Miltenyi Biotec

gentleMACS™ Octo Dissociator with Heaters

User manual

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Original instructions

Issued: 2022-10
140-004-386.06

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Read the user manual before using the instrument

⚠WARNING Before using the instrument, read chapter **Important safety information** and all other information contained in this user manual, including all safety and operating instructions. Pay special attention to 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 of components shortening the lifetime of the instrument. Such actions may void your warranty. Keep this user manual and any other safety and operating instructions provided with the instrument in a safe place that is accessible to all users for reference.

If you are concerned about the safe use of the instrument, please contact your authorized Miltenyi Biotec service provider or call Miltenyi Biotec Technical Support.

Content

EN

Important safety information

⚠WARNING The gentleMACS Octo Dissociator with Heaters is a laboratory instrument. The instrument can be used safely, if the following is ensured: The instrument is installed correctly. The instrument is only operated by professional laboratory personnel. General safety practices are followed. All instructions in this user manual are followed.

Warnings and precautions

The guidelines in this section explain the potential risk associated with operating this instrument and provide important supplemental safety information to minimize the risks. Follow the instructions carefully to protect yourself, others, and the equipment from potential hazards and create a safe work environment. Use this instrument only as specified by the manufacturer to avoid damage of equipment and injury to personnel.

Always follow local working area safety instructions and laboratory policies as well as standards for health, safety and prevention of accidents. Contact the local authorities governing electrical power supply, building constructions, maintenance, or safety for more information about the safe installation and operation of the instrument.

Hazard levels

Signal words are used to identify safety and property damage messages. The following signal words are used to throughout this user manual.

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

⚠CAUTION or **CAUTION!** indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

Symbols

The following symbols are used to highlight conditions that could cause injury to personnel.

Safety alert. Risk of danger. The documentation needs to be consulted in all cases where this safety alert symbol is used on the instrument, in order to find out the nature of the potential hazard and any actions that have to be taken.

Biohazard. Risk of contamination if potentially dangerous biological material is used.

Risk of electric shock.

Hazardous optical radiation.

Risk of unmeant trapping of finger by hazardous rotating part.

Hazardous hot surface.

Noise hazard.

Protective conductor terminal. Symbol is attached on the inside of the instrument. Information for service personnel.

Fuse.

WEEE (Waste of Electrical and Electronic Equipment).

On (Power supply).
Off (Power supply).

All operating instructions must be read before installing and operating the instrument.

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 label

The following safety label is attached to the back of the instrument and plays an important part in maintaining safety.

WARNING! Avoid serious injury. Read and understand operating instructions before installing or use. If manual is missing, obtain replacement from Miltenyi Biotec.

The Trough is marked with the following safety symbol.

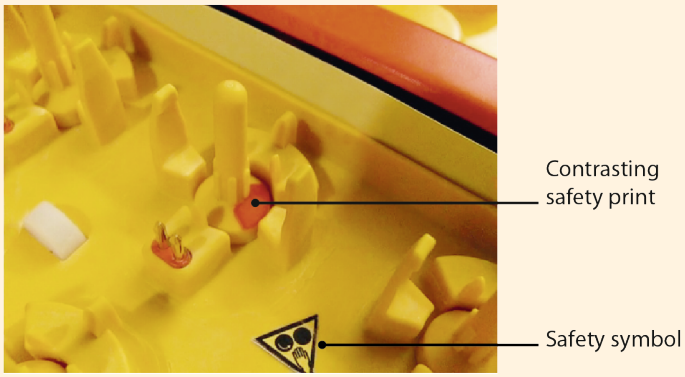


Figure 1: Safety symbol on the Trough of the gentleMACS Octo Dissociator with Heaters. The Sleeves are marked with a contrasting safety print.

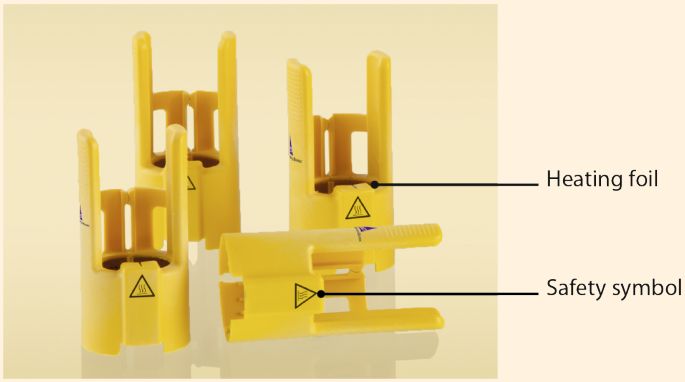


Figure 2: Safety symbol on the gentleMACS Heaters.

The Sleeves are marked with a contrasting safety print. The contrasting safety print allows the visual perception of the rotation of the Sleeves.

The mentioned above safety labels and safety markings must be kept clean and legible. Periodically inspect the safety labels and safety markings and replace them if they are not legible or perceptible from a safe viewing distance. Contact Miltenyi Biotec for replacement labels.

General safety instructions

Safe operation of the instrument is no longer ensured if the instrument is not working properly and/or the displayed instructions or messages advise you to contact Technical Support. Immediately switch off and unplug the instrument from the power outlet and contact an authorized Miltenyi Biotec service provider or Miltenyi Biotec Technical Support.

Electricity and fire hazards

Potential risks arising from electrical devices include electric shock, short, and overheating. Electric shock may lead to severe personal injury or even death. An electric short or overheating may cause a

fire. Electronic equipment might emit sparks, which could ignite combustible vapors or material resulting in explosion or fire. Do not use the instrument in areas classified as hazardous locations; for example, in oxygen-laden environments.

The housing of the instrument is designed to reduce the risk of electric shock, electric short, and spread of fire. Except for the Safety Shield and Trough, do not remove or penetrate any cover. Only authorized personnel must remove the other covers of the instrument. Never push a foreign object through an opening into the instrument. Do not use the instrument if

- it is opened or disassembled,
- it has been dropped or damaged,
- it has damaged or broken parts,
- it has a damaged power cable,
- an object has entered through the ventilation slots,
- a foreign object has been dropped into the instrument.

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

The instrument is intended for indoor use only. **If fluids enter the instrument, it may lead to electric shorts, electric shock or fire.** Take special care while handling fluids. Do not allow fluids to enter the interior of the instrument.
Protect the instrument against accidental spillages and splashes. Clean up spillages immediately. Do not operate the instrument if liquids have spilled into the instrument. Do not use the instrument in a wet or damp location. Avoid areas with high humidity or condensation. Moving the instrument from a cold environment – such as a cold room at 5 °C – to room temperature may cause condensation inside the instrument. In such cases, wait for the instrument to dehumidify before operating it. Unplug the instrument from the electrical outlet before cleaning.
Do not use liquid or aerosol cleaning agents; always use a damp cloth.

Ensure adequate air circulation in the room where the instrument is operated. In the absence of adequate circulation, ambient air may not cool the instrument to acceptable operating temperatures. Allow sufficient air circulation around the instrument – at least 15 cm on all sides – during operation to ensure adequate cooling. Do not place the instrument near radiators, heat registers, stoves, or other equipment (including amplifiers) that generate heat. Protect the instrument from direct sunlight. Do not cover the slots and openings of the instrument as these are provided for ventilation and protect the instrument from overheating. Do not place the instrument in a built-in rack or similar confined spaces unless the space has been specifically designed to provide proper ventilation. Follow the mounting instructions for the instrument.

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

The instrument is equipped with a three-wire electrical grounding-type plug that has a third pin for grounding. This plug only fits into a grounded power outlet.
This is a safety feature. Do not try to insert the plug into a non-grounded power outlet. If you cannot insert the plug into the outlet, contact your local electrician to replace the outlet.

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

Mechanical hazards

Moving and revolving parts are potential mechanical hazards. When operating the instrument, keep the Trough, Sleeves and Safety Shield attached to it. When the instrument's rotors are rotating, do not touch them or load or remove tubes from the instrument. Only use properly installed gentleMACS Tubes with tightly closed caps. Do not operate the instrument with only gentleMACS Tubes caps in place.
The exposed cutting edges of the gentleMACS Tubes caps may lead to incision wounds if touched while they are rotating. Do not circumvent any safety measures or devices.

Chemical and biological hazards

Depending on the biological material used, contamination infection may lead to severe personal injury or death. All clinical samples must be considered potentially infectious.
If biohazardous material is or has been used, the operator must choose and wear personal safety equipment as indicated in the warnings and precautions for the particular substance. The above safety precaution also accounts for any hazardous chemical, including toxic or corrosive chemicals, acidic or radioactive substances that may be present in the sample. Wear protective gloves and clothing, as well as safety glasses to prevent contact of the substance with skin and eyes. Defective or inadequate safety equipment is hazardous. The instrument must be operated in a safety hood if hazardous or unknown material is being processed. If hazardous material has been used or spilled, care must be taken to thoroughly decontaminate the instrument. It is strictly prohibited to continue to handle contaminated accessories or parts of the instrument.

Tubes and any other consumable that were in contact with biohazardous material must be decontaminated before disposal. All liquid and solid waste must be considered hazardous and, must be therefore handled taking universal laboratory precautions. Waste disposal must be in accordance with any local regulations.

Optical radiation hazards

The instrument is equipped with powerful light emitting diodes (LEDs) for illuminating the Safety Shield and the gentleMACS Tubes. According to the international standard IEC 62471, this lamp system has an exposure hazard value (EHV) of 0.91 and is in excess of the Exempt Risk Group. The hazard distance (HD) for the Exempt Risk Group is 61 cm. The hazard distance for Risk Group 1 is 20 cm. The viewer-related risk is dependent on how the instrument is installed and used. The optical radiation emitted from these LEDs may be harmful to the eyes at close viewing distances of the Trough is removed. Unplug the instrument before removing the Through. If the Trough is removed, do not stare at the operating illumination LEDs from a distance lesser than 20 cm.

In addition, the integrated 2D code reader uses LEDs for illuminating the reading area. Do not stare directly at the 2D code reader from a short distance while it is in operation.

Do not disassemble, modify, or remove any of the optical radiation sources. Optical radiation of disassembled instruments may be harmful to the eyes.

Hot surface hazards

The heating foil of the gentleMACS Heaters may become hot enough to cause burns if touched. Do not touch the heating foil, while the instrument is in operation.

Noise level hazards

If the instrument is used at maximum load, it might produce noise at a level, which could cause a hazard. Hazardous noise levels may result in hearing impairment. 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. If it is not ensured during installation that the sound pressure level from the device will not reach a value at its point of use, that could cause a hazard, then protective materials such ad noise reducing baffles or hoods, ear protection equipment has to be used. Observe local regulations regarding hearing protection.

Servicing, transportation, and disposal

Unless otherwise specifically noted in this user manual or other Miltenyi Biotec documentation, **do not service the instrument yourself**. Servicing and repair must be performed by qualified service personnel. Improper or incorrect servicing or repair of the instrument can cause hazards to users, lead to unpredictable results, cause instrument malfunction or damage, as well as premature wear and reduced life of the instrument. It may also void your warranty.

When replacement or spare parts are required, ensure that the service provider uses only genuine Miltenyi Biotec parts, or third-party parts specified and recommended by Miltenyi Biotec. Using unauthorized parts can cause malfunction of the instrument and impair results. Miltenyi Biotec does not honor any warranty or accept any responsibility for instrument failure or damages resulting from the use of inappropriate parts. After completing any service or repair work, ensure that your authorized Miltenyi Biotec service provider performs all safety checks as required by the repair procedure to ensure that the instrument is operating correctly.

Only use options and upgrades recommended by Miltenyi Biotec. Inquire with your local Miltenyi Biotec representative about Miltenyi Biotec's extensive instrument service and support arrangements, or refer to www.miltenyibiotec.com/support.

The instrument should be transported with care in packaging specified by Miltenyi Biotec. Internal damage can occur if the instrument is subjected to excessive vibration or dropped. If the instrument needs to be shipped back to the manufacturer for service, decontaminate the instrument to remove any hazardous material prior to shipment. If you have questions regarding proper decontamination or shipment, contact Miltenyi Biotec Technical Support for assistance.

Waste of Electrical and Electronic Equipment (WEEE) customer information

Please 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 and electronic equipment may contain hazardous substances which may have a serious detrimental effect on the environment and/or human health. That is why all equipment must be specifically collected and treated by designated waste facility centres and by qualified WEEE compliance schemes. By ensuring that you dispose 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 lets you recycle your end-of-life Miltenyi Biotec equipment free of charge. The terms and availability of this offer vary by geography because of differences in regulatory requirements. Please note that, depending on the type and use of your equipment, additional requirements may apply.

For more information, or if you wish to dispose of your end-of- life Miltenyi Biotec equipment, please contact your local Miltenyi Biotec representative or Miltenyi Biotec Technical Support.

DE

Wichtige Sicherheitsinformationen

⚠WARNING Der gentleMACS Octo Dissociator with Heaters ist ein Laborgerät. Das Gerät kann sicher verwendet werden, wenn Folgendes sichergestellt ist: Das Gerät ist ordnungsgemäß installiert. Das Gerät wird nur von professionellem Laborpersonal verwendet. Die allgemeinen Sicherheitsvorkehrungen werden befolgt. Sämtliche Anweisungen aus diesem Benutzerhandbuch werden befolgt.

Warnungen und Sicherheitshinweise

Die in diesem Kapitel enthaltenen Sicherheitsrichtlinien erläutern die mit dem Betrieb dieses Gerätes verbundenen möglichen Gefahren und geben wichtige zusätzliche Informationen zur Sicherheit, um diese Risiken zu minimieren.
Befolgen Sie diese Sicherheitshinweise sorgfältig um sich, andere und das Gerät vor möglichen Gefahren zu schützen und ein sicheres Arbeitsumfeld zu schaffen.
Um Sach- und Personenschäden zu vermeiden, benutzen Sie das Gerät ausschließlich nach Angaben des Herstellers.

Örtliche Arbeitsschutzbestimmungen, Laborrichtlinien, Sicherheitsnormen und Unfallverhütungsvorschriften müssen jederzeit beachtet und eingehalten werden. Wenden Sie sich für weitere Informationen zur Stromversorgung, Gebäudeinstallationen, Wartung und Sicherheit für die Installation dieses Gerätes an die örtlichen Behörden und Ihren Stromversorger.

Gefahrenstufen

Gefahrensymbole werden verwendet, um auf Sicherheits- und Sachschadenhinweise aufmerksam zu machen. Folgende Gefahrensymbole werden in diesem Benutzerhandbuch benutzt.

⚠WARNING oder **WARNING!** bezeichnet eine Gefahrensituation, die, falls sie nicht vermieden wird, zum Tode oder schwerwiegenden Verletzungen führen kann.

⚠CAUTION oder **CAUTION!** bezeichnet eine Gefahrensituation, die, falls sie nicht vermieden wird, zu leichten oder mittelschweren Verletzungen führen kann. Es kann auch verwendet werden, um vor unsicherem Gebrauch zu warnen.

Symbole

Die folgenden Symbole werden benutzt um Gefahrensituationen anzuzeigen, welche zu Sach- und Personenschäden führen können:

Warnzeichen. Gefahrenrisiko. Dieses Benutzerhandbuch muss immer konsultiert werden, wenn dieses Warnzeichen benutzt wird, um mehr über die möglichen Gefahren und entsprechende Handlungsanweisungen zu erfahren.

Biologische Gefährdung. Risiko der Kontamination, wenn mit möglicherweise gefährlichen biologischen

Substanzen gearbeitet wird.


Gefahr durch Stromschlag.


Gefahr durch optische Strahlung.


Gefahr unbeabsichtigten Einklemmens der Finger durch rotierende Bauteile.


Gefährdung durch heiße Oberfläche.


Gefahr durch Geräuschentwicklung.


Schutzleiteranschluss. Das Symbol ist innerhalb des Gerätes angebracht. Dies ist ein Hinweis für Servicepersonal.

Sicherung.


Elektro- und Elektronik-Altgeräte.


An (Stromversorgung).
Aus (Stromversorgung)


Vor der Installation und Inbetriebnahme des Gerätes ist das Benutzerhandbuch zu lesen.


Europäisches Konformitätskennzeichen


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

Der nachfolgende Sicherheitsaufkleber ist auf der Rückseite des Geräts befestigt. Seine Beachtung spielt für die Aufrechterhaltung der Sicherheit eine wichtige Rolle.

WARNUNG! Vermeiden Sie schwere Verletzungen. Vor der Installation oder Inbetriebnahme ist die Bedienungsanleitung zu lesen. Wenn die Anleitung fehlt, fordern Sie Ersatz bei Miltenyi Biotec an.

Der Einsatz trägt folgendes Sicherheitssymbol.

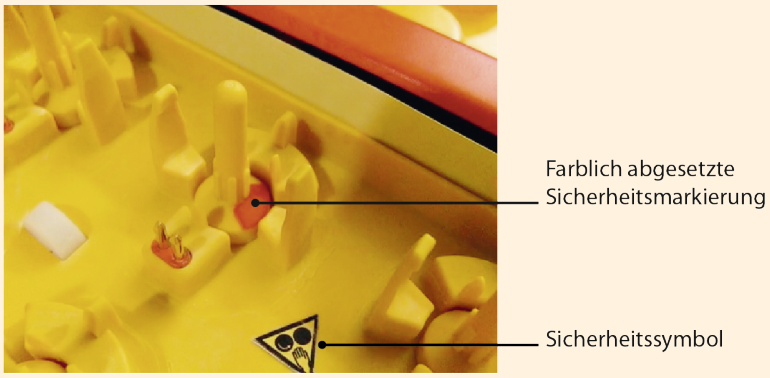


Figure 1: Sicherheitssymbol auf dem Einsatz des gentleMACS Octo Dissociator with Heaters. Die Sleeves tragen eine farblich abgesetzte Sicherheitsmarkierung.

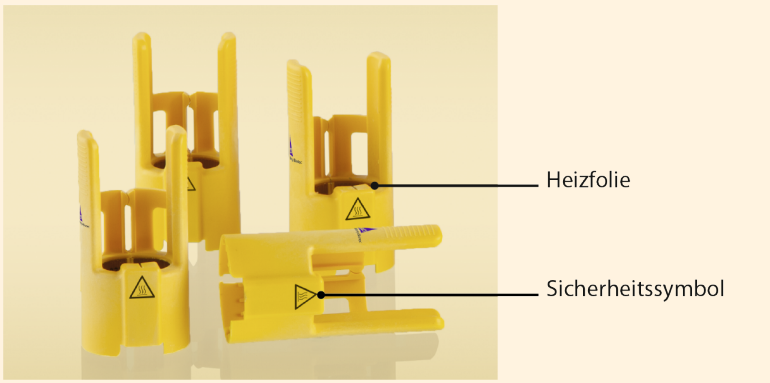


Figure 2: Sicherheitssymbol auf den gentleMACS Heaters.

Die Aufsteckhülsen tragen eine farbliche abgesetzte Sicherheitsmarkierungen. Diese Sicherheitsmarkierung ermöglicht die Rotation der Aufsteckhülsen optisch wahrzunehmen.

Alle Sicherheitsaufkleber und Markierungen müssen sauber und lesbar bleiben. Überprüfen Sie die Aufkleber regelmäßig und ersetzen Sie diese, sollten sie aus sicherem Abstand nicht mehr lesbar sein. Kontaktieren Sie Miltenyi Biotec um Ersatzaufkleber zu erhalten.

Allgemeine Sicherheitshinweise

Falls Ihr Gerät nicht einwandfrei funktioniert und/oder Anzeigen auf dem Display Sie dazu auffordern den technischen Kundendienst zu kontaktieren, ist die Betriebssicherheit des Gerätes nicht länger gewährleistet. Schalten Sie das Gerät sofort aus, ziehen Sie den Netzstecker und kontaktieren Sie einen autorisierten Miltenyi Biotec Servicedienstleister oder den Miltenyi Biotec Technical Support.

Elektrische Gefährdung und Brandgefahr

Elektrische Geräte bergen das Risiko eines Stromschlags, Kurzschlusses und der Überhitzung. Ein Stromschlag kann zu schweren Verletzungen und bis zum Tod führen. Ein elektrischer Kurzschluss sowie Überhitzung kann eine Brandursache darstellen. Elektrische Geräte können Funken schlagen,

welche leichtentflammbare Dämpfe oder Materialien entzünden und somit zu Feuer und Explosionen führen können. Benutzen Sie das Gerät nicht in ausgewiesenen Gefahrenzonen, z. B. in sauerstoffangereicherten Umgebungen.

Das Gehäuse des Gerätes dient dazu das Risiko eines elektrischen Stromschlags, Kurzschlusses und Feuers zu reduzieren. Entfernen oder durchdringen Sie keine Abdeckungen, mit Ausnahme des Troughs und des Safety Shields. Jegliche andere Abdeckung darf nur von autorisiertem Personal entfernt werden. Führen Sie nie einen Fremdkörper durch eine Öffnung in das Gerät ein. Benutzen Sie das Gerät nicht, wenn:

- es offen oder zerlegt ist
- es fallengelassen wurde oder beschädigt ist
- Teile beschädigt oder defekt sind
- die Netzanschlussleitung beschädigt ist
- ein Gegenstand in die Belüftungsschlitze eingedrungen ist
- ein Fremdkörper in des Gerät gefallen ist.

