








FDA-CLEARED PULSE OXIMETERS

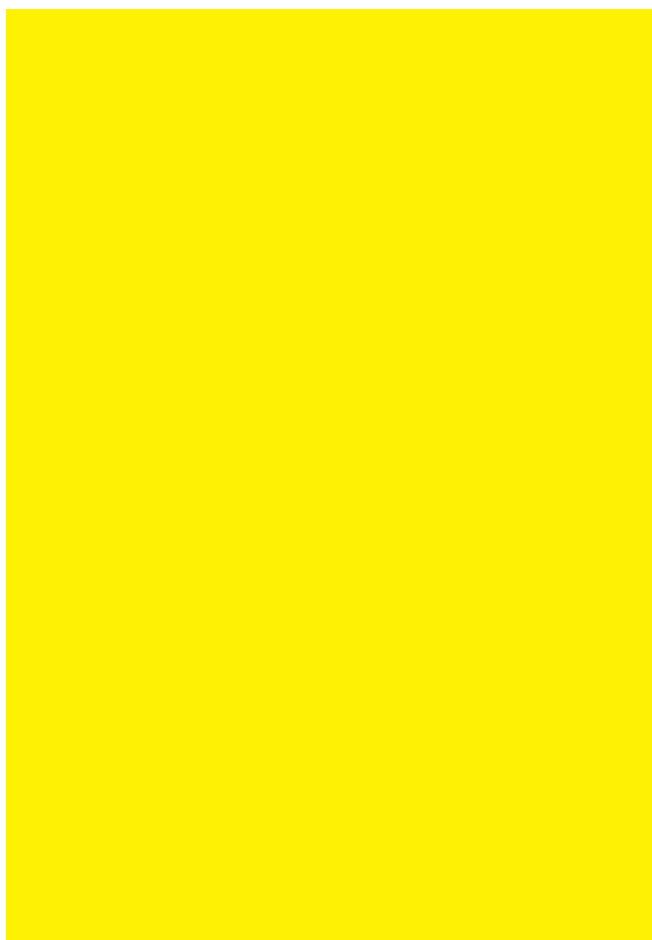
Company	BodiMetrics	Empatica	Nonin Medical, Inc	Nonin Medical, Inc	OxiWear
					
Pulse Ox	Circul+	EmbracePlus	Nonin Health Platform	Nonin WristOx2 Model 3150	OxiWear
Website	circul.health	empatica.com/platform/home	nonin.com/products/nonin-health-platform	nonin.com/products/wristox2-model-3150-with-ble	oxiwear.com
Description	No pigmentation issue. Continuous blood oxygen and continuous heart rate at 1/100 hz.	EmbracePlus leverages advanced sensors and validated algorithms to continuously monitor SpO ₂ , pulse rate, respiration rate, and a range of digital biomarkers, delivering reliable measurements across diverse skin tones and physiological conditions.	Nonin Health, a cloud-based, software platform, was designed to simplify and speed up the oximetry testing process, leveraging the WristOx2 Model 3150. With fewer manual steps, clinicians can receive results as soon as the patient completes the test, manage device inventory, and spend less time on paperwork and non-reimbursed services.	The Nonin WristOx2 Model 3150 delivers accurate oxygen saturation and pulse rate readings including low perfusion and motion.* It is compatible with a wide range of Nonin PureLight sensors and applications include overnight sleep tests, sleep apnea treatment monitoring, oxygen qualification, and pulmonary rehabilitation conducted at home and in the hospital. *Nonin data on file	Ear-wearable oximeter that provides real-time continuous data to an app as well as recording the data internally as a standalone device and provides haptic and text message alerts when oxygen levels are low.
FDA-Cleared Indications	spot check and/or continuous data collection of oxygen saturation hemoglobin and pulse rate	continuous data collection, supporting retrospective review of pulse rate, blood oxygen saturation, respiratory rate, peripheral skin temperature, electrodermal activity, activity associated with movement during sleep	measuring, displaying, and storing SpO ₂ and pulse rate; intended for spot-checking and/or data collection and recording, during both no motion and motion conditions, and for patients who are well or poorly perfused	measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (% SpO ₂) and pulse rate; intended for spot-checking and/or data collection and recording, during both no motion and motion conditions, and for patients who are well or poorly perfused	spot checking and/or continuous data collection of adult (22+) and adolescent (12-21) patients who are well or poorly perfused, during motion and non-motion conditions
Form Factor	ring	wrist-worn	wrist-worn	wrist-worn	ear-worn
SpO₂ Accuracy within 70% – 100% range (Arms)	±2.5	±2.6	±2	±2	±3.5
Pulse Rate Accuracy within 30 – 240 bpm (Arms)	±3	±3	±3	±3	±3
Patient Range	Adult	Adult	Pediatric, Adult	Pediatric, Adult	Pediatric, Adult
Battery Life (hours)	14	24-168, depending on the configuration (continuous vs intermittent)	53 (alkaline); 36 (rechargeable)	53 (alkaline); 36 (rechargeable)	12
Health Equity Study	Meira e Cruz, M, Zhou C, Kryger MH, Wang H. Validation of a smart ring oximeter in individuals with dark skin pigment. <i>Mayo Clinic Pro: Dig Health</i> . 2023. 1;3:357-65.	Gerboni G, Comunale G, Chen W, et al. Prospective clinical validation of the Empatica EmbracePlus wristband as a reflective pulse oximeter. <i>Front Digit Health</i> . 2023 Dec 4;5:1258915.	N/A	N/A	Performed as part of FDA-clearance testing (510(k) K233827)


