

Health Warning! - is CE marking being abused?

CE marking may be failing the very people it was intended to protect.

There are worrying signs that medical devices - and in particular, pulse oximeter probes - are not being made to the correct standard, and some of the worst culprits are foreign manufacturers.

It's all well and good having armies of bureaucrats churning out an endless stream of rules and regulations, laws, directives and what have you, but if the system becomes too complex or unwieldy to police, it's rather lost its point.

it's a minefield or a gift!

Any legislation is bound to have areas which are open to interpretation - sometimes interpreted as 'exploitation'. The Directive on CE marking of medical devices is no exception. Question: what's a list of rules littered with 'unless', 'except', and 'in which case' called? Answer: actually, there are two. It's a minefield for the legitimate operator, and it's also an absolute gift for those with shakier scruples. Complex rules are difficult to police and enforce, and create a window of opportunity for any manufacturer or importer who elects to act first and argue the toss later.

Dr Geoff Mathews, Director of Celtic ElectroMedical warns; "The best defence against being duped or baffled in this sort of area is to know exactly what medical device class the

the fact remains that many brands of pulse oximeter available in the UK are not properly marked



Dr Geoff Mathews & Sue Lawrence make final quality checks to a pulse oximeter component.

particular device should be in. In the case of pulse oximeters, it is unequivocally Class IIb."

He points out that the rules state - clearly, for once - that 'active devices intended for... monitoring... variations... that could result in immediate danger to the patient, for example variations in cardiac performance, respiration... are in Class IIb.'

Not a lot of room for argument, you might think. And you'd be right. Yet the fact remains that many brands of pulse oximeter available in the UK are not properly marked, and, more to the point, are not manufactured to the appropriate standard demanded under Class IIb. This is particularly the case for imported pulse oximeters, which

have the added disadvantage that in the event of problems, it can be difficult to get at the manufacturers for technical help or redress.

always check the small print

The best way to be certain that any medical equipment has been made to the relevant specification is to ask to see the manufacturer's CE certificate. If the category is not Class IIb, take your custom elsewhere.

If you need any further advice on CE marking, you can phone Dr Mathews on 01633 861 772. □

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CE marking - do your pulse oximeters conform to the correct standard?

Is CE marking of medical devices just another pan-European imposition of uniformity?

It may sound reasonable to have all medical devices comply with the same safety standards throughout the EC - after all, no-one wants to think that medical treatment received on the continent is below UK standards. But every Member State has its own regulatory system, laying down and monitoring minimum requirements for medical equipment, so surely that's enough. Why cover the same ground twice?

Well, look at it another way: why cover the same ground twice? Because that is effectively what medical device manufacturers were faced with if they wanted to sell their products in other Member States of the EC in pre-CE days. Which rather missed the point of a Single Market. But it's of interest to a wider audience than manufacturers. A once-and-for-all safety standard helps to keep product costs down - good news for purchasers and tax-payers alike - and it cuts the time it takes for a new device to get from drawing board to end-user. Another brownie point for CE marking.