Wenn Flammen oder Rauch auftreten, schalten Sie das Gerät unverzüglich ab, ziehen Sie den Netzstecker und kontaktieren Sie einen autorisierten Miltenyi Biotec Servicedienstleister oder den Miltenyi Biotec Technical Support.

Das Gerät ist ausschließlich für den Betrieb in Innenräumen ausgelegt.
Sollten Flüssigkeiten in das Gerät gelangen, kann es zu Kurzschluss, Stromschlag oder Feuer kommen. Seien Sie vorsichtig im Umgang mit Flüssigkeiten. Verhindern Sie, dass Flüssigkeit in das Innere des Gerätes gelangt. Schützen Sie das Gerät vor verschütteten oder verspritzten Flüssigkeiten.

Beseitigen Sie ausgetretene oder verschüttete Flüssigkeit sofort. Benutzen Sie das Gerät nicht, sollte Flüssigkeit in das Innere des Gerätes gelangt sein. Setzen Sie das Gerät nicht in einer nassen oder feuchten Umgebung ein. Vermeiden Sie Arbeitsbereiche mit hoher Luftfeuchtigkeit oder Kondensation. Das Überführen des Gerätes von einer kalten Umgebung, z. B. aus einem Kühlraum bei 5°C, in einen Raum mit Raumtemperatur, kann zu Kondensation im Inneren des Gerätes führen. Warten Sie in solchen Fällen mit der Benutzung des Gerätes, bis dieses getrocknet ist. Ziehen Sie den Netzstecker vor der Reinigung des Gerätes. Verwenden Sie keine Flüssig- oder Sprühreinigungsmittel, sondern nur ein feuchtes Tuch.

Ermöglichen Sie im Betrieb eine ausreichende Luftzirkulation. Die das Gerät umgebende Luft reicht nicht aus, das Gerät bei unzureichender Belüftung auf einer sicheren Betriebstemperatur zu halten. Ermöglichen Sie im Betrieb eine ausreichende Luftzirkulation – einen Abstand von mindestens 15 cm in allen Richtungen um das Gerät – um eine ausreichende Kühlung zu gewährleisten.
Das Gerät darf nicht in der Nähe von Radiatoren, Heißlüftern, Öfen, oder anderen Wärme erzeugenden Geräten aufgestellt werden (Verstärker eingeschlossen). Schützen Sie das Gerät vor direkter Sonneneinstrahlung. Öffnungen und Schlitze am Gerät sind zur Belüftung gedacht und sollten niemals bedeckt oder blockiert werden, da sie das Gerät vor Überhitzung schützen und einen sicheren Betrieb ermöglichen. Versuchen Sie nicht, das Gerät in eine Einbaukonstruktion zu integrieren oder auf begrenztem Raum unterzubringen, es sei denn, es wurde eine spezielle Vorrichtung entwickelt und für ausreichend Belüftung gesorgt. Befolgen Sie die Montageanleitung für den Aufbau des Gerätes.

Stellen Sie sicher, dass der Hauptstromschalter ebenso wie der Netzstecker für das Stromkabel leicht zugänglich sind und sich in möglichst unmittelbarer Nähe zum Bediener des Gerätes befinden. Sollte es erforderlich sein, die Stromzufuhr zu unterbrechen, ziehen Sie den Netzstecker aus der Steckdose.

Das Gerät ist mit einem Schutzkontaktstecker und einer dreiadrigen Anschlussleitung ausgestattet. Dieser Stecker passt nur in eine Steckdose mit Schutzkontakt. Das ist eine Sicherheitsvorrichtung. Versuchen Sie nicht, den Stecker in eine Steckdose ohne Schutzkontakt einzuführen. Wenn Sie den Stecker nicht in die Steckdose einführen können, bitten Sie einen ortsansässigen Elektriker, diese zu ersetzen.

Das Gerät sollte nur von einer Stromquelle aus betrieben werden, die den elektrischen Angaben auf dem Typschild entspricht. Sollten Sie Fragen zur Art der Stromversorgung haben, wenden Sie sich an einen autorisierten Miltenyi Biotec Servicedienstleister oder Ihren lokalen Stromversorger. Benutzen Sie keine Verlängerungskabel oder Steckdosenleiste. Überlasten Sie eine Steckdose nicht.

Mechanische Gefahr

Bewegliche und rotierende Teile sind potentielle mechanische Gefahrenquellen. Benutzen Sie das Gerät nicht ohne befestigtes Trough, Sleeves und Safety Shield. Wenn sich die Rotoren des Gerätes bewegen, berühren Sie diese nicht und laden oder entfernen Sie keine gentleMACS Tubes vom Gerät. Benutzen Sie nur korrekt installierte gentleMACS Tubes mit fest verschlossenem Deckel. Benutzen Sie das Gerät nicht mit nur aufgesteckten Deckeln der gentleMACS Tubes. Die freiliegenden scharfen Kanten der Deckel der gentleMACS Tubes können Schnittwunden verursachen, wenn diese im Betrieb berührt werden. Umgehen Sie keine Schutzmaßnahmen oder Sicherheitsvorrichtungen.

Chemische und biologische Gefahren

Abhängig von dem benutzten biologischen Material kann eine Kontamination oder Infektion zu schweren Verletzungen oder Tod führen. Klinische Proben müssen als potentiell infektiös angesehen werden. **Wird oder wurde mit biologischen Gefahrstoffen gearbeitet, muss der Bediener des Gerätes entsprechend den für die verwendeten Substanzen geltenden Warnhinweisen und Schutzbestimmungen eine persönliche Schutzausrüstung tragen.** Der oben genannte Sicherheitshinweis gilt auch für etwaige gefährliche Chemikalien, einschließlich toxischer oder korrosiver Chemikalien, ätzender oder radioaktiver Substanzen, die in der Probe anwesend sein können. Tragen Sie Schutzhandschuhe, Schutzkleidung und Schutzbrille, um Berührung der Gefahrstoffe mit Haut und Augen zu vermeiden. Mangelhafte oder unzureichende Schutzausrüstung ist gefährlich. Werden Gefahrstoffe oder unbekannte Substanzen eingesetzt, muss das Gerät unter einem Abzug oder einer Sicherheitswerkbank benutzt werden. Falls Gefahrstoffe verwendet wurden oder ausgetreten sind, muss auf eine sorgfältige Dekontamination des Gerätes geachtet werden. Es ist strengstens verboten, kontaminierte Geräteteile oder Zubehörteile weiter zu verwenden.

Röhrchen und alle weiteren Verbrauchsmaterialien, die in Kontakt mit biologischen Gefahrstoffen gelangt sind, müssen vor dem Entsorgen dekontaminiert werden. Alle flüssigen und festen Abfälle müssen als Gefahrstoffe angesehen werden. Die Handhabung der Abfälle muss daher unter Beachtung der allgemein geltenden Laborsicherheitsbestimmungen erfolgen. Die Entsorgung der Verbrauchsmaterialien muss gemäß den örtlichen Bestimmungen erfolgen.

Gefahr durch optische Strahlung

Das Gerät ist mit leistungsstarken lichtemittierenden Dioden (LEDs) ausgestattet, welche das Safety Shield und die gentleMACS Tubes beleuchten. Gemäß der internationalen Norm IEC 62471 hat dieses Lampensystem einen Gefahrenwert der Exposition (EHV) von 0,91 und fällt in die Freie Gruppe. Der Gefährdungsabstand (HD) für die Freie Gruppe beträgt 61 cm. Der Gefährdungsabstand für die Risikogruppe 1 beträgt 20 cm. Das Risiko für den Betrachter ist abhängig von der Installation und Benutzung des Gerätes. Die von den LEDs emittierte optische Strahlung kann gefährlich für die Augen sein, wenn man aus sehr geringer Entfernung in das Gerät

mit entferntem Trough schaut. Ziehen Sie den Netzstecker des Gerätes bevor Sie den Trough entfernen. Wenn der Trough während des Betriebs vom Gerät entfernt wird, blicken Sie aus einer Entfernung von weniger als 20 cm nicht direkt in das Licht der LEDs.

Ferner werden LEDs für die Beleuchtung des Lesebereiches eines integrierten 2D Code Lesegeräts benutzt. Blicken Sie im Betrieb nicht aus kurzer Entfernung direkt auf das 2D Code Lesegerät.

Nehmen Sie optische Strahlungsquellen nicht auseinander. Verändern oder entfernen Sie diese nicht. Die optische Strahlung aus geöffneten Geräten kann für die Augen schädlich sein.

Gefahr durch heiße Oberfläche

Die Heizfolie kann ausreichend heiß werden, um bei Berührung Verbrennungen zu verursachen. Die Heizfolie darf nicht berührt werden, während das Gerät in Betrieb ist.

Gefahr durch Geräuschentwicklung

Wird das Gerät bei maximaler Beladung benutzt, kann es zu einer Geräuschentwicklung kommen, dessen Pegel eine Gesundheitsgefährdung darstellt. Gefährliche Schalldruckpegel können zu Hörschäden führen. Es wird empfohlen, dass der Betreiber den Schalldruckpegel am Benutzerstandort und am Ort des höchsten Schalldruckpegels im Umkreis von 1 m des Gerätes misst und berechnet. Es sollten schützenden Maßnahmen, wie z. B. schalldämpfende Lärmschutzvorrichtung, Lärmschutzhauben, oder Gehörschutz benutzt werden, wenn während der Installation des Gerätes nicht sichergestellt werden kann, dass der Schalldruckpegel des Gerätes am Standort der Benutzung einen den die Gesundheit gefährdenden Wert nicht übersteigt. Beachten Sie lokale Vorgaben zum Gehörschutz.

Wartung, Transport und Geräteentsorgung

Versuchen Sie nicht, das Gerät selbst zu warten oder zu reparieren – es sei denn, es ist in diesem Benutzerhandbuch oder anderen technischen Unterlagen von Miltenyi Biotec ausdrücklich vermerkt. Wartung und Reparaturen müssen durch geschulte Fachkräfte ausgeführt werden. Falsche oder unsachgemäße Wartung oder Reparatur an Ihrem Gerät kann zur Gefährdung des Anwenders, unvorhersehbaren Resultaten, Fehlfunktionen, Geräteschäden, vorzeitigem Verschleiß und verringerter Lebensdauer führen. Es kann auch den Verlust Ihrer Garantieansprüche zur Folge haben.

Wenn ein Austausch oder Ersatzteile benötigt werden, stellen Sie sicher, dass Ihr Servicedienstleister nur Originalteile von Miltenyi Biotec oder Teile von Drittanbietern verwendet, die von Miltenyi Biotec spezifiziert und empfohlen werden. Die Verwendung unautorisierter Ersatzteile kann Fehlfunktionen des Gerätes verursachen und die Ergebnisse beeinträchtigen. Miltenyi Biotec akzeptiert keinerlei Garantieansprüche und haftet nicht für Fehlfunktionen oder Schäden am Gerät, die auf Verwendung ungeeigneter Verschleiß- oder Ersatzteile zurückzuführen sind.

Stellen Sie sicher, dass nach jeder erfolgten Wartungs- oder Reparaturleistung ein autorisierter Miltenyi Biotec Servicedienstleister alle notwendigen Sicherheitsprüfungen, welche die durchgeführten Reparaturmaßnahmen verlangen, durchführt, um sicherzustellen, dass das Gerät sich in vorschriftsmäßigem Zustand befindet.

Nutzen Sie nur von Miltenyi Biotec empfohlenes Zusatzgerät und Upgrades zu Ihrem Gerät. Fragen Sie Ihren örtlichen Miltenyi Biotec Vertriebsmitarbeiter nach Miltenyi Biotecs weit reichenden Vereinbarungen zum Geräteservice und Technical Support oder besuchen unsere Website: www.miltenyibiotec.com/support.

Das Gerät sollte vorsichtig gehandhabt in der von Miltenyi Biotec bereit gestellten Verpackung transportiert werden. Im Gerät können innere Schäden auftreten, falls es großer Erschütterung ausgesetzt oder fallengelassen wird. Sollte wegen Reparatur- oder Wartungsleistungen ein Rücktransport zum Hersteller notwendig sein, dekontaminieren Sie das Gerät vor dem Versand, um jegliche Gefahrenstoffe zu entfernen. Wenn Sie Fragen zur vorschriftsmäßigen Dekontaminierung oder zum Versand des Gerätes haben, wenden Sie sich zur Unterstützung bitte direkt an unseren Miltenyi Biotec Technical Support.

Kundeninformation zur Entsorgung von Elektro- und Elektronik-Altgeräten (Waste of Electrical and Electronic Equipment, WEEE)

Bitte entsorgen Sie Ihre Altgeräte von Miltenyi Biotec unter Einhaltung der jeweils geltenden Vorschriften für die Erfassung und Behandlung von Elektro- und Elektronik-Altgeräten und die Entsorgung von Gefahrstoffen. Diese können von Land zu Land sowie regional variieren.

Elektrische und elektronische Geräte können Gefahrstoffe enthalten, welche die Umwelt erheblich belasten und/oder die Gesundheit gefährden. Deshalb müssen Altgeräte speziell gesammelt und durch ausgewiesene Entsorgungsbetriebe 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 dazu bei, unsere natürlichen Ressourcen zu schonen und die menschliche Gesundheit zu schützen.

Miltenyi Biotec setzt sich für den Schutz der Umwelt ein. Miltenyi Biotec bietet in zahlreichen Ländern eigene 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. Bitte beachten Sie, dass je nach Art und Nutzung Ihres Gerätes zusätzliche Anforderungen gelten können.

Für weitere Informationen oder wenn Sie Ihr Miltenyi Biotec-Altgerät entsorgen möchten, wenden Sie sich bitte an Ihren lokalen Miltenyi Biotec-Vertreter oder den Miltenyi Biotec Technical Support.

ES

Información importante de seguridad

⚠WARNING El gentleMACS Octo Dissociator with Heaters es un aparato de laboratorio. El instrumento se puede utilizar de forma segura si se garantiza lo siguiente: el instrumento está instalado correctamente. El instrumento solo lo manejan personal de laboratorio profesional. Se siguen las prácticas generales de seguridad. Se siguen todas las instrucciones en este manual de uso.

Advertencias y precauciones

Las directrices en esta sección explican los riesgos potenciales asociados con el manejo de este instrumento y proporcionan una importante información complementaria para minimizar los riesgos. Siga las instrucciones atentamente para protegerse a sí mismo, a otros y al equipamiento, de riesgos potenciales y crear un ambiente de trabajo seguro. Use este instrumento solo como especificado por el fabricante para evitar daños en el equipo y lesiones en el personal.

Siga siempre las instrucciones de seguridad y política de laboratorio del área de trabajo local, así como los estándares de salud, seguridad y prevención de accidentes. Contacte la autoridad local a cargo de la fuente de energía eléctrica, construcciones, mantenimiento o seguridad para más información sobre la instalación segura y manejo del instrumento.

Niveles de riesgo

Se usan señales para identificar mensajes de seguridad y de daño de la propiedad. Las siguientes señales se usan a través de este manual de usuario.

⚠WARNING o **WARNING!** indica una situación potencialmente peligrosa, la cual, si no se evita, puede resultar en muerte o daños graves.

⚠CAUTION o **CAUTION!** indica una una situación potencialmente peligrosa, la cual, si no se evita, puede resultar en un daño menor o moderato. También puede ser usado para alertar contra prácticas peligrosas.

Símbolos

Los siguientes símbolos se usan para destacar condiciones que podrían causar daños al personal o daños al equipo:

Alerta de seguridad. Riesgo de peligro. Es necesario consultar la documentación del equipo siempre que este símbolo de alerta de seguridad aparezca, para de esta manera poder averiguar la naturaleza del peligro potencial existente y las acciones necesarias a realizar.

Riesgo biológico. Riesgo de contaminación si se usa material biológico potencialmente peligroso.

Riesgo de shock eléctrico.

Radiación óptica peligrosa.

Riesgo involuntario de captura de dedo por parte rotatoria peligrosa.

Peligro superficie caliente.

Riesgos del nivel de ruido.

Bloques de conexión para conductores de protección. El símbolo está pegado en el interior del instrumento. Esta información es para el personal de servicio.

Fusible.

RAEE (Residuos de Aparatos Eléctricos y Electrónicos).

ON (Fuente de energía).
OFF (Fuente de energía).

Lea todas las instrucciones de uso antes de instalar y utilizar el instrumento.

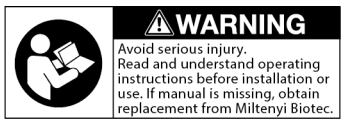
Aprobación de Conformidad Europea

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 el laboratorio de ensayo reconocido nacionalmente (Nationally Recognized Testing Laboratories (NRTL)) TÜV Süd.

Etiqueta de seguridad

La siguiente etiqueta de seguridad se encuentra pegada a la parte posterior del instrumento y juega un papel importante en el mantenimiento de la seguridad.



ADVERTENCIA! Evita las lesiones graves. Lea y comprenda las instrucciones de funcionamiento antes de la instalación o el uso. Si falta el manual, solicite su sustitución a Miltenyi Biotec.

La base presenta los siguientes símbolos de seguridad.

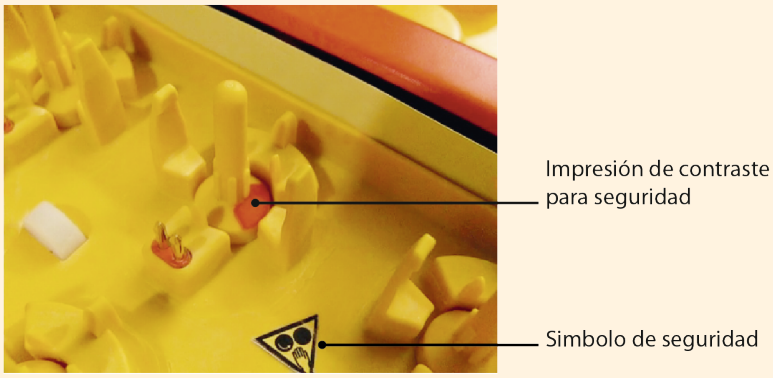


Figure 1: Símbolo de seguridad en la base del gentleMACS Octo Dissociator with Heaters. Los manguitos están marcados con una impresión de contraste para seguridad.

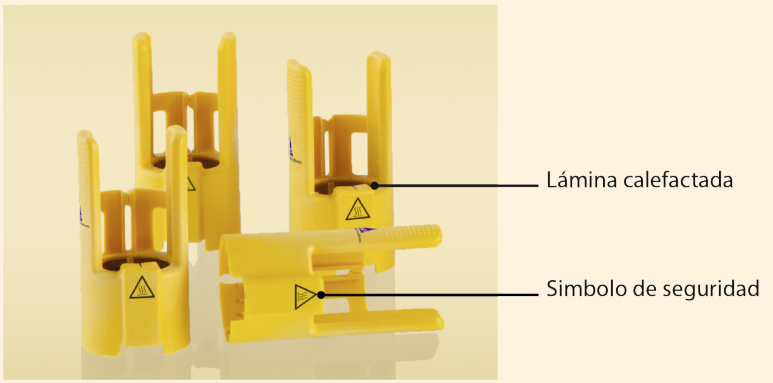


Figure 2: Símbolo de seguridad en los calefactores gentleMACS.

Los manguitos están marcados con una impresión de contraste para seguridad. Esta impresión de contraste para seguridad permite la percepción visual de los manguitos rotatorios.

Las etiquetas de seguridad arriba mencionadas y las marcas de seguridad deberán mantenerse límpias y legibles. Inspecionar periódicamente las etiquetas y marcas de seguridad y reemplazarlas en caso de que estas no sean legibles o perceptibles a una distancia visual segura. Contacte con Miltenyi Biotec para reemplazo de etiquetas.

Instrucciones generales de seguridad

Si el instrumento no funciona correctamente y/o las instrucciones o mensajes mostrados le aconsejan contactar con el servicio técnico, no es posible utilizar el instrumento de una manera segura. Apague y desenchufe inmediatamente el instrumento de la toma de corriente, y contacte un proveedor de servicios autorizado de Miltenyi Biotec o un servicio técnico autorizado.

Incendios y riesgos eléctricos

Los riesgos potenciales causados por aparatos eléctricos incluyen shock eléctrico, cortocircuito y sobrecalentamiento. Un shock eléctrico puede llevar a graves daños corporales o incluso la muerte. Un

cortocircuito eléctrico o sobrecalentamiento puede ser causa de incendio. El equipo electrónico puede emitir chispas, las cuales podrían encender vapores o material combustible resultando en explosión o incendio. No use el instrumento en áreas designadas como peligrosas; por ejemplo, en medios cargados de oxígeno.

La caja protectora del instrumento está diseñada para reducir el riesgo de shock eléctrico, cortocircuito eléctrico y propagación de fuego. Excepto la de la Safety Shield y la Trough, no quite o penetre ninguna tapa o cubierta. Solo el personal autorizado debe quitar las otras tapas del instrumento. Nunca introduzca un objeto extraño a través de una apertura en el instrumento. No use el instrumento si

- está abierto o desensamblado,
- se ha caído o ha sido dañado,
- tiene partes dañadas o rotas,
- tiene un cable de energía dañado,
- un objeto ha entrado a través de las ranuras de ventilación,
- un objeto extraño ha caído en el instrumento.

