Working with the Haemonetics® MCS®+
- Operation Manual -

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Legal disclaimer

This manual is intended for use as a guide, uniquely for material as supplied by the Haemonetics Corporation. It provides the operator with necessary information to safely carry out specific procedures and satisfactorily maintain Haemonetics produced equipment. The manual is to be used in conjunction with instruction and training as supplied by qualified Haemonetics personnel.

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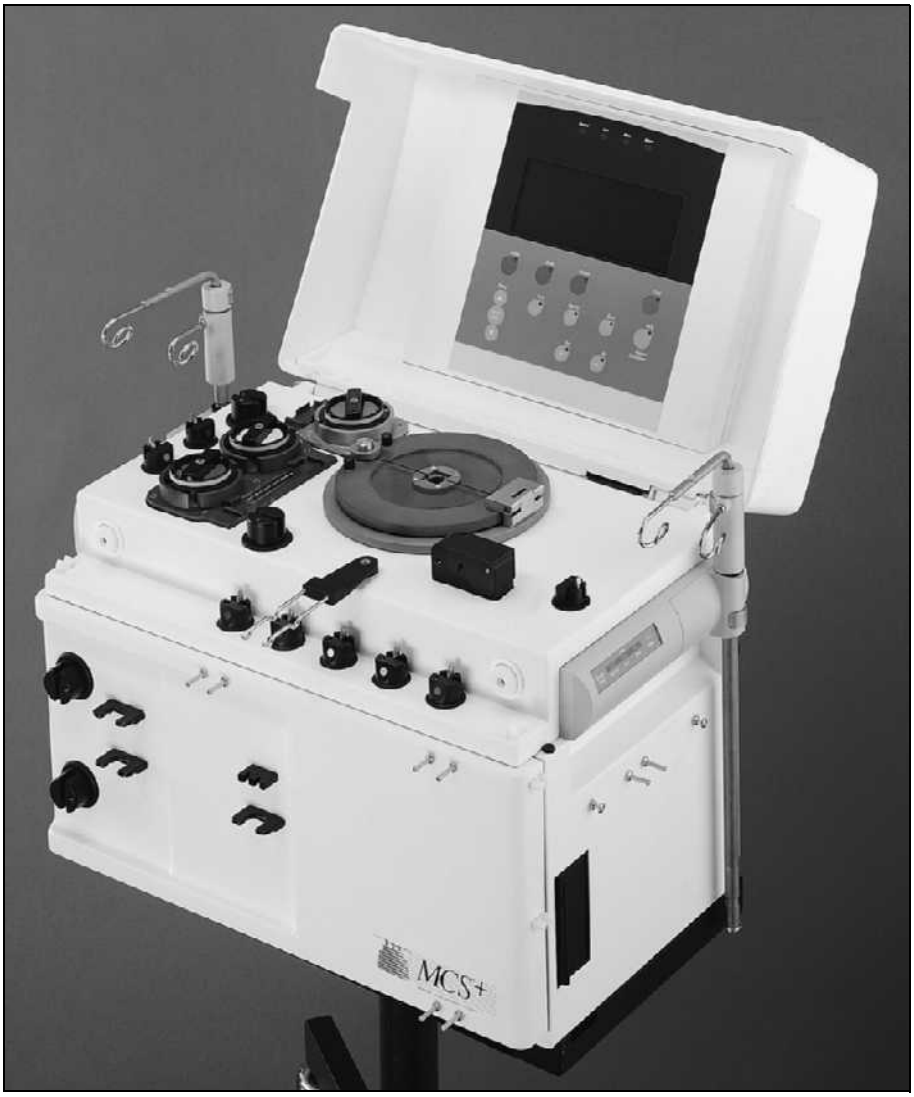
Preface



The Haemonetics MCS+ LN09000-220E/ED

INTRODUCING THE MCS+ TOTAL APHERESIS DEVICE

What is the purpose of this manual?

This manual is intended to supply anyone involved in using Haemonetics apheresis equipment with the essential tool for safe and successful operation – *information*. Using this tool of information, the operator can acquire knowledge to be applied throughout all levels of operating experience. This body of information should be consulted whenever necessary, starting from the initial contact with Haemonetics technology, in order to attain:

- An awareness of the purpose of the device and the implications of its collection procedures for the donor/patient and the apheresis center.
- An understanding of how to safely operate the Haemonetics system, correctly install the appropriate disposable material, and troubleshoot any difficulties.
- An ability to consistently apply the principles behind safe operation, proper maintenance and correct handling to ensure optimal, quality apheresis results.

This manual covers MCS+ device information for list numbers LN9000-220-E, LN9000-220-ED, LN9000-220-EW, and LN9000-110-EWC. Information that is specific to a certain protocol (disposable set installation and how to run the protocol), is located in the protocol manuals.

What is apheresis technology?

Apheresis is the general term used to describe the selective removal and collection of one or more individual components which together form whole blood. This term can be subdivided into two categories:

- **Cytapheresis:** selective removal of one or more of the formed, cellular components of whole blood. These elements include erythrocytes, thrombocytes, leukocytes and stem cells.
- **Plasmapheresis:** selective removal of plasma, the liquid suspension medium of blood. Plasma contains elements referred to as fractional components, such as clotting proteins and immunoglobulins.

Apheresis Technology permits:

- The collection and separation of whole blood.
- The selective removal of specific components.
- The subsequent return of the remaining components to the donor/patient.

What is the Haemonetics "Mobile Collection System"?

Using updated apheresis technology, Haemonetics has produced the MCS+, a highly mobile, compact, lightweight total apheresis system which is as easy and safe to use, as it is technologically advanced.

The MCS+ automated apheresis technology provides the operator with a maximum degree of flexibility in any type of apheresis location. The components collected such as platelets, red cells, stem cells, and plasma may be designated for use in therapeutic transfusion. Plasma collected can also be conserved and subsequently fractionated into plasma-derived products.

The MCS+ (Haemonetics "Mobile Collection System Plus"), consists of distinctive "parts" which collectively function as a "whole" to produce a designated final product. These system elements can be explained using the following distinctions:

- The automated total apheresis device produced by Haemonetics called the "MCS+".
- The single-use collection material manufactured by Haemonetics called a "disposable set".
- The collection procedure designed by Haemonetics called a "protocol".

Once the operator has initiated an MCS+ procedure, component collection will proceed automatically. The appropriate amount of anticoagulant solution will be mixed in the disposable tubing with whole blood from the donor/patient.
This anticoagulated blood will be drawn into a disposable collection bowl and separated by centrifugal force into its various components.

When the bowl reaches its collection capacity, the separated components will exit the bowl and be directed into collection containers for conservation, or returned to the donor/patient. This cycle is repeated until the desired amount of selected blood components have been collected.

The choice of the disposable material will depend on the selected MCS+ collection protocol. The MCS+ technology provides the operator with the option to infuse saline solution along with the blood components remaining in the bowl at the end of a procedure.

Haemonetics has designed the MCS+ technology with a degree of automation which permits the operator to interact with the device. The operator should remain attentive to the screen messages while monitoring the status of the donor/patient. It is possible to modify the collection procedures, based on the needs and requirements of the individual donor/patient, as well as the apheresis center.

What are the characteristics and special features of the MCS+?

MCS+ collection procedures are quick and easy to initiate, requiring the operator simply to:

- ➔ Select a collection protocol among the interchangeable Protocol cards.
- ➔ Install the disposable set elements.
- ➔ Enter donor information and modify procedure parameters as needed.
- ➔ Perform a single venous puncture and initiate the MCS+ procedure.

Haemonetics has incorporated advanced technological features into the portable MCS+ design. Examples of these features which ensure safety for the donor/patient and permit efficient time-management for the operator, are:

- A removable Protocol card: permits the operator to change between the various MCS+ collection procedures available without requiring extra technical service. Using this system, a collection procedure upgrade is very simple – a new MCS+ protocol card is provided when MCS+ procedure programming is revised.
- A large, interactive control panel: provides the operator with feedback and on-line assistance.
- The Haemo Calculator: an integral facet of the MCS+ function which calculates processed procedure volumes based on individual donor/patient characteristics and targeted product yields.
- The Haemo Update function: allows the operator to consult updated statistics at any time during the MCS+ procedure.
- The centrifuge chuck adapter: permits the operator to use a wide variety of disposable sets containing either the Haemonetics Latham bowl or the Haemonetics blow molded bowl.
- Self-loading pumps (including the Transfer pump): contribute to a well-managed collection procedure.
- Advanced optical sensor technology, including the anticoagulant drip monitor which counts drops and monitors AC solution flow.

The communication box and bar-code reader for data acquisition and procedure data transfer, either to a printer, or to the Haemonetics network, *HaemoNet*.

Setting up the device

The following guidelines should be observed when setting up the MCS+ device:

- Always place the device on a flat, stable surface.
- Allow the device to equilibrate to room temperature before use.
- Always ensure the IV poles are in the “down” position and the cabinet cover is closed when moving or transporting the device.

Symbols found in this document

The terms *Note, Caution* and *Warning* are used in this manual with the following symbols to emphasize certain details for the operator.

Note: provides useful information regarding a procedure or operating technique when using Haemonetics material.

Caution: *advises the operator against initiating an action or creating a situation which could result in damage to equipment, or impair the quality of the blood products; personal injury is unlikely.*

Warning: advises the operator against initiating an action or creating a situation which could result in serious personal injury to either the donor or the operator.

Symbols found on the device

The descriptions of the following symbols are based on information provided in the following documents:

- IEC 60601-1 Standard, Medical Electrical Equipment, Part 1: General requirements for safety.
- IEC 60417-1 Standard, Graphical symbols for use on equipment, Part 1: Overview and application.

Type BF applied part

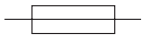
This symbol indicates that the applied portion (i.e. the part which comes in contact with the donor) of the device is electrically isolated. The device has an internal electrical power source providing adequate protection against electrical shock, in particular pertaining to acceptable leakage current and the reliability of the protective earth connection.

Protective earth (ground)

Used to identify any terminal intended for connection to an external conductor, for protection against electrical shock in case of a fault.

~ **Alternating current**

Used to indicate on the rating plate that the device is suitable for alternating current only.

 **Fuse symbol**

Used to identify fuse boxes or the location of a fuse box.

 **Power OFF**

Position of the main power switch indicating disconnection from the mains.

 Power ON

Position of the main power switch indicating connection to the mains.

IPX1 **Protection against ingress of liquid**

Indicates that the enclosure of the device is designed to provide a specified degree of protection against harmful ingress of water or liquid into the equipment (under applicable conditions).

 **Attention** (Consult accompanying documents)

 **Non-ionizing electromagnetic radiation**

Used to specify RF transmission for data communication.

 **Electrical and Electronic Equipment Waste**

Dispose of the device using a separate collection method (according to EU and local regulation for waste electrical and electronic equipment).

The following symbols have been designed for devices manufactured by Haemonetics:

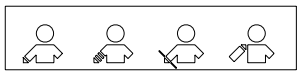
Bar-code reader connection

RS232 connection

RS232 connection with power to one pin

Pressure cuff connection

Engraved centrifuge locking knob



Flow indicator lights

Symbols found on disposable packaging

The following symbols are used by Haemonetics on disposable set packaging.

REF **CATALOG NUMBER**

EXPIRATION DATE

Lot Number

Sterilized by exposure to Ethylene Oxide

Fluid path STERILE by exposure to Ethylene Oxide

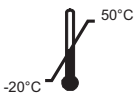
Sterilized by exposure to Gamma irradiation

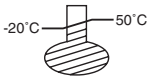
Fluid path STERILE by exposure to Gamma irradiation

DO NOT REUSE

Caution: consult operator manual for instructions

Storage conditions, humidity level





Storage conditions, temperature level

Specifications of the MCS+ device

The approximate weight and dimensions for the MCS+ device are as follows:

Characteristics	Values	
	Cabinet cover open	Cabinet cover closed
Height	68.5 cm	44 cm
Width	56.5 cm	
Depth	56.5 cm	36.5 cm
Depth with communication box	56.5 cm	38.5 cm
Weight	27.5 kg	
Weight with communication box	28.5 kg	

The following environmental conditions should be respected pertaining to operation and storage of the MCS+ device:

Conditions	Values
Ambient operating temperature	+18° C to +27° C
Tested storage temperature	-20° C to +50° C
Storage humidity level	8% to 80%, non-condensing

The electrical specifications for operating the MCS+ device are as follows:

Characteristics	Values (relative to input voltage)	
Input voltage	230 VAC ± 10%	110 VAC ± 10%
Operating current	~1.9 A	~ 2.6 A
Fuse rating	F2.5 A @ 250 V	F5.0 A @ 250 V
Operating frequency range	50 - 60 Hz	50 - 60 Hz

Note: Haemonetics will regulate the proper voltage setting upon installation. The power source used must be properly grounded.

Warning: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The shipping/ storage temp are -20C to 50C at 8% to 80% humidity. The artwork for the carton is only in the old film style.

Note: The MCS+ device contains no user serviceable/repairable parts.

Caution: *The MCS+ device must be operated in an environment compatible to the requirements of the IEC 60601-1-2 Standard, Electromagnetic compatibility.*

Mobile RF communication equipment not approved by Haemonetics and portable communication equipment can affect the MCS+ device. Any accessories and cables not approved by Haemonetics used in conjunction with the device may increase hazards and influence compatibility with EMC requirements. Therefore, non-approved accessories and cables must not be used.

In addition, the MCS+ device and accessories must not be placed directly adjacent to, or top of other equipment, unless specifically approved by Haemonetics.

Caution: *The MCS+ device must be operated in an environment compatible to the requirements of IEC60601-1-1 Standard, Medical electrical equipment.*

Any electrical equipment used inside or outside the "patient environment" (as defined in the Standard), whether connected or not connected to the MCS+ device, must provide a level of safety compliant with relevant IEC and ISO safety standards. Safe environmental conditions must be maintained for all devices inside and outside of the patient environment.

When properly operated and maintained, the MCS+ device provides a level of safety compliant with the IEC 60601-1-1 Standard, both inside and outside the patient environment.

The operator is responsible for making sure that the final configuration of the MCS+ device complies with IEC 60601-1-1 Standard, Medical electrical equipment.

Note: Refer to the Postscript to the MCS+ Operation Manual (P/N 85270-30), for information about Haemonetics approved devices, such as a printer or an external network, that can be connected to the MCS+ device.

Chapter 1

Describing the MCS+ Centrifuge System

P/N 85213-30, Manual revision: B

PRESENTING THE MCS+ CENTRIFUGE SYSTEM

The centrifuge system of the MCS+ device is designed to hold a disposable bowl which can be spun from a range of 3000 to 7000 revolutions per minute. This centrifugal force will separate anticoagulated whole blood in the bowl into its various components.

There are two types of centrifuge systems for the MCS+ devices currently in use. One system uses mechanical clips to secure the disposable bowl in place during operation; the other uses a vacuum effect for the same purpose.
The MCS+ centrifuge components consist of:

- The centrifuge base.
- The centrifuge well.
- The system-sealing mechanism.

All MCS+ centrifuge systems contain a split hinged lid as a cover to seal the system, however variations exist among the elements of the base and well.

1. Locking knob
2. Optical sensor
3. Long fluid detector
4. Round fluid detector
5. Mechanical chuck
6. Vacuum chuck

NOTE:
Any system containing one or two round fluid detector(s) could be retrofitted with one long fluid detector.

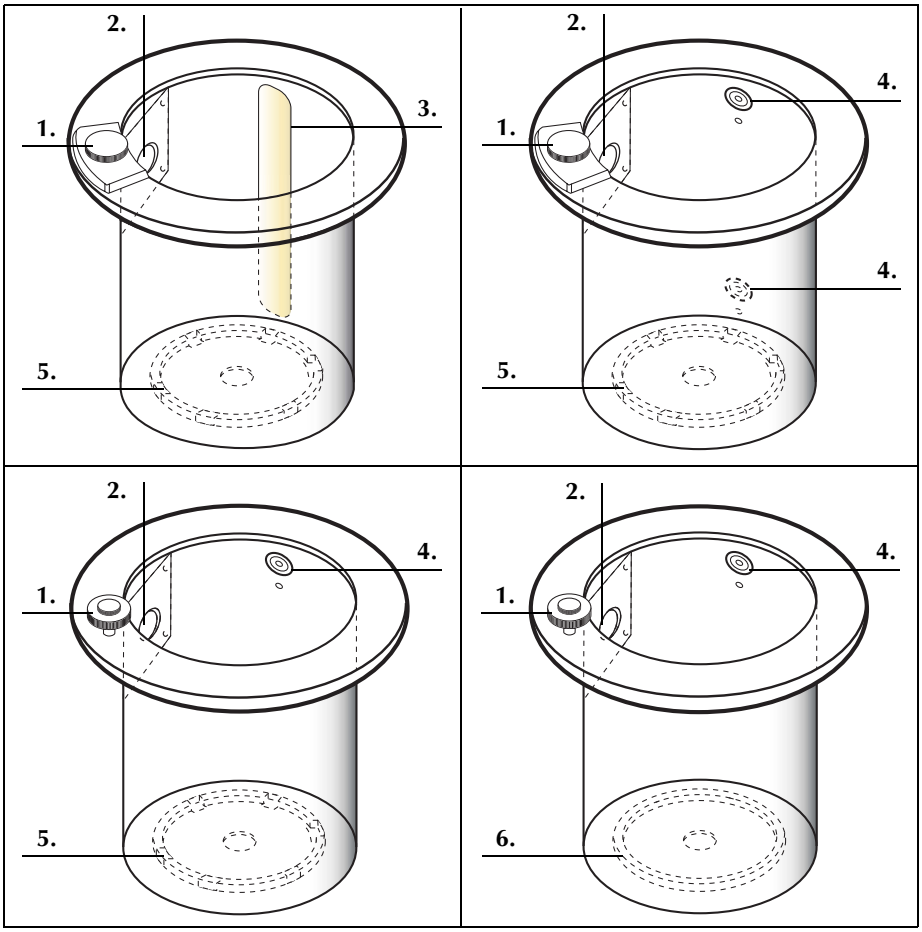


Figure 1-1, Variations among the MCS+ centrifuge systems

CENTRIFUGE BASE

The centrifuge base contains a chuck designed to hold a disposable centrifuge bowl in place during operation. The MCS+ disposable set can contain either a *Latham bowl*, or a *blow molded bowl (BMB)*. The type of bowl used will depend on the final collection product.
The technique used to install a bowl will depend on the design of the centrifuge chuck. The following variations exist among MCS+ devices in use:

- Centrifuge base with a mechanical chuck/factory origin.
- Centrifuge base with a vacuum chuck/factory origin.
- Centrifuge base with a mechanical chuck, retrofitted from a vacuum chuck/factory-origin.

Using a mechanical centrifuge chuck

If the MCS+ device contains a mechanical chuck, the clips on the centrifuge base will hold the bowl in place. When installing a bowl, the operator should exert a downward pressure on the head of the bowl and ensure that the bowl is completely seated. The operator will hear a “click” after applying the proper downward force.

To remove the bowl at the end of the procedure, the operator should grasp the head of the bowl and pull sideways to release the bowl from the clips while lifting the bowl out of the centrifuge well.

