LIFE 21® apheresis unit
General information – Instrument

User Manual

Software version from 7.3



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General information – Instrument

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Software version from 7.3

Issued: 2022-04
39501/06

MD CE 0123

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Essential information

This user manual provides instructions, warnings, precautions, and other important information for the use of the LIFE 21 apheresis unit (instrument). For further details on troubleshooting as well as specific procedures, refer to 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" on page 23 of this user manual) 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 Community, the regulatory approval of the products in your country must be confirmed.

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1 Introduction

1.1 General information

This user manual provides instructions, warnings, precautions, and other important information for the use of the LIFE 21 apheresis unit (instrument).
For further details on troubleshooting as well as specific procedures, refer to the LIFE 21 user manuals issued for the respective matter.

1.2 Service information

For any further information, support, or comments related to the instrument contact the Miltenyi Biotec Technical Support.
For easier identification of the problem, note the error number and service information on the screen for the Miltenyi Biotec Technical Support team.

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

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

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

The glossary lists and explains the symbols used for labeling of the instrument and of the other products of the LIFE 21 apheresis platform.

2.2.1 Safety symbols



General warning sign



Warning; Electricity



Warning; Magnetic field

2.2.2 Housing



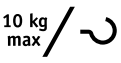
Brake position – wheels locked



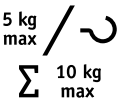
Brake position – wheels unlocked



Brake position – rear wheels fixed



Weight limit for hooks
Maximum load per hook: 10 kg



Weight limit for bag hanger (infusion stand)
Maximum load per bag hanger: 5 kg
Maximum load in total for infusion stand: 10 kg



Weight limit for mounting rod
Maximum load: 5 kg



Hook assignment green for priming solution
(e.g., TheraSorb - NaCl pro solution)



Hook assignment black for neutralization buffer
(e.g., TheraSorb - PBS pro buffer)

Hook assignment yellow for elution buffer
(e.g., TheraSorb - PA pro buffer)



Waste



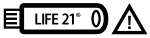
Position for Adsorber 1



Position for Adsorber 2



Interface for TheraSorb chip cards



Interface for TheraSorb USB flash drive



Refer to instruction manual/booklet
This symbol denotes the necessity to consult accompanying documents, supplied with instrument.

UDI

Unique Device Identifier

2.2.3 Main connector plate

“ON” (power)



“OFF” (power)



Loudspeaker (buzzer)



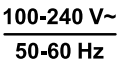
Interface for barcode reader



External alarm output (nurse call)

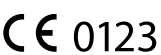


Caution
Plug in for max. 24 V/0.1 A



Label on the power interface indicating operating voltage of 100-240 volts at a frequency of 50-60 Hz.

2.2.4 Type label



European conformity approval with ID number 0123 (ID number of Notified Body: “TÜV SÜD Product Service GmbH, Munich”).



Medical Device



Manufacturer



Date of manufacture



Catalogue number



Serial number



Patient - Type B applied part
Note: There is no electrical connected applied part, but touchable metal parts are tested in accordance with applied part type B.



WEEE; waste electrical and electronic equipment
To indicate that separate collection for waste electric and electronic equipment (WEEE) is required.

200 VA 100–240 V~ 50–60 Hz	Electrical rating
IPX1	Ingress Protection X1
max	Mass of the device including its safe work load

2.2.5 Pump door label

PS	Priming solution (e.g., TheraSorb - NaCl pro)
NB	Neutralization buffer (e.g., TheraSorb - PBS pro)
EB	Elution buffer (e.g., TheraSorb - PA pro)
	Withdrawal blood
	Plasma
	Reinfusion blood
	Anticoagulant
	Bypass
	Patient
S	Substitute
1 2	Balance pump 1 and 2



Waste



Single needle (OUT)



Single needle (IN)

2.2.6 Miscellaneous



Auditory alarm temorarily/permantly disabled



Phone



Fax



E-Mail



Website



Hotline number

2.3 Glossary of terms

ACD-A solution	Anticoagulation solution; ACD-A solution is not part of the LIFE 21 apheresis platform.
Adsorber	Apheresis column filled with Speharose coupled to specific ligand.
Adsorber holder	Used for storage and mounting of adsorber(s) to the instrument
Anticoagulant	Needed to prevent clotting of blood processed in the extracorporeal circuit
Bag hanger	Located on infusion stand allows for hanging bags/ bottles up to 5 kg of weight and has a maximum of 10 kg for all five bag hangers
Balance	The balance refers to the patient's fluid balance at the end of the treatment. The balance can be as follows: Hypovolemic, limited to –10% of plasma exchange volume; Isovolemic, Hypervolemic, limited to +10% of plasma exchange volume.
Bar code	Machine-readable representation of data, e.g., part number, batch code, or use-by date, indicated on required materials
Bar code reader	The bar code reader serves as a data input device to scan product codes printed on, e.g., adsorber(s) or disposables.
Blood leakage	Presence of blood cells in the plasma
Brake pedal	Used to block all wheels for storage or during a treatment; or used to block rear wheels, or free all wheels for easy maneuverabilty during transportation
Bypass	Plasma bypasses the adsorber circuit and is immediately returned to the patient together with the cellular blood fraction.
Colloid	Solution that can be used as substitution solution in TPE. The permissible range of colloid is limited to ≤1.5% of body weight.

Consumables	Single use components to be used for a treatment in combination with the instrument.
Deaeration/particle filter	Positioned in adsorber(s) inflow line to prevent air and particles entering the adsorber(s)
Disk separator	Part of the tubing set separating blood in its components (cells and plasma).
Double column immunoadsorption	Application utilizing an adsorber pair for a treatment.
Elution buffer	Acidic solution used to regenerate the adsorber matrix within a loading cycle.
ERR log	List of all errors, that occurred during a treatment.
Error number	Reflects error cause and treatment phase information and is required for troubleshooting
Exchange volume	Volume of NaCl solution applied to the adsorber after plasma loading. NaCl solution is applied in order to maximize plasma return before regeneration of the adsorber.
External alarm output (nurse call)	Interface for the connection of the instrument to the inhouse call-system.
External pressure sensor EX1 (red)	Monitoring of blood withdrawal pressure (high pressure, low pressure, fluctuation).
External pressure sensor EX2 (blue)	Monitoring of blood return pressure (high pressure, low pressure, fluctuation).
External pressure sensor EX3 (yellow)	Monitoring of plasma-side separator pressure.
External pressure sensor EX4 (white)	Monitoring of blood-side separator pressure.
FFP	Fresh frozen plasma

Fresh frozen plasma	Solution that can be used as substitution solution in TPE. The permissible range of FFP is limited to ≤100% of plasma exchange volume and balance.
Hemolysis	Presence of hemoglobine in the plasma line.
Heparin	Anticoagulation solution; Heparin solution is not part of the LIFE 21 apheresis platform.
Hook	At side of instrument to hold solution bags (maximum of 10 kg per hook)
HSA	Human serum albumin
Human serum albumin	Pharmaceutical-grade HSA approved in your country can be used as substitution solution in TPE.
Hydrophobic filter	Used to prevent liquid entry into the instrument (EX1-EX4); facilitates deaeration of tubing set during priming (venous drip chamber service line)
Instrument	Short for LIFE 21 apheresis unit
Integrity test	Test that instrument performs to ensure the correct performance of the tubing set.
Internal optical sensor	Measures the color of the solutions and plasma, and also detects air bubbles
Internal pressure sensor	Measures the pressure in the respective tubing segment
LIFE 21 apheresis platform	Composed of LIFE 21 apheresis unit, adsorber(s) (only for immunoadsorption), and consumables
LIFE 21 apheresis unit	Instrument to perform single column and double column immunoadsorption as well as TPE
Main connector plate	Contains the power switch, power cord socket, instrument identification label, and other interfaces
Mounting bracket	Located on the instrument for mounting of the adsorber holder

Mounting rod	Used to mount, for example, a blood warmer or infusion pump to the instrument during a treatment run
Multiple pass	Alternating loading of an adsorber pair during double column imunoadsorption
Multiple use	Usage of adsorber(s) for several treatment of one and the same patient
Neutralization buffer	PBS solution used to regenerate the adsorber matrix within a loading cycle
Particle filter (5 µm)	Located in the central plasma return line to prevent the ingress of particles into the patient
Patient plasma volume	Calculated based on body weight, height, gender and age
Patient chip card	Used for storage of treatment and patient related data
PCC	Patient chip card
Plasma	The liquid portion of blood
Plasma loading cycles	Sequence of phases comprising of plasma loading, plasma return and regenernation of one adsorber
PPV	Patient plasma volume
Preservation buffer	PBS-azide solution used to preserve the adsorber matrix for storage
Priming	Step within treatment in which priming solution is flushed trough the tubing set.
Priming solution	Saline solution used to prime the extracorporeal circuit and regenerate the adsorber matrix within a loading cycle
Read standard	Saved patient-independent settings (substitution solutions, volumes, basic and final concentrations, sequence of substitution solutions, bag volume, and waste bag volume) from previous treatment can be used for the current treatment as standard.

Reduction	Reduction curve with all treatment parameters is displayed
Reinfused blood	Reconstituted whole blood from previously separated blood cells and pathogen depleted plasma or plasma substitution solution
Reinfusion balance	Balance during the blood return phase after the end of the treatment; Reinfusion balance starts at the negativ adsorber volume and ends either at 0 (blood is just returned) or +100 (blood is returned and some extra volume is given for minimizing blood loss).
Save standard	The substitution settings are saved as instrument-specific and patient independent standard on the instrument. Upon further treatments the standard can be retrieved by using the **read standard** button.
Separator drive	Instrument component for actuating/rotating the disk separator
Single column immunoadsorption	Application utilizing a single adsorber for a treatment
Substitution solution	Used for TPE to replace discarded plasma
Subst. vol	Substitution volume
Substitution volume	Refers to the total volume of substitution solutions If the total substitution volume is smaller or larger than the entered plasma exchange volume, the value will be depicted in red. The substitution solution need adjustment before continuation of the process.
Therapeutic plasma exchange	Therapeutic plasma exchange; application for the removal and substitution of plasma
TheraSorb LIFE 21 therapeutic apheresis platform	Medical devices by Miltenyi Biotec B.V. & Co. KG used together for therapeutic apheresis (e.g., instrument, adsorbers, tubing sets, solutions). Additional products from other manufacturers are required (e.g., cannulas, anticoagulant, plasma substitutes).
TMP	Transmembrane pressure

Touchscreen	Touch-sensitive color LCD monitor The touchscreen can be operated with gloves.
TPE	Therapeutic plasma exchange
TPV	Treated plasma volume
Transmembrane pressure	Pressure difference between the whole blood side and the plasma side of the disk separators plasma separation membrane
Treated plasma volume	Amount of plasma processed or intended to be processed
Tubing set	Used for the connection of the different components of the TheraSorb LIFE 21 apheresis platform and the patient for separation of whole blood into plasma and cellular components and channeling of blood, plasma and solutions in the course of a treatment
Type label	Label on back panel containing information such as ID of instrument and regulatory information
USB port	USB-A port on the display housing for data transfer
Waste bag	Bag containing discarded liquids during a treatment; the waste bag is not part of the LIFE 21 apheresis platform

3

Important safety information

To avoid potential risks and hazards associated with operating the instrument, read the safety information, warnings, precautions, and instructions contained in this user manual very 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 follow 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.

