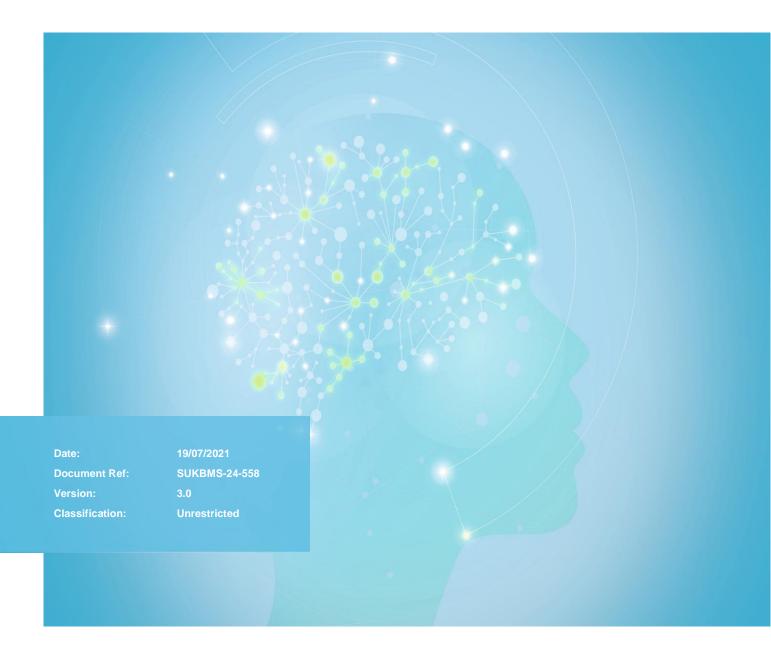


Routine Use Training Workbook

RPU-2100R





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Disclaimer

Please note, the information contained in training resources provided by Sysmex should not be used as an alternative to your sites Standard Operating Procedure (SOP)/Contract. If you have any particular questions regarding any site specific use of reagents, consumables and/or equipment please contact your Management Team.



RPU-2100R Overview

The RPU-2100R is an automated reagent preparation unit for Sysmex hematology integrated concept solutions, supporting large laboratories in processing high workloads. The RPU-2100R produces ready to use Cellpack by diluting a concentrate which is stored beside the RPU. The RPU-2100R can easily produce ready to use Cellpack from Cellpack DST for an XN-Series, as well as Cellpack-S for the XE-Series. Up to 600 sample per hour can be supported by one RPU-2100R without impacting the operation of the analysers at any time.

Facts and figures			
Throughput	Approximately 18 L/hour ready to use CellPack at 20°C to 25°C		
Operating Temperature	15°C to 30°C		
Dilution	1:25 (CellPack : Demineralised water)		
Water Container Volume	2.5L		
Storage Container Volume	2.5L		
Mix Container Volume	0.6L		
Overflow Container Volume	0.6L		



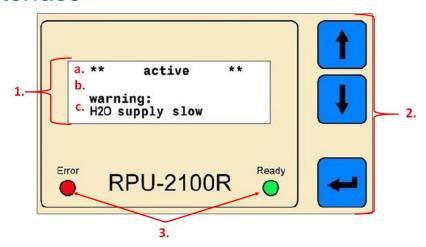
Analyser Components



- 1. RPU Reagent Preparation Unit
- 2. LCD Screen User interface LCD display screen where the menu can be accessed and any error messages will appear.
- 3. CellPack DST CellPack DST is loaded onto the trolley adjacent to the RPU unit.



User Interface



- **1. User Display –** This is the main display when the instrument is switched on. This display shows:
 - a. Status of the instrument
 - **b.** Status of reagent production
 - c. Error or warning messages.

Whenever an error or warning occurs, the status on the LCD screen switches at 1 second intervals between the error or warning message and the regular status information.

Status of the Instrument			
Active The instrument is operational and automatically produces reagent (Service functions are not available at this setting). After start up the instrument switches automatically to the Active mode after 15 seconds.			
Stand-by	The production of reagent is suspended so that the service functions and maintenance tasks can be performed.		
Service Function	The service function is used for the replacement of CellPack DST and other service functions.		

