BD

13th November 2020

URGENT: FIELD SAFETY NOTICE – MMS-20-3956

BD Alaris™ GW and GW800 Volumetric Pumps

Product Codes: Refer to Appendix 1

Type of Action: Advisory

Attention: EBME / Clinical Engineering Managers, Clinical Personnel, Risk Managers

This letter contains important information which requires your attention.

Dear Customer,

BD is issuing this Field Safety Notice for the **Alaris™ GW and GW800 Volumetric Pumps**. Our distribution records indicate that your organisation may have received impacted instruments.

Description of the Problem

BD is updating the Directions for Use to include additional warnings relating to the use of non-dedicated/non-compatible administration sets to mitigate against unregulated flow during infusion. BD has received customer feedback associated with unregulated flow as a result of the use of non-dedicated/non-compatible administration sets.

These additional warnings will be included in future shipments of the BD Alaris™ GW800 Volumetric Pumps. The BD Alaris™ GW Volumetric Pumps are no longer manufactured or distributed but they may still be in clinical use and therefore these additional warnings should be applied.

> *Additional Warnings to be followed for BD Alaris™ GW and GW800 Volumetric Pumps:*
> - *Administration sets which do not contain anti-siphon valves or free flow protection should not be used to deliver high risk medications or used on vulnerable patients. The use of sets without free flow protection can lead to unregulated flow, which could cause harm to the patient.*
>   *With set detection mode disabled always use a flow sensor.*
>
> - *Always use the IVAC® Model 180 Flow Sensor when using sets without anti-siphon valves or whenever the Pump set detection mode is disabled. The flow sensor automatically monitors the infusion flow rate through the drip chamber and will cause the Pump to alarm if a significant deviation from the infusion rate occurs. The flow sensor will detect empty containers.*

Appendix I of this Field Safety Notice contains the list of product codes (REFs) for the BD Alaris™ GW and GW800 Volumetric Pumps under scope. The product codes are affixed to the bottom of the pump per the sample photo contained in Appendix II.

Advice on actions to be taken by the user

1. Ensure the contents of this Field Safety Notice including the additional warnings are read and understood by those within your organisation who may use the BD Alaris™ GW and GW800 Volumetric Pumps.
   - If you have further distributed the product to other organisations, please identify those organisations and notify them at once of this Field Action.

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2.   Please complete the Customer Response form (Page 3) and return the completed form to BD at <<insert email address>> no later than **November 30th, 2020**.

3.   If you are no longer in possession of or no longer use the instruments listed in Appendix 1, please indicate this on the response form and return to BD so we may update our records.

Should you have any questions or experience any issues associated with the product or issue described in this Field Safety Notice, please contact your local BD representative. We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Yours sincerely,

William David
Senior Director Quality Compliance EMEA

Appendix 1: Impacted Product Codes and Descriptions
Appendix 2: Example of the Product Code located on the bottom of the instrument. The Product Code is the REF Number

Customer Acknowledgement Form – MMS-20-3956

BD Alaris™ GW and GW800 Volumetric Pumps

Please read in conjunction with Field Safety Notice MMS-20-3956 and return the completed and signed form as soon as possible or **no later than November 30th, 2020** to <<email>>.

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

Name of Facility	
Name of Hospital/s covered by this response:	
Email Address	
Telephone Number	
Name	
Signature	
Date	

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Appendix 1: Impacted Product Codes and Descriptions

