Natural Resources for Human Health
eISSN: 2583-1194

Original Research

Received 01 Aug 2026
Revised 15 Sep 2026
Accepted 03 Oct 2026

Natural Resources for Human Health 2026, Vol. 6 (23s): 688–705

KEYWORDS:
medical device readiness; sterile services; biomedical equipment; nursing; radiologic technology; health administration; integrative review.

From Device Readiness to Safe Clinical Use an Integrative Review of Nursing, Central Sterile Services, Biomedical Equipment Technology, Radiologic Technology, and Health Administration Roles

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ABSTRACT: Medical devices can be available for use while requirements for safe care remain unresolved. Reprocessing records, maintenance histories, clinical settings, and responsibility for release are often managed by different services. This review examines how nursing, central sterile services, biomedical equipment technology, radiologic technology, and health administration can connect these requirements without assuming that one form of clearance establishes complete readiness. A targeted integrative review purposively selected twenty verified publications within a 2010–2026 eligibility window. Indexed records and accessible full texts were examined using structured charting and qualitative comparison. The corpus addressed device contamination, cleaning verification, ultrasound infection prevention, maintenance management, monitoring alarms, imaging safety, and work system design. Findings indicate that biological suitability, technical functionality, and clinical appropriateness constitute distinct dimensions of readiness. Cleaning indicators do not independently establish sterility,

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eISSN: 2583-1194

maintenance completion does not confirm successful reprocessing, and a functioning monitor may still generate clinically unhelpful alarms. Evidence varied across laboratory experiments, observational studies, service evaluations, reviews, and professional recommendations. The synthesis proposes a conditional readiness framework in which unresolved requirements remain visible until the appropriate professional evaluates them. Three original figures illustrate complementary readiness requirements, the distribution of evidence across domains, and separate routes for technical and reprocessing concerns. No participants, institutional performance records, or patient outcomes were analysed. The framework has not been prospectively validated and does not establish reductions in infection, equipment failure, or adverse events. Future evaluation should examine documentation completeness, practical access to expertise, release decisions, workflow burden, equity, and patient outcomes before wider implementation.

1 INTRODUCTION

A medical device can be present in a clinical room without being ready for its intended use. Its maintenance record may be current while its reprocessing status is uncertain, or it may have completed a validated reprocessing procedure while a newly observed defect remains unresolved. Clinical configuration adds another requirement: a technically functioning device can be inappropriate for a particular patient or task. This review uses device readiness to describe the coordinated state in which applicable biological, technical, and clinical requirements have been evaluated before use. The question is how information and responsibilities across five professional domains can make that state visible.

The biological dimension begins with the intended use of the device. Rutala and Weber (2016) distinguish the reprocessing requirements of critical, semicritical, and noncritical items and emphasize the importance of cleaning before subsequent treatment. However, documented completion of a procedure is not identical to verified effectiveness. Ofstead et al. (2015) detected residual contamination during repeated observations of clinically used endoscopes, and Ofstead et al. (2017) linked inspection and testing with identification of devices needing further processing or repair. These studies concern particular devices and settings; their findings should not be generalized into a claim that every reprocessed device remains contaminated.

The choice of verification method also matters. Alfa et al. (2013) evaluated an ATP-based method in simulated endoscope cleaning, illustrating that a benchmark belongs to a particular test and sampling procedure. Leroy (2013) reviewed infection and contamination evidence associated with endovaginal and transrectal ultrasound, while Nyhsen et al. (2017) provided recommendations tailored to ultrasound practice. Westerway and Basseal (2017) described variation in practitioners' infection-control practices. Together, these publications connect reprocessing with the conditions of actual use, training, and communication. They also show why a device cover or the absence of visible residue cannot be treated as a universal substitute for appropriate processing.

Device design can make cleaning difficult even when staff understand the procedure. Kremer et al. (2025) examined the relationship between challenging geometries, soil drying, and cleaning performance in laboratory conditions. Rutala and Weber (2023) discussed developments in processing semicritical devices, and Ofstead et al. (2026) reviewed continuing problems involving residual contamination, damage, and moisture in endoscopes. These sources support attention to design compatibility, inspection, and quality assurance. Their implications require device-specific interpretation; this manuscript does not prescribe a single sterilization method for all equipment. Its concern is whether the relevant conditions and unresolved findings are communicated to the next responsible service.

The technical dimension introduces a different evidence base. Iadanza et al. (2019) combined work-order classification with performance indicators to support equipment management. Ye et al. (2026) evaluated a data-driven prioritization approach, while Massimino Ucin et al. (2024) examined maintenance practices and constraints in a resource-limited hospital. Teng et al. (2024) described a digital approach to maintenance records and workflow. These publications address how organizations identify, prioritize, and follow equipment problems. They do not establish that a completed maintenance entry proves clinical

suitability or successful decontamination. Information systems can support coordination, but the meaning of a recorded status still depends on its scope and the evidence supporting it.

Readiness must also include interaction between the device, its users, and the patient. Drew et al. (2014) documented a substantial burden of monitor alarms in intensive care, and Paine et al. (2016) reviewed alarm characteristics and interventions with attention to their limitations. Cvach (2012) integrated research and practice literature on alarm fatigue. This evidence illustrates how a working device can nevertheless contribute to an unhelpful or unsafe work environment. The clinical task is therefore not satisfied by asking whether a device powers on. Its configuration, the staff response arrangement, and the relevance of its output also require consideration within authorized practice.

Imaging services make this interaction especially visible. ESR and EFRS (2019) address patient safety from the perspectives of radiology and radiography, including technological, procedural, and organizational concerns. Carayon et al. (2014) place tools and technologies within a broader work system, and Gurses et al. (2012) demonstrate the identification of hazards through observation of clinical work. Their common implication is that equipment safety cannot be attributed to individual vigilance alone. Staffing, information access, environmental constraints, procurement, and competing tasks can shape what staff can actually do with the available technology.

