Miltenyi Biotec

autoMACS® Pro Separator

User manual

Version 3

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Version 3

Content

Thank you for choosing a Miltenyi Biotec product.

The autoMACS® Pro Separator is an innovative instrument for automated sensor-controlled multisample labeling and separation of various cells types. At the touch of a button, target cells are magnetically labeled, separated, and eluted in a fully automated fashion.

Purify and progress.

Important information

1

Please read before use!

Please read all information contained in this user manual before use. Failure to read and follow these guidelines could lead to improper or incorrect use, handling or care of your instrument and could cause hazards to users, unpredictable results, instrument malfunction or damage, premature wear and reduced life time of the instrument, and may void your warranty.

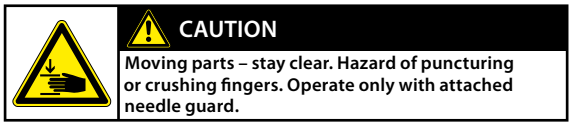
Keep this user manual in a safe place, accessible for anyone using the autoMACS Pro Separator.

This chapter describes the safety instructions and site requirements for your autoMACS Pro Separator. The following warnings and cautions are provided to help you prevent injury to yourself or damage to the instrument.

1.1 Symbols and hazard levels

Setup of safety notices

Example



The safety notices inform the user about potential risks if warnings and precautions outlined below are not followed. The icon on the left side specifies the risk. The hazard level at the top classifies the hazard, as mentioned above. The level, type, and source of the hazard as well as potential consequences, prohibitions, and measures are pointed as follows.

Symbols and hazard levels

The following chart is an illustrated glossary depicting the symbols that are used in this user manual and on the autoMACS Pro Separator.

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

CAUTION CAUTION indicates a potentially hazardous situation, which, if not avoided, could result in minor or moderate injury.

Attention, consult the user manual for further instructions and proceed with caution. Warnings include the risk of damage to the equipment, severe personal injury, or loss of life.

Hazard of crushing and shearing. Risk of crushing and shearing of bodily parts due to mechanical hazards.

Laser radiation. Risk of serious eye and skin injuries.

Strong magnetic field. The magnetic field can interfere with magnetizable objects and electronic devices or damage magnetic information carriers. Risk of severe personal injury to persons carrying pacemakers or electronic medical implants.

Risk of contamination if biohazardous material is used. Indicates the risk of death, severe injury to the instrument operator, or equipment damage due to potentially dangerous biological material.

Indicates the risk of death or severe injury to the instrument operator due to hazardous voltage.

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

ON (supply)

OFF (supply)

Documentation needs to be consulted before proceeding with installation and operation of the system.

1.2 Warnings and precautions

The autoMACS Pro Separator employs state-of-the-art technology. It is a computer-controlled instrument for the automated separation of magnetically labeled cells using MACS® Technology. The MACS MiniSampler connects to the autoMACS Pro Separator and thus represents a part of the cell separation instrument. The autoMACS Pro Separator and the MACS MiniSampler are designed to operate safely after installation and when used by trained personnel according to general safety practices and the instructions set forth in this user manual. The guidelines in this section explain the potential risks associated with the operation of the instrument and provide important safety information in order to minimize these risks.
By carefully following the instructions, you can protect yourself and the equipment from potential hazards and create a safe work environment. If this instrument is used in a manner not specified by the manufacturer, protection may be impaired.

IMPORTANT! Please read and follow all operating instructions in this user manual and pay attention to all warnings displayed on the instrument. Retain this user manual and any other safety and operating instructions provided with the instrument in a place accessible to all users for future reference.

IMPORTANT! The autoMACS Pro Separator is intended for indoor use only. Do not use the instrument in areas classified as hazardous locations such as oxygen-laden environments.

At all times, local working area safety instructions, laboratory policies, and standards regarding laboratory health and safety and prevention of accidents must be adhered to. Contact your local authority governing electrical power supply, building constructions, maintenance, or safety for more information regarding the installation of the equipment.

If you have a serious concern regarding the safe use of your insrument, please contact your authorized Miltenyi Biotec service provider or call Miltenyi Biotec Customer Service.

1.3 General precautions

To reduce potential risks associated with operating the autoMACS Pro Separator, please observe the following general precautions. Failure to observe these precautions could result in fire, bodily harm, and/or damage to the instrument.

1.3.1 Hazard of electric shock and spread of fire

WARNING

Hazardous voltages. Risk of loss of live severe personal injury. Unplug before cleaning. Do not use
- if device is opened or damaged,
- if liquids have been spilled into device,
- if objects device through ventilation slots.

WARNING! Electrical devices pose the risk of an electric shock. To reduce the risk of an electric shock, do not open any cover other than the front access covers of the autoMACS Pro Separator nor any other accessory hardware supplied by Miltenyi Biotec. All other covers of the instrument and accessory hardware are to be removed by authorized personnel only. Special care must be taken while handling fluids. Clean up spillages immediately. Do not allow fluids to enter the interior of the instrument. Unplug the power cord before manually cleaning the autoMACS Pro Separator.

WARNING! A potential risk exists if an opened, dropped, or damaged autoMACS Pro Separator is used, if liquids are spilled into the instrument, if an object has entered the instrument through the ventilation slots, or if an object has been dropped into the instrument. If flames or smoke appear immediately switch OFF the autoMACS Pro Separator, unplug the instrument from the electrical outlet, and contact an authorized Miltenyi Biotec service provider or the Miltenyi Biotec Customer Support team. Use of a damaged instrument or an instrument with a damaged power cable is expressly prohibited.

1.3.2 Strong magnetic field

WARNING

Extremely strong magnetic fields. Risk of severe personal injury to persons carrying pacemakers or electronical medical implants – stay clear. Keep all magnetically sensitive objects away from device.

WARNING! The autoMACS Pro Separator is equipped with an extremely powerful magnet. Keep any magnetic information carriers (such as credit cards, magnetic tapes and floppy disks), any electronic equipment (such as hearing aids, pacemakers, measuring and control instruments, computers, and watches), and magnetizable tools and objects at a distance of at least 20 cm from the magnet cover. These items may be affected or damaged by the magnetic field.

Figure 1.1: Location of warning sign for strong permanent magnet.

1.3.3 Hazard of crushing and shearing

CAUTION

Moving parts – stay clear. Hazard of puncturing or crushing fingers. Operate only with attached needle guard.

CAUTION! Do not open the front access covers while the instrument is in operation. Do not obstruct the movement of the automated arm and accessory hardware during operation. Keep fingers etc. away from all moving parts of the autoMACS Pro Separator and accessory hardware, to avoid crushing or shearing injuries, or damage to the instrument. Do not touch fluid pumps or adjust the tubing, while the instrument is in operation. Always switch OFF the instrument before adjusting any part of the fluidic system. Always stop or abort a procedure before handling accessory hardware, e.g., MACS MiniSampler, or loading/removing tubes from the tube rack placed on the sampler. Do not circumvent any safety measures or devices.

Figure 1.2: Open circle shows warning sign for hazard of crushing and shearing.

1.3.4 Laser radiation

WARNING! The instrument is equipped with four vertical cavity surface emitting lasers (VCSELs) for automated rack detection (Class 1M). The radiation is not visible. Do not view directly with optical instruments (e.g. lenses, magnifying glasses, and microscopes). Viewing the VCSEL port within 100 mm distance with optical instruments could be hazardous to the eye.

The instrument is also equipped with a 2D Code Reader which uses a visible semiconductor laser as a target pointer for adjusting the reading position and powerful light emitting diodes (LEDs) for illuminating the reading area.

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.

Do not look directly at laser or LED radiation or reflected laser or LED radiation from a mirrored surface. Otherwise, eye injury may result. Do not intentionally direct the laser beam at others.

Do not disassemble, modify or remove the installed laser or LED radiation sources or their mounting rackets. The laser or LED radiation sources do not automatically stop emitting when disassembled.

Radiation of disassembled units may lead to eye injuries.

Be careful of the path of the laser beam or reflection from a mirrored surface. Take care during installation of the autoMACS Pro Separator that the path of the laser beam is not at the same height as that of the human eye during operation.

Do not allow water, oil, dust, or other foreign substances to stick to 2D Code Reader aperture window. This may cause read errors. Be sure to stop the laser emission before cleaning the scanner. Otherwise, exposure to the laser may cause eye injury. Use a soft, dry cloth to wipe any substances from the scanner. Do not use alcohol or other cleaning substance.

The autoMACS Pro Separator is classified as a Class 1M laser product per standard IEC 60825-1:1993+A1:1997+A2:2001.

CAUTION! Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

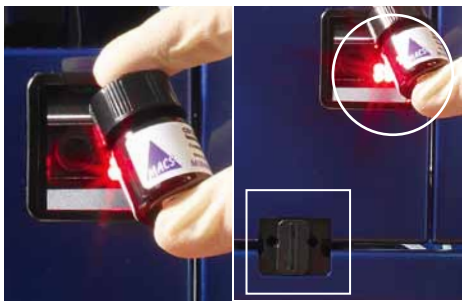


Figure 1.3: Position of lasers. Invisible rack detection lasers are located within the rectangle area. The 2D code reader (visible) is located within the open circle.

1.4 Secure installation

This section describes the requirements your site must meet for safe installation and operation of your autoMACS Pro Separator. Read the instructions in this section and ensure that your site is properly prepared before you connect the instrument to its power source. When planning your site layout and equipment locations, keep in mind the precautions described in this section to help avoid instrument failures and reduce the possibility of environmentally caused shutdowns.

1.4.1 Mounting accessories

Do not place the autoMACS Pro Separator 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 or sold with the instrument. Do not place the autoMACS Pro Separator within a built-in apparatus or a confined space such as a shelf rack unless the apparatus has been specifically designed to accommodate the instrument, proper ventilation is provided, and the mounting instructions for the instrument have been followed.

1.4.2 Air circulation

The instrument should not be placed next to radiators, heat registers, stoves, or other pieces of equipment (including amplifiers) that produce heat. Allow sufficient air circulation around the autoMACS Pro Separator – at least 15 cm on all sides – during operation to ensure adequate cooling of the instrument. Prevent direct exposure of the instrument to sunlight. Slots and openings of the instrument are provided for ventilation and should never be blocked or covered, as these ensure reliable operation of the autoMACS Pro Separator and protect the instrument from overheating. Never push a foreign object through an opening into the instrument.

1.4.3 Water and moisture

Do not use the instrument in a wet or damp location. Avoid high humidity or condensation and protect the machine against water splashes.

1.4.4 Grounded (earthed) product

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.

1.4.5 Power sources

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. Do not use extension cords or power strips. Do not overload an electrical outlet. The overall system load must not exceed 80% of the branch circuit rating.

1.4.6 Accessibility

Make sure that the main 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.

1.4.7 Peripheral devices

Only peripheral devices that comply to UL 60950 are allowed to be connected to the RS232 connector labeled "COM". The connector labeled "RS232/AUX" is not in use. In addition, only original autoMACS Pro equipment should be attached to the connectors labeled "External CAN", "CAN1", and "CAN2". The voltage levels on these connectors shall not exceed hazardous voltage levels of 30 V RMS. and 42.4 V peak or 60 Vdc. Only the autoMACS Pro Bottle Sensor Cable should be attached to the "Bottle Sensor" connector.

Only a 2D code reader recommended by Miltenyi Biotec should be connected to the "RS232/BCR" connector. External laser devices connected to the connector labeled "RS232/BCR" have to comply with the standard IEC 60825-1. Only use connector cables less than 3 m in length.

1.5 Secure operation, maintenance, transport, and disposal

Observe the following instructions to ensure secure operation, maintenance, transport, and disposal of your autoMACS Pro Separator.

1.5.1 Safe operation

If the instrument is not working properly and instructions or messages on the display screen advise to contact technical service, secure operation is no longer possible. Immediately switch OFF the autoMACS Pro Separator, unplug the instrument from the electrical outlet, and contact an authorized Miltenyi Biotec service provider or the Miltenyi Biotec Customer Support team.

1.5.2 Servicing

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

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

IMPORTANT! When replacement or spare parts are required, make sure that the service provider uses only genuine Miltenyi Biotec parts or third-party parts specified and recommended by Miltenyi Biotec. Using unauthorized replacement or spare parts can cause malfunction of the instrument and impair cell separation results. Miltenyi Biotec does not honor any warranty or accept any responsibility for instrument failure or damages resulting from the use of inappropriate replacement or spare parts. After completing any service or repair work, have your authorized Miltenyi Biotec service provider perform all safety checks required by the repair procedure to ensure that the instrument is in proper operational condition.

Only use options and upgrades recommended by Miltenyi Biotec.

1.5.3 Cleaning

Unplug the autoMACS Pro Separator from the outlet before cleaning. Do not use liquid or aerosol cleaning agents; always use a damp cloth.

1.5.4 Hazardous material

WARNING

Risk of loss of life if biohazardous material is used. Wear protective gloves, protective clothing, and safety glasses to prevent contact with skin and eyes. Operate device in a safety hood. Decontaminate device after spilling of biohazardous material.

If biohazardous material has been used, the operator shall choose and wear personal safety equipment in accordance with warnings and precautions for the used substances. Wear protective gloves, protective clothing, and safety glasses to prevent contact with skin and eyes. Also protect mouth and nose as aerosols might leak from the system. Defective or inadequate safety equipment might endanger the operator. The autoMACS Pro Separator shall be operated in a safety hood if hazardous or unknown materials are processed. If hazardous material has been used or spilled, care must been taken to thoroughly decontaminate the system. For details, refer to section 7.3.4.

Always inspect the fluidic system (complete tubing set, bottles and their closures, valves, columns, diluter, and needles) before switching ON the instrument. If leakage has been detected, replace all damaged parts before switching ON the instrument. If damaged parts cannot be replaced, unplug and do not use the instrument. Failure of parts containing biohazardous material or liquids that have been in contact with such material could cause a hazard.

Columns, tubes, and any other consumables that were in contact with biohazardous samples shall be autoclaved prior to disposal. Liquid waste shall be autoclaved or decontaminated using a disinfectant that is appropriate for the specific pathogen, e.g. 10% bleach, isopropyl alcohol, or 70% ethanol.

Waste disposal must be in accordance with any local regulations.

Figure 1.4: Warning signs for biohazard located on lower facing panel of the autoMACS Pro Separator (left) and on top of autoMACS Pro Separator fluid bottle (right).

Flammable

70% ethanol is used in Sleep and Store programs. The solvent is flammable. Therefore, keep the instrument away from fire.

1.5.5 Transport

The autoMACS Pro Separator should be transported with care in packaging specified by Miltenyi Biotec. Internal damage can occur, if it is subjected to excessive vibration or if it is dropped. If the instrument needs to be shipped back to the manufacturer for service, decontaminate the instrument from any hazardous material prior to shipment. If you have questions regarding proper decontamination or shipment, please contact Technical Support for assistance. Refer to section 7.3.4 for further information on instrument decontamination.

1.5.6 Instrument disposal

Please contact Technical Support for assistance if you wish to dispose of your instrument.

Informations importantes

1

À lire avant utilisation.

Veuillez impérativement lire toutes les informations fournies dans ce mode d'emploi avant d'utiliser l'appareil. Le non-respect de ces consignes peut donner lieu à une utilisation, une manipulation et une maintenance inappropriée ou incorrecte de votre appareil, ce qui pourrait mettre en danger les utilisateurs, fournir des résultats non attendus, entraîner le dysfonctionnement ou la détérioration de l'appareil, son usure prématurée et réduire la durée de vie de l'appareil, ainsi qu'annuler votre garantie.

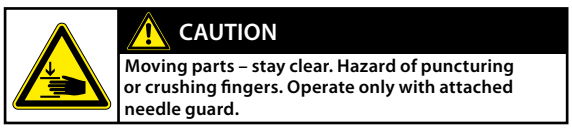
Conservez ce mode d'emploi dans un endroit sûr et accessible aux utilisateurs de l'unité de séparation autoMACS Pro® (séparateur autoMACS Pro).

Ce chapitre décrit les consignes de sécurité et les exigences d'installation s'appliquant à votre séparateur autoMACS Pro. Les avertissements et les mesures de précaution suivantes ont pour objectif de vous aider à éviter toute blessure corporelle ainsi que toute détérioration de l'appareil.

1.1 Symboles et niveaux de danger

Mise en place des consignes de sécurité

Example



Les consignes de sécurité informent l'utilisateur des risques potentiels pouvant survenir si les avertissements et les mesures de précaution décrits ci-dessous ne sont pas respectés. Le pictogramme visible à gauche définit le risque. En haut, le danger mentionné précédemment est affecté à un niveau de danger. Le niveau, le type et la source du danger ainsi que les éventuelles conséquences, les interdictions et les mesures à prendre sont mentionnés conformément au tableau ci-dessous.

Symboles et niveaux de danger

Le tableau suivant est un glossaire illustré expliquant les symboles utilisés dans ce mode d'emploi et sur le séparateur autoMACS Pro Separator.

WARNING AVERTISSEMENT indique une situation dangereuse qui, si elle n'est pas évitée, peut entraîner la mort ou des blessures graves.

CAUTION ATTENTION indique une situation dangereuse qui, si elle n'est pas évitée, peut entraîner des blessures mineures ou modérées.

Attention, consultez le mode d'emploi pour obtenir plus de consignes et agissez avec prudence. Les avertissements incluent le risque de détérioration de l'équipement, de blessure corporelle grave et le danger de mort.

Risque d'écrasement et de cisaillement. Risque d'écrasement et de cisaillement des membres corporels dû à des dangers mécaniques.

Rayonnement laser. Danger de graves lésions oculaires et cutanées.

Champ magnétique puissant. Le champ magnétique interfère avec les objets magnétisables et les appareils électroniques ou endommage les supports d'information magnétiques. Risque de grave blessure corporelle pour les personnes portant un pacemaker ou des implants médicaux électroniques.

Risque de contamination en cas d'utilisation de matières nocives pour l'organisme. Indique le danger de mort, le risque de blessure grave pour l'opérateur de l'appareil ou le risque de détérioration de l'équipement dû à des matières biologiques potentiellement dangereuses.

Indique le danger de mort, le risque de blessure grave pour l'opérateur de l'appareil en raison de la tension dangereuse.

Borne pour conducteur de protection. Le symbole est apposé à l'intérieur de l'équipement. Avertissement destiné au personnel de maintenance.

Alimentation électrique activée

Alimentation électrique désactivée

La notice d'utilisation doit être consultée avant de procéder à l'installation et à l'utilisation du système

1.2 Avertissements et précautions

Le séparateur autoMACS Pro fonctionne avec une technologie de pointe. Il s'agit d'un appareil commandé par ordinateur conçu pour la séparation automatique des cellules à marquage magnétique à l'aide de la technologie MACS®. Le mini-échantillonneur MACS est branché au séparateur autoMACS Pro et fait donc partie du dispositif de séparation des cellules. Le séparateur autoMACS Pro et le mini-échantillonneur MACS sont conçus pour fonctionner en toute sécurité après leur installation s'ils sont utilisés par des personnes qualifiées selon les pratiques de sécurité générales et les consignes mentionnées dans ce mode d'emploi. Les instructions de ce chapitre expliquent les risques potentiels liés à l'utilisation de l'appareil et fournissent des informations de sécurité importantes afin de réduire ces risques. Respectez strictement ces consignes pour protéger l'équipement et vous-même des risques potentiels et créer un environnement de travail sûr. La protection n'est pas garantie si cet appareil n'est pas utilisé conformément aux instructions données par le fabricant.

IMPORTANT! Veuillez lire et respecter toutes les instructions d'utilisation fournies dans ce mode d'emploi et observez tous les avertissements affichés sur l'appareil. Conservez ce mode d'emploi et les autres consignes de sécurité et d'utilisation fournies avec l'appareil à un endroit accessible pour tous les utilisateurs en vue de les consulter ultérieurement.

IMPORTANT! Le séparateur autoMACS Pro Separator est destiné à une utilisation intérieure uniquement. N'utilisez pas l'appareil dans des zones classées dangereuses telles que des environnements à teneur élevée en oxygène.

Les consignes de sécurité concernant la zone de travail locale, les bonnes pratiques de laboratoire, ainsi que les directives relatives à la santé, à la sécurité et à la prévention des accidents en laboratoire doivent être observées en permanence. Pour de plus amples d'informations concernant l'installation de l'équipement, veuillez vous adresser à votre organisme local responsable de l'approvisionnement en électricité, des travaux de bâtiment, de la maintenance et de la sécurité.

Si vous avez un doute sérieux quant à la sécurité d'utilisation de votre appareil, veuillez contacter votre prestataire de services Miltenyi Biotec agréé ou appelez le service après-vente de Miltenyi Biotec.

1.3 Précautions d'ordre général

Afin de réduire les risques potentiels liés à l'utilisation du séparateur autoMACS Pro Separator, veuillez observer les précautions générales suivantes. La non-observation de ces précautions peut provoquer un incendie, des dommages corporels, et/ou détériorer l'appareil.

1.3.1 Risque d'électrocution et de propagation de feu

WARNING

Hazardous voltages. Risk of loss of live severe personal injury. Unplug before cleaning. Do not use
- if device is opened or damaged,
- if liquids have been spilled into device,
- if objects device through ventilation slots.

AVERTISSEMENT! Les appareils électriques présentent un risque d'électrocution. Afin de réduire le risque d'électrocution, n'ouvrez aucun cache du séparateur autoMACS Pro Separator, ni d'autres équipements accessoires fournis par Miltenyi Biotec. Tous les caches de l'appareil et des équipements accessoires doivent être démontés par le personnel agréé uniquement. Soyez particulièrement prudent pendant la manipulation de fluides. Nettoyez immédiatement si des liquides se sont déversés. Veillez à ce que les fluides ne s'infiltrent pas à l'intérieur de l'appareil. Débranchez le câble électrique avant de nettoyer manuellement le séparateur autoMACS Pro Separator.

AVERTISSEMENT! Un risque potentiel existe si le séparateur autoMACS Pro Separator utilisé est ouvert, déformé ou endommagé, si des liquides se déversent dans l'appareil, si un objet est entré dans l'appareil par les fentes de ventilation ou si un objet a chuté dans l'appareil. En cas d'apparition de flammes ou de fumée, déconnectez immédiatement le séparateur autoMACS Pro Separator, débranchez l'appareil et contactez un prestataire de services Miltenyi Biotec agréé ou l'équipe de support technique de Miltenyi Biotec. Il est formellement interdit d'utiliser un appareil endommagé ou un appareil dont le câble électrique est endommagé.

1.3.2 Champ magnétique puissant

WARNING

Extremely strong magnetic fields. Risk of severe personal injury to persons carrying pacemakers or electronical medical implants – stay clear. Keep all magnetically sensitive objects away from device.

AVERTISSEMENT! Le séparateur autoMACS Pro est équipé d'un aimant extrêmement puissant. Veillez à laisser un espace d'au moins 20 cm entre le cache de l'aimant et les supports 'information magnétiques (cartes de crédit, bandes magnétiques et supports de données) ainsi que l'équipement électronique (appareils auditifs, pacemakers, dispositifs de mesure et de contrôle, ordinateurs et

montres). Ces éléments peuvent être affectés ou endommagés par le champ magnétique.distance d'au moins 30 cm par rapport au matériel magnétique mentionné ci-dessus. Plus ils sont proches l'un de l'autre, plus la force attractive entre les deux aimants ou entre un aimant et une matière magnétisable augmente. Par conséquent, n'approchez aucune matière magnétique – y compris tout autre aimant ou écran.

Figure 1.1: Symbole d'avertissement pour aimant puissant permanent.

1.3.3 Risque d'écrasement et de cisaillement

CAUTION

Moving parts – stay clear. Hazard of puncturing or crushing fingers. Operate only with attached needle guard.

AVERTISSEMENT! N'ouvrez pas les capots frontaux pendant le fonctionnement de l'appareil. Ne bloquez pas le mouvement du bras automatique ni des pièces correspondantes pendant le fonctionnement. N'approchez pas vos doigts, etc. des pièces mobiles du séparateur autoMACS Pro et des pièces correspondantes afin d'éviter toute blessure ainsi que toute détérioration de l'appareil due à l'écrasement et au cisaillement. Ne touchez pas les pompes à liquide et ne modifiez pas les tuyaux pendant le fonctionnement de l'appareil. Déconnectez toujours l'appareil avant de modifier une partie du système fluidique. Stoppez ou annulez toujours le processus avant de manipuler les appareils supplémentaires comme le mini-échantillonneur MACS ou de charger/retirer les éprouvettes du râtelier à éprouvettes placé sur l'échantillonneur. Ne bloquez pas les dispositifs de sécurité et respectez les mesures de sécurité.

Figure 1.2: Le symbole d'avertissement entouré d'un cercle blanc indique un risque d'écrasement et de cisaillement.

1.3.4 Rayonnement laser

AVERTISSEMENT! L'appareil est équipé pour la détection automatique de porte-éprouvettes (classe 1M) par quatre diodes laser à émission par la surface à cavité verticale (VCSEL). Le rayonnement est invisible. Ne pas regarder directement dans ce rayon au travers d'instruments optiques (p. ex. lentilles, verres grossissants et microscopes). Regarder dans l'ouverture du VCSEL à une distance inférieure à 100 mm au travers d'instruments optiques peut endommager les yeux.

L'appareil est également équipé d'un lecteur de code 2D utilisant un laser à semi-conducteur visible comme pointeur pour le réglage de la position de lecture ainsi que de diodes électroluminescentes (DEL) haute puissance pour l'éclairage du champ de lecture.

Selon la norme internationale IEC 62471 de sécurité photobiologique, ce système de LED a une valeur de risque d'exposition (EHV) de 0.91 et est au dessus du groupe de risque 0 (exempt risque). La distance de risque (HD) pour le groupe de risque 0 est de 61 cm. La distance de risque pour le groupe de risque 1 (risque faible) est de 20 cm.

Ne diriger le regard ni dans le rayon laser ou DEL direct, ni le rayon laser ou DEL réfléchi sur une surface de miroir. Sinon, des lésions oculaires peuvent en résulter. Ne pas diriger intentionnellement le rayon laser sur d'autres personnes.

Ne pas démonter, échanger ni retirer des sources de rayon laser ou DEL encastrées ni leur support. Les sources de rayon laser ou DEL ne cessent pas forcément d'émettre un rayonnement une fois démontées.

Le rayonnement d'appareils démontés peut entraîner des lésions oculaires. Prendre garde au chemin optique du rayon laser ou de sa réflexion sur une surface de miroir. Veiller lors de l'installation de l'autoMACS Pro Separator à ce que le chemin optique rayon laser ne se trouve pas à hauteur des yeux de personnes pendant le service. Eviter que de l'eau, de l'huile, de la poussière ou d'autres corps

étranger adhèrent sur la fenêtre de lecture du lecteur de code 2D, comme ceci risque d'entraîner des erreurs de lecture. S'assurer avant le nettoyage du scanner qu'aucun rayon laser n'est plus émis. La manipulation du laser risque sinon de provoquer des lésions oculaires. Utiliser un chiffon doux pour essuyer des substances sur le scanner. Ne pas utiliser d'alcool ou d'autres produits de nettoyage.

L'autoMACS Pro Separator est désigné comme produit laser de la classe 1M selon la norme CEI 60825-1: 1993 + A1: 1997 + A2: 2001.

AVERTISSEMENT! L'utilisation d'organes de commande autres wque ceux mentionnés dans ce document ainsi que toute adaptation ou utilisation d'autres procédés que ceux mentionnés dans ce document peuvent dégager des rayonnements dangereux.

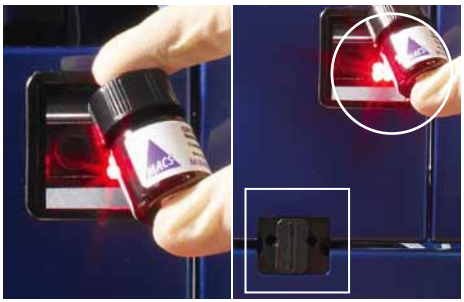


Figure 1.3: Position des lasers. Les lasers invisibles de détection de râteliers sont situés dans la zone rectangulaire. Le lecteur de code 2D (visible) est entouré d'un cercle blanc.

1.4 Sécurité de l'installation

Ce paragraphe décrit les exigences auxquelles votre site doit répondre pour garantir l'installation et la sécurité d'utilisation de votre séparateur autoMACS Pro Separator. Lisez les consignes de ce paragraphe et assurez-vous que votre site a été aménagé en conséquence avant de brancher l'appareil à sa source électrique. Lors de la planification de l'aménagement de votre site et de l'emplacement de l'équipement, tenez compte des précautions décrites dans ce paragraphe afin d'éviter que l'appareil ne tombe en panne et de réduire le nombre d'arrêts pouvant être causés par l'environnement de l'appareil.

1.4.1 Accessoires de montage

Ne placez pas le séparateur autoMACS Pro Separator sur une table, un chariot, un pied, un trépied ou un support. L'appareil pourrait sinon chuter, provoquant des blessures corporelles graves et/ou la détérioration considérable l'appareil. Utilisez le séparateur uniquement sur une table, un chariot, un pied, un trépied ou un support recommandé par Miltenyi Biotec ou vendu avec l'appareil. Ne placez pas le séparateur autoMACS Pro Separator dans un appareil intégré ou un espace restreint comme un casier, sauf si le dispositif a été spécialement conçu pour accueillir l'appareil, qu'une ventilation appropriée est garantie et que les instructions de montage relatives à l'appareil ont été respectées.

1.4.2 Circulation de l'air

Ne placez pas l'appareil à proximité de radiateurs, de registres de chaleur, de fours ou d'autres pièces d'équipement (amplificateurs) qui produisent de la chaleur. Veillez à ce que suffisamment d'air puisse circuler autour du séparateur autoMACS Pro Separator – au moins 15 cm de chaque côté – pendant le fonctionnement afin de garantir le refroidissement adéquat de l'appareil. Évitez d'exposer l'appareil à un ensoleillement direct. Les encoches et les fentes de l'appareil sont prévues pour la ventilation et ne doivent jamais être bloquées ou recouvertes, car elles assurent le fonctionnement fiable du séparateur autoMACS Pro Separator et protègent l'appareil de la surchauffe. N'introduisez jamais d'objet étranger dans l'appareil par l'une des fentes.

1.4.3 Eau et humidité

N'utilisez pas l'appareil dans un endroit humide ou mouillé. Évitez l'humidité et la condensation et protégez la machine des éclaboussures.

1.4.4 Produit relié à la terre

L'appareil est équipé d'une fiche électrique trifilaire avec mise à la terre dont la troisième borne est prévue pour relier l'appareil à la terre. Cette fiche fonctionne uniquement dans une prise de courant avec contact de mise à la terre. Il s'agit d'un dispositif de sécurité. N'essayez pas d'insérer la fiche dans une prise de courant sans contact de mise à la terre. Si vous ne pouvez pas insérer la fiche dans la prise de courant, veuillez vous adresser à votre électricien local qui remplacera la prise de courant.

1.4.5 Sources électriques

Ne faites fonctionner l'appareil qu'à partir d'une source électrique indiquée sur la plaque signalétique du produit. Si vous avez des questions sur le type de courant électrique que vous pouvez utiliser, contactez votre prestataire de services Miltenyi Biotec agréé ou votre fournisseur d'électricité local. N'utilisez pas de rallonges ni de barrettes de connexion. Ne surchargez pas la prise électrique. La charge totale du système ne doit pas dépasser 80& de la valeur nominale du circuit de dérivation.

1.4.6 Accessibilité

Assurez-vous que l'interrupteur principal et le connecteur du câble électrique soient facilement accessibles et placés aussi près que possible de l'opérateur de l'appareil. S'il s'avère nécessaire de déconnecter l'alimentation électrique, débranchez le câble.

1.4.7 Appareils périphériques

Seuls les appareils périphériques conformes à la norme UL 60950 peuvent être branchés au connecteur RS232 étiqueté «COM».
Le connecteur étiqueté «RS232/AUX» n'est pas utilisé. De plus, seuls des appareils autoMACS Pro originaux doivent être raccordés aux connecteurs étiquetés «External CAN», «CAN1» et «CAN2». Le niveau de tension mesuré sur ces connecteurs ne doit pas dépasser le niveau de tension dangereux de 30 Veff ainsi qu'un pic de 42,4 V ou 60 V DC. Seul le câble de capteur de flacon autoMACS Pro peut être raccordé au connecteur étiqueté «Bottle Sensor».
Seul un lecteur de code 2D recommandé par Miltenyi Biotec peut être branché au connecteur «RS232/BCR». Les appareils laser externes raccordés au connecteur étiqueté «RS232/BCR» doivent répondre à la norme IEC 60825-1. Utilisez uniquement des câbles de connexion de 3 mètres de longueur maximum.

1.5 Sécurité d'utilisation, maintenance, transport et élimination

Respectez les consignes suivantes afin de garantir la sécurité d'utilisation, la maintenance, le transport et l'élimination de votre séparateur autoMACS Pro Separator.

1.5.1 Sécurité d'utilisation

Si l'appareil ne fonctionne pas correctement et que les instructions ou les messages sur l'écran d'affichage conseillent de contacter le service technique, la sécurité d'utilisation de l'appareil n'est plus garantie. Déconnectez immédiatement le séparateur autoMACS Pro Separator, débranchez l'appareil et contactez un prestataire de services Miltenyi Biotec agréé ou l'équipe du service après-vente de Miltenyi Biotec.

1.5.2 Entretien et réparation

IMPORTANT! N'effectuez pas vous-même l'entretien du séparateur autoMACS Pro Separator, sauf autre consigne spécifique donnée dans ce mode d'emploi ou dans un autre document de Miltenyi Biotec. L'entretien et la réparation doivent être effectués par des réparateurs qualifiés. Tout entretien ou toute réparation inappropriée ou incorrecte de votre séparateur autoMACS Pro Separator peut mettre en danger les utilisateurs, fournir des résultats imprévisibles, entraîner le dysfonctionnement ou la détérioration de l'appareil, son usure prématurée et réduire la durée de vie de l'appareil, ainsi qu'annuler votre garantie.

Renseignez-vous auprès de votre représentant Miltenyi Biotec local sur les conditions d'entretien et de support complémentaires proposées par Miltenyi Biotec ou consultez le site www.miltenyibiotec.com/support.

IMPORTANT! Si des pièces de remplacement ou de rechange sont requises, assurez-vous que le prestataire de services utilise exclusivement des pièces Miltenyi Biotec d'origine ou des pièces de fabricants tiers spécifiées et recommandées par Miltenyi Biotec. L'utilisation de pièces de remplacement ou de rechange non autorisées peut entraîner le dysfonctionnement de l'appareil et fausser les résultats de la séparation des cellules. Miltenyi Biotec n'accorde pas de prestation de garantie ou décline toute responsabilité pour les pannes et les dommages de l'appareil résultant de l'utilisation de pièces de remplacement ou de rechange inappropriées. Une fois les travaux d'entretien ou de réparation achevés, demandez à votre prestataire de services Miltenyi Biotec agréé d'effectuer tous les contrôles de sécurité requis par la procédure de réparation afin de garantir que l'appareil est parfaitement opérationnel.

Utilisez uniquement les options et les mises à jour recommandées par Miltenyi Biotec.

1.5.3 Nettoyage

Débranchez le séparateur autoMACS Pro Separator avant le nettoyage. N'utilisez pas d'agents nettoyants liquides ou en aérosol; utilisez toujours un chiffon humide.

1.5.4 Matières dangereuses

WARNING

Risk of loss of life if biohazardous material is used. Wear protective gloves, protective clothing, and safety glasses to prevent contact with skin and eyes. Operate device in a safety hood. Decontaminate device after spilling of biohazardous material.

Si une matière nocive pour l'organisme est ou a été utilisée, l'opérateur doit choisir et porter un équipement de protection individuelle conforme aux avertissements et aux précautions pour les substances utilisées. Portez des gants de protection, des vêtements de protection et des lunettes de sécurité afin d'éviter tout contact avec la peau et les yeux. Protéger aussi la bouche et le nez des aérosols qui pourraient provenir du système. Un équipement de sécurité défectueux ou inadéquat peut mettre l'opérateur en danger. Le séparateur autoMACS Pro Separator doit être manipulé dans un couvercle de protection si des matières dangereuses ou inconnues sont traitées. Si une matière dangereuse a été utilisée ou s'est déversée, prenez les précautions appropriées pour décontaminer soigneusement le système.

Toujours vérifier le système fluidique (le jeu complet de tubulures, les bouteilles et leurs bouchons, les valves, les colonnes, la valve diluteur et les aiguilles) avant d'allumer l'instrument. Si des fuites sont détectées, remplacer les pièces endommagées avant d'allumer l'instrument. Si les pièces ne peuvent pas être remplacées, débrancher l'instrument et ne pas l'utiliser. Les pièces endommagées contenant du matériel biologique infectieux ou des liquides qui ont été en contact avec un tel matériel peuvent être potentiellement dangereuses.

Les colonnes, les plaques, les tubes et tous les autres consommables qui ont été en contact avec des échantillons nocifs pour l'organisme doivent être traités à l'autoclave avant l'élimination. Les déchets liquides doivent être traités à l'autoclave ou décontaminés à l'aide d'un désinfectant adapté à l'agent pathogène spécifique, par ex. 10 % eau de Javel, alcool isopropylique ou 70& d'éthanol.

L'élimination des déchets doit être effectuée conformément aux réglementations locales.

Figure 1.4: Les symboles d'alerte pour les dangers biologiques sont localisés sur la partie arrière de l'autoMACS Pro (en bas à gauche) et sur la bouteille poubelle (en haut à droite).

