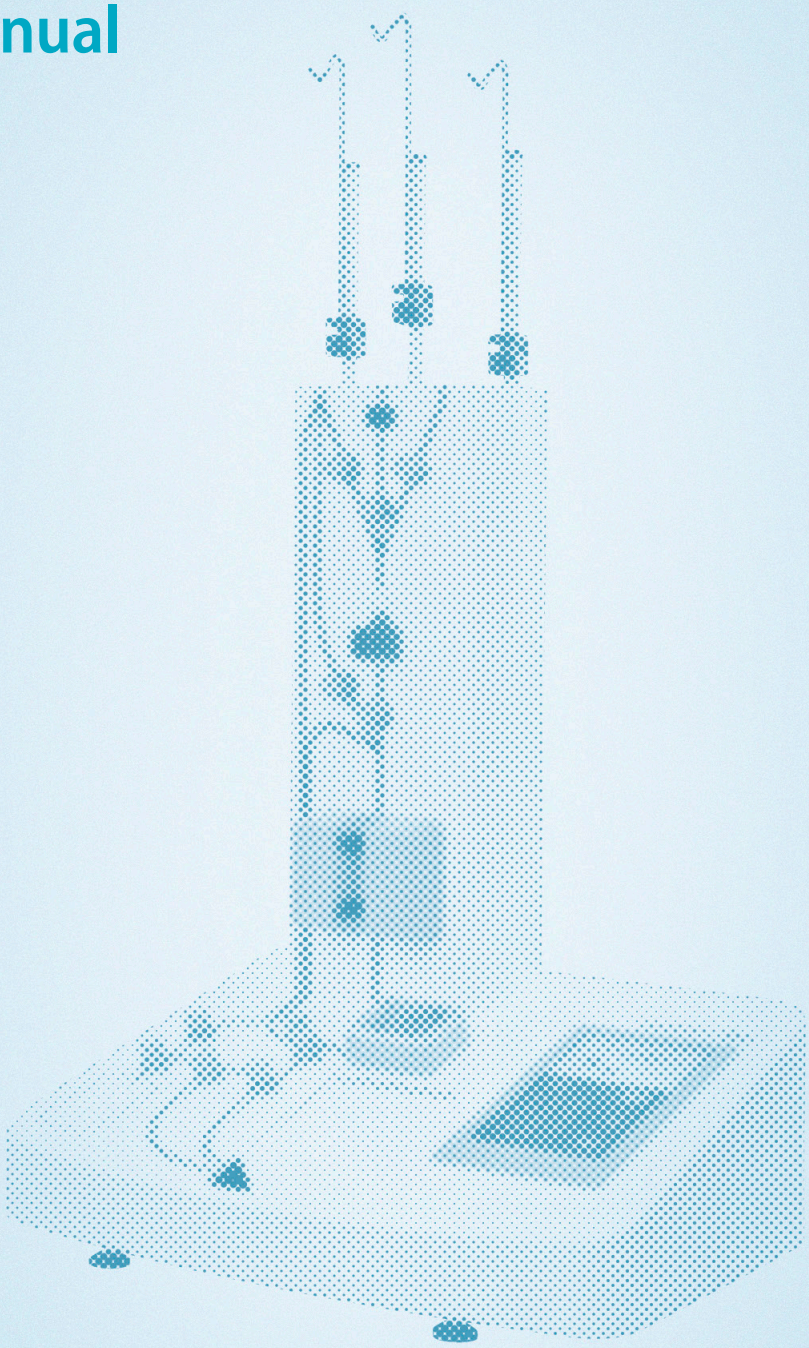
Miltenyi Biotec

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 device 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 Instrument (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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Essential information

This user manual provides information for the use of the CliniMACS Plus Instrument. For further details on the processes running on the instrument, refer to the CliniMACS Plus Applications user manual.

⚠ WARNING

The operation of the CliniMACS Plus System must be performed by trained operators only. Before putting the system into operation, carefully read and understand the safety information, warnings, precautions, and instructions for proper operation of the CliniMACS Plus Instrument provided in the instructions for use of the CliniMACS Plus System components (including, without limitation, the safety information in this user manual, chapter 3 "Important safety information") 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. The operator must adhere to all instructions and procedures at all times during the operation of the instrument, confirming that all safety information, warnings, precautions, and instructions are observed. Failure to follow the safety information, warnings, precautions, and instructions contained in the instructions for use could result in instrument malfunction, property damage, personal injury, and/or death. Equipment safety may be compromised if the instrument is not used according to the manufacturer's instruction.

Retain the CliniMACS Plus Instrument instructions for use 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.

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1 Introduction

1.1 General information

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

LIMITED WARRANTY
Should the CliniMACS Plus System be used in a manner not explicitly described in this manual, all warranties will be null and void.

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 – e.g., 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.

IMPORTANT
Before using the CliniMACS Plus System or any components outside the European Economic Community, the regulatory approval of the CliniMACS Plus System or any CliniMACS Component in the country must be confirmed.

1.2 CliniMACS Plus Instrument information

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

Model no: _____

Serial no: _____

Software version: _____

2 Glossary

2.1 Graphical depiction

The following chart depicts the panels used in this user manual to inform the user about potential risks if the outlined warnings and precautions are not followed. The hazard level classifies the hazard, as described below. The level, type, and source of the hazard, as well as potential consequences, prohibitions, and measures are indicated as follows. Icons on the left side specify the risk.

