MINISTRY OF SCIENCE AND HIGHER EDUCATION OF THE REPUBLIC OF KAZAKHSTAN

ҚАЗАҚСТАН РЕСПУБЛИКАСЫНЫҢ ҒЫЛЫМ ЖӘНЕ ЖОҒАРЫ БІЛІМ МИНИСТРЛІГІ

МИНИСТЕРСТВО НАУКИ И ВЫСШЕГО ОБРАЗОВАНИЯ РЕСПУБЛИКИ КАЗАХСТАН

KAZAKHSTAN

ХАЛЫҚАРАЛЫҚ УНИВЕРСИТЕТІ

INTERNATIONAL UNIVERSITY SINCE 2009

МЕЖДУНАРОДНЫЙ УНИВЕРСИТЕТ

INTERNATIONAL JOURNAL OF INFORMATION AND COMMUNICATION TECHNOLOGIES

Published since 2020.
Volume 7. 3 (27). 2026
July–September

ХАЛЫҚАРАЛЫҚ АҚПАРАТТЫҚ ЖӘНЕ КОММУНИКАЦИЯЛЫҚ ТЕХНОЛОГИЯЛАР ЖУРНАЛЫ

2020 жылдан бері шығарылады
Том 7. 3 (27). 2026
Шілде-Қыркүйек

МЕЖДУНАРОДНЫЙ ЖУРНАЛ ИНФОРМАЦИОННЫХ И КОММУНИКАЦИОННЫХ ТЕХНОЛОГИЙ

Издается с 2020 г.
Том 7. 3 (27). 2026
Июль-Сентябрь

Свидетельство о постановке на учет периодического печатного издания в Министерство информации и общественного развития Республики Казахстан № KZ82VPY00020475, выданное от 20.02.2020 г.

Зарегистрировано в Международном центре регистрации серийных изданий ISSN (ЮНЕСКО, Париж, Франция). ISSN 2708–2032 (print), ISSN 2708–2040 (online)

Журнал входит в Перечень научных изданий, рекомендуемых КОКНВО МНВО РК для публикации основных результатов научной деятельности.

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International Journal of Information and Communication Technologies
Periodicity: 4 times a year.
Languages: Kazakh, Russian, English
DOI prefix: 10.54309
ISSN 2708–2032 (print)
ISSN 2708–2040 (online)
Thematic focus: "Information technology"; "Digital technologies in the development of socio-economic systems"; "Information security and communication technologies".
Distribution: Materials are distributed under the Creative Commons Attribution 4.0
Journal website: https://journal.iitu.edu.kz
Owner: International Information Technology University JSC (Almaty).
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Халықаралық ақпараттық және коммуникациялық технологиялар журналы
ISSN 2708–2032 (print)
ISSN 2708–2040 (online)
Префикс DOI: 10.54309
Мерзімділігі: жылына 4 рет.
Басылым тілі: қазақ, орыс, ағылшын.
Тақырып бағыты: "Ақпараттық технологиялар"; "Ақпараттық қауіпсіздік және коммуникациялық технологиялар"; "Әлеуметтік-экономикалық жүйелерді дамытудағы цифрлық технология".
Журнал сайты: https://journal.iitu.edu.kz
Тарату: материалдар Creative Commons Attribution 4.0 лицензиясы бойынша таратылады
Меншік иесі: АҚ «Халықаралық ақпараттық технологиялар университеті» (Алматы қ.).
Авторлық құқық: © Халықаралық ақпараттық және коммуникациялық технологиялар журналы, 2026

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Международный журнал информационных и коммуникационных технологий
ISSN 2708–2032 (print)
ISSN 2708–2040 (online)
Префикс DOI: 10.54309
Периодичность: 4 выпусков в год.
Язык издания: казахский, русский, английский.
Тематическая направленность: "Информационные технологии"; "Информационная безопасность и коммуникационные технологии"; "Цифровые технологии в развитии социо-экономических систем".
Сайт журнала: https://journal.iitu.edu.kz
Распространение: материалы распространяются по лицензии Creative Commons Attribution 4.0
Собственник: АО «Международный университет информационных технологий» (г. Алматы).
Авторские права: © Международный журнал информационных и коммуникационных технологий, 2026

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INTERNATIONAL JOURNAL OF INFORMATION AND COMMUNICATION TECHNOLOGIES
ISSN 2708–2032 (print)
ISSN 2708–2040 (online)
Vol. 7. Is.3. Number 27 (2026). Pp. 338–356
Journal homepage: https://journal.iitu.edu.kz
https://doi.org/10.54309/IJICT.2026.27.3.018

KEY PUBLICATIONS OF 2021–2025 ON ARTIFICIAL INTELLIGENCE METHODS IN THE MANUFACTURING AND DIAGNOSTICS OF MEDICAL DEVICES FOR GLYCEMIC MONITORING: A THEMATIC ANALYTICAL REVIEW

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Abstract. Artificial intelligence is increasingly being applied in the manufacturing and diagnostics of medical devices, including systems for glycemic monitoring, where accuracy, reliability, and quality control are critically important. The aim of this study was to systematize key publications from 2021 to 2025 on the use of artificial intelligence in the manufacturing and diagnostics of glycemic-

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monitoring medical devices and to identify the main technological directions, practical opportunities, and implementation limitations. The review was based on 68 publications selected from Scopus, Web of Science, PubMed, IEE Xplore, and regulatory sources. The analysis identified five principal thematic areas: computer vision and defect detection, predictive quality management and anomaly detection, artificial intelligence in continuous glucose monitoring and biosensor systems, foundational computational architectures, and regulatory standards. The results show a clear shift from experimental studies to implementation-oriented and regulation-aware solutions. Overall, artificial intelligence demonstrates strong potential for improving production quality assurance, biosensor calibration, and medical device lifecycle support.

