Miltenyi Biotec

CliniMACS® Workbench

User Manual

For U.S. CAUTION:
Clinical Research System. Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval.

Version 4
Original instructions

The CliniMACS Workbench is a MACS GMP Instrument. MACS GMP Instruments are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications. They are intended to be used as manufacturing equipment for cell-based medicinal products. MACS GMP Instruments are manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines.

The availability of the CliniMACS Workbench models may vary depending on your geographic location and on the individual releases of the different models. For more information, contact your local Miltenyi Biotec representative. For Regulatory status in the USA, please contact your local representative. In the USA, 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.

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CliniMACS® Workbench

User Manual

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Essential information

This user manual provides instructions, warnings, precautions, and other important information for the use of the CliniMACS Workbench. Further safety information regarding the operation the CliniMACS Prodigy® System is provided in the CliniMACS Prodigy User Manual (Instrument).

⚠ WARNING

Equipment safety may be compromised. Equipment safety may be compromised if the instrument is not used according to the manufacturer's instructions.

The operation of the CliniMACS Workbench must be performed by professional users only. Before putting the CliniMACS Workbench into operation, the operator must read and understand the safety information, warnings, precautions, and instructions for proper operation of the CliniMACS Workbench provided in this user manual (including, without limitation, the safety information in chapter 3 of this document) and in the CliniMACS Prodigy User Manual (Instrument), and in any safety-related recommendations issued by Miltenyi Biotec. Pay special attention to all warnings displayed on the CliniMACS Prodigy, or provided with CliniMACS Workbench, consumables and accessories. 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.

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 lifecycle of the instrument for all personnel responsible for installation, operation, and maintenance.

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1 Introduction

1.1 General information

The CliniMACS Workbench is a movable workbench specifically designed for the CliniMACS Prodigy and its accessories. The CliniMACS Workbench enables the user to place the CliniMACS Prodigy in a flexible and stable way, with the possibility to establish power, data, alarm, and gas connections via the ceiling of the facility environment. In case of a temporary power interruption, a proper continuation of the processes on the CliniMACS Prodigy is ensured by the integrated uninterruptible power supply. Different models of the CliniMACS Workbench offer the selection between the CliniMACS Workbench for the CliniMACS Prodigy only and the CliniMACS Workbench Large for the CliniMACS Prodigy in combination with the CliniMACS Electroporator.

Model	Catalogue number
CliniMACS Workbench with central supplies, HV-UPS[1]	170-075-711
CliniMACS Workbench with central supplies, LV-UPS[2]	170-075-712
CliniMACS Workbench Large with central supplies, HV-UPS[1]	170-075-713
CliniMACS Workbench Large with central supplies, LV-UPS[2]	170-075-714

1 within the range of 208–240 V
2 within the range of 100–127 V

Table 1.1: Different available CliniMACS Workbench models

1.2 Service information

1.2.1 CliniMACS Workbench information

Record below the model and serial number located on the rear of the instrument. Refer to these numbers when requesting information about the instrument or when requesting instrument service.

Catalogue no. (REF): _____

Serial no. (SN): _____

1.2.2 Technical support

For information about the instrument and its components, contact Miltenyi Biotec Technical Support:

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

+49 2204 8306-3803
technicalsupport@miltenyi.com

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

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 and terms

An overview of symbols and terms used for the CliniMACS Prodigy System is provided in the CliniMACS Prodigy User Manual (Instrument). The glossary of symbols depicts the symbols used for labeling of the CliniMACS Products.

3

Important safety information

⚠ WARNING

Equipment safety will be compromised. If the instrument is not used according to the manufacturer's instructions equipment safety will be compromised. The operation of the instrument must be performed by professional users only. Before putting the instrument into operation, carefully read and understand the safety information, warnings, precautions, and instructions for proper operation of the instrument provided in the instructions for use of the CliniMACS Prodigy System components (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 on the CliniMACS Prodigy and CliniMACS Workbench 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.

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 lifecycle 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 lifetime of the instrument. If the following safety information, warnings, precautions, and instructions are not observed this can cause hazards to users, instrument damage, and/or malfunction, unpredictable results, premature wear and tear, and/or reduced lifetime of the instrument. Observe the following safety information, warnings, precautions, and instructions at all times when using the instrument.

- Always operate, handle, use, and maintain the instrument in accordance with the safety information, warnings, precautions, instructions and recommended procedures provided in the CliniMACS Workbench 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 professional 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 devices, as applicable at the location where the instrument is operated.
- Always use the instrument for its intended purpose only (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, parts, or accessories other than those approved by Miltenyi Biotec, to ensure safe and proper operation of the instrument. **Note:** The use of consumables, parts, or accessories not expressly approved by Miltenyi Biotec could void your 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:** 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 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 this instrument not expressly approved by Miltenyi Biotec could void your 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 lifetime. Failure to comply with the safety information, warnings, precautions, and instructions in the CliniMACS Workbench User Manual (and in other safety related publications issued by Miltenyi Biotec for use with your 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 lifetime, 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 require additional safety information regarding the instrument and its components, contact the authorized local Miltenyi Biotec Service Provider or Miltenyi Biotec Technical Support.

3.1 Safety instructions



In the event of unexpected process abortion or messages on the screen of the CliniMACS Prodigy 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 the instrument using the main switch 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 emissions or decreased electromagnetic immunity. The use of consumables, accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. 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.

⚠ CAUTION

Risk of injury. Installation of the instrument by unauthorized persons can cause personal injury. The installation of the instrument must be performed by an authorized local Miltenyi Biotec Service Provider.

The 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.

3.1.2 Hazards of electric shock and spread of fire



Electrical instruments pose the risk of an electric shock, electrical short, and overheating. Electric shock may lead to severe personal injury or death.

An electrical short and overheating may lead to the spread of fire.

Electronic equipment may emit sparks that could ignite combustible vapors or dusts leading to explosion or spread of fire. If flames or smoke appear, immediately switch off the instrument using the main switch, and contact an authorized Miltenyi Biotec Service Provider or Miltenyi Biotec Technical Support.

⚠ WARNING

Risk of electric shock, electrical short, and spread of fire. Electric shock can 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 open, 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.

The CliniMACS Workbench is a Protection Class I instrument and must be connected to a grounded outlet. Use the instrument only with the specified voltage given in the technical specifications. Do not connect any electrical device with more than 500 W to the accessory power outlet of the instrument.