⚠ 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 information considered important, but not hazard-related (e.g., messages relating to property damage)

IMPORTANT

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

2.2 Glossary of symbols

2.2.1 Safety symbols



General warning sign



Warning: Electricity



Warning: Magnetic field



Warning: Biological hazard



Warning: Crushing of hands

2.2.2 Symbols used for labeling products

CE 0123

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

MD

Medical Device

Eurasian Conformity mark

UK CA

UK Conformity Assessed mark

c UL us LISTED LABORATORY EQUIPMENT

UL listing mark, listed as laboratory equipment



Consult instructions for use



Caution



Strong magnetic field



Manufacturer

	Date of manufacture
	Non-ionizing radiation
	Separate collection for waste of electrical and electronic equipment
	Fuse
	Keep dry
	Fragile, handle with care
	This way up
	"OFF" (power)
	"ON" (power)
	Do not re-use
	Do not use if package is damaged
	The packaging is PVC free
	Use-by date
	Temperature limit
	Non-pyrogenic fluid path
	Batch code

P/N	Part number
QTY	Contents of the packaging
REF	Catalogue number
SN	Serial number
UDI	Unique Device Identification
STERILE EO	Sterilized using ethylene oxide
STERILE	Sterilized using steam or dry heat
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Phone
	E-Mail
	Website

2.3 Glossary of terms

Bag compartment	Compartment of the CliniMACS Plus Instrument in which the Negative Fraction Bag and Buffer Waste Bag are placed
Bag hanger	Support on the CliniMACS Plus Instrument to mount the Cell Preparation Bag, Non-Target Cell Bag, Priming Waste Bag, Reapplication Bag, and buffer bag
CliniMACS Depletion Tubing Set	Set of tubing, connectors, columns, and bags through which the magnetical 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
EDTA	Ethylene-diamine-tetra-acetic acid
HSA	Human serum albumin
Human serum albumin	Pharmaceutical grade HSA approved in your country is necessary as a buffer supplement when used with the CliniMACS Plus System.
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 CliniMACS Plus Instrument that detects liquid in the tubing
Magnetic antibody	A super-paramagnetically labeled antibody
Peristaltic pump	Tubing pump used in the CliniMACS Plus Instrument to control the flow rate of fluid in the tubing set

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
Selection column	See separation column.
Selection column holder	See separation column holder.
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
WBC	White blood cells

3 Important safety information

⚠ WARNING

The operation of the instrument must be performed by trained operators only. Operator training will be provided by a Miltenyi Biotec representative. Before putting the system into operation carefully read and understand the safety information, warnings, precautions, and instructions for proper operation of the CliniMACS Plus System provided in this user manual (including without limitation the safety information in this chapter) 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. The operator must adhere to all safety information, warnings, precautions, and instructions at all times when putting the instrument into 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.

⚠ WARNING

Hazards to users, instrument damage, and/or malfunction, unpredictable results, premature wear and tear, and/or reduced life time of the instrument if the following safety information, warnings, precautions, and instructions are not observed 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 that 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 instrument. 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 customer or user should assure that it is used in such an environment.
- 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 instruments, as applicable at 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, and/or cables other than those approved by Miltenyi Biotec to ensure safe and proper operation of the instrument. **Note:** The use of consumables, accessories, 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.
- Always follow the maintenance recommendations of Miltenyi Biotec and appropriate product standards. Note: 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:** Changes or modifications to the instrument not expressly approved by Miltenyi Biotec could void the warranty and/or invalidate the operator's authority to operate the instrument under applicable regulations.

⚠ WARNING

Risk of death, serious personal injury, and/or property damage,instrument malfunction, or damage, premature wear and tear, and reduced instrument life time. Failure to comply with the safety information, warnings, precautions, and instructions in the user manuals (and in other safety related publications issued by Miltenyi Biotec for use with the instrument) could lead to improper or incorrect use, handling or care of the product and cause a hazard, and could result in death, serious personal injury, and/or property damage, instrument malfunction, or damage, premature wear and tear, and reduced instrument life time, and may void the warranty and/or invalidate the authority to operate the instrument under applicable regulations. Miltenyi Biotec accepts no liability for consequences arising from failure to comply with the safety information, warnings, precautions, and instructions provided herein.

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

3.1 Safety instructions for the CliniMACS Plus Instrument



In the event of an unexpected process abortion or messages on the screen that advises the operator to contact technical support, immediately contact the Miltenyi Biotec Technical Support. 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.

3.1.1 Usage and installation

⚠ 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 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. Installation of the CliniMACS Plus Instrument must only be performed by an authorized local Miltenyi Biotec service provider.

⚠ CAUTION

Risk of process failure. If alarm signals are not recognized and the required actions are not executed or confirmed there is the risk of process failure. Confirm that acoustical alarm signals can be recognized by the operator at any time during the process.

The CliniMACS Plus instrument may be used repeatedly. It is not intended for disposal after single use.

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

Do not leave the instrument unattended during a run. If an error occurs, the cell separation can be interrupted by the user at the current step and the operator will have 600 seconds to correct certain errors. If the instrument has not been restarted after this time period, the run will be aborted.

Keep away from all moving parts.

⚠ WARNING

Risk of injury. If the separation column is inserted or removed while the magnet unit is switched on, there is the risk of personal injury. Only insert or remove the separation column when the magnet unit is switched off.

