Miltenyi Biotec

CliniMACS® Formulation Unit

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 7
Original instructions

The CliniMACS Formulation Unit 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 Products are designed, manufactured and tested under an ISO 13485 quality management system and are in compliance with relevant GMP guidelines.

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.

Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use.

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CliniMACS® Formulation Unit

User manual

Issued: 2025-08

38031/07

CE

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Essential information

This user manual provides instructions, warnings, precautions, and other important information for the use of the CliniMACS Formulation Unit. For information on specific applications related to the CliniMACS Formulation Unit, refer to the user manual issued for the respective application. Further safety information regarding the operation of the CliniMACS Formulation Unit in connection with 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 Formulation Unit must be performed by professional users only. Before putting the CliniMACS Formulation Unit into operation, the operator must read and understand the safety information, warnings, precautions, and instructions for proper operation of the CliniMACS Formulation Unit provided in this user manual (including, without limitation, the safety information in chapter 3 ´Important safety information´ 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 Formulation Unit, 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 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 System offers a set of tools that enables high-quality standardized cell processing for different applications. The CliniMACS System is based on the high-quality standardized cell processing and the magnetic cell separation technology (MACS® Technology) developed by Miltenyi Biotec.

The CliniMACS Formulation Unit is an instrument accessory for the final formulation and sampling of eukaryotic cells in combination with the CliniMACS Prodigy. The CliniMACS Formulation Unit enables the user to take cell samples during or after processing by the CliniMACS Prodigy.

The CliniMACS Formulation Unit is intended to be used in combination with the following components only: CliniMACS Prodigy, CliniMACS Reagents, CliniMACS Prodigy Tubing Sets, and the CliniMACS PBS/EDTA Buffer.

The different applications related with the CliniMACS Formulation Unit require the use of specific CliniMACS Materials as well as additional materials and equipment as described in this manual and in the CliniMACS Prodigy user manual issued for the respective application (see also section 5.1 ´CliniMACS® Prodigy Cell & Gene Therapy Manufacturing System components´).

1.1.1 CliniMACS Formulation Unit Information

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

Catalogue no. (REF): _____

Serial no. (SN): _____

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 CliniMACS Formulation Unit is not used according to the manufacturer's instructions. 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 Formulation Unit 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 Formulation Unit 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 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. Observe the following safety information, warnings, precautions, and instructions at all times when using the instrument.

- Always operate, handle, use, and maintain the CliniMACS Formulation Unit in accordance with the safety information, warnings, precautions, instructions and recommended procedures provided in the CliniMACS Formulation Unit user manuals and other written instructions issued by Miltenyi Biotec. Do not deviate from these operating instructions and procedures.
- Always ensure that the CliniMACS Formulation Unit 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 CliniMACS Formulation Unit 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 CliniMACS Formulation Unit is operated.
- Always use the CliniMACS Formulation Unit 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 CliniMACS Formulation Unit 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 your 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 CliniMACS Formulation Unit 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 CliniMACS Formulation Unit 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 life time. Failure to comply with the safety information, warnings, precautions, and instructions in the CliniMACS Formulation Unit 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 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 CliniMACS Formulation Unit or require additional safety information regarding the CliniMACS Formulation Unit and its components, contact the authorized local Miltenyi Biotec Service Provider or Miltenyi Biotec Technical support.

3.1 Safety instructions for the CliniMACS Formulation Unit



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 CliniMACS Prodigy and disconnect the power cord of the CliniMACS Prodigy 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 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 optical and acoustical alarm signals can be recognized by the operator at any time during the process.

⚠ CAUTION

Risk of injury. If installed improperly without consulting this user manual, the CliniMACS Formulation Unit may lead to injury. The installation of the CliniMACS Formulation Unit must be performed as described in section 4.5 ´Unpacking and installation´ of this user manual. The Formulation Unit must be installed on a CliniMACS Prodigy which is placed evenly on a flat and stable surface, which is capable of supporting at least 120 kg and free of vibrational or other mechanical forces.

The CliniMACS Formulation Unit 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.

NOTICE

Risk of damage to the tubing set. The tubing set can be damaged if the tubing is stretched by the bags hanging over the edge of the table. Leave sufficient space (approx. 15 cm) for bags for tubing set installation in front of the CliniMACS Formulation Unit.