Status of Reagent Production			
Filling	The water container is being filled.		
Heating:xx,x°C (xx,x°C)	The water heating is in progress. XX.X°C – this is the current temperate displayed (XX.X°C) – this is the final temperature		
Mixing, please wait	Reagent mixing is in progress		
Ready	Diluted reagent is available for the analysers		



2. Keyboard – The keyboard is used to control the LCD screen and access the menu. The menu is accessed by selecting [Enter].

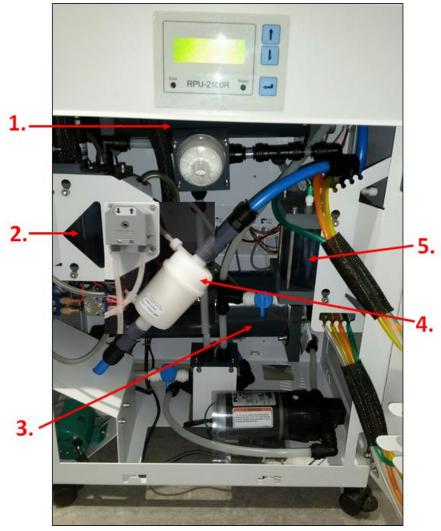
Button	Description	Use this key to:
1	Arrow Up	 Scroll up in the menu Increase the value of a parameter Switch the beeper temporarily off
1	Arrow Down	 Scroll down in the menu Decrease the value of a parameter Switch the beeper temporarily off
	Enter	Select a menu itemStart a functionConfirm an action

3. **LED Status –** There are two LED status lights on the RPU which along with an internal beeper indicate various conditions:

LED	Веер	Mode
GREEN Continuously ON	N/A	Active mode
GREEN FLASHING	N/A	Standby mode
RED Continuously ON	Short Beeps	Error
RED FLASHING	Long Beeps	Warning

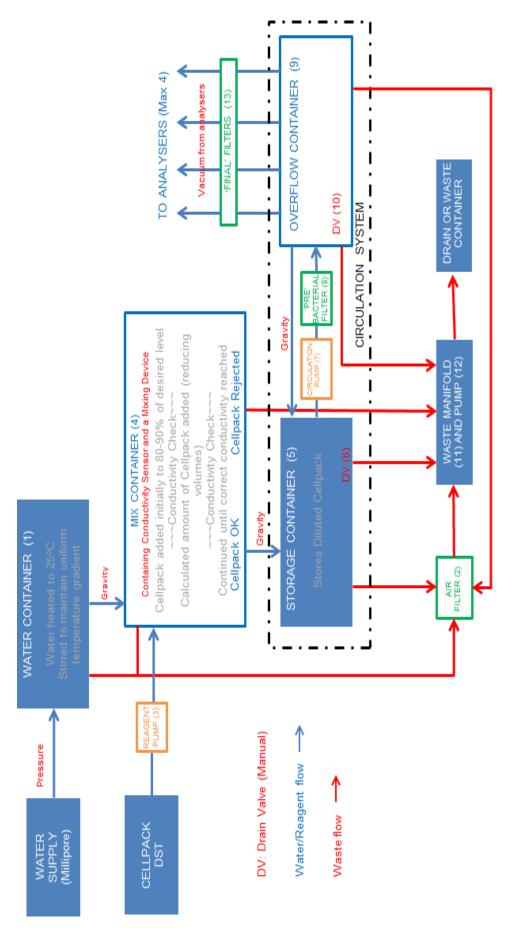


Internal Components



- 1. Water Container The water container holds a 2.5L supply of demineralised water from an external water supply. The water is heated to 25°C in this container. A stirring device provides a uniform temperature gradient in the water.
- **2. Mixing Container** The mix container is responsible for the dilution of the CellPack DST and houses the conductivity sensor and mixing devise. IT holds a volume of 0.6L.
- **3. Storage Container** The storage container holds approximately 2.5L of diluted CellPack DST. This stored mixture is continuously pumped through the bacterial filter into the overflow container.
- **4.** Fluid Pre-Filter Responsible for the removal of bacteria and particles from the diluted CellPack DST preventing contamination of the CellPack supply from the RPU.
- **5. Overflow Container** The storage container holds approximately 2.5L of diluted CellPack DST. This stored mixture is continuously pumped through the bacterial filter into the overflow container.

