



Miltenyi Biotec

gentleMACS™ Dissociator

User manual



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gentleMACS™ Dissociator

User manual

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Contents

Chapter 1	7	Important information
	11	Wichtige Informationen
	17	Informations importantes
	23	Informazioni importanti
	29	Información importante
Chapter 2	34	Introduction
	34	Intended use
Chapter 3	35	gentleMACS Products and Spare Parts
Chapter 4	37	Storage and handling
Chapter 5	38	Installation
Chapter 6	39	Operating the gentleMACS Dissociator
	39	General information
	41	Description of the instrument
	41	Layout of the keyboard
	41	Panel buttons
	42	gentleMACS Program Card
	42	Function of the LED
	42	Display
	42	Power on
	43	Function of the menus
	43	Select and run a program
	44	Copy a program
	45	Delete a program
	45	Emergency shutdown procedure
Chapter 7	46	Performance and limitations of use
Chapter 8	47	Maintenance
	47	Cleaning
	48	Cleaning procedure
	48	Disassembly for cleaning and reassembly
	49	Safety
	50	Internal quality control
	50	Disposal information
Chapter 9	51	Troubleshooting
Chapter 10	52	Technical specifications
Chapter 11	53	Limited warranty
Chapter 12	55	Technical support
Chapter 13	56	Declaration of conformity

Please read before use!

Please read all information contained in this chapter before use. The use of an instrument for a task other than that for which it is intended, as well as improper or insufficient maintenance can greatly reduce the life time of the instrument and will invalidate the instrument's warranty. Incorrect handling and care as well as misuse can lead to premature wear or can cause hazards to users. The following chart is an illustrated glossary depicting the symbols that are used in this user manual and on the gentleMACS Dissociator.

Symbols

Warning



Triangles indicate general warnings. Warnings include the risk of damage to the equipment, severe personal injury, or loss of life. Consult the user manual for further instructions and proceed with caution.

Warning



This symbol indicates the risk of loss of life or severe injury to the instrument operator due to high voltage. Consult the user manual for further instructions and proceed with caution.

Warning



This symbol indicates the risk of loss of life, severe injury to the instrument operator, or equipment damage due to potentially dangerous chemical or biological material. Consult the user manual for further instructions and proceed with caution.

Caution



This symbol indicates the risk of equipment damage if instructions in the user manual are not followed precisely. It is therefore strongly recommended that the instrument operator consult the corresponding chapters in the respective documentation.



Protective conductor terminal

Symbol is attached on the inside of the instrument. Warning for service personnel only.



On (supply)

Off (supply)



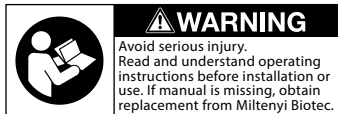
Fuse



WEEE (Waste of Electrical and Electronic Equipment)



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



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



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

Warnings and precautions



This chapter contains information for the safe operation of the gentleMACS Dissociator. Detailed instructions regarding safety are provided throughout this manual, marked with the symbols described above.

The operator is responsible for the correct use of the gentleMACS Dissociator following the instructions given in this manual and in full accordance with all local, state, and federal laws that may apply. The impeccable and safe operation of the instrument presumes that

any operator understands the user manual and pays attention to all safety information.

Keep this user manual in a safe place, accessible for anyone using the gentleMACS Dissociator.

At all times, all safety instructions in this user manual, local working area safety instructions, laboratory policies, and standards regarding laboratory safety and health, and prevention of accidents must be adhered to.

In the case of safety-relevant defects of the equipment, Miltenyi Biotec technical service must be contacted.

To ensure safe operation of the gentleMACS Dissociator all covers or parts that have been removed from the gentleMACS Dissociator must be re-installed prior to setting the instrument into operation. Do not allow fluids or objects to enter the interior of the instrument.

Incorrect handling of the gentleMACS Dissociator bears risks in the form of mechanical, electrical, chemical, and biological hazards.

The instrument must be used only with properly installed gentleMACS Tubes whose lids are tightly closed. Do not operate the instrument with gentleMACS Tube lids only.

Electrical hazards



Please be particularly aware of electrical hazards. Standard electrical safety precautions must be applied at all times. Only qualified personnel are permitted to perform electrical servicing. It is strictly forbidden to operate the instrument with disassembled or damaged parts.

The instrument is equipped with a three-wire electrical grounding-type plug. This is a safety feature. 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 indicated 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.

Make sure 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.

After moving the gentleMACS Dissociator from a cold environment, for example, a cold room at 4 °C to room temperature, it is necessary to wait a minimum of 4 hours before setting the instrument into operation. Condensing liquid droplets can severely damage the instrument.

Chemical and biological hazards



The proper handling of the gentleMACS Tubes minimizes exposure to the samples. However, potential hazards to the operator still exist. The operator must choose and wear personal safety equipment in accordance with warnings and precautions for the used substances. Defective or inadequate safety equipment might endanger the operator.

The gentleMACS Dissociator must be operated within a safety enclosure when hazardous or unknown materials are processed, to protect persons and the laboratory environment from contamination.

All liquid and solid waste must be considered biohazardous and, therefore, must be handled taking universal laboratory precautions. All clinical samples must be considered potentially infectious. Toxic or corrosive chemicals, poisonous, acidic, or radioactive substances may be present.

It is strictly prohibited for anyone other than the operator to handle contaminated accessories or contaminated parts of the gentleMACS Dissociator.

Servicing



Unless otherwise mentioned in the Miltenyi Biotec documentation, do not service the equipment yourself. Service needed on components inside the instrument must be carried out only by personnel trained and authorized by Miltenyi Biotec.

Bitte vor Gebrauch lesen!

Bitte lesen Sie vor Ingebrauchnahme alle Hinweise in diesem Kapitel. Eine nicht bestimmungsgemäße Verwendung des Geräts sowie eine falsche oder unzureichende Pflege können eine deutliche Verringerung der Lebensdauer und das Erlöschen der Produktgewährleistung nach sich ziehen. Falsche Bedienung und Wartung sowie missbräuchliche Verwendung können zu erhöhtem Verschleiß führen und Gefahren für die Benutzer des Geräts hervorrufen.

Im folgenden Abschnitt werden die Symbole beschrieben, die in diesem Handbuch und auf dem gentleMACS Dissociator verwendet werden, um Warnhinweise hervorzuheben.

Symbole



Warnung

Dreiecke deuten auf allgemeine Hinweise hin, die vor Beschädigungen des Geräts oder schweren und potenziell tödlichen Verletzungen warnen. Schlagen Sie im gentleMACS Dissociator Handbuch nach, um weitere Informationen zu erhalten und verfahren Sie mit Vorsicht.



Warnung

Dieses Symbol deutet auf das Risiko schwerer und potenziell tödlicher Verletzungen durch Hochspannung hin. Schlagen Sie im gentleMACS Dissociator Handbuch nach, um weitere Informationen zu erhalten und verfahren Sie mit Vorsicht.



Warnung

Dieses Symbol deutet auf das Risiko schwerer und potenziell tödlicher Verletzungen oder der Beschädigung des Geräts durch chemische oder biologische Gefahrstoffe hin. Schlagen Sie im gentleMACS Dissociator Handbuch nach, um weitere Informationen zu erhalten und verfahren Sie mit Vorsicht.



Vorsicht

Dieses Symbol deutet auf das Risiko der Beschädigung des Geräts bei Nichtbeachtung der Hinweise in diesem Handbuch hin. Es wird dringend empfohlen, die jeweiligen Kapitel in den entsprechenden Dokumenten zurate zu ziehen.



Schutzleiteranschluss

Dieses Symbol ist innerhalb des Geräts angebracht und stellt eine Warnung für das Service-Personal dar.



