

Risk Analysis Report

The sensors are accessories compatible with the Original Manufacturers product .
They are therefore subject to the same restraints and warnings as the originals.
They do not deviate from tried and tested methods and are not innovative.
Each sensor is typed and families of sensors are colour coded.
Many manufacturers use identical sensors with different connector configurations.
The sensor should only be connected to equipment designated for use on the enclosed leaflet.
Damage could result if the main instrument fails or the sensor is incorrectly fitted to the instrument or fitted to the wrong instrument
The sensors measure transmitted IR and visible light and should be used in conjunction with the manufactures advice as they can be affected by extraneous light, position, and movement.

Specific use

The sensor delivers IR and visible light to the patient and records the differential light absorbance of the tissue and the pulsating arterial component to produce a clinical value for oxygenation. The oximeter sensor will detect an approximated value of arterial oxygen saturation SpO2 and pulse rate by means of a continuous, non-invasive method. Th method and relative merits and accuracy have been the subject of several independent reports some have been included in the CE File for reference.
The intended environment of the device is for hospitals and clinics. The device labeling is self explanatory for installation and operation. Special attention is to be paid to individuals with perfusion problems in limbs and tissue.

It is intended that the product come in contact with patients

Disposable Oximeter sensors are applied to the patient with the use of tape. The tape is wrapped around the sensor and the measurement site (patient limb). Generally the sensor comes in contact with patient and healthcare provider only. The sensor site must be checked every eight (8) hours for tissue abnormalities. The sensor must be repositioned every 24 hours. The re-useable sensor is fastened to the patient by means of a spring loaded clip. The Flexible sensor can be attached using, an earclip, adhesive tape, velco straps

Materials and components used.

Oximeter sensor consists of the following components:

LED's (Light Emitting Diodes) Red & IR

Photodetector (Silicon Photodiode)

Adhesive Tape (Non-allergenic)

Medical Grade PVC, white cable and connector (5 wire conductor cable, PVC insulation)

Solder Paste (Tin, Lead, Silver component)

Silicon /Adhesive (Liquid Silicone rubber)

ABS clip

No substances are supplied or removed from the patient

The product is not Sterile when supplied.

Sterilization is not recommended. Instructions are given for disinfecting. The sensors are supplied Clean but not Sterile. If used on different patients there is a risk of cross infection if well established basic medical techniques are not followed correctly.

The product is not intended to change the patient environment?

Measuring function

The sensor does not measure but is an accessory to a measuring instrument. Each sensor group is matched accurately to the original sensor it is replacing by using matched components.

Product explanations

The user is given general guidelines in the information leaflet and is referred to the original manufacturers specific guidance notes. Compatibility labels (Flag tags) are attached to each sensor cable.

The product is not intended for the control of or interaction with, other products or medication?

The Product produces visible and infrared light

Light is absorbed by the patients tissue. The level of light is controlled by the monitor and depends on the type and pigmentation of the tissue.

Heat from the sensor should only be a problem if the sensor is left in situ beyond the manufacturers guidance information, or when it is connected to non-compatible Oximeter monitor. Current levels to sensor may be of higher or lower levels than required if connected to non-compatible Oximeter Monitors. The sensors are colour coded to reduce this possibility and are flagged.

The product can be sensitive to outside influences

Product literature specifies the use of sensor within the areas of ambient light which may influence the photodetectors absorption of infrared light and give false data to the Oximeter monitor. The literature recommends that the original manufacturers methods be followed.

Product does not require any consumables or accessories

Flexible probes will require wrap rounds and/or earclips.

No routine servicing or calibration is necessary

Product does not contain software

Some versions of the product have a limited shelf-life

This is clearly stated on the labels.

Products have serial numbers and lot numbers

Product has no known long term effects