Medtronic

autoLog®

Autotransfusion System
Including Associated Disposables

Operator's Manual

! USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

CE 0123

Classified by Underwriters Laboratories, Inc.® with respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1 and CSA/CAN C22.2 no. 601.1.

autoLog® is a registered trademark of Medtronic, Inc.

Explanation of symbols on package labeling

	Attention, See Instructions for Use
	Fuse
	Equipotentiality
	On/Off
	Power - Vacuum Pump
	Alternating Current
	Humidity Limitation
	Temperature Limitation
	Do Not Resterilize
	Do Not Reuse
	Nonsterile
REF	Catalog Number
LOT	Lot Number
SN	Serial Number
	Date of Manufacture
	Use By
STERILE EO	Sterilized Using Ethylene Oxide
PYROGEN	Nonpyrogenic Fluid Path
	Quantity
! USA	For US Audiences Only

	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Council Directive 93/42/EEC.
	autoLog Autotransfusion System Medical equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL2601-1 and CAN/CSA C22.2 No. 601.1.
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.
	This Way Up
	Keep Dry
	Fragile, Handle with Care
	Corrugated Recycles
	Protective Earth Ground
	China RoHS Standard (SJ/T11364-2006) Electric Information Products Pollution Control Symbol. The number represents the years the device can be used before it must be recycled (environmental protection use period).
	Contains di(2-ethylhexyl)phthalate (DEHP)
	Manufacturer
	Consult Instructions for Use
EC REP	Authorized Representative in the European Community

Introduction

Autologous blood is blood that is derived from the same individual. Therefore, an autologous transfusion is one in which the patient receives only his/her own blood. Autotransfusion is a procedure in which the blood lost by, or removed from, a patient (autologous blood) is subsequently returned to the patient's circulation.

Advantages of Autotransfusion Over Allogeneic Transfusion

Because of concern over blood-related diseases, increasing numbers of physicians and patients are focusing their attention on the risks of allogeneic transfusion, which has resulted in increased interest in autotransfusion. There are several benefits:

- Hepatitis risk is eliminated, as well as other blood-transmitted diseases.
- Cross-matching errors are eliminated.
- Use of autologous blood provides additional assurance when performing surgery on patients with multiple red blood cell antibodies or rare blood phenotypes.
- Valuable allogeneic blood is conserved.

Intended Use

The autoLog Autotransfusion System is intended for use in the collection, concentration, washing, and reinfusion of autologous blood. Such areas of application may include, but are not limited to, the following:

- General, cardiovascular, orthopedic, vascular, plastic/reconstructive, obstetric/gynecologic and neurosurgical surgery
- Postoperative treatment areas

Principles of Operation

The autoLog Autotransfusion System operates by separating whole blood into its individual components by centrifugation. Blood is an ideal biologic mixture for such a technique, because it is a suspension of heterogeneous elements of significantly different densities and, thus, is easy to separate. When subjected to a centrifugal force, the blood components will migrate relative to their respective densities, with the higher density blood components moving farther from the axis of rotation. An itemized list of recovered and removed material is shown here:

Recovered:

- washed, packed red blood cells

Removed examples include (materials less dense than red blood cells):

- lipids and fats
- plasma-free hemoglobin
- pharmacologic agents
- activated platelets
- irrigation solutions
- activated clotting factors

As blood continues to enter the spinning bowl, the amassing red cell pack begins to occupy more of the bowl volume and the excess plasma is pushed ahead of the red cells. When the total liquid volume of the bowl has been exceeded, the excess plasma exits the bowl through the effluent fluid outlet to the waste bag via connecting tubing.

To rid the red cell pack of contaminants, it is washed with isotonic saline (0.9% sodium chloride solution).

At the termination of washing, the clean, packed red cells are transferred to the holding bag. This is accomplished by reversing the fluid pump rotation, which draws blood from the base of the bowl and transfers it to the holding bag via the attached tubing. The blood is transferred to a blood transfer bag and then to the patient.

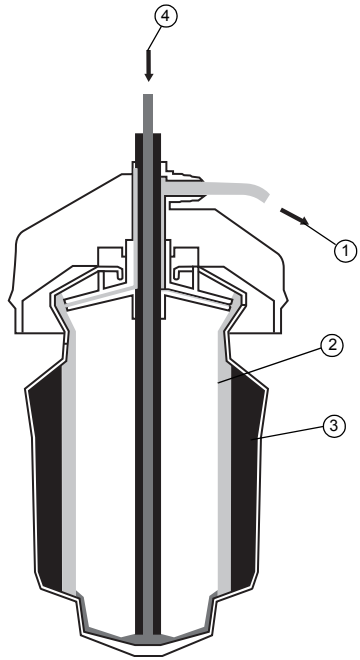

Figure 1.

1. Effluent Fluid Outlet
2. Plasma
3. Red Cells
4. Whole Blood Inlet

Warnings, Precautions, Contraindications, and Possible Complications

⚠ Read this Operator's Manual completely prior to using the autoLog Autotransfusion System.

Warnings and Precautions

1. **Direct Patient Reinfusion: Do not use** the autoLog Autotransfusion System for direct patient reinfusion (ie, from the machine directly into the patient) or direct patient draw (ie, from the patient directly into the machine). **Adequate safeguards do not exist to protect the patient in these situations.**
2. Reinfusion of washed red cells can be carried out by gravity or pressure infusion after transferring processed blood to blood transfer bags. Do not directly reinfuse processed blood from the holding bag to the patient. Directly reinfusing the blood from the holding bag exposes the patient to the risk of possible air embolism.
3. **Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.** Actual performance results may vary depending on many in-use variables. It is important to read and understand this Operator's Manual and understand the principles of cell washing before undertaking clinical operation of the autoLog Autotransfusion System. The responsibility for the use of this device in all cases belongs solely to the physician ordering its use.
4. The safe operation of all cell washing equipment requires the presence of a dedicated operator. It is the responsibility of the hospital to ensure that the individuals assigned to this task are well trained in the operation of the autoLog Autotransfusion System and alert to potential problems. **Never leave the machine unattended during operation as irrecoverable damage to the blood may occur.**
5. This device is intended for autotransfusion use in clinical patient care areas such as operating rooms, intensive care, or recovery rooms. This device is NOT intended for use in blood banks or apheresis centers, or for use where the blood bank has to handle, label, store, hold, or otherwise process the blood for later reinfusion into the same patient.
6. The disposable components utilized with this device are **for single patient use only**. This disposable was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Only Medtronic® sterilized disposable kits are approved for patient use with the autoLog Autotransfusion System. Maintain a sterile field at the collection site. It is important that aseptic technique be used to minimize the possibility of contamination to the disposables and/or the patient.
7. Due to the presence of phthalates in the product, the clinician must weigh the medical benefits of product use against the drawbacks of phthalate exposure for male children and pregnant or nursing women.
8. Do not attempt to reuse the disposables. Reuse may adversely affect the performance of this system and compromise patient safety.
9. The disposables must be used immediately after the removal of the protective packaging. Visually inspect the contents of the disposables. Should any evidence of damage to components be found during inspection or setup, do not use the disposable and return to Medtronic for replacement. Do not use silicone oils or greases near the disposables.