Keywords: artificial intelligence, medical devices, glycemic monitoring, diabetes mellitus, biosensors, quality management, machine learning

For citation: Karimkyzy B., Karasenko K.G., Alisherov N.A., Muratbek N.M., Karim A. (2026). Key publications of 2021–2025 on artificial intelligence methods in the manufacturing and diagnostics of medical devices for glycemic monitoring: a thematic analytical review // International journal of information and communication technologies. Vol. 7. No. 27. Pp. 338–356. https://doi.org/10.54309/IJICT.2026.27.3.018. (In Eng.).

Conflict of interest: The authors declare that there is no conflict of interest.

2021–2025 ЖЫЛДАР АРАЛЫҒЫНДАҒЫ ГЛИКЕМИЯЛЫҚ МОНИТОРИНГКЕ АРНАЛҒАН МЕДИЦИНАЛЫҚ ҚҰРЫЛҒЫЛАРДЫ ӨНДІРУ ЖӘНЕ ДИАГНОСТИКАЛАУДАҒЫ ЖАСАНДЫ ИНТЕЛЛЕКТ ӘДІСТЕРІ БОЙЫНША НЕГІЗГІ ЖАРИЯЛАНЫМДАР

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Аннотация. Соңғы жылдары жасанды интеллект әдістері медициналық құрылғыларды өндіру мен диагностикалауда, соның ішінде гликемиялық мониторинг жүйелерінде кеңінен қолданылып келеді, өйткені бұл салада дәлдік, сенімділік және сапаны бақылау аса маңызды. Осы зерттеудің мақсаты — 2021–2025 жылдар аралығындағы гликемиялық мониторингке арналған медициналық құрылғыларды өндіру мен диагностикалауда жасанды интеллектті қолдануға арналған негізгі жарияланымдарды жүйелеу, сондай-ақ басты технологиялық бағыттарды, практикалық мүмкіндіктер мен енгізу шектеулерін айқындау. Шолу Scopus, Web of Science, PubMed, IEEE Xplore базаларынан және ресми реттеуші дереккөздерден іріктелген 68 жарияланым негізінде жүргізілді. Талдау нәтижесінде бес негізгі тақырыптық бағыт анықталды: компьютерлік көру және ақауларды анықтау, сапаны болжамды басқару және аномалияларды табу, үздіксіз глюкоза мониторингі мен биосенсорлардағы жасанды интеллект, биомедициналық қолдануға бейім базалық есептеу архитектуралары, сондай-ақ нормативтік стандарттар мен нұсқаулықтар. Зерттеу нәтижелері эксперименттік жұмыстардан практикалық енгізуге және реттеушілік талаптарға бейімделген шешімдерге көшу үрдісін көрсетті. Қорытындысында жасанды интеллект әдістерінің өндіріс сапасын қамтамасыз ету, биосенсорларды калибрлеу және медициналық құрылғылардың өмірлік циклін қолдауда жоғары әлеуетке ие екені анықталды.

Түйінді сөздер: жасанды интеллект, медициналық құрылғылар, гликемиялық мониторинг, қант диабеті, биосенсорлар, сапа менеджменті, машиналық оқыту

Дәйексөздер үшін: Кәрімқызы Б., Карасенко К.Г., Әлішеров Н.А., Мұратбек Н.М., Кәрім А. (2026). 2021–2025 жылдар аралығындағы гликемиялық мониторингке арналған медициналық құрылғыларды өндіру және диагностикалаудағы жасанды интеллект әдістері бойынша негізгі жарияланымдар // Халықаралық ақпараттық және коммуникациялық технологиялар журналы. Т. 7. No 27. Б. 338–356. https://doi.org/10.54309/IJICT.2026.27.3.018. (Ағыл. тіл.).

Мүдделер қақтығысы: Авторлар осы мақалада мүдделер қақтығысы жоқ деп мәлімдейді.

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КЛЮЧЕВЫЕ ПУБЛИКАЦИИ 2021–2025 ГОДОВ ПО МЕТОДАМ ИСКУССТВЕННОГО ИНТЕЛЛЕКТА В ПРОИЗВОДСТВЕ И ДИАГНОСТИКЕ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ ГЛИКЕМИЧЕСКОГО МОНИТОРИНГА

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Аннотация. В последние годы методы искусственного интеллекта все активнее применяются в производстве и диагностике медицинских изделий, включая системы гликемического мониторинга, для которых особенно важны точность, надежность и контроль качества. Целью настоящего исследования является систематизация ключевых публикаций 2021–2025 годов, посвященных применению искусственного интеллекта в производстве и диагностике меди-

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цинских изделий для гликемического мониторинга, а также выявление основных технологических направлений, практических возможностей и ограничений внедрения. Обзор выполнен на основе 68 публикаций, отобранных из баз Scopus, Web of Science, PubMed, IEEE Xplore и официальных регуляторных источников. В результате анализа выделены пять основных тематических направлений: компьютерное зрение и обнаружение дефектов, предиктивное управление качеством и выявление аномалий, искусственный интеллект в системах непрерывного мониторинга глюкозы и биосенсорах, базовые вычислительные архитектуры с биомедицинским потенциалом, а также нормативные стандарты и руководства. Полученные результаты показывают переход от экспериментальных исследований к практико-ориентированным и регуляторно-адаптированным решениям. Сделан вывод о высоком потенциале методов искусственного интеллекта для обеспечения качества производства, калибровки биосенсоров и сопровождения жизненного цикла медицинских изделий.

