

Wearable Technology in Pediatric Cardiac Care: A Scoping Review of Parent Acceptance and Patient Comfort

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Abstract

While wearable technology has advanced pediatric medical monitoring, home-based success in cardiology depends heavily on human-centered design. This scoping review synthesizes evidence on the human factors—specifically parental acceptance, child comfort, and usability—that determine the real-world adoption of pediatric cardiac wearables. By systematically searching PubMed, Scopus, Cochrane Library, and ClinicalTrials.gov, we mapped the evidence surrounding diverse technologies, including vital sign and ECG monitors. Our findings reveal a persistent “performance-usability gap”: while devices show high clinical efficacy in controlled settings, their long-term utility is frequently compromised by poor wearability, skin irritation, and a lack of alignment with family routines. The review identifies that current research structures and regulatory pathways reward quantifiable biomedical outcomes, such as sensor accuracy, while routinely sidelining difficult-to-measure factors like parental buy-in and child autonomy. Consequently, we highlight critical gaps in the design process that prioritize clinical specs over the lived experience of the patient. We conclude that a paradigm shift toward human-centered engineering is required to move beyond controlled study success. These results provide a necessary roadmap for developers and regulators to prioritize the “invisible” outcomes of comfort and compliance, which are essential for the effective, sustained home-based monitoring of pediatric patients.

Keywords: wearable devices; wearable comfort; comfort assessment; pediatrics; congenital heart disease; parent acceptance



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1. Introduction

The use of wearable technologies in pediatric congenital heart disease (CHD) care has expanded significantly in recent years, offering new ways to support monitoring, diagnosis, and management of this common and complex condition. Congenital heart defects affect approximately 1% of newborns globally, often requiring ongoing physiological surveillance throughout childhood [1]. As delineated in Table 1, a variety of wearable devices—both clinical and commercial oriented—have been integrated into care strategies to assist in tracking pediatric cardiovascular and systemic health parameters.

In clinical practice, a diverse array of diagnostic and monitoring devices is essential for managing cardiac health, particularly in patients with CHD. Standard tools such as Holter monitors, event monitors, and implantable loop recorders are fundamental for detecting

arrhythmias and other cardiac abnormalities. By providing continuous or intermittent electrocardiogram (ECG) data, these technologies offer the longitudinal insights necessary to tailor treatment plans for those with suspected rhythm disturbances.

Table 1. Scope of Devices and Parameters for Pediatric Wearables.

Device	Purpose	How It Works	Parameters Monitored	Use in CHD
Pulse Oximeter	Real-time SpO ₂ monitoring	Uses light sensors on skin (finger, wrist, or foot)	Oxygen saturation (SpO ₂), pulse rate	Critical in cyanotic CHD (e.g., Tetralogy of Fallot), home/hospital hypoxemia monitoring, silent desaturation detection in infants
Holter Monitor	Continuous ECG monitoring for 24–72 h	Electrodes are attached to the chest and connected to a small portable device	Heart rate, rhythm, QT interval	Detects post-op arrhythmias, conduction defects (e.g., AV block), evaluates symptoms like palpitations or syncope
Event Monitor/ Loop Recorder	Long-term rhythm monitoring over weeks/months	Activated manually or automatically during arrhythmia events	Sporadic arrhythmias (e.g., SVT, VT)	For patients with intermittent symptoms or high arrhythmia risk; useful post-surgery to detect life-threatening arrhythmias
Implantable Loop Recorder	Continuous long-term rhythm surveillance (months–years)	Subcutaneous implant continuously records and transmits ECG	ECG, arrhythmia episodes	For high-risk arrhythmia surveillance, especially in Fontan/single ventricle physiology; not truly wearable but relevant for continuous monitoring
Wearable Blood Pressure Monitor	Detect blood pressure trends	Automated pediatric oscillometric-based wearable monitoring	Systolic and diastolic BP, heart rate	Monitors post-repair of coarctation of aorta, detects systemic/pulmonary hypertension, supports outpatient medication titration
Respiratory Monitor	Detect abnormal breathing, apnea	Chest straps or smart onesies measure motion, impedance, or stretch	Respiratory rate, movement (proxy for apnea)	Identifies apnea in neonates/infants with CHD, monitors respiratory effort in CHF or pulmonary congestion
Temperature Monitor	Continuous or frequent temperature tracking	Wearable patches or smart thermometers placed on skin	Skin or peripheral body temperature	Important for early fever detection in post-op patients; fever can exacerbate cardiac workload
Smartwatch/Fitness Band	Consumer-grade health tracking with clinical integration	Worn on wrist; uses optical sensors and accelerometers	Heart rate trends, activity levels, sleep; ECG in select models	For older children with milder CHD; monitors exertion, supports exercise safety, identifies early signs of decompensation
Smart Clothing	Long-term, multi-parameter monitoring	Fabric sensors embedded in clothing (e.g., shirts, onesies)	ECG, respiratory rate, HR variability, activity, sleep	Used in chronic CHD management, post-op monitoring, and research/telemonitoring in older children
Smart Diaper	Indirect hydration and perfusion tracking	Moisture and chemical sensors detect urination and urine composition	Urine output, frequency, possible electrolyte/pH	Helps in fluid management for neonates with critical CHD or post-op recovery; especially in heart failure cases

Physiological monitoring is critical for identifying hemodynamic instability in CHD patients. Pulse oximeters track oxygen saturation, vital for managing cyanosis or compromised pulmonary circulation. Wearable blood pressure monitors capture long-term trends

essential for post-operative care and hypertension management. Additionally, respiratory monitors detect apnea and abnormal breathing patterns caused by cardiac-pulmonary complications. Integrated together, these tools create a proactive framework that enhances patient management and improves clinical outcomes by allowing for early intervention and continuous oversight.

Beyond traditional clinical tools, a variety of wearables now capture physiological data in domestic and community settings. For instance, smartwatches and sensor-embedded clothing provide continuous monitoring of cardiovascular and respiratory responses during daily activity. Similarly, specialized applications—such as smart diapers for renal tracking or wearable thermometers for early fever detection—offer critical early warning signs of post-surgical infection or systemic inflammation in pediatric CHD patients.

1.1. Concept of Wearability

Wearability refers to how well a device can be tolerated or worn by a consumer over time and how effectively and accurately it can collect intended data. It is especially an important factor in pediatric settings where age, developmental stage, and physical size vary widely. In pediatric CHD care, wearability is often evaluated based on factors such as comfort, weight, device size, attachment method (e.g., adhesive, strap, implantable), battery life, and user compliance. Assessing wearability is influenced by many factors, including adherence tracking, caregiver feedback (particularly from legal guardians of the patient) and device usage data [2]. Devices intended for infants and toddlers may require different materials and form factors than those for older children or adolescents. Clinical-grade devices often prioritize data fidelity, while consumer devices may emphasize form and usability. Both considerations influence how devices are adopted in pediatric care.

Medical devices are typically developed through a structured, iterative design process that includes needs assessment, concept generation, prototyping, validation, and regulatory approval. This process often begins with identifying a clinical problem, followed by defining user and performance requirements based on technical feasibility, safety standards, and intended use. Engineers and designers then create prototypes that undergo bench testing, clinical input, and human factors evaluations to ensure functionality and usability [3–5]. Wearability is an essential attribute for devices intended for continuous or ambulatory use [6], and can be assessed through both objective and subjective measures [7]. Objective methods may include evaluating weight, skin contact pressure, thermal load, and range of motion interference, while subjective assessments rely on user feedback concerning comfort, appearance, and usability during daily activities. Unfortunately, traditional assessments are often conducted in controlled adult populations and may not adequately reflect the diverse and sensitive needs of pediatric users [8,9], particularly in populations with chronic conditions like CHD [10].

1.2. Human-Centered Design for Wearability

Wearable technologies are increasingly integrated into healthcare, yet their design and evaluation often overlook the distinct needs of pediatric populations [11]. Devices are frequently conceived for adults and subsequently adapted for children, a process that rarely accounts for critical pediatric considerations such as body size, developmental mobility, behavioral engagement, and the added responsibilities placed on caregivers. This discrepancy compromises functional usability and dilutes therapeutic impact, thereby undermining the long-term viability of these technologies within pediatric CHD contexts. Unlike adults, children interact with technology through evolving developmental stages, requiring solutions that are intuitive, adaptable, and supportive of family-centered care [12]. Addressing these challenges demands interdisciplinary collaboration that foregrounds the

voices of children, families, and pediatric clinicians. A human-centered design approach is essential to ensure wearable technologies not only monitor health but also integrate seamlessly into the lived experiences of young patients, ultimately advancing equity and outcomes in pediatric care.

1.3. Research Questions

The objective of this scoping review is to identify core concepts and assess the breadth of literature concerning user-centered design that influences the development of pediatric wearable technology. Our work follows the guidelines for the PRISMA extension for Scoping Reviews [13] (Supplementary Materials Tables S1 and S2). Although scoping reviews allow for broad exploration, we identified three research questions to guide our review:

1. What key factors influence the wearability of pediatric wearable devices?
2. What methodologies or measures are used to assess wearable device comfort?
3. What are the reported parental acceptance experiences and satisfaction levels regarding the different types of wearable devices?

Thus, our analysis (a) first identifies wearable functional design considerations, then (b) highlights aspects of wearability and comfort considerations, and finally (c) explores factors influencing overall parent and caregiver (secondary user) perception and acceptance of wearable technology.