⚠ 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.

⚠ CAUTION

Risk of damage to the bag hangers. Risk of damage to the bag hangers in case of overloading. The carrying capacity of a single bag hanger is 3 kg. Do not overload the bag hangers.

3.1.2 Electric hazards

The CliniMACS Plus Instrument is a Protection class I instrument and may only be plugged into an outlet with a grounded connection.

⚠ WARNING



Risk of electric shock, electrical short, and spread of fire. Electric shock may lead to severe personal injury or death. The housing of the instrument reduces the risks of electric shock, electrical short, and spread of fire. Opening any cover of the instrument interrupts this protective measure. Do not remove or penetrate any cover of the instrument. Only authorized local Miltenyi Biotec 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.

Before cleaning or maintenance of the instrument, the power cord must be disconnected. Use the mains plug to disconnect the instrument from the power supply. Only use the originally supplied power cord.

If flames or smoke appear, immediately switch off the instrument, unplug it from the electrical outlet, and contact an authorized local Miltenyi Biotec service provider or Miltenyi Biotec Technical Support.

The instrument is intended for indoor use only. Water ingress may lead to an electrical short and the risk of electric shock or spread of fire. 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. Clean spillages immediately. Do not allow fluids to enter the interior of the instrument. Avoid ingress of any liquid into the valves. Do not operate the instrument if liquids have spilled into the instrument. Fluid containers must be handled with caution when in the area of the instrument. 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. It is necessary to wait for the instrument to dehumidify before operating the instrument. Do not use liquid or aerosol cleaning agents; always use a damp cloth.

Ambient air temperature may not be adequate to cool the instrument to acceptable operating temperatures without adequate circulation. Overheating may lead to the spread of fire. Confirm 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. Allow sufficient space for air circulation around the instrument – at least 14 cm on all sides – during operation to ensure adequate cooling. Prevent direct exposure of the instrument to sunlight. Slots and openings of the instrument are provided for ventilation and should never be blocked or covered, as these 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, proper ventilation is provided, and the mounting instructions for the instrument have been followed.

Electronic equipment may emit sparks that could ignite combustible vapors or dusts leading to explosion or spread of fire. Do not operate the instrument in a dusty environment or near any vapors.

Confirm the main switch, as well as the connector for the power cord are easily accessible and located as close to the operator of the instrument as possible. If it is necessary to disconnect the power supply, unplug the cord from the power outlet.

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 power outlet. This is a safety feature. Do not try to insert the plug into a non-grounded power outlet. If the plug cannot be inserted into the outlet, contact your local electrician to replace the outlet.

The instrument should only be operated from a power source indicated on the product's electrical ratings label. For questions about the type of power source to use, contact the authorized local Miltenyi Biotec service provider or local power company. Do not use extension cords or power strips. Do not overload an electrical outlet.

⚠ 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. It is recommended that the CliniMACS Plus Instrument is powered from an uninterruptible power supply or a battery that starts within 10 ms.

3.1.3 Strong magnetic field

⚠ WARNING



Risk of severe personal injury for persons carrying pacemakers, brain shunts, or electronic medical implants. The CliniMACS Plus 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 magnet cover.

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.

3.1.4 Biological hazards

⚠ WARNING



Risk of severe personal injury or death. Depending on the biological material used, contamination or infection may lead to severe personal injury or death. Always wear personal safety equipment in accordance with warnings and precautions, in particular if biohazardous material is or has been used.

Wear protective gloves, protective clothing, and safety goggles to prevent contact with skin and eyes. Defective or inadequate safety equipment might endanger the operator. If hazardous material has been used or spilled, take care to thoroughly decontaminate the instrument.

After running the sample and prior to decontamination, the CliniMACS Plus Instrument should be treated as a biohazard (see section 4.8 "Cleaning and disinfection"). Waste disposal must be in accordance with local regulations.

3.1.5 Mechanical hazard

⚠ WARNING



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.

Movement or vibration may affect the instrument. Do not place the instrument next to equipment that vibrates or can cause the instrument to move.

3.1.6 Servicing and transport

⚠ WARNING

Hazards to users, unpredictable results, instrument malfunction or damage, premature wear and reduced life time of the instrument. Improper or incorrect servicing or repair of the instrument can cause hazards to users, lead to unpredictable results, instrument malfunction or damage, premature wear and reduced life time of the instrument, and may void the warranty. Do not service the CliniMACS Plus Instrument. Service and repair may only be performed by authorized local Miltenyi Biotec service provider.

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.

⚠ 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 personal injury. The transport should be performed by at least two people according to the instructions in section 4.5 "Unpacking". The instrument should be lifted in an upright position under each of the four corners at the base of the instrument.

Before transportation, the instrument must be switched off and disconnected from the power supply. All bag hangers and disposables should be removed from the instrument.

⚠ 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.

For details regarding proper decontamination refer to the instructions in section 4.8 "Cleaning and disinfection".

4 The CliniMACS Plus Instrument

4.1 Regulatory information

The CliniMACS Plus Instrument is a medical device in Europe.

For the regulatory status in countries outside Europe, contact the authorized local Miltenyi Biotec service provider.

In Canada, any clinical application of the output product must be performed in accordance with applicable Canadian legislation and regulations that pertain to cellular therapies (e.g., for advanced cellular therapies, the applicable sections of the Food and Drugs Act and the Food and Drug Regulations).

4.2 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.