Ключевые слова: искусственный интеллект, медицинские изделия, гликемический мониторинг, сахарный диабет, биосенсоры, управление качеством, машинное обучение

Для цитирования: Каримкызы Б., Карасенко К.Г., Алишеров Н.А., Муратбек Н.М., Карим А. (2026). Ключевые публикации 2021–2025 годов по методам искусственного интеллекта в производстве и диагностике медицинских изделий для гликемического мониторинга // Международный журнал информационных и коммуникационных технологий. Т. 7. No. 27. Стр. 338–356. https://doi.org/10.54309/IJICT.2026.27.3.018. (На англ.).

Конфликт интересов: авторы заявляют об отсутствии конфликта интересов.

Introduction.

Artificial intelligence has become increasingly important across medicine, engineering, and industrial production. This trend is especially evident in the medical device sector, where advanced computational methods are used not only to support the interpretation of clinical data, but also to improve manufacturing-related processes such as defect detection, quality control, sensor calibration, and product lifecycle management (Tercan et al., 2022; Guan et al., 2023; Fraser et al., 2023). These developments reflect the growing integration of intelligent methods into both the analytical and production dimensions of modern healthcare technologies.

This issue is particularly relevant to glycemic monitoring. The global growth of diabetes mellitus has intensified the demand for accurate, reliable, and practical blood glucose meters and continuous glucose monitoring systems for both clinical use and everyday self-management (International Diabetes Federation, 2025). In this context, device performance is not merely a technical characteristic; it has direct implications for patient safety, treatment quality, and long-term disease management (Jin et al., 2023; Alhaddad et al., 2022). Ensuring the reliability of such devices has therefore become both a technical and a clinical priority.

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From a manufacturing perspective, the stability and consistency of glycemic-monitoring devices are essential to product quality. Variations in enzyme-layer deposition, electrode geometry, sealing, and material uniformity may lead to measurement inaccuracies and reduce the quality of the final product. For this reason, intelligent computational methods have increasingly been investigated as tools for improving production quality, enabling early-stage inspection, and detecting defects during manufacturing (Cumbajin et al., 2023; Park et al., 2022; Zajec et al., 2024; Ördek et al., 2024). In particular, computer vision has shown considerable promise for automated visual inspection, while predictive models and anomaly-detection methods create new opportunities for preventive quality assurance.

At the same time, these technological developments are unfolding within a rapidly evolving regulatory environment. Standards and regulatory frameworks, including ISO 13485:2016, ISO/IEC 42001:2023, and the U.S. Food and Drug Administration's recommendations on predetermined change control plans, demonstrate that artificial intelligence is moving from an experimental tool to an increasingly integral component of a regulated engineering and quality-management ecosystem (International Organization for Standardization, 2016; International Organization for Standardization, 2023; U.S. Food and Drug Administration, 2025; Fraser et al., 2023). These changes underscore the growing importance of transparency, traceability, validation, and lifecycle control in the implementation of AI/ML-based medical technologies.

Despite the growing volume of research, the literature remains fragmented. Existing studies have often focused on isolated domains such as continuous glucose monitoring, biosensor modelling, manufacturing inspection, or regulatory governance, without offering a comprehensive view of the field as a whole (Jin et al., 2023; Guan et al., 2023; Fraser et al., 2023). As a result, it remains difficult to determine which methodological developments are most relevant for the practical manufacturing and diagnostics of glycemic-monitoring medical devices.

The aim of this study is therefore to review the literature on the application of artificial intelligence to the manufacturing and diagnostics of glycemic-monitoring medical devices. Particular attention is given to methodological approaches, technological designs, and practical solutions, including computer vision, predictive analytics, anomaly detection, biosensor-oriented modelling, and regulation-aware deployment. The review seeks to summarize the major studies published between 2021 and 2025, identify key technological directions and methodological developments, and evaluate their practical relevance for manufacturing and diagnostic contexts. To achieve this aim, the study examines recent publications in the field, categorizes them according to thematic focus, identifies the most relevant methods and application domains, and assesses their significance for the medical device industry and diagnostic practice.

The study is based on a thematic analysis of scientific and regulatory literature published between 2021 and 2025. It includes the selection, review, comparison, classification, and interpretation of publications related to glycemic-monitoring

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devices, biosensors, industrial quality control, and computational methods applicable to medical devices. In addition to domain-specific research, the review also considers influential methodological developments from adjacent fields, including AlphaFold 3, MedSAM, and DINO (Abramson et al., 2024; Ma et al., 2024; Caron et al., 2021). These architectures are treated as transferable and prospective methodological directions rather than as fully validated industrial tools for the manufacturing and diagnostics of glycemic-monitoring medical devices. Their relevance lies in their potential applicability to enzyme-layer modelling, medical-device segmentation, defect detection, and low-label industrial learning, but this transfer requires further empirical validation in biosensor-specific production environments. The scientific contribution of the study lies in its attempt to integrate fragmented research into a single analytical framework, while its practical significance lies in identifying methodological solutions with the greatest relevance for manufacturing quality control, biosensor calibration, device reliability, and future deployment in regulated medical technology settings.

Materials and methods.

This study was designed as a thematic analytical review of recent scientific and regulatory publications on the application of artificial intelligence towards the manufacture and diagnostics of medical devices for glycemic monitoring. The review used a structured thematic approach to analyze previous literature, identify technological trends, and evaluate computational methods for production quality assurance, biosensor calibration, defect detection, and regulatory compliance (Tercan et al., 2022; Fraser et al., 2023; Jin et al., 2023).