Figure 1-2, MCS+ mechanical centrifuge chuck

Caution: *The mechanical chuck clips must be kept clean, and should be thoroughly cleaned after any spills. A dirty or blocked clip may no longer hold the bowl correctly. If a clip is not functioning properly, the operator must contact an authorized Haemonetics representative.*

Using a vacuum centrifuge chuck

If the MCS+ device contains a vacuum chuck, a vacuum force will be created between the base of the bowl and the chuck to hold the bowl in place. When installing a bowl, the operator should exert a downward pressure on the head of the bowl and ensure that the bowl is completely seated. The bowl will be completely secured once the operator has locked the centrifuge lid.
To remove a bowl at the end of a procedure, the operator should simply pull upward on the bowl until the vacuum force is disrupted. The bowl can then be lifted out of the centrifuge well.

Figure 1-3, MCS+ vacuum centrifuge chuck

Caution: *If any residual vacuum force remains and the operator cannot remove the bowl using this technique, the manual vacuum release button can be used (refer to Manual vacuum release button in Chapter 2). However, the operator should not use this mechanism during routine MCS+ function, as this could damage the bowl and/or centrifuge components.*

Figure 1-4, MCS+ vacuum centrifuge retrofitted with the mechanical chuck

Applications for a centrifuge chuck adapter

When the selected MCS+ protocol uses a blow molded bowl (BMB), a centrifuge chuck adapter is required to secure the BMB in the centrifuge well, designed for the Latham bowl.

The chuck adapter is designed to be installed and removed using the same techniques as for the Latham bowl. The adapter will be secured by either vacuum force, or the mechanical clips, depending on the type of centrifuge chuck.

Once the adapter has been securely positioned, the BMB can be installed in the adapter, using a downward pressure to fully seat the bowl. A suction force will be created between the base of the adapter and the bowl. To remove a BMB at the end of a procedure, the operator should simply pull upward on the head of the bowl. The adapter can be removed from the centrifuge well using the same technique as when removing the Latham bowl.

Figure 1-5, MCS+ centrifuge with chuck adapter for blow molded bowl

Note: The chuck adapter is not a disposable element and should not be discarded after use. It is to be re-used for subsequent MCS+ procedures.

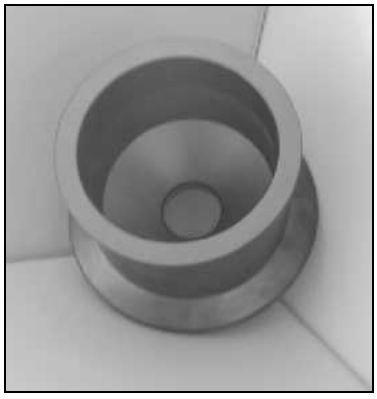


Figure 1-6, MCS+ centrifuge chuck adapter

CENTRIFUGE WELL

The MCS+ centrifuge well is designed with the following components.

Optical bowl sensor

There is an optical sensor located on the upper portion of the centrifuge well. The sensor is aimed at the core of the bowl and will measure optical reflection as the various blood components pass in front of the optical beam.

Note: The interface between the optical sensor in the centrifuge well and the contents of the bowl is often referred to as "bowl optics" and will be discussed in further detail in each respective MCS+ protocol manual.

1. Optical sensor
2. Long fluid detector
3. Round fluid detectors

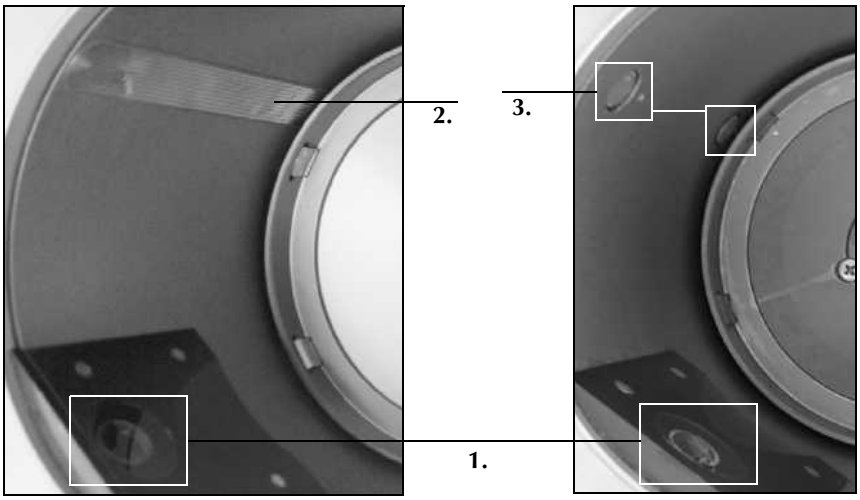


Figure 1-7, MCS+ optical bowl sensor and fluid detectors

Caution: *The optical bowl sensor must be kept clean, and should be cleared after any spills. A dirty or clouded lens will interfere with proper functioning of the MCS+ device.*

Fluid detector(s)

The MCS+ centrifuge well is equipped with an electronic fluid detection system designed to detect the presence of liquid. Depending on the style of centrifuge in use, there will be either one long fluid detector, or one or two round fluid detector(s) mounted on the wall of the centrifuge well. The MCS+ safety system will automatically stop the centrifuge (and the pumps) if there is contact between liquid of any sort and the fluid detector(s).

SYSTEM-SEALING MECHANISM

The MCS+ centrifuge contains a split, hinged lid (or cover) and a locking knob. These components "seal" the system by:

- Securing the contact of the disposable bowl with the centrifuge base.
- Isolating the spinning bowl from the operator.

Centrifuge cover

The centrifuge lid, referred to as the cover, has tabs located on the rimmed portion of each split side. The split halves are attached to the centrifuge rim by a hinge. As the halves of the lid are lowered to meet the rim, the tabs must be firmly pressed together in order to completely close the lid and provide a seal around the stationary head of the disposable bowl.

The split halves of the lid are made from a durable, transparent material, allowing the operator to observe changes in the bowl contents as the centrifuge spins.

Locking knob

The locking knob is positioned on the rim of the centrifuge well.
Two types of locking knobs exist among the MCS+ devices in use.

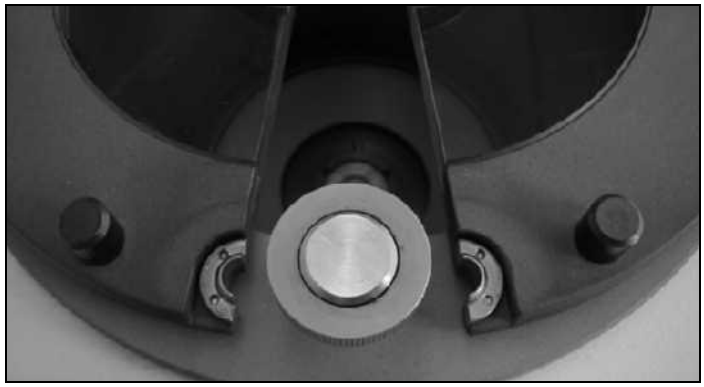


Figure 1-8, Locking knob (turn to open/close)

One style of knob requires a series of turns to lock or unlock the lid. Once the lid has been fully closed, the knob should be turned in a clockwise direction to lock the centrifuge and thus completely seal the system. The operator will be cued by the MCS+ display screen.

To unlock the centrifuge, the operator should turn the knob in a counter-clockwise direction until the split halves can be separated, then lifted to open the lid.

The second style requires that the operator press the knob to separate the halves of the split lid when opening the centrifuge. The knob can be engraved with either the text "PUSH TO OPEN", or a symbol of a lock.

The centrifuge can be locked once the split halves of the lid have been firmly pressed together using the tabs. This knob is incorporated into an elevated base. The knob needs to be turned and aligned with the appropriate symbol on the base to place it in the *locked* or *unlocked* position.

Figure 1-9, Locking knob
"PUSH TO OPEN", symbol version

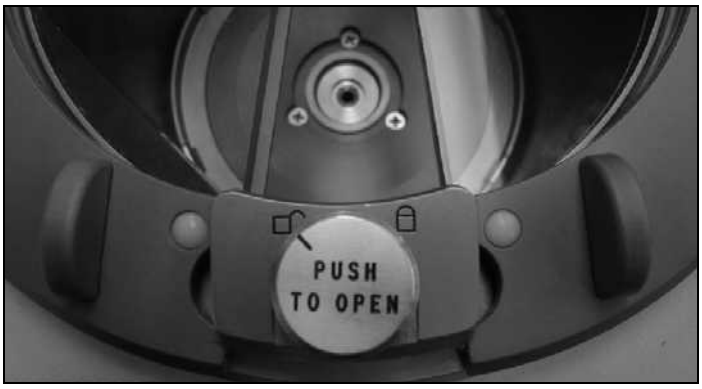


Figure 1-10, Locking knob
"PUSH TO OPEN", text version

Warning: The MCS+ device is equipped with a safety feature which will not allow the centrifuge to spin if the lid has been improperly closed. It is unlikely that a properly installed centrifuge bowl will become unaligned as it spins. However, if the operator should notice anything unusual about the bowl, under no circumstances, should the operator attempt to open the centrifuge lid if the bowl is still spinning. The operator must ensure that the centrifuge has come to a complete stop before attempting to open the lid for any reason.

Summarizing the MCS+ centrifuge components

The following table summarizes the combinations of centrifuge components which can be found among the MCS+ centrifuge systems in use.

Table 1-1, MCS+ Centrifuge component combinations

Component	Mechanical chuck	Vacuum chuck	Vacuum chuck mechanically retrofitted
Centrifuge chuck	Mechanical clips secure the bowl or chuck adapter.	Vacuum force secures the bowl or chuck adapter.	Mechanical clips secure the bowl or chuck adapter.
Fluid detector(s)	One long or two round	One round	One round
Optical bowl sensor	One	One	One
Split hinged lid	Designed with semi-circularly shaped tabs, pressed to close the sides of the lid.	Designed with cylindrically shaped tabs, pressed to close the sides of the lid.	Designed with cylindrically shaped tabs, pressed to close the sides of the lid.
Locking knob	Knob engraved with either: “PUSH TO OPEN” symbol or text.	Requires series of turns to lock or unlock the lid.	Requires series of turns to lock or unlock the lid.

Chapter 2

Describing the MCS+ Cabinet Components

PRESENTING THE MCS+ CABINET COMPONENTS

The individual components located on the MCS+ cabinet will be presented to the operator in this chapter, grouped by the following sections:

- Top deck components.
- Front panel components.
- Side panel components.
- Rear panel components.

Note: Any references made to "left", "right", "top", or "rear" are from the perspective of an operator facing the MCS+ device during an apheresis procedure.

1. Top deck
2. Front panel
3. Right side
4. Rear panel (not visible)

Figure 2-1, MCS+ section distinctions

The disposable elements will be explained in greater detail in *Chapter 4* and in each respective MCS+ protocol manual. As an explanation for the operator concerning any references made to disposable set elements in this chapter:

Donor line tubing refers to the tubing which is either:

- Transporting blood away from the donor before the blood enters the centrifuge bowl, or,
- Transporting blood from the bowl prior to re-infusion to the donor.

Effluent tubing refers to the tubing which is either:

- Exiting the bowl in the direction of the collection container(s), or,
- Transporting non-selected blood components back to the centrifuge bowl.

TOP DECK COMPONENTS

1. to 8. MCS+ pinch valves

Note: valve 3 is the "donor" valve or red-coded valve

9. AC pump
10. Transfer pump
11. Blood pump
12. Optical line sensor
13. Weigher
14. DPM
15. SPM
16. ACAD
17. BLAD

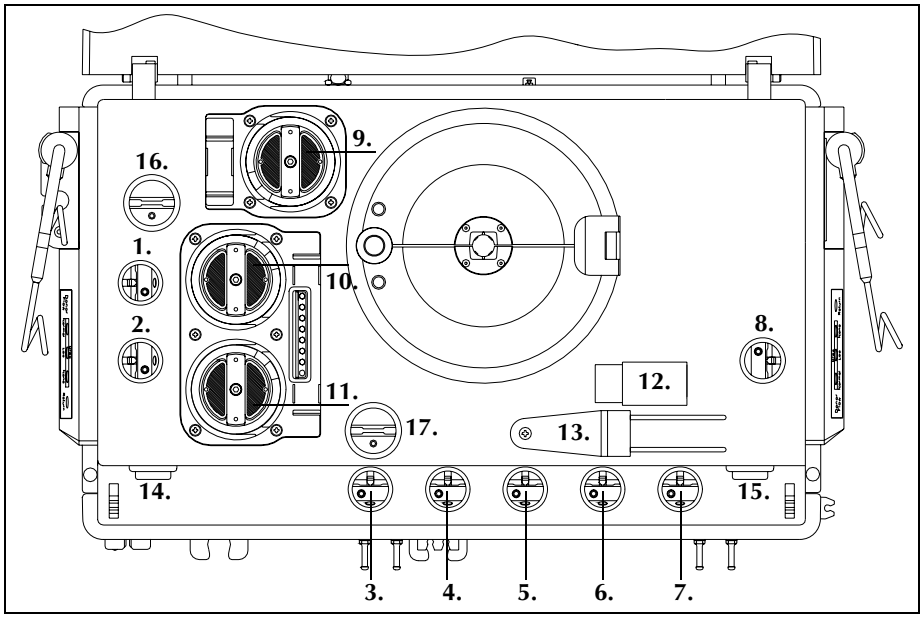


Figure 2-2, MCS+ top deck

Valves

There are eight valves located on the MCS+ top deck which automatically control the flow of fluids through the disposable set tubing. The valves are color-coded and correspond with specific sections of disposable set tubing. Each valve also contains a light to indicate an open (lit) or closed (not lit) state. The MCS+ safety system will control the valves during the power-up self-diagnostic tests. Once the operator has selected a collection protocol, the appropriate valves will open automatically and be lit, in preparation for loading the disposable tubing.

Note: The function of each valve will depend on the selected MCS+ protocol, however the red-coded valve (N° 3) is consistently used as the "donor" valve.

During the different modes of the selected MCS+ protocol, the valves will operate automatically, opening and closing depending on the passage of fluids. However, the valves can be opened manually if the disposable tubing should need to be adjusted during a procedure, by pressing the pinch-lever on each valve toward the cabinet.

Warning: Any manual adjustment to a valve should be attempted only if the MCS+ device is POWERED OFF, in the READY state, or when the pumps are stopped. At any other time, the MCS+ safety system will be alerted and will interrupt the procedure. Manipulating a valve could lead to flow problems, and eventually cause hemolysis. *Chapter 6* will discuss hemolysis in further detail.

Pump assemblies

Located on the left side of the MCS+ top deck are three pumps which use peristaltic movements to displace fluids through the disposable set tubing. Each pump is designated by a color and will function at particular moments during the apheresis procedure, as determined by the selected MCS+ protocol.

A pump assembly consists of a pump rotor, housed in a well containing the pump motor. The outer pump housing is designed to secure the correlating pump manifold of the disposable set. During installation of the disposable set, the MCS+ will perform an autoload of the tubing onto the pumps.

1. Single-pump housing
2. Dual-pump housing
3. Dual-pump identification window
4. AC pump rotor
5. Transfer pump rotor
6. Blood pump rotor

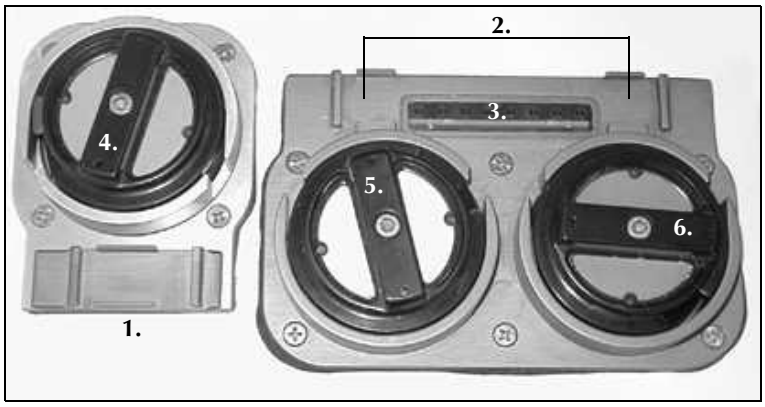


Figure 2-3, MCS+ pump assemblies

Single-pump assembly: Anticoagulant (AC) pump

The AC pump, designated by the color blue, moves AC solution from the solution bag up to the needle connector of the donor line tubing. The AC pump housing is designed to secure the corresponding single-pump manifold of the disposable set.

Dual-pump assembly: Blood pump and Transfer pump

The Blood pump, designated by the color red, moves fluids between the donor and the disposable centrifuge bowl.

The Transfer pump, designated by the color white, can serve a variety of functions during a collection procedure, depending on the selected MCS+ protocol. This pump can be used to “transfer” fluids such as collected plasma, saline, or platelets between the centrifuge bowl, collection bags or parts of disposable tubing.

These two pumps are grouped in a dual-pump housing, designed to hold the disposable set pump manifold containing disposable set identification information.

Dual-pump identification window

The information on the dual-pump manifold of each specific disposable will be scanned by the optical sensors located under the identification window.

Understanding the function of the pumps

The pumps function in a general manner during the different modes of MCS+ operation as follows:

When loading the disposable tubing:

- The AC pump and the Blood pump turn simultaneously to thread the disposable tubing onto the pump rotors.
- The Transfer pump will be active during certain MCS+ protocols.

During PRIME

- The AC pump and the Blood pump turn simultaneously to provide the inlet side of the donor-line tubing with AC solution.
- The Transfer pump will be active during certain MCS+ protocols.

During DRAW

- The AC pump will deliver AC solution from the AC solution bag to the needle connector.
- The Blood pump will pull anticoagulated whole blood past the blood filter of the disposable set and into the centrifuge bowl.
- The Transfer pump will be active during certain protocols. The Transfer pump speed will vary in relation to the Blood pump speed and the donor flow rate.

During RETURN

- The Blood pump pulls the remaining blood components from the centrifuge bowl and re-infuses the contents to the donor.
- The Transfer pump will be used to mix solutions with the uncollected blood components, prior to re-infusion to the donor.
- The AC pump will be inactive.

Table 2-1, MCS+ pump function according to MCS+ operating mode

MCS+ mode	AC pump	Transfer pump	Blood pump
PRIME	Yes	Protocol-specific	Yes
DRAW	Yes	Protocol-specific	Yes
RETURN	No	Protocol-specific	Yes

Note: The Blood pump and the AC pump will rotate at different speeds during DRAW, depending on the AC/Blood pump ratio parameter setting. Information related to the function of the pumps during sub states, such as SURGE and DWELL, will be provided in each relevant MCS+ protocol manual.

Optical line sensor

Located on the right side of the MCS+ top deck is the optical line sensor which monitors the blood components passing through the effluent tubing. This measurement is important for the MCS+ software in controlling the final collection product.

Caution: *The line sensor will not provide accurate readings if the optical lens is obstructed in any way; thus the lens must be cleared of any extraneous substances to ensure proper functioning of the system.*

Weigher

The "weigher" is the term used by Haemonetics to describe the MCS+ component which measures in grams the contents of the collection container(s) placed on the "weigher arm".

When the Draw key is pressed to begin a procedure, the weigher will automatically *tare*, or set the weigher to zero. Thus, the weight of the container will not be included in the weight displayed on the MCS+ screen.

To ensure optimal accuracy from the weigher during a collection procedure:

- The weigher arm must be fully extended, positioned at a 90 degree angle to the MCS+ top deck, prior to the system self-tests.
- The collection container must hang freely, without any contact with the MCS+ cabinet.

