



Miltenyi Biotec

MACSima™ Imaging System

User manual



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MACSima™ Imaging System

User manual

Original instructions

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Read the chapter **Important safety information** and all other information in this user manual before using the instrument

WARNING

Before using the MACSima Imaging System, read the chapter **Important safety information** and all other information contained in this user manual, including any safety and operating instructions. Pay special attention to all warnings displayed on the instrument. Failure to read and follow these guidelines could lead to improper or incorrect usage and result in damage to the instrument. Improper usage could also cause severe personal injury, death, unpredictable results, instrument malfunction, and premature wear to components shortening the lifetime of the instrument. Such actions may void your warranty. Keep the user manual and any other safety and operating instructions provided with the instrument in a safe place accessible to all users for future reference.

If you have a serious concern regarding the safe use of your instrument, contact your authorized Miltenyi Biotec service provider or call Miltenyi Biotec Technical Support.

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1

Important safety information

General safety instructions



THIS CHAPTER DESCRIBES POTENTIALLY HAZARDOUS SITUATIONS ASSOCIATED WITH THIS INSTRUMENT AND PROVIDES IMPORTANT SAFETY INFORMATION TO MINIMIZE THE RISKS AND PROTECT YOURSELF AND OTHERS.

This chapter provides important information for your personal safety and the correct use of the instrument. Read and observe all instructions carefully before proceeding with the installation and use of the instrument. Observe general safety practices in addition to this user manual.

- Use this instrument only as indicated in this user manual to avoid personal injury and property damage.
- Keep this user manual in a place that is always accessible to all users.
- Observe local working area safety instructions and laboratory policies, as well as standards for health, safety, and prevention of accidents.
- Ensure safe working conditions and provide sufficient lighting.
- Ensure that the power switch and the plug of the power cable of the instrument are easily accessible.
- To entirely disconnect the instrument from the power supply, unplug the power cable.
- Ensure that the power cable plug is close to the user.
- If it is necessary to cut the power supply, unplug the cable from the power outlet and contact an authorized Miltenyi Biotec service provider or Miltenyi Biotec Technical Support.
- Check the instrument before each use for visible damage.
- In case of severe accidents, damages to the instrument, or if smoke or flames appear, cut the power supply immediately.
- Do not use the instrument if it has been dropped or is damaged. Contact Miltenyi Biotec Technical Support immediately.

Hazard levels

Signal words are used to warn against hazardous situations and property damages. The following signal words are used in this user manual.

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

⚠ CAUTION or **CAUTION!** indicates a hazardous situation that, if not avoided, could result in minor or moderate injury. It is also used to warn against unsafe practices.

NOTICE or **NOTICE** indicates information considered important but not hazard related (e.g. messages relating to property damage).

Symbols



SAFETY WARNING: THE DOCUMENTATION MUST BE CONSULTED IN ALL CASES WHERE THIS SAFETY SYMBOL IS USED ON THE INSTRUMENT



BIOLOGICAL HAZARD



MOVING PARTS



OPTICAL RADIATION



ELECTROSTATIC SENSITIVE DEVICE (ESD)



WEEE (WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT)



READ THE USER MANUAL BEFORE USING THE INSTRUMENT



ON (POWER ON)



OFF (POWER OFF)



WEIGHT



SERIAL NUMBER



TYPE NUMBER



ORDER NUMBER



MANUFACTURER



DATE OF MANUFACTURE



EUROPEAN CONFORMITY MARKING



UNITED KINGDOM CONFORMITY ASSESSED MARKING



ETL CERTIFICATION MARK: THE PRODUCT MEETS CONSENSUS-BASED STANDARDS OF SAFETY, REQUIRED BY THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA), DETERMINED BY THE NATIONALLY RECOGNIZED TESTING LABORATORIES (NRTL) INTERTEK.

Safety labels

Pay attention to the hazard zones and safety symbols of the instrument.

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

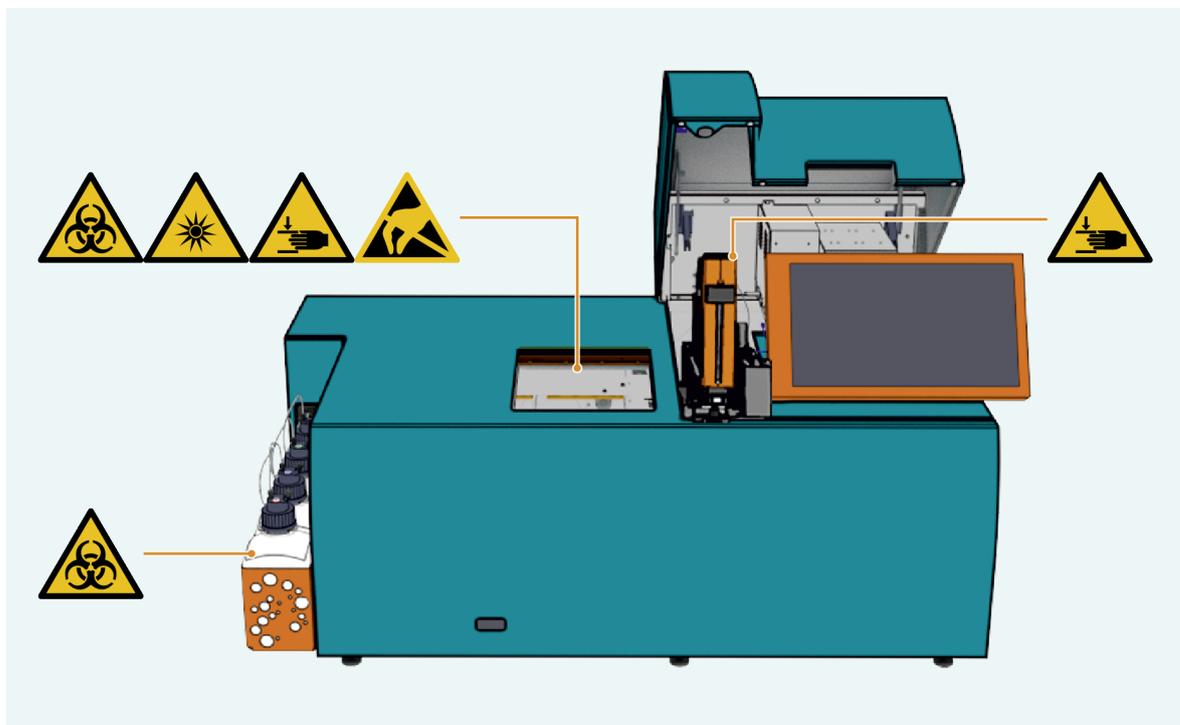


Figure 1.1: Hazard zones and safety symbols on the front side of the instrument. The symbol "optical radiation" applies to service personnel only.