Ein (Stromversorgung)

Aus (Stromversorgung)



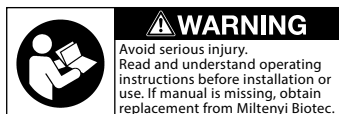
Sicherung



Elektro- und Elektronik-Altgeräte



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



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.



Europäische Konformitätskennzeichnung



Britische Produktkennzeichnung



NRTL-Prüfzeichen: Das Produkt entspricht den im Konsensverfahren erarbeiteten Sicherheitsanforderungen, welche von der Behörde für Sicherheit und Gesundheitsschutz am Arbeitsplatz (OSHA) gefordert und von der staatlich anerkannten Prüfstelle (NRTL) TÜV SÜD festgelegt wurden

Warnhinweise und Vorsichtsmaßnahmen



Dieses Kapitel enthält Informationen, die zur sicheren Handhabung des gentleMACS Dissociator beitragen sollen. Ausführliche Sicherheitsinformationen sind im gesamten Handbuch zu finden und sind mit den oben gezeigten Symbolen gekennzeichnet. Der Benutzer ist verantwortlich für die korrekte Anwendung des gentleMACS Dissociator unter Beachtung der Anleitungen in diesem Handbuch sowie unter Beachtung sämtlicher relevanter Gesetze. Eine fehlerlose und sichere Bedienung des Geräts setzt voraus, dass der Benutzer den Inhalt des Handbuchs versteht und alle Sicherheitsinformationen beachtet.

Bewahren Sie dieses Handbuch an einem sicheren Ort auf, an dem es für jeden Benutzer des gentleMACS Dissociator zugänglich ist.

Alle Sicherheitsanweisungen in diesem Handbuch, lokale Sicherheitsbestimmungen, die den Arbeitsbereich betreffen, Laborrichtlinien, sowie Standards, die die Laborsicherheit, Gesundheit, sowie die Unfallverhütung betreffen, müssen jederzeit eingehalten werden.

Im Falle sicherheitsrelevanter Defekte des Geräts muss Verbindung mit dem technischen Kundendienst von Miltenyi Biotec aufgenommen werden.

Um einen sicheren Betrieb des Geräts zu gewährleisten, müssen alle entfernten Abdeckungen oder Teile wieder eingebaut werden, bevor das Gerät in Betrieb genommen wird. Flüssigkeiten oder Gegenstände dürfen nicht in das Innere des Geräts gelangen.

Eine unsachgemäße Handhabung des Geräts kann mechanische, elektrische, chemische und biologische Gefährdungen verursachen.

Das Gerät darf nur mit korrekt installierten gentleMACS Tubes, deren Deckel fest verschlossen sind, betrieben werden. Nehmen Sie das Gerät nicht mit Deckeln ohne Röhrchen in Betrieb.

Gefahr eines Stromschlags



Bei elektrischen Geräten besteht die Gefahr eines Stromschlags. Um das Risiko eines Stromschlags zu reduzieren, müssen standardmäßige Vorsichtsmaßnahmen getroffen werden. Nur dafür qualifizierte Personen dürfen die Elektrik des Geräts warten. Es ist verboten, ein Gerät in Betrieb zu nehmen, das unvollständig zusammengebaut ist oder beschädigte Teile enthält.

Das Instrument ist mit einem Netzstecker versehen, der für die elektrische Erdung bestimmt ist. Dies ist eine Sicherheitsvorkehrung. Stecken Sie den Stecker nicht in eine Steckdose, die nicht geerdet ist. Falls Sie unsicher sind, ob die Steckdose geerdet ist, wenden Sie sich an einen Elektriker.

Das Instrument sollte nur aus einer Stromquelle versorgt werden, die mit der Klassifizierung übereinstimmt, die auf dem Typenschild angegeben ist. Falls Sie Fragen zur Stromversorgung haben, wenden Sie sich an Ihren Miltenyi-Biotec-Kundendienst oder an Ihre Stromversorgungsgesellschaft.

Stellen Sie sicher, dass der Hauptschalter und der Anschluss für das Stromkabel leicht zugänglich sind und sich in Reichweite der Person befinden, die das Instrument bedient. Falls es notwendig sein sollte, die Stromversorgung zu unterbrechen, ziehen Sie den Stecker aus der Steckdose.

Wenn der gentleMACS Dissociator aus einem Kälteraum (4 °C) in einen Raum mit Raumtemperatur überführt wird, muss ein Zeitraum von mindestens 4 Stunden abgewartet werden, bevor das Gerät in Betrieb genommen wird. Durch Kondensation entstandene Wassertropfen können das Gerät beschädigen.

Chemische und biologische Gefährdung



Eine sachgemäße Handhabung der gentleMACS Tubes minimiert das Risiko für den Benutzer, mit der Probe in Kontakt zu kommen. Die Möglichkeit einer Gefährdung bleibt jedoch bestehen. Der Benutzer des Geräts muss eine dem Gefahrenpotential angemessene Sicherheitsausrüstung tragen. Das Tragen defekter oder unzureichender Sicherheitsausrüstung kann eine Gefährdung des Benutzers darstellen.

Der gentleMACS Dissociator muss in einem umschlossenen Sicherheitsbereich betrieben werden, falls Gefahrstoffe oder unbekannte Stoffe verarbeitet werden.

Alle flüssigen und festen Abfälle müssen als biologische Gefahrstoffe angesehen werden. Die Handhabung der Abfälle muss deshalb unter Beachtung allgemeiner Vorsichtsmaßnahmen erfolgen.

Alle Proben klinischer Herkunft müssen als möglicherweise infektiös angesehen werden.

Gefährdung durch toxische oder ätzende Chemikalien, giftige, säurehaltige oder radioaktive Stoffe ist möglich.

Kontaminierte Geräteteile oder Zubehöerteile dürfen ausschließlich vom Benutzer gehandhabt werden.

Wartung



Falls nicht anders in den Dokumenten von Miltenyi Biotec vermerkt, warten Sie das Instrument nicht selbst. Wartungsarbeiten an Teilen im Innern des Instruments dürfen nur von Personen durchgeführt werden, die von Miltenyi Biotec geschult und dafür berechtigt wurden.

Avant toute utilisation, veuillez lire attentivement les indications suivantes!

L'utilisation d'un instrument à une fin autre que celle à laquelle il est destiné, ainsi qu'une mauvaise maintenance peut sérieusement réduire la durée de vie et annuler la garantie de l'instrument. Une mauvaise manipulation ou utilisation de l'instrument peut entraîner une usure précoce de ce dernier et peut représenter un danger pour les utilisateurs.

Le tableau suivant est un glossaire illustré expliquant la signification des symboles utilisés dans cette notice d'utilisation et apposés sur le gentleMACS Dissociator.

Symboles



Avertissement

Les triangles attirent l'attention sur des dangers d'ordre général. Ces avertissements incluent le risque de détérioration de l'équipement, de blessure corporelle sévère ou de décès. Consultez la notice d'utilisation pour obtenir des instructions complémentaires et soyez vigilant.



Avertissement

Ce symbole attire l'attention sur un risque de décès de l'opérateur sur machine ou de blessure sévère en raison de la tension élevée. Consultez la notice d'utilisation pour obtenir des instructions complémentaires et soyez vigilant.



Avertissement

Ce symbole attire l'attention sur un risque de décès de l'opérateur sur machine ou de blessure sévère ou sur la détérioration de l'équipement en raison d'un matériau chimique ou biologique potentiellement dangereux. Consultez la notice d'utilisation pour obtenir des instructions complémentaires et soyez vigilant.



