



## Accuracy study puts Masimo Top of OEMs

**Concerns about human error and its consequences for patient safety have recently prompted several studies into pulse oximeter reliability and accuracy. These have pinpointed untrustworthy monitoring and alarm equipment as contributing significantly to error situations.**

The benefits of reliability and the highest degree of pulse oximeter accuracy in terms of patient welfare are obvious – speedier recovery, fewer problems from hypoxia or hyperoxia (low and high body oxygen), to name just two. Less obvious are the benefits to the caregiving staff, the nurses and doctors who rely on pulse oximeter data in caring for the patient.

### Masimo tops league

A recent independent study in the USA led by Dr Charles Durbin and Dr Steven Barker, two of the most prominent researchers in the field, set out to check a vital aspect of pulse oximeter reliability and accuracy – the impact it can have on the time utilisation of caregivers. The results make for sobering reading: there was a tenfold difference in functional time between the best – the Masimo SET (Signal Extraction

Technology) device - and the worst pulse oximeters. These results show an alarming amount of nursing staff time can be spent checking or adjusting equipment, responding to false alarms, and re-testing patients where unreliable or inaccurate pulse oximeters are in use. Staff under this degree of added pressure are likely to make mistakes.

### hidden costs of downtime

Inevitably, this has a cost. Time spent attending to equipment is time taken from patient care. This could lead to patients suffering avoidable complications, or taking longer to recover; both could prove costly to hospitals. To



Oximeter	motion and low perfusion study		
	SpO <sub>2</sub> Sensitivity	SpO <sub>2</sub> Specificity	Drop Out
Masimo SET	99%	97%	0.0%
Agilent Viridia 24 C Rev B	78%	90%	1.6%
Agilent CMS Rev B	70%	83%	3.7%
Nellcor N-395	70%	73%	4.0%
Novamatrix MARS	40%	42%	2.4%

Data presented by Dr. Steven J Barker, Chairman and Head, Department of Anesthesiology, The University of Arizona, at Tucson, during Refresher course "New Directions in Oxygen Monitoring" at October 2000 ASA meeting in San Francisco, CA.

avoid these, hospitals may need to increase staff numbers - hardly a cheap option.

### Masimo does it again

A second study into the accuracy and reliability of pulse oximeters during motion and low perfusion again revealed an alarming gap between the best and worst. Pulse oximeters were tested for their reliability in false alarm rejection, and true alarm detection. Top scores, achieved by Masimo SET, were 97% and 99% respectively. By contrast the worst performer was Novamatrix MARS, with 42% and 40% respectively. Here, too, accurate and reliable pulse oximeters benefit patients by allowing nursing staff to focus on their patients, not the equipment.

CEM has built its business and its reputation on the highest possible standards of accuracy in both its own manufactured pulse oximeter probes and its refurbishment service. These studies confirm that there is no substitute for accuracy. □

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## New research fast-tracks amputee recovery

**One of Europe's more stunning statistics is the number of new amputees every year – over 100,000 of them. But the loss of a limb is only the start of a long and often painful process of readjustment and rehabilitation for new amputees.**

It is this lengthy process which is the focus of the MAPS project. MAPS – Monitoring Amputee Progress with Sensor Socket – is a major collaborative project drawing expertise from academia and industry across the EU and beyond, including Iceland, the UK, Belgium, the Netherlands, Israel and Sweden.

The aim of the project is to improve rehabilitation and aftercare for amputees, focusing initially on below-the-knee amputations.

### EU backs MAPS

It is a measure of the importance of this project to European health care systems that the EU has backed it with one of the biggest medical research grants of its kind.

The MAPS project will develop a Sensor Socket which will monitor



*amputees get on their bikes*

amputee progress remotely, allowing patients to download data via a phone or computer link, rather than attending a clinic or rehabilitation centre. Patients will even be able to download data in real time to their doctor if they are having problems. Less time spent attending rehab centres will allow amputees to rebuild their lives, as well as saving costs for hard-pressed health services.

### CEM's role

Poor blood flow in residual limbs is often a cause of problems, so

pulse oximetry will be used to detect early the signs, allowing remedial action to be taken well before a problem becomes a crisis. Celtic ElectroMedical's expertise in the field of high performance pulse oximetry and noise cancellation made the company an obvious choice for Ossur HF, the Icelandic company which originally proposed MAPS.