10. The disposables are sterile (ethylene oxide) and nonpyrogenic as long as package integrity has not been violated. Do not use if the package is damaged or open. Store all disposables in a dry place away from extremes of temperature.
11. The autoLog Autotransfusion System must not be used in the presence of flammable agents.
12. The basic concept of cell washing involves the removal of the contaminated plasma and debris, while leaving red cells suspended in clean saline. Removal of large amounts of plasma during autotransfusion can cause patient hypovolemia. Since platelets and coagulation factors are contained in the plasma, this plasma removal may also reduce coagulation factors or platelet levels below normal levels. It is also possible that inadequate washing of salvaged blood may result in insufficient removal of anticoagulant and/or the development of coagulopathies upon return of that blood to the patient. Therefore, careful monitoring of the patient's coagulation status is important to prevent complications.
13. Medtronic advises that all autologous collected blood be washed prior to reinfusion.
14. Medtronic does not have sufficient data to support the safety and efficacy of returning washed cells from partially filled bowls and therefore cannot recommend that practice.
15. Blood may be salvaged from body cavities, joint spaces, and other operative sites or trauma sites *only* if there is no clinical evidence of sepsis, malignancy, or wound contamination.
16. Never transfuse blood that is suspected of having high hemolysis.
17. Make sure no water or other irrigation, such as Betadine®[1], is aspirated into the autotransfusion system at any time, as this will hemolyze the red cells. Use an adequately sized suction tip to minimize hemolysis.
18. When using a hard-shell cardiotomy or blood collection reservoir, vacuum levels should not exceed 150 mm Hg.
19. Do not use any hot solutions over 42°C (108°F), since high heat can destroy red cells.
20. To avoid overheating the centrifuge, which could cause hemolysis, do not use the autoLog Autotransfusion System at temperatures higher than 30°C (86°F).
21. Plastic materials used in the autoLog Autotransfusion System and its disposable kits may be sensitive to chemicals (such as solvents and certain detergents). Under certain adverse conditions, exposure to these chemicals (including vapors) may cause the plastics to fail or malfunction.
22. Treat all blood and fluids using universal bloodborne pathogen precautions.
23. In the unlikely event of a power loss or other failure during the wash portion of the cycle, a lower than normal hematocrit will result. The blood should be tested for hematocrit so that the operator knows what is being given to the patient.
24. Do not restrict the flow in any tubing line. If a tubing line is inadvertently clamped or kinked during operation, pressure may build up in the centrifuge bowl causing failure or leakage. Always check the entire disposable kit to confirm that all tubing is free of any kinks, twists or flat areas. Double check the pump head and wash kit to ensure that all components are in the proper flow direction.
25. The standard waste bag for the autoLog Autotransfusion System holds approximately 10 L. Periodically check the waste bag volume and empty as required. The waste bag may be emptied at any time; however, a small amount of fluid (100–200 mL) should be left in the bag to provide for proper expansion during filling and emptying. Avoid the introduction of room air into the waste bag. A full waste bag will cause back pressure and bowl leaks to occur.

[1] Betadine® is a registered trademark of Purdue Frederick Company.

26. *The AABB Standards for Perioperative Blood Collection and Administration* (Third Edition, 2007), Reference Standard 5.1.8A, recommends the expiration period for blood recovered interoperatively with processing be stored at room temperature no longer than 4 hours from the time of collection. Interoperative blood collected with processing can be stored for 24 hours at 1°C and 6°C, if the storage is begun within 4 hours of completion of processing. The transfusion of shed blood collected under postoperative or post-traumatic conditions shall begin within 6 hours of initiating the collection. In the unlikely event of power failure, these guidelines should be strictly adhered to. If the blood is less than 4 hours old, it is permissible to continue processing and transfuse the blood to the patient.
27. Medtronic recommends the use of a blood transfusion filter between the reinfusion container and the patient in compliance with *The AABB Standards for Perioperative Blood Collection and Administration* (Third Edition, 2007), Reference Standard 5.4.5.1, which states, "Perioperative products intended for transfusion shall be transfused through a filter designed to retain particles that are potentially harmful to the patient."
28. Inside the autoLog Autotransfusion System cabinet there are various electrical components and wiring. Physical contact with any of these components while the unit is plugged in could result in severe electrical shock. Always turn off and unplug the unit prior to working inside the cabinet or changing any fuses. For continued protection against risk of fire, replace fuses only with the same type and rating. Internal grounding is provided for safety.
29. Although this system was tested for EMC compliance and passed, the potential exists that, in some situations, the autoLog Autotransfusion System and other devices might electromagnetically interfere with each other. Take steps to minimize this possibility.
30. The autoLog Autotransfusion System includes a centrifuge that rotates at 10,000 rpm. Parts that turn at high speeds may be dangerous. Safety rules related to the use of centrifuges must be followed. Do not open the centrifuge or remove the bowl before it comes to a complete stop.
31. Current leakage is a primary indicator of electrical shock hazard to personnel making contact with any exposed portion of the equipment. Each autoLog Autotransfusion System is checked during the final quality inspection to verify that current leakage is less than 100 µA. Have current leakage checked at least yearly, or as required by the operating facility's biomedical engineering department, or other qualified service technician. In addition, particular attention should be given to checking the current leakage and insulation after an event such as a fluid spill or major voltage surge in the power source has occurred, or after any machine repair.
32. Maintain the autoLog Autotransfusion System in good working order and calibrate it on a regular basis.

Transportation of Device

1. To avoid potential damage during transit, use the autoLog Autotransfusion System's original shipping packaging.
2. Never lay the autoLog Autotransfusion System on its side as this can damage the centrifuge.
3. Be careful not to move the autoLog Autotransfusion System by the IV pole. Over time this can cause the top panel of the machine to loosen and cause permanent damage.

Contraindications and Complications

1. The use of citrate-based anticoagulant in patients with impaired liver function may require additional monitoring and may, in certain circumstances, be contraindicated. Improperly processed red cells may contain residual citrate-based solution which, in excess quantities, could cause citrate toxicity, depression of serum calcium, or bleeding tendencies.

2. Gross contamination and/or septic procedures.
3. Surgery within the malignant area that may allow dissemination of tumor/malignant cells, if aspirated, into the autotransfusion system.
4. Caesarean sections (presence of amniotic fluid).
5. Presence of high concentrations of prostatic fluid.
6. Contamination of salvaged blood with drugs not intended for intravenous administration.
7. Collagen-based hemostatic agents, such as Gelfoam®[2], should not be used in combination with any autotransfusion system. In their presence, temporarily discontinue salvage during the time the agent is being used. After the agent has been given time to initiate hemostasis in the wound, irrigate the area copiously with saline and aspirate to non-autotransfusion collection containers before autologous blood salvage is continued. Failure to flush the area thoroughly could result in the hemostatic agent being drawn into the collected blood. This could result in coagulation of the collection blood or possible disseminated intravascular coagulopathy (DIC) complications in the patient.
8. Coagulopathy.
9. Morbidity and mortality in autotransfusion, as in allogeneic transfusions, are directly related to the volume of blood infused, if plasma and platelets are not concurrently transfused.