Attention

Ce symbole attire l'attention sur un risque de détérioration de l'équipement en cas de non-respect des instructions mentionnées dans la notice d'utilisation. Il est par conséquent strictement conseillé à l'opérateur sur machine de consulter les chapitres correspondants dans la documentation respective.



Protection de l'utilisateur final

Le symbole est placé à l'intérieur de l'instrument. Attention, pour le personnel de maintenance seulement.



Marche (alimentation)

Arrêt (alimentation)



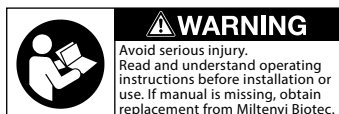
Fusible



DEEE (Déchets d'Équipements Électriques et Électroniques)



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



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.



Marquage de Conformité Européenne



Marquage de produit du Royaume-Uni



Marque de certification NRTL : Le produit répond aux normes de sécurité consensuelles imposées par l'administration de la santé et de la sécurité au travail (OSHA) et déterminées par le Laboratoire d'essais reconnu au niveau national (NRTL) TÜV SÜD

Avertissement et précautions à prendre



Ce chapitre contient des informations relatives au fonctionnement sans danger du gentleMACS Dissociator. Vous trouverez dans ce manuel des consignes de sécurité détaillées, précédées des symboles.

L'opérateur est responsable de l'utilisation correcte du gentleMACS Dissociator conformément aux instructions données dans ce manuel et conformément à la législation locale, régionale et fédérale en vigueur.

Afin de garantir le fonctionnement correct et sans danger de la machine, tout opérateur doit être en mesure de comprendre le manuel de fonctionnement et tenir compte de toutes les informations relatives à la sécurité.

Conservez cette notice d'utilisation dans un endroit sûr et accessible à toute personne utilisant le gentleMACS Dissociator. Toutes les consignes de sécurité mentionnées dans cette notice d'utilisation, les consignes de sécurité s'appliquant à la zone de travail locale, les réglementations du travail en laboratoire et les normes de sécurité des laboratoires, les normes de santé et les normes de prévention des accidents doivent être respectées en permanence.

Si vous constatez des défauts de sécurité sur l'équipement, contactez impérativement le service technique de Miltenyi Biotec. Afin de garantir le fonctionnement sans danger du gentleMACS Dissociator, toutes les protections ou pièces ayant été retirées du gentleMACS Dissociator doivent être remises en place avant de mettre la machine en fonctionnement. Empêchez tout fluide ou objet de parvenir à l'intérieur de la machine. Des risques peuvent survenir sous forme de dangers mécaniques, électriques, chimiques et biologiques en cas de manipulation incorrecte du gentleMACS Dissociator. L'instrument doit être utilisé seulement avec les gentleMACS Tubes correctement installés et dont le bouchon est bien fermé. N'utilisez pas l'instrument avec seulement les bouchons des gentleMACS Tubes.

Dangers électriques



Soyez particulièrement vigilant en ce qui concerne les dangers électriques. Les précautions de sécurité électrique standard doivent être appliquées en permanence. Seul le personnel qualifié est en droit de procéder à la maintenance du système électrique. Il est strictement interdit de faire fonctionner la machine lorsque des pièces sont démontées ou endommagées.

L'instrument est équipé d'une fiche électrique mâle. C'est une mesure de sûreté. N'insérez pas la prise mâle dans une prise femelle de courant non reliée à la terre. Si vous ne pouvez pas insérer la fiche dans une prise de terre ou si vous n'êtes pas sûr que ce soit une prise de terre, contactez votre électricien local.

L'instrument peut être seulement utilisé avec la source de courant électrique indiquée sur l'étiquette du produit. Si vous avez des questions à propos du type de voltage électrique à utiliser, contactez votre fournisseur de services Miltenyi Biotec ou la compagnie d'électricité locale.

Assurez-vous que l'interrupteur principal ainsi que le cordon d'alimentation sont facilement accessibles et localisés, autant que possible, près de l'utilisateur de l'instrument. S'il est nécessaire de déconnecter l'alimentation, débranchez la prise.

Après avoir retiré le gentleMACS Dissociator d'un environnement froid, par exemple après l'avoir fait passer d'une pièce où la température était de 4 °C à la température ambiante, il est nécessaire d'attendre au moins 4 heures avant de mettre la machine en fonctionnement. Les gouttelettes du liquide de condensation peuvent causer des dommages sévères à la machine.

Dangers chimiques et biologiques



La manipulation correcte des gentleMACS Tubes réduit l'exposition aux échantillons. Toutefois l'opérateur reste exposé à des risques potentiels. L'opérateur doit choisir et porter un équipement de sécurité personnel conformément aux avertissements mentionnés et aux précautions à prendre selon les substances utilisées. Un équipement de sécurité défectueux ou inapproprié peut représenter un danger pour l'opérateur.

Le gentleMACS Dissociator doit être utilisé dans une enceinte de protection en cas de manipulation de matériaux dangereux ou inconnus afin de protéger les personnes et l'environnement du laboratoire de toute contamination éventuelle.

Tous les déchets liquides et solides doivent être considérés comme nocifs pour l'organisme et doivent par conséquent être manipulés avec les précautions de laboratoire universelles. Tous les échantillons cliniques doivent être considérés comme potentiellement infectieux. La présence de substances chimiques toxiques ou corrosives, nocives, acides ou radioactives est possible.

Il est strictement interdit à toute personne autre que l'opérateur de manipuler des accessoires contaminés ou des pièces contaminées du gentleMACS Dissociator.

Services



Sauf indication contraire mentionnée dans la documentation Miltenyi Biotec, ne réparez pas l'instrument vous-même. Les réparations nécessaires sur les composants internes de l'instrument doivent être réalisées seulement par un personnel formé et autorisé par Miltenyi Biotec.



Si prega di leggere prima dell'uso!

Si prega di leggere tutte le informazioni contenute in questo capitolo prima dell'uso. L'impiego dello strumento per applicazioni diverse da quelle per cui è stato ideato, così come l'uso improprio dello stesso senza adeguata manutenzione, può ridurre la durata dello strumento e annullarne la garanzia. L'errato impiego e utilizzo così come l'uso improprio possono causare un logorio prematuro dello strumento o provocare situazioni di pericolo per gli utilizzatori. Di seguito viene riportato un glossario illustrato dei simboli utilizzati nel presente manuale d'impiego e sul gentleMACS Dissociator.

Simboli

Avvertenza



I triangoli indicano avvertenze di carattere generale. Le avvertenze includono il rischio di danni alle attrezzature, gravi lesioni personali o morte. Consultare il manuale d'impiego per ulteriori istruzioni e procedere con cautela.

Avvertenza



Questo simbolo indica il rischio di morte o gravi lesioni personali a danno dell'operatore a causa della presenza di alta tensione. Consultare il manuale d'impiego per ulteriori istruzioni e procedere con cautela.

Avvertenza



Questo simbolo indica il rischio di morte o gravi lesioni personali a danno dell'operatore o danni alle attrezzature a causa di materiale chimico e biologico potenzialmente pericoloso. Consultare il manuale d'impiego per ulteriori istruzioni e procedere con cautela.



Attenzione

Questo simbolo indica il rischio di danni alle attrezzature qualora le istruzioni del manuale d'impiego non vengano seguite scrupolosamente. Si raccomanda pertanto la consultazione da parte dell'operatore dei relativi capitoli nella documentazione fornita.



Terminale protettivo del conduttore

Questo simbolo è situato all'interno dello strumento. Questo segnale è rivolto esclusivamente al personale che effettua l'assistenza.



Acceso (corrente)

Spento (corrente)



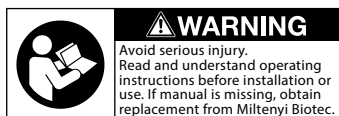
Fusibile



RAEEE (Rifiuti di apparecchiature elettriche ed elettroniche)



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



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.