RPU-2100R Flow Chart





Principle of Analysis

Thee demineralized water is filled into the water container by pressure provided by the external device. The water is heated to 25°C within the water container from where it flows, by the aid of gravity, into the mixing container.

On the initial dilution, 80-90% of the desired conductivity value is achieved by the addition of the required amount of CellPack DST. The solution is mixed and the conductivity measured. Subsequent dilutions, add decreasing amounts of CellPack DST until the conductivity value of the solution falls within a set range. Once the correct dilution is achieved it flows into the storage container with the aid of gravity. The diluted CellPack DST in the storage container is continuously fed through the pre-fluid filter to remove bacteria and particles from the diluted reagent. After the pre-fluid filter the reagent flows into the overflow container from where it is drawn by the analyzers under vacuum.

NOTE: the RPU does not pump reagent to the analyzers. Any excess reagent flows back into the storage container for re-circulation.

Dilution Principle

The dilution of the CellPack DST occurs in several steps during which the dilution rate is determined based on conductivity. Conductivity is defined as the ability of a substance to conduct an electrical current. The higher the number of ions in the solution the higher the conductivity. The dilution rate can be determined as the conductivity of both the demineralized water and CellPack DST are known. This process is highly temperature dependent and therefore the temperature of the solution is measured and converted to the conductivity value at 25°C. Inaccuracies are avoided by heating the demineralized water to 25 °C.

Dilutions which do NOT meet the required conductivity are rejected and flow into the waste container.



Quick Guides

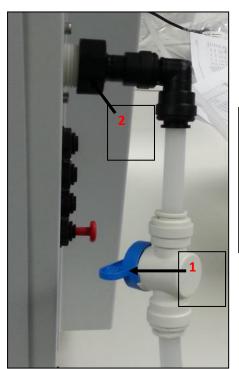
Maintenance

Daily Maintenance

Daily maintenance consists of checking for signs of leaks or fluid spills and check the demineralised water supply.

Cut off Points

If a leak is detected please turn off the water cut-off points. Behind the RPU there will be a one or both of the following water cut-off points:





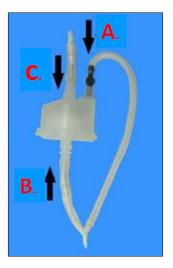


3 Monthly Maintenance (Approximately)

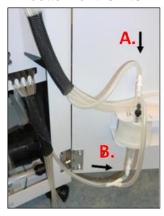
Three monthly maintenance consists of replacing the fluid final filters. Replacement of the fluid final filters should occur immediately when they are blocked and the analysers are no longer able to draw reagent. It is recommended that these filters are replaced preventively every 3 months or at the latest during the routine service maintenance (PMI).

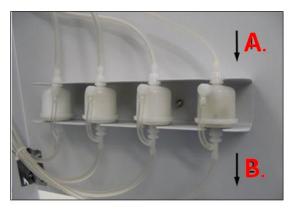
To Replace the Final Filters:

- 1. The filters are located on the inside of the door.
- 2. Switch the instrument into 'Stand-by' mode.
- 3. Remove the inlet and outlet tubes from the filter.
- 4. Remove the old filter from the clamps.
- **5.** Remove the vent port plug from the new filter and connect the tubing set as shown:
 - a. Connect the threaded connector to the vent port.
 - **b.** Push the tube on the outlet port
 - **c.** Connect the separator tube to the inlet port of the filter.



- **6.** Click the filter into the clamps as shown:
 - **a.** Connect the tubes coming from the overflow container to the top of the filter.
 - **b.** Connect the tubes leading to the reagent outlets to the Y-connector at the bottom of the filter.