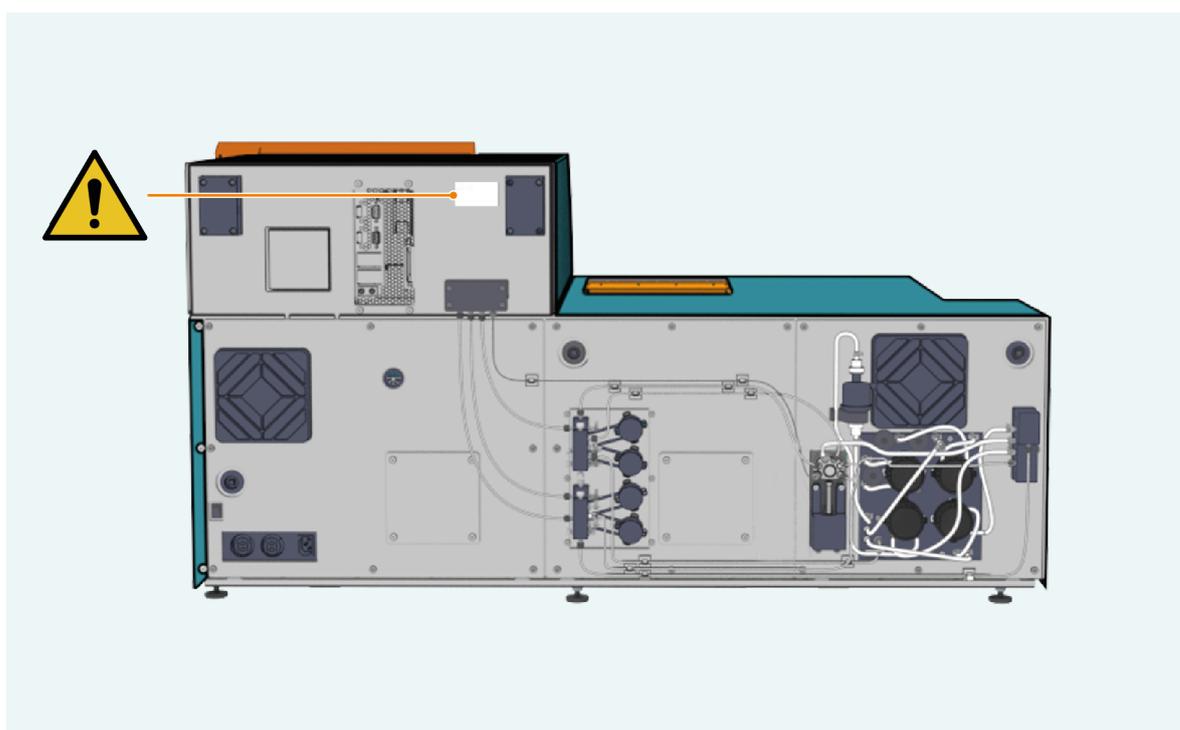


Figure 1.2: Hazard zones and safety symbols on the rear side of the instrument

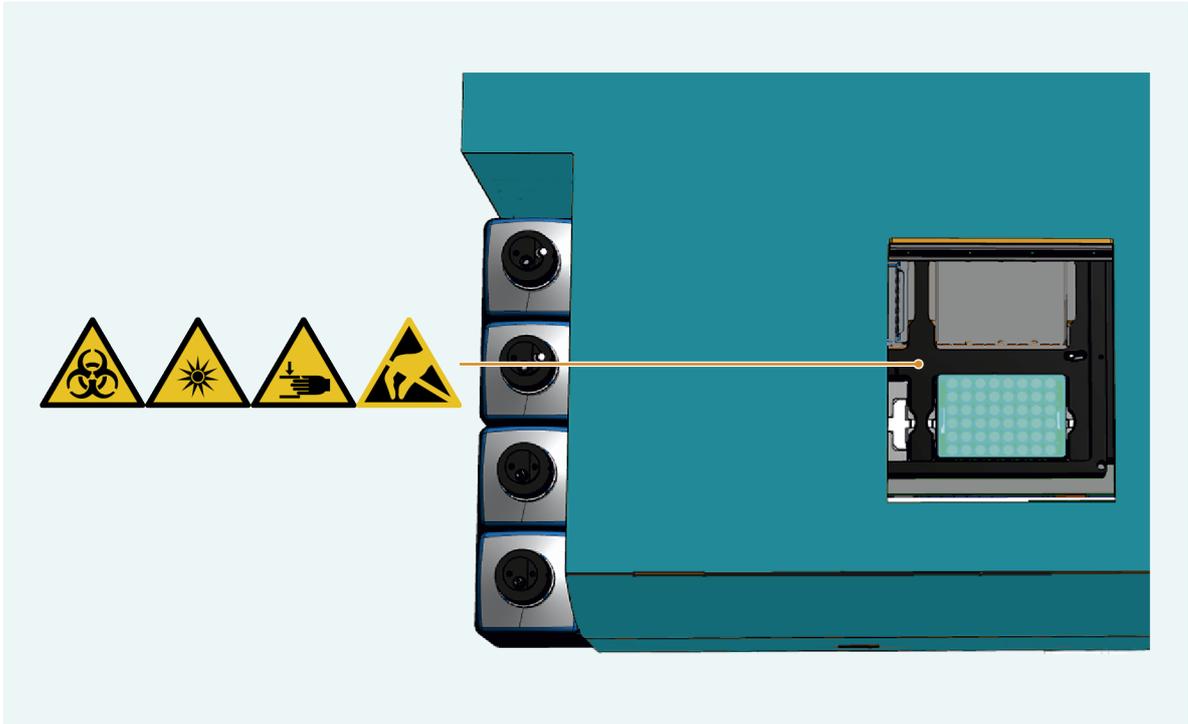


Figure 1.3: Hazard zones and safety symbols in the sample chamber. The symbol "optical radiation" applies to service personnel only.

