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THE NORTHUMBRIA WAY
PEOPLE CARING FOR PEOPLE

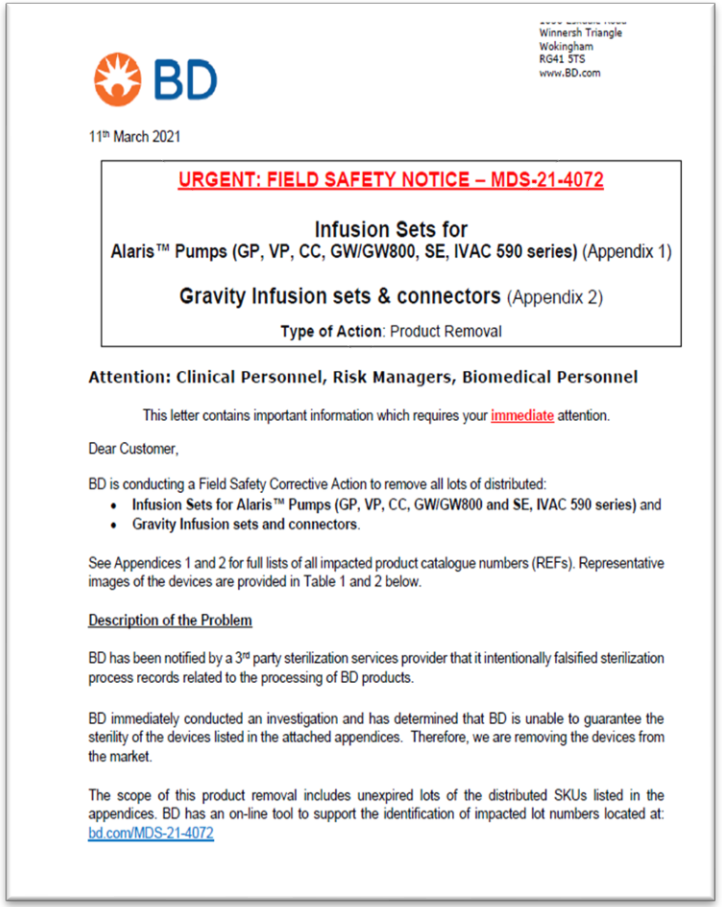
Collaborative Working for Patient Safety

Sheryle Miller – Clinical Education Coordinator

Chris Halcrow – Chief Technician Medical Electronics

Questions & Answers at the end

National Patient Safety Alert:11 March 2021



Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

BD

11th March 2021

URGENT: FIELD SAFETY NOTICE – MDS-21-4072

Infusion Sets for
Alaris™ Pumps (GP, VP, CC, GW/GW800, SE, IVAC 590 series) (Appendix 1)

Gravity Infusion sets & connectors (Appendix 2)

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove all lots of distributed:

- **Infusion Sets for Alaris™ Pumps (GP, VP, CC, GW/GW800 and SE, IVAC 590 series)** and
- **Gravity Infusion sets and connectors**.

See Appendices 1 and 2 for full lists of all impacted product catalogue numbers (REFs). Representative images of the devices are provided in Table 1 and 2 below.

Description of the Problem

BD has been notified by a 3rd party sterilization services provider that it intentionally falsified sterilization process records related to the processing of BD products.

BD immediately conducted an investigation and has determined that BD is unable to guarantee the sterility of the devices listed in the attached appendices. Therefore, we are removing the devices from the market.

The scope of this product removal includes unexpired lots of the distributed SKUs listed in the appendices. BD has an on-line tool to support the identification of impacted lot numbers located at: bd.com/MDS-21-4072

Impact / Issues

Standard infusion pumps used throughout the Trust

Large demographic area to manage change over

High clinical usage of infusion pumps

Before role out:

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Emergency response team: coordinated areas to use the pumps / protecting critical areas, daily meetings to monitor supply of stock.

