Miltenyi Biotec

CliniMACS® Plus Instrument

User manual



The CliniMACS System components, including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer, are designed, manufactured and tested under a quality system certified to ISO 13485. In the EU, the CliniMACS System components are available as CE-marked medical devices for their respective intended use, unless otherwise stated. In the US, the CliniMACS CD34 Reagent System, including the CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Set TS and CliniMACS Tubing Set LS, and the CliniMACS PBS/EDTA Buffer, is FDA approved as a Humanitarian Use Device (HUD), authorized by U.S. Federal law for use in the treatment of patients with acute myeloid leukemia (AML) in first complete remission. The effectiveness of the device for this indication has not been demonstrated. Other products of the CliniMACS Product Line are available for use only under an approved Investigational New Drug (IND) application, Investigational Device Exemption (IDE) or FDA approval. In Australia, the following components of the CliniMACS Plus System are included in the Australian Register of Therapeutic Goods (ARTG) and are therefore approved for supply: CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Set, CliniMACS Tubing Set LS, CliniMACS Depletion Tubing Set and CliniMACS PBS/EDTA Buffer. Only those products which are included in the ARTG may be used in Australia.

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CliniMACS Plus Instrument

User manual

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Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68
51429 Bergisch Gladbach
Germany

For U.S. distributed by:

Miltenyi Biotec Inc.
2303 Lindbergh Street
Auburn, CA 95602
USA

Miltenyi Biotec Technical Support
+49 2204 8306-3803
technicalsupport@miltenyi.com
www.miltenyibiotec.com

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1

About this user manual

This chapter provides general information about the importance of reading this user manual before using the instrument. It also covers the associated document series and the presentational conventions used in this manual.

This user manual provides instructions, warnings, precautions, and other important information for the use of the CliniMACS Plus Instrument.

For further details on the software running on the instrument, refer to the CliniMACS Plus Software user manual, for further details on the processes, refer to the CliniMACS Plus Applications user manual.

1.1 Read the manual first

⚠ WARNING

Risk of electrical shock, physical injuries, instrument damage, or malfunction.

Disregard of any instructions, warnings, or cautions at any time can endanger users and others and may compromise the electrical, electronical, electromagnetic, and mechanical safety. Disregard also excludes the manufacturer from any liability.

- The operation of the instrument must be performed by trained users only.
- Before using the instrument carefully read and understand the safety information, warnings, precautions, and instructions for proper operation provided in this user manual (including without limitation the safety information in section 'General safety notes') and in any safety-related recommendations issued by Miltenyi Biotec.
- Pay special attention to all warnings shown on the instrument or provided with consumables and accessories.
- Adhere to all safety information, warnings, precautions, and instructions 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.

1.2 Associated documents

This user manual is part of a series and should only be used in conjunction with the other user manuals of the series.

- CliniMACS Plus Software user manual
- CliniMACS Plus Applications user manual
- MACS® TubeSealer user manual

1.3 Presentational conventions

The following text styles are used to indicate specific information types in this user manual that are not safety-related. For safety-related information types, see section 'Hazard levels' and section 'Structure of warning messages'.

1.3.1 Text styles

• Bullet point list item with text	Indicates a list-item of an unordered list
1. Numbered list item with text	Indicates a list-item of a step-by-step instruction
Bold, colored text	Indicates a software element (for example a button or tab of the graphical user interface)
See section 'Text styles'	Indicates a reference to the section with the heading 'Text styles'
See Figure 4.2/Table 4.2	Indicates a reference to the second figure/table in chapter four

IMPORTANT:
Advises the user of important practices or information not related to personal injury nor property damage

1.3.2 Screens and figures

The screens and the figures in this manual are only representative screens and may slightly differ from those shown on the instrument.

2

Safety information

This chapter states safety notes to ensure the safe use of the CliniMACS Plus Instrument.

2.1 Intended purpose

The CliniMACS Plus System, consisting of the components CliniMACS Plus Instrument, CliniMACS Reagent(s), CliniMACS Tubing Sets, CliniMACS PBS/EDTA Buffer, and further accessories, which must be used in combination, is intended for the *in vitro* separation of specific human cells for clinical applications.

The CliniMACS Plus Instrument including application specific software is intended to operate the components of the CliniMACS Plus Cell Separation System to enable the *in vitro* separation of specific human cells for clinical applications.

For the operation of the CliniMACS Plus System, only the stated components as CE-marked medical device and accessories defined in the CliniMACS Plus Applications user manual for the respective applications must be used with the CliniMACS Plus Instrument.

2.2 Safety symbols


General warning sign


Electrical hazard


Magnetical hazard


Optical radiation hazard


Biological hazard


Crushing of hand hazard

2.3 Position of safety symbols

Notice the hazard points and the positions of the safety symbols of the instrument (see Figure 2.1 and Figure 2.2).

- Keep safety labels and safety markings clean and legible.
- Inspect the safety labels and safety markings regularly and replace them if they are not legible or identifiable from a safe viewing distance.
- Contact Miltenyi Biotec for replacement labels.