The five professional domains in this manuscript have complementary responsibilities. Nursing contributes observation during use, patient-specific checks, and escalation of unexpected device behaviour. Central sterile services contributes validated reprocessing and release documentation within its remit. Biomedical equipment personnel investigate technical faults and maintenance needs. Radiologic technology contributes modality-specific preparation and patient-facing checks. Health administration supports resources, procurement, traceability arrangements, and accountability. These descriptions do not transfer prescribing authority or permit one service to certify requirements outside its competence. A readiness record should identify which domain a clearance concerns rather than merely state that a device is safe.

The primary review question asks how the five domains can coordinate device readiness from preparation to clinical use. Subsidiary questions concern which evidence supports different forms of clearance, how uncertainty or disagreement should be handled, and which organizational arrangements remain theoretical. Twenty core publications are used to examine these questions. The review does not test the proposed combined framework, collect institutional data, or infer performance at the contributors' workplaces. Its contribution is to separate meanings of readiness that can otherwise become compressed into an ambiguous equipment status.

The remainder of the manuscript critically examines the twenty sources, explains the selection and qualitative synthesis, and presents a conceptual framework supported by three original figures. The emphasis is on conditional decisions, explicit handovers, and a traceable route for unresolved concerns. No infection rate, failure rate, or improvement percentage is generated for the framework. Its value must ultimately be evaluated through appropriately designed service and clinical research, with attention to workload, unintended consequences, and equitable access to functioning equipment.

2 LITERATURE REVIEW

Reprocessing requirements and intended use

Rutala and Weber (2016) reviewed disinfection and sterilization in healthcare facilities. Their account distinguishes critical, semicritical, and noncritical items according to intended contact and explains the need for cleaning before further processing. The review provides a foundation for identifying which biological requirement applies to a device. It is professional synthesis rather than an experimental comparison of every processing method. Its relevance to readiness is that the appropriate procedure depends on the intended use, not simply the department holding the equipment. A generic clean label therefore contains insufficient information. The proposed framework retains the applicable processing category and relevant manufacturer instructions. It does not infer that every device needs sterilization, or that technical maintenance can replace assessment of reprocessing requirements.

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Residual contamination after endoscope processing

Ofstead et al. (2015) assessed contamination during sixty encounters involving fifteen gastrointestinal endoscopes. Visual inspection, cultures, and rapid indicators were used at several processing stages while researchers observed adherence to guidelines. Residual biological material and viable organisms were identified despite reported procedural compliance. The repeated observations provide direct evidence about these devices, but do not represent sixty independent instruments or establish a corresponding patient infection rate. Their contribution is to separate recorded completion from verified processing effectiveness. For readiness, unresolved findings may require additional processing or investigation rather than acceptance of a completed checklist. The study's setting and selected methods limit generalization to other devices. It does not show that all processing systems fail or quantify the benefit of the interdisciplinary framework.

Comparative interpretation

These sources distinguish the requirement for a process from evidence that the intended result was achieved. The review provides a classification framework; the observational study shows why completion records require interpretation. Neither replaces manufacturer instructions or establishes a universal testing programme. The synthesis therefore retains both the applicable requirement and evidence of its fulfilment, allowing unresolved findings to remain visible rather than treating a completed step as an unrestricted safety certificate.

Damage and contamination over time

Ofstead et al. (2017) followed twenty colonoscopes and gastroscopes through repeated assessment over seven months. Investigators combined internal inspection, biochemical testing, and microbial cultures while comparing customary with more rigorous processing. Irregularities and contamination remained evident, and many devices required repair. The findings connect biological processing with physical condition, making the study particularly relevant to the interface between sterile services and equipment maintenance. However, the small device cohort and specific protocols limit inference about other models or hospitals. More intensive processing was not consistently associated with better culture findings. The framework therefore retains separate routes for contamination and damage, even when both occur together. The study does not establish a universal replacement interval or prove that routine inspection alone prevents patient infection.

Validation of a cleaning verification method

Alfa et al. (2013) evaluated an ATP-based method for auditing manual cleaning of flexible endoscope channels using simulated contamination. The investigation compared ATP findings with residual material and bioburden under controlled cleaning conditions. Its strength is explicit validation of a defined test and sampling approach. Its limitation is that laboratory performance cannot be assumed to establish clinical effectiveness across all devices and methods. In particular, an ATP finding is not equivalent to proof of sterility or absence of every pathogen. The framework uses this distinction to require that verification records identify what was measured. A benchmark should remain linked to its validated procedure and context. The study supports quality assurance without licensing universal adoption of its numerical threshold for unrelated products or sampling systems.

Comparative interpretation

The longitudinal device study and simulated cleaning study examine different questions. One concerns condition and contamination during use; the other validates a particular verification method. Their findings cannot be combined into a general sterility threshold. Together they support linking results to the device, procedure, and purpose of measurement. The framework preserves the distinction between identifying a concern and determining what additional action is needed.

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Ultrasound contamination and infection evidence

Leroy (2013) systematically reviewed endovaginal and transrectal ultrasound evidence and included thirty-two publications. The synthesis examined contamination after processing and infection associated with relevant procedures. It highlighted the difficulty of establishing transmission routes, especially outside recognized outbreaks. This distinction matters because contamination prevalence, infection following a procedure, and confirmed probe-mediated transmission are different outcomes. The review supports attention to processing rather than reliance on probe covers alone. Its older evidence base and heterogeneous methods constrain direct estimates for current equipment. In the framework, radiologic technology and reprocessing services share information about intended use and completed processing. The source does not establish one infection probability for every ultrasound examination or evaluate the proposed coordination arrangement.

