 Instructions for filter exchange (EX1, red). • For details see subsection 6.11.1 “Hydrophobic filter at pressure line EX1 (red) wet”. 4.1 Instructions for filter exchange (EX2, blue). • For details see subsection 6.11.2 “Hydrophobic filter at pressure line EX2 (blue) wet”.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 473		
Pressure test failed.	1. Patient lines affected. • Turn 3-way stopcock of blood withdrawal and blood return line to close fluid path completely. 2. Pressure line to EX3 (yellow) and to EX4 (white) affected. • Check if pressure lines were correctly connected to external sensors (mind color code). • Check pressure lines to external sensors for kinks or closed clamps. • Carefully tighten connections to external sensors and hydrophobic filters. Do not overtighten! 3. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 3.1 for detailed instructions on filter exchange. 4. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 4.1 for detailed instructions on filter exchange. Press RESTART to continue. If error persists, a new treatment must be started. 3.1 Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”. 4.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low
Category 1, 474		
Faulty pressure at external sensor EX[value].	1. Pressure line to EX[value] affected. • Check pressure line for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! • Press RESTART to continue.	low

Table 7.9: Category 1 External sensor errors (EX1-EX4)

7.10 Air detection errors (500–)

Error description	Instruction for operator action	Alarm priority
Category 1, 500		
Air in anticoagulation line.	1. Fluid path of anticoagulation line affected. • Check corresponding tubing line for kinks or closed clamps. • Check connector for open fluid path. • Press and release pillow of anticoagulation line for deaeration. • Press RESTART to continue. 2. Anticoagulation bag empty. • Press RESTART, Menu, Manual bag exchange, Anticoagulation, and follow the instructions. For details see section 4.8 “Manual bag exchange”.	low
Category 1, 501		
Air detector must detect air.	1. Tubing line in air detector affected. • Insert blood return line into air detector. • Correctly insert blood return line by moving the tubing up and down towards the back of the air detector. 2. Fluid droplets in air detector. • Remove blood return line and clean sensor with soft dry cloth or cotton swap. • Dry surface of blood return line. • Reinsert blood return line. 3. Blood return line filled with liquid. • Call Miltenyi Biotec Technical Support and submit error code. Press RESTART to continue.	low
Category 1, 502		
Air detector must detect liquid.	1. Tubing line in air detector affected. • Correctly insert blood return line by moving the tubing up and down towards the rear side of the air detector. 2. Wrong tubing line inserted. • Insert blood return line into the air detector. • Correctly insert blood return line by moving the tubing up and down towards the rear of the air detector. Press RESTART to continue.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 503		
Air detected in blood return line.	1. Tubing line in air detector affected. • Insert blood return line into air detector. • Correctly insert blood return line by moving the tubing up and down towards the rear side of the air detector. 2. Air in blood return line. • Visually check blood return line and venous drip chamber for air. • Turn 3-way stopcock of blood return line to close fluid path completely. Check for air reasons: 3. Patient line affected. • Turn 3-way stopcock of blood withdrawal line to close fluid path completely. • Check the connection of the blood withdrawal line to the patient. • Check the vascular access of the patient. 4. Pressure line to EX1 (red) affected. • Check if pressure line was correctly connected to the external sensor EX1 (mind color code). • Carefully tighten Luer Lock connection. Do not overtighten! 5. Venous drip chamber service line affected. • Close clamp in venous drip chamber service line. • Tighten or install a hydrophobic filter at the end of the service line. 6. Adsorber lines affected. • Adsorber inflow line and outflow line connectors must be tightened or reconnected underneath the deaeration/particle filter (line 1 to adsorber 1 and line 2 to adsorber 2). 7. Removal of air from the blood return line: • For details see section 6.6 “Notification: no plasma flow”. Press **CONFIRM**, **RESTART** and process at least 100 mL of blood volume without further alarms before the syringes are removed.	high
Category 1, 504		
Air detector alarm. Treatment cannot be continued for safety reasons!	1. Disconnect patient. • Immediately close clamps on patient lines. • Disconnect patient from blood return and withdrawal line. 2. Preservation of adsorber. • For manual regeneration and preservation of adsorber see section 6.2 “Manual adsorber regeneration and preservation”. Press **SHUTDOWN** to initiate system shutdown.	high