1.4. Functional Design Considerations

The translation of broad functional requirements into quantifiable design specifications remains a critical and well-known challenge in medical device development. For the scope of this work—and with a specific focus on devices pertaining to pediatric cardiology—Table 2 delineates 12 essential parameters. These parameters collectively define the requisite design landscape for robust, wearable pediatric cardiovascular monitoring solutions. Consistent with user-centered design, our search was not constrained by pre-existing specifications found in many commercially available devices for intermittent recreational use.

Table 2. User need and potential design specifications to consider in design of a wearable device.

User Need	Design Considerations
1. Comfort	Evaluate the comfort of the device when worn for extended periods. Includes assessing materials, fit, weight, and overall ergonomic design.
2. Fit and Adjustability	Ensure the device can fit various body types and sizes. This includes the design of adjustable straps, bands, or other mechanisms to secure the device properly.
3. Battery Life:	Assess duration the device can operate before needing a recharge. Longer battery life reduces the frequency of recharging, which affects wearability and user compliance.
4. Durability and Robustness:	The device should withstand daily wear and tear, including exposure to different environmental conditions like moisture, dust, and physical impact.
5. Ease of Use:	Evaluate how easy it is for users to operate the device. This includes the simplicity of putting it on and taking it off, and the user interface for any necessary interactions.
6. Data Accuracy and Reliability:	Assess the precision and consistency of the data collected by the device. Reliable sensors and accurate data collection are crucial for clinical trial validity.
7. Mobility and Range of Motion	Determine how the device affects natural movement and range of motion. Assess whether it restricts movement during various activities.

Table 2. *Cont.*

User Need	Design Considerations
8. Integration with Clothing and Accessories:	Determine how well the device integrates with different types of clothing and accessories. Assess whether it can be worn discreetly or if it interferes with other wearable items.
9. Aesthetic Appeal:	Consider the visual design of the device. It should be appealing or at least unobtrusive to encourage regular wear.
10. Skin Compatibility	Ensure the materials do not cause skin irritation or allergies. This includes testing for hypoallergenic properties and breathability of materials in contact with skin.
11. Connectivity and Data Transfer:	Evaluate how the device connects to other systems or devices for data transfer (includes reliability and security of connections).
12. Regulatory Compliance:	Ensure the device meets all necessary regulatory standards and guidelines for medical devices. This includes certifications and compliance with relevant health and safety standards.

The 12 design parameters in Table 2 are a scaffold for designs whereby the resulting wearable device is biocompatible, compliant with regulatory affairs, resilient, and aligned with clinical practice making it practical and clinically effective for deployment in pediatric applications. These design criteria set the stage to now discuss device wearability and comfort in the specialized area of pediatric cardiology.

1.5. Wearability and Comfort Considerations

We identified eight design factors for device wearability and comfort, extracted from technical features for the physical attributes and device design features in Table 1, and human factors related to wearability and comfort factors in Table 2. Features from these two tables were grouped into factor themes guiding comfort considerations, shown in Table 3.

Table 3. Factors guiding comfort and wearability considerations.

Factor	Why the Factor Matters
1. Size and Fit	Pediatric patients vary widely in size—infant-sized devices are essential.
2. Skin Sensitivity	Devices must be hypoallergenic and non-irritating
3. Data Accuracy	Especially critical for heart rate, oxygen, and ECG-related monitoring.
4. Connectivity	Secure, HIPAA-compliant cloud syncing with clinician portals
5. FDA Approval	Preferred in clinical-grade devices, especially for arrhythmia detection
6. Battery Life	Essential for continuous, long-term use.
7. Secondary Access	Easy app interfaces and alerts for secondary users (parent, caregiver).

Where extensive quantitative and qualitative evidence exists, Table 3 clarifies how various stakeholder perspectives influence the mechanics of complex design interventions. Bridging these different views often draws on strategies involving qualitative synthesis [14,15] or thematic synthesis [16,17] (sometimes supplemented with AI-based methods [18,19]). However, for the present work, our exploratory wearability, comfort, and technology acceptance analysis was accomplished with a simple holistic analysis, though we recognize a more formal framework would be required for a systematic review [20].

1.6. Parent and Caregiver Perceptions and Acceptance

Several psychological, social, and practical factors influence parent and caregiver acceptance of medical wearable devices for managing children with critical conditions, specifically CHD [21,22]. For remote patient monitoring, wearables offer the potential for early detection of hemodynamic shifts and life-threatening arrhythmia; success depends on parents and other caregivers (secondary users) who must manage device adherence, data transmission, and emotional factors. Wearable technology is both a source of parental reassurance and a potential driver of “medicalization” within the home, and also has the potential to inadvertently increase caregiver burden or anxiety [23]. The threshold at which the clinical benefits of continuous monitoring outweigh the perceived intrusiveness of the technology may impact acceptance and long-term compliance. Further, digital literacy can impact a caregiver’s trust in automated alerts versus their own intuition. Wearable designs informed about “family-centered” concerns will support the clinical safety of the child while preserving the quality of life and psychological well-being of the family unit [24].

Overall, parent and caregiver acceptance of medical wearables relates to: (a) clinical/technical concerns on the “validation gap” (devices aren’t always accurate for children), (b) the emotional/social “reassurance vs. anxiety” balance for heart disease parents and (c) the design/usability concerns if a device is “too hard” for daily life.

A substantial body of recent scholarship has begun to examine secondary user considerations related to pediatric wearable devices; this research moves beyond primary device functionality to explore broader developmental, social, ethical implications and form factors [11]. As we synthesized this emerging literature, five factors appear to shape how researchers conceptualize and evaluate secondary concerns. Table 4 provides recurring themes that we believe provide a useful framework for understanding the complexities surrounding secondary user engagement with wearable technologies.

Table 4. Factors guiding secondary user considerations (compiled from multiple sources).

Factor	Secondary User Concerns
1. Perceived utility vs. psychological burden	Does the device provide “peace of mind” through constant monitoring, or does it create “hyper-vigilance” and increased anxiety due to the fear of false alarms or constant data visibility? [25]
2. Usability and integration into daily routine	What is the “effort expectancy”? This includes the ease of donning/doffing the device, battery management, and whether the device interferes with normal childhood activities (e.g., play, bathing, or sleep) [26].
3. Data trust and actionability	Do caregivers feel confident in the accuracy of the data? More importantly, do they understand the threshold for when a reading requires a phone call to a doctor versus an emergency room visit? [27,28]
4. Privacy and ethical governance	How concerned are parents about the continuous collection of their child’s physiological data? This includes concerns regarding who has access to the data and how it might be used by third parties or insurance [27–29].
5. Physical design and “social stigma”	Does the device look like a medical “shackle” or a consumer gadget? Researching the “wearability” factor is crucial; parents may be more accepting of devices that allow their child to feel “normal” rather than visibly ill in social or school settings [30–32].

1.7. Research Strategy

Our research strategy first identifies relevant literature before evaluating how research outcomes inform overall comfort, wearability, and device acceptance. For clarity, we summarize the following process:

Section 2—Materials and methods:

- In Section 2.1, we define the search terms and selection criteria used to conduct our literature search on user comfort, wearability, and acceptance.
- Manuscript eligibility and screening criteria are detailed in Section 2.2 and employ the PRISMA framework to establish a core set of 32 target manuscripts for further analysis.

Section 3—Results:

- The 32 target manuscripts were subsequently examined and a brief narrative in Table 6 outlines “focus,” “findings,” and “relevance to” our research aims.
- The most relevant articles—identified through the triage process—are qualitatively synthesized in Table 6, while Table 8 presents a quantitative meta-analysis of the core evaluation criteria.

Section 4—Discussion:

- Section 4 provides a narrative review of each wearable device, building upon the foundational data in Tables 7 and 8. This review integrates comfort and wearability criteria with a summary assessment of parental perception and acceptance of pediatric wearables.

2. Materials and Methods

Given the lack of specific questions and concepts for critical appraisal, a mixed-methods (qualitative and quantitative data) scoping review was deemed more appropriate for the current work than a systematic review. In Section 1.6, we noted that a scoping review methodology was undertaken to comprehensively map the breadth of existing literature and to identify emerging areas of inquiry. This approach was selected to clarify emerging themes and identify evidence gaps that will inform the development of subsequent systematic reviews. While the current protocol is not registered, this scoping review was conducted in accordance with the PRISMA Extension for Scoping Reviews (See Table S1: PRISMA-ScR) guidelines and may be eligible for formal registration in future research. The initial research effort was conducted over the period June–December 2025, and the search results last reviewed in January 2026. Identified citations were exported to Zotero (V7) for duplicate removal.

This literature search identifies human-centered design principles for wearable devices tailored to pediatric patients with CHD. We assessed a wide range of technology—including consumer products, research prototypes, and medically cleared devices—to evaluate their tracking parameters and physical limitations. Rather than critiquing specific products, this review provides a high-level overview of the current technological landscape. We specifically examined how these devices function in a real-world context, looking at the technical trade-offs between data collection accuracy and the practicalities of daily wear for a child.

Beyond technical specifications, our analysis focused on the “secondary user” experience, specifically the role of parents and caregivers in successful device integration. We reviewed evidence regarding parental acceptance and their willingness to maintain the technology, as well as patient-centered factors like physical comfort, skin integrity, and long-term adherence. By examining interface usability and setup complexity for non-clinical users, this systematic mapping highlights the critical human factors that determine whether wearable technology succeeds or fails in the CHD population.