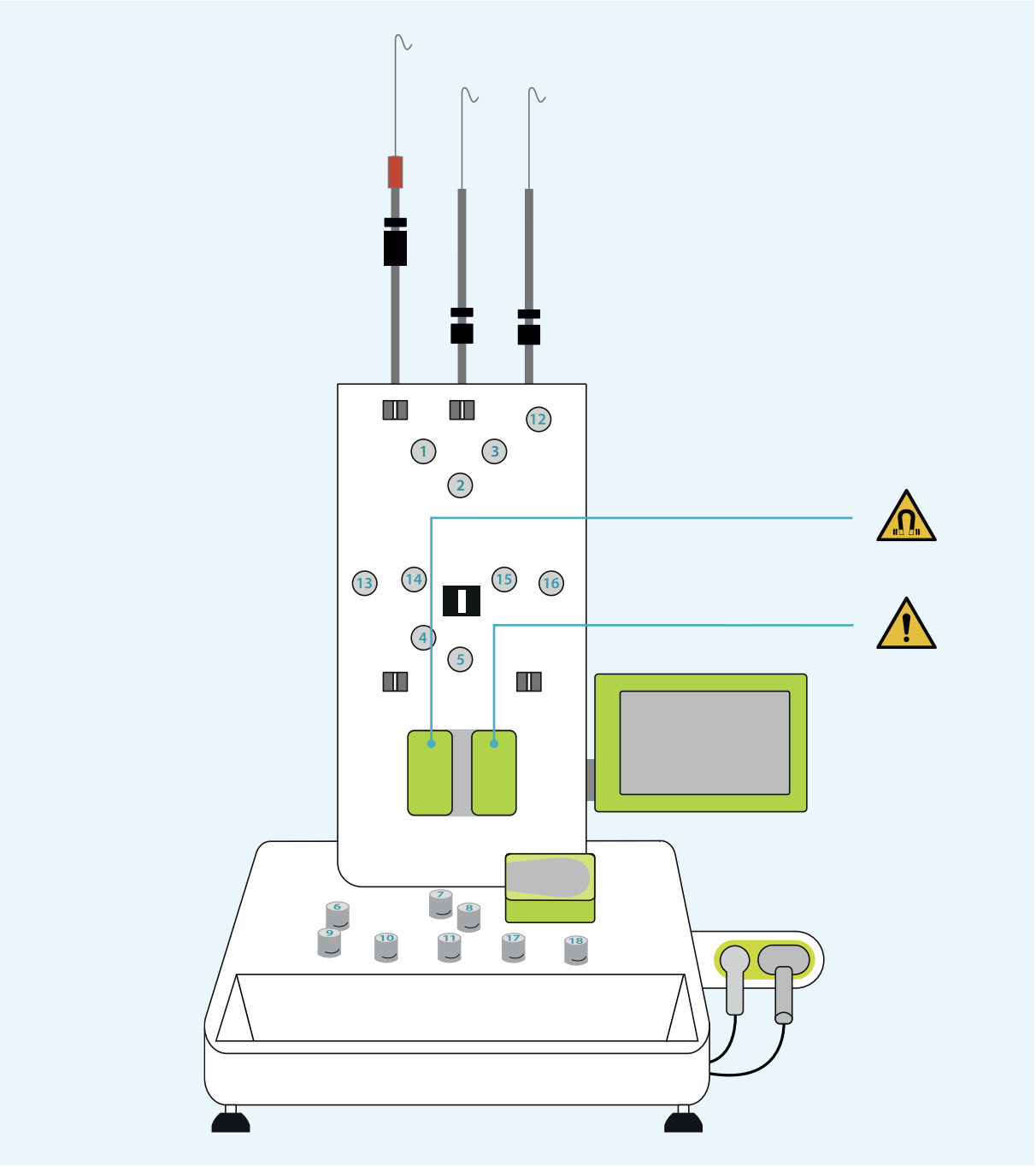


Figure 2.1: Safety symbols - front view

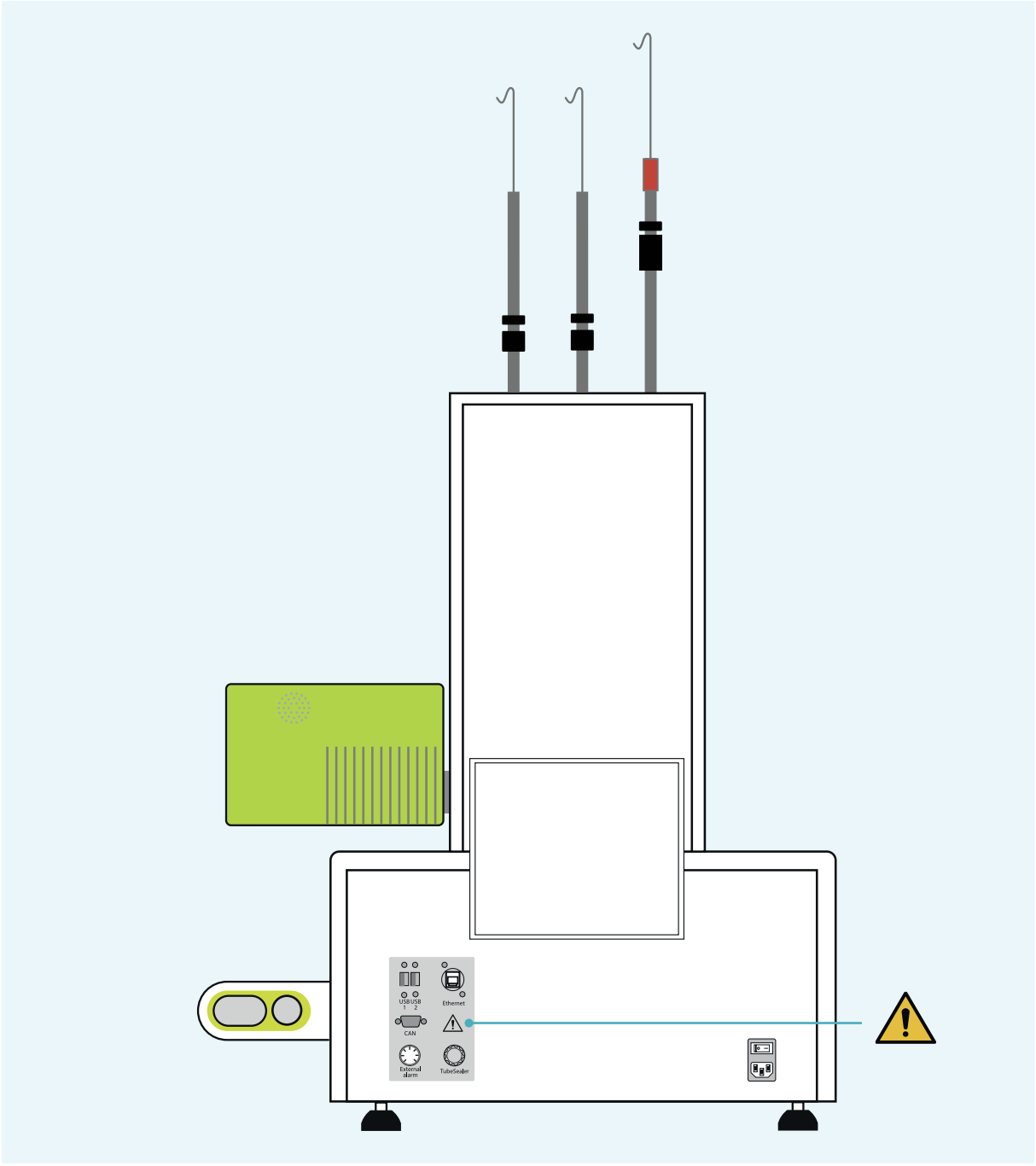


Figure 2.2: Safety symbols - rear view

2.4 Hazards

2.4.1 Hazard levels

The color and signal word of a warning message depend on the hazard level. The hazard level classifies the hazard as follows:

⚠ WARNING

indicates a hazardous situation that, if not avoided, could result in death or serious injury.

⚠ CAUTION

indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

indicates a hazardous situation that, if not avoided, could result in property damage. This does not indicate a risk of personal injury.

2.4.2 Structure of warning messages

Warning messages warn of hazardous situations. Warning messages specify the hazard level, the type and source of the hazard, the possible consequences, and the measures to avoid the hazard.

The following examples show the structure of warning messages at the beginning of a chapter or section where a hazard can occur:

⚠ WARNING

Type and source of hazard.

Consequences of noncompliance.

- Measures to avoid the hazard.

⚠ CAUTION

Type and source of hazard.

Consequences of noncompliance.

- Measures to avoid the hazard.

NOTICE

Type and source of hazard.

Consequences of noncompliance.

- Measures to avoid the hazard.

The following examples show the structure of embedded warning messages before an instructional step:

1. **WARNING! Type and source of hazard. Consequences of noncompliance. Measures to avoid the hazard.** Instructional step.

1. **CAUTION! Type and source of hazard. Consequences of noncompliance. Measures to avoid the hazard.** Instructional step.

1. **NOTICE Type and source of hazard. Consequences of noncompliance. Measures to avoid the hazard.** Instructional step.

2.4.3 General safety notes

⚠ WARNING

Risk of death, serious personal injury, damage, malfunction, reduced life time and/or premature wear and tear.

If the following safety information, warnings, precautions, and instructions are not observed at all times when using the instrument, this can cause death, serious personal injury, damage, malfunction, reduced life time, premature wear and tear and/or void the warranty, and/or invalidate the authority to operate the instrument under applicable regulations.

- Observe the following safety information, warnings, precautions, and instructions.

Operation, handling, use, and maintenance of the instrument

- Always observe the safety information, warnings, precautions, instructions, and recommended procedures provided in the user manuals and other written instructions issued by Miltenyi Biotec.
- Always comply with all applicable laws, rules, regulations and administrative provisions, including, without limitation, all regulations regarding health and safety at work. If applicable, also comply with the safety of medical devices at the location where the instrument is operated.
- Only allow appropriately skilled and trained personnel familiar with the construction, operation, and hazards of the instrument to operate it.
- Only use the instrument in a professional healthcare facility environment.
- Do not use the instrument near active HF surgical equipment.

User training is provided by a qualified Miltenyi Biotec representative.

Instrument purpose

- 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.
- Never use the instrument with consumables, components, accessories, transducers, and/or cables other than those approved by Miltenyi Biotec to ensure safe and proper operation of the instrument.
- The use of consumables, components, accessories, transducers, and/or cables not expressly approved by Miltenyi Biotec could void the warranty and/or invalidate the authority to operate this instrument under applicable regulations.

Maintenance and service

- Always follow Miltenyi Biotec's maintenance guidelines and relevant standards.
- Only authorized local Miltenyi Biotec service providers should install, maintain, or service the instrument.
- Do not operate the instrument until all required maintenance and safety checks are complete.
- Report any defects immediately.
- If you doubt the instrument's functionality, contact Miltenyi Biotec Technical Support and do not use the instrument.

2.4.4 Electrical hazards

⚠ WARNING

Risk of electric shock, short circuits, and spread of fire.

Overheating and liquids inside the instrument can cause electric shock, short circuits, and spread of fire. Electronic equipment may emit sparks that could ignite combustible vapors or dusts.

- Observe the following safety instructions/measures.

Protective housing

The housing of the instrument reduces the risks of electric shock, short circuits, and spread of fire. Opening any parts of the housing interrupts this protective measure.

- Do not remove or penetrate any parts of the housing.
- Only an authorized local service provider may open the instrument or exchange spare parts.
- Do not use the instrument in case of visible damage or if it has been dropped. Contact Miltenyi Biotec Technical Support.

Liquids

- Avoid ingress of any liquid into the instrument.
- Do not open the housing or remove any parts of the instrument.
- Do not operate the instrument if liquids have spilled into the instrument.
- Take special care while handling fluids. Clean spillages immediately.
- Do not use an excessive amount of cleaning or disinfection agents to avoid ingress of any liquid into the valves, sensors, and connectors.

Cables

The instrument is equipped with a three-wire electrical grounding-type plug that has a third pin for grounding. This plug only fits into a grounded electrical outlet.

- Do not try to insert the plug into a non-grounded electrical outlet. If the plug cannot be inserted into the outlet, contact the local electrician to replace the outlet.
- Do not use extension cables or power strips.
- Only operate the instrument with a power source indicated on the product's electrical ratings label. For questions about the type of power source to use, contact Miltenyi Biotec Technical Support.
- Do not overload an electrical outlet.

Environment

- The instrument is intended for indoor use only.
- Do not use the instrument in a wet or damp location or if it has been exposed to moisture.
- After moving the instrument from a cold environment, such as a cold room at +4 °C (+39 °F), to room temperature, condensing liquid droplets may form inside the instrument. Wait for the instrument to dehumidify before operating the instrument.

Overheating and fire hazards

Reduced air circulation carries the risk of overheating. Overheating of the instrument can cause fire or explosion. Slots and openings of the instrument are provided for ventilation and protect the instrument from overheating.

- Do not place the instrument within a built-in apparatus or a confined space, such as a shelf rack, unless the apparatus has been specifically designed to accommodate the instrument and proper ventilation is provided.
- Allow sufficient space around the ventilation slots at the rear and underneath the instrument.
- Never block or cover slots and openings of the instrument.
- Provide adequate air circulation in the room in which the instrument is operated.
- Do not place the instrument next to equipment that produce heat (e.g., radiators, heat registers, or amplifiers).
- Prevent direct exposure to sunlight.
- Do not use the instrument outside its specifications.
- Ensure that the main switch as well as the outlet for the power cable are easily accessible. If it is necessary to disconnect the power supply, unplug the cable from the electrical outlet.

2.4.5 Magnetical hazards

⚠ WARNING

Risk of severe personal injury for persons carrying pacemakers, brain shunts, or electronic medical implants.

The instrument is equipped with an extremely strong permanent magnet generating a strong magnetic field.

- Always maintain a distance of at least 30 cm from the instrument.

Keep any magnetic information carriers (such as credit cards or magnetic tapes), electronic equipment (such as hearing aids, measuring and control instruments, computers, and watches), and magnetizable tools and objects at a distance of at least 30 cm from the magnet cover. These items may be affected or damaged by the magnetic field.

2.4.6 Optical radiation hazards

⚠ CAUTION

Risk of eye injury.

The optical radiation emitted from the light emitting diode may be harmful to the eyes at close viewing distances. Light emission is especially powerful when bag hanger A is disassembled.

- Do not disassemble the bag hanger A while the instrument is switched on.

The instrument is equipped with an LED for the signal lamp at the left bag hanger (position A, see Figure 3.2).

2.4.7 Mechanical hazards

⚠ WARNING

Risk of crushing or cutting.

If the separation column is inserted or removed while the magnet unit is switched on, there is the risk of crushing or cutting.

- Only insert or remove the separation column when instructed to do so.

⚠ CAUTION

Risk of injury.

The safety measures of the instrument reduce the risk of injury.

- Do not circumvent any safety measures of the instrument.
- Shut down the instrument when substantially high vibrations occur. Contact Miltenyi Biotec Technical Support for assistance.
- Keep away from all moving parts.

⚠ CAUTION

Risk of serious harm and/or damage to the instrument.

The instrument could fall and cause serious harm and/or damage to the instrument if placed on an unstable surface.

- Place the instrument evenly on a flat and stable surface which is capable of supporting 100 kg and free of vibrational or other mechanical forces.
- Do not locate the instrument next to vibrating equipment which might cause movement during operation.

2.4.8 Biological hazards

⚠ WARNING

Biological hazard.

Depending on the biological material used, contact may lead to severe personal injury or death.

- Observe the following safety instructions/measures.

Biological material

- Always wear personal safety equipment, such as protective gloves, protective clothing, and safety goggles suitable for the materials processed on the instrument and in accordance with local regulations and work instructions. Defective or inadequate safety equipment might endanger the user.
- If hazardous material has been used or spilled, take care to thoroughly decontaminate the instrument.
- After running the sample and prior to decontamination, the instrument should be treated as a biohazard (see section 'Cleaning and disinfection').