1.5.5 Transport

Le séparateur autoMACS Pro Separator doit être transporté avec soin dans un emballage spécifié par Miltenyi Biotec. Un dommage interne peut survenir si l'appareil est soumis à des vibrations excessives ou s'il chute. Si l'appareil doit être réexpédié pour être remis en état, décontaminez l'appareil afin d'éliminer toute matière dangereuse avant le transport. Si vous avez des questions concernant la propre décontamination ou l'expédition, n'hésitez pas à contacter notre service technique assistance.

1.5.6 Élimination de l'appareil

Si vous souhaitez éliminer votre appareil, veuillez contacter notre service technique qui vous aidera.

Wichtige Informationen

1

Vor Inbetriebnahme bitte lesen!

Bitte lesen Sie vor Inbetriebnahme sorgfältig alle in diesem Benutzerhandbuch enthaltenen Informationen. Werden die folgenden Anleitungen nicht gelesen und beachtet, so könnte dies zu unsachgemäßer oder unvorschriftsmäßiger Anwendung, Bedienung oder Wartung des Gerätes führen. Auf diese Weise könnten Anwender gefährdet, Ihr Gerät beschädigt oder dessen Betrieb beeinträchtigt werden. Auch könnte sich vorzeitiger Verschleiß einstellen und somit die Lebensdauer des Gerätes verkürzen. Hierdurch könnten Ihre Garantieansprüche verfallen.

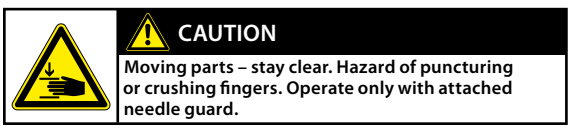
Bewahren Sie dieses Benutzerhandbuch an einem sicheren Ort, zugänglich für jeden Anwender des autoMACS® Pro Separators, auf.

Dieses Kapitel beschreibt die Sicherheitsvorschriften und die Anforderungen an den Gerätestandort ihres autoMACS Pro Separator. Die folgenden Warnhinweise und Vorsichtsmaßregeln sollen Ihnen dabei behilflich sein, Verletzungen für sich oder Schäden am Gerät zu vermeiden.

1.1 Symbole und Gefahrenstufen

Warnhinweis

Beispiel



Die Gefahrenhinweise informieren den Anwender über Gefahren, die bei Missachtung der nachstehend beschriebenen Warnungen und Vorsichtsmaßnahmen bestehen können. Das Gefahrensymbol links versinnbildlicht die Gefahr. Die Gefahrenwarnung oben bezeichnet die Schwere der vorliegenden Gefahr, wie vorstehend beschrieben. Schwere, Art und Ursprung der Gefahr sowie mögliche Folgen, Verbote und Vorsichtsmaßnahmen werden im Anschluss beschrieben.

Symbole und Gefahrenstufen

Im folgenden Glossar werden alle in diesem Benutzerhandbuch oder auf dem autoMACS Pro Separator verwendeten Symbole bildlich dargestellt und erklärt.

WARNUNG bezeichnet eine Gefahrensituation, die, falls sie nicht vermieden wird, zu sschweren Verletzungen oder Tod führen kann.

VORSICHT bezeichnet eine Gefahrensituation, die, falls sie nicht vermieden wird, zu leichteren oder mittelschweren Verletzungen führen kann.

Achtung, schlagen Sie im Benutzerhandbuch für weitere Anweisungen nach und gehen Sie umsichtig vor. Warnhinweise deuten auf das Risiko von Beschädigungen des Gerätes bzw. der Ausrüstung, die Gefahr von schweren Verletzungen oder Lebensgefahr hin.

Quetsch- und Schergefahr. Durch mechanische Gefährdungen können Brüche oder Quetschungen von Körperteilen verursacht werden.

Laserstrahlung. Gefahr von schweren Augen- und Hautverletzungen.

Starkes Magnetfeld. Das Magnetfeld kann auf andere, magnetisch aufladbare Gegenstände und elektronische Geräte störend einwirken oder magnetische Datenträger beschädigen. Für die Träger eines Herzschrittmachers oder von eletronischen Implantaten besteht die Gefahr schwerer Verletzungen.

Gefahr der Kontaminierung bei Verwendung von biologischen Gefahrenstoffen. Dieses Symbol weist auf Lebensgefahr, das Risiko schwerer Verletzungen für den Bediener des Gerätes oder Schäden am Gerät selbst hin, die durch Arbeit mit möglicherweise gefährlichen biologischen Substanzen entstehen können.

Weist auf Lebensgefahr oder das Risiko schwerer Verletzungen für den Benutzer des Gerätes aufgrund gefährlicher Stromspannung hin.

Gleichstrom. Mit diesem Symbol ist auf dem Gerät die Art der Energieversorgung gekennzeichnet: Gleichstrom.

Stromversorgung : AN.

Stromversorgung: AUS.

Vor Inbetriebnahme und Betrieb des Geräts ist die Dokumentation zu beachten.

1.2 Warn- und Sicherheitshinweise

Der autoMACS Pro Separator ist ein hochmodernes, computergesteuertes Gerät zur automatischen Separation magnetisch markierter Zellen mittels MACS® Technologie. Der MACS MiniSampler ist an den autoMACS Pro Separator angeschlossen und damit Teil der Zellseparationsvorrichtung. autoMACS Pro Separator und MACS MiniSampler gelten bei Einbau und Bedienung durch fachkundiges Personal und Beachtung der allgemein üblichen Sicherheitspraktiken und Hinweise in dieser Bedienungsanleitung als sicher. Dieses Kapitel erklärt die im Umgang mit dem Gerät möglichen Gefahren und gibt wichtige Sicherheitshinweise zur Vermeidung dieser Gefahren. Halten Sie sich genau an diese Hinweise, um sich selbst und das Gerät vor möglichen Gefahren zu schützen und ein sicheres Arbeitsumfeld zu garantieren. Bei Verwendung des Geräts unter Missachtung der Herstelleranweisungen ist die Sicherheit nicht gewährleistet.

ACHTUNG! Bitte lesen und befolgen Sie alle in diesem Benutzerhandbuch gegebenen Hinweise zum Betrieb des Gerätes. Beachten Sie auch alle auf dem Display erscheinenden Warnhinweise. Bewahren Sie dieses Benutzerhandbuch sowie alle weiteren, mit diesem Gerät erhaltenen Sicherheits- und Betriebsanleitungen an einem für alle Nutzer des Geräts zugänglichen Ort auf, so dass diese künftig jederzeit darauf zurückgreifen können.

ACHTUNG! Der autoMACS Pro Separator ist ausschließlich ausgelegt für den Betrieb in Innenräumen. Bitte benutzen Sie das Gerät nicht in ausgewiesenen Gefahrenzonen wie etwa sauerstoffangereicherten Arbeitsumgebungen.

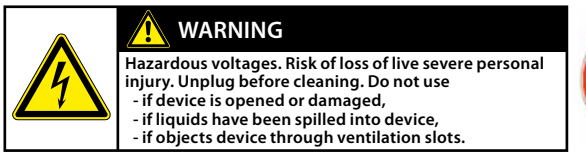
Örtliche Arbeitsschutzbestimmungen, Laborrichtlinien, Sicherheitsnormen und Unfallverhütungsvorschriften müssen auf jeden Fall beachtet werden. Wenden Sie sich an die örtlichen Behörden und Ihren Stromversorger für weitere Informationen zur Stromversorgung, Gebäudeinstallationen, Wartung und Sicherheit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

Wenn Sie Sicherheitsbedenken in Bezug auf die Gerätenutzung haben, setzen Sie sich bitte mit Ihrem autorisierten Miltenyi Biotec Service Provider in Verbindung oder kontaktieren den Miltenyi Biotec Customer Support.

1.3 Allgemeine Sicherheitshinweise

Um mögliche, mit dem Betrieb des autoMACS Pro Separators verbundene Sicherheitsrisiken zu verringern, beachten Sie bitte die folgenden allgemeinen Sicherheitshinweise. Eine Nichteinhaltung dieser Vorsichtsmaßnahmen könnte Feuer, Gesundheitsschäden, und/oder Schäden am Gerät verursachen.

1.3.1 Gefahr des Stromschlags und der Ausbreitung von Feuer



WARNUNG! Der Umgang mit elektrischen Geräten birgt das Risiko eines Stromschlags. Um diese Gefahr zu minimieren, öffnen Sie weder das Gehäuse des autoMACS Pro Separators noch anderes Zubehör. Alle Abdeckungen sowie das Geräte-Zubehör dürfen nur von geschultem Personal entfernt werden. Besondere Vorsicht ist geboten beim Umgang mit Flüssigkeiten. Beseitigen Sie ausgetretene oder verschüttete Flüssigkeit sofort. Es darf unter keinen Umständen Flüssigkeit in das Innere des Gerätes eindringen. Ziehen Sie den Netzstecker vor manueller Reinigung des autoMACS Pro Separators.

Eine potentielle Gefahrenquelle liegt auch im Betrieb eines geöffneten, zu Boden gefallenen oder beschädigten Gerätes. Ebenfalls sollte unbedingt vermieden werden, dass Flüssigkeit in das Gerät gelangt, Fremdkörper durch die Belüftungsöffnungen eindringen oder von außen in das Instrument hinein gelangen. Bei Auftreten von Flammen oder Rauchentwicklung schalten Sie das Gerät sofort aus, trennen es von der Stromzufuhr und kontaktieren einen autorisierten Miltenyi Biotec Service Provider oder das Miltenyi Biotec Customer-Support-Team. Der Betrieb eines beschädigten Gerätes oder eines Gerätes mit schadhaftem Stromkabel ist ausdrücklich verboten.

1.3.2 Starkes Magnetfeld

WARNUNG! Der autoMACS Pro Separator enthält einen extrem starken Magneten. Halten Sie mit magnetischen Datenträgern (Kreditkarten, Magnetbänder, Speichermedien und dergleichen) und elektronischen Geräten (wie Hörgeräte, Herzschrittmacher,

Mess- und Steuergeräte, PCs, Uhren) mindestens 20 cm Abstand zur Magnetabdeckung, da diese durch das Magnetfeld gestört und geschädigt werden können.

Abbildung 1.1: Warnsymbol für starken Dauermagnet.

1.3.3 Quetsch- und Schergefahr

CAUTION

Moving parts – stay clear. Hazard of puncturing or crushing fingers. Operate only with attached needle guard.

VORSICHT! Frontabdeckungen nicht öffnen, wenn das Gerät läuft. Bewegung des Automatikarms und der zugehörigen Komponenten im Betrieb nicht behindern. Finger usw. von allen bewegten Teilen des autoMACS Pro Separator und zugehörigen Komponenten fernhalten, es besteht sonst Gefahr von Quetsch- und Scherverletzungen und Schäden am Gerät. Flüssigkeitspumpen nicht berühren und Leitungen nicht verändern, wenn das Gerät läuft. Gerät immer ausschalten, bevor Arbeiten am Flüssigkeitssystem vorgenommen werden. Laufenden Vorgang immer anhalten oder abbrechen, bevor Arbeiten an Zusatzgeräten wie dem MACS MiniSampler ausgeführt oder Reagenzgläser aus dem Reagenzglasgestell im Sampler entnommen oder dort eingesetzt werden. Sicherheitsmaßnahmen und –vorrichtungen niemals umgehen oder manipulieren.

Abbildung 1.2: Der Kreis zeigt das Warnsymbol für Quetsch- und Schergefahr.

1.3.4 Laserstrahlung

WARNUNG! Das Gerät ist zur automatischen Reagenzglasgestell-erkennung (Klasse 1M) mit vier oberflächenemittierenden Lasern mit vertikalem Resonator (VSCLs) ausgestattet. Die Strahlung ist nicht sichtbar. Schauen Sie nicht direkt mit optischen Instrumenten (z. B. Objektiven, Vergrößerungsgläsern und Mikroskopen) hinein. Das Hineinschauen mit optischen Instrumenten in die VSCL-Öffnung innerhalb eines Abstandes von 100 mm kann Ihre Augen schädigen.

Das Gerät ist auch mit einem 2D-Code-Leser ausgestattet, der einen sichtbaren Halbleiterlaser als Target-Pointer (Zeiger) zur Einstellung der Leseposition sowie leistungsstarken Leuchtdioden (LEDs) zur Ausleuchtung des Lesefeldes verwendet.

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.

Schauen Sie weder direkt in die Laser- oder LED-Strahlung noch in eine durch eine Spiegelfläche reflektierte Laser- oder LED-Strahlung. Dies kann sonst zu Augenverletzungen führen. Richten Sie den Laserstrahl nicht absichtlich auf andere Personen.

Demontieren, wechseln oder entfernen Sie nicht eingebaute Laser- oder LED-Strahlungsquellen oder deren Halterung. Die Laser- oder LED-Strahlungsquellen hören bei Demontage nicht automatisch auf, Strahlung zu emittieren.

Strahlung von demontierten Geräten kann zu Augenverletzungen führen.

Achten Sie auf den optischen Weg des Laserstrahls oder der Reflektion durch eine Spiegeloberfläche. Achten Sie bei der Einrichtung des autoMACS Pro Separator darauf, dass sich der optische Weg des Laserstrahls beim Betrieb nicht auf gleicher Höhe mit dem menschlichen Auge befindet.

Vermeiden Sie, dass Wasser, Öl, Staub oder andere Fremdkörper dem Öffnungsfenster des 2D- Code-Lesers anhaften. Dies kann zu Lesefehlern führen. Stellen Sie vor der Reinigung des Scanners sicher, dass keine Laserstrahlen mehr emittiert werden. Der Umgang mit dem Laser kann sonst zu Augenverletzungen führen. Verwenden Sie zum Abwischen von Substanzen auf dem Scanner ein weiches, trockenes Tuch. Verwenden Sie keinen Alkohol oder andere Reinigungssubstanzen.

Der autoMACS Pro Separator ist nach Norm IEC 60825-1: 1993 + A1: 1997 + A2: 2001 als Klasse 1M-Laserprodukt eingestuft.

VORSICHT! Die Verwendung von anderen als hierin genannten Bedienungselementen sowie die Anpassung oder Durchführung von anderen als hier genannten Verfahren kann gefährliche Strahlung freisetzen.

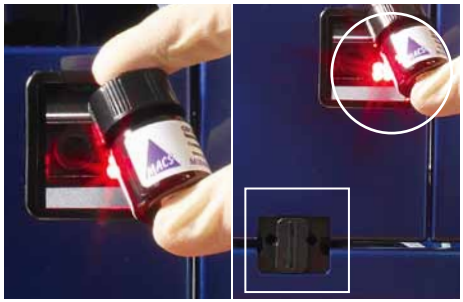


Abbildung 1.3: Position von Lasern. Im Bereich des Rechtecks befinden sich verdeckt montierte Laser zur Erkennung von Gestellen. Der (sichtbare) 2D-Barcodeleser ist hier mit einem Kreis gekennzeichnet.

1.4 Sichere Geräteinstallation

In diesem Abschnitt werden die Anforderungen an einen betriebssicheren Standort für Ihren autoMACS Pro Separator beschrieben. Lesen Sie die Anleitungen in diesem Abschnitt und stellen Sie sicher, dass der Gerätestandort entsprechend vorbereitet ist, bevor Sie das Gerät in Betrieb nehmen.

Berücksichtigen Sie bei der Aufstellungsplanung die in diesem Abschnitt beschriebenen Vorkehrungen, um Gerätestörungen zu vermeiden und die Wahrscheinlichkeit umgebungsbedingt Geräteausfälle zu verringern.

1.4.1 Montagezubehör

Stellen Sie den autoMACS Pro Separator niemals auf einen instabilen Labortisch, Laborwagen, Untersatz, Laborstativ, oder Laborkonsole. Als Folge davon könnte das Instrument zu Boden fallen, dadurch könnten schwere Verletzungen und/oder Schäden am Gerät verursacht werden. Benutzen Sie daher nur von Miltenyi Biotec empfohlenes oder direkt mit dem Gerät erhältliches Labormobiliar. Versuchen Sie nicht, den autoMACS Pro Separator in eine Einbaukonstruktion zu integrieren oder auf begrenztem Raum, z.B. in einem Laborregal, unterzubringen, es sei denn, es wurde eine spezielle Vorrichtung dafür entwickelt, es ist für ausreichende Belüftung gesorgt und die Montageanleitung für das Gerät wurde befolgt.

1.4.2 Belüftung

Das Instrument sollte nicht in der Nähe von Radiatoren, Heißlüfter, Öfen, oder anderen, Wärme erzeugenden Geräten stehen (Verstärker eingeschlossen). Ermöglichen Sie im Betrieb eine ausreichende Luftzirkulation im Abstand von mindestens 15 cm in allen Richtungen um den autoMACS Pro Separator, um eine ausreichende Kühlung zu gewährleisten. Vermeiden Sie, das Gerät direkter Sonneneinstrahlung auszusetzen. Öffnungen und Schlitze am Gerät sind zur Belüftung gedacht und sollten niemals bedeckt oder blockiert werden, da sie das Gerät vor Überhitzung schützen und sicheren Betrieb ermöglichen. Führen Sie niemals Fremdkörper durch Öffnungen in das Gerät ein.

1.4.3 Wassereintritt und Nässe

Setzen Sie das Instrument niemals in einer feuchten oder nasskalten Umgebung ein. Setzen Sie das Gerät nie hoher Feuchtigkeit oder Kondensation aus und schützen Sie es gegen Spritzwasser.

1.4.4 Geerdetes Produkt

Das Gerät ist ausgestattet mit einem Schutzkontaktstecker und einer dreiadrigen Anschlussleitung. Führen Sie den Stecker nicht in eine Steckdose ohne Schutzkontakt ein. Wenn Ihre Steckdose keinen Schutzkontakt aufweist, bitten Sie einen ortsansässigen Elektriker, diese zu ersetzen.

1.4.5 Stromquellen

Das Gerät sollte nur von einer Stromquelle aus betrieben werden, die den elektrischen Angaben auf dem Typschild entsprechen. Sollten Sie Fragen zur Art der Stromversorgung haben, wenden Sie sich an einen autorisierten Miltenyi Biotec Service Provider oder Ihren lokalen Stromversorger. Benutzen Sie keine Verlängerungskabel oder Steckdosenleiste. Überladen Sie eine Steckdose nicht. Die Gesamtlast darf 80& der Zweigstromkreis-bemessung nicht überschreiten.

1.4.6 Zugänglichkeit der Stromverbindungen

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

1.4.7 Peripheriegeräte

An die mit „COM“ beschriftete RS-232-Buchse dürfen nur Peripheriegeräte angeschlossen werden, die UL 60950 erfüllen. Die mit „RS232/AUX“ beschriftete Buchse ist nicht belegt. An die mit „External CAN“, „CAN1“ und „CAN2“ beschrifteten Buchsen dürfen nur Original autoMACS Pro Geräte angeschlossen werden. Die Spannung an diesen Buchsen darf die gefährlichen Werte von 30 Veff und 42,4 V Spitze bzw. 60 V DC nicht übersteigen. An die mit „Bottle Sensor“ beschriftete Buchse darf nur das autoMACS Pro

Flaschensensorkabel angeschlossen werden. An die mit „RS232/BCR“ beschriftete Buchse darf nur ein von Miltenyi Biotec empfohlener 2D-Barcodeleser angeschlossen werden. Externe Lasergeräte, die an die mit „RS232/BCR“ beschriftete Buchse angeschlossen werden, müssen IEC 60825-1 erfüllen. Es dürfen nur Anschlusskabel mit einer Länge von max. 3 Metern verwendet werden.

1.5 Sicherer Betrieb, Wartung, Transport und Entsorgung

Beachten Sie die folgenden die folgenden Hinweise bezüglich Betriebssicherheit, Wartung, Transport und Entsorgung Ihres autoMACS Pro Separators.

1.5.1 Sicherer Betrieb des Gerätes

Falls Ihr Gerät nicht einwandfrei arbeitet und Anzeigen auf dem Display Sie dazu auffordern, den technischen Kundendienst zu kontaktieren, ist die Betriebssicherheit nicht mehr länger gewährleistet. Schalten Sie das Gerät sofort aus, unterbrechen die Stromzufuhr und kontaktieren einen autorisierten Miltenyi Biotec Service Provider oder das Miltenyi Biotec Customer Support Team.

1.5.2 Wartung

WICHTIG! Versuchen Sie nicht, den autoMACS Pro Separator selbst zu warten oder zu reparieren – es sei denn, es ist in diesem Benutzerhandbuch oder anderen technischen Unterlagen der Miltenyi Biotec GmbH 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 und kann den Verlust Ihrer Garantieansprüche zur Folge haben.

Fragen Sie Ihren örtlichen Miltenyi Biotec Vertriebsmitarbeiter nach unseren weit reichenden Vereinbarungen zum Geräteservice und Kundendienst, oder besuchen unsere Website: www.miltenyibiotec.com/support

WICHTIG! Wenn Ersatzteile benötigt werden, stellen Sie sicher, dass Ihr Service Provider nur Originalteile der Miltenyi Biotec GmbH oder Teile von Drittanbietern verwendet, die von der Miltenyi Biotec GmbH spezifiziert und empfohlen werden. Die Verwendung unautorisierter Ersatzteile kann Fehlfunktionen des Gerätes verursachen und die Ergebnisse von Zellseparationen beieinträchtigen. Die Miltenyi Biotec GmbH akzeptiert keinerlei Garantieansprüche und haftet nicht für Fehlfunktionen oder Schäden am Gerät, die auf Verwendung ungeeigneter Verschleiß- oder Ersatzteile zurückzuführen sind. Nach jedweder erfolgter Wartungs- oder Reparaturleistung lassen Sie Ihren autorisierten

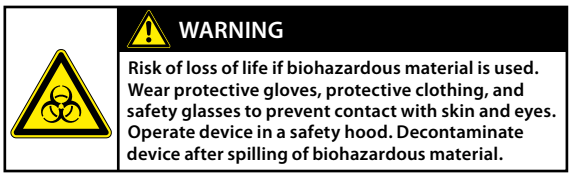
Miltenyi Biotec Service Provider alle notwendigen Sicherheitsprüfungen durchführen, um sicherzustellen, dass das Gerät sich in vorschriftsmäßigem Zustand befindet.

Nutzen Sie nur von Miltenyi Biotec empfohlenes Zusatzgerät und von uns empfohlene Upgrades zu Ihrem Gerät.

1.5.3 Reinigung

Ziehen Sie den Netzstecker vor Reinigung des Gerätes. Verwenden Sie keine Flüssig- oder Sprühreinigungsmittel, sondern nur ein feuchtes Tuch.

1.5.4 Gefährliches Material



Wird oder wurde mit biologischen Gefahrenstoffen gearbeitet, muss der Bediener des Gerätes entsprechend den für die verwendeten Substanzen geltenden Warnhinweisen und Schutzbestimmungen eine persönliche Schutzausrüstung tragen. Tragen Sie Schutzhandschuhe, Schutzkleidung, und Schutzbrille, um Berührung der Gefahrenstoffe mit Haut und Augen zu vermeiden. Schützen Sie auch Ihren Mund und Nase, da Aerosole aus undichten Stellen des Systems austreten könnten. Mangelhafte oder unzureichende Schutzausrüstung kann den Bediener des Instrumentes gefährden. Werden biologische Gefahrenstoffe oder unbekannte Substanzen eingesetzt, sollten Sie mit dem AutoMACS Pro Separator in einer Sterilbank arbeiten. Falls Gefahrstoffe verwendet wurden oder ausgetreten sind, achten Sie auf eine sorgfältige Dekontaminierung des Gerätes.

Vor Inbetriebnahme des Gerätes überprüfen Sie das fluidische System (das Schlauchsystem, Flaschen und deren Verschlüsse, Ventile, Säulen, Verdünnerventil und Nadeln) und ersetzen Sie beim Feststellen einer undichten Stelle alle beschädigten Teile. Können beschädigte Teile nicht ersetzt werden, ziehen Sie den Netzstecker und benutzen Sie das Gerät nicht. Beschädigte Teile, die mit biologischen Gefahrenstoffen in Kontakt waren, sind potentiell gefährlich.

Säulen, Auffanggefäße und alle weiteren Verbrauchsmaterialien, die in Kontakt mit biologischen Gefahrenstoffen gelangt sind, sollten vor Entsorgung autoklaviert werden. Flüssigabfall sollte autoklaviert oder unter Verwendung eines für das jeweilige spezifische Pathogen geeigneten Desinfektionsmittels dekontaminiert werden, z.B. 10% Bleichmittel, Isopropylalkohol, oder 70% Ethanol.

Die Entsorgung der Verbrauchsmaterialien muss gemäß lokal geltender Bestimmungen erfolgen.

Abbildung 1.4: Warnhinweise für biologische Gefahren befinden sich rückseitig auf dem autoMACS Pro Separator (links) und oben auf dem autoMACS Pro Separator Flüssigkeitsbehälter (rechts).

1.5.5 Transport

Der autoMACS Pro Separator 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 werden, dekontaminieren Sie das Gerät vor Versand von jeglichen biologischen Gefahrenstoffen. Wenn Sie Fragen zur vorschriftsmäßigen Dekontaminierung oder zum Versand des Gerätes haben, wenden Sie sich bitte direkt an unseren Technical Support.

1.5.6 Geräteentsorgung

Setzen Sie sich bitte direkt mit unserem Technical Support in Verbindung, falls Sie Ihr Gerät entsorgen möchten.

Informazioni importanti

1

Leggere prima dell'uso!

Si prega di leggere tutte le informazioni riportate nel presente manuale d'uso prima dell'utilizzo. La mancata lettura e l'inosservanza delle istruzioni possono condurre ad un impiego improprio o scorretto dello strumento, a manipolazione e manutenzione inadeguate o errate e potrebbero rappresentare un pericolo per l'operatore, avere conseguenze imprevedibili, causare il malfunzionamento o danni allo strumento, condurre ad un'usura prematura e ad una minore durata di esercizio dello strumento, nonché invalidarne la garanzia.

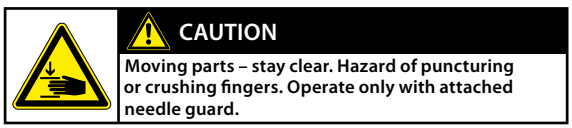
Conservare il presente manuale in un luogo sicuro, accessibile a tutti gi addetti che utilizzano l'unità di separazione autoMACS® Pro (autoMACS® Pro Separator).

Il presente capitolo illustra le istruzioni di sicurezza e i requisiti ambientali per l'installazione dello strumento autoMACS Pro Separator. I seguenti simboli di avvertenza e attenzione servono quale ausilio alla prevenzione di lesioni personali e danni al dispositivo.

1.1 Simboli e livelli di pericolo

Indicazioni di sicurezza

Esempio



Le indicazioni di sicurezza informano l'operatore dei rischi potenziali derivanti dal mancato rispetto delle avvertenze e precauzioni descritte di seguito. L'icona sul lato sinistro specifica il tipo di rischio. Il livello di rischio in alto classifica il tipo di pericolo, come indicato in precedenza. Il livello, il tipo e la fonte del pericolo, nonché le possibili conseguenze, i divieti e le misure da adottare vengono indicati come segue.

Simboli e livelli di pericolo

Di seguito viene presentato un glossario illustrato che descrive i simboli utilizzati nel presente manuale d'uso e sul autoMACS Pro Separator.

WARNING

ATTENZIONE indica una situazione pericolosa che potrebbe comportare lesioni gravi o morte, qualora non venga evitata.

CAUTION

CAUTELA indica una situazione pericolosa che potrebbe comportare lesioni di grado lieve o moderato, qualora non venga evitata.

Attenzione: consultare il manuale d'uso per ulteriori istruzioni e procedere con cautela. Le avvertenze includono il rischio di danni alle attrezzature, gravi lesioni personali o morte.

Pericolo di schiacciamento o di taglio. Rischio di schiacciamento o di taglio di parti del corpo a causa di componenti meccanici.

Radiazione Laser. Rischio di danni permanenti agli occhi ed alla pelle.

Forte campo magnetico. Il campo magnetico può interferire con oggetti magnetizzati e dispositivi elettronici o danneggiare i supporti magnetici per le informazioni. Rischio di lesioni personali gravi per soggetti portatori di pacemaker o impianti medici elettronici.

Rischio di contaminazione in caso di utilizzo di materiale a rischio biologico. Indica il rischio di morte, lesioni gravi a danno dell'operatore o danni alle attrezzature a causa di materiale biologico potenzialmente pericoloso.

Indica il rischio di morte o di lesioni gravi a danno dell'operatore a causa di un livello pericoloso di tensione.

Terminale per conduttore di protezione. Il simbolo è affisso all'interno dello strumento. Avvertenza per il personale di assistenza tecnica

On – acceso (alimentazione)

Off – spento (alimentazione)

E' necessario consultare la documentazione prima di procedere con l'installazione e l'utilizzo dell'apparecchio

1.2 Avvertenze e precauzioni

Il separatore autoMACS Pro Separator utilizza tecnologie all'avanguardia. Si tratta di un dispositivo gestito mediante computer per la separazione automatica delle cellule marcate magneticamente mediante la tecnologia MACS®. Il campionatore MACS MiniSampler è collegato al separatore autoMACS Pro Separator e rappresenta pertanto un componente del dispositivo di separazione delle cellule. Il separatore autoMACS Pro Separator e il campionatore MACS MiniSampler sono concepiti in modo da garantire un funzionamento sicuro dopo l'installazione, se utilizzati da personale addestrato secondo le norme generali di sicurezza e le istruzioni fornite nel presente manuale d'uso. Le linee guida riportate nella presente sezione illustrano i potenziali rischi associati al funzionamento dello strumento e forniscono importanti informazioni in materia di sicurezza atte a ridurre al minimo detti rischi. Seguendo scrupolosamente le istruzioni, è possibile proteggere se stessi e le attrezzature dai possibili pericoli e garantire un ambiente di lavoro sicuro. Qualora lo strumento venga impiegato in modo non conforme alle istruzioni fornite dal fabbricante, la sicurezza potrebbe risultare compromessa.

IMPORTANTE! Leggere e seguire tutte le istruzioni operative contenute nel presente manuale e prestare particolare attenzione alle avvertenze indicate sullo strumento. Conservare il presente manuale d'uso e tutte le altre istruzioni operative e di sicurezza fornite insieme alla strumento in un luogo accessibile a tutti gli operatori, per future consultazioni.

IMPORTANTE! AutoMACS Pro Separator sono destinati unicamente all'impiego interno. Non utilizzare lo strumento in ambienti classificati come luoghi pericolosi, quali gli ambienti con forte concentrazione di ossigeno.

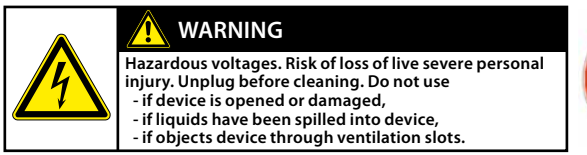
Vanno sempre osservate le istruzioni di sicurezza sul luogo di lavoro, le procedure di laboratorio e le norme relative alla salute e alla sicurezza del laboratorio, nonché alla prevenzione degli infortuni. Per ulteriori informazioni relative all'installazione della strumentazione, contattare le autorità locali competenti per la fornitura di energia elettrica, in materia di edilizia, manutenzione o sicurezza.

Qualora abbiate serie preoccupazioni in merito all'impiego sicuro dello strumento, contattare il rivenditore Miltenyi Biotec autorizzato o chiamare il servizio di assistenza clienti Miltenyi Biotec.

1.3 Precauzioni generali

Per ridurre i potenziali rischi associati all'utilizzo di autoMACS Pro Separator, osservare le precauzioni generali di seguito elencate. Il mancato rispetto di tali precauzioni può comportare il rischio di incendi, lesioni personali e/o danni allo strumento.

1.3.1 Pericolo di scossa elettrica e di incendio



ATTENZIONE! I dispositivi elettrici presentano il rischio di scosse elettriche. Per ridurre i rischi di scossa elettrica, non aprire alcun coperchio, tranne i coperchi di accesso anteriore di autoMACS Pro Separator, né altri accessori hardware forniti da Miltenyi Biotec. Tutti gli altri coperchi dello strumento e gli accessori hardware possono essere rimossi esclusivamente da personale autorizzato. Prestare particolare attenzione quando si manipolano liquidi. Pulire immediatamente eventuali schizzi. Non lasciare che i liquidi penetrino all'interno del dispositivo. Staccare il cavo dell'alimentazione prima di pulire manualmente lo strumento autoMACS Pro Separator.

Esistono potenziali rischi in caso di utilizzo di uno strumento AutoMACS Pro Separator aperto, caduto o danneggiato, in caso di infiltrazione di liquidi all'interno dello strumento, in caso di penetrazione di oggetti nello strumento attraverso le fessure di ventilazione o in caso di inserimento accidentale di oggetti nello strumento. In caso di presenza di fiamme o fumo, spegnere immediatamente il autoMACS Pro Separator, staccare lo strumento dalla presa di corrente e contattare un rivenditore Miltenyi Biotec autorizzato o il servizio di assistenza clienti Miltenyi Biotec. È severamente vietato utilizzare uno strumento danneggiato o provvisto di cavo dell'alimentazione danneggiato.

1.3.2 Forte campo magnetico

ATTENZIONE! autoMACS Pro Separator è provvisto di un magnete estremamente potente. Tenere i supporti magnetici (come carte di credito, nastri magnetici e supporti di memorizzazione) e i dispositivi elettronici (come apparecchi acustici, pacemaker, strumenti di misurazione e controllo, computer e orologi) ad una distanza minima

di 20 cm dal coperchio del magnete. Questi oggetti potrebbero essere danneggiati o il loro funzionamento essere compromesso dal campo magnetico.

Figura 1.1: Segnale di avvertenza per forte magnete permanente.

1.3.3 Pericolo di schiacciamento e di taglio

CAUTION

Moving parts – stay clear. Hazard of puncturing or crushing fingers. Operate only with attached needle guard.

CAUTELA! Non aprire i coperchi di accesso anteriore mentre il dispositivo è in funzionamento. Non impedire il movimento del braccio automatizzato e degli accessori hardware durante il funzionamento. Tenere le dita, ecc., lontano da tutte le parti in movimento del dispositivo autoMACS Pro Separator e degli accessori hardware, per evitare lesioni da schiacciamento e ferite da taglio o danni al dispositivo. Non toccare le pompe dei liquidi e non spostare i tubi mentre il dispositivo è in funzione. Spegnere sempre il dispositivo prima di regolare eventuali parti del sistema della fluidica. Interrompere o sospendere sempre una procedura prima di maneggiare gli accessori hardware, ad es. il campionatore MACS MiniSampler, o prima di caricare/rimuovere le provette dal portaprovette collocato sul campionatore. Non bypassare alcun dispositivo o misura di sicurezza.

Figura 1.2: Il cerchio indica il segnale di avvertenza per il pericolo di schiacciamento e di taglio.

1.3.4 Radiazioni laser

L'apparecchio è dotato di quattro laser a emissione superficiale a cavità verticale (VSCL) per il rilevamento automatizzato (classe 1M). La radiazione non è visibile. Non osservare direttamente il laser con strumenti ottici (p. es. lenti, lenti di ingrandimento e microscopi). Osservando la porta VSCL a una distanza inferiore a 100 mm con uno strumento ottico si potrebbero danneggiare i propri occhi.

L'apparecchio è dotato anche di un lettore di codici 2D dotato di un laser a semiconduttore visibile come puntatore per regolare la posizione di lettura e di potenti diodi luminosi (LED) per illuminare la zona di lettura.

Rispetto allo standard IEC 62471 la lampada ha un valore di rischio relativo all'esposizione (EHV) pari a 0.91 ed è in eccesso rispetto al Gruppo Esente da Rischio. La distanza a rischio (HD) per il Gruppo Esente da Rischio è 61 cm. La distanza a rischio per il Gruppo a Rischio 1 è di 20 cm.

Non guardare direttamente le radiazioni di diodi laser o LED o le radiazioni di diodi laser o LED riflesse da una superficie a specchio. In caso contrario si potrebbero danneggiare i propri occhi. Non rivolgere intenzionalmente il raggio laser verso altre persone.

Non smontare, modificare o rimuovere le sorgenti di radiazioni laser o LED installate o le loro staffe di montaggio. Le sorgenti di radiazioni laser o LED non cessano automaticamente di emettere radiazioni una volta smontate.

Le radiazioni di unità smontate possono essere causa di lesioni agli occhi.

Fare attenzione al percorso del raggio laser o a riflessi da una superficie a specchio. Durante l'installazione del separatore autoMACS Pro accertarsi che il percorso del raggio laser non si trovi alla stessa altezza degli occhi di chi esegue il lavoro.

Evitare che acqua, grasso, polvere o altre sostanze estranee si depositino sulla finestra di lettura del lettore di codici a barre 2D. Ciò potrebbe comportare errori di lettura. Accertarsi di aver arrestato l'emissione laser prima di pulire il lettore. Un'esposizione al raggio laser potrebbe danneggiare i propri occhi. Utilizzare un panno morbido e asciutto per rimuovere qualsiasi sostanza dal lettore di codici a barre. Non utilizzare alcol o altre sostanze detergenti.

Il separatore autoMACS Pro è classificato come prodotto laser della classe 1M secondo lo standard IEC 60825-1: 1993 + A1: 1997 + A2: 2001.

