**From:** nss iric <nss.iric@nhs.scot>
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**IRIC** **Incident Reporting & Investigation Centre**

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**Reference:** IM/2021/004
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This information message is sent to draw the attention of Equipment Co-ordinators to web-based safety information which may be relevant to the safety of equipment and facilities in local authorities and health boards.

The Medicines and Healthcare products Regulatory Agency (MHRA) has published web-based medical device guidance in partnership with devolved administrations which applies across the UK. Within Scotland, the guidance applies to NHS Boards, local authorities and any contractors providing publicly funded health and social care services.

The guidance is web-based and there are no print or PDF editions. Distribution is therefore by circulation of the URL and a PDF version of the web page for those unable to access it.

The URL for the above guidance is: https://www.gov.uk/guidance/the-use-and-regulation-of-pulse-oximeters-information-for-healthcare-professionals?utm_medium=email&utm_campaign=govuk-notifications&utm_source=f9cd0b26-bf49-4357-a2be-0ff3ebd8b48e&utm_content=daily

As the Equipment Co-ordinator for your organisation, we recommend that you assess whether or not to forward this information to managers and staff within your area of responsibility who might benefit from being aware of it.

For enquiries, if you received this message directly from IRIC, email us direct at nss.iric@nhs.scot or phone 0131 275 7575. Alternatively, if you have received this message from someone in your own organisation, please contact them in the first instance so they can collate enquiries and liaise with IRIC as required.

**Incident Reporting & Investigation Centre (IRIC)**
Health Facilities Scotland
**NHS National Services Scotland**

**Contact us:**
IRIC Email nss.iric@nhs.scot
Helpline 0131 275 7575
Web https://www.nss.nhs.scot/browse/health-facilities/incidents-and-alerts

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Guidance

# The use and regulation of pulse oximeters (information for healthcare professionals)

Information for healthcare professionals on how pulse oximeters are regulated, home use and issues to look out for when using the devices

From:
Medicines and Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)
Published:
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## Contents



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## Pulse oximeters and why they are used

Pulse oximetry is a well-established technique used in healthcare to take a non-invasive measurement of the blood-oxygen level of a patient. This measurement can help with the early detection of signs of deterioration. The value produced is just one part of the range of measurements that clinicians use to decide on the most appropriate treatment. The changes in the oxygen saturation value may be more important than just the number reported.

## Factors which can affect the accuracy of pulse oximeters

Typically, these devices work by shining a light into the skin and measuring how this is absorbed by the blood to estimate how much oxygen is present. Because of this, it is possible that patients with lighter skin may have small differences in the result reported when compared to those with darker skin. This is just one factor that can alter the result produced.

Other well-known factors include:

- low perfusion
- movement
- nail polish
- henna dye
- tattoos
- probe mispositioning
- ambient lighting hitting the sensor

The relative change in a patient's reading may be of greater significance to clinical management than the absolute value. The MHRA is not aware of any incidents where skin colour has had an adverse effect on the use of pulse oximeters when providing effective clinical care.

## Home use of pulse oximeters

The MHRA does not recommend that members of the public use oximeters at home unless they have been advised to do so by a qualified clinician, have been shown how to take an accurate measurement, and they are providing results for clinical review. General information on medical devices for users and patients is available from the MHRA (https://www.gov.uk/guidance/medical-devices-information-for-users-and-patients).

The NHS COVID Oximetry @home (https://www.england.nhs.uk/coronavirus/publication/novel-coronavirus-covid-19-standard-operating-procedure-covid-oximetry-home/) and COVID Virtual Wards (https://www.england.nhs.uk/coronavirus/publication/covid-virtual-ward/) services are aimed at high-risk patients with coronavirus (COVID-19). They are supported by teams of healthcare professionals who provide the necessary instructions on good practice in taking measurements and advice on passing results for clinical interpretation.

## Regulation of pulse oximeters

All medical devices on the UK market must meet stringent requirements for safety and performance under the UK Medical Device Regulations 2002 (SI 2002 No 618, as amended) (https://www.legislation.gov.uk/uksi/2002/618/contents/made). Pulse oximeters intended for clinical use are regulated as medical devices and should display a valid CE, CE UKNI or UKCA mark.

The MHRA does not approve medical devices directly. In the case of pulse oximeters and other higher risk medical devices, the manufacturer shows their compliance with the regulations with third-party approval by a designated approved body (https://www.gov.uk/government/publications/approved-bodies-for-medical-devices/approved-bodies-for-medical-devices). Although not mandatory, market approval is expected to include compliance with the relevant technical product standard BS EN ISO 80601-2-61:2019 (Medical Electrical Equipment. Particular requirements for basic safety and performance of pulse oximeter equipment).

See information on how medical devices are regulated (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk).

Manufacturers are required to report serious incidents involving their medical devices. Investigation of these reported incidents is an important aspect of the MHRA's medical device safety monitoring system.

## Advice for clinicians interpreting pulse oximetry readings in Sp02 sensors and standalone fingertip devices

The reading may vary between different devices and patients. To meet the accuracy requirements of the applicable technical standard, the root-mean-square difference between the oximeter and the true value must be below 4% across the range of 70-100% SpO2. Below 70% SpO2 the accuracy falls. Although pulse oximetry will not give a precise value of oxygen saturation, it is useful for following trends. It does not measure carbon dioxide (CO2) levels.

To get the best performance and precision, consider the following points that affect the calculation of SpO2.

**Use an appropriate device and ensure it fits securely.**

Too tight causes constriction; too loose lets light in. Do not pull or stretch the cable and beware of motion artefacts when transporting patients.

**Nail coatings**

Where possible remove nail polish, check for false nails or consider an alternative site.

**Poor peripheral blood circulation**

This may reduce the arterial pulsation, making it difficult to pick up a signal. Situations can include hypovolaemia; cold; cardiac failure; arrhythmias; peripheral vascular disease; and the position of a non-invasive blood pressure cuff.

**Darker skin pigmentation**

This may cause an overestimate of SpO2 saturations, so consider relative changes in an individual patient’s readings as well as the numerical result.

**Dyes, henna or tattoo ink**

The use of some dyes, such as methylene blue (as used in surgery), henna or tattoo ink may affect the absorption of light and the results produced.

Other factors

- clean and maintain devices according to the manufacturer’s recommendations
- replace damaged or faulty devices
- in an MRI environment only use probes designated MR CONDITIONAL or MR SAFE

## Reporting problems

We encourage healthcare professionals to report any suspected or actual adverse incidents involving these devices, as well as shortcomings with device performance or instructions for use. Report through your healthcare institution’s local incident reporting system and/or your national incident reporting authority as appropriate: England (https://yellowcard.mhra.gov.uk/), Scotland (https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/), Northern Ireland (https://www.health-ni.gov.uk/articles/reporting-adverse-incident), Wales (https://yellowcard.mhra.gov.uk/).

Members of the public in any part of the UK can report through the Yellow Card scheme (https://yellowcard.mhra.gov.uk/).

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- Medical devices regulation and safety (https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety)