the Pulse

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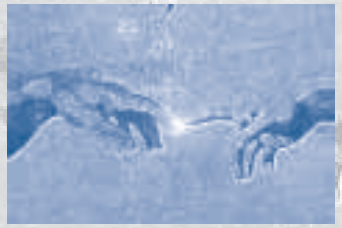

specialists in pulse oximetry

How safe is a safety margin?

When a piece of medical equipment is designed to monitor something as critical as blood oxygen levels, you should be willing to stake your life on its accuracy. But that may not always be a wise bet. The disturbing truth is that, in the case of pulse oximeters, Celtic ElectroMedical's testing facilities are exposing appalling inaccuracies in many brand-name and generic pulse oximeter probes.

For example, a recent test which CEM conducted using over 100 new probes revealed some disturbing statistics. Notably, ten probes from the same manufacturer gave a massive 8% difference in readings. Add that sort of error range in a probe to a patient whose blood oxygen levels are already dangerously low...

Monitoring blood oxygen should not be a lottery

truth economy

To make the figures look better, manufacturers are not above a little 'fudging', by quoting accuracy figures based on the monitor and probe combined. This has the effect of damping down the degree of inaccuracy, and presenting the equipment in a better light. It's bad enough to have errors like this present from new, but after the probe has been in use for several months things can get even worse, due to the deterioration that takes place with age.

the process can fall on its head

Fundamental to the whole system is the way blood oxygen is measured by two light-emitting diodes (LEDs) fitted within the probes. If they're not accurate, the entire monitoring process falls on its head. Although the quoted lifetime of an LED is in excess of 10,000 hours, the wavelength can drift over a much shorter period. Regular checking and re-calibration is advisable to keep the equipment within an acceptable error range.

less is more

Accuracy should always be a priority in probes, whether new or refurbished. To achieve this, CEM has designed and developed its own in-house technology to enable it to calibrate LEDs to less than 1% error range. By insisting on this sort of accuracy as a starting point, CEM's probes will still be within specification, even after many months of use.

Inside this issue:

Rapid Prototyping new probe
Generics ease the financial pain
Page 2
Blood Line
Lightman pocket probe tester
New calibration service
Kontron probe service
Page 3
Error margins: are you gambling patients' lives?
Page 4

photos - see inside p2 & p3

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Rapid Prototyping accelerates CEM's probe development - new

The world of pulse oximeter users is divided over the relative benefits of the parallel versus the fixed-hinge probe.

In fact, both types have their advantages. The parallel hinge allows a greater degree of articulation and better optical contact, but is generally considered to be less robust. But that was then. Now, CEM is bridging the divide with its design which features the best of both; a greater degree of articulation, and increased strength in the hinge.

The new probe will also have other improvements, such as non-allergenic, latex-free inserts. It is just the latest development to come from CEM, which has already set new standards with its research into calibrating light-emitting diodes.

keeping the lead

Research and development is an integral part of CEM's strategy. In a constantly moving market, it has to be. Customers' needs are always changing, and new developments and materials make a rolling R&D programme essential to stay ahead of the competition.

Speed is the essence of successful R&D. Every delay between drawing board and sales brochure runs the risk of reducing the sales impact when the product is finally unveiled. So CEM took its new probe design to the Design Engineering Research Centre to take advantage of its rapid prototyping facility. DERC's system scores over the conventional *'concept to working model, drawings to machining of prototype, to modification'* route, by using computer technology to cut out several 'middle men'.

skip the drawing board

DERC can scan a 3D object - the working model - and then, without any need for technical drawings, produce a 3D prototype by building up successive cross-

Generics ease the financial pain

NHS waiting lists are a touchy subject, no matter which side you stand. Patients are understandably fed-up at having to wait months, possibly years, for treatment. Hospital staff are equally frustrated at having beds empty through lack of trained nurses, or - even worse - through budgetary constraints which can mean cancellations for want of a comparatively inexpensive piece of equipment.

Some hospitals are now setting up 'Equipment Libraries', in an effort to ease the financial strangle-hold. The idea is as simple as it sounds. Equipment is kept in one location, and loaned out to the various wards as needed, after which it is, of course, returned promptly. The library is responsible for maintaining, and in some cases buying, its equipment.

Generics are, of course, a well-recognised lower cost source of medical equipment. But generics are often perceived as being not just lower in price, but also lower in quality - in many people's eyes, 'you get what you pay for'. Which is a pity, because there are excellent generics to be had. The secret is knowing what to look for and what questions to ask.

Take a look at the check-list below. It's not an exhaustive list of questions, but it will help you avoid some of the pitfalls.

BUYING GENERICS: 5 Questions You Must Ask:

1. ***does the manufacturer have an adequate quality system?***
   (ISO 9001 is the highest and should leave you in no doubt)
2. ***does the equipment carry the correct CE Marking?***
   (must be CE Class 11b. Class 11a is not sufficient)
3. ***does the manufacturer guarantee their accuracy to <= ±1% ?***
4. ***is the equipment made from medically approved materials?***
5. ***how good is the after-sales service?***
   (eg: do they give return-of-post service?)

vari-hinge gives parallel or fixed hinge operation

Concept to construct - one-step

Images courtesy of DERC 01222 506668

sections from the scan data.

The medium used is either a liquid resin - which sets when exposed to a UV laser - or adhesive backed paper. In either case, a 3D model is built up layer by layer, in a technique which needs no tooling, programming or machining. The time scale is massively reduced, modifications are easier to test, and the result is a product in better tune with the market, as well as a faster response to changing needs.

one-offs - no problem!

CEM has found that these techniques are also invaluable for its specialist probe department, which is often called upon to produce one-offs or small quantities at short notice for specialised applications.

Blood Line

While the world frets about being Year 2000 compliant, haemoglobin is clocking up around 800 million years, with no signs of crashing. It's a biological molecule which has been around for a long time, and can claim, without fear of contradiction, to have staying power.

In its early days, the only takers were low-profile life-forms like bacteria, and the early worms. But this was a molecule that would run and run. Haemoglobin has changed and evolved along with the life-forms, as fish filled the oceans, and then amphibians conquered dry land.

Mammals and birds may have gone off in different directions, but they were in one mind with regard to the usefulness of haemoglobin. And when the mighty Tyrannosaurus rex came along, tearing its less nippy dinosaur brethren limb from limb, what spilled out but good old haemoglobin, putting the 'red' into 'tooth and claw'.

The dinosaurs may have died out (or down-sized, according to recent thinking), but haemoglobin goes from strength to strength.

take a deep breath

And may go further still, with a bit of human meddling. Recent experiments have combined human and crocodile haemoglobin, to produce a form which imparts the croc's ability to stay underwater for prolonged periods.

How soon will it be before diving enthusiasts can ditch their air bottles, and go for a blood transfusion instead? Designer blood? It might throw up some odd readings on the pulse oximeter.

'Lightman', the new pocket probe tester

CEM is breaking new ground once again, this time with a pulse oximeter probe tester designed for ease and speed of use.

CEM has broken away from the conventional techniques of pulse oximeter testers, which work by mimicking the pulsing of blood, and cost around £3,000. The result is a much smaller, lower cost tester, with increased accuracy and reliability, since CEM's technology is not dependent on OEM's algorithms. Its mobility means that equipment can be tested without being taken off the ward.

The device will check for broken wires and integrity of the optical components, as well as for any wavelength drift. Its ease of use will mean that any drop in LED performance can be picked up immediately, rather than building up until the probe gets its once-a-year 'MoT'.

The tester is awaiting the outcome of patent application, and CEM is expecting to launch it later this year.

CEM's new calibration service

Celtic ElectroMedical is pleased to announce a new probe calibration service. Recommended as an annual 'MoT' for pulse oximeter probes, the service costs £23.50 inc. VAT. Carriage and insurance are free.

Kontron Probe Users safe with CEM...

Users of Kontron probes may have experienced difficulties in obtaining products or services from the company recently.