Marcatura di Conformità Europea



Conformità valutata del Regno Unito



Marchi di certificazione NRTL: Il prodotto è conforme alle norme di sicurezza, basate sul consenso, imposte dall'amministrazione della sicurezza e della salute sul lavoro (OSHA), determinate dal laboratorio di prova riconosciuto a livello nazionale (NRTL) TÜV SÜD

Avvertenze e precauzioni



Questo capitolo contiene informazioni relative al funzionamento sicuro del gentleMACS Dissociator. Nel manuale vengono riportate istruzioni dettagliate relative agli aspetti di sicurezza, evidenziate dai simboli.

L'operatore è responsabile dell'uso corretto del gentleMACS Dissociator, conformemente alle istruzioni riportate nel presente manuale e in osservanza di tutte le disposizioni locali e nazionali vigenti.

Per un utilizzo corretto e sicuro dello strumento è necessario che l'operatore abbia compreso le istruzioni riportate nel manuale d'impiego e che segua tutte le informazioni di sicurezza.

Conservare il presente manuale d'impiego in luogo sicuro, accessibile a tutti gli addetti che utilizzano il gentleMACS Dissociator.

È necessario seguire sempre tutte le istruzioni di sicurezza riportate nel presente manuale, le istruzioni di sicurezza locali per gli ambienti di lavoro, le politiche di laboratorio e le direttive relative alla sicurezza e alla salute nei laboratori e la prevenzione degli incidenti.

In caso di guasti alle attrezzature che possono comprometterne la sicurezza è necessario contattare il servizio di assistenza tecnica Miltenyi Biotec.

Per garantire il funzionamento sicuro del gentleMACS Dissociator, tutti i coperchi o le parti rimosse dallo strumento devono essere reinstallate prima di avviare il gentleMACS Dissociator. Evitare che liquidi o oggetti penetrino all'interno dello strumento.

L'impiego scorretto del gentleMACS Dissociator comporta rischi di tipo meccanico, elettrico, chimico e biologico.

Lo strumento deve essere utilizzato unicamente con i gentleMACS Tube correttamente installati e i cui tappi devono essere ben chiusi. Non utilizzare lo strumento con i soli tappi dei gentleMACS Tube.

Rischi elettrici



Si raccomanda di prestare particolare attenzione ai rischi elettrici. Vanno sempre adottate le precauzioni di sicurezza standard per le apparecchiature elettriche. Gli interventi sull'impianto elettrico devono essere eseguiti esclusivamente da personale qualificato. È severamente vietato utilizzare lo strumento con parti non installate o danneggiate.

Lo strumento è fornito di una presa a tre uscite con messa a terra. Questa è una caratteristica di sicurezza. Non provare ad inserire la presa in un'uscita di corrente non dotata di messa a terra. Qualora non si riuscisse ad inserire la presa nell'uscita corrispondente, o se non si è sicuri che la presa non è dotata di messa a terra, contattare un'elettricista.

Lo strumento dovrebbe essere messo in funzione solo attraverso la fonte d'alimentazione indicata sull'etichetta che indica il livello d'intensità elettrica del prodotto. Se si hanno domande circa la tipologia della fonte d'alimentazione da utilizzare, si contatti il servizio d'assistenza Miltenyi Biotec autorizzato o la compagnia di fornitura elettrica locale.

Assicurarsi che l'interruttore ed il connettore per il cavo di alimentazione siano accessibili e posti il più vicino possibile all'operatore che utilizza lo strumento. Se fosse necessario staccare la corrente, rimuovere il cavo dalla presa d'uscita.

In caso di trasferimento del gentleMACS Dissociator da un ambiente freddo, ad esempio un locale a 4 °C, ad un locale con temperatura ambiente, è necessario attendere almeno 4 ore prima di utilizzare lo strumento. Le gocce di condensa possono danneggiare gravemente lo strumento.

Rischi chimici e biologici



La corretta manipolazione delle gentleMACS Tubes riduce al minimo l'esposizione ai campioni. Esistono tuttavia rischi potenziali per l'operatore. L'operatore è tenuto a scegliere e indossare dispositivi di sicurezza personale appropriati e conformi alle avvertenze e precauzioni per le sostanze impiegate. L'uso di dispositivi di protezione personale inadeguati o difettosi può rappresentare un pericolo per l'operatore.

Il gentleMACS Dissociator deve essere utilizzato in un ambiente sicuro quando si manipolano sostanze pericolose o sconosciute, in modo da proteggere gli addetti e l'ambiente di laboratorio da possibili contaminazioni.

Tutti i reflui liquidi e solidi devono essere considerati come rifiuti biologicamente pericolosi e vanno pertanto manipolati adottando le precauzioni di laboratorio standard.

Tutti i campioni clinici vanno considerati come potenzialmente infetti.

Possono essere presenti agenti chimici tossici o corrosivi, sostanze acide, velenose o radioattive.

È severamente proibito ai non addetti di manipolare accessori o componenti contaminati del gentleMACS Dissociator.

Assistenza



Se non diversamente specificato nella documentazione fornita da Miltenyi Biotec, non effettuare assistenza sull'apparecchiatura da soli. L'assistenza necessaria per i componenti interni dello strumento deve essere eseguita solamente da personale addestrato e autorizzato da Miltenyi Biotec.



¡Por favor leer antes de usar!

Por favor, leer toda la información contenida en este capítulo antes de su uso. El uso de un instrumento para una tarea distinta de aquella para la que se ha creado, así como un mantenimiento impropio o insuficiente puede reducir la vida media del aparato grandemente, e invalidará la garantía del equipo. Su manejo o cuidado incorrecto, así como su uso inadecuado puede llevar a su desgaste prematuro o a riesgos para los usuarios.

El siguiente gráfico es un glosario ilustrado en el que se representan los símbolos empleados en este manual del usuario y en el gentleMACS™ Dissociator.

Símbolos



Advertencia

Los triángulos indican una advertencia de tipo general que incluye daños al equipo, lesiones corporales graves o muerte. Consulte el manual del usuario para obtener más información y actúe con precaución.



Advertencia

Este símbolo indica peligro de muerte o graves lesiones causadas por el alto voltaje para quien maneje el instrumento. Consulte el manual del usuario para obtener más información y actúe con precaución.



Advertencia

Este símbolo indica peligro de muerte, graves lesiones para quien maneje el instrumento o daños al equipo debido a materiales químicos o biológicos potencial-mente peligrosos. Consulte el manual del usuario para obtener más información y actúe con precaución.



Precaución

Este símbolo indica el riesgo de causar daños al equipo si no se siguen con exactitud las instrucciones recogidas en el manual del usuario. Por lo tanto, se recomienda que quien opere el instrumento consulte los capítulos pertinentes en la respectiva documentación.



Terminal conductor protector

El símbolo está situado en el interior del instrumento. Advertencia sólo para el personal de servicio.



Encendido (electricidad)

Apagado (electricidad)



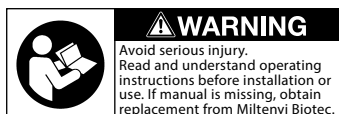
Fusible



RAEE (Residuos de Aparatos Eléctricos y Electrónicos)



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



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.



Marcado de Conformidad Europea



Conformidad evaluada del Reino Unido



Marca de certificación NRTL: El producto cumple los estándares de seguridad consensuados, requeridos por la administración de seguridad y salud ocupacional (OSHA), determinados por el laboratorio de ensayo reconocido nacionalmente (NRTL) TÜV SÜD



El presente capítulo contiene información para el manejo seguro del gentleMACS Dissociator. A lo largo de todo el manual, se recogen instrucciones detalladas sobre seguridad, las cuales están marcadas con los símbolos.

