



## Request for Expressions of Interest

### **Global Pulse Oximetry**

It is estimated that 234 million major surgical procedures occur throughout the world each year. Currently, large disparities exist between the safety of surgical care provided in low income versus high income countries. The risk of undergoing anaesthesia in the developing world is particularly high and multiple studies have shown that the death rate from anaesthesia alone can be 100 to 1,000 times greater than in developed countries. One factor contributing to this tremendous disparity is the poor availability of pulse oximeters in resource limited settings.

In high income and some middle income countries, pulse oximetry is an explicit standard of care for anaesthetised patients, and compliance with this standard is virtually 100%. In the developing world, this is not the case. Current estimates indicate that, on average, 50% to 90% of operating rooms in developing countries are not equipped with pulse oximeters. Preliminary data suggest that there are at least 120,000 operating rooms in countries which have been defined as low income by the World Bank. Recognizing this need, WHO recently recommended pulse oximetry as an important component of any surgical procedure involving general anaesthesia. WHO is now focusing on promoting that pulse oximeters will be available in every operating room in the world, in particular in Low- and Middle-Income Countries.

WHO would like to work with manufacturers interested in designing and developing a pulse oximeter which is suitable for use in developing countries. Such a pulse oximeter must be accurate (within one percentage point of true oxygen saturation), robust, affordable and equipped with a visible pulse waveform and audible alarm with a variable tone. The power source should be electrical with a rechargeable battery available for backup. Probes should be reusable, resistant to damage, and appropriate for use on patients ranging from neonates to adults. The pulse oximeter should also be easily transferable from one operating room to another and to postoperative areas.

Companies interested in designing, developing and producing such a pulse oximeter with a view to making it widely available for distribution including the public sector of developing countries are invited to express this interest on or before 30 September 2008 by letter or email addressed as indicated below.

Only entities having demonstrated capacity to produce, and track record in the manufacture of quality pulse oximeters under current Good Manufacturing Practices (cGMP), will be considered. In addition, companies will need to be prepared to provide information on:

- the status, structure and main activities of the company;
- a copy of the company's annual accounts over the last 3 years;
- other records demonstrating the entity's sound financial standing;
- the availability of suitable facilities to conduct large scale manufacture;
- a brief description of the pulse oximeter already being manufactured by the company or a potential design considered suitable;
- an indication of the maximum number of units that could be produced annually;
- a list of those developing countries which currently use products from the company (at least three);
- the company's capability and willingness to commit adequate financial and other resources to the development and marketing of a pulse oximeter which is suitable for use in developing countries.

WHO reserves the right to freely decide on the selection of those companies who will be invited for further discussions, in WHO's sole discretion, and without having to provide any justification to entities who will not be so invited. During discussions with invited companies, WHO may provide more complete documentation and/or information regarding the possible specifications for a pulse oximeter which is suitable for use in developing countries. If the company so requests, information provided can be made subject to an appropriate confidentiality agreement.

WHO further reserves the right not to follow up on any expression of interest at all. WHO will advise all companies who have submitted an expression of interest whether or not they will be invited for further discussions. However, no explanation for the selection or rejection of any expression of interest will be provided.

Incomplete expressions of interest and expressions of interest submitted after the deadline will, in principle, be disregarded (unless WHO, in its sole discretion, decides otherwise in respect of any such incomplete or late application).

Based on the further discussions as described above, WHO may select certain companies for inclusion in a shortlist and invite the short-listed companies to

submit a more detailed proposal to WHO. WHO reserves the right to freely decide on the selection of those companies who will be included in the shortlist, in WHO's sole discretion, and without having to provide any justification to entities who will not be so selected.

WHO may request interested companies to submit complementary information. The submission of expressions of interest, any possible requests to submit complementary information and/or to submit a more detailed proposal, as well as any discussions ensuing there from, will be exploratory only, and do not mean that the WHO will actually proceed to collaborating with the company or companies in question.

Any and all costs and expenses incurred in relation to, or ensuing from, the submission of an expression of interest, including the possible complementary information and/or a more detailed proposal, if so requested by WHO will exclusively be borne by the company concerned. The submission of expressions of interest and the subsequent selection process as set forth in this document will not be subject to claims for financial compensation, other claims of any kind whatsoever, or appeal.

The submission of more detailed proposals and final selection procedure will be subject to similar terms and conditions as those outlined in this document.

As noted above, the deadline for the receipt of Expressions of Interest is 30 September 2008.

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