

Automatic Cell Washing System Operation Manual

UltraCW[®] II



Document History

Revision	Date	CO	Supersession	Revision Description
A	30 NOV 2017	12878	n/a	Initial release.
B	20 DEC 2017	13200	B supersedes A	Clarified content.
C	15 JAN 2018	13276	C supersedes B	Added system error code table
D	20 AUG 2018	13855	D supersedes C	Updated Indications for Use (formerly Intended Use) statement; Updated Setup instructions; Included information about the Fill button in Flow Calibration section; Updated Unit Specifications table

* Date submitted for Change Order review. Actual release date may vary.

Document Updates

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The screenshots and component images appearing in this guide are provided for illustrative purposes only, and may vary slightly from the actual software screens and/or product components.

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1 About This Manual

This manual provides information on how to use the UltraCW®II in blood banking and other laboratory procedures. This manual is intended for use by end users of the UltraCW®II automatic cell washing system and authorized service technicians.

1.1 Safety Precautions and Symbols

Symbols found in this document

The following symbols are used in this manual to emphasize certain details for the user:



Task Indicates procedures which need to be followed.



Note Provides useful information regarding a procedure or operating technique when using Helmer Scientific products.



NOTICE Advises the user against initiating an action or creating a situation which could result in damage to equipment; personal injury is unlikely.



CAUTION Advises the user against initiating an action or creating a situation which could result in damage to equipment or impair the quality of the products or cause minor injury.



WARNING Advises the user against initiating an action or creating a situation which could result in damage to equipment and serious personal injury to a patient or the user.



Manufacturer

Symbols found on the units

The following symbols may be found on the cell washer or cell washer packaging:



CE Mark (European units only)



Product falls under the scope of the WEEE (Waste Electrical and Electronic Equipment) directive.



Caution: Risk of damage to equipment or danger to operator



Caution: Biohazard

Avoiding Injury

Review safety instructions before installing, using, or maintaining the equipment.

- ◆ Do not move or bump the cell washer during operation.
- ◆ Before moving unit, disconnect and secure the power cord.
- ◆ Never physically restrict any moving component.
- ◆ Avoid removing electrical service panels and access panels unless so instructed.
- ◆ Use manufacturer supplied power cords only.
- ◆ Using the equipment in a manner not specified by Helmer may impair the protection provided by the equipment.

CAUTION

Decontaminate parts prior to sending for service or repair. Contact Helmer or your distributor for decontamination instructions and a Return Authorization Number.

1.2 General Recommendations

Indications for Use

The Helmer UltraCW®II automatic cell washing system is intended to be used for the washing portion of routine blood bank and laboratory procedures calling for washed red blood cells such as antiglobulin testing, ABO compatibility, Rh, cross matching and anti-body screening.

The UltraCW®II automatic cell washing system should be operated by a trained individual, such as a clinical laboratory technologist or similar education, as determining whether desired results have been achieved is subjective and dependent upon user preparation of blood sample, and parameter selection/adjustment.

General Use

Allow the cell washer to come to room temperature before switching power on.

2 Unpacking

2.1 Unpacking Guidelines

- ◆ To avoid damage, unpack the appliance at or near the installation site.
- ◆ Support the cell washer on both sides when lifting to remove from box (2 people recommended).
- ◆ Use Emergency Release to open the lid and remove packing around the rotor.
- ◆ Check the packing slip to ensure delivery is complete.
- ◆ Inspect unit for damage which may have occurred during shipping. Contact your delivery carrier directly to report any damage.

2.2 Emergency Release

The emergency release allows the lid to be opened during a power failure or when the cell washer is not powered on.

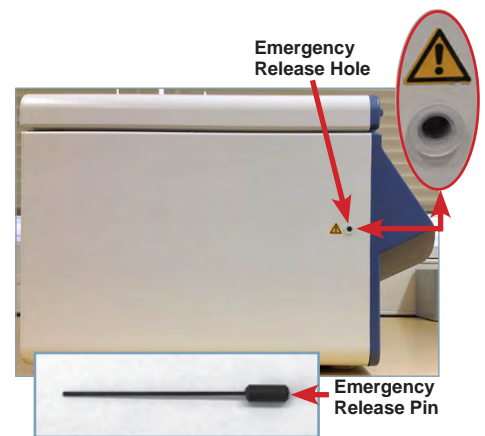
NOTICE

- Remove plug from emergency release hole, and disconnect power cord from power outlet prior to using the emergency release.
- Only the plastic release pin provided may be used for emergency release.