Si aparecen llamas o humo, inmediatamente apague la fuente de energía, desenchufe el instrumento de la toma de corriente, y contacte un proveedor de servicios autorizado de Miltenyi Biotec o un servicio técnico de Miltenyi.

El instrumento está destinado solo a uso en un lugar cubierto. **Si algún fluido entra en el instrumento, puede ocasionar cortocircuitos eléctricos, shock eléctrico o incendio.** No permita que fluidos penetren el interior del instrumento. Proteja el instrumento contra vertidos y salpicaduras accidentales. Limpie inmediatamente los vertidos. No utilice el instrumento si se han derramado líquidos en el instrumento. No utilice el instrumento en un lugar mojado o húmedo. Evite áreas con alta humedad o vapor. Transportar el instrumento de un medio frío – como una habitación fría a 5 °C – a temperatura ambiente, puede causar una condensación dentro del instrumento. En esos casos, espere a que el instrumento se deshumidifique antes de utilizarlo. Desenchufe el instrumento de la toma de corriente antes de limpiarlo. No utilice agentes limpiadores líquidos o aerosoles; use siempre un paño húmedo.

Asegúrese de que hay suficiente ventilación en el lugar donde se utilice el instrumento. En la ausencia de una circulación adecuada, el aire del ambiente puede no enfriar el instrumento a temperaturas de funcionamiento adecuadas. Permita una suficiente circulación del aire alrededor del instrumento – al menos 15 cm en todos los lados – durante el manejo para asegurar un enfriamiento adecuado. No coloque el instrumento cerca de radiadores, registros de calor, estufas, u otro equipamiento (incluyendo amplificadores) que genere calor. Proteja el instrumento de la luz directa del sol. No cubra las ranuras y aperturas del instrumento ya que están destinadas a la ventilación y protección contra el sobrecalentamiento del instrumento. No coloque el instrumento en un estante empotrado o espacios similarmente confinados a menos que el espacio haya sido específicamente designado para proveer una ventilación adecuada. Siga las instrucciones de montaje del instrumento.

Asegúrese de que el enchufe principal así como el conector para el cable de energía están fácilmente accesibles y colocados tan cerca del operador del instrumento como sea posible. Si es necesario desconectar la fuente de energía, desconecte el cable de la toma de corriente.

El instrumento está equipado con un enchufe eléctrico con tres cables para la toma de tierra, que tiene una tercera clavija para la toma. Este enchufe solo se adapta a una toma de corriente de tierra. Este es un procedimiento de seguridad. No intente insertar el enchufe en una toma de corriente que no sea de tierra. Si no puede insertar el enchufe en la toma, contacte a su electricista local para reemplazar la toma.

El instrumento debería ser utilizado desde una fuente de energía que cumple las especificaciones mencionadas en la etiqueta de potencia eléctrica del producto.
Si tiene preguntas sobre el tipo de fuente de energía que usar, contacte a su proveedor de servicios autorizado de Miltenyi Biotec o una compañía de energía local. No use alargadores o enchufes múltiples. No sobrecargue una toma de corriente.

Riesgos mecánicos

Mover y quitar piezas son potenciales riesgos mecánicos. Cuando utilice el instrumento, mantenga la Trough, Sleeves, y Safety Shield junto a él. No toque o quite los tubos del instrumento cuando los rotores del instrumento estén rotando. Utilice solo gentleMACS Tubes instalados adecuadamente con tapas fuertemente cerradas. No utilice el instrumento con solo las tapas de los gentleMACS Tubes en su lugar. Los bordes cortantes de las tapas de los gentleMACS Tubes pueden llevar a heridas por corte si se tocan mientras están rotando. No ignore ninguna medida o aparato de seguridad.

Riesgos químicos y biológicos

Dependiendo del material biológico utilizado, una contaminación o infección puede llevar a graves daños personales o muerte. Todas las muestras clínicas deben ser consideradas potencialmente infecciosas. **Si se ha usado material de riesgo biológico, el operador debe elegir y llevar puesto equipamiento personal de seguridad** como indicado en las advertencias y precauciones para la substancia particular. La precaución de seguridad anterior también es válida para cualquier químico de riesgo, incluyendo químicos tóxicos o corrosivos, ácidos, o substancias radioactivas que pueden estar presentes en la muestra. Lleve guantes, ropa y gafas de seguridad para prevenir el contacto de la substancia con la piel y ojos. Un equipamiento de seguridad defectuoso o inadecuado es peligroso. El instrumento debe ser utilizado con una cubierta de seguridad si están siendo procesados materiales peligrosos o desconocidos. Si se ha utilizado o derramado material peligroso, debe tenerse cuidado en descontaminar a fondo el instrumento. Está estrictamente prohibido continuar utilizando accesorios o piezas del instrumento contaminadas.

Los tubos y otros consumibles que han estado en contacto con material de riesgo biológico deben ser descontaminados antes de su eliminación. Todos los residuos líquidos o sólidos deben ser considerados peligrosos de acuerdo con las precauciones universales de laboratorio. El desecho de residuos debe hacerse de acuerdo con las regulaciones locales.

Riesgos de radiación óptica

El instrumento está equipado con poderosos diodos de emisión de luz (LEDs) para iluminar la Safety Shield y los gentleMACS Tubes. De acuerdo con el estándar internacional IEC 62471, este sistema de luces tiene un valor de riesgo por exposición (EHV) de 0.91 y es superior al Grupo Exento de Riesgo. La distancia de riesgo (HD) para el Grupo Exento de Riesgo es 61 cm. La distancia de riesgo para el Grupo de Riesgo 1 es 20 cm. El riesgo del visor depende de cómo se instala y utiliza el instrumento. La radiación óptica emitida por estos LEDs puede ser dañina para los ojos a distancias cortas si se quita la Trough. Desenchufe el instrumento antes de quitar la Trough. Si se quita la Trough, no mire fijamente la iluminación de los diodos LEDs en funcionamiento desde una distancia menor a 20 cm.

Además, el lector de códigos 2D integrado utiliza LEDs para iluminar el área de lectura. No mire directamente al lector de códigos 2D desde una distancia corta mientras está en funcionamiento.

No desensamble, modifique, o elimine ninguna de las fuentes de radiación óptica. La radiación óptica de instrumentos desensamblados puede ser perjudicial para los ojos.

Riesgos superficie caliente

La lámina calefactada de los calenfactores gentleMACS puede llegar a causar quemaduras si se toca. No tocar la lámina calefactada mientras el equipo está en funcionamiento.

Riesgos del nivel de ruido

Si el instrumento se usa en su carga máxima, puede producir problemas de oído. Se recomienda que el organismo responsable mida o calcule el nivel de presión del sonido en la posición del operador, y en cualquier punto alejado 1 metro del equipo, donde tiene su nivel de presión más alto. Si no se asegura durante la instalación que el nivel de presión del sonido del aparato no alcanzará en este punto de uso un valor que podría suponer un riesgo, entonces debe usarse equipamiento de protección como cubiertas reductoras del ruido. Observe las normas locales sobre protección auditiva.

Servicio, transporte y eliminación seguros

A menos que de otro modo señalado en este manual de usuario o en otra documentación de Miltenyi Biotec, no repare o revise el instrumento Usted mismo. Las revisiones y reparaciones deben ser llevadas a cabo por personal de servicio cualificado. Una reparación o revisión inadecuada o incorrecta del instrumento puede causar riesgos a los usuarios, llevar a resultados impredecibles, causar el mal funcionamiento o daño del instrumento, así como un prematuro desgaste y vida reducida del instrumento. También puede invalidar su garantía.

Cuando sean requeridas piezas de repuesto, asegúrese de que el proveedor de servicios usa solo piezas originales de Miltenyi Biotec, o piezas de terceros especificadas y recomendadas por Miltenyi Biotec. El uso de piezas no autorizadas puede causar un mal funcionamiento del instrumento y resultados dañados. Miltenyi Biotec no se hace responsable de ninguna garantía o de un error o daño del instrumento resultante del uso de piezas inadecuadas. Al finalizar cualquier servicio o reparación, asegúrese de que su proveedor de servicios autorizado de Miltenyi Biotec lleva a cabo todas las comprobaciones de seguridad como requerido por el procedimiento de reparación, para asegurarse de que el instrumento está funcionando correctamente.

Utilice solo opciones y actualizaciones recomendadas por Miltenyi Biotec. Consulte con su representante local de Miltenyi Biotec sobre el amplio servicio del instrumento, o diríjase a www.miltenyibiotec.com/support.

El instrumento debe ser transportado cuidadosamente en embalaje especificado por Miltenyi Biotec. Si el instrumento está sujeto a una vibración excesiva o caída, pueden ocurrir daños internos. Si el instrumento necesita ser enviado de vuelta al fabricante para su servicio, descontamine el instrumento para eliminar cualquier material peligroso antes del transporte. Si tiene preguntas respecto a una correcto descontaminización o transporte, contacte al Servicio Técnico Miltenyi Biotec.

Información sobre la Directiva de Residuos de Aparatos Eléctricos y Electrónicos (Waste of Electrical and Electronic Equipment, WEEE)

Por favor, al final de la vida útil de su equipo de Miltenyi Biotec disponga del mismo de acuerdo a la ley WEEE aplicable, la cual puede ser diferente según el país o región.

Los equipos eléctricos y electrónicos pueden contener sustancias peligrosas que pueden tener graves efectos perjudiciales sobre el medio ambiente y/o la salud humana. Por este motivo, todos los equipos deben ser específicamente recogidos y tratados por los centros de residuos designados y según planes de cumplimiento de la WEEE cualificada. Al asegurarse de que se está deshaciendo de su equipo eléctrico y electrónico no deseado de acuerdo con la legislación y la WEEE aplicable de disposición de residuos peligrosos, estará ayudando a preservar nuestros recursos naturales y a proteger la salud humana.

Miltenyi Biotec está comprometido con la protección del medio ambiente. Miltenyi Biotec ofrece productos que se encuentran en el final de su vida a programas de retorno de muchos países, y a socios con esquemas de cumplimiento de licencias WEEE en todo el mundo. Miltenyi Biotec le ofrece reciclar su equipo de Miltenyi Biotec en el final de su vida útil forma gratuita. Los términos y la disponibilidad de esta oferta pueden variar según la región geográfica, debido a las diferencias en los requisitos reglamentarios. Tenga en cuenta que, dependiendo del tipo y uso del equipo, pueden aplicarse requisitos adicionales.

Para más información, o si desea eliminar su equipo de Miltenyi Biotec en el final de su vida útil, por favor póngase en contacto con su representante local de Miltenyi Biotec o con el Servicio Técnico de Miltnyi Biotec.

FR

Informations de sécurité importantes

⚠WARNING Le gentleMACS Octo Dissociator with Heaters est un appareil de laboratoire. L'instrument peut être utilisé en toute sécurité si les conditions suivantes sont réunies : L'instrument est correctement installé. L'instrument est utilisé uniquement par des personnel de laboratoire professionnel. Les pratiques de sécurité générales sont observées. Toutes les instructions fournies dans ce Guide de l'Utilisateur sont observées.

Avertissements et précautions

Les directives dans ce chapitre décrivent les risques potentiels associés au maniement de cet appareil et fournissent d'importantes informations de sécurité supplémentaires pour réduire les risques. Suivez soigneusement les instructions, afin de vous protéger vous-même, des tiers et le dispositif d'éventuels dangers et de créer un environnement de travail sûr. Utilisez cet appareil uniquement en respectant les instructions du fabricant afin d'éviter une détérioration du dispositif et des blessures du personnel.

Suivez toujours les consignes de sécurité du champ d'opération et les bonnes pratiques de laboratoire ainsi que les normes pour la santé, la sécurité et la prévention d'accidents. Contactez les autorités locales gérant l'alimentation en courant électrique, la construction de bâtiments, la maintenance ou la sécurité pour plus d'informations sur l'installation et l'utilisation sûre de l'appareil.

Niveaux de danger

Des mots clé sont utilisés pour identifier des messages sur des détériorations matériels et de sécurité. Les mots clé suivants sont utilisés dans ce manuel.

⚠WARNING ou **WARNING!** indique une situation potentiellement dangereuse, pouvant entraîner la mort ou des blessures graves, si elle n'est pas évitée.

⚠CAUTION ou **CAUTION!** indique une situation potentiellement dangereuse pouvant causer des blessures mineures ou modérées, si elle n'est pas évitée. Il peut également servir d'alerte contre une utilisation risquée.

Symboles

Les symboles suivants sont utilisés pour souligner des conditions qui pourraient entraîner des blessures du personnel ou une détérioration du dispositif :

Alerte de sécurité. Risque de danger. La documentation doit être consulté dans les cas où un symbole d'alerte de sécurité est mentionné sur l'instrument afin de connaitre la nature du danger potentiel et les mesures à prendre.

Danger biologique. Risque de contamination, si des matières biologiques potentiellement dangereuses sont utilisés.

Risque d'un choc électrique.

Radiation optique dangereuse.

Risque de capture involontaire d'un doigt par rotation d'une partie dangereuse.

Surface dangereusement chaude.

Niveaux de bruits dangereux.

Borne pour conducteur de protection. Ce symbole est fixé à l'intérieure de l'appareil. Cette information est destinée au personnel de service.

Fusible.

DEEE (Déchets d'Équipements Électriques et Électroniques).

ON (Alimentation électrique).
OFF (Alimentation électrique).

Les instructions de service doivent être lues dans leur intégralité, avant l'installation et l'utilisation de l'appareil.

Approbation Européenne de Conformité

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) et déterminées par le laboratoire d'essais reconnu au niveau national (Nationally Recognized Testing Laboratories (NRTL)) TÜV Süd

Étiquette de sécurité

L'étiquette de sécurité est fixée à l'arrière de l'appareil et joue un rôle important pour la maintenance de sécurité.

AVERTISSEMENT! Évitez les blessures graves. Lisez et comprenez les instructions d'utilisation avant d'installer ou d'utiliser l'appareil. Si le manuel est manquant, demandez à Miltenyi Biotec de le remplacer.

La cuve est marquée avec les symboles de sécurité suivants.

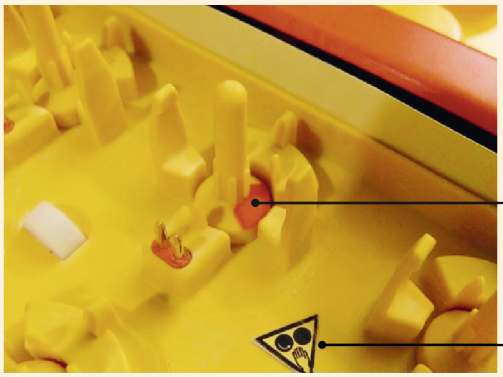


Figure 1: Symbole de sécurité sur la fosse du gentleMACS Octo Dissociator with Heaters. Les manchons bénéficient d'un marquage coloré.

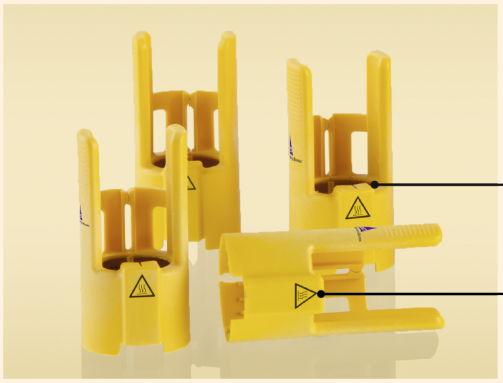


Figure 2: Symboles de sécurité relatifs à la partie chauffante du gentleMACS.

Les manchons présentent un marquage coloré afin de signaler visuellement la partie rotative.

Les étiquettes et marquage de sécurité doivent être maintenus propres et lisibles. Il convient de les inspecter périodiquement et de les remplacer si elles ne sont pas lisibles ou perceptibles à une distance d'observation garantissant la sécurité du manipulateur. Contactez Miltenyi Biotec pour le remplacement des étiquettes de sécurité.

Consignes de sécurité générales

Si l'appareil ne fonctionne pas correctement et/ou les instructions ou messages affichés vous avisent de contacter le support technique, l'utilisation sûre de l'appareil n'est plus longtemps garantie. Éteignez immédiatement l'appareil et débranchez-le de la prise électrique, puis contactez un prestataire de services Miltenyi Biotec agréé ou l'équipe de support technique de Miltenyi Biotec.

Dangers électriques et incendie

Les risques potentiels résultant d'appareils électriques sont le choc électrique, le court circuit et la surchauffe. Un choc électrique peut entraîner de graves blessures corporelles ou même la mort. Un court circuit ou une surchauffe peuvent provoquer un incendie. Des équipements électriques peuvent émettre des étincelles, pouvant enflammer des vapeurs ou matières combustibles, ce qui pourrait engendrer une explosion ou un incendie. N'utilisez pas cet appareil dans des endroits jugés dangereux; par exemple, dans un environnement riche en oxygène.

Le boîtier de l'appareil est conçu de façon à réduire les risques de choc électrique, de court circuit et de propagation du feu. A l'exception du Safety Shield et de la Trough, n'enlevez aucun couvercle et n'y pénétrez pas. Seul un personnel autorisé a le droit d'enlever les autres couvercles. N'introduisez jamais un corps étrangers à travers d'une fente à l'intérieure de l'appareil. N'utilisez jamais l'appareil lorsqu'

- il est ouvert ou démonté,
- il est tombé ou qu'il a été endommagé,
- il a des pièces endommagées ou abîmées,
- il a des câbles électriques endommagés,
- un objet y est entré par les fentes de ventilation,
- un corps étranger a pénétré dans l'appareil.

Si des flammes ou la fumée apparaissent, coupez immédiatement l'alimentation électrique, débranchez l'appareil de la prise électrique, puis contactez un prestataire de services Miltenyi Biotec agréé ou l'équipe de support technique de Miltenyi Biotec.

L'appareil est uniquement destiné à une utilisation intérieure. **Si des fluides pénètrent à l'intérieur de l'appareil, ceci peut entraîner des courts circuits, des chocs électriques ou des incendies.** Faites extrêmement attention lorsque vous utilisez des liquides. Veillez à ce qu'aucun fluide ne pénètre à l'intérieur de l'appareil. Protégez l'appareil contre des déversements et éclaboussements accidentels. Nettoyez immédiatement tout déversement. Ne pas utiliser l'appareil, si des liquides ont coulés dans l'appareil. Ne pas utiliser l'appareil dans des endroits humides et brumeux. Evitez des endroits ayant une forte humidité ou condensation. Le déplacement de l'appareil d'un environnement froid – comme une chambre froide à 5 °C – à un endroit à température ambiante peut causer une condensation à l'intérieur de l'appareil. Dans ces cas-là, attendez que l'appareil soit sec, avant de l'utiliser. Débranchez l'appareil de la prise électrique avant de le nettoyer. Ne pas utiliser des détergents liquides ou aérosols; utilisez toujours un tissue humide.

Assurez une circulation adéquate de l'air dans la pièce où l'appareil est utilisé.
Si une telle circulation adéquate n'est pas assurée, l'air ambiant ne peut pas refroidir l'appareil à des températures de fonctionnement acceptable. Veillez à ce que l'air puisse bien circulé au tour de l'appareil pendant son fonctionnement – au moins 15 cm des deux côtés – pour garantir un refroidissement adéquat. Évitez de placer l'appareil près de radiateurs, d'accumulateurs de chaleur, de poêles ou d'autres dispositifs (y compris des amplificateurs) générant de la chaleur. Ne pas exposer l'appareil au soleil. Ne couvrez pas les fentes et les lumières de l'appareil, car elles servent de ventilation et évite une surchauffe de l'appareil. Ne placez pas l'appareil dans un rack encastré ou des espaces confinés similaires, à moins que cet espace ait spécialement été conçu, pour fournir une ventilation convenable. Suivez les instructions de montage de cet appareil.

Assurez que l'interrupteur général ainsi que le connecteur pour le câble électrique soient facilement accessibles et qu'ils se trouvent le plus proche possible de l'opérateur de l'appareil. S'il est nécessaire de couper l'alimentation électrique, débranchez le câble de la prise électrique.

L'appareil est équipé d'une prise électrique à trois fils et mise à la terre avec une troisième broche de connecteur pour la mise à la terre. Cette prise ne s'emboîte que dans une prise de courant mise à la terre, ceci pour des raisons de sécurité. N'essayez pas d'introduire la prise dans une prise femelle de courant non mise à la terre. Si vous ne parvenez pas à introduire la prise dans une prise femelle, contactez votre électricien local pour remplacer la prise femelle.

L'appareil doit uniquement être utilisé à partir d'une source d'énergie qui remplit les spécifications mentionnées sur l'étiquette de puissance électrique du produit.
Si vous avez des questions sur le type de source de courant à utiliser, contactez votre prestataire de services Miltenyi Biotec agréé ou votre entreprise locale de production et de distribution d'énergie. N'utilisez aucune rallonge électrique ou multiprise. Ne surchargez pas une prise électrique.