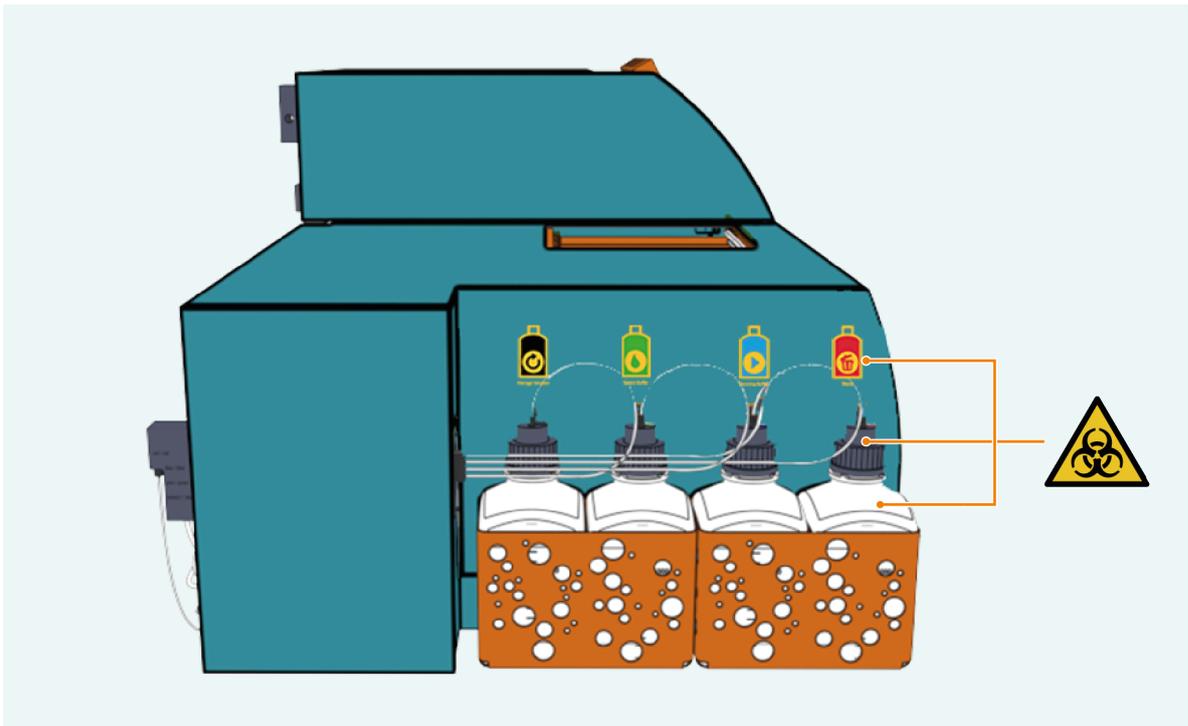


Figure 1.4: Hazard zones and safety symbols on the left side of the instrument

Electrical hazards

⚠ CAUTION

Electric shock, short circuit, overheating, fire, and explosion could result in death or serious injury.

Protective housing

The housing of the instrument reduces the risk of an electric shock and short circuits.

- Do not disassemble the instrument.
- Do not use the instrument if it has been dropped or is damaged.

Cables and power supplies

The instrument has a three-wire electrical grounding plug with a third pin for grounding. Using the instrument with other than the supplied cables is potentially hazardous.

- Only use the included power cable.
- Do not use the instrument if the power cable is damaged.
- Only insert the plug into a grounded electrical outlet. Do not try to insert the plug into a non-grounded electrical outlet.
- Operate the instrument only from a power source that meets the electrical specifications mentioned on the marking plate. If you have questions about the type of power source to use, contact the Miltenyi Biotec Technical Support or your local electricity supplier.

Liquids inside the instrument

Liquids inside the instrument can cause short circuits.

- Do not use the instrument if liquids have entered the inside of the instrument.
- Protect the instrument against spilled liquids.
- Do not allow liquids to enter the inside of the instrument.
- Clean up spilled liquids immediately.
- Unplug the instrument before cleaning it.
- Use only small amounts of cleaning agents on a soft cloth to wipe the instrument. Do not spray or pour liquid cleaning agents onto or into the instrument.

Humid and dusty environments

A change in the environmental temperature may cause condensation inside the instrument. Humidity, condensation, or dust inside the instrument can cause short circuits.

- Use the instrument only indoors.
- Do not use the instrument in a wet location or areas with high humidity or condensation.
- After moving the instrument from a cold environment to room temperature, wait for the instrument to dehumidify before using it.

Mechanical hazards

CAUTION

Risk of crushing or cutting.

Robotic needle arm

The robotic needle arm moves while the instrument is in operation.

- Do not open the top access cover while the instrument is in operation.
- Keep away from the robotic needle arm while the instrument is in operation.
- Do not obstruct the movement of the robotic needle arm.

Fluidics system

Syringe pumps are part of the fluidics system. They move while the instrument is in operation.

- Do not operate the instrument without the finger guard.
- Do not obstruct the movement of the syringe pumps.
- Keep away from the syringe pump while the instrument is in operation.

⚠ CAUTION**Risk of cutting.****Damaged disposables**

Damaged disposables can have sharp edges.

- Observe the instructions in the data sheet for each disposable.
- Do not use damaged disposables.
- Dispose of damaged disposables carefully.

Biological hazards**⚠ CAUTION****Contamination or infection could result in death or serious injury depending on the material used.****Biological material**

All biological material must be considered potentially infectious.

- Wear personal protective equipment (such as gloves, safety glasses, etc.) as indicated in the safety data sheet for the particular substance.
- If hazardous or potentially infectious material has been spilled or leaked from the system, decontaminate the affected area.
- Do not continue to use contaminated accessories or parts of the instrument. Contact Miltenyi Biotec Technical Support immediately.
- Droplets might leak from the system. Protect mouth and nose if processing hazardous or potentially infectious material that can be transmitted through the air.
- Operate the instrument in a biological safety cabinet suitable for the used specimen if hazardous or potentially infectious materials are processed.
- Accessible surfaces (protective housing and sample and reagent chamber) need to be cleaned after each use to avoid accumulation of substances carried in aerosols.
- To protect the instrument against spilled liquids, remove all caps and lids from any plastic vial before you place them into the instrument.
- As an exception, do not remove the aluminum sealing foils on antibody plates. Observe the instructions in the data sheet for each disposable.
- Take care when handling samples and reagents.

Waste

All liquid and solid waste must be considered hazardous.

- Observe local regulations regarding waste disposal.
- Label waste bottles with the provided biohazard stickers.

Equipment damage

Defective or inadequate equipment can cause a biological hazard. Some decontamination methods could damage the instrument.

- If parts of the instrument are damaged, unplug and do not use the instrument until damaged parts are replaced. Contact Miltenyi Biotec Technical Support, if necessary.
- Observe the instructions in the data sheet for each disposable.
- Use only 70% ethanol or isopropyl alcohol for disinfection.

- Before the instrument is being disposed or transported into a lower safety level laboratory, follow local regulations by ensuring an appropriate decontamination suitable for the appropriate specimen. Please note that other than the decontamination methods and agents described here may damage the instrument but may also be necessary for a suitable decontamination. The instrument specifications only apply to the instrument before such a decontamination.

Chemical hazards

CAUTION

Substances and reagents can be hazardous.