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.

The CliniMACS Formulation Unit is a Protection Class I device and may only be connected to the CliniMACS Prodigy. The CliniMACS Prodigy itself may only be plugged into an outlet with a grounded connection.

Electronic equipment may emit sparks that could ignite combustible vapors or dusts leading to explosion or spread of fire.

⚠ 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.

⚠ 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 or while switched on. Before cleaning or disinfection of the CliniMACS Formulation Unit, disconnect the instrument from the power supply. Unplug the mains plug of the CliniMACS Prodigy to disconnect the CliniMACS Formulation Unit 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 Miltenyi Biotec service provider or Miltenyi Biotec Technical Support.

⚠ WARNING

Risk of electric shock or spread of fire. The instrument is intended for indoor use only. Water ingress may lead to an electrical short circuit 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 up 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 CliniMACS Formulation Unit. 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.

⚠ CAUTION

Risk of overheating. Ambient air temperature may not be adequate to cool the instrument to acceptable operating temperatures without adequate circulation. Confirm the room in which you operate the instrument 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 CliniMACS Prodigy as described in the CliniMACS Prodigy user manual (instrument). Prevent direct exposure of the instrument to sunlight. 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 positioning instructions for the instrument have been followed.

Confirm the power CAN connector to the CliniMACS Prodigy is 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 power cord of the CliniMACS Prodigy from the power outlet.

3.1.3 Mechanical hazards

⚠ CAUTION



Risk of internal damage. Movement or vibration may affect the instrument. Do not place the instrument next to equipment that vibrates or can cause the instrument to move. Do not lean on the CliniMACS Formulation Unit.

3.1.4 Chemical and 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, the operator must take care to thoroughly decontaminate the instrument.

After running the process and prior to decontamination, the CliniMACS Formulation Unit should be treated as a biohazard (see section 4.6 ´Cleaning and disinfection´). Waste disposal must be in accordance with local regulations.

3.1.5 Servicing and transport

⚠ WARNING

Hazards 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. Unless otherwise specifically noted in this user manual, do not service the CliniMACS Formulation Unit. 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.

⚠ 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 3.1.4 ´Chemical and biological hazards´.

⚠ CAUTION

Risk of internal damage. Internal damage can occur if the instrument is subjected to excessive vibration or is dropped. If transportation of the CliniMACS Formulation Unit is required, contact the authorized local Miltenyi Biotec Service Provider or Miltenyi Biotec Technical Support.

4

The CliniMACS Formulation Unit

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, contact the authorized local Miltenyi Biotec Service Provider.

4.1.1 Intended use

The CliniMACS Formulation Unit is an equipment intended to enable the *in vitro* final formulation and sampling of cell populations for clinical applications in combination with the CliniMACS Prodigy only.

The CliniMACS Formulation Unit is for *ex vivo* cell processing only, and is not intended for human *in vivo* applications. It is intended to be used by professional users in a GMP environment.

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

4.1.2 Rationale

During applications of *in vitro* cell culture processing, 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 cannot be classified as Medical Devices. Instead, the CliniMACS Formulation Unit is considered as manufacturing equipment for cell-based medicinal products. Therefore, European GMP guidelines (EudraLex Vol. 4) have to be followed when using the CliniMACS Formulation Unit for manufacture of cell-based medicinal products in Europe.

For operating the CliniMACS Formulation Unit, only the stated products defined in the respective applications must be used with and connected to the CliniMACS Prodigy.

4.2 Compliance

The CliniMACS Formulation Unit conforms to the following directives:

CE

2014/30/EU (Electromagnetic compatibility)
2011/65/EU Restriction of the use of 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

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

Before connecting the instrument to the CliniMACS Prodigy, the configuration of the CliniMACS Prodigy must be checked and adjusted if necessary. Contact authorized local Miltenyi Biotec Service Provider or Miltenyi Biotec Technical Support for installation of the instrument.

