Original Article

Intermittent Failure of a Stockert/Shiley Multiflow Roller Pump Module

W.R. Leahy, BS, R.J. Massimino, BS, CCP, W.J. Wohlfert, CCP

St. Francis Hospital and Medical Center, Hartford, Connecticut

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ABSTRACT

Pump failures are an inherent problem associated with the operation of a heart lung machine. This report details the observation and identification of an unusual modular pump failure. Pump stoppage occurred intermittently over a period of two months with two separate Stockert/Shiley Computer Aided Perfusion System (CAPS) consoles. The mechanism was identified as a static discharge transferred to the module by a perfusion record clipboard. Electrical testing revealed that all modules could be stopped with a simulated static charge between 2 kilovolts (kV) and 25 kV. A sub-normal relative humidity in the operating room was a contributing factor but did not eliminate the problem when levels were returned to normal. Clinical engineering test results were forwarded to the manufacturer with recommendations. Preventive measures by this institution were adopted to reduce static discharge failure.

Address correspondence to:
Ronald J. Massimino
28 Hebron Road
Bolton, CT 06043

INTRODUCTION

One of the many problems inherent in the operation of a heart-lung machine is pump failure. Documented causes can be either mechanical (1) or electrical (2). In either case, the result can be disastrous. In most instances the cause can be identified and resolved quickly. However, there are situations where the failure is intermittent and the cause elusive.

This report deals with a unique case of electrical pump failure that has not been previously described in the literature. These failures occurred with two Stockert/Shiley[a] heart-lung machines used in two different operating rooms. Both machines received routine preventive maintenance and were problem-free prior to this series of events.

CASE DESCRIPTION

During a routine open heart procedure, a staff perfusionist experienced a roller pump failure involving the arterial pump head. The front panel indicated a pump failure related to its internal circuitry. It was restarted following the Stockert safety feature protocol. The Shiley field service technician was called in to diagnose the problem. Testing of the module's internal circuitry revealed no apparent problem and it was put back into service. There was no audible or visual alarm indicating any external problem involving the Computer Aided Perfusion System (CAPS).

The CAPS is a safety system consisting of two types of features: internal circuitry and external module control. The internal safety feature incorporates a self-diagnostic circuit to provide runaway protection and to verify the proper functioning of critical pump components and circuits. This check is made prior to as well as throughout the operation of the pump. If a fault is detected, the internal diagnostics will prevent the pump from starting or will stop a running pump. The alarm condition will be indicated by a continuous flashing of the numeric LED display.

The external safety feature is designed to stop the pump when unsafe conditions are present. These include low level detection and bubble detection. The existence of any of these externally detected conditions is indicated on both the external control module and on the pump front panel (Stockert/Shiley operator manual).

Several weeks later, multiple roller pump failures occurred involving the arterial pump and the adjacent pump module on the same console. Again, all alarms were indicating an internal circuitry problem and the pumps were started by resetting the circuitry. Even though the CAPS was disconnected from the arterial pump, the failure still occurred. After further testing by the Shiley technician failed to duplicate the problem, new modules were obtained and the problem modules were sent back to the company for more in-depth testing. An extensive rewiring of the console was done and the console was then placed back into service in another room to rule out environmental effects.

Approximately one month later, another pump failure occurred on the second console in the same room where the original failure was documented. Again, this problem was the same and the module was reset. An alert perfusionist noted that the pump failure was associated with placement of the perfusion record clipboard on the arterial pump module. Following the case, this failure was duplicated several times by touching the module with the clipboard. The clipboard was transferring a static charge to the module when contact was made.

Following this discovery, Shiley engineers were contacted and our hospital biomedical engineers began extensive testing of all the modules for electrostatic discharge susceptibility.

All four modules on both consoles were tested with the clipboard in both rooms. All modules were capable of being shut down with or without the CAPS connected to the arterial pump. At least 60% of the discharges stopped the pump under test. The module was then removed from the base and tested as a stand-alone unit. It was also capable of being shut down.

Further systematic testing was performed to determine the equipment interference susceptibility level, vulnerable points of discharge, and worst-case conditions. A Schaffer model NSG432[b] electrostatic discharge simulator with an E-field adapter was used to perform these tests. The E-field adapter is a 6 inch diameter plate with a discharge ball in the center. This type of adapter best duplicated the discharge by the clipboard. The discharge ball is the point of contact where the arc occurs. The adapter enables testing with an exact E-field orientation and allows for a larger electrostatic field. A simulation set-up was constructed in both the operating room and the clinical engineering department. The results have been summarized as follows:

- The simulator polarity (positive/negative) did not result in any major differences.
- A single electrostatic discharge was enough to stop the pump.
- The unit was most vulnerable around the top front of the control panel.
- No difference was noted when disconnecting the CAPS connector from the pump under test.
- All modules tested were capable of being stopped.
- Simulated electrostatic discharges without the E-field adapter produced failure rates as low as 3% up to 25kV.
- The worst case test was found when the E-field adapter was used. Failures began to occur at 2kV with a failure rate of up to 60% at 3kV.