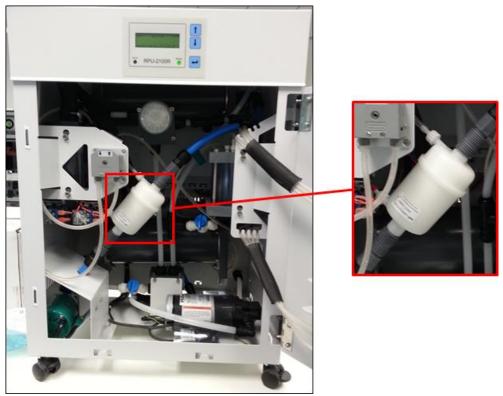
7. Switch the instrument back into 'Active' mode.



As Required Maintenance

C12 Circulation – change pre-filter

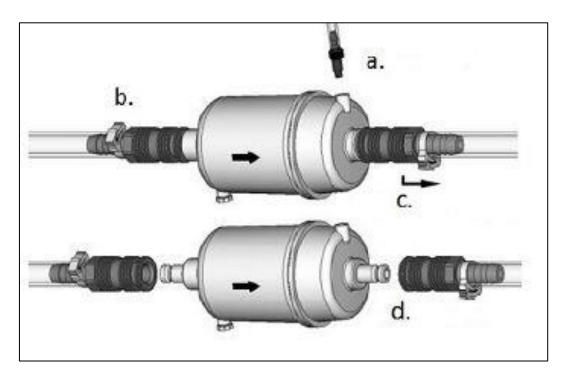
The flow capacity of the fluid pre-filter is monitored by the RPU-2100R and the software will indicate when the filter must be exchanged with a 'C12 circulation' message.



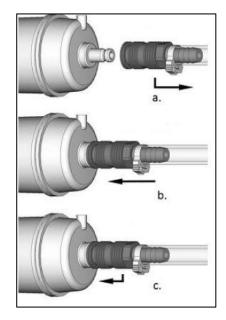
To Replace the Pre-filter:

- **1.** Switch the instrument into 'Stand-by' mode.
- 2. Activate the service function [Replace Filter]. The circulation pump will stop and the display shoes the following instructions; 'Change filter and press enter when ready' accompanied with a series of short beeps.
- 3. Open the door on the front of the RPU-2100R.
- **4.** Unscrew the connector with the small overflow tube from the filter and allow the fluid to flow from the filter back into the inlet tube.
- **5.** Remove the inlet and outlet tubes:
 - a. Remove overflow tube.
 - **b.** Wait until filter is empty.
 - c. Press coupling against filter and pull back the sliding ring.
 - **d.** Pull coupling from filter.





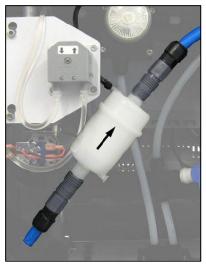
- **6.** Take the new filter out of the packing.
 - **NOTE:** observe the flow direction of the filter as indicated with an arrow on the filter housing.
- **7.** On the new filter make sure the vent trap on the intake side is closed and remove the vent trap plug from the outlet side.
- 8. Connect the inlet and outlet tubes to the filter:
 - a. Pull back sliding ring.
 - b. Press coupling against filter.
 - c. Push sliding ring towards filter.



- 9. Pull the tubes to check the connection (the tubes may not come off).
- **10.** Attach the small overflow tube with the connector on the vent trap at the outlet side of the filter.



11. The filter mush be installed with the exhaust side facing upward and the vent tube at the top position:



- 12. Press [Enter] on the LCD screen.
- **13.** Switch the instrument back into 'Active' mode.



Changing Reagents

When the CellPack DST on the RPU runs out the RPU will give an audible alarm and the LCD screen will display the error message 'C38 Conductivity - change Cellpack concentrate' and will automatically be placed into Standby mode.