Overloading the bag hangers

- Do not overload the bag hangers. The carrying capacity of a single bag hanger is 5 kg.

Waste

- Waste disposal must be in accordance with local regulations.

Process failure

Instrument malfunction or process failure can lead to leakage and delayed cell preparation.

- In any case of instrument malfunction or process failure, which cannot be corrected by the user, contact Miltenyi Biotec Technical Support.

2.5 Risks related to the process and cell product

This section describes risks concerning the process and the cell product.

2.5.1 Delay of cell preparation

⚠ CAUTION

Risk of delay of cell preparation.

Using the instrument outside its specifications or unauthorized equipment can lead to reduced performance.

- Observe the following safety instructions/measures.

- Do not use the instrument outside its specifications. Using the instrument outside its specifications can lead to reduced performance.

- In any case of instrument malfunction or process failure, which cannot be corrected by the user, contact Miltenyi Biotec Technical Support. Instrument malfunction or process failure can lead to delayed cell preparation.
- Only use authorized equipment. Unauthorized equipment can cause instrument malfunction.
- Make sure that acoustical, electronic, and visual notification signals can be recognized by the user at any time during the process. If notifications are not recognized and the required actions are not executed or confirmed, there is the risk of process failure.

2.5.2 Termination of the separation process

⚠ CAUTION

Risk of termination of the separation process.

Based on technical limitations of the internal power supply voltage, interruptions on power supply input lines for longer than 10 ms may lead to termination of the separation process (power failure). The separation process cannot be resumed after a power failure.

- Connect the instrument to an uninterruptible power supply using the supplied power cable. A connected battery should start within 10 ms.

2.5.3 Quality of target cells

⚠ CAUTION

Risk of reduced quality of target cells.

The target cells must be analyzed and confirmed to meet user requirements, otherwise the suitability for clinical application can be compromised.

- Examine the target cells regarding quality and quantity according to their intended use.

2.6 Cybersecurity

⚠ CAUTION

Risk of delay of cell preparation.

The instrument cannot detect malware on connected external devices. The operating site is responsible for security of their local IT systems.

- Always observe the local procedures for IT security.

2.7 Unpacking

⚠ CAUTION

Risk of personal injury or compromised performance of the instrument.

The instrument may tilt or slip if it is not installed adequately.

- Unpacking and installation of the instrument must only be performed by an authorized Miltenyi Biotec representative.
- Visually inspect and note any significant damage to the packaging. Damage of the packaging may require inspection by a representative of the shipping company.

2.8 Installation

⚠ CAUTION

Risk of damage to the instrument.

If the instrument is installed by unauthorized persons, the instrument can be damaged.

- Installation of the instrument must only be performed by an authorized Miltenyi Biotec service provider.

Contact the local authority governing electrical power supply, building construction, maintenance, or safety for more information regarding the installation of the equipment.

2.9 Disposal



The CliniMACS Plus Instrument must be separately collected according to the European directive of waste of electrical and electronic equipment (WEEE) or in the United Kingdom according to the 2013 No. 3113 – ENVIRONMENTAL PROTECTION The Waste Electrical and Electronic Equipment Regulations 2013. For final disposal, the instrument must be returned to Miltenyi Biotec. Clean the instrument according to the instructions given in section 'Cleaning and disinfection'.

Contact Miltenyi Biotec Technical Support for assistance prior to disposal of the instrument.

2.10 Electromagnetic compatibility

⚠ WARNING

Risk of improper operation due to increased electromagnetic emission or decreased electromagnetic immunity.

The use of consumables, accessories, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and placed in service according to the EMC information (see chapter 'Appendix').
- Portable and mobile RF communications equipment can affect medical electrical equipment. Only use the instrument with accessories, transducers, and/or cables approved by Miltenyi Biotec.

3

About the instrument

This chapter describes the different components of the CliniMACS Plus System and the instrument.

The CliniMACS Plus System offers a set of tools making high quality standard cell separations available for therapeutic applications.

3.1 Regulatory information

Clinical Research System. Limited by Federal (or United States) Law to Investigational Use or under an FDA approval.

IMPORTANT:
In the US, the CliniMACS Plus System components including the CliniMACS Reagents are available for use only under an Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or FDA approval.

The instrument conforms to Medical Device Regulation MDR (EU) 2017/745:

MD CE 0123

The instrument complies with the following standards:

- IEC/EN/SN EN 61010-1
- UL 61010-1
- CAN/CSA-C22.2 No. 61010-1
- IEC 60601-1-2
- EN 60601-1-2
- IEC TS 60601-4-2

For applied standard version refer to the respective Product Quality Certificate.

The instrument is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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.

The CliniMACS Plus System is based on the magnetic cell separation technology (MACS® Technology) developed by Miltenyi Biotec B.V. & Co. KG. Miltenyi Biotec has made these products available for clinical applications meeting the requirements of European Regulatory Standards.

The CliniMACS Reagents and Biotin Conjugates are intended for *in vitro* use only and are not designated for therapeutic use or direct infusion into patients.

The CliniMACS Reagents in combination with the CliniMACS Plus System are intended to separate human cells.

Miltenyi Biotec as the manufacturer of the CliniMACS Plus System does not give any recommendations regarding the use of separated cells for therapeutic purposes and does not make any claims regarding a clinical benefit.

For the manufacturing and use of target cells in humans the national legislation and regulations – for example for the EU the Directive 2004/23/EC (human tissues and cells) or the Directive 2002/98/ EC (human blood and blood components) – must be followed. Thus, any clinical application of the target cells is exclusively within the responsibility of the user of a CliniMACS Plus System.

3.2 Scope of supply

The content of supply is:

- 1× CliniMACS Plus (including user manuals for instrument, software, and applications)
- 1× MACS TubeSealer (including user manual)
- 1× barcode reader (including package insert)
- 1× external keyboard (including package insert)

3.3 Components

The key components of the CliniMACS Plus Instrument are a magnetic separation unit, a peristaltic pump, liquid sensors, and pinch valves.

The CliniMACS Plus Software offers the choice between various separation programs. For further details refer to the CliniMACS Plus Applications user manual.

3.3.1 Front view

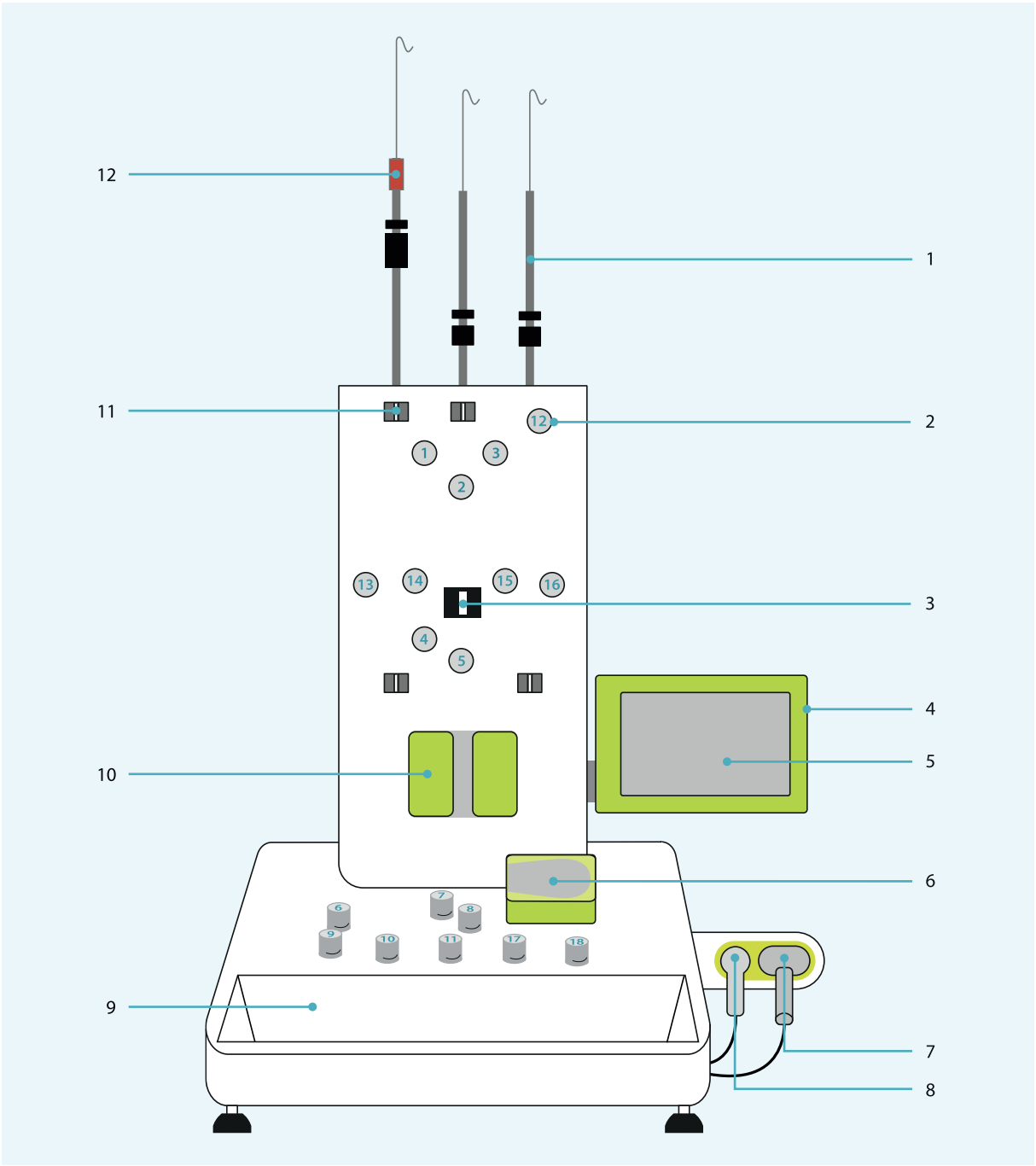


Figure 3.1: Front view of the instrument

1 Bag hangers
2 Pinch valves (18 in total)
3 Pre-column holder
4 USB ports
5 Monitor with touchscreen
6 Peristaltic pump
7 Barcode reader, see section 'Barcode reader'
8 MACS® TubeSealer, see section 'MACS TubeSealer'
9 Bag compartment
10 Magnetic separation unit
11 Liquid sensors (4 in total)
12 LED signal lamp

