

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 10/29/2012 - 01/11/2013*
	FEI NUMBER 1824206

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: John J. Greisch, President/CEO**

FIRM NAME Hill-Rom, Inc.	STREET ADDRESS 1069 State Route 46 East
CITY, STATE, ZIP CODE, COUNTRY Batesville, IN 47006-7520	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

*The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.*

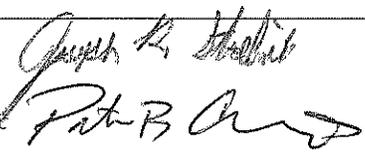
**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

Complaints involving the possible failure of a device to meet any of its specifications were not reviewed, evaluated, and investigated where necessary.

Specifically, your complaint handling system is inadequate in that Section 7.6 of your Complaint Management procedure, QS00097 Rev. 5, states "Any complaint involving the failure of the device, or one of its components to meet specification will be investigated, unless such investigation has already been performed and documented for a similar complaint," however in the time frame from 10/01/2011 to 10/26/2012:

- a. You had 563 complaints involving component failures within 14 days of distributing your beds, but your complaint records indicate that "investigations for these failures were not performed and these complaints were not associated with any ongoing/completed complaint investigations." These component failures were found in: 177 TotalCare beds, 326 medical surgical beds (i.e. VersaCare), 24 long term care beds, (i.e. GPAC and Resident), and 36 maternity care beds (i.e. Affinity). Your complaint records stated "an investigation was not necessary."
- b. You had 384 TotalCare complaints from 10/01/2011 to 10/26/2012 which involved replacing the graphic user interface due to failure and you documented "an investigation was not necessary". You did not conduct an investigation for these 384 component failures and these complaints were not associated with any ongoing complaint investigations.
- c. You had 603 TotalCare complaints from 10/01/2011 to 10/26/2012 which involved replacing the power control module due to failure and you documented "an investigation was not necessary". You did not conduct an investigation for these 603 component failures and these complaints were not associated with any ongoing complaint investigations.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Joseph R. Strelnik, Investigator Sean T. Creighton, Investigator Patrick B. Cummings, Investigator	DATE ISSUED 01/11/2013
		

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**OBSERVATION 2**

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, your handling of nonconformances is inadequate in that:

- a. You failed to follow your procedures in that six (6) nonconforming beds were found in an area that was designated as "Research and Development." Your Control of Nonconforming Material procedure, QS00088 Rev. 8, defines a nonconforming area as "a quarantined area that has been designated for the placement of nonconforming item(s)" and continues to state "Employees are responsible for routinely moving nonconforming items to an identified nonconforming location." During the inspection you removed five (5) TotalCare and one (1) VersaCare bed from the production area, brought them to a separate building, and placed the 6 hospital beds in an area clearly identified as "research and development." During a walkthrough of this area, we were unable to determine which hospital beds were research and development, which beds were production nonconformities, and which beds were returned from the field as "Returned Material Authorizations." Of these six (6) beds, the following issues were observed:
  1. TotalCare serial #N228AM1302 failed final inspection twenty-seven (27) times; Twenty-three (23) of these failures were due to the same defect, "failed 0 lb accuracy." This bed passed final inspection and was released for distribution on 08/16/2012. This bed then failed a product audit on 08/16/2012 with a rejection reason of "scale not communicating with the bed."
  2. TotalCare serial #N299AM2477 failed final inspection one (1) time and has yet to pass final inspection; the nonconformance read "Brake won't engage all the way, alarm going off."
  3. TotalCare serial #N235AM1426 failed final inspection two times with nonconformances that read "R/S F/R GUI inoperative" and "GUI keeps popping up air system error." The bed passed final inspection and was released for distribution on 08/23/2012.
  4. TotalCare serial #N306AM2575 passed final inspection with no nonconformances found and was released for distribution on 11/02/2012. This bed then failed a product audit on 11/02/2012 with a rejection reason of "Rotation doesn't work."
  5. TotalCare serial #N237AM1468 failed final inspection five (5) times with nonconformances that read "Failed UL ground test\*\*\*MCM blower not turning on\*\*\*L/S GUI flickering\*\*\* Still fails turning on MCM blower\*\*\*CAN error." The bed passed final inspection and was released for distribution on 08/31/2012. This bed then failed a product audit on 09/25/2012 with a rejection reason of "bed doesn't send nurse call when rail is down. Eng'g to review."
  6. VersaCare serial #N279AD9440 passed final inspection with no nonconformances found and was released for distribution on 10/05/2012. This bed then failed a product audit on 10/08/2012 with a rejection reason of "all lockouts activated from L/S head rail hilow down. -Relay 'chatters' in lower control board\*\*\*."
- b. In the process of producing TotalCare beds:
  1. You failed to document the evaluation and segregation of 1,986 in-line nonconformances from 10/01/2011 to 10/26/2012
  2. Your nonconformance documentation does not clearly indicate the disposition. For example, you documented the dispositions as: "completed, put oil on it, checked ground straps, resetted connectors, retried, restarted bed, put on, put and moved to other tester."