Hazardous substances and reagents

- All safety measures in section **Biological hazards** also apply to any hazardous substances and reagents that may be present in the sample.
- Use any substances and reagents only as stated in the respective safety data sheet.
- Operate the instrument in a fume hood if hazardous substances and reagents are processed.

Optical radiation hazards

CAUTION

Exposure to optical radiation could result in eye injury.

High-power LEDs

The instrument has a MACS Lightbox 3 that uses high-power LEDs for fluorochrome bleaching. The instrument has a Multicolor Light Unit with high-power LEDs for fluorochrome excitation. The LEDs are secured by a protective housing. The MACS Lightbox 3 emits UV light. Without the protective housing, the MACS Lightbox 3 and the Multicolor Light Unit are in Risk Group 2.

2D barcode reader

The instrument has a 2D barcode reader that uses powerful light emitting diodes (LEDs) for illuminating the reading area. The light is not visible.

Bottle illumination

Powerful LEDs are used to illuminate the bottles. According to the international standard IEC 62471, this lamp system is in excess of the Exempt Risk Group and there are risks dependent on the use of the instrument. The system classifies as Risk Group 1 with a retinal blue light hazard. The exposure hazard value (EHV) measured at a distance of 20 cm from the bottle holders is 0.91, hazard distances are 51 cm for Exempt Risk Group and 8 cm for Risk Group 1.

- Do not look directly at LED radiation or LED radiation reflected from a mirrored surface.
- Keep your eyes at a distance of at least 8 cm from the bottle holders.
- Do not remove the bottle holders.

Thermal hazards

CAUTION

Burn due to contact with material at a high temperature.

Disposables could overheat if handled incorrectly. Contact with overheated disposables could result in moderate burns. Overheating can lead to disposables melting and samples becoming unusable.

- Avoid using dark pens to label the used disposables.
- Avoid using dark or flammable mounting media and any light absorbing materials.
- Only use MACSwell Sample Carriers and MACSima Buffers for processing samples with the instrument.

Environmental hazards

CAUTION

Tripping could result in injuries.

- Check the environment around the instrument before each use for tripping hazards, such as cables lying on the floor.

Ergonomic hazards

WARNING

Risk of crushing.

Heavy instrument

The instrument could fall down and cause serious injury to hand or foot.

- Place the instrument only onto stable, even, and vibration free tables or laboratory benches.
- Only use tables or laboratory benches that support a weight of 200 kg.
- Do not install the instrument yourself.
- Only trained Miltenyi Biotec personnel or personnel authorized by Miltenyi Biotec are allowed to install the instrument.

WARNING

Risk of tearing or straining muscles.

- Do not move the instrument yourself.
- Only trained Miltenyi Biotec personnel or personnel authorized by Miltenyi Biotec are allowed to transport the instrument.

Servicing and transportation

Servicing

Improper servicing or repair of the instrument or use of unauthorized parts can cause malfunction of or damage to the instrument. This can cause hazards to users.

- Unless otherwise specifically stated in this user manual or other documentation by Miltenyi Biotec, do not service the instrument yourself.
- Servicing and repair must be performed by Miltenyi Biotec certified and qualified service personnel.
- If the instrument needs servicing, decontaminate the instrument to remove any hazardous material.
- If you have questions regarding proper decontamination or shipment, contact Miltenyi Biotec Technical Support for assistance.
- Only use accessories and upgrades recommended by Miltenyi Biotec.
- Inquire with your local Miltenyi Biotec representative about Miltenyi Biotec's extensive instrument service and service contracts, or refer to **www.miltenyibiotec.com/support**.

Transportation

The instrument must be transported with care in packaging specified by Miltenyi Biotec. Internal damage could occur if the instrument is subjected to excessive vibration or if it is dropped. If the instrument needs to be shipped back to the manufacturer for service, contact Miltenyi Biotec for instructions and packaging materials.

Disposal



WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) CUSTOMER INFORMATION

Dispose of your end-of-life Miltenyi Biotec products in accordance with the applicable WEEE and hazardous waste disposal legislation, which may differ by country or region. Electrical equipment may contain hazardous substances that may have a serious detrimental effect on the environment and/or human health. All equipment must be specifically collected and treated by designated waste facilities and by qualified WEEE compliance schemes. By ensuring that you dispose of your unwanted electrical and electronic equipment according to the applicable WEEE and hazardous waste disposal legislation, you are helping to preserve our natural resources and protect human health. Miltenyi Biotec is committed to protecting the environment. Miltenyi Biotec offers product end-of-life return programs in many countries and partners with licensed WEEE compliance schemes throughout the world. Miltenyi Biotec takes back your end-of-life Miltenyi Biotec equipment for recycling free of charge. The terms and availability of this offer vary by geography because of differences in regulatory requirements. Note that, depending on the type and use of your equipment, additional requirements may apply. Before shipping the instrument back to the manufacturer for disposal, decontaminate the instrument to remove any hazardous material. For more information or if you wish to dispose of your end-of-life Miltenyi Biotec equipment, contact your local Miltenyi Biotec representative or Miltenyi Biotec Technical Support.

2

Introduction

2.1 The MACSima Imaging System

The MACSima Imaging System is an ultra high-plex imaging system based on fluorescence microscopy. It uses the principle of iterative, antigen-based antibody staining to acquire hundreds of markers on one sample and multiple samples at a time. The instrument consists of a liquid handling system, the sample and reagent stage, and an integrated widefield microscope with which several types of fixed samples ranging from tissue sections to single cells can be analyzed in a fully automated manner. Thus, the MACSima Imaging System can generate multiplex data, while it is still convenient and easy to use.

2.2 Intended use

The MACSima Imaging System is a laboratory equipment for spatial analysis of cell and tissue preparations. The instrument stains samples, acquires high resolution images of the stained samples, erases the staining, and repeats this cycle fully automatically. These images can be merged to an ultra high-plex representation of the sample. One single sample can be stained with several fluorescence markers in each cycle and sequentially with up to several hundred fluorescence markers.

The MACSima Imaging System is for research use only in a laboratory environment. Only laboratory professional users are allowed to use the instrument.

