Miltenyi Biotec

gentleMACS™ Dissociator

User manual



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gentleMACS™ Dissociator

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 gentleMACS Dissociator, 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.

Supported instruments

This user manual applies to the gentleMACS Dissociator (# 130-134-030) running with the gentleMACS Software version 1.2.

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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.
- In case of severe accidents, damages to the instrument, or if smoke or flames appear, cut the power supply immediately.
- To entirely disconnect the instrument from the power supply, unplug the power cable.
- Ensure that the power switch and the plug of the power cable of the instrument are easily accessible.

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


ROTATING PARTS

ON (POWER ON)


OFF (POWER OFF)


READ THE USER MANUAL BEFORE USING THE INSTRUMENT


FUSE


WEEE (WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT)



ORDER NUMBER



TYPE NUMBER



SERIAL NUMBER


MANUFACTURER


DATE OF MANUFACTURE


EUROPEAN CONFORMITY MARKING



UNITED KINGDOM CONFORMITY ASSESSED MARKING



NRTL CERTIFICATION MARK: PRODUCT MEETS CONSENSUS-BASED STANDARDS OF SAFETY, REQUIRED BY THE OCCUPATIONAL SAFETY/HEALTH ADMINISTRATION (OSHA), DETERMINED BY THE NATIONALLY RECOGNIZED TESTING LABORATORIES (NRTL) TÜV SÜD

Safety labels

Notice the hazard points 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.

The gentleMACS Sleeves are marked with a contrasting safety print. The contrasting safety print allows the visual perception of the rotation of the gentleMACS Sleeves. The gentleMACS Trough is marked with the following safety symbol.

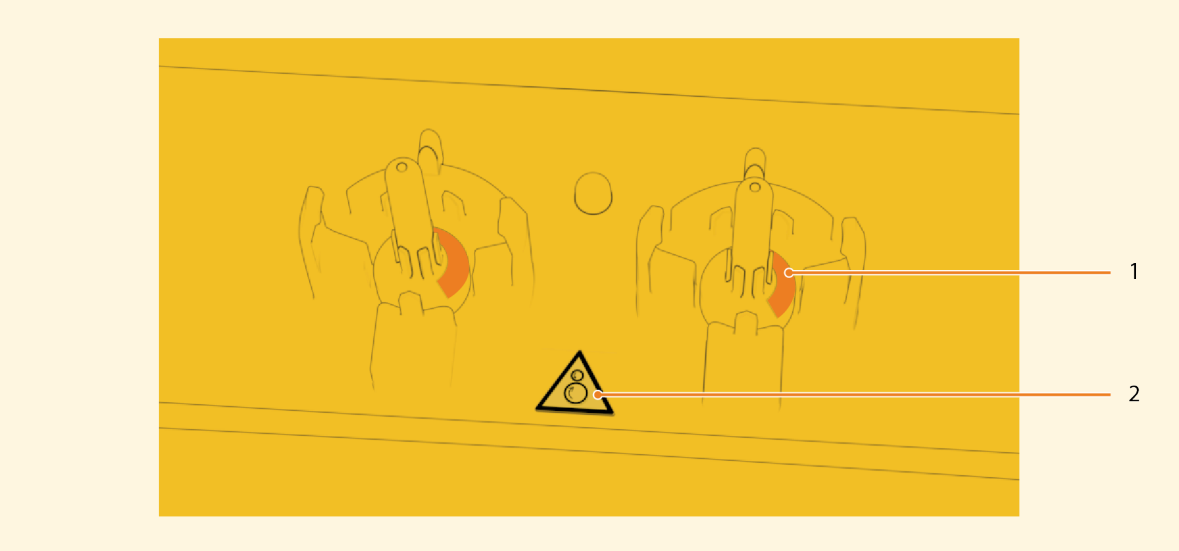


Figure 1: Safety symbol on the gentleMACS Trough and contrasting safety print on the gentleMACS Sleeves

1	Contrasting safety print on the gentleMACS Sleeves
2	Safety symbol on the gentleMACS Trough

Electrical hazards

⚠ WARNING

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 remove or penetrate any cover of the housing.
- Exceptions are maintenance procedures that are explicitly described in this manual.
- Do not use the instrument if it is opened or disassembled.
- Do not use the instrument if an object entered the inside of the instrument.
- Check the instrument before each use for visible damages.
- Do not use the instrument if it has been dropped or is damaged.

Cables and power supplies

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.
- The instrument has a three-wire electrical grounding plug with a third pin for grounding.
- 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 type label. 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.

- Protect the instrument against spilled liquids.
- Do not use the instrument if liquids have entered the inside of the instrument.
- If liquids have entered the instrument, unplug the instrument and contact Miltenyi Biotec Technical Support.
- 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.

Mechanical hazards

⚠ CAUTION

Risk of crushing.

The instrument will fall down if it is not placed on a flat and even surface, which could result in injuries.

- Place the instrument only onto stable, even, and vibration free tables or laboratory benches.
- Handle the instrument with care during carrying or relocation.

⚠ CAUTION

Risk of crushing or cutting.

gentleMACS Tube caps have sharp edges on the inside. This may lead to incision wounds if they were touched while rotating.

- Only use tightly closed tubes and ensure that they are properly installed.
- Do not install or remove tubes while the rotors of the instrument are in motion.

⚠ CAUTION

Risk of trapping fingers and hair pulled in.

Hair can be pulled in by the rotors when the instrument is running.

- Do not operate the instrument without gentleMACS Trough, gentleMACS Sleeves, and gentleMACS Safety Shield.
- Tie back long hair.
- Do not touch the rotors while the instrument is running.

Biological hazards

⚠ WARNING

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.
- Operate the instrument in a safety hood if hazardous or potentially infectious materials are processed.
- Decontaminate the instrument after processing hazardous or potentially infectious material.
- If hazardous or potentially infectious material has been spilled or leaked from the system, decontaminate the affected area.
- Use a disinfectant or cleaning agent that is appropriate for the specific pathogen or substance.

Waste

All liquid and solid waste must be considered hazardous.

- Observe local regulations regarding waste disposal.
- Autoclave or alternatively decontaminate waste with an appropriate disinfectant.

Chemical hazards

⚠ WARNING

Substances and reagents can be hazardous.

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

Noise

⚠ CAUTION

High noise levels could result in hearing impairment.

If running with maximum load, the instrument may produce loud noise. It is recommended that the responsible body measures or calculates the sound pressure level at the operator's position and at whatever point 1 m from the enclosure of the equipment has the highest sound pressure level.

- Noise level should be below 70 dB.
- Observe local regulations regarding hearing protection.
- If running the instrument with maximum load, then protective safety equipment such as noise reducing baffles or hoods, or ear protection has to be used.

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.

DE

Wichtige Sicherheitsinformationen

Allgemeine Sicherheitshinweise



DIESES KAPITEL BESCHREIBT POTENZIELL GEFÄHRLICHE SITUATIONEN IM ZUSAMMENHANG MIT DIESEM GERÄT UND ENTHÄLT WICHTIGE SICHERHEITSHINWEISE, UM RISIKEN ZU MINIMIEREN UND SICH SELBST UND ANDERE ZU SCHÜTZEN.

Dieses Kapitel enthält wichtige Informationen für Ihre persönliche Sicherheit und die richtige Verwendung des Instruments. Lesen und beachten Sie alle Anweisungen sorgfältig, bevor Sie mit der Installation und Verwendung des Instruments fortfahren. Beachten Sie zusätzlich zu diesem Benutzerhandbuch die allgemeinen Sicherheitsvorschriften.

- Verwenden Sie das Gerät nur wie in diesem Benutzerhandbuch angegeben, um Personen- und Sachschäden zu vermeiden.
- Bewahren Sie dieses Benutzerhandbuch an einem Ort auf, der jederzeit für alle Benutzer zugänglich ist.
- Beachten Sie die lokal geltenden Arbeitsschutzvorschriften und Laborrichtlinien sowie die gesetzlich geregelten Maßnahmen zu Sicherheit, Gesundheitsschutz und Unfallverhütung.
- Bei schweren Unfällen, Beschädigungen des Gerätes, Rauch oder Flammen unterbrechen Sie sofort die Stromversorgung.
- Ziehen Sie den Netzstecker, um das Gerät vollständig von der Stromversorgung zu trennen.
- Stellen Sie sicher, dass der Hauptschalter und der Netzstecker des Gerätes leicht zugänglich sind.

Gefahrenstufen

Es werden Signalwörter verwendet, um vor Gefahrensituationen und Sachschäden zu warnen. In diesem Benutzerhandbuch werden die folgenden Signalwörter verwendet.

⚠ WARNUNG oder WARNUNG! weist auf eine Gefahrensituation hin, die, falls sie nicht vermieden wird, zum Tod oder zu schweren Verletzungen führen kann.

⚠ VORSICHT oder VORSICHT! weist auf eine Gefahrensituation hin, die, falls sie nicht vermieden wird, zu leichten oder mittelschweren Verletzungen führen kann. Dies wird auch dazu verwendet, um auf unsichere Vorgehensweisen hinzuweisen.

***HINWEIS* oder HINWEIS weist auf wichtige, jedoch nicht gefahrenbezogene Informationen hin (z. B. Hinweise in Verbindung mit Sachschäden).**

Symbole


SICHERHEITSWARNUNG: BEACHTEN SIE DIE DOKUMENTATION IMMER, WENN DIESES WARNSYMBOL AM GERÄT VERWENDET WIRD


SICH DREHENDE TEILE

EIN (EINGESCHALTET)


AUS (AUSGESCHALTET)


LESEN SIE DAS BENUTZERHANDBUCH VOR VERWENDUNG DES GERÄTES


SICHERUNG


ELEKTRO- UND ELEKTRONIK-ALTGERÄTE (WEEE)



BESTELLNUMMER



MODELLNUMMER



SERIENNUMMER


HERSTELLER


HERSTELLUNGSDATUM


EUROPÄISCHE KONFORMITÄTSKENNZEICHNUNG



BRITISCHE PRODUKTKENNZEICHNUNG



NRTL-PRÜFZEICHEN: DAS PRODUKT ENTSPRICHT DEN IM KONSENSVERFAHREN ERARBEITETEN SICHERHEITSANFORDERUNGEN, WELCHE VON DER OCCUPATIONAL SAFETY/HEALTH ADMINISTRATION (OSHA) GEFORDERT UND VON DER STAATLICH ANERKANNTEN PRÜFSTELLE (NATIONALLY RECOGNIZED TESTING LABORATORIES (NRTL)) TÜV SÜD GEPRÜFT WURDEN

Sicherheitskennzeichnungen

Beachten Sie die Gefahrenhinweise und Sicherheitssymbole des Gerätes. Halten Sie die Warnaufkleber und Sicherheitskennzeichnungen sauber und lesbar. Überprüfen Sie die Warnaufkleber und Sicherheitskennzeichnungen regelmäßig und ersetzen Sie diese, wenn sie nicht mehr lesbar oder aus sicherer Entfernung nicht zu erkennen sind. Kontaktieren Sie Miltenyi Biotec, um Ersatzaufkleber zu erhalten.

Die gentleMACS Sleeves sind mit einem kontrastierenden Warnaufdruck gekennzeichnet. Der kontrastierende Warnaufdruck macht die Drehung der gentleMACS Sleeves sichtbar. Der gentleMACS Trough ist mit dem folgenden Sicherheitssymbol gekennzeichnet.

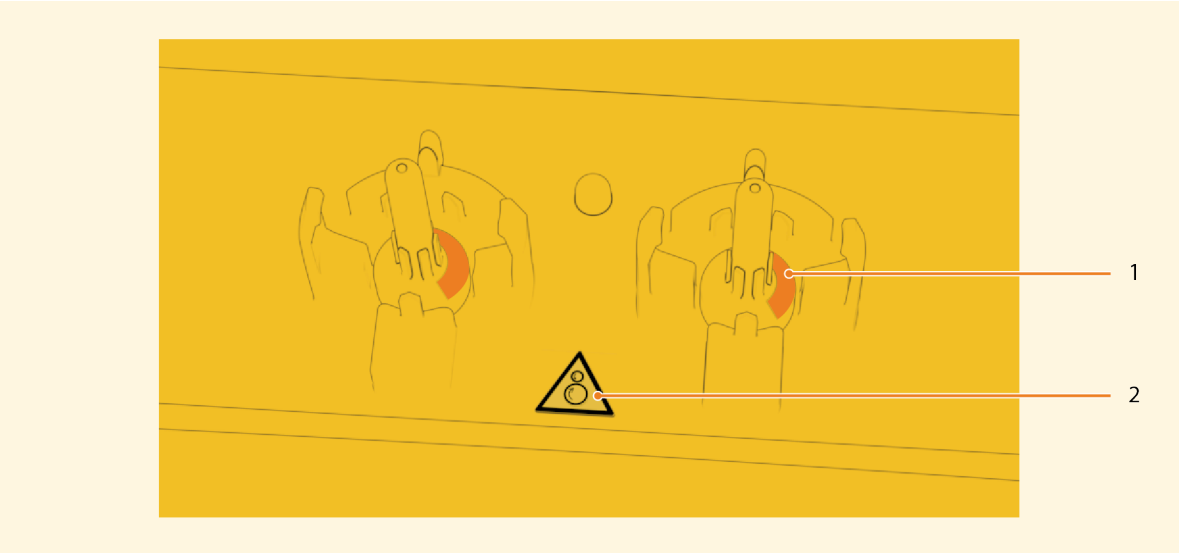


Abbildung 1: Sicherheitssymbol auf dem gentleMACS Trough und farblich abgesetzter Sicherheitsaufdruck auf den gentleMACS Sleeves

1 Farblich abgesetzter Sicherheitsaufdruck auf den gentleMACS Sleeves
2 Sicherheitssymbol auf dem gentleMACS Trough

Elektrische Gefahren

⚠ WARNUNG

Stromschlag, Kurzschluss, Überhitzung, Feuer und Explosion können zu schweren Verletzungen oder zum Tod führen.

Schützendes Gehäuse

Das Gehäuse des Gerätes reduziert das Risiko eines Stromschlags und von Kurzschlüssen.

- Entfernen oder öffnen Sie niemals Teile des Gehäuses.
- Ausnahmen hiervon sind ausdrücklich in diesem Handbuch beschriebene Wartungsvorgänge.
- Verwenden Sie das Gerät nicht, wenn es geöffnet oder demontiert ist.
- Verwenden Sie das Gerät nicht, wenn ein Objekt hineingefallen ist.
- Das Instrument vor jedem Gebrauch auf sichtbare Schäden überprüfen.
- Verwenden Sie das Gerät nicht, wenn es heruntergefallen oder beschädigt ist.

Kabel und Stromversorgung

Die Verwendung des Gerätes mit anderen als den mitgelieferten Kabeln ist potenziell gefährlich.

