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CASE REPORT

ECG failure in the operating room – bench testing to prevent bedside disaster

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Short Title: ECG failure in the operating room

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Summary

Electrocardiogram (ECG) false alarms are common in electrically hostile peri-operative environments. Newer integrated monitoring, with sophisticated hardware and software, has the potential to minimise artefacts. However, monitoring issues continue to occur, with the potential for critical incidents and unnecessary and harmful interventions. We describe the root cause analysis of a series of apparent ECG flatline asystolic events that appeared in the operating room shortly after the introduction of new intra-operative monitoring systems. Clinical events and biomedical laboratory testing revealed complete loss of ECG signal with increasing resistance. The new ECG systems had incorporated both software and hardware changes to improve the fidelity of signal acquisition and display, but had become much more sensitive to impedance changes. After we alerted the manufacturer, they added software and hardware updates that resulted in resolution of all incidents of ECG loss-of-signal.

Introduction

False alarm rates as high as 86% have been reported in perioperative and critical care environments [1]. These can result in 'alarm fatigue', where clinicians turn off or ignore potentially important changes in patient physiology. False alarms can also result in inappropriate or harmful therapy [2]. Electrocardiogram (ECG) false alarms are often due to poor quality signals or artefacts generated in an electrically hostile environment, such as the operating room [3]. To some extent, these can be minimised by filters and multimodal signal processing using the arterial pressure waveform or pulse oximetry signal [2, 3]. However, non-pulsatile physiology can occur in the operating room, such as during circulatory collapse or the commencement or weaning from cardiopulmonary bypass, when the impact of ECG false alarms could be critical and cannot be readily reduced.

In October 2015, our department acquired new intraoperative monitoring systems from Philips Healthcare, (IntelliVue MX800 with X2 and MMS modules, Philips Healthcare, Victoria, Australia). Both modules were supplied with ECG hardware Rev. E.01.01. The intensive care unit at our hospital, and other institutions, had an earlier version of the same ECG monitoring software, with no documented episodes of ECG signal loss.

By November 2015, several incidents of ECG signal/waveform loss and apparent asystole in both cardiac and non-cardiac operating rooms had been reported. In cases where an alternative reliable method of pulse detection with invasive arterial monitoring occurred, these were quickly dismissed as artefact or signalling issues. However, during periods of low peripheral perfusion pressure in two cardiac and thoracic cases, potentially harmful interventions were initiated or almost administered, including adrenaline boluses, cardiac pacing and cardiac massage. In one case, a transoesophageal echocardiography probe was inserted to exclude myocardial ischaemia. In a separate case, the patient appeared to be in asystole on the ECG monitor when they were clearly in ventricular tachycardia requiring cardioversion after cardio-pulmonary bypass.

Multiple cases of apparent flat-line asystole on the ECG signal occurred in all of our operating rooms, often after a prolonged period of normal/acceptable ECG morphology, but sometimes occurring before the induction of anaesthesia. Monitors displayed/sounded a technical 'INOP' (inoperable) or 'ECG No signal' alarm with an apparent asystole flat-line trace, rather than an 'ASYSTOLE' alarm.

These episodes required switching of ECG modules, cables and electrodes, either delaying the start of an operation or sometimes during surgery itself. However, these strategies did not reliably resolve the lack of ECG signal.

Both the manufacturer and the Therapeutic Goods Administration (TGA - the

Australian Government regulator of therapeutic goods and medical devices) were notified in December 2015.

Initially in January 2016, the manufacturer suggested the cause might be due to poor ECG skin electrode contact and advised replacing the Covidien®-Kendall 450 Foam Electrodes (22450, Medtronic Minimally Invasive Therapies, Minneapolis, MN, USA) our hospital had recently started using with Philips-branded electrodes (M2202A). This failed to resolve the problem.

