Status Draft PolicyStat ID 17732779

Origination	N/A
Last Approved	N/A
Effective	N/A
Last Revised	N/A
Next Review	N/A

Owner	Carolyn Webb: Heme Technical Specialist
Area	Hematology
Applicability	Community Physician

CP Sysmex RU-20 Reagent Unit Operation and Maintenance

SCOPE

Effective 3/19/25 at

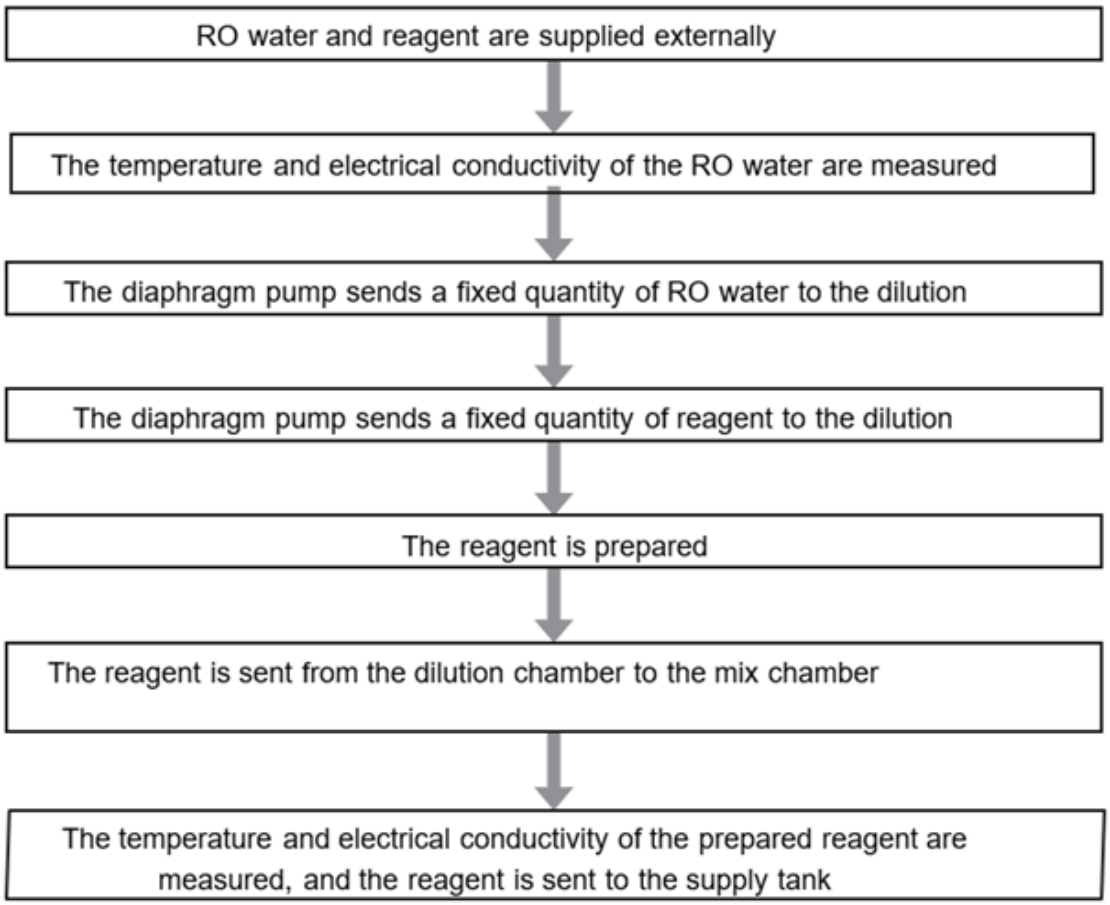
- Moorland Reserve Health Center
- Drexel Town Square Health Center

PURPOSE

The RU-20™ reagent unit prepares (dilutes) concentrated reagent (CELLPACK DST) using RO (Reverse Osmosis) water and feeds it to connected analyzers.

PRINCIPLE

The flowchart below shows the general sequence of processing by the instrument.



REAGENTS

CELLPACK DST (DST):

Concentrated diluent of reagent for use in hematology analyzers connected to RU-20.

CELLPACK DST Storage:

- Store at 2O – 35° C away from direct sunlight.
- Do not freeze. Do not use reagent that is suspected to have been frozen.
- CELLPACK DST is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.

CELLPACK DST Stability:

- Unopened, it is stable until the expiration date printed on the container.
- Opened, it is stable for 60 days.

CELLPACK DST Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. CELLPACK DST does not have ingredients with those characteristics.