Dangers mécaniques

Des pièces mobiles et tournantes sont de potentiels dangers mécaniques. Lorsque vous utilisez l'appareil, veillez à ce que la Trough, les Sleeves et le Safety Shield y soient bien fixés. Quand les rotors de l'appareil sont en rotation, ne les touchez pas. Ne chargez et n'enlevez pas les tubes de l'appareil. Utilisez uniquement des gentleMACS Tubes correctement installés avec des chapes étroitement fermées. N'utilisez pas l'appareil seulement avec des chapes de gentleMACS Tube en place. Les tranchants exposés des chapes de gentleMACS Tube peuvent provoquer des incisions, si ils sont touchés lorsqu'ils sont en rotation. Ne contournez aucune mesure ou dispositif de sécurité.

Dangers chimiques et biologiques

Selon la matière biologique utilisée, une contamination et infection peut entraîner des blessures corporelles graves ou même la mort. Tout prélèvement clinique doit être considéré comme potentiellement contagieux.

Si des matières biologiquement dangereuses sont ou ont été utilisées, l'opérateur doit choisir et porter un équipement et des vêtements de protection, tel indiqué dans les avertissements et mesures de sécurité pour la substance respective. La mesure de sécurité mentionnée ci-dessus s'applique également pour toute substance chimique dangereuse, y compris toxique ou corrosive, acide ou radioactive, pouvant être présente dans le prélèvement. Portez des gants et des vêtements de protection, ainsi que des lunettes protectrices, pour que la substance n'entre pas en contact avec le visage et les yeux. Un équipement de protection défectueux ou inadéquate est dangereux. L'appareil doit être utilisé dans une hotte de sécurité, si des matières dangereuses ou inconnues sont traitées. Si des matières dangereuses ont été utilisées ou renversées, l'appareil doit soigneusement et complètement être décontaminé. Il est strictement interdit de continuer l'utilisation d'accessoires ou de pièces de l'appareil contaminées.

Des tubes et tout autre consommable qui étaient en contact avec des matières biologiquement dangereuses doivent être décontaminés avant d'être jetés. Tout liquide et déchet solide doivent être considérés comme dangereux et pour cela être traités selon les précautions universelles de laboratoire. L'enlèvement de déchets doit être conforme aux réglementations locales.

Dangers de radiation optique

L'appareil est équipé de puissantes diodes électroluminescentes (DELs) pour illuminer le Safety Shield et les gentleMACS Tubes. Selon la norme internationale CEI 62471, ce système de lampe a une valeur d'exposition limite (ELV) de 0,91 et dépasse le groupe exempt de risques. La distance de sécurité (DS) pour le groupe exempt de risques est de 61 cm. La distance de sécurité pour le groupe de risques 1 est de 20 cm. Le risque lié au spectateur dépend de la façon dont est installée et utilisée l'appareil. La radiation optique émise de ces DELs

peut être nuisible aux yeux à une proche distance de vue, si la Trough est enlevée. Débranchez l'appareil avant d'enlever la Trough. Si la Trough est enlevée, ne pas regarder dans l'éclairage des DELs à une distance inférieure à 20 cm.

De plus, le lecteur de code 2D utilise des DELs pour illuminer la zone de lecture. Ne fixez pas directement le lecteur de code 2D des yeux à une courte distance, lorsqu'il fonctionne.

Ne démontez, modifiez, ou enlevez aucune des sources de radiation optique. Une radiation optique d'appareils démontés peut être nuisible aux yeux.

Surface chaude dangereuse

La surface des parties chauffantes du gentleMACS peut provoquer des brûlures en cas de contact. Ne touchez pas la surface chauffante pendant le fonctionnement de l'appareil.

Niveaux de bruits dangereux

Si l'appareil est utilisé à une charge maximale, il peut produire des bruits à un niveau dangereux. Des niveaux de bruits dangereux peuvent entraîner une défaillance auditive. Il est recommandé que le corps responsable mesure ou calcule le niveau de la pression acoustique à la position de l'opérateur. Il doit également définir à quel point à un mètre du boîtier du dispositif l'on mesure le plus haut niveau de pression acoustique. S'il n'est pas garanti pendant l'installation que le niveau de pression acoustique de l'appareil n'atteindra pas une valeur pouvant entraîner un danger à son endroit d'utilisation, des matériels de protection tels que des baffles ou hottes réduisant le bruit, ainsi que des protections sonores doivent être utilisées. Observez les réglementations locales en matière de protection auditive.

Maintenance, transport et élimination

N'entretenez pas vous-même l'appareil, à moins que ceci ait été spécifiquement mentionné dans ce manuel ou d'autres documentations de Miltenyi Biotec,.

La maintenance et les réparations doivent être effectuées par un personnel de maintenance qualifié. Une maintenance ou réparation impropre ou incorrecte de l'appareil peut causer des dangers pour l'utilisateur, amener des résultats imprévisibles, causer un dysfonctionnement ou une détérioration de l'appareil, ainsi qu'une usure prématurée et une réduction de la longévité de l'appareil. Ceci peut également faire expirer votre garantie.

Si des pièces de rechange sont nécessaires, assurez-vous que le prestataire de services utilise uniquement des pièces authentiques de Miltenyi Biotec, ou des pièces de tiers spécifiées et recommandées par Miltenyi Biotec. L'utilisation de pièces non autorisées peut entraîner un dysfonctionnement de l'appareil et impacter les résultats. Miltenyi Biotec n'accorde aucune garantie ou ne prend aucune responsabilité pour des défauts de l'appareil ou des détériorations résultant de l'utilisation de pièces inappropriées. Après l'achèvement de tout travail de maintenance et de réparation, assurez-vous que votre prestataire de services Miltenyi Biotec agréé entreprenne tous les contrôles de sécurité, comme le demande la procédure de réparation pour garantir un fonctionnement normal de l'appareil.

Utilisez uniquement des options et extensions recommandées par Miltenyi Biotec. Renseignez-vous auprès de votre représentant local Miltenyi Biotec sur les arrangements extensives de support et de maintenance de l'appareil, ou bien référez vous à www.miltenyibiotec.com/support.

L'appareil doit être transporté avec soin dans des emballages spécifiés par Miltenyi Biotec. Une détérioration intérieure peut se produire, si l'appareil fait l'objet de vibrations excessives ou d'une chute. Si l'appareil doit être expédié de retour au fabricant pour la maintenance, décontaminez l'appareil pour éliminer toute matière dangereuse avant le chargement. Pour toute question concernant une décontamination ou un chargement correct, veuillez contacter le support technique de Miltenyi Biotec.

Déchets d'Equipements Electriques et Electroniques (DEEE) – Information Client

Pensez à recycler vos produits Miltenyi Biotec en fin de vie en conformité avec la directive DEEE en vigueur dans votre pays.

Les équipements électriques et électroniques peuvent contenir des substances dangereuses, qui peuvent avoir un effet néfaste sur l'environnement et / ou la santé humaine. C'est pourquoi tous les équipements doivent être spécifiquement collectés et traités par les centres désignés et ce en conformité avec la

« Réglementation DEEE ». En vous assurant que vous éliminez vos équipements électriques et électroniques en accord avec la législation en vigueur, vous contribuez à préserver nos ressources naturelles et à protéger la santé humaine.

La protection de l'environnement est au cœur de nos préoccupations. Ainsi, nous finançons de nombreux programmes de collecte et de recyclage des équipements électriques que nous mettons sur le marché, en reversant une partie du prix de vente de nos produits à des éco-organismes agréés à travers le monde. Miltenyi Biotec vous permet de recycler 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 supplémentaires peuvent s'appliquer.

Pour plus d'informations, ou si vous souhaitez recycler votre équipement Miltenyi Biotec en fin de vie, contactez votre interlocuteur Miltenyi Biotec ou notre support technique.

IT

Importanti istruzioni di sicurezza

⚠WARNING Il gentleMACS Octo Dissociator with Heaters è un apparecchio da laboratorio. Lo strumento può essere utilizzato in sicurezza, se è garantito quanto segue: Lo strumento è stato installato correttamente. Lo strumento è gestito solo da personale di laboratorio professionalmente. Vengono seguite le pratiche generali di sicurezza. Vengono seguite tutte le istruzioni contenute in questo manuale d´uso dell'utente.

Avvisi e precauzioni

Le istruzioni in questa sezione spiegano i potenziali rischi associati all'uso di questo strumento e provvedono a fornire delle informazioni di sicurezza aggiuntive per minimizzare il rischio. Si seguano le istruzioni attentamente per proteggere Voi stessi, gli altri e l'attrezzatura da potenziali pericoli e creare un ambiente di lavoro sicuro. Si utilizzi questo strumento solo come specificato dal produttore per evitare danni al prodotto o lesioni al personale.

Si seguano sempre le indicazioni di sicurezza specifiche del luogo di lavoro e le disposizioni del laboratorio, nonché gli standard di salute, sicurezza e prevenzione incidenti. Si contatti l'autorità locale per il controllo delle forniture elettriche, le costruzioni della struttura, la manutenzione e la sicurezza, per ottenere maggiori informazioni in merito all'installazione sicura e l'impiego dello strumento.

Livelli di pericolo

Segnali di avviso sono in uso per identificare un uso sicuro e messaggi in caso di danni a cose personali. I seguenti segnali saranno in uso in questo manuale.

⚠WARNING o **WARNING!** indica una situazione potenzialmente pericolosa, che, se non evitata, protrebbe causare morte o gravi danni.

⚠CAUTION o **CAUTION!** indica una situazione potenzialmente pericolosa, che, se non evitata, protrebbe causare danni minori e lesioni moderate. Può essere impiegato per segnalare procedure pericolose.

Simboli

I seguenti simboli sono impiegati per sottolineare condizioni che potrebbero causare lesioni a persone o danni all´attrezzatura:

Avviso di sicurezza. Rischio di pericolo. Consultare il manuale di istruzioni ogni volta che questo simbolo di avvertimento viene utilizzato sul dispositivo, per identificare la natura del potenziale pericolo e stabilire quali azioni intraprendere.

Rischio biologico. Rischio di contaminazione se è in uso materiale biologio potenzialmente pericoloso.

Rischio di scosse elettriche.

Radiazione ottica pericolosa.

Rischio di intrappolamento involontario delle dita a causa di parti rotanti.

Superficie calda pericolosa.

Rischi di livello acustico.

Morsetto di protezione. Questo simbolo è applicato internalmente allo strumento. Si tratta di informazioni per il personale di servizio.

Fusibile.

RAEEE (Rifiuti di apparecchiature elettriche ed elettroniche).

On (Alimentazione).
Off (Alimentazione).

Tutte le istruzioni operative devono essere lette prima di installare ed impiegare lo strumento.

Conformità valutata del regno unito

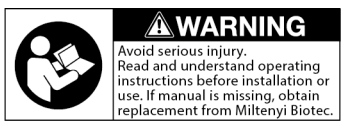
Approvazione di Conformità Europea

Conformità valutata del Regno Unito

Marcatura della certificazione NRTL: Il prodotto è conforme alle norme di sicurezza, basate sul consenso, imposte dall'Occupational Safety/Health Administration (OSHA), determinate dai laboratori di prova nazionali riconosciuti (Nationally Recognized Testing Laboratories (NRTL)) TÜV Süd

Etichetta di sicurezza

La seguente etichetta è applicata sul retro dello strumento e gioca un ruolo fondamentale nel mantenimento del livello di sicurezza.



ATTENZIONE! Evitare lesioni gravi. Leggere e comprendere le istruzioni per l'uso prima dell'installazione o dell'uso. In caso di mancanza del manuale, richiedere la sostituzione a Miltenyi Biotec.

I seguenti simboli di sicurezza sono esposti sul fondo della vaschetta.

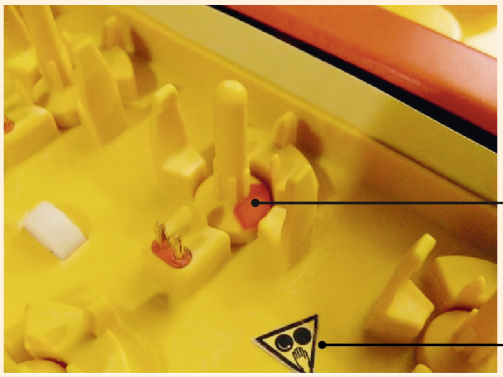


Figure 1: Simbolo di sicurezza sul fondo della vaschetta del gentleMACS Octo Dissociator with Heaters.

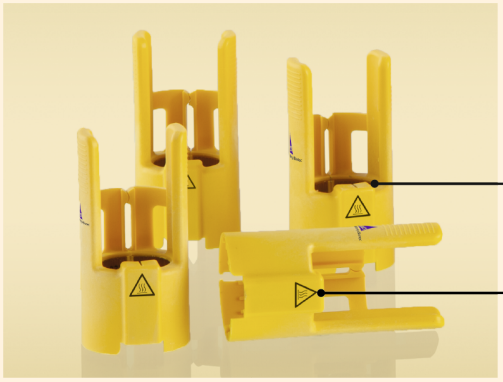


Figure 2: Simbolo di sicurezza sul gentleMACS Heaters.

I perni sono evidenziati da una marcatura di sicurezza di colore diverso. La funzione delle marcature è quella di evidenziare il movimento rotatorio del perno.

Le etichette di sicurezza e i marchi di sicurezza devono essere mantenuti puliti e leggibili. Ispezionare periodicamente le etichette di sicurezza e i marchi di sicurezza e sostituirli se illegibili o percettibili da una distanza di sicurezza. Contattare Miltenyi Biotec per delle etichette sostitutive.

Istruzioni generali di sicurezza

Se lo strumento non funziona correttamente e/o le istruzioni visualizzate dei messaggi di avviso suggeriscono di contattare l'assistenza tecnica, non è più possibile un uso sicuro dello strumento. Si spenga immediatamente lo strumento e lo si scolleghi dalla presa di corrente, quindi si contatti il service provider Miltenyi Biotec o Miltenyi Biotec Technical Support.

Rischi elettrici e pericolo d'incendio

Possibili rischi derivanti da dispositivi elettrici includono scosse elettriche, corti e surriscaldamenti. Una scossa elettrica potrebbe causare gravi lesioni personali o perfino la morte. Un corto elettrico o un surriscardamento potrebbero causare un incendio. Le apparecchiature elettriche possono generare scintille, che potrebbero incendiare vapori combustibili o materiali, causando esplosioni o incendi. Non si utilizzi lo strumento in aree classificate come postazioni pericolose, p.e. in ambienti carichi di ossigeno.

Il corpo dello strumento é stato realizzato per ridurre il rischio di scosse elettriche, corti elettrici e la dispersione di fuoco. Con eccezione per il Safety Shield e Trough, non si rimuova o si apra alcun rivestimento. Solo il personale autorizzato può rimuovere le altre protezioni dello strumento. Non si inserisca mai alcun oggetto esterno nelle aperture dello strumento. Non si usi lo strumento se:

- è aperto o smontato,
- è caduto o danneggiato,
- ha danni o ha parti rotte,
- ha il cavo di alimentazione danneggiato,
- un oggetto è entrato nelle fessure di ventilazione,
- un oggetto esterno è stato inserito nello strumento.

Se si vedono fiamme o fumo, si escluda immediatamente l'alimentazione, si scolleghi lo strumento dalla presa di corrente e si contatti un Miltenyi Biotec service provider autorizzato o Miltenyi Biotec Technical Support.

Lo strumento è stato realizzato per un uso esclusivanente al coperto. **Se dei fluidi entarno nello strumento, potrebbero verificrsi dei corti eletrici, scosse elettriche o fuoco.** Si faccia particolare attenzione quando si ha a che fare con sostaze liquide.
Si faccia in modo che le stesse non fluiscano internamente all'apparecchio.
Si protegga l'apparecchio da fuoriuscite improvvise o getti d'acqua. Si puliscano immediatamente le fuoriuscite. Non si faccia uso dello strumento se delle sostanze liquide sono venute a contatto con lo stesso. Non si usi l'apparecchio in un ambiente umido o con vapore. Si evitino aree con elevata umidità o rischio di condensazione. Spostrare lo strumento da un ambiente freddo (come p.e. una stanza fredda a 5 °C) potrebbe causare condensazioni interne allo stesso. In tal caso si aspetti che lo stesso si deumidifichi, prima di renderlo nuovamente operativo.
Si stacchi lo strumento dalla presa elettrica prima di pulirlo. Non si usino liquidi o prodotti di pulizia aerosol; si usi sempre un panno umido.

Si garantisca un adeguato ricircolo d'aria nella stanza dove è in uso lo strumento. Nel caso di assenza di un'adeguata circolazione, l'aria dell'ambiente circostante potrebbe non raffreddare lo strumento ad un'acccettabile temperatura operativa. Si permetta una circolazione sufficiente attorno allo strumento – almeno 15 cm su tutti i lati –durante il funzionamento, per garantire un adeguato raffreddamento. Non si posizioni lo strumento vicino a radiatori, fonti di calore, fornelli o qualsiasi altro apparecchio che generi calore (inclusi gli amplificatori). Non si coprano gli slots e le aperture dello strumento, poiché le stesse sono previste per la ventilazione e per proteggere lo strumento da surriscaldamento. Non si posizioni lo strumento in uno scomparto integrato o in un analogo spazio limitato, a meno che esso non si stato appositamente realizzato in modo tale da garantire un'appropriata ventilazione. Si seguano le istruzioni di montaggio dello strumento.

Ci si assicuri che gli interruttori di rete principali, così come il cavo di connessione alla corrente siano facilmente accessibili e ubicati il più vicino possibile all'operatore. Se è necessario sconnettaere l'alimentazione, si scolleghi il cavo dalla presa di corrente.

Lo strumento è fornito di una spina con tre conduttori ed un terzo pin per il collegamento a terra. Questa spina può essere collegata solamente con una presa di corrente a terra. Si tratta di una misura di sicurezza. Non si provi ad inserire la spina in una presa non a terra. Nel caso non si riesca ad inserire la spina nella presa, si contatti l'elettricista di fiducia per sostituirla.

Lo strumento dovrebbe venire alimentato solamente da una fonte di alimentazione che rispetti le specificazioni menzionate nell'etichetta di indicazione elettrica del prodotto. Nel caso ci fossero domande in merito al tipo di fontte energetica, si contatti il service provider Miltenyi Biotec autorizzato o la compagnia energetica di fornitura locale. Non si usino prolunghe o prese multiple. Non si sovraccarichi una presa elettrica.

Rischi meccanici

Spostare o far ruotare le parti potrebbe causare rischi di natura meccanica. Quando si fa uso dello strumento si mantengano collegati i Trough, i Sleeves e i Safety Shield ad esso connessi. Mentre i rotori dello strumento sono in funzione, non li si tocchi, non li si carichi o si rimuovano le provette dall´appaecchio. Si usino solamente i gentleMACS Tubes, opportunamente installati con chiusure ermetiche. Non si faccia funzionare l´apparecchio con solo i tappi dei gentleMACS Tubes in posizione. I bordi taglienti dei tappi dei gentleMACS Tubes potrebbero causare ferite, se toccati mentre in rotazione. Non si aggirino le misure di sicurezza o si usino diversi dispositivi.

Rischi chimici e biologici

In base al materiale biologico impiegato, alla contaminazione o all´infezione, possono verificarsi gravi lesioni a persone o anche la morte. Tutti i casi clinici devono essere considerati come potenzialmente infetti. **Se un materiale a rischio biologico è o è stato in uso, l´operatore deve scegliere ed indossare delle protezioni di sicurezza personali** come indicato negli avvisi e le precauzioni specifiche per la particolare sostanza. Le precauzioni di sicurezza sopra indicate considerano qualsiasi altra sostanza chimica rischiosa, incluse sostanze tossiche e corrosive, acide o radioattive che potrebbero essere presenti nel campione.

Si indossino guanti e abiti di sicurezza, nonché occhiali protettivi per prevenire il contatto tra la sostanza ed il corpo e gli occhi. L´uso di abbigliamento protettivo danneggiato o inadeguatoo può essere pericoloso. Lo strumento deve essere impiegato all´interno di un´area protetta nel caso vengano impiegati materiali pericolosi o sconosciuti. Nel caso in cui del materiale percoloso sia stato utilizzato o sia fuoriuscito, si faccia molta attenzione quando si sterilizzi (decontamini) lo strumento. E´severamente proibito continuare ad utilizzare parti contaminate o altri accessori dello strumento.

Le provette o il materiale ausiliario entrati in contatto con materiali biologici pericolosi dovranno essere sterilizzati prima dello smaltimento. Tutt i rifiuti liquidi e solidi dovranno essere considerati pericolosi e quindi essere trattati secondo le precauzioni universali da laboratorio. Lo smaltimento dei rifiuti dovrà avvenire in accordo con le normative locali vigenti.

Rischi di radiazioni ottiche

Lo strumento è fornito di un potente sistema di diodi luminosi (LEDs) per illuminare il Safety Shield ed i gentleMACS Tubes. Secondo gli standard internazionali IEC 62471, questo sistema di illuminazione ha un valore di rischio espositivo (EHV) di 0.91 ed è inoltre nel gruppo di rischio estremo (Exempt Risk Group). La distanza di rischio (HD) per il Exempt Risk Group è di 61 cm. La distanza di rischio per il gruppo di rischio 1 è di 20 cm. Il rischio per gli astanti dipende da come lo strumento è installato e dalla modalità di funzionamento. La radiazione ottica emessa dai LEDs può essere nociva per gli occhi a breve distanza, se il Trough viene rimosso. Si sconnetta lo strumento prima di rimuovere il Trough. Una volta rimossa il Trough non si guardi in direzione dell´illuminazione dei LEDs, se non ad una distanza di almeno 20 cm.

