DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	08/02/2010 - 08/18/2010* FEI NUMBER 1031452

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Chris K. Carter, Director of Operations

FIRM NAME	STREET ADDRESS
Invacare Corporation	2101 E. Lake Mary Blvd.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sanford, FL 32773	Medical Device 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

Corrective and preventive action activities and/or results have not been documented.

(A) Firm has failed to take adequate corrective action in response to reports of entrapment involving Invacare medical beds sometimes resulting in death.

(B) Firm implemented at least two design changes in 2007 regarding reducing risk of entrapment with Invacare models # 5490IVC, 5770IVC, 5890IVC, 5491IVC, 5891IVC, 5890PMI, 5490PMI, 5000IVC, 5000PMI, 6000PMI, 6010PMI, VC5000 and C5890 beds and bed rails models # 6628 and 6629. The firm has failed to implement these changes to the above models in the field except for recall of Careguard mattresses in October 2007.

(C) Firm fails to take preventive action to ICCI bed systems after its own risk assessments complted in May 2009 and July 2010 indicates increased risk of entrapment for: Echo bed, IHECRLPAR rail, SPS1080 bed system; Echo bed, IHECRLFUL rail, SPS1080 bed system; Echo bed, IHECRLPAR rail, SPS1080RSR bed system; Echo bed, IHECBAAR rail, SPS1080RSR bed system; Arro bed, IHARRLPAR rail, SPS1080 bed system; Arro bed, IHARRLFUL rail, SPS1080 bed system; Arro bed, IHARRLFUL rail, SPS1080RSR bed system; and Arro bed, IHARRLPAR rail, SPS1080RSR bed system.

OBSERVATION 2

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

Entrapment Issue

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Richard K. Vogel, Investigator Andrea H. Norwood, Investigator	08/18/2010

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(A) Firm received Complaint # 2010 dated 02/19/09 which references a patient was allegedly found deceased, trapped within the bed rail of an Invacare bed system. Firm's investigation is inadequate in that the firm failed to determine most likely root cause of the complaint. Firm did not determine if patient's size related to higher risk of entrapment and firm did not determine if bed rail dimensions put patient at increased risk of entrapment/death.

(B) Firm received Complaint # 2211 dated 03/09/09 which references a patient was found with her head in the left side of the rail face down in the mattress. Entrapment with affixation was most likely cause of death. Firm's investigation was inadequate in that:

(i) Firm failed to document attempt to obtain any information regarding mattress involved in the above event including but not limited to mattress type and condition.

(ii) Firm did not make a good faith effort to obtain information regarding this complaint in that the only documented effort was a letter date 03/11/09 for which there was no reply from the complainant and there was no further effort by Invacare to obtain information.

(iii) Firm did not determine most likely root cause. Firm did not determine if patient's size could relate to higher risk of entrapment and firm did not determine if bed system's dimensions/set-up put patient at increased risk of entrapment/death.

(C) Firm received Complaint # 2686 dated 05/15/09 which references a patient was found deceased with her legs on the floor and her head entrapped in the bed rail. Firm's investigation was inadequate in that:

(i) Firm failed to document attempt to obtain pertinent information regarding the identification and condition of the mattress used, the height and weight of the patient, the exact area of entrapment, or the age of the bed system.

(ii) Firm did not determine most likely root cause. Firm did not determine if patient's size related to higher risk of entrapment and firm did not determine if bed rail dimensions put patient at increased risk of entrapment/death.

(D) Firm received Complaint #3597 dated 10/06/09 which references a patient was found deceased with their chin in the bed rail. Reportedly, a specialty mattress was used. Firm failed to document attempt to obtain pertinent information regarding patient name and contact information and/or dealer name/contact information with which they could complete an adequate investigation.

(E) Firm received Complaint #4152 dated 02/01/10 which references a patient was found still breathing with his head resting between the bar and the mattress and face was on mattress, but patient expired later at hospital. According to firm's personnel the most likely root cause was the use of a non-Invacare mattress ((b) (4)) which was described as too thin and narrow and

was not tested for entrapment risk. Firm failed to send reply letter of this complaint investigation's conclusion.

(F) Firm received Complaint #4023 dated 01/05/10 which references an 18 year old patient with cerebral palsy (4 foot 4 inches tall weighing 53 lbs) fell from the Invacare bed and suffocated. Firm's complaint investigation was inadequate in that:

(i) Firm did not document good faith attempt to obtain pertinent information as to what area of the bed suffocation occurred and what mattress was used and its condition.