When CELPACK DST runs out on the RPU there is a reservoir of reagent on-board that will supply approximately 15 mins – 30 mins of reagent to the XN's depending on the workflow. If the CELLPACK DST isn't changed before the RPU reservoir runs out the XN analyser bubble detection system will be activated and the **ALL** the XN's on the system will alarm with one of the following:

- CELLPACK DCL aspiration error
- CELLPACK DCL aspiration error (Air bubbles detected)
- FCM sheath aspiration error
- RBC sheath motor error

There are two scenarios when changing the CELLPACK DST:

- 1. The CELLPACK DST is changed when the RPU alarms with a C38 change con error
- 2. The CELLPACK DST is changed when the RPU alarms with a C38 change con error AND the XN's are alarming with one of the above alarms.

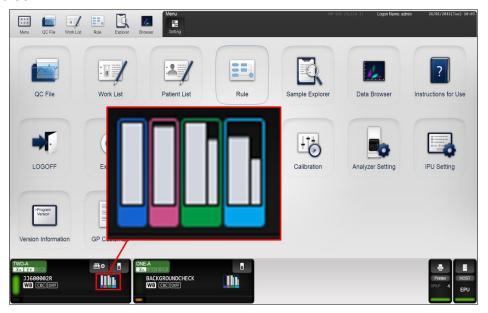
Changing Reagents when just the RPU is alarming

1. The instrument will give an audible alarm and the error message 'C38 Conductivity'. To mute the RPU alarm pressing one of the arrow keys on the RPU LCD screen.





- 2. Confirm the message by pressing [Entre].
- 3. The display will show 'Replace Concentrate and press entre when ready...'
- **4.** Replace the CELLPACL DST on the RPU unit by placing the probe directly from the old CELLPACK DST into the new CELLPACK DST.
- 5. Select [Entre]
- **6.** On the XN's select the [Reagent Menu]. This will take you to the Reagent Replacement Screen.



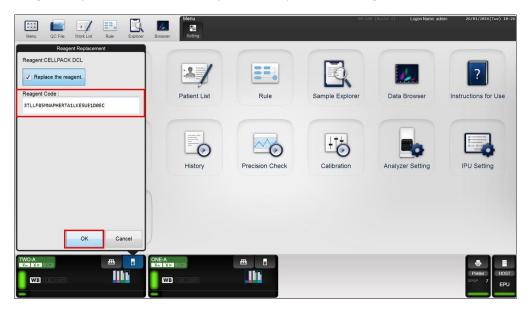
7. Select [CELLPACK DCL]





- **8.** Once selected place the curse into the Reagent Code box and using the barcode reader wand in the reagent barcode. When successfully barcoded in you will see the reagent barcode appear under Reagent Code.
- 9. Select [OK]

NOTE: Please wand in the RPU Reagent Barcode and **DO NOT** select [Execute] on the Reagent Replacement Menu until you have replaced the reagent on the RPU.



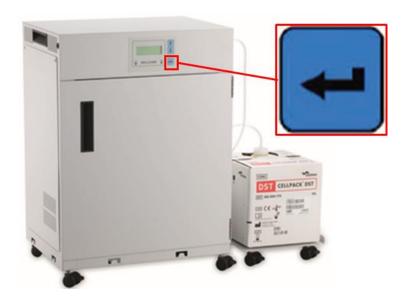
- **10.** Repeat this procedure (steps 6 9) on each XN analyser on the system.
- **11.** Select [Execute] on the reagent replacement screen to prime the new CELLPACK DST through



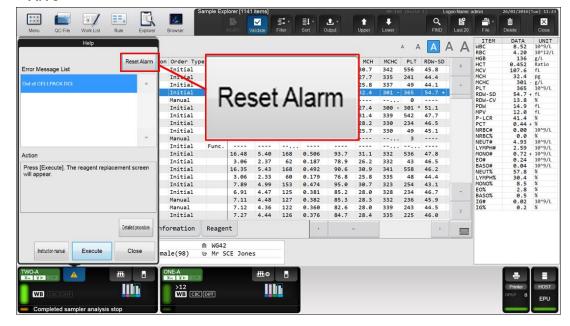


Changing Reagents when the RPU and XN's are alarming

1. The instrument will give an audible alarm and the error message 'C38 Conductivity'. To mute the RPU alarm pressing one of the arrow keys on the RPU LCD screen.