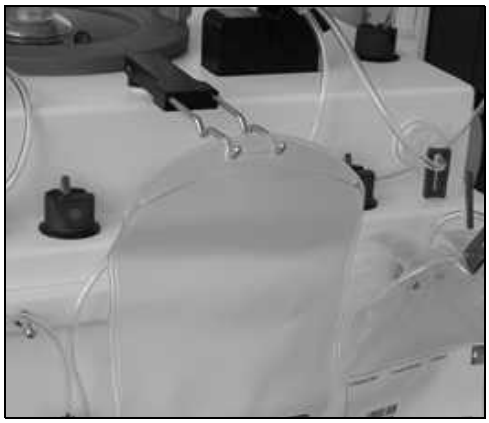


Figure 2-4, MCS+ weigher arm with collection bag installed

Caution: *The operator must be careful to **not** touch the weigher once the weight of the collection container has been set to zero. This could affect the collection procedure and a warning will be provided to the operator.*

Pressure monitors

The electronically controlled pressure monitors function with the correlating filter on the disposable set to measure pressure in the disposable tubing. The pressure monitors provide feedback to the system about the flow of blood components to and from the donor (DPM) as well as the centrifuge bowl (SPM). The MCS+ programming will automatically regulate the speed of the pumps based on this information.

Caution: *Once the DPM/SPM and the disposable set filters have been connected, they should not be disrupted at any point to ensure proper pressure readings.*

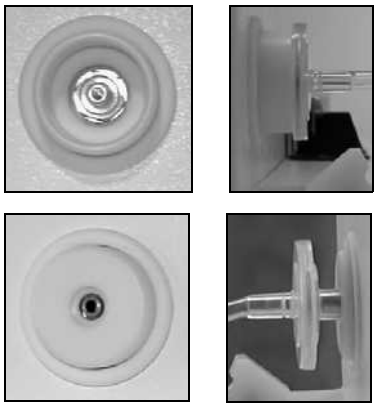


Figure 2-5, Existing variations in pressure monitor style (without and with filter installed)

Donor Pressure Monitor (DPM)

The DPM, located on the left side of the MCS+ top deck, measures pressure in the donor-line tubing. The information is depicted on the display screen using a bar graph. The bar graph is visible on the screen when donor pressure is adequate to maintain the programmed pump speed. The bar graph will not be visible if donor-line pressure is below what is required to maintain the programmed pump speed.

Variations will exist in the readings, depending on the operating mode. The MCS+ software is programmed to detect a range of "normal" values. If a pressure reading varies outside of this range, the MCS+ safety system will stop the pumps and provide an explanatory screen message, as well as an intermittent alarm.

DRAW mode

The pressure readings will vary as blood is drawn from the donor. If a significant pressure decrease is detected and the DPM readings drop below a programmed value, the pump speed will automatically decrease until a sufficient pressure increase is measured.

If the donor-line pressure is measured as insufficient, the pumps will stop, the NO FLOW indicator lights will be visible and an explanatory screen message will appear with an alarm. Once pressure is measured to be within normal operating range, the pumps will resume their programmed speed.

RETURN mode

The pressure readings will vary as blood is returned to the donor. If a significant pressure increase is detected, and the pressure readings rise above a programmed value, the pump speed will automatically decrease until a sufficient pressure change is measured. If pressure readings remain high, the Blood pump will stop, and an explanatory screen message will appear with an alarm.

When pressure is measured to be within the normal operating range, the pumps will resume operation until reaching the programmed pump speed.

Warning: The operator must remain aware of the fact that a high pressure warning can indicate a possible flow obstruction and could cause red blood cell hemolysis, and/or damage the vein. Corrective action is necessary and the operator should intervene immediately, following the actions listed on the HELP screen. The operator can also consult *Chapter 6* for information about avoiding flow restrictions.

System Pressure Monitor (SPM)

The SPM, located on the right side of the MCS+ top deck, measures pressure in the effluent tubing. This measurement verifies that the sterile seal, between the head and the body of the centrifuge bowl, remains intact.

If the SPM detects that pressure in the system increases or decreases abnormally, the MCS+ safety system will stop the pumps will stop and provide an explanatory message with an alarm. Centrifuge function will remain unaffected.

Air detectors (top deck)

The MCS+ is equipped with an assembly of ultrasonic sensors designed to detect the presence of air, bubbles or foam in the fluids flowing through the disposable set tubing.

If air is detected outside of the normal range during any mode (PRIME, DRAW or RETURN), the detectors will:

- Activate the MCS+ safety system.
- Stop the operation in progress.
- Provide the operator with an error message and an audible alarm.

Caution: *In the case of any air detection alarm, the operator must respond immediately, note the source and take immediate action, following the actions listed on the HELP screen.*

Figure 2-6, MCS+ air detector

The following air detectors are located on the MCS+ top deck.

Anticoagulant Air Detector (ACAD)

The passage of AC solution from the solution bag into the system occurs over a series of steps. The ACAD, located on the MCS+ top deck (adjacent to the AC pump), will monitor the AC line throughout the entire collection procedure.

Warning: If the AC solution is depleted prior to the end of the collection procedure, the operator may receive a NOTICE message and an alarm, signifying that the ACAD has detected air in the AC line tubing. Haemonetics recommends that the collection of blood components be discontinued at this point.

Blood Line Air Detector (BLAD)

This air detector will serve a dual purpose to the operator. It is located on the top deck of the MCS+ cabinet, to the right of the Blood pump. The BLAD will remain "active" throughout the entire procedure but will provide a specific function at the following moments:

- During a DRAW cycle, the BLAD will detect the presence of fluid passing through the blood-line tubing. This allows the system to account for the volume of blood being pumped.
- During a RETURN cycle, the BLAD will note the presence of any air in the tubing leaving the centrifuge bowl. This line contains the blood being returned to the donor and will pass through the donor valve after the BLAD. When the BLAD has detected air in the tubing within normal limits, this will signal that the bowl is empty and the RETURN cycle will be terminated.

Warning: Air detected (or lack of air detection) by the BLAD, outside of normal limits, will stop the collection procedure and alert the operator.

FRONT PANEL COMPONENTS

1. DLAD1
2. DLAD2
3. Blood filter chamber brackets
4. Re-circulation chamber brackets
5. Disposable set pins

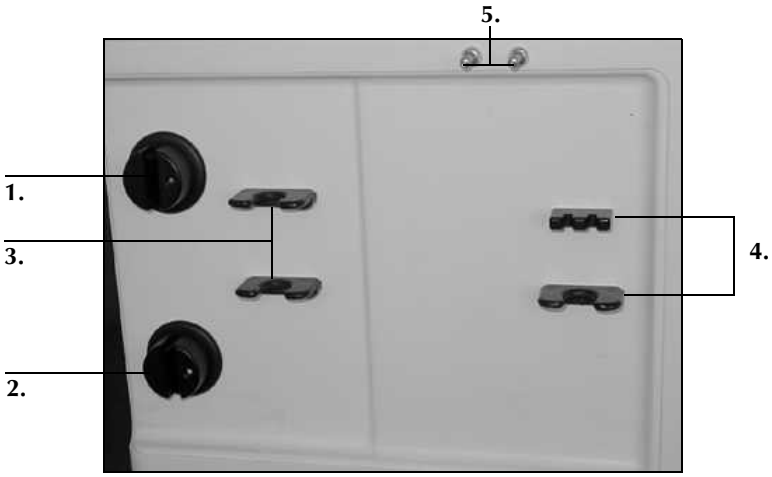


Figure 2-7, MCS+ front panel

Air detectors (front panel)

Donor line air detectors (DLAD1 and DLAD2)

The two donor line air detectors are located on the left side of the MCS+ front panel. Both air detectors monitor the donor line between the donor and the disposable set blood filter.

- During PRIME, the pumps draw AC solution into the donor line up to the DLAD. When the DLAD note fluid, the detectors signal to the MCS+ software that the line has been “primed” with AC solution and is prepared for DRAW.
- During DRAW, the DLAD will monitor the tubing containing anticoagulated whole blood and alert the operator if any air has been introduced into the system.
- During RETURN, the DLAD will monitor the donor line as it carries blood components to be infused to the donor. The DLAD monitor the line for any air which may have passed into the system undetected (probability very low) by the BLAD.

Warning: In the case of any air detection alarm, the operator must respond immediately, note the source and take immediate action, according to the list on the HELP screen. During RETURN, if either the DLAD1 and/or DLAD2 produce an air detection alarm, this could indicate a failure of the BLAD. The operator should carefully note the source of air detected – no blood should be sent to the donor until all air bubbles have been removed from the line.

Haemonetics recommends the following operator actions to remove any air bubbles detected in the tubing between the BLAD, DLAD1 and the DLAD2.

The operator should:

➔ Press the Draw key until blood enters the bowl to send any air bubbles to the bowl.

➔ Continue with a RETURN cycle only after any air bubbles have been removed.

Warning: If, after attempting this procedure to remove any air, the DLAD1 and/or DLAD2 detect air again, the operator should terminate the procedure, discontinue use of the device and contact the authorized Haemonetics representative.

Disposable set element holders

Located on the MCS+ front panel are the following various components used to secure elements from the disposable set during a collection procedure:

- Blood filter chamber brackets.
- Re-circulation chamber brackets.
- Disposable set pins.

SIDE PANELS COMPONENTS

Solution-bag poles (2)

Located on either side of the MCS+ cabinet is a height-adjustable pole. These poles are used to hang the solution bags during the collection procedure. The left pole should be used to hang the AC solution bag, whereas the right pole should be used to hang the saline solution and other bags.

Donor flow indicator lights

These color-coded lights indicate donor/patient blood flow status during DRAW mode and RETURN mode. They are used in conjunction with either a text, or a symbol.

DRAW
1. Green
2. Yellow
3. Red

RETURN
4. Yellow

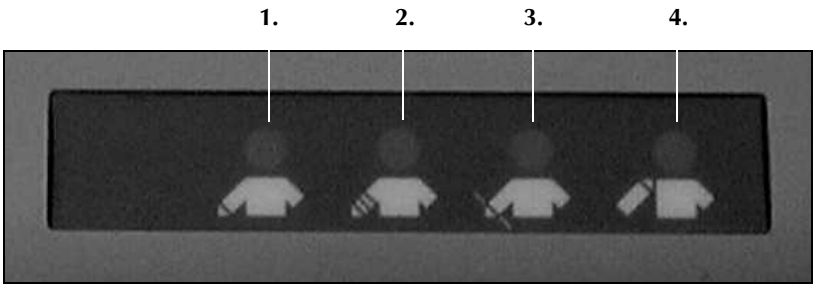


Figure 2-8, MCS+ donor flow lights (symbol version)

There are four sets of colored lights on the MCS+ device:

- Two sets are contained on each of the MCS+ side panels.
- A third set is located on the MCS+ control panel on interior of the MCS+ cabinet cover.
- A fourth set is found on the exterior of the MCS+ cabinet cover.

DRAW mode

- The GREEN LIGHT indicates that donor blood flow is sufficient for the Blood pump to maintain an adequate speed.
- The YELLOW LIGHT indicates that donor blood flow is decreasing and may be insufficient to maintain an adequate Blood pump speed.
- The RED LIGHT indicates that blood is not flowing adequately or not flowing at all from the donor/patient.

If the red flow light is lit, the Blood pump will automatically stop. The centrifuge will continue to spin to ensure continued separation of the collected blood components. When donor/patient blood flow is restored, the blood pump will automatically restart. The Transfer pump will continue to function if required by the selected MCS+ protocol.

RETURN mode

- The YELLOW LIGHT indicates that the non-selected blood components are being returned to the donor.

Note: If any of the DRAW mode lights are lit, the donor can promote blood flow by clenching and relaxing the hand below the needle site.
*When the RETURN yellow light is lit, the donor should **not** do this, because the blood components in the bowl are being returned. The operator should instruct the donor to observe the differences in the lights and act accordingly.*

1. Solution bag pole
2. AC drip monitor
3. Power entry module
4. Power cord
5. Flow indicator lights
6. Handle (one on each side)
7. Bar-code reader

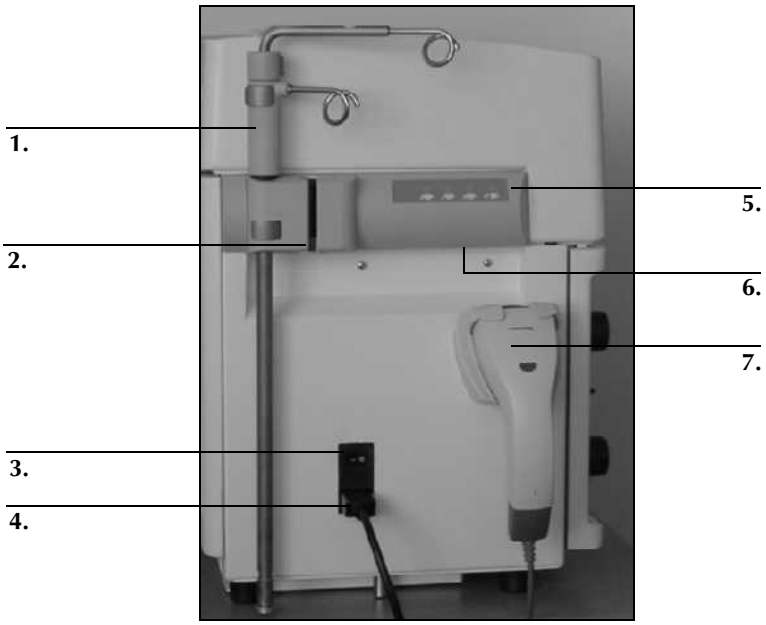


Figure 2-9, MCS+ left side panel

Anticoagulant (AC) drip monitor

The AC drip monitor contains an optical sensor, used to detect the flow of AC solution as it passes from the AC drip chamber into the AC tubing. If the AC drip monitor detects a problem with the AC flow, the MCS+ pumps will stop. The operator will receive an explanatory screen message, as well as an audible alarm.

- During PRIME and DRAW, it monitors the flow of AC solution being drawn through the tubing by the AC pump.
- During DRAW, the flow corresponds with the programmed AC ratio. The AC drip monitor works in conjunction with the ACAD to ensure the flow of AC solution to the donor-line tubing.
- During RETURN, the AC drip monitor functions as a safety feature to ensure that no AC solution is passing into the donor-line tubing.

Caution: *The lens of the optical sensor must be kept clean so that the AC drip monitor can provide accurate readings.*

Power entry module

The power entry module (PEM) is located on the left side panel of the device. Externally, the module consists of an ON/OFF switch and a power input receptacle for the power cord. Internally, the module contains the fuse panel. It will interrupt power supply to the system in the event of an electrical current surcharge.

The design of the power entry module also provides a filter-effect for the MCS+ device against the effects of a power surge.

In the case of an emergency, the ON/OFF switch can be used to stop all MCS+ function.

1. ON/OFF power switch
2. Power input receptacle

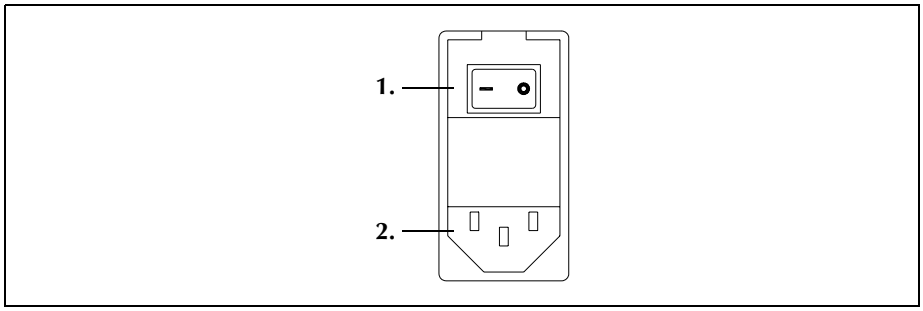


Figure 2-10, Power entry module (PEM)

Power cord

The power cord provided is designed to connect the MCS+ device with an external power source via the power input receptacle, located on the power entry module on the left side panel.

Bar-code reader

The bar-code reader is mounted on the left panel of the MCS+ device and can be used to enter the following types of data directly into the data storage memory.

- Disposable set lot and list number.
- Anticoagulant and solution bag codes.
- Donation number, donor number and operator code.

Note: The Postscript to the MCS+ contains further information on the use of the bar-code reader when entering data, as well as the role of the communication box (discussed later in this chapter), in the transfer of this data to an external device or to HaemoNet, the Haemonetics communication network.

Warning: The class II bar-code reader emits laser radiation. Do not look directly into the beam.

Handles

Handles for lifting the MCS+ device are located on the side panels.

Platelet filter holder

Located on the right side of the MCS+ device are brackets used to secure the filter contained on the MCS+ disposable sets designed for platelet collection.

Disposable set pins

The MCS+ right side panel contains pins designed to secure disposable bags from the disposable collection set.

Protocol card port

An MCS+ collection procedure is performed using the operating instructions provided on the MCS+ protocol card. Prior to powering on the device, the protocol card should be inserted into the card port located on the lower right side of the MCS+ device.

Once the protocol card has been correctly inserted, the door of the card port can be closed and should remain closed during the entire collection procedure. To remove the card at the end of a procedure, the operator should open the door and press the release tab above the card.

A.
1. Pins
2. Protocol card insertion into card port

B.
3. Release tab
4. Platelet filter holder
5. Tubing guide

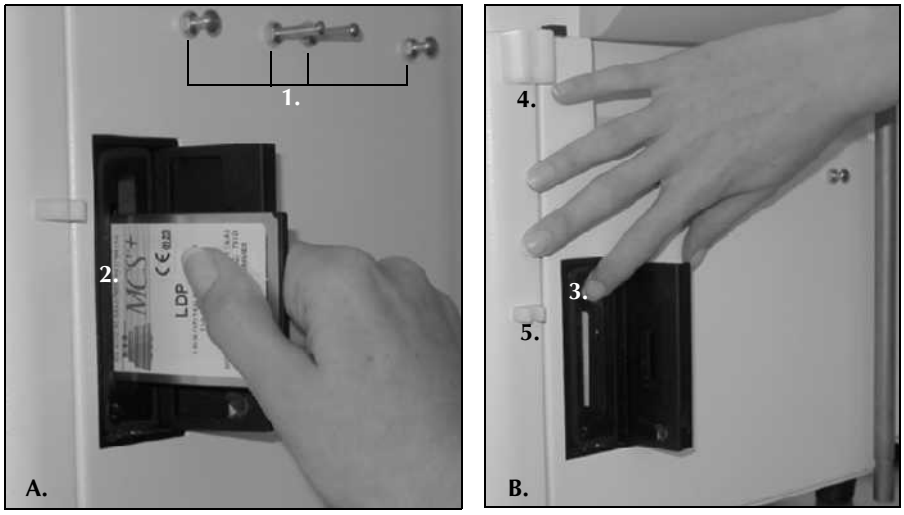


Figure 2-11, MCS+ right side panel

REAR PANEL COMPONENTS

1. Pressure cuff with cuff connection
2. Communication box
3. Biohazard waste bag
4. (Not shown) serial port connection
5. (Not shown) wireless antennae

Figure 2-12, MCS+ rear panel with external communication box

Pressure cuff

The tourniquet-style pressure cuff is used to maintain an optimal venous blood-flow from the donor during specific phases of the collection procedure. The cuff should be attached to the MCS+ cuff connection located on the rear panel of the MCS+ cabinet. The cuff meets the ANSI/AAMI SP-9 & SP-10 standards for accuracy and performance.