Each power supply line must be protected with a fuse:

- models with low voltage uninterruptible power supply (LV-UPS): Fuse 16 A
- models with high voltage uninterruptible power supply (HV-UPS): Fuse 10 A

3.1.3 Mechanical hazards

⚠ WARNING



Risk of personal injury. Opening of the lid covering the gas pressure spring might cause injury by the moving tilting joint. Do not open, remove or penetrate any screw or cover of the instrument. Only authorized local Miltenyi Biotec Service Provider may open the cover of the instrument.

⚠ WARNING

Risk of damage or injury. Damage can occur if the central supplies are subjected to excessive load or if the ceiling of the facility cannot support the weight. Do not apply any mechanical load on the central supplies. Only install the central supplies onto the ceiling if it can support at least 3.5 kg.

3.1.4 Gas hazards

⚠ WARNING

Risk of gas emission. Escaping CO_2 and N_2 can be a potential hazard to the user, especially during long-lasting incubation procedures. An automated gas alarm system and monitoring of the gas concentration in the room is required. An appropriate ventilation of the room must be ensured. Connection to the gas supply must be performed according to national and local requirements. Maximum gas concentration in the room may not be exceeded. A CO_2 concentration of more than 4.00 ppm (9,100 mg/m³) and an O_2 concentration of less than 17 vol.-% of the air is presently regarded by some authorities as the threshold at which a hazard may be caused. The safety of the gas supply system is the responsibility of the user. Risk of gas emission or process failure if excessive pressures are applied. Pressures of 1 bar to max 2.5 bar for each gas may be applied. If the gas connections to the CliniMACS Prodigy are removed, gas may emit from the system. Do not remove the gas connections from the CliniMACS Prodigy. In case the gas connections to the CliniMACS Prodigy need to be removed, remove the central supplies (which contains gas valves to prevent gas emissions) from the CliniMACS Workbench first before removing the gas connections to the CliniMACS Prodigy.

3.1.5 Chemical and biological hazards

⚠ WARNING



Risk of 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, the operator must take care to thoroughly decontaminate the instrument.

After running the process and prior to decontamination, the instrument should be treated as a biohazard (see section 4.6 "Cleaning and disinfection" on page 38). Waste disposal must be in accordance with local regulations.

3.1.6 Servicing and transport

⚠ WARNING

Risk of hazard to users, unpredictable results, instrument malfunction or damage, premature wear and reduced lifetime 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 lifetime of the instrument, and may void the warranty. Do not service the instrument. Service and repair may only be performed by authorized local Miltenyi Biotec Service Provider. Routine and preventative maintenance procedures should be conducted by the manufacturer's authorized service personnel at least once a year.

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.

⚠ WARNING

Risk of 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 4.6 on page 38.

3.2 Position of safety symbols

Notice the positions of the safety symbols (see Figure 3.1) on the instrument and keep them in an easily readable state. The safety labels must be kept clean and legible.

Note: Figure 3.1 shows the position of the general warning sign on the upper surface of the instrument. A second general warning sign is placed on the lower side of the table top at the equivalent position.

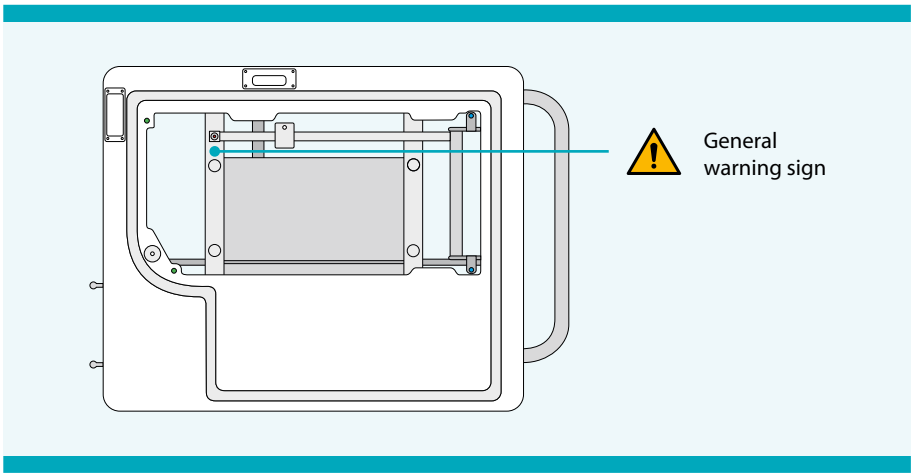


Figure 3.1: Warning sign on the upper surface of the instrument.

4

The CliniMACS Workbench

4.1 Regulatory information

The CliniMACS Prodigy Cell & Gene Therapy Manufacturing System is intended for genetic and/or other substantial manipulation (like transfection, proliferation, differentiation) steps of human cells.

- **CliniMACS Prodigy is no Medical Device in Europe if used as part of the CliniMACS Prodigy Cell & Gene Therapy Manufacturing System**

- **For U.S. CAUTION: Clinical Research System. Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval**

For regulatory status in countries outside Europe and the U.S., contact the authorized local Miltenyi Biotec Service Provider.

4.2 The CliniMACS Workbench within the CliniMACS Prodigy Cell & Gene Therapy Manufacturing System

4.2.1 Intended use

The CliniMACS Workbench is intended as a movable workbench for the CliniMACS Prodigy only, optional in combination with the CliniMACS Electroporator. The CliniMACS Workbench is for *ex vivo* cell processing only. It is intended to be used by professional users in a GMP environment.

The CliniMACS Workbench is intended as equipment in the manufacturing of cell-based medicinal products, e.g., in applications of the CliniMACS Prodigy Cell & Gene Therapy Manufacturing System. The CliniMACS Workbench is not intended to be used within Medical Device applications of the CliniMACS Prodigy Cell Separation System.

Rationale

During applications of the CliniMACS Prodigy Cell & Gene Therapy Manufacturing System, the cells are subjected to modification (genetic and/or substantial manipulation), cell separation, concentration or purification is not considered as substantial manipulation according to Regulation (EC) No. 1394/2007 by pharmacological, immunological or metabolic means as the principal intended action. The resulting cells are therefore considered as Advanced Therapy Medicinal Product (ATMP) in Europe.

As a consequence, the components of this CliniMACS Prodigy Cell & Gene Therapy Manufacturing System cannot be classified as Medical Devices. Instead, the CliniMACS Prodigy Cell & Gene Therapy Manufacturing System is considered as manufacturing system for medicinal products. Therefore, European GMP guidelines (EudraLex Vol. 4) have to be followed when using the CliniMACS Prodigy Cell & Gene Therapy Manufacturing System for manufacture of medicinal products in Europe.