The research question that framed the research work was as follows: From 2021 to 2025, which methodological approaches and technologies were most important for the production and diagnostics of glycemic-monitoring medical devices? In particular, the survey covered a comprehensive review of relevant research papers: classification based on common theme; the extent to which practical applications for manufacturing/ diagnostic activities are found to have the highest utility; recent publications from which regulatory and quality-management needs emerge as important drivers of the implementation of intelligent computing in medical devices (Guan et al., 2023; Fraser et al., 2023; U.S. Food and Drug Administration, 2025).

The working hypothesis of this study was that recent research progress is driven not only by developments in diabetes-related analytics and biosensors, but also by the transfer of methodological solutions from adjacent domains, including computer vision, self-supervised learning, multimodal models, and regulation-aware engineering (Jin et al., 2023; Cumbajin et al., 2023; Caron et al., 2021; Dai et al., 2023). Based on this it was presumed that a more comprehensive perspective of the analysis would allow the potential identification of common and novel techniques affecting medical device fabrication. Literature was drawn from scientific reports and official regulatory documents published from 2021 to 2025. Publications from 2021–2025 formed the main analytical corpus. Earlier standards and methodological works were used as contextual references because of their continuing relevance to regulatory interpretation and model explainability. The literature search was performed on the Scopus, Web

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of Science, PubMed, IEEE Xplore databases and the authoritative sources Nature, Science, arXiv, and official portals by the U.S. Food and Drug Administration and the International Organization for Standardization (Abramson et al., 2024; Wang et al., 2024; U.S. Food and Drug Administration, 2025; International Organization for Standardization, 2023).

The purpose of the selection of sources was to provide not only a disciplinary breadth, but also to ensure thematic relevance. Quantitatively, the preliminary search produced 412 records. After the exclusion of 89 duplicates, 323 records were retained for title & abstract screening. A total of 174 records were also excluded as not sufficiently related to the topic. The remaining 149 full-text sources were reviewed comprehensively and 81 publications were excluded after eligibility evaluation. Consequently, 68 sources were included in the subsequent analytical corpus. The comprehensive process of study selection is shown in Figure 1.

Collectively, from a qualitative perspective, the chosen corpus consisted of peer-reviewed journal articles, conference papers, methodological publications, and official regulatory documents. This combination allowed us to explore the topic not only from the tech point of view but also the quality assurance/compliance requirements (Tercan et al., 2022; Fraser et al., 2023; International Organization for Standardization, 2016).

In addition, inclusion and quality-assessment criteria were defined to maintain the scientific rigor and thematic integrity of the review. A source was included if it met three criteria: it was a peer-reviewed publication or an official regulatory document; it presented verifiable empirical findings or a clearly defined conceptual or regulatory contribution; and it had direct or indirect relevance to medical-device manufacturing, glycemic monitoring, biosensor technologies, or diabetes-related diagnostics (Jin et al., 2023; Alhaddad et al., 2022; Fraser et al., 2023). Each included source was then assessed according to five quality criteria: direct thematic relevance to glycemic monitoring or medical-device manufacturing; clarity of the described AI/ML method; availability of empirical, methodological, or regulatory evidence; applicability to manufacturing, diagnostics, biosensor calibration, or quality management; and reproducibility or traceability of the reported data, including the availability of datasets, performance metrics, implementation details, or regulatory documentation. Sources were not excluded solely because of limited reproducibility when they represented official regulatory documents or foundational methodological contributions. Instead, they were classified as indirect or prospective evidence rather than as direct validation for glycemic-monitoring device manufacturing.

On this basis, the reviewed sources were classified into three evidence levels: direct evidence, indirect transferable evidence, and prospective methodological evidence. Direct evidence included publications focused on glycemic monitoring, biosensors, diabetes diagnostics, or medical-device quality. Indirect transferable evidence included manufacturing, computer-vision, and anomaly-detection studies that were not originally designed for glycemic devices but were technically relevant to production inspection or quality control. Prospective methodological evidence included foundational architectures such as AlphaFold 3, MedSAM, and DINO,

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whose relevance is primarily translational and requires further empirical validation in biosensor-specific manufacturing environments.