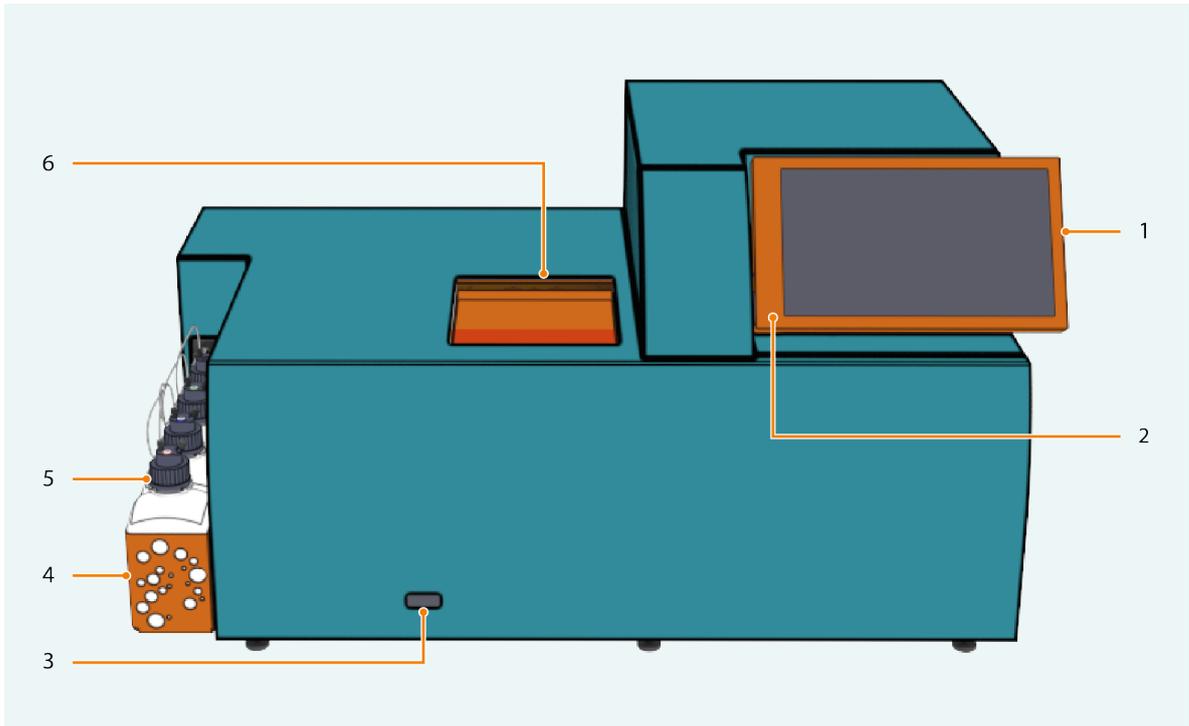


Figure 2.1: Front view of the instrument

- | | | | |
|---|-------------------|---|---------------------------------|
| 1 | Touchscreen | 4 | Bottle holder |
| 2 | Status LED | 5 | Buffer bottles and waste bottle |
| 3 | 2D barcode reader | 6 | Door, closed |

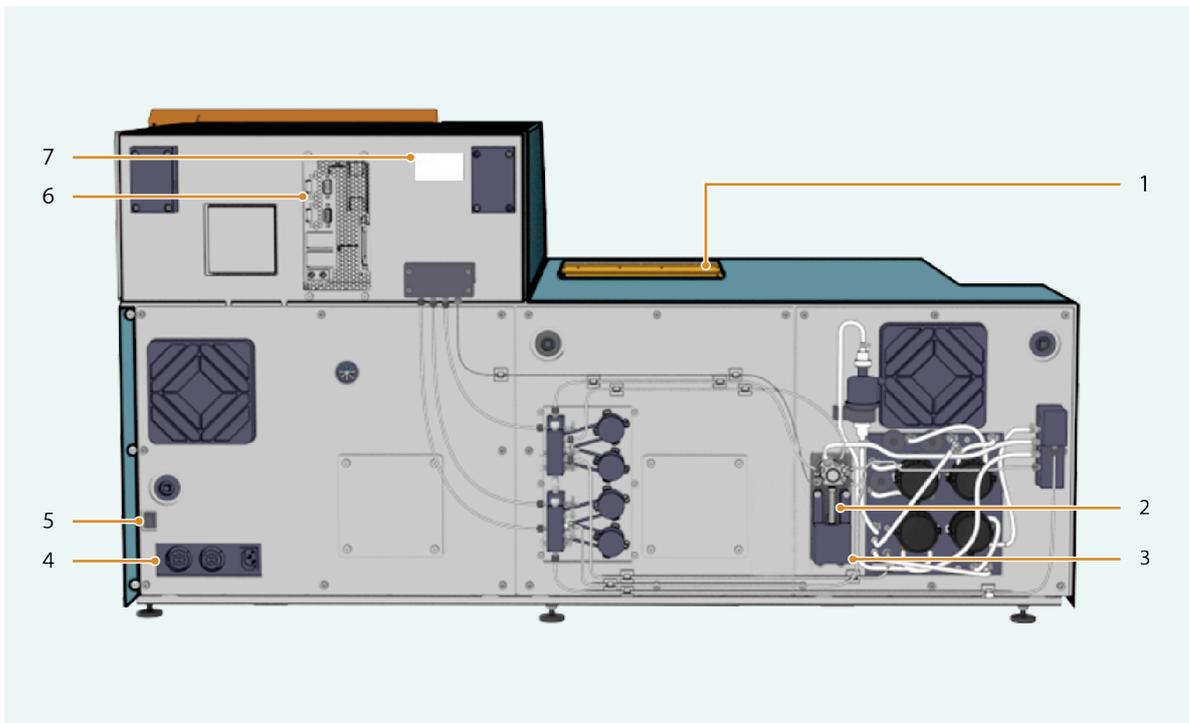


Figure 2.2: Rear view of the instrument

- | | | | |
|---|----------------------------------|---|--------------|
| 1 | Door, closed | 5 | Power switch |
| 2 | Syringe pump | 6 | I/O ports |
| 3 | Finger guard of the syringe pump | 7 | Type label |
| 4 | Power port | | |

3

Installation

This chapter describes the components, consumables, and installation of the MACSima Imaging System.

3.1 Components included in the delivery

Component
MACSima Imaging System
MACSima Table
PC 1 with preinstalled control software
PC 2 with preinstalled analysis software (Permanent License)
Bottle closure for MACSima System Buffer and empty bottle
Bottle closure for MACSima Running Buffer and empty bottle
Bottle closure for MACSQuant/MACSima Storage Solution and empty bottle
Bottle closure and waste bottle
Sheet of biohazard labels for labeling waste bottles
External 4K monitor
Power cable
Keyboard with trackball
Regular keyboard
Regular mouse
MACSima Imaging System user manual
MACS iQ View Software Control Module user manual
MACSwell Four Imaging Plates (10 pieces)
MACSwell Deepwell Plates (5 pieces)
MACSima System Buffer
MACSima Running Buffer
MACSQuant/MACSima Storage Solution