- Verwenden Sie nur das mitgelieferte Netzkabel.

- Verwenden Sie das Gerät nicht, wenn das Netzkabel beschädigt ist.
- Das Gerät verfügt über einen dreiadrigen elektrischen Erdungsstecker mit einem dritten Stift zur Erdung.
- Stecken Sie den Stecker nur in eine geerdete Steckdose. Versuchen Sie nicht, den Stecker an eine nicht geerdete Steckdose anzuschließen.
- Betreiben Sie das Gerät nur an einer Stromquelle, die den auf dem Typenschild angegebenen elektrischen Spezifikationen entspricht. Bei Fragen zur zu verwendenden Stromquelle wenden Sie sich an einen autorisierten Miltenyi Biotec-Vertreter oder Ihren Stromversorger.

Flüssigkeiten im Inneren des Gerätes

Flüssigkeiten im Gerät können Kurzschlüsse verursachen.

- Schützen Sie das Gerät gegen verschüttete Flüssigkeiten.
- Verwenden Sie das Gerät nicht, wenn Flüssigkeiten in das Innere eingedrungen sind.
- Wenn Flüssigkeit in das Instrument eingedrungen ist, ziehen Sie den Netzstecker und wenden Sie sich an den Miltenyi Biotec Technical Support.
- Nehmen Sie verschüttete Flüssigkeiten sofort auf.
- Trennen Sie das Gerät vor der Reinigung von der Stromversorgung.
- Verwenden Sie nur geringe Mengen an Reinigungsmittel auf einem weichen Tuch, um das Gerät abzuwischen. Sprühen oder gießen Sie keine flüssigen Reinigungsmittel auf oder in das Gerät.

Mechanische Gefahren

⚠ VORSICHT

Gefahr von Quetschungen.

Das Gerät kann herunterfallen, wenn es nicht auf eine flache und ebene Fläche gestellt wird, was zu Verletzungen führen kann.

- Stellen Sie das Gerät nur auf stabile, ebene und vibrationsfreie Tische oder Labortische.
- Behandeln Sie das Gerät beim Tragen oder Umstellen mit Sorgfalt.

⚠ VORSICHT

Gefahr von Quetsch- oder Schnittverletzungen.

Die Deckel der gentleMACS Tubes sind innen scharfkantig. Dies kann zu Schnittwunden führen, wenn sie bei der Drehbewegung berührt werden.

- Verwenden Sie nur fest verschlossene Tubes und stellen Sie sicher, dass diese ordnungsgemäß eingesetzt sind.
- Wechseln Sie keine Tubes, während sich die Rotoren des Gerätes bewegen.

⚠ VORSICHT

Gefahr des Einklemmens von Fingern und des Einziehens von Haaren.

Haare können bei laufendem Gerät von den Rotoren eingezogen werden.

- Das Instrument nur mit gentleMACS Trough, gentleMACS Sleeves und gentleMACS Saftey Shield betreiben.
- Langes Haar zurückbinden.
- Berühren Sie nicht die Rotoren während das Gerät läuft.

Biologische Gefahren

⚠ WARNUNG

Kontamination oder Infektion kann je nach verwendetem Material zu schweren Verletzungen oder zum Tod führen.

Biologisches Material

Alle biologischen Materialien müssen als potenziell infektiös eingestuft werden.

- Tragen Sie persönliche Schutzausrüstung (wie Handschuhe, Schutzbrille etc.), wie im Sicherheitsdatenblatt zum jeweiligen Material angegeben.
- Bei der Arbeit mit gefährlichen oder potenziell infektiösen Materialien betreiben Sie das Gerät in einer biologischen Sicherheitswerkbank.
- Dekontaminieren Sie das Gerät nach der Arbeit mit gefährlichen oder potenziell infektiösen Materialien.
- Wenn gefährliche oder potenziell infektiöse Materialien verschüttet wurden oder aus dem System ausgetreten sind, dekontaminieren Sie den betroffenen Bereich.
- Verwenden Sie kontaminiertes Zubehör oder kontaminierte Teile des Gerätes nicht weiter.

Abfall

Alle flüssigen und festen Abfälle müssen als gefährlich eingestuft werden.

- Beachten Sie die örtlichen Vorschriften zur Abfallentsorgung.
- Autoklavieren oder dekontaminieren Sie Abfall mit einem geeigneten Desinfektionsmittel.

Chemische Gefahren

⚠ WARNUNG

Stoffe und Reagenzien können gefährlich sein.

- Alle im Abschnitt **Biologische Gefahren** genannten Sicherheitsvorkehrungen gelten auch für gefährliche Stoffe und Reagenzien, die gegebenenfalls in der Probe enthalten sind.
- Betreiben Sie das Gerät unter einer Abzugshaube, wenn gefährliche Stoffe und Reagenzien verarbeitet werden.

Lärm

⚠ VORSICHT

Hohe Geräuschpegel können zu Hörschäden führen.

Bei Betrieb mit maximaler Last kann das Instrument starke Geräusche erzeugen. Es wird empfohlen, den Schalldruckpegel an der Bedienposition und in einem Meter Abstand zu dem Punkt des Gerätes, an dem der höchste Schalldruckpegel herrscht, von der zuständigen Fachstelle messen oder berechnen zu lassen.

- Der Lärmpegel sollte unter 70 dB liegen.
- Beachte lokale Vorgaben zum Gehörschutz.
- Wird das Gerät unter Volllast betrieben, müssen Schutzeinrichtungen wie lärmdämmende Leitbleche, Hauben oder Gehörschutz verwendet werden.

Wartung und Transport

Wartung

Unsachgemäße Wartung oder Reparatur des Gerätes oder die Verwendung von nicht zugelassenen Teilen kann zu Fehlfunktionen oder Schäden am Gerät führen. Dies kann zu Gefahren für den Benutzer führen.

- Soweit nicht ausdrücklich in diesem Handbuch oder anderen Unterlagen von Miltenyi Biotec erwähnt, darf das Gerät nicht vom Benutzer selbst gewartet oder repariert werden.
- Wartungs- und Reparaturarbeiten dürfen nur von Personen durchgeführt werden, die von Miltenyi Biotec zertifiziert und entsprechend qualifiziert sind.
- Vor der Wartung muss das Gerät dekontaminiert werden, um gefährliche Stoffe zu entfernen.
- Wenn Sie Fragen zur ordnungsgemäßen Dekontamination und dem Versand haben, kontaktieren Sie Miltenyi Biotec Technical Support.
- Verwenden Sie nur von Miltenyi Biotec empfohlene Zubehörteile und Upgrades.
- Wenn Sie mehr über das umfangreiche Serviceangebot und die Wartungsverträge in Verbindung mit den Geräten von Miltenyi Biotec erfahren möchten, wenden Sie sich an Ihren regionalen Miltenyi Biotec Vertreter oder besuchen Sie **www.miltenyibiotec.com/support**.

Transport

Das Gerät sollte immer vorsichtig und nur in der von Miltenyi Biotec vorgegebenen Verpackung transportiert werden. Muss das Gerät zur Wartung zurück an den Hersteller geschickt werden, so nehmen Sie bezüglich weiterer Anweisungen und der Verpackung Kontakt mit Miltenyi Biotec auf. Interne Beschädigungen können auftreten, wenn das Instrument übermäßigen Vibrationen ausgesetzt wird oder wenn es herunterfällt.

Entsorgung



KUNDENINFORMATION ZUR ENTSORGUNG VON ELEKTRO- UND ELEKTRONIK-ALTGERÄTEN (WEEE)
Entsorgen Sie Ihre Altgeräte von Miltenyi Biotec unter Einhaltung der jeweils geltenden Vorschriften für die Entsorgung von Elektro- und Elektronik-Altgeräten und die Entsorgung von Gefahrstoffen, die je nach Land oder Region unterschiedlich sein können. Elektrische Geräte können gefährliche Stoffe enthalten, welche die Umwelt erheblich belasten und/oder die Gesundheit gefährden. Sämtliche Altgeräte müssen gesondert gesammelt und von ausgewiesenen Abfallentsorgungseinrichtungen im Rahmen der hierfür vorgesehenen Entsorgungssysteme fachgerecht behandelt werden. Indem Sie sicherstellen, dass ihr Altgerät gemäß den geltenden Vorschriften zur Behandlung von Elektro- und Elektronik-Altgeräten sowie von Gefahrstoffen entsorgt wird, tragen Sie zum Erhalt unserer natürlichen Ressourcen und zum Schutz der menschlichen Gesundheit bei. Miltenyi Biotec hat sich dem Schutz der Umwelt verpflichtet. Miltenyi Biotec bietet in zahlreichen Ländern Rücknahmeprogramme für Altgeräte an und arbeitet weltweit mit lizensierten Partnern zusammen, die an bestehende Recycling- und Entsorgungssysteme angeschlossen sind. Miltenyi Biotec ermöglicht Ihnen ein kostenloses Recycling Ihres Altgerätes. Die Bedingungen und die Verfügbarkeit dieses Angebots unterscheiden sich geographisch aufgrund unterschiedlicher regulatorischer Anforderungen. Beachten Sie, dass je nach Art und Nutzung Ihres Gerätes zusätzliche Anforderungen gelten können. Bevor Sie das Altgerät an den Hersteller zur Entsorgung zurücksenden, dekontaminieren Sie es, um sämtliche gefährlichen Stoffe zu entfernen. Für weitere Informationen oder wenn Sie Altgeräte von Miltenyi Biotec entsorgen möchten, wenden Sie sich an Ihren lokalen Vertreter von Miltenyi Biotec oder an den Miltenyi Biotec Technical Support.

ES

Información importante de seguridad

Instrucciones generales de seguridad



EN ESTE CAPÍTULO SE DESCRIBEN SITUACIONES POTENCIALMENTE PELIGROSAS ASOCIADAS CON ESTE INSTRUMENTO Y SE PROPORCIONA INFORMACIÓN IMPORTANTE SOBRE SEGURIDAD PARA MINIMIZAR LOS RIESGOS Y PROTEGERSE A SÍ MISMO Y A LOS DEMÁS.

Este capítulo ofrece información importante para su seguridad personal y el correcto uso del instrumento. Lea y siga todas las instrucciones atentamente antes de la instalación y el uso del instrumento. Siga las prácticas de seguridad generales además de este manual de uso.

- Use este instrumento solo como se indica en este manual de uso para evitar lesiones personales y daños materiales.
- Guarde este manual de uso en un lugar que siempre esté accesible para todos los usuarios.
- Observe las instrucciones de seguridad de la zona de trabajo local y las políticas de laboratorio, así como las normas de salud, seguridad y prevención de accidentes.
- En caso de accidentes graves, daños en el instrumento o si aparece humo o llamas, corte de inmediato el suministro de la corriente eléctrica.
- Para desconectar completamente el instrumento del suministro de la corriente eléctrica, desenchufe el cable de alimentación.
- Asegúrese de que se pueda acceder fácilmente al interruptor de corriente y al enchufe del cable de alimentación del instrumento.

Niveles de riesgo

Las palabras de advertencia se utilizan para advertir contra situaciones peligrosas y daños materiales.En este manual de uso se utilizan las siguientes palabras de advertencia.

⚠ ADVERTENCIA o ¡ADVERTENCIA! indica una situación peligrosa que, de no evitarse, podría conllevar la muerte o lesiones graves.

⚠ ATENCIÓN o ¡ATENCIÓN! indica una situación peligrosa que, de no evitarse, podría conllevar lesiones leves o moderadas. También sirve para advertir sobre prácticas poco seguras.

***AVISO* o AVISO indica información que se considera importante, pero no relacionada con un peligro (p. ej., mensajes relacionados con daños materiales).**

Símbolos



ADVERTENCIA DE SEGURIDAD: SE DEBE CONSULTAR LA DOCUMENTACIÓN EN TODOS LOS CASOS EN QUE SE UTILICE ESTE SÍMBOLO DE SEGURIDAD EN EL INSTRUMENTO



PIEZAS GIRATORIAS

ON (ENCENDIDO)



OFF (APAGADO)



LEA EL MANUAL DE USO ANTES DE USAR EL INSTRUMENTO



FUSIBLE



INFORMACIÓN AL CLIENTE SOBRE LA DIRECTIVA DE RESIDUOS DE APARATOS ELÉCTRICOS Y ELECTRÓNICOS (RAEE)



NÚMERO DE PEDIDO



NÚMERO DEL MODELO



NÚMERO DE SERIE



FABRICANTE



FECHA DE FABRICACIÓN



MARCADO DE CONFORMIDAD EUROPEA



CONFORMIDAD EVALUADA DEL REINO UNIDO



MARCA DE CERTIFICACIÓN NRTL: EL PRODUCTO CUMPLE LOS ESTÁNDARES DE SEGURIDAD CONSENSUADOS, REQUERIDOS POR LA ADMINISTRACIÓN DE SEGURIDAD Y SALUD OCUPACIONAL (OSHA), DETERMINADOS POR LOS LABORATORIOS DE ENSAYO RECONOCIDOS NACIONALMENTE (NATIONALLY RECOGNIZED TESTING LABORATORIES, NRTL) TÜV SÜD

Etiqueta de seguridad

Observe los puntos de peligro y los símbolos de seguridad del instrumento. Mantenga las etiquetas y marcas de seguridad en un estado limpio y legible. Inspeccione las etiquetas y marcas de seguridad con regularidad, y reemplácelas si no son legibles o identificables desde una distancia de visualización segura. Póngase en contacto con Miltenyi Biotec si necesita etiquetas de recambio.

Los gentleMACS Sleeves están marcados con una impresión de seguridad de contraste. La impresión de seguridad de contraste permite la percepción visual de la rotación de los gentleMACS Sleeves. El gentleMACS Trough va marcado con el siguiente símbolo de seguridad.

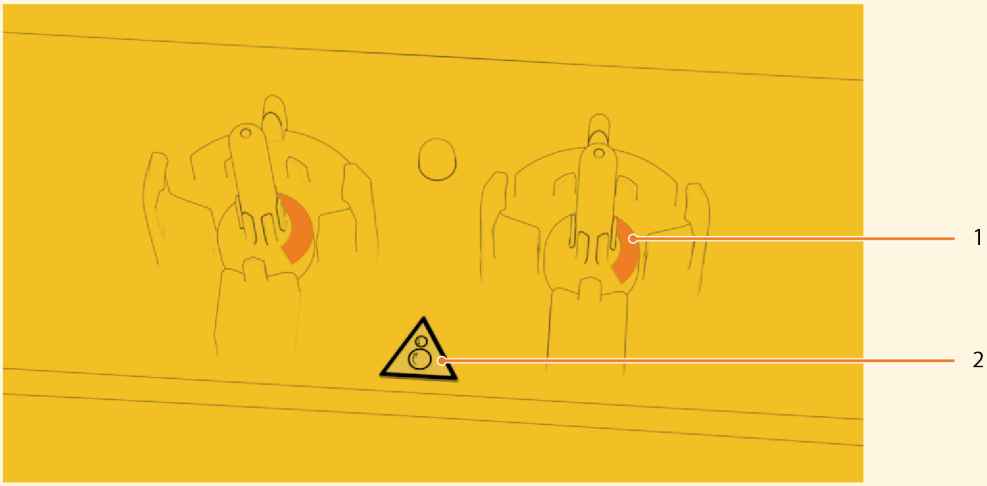


Figura 1: Símbolo de seguridad en el gentleMACS Trough y estampado de seguridad en contraste en los gentleMACS Sleeves

1 Estampado de seguridad en contraste en los gentleMACS Sleeves
2 Símbolo de seguridad en el gentleMACS Trough

Peligros eléctricos

⚠ ADVERTENCIA

Una descarga eléctrica, un cortocircuito, un sobrecalentamiento, un incendio o una explosión podría causar la muerte o lesiones graves.