Bag hangers

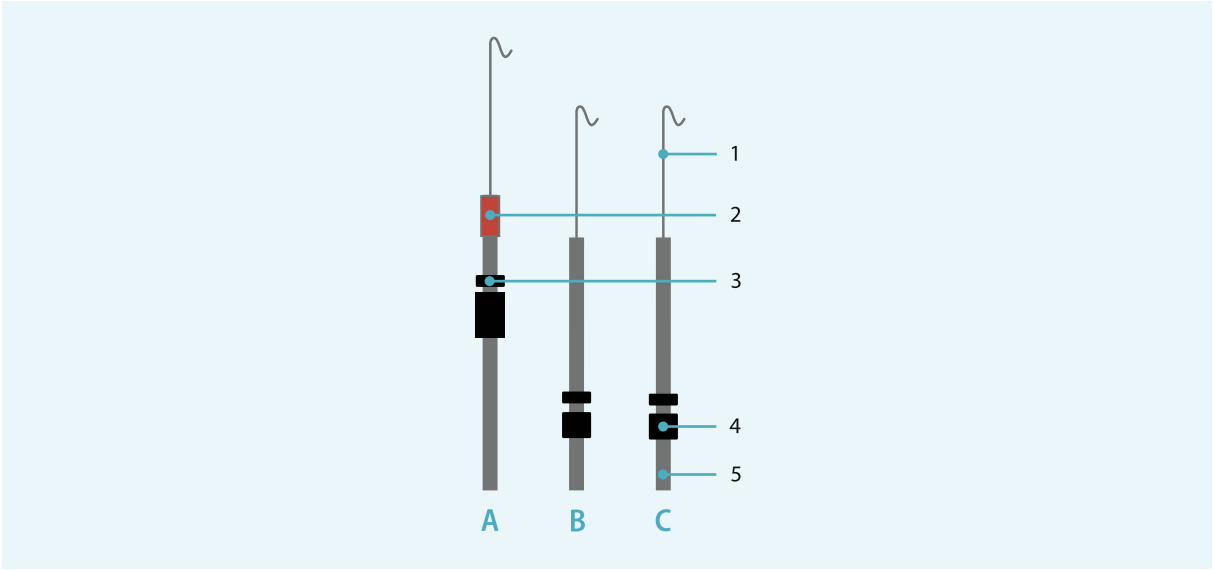


Figure 3.2: Bag hanger components

1 Hook
2 LED signal lamp
3 Clamping fixture
4 Pinch clamp
5 Rod

The housing incorporates a set of bag hangers and a designated compartment for storing bags. The instrument is equipped with three bag hangers at the top of the instrument (see Figure 3.2). Each individual bag hanger consists of a rod and a spring-loaded pinch clamp with a hook for bag attachment. The pinch clamp allows for adjustable hook height.

The signal lamp on bag hanger A provides instrument status information by showing different colors (see section 'LED signal lamp').

Magnetic separation unit

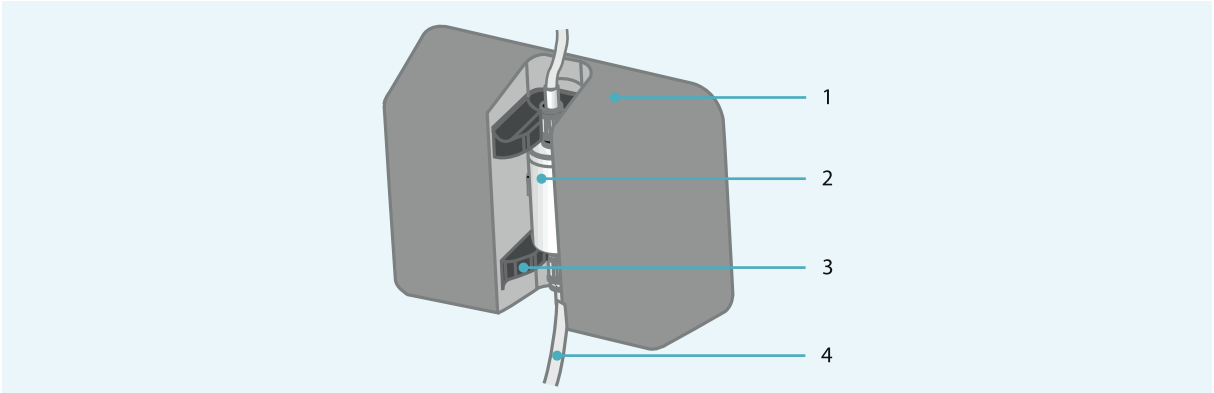


Figure 3.3: Separation column inserted into the magnet unit

1 Magnet unit
2 Separation column
3 Separation column holder
4 Tubing

The magnetic separation unit induces a magnetic field into the separation column to separate magnetically labeled cells from non-labeled cells. This unit includes the movable, permanent magnet and a holder for the separation column (see Figure 3.3). A linear motor with position sensors is used to place the magnet in the ON and OFF positions. Inside the separation column, a strong inhomogeneous magnetic field is created which retains magnetically labeled cells within the column.

Monitor with touchscreen

The user interface is operated via the touchscreen and manages all functions. Usage of the touchscreen is possible when wearing surgical gloves. The touchscreen guides through the setup procedure and allows monitoring of the instrument during operations. The monitor unit holds an internal speaker for acoustical signaling and alarm functionality. The integrated USB ports allows for easy data import and export (see Figure 3.1).

Peristaltic pump

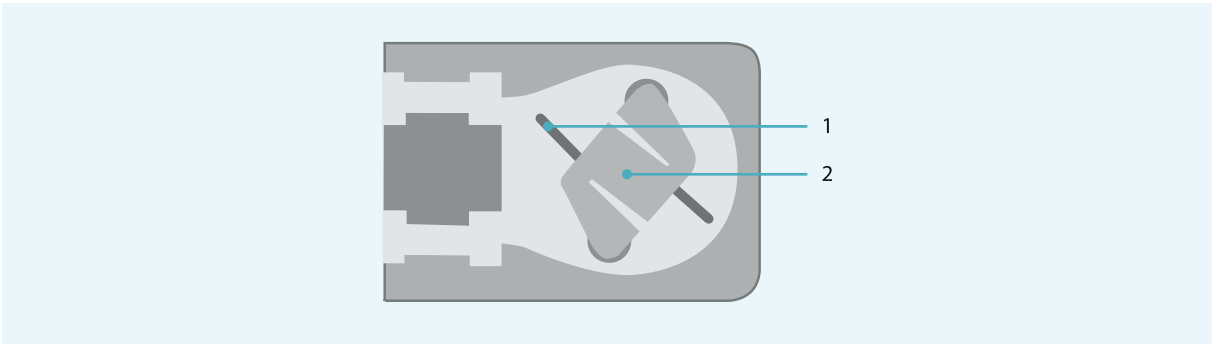


Figure 3.4: Components of the peristaltic pump

1 Guide pin
2 Pump head

The peristaltic pump is used to advance the liquids through specific flow pathways of the tubing set. A set of guide pins ensures the pump tubing stays in place. The pump has a rotational speed sensor and a rotor position detection.

If the protection cover lid is open, the pump stops working. Do not open the protection cover of the pump during operations unless prompted by the graphical user interface.

For the individual components of the peristaltic roller pump see Figure 3.4.

Pinch valves

18 pinch valves ensure controlled flow of buffer and cell suspension throughout the procedure.

Liquid sensors

Four liquid sensors at the front of the instrument (see Figure 3.1) monitor the flow of liquid within the tubing set. The monitoring is based on an ultrasonic principle which allows detection of air bubbles within certain parts of the mounted tubing set. Specific process steps are designed so that disruption of continuous fluid flow through these sensors automatically advances the process to the next phase.

3.3.2 Rear view

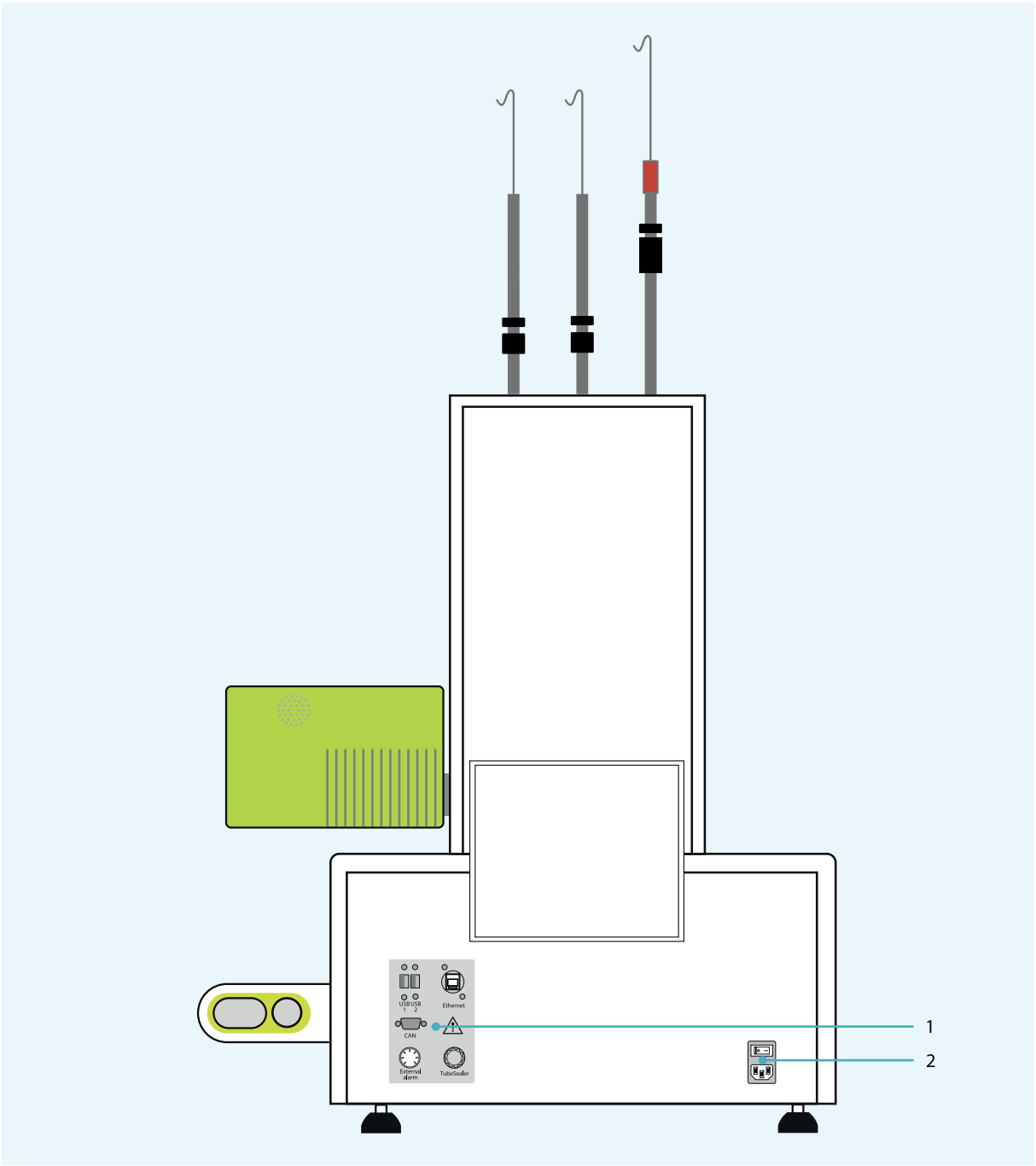


Figure 3.5: Rear view of the instrument

1 Connector panel
2 Power connection and power switch

Connector panel

A connector panel for input and output connections.

