Technical Notice

Engineering Change Notice for 00.00.15.357787 Software

DATE: June 17, 2024

TN S/N: TN-JY-2406001

FROM: Lifotronic International Service Department

ECN Number: ENIA5A0001

1. Background Information

In order to be compatible with changes in the RFID card of immunoreagents (see *Notification Letter of Lifotronic ECLIA Reagent doc-20240606* for details), software upgrade is necessary. In addition, the 00.00.15.350508 version of the software has been optimized the needs from users/markets and fixed some bugs. See section *4. Engineering Change Notice* for details.

2. Range of Involved Instruments

All eCL8000 analyzers that have been installed.

3. Involved Spare Parts / Tools

PC, USB flash drive.

4. Engineering Change Notice

4.1. Updated Software Version Information

System Software: 00.00.15.357787

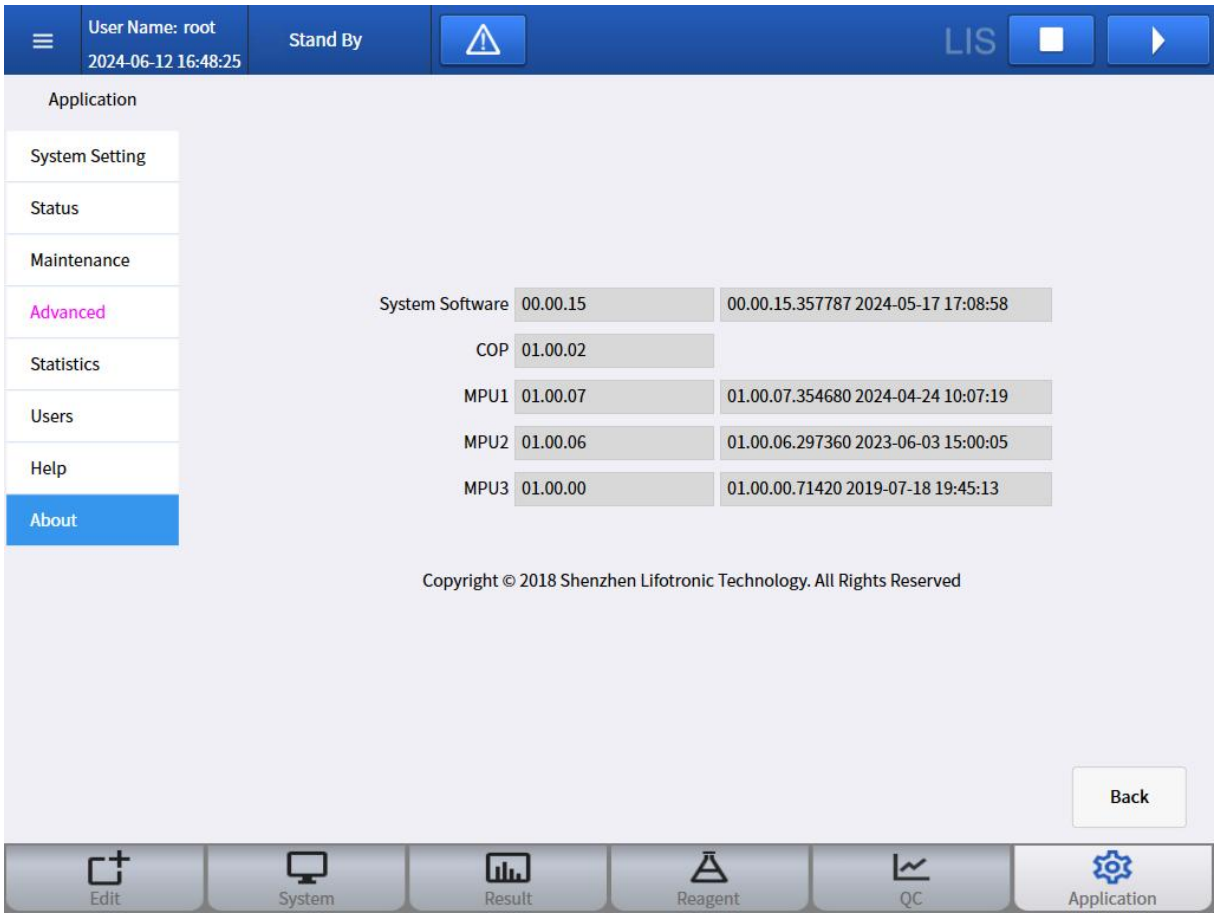
COP: 01.00.02

MPU1: 01.00.07.354680

