



31. srpnja 2026.

HITNA SIGURNOSNA OBAVIJEST
BECKMAN COULTER BIOKEMIJSKI ANALIZATOR AU480

Analizator	REF	UDI	Serijski broj
BECKMAN COULTER BIOKEMIJSKI ANALIZATOR AU480	Pogledajte Prilog A za zahvaćeni instrument		

Jedinstveni broj registracije (SRN): US-MF-000010288

Poštovani korisniče Beckman Coulter proizvoda,

Beckman Coulter pokreće terensku sigurnosnu korektivnu mjeru za gore navedeni proizvod. Ova obavijest sadrži važne informacije koje zahtijevaju vašu hitnu pozornost.

PROBLEM:	Tvrtka Beckman Coulter utvrdila je da biokemijski analizator AU480 s gore navedenim računalima s operativnim sustavom Windows 10 IoT Enterprise 2021 LTSC može prikazati poruku "System Stopped By Fatal Error: DBConnectionError AlarmDB" pri pokretanju softvera instrumenta na računalu s prethodno instaliranim sustavom Microsoft® SQL Server® 2022 Express. (Pogledajte sliku 1.) Kada se to dogodi, datoteka AlarmDB postaje nečitljiva i softver instrumenta se ne može pokrenuti. Uzrok ovog problema je obrada koju SQL Server izvršava prilikom automatskog povećanja broja zapisa (logova). Naša je istraga potvrdila da je vjerojatnost pojave ovog problema veća kada se novi indeks ne stvara svakodnevno. Zapisi vezani za alarme i rad na analizatoru se brišu prilikom prebacivanja indeksa. Brisanje zapisa za više dana odjednom povećava opterećenje sustava i može uzrokovati navedeni problem. Slika 1
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UTJECAJ:	- Ako alternativna metoda mjerenja nije dostupna, u najgorem slučaju kašnjenje u izdavanju rezultata pacijenta može dovesti do odgode dijagnoze i/ili liječenja pacijenta. - Ovaj problem ne uzrokuje netočne rezultate pretraga.
AKCIJA:	- Obavezno kreirajte novi indeks jednom ili više puta dnevno u odgovarajuće vrijeme. Molimo pogledajte odjeljak "5.1 Pokretanje sustava" u uputama za korištenje kako biste dovršili ovu radnju. Daily Startup 5 5.1 Start the System Figure 5.2 3 Select the Index and Group of Tests as needed. - Select New Index to create a new index, or Index to return to the previous index. - Select the group of tests to process from the "Group of Tests" drop-down list. - Select OK. The Home menu displays. Beckman Coulter preporučuje da se ova obavijest postavi na zahvaćene analizatore ili u njihovoj blizini.



RJEŠENJE:	Beckman Coulter utvrdio je osnovni uzrok problema te će ga riješiti primjenom softverskog rješenja na zahvaćene sustave. Servisni tim Beckman Coultera kontaktirat će vas radi dogovora o terminu primjene softverskog rješenja, a servisni inženjer (FSE) izvršit će radove na lokaciji.
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Nadležno nacionalno tijelo obaviješteno je o ovoj terenskoj sigurnosnoj korektivnoj mjeri.

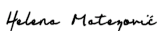
Molimo vas da ove informacije podijelite sa svojim laboratorijskim osobljem te da ovu obavijest pohranite kao dio dokumentacije sustava kvalitete vašeg laboratorija. Ako ste bilo koji od gore navedenih proizvoda prosljedili drugom laboratoriju, molimo dostavite im kopiju ovog pisma.

Molimo da ispunite i vratite priloženi obrazac odgovora u roku od 10 dana kako bismo bili sigurni da ste zaprimili ovu važnu obavijest.

Ako imate bilo kakvih pitanja vezanih uz ovu obavijest, molimo kontaktirajte naš Centar za korisničku podršku.

- Putem naše internetske stranice: <http://www.beckmancoulter.com>
- Lokalnog Beckman Coulter predstavnika

Ispričavamo se zbog neugodnosti koje je ovaj problem mogao prouzročiti vašem laboratoriju. S poštovanjem,

Signed by:

 Signer Name: Helena Matezović
 Signing Reason: I approve this document
 Signing Time: 10-Aug-2026 | 1:18:33 AM PDT
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Helena Matezović
 Beckman Coulter d.o.o.
 Odjel za kvalitetu i regulatorne poslove

Prilog: Obrazac za odgovor

Beckman Coulter, stilizirani logo i nazivi Beckman Coulter proizvoda i usluga navedeni ovdje zaštitni su znakovi ili registrirani zaštitni znakovi tvrtke Beckman Coulter, Inc. u Sjedinjenim Američkim Državama i drugim zemljama.

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Prilog A

Serijski brojevi isporučeni s prethodno instaliranim sustavom Microsoft® SQL Server® 2022 Express.

Analizator: BECKMAN COULTER CHEMISTRY ANALYZER AU480

REF	UDI	Serijski broj
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Serijski brojevi kod kojih je računalo zamijenjeno novim računalom s Microsoft® SQL Server® 2022 Express.

Analizator: BECKMAN COULTER CHEMISTRY ANALYZER AU480

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* Zbog starosti uređaja i činjenice da je istekao njegov rok skladištenja, UDI broj nije dostupan.

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