Ultrasound specific infection prevention guidance

Nyhsen et al. (2017) developed ultrasound infection-prevention recommendations through literature review and multidisciplinary discussion. The document differentiates requirements for standard scanning, endocavity examinations, and interventions, while addressing equipment, covers, gel, and the clinical environment. It also emphasizes that faulty transducers should not be used. Its contribution is to place processing and technical condition within the same practice context. As professional guidance, it does not provide a trial estimate for a complete readiness programme. Local procedures still require current device instructions and relevant authorization. The framework draws on the need to know both the intended examination and the condition of the equipment. It avoids assuming that every ultrasound application has identical infection-control requirements or that a cover resolves every processing concern.

Comparative interpretation

The ultrasound review and professional recommendations connect intended use with processing decisions, but their evidence types differ. Reported contamination and infection outcomes require interpretation, while recommendations also incorporate professional judgment. The framework does not convert either into one risk estimate. It uses them to identify information that must pass between clinical users and the service responsible for processing.

Variation in ultrasound workplace practices

Westerway and Basseal (2017) discussed findings from a United Kingdom survey of ultrasound hygiene and transducer disinfection. The account identified inconsistencies in processing methods, attention to surrounding equipment, and training in product use. These findings connect the written procedure with the resources and understanding needed to perform it. However, survey reports cannot establish the frequency of patient infection or confirm every reported practice through observation. The framework uses the source to make training, accessible instructions, and responsibility visible in readiness arrangements. Equipment surfaces beyond the transducer may also require an appropriate local procedure. The publication supports a coordinated approach, while its setting and reporting method limit transfer of specific prevalence estimates to other services.

Device geometry and dried soil

Kremer et al. (2025) investigated cleaning performance in reusable devices with challenging features under laboratory conditions. Different geometries and soil-drying conditions were assessed, including comparisons involving manual and less manual processing. Concealed or occluded features presented particular challenges, whereas performance differed for more accessible designs. The study contributes evidence that processing difficulty can originate in device construction, not only staff adherence. Its laboratory endpoints do not directly measure

patient infection or routine service workload. The framework therefore connects procurement and technical knowledge with reprocessing feasibility. A device's suitability for local processing should be considered before acquisition and after relevant changes. The source does not justify substituting an unvalidated cleaning method or applying one result indiscriminately to all device geometries.

Comparative interpretation

Variation in practice and difficulty arising from device geometry represent different sources of concern. Education can address a knowledge gap, but cannot necessarily overcome an inaccessible design feature. Conversely, purchasing a different device cannot resolve every training or workflow problem. The synthesis keeps procurement, validated methods, available resources, and staff preparation connected without attributing all failures to one cause.

Changing approaches to semicritical devices

Rutala and Weber (2023) reviewed reprocessing of semicritical items and developments concerning sterilization of endoscopes. The publication discusses infection risks and the potential advantages of different processing approaches for suitable equipment. Its contribution is to question whether existing arrangements provide an adequate margin of safety for particular complex devices. Nevertheless, a review cannot demonstrate that every device tolerates the same method or that a recommended transition is feasible in every service. The framework retains compatibility, validated instructions, and local capability as conditions for change. Decisions about processing technology should involve sterile services, equipment expertise, clinical users, and administration. The source supports reassessment of practice without establishing that universal sterilization is appropriate for all equipment described in this manuscript.

A contemporary endoscope processing update

Ofstead et al. (2026) synthesized recent studies, standards, and public reports concerning endoscope processing effectiveness. The review links outbreaks and processing breaches with concerns about residual soil, moisture, physical defects, and quality assurance. Its recent scope extends earlier endoscope evidence while retaining the limitations of the underlying reports. Some publications may concern overlapping technologies or settings, so the review should not be counted as an independent patient cohort. For the framework, the contribution is the simultaneous visibility of cleanliness, condition, and dryness where applicable. Routine documentation should identify unresolved findings and the route for action. The source supports consideration of audits and verification while providing no controlled estimate of the effectiveness of the five-domain readiness framework proposed here.

Comparative interpretation

These reviews support continuing scrutiny of endoscope processing, while the proposed actions remain dependent on compatible technology and local authorization. Newer publication dates do not remove limitations in the underlying evidence. The framework therefore records unresolved concerns and the basis for a release decision. It does not infer that a broad recommendation automatically validates a replacement method for every device.

Maintenance records and performance indicators

Iadanza et al. (2019) developed an evidence-based equipment management approach using work-order classification and performance indicators at a large Italian hospital. The study connected failure history with scheduled and corrective maintenance analysis. It provides a practical account of how operational records can inform resource allocation and investigation of recurring problems. However, a management indicator is not automatically a patient-safety outcome, and the experience of one institution does not determine every service's priorities. The framework uses the study to retain technical evidence behind a maintenance status rather than rely on an isolated completion date. Administrative teams can support consistent records

and follow-up, while equipment personnel interpret technical findings. The publication does not demonstrate that maintenance completion establishes biological or clinical readiness.

Data driven maintenance prioritization

Ye et al. (2026) developed and implemented a machine-learning-assisted system for prioritizing preventive and corrective equipment maintenance. The study used hospital device records and compared implementation across two campuses. Reported results supported feasibility and improvements in selected maintenance measures. However, predictive accuracy for study-defined categories is different from demonstrated reduction in patient harm. A campus comparison also requires attention to contextual differences and possible confounding. The framework treats such systems as decision support, with priorities and unresolved concerns remaining open to professional review. The source contributes recent evidence about technical management, not validation of the complete readiness concept. It does not justify transferring model thresholds to another hospital without checking data definitions, local risks, and implementation conditions.