For operating the CliniMACS Prodigy Cell & Gene Therapy Manufacturing System, only the stated products defined in the respective applications must be used with and connected to the CliniMACS Workbench and the CliniMACS Prodigy.

4.2.2 Compliance

The instrument conforms to the following directives:

CE

2014/30/EU (Electromagnetic compatibility)
2011/65/EU Restriction of the use or certain hazardous substances in electrical & electronic equipment (RoHS 2)
2006/42/EC (Machinery).

The instrument complies with the following standards:

- IEC 61010-1
- UL 61010-1
- CAN/CSA-C22.2 No. 61010-1
- IEC 60601-1-2

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

The instrument complies to the following guideline:

- EudraLex Vol. 4

UK CA

United Kingdom Conformity Assessed
Electromagnetic Compatibility Regulations 2016
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
Supply of Machinery (Safety) Regulations 2008

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.

4.3 Technical data

⚠ WARNING

Risk of compromised safety and performance. Safety and performance of the instrument may be compromised if the instrument is used outside its specifications or with other instruments than specified below. Do not use the instrument outside its specifications.

⚠ WARNING

Risk of injury or damage. The installation of the instrument, and mounting of CliniMACS Prodigy on the CliniMACS Workbench must be performed by an authorized local Miltenyi Biotec Service Provider only.

Technical data (general)	
CliniMACS Workbench	
Model	CliniMACS Workbench with central supplies, HV-UPS (REF 170-075-711) CliniMACS Workbench with central supplies, LV-UPS (REF 170-075-712)
Dimensions	Width (table top): 90.5 cm (plus 13.5 cm for hooks and handle) Depth (table top): 74 cm Width (base): 77 cm Depth (base): 68 cm Height (total): 86 cm
Weight	Approx. 125.5 kg including UPS
Max. load	Maximum load 200 kg Suitable for: • CliniMACS Prodigy • Required materials for the process
CliniMACS Workbench Large	
Model	CliniMACS Workbench Large with central supplies, HV-UPS (REF 170-075-713) CliniMACS Workbench Large with central supplies, LV-UPS (REF 170-075-714)
Dimensions	Width (table top): 137.5 cm (plus 13.5 cm for hooks and handle) Depth (table top): 74 cm Width (base): 77 cm Depth (base): 68 cm Height (total): 86 cm
Weight	Approx. 130 kg including UPS
Max. load	Maximum load 200 kg Suitable for: • CliniMACS Prodigy • CliniMACS Prodigy plus CliniMACS Electroporator • Required materials for the process

Technical data (general)	
All models	
Central supplies (included, P/N 220-001-283)	Suitable for all models
Connections to the CliniMACS Prodigy	• Power cable IEC-320-C13 • 3× gas connectors • USB (network connection) • External alarm connection
Storage space	Two storage trays: 1×8,5 L and 1×18 L volume Maximum load: 30 kg
Operation conditions	Temperature: +15 °C to +25 °C (+59 °F to +77 °F) Humidity: 10% to 75% relative humidity, non-condensing Altitude: <2,000 meters above sea level
Storage conditions	Room temperature Avoid condensing conditions.

Table 4.1: Technical data (general) of the CliniMACS Workbench

Technical data (electrical)		
Input voltage	208–240 VAC, 45–65 Hz	100–127 VAC, 45–65 Hz
Uninterruptible power source (UPS)	„Alpha pinnacle plus 3000 – 230 V“, included	„Alpha pinnacle plus 3000 – 120 V“, included
Instrument power via central supplies	All models **Note:** A ceiling socket (“Stäubli CombiTac ceiling socket, wired”, REF 150-001-914) must be installed onto the ceiling of the facility. See section 4.4.5.	All models **Note:** A ceiling socket (“Stäubli CombiTac ceiling socket, wired”, REF 150-001-914) must be installed onto the ceiling of the facility. See section 4.4.5.
Accessory power outlet	IEC appliance outlet Type F suitable for IEC-320-C14 cable Max. 500 W	

Table 4.2: Technical data (electrical) of the CliniMACS Workbench

The instrument complies to the EMC standard IEC 60601-1-2. For details refer to the appendix of this user manual. It is a Protection Class I instrument and must be connected to a grounded power outlet.

The instrument has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. **Note:** The emissions characteristics of this instrument make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this instrument might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the instrument. If this instrument does cause harmful interference to radio or television reception, which can be determined by turning the instrument off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the distance between the instrument and the receiver
- Connect the instrument to an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Changes or modifications of the instrument, unless expressly approved by Miltenyi Biotec, may void the authority to operate the instrument pursuant to FCC 47 CFR.

4.4 Components

The following section describes the components of the instrument. In Figure 4.1 and Figure 4.2 the CliniMACS Workbench models are shown. **Note:** The CliniMACS Workbench Large models have a larger table top to allow the positioning of the CliniMACS Electroporator in addition to the CliniMACS Prodigy. All other components shown in Figure 4.1 and Figure 4.2 are identical for the CliniMACS Workbench and the CliniMACS Workbench Large.

The front-side view is shown in Figure 4.1.