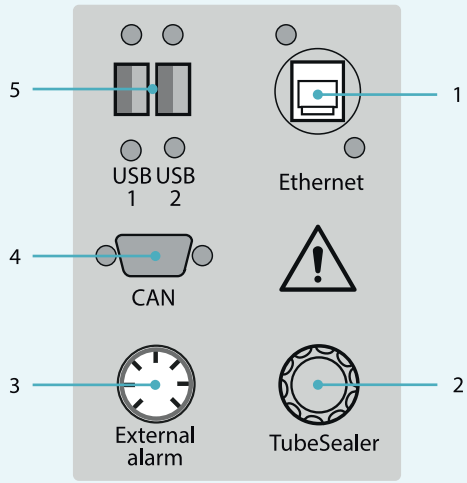


Figure 3.6: Connector panel

1 The Ethernet connection is used to connect the instrument to the Ethernet
2 Port to connect the MACS® TubeSealer
3 The alarm connector is used for connecting an external alarm system
4 The CAN connector may be used for service purposes
5 Two USB ports are available for data input and output functionalities

3.3.3 Additional accessories and components

Accessories and components	Specification
MACS TubeSealer	P/N 44364
Barcode reader	Zebra DS4308-HC, DS4608-HC, or equivalent
Ethernet cable to connect the Ethernet adapter	Cat5 or higher
External alarm cable	Shielded cable
External keyboard	InduProof® Smart Compact or equivalent

Table 3.1: Additional accessories and components of the instrument

MACS® TubeSealer

The MACS® TubeSealer is used for sealing PVC and EVA tubing of the tubing sets installed on the instrument. A detailed description of the MACS® TubeSealer and relevant safety information are provided in the MACS® TubeSealer user manual.

The MACS® TubeSealer must be connected to the instrument via the MACS® TubeSealer port at the rear side of the instrument (see Figure 3.6).

Barcode reader

The barcode reader is intended to scan barcodes printed on CliniMACS materials required for process execution. The scanned data serve as input of part and lot numbers of the CliniMACS materials required for an application. These numbers and any other process-related parameters may also be entered manually.

The barcode reader can be connected to any USB port of the instrument (see Figure 3.1 and Figure 3.6).

External keyboard

The external keyboard is intended to enable administrators to set up user accounts.

IMPORTANT:
Do not use the external keyboard when running any of the installed applications on the instrument. The external keyboard must be used for the "User Management" only! The external keyboard must be unplugged from the instrument before starting any application and tool.

Refer to the CliniMACS Plus Software user manual for detailed information on User Management.

3.4 Alarm management

The instrument is equipped with an integrated alarm management system which is spread over several components, providing optical and acoustical alarm signals if required. An additional relay circuit may be connected to an external alarm system.

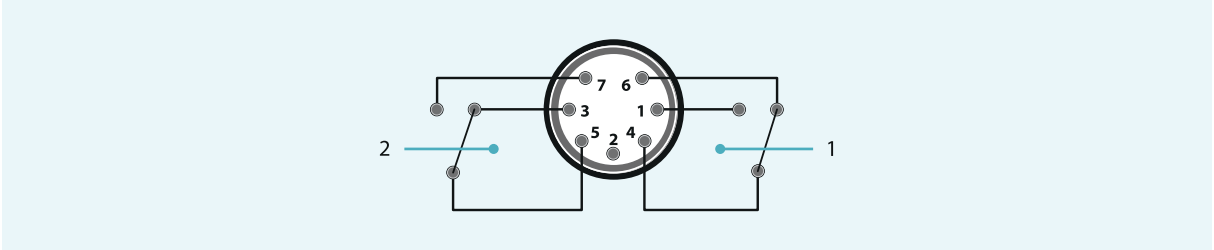


Figure 3.7: Relay circuit of alarm connector in idle state

1 Relay 1
2 Relay 2

Relay 1 indicates a critical situation which requires immediate user interaction. Relay 2 indicates a required user interaction.

The alarm management system of the instrument features a four-level alarm system. In case of a failure, a message is shown on the monitor, accompanied by an audible warning signal from a speaker within the touchscreen. The signal lamp at the bag hanger A (see Figure 3.1) will then show a blinking light.

The instrument distinguishes between three alarm levels as described in Table 3.2.

Alarm level	Description
Level 0: Normal/ Idle	The instrument is in an idle state and operating as expected. It awaits the initiation of a new process, or a current process is running smoothly.
Level 1: Hint	A hint message is used to provide information, e.g., on how to continue with the selected procedure. A user action may be necessary. If a user action is required, the signal lamp shows a blue blinking light. At this level, relay circuit 2 is inactive.
Level 2: Warning	A warning message shows warnings that require attention, e.g., sensors detect unexpected values. If a warning message appears, the signal lamp shows a yellow blinking light. In addition, relay circuit 2 is active.
Level 3: Alarm	Alarm messages point out system interruptions referring to safety relevant steps that await an obligatory user action. If an alarm message appears, the signal lamp shows a red blinking light. In addition, the speaker provides an acoustical alarm signal and relay circuit 1 is active.

Table 3.2: Alarm levels of the instrument

3.4.1 LED signal lamp

An LED signal lamp is positioned at the top end of bag hanger A (see Figure 3.1). This signal lamp provides instrument status information by showing different colors, as described in Table 3.3.

Alarm level	Description
White	The instrument is ready for use and a process may be started
Green	A process is running. No interaction required
Blue	The instrument requires user interaction
Yellow	Warning (time critical), user interaction required
Red	Alarm, critical situation, process failure possible, user interaction required

Table 3.3: Color code of the signal lamp

IMPORTANT:
Whenever a user interaction is required, the signal lights will blink. This is the case with the blue, yellow, and red color lights.

3.5 About the system

The CliniMACS Plus System consists of the following components:

- CliniMACS Plus Instrument (including MACS® TubeSealer and barcode reader)
- CliniMACS Reagents and Biotin Conjugates
- CliniMACS Tubing Sets
- CliniMACS PBS/EDTA Buffer
- Additional components

The CliniMACS Plus System and its components which must be used in combination, is intended for the *in vitro* separation of specific human cells for clinical applications. The CliniMACS Plus Instrument and CliniMACS Tubing Sets allow cell separations in a closed and sterile system.

The performance of the instrument that was determined to be essential performance:

- Establishing and maintaining the intended flow path
- Delivering the specified flow
- Setting the necessary magnetic field in the separation column
- Displaying user information on progress of the process
- Running the sequence as intended

IMPORTANT:
For instructions for use, e.g., warnings and precautions, concerning the CliniMACS Plus System components, refer to the instructions for use provided for the respective component.

3.5.1 CliniMACS Reagents and Biotin Conjugates

The CliniMACS Reagents are dark colored, non-viscous, colloidal solutions, containing the cell specific antibody conjugates in buffer. The reagents consist of the antibody chemically coupled to super-paramagnetic particles.

3.5.2 CliniMACS Tubing Sets

The CliniMACS Tubing Sets are sterile, single-use disposables designed to be used in combination with the CliniMACS Plus Instrument for the *in vitro* enrichment or depletion of human cells from heterogeneous haematologic cell populations.

3.5.3 CliniMACS PBS/EDTA Buffer

The CliniMACS PBS/EDTA Buffer is intended as wash and transport fluid to enable the separation of human cells.

4

Operation

This chapter describes the main functions for operating the instrument, such as switching on, shutdown, and touchscreen functionality.

IMPORTANT:
For safety reasons, the separation process will automatically stop if the pump door is opened. Keep the pump door closed while the instrument is in operation.

If concerned about the safe use of the instrument or if additional safety information is required, contact the authorized local Miltenyi Biotec service provider or Miltenyi Biotec Technical Support.

Do not leave the instrument unattended during a run. If an error occurs, the run can be interrupted at the current step. Correct the error immediately or contact Miltenyi Biotec Technical Support for further assistance.

The instrument is designed for repeated use and is not intended for disposal after a single use.

4.1 Power switch

The power connection module including the power switch is located at the rear side of the instrument (see Figure 4.1). The module consists of two sections. The upper section is the power switch. When positioned to the left, the switch is 'OFF' (O). When positioned to the right, the switch is 'ON' (I). The lower section is the recessed male 3-pin connector to which the power cord is attached.