MPU2: 01.00.06.297360

MPU3: 01.00.00.71420

Note: The COP version remains unchanged. Please skip the COP upgrade procedure. If the MPUs versions are the same, upgrading for MPUs are still needed.

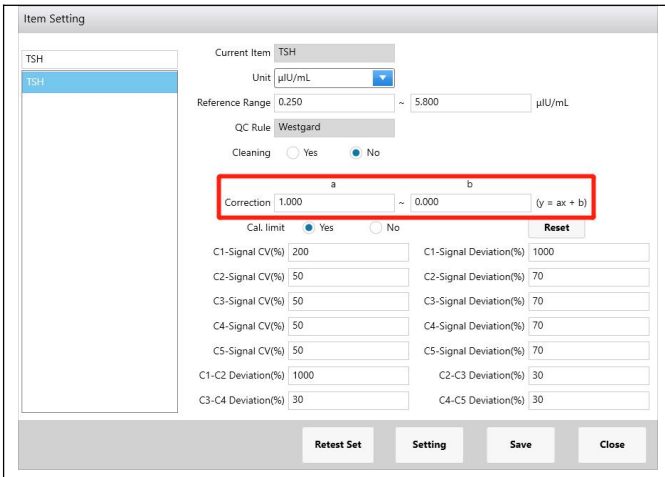


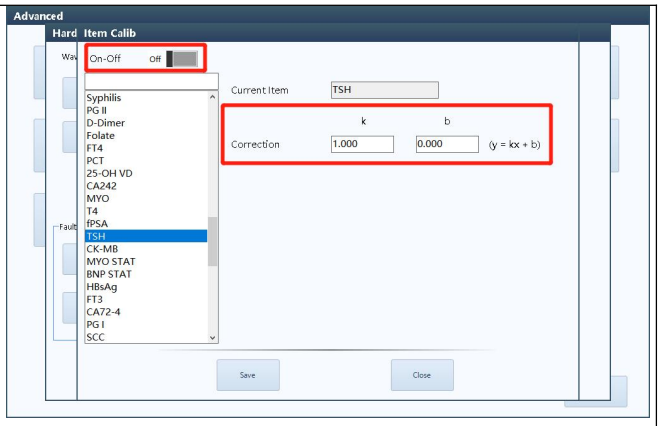
Software information after successful upgrade

4.2. Change Notice

Description (Current)	Description (New)
System Software: 00.00.13.275954 COP: 01.00.02 MPU1: 01.00.06.230613 MPU2: 01.00.05.263348 MPU3: 01.00.00.71420	System Software: 00.00.15.357787 COP: 01.00.02 MPU1: 01.00.07.354680 MPU2: 01.00.06.297360 MPU3: 01.00.00.71420
1. Only the immunoreagents with the RFID cards on the front (old) of the kits can be scanned and loaded. The immunoreagents with the RFID cards on the side (new) of the kits are not compatible.	1. Compatible with immunoreagents with RFID cards on the front (old) and side (new) of the kits.

