



08. rujna 2026.

HITNA SIGURNOSNA OBAVIJEST

DxC 500i klinički analizator

Konfiguracija	Analizator modula	REF	UDI	Softver
S ISE-om	DxC 500 AU modul s ISE, DxC 500i	C63522	14987666545089	1.3.5 ili ranije
Bez ISE	DxC 500 AU modul, DxC 500i	C63521	14987666545072	1.3.5 ili ranije

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

Poštovani korisniče Beckman Coulter proizvoda,

Beckman Coulter pokreće korektivnu sigurnosnu akciju na terenu za gore navedeni proizvod. Ovo pismo sadrži važne informacije koje zahtijevaju vašu hitnu pažnju.

PROBLEM:	Beckman Coulter je utvrdio softverski problem koji utječe na DxC 500i kliničke analizatore pri testiranju uzoraka plazme. Nakon što korisnik konfigurira biokemijski test s mjernim jedinicama različitim od zadanih postavki sustava, naknadna promjena konfiguracije i aktivacija privremene konfiguracije na stranici Postavke sustava (System Configuration) može uzrokovati da se jedinice testa vrate na zadane postavke sustava bez obavješćavanja korisnika. Sustav ne pruža upozorenje ili obavijest koja bi korisnika obavijestila da su konfigurirane jedinice vraćene na zadane jedinice. Napomena: U skladu s Uputama za uporabu (IFU), materijali za kontrolu kvalitete (QC) trebali bi se analizirati nakon promjena u konfiguraciji. Provjera i pregled rezultata kontrole kvalitete (QC) nakon svake promjene u konfiguraciji sustava omogućit će korisnicima otkrivanje nenamjernih povrata na zadane mjerne jedinice i identificiranje problema prije izvješćavanja o rezultatima pacijenata.
UTJECAJ:	- Ovaj problem može dovesti do lažno povišenih prijavljenih rezultata za sljedeće biokemijske pretrage: albumin, bikarbonat, kalcij-arsenazo, kolesterol, glukoza, HDL-kolesterol, anorganski fosfati, laktat, LDL-kolesterol, magnezij, trigliceridi i ureja. - Ova greška ne utječe na druge kemijske pretrage. - Imunokemijski testovi Access nisu pogođeni. - Kada se ovaj problem pojavi, analizator ispravno obrađuje uzorke pacijenata i prikazuje rezultate koristeći zadane jedinice sustava.



	Međutim, nenamjenski povrat na izvorne jedinice može dovesti do sljedećih neusklađenosti: 1. Utjecaj označavanja na analizatoru - Analizator će prikazati numerički rezultat generiran pomoću zadane jedinice sustava (npr. mg/dL). - Oznake rezultata (npr. Visoko [H]) generirat će se na temelju korisnički konfigurirane jedinice. - Kao rezultat, prikazani numerički rezultat pojavit će se u zadanoj jedinici sustava (npr. mg/dL), dok se oznaka primjenjuje prema granicama jedinice koje je korisnik postavio (npr. mmol/L). - Korisnici možda neće prepoznati nesklad između prikazanog rezultata i pripadajuće oznake, što može dovesti do pogrešnog tumačenja rezultata. 2. Utjecaj laboratorijskog informacijskog sustava (LIS) - Analizator izračunava i prenosi numeričke rezultate koristeći zadane sustavne jedinice (npr. mg/dL). - Ako je LIS konfiguriran za prikaz testa koristeći korisnički konfiguriranu jedinicu (npr. mmol/L), LIS će prikazati numeričku vrijednost generiranu analizatorom zajedno s nazivom korisnički konfigurirane jedinice. - U ovom scenariju numerički rezultat ne bi bio pretvoren u očekivanu mjeru, što rezultira netočno izviještenom vrijednošću. - U LIS-u se ne generiraju nikakve oznake ili upozorenja koja bi ukazivala na neskladnost. - Pacijent može biti podvrgnut nepotrebnom medicinskom liječenju i dodatnim neinvazivnim pretragama. - Na rezultate generirane na verziji softvera 1.5 nema utjecaja.
AKCIJA:	- Beckman Coulter preporučuje da sadržaj ovog pisma podijelite sa svojim laboratorijskim i/ili medicinskim direktorom kako biste procijenili utjecaj na laboratorij i pacijente. - Za analizatore s verzijama softvera starijim od 1.5: - Korisnici bi trebali provjeriti prikazuju li njihovi instrumenti namjeravane jedinice na stranici Izbornik testova (Test Menu) unutar stranice Konfiguracija sustava (System Configuration) prije izvještavanja o rezultatima pacijenata. - Beckman Coulter preporučuje objavljivanje ovog pisma na ili u blizini pogođenih analizatora ako imaju pogođenu verziju softvera.
RIJEŠENJE:	- Ovaj problem je riješen u softverskoj verziji 1.5. - Ako vaš analizator trenutno radi na verziji softvera starijoj od 1.5, vaš će vas predstavnik Beckman Coulter servisa kontaktirati kako biste dogovorili nadogradnju na verziju softvera 1.5.

Nacionalno nadležno tijelo obaviješteno je o ovoj korektivnoj akciji na terenu.



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

Molimo ispunite i vratite priloženi Obrazac za odgovor u roku od 10 dana kako bismo bili sigurni da ste primili ovu važnu obavijest.

Ako imate bilo kakvih pitanja u vezi s ovim obavještenjem, obratite se našem Centru za korisničku podršku.

Ispričavamo se zbog neugodnosti koju je ovo prouzročilo vašem laboratoriju.

S poštovanjem,

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