CAUTELA! L'utilizzo di comandi o regolazioni o l'esecuzione di procedure diverse da quanto qui specificato può essere causa di esposizione a radiazioni pericolose.

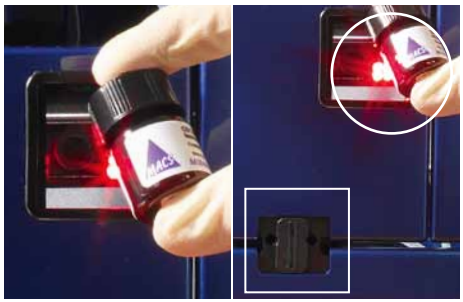


Figura 1.3: Posizione dei laser. Laser invisibili per il rilevamento dei portacampioni/portareagenti sono collocati nell'area indicata dal rettangolo. Il lettore per codice 2D (visibile) è collocato all'interno del cerchio.

1.4 Installazione sicura

Questa sezione descrive i requisiti che deve soddisfare il luogo in cui viene collocato il autoMACS Pro Separator onde garantirne un'installazione sicura e il funzionamento corretto. Leggere le istruzioni fornite nella presente sezione e accertarsi che il luogo prescelto sia adeguatamente predisposto, prima di collegare lo strumento alla presa di alimentazione.

Nel predisporre l'ambiente di installazione e nell'organizzare la disposizione delle attrezzature, tenere in considerazione le precauzioni descritte nella presente sezione, in modo da evitare guasti allo strumento e ridurre la possibilità di spegnimenti causati dall'ambiente.

1.4.1 Accessori di montaggio

Non collocare il autoMACS Pro Separator su un piano, un carrello, un supporto, un treppiede o una staffa poco stabile, che potrebbe provocare la caduta dello strumento, con la possibile conseguenza di lesioni personali gravi o di gravi danni allo strumento. Utilizzare unicamente piani, carrelli, supporti, treppiedi o staffe raccomandati da Miltenyi Biotec o venduti insieme allo strumento. Non collocare il autoMACS Pro Separator su sistemi incassati o in spazi angusti, come uno scaffale, a meno che non siano stati concepiti specificamente per accogliere lo strumento e a condizione che vi sia una ventilazione adeguata e che siano state seguite le istruzioni di montaggio dello strumento.

1.4.2 Circolazione dell'aria

Lo strumento non deve essere collocato in prossimità di radiatori, stufe o altri dispositivi (inclusi gli amplificatori) che producono calore. Accertarsi che via sia un'adeguata circolazione d'aria attorno al autoMACS Pro Separator, mantenendo uno spazio libero di almeno 15 centimetri su ogni lato durante il funzionamento, onde assicurare un adeguato raffreddamento dello strumento. Evitare l'esposizione diretta ai raggi solari. Le fessure e le aperture dello strumento sono necessarie per la ventilazione e non devono essere in alcun caso ostruite o coperte, poiché garantiscono il funzionamento corretto del autoMACS Pro Separator e proteggono il dispositivo dal surriscaldamento. Non inserire mai corpi estranei nelle aperture dello strumento.

1.4.3 Acqua e umidità

Non utilizzare lo strumento in ambienti bagnati o umidi. Evitare ambienti ad elevata umidità o condizioni di condensa e proteggere lo strumento dagli schizzi d'acqua.

1.4.4 Prodotto con messa terra

Lo strumento è dotato di un sistema di alimentazione a tre fili ed è provvisto di spina con un terzo polo per la messa a terra. La spina può essere inserita unicamente in una presa di corrente con messa a terra, per ragioni di sicurezza. Non cercare di inserire la spina in una presa sprovvista di messa a terra. Qualora non riusciate ad inserire la spina nella presa, vi consigliamo di contattare il vostro elettricista di fiducia per sostituire la presa.

1.4.5 Fonti di alimentazione

Lo strumento deve essere alimentato unicamente dalla fonte indicata sulla targa relativa alle caratteristiche di alimentazione del prodotto. In caso di domande sul tipo di alimentazione da usare, contattare il rivenditore Miltenyi Biotec autorizzato o la società elettrica locale. Non utilizzare prolunghe o ciabatte multi-presa. Non sovraccaricare la presa di corrente. Il carico complessivo del sistema non deve superare l'80% della potenza del circuito.

1.4.6 Accessibilità

Accertarsi che l'interruttore principale e l'attacco del cavo dell'alimentazione siano facilmente accessibili e posti quanto più vicino possibile all'operatore dello strumento. Qualora si renda necessario interrompere l'alimentazione, staccare il cavo dalla presa di corrente.

1.4.7 Periferiche

Soltanto le periferiche conformi a UL 60950 possono essere collegate al connettore RS232 contrassegnato con “COM”.
Il connettore contrassegnato come “RS232/AUX” non è in uso.
È inoltre possibile collegare soltanto apparecchi autoMACS Pro originali ai connettori contrassegnati con “External CAN”, “CAN1” e “CAN2”. I livelli di tensione su questi connettori non devono superare i livelli di tensione ammessi pari a 30 V rms e 42,4 V di picco o 60 V cc.
Al connettore del "sensore flacone" può essere esclusivamente collegato il cavo del sensore del flacone autoMACS Pro.

Al connettore “RS232/BCR” può essere collegato soltanto un lettore per codice 2D raccomandato da Miltenyi Biotec. I dispositivi laser esterni collegati al connettore contrassegnato come “RS232/BCR” devono essere conformi alla norma IEC 60825-1. Utilizzare unicamente cavi di connessione inferiori ai 3 metri di lunghezza.

1.5 Funzionamento, manutenzione, trasporto e smaltimento sicuri

Seguire le istruzioni di seguito riportate onde assicurare che il funzionamento, la manutenzione, il trasporto e lo smaltimento del vostro autoMACS Pro Separator avvengano in modo corretto e sicuro.

1.5.1 Funzionamento sicuro

Qualora lo strumento non funzioni correttamente e le istruzioni o i messaggi visualizzati sullo schermo invitino a contattare l’assistenza tecnica, la sicurezza di impiego non è più garantita. Spegnere immediatamente il autoMACS Pro Separator, staccare lo strumento dalla presa dell’alimentazione e contattare un rivenditore Miltenyi Biotec autorizzato o il servizio di assistenza clienti Miltenyi Biotec.

1.5.2 Manutenzione

IMPORTANTE! Se non diversamente indicato nel presente manuale d’uso o in altri documenti forniti da Miltenyi Biotec, non eseguire autonomamente la manutenzione del vostro autoMACS Pro Separator. Gli interventi di manutenzione e riparazione devono essere eseguiti da personale qualificato. Interventi di manutenzione e riparazione scorretti o impropri del autoMACS Pro Separator possono rappresentare un pericolo per l’incolumità degli operatori, avere conseguenze imprevedibili, causare malfunzionamenti o danni, provocare l’usura prematura e una minore durata di esercizio dello strumento, nonché invalidare la garanzia.

Per i contratti di assistenza e manutenzione offerti da Miltenyi Biotec contattare il rappresentante Miltenyi Biotec locale o consultare il sito www.miltenyibiotec.com/support.

IMPORTANTE! Qualora si rendano necessari la sostituzione o l'impiego di pezzi di ricambio, accertarsi che il tecnico utilizzi unicamente pezzi di ricambio originali Miltenyi Biotec o ricambi di altri fabbricanti specificati e raccomandati da Miltenyi Biotec. L'impiego di pezzi di ricambio non autorizzati può causare il malfunzionamento del dispositivo e compromettere il risultato della separazione cellulare. Miltenyi Biotec non fornisce alcuna garanzia né si assume la responsabilità per eventuali guasti o danni derivanti dall'impiego di pezzi di ricambio inappropriati. Al termine dell'intervento di assistenza o di riparazione, chiedere al tecnico Miltenyi Biotec autorizzato di eseguire tutti i controlli di sicurezza previsti dalla procedura di riparazione, onde assicurarsi che lo strumento funzioni correttamente.

Utilizzare esclusivamente le funzioni opzionali e gli aggiornamenti raccomandati da Miltenyi Biotec.

1.5.3 Pulizia

Staccare il autoMACS Pro Separator dalla presa di corrente prima di eseguire la pulizia. Non utilizzare detergenti liquidi o aerosol; utilizzare sempre un panno umido.

1.5.4 Materiale pericoloso

WARNING

Risk of loss of life if biohazardous material is used. Wear protective gloves, protective clothing, and safety glasses to prevent contact with skin and eyes. Operate device in a safety hood. Decontaminate device after spilling of biohazardous material.

Qualora si utilizzi o sia stato usato del materiale a rischio biologico, l'operatore deve indossare dispositivi di protezione personale conformi alle avvertenze e alle precauzioni relative alle sostanze impiegate. Indossare guanti protettivi, indumenti e occhiali di protezione per prevenire il contatto con la pelle e gli occhi. Proteggere sempre la bocca ed il naso dagli aereosol che possono provenire dal sistema. L'impiego di dispositivi di protezione difettosi o inadeguati rappresenta un rischio per l'incolumità dell'operatore. Lo strumento autoMACS Pro Separator va utilizzato con uno schermo protettivo in caso di trattamento di materiali sconosciuti o pericolosi. Qualora sia stato usato o versato del materiale pericoloso, il sistema deve essere accuratamente decontaminato.

Ispezionare sempre il sistema fluidico (il sistema di tubi, le bottiglie e le relative chiusure, le valvole, le colonne, il dispositivo di diluizione e gli aghi) prima di accendere lo strumento. In caso di perdita di liquidi, sostituire le parti danneggiate prima di accendere lo strumento. Nel caso non sia possibile sostituire le parti danneggiate, disconnettere lo strumento e non utilizzarlo. Il malfunzionamento di parti che contengono materiale potenzialmente infettivo o liquidi venuti in contatto con tali materiali possono rappresentare un pericolo.

Le colonne, le piastre, le provette e tutti gli altri materiali di consumo entrati in contatto con campioni a rischio biologico vanno sterilizzati in autoclave prima di essere smaltiti. I rifiuti liquidi vanno autoclavati o decontaminati utilizzando un disinfettante idoneo per il patogeno specifico, ed es. candeggina al 10%, alcol isopropilico o etanolo al 70%.

Lo smaltimento dei rifiuti deve avvenire in conformità alle disposizioni locali vigenti.

Figura 1.4: I simboli di pericolo biologico sono localizzati sulla superficie posteriore dello strumento (sinistra) e sulla parte superiore della bottiglia del fuido di scarto (destra).

1.5.5 Trasporto

Lo strumento autoMACS Pro Separator va trasportato con cautela in imballaggi specificati da Miltenyi Biotec. In caso di cadute o di vibrazioni eccessive, lo strumento può subire dei danni interni. Qualora si renda necessario rispedire lo strumento al produttore per interventi di manutenzione, decontaminare lo strumento da eventuali materiali pericolosi prima della spedizione. In caso di domande circa la decontaminazione o il trasporto adeguati, contattare l'assistenza tecnica.

1.5.6 Smaltimento

Contattare il servizio di assistenza tecnica per lo smaltimento dello strumento.

Información importante

1

Lea la siguiente información antes de usar el instrumento/ equipo!

Por favor, lea íntegramente la información contenida en este manual de usuario antes de utilizar el instrumento/equipo. La lectura y/o seguimiento incorrectos de estas directrices pueden llevar a un uso, manejo o mantenimiento incorrectos del equipo, lo cual puede poner en peligro a sus usuarios, producir resultados impredecibles, derivar en un mal funcionamiento del aparato o que éste sufra daños así como causar un desgaste prematuro y reducir el tiempo de vida del instrumento, pudiendo anular su garantía.

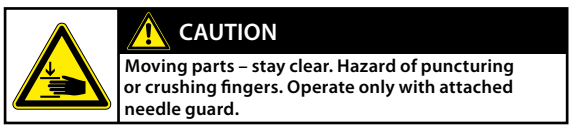
Mantenga este manual de usuario en un lugar seguro, al alcance de todo aquel que esté usando la Unidad de Separación autoMACS® Pro (separador autoMACS Pro).

El presente capítulo describe las instrucciones de seguridad y los requisitos de emplazamiento de su separador autoMACS Pro. Las siguientes advertencias y precauciones tienen como objetivo evitar daños personales o materiales.

1.1 Símbolos y niveles de peligro

Disposición de advertencias de seguridad

Ejemplo



Las advertencias de seguridad informan al usuario sobre riesgos potenciales en caso de que no se sigan las advertencias y precauciones resumidas a continuación. El símbolo que aparece a la izquierda especifica el riesgo de que se trate. El nivel de peligro que encabeza la advertencia clasifica el peligro de que se trate tal y como se mencionó más arriba. El nivel, tipo y fuente del peligro así como las posibles consecuencias, prohibiciones y remedios se indican tal y como aparece a continuación.

Símbolos y niveles de peligro

El siguiente recuadro recoge un glosario ilustrado que describe los símbolos usados en el presente manual de usuario y en el separador autoMACS Pro.

WARNING

ADVERTENCIA indica una situación de peligro que si no se impide puede producir la muerte o lesiones graves.

CAUTION

PRECAUCIÓN indica una situación de peligro que si no se impide puede producir lesiones leves o moderadas.

Atención, consulte el manual de usuario para obtener más información y proceda con precaución. Las advertencias incluyen el riesgo de dañar el equipo, las lesiones personales graves o la muerte.

Peligro de aplastamiento o corte. Riesgo de que se aplaste o corte alguna parte del cuerpo debido a peligros mecánicos.

Radiación láser. Riesgo de graves lesiones oculares y de piel.

Campo magnético intenso. El campo magnético puede interferir en objetos magnetizables e instrumentos electrónicos o dañar portadores magnéticos de información. Riesgo de producir lesiones personales graves a personas que lleven un marcapasos o implantes médicos electrónicos.

Riesgo de contaminación si se usan sustancias peligrosas biológicamente. Indica el riesgo de muerte, lesiones graves al operario del aparato o daños al equipo debido a sustancias biológicas potencialmente peligrosas.

Indica el riesgo de muerte o lesiones graves al operario del aparato debido a un voltaje peligroso.

Corriente continua. El equipo está marcado con el tipo de suministro: corriente continua.

Encendido (suministro)

Apagado (suministro)

La documentación del equipo debe ser consultada antes de proceder con la instalación y operación del sistema

1.2 Advertencias y precauciones

El separador autoMACS Pro emplea tecnología puntera. Se trata de un dispositivo controlado por ordenador desarrollado para la separación de células magnéticamente rotuladas con la tecnología MACS®. El MACS MiniSampler conecta el separador autoMACS Pro y forma de esta manera parte del dispositivo de separación de célula. El separador autoMACS Pro y el MiniSampler están diseñados para funcionar con seguridad una vez instalados y siempre que sean manejados por personal cualificado de conformidad con las normas generales de seguridad y las instrucciones contenidas en este manual del usuario. Las directrices del presente capítulo explican los potenciales riesgos asociados al manejo del instrumento y suministran información importante a fin de reducir dichos riesgos al mínimo. Si sigue cuidadosamente las instrucciones, se protegerá a sí mismo y al equipo de posibles peligros y creará un ambiente de trabajo seguro. Si este instrumento es manejado de un modo no previsto por su fabricante la seguridad se verá mermada.

IMPORTANTE! Por favor, lea y siga todas las instrucciones de uso recogidas en el presente manual de usuario y preste atención a todas las advertencias que aparecen en el instrumento. Guarde para futuras consultas este manual y todas las demás instrucciones de seguridad o de funcionamiento recibidas junto con el instrumento en un lugar accesible para todos sus usuarios.

IMPORTANTE! El separador autoMACS Pro está diseñado para ser usado exclusivamente en interior. No utilice el equipo en áreas clasificadas como peligrosas como ambientes con alta concentración de oxígeno.

En todo momento se debe observar la normativa nacional de seguridad en el trabajo, las normas del laboratorio, y los estándares de salud y seguridad en el laboratorio y de prevención de accidentes. Póngase en contacto con la autoridad local competente para el suministro de electricidad, construcción de edificios, mantenimiento o seguridad para obtener más información sobre la instalación del equipo.

Si tiene serias dudas sobre el manejo seguro del equipo, póngase en contacto con su proveedor de servicios de Miltenyi Biotec autorizado o llame al servicio de atención al cliente de Miltenyi Biotec.

1.3 Precauciones generales

Para reducir los potenciales riesgos asociados al manejo del separador autoMACS Pro, por favor observe las siguientes precauciones generales. En caso de no seguir estas precauciones, puede producirse un incendio o causar daños corporales o al equipo.

1.3.1 Peligro de descarga eléctrica y propagación de fuego

WARNING

Hazardous voltages. Risk of loss of live severe personal injury. Unplug before cleaning. Do not use
- if device is opened or damaged,
- if liquids have been spilled into device,
- if objects device through ventilation slots.

ADVERTENCIA! Los aparatos eléctricos pueden producir una descarga eléctrica. Para reducir este riesgo, no abra ninguna cubierta ni abra tampoco ningún otro accesorio de harware suministrado por Miltenyi Biotec. Cualquier cubierta asi como hardware accesorios deberán ser retirados únicamente por personal autorizado. Se debe tener especial cuidado cuando se manejen líquidos. Limpie inmediatamente los líquidos vertidos. Impida que éstos accedan al interior del aparato. Desenchufe el cable de electricidad antes de proceder a limpiar manualmente el separador autoMACS Pro.

Existe un riesgo potencial en caso de usar separador autoMACS Pro abierto, que se haya caído o que esté averiado, si se han derramado líquidos en el equipo, si se ha colado algún objeto por las ranuras de ventilación o si ha caído algo dentro del equipo. Si salen llamas o humo, apague inmediatamente el separador autoMACS Pro, desenchúfelo y póngase en contacto con un proveedor de servicios de Miltenyi Biotec autorizado o con el servicio técnico de Miltenyi Biotec. Está expresamente prohibido utilizar un instrumento estropeado o cuyo cable de corriente esté dañado.

1.3.2 Campo magnético intenso

WARNING

Extremely strong magnetic fields. Risk of severe personal injury to persons carrying pacemakers or electronical medical implants – stay clear. Keep all magnetically sensitive objects away from device.

ADVERTENCIA! El separador autoMACS Pro Separator está equipado con un imán extremadamente potente. Mantenga todos los portadores de información magnética (tarjetas de crédito, cintas magnéticas y medios de almacenamiento) y todos los equipos electrónicos (audífonos, marcapasos, instrumentos de medición y control, ordenadores y relojes) a una distancia mínima de 20 cm de la cubierta magnética. El campo magnético puede alterar o dañar dichos objetos.

Figura 1.1: Señal de advertencia para imán permanente potente.

1.3.3 Peligro de aplastamiento y corte

CAUTION

Moving parts – stay clear. Hazard of puncturing or crushing fingers. Operate only with attached needle guard.

PRECAUCIÓN! No abrir las cubiertas de acceso frontal durante el servicio del dispositivo. No obstruir el movimiento del brazo automatizado y de los accesorios durante la operación. Mantener los dedos etc. lejos de todas las piezas móviles del separador autoMACS Pro y de los accesorios, para evitar aplastamientos, lesiones de corte o daños en el dispositivo. No tocar las bombas de fluido ni ajustar la tubería durante la operación del dispositivo. Desactivar siempre el dispositivo antes de ajustar cualquier parte del sistema de fluidos. El procedimiento debe pararse o interrumpirse antes de maniobrar los accesorios, p. ej. el MACS MiniSampler, o antes de colocar o retirar los tubos del soporte de tubo colocado en el sampler. No omitir ninguna de las medidas o los dispositivos de seguridad.

Figura 1.2: El círculo abierto muestra la señal de advertencia para el peligro de aplastamiento o corte.

1.3.4 Radiación láser

ADVERTENCIA! El dispositivo está equipado de cuatro unidades láser de emisión superficial de cavidad vertical (VSCLs) para la detección automatizada de reactivos (clase 1M). La radiación no es visible. No mire directamente con instrumentos ópticos (por ejemplo, gafas, lupas y microscopios). Puede ser peligroso para el ojo mirar el puerto VSCL con instrumentos ópticos a una distancia de 100 milímetros.

El dispositivo también está equipado de un lector de código 2D que utiliza un láser semiconductor visible como indicador de blanco para ajustar la posición de lectura y diodos electroluminosos de gran alcance (LED) para iluminar el área de la lectura.

De acuerdo con la normativa internacional IEC 62471, este sistema de lámpara tiene un valor de riesgo por exposición (EHV) de 0.91 siendo en exceso para el grupo exento de riesgos (Exempt Risk Group). La distancia de riesgo (HD) para el grupo exento de riesgos es de 61 cm. La distancia de riesgo para el Grupo de Riesgo 1 (Risk Group 1) es de 20 cm.

No mirar directamente el láser, radiación LED, láser reflejado o radiación del LED de una superficie reflejada. De otra manera, podría ocasionarse una lesión ocular. No dirigir intencionalmente el rayo láser a otras personas.

No desmontar, modificar ni quitar el láser o la fuente de radiación LED o sus soportes de montaje. El láser o las fuentes de radiación LED no interrumpen la emisión cuando están desmontados.

La radiación de unidades desmontadas puede ocasionar lesiones oculares.

Tener cuidado con la trayectoria del rayo o la reflexión láser de una superficie reflejada. Durante la instalación del autoMACS Pro Separator, tener cuidado de que durante la operación la trayectoria del rayo láser no esté a la misma altura que el ojo humano.

No permitir que agua, aceite, polvo u otras sustancias ajenas se peguen a la ventana de abertura del lector 2D Code. Esto puede causar errores de lectura. Asegúrese de parar la emisión del láser antes de limpiar el escáner. De no ser así, la exposición al láser puede ocasionar lesiones oculares. Utilizar un paño suave y seco para limpiar cualquier sustancia del escáner. No utilizar alcohol u otra sustancia de limpieza. El autoMACS Pro Separator está clasificado como producto láser 1M de estándar IEC 60825-1: 1993 + A1: 1997 + A2: 2001.

PRECAUCIÓN! El uso de controles, el ajuste o la realización de procedimientos con excepción de los aquí especificados puede dar lugar a una peligrosa exposición de radiación.

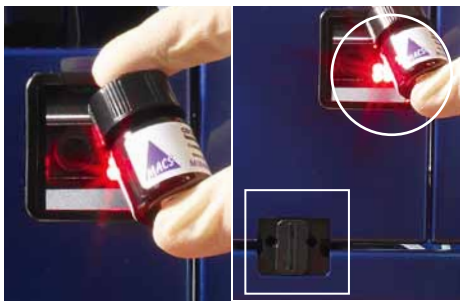


Figura 1.3: Posición de los láseres. El láser de detección del rack es invisible y se localiza dentro del área rectangular. El lector de códigos de barra (visble) está localizado dentro del círculo abierto.

1.4 Instalación segura

El presente capítulo describe los requisitos que debe reunir el lugar donde desea instalar y operar el separador autoMACS Pro. Lea las instrucciones de este capítulo y asegúrese de que el emplazamiento está correctamente preparado antes de conectar el instrumento a la corriente eléctrica.

Cuando planee la distribución del emplazamiento y la ubicación del equipo tenga en cuenta las precauciones recogidas en este capítulo para evitar averías del instrumento y reducir la posibilidad del cierre de la empresa por razones medioambientales.

1.4.1 Accesorios de montaje

No coloque el separador autoMACS Pro sobre una mesa, carrito, estante, trípode o soporte inestable puesto que podría caerse, causando lesiones corporales graves y/o daños graves al equipo. Utilice exclusivamente una mesa, carrito, estante, trípode o soporte recomendado por Miltenyi Biotec o vendido junto con el instrumento. No coloque el separador autoMACS Pro en un mueble empotrado o un espacio reducido como por ejemplo una estantería, a menos que el mismo haya sido diseñado específicamente para dar cabida al instrumento, que provea una ventilación adecuada y que se hayan seguido las instrucciones de montaje del equipo.

1.4.2 Circulación de aire

El instrumento no debería ser colocado cerca de radiadores, rejillas de calor, estufas o cualquier otra pieza de equipamiento (incluidos los amplificadores) que produzca calor. Permita que circule suficiente aire alrededor del separador autoMACS Pro – deje al menos 15 cm de

separación en todas direcciones- mientras está en funcionamiento para garantizar que el instrumento se enfríe adecuadamente. Evite la exposición directa a la luz solar. Las ranuras y aberturas del instrumento sirven para que se ventile y no deben ser bloqueadas o cubiertas, puesto que contribuyen a un funcionamiento seguro del separador autoMACS Pro, evitando que se recaliente. No introduzca ningún cuerpo extraño por las aberturas del instrumento.

1.4.3 Agua y humedad

No use el instrumento en un lugar húmedo. Evite la elevada humedad o la condensación y proteja a la máquina de salpicaduras.

1.4.4 Producto conectado a tierra

El instrumento está equipado con un tipo de enchufe de tres varillas que tiene un tercer contacto para toma de tierra. Este enchufe sólo encaja en una toma conectada a tierra. Se trata de una medida de seguridad. No intente enchufarlo en una toma de electricidad no conectada a tierra. Si el enchufe no encaja, póngase en contacto con un electricista para que reemplace la toma de corriente.

1.4.5 Fuentes eléctricas

Sólo se debería maniobrar el instrumento utilizando la fuente eléctrica indicada en la etiqueta con los valores eléctricos del producto. Si tiene alguna pregunta sobre qué tipo de fuente eléctrica utilizar, póngase en contacto con su proveedor de servicios de Miltenyi Biotec autorizado o con su compañía eléctrica. No utilice alargadores o regletas. No sobrecargue la toma de corriente. La carga total del sistema no debe sobrepasar el 80% de la rama del circuito.

1.4.6 Accesibilidad

Asegúrese de poder acceder fácilmente tanto al interruptor principal como al conector para el cable de corriente eléctrica y de que éstos estén situados tan cerca del operario como sea posible. Si es necesario desconectar el suministro eléctrico, desenchufe el cable de la toma de corriente.

1.4.7 Aparatos periféricos

Solamente los dispositivos periféricos que cumplen con la UL 60950 pueden ser conectados con el conector RS232 rotulado con “COM”. No se utiliza el conector rotulado con “RS232/AUX”. Adicionalmente deben conectarse exclusivamente equipos originales de autoMACS Pro con los conectores rotulados con “External CAN”, “CAN1” y “CAN2”. Los niveles de voltaje de estos conectores no debe sobrepasar los niveles de voltaje peligroso de 30 V CA y 42.4 V punta o 60 V CC. Se debe conectar solamente el cable de sensor de botella MACS Pro con el conector del sensor de botella. Con el conector“RS232/BCR” debe conectarse solamente un lector de código 2D recomendado por Miltenyi Biotec. Los dispositivos de láser externos conectados con el conector rotulado con “RS232/BCR” deben cumplir con la norma IEC 60825-1. Utilice exclusivamente cables de conexión con un largo menor a 3 m.

1.5 Manejo, mantenimiento, transporte y eliminación seguros

Observe las siguientes instrucciones para asegurar un manejo, mantenimiento, transporte y eliminación de su separador autoMACS Pro seguros.

1.5.1 Manejo seguro

Si el instrumento no funciona correctamente y las instrucciones o mensajes que aparecen en la pantalla aconsejan ponerse en contacto con el servicio técnico, el uso del instrumento ya no es seguro. Apague inmediatamente el separador autoMACS Pro, desenchúfelo y póngase en contacto con el proveedor de servicios de Miltenyi Biotec autorizado o con el servicio de atención al cliente de Miltenyi Biotec.

1.5.2 Revisión técnica

IMPORTANTE! Salvo que el presente manual de usuario u otra documentación de Miltenyi Biotec especifique lo contrario, no revise usted mismo el separador autoMACS Pro. Las revisiones y reparaciones deben ser llevadas a cabo por personal cualificado. Las revisiones y reparaciones del separador autoMACS Pro incorrectamente realizadas pueden poner en peligro a sus usuarios, producir resultados impredecibles, derivar en un mal funcionamiento del aparato o que éste sufra daños así como causar un desgaste prematuro y reducir el tiempo de vida del instrumento pudiendo anular su garantía.

Pregunte a su representante de Miltenyi Biotec por los contratos de servicios de asistencia técnica de Miltenyi Biotec o consulte www.miltenyibiotec.com/support

IMPORTANTE! Cuando se necesiten piezas de recambio o de repuesto, asegúrese de que el proveedor de servicios utiliza exclusivamente piezas originales de Miltenyi Biotec o de otros fabricantes especificados y recomendados por Miltenyi Biotec. El uso de piezas de recambio o de repuesto no autorizadas puede producir un mal funcionamiento del aparato y alterar los resultados de la separación celular. Miltenyi Biotec no cubrirá la garantía ni aceptará ninguna responsabilidad por la avería de aparatos o por los daños resultantes del uso de piezas de recambio o de repuesto inapropiadas. Una vez completado el servicio o la reparación, haga que su proveedor de servicios autorizado por Miltenyi Biotec realice todos los controles de seguridad requeridos por el proceso de reparación para asegurarse de que el instrumento está en buenas condiciones de funcionamiento.

Utilice exclusivamente las opciones y actualizaciones recomendadas por Miltenyi Biotec.

1.5.3 Limpieza

Desenchufe el separador autoMACS Pro de la toma de corriente antes de proceder a su limpieza. No emplee productos de limpieza líquidos ni aerosoles y use siempre un trapo húmedo.

1.5.4 Sustancias peligrosas

WARNING

Risk of loss of life if biohazardous material is used. Wear protective gloves, protective clothing, and safety glasses to prevent contact with skin and eyes. Operate device in a safety hood. Decontaminate device after spilling of biohazardous material.

Si se utilizan o se han utilizado sustancias biológicamente peligrosas, el operario debería utilizar el equipo de seguridad que aparece en las señales de aviso de las sustancias empleadas. Póngase guantes, ropa y gafas de seguridad para evitar el contacto con la piel y con los ojos. También proteja la boca y la nariz pues los aerosoles podrían escaparse del sistema. Un equipo de seguridad defectuoso o inadecuado puede poner en peligro al operario. El separador autoMACS Pro deberá ser manejado dentro de una campana de seguridad si se procesan sustancias peligrosas o desconocidas.
Si se han utilizado sustancias peligrosas o éstas se han derramado, se debe velar por una desinfección meticulosa del sistema.

Antes de encender el instrumento siempre inspeccione todo el sistema de fluidos (todas las conexiones y tubos, válvulas, columnas, jeringas y agujas). Si detectase alguna rotura o fuga, sustituya todas las piezas dañadas antes de encender el instrumento.Si alguna parte dañada no puede ser sustituida, desconecte y no use el equipo.
La falta de piezas por donde pasa material de riesgo biológico o el contacto con líquidos que han estado en dichas piezas podría ser peligroso.

Las columnas, placas, tubos de ensayo y cualquier otro objeto que haya estado en contacto con las muestras peligrosas deberán ser autoclavados antes de poder volver a ser utilizados. Los residuos líquidos deberán ser autoclavados o descontaminados usando un desinfectante industrial apropiado para el patógeno específico, por ejemplo, hipoclorito de sodio al 10%, alcohol isopropílico o etanol al 70%.

La eliminación de los residuos debe cumplir la normativa nacional.

Figura 1.4: Señal de cuidado de riesgo biológico localizada en la parte inferior del panel delantero del separador autoMACS Pro (izquierda) y en la parte superior de la botella de Fluido del Separador autoMACS Pro (derecha).

1.5.5 Transporte

El separador autoMACS Pro debe ser transportado con cuidado en el embalaje especificado por Miltenyi Biotec. Se pueden producir daños internos si es expuesto a vibraciones excesivas o si se cae. En caso de que sea necesario devolver el instrumento a su fabricante para su revisión, límpielo y desinféctelo de cualquier sustancia peligrosa antes de realizar el envío. Si tiene preguntas relativas a la descontaminación o el envío, póngase en contacto con el servicio de asistencia técnica.

1.5.6 Eliminación del instrumento/ equipo

Póngase en contacto con el servicio de asistencia técnica si desea desprenderse de su instrumento.

Introduction

2

2.1 MACS® Technology – the gold standard in cell separation

MACS® Technology has become the standard method in cell separation. It is based on i) MACS MicroBeads, i.e., highly specific antibodies coupled to superparamagnetic 50-nm particles, ii) MACS Columns containing a matrix of ferromagnetic spheres, and iii) MACS Separators providing a strong magnetic field. When a MACS Column is placed in a MACS Separator, the ferromagnetic spheres amplify the magnetic field by 10,000-fold, thus inducing a high gradient within the column. This magnetic field is strong enough to retain cells that are labeled with minimal amounts of MACS MicroBeads. Columns rapidly demagnetize when the column is removed from the separator, or in case of the autoMACS Pro Separator, the magnet is automatically retracted from the autoMACS Column to elute the labeled cells.

The colloidal suspensions of MACS MicroBeads allow easy handling and short incubation times. Cells can be separated in less than 30 minutes. As minimal amounts of MicroBeads are required for magnetic cell labeling, a large number of epitopes remains available for fluorescent labeling. Thus, staining of cells with fluorochrome-conjugated antibodies for subsequent cell analysis can be performed simultaneously.

MACS MicroBeads are non-toxic, biodegradable, and do not need to be removed from cells after the separation process. MicroBeads do not alter structure, function, or activity status of labeled cells. Isolated cells can be immediately used for downstream applications, including flow cytometric analysis, cell culture, and molecular analysis.

It takes only a few simple steps to get pure cell populations
Cells in a single-cell suspension are magnetically labeled with MACS MicroBeads. The sample is applied to the autoMACS Column placed in the autoMACS Pro Separator. The unlabeled cells pass through while the magnetically labeled cells are retained within the column. The unlabeled cells are collected as the negative fraction. After a short washing step, the magnet is retracted from the autoMACS Column, and the magnetically labeled cells are eluted from the column as the positive fraction. Thus, with MACS Technology both labeled and unlabeled cells can easily be isolated with high purity and recovery.

2.2 The autoMACS® Pro Separator

The autoMACS® Pro Separator is a benchtop magnetic cell sorter that allows gentle sorting of more than ten million cells per second from a sample of up to 4×10^9 total cells. The instrument is designed for use with more than 250 MicroBead-based cell separation reagents for research applications. Thus, it is possible to choose between different cell separation strategies according to the respective experimental design – from positive selection of abundant or rare cells, to the isolation of untouched cells by depletion of non-target cells, or to the isolation of sophisticated cell subsets by sequential sorting. Twelve preset separation programs simplify and standardize the application.

The autoMACS Pro Separator features automated sample labeling (autolabeling), sample loading, elution of the non-labeled negative, as well as the labeled positive cell fractions. Up to six samples can be processed in one programming step. Furthermore, automated procedures for maintenance of the system are included. Different wash programs are available to rinse the columns before a new separation is performed. One pair of columns can be used for up to 100 cell separations or for two weeks, whichever comes first. The thin-film transistor (TFT) color touchscreen with intuitive screen menus makes operation and monitoring of the instrument user-friendly and easy. Finally, standard MACS Fluid Bottles, which are directly attached to the instrument and ready-to-use sterile MACS Buffers are available for maximum convenience.

The autoMACS Pro Separator is supplied with the MACS MiniSampler and therefore offers an additional sampling option. This feature allows the sequential processing of multiple samples without further manual handling. The MiniSampler is supplied with three different tube racks and an additional reagent rack. The MiniSampler and tube racks are automatically detected by the autoMACS Pro Separator, adding to its operational efficiency.

The user manual aims at explaining the principles of cell sorting with the autoMACS Pro Separator and assists you by providing step-by-step protocols for the separation and quality control. Tips and hints in the troubleshooting section are intended to help optimize your magnetic cell separations.

Figure 2.1: Front image of the autoMACS Pro Separator – the access cover was made transparent for the purpose of illustration.

Assembly and installation

3

The autoMACS Pro Separator is a benchtop instrument that fits in laminar flow hoods or safety cabinets. If the instrument is placed in a laminar flow hood, the following accessories might be required: autoMACS Pro Laminar Hood Plate (# 130-093-246) and, optionally, autoMACS Pro Angle Connector Kit (# 130-093-245). The laminar hood plate provides a stable and even surface, even on potentially bending surfaces. The angle connectors reduce the depth of the instrument to 455 mm (including MACS MiniSampler) for placement in a location with limited space.

The operating environment should be stable and vibration-free, dust-free, sufficiently ventilated, and free from sources of electromagnetic radiation.

Before operating the autoMACS Pro Separator for the first time, carefully read the user manual and contact your local Miltenyi Biotec representative for assistance.

The following components are included in the delivery of the autoMACS Pro-Starter Kit (# 130-092-545):

- autoMACS Pro Separator
- MACS MiniSampler
- MACS Reagent Rack 4
- 1 MACS Chill 5 Rack (for 5 mL tubes)
- 1 MACS Chill 15 Rack (for 15 mL tubes)
- 1 MACS Chill 50 Rack (for 50 mL tubes)
- Software
- Barcode reader
- 5×2 autoMACS Columns
- 2×2 column substitutes
- autoMACS Pro buffer combination
- user manual and short instructions
- one-year warranty

3.1 Unpacking and installing the autoMACS® Pro Separator

Read through the following instructions carefully before commencing the installation procedure. Before opening the transportation box, check for any visible external damage to the box. Check also to see if the shock and position indicators (if present) suggest incorrect transportation of the instrument. If there is apparent damage please contact Technical Support for assistance (refer to section 12).

CAUTION! Due care must be taken while lifting the autoMACS Pro Separator. Miltenyi Biotec accepts no liability for potential injuries and damages sustained during lifting and/or movement of the instrument.

