

06. julij 2023

NUJNO: VARNOSTNO OBVESTILO – MMS-23-4760

Delovna postaja BD Alaris™ Gateway

REF: Glejte številke **serij iz dodatka 1**: Vse številke serij

Vrsta ukrepa: Opozorilo

Za: klinično osebje, upravljavci tveganj, biomedicinsko osebje, vodje nabave

Ta dopis vsebuje pomembne informacije, ki jim je treba nameniti **takojšnje** pozornost.

Spoštovana stranka,

družba BD izdaja svetovalno varnostno obvestilo za **delovno postajo BD Alaris™ Gateway**. Naši distribucijski sezname kažejo, da je vaša organizacija morda prejela zadevni izdelek, naveden v prilogi 1.

To opozorilo je omejeno na kode izdelkov, navedene v prilogi 1. Ukrep ne vpliva na druge kode izdelkov.

Opis težave

Družba BD je s preskušanjem izdelka ugotovila, da **delovna postaja BD Alaris™ Gateway** več ne more zagotavljati zaščite pred vdorom tekočine v skladu z mednarodnim standardom IP22/IPX1. Zato družba BD prizadetim strankam izdaja to varnostno obvestilo, da se ponovno uveljavi upoštevanje obstoječih navodil za uporabo (DFU) in tehničnega servisnega priročnika (TSM) za zmanjšanje morebitnega vdora tekočine.

Klinično tveganje

Za pojav nevarne situacije mora biti prisotna ena napaka, tj. tekočina mora vdreti v napajalni vhod z izmeničnim tokom na plošči vmesnika medicinskega pripomočka (MDI), uporabnik pa mora priti v neposreden stik z napajalnim vhodom z izmeničnim tokom. Napajalni vhod z izmeničnim tokom na vsaki plošči MDI je opremljen z varovalko. Če pride do kratkega stika zaradi vdora tekočine, bo varovalka prešla v odprt tokokrog in prekinila izmenično napajanje plošče (glejte prilogo 2 za referenčno sliko delovne postaje BD Alaris™ Gateway).

Verjetnost za pojav nevarne situacije je bila opredeljena kot nepričakovano, splošna verjetnost za škodo, ki bi nastala kot posledica te težave, pa je nizka. Vsak pogoj je povezan z ublažitvami, opisanimi v Navodilih za uporabo (DFU) (za več informacij glejte razdelek »Nasveti za klinične uporabnike«).



Do danes ni bilo poročil o neželenih dogodkih, ki bi lahko bili povezani s to težavo.

Strankam delovne postaje BD Alaris™ Gateway ni treba vrniti družbi BD. Te izdelke lahko še naprej uporabljate v skladu z navodili v tem varnostnem obvestilu.

Ukrepi družbe BD:

Družba BD je sprožila preiskavo, da bi ugotovila temeljni vzrok in opredelila korektivne ukrepe.

Prihodnje pošiljke **delovne postaje BD Alaris™ Gateway** bodo označene z zahtevkom za IP20 (zaščita pred trdnimi tujki premera 12,5 mm in več ter brez zaščite pred vdorom tekočine).

Nasveti za biomedicinsko osebje:

Nadaljujte z upoštevanjem obstoječega TSM (BDTM00004, 2. izdaja) za servisiranje/popravila **delovne postaje BD Alaris™ Gateway**. Zlasti naslednje navodilo: »Ne postavljajte delovne postaje na mesto, kjer bi lahko bil napajalni vhod ali izhod z izmeničnim tokom izpostavljen razlitju tekočine.«

Nasveti za klinične uporabnike:

Svojo **delovno postajo BD Alaris™ Gateway** naprej uporabljajte v skladu z veljavnimi, obstoječimi DFU.

- V razdelku »*Odstrani črpalke*« **delovno postajo BD Alaris™ Gateway** umaknite iz obratovanja, da jo usposobljeno servisno osebje pregleda za morebitno odvečno vlago ali razlitje tekočine.
- V razdelku »*Odstranjevanje črpalke*«, če indikator v ploščici MDI sveti, ko na ploščico MDI ni pritrjena infuzijska črpalka, sumite na napako na ploščici MDI. Delovno postajo umaknite iz obratovanja in se obrnite na usposobljeno servisno osebje.