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

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.

In the United Kingdom the instrument complies with all essential requirements of The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012.

The instrument is UL Listed:

In Canada, for the operation of the CliniMACS Plus System, only the stated components and accessories defined in the CliniMACS Plus Applications user manual for the respective applications must be used with the CliniMACS Plus Instrument.

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.

4.3 Technical data

⚠ WARNING

Safety and performance of the instrument may be compromised. Safety and performance of the instrument may be compromised if the CliniMACS Plus Instrument is used outside its specifications. Do not use the instrument outside its specifications.

Technical data		
Model	**CS2-CE/UL**	**CS3**
REF	151-01	
Serial number	0001-1999	2000-XXXX
Dimensions	Width: 70 cm Height: 90–140 cm Depth: 60 cm	
Weight	35 kg	
Input voltage	100–240 VAC (Single phase alternating current)	
Power consumption	180 VA	350 VA
Power source	An uninterruptible power source is recommended (reliable, noise free utility). Recommended UPS: APC Smart-UPS 1,500 VA USB & Serial 230 V, manufactured by APC (American Power Conversion) or equivalent.	
Instrument power	Instrument power inlet IEC-320-C13 A country specific power cord is supplied with the instrument.	
Frequency	50/60 Hz	
Fuses	2× T4A/250 V, 5×20 mm Use only fuses with UL and European approvals, acc. to IEC 127-2/III, EN 60127-2/III, DIN 41662.	
Operation conditions	+10 to +30 °C (+50 to +86 °F) with 0% to 85% humidity at an altitude of max. 2,000 m. Supply voltage fluctuations up to ±10% of the nominal voltage. Transient over-voltages present on the mains supply: category II. The instrument is suitable for rated pollution degree 2. The instrument is intended for indoor use only.	
Storage	–10 to +60 °C (+14 to +140 °F) with 0% to 85% humidity, when contained and sealed in the outer packaging provided by the manufacturer	

Table 4.1: Technical data of the CliniMACS Plus Instrument

Protection class

The instrument is a protection class I instrument (acc. to DIN 61140) and may only be plugged into an outlet with a grounded conductor. The protection category according to DIN EN 60529 is IPX 0.

4.4 Power connection

Model CS2-CE/UL

The power connection module is located at the rear of the instrument. Viewed from behind, the connection consists of three sections (see Figure 4.1). The left section is the recessed male 3-pin connector to which the power cord is attached. The center section is the main ON/OFF switch. When positioned to the left, the switch is 'OFF' (O). When positioned to the right, the switch is 'ON' (I).

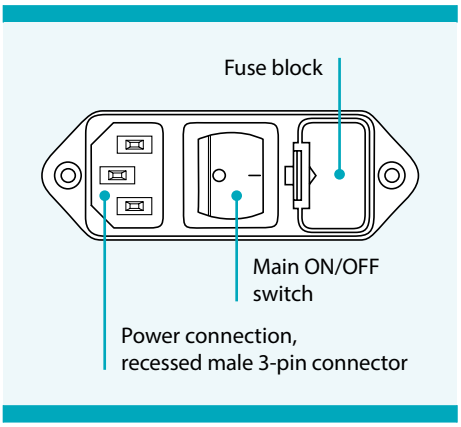


Figure 4.1: Power connection model CS2-CE/UL

The right section is the fuse box. The instrument must be unplugged and switched off before opening the fuse box.

To open the fuse box, insert a thin-bladed screwdriver into the slot and twist the screwdriver to release the catch. To replace the fuses, remove the fuses from the rear, insert new fuses and slide the module back in until the latch clicks to the closed position. The module will only slide in one direction. Only fuses with UL and European approvals are to be used.

Model CS3

The power connection module is located at the rear of the instrument. Viewed from behind, the connection consists of two sections (see Figure 4.2). The left section is the recessed male 3-pin connector to which the power cord is attached. The right section is the main ON/OFF switch. When positioned to the left, the switch is 'OFF' (O). When positioned to the right, the switch is 'ON' (I).

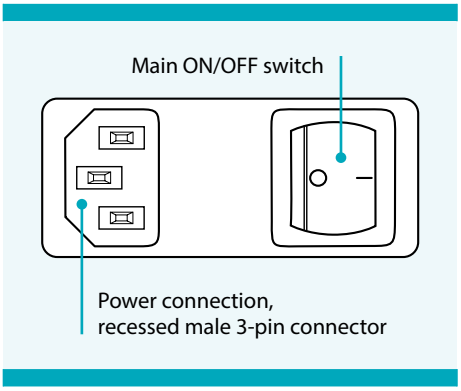


Figure 4.2: Power connection model CS3

Interferences

This equipment has been tested and found to comply with the limits for a class A (model CS3, manufactured 2019 and beyond) or class B (model CS2-CE/UL, manufactured until 2019) digital instrument, pursuant to part 15 of the FCC Rules. These limits are

designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by switching the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures.

- Redirect or relocate the receiving antenna.
- Increase the space between the equipment and receiver.
- Connect the equipment to an outlet which is not on the same circuit as the receiver.
- Consult the dealer or an experienced radio/TV technician for help.

Performance

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.

4.5 Unpacking

⚠ WARNING

Risk of electromagnetic emissions. Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and placed in service according to the EMC information. Portable and mobile RF communications equipment can affect medical electrical equipment.