Comparative interpretation

Maintenance indicators and predictive prioritization address different levels of technical management. A work-order system describes events and their resolution, while a model may assist allocation of attention. Neither supplies all information required for a clinical-use decision. The synthesis retains professional interpretation, local definitions, and the possibility that a biologically or clinically important concern lies outside the model's inputs.

Maintenance constraints in a resource limited hospital

Massimino Ucin et al. (2024) examined on-site equipment maintenance practices at Wau Teaching Hospital using a cross-sectional design. Questionnaire information was supplemented by document review and an observational checklist. The study identified constraints involving personnel, device information, inspection, and maintenance arrangements. Its value is to place equipment management within actual organizational resources. Convenience sampling, self-report, and one institutional setting limit causal inference and generalization. The framework uses these findings to distinguish an individual's responsibility from the resources needed to discharge it. Administration can facilitate access to expertise and information rather than assign unsupported clearance duties. The publication does not establish which staffing level is sufficient everywhere or demonstrate that introducing a readiness form would resolve underlying maintenance limitations.

Digital support for maintenance workflow

Teng et al. (2024) described the use of a digital platform to manage maintenance records, submissions, automated reminders, and reporting. The brief service account emphasizes timeliness and transparency in routine equipment work. Its contribution is an example of connecting requests, records, and follow-up within an operational system. However, the report provides limited detail for causal evaluation, and its claims should not be treated as a controlled patient-outcome study. The framework draws on the need for an identifiable recipient and an accessible record, rather than endorsing a particular software product. Digital status labels require clear definitions and professional ownership. The source does not show that automation verifies processing quality, detects every defect, or substitutes for clinical judgment before use.

Comparative interpretation

The two service studies show why implementation conditions matter. Limited personnel and information access cannot be corrected by a status label alone. Digital coordination may help trace requests, but its value depends on a workable response process. The framework accordingly treats administrative support as an enabling responsibility rather than authority to overrule an unresolved technical or reprocessing concern.

Alarm burden during intensive care monitoring

Drew et al. (2014) observed physiological monitoring in 461 intensive care patients over thirty-one days. The study collected device outputs and examined a defined subset of arrhythmia alarms using an annotation protocol. It identified a high alarm burden and substantial false-positive findings within that subset. The detailed observational approach supports analysis of interaction between patient conditions, device algorithms, and settings. However, its counts should not be generalized to all monitoring environments or interpreted as proof that every alarm can safely be suppressed. For readiness, the study shows why technical function and clinically appropriate configuration are different questions. Nursing and equipment expertise can contribute complementary observations, while authorized teams retain responsibility for patient-specific monitoring decisions.

Evidence on monitor alarms and interventions

Paine et al. (2016) systematically reviewed physiological monitor alarms, response times, and interventions intended to reduce alarm frequency. The included evidence contained observational studies and intervention evaluations with differing designs. The review identified promising approaches but emphasized the need for stronger research and attention to unintended consequences. Its contribution is to distinguish reduced alarm counts from evidence that patient deterioration remains detectable. The framework consequently treats alarm configuration as a clinical and operational issue, rather than an automatic consequence of technical maintenance. Any local evaluation should include balancing measures when alert behaviour changes. The publication does not establish one configuration for every patient group, nor does it validate an integrated readiness programme spanning sterile services and imaging.

Comparative interpretation

The observational alarm study and systematic review link device output with clinical work. Their evidence concerns monitoring rather than sterilization, yet it exposes a gap in purely technical definitions of readiness. Fewer alerts can represent improvement or loss of useful detection. The framework therefore requires clinically authorized configuration and evaluation of unintended consequences when changes are introduced.

An integrative account of alarm fatigue

Cvach (2012) integrated research and nonresearch literature on alarm fatigue using a nursing evidence-based practice model. The review organized findings around alarm burden, staff response, audibility, technological approaches, and notification systems. It supplies an account of how multiple work-system features can affect the usefulness of device output. Its broad evidence mix also limits causal conclusions about individual interventions. The framework uses the source to include user competence and response arrangements in readiness, alongside equipment condition. A working alarm function cannot establish that notification reaches the right person or prompts a suitable response. The publication supports shared investigation of problems while leaving the effectiveness of particular organizational changes to subsequent local evaluation.

Patient safety in medical imaging

ESR and EFRS (2019) issued a joint professional statement covering major patient-safety concerns in medical imaging. It addresses technology, procedures, patient wellbeing, and organizational responsibilities from complementary professional perspectives. Its relevance is to locate equipment checks within the broader context of the examination and the person receiving care. As a consensus-oriented statement, it does not estimate the effect of a particular readiness checklist. The framework therefore uses it to support modality-specific

interpretation rather than generic clearance. Radiologic technology staff contribute preparation and escalation within their authorized role, while technical and reprocessing questions retain appropriate specialist ownership. The statement does not imply that one imaging department's procedures should be copied unchanged to every device or clinical service.

Comparative interpretation

The alarm review and imaging statement both locate safety within the relationship between technology and care delivery. They support attention to competence, communication, and the intended patient task. Their broad scope should not be mistaken for direct experimental validation of a shared readiness system. The proposed responsibilities remain conditional on local practice and access to appropriate expertise.

A work system approach to safety

Carayon et al. (2014) explained a human-factors systems approach to healthcare quality and patient safety through the SEIPS model. The paper describes relationships among people, tasks, tools, organizational conditions, and the environment, with examples of application. It offers a theoretical basis for examining device readiness as more than an individual checking task. However, a general systems model is not direct evidence that the framework developed here improves outcomes. The present synthesis uses its concepts to connect device condition with information availability, workload, and professional coordination. This avoids attributing every problem to user vigilance. The source supports examining the conditions of work and the consequences of redesign, while requiring separate evaluation of any specific readiness intervention.

