

03. srpnja 2023.

HITNO: SIGURNOSNA OBAVIJEST – MMS-23-4760

Pristupna radna stanica BD Alaris™

REF: Vidjeti Dodatak 1 **Brojevi serije:** Svi brojevi serije

Vrsta radnje: savjetodavna

**Dostaviti: kliničkom osoblju, voditeljima upravljanja rizikom,
biomedicinskom osoblju, voditeljima nabave**

Ovo pismo sadrži važne informacije koje zahtijevaju vašu **hitnu** pozornost.

Poštovani korisniče / poštovana korisnice,

BD izdaje savjetodavnu sigurnosnu obavijest za **pristupnu radnu stanicu BD Alaris™**. Prema našoj evidenciji distribucije postoji mogućnost da je vaša organizacija primila proizvode navedene u Dodatku 1.

Ova je savjetodavna obavijest ograničena na šifre proizvoda navedene u Dodatku 1. Druge šifre proizvoda nisu obuhvaćene.

Opis problema

BD je testiranjem proizvoda utvrdio da **pristupna radna stanica BD Alaris™** više ne može pružiti zaštitu od prodora tekućine prema međunarodnom standardu IP22/IPX1. Dakle, BD pruža ovu Sigurnosnu obavijest zahvaćenim kupcima kako bi se ponovno nametnula upotreba postojećih uputa za uporabu (DFU) i tehnički priručnik za servisiranje (TSM) kako bi se smanjio mogući prodor tekućine.

Klinički rizik

Da bi se dogodila opasna situacija, mora postojati jedno stanje kvara, tekućina mora ući u utičnicu za izmjeničnu struju na pločici sučelja medicinskog uređaja (MDI), a korisnik mora doći u izravan kontakt s utičnicom za izmjeničnu struju. Utičnica za izmjeničnu struju na svakoj pločici MDI-a opremljena je osiguračem. Ako dođe do kratkog spoja kao rezultat prodora tekućine, osigurač prekida otvoreni krug i izmjenično napajanje pločice (pogledajte Dodatak 2 za referentnu sliku pristupne radne stanice BD Alaris™).

Vjerojatnost nastanka opasne situacije smatrala se neočekivanom i ukupna vjerojatnost nastanka štete kao posljedica ovog problema je malo vjerojatna. Svako stanje ima mjere rješavanja opisane u Uputama za uporabu (DFU) (za više informacija pogledajte odjeljak Savjeti za kliničke korisnike).

Do danas nije bilo izvješća o štetnim događajima koji bi mogli biti povezani s ovim problemom.

Kupci nisu dužni vratiti bilo koju pristupnu radnu stanicu BD Alaris™ tvrtki BD. Navedeni proizvodi mogu se i dalje upotrebljavati u skladu s uputama u ovoj sigurnosnoj obavijesti.

Radnje koje poduzima tvrtka BD:

BD je pokrenuo istragu radi utvrđivanja osnovnog uzroka i definiranja korektivnih radnji.

Buduće pošiljke **pristupne radne stanice BD Alaris™** bit će označene zahtjevom za IP20 (zaštićeno od čvrstih stranih predmeta promjera 12,5 mm i većeg, bez zaštite od prodora tekućine).

Savjeti za biomedicinske djelatnike:

Nastavite slijediti postojeći tehnički priručnik za servisiranje (BDTM00004 2. izdanje) za aktivnosti servisiranja/popravka **pristupne radne stanice BD Alaris™ tvrtke BD**. Konkretno, sljedeće upute: „Ne postavljajte radnu stanicu tamo gdje bi njezin ulaz ili izlazi za izmjeničnu struju mogli biti izloženi izlivanje tekućine”.

Savjeti za kliničke korisnike:

Nastavite upotrebljavati **pristupnu radnu stanicu BD Alaris™** u skladu s primjenjivim, postojećim uputama za uporabu.

- U skladu s odjeljkom „Mjere opreza” uklonite **pristupnu radnu stanicu BD Alaris™** iz uporabe kako bi je pregledalo kvalificirano servisno osoblje ako postoji prekomjerna vlaga ili prolijevanje tekućine.
- U skladu s odjeljkom „Uklanjanje pumpe”, ako indikator u pločici MDI svijetli kada na pločicu MDI nije pričvršćena infuzijska pumpa, posumnajte na kvar s pločicom MDI. Uklonite radnu stanicu iz upotrebe i obratite se kvalificiranom servisnom osoblju.

