# NON-INVASIVE TECHNOLOGY to determine the haemoglobin level of blood donors at the SANBS

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## ABSTRACT

### BACKGROUND
Predonation haemoglobin (Hb) check has been done traditionally by the copper sulphate (CuSO4), or the haemocue haemoglobinometer methods. Both of these require a fingerprick of the donor to obtain capillary blood samples. It is thought that a non-invasive, but accurate method of Hb check will reduce stress to the donor and improve the donation experience.

### AIM
This study aims to establish the suitability of a non-invasive method, the Haemospect[R] transcutaneous Hb measurement system for screening prospective donors at the cut-off Hb value of 12.5g/dl.

### MATERIALS AND METHODS
All donors who presented for platelet and/or plasma donation at the multi-disciplinary donor centre of SANBS in Port Elizabeth were considered for enrolment. Hb was measured by both the standard automated method on venous EDTA samples, and by the Haemospect[R] transcutaneous Hb measuring device.

### RESULTS
A total of 161 subjects were studied, including white, black, and coloured, male and female donors. The calculated sensitivity of the Haemospect[R] was 94.6%. The average percentage variance in Hb measurement between the two methods was 1.2%, while 70.8% of subjects had a percentage variance within10% of the venous Hb result.

### DISCUSSION AND CONCLUSION
The result shows that the accuracy of the Haemospect[R] measurement was within the 1.5g/dl ascribed to the $CuSO_4$ method. This suggests that the non-invasive method was at least as sensitive as the traditional screening methods. Further large-scale study is recommended to validate the findings in this pilot study.

## INTRODUCTION/BACKGROUND

According to the Standards of Practice for Blood Transfusion in South Africa (6th ed.), all blood donors must have a haemoglobin (Hb) level of at least 12,5g/dL to be eligible to donate blood and their Hb levels must be screened prior to each donation. Currently, the prevailing screening method used is the Copper Sulphate ($CuSO_4$) test which requires a finger prick, using a lancet and the collection of a capillary blood sample. The capillary blood is allowed to drop by gravity into a CuSO4 solution of predetermined specific gravity. The blood drop should sink within 10 – 15 seconds. If this test is not passed with the first drop of blood, it is repeated with a new sample. If it fails for a second time, a quantitativeHb screen is then performed with the Hemocue® machine, again using a capillary blood sample.

Capillary blood sampling is not without challenges. Accurate Hb estimates require correct technique when collecting the blood sample, failure to do so may result in inaccurate Hb measurements. The need for a finger prick in capillary blood sampling contributes to donor discomfort and this is a frequently encountered complaint from donors.

Not having to collect the capillary sample will significantly improve the donor experience. In addition, it is common knowledge that the use of sharp instruments carries the risk of needle-stick injury and results in the production of bio-hazardous waste.

However, technology is available to perform point-of-care Hb screening without the need of collecting a capillary blood sample. The concept of non-invasive Hb measurement has been developed for some time, but has been limited as a point-of-care test due to the size and immobility of previously available devices. This technology potentially offers a more efficient and user friendly alternative to screen the Hb levels of donors with the use of a non-invasive, mobile handheld device which uses transcutaneous light spectrometry technology.

In vivo photometric devices have been designed for measuring Hb concentration non-invasively since the 1990's. The first blood-free assessment of Hb concentrations using the Erlangen photometer (EMPHO) was published in 1996[1]. This method was based on deeply penetrating white light and lead to proof-of-principle results under laboratory condition. Nadeau and Groner[2] followed suit with a device for in vivo microscopic imaging of superficial, mucosal microcirculation using polarized light. Rabe[3] found solid reliability of a transcutaneous photometric technique using white light to estimate haemoglobin concentrations in new-borns, which was a precursor of the Haemospect® device. All these devices were used in institutional settings. They were too large to be transported and depended on permanent electric power supply. This technology then was not suitable to use in the field.

Several studies in the field with Haemospect®: MBR Optical Systems (Wuppertal, Germany) tested the device in diverse countries in Europe (United Kingdom, Spain, Italy) and the rest of the world (Turkey, Russia). The first two versions of portable transcutaneous Haemospect® were tested in diverse studies in Guatemala[4-6]. The spectra obtained with the second version had to be analysed on a computer by MBR in Wuppertal. To calculate an algorithm, i.e. the iterative calculations required to transform the spectra into a corresponding haemoglobin value. After processing, the device yielded haemoglobin values that correlated closely with those obtained in whole blood of the same volunteers on the same day[5]. These studies were carried out in people with skin colour 1 to 4 according to the Fitzpatrick Scale. In this scale, skin colour is divided in 6 categories. Although previous experience had suggested that differences in skin colours had no influence on the measurement accuracy; measuring times had to vary. Therefore, it is essential to test this device in dark skinned population.