Quien maneje el gentleMACS Dissociator es responsable de su correcto uso en cumplimiento de las instrucciones del presente manual y respetando la regulación local o nacional que sea aplicable. Para un uso impecable y seguro del instrumento, se presume que quienes lo manejan comprenden el manual y prestan atención a toda la información sobre seguridad.

Mantenga este manual del usuario en lugar seguro, accesible para quienes manejen el gentleMACS Dissociator.

Se deberán observar en todo momento todas las instrucciones de seguridad del presente manual del usuario, las instrucciones de seguridad en el trabajo, las normas del laboratorio y los estándares sobre seguridad en el laboratorio y salud, y de prevención de accidentes.

En caso de defectos del equipo que afecten a la seguridad, se deberá contactar con el servicio técnico de Miltenyi Biotec.

Para garantizar el seguro manejo del gentleMACS Dissociator, todas las tapas o partes que le hayan sido quitadas al gentleMACS Dissociator deben ser instaladas de nuevo antes de poner en funcionamiento el instrumento. Evite la entrada de fluidos u otros objetos.

El manejo incorrecto del gentleMACS Dissociator conlleva riesgos mecánicos, eléctricos, químicos y biológicos.

El instrumento sólo debe ser usado con Tubos gentleMACS Tubes adecuadamente instalados, cuyas tapas estén firmemente cerradas. No utilice el instrumento sólo con las tapas de los gentleMACS Tubes.

Riesgos eléctricos



Tenga especial cuidado con los riesgos eléctricos. Se deberán respetar en todo momento las normas de seguridad eléctrica. Sólo el personal cualificado podrá realizar servicios eléctricos. Está estrictamente prohibido manejar el instrumento cuando alguna parte esté desmontada o estropeada.

El instrumento está equipado con un enchufe de tres alambres con toma tierra. Esto es una medida de seguridad. No introduzca el enchufe en una conexión que no tenga toma tierra. Sino es posible

insertar el enchufe en la toma o si no está seguro que la conexión tiene toma tierra, contacte con su electricista local.

El equipo sólo debe hacerse funcionar en una fuente de alimentación de la potencia indicada en la etiqueta de potencias eléctricas del producto. Si tiene dudas sobre qué fuente de alimentación debe utilizar, póngase en contacto con su representante autorizado de Miltenyi Biotec o la compañía de suministro eléctrico local.

Asegúrese de que el interruptor principal, así como el conector para el cable de transmisión están fácilmente accesibles y localizados lo más cerca posible del operario del equipo. Si es necesario desconectar el suministro de energía, desenchufe el cable de la toma de electricidad.

Después de pasar el gentleMACS Dissociator de una temperatura baja, por ejemplo, de una cámara refrigeradora a 4 °C, a temperatura ambiente, habrá que esperar 4 horas como mínimo antes de poner en funcionamiento el instrumento. Las gotas de líquido condensado pueden dañar severamente el instrumento.

Riesgos químicos o biológicos



El correcto manejo de los gentleMACS Tubes minimiza la exposición a las muestras. Sin embargo, siguen existiendo riesgos para quien los maneje. Dicha persona deberá llevar puesto el equipo de seguridad de acuerdo con las advertencias y precauciones para las sustancias utilizadas. Un equipo de seguridad defectuoso o inadecuado puede poner en peligro su seguridad.

Cuando se procesen materiales peligrosos o desconocidos, el gentleMACS Dissociator se manejará en un recinto de seguridad a fin de proteger de la contaminación a las personas y al laboratorio.

Todos los residuos líquidos o sólidos que se generen deben ser considerados peligrosos biológicamente y, por ello, deben ser manejados siguiendo las normas de seguridad en el laboratorio. Todas las muestras clínicas deben ser consideradas potencialmente infecciosas.

Podrán estar presentes sustancias químicas tóxicas o corrosivas, o sustancias venenosas, ácidas o radiactivas.

Está terminantemente prohibido que alguien distinto del responsable maneje accesorios contaminados o partes contaminadas del gentleMACS Dissociator.

Mantenimiento



A menos que se mencione lo contrario en la documentación de Miltenyi Biotec, no haga usted mantenimiento del equipo. El

mantenimiento de los componentes del interior del equipo debe llevarlo a cabo únicamente personal preparado y autorizado por Miltenyi Biotec.

2 Introduction

The gentleMACS™ Dissociator is a benchtop instrument for the automated dissociation of tissues to obtain single-cell suspensions. Single-cell suspensions are a crucial prerequisite to achieve reliable results in cell separation, cell analysis, and cell culture. Moreover, the gentleMACS Dissociator can be used for the homogenization of cells and tissues to extract biomolecules for molecular biology or protein biochemistry applications.

Two types of gentleMACS Tubes have been specially designed: C Tubes for the gentle preparation of single-cell suspensions from tissues and M Tubes for the homogenization of tissues and cells. Both types of tubes are designed for safe and sterile sample handling.

A number of gentleMACS Programs have been specifically developed to offer standardized procedures for the gentle dissociation or homogenization of various tissues. A single sample or two samples in parallel can be processed.

A comprehensive gentleMACS Program overview and specific protocols for numerous applications are available for download at **www.gentlemacs.com**.

Intended use

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

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

gentleMACS Products and Spare Parts 3

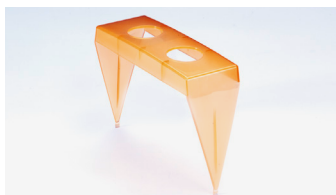
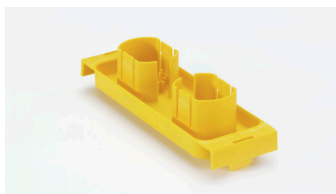
gentleMACS Products



Product	Description	Order no.
gentleMACS Dissociator	gentleMACS Dissociator 1 Power cord 1 gentleMACS Dissociator user manual	130-093-235
C Tubes	For the dissociation of tissues to obtain single-cell suspensions. 25 tubes, single-packed	130-093-237
	100 tubes, 4×25 tubes per bag	130-096-334
M Tubes	For the homogenization of tissues or cells to isolate subcellular material. 25 tubes, single-packed	130-093-236
	100 tubes, 4×25 tubes per bag	130-096-335
M Tubes with Strainer	50 tubes per bag (strainer: 600 µm mesh)	130-094-392

For more information, visit www.gentlemacs.com.

gentleMACS Spare Parts



Product	Description	Order no.
gentleMACS Sleeves	2 adapters for attachment of gentleMACS Tubes	130-093-464
gentleMACS Trough	Safety container for spilled liquid	130-093-465
gentleMACS Safety Shield	Safety shield for protection	130-093-466
gentleMACS Program Card	Memory card containing gentleMACS Programs	130-093-462



Only use 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.

The gentleMACS Dissociator must be stored and operated under dry conditions (non-condensing humidity). Storage temperature must be between -15°C and $+70^{\circ}\text{C}$. The instrument should be operated at a temperature between $+4^{\circ}\text{C}$ and $+35^{\circ}\text{C}$.

5 Installation

Please unpack the instrument carefully and check for completeness and for any damage that may have occurred during transportation. If there is any damage, contact your local Miltenyi Biotec representative or Miltenyi Biotec technical service. Please keep the original packaging material.



The gentleMACS Dissociator is designed exclusively for indoor use.

Components included in delivery

- 1 gentleMACS Dissociator
- 1 Power cord
- 1 gentleMACS Dissociator user manual

Installation

The gentleMACS Dissociator requires a flat surface with the dimensions 250 mm × 400 mm and a power connection. To operate the instrument, the keyboard area and the top of the instrument must be accessible. The gentleMACS Dissociator is a ready-to-use instrument.

