



Vital New Product - Sorry No Budget

Budget shortfalls are preventing a vital new low-cost product, which could help prevent deaths and complications as diverse as strokes, cerebral palsy, and visual impairment in premature babies, from reaching the baby units, wards and operating theatres where it is needed.

The LIGHTMAN SpO2 sensor tester micro spectrometer, the only tester on the market to measure pulse oximeter sensor LED wavelength accuracy, has been greeted with massive enthusiasm in hospitals where it has been trialled. But budgets rule, so for many medical institutions it's a case of having to wait for possibly many months until funding is sourced before they can purchase the LIGHTMAN.

In the words of one disappointed medical professional: "Inaccurate (pulse oximeter) sensors are a danger to the patients, and as it stands at the moment (*i.e. without the LIGHTMAN*) we have no idea as to the quality of the readings."

simulators pass dangerous sensors

In the meantime, hospitals and healthcare professionals are having to make do with inadequate testing systems using simulators to check pulse oximeter sensors, a situation which is leaving patients at risk. (See 'CE Marking & FDA Clearance no Guarantee of Sensor accuracy', p2 this issue.) To cite just one example: a demonstration of the LIGHTMAN on the Special Care Baby Unit (SCBU) of

a major teaching hospital revealed that out of twenty pulse oximeter sensors – all OEMs – being used on the ward, one was non-functioning, one was reading substantially higher than its claimed error range, and two, including one disposable sensor, were reading low. Yet the only fault a simulator would have picked up was the single non-functioning sensor. Worse, a simulator would have passed as safe the three sensors which were reading beyond the stated error range.



Of course, budgets cannot be ignored, and those holding the purse-strings could reasonably point out that not only is the LIGHTMAN a cost in itself, but would inevitably lead to further costs, with each faulty pulse oximeter sensor it found. But offset against that are the savings to be made when, as in the case cited earlier, a new sensor is faulty. Checking all new sensors, prior to use, would allow faulty examples to be returned to the supplier for replacement. Then there is the question of medical negligence, and any concomitant compensation payouts. These are likely to be far

more eye-watering than the cost of equipping health carers with the LIGHTMAN.

a duty of care?

With the advent of the LIGHTMAN, it is only a matter of time before it becomes a Duty of Care to assess the accuracy of every pulse oximeter sensor before it is used on a patient, and regularly thereafter as part of a planned maintenance schedule. The opportunity is there for individual hospitals to lead the field and become Exemplars of Best Practice.

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CE Marking & FDA Clearance No Guarantee of Sensor Accuracy

" Simulators test for functionality only, and do not indicate the accuracy of a pulse oximeter sensor."

Jim Wobermin, Datex
Ohmeda, 2005

"We believe that the simulator is only appropriate for testing functionality, as opposed to accuracy"

Brian C. Earp, Director
of Marketing – Oximetry at
Nellcor

"While the Index, and several other commercially available patient simulators, can test sensor and pulse oximeter functionality, they are incapable of providing the required data needed to properly evaluate the accuracy of SpO2 readings."

- letter from Bio Tek
Instruments, Anesthesia &
Analgesia 2004

Brave talk about leading edge medical science somehow gives the impression of a steady, though not equal, advance on all fronts; a spearhead of thrusting new techniques, backed up by possibly less thrusting, but thoroughly reliable, systems. And all, of course, thoroughly compliant with regulatory requirements. Ah, if only it was really like that...

a misleading picture

It is, alas, sometimes a misleading picture. For every brilliant advance, somewhere in the bowels of the support system is an embarrassing little detail, a sort of sad relative everyone knows about, but won't admit to in public. When we put up with a situation like this, it's usually because we have no option. And such has been the case when using simulators to test pulse oximeter sensors; not unreasonably, we have believed CE marking and FDA clearance to be guarantees of sensor accuracy in this as in all aspects of patient safety.

Pulse oximeter sensors are the equivalent of the nail, for want of which – long story – the battle was lost. In other words, workaday pieces of kit, which are nonetheless crucial to the success of the treatment.

Pulse oximetry, a data-gathering technique in daily use on millions of patients world-wide, works by shining light from two LEDs, one emitting red, the other infrared light of – and this is the critical bit – very specific wavelengths, through a patient's blood, to measure the oxygen saturation levels, or SpO₂. The great value of pulse oximetry is that it is a non-invasive process, giving real-time data on SpO₂. This allows medical staff to instantly adjust the oxygen supply to a sick patient – something of critical importance for example during an operation, or for a premature baby.

the embarrassing little detail

Obviously, a system like this

depends utterly on data which is 100% accurate, and the key to this is to be sure that the sensor LEDs are giving out precisely the wavelengths the system was designed to deal with. The big question is how. Because here is where the embarrassing little detail comes in: current testing systems for pulse oximeter sensors, using simulators, cannot actually measure the LED wavelengths for accuracy. Which is a bummer, to say the least. This means that sensors may be passed as 'in working order', when all that has been checked is whether or not the LEDs are emitting light – in other words, only a yes/no answer is possible, with no detailed information on whether the wavelengths are all they should be.