Hazards identified in clinical work

Gurses et al. (2012) investigated hazards in cardiovascular operating rooms through observations, contextual inquiry, and related methods across five hospitals. Twenty-two operations informed a work-system-guided analysis that identified multiple categories of potential hazards. The findings connect safety concerns with workload, practice variation, communication, and technology-related decisions, including purchasing. Their strength is attention to actual work rather than exclusive reliance on a written procedure. The specialized setting and qualitative design limit estimation of prevalence or intervention effectiveness elsewhere. The framework draws on this approach to propose that device readiness procedures be assessed in context. A new record should support usable communication rather than add work without resolving uncertainty. The study does not directly evaluate the five-domain model.

Comparative interpretation

Systems theory and observational hazard identification provide a foundation for integrating the preceding device-specific findings. They do not supply an effect estimate for the proposed model. The literature gap concerns how separate forms of clearance remain visible across services, particularly after a fault, processing deviation, or change in intended use. The results therefore present conceptual relationships and an evaluation agenda rather than simulated performance data.

3 Methodology

This manuscript uses a targeted integrative review with conceptual framework development. Existing literature is compared across device processing, technical management, clinical use, and work-system design. The purpose is to connect distinct kinds of readiness evidence rather than estimate a pooled treatment effect. The integrative rationale is informed by Torraco (2016), which describes synthesis as a route to developing new conceptual understanding. Twenty core publications provide the substantive corpus, and five supplementary sources support methods and equipment-management context. No original clinical, microbiological, engineering, or organizational dataset was collected.

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Discovery and verification were completed on 16 November 2026. Public scholarly searches used combinations of medical device readiness, reprocessing, cleaning verification, ultrasound infection prevention, equipment maintenance, monitor alarms, and patient safety. Europe PMC was used to retrieve indexed metadata and abstracts through title, DOI, or PMID queries. Examples include EXT_ID:26234219 AND SRC:MED, EXT_ID:31399897 AND SRC:MED, and DOI:10.1038/s41598-025-13740-7. Accessible full texts were examined when available. This was a purposeful discovery and verification process rather than a comprehensive search of every database. A protocol was not preregistered.

Eligible sources were published from January 2010 through 16 November 2026 and addressed a relevant device process, professional interface, or work-system issue. The selected core publications actually span 2012–2026. Empirical studies, laboratory validations, service evaluations, reviews, and professional recommendations were eligible. Reports without sufficient accessible information, unrelated drug interventions, and duplicate versions of the same article were excluded from the substantive corpus. The simultaneously published imaging statement was counted once. The twenty sources are not described as twenty independent trials. Table 1 states the inclusion and interpretation boundaries.

Table 1 Eligibility and interpretive boundaries

Dimension	Procedure or inclusion	Boundary
Period	2010 to 16 November 2026	Selected core sources span 2012–2026
Scope	Biological, technical, and clinical device readiness	No exhaustive coverage of all devices
Design	Empirical work, reviews, and guidance	Design-specific limitations retained
Verification	Indexed record plus available source text	Abstract-based interpretation identified
Unit	A relevant finding, recommendation, or task requirement	No participant-level reanalysis
Output	Qualitative synthesis and proposed framework	No pooled effect or validated release score

Bibliographic verification checked the publication title, author list, year, journal, volume, pagination or article identifier, and DOI. The final journal publication year was used when different from early online indexing. Duplicate corporate-author records and duplicated database author entries were checked against the source article. Table 2 documents the material available for each core publication. Access status describes what could be examined; it is not a quality score. The framework was not inferred from a title alone, and claims from abstracts were restricted to the information those abstracts supplied.

Structured charting recorded design, setting or material, main result, outcome type, principal limitation, and the readiness question addressed. Three readiness dimensions were defined before cross-source comparison: biological suitability after applicable processing, technical functionality for the intended purpose, and clinical appropriateness for the patient and task. Organizational conditions were charted separately as enablers or constraints. The unit of interpretation was the relationship between an action, its evidence, and the professional responsible for the next decision. Detection of contamination, a completed maintenance order, an alarm count, and a professional recommendation were not treated as interchangeable outcomes.

Selection and charting were not independently duplicated, and no inter-rater reliability statistic was calculated. No fabricated identification or exclusion totals are presented. Transparency principles from Page et al. (2021), Peters et al. (2020), and Tricco et al. (2018) informed reporting, without a claim of complete systematic-review or scoping-review compliance. Sources could contribute to several conceptual domains; Figure 2 uses explicit primary-topic coding rather than an inferred quality ranking. Publication counts describe the chosen corpus only and cannot be interpreted as the proportion of all available evidence supporting a particular practice.

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Table 2 Core publications and source material examined

Publication	Design family	Main contribution	Access
Rutala and Weber (2016)	Review	Biological processing	Full text
Ofstead et al. (2015)	Empirical	Biological processing	Abstract
Ofstead et al. (2017)	Empirical	Biological processing	Abstract
Alfa et al. (2013)	Empirical	Biological processing	Abstract
Leroy (2013)	Review	Biological processing	Abstract
Nyhsen et al. (2017)	Guidance	Biological processing	Full text
Westerway and Basseal (2017)	Empirical	Biological processing	Abstract
Kremer et al. (2025)	Empirical	Biological processing	Full text
Rutala and Weber (2023)	Review	Biological processing	Abstract
Ofstead et al. (2026)	Review	Biological processing	Abstract
Iadanza et al. (2019)	Empirical	Technical management	Full text
Ye et al. (2026)	Empirical	Technical management	Full text
Massimino Ucin et al. (2024)	Empirical	Technical management	Full text
Teng et al. (2024)	Empirical	Technical management	Abstract
Drew et al. (2014)	Empirical	Clinical use	Full text
Paine et al. (2016)	Review	Clinical use	Abstract
Cvach (2012)	Review	Clinical use	Abstract
ESR and EFRS (2019)	Guidance	Clinical use	Abstract
Carayon et al. (2014)	Review	Work system	Abstract
Gurses et al. (2012)	Empirical	Work system	Abstract

Within-source interpretation retained the study's own population, device, method, and endpoint. Cross-source comparison then examined whether a finding concerned a processing requirement, evidence of technical condition, clinical configuration, or an organizational dependency. Apparent disagreement prompted review of the underlying question and outcome. For example, detecting residual material differs from measuring infection, and classifying maintenance urgency differs from

demonstrating patient benefit. No new numerical weighting, meta-analysis, or readiness score was calculated. Table 3 records the proposed responsibilities and their limits.