Communication box

Note: The communications box may not be present on all MCS+ devices. Refer to the Postscript to the MCS+ Operation Manual (P/N 85270-30), for further information on the communication box and other communication options such as the data card reader or wireless antenna.

The communication box (either internal or external) transfers data via a serial connection from the MCS+ device to an external device such as a printer, or to HaemoNet, the Haemonetics communication network. A Haemonetics trained technician must configure the communication box to communicate with a specific device. Refer to the Postscript for information about Haemonetics approved devices that can be connected to the MCS+ device.

HaemoNet provides any establishment using Haemonetics equipment with the possibility of linking several Haemonetics apheresis devices to a central monitoring computer. Using HaemoNet, procedure data can be exchanged and stored in a database and/or viewed directly.

Note: The MCS+ communication box has been tested according to standards required by EN 60601-1-2 (EMC of medical electrical equipment). The measured error rate of data communicated to HaemoNet at certain specific electromagnetic

frequencies rises above the standards. However, there is no impact on the integrity of the procedure information stored in the database. HaemoNet communication is designed with CRC error checking, performed upon the reception of all data.

Wireless antenna

Note: The wireless antenna may not be present on all MCS+ devices. Refer to the Postscript to the MCS+ Operation Manual (P/N 85270-30), for further information on the wireless feature and other communication options such as the data card reader or communication box.

The antenna, located on the rear panel and protected by a hard plastic cover, allows the transmission of procedure data to a wireless access point connected to a handheld device, internal PC or network, the eLynx communication system, or to an external computer network over the Internet.

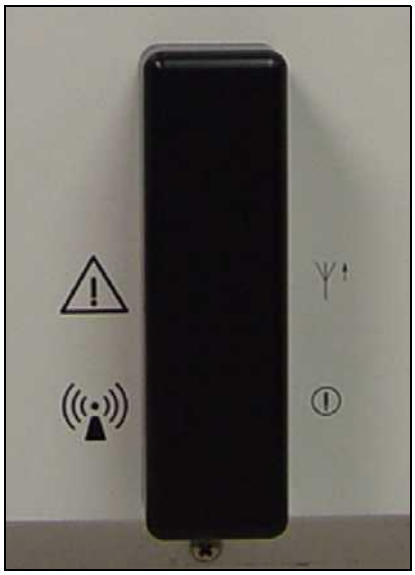


Figure 2-13, Example of the wireless antenna located on the device rear panel

Manual vacuum release button

Any MCS+ device with a vacuum centrifuge contains this mechanism which can interrupt the vacuum effect on the bowl. An MCS+ protocol functioning with the vacuum centrifuge is designed to automatically release the vacuum force at a specific point in the procedure. However, it may be necessary for the operator to do this manually, as in the case of a power failure. In this type of situation, the operator can depress the button to interrupt the vacuum force and release the bowl, **once the centrifuge and bowl have come to a complete stop**.

Note: If the MCS+ device is equipped with a retrofitted mechanical centrifuge, this release button will still be present, but will no longer be functional. A device equipped with a factory-origin mechanical chuck does not have this component.

1. Vacuum release button
2. Biohazard waste bag connection and clamp
3. RS232 connection
4. Bar-code reader connection

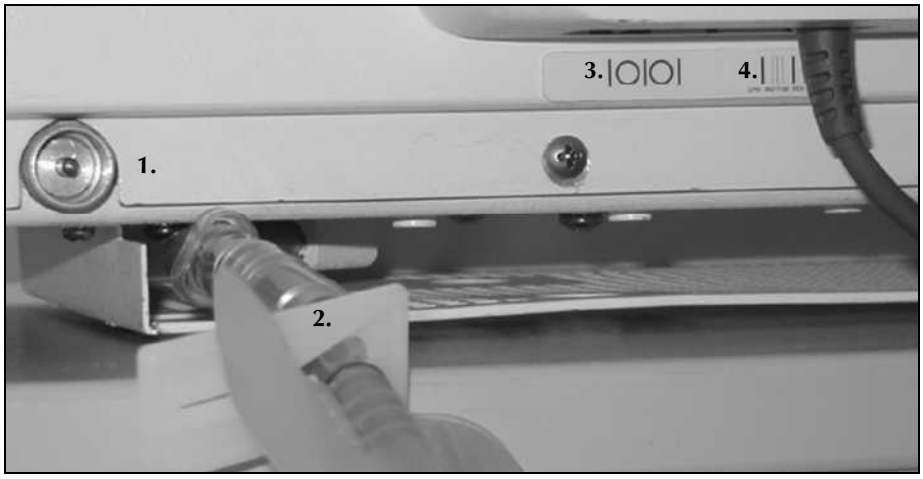


Figure 2-14, Lower rear panel

Caution: *The operator must not use the manual vacuum release button during routine MCS+ function, unless specifically warranted, as this could damage the bowl and/or the centrifuge components.*

Biohazard waste bag

The biohazard waste bag is designed to collect any biologically contaminated material from the centrifuge well in the rare case of a spill or leak. Two biohazard waste bags are supplied with the delivery of each MCS+ device.

A bag must be attached at all times to the centrifuge drain tube, located at the rear of the device. The bag must hang freely, with the clamp open, visible to the operator.

Warning: The biohazard waste bags are not to be used to collect or store apheresis products. When a bag contains evacuated waste products, it must be clamped, removed and properly disposed of, according to the local standard operating procedure concerning biologically contaminated material. A new bag must be placed before resuming operation.

Chapter 3

Describing the MCS+ Control Panel

PRESENTING THE MCS+ CONTROL PANEL

The MCS+ control panel provides the operator with the means to interact with the Haemonetics total apheresis device by allowing the operator to:

- Enter data into the system prior to a procedure.
- Modify program parameters to provide an optimal procedure result.
- Observe feedback about the status of the donor.
- Monitor continuously updated procedure statistics.
- Receive NOTICE messages from the MCS+ safety system.
- Obtain on-line assistance and troubleshoot with HELP messages.

A. Upper control panel
1. Flow indicator lights
2. Display screen

B. Lower control panel
3. Mode control keys
4. STOP key
5. Pump control keys
6. Cuff control key
7. Programming keys

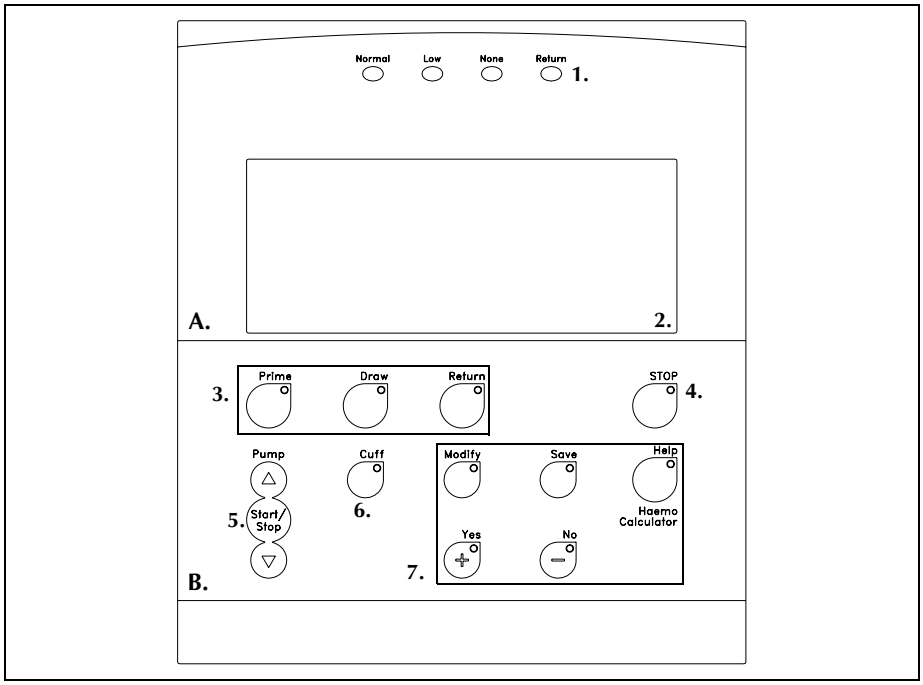


Figure 3-1, MCS+ control panel

The control panel is located on the inside of the hinged MCS+ cabinet cover and contains:

- A set of **flow indicator lights.**
- A **display screen.**
- A **keypad.**

The upper portion of the control panel communicates information to the operator by means of the **flow indicator lights** and the **display screen**. The lower portion of the control panel allows the operator to directly interact with the device prior to and during a procedure by using the **keypad.**

UPPER CONTROL PANEL

The upper section of the MCS+ control panel will provide the operator with visual information concerning the status of the donor and donor blood flow, as well updated procedure statistics throughout the entire MCS+ collection protocol.

Donor flow indicator lights

There is a set of flow indicator lights located on the top of the MCS+ control panel, above the display screen. These lights provide the same information about donor/patient blood flow status during the apheresis procedure as the other sets of flow indicator lights located on the MCS+ cabinet side panels.

The lights are arranged as follows:

DRAW
1. Green
2. Yellow
3. Red

RETURN
4. Yellow

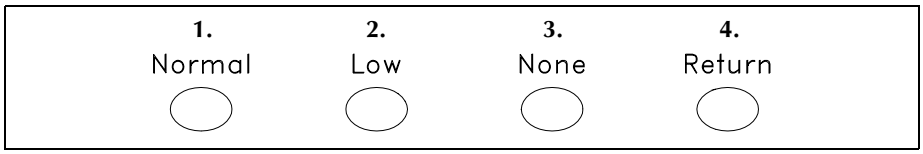


Figure 3-2, MCS+ control panel flow indicator lights (text version)

Note: The design of the fourth set of flow indicator lights, located on the exterior of the MCS+ cabinet cover, is identical to those located on the control panel. All of the lights provide the same information simultaneously throughout the MCS+ procedure.

Display screen

The MCS+ screen will display different types of information to the operator throughout a collection protocol. All MCS+ protocols will use the same screen layouts and provide the operator with the same types of information on the display screen. This information will concern:

- MCS+ self-testing protocol option selection.
- Disposable set installation.
- Procedure parameter modification.
- Haemo Calculator and Haemo Update information.
- MCS+ anticoagulant priming sequence.
- MCS+ operating mode and sub state.
- NOTICE messages and related HELP messages.

Note: Protocol-specific screen data will be explained in each MCS+ protocol manual.

Explaining the screen layout

The information and data, updated throughout the procedure, is displayed on specific areas of the MCS+ display screen. The following screen illustrates the MCS+ display screen as it could appear during an apheresis procedure.

Generic information
1. Current selected protocol
2. Operating mode
3. Current phase
4. Pump(s) state(s)
5. Donor Pressure Monitor
6. Current procedure and product statistics

Specific information
7. Caution message area
8. Last Cycle indication (appears during the last Return phase)

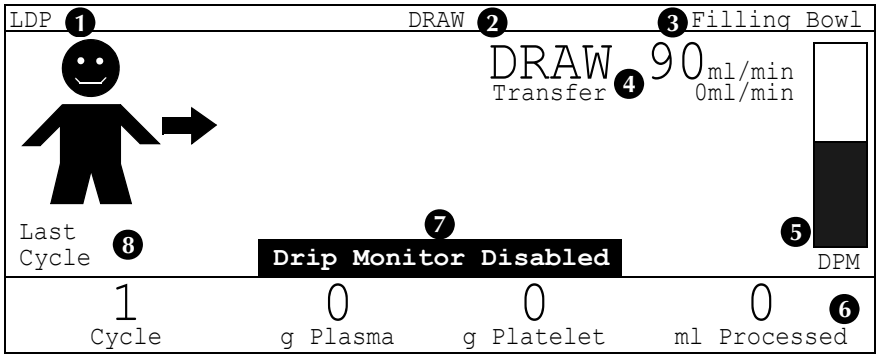


Figure 3-3, Example of an MCS+ display screen layout (platelet protocol)

The **upper screen area** will provide information for the operator identifying the selected MCS+ protocol, as well as describe the mode of operation in progress.

The **center screen area** contains an icon (to represent the donor), the current mode of operation, the relevant pump speed and a visual representation of the pressure reading in the donor-line tubing, depicted by the DPM bar graph (when visible).

Note: The contrast between filled and non-filled area in the DPM bar graph column will vary to depict the fluctuations registered in the donor-line pressure readings.

The **lower screen area** communicates data to the operator concerning the cycle in progress, as well as the volume of blood processed during the MCS+ procedure. Other protocol-specific measurements will made be by the system and will be displayed in this procedure statistics portion of the screen.

Note: There will also be slight variations present with the display screen layout when the Haemo Update and Haemo Calculator messages appear. The procedure statistics from the lower portion of the screen will be visible with the upper portion information, when an operator-action HELP menu is displayed.

Understanding an operating mode

An MCS+ mode can be described as the operating state of the device during specific phases of the apheresis process. Each MCS+ protocol will:

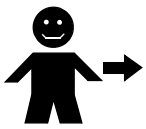
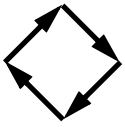
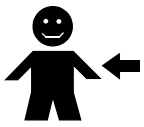
- Prepare the disposable set with AC solution during PRIME.
- Collect donor whole blood, mix the whole blood with AC solution and spin the anticoagulated blood in the centrifuge bowl, then selectively remove the desired components during DRAW.
- Re-infuse the non-collected blood components to the donor during RETURN.

Note: Certain MCS+ protocols, designed to collect components such as platelets, will contain sub states which are part of the DRAW mode, referred to as SURGE and DWELL.

Defining the screen icons

These symbols, located on the left side of the center screen area, provide a pictorial representation of the MCS+ mode in progress.

Table 3-1, Display screen icons

Screen icons	Explanation	State
	Displayed during AC and saline solution priming sequences.	PRIME
	Displayed prior to initiating the first cycle. Displayed when the device is in a non-active state, ready for an operator command.	READY
	Displayed as donor/patient blood is being drawn into the centrifuge bowl.	DRAW
	Displayed as collected plasma is being recirculated through the disposable set.	DWELL/ SURGE (sub states)
	Displayed as blood components/fluids are being returned to the donor/patient.	RETURN
	Displayed on all operator warning screens. Displayed when the centrifuge is stopping.	NOTICE

LOWER CONTROL PANEL/KEYPAD

The lower section of the MCS+ control panel consists of a keypad, located directly below the display screen. There is a protective plastic coating on the keypad, which allows for efficient cleaning and disinfecting.

The keys are grouped on the MCS+ keypad according to function, as depicted in the following illustration:

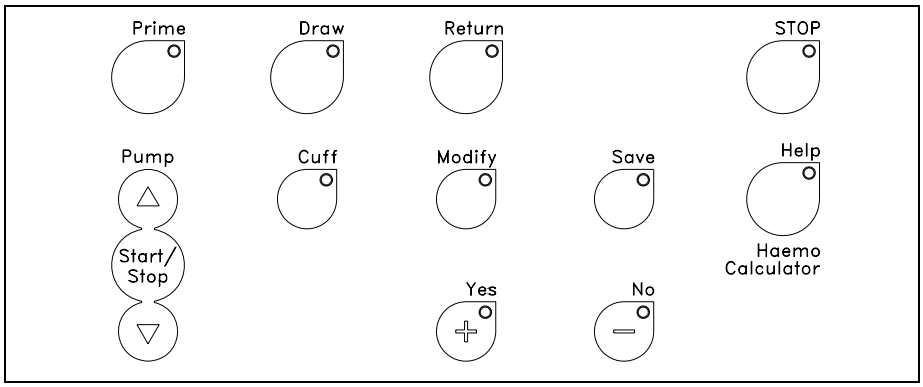


Figure 3-4, MCS+ keypad

Mode control keys

Prime key

This key is used to initiate the PRIME mode of operation. The PRIME mode will bring anticoagulant solution from the anticoagulant line tubing into the donor-line tubing.

Draw key

This key is used to initiate the first DRAW cycle, or resume the DRAW mode of operation. The DRAW mode will move anticoagulated whole blood from the donor through the donor-line tubing into the centrifuge bowl, where apheresis will be initiated.

Return key

This key is used to initiate, or resume, the RETURN mode of operation. During RETURN, the MCS+ device will return the non-selected blood components in the disposable set to the donor. During standard protocol function, a RETURN cycle will automatically be initiated. However, the operator can press this key if it becomes necessary to return of the contents of the bowl to the donor before the end of a cycle.

STOP key

This key is used to immediately stop the centrifuge and pumps.

Caution: *If the STOP key has been used, the bowl contents should be* ***returned*** *to the donor before resuming the collection procedure. Stopping the procedure could affect the separation of the blood components in the bowl. This could eventually interfere with the quality of the final collection product (and/or the collection procedure).*

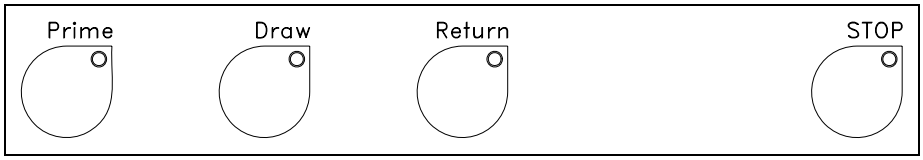


Figure 3-5, MCS+ mode control keys and STOP key

Pump control keys

These keys can be used by the operator to manually change the programmed pump speed during a collection procedure.

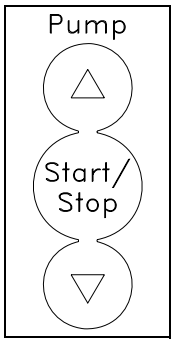


Figure 3-6, MCS+ pump control keys

Pump arrow keys

These keys can be used to temporarily modify the default parameter settings by respectively increasing (arrow up) or decreasing (arrow down) the speed in which the pumps will rotate. The adjustment should be made based on individual donor needs during a specific collection procedure.

Caution: *The operator should observe the DPM bar graph and flow indicator lights in order to correctly asses for "low" donor blood flow. However, before using the arrow keys to adjust for "low" donor flow, it is important that the operator allow the MCS+ device to first reach the target pump speed.*

Pump Start/Stop key

This key can be used to either stop the pumps, or re-start the pumps (if stopped by the operator). Pressing this key does not affect centrifuge operation.

Caution: *If the pumps have been stopped using this key, and remain stopped for longer than two to three minutes during DRAW later, the bowl may become over-packed with red cells, because the centrifuge will continue to spin. This can create a potential flow problem during RETURN. The operator should return the bowl contents to the donor before proceeding with DRAW.*

Cuff control key

During normal MCS+ operation, the cuff will automatically inflate during DRAW and deflate during RETURN. The operator can use the cuff key to manually control the pressure cuff prior to a procedure when performing the venipuncture, or during READY or DRAW mode to modify cuff pressure. The cuff cannot be inflated during RETURN.