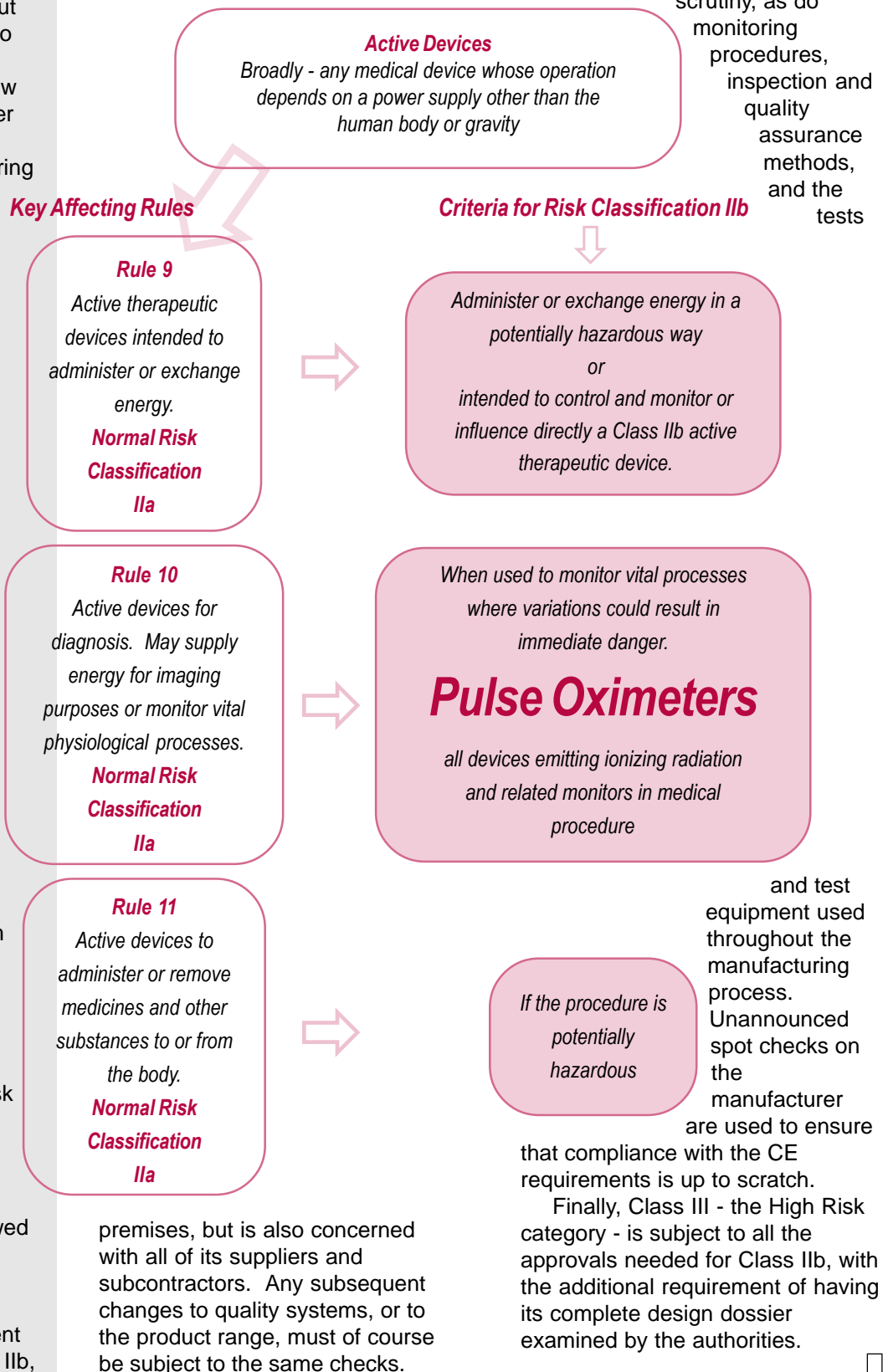
risk classification

So what can you deduce from the CE marking which pulse oximeters, and all medical equipment, should display? There are three categories of medical device risk classification. Class I is Low Risk - essentially, the sticking plaster end of medical equipment. Conformity with this category is self-assessed and self-declared, with the declaration being reviewed by the relevant authority.

Class II is Medium Risk, and divides into two sub-sections. Class IIa requires self-assessment plus outside assessment. Class IIb,

which covers pulse oximeters, involves a more stringent route of a full audit of all Quality Assurance systems by an outside assessment team. This audit covers not only an inspection of the manufacturer's

The manufacturer must also document all aspects of its quality systems, from quality programmes through to manuals and records. The organisational structure of the business also comes under scrutiny, as do monitoring procedures, inspection and quality assurance methods, and the tests



Cem's technology raises the stakes in probe accuracy

Pulse oximetry belongs to that group of medical tools and practises which are as much 'black art' as hard science.

The measurements are relative, rather than absolute; there is no ultimate calibration. Yet, more and more over the past ten years, pulse oximetry has become established as the most convenient non-invasive way to continuously monitor arterial oxygen saturation (SaO₂).

The pragmatic approach has a long pedigree in medicine - we may not know how aspirin works, but we know that it does. Blood pressure cannot be measured absolutely by non-invasive methods, yet it is monitored constantly.

don't accept inaccuracy

But pragmatism must never rule out accuracy, and the accuracy of an individual pulse oximeter probe can be defined and measured precisely.

The starting point is the monitor software. Pulse oximetry measures SaO₂ using two wavelengths of light. But monitor manufacturers have a surprisingly free-spirited approach, designing their software around two wavelengths of their choosing. That's no problem, but the LEDs used in the probe must be closely compatible with that choice.

too complacent?

It is usual for LEDs to be manufactured to a tolerance of ± 10 to 15 nm (nanometres). Many pulse oximeter manufacturers are content to use these LEDs with no further attempt to reduce the error range. Yet with the right technology and expertise - the sort that Celtic ElectroMedical has designed and developed - it is possible to calibrate LEDs to ± 2 nm. A much closer match with the monitor software

is then possible with, ultimately, a far more accurate measurement.

no room for error

Most of the deaths and major neurological damage which occur during anaesthesia and the perioperative period are the result of hypoxia, or oxygen starvation, brought about by a drop in arterial oxygen saturation.

Obviously, it is critical that the oxygen saturation of the patient's blood is not only monitored constantly, but is monitored accurately. If, in a situation such as this, a pulse oximeter probe with a high error range is being used on a patient who is already at the margin of acceptable SaO₂ levels, a critical situation could quickly develop.

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First catch your Tiger...

As a human life-saver pulse oximetry has earned a well-deserved reputation over the past ten years, being used not only by hospitals and medical practices, but also by the emergency services and paramedics.