Technical data (electrical)	
Model	CliniMACS Formulation Unit
Dimensions	Width: 62.4 cm housing Depth: 9 cm housing (without mounting guide) Height: 8.5 cm housing (without valves)
Weight	Approx. 9 kg (excluding the weight of attached consumables)
Emission sound pressure level	<79 dB(A)
Input voltage	24 V DC 5.5 A max (supply by CliniMACS Prodigy)
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.
Positioning	Installed on the bag compartment of the CliniMACS Prodigy CliniMACS Formulation Unit and CliniMACS Prodigy must have a distance of at least 14 cm to walls and other obstacles.

Table 4.1: Technical data (electrical) of the CliniMACS Formulation Unit

The CliniMACS Formulation Unit including accessories 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 the CliniMACS Prodigy which must be plugged into a grounded power outlet.

Conditions of operation: 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 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 of the CliniMACS Formulation Unit

The following section describes the components of the CliniMACS Formulation Unit.

The key components of the CliniMACS Formulation Unit are the 13 pinch valves, the liquid sensor, the mounting guide, the power cable, and the locking clasp (see Figure 4.1 and Figure 4.2).

The top view of the instrument is shown in Figure 4.1.

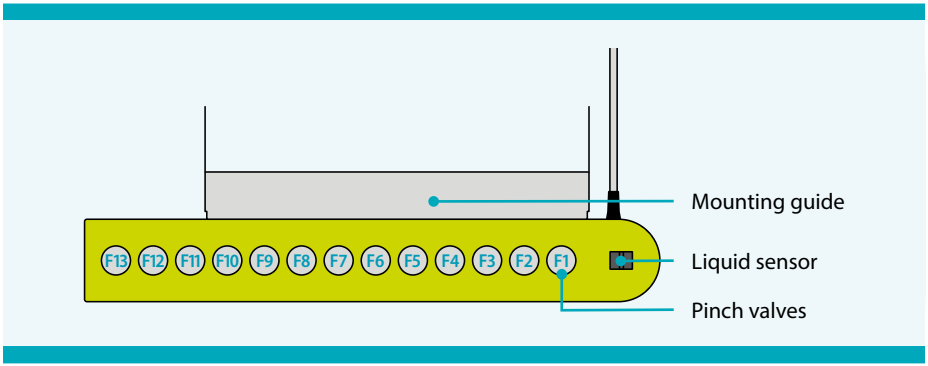


Figure 4.1: Top view of the CliniMACS Formulation Unit

The right-side view of the instrument is shown in Figure 4.2.

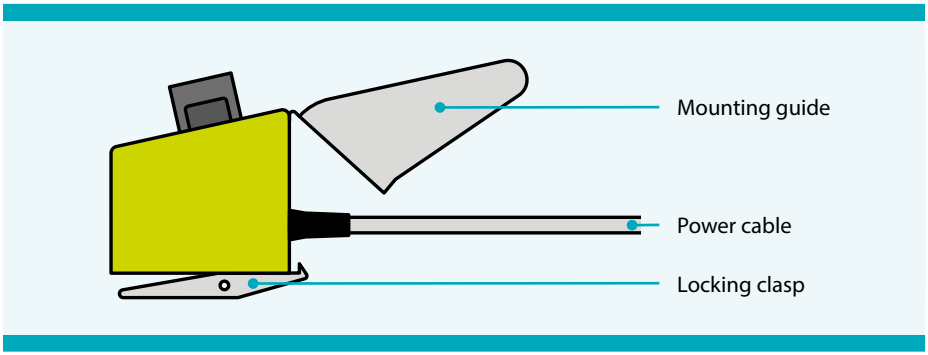


Figure 4.2: Right-side view of the CliniMACS Formulation Unit

4.4.1 Pinch valves

In total, 13 magnetic pinch valves (see Figure 4.1) can be used during operation to ensure controlled flow pathways within the tubing set. Additionally, the valves fix the tubing on the front plate of the instrument.

4.4.2 Liquid sensor

One liquid sensor at the front of the instrument (see Figure 4.1) monitors the flow of liquid within the tubing set based on an ultrasonic principle which allows detection of air bubbles within certain parts of the mounted tubing set. Specific process steps are designed so that disruption of the continuous fluid flow through this sensor automatically advances the process to the next phase.

4.4.3 Mounting guide and locking clasp

The mounting guide and locking clasp (see Figure 4.2) are used to mount and secure the CliniMACS Formulation Unit onto the CliniMACS Prodigy. The mounting guide helps the insertion and mounting of the CliniMACS Formulation Unit onto the bag compartment on the CliniMACS Prodigy. The locking clasp locks the CliniMACS Formulation Unit on the bottom side of the CliniMACS Prodigy.

