VIASYS HIGH FREQUENCY OSCILLATOR FAILURE 3100B CASE STUDY: *A REGIONAL ADVANTAGE FOR INVESTIGATIONS*

Andrew Ibey, M.Eng, P.Eng, Stephen Gorelik, BMET
Providence Healthcare, St. Paul's Hospital,
Department of Biomedical Engineering Vancouver, BC

INTRODUCTION

Incident investigation remains a specialized area of clinical engineering (CE) in hospitals. Institutions able to provide this as a core service yield numerous positive learning experiences leading to systemic improvements within the organization and perhaps even provincially, or nationally [1]. Investigations requiring clinical engineering input are triggered by critical patient events, either involving medical equipment in highly acute areas, unique medical equipment that fails without patient injury, or clinical observations of peculiar trends with equipment failure.

As patient safety culture grows, healthcare continues to move away from the old world view of a culture of blame and towards the new world view of systemic issues [2]. A CE investigator must have appropriate training and education in techniques for conducting personnel interviews, systems and process analysis, human error theory, human factors design and the application of engineering principles [3].

The most valuable component of any investigation remains drawing conclusions and promoting complete, impartial and ethical recommendations to improve healthcare safety [3]. The difficult aspect of incident investigation is the learning piece. Often investigations stop once reason for cause is found. Learning from incident investigations is an area that CE must lead by encouraging discussion, publication and presentations amongst colleagues and peers of learning outcomes from CE investigations [3].

In an effort to increase learning outcomes, British Columbia initiated a provincial system to capture safety events, called the patient safety learning system (PSLS) (*Datix Ltd, London, UK*). This system provides electronic reporting for end-users to document safety events that occur in their clinical area. Each reported event supports the inclusion of one or more people that should be involved with the incident investigation. The case presented herein summarizes a PSLS event, provides details about the ensuing CE investigation and discusses the learning outcomes of the adverse event.

Keywords: patient safety, incident investigation, high frequency oscillation (HFO) ventilator

INDICATION FOR USE

The 3100B High Frequency Oscillation (HFO) ventilator (*Carefusion, San Diego, CA*) is indicated for use in cases ideal for lung-protection. "HFO is a method of mechanical ventilation designed to deliver extremely small tidal volumes around a set mean airway pressure at high respiratory rates (frequencies) of 3-15 Hz. Critically ill patients with acute respiratory distress syndrome (ARDS) require life support with mechanical ventilation. Ventilator-induced lung injury, however, contributes to the high mortality (40-70%) of ARDS. Randomized control trials suggest important mortality reductions resulting from lung-protective ventilation. Because tidal volumes are very low, HFO is theoretically better suited for lung protection than any conventional ventilator."[4]

Figure 1: Viasys 3100B HFO Ventilator

The 3100B HFO for adult ventilation is approved for the treatment of acute respiratory

failure in adults to recruit and normalize lung architecture while ventilating the patient with near dead space tidal volumes for low stretch lung protection [5].

DESCRIPTION OF EVENT

St. Paul's Hospital experienced a high profile incident involving a Viasys 3100B HFO ventilator. Subsequently, three additional HFO ventilator drivers failed prematurely before their recommended 4000 hours within a span of 2 months. The first driver failed on a critically ill patient, another during routine testing on the vent, and the remaining two were found due to review on the first two failure trends. A regional CE investigation in the lower mainland Vancouver area uncovered a serious safety concern with similar manufactured dates for all failed components, inconsistencies with the manufacturer's documentation, and compromised integrity of the rubber on the ventilator driver hidden from visual inspection. The investigation worked in collaboration with ECRI institute to obtain answers from the company and to publish the concerns with the equipment to a broader audience via an ECRI Hazard Report in Health Devices magazine in August 2011[6].

The following paragraph is a description of the event in the words of the PSLS reporter "*RT & RN staff had noticed previously that oscillator sounded "louder" than it normally did, although appeared to be working well (maintaining pressures, patient's status improving with transition to HFO)…patient ventilated on high frequency oscillator (HFO) in ICU, found that plastic faceplate covering ventilator diaphragm cracked in two places and rubber seal behind diaphragm split, causing oscillator to lose ventilation pressures and causing patient's oxygenation to deteriorate (SpO2) to 78%. This happened approximately 2 hours prior to patient meeting criteria for discontinuation of HFO and transition to conventional ventilation; post incident, oxygenation & ventilation parameters had to be increase, so patient remained on HFO.*"

OBSERVATIONS AND FINDINGS

The investigation involved: 1) Review of adverse event literature, 2) Investigation on the failed ventilator, 3) Regional inspection of similar devices, 4) Engagement with ECRI and 5) sharing learning experiences from the investigation.