Subsequently, the manufacturer suggested the ECG cables might have become contaminated during routine cleaning between patients with non-ionic, alcohol- and chloride-free wipes (Tuffies, Vernacare, Bolton, UK). Replacing these with lower-residue, benzalkonium chloride wipes (V Wipes, Whiteley, Australia) to reduce ingress of the cleaning solution into the ECG cable junction points, failed to resolve the problem. The ECG cables were sent to the manufacturers, but no obvious defects were identified. We began routinely applying defibrillation pads on all cardiothoracic patients, so that a reliable ECG signal could be monitored, in the event of ECG monitor signal loss.

The failure of the measures suggested above, and the inconsistent and intermittent nature of the problem, suggested that the cause related to how the monitor responded to poor signal quality. The quality of a signal entering monitor depends on the signal-to-noise ratio, which is the product of the size of the biological signal compared to any external interference and the impedance of the cables and electrodes.

We conducted a laboratory test to determine whether X2 modules with differing ECG hardware revisions (A.00.04 and E1.01.01) behaved in the same manner under varying input conditions, using an ECG simulator (Fluke MPS 450 Multiparameter Simulator, Fluke Biomedical, Everett, WA, USA) and a new Phillips 5 'EASI' lead ECG cabling set (identical to that used in our operating rooms). The right arm, left arm, left leg, right leg and precordial V lead were attached to the simulator; the same lead was used on both modules. Resistance was artificially controlled via a series of potentiometers in the system. The ECG was displayed from lead II and lead V.

Using an older version of the X2 ECG module with J.10.30 software and A.00.04 hardware, as used reliably in our intensive care unit, we progressively increased resistance in the precordial lead with no loss of signal in either lead II or V5, although degradation of signal quality was noted as resistance increased.

Repeating this test using the newer, faulty version of the X2 ECG module with K.21.54 software and B.00.04 hardware, we progressively increased resistance in the right

arm lead and total loss of signal occurred, at which point the system software followed its design parameters and 'autoswitched' to lead III, trying to find a more usable signal, a process that took 13 seconds. Removing the artificial resistance reverted the system to a lead II and V5 configuration with normal waveform display. When we repeated this experiment increasing resistance in the precordial lead, there was loss of signal in V5 and no attempt to autoswitch to another lead; removing resistance restored a normal signal in V5. Importantly, we observed that signal loss occurred was at a much lower threshold in the newer ECG hardware revision than occurred with the older version, in which lead signal loss did not occur.

This report highlights the challenges that arise when monitoring equipment behaves unexpectedly, and the issues associated with identifying and rectifying the cause in a clinical environment. The use of experienced biomedical support is very helpful in pinpointing the problem, because a controlled environment can create a consistently reproducible scenario. Furthermore, it highlights the importance of understanding equipment use in different environments. Although the best quality ECG waveform possible is important, even a poor signal is better than none in the electromagnetically 'hostile' operating room environment.

Initially, discussion with the company focussed on clinical events, and resulted in a prolonged process of ineffectively changing ECG electrodes and cleaning procedures, during which patients could have been harmed. Only after our laboratory testing did the manufacturer inform us that the ECG system had become much more sensitive to changes in impedance after software and hardware redevelopment. Upgrades were introduced to comply with International Standards for the International Electrotechnical Commission (IEC) standards 60601-2-25 and 60601-2-27, which require a minimum instrument input impedance of the instrument. Autoswitching is a process during which a multilead ECG monitor switches to another reference electrode in the event of disconnection or change in impedance. The threshold at which this occurs is set by the manufacturer and the amplitude and frequency response of the system can be altered if minimum input impedance is not achieved. This threshold had been altered in the new monitor/software system compared to earlier versions with the system displaying a 'flat-line' ECG signal. In older versions, some ECG signal remained despite the degraded signal.

Although our laboratory tests showed increasing impedance produced the fault, the manufacturer maintained the fault was caused by decreased shunt impedance in the cabling, the root cause of which was fluid ingress in the ECG cable junction points. We accept that

this may have been a trigger, but maintain that the underlying cause of the 'flat-line' display was the way the monitor/software processed the degraded signal.