⚠ WARNING

Observe the following safety information, warnings, precautions, and instructions at all times when using the instrument:

- **Always operate, handle, use, and maintain the instrument in accordance with the safety information, warnings, precautions, instructions, and recommended procedures provided in the user manuals and other written instructions issued by Miltenyi Biotec. Do not deviate from these operating instructions and procedures.**
- **Always ensure the instrument is operated, handled, used, and maintained only by appropriately skilled and trained personnel familiar with the construction, operation, and hazards involved with the equipment.**
- **Always operate, handle, use and maintain the instrument in compliance with all applicable laws, rules, regulations, and administrative provisions, including, without limitation, all regulations regarding health and safety at work and, as appropriate, the safety of medical devices, as applicable to the location where the instrument is operated.**
- **Always use the instrument for its designated purpose (in accordance with the product documentation and within its performance limits), and not in any other manner or for any other purpose.**
- **Safety and performance of the instrument may be compromised. Never use the instrument with consumables, accessories, parts, and/or cables other than those approved by Miltenyi Biotec to ensure safe and proper operation of the instrument. The use of consumables, accessories, parts, and/or cables not expressly approved by Miltenyi Biotec could void your warranty and/or invalidate your authority to operate this instrument under applicable regulations.**
- **Always follow the maintenance recommendations of Miltenyi Biotec and appropriate product standards. Note that the installation, maintenance, and service of the instrument must only be performed by authorized local Miltenyi Biotec service provider. Confirm that the instrument is not put into operation unless and until all initial and periodic maintenance and instrument safety checks have been successfully performed.**
- **Defects should be addressed immediately. If there is any doubt regarding the proper functioning of the instrument, DO NOT use the instrument and contact the authorized local Miltenyi Biotec service provider or Miltenyi Biotec Technical Support as soon as possible.**

- **Never change or modify the instrument except with Miltenyi Biotec's prior written approval. Note that changes or modifications to this instrument not expressly approved by Miltenyi Biotec could void the warranty and/or invalidate the authority to operate the instrument under applicable regulations.**

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 user of this product is established and in which the patient has been treated.

3.1 Safety instructions

⚠ 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. If the instrument is not working properly and instructions or messages on the display screen advise the operator to contact Miltenyi Biotec Technical Support, immediately follow the instructions. If secure operation is no longer possible, immediately switch off and unplug the instrument from the power outlet, and contact Miltenyi Biotec Technical Support or an authorized local Miltenyi Biotec service provider. Make sure the plasma from the extracorporeal circuit is manually reinfused to the patient and the adsorber(s) are manually preserved to prevent the risk of plasma loss and microbial infection.

3.1.1 Installation and operation

- Only an authorized Miltenyi Biotec service engineer is permitted to perform the installation of the instrument.
- Only trained personnel are permitted to operate the instrument. A Miltenyi Biotec application specialist will provide the training. Equipment safety will be compromised if it is not used according to the manufacturer's instructions.
- Make sure that the operator can recognize and react to optical and acoustical alarm signals at any time during the process.

- The power switch located on the back side of the instrument must be accessible for an emergency shut off at any time.
- The instrument should only be operated when connected to a power outlet. The battery power is for emergencies only, in case of a power failure.
- Do not use an opened or disassembled instrument.
- Do not use the instrument if it has been dropped or damaged.
- Do not use the instrument with damaged or broken parts.
- Do not operate the instrument with a damaged power cable.
- To prevent unintended movement of the instrument, arrest the wheels of the instrument during preparation, treatment, and storage.
- Before cleaning the instrument must be switched off and the power cord disconnected. Use the main plug to disconnect the instrument from the power supply.
- The instrument may be used repeatedly. It is not intended for disposal after single use.

⚠ WARNING

Risk of loss of function. Portable and mobile RF communications equipment can affect medical electrical equipment. The risk of electromagnetic interference can compromise the performance or safety of both the LIFE 21 apheresis unit and other equipment up to a loss of function. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information (see appendix “Guidance and manufacturer’s declaration on electromagnetic compatibility” on page 73).

3.1.2 Risk of electric shock and spread of fire

⚠ WARNING



Risk of severe personal injury or death. Electrical devices pose the risk of an electric shock, electrical short, and overheating. Electric shock may lead to severe personal injury or death. An electrical short and overheating may lead to the spread of fire and serious burns for patients and operators. The instrument is a Protection Class I device. To avoid risk of electrical shock this equipment must only be connected to a supply mains with protective earth. Use only the specific power cord supplied by Miltenyi Biotec with each instrument. For better identification, the power cord label contains the identifier "LIFE 21®". Electrical equipment may emit sparks that could ignite combustible vapors or dust leading to the risk of explosion or spread of fire with physical injuries or serious burns for patient or operator. Do not use the instrument in areas classified as hazardous locations, such as oxygen-laden environments.

⚠ WARNING

Risk of reduced electric and electromagnetic safety. Connecting another electrical equipment to the instrument effectively leads to creating a medical device system. This can result in reduced electric and electromagnetic safety. For this reason, it is forbidden to connect other than the supplied parts to any other interface of the unit (excl. nurse call).

⚠ WARNING

Risk of electric shock or mechanical hazards. Do not remove or penetrate any cover of the instrument to prevent the risk of electric shock or mechanical hazards which could cause personal injuries by moving parts (e.g., lacerations, bruises or contusions). All covers of the instrument and accessory equipment are only to be removed by authorized personnel. Only authorized personnel may open the instrument for maintenance, repair and replacement of defective components. If flames or smoke appear, immediately switch off the instrument, unplug it from the electrical outlet, and contact an authorized Miltenyi Biotec service provider or Miltenyi Biotec Technical Support. Make sure the plasma from the extracorporeal circuit is manually reinfused to the patient and the adsorber(s) are manually preserved to prevent the risk of plasma loss and microbial infection.

⚠ WARNING

IPX1

Risk of electric shock or spread of fire. The instrument is intended for indoor use only. Ingress of water or other fluids may lead to an electrical shortage and the risk of electric shock or spread of fire. Electric shock may lead to severe personal injury or death. Fire may lead serious burns for

patient or operator. Do not use the instrument in a wet or damp location or if it has been exposed to moisture. Avoid high humidity or condensation and protect the instrument from contact with water. Special care must be taken while handling fluids, and spillages should be cleaned immediately. Do not allow fluids to enter the interior of the instrument. Do not operate the instrument if liquids have spilled into the instrument. Unplug the instrument from the power outlet before cleaning.

Make sure the room in which the instrument is operated has adequate air circulation. The instrument should not be placed next to radiators, heat registers, stoves, or other pieces of equipment (including amplifiers) that produce heat. Prevent direct exposure of the instrument to sunlight.

Make sure the main switch, as well as the connector for the power cord is easily accessible and located as close to the operator of the instrument as possible. If it is necessary to disconnect the power supply, make sure that the power switch is set to (○), and unplug the cord only from the power outlet.

200 VA $\frac{100–240\ V\sim}{50–60\ Hz}$

The instrument should only be operated from a power source as indicated on the type label. To receive an information about the type of power source to use, contact your authorized local Miltenyi Biotec service provider or local power company. Do not use extension cords or power strips. Do not overload an electrical outlet.

3.1.3 Magnetic field



The treatment-specific door label is placed on the pump door. The magnets implemented to hold the door label are incorporated in such a way that no special safety precautions are required.

⚠ WARNING

Persons with active implantable medical devices, such as pacemakers, defibrillators or insulin pumps should keep a safe distance, to prevent the risk of electromagnetic interference and any subsequent critical or serious malfunction of these devices.

NOTICE

Risk of damage to electronic equipment or magnetic information carriers. The magnetic field behind the specific door label may influence items such as wristwatches, data cards or other electronic devices. Keep a safe distance to the magnetic field.

3.1.4 Chemical and biological hazards

If blood or blood components have been spilled, the operator must take care to thoroughly decontaminate the instrument (see section 5.6 “Cleaning and disinfection” on page 54). Waste disposal must be in accordance with local regulations.

⚠ WARNING

Risk of contamination. If contact with blood or blood components does occur, the risk of contamination may lead to viral or microbial infection. The operator should wear personal safety equipment in accordance with warnings and precautions for blood and blood components.

3.1.5 Mechanical hazards

⚠ CAUTION

Risk of injury. Moving and revolving parts imply mechanical hazards which can cause physical injury (e.g., lacerations, hematomas, or contusions). Keep away from all moving parts. Do not circumvent any safety measures of the instrument. Follow all instructions given in the user manual especially regarding transport and storage.

3.1.6 Servicing and transport

Unless otherwise specifically noted in this user manual or other Miltenyi Biotec accompanying documents, do not service the instrument. Only an authorized Miltenyi Biotec service engineer may perform service and repair.
The instrument can be transported over short distances, e.g., from ward to ward. If the instrument is transported over longer distances, especially over uneven surfaces, or if it will be subjected to excessive vibrations, a safety test might be necessary to allow proper operation of the instrument during a treatment. Refer to section 5.4 “Transport and storage” on page 51 of the user manual.

⚠ WARNING

Risk of electrical shock and/or physical injuries. Improper or incorrect servicing or repair of the instrument 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, and may void your warranty.

4

The LIFE 21 apheresis unit

4.1 Intended purpose

The intended purpose of the instrument is the therapeutic removal of pathogens from human blood plasma in combination with specific adsorber(s) and their disposables. The instrument is also intended to perform the non-specific removal of pathogens by therapeutic plasma exchange (TPE).
The instrument is for plasma separation and treatment in an extracorporeal circulatory fluid path. It controls and facilitates the withdrawal and anticoagulation of the whole blood from the patient, the separation of the plasma via the disk separator and the return of the purified plasma (e.g., after immunoadsorption) or of plasma substitutes (TPE), together with the blood cell concentrate to the patient. Depending on the selected treatment option the plasma will be discarded or it will be passed over specific adsorber(s) in which the pathogenic substances will be eliminated by retention on the adsorber matrix.

IMPORTANT
Refer to the appropriate user manuals for specific treatments and components needed.

4.2 Specifications

MD

The instrument (S/N 4-XXX) conforms to the Medical Device Directive MDD 93/42/EEC.

CE 0123

The instrument (S/N 5-XXX) complies with all requirements of the European Medical Device Regulation (MDR) (EU) 2017/745.

Conformity is achieved by following applicable European or other international standards on safety and design, e.g., EN (IEC) 60601-1, 60601-1-2, 60601-1-8, 62304.

The instrument is in conformity with the European Directives 2012/19/EU (WEEE), 2011/65/EU (RoHS) and 2006/66/EC (batteries).

For further information on the conformity and regulatory status of the instrument, contact Miltenyi Biotec B.V. & Co. KG. Design and specifications are subject to change without notice.

The technical specifications of the instrument are listed in Table 4.1.

Technical specifications	
Model (class II b medical device)	LIFE 21 apheresis unit (REF 330-000-621 or 330-000-622)
Dimensions	Width: 58 cm Depth: 65 cm Height: 155 cm (without infusion stand)
Weight	85 kg
Safe work load	35 kg
Input voltage	100–240 V
Power consumption	200 VA
Frequency	50–60 Hz
Operation	Continuous
Housing	Fire retardant polyurethan plastic with a paint lacquer resistent to disinfectants.
Operation conditions	Temperature: +16 °C to +27 °C (+61 °F to +81 °F) Air humidity: 20% to 80%
Storage/transport conditions	Temperature: –20 °C to +60 °C (–4 °F to +140 °F Air humidity: <95%
Battery	24 V/3.4 Ah built in valve-regulated lead-acid batteries for treatment continuation in case of power loss 3 V/285 mAh built in Li-battery for real time clock

Technical specifications	
Maximum operating altitude	2,000 m
Protection Class	I
Type	B
Protection against ingress of water	IPX1

Table 4.1: Technical specifications of the instrument

⚠ WARNING

Risk of electrical short. Condensation due to temperature variations can cause electrical short. Do not use the instrument until it has reached the permissible temperature. Ordinarily this will be the case after two hours.

4.3 Guidance and manufacturer's declaration

For the safe operation of the instrument it is necessary to follow some precautions to prevent potential electromagnetic disturbances. The requirements to premises and necessary precautions in relation to other devices are described in this chapter.
The instrument comes with the following detachable parts:

- power cable
- barcode reader

These parts are labelled as accessories for the instrument.
EMC compliance with EN IEC 60601-1-2 has been attested for the instrument with the provided power cable and barcode reader.
If the provided power cable or the barcode reader is missing, contact Miltenyi Biotec Technical Support for information on a replacement part.

⚠ WARNING

Risk of increased electromagnetic emissions or decreased immunity. The use of other power cables or other barcode readers may result in increased electromagnetic emissions or decreased immunity of the instrument. The risk of electromagnetic interference can compromise the performance or safety of both the LIFE 21 apheresis unit and other equipment up to a loss of function.

5 Instrument components

The key components of the instrument are the housing, touchsensitive monitor, pump module, separator drive, sensor modules, chip card drive, an USB interface, and an integrated infusion stand with bag hangers. In addition, a bar code reader is connected to the corresponding interface of the instrument.

