
Some Considerations Regarding the Use of the Delta Lev-L-Sentry Low Level Alarm System

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Abstract

The possibility of infusing an air embolus during extracorporeal circulation is of concern to every perfusionist. The perfusionist uses a variety of devices to prevent such an accident. The Delta Lev-L-Sentry alarm system is one such device. It consists of a disposable sensor tape, an electronic sensor head, and a power/control box. The sensor head and tape are attached to the oxygenator. The unit will warn of a low level situation in the oxygenator when the fluid falls below the preset sensor tape position. This paper describes two possible situations where the Delta-L-Sentry alarm system may not activate properly, and one situation in which it will activate improperly.

A protein coating from the blood can result in a low sensitivity of the sensor tape. This, combined with a rapid draining of the oxygenator, can produce a false negative alarm. To avoid this false negative alarm mode it is recommended that the sensor tapes be cut and attached at the prescribed 50 degree angle (from the horizontal) regardless of the angle supplied by the manufacture. Another situation which can cause a false negative alarm mode is spilling electrolyte solution on the sensor tape. This can be avoided by protecting the sensor head. The one instance of a false positive alarm mode was caused by electrocautery interference during surgery. The use of a grounding cable will reduce the interference thus avoiding the false positive alarm signals.

Introduction

During extracorporeal circulation the possibility of

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infusing a gas embolus to the patient is always present. This is of constant concern to the perfusionist and an ever present danger to the patient. According to a recent report by Stoney, et.al. about once in every 1,000 procedures an accident occurs serious enough to produce injury or death to the patient. One of the most common causes of an air embolus is the inadvertent emptying of the oxygenator.^{1,2} There are many devices available to the perfusionist which can help prevent an air accident.² This report deals with one such device, the Delta Lev-L-Sentry.³

We have been using the Delta Lev-L-Sentry alarm system since April 1981. We would like to discuss two areas of concern to us. First, the possibility of a false negative. A false negative signal is defined as a situation where the alarm should have signaled, but failed. This could leave the perfusionist with a false sense of security and a low or empty arterial reservoir. The Delta literature describes two situations where the Lev-L-Sentry may produce a false negative signal: 1) protein build-up on the inside of the arterial reservoir in combination with a sensor tape angled at less than 45 degrees to the horizontal; 2) spilled electrolyte solution across the sensor tape. The second situation can be prevented by protecting the sensor head and tape from fluid. If the tape becomes wet, Delta Medical suggests that a new tape be attached.

Second, the electrocautery interference with the alarm system produces a false positive signal. A false positive signal is defined as a situation where the alarm does signal, but should not have. False positive signals increase the anxiety level of the perfusionist and reduce the subsequent reactivity of the perfusionist, thereby neutralizing the purpose of the safety device.

a Delta Medical Industries, Costa Mesa, CA 92626

Methods and Materials

The construction and operation of the Delta Lev-L-Sentry have been described in detail prior to this writing.^{3,4} However, a brief summary will be presented here. The alarm system is composed of a control box and power supply, electronic sensor head, and disposable sensor tapes. The control box and power supply has a switch to override the arterial pump shut-off mode, and a reset button to reset the alarm. The alarm signal consists of a red light and audible alarm. There is also a switch to turn off the audible alarm. The sensor head is connected by a cable to the control box. The sensor head has two capacitance circuits which, when a disposable sensor tape is attached, will form two capacitance fields. These two fields, one field formed by the upper two metal strips and one formed by the center and bottom metal strips, will be electrically balanced when the fluid in the reservoir is above the three metal strips or when the fluid is completely below the three metal strips. As the fluid level falls in the reservoir the capacitance field becomes unbalanced. When this happens, the sensor head triggers the control box, the buzzer alarms, a red light goes on, and, if connected, the arterial pump will stop.

Since the alarm system can be reset when the fluid level is completely below the sensor head and tape, we were concerned that the fluid could drop fast enough to fall past the tape and the alarm never trigger (false negative action).

A test situation was set up to discover whether we could produce a false negative action. The equipment used was a Bentley BOS-10S^b oxygenator, a Bentley Q-120^b reservoir, and Tygon S-50-HL^c tubing. The set-up is diagramed in Figure 1. By clamping line C we could recirculate the fluid which consisted of outdated human blood and lactated Ringers solution with a hematocrit of about 25 percent. By clamping lines A and B we could divert the fluid to the cardiotomy reservoir and rapidly pump the oxygenator dry. By opening line A we could refill the oxygenator from the cardiotomy reservoir. We used the pre-angled sensor tapes as provided by Delta Medical without cutting and angling the upper strip and conducted several trials. We cut and angled (50 degrees to the horizontal) the top strip and conducted several more trails.