2.1. Search Strategy

We conducted a mixed-methods scoping literature review using four major databases: PubMed, ScienceDirect (Scopus), Cochrane Library, and ClinicalTrials.gov. No date re-

strictions were specified but the search was limited to English-language publications and studies available in open-access format. Our strategy was designed to identify scholarly works that explicitly link specific systems and wearable devices to parent perceptions, acceptance, and user comfort. This approach was grounded in the principle that the utility of devices in CHD are not merely based on sensor technical specifications, but on a user-centered construct shaped by the lived experience of device interaction. Figure 1 presents the initial keyword-based search algorithms applied to multiple databases to identify those manuscripts to serve as the foundation for subsequent analysis in this scoping review.

Search A—PubMed search focused on device wearability features for CHD Search returned 21 papers: <pre> ("pediatric" OR "child*") AND ("wearable*" OR "wearabilit*") AND ("technolog*" OR "device*" OR "system*") AND (("cardiovascular") OR ("CHD") OR "Congenital Heart Dis- eases") AND ("design") </pre> Search B—PubMed search focused on secondary user acceptance and perceptions Search returned 10 papers: <pre> ("pediatric*[title/abstract] OR "child*[title/abstract]) AND "comfort*[title/abstract] AND "wearable*[title/abstract] AND ("device*[title/abstract] OR "technolog*[title/abstract] OR "system*[title/abstract] OR "monitor*[title/abstract]) AND ("parent*[title/abstract] OR "care giver*[title/abstract] OR "caregiver*[title/abstract] OR "guardian*[title/abstract]) AND ("accept*[title/abstract] OR "precept*[title/abstract]) </pre> Search C—ScienceDirect (SCOPUS) focused on secondary user perceptions Returned 26 papers: <pre> ("comfort" OR "perception") AND (("wearable" OR "wearability") AND "device") AND ("pediatric") AND ("parent" OR "caregiver") AND "cardiovascular" </pre> Search D—Cochrane Returned no studies (all Title/Abstract Search): <pre> "pediatric cardiology" AND "wearable" OR "wearability" "comfortability" AND "devices" </pre> Search E—ClinicalTrials.gov Returned 14 studies: <pre> Cardiovascular OR CHD OR "Congenital Heart Disease in Children" Other terms: (pediatric OR child) OR "Wearable Devices" comfort Completed studies Child (birth—17) </pre>

Figure 1. Key word search results from a mixed-methods scoping review conducted across four databases, yielding 71 documents as the foundation for further scrutiny in the current work. Note that an "*" indicates the search involved a wildcard option.

Figure 2 depicts the process for manuscript screening and selection in the form of a PRISMA flow diagram; this process outlines the number of records identified through

database searches and other sources, and the final set of manuscripts subjected to full-text review. Specific criteria for eligibility and screening are presented next, in Section 2.2.

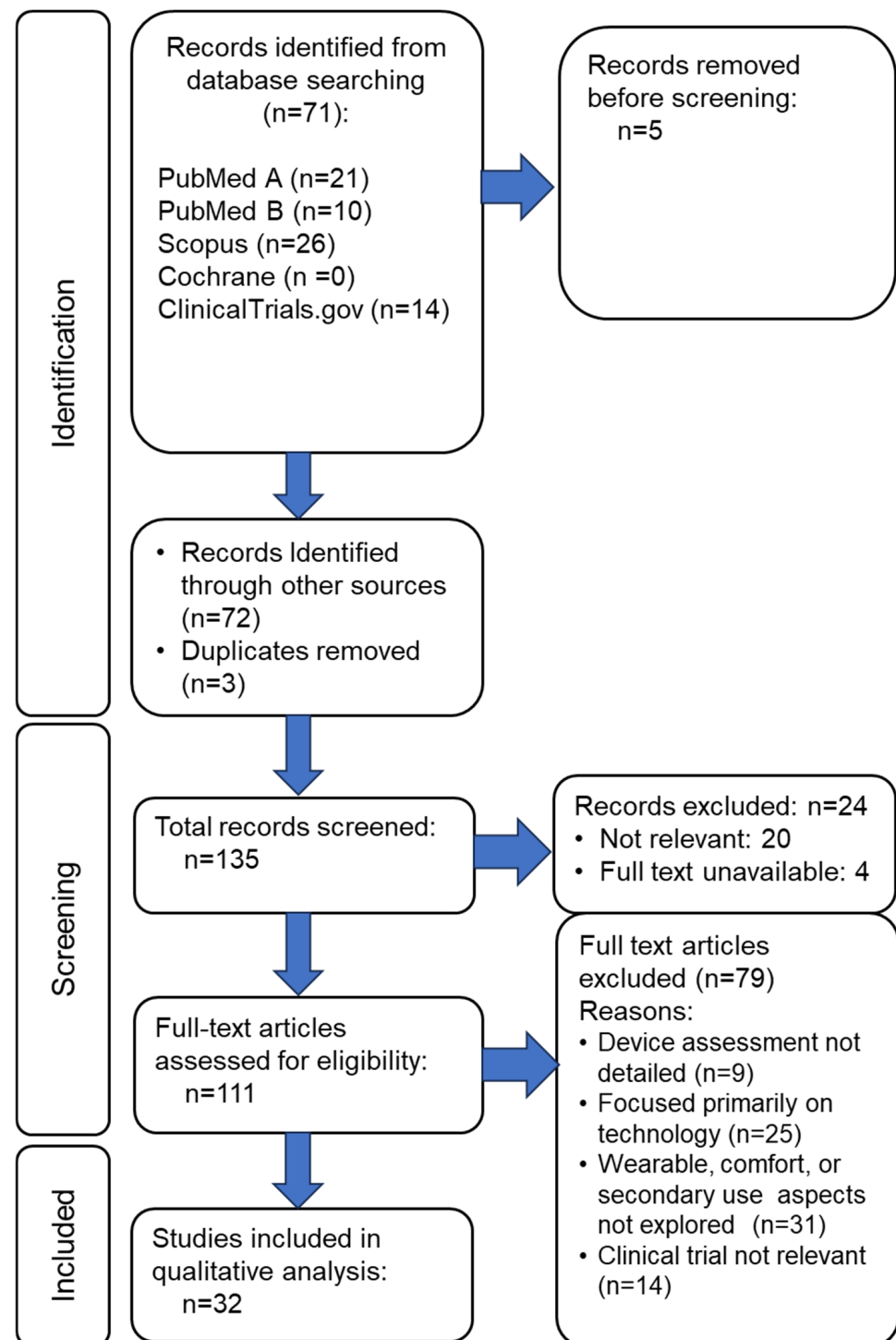


Figure 2. PRISMA flow diagram of the wearability literature review process for studies on the wearability of wearables for CHD.

2.2. Eligibility Criteria and Screening

Inclusion criteria for our scoping review required a focus on the qualitative aspects of wearability. This ensured inclusion of studies examining user experiences, perceptions, and subjective evaluations of device comfort, usability, and overall satisfaction. Papers meeting this criterion were intended to provide insights into dimensions of wearability as well as

highlighting factors influencing user acceptance and adoption. Table 5 presents a rubric for the first-pass evaluation of published studies against relevance to our scoping review. This involved creating three categories of papers—those with high (H), medium (M) and low (L) relevance. Two reviewers independently screened titles and abstracts against the inclusion criteria.

Table 5. Cross-reference for the evaluation of the potential impact a reviewed manuscript may have as a data source to address our research questions.

Assessment	Impact
Limited value as CHD data source for design for device wearability, comfort, acceptance.	Low
Provides indirect linkage to studies or reviews with limited data or discussion of medical condition not related to CHD.	Medium
Recites data or surveys that inform on wearability, comfort, or secondary user acceptance.	High

The initial keyword search identified a core set of 71 documents. To ensure a more comprehensive review, we applied a “pearl-growing” strategy to these primary sources, leveraging their citations and references to identify related literature. This iterative process yielded a net additional 69 records, categorized as Other Sources in Figure 2. Pearl growing is a search strategy where you use a key relevant paper (the “pearl”) to find more sources.

A significant number of papers identified during the initial search were excluded as their primary focus remained on sensing materials, hardware design, or data analytics. While these studies offer valuable technical contributions to the broader wearable technology landscape, they did not directly address the important themes of this review. Papers highlighting future applications of wearables were eliminated.

To contextualize the existing literature, we reviewed eight relevant textbooks addressing wearables in healthcare. Most of these resources prioritized sensor design, technical performance, and prospective clinical applications over human factors such as parent acceptance and patient comfort [33–36]. However, a subset of the literature did acknowledge the need for future research to incorporate direct feedback from patients and caregivers [37,38].

Analysis of the literature search results followed a structured, criterion-based approach to ensure consistent assessment of relevance. All papers identified through the PRISMA-guided search were compiled into an annotated bibliography for detailed review. Each annotation drew on key excerpts from the original article, reviewer notes, and preliminary assessments to capture the study’s purpose, methods, and contributions. This annotated set then served as the foundation for a manual triage process using the relevance criteria outlined in Table 5. During triage, each paper was evaluated for its alignment with the predefined pediatric user needs, design considerations, and evidence requirements central to the review. Studies demonstrating strong conceptual or empirical relevance were prioritized for full analysis, while those offering limited or peripheral insight were deprioritized. This multi-stage process provided a transparent, replicable method for distilling a broad search output into a focused body of literature directly responsive to the review’s objectives.

While Table 5 narrowed the selection to 32 papers for detailed review, a quantitative meta-analysis is derived from Table 6. By applying the Table 6 rubric to high- and medium-relevance articles, we were able to quantify the specific contributions of each study to our core thematic areas.

Table 6. Criterion assessment rubric for evaluating reference sources based on comfort, wearability, and secondary user criteria.