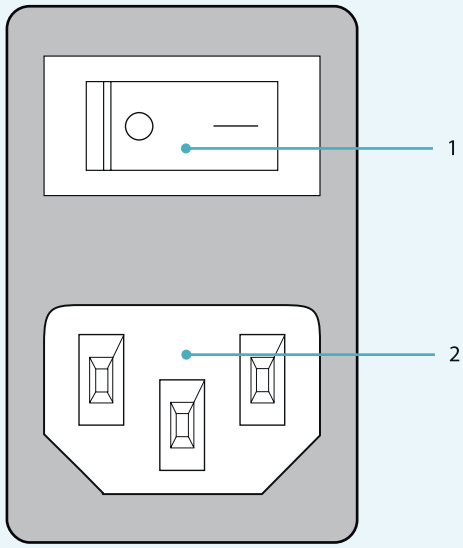


Figure 4.1: Power connection and power switch

1 Power switch

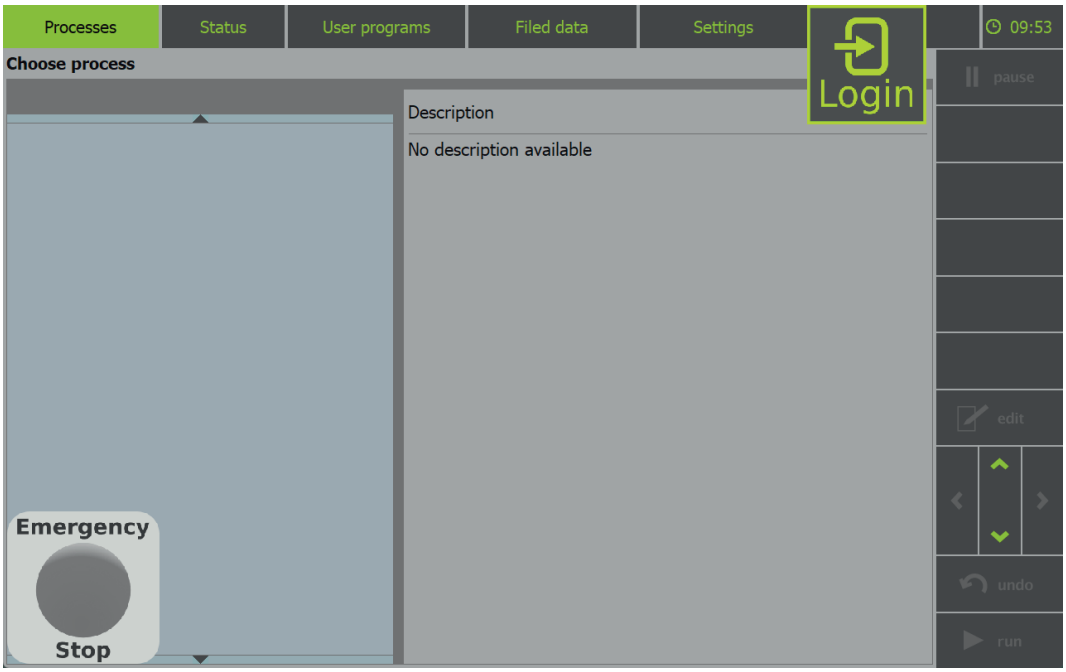
2 Power connection, recessed male 3-pin connector

4.1.1 Switching on the instrument

1. Plug the power cable of the instrument into a grounded electrical outlet.

2. Switch on the CliniMACS Plus with the power switch located on the rear side of the instrument (see Figure 4.1).

   The start screen appears and shows the current software version. During the initialization, the instrument performs self-checking procedures. After the initialization process, a locked screen appears and only the Login button is active.



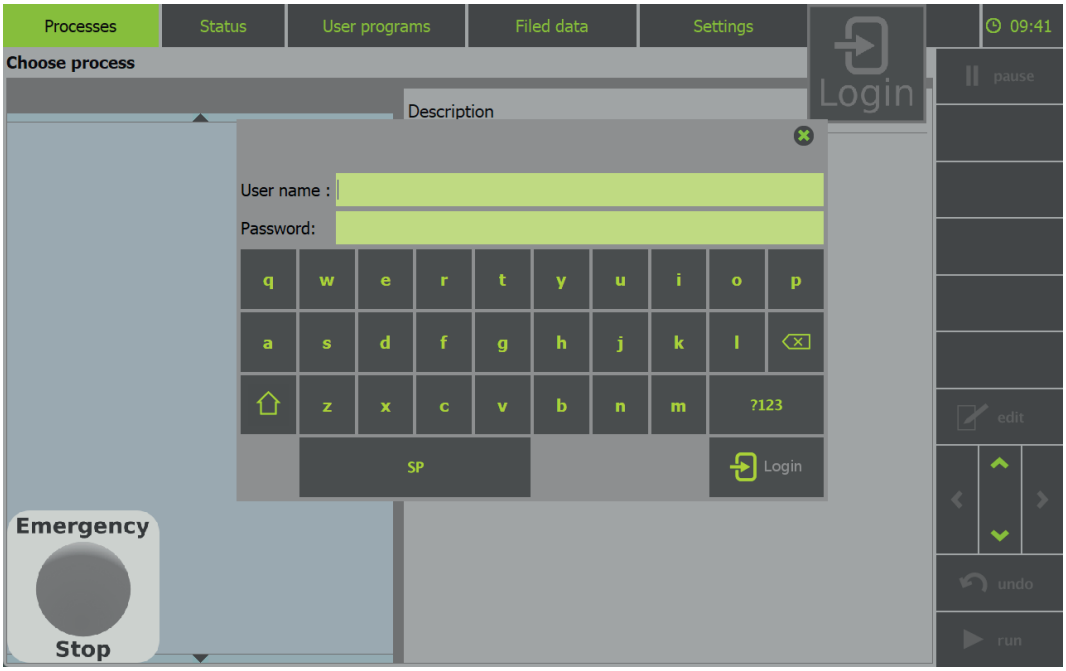
   If the instrument does not start up, switch off the instrument by using the power switch and disconnect it from the power supply. Check the power port. Then switch on the instrument again. If the instrument does not start correctly or the window shows an error message, note the error message number, switch off the instrument, and contact Miltenyi Biotec Technical Support.

4.1.2 Login

IMPORTANT:

- The username and password should be set up before login (refer to the CliniMACS Plus Software user manual for details).
- Maxing out the login attempts locks the user completely. There is no option to reset the password, also not by Miltenyi Biotec Technical Support.
- In case of login failure, refer to the CliniMACS Plus Software user manual.

1. To open the login window, tap **Login** in the upper right corner of the locked screen.
   A pop-up window appears, allowing the user to enter the user credentials:



2. Enter username and password and tap **Login** within the pop-up window.

4.1.3 Logout

IMPORTANT:
After 20 minutes (default) without interaction with the software, the user is logged out automatically.

1. Tap (**quick access menu**) and select **Logout** from the list.
2. To confirm the logout, tap **ok** in the pop-up window.

4.1.4 Shutting down the instrument

1. To shut down the instrument, choose one of the following options:
   - Tap (**quick access menu**) and select **Shutdown** from the list or
   - navigate to **Settings** > **Tools** > **Shutdown** and tap **run**.
2. In the pop-up window, confirm with **shutdown**.
3. Wait for the shutdown process to finish and switch off the instrument using the power switch located at the rear side of the instrument.

4.2 Touchscreen

The instrument is equipped with a high-resolution touchscreen. The touchscreen guides the user through the set-up procedure and allows monitoring of automatic system operations.

All elements of the instrument software are operated via the touchscreen. The touchscreen can detect gestures with gloved fingers.

The following gestures of fingers are detected by the touchscreen:

- Tap: A short contact of the finger with the touchscreen elements to start a process, to mark data, or to interact with a process during dialog control
- Hold: Tap and hold a spot on the touchscreen to quickly scroll through lists

Refer to the CliniMACS Plus Software user manual for detailed information regarding the graphical user interface (GUI) and software features.

5 Maintenance

This chapter describes the maintenance of the instrument. It gives information regarding cleaning and disinfection, servicing, and transportation of the instrument.

5.1 Cleaning and disinfection

5.1.1 General information

- Ensure the instrument is switched off and the power cable is unplugged before cleaning.
- Wear medical-grade disposable gloves made of latex or nitrile when cleaning and disinfecting surfaces.
- It is recommended to use a ready-to-use (RTU) premoistened disinfecting wipe.
- If using a freshly prepared solution, moisten a sterile lint-free cleaning cloth with a cleaning and disinfectant solution.
- Using any material other than a sterile lint-free cleaning cloth or a sterile RTU premoistened cloth can damage the product.
- Do not apply liquid directly to the instruments.
- To prevent ingress of any liquid into sensitive parts, such as valves, the cloth should be damp but not dripping wet. Remove excess moisture.
- Do not spray liquids directly onto the instrument.
- Gently wipe all surfaces to be cleaned or disinfected with the moistened cloth.
- Excessive wiping can damage the surface coating.
- To prevent scratching the surface, especially the underside of the instrument's housing, do not use mops or metallic tools/rods for cleaning or disinfection.
- When cleaning and disinfecting a display screen, gently wipe in one direction, moving from the top to the bottom. Do not rub the control panel forcefully, as it can be easily scratched or cracked.
- UV light can damage the plastic parts of the instrument. Do not use UV irradiation.
- If room decontamination is necessary, use fumigation with vaporized hydrogen peroxide (VHP). VHP may be used to decontaminate the instrument without adversely affecting its intended functionality.

IMPORTANT:
Disconnect the MACS® TubeSealer and the barcode reader before exposing the instrument to VHP.

- Treat biohazardous material as potentially infectious at all times. In the event of a spill, wear appropriate protective clothing during cleanup. After removing residual biological material, disinfect surfaces that have been in contact with biohazardous material.
- Discard all materials that have come into contact with biohazardous material according to institutional policies for biohazardous waste disposal.

5.1.2 Cleaning and disinfection intervals

Cleaning is required to remove dirt and other soiling that could impair the function of components of the instrument. Disinfection is required to destroy potentially infectious material, especially after spillage of blood or plasma onto the instrument. In case of visible soiling, clean the instrument before disinfection.

IMPORTANT:
The surface of the instrument should be cleaned and disinfected at regular intervals and after each application. Cleaning and disinfection after unpacking and installation is also recommended.

5.1.3 Cleaning and disinfection agents

Use the following cleaning agents and disinfectants for general cleaning:

- Isopropanol up to 70%
- Ethanol up to 80%
- A combination of quartenary ammonium compounds
- For decontamination or special cleaning procedure use up to 2% peracetic acid

5.1.4 Cleaning and disinfection instructions

Clean and disinfect the instrument according to the given information (see section 'General information').

⚠ WARNING

Electric hazard.

Risk of electric shock or damage to the instrument if the instrument is cleaned with excessive amount of cleaning agent.

- Use only small amounts of cleaning agents on a sterile lint-free cleaning cloth to wipe the instrument.
- Do not spray or pour liquid cleaning agents onto or into the instrument.
- Do not use UV light for disinfection of the instrument.

⚠ WARNING

Biological hazard

Contamination or infection could result in death or serious injury depending on the material used.

- Only use cleaning agents stated in this user manual.

