

April 4, 2024

Technical Bulletin 1003

iSED®/iSED ELITE LCD Issue and Software Update 1.4.0

Products Impacted:	Product	Part Number
	iSED with serial numbers >5000	112-00101
	iSED ELITE	112-00222

Attention

All iSED ELITE and iSED (with serial #s > 5000) customers

Introduction

It has come to our attention that the LCD screen on all iSED ELITE and iSED (serial #s > 5000) analyzers has been powering off under certain circumstances. When this occurs, the analyzer will not successfully reboot without this software update.

Measurement of erythrocyte sedimentation rate results are not affected.

There are no additional safety risks to the users or patients as a result of this situation.

Actions Required

1. A software update (version 1.4.0) is required to fix the issue associated with the LCD powering off. ALCOR® Scientific Technical Support will contact iSED/iSED ELITE customers with software update 1.4.0 (provided on a USB Flash Drive). You must update software on all your iSED ELITE and iSED (serial #s > 5000) analyzers as per ALCOR Scientific’s Software Update Instructions referenced below.
2. If the LCD on your device has already unexpectedly powered off, you must contact ALCOR Scientific Technical Support at techservice@alcorscientific.com or 401-737-3774 for assistance.
3. File this Technical Bulletin as part of your Quality System, as required.
4. Provide an update to ALCOR Scientific by completing the Software Update Completion Form at the end of the bulletin.



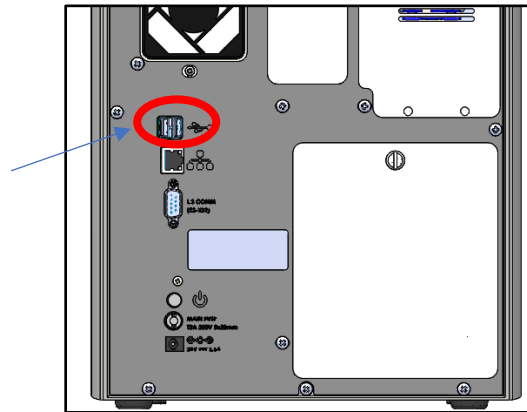
ALCOR Scientific, LLC
 20 Thurber Boulevard
 Smithfield, Rhode Island 02917 USA
 (Phone) 800.495.5270 □ 401.737.3774
WWW.ALCORSCIENTIFIC.COM

Software Update Instructions

You must have access to the software update before starting the protocol. ALCOR Scientific Technical Support will provide the update on a USB Flash Drive. The software update file can also be accessed online if necessary.

1. Be sure your iSED/iSED ELITE device is connected to a power source.
2. Perform a successful Quick Clean prior to starting procedure.
3. Insert the USB Flash Drive with software version 1.4.0 into one of the two USB ports on the rear of the device (Figure 1).

Figure 1



4. Confirm both of the following messages appear: “USB device attached” and “USB Storage found”.
5. Navigate through Menu → Settings → General → Upgrade
6. Press “Validate Upgrade”. Device will check the USB for a valid upgrade package.
7. Once validated, device will display the version to be installed. Confirm and start upgrading by pressing the “Upgrade” button (Figure 2).

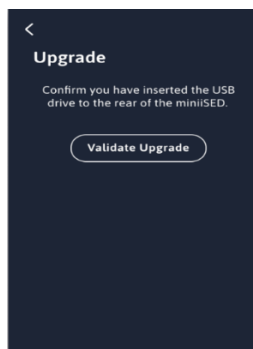


Figure 2



Figure 3



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- Depending on the current software already on the device, the device will either power off completely or will reboot itself. If it powers off completely, press the power button to power on the device again. Device will remain on the ALCOR Scientific “splash” screen (Figure 3) while installing the robotics firmware, then advance to the Graphical User Interface upon completion.

NOTE: This may take up to two minutes and the “splash” screen may appear more than once.

- Confirm the update was installed properly by verifying that the cooling fan is powered on. In some instances, the cooling fan may not be powered on and the number of available credits might show zero. In these cases, wait 5 minutes and then power cycle the device.

NOTE: If the credits are still zero and the cooling fan is not powered, contact ALCOR Scientific Technical Support.

- Confirm the Package Version is now showing software version 1.4.0 by navigating to Menu → Settings → Advanced Settings and scrolling down (Figure 4)

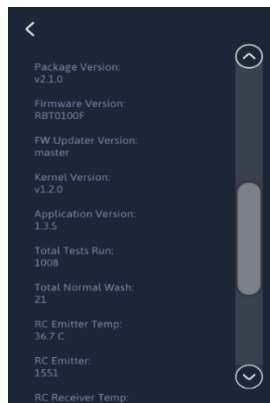


Figure 4

For additional information on this product notification or issues completing the software update, please contact ALCOR Scientific Technical Service at techservice@alcorscientific.com or 401-737-3774.



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Technical Bulletin 1003: Software Update Completion Form

Please inform ALCOR Scientific Technical Support that you were able to successfully install software version 1.4.0 on your iSED or iSED ELITE analyzer by completing this form and faxing it to 401-737-4519 or emailing it to techservice@alcorscientific.com.

Facility Name: _____

Contact Person: _____

Analyzer Serial #: _____

Date Completed: _____



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