Note: The top compartment holds the autoMACS Pro user manual, the short instructions, and various bags containing accessories. Carefully remove these parts.

1 Open the box and remove the top compartment of the packaging to reveal the instrument and associated packaging.

Figure 3.1: Top compartment of the autoMACS Pro Separator box.

2 Remove boxes containing the MACS MiniSampler and cover, and the MACS Chill Racks. Remove the foam packaging from both sides of the autoMACS Pro Separator.

Figure 3.2: Packing format of the autoMACS Pro Separator and accessories.

3 Place the instrument onto a stable worktop surface, e.g., laboratory bench. Remove the plastic bag surrounding the instrument.

Note: Two people are required to lift the autoMACS Pro Separator. The instrument must be gripped at the base of the orange bottle baskets located at both sides of the instrument. Note that the instrument is heavier at the front. Ensure the front of the instrument is stabilized while lifting it.

Figure 3.3: Positioning the autoMACS Pro Separator securely onto a laboratory bench.

4 Note the positions of the MACS MiniSampler guiding (2) and its corresponding slot (1) located at the front of the instrument. Tilt the MiniSampler and slide the guiding into the receiving slot until resistance is met; lower the rack to a horizontal position, i.e., the rack is locked in the position illustrated by the figure below.

Figure 3.4: Location of the MiniSampler guide (2) and receiving slot (1) for the MACS MiniSampler.

5 Ensure that the MiniSampler is completely inserted and secure the connection by fastening the MiniSampler screw as shown in the figure below.

Figure 3.5: Securing the MiniSampler by fastening the MiniSampler screw.

6 Attach the sensor cables to the cable guide at the back of the autoMACS Pro Separator.

Figure 3.6: Sensor cables are attached to the back of the instrument as shown above.

7 Place the MiniSampler cable underneath the autoMACS Pro Separator and connect it to the socket labeled “External CAN” at the rear panel of the instrument. Use the screw driver to fasten the screws of the connecter.

8 Guide the 2D code reader cable underneath the instrument. Connect the 2D code reader plug with the corresponding outlet at the back of the instrument labeled “RS232/BCR”. Use the screw driver to fasten the screws of the connecter.

9 Attach the sensor cable plug to the socket for sensor cables at the back of the autoMACS Pro Separator labeled “Bottle Sensor“ and fasten securely. Use the screw driver to fasten the screws of the connecter.

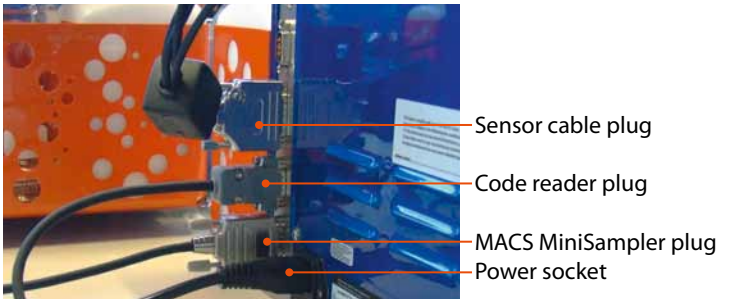


Figure 3.7: Location of the MACS MiniSampler, sensor cable, code reader, and power sockets at the back of the instrument.

10 Carefully remove the uptake port needle from the foam packaging.

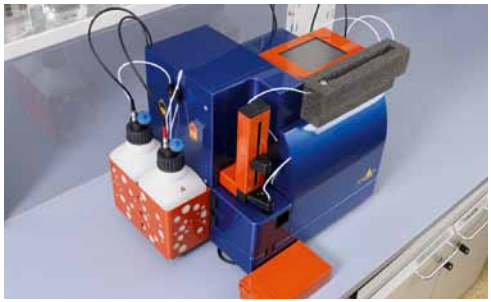


Figure 3.8: Close-up of the autoMACS Pro Separator – the needle arm and underside of the touch screen are supported by foam.

11 Place the uptake port needle into its guiding at the needle arm.

Figure 3.9: The needle port is positioned as illustrated above.

12 Note the position of the power socket on the rear panel of the autoMACS Pro Separator (figure 3.7). Ensure that the main power switch is in position “0”.

13 Connect the power cord.

14 Elevate the touchscreen and insert the memory card as shown below.

Figure 3.10: Inserting the software memory card.

15 Replace the fluid bottles. Refer to section 3.2 for full details.

16 Switch ON the autoMACS Pro Separator.

17 Secure the MACS Reagent Rack 4 onto the MiniSampler into the left recess. The engagement hook has to snap into the undercut.

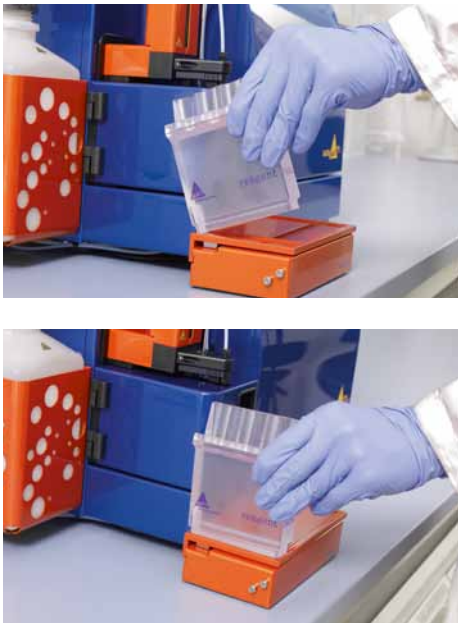


Figure 3.11: Securing the MACS Reagent Rack 4 onto the MACS MiniSampler.

Note: Racks can be pre-cooled for 3–4 hours at 2–8 °C. Do not cool below 0 °C since samples may freeze. If recognition of the tube rack fails, the instrument will display a screen for manual selection of the tube rack. Before confirming the choice, ensure that the rack is placed correctly into the recess. The MACS Triangle should face towards the user.

18 Set a tube rack (e.g. Chill 5 Rack) onto the MiniSampler into the right recess ensuring that the rack barcode is facing the autoMACS Pro Separator.

Figure 3.12: Positioning the Chill 5 Rack adjacent to a MACS Reagent Rack 4 on the MACS MiniSampler.

19 Perform a system calibration test: refer to section 3.3 for more details.

3.2 Replacing fluid bottles and the connection of fluid sensor cables

Note: The 70% ethanol does not contain electrolytes. Therefore, the filling status of the storage solution bottle cannot be determined.

Operating the autoMACS Pro Separator requires Running Buffer, Washing Solution, and storage solution (absolute ethanol diluted to 70% with double-distilled water). It is recommended to operate the instrument with ready-to-use MACS Buffers. The autoMACS Pro Separator is delivered with four empty fluid bottles which are connected to the instrument with specifically designed bottle closures. The bottle closures consist of a fluid uptake port or a fluid outlet port (waste bottle) as well as a sensor for measuring electrolyte conductivity. The fluid bottles, bottle closures, and fluid sensor cables are color-coded for easy handling (refer to table 3.1 below).

WARNING! When working with biohazardous samples, it is recommended to fill the waste bottle with 100 mL of disinfectant before use, e.g., MACS Bleach Solution (# 130-093-663). For proper disposal, please follow local regulations and carefully read the chapter 1.

Note: When removing the waste bottle, unscrew the bottle closure and then fasten a standard lid, i.e., without sensor cables, onto the bottle before removing the waste bottle from the basket. This is to ensure that the content of waste bottle is not accidentally spilt over the autoMACS Pro Separator during removal from the basket.

Note: The correct positioning of each solution bottle – recognizable by the color code and the symbols – is crucial in order to perform successful procedures using the autoMACS Pro Separator.

To keep buffers sterile, each bottle closure should be equipped with a hydrophobic air filter. Avoid any contact of hydrophobic air filters with fluids as this may cause clogging of the filter.

Bottle	Symbol	Bottle	Symbol
Running Buffer (blue)		Storage solution (black)	
Washing Solution (green)		Waste (red)	

Table 3.1: Symbols and color-coding of fluid bottles.

1 Install one fluid bottle at a time. Please note the corresponding color-coding (refer to table 3.1).

2 Unscrew bottle closures counter-clockwise and remove the empty bottle. Do not disconnect the color-coded tubing.

3 Do not open a fresh bottle until it is placed in the basket! Place the bottle in its appropriate position, remove the cap, and fasten the bottle closure. Note the color-coding and connect each sensor cable to the respective bottle closure.

4 Attach the sensor cable plug to the socket for sensor cables at the back of the autoMACS Pro Separator labeled "Bottle Sensor" and fasten securely.

5 Connect the hydrophobic air filters (0.2 µm) to the appropriate connectors on the bottle closures.

Figure 3.13: Positioning of the hydrophobic air filters on the bottle closures.

3.3 Running the autoMACS® Pro Separator for the first time: performing a test calibration

Note: Ensure that the autoMACS Pro Separator has been correctly installed (section 3.1) and that the empty fluid bottles used for transport purposes have been replaced by fresh fluid bottles (section 3.2).

3.3.1 Switch ON the autoMACS® Pro Separator

The main power switch is located on the right side of the instrument in front of the bottle baskets ("I" indicates ON, "O" indicates OFF). Switch on the autoMACS® Pro Separator.

Figure 3.14: Location of the ON/OFF switch.

3.3.2 Check the date and time

1 To set the time and date perform the following steps:
Select **Option**, **User settings**, and **Set_time**. Select **Run**.
Highlight either the **time** or **date** fields by touching the display.
Use the keypad to change the date or time accordingly.

Figure 3.15: Select the desired field and use the numeric keypad to modify the date and/or time.

2 Select **Ok** to return to the **Option** menu. The procedure can be cancelled at anytime by selecting **Cancel**.

Note: If test calibration 1 fails, perform a calibration 1. Refer to section 11.2 for details.

3.3.3 Perform a test calibration

During test calibration, ensure the correct location of the needle arm at the following positions:

- Washing station: needle should be positioned directly above the center of the rear opening of the washing station (figure 3.16).
- Chill Rack positions A1, B1, C1: needle should be positioned at the bottom center of the tube (figure 3.17).
- X-position: needle should be positioned in the middle of the x-axis of tube B1.
- Reagent Rack positions 1–4: needle should be located at the lowest point of the vial to ensure full uptake of the substrate (figure 3.18).

Figure 3.16: Test calibration of the needle arm position in the washing station.

Figure 3.17: Test calibration of the needle arm position in the Chill Rack positions.

Figure 3.18: Test calibration of the needle arm position in the reagent vial.

1 Go to the **Option** menu. Under **User settings** select **Calibr_1**. Click **Run** and **Test**.

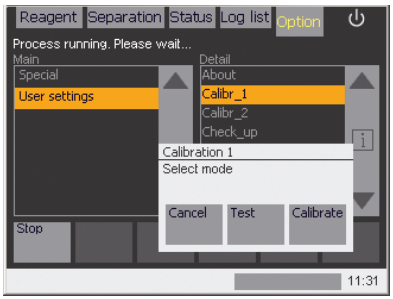


Figure 13.19: Instructing the instrument to perform a test calibration.

2 Place a Chill 15 Rack, containing three 15 mL plastic tubes in positions A1, B1, and C1, onto the MACS MiniSampler. Select **Done**.

3 Place the MACS Reagent Rack 4 onto the MACS MiniSampler. Select **Done**.

4 **Test position: Washing station** will be displayed on the screen. Select **Test position**. The instrument will automatically place the needle in the washing station. Ensure that the needle is positioned directly above the center of the rear opening of the washing station. Click **Done**. The next position will be addressed automatically.

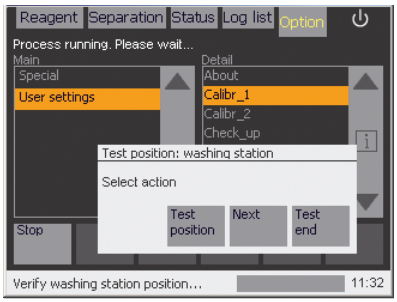


Fig. 3.20: Test calibration of the washing station.

5 In the following steps, further calibration settings regarding the needle arm can be tested, including the tube rack positions A1 (Ori), B1 (Neg), and C1 (Pos), the x-position, and vials one to four in the Reagent Rack. To test a position, select **Test position**. Check all approached positions by using the needle navigation buttons **Move up** and **Move down**, then select **Done**. To skip a position select **Next**. The test calibration can be canceled at any time by selecting **Test end**.

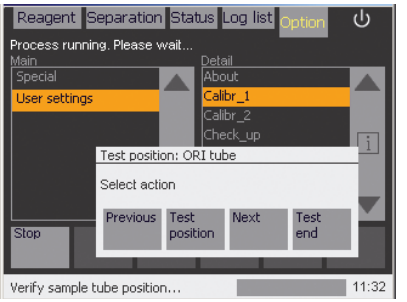


Fig. 3.21: To test a position, select 'Test position'. To skip the test position, select 'Next'. To test a previous test position, select 'Previous'. To end the test calibration, select 'Test end'.

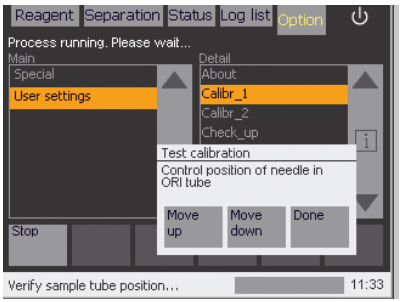


Fig. 3.22: After selecting 'Test position, the 'Move up' and 'Move down' buttons can be use to check the exact positioning of the needle.

Note: When delivered, the autoMACS Pro fluidic system is filled with double-distilled water.

The autoMACS Columns are reusable for two weeks or up to 100 separations, whichever comes first.

The instrument automatically records the date of the column exchange and can display the due date for the next column replacement if the Column exchange program **Col_ex** has been used for column installation.

Columns do not have a top or bottom and do not require special orientation in the column holder.

6 After testing the fourth vial position as the last position select **Done**. Select **Done** once again to leaf the test calibration. Select **Cancel** to leave the calibration program.

7 Test calibration is completed.

3.3.4 Installation of the autoMACS® Columns

Remove the column substitutes and install the autoMACS® Columns according to the following instructions:

1 Open the front door and note the position of the tubing and autoMACS Column slots in the magnet cover (column 1 to the left, column 2 to the right).

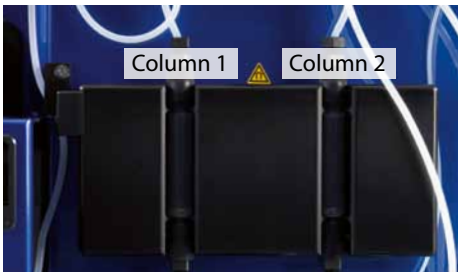


Figure 3.23: Position of the MACS Columns.

2 Ensure that the fluid bottles are filled with solutions.

3 Using the touch screen, select **Option** and **Special** from the **Main** submenu.

4 Select **Col_ex** (column exchange) from the **Detail** panel.

5 Select **Run** to start the **Col_ex** program.

Figure 3.24: Selecting **Col_ex** from the Option menu.

6 Wait until the instrument prompts you to exchange the autoMACS Columns before proceeding.

7 Using both hands take the top and bottom of the column 1 substitute and pull gently but firmly to remove it from its slot.

Figure 3.25: Removal of the column substitutes from the column slots.

8 Place a wide mouth bottle under the column substitute. Hold the column substitute in one hand and gently unscrew the bottom column connector counter-clockwise. Unscrew the top column connector while holding the column over the bottle to catch any fluids. Store the column substitute in the autoMACS Pro-Starter Kit box.

Figure 3.26: Unscrewing the top column connector for column removal.

9 Insert one end of a fresh column into the bottom column connector and gently screw in the column by turning it clockwise until you feel a resistance. Point the column towards the top of the instrument and screw in the top column connector.

10 Align the column with the top column connector sitting on the guiding of the magnet cover. Press the column into the slot until you feel the guides click. Verify that the column is placed in the center of the magnet cover.

Note: The program will then proceed to wash the columns with autoMACS Running Buffer. Check that the columna are securely fastened to the column connectors and that no buffer is leaking.

11 Repeat steps 8 through 11 to install the second column.

12 Ensure that the tubes are securely fastened to the columns and that the tubing is neither pinched nor obstructed.

13 Press **Done**.

14 Close the front door. The unit is now ready to perform cell separations.

3.3.5 Priming the autoMACS® Pro Separator

Priming implicates the initial cleaning and filling of the autoMACS® Pro Separator tubing system before cell separations are performed. The autoMACS Pro Separator must be primed each time the instrument is switched ON.

WARNING! Read the warnings and precautions section before priming the autoMACS Pro Separator for the first time.

WARNING! When working with biohazardous samples, it is recommended to fill the waste bottle with 100 mL of disinfectant before use, e.g., MACS Bleach Solution (# 130-093-663). For proper disposal, please follow local regulations and carefully read the chapter 1.

1 Fill all bottles with the appropriate solutions and empty the waste bottle.

2 Switch ON the instrument. After initialization is completed, the **Status** menu will be displayed. Verify that the touchscreen symbols for all fluid bottles are green. If this is not the case, check if the fluid sensor cables are connected to the correct fluid bottles. The symbol for the ethanol bottle remains gray (fluid level can not be checked by system). At this point, the fluid bottle illumination is yellow.

Figure 3.27: The ˝Status˝ menu. The fluid level status and column are green for ready. A wash or instrument prime has not yet been performed.

3 Go to the **Separation** menu and select **Wash Now** from the lower menu. You now have the option to perform a quick rinse (**Qrinse**) or full rinse (**Rinse**).

Figure 3.28: Select “Rinse“ to prime the autoMACS Pro Separator.

4 Select **Rinse** and **Run** to start the priming process. The progress will be displayed at the bottom of the touchscreen menu.

5 When priming is finished, the instrument will display **Ready for separation** in the **Status** menu. The fluid bottles are now illuminated green.

Figure 3.29: The instrument has been primed (rinsed).

Note: A cell separation template can already be programmed or reloaded during the priming procedure. When selecting **Run** the user will be asked to confirm that enough running buffer is available; thereafter priming will begin.

The autoMACS Pro Separator will display a warning screen if the buffer supply is low or if the waste bottle is full. If no wash program has been performed before the first separation, a warning screen will ask to rinse the system.

You may interrupt any program by selecting **Stop**. The **Stop** button is located at the bottom left hand corner in all menus.

When priming the instrument for the first time or when the instrument was not serviced for a long period of time, it is recommended to visually inspect the fluidic system for potential leaks. Open the front door after priming the instrument. If there is any sign of leakage (e.g. salt deposits), tighten the respective tubing connection. Close the front door and proceed with the separation.

3.3.6 Checking the fluid levels

The autoMACS Pro Separator automatically ensures that the uptake port is filled with buffer, that fluid bottles carry enough fluid for one separation, and that the waste bottles can collect fluid from at least one separation. If more than one separation is performed, ensure that the bottles contain sufficient fluid for all the separations and that the waste bottle is empty.

To verify the status of the bottles, select the menu **Status** from the upper navigation bar. On the left hand side of the menu, four symbols display the solution bottles and their filling status. If the fluid bottles are full and the waste bottle is empty, the symbols are green. If the solution bottles are empty or the waste bottle is full, the respective symbols are red. The symbol for the storage solution bottle remains gray. It is recommended to select the **Status** menu when the autoMACS Pro Separator is in operation.

Figure 3.30: Status of the fluid bottles is green for ready.

3.3.7 Test of barcode scanner

1 Select **Reagent**.

2 Press **Read Reagent**.

3 Place the barcode, e.g. the barcode below, in front of barcode scanner (also refer to figure 1.3).

4 The name of the scanned reagent will appear in the display.

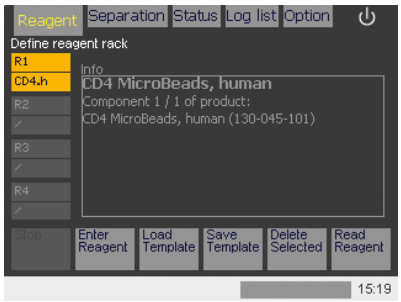


Figure 3.31: The name of the scanned reagent, here "CD4 MicroBeads, human (# 130-045-101)", appears in the display.

An overview of the autoMACS® Pro touchscreen user interface

4

The autoMACS® Pro Separator is operated through a TFT color touchscreen. After switching ON the instrument, the startup screen will appear.

Figure 4.1: The autoMACS Pro Separator startup screen.

4.1 Working with the lower menu bar

Figure 4.2: The lower menu bar of the ˝Separation˝ menu.

A lower menu bar is accessible from all menu screens. Depending on the status of the instrument and the selected upper tabbed menu option, the lower menu buttons switches between an inactive (grey background) and active (white background) state. For example, **Stop** can only be selected when the instrument is actively performing a process such as cell separation.

Figure 4.3: Left: ˝Stop˝ button is active and can be selected. Right: ˝Stop˝ button is inactive and cannot be selected.

4.2 The main menu screen

Five main menus allow easy interaction with the instrument. They are accessed through the upper tabbed menu:

Tab	Function
Reagent	To define the position of MACS Reagents on the MACS Reagent Rack 4.
Separation	To define an autolabeling and/or cell separation strategy for up to six samples. In addition, cell processing procedures can be saved as templates for regular use.
Status	The instrument status is displayed at a glance.
Log list	The log list details completed actions and errors.
Option	Users can perform special procedures such as exchange of MACS Columns, instrument calibration, and service steps.

Table 4.1: Feature overview of the upper tabbed menu.

After instrument initialization the screen automatically displays the **Status** menu, which helps to monitor the instrument during installation and operation. Color-coded symbols indicate the status of the hardware components. Further information on a particular component can be obtained by touching the symbol.

Figure 4.4: The main "root" menu screen displays instrument "Status" at startup.

4.3 Status menu

The autoMACS Pro Separator is a sensor-controlled instrument that allows easy monitoring during operation. At a glance the instrument status can be determined by viewing the **Status** menu at any time.

1 Sample status
2 Fluid bottle filling status
3 Column status
4 Tube rack status
5 MiniSampler status

Figure 4.5: Overview of the instrument status panels.

A description of how to monitor the instrument's status using the **Status** menu follows.

4.3.1 Status of fluid bottles

Figure 4.6: Fluid bottle status symbols. Left: Fluid bottles are ready. Right: Fluid bottles need to be replaced.

The status of fluid bottles is indicated by color-coded graphic symbols and by a text table.

Bottle	Symbol	Symbol color and user action
Running Buffer		Green: no action required Red: refill bottle Gray: connect bottle sensor
Washing Solution		Green: no action required Red: refill bottle Gray: connect bottle sensor
Storage solution		Gray: no liquid detection; visually check volume
Waste		Green: no action required Red: empty waste Gray: connect bottle sensor

Table 4.2: Status of fluid bottles displayed in the "Status" menu

In addition to color-coded graphic symbols of the fluid bottles, a pop-up text table also reports fluid bottle status. Touch any fluid bottle symbol to activate the pop-up textbox. To close the pop-up table, select ●. Moreover, the symbols are also red, when the sensor cables are connected to a wrong bottle closure.

Figure 4.7: Fluid bottle status. By touching any fluid bottle symbol a pop-up box displays a text report of the fluid bottle status.

4.3.2 Column status

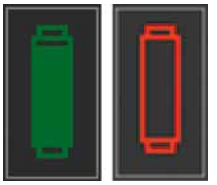


Figure 4.8: The column status graphic. Left: The column is ready. Right: The column must be changed.

If the column symbol is green, no action is required. If the symbol is red, the columns must be exchanged. The level of the green fill on the column symbol indicates the remaining operation-life of the autoMACS Columns. Touch the column symbol to activate the column status pop-up text box.

Figure 4.9: Column status. By touching the column symbol a pop-up box displays a text report of the column status.

4.3.3 Tube rack status

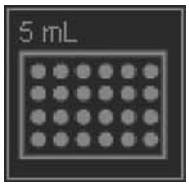


Figure 4.10: Tube rack status graphic: a 5 mL Chill 5 Rack was detected. If no tube rack is detected no graphic is displayed.

Rack detection occurs prior to starting the separation process. Before cell labeling and/or cell separation is performed the instrument will not attempt to detect the rack. Touch the position of the rack status graphic in order to view the tube rack pop-up text table.

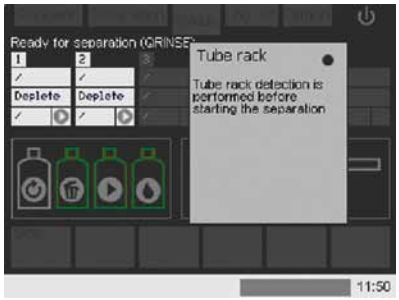


Figure 4.11: Tube rack status text box: No rack is detected until cell separation is performed.

4.3.4 MACS® MiniSampler status

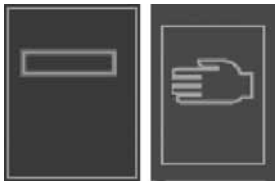


Figure 4.12: MACS MiniSampler status graphic. Left: The MiniSampler was successfully installed. Right: No MiniSampler was detected.

If the MACS® MiniSampler has been detected correctly a rectangular symbol is displayed. If it has not been detected a hand symbol will be displayed in the same field.

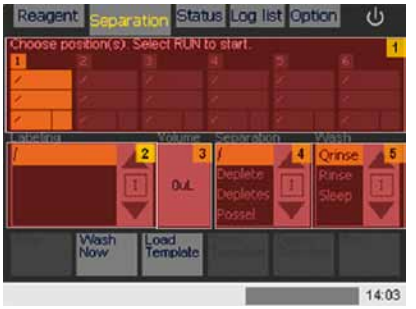
4.4 Separation menu

The **Separation** menu schematically represents a sample rack and allows definition of sample processing strategies for each sample rack position. For each sample rack position it is possible to define cell labeling, cell separation, and washing programs.

A single wash program can be performed by selecting **Wash Now** from the lower navigation bar.

Figure 4.13: The ˝Separation˝ menu.

An overview of the **Separation** menu follows:



1 Sample rack template
2 Sample labeling options
3 Sample processing volume
4 Separation program
5 Wash procedure

Figure 4.14: Overview of the submenus in the ˝Status˝ menu.

Sample rack template
The positions in the sample rack programming field (1) correspond to the sample positions in the tube rack. Positions 1–6 are used in combination with Chill 5 Rack, positions 1–5 with Chill 15 Rack, and positions 1–3 with Chill 50 Rack.

1 To select/deselect a sample position touch to highlight the desired position 1–6.

2 Select/deselect a sample position by touching the display.

Figure 4.15: Sample positions 1, 3, and 4 were selected.

Sample labeling options

The **Labeling** submenu (2) is used to instruct the instrument:

- if autolabeling is to be performed on a sample.
  The default setting is "/", which indicates that NO autolabeling will be performed.
- the type of autolabeling that will be performed.
  A list of product options is only visible if reagents have already been assigned to positions on the reagent rack using the **Reagent** menu.

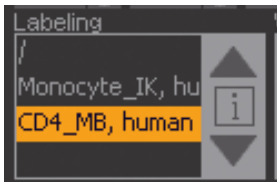


Figure 4.16: "Labeling" submenu. Using the MACS Reagent Rack 4, a total of four reagents may be used at any given time.

Assigning sample volumes

The **Volume** submenu (3) is used to inform the instrument about the available sample volume. To enter or modify a volume:

1 Ensure that the appropriate sample template position is highlighted.

2 Select the **Volume** submenu.

3 Using the numeric keypad enter the sample volume.
For autolabeling enter the sample volume for the first labeling step as outlined in the corresponding data sheet (e.g. 160 µL / 2×10^7 cells for labeling with CD4$^+$ MicroBeads, human or 120 µL / 4×10^7 cells for labeling with Monocyte Isolation Kit II, human).

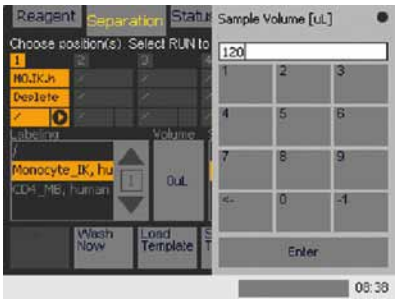


Figure 4.17: Entering the sample volume in microliters (µL) for Monocyte Isolation Kit II, human.

4 Note that the minimal incubation volume after the addition of the first reagents may not be less than 200 µL.

5 Select **Enter**.

Assigning a cell separation program

The **Separation** submenu (4) is used to instruct the autoMACS Pro Separator which cell separation program should be applied to each sample. Several sample positions can be highlighted to assign a separation condition for multiple samples. Refer to section 6.1.2 for a detailed explanation of the various cell separation strategies. To assign or modify a cell separation program:

1 Highlight the appropriate sample(s) using the sample template.

2 Scroll through the **Separation** submenu using the arrows ▲/▼.

3 Select and highlight a **Separation** program.

Figure 4.18: Positive cell separation-sensitive mode (˝Possel_s˝) was selected.

Assigning a wash program

The **Wash** submenu (5) is used to instruct the autoMACS Pro Separator which wash program should be applied to each sample. Four wash programs are available to choose from:
Qrinse (quick rinse) - : Recommended to save time between sample separation steps. The tubing and column receive a quick rinse.
Rinse - : The system is 'primed', receiving an extensive wash. Rinse is recommended between rare cell, whole blood, cord blood, and bone marrow separations.

Note: If the **Clean** program has been enabled, it will also appear in the **Wash** submenu.

Sleep - : A rinse is performed before the system is shutdown.
Clean - : An optional, very extensive rinsing program. Clean may be used after whole blood, cord blood, and bone marrow separations.

To assign or modify a wash program:

1 Highlight the appropriate sample(s) using the sample template.

2 Scroll through the **Wash** submenu using the arrows ▲/▼.

3 Select (highlight) a **Wash** program.

Figure 4.19: (Top) "Qrinse" program was selected. (Bottom) The "Clean" program has been enabled and was selected as the last wash program.

Working with separation templates
For convenience it is possible to load and save separation templates. Separation templates can be used in combination with reagent templates (refer to above).

To save a separation template:

1 Configure the sample template, an example follows.

Figure 4.20: A sample template was setup to process two samples. Sample 1: Isolation of untouched human monocytes using the Monocyte Isolation Kit II, human (# 130-091-153); autolabeling program MO.IK.h; separation program "Deplete". Sample 2: Direct labeling and positive selection of $CD4^+$ cells using CD4 MicroBeads, human (# 130-045-101); autolabeling program CD4.h; separation program "Possel".

2 Select **Save Template**.

3 Allocate a name to the template. In this example the template was saved as "EXPT_2A" (experiment 2a).

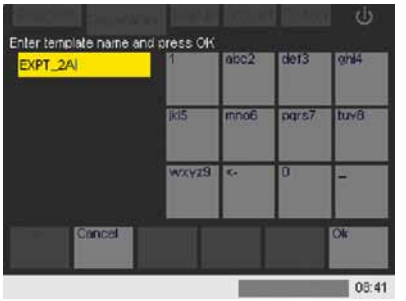


Figure 4.21: Using the alphanumeric keypad assign a name to the template.

4 Select **Ok**.

To load a reagent template:

1 Select **Load Template** from the lower navigation bar. To scroll through the list of saved templates use the navigation arrows ▲/▼. The corresponding template is displayed on the sample template panel.

Figure 4.22: Selecting a separation template. “Expt_2a“ was selected.

2 Select and highlight the desired template; in this case **Expt_2a**.

3 Select **Ok**.

Figure 4.23: The template “Expt_2a“ was successfully loaded.

Note: The sample separation template was loaded; however, the reagent rack has not yet been configured. It is necessary to configure the reagent rack before starting the run.

Figure 4.24: The reagent rack has to be configured before starting the run.

To delete a separation template:

1 Select **Load Template** from the lower navigation bar.

2 Scroll through the list of saved templates use the navigation arrows ▲/▼.

3 Select the template for deletion.

Figure 4.25: "Expt_3" template was selected for deletion.

4 Select **Delete Template**.

4.5 Reagent menu

The **Reagent** menu is used to program any reagent vials that are required for automated magnetic labeling and subsequent cell sorting. Reagents can be entered using the 2D code reader or manually using the **Enter Reagent** input panel. For convenience it is possible to load and save reagent templates. For more information on the Reagent menu please refer to section 6.2.4.

Figure 4.26: The ″Reagent″ menu.

4.6 Log list menu

Figure 4.27: The "Log list" display.

The log list records a complete log of actions performed by the autoMACS Pro Separator. An overview of the log list table follows:

Name	Definition	Name	Definition
Date	Indicates the date the action was performed.	Program	Name of program, for example: **Deplete:** Cell depletion **Possel:** Positive selection **Qrinse:** Quick rinse performed
Type	Description of the action, for example: **Rack:** Action involving rack **Init:** Initiation of instrument **Wash only:** Wash only performed **Service:** Service step performed **Special wash:** Special wash performed	Protocol	If a protocol is associated with the log, its name will be listed under this heading, for example: **CD4.h:** CD4 MicroBeads, human were used for autolabeling and cell separation.
Pos	Corresponding position on sample tube rack.	Status	The status of the log is depicted as follows: ✓ successfully completed ✗ action failed

Table 4.3: Overview of the log list table parameters.

To display further details about an individual log:

1 Select **Log list** tab and highlight a log from the log list.

2 Select **Details**. A detailed view of the program status is shown.

3 Select **Ok** to return to the log list screen or select **Log Details** to view a detailed log of performed actions.

Figure 4.28: Viewing log details. A: A positive selection using CD4 MicroBeads, human, was performed on March, 26th 2009. B: An overview of program actions and corresponding times are displayed. C: Details of each instrument action are listed.

4.7 Option menu

Figure 4.29: The "Option" display.

The **Option** menu allows maintenance procedures, such as exchange of autoMACS Columns or decontamination of the system. The menu is divided into two main categories, **Special** and **User settings**.

An overview of the functions available under each category are given below.

4.7.1 Special

Special options comprise three special programs for column exchange (**Col_ex**), instrument decontamination (**Safe**), and cleaning of the instrument for long-term storage (**Store)**.

Safe

This is a disinfectant procedure which uses MACS Bleach Solution for cleaning and decontamination of the autoMACS Pro Separator. Depending on the level of use and general instrument maintenance, it is recommended to decontaminate the fluidic system every 3 to 6 months using the **Safe** program.

Store

The program **Store** should be applied to prepare the instrument for long-term storage. Upon completion of the **Store** program, the fluidic system contains 70% ethanol.

To store the autoMACS Pro Separator for a period longer than two weeks, the tubing system should be cleaned and the columns should be replaced with column substitutes. The **Store** program automatically performs the cleaning procedure and prompts the user to install column substitutes.

4.7.2 User settings

The **User settings** are for maintenance and setup of the autoMACS Pro Separator. Each program is briefly discussed below.

About

About informs the user about the software version, serial number of the instrument, and other hardware information.

Calibr_1: Performing "calibration 1" of the needle arm positioning

This program is used for the calibration of the needle arm to the washing station and tube racks. Refer to section 11.2 for more information.

Calibr_2: Performing "calibration 2" of the instrument tubing

This program is used for the calibration of the instrument tubing. Refer to section 11.2 for more information.

Check_up: Performing a system check-up

The **Check_up** program allows the user to perform a system check-up. It is recommended to use the program if hardware errors occur. The program starts after highlighting **check_up** and pressing **Run**.

O_bcr: 2D code reader setup, configuration, and initialization

The **O_bcr** program allows the user to setup, configure, and initialize a recently installed autoMACS Pro Separator 2D code reader.

Note: In case of malfunction during cell separation the option ˝O_init˝ must be disabled in order to perform a cell rescue procedure.

O_init: Optional priming of the instrument at startup
By default, the autoMACS Pro Separator does not perform a wash program after initialization. The option **O_init** allows the user to add an initial rinse program that will be performed automatically after each initialization to prime the instrument.

O_led: Activating/deactivating fluid bottle illumination
The autoMACS Pro Separator has a bottle illumination designed to facilitate monitoring the instrument's status. The bottle illumination can be switched ON or OFF

O_progs: Enabling/disabling special separation protocols
The **O_progs** are used to enable or disable special separation programs. To enable or disable these protocols, perform the following steps:

1 Select **Option**, **User settings**, and **O_progs**.

2 Select **Run**. A dialog box will report the current status.

Figure 4.30: "O_progs": Enabling or disabling special separation protocols. Select "Disable" to disable special separation programs.

3 Select **OK** if the current reported status should not be changed. Alternatively, select **Disable** (or **Enable**) to change the status.

Sepcount: Displaying the number of performed separations
The **Sepcount** or **Sep. counter** program is used to display the number of separations that have been on the autoMACS Pro Separator. To view this statistic, perform the following steps:

1 Select **Option**, **User settings**, and **Sepcount**.

2 Select **Run**. A dialog box will report the number of separations.

Figure 4.31: "Sepcount": viewing the number of performed separations.
In this example, no separations have been performed using this instrument.

3 Select **OK** to return to the **Option** menu.

Set_time: Setting the time and date
To set the time and date perform the following steps:

1 Select **Option**, **User settings**, and **Set_time**. Select **Run**.

2 Highlight either the time or date fields by touching the display.

3 Use the keypad to change the date or time accordingly.

4 Select **OK** to return to the **Option** menu. The procedure can be cancelled at anytime by selecting **Cancel**.

Valve_ex: Exchanging the instrument valves
This program is used for valve exchange. Use of this program turns the valve to the exchange position for removal. Valves may require periodical exchange. Refer to section 7.4 for more details.