1. Switch off the instrument and unplug the power cable.
2. For general cleaning and disinfection, use an RTU premoistened disinfecting wipe or a moistened sterile lint-free cleaning cloth. Remove excess moisture.
3. For sporicidal solutions, follow the contact time recommended in the disinfectant's instructions. Ensure the contact time does not exceed 1 hour. After the incubation time, wipe the surfaces with a moistened sterile lint-free cleaning cloth or an RTU premoistened disinfectant wipe.
4. Gently wipe all surfaces with the moistened sterile lint-free cleaning cloth.
5. When cleaning and disinfecting a display screen, gently wipe in one direction, moving from the top to the bottom.

6. Regardless of the sterilant or disinfection solution used, remove any residue to ensure the surfaces are not subject to corrosion or discoloration.
7. Make sure all soil is removed. If the soil remains on the instrument, repeat the entire reprocessing steps.
8. Ensure surfaces are completely air-dried before turning on the instrument. No moisture should be visible on the surfaces before it is plugged in and powered on.

5.2 Servicing

⚠ WARNING

Electrical hazards

Improper or incorrect servicing or repair of the instrument can cause hazards to users, instrument malfunction or damage, premature wear and tear and reduced life time of the instrument, and may void the warranty.

- Unless otherwise specifically noted in this user manual, do not service the instrument.
- Service and repair may only be performed by authorized local Miltenyi Biotec service providers.

The instrument does not contain user serviceable parts. Routine and preventative maintenance procedures should be conducted by an authorized Miltenyi Biotec service provider at least once a year. The user does not need to perform a calibration.

Using unauthorized replacement or spare parts can cause malfunction of the instrument and impair results. Miltenyi Biotec does not honor any warranty or accept any responsibility for instrument failure or damages resulting from the use of inappropriate replacement or spare parts. After completing any services or repairs, authorized local Miltenyi Biotec service providers perform all required safety checks to ensure that the instrument is fully functional.

For information about Miltenyi Biotec's instrument service and support arrangements, contact the authorized local Miltenyi Biotec service provider or Miltenyi Biotec Technical Support.

5.3 Transportation

⚠ WARNING

Chemical and biological hazard.

Risk of chemical or biological hazards due to contaminated surfaces.

- If the instrument needs to be shipped back to the manufacturer for service, decontaminate the instrument from any hazardous material prior to shipment.

⚠ CAUTION

Risk of internal damage.

Internal damage can occur if the instrument is subjected to excessive vibration or is dropped.

- The instrument should be transported with care in packaging specified by Miltenyi Biotec.
- Do not lift the instrument by the touchscreen, the peristaltic pump unit, or the magnet unit.

⚠ CAUTION

Ergonomic hazard.

If the instrument is lifted by one person, there is the risk of tearing or straining muscles.

- The transport should be performed by at least two people.

If the instrument needs to be transported, proceed as follows:

1. Switch off and disconnect the instrument from the power supply.
2. Decontaminate the instrument. For details regarding proper decontamination refer to the instructions in section 'Cleaning and disinfection'.
3. Remove all bag hangers and disposables from the instrument.
4. Lift the instrument in an upright position under each of the four corners at the base of the instrument.
5. Pack and transport in packaging specified by Miltenyi Biotec.

6

Troubleshooting

This chapter gives troubleshooting information and how to act in the case of an error.

6.1 Service information

Record below the serial number located on the rear of the CliniMACS Plus Instrument. Refer to these numbers when calling Miltenyi Biotec Technical Support to obtain information or request service on the instrument.

Catalog no. (REF): _____

Serial no. (SN): _____

Software version: _____

IMPORTANT:
The software version is shown during the start-up phase of the instrument.

6.2 Miltenyi Biotec Technical Support

In any case of instrument malfunction or a process failure that cannot be corrected by the user, contact the Miltenyi Biotec Technical Support team:

+49 2204 8306-3803

technicalsupport@miltenyi.com

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

6.3 Error messages

The instrument and software can have malfunctions. Error messages are shown on the screen and marked as such. If the error cannot be corrected by the user, record the shown error number and contact Miltenyi Biotec Technical Support as soon as possible. One possible error message is shown in Figure 6.1.

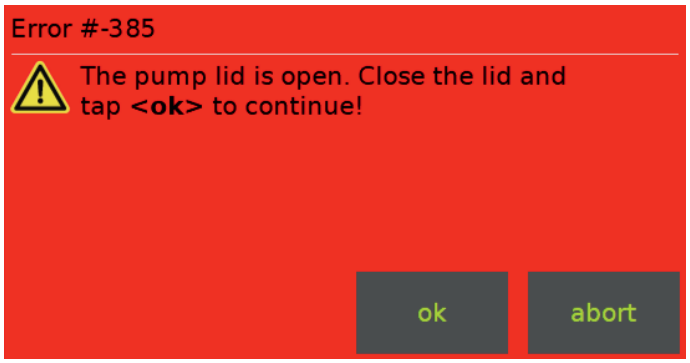


Figure 6.1: Error message

For details regarding application-specific warning and error messages, refer to the 'Troubleshooting' chapter of the CliniMACS Plus Applications user manual.

7

Technical data and specifications

This chapter provides the technical data and specifications for the instrument, including electrical requirements and operating conditions.

Technical data	Specification
Height	815 mm (without bag hangers) 1280 mm (with bag hangers)
Width	732 mm (including barcode reader and TubeSealer holder)
Depth	558 mm
Weight	approx. 38 kg
Input voltage	100–240 VAC (single phase alternating current)
Frequency	50/60 Hz
Power consumption	maximum 600 VA
Fuses	2 × T4 A / 250 V, 5 × 20 mm Use only fuses with UL and European approvals, according to IEC 127-2/III, EN 60127-2/III, DIN 41662.
Protection class	I
Pump speed	From –800 mL/min to +800 mL/min (counterclockwise, clockwise)
Noise level	up to 63 dB
Maximum ratings for the external alarm connector	AC/DC 25 V SELV or PELV 1 A

Table 7.1: Technical data

Condition	Range/Value
Operating conditions	
Temperature	From +10 to +30 °C (from +50 to +86 °F)
Humidity	From 0% to 85%
Altitude	maximum 2000 m above sea level
Power supply	Use a reliable, noise-free uninterruptible power source. Ensure supply voltage fluctuations do not exceed ±10% of the nominal voltage. Ensure transient over-voltages on the mains supply are within Category II limits. Plug the instrument into an outlet with a grounded connection only.
Environments	The instrument is intended for indoor use only. It is suitable for rated pollution degree 2.
Storage conditions	
Temperature	Room temperature
Humidity	Avoid condensing conditions

Table 7.2: Operating and storage conditions

8

Legal notes

8.1 Limited warranty

Except as stated in a specific warranty statement, which may accompany this Miltenyi Biotec product, or unless otherwise agreed in writing by a duly authorized Miltenyi Biotec representative, Miltenyi Biotec's warranty for products purchased directly from Miltenyi Biotec shall be subject to the terms and conditions of sale under which it was provided to you by the respective Miltenyi Biotec sales organization. These terms and conditions are available on request or at www.miltenyibiotec.com. The applicable terms and conditions of sale may vary by country and region. Nothing herein should be construed as constituting an additional warranty.

For products purchased from third-party retailers or resellers (e.g., purchased from an Authorized Distributor of Miltenyi Biotec), different terms and conditions may apply.

To determine the warranty that came with your product, see your packing slip, invoice, receipt or other sales documentation. Some components of a product combination you purchased may have a shorter warranty than that listed on your packing slip, invoice, receipt or other sales documentation (e.g., goods subject to shelf life and obsolescence).

Miltenyi Biotec's warranty for this product only covers product issues caused by defects in material or workmanship during normal use. It does not cover product issues caused by any other reason, including but not limited to product issues due to use of the product in a manner other than specifically described in this manual, for example: inappropriate or improper use; incorrect assembly or installation by an operator or a third-party; reasonable wear and tear; negligent or incorrect operation, handling, storage, servicing, or maintenance; non-adherence to the operating instructions; unauthorized modification of or to any part of this product; or use of inappropriate consumables, accessories, or work materials.

Miltenyi Biotec's warranty does not cover products sold AS IS or WITH ALL FAULTS or consumables. Nothing herein should be construed as constituting an additional warranty.

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 the instrument.

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 countries/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 vary from state to state or jurisdiction to jurisdiction.

8.2 Trademarks

CliniMACS, MACS, and the Miltenyi Biotec logo are registered trademarks or trademarks of Miltenyi Biotec B.V. & Co. KG and/or its affiliates in various countries worldwide. All other trademarks mentioned in this document are the property of their respective owners and are used for identification purposes only.

9

Appendix

9.1 Glossary

9.1.1 Symbols used for labeling products



European conformity mark with ID number of Notified Body



Medical Device


Eurasian Conformity mark



NRTL certification mark: Product meets consensus-based standards of safety, required by the Occupational Safety/Health Administration (OSHA), determined by the Nationally Recognized Testing Laboratories (NRTL) TÜV SÜD


Consult instructions for use


Caution


Warning of magnetic field


Manufacturer


Date of manufacture


Nonionizing radiation


WEEE (waste electrical and electronic equipment)

Fuse


Keep dry


Fragile, handle with care


This way up


Power off

Power on


Do not reuse


Do not use if package is damaged



The packaging is PVC free


Use-by date


Temperature limit


Non-pyrogenic fluid path



Lot number



Part number



Contents of the packaging



Catalog number



Serial number



Unique device identifier

Sterile fluid path, sterilized using ethylene oxide



Sterilized using steam or dry heat


Single sterile barrier system


Single sterile barrier system with protective packaging outside


Phone


E-mail


Website


Fax

9.1.2 Abbreviations

CAN	Controller Area Network
EDTA	Ethylenediaminetetraacetic acid
EMC	Electromagnetic compatibility
EVA	Ethylene-vinyl acetate
GUI	Graphical user interface
HF	High frequency
HSA	Human serum albumin
LED	Light-emitting diode
PBS	Phosphate-buffered saline
PVC	Polyvinyl chloride
REF	Catalog number
RF	Radio frequency
RTU	Ready-to-use
SN	Serial number
VHP	Vaporized hydrogen peroxide
WEEE	Waste Electrical and Electronic Equipment