Critical appraisal was narrative. Laboratory studies were considered in terms of the test system and transfer to routine work; observational studies in terms of sampling, confounding, and setting; service accounts in terms of reporting detail and comparison; reviews in terms of scope and heterogeneity; and guidance in terms of development and applicability. The World Health Organization (2011) equipment-maintenance overview provided supplementary context for maintenance programme organization. The final framework integrates component findings but does not inherit validation from any one source. It requires separate assessment before institutional adoption.

Ethical considerations

Only published literature was analysed. There were no participants, patient records, identifiable institutional performance data, or collected specimens. The manuscript therefore claims no ethics approval, consent waiver, or institutional permission. Ethical considerations relate to the proposed use of the framework. A device should not be represented as fully ready when an applicable requirement remains unresolved, and an administrative status must not conceal a known concern. Investigation should use proportionate documentation and a clear route to authorized clinical, technical, or reprocessing expertise.

Future evaluation should protect confidentiality in incident and maintenance records, minimize unnecessary patient information, and consider unequal access to replacement devices or specialist support. Reporting should support learning rather than automatic blame. Commercial relationships affecting equipment or processing evaluations require transparent declaration by contributors. Affiliations do not imply organizational endorsement, and contributor roles, funding, and conflicts require confirmation before submission. A prospective study would require its own ethical and governance review, particularly if workflow changes might affect treatment access or safety.

Table 3 Proposed professional responsibilities and boundaries

Domain	Contribution to readiness	Limit of authority
Nursing	Observe patient-device interaction; check preparation; escalate concerns	Clinical settings follow authorized practice
Central sterile services	Process compatible devices and document relevant release evidence	Processing clearance does not certify technical performance
Biomedical equipment technology	Investigate faults; document maintenance and technical tests	Technical clearance does not establish biological suitability
Radiologic technology	Apply modality-specific preparation and patient-facing checks	Unresolved processing or technical issues require specialist input
Health administration	Provide resources, procurement support, traceability, and accountability	Administrative availability does not override unresolved concerns

4 RESULTS

The core corpus contains twenty publications spanning 2012–2026. It combines device-level and laboratory investigations, observational research, service and management evaluations, reviews, and professional guidance. Its heterogeneity is informative because readiness involves different questions, but prevents a common effect estimate. The synthesis identifies biological suitability, technical functionality, and clinical appropriateness as complementary requirements. Organizational resources and communication affect whether those requirements can be evaluated. No included publication tests the combined five-domain framework.

The first result is a conditional definition of readiness. Figure 1 shows three evidence streams converging on an authorized decision about a particular use. A processing record concerns biological suitability within its stated scope. A technical

assessment concerns function and condition. Clinical preparation concerns the patient, procedure, and configuration. These are connected requirements rather than substitutes. The central relationship is logical and conceptual: unresolved information in an applicable stream remains unresolved even when the other streams are satisfactory.

Reprocessing studies support distinguishing procedural completion from the result achieved (Ofstead et al., 2015; Ofstead et al., 2017). Cleaning validation further demonstrates why a measurement retains its test-specific meaning (Alfa et al., 2013). Maintenance analysis supports a similarly bounded interpretation of technical records (Iadanza et al., 2019). The synthesis consequently rejects an ambiguous all-purpose status that could be mistaken for several kinds of clearance. It proposes that records identify the domain evaluated, date or event to which the conclusion applies, remaining concern, and responsible next recipient.

The framework is proportional rather than universal. The applicable processing requirement depends on intended contact and compatible methods, while clinical preparation differs between monitoring, imaging, and other uses. Not every device travels through central sterile services, and not every use requires a new maintenance investigation. Nevertheless, a new fault, processing deviation, or change in intended use can invalidate an earlier assumption. The proposed model makes that dependency explicit without estimating its frequency or assigning a probability to harm.

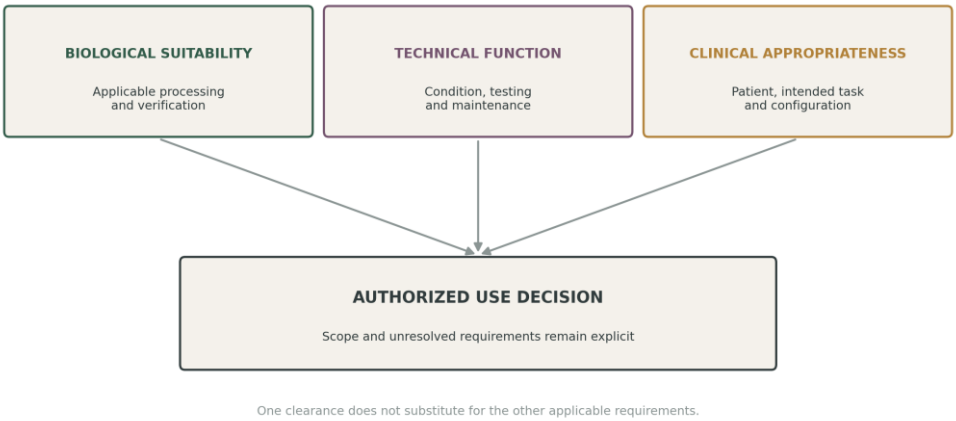


Figure 1 Three complementary evidence streams for a proposed readiness decision. The diagram represents conditional requirements, not a validated clinical checklist or a quantified model of risk.