5.1 Front view

The front view of the instrument with the main components is summarized in Figure 5.1 on page 36.

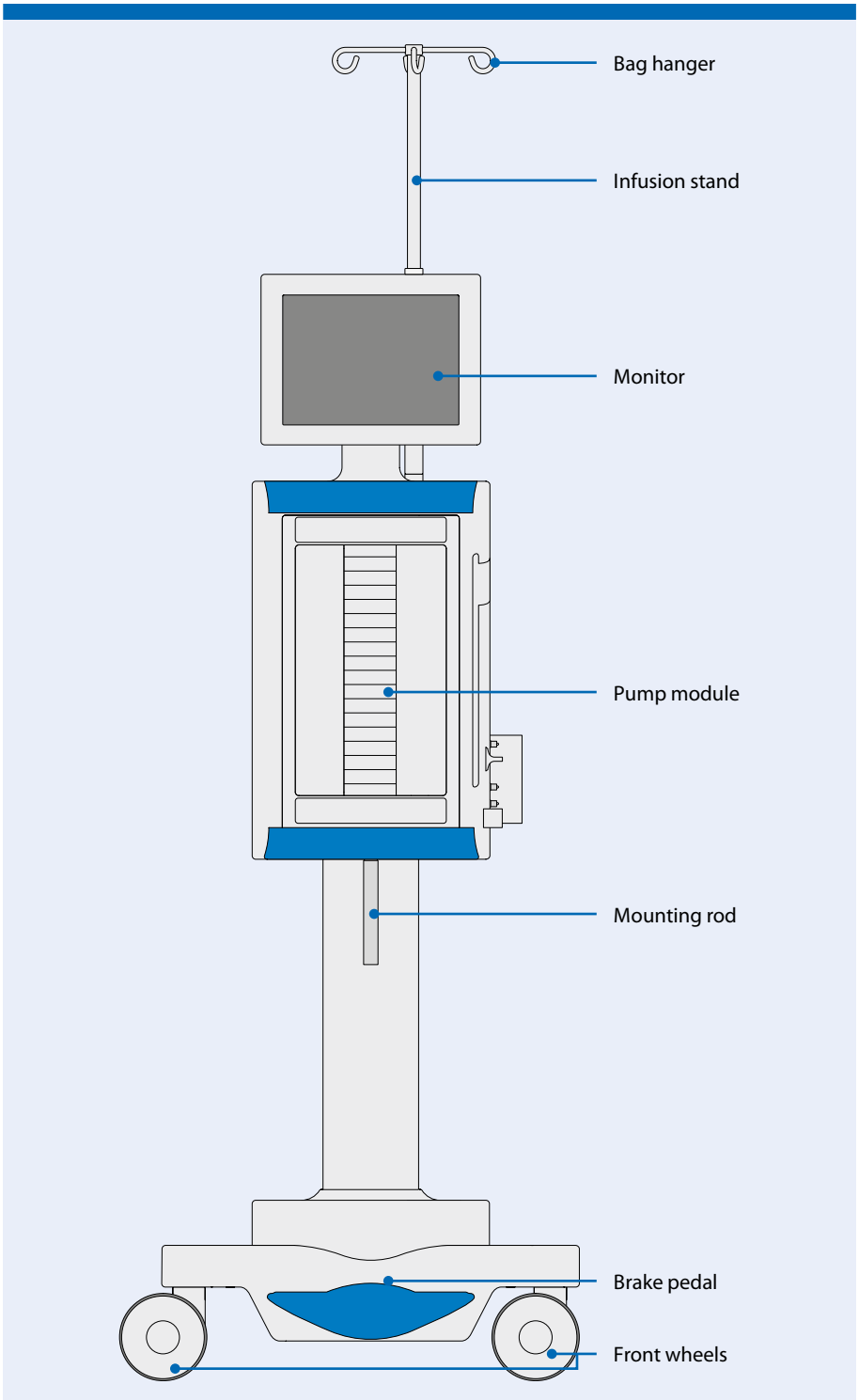


Figure 5.1: Front view of the instrument

5.1.1 Housing

The housing is made from fire retardant polyurethan plastics, and the paint lacquer is resistant to disinfectants. The instrument is mounted on four wheels, and all wheels are equipped with locking brakes. The brakes are activated depressing the brake pedal. Also, the instrument has a mounting rod, which can be used optionally to install, for example, an external blood warmer unit during a treatment.

5.1.2 Brake pedal

The different brake pedal positions are important for the handling of the instrument (see Figure 5.2).



During storage or operation, the brake pedal should be depressed on the left side. All wheels are locked. The instrument is in parking mode and not maneuverable.



The brake pedal is in horizontal position. All wheels are unlocked and the instrument is maneuverable to all sides without restriction.



The brake pedal is depressed on the right side. Rear wheels are fixed in straight position. The instrument is better maneuverable, especially on inclined planes and in curves.

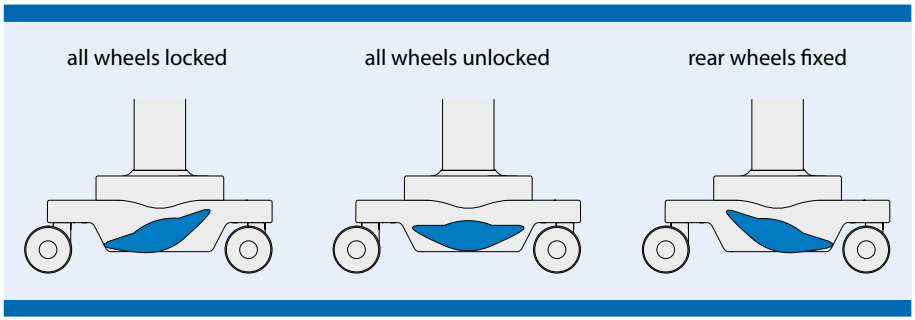


Figure 5.2: Different positions of the brake pedal (front view)

⚠ CAUTION

Risk of physical injury. Moving parts or moving masses can present mechanical hazards which can cause physical injury. Immobilize the instrument by locking all wheel brakes when preparing or performing a treatment. It is also recommended to apply all wheel brakes when the instrument is not in use by pressing the break pedal to the left side when preparing or performing a treatment. This also applies when the instrument is not in use.

5.1.3 Monitor

A touch-sensitive color LCD monitor is used for the communication between the operator and the instrument. The touchscreen surface of the monitor can be operated while wearing gloves. The monitor can be tilted vertically and turned horizontally for better visibility (see Figure 5.3). The loudspeakers for internal acoustic alarms are built into the monitor housing.

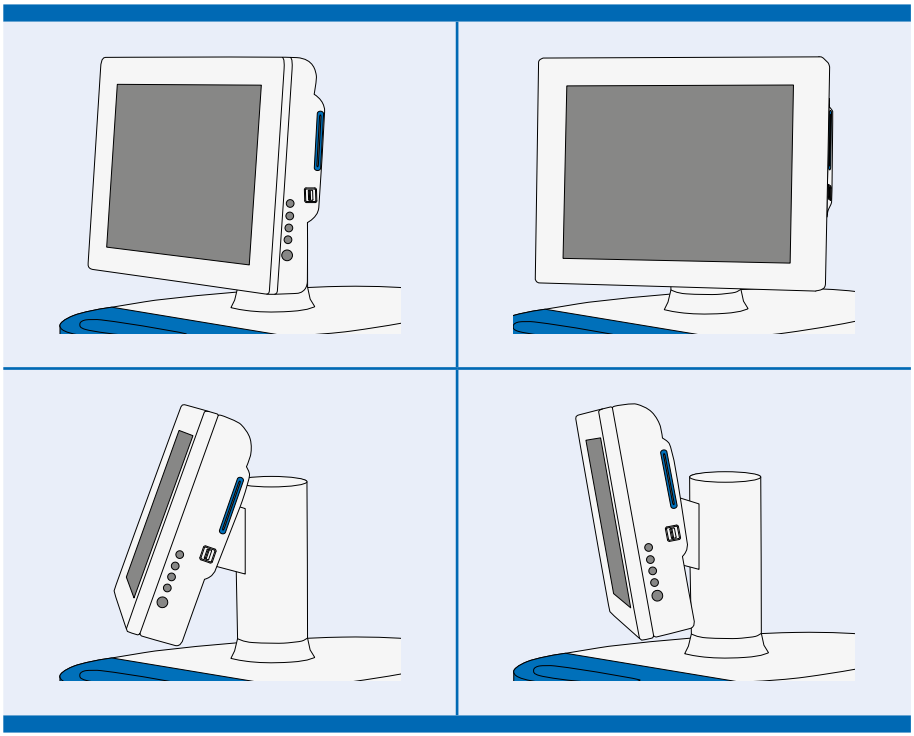


Figure 5.3: Adjustment of the monitor

IMPORTANT

In the case the monitor is dark after the instrument has been switched on check if the off-function of the monitor has been acidentially activated.

5.1.4 Chip card drive

The instrument uses chip cards, which are part of the safety concept, during a treatment. The chip card drive is located on the right side of the monitor (see Figure 5.4).

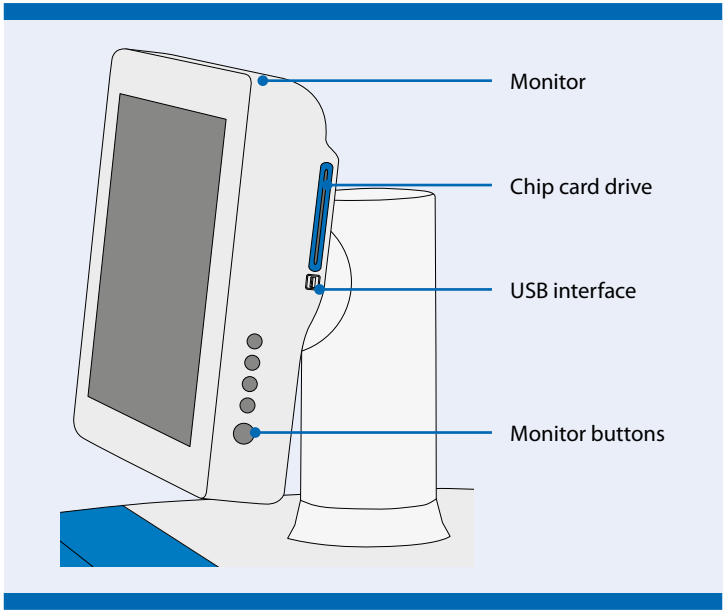


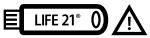
Figure 5.4: Position of the chip card drive and USB interface

The chip card drive that is built into the instrument performs plausibility checks, reads and writes treatment data from and to the patient-related chip card.

IMPORTANT

Only the chip cards, which are provided by the manufacturer can be used with the instrument. Do not use chip cards from other manufacturers. Do not insert or remove a chip card unless prompted by the instrument. Incorrect insertion or removal may lead to data loss or data corruption.

5.1.5 USB interface



The USB interface is used for the TheraSorb USB flash drive only. The software of the instrument allows the transfer of a PDF version of a treatment protocol of the current or a former treatment to the TheraSorb USB flash drive (see Figure 5.4 on page 39). The PDF files can be saved at the beginning of a treatment by selecting the **HISTORY** button or on the treatment status sceen at the end of a treatment by selecting the **PROGRESS** button.
All previous treatments can only be saved in a anonymized format, using patient initials without birth date.
If you need an non-anonymized PDF protocol, consider to save the protocol immediately after the end of treatment in the treatment status screen.

⚠ WARNING

Risk of reduced electric and electromagnetic safety. The USB flash drive provided by the manufacturer or distributor may be attached to the instrument. Connecting another electrical equipment to the USB interface effectively leads to creating a medical device system and can result in a reduced level of electrical or electronic safety, including electromagnetic immunity or emission. Do not connect other than the foreseen USB flash drive to the instrument. For this reason it is forbidden to connect other than the supplied parts to any other interface of the unit (excl. nurse call).

5.1.6 Pump module

The pump module of the instrument consists of 18 separate pump segments, which are arranged one above the other (see Figure 5.5 on page 41). Each pump segment contains six rollers. The pumps are numbered from top to bottom in ascending order. A magnetic door label identifies the pump segment number and its function during a process. The magnetic door label helps to identify the allocation of each pump to parts of the disposable/solution (blue side = TheraSorb IA, yellow side = TheraSorb TPE).

