

Positive Results from Point of Care Pelorus 1500 Study in Cardiac Surgery Patients



Technology meets primary end point and demonstrates equivalent performance to gold standard method for propofol analysis

Sphere Medical, a leading developer of innovative monitoring and diagnostic products for the critical care setting, is pleased to announce that Pelorus 1500, the world's first in-vitro diagnostic medical device for the rapid measurement of the intravenous anaesthetic propofol at the point of care, has met its primary end point in a clinical study and has demonstrated equivalent performance to a gold standard method of analysis.

A total of 111 whole blood samples from 32 patients undergoing cardiopulmonary bypass surgery at the Papworth Hospital, Cambridge, UK were analysed. Each sample was tested using both Sphere Medical's Pelorus 1500 and the current gold standard High Performance Liquid Chromatography (HPLC) reference test. The results from the Pelorus 1500 showed excellent agreement with the reference method (1).

The results will be presented at the Society for Intravenous Anaesthesia (SIVA) Annual Scientific Meeting in Edinburgh, 29th – 30th November 2012.

Sphere Medical is working with a number of the UK's leading anaesthetists to investigate novel approaches to take propofol measurements during infusion with the aim of allowing anaesthetists to know the actual, rather than predicted concentration of propofol thereby creating the personalisation of dosing to the patient. This work is expected to result in the next generation of infusion protocols and control systems which would be a significant opportunity to improve patient care and consequently is a large commercial opportunity for Sphere Medical.

Propofol is one of the world's most widely used intravenous anaesthetics and clinical studies have already shown that a single measurement carried out during general anaesthesia can significantly improve the clinicians' understanding of propofol levels during an operation (2).

Commenting on this announcement: Dr Stuart Hendry, CEO of Sphere Medical, said: "This study further validates Pelorus 1500 for the rapid measurement of propofol in whole blood in the critical care setting. Following on from CE Marking earlier this year we are delighted to see Pelorus demonstrate equivalence to the gold standard analytical method. Enthusiasm from anaesthetists for this real time product has been very encouraging and Pelorus will allow anaesthetists to provide patients with individualised and optimised point of care technology. We are focused on driving this product to the market in the UK and through our Japanese distributor."

Dr Alain Vuylsteke, Chief Investigator for the study at Papworth Hospital, Cambridge, UK, commented: "Propofol is widely used as an anaesthetic for cardiac surgery patients, but the nature of the procedures used means that the dosing can be quite uncertain. Until now, we have had no clinical tool that will allow us to determine in real time the concentration of the drug in the individual patient in front of us. The results from this study demonstrate that the Pelorus 1500 has the accuracy required for me to understand exactly what is happening to drug concentrations in this patient group. It opens many clinical possibilities, including tailoring the infusion to the patient's specific and complex needs."

References:

- (1) The results from the Pelorus 1500 showed excellent agreement with the reference method with an R2 value of 0.988, slope of 1.004 and a bias of -0.021 µg/ml over the range of 0 – 12 µg/ml.
- (2) Analysis within a recent paper presented to the UK Society for Intravenous Anaesthesia Annual Scientific meeting in 2011 indicated that the single point correction improved the average prediction imprecision of the dosing pump by approximately 60% (from 38.3% to 15.8%). "Use of a device to measure blood propofol levels to improve inter-patient bias of propofol target controlled infusion (TCI)" by Nick J Cowley and Thomas H Clutton-Brock, November 2011

Source: *Sphere Medical*
www.spheremedical.com

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