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(REVIEW ARTICLE)

Health-related device instrumentation for healthcare improvement: A critical review of design, integration, performance and lawful adaptation frameworks

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Abstract

Healthcare engineering is increasingly shifting from de novo device invention toward instrumentation-based adaptation of existing care technologies, augmenting mature mechanical platforms with sensing, control, automation, and connectivity to improve safety, efficiency, and clinical decision support. This review synthesizes evidence across point-of-care testing (POCT), hand sanitation devices, assistive patient positioning systems, wearables, and Internet of Medical Things (IoMT) ecosystems, motivated by publication growth (2010–2025) indicating sustained expansion of POCT and hygiene-device engineering research. We critically examine how instrumentation choices translate into real-world healthcare impact through three interlinked dimensions: (i) design (sensor selection, hardware architecture, power management, reliability, and human factors), (ii) system integration (embedded platforms, interoperability, cybersecurity, and data governance), and (iii) performance evaluation (accuracy, precision, robustness, latency, safety, scalability, and regulatory validation readiness) in alignment with the United Nation's Sustainable Development Goals 3, 9, 10 and 17 as well as patent laws. Across domains, recurring limitations are systemic rather than purely device-specific: POCT platforms remain constrained by manual sample handling and heterogeneous validation practices; hygiene systems show gains from non-contact actuation but often lack analytics for optimization; assistive positioning devices suffer from insufficient sensing and automation despite strong ergonomic need; and wearable/IoMT systems face persistent barriers in battery life, drift/motion artifacts, data overload, interoperability, and cybersecurity. To address fragmented reporting and weak comparability, the review consolidates a regulatory-aligned metrics framework linking analytical performance, repeatability, operational robustness, real-time behavior, safety risk reduction, and system scalability to standards-based verification and validation constructs. Importantly, we position data governance and regulatory frameworks (quality management, risk management, software lifecycle, usability engineering, and electrical safety) as pivotal determinants of scalability, cost, and deployment feasibility, especially in resource-constrained settings where infrastructure, maintenance capacity, and supply-chain constraints dominate outcomes. The review concludes that modular, non-invasive, and patent-conscious instrumentation can deliver credible, scalable healthcare upgrades when integration and evaluation are structured around risk-based, standards-conformant evidence generation, and when interoperability and cybersecurity are treated as safety-critical design requirements.

Keywords: Instrumentation-based adaptation; Point-of-care testing; Interoperability; Internet of medical things; Data governance and cybersecurity; Regulatory compliance

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1. Introduction

A growing consensus in healthcare engineering is that meaningful improvements in care delivery can be achieved not only by developing entirely new medical devices, but, often more efficiently, by adapting and instrumenting existing care devices with sensing, control, and automation capabilities [1-5]. Many devices currently deployed in clinical and community healthcare settings possess mature mechanical designs, proven usability, and established workflows, yet remain limited by the absence of integrated instrumentation for monitoring, automation, and data-driven decision support [6-8]. Instrumentation-driven adaptation leverages these existing platforms to enhance functionality while avoiding the cost, time, and regulatory complexity associated with de novo device development. This approach is particularly compelling for point-of-care testing (POCT) devices, where the integration of automated fluid handling, embedded sensors, and digital signal processing can improve diagnostic accuracy and reduce operator dependence [9-13] hand sanitation-related devices, where non-contact, sensor-based actuation and usage monitoring have been shown to reduce cross-contamination and pathogen transmission [14-18], and assistive patient-positioning devices used during surgeries and clinical care, where instrumented mechanical systems can minimize manual repositioning by healthcare workers, thereby reducing contamination risks, occupational injuries, and human-factor variability [19-23]. Collectively, these examples underscore the strategic value of adapting existing healthcare devices through targeted instrumentation as a pragmatic pathway for healthcare system upgrade, particularly in high-throughput, infection-sensitive, and resource-constrained environments over the years (Figure 1).

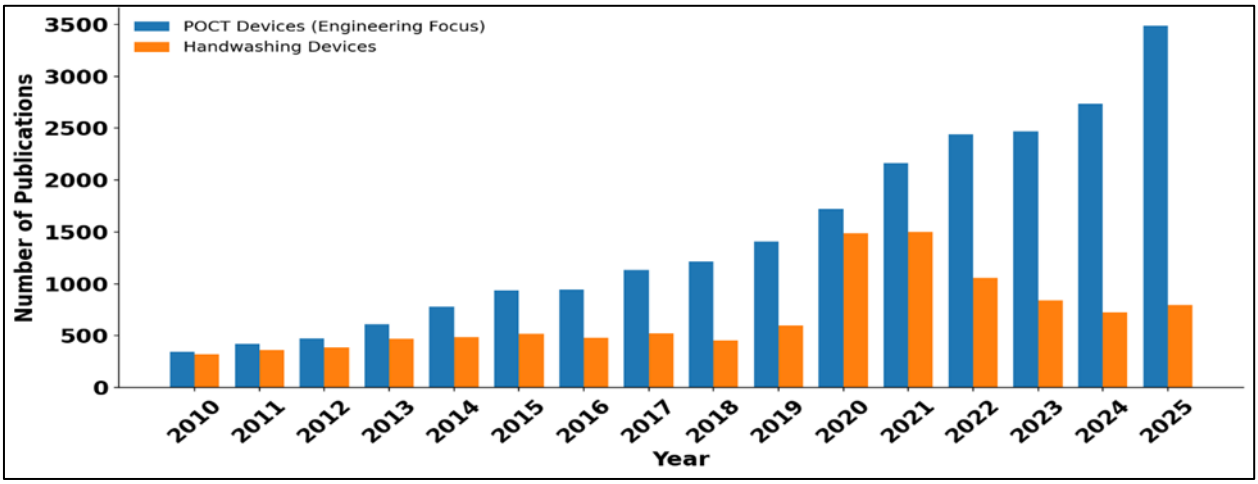

Figure 1 Publication Trend (2010-2025): Handwashing and POCT Devices (Source: Scopus)

However, despite the demonstrated potential of instrumentation-driven adaptation across POCT, sanitation, and patient-assistive devices, existing studies remain fragmented and application-specific, providing limited critical insight into how design, lawful integration, and validation jointly shape real-world healthcare impact, and highlighting the need for a focused cross-domain review.

1.1. Innovative Advancements and Lawful Adaptation Frameworks

Healthcare systems worldwide are undergoing a rapid transformation driven by increasing clinical demand, aging populations, recurrent public-health crises, and the growing need for efficient, data-driven care delivery. Central to this transformation is the evolution of health-related devices, which increasingly rely on advanced instrumentation, embedded sensing, and intelligent data acquisition to enhance diagnostic accuracy, therapeutic effectiveness, and patient safety [24-28]. Instrumentation, defined here as the integration of sensors, signal conditioning, data processing, and communication capabilities into healthcare devices has become a foundational enabler of modern medical technologies, ranging from wearable monitoring systems to automated clinical assistive devices [29-33]. Recent advances in microelectronics, MEMS sensors, wireless communication, and embedded intelligence have significantly expanded the functional capabilities of health-related devices. These developments allow real-time physiological monitoring, remote diagnostics, closed-loop control, and interoperability with digital health infrastructures such as electronic health records (EHRs) and telemedicine platforms [34-38]. Importantly, many of these advances are increasingly realized through the instrumentation-based adaptation of existing device platforms, rather than the creation of entirely new medical devices, enabling incremental innovation within established clinical workflows and regulatory pathways.

From a legal and innovation-governance perspective, this trend aligns with established patent and regulatory frameworks that permit lawful modification, design-around strategies, and functional augmentation of existing inventions, provided that protected claims are respected and freedom-to-operate is maintained. Effective governance in innovative health related device instrumentation requires balancing patent protections with public health interest by ensuring access to life-saving technologies and also incentivises innovation which is crucial for achieving Sustainable Development Goal (SDG) 3- Good health and well-being.