Table 3.1: Components included in the delivery

Consumable*	Order no.
MACSwell Sample Carriers for ultra high-plex imaging	
MACSwell One	130-124-673
MACSwell Two	130-124-675
MACSwell Four	130-124-676
MACSwell One Small	130-126-794
MACSwell One Small Express	130-126-796
MACSwell 24	130-124-677
MACSwell Slides for ultra high-plex imaging	
MACSwell HighRes Slides	130-126-799
Manual antibody panel preparation	
MACSwell Deepwell Plates	130-126-865
MACSwell Sealing Foils	130-126-866
Predefined antibody and RNAsky panels*	
REAscreen MAX Kit, human, FFPE, version 02	130-129-734
REAscreen MAX Kit, human, PFA, version 02	130-129-737
REAscreen MAX Kit, mouse, PFA, version 02	130-129-735
REAscreen Immuno-oncology Kit, human, FFPE, version 01	130-132-525
REApex Immuno-oncology Core, human, FFPE	130-136-302
RNAsky IO Explore Panel, human	130-134-683
Ready to use reagent kit	
MACSima Stain Support Kit, human	130-127-574
MACSima Stain Support Kit, mouse	130-127-575
RNAsky Sample Preparation Kit	130-134-682
RNAsky Support Kit	130-134-684
MACSima Buffers	
MACSima System Buffer	130-125-315
MACSima Running Buffer	130-121-565
MACSQuant/MACSima Storage Solution	130-092-748
MACSima Buffer Starting Kit	130-125-753

Table 3.2: Consumables that have to be ordered separately. * For an up-to-date list and details, visit www.miltenyibiotec.com.

3.3 Unpacking and installation

Protect the instruments from shock and vibration. Do not place vibrating devices (e.g., vortex mixers) on the same table as the MACSima Imaging System. This could impair the quality of the results.

Only Miltenyi Biotec service personnel are allowed to unpack and install the instrument. Contact Miltenyi Biotec Technical Support for further information.

Before installation, ensure that your site is properly prepared. The instrument must be installed on the MACSima Table or a standard laboratory tables that can carry a weight of at least 200 kg and is certified by Miltenyi Biotec. Allow a minimum of 15 cm free space to the rear side and both sides of the instrument. Allow a minimum of 100 cm free space in front of the instrument. All sides of the instrument must be accessible for service and maintenance.

The plastic tube end at the lower edge of the housing must not be closed or lifted above the table surface.

4

Operation

4.1 Switching on the instrument

- 1 Switch on the instrument. The power switch is located on the rear right side of the instrument when viewed from the front.
- 2 Tap the screen to boot the instrument and open the MACS iQ View Software Control Module.
- 3 Log in with your user credentials.

4.2 Switching off the instrument

Under normal circumstances, it is unnecessary to switch off the instrument. In case of an error, or if cleaning and maintenance is required, switch off the instrument as follows:

- 1 To close the MACS iQ View Software Control Module, press the **System Off/Restart** button in the upper right corner of the **Top Indicator Bar** (refer to the MACS iQ View Software Control Module user manual for details).
- 2 Switch off the instrument using the power switch on the rear side of the instrument. If for any reason it is necessary to disconnect the power supply, unplug the power cable from the electrical outlet.

4.3 Long-term storage

The instrument is flushed automatically with Storage Solution after each run. No special precautions have to be taken to store the instrument.

5

Monitoring the instrument

5.1 LED status indicators of the touchscreen

LED color	Description
Green	Instrument is booting
Red	Instrument is in standby mode
Off	All other cases

Table 5.1: LED status indicators of the touchscreen

5.2 LED status indicators of the door handle

LED color and pattern	Description
Green, solid	Door is fully closed
Orange, solid	Door is moving
Orange, pulsing	Door is stopped between fully open and closed position
White, solid	Door is fully open
Red, solid	Door move has failed

Table 5.2: LED status indicators of the door handle

5.3 Bottle illumination

Illumination color and pattern	Description
Green, solid	Ready for measurement / Waiting for user input
White, solid	Busy/Operating
Three bottles red, solid and one bottle red, blinking	Bottle with blinking light requires exchange
Purple, blinking	Fluid sensor cable is disconnected
Orange, solid	Bottle is prepared for exchange

Table 5.3: Bottle illumination

6

Preparing the instrument

CAUTION

Burn due to contact with material at a high temperature.

Disposables could overheat if handled incorrectly. Contact with overheated disposables could result in moderate burns. Overheating can lead to disposables melting and samples becoming unusable.

- Avoid using dark pens to label the used disposables.
- Avoid using dark or flammable mounting media and any light absorbing materials.
- Only use MACSwell Sample Carriers and MACSima Buffers for processing samples with the instrument.

First, create the experiment as described in the MACS iQ View Software Control Module user manual. For more information about the preparation of the reagents, read the corresponding data sheets.

6.1 Inserting MACSwell Imaging Frames

- 1 Insert the samples by placing up to four MACSwell 1/2/4 Imaging Frames on the left and/or the right imaging stage rack position(s) (**Figure 6.1**) as defined in the MACS iQ View Software Control Module.
- 2 Align the rear side of the frame with the rack position and press the front side down until you hear a click sound.