⚠ WARNING

Risk of electrical shock or mechanical hazards. Opening the pump door under operation may cause the risk of electrical shock or mechanical hazards with physical injury to the operator and infection or blood or plasma loss for the patient. Do not open the pump door under operation.

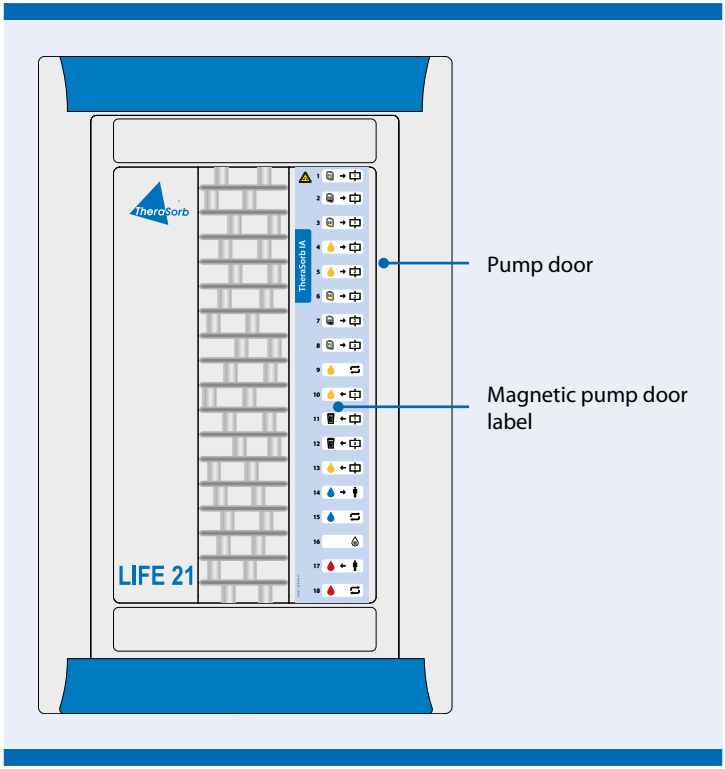


Figure 5.5: Pump module with pump door closed and representative magnetic pump door label

The internal sensors are located on the right hand side of the pump module (see Figure 5.6 on page 42), and are hidden by the closed pump door. A combined light and pressure sensor monitors each pump segment. The light sensors measure the color of the solutions and the pressure sensors the pressure in the respective tubing segment.

⚠ CAUTION

Risk of hemolysis or blood loss. Overexposure can cause a sensor-related warning, indicating incorrect sensor function which may impair the detection of air or hemoglobin and red blood cells (risk of hemolysis or blood loss). Avoid direct lateral light exposure (sunlight or artificial) on the pump module.

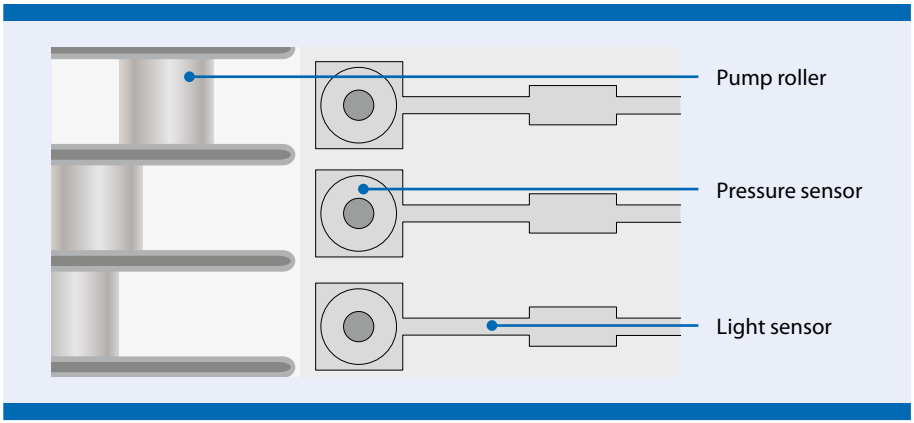


Figure 5.6: Schematic view of the light and pressure sensors

It is recommended to visually check the light and pressure sensors for dirt and particles before the installation of the tubing set. Details on cleaning can be found in section 5.6 “Cleaning and disinfection” on page 54.

5.1.7 Mounting rod

5 kg max

The mounting rod could be used to mount, for example, a blood warmer to the instrument during a treatment.

5.2 Side view

The side view of the instrument with the main components is summarized in Figure 5.7 on page 43.

10 kg max

There are three hooks for solution bags on each side of the instrument, which should be used to hang up solutions/waste bags needed for a treatment with a maximal weight of 10 kg/hook. Each hook on the right hand side of the instrument is labeled with an individual color label. This allows for correct identification of the position of the solutions attached to the instrument.

5 kg max

Σ 10 kg max

In addition, an infusion stand with bag hangers is installed on the instrument, which can hold solutions with a maximal load of 5 kg/bag hanger and in total not more than 10 kg.

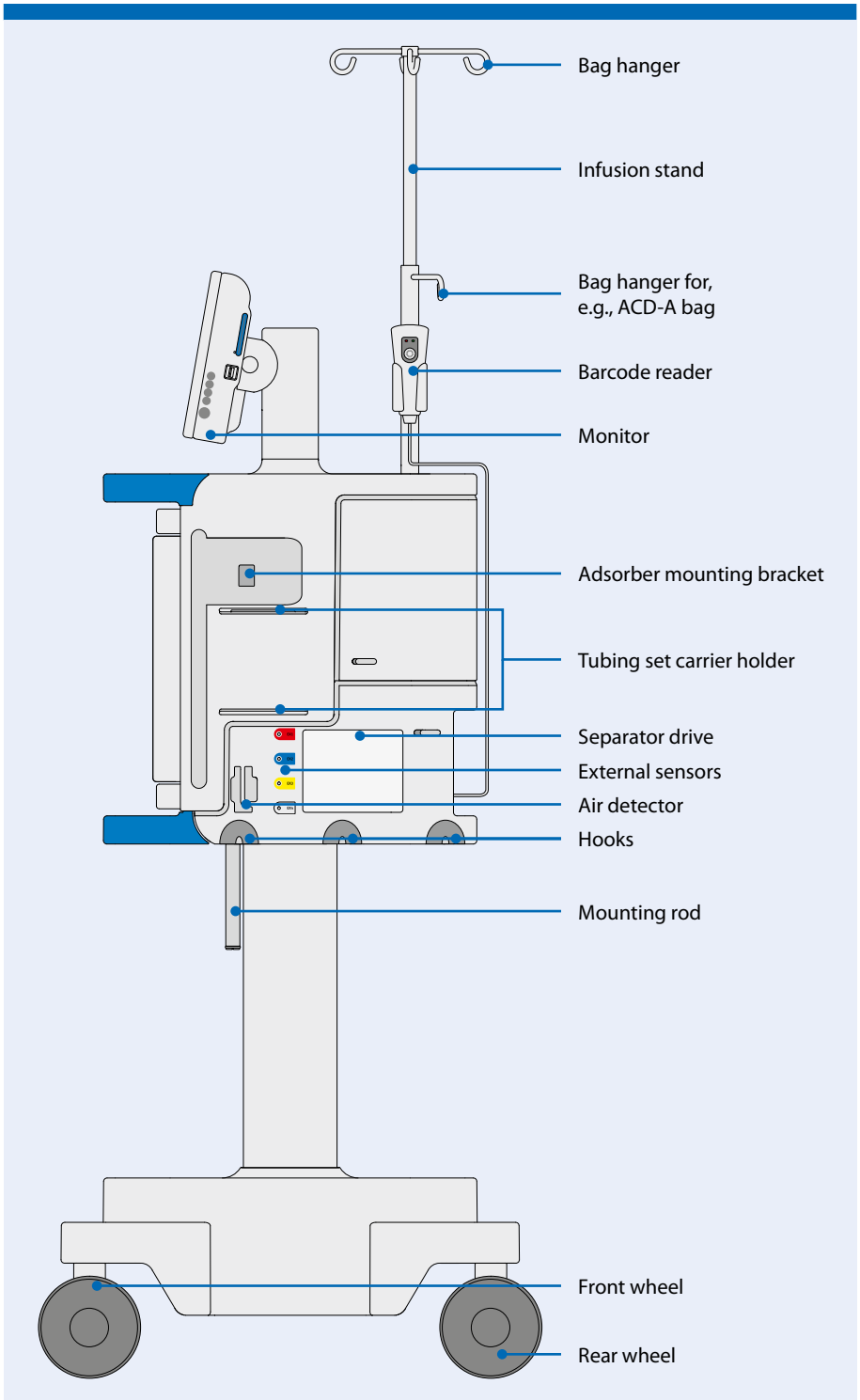


Figure 5.7: Side view of the instrument

5.2.1 Adsorber and tubing set carrier holder

The adsorber mounting bracket is used for the installation of the adsorber holder onto the instrument.
The tubing set carrier holder is used for the installation of the tubing set carrier as part of the tubing set.

5.2.2 External pressure sensors

The external pressure sensors are located in-between the air detector and the separator drive (see Figure 5.8).

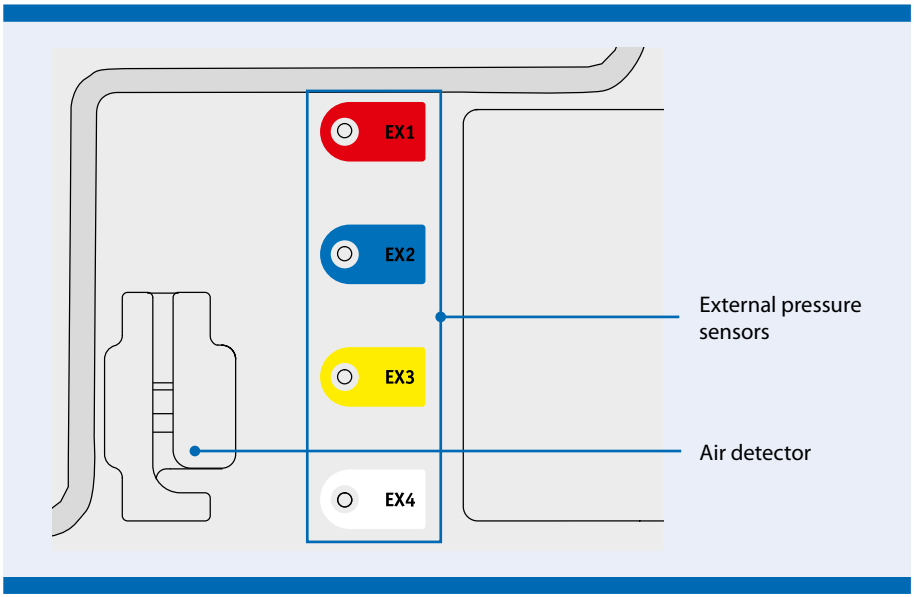


Figure 5.8: External pressure sensors

The different functionalities of the external pressure sensors are summarized in Table 5.1.

Sensor	Color coding	Function
EX1	red	Monitoring of blood withdrawal pressure (high pressure, low pressure, fluctuation)
EX2	blue	Monitoring of blood return pressure (high pressure, low pressure, fluctuation)
EX3	yellow	Monitoring of plasma-side separator pressure
EX4	white	Monitoring of blood-side separator pressure

Table 5.1: Functions of the four external pressure sensors

The tubing set is connected via hydrophobic filters to the external pressure sensors (EX1–EX4). Sensor and corresponding tubing sections are identified by a color code (see above).

⚠ WARNING

Risk of electrical shock or infection. Without filters, electrical shock or microbial infection can occur. Do not operate the instrument without the hydrophobic filters placed between the tubing set and the sensors to protect the sensors and the internal fluid path and to avoid cross-contamination.

5.2.3 Air detector

The air detector is located on the left side of the external pressure sensors (see Figure 5.9).