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3. There is no documentation of a need for an investigation for the 1,986 in-line nonconformances you documented from 10/01/2011 to 10/26/2012.
4. You did not document the dates of the occurrences or the production stages where the defect occurred.

**OBSERVATION 3**

Procedures for corrective and preventive action have not been adequately established.

Your CAPA system is inadequate in that:

- a. You had 400 TotalCare complaints from 10/01/2011 to 07/31/2012 which involved replacing the scale printed circuit boards due to failure and you did not evaluate whether to open a corrective action. Physicians use daily weights for critical care patients to determine intravenous medication delivery.
- b. From 10/01/2011 to 10/26/2012, your CAPA trending of nonconformances based on date of occurrence is inaccurate because it did not use the correct data inputs for time. For example, you trended nonconformances based on "date of origin" (i.e. the date that the information was entered into the (b) (4) system) instead of using the "date of discovery" (i.e. the date the nonconforming materials were identified and segregated). In the time period from 10/01/2011 to 10/31/2012, there were 575 NCMRs involving 2,476 components that had a date of origin/discovery time difference greater than 30 days; this accounts for 7.3% of the 7,816 total NCMRs discovered during this time frame.
- c. Quality problems were identified, but you failed to implement your procedures to ensure that these problems were corrected and prevented from occurring in the future. For example, two (2) field action assessments were not completed until 11 months and 16 months after they were initiated. Your procedure requires "timely evaluation" of information that may require action in the field.

Corrective and Preventive Action Procedure (QS00128) includes requirements for reviewing and analyzing quality data sources to identify existing and potential causes of quality problems. Your Quality Trending Work Instruction (QS00096) identifies CAPA and Field Actions as quality elements requiring proactive monitoring of quality data. Your Field Action Process Procedure (QS00120) states that a Field Action Team will conduct a timely evaluation of quality data, including product failures and safety hazards to make appropriate recall recommendations.

I reviewed two field corrective actions that demonstrated failures to conduct timely field action evaluations. For example, on 10/21/2010 your firm concluded that a field action assessment was necessary relative to initial reports of liftstrap seam failures common to all Likorall overhead lift systems. However, the Field Action Assessment and Health Hazard Evaluation which recommended a field action was not completed until 3/12/2012, over sixteen (16) months after learning of initial product failures. Additionally, on 5/05/2011 your firm concluded that a field action assessment was necessary relative to complaints alleging that Liko Lulea overhead lift rail systems have failed due to corrosion and cracking of stainless steel bolts and nuts in highly chlorinated areas such as swimming pool environments. However, the Field Action Assessment and Health Hazard Evaluation which recommended a field action was not completed until 4/30/2012, over eleven (11) months after learning of the initial product failures.

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**OBSERVATION 4**

The device history record does not demonstrate that the device was manufactured in accordance with the device master record and 21 CFR 820.

Specifically:

- a. You failed to follow your device master record work instructions in that components and processes were determined to be missing after the beds failed your finished device inspection and testing. For example:
  1. 376 components were missing from your TotalCare beds at final inspection and testing from 10/01/2011 to 10/26/2012; you produced (b) (4) TotalCare beds in this time period.
  2. 191 components were missing from your VersaCare beds at final inspection and testing from 10/01/2011 to 10/26/2012; you produced (b) (4) VersaCare beds in this time period.
- b. Your device history record documentation is inadequate in that:
  1. Four out of four TotalCare device history records reviewed did not document the dates of when your beds are processed through assembly stations. In the time period from 10/01/2011 to 10/26/2012, your quality assurance final product inspection and testing showed that TotalCare beds were re-worked 1,986 times and then re-tested/inspected.
  2. Five out of five VersaCare device history records reviewed did not document the dates of when your beds are processed through assembly stations.
  3. Five out of five Affinity device history records reviewed did not document the dates of when your beds are processed through assembly stations.
  4. Five out of five Resident device history records reviewed did not document the dates of when your beds are processed through assembly stations.
  5. Five out of five GPAC device history records reviewed did not document the dates of when your beds are processed through assembly stations.

**OBSERVATION 5**

Written MDR procedures have not been implemented.

Specifically, since your revised Medical Device Reporting procedure (SOP #QS03635) became effective on 12/06/2011, eighty-eight (88) MDR events were reported to FDA later than 30 calendar days after the awareness date. Of the eighty-eight (88) late MDRs, forty-three (43) were reported 60 or more days after you initially became aware of the event.

For example:

- MDR 1824206-2012-03087 reported 5/28/2012 - 81 days late

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- MDR 1824206-2012-03190 reported 6/01/2012 - 103 days late
- MDR 1824206-2012-04337 reported 7/27/2012 - 201 days late
- MDR 1824206-2012-06614 reported 10/17/2012 - 88 days late

**OBSERVATION 6**

Design verification does not confirm that design output meets design input requirements.