 	 
2. Additional manual calibration of test results can only be set in *Item Setting*, and the corresponding QC target values will not change together, requiring additional manual setting in QC interface.	2. A new manual calibration function for results has been added in **Advanced**. The corresponding QC target values will change with the attached coefficients. This function has a unified setting interface with the login password 568900, and a unified switch for all items. **Note: This function will interact with the old manual calibration function in Item Setting, and must be used separately.* *Interface Path: Application→ Advanced→ HD Setting→ Item Calib (Password: 568900)*

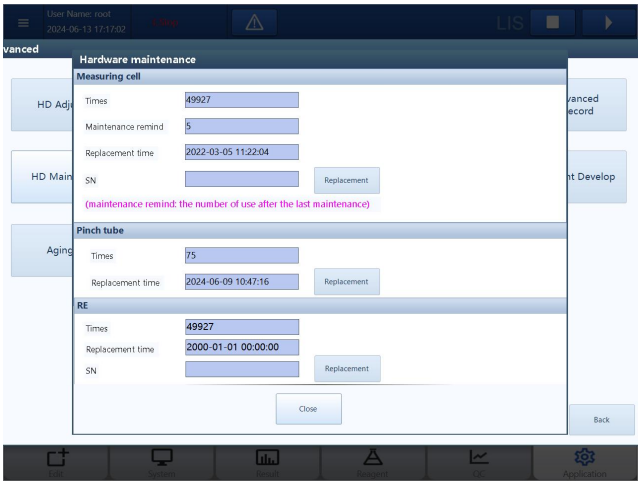


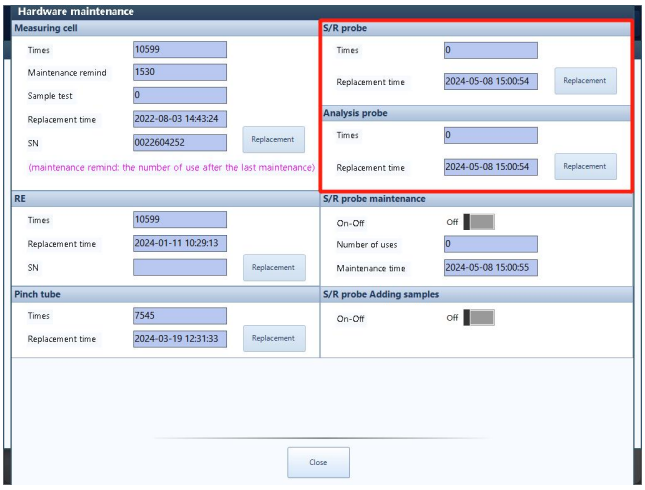


3. No such function.

3. S/R Probe and Analysis Probe usage counting and statistics functions are added in to **Advanced**. When replacing two probes, resetting the counters on this interface is required.