1. Ensure power is switched power off "O", and disconnect power cord from power outlet.
2. Look through the window on top of the lid to ensure the rotor is at a complete stop.
3. Insert the release pin into the Emergency Release hole and push in to release the lid and open.

Note

An error message will appear on the display once unit is powered back on. Select the Return button to clear.



2.3 Transport Bolts

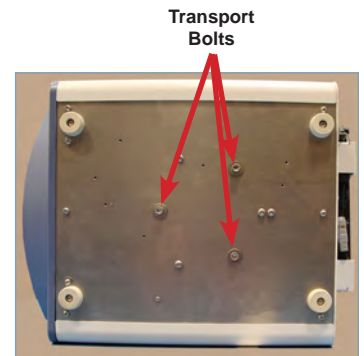
Transport bolts are located on the bottom of the cell washer and prevent the motor from moving during shipping. Transport bolts are necessary when moving or shipping the cell washer.

NOTICE

Keep transport bolts and Allen wrench provided for future use.

Remove Transport Bolts

1. With the cell washer powered off, open the lid using the emergency release and remove the rotor.
2. With the lid closed, place the cell washer in a position allowing access to the bottom of the unit.
3. On the bottom of the cell washer, locate the 3 transport bolts.
4. Using the Allen wrench included in the packaging, remove the bolts.
5. Return the cell washer to the upright position.



Install Transport Bolts

1. With the cell washer powered off, open the lid using the emergency release and remove the rotor.
2. With the lid closed, carefully place the cell washer in a position allowing access to the bottom of the unit.
3. On the bottom of the cell washer, locate the threaded holes for the 3 transport bolts and hand thread the bolts in each location.
4. Using the Allen wrench included in the packaging, tighten bolts until snug.
5. Carefully return the cell washer to the upright position.



3 Installation and Configuration

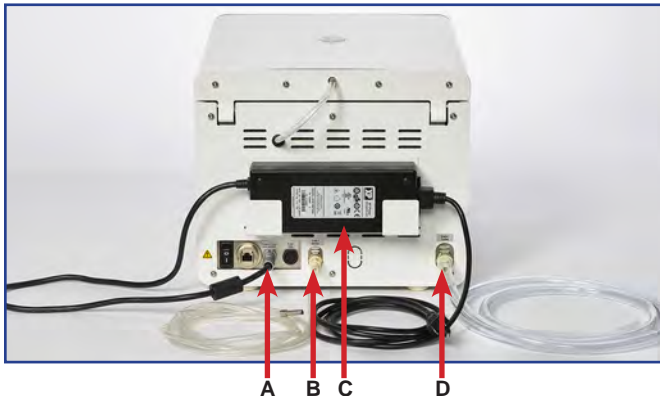
3.1 Location and Placement

- ◆ Has a sturdy, level surface
- ◆ Has a grounded outlet meeting national electric code (NEC) and local electrical requirements
- ◆ Has access to a supply of saline solution
- ◆ Has access to a waste container or drain suitable to receive decanted saline and human blood waste product
- ◆ When the cell washer is running, per EN/IEC 61010-2-020, no individuals or dangerous objects such as flammable or explosive materials may be within a safety margin of 12" (300mm) around the unit

CAUTIONS

- Use only manufacturer supplied power cord.
- Ensure drain tube is installed at a downward slope for proper drainage.
- Unplug power cord from power receptacle prior to moving.
- Ensure rotor is empty prior to moving.

3.2 Setup



	Description
A	Power Input
B	Inlet 1 Saline
C	Power Supply
D	Drain Outlet

1. Plug saline tube in inlet 1 and place the weighted end of the tube in the Saline box.
2. Connect drain tube in drain outlet ensuring drain tube is installed at a downward slope for proper drainage.
3. Connect power supply to Power-Input.
4. Connect power cord to power supply.