The second result concerns the distribution and limits of the selected evidence. Figure 2 maps primary topic contributions across the twenty publications. Biological processing sources are prominent, maintenance studies provide technical-management evidence, alarm studies address clinical use, and broader safety sources connect organizational conditions. A marked cell indicates a predefined primary contribution in this synthesis, not proof of effectiveness or superiority. Blank cells do not mean that the source is irrelevant to every other aspect of readiness.

The map exposes a difference between evidence for individual components and evidence for their integration. Endoscope and cleaning studies can identify a biological concern, but cannot determine a universal equipment staffing model. Maintenance evaluations can describe records or prioritization, but cannot establish whether a particular reprocessing method is adequate. Alarm literature demonstrates that a technically functioning device still requires appropriate configuration and response arrangements (Cvach, 2012; Drew et al., 2014; Paine et al., 2016). These separate contributions inform the framework without forming an independent trial of the whole system.

Ultrasound provides a practical bridge between technical condition, processing, and clinical use. Recommendations address both examination-specific requirements and faulty equipment (Nyhsen et al., 2017), while survey evidence identifies gaps between recommended and reported practice (Westerway & Basseal, 2017). The synthesis therefore places intended use and relevant instructions at the interface between services. Procurement and replacement decisions should consider local processing capability and staff access to usable information. Laboratory evidence about difficult device geometries provides a

reason to examine those conditions, rather than assume every problem can be resolved through reminders alone (Kremer et al., 2025).

The evidence map also limits interpretation of publication counts. Several reviews summarize some of the same underlying research, and repeated endoscope publications may involve related technologies. The twenty sources must not be treated as twenty independent confirmations of one effect. Their value lies in identifying compatible principles and unresolved interfaces. The figure is consequently a transparent record of how the selected literature informed the conceptual analysis, rather than a quantitative ranking of professions or safety practices.

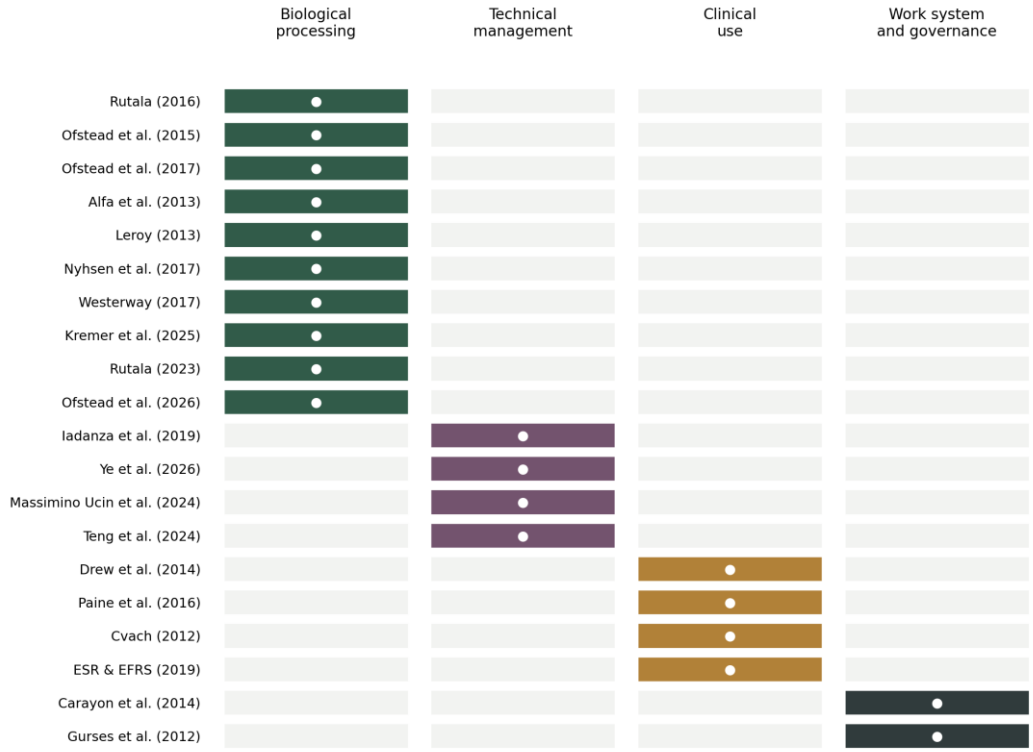


Figure 2 Primary-topic evidence map for the twenty selected publications. Filled cells indicate conceptual contributions assigned in this review. The map is not a risk-of-bias rating, effect-size chart, or exhaustive count of the literature.

The third result is a proposed separation of routes for unresolved concerns. Figure 3 shows how a reported technical defect and uncertain processing status require different specialist responses before returning to an authorized use decision. Both concerns can occur simultaneously. A repair entry should therefore not erase an unresolved processing issue, and a processing record should not be interpreted as proof that a damaged device functions correctly. The framework links the routes through a shared device identity and explicit responsibility for the next action.

Technical routing draws on work-order analysis and newer approaches to prioritization (Iadanza et al., 2019; Ye et al., 2026). Administrative support concerns response capacity, information access, and follow-up, which resource and workflow studies show cannot be assumed (Massimino Ucin et al., 2024; Teng et al., 2024). Processing routing draws on the distinction between compatibility, method completion, and verification. Broad reviews support continuing scrutiny of complex devices while leaving the selection of an appropriate method dependent on instructions, evidence, and available capability (Ofstead et al., 2026; Rutala & Weber, 2023).