Assessment of Comfort, Wearability, and Secondary User Criteria	Score
Reference only alludes to criterion or does not provide significant mention	0
Reference mentions or only briefly mentions, without detail	1–2
Reference mentions with some detail.	3–4
Reference discusses with moderate detail and some context	5–6
Reference provides detailed discussion w/relevant data/examples.	7–8
Reference extensively comprehensive data, examples, and critical analysis.	9–10

3. Results

The literature search yielded 32 core references spanning from 2014 to 2025, with a notable concentration of research (over 65%) published within the last five years. The final selection is primarily composed of empirical research, including clinical trials, pilot studies, and survey reports; notably, only five of the 32 manuscripts are review papers. This distribution highlights a recent and significant shift toward primary data collection in the field of pediatric wearable technology.

To establish a clear evidentiary foundation, Section 3.1 provides a qualitative snapshot of each individual publication. This section utilizes a “what and who” framework to summarize the specific focus, findings, and clinical relevance of each study. By detailing individual contributions, this qualitative overview creates the necessary context for the thematic synthesis that follows.

The quantitative analysis in Section 3.2 complements these summaries by applying the evaluative “lens” established in Table 6. This rubric allows for a consistent assessment of the literature across 12 distinct criteria related to wearability, comfort, and secondary user experience. By transitioning from individual descriptions to a cross-cutting analysis, Section 3.2 identifies broader research trends and synthesizes the complex relationship between technical performance and caregiver acceptance.

3.1. Qualitative Outcomes

Table 7 provides a foundational overview of the literature by summarizing the characteristics and scope of each publication selected for this review. Based on the summary of the 32 publications provided in Table 7, the literature explores the integration of wearable technology and remote monitoring across a diverse range of pediatric conditions, including cardiovascular disease, epilepsy, and neonatal care. The research spans a wide spectrum of technological maturity, from experimental “imperceptible” soft wearables and textile-based sensors to consumer-grade smartwatches and pulse oximeters.

A central theme across these studies is the critical role of the secondary user, typically the parent or caregiver. While many devices are designed for clinical accuracy, their real-world success is heavily dictated by parental perceptions of trust, ease of use, and the “peace of mind” they provide. However, this psychological benefit often exists in tension with technical challenges, such as alarm fatigue, connectivity issues, and the potential for increased anxiety due to false positives or complex data interpretation. Ultimately, the literature suggests that for pediatric wearables to move from pilot studies to standard clinical practice, designers must balance technical precision with the practical and emotional needs of the family unit.

The impact of physical design on long-term adherence appears to be understudied. Across diverse clinical applications ranging from arrhythmia detection to physical activity tracking, user compliance would seem to be heavily influenced by factors such as comfort,

discreet appearance, and a secure fit; however, little new insight was gained from the manuscripts reviewed.

Table 7. Summary description for each of the publications selected for detailed review.

Paper	Author	Scale	Summary Description
1.	Bolourchi et al. [39]	H	<u>Focus:</u> Clinical study to compare wireless arrhythmia detection devices with the standard Holter monitor. <u>Findings:</u> The standard for ambulatory arrhythmia detection in children has been the Holter monitor, which is typically worn for 24 to 48 h. However, the multiple wires and inability to shower can be prohibitive. <u>Relevance:</u> Parents find wireless systems more appealing as long as accuracy is not compromised.
2.	Brown et al. [40]	M	<u>Focus:</u> Conducted participatory design workshops with children with unilateral cerebral palsy, their peers, and parents to co-develop a wearable system for therapy. <u>Findings:</u> Children and parents prioritized comfort, discreet appearance, and secure fit. Parents highlighted lack of therapy access and saw the device as a helpful tool. Teachers and clinicians also contributed, ensuring design feasibility in real settings. Not specific to any device. <u>Relevance:</u> Details how device comfort directly inform user-centered design and builds trust and engagement among parents.
3.	Butler et al. [41]	M	<u>Focus:</u> Study with five children (11–17) with juvenile idiopathic arthritis to explore smartwatch management of chronic condition. <u>Findings:</u> Challenges connecting smartphones with a smartwatch were common related to connectivity, passwords, and general parent digital health literacy, and set-up of system. <u>Relevance:</u> Smartwatch barriers persist for secondary users.
4.	Caswell et al. [42]	L	<u>Focus:</u> Focus group on wearable device for chronic enuresis detection. <u>Findings:</u> Need informative instructions relating to how the device should be used to be able to maximize performance, efficiency and acceptance. Enhance alarm types and options for the design of device enclosure. <u>Relevance:</u> User-centered design impacts secondary user acceptance.
5.	Charland and Kovesi [43]	H	<u>Focus:</u> Study to assess why parents purchased a consumer-grade pulse oximeter for use at home as part of cardiorespiratory monitoring. <u>Findings:</u> In a survey of 200 families attending clinic, 53 had used an oximeter at home. Many respondents misunderstood the attributes of the device, though they still used the devices when they were worried, however, were unclear whether the devices were accurate. <u>Relevance:</u> Device education in the clinic setting would improve parent confidence in the use and interpretation of readings.
6.	Chi et al. [44]	M	<u>Focus:</u> Informing parental perspectives on overdiagnosis related to continuous pulse oximetry (CPOX) after discharge from the hospital. <u>Findings:</u> Despite warnings of potential harm with CPOX, parents found security in CPOX. In addition, approximately 25% of the parents agreed that hospital monitors made them feel anxious, yet 98% agreed that the monitors were helpful. Compared to other vital signs, respiratory rate (87%) and oxygen saturation (84%) were commonly rated as “extremely important.” <u>Relevance:</u> Parental perspectives significantly influence CPOX technology use even when best practice recommends intermittent use.

Table 7. Cont.

Paper	Author	Scale	Summary Description
7.	Choo et al. [45]	M	<u>Focus:</u> Explored parental and clinical priorities in the design of a language-tracking wearable device for children to support parent-child interaction. <u>Findings:</u> Comfort, reliability and result clarity were top priorities across a survey of 23 participants; useful results were of greater importance than device functions. <u>Relevance:</u> Illustrates how comfort and usefulness drive user-centered acceptance, particular among parents in language or development interventions.
8.	Chow et al. [27]	L	<u>Focus:</u> Mixed method survey of caregiver on device characteristics that influence trust in digital health platforms. <u>Findings:</u> Living in a rural area (vs. urban) resulted in lower concern over privacy versus those with higher level of education. Chronic disease patients would still use digital platforms though trust remained an issue. <u>Relevance:</u> Trust in digital health varies widely among users and is a prominent concern for patients with chronic conditions.
9.	Dangerfield et al. [46]	H	<u>Focus:</u> Survey to understand rate of adoption of the Owlet Smart Sock (OSS) device for tracking heart rate and oxygen saturation. <u>Findings:</u> In a study of over 47,000 newborns using the OSS technology, parental desire for a feeling of peace of mind accounted for 75% of the reasons to own the OSS. Parents felt significantly less anxious and reported better quality of sleep, despite the device not being FDA-cleared. <u>Relevance:</u> Although the study does not address adherence for this consumer product, it demonstrates motivation for systems providing “piece of mind”.
10.	Ferro et al. [47]	M	<u>Focus:</u> Human factors impact on design of effective improvement interventions for complex systems to reduce caregiver stress. <u>Findings:</u> In this study of 13 parents involved in-home monitoring of infants with pulse oximeters, parents overwhelmingly reported that despite excessive alarms, oximeters created a sense of reassurance and peace of mind that the infant’s condition was stable. This subset was for parents that served as primary caregivers at home. <u>Relevance:</u> The benefit of peace of mind can occur at the cost of navigating cumbersome devices and overly sensitive alarms, that paradoxically resulted in heightened stress and anxiety at constantly being alerted.
11.	Freitas et al. [48]	L	<u>Focus:</u> Inpatient survey of parental, children and clinician acceptability of a bulky, non-invasive transdermal sensor for overdose detection. <u>Findings:</u> Of 139 surveys returned, there was 81.5% acceptance to wear the transdermal device, but concerns about size weight and comfort were commonly raised as a potential barrier to adoption. Accuracy was rated more important than comfort. Parents value blood test avoidance more than children. <u>Relevance:</u> Not central to CHD, but included in our study as it indicates comfort issues may not dominate in-patient acceptability if clinical advantages are present.
12.	Garcia et al. [49]	H	<u>Focus:</u> Retrospective survey of parent’s perception of home CR monitoring for preterm infants discharged, 1- and 2-years post-discharge. <u>Findings:</u> Forty-four infants were discharged home on CR monitor with an event or condition occurring of 8.1% during the study period. Of the 28 parents surveyed, most reported feeling secure but anxious using the CR monitor. Heightened anxiety was present for parents reporting frequent false alarms while using the CR monitor. <u>Relevance:</u> The importance of understanding perceptions of parent anxiety and stress while also feeling secure about infant care with CR monitors.

Table 7. Cont.