4.5 Unpacking and installation

⚠ CAUTION

Unpacking and installation of the CliniMACS Formulation Unit must only be performed by a professional user. 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.

4.5.1 Scope of supply

The content of supply is:

- one CliniMACS Formulation Unit
- one CliniMACS Formulation Unit user manual
- two rubber pads

4.5.2 Unpacking

1. Open the top carton by cutting the adhesive tape.
2. Open the carton and remove any loose content (for example, the CliniMACS Formulation Unit user manual).
3. Lift the CliniMACS Formulation Unit together with the protective foam.
4. Remove the protective foam and unwrap the shipping bag around the CliniMACS Formulation Unit.

4.5.3 Installation

1. Attach the two rubber pads provided onto the bag compartment of the CliniMACS Prodigy as shown in Figure 4.3 and insert the bag compartment back into the CliniMACS Prodigy.

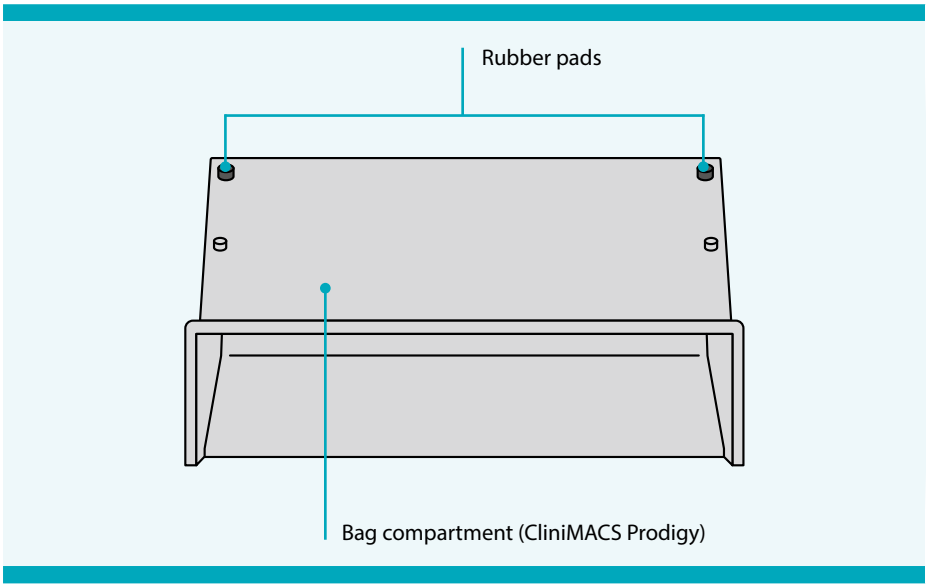


Figure 4.3: Placement of the rubber pads on the bag compartment of the CliniMACS Prodigy (top view)

2. Hold the CliniMACS Formulation Unit with the mounting guide facing the CliniMACS Prodigy.
3. Tilt the Formulation unit as shown in Figure 4.4 and insert the mounting guide into the bag compartment of the CliniMACS Prodigy.

