Clear–IT™ – Closed Blood Sampling System
Flushing study

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Introduction

Patient safety is a major concern in the healthcare industry. The World Health Organization (WHO) estimates that 1 in every ten patients admitted to the hospital in developed countries is harmed due to various conditions and occurrences within the hospital (1). Patient safety is even more crucial in patients admitted to high pressure departments, such as the intensive care unit (ICU).

A specific concern for patient safety in the ICU is related to blood loss and infections associated with blood sampling. These issues are a major concern in the ICU because taking blood samples is standard practice and a common procedure in ICU treatment. Blood loss and catheter related infections can complicate the overall condition of these patients, which in turn can delay their recovery.

ICU Anemia is a common problem in intensive care unit (ICU) patients caused by several factors, one of which is frequent blood sampling for measurements of arterial blood gases and other laboratory parameters(2). A variety of observational studies have established an association between anemia and worsened outcomes, including mortality, failure to wean from mechanical ventilation, and myocardial infarction(3).

As daily phlebotomy in the ICU comes to 40-70 mL of blood while the healthy replacement rate for red blood cells is 15-20 mL/day, the development of anemia is a real concern(3). Studies show that 95% of all patients admitted to ICU have a lower than normal hemoglobin level after one week of admission (4).

Blood sampling through arterial catheters requires discarding of the flush solution (clearing volume) that is inside the line for monitoring purposes. It is recommended that 3 X of the dead space volume be withdrawn and discarded (5). In order to receive 1 mL of undiluted blood sample that is needed for a test, 5 to 10ml of blood is wasted each time a blood sample is taken from the patient's indwelling catheter. Eliminating the loss of discarded blood before diagnostic testing was associated with higher hemoglobin levels than levels in control patients (6). These amounts can be saved by using newly conservative devices, often referred to as 'closed systems', and help to reduce iatrogenic anemia risks/ diagnostic blood loss.

A study conducted by Silver et al, compared the blood loss in patients with or without the usage of a conservative device. In a seven-day period, 340ml of blood was saved per patient averaging to 49ml per day when a conservative device was used (7). Another study conducted by Peruzzi showed a reduction of almost 80 to 90 ml of blood loss per day when a conservative device was used for a four-day trial period (8).

Catheter-related bloodstream infections are associated with significant costs and adverse consequences. Infection to the already critically ill patients of the ICU can prove fatal. Many studies show that hospital-acquired infections in intensive care patients are commonly due to an indwelling catheter (9). Arterial catheters are commonly used in the critical care setting and are among the most heavily manipulated vascular access devices. A systematic review and meta-analysis published in 2014 sought to evaluate the prevalence of arterial catheter-related bloodstream infection. The review concluded that arterial catheters are a substantial but under recognized cause of catheter-related bloodstream infection. Future studies should evaluate technologies applied to preventing central venous catheter-related bloodstream infection to arterial catheters as well (10).

Closed blood sampling systems can reduce consequential blood loss and catheter-related infections and hence can have a positive effect on improvement of the patient.

Elcam's Clear-IT™

Closed blood sampling systems enable the clearing volume to be reinfused back to the patient in a safe manner which helps to reduce contamination and also prevent blood waste. Elcam's Clear-IT™ closed blood sampling system (figure 1) combines an In-Line Reservoir for collecting clearing volume and a Marvelous™ stopcock to facilitate flushing of the line and syringe tip.