Paper	Author	Scale	Summary Description
13.	Ghahjaverstan et al. [50]	L	<u>Focus:</u> Study of a textile-based heart rate (HR) device for children for different tasks: lying down, sitting, standing, exercising, or resting. <u>Findings:</u> Pilot study of twenty participants between 10 and 18 years of age, comparing textile-based system versus chest band. The textile device was viewed favorably by the children and parents, over 95% finding the textile device comfortable, easy to wear, simple to use, and non-irritating. <u>Relevance:</u> Findings support textile-based HR devices comfort and non-irritating, providing similar accuracy to standard chest-strap devices.
14.	Hartog et al. [51]	L	<u>Focus:</u> Application, ability, and issues in use of smartwatches to track cancer patients at risk of reduced physical activity. <u>Findings:</u> Thirty children between 8 and 18 years of age were divided into two cohorts that wore the watch for 12 weeks. Although regular prompts, customized plans, personalized setup, and improved aesthetics and comfort improved sustained use, a high dropout rate related to disliking the watch feeling, appearance, and as sense the smartwatch was a burden. <u>Relevance:</u> Enhanced prompts, parental engagement, and perceived value promoted inclusion of the smartwatch in daily routines.
15.	Hendaus et al. [52]	M	<u>Focus:</u> Parental preference of continuous pulse oximetry (CPOX) for children with acute disease, despite being a relatively weak prognostic distress factor. <u>Findings:</u> The survey of 102 parents of infants and children hospitalized with bronchiolitis prefer CPOX to monitor their offspring's condition. Parents were predominantly satisfied with continuous pulse-oximetry monitoring, though about half felt a good bedside examination would obviate the need for continuous pulse oximetry. <u>Relevance:</u> Parental preference and perspectives on CPOX in acute disease, perceiving it important and valued to keep children safe.
16.	Kumar et al. [53]	L	<u>Focus:</u> Inclusion of usability, user experience and behavioral approaches in the design of mobile health interventions for atrial fibrillation. <u>Findings:</u> When developing and evaluating complex interventions, there are often significant differences between the needs of patients and health care workers. <u>Relevance:</u> User-centered design must include user goals and feedback in the design of long-term behavioral intervention
17.	Levin et al. [54]	H	<u>Focus:</u> Parent willingness to participate in pediatric sensor studies using surveys and real-world recruitment. <u>Findings:</u> Comfort, privacy, and data use greatly influenced parental decision-making. Willingness to participate increased when data were kept private or feedback was provided. Around 25% of parents had concerns due to sensor discomfort or visibility. <u>Relevance:</u> Privacy and feedback are important factors for understanding how comfort and perceived burden shape acceptance of wearable use
18.	Lim et al. [55]	M	<u>Focus:</u> Review of studies to understand prevalence, perception and interpretation of smartwatch data collected for cardiac information. <u>Findings:</u> Increased prevalence has enabled ease of data collection, but misinterpretation of the data and false positives from poor algorithms have led to increased healthcare presentations, as well as parental anxiety. <u>Relevance:</u> Ongoing education is essential for parents to understand the variability of the smartwatch heart rate, especially in children.

Table 7. Cont.

Paper	Author	Scale	Summary Description
19.	Mack et al. [56]	L	<u>Focus:</u> Pilot study on wearable technology for continuous monitoring of HR and oxygen saturation for patients with infectious diseases. <u>Findings:</u> Despite substantial data gaps with consumer devices, acceptance and feasibility were high in 21 hospitalized patients. Patients and health-care workers reported being satisfied with wearing the smart armband and study participants agreed that wearing the wireless device was not stressful or restrictive; daytime use improved mobility and patient comfort. <u>Relevance:</u> Wearable device validation in the target population is essential.
20.	McElwain et al. [8]	L	<u>Focus:</u> Assessing parent experiences and perspectives on participating in research on collection of wearable data from children at home. <u>Findings:</u> Phone interviews with 42 parents of children between 1 and 9.5 years explored parents' and children's experiences of using a new wearable device at home. The wearable device was designed specifically for use with infants and young children, integrating audio, electrocardiogram, and motion sensors. Parents felt comfortable putting the device on the child and felt the child was safe answering the device. But several product improvements were identified to address in the next version device design. <u>Relevance:</u> Engaging secondary users of wireless devices helps identify parent concerns about safety, comfort and burden of use.
21.	Memon et al. [57]	L	<u>Focus:</u> Review of technology value and limitations of single-parameter vs. multi-parameter wearable infant health monitoring systems (WIHMS). <u>Findings:</u> Extensive, contemporary review of many prototype and commercial state-of-the-art wireless devices, elucidating advantages, limitations and the challenges faced by such systems. Common issues were inadequate alarms, calibration requirements, and data errors. <u>Relevance:</u> Despite advances in technology, many systems struggle with the trade-off between size, comfort, accuracy and an adequate power supply.
22.	Morris et al. [58]	L	<u>Focus:</u> Interviews to assess parents' concerns about temperature measurement with conventional thermometers and ideal attributes. <u>Findings:</u> Although the diagnostic value of temperature measurement seems to be clear with parents, selection of a specific device and correct use can cause anxiety and practical challenges. It seems that the absence of third-party information calls improved communication between parents and providers to support parents to manage a child's febrile illness with greater confidence at home. <u>Relevance:</u> Ambiguity over the "best" thermometer to purchase and its use for a sick child suggests the value of third-party patient education.
23.	Priorreschi et al. [59]	H	<u>Focus:</u> Designed and tested a wrist-worn accelerometer for infants/toddlers (3–24 months) assessing comfort and caregiver acceptance. <u>Findings:</u> 94% compliance rate, with 80–90% of parents rating the devices as comfortable and safe. Parents accepted the device even when it attracted public attention. Low device loss and high data quality affirmed real-world feasibility <u>Relevance:</u> provided strong quantitative evidence linking device comfort to parental acceptance and compliance.

Table 7. Cont.

Paper	Author	Scale	Summary Description
24.	Rai et al. [28]	M	<u>Focus:</u> Study to understand how trust is formed around devices using artificial intelligence. <u>Findings:</u> Researchers conducted semi-structured interviews with a sample of 20 neurodivergent and anxious adolescents, their 20 caregivers, and 20 practicing clinicians across psychiatry, psychology, and pediatrics. Trustworthiness was primarily driven by “epistemic alignment”—whether AI outputs matched users’ preexisting beliefs—and “relational trust,” where confidence stemmed from endorsements by respected peers, academic institutions, or regulatory bodies. <u>Relevance:</u> Trust in AI clinical tools depends less on technical performance and more on social relationships, personal mental shortcuts, and how well the technology fits existing professional beliefs.
25.	Sasangohar et al. [60]	L	<u>Focus:</u> A review to examine how remote patient monitoring and telemedicine function within categories of remote monitoring, teleconsultation, and contact-free in-hospital patient observation. <u>Findings:</u> Three major trends can help reduce infection risks and improve health outcomes while noting current gaps in the field. Emphasis is on the critical role of data sharing between hospitals to optimize the use of remote monitoring technology. <u>Relevance:</u> By identifying technical weaknesses and research gaps, these findings serve as a practical roadmap for providers looking to implement safer, more efficient pediatric telehealth systems.
26.	Schaefer et al. [61]	L	<u>Focus:</u> Application, ability, and issues in use of accelerometer activity devices to track children’s physical activity to prevent obesity. <u>Findings:</u> Although the commercial devices were not intended to be used for research, the wrist worn device had high level of compliance since they was comfortable to wear, fit properly, were engaging and waterproof. <u>Relevance:</u> Mature wearable consumer sensor technology can be satisfactorily used for clinical research.
27.	Thompson et al. [62]	M	<u>Focus:</u> This study evaluated a seizure-detecting smartwatch used by ten adolescents and their caregivers to assess its practical utility. <u>Findings:</u> While caregivers reported significant “peace of mind,” the device inadvertently increased the social visibility of the user’s epilepsy. <u>Relevance:</u> The results highlight that while wearable tech offers clinical and psychological benefits, developers must address social stigma and device aesthetics to improve the adolescent user experience.
28.	Voss et al. [63]	L	<u>Focus:</u> Methods for measuring physical activity in children with CHD to facilitate clinical counseling and exercise prescription. <u>Findings:</u> While routine exercise testing measures functional status, it does not reflect habitual activity. Commercial wearables offer an appealing user experience and valid data for remote monitoring. <u>Relevance:</u> Integrating wearable trackers into clinical care allows for continuous data collection, helping clinicians optimize cardiovascular health and tailor physical activity interventions.
29.	Wannheden et al. [64]	L	<u>Focus:</u> A review of 32 studies to assess the features of participatory health technologies designed to support partnerships between patients, caregivers, and clinicians in chronic disease management. <u>Findings:</u> While most technologies positively influenced partnerships, challenges to success depends heavily on how technology impacts the collaborative workload. <u>Relevance:</u> For digital health tools to succeed, designers and clinicians must clarify user roles and integrate technology into the collaborative workflow of all stakeholders.

Table 7. Cont.

Paper	Author	Scale	Summary Description
30.	White et al. [65]	L	<u>Focus</u>: introduction of a cardiac exercise therapeutics (CET) model, providing a systematic approach to increasing physical activity in children and adolescents with heart disease. <u>Findings</u>: The model utilizes clinical assessments to guide three progressive intervention levels: clinic-based promotion, unsupervised exercise prescriptions, and medically supervised fitness training. <u>Relevance</u>: The CET framework offers a structured methodology for clinicians to address inactivity. Long-term success depends on investing in such programs and shifting toward individualized exercise prescriptions.
31.	Wong et al. [66]	M	<u>Focus</u>: This study surveyed families to evaluate their experiences with the a wireless EEG system compared to conventional wired monitoring. <u>Findings</u>: Most respondents (86%) preferred the wireless system. Families reported that the technology facilitates increased physical contact, which over 80% believed would improve emotional health and parent-child attachment. <u>Relevance</u>: These results emphasize the psychological benefits of wireless medical devices, suggesting that reducing technical barriers to physical touch can enhance the overall family experience in clinical settings.
32.	Zhou et al. [67]	M	<u>Focus</u>: evaluation of “imperceptible” soft wearables designed for at-home cardiovascular monitoring of infants with single ventricle heart disease. <u>Findings</u>: The device’s built-in alerts assist non-clinical caregivers in making hospital-return decisions. Additionally, patient-tailored databases streamline home-to-hospital communication, reducing caregiver stress. <u>Relevance</u>: Specialized wearable technology can bridge the gap between clinical observation and home care, improving safety and psychological well-being for families managing complex pediatric conditions.

