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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22201 23rd Drive SE Bothell, WA 98021-4421 (425) 486-8788 Fax:(425) 483-4996 Industry Information: www.fda.gov/oc/industry	09/01/2009 - 10/01/2009* FEI NUMBER 3014398

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David L. Marver, CEO and President

FIRM NAME	STREET ADDRESS
Cardiac Science Corporation	3303 Monte Villa Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bothell, WA 98021-8969	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

Not all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified.

a. No corrective action has been taken with AED units in the field that contain suspect (b) (4)(b) (4)(b) (4)(b) (4) resistors associated with CA-815. Failed resistors are not always detected during unit self-testing, and can result in a failure to treat.

b. No corrective action has been initiated with AED units in the field that contain suspect (b) relays associated with CA-922.

c. The Health Hazard Evaluation dated 8-1-07 for (b) errors covered by CA-698 concluded that no field action was required. Incident I088338, dated 1-9-08, reported the failure of a G3 AED to treat a patient during a rescue attempt. Complaint investigation determined that component (b) (4) would be out of tolerance (b) (4) and could cause an (b) error.

d. CA-698 does not include any preventive actions related to the quality issue caused by out of specification (b) components at (b) (4)(b) (4) and software (b) (4)

OBSERVATION 2

Corrective and preventive action activities have not been documented, including investigations of causes of nonconformities, the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, the verification or validation of corrective actions, and implementation of corrective and preventive actions.

a. Incident I067162, dated 11-29-06 reported an AED failed to analyze and shock simulated VF during a demonstration. The failure was confirmed and resistor (b) (4) was replaced. There is no documentation a failure investigation was initiated despite

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(b) (4) similar previous complaints associated with open or out of tolerance (b) (4) or (b) (4) resistors (same part) in a seven month period.

b. Incident I066907, involving AED 9300A-515, serial number 4034935, reported on 11/22/06 the unit failed to deliver a shock during an SCA. Complaint information indicates the unit was not used during a rescue. The complaint investigation found (b) (4) error code and that the potential cause of the (b) error code appears to be related to software (b) (4) There is no documented failure investigation into the potential (b) (4) issue as a result of this complaint.

c. There is no documented conclusion of the (b) (4)(b) (4)(b) (4) issue raised by (b) for components (b) and (b) (4) in August 2008. A meeting between (b) and CSC was to be held to discuss this issue.

d. There is no documented investigation to determine if there other components in the AEDs that could lead to a failure to deliver a shock and are not fully tested during the AED's internal self-tests.

e. There is no documented validation of the change of component (b) and the software change implemented to correct occurrences of (b) errors in AED units.

f. Document 90-00437-01, Rev A., (b) (4)(b) (4)(b) (4) Resistor, Screening Specification states that the "fixturing" shall be approved by CSC or their authorized designate prior to conducting the screening process. There is no documented approval of the screening fixture(s).

OBSERVATION 3

Risk analysis is incomplete.

a. Document 103-0036, Rev A., System Hazard Analysis AED G3, G3A, G3Plus and G3PlusA indicates that for the Hazard/Potential Cause of a failure to deliver a shock due to a component failure, the Risk Reduction Measure is performing self-tests to provide a warning if a failure occurs. That Risk Reduction Measure has not been fully applied for resistors (b) (4) (b) (4)(b) (4)(b) (4) Open or out of specification (b) (4)(b) (4)(b) (4)(b) (4) resistors that could result in a failure to deliver a shock are not always identified during AED self-tests.

b. Document 103-0036, Rev A., System Hazard Analysis AED G3, G3A, G3Plus and G3PlusA, does not include any (b) (4) issues as a Potential Cause when the AED cannot proceed to perform an initial analysis.

OBSERVATION 4

Sampling plans are not based on valid statistical rationale.

a. The battery validation documented in Doc 106-6074-020, Rev A., used a sample of (b) (4) for each of the (b) (4) test conditions.

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b. The validation of the (b) (4) battery, documented in Document Number DHF-00131-02, Rev A., used a sample of (b) (4) for testing the number of shocks at Cold ((b)) and (b) (4) for testing the number of shocks at Hot ((b) C).

OBSERVATION 5

Design input requirements that are incomplete and ambiguous were not addressed.

a. The Product Requirements document for the PH AED 2 (G3), 102-0083, Rev A., states the battery shall have a guaranteed 3 year operating life under normal operating conditions. Exactly what constitutes the "operating life under normal use conditions" is not defined.

b. The G3 AED (b) (4) Battery Product Design Inputs, DHF-00048-01, Rev B., lists the operating ambient temperature as 0C to 50C, but only lists Electrical Specifications for operation at 25C.

OBSERVATION 6

Design verification did not confirm that the design output meets the design input requirements.

Specifically, the Product Requirements document for the PH AED 2 (G3), 102-0083, Rev A., indicates the battery shall be designed to have adequate capacity for 300 shocks and a guaranteed 3 year operating life under normal operating conditions. There is no documented testing that verifies a battery can meet both requirements.

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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.

*** DATES OF INSPECTION:**
09/01/2009(Tue), 09/02/2009(Wed), 09/03/2009(Thu), 09/08/2009(Tue), 09/09/2009(Wed), 09/10/2009(Thu), 09/11/2009(Fri), 09/14/2009(Mon), 09/15/2009(Tue), 09/16/2009(Wed), 09/17/2009(Thu), 09/18/2009(Fri), 09/21/2009(Mon), 09/22/2009(Tue), 09/23/2009(Wed), 09/24/2009(Thu), 09/25/2009(Fri), 09/28/2009(Mon), 09/29/2009(Tue), 09/30/2009(Wed), 10/01/2009(Thu)

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