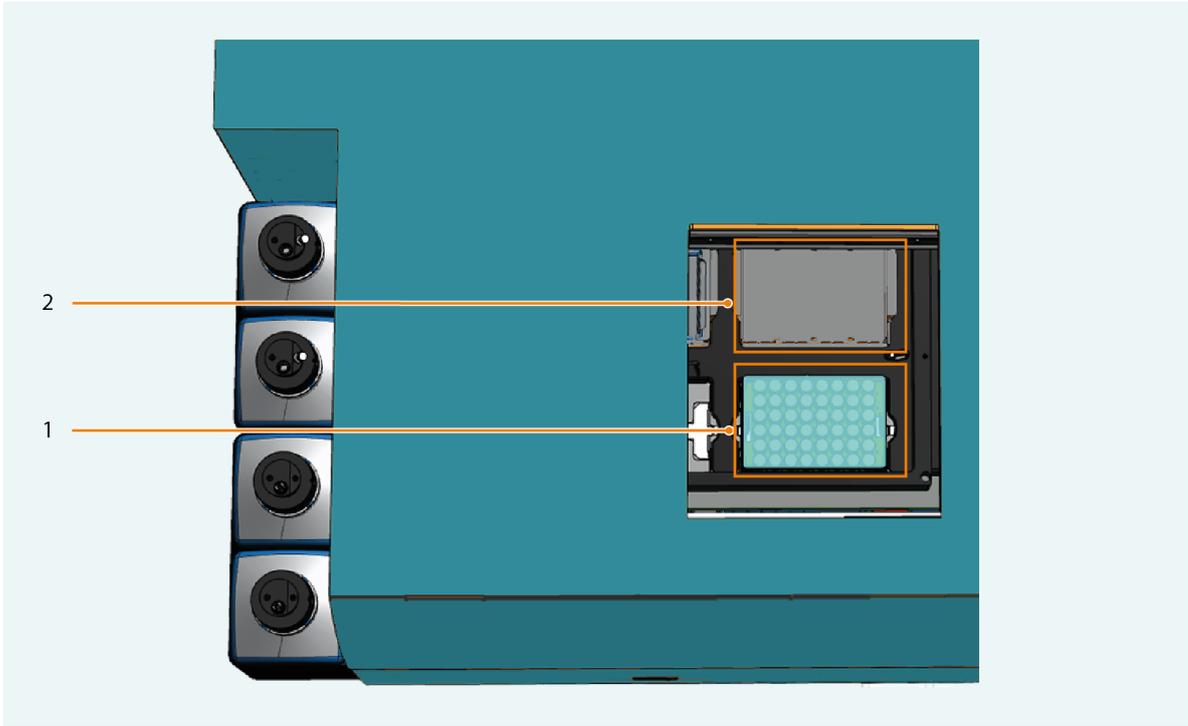


Figure 6.1: Top view of the sample chamber in the instrument

- 1 Reagent stages
- 2 Imaging stages

6

6.2 Inserting a MACSwell 24 Imaging Plate

- 1 Insert the samples by placing a MACSwell 24 Imaging Plate onto the right and/or the left imaging stage rack positions (**Figure 6.1**) as defined in the MACS iQ View Software Control Module.
- 2 Press the plate down on the rack.

6.3 Inserting a MACSwell Deepwell Plate

- 1 Prepare the MACSwell Deepwell Plate(s) and seal it/them with a MACSwell Sealing Foil.
- 2 Place the sealed plate(s) onto the reagent stage rack position(s) (**Figure 6.1**) as defined in the MACS iQ View Software Control Module.
- 3 Make sure the plate is securely in place.

6.4 Inserting a REAscreen plate

- 1 Place the REAscreen plate(s) onto the reagent stage position(s) (**Figure 6.1**) as defined in the MACS iQ View Software Control Module.
- 2 Optional: Place a REAscreen plate onto the right imaging stage position (**Figure 6.1**) as defined in the MACS iQ View Software Control Module.
- 3 Make sure the plate is securely in place.

6.5 Inserting the vials

- 1 Remove the lid of the MACSima Mixing Vials and the reagent vials.
- 2 Insert the vials between the antibody stage rack positions as defined in the MACS iQ View Software Control Module.

7

Maintenance

7.1 Servicing

Service the instrument every 6 months. Contact Miltenyi Biotec for support.

7.2 Cleaning the instrument

⚠ WARNING

Electric shock, short circuit, overheating, fire, and explosion could result in death or serious injury.

- Unplug the instrument before cleaning it.
- Use only small amounts of cleaning agents on a soft cloth to wipe the instrument. Do not spray or pour liquid cleaning agents onto or into the instrument.

- 1 To disinfect, wipe accessible surfaces with 70% ethanol or isopropanol.
- 2 If necessary, additionally wipe the instrument with a damp tissue.

7.3 Bottle exchange

⚠ WARNING

Electric shock, short circuit, overheating, fire, and explosion could result in death or serious injury.

Liquids inside the instrument can cause short circuits.

- Do not use the instrument if liquids have entered the inside of the instrument.
- Protect the instrument against spilled liquids.
- To avoid spillages, install only one bottle at a time.
- Clean up spilled liquids immediately.

7.3.1 Exchanging fluid bottles

- 1 Remove the empty bottle from the bottle holder. Keep the bottle closure attached.
- 2 Place a new sealed bottle into the orange bottle holder. Check the corresponding color coding.
- 3 Unscrew the screw cap of the new fluid bottle.
- 4 Remove the bottle closure from the old bottle. Make sure not to invert the bottle closures as liquids could enter the hydrophobic air filter.
- 5 Install the bottle closure on the new bottle.

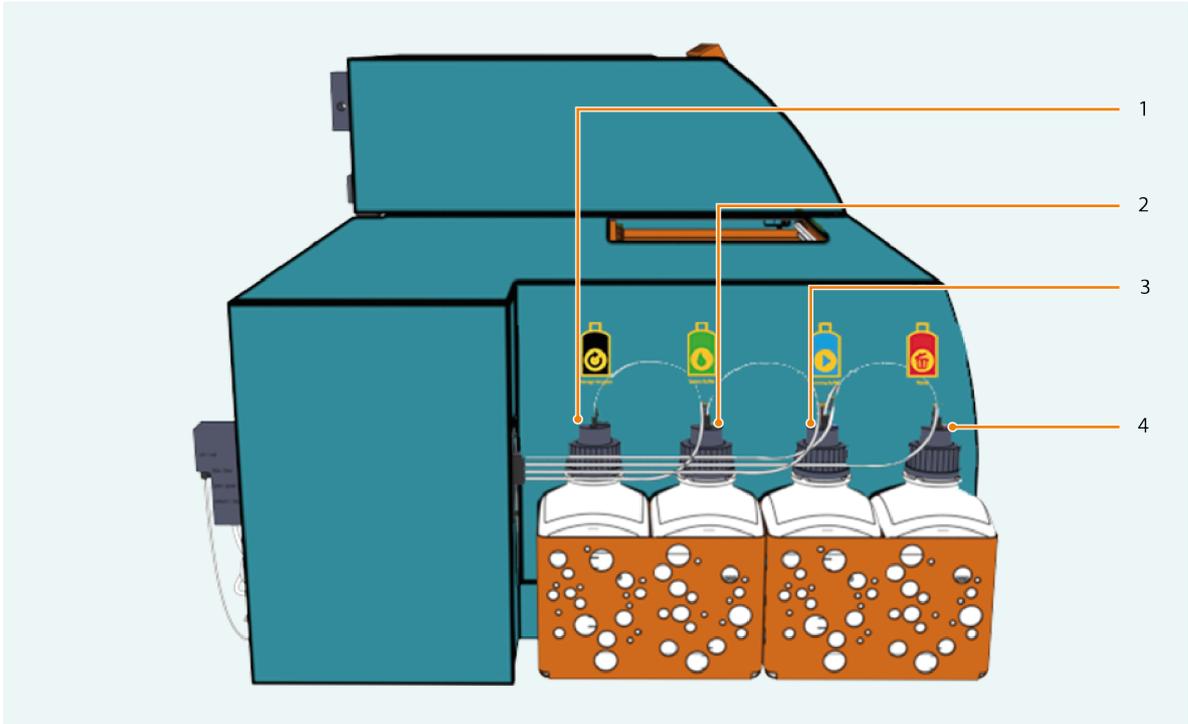


Figure 7.1: Side view of the instrument

- | | | | |
|---|------------------------|---|------------------------------------|
| 1 | Waste bottle | 3 | MACSima System Buffer |
| 2 | MACSima Running Buffer | 4 | MACSQuant/MACSima Storage Solution |

7.3.2

Emptying the waste bottle

⚠ WARNING

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

All liquid and solid waste must be considered hazardous.

