Mechanical Engineering of Tech Service, complaints 13-0067, 14-0021 and 14-0057 are possibly attributed to the welding process.

4. Failure to clearly define the type and extent of control to be exercised over suppliers, as required by 21 CFR 820.50(a)(2). Specifically,

a. Purchasing Control Procedures (QSP 7.5) do not clearly describe the criteria for the continuous monitoring of suppliers. The procedures only state that "Approved Supplier shall be routinely monitored by Purchasing and Quality ..." The procedures do not describe how the suppliers will be monitored, how often, acceptable levels of performance or when to place additional controls or disqualify a supplier. Additionally, there is only evidence of some level of supplier monitoring (NCM review) since July 2014 during quality review meetings.

b. According to your procedures for Purchasing Control Procedures (QSP 7.5), suppliers are to be re-evaluated every two years. The evaluation criteria includes elements such Product Quality (evaluated through non-conforming product) and corrective action responses. These re-evaluations do not provide evidence that the quality system elements are being considered during this process. For example, the re-evaluation form for **(b)(4)**, a critical supplier states "No NCM's have been issued." Your non-conforming product logs shows 6 instances of NCMs since the last evaluation.

c. Your firm does not have evidence of review or acceptance of validated processes used by critical suppliers to manufacture components for your fluid management device. For example, **(b)(4)** provides the electronic control boards which undergo processes such as pick and place, reflow and wave soldering.

5. Failure to have complete risk analysis, as required by 21 CFR 820.30(g).

Specifically, your risk analyses for your fluid management system does not include all hazards or those identified through post market data. For example, complaint numbers 13-0067, 14-0021 and 14-0057 are reports of cartridges leaking. This hazard is not identified in your risk management documents.

Also, your risk estimation/acceptability determination is based on a scale of 1-10 for both severity level and likelihood of occurrence. You have not defined values of 2, 4, 6, 7 or 9 for these variables.

6. Failure to confirm through design verification that design output meets design input requirements, as required by 21 CFR 820.30(f). Specifically,

a. Your functional specification for warming fluids in the fluid management system is the ability to warm fluid from 15.5 degrees C to 40 degrees C. You did not document the temperature at which the fluids were tested, which may influence the results.

b. You did not test Sorbatol (listed as a compatible fluid in the operators manual) to ascertain whether it meets the temperature change requirement listed above.

c. Your requirement for noise of the system was less than 45db at 6 feet. Testing showed levels of 60-70db.