Of interest is that some of the studies imply that trust in a specific device is a social construct. That is, for many caregivers, the perceived reliability of a device depends less on technical specifications and more on “relational trust,” such as endorsements from clinical providers or alignment of the device’s data with the user’s preexisting beliefs of what the data should be (even if erroneous). This draws in the ethical landscape of pediatric wearable research, specifically addressing data privacy and participant safety. Given the vulnerability of children with CHD, it is clear that those research studies involving children do, indeed, address informed assent and the protection of sensitive physiological data stored on cloud-based platforms. The literature does acknowledge risks such as potential therapeutic misconception, where parents may over-rely on non-validated devices for acute clinical decisions, and the physical risk of skin integrity or discomfort during continuous monitoring. Surprisingly, manuscripts did not appear to extensively examine the justice dimension of digital health, in which, say, socioeconomic barriers (such as device cost and digital literacy) impact equitable access. Such an approach ensures that pediatric human-centered design is not merely viewed through a lens of convenience, but through a framework of non-maleficence and health equity.

3.2. Quantitative Review

For a scoping review to produce higher-order insights, a cross-cutting analysis is needed to identify recurring themes and significant gaps across the collective body of research. To achieve this, the analytical rubric established in Table 6 was utilized as a conceptual framework for evaluating the data. Table 8 presents the results of the cross-cutting analysis, evaluating each selected publication against the twelve user-centered criteria (A–L). The “Average Score” column provides a composite metric for each study,

calculated as an unweighted average across all assessment categories. To identify broader literature trends and research gaps, the bottom row of the table quantifies the performance of each specific criterion as a percentage across the entire set of 32 references. This structured mapping allows for a direct comparison between technical performance, wearability, and secondary user impact across the diverse study types included in this review.

Table 8. Cross-cutting analysis evaluating each selected publication against the user-centered criteria (A–L) defined in Table 6. The bottom row of the table quantifies the performance of each specific criterion as a percentage across the entire set of 32 references.

		Comfort and Wearability Criteria						Secondary User Criteria						Average
Reference		A	B	C	D	E	F	G	H	I	J	K	L	Score
1.	Bolourchi et al. [39]	1	1	9	1	1	1	2	0	0	0	0	0	1.3
2.	Brown et al. [40]	0	0	0	1	1	1	3	6	10	7	7	10	3.8
3.	Butler et al. [41]	0	0	0	0	0	0	0	10	7	3	1	1	1.8
4.	Charland and Kovesi [43]	0	0	10	7	0	1	5	10	5	5	0	0	3.6
5.	Chi et al. [44]	0	0	10	5	0	0	7	10	5	10	1	1	4.1
6.	Choo et al. [45]	7	7	10	0	0	0	10	10	10	5	4	10	6.1
7.	Dangerfield et al. [46]	1	5	10	10	1	10	10	9	9	9	1	2	6.4
8.	Ferro et al. [47]	0	0	0	10	0	5	10	10	5	10	5	2	4.8
9.	Garcia et al. [49]	0	0	10	0	0	0	10	7	7	10	0	0	3.7
10.	Hendaus et al. [52]	0	0	0	2	0	0	7	10	0	10	0	0	2.4
11.	Levin et al. [54]	0	0	10	10	0	0	7	5	5	10	10	0	4.8
12.	Lim et al. [55]	5	5	7	1	0	0	9	10	3	10	10	0	5.0
13.	Prioreschi et al. [59]	10	10	8	7	0	0	10	9	5	2	2	9	6.0
14.	Rai et al. [28]	0	0	0	0	0	0	0	10	9	10	0	0	2.4
15.	Thompson et al. [62]	0	0	8	0	0	0	9	10	10	8	8	0	4.4
16.	Wong et al. [66]	2	0	10	5	0	0	5	5	5	10	0	0	3.5
17.	Zhou et al. [67]	8	8	10	8	0	2	8	8	8	5	0	0	5.4
Percentage of Studies with score > 0		41	35	71	71	18	35	88	94	88	94	59	41	
Studies with score > 5		18	18	71	35	0	6	65	82	47	65	24	18	

Legend: A. Size and Fit; B. Skin Sensitivity; C. Data Accuracy; D. Connectivity; E. FDA Approval; F. Battery Life; G. Secondary Access; H. Perceived utility vs. psychological burden; I. Usability and integration into daily routine; J. Data trust and actionability; K. Privacy and ethical governance; L. Physical design and “social stigma”.

Several general trends can be drawn from Table 8:

- *There is a reliability gap in clinical vs. consumer devices.* A prominent trend is the stark contrast in scoring between traditional medical-grade devices and emerging wireless or consumer-grade technologies. For instance, early studies, such as Bolourchi et al., highlight that while Holter monitors are the clinical standard, their lack of comfort (Criteria A–B) often leads to poor adherence. In contrast, wireless systems are preferred by parents because they remove physical barriers to daily activities like showering.
- *High sensitivity and low specificity.* Multiple studies on continuous pulse oximetry (CPOX) show high scores for “reassurance” but low scores for technical burden. Parents find these monitors “helpful” (98% agreement), yet many also report they cause anxiety due to over-sensitivity or false alarms.
- *Prioritization of physical comfort over feature complexity.* The data indicates that the physical design of a device—specifically its weight, size, and appearance—is a primary driver of long-term compliance.
- *Aesthetic and tactical needs:* In participatory design workshops, children and parents prioritized “discreet appearance” and a “secure fit” over advanced device functions.
- *Wireless advantages:* A significant trend across the literature is the psychological benefit of wireless systems. For example, 86% of families preferred wireless EEG systems because they facilitated increased physical contact, which parents believed improved emotional health and attachment.

- *The secondary user as the “gatekeeper”*. Because pediatric patients often rely on caregivers for device management, the “Secondary User” criteria (G–L) often determine the success of a technology.
- *Digital health literacy*: Studies like Butler et al. identified that even when children are the wearers, technical barriers—such as connectivity issues, password management, and general “digital health literacy”—are significant hurdles for the parents responsible for the system setup.
- *Education as a trust-builder*: A recurring gap identified in the quantitative mapping is the lack of “device education.” Parents frequently purchase consumer-grade monitors but misunderstand their attributes; the literature suggests that providing clearer clinical guidance would significantly improve parent confidence and data interpretation.

Summary of Quantitative Trends.

- Specific percentages from the bottom of Table 8 highlight research gaps, with the general trends showing high percentages for secondary user criteria related to general helpfulness and reassurance.
- Significant gaps are reflected with lower percentages for criteria addressing adherence over time and minimized technical burden (alarms/connectivity), indicating that while devices are useful, they remain difficult to integrate seamlessly into daily family life.
- The “average values” associated with each manuscript provide insight on “depth vs. breadth.” A high average score indicates that the study did not just focus on one technical aspect (like data accuracy) but addressed multiple “human factors” such as skin sensitivity (B), perceived utility (H), and privacy governance (K). Only 6 out of the 17 listed studies (approximately 35%) achieved an average score greater than 5. These manuscripts—specifically Choo et al. [45], Dangerfield et al. [46], Lim et al. [55], Pioreschi et al. [59], and Zhou et al. [67]—represent comprehensive evidence for wearable integration in pediatric care.

In summary, current research frequently highlights the potential of wearable sensors in pediatric settings [42,56,68], yet these discussions often prioritize technical performance over comfort and “secondary user” concerns [69]. Some studies, such as Mackintosh [70] have explored the usability of devices for general physical activity and sleep monitoring, noting their utility for parental oversight in non-clinical contexts. Other research identifies attitudes and beliefs that influence the intention to use wearables, but fails to link these sentiments to specific design attributes that enhance wearability [71]. Furthermore, while the need for robust assessment tools is recognized [72], the development of such instruments falls outside our current scope.

4. Discussion

The findings of this scoping review highlight how limited and uneven the existing literature is regarding how the wearability, comfort, and secondary-user experiences are related to wearable devices for pediatric cardiology care. Although wearable monitoring technologies in general continue to expand in clinical availability, only a subset of published studies meaningfully provide actionable insight on how these devices are tolerated by children, how they fit into daily routines, or how parents and caregivers perceive their usability and acceptability. Across the literature identified as part of this scoping review, discussions of device performance tend to overshadow the lived experience of wearing them (i.e., ensuring wearability is crucial for real-world adoption of wearable devices) leaving notable gaps in understanding the practical, behavioral, and emotional dimensions that influence successful adoption. This review therefore provides a grounded synthesis of what is known about the real-world feasibility of these devices for pediatric patients and their families.

Although not immediately thought of as a “wearable” device, the topic of devices as a technology platform arises in the value of a architecture of a system for remotely monitoring pediatric patients with CHD, with the final aim of improving quality of life of the whole family and reducing hospital admissions [73]. Telemedicine platforms have not been widely used in pediatric patients with CHD, but there is evidence in the literature that they can reduce anxiety in parents and improve the outcomes.

Possibly not surprising is the absence of relevant clinical trials from ClinicalTrials.gov as trials focused more on quality of life with healthy children in mind (NCT04712136 [74]), or for special conditions such as fetal telemedicine (NCT06366711 [75]).