Operating the gentleMACS Dissociator 6



The instrument must be used only with properly installed gentleMACS Tubes whose lids are tightly closed. Do not operate the instrument with gentleMACS Tube lids only.

General information

The gentleMACS Dissociator is used as a stand-alone, benchtop instrument. A number of pre-defined programs offer a variety of processes for tissue dissociation and tissue homogenization. The specially designed gentleMACS Tubes are required for processing the samples. The gentleMACS Dissociator must be used exclusively with these Tubes.

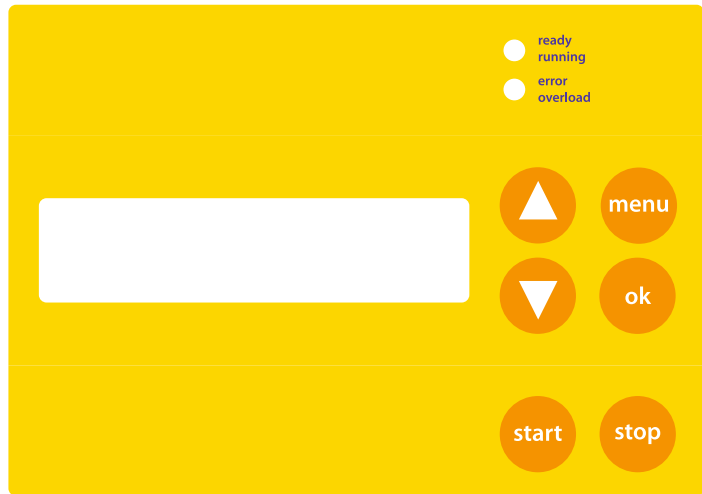
C Tubes are designed for the dissociation of tissues to obtain single-cell suspensions. M Tubes are designed for homogenization of tissues or cells to isolate subcellular material. A single sample or two samples in parallel can be processed.

For details on the sample preparation, see the respective gentleMACS Protocols, which are available at **www.miltenyibiotec.com/protocols**.

Below, please find brief instructions for the use of the instrument.
For detailed information, see the next sections.

1. Make sure that the gentleMACS Dissociator is switched on.
The mains switch is located at the back panel of the instrument.
2. Pre-defined programs are provided by the internal gentleMACS Dissociator memory.
Alternatively: Insert the gentleMACS Program Card to run a program from the Program Card or to copy a program from the Program Card to the internal memory of the instrument.
3. Transfer the samples into the Tubes. Make sure that the Tubes are securely closed.
4. Make sure to properly install the Tubes vertically and upside down onto the Sleeves. Proper installation will ensure that the Tubes are held in position against rotational and axial forces.
5. All functions of the gentleMACS Dissociator must be controlled via the display; see the following sections for details.
6. Select one of the programs offered by the instrument memory or by the gentleMACS Program Card.
7. Start the process by pressing the start button.
8. The display indicates the program name and the remaining time (seconds) for the current program to finish.
9. The end of the process is displayed for 5 seconds. Subsequently, the display indicates the program that has just been used.
By pressing the start button, this program can be applied immediately to process the next sample.
10. Remove the Tubes containing the sample by pulling it vertically from the Sleeve.

Layout of the keyboard



Panel buttons



Selection of one of the three modes that allow the user to select a program for sample processing, or copy, or delete programs



Selection of a program



Confirmation of a selection or function



Run or stop a process

gentleMACS Program Card

Insert the gentleMACS Program Card in the direction indicated by the arrow. The card will then automatically be selected to access programs.

If the gentleMACS Program Card is inserted, only the programs from the Program Card are available. The programs from the Program Card can be copied to the internal gentleMACS Dissociator memory. To select programs from the internal memory, remove the gentleMACS Program Card.

Function of the LED

The LED indicates the instrument status for convenient monitoring.

Green:	System ready
Green flashing:	Process running
Red:	System error
Red flashing:	Error during process

Display

Using the menu button, the operator can switch between **select**, **copy**, and **delete** modes.

<Program name> <Tube name>	Select mode
Copy <Program name>	Copy mode
Delete <Program name>	Delete mode

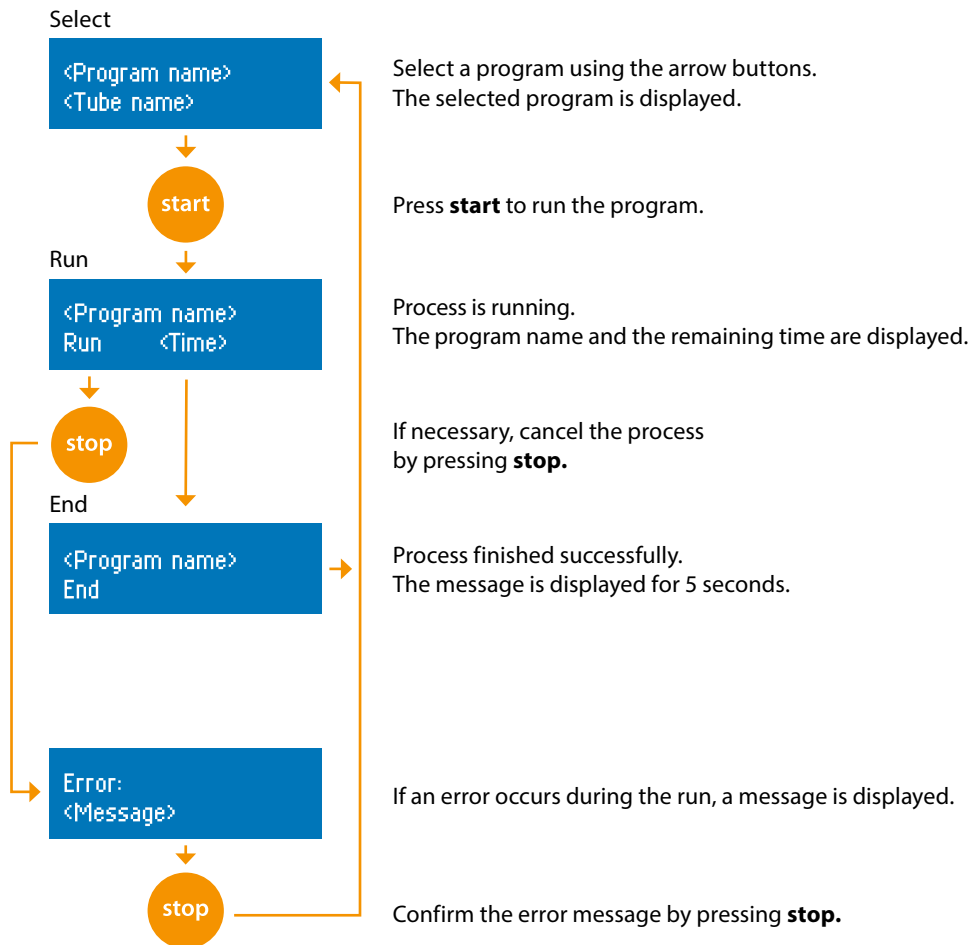
Power on

gentleMACS V1.xx Miltenyi Biotec	Display during initialization.
<Program name> <Tube name>	After initialization, the green LED is on and the gentleMACS Dissociator is ready for operation.

Select and run a program

To select a program from the internal gentleMACS Dissociator memory, press the menu button until the select menu is displayed. If the gentleMACS Program Card is inserted, only the programs from this card are available.

To select programs from the gentleMACS Dissociator memory, remove the gentleMACS Program Card. To copy programs from the gentleMACS Program Card to the gentleMACS Dissociator memory, see the section Copy a program.