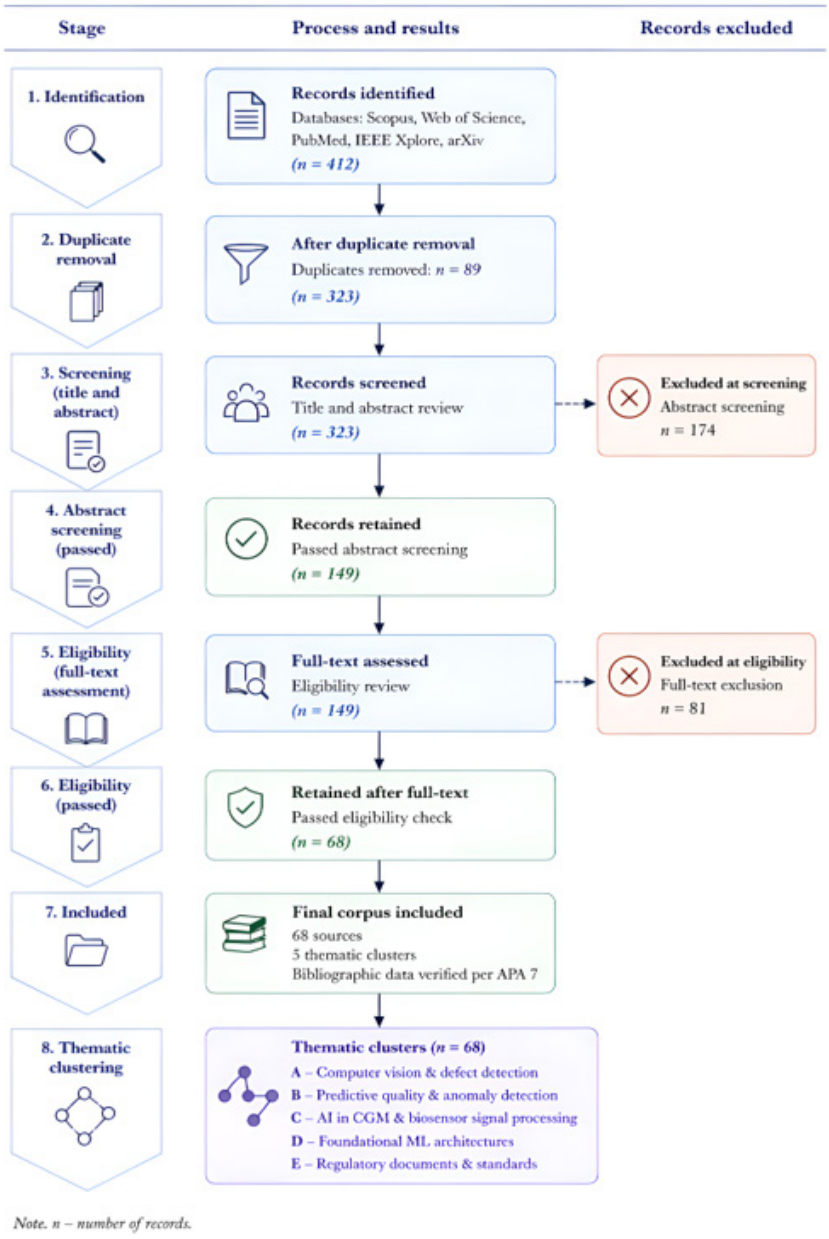


Fig. 1. PRISMA flow diagram of the literature selection process

For all included sources, bibliographic metadata, including authorship, year of publication, publication venue, volume, page range, and DOI, were checked and normalized according to APA 7 formatting. The research process consisted of five stages. In the first stage, a focused literature search was conducted using predefined thematic areas and keyword combinations related to artificial intelligence, machine

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learning, medical-device manufacturing, glycemic monitoring, biosensors, quality control, defect detection, anomaly detection, and regulatory requirements. In the second stage, the retrieved papers were screened for relevance based on their titles and abstracts. In the third stage, full-text analysis was conducted to assess methodological content, application domain, and practical significance. In the fourth stage, the selected studies were arranged into thematic clusters. In the final stage, the extracted data were synthesized through a comparative and interpretive approach to identify significant research trends, transferable methods, and implementation-oriented developments (Tercan & Meisen, 2022; Ördek et al., 2024). Figure 2 summarizes the conceptual logic of the review in relation to computational methods, manufacturing tasks, diagnostic applications, and expected outcomes.

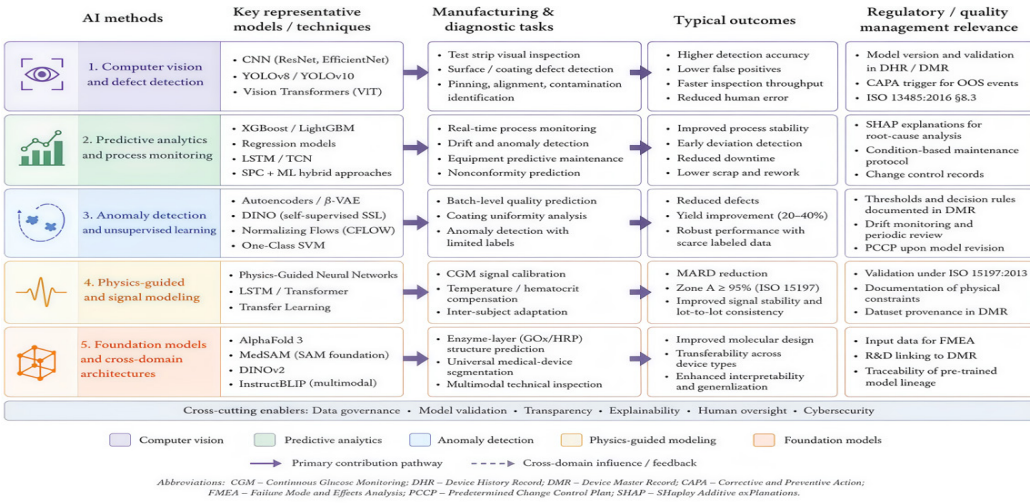


Fig. 2. Conceptual map of artificial intelligence applications in the manufacturing and diagnostics of glycemic-monitoring medical devices

The study employed several research methods. This encompassed bibliographic search, source selection, thematic classification, comparative analysis, and interpretive synthesis. Selected papers were organised into the following groupings; computer vision and defect detection; predictive quality management and anomaly detection; artificial intelligence in continuous glucose monitoring systems and biosensor signal processing; foundational computational architectures with biomedical applicability; and governmental/regulatory documents/standards (Cumbajin et al., 2023; Zajec et al., 2024; Jin et al., 2023; Ma et al., 2024; International Organization for Standardization, 2023). Moreover, the available literature was analyzed at a temporal level, examining the important methodological and regulatory advancements during the analysis context (Fraser et al., 2023; U.S. Food and Drug Administration, 2025). In order to strengthen the analytical part of the review, the chosen methodologies were also mapped to key manufacturing and diagnostic tasks linked to glycemic-monitoring devices. This comparative mapping permitted us to differentiate between different levels of relevance, from strong to emerging, and how each of these approaches contributed to

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inspection, predictive quality assessment, calibration, biosensor design, and regulatory interpretability. This systematic approach is shown in Figure 3.

