

Name
Address

URGENT FIELD SAFETY NOTICE

Product Name: **Alaris™ / Asena™ GS, GH, CC, TIVA, PK, Syringe Pump
(pumps manufactured before September 2008 only)**

Product codes with prefix (all variants): **8001, 8002, 8003, 8004, and 8005**

FSN Identifier: **RA-2017-02-01**

Date: **September 2017**

Type of Action: **Field Safety Notice**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

BD/CareFusion recently received a report from one customer regarding re-occurring PL3 alarms. A PL3 alarm is an internal **malfunction error code**, which will result in the pump stopping and alerting the user of **an internal failure**.

BD/Carefusion would like to advise customers to immediately remove pumps displaying any internal malfunction error code, such as the PL3 error message, from clinical use and send them for servicing by qualified service personnel. An overview of all the malfunction codes can be found in the Troubleshooting section of the Technical Service Manual 1000SM00001.

Internal malfunction error codes are identified by the pump stopping, issuing an error message along with a red illuminated beacon, and a high pitched constant alarm tone that cannot be silenced.

Patient populations in need of critical infusions may be more impacted due to the potential for an interruption of the infusions.

Impacted Syringe Pumps

Any pump manufactured prior to September 2008 could exhibit error code PL3.

BD/CareFusion has recently published an updated Technical Service Manual 1000SM00001 (latest issue 31) where we have removed the serial number range associated with pumps that may have PL3 alarms (Page 27). On investigation we conclude that the manufacturing date prior to September 2008 would give full coverage of the pumps that would potentially have a PL3 alarm. The related SKUs can be found in Appendix 2.

Syringe Pump Technical Service Manual MK3

http://www.bd-products.com/assets/supportdocs/protected/TSM_manual/1000SM00001.pdf

The required details are: Username = uk-tech, Password = safe8belt

Alaris System Pumps, sometimes referred to as Alaris Medley Infusion Pumps are not impacted by this communication.

Action Required

- 1. If a PL3 alarm occurs the syringe pump should be immediately removed from clinical use and examined by qualified service personnel.**
- 2. Please verify if you are in possession of any pumps that have been manufactured prior to September 2008. For such pumps, you need to follow the procedure outlined in the Technical Service Manual 1000SM00001 Issue 31. Appendix 2 indicates the SKUs impacted by this Field Safety Notice.**

Your competent authority has already been notified of this Field Safety Notice by BD/CareFusion legal Manufacturer.

Should you have any questions or require assistance relating to this Field Safety Notice, please contact your Local BD/CareFusion representative.

We sincerely apologise for any inconvenience this action may have caused you or your staff.

Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.

If you are no longer in possession of these pumps please do the following:

1. Pass this notice and all the related documentation on to the current user.
2. If these pumps are no longer in clinical use, please inform BD/Carefusion and communicate the serial numbers that are implicated.

Sincerely,

Appendix 1 – To be completed and returned by End User
URGENT FIELD SAFETY NOTICE – Acknowledgement Form

Product Name: **Alaris™ / Asena™ GS, GH, CC, TIVA, PK, Syringe Pump
(pumps manufactured prior to September 2008 only)**

Product codes with prefix all variants: **8001, 8002, 8003, 8004, and 8005**

FSN Identifier: **RA-2017-02-01**

Date: **September 2017**

Type of Action: **Field Safety Notice**

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

- I have read and understood the contents of this Field Safety Notice and will distribute this notice to all those who need to be made aware.
- I am no longer in possession of these pumps and I will pass the information to rightful owner.
- I confirm these pumps have been taken out of service and I can confirm related serial numbers.

Please return to:

Local CareFusion Representative

Address:

Via Fax:

Or preferred option: Please scan the Acknowledgement Form and send via email to: fsca.infusion@bd.com (Only emails in English are accepted).