Such patent-conscious adaptation supports responsible innovation by allowing inventors, researchers, and healthcare providers enhance device performance, safety, and usability without duplicative redevelopment of core technologies. Consequently, instrumentation serves not only as a technical enabler but also as a mechanism for legally compliant innovation as illustrated in Figure 2, particularly in applied healthcare settings where rapid deployment and scalability are essential.

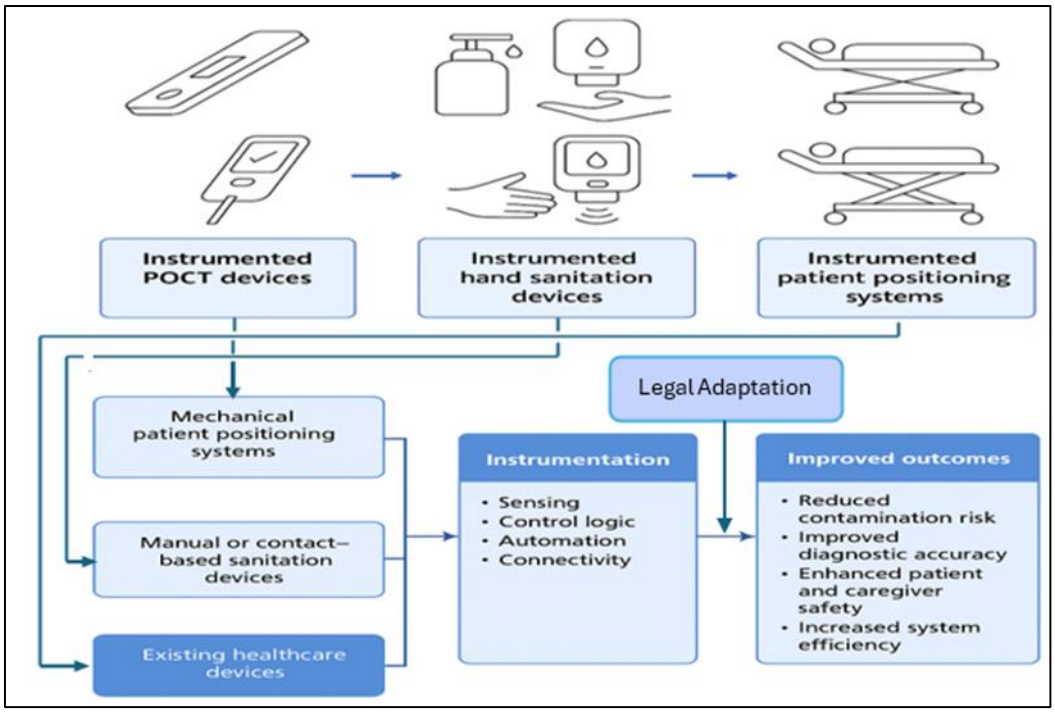

Figure 2 Instrumentation-driven Adaptation across healthcare domains with conceptual pathway for upgrade. Adapted from [38-42]

As a result, device instrumentation now plays a critical role in enabling healthcare system upgrades, particularly in improving responsiveness, continuity of care, and resource utilization across both high-income and resource-constrained settings [43-47]. Despite this progress, the rapid proliferation of instrumented health devices has introduced new technical, clinical, and systemic challenges. Studies consistently report limitations related to sensor accuracy, calibration drift, power consumption, cybersecurity vulnerabilities, interoperability gaps, and inconsistent performance validation, which collectively hinder large-scale adoption and clinical trust [48-52].

Moreover, while many instrumented devices demonstrate promising laboratory-level performance, their translation into re.iable and sustainable healthcare solutions remains uneven due to fragmented design practices, heterogeneous validation methodologies, and limited consideration of regulatory and intellectual-property constraints during early-stage development [53-54]; [7]; [5]. These challenges highlight the need for a critical synthesis of existing research on health-related device instrumentation, with emphasis not only on technological advances but also on how design decisions, integration strategies, performance evaluation approaches, and patent-respectful adaptation pathways collectively influence healthcare improvement outcomes. While prior review studies have addressed specific subdomains such as wearable sensors, the Internet of Medical Things (IoMT), or smart medical devices, there remains a shortage of integrative reviews that critically compare instrumentation approaches across device classes while situating them within applicable legal and innovation frameworks [55-59].

1.2. Scope, Classification and Adaptation Framework

The central problem addressed in this review is the absence of consolidated, critical insight into how instrumentation strategies in health-related devices either enable or constrain measurable improvements in healthcare systems via legal adaptation of existing non-instrumented health solutions. Current evidence remains fragmented across engineering, clinical, and digital health literatures, which obscures best practices, recurring design limitations, and real-world performance trade-offs that shape deployment outcomes [5, 60]. Compounding this, studies often report performance using heterogeneous metrics and validation protocols, making cross-study comparison difficult and weakening the basis for evidence-informed design and procurement decisions [48, 49].

Accordingly, this review covers instrumented health-related devices used for monitoring, diagnosis, assistance, and therapeutic support across both clinical and non-clinical environments, focusing on three interlinked dimensions: (i) design (sensor selection, hardware architecture, power management, and user-centred considerations), (ii) system integration (embedded platforms, connectivity, interoperability, and data management), and (iii) performance (accuracy, robustness, validation approaches, and clinical relevance). The review aims to (1) synthesise and classify dominant instrumentation approaches [32, 33], (2) evaluate integration strategies for interoperability within IoMT and remote-care ecosystems [37, 59], (3) assess how metrics and validation methods are defined and applied, identifying inconsistencies that impede clinical translation [48, 49], (4) surface technical and practical constraints affecting scalability, reliability, and low-resource deployment [7, 45], and (5) highlight emerging research directions to support sustainable, system-level healthcare improvements through robust device instrumentation. Table 1 shows the governance adaptation of existing devices

Table 1 Studies on design, Integration, Performance, and Lawful Adaptation Frameworks'

Study/Device ID	Device Focus and Care setting	Instrumentation approach	Integration & architecture (hardware/power/connectivity/interoperability)	Performance & validation (comparability)	Deployment feasibility: (scale + low-resource)	Key implications	Legal Adaptation Procedure
Majumder et al. [5], 'Wearable Sensors for Remote Health Monitoring'	Wearables & remote monitoring — Home/community with clinical oversight	Non-invasive wearable sensing; smart textiles; body sensor networks	Emphasises design trade-offs (battery, usability) and need for compatible communication; interoperability often ad hoc in reported systems	Review-level synthesis; highlights fragmented metrics/protocols across studies	Battery life + usability + interoperability repeatedly constrain real-world deployment	Demonstrates why instrumentation + communication must be co-designed for adoption at scale	Apply QMS + risk mgmt + software/usability controls when modifying devices: ISO 13485, ISO 14971, IEC 62304, IEC 62366-1; for EHR integration, align to HL7 FHIR; for software changes in cleared devices, follow FDA "when to submit" framework
Pantelopoulos & Bourbakis [7], 'Survey on wearable sensor-based system'	Wearable sensor systems — Ambulato	Multiparameter physiological sensing + transmission modules	Wireless transmission central; interoperability recognized as a limitation in practice	Validation methods vary across systems; no shared	Integration maturity and mainten	Positions instrumentation as an enabler of proactive monitoring, but	Use lifecycle risk management and usability/sof