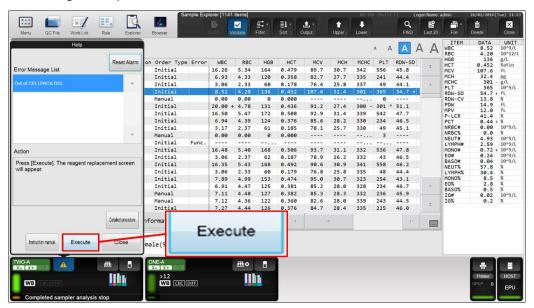


- 2. Confirm the message by pressing [Entre].
- 3. The display will show 'Replace Concentrate and press entre when ready...'
- 4. To mute the alarm on the XN's select [Reset Alarm].
 NOTE: ALL XN's on the system will be alarming so please select [Reset Alarm] on all XN's





- **5.** Replace the CELLPACL DST on the RPU unit by placing the probe directly from the old CELLPACK DST into the new CELLPACK DST.
- 6. Select [Entre]
- **7.** On the XN's select the [Execute] on the current alarm message. This will take you to the Reagent Replacement Screen.



8. Select [CELLPACK DCL]

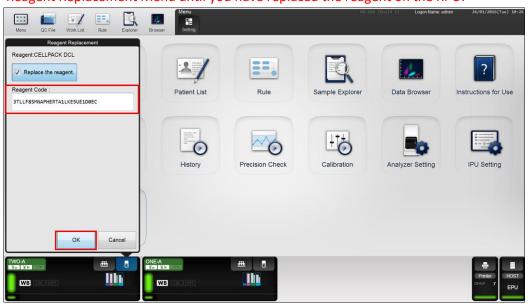




9. Once selected place the curse into the Reagent Code box and using the barcode reader wand in the reagent barcode. When successfully barcoded in you will see the reagent barcode appear under Reagent Code.

10. Select [OK]

NOTE: Please wand in the RPU Reagent Barcode and **DO NOT** select [Execute] on the Reagent Replacement Menu until you have replaced the reagent on the RPU.



- **11.** Repeat this procedure (steps 7 10) on each XN analyser on the system.
- **12.** Select [Execute] on the reagent replacement screen to prime the new CELLPACK DST through.





Reagent Replenishment

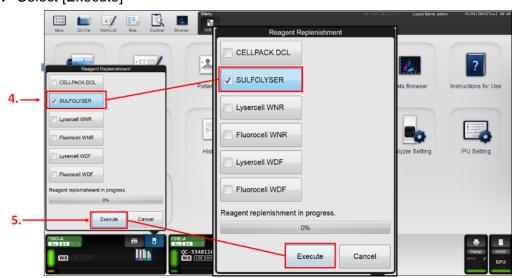
It is then recommended that a Reagent Replenishment is preformed if you encounter any errors such as bubbles in the system after changing a regent.

To Perform a Reagent Replenishment:

- 1. Select [Analyser Menu]
- 2. Select [Maintenance]
- 3. Select [Reagent Replenishment]



- 4. Select the reagent for replenishment
- 5. Select [Execute]



Reagent Replenishment will take a few minutes to complete. The progress is shown with a progress bar and when complete the dialog box will automatically close.



Dealing with errors

The RPU displays 3 types of error: Warnings, Conditions and Errors.

Error	Cause	Display	LED	Audible Sound
Warning	Indicates a situation has occurred that might interfere with the desired output of diluted reagent i.e. slow filling and draining cycles. Warnings turn into errors, when specific limits for that situation are exceeded.	Shows the warning number and description	Error LED is flashing	Beeper produces long beeps (1 second) with evenly long pauses (1 second)
Condition	Indicates a situation that interferes with the correct function of the instrument and need the immediate attention of the user. Conditions are usually related to external factors which must be resolved by the user.	Shows the condition number and description and a short advice for user action	Error LED is flashing	Beeper produces long beeps (1 second) with evenly long pauses (1 second)
Error	Errors need immediate attention of the user because the function of the instrument is no longer guaranteed. All ongoing processes are halted with the exception of waste removal and storage circulation.	Shows the error number and description and a short advice for user action	Error LED is continuously ON	Beeper produces short beeps (0.3 seconds) with evenly short pauses (0.3 seconds)