3.3 Initial Start-Up

Notes

- Allow unit to reach room temperature before powering on.
 - In the event of an error, an error message will appear at the top of the screen and an audible signal will sound.
1. Plug the power cord into a grounded outlet that meets the electrical requirements on the product specification label.
 2. Switch the power switch located on the back of the unit ON. Initialization takes approximately one minute. The Start screen will appear.



Start screen

3.4 Rotor Installation and Setup

Either a 12-place rotor or a 24-place rotor may be installed in the cell washer. Both rotors can hold either 10 mm x 75 mm tubes or 12 mm x 75 mm tubes. Inserts must be used to secure the 10 mm tubes to prevent damage during operation.

Install Rotor

1. Select the open lid button
2. Grasp the rotor on the grip area and place the rotor over the shaft.
3. Align the markings on the top of the rotor with the slots on the rotor shaft.
4. Lower the rotor onto the shaft.



Install Tube Inserts

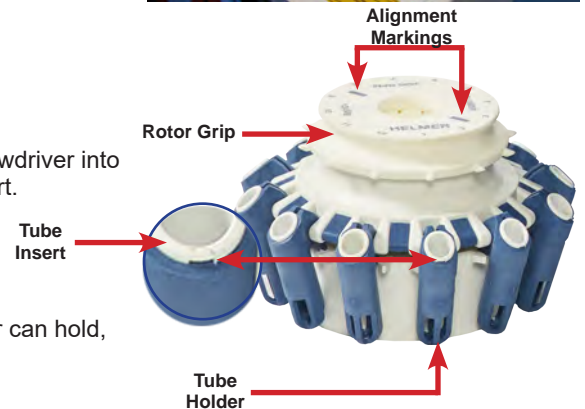
1. Remove rotor by lifting upward and place on solid surface.
2. Align the key on the insert with the groove in the tube holder.
3. Press the insert into the tube holder all the way down.

Remove Tube Inserts

1. Remove rotor by lifting upward and place on solid surface.
2. While holding the tube holder with one hand, insert a flat-head screwdriver into the slot and slightly twist the screwdriver to raise the top of the insert.
3. Grasp the top of the insert and pull it straight out.

Load Tubes

Gently place tubes in tube holder. If loading fewer tubes than the rotor can hold, distribute the tubes evenly around the rotor to maintain balance.







3.5 Rotor Type

It is necessary to enter the rotor type prior to running a program. Either a 12-place or 24-place rotor may be used in the cell washer. Both rotors can hold either 10 mm x 75 mm tubes or 12 mm x 75 mm tubes.

Notes



- This process requires an authorized user.
- If accessing unit for the first time, use factory created Service User password 46060.

Select Rotor Type

1. From the Start screen, touch the login button .
2. Enter a Service User password and select the green checkmark when finished.
3. Select the settings button . The Settings screen opens.
4. Select the desired rotor type (12-place or 24-place)  .
5. Select the green checkmark to save.
6. Select the red return button to return to the previous screen.

3.6 Balance Rotor

The rotor must be balanced for the cell washer to operate correctly. If the rotor is not balanced, the process is stopped and the imbalance error is displayed.

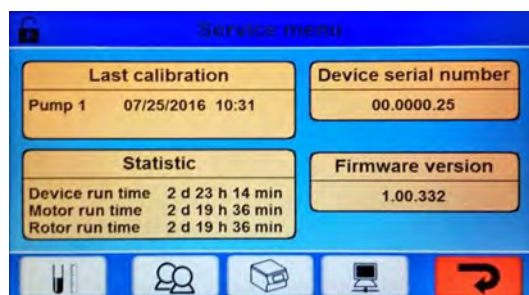
1. From the Start screen, select the Menu button .
2. Select the Spin program. The program screen is displayed.
3. Verify parameter settings are accurate prior to running the program (3500 RPM for 20 seconds).
4. Select the green checkmark to load the program. The Start screen appears with the loaded program name at the top of the screen.
5. Press the "Start Program" button  to begin the process.
6. The "Program successful" dialog box appears once the program is completed.

Note

Refer to the service manual for additional instructions in balancing the rotor.

3.7 Flow Calibration

To calibrate the dispensed saline volume, the amount of dispensed saline must be measured and compared to the value displayed. The displayed value is the volume per tube multiplied by the number of tubes placed in the rotor.









