

Opioid Halo™

Opioid Overdose Prevention & Alert System*



SELECTED FOR THE FDA OPIOID
INNOVATION CHALLENGE

FIRST AND ONLY FDA-AUTHORIZED DEVICE TO
ALERT YOU IN THE EVENT OF AN OPIOID OVERDOSE

GRANTED "BREAKTHROUGH"
DEVICE STATUS

Help Patients Taking Opioids Create a Halo of Protection

You've educated your patients about the potential side effects of opioids, including opioid-induced respiratory depression. Now you can provide them with an extra layer of protection in case of an accidental opioid overdose emergency.

Opioid Halo is an opioid overdose prevention and alert system designed to help protect patients at risk.†

- Provides real-time monitoring to identify the risk of opioid-induced respiratory depression
- Sends escalating alerts to the patient and their designated emergency contacts, followed by an automated wellness call that may lead to EMS being dispatched
- Powered by clinically proven Masimo SET®—the same advanced pulse oximetry technology that's trusted by 9 of the top 10 U.S. hospitals¹
- No prescription required

All Opioids Carry Risks

The FDA states:

Like all medicines, opioid pain medicines can have side effects, even when used as prescribed. A person's health, disease states, genetic factors, and other medicines they are taking can also play a role in the likelihood of side effects.²

The CDC, NIH, and WHO report:

In 2021, over 80,000 lives were lost to opioid overdose in the U.S.³ In 2020, nearly 24% of all opioid-related deaths involved a prescription opioid.⁴ Certain factors put patients at higher risk:⁵⁻⁸

- ✓ Being opioid naïve
- ✓ Respiratory condition(s) such as sleep apnea
- ✓ Combining opioids with other sedating medications such as benzodiazepines and/or alcohol
- ✓ Taking medical high prescribed doses (>50 MME)
- ✓ Medical conditions such as HIV, liver or lung diseases, or mental health conditions
- ✓ Opioid use disorder or a history of addiction
- ✓ Taking opioids for nonmedical purposes
- ✓ Taking opioids again after stopping for an extended period of time
- ✓ Older age (65+)

Over half of all opioid-related deaths occur when the person is alone, but even if they are not, it may be hard for a loved one to recognize the signs before it's too late.⁹

Opioid Halo

Opioid Overdose Prevention & Alert System



Continuous monitoring and alerts can raise awareness when help may be needed.

Escalating Alerts Help Keep Your Patients Safe

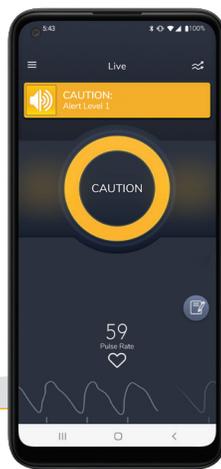
Uses an advanced pattern recognition algorithm that has been developed and tested using data from naïve, chronic, hospital, and illicit users **to detect and quantify the risk of overdose** by identifying physiological patterns unique to opioid-induced respiratory depression.

Monitoring



System is active

Alert 1: Caution



When physiological marker data shows high risk for overdose, alerts appear visually on the patient's mobile device and sound audibly at the Home Medical Hub, to facilitate self recovery.

Alert 2: Warning



As the risk level rises, the system alerts them again and sends automatic texts to designated emergency contacts.[‡]

Alert 3: Emergency

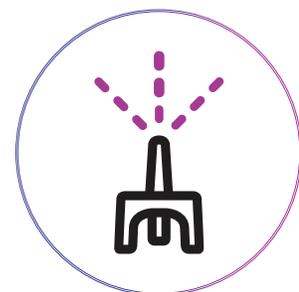


If the risk level continues to worsen, the system triggers an automated wellness call that may lead to EMS being dispatched.

Opioid Halo Alerts. Naloxone Reverses.

Complement naloxone with monitoring

Naloxone is an effective tool for overdose reversal. However, it cannot be self-administered during an emergency.⁹ Early detection of the risk of overdose with alerts can recognize when help may be needed, including naloxone administration—adding another layer of protection for patients at risk.