[2] Gelfoam® is a registered trademark of Pharmacia & Upjohn Company.

Device Description and Specifications

Features and Specifications

Note: Technical data, features, and options referenced in this manual are based on the latest information available at the time of printing. Medtronic reserves the right to change specifications without notice.

Electrical Classification:	
	Class I, Ordinary, Continuous Operation
Power:	
Voltage:	110 – 120 / 220 – 240 V~
Frequency:	50 – 60 Hz
Phase:	Single
Current:	1.6 / 0.8 A (depending upon voltage selection)
Fuses:	4 A / 250 V~ / T
Power Cord:	2 wires plus ground (earth) connector 3 prong hospital grade (USA only)
Speed and Flow Rate Specifications:	
Centrifuge:	0 – 10,000 rpm (± 5%)
Pump:	0 – 600 mL/min (± 5%)
Vacuum:	150 – 200 mm Hg
Dimensions:	
Width:	33 cm (13 in)
Height:	75 cm (30 in)
Depth:	22 cm (9 in)
Weight:	
	32 kg (70 lb)
Temperature Limit:	
Operational:	10°C – 30°C (50°F – 86°F)
Storage:	5°C – 50°C (41°F – 122°F)
Humidity Range:	
Operational:	10 – 95% noncondensing
Storage:	10 – 95% noncondensing

- **Sound Signals—the autoLog Autotransfusion System has five different sound signals:**

Sound Signal	Description
OK signal or Acknowledgment (2 beeps)	Signals the beginning or end of an automatic cycle, or everything is normal.
Warning signal (2 series of 3 beeps)	This signal is always accompanied by a warning message on the display. After taking appropriate action, restart the machine by pressing the flashing key.
Machine error signal (6 beeps)	Indicates a machine error. Turn off the machine and then turn it back on. If the problem persists, write down the error type and contact Technical Service.
5V supply or processor error (continuous tone)	Signals a 5V supply or processor error. Turn off the machine and then turn it back on. If the sound persists, contact Technical Service.
Power failure signal (continuous tone that fades out)	Signals a machine or supply failure. See the Troubleshooting section.

- **Control Panel:**

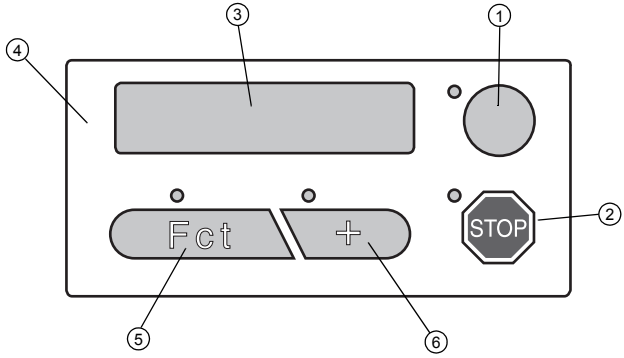

Figure 2.

1. **Go key (green):** This key starts or resumes the process from the point where it was stopped.
2. **Stop key (red):** In case of emergency during the fill and wash cycles, press this key; the machine will stop and automatically return the contents of the bowl to the collection reservoir. The autoLog Autotransfusion System will not automatically restart. To resume the cycle where it has stopped, press the key identified by the flashing LED or select one of the functions available in the function mode.
3. **Control display panel:** 20-character, 2-line display.
4. **Control panel:** The control panel consists of 4 keys (each with its own green LED).

5. **Function key:** Available only when the machine is stopped. Press the Function key several times to scroll through the various functions. To exit the function mode, keep the key pressed for a few seconds or press the Stop key. Exit also occurs automatically after 10 seconds.
   These functions allow manual transfer of the various volumes in specific circumstances as listed below:

EMPTY CENTRI> RESERVOIR	Keep the Go key pressed to force the pump to transfer the contents of the bowl back into the reservoir.
EMPTY CENTRI> HOLDING BAG	Keep the Go key pressed to force the pump to transfer the contents of the bowl directly into the holding bag.
REMOVE AIR INVERT HOLDING BAG	Keep the Go key pressed to force the pump to suck the air out of the inverted holding bag.

   Language: To select a preferred language, turn the machine off. Then, turn it on again while simultaneously pressing the Go and Stop keys. The machine will display:

CHOOSE YOUR LANGUAGE ENGLISH	Select the appropriate language by pressing the Function key.

   Turn the machine off to record the language chosen.

6. **Incrementation (+) key:** This key has two functions:
   1. **Operator Choice** – Toggles between YES and NO whenever a displayed request must be answered.
   2. **Process Acceleration** – Quickly press this key twice during the wash phase to jump directly to the emptying phase.

- **autoLog Autotransfusion System Components:**

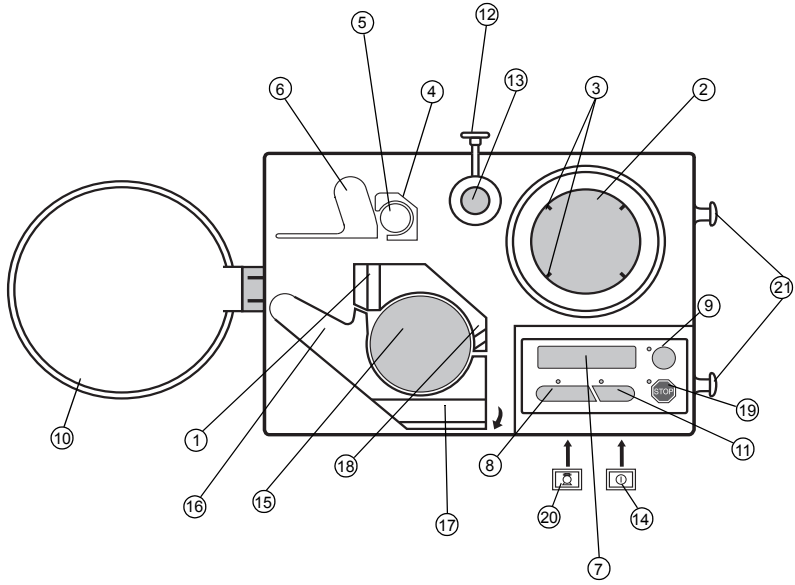

Figure 3.

1. Air Detector Guide
2. Centrifuge Chamber
3. Centrifuge Notches
4. Clamp Valve Cover
5. Clamp Valve Head
6. Clamp Valve Lever
7. Control Display Panel
8. Function Key
9. Go Key
10. Hardshell Bracket
11. Incrementation (+) Key
12. IV Pole Lock Bolt
13. IV Pole Mast
14. Power Switch
15. Pump Head
16. Pump Lever
17. Pump Lever Groove
18. Pump Outlet Tubing Guide
19. Stop Key
20. Vacuum Switch
21. Waste Bag Holding Pins

- **Alarms:**
  When an alarm condition occurs, the cause for the alarm appears on the display. The autoLog Autotransfusion System then sounds 2 series of 3 beeps and the warning message displays.