Service Menu screen



Calibration screen

Notes

- The cell washer lid must be open to perform the calibration.
- Ensure air bubbles are purged from saline tubes prior to calibration using the Fill program or fill button .
- This process requires an authorized user.
- If accessing the unit for the first time, use factory created Service User password 46060.

1. From the Start screen, touch the login button .
2. Enter a Service User password and select the green checkmark to confirm.
3. Select the settings button .
4. On the System Settings screen, select the tools button .
5. On the Service Menu screen, select the ruler icon  to open the Calibration screen.
6. Touch the target calibration volume.
7. Hold a clean, dry graduated cylinder below the spout on the lid and press the start button . Wait until liquid has stopped flowing from spout.
8. Measure the liquid collected in the graduated cylinder.
9. Use the "+", "++", "-", and "--" on the right side of the screen to adjust the number as needed.
10. Select the green checkmark to finish calibration.
11. Use the red arrow to return to the home screen.

4 Programming

One or more individual processes make up a program. A program can include up to 20 different processes, but only one Loop process can occur within a program.

4.1 Process Descriptions

Spin Process

During the Spin step, the rotor accelerates to the selected speed, spins for the specified time, then stops quickly. This step separates unwanted particles and creates a “button” of red blood cells at the bottom of each tube. The quick stopping prevents the re-suspension of the red blood cells and dislodging of the red blood cell button.

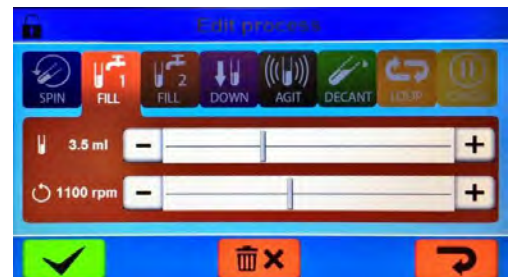
The number of revolutions per minute is adjustable from 0 RPM to 3500 RPM. The time duration is adjustable from one second to two hours (0:00:01 to 2:00:00). The default values are 3500 RPM and 30 seconds.



Fill Process

During the Fill process, the tubes containing cells are filled with the desired amount of saline solution. As the rotor spins at 1100 RPM, saline is pumped from the reservoir through the flow meter to the saline dispensing nozzle. The nozzle directs the saline solution into the rotor, then the fill ports direct the saline solution into the tubes. Saline solution enters the tubes in a direct stream to maximize cell re-suspension.

The number of revolutions per minute is adjustable from 0 RPM to 2500 RPM. The fill volume is adjustable from 0.1ml to 10ml per tube. The default values are 800 RPM and 3.0ml.



Down Process

During the Down process, the rotor spins at 2000 RPM for the specified time. The drops clinging to the tube sides are forced to the bottom of the tubes, thereby increasing the sample yield.

The number of revolutions per minute is adjustable from 0 RPM to 3500 RPM. The time duration is adjustable from 0 seconds to 20 seconds (0 s - 20 s). The default values are 2000 RPM and 5 seconds (5 s).



Agitation Process

During the Agitation process, the rotor accelerates then stops frequently and briefly, disrupting (breaking apart) the cell buttons.

The number of shakings is adjustable from 0 times to 500 times (0x - 500x). The default value is 15 times (15x).



Decant Process

During the Decant step, the rotor rapidly accelerates to the specified speed then decelerates, allowing the tubes to move back to the neutral position so the rotor lock can engage. The rotor spins in the opposite direction at the specified speed, while the rotor lock holds the tubes at a slight negative angle. Waste solution is expelled from the tubes by low centrifugal force, while virtually all the cells are retained in the tubes in the form of red blood cell buttons. The waste solution is directed to the drain hole in the bowl by the drainage system. The spent solution flows out of the cell washer, into the drain tubing, to the waste container or sanitary drain.

The number of revolutions per minute is adjustable from 0 RPM to 1500 RPM. The default value is 370 RPM.



Loop Process

The Loop process allows one or more previous processes to be repeated. Only one Loop process can be included in a program.

The number of loops is adjustable from 1 to 100 times (1x to 100x). The selected number of loops includes the initial run of the process(es) included in the loop (e.g. selecting to loop a process 3 times means that process will run a total of 3 times).