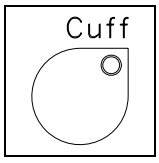


Figure 3-7, MCS+ cuff control key

Programming keys

Certain system operating parameters have been selected by Haemonetics as default values. These parameters provide optimal results in MCS+ apheresis procedures with the average donor, as well as for average collection requirements. However, it is possible to alter and subsequently retain the altered parameters for specific collection requirements using the MCS+ programming keys.

```
LDP                                STOP
Cycle 0              0 Platelet Weight        0 ml Processed

                MODIFY PARAMETERS

Cuff Pressure       50 mmHg    Min Plt Weight       0 g
Draw Speed          90 ml/min  AC Ratio           1: 9
Return Speed       120 ml/min
NaCl Vol/Cycle       0 ml

Press MODIFY to select, +/- to change values.
Press SAVE to save all values.
Press HELP to return to Main display.
```

Figure 3-8, Example of MCS+ program parameters display screen

Note: Further explanation about these parameters is provided in each respective MCS+ protocol manual.

This section of the MCS+ keypad consists of:

- Four keys which enable the operator to modify and save specific MCS+ protocol parameters.
- A Help/Haemo Calculator key which provides the operator with access to the Haemo Calculator screen and the Haemo Update screen.

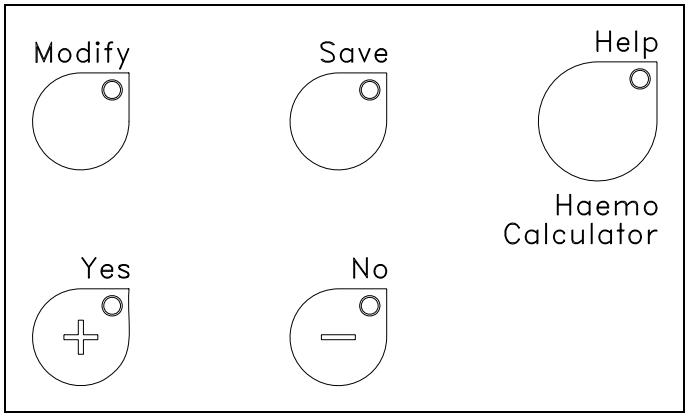


Figure 3-9, MCS+ programming keys

Modify program key

This key is used to view the existing parameters and can be pressed during any of the operating modes. Each time that this key is pressed, a different program parameter will be highlighted on the screen, along with the currently selected value for that parameter.

Note: This key can be used to access the Modify Parameter screen and adjust the program parameters, or to scroll through the parameters when listed on the Haemo Calculator screen.

Save program key

The operator can use this key to retain all modified values in the MCS+ memory. If this key is pressed after any modification, the selected value will become the new system value until any further modification is made during a subsequent MCS+ collection procedure.

Note: Once the program parameters have been consulted and/or modified, the operator can return to the screen depicting the current mode of operation by pressing the respective MODE key, without interruption to the collection procedure.

Yes +/No – program keys

To modify a displayed parameter value as it appears on the MCS+ display screen, the operator should:

➔ Press Yes + to increase the value.

➔ Press No – to decrease the value.

The parameters will be altered according to specific increments as determined by Haemonetics. Default values and increments for modification will be listed in each respective protocol manual.

Help/Haemo Calculator key

This key is used during MCS+ operation for different purposes, depending on the operating state of the device.

During normal MCS+ protocol operation, the operator can:

➔ Consult the Haemo Update display screen by pressing this key once.

```
LDP                              STOP
Cycle 0                0 Platelet Weight          0 ml Processed
                    HAEMO UPDATE
AC Volume Used      28 ml       Plasma Weight          0 g
Elapsed Time         0 min      Platelet Weight        0 g
Target Cycles        8          Estimated Yield      0.0 10e11
NaCl Volume Used     0 ml       Target Yield         5.0 10e11


Press STOP to return to Main display.
Press HELP for the Haemo Calculator.
```

➔ Consult the Haemo Calculator display screen by pressing this key twice.

```
LDP                              STOP
Cycle 0                0 Platelet Weight          0 ml Processed
                   HAEMO CALCULATOR
Sex                     M          Target Plasma Wgt    0 g
Height                170 cm       Target Yield       5.0 10e11
Weight                 65 kg      *Process Volume    4000 ml
Blood Volume         4800 ml       Target Cycles        8
HCT                    40 %        Time (estimated)    80 min.
Plt Pre-Count         250 10e3

Press MODIFY to select, +/- to change values.
Press SAVE to save all values.
Press HELP to return to Main display.
```

If the operator receives a NOTICE display screen due to an error detection by the MCS+ safety system, the operator can press this key to receive the HELP screen display.
The HELP screen will contain the most likely source of error and a list of the appropriate operator actions.

Note: A complete listing of all MCS+ operating NOTICE messages and related HELP messages is provided in the Section 1 of the Postscript to the MCS+.

Chapter 4

Describing the MCS+ Disposable Collection Material

Figure 4-1, Example of an MCS+ disposable set tub

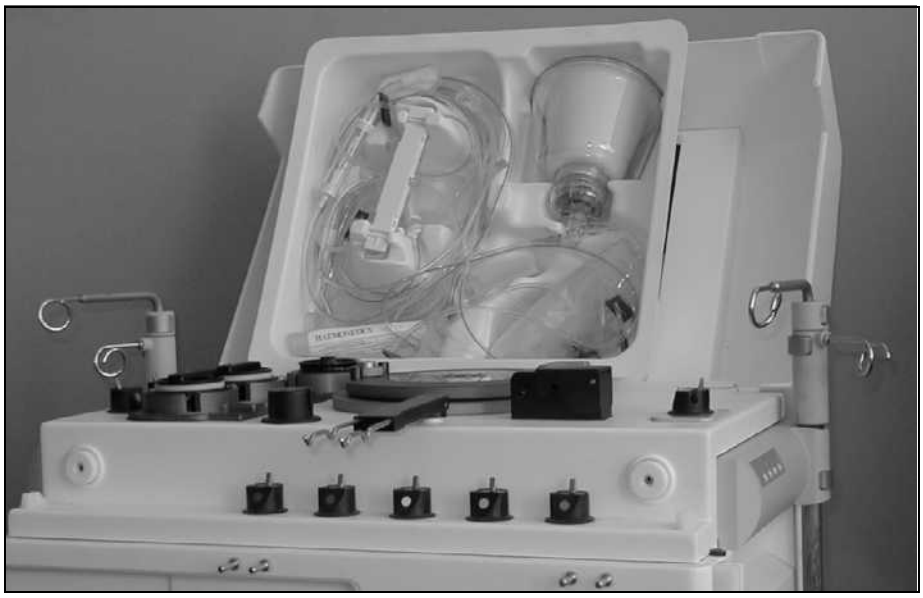


Figure 4-2, The MCS+ disposable set tub is tailored for practical installation

PRESENTING AN MCS+ DISPOSABLE SET

Haemonetics has designed single-use, disposable elements for MCS+ apheresis procedures. The disposable elements, when grouped together, are referred to as the **disposable set**. The disposable sets are described in greater detail in each specific protocol manual.

All disposable sets will contain three basic sections:

- A disposable centrifuge bowl.
- "Harness-in" tubing and elements.
- "Harness-out" tubing and elements.

The centrifuge bowl is the central element of any disposable set. The "harness-in" section is attached to the inlet port of the bowl and extends to the donor. The "harness-out" section is attached to the outlet port of the bowl and extends to the final collection product(s).

The disposable tubing sections manufactured by Haemonetics contain various combinations of elements and the choice of disposable material depends on:

- The final blood components to be collected.
- The selected MCS+ protocol.

The following general categories exist among the types of disposable set material which can be used for an MCS+ collection protocol.

Closed set

This type of disposable set will contain the basic elements required for blood component collection as well as a pre-attached needle and a bacteriological filter on each solution line tubing section. These factory-attached elements will guarantee an extra measure of sterility and security for the final collection product(s).

Bundled set

A bundled set contains disposable material with a pre-connected bowl. Various pre-assembled combinations of elements can be used, depending on the type of final plasma product to be collected.

Unbundled set

It is possible to combine individually packaged MCS+ disposable elements to form a collection set. These elements can be combined in different ways to meet specific apheresis center procedure requirements.

Note: Certain disposable sets used for MCS+ plasmapheresis applications will require the use of pump manifold adapters, ordered separately from Haemonetics.

HARNESS-IN TUBING AND ELEMENTS

The "harness-in" tubing extends from the donor to the disposable bowl. It contains distinct sections of disposable tubing, plus various combinations of disposable elements.

Donor-/Blood-line section

This section will deliver blood from the donor to the centrifuge bowl. Donor whole blood is drawn through the needle into a single lumen section to a junction where the tubing splits into two sections: one for donor blood, the other for anticoagulant solution.
Donor whole blood is mixed with AC from the AC tubing section and continues up to the blood filter. On the opposite side of the blood filter are two sections of tubing. One section leads to the DPM filter. The other section contains the blood drawn into the centrifuge bowl by the Blood pump.

1. Pre-attached needle
2. Ratchet clamp (x 2)
3. Needle connector
4. Three-way connector
5. Injection port
6. Donor-line sample pouch

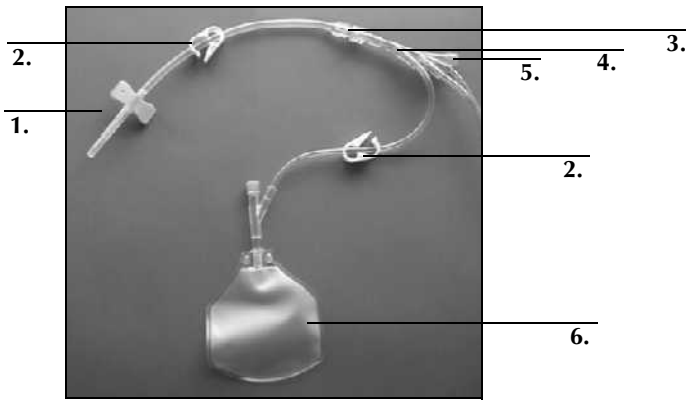


Figure 4-3, MCS+ needle tubing/sample pouch section

Pre-attached needle/tubing

This section of tubing will contain a 16G needle, a ratchet clamp and a female luer connection. The established sterile needle connection can eliminate a certain degree of potential contamination and contribute to the storage life of the collection product.

Needle connector

This male luer connector attaches the needle tubing, containing a female luer connector, to the rest of the donor/blood-line tubing.

Y-connector/three-way connector

These connectors create the junction in which the single lumen needle tubing section can branch into multiple sections.

Injection port

This branch of the three-way connector should only be used for the emergency administration of medication or fluids, as the "closed" system can be altered.

Donor-line sample pouch

This element branches from the three-way connector and permits the operator to collect a donor/patient blood sample without the need for a separate venipuncture.

Caution: *The sample pouch tubing must clamped, then sealed before drawing the sample, in order to isolate it from the rest of the disposable tubing and maintain a "closed" system.*

Blood filter/chamber

The 170 µm blood filter is contained in a chamber located between the needle adapter and the disposable bowl. The filter will eliminate aggregates; the chamber will serve as a reservoir for blood being drawn into the bowl.

Dual-pump manifold and tubing

This element has a dual function. It will secure the blood-line tubing as it is loaded onto the Blood pump and the Transfer pump, as well as during MCS+ operation. It identifies the type of disposable set being installed when the information printed on the manifold is scanned by identification window.

Note: This provides a safety feature for the operator. It is not possible to install a disposable set containing a dual-pump manifold which does not correspond with the inserted MCS+ protocol card, without receiving a NOTICE message.

Figure 4-4, Examples of MCS+ pump manifolds

Blood pump “stops” and tubing

These elements, found on disposable sets which do not utilize the Transfer pump, will secure the pump tubing in preparation for pump autoloading.

Note: Pump tubing can be easily distinguished because it is more elastic. This elasticity helps to reduce twists and occlusions when the tubing is thread around the pump rotors.

Dual-pump manifold adapter

The adapter is necessary when using MCS+ disposable sets which do not require the Transfer pump. It adapts the tubing which contains pump “stops”, so that it can be secured on the dual-pump housing, during autoloading and operation of the MCS+ Blood pump. It also contains specific identification information.

Figure 4-5, Examples of MCS+ pump manifold adapters

Note: These elements should not be discarded after use, but saved for subsequent MCS+ collection procedures.

Bowl connector

This element on the harness-in section attaches the donor-line tubing assembly to the inlet port of the centrifuge bowl.

DPM line section

The 0.22 µm hydrophobic filter on this section links the disposable set to the MCS+ donor pressure monitor. The filter also provides a bacteria-free connection between the disposable set and the DPM.

There is a slide clamp on the tubing leading to the DPM filter. The clamp is used when connecting and disconnecting the filter from the DPM.

AC line section

This section of the disposable tubing will deliver AC solution to the section of tubing containing donor whole blood. The elements found on the AC line section can vary according to the selected disposable set.

Anticoagulant spike

This element permits the operator to attach the AC solution bag to the disposable set.

Note: Haemonetics recommends spiking the AC solution bag prior to hanging it on the solution pole, to avoid any possible AC solution drops on the device. AC solution becomes "sticky" as it dries and can become difficult to properly clean.

Anticoagulant drip chamber

A drip chamber for the AC solution is present on the "closed" MCS+ disposable sets. It is also available on certain bundled and unbundled harness-in sections.

Bacterial filter

This element can be found on a "closed" set. The 0.22 µm filter can eliminate bacteria from entering the system, due to spiking the AC solution bag.

Single-pump manifold and tubing

This element will secure the AC tubing as it is autoloaded on the AC pump, as well as during MCS+ operation.

AC pump "stops" and tubing

These elements, found on disposable sets which do not utilize the Transfer pump, will secure the pump tubing in preparation for pump autoloading.

Note: Pump tubing can be easily distinguished because it is more elastic. This elasticity helps to reduce twists and occlusions when the tubing is thread around the pump rotors.

Single-pump manifold adapter

The adapter will provide a means to secure tubing containing AC pump "stops" onto the MCS+ single-pump housing, during autoload and operation of the AC pump.

CENTRIFUGE BOWL

The Haemonetics disposable centrifuge bowl is the central element of any MCS+ disposable set. Two types of disposable bowls exist for the various MCS+ procedures: the bell-shaped Latham bowl and the cylindrically-shaped blow molded bowl (BMB).

An MCS+ disposable centrifuge bowl is comprised of the following sections:

- The stationary section referred to as the “head” of the bowl.
- The rotating section referred to as the “body” of the bowl.
- The seal between these two sections.

Explaining the general design of the bowl

The head of the bowl, containing an inlet port and an outlet port, provides a shield for the seal of the bowl. When the bowl is held upright, the inlet port is located above the outlet port.

Note: When installing a bowl, the inlet port should be positioned facing the left side of the centrifuge, and the outlet port should be positioned facing the right side of the centrifuge.

The inlet port is used for attaching the donor-line disposable tubing. The inlet port leads to the feed tube which passes through the core and transports blood into the processing chamber.

The feed tube also allows non-selected elements to exit the inlet port as they are returned to the donor. The outlet port provides the exit for the collected blood components and connects to the effluent tubing of the disposable set.

The body of the bowl contains a core and the processing chamber for the blood components.

The rotary seal of the bowl is attached to the body of the bowl by a ceramic section. A properly functioning rotary seal is essential to MCS+ operation.

Caution: *The functional characteristics of the rotary seal can be altered if the pressure in the bowl becomes excessive. This can cause the seal to be raised like a pressure valve. The operator must remain attentive to avoid twists or occlusions in the effluent tubing, which could obstruct either the flow of air or fluids in the effluent pathway.*

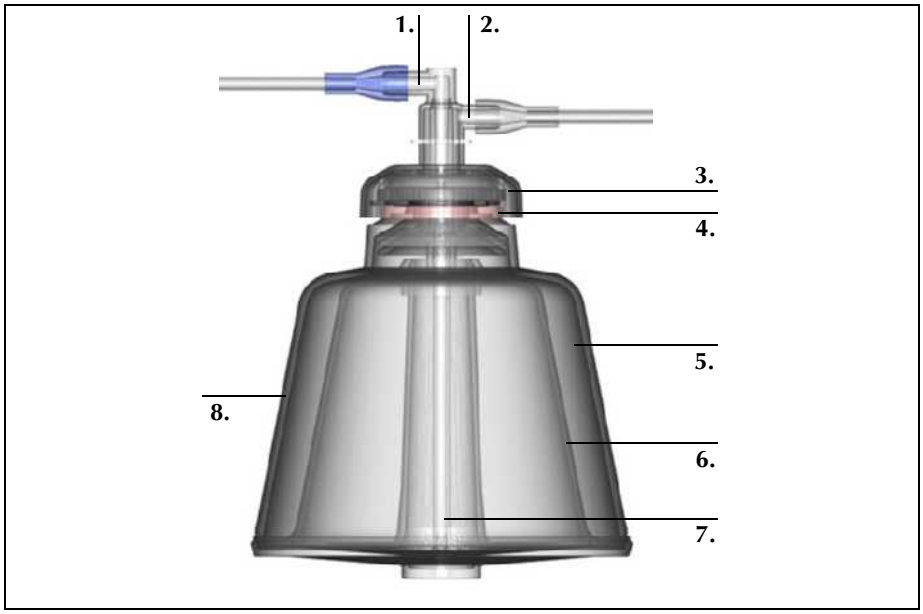


Figure 4-6, Latham centrifuge bowl

1. Inlet port
2. Outlet port
3. Header shield
4. Bowl seal
5. Processing chamber
6. Bowl core
7. Feed tube
8. Bowl body

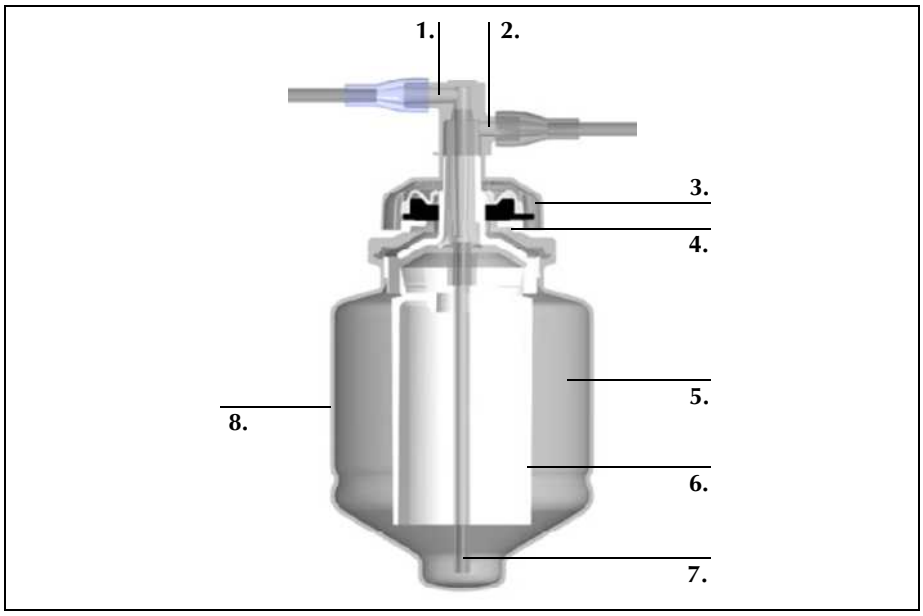


Figure 4-7, Blow molded centrifuge bowl

Understanding bowl operation

Both types of centrifuge bowls will function during the first part of the DRAW cycle in the following way:

- The head of the bowl remains stationary during operation. The body of the bowl, held in the centrifuge chuck by the system-sealing mechanism will be spun between 3000 and 7000 rpm, depending on the selected MCS+ protocol. The header shield covers the rotary seal between the head and body of the bowl and slightly compresses the seal when the bowl is installed.
- Anticoagulated whole blood arrives from the donor-line tubing, passes the inlet port, moves through the feed tube and enters the processing chamber at the base of the bowl.
- As the bowl spins, the centrifugal force inside of the bowl separates the products into the cellular components and plasma. The denser cellular components move to the outside of the bowl, while the lighter components move toward the center.
- When the bowl is full, plasma, the lightest of the separated blood components, will exit the bowl first through the outlet port, pass through the effluent tubing and be collected. The red blood cells, being the densest of the cellular components, will exit the bowl last.