Carcasa protectora

La carcasa del instrumento reduce el riesgo de un shock eléctrico y cortocircuitos.

- No retire ni perfore ninguna cubierta de la carcasa.
- Las excepciones son los procesos de mantenimiento que se describen explícitamente en este manual.
- No utilice el instrumento si se ha abierto o desmontado.
- No utilice el instrumento si un objeto ha entrado en el interior del mismo.
- Antes de cada uso, revise el instrumento para ver si presenta daños visibles.
- No utilice el instrumento si se ha caído o dañado.

Cables y suministros de corriente eléctrica

Usar el instrumento con otros cables que no sean los suministrados es potencialmente peligroso.

- Utilice únicamente el cable de alimentación incluido.

- No utilice el instrumento si el cable de alimentación está dañado.
- El instrumento tiene un enchufe eléctrico de tres hilos con una tercera clavija para la conexión a tierra.
- Inserte el enchufe solo en una toma de corriente con conexión a tierra. No intente insertar el enchufe en una toma de corriente sin conexión a tierra.
- Utilice el instrumento solo con una fuente de alimentación que cumpla las especificaciones eléctricas mencionadas en la placa de identificación. Si tiene alguna pregunta sobre la fuente de alimentación que debe utilizarse, póngase en contacto con el Miltenyi Biotec Technical Support o con la compañía eléctrica local.

Líquidos en el interior del instrumento

Los líquidos que hay dentro del instrumento pueden provocar cortocircuitos.

- Proteja el instrumento contra líquidos derramados.
- No utilice el instrumento si ha entrado algún líquido en el interior del instrumento.
- Si han entrado líquidos en el instrumento, desenchúfelo y póngase en contacto con Miltenyi Biotec Technical Support.
- Limpie los líquidos derramados inmediatamente.
- Desenchufe el instrumento antes de limpiarlo.
- Use solo pequeñas cantidades de productos de limpieza en un paño suave para limpiar el instrumento. No rocíe ni vierta productos de limpieza líquidos sobre o dentro del instrumento.

Peligros mecánicos

⚠ ATENCIÓN

Riesgo de aplastamiento.

El instrumento se caerá si no se coloca sobre una superficie plana y uniforme, lo que podría causar lesiones.

- Coloque el instrumento sobre una mesa o bancada de laboratorio estable, uniforme y sin vibraciones.
- Manipule el instrumento con cuidado al transportarlo o trasladarlo.

⚠ ATENCIÓN

Riesgo de aplastamiento o corte.

Los tapones de los Tubos gentleMACS tienen bordes afilados en el interior. Pueden causar heridas por incisión si se tocan mientras giran.

- Utilice únicamente tubos bien cerrados y asegúrese de que estén correctamente instalados.
- No instale ni retire tubos mientras los rotores del instrumento están en movimiento.

⚠ ATENCIÓN

Riesgo de atrapamiento de los dedos y el cabello.

Los rotores pueden arrastrar el cabello mientras el instrumento está en funcionamiento.

- No utilice el instrumento sin el gentleMACS Trough, los gentleMACS Sleeves ni el gentleMACS Safety Shield.
- Recoge el pelo largo.
- No toque los rotores mientras el instrumento está en funcionamiento.

Peligros biológicos

⚠ ADVERTENCIA

La contaminación o infección podría causar la muerte o lesiones graves en función del material utilizado.

Material biológico

Todo material biológico debe considerarse potencialmente infeccioso.

- Use equipo de protección personal (como guantes, gafas de seguridad, etc.) como se indica en la hoja de datos de seguridad de la sustancia en particular.
- Maneje el instrumento en una cubierta de seguridad si se procesan materiales peligrosos o potencialmente infecciosos.
- Descontamine el instrumento después de procesar material peligroso o potencialmente infeccioso.
- Si se ha derramado o fugado del sistema un material peligroso o potencialmente infeccioso, descontamine el área afectada.
- Use un desinfectante o producto de limpieza que sea apropiado para el patógeno o sustancia en cuestión.

Desechos

Todos los desechos líquidos y sólidos deben ser considerados peligrosos.

- Observe las regulaciones locales sobre la eliminación de desechos.
- Ponga en autoclave o, como alternativa, descontamine los desechos con un desinfectante apropiado.

Peligros químicos

⚠ ADVERTENCIA

Las sustancias y los reactivos pueden ser peligrosos.

- Todas las medidas de seguridad del apartado **Peligros biológicos** se aplican también a todas las sustancias y reactivos peligrosos que puedan estar presente en la muestra.
- Utilice el instrumento en una campana para vapores si se procesan sustancias y reactivos peligrosos.

Ruido

⚠ ATENCIÓN

Un alto nivel de ruido puede conllevar una pérdida auditiva.

Si se utiliza con la carga máxima, el instrumento puede producir un ruido fuerte. Se recomienda que el cuerpo responsable mida o calcule el nivel de presión acústica en el puesto del operario y en cualquier punto a 1 metro del recinto del equipo que tenga el mayor nivel de presión acústica.

- El nivel de ruido debe ser inferior a 70 dB.
- Observe las normas locales sobre protección auditiva.
- Si se utiliza el instrumento con la carga máxima, se debe usar equipo de seguridad de protección como, por ejemplo, deflectores que reduzcan el ruido, cubiertas o protección auditiva.

Reparación y transporte

Reparación

La reparación inadecuada del instrumento o el uso de piezas no autorizadas pueden provocar un mal funcionamiento o daños en el instrumento. Esto puede constituir un peligro para los usuarios.

- A menos que se indique específicamente lo contrario en este manual del usuario o en otros documentos de Miltenyi Biotec, no realice usted mismo los trabajos demantenimiento y reparación del instrumento.
- La reparación debe ser realizada por personal de servicio cualificado y certificado por Miltenyi Biotec.
- Si el instrumento necesita reparación, descontamínelo para eliminar cualquier material peligroso.
- Si tiene alguna pregunta relativa a la descontaminación o el envío adecuados, póngase en contacto con el Miltenyi Biotec Technical Support para que le ayuden.
- Utilice solo accesorios y actualizaciones recomendados por Miltenyi Biotec.
- Consulte a su representante local de Miltenyi Biotec sobre el amplio servicio de reparaciones de instrumentos y los contratos de reparaciones de Miltenyi Biotec, o visite **www.miltenyibiotec.com/support**.

Transporte

El instrumento deberá transportarse con cuidado en el embalaje especificado por Miltenyi Biotec. Se podrían producir daños internos si el instrumento se somete a un exceso de vibraciones o se cae. Si es necesario enviar el instrumento al fabricante para su reparación, comuníquese con Miltenyi Biotec para obtener instrucciones y materiales de embalaje.

Eliminación



INFORMACIÓN AL CLIENTE SOBRE LA DIRECTIVA DE RESIDUOS DE APARATOS ELÉCTRICOS Y ELECTRÓNICOS (RAEE)

Elimine los productos de Miltenyi Biotec al final de su vida útil de acuerdo con la legislación aplicable en materia de eliminación de residuos peligrosos y RAEE, que puede variar según el país o la región. El equipo eléctrico puede contener sustancias peligrosas que pueden tener un efecto perjudicial grave en el medio ambiente y/o la salud humana. Todo el equipo debe ser recogido y tratado específicamente en instalaciones de desechos designadas y en sistemas conformes a la legislación sobre RAEE. Al asegurarse de desechar sus aparatos eléctricos y electrónicos no deseados de acuerdo con la legislación aplicable sobre eliminación de desechos peligrosos y RAEE, está ayudando a preservar nuestros recursos naturales y proteger la salud humana. Miltenyi Biotec se compromete a proteger el medio ambiente. Miltenyi Biotec ofrece programas de devolución de productos al final de su vida útil en muchos países y socios con licencia que disponen de sistemas conformes a la legislación sobre RAEE en todo el mundo. Miltenyi Biotec recoge su equipo Miltenyi Biotec al final de su vida útil para reciclarlo de forma gratuita. Los términos y la disponibilidad de esta oferta pueden variar según la región geográfica, debido a las diferencias en los requisitos reglementarios. Tenga en cuenta que, dependiendo del tipo y uso del equipo, pueden aplicarse requisitos adicionales. Antes de devolver el instrumento al fabricante para que lo deseche, descontamine el instrumento para eliminar cualquier material peligroso. Para obtener más información, o si desea desechar su equipo Miltenyi Biotec al final de su vida útil, póngase en contacto con su representante local de Miltenyi Biotec o con el Miltenyi Biotec Technical Support.

FR

Informations de sécurité importantes

Instructions générales de sécurité



CE CHAPITRE DÉCRIT LES SITUATIONS POTENTIELLEMENT DANGEREUSES ASSOCIÉES À CET INSTRUMENT ET FOURNIT DES INFORMATIONS DE SÉCURITÉ IMPORTANTES DESTINÉES À RÉDUIRE LES RISQUES ET À VOUS PROTÉGER AINSI QU'À PROTÉGER LES AUTRES.

Le présent chapitre donne des informations importantes pour votre sécurité personnelle et pour l'utilisation correcte de l'instrument. Veuillez lire attentivement toutes les instructions et les retenir avant de procéder à l'installation de l'instrument et d'utiliser celui-ci. Appliquez les mesures de sécurité générales en plus de celles exposées dans le manuel d'utilisation.

- Utilisez toujours cet instrument en suivant les indications fournies dans ce manuel d'utilisation, afin d'éviter toute blessure et tous dommages matériels.
- Conservez ce Guide de l'Utilisateur dans un endroit qui reste toujours accessible à tous les utilisateurs.
- Respecter les consignes de sécurité sur le lieu de travail et les protocoles de laboratoire, ainsi que les normes en matière de santé, de sécurité et de prévention des accidents.
- En cas d'accident grave, d'endommagement de l'instrument ou si de la fumée ou des flammes apparaissent, coupez immédiatement l'alimentation électrique.
- Pour éteindre entièrement l'instrument de l'alimentation électrique, débranchez le câble d'alimentation.
- Assurez-vous que l'interrupteur principal et la prise du câble d'alimentation de l'instrument soient facilement accessibles.

Niveaux de danger

Les mots d'avertissement sont utilisés pour mettre l'utilisateur en garde contre des situations dangereuses et des dommages matériels. Les mots d'avertissement suivants sont utilisés dans ce Guide de l'Utilisateur.

⚠ AVERTISSEMENT ou AVERTISSEMENT ! signale une situation dangereuse qui, si elle n'est pas évitée, peut causer la mort ou des blessures graves.

⚠ ATTENTION ou ATTENTION ! signale une situation dangereuse qui, si elle n'est pas évitée, peut causer des blessures de gravité mineure ou modérée. Il est aussi utilisé pour mettre en garde contre des pratiques dangereuses.

***AVIS* ou AVIS signale des informations jugées importantes mais qui ne concernent pas un danger (p. ex. les messages relatifs à des dommages matériels).**

Symboles



AVERTISSEMENT DE SÉCURITÉ : LA DOCUMENTATION DOIT ÊTRE CONSULTÉE DANS TOUS LES CAS OÙ CE SYMBOLE DE SÉCURITÉ EST UTILISÉ SUR L'INSTRUMENT



PIÈCES EN ROTATION

MARCHE (INSTRUMENT ALLUMÉ)



ARRÊT (INSTRUMENT ÉTEINT)



LISEZ LE GUIDE DE L'UTILISATEUR AVANT D'UTILISER L'INSTRUMENT



FUSIBLE



DEEE (DÉCHETS D'ÉQUIPEMENTS ÉLECTRIQUES ET ÉLECTRONIQUES)



NUMÉRO DE COMMANDE



NUMÉRO DE MODÈLE



NUMÉRO DE SÉRIE



FABRICANT



DATE DE FABRICATION



MARQUAGE DE CONFORMITÉ EUROPÉENNE



MARQUAGE DE PRODUIT DU ROYAUME-UNI



MARQUE DE CERTIFICATION NRTL : LE PRODUIT RÉPOND AUX NORMES DE SÉCURITÉ CONSENSUELLES IMPOSÉES PAR L'OCCUPATIONAL SAFETY/HEALTH ADMINISTRATION (OSHA), DÉTERMINÉES PAR LES NATIONALLY RECOGNIZED TESTING LABORATORIES (NRTL) TÜV SÜD

Étiquettes de sécurité

Repérez les points dangereux et les symboles de sécurité de l'instrument. Maintenez les étiquettes et les marquages de sécurité propres et lisibles. Contrôlez régulièrement les étiquettes et marquages de sécurité et remplacez ceux qui ne sont pas lisibles ou identifiables à une distance sûre. Contactez Miltenyi Biotec pour obtenir des étiquettes de rechange.

Les gentleMACS Sleeves comportent une impression de sécurité contrastante. Le marquage de sécurité contrastant signale visuellement la rotation des gentleMACS Sleeves.Le gentleMACS Trough comporte le symbole de sécurité suivant.

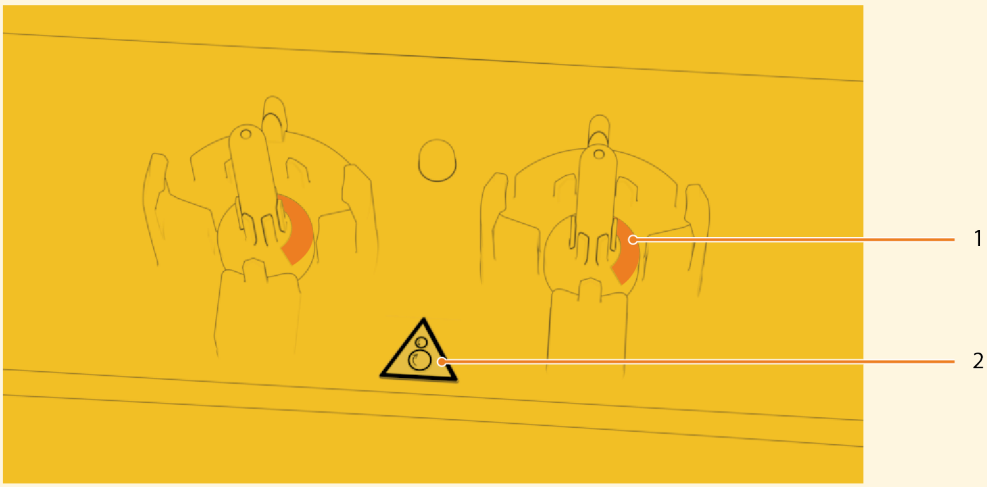


Figure 1: Symbole de sécurité sur le gentleMACS Trough et impression de sécurité contrastée sur les gentleMACS Sleeves

1 Impression de sécurité contrastée sur les gentleMACS Sleeves
2 Symbole de sécurité sur le gentleMACS Trough

Dangers électriques

⚠ AVERTISSEMENT

Un choc électrique, un court-circuit, une surchauffe, un incendie ou une explosion peuvent causer des blessures graves ou la mort.

