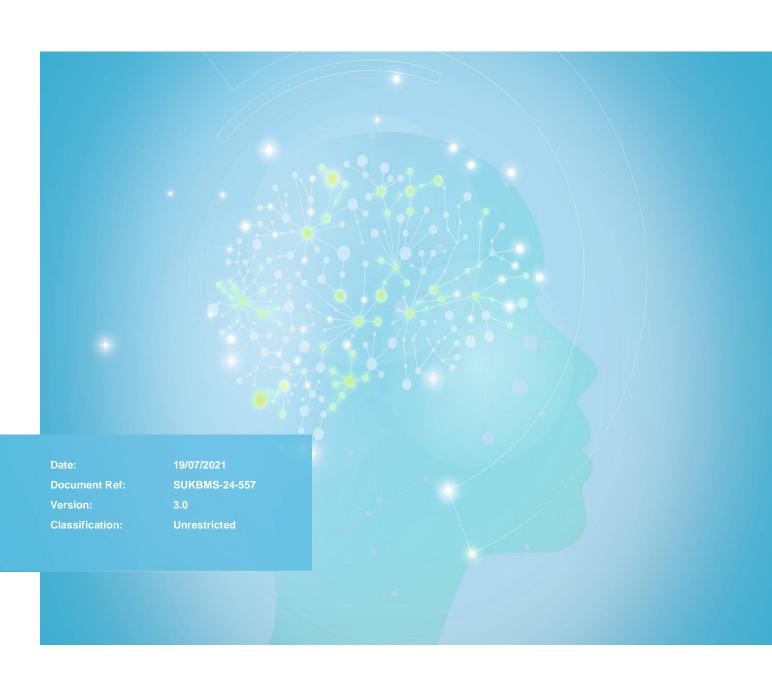


Routine Use Training Workbook

RPU-2100





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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.

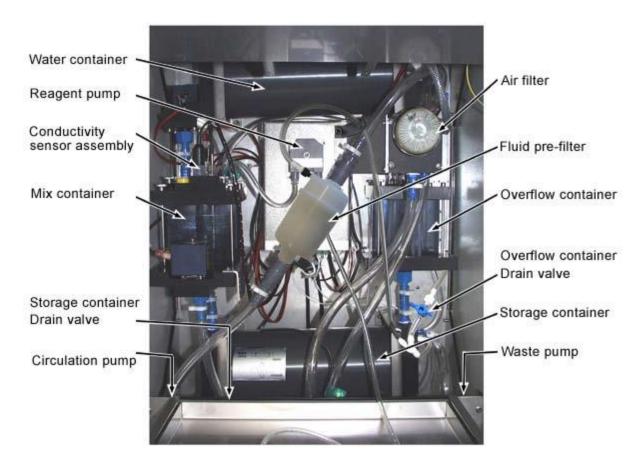
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Analyser Components

The Reagent Processing unit (RPU) uses demineralized water supplied from an external device to dilute CellPack-S stored on board the RPU.

RPU Components



Water container: Holds supply of demineralized water from external water supply where it is heated to 25°C. The demineralized water is mixed to ensure a uniform temperature gradient.

Reagent pump: Pumps CellPack-S into the mix container.

Conductivity sensor assembly: Responsible for monitoring of the reagent conductivity.

Mix container: The mix container is responsible for the dilution of the CellPack-S and houses the conductivity sensor and mixing device.



Storage container drain valve: Located at the lowest point between the storage container and circulation pump. The valve is operated MANUALLY to drain the system by redirecting the flow of reagent to the waste pump.

Air Filter: Protects the system from pollution and airborne particles.

Fluid pre-filter: Responsible for the removal of bacteria and particles from the diluted CellPack-S preventing contamination of the CellPack supply from the RPU.

Circulation pump: Responsible for the circulation of diluted CellPack-S through fluid pre-filter into an overflow container.

Overflow container: Transparent closed vessel from which the connected analyzer/s draws diluted CellPack-S. There is a separate connection to each analyzer and each analyzer is connected to a separate final bacterial filter. Excess reagent flows back into the storage container.

Overflow drain valve: Operated MANUALLY to drain the over flow container.

Storage container: Non-transparent closed vessel responsible for holding approximately 3L of diluted CellPack-S. The stored mixture is continuously pumped via the circulation pump, through the fluid pre-filter into the overflow container. Excess reagent from the overflow container flows back into the storage container.

Waste pump: waste pump is triggered by a float switch within the waste manifold to which all containers are connected.



Principles of Reagent Production

The 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.

The dilution of the CellPack-S 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 greater the number of ions in the solution, the greater the conductivity. The dilution rate can be determined as the conductivity of both the demineralized water and CellPack-S 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.

On the initially dilution, 80-90% of the desired conductivity value is achieved by the addition of the required amount of CellPack-S. The solution is mixed and the conductivity measured. Subsequent dilutions, add decreasing amounts of CellPack-S 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-S in the storage container is continuously fed through the prefluid 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 to 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.

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



Quick Guides to Using RPU

Changing CellPack-S

When the CellPack-S on the RPU runs out the RPU and the analyzers will give an audible alarm. The RPU LCD screen will display the error message 'C38 conductivity – change CellPack-S' and will automatically be placed in to 'Standby' mode. Any analyzers connected to the RPU will alarm and display one of the following error messages:

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

To mute the RPU alarm press [enter] button on the RPU. To mute any analyzer alarm, attached to RPU press 'Help'.

On the RPU, using the LCD screen press [enter] to confirm the error message and the following message will be displayed 'replace reagent container and press ENTER when ready'. Pull out sliding tray and unscrew the dispensing set from the empty reagent and place straight into the new reagent. Tighten the dispensing set and push tray back into RPU. Press [enter] on the RPU to replenish reagent. Record the Lot number, expiry date and date CellPack-S changed on a reagent log. **NOTE**: Lot numbers need to be recorded manually as there is no electronic record on the RPU and the XE analyzers are unable to register the concentrated CellPack-S barcode.