NOTE: Do not ingest. Avoid skin and eye contact. Flush with plenty of water immediately. Consult with a physician in case of ingestion and/or eye contact.

RO WATER

RO water is used to dilute CELLPACK DST concentrated reagent for use on XN-Series analyzers. Water must meet the following specifications:

Electrical conductance	1.0 µS/cm or less
Supply pressure	0.2 MPa to 0.4 MPa
Supply volume	10 L/hr to 50 L/hr
Water temperature	100C to 300C
TOC (Total Organic Compounds)	500 ppb or less

Water meeting these specifications is commonly referred to as Clinical Laboratory Reagent Water (CLRW) or Instrument Feed Water (formerly CLSI Type II) defined by Clinical and Laboratory Standards Institute (CLSI) guidelines.

QUALITY CONTROL

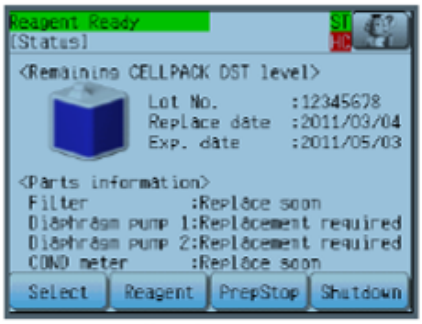
There is no external quality control material required for the RU-20.

To ensure consistency in the quality of the diluent produced, incoming water quality is monitored. Prepared diluent is checked internally by a conductivity sensor, which allows the system to determine if it is within specifications. Within the software menu, the Quality Log records the reagent preparation history with: Date, Time, Result, Temperature, Conductivity, Reference Voltage, Electrode and Thermistor voltage results. This continuous evaluation of production factors ensures consistent quality. Up to 1000 events can be recorded in this log and are removed from the list by first-in-first-out process.

OPERATION

Start Up

A. Press the power switch on the main unit.
   The display screen on the front of the RU-20 unit will display the following:



[Status] screen

B. Turn on the power of the analyzer(s) connected to the instrument.

After startup is executed, the reagent preparation sequence is automatically executed. When the reagent supply tank fills with prepared reagent, the reagent status display shows [Reagent Ready] and the prepared fluid can be supplied to the instrument.

If the analyzer is started before the RU-20 is started, notification of the diluted reagent level cannot take place and an error may occur on the analyzer.

If you need to turn off and then turn on the instrument power, wait at least 5 seconds after turning off the power before turning the power on again.

During Operation

If an error occurs during operation, a message will appear on the front of the RU-20 device or on the XN IPU screen. An error that has occurred can be cleared from the error list, which is opened by touching the help button. The errors that appear in the error list will be displayed in order of priority.

The Help button is in the upper right corner of the image below and Error message displayed in the lower section of the image. Errors can be cleared by following any prompts at the bottom of the screen. A complete description of error messages and next steps can be found in Chapter 7 of the RU-20 IFU.

Shutdown

Shutdown is not routinely performed. Perform it when shutdown is needed, for example, when an error occurs.

A. Turn off the power of the analyzer(s) connected to the instrument.

B. Touch [Shutdown]. The follow image appears on the front of the RU-20.

C. Touch [OK]. The shutdown completion screen appears.

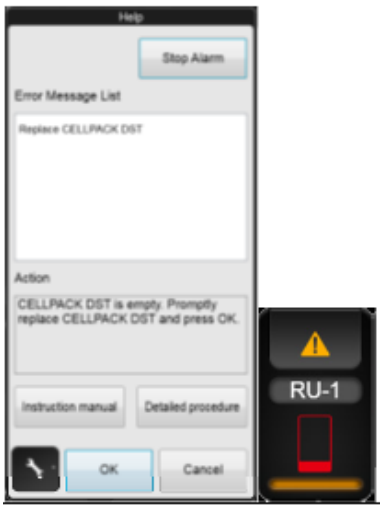
D. Press the power switch off the main unit.