Alarm Text	Corrective Action
Kit Not Installed Lock Centri Cover	The wash kit is not installed or is incorrectly installed in the centrifuge. Install the wash kit or check the installation of the wash kit in the centrifuge.
Kit Misinstalled In Valve	The wash kit is incorrectly installed. Install the kit correctly in the valve. Press Go to resume operation after causing the valve to rotate once.
Centri Cover Not Locked	The centrifuge cover is not properly locked into place. Lock the centrifuge cover correctly by twisting until an audible click is heard (the wings should be in front of the two arrows).
Air in Reserv. Line Final Cycle? No	The reservoir is empty, not connected properly, or the collection line is obstructed. If no reply is given, the centrifuge stops after approximately one minute and automatically returns the bowl's contents to the reservoir. The machine restarts as soon as the reservoir is sufficiently full again. If this is the end of the blood recovery cycle, select Yes with the "+" key and confirm with the Go key. If not, check the reservoir valve line and resume by pressing the Go key.
Air In Saline Line	The saline bag is empty, is not connected, or one of the lines is obstructed. Replace the empty saline bag or check the saline valve line. Resume by pressing the Go key.
Empty too Short (air in line?)	There are air leaks between the bowl and air detector or in the waste bag. Check the tubing in the roller pump. Resume by pressing the Go key.
Empty too Long (Occlusion?)	There is an obstruction in the bowl transfer line. Check the bowl – roller pump – transfer line.
Waste Bag Full	The waste bag is full. Empty the waste bag.
Holding Bag Full	The holding bag is full. Change the holding bag.
Optics Obstructed	The optics in the centrifuge are dirty or obstructed. Open the centrifuge cover and clean the emitter and receptor in the centrifuge with deionized water. Resume by pressing the Go key.

- **In Vitro Specifications**
  - Anticipated Hematocrit

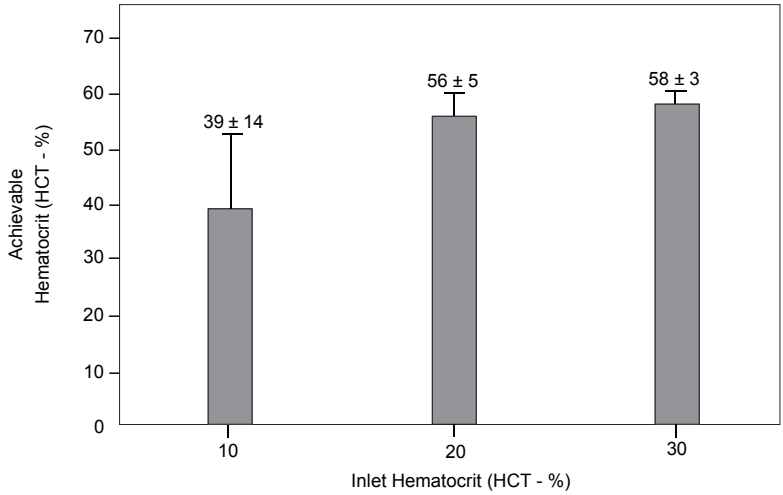

Figure 4.

The above data is from in vitro research using bovine blood. Clinical data may vary significantly. For the 10 and 20% Hct, n=6; and n=12 for the 30% Hct. Accuracy of the inlet Hct was ± 0.5%.

Operation

Supplies Required

- Wash Kit, which includes:
  - Centrifuge bowl (135 mL capacity) with tubing
  - Holding bag (1000 mL capacity)
  - Waste bag (10 L capacity)
- Blood collection reservoir
- Adequate quantity of 0.9% normal saline for washing
- Adequate quantity of anticoagulant solution
- Blood transfer bags
- Suction/anticoagulant line

Setup: Blood Collection System

1. Ensure that the power is off.
2. Open the sterile hardshell reservoir and remove the step down connector.
3. Attach the sterile step down connector to the bottom of the reservoir and clamp.
4. Place the reservoir in the holder. Attach the vacuum line to the yellow capped port.
5. Attach the other end of the vacuum line to the regulated vacuum source (VR702).
6. Ensure the regulated vacuum source is attached to the vacuum port on the cabinet.
7. Open the suction/anticoagulant line pouch and aseptically pass that line to the sterile field. Aseptically pass the blue end of the suction/anticoagulant line to the operator and attach the blue capped straight end to either the blue or white capped port on top of the reservoir.
8. Close the clamp on the anticoagulant IV drip line. If the anticoagulant solution is non-vented, open the vent cap on the drip chamber.
9. Plug the autoLog Autotransfusion System into a power outlet.
10. Turn on by pressing the power switch followed by the vacuum switch. The unit will power up, do a quick self-test, and display “AUTOLOG VERSION XX.X.” If no kit is installed, the machine will display “KIT NOT INSTALLED: LOCK CENTRI COVER.”
11. Set the vacuum regulator gauge to approximately 120 mm Hg. Do not set it higher than 200 mm Hg.
12. Spike the anticoagulant solution. Open the clamp and prime the reservoir with a minimum of 100-200 mL of anticoagulant solution. Reduce the anticoagulant flow to a ratio of approximately 15 mL of solution/100 mL blood. Monitor collection reservoir periodically for appropriate anticoagulation.
13. If the blood collection will not start within 5–10 minutes, the anticoagulant flow may be stopped. Be sure to restart the anticoagulant solution prior to the collection of blood.
14. Blood collection may now begin.