This is hardly a satisfactory situation. In the words of Brian C. Earp, Director of Marketing – Oximetry at Nellcor: "We believe that the simulator is only appropriate for testing functionality, as opposed to accuracy. Evaluating SpO₂ measurement accuracy for any sensor would require... the wavelength characteristics of the sensor."

Of course, simulators have their uses; checking the electrical continuity of the system, the software, and LED light emission. And while there was nothing better on offer, simulators it had to be. Now, though, there is something far better on offer: the LIGHTMAN is a hand-held, portable micro spectrometer – *not* a simulator – which measures LED wavelengths and gives an immediate read-out of the results.

the most sobering fact of all

When the LIGHTMAN was used in recent tests of pulse oximeter sensors – all of which were in use at the time – it found one sensor with a positive error of 15%, another with a negative error of 16%. For a patient with an SpO₂ of 70%, these would have given readings of 85% SpO₂ and 54% SpO₂ respectively. These were extreme, but by no means unique, examples. And the most sobering fact of all is that a simulator would have passed both of these CE marked, FDA cleared sensors as fit for use. □

LIGHTMAN Case Studies

Pulse oximeter systems have formed a crucial part of medical testing equipment for many years now, but in the past, due to the lack of any means of testing sensor accuracy, medical staff had to use their own instincts and experience to augment pulse oximeter readings.

The following case vignettes give some flavour of how things were, and how they are now that the LIGHTMAN is being adopted by more and more hospitals.

Case A: Hypoxic Patients – No Alarm: The following two cases both involve sensors with a high positive error. In the first incident, a patient who had been anaesthetised began to look blue. Medical staff checked the pulseoximeter system, but the readings were normal, and the alarms were not sounding, so the staff were reassured. However, subsequent testing by the LIGHTMAN showed that the sensor was faulty, with a +5% error at 97% SpO₂.

The second incident took place in the Neonatal Intensive Care Unit (NICU) of a major teaching hospital. In this case, a baby was beginning to turn blue, but again, the pulse oximeter alarms were not sounding. In the first instance, nursing staff were accused of turning off the alarms, and failing to notice that the baby was desaturating. But once again, when the LIGHTMAN was brought into use on the unit, it was a high positive error in the sensor which was pinpointed as the root of the problem, and the nurses were totally vindicated.

Case B: Patient Really Was Blue: On the face of it, a sensor which is reading within the manufacturer's error range shouldn't be a problem. But in this particular case, the patient had been injected with methylene blue in the course of an operation, and appeared blue partly as a result of this. Unfortunately, the methylene blue was not solely responsible for the patient's blue colour; low SpO₂ accounted for part of it, too. The pulseoximeter system picked this up, and the alarm went off, but the clinicians took this to be a false alarm, and so there was a delay in administering extra oxygen. Subsequent testing using the LIGHTMAN found that the sensor was in perfect working order. Had the clinicians had access to the LIGHTMAN at the time of the operation, they could have checked the pulseoximeter system fully, and so had confidence in the readings.

Case C: Retinopathy of Prematurity (ROP): A major cause of ROP – visual impairment in premature babies – is too much oxygen during the crucial early weeks. Special Care Baby Units (SCBUs) and Neonatal Intensive Care Units have therefore a particular need for pulseoximeter systems and sensors to be as accurate as possible.

For this reason, nursing staff at Hospital C routinely use the LIGHTMAN to check all sensors. And it was while testing a batch of brand-new sensors, prior to use, that one was found to be reading well below the manufacturer's stated error range. If this sensor had been used on a baby, there is every possibility that visual impairment would have occurred, through excess oxygen being administered.

Case D: Machine or Sensor?: Often, medical staff suspect that a pulseoximeter system is developing a problem, but lack the testing systems to confirm or allay their suspicions. Result: serviceable equipment not being used, or worse, inaccurate pulseoximeters in use on patients. Either way, a highly unsatisfactory situation.