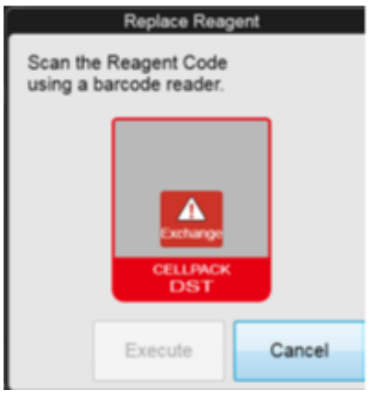
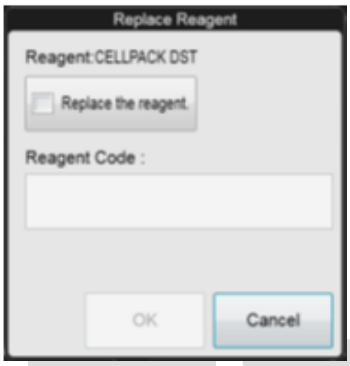
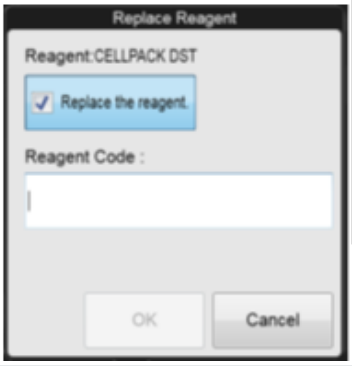
The system cannot be shut down when the instrument is in the [Not ready] state. If the reagent adjustment operation is not finished, shutdown will take place without starting the next adjustment operation currently being executed is completed.

If an error occurs during shutdown, the [Error] dialog will appear. Touch [OK] to close the dialog, clear the error, and then re-execute shutdown.

MAINTENANCE

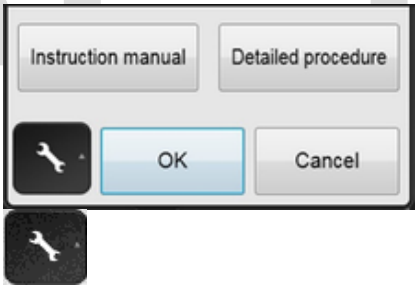
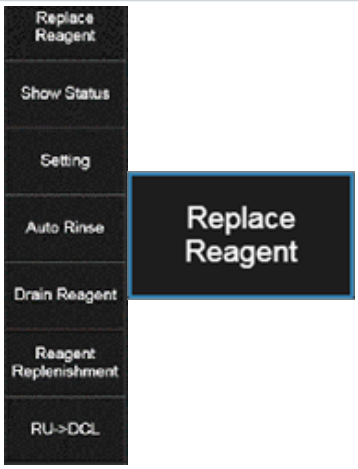
Reagent Replacement "Replace CELLPACK DST" | Error

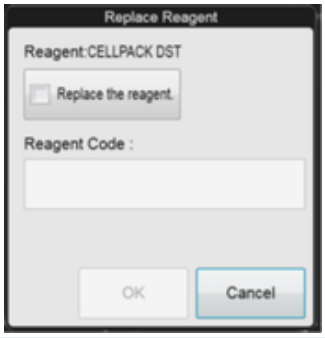
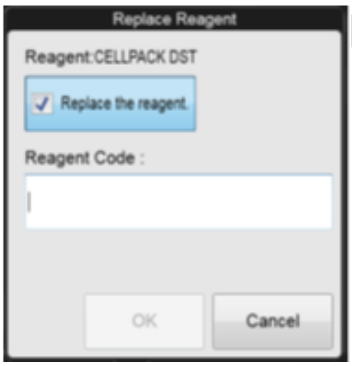
STEP	IMAGE
A. On the XN-IPU a Help window from the RU-20 menu will display 'Replace CELLPACK DST" in the error message list.	
B. Click [OK] to display the Replace Reagent window.	

C. Click the "Exchange" alert triangle.	
D. Verify that the "Replace the reagent' box is checked.	
E. Click in the Reagent Code text entry field.	
F. Using the handheld barcode reader, scan the reagent code on the new box of CELLPACK DST.	
G. Click [OK].	
H. Remove the cap from the new and old reagent containers.	
I. Pull the dispensing set straight up.	
J. Insert the spout kit straight into the new reagent container.	
K. Close the cap.	

L. Click Execute in the Replace Reagent Window.	
M. The RU-20 will begin priming the new reagent.	

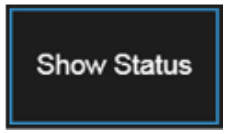
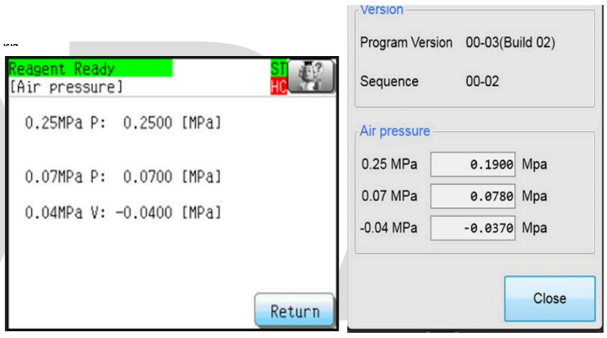
Reagent Replacement "Replace CELLPACK DST" | Initiated by User

STEP	IMAGE
A. On the XN-IPU, click on the RU control menu button.	
B. Click on the submenu button (the wrench).	
C. Select Replace Reagent from the menu that appears.	