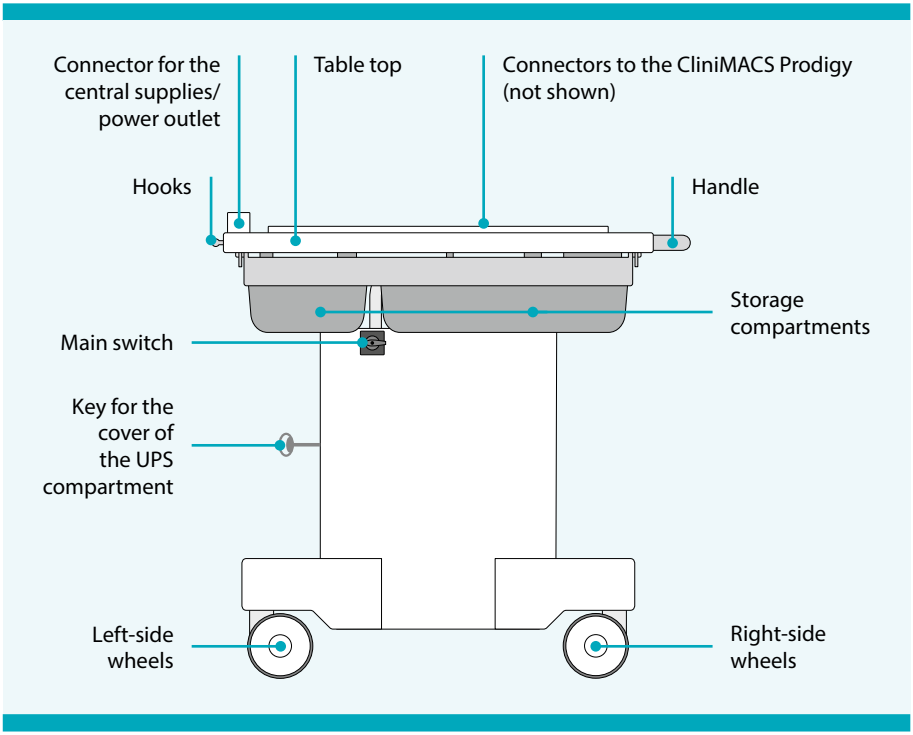


Figure 4.1: Exemplary front-side view

The right-side view is shown in Figure 4.2.

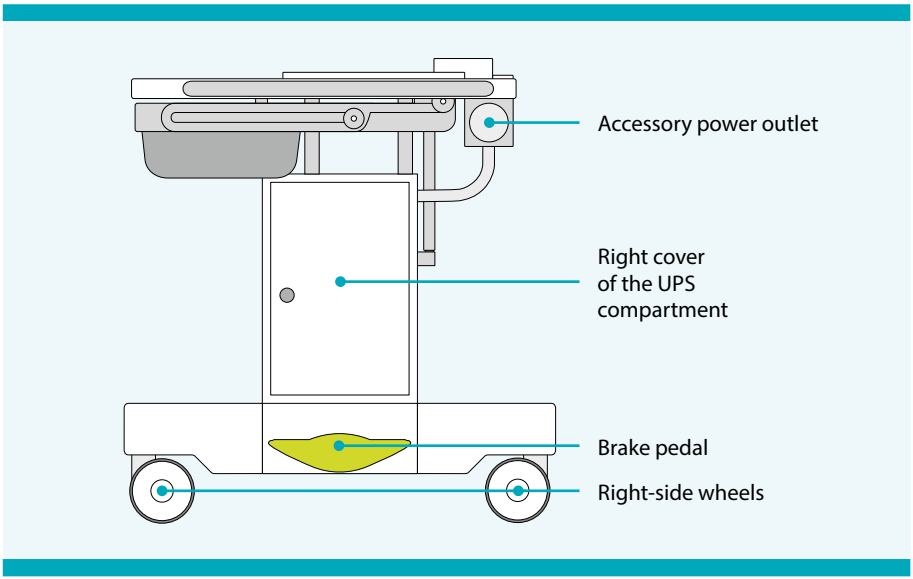


Figure 4.2: Exemplary right-side view

4.4.1 Accessory power outlet

The workbench is equipped with an IEC appliance outlet Type F (see Figure 4.3) to power accessories (e.g., sterile welder) which might be needed during applications. Accessories with max. 500 W must be plugged in into the accessory power outlet using an IEC-320-C13-C14 cable (not included).

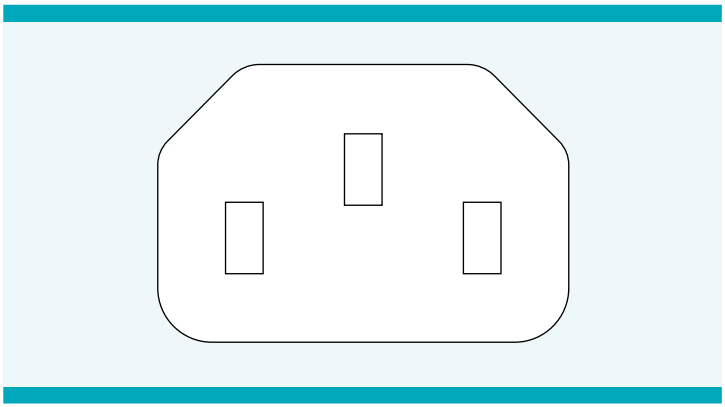


Figure 4.3: Accessory power outlet (IEC appliance outlet Type F)

4.4.2 Main switch

⚠ WARNING

Risk of electric shock, electrical short, and spread of fire. Electric shock can lead to severe personal injury or death. If flames or smoke appear, immediately switch off the instrument using the main switch, and contact an authorized Miltenyi Biotec Service Provider or Miltenyi Biotec Technical Support.

The main switch is positioned on the front side of the instrument (see Figure 4.1). In the event of emergency, turn the main switch to the off (O) position (see Figure 4.4). This will turn off the instrument and cut the power to all connected devices.

Note: Turning the main switch to the off position results in the hard shutdown of the UPS. At this time, turning the main switch to the on (I) position will not turn on the UPS automatically. Open the right cover of the UPS compartment to access the UPS and push the ON/OFF button on the UPS for at least 3 seconds to turn it back on. Contact Miltenyi Biotec Technical Support for assistance.

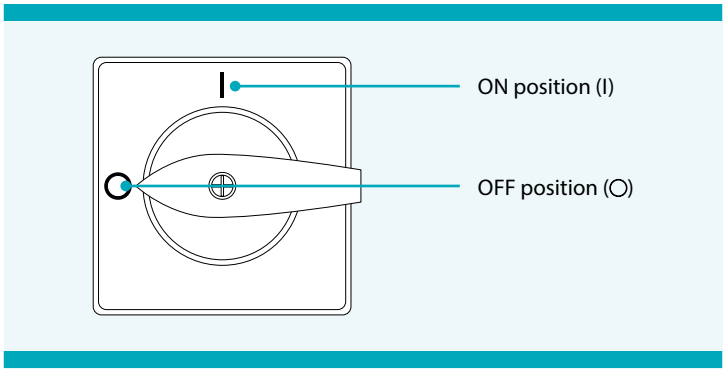


Figure 4.4: Main switch

4.4.3 Brake pedal

The brake pedal is positioned on the right side of the instrument (see Figure 4.2). The different brake pedal positions are important for the handling of the instrument. The pedal can be depressed to the left, positioned horizontally, or depressed to the right side.



