

SWOT – VM-2400

Information compiled from feedback received at Arab Health and visits to hospitals within Saudi Arabia.

Strengths

- Non-Invasive; all the people we spoke to in the blood donor and blood bank departments, were aware of the advantages for using a non-invasive device and are very excited at the prospect.
- We witnessed blood contamination on some of the invasive devices.

Weakness

- Accuracy? The Blood banks are expecting a $\pm 0.05\text{g/dl}$, I am struggling to find any written protocols, but I have seen this figure mentioned. The invasive devices tend to give the accuracy in CV%.
- Accuracy? The need to warm the hand prior to measurement appears to be critical, as I have seen a large difference in readings.
- QC – Quality control, the users want to be able to test the accuracy at the start of each shift.
- Time; if we need to warm the patient for a 2+ minutes before testing and then it takes 40 seconds once a signal is confirmed, it could double the interview process time.

Opportunities

- The concept of non-invasive POCT is of interest to all users, providing the accuracy and consistency is acceptable and testable.
- None of the blood donation centres and blood banks had a non-invasive POCT device
- Orsense can not sell in to the GCC with being from Israel
- Masimo are present, but appear to be concentrating on the ICU areas and do not appear to have approached the blood donation areas

Threats

- Masimo, do not require calibration of the sensors, as you replace them as part of the counter key system.
- Device cost
- FDA, some of the blood banks I visited have adopted the US standards and accreditation, which recognises FDA registered products. Introducing a product that is only CE will be a more involved process.

17/02/16

Tested in the office on RS

Right hand, middle finger:

Stress ball 1 minute = 10.2

Hot tap = 13.5

2min Lamp = 13.8

ex2min = 14.2

ex2 min = 14.5

Left hand, middle finger

No prep = 13.3

Stress ball 2 mins = 13.8

2 min lamp = 15.3

2 more min lamp = 13.8

Hot water 2 mins = 16.8

Test in IEC (Jeddah) 01/02/16

Test Data (001)

Tested conducted by doctor on a healthy biomedical engineer. Used stress ball for 1 minute:

Dispect (checked with control daily) = 16.6

VM-2400 = 15.3

Results not acceptable, but doctor willing to evaluate over a week.

Requires QC or some very sturdy documentation.

Test in Astoon / GAMA Hospital 03/02/16

Tested on patient, hands were a little cold, but we tried to warm them with the stress ball:

Full Haematology test = 17.2

VM-2400 (Raw 20) = 14.5

Tried in ICU setting with 2x patients; one patient was ventilated and the other was not:

Could not obtain strong enough signal to initiate testing

IMC (Jeddah)

Dr. Hamad – Head of the Blood Bank

Testing 30-50/ day (4-5 day week)

Using Hemocue and have tested results against Sysmex 1000 CBC and have witnessed some variation. Willing to run a trial on the VM-2400 against Hemocue and CBC and share the results with us, providing they are not used for marketing and the hospitals name is not used.

Questions

- What is involved in the calibration of the sensor and does it have to be returned to Viamed or Bluepoint?
- QC – Quality Control, is there a way that the device can be tested at the start of each shift, without running an ABG (manual) or running a full haematology test? If not, do we have any documentation to back this up.
- Do we know what the accuracy protocols are for blood donation centres? Is ± 1 standard deviation enough? How does it compare with EKF = $CV < 1\%$ (Coefficient of Variation). Some of the doctors mentioned a tolerance of $\pm 0.5\text{g/dl}$, but I do not know what this is based on.