D. Click in the remaining reagent volume indicator for CELLPACK DST.	
E. Verify that the 'Replace the reagent' box is checked.	
F. Click in the Reagent Code text entry field. Using the handheld barcode reader, scan the reagent code on the new box of CELLPACK DST. Click [OK].	
G. Remove the cap from the new and old reagent containers.	
H. Pull the dispensing set straight up.	
I. Insert the spout kit straight into the new reagent container.	
J. Close the cap.	
K. Click Execute in the Replace Reagent Window.	

L. The RU-20 will begin priming the new reagent.	

Pressure Adjustment [0.07 MPa Pressure Error]

STEP	IMAGE
A. Click the RU control menu button on the XN-IPU.	
B. Click the submenu button (the wrench).	
C. Click [Show Status]	
D. The current air pressure will be displayed in the Show Status window from the RU menu.	
E. The 'Air Pressure' screen will also be displayed on the RU-20 LCD display so the changes will be easily visible during adjustment.	
F. Push the cover located on the right side of the RU-20 so that it pops up, then open the door.	
G. Pull out the adjustment knob on the 0.07 MPa regulator to	

unlock it.	
H. Turn clockwise to increase pressure and continue counter-clockwise to decrease pressure (0.070 MPa ± 0.005).	***Watch the RU-20 LCD while you make the adjustment***
I. After reaching an acceptable level, push the adjustment knob on the 0.07 MPa regulator to lock it.	
J. Click [Close] on the Show Status window from the RU menu.	
Note: When adjusting pressure and vacuum always turn counterclockwise until below your target value. Then turn clockwise to adjust up to the value.	

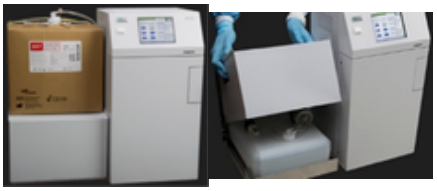
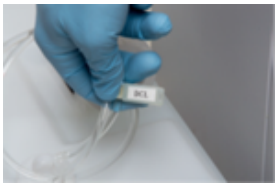
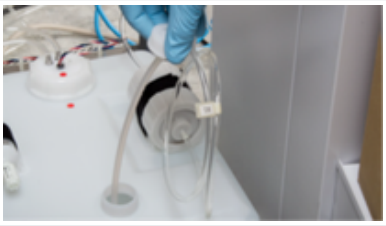
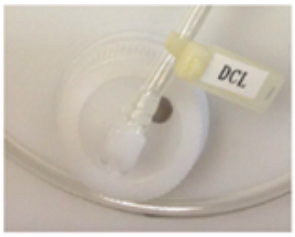
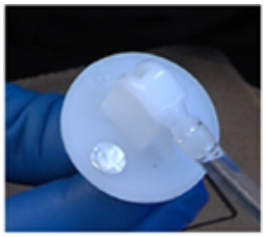
TROUBLESHOOTING

Switch DST to CELLPACK (Emergency Use)

Purpose: The switch to CELLPACK DCL may be made in the following circumstances:

- Problem with the Type II water / Type II water system
- Problem with the RU-20

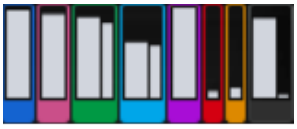
STEP	IMAGE

A. Remove the cubitainer of CELLPACK DST to access the supply tank.	
B. The spout kit in the supply tank is labeled 'DCL'	
C. Remove the spout kit from the supply tank.	
D. Remove the silver sticker from the spout kit of the Supply Tank to uncover the vent hole, store the sticker elsewhere on the cap (you will need again to cover the vent hole).	 
E. Insert the "DCL" spout kit into a new cubitainer of CELLPACK DCL and tighten.	
F. Use the original cap from the new cubitainer of CELLPACK DCL to close the supply tank.	 
G. Click the RU control menu button.	
H. Click on the submenu button (the wrench	
I. Click [RU -> DCL].	
J. Read the warning message and click [OK].	
K. The Help window will appear with the message "Register CELLPACK DCL."	

L. Click [Execute].	
M. Click CELLPACK DCL in the Reagent Replacement window (red "exchange").	
N. Click in the 'Reagent Code' entry field.	
O. Using the hand-held reader, scan the reagent code on the container of CELLPACK DCL that you connected to the system.	
P. Click [Execute].	
Q. CELLPACK DCL is now ready for use.	

