



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoulah Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 41 dated 21/2/2023 Regarding NCMDR Field Safety Notice of BD Alaris™ System PC Unit 8015; Alaris™ PC Unit 8015 from (mfr: Becton Dickinson & Co. (BD)).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADDC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

Twitter: dgpa_dc Email: dg-padcc@moh.gov.om



Circular No. 41 / 2023

30 -07-1444 H

21 -02-2023

نتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

Field Safety Notice of BD Alaris™ System PC Unit 8015; Alaris™ PC Unit 8015 from Becton Dickinson & Co. (BD).

| | |
|-----------------------|---|
| Source | NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18432 |
| Product | BD Alaris™ System PC Unit 8015; Alaris™ PC Unit 8015. |
| Description | IV medication safety system. |
| Manufacturer | Dickinson & Co. (BD). |
| Local agent | Mustafa Sultan Science & Industry. |
| The affected products | Product code (REF): 8015 Software version: 12.1.0 and above (12.1.1, 12.1.2, 12.1.3). |
| Reason | When a BD Alaris™ System PC Unit with software versions 12.1.0, 12.1.1, 12.1.2 or 12.1.3 is used with a 802.11 b/g or 802.11 a/b/g wireless network card, failure to establish a network connection can occur for IP addresses that are in a specific range from, x.x.x.224 to x.x.x.255. |
| Action | 1. Please refer to Actions for customers, IT users, clinical users in the attached FSN. 2. Contact the local agent for remedial action. |
| comments | Healthcare professionals are encouraged to report any adverse events. Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om |

Dr. Mohammed Hamdan Al Rubaie

Director General





26th January 2023

PRODUCT NOTIFICATION – MMS-23-4612

BD Alaris™ System PC Unit 8015; Alaris™ PC Unit 8015

REF: See Table 1

Type of Action: Advisory

Dear Customer,

BD is issuing this advisory product notification for the BD Alaris™ System software version 12.1.0 and above (12.1.1, 12.1.2, 12.1.3). According to our distribution records your organisation has received and/or uses Alaris™ System/s, with a software version of 12.1.1 or a prior version.

| Product | Product code (REF) | Software version |
|---|--------------------|--|
| BD Alaris™ System PC Unit 8015; Alaris™ PC Unit 8015 | 8015 | 12.1.0 and above (12.1.1, 12.1.2, 12.1.3) |

Table 1: Impacted product

This advisory is limited to the product codes / software version listed in Table 1. No other product codes or software versions are affected.

Description of the Problem

Based on customer feedback, BD has identified that when a BD Alaris™ System PC Unit with software versions 12.1.0, 12.1.1, 12.1.2 or 12.1.3 is used with a **802.11 b/g** or **802.11 a/b/g** wireless network card (refer to Figure 1), failure to establish a network connection can occur for IP addresses that are in a specific range from, **x.x.x.224** to **x.x.x.255**.

BD Alaris™ System PC Unit with the **802.11 a/b/g/n** wireless network card (refer to Figure 2) is not impacted by this issue.

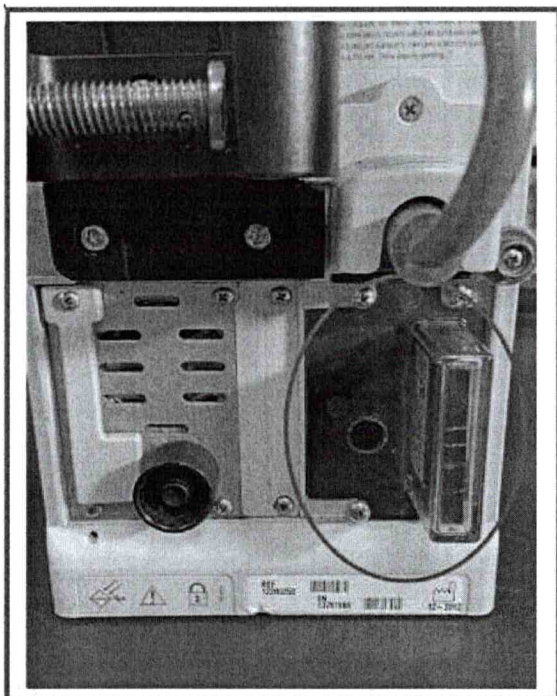


Figure 1: The back of the BD Alaris™ System PC Unit with the 802.11 b/g or 802.11 a/b/g wireless network card; the wireless network card protrudes out from the Alaris PC Unit.