Error Groups

The errors are divided into groups for the main processes in the instrument (see page 12 for list):

Process	Errors	Conditions	Warnings
Waste	E1 – E10	C1 – C10	W1 – W10
Storage	E11 – E20	C11 - C20	W11 – W20
H2O	E21 – E30	C21 - C30	W21 – W30
Mix	E31 – E40	C31 - C40	W31 – W40
Internal	E41 – E50		

Error Codes

Errors (E)

Err. No.	Error message	Triggered by	Possible causes
E1	waste	Waste manifold float switch timeout	Waste tube kinked or blocked Water pressure too high Waste manifold float switch malfunction Waste pump malfunction H2O inlet valve malfunction Variable setting "twaste" too short
E11	sensor conflict	sensor "storage empty" = OFF, sensor "storage full" = ON detected	Storage container float switch malfunction
E22	H2O heating	water temp. sensor timeout (< 24,5°C)	Mechanical heater setting too low Heater malfunction Water temp. sensor malfunction Variable setting "theat" too short
E23	H2O stirring	H2O stirring sensor timeout	Stirrer motor or sensor malfunction. Stirrer jammed
E31	mix supply	Mix container float switch timeout	No water supply from water container "Mix container IN" valve malfunction Mix container float switch malfunction Variable setting "tmixfull" too short
E32	drain poor	Mix container float switch timeout	"Mix container Out poor" valve malfunction Mix container float switch malfunction Variable setting "tmixempty" too short

E33	drain OK	Mix container float switch timeout	"Mix container Out OK" valve malfunction Mix cont. float switch malfunction Variab. setting "tmixempty" too short
E34	mix full	Mix container float switch triggered prematurely	Leaking "mix container Out" valves Mix container float switch malfunction
E35	H2O cond. not OK	External H2O device	H2O device is depleted or malfunctioning
E36	H2O temperature>	Water temp. in mix container > 27°C	Water temp. sensor malfunction Heater malfunction
E37	H2O temperature<	Water temp. in mix container < 23°C	Water temp. sensor malfunction Too much temp. drop due to cold environment
E41	parameter	CPU	Conflicting data read from Eeprom
E42	communication	CPU	Communication error between instrument CPU and conductivity measurement CPU
E43	NTC H2O sensor	water temperature > 40°C	Malfunction in water temperature sensor circuit
E44	NTC Mix sensor	Mix container temperature > 40°C	Malfunction in Mix container temperature sensor circuit
E45	Gx sensor	CPU	Conductivity or temperature sensor malfunction
E46	internal communication	CPU	electronics malfunction

Conditions (C)

Cond. No.	Cond. message	Triggered by	Possible causes
C2	waste container full	Waste container float switch	Waste container is full External waste sensor or Loop connector malfunction or not connected
C12	circulation	overflow container float switch (circulation < 14l/h)	Internal filter is blocked Circulation pump malfunction Overflow container float switch malfunction
C21	H2O supply	water container float switch timeout	Insufficient or no water supply Water container float switch malfunction H2O inlet valve malfunction Variable setting "tro" too short
C38	conductivity		Concentrated reagent container empty Reagent pump malfunction Large air bubbles in concentrated reagent line

Warnings (W)

Wrn No.	Warning message	Triggered by	Possible causes
W12	slow circulation	overflow container float switch (circulation < 28l/h)	Internal filter is partially blocked
W21	H2O supply slow	water container float switch timeout	Slow water supply "H2O container IN" valve not fully open Variable setting "tro" too short
W31	drain poor slow	Mix container float switch timeout	"Mix container Out poor" valve not fully open
W32	drain OK slow	Mix container float switch timeout	"Mix container Out OK" valve not fully open
W33	mix supply slow	Mix container float switch timeout	"Mix cont. in" valve not fully open



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