Interface Path: Application→ Advanced→ HD Maintain→ S/R probe, Analysis probe

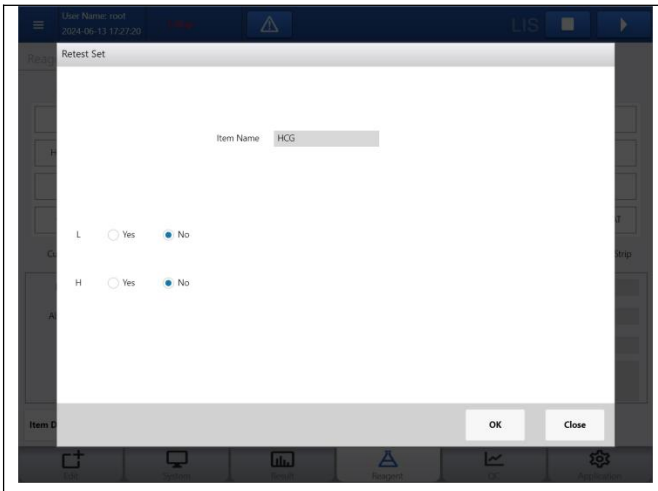


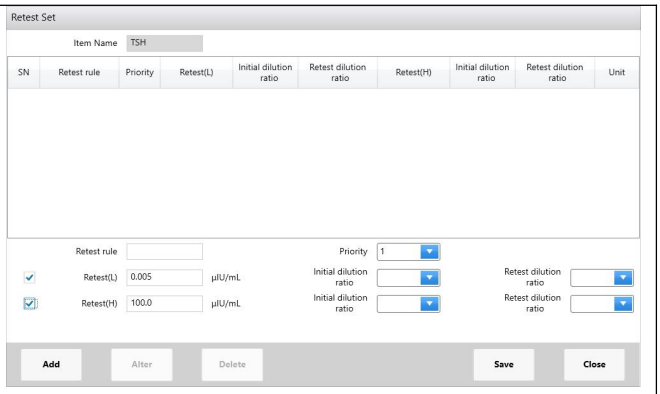


4. The automatic retest function of the old version has defects and cannot meet the testing requirements in some usage scenarios.

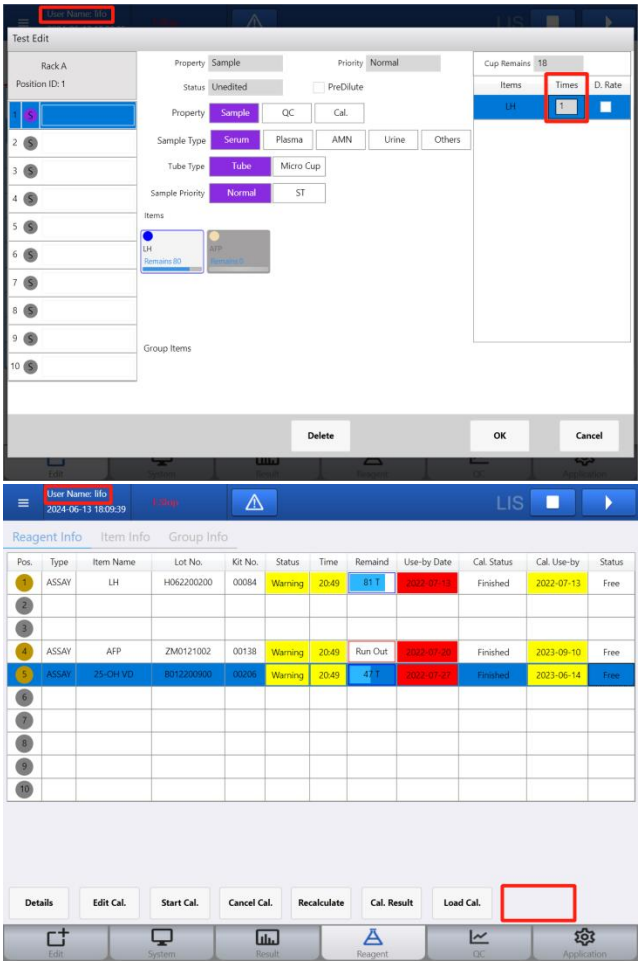
4. Optimize the automatic retest function. Add automatic retest screening conditions. When the test result is lower or higher than the set values, the sample will be retested according to the corresponding set retest dilution ratios.

Interface Path: Application→ System Settings→ Software Setting→ Item Setting→ Retest Set