In the sections that follow, we draw on the 32 identified studies to examine the ten wearable devices previously mentioned in Table 1 that currently used or emerging in pediatric cardiology, focusing specifically on evidence related to wearability factors, comfort considerations, and parent and caregiver acceptance of wearable technology. Rather than evaluating sensor performance or technical specifications, our aim is to contextualize each device within the practical aspects described in the literature. By organizing the discussion device-by-device, we highlight where the literature provides actionable insights and where it remains sparse or absent. This structure also allows us to identify cross-cutting patterns that may inform future research priorities, clinical decision-making, and the design of more patient-centered and family-centered wearable technologies. We begin with device discussions ranked by direct impact on cardiac safety, diagnostic value, and frequency of use.

4.1. Pulse Oximeter

Continuous oxygen saturation (SpO₂) monitoring remains a cornerstone of postoperative care and the management of CHD, where it is vital for detecting hypoxemia and early clinical decompensation. While research continues to evaluate the technical accuracy of various form factors—including fingertip clamps and wearable devices—limited data exists regarding their specific application in pediatric populations [76,77]. This gap is significant because the efficacy of these tools is heavily influenced by caregiver interpretation and the psychological impact of home monitoring.

Recent studies highlight a concerning disparity between device reliance and parental health literacy. For instance, nearly 18% of families expressed alarm at SpO₂ readings above 95%, while many others could not define a “normal” range [43]. Despite these knowledge gaps, trust in device accuracy remains high. This often leads to increased healthcare utilization; 37% of families using consumer-grade oximeters and 60% of those with medical-grade devices reported visiting the emergency department solely due to SpO₂ concerns [43,44].

Furthermore, the clinical utility of home monitoring is often undermined by frequent false alarms, which contribute to caregiver stress and sleep deprivation [47]. While many parents find continuous monitoring reassuring and consider SpO₂ an “extremely important” metric, provider education is essential to mitigate over-reliance [44,52]. Counseling should emphasize that while pulse oximetry is a helpful adjunct, it is a complementary tool that must be balanced against clinical observation to ensure safe and effective home management [52].

4.2. Holter Monitor

While the Holter monitor remains the standard for ambulatory arrhythmia detection in pediatric cardiology, its practical application is often limited by significant logistical hurdles. Typically worn for 24 to 48 h, the device’s bulky hardware and multiple wires present a challenge for active children, frequently leading to loose connections or skin irritation from the electrodes [39]. Furthermore, the inability to shower or bathe while wearing the monitor

can be prohibitive for many families. These comfort and lifestyle restrictions often result in poor patient compliance, with many parents and children expressing a clear preference for more streamlined, patch-based alternatives like the Zio XT [39].

Despite these usability issues, the Holter monitor remains a safe, non-invasive, and high-yield diagnostic tool, particularly in emergency settings. For low-risk pediatric patients presenting to the emergency department with symptoms suggestive of arrhythmia, the device is effective at both excluding cardiac causes and capturing potentially relevant “silent” arrhythmias that might otherwise go undetected [78]. However, the diagnostic success of the Holter is contingent upon the caregiver’s ability to accurately log symptoms and ensure the child wears the device properly—a task that proves difficult with younger patients. Consequently, while Holter’s multi-lead configuration offers higher accuracy than some single-lead devices, its clinical utility is frequently balanced against the physical and emotional burden it places on the pediatric patient.

4.3. Event Monitor (External Loop Recorder)

For symptoms that occur infrequently, such as episodic syncope or palpitations, intermittent arrhythmia capture via event monitors (also known as loop recorders) is essential. Unlike standard Holter monitors, these devices are worn for several weeks, recording data when manually triggered by the user during a symptomatic episode or automatically when the device detects a rhythm anomaly. This extended monitoring window is vital for diagnosing elusive heart rhythm issues and evaluating treatment efficacy over time [79].

However, the transition of this technology into the home environment introduces significant challenges, particularly within the pediatric landscape. While event monitors provide a sense of security for families, they are often a profound source of caregiver anxiety. Research indicates that frequent false alarms are a primary stressor, often leading to a state of heightened hyper-vigilance and sleep disruption for parents [49]. Unlike adult patients who manage their own triggers, pediatric monitoring places the burden on a secondary user who must maintain electrode integrity on an active child and remember to manually trigger the device during a stressful symptomatic event, such as a fainting spell.

The logistical complexity of these devices often impacts long-term compliance and data quality. Challenges include skin irritation from prolonged adhesive use, the technical difficulty of troubleshooting device connectivity, and the psychological toll of being “tethered” to medical equipment for weeks at a time. In a home monitoring study, while only 8.1% of infants experienced a significant cardiac event [49], the universal experience was one of conflicting emotions: feeling medically secure yet emotionally drained. Understanding this delicate balance between parental security and the psychological burden of device-related anxiety is critical. Future clinical practice must prioritize secondary user education and device interoperability to improve the adoption and effectiveness of home cardiac monitoring [49,79].

4.4. Implantable Loop Recorder

While not typically categorized as traditional wearables, Implantable Loop Recorders (ILRs) offer essential long-term rhythm surveillance for high-risk pediatric patients suffering from unexplained syncope or suspected tachy/bradyarrhythmias. Although more invasive, these devices are extremely valuable for capturing rare, infrequent events that non-invasive monitors often miss. Our review did not identify any specific reference works that discussed ILR. In hindsight, this seems logical since ILR use in children has been limited by size constraints, higher risks of complications such as infection or device migration, and a lack of pediatric-specific guidelines. However, the development of miniaturized, devices [80] and specialized surgical techniques has made them increasingly viable for

smaller patients [81]. Despite the greater risks involved, ILRs remain a critical diagnostic tool when long-term data is necessary, bridging the gap between external wearables and permanent cardiac interventions.

4.5. Wearable Blood Pressure Monitor

Ambulatory blood pressure (BP) monitoring is key for hypertension evaluation, coarctation follow-up, and medication titration. Our literature search identified that wearables for the noninvasive, continuous BP measurement technique needs to evolve further to make it reliable, accurate, and user-friendly. Efforts for possible direction toward a more reliable and comfortable noninvasive continuous BP measurement technique have been explored [79], and, in spite of its long history, the measurement of blood pressure remains controversial. This is largely due to the variety of factors that influence the measurement, as well as its interpretation is a critical diagnostic cornerstone in pediatric cardiology, particularly for evaluating primary hypertension, monitoring postoperative coarctation of the aorta, and fine-tuning medication titration. Unlike static office readings, automated provides a comprehensive profile of a child's blood pressure during normal daily activities and sleep. However, its implementation in pediatric populations remains fraught with challenges, largely because current technologies often fail to account for the unique physiological and behavioral needs of children [79].

The “gold standard” remains the oscillometric cuff, yet the frequent, forceful inflation required for continuous measurement can be distressing for younger patients. This discomfort often leads to poor compliance, sleep disruption, and “white coat” effects even in the home setting. Furthermore, the accuracy of these devices is highly dependent on proper cuff sizing—a significant hurdle given the rapid growth and varying limb circumferences found in pediatrics. As noted by Silvestri [82], there is an urgent need for the technology to evolve toward more reliable, non-invasive, and “user-friendly” form factors that minimize the physical and psychological burden on the child.

Beyond hardware limitations, the interpretation of pediatric BP data remains controversial. Factors such as height, age, sex, and activity levels introduce variables that are less pronounced in adult medicine.

4.6. Respiratory Monitor

Tracking respiratory rate and physical effort is a vital component of cardiopulmonary assessment in pediatric cardiology, particularly for infants managing heart failure or pulmonary hypertension. In these populations, respiratory monitors serve as an early warning system for apnea and abnormal breathing patterns—complications that frequently arise from the complex physiological interplay inherent in CHD.

While these systems provide critical data, they are often classified as bedside or tethered monitors rather than true “wearables,” which impacts their integration into daily life [82]. Research into home cardiorespiratory monitoring suggests that patient and caregiver adherence during the first week is a primary determinant of long-term success. However, it remains to be established whether targeted clinical interventions or improved device design can effectively alter these adherence patterns. For clinicians, the challenge lies in balancing the necessity of continuous respiratory surveillance with the logistical hurdles that these non-wearable monitors place on families during the high-risk post-discharge period.

4.7. Temperature Monitor

In pediatric cardiology, fever detection is a critical clinical marker for identifying postoperative infections, endocarditis, or myocarditis. While temperature is less directly tied to acute cardiac hemodynamics than heart rate or saturation, it remains a primary driver of healthcare utilization. Parents frequently rely on numerical temperature values to

determine the severity of a “bad” fever, calibrate the timing of antipyretics, and monitor treatment response. However, this reliance is often complicated by “fever phobia”—a phenomenon where unrealistic misconceptions lead parents to view fever as a primary disease rather than a physiological sign [83].

The integration of continuous temperature monitoring, such as the iThermonitor, presents an opportunity to mitigate this anxiety and improve home management. Research indicates that most caregivers find these devices easy to adopt, reporting high levels of confidence in the data provided [84]. Crucially, unlike other cardiac monitoring modalities that can increase caregiver stress, continuous thermometry has not been associated with a rise in parental anxiety. Instead, it serves as a tool for empowerment, providing objective data that can guide parental action and reduce unnecessary medical consultations.

The variability in how parents perceive “accuracy” suggests a significant opportunity for clinicians to improve communication. By educating families on the role of fever in the recovery process and utilizing reliable digital monitoring, healthcare providers can help parents navigate febrile episodes with greater clinical confidence and less psychological distress [83,84].

