3.1 An effective low cost pulse oximeter for the developing world

Any pulse oximeter should be judged by the degree to which a provider can monitor patients undergoing anaesthesia, interpret the data, and respond appropriately to the information provided in a given setting. Highly trained providers are more likely than poorly trained providers to have access to oximeters and adequate resources for their maintenance, even in low-resource settings. The cost of the machines, the logistics of their maintenance, their intuitive ease of use, and the education of anaesthesia providers are therefore highly relevant to clinical personnel providing anaesthesia without oximetry today. Thus, an oximeter which may be ideal in other respects is unlikely to be used on an ongoing basis unless:

1. Its life-time cost is affordable (including the costs of probes, maintenance and education).
2. The maintenance package and logistics are workable.
3. It is intuitive and easy to use.
4. Anaesthesia providers receive sufficient education to use the oximeter, interpret the information provided, and respond appropriately.

Experience from the GO Vietnam project illustrated a number of these points. Technician and physician providers successfully used a variety of donated oximeters from simple single-purpose units to complex and integrated ones. Yet, oximeters of all types and degrees of complexity were occasionally discarded because of perceived unreliability. Due to inadequate oximetry education, providers either misinterpreted correct indications of desaturation because they believed the device was unreliable or were not confident in adjusting the position of a probe to obtain a reliable signal. Failures in maintenance were also noted, with oximeters designated as “broken” simply because the battery was flat and the providers did not appreciate that several hours of charging is needed before any functionality would return. Oximeters were also consigned to the cupboard because the probe had broken and the providers had no mechanism for ordering a replacement due to lack of knowledge, protocol, or funding. The risk of this last point was highest for oximeters for which there was no local distribution agency, a common situation when using donated equipment. The ideal pulse oximeter may be defined more by the package with which it is provided than by its features.

A simple, portable and robust device providing only oxygen saturation and a pulse rate is likely to be more affordable, safer, and easier to use for providers with limited training. More complex monitoring which integrates other modalities such as capnography, non-invasive blood pressure, electrocardiogram and/or temperature is less feasible in these settings. Complexity may well imply the need for a more highly trained anaesthesia provider to interpret multiple signals simultaneously and relate this information to the clinical situation. Cost is less straightforward; saving money on an inexpensive oximeter would serve little purpose if hospitals proceeded to purchase the other monitors as stand alone devices which resulted in higher overall costs. Thus if an integrated multi-modal device was affordable, robust, easy to use, and came with an
excellent maintenance package and bundled educational material, it might be a good option.

Much of the surgery performed in low-resource settings is provided in circumstances of such severe financial constraints that capnography and automated blood pressure measurement are unlikely to be attainable. Therefore, the following comments will assume that the ideal low cost oximeter will be a stand alone device. Some allowance should be made, however, for imaginative solutions that go beyond the limits described below. Even if some integration of other modalities is offered, the following comments will still apply to the oximeter.

**Alarms**

Alarms are critical for any monitor. On a pulse oximeter they should alert providers to transgressions of safe limits of the oxygen saturation and to failures in obtaining a reliable signal. Alarms should be audible and supplemented with a visible change in the display (such as flashing). Alarms for one variable should be distinguishable from those of another and, if possible, should intuitively suggest the variable for which attention is required. The pulse tone should vary with the oxygen saturation (SpO2), with the pitch decreasing as the SpO2 falls. It should be possible to vary the volume of the pulse signal and the alarm signals, but not to mute the sound altogether. A switch to override or mute alarms might be considered, but in such cases these alarms should be suppressed for less than 1 minute.

Default limits are highly desirable. It is debateable whether these limits should be configurable or whether it should ever be possible to disable the alarm altogether. An argument in favor of these two options relates to the possibility of using the device in patients with chronic causes of abnormal signals (such as cyanotic congenital heart disease). However, experience in the GO project has shown that defaults may be set to generally inappropriate limits for some specific reason and then left on indefinitely. The ideal default limits are probably the lower end of adequate oxygen saturation (90%) and the lower and upper limits of pulse rate (e.g. 50 and 120 beats per minute). Alternative defaults should be provided for paediatric patients. These defaults should be configurable on a case-by-case basis, but the device should return to its defaults each time it is restarted.

**Oxygen saturation**

Arterial oxygen saturation (SpO2) should be measured between clinically relevant limits (e.g. between 70-100%) with reasonable accuracy (e.g. within 2% of true saturation). This accuracy needs to be retained at low blood pressures (e.g. systolic of 50 mmHg) as well as high. The signal should be maintained in the face of some patient movement which may occur during general or regional anaesthesia.

**Pulse display**
The device should have a plethysmograph display of the pulse (either waveform or bar graph). The unit should measure pulse rate between clinically appropriate limits (e.g. 20 to 200 beats per minute) to an accuracy of ± 3 beats per minute. The pulse rate should also be displayed numerically.

**Ease of use**

The oximeter should be intuitive and simple to use. Its interfaces should be language free to the extent possible, although it may be appropriate to have configurable language displays. High and low alarm limits should be pre-programmed and, should they be adjustable, must automatically reset to default limits each time the device is switched on and off.

**Sensors/probes**

These are possibly the most critical part of an oximeter and over the life of the unit may be its most expensive component. They should be as robust as possible. A range of sensors covering various sizes and ages of patient should be available, including adults, children, and neonates. Both finger probes and ear probes should be available, and all probes should be reusable. Ideally an alarm should indicate sensor misplacement.

**Display**

The display should have optional backlighting which can be switched off during battery operation to prolong battery life. The readout should be interpretable from 5 meters.

**Connectivity**

Oximeters should ideally have internal memory to record readings and a printer port to print a patient’s recorded parameters. It is also desirable to be able to connect this port to a computer.

**Power supply**

The device should operate at all commonly used power supplies (e.g. 240V, 50 Hz or 120V, 60Hz) or contain a converter for this purpose. It should have a rechargeable battery in case the power fails and for use when transferring patients. A fully charged battery should operate for at least 6 hours. A battery should take no more than 10 hours to charge, and charging should be possible while using the oximeter. A display of residual charge and low battery alarms are essential when operating on battery power. The typical life of the battery should be known and should not be less than two years under normal use; the battery should also be replaceable.

**Physical features**
The dimensions and weight of the device should be specified by the manufacturer. Portability and ease of handling is desirable. The unit should be robust and should ideally withstand mishandling, including several drops onto a concrete floor from the height of the machine’s normal working surface.

**Environmental issues and other specifications**

The machine should work reliably in a wide range of operating temperatures (e.g. 10°C to 40°C) and humidities (e.g. rH 15 to 95%). It should resist dust and mild exposure to liquids (e.g. water or blood). It should be easily cleaned with a disinfectant solution in case of bodily fluid contamination.

The oximeter should comply with relevant standards such as International Electrotechnical Commission (IEC) 60601-1 and International Standards Organization (ISO) 9919:2005. Where appropriate, it should carry a Conformity European (CE) mark.

**Warranties and maintenance**

The expected life of the oximeter and its probes should be specified and appropriate warranties provided. Provisions for maintenance should be described, including the contact details of the relevant suppliers, how much stock will be maintained of spare parts, whether the unit will come with spare parts to help with repair/replacement, whether support will be on a return to supplier basis, whether loan units will be provided during service, what turnaround times can be anticipated and what limitations will be placed on maintenance under warranty. An extended warranty or maintenance package would be highly desirable.

User and service manuals should be provided, electronically and by hard copy, in a variety of languages (which should be specified).

**Track record of company**

Information should be supplied on the year the model was introduced, the number that have been produced, and the size, global presence and track record of the company.