The default value is 2 times (2x).



Check Process

The Check process allows a program to be paused after one or more processes in the program have run. Once the previous process(es) has finished, the Check process will cause the program to be paused and the lid to open. This allows the user to check the tubes and/or add other fluids. The program will continue once the lid is closed.



5 Operation

The UltraCW®II provides both pre-installed programs as well as the ability to create custom programs to fit user needs. Custom programming allows multi-cycle wash and basic spin programs to be created.



Program menu screen (showing examples of custom programs)


5.1 Pre-Installed Programs

Select system and user programs have been pre-installed to accommodate common functions of the cell washer.

Table 1. Pre-Installed User Programs

Process	Program				
	10x75 45sec wash	12x75 45sec wash	10x75 35sec wash	12x75 35sec wash	20sec spin 3500
Fill	3.5ml, 1100rpm	4.3ml, 1100rpm	3.5ml, 1100rpm	4.3ml, 1100rpm	
Spin	45 seconds, 3500rpm	45 seconds, 3500rpm	35 seconds, 3500rpm	35 seconds, 3500rpm	20 seconds, 3500rpm
Decant	460rpm	460rpm	460rpm	460rpm	
Agitate	15x	15x	15x	15x	
Loop	3x	3x	3x	3x	
Fill	3.5ml, 1100rpm	4.3ml, 1100rpm	3.5ml, 1100rpm	4.3ml, 1100rpm	
Spin	45 seconds, 3500rpm	45 seconds, 3500rpm	35 seconds, 3500rpm	35 seconds, 3500rpm	
Decant	460rpm	460rpm	460rpm	460rpm	
Check					
Agitate	15x	15x	15x	15x	
Spin	15 second, 3500rpm	15 second, 3500rpm	15 second, 3500rpm	15 second, 3500rpm	

Select Program

1. From the Start screen, select the Menu button .
2. Select the desired program. The program screen is displayed.



Program screens

3. Use the green and yellow directional arrows to scroll through and review each process and verify settings are accurate prior to running the program.
4. Select the green checkmark to load the program. The Start screen appears with the loaded program name at the top of the screen.



Start screen



Process screen

5. Select Start Program. The Process screen appears with the process being executed highlighted.
6. The "Program successful" dialog box appears once the program is complete.

Notes

- The CHECK button can only be selected when a process is completed.
- Selecting the CHECK button allows the user to pause the program and open the lid to check tubes and/or add fluids.
- To interrupt a program in progress, select the STOP button.

5.2 Stop/Check Program

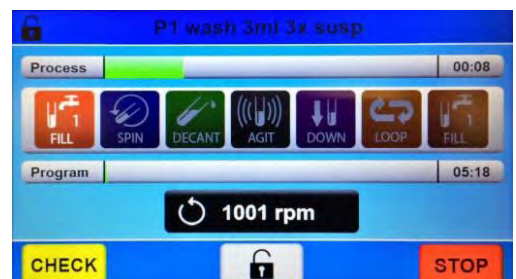
It is sometimes necessary to stop or pause a program in process. Selecting STOP will end the current program while selecting CHECK will pause the program once the current process is complete. Pausing the program allows the user to check tubes or add fluids.

Stop Program

1. Select the STOP button. Stop Program text box appears.
2. Select the green checkmark to confirm.
3. Select the return arrow to return to the previous screen.

Check Program

1. Select the CHECK button to pause the program. The lid will open once the process is complete.
2. Close the lid to return to the program.






5.3 Custom Program

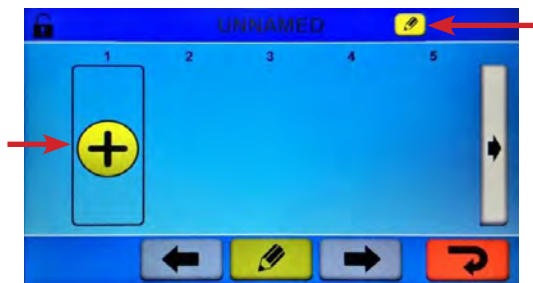
Customized programs can be created to accommodate the user’s needs. A program may contain up to 20 different processes. A loop process may be added to repeat a single process or set of processes multiple times within the program.