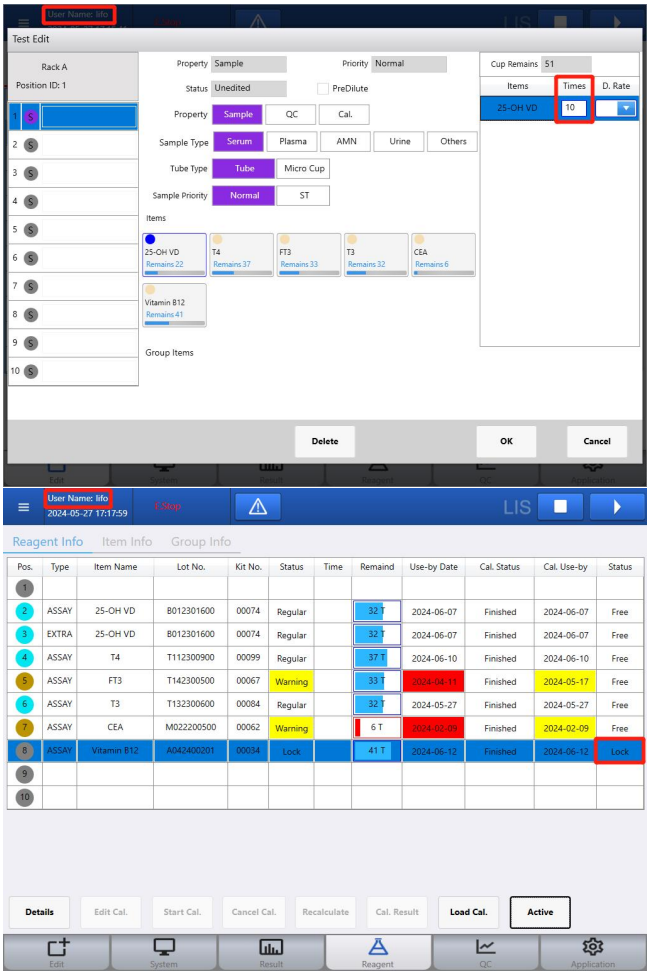


5. Setting the number of tests (for testing repeatability) and locking reagents can only be performed by the root account.

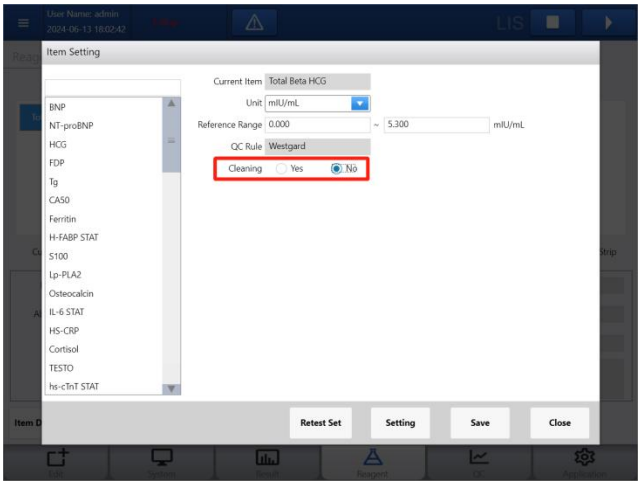
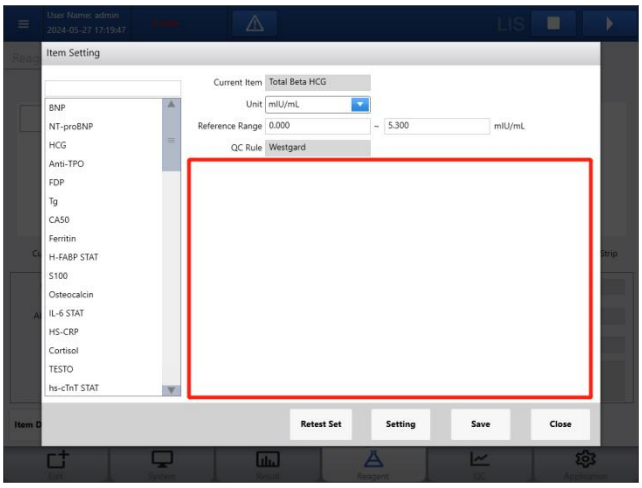
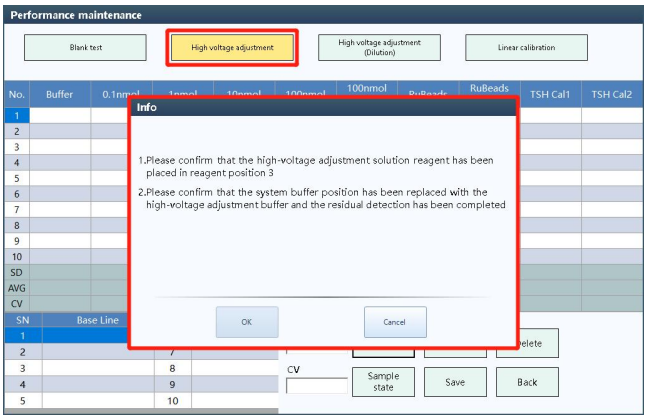
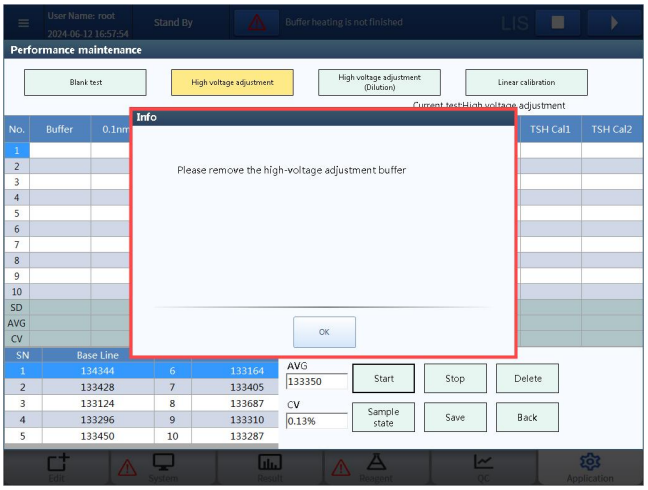