Materials required

5

This chapter describes the consumables and accessories required for the operation of the autoMACS Pro Separator.

IMPORTANT! Please be advised that the autoMACS Pro Separator is specified for use with MACS MicroBeads, autoMACS Columns, and other genuine Miltenyi Biotec consumables and accessories only. Please only use consumables and accessories recommended by Miltenyi Biotec. Failure to use recommended consumables and accessories may result in inaccurate results, instrument malfunction or damage, premature wear, 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 consumables or accessories.

5.1 Materials required for operation

5.1.1 Buffers and Solutions

For daily operation, the following solutions are required: autoMACS Running Buffer, autoMACS Pro Washing Solution, and storage solution. Solution bottles can be identified by color-code and symbols (table 3.1). For proper operation of the autoMACS Pro Separator, solution bottles must be filled with a minimum volume of 150–200 mL. It is recommended to use ready-to-use MACS Buffers or fresh, filter-sterilized solutions to prevent potential contamination of the tubing system.

Please note that autoMACS Running Buffer contains azide as a preservative. To obtain an azide-free running buffer, prepare a 1:20 dilution using the autoMACS Rinsing Buffer and MACS BSA Stock Solution, e.g., add 10 mL of MACS BSA Stock Solution to 190 mL of autoMACS Rinsing Buffer.

The autoMACS Pro Washing Solution is a filter-sterilized and ready-to-use solution to rinse the fluidic system after any autoMACS Pro cell separation. It contains a detergent that dissolves cell aggregates. It was developed for optimal cleaning of the autoMACS Pro Separator tubing system.

Note: Do not use denatured ethanol (technical ethanol), as the autoMACS Columns are not resistant to oxidative compounds. Use 100% ethanol, analytical reagent grade, without additive.

The storage solution consists of 70% ethanol and has to be prepared from absolute ethanol, p.a. grade, and distilled water.

MACS Bleach Solution is used in combination with the **Safe** program.

Note: Program **Safe** can also be used for decontaminating the autoMACS Pro fluidic system. For special decontamination procedures contact the technical support team for further advice.

Depending on the level of use, it is recommended to run a **Safe** program at least every 3 to 6 months. If material like whole blood or tissue is primarily used, it is recommended to run the **Safe** program once a month.

Buffers & Solutions	Description	Capacity	Order no.
autoMACS Running Buffer	Cell separation buffer, containing azide as preservative	6×1.5 L	130-091-221
autoMACS Rinsing Solution	For rinsing of the autoMACS Pro Separator's fluidic system and preparation of preservative-free cell separation buffer	6×1.45 L	130-091-222
MACS BSA Stock Solution	For preparation of preservative-free cell separation buffer	6×0.75 L	130-091-376
autoMACS Pro Washing Solution	For rinsing of the autoMACS Pro Separator's fluidic system	6×1.5 L	130-092-987
Storage solution	70% v/v ethanol in distilled water (prepared from absolute ethanol, p.a.)		Not available
MACS Bleach Solution	used in combination with "Safe" program	1×1 L	130-093-663

Table 5.1: Buffers and solutions required for operation.

5.1.2 Hardware

autoMACS Columns (5×2 columns) (# 130-021-101)
autoMACS Columns can be used for up to 14 days or 100 separations within these 14 days. Their capacity reaches up to 2×10^8 magnetically labeled cells from up to 4×10^9 nucleated total cells or up to 15 mL of whole blood.

5.2 autoMACS® Pro Separator accessories

Accessory	Description	Order no.
Chill 5 Rack	Chill Rack for 5 mL tubes.	130-092-951
Chill 5 Rack, Box of 3	3×Chill Rack for 5 mL tubes.	130-097-041
Chill 15 Rack	Chill Rack for 5 and 15 mL tubes.	130-092-952
Chill 15 Rack, Box of 3	3×Chill Rack for 5 and 15 mL tubes.	130-097-036
Chill 50 Rack	Chill Rack for 5, 15, and 50 mL tubes.	130-092-953
Chill 50 Rack, Box of 3	3×Chill Rack for 5, 15, and 50 mL tubes.	130-097-037
Chill 5, 15, 50 Rack Set	Set of three Chill Racks	130-097-038
MACS Reagent Rack 4	Accommodates 4 vials of MACS Reagents	130-094-574
Air-Filter Extension Set	Extension tube and hydrophobic air filter for the autoMACS Fluid Bottles	130-091-339
autoMACS Pro Laminar Hood Plate	Metal plate for operating the autoMACS Pro Separator in a laminar flow hood	130-093-246
autoMACS Pro Angle Connector Set	Space-saving angle adaptors for cables connecting to the autoMACS Pro Separator	130-093-245
autoMACS Pro Protection Cover	Protection foil for long-term storage of the autoMACS Pro Separator	130-093-532

Table 5.2: List of accessories for the autoMACS Pro Separator.

For information on spare parts, please refer to section 7.8.

Cell separation using the autoMACS® Pro Separator

6

The following chapter describes how to perform cell separations using the autoMACS® Pro Separator.

IMPORTANT! The autoMACS Pro Separator is intended for research applications only and not for diagnostic or therapeutic use.

6.1 General considerations

The autoMACS Pro Separator can perform fully automated cell separations. This includes all steps of the separation procedure, from cell labeling to sample loading, the separation over autoMACS Columns, and the collection of unlabeled and labeled cell fractions. Cell labeling can be performed manually or using the autolabeling feature of the instrument. The pre-set separation programs of the autoMACS Pro Separator have been developed for optimal separation results, independent from the applied labeling and separation strategy.

6.1.1 Cell labeling strategies

There are two basic approaches for magnetic labeling of cells with MACS MicroBeads: direct and indirect magnetic labeling. For direct labeling, MACS MicroBeads bind directly to a specific cell surface marker protein. For indirect labeling, MACS MicroBeads recognize a primary antibody, its conjugates, or a ligand, binding to a specific cell surface marker protein.

Direct magnetic labeling

Direct labeling with MACS MicroBeads is the fastest way of magnetic labeling. MACS MicroBeads specifically bind to antigens on the cell surface. Only one incubation step is necessary. Direct magnetic labeling requires a minimal number of washing steps and therefore minimizes cell loss. Highly specific cell separation reagents for direct labeling of numerous cell types with MACS MicroBeads are available for human, mouse, rat, and non-human primate cells.

Indirect magnetic labeling

Indirect magnetic labeling is based on a two-step procedure. In a first step, cells are labeled with a primary antibody directed against a cell surface marker. The primary antibody can either be unconjugated, biotinylated, or fluorochrome-conjugated. In a second step, cells are magnetically labeled with MACS MicroBeads, which either bind to the primary antibody or to a molecule conjugated to the primary antibody. Accordingly, magnetic labeling is achieved with Anti-Immunoglobulin MicroBeads, Anti-Biotin MicroBeads, or Anti-Fluorochrome MicroBeads. Indirect labeling can also be performed using a cocktail of primary antibodies to concurrently label a number of unwanted cell types, e.g., for the untouched isolation of target cells.

6.1.2 Cell separation strategies

There are two basic strategies for separating specific cell populations: positive selection and depletion. During positive selection, the target cells are magnetically labeled and collected as the positive fraction. During depletion, the unwanted cells are labeled and depleted from the target cells. The target cells are collected as the negative fraction. Furthermore, sequential sorting allows the performance of two consecutive separations.

Positive selection

Positive selection means that a particular target cell type is magnetically labeled. During separation, the magnetically labeled cells are retained within the column. Unlabeled cells flow through and are collected as the negative fraction. After automated retraction of the magnet, the magnetically labeled target cells are eluted from the autoMACS Column as the positive fraction. Positive selection can be performed after direct or indirect magnetic labeling using various MACS MicroBeads or MicroBead Kits. MACS Whole Blood MicroBeads are specially developed for the positive selection of leukocyte subsets directly from human whole blood or bone marrow.

Depletion

To remove a certain cell type from a mixture of cells, the unwanted cell type is magnetically labeled. During separation, the unwanted labeled cell type is retained within the column. The unlabeled target cells flow through the column and are collected as the negative fraction. After retraction of the magnet the retained cells are eluted from the autoMACS Column.

Untouched isolation
To isolate a particular target cell type in an unlabeled, i.e., untouched form, non target-cells are magnetically labeled and depleted. During separation, the unlabeled target cell type is collected in the flow-through, i.e., the negative fraction. The mixture of magnetically labeled non-target cells is retained within the autoMACS Column and will be eluted at the end of the separation process.

MACS Cell Isolation Kits for untouched isolation contain a cocktail of titrated antibodies and MACS MicroBeads for indirect magnetic labeling. They are the preferred choice if binding of antibodies to the target cells is not desired.

Sequential sorting
A combination of two subsequent separations is applied to isolate cell subsets that can be distinguished from other cell types through their expression of two different markers. This includes cell types for which a specific marker has not been defined.

A Depletion followed by positive selection
This separation strategy is useful, if undesired cells and target cells have one marker of interest, needed for separation, in common. In this case, the target cells cannot be isolated in a single positive selection step. Therefore, the undesired cells expressing the common marker are magnetically labeled *via* antigens distinct from the common marker, and depleted. Cells in the flow-through fraction of the depletion step, including the target cells, are subsequently labeled with MACS MicroBeads that bind to the common marker. Target cells are then isolated by positive selection.

Sophisticated MACS Cell Isolation Kits based on this strategy are available for fast and convenient isolation of specific cell subsets.

B Two subsequent positive selections
Multiparameter sorting with MACS MultiSort MicroBeads allows the performance of two sequential positive selections according to two different markers. Labeling cells with MACS MultiSort MicroBeads specific for the first marker allows the first positive selection. After the separation, the cells are incubated with the MultiSort Release Reagent, which enzymatically removes the MultiSort MicroBeads from the cells. In the next step, the target cells are magnetically labeled with MACS MicroBeads directed against the second marker and again subjected to positive selection.

6.1.3 autoMACS® Pro separation, wash, and maintenance programs

6.1.3.1 Separation programs

The autoMACS® Pro Separator provides a selection of twelve pre-set separation programs. The appropriate program is generally chosen depending on the separation strategy, the target cell frequency, and the level of antigen expression. A decision tree on what cell separation strategy to follow is located on the last page of this chapter (section 6.3).

Positive selection programs:

Possel – Positive selection in standard mode:

- for the isolation of cells with frequencies higher than 5% and normal antigen expression.

Possel_s – Positive selection in sensitive mode:

- for the isolation of cells with frequencies higher than 5% and low antigen expression.
- for the isolation of cells with frequencies higher than 5% and normal antigen expression, if recovery is the highest priority.

Posseld – Positive selection in standard mode I, double-column program:

- for the isolation of cells with frequencies lower than 5% and normal antigen expression, in a small elution volume.

Posseld2 – Positive selection in standard mode II, double-column program:

- for the isolation of cells with frequencies lower than 5% and normal antigen expression, if purity is the highest priority.

Posselds – Positive selection in sensitive mode, double-column program:

- for the isolation of cells with frequencies lower than 5% and low antigen expression.

Posselwb – Special positive selection in special mode, double-column program:

- for the isolation of cell subsets from whole blood; cell samples are automatically diluted with Running Buffer.

Note: When using the program **Posselwb**, the whole blood sample will be diluted to the 3-fold of the starting volume.

Depletion programs:

Deplete – Depletion in standard mode:

- for removal of cells with normal antigen expression, if recovery is the highest priority.
- for untouched isolation with MACS Cell Isolation Kits

Depletes – Depletion in sensitive mode I:

- for removal of cells with normal antigen expression, if purity is the highest priority.
- for removal of cells with low antigen expression
- for untouched isolation with MACS Cell Isolation Kits, if purity is highest priority.

Depl05 – Depletion in sensitive mode II:
- for removal of cells with low antigen expression, special program for very sensitive depletion

Depl025 – Depletion in sensitive mode III:
- for removal of cells with low antigen expression, special program for very sensitive depletion

A_Depl07 – Depletion in standard mode *via* loading of sample in separate 1 mL stages:
- for removal of cells with normal antigen expression, if recovery is the highest priority. This special program is disabled by default. To enable **A_Depl07**, select **Option**, **User settings**, and **O_progs**.

A_Depls7 – Depletion in sensitive mode *via* loading of sample in separate 1 mL stages:
- for removal of cells with low antigen expression, if purity is the highest priority. This special program is disabled by default. To enable **A_Depls7**, select **Option**, **User settings**, and **O_progs**.

During programs **Possel** and **Possel_s**, the magnetically labeled target cells are retained in the autoMACS Column 1. The unlabeled cells are released, as the negative fraction, into the negative fraction collection tube, i.e., row "B" of the tube rack. After automated retraction of the magnet, the magnetically labeled cells are eluted, as the positive fraction, into the positive fraction collection tube, i.e., row "C" of the tube rack.

During double-positive selection programs **Posseld**, **Posseld2**, **Posselds**, and **Posselwb**, the magnetically labeled target cells are first retained in the autoMACS Column 1. The negative fraction containing the non-labeled cells is retrieved in the negative fraction collection tube, i.e., row "B" of the tube rack. Then, the magnetically labeled cells are held in a reservoir and loaded onto the autoMACS Column 2. Again, the unlabeled cells are released into the negative fraction collection tube, i.e., row "B" of the tube rack. Finally, the magnetically labeled cells are eluted into the positive fraction collection tube, i.e., row "C" of the tube rack.

When running any depletion program, the magnetically labeled non-target cells are retained in the autoMACS Column 1. The non-labeled target cells pass through the column and are released into the negative fraction collection tube, i.e., row "B" of the tube rack. The magnetically labeled fraction, containing the unwanted cells, is eluted into the positive fraction collection tube, i.e., row "C" of the tube rack.

Program	Volume of non-labeled fraction (i.e. negative fraction)	Volume of labeled fraction (i.e. positive fraction)	Loading rate
Possel	2 mL + sample volume	2 mL	4 mL/min
Possel_s	2 mL + sample volume	2 mL	1 mL/min
Posseld	2 mL + sample volume	0.5 mL	4 mL/min (column 1) 1 mL/min (column 2)
Posseld2	2 mL + sample volume	2 mL	4 mL/min (columns 1 and 2)
Posselds	2 mL + sample volume	2 mL	1 mL/min (columns 1 and 2)
Posselwb[§]	2 mL + 3× sample volume (predilution)	2 mL	4 mL/min (columns 1 and 2)
Deplete	2 mL + sample volume	2 mL	4 mL/min
Depletes	2 mL + sample volume	2 mL	1 mL/min
Depl05	2 mL + sample volume	2 mL	0.5 mL/min
Depl025	2 mL + sample volume	2 mL	0.25 mL/min
A_Depl07*	3 mL per 1 mL sample volume	2 mL per 1 mL sample volume	4 mL/min
A_Depls7*	3 mL per 1 mL sample volume	2 mL per 1 mL sample volume	1 mL/min

* This program must only be used with manual labeling.
[§] Predilution 3-fold of the sample volume.

Table 6.1: Output volumes and loading rates of separation programs.

6.1.3.2 Wash and maintenance programs

The autoMACS® Pro Separator is equipped with reusable autoMACS Columns. Therefore, after each cell separation, a thorough washing procedure rinses the columns of the autoMACS Pro Separator. After the wash program is completed, columns and tubing system are filled with Running Buffer. Moreover, there are obligatory and optional wash programs, which have to be performed daily or at times to ensure proper operation and maintenance of the instrument. Please find below a list of the available wash and maintenance programs.

Note: The autoMACS Pro Separator will not start a separation program before a wash program has been completed.

Wash programs

Qrinse is the standard short wash program that only uses Running Buffer. It is recommended to use this program between separations of cells with normal frequency.

Rinse is an extensive rinsing program that uses Washing Solution and Running Buffer. It is recommended to use this program between separations of rare cells, e.g., stem cells, the separation of cells from different species, and is mandatory between whole blood separations.

Clean is an optional, very extensive rinsing program that uses storage solution, Washing Solution, and Running Buffer. It may be used after whole blood and bone marrow applications.

Sleep is mandatory as the last wash program before overnight storage. Upon completion of this program, the fluidic system contains 70% ethanol.

Maintenance programs

Safe is designed for decontamination of the fluidic system. For details, refer to section 7. Upon completion of this program, the fluidic system contains Running Buffer. The program includes an exchange of autoMACS Columns.

Store should be applied to prepare the instrument for long-term storage. Upon completion of this program, the fluidic system contains 70% ethanol. For details, refer to section 7.

Col_ex is used for column exchange. Upon completion of the **Col_ex** program, the fluidic system contains Running Buffer.

Program	Washing Solution	Running Buffer	Storage solution	MACS Bleach Solution	Time
Qrinse	–	48 mL	–	–	1.5 min
Rinse	96 mL	48 mL	–	–	4 min
Clean	96 mL	48 mL	48 mL	–	7 min
Sleep	96 mL	–	48 mL	–	5 min
Safe	96 mL	96 mL		40	21 min*§
Store	96 mL	–	96 mL	–	8 min*
Col_ex	96 mL	96 mL	–	–	6 min*

* Not including the time required for column exchange.
§ Not including the time required for disconnecting and reconnecting bottle tubing.

Table 6.2: Liquid usage and time of wash and maintenance programs.

6.2 Experimental considerations

6.2.1 Preparation of samples

In order to obtain optimal separation results, some crucial points must be considered regarding sample preparation.

6.2.1.1 Prepare single-cell suspensions

Cell aggregates may contain mixtures of target and non-target cells and therefore can impair the separation results. MACS Separation Buffer/MACS Running Buffer should be used during sample handling steps to minimize the risk of cell aggregation. Resuspend cells carefully after centrifugation.

Moreover, large cell aggregates may interfere with the separation process and may cause pressure variations in the autoMACS Pro fluidic system. It is recommended to use Pre-Separation Filters, 30 µm (# 130-041-407) or Pre-Separation Filters, 70 µm (# 130-095-823) to remove cell clumps that may clog the column.

Dead cells and cell debris may bind non-specific to MACS MicroBeads, antibodies, and antibody conjugates. To remove dead cells, it is recommended to use density gradient centrifugation or the Dead Cell Removal Kit (# 130-090-101).

For specific recommendations on the preparation of single-cell suspensions, please refer to the respective Cell Separation Reagent data sheet.

6.2.1.2 Adjusting sample volumes

Typically, 1×10^7 cells are resuspended in 80 µL of buffer and labeled with 20 µL of MicroBeads, leading to a total labeling volume of 100 µL. When working with higher cell numbers, scale-up all reagent volumes and total volumes accordingly. For example, for 2×10^7 total cells use twice the volume of all indicated reagent volumes and total volumes indicated in the respective data sheet. When working with fewer than 1×10^7 cells, do NOT scale down the volumes, but use the same volumes as indicated.

In the table below, the dilution volumes account for the first step of labeling. For manual labeling, please refer to the respective Cell Separation Reagent data sheet for ongoing procedures. Minimal and maximal volumes and total cell numbers in table 6.3 account for autolabeling samples only. Autolabeling protocols are being continually developed and optimized by Miltenyi Biotec. For a current list of Cell Separation Reagents that are optimized for cell separations with the autoMACS Pro Separator autolabeling feature, please contact Technical Support.

Cell Separation Reagent	Strategy	Number of Reagents	Dilution volume	autolabeling			
				Minimal volume*	Minimal total cell number	Maximal volume	Maximal total cell number
Chill 5 Rack[1]							
Direct MicroBeads human, rat, non-human primate	Positive selection or depletion	1	10^7 cells per 80 µL	160 µL	2×10^7	1600 µL	2×10^8
Direct MicroBeads, mouse	Positive selection or depletion	1	10^7 cells per 90 µL	180 µL	2×10^7	1800 µL	2×10^8
Whole Blood MicroBeads	Whole blood or bone marrow	1	Original volume	0.25 mL		1 mL	
Cell Isolation Kits	Untouched isolation	2	10^7 cells per 40 µL	160 µL	4×10^7	1600 µL	4×10^8
Cell Isolation Kits	Untouched isolation	3	10^7 cells per 30 µL	120 µL	4×10^7	1200 µL	4×10^8
MicroBead Kits	Positive selection or depletion	2	10^7 cells per 60 µL	120 µL	2×10^7	1200 µL	2×10^8
Chill 15 Rack[2]							
Direct MicroBeads human, rat, non-human primate	Positive selection or depletion	1	10^7 cells per 80 µL	160 µL	2×10^7	5200 µL	6.5×10^8
Direct MicroBeads, mouse	Positive selection or depletion	1	10^7 cells per 90 µL	180 µL	2×10^7	5850 µL	6.5×10^8
Whole Blood MicroBeads	Whole blood or bone marrow	1	Original volume	1 mL		4 mL	
Cell Isolation Kits	Untouched isolation	2	10^7 cells per 40 µL	160 µL	4×10^7	5200 µL	1.3×10^9
Cell Isolation Kits	Untouched isolation	3	10^7 cells per 30 µL	120 µL	4×10^7	5850 µL	1.3×10^9
MicroBead Kits	Positive selection or depletion	2	10^7 cells per 60 µL	120 µL	2×10^7	5850 µL	6.5×10^8
Chill 50 Rack[3]							
Whole Blood MicroBeads	Whole blood or bone marrow	1	Original volume	4 mL		8 mL	

[1] Max. number of samples: 6; min. first incubation volume: 0,2 mL; max. final labeling volume: 2 mL
[2] Max. number of samples: 5; min. first incubation volume: 0,2 mL; max. final labeling volume: 6,5 mL
[3] Max. number of samples: 3; min. first incubation volume: 4 mL; max. final labeling volume: 8 mL.
*When working with fewer cells than the necessary minimal volume, resuspend cells in the stipulated minimal volume.

Table 6.3: Dilution volumes for the first labeling step and MACS Chill Rack specifications for **autolabeling**, including minimal and maximal volumes and cell numbers.

6.2.2 Select appropriate tube rack

Three different tube racks are available for processing sample volumes between 0.2 mL and 50 mL. Unless otherwise specifically indicated in the Cell Separation Reagent data sheet, the magnetically labeled cell samples are resuspended at 10^8 total cells per 500 µL when using manual labeling. The cell numbers and volumes for autolabeling are slightly different. Refer to table 6.3 for further details.

Regarding the tube positioning of the chill racks, please note that:

- **Row ″A″ of the chill rack holds the sample tubes.**
- **Row ″B″ of the chill rack holds the tubes for the non-labeled fractions (negative fractions).**
- **Row ″C″ of the chill rack holds the tubes for labeled fractions (positive fractions).**

1 Select the appropriate tube rack according to table 6.4.

2 (Recommended) Cool down the tube rack for 3–4 hours in a refrigerator (2–8 °C) or until the coolant becomes solid. Do not cool below 0 °C as samples may freeze.

3 Equip the tube rack with sample tubes and fraction collection tubes.

Rack type and symbol	Slots	Maximal number of samples	Manual labeling	Autolabeling	
			Maximal sample volume	Minimal first incubation volume	Maximal final labeling volume
Chill 5 	24×5 mL	6 (5 mL tubes)	2.5 mL	0.2 mL 0.25 mL*	2.0 mL 1 mL*
Chill 15 	15×15 mL 5×5 mL	5 (15 mL tubes)	12.5 mL	0.2 mL 1 mL*	6.5 mL 4 mL*
Chill 50 	6×50 mL 3×15 mL 3×5 mL	3 (50 mL tubes)	50 mL	4 mL*	8 mL*

* Volumes refer to whole blood samles, only.

Table 6.4: MACS Chill rack specifications for manual labeling and autolabeling. For further details on samples volumes for autolabeling, refer to table 6.3.

6.2.3 Prime the autoMACS® Pro Separator

Note: It is assumed that the MACS MiniSampler has been already installed, the waste bottle is empty, and that all fluid bottles are filled with recommended solutions (refer to section 3 for more details).

1 Switch ON the autoMACS® Pro Separator and wait for the instrument to complete initialization.

2 After initialization, the autoMACS Pro Separator will display the **Status** menu. For more details on the **Status** menu, please refer to section 4.3.

1 Sample status
2 Fluid bottle filling status
3 Column status
4 Tube rack status
5 MiniSampler status

Figure 6.1: Overview of the instrument's status panel.

Note: 70% ethanol does not contain electrolytes. Therefore, the fluid level cannot be determined and the symbol for the storage solution bottle is always gray. Please ensure that the volume of each solution is sufficient for the number of separation and washing programs to be performed.

3 Ensure that the symbols for the fluid bottles are colored green. If they are red, check whether the fluid bottles are filled, the waste bottle is empty, and the color-coded bottle sensors are connected to the appropriate bottle. If symbols are gray, check the bottle sensors for proper connection.

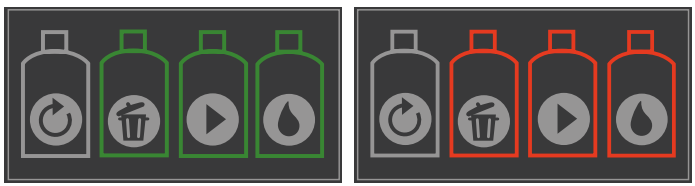


Figure 6.2: Fluid bottle status symbols. Left: Fluid bottles are ready. Right: Fluid bottles need to be replaced.

Note: The autoMACS Pro Separator automatically records the date of the last column exchange and displays the date for column replacement only if the column exchange program **Col_ex** has been used for column installation.

4 Ensure that the symbol for the columns is colored green. For more details refer to section 4.3.2. If the symbol for the columns is red, the columns must be exchanged. The fill level on the symbol is an indicator for the remaining operation-life of the columns.

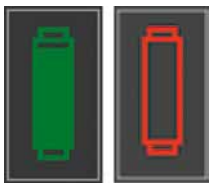


Figure 6.3: The column status graphic. Left: The columns are ready. Right: The columns must be changed.

5 Ensure that the MACS MiniSampler is installed correctly. For more details concerning correct installation of the MACS MiniSampler refer to section 3.

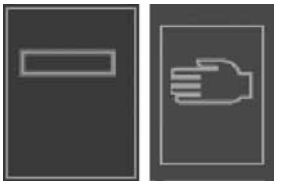


Figure 6.4: MACS MiniSampler status graphic. Left: The MiniSampler was successfully installed. Right: No MiniSampler was detected.

6 The autoMACS Pro Separator is now ready for priming. Select **Separation** and **Wash Now** from the lower navigation bar.

Note: If priming of the instrument has not been performed, the autoMACS Pro Separator will automatically ask to run a **Rinse** program before starting the separation. The process can be monitored in the **Status** menu. At this point, the fluid bottles are illuminated yellow.

It is possible to include an initial **Rinse** program that will be performed automatically upon switching ON the instrument. The setting of this option is described in section 4.7. **O_init**: Optional priming of the instrument at startup.

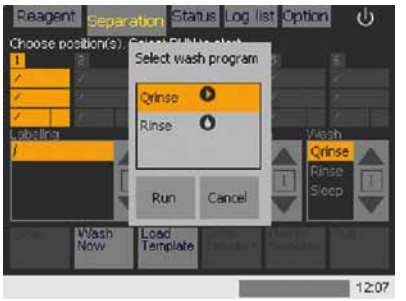


Figure 6.5: The "Wash Now" command displays two options: "Qrinse", for a quick rinse, and "Rinse". A full rinse is required for instrument priming.

7 Select **Rinse** and **Run**.

6.2.4 Labeling of cells

Cells can be labeled manually with MACS MicroBeads. For detailed information on manual labeling, please refer to the Cell Separation Reagent data sheet. Autolabeling may be performed prior to cell separation. Miltenyi Biotec continually develops and optimizes autolabeling protocols. For a list of Cell Separation Reagents optimized for autolabeling, please contact Miltenyi Biotec Technical Support.

6.2.4.1 Entry of reagents for autolabeling

Note: For autolabeling the reagent rack configuration must be programmed using the **Reagent** tab menu. Refer to section 4.5 for an overview of the **Reagent** tabbed menu.

The **Reagent** menu is used to program any reagent vials that are required for automated magnetic labeling and subsequent cell sorting. Reagents can be entered using the 2D code reader or manually using the **Enter Reagent** input panel.

Figure 6.6: The "Reagent" menu is displayed.

Entry of reagents with 2D code reader

1 Select **Reagent** tab and highlight the position where the vial will be placed in the reagent rack. Four positions are available: **R1**, **R2**, **R3**, and **R4**.

Figure 6.7: Position "R1" was selected for the reagent vial.

Note: If the reagent vial cannot be identified by the 2D code reader please enter the reagent information manually; refer to "Entering reagents manually" below.

2 Activate the reader by selecting **Read Reagent** and present a reagent vial in front of the 2D code reader. Ensure the 2D code is facing the blinking code reader–light. The optimal reading distance is 0.5–2.5 cm from the code reader-cover, tilt the vial as depicted in figure 6.8.

Figure 6.8: Scanning a reagent vial using the 2D code reader.
In this example, the vial "CD4 MicroBeads, human" was scanned.

3 The vial is automatically recognized by the software. The next reagent rack position **R2** will be automatically highlighted.

Figure 6.9: CD4 MicroBeads, human (# 130-045-101) was identified by the 2D code reader software and assigned to the reagent rack position "R1".

4 Using the same procedure another reagent vial can be scanned using the 2D code reader. The reagent rack position **R3** is automatically assigned. Having entered the desired reagent(s), assign MicroBead reagent vials to positions on the MACS Reagent Rack. Click the **Separation** tab to proceed with programming a cell separation (refer to section 6.2.5).

Manual entry of reagents

1 Select **Reagent** tab and highlight the position where the vial will be placed on the reagent rack. Four positions are available: **R1**, **R2**, **R3**, and **R4**.

Figure 6.10: Position "R2" was selected for the reagent vial.

2 Select **Enter Reagent** from the lower navigation bar. Enter the reagent-specific product order number. The order number is located on the product data sheet. In the event that the data sheet is misplaced, visit www.miltenyibiotec.com to download a printable PDF of the document.

Figure 6.11: Reagent information is manually entered using the reagent order number.

3 Select **Ok**.

4 If a correct number is inserted the software will immediately recognize the reagent or kit. To confirm, select the reagent from the list by using the touch screen.

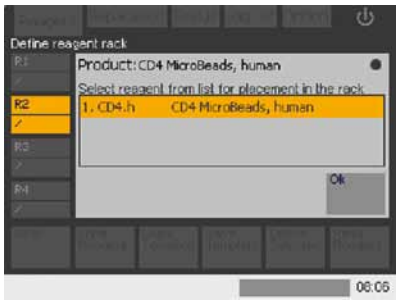


Figure 6.12: CD4 MicroBeads, human (# 130-045-101) was manually entered.

5 Select **Ok** to confirm the identified reagent and reagent vial position “R2“.

Figure 6.13: Reagent vial "CD4 MicroBeads, human" was assigned to the reagent rack position "R2".

6.2.4.2 Deleting reagents or reagent lists

In this example the following reagents were scanned and assigned to the following reagent rack positions:

- **R1**: FcR Blocking Reagent, human (component 1/3 of product Monocyte Isolation Kit II, human; # 130-091-153)
- **R2**: Monocyte Antibody Cocktail , human (component 2/3 of product Monocyte Isolation Kit II, human; # 130-091-153)
- **R3**: Anti-Biotin MicroBeads (component 3/3 of product Monocyte Isolation Kit II, human; # 130-091-153)
- **R4**: CD4 MicroBeads, human (# 130-045-101)

Deleting an individual reagent from the reagent rack lists

1 Select the reagent name that must be deleted. In this example CD4 MicroBeads, human on position **R4** must be removed.

2 Select **Delete Selected** to remove the highlighted reagent.

Figure 6.14: CD4 MicroBeads, human, assigned to reagent rack position "R4", was selected for deletion.

Deleting the entire reagent list

1 Select an unassigned position on the reagent rack. In this example position **R4** was selected. (If there are no unassigned positions, delete an individual reagent as described above).

Figure 6.15: To delete all reagents from the reagent rack, the unassigned position "R4" was selected.

2 Select **Delete All**.

6.2.4.3 Working with reagent templates

For convenience it is possible to load and save reagent templates. In this example the following reagents were scanned into the following reagent rack positions:

- **R1**: CD4 MicroBeads, human (# 130-045-101)
- **R2**: CD8a (Ly-2) MicroBeads, mouse (# 130-049-401)
- **R3**: No reagent
- **R4**: No reagent

Saving a reagent template

1 Assign reagent vials to reagent rack positions as outlined above (refer to section 6.2.4.1).

Figure 6.16: Using the 2D code reader, two reagent vials were assigned to the reagent rack positions "R1" and "R2".

2 Select **Save Template**.

3 Allocate a name to the template. In this example the template was saved as "EXPT_2" (experiment 2)

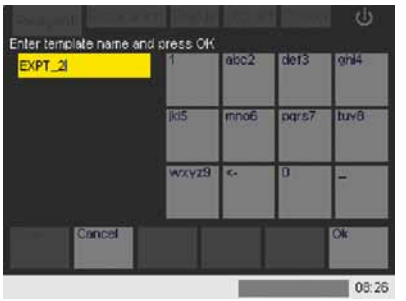


Figure 6.17: Using the alphanumeric keypad assign a name to the template.

4 Select **Ok**.

Loading a reagent template

1 Select **Load Template** from the lower navigation bar. To scroll through the list of saved templates use the navigation arrows ▲/▼. The corresponding template is displayed in the adjacent panel.

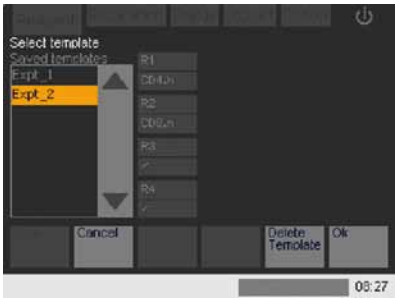


Figure 6.18: Selecting a reagent template. Expt_2 was selected which comprises CD4.h and CD8.m on rack positions "R1" and "R2", respectively.

2 Select and highlight the desired template, in this case "Expt_2".

3 Select **Ok**.

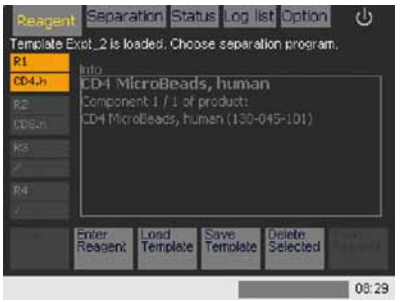


Figure 6.19: The template "Expt_2" was successfully loaded.

Deleting a reagent template

1 Select **Load Template** from the lower navigation bar.

2 Scroll through the list of saved templates using the navigation arrows ▲/▼.

3 Select the template for deletion.

4 Select **Delete Template**.

6.2.5 Cell separation

6.2.5.1 Cell separation after autolabeling

It is an option to use the autolabeling feature to label cells with MACS MicroBeads. After entering the desired reagent(s) in the **Reagent** menu, assign the MicroBead reagent vials to the respective positions in the MACS Reagent Rack and go to the **Separation** menu.

Note: To obtain brief information on the separation and wash programs, highlight the program of interest and press the information button located between the arrows. A pop-up window will be displayed. Alternatively, refer to sections 4.4 and 6.1.3 for more information on the **Separation** menu and separation programs.

Figure 6.20: A reagent vial containing CD4 MicroBeads, human was placed into the Reagent Rack position "R1".

1 In the **Separation** menu, select the desired position(s) in the sample rack template field by touching it.

2 Assign a reagent for autolabeling from the **Labeling** submenu to each position. The recommended separation and wash programs will be automatically displayed in the **Separation** menu.

3 Optional: The pre-selected separation and wash programs can be changed in the corresponding submenus.

4 To assign a sample volume click on the **Volume** submenu and enter the corresponding value using the numeric keypad. Select **Enter**.

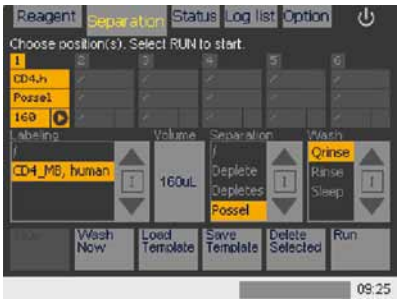


Figure 6.21: Performing a cell separation with CD4 MicroBeads, human using the autolabeling feature. The cell separation program "Possel" and wash program "Qrinse" were selected.

5 Select **Run**.

6.2.5.2 Cell separation after manual labeling

After completing the priming process or a wash program, the autoMACS® Pro Separator is ready for separation. The status of the instrument is displayed in the **Status** menu. The fluid bottles are illuminated green. Select the **Separation** menu.

Note: "/" option under **Labeling** denotes that NO autolabeling will be performed.
Only a cell separation will be performed; manual magnetic labeling must be performed prior to placing the sample in the Chill Rack.

1 Select the desired position(s) in the sample rack template field by touching it.

2 Select "/" from the **Labeling** submenu for manual labeling.

3 Optional: It is not mandatory to assign a volume for manually labeled samples. However, the autoMACS Pro Separator requires this information to calculate and display the total sample processing time. Enter the sample volume in the **Volume** submenu using the numeric keypad. Select **Enter**.

Note: If the **Clean** program has been enabled, it will also appear in the **Wash** submenu.

4 Select a separation program and a washing program for each sample position. The selected programs will be displayed in the programming field.

Fig. 6.22: Performing a cell separation after manual labeling with CD4 MicroBeads, human. The cell separation program "Possel" and wash program "Qrinse" were selected.