9.1.3 Terms

Alarm connector	Relay circuit connector for the connection of the instrument to an external alarm system
Bag compartment	Compartment of the instrument in which the Negative Fraction Bag and Buffer Waste Bag are placed
Bag hanger	Support on the instrument to mount the Cell Preparation Bag, Non-Target Cell Bag, Priming Waste Bag, Reapplication Bag, and buffer bag
Barcode	Machine-readable representation of data, e.g., part number, batch code, or use-by date, indicated on required materials
Barcode reader	The barcode reader serves as a data input device to scan barcodes printed on, e.g., CliniMACS materials, needed for process execution
CAN connector	Connector used for service purposes only
CliniMACS Depletion Tubing Set	Set of tubing, connectors, columns, and bags through which the magnetically labeled cell suspension is processed and in which the magnetic cell separation takes place, especially designed for the specific depletion needs
CliniMACS PBS/ EDTA Buffer	Buffer used for cell preparation and cell separation with the CliniMACS Plus System: PBS (phosphate buffered saline), supplemented with 1 mM EDTA, pH 7.2. Before use, CliniMACS PBS/EDTA Buffer must be supplemented with pharmaceutical grade HSA to a final concentration of 0.5% (weight/volume, i.e., 5 g HSA per liter buffer)
CliniMACS Plus Instrument	Magnetic cell separation instrument based on the MACS Technology
CliniMACS Tubing Set, CliniMACS Tubing Set LS	Set of tubing, connectors, columns, and bags through which the magnetically labeled cell suspension is processed and in which the magnetic cell separation takes place, especially designed for the enrichment process
Guide pin	Part of the peristaltic pump to hold the pump tubing in place
Human serum albumin	Pharmaceutical grade HSA approved in your country is necessary as a buffer supplement when used with the CliniMACS Plus System
Housing	Cabinet of the CliniMACS Plus including bag hangers and a bag compartment. A touchscreen is connected to the housing
Labeling	Reaction of cells with magnetic labeling reagent, e.g., CliniMACS CD34 Reagent to CD34 positive cells
Leukapheresis	Apheresis collecting leukocytes
Liquid sensor	Component of the instrument that detects liquid in the tubing
MACS TubeSealer	Heat sealer used for sealing PVC and EVA tubes of the tubing sets installed on the instrument
Magnet unit	The magnet unit is used to separate magnetically labeled cells from non-labeled cells. It includes a movable, strong permanent magnet and a column holder for the separation column in which the magnetically labeled cells are retained
Magnetic antibody	A super-paramagnetically labeled antibody
Non-Target Cell Bag	Bag containing the non-target cell fraction, part of specific tubing sets
Peristaltic pump	Tubing pump used in the CliniMACS Plus Instrument to control the flow rate of fluid in the tubing set
Pinch valve	18 magnetic valves are used to fix the tubing set onto the instrument and to ensure controlled flow pathways within the tubing set throughout the procedure
Pre-column	First column in the CliniMACS Tubing Set and the CliniMACS Tubing Set LS, serves as filter to trap cells having non-specific interactions with the column matrix
Pre-column holder	Support mounted on the CliniMACS Plus Instrument that holds the pre-column in place
Pump safety switch	Sensor that prevents pump operation when the pump door is open

Separation column	Column in which magnetically labeled cells are separated when exposed to the magnetic field
Separation column holder	Molded guides in the magnet housing that holds the separation column in place
Separation program	Software program designed for the enrichment or depletion of magnetically labeled cell subsets from a mixed cell population. Choose from a menu of separation programs depending on the intended separation.
Separation reagent	Reagent for magnetic labeling of cells, e.g., CliniMACS CD34 Reagent
Signal lamp	LED signal lamp positioned at the top of bag hanger A to provide optical signals about the status of the instrument
USB ports	Standard USB ports to allow easy data transfer

9.2 Guidance and manufacturer's declaration on electromagnetic compatibility

⚠ WARNING

Risk of compromised safety or performance.

Using the instrument while adjacent to or stacked with other equipment may compromise the safety or performance.

- Do not use the instrument if adjacent to or stacked with other equipment.
- If adjacent or stacked use is necessary, carefully observe the instrument to verify normal operation.

⚠ WARNING

Degradation of the performance of this equipment.

If portable RF communications equipment is used in close proximity to any part of the instrument, this can degrade the performance of this equipment.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the instrument, including cables specified by the manufacturer.

IMPORTANT:
The instrument is intended for the use in the professional facility healthcare environment. The instrument is not intended to be used near active HF surgical equipment. The user must assure that the instrument is used in such an environment.

The CliniMACS Plus Instrument was tested according to the recommendations of IEC TS 60601-4-2:2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

EMC compliance with IEC 60601-1-2:2014 + AMD1:2020 (Edition 4.1) has been attested for the provided power cable. The use of other power cables may result in increased electromagnetic emissions or decreased immunity of the instrument.

Emissions test	Compliance
RF Emissions CISPR 11	Group 1, Class A
RF Emissions CISPR 32	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

Table 9.1: Guidance and manufacturer's declaration – Electromagnetic emissions

Based on technical limitations of the internal power supply voltage, interruptions on power supply input lines for longer than 10 ms may lead to cessation of the separation process (power failure). The separation process cannot be resumed after a power failure. It is recommended that the instrument is powered from an uninterruptible power supply or a battery that starts up within 10 ms.

Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge
Electrical fast transients (bursts) IEC 61000-4-4	±2 kV 100 kHz repetition frequency Power supply lines ±1 kV 100 kHz repetition frequency Input/output lines	±2 kV 100 kHz repetition frequency Power supply lines ±1 kV 100 kHz repetition frequency Input/output lines
Surges IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground
Voltage dips, interruptions, and variations IEC 61000-4-11	0% U_T during 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% $U_T$during 1 cycle and 70% U_T during 25/30 cycles (single phase) at 0° 0% U_T during 250/300 cycle	0% U_T during 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% $U_T$during 1 cycle and 70% U_T during 25/30 cycles (single phase) at 0° 0% U_T during 250/300 cycle
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V (0.15 MHz to 80 MHz) 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V (0.15 MHz to 80 MHz) 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF EM fields IEC 61000-4-3	3 V/m (80 MHz–2.7 GHz) 80% AM at 1 kHz	3 V/m (80 MHz–2.7 GHz) 80% AM at 1 kHz
Proximity fields from RF wireless communication equipment IEC 61000-4-3	See Table 9.3	See Table 9.3
Proximity magnetic fields in the frequency range from 9 kHz to 13.56 MHz IEC 61000-4-39	See Table 9.4	See Table 9.4

Table 9.2: Guidance and manufacturer's declaration – Electromagnetic immunity

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

Table 9.3: Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment

Test frequency (MHz)	Modulation	Immunity test level (A/m)	Compliance level (A/m)
134.2 kHz	2.1 kHz (pulse modulation)	65	65
13.56 kHz	50 kHz (pulse modulation)	7.5	7.5

Table 9.4: Guidance and manufacturer's declaration – Electromagnetic immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz

Miltenyi Biotec

Germany/Austria
Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68
51429 Bergisch Gladbach
Germany
+49 2204 8306-0
+49 2204 85197
macsde@miltenyi.com

USA/Canada
Miltenyi Biotec, Inc.
1201 Clopper Road
Gaithersburg, MD 20878
USA
800 FOR MACS
+1 866 811 4466
+1 877 591 1060
macsus@miltenyi.com

Australia
Miltenyi Biotec Australia Pty. Ltd.
Unit 11, 2 Eden Park Drive
Macquarie Park NSW 2113
Australia
+61 2 8877 7400
+61 2 9889 5044
macsau@miltenyi.com

Benelux
Miltenyi Biotec B.V.
Dellaertweg 9C
2316 WZ Leiden
The Netherlands
macsnl@miltenyi.com
Customer service for:
The Netherlands
0800 4020120
0800 4020100
Belgium
0800 94016
0800 99626
Luxembourg
800 24971
800 24984

China
Miltenyi Biotec Technology & Trading (Shanghai) Co., Ltd.
Room A401, 4/F
No. 1077, Zhangheng Road
Pudong New Area
201203 Shanghai
P.R. China
+86 21 6084 0210
+86 21 6235 0953
macscn@miltenyi.com.cn

France
Miltenyi Biotec SAS
10 rue Mercoeur
75011 Paris
France
+33 1 56 98 16 16
macsfr@miltenyi.com

Hong Kong
Miltenyi Biotec Hong Kong Ltd.
Unit 301, Lakeside 1
No. 8 Science Park West Avenue
Hong Kong Science Park
Pak Shek Kok, New Territories
Hong Kong
+852 3751 6698
+852 3619 5772
macshk@miltenyi.com.hk

India
Miltenyi Biotec India Pvt. Ltd.
Vatika Business Centre,
Floor No. 6
Divya Sree Omega
Kondapur, Serilingampally
K.V. Rangareddy
Telangana 500084
India
+91 040 45175910
macsin@miltenyi.com

Italy
Miltenyi Biotec S.r.l.
Via Paolo Nanni Costa, 30
40133 Bologna
Italy
+39 051 6460 411
+39 051 6460 499
macsit@miltenyi.com

Japan
Miltenyi Biotec K.K.
NEX-Eitai Building 5F
16-10 Fuyuki, Koto-ku
Tokyo 135-0041
Japan
+81 3 5646 8910
+81 3 5646 8911
macsjp@miltenyi.com

Nordics and Baltics
Miltenyi Biotec Norden AB
Medicon Village
Scheeletorget 1
223 81 Lund
Sweden
macsse@miltenyi.com
Customer service for:
Sweden
0200 111 800
+46 280 72 99
Denmark
80 20 30 10
+46 46 280 72 99
Norway, Finland, Iceland, and Baltic countries
+46 46 280 72 80
+46 46 280 72 99

Singapore
Miltenyi Biotec Asia Pacific Pte Ltd.
438B Alexandra Road, Block B
Alexandra Technopark
#06-01
Singapore 119968
+65 6238 8183
+65 6238 0302
macssg@miltenyi.com

South Korea
Miltenyi Biotec Korea Co., Ltd.
Donggeuk 7F
562 Nonhyeon-ro
Gangnam-gu
Seoul 06136
South Korea
+82 2 555 1988
+82 2 555 8890
macskr@miltenyi.com

Spain
Miltenyi Biotec S.L.
C/Virgilio 2, Edificio II, Planta –1
28223 Pozuelo de Alarcón, Madrid
Spain
+34 91 512 12 90
+34 91 512 12 91
macses@miltenyi.com

Switzerland
Miltenyi Biotec Swiss AG
Soodstrasse 52
8134 Adliswil
Switzerland
+41 32 623 08 47
+49 2204 85197
macsch@miltenyi.com

United Kingdom
Miltenyi Biotec Ltd.
Almac House, Church Lane
Bisley, Surrey GU24 9DR
United Kingdom
+44 1483 799 800
+44 1483 799 811
macsuk@miltenyi.com

www.miltenyibiotec.com

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