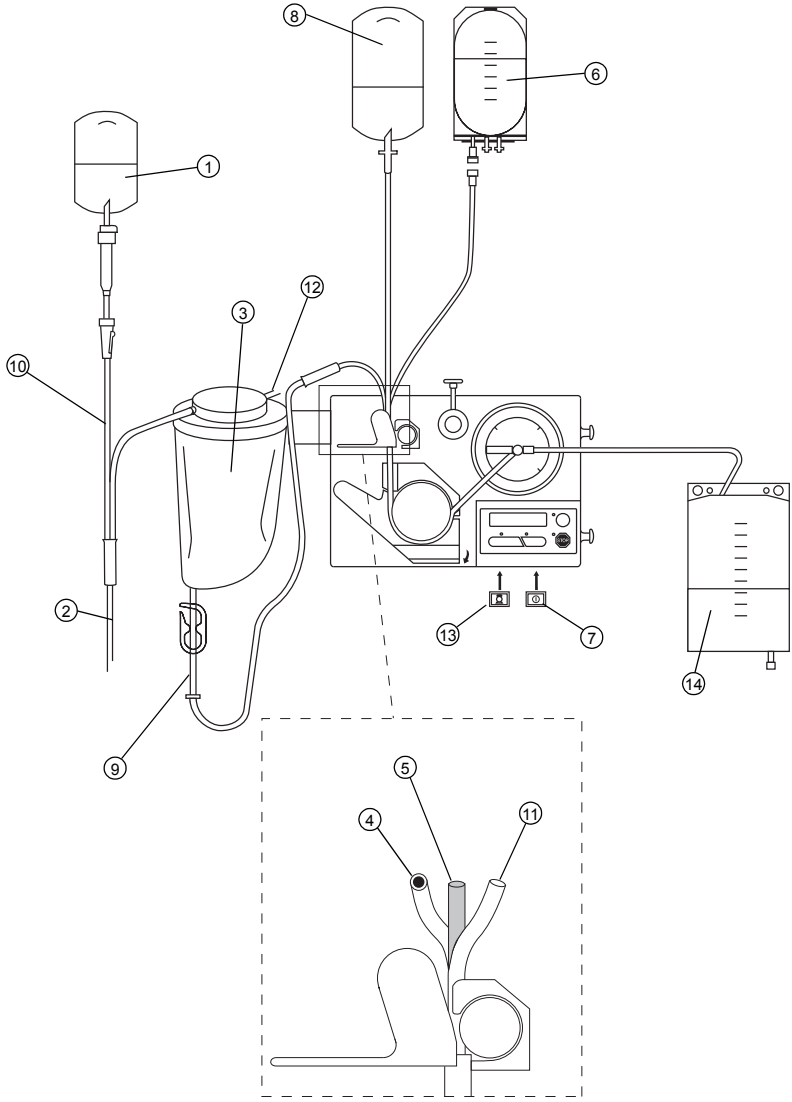

Figure 5.

1. Anticoagulant Solution
2. Blood Source
3. Collection Reservoir
4. From Collection Source
5. From Saline Bag
6. Holding Bag
7. Power Switch
8. Saline Bag
9. Step Down Connector
10. Suction/Anticoagulant Line
11. To Holding Bag
12. To Vacuum Regulator
13. Vacuum Switch
14. Waste Bag

Setup: Centrifuge Bowl and Tubing Harness

1. Hang the saline wash solution on the lower IV pole hanger. This must be either a minimum of a 2-liter bag or two 1-liter bags.
2. Open the wash kit, remove the holding bag, and hang it on the upper IV pole hanger. Close any clamps.
3. Remove the waste bag from the wash kit, verify that the drain valve is closed, and install the waste bag on the posts provided at the side of the autoLog Autotransfusion System (volume markers facing away from the machine).
4. Make sure no dust, dirt, or other foreign material is in the centrifuge chamber or in the air detector tubing guide. If needed, clean (see the Calibration, Cleaning, and Maintenance section). **If it is not clean, the bowl may not seat properly and vibration may result, or the air detector may not function properly.**
5. Place the bowl into the chamber with the side tubing facing the waste bag. Align the centrifuge notches with the openings on the wings of the centrifuge bowl. Press down and turn clockwise to lock the bowl in place (you should hear an audible snap). If the machine is on, it will display "INSERT KIT IN VALVE AND PUMP." **Make sure that the bowl is completely inserted. Remove, clean, and reinsert if necessary.**
6. Connect the side (waste) tubing to the waste bag. **Confirm that there are no kinks in the tubing.** Use the red stripe as an indicator that no kinks have occurred.
7. Place the manifold into the opening between the lever and the valve head with the three tubes toward the back of the machine, and the bevel on top. Once the manifold is correctly inserted, release the valve lever to complete the installation. Each of the three tubes should be in its own guide and the manifold should be partially covered by the valve lever. **Confirm that there are no kinks in the tubing. Correct if necessary.**
8. While holding the machine firmly, place your thumb into the pump lever groove and open the pump lever in the direction of the arrow. **Be careful not to pinch your fingers in the pump lever.**
9. Place the pump header tubing into the space between the pump head and the pump lever. Stretch the tubing over the pump outlet tubing guide and into the groove to engage the pump header positioner in the socket. Make sure no kinks or twists have occurred using the red stripe as an indicator. Once the tubing is correctly inserted, release the pump lever to complete the installation.
10. Insert the pump header tubing into the air detector guide. Use the blue tubing insertion tool only, as other instruments can damage the air detector. It is important to fully insert the tubing into the guide.
11. Press the Go key. The machine will perform a complete rotation of the valve head. The machine will display "CONNECT SAL, HOLDING, RESERVOIR AND WASTE."
12. Verify the connection of the kit to the holding bag.
13. Spike the middle manifold tubing into the saline bag. Release the saline clamp.
14. Connect the bottom manifold tubing to the step down connector on the bottom of the reservoir.
15. Setup of the disposable components is now complete. Press Go to confirm completion. The machine will prime the system with a small amount of saline and place the machine into standby. The display will read: "STOP 0 mL 0 mL." In the standby mode, the machine will not start automatically.

Operation

1. To move the machine out of standby mode and into automatic mode, press the Go key. The display will read: “MACHINE READY 0 mL 0 mL.”
   Manual: To manually start processing, press the Go key a second time.
   Automatic: In this mode, the machine will begin processing the blood once the volume in the reservoir reaches approximately 800 mL.
2. If the blood volume in the reservoir remains sufficient, the machine will automatically complete a minimum of seven wash cycles.
3. Each wash cycle consists of the following phases:

Phase	Sample Display Message	Description
Idle	MACHINE READY 0 mL 0 mL	The LED of the Go key flashes. The machine is waiting for automatic start or the Go key to be pressed.
Filling	INPUT TRANSFERRED 32 mL 0 mL	The centrifuge and pump rotate and the bowl fills at a rate of approximately 600 mL/min. Once the level sensor initially detects that the bowl is full and the input volume is greater than 225 mL, the second fill cycle drops to approximately 250 mL/min. If the initial input volume is 225 mL or less, the second fill cycle remains at approximately 600 mL/min (fast second fill).
Wash	WASH TRANSFERRED 105/250 mL 0 mL	The wash phase starts as soon as the level sensor detects a full bowl at 250 mL/min. The display shows the volume of wash saline used / total saline volume needed. The wash phase can also be aborted manually by pressing the Incrementation (+) key twice.
Emptying	INPUT TRANSFERRED 1250 mL 0 mL	As soon as the full wash volume has been processed and the centrifuge has come to a complete halt, the pump transfers the washed and concentrated cells to the holding bag. The display shows the total transferred volume as it is pumping.
Post-cycle	INPUT TRANSFERRED 1340 mL 0 mL	The total volume transferred is displayed. If the volume in the reservoir is sufficient, another wash cycle will start. If the volume is inadequate, the machine will return to the MACHINE READY state. The machine will automatically start when sufficient volume is in the reservoir. When the machine has filled the holding bag to capacity (approximately 979 mL), a message prompts you to change the bag. After changing to a new holding bag, you may start another series of cycles by pressing the Go key, thereby placing the machine in the MACHINE READY state.

4. Final Cycle/Return Function:
   The machine will stop during a fill phase due to lack of blood in the reservoir. When this happens, there are three options:
   - Do Nothing - The centrifuge will continue to rotate for one minute, then stop. The contents of the bowl will be returned to the reservoir and the machine will start again when the blood volume is sufficient.
     OR
   - Continue Normally - This option is usually used to restart when air is falsely detected. When the Go key is pressed, a normal cycle fill phase is attempted.
     OR

- Final Cycle/Return Function - Press the Incrementation (+) key, then the Go key to confirm the final cycle. The machine will finish filling a partially filled bowl with concentrated cells from the holding bag and start the wash phase of the cycle.