Another area of concern was the repeated false

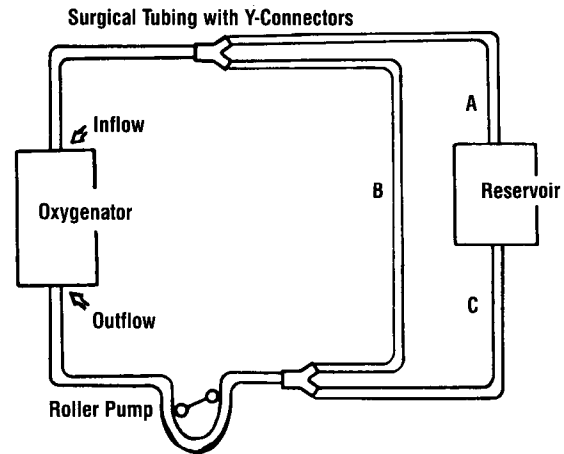


Figure 1: Experimental Cardiopulmonary Bypass Circuit.

alarms experienced during the use of our cautery equipment. The cautery signal can trigger a false alarm which turns the pump head off even with an adequate reservoir level. This not only becomes a nuisance, but causes the perfusionist great consternation thinking that his arterial reservoir is dangerously low.

We informed Delta Medical of this problem, but they offered no solution. We received some help from our BioMedical department. Apparently, the sensor tape acts as an antennae, picks up the cautery signal, and results in the observed false negative alarm. The BioMedical department suggested that we ground the signal out before it reaches the sensor head. Since we rarely use the blood temperature probe ports on the oxygenator, we thought that this would be an ideal point to insert a grounding cable. The BioMedical department gutted out a temperature probe, filled it with solder, and attached it to a 12 gauge grounding conductor with an alligator clip on the other end (Figure 2). The probe is placed in the arterial temperature port (venous port will work equally as well) and the alligator clip is clamped to the pump. The pump must also be properly grounded.*

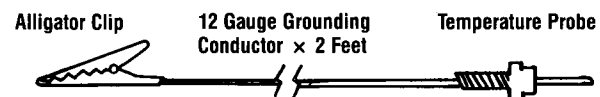


Figure 2: Grounding Cable.

Results and Discussion

Several trials were conducted at flows between 4.7 and 5.4 LPM using the pre-angled sensor tapes. The venous return was stopped and the oxygenator was

^b American Bentley, Irvine, CA 92714
^c Norton Company, Akron, OH 44309

rapidly pumped dry. We produced a random false negative alarm. When the sensor tape was cut and angled at 50 degrees to the horizontal, several trials produced all positive alarm action. At flows less than 4.5 LPM the pre-angled sensor tapes will sense the fall of the fluid and activate the alarm signal. The pre-angled tapes seem to consistently sense a slow fluid drop (arterial pump flow of less than 4.5 LPM) within the arterial reservoir.

When we first purchased the Lev-L-Sentry, Delta Medical supplied us with several sensing tapes with the strips in a parallel configuration as described by Paul A. Page.³ After receiving our first order of sensor tapes we discovered that they came pre-angled. There was some question as to whether these new pre-angled sensor tapes needed to be cut and angled. One could assume that these were the new tapes which were "pre-cut and folded—eliminating the described cutting necessary for proper operation."³ We contacted Delta Medical by telephone, and they assured us that it was still necessary to cut and angle the upper strip for proper function, as we also discovered by our testing. When asked if Delta Medical was ever going to supply a strip that needed no cutting, the answer was "no."

The purpose of this paper is to clear up any confusion that might arise regarding the preparation of the sensor tapes (parallel vs. pre-angled configuration). It is beyond the purpose of this paper to statistically evaluate two methods of set-up. We are not advocating an alternate methods of set-up and use. If, by not cutting and angling the tapes, one false negative alarm can be

Editor's Note: The reader must be aware that the technique described to ground the CPB patient's bloodstream to the heart-lung machine increases the **electrical susceptibility of the patient. The heart-lung machine must be tested for electrical safety by qualified biomedical personnel prior to employing the grounding technique.*

produced, the pre-angled tapes are not acceptable for clinical use as provided by the manufacture. One air embolus accident is unacceptable! No false negative alarms could be produced when the tape was cut and angled as described in this paper and recommended by Delta Medical. The purpose of this paper is to clarify any confusion that might arise regarding the instructions, accompanying papers, and two different tape configurations provided by Delta Medical. When used and set-up properly, the Delta Lev-L-Sentry is a reliable low level alarm system.

The cautery interference was completely grounded out when using the described grounding cable from the oxygenator to the pump, and the integrity of the system was not compromised. The alarm works as it should whenever the fluid level falls below the sensor tape without the annoying false negative alarms. The one obvious disadvantage is the loss of one of the oxygenator temperature probe sites.

We recommend that the arterial pump head be attached to the control box so that when the alarm sounds the arterial pump will stop. If the pump head is not plugged into the box or the override switch is on, the perfusionist may become less sensitive with the passage of time to the auditory-only alarm.

References

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