



July 06, 2018

Luminex Corporation
12212 Technology Blvd
Austin, Texas 78727

URGENT: FIELD SAFETY NOTICE
**Incorrect Sample Identification by ARIES® hand-held
Barcode Scanner**

**Subject: Field Investigation-ARIES® Systems ARIES®-M12V1-IVD & ARIES®-M6V1-IVD;
Hand-Held Barcode Scanner CN-0321-01 /JDK-2330**

Dear Valued Luminex Customer,

We have recently received a report through our complaint handling system regarding a potential discrepancy in the firmware for a subset of ARIES® System barcode scanners (CN-0321-01). You are receiving this letter because our records indicate that you may have received a barcode scanner affected by this recall at your facility. When the potentially affected barcode scanner is used on multiple ARIES® cassettes at the same time, the system may prepopulate the "Sample ID" field with a previously stored sample ID. This field will be overwritten by scanning or manually entering a sample, but in the event the ARIES cassette is not scanned, the prepopulated field may cause the incorrect association of sample identification to occur. To date, our internal investigation has only shown that the firmware version on one hand-held barcode scanner was the incorrect version of firmware approved for use with the ARIES® Systems.

Given that the ARIES® System barcode scanner (CN-0321-01 /JDK-2330 Rev B) has the potential to contribute to an incorrect result by creating the possibility that a Patient/Sample ID may be assigned to the wrong cassette, we are voluntarily initiating a recall to ensure no additional handheld scanners have this discrepant firmware. There have not been any adverse events associated with the use of the ARIES® System barcode scanners at this time.

To confirm whether or not your particular barcode scanner is affected, please verify the firmware version of the handheld barcode scanner by following the attached instructions. An affected unit will include the labeling "JDK-2330 Rev B" on the underside of the scanner AND will have firmware version PAACES00-002-R03 or CAACES00-002-R03. Please contact Technical Support if you identify a discrepant barcode scanner model.

Luminex Corporation

12212 Technology Blvd., Austin, TX 78727 USA

📞 1.877.785.2323 (US) 1.512.381.4397 (OUS/CANADA)

📞 512.219.5114

✉ support@luminexcorp.com

www.luminexcorp.com



If your barcode scanner identifies the following labeling/firmware version combination, please continue usage as normal, and complete the Acknowledge and Receipt Form attached to this letter.

| Correct Firmware | |
|------------------|------------------|
| Model/Rev. | Firmware Version |
| JDK-2330 Rev B. | PAACES00-001-R03 |
| | CAACES00-001-R03 |

If the incorrect firmware version is found, please contact Technical Support immediately at support@luminexcorp.com or by calling **1-877-785-2323**.

This recall is being made with the knowledge of the US Food and Drug Administration and Health Canada, and additional regulatory agencies may also be notified. This notice should be passed on to all who need to be aware within your organization.

Although no adverse events have been reported for the scanners, adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

We appreciate your assistance in this matter. Please call the Luminex Customer Experience Team if you have any questions or concerns.

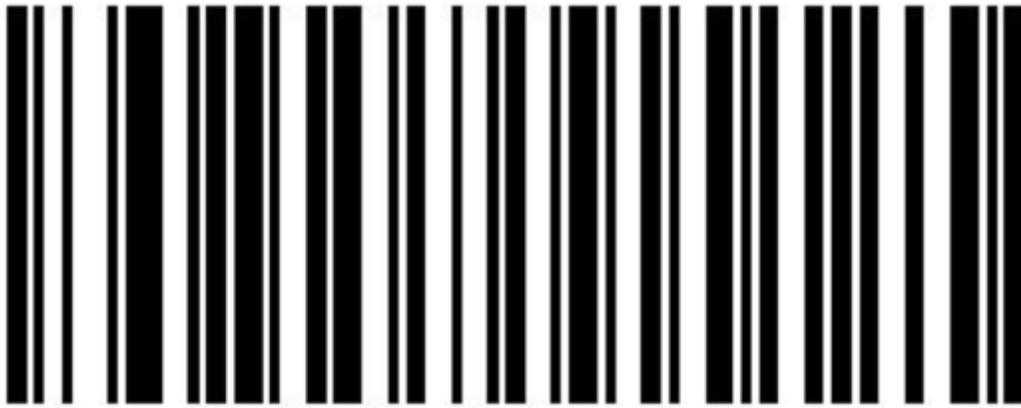
Luminex Customer Experience Team
1-877-785-2323 (U.S. and Canada)
+1-512-381-4397 (Outside U.S. and Canada)
CAN-0218 Rev A


Vice President, Global Regulatory & Clinical Affairs
Luminex Corporation



Confirming the Firmware Version on the ARIES Hand-Held Barcode Scanner

1. Connect the handheld scanner to a Windows PC/Laptop and allow it to power on (scanner will beep).
NOTE: If prompted, please do not upgrade Zebra firmware.
2. Open Microsoft Word or Notepad then copy and paste the following barcode into a blank document.



Report Firmware Version

3. Scan the barcode
NOTE: The scanner will read the barcode above and display the firmware version installed wherever the cursor is located on the open document (Word or Notepad).
4. Verify the firmware version installed using the table below, and print/PDF the page as evidence of the firmware confirmation process:

| Correct Firmware | |
|--------------------|------------------|
| Model/Rev. | Firmware Version |
| JDK-2330 Rev B. | PAACES00-001-R03 |
| | CAACES00-001-R03 |
| Incorrect Firmware | |
| JDK-2330 Rev. B | PAACES00-002-R03 |
| | CAACES00-002-R03 |

5. If the incorrect firmware version is found, please contact Technical Support at support@luminexcorp.com or by calling **1-877-785-2323**.
6. Complete the Product Recall Acknowledgment and Receipt Form (next page) and return to Luminex via email or fax (contact information located within footer on this page).



PRODUCT FIELD SAFETY CORRECTIVE ACTION

Acknowledgment and Receipt Form

PLEASE FILL OUT AND RETURN

RECALL - ARIES® System and ARIES M1® System Handheld Barcode Scanner

Manufacturer's Product Number/Catalog Number: ARIES-M12V1-IVD, ARIES® System

ARIES-M6V1-IVD, ARIES M1® System, CN-0321-01

UDI: ARIES System UDI: 00840487101537; ARIES M1 System UDI: 00840487100080

I have read and understand the recall instructions provided in **[CAN 0218]: URGENT MEDICAL DEVICE FIELD SAFETY** letter date **Jul 06, 2018** Yes No

Have you observed any adverse events associated with recalled product? Yes No

If yes, please explain:

Please select one of the following before returning this form and attach a copy of the firmware confirmation process:

- The scanner has the CORRECT firmware and a copy of the firmware confirmation process is attached
- The scanner has the INCORRECT firmware (**PAACES00-002-R03** or **CAACES00-002-R03**); a copy of the firmware confirmation process is attached

DATE: _____

COMPANY/Site NAME: _____

CONTACT NAME: _____

EMAIL ADDRESS: _____

NUMBER OF SCANNERS ASSESSED: _____

Luminex Corporation

12212 Technology Blvd., Austin, TX 78727 USA

📞 1.877.785.2323 (US) 1.512.381.4397 (OUS/CANADA)

📞 512.219.5114

📧 support@luminexcorp.com

www.luminexcorp.com