5 Optional: autolabeling and manual labeling can be assigned in parallel to two independent samples. To assign a reagent for autolabeling to a sample, select the position of interest in the sample rack template field and assign the respective reagent from the Labeling submenu. Note: The reagent has to be entered in the Reagent menu to be displayed in the Labeling submenu.

6 Optional: Templates can be saved by selecting **Save template** from the lower navigation bar. Follow the prompt to enter a template name.

7 Select **Ok** and **Run**.

To select a particular sample position in the programming field, touch it once. To deselect it, touch it once again.

If the same combination of separation program and washing program is required for more than one sample, highlight all the desired sample positions first and then select the programs. Alternatively, define the program combination for one position and then highlight the other desired positions to adopt the program combination.

To erase selected program combinations from the programming field, first mark the respective positions and choose **Delete selected** from the lower navigation bar. If positions are not marked, the button can be used to delete the entire template. In this case, the option **Delete selected** will switch to **Delete all**.

Alternatively, start the separation from a previously saved separation template.

1 Select **Load template** from the lower navigation bar.

2 Select the desired template by using the arrows.

3 Select **OK**.

4 Select **Run** to start the separation..

5 Check that there is enough buffer for the number of programmed separations as instructed by a pop-up dialog box. Click **Continue** to proceed.

Note: The touchscreen displays the type of tube rack upon starting the separation.

The autoMACS Pro Separator automatically detects the type of tube rack in use and allows the user to utilize only the number of samples and sample positions the tube rack can handle. If the tube rack does not match the template definition, a warning screen will be displayed upon starting the separation.

6.2.5.3 Example of application: entry of sample separation instructions

The purpose of the following example is to demonstrate how sample processing conditions can be easily modified and to clarify the differences between autolabeling and manual labeling. Alternatively, each sample could be programmed individually.

Two samples were placed in positions 1 and 2 of a Chill 15 Rack. Sample 1 was already manually labeled using CD4 MicroBeads, human. Sample 2 has not yet been labeled; the autoMACS Pro Separator will perform autolabeling using CD4 MicroBeads, human. For further details on using the **Reagent** menu, please refer to section 4.5.

1 Highlight sample positions 1 and 2 on the sample template.

Figure 6.23: Sample positions 1 and 2 were selected.

2 Select **CD4_MB.human** under the **Labeling** submenu. By default the software selects the separation program **Possel** and the wash program **Qrinse**.

Figure 6.24: The current display indicates that autolabeling will be performed on both samples.

3 Select the **Volume** submenu to enter the required sample volume. Select **Enter.**

For this experiment a minimal starting volume of 160 µL is required for autolabeling (for autolabeling with CD4 MicroBeads 40 µL MicroBeads are added to the entire 160 µL sample volume). For details, please refer to the data sheet.

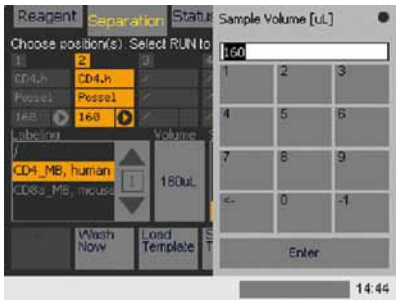


Figure 6.25: A volume of 160 µL was entered for both sample positions.

4 Optional: If a change of the pre-set wash program is necessary, e.g., when working with rare cells, highlight the wash program to be performed before cell separation. In this case the program was not changed and **Qrinse** stayed selected.

Figure 6.26: Qrinse was selected as a wash program.

Note: If the **Clean** program has been enabled, it will also appear in the **Wash** submenu.

Note: The **Sleep** program can only be selected as the last step in the program sequence.

5 The sample in position 1 was manually labeled with CD4 MicroBeads and therefore must be setup for a cell separation without autolabeling. Deselect sample position 2 by touching the display at this position. Only sample position 1 is now highlighted.

Figure 6.27: Only sample position 1 is selected.

6 Deselect autolabeling for sample 1 by selecting "/" in the **Labeling** submenu. Change the sample volume as recommended in the data sheet. After manual labeling it is recommended to dilute cells to a volume of 500 µL per 10^8 total cells. For further information, please refer to the corresponding data sheet.

Figure 6.28: The separation program "Possel" was selected for sample 1.

7 View and recheck the sample setup.

8 Select **Run** to start.

9 Check buffer levels as instructed by a pop-up dialog box. Click **Continue** to proceed.

10 It is recommended to monitor the process from the **Status** menu. Click the **Status** menu.

Figure 6.29: Sample processing is underway as instructed.

6.2.5.4 Monitoring the cell separation process

The autoMACS Pro Separator is a sensor-controlled instrument that allows easy monitoring during operation.

6.2.5.4.1 Status menu before separation

Refer to section 4.3 for an overview of how to monitor the instrument status using the **Status** menu prior to performing a cell separation. However, a brief summary is included below.

Status of fluid bottles

The status of fluid bottles is indicated by color-coded graphic symbols and by a text table.

Bottle	Symbol	Symbol color and user action
Running Buffer		Green: no action required Red: refill bottle Gray: connect bottle sensor
Washing Solution		Green: no action required Red: refill bottle Gray: connect bottle sensor
Storage solution		Gray: no liquid detection; visually check volume
Waste		Green: no action required Red: empty waste Gray: connect bottle sensor

Table 6.5: Status of fluid bottles displayed in the “Status“ menu.

Column status
If the column symbol is green, no action is required. If the symbol is red, the columns must be exchanged. The level of the green fill on the column symbol indicates the remaining service-life of the autoMACS Columns.

Rack detection
Rack detection only occurs upon starting the separation process.

MACS MiniSampler detection
If the MACS MiniSampler has been detected correctly a rectangular symbol is displayed. If it has not been detected a hand symbol will be displayed in the same field.

6.2.5.4.2 Status menu during the separation process

It is recommended to monitor the instrument's status during cell separation using the **Status** menu. Programs yet to be processed appear in yellow fields. Programs currently undergoing autolabeling appear in lilac. Programs in progress in which no autolabeling is being performed switch to orange; completed programs switch to white. The current action is always displayed in the status bar located below the lower navigation bar. The status bar also displays the overall progress in minutes (min).

Figure 6.30: Monitoring the status during cell separation. Sample processing at position 1 is completed (white color). Sample at position 2 has finished the separation and is now performing a Rinse.

Note: Interrupting the process after labeling will prolong the incubation period.

Interrupting cell separation
The cell separation process can be paused at any time from all menu screens by selecting **Stop**.

1 From any menu screen, select **Stop**. The autoMACS Pro Separator will then immediately stop operation and will display a pop-up warning screen from which the current program can be continued or canceled.

Figure 6.31: Select "Stop" to pause cell separation. To continue cell separation select "Continue". To cancel the entire procedure, select "Cancel".

2 Select **Cancel** to cancel the procedure. Alternatively, select **Continue** to carry on with cell separation.

Figure 6.32: The process has been cancelled.

Fluid Bottle illumination

The autoMACS Pro Separator has a fluid bottle illumination that facilitates monitoring of the instrument's status. The table below summarizes the color code of the fluid bottle illumination and the respective user action required.

Code	Status	User action
Green	Ready for separation	No action required
Blue	Instrument operating	No action required
Yellow	Not ready for separation	Run wash program ("Rinse" or "Qrinse") before starting a separation
Red	Error	Check screen for error detection
Purple	Program "Sleep" is completed	Switch OFF autoMACS Pro Separator
Blinking	Action required	Check screen for required action

Table 6.6: Various fluid bottle illumination statuses.

The fluid bottle illumination can be switched ON/OFF.

1 Select the **Option** menu and **User settings**.

2 Highlight **O_led** and press **Run**. The fluid bottle illumination can now be enabled or disabled.

6.2.6 Shut down of the instrument

6.2.6.1 Sleep program for regular use

Note: If **Sleep** is chosen as a wash program, the autoMACS Pro Separator will not allow definition of any programs beyond this position.

The autoMACS Pro Separator automatically performs the **Sleep** program if the device is inactive for more than six hours.

Ensure enough Storage Solution is available.

1 Combine a separation program and the **Sleep** program for the last position in the programming field.

2 Upon completion of the **Sleep** program, switch OFF the autoMACS® Pro Separator using the main power switch.

6.2.6.2 Store program for long-term storage

To store the autoMACS Pro Separator for a period longer than two weeks, the tubing system should be cleaned and the columns should be replaced with column substitutes. The **Store** program automatically performs the cleaning procedure and prompts the user to install column substitutes.

1 Select **Option** and **Special**.

2 Select **Store** and press **Run**. The system will be rinsed automatically.

Figure 6.33: Running the “Store“ program.

3 Install the column substitutes (refer to section 3.3.4 for details on column exchange).

4 Select **Done**.

5 Switch OFF the autoMACS Pro Separator using the main power switch.

6.2.6.3 Shutdown button

1 Press the shutdown button on the upper right hand corner of the screen (⏻).

2 Select **Yes** from the pop-up dialog box.

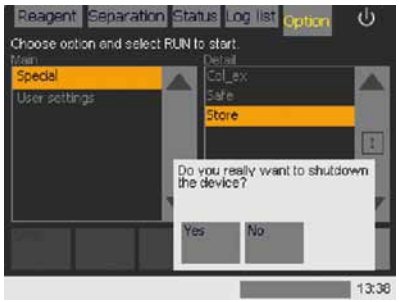
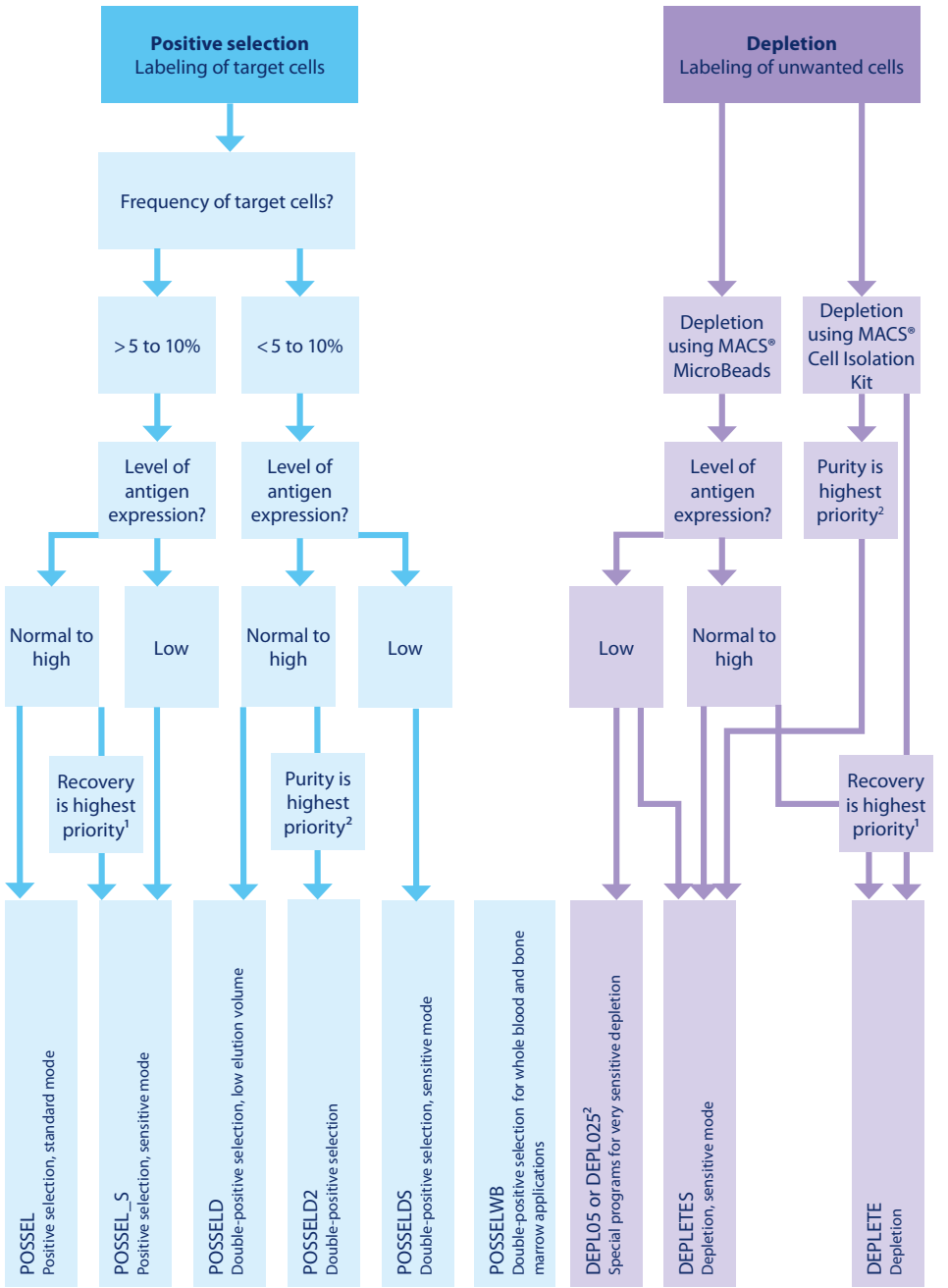


Figure 6.34: Shutting down the autoMACS Pro Separator.

3 The autoMACS Pro Separator will automatically perform a **Sleep** program.

4 Upon completion of the **Sleep** program, you will be prompted to shut down the instrument. The fluid bottle illumination is purple at this point. Switch OFF the autoMACS Pro Separator by using the main power switch.

6.3 Decision tree for the optimal separation program



[1]Purity will slightly decrease
[2]Recovery will slightly decrease

Maintenance

7

Appropriate maintenance of the autoMACS Pro Separator helps to maintain excellent reproducibility of the cell separation results. The following section gives you an overview on the procedures required for efficient maintenance of the instrument.

NOTICE! Insufficient or improper maintenance of your autoMACS Pro Separator can cause unpredictable results, avoidable malfunction and premature failure of the instrument, and may void your warranty.

NOTICE! Please do not perform any maintenance procedures other than specifically described in this user manual. Any other maintenance procedures must be performed by qualified service personnel.

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

NOTICE! When replacement or spare parts are required for maintenance, only use genuine Miltenyi Biotec parts or third-party parts specified and recommended by Miltenyi Biotec. Using unauthorized replacement or spare parts can cause malfunction of the instrument and impair cell separation results. Miltenyi Biotec does not honor any warranty or accept any responsibility for instrument failure or damages resulting from the use of inappropriate replacement or spare parts.

WARNING! During a maintenance procedure, potentially contaminated liquid may spill out of the orifice of the washing station and the tubing. Therefore, wear protective gloves, protective clothing, and safety glasses to avoid contact with skin and eyes. Dispose used gloves and clothing appropriately.

Note: Do not use a dishwasher to clean and do not autoclave any of the removable parts unless indicated otherwise.

7.1 General considerations

Please consider that the sample quality has a significant influence on the system's performance. It is crucial to use single-cell suspensions for cell separation. Furthermore, dead cells and other small particles potentially derived from the sample preparation should be removed prior to cell separation. For further information on sample preparation, refer to section 6.2.1.

7.2 Daily maintenance

The following maintenance procedures must be performed on a daily basis. If the instrument is not to be used for an extended period of time the store procedure must be performed; refer to 7.2.3 for further details.

Note: In case of malfunction during cell separation the **O_init** program must be disabled in order to perform a cell rescue procedure.

The instrument automatically prompts the user to perform a rinse before performing a cell separation.

7.2.1 Instrument priming

A rinse program must be performed before performing the first cell separation after the instrument has been switched ON.

Performing an instrument rinse

1 Click the **Separation** menu and **Wash Now** from lower menu bar.

2 Select **Rinse**.

3 Click **Run**.

O_init: Optional priming of the instrument at startup

By using the **O_init** program, the instrument can be instructed to perform an automated rinse sequence at startup. The **Rinse** program is used for efficient washing and equilibration of the fluidic system.

1 Select **Option**, **User settings**, and **O_init**. Press **Run**.

2 Follow the prompt on the screen to enable or disable the initial wash.

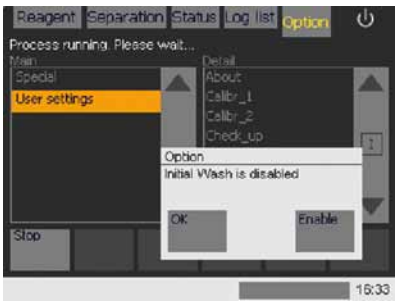


Figure 7.1: Initial wash program is used to activate or deactivate an automatic instrument prime on instrument startup.

Note: To prevent the formation of salt deposits, wipe the outlet ports with a tissue soaked with distilled (or deionized) water before each **Sleep** program.

7.2.2 Clean uptake/outlet ports

It is recommended to clean uptake and outlets daily. This should be performed before running the **Sleep** program (shutdown).

1 Switch OFF the instrument.

2 The ports can be wiped with tissue soaked with 70% ethanol, isopropyl alcohol, or MACS Bleach Solution followed by distilled or deionized water.

3 Remove the finger-guard that is attached underneath the outlet port holder by pulling gently. Clean the finger guard as described for the ports.

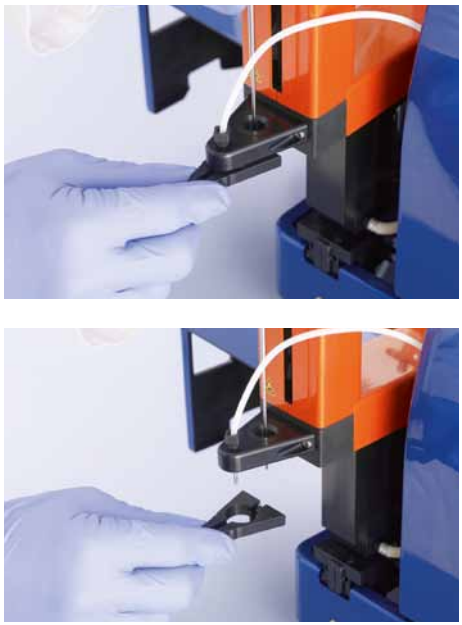


Figure 7.2: Removing the finger guard for cleaning.

4 Wipe the outlet port for the negative fraction as indicated above. The port can be flushed by using a syringe.

5 To clean the uptake port, ensure the instrument is switched OFF. Move the needle holder up and down to get access to the entire surface of the needle.

6 Push the finger-guard back into position.

7 Switch ON the instrument.

8 Run the **Sleep** program

7.2.3 Instrument shutdown

Make sure to run the **Sleep** program prior to switching the instrument OFF. This program ensures most efficient preservation of the fluidic system by rinsing with storage solution.

Shutdown button

1 Press the shutdown button on the upper right hand corner of the screen (⏻).

2 Select **Yes** from the pop-up dialog box.

Figure 7.3: Shutting down the autoMACS Pro Separator.

3 The autoMACS Pro Separator will automatically perform a **Sleep** program.

4 Upon completion of the **Sleep** program, you will be prompted to shut down the instrument. The fluid bottle illumination is purple at this point. Switch OFF the autoMACS Pro Separator by using the main power switch.

Note: Ensure enough storage solution is available.

Store: the program for long-term storage

To store the autoMACS Pro Separator for a period longer than two weeks, the tubing system should be cleaned and the columns should be replaced with column substitutes. The **Store** program automatically performs the cleaning procedure and prompts the user to install column substitutes.

1 Select **Option** and **Special**.

2 Select **Store** and press **Run**. The system will be rinsed automatically.

Figure 7.4: Running the “Store“ program.

3 Install the column substitutes (refer to section 3.3.4 for details on column exchange).

4 Select **Done**.

5 Switch OFF the autoMACS Pro Separator using the main power switch.

7.3 Periodic maintenance

7.3.1 Column exchange

autoMACS Pro Seperator Columns must be exchanged every two weeks or after 100 separations, whichever comes first. Refer to section 3.3.4 for more details.

7.3.2 Clean the pump syringe

The pump syringe must be cleaned every 1–3 months.

1 Go to the **Option** menu. Select **User settings** and **Syrin_ex** from the **Main** and **Detail** submenu, respectively.

2 Press **Run** to start the program.

3 Loosen the plunger lock screw at the bottom of the plunger as prompted on the screen. Press **OK**. The plunger holder will move to the lowest position.

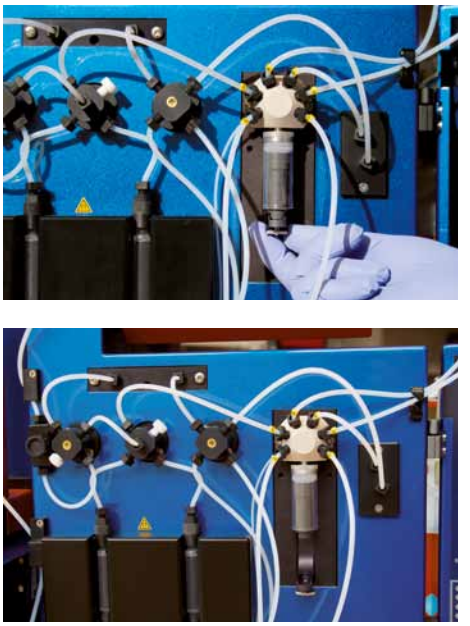


Figure 7.5: Top: Unscrewing the plunger lock screw.
Bottom: The plunger holder is in the lowest position.

4 The sceen prompts to switch the instrument OFF, replace the syringe, and tighten the plunger screw. Select **OK**.

5 Select **OK** when asked to switch OFF the device.

6 Switch OFF the instrument.

7 Unscrew the syringe from the dilutor valve housing.

Figure 7.6: To remove the pump syringe the top screw must be turned counter-clockwise.

8 Carefully remove the plunger from the syringe.

9 Remove salt crusts with distilled or deionized water.

Figure 7.7: Washing the pump syringe with distilled water.

10 Gently push the plunger back into the syringe, but not all the way. Dry the plunger lock screw before proceeding with installation of the syringe.

11 Fasten the syringe at the dilutor valve by turning it until a resistance can be felt. Unfasten again by one rotation.

Figure 7.8: The syringe is fastened at the dilutor valve.

12 Pull the plunger out of the syringe until it reaches its fitting in the plunger holder. In order to fit, the plunger must have the same orientation as its fitting. Tighten the plunger lock screw.

Figure 7.9: The plunger is placed in its fitting in the plunger holder. The plunger screw is fastened.

13 Tighten the syringe at the diluter valve by turning until a resistance can be felt.

14 Switch ON the instrument.

Note: If symptoms of wear such as leakage persist, contact Technical Support.

15 Prime the autoMACS Pro Separator as described in section 7.2.1.

16 Run the program **Calibr_2** to calibrate the fluidic volume control of the instrument. Refer to section 11.2 for details.

7.3.3 Clean the washing station

The washing station is designed for the automated rinsing of the outlet and uptake ports as well as surface cleaning of the uptake port needle. The washing station should be cleaned as necessary to remove spills and salt crusts.

1 Switch OFF and unplug the instrument.

2 Make sure that the needle arm is in the uppermost position.

3 Swivel the front cover to the right side; swivel the cover of the washing station to the left side. The cover can be removed by lifting it.

4 Press the tubing clamp on the right hand side of the washing station and pull to remove the tubing.

Figure 7.10: Remove the peristaltic pump tube from the washing station.

5 Unscrew the thumb screw that attaches the washing station to the instrument.

Figure 7.11: Unscrew the thumb screw.

6 Pull out the washing station.

7 Clean the washing station by soaking it in 10% bleach and 70% ethanol for 15 min each. Optionally, sonicate it in water. Rinse with distilled water.

8 Reassemble the unit in reverse order.

9 Run a **Safe** program.

Note: Do not autoclave the washing station or wash using a dish washer.

7.3.4 Instrument decontamination

The **Safe** program is a disinfectant procedure which uses MACS Bleach Solution for cleaning and decontamination of the autoMACS Pro Separator. Depending on the level of use and general instrument maintenance, it is recommended to decontaminate the fluidic system every 3 to 6 months using the **Safe** program. If predominantly whole blood, bone marrow, or tissue samples are separated the safe procedure can be performed more often without harming the instrument, e.g., every four weeks instead of performing a column exchange.

CAUTION! If sample tubes and fraction collection tubes have been in contact with biohazardous material, they should be autoclaved after use. Bottle closures can be autoclaved.

In case of spillage, it is recommended to use a disinfectant that is appropriate for the potential pathogen, e.g., bleach, isopropyl alcohol, or 70% ethanol, to decontaminate surfaces with tissue or swabs. Switch OFF and unplug the instrument before decontaminating the device. Dispose tissues and swabs appropriately. It is recommended to wear protective gloves, protective clothing, and safety glasses to prevent contact with skin and eyes.

Perform instrument decontamination according to the following instructions:

1 Select menu **Option**, **Special**, and the **Safe** program.

Figure 7.12: "Safe" program is underway.

2 Press **Run**. Follow the screen prompts.

3 Disconnect the tubings from storage solution and buffer bottles. Select **OK**.

4 Place the ends of the tubing in a minimum of 15 mL of disinfectant solution, e.g., MACS Bleach Solution. Select **OK**.

5 Fill a sample tube with 25 mL of disinfectant solution. Select **Done**.

6 (Optional) Wash fluid bottles and bottle closures using detergent, 1% hypochlorite, or 70% ethanol. Rinse thoroughly using deionized water.

7 Reconnect all tubing. Select **OK**.

8 Clean the entire needle manualley using 70% alcohol swaps. Select **OK**.

9 Install fresh columns. Select **OK**.

7.3.5 Instrument long-term storage

Note: Run the **Store** program and exchange the autoMACS Columns with substitute columns if you intend to store the instrument for a period longer than two weeks.

The program **Store** should be applied to prepare the instrument for long-term storage. Upon completion of the **Store** program, the fluidic system contains 70% ethanol.

To store the autoMACS Pro Separator for a period longer than two weeks, the tubing system should be cleaned and the columns should be replaced with column substitutes. The **Store** program automatically performs the cleaning procedure and prompts the user to install column substitutes.

1 Select the **Option**, **Special**, and **Store**. Select **Run**. The system will be rinsed automatically.

Figure 7.13: "Store" program is underway.

2 Install the column substitutes as described by the section 3.3.4.

3 Select **Done**.

4 Switch OFF the autoMACS Pro Separator using the main power switch.

7.4 Planned maintenance

7.4.1 Valve exchange

Note: It is recommended to exchange valves once a year.

The fluidic system of the autoMACS Pro Separator is regulated by five valves. The valve that is connected with the pump syringe is referred to as dilutor valve. If a valve of the autoMACS Pro Separator starts to leak, an exchange of the valve should be performed.

Note: If wear of a valve is suspected, use the **Check_up** program to analyze functionality.

Exchange one valve at a time according to the following instructions:

1 Select **User settings** from the **Options** menu. Highlight **Valve_ex** and press **Run** to start the program. Select valves which have to be exchanged. Valves will automatically be turned to exchange position.

2 Switch OFF and unplug the autoMACS Pro Separator. Open the front cover. For exchange of the lower valve, remove the bottom cover by pulling firmly.

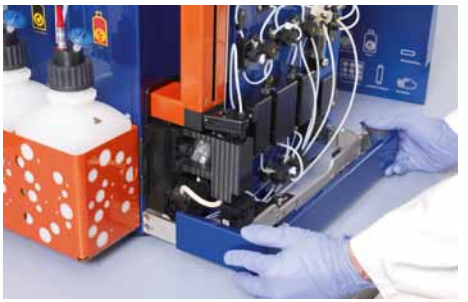


Figure 7.14: The bottom cover must be removed for access to the lower valve.

3 Using the supplied wrench, unscrew the valve cover-screw which releases the tubing.

Figure 7.15: The valve cower-screw is unscrewed.

4 Detach all tubing and valve port locks or blind screws from the respective valve.

Figure 7.16: The valve cover-screw is unsrewed. Tubing and valve port locks or blind screws are detached.

5 Loosen the two valve screws using the screwdriver from the autoMACS Pro Separator Starting Kit and pull out the valve.

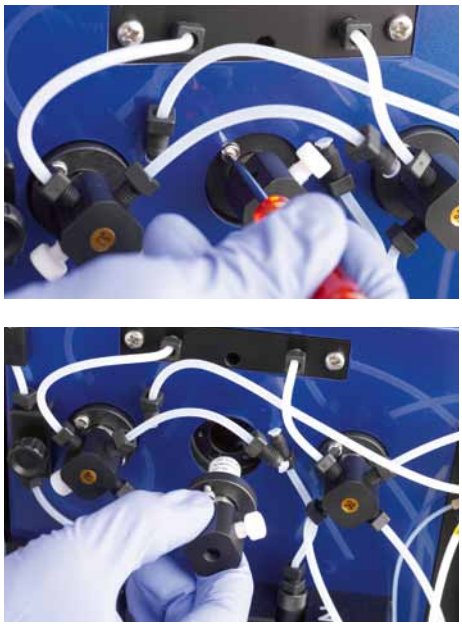


Figure 7.17: Detachment of the valve.

6 Check if the groove in the valve drive is positioned horizontally and in the lower half of the axis.

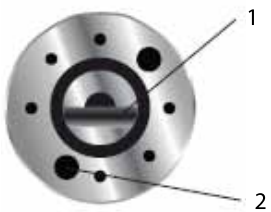


Figure 7.18: Valve plate driving section. 1 = groove;
2 = hole for adjustment pins

Note: In case the valve exchange program **Valve_ex** cannot be performed, e.g., valve does not turn any more, switch OFF instrument and turn the valve bracket manually to the position corresponding to the groove in the valve drive.

7 Make sure that the bracket of the new valve is positioned horizontally.

Figure 7.19: Rear view of the autoMACS Pro Separator valve.
1 = bracket; 2 = adjustment pins

8 Carefully insert the new valve allowing the bracket to find the groove in the drive. At first, the bracket will slide in only halfway.

Figure 7.20: Inserting the new valve.

9 Gently rotate the valve. The two adjustment pins will slide into their corresponding holes in the valve plate.

10 Make sure that the valve is fully inserted into the driving station. Fasten valve screws using the screwdriver.

11 Connect the tubing with the installed new valve and fasten tubing by hand until finger tight.

12 Plug in and switch ON the autoMACS Pro Separator.

13 Perform a **Rinse** program and check the valves visually for leakage and air inlet.

14 Refasten tubing connectors using caution. If leakage persists call Technical Support.

15 Take care not to pinch the tubings at the bottom left of the instrument when closing the bottom cover.

7.4.2 Exchange of dilutor valve

1 Switch OFF and unplug the instrument.

Note: The pump syringe should be exchanged once a year.

2 Remove the pump syringe as described in section 7.3.2.

3 Unscrew the tubing.

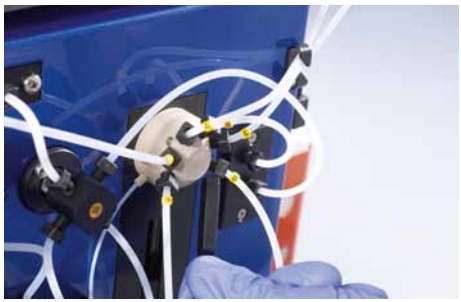


Figure 7.21: Unscrewing the tubing connected to the dilutor valve.

4 Unscrew the two hexagonal socket screws using the key that was delivered with the new or exchange valve.

Figure 7.22: Unscrewing the dilutor valve's socket srews.

5 Pull the valve out of the coupling. Take care to note the orientation of the valve shaft as shown below.

6 When inserting the new valve into the coupling, make sure that the short side of the trapezoid-shaped valve shaft points towards the triangle in the coupling.

Note: The profile of the valve shaft is shaped asymmetrically, similar to a trapezoid (refer to figure 7.23)

Figure 7.23: Inserting a new valve: take care to note the orientation of the valve.

7 When the valve is properly inserted, mount the hexagonal socket screws.

8 Connect the tubing according to the positioning of the diluter valve.

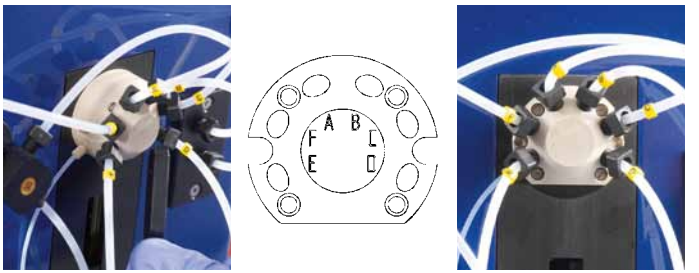


Figure 7.24: Connect tubing to the dilutor value as shown above.

9 Guide the draining tube towards the washing station as shown below.

Figure 7.25: Red colored line indicates the positioning of the draining tube. The draining tube connects the valve to the washing station.

10 Remove the washing station. Take care to clean spilled fluids with ethanol or disinfectant.

Figure 7.26: Disassembly of the washing station.

11 Carefully remove the waste distributor from its position by pulling in an upward direction and remove the draining tube from the old diluter valve.

Figure 7.27: The waste distributor.

12 Mount the new draining tube and finger tighten. Take care to clean spilled fluids with ethanol or disinfectant.

Figure 7.28: The draining tube is attached.

13 Install the waste distributor back to its former position and reinstall the washing station.

14 Install the syringe.

15 Switch ON the autoMACS Pro Separator.

16 Check for correct function by running the **Rinse** program.

17 Run the program **Calibr_2** to calibrate the fluidic volume control of the instrument.

7.4.3 Exchange of the peristaltic pump head

Note: The peristaltic pump head should be exchanged once a year.

1 Switch OFF and unplug the instrument.

2 Remove the washing station as described in section 7.3.3, steps 1–6.

3 Press the tubing clamp on the left hand side of the waste distributor and remove the tubing.

Figure 7.29: Disconnecting the tubing from the waste distributor.

4 If necessary, pull out the bottom cover as depicted in figure 7.14.

5 Press clamps on both sides of the pump and pull out the pump head.

Figure 7.30: Detachment of the pump head.

6 This will uncover a pin that protrudes from the instrument. Clean the pin using 70% ethanol but do not attempt to pull it out. The pin drives the pump during operation.

7 Replace pump head with the spare part.

8 Reassemble in reverse order. Take care not to pinch the tubing at the bottom left when pushing the bottom cover back into place.

Note: The hydrophobic air filters should be exchanged once a year.

7.4.4 Exchange of hydrophobic air filter

Hydrophobic air filters (0.2 µm) are attached to the bottle closures to vent the liquid bottles and to prevent release of aerosols. To avoid clogging of the filters and to prevent contamination of liquids, air filters should be exchanged if they come into direct contact with any liquid, i.e., become wet. They also should be exchanged once a year to avoid clogging through dust deposits.

1 Hydrophobic air filters are attached to all fluid bottles.

Figure 7.31: Hydophobic air filter attached to a fluid bottle.

2 Unscrew the hydrophobic air filter from the fluid bottle. Replace the new filter in a similar manner.

7.5 Exchange of the tubing system

If there is any leakage in the tubing system, the affected tubing part should be exchanged. Please note that each tubing has a specific length and should be exchanged exclusively with the corresponding spare part.

1 Switch OFF and unplug the instrument.

2 Remove the affected tubing by loosening the tube connectors using the black wrench.

3 Replace the tubing with the correct part.

4 Pull back the connector from the tubing, so that the tubing can be easily inserted into the appropriate port.

5 Insert the connector cautiously and precisely and fasten it by hand. Make sure not to overtighten the screw.

6 Plug in and switch ON the instrument. Run the program **Rinse** and check for leakage.

7 Run the **Calibr_2** program to calibrate the volume control of the instrument. For details, refer to section 11.2.

8 If there are any leakage, refer to to section 10.1.2 for advice on how to improve the tubing connection.

7.6 Exchange of fuses

If the instrument fails to start upon switching it ON or if operation suddenly stops and the screen is dark, an exchange of the fuses might be required.

CAUTION! Fuse specifications are given in section 11.2 and on the marking plate on the rear of the instrument close to the fuse holder. Do not use other fuses than specified.

1 Switch OFF the instrument.

2 Unplug the main power cord from the power outlet as well as from the instrument. The fuse holder is located below the main power connector on the rear panel of the instrument.

3 Pull out the fuse holder from the housing and exchange fuses.

Figure 7.32: Removing the fuse holder.

4 Push the fuse holder back into the housing and reconnect the main power cord.

7.7 Rescue procedure

Should the separation be interrupted before target cells are eluted, it is possible to perform a cell rescue procedure to recover the sample. If the instrument can be restarted, follow procedure A; if the instrument cannot be restarted, follow procedure B.

CAUTION! Depending on the nature of your sample it is recommended to wear protective gloves, protective clothing, and safety glasses to prevent contact with skin and eyes. Dispose tissues, swabs, and vials appropriately.

7.7.1 Rescue procedure A

Note: In order to perform a cell rescue procedure, the **O_init** programm must be disabled.

If initial wash (**O_init** program) is enabled, press **Stop** as soon as the **Status** menu appears on the screen. A window opens displaying that the process is paused. Press **Cancel**.

1. Restart the instrument by switching it OFF and ON again.
2. Undo the tubing connector at the negative port and place into a 50 mL tube.
3. Take out the uptake port needle from the needle holder and place it into a 50 mL tube.
4. Undo the tubing connector of the waste tube at the waste bottle and place it into a 50 mL tube; place a second 50mL tube beside this one.
5. Run the program **Qrinse**. This will rinse the complete fluidic system with autoMACS Pro Running Buffer eluting the cells into the 50 mL tubes. Depending on which step of the separation program that the interruption occurred the cells will be found in any one of the vials.
6. Combine all fractions and centrifuge at 350×g for 10 minutes.
7. Discard the supernatant and apply cells to a reseparation as soon as possible. Keep cells on ice until the separation.
8. Reconnect all tubing at the appropriate positions and reposition up-take needle in needle holder

7.7.2 Rescue procedure B

If it is not possible to restart the instrument the cells retained on the columns can be recovered.

