

PRODUCT BULLETIN

Type:Field Service

Bulletin Number SB 2021002 rev.1

Subject: Mandatory addition in Start-up and End-of-day wash routine

Date: March 2021

From: Support department

Number of pages: 5

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Instruments:

All Lorrca instruments.

Maintenance:

The advised Start-up and End-of-Day wash routines are changed. It is mandatory to perform extra steps during start-up and during the End-of-day wash routine (revised). See additional information.

Reason:

The contents of Starrsed X-clean has been changed due to regulatory reasons

In the process of verifying the effectiveness of this change, we discovered the first measurement is influenced after the end-of-day wash.

To prevent the effect of an end-of-day wash on the first measurement we adapted the procedure of the end-of-day wash and a start of day rinse.

Impact on **Quality / validity of results:** Yes
 Reliability of the instrument: Yes
 Safety of the instrument: No

Effective from:

Starrsed X-Clean from batch **2101409818** and up.

Compatibility:

N/A

Is field modification possible?

N/A

Order information:

N/A

Notes on stock and obsolescence:

N/A

Additional information:

Changed Standard Start-up procedure

Changed Standard End-of-day wash procedure (revised at step 2 DI Water)

This information will be incorporated in the next version of the User Manual.

If you have questions do not hesitate and send your email to support@rrmechatronics.com

Changed Standard Start-up procedure(revised)

Preparations

1. Check de-ionized water bottle, should be filled
2. Check Waste bottle, should be empty
3. Place X-Clean bottle
4. *If an Osmoscan is foreseen:* Place the Osmo LOW and Osmo HIGH bottles
5. Check applicable viscosity of reagents
6. Check the gradient pump tubes by pushing cassettes downwards (no click if correctly fixed and in parallel position)
7. In case of a period of inactivity: Check the functioning of the valves with [HARDWARE CHECK/LORRCA IO/VALVES](#). During toggling ON/OFF each valve should give a "click". If a pinch valve sticks, perform a "PRIME ALL" and check the flow of the Osmo LOW and Osmo HIGH through the tubing.



2023-05-01

Always check reagents for "USE-BY" date before starting preparation.

Discard if "USE-BY" date has passed.

Start of day rinse

For Instruments without Oxygenscan and without Luer connection on top of the bob:

1. Prepare 5 ml vial of Elon ISO or Oxy ISO
2. Select from the menu Deformability Curve
3. Draw 1 ml Elon or Oxy ISO from the vial with a pipette or pastette and insert this into the cup
4. Lower the bob and select the **Rinse** tab
5. Repeat step 3 and 4
6. Dry the bob and cup with a tissue

The instrument is ready to go.

For Instruments with Oxygenscan or with Luer connection on top of the bob:

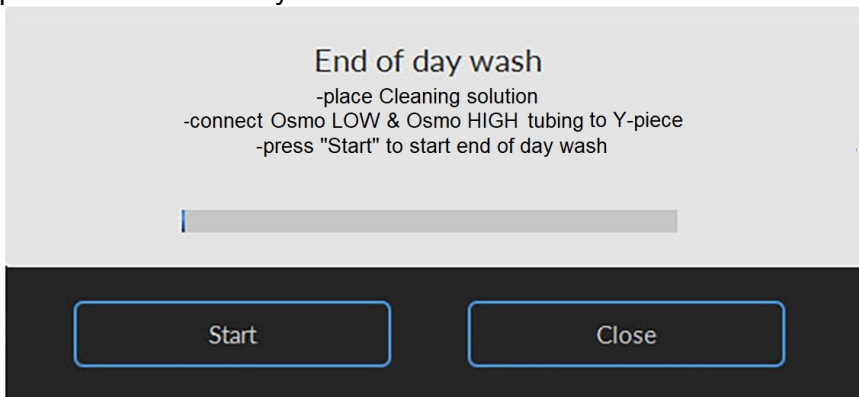
1. Prepare 5 ml vial of Elon ISO or Oxy ISO
2. Select from the menu Deformability Curve
3. Draw 1,4 ml Elon or Oxy ISO from the vial with a syringe
4. Lower the bob
5. Empty the syringe through the Luer connection on top of the bob
6. Select the **Rinse** tab
7. Repeat step 3 to 6
8. Dry the bob and cup with a tissue

The instrument is ready to go.

Start each day with performing a control sample (containing blood with normal values) before a sample measurement. This control sample gives reference values for the patient samples.