⚠ CAUTION

Risk of personal injury or compromised performance of the instrument. The instrument may tilt or slip if it is not installed adequately, which might result in personal injury or compromised performance. Unpacking and installation of the CliniMACS Plus Instrument must only be performed by an authorized Miltenyi Biotec representative. Visually inspect and note any significant damage to the package. Damage may require inspection by a representative of the shipping company.

4.6 Transport

⚠ WARNING

Chemical and biological hazard. Risk of chemical or biological hazards due to remnants of hazardous material. If the instrument needs to be shipped back to the manufacturer for service, decontaminate the instrument from any hazardous material prior to shipment. For details regarding proper decontamination refer to the instructions in section 4.8.

⚠ 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 personal injury. The transport should be performed by at least two people according to the instructions in section 4.5. The instrument should be lifted in an upright position under each of the four corners at the base of the instrument.

4.7 Positioning

⚠ WARNING

Electrical hazard. To avoid electrical hazards it must be possible to interrupt the power supply at any time. The power connection including the fuse holder and the main switch must be accessible at all times.

⚠ CAUTION

Risk of overheating. Risk of overheating in case of reduced air circulation. Do not place instrument with the back side directly against the wall. Keep at least 10 cm distance to allow free air circulation. Allow sufficient space around the ventilation slots at the rear and underneath the instrument. Take into consideration that the instrument requires adequate air circulation for heat exchange and cooling. Read the chapter 3 "Important safety information" to avoid the risk of overheating.

⚠ CAUTION

Risk of serious harm and/or serious damage to the instrument. The CliniMACS Plus Instrument could fall and cause serious harm and/or serious damage to the instrument if placed on an unstable surface. The CliniMACS Plus Instrument must be placed 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.

4.8 Cleaning and disinfection

⚠ WARNING

Risk of electric shock or damage to the instrument. Risk of electric shock or damage to the instrument if the instrument is cleaned with excessive amount of cleaning agent or while switched on. Only clean the CliniMACS Plus Instrument when it is switched off and the power cord is unplugged. Avoid ingress of any liquid into the valves and into the liquid sensor. After cleaning, dry all excess liquid from the valves, pump head, etc.

Clean the instrument with disinfectant, e.g., Bacillol® plus or Meliseptol®, which are compatible with the surface of the instrument.

Dust off the valves, peristaltic pump, and magnet unit using a paper towel or absorbent material.

⚠ WARNING

Safety and performance of the instrument may be compromised. Safety and performance of the instrument may be compromised if other than the above mentioned cleaning methods are used. UV radiation may damage plastic parts of the instrument. Do not use UV irradiation. The instrument should not be sterilized, e.g., with H_2O_2.

Clean the labels of CliniMACS Plus Instrument with a mild detergent only.

IMPORTANT

The surface of the CliniMACS Plus Instrument should be cleaned at regular intervals and after each application. Cleaning after unpacking and installation is also recommended.

4.9 Maintenance

⚠ WARNING

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

The CliniMACS Plus Instrument does not contain operator serviceable parts. Routine and preventative maintenance procedures should be conducted by the manufacturer's authorized service personnel at least once a year. Calibration is not required.

4.10 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 4.8.

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

4.11 Description

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

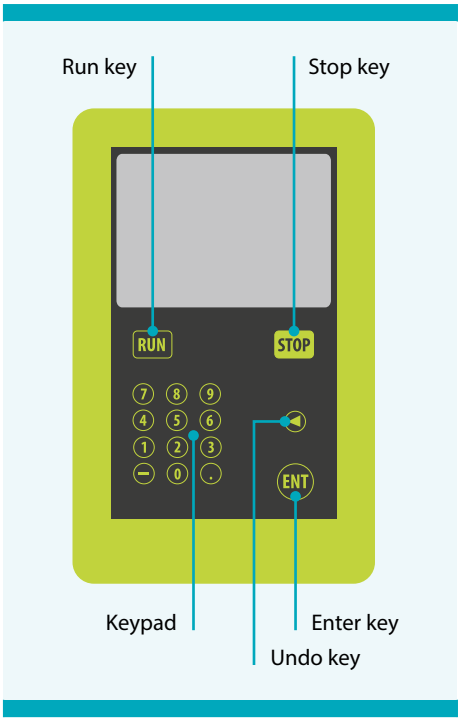


Figure 4.3: Display with touchscreen (model CS3)

The integrated microcomputer controls all electromechanical components of the instrument and directs the system to perform procedures in a standard sequence. The touchscreen guides the operator through the set-up procedure and allows monitoring of automatic system operations (see Figure 4.3). In the user manuals, text in bold gray indicates elements available for selection (e.g., buttons).

The magnetic separation unit includes the movable permanent magnet and the separation column holder for the separation column.

During the separation, the peristaltic pump controls the flow rate through the tubing sets. The liquid sensor monitors the flow of labeled cell suspension into the tubing set. Disruption of continuous fluid flow through the sensor automatically advances the separation program to the next phase of the separation process.

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

The CliniMACS Plus Instrument and CliniMACS Tubing Sets allow the operator to perform cell separations in a closed and sterile system.

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

NOTICE

Risk of process abortion. For safety reasons, the separation in progress will automatically stop during the instrument run if the pump door is opened. While the instrument is in operation keep the pump door closed.

