

URGENT MEDICAL DEVICE NOTIFICATION

RE: STRYKER MODELS 2130, 2131, 2140, 2141, 2151, 2152, 2155, and 2156 InTouch Critical Care Bed

ATTENTION: Recall Coordinator

Date June 30, 2014

Product Affected Models 2130, 2131, 2140, 2141, 2151, 2152, 2155, and 2156
InTouch Critical Care Beds

Manufacturer Model Number	Product Description	Serial Number
2130, 2131, 2140, 2141, 2151, 2152, 2155, 2156	InTouch Critical Care Bed	See Attachment

Product Description InTouch is an AC-powered adjustable hospital bed, intended for medical purposes, which consists of built-in electric motors and controls that can be operated by the patient or the caregiver to adjust the height and surface contour of the bed. The device includes movable and latchable siderails, as well as an integrated weighing system, which can be used in conjunction with the product to provide a patient weight reading as well as bed-exit and/or patient movement alarm. All models of InTouch beds are equipped with battery backup. The battery backup power allows the bed to be fully functional for a limited amount of time (e.g. during patient transports). InTouch bed models 2140 and 2141 are equipped with Zoom drive and provide assistance to the caregiver when transporting the bed / patient via powered-drive assistance. The InTouch bed is a patient handling device primarily used in the Critical Care environment

Product Issue Stryker has received complaints from the field regarding InTouch beds, which allege that a caster has broken on the top of the caster stem where the brake rod inserts into the caster. These broken casters are identified when the InTouch beds are hoisted or lifted from the floor during regular maintenance. If more than one caster on a unit is damaged, brake functions may be affected and result in reduced brake holding force. If only one caster on the bed is damaged, brake functionality continues to meet specifications.

Stryker's investigation determined that the root cause of this issue is attributable to a potential use error in which the bed's electric brakes are activated while the bed is in motion. The caster braking system on InTouch beds is designed to be activated when the bed is in a stationary position, as stated in the operations manual. When transporting the bed, the bed should be brought to a complete stop before applying the bed's caster brake system. The caster brake system is intended to keep the bed from moving while in a stationary position.

Potential Hazard A Medical Risk Assessment determined that the probability of life-threatening harm is negligible for the population at greatest risk (Patients who are sedated, have decreased mobility, are elderly or physically handicapped, have increased weakness, decreased agility or decreased response/reaction time). The probability of harm requiring medical intervention is remote for the overall patient population. For individuals other than patients, a remote probability of temporary or reversible harm (not requiring medical intervention) has been identified. While there have been no instances of life-threatening harm to an individual as a result of this issue, we have received reports of non-life threatening injury.

Risk Mitigation The enclosed “Brake Only While Stationary” labels are included with this notification and are to be placed near the electric brake buttons, per the accompanying instruction sheet. The purpose of the label is to remind users to active the electric brake only when the bed is stationary, and that it is not be used as a means to stop the bed when it is in motion.

Actions Needed

1. Locate the beds with serial numbers listed on the enclosed business reply form.
2. Inspect the brake holding force per the instructions provided.
3. If you experience a loss or reduction in brake force, remove the bed from service and contact Stryker at (1-800-327-0770, Option 2, and then Option 3, or https://techweb.stryker.com/account/call_dispatch/verify.html to arrange a service call.

Note: If the brakes function properly, the bed may remain in service.

4. Apply the enclosed labels per the instructions provided.
5. Refer to the enclosed updated Operation instructions for applying or releasing the electric brakes, and make sure users are aware that they **should not** use the electric brake to slow or stop the product while it is in motion.
6. Continue to follow the preventative maintenance program as called out in the operations and maintenance manuals.
7. Fax (269) 488-8691 or email productfieldaction@stryker.com the enclosed business reply form to confirm receipt of this notification.
8. If you have loaned or sold any of the beds listed in this letter, please forward a copy of this notice to the new users and advise us of their new location in the space provided on the business reply form.
9. If you have disposed of any of the beds and they are no longer in use, please advise us of their obsolescence by providing us with their serial number in the space provided on the business reply form.

*For additional information, please refer to the product’s operations and/or maintenance manuals.

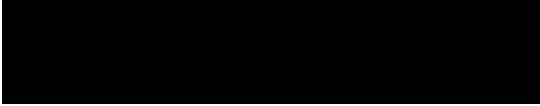
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- 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 Stryker 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,



Blaine Burnett
Regulatory Affairs Representative - Associate
Stryker Medical

Once again, please fax (269-488-8691) or e-mail (ProductFieldAction@stryker.com) the enclosed acknowledgement of this notification.