DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	02/23/2009 - 03/13/2009* FEI NUMBER 3002803444

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Heather L. Mason, President

FIRM NAME	STREET ADDRESS
Abbott Diabetes Care, Inc.	1360 South Loop Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Alameda, CA 94502-7000	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

Complaint handling procedures have not been defined and implemented to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report.

Specifically, during the review of your firm's complaint handling process and case/complaint files, it was revealed that:

A) A customer reported (Case #(b) (4)) that "her son who was using the navigator and was in pain and wanted to return the system." No further investigation was conduct to determine the seriousness of the potential injury and no MDR report as submitted. The Case text stated a reason for no further investigation conducted as "DID NOT CONTACT THE CUSTOMER DUE TO HIPPA REGULATIONS." A further review of this Case file revealed that a Medical Event Non-Reportable evaluation was completed on or about "08/27/2008" which states "After reviewing the case, it has been determined there is no reasonable suggestion of serious injury or device malfunction." Both Potential Reportable Event and Medical Complaint surveys were blank with no detailed information available.

B) Individuals/employees responsible for evaluating and/or investigating complaints/cases were not adequately trained to perform their tasks. Documentation of their training showed that these individuals did not complete their training pertaining to complaint investigation or were trained to analyze uploaded data prior to perform their duties/tasks.

OBSERVATION 2

Employees have not been adequately trained.

Specifically, during a review of your quality system pertaining to employee training, several employees' training records/files were reviewed and it was revealed that (b) (4) employees responsible for performing complaint/device failure investigations were either not adequately trained prior to performing their duties, or training was not established and documented for duties performed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mark E Chan, Investigator Alla Dubrovsky, Investigator	03/13/2009

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For example:
A) A review of the (b) (4) employee's training records revealed that they were trained to Revision B and C of Document No. (b) (4), Work Instruction - Navigator Phase 1 and 2 Investigation on or about February 23, 2009. Revision B of this work instruction was effective on or about "08-Nov-08" and updated the procedure to include the use of the (b) (4) (b) (4); downloading manufacturing parameters using the upload utility, added Appendix 4 to show instructions on how to open Sensor Delivery units, and added process on how to investigate Sensor Delivery units mount and sensor. Revision C of this work instruction was approved on or about 02-Dec-08 and effective on 10-Dec-08, which added additional investigative steps/procedures.

B) A review of complaint/case (QS Contact Summary Reports) revealed that these (b) (4) employees performed a log analysis on Navigator receiver memory uploaded data to determine/confirm the complaint issue/perception. No work instruction(s)/procedure(s) have been established, and on the job training for this process/operation has not been documented.

QS Contact Summary Report, Case #s:
(b) (4) documents that on or about 11/26/2008 that an employee "Performed Phase I Investigation per work instruction (b) (4)" and determined that "Complaint is not confirmed".

(b) (4) documents that on or about 11/26/2008 and (b) (4) documents on or about 1/20/2009 that an employee "Performed phase I investigation per work instruction (b) (4), performed a log analysis on data upload and "Did not observe high readings in continuous mode (CM) or during calibration.", to determine/confirm the perception code of "High Readings of the CM". From the investigation performed the employee determined that "Complaint is not confirmed." For Case # (b) (4), a review of the data upload for this case was conducted during this inspection (2/23/2009 to 3/13/2009) which showed that the continuous mode readings were reading higher than the discreet built-in meter readings.

OBSERVATION 3

Procedures for identifying training needs were not implemented.

Specifically,

A) from a review of your training procedure, Document (b) (4), Training Process, Implementation Date 11-Jul-07, it states under section 7.0 "REQUIREMENTS" in item 7.1.2, that (b) (4) (b) (4) (b) (4). From a review of QS Contact Summary Reports (Complaint/Case Reports) it was revealed that several employees responsible for evaluating/investigating complaint cases were not trained to the current revisions of the Work Instruction - Navigator Phase 1 and 2 Investigation, Document Number (b) (4) Revisions B and C.

B) There are no established procedures/work instructions for performing analysis of uploaded data from the Navigator receivers/meters.

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Observation Annotations

Observations intentionally left blank.

*** DATES OF INSPECTION:**
02/23/2009(Mon), 02/24/2009(Tue), 02/26/2009(Thu), 03/02/2009(Mon), 03/03/2009(Tue), 03/04/2009(Wed), 03/05/2009(Thu), 03/06/2009(Fri), 03/09/2009(Mon), 03/11/2009(Wed), 03/13/2009(Fri)

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