**Problem**

**What**
- Problem(s): Warning letter from FDA; patient safety issues

**When**
- Date: August 12, 2014
- Time: N/A

**Where**
- Facility, site: Irvine, California
- Unit, area, equipment: Noninvasive Pulse Oximeters
- Task being performed: Monitoring pulse and blood oxygen on patients

**Impact to the Goals**
- Patient Safety: Potential for injury, death
- Employee Safety: ?
- Environmental: ?
- Compliance: Warning letter from FDA
- Patient Services: Potential for equipment failure?
- Schedule/ Operations: ?
- Property/ Equipment: Potential for equipment failure?
- Labor/ Time: Investigation, response
- Frequency: First warning letter in 25-year history

**Analysis**

**Basic Level Cause Map**
- Start with simple Why questions.
- The FDA has issued a warning to the manufacturer of pulse oximeters after it found the response to violations found during an inspection unacceptable.

**More Detailed Cause Map**
Add detail as information becomes available.

**Solutions**

Pulse oximeters are used to monitor a patient’s pulse and blood oxygen. Abnormal readings can indicate a change in a patient’s condition which may require medical intervention. If the device fails to function, it can lead to patient injury or even death. Because the devices are intended for use in diagnosis, they are regulated by the FDA and have to conform with FDA practices. If the violations identified by the FDA in the warning letter are not corrected, the company may face regulatory action.

For now, the company has not released its plans to ensure compliance with the FDA requirements. The FDA is clearly looking at updates to the investigation process used to respond to customer complaints and ensuring that causes identified as part of those reviews result in changes to other processes, such as manufacturing and quality control.

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**INSUFFICIENT INVESTIGATION RESULTS IN FDA WARNING**

“It may well be that it’s a user error. But you have to investigate that and show that it’s a user error and not a device error.”

- Diana Zuckerman, President of National Center for Health Research

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**Cause Map**

**Products regulated by the FDA**

**Intended for diagnosis/mitigation of disease**

**Failure to evaluate/investigate**

**Evidence:**
- FDA warning letter violation #1
- FDA warning letter violation #2
- FDA warning letter violation #3

**Company’s response to violations unacceptable**

**Evidence:**
- Manufacturer response that issue did not effect accuracy or performance
- Manufacturer response that degradation was not due to process being tested

**Warning letter from FDA**

**Investigation, response**

**Violations identified by FDA**

**Evidence:**
- Records did not contain required information
- Corrective/preventive actions not identified
- FDA warning letter violation #4

**Inadequate procedures for implementing corrective actions**

**Evidence:**
- Manufacturer response that issue did not effect accuracy or performance

**Inaccurate readings?**

**Evidence:**
- User complaints

**Exposed/ separated wiring**

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For a free copy of our Root Cause Analysis Template in Microsoft Excel, used to create this page, visit our web site.