	ry and home use			consensus on test parameters in the surveyed landscape	ance burden are recurring constraints	highlights maturity gaps	tware controls for adaptations: ISO 14971 + IEC 62366-1 + IEC 62304 (where software exists)
Islam et al. [38], 'Wearable cuffless BP devices: systematic review/meta-analysis	Cuffless BP wearables — Home/community with clinical use	PPG-dominant; also tonometry/ECG variants	Device/app ecosystems vary; interoperability not consistently addressed across studies	Focus on bias/validity vs reference; explicitly notes that precision criteria (e.g., SD) are often omitted or inconsistently applied	Model/device variability undermines comparability; scaling requires consistent validation evidence	Reinforces need for standardised validation to support clinical translation	For algorithm/software updates, apply risk-based change control + FDA software-change decision logic (if applicable), with ISO 14971 documentation updates
Kim et al., [61], 'Wearable biosensors for healthcare monitoring'	Wearable biosensors — Mixed settings (home + clinical)	Electrochemical + optical biosensors; microfluidics + flexible materials	Miniaturization and wearability emphasized; system integration varies by platform	Calls for large-cohort validation and improved reliability; highlights biofluid correlation challenges	Scaling assays and maintaining robustness remain challenges	Sets requirements for clinical acceptance (robustness, validation, reliability)	Use ISO 14971 risk management integrated with biological evaluation planning where relevant; apply usability

							engineering as needed
Osama et al. [62], 'IoMT & Healthcare 4.0: Trends/requirements/challenges'	IoMT ecosystems — Remote care and health-system settings	IoT/AI/edge/cloud enabling technologies	Emphasizes 5G/edge/cloud and system requirements (security, latency, etc.)	Review-level; focuses on requirements rather than uniform KPIs	Implementation depends on infrastructure and governance capacity	Frames integration/interoperability/security as prerequisites for scalable remote care	Use HL7 FHIR for exchange + QMS/risk governance for lifecycle change; consider PCCP-style structured change planning where relevant
Seth et al. [63], Interoperable IoMT platforms for home/prehospital care'	IoMT interoperability platforms — Home and prehospital care	Multi-device IoMT platforms (systems view)	Interoperability is central; best-practice technologies identified for higher-level interoperability	Scoping review approach; comparability limited by diversity of platforms and interoperability levels	High integration burden; dependent on connectivity and governance	Treat interoperability as safety-critical for remote and prehospital workflows	Align device-to-system exchange to FHIR, document security/auditability; maintain QMS evidence trails for integration changes
WHO [45], 'Compendium of innovative health technologies for low-resource settings'	Innovative health technologies — Low-resource settings	Device-dependent (varies)	Includes lifecycle assessment domains (clinical, technical specs, regulatory, engineering management, IP/local production)	Evidence basis varies by technology; comparability depends on consistent assessment basis	Strong emphasis on deployability: supply chain, management, local	Provides benchmark for what "deployable" means in constrained environments	Document regulatory pathway + risk management updates for any local adaptation; ensure verification

					production feasibility		evidence and lifecycle management documentation
Badawi et al. [64], 'ISO/IEEE 11073 Personal health device standards compliant systems review'	PHD systems (incl. weight scales) — Home/telehealth	Standardisation/adaptation techniques for PHDs	Highlights conversion from non-standard to standard devices as a practical pathway	Notes proportion of standardized vs non-standard devices; discusses adoption challenges	Standardisation reduces integration complexity; adaptation effort still non-trivial	Provides a concrete interoperability route for scaled telehealth deployments	Apply ISO/IEEE 11073 for PHD, verify conversions; add security/privacy controls and QMS documentation for integration changes
HL7 FHIR [65], (FHIR overview/specification)	Health data exchange for EHR integration — Health-system settings	Resource-based exchange standard (FHIR resources)	API-focused; supports structured exchange and extensions	Standardizes healthcare data representation/exchange, improving interoperability	Scales well with governance and profiling; avoids brittle proprietary mappings	Enables consistent integration of device data into clinical workflows	Use FHIR profiles + transformation validation + provenance/audit; ensure governance under QMS where regulated
FDA [66], 'Deciding When to Submit a 510(k) for a Software Change'	Software change-control guidance — Regulated markets	Applies to software/firmware modifications	Provides least-burdensome decision framework for change submissions	Not a KPI/validation paper; a regulatory decision tool	—	Supports predictable compliance for iterative updates	Use decision framework; document risk impact; update verification/validation

							evidence and records
ISO 14971 [67], 'risk management for medical devices'	Risk management standard — All care settings	Hazard identification → control → post-market loop	Lifecycle governance for safety impacts	Standard framework rather than KPIs	—	Essential for safe scaling and change control	Foundation for "lawful adaptation" evidence
ISO 13485 [68], 'medical device QMS'	QMS standard — All care settings	Design controls, traceability, CAPA, supplier controls	Governs how adaptations are documented and audited	Standard framework rather than KPIs	—	Enables scalable compliance across lifecycle	Backbone for lawful adaptation documentation
IEC 60601-1 [69], 'medical electrical safety overview'	Medical electrical equipment safety — Clinical settings	Safety & essential performance of medical electrical equipment	Determines test and compliance burden for powered/instrumented devices	Not a KPI source; compliance standard	—	Can be a major barrier if not designed-in early	Critical for patient-connected instrumentation
IEC 62304 [70], 'medical device software lifecycle'	Medical software lifecycle standard: All care settings	Development/maintenance/configuration management for medical software	Supports controlled software evolution and maintenance	Process standard rather than KPI	—	Enables safe scaling of software updates	Central for lawful software adaptation
IEC 62366-1 [71], 'usability engineering'	Usability/ human factors standard: Clinical and home settings	Usability process linked to safety (use errors)	Reduces use-related risk via structured evaluation	Process standard rather than KPI	—	Improves adoption and safety in real settings	Important for workflow/UI adaptation

Based on the Table 1, wearables studies focus on home/ambulatory patient sensing and show that adoption is constrained by battery life, usability, and inconsistent validation/comparability, whereas IoMT work shifts to system-level remote and prehospital integration where feasibility depends on connectivity, security, and governance and interoperability becomes safety-critical; interoperability standards (ISO/IEEE 11073, HL7 FHIR) reduce integration friction by standardizing data exchange, while WHO low-resource guidance emphasizes deployability constraints, and regulatory/QMS standards frame all adaptations through risk management, software/usability control, and safety compliance to make scaling both credible and lawful.

2. Overview of Health-Related Device Instrumentation

Health-related device instrumentation refers to the systematic integration of sensing, signal conditioning, data processing, and communication components into healthcare devices to enable measurement, automation, control, or decision support beyond the device's original mechanical or structural function [4, 7]. In this context, instrumentation does not necessarily imply the creation of entirely new medical devices; rather, it emphasizes the augmentation of existing or conventional care devices with embedded intelligence that enhances performance, safety, and usability [5, 33].

Instrumented health devices can be broadly classified based on functional purpose, level of integration, and deployment context. From a functional perspective, the literature commonly distinguishes between:

- Monitoring devices, which acquire physiological or environmental data (for example, wearable sensors, vital-sign monitors);
- Diagnostic devices, including instrumented poct platforms that incorporate sensing, microfluidics, or signal processing to support rapid decision-making;
- Assistive and therapeutic devices, such as patient-handling or positioning systems enhanced with sensors or actuators; and
- Preventive and hygiene-related devices, where instrumentation enables non-contact operation, usage logging, or compliance monitoring [10, 58, 28].

From an integration standpoint, devices may be categorized as partially instrumented systems, in which instrumentation supports a single function (for example, proximity-triggered actuation in hand sanitation devices), or fully instrumented systems, where sensing, control, data processing, and communication are tightly coupled in a closed-loop architecture [72, 37, 38, 73]. Studies consistently show that even limited instrumentation such as adding proximity sensors, force sensors, or basic microcontrollers can substantially reduce human error and contamination risks without altering the core device structure [74, 75, 189, 17, 23]. Deployment context further distinguishes instrumented devices designed for hospital-based clinical care, outpatient or community settings, and resource-constrained environments, where robustness, cost, and ease of maintenance are often prioritized over advanced analytics [76-79]. This classification is particularly relevant for POCT and sanitation devices, where instrumentation strategies must balance diagnostic performance with affordability and operational simplicity [80, 12, 59, 81].