Boîtier de protection

Le boîtier de l'instrument réduit le risque de choc électrique et de court-circuit.

- Ne retirez pas et ne franchissez pas les capots du boîtier.
- Les procédures de maintenance explicitement décrites dans le présent manuel sont les seules exceptions.
- N'utilisez pas l'instrument s'il est ouvert ou démonté.
- N'utilisez pas l'instrument si un objet a pénétré à l'intérieur de l'instrument.
- Avant chaque utilisation, vérifiez que l'instrument ne présente pas de dommages visibles.
- N'utilisez pas l'instrument s'il est tombé ou endommagé.

Câbles et alimentation électrique

L'utilisation de l'instrument avec d'autres câbles que ceux fournis peut être dangereuse.

- Utilisez uniquement le câble d'alimentation fourni.

- N'utilisez pas l'instrument si le câble d'alimentation est endommagé.
- L'instrument a une prise trifilaire dont une troisième fiche pour la mise à la terre.
- Insérer la fiche uniquement dans une prise électrique reliée à la terre. Ne pas essayer d'insérer la fiche dans une prise électrique non reliée à la terre.
- Utilisez l'instrument uniquement avec une source d'alimentation qui est conforme aux spécifications électriques figurant sur la plaque signalétique. Si vous avez des questions sur le type de source d'alimentation à utiliser, contactez le Miltenyi Biotec Technical Support ou votre fournisseur d'électricité local.

Liquides à l'intérieur de l'instrument

Du liquide dans l'instrument peut entraîner des courts-circuits.

- Protégez l'instrument des liquides renversés.
- Ne pas utiliser l'instrument si du liquide s'est répandu à l'intérieur.
- Si du liquide s'est répandu dans l'instrument, le débrancher et contacter le service Miltenyi Biotec Technical Support.
- Nettoyez immédiatement tout liquide renversé.
- Débranchez l'instrument avant de le nettoyer.
- Utilisez uniquement de petites quantités d'agents de nettoyage sur un chiffon doux pour essuyer l'instrument. Ne vaporisez et ne versez pas d'agents de nettoyage sur ou dans l'instrument.

Dangers mécaniques

⚠ ATTENTION

Risque d'écrasement.

S'il n'est pas placé sur une surface plane et régulière, l'instrument peut tomber et causer des blessures.

- Placez l'instrument uniquement sur des tables ou des paillasses stables, planes et sans vibrations.
- Manipuler l'instrument avec précaution lors du transport ou repositionnement.

⚠ ATTENTION

Risque d'écrasement ou de coupure.

Les bouchons des tubes gentleMACS ont des bords tranchants à l'intérieur. Il existe un risque de blessure par incision en cas de contact avec les bouchons en rotation.

- Utilisez uniquement des tubes rigoureusement fermés et assurez-vous qu'ils sont correctement installés.
- N'installez et ne retirez pas les tubes lorsque les rotors de l'instrument sont en mouvement.

⚠ ATTENTION

Risque de pincement des doigts et de happement des cheveux.

Les cheveux peuvent être happés par les rotors lorsque l'instrument est en cours de fonctionnement.

- N'utilisez pas l'instrument sans le gentleMACS Trough, les gentleMACS Sleeves, et le gentleMACS Safety Shield.
- Attacher les cheveux longs.
- Ne touchez pas les rotors lorsque l'instrument est en cours de fonctionnement.

Dangers biologiques

⚠ AVERTISSEMENT

Selon le matériel utilisé, une contamination ou une infection peuvent causer des blessures graves ou la mort.

Matériel biologique

Tous les matériels biologiques doivent être considérés comme potentiellement infectieux.

- Portez des équipements de protection individuelle (tels que des gants, lunettes de protection, etc.) suivant les indications fournies dans la fiche de données de sécurité de la substance en question.
- Utilisez l'instrument dans une hotte de protection si vous manipulez des matériels dangereux ou potentiellement infectieux.
- Décontaminez l'instrument après la manipulation de matériel dangereux ou potentiellement infectieux.
- En cas de dispersion ou de fuite de matériel dangereux ou potentiellement infectieux du système, décontaminez la zone touchée.
- Utilisez un agent de désinfection ou de nettoyage approprié pour l'agent pathogène ou la substance particulière.

Déchets

Tous les déchets liquides et solides doivent être considérés comme dangereux.

- Respecter les réglementations locales relatives à l'élimination des déchets.
- Autoclavez les déchets ou décontaminez-les à l'aide d'un désinfectant approprié.

Dangers chimiques

⚠ AVERTISSEMENT

Les substances et les réactifs peuvent être dangereux.

- Toutes les mesures de sécurité indiquées à la rubrique **Dangers biologiques** s'appliquent également à toutes les substances ou tous les réactifs susceptibles d'être présents dans l'échantillon.
- Utilisez l'instrument sous une hotte si des substances et réactifs dangereux sont traités.

Bruit

⚠ ATTENTION

Les niveaux sonores élevés peuvent provoquer une déficience auditive.

S'il fonctionne à pleine charge, l'instrument peut produire un bruit fort.Il est recommandé que l'instance responsable mesure ou calcule le niveau de pression acoustique au poste de l'opérateur et en tout point à 1 m autour de l'équipement qui présente le niveau de pression acoustique le plus élevé.

- Le niveau de bruit doit être inférieur à 70 dB.
- Observez les réglementations locales en matière de protection auditive.
- Si l'instrument fonctionne à pleine charge, des équipements de sécurité tels que des écrans acoustiques, des capots ou une protection auditive doivent être utilisés.

Maintenance et transport

Maintenance

Une maintenance ou une réparation inappropriée de l'instrument ou l'utilisation de pièces non autorisées peut provoquer un dysfonctionnement de l'instrument ou l'endommager. Cela peut mettre en danger les utilisateurs.

- Sauf indication contraire dans ce manuel d'utilisation ou dans toute autre documentation fournie par Miltenyi Biotec, ne procédez pas vous-même à l'entretien ou la réparation de l'instrument.
- La maintenace et la réparation doivent être effectuées par du personnel de maintenance Miltenyi Biotec qualifié et certifié.
- Si l'instrument doit être révisé, décontaminez-le pour éliminer toute matière dangereuse.
- Si vous avez des questions sur la décontamination ou l'envoi, veuillez contacter le Miltenyi Biotec Technical Support pour obtenir de l'aide.
- Utilisez uniquement les accessoires et les mises à jour recommandés par Miltenyi Biotec.
- Contactez votre représentant local Miltenyi Biotec pour en savoir plus sur la révision des instruments et les contrats de révision de Miltenyi Biotec, ou consultez le site **www.miltenyibiotec.com/support**.

Transport

L'instrument doit être transporté avec soin dans l'emballage indiqué par Miltenyi Biotec. Des dommages internes peuvent se produire si l'instrument est soumis à des vibrations excessives ou à une chute. Si l'instrument doit être renvoyé au fabricant pour maintenance, contactez Miltenyi Biotec pour obtenir les instructions et le matériel d'emballage.

Élimination



INFORMATION CLIENT SUR LES DÉCHETS D'ÉQUIPEMENTS ÉLECTRIQUES ET ÉLECTRONIQUES (DEEE)
Éliminez vos produits Miltenyi Biotec en fin de vie conformément à la directive DEEE et à la législation applicable relative à l'élimination des déchets dangereux, qui peut varier en fonction du pays ou de la région. Les équipements électriques peuvent contenir des substances dangereuses susceptibles d'avoir un effet nocif grave sur l'environnement et/ou la santé humaine. Tous les équipements doivent être spécifiquement collectés et traités par des établissements désignés de gestion des déchets et des systèmes qualifiés de conformité à la directive DEEE. En veillant à éliminer vos déchets d'équipements électriques et électroniques en accord avec la directive DEEE et la législation applicable relative à l'élimination des déchets dangereux, vous contribuez à la préservation des ressources naturelles et à la protection de la santé humaine. Miltenyi Biotec s'engage à protéger l'environnement. Miltenyi Biotec propose des programmes de retour des produits en fin de vie dans de nombreux pays, et conclut des partenariats avec des établissements conduisant des systèmes de conformité DEEE agréés dans le monde entier. Miltenyi Biotec reprend et recycle gratuitement vos équipements Miltenyi Biotec en fin de vie. Les conditions et la disponibilité de cette offre varient selon les pays et les différentes exigences réglementaires. Selon le type et l'utilisation de votre équipement, des exigences suppléméntaires peuvent s'appliquer. Avant d'expédier l'instrument au fabricant pour élimination, décontaminez-le pour éliminer tout matériel dangereux. Pour de plus amples informations, ou si vous souhaitez éliminer votre équipement Miltenyi Biotec arrivé en fin de vie, veuillez contacter votre représentant Miltenyi Biotec local ou le Miltenyi Biotec Technical Support.

IT

Importanti istruzioni di sicurezza

Istruzioni generali di sicurezza



NEL PRESENTE CAPITOLO SI DESCRIVONO LE SITUAZIONI POTENZIALMENTE PERICOLOSE ASSOCIATE A QUESTO STRUMENTO E SI FORNISCONO INFORMAZIONI IMPORTANTI SULLA SICUREZZA PER RIDURRE AL MINIMO I RISCHI E PROTEGGERE SE STESSI E GLI ALTRI.

Nel presente capitolo si forniscono informazioni importanti per la sicurezza personale e l'uso corretto dello strumento. Leggere e osservare attentamente tutte le istruzioni prima di procedere all'installazione e all'utilizzo dello strumento. Osservare le prassi generali in materia di sicurezza, oltre al presente manuale d'uso.

- Per evitare lesioni personali e danni materiali, utilizzare lo strumento solo come indicato nel presente manuale d'uso.
- Conservare il manuale d'uso in un luogo che sia sempre accessibile a tutti gli utilizzatori.
- Osservare le istruzioni locali per la sicurezza sul posto di lavoro, le prassi di laboratorio locali e le norme in materia di salute, sicurezza e prevenzione degli incidenti.
- In caso di incidenti gravi, danni allo strumento o comparsa di fumo o fiamme, interrompere immediatamente l'alimentazione elettrica.
- Per scollegare completamente lo strumento dall'alimentazione elettrica, staccare il cavo di alimentazione dalla presa.
- Assicurarsi che l'interruttore di alimentazione e la spina del cavo di alimentazione dello strumento siano facilmente accessibili.

Livelli di pericolo

Le indicazioni di avvertenza servono a mettere in guardia su situazioni pericolose e danni materiali. Nel presente manuale d'uso si utilizzano le seguenti indicazioni di avvertenza.

⚠ AVVERTENZA o AVVERTENZA! indica una situazione pericolosa che, se non evitata, potrebbe provocare decesso o gravi lesioni.

⚠ ATTENZIONE o ATTENZIONE! indica una situazione pericolosa che, se non evitata, potrebbe provocare lesioni di entità minore o moderata. Serve anche a mettere in guardia su pratiche non sicure.

***AVVISO* o AVVISO indica informazioni considerate importanti ma non correlate a pericoli (ad esempio messaggi relativi a danni materiali).**

Simboli


AVVERTENZA DI SICUREZZA: CONSULTARE LA DOCUMENTAZIONE IN TUTTI I CASI IN CUI SULLO STRUMENTO COMPARE QUESTO SIMBOLO DI SICUREZZA


PARTI ROTANTI

ON (ACCESO)


OFF (SPENTO)


LEGGERE IL MANUALE D'USO PRIMA DI UTILIZZARE LO STRUMENTO


FUSIBILE


RAEE (RIFIUTI DI APPARECCHIATURE ELETTRICHE ED ELETTRONICHE)



NUMERO D'ORDINE



NUMERO DI IDENTIFICAZIONE



NUMERO DI SERIE


FABBRICANTE


DATA DI FABBRICAZIONE


MARCATURA DI CONFORMITÀ EUROPEA



CONFORMITÀ VALUTATA DEL REGNO UNITO



MARCHI DI CERTIFICAZIONE NRTL: IL PRODOTTO È CONFORME ALLE NORME DI SICUREZZA, BASATE SUL CONSENSO, IMPOSTE DALL'AMMINISTRAZIONE DELLA SICUREZZA E DELLA SALUTE SUL LAVORO (OSHA), DETERMINATE DAL LABORATORIO DI PROVA RICONOSCIUTO A LIVELLO NAZIONALE (NRTL) TÜV SÜD

Etichette di sicurezza

Prestare attenzione ai punti pericolosi e ai simboli di sicurezza dello strumento.Mantenere le etichette e i contrassegni sicurezza puliti e leggibili.Controllare regolarmente le etichette e i contrassegni di sicurezza e sostituirli se non sono leggibili o identificabili da una distanza sicura.Contattare Miltenyi Biotec per la sostituzione delle etichette.

I gentleMACS Sleeves sono contrassegnati da una stampa di sicurezza a contrasto. La stampa di sicurezza a contrasto rende visibile la rotazione dei gentleMACS Sleeves.Il gentleMACS Trough è contrassegnato dal seguente simbolo di sicurezza.