Medical Electronics	**Procurement**
Function testing Devices calibrated IV lines sourced compatible with device Reviewed user manual Support training roll out and walk abouts	Sourcing and coordinating items for IV therapy
Clinical Educators	Departmental Teams inc pharmacy
Pumps evaluated for usability Training programme developed Training on the device to departments Daily walk abouts to support staff	Promoting fluids to be given via gravity sets Evaluating new resources and feedback Datix monitoring

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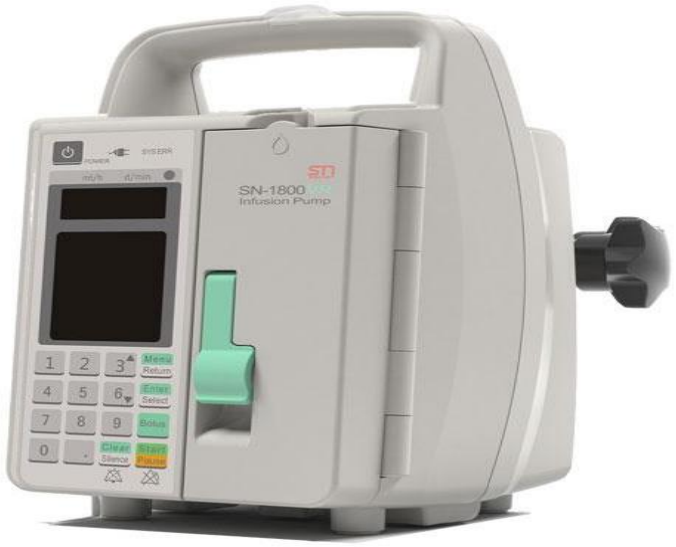
Learning Together Event

Who - Medical Electronics, Human Factors Lead, Clinical Governance lead, Practice Development Team, Clinical Education Coordinator, Director of Patient Safety.

What - Reviewing the device, user guides and the procedure

Why - To ensure that we could make the usage of the devices as safe as it could be

How - Everyone in one area, simulation, discussion and innovation, plan



Risks identified with the pump

Technology - alarm
Terminology - (Preset = VTBI)
Device Lock
No device representative

Risks identified with the infusion set

Free flow infusion set – no safety clamp

Gravity set required to be repositioned after 6 hours and changed after two infusions

Bespoke User Guide

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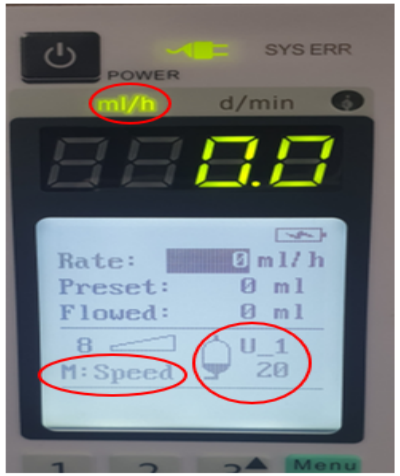
Sinomed SN-1800 Short Form User Instructions

DO NOT USE THIS DEVICE UNLESS YOU HAVE RECEIVED TRAINING
&
TO BE USED ALONGSIDE INFUSION PUMP CHECKLIST

1. Prepare infusion, prime set, clamp the line and load set into pump. Use only ***B Braun Intrafix Safeset*** giving set.
2. Ensure pump is plugged in and that the charging light is illuminated.
3. Switch on pump, allow it to run a self-check and check that no errors are indicated on the display and that the ***'SYS ERR'*** indicator isn't illuminated.
4. Check display shows ***'Rate' (ml/h not d/min), 'Preset'(ml)*** and ***'Flowed' (ml)***, along with ***'U_1'*** and that ***'M:Speed'*** is shown in the bottom left of the display. Check that the ***ml/h*** indicator is illuminated. (See photo)



This confirms that the pump is in the correct mode. If not, switch pump off and back on, **if the display is still incorrect then select an alternative pump and contact Medical Electronics for assistance.** Please clearly label the faulty pump and put to one side for the Electronics team to collect.