2.1. Evolution and Current Trends

The evolution of health-related device instrumentation closely parallels advances in electronics, sensing technologies, and embedded systems. Early generations of medical devices relied primarily on analog instrumentation, focusing on basic signal acquisition and display, often confined to centralized clinical settings [82, 32]. With the advent of low-power microcontrollers and digital signal processing, instrumentation expanded to support portable and bedside devices, enabling broader adoption of monitoring and diagnostic technologies [83, 7, 84, 5]. Over the past decade, the field has shifted toward miniaturized, distributed, and networked instrumentation, driven by developments in MEMS sensors, wireless communication, and embedded computing [85, 86, 37, 38, 87]. These advances have facilitated the instrumentation of devices traditionally considered non-electronic, such as hand sanitation systems and patient-positioning aids, transforming them into semi-automated or smart assistive tools capable of reducing caregiver workload and contamination exposure [22, 23].

Current trends emphasise instrumentation-driven adaptation (Figure 3) rather than wholesale device replacement, particularly in response to global healthcare system pressures. In POCT, for example, recent studies highlight the integration of optical, electrochemical, and biosensing instrumentation into compact platforms, improving sensitivity and reproducibility while preserving established testing workflows [88, 13, 10, 12]. In hygiene and infection-control domains, non-contact, sensor-based actuation and monitoring have become increasingly prevalent, supported by

evidence linking automated sanitation systems to improved compliance and reduced pathogen transmission [89, 90, 18, 17].

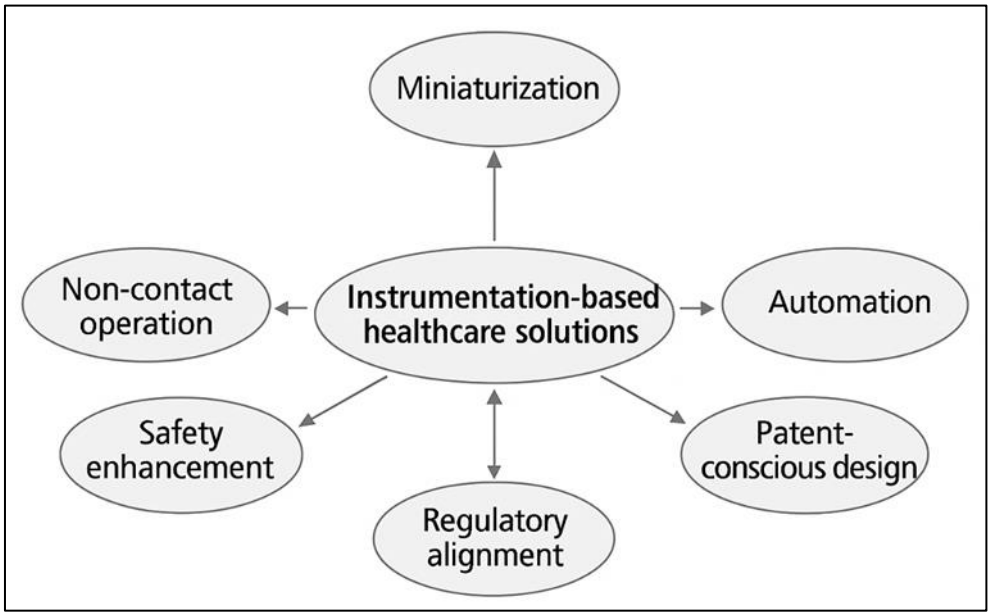

Figure 3 Current trends driving instrumentation-based healthcare solutions

Concurrently, the convergence of instrumentation with IoMT, edge computing, and data analytics is reshaping expectations for device interoperability and performance evaluation (Figure 3). Instrumented devices are increasingly designed to interface with digital health infrastructures, prompting renewed focus on calibration stability, cybersecurity, and validation under real-world operating conditions [48-50]. These trends underscore a broader shift from isolated device functionality toward system-level healthcare improvement, where instrumentation acts as a critical enabler of safety, efficiency, and scalability, which are based on device overall designs.

3. Design Considerations and Architectures

The design of instrumented health-related devices requires a multidisciplinary approach that balances technical performance, clinical usability, safety, and long-term reliability [91-93]. Unlike conventional device development, instrumentation-driven adaptation often operates within existing mechanical structures, form factors, and regulatory constraints, making careful design trade-offs essential. This section reviews key design considerations related to sensing technologies and hardware architecture, power management, reliability, and safety, and user-centered and clinical constraints.

At the core of any instrumented health-related device is the selection and integration of appropriate sensing technologies, which determine the accuracy, responsiveness, and clinical relevance of the system. Commonly employed sensors include optical, electrochemical, pressure, force, proximity, inertial, and biosensors, each chosen based on the physiological variable or operational parameter being measured [32, 58]. For POCT devices, for example, optical and electrochemical biosensors are widely used to detect analytes with high sensitivity, while proximity and force sensors are frequently employed in sanitation and assistive devices to enable non-contact operation and controlled mechanical actuation [10, 23].

Hardware architecture design extends beyond sensor selection to include signal conditioning, analog-to-digital conversion, embedded processing, and communication interfaces. Modern instrumented devices increasingly rely on modular and scalable architectures, often built around low-power microcontrollers or system-on-chip platforms, which facilitate adaptation of existing devices while minimizing redesign complexity [7, 33]. Studies emphasize that modular architectures not only support rapid prototyping and functional upgrades but also align with lawful design-around and freedom-to-operate strategies by enabling functional enhancement without altering patented core mechanisms [5].

Additionally, the integration of wired or wireless communication modules, such as Bluetooth Low Energy, Wi-Fi, or near-field communication allows instrumented devices to interface with external displays, data-logging systems, or

digital health platforms [37, 38]. However, hardware complexity must be carefully managed to avoid unnecessary increases in cost, power demand, and failure risk, particularly in resource-constrained healthcare settings.

3.1. Power Management and Clinical Design Constraints

Power management is a critical design consideration for instrumented health-related devices, especially those intended for portable, wearable, or intermittently powered use. Energy efficiency directly affects device autonomy, maintenance burden, and user acceptability. Common strategies include the use of low-power components, duty-cycling of sensors, event-based activation, and energy-efficient communication protocols, all of which have been shown to significantly extend operational lifetime [7, 5]. Reliability is equally essential, as instrumented devices are often deployed in safety-critical or infection-sensitive environments. Reported failure modes include sensor drift, signal noise, mechanical wear, and power instability, which can compromise data integrity and clinical trust if not adequately addressed [48, 33]. Long-term calibration stability and fault-tolerant design are therefore emphasized in the literature, particularly for devices supporting diagnostic or assistive functions.

Safety requirements further shape design decisions, encompassing electrical safety, electromagnetic compatibility, mechanical robustness, and infection-control considerations. Non-contact sensing and automated actuation have gained prominence as design responses to contamination risk, especially in sanitation and patient-handling applications [18, 17]. Moreover, as instrumented devices increasingly connect to digital health infrastructures, cybersecurity and data-protection measures are now recognized as integral to patient safety, rather than optional system features [49, 50].

Beyond technical performance, successful instrumentation requires close alignment with user-centered and clinical design principles. Healthcare devices are operated by diverse user groups, clinicians, caregivers, and patients with varying levels of technical expertise, time constraints, and environmental pressures. Consequently, instrumented devices must prioritize intuitive operation, minimal training requirements, and seamless integration into existing clinical workflows [22, 23], as some of these classes of devices can be enhanced through instrumentation as shown in Table 2.