(ii) Firm did not determine most likely root cause. Firm did not determine if patient's size related to higher risk of entrapment and did not determine if the bed's dimensions put patient at higher risk.

(G) Firm received Complaint #4181 dated 02/11/10 which references a consumer alleges an Invacare bed system allowed his wife's head to get stuck between rail and mattress causing her suffocation. Firm's complaint investigation is adequate in that:

(i) Firm failed to document attempt to obtain pertinent information including actual user's name, contact information and patient's height/weight.

(ii) Firm did not determine most likely root cause. Firm did not attempt to determine if patient's size could relate to higher risk of entrapment. Firm did not determine if bed system's dimensions put patient at higher risk of entrapment/death.

(H) Firm received Complaint #4234 dated 02/17/10 which references that there was an alleged death of patient and entrapment with Invacare bed between the bottom of the rail and the top of the mattress. It is documented in firm's investigation that health care facility personnel stated a coroner's report indicated that the patient suffered a heart attack and then was allegedly entrapped post mortem. Firm's complaint investigation was inadequate in that:

(i) Firm failed to obtain copy of subject coroner's report.

(ii) Firm failed to obtain pertinent information including contact information for patient's family and patient's height/weight.

(iii) Firm states that non-Invacare mattress was used, however no identification of brand name/manufacturer/dimensions/condition and firm failed to send reply letter to complainant cautioning them not to use a non-Invacare mattress.

(I) Firm received Complaint #4522 dated 04/13/10 which references an Invacare bed and bed rail was allegedly involved in a bed entrapment death of a child (age 11). Firm's complaint investigation was inadequate in that:

(i) Firm did not attempt to get pertinent information regarding bed model #, mattress type/condition, patient weight/height, where the child was entrapped and whether there is a history of entrapment with this particular bed rail.

(ii) It was documented that bed was inspected by counsel and engineering but firm failed to document what was inspected and results of inspection.

(iii) Firm fails to document most likely root cause. Firm did not determine if patient's size caused higher risk of entrapment and firm did not determine if bed rails' dimensions put patient at risk of entrapment/death.

Potential Fire Issue

(J) Firm received Complaint #2267 dated 02/23/09 which references a one year old bariatric bed was brought back to dealer for testing and after hand control was activated the junction box burnt with flames shooting out of it. Although there was no injury Invacare reported this incident as an MDR event. Firm contacted dealer several times to have subject bed returned however bed was not returned. Invacare Safety Committee closed this complaint on 01/28/10 and it was stated the nature of the complaint suggests a service error. Firm failed to document review for similar incidents in the past, failed to identify any root causes related to Invacare's design and manufacture of the bed, and failed to take any corrective action.

(K) Firm received Complaint #4521 dated 04/13/10 which references a fire started at the foot of Invacare bed (model # unknown) resulting in a consumer's death. Firm failed to document review for any similar incidents in the past, failed to identify any potential root causes, and assure no corrective action was needed for subject root causes.

(L) Firm received Complaint #2598 dated 05/07/09 which references the dealer went to plug in Invacare unit (Careguard APP pump and pad) and it sparked. Invacare states device was received and would not power on and no sparking was noted. Invacare states no history to suggest this was a product problem. Firm failed to document an attempt to determine from the dealer what area of the unit spark came from. Firm failed to identify any potential root causes (of sparks or what caused unit not to power on) and assure no corrective action is needed for subject root causes.

(M) Firm received Complaint # 2837 dated 06/24/09 which references a dealer was setting up a new Invacare bariatric bed and when he engaged pendant, he observed sparks from motor, a surge came across, and sparks flew from the motor (thinks foot motor). Firm failed to document a review for similar incidents in the past and failed to identify any potential root causes and assure no corrective action is needed for subject root causes.

(N) Firm received Complaint #2850 date 06/04/09 which references a patient stating her control (junction) box on Invacare bariatric bed caught on fire. During Invacare inspection a white/brown spot was observed on control box. Upon pressing the head up button, white smoke

(no fire or sparks) emitted out from bottom of the head connector of the control box. It is documented that reported incident occurred as a result of a failed component within the bed control box and although localized heating of the component occurred, incident did not result in a fire. Invacare states both the case body and potting material that encapsulates the pcb assembly are produced from flame rated materials and potting material would contain any debris. Firm failed to document a review for similar incidents in the past, failed to identify what failed component was and how it failed (over heating, etc.), failed to include documentation of testing of potting material/case body would eliminate risk of fire, and failed to include documentation that potting material meets specifications consistently.