  This function should only be used to supplement the volume of the blood in the bowl to allow the remainder of the blood to be processed. Do not over process the blood by repeating the return function multiple times for the same blood volume. Once a bowl has been processed using the return function, it should be transferred to a blood bag for subsequent administration to the patient as soon as possible.

  If the volume remains insufficient, “INCOMPLETE BOWL RECOVERABLE? NO” is displayed.

  The operator should reply “no” by pressing the Go key. Medtronic does not have sufficient data to support the safety and efficacy of returning washed cells from partially filled bowls and therefore cannot recommend that practice.

5. Line Flush:
   When the cycle is finished, the machine flushes the holding bag line to collect its contents; “PROCESSING COMPLETE REMOVE AIR ⟶ FCT” will be displayed. Press the Function key, hold the holding bag upside down and press and hold the Go key to clear the line of air. Once the air is removed, the blood is to be transferred from the holding bag to a blood transfer bag, then administered to the patient using a **filtered IV transfusion set. Do not reinfuse the blood back into the patient directly from the autoLog Autotransfusion System (see the Warnings, Precautions, Contraindications, and Possible Complications section).**

Postoperative Wound Drainage

Supplies Required

- Blood collection reservoir
- Adequate quantity of anticoagulant solution
- Suction/anticoagulant line
- Vacuum source

Setup: Blood Collection

1. Open the sterile hardshell reservoir and remove the step down connector.
2. Attach the sterile step down connector to the bottom of the reservoir and clamp.
3. Place the reservoir in a ring holder. Attach a vacuum line to the yellow capped port.
4. Attach the other end of the vacuum line to a regulated vacuum source.
5. Open the suction/anticoagulant line pouch and aseptically pass that line to the sterile field. Aseptically pass the blue end of the suction/anticoagulant line to the operator and attach the blue capped straight end to either blue or white capped port on top of the reservoir.
6. Close the clamp on the anticoagulant IV drip line. If the anticoagulant solution is nonvented, open the vent cap on the drip chamber.
7. Spike the anticoagulation solution. Open the clamp and prime the reservoir with 100-200 mL of solution. Reduce the anticoagulant flow to a ratio of approximately 15 mL of solution/ 100 mL blood.
8. If the blood collection will not start within 5 – 10 minutes, the anticoagulant flow may be stopped. Be sure to restart the anticoagulant solution prior to the collection of blood.

9. Blood collection may now begin. Once adequate blood is collected, the reservoir can be disconnected from the vacuum source and moved to the autoLog Autotransfusion System for processing.
10. If simultaneous blood collection is needed, a second reservoir and vacuum source may be used.

Setup: Centrifuge Bowl, Tubing Harness, and Operation

The bowl and tubing setup and operation is identical to normal autotransfusion with the device (Figure 5).

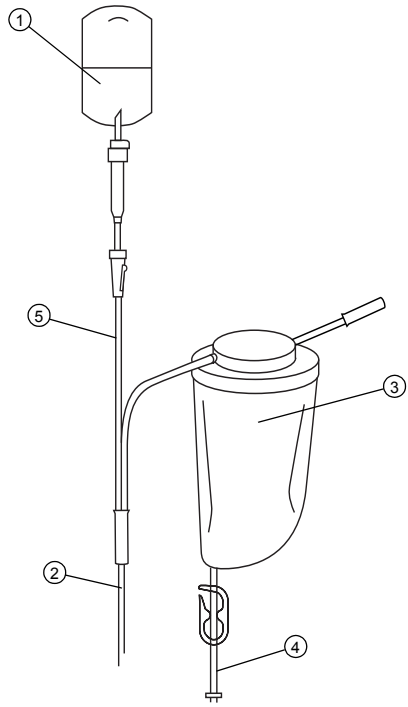

Figure 6.

1. Anticoagulant Solution
2. Blood Source
3. Collection Reservoir
4. Step Down Connector
5. Suction/Anticoagulant Line

Troubleshooting Chart

Problem	Explanation/Corrective Action
Machine Errors	• The autoLog Autotransfusion System can detect operation errors that cause the machine to stop. When this happens, the control panel is rendered inoperative. In some cases the display may also be inoperative. Examples are: – Power supply interrupted – Loss of 5V power – Internal processor error • In case of a machine error, turn off the machine and then turn it back on. If the problem persists, document the type of error and contact Medtronic Technical Service.
Power Failure	• Normally, each time the instrument is turned on, parameters are initialized to prepare it for use with a new patient. However, after a power failure or interruption (if the machine is restarted within 6 hours), the message RESTORE PREVIOUS STATE? is displayed. • The Incrementation (+) key permits changes between YES and NO. The Go key confirms the selection. • YES = The machine restarts where it left off before the power failure (state, volumes counted, current phase, etc), as if the machine had not been stopped. • NO = The machine parameters are initialized for a new patient. The software assumes that the kit installed in the machine is new and empty. • Note that the centrifuge brake does not operate in the case of a power failure. Do not remove the centrifuge cover until it has come to a complete stop.

Troubleshooting Guide

Introduction

This guide is intended to provide a simple description of the messages the autoLog Autotransfusion System will display during its operation. A brief description of the cause of the message is also included.

The guide is divided into three sections: normal messages, recoverable warnings and errors, and fatal (unrecoverable) warnings.

Normal messages will occur typically during system operation, such as “Air in Saline Line.”

Recoverable warnings and errors most likely can be fixed by a quick adjustment of the device or the disposable kit.

However, in the event of a fatal error, Medtronic CardioVascular Service should be called and the device should not be used again until it is repaired.

Normal Startup Messages

	Message Displayed	Notes
A	MEDTRONIC AUTOLOG VERSION X.X	After the machine performs some internal tests, the version of the software is displayed for a few seconds.
B	KIT ABSENT	The software checks the disposable at startup. This warning is issued if the disposable is not installed in the valve AND the centrifuge. Pressing the Go key makes the software check the valve again. The warning is cleared if the disposable is properly installed.
C	KIT NOT INSTALLED: LOCK CENTRI COVER	If the software knows the valve is properly installed, but does not detect the bowl in the centrifuge, this message is issued along with three short beeps from the speaker. The software waits indefinitely until the centrifuge cover is properly locked. After the bowl is inserted, the software then tests the valve.
D	INSERT KIT IN VALVE AND PUMP	If the valve is not installed in the valve head, this message is issued along with three short beeps from the speaker. The Go LED flashes continuously. Each time the user presses the Go key, the software tests the valve again. If the kit is still not installed correctly, this message is issued along with three short beeps from the speaker.
E	CONNECT SAL, HOLDING RESERVOIR AND WASTE	The Go LED flashes continuously. When the user presses the Go key, the valve is set to access the saline (wash) bag, the pump rotates counterclockwise and attempts to pump saline into the centrifuge. If an adequate volume of saline is present, the machine enters the stop state. The software cannot verify the presence or absence of the waste and holding bag.
F	AIR IN SALINE LINE	If the software detects air in the saline line, this message is issued along with three short beeps from the buzzer. When the user presses the Go key, the device again attempts to pump saline into the bowl. If the machine never detects saline, check the air detector jumper (J5). If no air is detected, the system automatically enters the Stop state.
G	STOP 0mL 0mL MACHINE READY 0mL 0mL	The system enters the Stop state automatically after a successful startup and whenever the user presses the Stop key. The software will not leave Stop until the Go key is pressed. When the machine is in the Stop state, if the user presses the Go key once, the machine enters the Machine Ready state. The device is now ready to collect and wash blood.

