Urgent Field Safety Notice

Commercial Name of Affected Product: Progressa® Bed

FSCA-identifier: MOD1278

Type of action: Device Correction

Date: 28 February 2018

Attention: Chief Executive, Facility Engineer, Biomedical Engineering, Medical Device Liaison Officer

CC: Chairman Medical Board and relevant Head of Departments

Details on Affected Devices:

Affected Devices: Progressa® Bed Systems P7500

Serial Numbers: [redacted]

Production Dates: June 8, 2017 to November 1, 2017

Description of the Problem:

Progressa® Beds manufactured between the dates specified above may experience a problem with the braking system. A component used within the braking system may malfunction resulting in one or more brake pedals either not engaging or become stuck in the “brake” position. If the brake is not engaging, there is a risk for unwanted bed movement which could possibly result in patient or user injury; this failure mode is prevalent during patient transfers from one surface to another or during patient egresses.

Action to be taken by the user:

Hill-Rom has developed a correction for the braking system. We will contact you to schedule a Hill-Rom technician to update your affected Progressa® Beds with this correction.

Until your affected beds are updated, we ask that you follow the safety information as outlined in the Progressa® User manual when setting the brakes.

Warning: *Always set the brakes when the bed is occupied, except during patient transport. To help make sure the bed will not move, push and pull on the bed to check it after the brakes are engaged. Brakes should always be set when the bed is occupied and especially when moving a patient from one surface to another. Patients often use the bed for support when getting out of bed and could be injured if the bed unexpectedly moves. After setting the brakes, push and pull the bed to make sure of stability.*

If the brakes do not hold after following the instructions above, take the bed out of service until the bed is updated.

Transmission of this Field Safety Notice:

Please forward this notice to other organizations as appropriate and maintain awareness of this notice for an appropriate period to ensure effectiveness.

Contact reference person:

Hill-Rom has developed a partnership with Docapost (La Poste Group in France) for the distribution of information related to the Hill-Rom medical devices.

Please do not contact Docapost directly with enquiries, they will not be able to respond or assist you. If you have any questions concerning this Field Safety Corrective Action, please contact Joe Fogel, Regional QA/RA Director, at MedicalDevicesEMEA@hill-rom.com or your local Hill-Rom representative.

Hill-Rom confirms that the relevant Regulatory and Competent Authorities have been informed of this Field Safety Corrective Action.

Yours Sincerely,

Hill-Rom Technical Support