Anche il lettore di codice 2D integrato usa LEDs per l´illuminazione dell´area di lettura. Non si fissi direttamente nel lettore di codice 2D a breve distanza, se questo è in funzione.

Non si smonti, si modifichi o si rimuova alcuna delle fonti di radiazione ottica.
La radiazione ottica degli strumenti smontati potrebbe essere nociva per gli occhi.

Rischio superficie calda

La lamina di riscaldamento del gentleMACS Heaters può diventare abbastanza calda da causare ustioni se toccata. Non toccare la lamina di riscaldamento mentre lo strumento è in funzione.

Rischi di livello acustico

Se lo strumento è in uso con carico massimo, può generare rumore a livelli che possono essere pericolosi. Rumori a livelli pericolosi potrebbero causare danni all´udito. Si raccomandano le misure indicate dall´organismo responsabile o il calcolo dell livello della pressione sonora in prossimità della posizione dell´operatore ed a una qualunque posizione ad 1 m dalla zona dove si trova l´attrezzatura, che abbia il più alto livello di pressione sonora. Se non viene verificato durante l´installazione che il livello di pressione del suono dal dispositivo non raggiunga un valore tale durante il suo uso, che possa causare dei rischi, allora deve essere impiegato del materiale protettivo come pannelli acustici, cappe o tappi per le orecchie. Osservare le norme locali sulla protezione dell'udito.

Manutenzione, trasporto e smaltimento

A meno che non differentemente specificato in questo manuale o in altra documentazione Miltenyi Biotec, **non si faccia la manutenzione dello strumento da soli**. La manutezione e le riparazione devono essere condotte da personale di servizio qualificato. Una manutenzione impropria o scorretta, ovvero riparazioni dello strumento possono causare pericolo per gli utenti o portare a danni irreparabili, causare un malfunzionamento dello strumento o danni, nonchè usura prematura e ridotta vita utile dello stesso. Potrebbe inoltre fare cadere la Vostra garanzia.

Sostituendo componenti o se sono necessari pezzi di ricambio, assicurarsi che il service provider usi solo parti originali Miltenyi Biotec o altrimenti terze parti consigliate e raccomandate da Miltenyi Biotec. L´utilizzo di parti non originali può causare malfunzionamenti dello strumento e risultati imprecisi. Miltenyi Biotec non offre alcuna garanzia nè accetta alcuna responsabilità per danni alla strumentazione o guasti dovuti ad un uso sconsiderato del componenti. Dopo aver completato ogni servizio di manutenzione e lavoro di riparazione, ci si assicuri che il service provider Miltenyi Biotec autorizzato esegua tutti i controlli di sicurezza previsti dalle procedure, per garantire che lo strumento funzioni in modo corretto.

Si usino solo opzioni ed aggiornamenti raccomandati da Miltenyi Biotec.
Si chiedano informazioni al rappresentante locale di Miltenyi Biotec in merito al servizio esteso di strumenti Miltenyi Biotec's e le modalità di supporto, o ci si riferisca a www.miltenyibiotec.com/support.

Lo strumento dovrebbe essere trasportato con cura nell´imballo specificato da Miltenyi Biotec. Danni interni possono essere provocati da eccessive vibrazioni o se lo strumento dovesse cadere. Nel caso l´apparecchio debba essere spedito al produttore, lo si sterilizzi per eliminare ogni sostanza pericolosa prima della spedizione. Nel caso ci fossero domande in merito all´adeguata pulizia o la spedizione, si contatti per l´assisenza il Miltenyi Biotec Technical Support.

Informazioni per i clienti riguardo lo smaltimento delle apparecchiature elettriche ed elettroniche secondo le normative WEEE (Waste of Electrical and Electronic Equipment)

Si prega di smaltire i prodotti Miltenyi Biotec in disuso secondo le disposizioni di legge riguardanti lo smaltimento di apparecchiature elettriche ed elettroniche (WEEE) e dei rifiuti pericolosi, che possono differire da paese a paese.

Le apparecchiature elettriche ed elettroniche possono contenere sostanze pericolose, che possono avere un grave effetto dannoso per l'ambiente e / o la salute umana. È per questo che tutte le attrezzature devono essere specificamente raccolte e trattati da centri di smaltimento abilitati e qualificati in conformità con la normativa WEEE. Il corretto smaltimento delle apparecchiature elettriche ed elettroniche secondo le disposizioni di legge WEEE e dei rifiuti pericolosi, possono aiutare a preservare le risorse naturali e a tutelare la salute umana.

Miltenyi Biotec si impegna a proteggere l'ambiente. Miltenyi Biotec offre programmi per lo smaltimento dei prodotti dismessi in molti paesi e partner accreditati per lo smaltimento secondo le normative WEEE in tutto il mondo. Miltenyi Biotec consente di riciclare le apparecchiature Miltenyi Biotec gratuitamente. Le condizioni e la disponibilità di questa offerta variano da zona a zona a causa di differenze legislative. Si prega di notare che, a seconda del tipo e dell'utilizzo delle apparecchiature, possono essere necessari requisiti aggiuntivi.

Per ulteriori informazioni, o se si desiderassero smaltire le apparecchiature Miltenyi Biotec in disuso, si prega di contattare il Responsabile di Zona o il Supporto Tecnico Miltenyi Biotec.

1 Introduction

1.1 Preparation of single-cell suspensions and homogenates from tissues

The gentleMACS Octo Dissociator with Heaters provides the perfect solution for the fast and easy preparation of single-cell suspensions and homogenates from virtually any tissue. Samples are processed using unique gentleMACS Tubes with caps that have specially designed rotors and stators. C Tubes provide gentle but efficient tissue dissociation for cell suspensions with high viability rate. M Tubes provide thorough homogenization of tissues or cells.

Figure 1.1: The gentleMACS Octo Dissociator with Heaters equipped with gentleMACS Tubes and Heaters.

The gentleMACS Octo Dissociator with Heaters provides:

- the preparation of viable single-cell suspensions by mechanical and enzymatic dissociation, including incubations at 37 °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 up to eight samples, even using different programs,
- easy access to pre-defined gentleMACS Programs which are optimized for particular applications,
- the option to create user-defined programs.

1.2 Sample preparation for cell and molecular biology applications

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

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

gentleMACS Tubes allow for:

- the processing of sample volumes from 300 µL to 10 mL and from 20 mg to 4,000 mg of tissue in a single tube,
- sterile sample handling.

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, respectively.

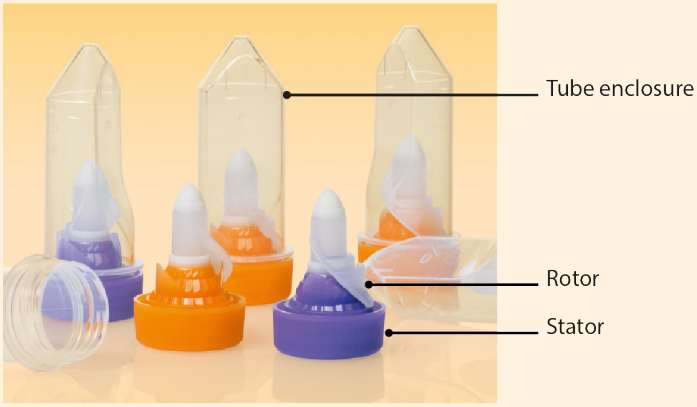


Figure 1.2: Caps of the gentleMACS Tubes (exemplary, M Tubes: orange, C Tubes: purple).

1.3 Sample preparation combining enzymatic and mechanical dissociation

For combined enzymatic and mechanical dissociation processes the instrument comes equipped with gentleMACS Heaters for each of the eight tube positions. The gentleMACS Heaters allow to apply 37 °C either to all eight positions or individually to each tube. By gently pressing the clamps, the gentleMACS Heaters can be easily attached to the tube positions, thus connecting the gentleMACS Heaters to the instrument via its electrical contact pins.

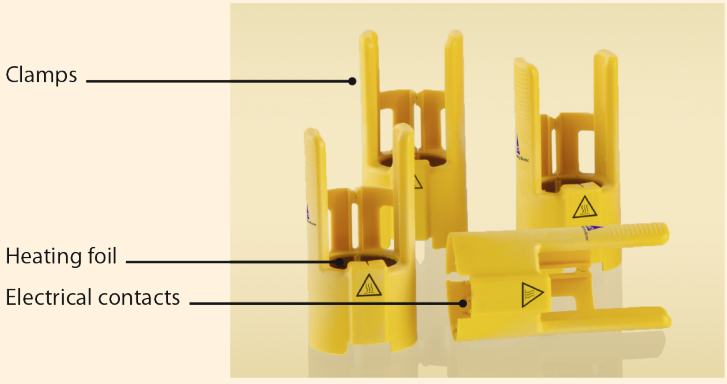


Figure 1.3: The gentleMACS Heaters for incubation of samples at 37 °C.

1.4 MACS Tissue Dissociation Kits

A broad selection of optimized and easy-to-use MACS Tissue Dissociation Kits, including pre-defined enzyme mixes, allows for convenient and reproducible tissue dissociation using the gentleMACS Octo Dissociator with Heaters. A comprehensive list of MACS Tissue Dissociation Kits for numerous applications is available for download at **www.gentlemacs.com**.

1.5 Pre-defined tissue dissociation and homogenization programs

More than 40 pre-set gentleMACS Programs without heating step and including an incubation step at 37 °C 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.gentlemacs.com**.

1.6 Customized dissociation programs

In addition to the ready-to-use gentleMACS Programs optimized for specific applications, the gentleMACS Octo Dissociator with Heaters also allows users to create new programs. This can be accomplished afresh or by modifying pre-defined templates.

1.7 Intended use

The gentleMACS Octo Dissociator with Heaters is a benchtop instrument for the fully automated and standardized tissue dissociation or homogenization of up to eight samples.

Equipped with eight individual heating units and numerous optimized and ready-to-use gentleMACS Programs the gentleMACS Octo Dissociator with Heaters offers a fully automated workflow for tissue dissociation. In addition the instrument allows the user to create user-defined programs for almost any biological material. All eight positions can be operated independently.

Single-cell suspensions or thorough homogenates are easily and reproducibly obtained using the unique C Tubes or M Tubes. These single-use gentleMACS Tubes allow sample preparation in a closed and sterile system, providing a high level of user safety and minimize cross-contamination.

The gentleMACS Octo Dissociator with Heaters is for research-use only in laboratory environment. It is to be used by laboratory professional users only.

2 Installation

Please 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.

Please retain the original packaging material.

2.1 Components included in the delivery

The following components are included in the delivery of the gentleMACS Octo Dissociator with Heaters (# 130-096-427):

- 1× gentleMACS Octo Dissociator with Heaters
- 8× gentleMACS Heaters
- 1× Power cord
- 1× User manual

2.2 Installation

⚠WARNING Read the chapter **Important safety information** and ensure that the site is properly prepared before continuing with installation and assembly. Incorrect installation can lead to the spread of fire, explosion, the risk of electric shock, or mechanical hazards.

Note: The gentleMACS Octo Dissociator with Heaters is a ready-to-use instrument that requires a power connection and a flat surface of the dimensions 465×285 mm **plus at least 15 cm on all sides to allow sufficient air circulation.** To operate the instrument, the display and the top of the instrument must be accessible.

To install the gentleMACS Octo Dissociator with Heaters:

1. Carefully remove the device from the cardboard box.
2. Place the instrument on a secure and stable workbench that can support its weight and size. Ensure that the instrument is not exposed to direct sunlight.

   CAUTION! Do not place the instrument on an unstable table, cart, stand, tripod, or bracket. As a consequence, the instrument might fall down. This may cause serious bodily harm and/or serious damage to the instrument. Use only on a table, cart, stand, tripod, or bracket recommended by Miltenyi Biotec.

3. Plug the instrument into the power mains.

   WARNING! The instrument is equipped with a three-wire electrical groundingtype plug. This is a safety feature to reduce the risk of electric shock. Do not insert the plug into a non-grounded power outlet. If you cannot insert the plug into the outlet or if you are not sure whether the outlet is grounded, contact your local electrician.

   The instrument should only be operated from a power source whose specifications match those indicated on the instrument's electrical ratings label. If you have questions about the type of power source to use, contact your authorized Miltenyi Biotec service provider or local power company. Ensure that the mains switch as well as the connector for the power cable are easily accessible and located as close to the operator of the instrument as possible. If it is necessary to disconnect the instrument's power supply, unplug the cable from the power outlet.

4. Set the switch located above the plug socket to ON ("**I**" indicates "ON", "**O**" indicates "OFF").
5. The instrument will perform a start-up check that runs for a few seconds.

3 Materials required

3.1 Materials required to operate the instrument

The following materials are required to operate the gentleMACS Octo Dissociator with Heaters.

Product	Description	Capacity	Order no.
C Tubes	For gentle preparation of single-cell suspensions from tissues for subsequent cell separation, cell analysis, and cell culture.	25 tubes, sterile, single-packed 100 tubes, sterile, packed as 4×25 tubes	130-093-237 130-096-334
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 per bag, sterile (strainer: 600 µm mesh)	130-094-392

Table 3.1: Disposables required for the gentleMACS Octo Dissociator with Heaters.

MACS SmartStrainers are filters that are designed for the easy removal of cell aggregates or large particles after tissue dissociation. The 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), and 100 µm (50 pieces # 130-098-463, 4×25 pieces #130-110-917). They easily fit into standard 15 and 50 mL conical tubes of all major suppliers. Strainers are stackable and thus allow filtration with decreasing mesh sizes in one go.

MACS Tissue Dissociation Kits were specifically designed for the convenient and standardized enzymatic dissociation of multiple tissues in combination with the gentleMACS Octo Dissociator with Heaters. For a comprehensive list of MACS Tissue Dissociation Kits, please refer to **www.gentlemacs.com**.

3.2 Spare parts

Product	Description	Order no.
gentleMACS Sleeves	Adapters for attaching the gentleMACS Tubes	130-093-464
gentleMACS Heaters	Heating units	130-105-228
gentleMACS Octo Trough	Safety container for spilled liquid	130-096-541
gentleMACS Octo Safety Shield	Safety shield for protection	130-096-542

Table 3.2: Spare parts of the gentleMACS Octo Dissociator with Heaters

Note: 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 life-time 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

⚠WARNING Read the instructions in the chapter **Important safety information** before operating the instrument.

- When processing infectious, radioactive, poisonous, or any other hazardous liquids, always take the necessary safety precautions.
- Before using organic solvents or aggressive chemicals in the dissociation or homogenization process, the compatibility with the instrument's parts and tubes must be tested.
- Do not operate the instrument if the Sleeves, the Trough, or the Safety Shield are removed. For instrument schematics, refer to section 4.2.
- Do not leave the gentleMACS Heaters attached to the tube position while not in use to avoid wearing of the gentleMACS Heaters.
- Do not switch off the instrument while running a program to avoid severe damage of the instrument.

4.1 General information for operating the instrument

The gentleMACS Octo Dissociator with Heaters is used as a stand-alone, benchtop instrument. A number of pre-defined programs offer a variety of optimized protocols for the automated dissociation and homogenization of tissues. The instrument also allows creation and use of user-defined programs for specific applications.

gentleMACS C or M Tubes are required for processing the samples. The gentleMACS Octo Dissociator with Heaters must be used exclusively with these gentleMACS Tubes. Moreover, the gentleMACS Heaters are specially designed for use with the instrument, when running a program that includes an incubation step.

4.2 Instrument schematics

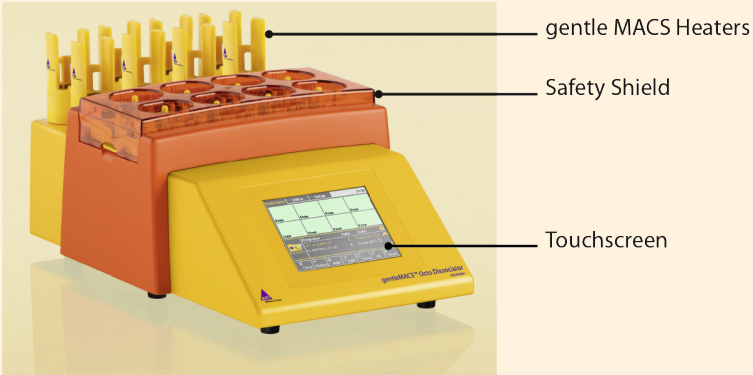


Figure 4.1: Front of the gentleMACS Octo Dissociator with Heaters.

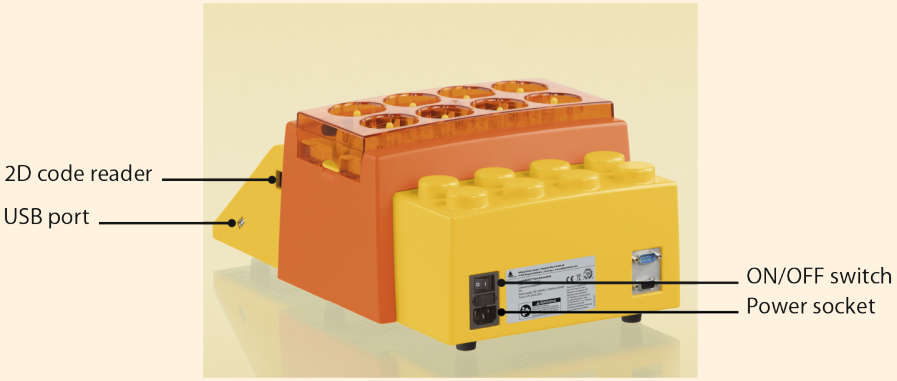


Figure 4.2: Back of the gentleMACS Octo Dissociator with Heaters.

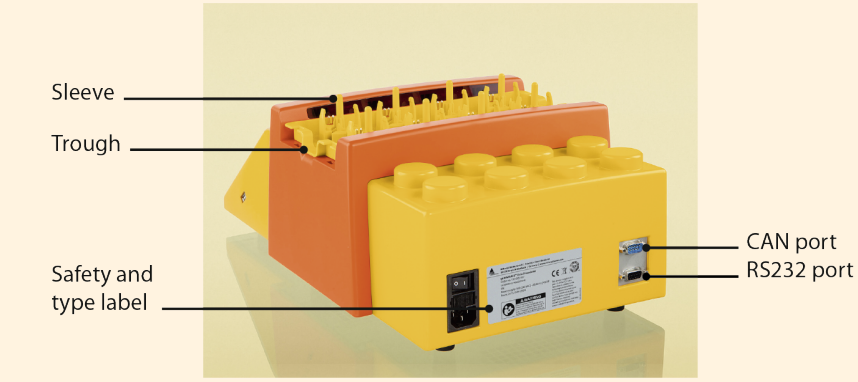


Figure 4.3: Back of the gentleMACS Octo Dissociator with Heaters, Safety Shield removed.

4.3 Starting the Instrument

To start the instrument:

1. Ensure that the device is plugged in before setting the switch to the **ON** position ("**I**" indicates "ON", "**O**" indicates "OFF").
2. The instrument starts within a few seconds and displays the **Main menu.**

Note: Do not switch off the instrument while running a program to avoid severe damage of the instrument!

The gentleMACS Octo Dissociator with Heaters is operated using the touchscreen display. Items that can be selected are displayed in yellow, while items that cannot be selected are displayed in white.

Buttons and symbols:

Buttons

Icon	Function	Description
 	scroll up scroll down	The scroll buttons are used to scroll up or down, e.g., to highlight a gentleMACS Program in the **Main menu** tab, or device settings in the **Setup** tab.
	Info button	A pop-up screen is displayed when pressing on the **Info** button, and displays information about the highlighted gentleMACS Program, including program name, selected tube type, date of program creation, duration of the program, rounds per run (rpr), and temperature (°C) applied.

Table 4.1: Buttons of the gentleMACS Octo Dissociator with Heaters display.

Folders

Different folders can be accessed by pressing a folder icon. The arrow indicates scroll function.

Icon	Folder	Description
	Miltenyi	The **Miltenyi** folder contains gentleMACS Programs provided by Miltenyi Biotec. The lock on the Miltenyi folder indicates that programs in this folder cannot be edited or deleted.
	Templates	The **Templates** folder contains gentleMACS Programs provided by Miltenyi Biotec. Programs in this folder can be edited but must be renamed and saved in a User folder.
	User - 1	Five **User** folders are available to manage user-defined programs.
	User - 2	
	User - 3	
	User - 4	
	User - 5	
	Favorites	Links of programs in the **Favorites** folder enable quick access.
	USB stick	A USB stick can be installed to transfer programs to and from a folder.

Table 4.2: Overview of folders and respective icons.

LEDs

Various statuses of the instrument are indicated by LEDs illuminating the Safety Shield and the gentleMACS Tubes.

Color	LED mode	Main menu
Green	Steady	Status of one or more positions is “Free”. Note that **Editor** and **Setup** menus are illuminated by a steady green light.
Blue	Steady	Status of all eight positions is “Running”.
Blue	Flashing	Status of one or more positions is “Done”.
Red	Flashing	Error occurred on one or more positions.