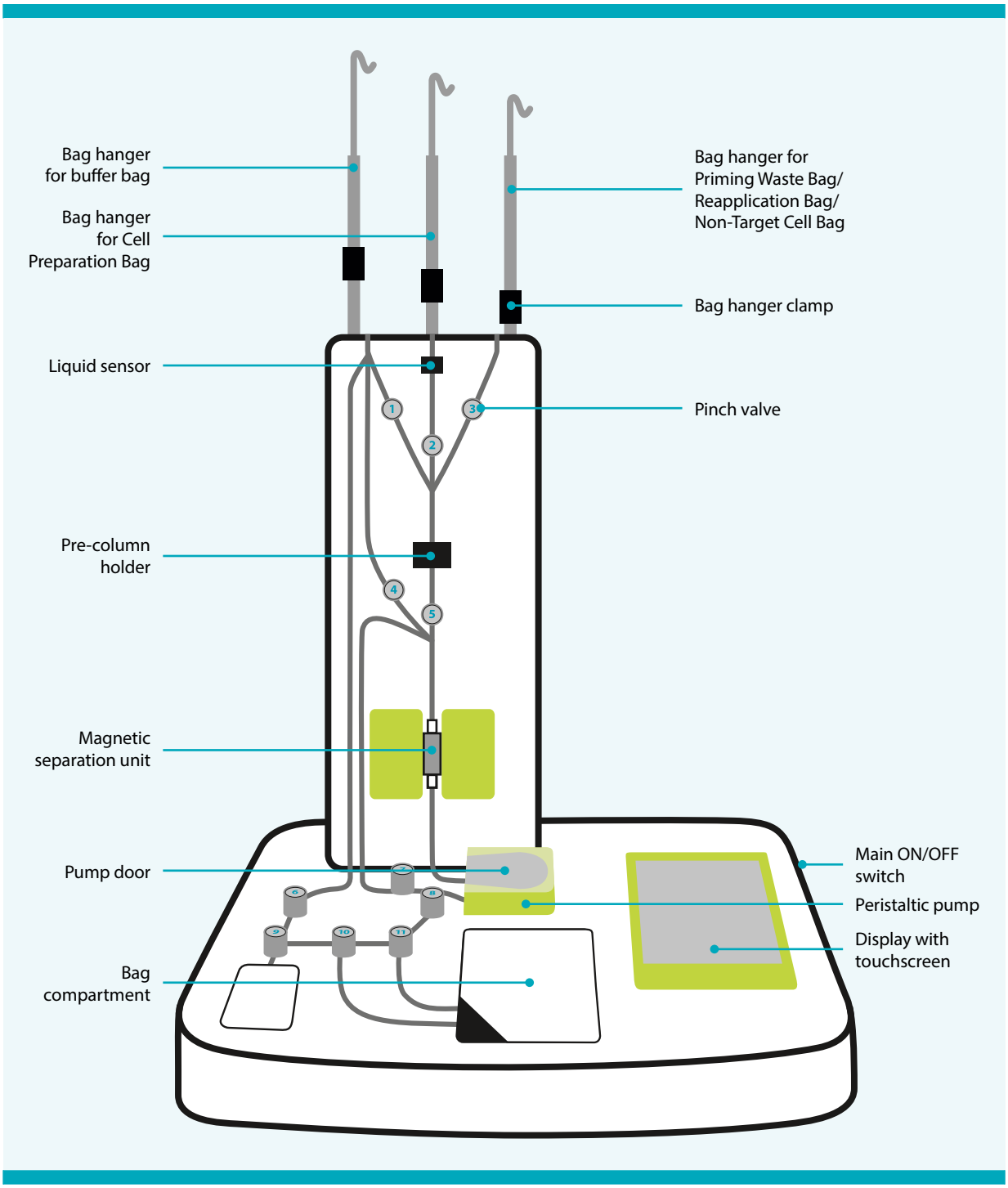


Figure 4.4: The CliniMACS Plus Instrument (model CS3)

4.12 Installation

4.12.1 Connect and switch on the CliniMACS Plus Instrument

⚠ CAUTION

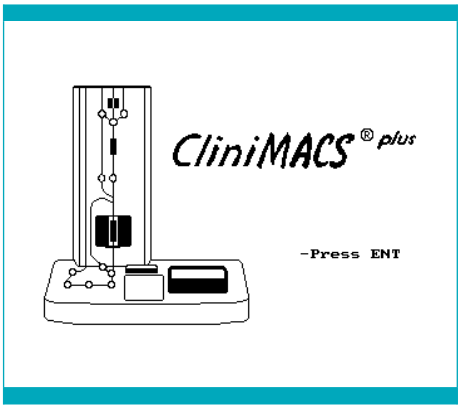
Risk of damage to the instrument. Risk of damage to the instrument if the instrument is installed by unauthorized persons. Installation of the CliniMACS Plus Instrument must only be performed by an authorized Miltenyi Biotec representative. Read the chapter 3 "Important safety information" before installation and use of the instrument.

Connect the CliniMACS Plus Instrument to an uninterruptible power supply using the supplied power cord.

Switch on the instrument by using the main ON/OFF switch (see Figure 4.1 and Figure 4.2) located on the right-hand back panel of the instrument.

For safety reasons, the instrument should be switched off after each run and the power cord cable should be disconnected during the instrument clean-up procedures.

Upon startup, the instrument will perform self-checking procedures. The program will automatically be loaded and Screen 4.1 will appear in the display window.