Clinical constraints frequently dictate strict limits on device size, weight, response time, and maintenance procedures. In POCT and sanitation applications, for instance, the need for rapid turnaround and high throughput places significant emphasis on ease of use and operational consistency [12, 10]. Similarly, assistive patient-positioning devices must account for ergonomic safety, load variability, and compatibility with sterile or semi-sterile environments. Importantly, user-centered design in the context of instrumentation-based adaptation must also consider regulatory and intellectual-property boundaries, ensuring that modifications enhance usability and safety without compromising compliance or device integrity. Studies increasingly emphasize participatory design approaches and iterative clinical feedback as effective strategies for aligning instrumentation upgrades with real-world healthcare needs [22, 45].

Table 2 Instrumentation-based constraints and adaptation across health-related device classes

Device class	Study summary (with citations)	Method used	Findings / remarks / bias	Instrumentation-driven improvement methods
POCT devices (general)	Early and contemporary POCT studies emphasize rapid diagnostics but report strong dependence on manual sample handling and user expertise, limiting reproducibility despite high analytical sensitivity [10, 12].	Experimental prototyping; clinical validation	Bias toward laboratory environments; limited field realism	Automated microfluidics; embedded biosensors; digital signal processing; internal calibration
POCT in low-resource settings	Field studies show performance degradation of POCT	Field deployment trials;	Contextual bias; under-instrumented designs	Ruggedized sensors; low-power electronics; onboard diagnostics

	devices in resource-constrained settings due to environmental stressors and lack of instrumentation for robustness [12, 45].	observational analysis		
Hand sanitation devices	Infection-control literature consistently links manual or contact-based hygiene systems to cross-contamination and inconsistent compliance [17].	Compliance audits; intervention studies	Focus on behavior rather than device design	Proximity sensing; non-contact actuation; compliance monitoring
Automated hygiene systems	Studies on automated dispensers demonstrate improved compliance but note limited feedback and data capture for optimization [18].	Controlled trials; hospital studies	Limited instrumentation beyond actuation	Usage analytics; sensor-based feedback; connectivity
Assistive patient-positioning devices	Ergonomic studies report high rates of caregiver injury and contamination risk from manual patient handling, with limited sensing in assistive tools [22, 23].	Ergonomic analysis; workflow observation	Bias toward mechanical solutions	Force and load sensors; motorized actuation; closed-loop control
Surgical positioning aids	Clinical workflow studies identify positioning inaccuracies and infection risks during intraoperative manual adjustments [23, 32].	Safety assessments; observational studies	High operator variability	Position sensors; automated alignment; sterile non-contact controls
Wearable monitoring devices	Wearable sensor literature demonstrates strong monitoring capability but highlights challenges with power consumption, drift, and motion artifacts [5, 58].	Longitudinal monitoring; system validation	Usability underreported	Sensor fusion; adaptive filtering; power-management instrumentation
Wearables for chronic disease	Disease-specific wearable studies show clinical value but reduced long-term adherence due to user fatigue	Clinical trials; adherence analysis	Bias toward short-term outcomes	Context-aware sensing; adaptive sampling; user feedback loops

	and maintenance burden [46, 5].			
Remote patient monitoring	Home-based monitoring literature reports data overload and clinician burden from continuous instrumentation [46, 38].	Platform development; pilot studies	Connectivity prioritized over clinical usability	Edge analytics; event-driven sensing; intelligent alerts
IoMT-enabled devices	IoMT surveys highlight scalability benefits alongside cybersecurity and interoperability challenges [38, 59].	Architecture design; simulation	Security often treated as secondary	Secure communication; standardized protocols; embedded encryption
Legacy medical devices	Retrospective surveys show many legacy devices remain under-instrumented due to regulatory and IP concerns rather than technical infeasibility [7, 33].	Design surveys; technical audits	Innovation avoidance bias	Non-invasive sensor add-ons; modular instrumentation
Diagnostic assistive tools	Imaging and diagnostic workflow studies report operator-dependent variability and lack of real-time guidance [32].	Clinical performance analysis	Hardware-centric bias	Instrumented alignment sensors; embedded decision support
Clinical workflow support devices	Human-factors research identifies workflow disruption caused by poorly instrumented tools lacking contextual awareness [22].	Time–motion studies; usability testing	Limited systems thinking	Context-aware sensing; task-triggered automation
Infection-sensitive care devices	Cross-cutting safety literature during outbreaks highlights human contact as a primary contamination vector [18, 45].	Safety audits; emergency deployment studies	Reactive rather than proactive design	Non-contact sensing; automated actuation; compliance logging
Regulatory-constrained devices	Policy-oriented studies note that fear of infringement and re-certification slows innovation, even when technical upgrades are low-risk [7, 45].	Regulatory and standards analysis	Conservative design bias	Patent-conscious instrumentation; design-around strategies

Table 2 synthesizes representative study groups across diagnostic, preventive, assistive, monitoring, and networked healthcare devices, revealing that dominant performance and adoption constraints are largely systemic rather than device-specific. Across domains, limitations consistently arise from high dependence on human operation, lack of sensing and feedback, safety and contamination risks, power and reliability challenges, and regulatory or intellectual-property conservatism, rather than from deficiencies in core mechanical design. While POCT and hygiene-related devices are primarily constrained by manual handling and contact-based operation, assistive and workflow-integrated devices suffer from insufficient automation and real-time feedback, and wearable and IoMT-enabled systems face escalating challenges related to power management, data burden, interoperability, and cybersecurity. Collectively, these patterns position instrumentation applied modularly and, in a patent-conscious manner as a cross-domain enabling strategy capable of mitigating recurring constraints without necessitating wholesale device reinvention. Building on this synthesis, the following section examines how system integration and connectivity architectures translate instrumentation-level design choices into scalable, interoperable healthcare solutions.

4. System Integration and Connectivity

The effectiveness of instrumented health-related devices depends not only on sensing and hardware design, but also on robust system integration and connectivity architectures that enable reliable data acquisition, interoperability, and secure information exchange. As healthcare systems increasingly rely on distributed and data-driven care models, integration considerations have become central to translating device-level instrumentation into scalable clinical value.

4.1. Embedded systems, data-acquisition and Interoperability

At the device level, system integration is typically realized through embedded computing platforms that coordinate sensing, control, data processing, and communication functions. Contemporary instrumented health devices commonly employ low-power microcontrollers or system-on-chip architectures to support real-time data acquisition while maintaining energy efficiency and compact form factors [7; 33]. These embedded systems enable event-driven sensing, local preprocessing, and conditional actuation, which are particularly important for POCT, sanitation, and assistive devices operating under time-critical or resource-constrained conditions. The emergence of the Internet of Medical Things (IoMT) has further expanded integration requirements by connecting instrumented devices to local gateways, cloud platforms, and clinical information systems. IoMT-oriented frameworks emphasize modular data acquisition pipelines, often combining edge-level preprocessing with higher-level analytics to reduce data volume and latency [38, 59]. Studies consistently highlight that effective IoMT integration depends on balancing computational load across device, edge, and network layers, ensuring that connectivity enhances rather than burdens clinical workflows.

Beyond device-to-device communication, instrumented health technologies must interoperate with existing healthcare infrastructure, including electronic health records (EHRs), hospital information systems, and telemedicine platforms. Lack of interoperability remains a persistent barrier to adoption, as heterogeneous data formats, proprietary interfaces, and inconsistent communication standards prevent seamless integration into clinical workflows [37, 38].

The literature increasingly emphasizes standardized data models, open communication protocols, and middleware solutions as mechanisms for improving interoperability without requiring fundamental redesign of existing devices [59]. For instrumentation-based adaptation of legacy systems, this approach is particularly critical, as it allows enhanced functionality, such as automated reporting or remote monitoring while preserving established device configurations and regulatory certifications. Interoperability thus functions not only as a technical requirement, but also as a facilitator of scalable and patent-conscious innovation within healthcare ecosystems (Figure 4).