However, Kontron customers with faulty probes need not despair - Celtic ElectroMedical can either refurbish your existing Kontron probe, or supply a generic replacement.

Error margins: are you gambling patients' lives?

It's a sobering fact that many pulse oximeter manufacturers and refurbishers do not have the technology, or the in-house technical expertise, to test probe accuracy themselves, or to calibrate one of the most vital components - LEDs - used in pulse oximeter probes. In fact, tests which CEM conducted recently on OEM probes uncovered an 8% difference in readings - not exactly confidence-inspiring.

Accuracy standards are a form of insurance for medical device users, who may be placing not only their trust, but their patients' lives, on the word of a manufacturer.

Unfortunately, in the case of pulse oximeters, even though the accuracy of individual probes can be measured precisely, there is no way of checking absolute accuracy. One of the effects is that there is no accepted test protocol, with the consequence that the Medical Devices Agency (MDA) cannot recommend any formal tests.

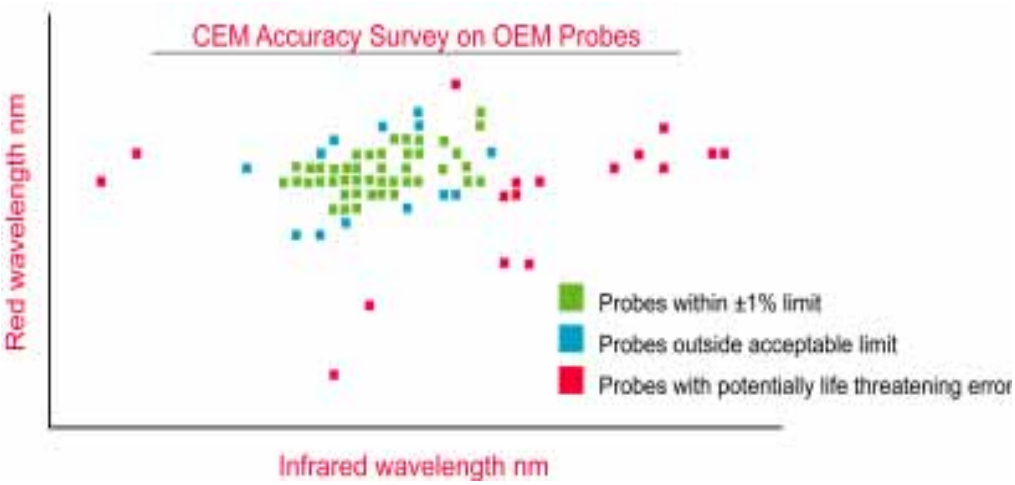
MDA doubts

In some instances, the MDA has refused to allow major refurbishing companies to replace probe LEDs because the companies don't have the facilities and technical expertise to calibrate them. Bearing in mind that the wavelengths chosen by individual manufacturers vary markedly - so much so that swapping LEDs between makes seriously affects probe accuracy - it doesn't exactly overwork the imagination to see that the whole calibration question is a minefield.

The situation is compounded by the fact that pulse oximeter probes are commonly used until they have obviously broken down. Routine checks on their accuracy are at best, rare, at worst non-existent.

no 'pre-packaged' technology

The fact is, calibration technology simply is not available 'off the shelf'. So CEM has generated and developed its own testing equipment, along with the expertise to apply it. At present, the company's research and development is concentrated on the calibration of pulse oximeter probes, and the application of optical transducers in medicine. The company is also addressing the lack of user-friendly probe testers (see p3.) as part of its commitment to raising standards of accuracy in pulse oximetry.



And the work involved has paid off. Not only does CEM hold a number of patents for optical sensors, but the company has a clutch of awards - two SMART, and one SPUR award - for research in optical sensors, and the innovative application of new techniques in pulse oximetry.

CEM guarantees ±1%

Ok, R&D is important, and maybe the patents and awards are too. But far more important for the end-user is that CEM has cracked the accuracy problem, and is able to guarantee its LEDs to less than 1% error range.

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