

## **FSN 2020-02 – Bolts need to be replaced at the next product service**

### **Details of the affected devices:**

Affects both the UNIVERSAL/SR/MAG/CH Standard bed rails and UNIVERSAL/SR/HI/MAG/CH Extended bed rail supplied onto the market after Nov 2017.

### **Description of the issue:**

Drive DeVilbiss Healthcare Ltd has identified an issue relating to the service and maintenance of the affected bed rails. When the two bolts that hold the clamp bracket in place (as shown below) are over-tightened the head of the bolt can shear off.

Bed rails with the bolts that are intact remain safe to use and will continue to meet the physical test requirements of BS EN 60601-2-52.



### **Advice on the actions to be taken:**

Drive DeVilbiss Healthcare Ltd will be contacting affected customers to issue this Field Safety Notice. This notice can also be downloaded from our website: <https://drivedevilbiss.co.uk/technical-support>

If checking a rail prior to its next scheduled service interval, check there is no movement between the plate and clamp bracket shown in this document; whilst no movement is present there would not be a requirement to further tighten the fixings.

Providers should ensure that the fixing bolts are changed at the next service of the bed rail. Providers should contact Drive DeVilbiss Healthcare Ltd to arrange for replacement bolts to be delivered. Replacement bolts will be supplied free of charge. Providers are not to source their own bolts unless permission is granted by Drive DeVilbiss Healthcare Ltd.

**Transmission of this Field Safety Notice:**

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and/or customer base, and/or any organisation where the bed rails are used. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of this action.

**e-mail feedback form:**

As part of the MHRA vigilance and reporting structure, we are required to feedback that the Field Safety Notice has been acknowledged and the appropriate actions have taken place. Please confirm that this Field Safety Notice has been received and that the bolts have been replaced on all affected bed rails.

PLEASE USE BLOCK CAPITALS

**Name:**

**Position:**

**Organisation:**

**Signed:**

**Date:**

Following completion, please sign and e-mail this completed form to:

**Mr Roy Smith**                      **Quality and Environmental Manager**  
**e-mail:**                              **quality@drivedevilbiss.co.uk**