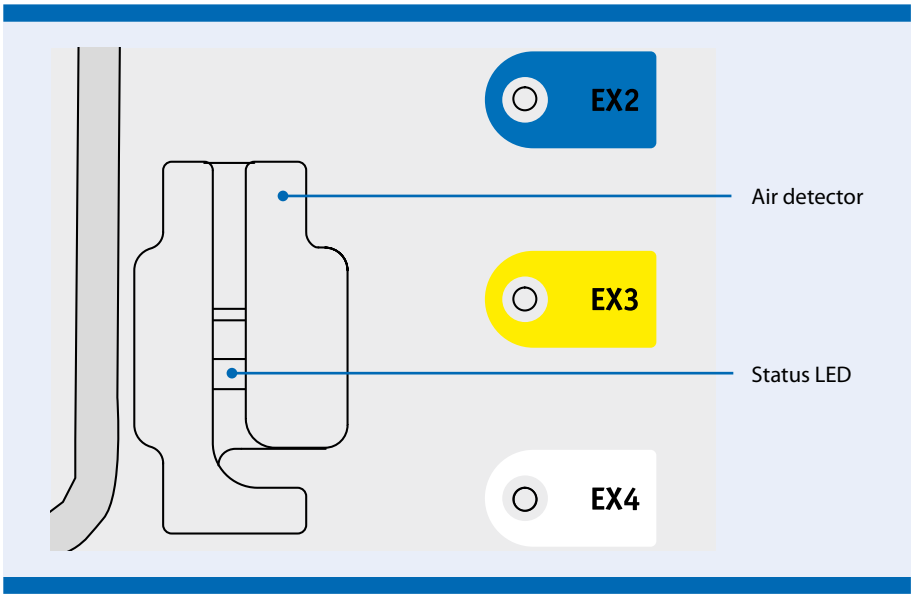


Figure 5.9: Position of the air detector

The air detector is designed to identify the presence of air bubbles in the blood return line by ultrasound. Additionally, the air detector is equipped with a status LED.

- The blue light represents a short initialization phase after switching on the instrument.
- The green light represents the detection of fluid.
- The red light represents the detection of air.

During regular self-tests of the air detector a red flash light within green light is common even though the air detector did not detect any air. If air is detected, all pumps are stopped and both optical and acoustical alarms are set off.

⚠ WARNING

Risk of embolism. Undetected air bubbles can cause embolism. Always verify that only the blood return line is placed into the air detector. Otherwise air bubbles being returned to the patient will not be detected.

5.2.4 Separator drive

The separator drive is located on the right side of the air detector (see Figure 5.10).

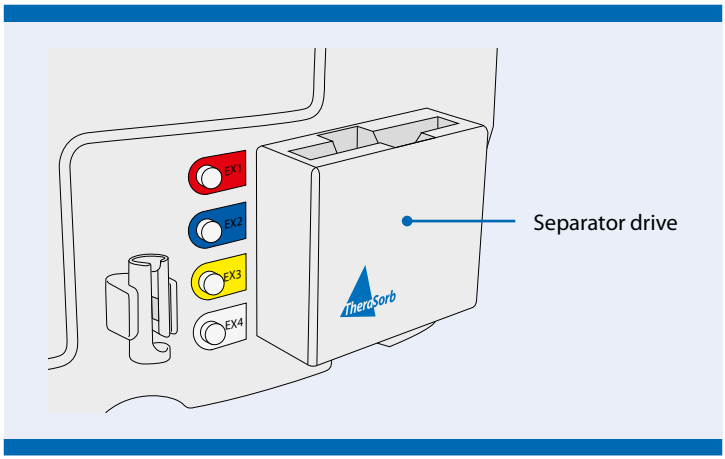


Figure 5.10: Pump module with pump door closed and representative magnetic pump door label

The separator drive is responsible for the rotation of the disk separator, which is part of the tubing set.

5.3 Rear view

The rear view of the instrument with the main components is summarized in Figure 5.11 on page 48.

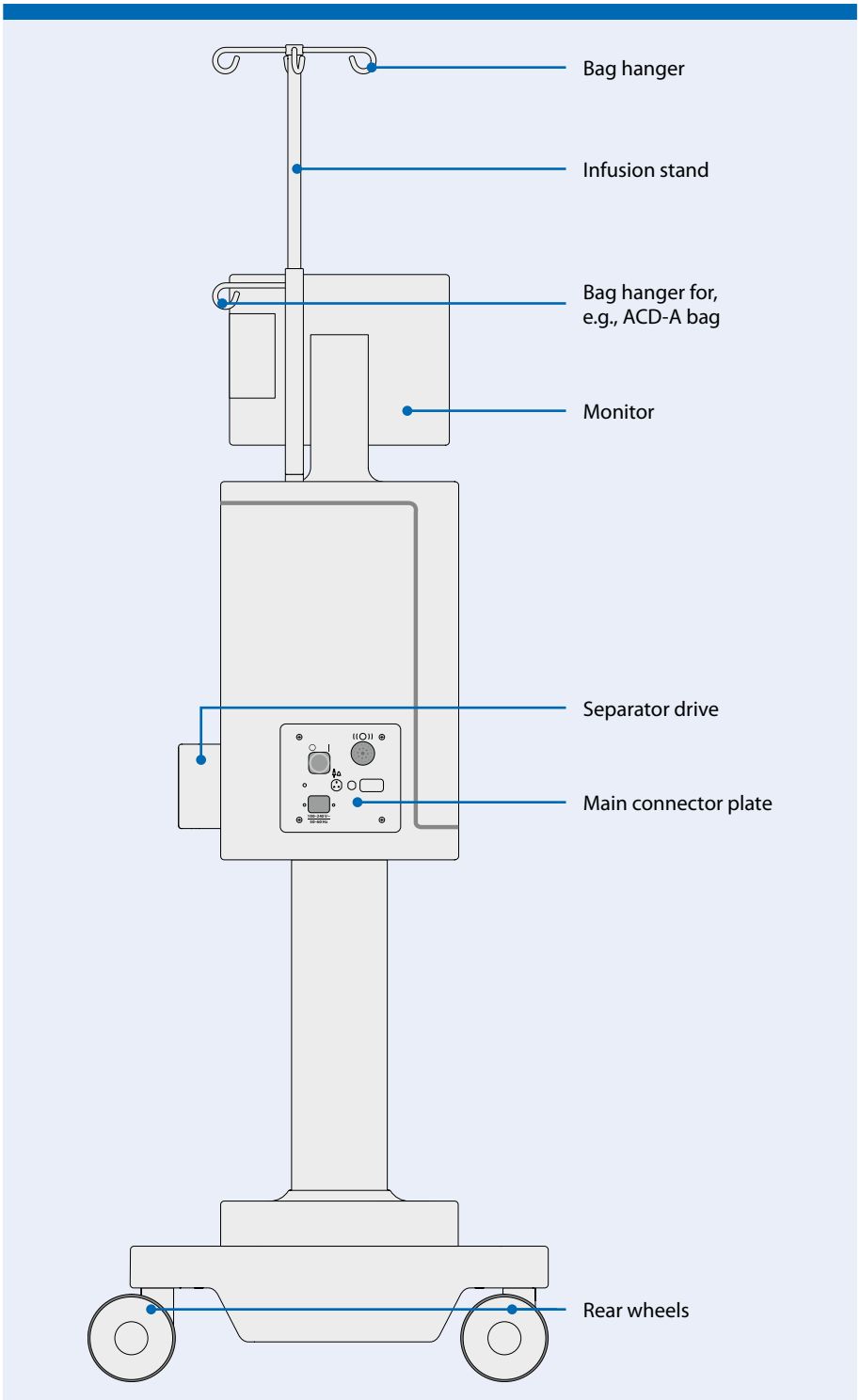


Figure 5.11: Rear view of the instrument

5.3.1 Main connector plate

The components positioned on the main connector plate of the instrument are summarized in Figure 5.12.

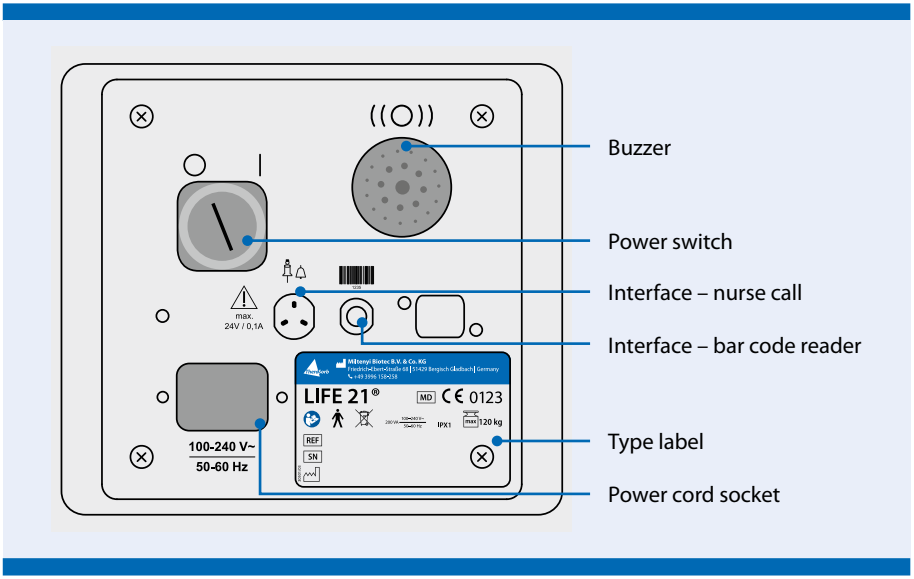


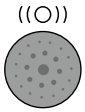
Figure 5.12: Main connector plate of the instrument



The instrument can only be switched on (I) or off (O) by using the power switch located on the main connector plate.
The power interface is an IEC-socket for connecting the power cord to the instrument. In the case, the instrument is switched on and the power cord is disconnected from the mains socket the instrument will run on battery power, which provides continuous power for at least 15 minutes.

⚠ WARNING

Risk of loss of function. Electromagnetic interference can compromise the performance or safety of both the LIFE 21 apheresis unit and other equipment up to a loss of function. Use only the specific power cord supplied by Miltenyi Biotec with each instrument. For better identification, the power cord label contains the identifier "LIFE 21®".



The buzzer is a piezo buzzer for acoustic alarm signals. Refer to section 6.3 "Alarm management" on page 64 of the user manual.



The nurse call is an interface for the connection of the instrument to the inhouse call-system. The interface for the nurse call is fitted with a three-pin code socket and a switching relay. This relay may only be used to switch a maximum of 24 V/0.1A.

⚠ WARNING

Risk of electrical shock, fluid imbalance, vascular damage hemolysis or embolism. Unauthorized equipment may compromise the electrical and electronic functional safety with risks of electrical shock, fluid imbalances, vascular damage, hemolysis or embolism. Any additional equipment, which is connected to the nurse call interface of the instrument, must be certified as complying with EN IEC 60601-1 for Medical Electrical Equipment. Any changes to the instrument not performed by persons authorized by the manufacturer, results in exclusion of any liability.

The type label contains serial number, product number, product name, manufacturing year and manufacturer of the instrument as well as details of the power supply of the instrument.

5.3.2 Bar code reader



The socket for the barcode reader is located besides the nurse call interface (see Figure 5.12 on page 49). The barcode reader serves as a data input device for input of the article number, expiration date and batch number of materials required for a treatment. However, it is possible to enter the data manually via the on-screen keyboard, if needed.

⚠ WARNING

Risk of electrical shock, physical injuries, fluid imbalances or loss, vascular damage, hemolysis or embolism. Unauthorized equipment 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. Only the barcode reader provided by the manufacturer or distributor may be attached to the instrument. Do not connect barcode readers or equipment from other manufacturers to the instrument.

5.4 Transport and storage

It might be necessary to move the instrument within or beyond the ward of the hospital. Before transporting the instrument, switch off the power and remove the power cord from the socket.

⚠ WARNING

Risk of electrical shock, physical injuries, fluid imbalances or loss, vascular damage, hemolysis or embolism. Excessive vibration may compromise the electrical, electronical, electromagnetic and mechanical safety which can endanger patients, operator and others due to possible instrument damage or malfunction. Moving parts or moving masses can present mechanical hazards which can cause physical injury. For transportation over longer distances, make sure the instrument is transported on level surfaces and excessive vibrations are avoided. If this is not guaranteed, the instrument must be subjected to a technical safety test before being put into operation after transport. For storage of the instrument, make sure the power cord is unplugged and the disposables and solutions are completely removed. For safety reasons lock the front wheel brakes to prevent unintentional movement of the instrument.