DISCUSSION

The most common pump stoppage with the Stockert/Shiley console results from a real alarm condition, external to the pump, detected by the CAPS module. However, some causes of intermittent failures resulting from internal alarm conditions

a Sorin Biomedical Inc., Irvine, CA 92713
b Schaffer EMC Inc., Union, NJ 07083

have not been previously identified. This unique case report deals with pump failure caused by two contributing factors: static electricity and humidity.

Static is a stationary electric charge that forms on the surface of non-conductors and isolated conductors. Any movement of this charge is current and can be measured in volts. Friction, pressure and separation are the major causes of static electric discharge (3). Similarly, the clipboard is made of plastic with a metal clip. When it was rubbed against the operating room uniform, it built up and stored an electrical charge. When the clipboard was placed on the front of the pump module, its electrostatic charge was released onto the pump case, causing the pump to fail.

Relative humidity is a major influence on the level of electrostatic charge. The lower the humidity, the higher the electrostatic charge. A relative humidity of 60% is adequate to limit static. Unfortunately, it is also conducive to the introduction of contaminants (3).

Our institution's engineering department periodically tests relative humidity levels in the operating rooms suites. They attempt to maintain a range between 40% and 60%, which is required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The humidity level during the time of the pump failures was 38%. Subsequent to our inquiry, levels were adjusted to the appropriate percentages. However, even at increased humidity levels, pump failures could be duplicated in the same manner.

At the present time, Stockert engineers are trying to determine the sequence of events leading to the module internal circuitry failure. All of our testing results have been forwarded for their review. Since changing environmental conditions did not change the module's susceptibility to electrostatic charge, we feel that there may be other inherent internal circuitry design problems. Some suggested solutions offered by our clinical engineering department include improvements with the grounding and shielding of the modules as well as possible design changes to the module control circuitry.

At our institution, preventive measures have been adopted to reduce the incidence of pump failure from static discharge. These include discontinuing the practice of placing the clipboard on the pump module and maintaining the relative humidity at the required levels.

It should also be mentioned that although these conditions were identified as the cause of this pump failure, other conditions can contribute to failure and should not be overlooked in the identification process.

The best protection against any type of pump failure is to be thoroughly versed in the operation and emergency procedures contained in the operator's manual.

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REFERENCES

1. Albright HH, Gray DW. Prevention of introduction of foreign objects into the Sarns Series 5000 arterial pumphead. J Extra-Corpor Technol. 1984; 16(1): 102-103.
2. Lavanchy CP. Stockert/Shiley CAPS multiflow roller pump stoppages. Health Devices. 1992; 21(1): 37-39.
3. Chapman Corp. Electrostatic Discharge. Medical Electronics. 1993; 139: 139-141.

Comment

We at Sorin Biomedical and Stockert Instrumente wish to express our gratitude to the perfusion staff at St. Francis Hospital and Medical Center for their cooperation in bringing this unusual event to our attention, and in providing their valuable insight into the cause of the pump stoppages at their facility. Their input was the catalyst for intensive investigation at both Sorin Biomedical (Irvine, CA) and at our Sorin affiliate, Stockert Instrumente (Munich, Germany).

As we write this comment in early July 1993, we can say that we understand the mechanism involved in the pump stop and that a solution has been identified, tested and successfully installed at St. Francis Hospital and Medical Center. In good faith we have also informed all of our customers of this potential cause of pump stoppage in a technical bulletin and explained our action plan to ensure that all CAPS Multiflow Roller Pumps are modified to guard against pump stoppages of this kind.

The results of our investigation only became known after the submission of this article. For that reason, the authors were not able to include these results within their own report. It seems appropriate here, then, to supplement the information contained in the article by briefly explaining what was found.

The Stockert CAPS Multiflow Roller Pump employs self-diagnostic software and circuitry that monitor various system parameters, including unusual electrical events. The discharge of a large amount of static electricity onto the roller pump housing triggered the pump's self-diagnostic circuit and stopped the roller head. This was not a malfunction or pump failure. It was and remains the normal function of the roller pump's safety features to recognize potentially dangerous circumstances (e.g., power surge) and react appropriately, often by stopping the roller head. In this way, critical pump circuitry is protected from damage. Devices without this type of protection are more susceptible to serious, "hard failures" which might render the device dysfunctional. It is important to note that the function and sensitivity of the roller pump's diagnostic circuitry has not been altered in any way by our modification.

The source of the electrostatic discharge in this particular case was a standard size plastic clipboard with a metal clasp and built-in calculator. It was found that, when the clipboard was charged by rubbing it vigorously on O.R. clothing, it acted like a very large capacitor, able to accumulate and store an electrical potential of up to 10,000 Volts. The capacitance of the clipboard coupled with the sudden discharge of current through the metal clasp onto the roller pump housing was sufficient in some cases to cause the roller pump to stop. We want to emphasize that the roller pump sustained no damage and always restarted by simply recycling the directional switch (in accordance with the Multiflow Roller Pump Module Instructions for Use).

We trust that this comment has been informative, while at the same time we wish to give all the credit to the authors for their hard work and accurate description of this unusual phenomenon.

As always, we at Sorin Biomedical and Stockert Instrumente remain committed to our customers and to the safety of the patients they serve.

Sincerely,
Sorin Biomedical Incorporated
Stockert Instrumente