Normal Operating Messages

	Message Displayed	Notes
A	INPUT TRANSFERRED 0mL 0mL	Filling: “INPUT” refers to the blood volume pumped from the reservoir to the bowl. “TRANSFERRED” refers to the blood volume that has been washed and transferred to the holding bag. The “INPUT” volume is continually updated during filling.
B	AIR IN RESERV. LINE FINAL CYCLE? NO AIR IN RESERV. LINE FINAL CYCLE? YES	The software checks for air during filling. If 50 mL of air is pumped, this warning is issued. If the user presses the Go key, the machine will again try to fill from the reservoir. If the user presses the “+” key to change the answer to YES, and presses the Go key, the machine fills the bowl from the holding bag (concentrates) and begins a wash cycle.
C	INCOMPLETE BOWL RECOVERABLE? NO	If the blood volume withdrawn from the holding bag is still not sufficient to fill the bowl, this warning is issued. The default answer is NO. If the Go key is pressed, the blood in the bowl is returned to the reservoir. If the user presses the “+” key and changes the answer to YES, the machine starts a wash cycle. When the wash is complete, the bowl volume is transferred to the holding bag. When the Final Cycle prompt appears, 100 mL of wash solution is pumped into the centrifuge. The centrifuge will continue to spin for 1 minute if no response is received from the user.
D	WASTE BAG FULL	When the waste bag contains approximately 7 liters, this warning is issued. The user should replace the waste bag and press the Go key to resume normal operation.
E	UNLOCK THEN RELOCK CENTRI COVER	This warning will be displayed as filling starts. This means the centrifuge cannot turn the bowl. Remove the bowl completely from the centrifuge and reinstall it.
F	OPTICS OBSTRUCTED	The level sensor optics are tested once during the first filling cycle. If the level sensor output indicates a full bowl, this warning is issued. If the bowl is empty, clean the level sensors with a soft, wet cloth. If the bowl contains blood, manually pump the blood to the reservoir and restart.
G	WASH TRANSFERRED 102/250mL 0mL	While the device is washing the blood, this display will appear. The WASH volume is updated continually during the wash. After 250 mL of wash has been delivered, the software advances to the Empty phase.
H	AIR IN SALINE LINE	If the device detects air during wash, this message will appear. When the Go key is pressed, the device will again check for saline. This process repeats until adequate saline is detected. If no response is given within 1 minute, the bowl stops spinning.
I	INPUT TRANSFERRED 0mL 0mL	When the device is emptying blood to the holding bag, this message appears just as it does during filling. The TRANSFERRED volume is updated to reflect the washed RBCs being moved to the holding bag.
J	EMPTYING TOO SHORT (AIR IN LINE?)	The software monitors the air detector while the centrifuge is emptied to the holding bag. If air is detected before 100 mL has been pumped to the holding bag, this warning is issued to the display. Pressing the Go key resumes emptying from the bowl to the holding bag.
K	EMPTYING TOO LONG (OCCLUSION?)	The software calculates the time required to empty each bowl after each washing cycle. Typically, this time is around 37 seconds for a full bowl. If this time is exceeded, meaning the device has not detected air from the bowl, this warning is issued to the display. Users should check for a clamp on the holding bag line. When then Go key is pressed, the software will advance to either the Ready state or resume filling if enough blood is in the reservoir.

	Message Displayed	Notes
L	HOLDING BAG FULL	When approximately 1000 mL of RBCs have been transferred to the holding bag, the software stops and requires the user to change the holding bag. This warning is issued. The user presses the Go key after a new holding bag has been installed to resume operation.
M	KIT MISINSTALLED IN VALVE	If at any time when the pump and centrifuge are running and the valve clamp is opened or closed too far, the software will issue this warning. Pressing the Go key rechecks the kit.
N	CENTRI COVER NOT LOCKED	If the bowl is not properly inserted and locked in the centrifuge, the software will issue this warning. Properly inserting the bowl in the centrifuge will automatically clear this warning. The Go key does not need to be pressed.
O	BATTERY LOW	At startup, the software checks the battery voltage. If it is low, the machine can still run, but this warning is displayed. This can happen 14 times before the machine will not run. Press the Go key to clear it. **Replace the battery immediately after the procedure.**

Possible User Correctable Errors

These errors will still disable the machine. The recommended actions could be attempted prior to calling Medtronic CardioVascular Service. Should the errors in this section occur more than once, service must be called immediately, and the autoLog Autotransfusion System removed from use.

	Message Displayed	Notes
A	ABNORMAL RESET	If a glitch occurs on the power supply, this message can appear. The error can be cleared by cycling the front panel power. If the error does not reappear, the device can be used. If it repeats every time the power is turned on, the device must not be used.
B	ERROR CENTRI SPEED <	If the centrifuge speed drops below 9500 rpm, this fatal error is issued to the display. This indicates that the bowl cannot be turned in the centrifuge. Unlock and then re-lock the bowl. Turn the device off and back on and start processing. If the problem persists, replace the disposable. If the problem still occurs with a new kit, call service.
C	ERROR PUMP SPEED <	If the pump speed falls below 5% of the correct speed, this fatal error is displayed. Check the tubing around the pump header. Turn the device off and back on. If the problem persists, replace the disposable. If the problem still occurs with a new kit, call service.

Unrecoverable Errors

These fatal errors are unrecoverable by the system and/or operator. The system should be taken out of service until checked by a qualified service technician.

	Message Displayed	Notes
A	ROM CRC FAILURE	If the ROM chip contains invalid data, this fatal error is issued.
B	RAM TEST FAILURE	If the RAM does not function properly, this fatal error is issued.
C	EEPROM NOT ACCESSIBLE	If the EEPROM storing all the device history cannot be accessed, this fatal error is issued.
D	RTC ACCESS FAILURE	If the clock chip does not function properly, this fatal error is issued.

