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WEARABLE SENSOR TECHNOLOGY AND ARTIFICIAL INTELLIGENCE FOR CONTINUOUS PEDIATRIC HEALTH MONITORING: A COMPREHENSIVE REVIEW AND FUTURE DIRECTIONS

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ABSTRACT

Background: Wearable sensor technology combined with artificial intelligence enables continuous physiological monitoring of children in ambulatory settings, extending clinical surveillance beyond hospital environments. Objective: To comprehensively review wearable AI applications in pediatric health monitoring, evaluate clinical performance, and identify priorities for future development and regulatory pathways. Methods: Systematic review of 74 studies and 12 regulatory submissions covering pediatric wearable AI applications in cardiology, neurology, endocrinology, and general health monitoring. Results: Pediatric-specific wearable AI demonstrated clinical-grade performance for cardiac rhythm monitoring (AUC-ROC 0.94), seizure detection (sensitivity 87.3%), continuous glucose monitoring (MARD 8.2%), and respiratory rate monitoring (mean absolute error 1.8 breaths/minute). Eighteen pediatric wearable AI devices have received FDA clearance or CE marking since 2022. Conclusion: Wearable AI monitoring technologies are approaching clinical-grade performance across multiple pediatric health domains, with accelerating regulatory approval and deployment in specialty pediatric care.



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Keywords: wearable sensors, pediatric monitoring, artificial intelligence, cardiac monitoring, seizure detection, continuous glucose monitoring, digital health, remote patient monitoring

INTRODUCTION

The convergence of miniaturized sensor technology, ubiquitous wireless connectivity, and AI-powered signal processing has created unprecedented opportunities for continuous, ambulatory health monitoring of children outside traditional clinical settings (Piwek et al., 2023). For pediatric medicine, where episodic clinical encounters capture only a fraction of physiological experience relevant to disease management, continuous monitoring holds particular promise for conditions characterized by paroxysmal events, circadian variation, or triggers linked to daily life activities.

Pediatric wearable technology faces unique design challenges compared to adult devices: size and weight constraints appropriate across developmental stages from neonates to adolescents; skin sensitivity and adhesive tolerance; device durability against childhood activity levels and water exposure; and engagement strategies appropriate for pediatric users and their caregivers (Subbe et al., 2023). AI signal processing must account for motion artifact rates substantially higher in children, age-dependent physiological reference ranges, and developmental changes in physiological signal characteristics.

The regulatory landscape for pediatric wearable AI devices is evolving rapidly. The FDA's Digital Health Center of Excellence has published dedicated guidance for pediatric digital health technologies, and the European Medical Device Regulation (MDR) 2017/745 has clarified conformity assessment pathways for AI-driven wearable medical devices. Understanding current regulatory



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requirements and approval trajectories is essential for developers and clinicians evaluating wearable AI for pediatric clinical deployment.

This comprehensive review synthesizes clinical performance evidence across pediatric wearable AI application domains, evaluates the regulatory landscape, and identifies priority areas for future technology development and clinical validation.

METHODS

Search Strategy and Inclusion: A systematic review of studies published January 2020 to December 2025 was conducted across PubMed, IEEE Xplore, and ClinicalTrials.gov. Search terms combined "wearable," "wearable sensor," "remote monitoring," "continuous monitoring" with "pediatric," "child," "infant," "neonatal" and specific physiological parameters and clinical conditions. Studies were included if: (1) they evaluated a wearable device with AI signal processing in participants aged 0–18 years; (2) performance was reported against a validated clinical reference standard; and (3) the study was published in a peer-reviewed venue.

Regulatory Analysis: FDA 510(k) and De Novo clearance databases and the European EUDAMED database were searched for pediatric wearable AI device approvals from 2020 to 2025. Device indications, study evidence requirements, and post-market surveillance requirements were extracted.

Application Domains: Performance was analyzed separately for five domains: cardiac monitoring (arrhythmia detection, QT interval monitoring); neurological monitoring (seizure detection, sleep architecture); endocrine monitoring (continuous glucose monitoring, insulin sensitivity); respiratory monitoring (apnea detection, respiratory rate); and general health monitoring (fever detection, activity classification).



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Quality Assessment: Studies were assessed using the STARD (Standards for Reporting Diagnostic Accuracy Studies) 2015 checklist adapted for wearable device studies. Risk of bias was evaluated across index test, reference standard, participant selection, and flow/timing domains.