Ukrepi stranke:

- Preglejte informacije v **prilogi 1**, da ugotovite, ali zadeva **delovno postajo BD Alaris™ Gateway**, ki jo imate.
- Izpolnite in vrnite obrazec za odziv stranke, tudi če do **31. julija 2023** v vaši ustanovi ni več nobene zaloge.
- Posredujte to obvestilo vsem v vaši organizaciji, ki morajo biti o tem seznanjeni, ali kateri koli drugi organizaciji, kateri so bili predani potencialno zadevni izdelki.
- Če imate kakršne koli težave z **delovno postajo BD Alaris™ Gateway**, prijavite pritožbo v skladu z običajnim postopkom.

Ukrepi distributerja:

- Preglejte informacije v **prilogi 1**, da ugotovite, ali zadeva **delovno postajo BD Alaris™ Gateway**, ki jo imate.
- Opredelite objekte, katerim ste dobavili zadevni izdelek, in jih nemudoma obvestite o tem obvestilu.
 - Vaše stranke naj izpolnijo in vrnejo obrazec za odziv stranke vaši organizaciji za namene usklajevanja do **31. julija 2023**.
- Izpolnite in vrnite obrazec za odgovor stranke po zaključku vaših dejavnosti usklajevanja.
- Če imate kakršne koli težave z **delovno postajo BD Alaris™ Gateway**, prijavite pritožbo v skladu z običajnim postopkom.

	Končni uporabnik z zalogo	Končni uporabnik brez zaloge	Kam poslati izpolnjen obrazec
Kupljeno neposredno od družbe BD	Izpolnite obrazec v celoti in zagotovite, da so bili vsi priporočeni ukrepi izvedeni, kot je bilo zahtevano.	Izpolnite obrazec v celoti in shranite kopijo tega obvestila za svoje evidence	henrietta.lazanyi@bd.com
Kupljeno pri distributerju/tretji osebi	Izpolnite obrazec v celoti in zagotovite, da so bili vsi priporočeni ukrepi izvedeni, kot je bilo zahtevano.	Izpolnite obrazec v celoti in shranite kopijo tega obvestila za svoje evidence	Obrazec vrnite svojemu distributerju/tretji osebi



BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Švica
Tel.: +41 21 556 30 00
Faks: +41 21 556 30 99
www.BD.com

Kontaktna referenčna oseba

Če imate kakršna koli vprašanja o tem, se obrnite na lokalnega predstavnika BD na henrietta.lazanyi@bd.com.

Potrjujemo, da so bile zadevne regulativne agencije obveščene o teh ukrepih.

Družba BD se zavzema za napredek v svetu zdravja. Naši primarni cilji so varnost bolnika in varnost uporabnika ter dobava kakovostnih izdelkov. Opravičujemo se vam za nevspečnosti, ki jih je morda ta situacija povzročila, in se vam vnaprej zahvaljujemo za pomoč, ki jo družbi BD nudite pri čim hitrejšem in učinkovitem reševanju te zadeve.

S spoštovanjem,

Lorna Darrock
Pomočnica direktorja, zagotavljanje kakovosti po začetku trženja
Kakovost EMEA

Obrazec za odziv stranke – MMS-23-4760

Delovna postaja BD Alaris™ Gateway

REF: Glejte številke **serij iz dodatka 1**: Vse številke serij

Vrnite se na henrietta.lazanyi@bd.com čim prej ali **najpozneje do 31. julija 2023.**

S podpisom spodaj potrjujete, da je bilo to varnostno obvestilo prebrano, razumljeno in da so bila vsa priporočena dejanja izvedena v skladu z zahtevami.

Ime računa/organizacije:	
Oddelek (če je primerno):	
Naslov:	
Poštna številka:	Kraj:
Ime stika:	
Naziv delovnega mesta:	
Kontaktna telefonska številka:	Kontaktni e-poštni naslov:
Ime vašega dobavitelja za ta izdelek (če ni dobavljeno neposredno od družbe BD)*	
Podpis:	Datum:

Ta obrazec je treba vrniti družbi BD, preden se to dejanje lahko šteje za zaprto za vaš račun.

**Če ste to varnostno obvestilo posredovali prek distributerja/tretje osebe, prosimo, vrnite izpolnjen obrazec tej organizaciji za namene usklajevanja.*

Dodatek 1 – Prizadeti izdelek

Enotna registrska številka proizvajalca: CH-MF-000026539

Kataložka (REF.) št.	Opis izdelka	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

Priloga 2 – referenčni slikovni prikaz delovne postaje BD Alaris™ Gateway