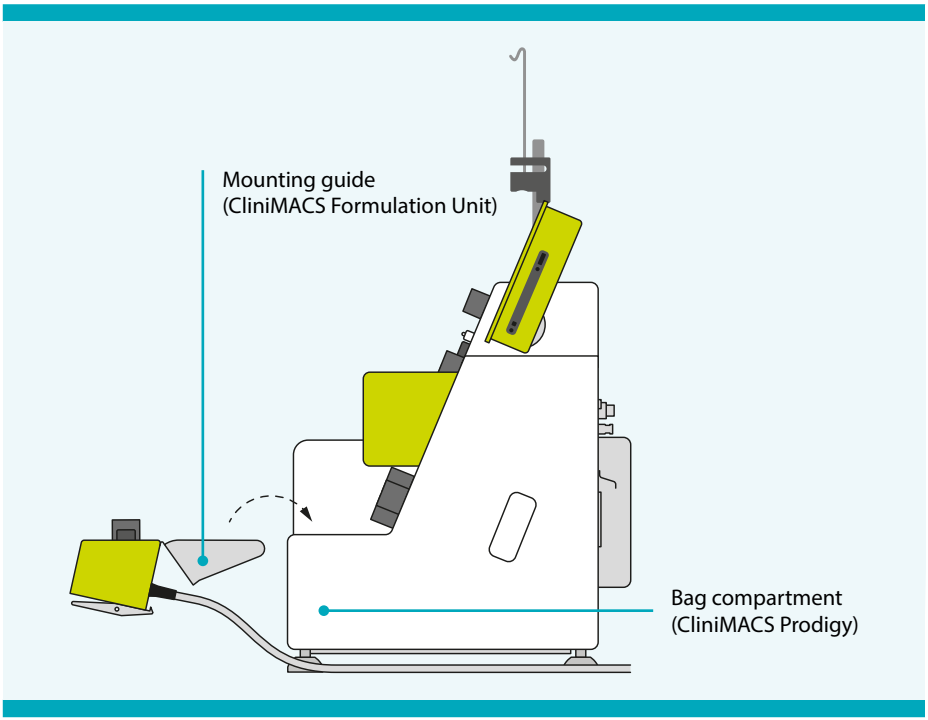


Figure 4.4: Tilting the CliniMACS Formulation Unit for installation (right-side view)

4. Open the locking clasp (see Figure 4.5) by pushing on the front side of the trigger, slide it towards the CliniMACS Prodigy and lock it by releasing the trigger. Make sure the back side of the clasp is securely placed on the bottom of the CliniMACS Prodigy (see Figure 4.5).

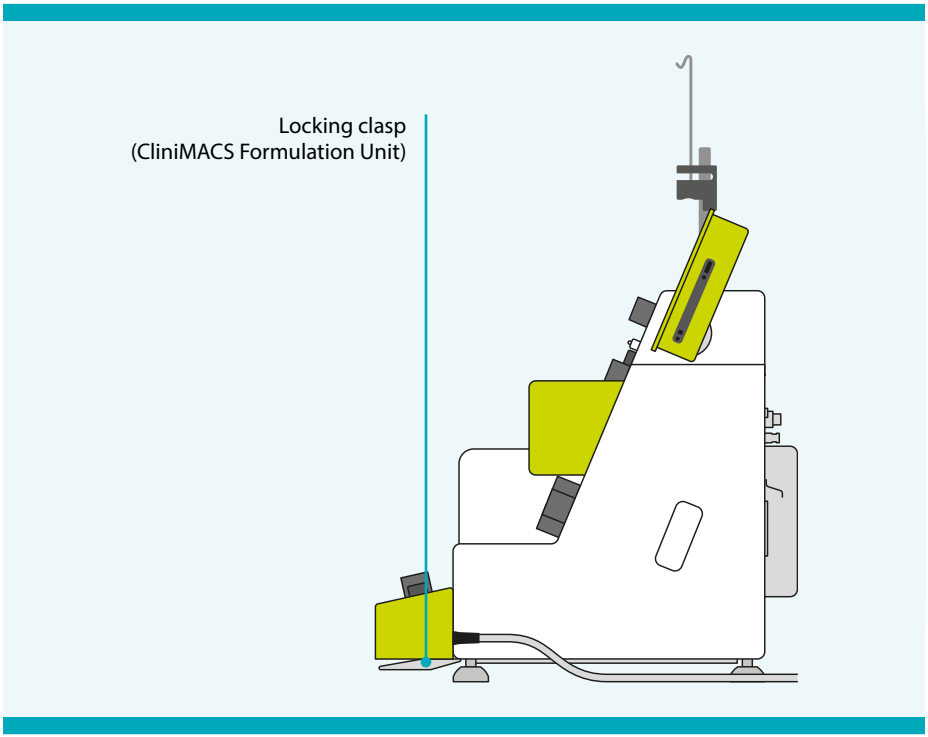


Figure 4.5: Right-side view of the CliniMACS Formulation Unit installed on the CliniMACS Prodigy

5. Make sure that the CliniMACS Prodigy is switched off before connecting the CliniMACS Formulation Unit. Plug the Power-CAN plug of the CliniMACS Formulation Unit into the "Power-CAN" connector located on the Connector Panel of the CliniMACS Prodigy (see Figure 4.6). Refer to CliniMACS Prodigy user manual (instrument) for more information on the Power-CAN connector. Carefully connect the plug to the socket to avoid damaging the connector pins. The connector fits only in one position. Check the orientation if the plug does not slide in smoothly.