Table 4.3: Overview of LED colors, modes, and status.

4.3.1 Menu tabs

The gentleMACS Octo Dissociator with Heaters is controlled using three menus present on the touchscreen of the instrument.

Main menu

The **Main menu** displays the availability and status of all eight gentleMACS Tube positions. Each tube position is diagrammatically shown as a square panel at the top of the screen. In this user manual, each panel is referred to as a tube position.

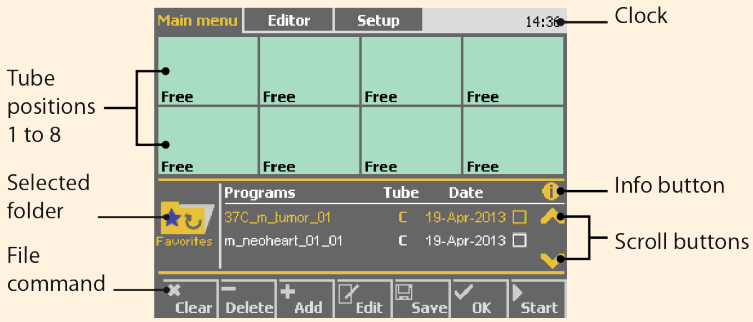


Figure 4.4: Main menu of the gentleMACS Octo Dissociator with Heaters.

The **Main menu** is used to assign gentleMACS Programs to each tube position and run the respective process. Programs can be loaded from a total of eight folders, a **Favorites** folder, a **Miltenyi** program folder, a **Templates** folder, and five **User** folders. Please refer to section 4.4 for more details.

Editor menu

The **Editor menu** is used to create and edit programs. Moreover, programs are managed here. Links to programs can be added to the **Favorites** folder and programs can be transferred among folders. Please refer to section 4.5 for more details.

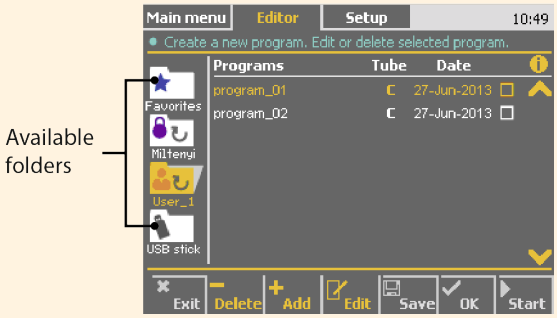


Figure 4.5: Editor menu of the gentleMACS Octo Dissociator with Heaters.

Setup menu

Instrument settings can be modified using the **Setup** menu. This includes switching the LEDs on or off, setting the time and date, and naming **User** folders. Moreover this menu provides information on software and program versions. Please refer to section 4.6 for more details.

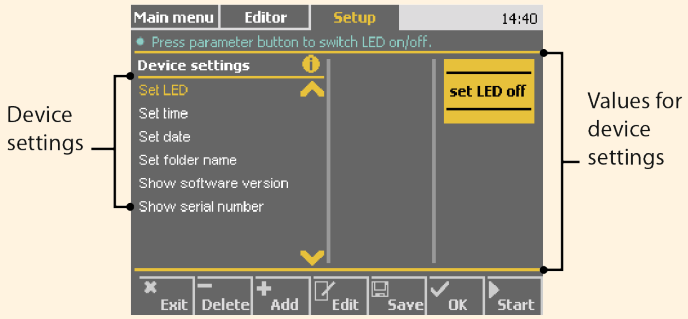


Figure 4.6: Setup menu of the gentleMACS Octo Dissociator with Heaters.

4.4 Main menu

The **Main menu** is used to select and run dissociation programs for each of the eight tube positions. Users have the flexibility to run multiple programs simultaneously or sequentially. Samples can also be run individually. The **Main menu** also reports the status of each tube position.

4.4.1 Status of sample tube positions

All possible statuses of tube positions are shown in **4.4.1** and described in**Table 4.4**.

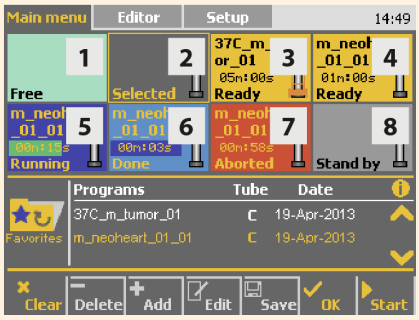


Figure 4.7: Overview of tube position statuses displayed in the Main menu.

Tube position	Status	Description
1	Free	No tube is inserted. The position is free to use.
2	Selected	Tube is inserted. After inserting a tube, the position is automatically assigned the status “Selected”. Programs can only be designated to positions with the status “Selected”.
3	Ready and Heater installed	The tube position is ready. A tube and a heater were inserted and a program was subsequently assigned by confirming the selection with “OK”. The program may be commenced by pressing “Start”. The program name and duration are displayed. In this example, program ”37°C_ m_tumor_01” will be completed within 5 minutes.
4	Ready	The tube position is ready. A tube was inserted and a program was subsequently assigned by confirming the selection with “OK”. The program may be commenced by pressing “Start”. The program name and duration are displayed. In this example, program” m_neoheart_01_01” will be completed within 1 minute.
5	Running	The program “m_ neoheart_01_01” is running. The progress bar and timer display the time remaining to complete the program, in this example, 15 seconds.
6	Done	The program “m_ neoheart_01_01” is finished. The timer displays the elapsed time since completion of the program, in this example, 3 seconds.
7	Aborted	The program was stopped. It is possible to abort any program by pressing the required tube position on the touchscreen. The timer displays the remaining time to complete the program since abortion, in this example, 58 seconds.
8	Stand by	The tube position was deselected. Inserted tubes are automatically assigned the status “Selected”. Deselection of an inserted tube is achieved by pressing the required tube position on the touchscreen. The status of the tube position will change to “Stand by”. Note that programs cannot be assigned to tube positions in the Stand by mode.

Table 4.4: Overview of tube position statuses.

4.4.2 Processing samples

Tips and hints for the processing of samples:

- The tubes are for single use only, (single procedure).
- Only use C Tubes with the gentleMACS Heaters.
- Sample sizes range from 300 µL to maximal 10 mL total volume and 20 to 4,000 mg of tissue.
- The maximal amount of tissue depends on the consistency of the tissue as well as on the respective gentleMACS Protocol.
- Dependent on the stiffness of the tissue it might be recommended to cut the sample into smaller pieces before processing on the gentleMACS Octo Dissociator with Heaters.
- The tubes are suitable for a broad range of tissues, for example, spleen, liver, or brain. However, very hard material, such as bone, may damage the tubes.

For further details, refer to the respective gentleMACS Tube data sheets and to the gentleMACS Protocols at **www.gentlemacs.com**.

The following instructions assume that the instrument was successfully installed and initiated as outlined in sections 2.2 and 4.3.

To process samples, transfer an appropriate amount of tissue and buffer or other appropriate fluid into a gentleMACS C Tube or M Tube.

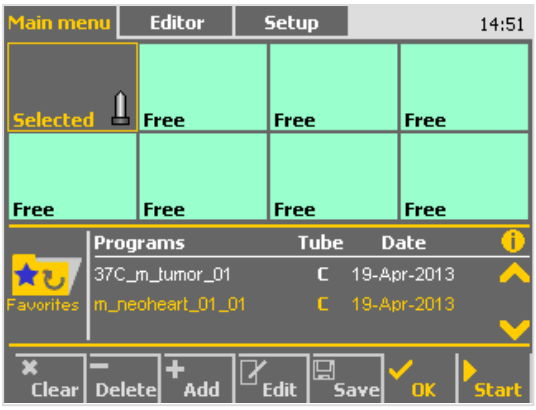
Note: Tightly close the tube beyond the first resistance.

Running a single sample

Note: Do not switch off the instrument while running a program to avoid severe damage of the instrument.

1. Available tube positions are indicated as **Free.**

2. Attach the tube upside down to the Sleeve of an available tube position. The instrument will automatically detect the inserted tube and assign the tube status **Selected**.



Note: Please make sure that the tube is inserted and removed in an upright position without tilting. Tilting the tube at an angle might result in damage of the tube seal and subsequent leakage.

Note: Ensure that the tube is securely fastened to its sleeve and socket. It should 'click' into position. Do not force the tube into the position. In case of resistance slightly turn the tube clockwise in order to find the right position to click in.

3. (Optional) If running a program including an incubation step, apply a gentleMACS Heater to the respective tube position. Slightly open the clamp of the gentleMACS Heater by pressing the upper handles and adjust it over the tube. Make sure the lower side of the gentleMACS Heater is facing towards you therefore allowing the electrical contact to close tightly. The instrument will automatically detect the attached gentleMACS Heater.

   Note: Make sure that the gentleMACS Heater is securely fastened around the tube and to the socket. Do not use the gentleMACS Heater without a tube.

4. To select a dissociation program, press the **Folder** icon to select the required folder.

   Note: Programs can be selected from a total of eight folders: **Favorites, Miltenyi, Templates**, and five **User** folders. Press the folder icon several times to scroll through.

5. The list of gentleMACS Programs in the respective folder will be displayed.

6. Highlight the required gentleMACS Program touching the screen or using the scroll buttons.

   Note: Press the column header **Programs** to sort programs within a folder alphabetically. Press the column header **Date** to sort programs by the date of creation.

7. Select the required program and press **OK** to confirm. The status of the tube position will change to **Ready**. The timer indicates the duration of the program.

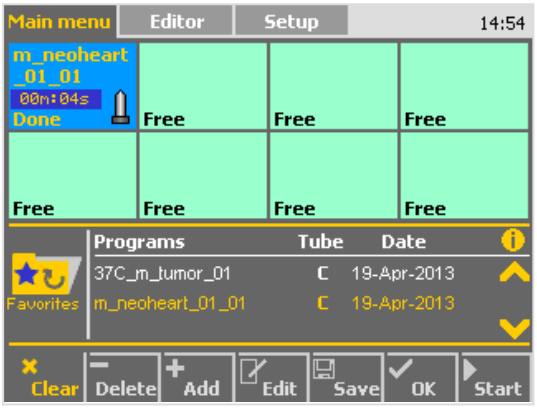
Note: Use the **Clear** button to reset the position from the **Ready** status into the **Selected** status to assign a new program.

8. Press **Start** to commence the program. The status of the tube position will change to **Running**. The progress bar and timer indicate the time remaining.

   Note: After selecting the program it is possible to skip the confirmation step **OK** by immediately pressing **Start.**

The program will immediately start, and the status of the tube position will change to **Running.**

9. On completion of the program, the status of the tube position will change to **Done**. The progress bar and timer display the elapsed time since completion of the program.



Note: For further processing, use the **Clear** button to reset the position from the **Done** status into the **Selected** status to assign a new program.

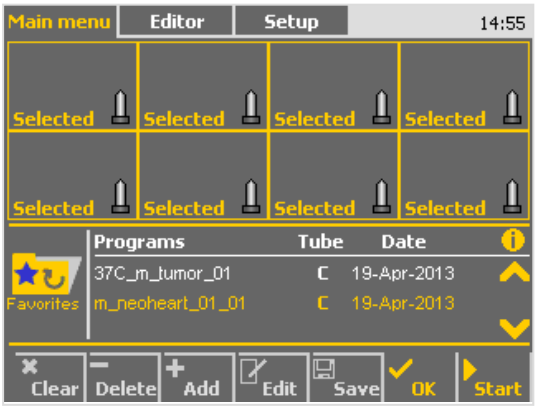
10. Remove the tube from the tube position. The status of the tube position will change to **Free**.

Running multiple samples simultaneously

Up to eight samples can be run simultaneously using the same or different programs. In this example, eight samples will be processed using the same program.

Note: Do not switch off the instrument while running a program to avoid severe damage of the instrument!

1. Attach the tubes upside down to the Sleeves of the free tube positions. The status of the tube positions will change from **Free** to **Selected.**



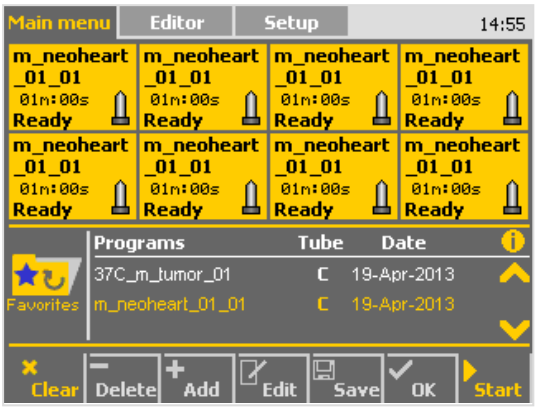
2. To select a dissociation program, press the **Folder** icon to select the required folder. The list of gentleMACS Programs in the respective folder will be displayed.

Note: Programs can be selected from a total of eight folders: **Favorites, Miltenyi, Templates,** and five **User** folders. Press the folder icon several times to scroll through.

3. Highlight the desired gentleMACS Program touching the screen or using the scroll buttons.

   Note: Press the column header **Programs** to sort programs within a folder alphabetically. Press the column header **Date** to sort programs by the date of creation.

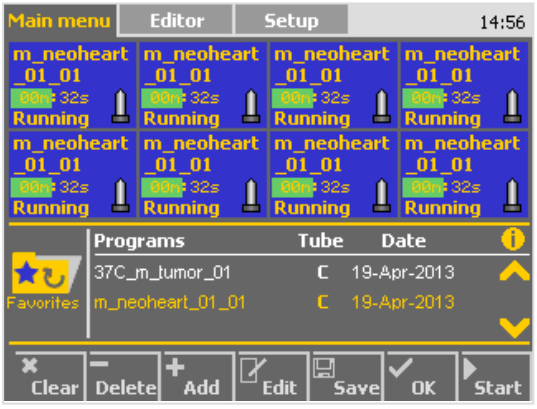
4. Select the required program and press **OK** to confirm. The program will be assigned to all eight tube positions. The status of the tube positions will change to **Ready**.



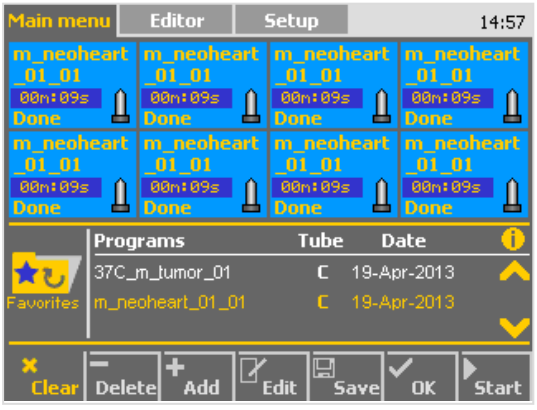
Note: Use the **Clear** button to reset positions from the **Ready** status into the **Selected** status to assign new programs.

5. Press **Start** to commence the program. The status of the tube positions will change to **Running**. The progress bar and timer indicate the time remaining.

   Note: After selecting the program it is possible to skip the confirmation step **OK** by immediately pressing **Start**. The program will immediately start, and the status of the tube positions will change to **Running**.



6. On completion of the program, the status of the tube positions will change to **Done**. The progress bar and timer display the elapsed time since completion of the program.



Note: For further processing, use the **Clear** button to reset all positions from the **Done** status into the **Selected**

status to assign new programs.

7. Remove the tubes from the tube positions. The status of the tube positions will change to **Free**

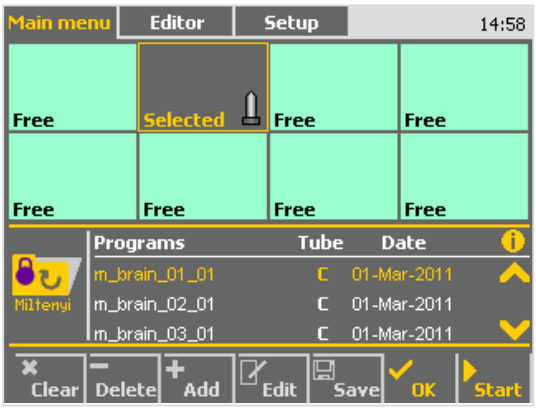
Running multiple samples sequentially

Multiple samples can be run sequentially. In this example, three samples are processed using three different programs.

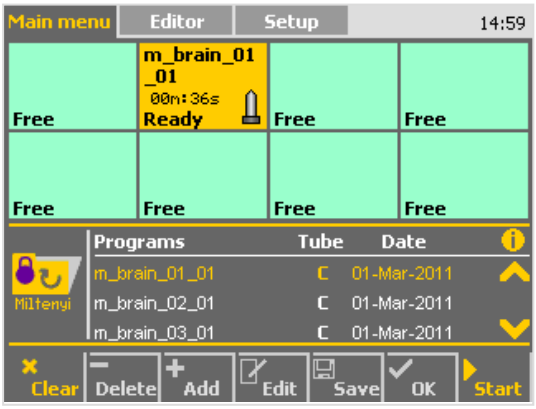
- **Sample A** is processed with program **m_brain_01_01**:
  a Miltenyi Biotec program in the **Miltenyi** folder, optimized for the preparation of single-cell suspensions from mouse neural tissue.
- **Sample B** is processed with program **37°C_m_tumor_01**:
  a Miltenyi Biotec program in the **Miltenyi** folder, optimized for the preparation of single–cell suspensions from mouse tumor, including an incubation step.
- **Sample C** is processed with program **C_01**:
  a template program provided by Miltenyi Biotec in the **Templates** folder. Programs in the **Templates** folder can also be used as a basis to develop customized programs.

Note: Do not switch off the instrument while running a program to avoid severe damage of the instrument!

1. Insert **Sample A** into a free position. The status of the tube position will change from **Free** to **Selected.**
2. Press the **Folder** icon to locate the **Miltenyi** folder.

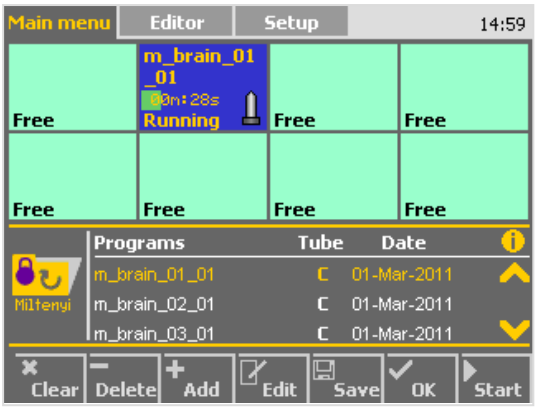


3. Select the program **m_brain_01_01** from the list and press **OK** to confirm. The status of the tube position will change to **Ready**.

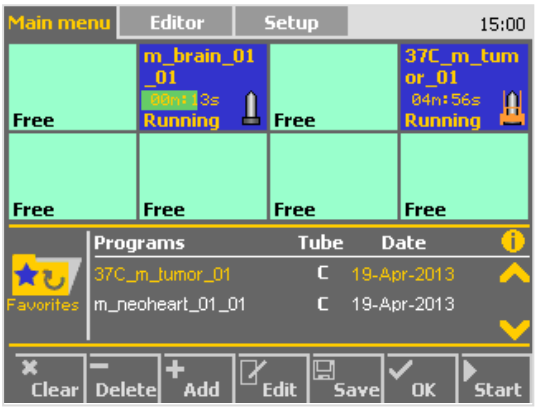


4. Press **Start** to commence the program. The status of the tube position will change to **Running**.

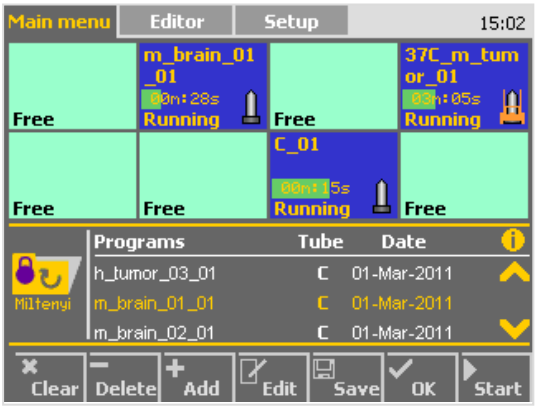
   Note: After selecting the program it is possible to skip the confirmation step **OK** by immediately pressing **Start**. The program will immediately start, and the status of the tube position will change to **Running**.



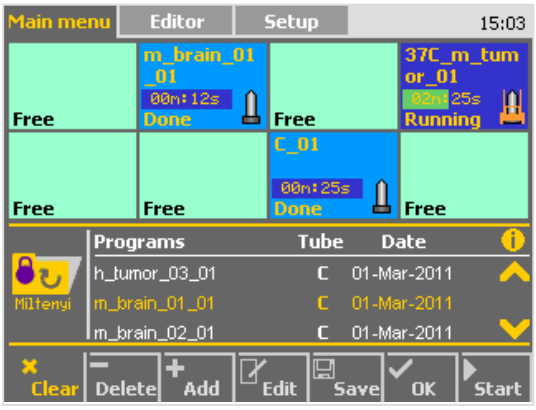
5. While **Sample A** is still running, insert **Sample B** into a free position, attach a gentleMACS Heater to the selected position as described in section 4.4.2.1 and select the program **37°C_m_tumor_01** as described in steps 2 and 3.
6. Press **OK** and **Start** to commence processing of **Sample B.**



7. While **Sample A** and **Sample B** are running, insert **Sample C** into the next free position and select the program **C_01** from the **Templates** folder. Press **OK** and **Start** to commence processing of **Sample C**.



