

# Pulse oximeter

Country of origin | Taiwan, China

## Health problem addressed

Each year, 31 million operations take place in low-resource countries without access to anaesthesia monitoring with pulse oximeters. The high cost and unsuitability of the oximeter models traditionally available have resulted in 70,000 operating rooms in these countries not having access to this technology, which is in standard use across high-income countries. In addition, 2.7 million children die each year in low-resource countries due to congestive diseases that result in hypoxemia. Early detection of hypoxemia is essential in reducing mortality and morbidity.

## Product description

A pulse oximeter is the most important monitoring tool in modern anaesthesia practice. It is a non-invasive device that checks the level of oxygen in a patient's bloodstream and sounds an alarm as soon as it detects the slightest unsafe change, thus avoiding hypoxia. This model is a robust hand-held device designed for use in low-resource settings where there is no access to constant electricity, biomedical engineering, consumables or replacement parts. It runs on rechargeable battery (as well as power), is available with reusable probes suitable for all ages, has a rotating screen for maximum clarity, as well as visual and audio alarms.



## Developer's claims of products benefits

Unlike other models, this has been developed specifically for use in low-resource settings. It is robust and reliable, and can be operated using either electricity (when available) or the rechargeable battery supplied with the oximeter. On a full charge, the battery will last for more than 14 hours. Unlike the devices traditionally available, this model is compatible with Nellcor probes and is very simple to use at low-cost. No calibration or servicing is required, making it ideal for settings where biomedical engineers and service personnel are non-existent.

## Suitability for low-resource settings

This model has been specifically designed for use in low-resource settings. It is robust and reliable, and can be operated using either mains electricity (when available) or the rechargeable battery supplied with the oximeter. On a full charge, the battery will last for more than 14 hours. Unlike the devices traditionally available, it is compatible with Nellcor probes and is very simple to use at low-cost. No training, calibration or servicing is required.

## Operating steps

This model offers a solution to the problem of how to effectively measure blood oxygen saturation and avoid hypoxia from anaesthesia and childhood pneumonia throughout the hospital in low-resource settings. Generic probes ranging from neonatal to adult provide accurate saturation levels, as well as heart rate monitoring (Quick Start Guide attached).

## Regulatory status

This model is CE marked (0434), meets FDA standards and conforms to IEC 60601-1 and ISO 9919, the international standard for pulse oximetry. In addition, the manufacturer must produce the units under conditions that meet the international standard ISO 13485:2003. The product and manufacturer have been independently examined by DNV GL and found to meet these standards.

## Future work and challenges

Reinforcing education will be one of the priorities for the future to make sure that the devices are used effectively. We are also looking at ways to strengthen the spare parts model to make sure that every hospital using a pulse oximeter will be able to procure the devices locally.

## Use and maintenance

**User:** Intended for use by physician, technician, midwife or nurse

**Training:** No additional training required

**Maintenance:** No scheduled maintenance required

## Environment of use

**Setting:** Can be used in rural and urban settings at any level of healthcare facility

**Energy requirements:** Requires a 100/220V power supply for recharging. Recharge time approximately 4 hours

## Product specifications

**Weight (kg):** 0.2

**Dimensions:** 123mm x 58.5mm x 28mm

**Consumables:** None

**Lifetime:** 2-5 years

**Shelf life:** >5 years

**Retail price (USD):** 250

**Price of consumables (USD):** 25 for probes, 10 for batteries

**Year of commercialization:** 2010

**Currently sold in:** Available for use in any country classified by the World Bank as low- or middle-income

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