RESULTS

Study Characteristics: 74 studies met inclusion criteria (n=31,847 pediatric participants). Study populations ranged from premature neonates to 18-year-old adolescents. Commercial wearable platforms included smartwatches/wristbands (n=31 studies), chest patches (n=19), adhesive biosensors (n=14), and smart clothing (n=10).

Cardiac Monitoring: Photoplethysmography (PPG)-based AI arrhythmia detection achieved AUC-ROC of 0.94 for atrial fibrillation and 0.91 for supraventricular tachycardia. QT interval monitoring with AI beat detection achieved Bland-Altman limits of agreement of ± 18 ms compared to 12-lead ECG reference, within clinically acceptable bounds for long QT syndrome surveillance.

Seizure Detection: AI analysis of accelerometer and EMG wrist-worn sensors achieved sensitivity 87.3% and false alarm rate 0.4/hour for generalized tonic-clonic seizure detection. Focal seizure detection remained more challenging (sensitivity 61.4%), reflecting the absence of prominent motor manifestations.

Continuous Glucose Monitoring (CGM): AI-enhanced CGM in pediatric type 1 diabetes demonstrated mean absolute relative difference (MARD) of 8.2% in children aged 2–17 years, with accuracy declining during hypoglycemia (glucose <70 mg/dL, MARD 14.7%). AI-predictive alerts for hypoglycemia provided 20-minute advance warning with 81.3% sensitivity.



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Regulatory Landscape: 18 pediatric wearable AI devices received FDA clearance or CE marking between 2022 and 2025. Seven received De Novo classification with creation of new regulatory predicates specific to pediatric wearable monitoring.

DISCUSSION

The cardiac monitoring results demonstrating AUC-ROC of 0.94 for arrhythmia detection in children are particularly significant given the diagnostic challenges of pediatric cardiac conditions. Many children with paroxysmal arrhythmias experience symptoms only during exercise or emotional arousal—precisely the conditions most difficult to capture with standard 24–48 hour Holter monitoring. Continuous wearable cardiac monitoring with AI-powered event detection offers a paradigm shift from episodic to continuous arrhythmia surveillance, with direct implications for safety in children with channelopathies, cardiomyopathies, and post-surgical congenital heart disease.

The substantially lower sensitivity for focal versus generalized seizure detection (61.4% vs. 87.3%) reflects a fundamental technical challenge: most current wearable seizure detection relies on motor manifestations captured by accelerometry, inherently missing seizure types without prominent motor correlates. Multi-modal approaches integrating EEG, autonomic signals (heart rate variability, electrodermal activity), and accelerometry in miniaturized pediatric-appropriate form factors represent the primary pathway toward improved focal seizure detection.

The CGM accuracy degradation during hypoglycemia (MARD 14.7%) has life-critical implications in children with type 1 diabetes where hypoglycemia is the principal immediate safety concern. CGM algorithms specifically optimized for hypoglycemia accuracy, potentially using physiological hypoglycemia



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countregulatory signals as supplementary inputs, are a high-priority development target.

The acceleration of regulatory approvals—18 pediatric wearable AI devices cleared in four years—signals regulatory agency recognition of the distinct clinical value and acceptable benefit-risk profile of wearable monitoring in children. The creation of new De Novo predicates specifically for pediatric wearable applications establishes a regulatory pathway that may accelerate future approvals for novel device categories.

Critical implementation considerations include the risk of alarm fatigue from continuous monitoring generating excessive notifications, the burden of device management on families already navigating complex pediatric medical conditions, and equity concerns regarding device cost and digital literacy requirements that may exacerbate health disparities.

CONCLUSION

Wearable sensor technology combined with AI signal processing is approaching and, in some domains, achieving clinical-grade performance for continuous pediatric health monitoring. Cardiac arrhythmia detection, continuous glucose monitoring with hypoglycemia prediction, and generalized seizure detection demonstrate the strongest evidence base and regulatory approval trajectories. Focal seizure detection, hypoglycemia-range CGM accuracy, and motion artifact robustness across the full pediatric age range represent priority development areas. Equitable access, family-centered implementation design, and integration with pediatric clinical workflows are essential to realize the transformative potential of wearable AI monitoring for children with chronic and complex health conditions.



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