Literature Review:

A search of the ECRI MAUDE database on November 19th, 2010 using the keyterms: Manufacturer: *Sensormedics or Viasys*, Model No.: *3100 or 3100B* and a problem description as: *tear, failure or cleaning* revealed 9 relevant ECRI reports. It was found the 4 reports resulted in a diaphragm tear, 3 reported excessive noise, 1 reported cleaning concern, 1 reported failure of the diaphragm assembly (with no mention of a tear).

Physical Inspection:

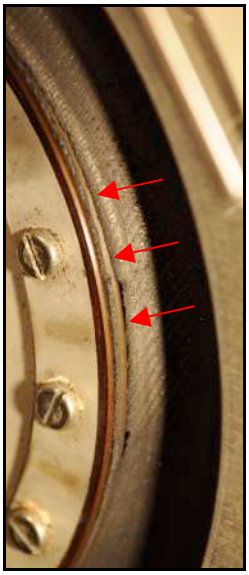
It was apparent that the diaphragm had a distinct "star pattern" on the aluminum driver faceplate which is exposed to the bellows on the patient circuit (Figure 2). This star pattern is hypothesized to have been caused by overheating of the internal driver mechanism conducted to the surface. The scarring could be indicative of a heating/cooling sequence over a period of time. This conclusion was drawn by two observations: 1) The internal wear noticed on the driver mechanism and, 2) The characteristic circles around the screws which would have created heat sinks which could have dissipated the heat so there would be minimal scarring.

Figure 2: Heat stress star pattern on driver faceplate

Figure 3 illustrates wear on both sides of the driver mechanism, giving evidence that there was heavy wear on the piston in the driver mechanism. The right side of the driver shows the heaviest wear, which coincides with the side that had the diaphragm tear. The loud

noise as described in the incident report could have been due to metal on metal friction at high frequency and also could have been the source of the heat stress exhibited in Figure 1 above.

Figure 3: Piston wear



The most obvious fault of the ventilator and the ultimate cause of failure was due to a significant tear in the diaphragm of the ventilator on the external side of the driver mechanism (Figure 4). The diaphragm tear was found to be from 1-7 o'clock on a clock face, or 180 degree tear of the diaphragm. Figure 3 clearly illustrates the disjoined rubber.

Figure 4: External diaphragm tear

Disassembling the failed driver mechanism showed cracking of the rubber on the internal side of the driver mechanism that did not completely wear through to the external side (Figure 5). *This is a critical discovery as we believe it is indicative of the premature failure of the diaphragm. It is, however, unable to be detected by a visual inspection of the external side of the driver mechanism*.

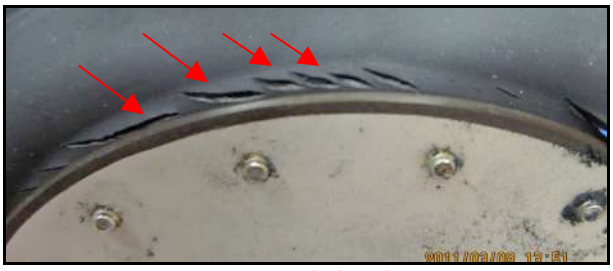


Figure 5: Internal diaphragm tear

After completing the investigation on the failed ventilator the results were communicated to the other 6 clinical engineering departments to perform a visual inspection of their Viasys 3100B ventilators. In total 13 additional ventilators were interrogated, and three more drivers were found to have failed.

Table 1: Discovery of the four failed diagrams

ECN	Date Stamp on Diaphragm	External Tear (clock face)	Internal Cracking (clock face)	Wear on Internal Piston	Hours of use at failure
VNT00341	APR 2004	12 to 6	5 to 7	12-3 heavy, 9-12 medium	2237
VNT00342	APR 2004	1 to 7	7 to 9	11-1 heavy, 3-7 heavy	1527
C248969	APR 2004	8 to 9	9 to 11	12 low	~3500
C248968	APR 2004	2 to 6	2 to 6	11-1 heavy, 2-4 heavy	3771

The investigation revealed the following:

- All diaphragms had a failure characterized by a tear on the external side of the rubber diaphragm.
- All diaphragms failed before the recommended 4,000 hours preventative maintenance driver mechanism replacement
- All failed diaphragms had an internal manufacturing stamp of APR2004
- All failed diaphragms exhibited internal cracking that would not have been seen by an external visual inspection
- Internal wear on the driver mechanism's piston could be indicative of the reported loud noise and overheating characteristics.