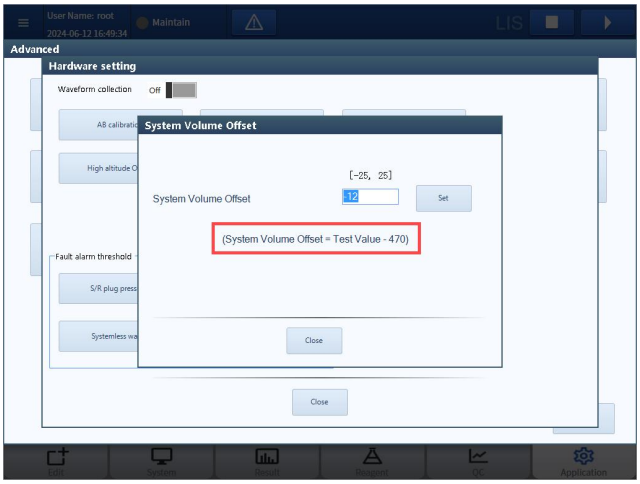
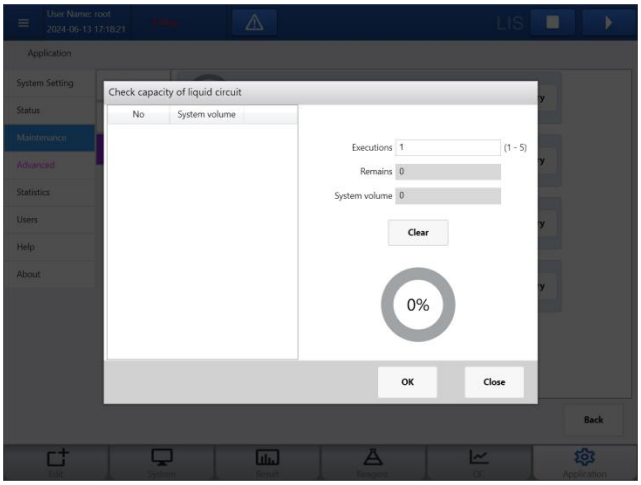
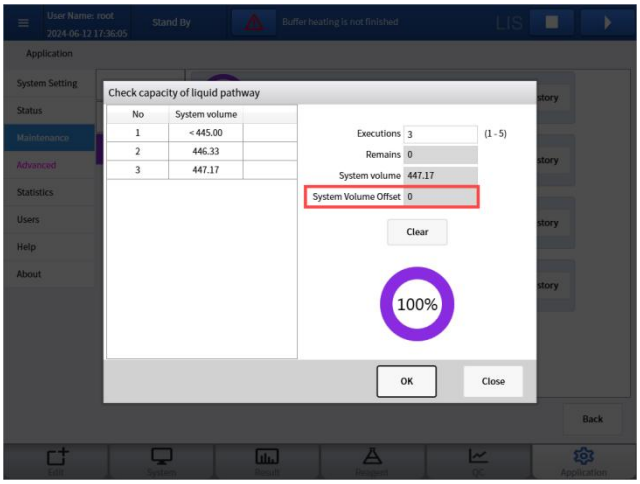
The user account with the lowest permissions is used for demonstration and cannot perform the above operations