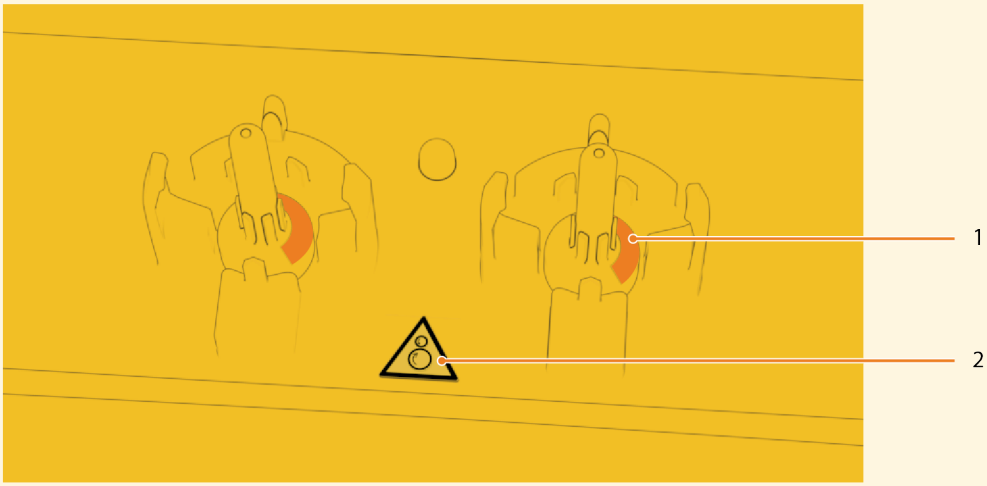


Figura 1: Simbolo di sicurezza sul gentleMACS Trough e stampa di sicurezza a contrasto sui gentleMACS Sleeves

1	Stampa di sicurezza a contrasto sui genleMACS Sleeves
2	Simbolo di sicurezza sul gentleMACS Trough

Pericoli elettrici

⚠ AVVERTENZA

Scosse elettriche, cortocircuiti, surriscaldamento, incendi ed esplosioni potrebbero causare morte o gravi lesioni.

Alloggiamento di protezione

L'alloggiamento dello strumento riduce il rischio di scosse elettriche e corto circuiti.

- Non rimuovere né perforare le coperture dell'alloggiamento.
- Fanno eccezione le procedure di manutenzione esplicitamente descritte nel presente manuale.
- Non utilizzare lo strumento se è aperto o smontato.
- Non usare lo strumento se un oggetto è entrato al suo interno.
- Prima di ogni utilizzo, verificare che lo strumento non presenti danni visibili.
- Non usare lo strumento se è caduto o danneggiato.

Cavi e alimentazione elettrica

L'uso dello strumento con cavi diversi da quelli forniti in dotazione è potenzialmente pericoloso.

- Utilizzare esclusivamente il cavo di alimentazione incluso.

- Non utilizzare lo strumento se il cavo di alimentazione è danneggiato.
- Lo strumento è dotato di una spina elettrica a tre contatti, che presenta un terzo pin per la messa a terra.
- Inserire la spina solo in una presa elettrica con messa a terra. Non cercare di inserire la spina in una presa elettrica priva di messa a terra.
- Utilizzare lo strumento solo da una fonte di alimentazione conforme alle specifiche elettriche indicate sulla targhetta. In caso di domande sul tipo di fonte di alimentazione da utilizzare, contattare il Miltenyi Biotec Technical Support o il fornitore di elettricità locale.

Liquidi all'interno dello strumento

I liquidi all'interno dello strumento possono causare corto circuiti.

- Proteggere lo strumento da liquidi versati.
- Non utilizzare lo strumento se sono penetrati liquidi all'interno dello strumento.
- In caso di infiltrazione di liquidi all´interno dell´ instrumento, scollegare immediatamente l´instrumento stesso e contattare il Miltenyi Biotec Technical Support.
- Pulire immediatamente i liquidi versati.
- Scollegare lo strumento dall'alimentazione elettrica prima di pulirlo.
- Per pulire lo strumento utilizzare solo piccole quantità di detergente su un panno morbido. Non spruzzare né versare detergenti liquidi sullo strumento o al suo interno.

Pericoli meccanici

⚠ ATTENZIONE

Rischio di schiacciamento.

Lo strumento cade se non viene posizionato su una superficie piana e uniforme, con il rischio di lesioni.

- Posizionare lo strumento solo su tavoli o banchi da laboratorio stabili, piani e senza vibrazioni.
- Maneggiare con cura lo strumento durante il trasporto o il riposizionamento.

⚠ ATTENZIONE

Rischio di taglio o schiacciamento.

I tappi della provetta gentleMACS Tube hanno bordi taglienti all'interno. Ciò può causare tagli se vengono toccati durante la rotazione.

- Utilizzare solo provette ben chiuse e assicurarsi che siano inserite correttamente.
- Non inserire o rimuovere le provette mentre i rotori dello strumento sono in movimento.

⚠ ATTENZIONE

Rischio di intrappolamento di dita e capelli.

I capelli possono essere trascinati dai rotori quando lo strumento è in funzione.

- Non mettere in funzione lo strumento senza il gentleMACS Trough, i gentleMACS Sleeves, e il gentleMACS Safety Shield.
- Legare i capelli lunghi.
- Non toccare i rotori quando lo strumento è in funzione.

Pericoli biologici

⚠ AVVERTENZA

La contaminazione o l'infezione potrebbe causare morte o gravi lesioni, a seconda del materiale utilizzato.

Materiale biologico

Tutto il materiale biologico deve essere considerato potenzialmente infetto.

- Indossare dispositivi di protezione individuale (ad esempio guanti, occhiali di sicurezza ecc.) come indicato nella scheda di dati di sicurezza della specifica sostanza.
- Utilizzare lo strumento in una cappa di sicurezza se vengono trattati materiali pericolosi o potenzialmente infettivi.
- Decontaminare lo strumento dopo aver trattato materiale pericoloso o potenzialmente infetto.
- In caso di perdita o fuoriuscita di materiale pericoloso o potenzialmente infetto dal sistema, decontaminare l'area interessata.
- Utilizzare un disinfettante o un detergente appropriato per l'agente patogeno o la sostanza specifica.

Scarti

Tutti gli scarti solidi e liquidi devono essere considerati pericolosi.

- Osservare le norme locali sullo smaltimento dei rifiuti.
- Sterilizzare gli scarti in autoclave o decontaminarli con un apposito disinfettante.

Pericoli chimici

⚠ AVVERTENZA

Sostanze e reagenti possono essere pericolosi.

- Tutte le misure di sicurezza riportate nella sezione **Pericoli biologici** valgono anche per le sostanze e i reagenti pericolosi eventualmente presenti nel campione.
- Se si stanno trattando sostanze e reagenti pericolosi utilizzare lo strumento sotto cappa.

Rumore

⚠ ATTENZIONE

Livelli di rumore elevati potrebbero provocare danni all'udito.

In caso di funzionamento a carico massimo, lo strumento può produrre un forte rumore.Si raccomanda che l'organismo responsabile misuri o calcoli il livello di pressione sonora nella postazione di lavoro dell'operatore e nel punto a 1 m dall'involucro dell'apparecchiatura che presenta il livello di pressione sonora più elevato.

- Il livello di rumore consigliato dovrebbe essere inferiore a 70 dB.
- Osservare le norme locali in materia di protezione dell'udito.
- Se si utilizza lo strumento con il massimo carico, è necessario utilizzare dispositivi di sicurezza protettivi come baffles fonoassorbenti o cappe per la riduzione del rumore o protezioni per le orecchie.

Manutenzione e trasporto

Interventi di manutenzione

Interventi di manutenzione o riparazione impropri sullo strumento o l'uso di parti non autorizzate possono causare malfunzionamento o danni allo strumento. Ciò può comportare pericoli per gli utilizzatori.

- Salvo quanto altrimenti specificato nel presente manuale d'uso o in altra documentazione di Miltenyi Biotec, la manutenzione o la riparazione dello strumento da soli.
- Gli interventi di manutenzione e riparazione devono essere eseguiti da personale di servizio Miltenyi Biotec certificato e qualificato.
- Se lo strumento necessita di un intervento di manutenzione, decontaminarlo per rimuovere eventuali materiali pericolosi.
- In caso di domande relative a una decontaminazione o a una spedizione corrette, contattare il Miltenyi Biotec Technical Support per ricevere assistenza.
- Utilizzare esclusivamente accessori e aggiornamenti raccomandati da Miltenyi Biotec.
- Per informazioni sull'assistenza estesa e sui contratti di assistenza di Miltenyi Biotec relativi allo strumento, rivolgersi al rappresentante Miltenyi Biotec di zona o visitare la pagina **www.miltenyibiotec.com/support**.

Trasporto

Lo strumento deve essere trasportato con cura nell'imballaggio specificato da Miltenyi Biotec. Danni interni potrebbero verificarsi se lo strumento è soggetto a vibrazioni eccessive o viene fatto cadere. Se lo strumento deve essere rispedito al fabbricante per assistenza, contattare Miltenyi Biotec per istruzioni e materiali di imballaggio.

Smaltimento



INFORMAZIONE PER L'UTILIZZATORE SUI RIFIUTI DI APPARECCHIATURE ELETTRICHE ED ELETTRONICHE (RAEE)
Smaltire i prodotti Miltenyi Biotec al termine del ciclo vita conformemente alla legislazione applicabile in materia di smaltimento dei RAEE e dei rifiuti pericolosi, che può variare da regione a regione e da Paese a Paese. Le apparecchiature elettriche possono contenere sostanze pericolose che a loro volta possono avere un grave effetto deleterio sull'ambiente e/o sulla salute dell'uomo. Tutte le apparecchiature devono essere raccolte e trattate in maniera specifica dagli appositi impianti per la gestione dei rifiuti e tramite piani di conformità RAEE qualificati. Provvedendo a smaltire le apparecchiature elettriche ed elettroniche non più necessarie secondo la legislazione applicabile in materia di RAEE e rifiuti pericolosi, si contribuisce a preservare le risorse naturali e a proteggere la salute dell'uomo. Miltenyi Biotec si impegna a proteggere l'ambiente. Miltenyi Biotec offre in molti Paesi programmi per la restituzione dei prodotti al termine del ciclo vita e collabora in tutto il mondo con piani di conformità RAEE autorizzati. Miltenyi Biotec accetta gratuitamente la restituzione delle apparecchiature Miltenyi Biotec al termine del ciclo vita per avviarle al riciclo. I termini e la disponibilità di questa offerta variano in base all'area geografica a causa delle differenze nei requisiti regolatori. Si noti che, a seconda del tipo di apparecchiatura e del suo impiego, possono valere requisiti aggiuntivi. Prima di rispedire lo strumento al fabbricante per lo smaltimento, decontaminare lo strumento per rimuovere eventuale materiale pericoloso. Per ulteriori informazioni o se si desidera smaltire le apparecchiature Miltenyi Biotec al termine del ciclo vita, contattare il rappresentante locale Miltenyi Biotec oppure il Miltenyi Biotec Technical Support.

1 Introduction

1.1 Intended use

The gentleMACS Dissociator is used as a stand-alone, benchtop, research use only instrument for the generation of single cell suspensions from solid tissue or homogenization of tissues or cells to isolate subcellular material. A number of predefined programs offer a variety of processes for tissue dissociation and tissue homogenization. A single sample or two samples in parallel can be processed in gentleMACS Tubes. The gentleMACS Dissociator is for research-use only in laboratory environment. It is to be used by laboratory professional users only.

1.2 Instrument schematics

1	gentleMACS Safety Shield, referred to as Safety Shield	**6**	Power port
2	Touchscreen	**7**	LAN port
3	gentleMACS Sleeve, referred to as Sleeve	**8**	USB port
4	Type label	**9**	2D barcode reader
5	Power switch	**10**	gentleMACS Trough, referred to as Trough

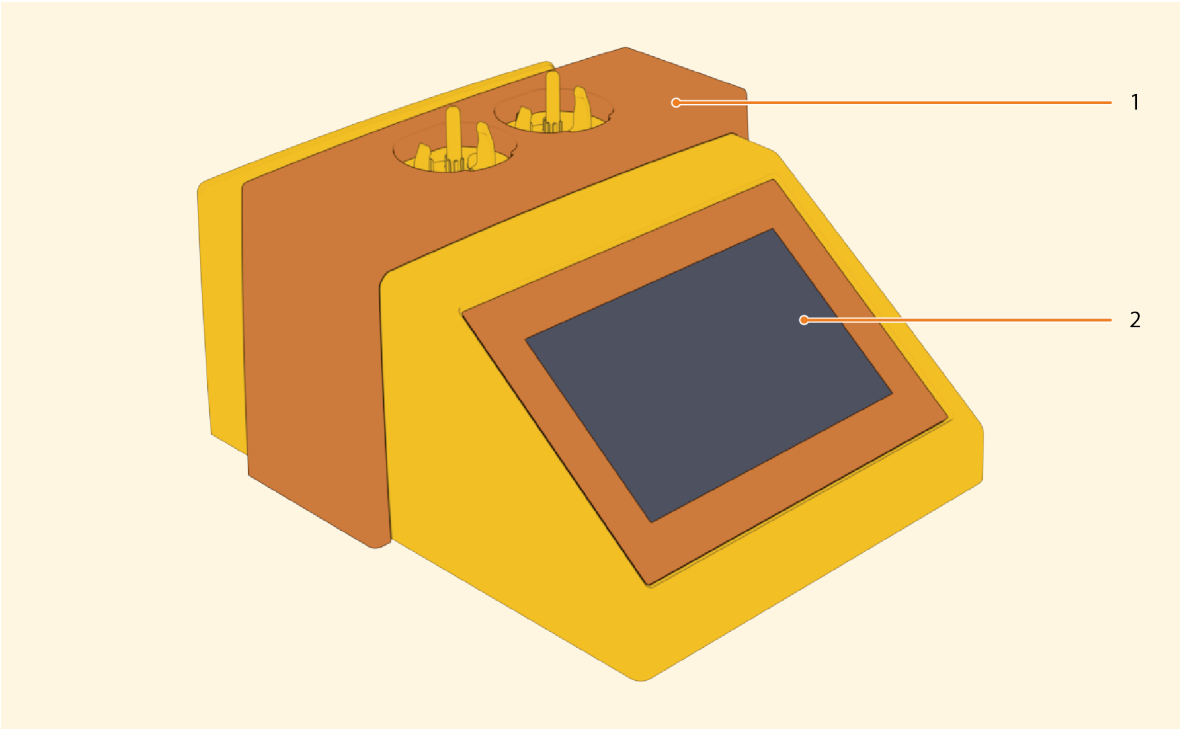


Figure 1.1: Front view of the gentleMACS Dissociator

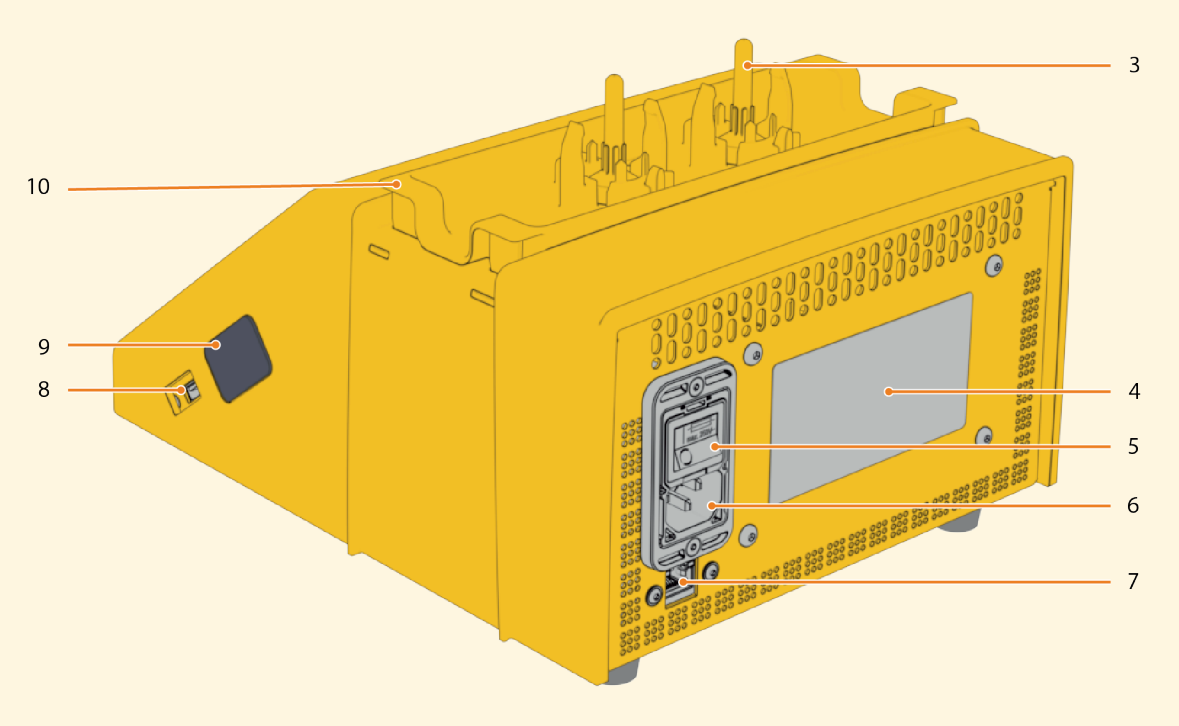


Figure 1.2: Rear view of the gentleMACS Dissociator, Safety Shield removed

1.3 Sample preparation

The gentleMACS Dissociator provides the solution for the preparation of single-cell, or single-nuclei suspensions, and homogenates from a wide range of tissues. Samples are processed using gentleMACS Tubes, which have caps with specially designed rotors and stators.