Radnje korisnika:

- Pregledajte informacije u **Dodatku 1** kako biste utvrdili je li **pristupna radna stanica BD Alaris™** u vašem posjedu.
- Ispunite i vratite Obrazac za odgovor korisnika čak i ako više nemate preostalih zaliha u svom objektu do **31. srpnja 2023.**
- Prosljedite ovu obavijest svima u svojoj organizaciji koji o njoj moraju biti obaviješteni ili bilo kojoj organizaciji u koju su sporni proizvodi preneseni.
- Ako imate bilo kakvih problema s **pristupnom radnom stanicom BD Alaris™**, uputite pritužbu u skladu s uobičajenim postupkom.



Radnje distributera:

- Pregledajte informacije u **Dodatku 1** i utvrdite je li **pristupna radna stanica BD Alaris™** u vašem posjedu.
- Utvrdite u koje ste ustanove distribuirali sporni proizvod i odmah im prosljedite ovu obavijest.
 - Neka vaši klijenti ispune i vrate obrazac za odgovor korisnika vašoj organizaciji u svrhu usklađivanja do **31. srpnja 2023.**
- Ispunite i vratite Obrazac za odgovor korisnika nakon dovršetka radnji usklađivanja.
- Ako imate bilo kakvih problema s **pristupnom radnom stanicom BD Alaris™**, uputite pritužbu u skladu s uobičajenim postupkom.

	Krajnji korisnik s inventarom	Krajnji korisnik s NULTIM inventarom	Gdje poslati ispunjeni obrazac
Kupljeno izravno od tvrtke BD	Ispunite obrazac u cijelosti i osigurajte da su sve preporučene radnje provedene prema potrebi.	Ispunite obrazac u cijelosti i zadržite kopiju ove obavijesti za svoju evidenciju	henrietta.lazanyi@bd.com
Kupljeno od distributera/3 strane	Ispunite obrazac u cijelosti i osigurajte da su sve preporučene radnje provedene prema potrebi.	Ispunite obrazac u cijelosti i zadržite kopiju ove obavijesti za svoju evidenciju	Vratite obrazac svom distributeru/3 strani

Referentna osoba za kontakt

Ako imate bilo kakvih pitanja o ovome, obratite se lokalnom predstavniku tvrtke BD ili lokalnom uredu tvrtke BD na +36301633166 ili putem e-pošte henrietta.lazanyi@bd.com.

Potvrđujemo da su odgovarajuće regulatorne agencije obaviještene o ovim mjerama.

Tvrtka BD posvećena je unaprjeđivanju svijeta zdravlja. Naši su glavni ciljevi sigurnost pacijenata i korisnika te pružanje kvalitetnih proizvoda. Ispričavamo se zbog neugodnosti koje Vam je ova situacija možda prouzročila i unaprijed Vam zahvaljujemo za pomoć tvrtki BD u rješavanju navedenog problema na najbrži i najučinkovitiji mogući način.

S poštovanjem,

Lorna Darrock
Pomoćnica direktora, Odjel za upravljanje kvalitetom proizvoda nakon stavljanja na tržište
EMEA kvaliteta



Obrazac za odgovor korisnika – MMS-23-4760

Pristupna radna stanica BD Alaris™

REF: Vidjeti Dodatak 1 **Brojevi serije:** Svi brojevi serije

Vratite na adresu henrietta.lazanyi@bd.com što prije, a **najkasnije 31. srpnja 2023.**

Potpisivanjem u nastavku potvrđujete da je ova Sigurnosna obavijest pročitana, shvaćena i da su sve preporučene radnje provedene prema potrebi.

Naziv računa/organizacije:	
Odjel (<i>ako je primjenjivo</i>):	
Adresa:	
Poštanski broj:	Grad:
Ime kontakta:	
Naziv radnog mjesta:	
Broj telefona za kontakt:	Adresa e-pošte za kontakt:
Naziv vašeg dobavljača za ovaj proizvod (<i>ako nije kupljen izravno od tvrtke BD</i>)*	
Potpis:	Datum:

Ovaj obrazac mora biti vraćen tvrtki BD prije nego što se ova radnja može smatrati zatvorenom za vaš račun.