Now, its use is spreading to veterinary medicine where it is proving its worth. After all, committing surgery on a tiger with all those teeth and claws around must focus the mind quite enough, without the added pressure of knowing that it's a valuable beast, possibly with aspirations to star in a series of TV commercials.

But the transfer of technology is not exactly problem free. Clipping on a pulse oximeter probe is no big problem with a human patient - toes, fingers, ear lobes, will all do. Animals, though, are frequently extremely hairy, or have deeply unsuitable digits. A pulse oximeter clip designed for a human finger

just won't work. So Celtic ElectroMedical addressed the problem, and has come up with a whole series of specially designed clips.

The payoff makes the effort worthwhile. Whether dealing with domestic pets, farm animals, race horses or exotic breeds, there's a lot at stake. Animal care is big business, and vets, like hospitals, cannot afford to lose patients.



Say AARRRRRRGH!

Tiger Images by courtesy of TM Manufacturing Ltd

On your wavelength - how pulse oximetry works

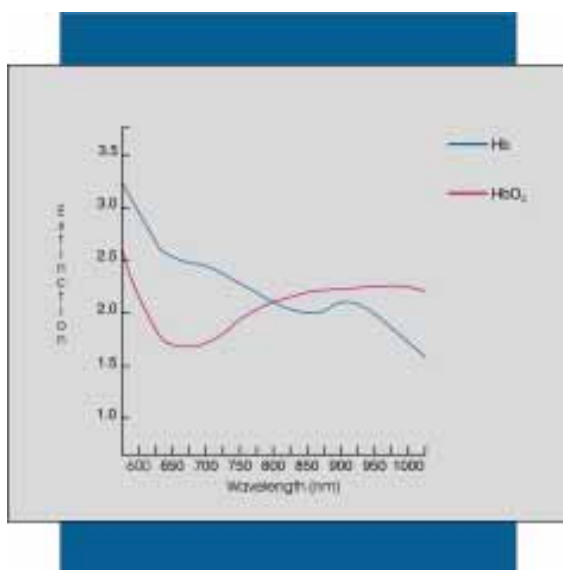
The first 'oximeter' was built and used in the early 1930s, by a physiologist, K Matthes, who needed a non-invasive method of monitoring blood oxygenation.

The device passed two wavelengths of light through the thin web of tissue between the thumb and forefinger.

Matthes was able to show that the ratio of light absorbed was related to the average blood oxygenation. However, absolute measurements were out of the question, since the absorption

properties of non-blood-containing tissue were an unknown.

The basic 'oximeter' was developed and improved over the next forty or so years, but it still only measured the average oxygenation of all the blood in the tissues - venous and capillary, as well as arterial.



Extinction (absorption) versus Wavelength Graph

that 'eureka' moment

It wasn't until 1975 that a major breakthrough came. The optical signal picked up by pulse oximeters had always had a pulsating component, matching the heartbeat. It was realised that the pulsating signal was from arterial blood alone, since it is only in the arteries that the pressure pulses produced by the heart can be observed. So by concentrating on this signal, arterial oxygenation could be measured. The 'pulse' part of the device had arrived.

Pulse oximeters today still use the same principles, in 90s form, as the original devices. Two light-emitting diodes (LEDs) pass light at around 660nm and 940nm through the tissue. The light which emerges - and the arterial, pulsating component accounts for only 0.5% - 1.5% of this - is then picked up by a photodetector, which measures the ratio of light absorbed at each wavelength. The percentage of oxygenated arterial haemoglobin is then calculated and displayed on a continuous, real-time basis,

giving valuable trend information, as well as current status.

belt & braces

Two wavelengths are used because the absorption of blood at any particular wavelength is dependent on the ratio of HbO₂ to Hb, as well as to the total volume of blood in the light path. Measuring at two wavelengths allows the effect of blood volume to be cancelled out, leaving a measurement which is related to blood oxygen saturation alone.

The particular wavelengths used in pulse oximetry must fulfil two basic requirements. Firstly, the light must be able to penetrate the tissues. Secondly, the absorption characteristics of the two wavelengths must be different for HbO₂ and Hb. Pulse oximetry uses the redness or blueness of arterial blood to

determine the oxygen content. To do this as accurately as possible, it is crucial that the exact wavelength of light emitted from the LEDs is known. The wavelength itself is not critical, within the limits of being able to penetrate the tissue, and giving different readings for HbO₂ and Hb.

patient history is essential

Because pulse oximetry works from the colour of arterial blood, it can, under certain circumstances, give a false reading. Carbon monoxide, for example, which binds firmly to haemoglobin, produces a similar bright red blood colour to oxygen, and consequently, gives an apparently high oxygen saturation reading. Blood loss or shock may lead to reduced blood-flow at the probe site, and so give rise to a 'false negative' reading.

Because of this type of problem, it is vital that the immediate history of the patient is taken into account when a pulse oximeter is being used.

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