The gentleMACS Dissociator provides:

- the preparation of viable single-cell suspensions by mechanical and enzymatic dissociation, in combination with the MACSmix Tube Rotator in an incubator at 37 °C,
- the preparation of intact nuclei suspension by mechanical disruption at low temperature in combination with the gentleMACS Octo Coolers (+2°C to +8 °C),
- the preparation of thorough tissue homogenates for subsequent extraction of sub-cellular material, such as total RNA, DNA, proteins, organelles, and pathogens,
- simultaneous or independent processing of two samples, even using different programs,
- easy access to predefined gentleMACS Programs which are optimized for particular applications,

1.4 gentleMACS Tubes

gentleMACS Tubes consist of a stator and rotor element that provides the exact sheer forces necessary to gently pull cells from tissues or intact molecules from cells. A specially engineered tube enclosure always directs the sample flow towards the rotor and stator element. This sophisticated design results in highly efficient tissue dissociation and homogenization using C Tubes and M Tubes.

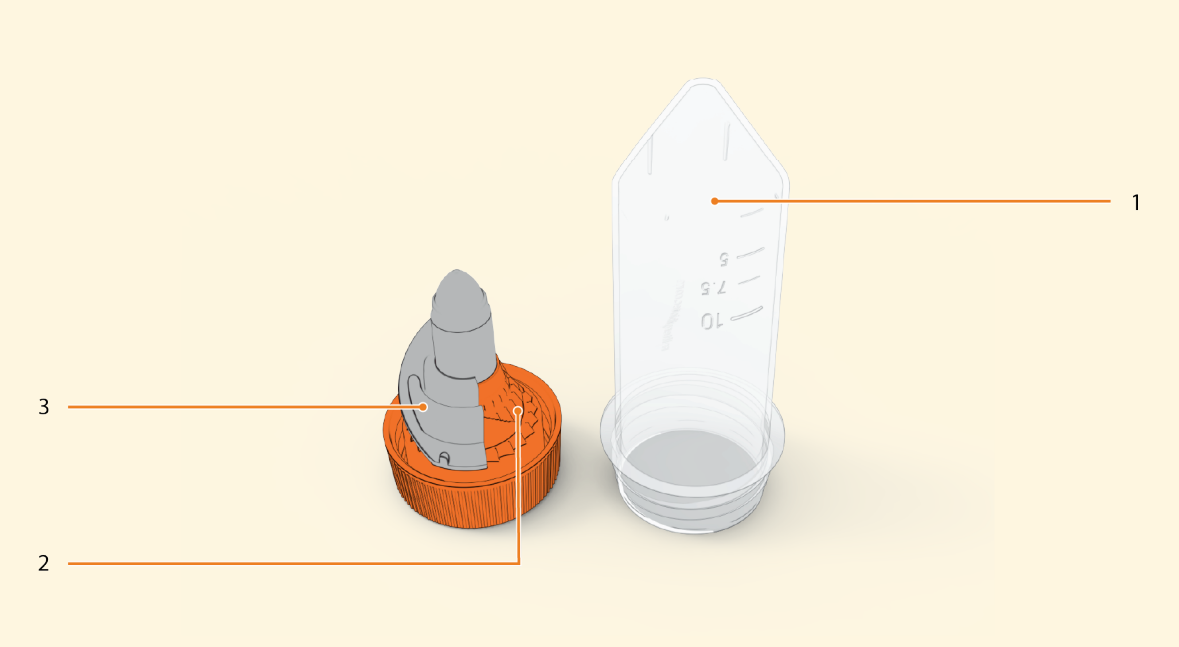


Figure 1.3: Cap of the gentleMACS Tubes (exemplary)

1	Tube enclosure	**3**	Rotor
2	Stator		

Two dedicated types of gentleMACS Tubes have been designed for the preparation of samples for cell biology or molecular biology applications:

- Purple C Tubes are designed for the gentle preparation of single-cell, or single-nuclei suspensions from tissues for subsequent cell separation, cell analysis, or cell culture.
- Orange M Tubes are designed for the homogenization of tissues and cells for subsequent subcellular or molecular analysis.

gentleMACS Tubes are suitable for:

- the processing of sample volumes from 500 µL to 10 mL and from 20 mg to 4,000 mg of tissue in a single tube,
- sterile sample handling.

1.5 MACS Tissue Dissociation Kits

A broad selection of MACS Tissue Dissociation Kits, including predefined enzyme mixes, provide convenient and reproducible tissue dissociation using the gentleMACS Dissociator. A comprehensive list of MACS Tissue Dissociation Kits for numerous applications is available for download at **www.miltenyi.com/epitopes**.

1.6 Predefined tissue dissociation and homogenization programs

More than 50 preset gentleMACS Programs have been specifically developed to offer standardized procedures for tissue dissociation in virtually any research field. A comprehensive list of optimized gentleMACS Programs and detailed gentleMACS Protocols for numerous applications are available for download at **www.miltenyi.com/brochureapps**.

1.7 gentleMACS Octo Coolers

The gentleMACS Octo Coolers are an accessory for gentleMACS Dissociators. They are designed to maintain the temperature of samples inside the tubes between +2°C to +8 °C during cold dissociation or homogenization. The coolers are compatible with all types of gentleMACS Tubes.

1.7.1 Storage and applications

The gentleMACS Octo Cooler must always be stored in an upright position. See **Figure 1.4**.

- Frozen use: The gentleMACS Octo Cooler must be stored at –20 °C for at least 10 hours and used in its frozen state for applications such as nuclei extraction and RNA or protein extraction. In this state, the temperature of the liquids inside the gentleMACS Tubes is maintained between +2 °C and +8 °C for up to 1 hour (at a maximum ambient temperature of +35 °C), without risk of freezing of the liquid in the gentleMACS Tubes.
- Precooled use: For applications such as StraightFrom Spleen Isolation Kits, the gentleMACS Octo Cooler should be precooled in a refrigerator at +2 °C to +8 °C for at least 10 hours prior to use.

1.7.2 Instructions for use

- Before putting the gentleMACS Octo Cooler in the freezer or refrigerator, shake it gently and wipe off any condensate on the surface with a soft cloth.
- Always store and freeze in an upright position. See **Figure 1.4**.
- Do not freeze the gentleMACS Octo Cooler at temperatures below –20 °C.
- The frozen or cold gentleMACS Octo Cooler can be placed over already installed gentleMACS Tubes.
- In case of a short gentleMACS program, e.g., 4C_nuclei_1, the gentleMACS Octo Cooler can be used multiple times (up to five times) before it is placed back in the freezer.
- The visible, non-soluble particles in the cooling liquid are present intentionally and do not affect use.
- Remove the gentleMACS Octo Cooler from the gentleMACS Dissociator directly after completion of the run.

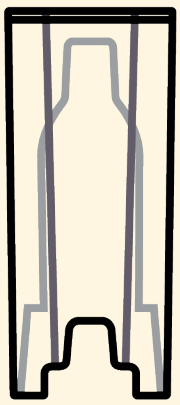


Figure 1.4: Upright positon of gentleMACS Octo Cooler. Gray outlines: inside, black outline: outside.

2 Installation

Unpack the instrument carefully and confirm that all components have been successfully delivered without damage that may have occurred during transportation.

WARNING! If there is any damage, do not use the instrument. Contact your local Miltenyi Biotec representative or Miltenyi Biotec Technical Support. Operating a damaged instrument may cause mechanical hazards, optical radiation hazards, fire hazards, or electric shock. Read the chapter Important safety information before installing and assembling the instrument.

Retain the original packaging material.

2.1 Components included in the delivery

The following components are included in the delivery of the gentleMACS Dissociator (# 130-134-030):

1× gentleMACS Dissociator

2× gentleMACS Octo Coolers

1× Power cable

1× User manual

2.2 Requirements

Meet the following requirements to install the instrument:

- The instrument requires a power supply.
- Place the instrument on a flat and clean surface of the dimensions 400 mm × 250 mm plus at least 15 cm on all sides to ensure for sufficient air circulation.
- The display and top of the instrument must be accessible.
- The instrument must be operated in a safety hood if hazardous or unknown materials are being processed.
- Do not place the instrument near radiators, heat registers, stoves, or other equipment (including amplifiers) that generate heat.
- Protect the instrument from direct sunlight.

2.3 Installation

To install the gentleMACS Dissociator:

1 Carefully remove the device from the cardboard box.

CAUTION! 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.

2 Place the instrument on a secure, clean, and stable workbench that can support its weight and size.

3 Plug the instrument into an electrical outlet.

4 Set the switch located above the plug socket to ON ("**I**" indicates "ON", "**O**" indicates "OFF").

The instrument performs a start-up check that runs for a few seconds.

3 Required materials

3.1 Disposables

The materials listed in **Table 3.1** are compatible with the gentleMACS Dissociator.

Product	Description	Capacity	Order no.
gentleMACS C Tubes	For gentle preparation of • single-cell suspensions from tissues for subsequent cell separation, cell analysis, and cell culture. • intact nuclei suspension for genomic analysis.	25 tubes, sterile, single-packed 100 tubes, sterile, packed as 4×25 tubes	130-093-237 130-096-334
gentleMACS M Tubes	For homogenization of tissues and cells for subsequent subcellular and molecular analysis.	25 tubes, sterile, single-packed 100 tubes, sterile, packed as 4×25 tubes	130-093-236 130-096-335
M Tubes with Strainer	For homogenization of tissues and cells for subsequent subcellular and molecular analysis. The strainer removes aggregates or large particles from the sample.	50 tubes, sterile, packed as 2×25 tubes (strainer: 600 µm mesh)	130-094-392

Table 3.1: Disposables compatible with the gentleMACS Dissociator

3.1.1 Additional disposables

MACS SmartStrainers are filters that are designed for the removal of cell aggregates or large particles after tissue dissociation. The MACS SmartStrainers are available with three mesh sizes:

- 30 µm (50 pieces # 130-098-458, 4×25 pieces # 130-110-915),
- 70 µm (50 pieces # 130-098-462, 4×25 pieces # 130-110-916),
- 100 µm (50 pieces # 130-098-463, 4×25 pieces # 130-110-917).

They fit into standard 15 and 50 mL conical tubes of all major suppliers.

MACS Tissue Dissociation Kits were designed for the convenient and standardized enzymatic dissociation of multiple tissues in combination with the gentleMACS Dissociator. For a comprehensive list of MACS Tissue Dissociation Kits, see **www.miltenyi.com/epitopes**.

3.2 Accessories

Product	Description	Order no.
gentleMACS Octo Coolers (4×)	For protocols with a cooling step	130-130-533
MACSmix Tube Rotator	For enzymatic dissociations in an incubator at 37 °C	130-090-753

Table 3.2: Accessory for the gentleMACS Dissociator

3.3 Spare parts

Product	Description	Order no.
gentleMACS Sleeves (2×)	Adapters for attaching gentleMACS Tubes	130-093-464
gentleMACS Octo Cooler (1×)	For protocols with a cooling step	130-140-667
gentleMACS Trough	Safety container for spilled liquid	130-093-465
gentleMACS Safety Shield	Safety shield for protection	130-093-466

Table 3.3: Spare parts of the gentleMACS Dissociator

Only use spare parts and accessories recommended by Miltenyi Biotec. Failure to use recommended spare parts and disposables may compromise safe operation and may result in inaccurate results and reduced lifetime of the instrument. Miltenyi Biotec does not honor any warranty or accept any responsibility for damages resulting from the use of inappropriate accessories.

4 Instrument operation

4.1 Switching on

Switch on the instrument with the power switch on the rear side of the instrument (**Figure 1.2**).
The instrument starts and the software opens. The internal fan automatically starts operating and reduces its speed after a few seconds.

After the first start of the instrument, naming the instrument and setting date and time is required. This information can be edited. See **Editing instrument name on page 53** and **Editing date and time on page 53**.

4.2 Switching off

1. Shut down the software before switching off the instrument. Tap the shut down button in the top indicator bar (**Figure 4.1**).
2. Tap **Shutdown** in the message window to proceed.
   The software shuts down.
3. Switch off the instrument with the power switch on the rear side of the instrument (**Figure 1.2**).