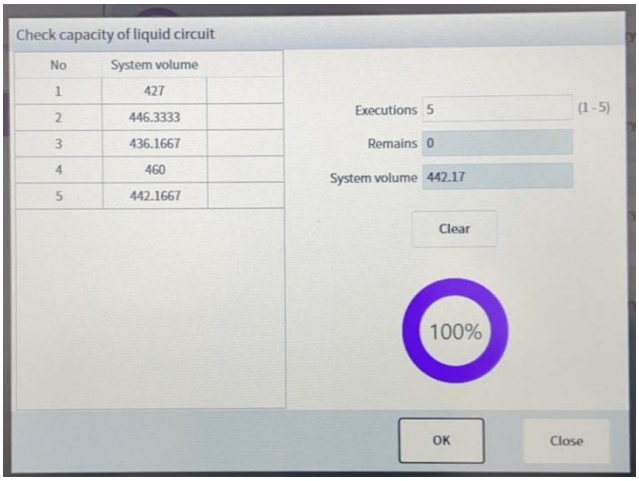
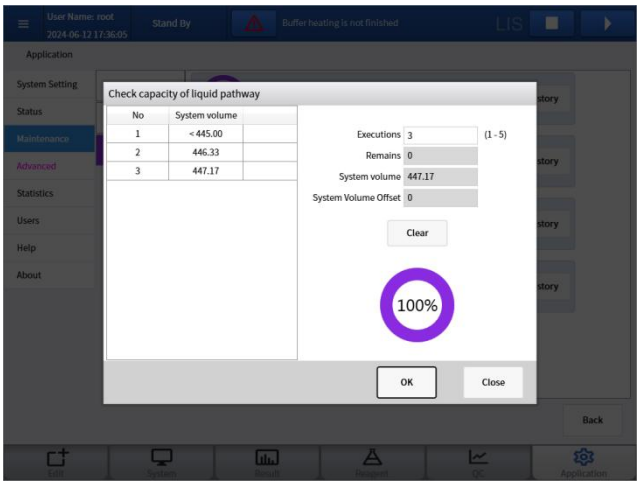
5. Setting the number of tests and locking reagents can be performed by all the accounts (root, admin, and user).

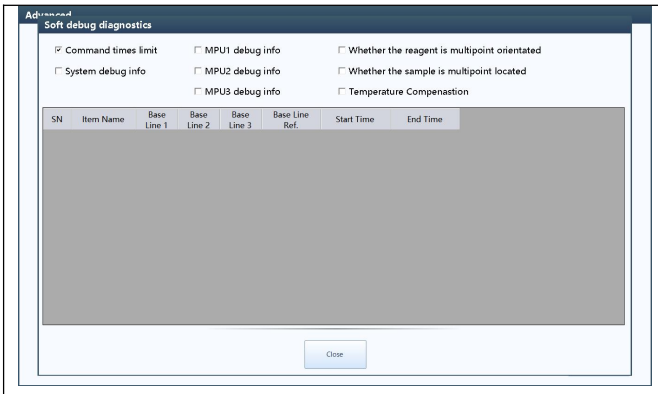
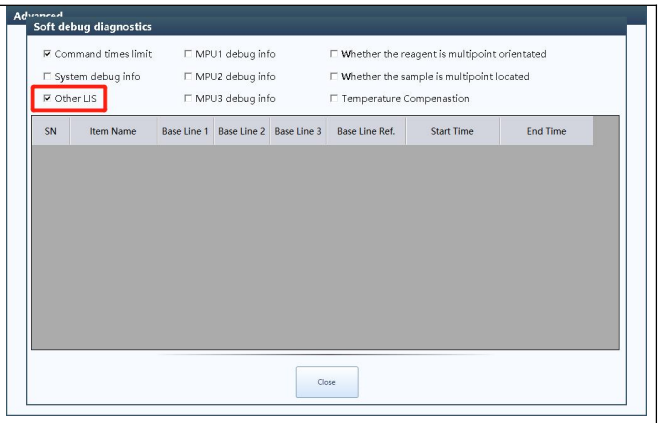