1. Switch OFF the instrument and disconnect from the power supply.
2. Prepare two 50 mL tubes in a rack and fill two 5 mL syringes with Running Buffer/Separation Buffer.
3. Open the front cover and place absorbent tissue underneath the columns.
4. Pull out the column from the column holder and replace the top connector with a 5 mL syringe filled with Running Buffer.
5. Undo the bottom connector and flush the column into a 50 mL tube. Discard column and syringe appropriately.
6. Repeat steps 4 to 5 with the second column.
7. Centrifuge tubes at 350×g for 10 minutes.

8 Discard the supernatant and perform reseparation on the recovered cells as soon as possible. Keep cells on ice until the separation.

9 Install new columns or column substitutes in place of the discarded ones.

7.8 Spare parts list

Spare part	Order no.
Pump Seal	130-022-101
Pump Syringe	130-090-339
Square Key	130-090-378
Hydrophobic Air Filter	130-090-385
O-Ring for Bottle Closure	130-090-386
Air Filter Connector	130-090-387
Power Cord (D)	130-090-389
Power Cord (USA)	130-090-391
Plunger Lock Screw	130-090-644
Column Connector	130-090-676
4-port 4-way Valve	130-090-684
4-port Distribution Valve	130-090-685
Fuse Holder	130-090-834
Column substitutes, 2 pieces	130-090-835
Valve Blind Screw, 5 pcs.	130-091-996
autoMACS Pro Tube (t27)	130-093-284
autoMACS Pro Tube (t2)	130-093-285
autoMACS Pro Tube (t7)	130-093-286
autoMACS Pro Tube (t21)	130-093-287
autoMACS Pro Tube (t5)	130-093-288
autoMACS Pro Tube, reservoir (t9, t24)	130-093-289
autoMACS Pro Uptake Port Needle	130-093-290
autoMACS Pro Bubble Sensor	130-093-291
MACS Fluid Container (1,5 L)	130-093-292
autoMACS Pro Tube (t4)	130-093-293
Fuse 5×20 T4A, set	130-093-302
autoMACS Pro Sensor Cable	130-093-303
autoMACS Pro Bottle Closure, green	130-093-304

Spare part	Order no.
autoMACS Pro Bottle Closure, blue	130-093-305
autoMACS Pro Bottle Closure, black	130-093-306
autoMACS Pro Bottle Closure, red	130-093-307
Dilutor Valve, 6-port distribution	130-093-308
autoMACS Pro Tube (t32)	130-093-309
autoMACS Pro Tube (t26)	130-093-310
autoMACS Pro Tube (t20)	130-093-311
autoMACS Pro Tube (t12, t14)	130-093-312
autoMACS Pro Tube (t3)	130-093-313
autoMACS Pro Tube (t18)	130-093-314
autoMACS Pro Tube (t11, t25)	130-093-315
autoMACS Pro Tube (t6, t8, t23)	130-093-316
autoMACS Pro Tube (t10, t16, t17, t19, t22)	130-093-317
Washing Station, needle arm	130-093-349
autoMACS Pro Tube (t1, t13)	130-093-350
Tube Connector 2×2 Ports (1/4"-28 UNF)	130-093-362
Tube Guiding Ball, needle arm	130-093-364
Peristaltic Pump Head incl. Tube	130-093-365
Outlet Port Unit, needle arm	130-093-366
Guard, needle arm	130-093-367
Thumb Screw (M5×16)	130-093-368
Cover, MiniSampler	130-093-669
Magnet Lock, front cover	130-093-370
4-port 3-way Valve	130-093-371
autoMACS Pro Tube (t31)	130-093-372
Uptake Port Needle Guiding, needle arm	130-093-397
Thumb Screw (M5×40), MiniSampler	130-093-407
Pump Syringe, Hamilton, 5mL, Cavro XP	130-094-682
Dilutor Valve, 6-port distribution, V2	130-094-729

Table 7.1: List of available spare parts.

Quality control of separations performed with the autoMACS® Pro Separator

8

To evaluate any MACS Cell Separation, the separated cells can be analyzed with regard to purity, recovery, and viability. Using MACS MicroBeads, the magnetically labeled cells can be simultaneously stained with fluorochrome-conjugated antibodies. Antibodies of the same specificity can be used in most cases. MACS Fluorochrome-conjugated Antibodies are standardized to evaluate MACS Cell Separations. The stained cells can subsequently be analyzed by flow cytometry, fluorescence microscopy, or other techniques.

8.1 Recovery of cells

Note: To count the cells of the original fraction, collect an aliquot of the cell sample after magnetic labeling directly before the magnetic separation to analyze whether cell losses are due to centrifugation steps OR to magnetic separation. Also take counting statistics into consideration. The standard deviation when counting cells is N± N1/2. Therefore, cell counting might be associated with large statistical errors.

In most cases, the number of isolated cells will be compared to the number of cells theoretically expected from the heterogeneous starting population. To calculate the target cell recovery, take an aliquot from the magnetically labeled fraction just before starting the cell separation.

The target cell recovery, e.g., positive cells in the magnetically labeled cell fraction can be calculated as follows:

$$\text{Target cell recovery (\%)} = 100 \times \frac{\text{No. of cells in pos. fraction} \times \text{\% positive cells in pos. fraction}}{\text{No. of cells in orig. sample} \times \text{\% positive cells in orig. sample}}$$

The overall cell recovery can be calculated as follows:

$$\text{Overall cell recovery (\%)} = 100 \times \frac{\text{No. of cells in pos. fraction} + \text{No. of cells in neg. fraction}}{\text{No. of cells in orig. sample}}$$

8.2 Purity of isolated cell population

For most experiments that follow the cell separation, it is necessary to document the purity of the isolated cell subset. It is recommended to analyze the cells by flow cytometry. Alternatively, fluorescence microscopy or immunocytochemistry can be used.

Purity of the positively selected cell fraction:

Purity = % positive cells in positive (magnetically labeled) fraction

Purity of the depleted cell fraction:

Purity = % negative cells in negative (non-labeled) fraction

8.3 Viability of the cells

Different dyes are available to discriminate between live and dead cells. The most common method to discriminate between live and dead cells is based on trypan blue staining and analysis by light microscopy. Trypan blue crosses the cell membrane of dead cells and stains the cells. Live cells are not stained.

Propidium iodide (5.0 µg/mL) is most often used for flow cytometry and fluorescence microscopy. It crosses the permeable cell membrane of dead cells, enters the nucleus, and interacts with DNA. Therefore, the nucleus of dead cells is fluorescently stained. Other fluorescent dyes, for example, DAPI [4',6-diamidino-2-phenylindole] can be used depending on the properties of the flow-cytometer, i.e., its excitation wavelength capabilities, particularly in the UV range.

When working with fixed cells, it is recommended to use the Fixation and Dead Cell Discrimination Kit (#130-091-163) for both the cell fixation as well as the discrimination of dead cells.

The viability can be calculated as follows:

$$\text{Viability (\%)} = 100 \times \frac{\text{No. of live cells}}{\text{No. of total cells (live \& dead)}}$$

Troubleshooting

9

Note: If general hardware errors occur, it is recommended to run the **Check_up** program. Select the **Options** menu from the upper navigation bar. Then select **User settings**. Highlight **Check_up** and press **Run**.

The program automatically analyzes the functionality of moving hardware components. A report is displayed after the analysis of each single component.

The procedure can be canceled after each step or continued by pressing **OK**. Following hardware components are analyzed: dilutor valve, valves 1–4, peristaltic waste pump, magnet 1–2, needle arm (movement along the z-axis and the y-axis), and MACS MiniSampler. Furthermore, the calibration data is checked.

In the unlikely event of problems using the autoMACS Pro Separator the following section aims to address any relevant issues. If the outcome of a cell separation procedure is deemed unsatisfactory, this may either be due to incorrect function of the instrument or to inappropriate sample preparation. Both of these factors are discussed in this section. At the end of this section, a list of numerically encoded errors and warning messages are presented along with user actions for troubleshooting.

This section addresses problems that are not indicated by a warning or error screen, but might occur during the separation or rinsing programs. Identify the problem and refer to the appropriate section.

9.1 Hardware problems not indicated by a warning or error screen

9.1.1 Column leakage

1 If a freshly installed autoMACS Column shows signs of leakage, check if the column is installed properly. The column should be inserted precisely into the column connector and fastened to the point of resistance. If this is not the case, loosen the column connector, insert the column precisely, and tighten the connector again.

2 Run the **Qrinse** program: Select the **Separation** menu from the upper navigation bar and **Wash now** from the lower navigation bar. Select **Qrinse** and press **Run**. Check if the leakage persists. If so, unscrew the column and check if the luer connectors of the columns are damaged. If this is the case, exchange the leaking column with a new autoMACS Column (refer to section 3.3.4).

3 Check if the column connector is fastened properly. If not, use second wrench to counter and tighten another quarter-turn.

4 If the problem persists, contact Technical Support.

9.1.2 Tubing leakage

1 Identify the location of the leaky tubing by running the **Rinse** program. Select **Wash Now** from the lower menu bar in the **Separation** menu. Highlight **Rinse** and click **Run**.

2 Check whether the tubing is tightened properly. If this is not the case, tighten the tube connector. The connector should be inserted precisely.

Note: Do not remove the connector from the tubing.

3 If the problem persists, loosen the tube connector and pull back the connector from the tubing.

4 Check the ends of the tubing for wear and fissures. If necessary, replace tubing with the appropriate spare part. Insert the tubing into the appropriate port. Then cautiously insert and fasten the tube connector.

Note: Please note that each tubing has a specific length and should be exchanged with the corresponding spare part only.

5 Run the **Rinse** program and check if the leakage persists. If so, unscrew the tubing and check if the screw thread is damaged. If this is the case, order and install new tubing.

6 If the problem persists, contact Technical Support.

9.1.3 Pump syringe leakage

Verify that the Running Buffer has equilibrated to room temperature before performing a washing or separation program. Cold buffer will make the plunger seal constrict more than usual and may lead to leakage. Salt crystals may also damage the pump syringe seal.
To clean the pump syringe refer to section 7.3.2 and retry. If the problem persists follow the guidelines below.

1 Run the **Sleep** program. Press the shutdown button on the upper right hand corner of the screen (⏻). Click **Yes** to shutdown the instrument.

2 Switch OFF the instrument.

3 Wash the pump syringe as described in section 7.3.2.

4 Switch ON the instrument and run a **Qrinse** program to ensure that the problem is solved. Select **Wash Now** from the lower menu bar in the **Separation** menu. Highlight **Qrinse** and click **Run**.

5 If the leakage persists, order and install either a new pump syringe (# 130-090-339) or a new pump seal (# 130-022-101). For details on the installation, refer to section 7.3.2.

Note: Depending on the level of use, the pump syringe should be cleaned every 1–3 months.

Appropriate maintenance and long-term storage assures that no salt deposits accumulate in the pump syringe. Salt deposits may cause wear of the pump seal and thus may lead to leakage.

The pump syringe should not run dry at any time. This can damage the pump seal and thereby may lead to leakage of the pump syringe.

9.1.4 Pump syringe is filled with air during operation

If there is any air inlet into the pump syringe during operation, the correct proceeding of a separation will be impaired.

1 Check all tubings that are connected to the fluid bottles. Make sure that all tubings are fastened properly. If a screw thread is damaged, order and install new tubing.

2 Check if the hydrophobic air filters connected to the fluid bottles are clogged. Clogging may cause positive or negative pressure in the fluid bottles, which can lead to pressure problems in the fluidic system. If filters are clogged, replace them with new hydrophobic air filters (refer to section 7.4.4).

3 Check if the connections and pump syringe are leaky (refer to section 9.1.3).

4 Check if the uptake port needle is connected correctly and no air inlet is possible. If not, unscrew and check screw threads. If they are undamaged, reinsert precisely and fasten. Then use the wrench to turn an extra quarter-turn. Do not to overtighten the screw.

5 If the problem persists, contact Technical Support.

9.1.5 Washing station overflow

1 Verify that the washing station is not clogged with salt deposits. Take out the washing station and clean as indicated in section 7.3.3.

2 Reassemble washing station and run a **Rinse** program. Select **Wash Now** from the lower menu bar in the **Separation** menu. Highlight **Rinse** and click **Run**.

3 If the problem persists follow the steps below.

4 Make sure that the peristaltic waste pump works properly. Run the **Check_up** program. Select **User settings** from the **Option** menu. Highlight **Check_up** and click **Run**.

Note: To prevent the formation of salt deposits, wipe the outlet ports with a tissue soaked with distilled (or deionized) water before each **Sleep** program.

5 If the **Check_up** program reports a problem with the waste pump, remove the pump head and clean the pin that drives the pump (for details, refer to section 7.4.3). Clean the washing station (refer to section 7.3.3). Reassemble the unit and check whether the problem persists.

6 If the problem persists, replace the pump head (refer to section 7.4.3).

9.1.6 Outlet port is clogged

1 If the outlet ports are clogged, e.g., due to salt deposits, the elution process might be affected.

2 Wipe the outlet port with a tissue soaked with 70% ethanol or double-distilled water.

3 Flush the outlet port manually using a syringe filled with 70% ethanol or double-distilled water.

9.1.7 MACS® MiniSampler does not move properly

1 Check whether the guiding of the MACS® MiniSampler is connected properly to the connector at the autoMACS Pro Separator labeled "External CAN".

2 Check whether the bolt below the rack detection protrudes from the instrument. If this is the case, push it in and turn it clockwise to lock the bayonet mount.

3 Check the cable connection between MiniSampler and autoMACS Pro Separator. Check for cable damages.

4 Check whether the MiniSampler can freely move to both sides and check for any resistance or collision.

5 If the problem persists, contact Technical Support.

9.1.8 Touchscreen remains dark

1 Switch OFF the instrument, wait 5 seconds, and switch ON again.

2 If the autoMACS Pro Separator still does not initialize check if the power cord is plugged in correctly and if the electric power is switched ON.

3 Replace the fuses (refer to section 7.6). Spare fuses are included in the autoMACS Pro Separator Starting Kit.

4 If the problem persists, contact Technical Support.

9.1.9 Disruption of power supply during cell separation

In the unexpected event of a power supply failure during the cell separation procedure, follow the rescue procedure to recover the cell sample trapped in the autoMACS Pro Separator fluidic system. For detailed information, refer to section 7.7.

Note: If initial wash (**Rinse** program) is enabled, press **Stop** as soon as the **Status** menu appears on the screen. A window opens displaying that the process is paused. Press **Cancel**.

1 Switch ON the autoMACS Pro Separator.

2 Disconnect the outlet tubing from the waste cap and put the end of the tubing in a 50 mL tube. The rescued cell sample will be rinsed out at the waste port.

3 Select the **Separation** menu and **Wash now**. Select **Qrinse** and press **Run**. The cells will be rinsed out with Running Buffer.

4 Reconnect waste closure and waste bottle.

5 Perform the **Rinse** program to prime the autoMACS Pro Separator.

6 The rescued cell sample can now be centrifuged and subsequently be reprocessed with the autoMACS Pro Separator.

9.2 Performance errors not indicated by a warning or error screen

9.2.1 Output volumes are not correct

1 Check for air inlet and leakage in the fluidic system by running the **Rinse** program. Select **Wash Now** from the lower menu bar in the **Separation** menu. Highlight **Rinse** and click **Run**.

2 If the tubing is leaking, go to section 9.1.2.

3 If the pump syringe is leaking, go to section 9.1.3.

4 If the column is leaking, go to section 9.1.1.

5 If one or more valves are leaking, go to section 7.4.1.

6 Check whether all tubing connections including column connections, bottle connections, and connections at the pump syringe are fastened. Loose connections may allow air to enter the system and therefore affect the performance.

7 If the problem persists, run the **Calibr_2** program. Select **User settings** from the **Option** menu. Highlight **Calibr_2** and click **Run**.

8 If the problem persists, contact Technical Support.

9.2.2 Low cell viability in final fraction

1 Low cell viability can result from problems during both the cell preparation and the autoMACS Pro Cell Separation. Hence, also check section 9.3.

2 Check the 70% ethanol. Make sure that analytical reagent grade ethanol (without additives) is used to prepare the solvent.

3 Check the Running Buffer. Make sure that the appropriate buffer has been used and that no contamination has occurred.

4 Check Washing Solution. Make sure that the appropriate solution has been used and no contamination has occurred.

5 Check the pump syringe for contamination. If contamination is obvious, refer to section 9.1.3 and change columns afterwards. Check for contamination of the tubing system and refer to the appropriate section.

6 Run the **Safe** program to decontaminate the fluidic system.

7 Check the column status. The autoMACS Columns should be exchanged after 100 separations or two weeks after the last column exchange, whichever comes first. The procedure is described in detail in section 3.3.4.

8 If the problem persists, contact Technical Support.

9.2.3 Low purity of isolated cells

1 Low purities can be caused by problems during both the cell preparation and the autoMACS Pro Separation. Hence, also check section 9.3.

2 Low purities can also result from using an inappropriate separation program or labeling approach. Please also refer to section 6.

3 Check the exchange date of the autoMACS Columns. Using the autoMACS Columns for longer than two weeks or for more than 100 separations within two weeks may affect purity.

4 Check whether the autoMACS Pro Separator has been set to **Sleep/Store** correctly. Inappropriate storage or allowing the autoMACS Pro Separator fluidic system to run dry will affect the columns and therefore the purity.

5 Make sure that the appropriate Running Buffer has been used.

6 Perform the **Qrinse** program. If pumps are filled with air during the process, refer to section 9.1.4.

7 Perform a test run using PBS as a mock sample and check output volumes. For correct volumes refer to table 6.1 in section 6.1.3.1. If volumes are not correct, go to section 9.2.1.

8 Run the **Safe** program (refer to section 4.7).

9 If the problem persists, contact Technical Support.

When using the autolabeling feature

1 Check whether the uptake needle is positioned in the middle of the sample tube during the mixing procedure. If not, mixing will be inadequate.

2 Check whether the reagent volume (contents of reagent vial) is sufficient for labeling.

3 Check that the recommended maximal sample processing time of 90 minutes was not exceeded. In the event of an elevated room temperature the cooling capacity of the Chill Racks may be compromised. Higher labeling temperatures could cause non-specific binding which may lead to lower purities when using positive selection kits.

9.2.4 Low recovery of isolated cells

1 Low recoveries and low purities may be due to similar problems. Go to section 9.2.3, steps 1–4.

2 Low recoveries can also be caused by partial column blockage. Run the **Safe** program and exchange the autoMACS Columns (refer to sections 4.7 and 3.3.4).

3 Perform a test run using PBS as a mock sample and check output volumes. For correct volumes refer to table 6.1 in section 6.1.3.1. If volumes are not correct, go to section 9.2.1

4 If the problem persists, contact Technical Support.

When using the autolabeling feature

1 Check whether the uptake needle is positioned in the middle of the sample tube during the mixing procedure. If not, mixing will be inadequate.

2 Check whether the reagent volume (contents of reagent vial) is sufficient for labeling.

3 Check that the recommended maximal sample processing time of 90 minutes was not exceeded. In the event of an elevated room temperature the cooling capacity of the Chill Racks may be compromised. Higher labeling temperatures could cause unspecific binding which may lead to lower purities when using positive selection kits.

9.2.5 Sample not or only partly taken up

1 If the sample has been taken up only partly, check if the sample contains clumps larger than 1 mm. Continue with the separation of this sample. As soon as the separation is finished, continue with step 2. Before processing any remaining samples, use a Pre-Separation Filter (# 130-041-407) to remove the clumps from the sample.

For separating cells that tend to aggregate (e.g. tissue cells), it may be helpful to dilute the sample 1:2.

2 Remove the sample tube. Wipe the uptake port needle with a tissue soaked with 70% ethanol. Run the **Qrinse** program.

3 Check for cell clumps in the tubing system. If cell clumps are suspected, run the **Safe** program.

5 Run the **Qrinse** program. Check tubing system and pump syringe for air inlet.

6 Make sure that all tubing are connected properly, especially the tubing connected to the columns and to the buffer bottles.

7 Verify that the uptake port needle is connected correctly and that no air inlet is possible. Tighten if necessary.

8 Make sure that both columns are installed correctly.

9 Clean pump syringe as described in section 7.3.2 to remove salt deposits. Salt crusts might allow air to enter the fluidic system.

10 Check whether the hydrophobic air filters connected to the bottles are clogged. If filters are clogged, replace them with new hydrophobic air filters.

11 Run the **Check_up** program to identify hardware malfunctions.

12 If problem persists, call Technical Support.

9.2.6 Reagent vial runs dry

As the liquid levels in the reagent vials are not controlled by the system before uptake of reagent, it will not be detected if the reagent volume provided in the vial is sufficient for the current separation process or not. Ensure enough reagent is present in all vials for all programmed processes. As the residual volume in the vial is about 20 µL, please be sure to overfill the vial with reagent accordingly.

9.3 Magnetic labeling and separation

9.3.1 Positive selection

Magnetically labeled cells have not been retained on the column

1 Magnetic labeling of the cells was insufficient because the MicroBead concentration was too low. This may be due to the

fact that either too much buffer was added to the cells or too much buffer was left on the cell pellet after centrifugation before adding the MicroBeads. Furthermore, the total number of cells may have been miscounted. Use a ratio of MicroBeads and cells as stated in the respective MACS Cell Separation Reagent data sheet.

2 Labeling of cells was ineffective due to too much debris and/or dead cells in the sample. Debris and dead cells will non-specifically bind to all other components present. Antibodies and MicroBeads will be captured non-specifically and not be able to label the cells in the positive fraction sufficiently any more.

3 Labeling of cells was ineffective due to an incubation temperature lower than recommended. It is recommended to incubate cells in the refrigerator (2–8 °C) for labeling.

4 The number of magnetically labeled cells exceeded the column capacity. Calculate the number of magnetically labeled cells, e.g., by staining with flurochrome-conjugated antibodies, and subsequent fluorescence analysis. The number should not exceed 2×10^8 cells per sample. If necessary, split the sample.

5 Cells were not labeled with MicroBeads because the MicroBeads were degraded. Check the expiration date. Check for sterility of the MicroBeads, if the vial has been opened before.

6 Cells were labeled, e.g., with fluorochrome-conjugated antibodies, prior to magnetic labeling with direct MicroBeads. When antibodies recognizing the same epitope are used for fluorescent and magnetic labeling, fluorochrome-conjugated antibodies and MicroBeads might compete for the binding sites. This can result in insufficient magnetic labeling. It is recommended to perform magnetic labeling prior to staining with fluorochrome-conjugated antibodies. Alternatively, use indirect MicroBeads.

7 A non-optimal separation program was chosen, e.g., Possel instead of Possel-s for dimly labeled cells.

When using the autolabeling feature

1 Check whether the uptake needle is positioned in the middle of the sample tube during the mixing procedure. If not, inadequate mixing will be performed.

2 Check whether the reagent volume (contents of reagent vial) is sufficient for labeling.

3 Verify whether the sample volume was programmed correctly. A reduced input volume will result in insufficient labeling of cells.

Low purity of magnetically labeled cell fraction

1 Check for cell aggregates. Negative cells may be retained when forming clusters with positive cells and, thus, contaminate the positive fraction. Use buffers devoid of Ca^{2+} and Mg^{2+} in order to reduce formation of cell aggregates.

2 Dead cells in the cell suspension may non-specifically bind to MicroBeads and will then be co-enriched in the positive fraction. Remove dead cells before separation by using the MACS Dead Cell Removal Kit (# 130-090-101) or by Ficoll-Paque™ density gradient.

3 The concentration of MicroBeads or the temperature used for magnetic labeling were too high. It is recommended to dilute the MicroBeads according to the data sheet. Cells should be incubated with MicroBeads in the refrigerator (2–8 °C).

4 The total number of cells may have been miscounted leading to an inappropriate ratio of MicroBeads and cells. Use a ratio of MicroBeads and cells as stated in the respective MACS Cell Separation Reagent data sheet.

5 Incubation time with MicroBeads was too long, leading to background labeling. Reduce the incubation time to the recommended values in the respective MACS Cell Separation Reagent data sheet. Typically, an incubation time of 15 minutes is required when incubating in the refrigerator (2–8 °C).
For exceptions, refer to the respective data sheet.

6 When target cells are extremely rare (<5% of total cells), few non-labeled cells which are retained non-specifically may constitute a high portion compared to the target cells. Perform a second separation without re-labeling to remove non-specifically retained cells or choose a double column separation like PosselD, PosselD2, or PosselDS.

When using the autolabeling feature

1 Check that the recommended maximal sample processing time of 90 minutes was not exceeded. In the event of an elevated room temperature the cooling capacity of the Chill Racks may be compromised. Higher labeling temperatures could cause unspecific binding which may lead to lower purities when using positive selection kits.

2 Check whether the correct sample volume was programmed. Higher sample input volumes will result in an excess concentration of MicroBeads leading to non-specific labeling.

Recovery of magnetically labeled cells is low

Refer to the beginning of this section “Magnetically labeled cells have not been retained on the column”.

Viability of magnetically labeled cells is low
Dead cells have been co-enriched in the positive fraction due to non-specific binding. Remove dead cells before separation by using the MACS Dead Cell Removal Kit. Refer to section 9.2.2. This is prone to occur if the number of dead cells in the starting material exceeds the number of target cells.

Overall recovery is low
Cells are often lost during washing steps. Determine the number of cells immediately before magnetic separation to check whether the low recovery is due to this or due to problems during the cell separation.

9.3.2 Depletion

Too many cells are retained on the column

1. Magnetic labeling of the cells was non-specific. In order to block non-specific binding, use MACS FcR Blocking Reagent, human (# 130-059-901) or FcR Blocking Reagent, mouse (# 130-092-575) before labeling.

2. The concentration of MicroBeads and/or the temperature used for magnetic labeling were too high. It is recommended to dilute the MicroBeads according to the data sheet. Cells should be incubated with MicroBeads in the refrigerator (2–8 °C).

3. Incubation time with MicroBeads was too long, leading to background labeling. Reduce the time for incubation to the recommended values in the respective MicroBeads data sheet.

4. Dead cells in the cell suspension may bind non-specifically to MicroBeads and will then be co-enriched in the positive fraction. Remove dead cells before separation by using the MACS Dead Cell Removal Kit (# 130-090-101) or by Ficoll-Paque™ density gradient centrifugation.

5. Incubation temperatures were higher than recommended, typically 2–8°C, leading to non-specific binding.

6. Inadequately stringent separation programs were chosen, e.g., Deplete instead of Deplete. Please refer to the respective data sheet for the recommended program.

When using the autolabeling feature

1. Check that the recommended maximal sample processing time of 90 minutes was not exceeded. If the room temperature is too high the cooling capacity of the Chill Racks may be compromised. Higher labeling temperatures could cause unspecific binding which may lead to lower purities when using positive selection kits.

Non-labeled fraction shows low purity

1 Magnetic labeling was insufficient due to a low expression level of the surface marker. It is recommended to use MACS MicroBeads for indirect labeling (e.g. MACS Anti-Biotin MicroBeads) in order to increase magnetic labeling of the cells.

2 The number of magnetically labeled cells exceeds the column capacity. Calculate the number of expected magnetically labeled cells. The number of cells should not exceed 2×10^8 per sample. If necessary, split the sample.

3 Labeling of cells was ineffective due to an incubation temperature lower than recommended. Incubate the cells in the refrigerator (2–8 °C) for labeling.

4 Labeling of cells was ineffective due to too much debris and or dead cells in the sample. Debris and dead cells will non-specifically bind to all other components present. Antibodies and MicroBeads will be captured non-specifically and not be able to label the cells in the positive fraction sufficiently any more.

5 Cells were not labeled with MicroBeads because the MicroBeads were degraded. Check the expiration date. Check for sterility of the MicroBeads, if the vial has been opened before.

6 Labeling of cells was performed for a shorter time than recommended. The typical incubation time is 15 min. Please refer to the respective data sheet for more details.

When using the autolabeling feature

1 Check whether the reagent vial has enough reagent to perform magnetic cell labeling.

2 Check whether the uptake needle is positioned in the middle of the sample tube during the mixing procedure. If not, limited mixing could lead to low purity.

3 Refer to the respective data sheet for the recommended separation program.

Recovery of target cells is low

Refer to section 9.3.1.

Overall recovery is low

Refer to section 9.3.1.

9.3.3 MACS® MicroBeads for indirect labeling

Positive cells have not been retained on the column

1 The unbound primary antibody was not completely removed and inhibits magnetic labeling with MACS® MicroBeads for indirect labeling. Wash cells carefully (optionally, wash twice) by adding 1–2 mL of buffer per 10^7 cells, i.e., 10–20 times the incubation volume, after incubation with primary antibody. Centrifuge and remove supernatant completely, preferably with a pipette or by vacuum.

2 The concentration of the primary antibody was too low. Therefore, magnetic labeling was not sufficient to retain the desired cells on the column. To avoid this, the primary antibody should be titrated carefully. For tips and hints on titration, refer to the FAQs under Customer Support at **www.miltenyibiotec.com**

3 The isotype of the primary antibody was not recognized by the Anti-Immunoglobulin MicroBeads. Make sure to use appropriate MicroBeads.

4 Check the expression of the antigen/epitope with flow cytometry.

5 Antibodies may have degraded. Check the antibody for its function. Storage of diluted reagents at 4 °C or –20 °C may lead to degradation.

6 Cells were not labeled with MicroBeads because the MicroBeads were degraded. Check the expiration date. Check for sterility of the MicroBeads, if the vial has been opened before.

Positive fraction shows poor purity

1 The concentration of the primary antibody was too high, leading to non-specific binding of unwanted cells. The primary antibody should be titrated carefully. For tips and hints on titration, refer to the FAQs under Customer Support at **www.miltenyibiotec.com**

2 The primary antibody shows non-specific binding. Add blocking reagents such as BSA or immunoglobulin before labeling the cells.

3 The incubation time during labeling was too long. Do not exceed the incubation times specified in the respective data sheet.

4 Check the primary antibody for its specificity. When antiserum is used, it is recommended to pre-adsorb the antiserum, e.g., on cells which do not express the antigen, or to purify it by affinity chromatography, ammonium sulfate precipitation, ion chromatography, etc. in order to avoid non-specific cross-reaction.

9.4 Fluorescent staining

Note: Generally, MACS Fluorochrome-conjugated Antibodies are used in a 1:11 dilution (resuspend up to 10^7 cells in 100 µL of buffer and add 10 µL of MACS Fluorochrome-conjugated Antibodies). For details or exceptions, refer to the MACS Reagent data sheet. If other than MACS Antibodies are used, carefully titrate staining reagents. For tips and hints on titration, refer to the FAQs under Customer Support at www.miltenyibiotec.com.

9.4.1 Cells are poorly stained

1 Fluorochrome-conjugated antibodies may have deteriorated. Store MACS Fluorochrome-conjugated Antibodies at 2–8 °C.

2 Fluorochrome-conjugated antibodies and MACS MicroBeads might compete for epitopes. Check the efficiency of the fluorescent staining on cell samples that are not magnetically labeled. Especially for weakly expressed antigens, it might be necessary to use a fluorochrome-conjugated antibody that is directed against an epitope different from that recognized by the MicroBeads.

3 For indirect staining of biotinylated antibodies with streptavidin-fluorochromes, please note that buffers supplemented with fetal bovine serum (FBS) or bovine serum albumin (BSA) may contain free biotin which can inhibit streptavidin binding to the biotinylated antibody. Alternatively, use MACS Anti-Biotin-VioBlue, -FITC, -PE, or -APC. MACS Anti-Biotin antibodies do not bind to free biotin.

9.4.2 Cells are excessively stained

1 High background staining may occur when the concentration of the staining reagents is too high and the incubation time for the staining procedure is too long. The use of the pre-titrated MACS Fluorochrome-conjugated Antibodies is recommended to achieve optimal results.

2 Check the staining reagent for its specificity.

9.5 Contamination of tubing system

Note: To prevent contamination, run a **Sleep** program before turning OFF the instrument.

1 Decontaminate the instrument. Refer to section 7.3.4 for details.

2 If the problem persists, call Technical Support.

9.6 Problems indicated by error or warning screens

If errors or warnings are displayed on the screen of the instrument, please refer to the following table. If the below measures do not clear the fault, call Miltenyi Biotec Technical Support. To assist in the troubleshooting process, please have the instrument serial number and details of the error message at hand, i.e., error number, module number, file, and error line. If this is not possible, please go to the instrument log list and view the log list details taking care to note the displayed parameters exactly. To discuss the table below, please call Technical Support.

Error code	Cause	Possible remedies
-5	Hardware module is not initialized. After a module malfunction an initialization of the module is neccessary. This might also be a subsequent error if another error has been displayed shortly before.	Restart instrument. Please call Technical Support if error is displayed again.
-27	Standard valve initialization failed. Valve may be blocked or worn and cannot be turned correctly or valve drive is damaged.	Switch OFF the instrument, wait for 5 seconds, and switch the instrument ON again. If error persists touch the button ″Details″. Exchange displayed valve. If error is displayed again call Technical Support.
-28	Motor rotation detection failed. Valve may be blocked or worn and cannot be turned correctly. Otherwise valve or magnet drive malfunction.	Touch button ″Details″. Exchange displayed valve if applicable. If error is displayed again or magnet is displayed call Technical Support.
-29	Valve rotation hindered. Valve may be blocked or worn and cannot be turned correctly.	Switch OFF the instrument for 5 seconds and turn it ON again. If error persists, switch OFF instrument, loosen air filters on buffer/waste bottles by a half turn, exchange columns for dummy columns, verify that washing station is free of clogs and salt deposits (eventually clean washing station), verify that uptake needle is not clogged. Switch on instrument, if error persists, touch ″Details″. Exchange displayed valve if applicable. Make sure to prepare samples as specified. If error is displayed again call Technical Support.
-257	Needle arm movement has been hindered.	If object blocked movement, remove object. Switch OFF instrument. Wait 5 seconds. Switch ON instrument. Otherwise or if error is displayed again call Technical Support.
-263	Unable to read rack bar code correctly.	Check bar code on rack or try different rack. Make sure ambient or direct sun light does not hit sensor. Clean sensor to remove salt or dust using a cloth soaked in 70% ethanol or double distilled water and wipe dry.
-264	Unable to read rack bar code correctly.	Check bar code on rack or try different rack. Make sure ambient or direct sun light does not hit sensor.
-769	Diluter plunger could not be initialized. Syringe not mounted correctly, syringe damaged, or diluter valve not positioned correctly.	Check if syringe is fastened correctly. Exchange if broken or damaged. If error is displayed again call Technical Support.
-775	Diluter is not initialized. After a diluter malfunction an initialization of the module is necessary. This might also be a subsequent error if another error has been displayed shortly before.	Restart instrument. Please call Technical Support if error is displayed again.
-777	Plunger movement blocked because of column clogging, blocked tubing set, or any other cross-section constriction.	Restart instrument and try a ″Qrinse″ to wash out clogged material. If error persists run ″Safe″ program. Otherwise exchange diluter valve or standard valves depending on where a constriction is suspected. Please call Technical Support if error is displayed again.

Error code	Cause	Possible remedies
-6006	Air intake during sample uptake although needle did not yet hit bottom of tube. Leakage of air into system in front of bubble sensor, liquid level has been overestimated, or needle did not move to bottom (as fast as necessary).	Make sure foam on top of sample is not higher than 5 mm above liquid level. Verify that sample was filtered before separation and that uptake needle is not clogged. Check for leakage at the point where the needle and tubing meet, and where the tubing to bubble sensor meet. Verify that connectors are appropriately fastened.
-6009	Unexpected air in system during sample uptake.	Check for leakage or air bubbles in tubing from uptake needle to valve 1. Verify that connectors are appropriately fastened. Calibrate needle arm. Check for buffer supply. Otherwise call Technical Support.
-6216	The reagent designated for the current labeling process is not assigned a position in the reagent rack.	Provide all necessary reagents in reagent rack und correct reagent rack definition.
-7001	Needle could not be retreated completely.	Try reinitialization by touching ″Retry″. Otherwise call Technical Support.
-7002	Collision of the needle with the bottom of the tube (or any other object) has been detected, but resetting the collision sensor failed although the needle has been lifted.	Push back needle to it's proper position in the needle holder, check for smooth running of the needle in its support then touch ″Continue″. Otherwise calibrate needle arm, especially if using a Chill 15 Rack.
-7003	Collision of the needle with an unexpected object. Resetting the collision sensor failed as the needle could not be lifted (already too close to top).	Check for objects hindering the movement of the needle. Remove the uptake needle from the needle holder and verify that there are no physical obstructions. Press ″Continue″.
-7004	Collision of the needle with an unexpected object far above expected tube bottom.	Check that cover of the washing station is properly closed. Remove any objects hindering the movement of the needle. If needle hits rim of tube or top of rack calibrate needle arm using ″Calibr_1″ program. Touch ″Lift″ for needle retreat.
-7005	Collision of the needle with an unexpected object far above expected tube bottom.	Check that cover of the washing station is properly closed. Remove any objects hindering the movement of the needle. If needle hits rim of tube or top of rack calibrate needle arm. Touch ″Retry″ to try again.
-7006	Collision of the needle with an unexpected object far above expected tube bottom.	Check that cover of the washing station is properly closed. Remove any objects hindering the movement of the needle. If needle hits rim of tube or top of rack calibrate needle arm. Touch ″Retry″ to try again.
-7007	Sample volume exceeds maximum volume specified for rack or program type. Remaining portion of sample will not be processed.	Do not use sample volumes exceeding the maximum volume specified for rack or program type. If volumes are in specified range but error is displayed anyway, please call Technical Support.
-7008	The sample volume has been underestimated. The needle has been rinsed but might still be contaminated.	Please clean outside of needle manually. If this error is displayed frequently, please call Technical Support.
-7009	Collision of needle with bottom of tube could not be detected at expected position.	Check if tubes are correctly positioned in rack corresponding to template programming. Check MACS MiniSampler connection in front of autoMACS Pro Separator.