Copy a program

To copy a program from the gentleMACS Program Card to the gentleMACS Dissociator memory, insert the gentleMACS Program Card. Press the menu button until the copy menu is displayed. If the gentleMACS Program Card is not inserted, a program from the gentleMACS Dissociator memory will be selected.

Select source

Copy card
<Program name>



ok



Remove card



Select destination

Destination <...>
<Program name>



ok

menu



Confirm

Destination <...>
Overwrite ?



ok

menu



Copying

Copy done



Error:
<Message>



stop

Select the desired program from the gentleMACS Program Card using the arrow buttons. If a program is copied within the internal memory, "Copy memory" is displayed instead of "Copy card".

Press **ok**.

Remove the gentleMACS Program Card.

Select the destination on the gentleMACS Dissociator memory using the arrow buttons. If there is already a program stored at the selected destination, the name of this program is displayed. If the destination is empty, the line remains blank.

Press **ok** to store the program or press **menu** to cancel and select a different program.

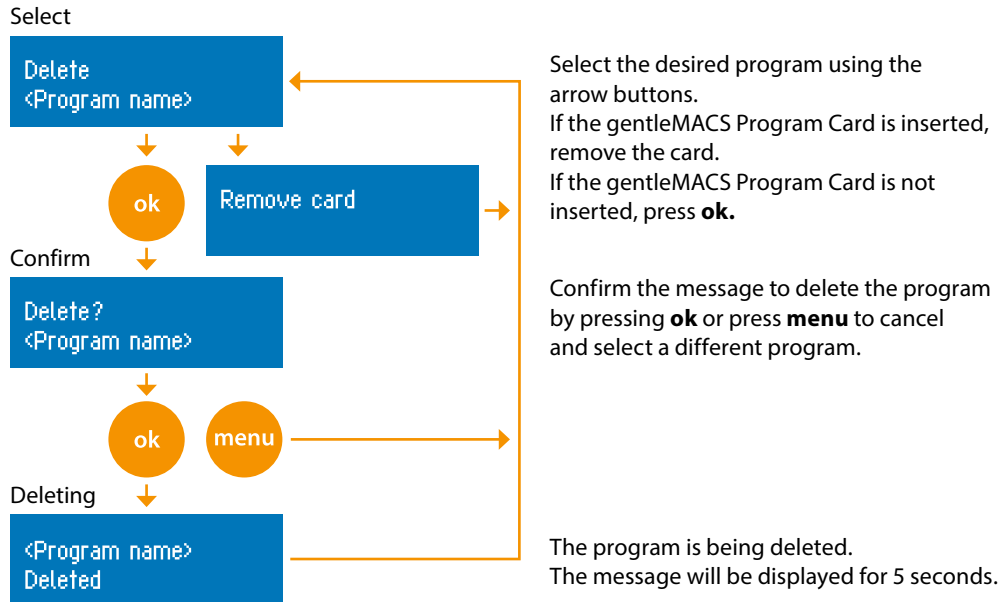
If there is already a program stored at the selected destination, confirm "overwrite?" by pressing **ok** or cancel by pressing **menu**.

The program is being copied.

If an error occurs, confirm the error message by pressing **stop**.

Delete a program

To delete a program from the gentleMACS Dissociator memory, press the menu button until the delete menu is displayed.



Emergency shutdown procedure

1. Press the **stop** button.
2. Press the mains switch at the back panel of the instrument.
3. Unplug the instrument.

7 Performance and limitations of use

- A maximum of 99 programs can be stored on the internal gentleMACS Dissociator memory.
- Editing programs on the gentleMACS Dissociator is not possible.
- If an error occurs, the gentleMACS Dissociator displays a message that needs to be confirmed by the operator. Press the **stop** button in order to continue operation.
- Both motors run at the same time, theoretically at identical speed and acceleration. However, the friction and resistance of the sample will decrease the effective speed. The gentleMACS Dissociator will display an error message if a pre-set tolerance has been exceeded during the process.
- If one of the motors is blocked due to high resistance of the sample in the tube, the instrument will try four times to get started again. The message "Error: Motor 1 / 2 blocked" appears and the red LED flashes. The operator must confirm the incident by pressing the **stop** button.
- If a motor blockage can be resolved, the gentleMACS Dissociator continues the procedure from where it was interrupted. The message "Warning: x Retries" appears for 5 seconds during the incident and disappears automatically.
- If a motor blockage cannot be resolved, the power of the motor is turned off.

Cleaning

In case of spillage or contamination, clean the instrument appropriately. For decontamination, use 70% ethanol or a 1% hypochlorite solution.

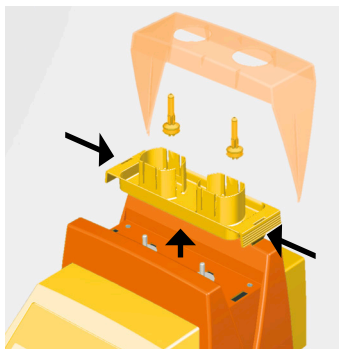


- Do not allow fluids or objects to enter the interior of the gentleMACS Dissociator.
- Make sure to clean the instrument exclusively with cleaning agents recommended by Miltenyi Biotec. Do not use acetone or any aggressive agents.
- Do not leave Tubes attached to the instrument while it is not in use.
- When processing infectious, radioactive, poisonous, or any other hazardous liquids, always abide by the necessary safety precautions.
- Before using organic solvents or aggressive chemicals in the dissociation or homogenization process, the compatibility with the gentleMACS Dissociator parts and Tubes must be tested.
- Large amounts of accidentally spilled liquid are automatically collected in the gentleMACS Trough. Use a pipette to aspirate the liquid before removing the Trough for cleaning and sterilizing.
- If servicing of the gentleMACS Dissociator is required, send the instrument back to a service provider authorized by Miltenyi Biotec. Make sure that all parts are decontaminated and sterilized. Use the original packaging material.
- Always use your personal safety equipment while removing or disassembling parts of the gentleMACS Dissociator for cleaning or sterilization.

Cleaning procedure

For details on disassembly and reassembly, see the picture below.

1. Remove the Safety Shield.
2. Remove the Sleeves from the instrument for cleaning and/or sterilization.
3. Remove the Trough for cleaning and/or sterilization.
4. The remaining surface of the gentleMACS Dissociator should be cleaned with a cloth soaked with a detergent-containing aqueous solution. Carefully wipe all parts.
5. Repeat the procedure with another cloth soaked with distilled water.
6. If the homogenized substances are not water-soluble, it is recommended to wipe all parts with ethanol or an alternative organic solvent. Contact Miltenyi Biotec technical support for further advice.
7. The removed parts should be washed in a laboratory dishwasher. It is recommended to use a cleaning agent containing detergent and alkaline cleaning solution.
8. If necessary, exchange the Sleeves and the Trough.
9. Reassemble the parts and make sure that the removed parts snap into position to ensure the correct positioning.



Disassembly for cleaning and reassembly

- Safety Shield, Sleeves, and Trough are removed by pulling precisely vertically with a slight force.
- The Trough can be detached easily by slightly pressing the rippled sides.
- Do not use any tools to detach the described parts.
- Reassemble the parts in reverse order.
- Correct assembly of all parts can be sensed by a slight snap as the part slips into its final position.

The gentleMACS Dissociator and the removable parts must be cleaned as described above. The lifetime of the Sleeves might be limited due to the mechanical strain during the homogenization procedure. Periodically, check the parts for wear.