**Ako vam je ova Sigurnosna obavijest prosljeđena putem distributera/3. strane, molimo vas da ispunjeni obrazac vratite toj organizaciji u svrhu usklađivanja.*

Dodatak 1 – Sporni proizvod

Jedinstveni registracijski broj proizvođača (SRN): CH-MF-000026539

Kataloški (REF) br.	Opis proizvoda	UDI-DI
80203UNS01-035	Alaris™ Gateway Workstation 0x3x5 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-235	Alaris™ Gateway Workstation 2x3x5 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-30	Alaris™ Gateway Workstation 3x0 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-32	Alaris™ Gateway Workstation 3x2 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-33	Alaris™ Gateway Workstation 3x3 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-34	Alaris™ Gateway Workstation 3x4 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-50	Alaris™ Gateway Workstation 5x0 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-52	Alaris™ Gateway Workstation 5x2 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-53	Alaris™ Gateway Workstation 5x3 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-54	Alaris™ Gateway Workstation 5x4 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-70	Alaris™ Gateway Workstation 7x0 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-72	Alaris™ Gateway Workstation 7x2 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-73	Alaris™ Gateway Workstation 7x3 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-74	Alaris™ Gateway Workstation 7x4 Configuration without intelligent base unit	N/A – Released prior to UDI being assigned.
80203UNS01-92	Alaris™ Gateway Workstation 9x2 Configuration	N/A – Released prior to UDI being assigned.
80203UNS02-035	Alaris™ Gateway Workstation 0x3x5 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-235	Alaris™ Gateway Workstation 2x3x5 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-30	Alaris™ Gateway Workstation 3x0 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-32	Alaris™ Gateway Workstation 3x2 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-33	Alaris™ Gateway Workstation 3x3 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-34	Alaris™ Gateway Workstation 3x4 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-50	Alaris™ Gateway Workstation 5x0 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-52	Alaris™ Gateway Workstation 5x2 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-53	Alaris™ Gateway Workstation 5x3 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-54	Alaris™ Gateway Workstation 5x4 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-70	Alaris™ Gateway Workstation 7x0 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-72	Alaris™ Gateway Workstation 7x2 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.



80203UNS02-73	Alaris™ Gateway Workstation 7x3 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-74	Alaris™ Gateway Workstation 7x4 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80203UNS02-92	Alaris™ Gateway Workstation 9x2 Configuration with the wired Ethernet communication capability and bar code reader interface	N/A – Released prior to UDI being assigned.
80223UNS02-30	Alaris™ Gateway Workstation 3x0 Configuration with wired Ethernet connectivity to ACE	10885403478659
80223UNS02-035	Alaris™ Gateway Workstation 0x3x5 Configuration with wired Ethernet connectivity to ACE	10885403478789
80223UNS02-32	Alaris™ Gateway Workstation 3x2 Configuration with wired Ethernet connectivity to ACE	10885403478666
80223UNS02-33	Alaris™ Gateway Workstation 3x3 Configuration with wired Ethernet connectivity to ACE	10885403478673
80223UNS02-34	Alaris™ Gateway Workstation 3x4 Configuration with wired Ethernet connectivity to ACE	10885403478680
80223UNS02-50	Alaris™ Gateway Workstation 5x0 Configuration with wired Ethernet connectivity to ACE	10885403478697
80223UNS02-52	Alaris™ Gateway Workstation 5x2 Configuration with wired Ethernet connectivity to ACE	10885403478703
80223UNS02-53	Alaris™ Gateway Workstation 5x3 Configuration with wired Ethernet connectivity to ACE	10885403478710
80223UNS02-54	Alaris™ Gateway Workstation 5x4 Configuration with wired Ethernet connectivity to ACE	10885403478727
80223UNS02-70	Alaris™ Gateway Workstation 7x0 Configuration with wired Ethernet connectivity to ACE	10885403478734
80223UNS02-72	Alaris™ Gateway Workstation 7x2 Configuration with wired Ethernet connectivity to ACE	10885403478741
80223UNS02-73	Alaris™ Gateway Workstation 7x3 Configuration with wired Ethernet connectivity to ACE	10885403478758
80223UNS02-74	Alaris™ Gateway Workstation 7x4 Configuration with wired Ethernet connectivity to ACE	10885403478765
80223UNS02-92	Alaris™ Gateway Workstation 9x2 Configuration with wired Ethernet connectivity to ACE	10885403478772
80223UNS02-235	Alaris™ Gateway Workstation 2x3x5 Configuration with wired Ethernet connectivity to ACE	10885403478796
80203UNS03-30	Alaris™ Gateway Workstation 3x0 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-32	Alaris™ Gateway Workstation 3x2 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-33	Alaris™ Gateway Workstation 3x3 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-34	Alaris™ Gateway Workstation 3x4 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-50	Alaris™ Gateway Workstation 5x0 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-52	Alaris™ Gateway Workstation 5x2 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-53	Alaris™ Gateway Workstation 5x3 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-54	Alaris™ Gateway Workstation 5x4 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-70	Alaris™ Gateway Workstation 7x0 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-72	Alaris™ Gateway Workstation 7x2 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-73	Alaris™ Gateway Workstation 7x3 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80203UNS03-74	Alaris™ Gateway Workstation 7x4 Configuration with a wireless communications interface	N/A – Released prior to UDI being assigned.
80300UNS01-035	Alaris™ Gateway Workstation 0x3x5 Configuration without intelligent base unit	10885403478611
80300UNS01-235	Alaris™ Gateway Workstation 2x3x5 Configuration without intelligent base unit	10885403478635
80300UNS01-30	Alaris™ Gateway Workstation 3x0 Configuration without intelligent base unit	10885403478239