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



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



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

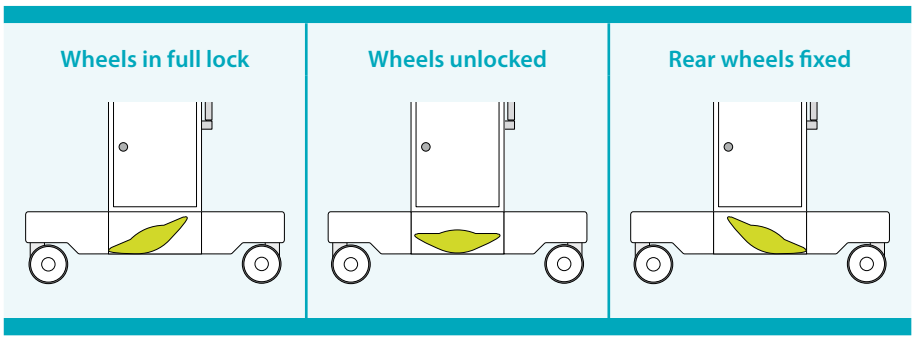


Figure 4.5: Different positions of the brake pedal (front view)

It is the responsibility of the user to evaluate the consequences of moving of the instrument within the context of qualification in a clean room setting. A re-qualification of the CliniMACS Prodigy installed on the CliniMACS Workbench may be necessary if it is moved beyond certain limits, such as:

- Movements within the radius of the connected central supplies, e.g., for cleaning or disinfection purposes
- Movements after disconnecting the central supplies and returning it back to the spot where the instrument has been previously qualified and connecting it to the original central supplies. After the reconnection and locking all wheel brakes the CliniMACS Prodigy must be checked using the instrument check tool.
- In case of a repair situation the instrument may have to be wheeled out of the cleanroom by the Miltenyi Biotec service engineer. After the repair the service engineer will move the instrument back to its original spot and reconnect the instrument to the central supplies. Depending on the issue of the repair the service engineer will then perform an instrument check or a partial requalification of the CliniMACS Prodigy.

Before moving the instrument perform a shutdown of the CliniMACS Prodigy and detach any disposables. The movement of the instrument must only be performed on plane and smooth surfaces to avoid any vibrations. The movement within the cleanroom should be restricted as much as possible. If necessary the instrument may be moved outside the cleanroom provided that the rooms are connected via an even and uninterrupted floor surface.

4.4.4 Hooks

⚠ CAUTION

Risk of process failure. If excessive load is placed on the hooks there is the risk of process failure. The maximum load on each hook is 10 kg.

There are two hooks placed on the left side of the instrument for solution bags related to the process where applicable (see Figure 4.1).

4.4.5 Central supplies

The central supplies assembly contains the cables and lines to connect the instrument to a ceiling socket. In order to connect the instrument to the ceiling of a facility using the central supplies, a ceiling socket with down-pointing connectors must be installed onto the ceiling. It is the responsibility of the user to install the ceiling socket according to the applicable local or national legislation and regulations.

Central supplies include:

- power cable
- external alarm connection
- one ethernet connection (RJ45)
- three gas lines to support the supply of compressed air, CO_2, and N_2

In order to connect the instrument to the ceiling of a facility using the central supplies, a ceiling socket ("Stäubli CombiTac ceiling socket, wired", REF 150-001-914) must be installed onto the ceiling. It is the responsibility of the customer to install the ceiling socket according to the local or national regulations. The ceiling socket is based on a Stäubli CombiTac standard industry connector. For installation details refer to the official Stäubli instruction MA213 as provided with the ceiling connector or at the official webpage from Stäubli. It consists of a power, data, gas, and network module.

Refer to the instructions provided with the ceiling socket. The correct connections between the CliniMACS Prodigy and the ceiling socket are shown and described in Figure 4.6 on page 32.

NOTICE

Risk of damage to the instrument. Damage of the instrument and the UPS can occur if the power connectors are not connected correctly. It is essential that the external and neutral conductors of the supply voltage are connected to the correct pins on the ceiling connector.

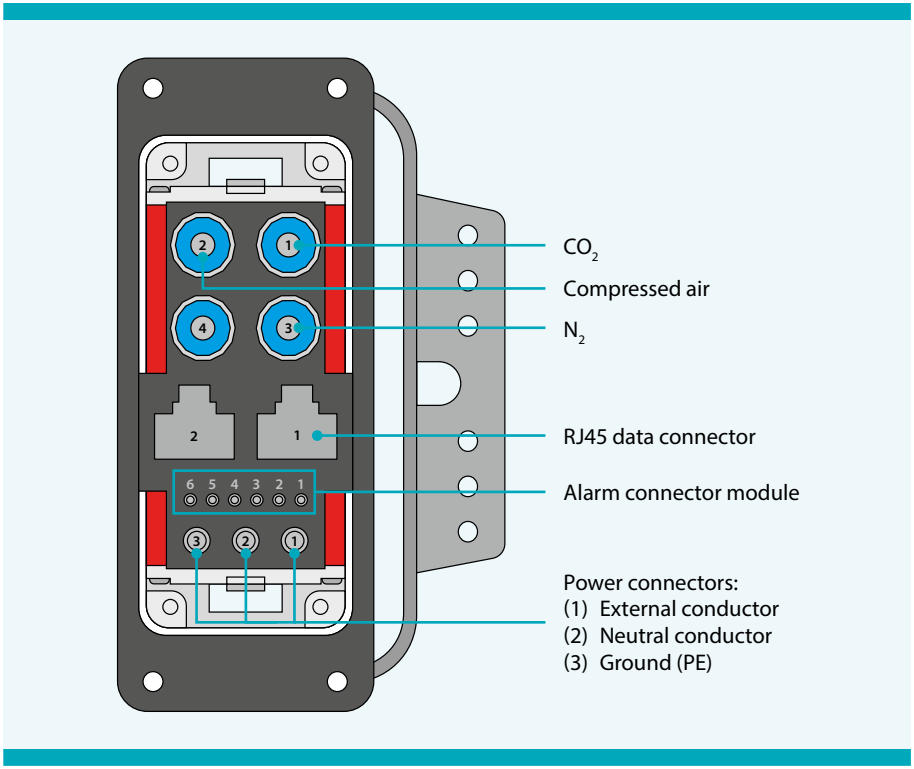


Figure 4.6: Top view (ceiling side) of the ceiling socket

Coloring scheme of the alarm connector cables:

Connector	Cable color
1	Pink
2	White
3	Green
4	Blue
5	Brown
6	Grey

Table 4.3: Alarm connector cables colors

Note: Pin 2 of the alarm connector module of the ceiling socket corresponds to Pin 7 of the alarm connector of the CliniMACS Prodigy (see also the wiring details of the relay circuit in section “Connector panel” within the user manual of the CliniMACS Prodigy).