A BD Alaris™ System PC Unit with this wireless network card is impacted by the issue.

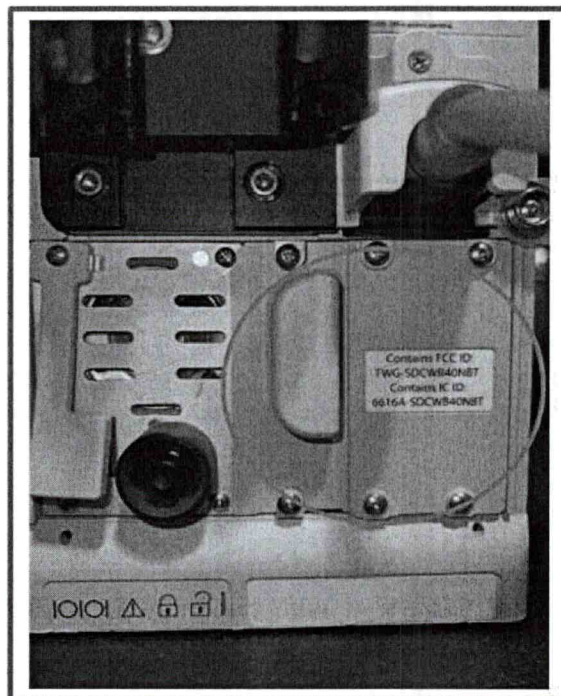


Figure 2: The back of the BD Alaris™ System PC Unit with the 802.11 a/b/g/n wireless network card; the wireless card is near flush with the Alaris PC Unit.

A BD Alaris™ System PC Unit with this wireless network card is not impacted by the issue

The following potential consequences will occur if the BD Alaris™ System PC Unit is not connected to a wireless network (BD Alaris™ Systems Manager):

1. The BD Alaris™ System PC Unit will be unable to wirelessly receive a new dataset, which could potentially result in the use of a previously existing dataset until a wireless connection is established.
2. The BD Alaris™ System PC Unit will be unable to transfer retrospective analytics data to any connected systems until a wireless connection is established.

For impacted customers using the BD Care Coordination Engine (CCE) as an interface to their Electronic Medication Record (EMR), including for purposes of BD Alaris™ EMR Interoperability:

If the BD Alaris™ System PC Unit is not connected to a wireless network, the following potential consequences can occur:



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

1. The BD Alaris™ System PC Unit will be unable to receive an automated programming request (APR), resulting in the need to manually program the infusion with the support of existing Guardrails™ safety limits.
2. The BD Alaris™ System PC Unit will be unable to send or receive data from any connected systems, such as an EMR.

To date there has been no adverse events worldwide related to this issue.

There is no requirement for customers to return any BD Alaris™ System PC Unit to BD. The product can continue to be used in accordance with the guidance in this safety notice.

Actions taken by BD:

BD will notify customers when the next version of software is available.

Actions for customers:

1. If you do not use the BD Alaris™ System Manager, you are **not** affected by this advisory notice.
2. Circulate this advisory to all those within your organisation that may use the BD Alaris™ System PC Unit(s).
3. If you have further distributed the product, please identify those users and notify them at once of this advisory. Ensure they follow the instructions listed in this product notification.
4. If you use the BD Alaris™ System Manager, review the information in **Appendix 1** to determine if the BD Alaris™ System PC Unit(s) in your possession are impacted by this advisory.
5. Follow the instructions below for **IT Users** and/or **Clinical Users** as appropriate.
6. If you experience any issues with the BD Alaris™ System PC Unit, please report as a complaint as per your normal process.
7. Complete the Customer Response Form on page 5 and return it to Ahmed.Shebah@bd.com **as soon as possible or no later than 28th February 2023.**

NB. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

IT Users:

8. To prevent this issue from occurring, do **one** of the following:



BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
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- i. Exclude IP address ranges ending in **x.x.x.224** to **x.x.x.255** from all the DHCP scopes where the BD Alaris™ System PC Units are being utilised.
- ii. Assign the BD Alaris™ System PC Units IP addresses utilising DHCP reservations to prevent the BD Alaris™ System PC Unit from obtaining an IP address in the aforementioned range.
- iii. Assign the BD Alaris™ System PC Units a static IP address outside of the aforementioned range.

