

Know the difference between pulse oximeters

Pulse oximeters may be prescribed by a doctor or purchased over the counter. The FDA recommends knowing the difference so that patients use pulse oximeters safely. Prescription oximeters are reviewed by the FDA; available by prescription only; have undergone clinical testing; and are used for medical purposes. Over-the-counter oximeters are available without a prescription (i.e. purchased in stores, online, or via mobile app); and used for general wellness or fitness activities. Both types of oximeters can be used at home.

Who uses pulse oximeters?

The U.S. Food and Drug Administration (FDA) currently states that there are two categories of pulse oximeters: those for prescription use and those that can be purchased over the counter.

- Prescription oximeters have been vetted by the FDA and are available only with a prescription. These devices have undergone clinical testing to confirm their accuracy and are typically used in clinical settings, although they can be prescribed for at-home use.
- Over-the-counter oximeters are sold directly to consumers and may use apps to estimate oxygen saturation. These products do not undergo FDA review and should not be used for medical purposes.

Doctors, nurses, and paramedics use prescription pulse oximeter readings as one factor to help decide how to best care for patients.

More people are buying non-FDA-cleared, over-the-counter oximeters intended for fitness and general wellness to track their oxygen saturation at home. However, these versions of the device are not approved or cleared for medical purposes or decisions.

What factors can affect pulse oximeter readings?

Any of these factors can affect pulse oximeter readings:

- Fingernail polish or artificial nails
- Skin temperature: A skin temperature of about 33°C is recommended
- Altitude
- Intravenous dyes: These are used to color blood serum for surgical or diagnostic purposes and can affect light absorption
- Poor circulation
- Skin thickness
- Tobacco use
- Skin pigmentation

REF: <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>; Pulse Oximeter Accuracy and Limitations: FDA Safety Communication; UPDATE: November 7, 2022

* The data is subject to change without notice.

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