

# Become a first mover in racially equitable pulse oximetry

Innovate for good by supporting the development of EarMetrics®-Oximetry, licensable in-ear technology that we believe will set the new standard of reliable, racially inclusive oxygen monitoring.

## Pulse oximetry challenges – and a proposed solution

### A market in need of **action**

The pulse oximetry market has faced increased scrutiny since 2020, when the limitations of finger-clip oximetry methods for people with darker skin pigmentation became more widely known.

Although these limitations have been [documented since 1990](#), [increased covid-19 mortality rates](#) for people from Black and Asian ethnic groups ignited a widespread conversation.

The subsequent call to arms has been significant, and global. In 2021, the US Food and Drug Administration (FDA) issued a [safety communication](#) recognising the limitations of pulse oximeters. In the UK, the [Equity in Medical Devices: Independent Review 2023](#) called upon the Medicines and Healthcare products Regulatory Agency (MHRA) to strengthen the approval standards for new pulse oximeters.

### The next generation of **pulse oximetry**

Finger-clip oximetry has inherent flaws. The time to act is now – and we believe we are developing the solution.

EarMetrics®-Oximetry is an in-ear pulse oximeter that could provide a racially inclusive alternative to current methods.

Using reflective oximetry, it allows you to detect oxygen levels in the blood.

Unlike finger-clip oximetry, EarMetrics®-Oximetry takes readings from the inner ear canal. As the inner ear canal is unpigmented, it provides a measurement site that is likely to be less vulnerable to racial bias due to skin colour.



# Why EarMetrics®-Oximetry?

## Record more **robust health data**

Alongside mitigating racial bias, taking oxygen readings from the inner ear canal could also ensure greater data accuracy. It's a core site, closer to the heart and brain than finger-, arm-, and wrist-worn devices, and is therefore better protected against external movement, temperature, and poor blood circulation.



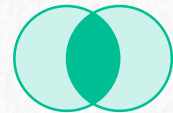
### Core measurement

Recorded close to the brain and heart.



### Unpigmented site

Where everyone's skin is the same colour.



### Easily integrated hardware

For use in medical and lifestyle devices.



### Robust to movement

Protected against movement of the body.



### Convenient

User-friendly for long-term wear.

## Recognised by a national **NHS pilot**

EarMetrics®-Oximetry was one of eight products to be accepted onto the MHRA's Innovative Devices Access Pathway (IDAP) pilot programme, which will accelerate how life-saving medical devices are developed and rolled out to patients of the UK's National Health Service (NHS).

[Read more](#)

## Funded by **research experts**

**NIHR** | National Institute for Health and Care Research



**UK Research and Innovation**



# An **accelerated** path to differentiation

We believe that **EarMetrics®-Oximetry** presents an opportunity for pulse oximetry manufacturers to overcome some of the major issues facing them today, while providing an accelerated path to differentiation.

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## **Enhance** your product

EarMetrics®-Oximetry is miniaturised hardware that can be integrated into in-ear devices during manufacture. It could enable greater data accuracy and racial inclusivity via pulse oximeters, as well as digital blood pressure monitors, in-ear thermometers, hearing aids, and other in-ear devices.

The solution is currently in development as part of a multi-biometrics in-ear monitor: EarMetrics®-Healthcare. This aims to record interoperable, medical-grade health data – from heart function measures to blood pressure indicators – for a variety of clinical use cases.

Discover EarMetrics®

## **Protect** your reputation

[2023 saw a landmark lawsuit filed against leading pulse oximeter manufacturers and sellers](#), based on evidence that they overestimate the blood oxygen levels of people with darker skin pigmentation. With the threat of litigation, it's clear that the decision to address racial bias in your medical devices shouldn't just be ethically driven, but commercially driven too.

By helping to develop and implement EarMetrics®-Oximetry into clinical practice, you could become a first mover in the racially equitable pulse oximetry space, while protecting yourself against the financial and reputational damage of legal action.

## **Future-proof** your market position

The pulse oximetry market is growing, with [an expected compound annual growth rate \(CAGR\) of 6.6% between 2024 and 2030](#).

However, the path to approval for pulse oximetry devices is likely to become stricter, with both the [FDA](#) and [MHRA](#) currently reviewing their regulatory frameworks.

To future-proof your devices, and cement your position in the pulse oximetry market, it's going to be essential to address race-related inaccuracies. You could start by helping to prove EarMetrics®-Oximetry as a racially equitable solution, and ultimately accelerate its approval under new and improved guidance.





## A way forward for **racially equitable oximetry**

Together, let's address racial inequality in pulse oximetry to save lives, protect your reputation, and future-proof your medical devices against regulatory change.

**Find out how** you can get involved with **EarMetrics®-Oximetry today.**

### Contact us

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