Figure1

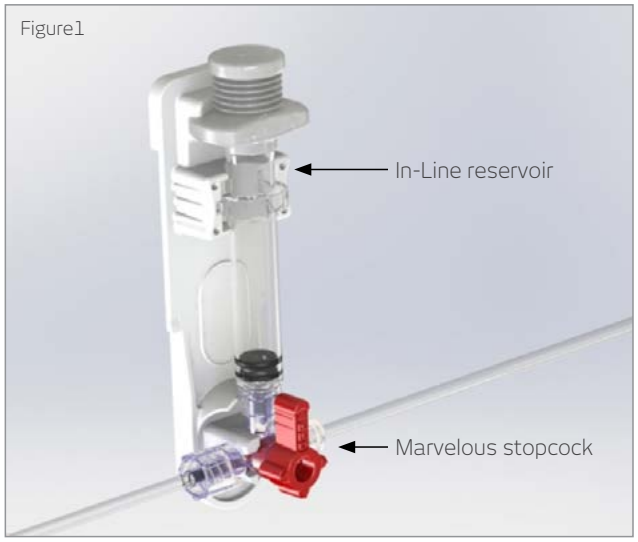
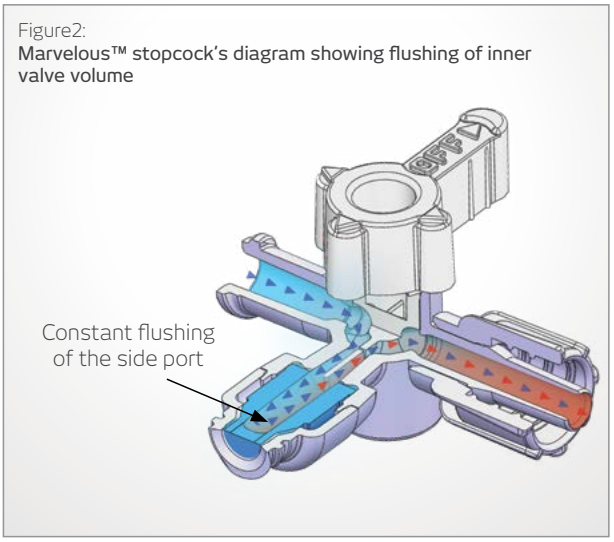


Figure2:
Marvelous™ stopcock's diagram showing flushing of inner valve volume



The Clear-IT™ is intended for blood sampling taken from the blood pressure monitoring line. The system minimizes blood waste, thus decreasing the risk of anemia as the clearing volume is reinfused back to the patient after sampling is completed. The closed in-line design also helps in reducing microbial contamination.

The risk of microbial contamination is further decreased with the unique Marvelous™ stopcock design featuring a circumferential fluid channel that assures clearing of the line and syringe with minimal non-flushable (residual) volume after blood reinfusion (figure 2).

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Safety and functionality of the Clear-IT™

A drawback of closed systems is their incomplete flushability that can result in blood residues and consequent complications such as contamination and clotting. In order to avoid the risk of blood residues, Elcam has incorporated the Marvelous stopcock with its circumferential channel feature that assures minimal residual volume into the Clear-IT.

Elcam Medical has conducted an initial study in order to compare the minimal residual volume feature of the Clear-IT™ to a similar device in the market. The tests were conducted by well-established certified laboratories.

Flushing Study

The purpose of this study was to show that the Clear-IT™ minimal residual volume feature functions as good as other devices in the market with regard to blood residuals after flushing.

This purpose was achieved by quantifying blood residues in the device vs. other corresponding closed blood sampling device, after line clearing. The test procedure was designed to mimic real-life hospital procedures (11).

Elcam's Clear-IT™ was tested in comparison to a competitor blood sampling device

The sets were modified to allow for a direct comparison between the devices.

The sets were designed as follows (see figure 3 below):

1. An arterial catheter was connected to the tubing via luer connector.
2. A sampling system (Reservoir) placed up the line, 15cm from the joint of the catheter and the tubing
3. A syringe with prefilled 5ml saline was connected to the transducer through STP 2.