Applications for the Latham bowl

During the DRAW cycle, the design of Latham bowl permits the MCS+ device to conduct the “surge” process when the optical bowl sensor has detected the buffy coat at the appropriate level.

Surge involves the *elutriation* (or extraction) of platelets from the buffy coat, by re-circulating collected plasma through the bowl at a high speed. The “surging” plasma passes through the cellular layers of the blood components and promotes separation between the layers. This allows the platelets, being the lightest of the cellular components, to exit the bowl with the plasma. The other heavier cellular components remain in the bowl.

Once the desired components have been collected, the bowl will stop spinning. The remaining components will settle to the base, re-mix and subsequently be returned to the donor/patient.

Applications for a Blow Molded bowl

Once a DRAW cycle has been completed, the bowl will stop spinning and the uncollected cellular components in the bowl will be pumped through the feed tube and returned to the donor. The cycle will be repeated until the programmed target volume of the selected blood component has been collected.

Managing the bowl air inventory

The disposable bowl contains sterile air which is displaced into a collection container as the bowl is filled during a DRAW cycle. This same air returns to the bowl when the non-collected components are returned to the donor during a RETURN cycle. It is important that this air return to the bowl from the collection container in order to avoid negative pressure in the bowl.

A. Filling the bowl
1. Anticoagulated whole blood
2. Air
3. Plasma
4. Red blood cells

B. Collecting plasma
1. Anticoagulated whole blood
2. Plasma

C. Surge (elutriation)
1. Plasma
2. Platelets and plasma
3. Buffy coat

D. Returning components
1. Non-collected blood components
2. Air from plasma bag

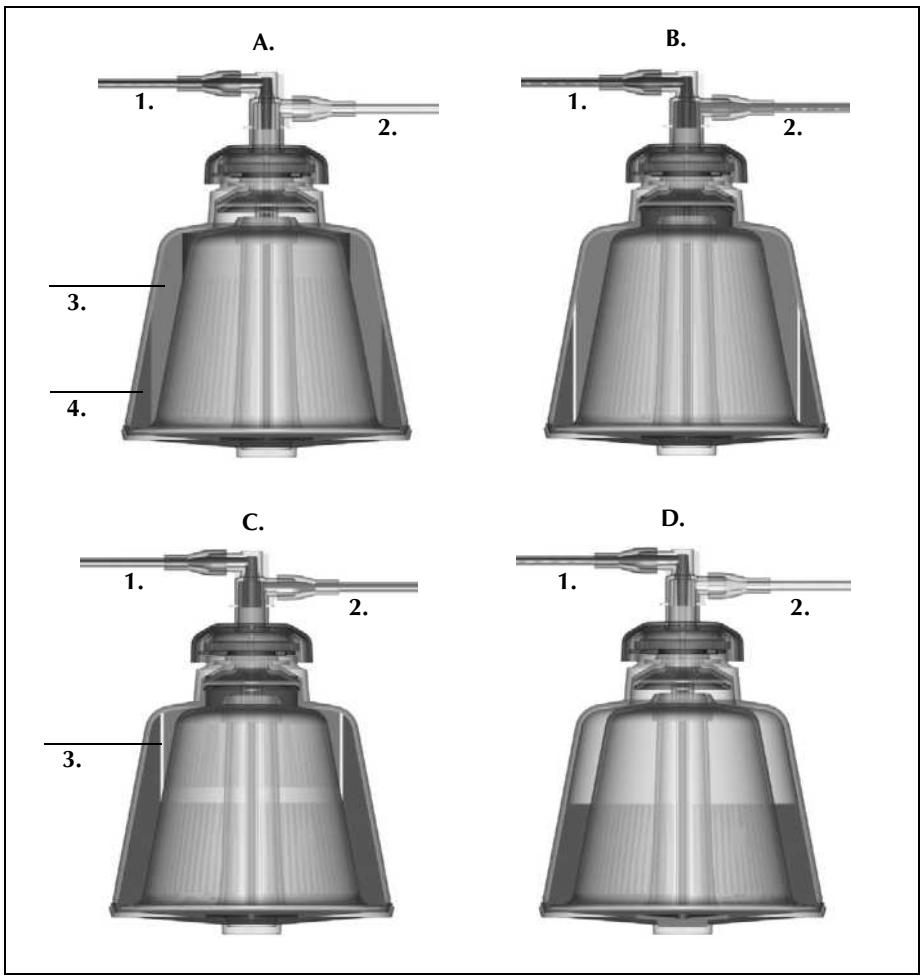


Figure 4-8, Latham bowl operation

A. Filling the bowl
1. Anticoagulated whole blood
2. Air

B. Collecting plasma
1. Anticoagulated whole blood
2. Plasma

C. Returning components
1. Non-collected blood components
2. Air

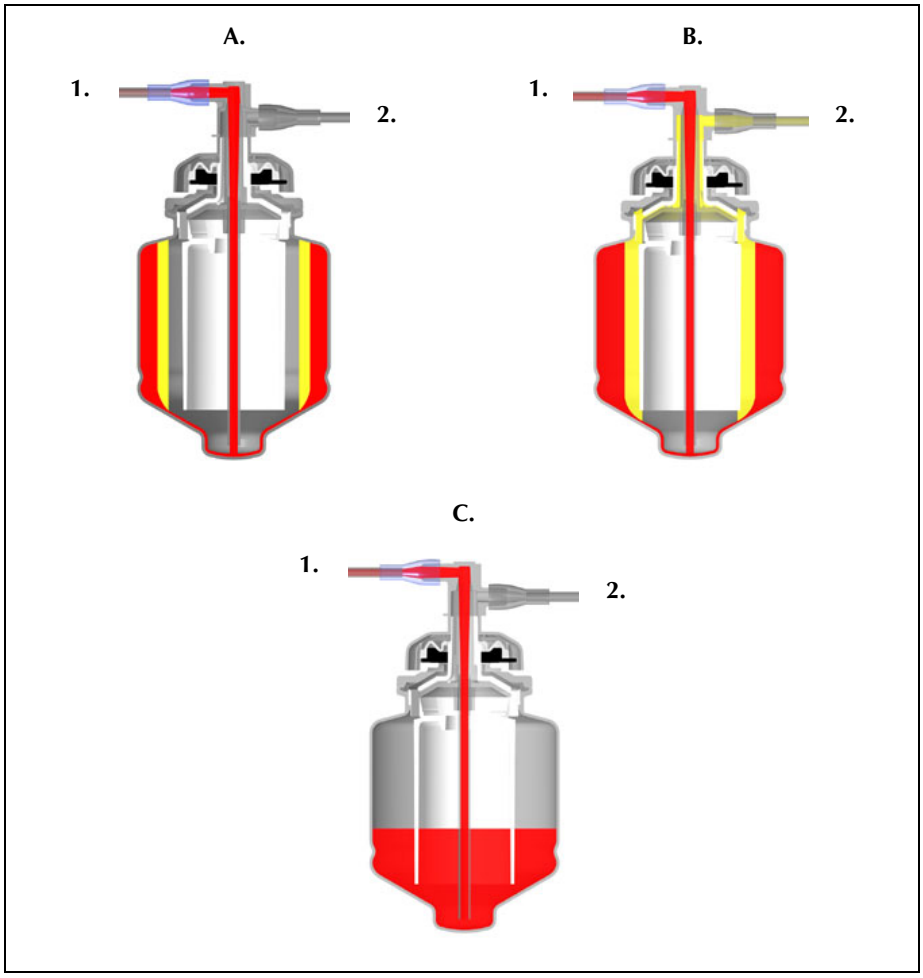


Figure 4-9, Blow molded bowl operation

HARNESS-OUT TUBING AND ELEMENTS

Effluent line section

This section of disposable tubing extends from the centrifuge bowl to the collection container(s). It will transport centrifuged blood components through the line sensor before being collected. The following elements will be present on the MCS+ effluent tubing section.

Bowl connector

This element on the harness-out section attaches the effluent tubing assembly to the outlet port of the centrifuge bowl.

Y-connector/three-way connector

These connectors create the junction in which the single-lumen needle tubing section can branch into multiple sections.

Collection bags

The blood components can be collected in a variety of sizes and forms of bags, depending on the MCS+ protocol requirements.

Plasma collection container(s)

Plasma can be collected in either a bag or a bottle. The type and number of plasma collection containers used for a procedure will depend on the disposable material chosen by the apheresis center. The plasma collection bags vary in total volume capacity.

Leukocyte reduction filter

A PALL membrane filter can be found in various combinations of size, number and location on certain MCS+ disposable sets. This type of filter will reduce the quantity of leukocytes which pass into the final collection product(s).

SPM line section

The hydrophobic 0.22 µm filter on this section links the disposable set to the MCS+ system pressure monitor. It is located on the harness-out section of a "closed" set and provides a bacteria-free connection between the disposable set and the SPM.

PROTOCOL-SPECIFIC SOLUTION LINE SECTIONS

Solution line section(s)

These sections of disposable harness tubing are designed for use with MCS+ protocol-specific additives and solutions.

A solution line on a "closed" set will contain a bacteriological filter separating the spike, or solution bag connector, from the rest of the disposable set. This filter will eliminate bacteria from entering the collection system as the operator connects the solution/additive bag(s).

A saline solution line section can also be included in the preparation of an unbundled set, if the selected MCS+ plasmapheresis application uses saline compensation.

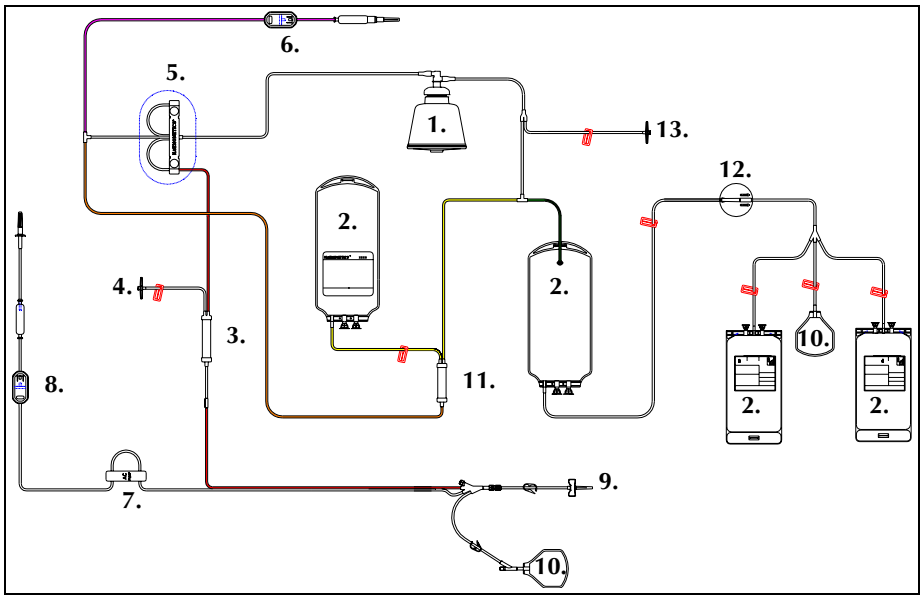
Note: The saline solution line designed for an MCS+ unbundled set does not contain a bacteriological filter.

ILLUSTRATING TYPES OF MCS+ DISPOSABLE MATERIAL

Closed sets

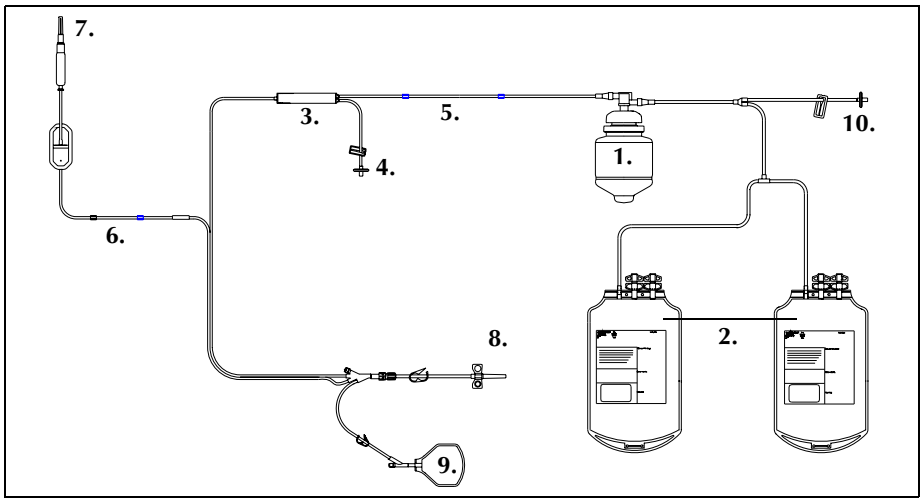
Latham bowl closed set

1. Centrifuge bowl
2. Collection bags
3. Blood filter chamber
4. DPM line
5. Dual-pump manifold
6. Solution line with filter
7. Single-pump manifold
8. AC line with filter
9. Pre-connected needle
10. Sample pouch
11. Recirculation chamber
12. Leukocyte reduction filter
13. SPM line



BMB closed set

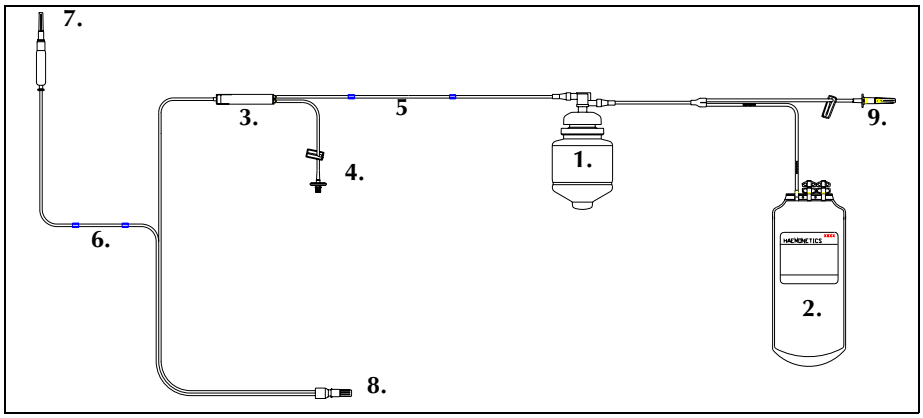
1. Centrifuge bowl
2. Collection bags
3. Blood filter
4. DPM line
5. Blood pump “stops”
6. AC pump “stops”
7. AC line with filter
8. Pre-connected needle
9. Sample pouch
10. SPM line



Bundled set

Bundled set with NaCl spike

1. Centrifuge bowl
2. Collection bag
3. Blood filter
4. DPM line
5. Blood pump “stops”
6. AC pump “stops”
7. AC solution line
8. Needle connector
9. NaCl spike



Unbundled set sections

Commonly used set elements

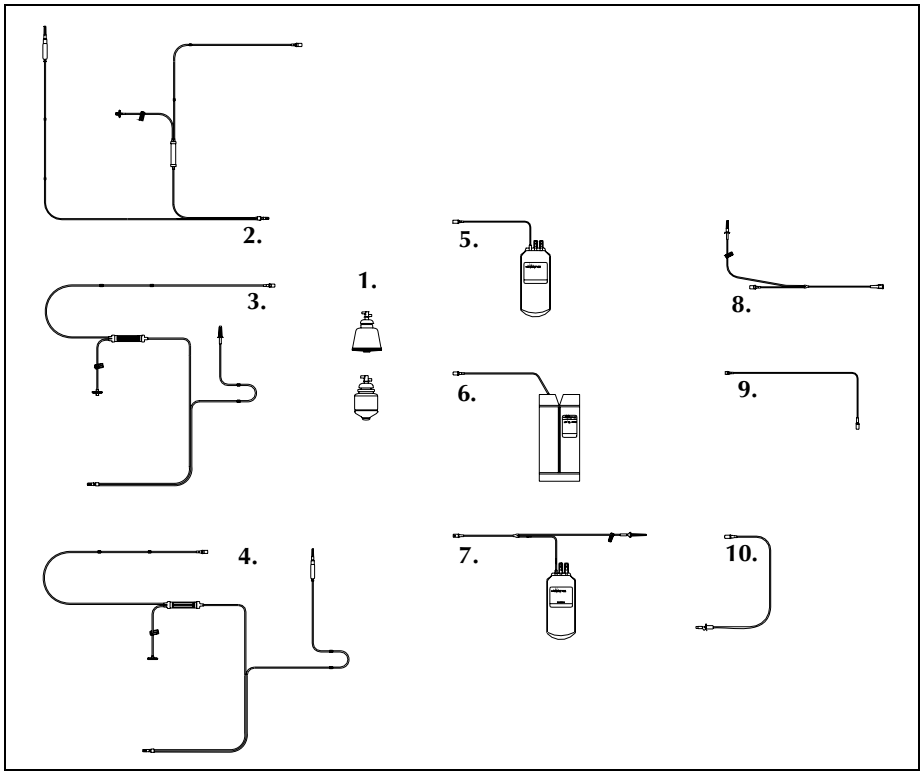
1. Centrifuge bowl (Latham LN5810 & BMB LN625B)

Harness-in

2. Plasma collection set (LN799)
3. Plasma collection set (LN620)
4. Plasma collection set (LN620E)

Harness-out

5. PPP collection bag (vented cap) (LN690)
6. Collection set - EVA (LN691)
7. Collection bag with NaCl adapter (LN692)
8. Saline adaptor (LN695)
9. Effluent line adaptor (LN697)
10. Effluent line with bottle spike (LN698)



Chapter 5

Maintaining the MCS+ Equipment

P/N 85213-30, Manual revision: B

CLEANING PROCEDURES

The MCS+ device has been designed to require minimal maintenance for the operator. To maintain the precision function of the MCS+ device, the operator needs to primarily perform routine cleaning procedures of certain key components. A record of routine cleaning schedule can be kept along with any routine or preventive service maintenance performed by a Haemonetics representative.

The frequency of cleaning each individual MCS+ device will depend on the number of procedures performed. Special cleaning needs may arise and should be dealt with promptly. Haemonetics recommends the following routine cleaning schedule for each MCS+ device, **based on an average of three collection procedures per day, or approximately sixty per month**.

- **Daily:** Clean the exterior surfaces as well as the pressure monitors.
- **Weekly:** Clean the air detectors, the optical sensors (line sensor and optical bowl sensor), the fluid detector, and the inside of the centrifuge well.
- **Monthly:** Clean the pump rotors and the pump wells.
- **Quarterly:** Clean the filter screens.

Warning: To eliminate the potential danger of electrical shock, the operator must clean the MCS+ device only when it is disconnected from an external power source.

The following list describes the basic material required for routine cleaning.