Notes

- This process requires an authorized user.
- If accessing unit for the first time, use factory created Service User password 46060.

Create Program

1. From the Start screen, touch the login button .
2. Enter a Service User password and select the green checkmark to confirm.
3. Select the Menu button .
4. Select the Add New Program button .



New Program screen

5. Select the Edit button at the top of the screen to name the program.
6. Select the Add button to add a process. A menu of available processes is displayed.








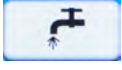




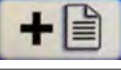





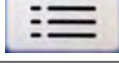




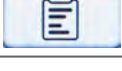

Process Menu screen



Parameters screen

7. Select the desired process from the options displayed. Programmable parameters appear below the selected process.
8. Touch the + or - to adjust the parameters.
9. Select the green checkmark to save.
10. Repeat steps 4 - 7 as needed to complete the program.

Table 2. Common Buttons Reference Guide

Icon	Description	Icon	Description	Icon	Description	Icon	Description
	Start		Calibration		Set/Edit password		Confirm/Save
	Stand-by		Fill		Delete user		Rotor selection
	Settings		User settings		Add new program		Program end alarm setting
	Login		Device settings		Edit		Return to previous screen
	Program menu		Service menu		Add process		Cancel
	Open lid		History		Delete process		

6 Product Specifications

6.1 Operating Standards

These units are designed to operate under the following environmental conditions:

- ◆ Indoor use only.
- ◆ Altitude (maximum): 2000 m.
- ◆ Ambient temperature range: 5 °C to 40 °C.
- ◆ Relative humidity (maximum for ambient temperature): 80% for temperatures up to 31 °C, decreasing linearly to 50% at 40 °C.
- ◆ Transient over-voltages typically present on the MAINS supply.
- ◆ Do not exceed maximum loaded weight (including tubes and contents). Maximum weight is printed on rotor.

Table 3. Unit Specifications

UltraCW®II	
Physical	
Height	11" (280mm)
Width	13" (330mm)
Depth	18.9" (480mm)
Weight	53.8 lb (24.4 kg)
Rotor Radius	4.1" (105mm)
Maximum RPM / RCF	3500 RPM / 1438 RCF
Speed Tolerance	± 20 RPM
Kinetic Energy	250 Nm
Maximum Density	1.2 kg/dm ³
Noise Level	≤ 49db
Electrical	
Electrical Power (AC)	100V - 240V, 50/60 Hz
Electrical Power (DC)	6A @ 24 VDC
Fuses	10A / 250V
Maximum Current Consumption	2.2 A
Power Source	150W

7 Preventive Maintenance

Maintenance tasks should be completed according to the following schedule. Refer to the service manual for more detail on the various tasks.

Note

These are recommended minimum requirements. Regulations for your organization or physical conditions at your organization may require maintenance items to be performed more frequently, or only by designated service personnel.

Table 4. Preventive Maintenance Schedule

Task	Frequency				
	Daily	Weekly	Monthly	Annually	4 years
Inspect tubing and drain and clear obstructions if necessary.	✓				
Inspect tubing connections and secure if necessary.	✓				
Clean and dry interior after normal usage to prevent corrosion and contamination.	✓ ⁽¹⁾				
Flush system with distilled water.	✓ ⁽¹⁾				
Flush system with cleaning solution.		✓			
Clean fill ports on the rotor.		✓			
Check the saline volume setting and calibrate it if necessary. Frequency varies by length of service.			✓		
Check rotor speed and ensure within tolerance.				✓	
Inspect rotor for wear, corrosion, and damage. Replace rotor if these conditions exist.			✓		
Replace rotor					✓
Inspect tube holders for wear and damage. Replace tube holders if worn or damaged, or after they have been in use for two years.			✓		
Clean exterior.			✓		
Replace supply and drain tubing.				✓	
Replace tube holder inserts for 10 mm x 75 mm tubes.				✓	

(1) Perform daily or if unit has been idle for 4 hours or more.

8 Compliance

8.1 Regulatory Compliance

Pollution degree: 2 (for use in USA and Canada only)

This product is certified to applicable UL and CSA standards by a NRTL.