Error code	Cause	Possible remedies
-7010	Not certain if liquid surface of sample has been detected correctly.	Touch ″Ignore″ to continue without liquid detection. Needle will be moved to bottom directly. This might result in a subsequent warning -7008 if the liquid level is higher than 60 mm above the tube bottom (see above). Touch ″Retry″ to continue with liquid detection. Ensure that the tubing from the needle arm to bubble sensor can move freely. Adjust the tubing if necessary. Otherwise call Technical Support.
-7011	Restart of the device is required.	Please restart instrument.
-7012	Calibration data not found.	Please calibrate needle arm axes. Run program ″Calibr_1″.
-7013	Calibration data not found.	Please calibrate needle arm axes. Run program ″Calibr_1″.
-7014	Calibration data not found.	Please calibrate tubing. Run program ″Calibr_2″.
-7015	Columns are not installed.	Please install columns.
-7018	Calibration data not found.	Please calibrate MACS MiniSampler using program ″Calibr_1″.
-7021	A separation program has been started but system had not been rinsed properly.	Please rinse system by touching ″Wash″ or abort with ″Cancel″.
-7022	Columns are overdue.	Please install new columns. Touch ″Cancel″ to abort and then install columns, touch ″Continue″ to ignore and use old columns (not recommended).
-7023	Plunger movement blocked because of column clogging, blocked tubing set or any other cross-section constriction during output of the negative fraction. The negative fraction has not been eluted completely. Negative cells are still remaining in the system.	Touch ″Cont″ to discard the remaining negative cells into the waste bottle. To output negative fraction again at lower speed, exchange negative tube with an empty tube and touch ″Retry″.
-7024	The number of programmed sample positions exceeds the actual positions of the rack on the MACS MiniSampler.	Exchange rack with rack holding more samples and touch OK or touch ″Cancel″ to abort and reprogram.
-7026	The protective cover of the MACS MiniSampler seems to be opened by the moving needle arm hitting the cover.	Check configuration and connection of the protective cover, the MACS MiniSampler, and the front support at the autoMACS Pro Separator then touch ″Continue″. Touch ″Cancel″ to abort.
-7027	The protective cover of the MACS MiniSampler needs to be closed.	Please close protective cover and touch ″Continue″. Touch ″Cancel″ to abort.
-7028	Bar code on chill rack could not be read. MACS MiniSampler is not connected (properly).	Check electrical connection of MACS MiniSampler. If detected the MACS MiniSampler symbol would be displayed in the status screen.
-7029	Unable to read rack bar code correctly	Check bar code on rack or try different rack. Make sure ambient or direct sun light does not hit sensor. Touch ″Retry″ to try again, touch ″Select″ to set chill rack type without automatic bare code reading.
-7030	The instrument has been shut down without using ″Sleep″.	Always use ″Sleep″ to shut down the instrument.

Error code	Cause	Possible remedies
-7031	The given whole blood sample size exceeds the maximum volume specified. The sample cannot be diluted sufficiently.	Do not use sample volumes exceeding the maximum whole blood sample volume specified for the used chill rack type. Split sample into several tubes, reprogram separation parameters and restart separation. If volumes are in specified range but error is displayed anyway, please call Technical Support.
-7032	Air in system during calibration of tubing.	Check buffer supply. Check for leakage of system (unintended air intake). Start a rinse program (˝Wash only˝) and then retry calibration. Otherwise call Technical Support.
-7033	Date and time is outdated.	Set time and date to actual values.
-7034	Air intake during sample uptake although needle did not yet hit bottom of tube. Leakage of air into system in front of bubble sensor, liquid level has been overestimated or needle did not move to bottom (as fast as necessary).	Make sure foam ontop of sample is not higher than 5 mm above liquid level. Check for leakage at transition of needle to tubing and tubing to bubble sensor. Touch ˝Cont˝ to process currently uptaken sample volume. Touch ˝Cancel˝ to abort.
-7035	Air intake during sample uptake although needle did not yet hit bottom of tube. Leakage of air into system in front of bubble sensor, liquid level has been overestimated, or needle did not move to bottom (as fast as necessary). Uptaken sample has been processed. Portion of sample is remaining in tube.	Make sure foam on top of sample is not higher than 5 mm above liquid level. Check for leakage at transition of needle to tubing and tubing to bubble sensor.
-7036	Plunger movement blocked because of column clogging, blocked tubing set, or any other cross-section constriction during output of the positive fraction. The positive fraction has not been eluted completely. Positive cells are still remaining in the system.	Touch CONT to discard the remaining positive cells into the waste bottle. To output positive fraction again at lower speed, exchange positive tube with an empty tube and touch RETRY.
-7037	Resuspensed sample could not be taken up completely (no final air intake detected). Leakage of air into system behind bubble sensor. Portion of resuspended sample is remaining in tube.	Check for air inlet into system behind bubble sensor. Touch CONT to process currently uptaken sample volume. Touch CANCEL to abort.
-7038	Resuspensed sample could not be taken up completely (no final air intake detected). Leakage of air into system behind bubble sensor. Portion of resuspended cells are remaining in tube.	Check for leakage of air into system behind bubble sensor. Readjust tubing connectors and verify correct fastening of columns.
-7039	Required volume cannot be provided in given Chill Rack.	Exchange rack with rack able to provide requested volume (e. g. Chill 50 instead of Chill 15). Touch RETRY to try again. Touch CANCEL to abort.
-7048	Miscalculation of diluter movement. Target position is negative.	Touch RETRY to use target position 0 instead of negative value for current diluter move. Touch CANCEL to abort. Please contact the Technical Support in all cases – also if the sample has been processed completely after touching RETRY.

10.1 Schematics of the autoMACS® Pro Separator

Integrated computer for control of cell processing
All interactions with the computer are performed with a TFT color touchscreen (figure 10.1). A memory card is used to run all programs and to log processes.

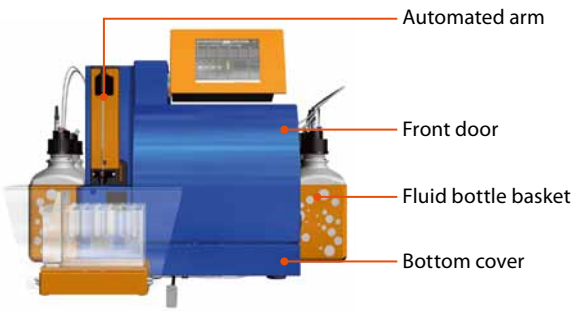


Figure 10.1: Front view of autoMACS Pro Separator.

Automated arm with ports for sample uptake and release of cell fractions
The automated arm (figure 10.1) is a computer-controlled part of the autoMACS® Pro Separator. It holds two ports, one for sample uptake and release of the magnetically labeled, positive cell fraction and one for release of the non-labeled negative cell fraction. The automated arm moves in y- and z-directions. The ports are automatically washed in the autoMACS Pro washing station during and after the separation process to prevent cross-contamination between samples.

Access covers
The front door (figure 10.1) is opened sideways to allow access to the parts of the fluidic system that require periodic maintenance by the user. This includes the autoMACS Columns, pump syringe, and upper valves. The bottom cover (figure 10.1) gives access to the lower valves and can be removed by pulling gently. The washing station cover is opened sidewards giving access to the washing station, the peristaltic pump, and the tubing of the autoMACS Pro washing station.

Fluid Bottles and fluid bottle baskets

Two baskets holding two fluid bottles each, are located at each side of the instrument. Fluid bottles are connected to the autoMACS Pro system with color-coded tubing and sensors at the bottle closures for fluid level control (figure 10.2 and 10.3).

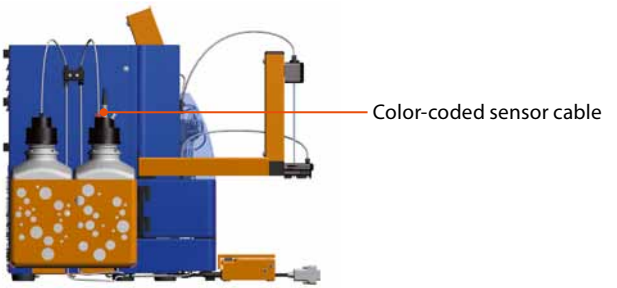


Figure 10.2: Left side view of the autoMACS Pro Separator.

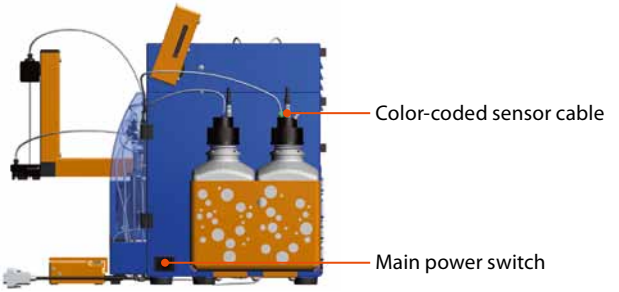


Figure 10.3: Right side view of the autoMACS Pro Separator.

Plugs, connections, and guidings

Sockets for the main plug, the fluid sensor cables, the 2D code reader cable, and the MACS MiniSampler are installed at the rear of the instrument (figure 10.4). Additional sockets are implemented for further instrument development. The main power switch is located at the right hand side of the instrument (figure 10.3). Several guidings at the rear and sides of the instrument ease the safe connection of tubing and sensor cables.

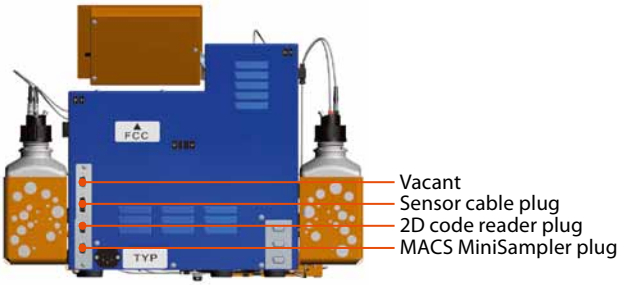


Figure 10.4: Rear view of the autoMACS Pro Separator.

MACS MiniSampler, chill racks, and MACS Reagent Rack

The MACS MiniSampler (figure 10.5) can be loaded with one of three different chill racks that carry cell samples and fraction collection tubes and the MACS Reagent Rack 4. The upper plate of the MiniSampler moves in an x-direction and aligns the tube openings with the port of the automated arm. The guiding of the MiniSampler is directly attached to the corresponding slot below the washing station. When attaching the MiniSampler sensor cable to the corresponding socket at the rear of the instrument the MiniSampler will be automatically detected. The type of tube rack carried by the MiniSampler is automatically recognized by the rack detector after starting the separation process. During operation, the tube rack should be covered with the MiniSampler lid that is connected to the lid guiding (figure 10.5). The MiniSampler can be disconnected from the autoMACS Pro Separator by pulling it up on the front side and pulling it towards the user.

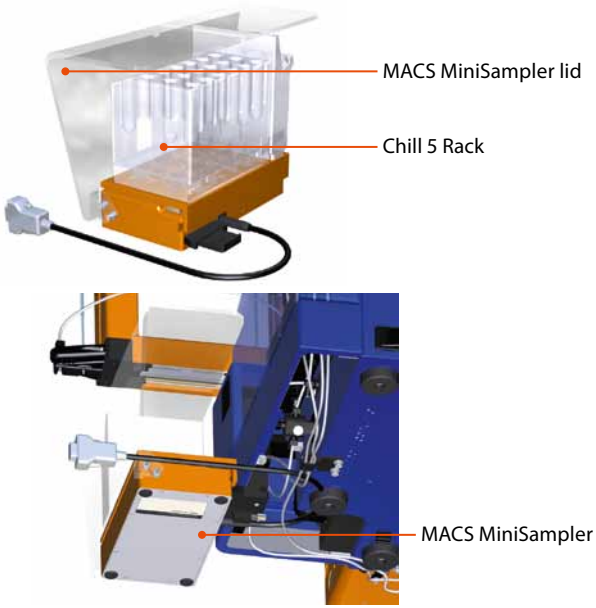


Figure 10.5: Rear view of MACS MiniSampler with MACS Reagent Rack 4 and Chill 5 Rack.

The cell separation unit

The central part of the cell separation unit consists of a magnet and two autoMACS Columns (figure 10.6). Once installed, the autoMACS Columns become part of a closed fluidic system and can be used for up to two weeks OR 100 separations, whichever comes first. Fluids are put through the fluidic system with the help of a syringe pump and four valves.

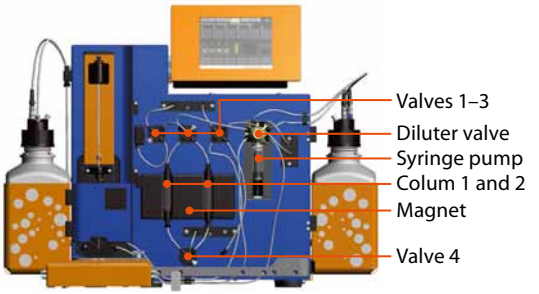


Figure 10.6: Front of autoMACS Pro Separator with access and bottom covers removed.

2D code reader (barcode reader)

The autoMACS Pro Separator is equipped with a 2D code reader that uses lasers and powerful light-emitting diodes (LEDs) for illuminating the reading area. The 2D code reader is classified as a Class 1 laser product per standard IEC 60825-1: 1993 + A1: 1997 + A2: 2001 (maximum output 116 µW, wavelength 655 nm, pulse duration 1 ms). Please refer also to section 1.3.4 of the autoMACS Pro Separator user manual for associated warning and precautionary information.

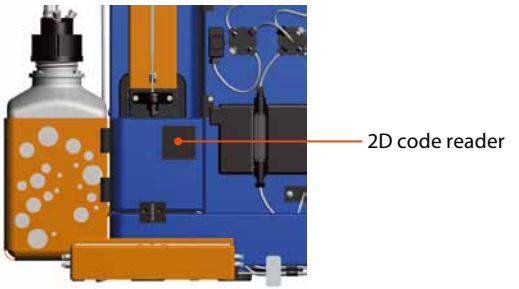


Figure 10.7: Expanded view of the autoMACS Pro Separator 2D code reader (barcode reader).

10.2 Technical data and specifications of the autoMACS® Pro Separator

Technical data	
Model	**autoMACS Pro Separator**
Color	Blue/orange
Footprint*	605×343 mm (W×D)
Footprint with MiniSampler*	605×455 mm (W×D)
Height	392.5–454 mm (adjustable touchscreen)
Weight	25 kg
Input voltage	100–240 VAC, 50–60 Hz
Power consumption	200 VA
Fuses	2×T4A/250
Programs	12 preset
Sample volume (input)	0.25–50 mL
Sample volume (output)	0.5–52 mL
Column capacity	4×10^9 cells/sample 2×10^8 magnetically labeled cells/sample 15 mL of whole blood
RS232-Interface (labeled "COM")	Pins 1, 4, 6, 9: NC Pin 2: RXD Pin 3: TXD Pin 5: GND Pin 7: RTS Pin 8: CTS
RS232-Interface (labeled "RS232/AUX") Not in use	Pins 1, 4, 6, 7, 8, 9: NC Pin 2: RXD Pin 3: TXD Pin 5: GND
RS232-Interface + DC-Output (labeled "RS232/BCR")	Pins 4, 6: NC Pin 1: Input Pin 2: RXD Pin 3: TXD Pin 5: GND Pins 7, 8: Shorted Pin 9: 5 VDC/0.5 A
CAN-Bus + DC-Output (labeled "External CAN")	Pins 1, 4, 8: NC Pin 2: CAN-L Pins 3, 6: GND Pins 5, 9: 24 VDC/2A Pin 7: CAN-H

Model	autoMACS Pro Separator
AC-Output (labeled “Bottle Sensor”)	Pins 1, 2, 3, 4, 5: 5 VAC/10 kΩ Pins 6, 7, 8, 14, 15: GND Pins 9, 10, 11, 12, 13: Input
CAN-Bus (labeled “CAN1” or “CAN2”)	Pins 1, 4, 5, 8, 9: NC Pin 2: CAN-L Pins 3, 6: GND Pin 7: CAN-H

Model	MACS MiniSampler
Footprint without lid	182 × 148 × 47 mm (W×D×H)
Footprint with lid	280 × 153 × 172 mm (W×D×H)
Weight	1,5 kg
Input voltage	24 VDC
Current	0.8 A
Sub D9 interface with shielding	Pins 1, 4, 8: NC Pin 2: CAN-L Pins 3, 6: GND Pins 5, 9: 24 VDC/2A Pin 7: CAN-H

*Depending on the type of power plug chosen, the depth increases by 27 mm or 62 mm.

Table 10.1: Technical data.

The autoMACS Pro Separator is labeled as a protection class I instrument and must be plugged into a grounded power outlet, refer to section 1. The MACS® MiniSampler is labeled as a protection class III instrument and must only be plugged into the connector labeled with “External CAN” of the autoMACS Pro Separator, refer to section 1.2.

The main power supply cord and plug of the instrument shall 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) attachment plug, rated 125 Vac, 10 A. Opposite end terminates in IEC 320 style connector, rated 125 Vac, 10 A.

Conditions of operation: 15–30 °C with 0–85% humidity (non-condensing) at a maximum altitude of 2000 m. 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. The autoMACS Pro Separator is not specified for use in the cold room.

WARNING! Read the chapter Warnings and precautions for important safety information before installation and use.

The emission sound pressure level at the workstation is <70 dB(A).

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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

The autoMACS Pro Separator in combination with the MACS MiniSampler complies with all essential requirements of the following directives

2004/108/EC (electromagnetic compatibility)
2006/42/EC (machinery)

and is in conformity with the following harmonized standards

EN 61010-1
EN 61010-2-081
EN 61326-1.

The autoMACS® Pro Separator has been investigated by Underwriter Laboratories in accordance with the standards

UL 61010-1
CAN/CSA-C22.2 No. 61010-1
IEC 61010-2-081.

The MACS MiniSampler has been investigated by Underwriter Laboratories in accordance with the standards

UL 61010-1
CAN/CSA-C22.2 No. 61010-1.

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

Design and specifications are subject to change without notice.

Hardware and software installation 11

11.1 Installation of new software

Note: Do not remove or insert a memory card while the instrument is turned ON. The memory card must remain in the unit. Removing the memory card during operation will abort all running processes.

After installing an autoMACS Pro software update it is necessary to calibrate the instrument as instructed below. The autoMACS Pro Separator contains various control boards. During initialization of the instrument with a software card, all of these components are automatically checked for the currently installed software.

11.1.1 Exchanging the software cards

1 Ensure the instrument is switched OFF before proceeding.

2 Note the memory card slot at the right hand side of the touch screen.

Figure 11.1: Location of the memory card slot.

3 Remove the old memory card by pressing the black release button beneath the card slot.

4 Insert the new memory card.

5 Switch the instrument ON. A dialog box will appear prompting the operator to proceed if desired.

6 Select **Update** to confirm that you wish to proceed.

Note: During the panel software update process, the display may turn black or white or may freeze or flicker. This process may take several minutes. The progress will be indicated by an acoustic signal.
* If warning -7030 is reported, confirm by selecting **OK**.
* If warning -7016 is reported, select **Ignore**.

Figure 11.2: The user must confirm any update.
The current software (panel software version) will be overwritten.

11.2 Calibration of the autoMACS® Pro Separator

The autoMACS Pro® Separator is calibrated by using the two programs, **Calibr_1** and **Calibr_2**. Calibration 1 is recommended after
installation of new software. Calibration 2 is always necessary when the pump syringe, the Diluter Valve, or the tubing are changed.

Calibr_1 is used to calibrate the settings of the needle arm (x-, y-, and z-axis), including the alignment of the needle arm with the washing station and the MACS Chill Racks.

Calibr_2 automatically calibrates the liquid volume control. This is crucial for the correct measurement and processing of the sample volumes. The fluidic system must be filled with buffer before commencing this step, i.e., the **Rinse** program must be performed.

Calibration 1: Beginning the calibration sequence

1 Select menu **Option.**

2 Highlight **User settings** and select **Calibr_1.**

3 Select **Run.**

4 Select **Calibrate** to proceed. The first of four (1/4) calibration steps will begin, namely, calibration of the washing station.

Note: If warning -7016: ˝Columns are not installed. Start column exchange program.˝ appears, select **Ignore**.

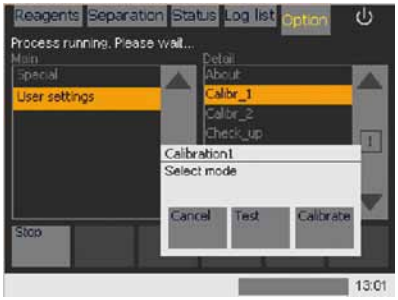


Figure 11.3: Performing calibration of the needle arm: a 4-step calibration process.

Calibration 1: Calibration of the washing station – step 1/4

5 Select **Calibrate** and then **Use** to proceed with calibration. The needle arm will automatically move towards the washing station and should be located directly above the center of the rear opening of the washing station.

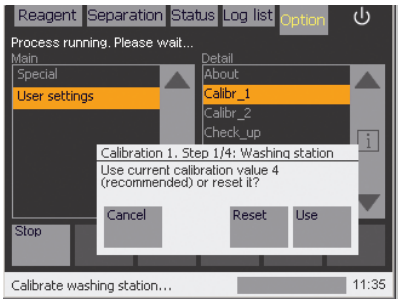


Figure 11.4: Calibration of the washing station. To use already saved settings select “Use“. To reset calibration settings (not recommended) select “Reset“.

6 Select **Height** and check the central positioning of the uptake needle by using the buttons **Move up** and **Move down**. Select **Position** and adjust by using the **Move back** and **Move fwd** buttons. Select **Done** after making necessary adjustments.

Figure 11.5: Test calibration of the needle arm position in the washing station. The position of the uptake needle should appear as shown above.

7 Select **Save** to save the new configuration.

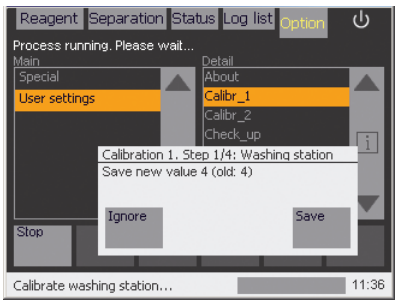


Figure 11.6: Saving new settings for calibration of the washing station.

Calibration 1: Calibration of the tube rack – step 2/4

8 Select **Calibrate** to continue with the calibration process.

9 Place a MACS Chill Rack with sample tubes onto the MiniSampler. It is recommended to use a Chill 15 Rack.

10 Select **Done**. The needle arm will move to position A1 of the tube rack.

11 Check the central positioning of the uptake needle on the bottom of the tube by using the needle navigation buttons **(Move back, Move fwd, Height)**. Ensure the needle is positioned at the bottom center of the tube in row A of the tube rack. Select **Done** to continue.

Figure 11.7: Calibrating the position of the needle arm in the sample tube.

12 Select **Save** to store the new settings.

Calibration 1: Calibration of the x-axis – step 3/4

13 Select **Calibrate** to proceed with calibration.

14 Place a MACS Chill Rack and a MACS Reagent Rack 4 onto the MACS MiniSampler. It is recommended to use a Chill 15 Rack.

15 Select **Done**.

Note: It is possible that the stored calibration value is zero! In this event, step 16 will be skipped. Continue with step 17.

16 Select **Use** to start the calibration at current position (recommended). Select **Reset** to use factory settings.

17 If necessary, adjust the central positioning of the uptake needle by using the needle navigation buttons **(Move left, Move right, Height)**. The uptake needle must be positioned above the center of the tube in row A of the tube rack. Select **Done** to continue.

Figure 11.8: The uptake needle should be positioned as shown above.

Note: Due to mechanical limits of the MiniSampler the correction potential is limited. Exceeding these limits is reported by the message "standard range exceeded".

Calibration outside the standard range is not recommended. The outer positions (reagent vial and sample row 6) will not be reached properly. Labeling in sample position 6 will be prohibited.

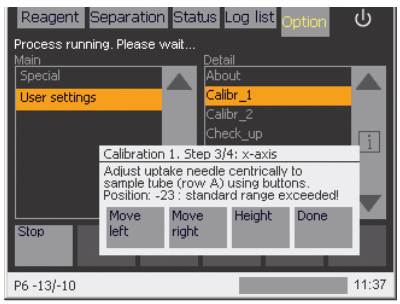


Figure 11.9: Adjust MiniSampler position.

18 Select **Save** to store new settings.

Calibration 1: Test current calibration settings – step 4/4

19 Select **Test** to test new configurations. The autoMACS Pro Separator will perform a complete test of Calibration 1 settings.

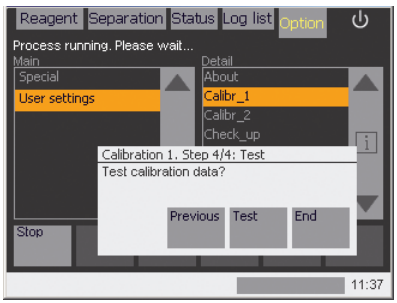


Figure 11.10: It is important to test the new calibration settings. To navigate back through the calibration steps, select "Previous".

20 Place a Chill 15 Rack onto the MACS MiniSampler.

21 Select **Done**.

22 Place the MACS Reagent Rack 4 onto the MACS MiniSampler.

23 Select **Done**.

24 In the next steps, you can test the calibration settings of the washing station, the tube rack position A1, B1, and C1, the x-position, and vials 1–4 in the Reagent Rack. To test a postion select **Test postion**. To skip a postion select **Next**. Check all approached positions by using the needle navigation buttons **Move up** and **Move down**, then select **Done**. After testing the last postion the Calibr_1 screen (figure 11.3) will reappear. Select **Cancel** to leave the calibration program.

25 If any errors or misalignments were noted, repeat the entire process.

Calibration 2

1 Select menu **Option.**

2 Highlight **User settings** and select **Calibr_2.**

3 Select **Run**.

Figure 11.11: Performing Calibration 2 by selecting program “Calibr_2“.

4 Select **Calibrate**. The calibration is performed automatically.

5 Press **Save** to finish **Calibr_2**.

Technical support

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Miltenyi Biotec offers a full range of customer technical support options for your autoMACS Pro Separator.

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Limited warranty

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Except as stated in a specific warranty statement, which may accompany your autoMACS Pro Separator (the "Product"), or unless otherwise agreed in writing by an authorized representative of Miltenyi Biotec, Miltenyi Biotec's warranty, if any, with respect to this Product is subject to the terms and conditions of sale (the "Terms") of the company within the Miltenyi Biotec group which supplied the Product. The Terms may vary by country and region. Copies of these Terms are available on request or at www.miltenyibiotec.com.

Nothing in this document should be construed as constituting an additional warranty.

Miltenyi Biotec's product warranty only covers Product issues caused by defects in material or workmanship encountered during ordinary use, as described in the user manual or other documentation provided by Miltenyi Biotec; it does not cover Product issues not arising out of defects in material or workmanship, including but not limited to Product issues resulting from: failure to follow installation, operating and/or maintenance instructions, or environmental conditions prescribed in, this user manual or other Product documentation; misuse; abuse; neglect; mishandling; unauthorized or improperly performed maintenance or repairs; accident; acts of God; limitations of technology; electrical current fluctuations; modification of or to any part of the Product; use of accessories, spare parts and/or consumables other than those recommended by Miltenyi Biotec; or normal wear and tear. Miltenyi Biotec's product 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; those third-party accessories or parts may be covered by a separate warranty from their manufacturer.

Miltenyi Biotec must be informed immediately, if a claim is made under such warranty. If a material or manufacturing defect occurs within the warranty period, Miltenyi Biotec will take the appropriate steps to restore the full usability of your Product.

Limitation on damages:
Miltenyi Biotec shall not be liable for any incidental or consequential damages for breach of any express or implied warranty or condition on this Product.

Some states or jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to you. This warranty statement gives you specific legal rights and you may have other rights, which may vary from county to country or jurisdiction to jurisdiction.

Glossary

Air filter: Hydrophobic 0.2 µm air filter attached to the bottle closure. Used to vent the bottle and – at the same time – prevent contaminants from entering the fluid bottle.

Air filter connector: Luer-to-thread connector for attaching the air filter to the threaded bottle closure vent.

APC: Allophycocyanin

autoMACS Columns: Specifically designed autoMACS Columns; reusable for two weeks or for 100 separations within these two weeks.

autoMACS Column 1: First autoMACS Column in which labeled cells are retained during positive selection and depletion programs. The autoMACS Column 1 occupies the left slot of the black magnet cover.

autoMACS Column 2: The second autoMACS Column is used during double selection programs. The autoMACS Column 2 occupies the right slot of the black magnet cover.

autoMACS Pro Separator: Automated magnetic cell separator, also referred to as device or instrument.

autoMACS Running Buffer: Sterile and ready-to-use solution for cell separation and washing programs. The tubing connector is color-coded blue.

autoMACS Pro Washing Solution: Sterile and ready-to-use solution for washing and special rinsing programs. The tubing connector is color-coded green.

Bottle closure: Vented screw-on closure with fluid uptake ports / canules and distribution tubes. The bottle closures contain fluid sensors and are equipped with sensor cable connectors.

Column connector: Luer-to-thread connector connecting the autoMACS Columns to the fluidic system.

Column substitute: Column without spheres that replace the autoMACS Columns for long-term storage and shipment. Column substitutes cannot be used for cell separations.

Depletion: Isolation of target cells by labeling all cells other than the target cells with MACS MicroBeads and subsequently performing a MACS Separation. The non-labeled fraction contains the target cells.

Deplete: Depletion program, standard mode: a normal cell deposition rate is used. The non-labeled cells are eluted in row B of the sample rack. This is the optimal program to be used in combination with MACS Cell Isolation Kits or to achieve the highest recovery rate of untouched cells.

Depletes: Depletion program, sensitive mode: a slow cell deposition rate is used (1 mL/min). The non-labeled cells are eluted in row B of the sample rack. This program is optimized for depletion of those cells that weakly express the antigens used for magnetic labeling, or to achieve optimal purity of the untouched cell fraction.

Depl05: Special depletion program: the cell deposition rate is 0.5 mL/min. The non-labeled cells are eluted in row B of the sample rack. This program is used for strong depletion of those cells that weakly express the antigens used for magnetic labeling, or to achieve the highest purity of the untouched cell fraction. However, choosing Depl05 might result in a reduced recovery of the target cell fraction.

Depl025: Special depletion program: the cell deposition rate is 0.25 mL/min. The non-labeled cells are eluted in row B of the sample rack. This program is used for very strong depletion of those cells that weakly express the antigens used for magnetic labeling, or to achieve the highest purity of the untouched cell fraction. However, choosing Depl025 might result in a reduced recovery of the target cell fraction.

FITC: Fluorescein isothiocyanate

Fluid bottle: 1.5 L bottles holding the fluids for operational use of the autoMACS Pro Separator. Fluid sensors monitor the fluid levels in the bottles for Running Buffer, Washing Solution, and waste *via* electrolyte conductivity. The fluid level in the bottle for the storage solution cannot be monitored as no electrolytes are present in the solvent.

Fluid sensors: This sensor type measures electrolyte conductivity and is an integral part of the bottle closures of the fluid bottles for waste, Running Buffer, and Washing Solution.

Fluid sensor cable: Cable connecting the fluid sensor to the autoMACS Pro Separator. The sensor cable connectors on the bottle closures are color-coded: red for waste, green for Washing Solution, and blue for Running Buffer.

Fraction collection tube: 5 mL, 15 mL, or 50 mL plastic sample tubes to collect the positive and negative fractions. The process has been optimized using tubes from BD Falcon.

Front door: The front door opens sidewards, giving access to the autoMACS Columns, pumps, valves, washing station, and tubing.

MACS Technology: Technology developed by Miltenyi Biotec for immunomagnetic labeling and subsequent separation of cells or biomolecules in a high-gradient magnetic field.

MACS MicroBeads: Super-paramagnetic particles conjugated to antibodies for magnetic labeling of cells or biomolecules.

Magnet cover: Black cover surrounding the magnets. The magnet cover is located in the center of the fluidic system and has slots for the autoMACS Columns.

Memory card: Removable compact flash/SD RAM card containing the autoMACS Pro programs.

Memory card slot: Slot located on the right hand side of the autoMACS Pro touchscreen, giving access to the memory card. The memory card should be removed by trained personnel only.

Negative fraction: Sample fraction containing the non-labeled cells that pass through the autoMACS Column while the column is placed in the magnetic field.

PE: Phycoerythrin

Ports: The automated arm carries two ports: the port located proximal to the instrument is designed for computer-controlled fluid detection and distribution such as magnetic labeling, sample mixing, sample uptake, and release of the magnetically labeled fraction while the port in the front releases the non-labeled fraction.

Positive fraction: Sample fraction containing the cells labeled with MACS MicroBeads. These cells are retained on the column while the column is placed in the magnetic field. The cells are eluted from the column after the magnet has been removed from the column.

Positive selection: Process of isolating cells by labeling the target cells with MACS MicroBeads and performing a MACS Separation. The labeled target cells are eluted in row C of the tube rack.

Possel: Positive selection program in standard mode using one autoMACS Column. The target cells are eluted in row C of the sample rack. This program is used for cells with normal to high frequency and with normal antigen expression.

Possel_s: Positive selection program, sensitive mode, using one autoMACS Column. The target cells are eluted in row C of the sample rack. This program is used for cells with normal to high frequency which weakly express the antigens used for magnetic labeling, or to achieve the highest recovery of the target cells.

Posseld: Positive selection program, normal mode, using both autoMACS Columns. The target cells are eluted in row C of the sample rack in a volume of 0.5 mL. This program is used to isolate rare cells or to achieve a higher purity of the target cells.

Posseld2: Special positive selection program, normal mode, using both autoMACS Columns. The target cells are eluted in row C of the sample rack in a volume of 2 mL. This program is used to isolate rare cells from whole blood, cord blood, or large cell samples, and to achieve a higher recovery of the target cells.

Posselds: Positive selection program, sensitive mode, using both autoMACS Columns. The target cells are eluted in row C of the sample rack in a volume of 2 mL. This program is used to isolate rare cells that weakly express antigens used for magnetic labeling, e.g., CD133.

Posselwb: Special positive selection program using both autoMACS Columns for the isolation of cell subsets from of whole blood. The target cells are eluted in row C of the sample rack.

Running Buffer bottle: Bottle for Running Buffer. The bottle closure is equipped with a fluid sensor. The closure, the fluid sensor cable, and the tubing connector are color-coded blue.

Safe solution: Solution of 1% (w/v) sodium hypochlorite in distilled water used to decontaminate the autoMACS Pro fluidic system with the **Safe** program. The safe solution is fed into the system from a 50 mL tube. Upon completion of the Safe program, the fluidic system contains Running Buffer.

Storage solution: Solvent used during the **Sleep**, **Store**, **Safe, Clean**, and Column Exchange (**Col_ex**) programs to minimize the contamination risk. The fluidic system of the autoMACS Pro Separator is filled with storage solution (70% ethanol).

Storage solution bottle: Bottle for 70% ethanol. The bottle closure, the fluid sensor cable, and the tubing connector are color-coded black.

Store program: Prior to long term storage, the **Store** program should be applied. During this procedure the autoMACS Columns are replaced with substitutes. Upon completion of the **Store** program, the fluidic system contains 70% ethanol.

Syringe pump: Computer-controlled high precision syringe pump with Teflon® seal plunger that drives fluids through the autoMACS Pro fluidic system.

Touchscreen: High resolution TFT color touchscreen located on top of the autoMACS Pro Separator. The touchscreen is used to operate and monitor the instrument through on-screen menus.

Tubing connector: Plastic threaded connector with square nut used to connect the tubings to the bottle closures, the columns, the pump, or valves.

Tubing system: Permanent set of Teflon® tubing through which fluids circulate in the autoMACS Pro Separator fluidic system.

Chill racks: Three different acrylic tube racks are provided with the instrument. They are designed for optimal positioning of sample tubes and fraction collection tubes at the ports of the automated arm. They contain a coolant allowing to pre-cool the racks in the refrigerator for cooling of the cells during the separation process. The racks have four tube positions for each sample. Position A holds the sample tube containing the starting material. Position B holds the tube for the non-labeled fraction. Position C holds the tube for the magnetically labeled fraction. Position D is auxiliary. For details, refer to the table in section 4.1.2.

Washing Solution bottle: Bottle for autoMACS Pro Washing Solution. The bottle closure is equipped with a fluid sensor. The closure, the fluid sensor cable, and the tubing connector are color-coded green.

Waste bottle: Bottle for waste fluid. The closure is equipped with a fluid sensor. The closure, the fluid sensor cable, and the tubing connector are color-coded red.

Whole Blood MicroBeads: MACS MicroBeads developed for isolating target cells directly from human whole blood.

Wrench: Black wrench used to tighten and loosen tubing connections.

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