DCL TO DCL Reagent Replacement (For Emergency Use Only)

PURPOSE: Extended RU-20 / Type II water system downtime. If you have made the switch to DCL and that cube runs out, you will need to replace it with the following procedure.

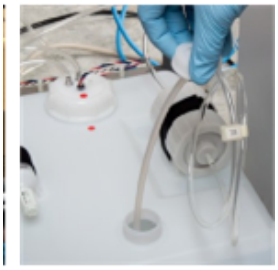
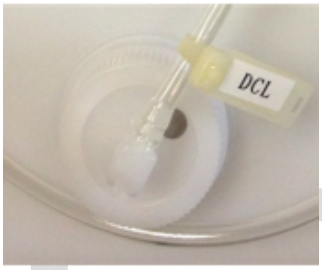
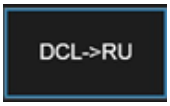
STEP	IMAGE
A. The 'Help' dialog box on the XN-IPU will appear when the system detects an empty reagent container.	
B. Click [Reset Alarm] to silence the audible alert.	
C. The errors include: 'CELLPACK DCL aspiration error', 'RBC sheath fluid aspiration error', and FCM sheath aspiration error'.	
D. Wait for these errors and the solid red status light on the analyzer menu.	
E. Replace the empty CELLPACK DCL cubitainer with a full one	
F. DO NOT click [Execute] in the Help dialog box.	
G. Click [Close] to minimize the Help dialog box.	
H. Click the Remaining Reagent Volume Indicator.	

I. Click CELLPACK DCL.	
J. Place a checkmark next to 'Replace the Reagent'.	
K. Click in the 'Reagent Code' entry field.	
L. Using the hand-held reader, scan the reagent code on the new container of CELLPACK DCL that you connected in step 3 above.	
M. Click [Execute].	
NOTE: *If the aspiration errors appear again after reagent replacement, check to ensure that the new cube of CELLPACK DCL is connected properly and that the tubing is free of kinks. Then, highlight the error in the Error Message List and click [Execute] to perform a replenishment of CELLPACK DCL.*	

DCL Reagent > Return to DST Reagent use.

Purpose: Returning to standard reagent operation DCL > RU (DCL to DST). This process describes return to use of DST reagent post RU-20 hardware issue or water quality concern resolution.

STEP	IMAGE
A. Locate the Supply Tank.	
B. Remove the cap from the Supply Tank.	

C. Loosen and remove the spout kit from the CELLPACK DCL.	
D. Insert the spout kit into the supply tank.	
E. Move the silver sticker back into place covering the vent hole.	
F. Tighten the cap of the spout kit on the Supply Tank and cover the Supply Tank.	
G. Click the RU control menu button.	
H. Click on the submenu button (the wrench).	
I. Click [DCL -> RU].	
J. Read the warning message and click [OK].	
K. Click the Remaining Reagent Volume Indicator for CELLPACK DST.	
M. Click CELLPACK DST in the Reagent Replacement window.	
N. Place a check mark next to 'Replace the Reagent.'	
O. Click in the 'Reagent Code' entry field.	
P. Using the hand-held reader, scan the reagent code on the container of CELLPACK DST that is connected to the system.	

Q. Click [Execute].	
R. The RU and CELLPACK DST are now ready for use.	

REFERENCES

A. Reagent Unit RU-20 Instructions for Use, Sysmex Corporation, Kobe, Japan.

B. Control or Pre-Analytical Variation in Trace Element Determination, CLSI C38-A; Vol 17, No 13; 1997.

C. Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline – Fourth Edition, CLSI GP40-A4-AMD, Clinical and Laboratory Standards Institute, 2012.

D. Sysmex RU-20™ Concentrated Reagent Deliver System, Quick Guide, Document CF-07343, Rev. 1, 7/2022, www.sysmex.com/us.

Attachments

- Cellpack DCL with spout kit.png
- Insert spout kit into supply tank.png
- New DCL cubitainer.png
- Pressure status window.png
- Remaining Reagent Volume Indicator.png
- RU Replace Reagent Execute.png
- RU-20 Instructions for Use.pdf
- RU20 Display Screen.png
- RU20 Error.png
- RU20 Exchange.png
- RU20 Flowchart.png
- RU20 Prime.png
- RU20 Reagent Code.png
- RU20 Replace DST Error.png
- RU20 Replace RGT.png
- RU20 Shutdown screen.png

RU20 Submenu Wrench.png

Select CELLPACK DCL.png

Show Status.png

silver sticker covering vent hole.png

Silver sticker.png

Approval Signatures

Step Description	Approver	Date

Applicability

Community Physician

Standards

No standards are associated with this document