The cutout dimensions for the ceiling socket.

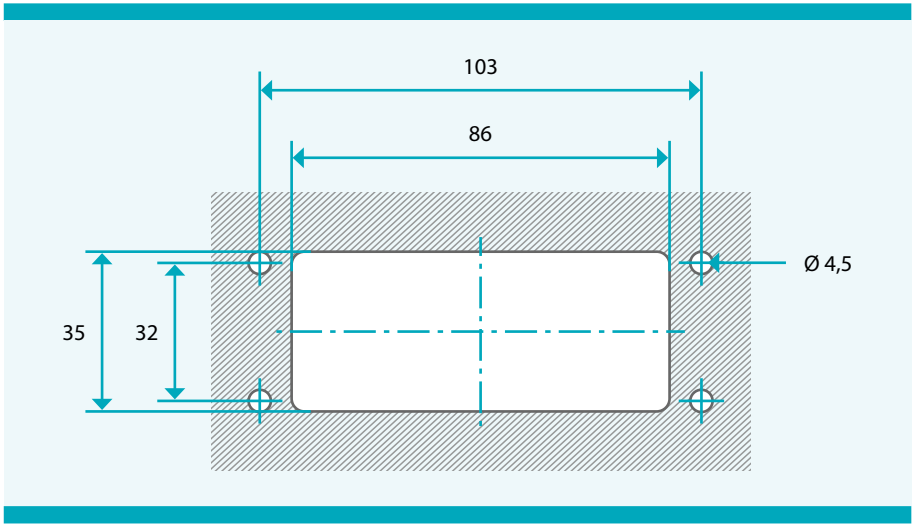


Figure 4.7: Cutout dimensions (mm) for the ceiling socket

4.4.6 Storage compartment

Two storage compartments are available for storing equipment and/or consumables related to the applications (see Figure 4.1 on page 27). The storage volume is 1×8.5 L and 1×18 L, and maximum load is 30 kg.

4.4.7 Uninterruptible power supply (UPS)

One UPS is included with the instrument (see Table 4.2 on page 25). The UPS starts automatically in case of power interruptions or power failure. In case of a power failure, the UPS will ensure a continuity of power (see below) allowing some time to save the processed or partially processed cells and to safely shutdown the CliniMACS Prodigy.

⚠ CAUTION

Limited duration of power supply by the UPS. The UPS can supply power to the CliniMACS Prodigy during its full power consumption for about max. 15 minutes. If the CliniMACS Prodigy is only powered through the UPS, the separation process should not be resumed and the cellular material remaining in the CliniMACS Prodigy Tubing Set should be immediately collected. In this case, contact the Miltenyi Biotec Technical Support.

4.4.8 Connectors to the CliniMACS Prodigy

The CliniMACS Workbench provides power, alarm, network, and gas connections to the CliniMACS Prodigy. The connection between the CliniMACS Workbench and the CliniMACS Prodigy is established by an authorized local Miltenyi Biotec Service Provider during installation of the CliniMACS Workbench.

4.5 Unpacking and installation

⚠ CAUTION

Risk of damage to the instrument. Risk of damage to the instrument if the instrument is installed by unauthorized persons. The installation of the instrument must only be performed by an authorized local Miltenyi Biotec Service Provider. Read the chapter 3 "Important safety information" before installation and use of the instrument. Visually inspect and note any significant damage to the package. Damage may require inspection by a representative of the shipping company. Risk of external damage if the packaging of the instrument is opened with sharp tools. Make sure not to damage any external parts of the instrument (e.g., cables) while using sharp tools. Internal damage can occur if the instrument is subjected to excessive vibration or if it is dropped. The instrument should be unpacked by at least two people.

⚠ CAUTION

Risk of injury. Installation of the instrument by unauthorized persons can cause personal injury. The installation of the instrument must be performed by an authorized local Miltenyi Biotec Service Provider.

4.5.1 Scope of supply

The content of supply is:

- One CliniMACS Workbench
- One central supplies
- One UPS
- User manual

4.5.2 Connection of the central supplies to the ceiling socket

In order to (re)install the central supplies to a ceiling socket, make sure to securely lock the latch of the ceiling socket on the central supplies to fix the connectors (see Figure 4.8).

⚠ WARNING

Risk of injury. If the central supplies is not fixed onto the ceiling socket properly, there is the risk of injury. Make sure to lock the latching mechanism to securely fix the central supplies onto the ceiling socket.

⚠ CAUTION

Risk of damage to the instrument. Damage can occur if the central supplies cable is subjected to excessive load, or if the ceiling of the facility cannot support the weight. Do not apply any mechanical load on the central supplies cable. Only install the central supplies onto the ceiling if it can support at least 3.5 kg.

Figure 4.8 shows the side view of the ceiling socket and the connector of the ceiling socket and the central supplies. Insert the plug (1) of the central supplies and use the latching mechanism (2) to securely fix the connection.

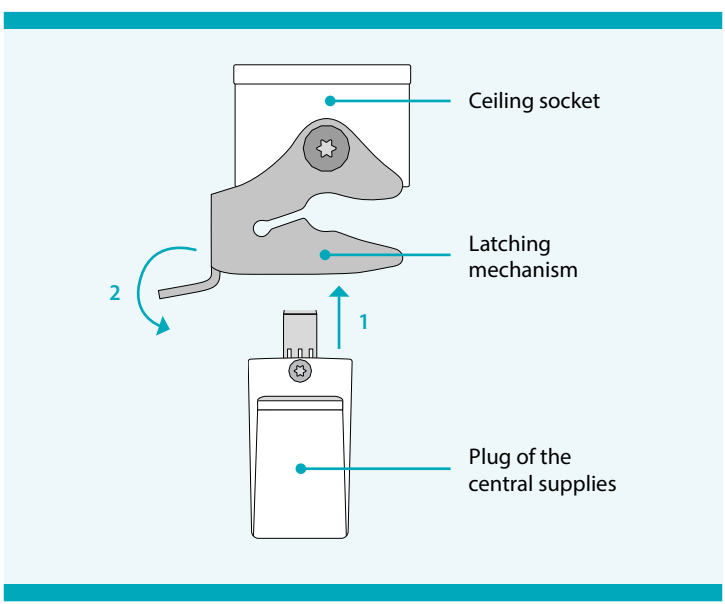


Figure 4.8: Connection of the ceiling socket and the central supplies

4.5.3 Placement of Supplementary Bag

The CliniMACS Prodigy Supplementary Bag and the Supplementary Bag Workbench are intended to reduce the risk of contact with infectious sample material in case of a leakage of a CliniMACS Prodigy Tubing Set.
The CliniMACS Prodigy Supplementary Bag must only be used in combination with the CliniMACS Prodigy. The Supplementary Bag Workbench must only be used in combination with the CliniMACS Prodigy and the CliniMACS Workbench. If a Supplementary Bag contains sample material caused by a leakage the bag must be exchanged by a new one.