Screen 4.1: Main screen

If the instrument does not start up, switch off the instrument and disconnect it from the power supply. Check the power cord connection and the fuses (model CS2-CE/UL only) located on the right-hand back panel (see section 4.4 "Power connection"). Then switch on the instrument again.

If the instrument does not start correctly or the window displays an error message, note the error message number, switch off the instrument and contact the Miltenyi Biotec Technical Support.

⚠ WARNING

Risk of process failure or damage to the instrument. Risk of process failure or damage to the instrument if procedures are perfomed by untrained operators. All processing procedures must be performed by trained operators only. Operator training will be provided by a qualified Miltenyi Biotec representative.

4.12.2 Language selection and service menu

The CliniMACS Plus Instrument provides a menu to set-up the language and a service menu (see section 4.13).

To enter these menus, wait until Screen 4.1 appears in the display window and **do not** press ENT as shown on the window display.

To start the general menus, refer to section 4.13.

4.13 General set-up menus

Language selection

The language selection menu allows the operator to change the language used in the display. It is possible to choose between English, German, French, Spanish, Italian, and Dutch.

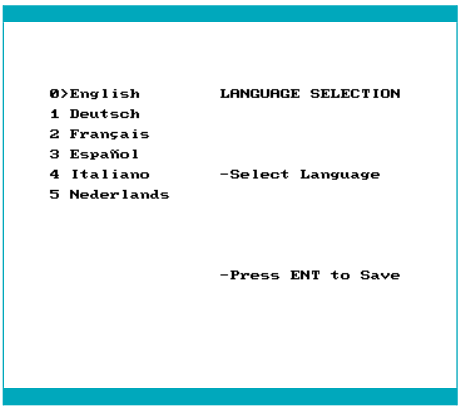
To change the language, wait until the window displays Screen 4.1 and **do not** press ENT then.

To start language selection, press **2**.

The window will display Screen 4.2 as shown.

To select a language, press the corresponding number.

To save the language, press **ENT**.



Screen 4.2: Language selection

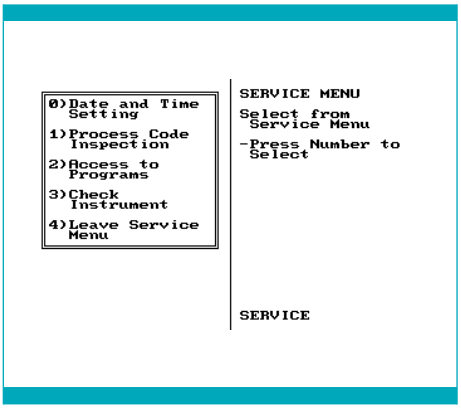
Service menu

The service menu contains some programs that might be useful for the operator.

To open the service menu folder, wait until the window displays Screen 4.1 and **do not** press ENT then.

Then press **5**.

The window will display Screen 4.3 as shown.



Screen 4.3: Service menu

Date and time setting

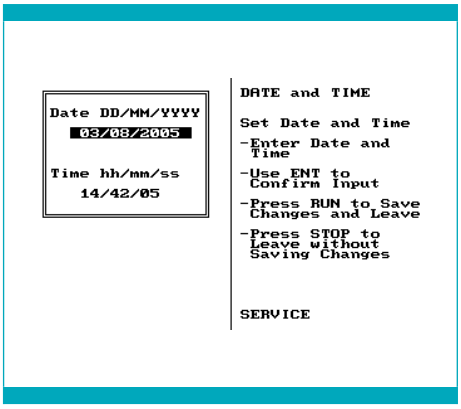
To set date and time, press **0**.

Follow the instructions shown on Screen 4.4.

Date or time can be changed, when the respective field is highlighted by the black bar.

To move the black bar between date and time input, press **ENT**.

Enter the current date (order: day/month/year) and time (order: hours/minutes/seconds). A wrong input can be amended by pressing **9** (see Figure 4.3).



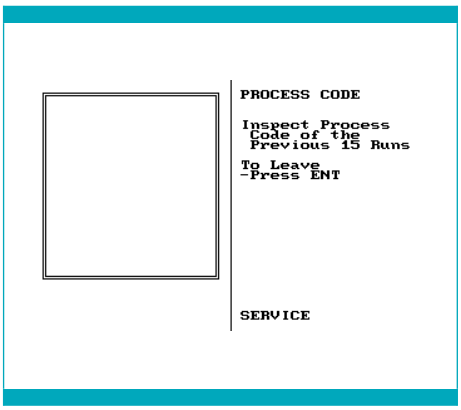
Screen 4.4: Service menu (date and time)

To save the data and leave, press **RUN**.

To leave the program without saving the changes, press **STOP**. After pressing **RUN**, the program will automatically return to the service menu.

Process code inspection

The operator is able to call up the process codes of the last 15 separations. A process code is saved when the operator has started the installation of the tubing set or when the emergency program (see CliniMACS Plus Applications user manual) has been used. Saving a process code is independent from whether the separation has been completed or interrupted.



Screen 4.5: Process code

To call up a process code, press **1**.

The process codes from the last 15 separations are listed chronologically. The list begins with the most recent procedure.

To return to the service menu, press **ENT**.

Access to programs

This program allows for the activation of additional separation programs by Miltenyi Biotec authorized personnel. Contact the Miltenyi Biotec Technical Support for further information and instructions to continue.

If this program has been entered by mistake, press **STOP** to leave the program.