Sound level (dependent on rotor): ≤ 49 dB(A)



8.2 WEEE Compliance

The WEEE symbol (right) indicates this product falls under the scope of the WEEE (Waste Electrical and Electronic Equipment) directive.



When disposing of this product in countries affected by this directive:

- ◆ Do not dispose of this product as unsorted municipal waste.
- ◆ Collect this product separately.
- ◆ Use collection and return systems available locally.

For more information on the return, recovery, or recycling of this product, contact your local distributor.

Appendix A

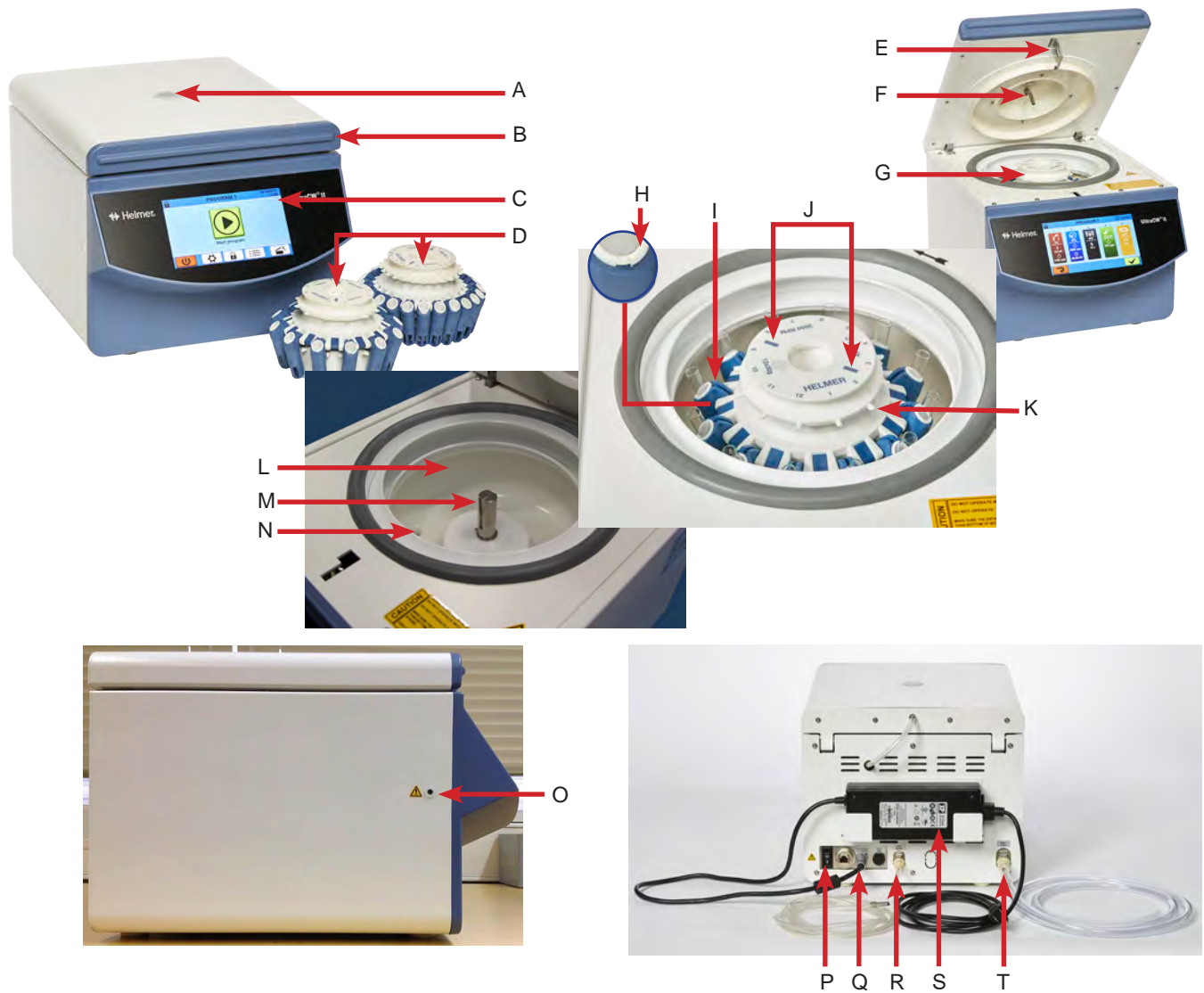
Error Codes

Error Code	Error Name	Description	Possible Causes
0	No Error	Program occurred	
1	Running	Program is still running, no error has been detected (should never be visible in history)	
Motor Errors			
10	Motor Startup Error	Motor could not be started (no speed could be detected)	<ul style="list-style-type: none"> • Motor is blocked • Motor cable connection problem • Motor power supply problem
11	Motor Acceleration Error	Motor could not accelerate within tolerance (motor was too slow)	<ul style="list-style-type: none"> • Wrong rotor type selected • Too much mechanical friction
12	Motor Acceleration Error	Motor could not accelerate within tolerance (motor was too fast)	<ul style="list-style-type: none"> • Wrong rotor type selected
13	Motor Speed Error	Motor could not hold the desired speed (motor was too slow)	<ul style="list-style-type: none"> • Wrong rotor type selected • Maximum motor speed limit too high (not able to maintain 4000 RPM) • Motor speed control does not work properly • Motor speed reading failure
14	Motor Speed Error	Motor could not hold the desired speed (motor was too fast)	<ul style="list-style-type: none"> • Motor speed control does not work properly • Motor speed reading failure
15	Motor Break Error	Motor could not slow down within tolerance	<ul style="list-style-type: none"> • Wrong rotor type selected
16	Motor Internal Error	Motor has indicated an error	<ul style="list-style-type: none"> • Motor blocked • Motor overheated • Motor power supply error
17	Motor Power Supply	The 24 V of the motor supply is not available	<ul style="list-style-type: none"> • Lid detected open
Liquid Injection System Errors			
20	Pump Error	Pump was not able to pump the desired amount of liquid	<ul style="list-style-type: none"> • Tube blocked • Pump not working • Flow sensor not working