Information for this guide based on data submitted by pulse oximeter marketers. Sleep Review strives for accuracy in all data but cannot be held responsible for claims made by marketers. All pulse ox marketers get one listing at no charge. Advertisers are offered multiple listings. All FDA-cleared pulse oximeters may not be included. Email editor@sleepreviewmag.com to be considered for the next update.



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Company	Patient Safety, Inc	Viatom
		
Pulse Ox	SleepSat BLE	O2RingS (P02B)
Website	patientsafetyinc.com	viatomtech.com/po2b-o2rings
Description	Short averaging time and 0.1% high-resolution provide better patterns of sleep-disordered breathing endotypes. Also included: motion, perfusion, and PPG.	An improved O2RingS for overnight continuous oxygen tracking with the upgraded frequency domain algorithm and upgraded PPG storage. Continuous recording at 1s intervals provides detailed data for sleep analysis reports.
FDA-Cleared Indications	measure, display, store, and transfer functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, adolescent, and child; intended for spot-checking and can be reused; not intended for continuous monitoring, use during motion, or use with low perfusion	measuring, displaying, storing, and transmitting functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate for adult patients; intended for spot-check and/or continuous data collection, and not continuous monitoring
Form Factor	wrist-worn	ring
SpO₂ Accuracy within 70% – 100% range (Arms)	±3	±3
Pulse Rate Accuracy within 30 – 240 bpm (Arms)	±2	±2
Patient Range	Pediatric, Adult	Adult
Battery Life (hours)	20	24
Health Equity Study	Performed as part of FDA-clearance testing (510(k) K230587).	Validated reading accuracy across Caucasian, Asian, and African skin tones using the Fitzpatrick Scale in a study by Shenzhen University General Hospital.



Company	VirtuOx
	
Pulse Ox	Virtusleep
Website	virtuox.net
Description	The VirtuOx Virtusleep accelerates the identification of sleep-disordered breathing events with AI-driven analysis of photoplethysmogram signals. It can be used for overnight oximetry and can transition to a home sleep test, if medically indicated, with stream or store modes for data transmission.
FDA-Cleared Indications	spot-check and/or continuous data collection of oxygen saturation of arterial hemoglobin and pulse rate
Form Factor	wrist-worn
SpO₂ Accuracy within 70% – 100% range (Arms)	±2
Pulse Rate Accuracy within 30 – 240 bpm (Arms)	±3
Patient Range	Pediatric, Adult
Battery Life (hours)	24
Health Equity Study	Performed as part of FDA-clearance testing (510(k) K243049). ●