Check instrument

In case of a suspected malfunction of the instrument contact the Miltenyi Biotec Technical Support. If an instrument check is indicated the specialist will assist the operator in performing the instrument check sequence.

IMPORTANT
Important data collected by the instrument software during a CliniMACS Plus Separation are saved within the process code.

It is strongly recommended to record the process code.

If this program has been entered by mistake, press **STOP** to leave the program.

To leave the service menu, press **4**.

5 The CliniMACS Plus System

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.

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.

5.1 CliniMACS Plus Instrument

The CliniMACS Plus Instrument is an electromechanical instrument incorporating a permanent magnet, a peristaltic pump, pinch valves, electronics, and software.

5.2 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.

5.3 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.

5.4 CliniMACS PBS/EDTA Buffer

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

5.5 Additional materials required

In addition to the CliniMACS Products, additional materials may be required for a CliniMACS Plus Separation. Refer to the CliniMACS Plus Applications user manual for further information.

6 Troubleshooting

6.1 Miltenyi Biotec Technical Support

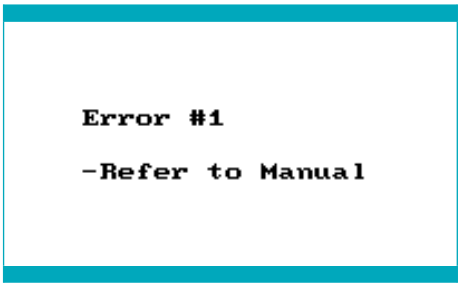
In any case of instrument malfunction or process failure, contact the Miltenyi Biotec Technical Support team:

+49 2204 8306-3803
technicalsupport@miltenyi.com

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

6.2 Error messages

There are a number of possible instrument or software malfunctions. These are marked as such and will be displayed on the screen. They refer to internal errors that cannot be corrected by the operator. Record the displayed error number and contact Miltenyi Biotec Technical Support as soon as possible. One possible error message is shown in Screen 6.1. Malfunctions which can be corrected by the operator are marked “Warning messages”. Refer to chapter “Troubleshooting” of the CliniMACS Plus Applications user manual.



Screen 6.1: Error message no. 1

7 Legal notes

7.1 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.

7.2 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.

Appendix

Guidance and manufacturer's declaration on electromagnetic compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

EMC compliance with IEC 60601-1-2:2014 + AMD1:2020 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 CliniMACS Plus Instrument.

If the provided power cable is missing, contact Miltenyi Biotec for information on a replacement part.

Guidance and manufacturer's declaration – Electromagnetic emissions		
The CliniMACS Plus 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 customer or user of the instrument should assure that it is used in such an environment.		
Emissions test	**Compliance**	
Model	**CS2-CE/UL**	**CS3**
RF Emissions CISPR 11	Group 1	Group 1
RF Emissions CISPR 11	Class A	Class A
RF Emissions CISPR 32	–	Class A
Harmonic emissions IEC 61000-3-2	Class A	Class A
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	Complies

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

⚠ WARNING

The instrument should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the instrument should be observed to verify normal operation in the configuration in which it will be used.

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.

Guidance and manufacturer's declaration – Electromagnetic immunity			
The CliniMACS Plus Instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the instrument should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients (Bursts) IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	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 IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment but if the user of the instrument requires continued operation during power mains interruptions longer than 10 ms, it is recommended that the instrument be powered from an uninterruptible power supply or a battery that starts up within 10 ms.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Table A.2: Guidance and manufacturer's declaration – Electromagnetic immunity (model CS2-CE/UL)

Guidance and manufacturer's declaration – Electromagnetic immunity			
The CliniMACS Plus Instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the instrument should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/mr	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Table A.3: Guidance and manufacturer's declaration – Electromagnetic immunity (model CS2-CE/UL)

Guidance and manufacturer's declaration – Electromagnetic immunity		
The CliniMACS Plus 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 customer or user of the instrument should assure that it is used in such an environment.		
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
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 d
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz z	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 A.5 and Table A.6 below: Specifications for immunity to RF wireless communication equipment	See Table A.5 and Table A.6 below: Specifications for immunity to RF wireless communication equipment
Proximity magnetic fields in the frequency range from 9 kHz to 13.56 MHz IEC 61000-4-39	See Table A.7 below: Specification for immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz	See Table A.7 below: Specification for immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

Table A.4: Guidance and manufacturer's declaration – Electromagnetic immunity (model CS3)

Recommended separation distances between portable and mobile RF communications equipment and the CliniMACS Plus Instrument

The CliniMACS Plus Instrument is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user 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 – as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
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 metres (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.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table A.5: Recommended separation distances between portable and mobile RF communications equipment and the instrument (model CS2-CE/UL)

Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment					
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 A.6: Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment (model CS3)

⚠ WARNING

Degradation of the performance of this equipment. Degradation of the performance of this equipment if portable RF communications equipment is used in close proximity to any part of the instrument. 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 CliniMACS Plus Instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration – Electromagnetic immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz			
Test frequency (MHz)	**Modulation**	**Immunity test level (A/m)**	**Compliance level (A/m)**
134.2 kHz	Pulse modulation 2.1 kHz	65	65
13.56 MHz	Pulse modulation 50 kHz	7.5	7.5

Table A.7: Guidance and manufacturer's declaration – Electromagnetic immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz (model CS3)

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