5. Enter rate e.g. 10ml/hr and press ***'Enter'*** key.

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6. Enter ***Preset*** volume (VTBI) e.g. 20mls, press ***'Enter'*** key.
7. Ask a qualified nurse/nurse associate to check the above settings are correct using the **Infusion Pump Checklist**.
8. Connect to patient.
9. Unclamp the line.
10. Press ***'Start'*** key, infusion will commence with green indicator illuminated and ***'Delivering'*** is displayed on screen.
11. Press and hold the ***Clear/Silence*** button for 2 seconds to lock the screen. To unlock, press and hold the ***Clear/Silence*** button for 2 seconds. ***Important Note- after each alarm event the pump keypad will unlock. You must lock the keypad again after acknowledging and resetting each alarm event.***
12. Every 6 hours, inspect the administration set **AND** reposition a new section in the peristaltic mechanism. ***(Ensure infusion is paused and the line clamp is in place before doing so and you are not repositioning a previously used section of the giving set).***
13. On completion of the infusion, the pump will alarm with a red indicator and show ***'Finished'*** in the display. It will go into ***KVO mode at 0.5ml/hr***.
14. Press ***'Pause'*** key, display will show ***'Paused'***, CLAMP LINE and switch pump off.
15. Disconnect from patient, remove and dispose of administration set.
16. Decontaminate pump in accordance with Trust policy and place on charge.

For help and advice please contact:

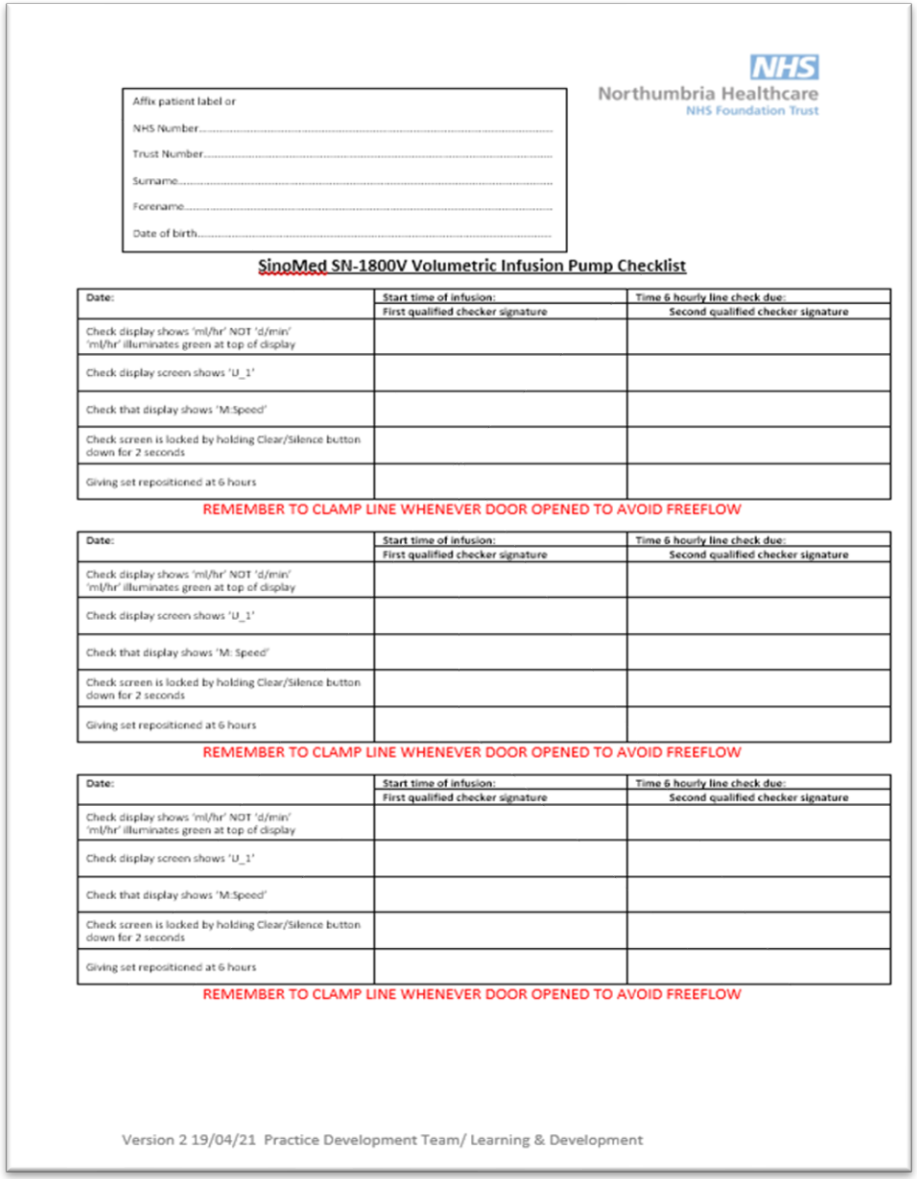
WGH: Sheryle Miller, Clinical Education Coordinator: ext. 33020
NTGH: Practice Development Team: ext. 32031
Medical Electronics:
WGH 33020
NTGH 34233
HGH 35403
NSECH 72142