4.3 The user interface

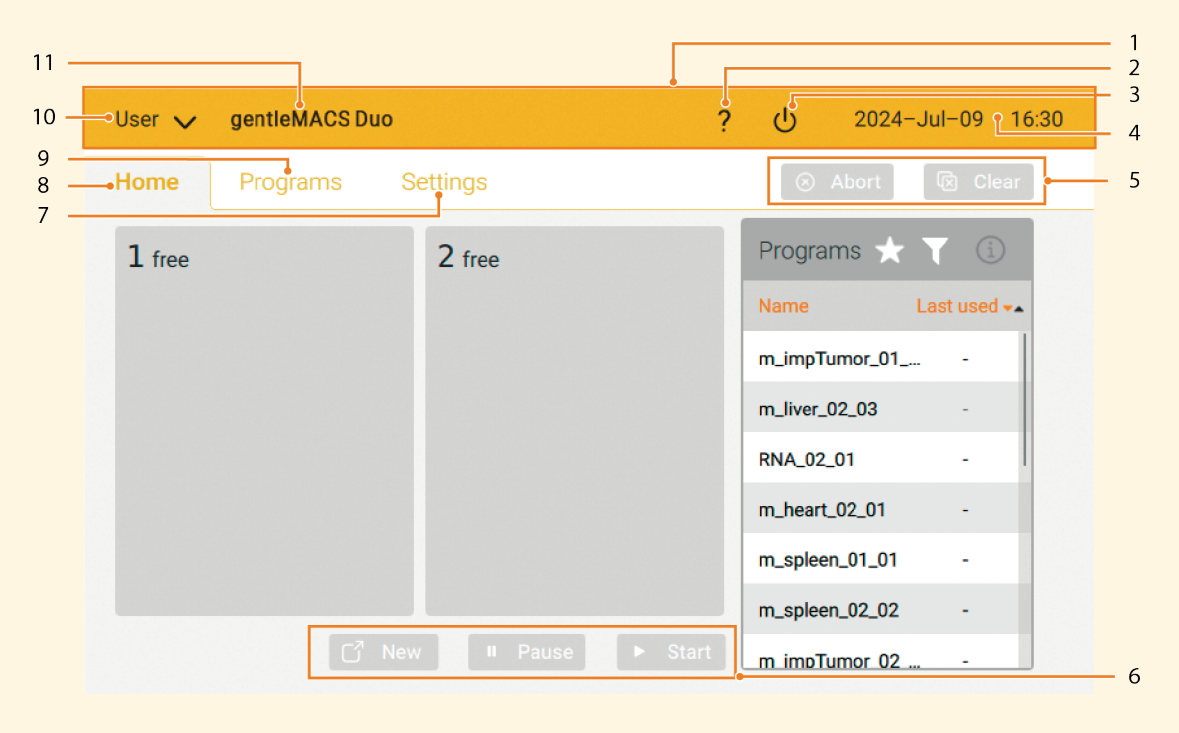


Figure 4.1: Overview of the user interface

1	Top indicator bar	Shows name of current user, instrument name, date and time; includes the help button and shut down button
2	Help button	Opens the help information on the instrument
3	Shut down button	Button to shut down the software before switching off the instrument
4	Date and time	Current date and time set on the instrument
5	Local position buttons	Buttons controlling the functions **Abort**, and **Clear** for all selected positions
6	Global position buttons	Buttons controlling the functions **New**, **Pause** and **Start** for all positions in the corresponding status
7	**Settings** hub	Menu hub for managing instrument and user settings
8	**Home** hub	Menu hub with instrument position overview and **Programs** list; gives an overview of the status of each position and is the starting point for assigning programs to positions and controlling sample runs
9	**Programs** hub	Menu hub for managing programs
10	User	Shows the current user of the instrument, users can be switched in the dropdown list
11	Instrument name	Name of the instrument

4.4 Home hub

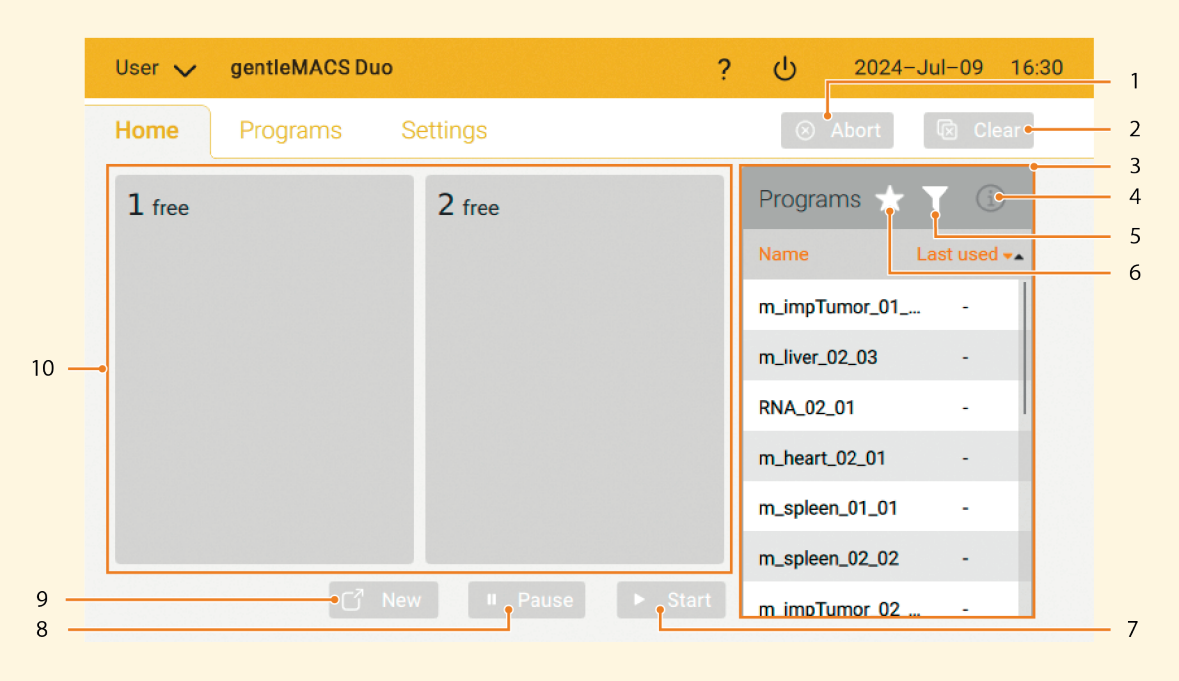


Figure 4.2: Overview Home hub

1	**Abort** button	Aborts run of the selected position boxes
2	**Clear** button	Clears the assigned programs or **Done** status of the selected position boxes
3	**Programs** list	List of programs available
4	Program details button	Shows information about the selected program like tube type needed, duration, rotations per run, species, starting material etc.; option to mark selected program as **Favorite**
5	Filter button	Opens Filter attribute window; option to filter by tube type, species, starting material, and favorite
6	Favorites button	Filters for favorite programs of the logged-in user
7	**Start** button	Starts runs on all positions in the status **Ready**
8	**Pause** button	Pauses all active sample runs
9	**New** button	Clears the assigned programs of all position boxes that are not running or paused
10	Position boxes	Managing the runs on the 2 instrument positions; shows status of each position (see **Status of position boxes on the next page**).

4.4.1 Status of position boxes

Status	Color	Description
free	Gray	No tube inserted, no program assigned. The position is free to use.
selected	Gray with orange border	The position is selected.
ready	Green	The position is ready. A tube is inserted and a program is assigned.
running	Blue	A program is running on the position. The progress bar and timer display the remaining time to complete the program.
paused	Blue, pulsing	The current running program on the position is paused.
break	Blue, pulsing	The current running program on the position has reached a break state. To resume the program, tap the local **Start** button in the position box and tap **Resume** in the pop-up window.
done	Gray	The program is finished. The position details button shows the elapsed time since completion of the program. The position box status changes to **Done** also after a run is aborted.
error	Red	An error occurred. See **Troubleshooting table on page 61**.

Table 4.1: Overview of position box statuses

4.5 Programs hub

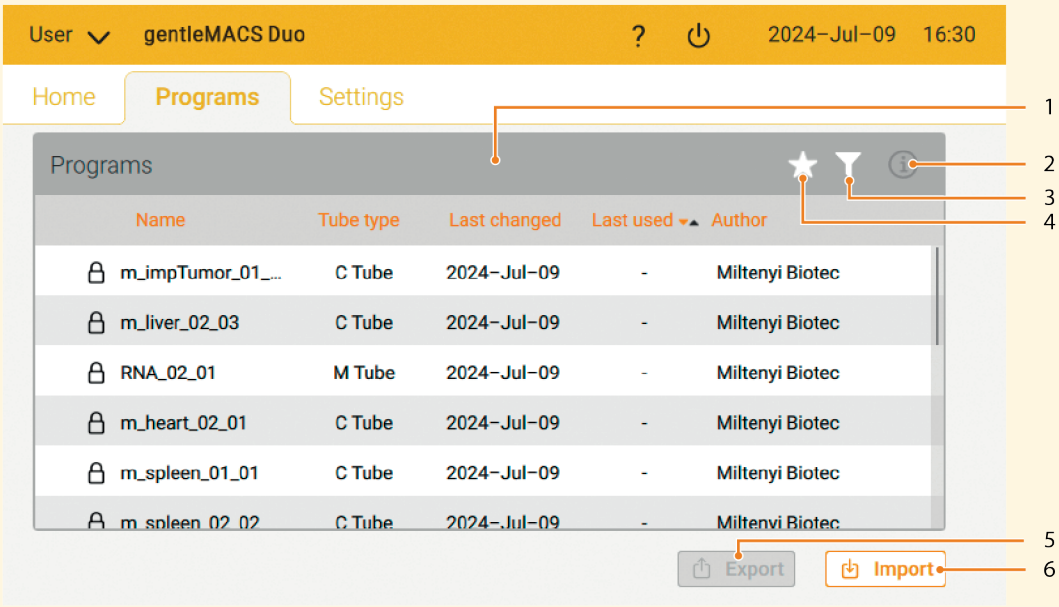


Figure 4.3: Overview Programs hub

1	**Programs** list	List of programs available. Programs can be sorted by Name, Tube type, Last changed, Last used, and Author by tapping the row heading.
2	Program details button	Shows information about the selected program like tube type needed, duration, total rotations oer run, species, starting material etc.; option to mark selected program as **Favorite**.
3	Filter button	Opens filter attribute window with the option to filter by tube type, species, starting material, and favorite.
4	Favorites button	Filters for favorite programs of the current user.
5	**Export** button	Exports selected program files to the USB flash drive.
6	**Import** button	Imports selected program from the USB flash drive.

4.5.1 Filtering programs

The system combines multiple filter attributes. Attributes of the same category are combined with the filter requirement "or", attributes from different categories are combined with the filter requirement "and".

Users can filter the **Programs** list for programs with certain attributes.

1 Tap on the filter button in the **Home** hub or **Programs** hub to open the **Filter** window.

2 Select all the attributes that the program should have. Filter attributes are:

- tube type,
- species,
- starting material, and
- favorite.

3 Tap X to close the **Filter** window. The **Programs** list shows only programs with the selected attributes.

4.5.2 Deselecting program filters

To remove the filter applied to the program list, perform the following steps:

1. Tap on the filter button in the **Home** hub or **Programs** hub to open the **Filter** window.
2. Tap **Deselect all**.
3. Tap X to close the **Filter** window.

4.5.3 Exporting programs

You can export programs to a USB flash drive and transfer them to another gentleMACS instrument. Programs are exported as bundles containing one or several programs. Make sure that the USB flash drive is formatted as exFAT for compatibility with the operating system. If required, change the format on a PC.

1. Insert the USB flash drive to the USB port of the gentleMACS Dissociator.
2. Go to the **Programs** hub.
3. Tap on the program to export.
   To select several programs for export, tap and hold on the first program and then select all other programs to be exported.
4. Tap **Export**.
5. Choose the target folder on the USB flash drive to export the program to.
6. Confirm to resume the export to the USB flash drive.
7. After the export is finished, remove the USB flash drive from the instrument.

4.5.4 Importing programs

Use this function to import programs from a USB flash drive to transfer them to another gentleMACS instrument, or to update the Miltenyi Biotec program database with new Miltenyi Biotec programs. Only programs which are supplied by Miltenyi Biotec, with Miltenyi Biotec as specified author, are permitted for import. Programs are imported as bundles containing one or several programs. Programs or program bundles that require gentleMACS Heater or gentleMACS Perfusers cannot be imported. Make sure that the USB flash drive is formatted as exFAT for compatibility with the operating system. If required, change the format on a PC.

1. Insert the USB flash drive to the USB port of the gentleMACS Dissociator.
2. Go to the **Programs** hub.
3. Tap **Import**.
4. Choose the program bundles to be imported from the USB flash drive.
5. Confirm to resume the import from the USB flash drive.
6. After the import is finished, remove the USB flash drive from the instrument.

4.6 Settings hub

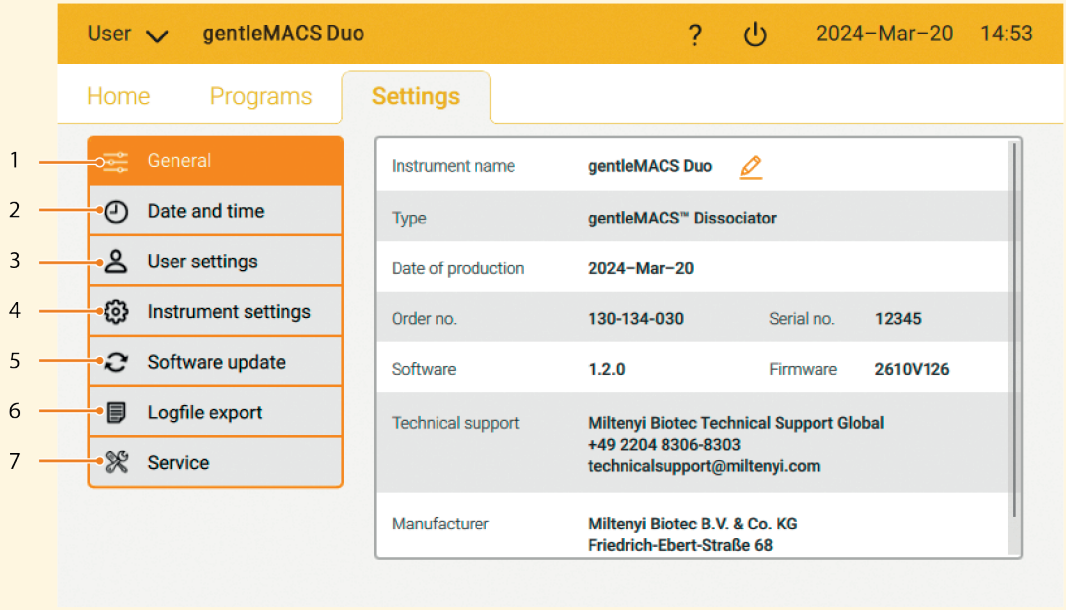


Figure 4.4: Overview Settings hub

1	**General** tab	General information about the instrument; tap the pen icon to change the instrument name
2	**Date and time** tab	Set date and time
3	**User settings** tab	Overview of all user profiles on this instrument, option to switch users, delete, clone, or edit user profiles, and to add new user profiles
4	**Instrument settings** tab	Settings for notifications, automatic tube confirmation, and display brightness
5	**Software update** tab	Check and update the software version
6	**Logfile export** tab	Export log files to a USB flash drive, see **Exporting log files on page 62**
7	**Service** tab	Access to service mode for authorized service personnel

4.6.1 Editing instrument name

1. Go to **Settings** > **General**.
2. Tap on the pen symbol next to the instrument name.
3. Edit the instrument name.
4. Confirm the changes.