(O) Firm received Complaint #3599 dated 10/07/09 which references a dealer setting up an Invacare bariatric bed in a patient's home and it sparked when plugged in. The firm stated that a potential set-up error may have occurred which damaged the control box, the control box had an internal failure and considering the controller (junction) box is potted in a flame rated material, no risk of fire is presented to the user. Firm's complaint investigation is inadequate in that:

(i) Firm did not document attempt to find out from dealer from what are the sparking was emitted and frequency/severity of sparking.

(ii) Firm failed to attempt to identify what component failed in the control box, failed to identify the cause of the failure and of the sparks and did not assure corrective action was taken regarding most likely root cause.

(P) Firm received Complaint #3660 dated 10/08/09 which references that a delivery man went to set-up an Invacare bariatric bed. When he tried to get foot end to work, he smelled burning wire and the bed would not work. The dealer replaced the junction box. Firm stated there was no malfunction because this was an installation error and considering this even occurred when the dealer first set-up the bed misconnection of motor cables was most likely root cause. Upon return, Invacare stated a potential bed assembly error which resulted in an open circuit in the control box (an internal component failure) left the control box inoperable. Firm failed to identify failed component, failed to identify any other root cause other than installation error and failed to assure the appropriate corrective action is taken regarding potential root causes.

(Q) Firm received Complaint #3790 dated 11/12/09 which references that a dealer was setting up an Invacare bariatric bed, a spark shot out of the head motor when they plugged the bed in then the bed had no power at all. Firm stated that considering this event occurred during dealer set-up, misconnection of the motor cables is most likely cause and this is an installation error not a malfunction. On 07/29/10 when the firm documented MDR decision rationale it was stated this was a possible malfunction but not likely to cause serious injury. Upon return, it was found the bed did not function and it was stated that the control box likely had an internal failure. Invacare

states a potential set-up error may have occurred which damaged the control box and considering the controller is potted in a flame rated material no risk of fire is presented to the user. Firm failed to identify the failed component, and any other potential root cause other than installation error and failed to assure the appropriate corrective action is taken regarding potential root causes.

(R) Firm received Complaint #4352 dated 03/09/10 which references a consumer reported a power unit to a low air loss mattress (MA85) had a burning smell and set off their smoke detector. Firm stated an MDR decision rationale dated 07/29/10 that this was a possible malfunction but not likely to cause serious injury. It is stated nature of complaint suggests a new product and new compressor will have a slight odor as it wears in. Upon return, it is stated blower motor did not turn on. Firm failed to identify most likely root cause of failure and the appropriate corrective action is taken regarding potential root cause.

(S) Firm received Complaint # 4470 dated 03/30/10 which references a dealer observed a head motor of an Invacare bariatric bed sparked and smoked during set-up and bed is not working. Firm failed to identify most likely root cause regarding failure of components of device adequately. Firm stated misconnection of motor cables was likely cause because this occurred during set-up by dealer however firm does not state why this is most likely to cause head motor to spark and smoke and unit not to work. Firm did not attempt to verify with dealer that a misconnection of motor cables actually occurred.

(T) Firm received Complaint #4894 dated 06/02/10 which references that the junction (control) box of an Invacare bariatric bed caught fire and two patients were taken to the hospital and treated for smoke inhalation and chest pain. Visible flames were observed, however when the unit was unplugged the fire went out. The fire department reportedly is contributing the fire to the control box. It is stated that Invacare received the suspect product back on 08/04/10. Firm's investigation is inadequate in that:

- (i) Firm failed to determine if treatment for smoke inhalation and chest pain was to preclude a serious injury which would require submitting a serious injury MDR instead of the malfunction MDR that the firm submitted.
- (ii) Firm does not document attempt to obtain fire department's report.
- (iii) Firm has no documentation of its inspection of the suspect product returned on 08/04/10.
- (iv) Firm has failed to document potential root causes and failed to take appropriate corrective action to potential root causes.

