Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/040 Issued: 27 November 2019 at 12:00 Valid until November 2020

Alaris™ Gateway Workstation and Alaris™ Gateway Workstation web browser user interface

Summary

Manufactured by Becton Dickinson – if a software security vulnerability is exploited, an attacker with malicious intention could remotely install unauthorized firmware.

Action

- Identify affected devices in your organisation.
- Ensure that staff are aware of the recommendations given in the manufacturer's Customer Letter.
- Make sure staff know that the manufacturer has developed a way to fix the product security vulnerability; this was released in October 2019 and is available for download from the BD website through the following link:
  http://www.bd-products.com/assets/supportdocs/protected/software/agw-smb-patch_1.0.0.7_c364412.zip
- The link is password protected. Use the following log in details to access it:
  Username: uk-tech
  Password: safe8belt
- Once logged in, you will find the instructions in the file called BDPB00106 and the CAB file is in the folder called Release.
- Documentation is also available on the BD website using the same log in details as above:
  http://www.bd-products.com/assets/supportdocs/protected/information_notices/BDIN00325.pdf
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Action by
All medical, nursing and technical staff involved in the use and maintenance of these devices.

Deadlines for actions
Actions underway: 11 December 2019
Actions complete: 27 December 2019

Problem / background

The Alaris Gateway Workstation is aimed at integrating infusion data with a hospital's central clinical information system.

Alaris Gateway Workstation:
Potential vulnerability that can impact the Workstation. If exploited, this vulnerability may allow an attacker with malicious intention to remotely install unauthorized firmware.

Alaris Gateway Workstation web browser user interface:
Potential vulnerability that can impact the user interface in standalone configuration only. If exploited, this vulnerability may allow an attacker with knowledge of the IP address of the Alaris Gateway Workstation terminal to gain access to information on the web browser user interface.

Manufacturer contacts

Becton Dickinson
Tel: 0800 917 8776 option 2, option 3
Email: BDUK_CustomerService@bd.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and NICAS liaison officers for onward distribution to all relevant staff including:
• All departments
• All staff
• All wards
• Ambulance services directors

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
• Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/040** or **2019/006/014/302/001**

Technical aspects

Guido Fumagalli or David Grainger, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).