6. After mounting and plugging the CliniMACS Formulation Unit, switch on the CliniMACS Prodigy. The operator can survey the valves and the liquid sensor of the CliniMACS Formulation Unit using the test tools provided in the CliniMACS Prodigy (software version higher than 1.4.19) and document the installation and operation of the instrument if necessary. Contact Miltenyi Biotec Technical Support to request the test documentation.

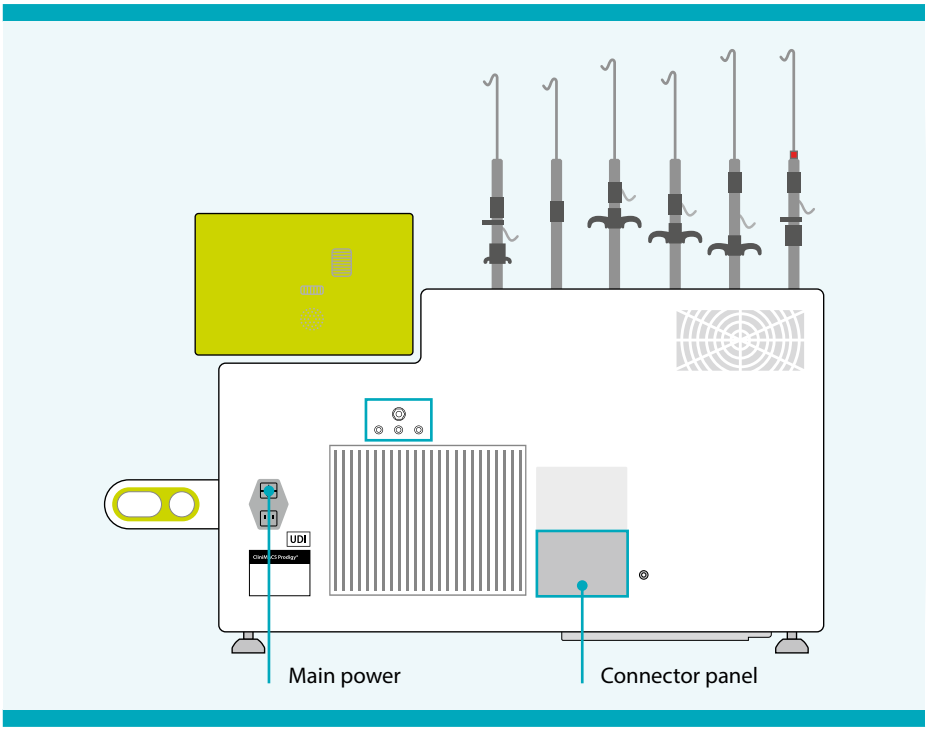


Figure 4.6: Location of the connector panel on the rear side of the CliniMACS Prodigy for connecting the CliniMACS Formulation Unit

4.5.4 Positioning

The CliniMACS Formulation Unit must only be installed on the Bag compartment of the CliniMACS Prodigy (see Figure 4.7). Do not install the CliniMACS Formulation Unit on any other location.