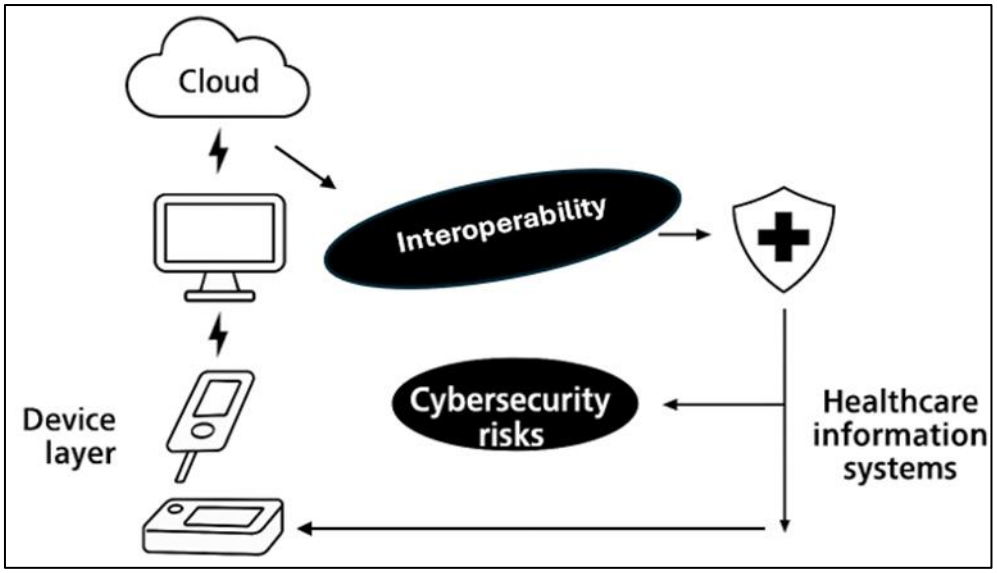

Figure 4 Cybersecurity and interoperability challenges of instrumented health-related devices. Adapted from [38; 59; 49]

4.2. Cybersecurity challenges and Performance Evaluation

As connectivity increases, cybersecurity and data integrity have become integral design considerations rather than ancillary concerns. Instrumented and networked health devices handle sensitive clinical data and, in some cases, directly influence therapeutic actions, making them attractive targets for cyber threats and system misuse [48]. Documented vulnerabilities include insecure communication channels, insufficient authentication mechanisms, and weak protection of stored data, all of which undermine clinical trust and regulatory compliance.

Recent studies stress that cybersecurity must be addressed across the full integration stack, incorporating secure communication protocols, encryption, access control, and fault-tolerant data-handling strategies at both device and system levels [49, 50]. Importantly, cybersecurity measures must be proportionate to device capabilities and clinical context, as excessive computational overhead can compromise performance and usability. Ensuring data integrity and secure interoperability is therefore essential to realizing the full potential of instrumentation-based healthcare solutions. Together, these integration and connectivity considerations underscore that instrumentation design choices extend beyond the device boundary, shaping how data are shared, trusted, and acted upon within healthcare systems, and ensures proper performance evaluation and validation practices assess the real-world impact of integrated, instrumented health-related devices.

Performance evaluation and validation are critical to establishing the clinical credibility, safety, and scalability of instrumented health-related devices. Unlike purely mechanical systems, instrumented devices introduce sensing, computation, and connectivity layers that must be assessed not only for functional correctness but also for reliability under real-world operating conditions. Consequently, evaluation frameworks in the literature increasingly emphasize accuracy, robustness, real-time capability, clinical relevance, and comparability across devices and deployment contexts.

4.3. Real-time, Clinical Validation, and Regulatory Perspectives

Accuracy remains a primary performance metric for instrumented healthcare devices, particularly in diagnostic and monitoring applications where erroneous measurements may directly affect clinical decision-making. Studies on POCT and wearable monitoring systems typically assess analytical accuracy against laboratory standards or reference instruments, reporting sensitivity, specificity, repeatability, and measurement error [10, 5]. However, accuracy alone is insufficient; robustness under variable operating conditions, such as motion, temperature variation, or repeated use has been shown to significantly influence real-world performance [7, 58].

Real-time capability is increasingly recognized as a defining requirement for many instrumented devices, particularly those supporting assistive control, hygiene automation, or continuous monitoring. Embedded processing latency, communication delays, and power-management strategies all affect a device's ability to respond promptly and reliably

[33, 37]. The literature consistently reports that event-driven sensing, edge-level preprocessing, and streamlined data pipelines improve both responsiveness and energy efficiency, thereby enhancing overall system performance.

Clinical validation extends performance evaluation beyond technical metrics to assess safety, usability, and effectiveness in real healthcare environments. Validation studies often involve pilot deployments, controlled clinical trials, or workflow-integrated assessments that examine how instrumented devices perform when operated by intended users under realistic constraints [23, 46]. Importantly, discrepancies are frequently observed between laboratory performance and clinical outcomes, underscoring the need for validation protocols that account for human factors, environmental variability, and integration with existing clinical practices [22].

From a regulatory perspective, performance validation must align with applicable medical-device standards and post-market surveillance expectations. The literature highlights that instrumentation-based adaptation of existing devices may facilitate compliance by preserving established mechanical designs while augmenting functionality through modular, non-invasive instrumentation [7, 45]. This approach can reduce regulatory burden while still requiring rigorous verification and validation of added electronic and software components.

4.4. Benchmarking and Comparative Evaluation

Benchmarking and comparative evaluation are essential for contextualizing device performance and guiding adoption decisions. Comparative studies commonly evaluate instrumented devices against conventional counterparts, alternative instrumentation strategies, or reference systems, using standardized test scenarios and performance metrics [32, 10]. In POCT and wearable sensing literature, cross-device comparisons have been instrumental in identifying trade-offs between accuracy, power consumption, and usability [5, 58]. Table 3 consolidates the primary performance metrics and validation dimensions reported across studies of instrumented health-related devices, linking technical accuracy and robustness with real-time behaviour, safety, scalability, and regulatory readiness.

Table 3 Key performance metrics and validation dimensions for instrumented health-related devices

Regulatory-aligned metric category (with citations)	**Representative metrics (regulatory language)**	**Application context**	**Regulatory interpretation / evaluation focus**
Analytical / measurement accuracy (ISO 5725, [94])	Trueness, bias, accuracy error, sensitivity, specificity	POCT, diagnostic devices, physiological monitoring	Demonstrates conformity to essential performance; typically verified against reference or predicate methods.
Real-time performance / latency (IEC 62304, [95])	Response time, control-loop delay, end-to-end latency	Assistive control, hygiene automation, continuous monitoring	Critical for time-dependent safety functions; evaluated as part of software system performance.
Electrical, mechanical, and infection-related safety performance (IEC 60601, [96])	Leakage current, mechanical safety margins, contamination risk reduction	Hygiene systems, patient-handling and assistive devices	Directly mapped to risk control effectiveness and residual risk acceptability.
Safety & Risk Management (Manickam et al. [97])	Hazard identification, failure modes, residual risk, risk acceptability	AI-enabled IoMT devices for cardiac monitoring, diabetes management, cancer diagnostics	Regulators evaluate whether AI introduces new failure modes and whether risk-control measures remain effective across software updates and adaptive learning cycles.
Regulatory validation readiness / conformity evidence (ISO 13485, [98])	Design verification completeness, validation coverage, traceability	Legacy devices and instrumentation-based adaptations	Instrumentation upgrades allow incremental conformity assessment while preserving validated core architecture

Table 3 aligns commonly reported performance metrics for instrumented health-related devices with ISO, FDA, and EU MDR evaluation terminology, highlighting how analytical performance, robustness, real-time capability, safety, scalability, and validation readiness are addressed in regulatory and clinical verification frameworks.