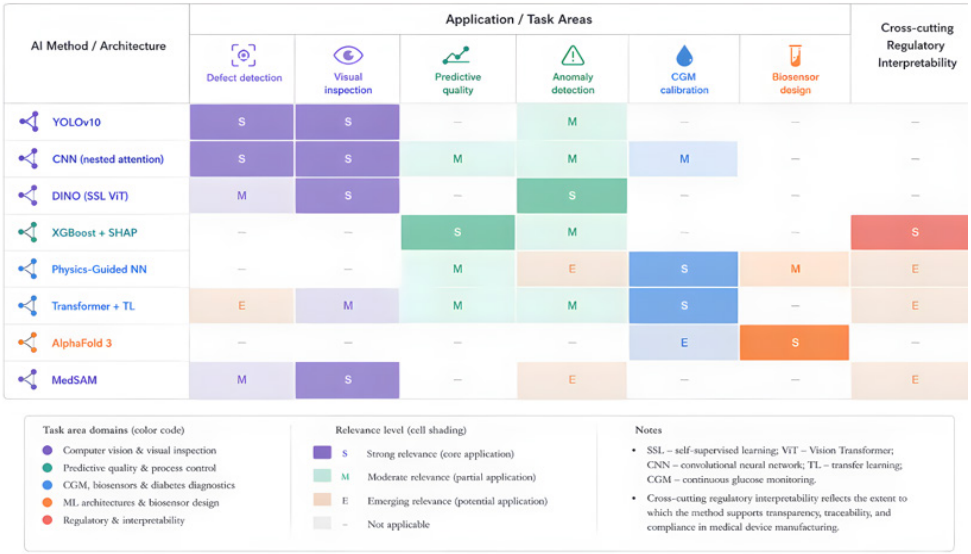


Fig. 3. Mapping of artificial intelligence methods to manufacturing and diagnostic tasks in glycemic-monitoring devices

The methodological novelty of this review is that it is not restricted to publications focused exclusively on glycemic-monitoring systems. It also includes influential methodological advances from adjacent domains, such as AlphaFold 3, MedSAM, and DINO, but these sources were classified as prospective or transferable evidence rather than direct validation for glycemic-monitoring device manufacturing. This broader analytical scope made it possible to distinguish between established methods with direct domain relevance and emerging architectures whose future application to biosensor design, inspection, calibration, and regulated deployment remains to be experimentally validated (Abramson et al., 2024; Ma et al., 2024; Caron et al., 2021). This qualitative diversity, along with the quantitative structure of the selected material, the explicit inclusion criteria, the staged selection procedure, and the thematic and comparative methods of analysis, strengthens the conclusion. All taken together, the methodological decisions make up a solid framework through which to identify important directions of research in the fields of glycemic-monitoring medical devices manufacturing and diagnostics.

Results and discussion.

We show a detailed overview of the published works included in the review in Figure 4, which displays the linkage among the studies, thematic clusters, and significant areas of application within the utilization of artificial intelligence for glycemic-monitoring medical devices. In contrast with a traditional comparison chart, the knowledge graph elucidates links between literature on computer vision, predictive quality, continuous glucose monitoring and biosensors, main computational

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architectures, and regulatory frameworks. This representation allows not only the internal structure of the reviewed body of work to be delineated, but also the methodological bridges connecting various research streams.

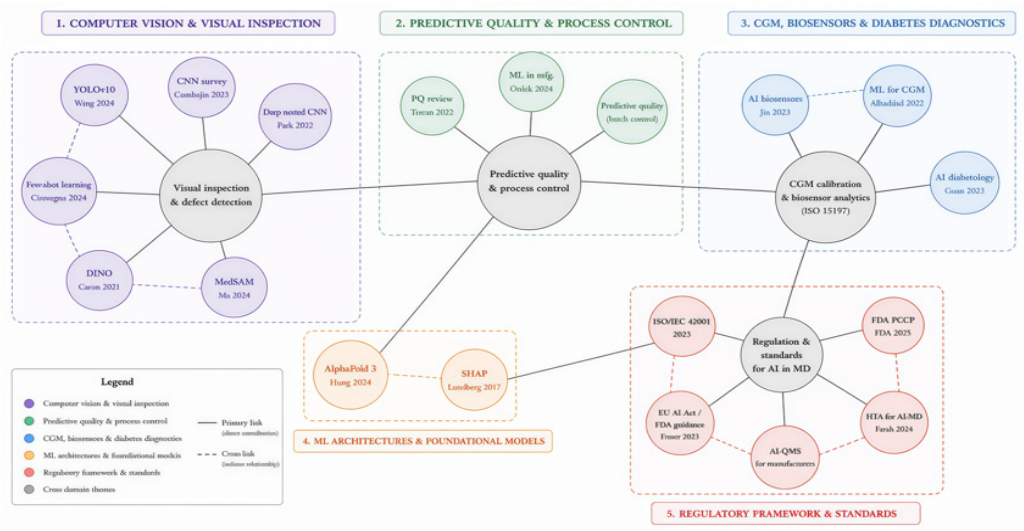


Fig. 4. Knowledge graph of key publications and thematic relationships in artificial intelligence for glycemic-monitoring medical devices (2021–2025)

