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URGENT:
MEDICAL DEVICE **CORRECTION**

InTouch ® Critical Care Bed
Bed Exit alarm volume may be low
Models: 2131, 2141, 2151, 2152
October 30, 2019

Dear Customer,
Cc: Chairman Medical Board and relevant Head of Department

Product affected

Model numbers	GTIN	Serial number(s)
2131000000 2131PX1000 2141000000 2141PX2000 2141PX3000 2151000000 2152000000	07613327169294 07613327473001 07613327169232 07613327385427 07613327472998 07613327419825 07613327419818	See Attachment
Product description		
InTouch ® Critical Care Bed manufactured between December 20th, 2018 and May 8th, 2019, and units that received footboard upgrade to software Rev_0665-C.		

Product description

InTouch is an AC-powered, adjustable hospital bed designed to position human patients for procedures, therapy, and recovery in a healthcare environment, and transport patients between bays and procedural rooms. When the Chaperone bed exit system is active, it monitors a chosen zone, and alerts the operator of a deliberate or non-deliberate bed exit.

The Bed Exit has three optional sensitivity zones which the user can set depending on preference or patient need. When Bed Exit is set, visual indicators on the footboard illuminate green. If a patient attempts to exit the bed, the visual indicators flash amber and an audible alarm can sound locally and/or remotely depending on bed setup. Bed Exit is intended only to aid in the detection of a patient exiting the product. It is not intended to replace patient monitoring protocol.

Product issue

It has been identified that the audible Bed Exit alarm is affected by a software issue in the footboard that prevents users from being able to change the alarm volume. The impacted footboard software is Rev_0665-C. If a user attempts to adjust the Bed Exit alarm volume, the slider may indicate that it is set to high volume, however, the audible alarm will sound at the low volume setting. The volume then cannot be changed by the user.

Wireless connections to the nurse's station and visual indicators are not impacted by this issue

All InTouch beds built between December 20th, 2018 and May 8th, 2019 were manufactured with the impacted software. In addition, beds manufactured before December 20, 2018 may have been upgraded to the impacted software.

Potential risks

A Health Hazard Evaluation was completed which determined that there is no additional health risk related to this issue. The Bed Exit function is intended only to aid in the detection of a patient exiting the product, and not to replace local patient monitoring protocols.

Actions needed

1. Please refer to the enclosed business reply form to verify units at your facility that may be impacted.
2. The footboard software version can be confirmed by following the steps outlined in Appendix A.
3. Return the enclosed business reply form to confirm receipt of this notification by fax **269 488 8691** or email **productfieldaction@stryker.com** no later than November 29, 2019.
4. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the modification/repair of your beds.
5. If you have loaned or sold any of the products listed in this letter, please forward a copy of this notice to the new users and advise us of their new location.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to MedWatch , P.O. Box 3002, Rockville, MD 20847-3002
- Fax: +1 800 FDA 0178

If you have any questions or concerns, please contact Customer Service +1 800 327 0770. Our normal business hours are Monday-Friday 8 a.m-6 p.m. (EST).

We apologize for any disruption that this notification may cause. We strive to make products that meet our customers' expectations for quality and durability.

Sincerely,

[redacted]

Sean Honard
Staff Regulatory Affairs Specialist
Stryker Medical

Appendix A:

To verify whether your product has the impacted footboard software (Rev_0665-C), perform the following steps:

1. Remove the footboard by grasping the handles and lifting the footboard straight up and off the product (Figure 1).
2. Replace the footboard by lowering the footboard onto the footboard connector. Make sure that the footboard properly fits onto the footboard connector on the foot end of the litter (Figure 2).