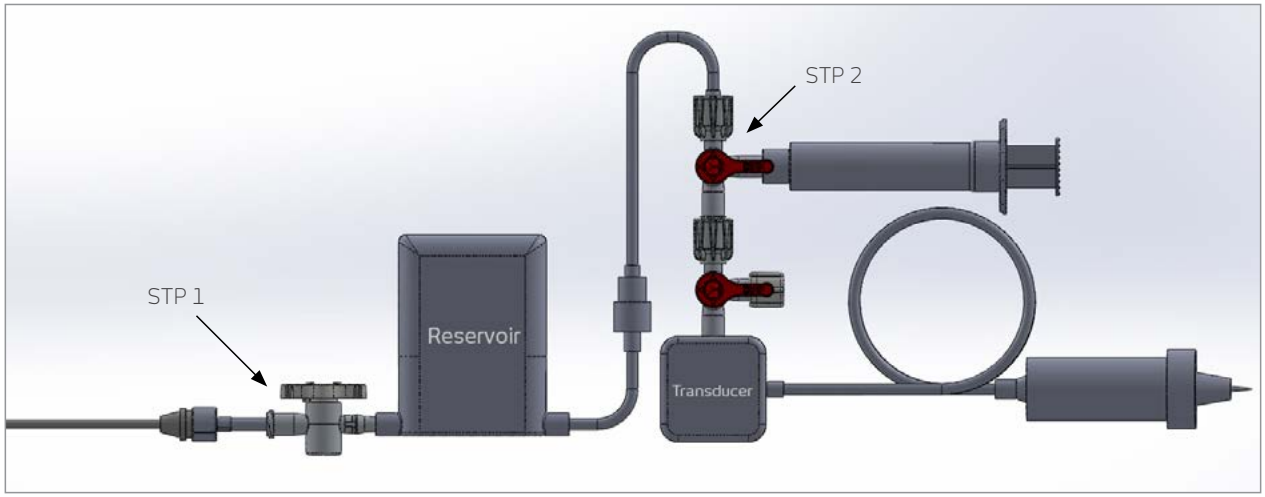

Figure 3: **Schematic structure of the tested blood sampling**

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Test procedure:

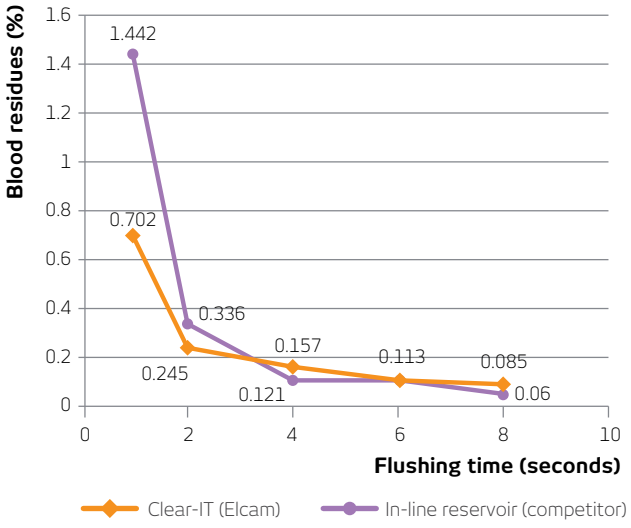
- The drip chamber of the set was connected to a saline bag under pressure of 300 mmHg applied by a pressure sleeve
- The set was primed with saline
- The line was closed between the transducer and saline bag
- The arterial catheter was dipped in a container with sheep blood
- Blood was drawn by the sampling system untill the reservoir was filled with blood
- The reservoir was emptied from blood, returning the blood to the blood container
- The set was closed toward the syringe
- The line was flushed by the in-line flush device for X seconds [X= 1, 2, 4, 6, 8]
- STP 2 was turned OFF toward the transducer
- The arterial introducer was disconnected from the set and the feamle luer was directed to a new clean container
- 5 mL saline were injected from the syringe and through the sampling system
- The blood residues that exited through STP 1 were collected in the new container
- Blood residues were quantified by DAS* photo spectroscopy at 234nm wavelength

Each tested group included 5 samples.
*DAS –Diode Array Spectrophotometer

Test results:

Results showed an initial difference in blood residues after 1 second flushing time between the two tested systems in favor of the Clear-IT; followed by no significant differences after in-line flushing for 2, 4, 6 & 8 seconds (Wash Time). Therefore we concluded that the Clear-IT™ flushing feature is as good as that of the other tested system (Graph1).

Graph 1: **Blood residues vs. flushing time – Clear-IT in comparison to competitor system**



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