

ADVISORY NOTICE

24_2024_New software version for EC 90

Dear customer,

We hereby inform you that there is a **new software version 1.24.0** for device EC 90. This version is released on 19th August 2024 and, among other bugfixes, features these changes based on customer feedback:

1. *First Outlier Detection Algorithm and Drift correction*

An algorithm was developed to detect outlier which users are experiencing in a case of a first measurement. Additionally, a drift correction was added. These steps improve the precision of the instrument.

2. *Bugfix: Westgard rule issues for 2x2s and 2of3x2s*

3. *Extended Put Into Operation (Commissioning) Process*

In the current software version, the Put Into Operation Process (Commissioning) consist of the following steps:

- Set System Time, System Date and Language
- Remove the Valve Clips
- Insert EC Cartridge
- Prime Up (Cal 1, Cal 2 and KCL is aspirated, Calibration for ready done)
- Wetting (Human sample 10x to prepare the fluidics)
- 2-Point Calibration

The Put Into Operation process (Commissioning) is extended with the following steps:

- **30 Minutes waiting time after the Wetting is finished**

The users are prompted with 30 minutes waiting time after the Wetting is finished. If the user cancels the Wetting, the waiting time remains 30 minutes.

- **Users are prompted to do at least 5 QC Measurements**

After the waiting time is over and the 2-Point calibration is finished the instrument is unlocked, the user is instructed to do 5 measurements in QC mode. This information will be presented on a pop-up screen on the Main Screen.

Additionally, the System Info will also include the same instructions for the user. Lastly the footer will include Put Into Operation pending (similarly to Maintenance Pending) to showcase that the QC Measurements were not done yet.

The series of 5 measurements are evaluated by the default Westgard Multirules; which are 2x2sd, 2x3 of 2sd, 1x3sd; the Put Into Operation process is finished, and the result will be saved in the device log.

4. *Cleaning Process Optimization*

The cleaning process is optimized for speed and waste production. Currently the delivered waste container is smaller than the waste produced during the cleaning routine.

The updated process is following:

- Emptying
- User prompted to insert Washing Unit and Cleaning Solution

- Cleaning with Cleaning Solution
- User prompted to remove cleaning Solution
- Cleaning with Air
- User prompted to insert DI water
- Cleaning with DI water
- User prompted to remove DI water
- Cleaning with Air
- User prompted to remove Washing Unit
- User Prompted to Insert EC Cartridge

Once the EC Cartridge is inserted and the process finishes the users are prompted with Wetting. The updated process reduces the total solution consumed to ~20 ml, thus accomplishing a waste production that doesn't exceed the size of the waste container. The process is also significantly shorter, requiring only ~11 minutes (depending on User handling). The users are also notified how long the process is via a timer on the screen.

Another change in the process that after the Cleaning is finished the users are prompted with Wetting.

5. *Calibration Intervals other than 12 hours for 2P and 1 hour for 1P removed*

The Calibration Interval options are removed from the Operation Settings. The default 12 Hours for 2P Calibration and 1 hour for 1P calibration settings are active.

6. *Lab Mean: Option to Apply Only Mean without Standard Deviation*

The Lab Mean feature allows the users to recalculate the mean from their own QC Measurements for a defined QC Material. In the current implementation, the mean and standard deviation are recalculated. In this change a new option is introduced: Lab Mean without Standard Deviation. The users now have an option to retain the original SD limits of the QC Material.

7. *Prime Up Workflow Update*

Prime up process is optimised and is now faster.

8. *Pack Change Workflow Adaptations*

In case of a Pack Change/Sensor Change (new Pack or Sensor) the Wetting procedure can be skipped. This feature is important for the stability of the sensor and should be concluded. The change to the workflow introduces a seven and half minutes (7,5) screen lock for users who skip the Wetting procedure. During this time, 1P calibrations are automatically done by the instrument. The waiting time is inversely proportional to the executed Wetting measurements: the more Wetting measurements have been done out of the ten prescribed ones, the less waiting is needed by the users.

9. *Serum as separate measurement type*

The serum and plasma measurements are handled the same by the instrument: the user can only select Plasm/Serum from the measurement dropdown menu. This change introduces Serum as separate type. User can select Serum from the dropdown menu and the results are saved as Serum type.

Changes can be also found in a User Manual, apart from smaller updates based on changes described above, following chapters were added/extended:

- *4.1.4 Guided start-up* – chapter extended with a new commissioning routine to ensure proper startup of the instrument.

- 5.6.3 *Cleaning the tubing* – procedure updated according to new routine.
- 5.6.5 *Cleaning fluidic path in case of blockage* – new chapter which describes proper use of a plunger which is sent as an accessory. This plunger is used for manual cleaning in case of blockage in fluidic paths.

In case you have any additional question, please do not hesitate to contact us.

Best regards,

Erba Lachema s.r.o.

A handwritten signature in blue ink, appearing to read "Serd".

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Brno, 19th August 2024

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