Theoretical integration yields an evaluation agenda. A feasibility study could examine whether records distinguish biological, technical, and clinical questions; whether unresolved concerns reach the appropriate service; and whether the final decision is traceable to its supporting information. Measures would require explicit denominators, such as eligible device-use episodes or investigated incidents. Technical response time, processing verification, and clinical outcomes should remain separate

measures. Improved documentation alone would not demonstrate fewer infections, and faster repair would not establish safe clinical configuration.

The model also requires assessment of unintended consequences. Excessive documentation could divert staff from useful checks, and indiscriminate withdrawal of equipment could delay care when alternatives are limited. Systems theory supports examining these interactions rather than attributing readiness to a single person (Carayon et al., 2014; Gurses et al., 2012). Local implementation should therefore define escalation and authorized decision-making, including situations involving competing needs. The framework does not authorize use contrary to applicable requirements; it identifies where a reasoned decision and specialist input are needed.

Several limitations remain. Selection was purposive, some sources were accessible only as abstracts, and no independent duplicate extraction or formal evidence grading was performed. No field validation, stakeholder consultation, or organizational performance measurement was undertaken. The framework is thus an evidence-informed theoretical proposal. It offers a structure for investigation, not a demonstrated reduction in infection, equipment failure, alarm-related harm, or service interruption. Its transferability requires evaluation across different device groups, staffing arrangements, and resource conditions.

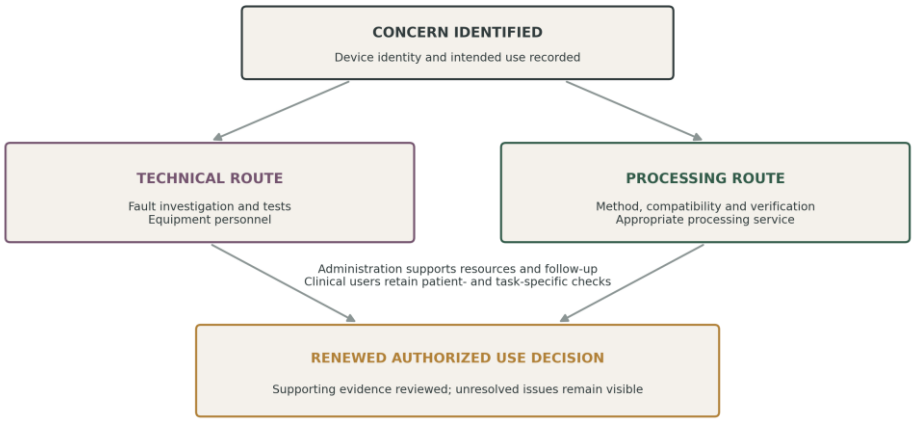


Figure 3 Proposed routing of technical and processing concerns before a renewed use decision. Connections represent suggested responsibilities and information exchange; they do not imply measured reductions in risk or delay.

5 CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

Medical device readiness is a relationship among evidence, intended use, and professional responsibility. This integrative review examined twenty publications concerning processing, maintenance, clinical use, and work-system design. The synthesis distinguishes biological suitability, technical functionality, and clinical appropriateness, showing why a positive finding in one domain cannot automatically establish the others. Equipment availability is therefore an incomplete description of readiness when relevant information remains unresolved.

The evidence supports component practices while retaining limits. Reprocessing studies distinguish recorded procedures from residual contamination and device condition. Cleaning verification remains method-specific. Maintenance studies show how records and prioritization can inform technical management without proving patient benefit. Alarm research demonstrates that a functioning device can still create difficulties through configuration, output, and response arrangements. Imaging guidance places these issues within the requirements of the patient and examination.

The proposed framework connects these findings through explicit responsibilities and conditional decisions. Its three figures describe complementary readiness evidence, the distribution of source contributions, and separate routes for unresolved

technical and processing concerns. These representations are theoretical and have not been prospectively tested. They do not establish reductions in infection, failure, treatment delay, or adverse events.

The contribution is an account of what different forms of clearance mean and how their limits should remain visible across services. Nursing, sterile services, equipment personnel, radiologic technology, and administration can contribute without assuming identical authority. Future research should assess feasibility, workload, confidentiality, access to expertise, and clinical consequences before the framework is considered effective or adopted beyond a locally evaluated setting.

5.2 Recommendations

Organizations considering this framework should first define which biological, technical, and clinical requirements apply to each device group and intended use. Records should identify the requirement assessed, the supporting information, unresolved concerns, and the person or service responsible for the next action. Staff should have access to current manufacturer instructions and an understandable route for specialist advice. A generic ready label should not replace domain-specific evidence.

Nursing and radiologic technology teams should contribute observations from clinical use and patient preparation within their authorized roles. Sterile services should document applicable processing and verification, while equipment personnel should explain the scope and outcome of technical investigations. Administration should support staffing, procurement, training, information access, and suitable alternatives when devices are unavailable. These responsibilities should be adapted to local arrangements rather than copied as fixed staffing prescriptions.

Technical and processing concerns should remain separately traceable until evaluated by the appropriate professionals. Digital tools may support communication, but status definitions and response ownership require design. Local education should distinguish cleaning indicators, microbiological findings, technical test results, and clinical outcomes. Changes to alarms or processing methods require appropriate authorization and consideration of unintended consequences.

A prospective feasibility evaluation should precede wider implementation. Measures should address information completeness, escalation, workflow burden, equipment access, and the quality of release decisions. Clinical outcomes require separate definitions and an appropriate comparison strategy. Contributors should confirm affiliations, authorship, funding, and conflicts before submission. Findings from evaluation should guide revision, with independent professional review before the framework becomes an institutional procedure.

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