The MAPS project will have a huge impact on the quality and delivery of medical care for amputees, benefiting patients and health care services alike. □

## Vari-hinge probe is here

**CEM's own design vari-hinge pulse oximeter probe is now in production, and already the feedback from users is very positive.**

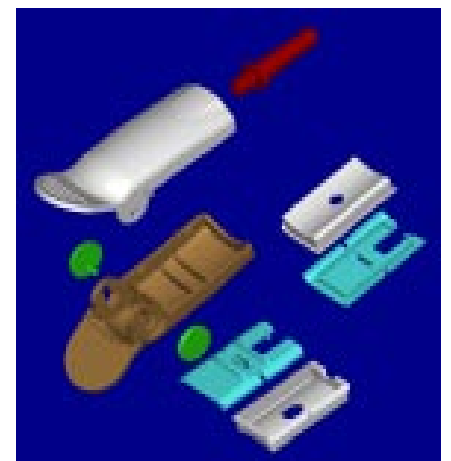
The vari-hinge probe is a highly original answer to the parallel versus fixed-hinge dilemma. By combining the best features of both, CEM has achieved a probe which pairs excellent optical contact with a robust constitution.

In keeping with CEM's high design standards, the probe is latex- and PVC-free, and the non-allergenic rubber insert is fully bio-compatible.

As ever, accuracy is at the core of all CEM's products and services. Every single LED used in CEM's

manufacturing or refurbishment sectors is tested, using equipment designed and developed by CEM for the purpose. As a result, every probe, whether new or refurbished, which leaves the premises, is guaranteed to an error range of less than  $\pm 1\%$ .

The reasoning behind this is explained by Dr Geoff Mathews, Director of CEM; "Health care professionals know every patient is different; that means a huge degree of variability is already present. It is all the more important, therefore, that every pulse oximeter probe is as accurate as possible." □



*CEM's new vari-hinge probe*

## Extreme Pulse Oximetry?

**Picture the scene – there you are, in the veterinary Accident & Emergency Department, ready to save lives just like all those TV vets you've seen.**

Pulse oximeter probe at the ready, you take a look at your first case and.... Oh dear, is this where it all goes horribly wrong? There on the examination table, hovering between life and death, lie a flea and a mite. You can't save both – there just isn't the time – so which one do you choose?

**well that's the theory...**

You rack your brains for the theory behind pulse oximetry – what are the three essential elements for it to work???

Ah yes – it's all coming back to you now. First, it needs haemoglobin-based blood. Pulse oximetry works by measuring the changes in colour between oxygenated and deoxygenated haemoglobin.

Second, no pulse, no pulse oximetry. And to have a pulse, your patient needs the third requirement of pulse oximetry, a closed blood system; that is, one where the blood flows through a continuous 'loop' of arteries and veins.

With a tear in your eye, you look

at your two tiny patients. Mites, you recall, have the haemoglobin-based blood, the closed blood system, and the pulsatile blood flow without which your pulse oximeter probe cannot work. The flea, sadly, has none of these; it breathes through holes in its sides, and the oxygen is delivered direct to the cell, so no need for haemoglobin. On top of



*it mite just work....*

that, it lacks a closed blood system, and the concomitant pulsatile blood flow. In short, it's curtains for the flea. All you can do is break the sad news to its family....

## Lightman probe tester

**The pocket-sized Lightman probe tester nears its launch date with even more improvements, thanks to recent advances in mobile phone technology. These have been the source of invaluable spin-offs – surely the twentieth century's greatest legacy? – which CEM have been quick to incorporate into their groundbreaking design.**

**The Lightman pulse oximeter probe tester performs to CEM's usual exacting standards of accuracy. On top of that, its portability means that probes can be tested quickly and easily right there on the ward, or wherever they may be in use. Such ease of operation means that probes can be tested more often, too – no more 'once a year check-up'.**

**The benefits to patients and caregivers are obvious, but there are benefits for the admin staff too – the Lightman will cost substantially less than conventional testers.**

## Masimo buy CEM patent

**The patent for a noise cancellation device developed by CEM has recently been sold to Masimo, the California-based pulse oximeter manufacturing company.**

**Masimo has invested a great deal of its energies into solving the problem of motion artefacts – the 'noise' and interference on pulse oximeter readings caused by patients' movements.**

## Website in Order

**Last year, with the help of a grant from Torfaen Borough Council, CEM made much needed improvements to its website. Now the results are there for all to see at [www.electro.co.uk](http://www.electro.co.uk).**

**The new site so impressed Ossur HF, the Icelandic company behind the MAPS project (see p2) that it invited CEM to join the project, along with companies and research institutions from England, Scotland, Belgium, the Netherlands, Israel and Sweden.**

## Pain-free Shopping Online

**At last, something to make the web-weary shopper breathe a sigh of relief - a pain-free purchasing experience.**

CEM's plans for its website redesign and general upgrade included an online ordering facility. But CEM's personnel have experienced untold suffering at the hands of user-hostile websites, so top priority for the redesign was to make the new site a tantrum-free zone.