The user account with the lowest permissions is used for demonstration and can perform the above operations

6. All accounts have the authority to enable the enhanced cleaning program.  *The admin account, which has the second-highest authority after root, is used for demonstration here*	6. Added restriction that only the root account has the authority to enable or disable the enhanced cleaning program.  *The admin account, which has the second-highest authority after root, is used for demonstration here*
7. No such prompt.	7. Added prompts on using related reagents before and after performing High-voltage Adjustment test.  

8.1. The calculation formula is not displayed on the System Volume Offset function interface (no examples to show here).	8.1. A calculation formula prompt ‘System Volume Offset = Test Value - 470’ has been added to the System Volume Offset. The usage scenario is that when the system volume values are within the adjustable range, the manual offset can be adjusted to around 470. *Interface Path: Application→ Advanced→ HD Setting→ System Volume Offset* 
8.2. There is no System Volume Offset value column in the Check Capacity of Liquid Pathway (System Volume) test interface. 	8.2. A System Volume Offset value column is added to the Check Capacity of Liquid Pathway (System Volume) test interface, through which the current offset value can be inspected. *Interface Path: Application (login with root account)→ Maintenance→ Maintain Instruction→ Service Maintain→ Check capacity of liquid pathway* 

9. System volume test results are actual test values.  	9. Optimize the display of system volume test results. Results within the range of 445~487 will display values, and results outside the range will display <445 or >487. **Note: When the system volume result exceeds 445~487 or unstable, the offset function cannot be used for adjustment, it is necessary to check the instrument hardware.*  *Here <445 is taken as an example*
10. No relevant alarm.	10. Added Measuring Cell replacement reminder function (alarm). When the Measuring Cell usage count reaches 60,000 times, an alarm will be issued to remind for replacing the Measuring Cell. **Note: If the Measuring Cell is not replaced and the counter is not reset in time, the instrument can continue to perform the test, and then an alarm will be issued once a day until the Measuring Cell is replaced and the counter is reset.*
11. No such switch.	11. **Advanced** adds an additional 'Other LIS' upload switch. After turning on the switch, the signal value of the test result, the result mark (*), the reagent LOT number, and the reagent loading position will be transmitted to the LIS system. *Interface Path: Application→ Advanced→ Diagnostics→ Other LIS*

	
12. The validity periods on the IFUs of some reagent items do not match the actual validity period after loading. *For example, Vitamin B12 IFU claims the validity period after opening the bottle is 8 week. After loading, the instrument shows that the available period is 4 weeks.*	12. Added dynamically obtain function to solve the above-mentioned problem of mismatch between the actual validity periods on the instrument and the validity periods declared by the reagent IFUs.
13. A Bug in LIS transmission that the eCL8000 instrument still accepts test information obtained from LIS system when the actual status does not meet the test requirements. *For example, the reagents for the requested tests are not loaded, the remaining test number of reagents does not meet the number of requested tests, the remaining assay cups do not meet the number of requested tests, etc.*	13. This bug has been fixed. When the actual status of the eCL8000 instrument does not meet the test information obtained from the LIS, the instrument will block these test applications.
14. When performing S/R Probe positioning, the E_Stop alarm will appear when resetting the probe after unlocking the Y-axis.	14. This bug has been fixed.