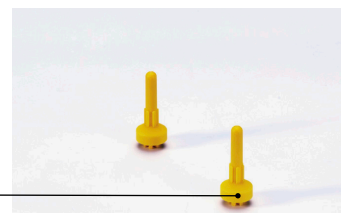
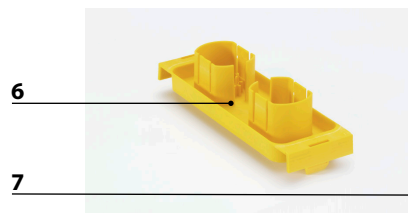
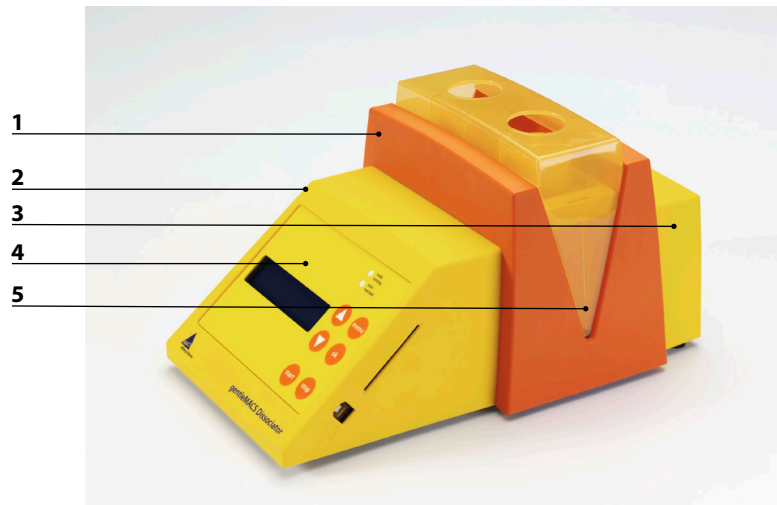


Decontamination is within the responsibility of the operator of the instrument. Contaminated instruments or removable parts must not be given to any person.

After detachment and reassembly of any removable part, it is necessary to check that the part still functions properly.

Applied materials

- 1 Housing middle part: PA 66/6 (with 30% glass fibers)
- 2 Housing front part: PA 66/6 (with 30% glass fibers)
- 3 Housing rear part: PA 66/6 (with 30% glass fibers)
- 4 Keyboard: Polyester film
- 5 gentleMACS Safety Shield: PP
- 6 gentleMACS Trough: PA 66/6 (with 30% glass fibers)
- 7 gentleMACS Sleeve: PA 66/6 (with 30% glass fibers)



Internal quality control

During the lifetime of the instrument no calibration is necessary. To check the quality of the instrument, the gentleMACS Dissociator must be sent to Miltenyi Biotec.

Disposal information



The gentleMACS Dissociator shall be disposed of according to the biosafety level of its use. Potentially contaminated parts must be sterilized before being disposed of, according to local laboratory regulations.

Decontamination is within 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.



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 of your unwanted electrical and electronic equipment according to the applicable WEEE and hazardous waste disposal legislation, you are helping to preserve our natural resources and protect human health.

Miltenyi Biotec is committed to protecting the environment. Miltenyi Biotec offers product end-of-life return programs in many countries, and partners with licensed WEEE compliance schemes throughout the world. Miltenyi Biotec 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.

Error	Source of error	User action
Liquid droplets in Trough	Tube is not closed properly.	Close Tube tightly beyond the first resistance.
	Content of Tube is jammed between cap and Tube.	The top area of cap and Tube must be perfectly clean for proper functionality of the seal.
	Tube seal is leaky.	Replace Tube. Clean the instrument as described in chapter 8.
Tube vibrates during run	Sleeve is not installed correctly.	Ensure correct installation of the Sleeve. Make sure that the Sleeve snaps into position.
	Inappropriate sample material.	Refer to the respective datasheet for technical specifications of the gentleMACS Tubes.
Tube is not tightly held in position during run	Tube does not fit properly into the snap-fit of the Trough.	Ensure correct installation of the Tube.
	Tube is not closed properly.	Close Tube tightly beyond the first resistance.
gentleMACS Dissociator is without power	Power cord is not connected.	Check power cord.
	Instrument is not switched on.	Check mains switch at the rear panel of the instrument.
	Fuse is blown.	Check fuses at the rear panel of the instrument. Replace fuses only with those of the same type and rating.
gentleMACS Dissociator does not read the Program Card	Dust deposit on Program Card, or Program Card is damaged.	Check Program Card.

If any of the problems persist, please contact Miltenyi Biotec technical support.

10 Technical specifications

Technical specifications		
Size	Length × Width × Height	347 mm × 215 mm × 195 mm
Weight		4.7 kg
Main power	Power consumption	max. 320 VA
	Supply voltage	100–240 V~, 50/60 Hz
	Fuse	2× T4AH250V
Motor	Rotational speed	200–4,000 rpm
	Rotation	clockwise or counter clockwise
	Rotational acceleration	100 r/s ²
	Torque	minimum 150 mNm. Overload restriction over the range of 200–4,000 rpm
Conditions of operation	Working temperature:	+4 °C to +35 °C
	Humidity	15–80 %, relative, non-condensing
	Altitude	maximum 2000 m
	Storage temperature	–15 °C to +70 °C
USB interface	For service purposes only	Pin 1: USB +5 V Pin 2: USB – Pin 3: USB + Pin 4: USB GND

The gentleMACS Dissociator is labeled as a protection class I device and must be plugged into a grounded power outlet.

Supply voltage fluctuations up to +/- 10% of the nominal voltage.
Transient overvoltages present on the mains supply: category II.
The instrument is suitable for rated pollution degree 2.
Emission sound pressure level at workstation < 70 dB(A).
Design and specifications are subject to change without notice.

The gentleMACS Dissociator is designed to meet the requirements of the following standard:

- FCC 47 CFR Ch.1 part 15, class B (electromagnetic compatibility)

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

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

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

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

Miltenyi Biotec shall have no obligation to make repairs, replacements or corrections to the product or any component thereof required, in whole or in part, as the result of (i) normal wear and tear, (ii) improper handling, installation, operation, storage, service, maintenance or repair, (iii) failure to follow the instructions, cautions, warnings, and notes set forth in the product documentation provided with the product or provided by Miltenyi Biotec from time to time, (iv) abnormal use, misuse, neglect, abuse, mishandling, misapplication, modification or alteration of the product, (v) use of the product in a manner for which it was not designed, (vi) causes external to the product such as, but not limited to, power failure or electrical power surges, (vii) use of the product in combination with equipment, accessories, consumables or software not supplied or approved

by Miltenyi Biotec, or (viii) accident, disaster or acts of God. ANY INSTALLATION, MAINTENANCE, REPAIR, SERVICE OR ALTERATION TO OR OF, OR OTHER TAMPERING WITH, THE PRODUCT PERFORMED BY ANY PERSON OR ENTITY OTHER THAN MILTENYI BIOTEC AUTHORIZED PERSONNEL WITHOUT MILTENYI BIOTEC'S PRIOR WRITTEN APPROVAL, OR ANY USE OF REPLACEMENT PARTS NOT SUPPLIED BY MILTENYI BIOTEC, SHALL IMMEDIATELY VOID AND CANCEL ALL WARRANTIES WITH RESPECT TO THE AFFECTED PRODUCT.

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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.

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

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technicalsupport@miltenyi.com

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

13 EC Declaration of conformity

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

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

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

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

Description: Laboratory equipment
Model: gentleMACS Dissociator

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

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

The machinery is in conformity with the following harmonized standards:

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

Person authorized to compile the relevant technical documentation:

Dr. Bernd Schröder
Global Head Regulatory Affairs
Miltenyi Biotec B.V. & Co. KG
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51429 Bergisch Gladbach
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This declaration of conformity is issued under the sole responsibility of the manufacturer:

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51429 Bergisch Gladbach
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This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

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

Description: Laboratory equipment
Model: gentleMACS Dissociator

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

Person authorized to compile the relevant technical documentation:

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