Switching between CellPack-S and CellPack DCL

At any one time on the analyzers connected to the RPU you will have both CellPack-S and CellPack (EPK) on the system. As a result once every 60 days you need to switch from using the RPU to using the CellPack (EPK) underneath the analyzers to prevent reagent wastage.

To do this when the analyzer is not in use turn the three way valve on the analyzer from the RPU to the CellPack (EPK). There is no need to put the RPU into standby as it will not continue to produce reagent as the analyzer is NOT trying to draw reagent from the RPU **REMEMBER**: the RPU only mixes the CellPack-S it does not pump it to the analyzer.

Register the diluted reagent keg (EPK) on analyzer according to standard laboratory protocol.

When switching back from CellPack (EPK) to RPU ensure no work is going through analyzer and turn 3-way valve from CellPack (EPK) to RPU. Perform reagent replace procedure described above.



Dealing with errors

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

Warnings (W) Indicates a situation has occurred that might interfere with the output of

diluted reagent. Warnings do not effect ongoing process.

Example; slow filing or draining cycles

Alarm sound: long bleeps (1sec) long pauses (1sec)

Conditions (C) Indicates a situation has occurred that will affect the correct function of the

RPU and IMMEDIATE action is required. All

Example: CellPack-S reagent run out

Alarm sound: Long bleeps (1sec) longer pauses (3sec)

Error (E) Fatal error. Correct function of the analyzer cannot be guaranteed and all

processes are halted. IMMEDIATE action is required

Alarm sound: short bleeps (0.3sec) and short pauses (0.3sec)

To silence the alarm press one of the arrow buttons next to LCD display. For warnings the LCD displays warning number and description. Warnings reset automatically when situation is over. However warnings can turn into errors when specific limits are reached. If warning is persistent without turning into an error call service. For Condition and Errors the LCD screen will display the condition number and description with advice for the user.

Error Groups

The errors are divided into groups for the main processes in the instrument (see manual for specific error messages):

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		

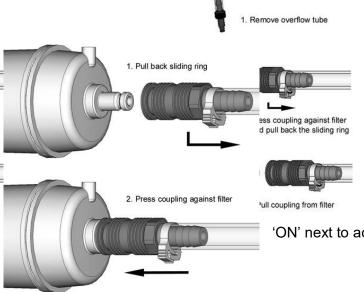


C12 circulation - change internal filter



The bacterial filter needs to be replaced approximately every three months to prevent bacterial contamination of diluted reagent. When the filter needs changing the following error will be displayed on LCD screen 'Slow circulation error'.

To do this either ensure no work is going through the system or switch over from RPU to CellPack DCL (see page 7). On the RPU main menu scroll to 'active/standby'. Press [enter] to switch RPU into standby mode, indicated by 'OFF' next to active/standby option. Scroll down to the 'Go to service menu' and press [enter]. Using the arrow buttons scroll to 'replace filter' and press [enter]. The circulation pump will stop and the LCD screen will display 'replace filter and press enter when ready', accompanied by short bleeps. Remove the old filter as indicated in the diagrams below.



3. Push sliding ring towards filter.

When replacing the new filter the arrow should be placed in the direction of flow, from bottom left to top right.

Reconnect the couplings and connect the overflow tube to the top vent line.

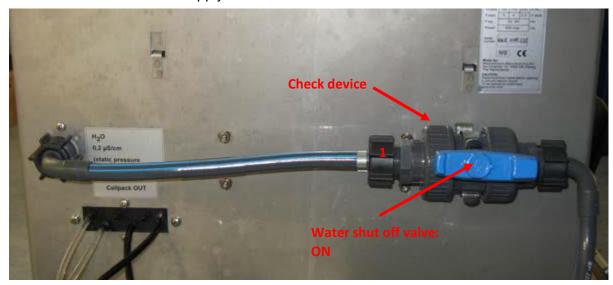
Once all tubing is connected press [enter]. On the RPU main menu scroll to 'active/standby'. Press [enter] to switch RPU back into active mode, indicated by

'ON' next to active/standby option.



C21 no H₂O supply – check water supply

If this condition occurs the water supply to the RPU needs to be checked.



Firstly check the blue water check device 'water shut off valve' is set to 'ON' (as shown above) and all pipes connected to device are in place. This is set to cut off water supply after 10L if activated. If this is OK check the water supply to the device. Turn 'OFF' water shut off valve by turning handle 90°.

Remove the piping from the end of the check device connected to RPU by unscrewing black nut (1) indicated in above picture. Hold check device in a bucket and turn on water shut off valve. If no water is flowing into bucket the red activation pin inside the check device needs to be checked.

Turn 'OFF' water shut off valve and examine the red check device pin. If the pin has been activated it will be pushed out preventing further flow of water. To reset pin push back into position. Check flow of water has been restored by holding check device in bucket and turning 'ON' water shut off valve. If water supply restored turn water shut off valve 'OFF'. Reconnect piping to RPU and turn 'ON' water shut off valve.







If the supply to the water shut off valve and water check device are ok the connection at the back of the RPU needs checking.

Turn the water shut off valve (1) indicated in the picture to the 'OFF' position. Unscrew the black bolt (2) attaching the water supply to the back of the RPU. Hold piping in bucket and turn 'ON' water shut off valve *Note:* Blue lever will be pointing in the direction of flow.

Once both connections have been checked and error identified using the LCD screen on RPU select 'Reset error' from main menu and press [enter]. If problems persist contact service.



C38 conductivity - change CELLPACK S conc

Please refer to page 6.



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