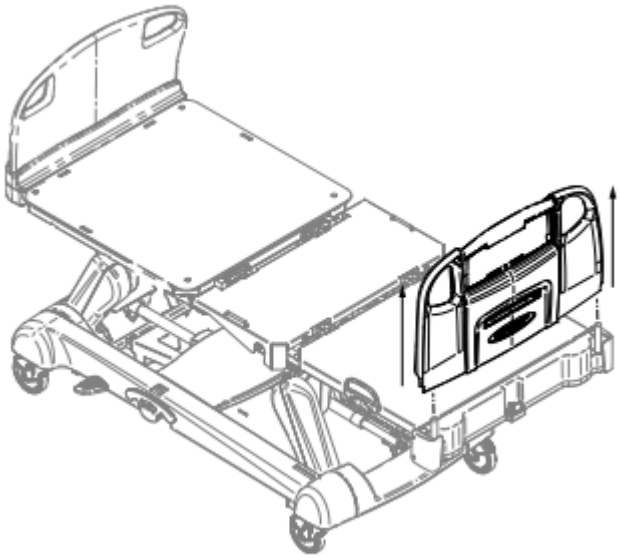

Figure 1

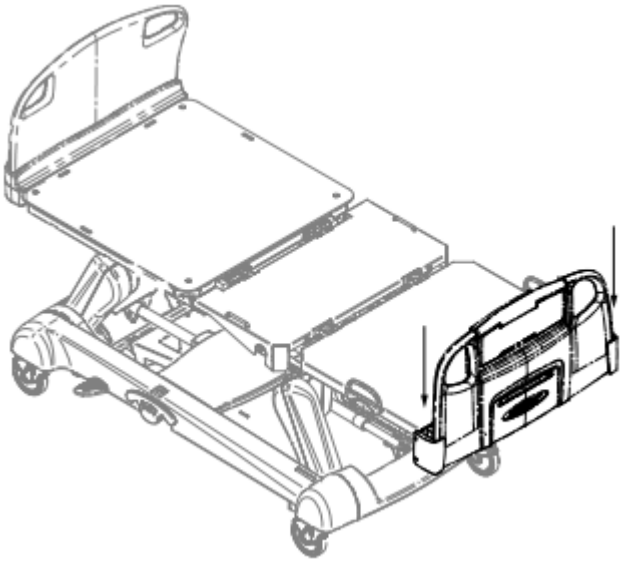

Figure 2

3. After replacing the footboard, the footboard software revision can be seen in the lower left corner during the start-up screen (Figure 3). If the software revision displayed is "Rev_0665-C", then the unit being inspected has the impacted software.

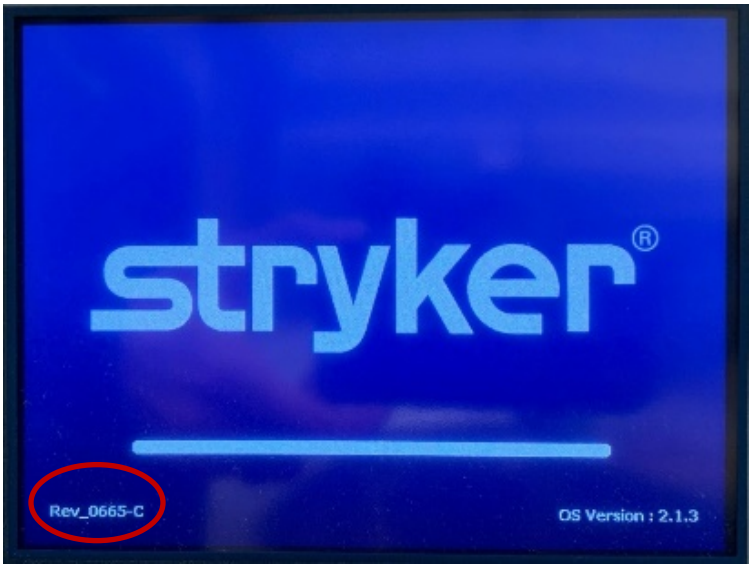

Figure 3

For further information on removing or replacing the footboard and navigating the InTouch footboard control panel, please refer to the Operations Manual that was provided with your product or on http://techweb.stryker.com.

Business reply **form**

InTouch Critical Care Bed
Bed Exit alarm volume may be too low

Models: 2131, 2141, 2151, 2152

On the reverse side of this page, please find a list of impacted serial numbers at your location.

If you received service footboards or software upgrade kits within the suspected time frame, purchase order information will be listed below. If the suspect upgrade kits remain in your inventory, please dispose of them and notify Stryker's regulatory department.

Account number:	
Account name:	

PO number	Part number	Part description	Quantity	Date shipped

If you or a third party performed software upgrades without the assistance of a Stryker service representative, please provide a list of the serial numbers that received the software upgrade.

Complete and sign this form to indicate that you have received and understand the enclosed notification.
Fax **269 488 8691** or email **productfieldaction@stryker.com** the form to Stryker's Regulatory Department.

☐ I have received and understand the enclosed notification

_____ _____
Printed name Signature Date

_____ _____
Contact phone number Email address

Regulatory Affairs
Phone: 269 389 8306
Fax: 269 488 8691
Email: productfieldaction@stryker.com

Note: Please keep a copy of this completed, executed form for your records.

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Serial numbers