The reviewed literature indicates that instead of a single linear path, the field has progressed along multiple intersecting trajectories. Among these, computer vision and automated defect detection in manufacturing represent one of the most developed research directions. The studies in this area have addressed a particular challenge by demonstrating that visual inspection can be enhanced to a substantial degree with the use of convolutional and transformer-based models, especially when evaluating surface defect recognition, structural anomaly detection, and few-shot adaptation to small numbers of labelled data (Cumbajin et al., 2023; Park et al., 2022; Zajec et al., 2024). Their scientific contribution is to show that production quality control is finally a viable pattern-recognition problem and not a rule of thumb or manual inspection. At the same time, there are several studies in these categories but many still centre on industrial data or general manufacturing conditions, not considering the specific needs for glycemic-monitoring. This results in a substantial gap between methodological capability and domain-specific implementation. The second main direction concerns the area of predictive quality management and anomaly detection. This group of studies contributes to the literature by shifting the perspective from post hoc error detection to early identification of nonconformities, process drift, and equipment disturbances. Reviews and empirical works have shown that the strength of manufacturing process is not only observed in addition to traditional detection capabilities, but also may be enhanced by anticipatory modeling of process behavior which could be developed in the future (Tercan et al., 2022; Ördek et al., 2024). This is especially important in the production of biosensors and test strips, where small variations in process parameters

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may significantly affect measurement performance. Yet, prior research has discussed predictive quality methods in general industrial terms, without making direct tie-ins to the design limitations to the calibration parameters and clinical sensitivity of those glucose-interpreter sensors. For this reason, a mature body of literature, on the other hand, does not present an adequately integrated analysis of how predictive manufacturing analytics can be leveraged to be applied for glycemic-monitoring. Recent publication trends in this field include continuous glucose monitoring, biosensor modeling, and data-driven intelligent support for diabetes diagnosis. While these studies make a significant contribution to the existing literature by responding to clinical and functional aspects of the problem such as sensor accuracy, signal interpretation, cross-subject calibration, and system reliability (Jin et al., 2023; Alhaddad et al., 2022; Guan et al., 2023). They are essential because they show that glycemic-monitoring systems are not restricted to passive means of data collection, and, indeed, rely more and more on adaptive computational approaches to enhance their accuracy and robustness. However, little of this literature relates to upstream data and manufacturing quality but more to device operation and downstream analysis. This says that while the diagnosing value associated with intelligent methods is well defined, their link with the manufacturing environment remains underdeveloped in the published literature.

Foundational architectures originating from adjacent fields constitute an additional methodological direction in the reviewed literature. Their value for glycemic-monitoring devices should not be interpreted as direct industrial validation, but rather as an indication of possible methodological transfer. AlphaFold 3 may be relevant for future modelling of biomolecular interactions in enzyme layers of biosensors, MedSAM may support the development of adaptable segmentation approaches for medical-device inspection, and DINO demonstrates the potential of self-supervised learning in low-label manufacturing environments (Abramson et al., 2024; Ma et al., 2024; Caron et al., 2021). However, a substantial gap remains between architectural promise and validated implementation in practical production pipelines for glycemic-monitoring devices. Therefore, these architectures should be classified as prospective methodological evidence rather than as established industrial solutions for this specific domain.

Another important component of the reviewed literature is the regulatory dimension. Recent standards and guidance documents have reframed AI/ML-based methods in medical devices not simply as computational tools, but as elements of a regulated engineering ecosystem in which traceability, validation, change control, lifecycle monitoring, and documented reliability are mandatory requirements (Fraser et al., 2023; International Organization for Standardization, 2016; International Organization for Standardization, 2023; U.S. Food and Drug Administration, 2025). This body of literature is scientifically important because it defines the conditions under which AI/ML-based systems can be deployed in healthcare technologies. Although regulatory publications are fewer than technical studies and are often weakly connected to algorithmic research, recent standardization efforts and guidance documents increasingly address this gap. Thus, the main limitation is not the absence of regulation

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itself, but the lack of well-integrated studies that combine model development, manufacturing application, validation evidence, and compliance requirements within a single analytical framework.

To highlight the evolution of the most important research directions, Figure 5 presents a temporally organized summary of landmark publications and regulatory developments. The timing distribution of the corpus shows a clear increase in publication activity in 2023–2024, when more than 60% of the reviewed sources were published. This acceleration reflects the interaction of several processes: the maturation of transformer-based and self-supervised architectures, growing interest in automated quality control, broader adoption of continuous glucose monitoring systems, and the development of more regulation-oriented frameworks for AI/ML-based medical systems.

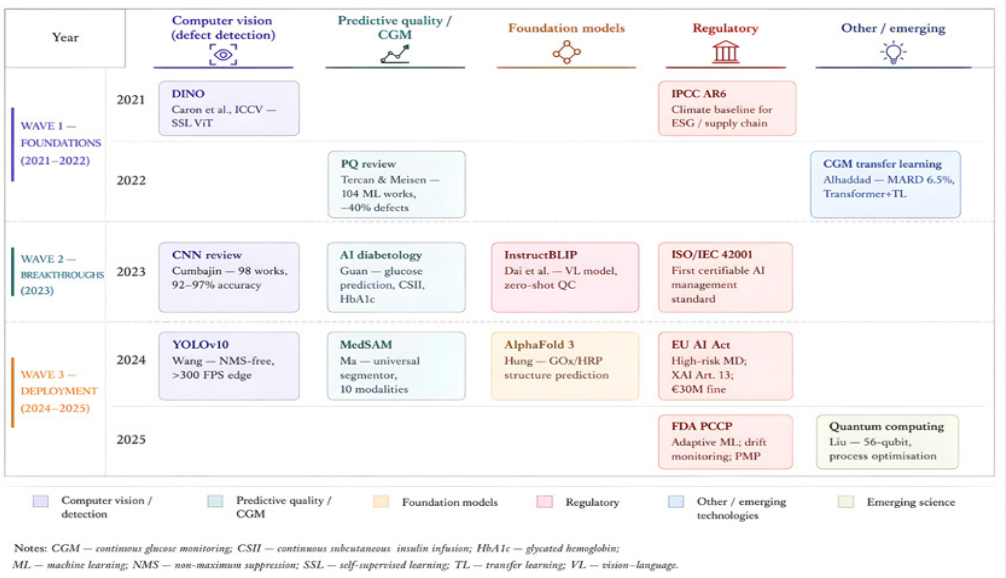


Fig. 5. Timeline of key methodological and regulatory developments in artificial intelligence for glycemic-monitoring medical devices, 2021–2025