80300UNS01-32	Alaris™ Gateway Workstation 3x2 Configuration without intelligent base unit	10885403478246
80300UNS01-33	Alaris™ Gateway Workstation 3x3 Configuration without intelligent base unit	10885403478253
80300UNS01-34	Alaris™ Gateway Workstation 3x4 Configuration without intelligent base unit	10885403478260
80300UNS01-50	Alaris™ Gateway Workstation 5x0 Configuration without intelligent base unit	10885403478277
80300UNS01-52	Alaris™ Gateway Workstation 5x2 Configuration without intelligent base unit	10885403478284
80300UNS01-53	Alaris™ Gateway Workstation 5x3 Configuration without intelligent base unit	10885403478291
80300UNS01-54	Alaris™ Gateway Workstation 5x4 Configuration without intelligent base unit	10885403478307
80300UNS01-70	Alaris™ Gateway Workstation 7x0 Configuration without intelligent base unit	10885403478314
80300UNS01-72	Alaris™ Gateway Workstation 7x2 Configuration without intelligent base unit	10885403478321
80300UNS01-73	Alaris™ Gateway Workstation 7x3 Configuration without intelligent base unit	10885403478338
80300UNS01-74	Alaris™ Gateway Workstation 7x4 Configuration without intelligent base unit	10885403478345
80300UNS01-92	Alaris™ Gateway Workstation 9x2 Configuration without intelligent base unit	10885403478352
80300UNS02-035	Alaris™ Gateway Workstation 0x3x5 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478628
80300UNS02-235	Alaris™ Gateway Workstation 2x3x5 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478642
80300UNS02-30	Alaris™ Gateway Workstation 3x0 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478369
80300UNS02-32	Alaris™ Gateway Workstation 3x2 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478376
80300UNS02-33	Alaris™ Gateway Workstation 3x3 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478383
80300UNS02-34	Alaris™ Gateway Workstation 3x4 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478390
80300UNS02-50	Alaris™ Gateway Workstation 5x0 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478406
80300UNS02-52	Alaris™ Gateway Workstation 5x2 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478413
80300UNS02-53	Alaris™ Gateway Workstation 5x3 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478420
80300UNS02-54	Alaris™ Gateway Workstation 5x4 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478437
80300UNS02-70	Alaris™ Gateway Workstation 7x0 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478444
80300UNS02-72	Alaris™ Gateway Workstation 7x2 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478451
80300UNS02-73	Alaris™ Gateway Workstation 7x3 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478468
80300UNS02-74	Alaris™ Gateway Workstation 7x4 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478475
80300UNS02-92	Alaris™ Gateway Workstation 9x2 Configuration with the wired Ethernet communication capability and bar code reader interface	10885403478482

Dodatak2 – Referentna slika pristupne radne stanice BD Alaris™