21	Liquid Container Empty	Not enough liquid available or air is in the tube	<ul style="list-style-type: none"> • Liquid container empty • Air in the tube • Flow sensor problem
Lid Errors			
30	Lid Blocked	Open or check button was pressed, but the lid could not be opened.	<ul style="list-style-type: none"> • Lid mechanically blocked
31	Unlocking Failed	Open or check button was pressed, but the lock could not be unlocked.	<ul style="list-style-type: none"> • Motor was still rotating when unlocking command was received • Problem with the lock
32	Unexpected Unlocking	Lid was opened without a request.	<ul style="list-style-type: none"> • Emergency unlocking was used
33	Lid Detection Failure	Lid sensor has detected an opening of the lid, but lock sensor still recognizes lock is closed	<ul style="list-style-type: none"> • Wrong lid detection of the lid sensor • Wrong lock detection of the lock sensor
System Errors			
40	Program Reading Error	It was not possible to read the complete program.	<ul style="list-style-type: none"> • Program file is corrupted • Not enough heap memory was available
42	Eeprom Error	Loading data from eeprom failed. (reading not possible or checksum for data is incorrect)	<ul style="list-style-type: none"> • Eeprom not initialized (Service User login needed) • Communication failure

Error Code	Error Name	Description	Possible Causes
Miscellaneous			
50	Unknown	An error has occurred, but the kind of the error could not be identified	<ul style="list-style-type: none">• Unexpected behavior
51	Program Interrupted	A running program was interrupted.	<ul style="list-style-type: none">• Power interrupted during a running program
52	Program Aborted by User	The program was aborted by the user	<ul style="list-style-type: none">• User has aborted the program
53	Imbalance	The program was stopped because of an imbalance of the rotor	<ul style="list-style-type: none">• Rotor was not loaded symmetrically• Positioning of the imbalance sensor not correct

Appendix B

Parts



Letter	Description	Letter	Description
A	Sight window	K	Fill port
B	Lid handle	L	Bowl
C	Display	M	Rotor shaft
D	Rotor	N	Drain
E	Latch	O	Emergency lid release hole
F	Spout	P	Power switch
G	Rotor Grip	Q	Power input
H	Tube insert	R	Saline inlet 1
I	Tube holder	S	Power supply
J	Alignment markings	T	Drain outlet

END OF MANUAL