Specifically, your design verification activities for the TotalCare Bariatric Plus are inadequate in that you used the Housekeeping script in Protocol NPD10663 Rev. 2 to verify Design Requirement Specification (DRS) 8.143, but the script was not executed as it was written. There is no documentation to show that firm management evaluated the deviation to determine if it would have an impact on the test results and if the design outputs would satisfy the design inputs.

**OBSERVATION 7**

Procedures for training and identifying training needs have not been adequately established.

Specifically, your training procedures are inadequate in that:

- a. Your training procedure allows for new procedures and work instructions to become effective prior to employees being trained to the new procedure. Training SOP QS04572 states "Employees will be trained within 30 calendar days from the date effective."
- b. You failed to train employees in a time frame that was consistent with your training procedure. For example, four employees were trained to (b) (4) Revision 1 on 12/23/2011; this job instruction became effective on 10/18/2011 and these employees were the first round of employees trained to this procedure. In the time frame from 10/18/2012 to 12/22/2012 your firm had 19 nonconforming material reports which encompassed 266 components that were related to components found in this job instruction and had responsibility codes listed as "Manufacturing."
- c. You failed to adequately train employees manufacturing TotalCare beds to ensure that they are capable of performing their work. You identified 861 beds that failed to meet your processing specifications during finished device inspection and testing. For example: 376 beds had missing components or processes, 156 beds had loose components or assemblies, 281 beds had incorrect components or processes and 48 beds had misassembled components or processes during your final inspection and testing in the last year.

**OBSERVATION 8**

Procedures for design validation have not been adequately established.

Specifically, your design validation activities are inadequate in that:

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1. You did not ensure that the TotalCare Bariatric product line conformed to intended uses and perform testing of production units under actual or simulated conditions. For example, you identified a new use case in which there are "up to 2 people pushing and 2 people pulling to roll a patient on their side," but you did not perform any testing to determine if your bed conformed to this new intended use. Instead, production units were tested in October of 2011 for use cases in which up to 2 personnel were pushing or up to 2 personnel were pulling to turn a patient sideways.
2. Your acceptance criteria are not clearly defined to ensure that the design will allow for the identification of test protocol failures. For example, test script "Bath Patient in Bed" used in Protocol NPD10663 Rev. 2 has acceptance criteria of "bed does not overbalance (tip), it is ok if the casters momentarily leave the floor, or one caster is raised" and "Either no damage was observed, or the observed damage does not create a hazard for the patient, caregiver, or visitor." This language does not identify how high one caster is allowed to leave the floor and how long one or more casters can be off the floor.

**OBSERVATION 9**

Procedures for design verification have not been adequately established.

Specifically, your design verification of your TotalCare beds used in critical care patient settings was inadequate in that:

- a. Your sample size selection of testing (b) (4) beds for weigh/scale accuracy did not prove repeatability and reproducibility of the scales ability to weigh patients accurately and over time
- b. You did not address bed to bed variability
- c. You did not address long term stability of the scale when your beds have a 10 year life expectancy.

**OBSERVATION 10**

Document control procedures have not been adequately established.

Specifically, your document control procedures are inadequate in that you identify test scripts with a script title and a revision number, but this information is not unique for each individual script. When we compared two revision 4 documents with the same title, "Scale Calibration.doc," they were not the same. You do not obsolete previous revisions of test scripts and they can be used in any protocol that calls for their use. This means that based on the title and revision number, you cannot guarantee that you are using the correct approved protocol. These test scripts were used for design verifications activities for the VersaCare product line.

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**OBSERVATION 11**

Procedures for identifying product during all stages of receipt, production, distribution, and installation have not been adequately established.

Specifically, you have inadequate control of components in your Affinity bed production line in that components used in production are stored in bins which had part number identification numbers crossed out, written over, and additional writing added to the original identification information.

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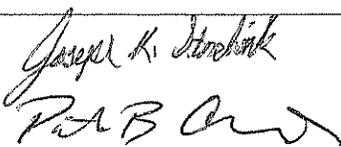
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**Observation Annotations**

- |                                      |                                      |
|--------------------------------------|--------------------------------------|
| Observation 1: Promised to correct.  | Observation 2: Promised to correct.  |
| Observation 3: Promised to correct.  | Observation 4: Promised to correct.  |
| Observation 5: Promised to correct.  | Observation 6: Promised to correct.  |
| Observation 7: Promised to correct.  | Observation 8: Promised to correct.  |
| Observation 9: Promised to correct.  | Observation 10: Promised to correct. |
| Observation 11: Promised to correct. |                                      |

**\* DATES OF INSPECTION:**

10/29/2012(Mon), 10/30/2012(Tue), 10/31/2012(Wed), 11/01/2012(Thu), 11/02/2012(Fri), 11/05/2012(Mon), 11/06/2012(Tue), 11/07/2012(Wed), 11/08/2012(Thu), 11/09/2012(Fri), 11/12/2012(Mon), 11/13/2012(Tue), 11/14/2012(Wed), 11/15/2012(Thu), 11/16/2012(Fri), 11/26/2012(Mon), 11/27/2012(Tue), 12/05/2012(Wed), 01/11/2013(Fri)

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