CliniMACS Prodigy Supplementary Bag

While using the CliniMACS Prodigy mounted onto the CliniMACS Workbench, the CliniMACS Prodigy Supplementary Bag should be placed within the Supplementary Bag compartment underneath the benchtop of the instrument (see Figure 4.9). The CliniMACS Prodigy Supplementary Bag has to be inserted from the side of the Supplementary Bag compartment as shown in Figure 4.9. For instructions regarding the use of the CliniMACS Prodigy Supplementary Bag, refer to the instructions for use provided with the bag and the corresponding CliniMACS Prodigy User Manuals. Figure 4.9 shows the Supplementary Bag compartment (view shown without the left storage compartment).

Supplementary Bag Workbench

The Supplementary Bag Workbench has a connector on a long tube for connection to the CliniMACS Prodigy and a connector on a short tube for the connection to the CliniMACS Workbench.
Hang the Supplementary Bag Workbench on the hook on the left side of the CliniMACS Workbench (see Figure 4.1)
Connect the Supplementary Bag Workbench by pushing the connector of the longer tubing over the tubing port under the CliniMACS Prodigy and by pushing the connector of the shorter tubing over the tubing port under the CliniMACS Workbench (see Figure 4.9).
Make sure that the tubing ports are fully covered by the tubing connector.
It is recommended to replace the Supplementary Bag no longer than one year after it has been installed not exceeding the use-by date.
Therefore, the installation date has to be written onto the Supplementary Bag label next to the calendar symbol.

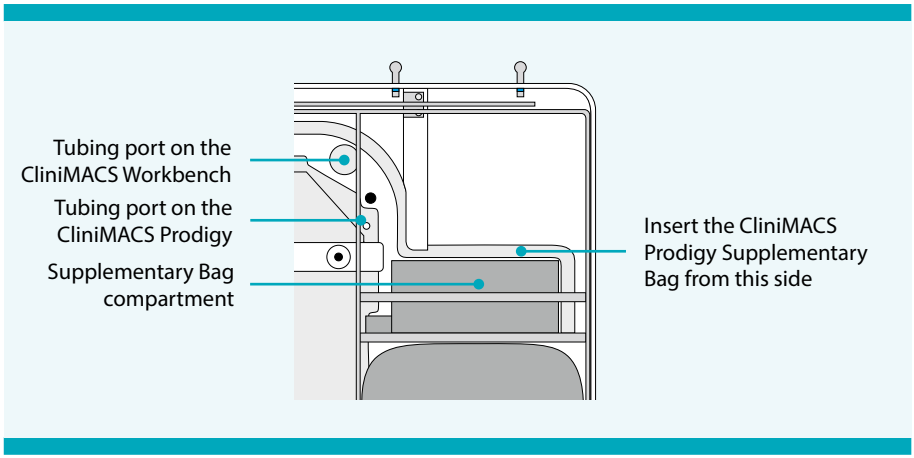


Figure 4.9: Supplementary Bag compartment

4.5.4 Positioning

The CliniMACS Workbench must only be used in combination with the CliniMACS Prodigy and accessories related to the application (see Figure 4.10 and Table 4.1 on page 25 and Table 4.2 on page 25).

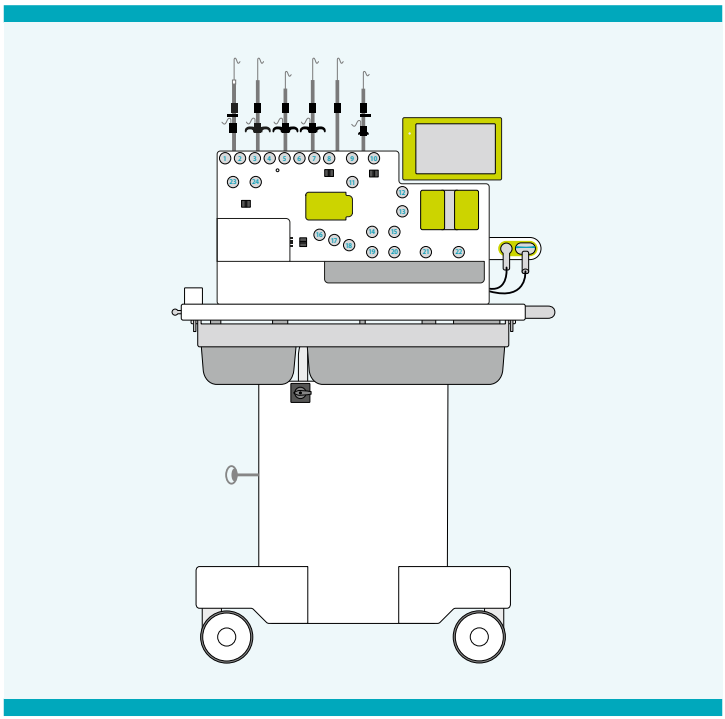


Figure 4.10: CliniMACS Prodigy installed on an exemplary CliniMACS Workbench

4.5.5 Transport

⚠ CAUTION

Risk of internal damage. Internal damage can occur if the instrument is subjected to excessive vibration or if it is dropped. The instrument should be transported with care in a packaging specified by Miltenyi Biotec and carried by at least two people.

⚠ CAUTION

Chemical or biological hazards. 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 questions regarding proper decontamination or shipment, contact Miltenyi Biotec Technical Support for assistance.

4.6 Cleaning and disinfection

Clean the instrument with a damp cloth, or one of the following disinfectants, which are compatible with the surface of the instrument:

- Aldehyde up to 3%, e.g., Kohrsolin® FF 3%
- Ethanol up to 80%

⚠ WARNING

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

IMPORTANT

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

4.7 Maintenance

4.7.1 Servicing

⚠ WARNING

Hazard to users, unpredictable results, instrument malfunction or damage, premature wear and reduced lifetime 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 lifetime of the instrument, and may void the warranty. Do not service the instrument. Service and repair may only be performed by authorized local Miltenyi Biotec Service Provider. Routine and preventative maintenance procedures should be conducted by the manufacturer's authorized service personnel at least once a year.