8. Remove the samples when the status of the tube positions changes to **Done**. In this example, **Sample A** and **Sample C** can be removed while **Sample B** is still running.



4.5 Editor menu

The **Editor** menu is used to

- create new programs (for details, refer to section 4.5.1),
- edit programs (for details, refer to section 4.5.2),
- create program shortcuts into the **Favorites** folder (for details, refer to section 4.5.3),
- transfer programs between folders and to a USB stick and vice versa (for details, refer to section 4.5.4).

Note: Programs from the **Miltenyi** folder are not editable. Miltenyi templates from the **Templates** folder can be edited but must be renamed and saved in one of the **User** folders.

4.5.1 Creating a new program

There are several optional commands to design a user-defined program, including options on the temperature, rotation speed, direction, and duration, acceleration, and iteration. An overview of program commands is shown in **Table 4.5**.

Tips and hints for user-defined programs:

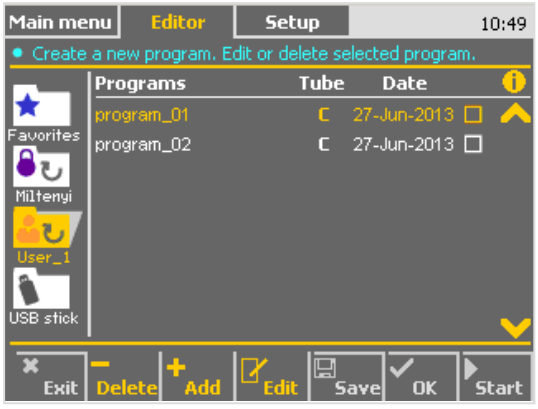
- Do not exceed a maximum of **3,200 rounds per run**, when creating a new program. Running higher numbers of rounds per run may result in damage of the sealing of the gentleMACS Tube.
- Typically, gentleMACS Programs consist of several spin commands, each with a different speed and clockwise rotation. Integration of short counterclockwise **spin** commands can increase the efficiency of the dissociation or homogenization.
- Incubation periods typically run at –20 rpm. A counter-clockwise rotation has been beneficial in many cases.

Command	Description
temp ON	Defines the beginning of an incubation period. Any command between the temp ON and temp OFF command will be performed at 37 °C.
temp OFF	Defines the end of an incubation period. This command must be entered to stop the heating function.
spin	Defines the speed, direction, and duration of rotation. Speed is defined as revolutions per minute (rpm). Prefixing the rpm value with minus (–) results in a counter-clockwise rotation. The total duration is given in minutes and seconds. The following are the speed restrictions: Clockwise: +20 to +4,000 rpm Counter-clockwise: –20 to –4,000 rpm The change of velocity must not exceed 6,000 rpm per second.
ramp	Defines the time required to reach a certain speed. This is given in revolutions per minute (rpm). If a program starts with a ramp command, the starting speed will be 0 rpm. If a ramp command is added after a spin command, the starting speed will be from the rpm of the spin command.
loop	Defines the beginning of a loop cycle. Commands between the loop and end loop commands are repeatedly executed for the defined number of cycles. A maximum of 200 cycles can be defined.
end loop	Defines the end of a loop cycle. This command must be entered as the last step of a loop cycle.

Table 4.5: Overview of program commands.

Creation of a user-defined program

1. Highlight a particular **User** folder. In this example, the folder **User_1** is selected.



2. Press **Add**. A **new_program** file template will be displayed.
3. Press the tube button to select a **C Tube** or **M Tube.**
4. To select further options, e.g., **spin, ramp, temp, loop**, and **endloop** press **Add**. A dotted line will appear above the **end** command.

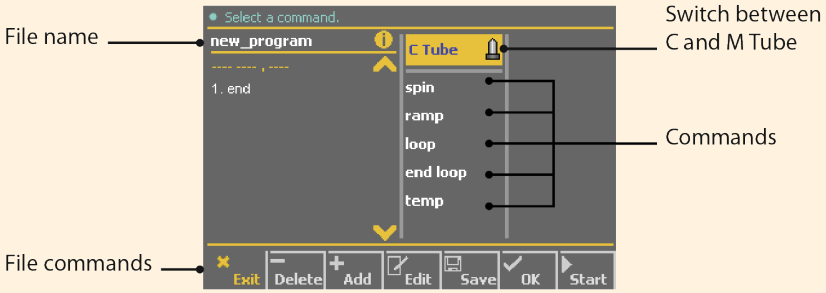


Figure 4.8: New_program file template to create user-defined program.

5. Enter respective values and press **OK.**
6. Press **Add** to insert the next command or **Save** to name and store the program.

Example of an user-defined program

1. ramp 2,000 rpm, 10''
2. loop 3×
3. spin –2,000 rpm, 10''
4. spin 2,000 rpm, 10''
5. end loop
6. temp ON
7. spin –20 rpm, 30'
8. spin 3,000 rpm, 10''
9. temp OFF
10. end

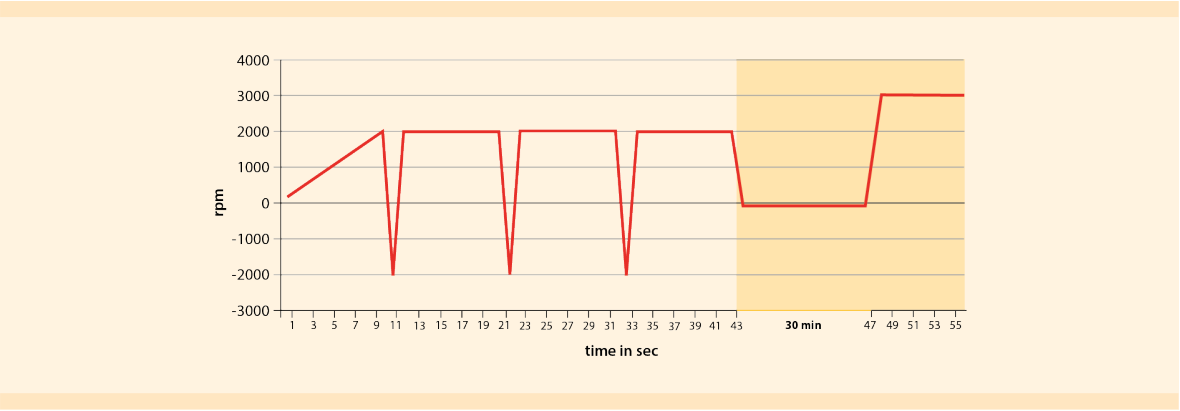
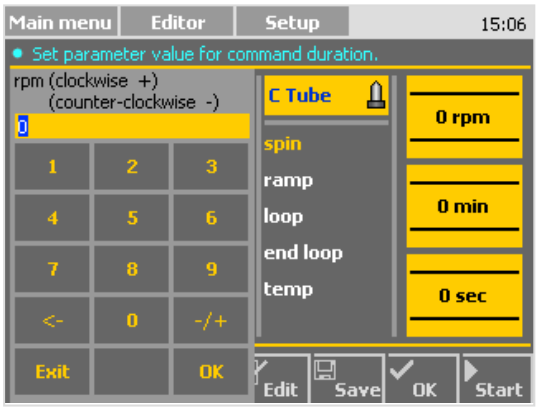


Figure 4.9: Graph of the example user-defined program.

Note: It is possible to insert or edit a command at any step above the end command. A new command will be inserted above a highlighted command. Commands can be highlighted using the touchscreen or the scroll buttons.

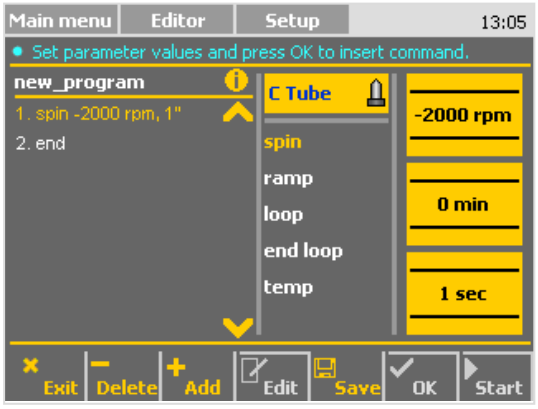
Note: Highlighted commands, except for the end command, can be deleted by pressing **Delete**.

1. Press **spin**. Enter all parameters for the selected command using the pop-up keypad. Enter speed (rpm) and time (min and sec).

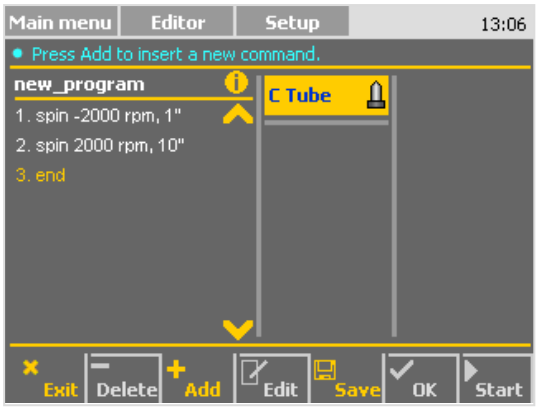


2. Press **OK** to confirm a value or **Exit** to cancel.

Parameters for an individual step will be displayed in an abbreviated form. In this example, **spin –2,000 rpm, 1”** indicates a counter-clockwise spin of 2,000 rpm for 1 second.

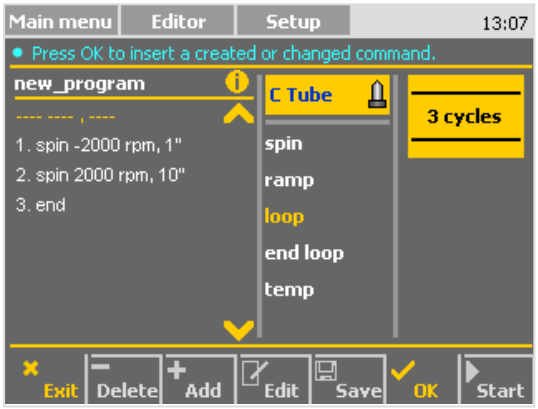


3. Press **Add** to insert the next command or **Save** to name and store the program for future use (refer to step 11.). In this example, a second spin command is added, namely a clockwise spin at 2,000 rpm for 10 seconds.



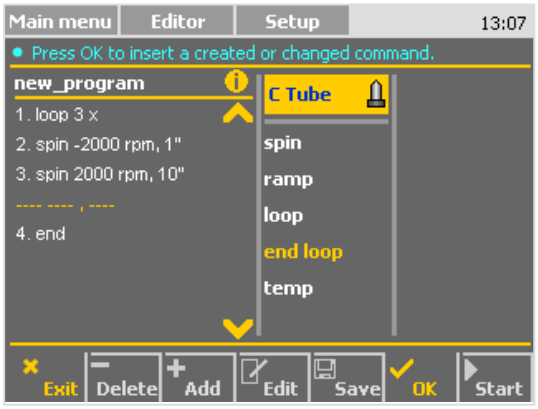
Note: Loop commands enable the repetition of program steps. The iterations will only include the steps between a **loop** and **end loop** command. In this example, the two spin commands shall be repeated three times.

4. Highlight the first command and press **Add** to select the next command. Select **loop** to mark the beginning of an iteration. Enter the number of iterative cycles. In this example, 3 cycles are chosen.



5. Click **OK** to confirm the selection. The command **loop** and the number of cycles are displayed as a new step.

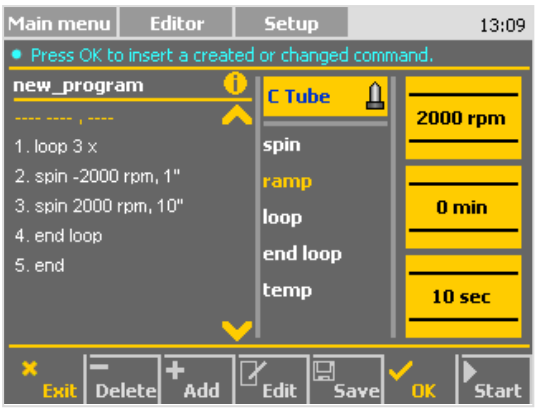
6. Highlight the **end** command and press **Add**. Select **end loop** to close the iterative cycle.



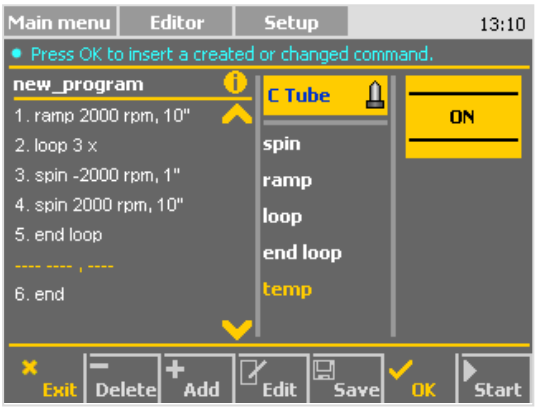
7. Press **OK** to confirm.

8. Highlight the first command and press **Add** to insert another command. Select **ramp** to reach a certain speed in a defined time.

9. Enter speed and time. Press **OK** to confirm the values. In this example, a ramp of 2,000 rpm in 10 seconds has been added.

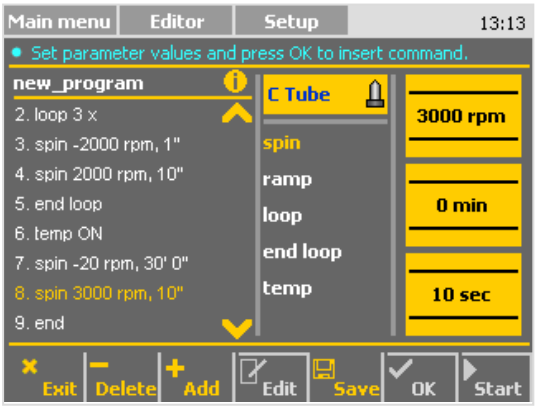


10. Highlight the **end** command and press **Add**. Select **temp** and **ON** from the pop-up screen to mark the beginning of the heating period. Press **OK** to save the value.

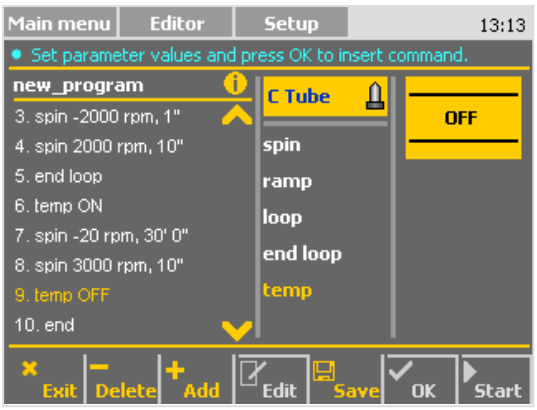


Note: The **temp** command enables the heating of a sample to 37 °C during a series of program steps, e.g., for incubation purposes. The incubation period will only include the steps between a **temp ON** and **temp OFF** command.

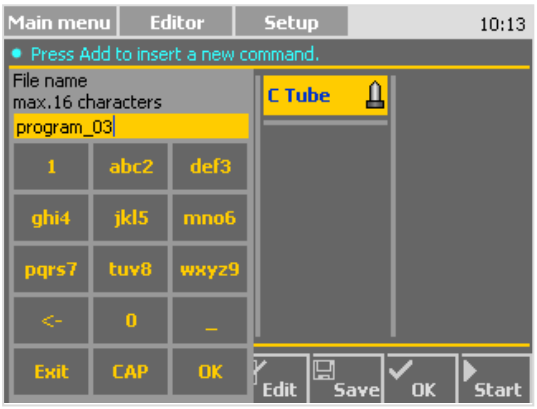
11. Highlight the **end** command and press **Add**. In this example, two spin commands are added, a counter-clockwise spin at 20 rpm for 30 minutes and a clockwise spin at 3,000 rpm for 10 seconds.



12. Highlight the **end** command and press **Add**. Select **temp** and **OFF** from the pop-up screen to switch off the heating function. Press **OK** to save the value.

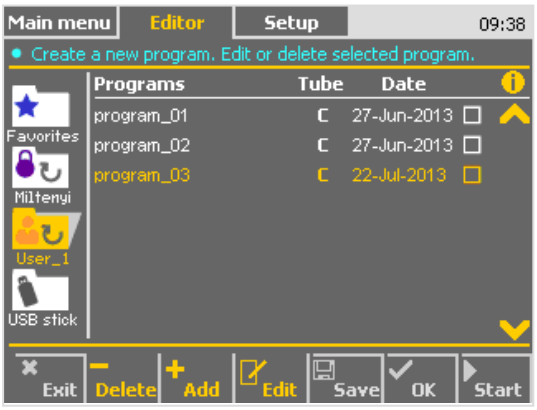


13. Press **Save** to store the new program. Enter the filename when prompted. In this example, the new program is named **program_03.**



Note: Program names can be a maximum of 16 characters. Select **CAP** to alternate between upper- and lower-case characters.

14. Select **OK** on the keypad to save the program. The program will be automatically saved to the folder selected in step 1. In this example, this is the folder **User_1.**



Note: The duration of a gentleMACS Program is limited to **3,200 rounds per run**. For example, a program that consists of one **spin** command at 4,000 rpm can run for a maximum of 48 seconds; a program that consists of one **spin** command at 200 rpm can run for a maximum of 960 seconds (16 minutes). A program that consists of one **spin** command at 20 rpm can run for a maximum of 160 minutes.

It is not recommended to run programs exceeding this limitation! Miltenyi Biotec does not guarantee proper function of the instrument and disposables above this value. However, when saving a program exceeding 3,200 rpr a pop-up screen will appear displaying a warning message and the current rpr value. Press **OK** to save the program. Press **Abort** to re-edit the program.

4.5.2 Editing programs

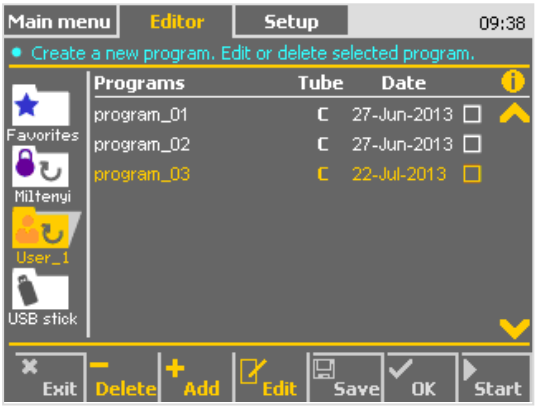
To edit a program:

1. Select the **Templates** or **User** folder containing the required program.

   Note: Files located in the **Miltenyi** and **Favorites** folders cannot be edited. The **Miltenyi** folder contains gentleMACS Programs that have been optimized by Miltenyi Biotec for a variety of applications. These programs cannot be altered. The **Favorites** folder contains shortcuts to the original programs located in the **Templates, Miltenyi**, or **User** folders.

   Note: The template programs **A** to **E** provided by Miltenyi Biotec can be used to create a user-defined program. The newly created program has to be renamed and saved in one of the five **User** folders.

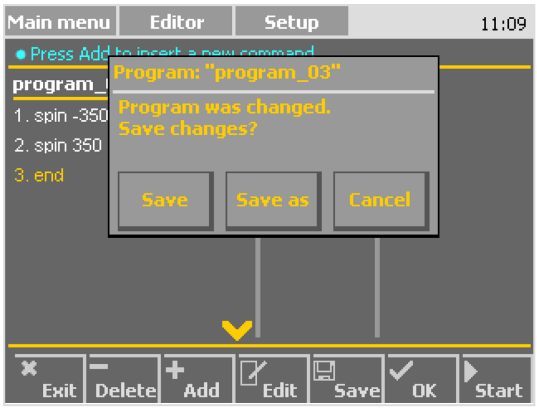
2. Highlight the program of interest. In this example, **program_03** in the folder **User_1** is selected.



3. Press **Edit** to open the respective program.
4. Highlight the required step. Edit the highlighted command by changing or adding required values (rpm, min, sec), or use the following command buttons to modify the program:
   - **Delete** to remove the highlighted step from the list,
   - **Add** to insert an additional step above the highlighted step.

   Note: Steps can be highlighted using the touchscreen or the scroll buttons.

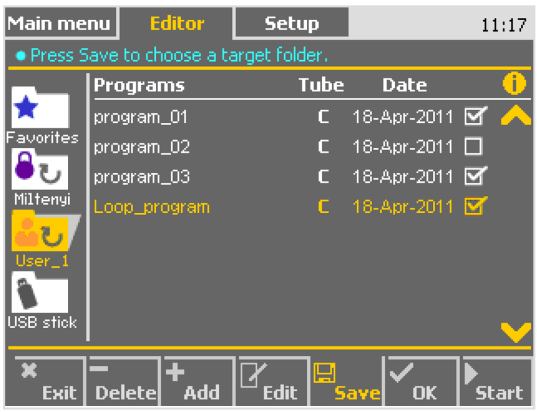
5. Select **Save** to store the modified file or **Exit** to discard all changes. When selecting **Save**, a pop-up window displays the following options for selection:
   - **Save** to overwrite the existing program,
   - **Save as** to save the program with another name,
   - **Cancel** to abort the process.