Appendix 2 – Impacted SKUs

Alaris™ GS, GH, CC, TIVA, PK Syringe Pump

Asena™ GS, GH, CC, TIVA, PK Syringe Pump

Material description	Material	Product Type
ASENA GS GERMAN	80013DE00	GS
ASENA GS GERMAN	80013DE00-R	GS
ASENA GS SYRINGE PUMP-USED	80013DE00-U	GS
ASENA GS GERMAN + RS232	80013DE01	GS
ASENA GS USED	80013DM00	GS
ASENA GS SPANISH	80013ES00	GS
ASENA GS SPANISH + RS232	80013ES01	GS
ASENA GS FRENCH	80013FR00	GS
ASENA GS FRENCH - USED	80013FR00-U	GS
ASENA GS FRENCH + RS232	80013FR01	GS
ASENA GS ENGLISH	80013GB00	GS
ASENA GS ENGLISH + RS232	80013GB01	GS
ASENA GS ITALIAN	80013IT00	GS
ASENA GS ITALIAN + RS232	80013IT01	GS
ASENA GS DUTCH	80013NL00	GS
ASENA GS DUTCH + RS232	80013NL01	GS
ASENA GS NORWEGIAN	80013NW00	GS
ASENA GS NORWEGIAN + RS232	80013NW01	GS
ASENA GS REFURBISHED	80013RF00	GS
ASENA GS REFURBISHED + RS232	80013RF01	GS
ASENA GS SWEDISH	80013SE00	GS
ASENA GS SWEDISH + RS232	80013SE01	GS
ALARIS GS UNIVERSAL	80013UN00	GS
ASENA GS SYRINGE PUMP-USED	80013UN00-U	GS
ALARIS GS UNIVERSAL+RS232	80013UN01	GS
ASENA GS UNIVERSAL+RS232-USED	80013UN01-U	GS
ALARIS GH PFS V1.0 - USED	8002PFS01-G-U	GH
ALARIS GH PFS V1.0	8002PFS01-G	GH
ASENA GH UNIVERSAL+RS232-USED	80023UN01-U	GH
ASENA GH GUARDRAILS + RS232-USED.	80023UN01-G-U	GH
ALARIS GH UNIVERSAL GUARDRAILS + RS232	80023UN01-G	GH



ALARIS GH UNIVERSAL+RS232	80023UN01	GH
ASENA GH SYRINGE PUMP-USED	80023UN00-U	GH
ASENA GH UNIVERSAL	80023UN00-G	GH
ALARIS GH UNIVERSAL	80023UN00	GH
ASENA GH SWEDISH + RS232	80023SE01	GH
ASENA GH SWEDISH	80023SE00	GH
ASENA GH +RS232 - USED	80023RF01	GH
ASENA GH USED	80023RF00	GH
ASENA GH GUARDRAILS + RS232-USED.	80023NW01-G-U	GH
ASENA GH NORWEGIAN + RS232 +GUARDRAILS	80023NW01-G	GH
ASENA GH NORWEGIAN + RS232	80023NW01	GH
ASENA GH NORWEGIAN	80023NW00	GH
ASENA GH DUTCH + RS232	80023NL01	GH
ASENA GH DUTCH	80023NL00	GH
ASENA GH ITALIAN + RS232	80023IT01	GH
ASENA GH ITALIAN	80023IT00	GH
ASENA GH UNIVERSAL+RS232-USED	80023GB01-U	GH
ASENA GH ENGLISH + RS232+GR - USED	80023GB01-G	GH
ASENA GH ENGLISH + RS232	80023GB01	GH
ASENA GH ENGLISH-USED	80023GB00-U	GH
ASENA GH ENGLISH	80023GB00	GH
ASENA GH FRENCH + RS232	80023FR01	GH
ASENA GH SYRINGE PUMP-USED	80023FR00-U	GH
ASENA GH FRENCH	80023FR00	GH
ASENA GH SPANISH + RS232	80023ES01	GH
ASENA GH SPANISH	80023ES00	GH
ASENA GH UNIVERSAL+RS232 - USED	80023DM01	GH
ASENA GH UNIVERSAL - USED	80023DM00	GH
ASENA GH GERMAN + RS232 USED	80023DE31-U	GH
ASENA GH GERMAN + RS232 USED	80023DE01-U	GH
ASENA GH GERMAN + RS232	80023DE01	GH
ASENA GH GERMAN - USED	80023DE00-U	GH
ASENA GH GERMAN	80023DE00-R	GH
ASENA GH GERMAN	80023DE00	GH
ALARIS CC ENGLISH	80033GB00	CC
ALARIS CC UNIVERSAL DEDICATED	80033UND0	CC
ALARIS CC UNIVERSAL DEDIC+RS232	80033UND1	CC
ALARIS CC GUARDRAILS UNIV. DEDIC+RS232	80033UND1-G	CC
ALARIS CC	80033UNN0	CC
ASENA CC + RS232	80033UNN1	CC
ASENA CC 110/240V - PLANNING FAMILY	80033VPD1	CC
ALARIS CC PFS V1.0	8003PFS01-G	CC



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ALARIS CC PFS V1.0 - USED	8003PFS01-G-U	CC
ASENA TIVA UNIVERSAL+RS232 - USED	80043UN01-U	TIVA
ALARIS TIVA UNIVERSAL+RS232	80043UN01	TIVA
ALARIS TIVA UNIVERSAL	80043UN00	TIVA
ASENA PK UNIVERSAL RS232- USED	80053UN01-U	PK
ALARIS PK + RS232	80053UN01	PK