Clinically, the autoswitching process took an unacceptably prolonged time (13 seconds) without a visual ECG trace in any monitor lead. Furthermore, if any applied impedance fluctuates around the autoswitch threshold, the module may oscillate between autoswitching and reversion, with only occasional ECG morphology displayed on an otherwise 'flatlined' screen.

Although experienced anaesthetists might be able to differentiate true from artefactual asystole, perhaps by reference to clinical examination or an alternative monitoring source such as invasive arterial blood pressure or pulse oximetry, there are many occasions when differentiation would not be possible. For example, cold, hypotensive patients might not display a reliable pulse oximetry trace, and patients on cardiopulmonary bypass (CPB) would not display pulsatile reactions to aortic cross clamp removal or CPB weaning. ECG signal loss in these circumstances could result in inappropriate interventions, including bolus administration of inochronotropic drugs, alterations in epicardial pacing, return to CPB or defibrillation.

Advanced Cardiac Life Support algorithms advise checking equipment to discern true asystole, software malfunction is not recognised as a potential cause of a 'flatline' ECG trace [4].

Other, electronic algorithms have been developed in critical care environments to improve the sensitivity and specificity of life threatening alarm detection, by integrating input signals from different sources, including ECG, arterial blood pressure and plethysmography traces [5]. Nevertheless, artefact/false alarm rates remain as high as 90% in operating room and critical care environments, resulting in alarm fatigue and desensitisation among personnel and consequent failure to respond to life threatening events [6].

In developing new software and hardware to improve the fidelity of signal acquisition and display, however, a system risks oversensitively reacting to impedance changes, as occurred in this case. Information supplied by the manufacturers states that "signal loss can occur when a system detects shunt impedances in the ECG signal. The new ECG hardware has enhanced self-test capabilities that can detect shunt impedances between conductors and shield inside the cable. Former ECG hardware revisions were not able to detect shunt impedances inside the cable". Shunt impedance changes can occur when electrode/cabling/machine connectors become wet, as can occur during cleaning, disinfection,

application of liquid skin preparation during surgery or invasive procedures, patient sweating or high humidity.

Since these episodes reported above, the manufacturers have released an improved cable design which reduces fluid ingress and therefore shunting, a new software update displaying 'Check ECG cable' in place of an artefactual flatline ECG, and customer alerts about the potential loss-of-signal issues. The root cause of the fault (software processing of impeded signal) has not changed, but we have experienced no ECG flatline incidents at our hospital since the manufacturer's changes were introduced.

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Manufacturer's comment

The accuracy of electrical measurements depends highly on the performance of the overall measurement chain. In case of the ECG measurement in a patient monitor, this includes the quality of ECG electrodes and their connection to the patient, the quality of the ECG lead set/cable, processing of the acquired ECG signals in the patient monitor and the way these are displayed.

Before introducing a new medical device or making changes to existing devices, Philips tries to best possibly anticipate foreseeable misuse by performing clinical validation and gathering feedback from post market surveillance based on preceding devices. The resulting insights are then incorporated into both design and labelling.

In 2015, Philips introduced new ECG/RESP hardware providing enhanced self-test capabilities, capable of detecting leakage currents inside the ECG cable. This was done to alert the user to lowered shunt resistance originating from leakage current inside the ECG cable, which can lead to inaccurate ECG measurements.

Before the release of a new design, Philips performs thorough design and clinical validation as well as post market surveillance and literature studies. The sensitivity threshold of the new ECG/RESP hardware for detecting leakage current was set to a level based on a widely normal performance range of the overall measurement chain, as defined by applicable IEC ECG safety and performance standards.

In the case described by Cowie et al., leakage current of some of the ECG cables exceeded the specified range, consequently causing the monitor to blank the ECG signal. It is evident that it is impossible to anticipate all situations arising during clinical use. For this reason, Philips closely monitors feedback from individual customers as well as general market surveillance and regularly evaluates the feedback to support continuous product improvement. In the case described, Philips issued a software update within 3 months adapting the sensitivity of the algorithm for reacting to increased leakage current, and the way the patient monitor reacts to these situations.

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