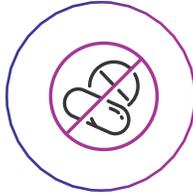


Who Can Benefit from Opioid Halo?

Accidental opioid overdose can happen to anyone taking opioids. No matter what the situation, we can help them stay alert.



Patients taking prescription opioids



Non-medical use



Patients already using naloxone

Powered By Clinically Proven Pulse Oximetry

Masimo SET®

- Trusted by physicians for over 25 years and used to monitor over 200 million patients a year around the world¹¹
- Features multiple parallel signal processing engines for accurate and reliable readings
- Demonstrated significantly fewer false alarms and more true alarms than conventional pulse oximetry technologies in hospital settings¹²
- Accurate across all skin pigmentations¹³

Based on a Proven Hospital Approach

A 10-year study at Dartmouth-Hitchcock Medical Center found zero opioid-related preventable deaths or brain damage in hospitalized patients who were continuously monitored with Masimo SET® and a notification system.¹⁴

Opioid Halo leverages the same pulse oximetry technology and a similar notification system to help protect your patients at home.

Recommend Opioid Halo to any patient taking opioids.

Help Safeguard Your Patients at Home.

Visit www.opioidhalo.com to learn more.



¹ Masimo SET® is the primary pulse oximetry at 9 of 10 top U.S. hospitals as ranked in the 2022-23 U.S. News and World Report Best Hospitals Honor Roll, available at: <https://health.usnews.com/health-care/best-hospitals/articles/best-hospitals-honor-roll-and-overview>. ² FDA. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use>. ³ National Center for Health Statistics. CDC. https://www.cdc.gov/nchs/presroom/nchs_press_releases/2021/20211117.htm. ⁴ National Institute on Drug Abuse. Overdose Death Rates. NIH. <https://nida.nih.gov/drug-topics/trends-statistics/overdose-death-rates>. ⁵ CDC. <https://www.cdc.gov/opioids/providers/prescribing/pdf/identifying-opioid-risk-factors.pdf>. ⁶ Opioid Overdose. World Health Organization, 28 Aug. 2020, www.who.int/news-room/fact-sheets/detail/opioid-overdose. ⁷ Gupta K et al. *Curr Opin Anaesthesiol*. 2018;31(1):110-119. ⁸ Dunn KM et al. *Annals of internal medicine*. 2019;152(2):85-92. ⁹ Public Health Ontario. *Opioid Mortality Surveillance Report*. <https://www.publichealthontario.ca/-/media/documents/opioid-mortality-surveillance-report.pdf?la=en>. ¹⁰ Lifesaving Naloxone. CDC. <https://www.cdc.gov/stopoverdose/naloxone/index.html>. ¹¹ Estimate: Masimo data on file. ¹² Shah et al. *J Clin Anesth*. 2012;24(5):385-91. ¹³ Barker SJ, Wilson WC: Accuracy of Masimo SET® Pulse Oximetry in Black and White Volunteer Subjects: A Retrospective Review—in press—Abstract accepted by *Society of Technology in Anesthesiology*—Available online Jan 15, 2022. ¹⁴ McGrath S et al. *J Patient Saf*. 2020 14 Mar. DOI: 10.1097/PTS.0000000000000696.

^{*} It is strongly recommended that naloxone be used with supervision. Be sure that anyone providing supervision is aware of the signs of opioid overdose and understands how to help.

[†] Opioid Halo continuously monitors certain physiological parameters that are indicative of opioid-induced respiratory depression—a sign of opioid overdose—in order to alert users and their emergency contacts so that action can be taken to avoid adverse consequences of an overdose.

[‡] Emergency contacts must agree to receive alerts.

iOS is a trademark or registered trademark of Cisco in the U.S. and other countries and is used under license. ANDROID™ is a registered trademark of Google Inc. Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG Inc.