

VAŽNA OBAVIJEST O PROIZVODU

PROIZVOD	REF	VERZIJA SOFTVERA
UniCel DxH 800 Coulter Cellular Analysis System	629029, B24465, B24802, B68304	2.0.0.0 i više
UniCel DxH 600 Coulter Cellular Analysis System	B23858	1.0.0.0 i više
UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System	775222	1.5.0.0 i više

Dragi korisnici Beckman Coulter proizvoda,

Beckman Coulter Vam šalje ovu obavijest zbog mogućnosti da se ne pojavi alarm na DxH 800, DxH 600, i DxH Slidemaker Stainer instrumentima. Rezultati pacijenata nisu zahvaćeni ovim problemom.

PROBLEM	<p>DxH 800, DxH 600, i DxH Slidemaker Stainer možda neće obavijestiti korisnika o upozorenjima ili greškama vezanim za količinu preostalog reagensa, neprolazak dnevne kontrole za analizator, prekid veze s LIS-om ili printerom kod:</p> <ul style="list-style-type: none"> • Ikone o statusu upozorenja na upravitelju sustava • Zvučnog alarma na upravitelju sustava • Svjetla upozorenja na instrumentu <p>Greška se može javiti kada se aplikacija upravitelja sustava ponovno pokrene, isključili ili uključili.</p>
UTJECAJ	<p>Ova greška može uzrokovati:</p> <ul style="list-style-type: none"> • Da korisnik ne primjeti potrebu za zamjenom reagensa. • Instrument nastavlja s radom • Netočnost informacija o razinama reagensa prikazanih na zaslonu o potrošnom materijalu, rezultatima o prolasku dnevne kontrole i statusu veze s LIS-om i printerom.
RADNJA	<ul style="list-style-type: none"> • Pratite razinu i status reagensa na zaslonu za potrošni material. Polje o "preostalim ciklusima" se nalazi na dnu zaslona, iznad lokalne navigacijske trake. Polje će biti označeno žuto za upozorenje ili crveno za grešku kada je reagens potrošen ili pri kraju. • Pratite stanje LIS-a i/ili printera pomoću grafike na zaslonu sustava. Crvena, siva ili crna označavaju status koji ukazuje na moguće probleme unutar grafike.
RJEŠENJE	Ovaj softverski kvar će biti ispravljen u budućoj softverskoj inačici.

IPN-27736



Molimo Vas da ove informacije podijelite s osobljem svog laboratorija. Ovu obavijest zadržite u dokumentaciji sustava kontrole kvalitete laboratorija. Ako ste bilo koji od navedenih proizvoda proslijedili u drugi laboratorij, osigurajte im kopiju ovog dopisa.

Ispunite Obrazac o potvrdi primitka i vratite nam ga unutar 10 dana kako bismo bili sigurni da ste primili ovu važnu informaciju.

Beckman Coulter upravlja logističkim postupkom ove obavijesti.
Ako imate dodatnih pitanja u vezi s ovom obavijesti, obratite nam se:

- Putem naše web stranice: <http://www.beckmancoulter.com>
- Telefonski putem centralnog broja: 01/4899-011

Ispričavamo se ako je ovaj problem izazvao poteškoće u radu Vašeg laboratorija.

S poštovanjem,

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs

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Beckman Coulter, Inc.
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Mailing Address:
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Customer Service: (800) 526-7694
Product Information: (800) 526-6932
(800) 327-6531 (305) 380-3800
Internet : www.beckmancoulter.com



April 05, 2016

IMPORTANT PRODUCT NOTICE

PRODUCT	REF	SOFTWARE VERSION
UniCel DxH 800 Coulter Cellular Analysis System	629029; B24465, B24802; B68304	2.0.0.0 and greater
UniCel DxH 600 Coulter Cellular Analysis System	B23858	1.0.0.0 and greater
UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System	775222	1.5.0.0 and greater

Dear Beckman Coulter Customer,

Beckman Coulter is sending you this letter because of possible alarm notification failures for the DxH 800, DxH 600, and DxH Slidemaker Stainer instruments. Test values are not affected.

ISSUE	<p>The DxH 800, DxH 600, and DxH Slidemaker Stainer may fail to notify the user of warnings or error conditions for low or depleted reagent conditions, Daily Checks failures, LIS disconnection, and Printer failures at:</p> <ul style="list-style-type: none"> • The Alert Status icon(s) on the System Manager • The audible alarm at the System Manager • The instrument beacon on the Specimen Processing Module or Slidemaker Stainer <p>The failure may occur when the System Manager application is restarted or powered OFF/ON.</p>
IMPACT	<p>When the failure occurs:</p> <ul style="list-style-type: none"> • The user may not notice the need to change reagents before depletion. • Instrument operation will continue. • Information about reagent levels shown on the Supplies screen, results on the Daily Checks screen, and the status of the LIS connection and Printer on the System Status screen are correct.
ACTION	<ul style="list-style-type: none"> • Monitor the reagent levels and status on the reagent Supplies screen. The 'Cycles Remaining' field is located at the bottom of the screen, above the local navigation buttons. The field will be highlighted yellow (warning) or red (error) when a reagent is low or depleted. • Monitor the status of the LIS and/or Printer using their graphics on the System Status screen. Red, gray, or black status spheres within a graphic indicate possible concerns.
RESOLUTION	This software defect will be corrected in a future software release.

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Share this information with your laboratory staff and retain this notice as part of your laboratory Quality System documentation. If you have forwarded the affected product to another laboratory, please provide them with a copy of this letter.

Complete and return the enclosed response form within 10 days so that we are assured you have received this important communication.

If you have any questions regarding this notice, contact our Customer Support Center:

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via phone call 800-526-7694 in the United States and Canada
- Outside the United States and Canada, contact your local Beckman Coulter Representative

We apologize for the inconvenience to your laboratory.

Sincerely,

A handwritten signature in black ink, appearing to read "Marwan Fathallah", with a horizontal line underneath.

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs
Encl: Response Form

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