Contact the authorized local Miltenyi Biotec Service Provider for Miltenyi Biotec's Instrument service and support arrangements.

4.8 Disposal



Contact Miltenyi Biotec Technical Support for final disposal. The instrument must be separately collected according to the European directive of waste of electrical and electronic equipment (WEEE). For final disposal, the instrument must be returned to the manufacturer.

⚠ WARNING

Biological hazard. If the instrument is transported without prior disinfection there is the risk of infection. Clean and disinfect the instrument according to the instructions given in section 4.6.

The instrument should be transported with care in packaging specified by Miltenyi Biotec.

For UK: 2013 No. 3113 - ENVIRONMENTAL PROTECTION The Waste Electrical and Electronic Equipment Regulations 2013 applies.

5

The CliniMACS Workbench within the CliniMACS Prodigy Cell & Gene Therapy Manufacturing System

5.1 System components

The different applications running on the CliniMACS Prodigy require the use of specific CliniMACS Materials as well as additional materials and equipment as described in the CliniMACS Prodigy User Manual for the respective application.

IMPORTANT

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

5.2 Additional materials and equipment

Additional materials, e.g., MACS® GMP Products, and equipment required for the different applications are described in the CliniMACS Prodigy User Manual of the respective application.

IMPORTANT

The procedures may require the use of components which are not part of the CliniMACS Prodigy System. Therefore either materials of pharmaceutical grade must be used or the user has to evaluate all risks arising from these materials. In addition, no inflammable or explosive materials should be used, or solutions that will lead to a hazardous chemical reaction that could represent a potential risk for the user.

5.3 Limitation

Miltenyi Biotec as the manufacturer of the CliniMACS 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.

5.4 Warnings and precautions regarding the process

⚠ WARNING

Risk of process failure or damage to the instrument. Non-professional users can cause process failure or damage to the instrument. All processing procedures must be performed by professional users only.

For further information, refer to the corresponding CliniMACS Prodigy User Manual (Instrument) and the CliniMACS Prodigy User Manual for the respective application.

6 Troubleshooting

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

+49 2204 8306-3803
technicalsupport@miltenyi.com

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

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 local Miltenyi Biotec Service Provider), 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, CliniMACS Prodigy, 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.

7.3 EU/EC Declaration of conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer:

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

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The declaration of conformity refers to the machinery identified as follows:

Description: Laboratory equipment
Model: CliniMACS Workbench with central supplies, HV-UPS,
CliniMACS Workbench Large with central supplies, HV-UPS

The machinery complies with all essential requirements of the following directives:

2006/42/EC Machinery
2011/65/EU Restriction of the use of certain hazardous substances in electrical & electronic equipment
2014/30/EU Electromagnetic compatibility

The machinery is in conformity with the following harmonized standards:

EN 61010-1:2010
EN 60601-1-2:2015

Person authorized to compile the relevant technical documentation:

Dr. Bernd Schröder
Global Head Regulatory Affairs
Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Str. 68
51429 Bergisch Gladbach
Germany

7.4 UK Declaration of conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer:

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

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The declaration of conformity refers to the machinery identified as follows:

Description: Laboratory equipment
Model: CliniMACS Workbench with central supplies, HV-UPS,
CliniMACS Workbench Large with central supplies, HV-UPS

The machinery complies with all essential requirements of the following legislations:

Supply of Machinery (Safety) Regulations 2008
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
Electromagnetic Compatibility Regulations 2016

The machinery is in conformity with the following UK designated standards:

EN 61010-1:2010
EN 60601-1-2:2015

Person authorized to compile the relevant technical documentation:

Dr. Bernd Schröder
Global Head Regulatory Affairs
Miltenyi Biotec B.V. & Co. KG
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APPENDIX

Guidance and manufacturer's declaration on electromagnetic compatibility

⚠ WARNING

Risk of improper operation due to increased electromagnetic emissions or decreased electromagnetic immunity. The use of consumables, accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. If the provided connecting cables are missing, contact Miltenyi Biotec Technical Support.

EMC compliance with IEC 60601-1-2:2014 (Edition 4) has been attested for the instrument.

Guidance and manufacturer's declaration – Electromagnetic emissions	
The equipment 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**
Conducted RF Emission CISPR 11	Group 1, Class A
Radiated RF Emission CISPR 11	Group 1, Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies with maximum ratings

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

EMC compliance with IEC 62040-2:2016 has been attested for the provided uninterruptible power supply (classification VFI-SS-111).

Guidance and manufacturer's declaration – Electromagnetic immunity		
The 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 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±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 @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T during 1 cycle and 70% U_T during 25/30 cycles (single phase) @ 0° 0% U_T during 250/300 cycle	0% U_T during 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T during 1 cycle and 70% U_T during 25/30 cycles (single phase) @ 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 @ 1 kHz	3 V (0.15 MHz to 80 MHz) 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM @ 1 kHz
Radiated RF EM fields IEC 61000-4-3	3 V/m (80 MHz–2.7 GHz) 80% AM @ 1 kHz	3 V/m (80 MHz–2.7 GHz) 80% AM @ 1 kHz
Proximity fields from RF wireless communication equipment IEC 61000-4-3	See table below: Specifications for immunity to RF wireless communication equipment	See table below: Specifications for immunity to RF wireless communication equipment

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

Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment							
Test Frequency (MHz	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**	**Compliance Level (V/m)**
385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
450	430–470	GMR S460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745 780	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
810 870 930	800–960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
1720 1845 1970	1700–1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band	Pulse modulation 217 Hz	2	0.30	28	28
5240 5500 5785	5100–5800	WLAN 800.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9

Table A.3: Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment

⚠ WARNING

Degradation of the performance of this instrument 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 to any part of the instrument, including cables specified by the manufacturer.

For the CliniMACS Prodigy System components including the CliniMACS Prodigy and the CliniMACS Workbench, special care needs to be taken for sensitive parts equipped with sensors, data interfaces or camera systems (e.g., CentriCult Unit, peristaltic pump, liquid sensors, or monitor with touchscreen (refer to the corresponding CliniMACS Prodigy User Manual)). Placing wireless devices such as RFID/NFC reader, smartphone, tablet or Bluetooth music player in close proximity to the instrument could manipulate the functional range of high-precision components and could lead to malfunction.

For the reliable functionality of the UPS located inside the CliniMACS Workbench, always keep the doors to the UPS compartment closed during use.



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