So now, visitors will find that the website is much faster to download, as well as being clearer and easier

to navigate. There are new features too, including a full list of all CEM's products and services, as well as a comprehensive ordering facility. And there's more; buyers now have the option to ask for a quote before committing themselves.

The order form has all the qualities an Internet shopper prays for, but seldom finds - it's clear, comprehensive, unambiguous, simplicity itself to use and asks for only a minimal input from users. If you can't wait to try it out, visit us at [www.electro.co.uk](http://www.electro.co.uk). Enjoy.

## Age takes its toll

**Unless you had a spectacularly heavy night out last night, when you looked in your mirror this morning, you probably didn't look any older than you did yesterday. But without wishing to depress you, if you compared today's reflection with last year's, you'd certainly notice the difference; it's just scary the way those tiny changes add up.**

Of course, everything ages, but with some things the consequences can be critical. Take pulse oximeter probes; these are in constant use in health care situations, monitoring blood oxygen levels of patients in every state of health. Yet how often are the probes checked? More to the point, how often should they be monitored, and what are the signs of failure?

Pulse oximetry works by shining light through blood, using its colour to calculate oxygen saturation. Changes in the wavelength of the LEDs - the light source - in a pulse oximeter probe will mean inaccurate readings.

### what's to blame?

So what can cause changes in the wavelength? The foundations of future LED performance are laid down during the manufacturing process. Even during the 'growing' of semiconductors, stacking faults - breaks in the regular stacking of layers of atoms in the crystals - can occur. These show up in later use as Dark Line Defects, which may get worse over time.

During the assembly of a pulse oximeter probe, poor mounting of the LED can create mechanical distortion and stress within it. Everyday wear and tear exacerbates the problem. The result will be a sharp decline in performance.

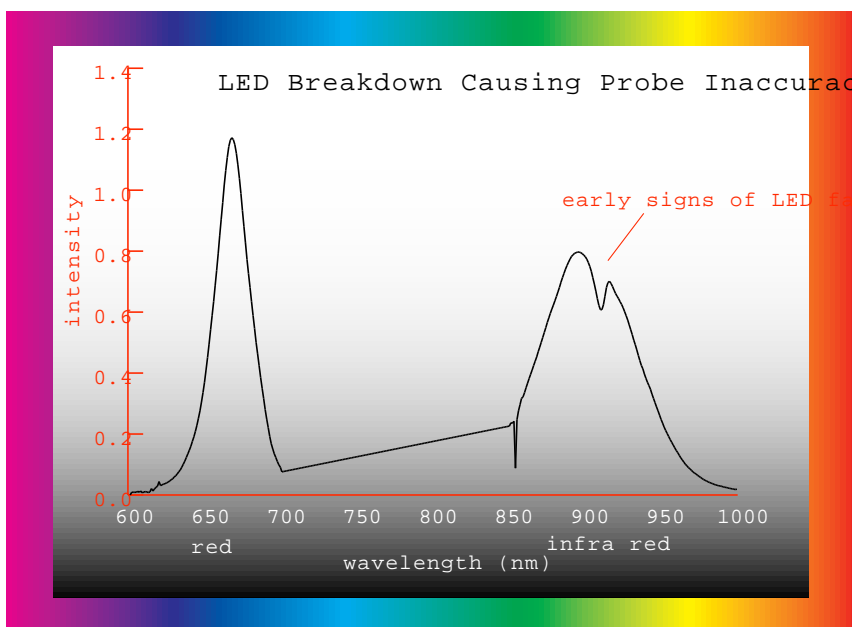
A complicating factor is that LEDs can fail unpredictably, even very early in their life. By definition, it's impossible to weed out those most likely to fail. Regular and

lifelong checks are the only safeguard. The problem is greater in pulse oximeter probes with multiple pairs of LEDs. Here, more frequent checks should be carried out as a matter of course.

### check the warning signs

What, then, are the warning signs of LED failure? As an LED deteriorates, changes within the crystal alter the wavelength of emitted light. Look out for signs of drift in the peaks of the wavelength graph, or a double peak in the IR range. These may happen gradually, so check every pulse oximeter probe at regular intervals, even those apparently functioning well.

It's difficult to overstate the importance of



regular checks on LEDs. Even slight deterioration will increase the error range of the readings. This is particularly serious for patients with low oxygen saturation; pulse oximeter error range increases with falling oxygen saturation (see 'Accuracy - more than a Beat That exercise', Issue 3 of 'the Pulse', on our website, [www.electro.co.uk](http://www.electro.co.uk)).

### use the Lightman - often

Without regular testing, ageing and deterioration of LEDs may escape detection until well advanced, by which time the pulse oximeter probe will be so unreliable as to be all but useless. CEM's new Lightman pocket probe tester will deliver testing on the spot, quickly, easily, accurately, and most importantly, often. □

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