4.8. Smartwatch/Fitness Band

Consumer-grade heart rate and activity data can be helpful for older children/adolescents but lacks diagnostic precision. Consumer-grade wearables, such as smartwatches and fitness trackers, are increasingly integrated into the management of chronic pediatric conditions, yet their clinical utility is often hampered by a lack of diagnostic precision and established foundational protocols [41]. While these devices are effective for promoting physical activity in adolescents and managing postoperative weight gain, real-world feasibility varies significantly [41]. For instance, longitudinal studies in high-acuity cohorts have noted that long-term adherence is often low unless the intervention is highly personalized to the child’s physical condition and individual preferences [51].

Parents view these devices with cautious optimism. They value features like continuous heart rate and oxygen saturation monitoring for motivation and “peace of mind,” yet they remain concerned about data inaccuracy, false alarms, and the potential for misinterpretation [56]. This “double-edged sword” is supported by technical evaluations: while smartwatch oxygen saturation readings are often satisfactory, their ECG and heart rate variability (HRV) capabilities frequently lack the diagnostic rigor required for medical-grade decision-making [85,86].

It appears that the existing literature on research, development, and device often prioritizes longitudinal accuracy over the secondary user experience. Studies frequently overlook caregiver burden, data overload, and the logistical challenges of device setup [81,82]. Whether applied to seizure detection or stress monitoring, the successful adoption of smartwatches in pediatric cardiology requires a shift in focus -from mere data collection to a user-centric model that integrates parental feedback, ensures privacy, and bridges the gap between consumer technology and professional medical care [56,62].

4.9. Smart Clothing

Emerging multi-sensor garments and wireless, skin-interfaced biosensors represent a transformative shift in pediatric monitoring. Constructed from soft, flexible electronics, these innovations enable the continuous tracking of heart rate, blood pressure, temperature, and oxygen saturation without the constraints of traditional wired systems [57,85,87]. By eliminating adhesive-related iatrogenic skin damage and enhancing mobility, these devices facilitate essential developmental practices such as “kangaroo care,” allowing infants to be held by caregivers during active monitoring.

Despite these advantages, clinical validation has been largely confined to controlled environments like the NICU and PICU. Their feasibility in “free-living” home conditions remains a significant question, as movement and environmental variables can impact signal reliability. Furthermore, systems designed for comprehensive vital sign monitoring often necessitate multiple sensor placements across various anatomical sites [66,86,88]. This adds logistical complexity for the caregiver and may introduce physical discomfort or restricted movement for the infant. To make these advanced garments viable for home use, future development must prioritize simplifying the setup process and ensuring that multi-sensor integration does not compromise the infant’s comfort or the device’s diagnostic accuracy.

4.10. Smart Diaper

Smart diapers are increasingly used in pediatric patients with CHD to support continuous, non-invasive monitoring of urine output, a key indicator of cardiac output and end-organ perfusion. In both hospital and home settings, especially during high-risk interstage periods, smart diapers help detect early signs of low cardiac output, renal hypoperfusion, or worsening heart failure. When used for home monitoring, they complement tools such as pulse oximetry and weight checks, enabling earlier intervention and potentially reducing preventable readmissions for medically fragile CHD infants.

Smart diaper represents an emerging class of wearable sensing technologies that, while not traditionally emphasized in the literature, offers meaningful utility in pediatrics. Although parents may not immediately think of diapers as wearables, integrating hydration and urine-output monitoring can support early detection of dehydration, feeding issues, or evolving illness. These systems provide continuous, low-burden data that can complement routine care, particularly for infants who cannot communicate symptoms. Smart diaper concepts illustrate how unobtrusive sensors can expand clinical insight and potentially inform broader physiologic monitoring strategies.

4.11. Summary of Implications

Because the preceding sections focus on device-specific details, cross-cutting themes may be less immediately apparent. This section synthesizes those findings to highlight the key overarching implications.

- Funding mechanisms prioritize biomedical outcomes. Grant review criteria emphasize measurable clinical endpoints, device accuracy, and disease specific outcomes over behavioral or contextual factors.
- Regulatory pathways focus on safety and performance, not adherence. FDA requires evidence of safety, accuracy, and risk mitigation; comfort, caregiver burden, and long term use are not central to approval.
- Pediatric human factors studies are logistically complex. Child assent, developmental variability, and the need for caregiver involvement increase study burden and cost, potentially discouraging comprehensive usability research.
- Engineering driven innovation outpaces behavioral integration. Wearables are often developed in engineering contexts where technical feasibility dominates, and human centered design expertise is not embedded early.
- Human factors constructs lack standardized measures. Comfort, acceptability, stigma, and caregiver workload are difficult to quantify, making them less competitive in traditional research frameworks.
- Real world adherence is harder to study than controlled performance. Adherence depends on family routines, child preferences, and social context—factors that require longitudinal, mixed methods designs that are costlier and slower.

- Adult derived design assumptions are often applied to children. Many devices are adapted from adult wearables without dedicated pediatric usability testing, reducing the perceived need for child specific human factors research.

4.12. Limitations

Our review has several limitations.

1. Despite providing insight into the limited data available to support regarding the wearability, comfort, and secondary-user experiences, the sample size for the scoping review was small and the search terms may not have been adequate to tease out more insights or subtle issues. The field of digital medicine continues to evolve rapidly, and investigators may use terms in their studies that we did not use in our search.
2. Our search was limited to peer-reviewed literature. It seems reasonable that we are unaware of many usability studies are undertaken by technology manufacturers—clinical trials we reviewed did not provide insight pertinent to our study objectives.

Given that our comprehensive scoping effort yielded few relevant manuscripts from the research pool, it may be worth considering whether a shift in the research question should have been explored. Our primary PubMed searches were not as productive as our pearl-growing approach, and revising our search strategy would be essential for a more complete review.

5. Conclusions

The landscape of pediatric cardiac monitoring is undergoing a significant transition from hospital-based, wired systems to integrated, home-based technologies. This shift offers the potential for early detection of decompensation and improved chronic disease management, yet it introduces a complex interplay between clinical utility and the “secondary user” experience.

Our review shows that, despite the growing promise of pediatric wearables in controlled studies, research continues to prioritize clinical efficacy and sensor performance over the human factors that ultimately shape real-world use. This pattern stems from long-standing structures in digital health research: funding priorities and regulatory pathways reward quantifiable biomedical outcomes, while elements such as parental buy-in, child comfort, and family routines remain difficult to measure and therefore routinely sidelined. We also found that rigorous human-factors studies with children face additional logistical and ethical barriers, making them more resource-intensive than traditional performance evaluations. Consequently, devices that excel in laboratory settings often fail to achieve sustained adherence once deployed in everyday environments.

The integration of wearable and ambulatory technology into pediatric cardiology marks a pivotal shift toward decentralized, longitudinal care. However, as this review demonstrates, the transition from clinical to home-based monitoring is not merely a technical challenge but a complex behavioral and psychological one. The efficacy of these devices—ranging from gold-standard Holter monitors to emerging multi-sensor garments—is intrinsically tied to the “secondary user” experience, where caregiver interpretation and burden directly influence clinical outcomes. Across the literature, caregiver burden, developmental variability, and the social context of device use consistently emerged as central determinants of success—yet they are rarely integrated early in design or evaluation. Addressing these human-centered considerations is essential for pediatric wearables to advance beyond technical feasibility and deliver meaningful, lasting benefit for children and their families.

Two major trends are identified:

- **The Paradox of Parental Reassurance and Anxiety.** A recurring theme across the literature is the dual nature of home monitoring. While continuous SpO₂ and heart rate tracking are foundational for detecting early decompensation in CHD, they often serve as significant stressors. The high incidence of false alarms in home pulse oximetry leads to “alarm fatigue” and unnecessary healthcare utilization. Conversely, continuous temperature monitoring appears to empower parents, reducing the psychological impact of “fever phobia” without increasing baseline anxiety. This suggests that the clinical value of a device must be balanced against its potential to induce hyper-vigilance.
- **Logistical Barriers to Long-Term Compliance.** Practicality remains a significant hurdle for pediatric adoption. Traditional tools like the Holter monitor and Ambulatory BPM provide high diagnostic yield but are frequently hindered by their physical form factors. Multiple wires, bulky cuffs, and the inability to maintain normal hygiene (e.g., showering) create prohibitive barriers for active children and their caregivers. While newer, patch-based monitors and miniaturized Implantable Loop Recorders (ILRs) offer more streamlined alternatives, their use is often limited by a lack of pediatric-specific guidelines and the inherent risks of invasiveness in smaller patients.

Future Directions

Advancements must move beyond mere technical accuracy to address the psychological and logistical burdens placed on caregivers. While tools like continuous thermometry have shown the potential to empower parents, others—such as home pulse oximeters—frequently trigger anxiety and healthcare overutilization due to false alarms and a lack of health literacy.

Pediatric-centered wearable design in CHD should prioritize technologies that are not only clinically informative but also developmentally appropriate and family-centered. Wearables are currently designed for functionality but can also be designed with child-specific physiology, growth patterns, and activity levels in mind, incorporating comfortable materials, intuitive interfaces, and minimal obtrusiveness to support long-term adherence. Future innovations should emphasize seamless integration of data into clinical workflows, enabling real-time monitoring and early detection of decompensation while reducing caregiver burden. Recommendations include co-designing devices with children, caregivers, and clinicians; ensuring interoperability with electronic health records; and embedding equity-focused features such as affordability and accessibility. By aligning technological advancement with pediatric needs and family experiences, wearable technologies can evolve from passive monitoring tools into proactive support that improve outcomes and quality of life for children living with CHD.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/computers15020109/s1>, Table S1: Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist; Table S2: PRISMA 2020 Checklist.

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