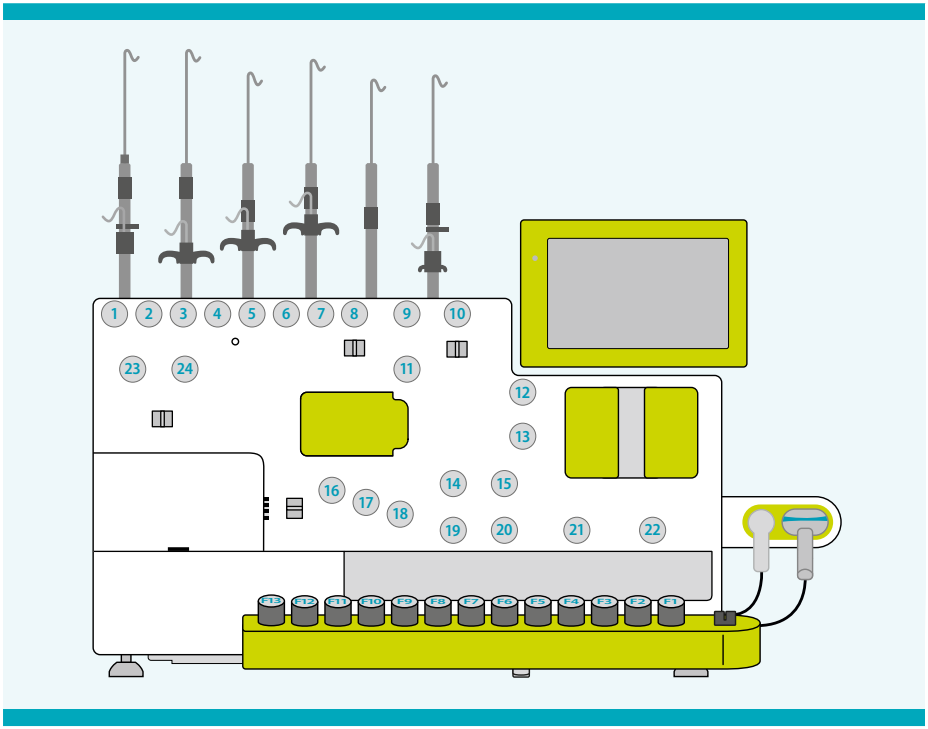


Figure 4.7: CliniMACS Formulation Unit located on the Bag compartment of the CliniMACS Prodigy (front view)

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 CliniMACS Formulation Unit should be transported with care in packaging specified by Miltenyi Biotec.

⚠ CAUTION

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

4.6 Cleaning and disinfection

⚠ WARNING

Risk of electric shock or damage to the instrument if the instrument is cleaned with excessive amount of cleaning or while switched on. Only clean the CliniMACS Formulation Unit when the CliniMACS Prodigy is switched off and the power cord of the CliniMACS Prodigy is unplugged. Avoid ingress of any liquid into the pinch valves.

Clean the instrument with one of the following disinfectants, which are compatible with the surface of the instrument:

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

⚠ WARNING

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.

Dust off the valves using a paper towel.

IMPORTANT

The surface of the CliniMACS Formulation Unit should be cleaned at regular intervals and after each application. Cleaning after unpacking before 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.

The instrument does not require any form of calibration. Contact the authorized local Miltenyi Biotec Service Provider for Miltenyi Biotec Instrument Service and support arrangements.

4.7.2 Instrument disposal



Contact Miltenyi Biotec Technical Support for final disposal. The CliniMACS Formulation Unit 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 ´Cleaning and disinfection´.

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

In the UK, 2013 No. 3113 – ENVIRONMENTAL PROTECTION The Waste Electrical and Electronic Equipment Regulations 2013 applies.

5

CliniMACS Prodigy Cell & Gene Therapy Manufacturing System

5.1 CliniMACS® Prodigy Cell & Gene Therapy Manufacturing System components

The different applications running on the CliniMACS Formulation Unit 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. The CliniMACS Prodigy System is described in the CliniMACS Prodigy user manual (instrument).

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

For further information refer to the CliniMACS Prodigy user manual (instrument).

6 Troubleshooting

In any case of instrument malfunction or process failure, contact the Miltenyi Biotec Technical Support 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 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, CliniMACS Prodigy, MACS, and the Miltenyi Biotec logo are registered trademarks or trademarks of Miltenyi Biotec 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-Straße 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 Formulation Unit

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-Straße 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-Straße 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 Formulation Unit

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
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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.

EMC compliance with IEC 60601-1-2:2014/AMD1:2020 (Edition 4.1) has been attested for the CliniMACS Formulation Unit and the provided components (see Table A.1).

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 (d_max = 4%)

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

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

Guidance and manufacturer's declaration – Electromagnetic immunity

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

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	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	1700–1900	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.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 (12 inches) to any part of the instrument, including cables specified by the manufacturer.

Guidance and manufacturer's declaration – Electromagnetic immunity to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

Test Frequency	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.4: Guidance and manufacturer's declaration – Electromagnetic immunity to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

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38031/07 | Issued: 2025-08