4.4.1. Regulatory and Comparative Implications

The regulatory implications of instrumenting existing health-related devices are closely tied to how performance metrics are framed, verified, and validated under established standards. As summarized in Table 3, metrics such as analytical accuracy, precision, robustness, and real-time performance align directly with concepts of essential performance, normal use conditions, and risk control effectiveness articulated in ISO 13485, ISO 14971, IEC 60601, and IEC 62304 frameworks. Notably, instrumentation-based adaptation offers a pragmatic pathway to regulatory compliance by enabling incremental verification and validation of added sensing, control, and software layers while preserving the validated mechanical core of legacy devices.

From an EU MDR and FDA design-control perspective, this modular approach can reduce regulatory burden provided that clear traceability is maintained between new instrumentation elements and corresponding verification and validation evidence. Metrics such as robustness under foreseeable misuse, real-time response latency in safety-critical functions, and safety performance related to contamination and electrical risk become central to demonstrating residual-risk acceptability. Importantly, scalability and cybersecurity considerations, often peripheral in traditional device evaluation are increasingly relevant for demonstrating fitness for intended use in networked and multi-device deployments. Collectively, the regulatory-aligned metrics in Table 3 indicate that instrumentation-driven innovation is most viable when performance evaluation is structured around risk-based, standards-conformant evidence generation, rather than ad hoc performance claims.

Comparatively, Table 3 reveals that regulatory expectations converge across device classes around a small set of critical performance dimensions, despite substantial differences in application context. Diagnostic and POCT devices emphasize analytical accuracy and precision, whereas assistive and hygiene-related systems prioritize robustness, real-time performance, and safety risk reduction. Networked and IoMT-enabled devices shift the evaluation focus further on scalability and system-level integrity, extending traditional device validation beyond single-unit performance.

Across all categories, instrumentation consistently acts as a regulatory enabler rather than a liability, if evaluation metrics are aligned with established verification and validation constructs. Device classes differ primarily in emphasis, not in the nature of regulatory metrics, underscoring that instrumentation-based adaptation can satisfy diverse regulatory expectations through a common, well-structured performance framework. This comparative perspective supports the broader conclusion of the review: that lawful, instrumentation-driven upgrades are compatible with regulatory rigor when performance evaluation is systematic, risk-based, and standards-aligned. Despite their importance, benchmarking practices remain heterogeneous, with variations in test conditions, datasets, and reporting standards limiting cross-study comparability. Recent surveys emphasize the need for harmonized evaluation frameworks that integrate technical performance, clinical validation outcomes, and system-level considerations such as interoperability and security [38, 59]. Establishing such frameworks is critical for objectively assessing the value of instrumentation-based adaptations across diverse healthcare contexts.

Collectively, performance evaluation and validation from reported studies demonstrate that instrumentation efficacy should be judged holistically, encompassing accuracy, robustness, real-time behaviour, clinical relevance, and comparative performance. These considerations inform the final discussion on limitations, research gaps, and future directions for instrumentation-driven healthcare improvement.

5. Critical Analysis, Limitations and Emerging technologies

Despite substantial progress in the instrumentation of health-related devices, existing approaches exhibit recurring limitations that constrain real-world impact. A dominant issue across diagnostic, assistive, and monitoring technologies is the disconnect between laboratory-validated performance and behavior under clinical conditions, where environmental variability, user heterogeneity, and workflow pressures degrade accuracy and reliability [7, 5, 23]. Many studies prioritize analytical accuracy while under-reporting robustness, repeatability over time, and fault tolerance—metrics that are critical for sustained deployment [32, 33]. Another limitation is the fragmented consideration of system integration and security. Instrumentation is often evaluated at the device level without sufficient assessment of interoperability, data integrity, and cybersecurity risks introduced by connectivity to healthcare information systems [48, 38, 59]. As a result, promising prototypes frequently encounter adoption barriers related to data governance and trust rather than core technical performance. Additionally, performance evaluation practices remain heterogeneous,

with limited benchmarking against standardized protocols, hindering cross-study comparison and evidence-based selection [10, 58].

5.1. Scalability, Cost, and Deployment Challenges

Scalability and cost represent persistent gaps in the translation of instrumented devices from pilot studies to routine care. Many solutions demonstrate effectiveness at small scale but fail to maintain performance as device numbers, data volume, or network complexity increase, particularly within IoMT-based deployments [38, 59]. Scalability assessments are frequently inferred through simulation or short-term trials rather than validated empirically, limiting confidence in large-scale adoption.

Cost-related challenges are equally significant, especially in resource-constrained settings. Advanced sensors, embedded processing, and connectivity increase device cost and maintenance burden, often without parallel strategies for cost reduction through modularization or selective instrumentation [12, 45]. Furthermore, regulatory uncertainty and intellectual-property concerns can discourage incremental upgrades to legacy devices, even when instrumentation-based adaptation could offer cost-effective and compliant improvements [7, 32]. The figure 5 illustrates how interoperable data governance and explicit regulatory standards translate into scalable, cost-efficient, and deployment-feasible healthcare technologies, enabling equitable and sustainable device deployment in resource-constrained settings.

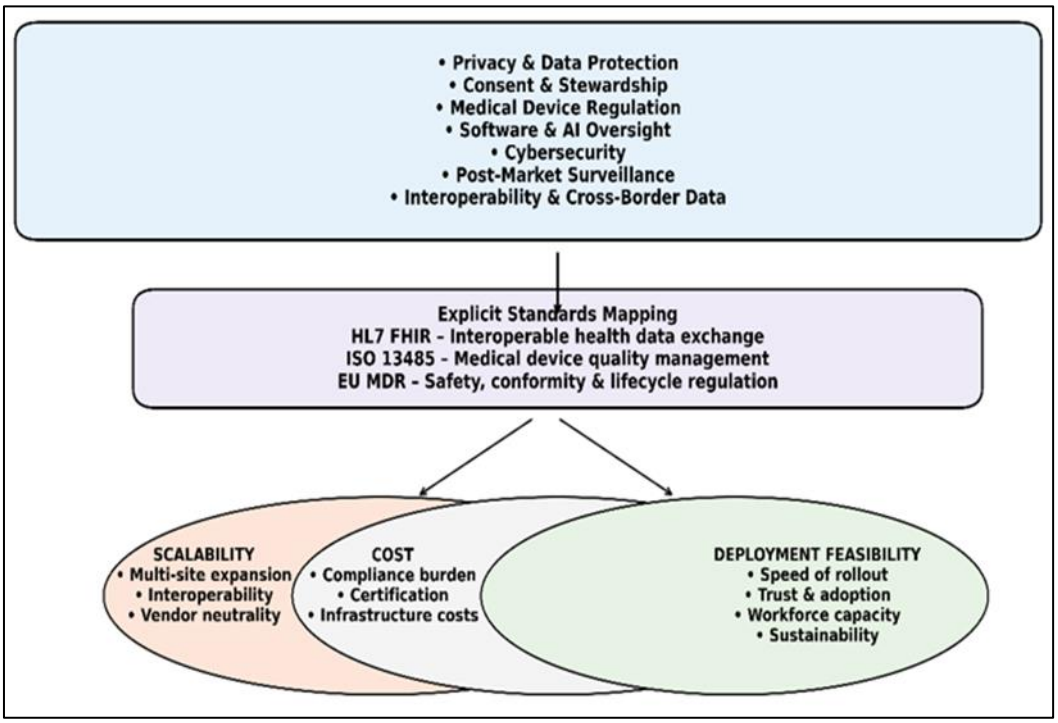

Figure 5 Data Governance and Regulatory Framework on Healthcare Device Deployment. Adapted from [65-67]

Collectively, these gaps highlight the need for holistic research frameworks that integrate technical performance, system-level scalability, cost considerations, and regulatory readiness. Future work should emphasize standardized evaluation protocols, long-term field validation, and patent-conscious, modular instrumentation strategies to support sustainable deployment across diverse healthcare contexts.