⚠ CAUTION

Risk of hemolysis, blood loss or cytopenia. Instability can result in mechanical hazards with resulting physical injury. It is recommended that the instrument is moved without any mounted treatment equipment in order to prevent any instability of the instrument. Avoid any mechanical impact on the disk separator drive.

NOTICE

Risk of damage to the instrument. Always switch off the power before any transportation to prevent damage to the instrument. Do not transport the instrument while running on battery power. For transportation the rear wheels can be blocked by pressing the pedal to the right in order to prevent an instability of the instrument.

5.5 Maintenance

⚠ WARNING

Risk of electrical shock, physical injuries, fluid imbalances or loss, embolism, vascular damage or insufficient treatment. If the following instructions in section 5.5 are not observed, electro-mechanical hazards resulting in electrical shock, physical injuries, fluid imbalances or loss, embolism, vascular damage or insufficient treatment may result. 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. Always follow the instructions, warnings, or cautions at any time.

Unpacking of the instrument, installation, maintenance, and service should only be performed by an authorized Miltenyi Biotec service engineer. Make sure that the instrument is not put into operation unless, and until all initial and periodic maintenance and instrument safety checks have been successfully performed. A maintenance of the instrument is necessary periodically. This periodic maintenance must be performed only by an authorized Miltenyi Biotec service engineer.

5.5.1 Servicing

As defined by the manufacturer, the instrument must be subjected to, and pass, a technical safety test before being put into operation after shipment. The technical safety test must be performed by an authorized Miltenyi Biotec service engineer, and needs to be repeated at defined intervals. If the end of an interval has been reached a screen will be displayed on the instrument during start-up, to inform the operator to contact Miltenyi Biotec Technical Support (see Screen 5.1).



Screen 5.1: Required service check of the instrument

Service, repair or modification of the instrument and its software, including the technical safety test, may only be performed by an authorized Miltenyi Biotec service engineer.
Only accessories authorized by Miltenyi Biotec may be used to replace defective parts such as the bar code scanner or the power cord. Accessories are clearly labeled with the identifier "LIFE 21®".

5.5.2 Shipment

Miltenyi Biotec is responsible for the delivery of instrument to the customers premises in a specified transport container. Unpacking, assembly, installation, and safety testing must be be performed by an authorized Miltenyi Biotec service engineer before first operation of the instrument. Miltenyi Biotec will also be responsible for returning the transport container.

If the instrument has to be returned to the manufacturer for any reason, the shipment will be under the sole responsibility of Miltenyi Biotec. Miltenyi Biotec will provide the transport container for the return shipment. On the agreed date, an authorized Miltenyi Biotec service engineer will disinfect and uninstall the instrument. It will be placed into the transport container according to internal Miltenyi Biotec specifications. The instrument and contents will then be returned to Miltenyi Biotec.

5.6 Cleaning and disinfection

Cleaning of the instrument is the only maintenance action that an operator may perform. Before cleaning, switch off the power and disconnect the instrument from the power supply.

⚠ WARNING

IPX1

Risk of electrical shock. Cleaning and disinfection may cause electrical shock, if the instrument is under current and fluids enter the housing. The instrument is not watertight, but it is resistant to falling water according to European standards (IPX1). The instrument should only be cleaned with a soft cloth, slightly moistened with disinfectant. Special care must be taken with the cleaning of the internal pressure and optical sensors (pump unit) as well as the external sensors (EX1–EX4 and air detector).

Cleaning with a disinfectant should include the following components:

- housing
- adsorber mounting bracket
- monitor surface
- separator drive surface

Dust and dirt particles on the internal pressure sensors should be removed with a soft, dry cloth and/or cotton swab.
Dust and dirt particles on the internal optical sensors (pump unit), external sensors (EX1–EX4), and air detector should be removed with a soft, dry cloth and/or cotton swab moistered with 70% Ethanol, or equivalent.

The manufacturer recommends usage of the following cleaning agents:

- soap solution
- approved surface disinfectants (do not use floor disinfectants)

⚠ WARNING

Risk of electrical shock. Detergents or other fluids entering the instrument may cause electrical shock when the instrument is powered on. Avoid any contact of detergents or other fluids with the pump unit and its electro-mechanical components. If this occurs, the manufacturer must be informed immediately and the instrument may not be turned on.

5.7 Instrument disposal



Contact Miltenyi Biotec Technical Support for assistance on the disposal of the instrument. Do not dispose of the instrument or its accessories using regular waste disposal procedures. Final disposal of the instrument must be performed in accordance with current European regulations (WEEE and RoHS).

6 Software

6.1 Touchscreen

The instrument is equipped with a touch-sensitive color LCD monitor. The elements of the instrument software are operated via the touchscreen. The touchscreen can be operated with gloves.

Press: A short contact of the touchscreen elements with fingers or a blunt item is called a “press”. This gesture is used to start a process, to mark data, or to interact with a process during dialog control.

Hold: Contact and holding of a designated spot on the touchscreen will be detected as a gesture by some control elements (e.g., list).

Drag & Drop: After holding a designated spot some elements can be moved on the screen and dropped to a new position.

6.2 Graphical user interface

The graphical user interface (GUI) allows the operator to interact with the instrument via software screens using touch-sensitive functions.

IMPORTANT

Screenshots presented in this manual are examples and may differ slightly from screens displayed on the instrument during a treatment. Refer to the appropriate treatment manuals for more details.

6.2.1 Operating controls

The display of the GUI is divided into several sections (operating controls), which perform different tasks during a treatment. During the process operating controls are adapted automatically to different process requirements. The following section gives an overview on the main functionalities of the GUI. Figure 6.1 or Figure 6.2 on page 59 show typical software screens that display general functionalities of the GUI. The context-dependent menu bar allows the operator to retrieve further information or instructions related to the treatment. The **ERR log** button displays all error codes during a treatment. During the treatment the **History/Progress** button displays all treatment- and progress-related information. At the end of a treatment a list of all completed protocols for a possible transfer to the TheraSorb USB flash drive is shown. The **Comment** button allows the operator to enter additional treatment-relevant information, and the **Menu** button displays treatment-related options. The **information/instruction area** helps the operator to identify the different phases within a treatment. The **Selection** button in general selects a software action when pressed. The **status/progress information area** displays the progress of currently executed steps. The **instruction field** asks the operator for actions that should be fulfilled before the process continues. The **Confirmation** button starts a software action when pressed and usually switches to the next software screen.

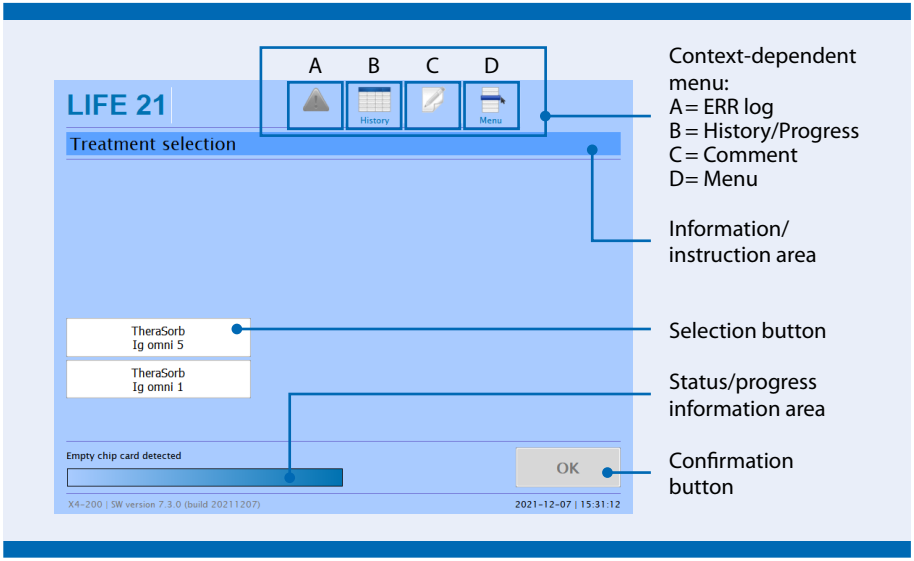


Figure 6.1: Main screen to select a treatment process

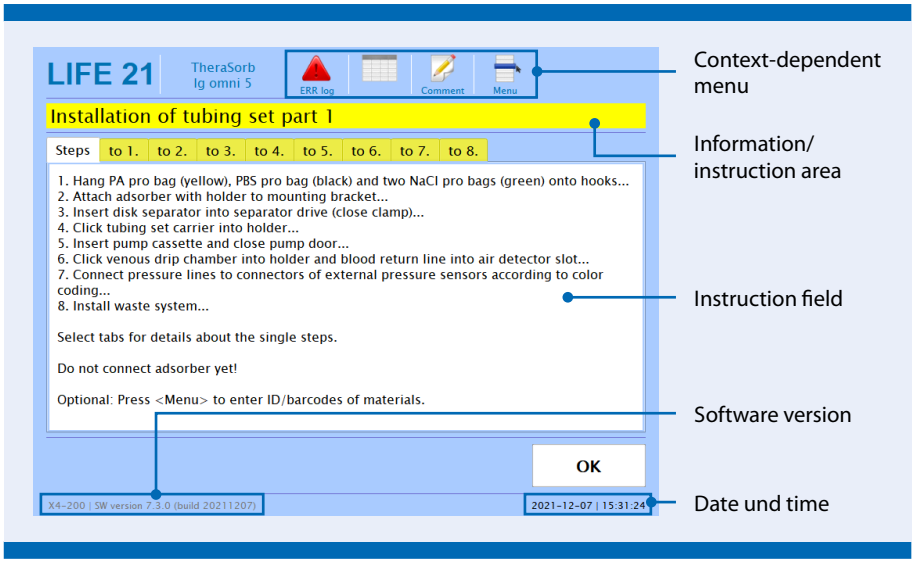
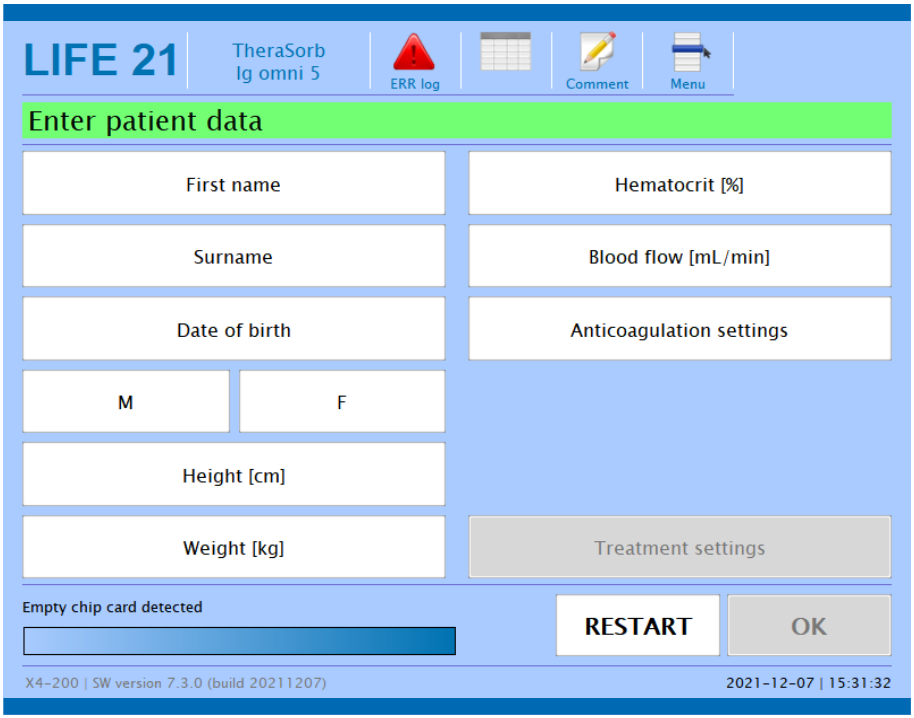
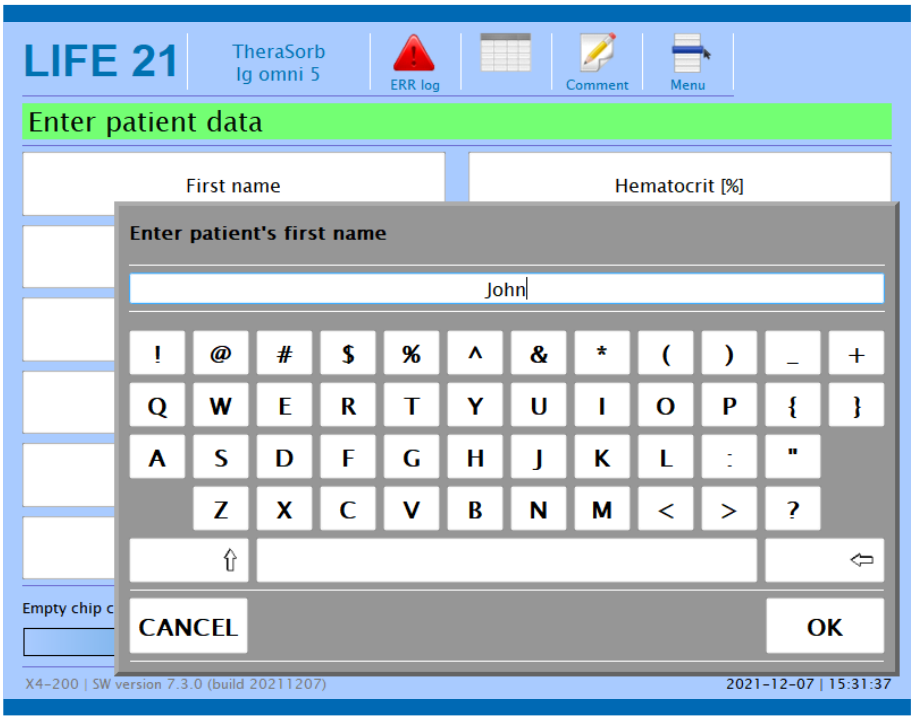