Changed Standard End-of-day wash procedure

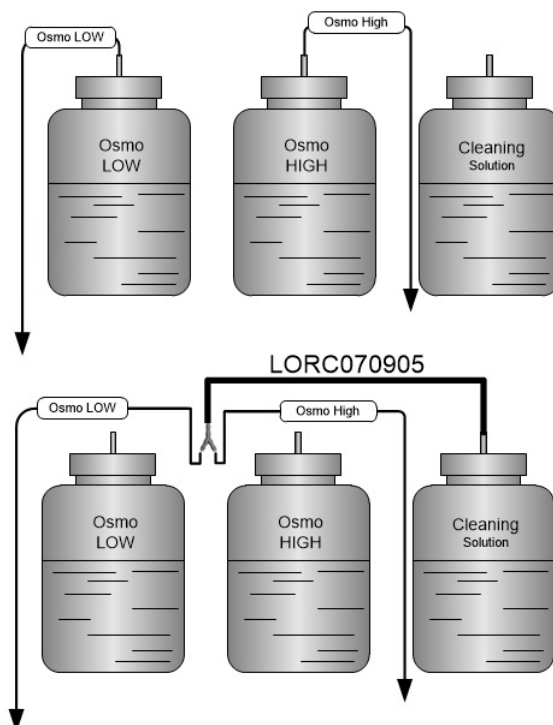
When the program is shut down a pop-up screen appears with <END OF DAY WASH> message. To perform an End of day wash:



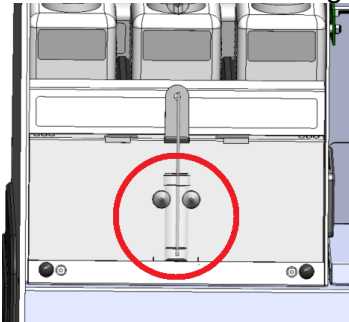
End-of-day wash procedure

Step 1: X-Clean

1. Remove both tubes on the reagent bottles.
2. Mount the reagent tubes to the cleaning tube LORC070905 from the cleaning solution bottle.



- Place a tube with cleaning solution at the Osmoscan sample position.



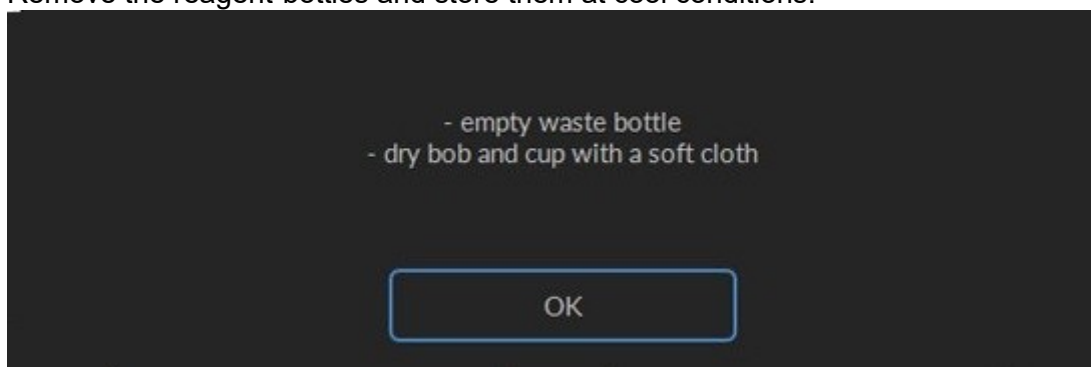
- Close the Lorrca program window.
- Press **Start** and press **OK** when asked at the end

Step 2 DI water

- Restart the Lorrca program on the computer
- If applicable skip the Sensor calibration procedure
- Place a tube with DI water at the Osmoscan sample position.
- Remove the tube from the cleaning solution and place it on the DI water bottle
- Close the Lorrca program window.
- Press **Start** and press **OK** when asked at the end
The tubing and the bob and cup have now been rinsed with DI water so that no crystals of remaining dried detergent can block any tubing

Step 3 run dry

- Restart the Lorrca program on the computer
- If applicable:* skip the Sensor calibration procedure
- Remove the tube from the DI water bottle
- Close the Lorrca program window. Press **Start**
The water in the tubing and the bob and cup has largely been removed
- Remove the cleaning tube from the reagent tubes after finishing of the End-of-day wash
- Place the water connection tube back on the DI water bottle
- Remove the reagent-bottles and store them at cool conditions.



- Empty the waste bottle.
- Clean and dry bob and cup, drip plate and sample unit plate. Press **OK**