## AIMS AND OBJECTIVES

This study aims to establish the sensitivity and specificity of the Haemospect® transcutaneous Hb measurement in screening donors at the cut-off Hb value of 12.5 g/dl.The Haemospect® measures in a range from 9 to 18 g/dL. However, the error is minimal in the window of decision from 11 to 14 g/dL and comparable to that from the capillary based testing.The purpose of this study, therefore, is to determine whether Haemospect®. Hb measurement will be a viable alternative to capillary based testing.

Being able to identify an effective technique for the non-invasive measurement of Hb, holds significant advantages for a Blood Transfusion Service such as SANBS, and includes:

- Reduced risk of spreading blood-borne diseases such as HIV and hepatitis with reduced risk of needle stick injuries.
- Elimination of consumables such as the lancet, alcohol swab, capillary tube, cotton wool, $CuSO_4$ solution and its container, Hemocue® machine and cuvette, the personal protective equipment (PPE) and elimination of bio-hazardous waste generation.
- The elimination of the previously mentioned consumables may reduce cost, but this is not a specific aim of the study.
- A more acceptable procedure to the donor as the pain and stress of the preliminary fingerprick is avoided.
- The potential reduction in turn-around time of donors, as the transcutaneous Hb result will be available within 60 seconds.

## STUDY DESIGN, MATERIALS AND METHODS

This study was conducted after obtaining ethical approval from the SANBS Human Research Ethics Committee as well as administrative approval from the SANBS management and Medical Director.The study was performed at the Multidisciplinary Donor Centre of SANBS in Port Elizabeth, Eastern Cape, South Africa. All donors who presented for platelet and/or plasma donation were considered for enrolment. This represented a non-random, convenience sample. To ensure adequate inclusion of participants with dark skin color, additional whole blood donors of African descent were included in the study.

Data collected during the study included the following variables:

- Date of procedure
- Donor number
- Age
- Gender
- Race/skin colour
- Pre-FBC Hb result
- Haemospect® Hb result
- Variance
- Percentage of variance

Haemospect® (MBR Optical Systems GmbH, Wuppertal, Germany) which is a non-invasive, mobile handheld device was used to determine the transcutaneous Hb. The device consists of a battery-powered meter that uses reflection spectroscopy, a button sensor and a digiclip. It operates in temperatures ranging from + 10 to + 40 $^{o}$C and humidity up to 85%.

It is part of the standard operating procedure (SOP) for all apheresis donors to have a FBC performed prior to the commencement of the apheresis procedure. This sample formed the basis of the comparison.

After completion of the initial donor assessment, the donor was seated on the donor chair and the arm of the donor comfortably positioned on the armrest at heart level. As per SOP, the blood pressure was measured. This gave the heart rate a chance to stabilize and time for the donor to relax. The procedure and purpose of this study was explained to the donor and consent was obtained.

The measurements with the Haemospect® were carried out by a registered nurse, who received previous training for the handling of the device. The non-invasive digiclip of the appropriate size (small and large available) was applied to the middle finger of the donor after having been wiped with an alcohol swab to remove any dirt and deposits. Measurement with the Haemospect® should not be taken on any injured, scarred or tattooed areas or over hairy growth or heavy pigmentation. The reading to determine the transcutaneous Hb level takes approximately 30 seconds. The result on the screen of the Haemospect® was documented in an Excel spread sheet, specifically created for data collection of this study. The digiclip was removed and the apheresis procedure commenced by cleaning the venesection site according to standard procedures, the needle was inserted into a vein in the anterior cubital fossa, secured with tape and the sampling pouch filled.