Error description	Instruction for operator action	Alarm priority
Category 1, 505		
Air in PA line of adsorber [value].	1. Fluid path of PA line (yellow) affected. • Check corresponding tubing line for kinks or closed clamps. • Check connector/break-off tip for open fluid path. • Check if fluid path from suction tube of bag is open. • Press CONFIRM and/or RESTART to continue. 2. Treatment: PA pro elution buffer bag empty. • Press CONFIRM, RESTART, Menu, Manual bag exchange, PA pro, and follow the instructions. 3. Microbubbles in PA line. • Clamp off tubing line of the respective sensor. • Press CONFIRM and/or RESTART to continue. • Open clamp in tubing line after 5 seconds. • Repeat if problem persists.	low
Category 1, 506		
Air in PBS line of adsorber [value].	1. Fluid path of PBS line (black) affected. • Check corresponding tubing line for kinks or closed clamps. • Check connector/break-off tip for open fluid path. • Check if fluid path from suction tube of bag is open. • Press CONFIRM, RESTART to continue. 2. Treatment: PBS pro neutralization buffer bag empty. • Press CONFIRM, RESTART, Menu, Manual bag exchange, PBS pro, and follow the instructions. For details see section 4.8 “Manual bag exchange”. 3. Microbubbles in PBS line. • Clamp off the tubing line of the respective sensor. • Press CONFIRM and/or RESTART to continue. • Open clamp in tubing line after 5 seconds. • Repeat if problem persists.	low
Category 1, 507		
Air in NaCl line of adsorber [value].	1. Fluid path of NaCl line(s) (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Check if fluid path from suction tube of bag(s) is open. • Press CONFIRM and/or RESTART to continue. 2. Treatment: NaCl pro priming solution bag 1 or 2 empty. • Press CONFIRM, RESTART, Menu, Manual bag exchange, NaCl pro bag 1/2, and follow the instructions. For details see section 4.8 “Manual bag exchange”. 3. Microbubbles in NaCl line. • Clamp off the tubing line of the respective sensor. • Press CONFIRM and/or RESTART to continue. • Open clamp in tubing line after 5 seconds. • Repeat if problem persists.	low

Error description	Instruction for operator action	Alarm priority
Category 1, 511		
Air in PBS-Azide line of adsorber [value].	1. Fluid path of PBS-Azide lines (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Open ventilation port(s) on spike connector(s). • Press RESTART to continue. 2. Microbubbles in PBS-Azide line. • Clamp off the tubing line of the respective sensor. • Press RESTART to continue. • Open clamp in tubing line after 5 seconds. • Repeat if problem persists.	low

Table 7.10: Category 1 Air detection errors

7.11 Tubing set-related errors (550–)

Error description	Instruction for operator action	Alarm priority
Category 1, 550		
Pump calibration failed.	1. Fluid path of NaCl line(s) (green) affected. • Check corresponding tubing line(s) for kinks or closed clamps. • Check connector(s) for open fluid path. • Check if fluid path from suction tube of bag(s) is open. • Press RESTART to continue. • If error persists, a new treatment must be started.	low
Category 1, 551		
Pump calibration failed.	1. Pump cassette affected. • Check if pump cassette is correctly inserted. • Press RESTART to continue.	low

Table 7.11: Category 1 Tubing set-related errors

7.12 Internal monitoring errors (600–)

Error description	Instruction for operator action	Alarm priority
Category 1, 600		
Internal error. The current rinsing Step is repeated for safety reasons.	• Press RESTART to continue.	low
Category 1, 601–602		
Internal error.	• Press RESTART to continue.	medium
Category 1, 603		
Emptying of SN chambers through adsorber [value] failed.	1. Pressure line to EX3 (yellow) and/or to EX4 (white) affected. • Check if pressure line was correctly connected to EX3 and/or to EX4 (mind color code). • Check pressure line to EX3 and/or to EX4 for kinks or closed clamps. • Carefully tighten connection to external sensor and hydrophobic filter. Do not overtighten! 2. Hydrophobic filter at pressure line to EX3 (yellow) wet. • Check if filter is wet. See 2.1 for detailed instructions on filter exchange. 3. Hydrophobic filter at pressure line to EX4 (white) wet. • Check if filter is wet. See 3.1 for detailed instructions on filter exchange. Press RESTART to continue. 2.1 Instructions for filter exchange (EX3, yellow). • For details see subsection 6.11.3 “Hydrophobic filter at pressure line EX3 (yellow) wet”. 3.1 Instructions for filter exchange (EX4, white). • For details see subsection 6.11.4 “Hydrophobic filter at pressure line EX4 (white) wet”.	low
Category 1, 605		
Internal error.	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	high
Category 1, 607–609		
Internal error.	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	medium
Category 1, 610–611		
Internal error.	• Press RESTART to continue.	medium
Category 1, 612–614		
Internal error.	• Press SHUTDOWN to initiate system shutdown. • Do not switch off the instrument before the switch-off screen is shown.	medium

Table 7.12: Category 1 Internal monitoring errors

8 Legal notes

8.1 Limited warranty

Except as stated in a specific warranty statement, which may accompany the product, or unless otherwise agreed in writing by an authorized representative of Miltenyi Biotec, Miltenyi Biotec's warranty, if any, with respect to this product is subject to the terms and conditions of sale of the company within the Miltenyi Biotec group, which supplied the product. Copies are available on request or at www.miltenyibiotec.com. Terms and conditions of sale may vary by country and region. Copies of these terms are available on request or at www.miltenyibiotec.com. Nothing in this document should be construed as constituting an additional warranty.

Should the instrument be used in a manner not explicitly described in this manual, all warranties will be null and void.

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