(U) Firm received Complaint #4948 dated 06/02/10 which references user alleges junction (control) box of an Invacare bariatric bed was sparking and bed does not work at all. Invacare sent

replacement junction box and pendant. Firm states nature of complaint suggests set-up error. It is stated on 06/11/10 that product is being returned for inspection but it is not documented that product had been returned or that it has been inspected. Firm failed to document potential root causes not related to set-up error and failed to take appropriate corrective action to any potential root causes.

(V) Firm received Complaint # 5208 date 06/25/10 which references a driver set-up an Invacare bariatric bed and found no power to the bed. A burning smell was noted but no actual smoke. It is stated considering this event occurred when the dealer first set-up the bed, misconnection of motor cables is likely cause. It is stated this is most likely a service/installation error and not a malfunction. No return of product yet. Firm has failed to document potential root causes not related to installation error and failed to take appropriate corrective action to any potential root causes.

Other Issues

(W) Firm received Complaint # 2182 dated 02/27/09 which references an incorrectly set-up bed (model #5310IVC bed with model # 6628 rail) that caused a patient to fall out of bed and break his shoulder. The firm evaluated the returned bed system and concluded that all the defects noted are non manufacturing defects. The firm's complaint investigation was inadequate in that firm did not document a good faith effort to obtain further information as to how the bed was not set-up correctly, who set-up the bed incorrectly and when the bed was set-up incorrectly.

(X) Firm received Complaint # 3839 dated 11/23/09 which references a bed rail becoming loose, causing the patient to fall. The firm's complaint investigation was inadequate in that:

(i) Firm did not document a good faith effort to obtain the extent of the patient's injury.

(ii) It is stated that the consumer was using the rails to assist herself in getting out of bed despite being instructed not to do so in the instruction manual. The firm failed to document a review for similar incidents in the past.

(Y) Firm received Complaint # 2902 dated 06/16/09 which references a bed collapse resulting in an injury to an aid's foot or neck. The firm's complaint investigation was inadequate in that the firm failed to document a potential root cause of the bed's collapse.

(Z) Firm received Complaint # 2848 dated 06/04/09 which references a patient who incurred head injuries after falling out of bed. The firm's complaint investigation was inadequate in that:

(i) Firm failed to document attempts to obtain further information about the event including but not limited to the bed type and bed rail type and if the rails were up at the time of the event.

(ii) Firm inspected returned product documented user misuse/error and incorrect installation. Firm has not conducted a root cause analysis for improper installation of bed rails.

(AA) Firm received Complaint # 3332 dated 08/25/09 which references a patient who broke her nose due to an issue with the bed motor. The firm's complaint investigation was inadequate in that the firm failed to document a good faith effort to obtain further information about the event.

(BB) Firm received Complaint # 3838 dated 11/20/09 which references the pin of the bed rail came out, allowing the patient to fall out of bed. The firm's complaint investigation was inadequate in that the firm failed to document a good faith effort to obtain further information about the event including failure to identify manufacturer and model of rails being used.

(CC) Firm received Complaint # 3452 dated 09/15/09 which references a bed rail becoming loose after an Alzheimer patient banged on the rails. The firm's complaint investigation was inadequate in that the firm failed to document a good faith effort to obtain further information about the event including failure to identify manufacturer and model of rails being used.

OBSERVATION 3

Risk analysis is incomplete.

(A) Firm fails to include risk of entrapment in its formal risk analysis for its bed systems including but not limited to non-Invacare mattresses/bed rails or use with smaller size patients except for CS (Carroll Series) Long Term Care Bed Systems, whose formal risk analysis does include patient entrapment issue but also does not include use of devices by smaller size patients.

(B) Firm has failed to complete any risk assessment in regards to entrapment for TSS (Therapeutic Support Services) air mattresses group 2 including but not limited to model # MA65.

(C) Firm has not completed risk assessment concerning Echo, Arro, and CS Invacare Beds with all Invacare mattresses including but not limited to models # 5180, 5184 and 5185.

(D) Firm fails to include risk of improper installation of bed rails in its formal risk analysis for its bed systems except for CS (Carroll Series) Long Term Care Bed Systems.

(E) Firm began labeling Invacare model # 5185 mattresses with warning label in order to reduce risk of entrapment on 08/01/07. Firm stopped using this label on model # 5185 mattresses on 02/21/08 because they believed it was redundant since the same information was being included in instructions for use for full length bed rails which was released on 12/06/07 but firm does not document on what date it was initially used. No risk assessment was

completed to determine if this action increased the risk of entrapment.