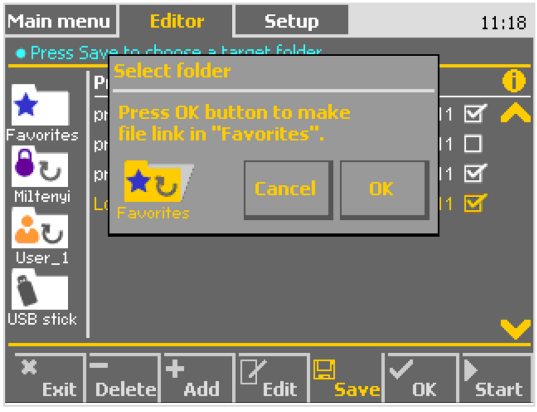
4.5.3 Creating program shortcuts into Favorites

Shortcuts to frequently used programs in the **Miltenyi, Templates**, or **User** folders can be created in the **Favorites** folder. These shortcuts can be used to quickly access the required programs.

1. Highlight the folder containing the required program.
2. Check the corresponding checkbox to select the program. Note that it is possible to select multiple programs. Any program, highlighted or not, can be selected. In this example, three programs in the folder **User_1** are selected for transfer.



3. Press **Save**.
4. Select the **Favorites** folder in the pop-up window. Confirm by pressing **OK**.



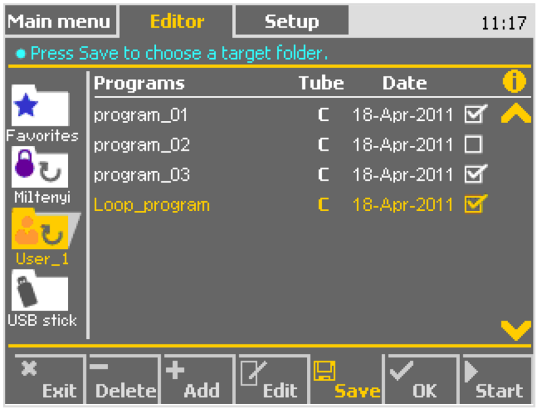
4.5.4 Transfering programs to other folders

Programs can be transferred across folders and USB drives. Refer to table 4.6 for an explanation of program transfer rights.

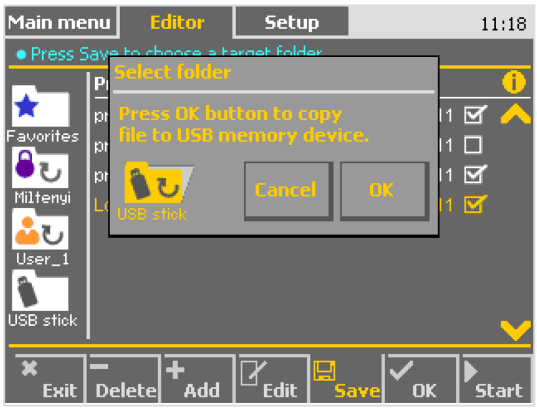
Note: The **Favorites** folder contains only links to programs in other folders and cannot be used to transfer programs.

Note: Before transferring programs to a USB stick, ensure that the USB stick is inserted securely into the USB port.

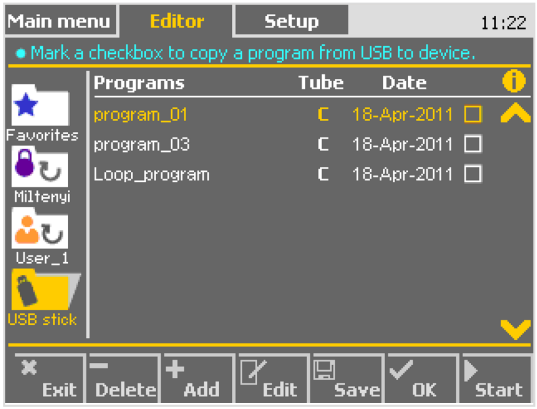
1. Highlight the folder containing the required program.
2. Check the corresponding checkbox to select the program. Note that it is possible to select multiple programs. In this example, three programs in the folder **User_1** are selected for transfer.



3. Press **Save**.
4. Choose the destination folder by pressing the folder icon in the pop-up window until the respective folder appears. Press **OK** to save the programs, or **Cancel** to abort the process. In this example, the programs are transferred to a USB stick.



5. Open the destination folder to ensure that the transfer was successful.



Folder	Description	Program transfer rights
Favorites	It is recommended to create shortcuts to frequently used programs in this folder. The shortcut, when used, will run the latest version of the associated program. A maximum of 20 shortcuts can be created.	Shortcuts can only be deleted
Miltenyi	This folder contains gentleMACS Programs that have been developed by Miltenyi Biotec for a variety of applications.	From Miltenyi to: - Favorites folder
Templates	Contains generic programs for tissue dissociation and homogenization protocols. These programs provide an excellent basis to develop and optimize customized programs for user-specific applications. Altered templates have to be renamed and saved in a **User** folder.	From Templates to: - Favorites folder
User folder	There are a total of five user folders. Their names can be modified using the **Setup** menu.	From any user folder to: - Favorites folder - USB stick - User folders
USB stick	gentleMACS Programs provided by Miltenyi Biotec and user programs can be transferred from the USB stick to the instrument.	From USB stick to: - User folders

Table 4.6: Overview of the gentleMACS Octo Dissociator with Heaters folders and program transfer rights.

4.5.5 Deleting programs

To delete a program:

1. Select the **User** folder containing the required program.
2. Highlight the program to be deleted.
3. Press **Delete** to remove the program.
4. Press **OK** to confirm or **Cancel** to abort the process.

Note: Files located in the **Miltenyi** and **Template**s folder cannot be deleted.

Note: Deleting a shortcut in the Favorites folder will not delete the original program.

4.6 Setup

The **Setup** menu is used to manage the following device settings:

- **Set LED** – switch the LEDs on or off
- **Set time** – set the time
- **Set date** – set the date in the format dd-mm-yyyy
- **Set folder name** – name/rename **User** folders
- **Software version** – get information on the software version that is installed on the instrument.
- **Serial number** – get information on the serial number of the instrument.

4.6.1 Set LED

To set the LED for the instrument:

1. Press **Set LED**.
2. Press **Set LED on** or **Set LED off** as required.

4.6.2 Set Clock and date

The procedures to modify the time and date are identical. The following example shows the change of date.

1. Press **Set date**.
2. Press the desired parameter: day (dd), month (mm), and year (yyyy).
3. Modify the parameter using the touchscreen.
4. Press **OK** to confirm or **Exit** to cancel.

4.6.3 Set folder name

To name or rename **User** folders:

1. Press **Set folder name**.
2. Select the required folder.

   Note: Default values for **User** folders are **User_1, User_2, User_3, User_4, User_5**.
3. Enter the new name using the touchscreen. The folder name cannot exceed nine characters.
4. Press **OK** to save or **Exit** to cancel.

4.6.4 Software version

To display the software version:

Press **Software version**. The software versions and gentleMACS Program database version will be displayed.

4.6.5 Serial number

To display the serial number of the instrument:

Press **Serial number**. The serial number will be displayed.

5 Maintenance

5.1 Servicing

⚠WARNING If the gentleMACS Octo Dissociator with Heaters needs servicing, send the instrument back to an authorized Miltenyi Biotec service provider. Ensure that all parts are decontaminated and sterilized (for details, refer to section 5.2). Use the original packaging material.

Do not service the instrument yourself. Service needed on components inside the instrument must be carried out only by personnel trained and authorized by Miltenyi Biotec. Servicing and an improperly serviced instrument may result in mechanical hazards, optical radiation hazards, electric shock, or personally injury or even death. Read the chapter **Important safety information**.

5.2 Cleaning

⚠WARNING Read the section **Risk of electric shock** in the chapter **Important safety information**. Unplug the power cord before cleaning the instrument. Do not allow fluids or objects to enter the interior of the instrument. Large amounts of accidentally spilled liquid are automatically collected in the Trough of the gentleMACS Octo Dissociator with Heaters. Use a pipette to aspirate the liquid before removing the Trough for cleaning and sterilizing. If biohazardous material is or has been used always use personal safety equipment while removing parts of the gentleMACS Octo Dissociator with Heaters for cleaning or sterilization.

In case of spillage or contamination, clean the instrument appropriately.
For decontamination, wipe the instrument with 70% ethanol. Clean the instrument only with cleaning agents that are non-corrosive and not damaging to the plastic housing of the gentleMACS Octo Dissociator with Heaters. Suitable cleaning agents include household detergents and 70% ethanol. Do not use acetone or any aggressive agents. If in doubt, contact Miltenyi Biotec Technical Support.

Note: Do not leave gentleMACS Heaters and Tubes attached to the instrument while it is not in use.

1. Unplug the power cord before cleaning the instrument.
2. Remove the Safety Shield.
3. Remove the Sleeves from the instrument for cleaning and/or sterilization.
4. Remove the Trough for cleaning.

Note: To remove the Trough pull on one side of the Trough. Avoid pulling on both sides at the same time.

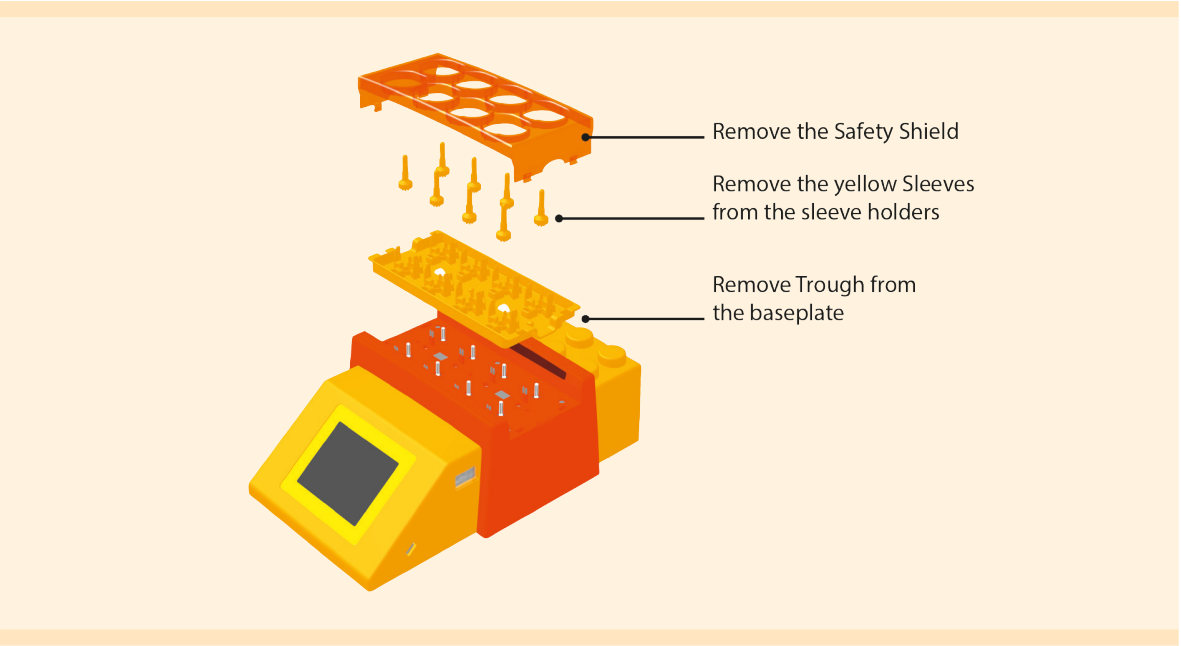


Figure 5.1: Disassembly of the gentleMACS Octo with Heaters for cleaning.

WARNING! Optical radiation emitted from gentleMACS Tube and Safety Shield illumination light emitting diodes (LEDs) may be harmful to the eyes at close viewing distances when the Trough is removed. Do not stare at operating LEDs from a distance less than 20 cm when the Trough is removed. Read the chapter **Important safety information.**

5. The surface of the gentleMACS Octo Dissociator with Heaters should be cleaned with a cloth soaked with a detergent-containing aqueous solution or 70% ethanol. Carefully wipe all parts.

Note: For cleaning, wipe the gentleMACS Heaters carefully with a soft cloth soaked with 70% ethanol. Do not use any detergents. Do not soak the gentleMACS Heaters directly into any cleaning solution.

6. Repeat the procedure with another cloth soaked with distilled water.
7. If the homogenized substances are not water-soluble, it is recommended to wipe all parts with ethanol. Contact Miltenyi Biotec Technical Support for further advice.
8. If necessary, exchange the Sleeves and the Trough.
9. Reassemble the parts while ensuring that the removes parts snap into position correctly. Ensure that the orientation of the Trough and the Safety Shield is correct.

5.3 Instrument disposal

The gentleMACS Octo Dissociator with Heaters must be disposed of in accordance with the biosafety level of its use. Potentially contaminated parts must be sterilized before disposal, in accordance with local laboratory regulations.

WARNING! Decontamination is the responsibility of the operator of the instrument. Contaminated instruments or contaminated parts of the instrument must not be sent or given to any person.

6 Troubleshooting

Error	Cause of error	Remedy
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 trough 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.	Refer to 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 press continue to resume the program.
Tube comes off the instrument	Tube is not correctly fitted 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.
A warning message appears in a pop-up window when saving an edited program. "Input error - Maximum rounds per run (3200) exceeded!"	The duration of the program exceed 3,200 rounds per run (rpr). It is not recommended to run programs exceeding this limitation! Miltenyi Biotec does not guarantee proper function of the instruments and disposables above this value.	Press OK to save the program. Press Abort to re-edit the program.
New program containing iterations cannot be saved. The instrument displays an error message with the cause of the error.	"Loop command is faulty. End loop command is missing." indicates that the end loop command has not been specified.	Close iterations by adding an end loop command.
	"Loop command is faulty. The command is nested." indicates that there are more than one loop commands.	Use only one loop command and close the iteration by adding an end loop command.
	"Loop command is faulty. Loop has no body." indicates that there is no command between the loop and end loop commands.	At least one program step must be included between a loop and end loop command. Add steps and define commands that shall be iterated.
A warning message "The heater was removed!" appears in a pop-up window, while running a heaters program.	The heater was removed.	Reinstall heater.
	The heater is not installed properly.	Make sure that the heater is installed properly.
	The electrical contacts of the instrument or the	Carefully clean the heater

Error	Cause of error	Remedy
	heater are dirty or corroded.	contacts of the instruments and the resp. heater using a cloak soaked with water or 70% ethanol. Carefully check the heater for signs of damage. If no visible signs of damage can be detected, switch the instrument OFF and ON again and retry to run the program. Contact Technical Service.
Program is assigned to a tube position and displays a red error message.	Program contains a heating step and no heater is installed.	Press the tube position on the instrument's display for more information. Install heater.
Shortcut to a program cannot be created in the Favorites folder. The instrument displays the message "Memory is worn out. File cannot be saved."	The Favorites folder has reached the maximum limit of 20 shortcuts.	Delete other program shortcuts in the Favorites folder.
Folder cannot be accessed. The instrument displays the message "Program folder cannot be opened!".		Restart the device and try again. If the problem persists, contact Miltenyi Biotec Technical Support.

Table 6.1: Errors, sources of errors, and user actions

7 Technical specifications

Technical data	Specification
Colors	Yellow / orange
Size	465x285x185 mm (Length x Width x Height)
Weight	11 kg
Main power	
Power consumption	max. 450 W
Supply voltage	100-240 VAC, 50/60 Hz
Fuse	2xT3.15AH250V
Motor	
Rotational Speed	20-4,000 rpm
Rotational direction	Clockwise or counter-clockwise
Rotational acceleration	100r/s^2
Torque	max. 150 mNm; Overload restriction over the range of 200-4,000 rpm
Conditions of operation	
Working temperature without use of heaters	+4 °C to +35 °C
Working temperature with use of heaters	+4 °C to +30 °C
Humidity	15-80%, relative, non-condensing
Altitude	Maximum 2,000 m
Storage temperature	-15 °C to +70 °C
USB interface (for service purposes and for loading and storage of programs)	Pin 1: USB + 5 V Pin 2: USB - Pin 3: USB + Pin 4: USB GND
RS232 port	Pin 1, 4, 6, 9: NC Pin 2: RxD Pin 3: TxD Pin 5: GND Pin 7: CLK Pin 8: CTS
CAN port	Pin 1, 4, 5, 8: NC Pin 2: CAN-L Pin 3, 6: GND Pin 7: CAN-H Pin 9: 24VDC/1A
Maximum number of programs	500
Number of heatable positions	8

Technical data	Specification
Maximum noise emissions	
Sound pressure level at workstation	86 dB(A) +/- 2.5 dB(A)
Sound power level Measurement operation conditions: 8x C Tubes containing 500 µl of liquid, processed at 4,000 rpm	92 dB
Working temperature heaters	37 °C

Table 7.1: Technical specifications of the gentleMACS Octo Dissociator with Heaters.

The gentleMACS Octo Dissociator with Heaters is a Protection Class I instrument and must be plugged into a ground power outlet. The main power supply cord and plug of the instrument must comply with following specifications (USA and Canada only): 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-9 attachment plug, rated 125 VAC, 10 A. Opposite end terminates in IEC 320 style connector, rated 125VAC, 10A.

Conditions of operations: Supply voltage fluctuations up to +/- 10% of the nominal voltage. Transient over-voltages present on the main supply: category II.
The instrument is suitable for rated pollution degree 2.

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 distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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

For other safety considerations, refer to the product label, or visit **www.miltenyibiotec.com**.

Design and specifications are subject to change without notice.

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 product 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 Octo Dissociator with Heaters

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

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

The machinery is in conformity with the following harmonized standards:

EN 61010-1:2010
EN 61010-2-010:2014
EN 61010-2-051:2015
EN 61326-1:2013

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

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 product 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 Octo Dissociator with Heaters

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 61010-2-010:2014
EN 61010-2-051:2015
EN 61326-1:2013

Person authorized to compile the relevant technical documentation:

Dr. Bernd Schröder
Global Head Regulatory Affairs
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Friedrich-Ebert-Straße 68
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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
Email: technicalsupport@miltenyi.com

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

9 Legal notes

9.1 Limited warranty

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

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

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

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

Miltenyi Biotec's warranty does not cover products sold AS IS or WITH ALL FAULTS, or which had its serial number defaced, altered, or removed, or any consumables or parts identified as being supplied by a third party.

Miltenyi Biotec must be informed promptly if a claim is made under this limited warranty. If a material or manufacturing defect occurs within the Warranty Period, Miltenyi Biotec will take the appropriate steps, at Miltenyi Biotec's option, to make repairs, replacements, or corrections to the product or any component thereof as may be required to restore the full usability of your product. If Miltenyi Biotec determines that a product for which you have requested warranty services is not covered by the warranty hereunder, you shall pay or reimburse Miltenyi Biotec for all costs of investigating and responding to such request at Miltenyi Biotec's then prevailing time and materials rates. If Miltenyi Biotec provides repair services or replacement parts that are not covered by this warranty, you shall pay Miltenyi Biotec therefor at Miltenyi Biotec's then prevailing time and materials rates.

THE OBLIGATIONS CREATED BY THIS WARRANTY STATEMENT TO REPAIR OR REPLACE A DEFECTIVE PRODUCT ARE EXCLUSIVE AND SHALL BE THE SOLE REMEDY OF BUYER IN THE EVENT OF A DEFECTIVE PRODUCT. EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY STATEMENT, MILTENYI BIOTEC HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, ORAL OR WRITTEN, WITH RESPECT TO THE PRODUCT, INCLUDING WITHOUT LIMITATION ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. MILTENYI BIOTEC DOES NOT WARRANT THAT THE PRODUCT IS ERROR-FREE OR WILL ACCOMPLISH ANY PARTICULAR RESULT.

UNDER NO CIRCUMSTANCES WILL MILTENYI BIOTEC BE LIABLE FOR ANY LOSS OF USE, INTERRUPTION OF BUSINESS, OR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES OF ANY KIND (INCLUDING LOST PROFITS) REGARDLESS OF THE FORM OF ACTION WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT PRODUCT LIABILITY, OR OTHERWISE, EVEN IF MILTENYI BIOTEC HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL THE TOTAL LIABILITY OF MILTENYI BIOTEC HEREUNDER EXCEED THE GREATER OF 100.00 EUROS OR THE AMOUNT YOU ACTUALLY PAID FOR THE PRODUCT GIVING RISE TO SUCH LIABILITY, REGARDLESS OF THE CAUSE OF ACTION, IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE.

NOT ALL JURISDICTIONS ALLOW SUCH LIMITATIONS OF DAMAGES SO THE FOREGOING LIMITATIONS MAY NOT APPLY TO YOU. This warranty statement gives you specific legal rights and you may have other rights, which may vary from jurisdiction to jurisdiction.

9.2 Trademarks

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