BD Alaris™ GW Volumetric Pumps		BD Alaris™ GW800 Volumetric Pumps	
25041ESD1	Alaris™ GW, Spanish, Dedic, RS232	800TIG2BGN1	Alaris™ GW800, 240v Bulgarian, Multidedicated
25041GBD1	Alaris™ GW, English, Dedic, RS232	800TIG2HRD1	Alaris™ GW800, 240v Croatian, Dedicated
25041GBN1	Alaris™ GW, English, Multidedic, RS232	800TIG2CZD1	Alaris™ GW800, 240v Czech, Dedicated
25041RWN1	Alaris™ GW, Rest of World, Multidedic	800TIG2CZN1	Alaris™ GW800, 240v Czech, Multidedicated
25042NLD1	Alaris™ GW, Dutch, Dedic., RS232	800TIG2NLD1	Alaris™ GW800, 240v Dutch, Dedicated
25042NLN1	Alaris™ GW, Dutch, Multidedic., RS232	800TIG2NLN1	Alaris™ GW800, 240v Dutch, Multidedicated
25042GBD1	Alaris™ GW, English, Dedic., RS232	800TIG2GBD1	Alaris™ GW800, 240v English, Dedicated
25042FRD1	Alaris™ GW, French, Dedic., RS232	800TIG2RWN1	Alaris™ GW800, 240v ROW, Multidedicated
25042FRN1	Alaris™ GW, French, Multidedic., RS232	800TIG2EED1	Alaris™ GW800, 240v Estonian, Dedicated
25042DED1	Alaris™ GW, German, Dedic., RS232	800TIG2FID1	Alaris™ GW800, 240v Finnish, Dedicated
25042DEN1	Alaris™ GW, German, Multidedic., RS232	800TIG2FRD1	Alaris™ GW800, 240v French, Dedicated
25042ITD1	Alaris™ GW, Italian, Dedic., RS232	800TIG2FRN1	Alaris™ GW800, 240v French, Multidedicated
25042PTD1	Alaris™ GW, Portuguese, Dedic., RS232	800TIG2DED1	Alaris™ GW800, 240v German, Dedicated
25042ESD1	Alaris™ GW, Spanish, Dedic., RS232	800TIG2DEN1	Alaris™ GW800, 240v German, Multidedicated
25042RWN1	Alaris™ GW, Rest of World, Multidedic.	800TIG2ELD1	Alaris™ GW800, 240v Greek, Dedicated
25042SED1	Alaris™ GW, Swedish, Dedic,, RS232	800TIG2HUD1	Alaris™ GW800, 240v Hungarian, Dedicated
25042CZN1	Alaris™ GW, Czech, Multidedic., RS232	800TIG2ITD1	Alaris™ GW800, 240v Italian, Dedicated
25042POD1	Alaris™ GW, Polish, Dedic., RS232	800TIG2LTD1	Alaris™ GW800, 240v Lithuanian, Dedicated
25042HUD1	Alaris™ GW, Hungarian, Dedic., RS232	800TIG2PLD1	Alaris™ GW800, 240v Polish, Dedicated
25042RUD1	Alaris™ GW, Russian, Dedic., RS232	800TIG2PTD1	Alaris™ GW800, 240v Portuguese, Dedicated
25042DKD1	Alaris™ GW, Danish, Dedic., RS232	800TIG2ROD1	Alaris™ GW800, 240v Romanian, Dedicated
25042TRD1	Alaris™ GW, Turkish, Dedic., RS232	800TIG2SRD1	Alaris™ GW800, 240v Serbian, Dedicated
25042TRN1	Alaris™ GW, Turkish, Multidedicated	800TIG2ESD1	Alaris™ GW800, 240v Spanish, Dedicated
25042ESN1	Alaris™ GW, Spanish, Multidedic, RS232	800TIG2SED1	Alaris™ GW800, 240v Swedish, Dedicated
25042FID1	Alaris™ GW, Finnish, Dedic., RS232	800TIG2TRD1	Alaris™ GW800, 240v Turkish, Dedicated
25042ELD1	Alaris™ GW, Greek, Dedic., RS232	800TIG2TRN1	Alaris™ GW800, 240v Turkish, Multidedicated
25042SRD1	Alaris™ GW, Serbian, Dedic., RS232		
25042ROD1	Alaris™ GW, Romanian, Dedic, RS232		
25042SLD1	Alaris™ GW, Slovenian, Dedic, RS232		
25042EED1	Alaris™ GW, Estonian, Dedic, RS232		
25042LVD1	Alaris™ GW, Latvian, Dedic, RS232		
25042HRD1	Alaris™ GW, Croatian, Dedic, RS232		

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Appendix 2: Example of the Product Code located on the bottom of the instrument. The Product Code is the REF Number