DISCUSSION

The ECRI literature review revealed that similar failures have occurred on the driver assembly reported through other hospitals. These failures exhibited similar symptoms in regards to the noise and failure characteristics of torn diaphragms.

The first ventilator that failed presented with heat stress on the faceplate of the diaphragm. Many of the ECRI reports, discussions with Biomed departments in Canada and our own experience has proved

that some of the refurbished driver assemblies have had overheating alarms.

It was found that the same date was stamped on all 4 failed drivers was APR 2004. It was confirmed with Carefusion that this is the manufacturing date. The fact that all four failed drivers have a manufacturing date of April 2004, suggests that this may be a faulty manufacturing lot that needs to be recalled.

Due to the fact that 4 of 13 driver assemblies failed prior to their recommended 4,000 hour preventative maintenance (PM) replacement of the driver mechanism, Carefusion must review their recommended practice for replacement. Rubber has a natural tendency to degrade with age and exposure to light and oxygen rich environments. The PM stipulates only device operating hours as the sole factor for replacement; the PM should include an either/or statement that includes the age of the parts in calendar years for replacement of the driver mechanism.

It is a respiratory therapy protocol to inspect the driver diaphragm before patient use at St. Paul's. The wording of the procedure has been modified to highlight that the respiratory therapist (RT) must perform an inspection for *wear and tear* before placing a new patient set on the ventilator. The procedure reads as follows:

"Prior to re-circuiting the oscillator, inspect the driver and rubber ring. If there are any signs of wear and tear, including discoloration, that may be indicative of an early signal of tearing/ripping of the diaphragm, immediately remove the oscillator from use. Send the oscillator to Biomedical Engineering for inspection."

CONCLUSIONS

The authors of this paper present a clinical engineering incident investigation case study that takes their findings past the point of finding cause and towards a learning objective. Sharing this information regionally across the lower mainland Vancouver area enabled 3 other ventilators to be identified as problematic before they failed in a clinical area on a patient.

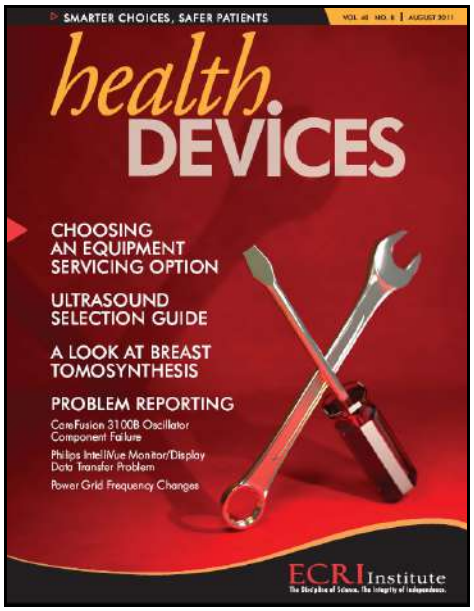


Figure 6: ECRI health devices journal

This case study reinforces the importance of clinical engineering investigators to share their findings, locally, provincially and nationally to potentially intervene before a critical failure occurs. Working with reporting bodies such as ECRI institute (see Figure 6) can help to disseminate discovery of equipment quickly and efficiently.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Liz Jolley and Chris Gagnon of the Respiratory Therapy department for their cooperation with the investigation.

REFERENCES

[1] J.S. Williams, "Adverse event reporting: making the system work", Biomedical Instrumentation & Technology, pp.111-118, 2005

[2] S. Dekker, "The field guide to understanding human error", Ashgate Publishing, England Limited, 2008

[3] "Guidelines for incident investigators", www.accenet.org Published: January 27, 2006, Accessed: March 21, 2012

[4] The Oscillation for ARDS Treated Early (OSCILLATE) Trial, Collaborative Research w/McMaster University

[5] www.viasyshealthcare.com

[6] "Hazard Report: CareFusion 3100B high-frequency oscillatory ventilator diaphragms require pre-use inspection", Health Devices, Vol.40 (8), pp.263-264, 2011

[7] S. Staender, "Incident reporting in anaesthesiology", Best practice & clinical research anaesthesiology, vol.25, pp.207-214, 2011