Clinical Users:

9. When using the BD Alaris™ System PC Unit for wireless network connection, ensure that the wireless network indicator icon is illuminated on the front panel of the unit (refer to **Appendix 2**). Users can also check the wireless status through the Systems Options menu on the Alaris™ PC Unit.
10. If the BD Alaris™ System PC Unit is not connected to the wireless network when using Interoperability, the clinical end user can input all infusion parameters manually through the BD Alaris™ System PC Unit to initiate an infusion. Refer to the Alaris™ System with Guardrails™ Suite MX User Manual for guidance. Manual programming includes normal access to the Alaris Guardrails™ dose error reduction software and configurations. In addition, the clinical end user can manually document the infusion in the EMR.
11. If the BD Alaris™ System PC Unit is not connected and does not have the expected dataset, the clinical end user can utilise manual programming as described in the Alaris™ System with Guardrails™ Suite MX User Manual. In addition, a new dataset can be uploaded to the BD Alaris™ System PC Unit using a serial cable, refer to the BD Alaris™ System Maintenance User Manual or the BD Alaris™ Guardrails™ Editor User Manual for guidance.

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on +966.11.4551771. or e-mail [**Ahmed.Shebah@bd.com**](mailto:Ahmed.Shebah@bd.com)

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

Lorna Darrock
Associate Director, Post Market Quality
EMEA Quality



Appendix 1 - to determine if the BD Alaris™ System PC Unit(s) in your possession are impacted by this advisory

1. To determine if you have a BD Alaris™ system PC Unit with the **802.11 b/g** or **802.11 a/b/g** wireless network card, refer to Figure 1 and 2 above.
 - a. A BD Alaris™ System PC Unit with a wireless network card as shown in Figure 1 is **impacted by the issue**.
 - b. A BD Alaris™ System PC Unit with the wireless network card as shown in Figure 2 is **not impacted by the issue**
2. Next identify the software version of the unit(s) in your possession to determine if you have an Alaris™ PC Unit with the impacted software:
 - a. Check the main processor version by following the steps outlined in Figure 3 below which are taken from the BD Alaris™ System with Guardrails™ Suite MX User Manual.

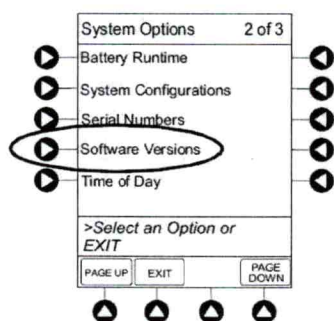
Figure 3; BD Alaris™ System with Guardrails™ Suite MX User Manual – Viewing Software Version steps

Powering On the System

Viewing Software Versions

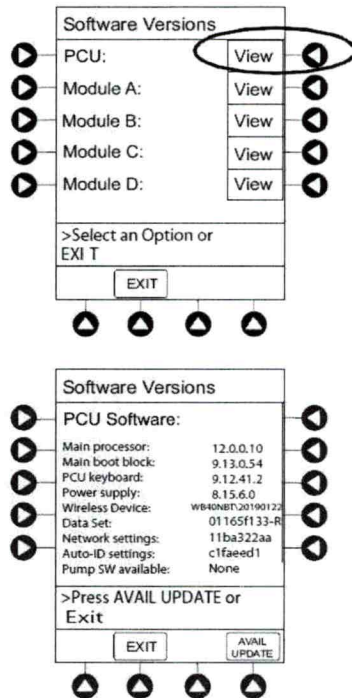
The software versions screens display the active running software components on the PCU and the attached modules that are available on the PCU.

1. Press the **OPTIONS** key.
2. Press the **PAGE DOWN** soft key.
3. Press the **Software Versions** soft key to display the Software Versions menu.



4. Do one of the following:

- To view software components and configurations on the PCU, press the **View** soft key for the PCU.



3. If you use wireless connection on the BD Alaris™ System PC Unit and have identified that any BD Alaris™ system PC Unit(s) in your possession have the impacted software version in combination with the **802.11 b/g** or **802.11 a/b/g** wireless network card, then the unit(s) are impacted by this advisory.

Appendix 2- image to show the BD Alaris™ System PC Unit front panel with the Wireless Network Indicator Icon



Figure 4; When the wireless network indicator icon is illuminated, the BD Alaris™ PC System Unit is connected to the wireless network