Figure 6.2: Representative sreen for detailed instructions for the operator

The operator needs to enter patient/treatment-related information (see Screen 6.1 on page 60). The buttons in gray require an operator action before continuation of the process. The required data are entered using an on-screen keyboard (see Screen 6.2 on page 60). After pressing **OK**, the button displays a check mark. After the fulfillment of all data entry requirements the process can be continued. In general, the **RESTART** button allows the operator to continue with a process after interruption. Also, during patient data entry the **RESTART** button guides the operator back to the treatment selection screen to reselect the treatment.



Screen 6.1: Representative screen for data entries



Screen 6.2: Representative screen with an on-screen keyboard

After the process has been started, it may be necessary to change or adjust treatment-related parameters. Figure 6.3 shows a typical treatment status screen. Pressing the **STOP** button will immediately stop the pumps.
During the treatment the **STOP** button will change to **RESTART** after confirmation of an alarm screen to continue with the treatment.
The acceptable limits or positions of, for example, substitution solutions can be changed by using the **drag & drop function** of the GUI. Parameter fields allow the operator to change factors during the treatment.
The **Next user action** displays residual time and residual volumes before next bag exchange is required. The background color changes to yellow if the time is less than one minute.
The **Status area** (yellow) diplays current information relevant to the operator. The red and blue bars located on the left side of the screen show the current blood withdrawal and return pressure.
The adsorber symbols in the lower right part of the screen visualize the adsorber status. The colors correspond to the medium, for example, during plasma loading the adsorber symbol is coloured yellow.

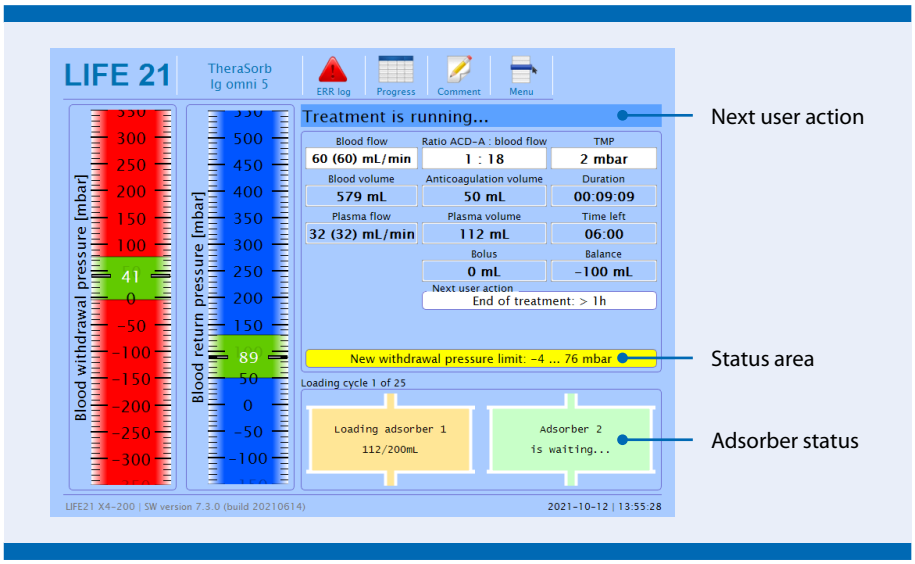
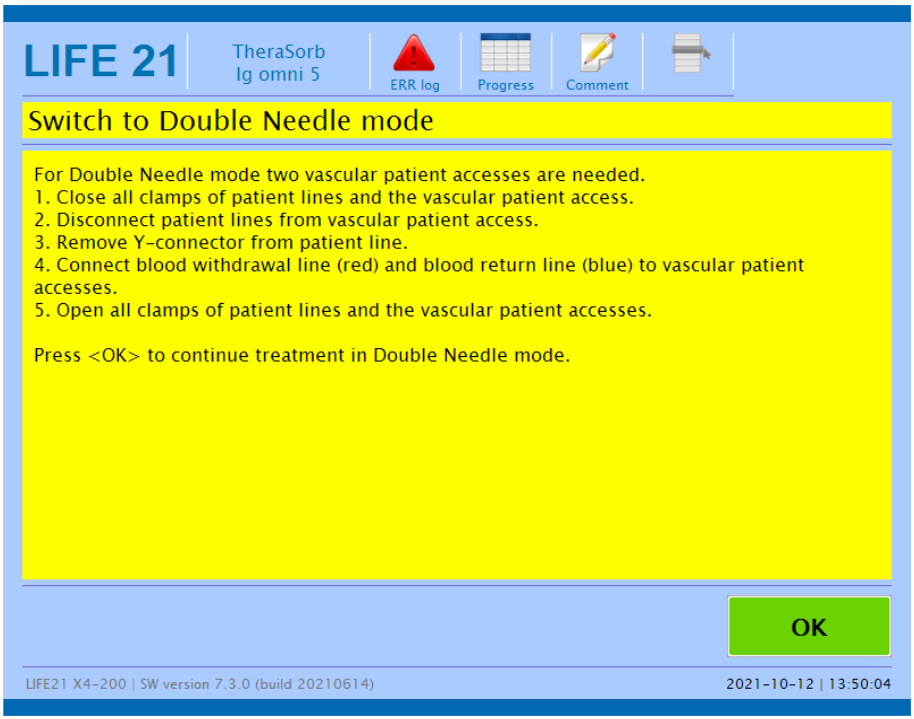


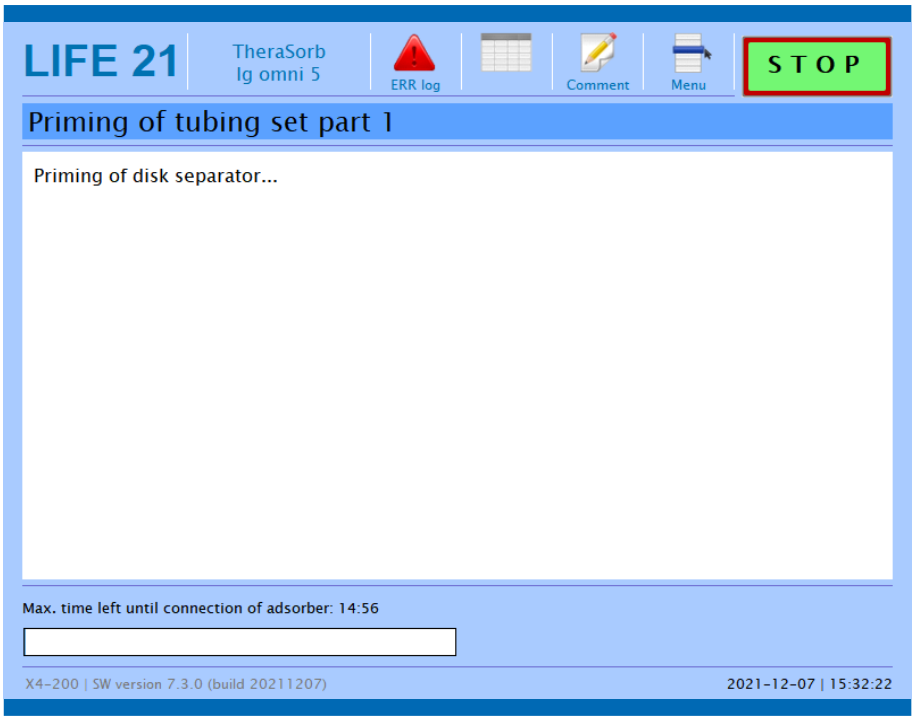
Figure 6.3: Interactive screen showing real-time treatment parameters

The instruction screen (see Screen 6.3) will be displayed, if additional actions are required by the operator to allow the continuation of the treatment.



Screen 6.3: Representative instruction screen

During preparation and preservation a status screen informs the operator about the current software action (see Screen 6.4).



Screen 6.4: Representative status screen in preparation and preservation

6.3 Alarm management

A list of possible error messages, their causes and applicable countermeasures can be found in the user manual “Warnings, precautions, and troubleshooting”.

A multi-stage alarm system notifies the operator in case of an error (see Table 6.1 and Figure 6.4 on page 65). Alarms use both visual and acoustic signals to notify the operator.

Alarm level	Description	
Warning	Visual:	An instruction is shown on the monitor by a flashing yellow screen.
	Acoustic:	The warning signal uses the following characteristics: 2 impulses per signal signal duration: 1 s, 30 s pausing sound level: 61 dB(A) The acoustical signal can be suppressed for a duration of 2 minutes by touching the yellow alarm field on the screen.
Alarm	Visual:	An alarm message is shown on the monitor by a flashing red screen.
	Acoustic:	The internal audio alarm signal uses the following characteristics: 3 impulses per signal impuls duration: 250 ms, 250 ms pausing signal duration: 1.5 s, 3 s pausing sound level: 70 dB(A) If an alarm screen is not acknowledged within 3 minutes, the loudspeaker (buzzer) at the rear side of the instrument will give an external alarm signal. The external audio signal uses the following characteristics: 1 impulse per signal impuls duration: 1 s signal duration: 1 s, 5 s pausing frequency: 3,500 Hz sound level: >72 dB(A) up to a distance of 1 m from the instrument
	Audio alarm function muted: 	The internal and external acoustical signal can be suppressed for a duration of 2 minutes by touching the red alarm field on the screen. During this time the symbol on the left is shown.