(F) Firm has failed to complete any risk assessment with regards to entrapment with Invacare beds/rails used with Invacare model # 5085 mattresses.

OBSERVATION 4

Requirements that must be met by suppliers and contractors have not been adequately established.

(A) Firm has documentation that (b) (4) (third party testing facility) did a test of bariatric bed control (junction) box to demonstrate potting material met UL94 (UL V-0) (burning stops within 10 seconds of flame application of test bar), however this test does not substantiate statement by Invacare that because of flame rated potting material there is no risk of fire presented to the user. No other testing was completed regarding this subject.

(B) The firm's purchasing control for bariatric control (junction) box supplier is inadequate in that only one audit of this supplier was documented in 2001. Firm's Survey Rating Sheet used to qualify firm's bariatric bed control (junction) box supplier in 2001 allows certain sections to fail the onsite audit such as design control, purchasing control and training and yet allows the supplier to pass the audit and qualify as a suppler. It is stated that the pc board in the control box is populated by using manual soldering only and training section was failed in 2001. The supplier was passed and qualified as a supplier for the bariatric control box. No follow-up audit was documented.

OBSERVATION 5

Design validation did not ensure the device conforms to defined user needs and intended uses.

Firm did no design validation study to assure labeling (Invacare User Manuals and Owner's Operator and Maintenance Manuals) which states accessories designed by other manufactures have not been tested by Invacare and are not recommended for use with Invacare products is clear enough to communicate that use of non-Invacare mattresses could lead to higher risk of death of patient via entrapment.

OBSERVATION 6

Personnel do not have the necessary training to perform their jobs.

Firm's training of regulatory affairs personnel, consumer affairs personnel, territory business managers (sales reps) and customer service personnel fails to assure that they have the knowledge necessary to attempt to obtain all pertinent information from complainants in order to complete adequate investigation of complaint regarding entrapment and potential fire issues related to their medical beds.

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OBSERVATION 7

Personnel training is not documented.

(A) There is no documentation that the following customer service personnel have ever received training on your complaint handling procedures although they received at least the following complaints:

(b) (6) (File # 2837 dated 06/24/09), (b) (6) (File # 3490 dated 09/21/09), (b) (6) (File # 4152 dated 02/01/10) and (b) (6) (File # 4181 dated 02/11/10).

(B) The following Invacare customer service personnel took part in complaint handling activities prior to obtaining documented training on complaint handling:

(b) (6) (# 2045 dated 02/09/09), (b) (6) (File # 2267 dated 02/23/09), (b) (6) (File # 2848 dated 06/04/09), (b) (6) (File # 3839 dated 11/23/09) and (b) (6) (File # 4023 dated 01/05/10).

OBSERVATION 8

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Firm received Complaint #4234 dated 02/17/10 which references that there was an alleged death of patient and entrapment with Invacare bed between the bottom of the rail and the top of the mattress. It is documented in firm's investigation that health care facility personnel stated a coroner's report indicated that the patient suffered a heart attack and then was allegedly entrapped post mortem. The firm failed to obtain subject coroner's report. Firm failed to report this complaint as death MDR to FDA.

OBSERVATION 9

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Firm received Complaint # 4250 dated 02/19/10 which references a patient who was in an Invacare bed who reached down to get something off of the floor and when he tried to sit back up he was prevented because his neck was resting under the rail. He did not have enough strength to move back away from the bar, staff had to assist him and allegedly he received a neck injury. Firm failed to report a malfunction MDR to FDA.

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OBSERVATION 10

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

(A) Firm fails to analyze MDRs, adverse events, or product complaints during trend analysis by problem codes such as entrapment or potential fire hazard.

(B) CAPA CP14-008 Invacare Corporate Corrective and Preventive Procedure does not require all corrective and preventive actions be verified and/or validated as effective prior to implementation and that they do not adversely affect the finished device.

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Observation Annotations

Observations intentionally left blank.

*** DATES OF INSPECTION:**
08/02/2010(Mon), 08/03/2010(Tue), 08/04/2010(Wed), 08/05/2010(Thu), 08/06/2010(Fri), 08/09/2010(Mon), 08/10/2010(Tue), 08/11/2010(Wed), 08/12/2010(Thu), 08/13/2010(Fri), 08/16/2010(Mon), 08/18/2010(Wed)

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