4.6.2 Editing date and time

1. Go to **Settings** > **Date and time**.
2. Tap on the number to be changed. The selected numbers turn orange.
3. Edit date and time.
4. To confirm the changes, tap **Apply**.

4.6.3 User settings

Settings for notifications and brightness, favorite programs and the date of last use of programs by a user are saved in the profile of the signed-in user. User profiles help the different users to access their frequently used programs easier.

Adding new user profiles

1 Go to **Settings** > **User settings**.
2 Tap **New**.
3 Enter the user profile name.
4 To confirm, tap enter.
The new user profile is now included in the user profile list.

Switching user profiles

To switch between user profiles, do one of the following:

- Tap on the user name in the upper left corner of the top indicator bar and select the user profile to use.
- Go to **Settings** > **User settings** and select the user profile to use. Tap **Switch** to change the user profiles. The person icon indicates the currently active user.

Editing user profile names

1 Go to **Settings** > **User settings**.
2 Tap on the user profile to be edited.
The selected user profile is shown in orange.
3 Tap **Edit**.
4 Change the user profile name.
5 To confirm, tap enter.

Copying user profiles

Copying user profiles creates a copy of an existing user profile with the same settings defined in the user profile.

1 Go to **Settings** > **User settings**.
2 Tap on the user profile to be copied.
The selected user profile is shown in orange.
3 Tap **Clone**.
4 Enter a name for the new user profile.
5 To confirm, tap enter.

Deleting user profiles

The currently active user profile cannot be deleted. The user profile **Unnamed User** is the default user and cannot be deleted or edited.

1 Go to **Settings** > **User settings**.
2 Tap on the user profile to be deleted.
The selected user profile is shown in orange.

3 Tap **Delete**.

A pop-up window appears.

4 To confirm deletion of the user profile, tap **Delete**.

4.6.4 Instrument settings

Notifications for errors cannot be disabled.

The user can change the following settings for the respective user profile:

- information notifications,
- automatic tube confirmation, and
- display brightness.

Tap the respective toggle switch to enable or disable the notifications. To receive further information about the respective setting, tap on the info icon.

Move the slider to increase or decrease the display brightness.

4.6.5 Software update

New software versions can be installed from a USB flash drive by the user. Make sure that the USB flash drive is formatted as exFAT for compatibility with the operating system. If required, change the format on a PC.

To update the Miltenyi Biotec program database and import new Miltenyi Biotec pograms, see **Importing programs on page 52**.

1 Insert the USB flash drive to the USB port of the gentleMACS Dissociator.
2 Go to **Settings** > **Software update**.
3 Tap **Install**.
4 Choose the new software version to be installed from the USB flash drive.
5 Confirm to resume installation.

The instrument system checks if the software version is compatible with the instrument and installs the software.

6 The instrument reboots automatically with the newly installed software version and notifies the user about successful installation.

5 Performing runs

5.1 Running a sample

1 Attach a tube upside down to the Sleeve of the respective position on the instrument.

Insert and remove tubes in an upright position without tilting. Tilting might result in damage of the tube seal and subsequent leakage. Ensure that the tube is securely fastened to its Sleeve and socket. It must 'click' into position. Do not force the tube into the position. In case of resistance slightly turn the tube clockwise to find the right position to click in.

2 To select one or both position boxes, tap on the respective position box.

The orange border indicates the selected position box.

3 Tap on the desired program to run in the programs list.

The selected program is applied to the selected position box. The position status changes from **free** to **partly**.

4 To confirm the tube attachment, tap on the tube icon in the top right corner of the position boxes.

The position status changes from **partly** to **ready** and the local start symbol is enabled.

To activate automatic tube confirmation, go to **Settings** > **Instrument settings**. If the automatic tube confirmation is on, the position box status is **ready** after selecting a program, even if no tube is attached.

5 Tap the local start symbol in the position box to start the run.

The progress bar and timer indicate the remaining time until the program is done.

6 On completion of the program, the status of the position box changes to **done**.

7 Optional: For further processing, select the position box and tap the **Clear** button to reset the status from **done** to **free**.

The position box is free to assign a new program.

8 Remove the tube from the tube position.

5.2 Pausing and resuming samples

To pause a running sample, do one of the following:

- Tap the local **Pause** button of the respective position box. The status of the position changes from **running** to **paused**.
- Tap the global **Pause** button. All running samples will be paused. The status of all affected positions changes from **running** to **paused**.

To resume a paused sample, do one of the following:

- Tap the local **Start** button of the respective position box. The status of the position changes from **paused** to **running**.
- Tap the global **Start** button. All running samples will be paused. The status of all affected positions changes from **paused** to **running**.

To resume a break, tap the local **Start** button of the respective position box.

5.3 Aborting a running sample

1. Tap on the position boxes with runs to abort.
2. Tap **Abort**.
3. Confirm the notification by tapping **Abort**. The status of the selected position boxes changes from **running** to **done**.

6 Maintenance

⚠ WARNING

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

- Wear personal protective equipment (such as gloves, safety glasses, etc.) as indicated in the safety data sheet for the particular substance.

⚠ 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.

Larger amounts of accidentally spilled liquid are automatically collected in the Trough of the gentleMACS Dissociator. Use a pipette to aspirate the liquid before removing the Trough for decontamination and cleaning.

Instrument parts wear over time, especially Sleeves. Depending on the sample material and frequency of use, these parts require regular maintenance and/or replacement. Contact Miltenyi Biotec Technical Support regarding spare parts. Miltenyi Biotec also offers service contracts for the gentleMACS Dissociator. Visit **www.miltenyibiotec.com/gentlemacs-service** for further information.

6.1 Decontamination and cleaning

In case of spillage or contamination, clean the instrument appropriately.
For disinfection, wipe the instrument with 70% ethanol or 70% isopropanol.
Clean the instrument only with cleaning agents that are noncorrosive and not damaging the plastic housing. Suitable cleaning agents include household detergents, 70% ethanol, and 70% isopropanol. Do not use acetone or any aggressive agents. If in doubt, if a certain cleaning agent is suitable for disinfection and/or cleaning the gentleMACS Dissociator, contact Miltenyi Biotec Technical Support.

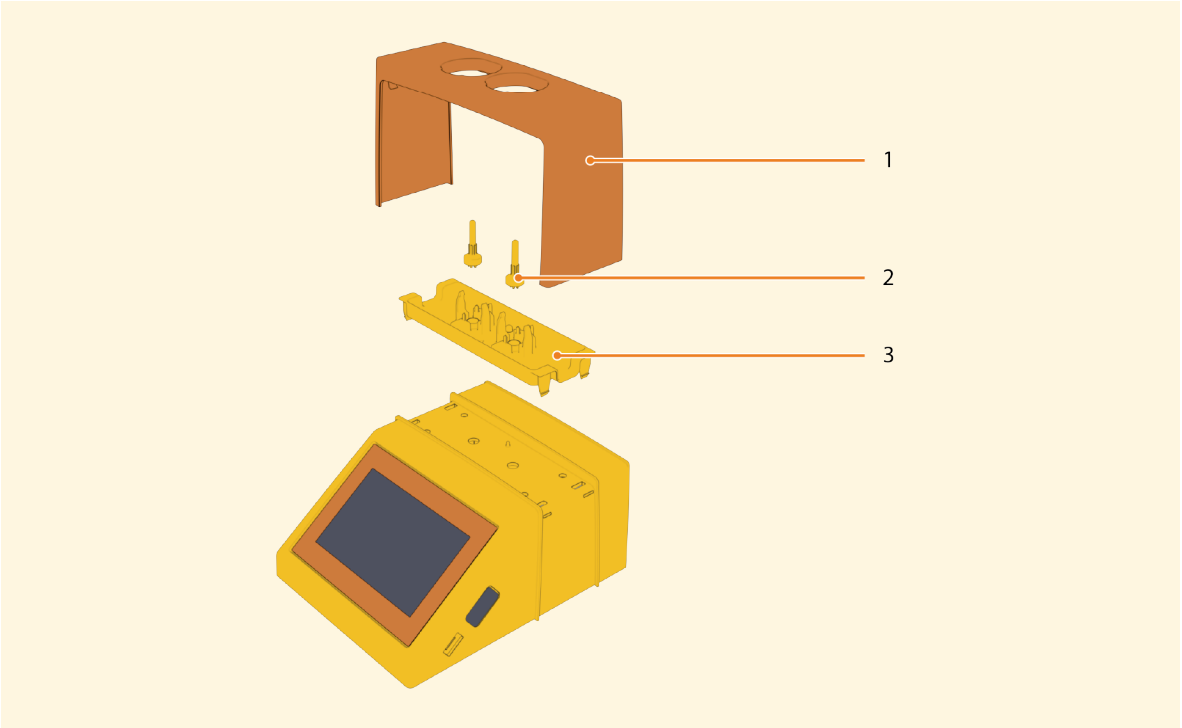


Figure 6.1: Steps 2-4 of the gentleMACS Dissociator disassembly for cleaning

1 Unplug the power cable from the electrical outlet before cleaning the instrument.

2 Remove the Safety Shield (1).

3 Remove the Sleeves from the Sleeve holders (2).

4 Remove the Trough from the baseplate (3).
To remove the Trough, pull on one side. Do not pull on both sides at the same time.

5 Carefully wipe the surface of the instrument and all removed parts with a cloth soaked with a detergent-containing aqueous solution, 70% ethanol or 70% isopropanol.

6 Repeat the procedure with another cloth soaked with distilled water.

7 Reassemble the removed parts. Start with the Trough, followed by the Sleeves, and the Safety Shield. Make sure that the orientation of the Trough and Safety Shield is correct.

7 Troubleshooting

7.1 Troubleshooting table

Issue	Possible reason	Solution
Liquid droplets appear in the Trough.	Tube is not closed properly.	**Close the tube tightly beyond first resistance.**
	Sample is jammed between the cap and the tube and damages the seal. This might cause liquid to run through the seal.	**The top area of the cap and the tube must be perfectly clean for proper functioning of the seal.**
	Tube seal is leaky.	**Replace the tube.**
	Sleeve is worn.	**Exchange Sleeve.**
Tube is blocked during a run.	Inappropriate sample material.	**Check the respective data sheet for technical specifications of the tubes.**
Program is automatically aborted and the instrument displays the message "Motor is blocked. Program was aborted."	If the motor is blocked due to a high resistance of the sample material, the instrument will try three times to get started again	**Process a smaller amount of tissue, or use a different gentleMACS Program.**
	If the blockage can be resolved, the instrument will continue the run of the program. If the blockage cannot be resolved, the program will automatically be aborted.	**Check if tissue is trapped between the stator and rotor. Release tissue, reinstall tube, and tap Continue to resume the program.**
Tube comes off the instrument.	Tube is not correctly mounted into the snap-fit of the Trough.	**Ensure correct installation of the tube.**
	Tube is not closed properly.	**Close the tube tightly beyond first resistance.**
USB flash drive is not recognized.	The USB flash drive has the wrong format.	**Format the USB flash drive as exFAT.**

Table 7.1: Troubleshooting for the gentleMACS Dissociator

7.2 Exporting log files

Log files can help Miltenyi Biotec Technical Support with troubleshooting. Log files can be exported to a USB flash drive. Make sure that the USB flash drive is formatted as exFAT for compatibility with the operating system. If required, change the format on a PC.

1 Insert the USB flash drive to the USB port of the gentleMACS Dissociator.

2 Go to **Settings** > **Logfile export**

3 Tab **Export logfile** to start the export.

4 After notification that the export is finished, remove the USB flash drive from the instrument.

8 Technical support

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

Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68
51429 Bergisch Gladbach
Germany
Phone: +49 2204 8306 3803
technicalsupport@miltenyi.com

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

9 Technical data and specifications

Technical data	Specification
Instrument	
Colors	Yellow / orange
Dimensions (width x depth)	245 mm × 279 mm
Height	180 mm
Weight	4.7 kg
Main power	
Power consumption	Max. 500 W
Supply voltage	100–240 V~, 50/60 Hz
Fuses	2 x T3.15 AH, 250 V
Motor	
Rotational speed	20–4,000 rpm
Rotational direction	Clockwise or counterclockwise
Rotational acceleration	100 r/s²
Torque	Max. 150 mNm; Overload restriction over the range of 200–4,000 rpm
Conditions of operation	
Working temperature	+5 °C to +35 °C
Humidity	15–80%, relative, noncondensing
Altitude	Max. 2,000 m
PC	
Ports	1 × USB 2.0 1 × Ethernet (10/100/1000 MBit/s)
RAM	4 GB LPDDR4×
Mass storage	32 GB onboard eMMC
Mainboard battery	Button cell, lithium metal
Monitor	7" TFT LCD touchscreen

Technical data	Specification
Maximum noise emission	
Measurement operation conditions: 2× C Tubes containing 500 µL of liquid, processed at 4,000 rpm	
Sound pressure level at workstation	85 dB(A) +/- 2.5 dB(A)
Sound power level	91 dB

Table 9.1: Technical data of the instrument

The gentleMACS™ Dissociator is classified as protection class I device and must be plugged into a grounded electrical outlet.

Note that for USA and Canada, the main power supply cord and plug of the instrument shall comply with the following specifications: UL listed and KAM cord, minimum type SJ, minimum 18 AWG, 3 conductors. Rated for a minimum temperature of 60 °C. Provided with grounding-type (NEMA 5-15P) attachment plug, rated 125 VAC, 10 A. Opposite end terminates in IEC 320-style connector, rated 125 VAC, 10A.

Supply voltage fluctuations up to +/– 10% of the nominal voltage.

Transient overvoltages present on the mains supply: category II.

The instrument is suitable for pollution degree 2 environments.

The instrument has been designed for a lifetime of 10 years.

9.1 FCC compliance statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment 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 separation between the equipment and receiver.
- Connect the equipment into 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 made to this equipment not expressly approved by the party responsible for compliance may void the FCC authorization to operate this equipment. For other safety considerations, refer to the product label or visit **www.miltenyibiotec.com**. Design and specifications are subject to change without notice.

9.2 EC/EU 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: gentleMACS Dissociator G3 (A44111)

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 IEC 61010-2-010:2020
EN IEC 61010-2-051:2021
EN IEC 61326-1:2021

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

9.3 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: gentleMACS Dissociator G3 (A44111)

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 IEC 61010-2-010:2020
EN IEC 61010-2-051:2021
EN IEC 61326-1:2021

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

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.

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