In the case in question, medical staff felt they could no longer trust the readings from an old pulseoximeter system. As soon as the LIGHTMAN was available, a hospital technician was asked to check the whole system thoroughly. Because the LIGHTMAN can test sensors independently from the rest of the pulseoximeter equipment, he quickly confirmed that, while the sensors were accurate, the rest of the system was no longer working properly.

The Electrode Company: the team behind LIGHTMAN



The Electrode Company was formed in 1986 and is a completely self-financed private company wholly owned by its two founders - Dr GR Mathews and Dr VM Hickson.

The company's credibility with the end user comes from its complete independence from pulse oximeter manufacturers and from maintaining the very best technical expertise and delivery of the highest quality service.

Specialising in non-invasive monitoring, optical sensors and high performance pulse oximetry, The Electrode Company has a personnel list with impressive qualifications and



experience in the field of medicine, biology and medical physics.

The technical achievements of The Electrode Company have received wide acclaim and it has been rated as one of the top five most innovative companies in Wales. Its research & development has redefined the accuracy of pulse oximeter probe measurement.

Patient Safety - A New Gold Standard

A test that doesn't ask the right questions is no test at all. And using a simulator to test a pulse oximeter sensor is to ask only part of the question. (See also p2 of this issue.)

Pulse oximetry measures blood colour, and hence blood oxygen saturation (SpO₂), by using two precise wavelengths of light emitted by LEDs in the sensor. If these wavelengths are inaccurate for any reason, the readings, too, will be inaccurate, having been based on faulty data. Hence the need to test the entire system, and particularly the LEDs. Which is where the 'right question' business comes into play.

Two methods have been favoured up till now. One is the hi-tech approach, using a simulator. But while simulators can test certain aspects of pulse oximeters, they cannot, crucially, measure wavelengths, and cannot therefore measure accuracy.

pragmatic, but liable to error

The second method is rather more low-tech and, quite literally, hands-on. In what might be called the digital method, a technician's digit is introduced into the sensor, the read-out is eyeballed, and the sensor is passed or failed accordingly. All admirably pragmatic, but unfortunately also liable to error. A technician well enough to work can be reasonably assumed to be well, period. But if he or she is a smoker, then carbon monoxide levels in their blood will affect the colour – cherry-red blood is one indicator of CO poisoning – and will be interpreted by the sensor as oxygenated blood.

Similarly, any length of time spent sitting in traffic jams on the way to work, breathing in the fragrant exhalations of buses, people carriers and 4WDs, will also load up the blood nicely with CO. And even the cleanest-living, non-smoking, cycle-riding technician will have difficulty avoiding that particular health-hazard.

normal might not be normal

The upshot to these two possibilities is that a low-reading sensor could produce a 'normal' reading, and so be assumed to be in good working order.

Another problem with the digit method occurs with high-reading sensors. A sensor has a read-out 'ceiling' of 100%, but might actually be reading even higher – say 101% or 102%. If a sensor like this is passed fit for use, and is then used on a patient with low SpO₂, the readings would, falsely, indicate that the patient's oxygen levels were fine. In one recent case, a high-reading sensor in a Special Care Baby Unit (SCBU) failed to trigger the alarm when the baby became hypoxic.

not nerdy one-upmanship

What makes the situation even worse, is that sensor error range increases as patient SpO₂ levels drop: a 2% error range at normal SpO₂ will have risen to a 7% error range by the time SpO₂ has fallen to 80%. Spot-on accuracy in sensors is

to a patient it means the difference between a full recovery, or permanent hospital-induced brain damage

not just a piece of nerdy one-upmanship. To a patient it can mean the difference between a full recovery, or permanent hospital-induced brain

damage. It can even mean an early death, and that's about as permanent as you can get. All in all, a pretty raw deal if you happen to be the patient.

testing wavelengths is now possible

Until now, there has been no way to test the accuracy of sensor LED wavelengths. But the advent of the LIGHTMAN micro spectrometer, designed specifically to test LEDs – for wavelength accuracy, intensity, and incipient failure – is set to change all that. It must be stressed that the LIGHTMAN is not a simulator. It is a miniaturised, hand-held, portable spectrometer, which self-calibrates against an internal argon/neon source immediately before each sensor test. It then goes on to measure the wavelengths emitted by the sensor LED, and give a clear read-out of the result. Any sensor inaccuracies, positive or negative, will be picked up and indicated immediately.

And using the LIGHTMAN should not be confined to older equipment. Sensors can be faulty from new, and for this reason, every new sensor should be tested before being put into use on the wards, operating theatres, or SCBUs.

There's no excuse now for sub-standard sensor testing. The LIGHTMAN has put a new benchmark for accuracy within every sensor user's reach.

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