- Disinfectant cleaning solution, specific for blood-born pathogens.
- Warm water.
- 70% Isopropyl alcohol.
- Lint-free gauze or cloth (for cleaning and drying).
- Cotton swabs.
- Protective gloves.
- Hexagonal-head wrench #10 (provided with the device).
- Silicon lubricant (for the “L” gasket of the centrifuge vacuum chuck).
- Phillips-head screwdriver.

Cabinet and control panel

The exterior cabinet, valves, keypad and display screen should be wiped daily, (as well as following any spill), using the cleaning solution.

Pressure monitors

The pressure monitors (DPM/SPM) should be cleaned daily in the following manner:

- ➔ Depress and hold the white ring (as if installing the disposable filter).
- ➔ Wipe the silver rod thoroughly with a damp, lint-free cloth, using a circular motion. Cloth may be dampened with water, disinfectant solution or alcohol per the site's local standard operating procedures.
- ➔ Dry the rod and release the pressure on the ring.

Caution: *Ensure that the pressure monitor is allowed to dry completely before installing the disposable set.*

Air detectors

The air detectors are designed with a groove to hold the disposable tubing. The contents of the tubing are monitored by the sensors, which are located internally on either side of this groove.

The operator should use warm water and lint-free gauze to clean and dry in between the tubing groves. The groove should be kept free of any particles, such as powder residue from disposable gloves, since this could lead to an erroneous detection of air.

Note: If a procedure is interrupted due to an air detector alarm and no air bubble(s) are visible, the operator should remove the tubing and clean the groove before continuing the collection procedure.

Optical sensors

The lenses of the optical sensors must be kept completely free of particles or debris, which could produce inaccurate readings and influence the MCS+ performance. The operator should use only water and lint-free gauze to clean and dry the lenses.

Caution: *If any cleaning solution should come into contact with the optical sensor lenses, they should be immediately cleaned with lint-free gauze and warm water, then thoroughly dried. Cleaning solution can leave a "opaque" film on the lens.*

Anticoagulant drip monitor

The optical sensor of the AC drip monitor is located on the interior of the drip chamber holder. The operator should immediately wipe away any AC solution or other liquid which may have dripped on the lens to avoid erroneous readings.

Line sensor

The line sensor, located on the MCS+ top deck, contains two very small lenses which are centered on either side of the disposable tubing groove. The operator should carefully pass the gauze through this groove to clean and dry the lenses.

Optical bowl sensor

The optical bowl sensor lens is located in the upper portion of the centrifuge well. The operator should ensure that no spots remain after it has been cleaned and dried.

Dual-pump identification window

The dual-pump identification window should be wiped clean immediately after any spills to ensure that the information can be read from the disposable set pump manifold.

Fluid detector(s)

The fluid detector(s) is/are located inside of the centrifuge well. The surface of the detector should be cleaned using a cotton swab moistened with 70% alcohol.

Centrifuge components

Except for the optical sensor and fluid detector(s), the other centrifuge components can be wiped routinely using the cleaning solution and a lint-free cloth. This includes the centrifuge well and chuck, chuck adapter, hinged lid and locking knob.

Haemonetics Technical Services provides silicon lubricant for the “L” gasket, located at the base of the vacuum centrifuge chuck. After a major cleaning, the operator should apply a small amount of the lubricant to the gasket to prevent it from cracking. It is not necessary to remove the gasket when applying the lubricant.

If a fluid spill should occur, the operator should:

- ➔ Power off the device and disconnect it from the external power source before cleaning.
- ➔ Ensure that the biohazard waste bag is attached to the drain tube and hanging freely.
- ➔ Wipe the centrifuge lid with cleaning solution.
- ➔ Clean the centrifuge chuck and well, (avoiding the optical bowl sensor lens), using the disinfectant solution and a lint-free cloth until all traces of blood components are removed.
- ➔ Lubricate the “L” gasket with a small amount of the silicon lubricant.

Haemonetics recommends that the operator wear protective gloves to avoid direct contact with the cleaning solution and/or any spilled blood which may be present.

In the case of a larger spill, fluid and/or blood may be evacuated into the biohazard waste bag. The operator should complete the following additional steps and contact the local Haemonetics representative for further instructions before using the device:

- ➔ Irrigate the centrifuge drain holes with cleaning solution, until the drain tube is rinsed clear of the spilled material.
- ➔ Remove the bag and replace it with a new bag.
- ➔ Dispose of the used waste bag according to local established policies concerning the disposal of biohazard waste.

Note: A 50 ml syringe of attached to a 20 cm section of disposable tubing placed in the drain holes can be used for irrigation. The biohazard waste bag should be monitored to avoid overfilling.

Warning: An authorized Haemonetics technician should perform a leakage current control after any major fluid spill involving the MCS+ device. Leakage current represents a primary indication of electrical shock hazard and should be checked according to guidelines as described in local standard operating procedures.

Pumps

The pump rotors should be removed from the well with the hexagonal head wrench.

Debris should be removed from the rotors and the pump wells on a routine basis, as well as after any spills, to contribute to efficient MCS+ operation.

For routine cleaning, the operator should:

- ➔ Remove the pump rotor from the housing, using the hexagonal head wrench to remove the pump screw.
- ➔ Wipe the rotor and remove all debris from the rollers, using warm water and lint-free cloth or gauze.
- ➔ Dry with lint-free cloth (or compressed air, if is available).
- ➔ Clean and dry the pump well using the same method.
- ➔ Ensure that all of the rollers spin freely and replace the pump rotor in the well, aligning the cross pin in the rotor with the pump shaft.
- ➔ Replace and tighten the hexagonal head screw.

In the case of a fluid spill, the same cleaning method should be followed; however, disinfectant cleaning solution should be used, followed by a clear water rinse. The pump rotor should not be immersed in water.

Filter screens

The MCS+ device is equipped with filter screens on the bottom of the cabinet, which eliminate dust from incoming cool air. The filters should be cleaned routinely, especially if dust becomes visible on the screens.

To clean the filters, the operator should:

- ➔ Remove the retainer plates using a Phillips-head screwdriver.
- ➔ Remove the filter screens from the panel.
- ➔ Rinse the screens under running water – **DO NOT** use any cleaning agents.
- ➔ Gently squeeze the screens to remove excess water.
- ➔ Place the screens on a clean, dry cloth and allow to dry completely.
- ➔ Reinsert the screens into the panel, ensuring that all openings are completely covered by the filter.
- ➔ Replace the retainer plates and tighten the screws.

Warning: To avoid electrical shock, the filter screen should be completely dry before it is reinstalled on the MCS+ cabinet.

Bar-code reader

The bar-code reader window should be wiped using a lint-free cloth or gauze and water, then dried. It should be cleaned whenever there is an accumulation of dust or spilled fluid. For optimal cleaning, the operator should remove the protector around the window and replace it once the window has been cleaned.

Pressure cuff

If it is determined that the cuff has been contaminated, clean the affected area with a 10% bleach solution (or equivalent). If this cleaning is determined to be insufficient based on the severity of the contamination, a replacement cuff may be ordered and installed by the user.

CUSTOMER SERVICE

Clinical training

Haemonetics employs a staff of Clinical Specialists to provide training for apheresis personnel concerning the use of the MCS+ equipment. The local Haemonetics representative will schedule staff training upon delivery of MCS+ equipment and should be contacted to organize further instruction when needed.

Field service

Haemonetics maintains a worldwide network of company-trained service representatives responsible for responding to technical needs concerning equipment. These technical specialists are available to diagnose and repair any malfunctions, as well as provide routine annual or semi-annual maintenance of the apheresis equipment, including leakage current tests. If service beyond the routine maintenance and cleaning described in this manual is required, the local Haemonetics representative should be contacted to provide specific instruction.

Returned Goods Authorization system

Haemonetics seeks to provide the apheresis customer with equipment and material which respects the highest established standards of quality in design and manufacturing. If for any reason merchandise must be returned to the company, the customer should refer to the Haemonetics Returned Goods Authorization (RGA) system procedure to ensure proper handling and subsequent analysis of the material.

First, the customer should contact the local Haemonetics representative [or the Haemonetics Customer Service Department] and provide the following information:

- Product list number, lot number and manufacture date.
- Number of articles to be returned.
- Description of defect.
- Number of parcels being shipped.

The Haemonetics representative may ask for additional details, depending on the nature of the problem. The customer should be prepared to provide a thorough description of the problem encountered, as well as the product information listed above.

If a contaminated disposable set must be returned by courier services, the Haemonetics representative may provide specific instructions concerning preparation for shipping blood-contaminated products. In addition to the Haemonetics guidelines, the consumer should strictly follow the local standard operating procedure related to the shipment of blood-contaminated materials and thus minimize any potential health hazards involved.

In some cases, it may be necessary to dispose of the contaminated goods after reporting the problem to the Haemonetics representative. This should be done according to the locally established guidelines pertaining to the disposal of biologically contaminated material.

Warning: Haemonetics products must be properly cleaned and packed prior to their return. It remains an important responsibility of the customer to reduce this serious potential health hazard, by being aware of the risks involved in the shipping, handling and testing of this material.

Disposal

Follow all local standard regulations for the disposal of medical equipment when disposing of the MCS+ device.

HAEMONETICS®

Cleaning and maintenance record for the year

MCS+ device serial number .....

Action	Jan.	Feb.	March	April	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Clean cabinet and control panel												
Clean air detectors												
Clean optical line sensor												
Clean DPM and SPM												
Clean anticoagulant drip monitor												
Clean centrifuge cover and well												
Inspect "L"-gasket and apply silicon lubricant												
Clean optical bowl sensor												
Clean dual-pump identification window												
Clean pump rotors												
Clean air filters												
Verify biohazard waste bag												
Maintenance performed by (date and initials)												
Reviewed by (date and initials)												

Annual preventive maintenance should be scheduled by a supervisor when appropriate and performed by a Haemonetics service representative or a qualified biomedical engineer.

Name of person performing preventive maintenance: ..... Date performed: .....

Reviewed by: ..... (Date and supervisor initials)

Chapter 6

Ensuring Safety and Quality for an MCS+ Procedure

HANDLING THE MCS+ EQUIPMENT

Safe and successful MCS+ operation will depend in part on the proper routine handling of the MCS+ equipment. The operator should be aware of the problems which could result if the device or disposable material is stored, installed or used incorrectly.

Storing the device and material

The MCS+ device must not be operated or stored in an area where flammable gases or vapors are present. The MCS+ disposable set material should be kept in a dry, well-ventilated area and isolated from any chemical vapors. The operator should handle the disposable set elements with clean, dry hands or gloves

The ranges for storing the material should be within 8% to 80% rh and –20° C to +50° C. The recommended temperature for the working environment is between 18° C to 27° C.

Inspecting the material

Prior to installation, the operator should complete a visual inspection of the disposable set elements and control for twisted or flattened sections.

After installing the disposable set, the operator should verify the correct placement of the individual elements, prior to initiating a collection procedure. It is important that the tubing remain free of any twists or occlusions which could cause a flow obstruction.

Transporting the device

Use caution when lifting and transporting the device. Lift the device only by the handles. Always ensure that the IV poles are in the “down” position and the cabinet cover is closed before transporting or moving the device. Do not hold or lift the device by the IV poles or weigher arm. Two people should lift the device in order to avoid injury.

PREVENTING PROBLEMS DURING AN MCS+ PROCEDURE

Understanding the risk of hemolysis

Hemolysis involves the destruction of red blood cell membranes, with the release of free hemoglobin into the plasma portion of the blood. Free hemoglobin does not have the capacity to transport oxygen and can produce serious problems. The remnants of the red cell can stimulate clot formation and damage the vascular nature of the lungs and the kidneys. This could lead to respiratory complications and/or renal failure.

Hemolysis of red cells can occur during an apheresis procedure in the rare event of a mechanically induced situation, such as overheating, or excessive pressure.

Warning: Forcing a pump to work against a severe flow restriction can lead to hemolysis, and thus, consequently high levels of free hemoglobin in the plasma. It is important that the operator remain attentive to this fact in the case of any "high return pressure alarms" during MCS+ operation.

If there is any suspicion that hemolysis has occurred, the operator should not return the contents of the bowl to the donor. The local Haemonetics representative should be informed of the problem to provide the operator with further instruction.

Avoiding the consequences of flow restriction

During DRAW, a flow restriction in the effluent tubing can create pressure on the outlet port of the disposable bowl. This unrelieved pressure can deform the rotary seal of the disposable bowl. If the functional characteristics of the rotary seal are altered, the increased friction and excessive heat can make the contents of the bowl unsuitable for return to the donor.

During RETURN, a flow restriction in the effluent tubing can cause the pressure in the centrifuge bowl to drop severely. This sudden drop in pressure could potentially produce hemolysis.

To eliminate these potential problems, the operator should:

➔ Ensure against inadvertent clamping of the effluent tubing.

➔ Observe the following changes in flow rate (possible indications of a flow restriction):

- Decreased donor flow rate during DRAW.
- Abnormally increased time required to return the disposable bowl contents to the donor.

Avoiding bowl misalignment

An improperly installed disposable bowl can become misaligned as it spins. This can create excessive friction, and consequently overheat the bowl contents. The operator should verify the alignment of the bowl at the time of installation.

Note: In certain MCS+ protocols, the programming will instruct the centrifuge to spin the bowl during PRIME, as a control for proper bowl placement.

Warning: The operator must not use any bowl which cannot be properly seated in the centrifuge chuck. Overheating can occur (subsequently leading to hemolysis) and make any blood being processed unsafe for re-infusion. During MCS+ operation, the operator should interrupt the collection procedure if an abnormal or excessive noise appears, related to the spinning bowl.

Avoiding overheating due to mechanical situations

Overheating could also result from a mechanical or maintenance-related problem, such as a defective bearing or seal within the centrifuge well. In this case, the operator should contact the local Haemonetics representative and discontinue use of the MCS+ device until it is serviced.

Warning: If any component of the MCS+ device has become overheated during a procedure, and thus overheats the blood being processed, the blood components cannot be considered safe for re-infusion.

Controlling for red cell overrun

Red Cell Overrun is the term used to describe the presence of erythrocytes in the effluent tubing and/or product collection container during an apheresis procedure. It is important that the operator observe the appearance of the plasma as it is collected. A pink or reddish hue could indicate a possible red cell spillage which should be investigated immediately.

If the cause of the reddish hue cannot be determined to be a normal result of the selected MCS+ protocol, the procedure should be discontinued immediately and the blood components in the bowl must not be returned to the donor/patient.

WARNINGS FOR THE OPERATOR

Electrical shock hazards

The operator should always use the MCS+ device with clean dry hands, or gloves. The internal parts of the MCS+ device contain various electrical components. Contact with any of these components, when the device is connected to an external powered source, could result in an electrical shock to the operator and/or donor/patient.

The operator should never remove any of the MCS+ cabinet panels. Maintenance requiring access to the inner cabinet remains the responsibility of a Haemonetics-trained technician.

The operator should not touch any internal parts of a non-medical device that, after the removal of covers, connectors, etc., without a tool, could result in an electrical shock. Likewise, the operator should not simultaneously touch the donor/patient and any internal parts of a non-medical device that, after the removal of covers, connectors, etc., without a tool, could result in an electrical shock to the operator and/or donor patient.

Equipment in which protection against electric shock relies on basic insulation only should not be used with the MCS+ device.

Leakage current control

Each MCS+ device receives a careful inspection for leakage current prior to leaving the factory. Haemonetics recommends that a control be performed for current leakage by an authorized representative as part of the annual preventative maintenance. It remains the responsibility of the apheresis center to ensure that this control is performed.

In the event of any major spill in which fluid may enter the cabinet, or an important voltage surge, the operator is responsible to ensure that a leakage current test is performed before re-using the device. The control is necessary to avoid the risk of electrical shock and should be conducted by an authorized Haemonetics representative.

The operator is responsible for making sure that the leakage current of the final configuration (the MCS+ device and any ancillary equipment attached to the MCS+ device), comply with IEC 60601-1-1 Standard, Medical electrical equipment in normal and single fault conditions.

Mechanical hazards/rotating parts

As with any equipment containing rapidly rotating parts, the potential for severe injury exists if personal contact is made, or if clothing becomes entangled with the moving parts. The MCS+ device contains a safety feature, designed to prevent the centrifuge from spinning if the system has not been properly secured. However, the operator should respect the usual precautions taken when working with equipment containing rotating mechanical parts.

Power outlet connection

To comply with the IEC 60601-1-1:2000 Standard for Medical Electrical Equipment, general requirements for safety do not connect more than one multiple portable socket outlet or extension cord to the system. In addition, do not power the MCS+ device using a power cord other than the one originally supplied by Haemonetics for your instrument. Always ensure the power cord is connected to an appropriately grounded power source.

Communicable disease precautions

Despite testing and screening to detect communicable diseases such as hepatitis, syphilis or HIV, the risk remains that the blood being processed may be infected. The operator must take the appropriate precautions when handling blood products and disposing of blood-contaminated material, to ensure personal safety as well as the safety of others who may come in contact with the material.

Proper handling of blood-contaminated material

If a leak or blood-spill should occur, it should be cleaned immediately. The operator should follow the local standard operating procedure outlining the steps to follow and product(s) to be used for the disinfection of material contaminated by blood.

If any blood-contaminated material must be returned to Haemonetics for further inspection, the operator should consult the “RGA” Procedure, described in *Chapter 5*.

Proper disposal of biologically contaminated materials

Any MCS+ disposable material used during an apheresis process is considered as biologically contaminated. It must be disposed of according to local standard operating procedure for the removal of such material and should not be mixed with non-biologically contaminated waste.

Chapter 7

Troubleshooting during an MCS+ Procedure

P/N 85213-30, Manual revision: B

UNDERSTANDING A NOTICE AND RELEVANT HELP MESSAGE

The MCS+ device is monitored from the moment it is powered on by two safety systems- a “hardware” based safety system and a “software” based safety system. The operator is notified of any irregularities by a display screen message and an audible alarm. This type of message is referred to as a NOTICE message.

In the case of a rare major system malfunction, the operator will receive a message on the screen and hear a continuous alarm. If this occurs, the operator should record the error detected and immediately power off the device. The operator should discontinue use of the device and inform the local Haemonetics representative, who will provide further instruction.

For other system alerts, the operator will receive a screen message and hear an intermittent alarm. The operator can use troubleshooting techniques provided on the Haemonetics HELP screen display and attempt to resolve these “errors”.

An MCS+ NOTICE message will describe the problem to the operator and display a reference number. A numerical listing of MCS+ NOTICE messages, along with each related HELP message is provided in the Postscript to the MCS+.