	Message Displayed	Notes
E	ERROR BATTERY LOW	If the battery has not been replaced after 14 battery low warnings, this fatal error is issued.
F	EXTERNAL WATCHDOG FAILURE	If the microprocessor safety chip does not function, this fatal error is issued.
G	24 VS RELAY STUCK	If the 24V relay cannot be opened, this fatal error is issued.
H	24V SENSING	If the 24V relay cannot be controlled, this fatal error is issued.
I	5V OFF BEFORE 24V OFF	If the power supplies do not shut down in the proper order, this fatal error is issued.
J	AIR DETECTOR TEST	If the air detector stops working, this fatal error is issued.
K	ERROR VALVE TIME-OUT	The valve must reach its requested position within 3 seconds or a time-out expires and a fatal error is issued.
L	ERROR VALVE POSITION	If the valve position is wrong, or if the valve turns while the pump is active, the error routine is entered, and fatal error is issued to the display. These checks are performed every 25 milliseconds.
M	ERROR CENTRI SPEED >	Uncontrolled Centrifuge Motion: If the centrifuge moves when it should be stopped, this fatal error is issued to the display.
N	ERROR CENTRI SPEED >	If the centrifuge speed is too fast, this fatal error is issued to the display. If the centrifuge speed is too slow, a fatal error is issued to the display.
O	ERROR CENTRI DIRECTION	If the centrifuge spins counterclockwise, this error is displayed.
P	ERROR: NMI	A short circuit of the 5V power supply causes this fatal error.
Q	ERROR 24VS OVERLOAD	A short circuit of the 24V power supply is also detected by the processor, and this fatal error is issued to the display.
R	ERROR PUMP SPEED >	Uncontrolled Pump Motion: If the pump moves when it should be stopped, this fatal error is issued to the display.
S	ERROR PUMP SPEED >	If pump speed is too fast, this fatal error is issued to the display. If pump speed is too slow, a fatal error is issued to the display.
T	ERROR: DIRTY BLOOD TRANSFER	If the software should somehow skip the washing phase, this fatal error occurs.
U	UNEXPECTED INTERRUPT	If the software jumps somewhere unknown, this fatal error is issued to the display.
V	ERROR PROGRAM COUNTER LOST	Certain illegal software actions will cause a fatal error.
W	ERROR TOO MUCH OVERHEAD	Before the washed bowl is emptied, the software verifies that the RAM and ROM tests have been executed at least once. If the tests have not been completed, this fatal error is issued.

Calibration, Cleaning, and Maintenance

Calibration requires trained service personnel. Have a qualified biomedical technician or the service department of your institution make calibration adjustments as shown in the autoLog Service Manual.

Patient safety requires that the machine be checked at least once a year by a trained technician. Before any maintenance is performed, ensure that the unit is unplugged.

Component/Area	Corrective Action
External	• Anytime the external portions of the device become dirty (eg, blood spills), they should be cleaned according to approved hospital protocols with a 10% bleach solution or other appropriate disinfectant solution. After cleaning, the unit should be wiped with a cloth and water to remove any cleaning solution residue. • If it is suspected that fluid has penetrated into the machine, it should be immediately examined by a trained technician.
Level Sensor	• If blood or other solutions are spilled, or dust builds up on the level sensor during use, the residue can render the sensor inoperative. To clean the level sensor: Use a cotton swab dipped in deionized water (do not use liquids that may leave a film, such as disinfectants or alcohol). Wipe gently across the sensor to remove any blood, dust, or debris. Carefully wipe with another dry cotton swab to remove any remaining moisture.
Centrifuge	• If blood or fluids are spilled in the centrifuge chamber, remove the wash kit after the case has been completed. Place a flat container under the machine to collect the disinfecting solution used during the cleaning process. **Caution: Use appropriate bloodborne pathogen and engineering controls such as eye protection, mask and gloves to protect yourself from the blood, cleaning fluids, and to discard the used fluids.** • Switch the machine off, then turn it back on while pressing the Go key. This places the machine in a centrifuge cleaning mode. Press Go again to start the centrifuge rotating. **Caution: There is no safety catch. Do not put your fingers into the centrifuge chamber while it is running.** • Slowly, over a 1-2 minute period, pour 1 L of a 10% bleach solution or other appropriate disinfectant solution into the centrifuge while it is rotating. Press Stop, turn the machine off, and wait until the centrifuge has completely stopped rotating before placing your fingers into the centrifuge chamber. Dry the chamber with a soft cloth.
Pump Head	• The tubing guides and pump header should be checked periodically for burrs and sharp edges that could lead to tubing damage and/or failure. Any defective parts should be replaced immediately. • On occasion, it may be necessary to clean the exterior and interior of the fluid pump. To clean the pump head, perform the procedure below: 1. Turn the unit off and unplug it from the power source. 2. Open the pump lever **(be careful not to pinch your fingers in the pump lever)** and lift the pump head out. **Caution: Use appropriate bloodborne pathogen and engineering controls such as eye protection, mask and gloves to protect yourself from the blood, cleaning fluids, and to discard the used fluids.** 3. Clean up the spilled fluids as much as possible, using towels and cotton swabs dampened in water, a 10% bleach solution, or other appropriate disinfectant solution. Dry the area thoroughly. 4. Open the pump lever. Align the indentation on the top of the pump head with the key on the shaft. Replace the pump head. 5. Plug in the unit.

End of Life Disposition

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

EQUIPMENT LIMITED WARRANTY[1]

(U.S. Customers Only)

A. This LIMITED WARRANTY provides the following assurance to the purchaser of the Medtronic® autoLog® Autotransfusion System, hereafter referred to as the "Equipment":

(1) Should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the delivery of the Equipment to the purchaser, Medtronic will at its option: (a) repair or replace any defective part or parts of the Equipment; (b) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement Equipment; or (c) provide a functionally comparable replacement Equipment at no charge.

(2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement, Equipment.

B. To qualify for this repair, replacement or credit set forth in Section A, the following conditions must be met:

(1) The Equipment must be returned to Medtronic within sixty (60) days after discovery of the defect (Medtronic may, at its option, repair the Equipment on site).

(2) The Equipment must not have been repaired or altered outside of Medtronic's factory in any way which, in the judgment of Medtronic, affects its stability and reliability. The Equipment must not have been subjected to misuse, abuse or accident.

C. This LIMITED WARRANTY is limited to its express terms. In particular:

(1) Except as expressly provided by this LIMITED WARRANTY, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE EQUIPMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

(2) This LIMITED WARRANTY is made only to the purchaser of the Equipment. AS TO THE PURCHASER OF THE EQUIPMENT AND ALL OTHERS, MEDTRONIC MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PURCHASER SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this LIMITED WARRANTY is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid. This LIMITED WARRANTY gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

(4) No person has any authority to bind Medtronic to any representation, condition or warranty except this LIMITED WARRANTY.

1 This limited warranty is provided by Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

EQUIPMENT LIMITED WARRANTY[1]

(For countries outside the U.S.)

A. This LIMITED WARRANTY provides the following assurance to the purchaser of the Medtronic® autoLog® Autotransfusion System, hereafter referred to as the “Equipment”, that should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the delivery of the Equipment to the purchaser, Medtronic will at its option: (a) repair or replace any defective part or parts of the Equipment; (b) issue a credit equal to the original Equipment purchase price (but not to exceed the value of the replacement Equipment), against the purchase of replacement Equipment; or (c) provide functionally comparable replacement Equipment at no charge.

B. To qualify for the repair, replacement or credit set forth in Section A, the following conditions must be met:

   (1) The Equipment must be returned to Medtronic within sixty (60) days after discovery of the defect (Medtronic may, at its option, repair the Equipment on site).

   (2) The Equipment must not have been repaired or altered by someone other than Medtronic in any way which, in the judgment of Medtronic, affects its stability and reliability.

   (3) The Equipment must not have been subjected to misuse, abuse or accident.

C. This LIMITED WARRANTY is limited to its express terms. In particular, Medtronic is not responsible for any incidental or consequential damages based on warranty, contract, tort or otherwise.

D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portions of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

1 This limited warranty is provided by Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

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