A QR barcode on top of the pump will take you to the user guide on YouTube, alternatively the user guide video can be viewed at:

https://youtu.be/QIdscmX77Fo

Training manuals and resources can be found on the medical devices page
http://nww.northumbria.nhs.uk/home/tlc/medical-devices-training/

Version 1.4 17/05/21 (Practice Development Team /Medical Electronics /Learning & Development)



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Affix patient label or

NHS Number.....

Trust Number.....

Surname.....

Forename.....

Date of birth.....

SinoMed SN-1800V Volumetric Infusion Pump Checklist

Date:	Start time of infusion: First qualified checker signature	Time 6 hourly line check due: Second qualified checker signature
Check display shows 'ml/hr' NOT 'd/min' 'ml/hr' illuminates green at top of display		
Check display screen shows 'U_1'		
Check that display shows 'M:Speed'		
Check screen is locked by holding Clear/Silence button down for 2 seconds		
Giving set repositioned at 6 hours		

REMEMBER TO CLAMP LINE WHENEVER DOOR OPENED TO AVOID FREEFLOW

Date:	Start time of infusion: First qualified checker signature	Time 6 hourly line check due: Second qualified checker signature
Check display shows 'ml/hr' NOT 'd/min' 'ml/hr' illuminates green at top of display		
Check display screen shows 'U_1'		
Check that display shows 'M: Speed'		
Check screen is locked by holding Clear/Silence button down for 2 seconds		
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Date:	Start time of infusion: First qualified checker signature	Time 6 hourly line check due: Second qualified checker signature
Check display shows 'ml/hr' NOT 'd/min' 'ml/hr' illuminates green at top of display		
Check display screen shows 'U_1'		
Check that display shows 'M:Speed'		
Check screen is locked by holding Clear/Silence button down for 2 seconds		
Giving set repositioned at 6 hours		

REMEMBER TO CLAMP LINE WHENEVER DOOR OPENED TO AVOID FREEFLOW

Version 2 19/04/21 Practice Development Team/ Learning & Development

Change in Practice

- New device
- Double check to set up infusion
- New documentation
- Use of gravity IV lines
- Datix – new category

- Base Sites Departments identified to use new pumps –using gravity sets as an alternative
- Over 120 Staff identified as needing training
- 2 Training devices left on departments for familiarisation of set up and use
- Train the trainers identified and supported to cascade training
- User training monitored daily and feedback to central command
- Devices/ IV giving sets released for use and GP pumps removed from practice with BD giving sets

Medical Day Units

Micro bubbles triggering air in line detector
resulting in infusions taking longer,
which increased patient time – caused patient flow delays

Reintroduced GP pumps to be used on the unit for a small number of infusions that had been problematic

Our reflections after the event