- Observe local regulations regarding waste disposal.
- Autoclave or alternatively decontaminate waste with an appropriate disinfectant.
- Observe the general laboratory safety regulations when handling liquid and solid waste.
- Prefill the empty waste bottle with an appropriate disinfectant according to the specification of the manufacturer.

Empty the waste bottle regularly. If the waste bottle is full, the user will be prompted to empty the bottle before proceeding. Do not empty the waste bottle while the instrument is running, unless you are prompted to do so.

- 1 Keep a new empty waste bottle and a corresponding screw cap at hand. Label the new waste bottle with a biohazard safety symbol.
- 2 Remove the bottle closure from the full waste bottle and install it on the empty waste bottle. Do not disconnect the color-coded tubing and sensor cable from the bottle closure. Make sure not to invert the bottle closures as liquids could enter the hydrophobic air filter.
- 3 Screw a screw cap onto the full waste bottle before taking it out of the bottle holder.
- 4 Place the empty waste bottle into the bottle holder.

8

Technical data and specifications

8.1 Specifications

The MACSima Imaging System is classified as protection class I device and must be plugged into a grounded electrical outlet. The instrument is suitable for pollution degree 2 environments.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Supply voltage fluctuations up to +/- 10% of the nominal voltage. Transient overvoltages present on the mains supply: category II. Changes or modifications of the instrument, unless expressly approved by Miltenyi Biotec, may void your authority to operate the instrument pursuant to FCC 47 CFR. For other safety considerations, refer to the product label or visit www.miltenyibiotec.com. Design and specifications are subject to change without notice.

8.2 Technical data

The safety of the instrument may be compromised if used outside its specifications.

MACSima Imaging System

Footprint	1,210 mm × 750 mm (w × d)
Dimensions	1,220 mm × 780 mm × 650 mm (w × d × h)
Weight	170 kg
Nominal input voltage	100–240 V ~, 50/60 Hz, max. 7/13 A
Power consumption	1,300 W

Interfaces

Network PC 2	1× 10GbE RJ45 (compatible with 1GbE)
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Ports PC 1	<ul style="list-style-type: none">• 2× USB 3.0• 2× USB 2.0• 1× HDMI 2.0
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Ports PC 2	<ul style="list-style-type: none">• 2× USB 3.0• DP 1.2
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Altitude	Max. 2,500 m
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Emission sound pressure level at workstation	<70 dB(A)
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Working conditions

Temperature	18–30 °C, temperature should not vary by more than +/- 2 °C during a 12-hour period
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Humidity	Max. 20%–80% relative humidity, noncondensing
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Storage conditions

Temperature	5–40 °C
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Humidity	Max. 20%–80% relative humidity, noncondensing
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Transport conditions

Temperature	5–40 °C
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Humidity	Max. 20%–85% relative humidity, noncondensing
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Table 8.1: Technical data of the instrument

8.3 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: MACSima Imaging System

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

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 61010-2-081:2015
EN 62471:2008	EN 61326-1:2013
EN ISO 13849-1:2015	EN ISO 13849-2:2012

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
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8.4 EU/EC Declaration of Conformity

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

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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: MACSima Imaging System

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 61010-2-051:2015
EN 62471:2008	EN 61326-1:2013
EN ISO 13849-1:2015	EN ISO 13849-2:2012

Person authorized to compile the relevant technical documentation:

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Technical support

For technical support, contact your local Miltenyi Biotec representative or Miltenyi Biotec Technical Support at Miltenyi Biotec headquarters:

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technicalsupport@miltenyi.com

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

10

Legal notes

10.1 Limited warranty

Except as stated in a specific warranty statement which may accompany this product or as otherwise agreed in writing by an authorized representative of Miltenyi Biotec, Miltenyi Biotec's warranty to you, the original purchaser and end user ("you" or "your"), with respect to the product accompanied by this limited warranty shall be subject to the following provisions and the general terms and conditions of sale of the company within the Miltenyi Biotec group which supplied the product in effect at the date of purchase. Those terms and conditions of sale may vary by country and region. Nothing in this document should be construed as constituting an additional warranty.

Miltenyi Biotec warrants that this product will operate or perform substantially in conformance with Miltenyi Biotec's published specifications and be free from material defects in material and workmanship, when subjected to normal, proper, and intended usage by properly trained personnel, for the period of time set forth in the product documentation or package inserts accompanying the product (the "Warranty Period").

Miltenyi Biotec agrees, during the Warranty Period, to repair or replace, at Miltenyi Biotec's option, the defective product so as to cause the same to operate in substantial conformance with said published specifications; provided that you shall (a) promptly notify Miltenyi Biotec in writing upon the discovery of any nonconformity or defect, which notice shall include the product model and serial number (if applicable) and details of the warranty claim; and (b) return the nonconforming or defective product to Miltenyi Biotec, freight prepaid, only after receipt of a Return Material Authorization ("RMA") from Miltenyi Biotec, which may include biohazard decontamination procedures and other product-specific handling instructions, if applicable.

Miltenyi Biotec shall have no obligation to make repairs, replacements, or corrections to the product or any component thereof required, in whole or in part, as the result of (i) normal wear and tear, (ii) improper handling, installation, operation, storage, service, maintenance, or repair, (iii) failure to follow the instructions, cautions, warnings, and notes set forth in the product documentation provided with the product or provided by Miltenyi Biotec from time to time, (iv) abnormal use, misuse, neglect, abuse, mishandling, misapplication, modification, or alteration of the product, (v) use of the product in a manner for which it was not designed, (vi) causes external to the product such as, but not limited to, power failure or electrical power surges, (vii) use of the product in combination with equipment, accessories, consumables, or software not supplied or approved by Miltenyi Biotec, or (viii) accident, disaster, or acts of God. ANY INSTALLATION, MAINTENANCE, REPAIR, SERVICE, OR ALTERATION TO OR OF, OR OTHER TAMPERING WITH, THE PRODUCT PERFORMED BY ANY PERSON OR ENTITY OTHER THAN MILTENYI BIOTEC AUTHORIZED PERSONNEL WITHOUT MILTENYI BIOTEC'S PRIOR WRITTEN APPROVAL, OR ANY USE OF REPLACEMENT PARTS NOT SUPPLIED BY MILTENYI BIOTEC, SHALL IMMEDIATELY VOID AND CANCEL ALL WARRANTIES WITH RESPECT TO THE AFFECTED PRODUCT.

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