Table 6.1: Visual and acoustic signals

Additional information about characteristics of the alarm system is given in Table 6.2:

General alarm system characteristics	Application to LIFE 21 apheresis unit
Delay of alarm conditions	Not applicable
Operator position	Instrument shall be positioned in such a way and/or monitor shall be rotated in a position that: Alarm conditions can be recognized from a distance of 4 m, Alarm information can be recognized from a distance of 1 m.
Priorization of alarm conditions	No priorization
Nurse call	May only be used as additional information about alarm condition and not as primary remote alarm signal indicator

Table 6.2: Application of general alarm system characteristics

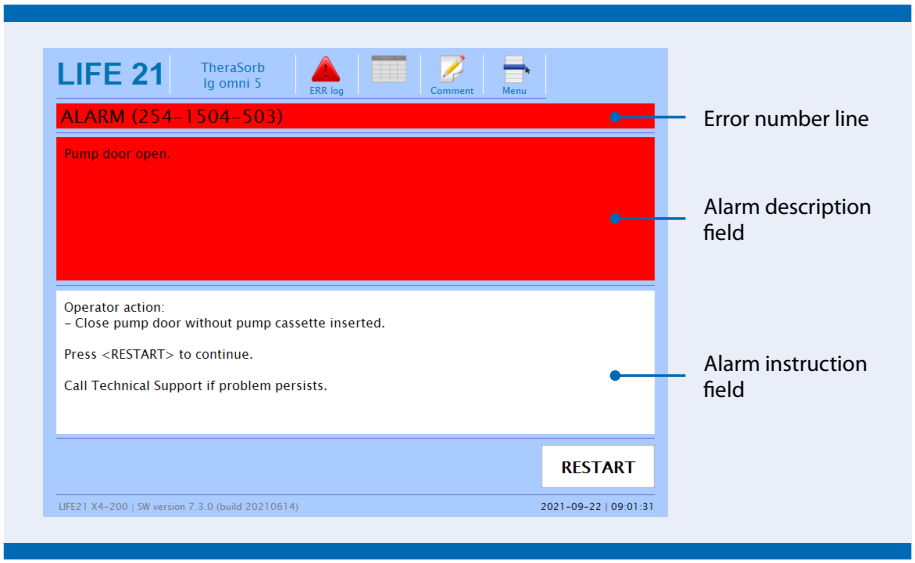


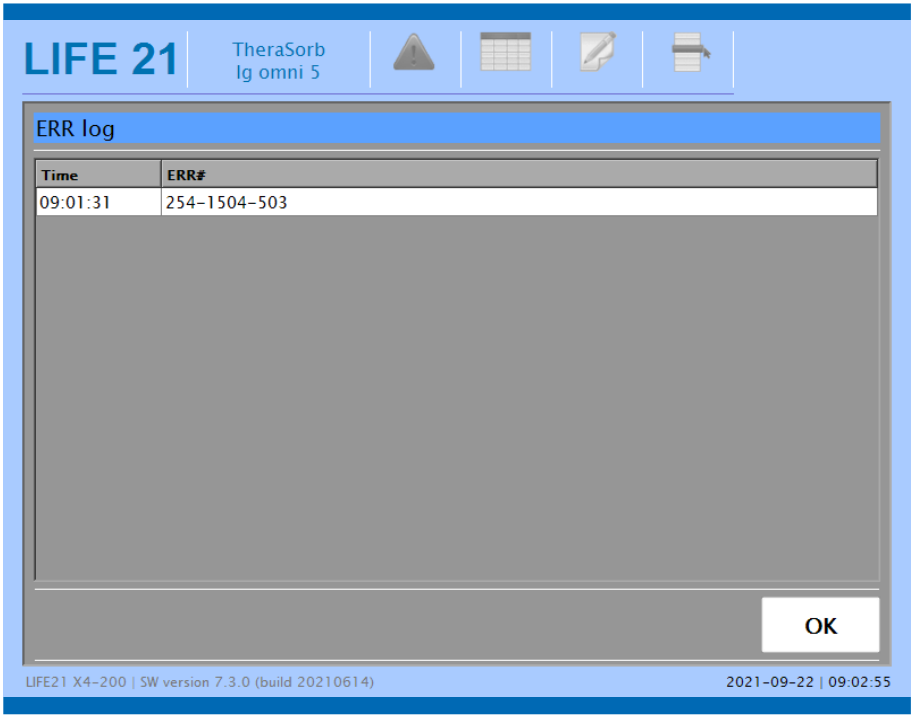
Figure 6.4: Example for an alarm screen

6.3.1 Access to alarm log list

An alarm log is accessible during several steps of a treatment via the ERR log button (see Figure 6.4 on page 65 and Screen 6.5).
The displayed alarm log list gives an overview about all alarms of the actual treatment (time of occurrence, alarm ID, service info).
The alarm log may be used in troubleshooting cases where the error ID was not noted down during the occurrence of an alarm.

IMPORTANT

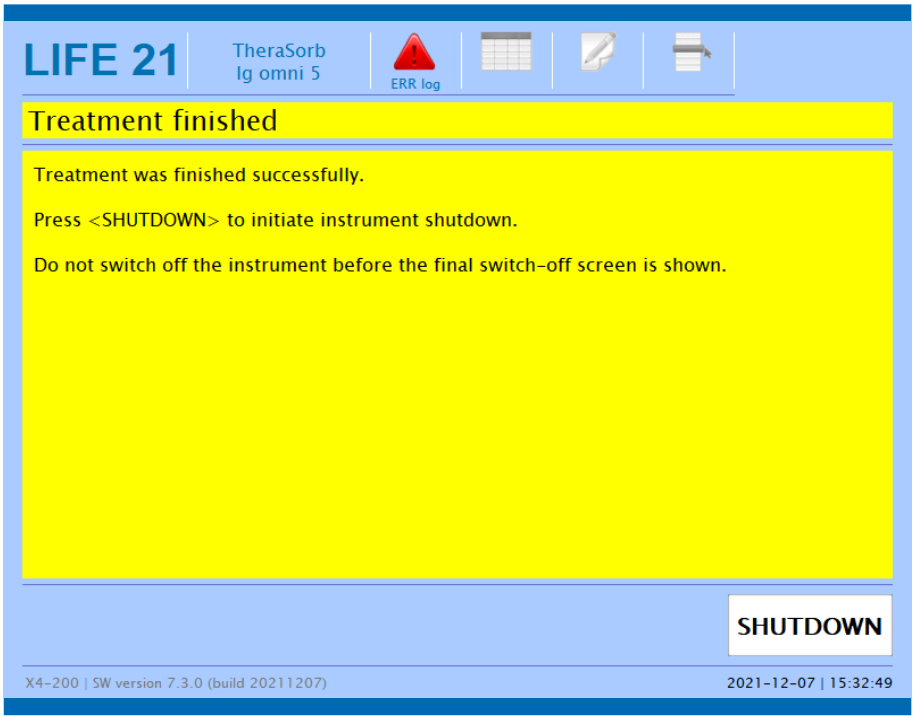
The alarm log is persisting after the treatment has been aborted and resumed (e.g., after a power loss), however, the alarm log is non-persisting after the treatment is finished and the instrument has been switched off.



Screen 6.5: Example for error log list

6.4 Shutdown

At the end of a treatment the operator will be prompted to shutdown the instrument and turn the power off (see Screen 6.6).



Screen 6.6: Shutdown screen

⚠ WARNING

Risk of electrical shock and contamination. All materials, which have been in contact with blood or plasma must be treated and disposed as biohazardous materials according to standard hospital or institutional requirements and national legislations, to prevent viral or microbial infection. Cleaning and disinfection of the instrument may only be performed after the power has been shut-off and the power cord has been disconnected from the power supply socket, to prevent electrical shock.

In case of a manual or emergency shutdown during a treatment, the instrument will automatically save the current treatment status. The procedure can be restarted upon restoration of the power or terminated as desired.

7 Troubleshooting

For troubleshooting issues regarding the instrument refer to the user manual “Warnings, precautions, and troubleshooting”.

If an error cannot be overcome by countermeasures described in the user manuals inform the Miltenyi Biotec Technical Support. Note the error number and service information on the screen for easier identification of the problem.

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.

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.

Miltenyi Biotec's product warranty only covers product issues caused by defects in material or workmanship encountered during ordinary use, as described in the user manual or other documentation provided by Miltenyi Biotec; it does not cover product issues not arising out of defects in material or workmanship, including but not limited to product issues resulting from: failure to follow installation, operating and/or maintenance instructions, or environmental conditions prescribed in, this user manual or other product documentation; misuse; abuse; neglect; mishandling; unauthorized or improperly performed maintenance or repairs; accident; acts of God; limitations of technology; electrical current fluctuations; modification of or to any part of the product; use of accessories, spare parts and/or consumables other than those recommended by Miltenyi Biotec; or normal wear and tear.

Miltenyi Biotec's product warranty does not cover products sold AS IS or WITH ALL FAULTS, or which had its serial number defaced, altered or removed, or any consumables, or parts identified as being supplied by a third party; those third-party accessories or parts may be covered by a separate warranty from their manufacturer.

Miltenyi Biotec must be informed immediately, if a claim is made under such warranty. If a material or manufacturing defect occurs within the warranty period, Miltenyi Biotec will take the appropriate steps to restore the full usability of your product.

Limitation on damages:
Miltenyi Biotec shall not be liable for any incidental or consequential damages for breach of any express or implied warranty or condition on this product.

Some states or jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to you. This warranty statement gives you specific legal rights and you may have other rights, which may vary from country to country or jurisdiction to jurisdiction.

8.2 Trademarks

LIFE 21, the Miltenyi Biotec logo, and TheraSorb are registered trademarks or trademarks of Miltenyi Biotec B.V. & Co. KG and/or its affiliates in various countries worldwide.

APPENDIX

Guidance and manufacturer's declaration on electromagnetic compatibility

The instrument has been tested for electromagnetic compatibility (EMC) and immunity as part of the conformity assessment procedure for medical devices and complies with these harmonized standards (see Table A.1).

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The instrument is intended for use in the electromagnetic environment specified below.		
Emission tests	**Compliance**	**Electromagnetic environment–guidance**
RF emissions CISPR 11:2009 and A1:2010	Group 1 Class A	The instrument uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2:2018 and A1:2020 **Voltage fluctuations/ flicker emissions** IEC 61000-3-3:2013 and A1:2017	Class A	The instrument is suitable for use in professional healthcare environment.

Table A.1: Guidance and manufacturer's declaration – Electromagnetic immunity

NOTICE

Risk of compromised functionality of other electrical or electronic equipment in residential enviroments. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration – Electromagnetic Emissions			
The instrument is intended for use in the electromagnetic environment specified below.			
Immunity tests	**EN IEC 60601 test level**	**Compliance level**	**Electromagnetic environment–guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV direct and air discharge	±8 kV ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Bursts IEC 61000-4-4	±2 kV power cable	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV ±0.5 kV, ±1 kV, ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according IEC 6100-4-11 at 50Hz/240V and 60Hz/100V	100% dip for 0.5 cycle 100% dip for 250 cycle 30% dip for 25 cycle 60% dip for 5 cycle	100% dip for 0.5 cycle 100% dip for 250 cycle 30% dip for 25 cycle 60% dip for 5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic field at Power frequency (50/60 Hz) according IEC 61000-4-8	30 A/m	30 A/m	Mains power quality should be at levels characteristics of a typical location in a typical commercial or hospital environment
Conducted RF according IEC 61000-4-6	U_1 = 10 V 150 kHz–80 MHz 80% AM 1kHz	10 V	

Table A.2: Guidance and manufacturer's declaration – Electromagnetic immunity

⚠ WARNING

Risk of critical malfunctions. Electromagnetic interference can cause malfunctions of the LIFE 21 apherisis unit or other active devices in the vincinity and cause critical malfunction. The use of the instrument directly next to other equipment or stacked with other equipment should be avoided because it could result in a faulty operation. If the use in the described configuration is necessary, the instrument and the other equipment should be monitored for correct function.

NOTICE

Electromagnetic disturbances can lead to a loss of functionality of the communication interface and/or to a termination of the treatment, regeneration or conservation process. If these disturbances exist for a longer period a restart for a continuation of the treatment may be not possible.

Communication equipment – safety distances

The instrument is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The operator of the instrument can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters including RFID readers) and the instrument according to the maximum output power of the communications equipment, as recommended below.

Nominal output of the transmitter (W)	Safety distance (m) depending on transmitted frequency		
	150 kHz–80 MHz	80 MHz–800 MHz	800 MHz–2,5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Table A.3: Recommended minimum distance to portable and mobile communication equipment

⚠ WARNING

Risk of loss of function. Electromagnetic interference can compromise the performance or safety of the LIFE 21 apheresis unit up to a loss of function. Portable RF-equipment (including their accessories like, e.g., antenna cables and external antennas) should not be used closer than 30 cm to any part of the instrument including cables. A disregard may result in a degradation or of functionality, safety and performance of the instrument which can prevent access to the user interface or can cause an interuption of a treatment.

NOTICE

These guidelines are not applicable to all cases. The propagation of electromagnetic fields is influenced by absorption and reflection by buildings, objects, and people.



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39501/06 | Issued: 2022-04