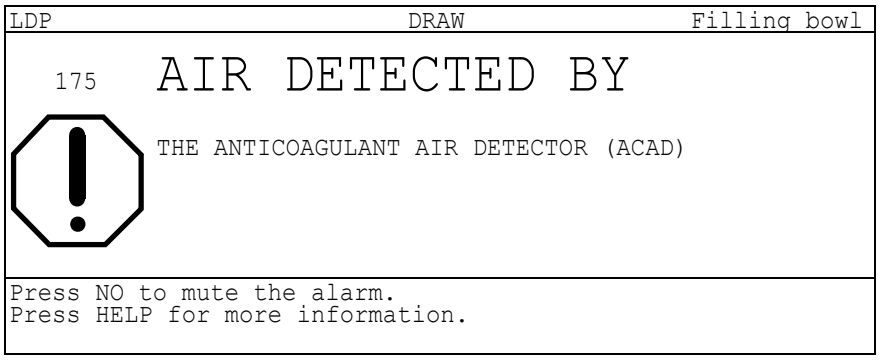


Figure 7-1, Example of an MCS+ NOTICE message

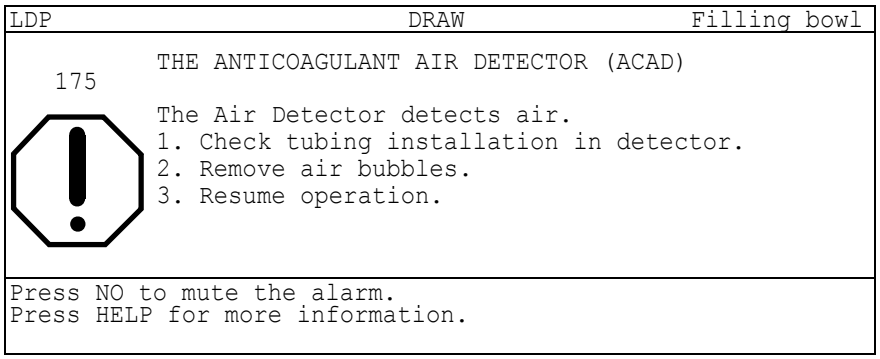


Figure 7-2, Example of an MCS+ HELP message

PERFORMING A RECOVERY PROCEDURE

The MCS+ programming will provide the operator with a particular screen message in certain situations called PROCEDURE RECOVERY. The Procedure Recovery screen message will appear:

- If the power supply to the device has been interrupted as in the case of an external power failure.
- If the operator has powered-off the device for any reason before the normal termination of a collection procedure.

If at any point during a collection procedure, the operator should receive a HELP message indicating that the device should be powered-off, then powered-on in an attempt to "recover" the procedure, the following screen will be displayed:

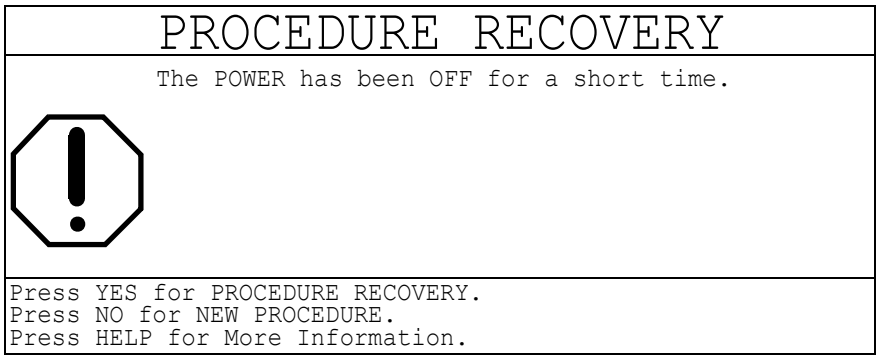


Figure 7-3, MCS+ Procedure Recovery Screen
(refer to message 375)

If the donor/patient has remain connected to the system, and the disposable set has remained fully installed, the operator can resume the procedure simply by pressing the Yes key.

The MCS+ safety features will conduct the necessary testing to ensure that the procedure can be continued. The device will first conduct a RETURN cycle of components remaining in the disposable set and bowl, then proceed with the next DRAW cycle.

The on-line HELP screen will provide further information. Full procedure statistics can be retrieved from the Haemo Update screen by pressing the Help key twice.

Note: If the operator presses the No key to begin a new procedure, rather than the Yes key to attempt a Procedure Recovery, new disposable material must be installed.

APPLYING SPECIFIC TROUBLESHOOTING TECHNIQUES

Power failure procedure

Policies may vary among apheresis centers concerning the procedure to follow in the event of a power failure.

It is important for the operator to remember that during DRAW, the blood in the needle tubing is **not** anticoagulated. All needles should be considered as containing non-anticoagulated blood, in the event that processing should be interrupted during DRAW.

The operator can bring anticoagulated blood to the needle site by the following actions:

- ➔ Place the power ON/OFF switch in the OFF position.
- ➔ Press the donor valve lever to hold the valve open.
- ➔ Manually turn the blood pump in a counter-clockwise direction, providing 5 full, slow rotations.

This will bring approximately 5 ml of anticoagulated blood through the needle tubing to the venipuncture site. If power has not been restored within 5 minutes, the operator should begin to manually return the blood components in the bowl and tubing to the donor using the "Manual Gravity Infusion" procedure.

If power is restored, and the original venipuncture has been maintained open for blood to flow freely, the operator can re-install the tubing in the valves and attempt to recover the procedure and continue component collection.

Manual gravity infusion procedure

During an apheresis procedure, an unusual circumstance may arise (such as a power failure or other technical reason) in which the MCS+ device cannot pump the contents of the disposable bowl and tubing back to the donor. Haemonetics suggests a technique using gravity to manually infuse the remaining contents. This can eliminate unnecessary blood loss for the donor.

This procedure is applicable for all of the MCS+ protocol options. Policies may vary among apheresis centers concerning the return of cells by gravity. The operator should consult and apply the local standard operating procedure for gravity infusion of cells if variation in procedure exists.

Without an external power source, the MCS+ valves must be opened manually to release the tubing. To do this, the operator must press the lever of the pinch valve toward the cabinet until the tubing can be removed.

Warning: The operator should carefully monitor the venipuncture site. If infiltration of the vein is observed at any point, the procedure should be discontinued.

Preparing the tubing

- ➔ Disconnect the MCS+ device from the external power source.
- ➔ Clamp the donor-line double lumen tubing close to the Y-connector.
- ➔ Clamp the AC line above the Y-connector to isolate the tubing from the donor.
- ➔ Clamp the solution line(s) and remove the tubing from the valve(s).
- ➔ Remove the tubing from plasma valve, the donor valve, the line sensor and the BLAD to provide necessary slack in the tubing.
- ➔ Clamp the DPM and SPM lines and remove the filters from the pressure monitors.
- ➔ Remove the tubing from the Blood and Transfer pumps.

Caution: *Turn the pump rotors clockwise until the groove on each pump rotor is aligned with the tubing guide, then pull the tubing upward. The operator should verify that the tubing remains in the groove as the pump rotor is turned, in order to avoid pinching or tearing the tubing.*

- ➔ Remove the tubing from the DLAD1, DLAD2 and the tubing guide.

Removing the bowl/beginning re-infusion

- ➔ Unlock the centrifuge and open the lid.
- ➔ Remove the disposable bowl from the centrifuge well and the blood filter from the brackets.

Caution: *The operator should hold the disposable bowl and blood filter upright and higher than the donor at all times.*

- ➔ Unclamp the donor line tubing. Allow gravity force to infuse the entire contents of the bowl up to the point of the needle connector.
- ➔ Re-clamp the double lumen tubing approximately 5 cm from the Y- connector to prevent blood from returning in the direction of the bowl.

Discontinuing the procedure

- ➔ Remove the needle from donor, disconnect the needle tubing from the disposable harness and dispose of appropriately.
- ➔ Clamp the effluent line close to the centrifuge bowl and disconnect the collection product(s). Handle any collection products according to local standard operating procedure.
- ➔ Remove the remaining disposable set elements and dispose of appropriately.

Repeat venipuncture procedure

If a vein becomes infiltrated at any point during a collection procedure, and blood can no longer flow through the needle, Haemonetics recommends that the uncollected blood components in the bowl and tubing be returned to the donor using a new intravenous pathway.

The MCS+ operator should be familiar with the local standard operating procedures when repeating a venipuncture, as well as product storage-duration requirements when changing a needle.
This procedure as described by Haemonetics must be performed using strict aseptic technique or a sterile connection device.

➔ Press the STOP key on the control panel.

➔ Hermetically seal the donor-line tubing by clamping both sides of the needle connector as follows:

- Close the ratchet clamp on the needle tubing.
- Place a second clamp on the double-lumen tubing on the opposite side of the Y-connector.
- Remove the needle from the donor, cut the contaminated needle and dispose of correctly.
- Place the donor-line tubing aside to prevent contamination.

Caution: *At this point, the operator should remove the pressure cuff from the donor and appropriately treat the vein, if infiltrated.*

➔ Prepare and perform a new venipuncture, securing the new needle and tubing.

➔ Prime the new needle tubing with donor blood and close the ratchet clamp.

➔ Disconnect the old needle tubing (minus the needle) from the disposable set and dispose of correctly.

➔ Connect the new needle tubing to the disposable harness and unclamp at both sites.

If aseptic technique has been used, any air in the tubing is considered as sterile, and the collection product will remain viable. Any air in the tubing can be displaced toward the blood filter or disposable bowl by the following actions:

➔ Press the Draw key to advance any air present from the needle through the DLAD1 and DLAD2 into the blood filter.

Note: Depending on the quantity of blood already present in the bowl, the operator may receive the NOTICE message "DRAW not allowed, press RETURN to continue". If this should occur, the operator should press the STOP key, followed by the Draw key. The MCS+ DRAW mode will then be initiated automatically.

Once any air from the needle has reached the bowl, the operator should:

➔ Press the Return key to re-infuse the blood components in the bowl.

AC depletion procedure

During an MCS+ collection procedure, the anticoagulant solution may be depleted before the target collection product volume has been reached. If the AC solution bag is empty, the operator will hear an alarm and receive the screen message “AIR DETECTED BY THE ACAD”.

Warning: Haemonetics recommends that the collection of blood components be discontinued at this point.

The operator can attempt to return any blood components remaining in the bowl using manual gravity infusion.

Chapter 8

Consulting Reference Information

EXPLAINING COMMONLY USED CALCULATIONS

Calculating AC concentration in the final product

The concentration of anticoagulant solution found in an MCS+ platelet or plasma product depends on a combination of the following two variables:

- The selected anticoagulation ratio (or AC ratio) for the procedure.
- The individual donor hematocrit.

The AC ratio is a MCS+ parameter setting which signifies the proportion between the number of AC pump rotations to the number of Blood pump rotations during the same time span. This ratio will determine the quantity of AC solution being administered to the donor-line tubing as whole blood is being drawn from the donor.

The donor hematocrit is determined prior to the collection procedure at the time of donor blood screening.

The following table summarizes the concentration of AC in the collected plasma or platelet product according to selected ratios for the listed donor hematocrit values.
To determine the total volume of AC solution in a plasma or platelet final product, the following procedure should be used:

➔ Determine the concentration of AC solution in the product according to the values listed in the following table.

➔ Calculate the total volume of AC solution in collected products by multiplying the concentration of AC solution in the plasma or platelet product by the volume of the final product:

$$\text{AC Volume in Product} = \frac{\%\ \text{AC in Product}}{100} \times \text{Product Volume}$$

Table 8-1, AC solution concentration in MCS+ final collection products

AC Ratio	1:8	1:9	1:10	1:11	1:12	1:16
Donor Hematocrit	**% Anticoagulant in the plasma or platelet product**					
20	15.2	13.5	12.2	11.1	10.2	7.7
22	15.5	13.8	12.5	11.4	10.4	7.9
24	15.8	14.1	12.8	11.6	10.7	8.1
26	16.2	14.5	13.1	11.9	10.9	8.3
28	16.6	14.8	13.4	12.2	11.2	8.5
30	16.9	15.2	13.7	12.5	11.5	8.7
32	17.4	15.5	14.0	12.8	11.8	8.9
34	17.8	15.9	14.4	13.2	12.1	9.2
36	18.2	16.3	14.8	13.5	12.4	9.4
37	18.5	16.6	15.0	13.7	12.6	9.6
38	18.7	16.8	15.2	13.9	12.8	9.7
39	19.0	17.0	15.4	14.1	13.0	9.9
40	19.2	17.2	15.6	14.3	13.2	10.0
41	19.5	17.5	15.8	14.5	13.4	10.2
42	19.8	17.7	16.1	14.7	13.6	10.3
43	20.0	18.0	16.3	14.9	13.8	10.5
44	20.3	18.2	16.6	15.2	14.0	10.6
45	20.6	18.5	16.8	15.4	14.2	10.8
46	20.9	18.8	17.1	15.6	14.4	11.0
47	21.2	19.1	17.3	15.9	14.6	11.2
48	21.6	19.4	17.6	16.1	14.9	11.4
49	21.9	19.7	17.9	16.4	15.1	11.6
50	22.2	20.0	18.2	16.7	15.4	11.8
60	26.3	23.8	21.7	20.0	18.5	14.3

Calculating the AC volume infused to the donor/patient

The volume of AC solution infused to the donor/patient can be calculated as follows:

➔ Consult the "Haemo Update" or "Procedure Complete Screen" to determine the volume of AC solution used (AC Used) during the collection procedure.

➔ Determine the total volume of AC solution in the final plasma and platelet products referring to the previous table.

➔ Subtract the volume of AC solution volume in the final products from the volume of AC solution used during the procedure to determine the volume of AC solution infused to the donor/patient.

$$\text{AC volume infused} = \text{AC used} - \text{AC in final product}$$

Estimating total blood volume

The MCS+ device displays the estimated total blood volume of the donor/patient, according to the method provided by the AABB *Technical Manual* (13th edition, appendix 5, page 757). The equations used by the MCS+ device are as follows:

- For males:

$$\text{Estimated Blood Volume} = 2740 \times \sqrt{\frac{\text{Height (cm)} \times \text{Weight (Kg)}}{3600}}$$

- For females:

$$\text{Estimated Blood Volume} = 2370 \times \sqrt{\frac{\text{Height (cm)} \times \text{Weight (Kg)}}{3600}}$$

Estimating the expected extra corporeal volume

The maximum Extra Corporeal Volume (ECV) for each donor/patient per procedure can be estimated by subtracting the volume of AC solution used from the blood volume processed, then dividing by the number of cycles performed.

Note: The most accurate estimation is obtained during the first RETURN cycle.

Prior to a collection procedure, the maximum ECV can be estimated by using the following equation:

$$\text{Estimated Maximum ECV} = \frac{17{,}000}{\text{Donor Hematocrit} \times \{1 - \text{AC Ratio}\}}$$

If the AC Ratio is programmed at 1:9 then AC Ratio = 1/9 = 0.11.
The hematocrit should be entered as a whole number.

To determine if the 15% ECV limit may be exceeded, the estimated maximum ECV should be divided by the Estimated Total Blood Volume of the donor/patient.

A donor/patient with a hematocrit of less than 38% and an estimated blood volume of less than 3600 ml can be expected to reach the 15% ECV limit during the procedure.

Determining final product volume(s)

The MCS+ device is designed to determine final product volume(s) either by:

- Counting the number of pump revolutions.

or

- Weighing the product.

In certain MCS+ protocols, the plasma and platelet product volumes are determined by the weigher. To convert the product weight to a volume, the device utilizes a conversion factor of 1.026 g/ml. The Procedure Complete Screen and Haemo Update Screen will provide the operator with detailed product volume information.

To manually determine the collection product volume, the operator should:

➔ Weigh the final product on a calibrated scale.

➔ Subtract the weight of the empty collection container(s) from the product weight.

➔ Divide by 1.026 g/ml.

$$\text{Product Volume} = \frac{\text{Total Weight} - \text{Empty Bag Weight}}{1.026} \text{ ml}$$

Calculating platelet yield

The platelet yield in a final platelet product can be calculated by multiplying the platelet concentration of the final product by the total final product volume. The platelet yield is calculated in 10e11 platelets.

$$\text{Platelet Yield} = \frac{\text{Platelet Concentration} \times \text{Product Volume}}{100{,}000} 10^{11} \text{ Platelets}$$

Note: When the platelet concentration is provided using the units of 10e3/µl or 10e6/ml, the factor 100,000 should be used to arrive at the correct number of digits.
For example, if the platelet concentration in the product is 1300 x 10e3/µl and the product volume was 300 ml, the platelet yield can be calculated to be 1300 x 300/100,000 or 3.9 x 10e11 platelets.

Calculating platelet collection efficiency

The platelet collection efficiency can be calculated by dividing the platelet yield by the total number of platelets processed. The preferred method of calculating the platelet collection efficiency is based on the average of pre-collection and post-collection platelet counts.

The mean platelet collection efficiency of the MCS+ device can be entered by an authorized Haemonetics representative, once a sufficient number of platelet collection procedures have been completed.

To calculate the platelet collection efficiency:

➔ Determine the average platelet count of the donor.

Note: If both a platelet pre-count and a post-count are available, the average of the pre- and post-counts can be used. When a post-collection platelet count is not available, and only a pre-collection platelet count is available, this value can be used.

➔ Determine the net volume of donor blood processed by subtracting the volume of AC used from the total volume processed during the procedure.

$$\text{Donor Blood Processed} = \text{Total Volume Processed} - \text{AC Volume Processed}$$

➔ Calculate the number of platelets which have passed through the bowl during the procedure:

$$\text{Platelets Processed} = \frac{\text{Platelet Count} \times \text{Donor Blood Processed}}{100{,}000} \text{ Platelets}$$

Example: If the donor platelet count was 250 10e3/µl and the total donor blood processed was 3500 ml, the total number of platelets processed was 250 x 3500/100,000 equaling 8.75 10e11 platelets processed through the bowl.

➔ Calculate the platelet collection efficiency as follows:

$$\text{Platelet Efficiency} = \frac{\text{Platelet Yield}}{\text{Platelets Processed}} \times 100\%$$

IEC 60601-1-2 STANDARD REQUIREMENTS

Operation precautions

Caution: *The Haemonetics device must be operated in an environment compatible to the requirements of the IEC 60601-1-2 Standard, Electromagnetic compatibility.*

To comply with the IEC 60601-1 collateral standards for medical electrical equipment, general requirements for safety, do not connect more than one multiple portable socket outlet or extension cord to the system. In addition, do not power the MCS+ device using a power cord other than the one originally supplied by Haemonetics for your instrument. Always ensure the power cord is connected to an appropriately grounded power source.

Mobile RF communication equipment not approved by Haemonetics and portable communication equipment can affect the system. Any accessories and cables not approved by Haemonetics used in conjunction with the device may increase hazards and influence compatibility with EMC requirements. Therefore, non-approved accessories and cables must not be used.

In addition, the Haemonetics device and accessories must not be placed directly adjacent to, or top of other equipment, unless specifically approved by Haemonetics.

Electromagnetic immunity

The Haemonetics system is intended for use in the electromagnetic environment specified in the following tables and the operator must ensure that each system is used in such an environment.

IEC 60601-1-2, Table 201: Guidance and manufacturer's declaration - electromagnetic immunity

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CSIPR 11	Group 1	The Haemonetics system uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CSIPR 11	Class B	The Haemonetics system is suitable for use in all establishments including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

IEC 60601-1-2, Table 202: Guidance and manufacturer's declaration - electromagnetic immunity

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
*Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
*Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
*Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the Haemonetics system requires continued operation during power mains interruptions, it is recommended that the Haemonetics system be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

* Authorized maximum value

IEC 60601-1-2, Table 204: Guidance and manufacturer's declaration - electromagnetic immunity
Non-live supporting equipment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the Haemonetics system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a)] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Haemonetics system is used exceeds the applicable RF compliance level above, the Haemonetics system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Haemonetics system.

[b)] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The Haemonetics system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Haemonetics system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Haemonetics system as recommended below, according to the maximum output power of the communications equipment.

IEC 60601-1-2, Table 206: Recommended separation distance between portable RF communications equipment and the Haemonetics device - Non-live supporting equipment

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz, the separation for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.