5.2. Future Governance in Digital Healthcare Upgrade

Emerging technologies are expected to play a central role in advancing instrumentation-based healthcare solutions beyond current capabilities. Artificial intelligence (AI) and machine learning (ML) are increasingly integrated with instrumented health devices to support data interpretation, anomaly detection, and adaptive system behavior. Recent studies demonstrate that embedding lightweight ML models at the edge or device level can enhance diagnostic accuracy, reduce false alarms, and enable personalized responses without relying exclusively on cloud-based analytics [27, 37].

It is important to note that advancing instrumentation-based healthcare solutions beyond current capabilities ties into the United Nations Sustainable Development Goals (SDGs). Existing literature indicates consensus that instrumentation-based health care solutions are critical enablers of SDG 3 (Good Health and Well-Being), SDG 9 (Industry, Innovation and Infrastructure), SDG 10 (Reduced Inequalities) and SDG 17 (Partnerships for Goals) [99]. To the extent that health device instrumentation supports strengthening primary healthcare systems, addresses shortages of medical equipment and promotes innovation and manufacturing [27]. Health devices are not just technological innovations; they are important as both tools of healthcare delivery and as drivers of systemic transformation. They influence how health systems operate and how services are accessed and their successful integration into development strategies require careful attention to ethical legal and regulatory considerations.

In addition to the SDGs, nationals' laws need to be adapted to support the development and integration of digital health technologies, in consideration of how patent law frameworks that promote technology transfer and compulsory licensing can address health disparities and ultimately drive progress towards SDGs.

When combined with instrumentation, governments can foster environments that ensure that AI-enabled systems can move beyond passive data acquisition toward intelligent decision support, especially in POCT, assistive devices, and continuous monitoring applications [28]. Parallel advances in smart sensor technologies, including multi-modal, self-calibrating, and low-power sensors—are expanding the scope of what can be instrumented within existing devices. Sensor fusion approaches, which combine data from multiple sensing modalities, have shown promise in improving robustness and reliability under real-world conditions [5, 33]. These developments are complemented by progress in digital health platforms that facilitate data aggregation, visualization, and integration with electronic health records, reinforcing the role of instrumentation as a bridge between physical devices and digital healthcare ecosystems while also increasing accessibility, reducing costs, highlighting the critical role of lawful adaptation frameworks in health-care instrumentation [38, 59].

In addition, a key opportunity lies in shifting from device-centric innovation toward system-level healthcare upgrades enabled by instrumentation-based adaptation. Rather than replacing established devices, future efforts are likely to focus on modular, non-invasive instrumentation that enhances safety, automation, and connectivity while preserving validated mechanical designs and clinical workflows [7, 32]. This approach aligns with regulatory and economic realities by supporting incremental improvement pathways that are more feasible for deployment at scale. From a system perspective, instrumentation offers pathways to upgrade healthcare delivery through improved workflow efficiency, infection control, remote care capability, and data-driven resource management. Integrating instrumented devices into interoperable digital infrastructures enables coordinated care across clinical settings, supporting continuity of care and population-level health monitoring [45, 46]. Future research should therefore emphasize long-term field validation, standardized evaluation frameworks, and patent-conscious design strategies to ensure that instrumentation-based solutions are scalable, cost-effective, and legally viable.

Agreeably, balancing patent rights with public health needs can pose challenges like ensuring access to essential medical technologies, while maintaining innovation incentives, particularly in low resource settings like Nigeria, where affordability can be a significant barrier. Also, navigating diverse national laws and intellectual property could delay or limit the availability of life-saving healthcare innovations, however, these also highlight the need for flexible frameworks that will prioritise health outcomes [100].

Collectively, these opportunities suggest that the next phase of healthcare innovation will be characterized less by the introduction of entirely new devices and more by the intelligent instrumentation and integration of existing technologies, guided by advances in AI, smart sensing, and digital health systems for device optimization.

Nomenclature

- ISO - International Organization for Standardization (ISO)
- FDA - United States Food and Drug Administration
- EU MDR- European Union Medical Device Regulation
- IEC - International Electrotechnical Commission
- FTO - Freedom to Operate
- POCT - Point-of-care testing
- IoMT - Internet of Medical Things
- HER - Electronic Health Record
- RPM - Remote Patient Monitoring
- HCP - Healthcare Provider

- PHD - Personal Health Device (e.g., home BP monitor, scale)
- MEMS - Micro-Electro-Mechanical Systems (miniaturized sensors/actuators)
- MCU - Microcontroller Unit
- SoC - System-on-Chip
- SDGs - Sustainable Development Goals
- ADC - Analog-to-Digital Converter
- DSP - Digital Signal Processing
- HL7 - Health Level Seven (standards organization for health data exchange)
- FHIR - Fast Healthcare Interoperability Resources
- PCCP - Predetermined Change Control Plan
- API - Application Programming Interface
- BLE - Bluetooth Low Energy
- NFC - Near Field Communication
- PPG - Photoplethysmography (optical pulse/blood volume waveform)
- ECG - Electrocardiography (electrical cardiac signal)
- KPI - Key Performance Indicator
- LOD - Limit of Detection
- QMS - Quality Management System
- CAPA - Corrective and Preventive Action
- ISO 13485 - Medical device Quality Management System standard
- ISO 14971 - Medical device risk management standard
- IEC 60601-1 - Medical electrical equipment safety and essential performance standard
- IEC 62304 - Medical device software lifecycle processes standard
- IEC 62366-1 - Usability engineering/human factors standard for medical devices

6. Conclusion

Instrumentation-based adaptation of existing health-related devices offers a practical, scalable, and regulation-aligned pathway for healthcare improvement. Across diagnostic, assistive, hygiene, and connected systems, limitations in real-world performance are shown to arise primarily from insufficient sensing, manual dependence, fragmented integration, and inconsistent validation, rather than from intrinsic device inadequacy. By synthesizing design, integration, performance, regulatory, and future-technology perspectives, the review demonstrates that modular, non-invasive, and patent-conscious instrumentation can enhance accuracy, robustness, safety, real-time capability, and scalability while remaining consistent with ISO, FDA, and EU MDR frameworks. Overall, the findings suggest that sustainable healthcare advancement will be driven less by replacing devices and more by intelligently instrumenting and integrating established technologies within interoperable digital ecosystems.

6.1. Future Directions

The future of healthcare innovation lies in upgrading, not reinventing existing devices through smart, modular, and regulation-aligned instrumentation.

Future research directions may include the following based on gaps identified in the study:

- Development of harmonized, cross-device performance and validation protocols that jointly assess accuracy, robustness, real-time behavior, interoperability, and regulatory readiness across healthcare contexts.
- Prioritized longitudinal field studies to evaluate reliability, usability, and safety of instrumented devices under realistic clinical and environmental conditions.
- Investigation of lightweight, explainable AI models embedded within devices to enhance decision support, reduce latency, and preserve data privacy.
- Advancement of design methodologies that enable instrumentation-based adaptation of legacy devices while maintaining freedom to operate and incremental regulatory compliance.
- To explore cybersecure designs and standards-based interoperability solutions tailored to scalable IoMT deployments.
- Focus on low-power, low-cost sensor and integration strategies to support equitable healthcare system upgrades, especially in low-resource settings.

These directions collectively point toward instrumentation-driven, systems-level innovation as a priority for advancing safe, scalable, and regulation-aligned healthcare technologies.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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