The time between the non-invasive Hb measurement and the blood sampling was no longer than 15 minutes. The sample pouch line was hermetically sealed and the Haemonetics MCS+ machine started to procedure when the operator selected the "Draw" button. At this point, 3 - 4 ml of blood was collected from the sample pouch, into a 4 ml EDTA tube for the FBC sample. The sample was placed in a small cooler box. The temperature should be kept between 2 - 8 °C, according to SOP. At the end of the clinic, the samples were dispatched to the testing laboratory of SANBS. The venous blood sample was analyzed and reported by SANBS's Quality Control Laboratory, which uses the ADVIA2120 to perform the FBC tests. Pre-FBC results were available on Meditech the following day from 09:30 and then documented on the data sheet. All data was collated and analyzed using Microsoft Excel 2010 standard statistical functions. Quality Control and Data Management focused on ensuring that the data collected were recorded and interpreted in a precise and consistent manner.

## RESULTS

The testing was done from February 3 – 20 March 2014. A total of 161 participants were included of which 44% were female, 6.2% were Black and 8.7% were Coloured. The average age was 48years. The mean venous Hb was 14.11g/dL and 14.14g/dL by the non-invasive method. This difference is not statistically significant (p=0.77; paired t-test).

The Bland-Altman analysis indicated that the limits of agreement were 2.72 and 2.65 below and above the reference values. With the FBC sample, 12 donors with an Hb level below the cut-off were detected, of which all 12 were found eligible by the Haemospect®, while the Haemospect® failed 8 donors, who had an Hb level above 12,5g/dL on the FBC result.

**FIGURE 1: Bland-Altman plot**

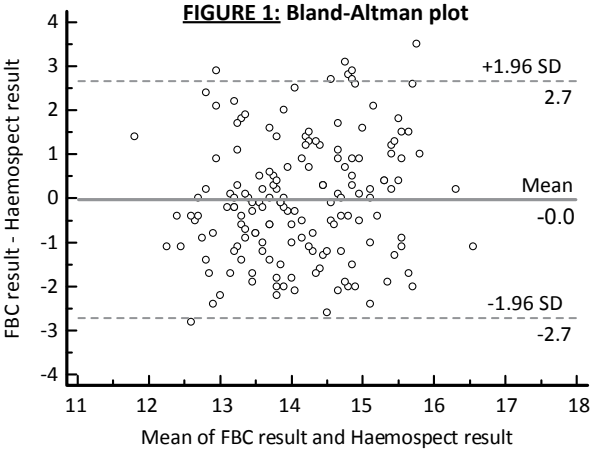
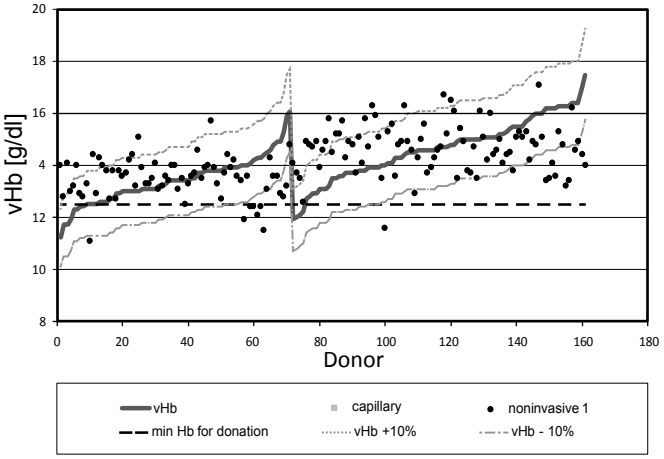



**FIGURE 2: vHb Overview**




The calculated sensitivity to detect Hb levels above 12.5g/dL was 94.6% and the specificity 0%.

The average percentage variance in Hb measurement between the Haemospect® and the FBC was -1.2%.

A total of 70.8% of the study subjects had a percentage variance within 10% of the FBC result

## CONCLUSION

Even though the specificity of the testing method was very low, the sensitivity was within acceptable range and the Bland-Altman plot showed stronger limits of agreement than previously noted for $CuSO_4$ screening.[7] Just more than 70% of the samples were accurate within a 10% variance, which equates to accuracy within 1.5g/dL. This accuracy falls within the parameters previously noted for $CuSO_4$[7-9], the current screening method in use at the SANBS. The nature of the sample is biased in selection as only donors who passed previous screening tests were included in the study. This is suggesting that the non-invasive technology was at least as sensitive as the other screening methods. The findings of this pilot study suggest the need for further large scale evaluation and validation of this technology on whole blood donors in comparison with the $CuSO_4$, Hemocue and automated FBC methods.

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