Chronologically, there are three major waves of activity. The first wave (2021–22) saw the development of base architectures and the first formal efforts to evaluate the effectiveness of predictive quality methods and self-supervised learning technologies in the industrial landscape. The second wave, initiated in 2023, led to a more focused concentration of work on continuous glucose monitoring, biosensor-related analytics, industrial defect detection and methodological investigations. The third wave, from 2024 through 2025, is characterized by a transition to implementation-driven, regulation-aware research (e.g., YOLOv10, AlphaFold 3, MedSAM, and the emergence of newer regulatory frameworks). This evolution implies, then, that there is an evolution from piecemeal methodological innovation to the domain becoming applied and system level. Based on the outcomes of the present review, some trends are evident. First, the distribution was found by year, confirming that the field is

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relatively young but rapidly becoming organized. Six (6) of the 68 sources included were published in 2021, nine (9) in 2022, twenty-one (21) in 2023, twenty-three (23) in 2024 and nine (9) in 2025. It is expected that this is the period of main acceleration in the field, as it has recorded 64.7% of all reviewed publications in 2023–2024. Second, the thematic distribution indicates a strong concentration of studies related to computer vision and defect detection, totaling 18 publications, or 26.5% of the corpus. Predictive quality and anomaly detection are the second largest group with 16 publications (23.5%), and continuous glucose monitoring as well as biosensor-related studies next up with 14 publications (20.6%). Twelve (12) publications (17.6%) refer to foundational architectures that demonstrate biomedical relevance and the remaining eight (8) (11.8%) refer to regulatory documents and standards. These results indicate that the greatest focus still lies on inspection and quality-control applications to the generalisation and generalizability of the use to more general manufacturing scenarios at present. In contrast, the smaller share of explicitly regulatory papers should not be taken to be evidence of little relevance. Nevertheless, regulation functions as a cross-cutting constraint and enabling condition, even when it is not the primary focus of technical studies. Likewise, the low proportion of biosensor- and CGM-centric studies shows that the field is widely acknowledged clinically useful, yet the literature is far from bridging the gap between device operation and manufacturing design. A summary matrix produced in this review outlines the functioning spectrum of methods and practical relevance. The study demonstrates that architectures such as YOLO-based detectors, EfficientNet, DINO, XGBoost and SHAP, models LSTM/TCN, beta-VAE, normalising flows, physics-guided neural networks, transfer-based transformer architectures are capable of tackling some layers of fabrication and diagnostic pipeline that are somewhat contrasting and yet serve to add mutual value. Some are mainly used for visual observation and anomaly detection, while others for quality prediction or biosensor calibration, and a smaller number of them is strategically valuable for later design and modelling tasks. The comparative benefit of this matrix is that it demonstrates that each tool does not account for every associated task, but is marked by methodical complementarity and task relevance. A summary matrix was derived based on the systematic approach that I applied to the literature to associate particular machine learning libraries with manufacturing quality management problems, diagnostic capabilities, performance assessments, data sources, code availability, and regulatory artifacts. The matrix describes how the mentioned techniques could be implemented into glycemic-monitoring medical devices and their production environments. The results are indicated in Table 1.

Note. Evidence levels: Direct evidence – studies conducted directly on glycemic-monitoring devices, biosensors, CGM systems, or diabetes diagnostics; Indirect transferable evidence–studies originating from manufacturing, computer vision, predictive quality management, or anomaly detection domains that are technically transferable; Prospective methodological evidence – foundational architectures whose relevance remains primarily translational and requires further validation in glycemic-monitoring device manufacturing.

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Table 1. Summary matrix of ML methods, quality management system tasks, performance metrics, and regulatory artifacts for medical device manufacturing and diabetes diagnostics.

Method / Architecture	Task in Medical Device Manufacturing	Key Metric	Data Source	Code Availability	Evidence level	Industrial readiness	Regulatory Artifact
YOLO v8-m	Inline defect detection for test strips	Accuracy 95–97%; FPS 120 on GPU	MVTec / proprietary	Open-source	Indirect transferable evidence	Medium–High	Model version in DHR; CAPA trigger; ISO 13485 §8.3
EfficientNet-B4	Surface defect classification	Accuracy 95–97%; 35 FPS	NEU / proprietary	Open-source	Indirect transferable evidence	Medium	Software Validation Plan; version record in DMR
DINO (ViT SSL)	Label-free pretraining; few-shot fine-tuning	F1 > 0.90 at n=10	Manufacturing data	Open-source	Prospective methodological evidence	Low–Medium	Documentation of the SSL dataset in the validation procedure
XGBoost + SHAP	Prediction of batch nonconformity	AUC > 0.95	ERP/MES	Open-source	Indirect transferable evidence	Medium	SHAP log in CAPA; root-cause justification
LSTM / TCN	Predictive maintenance of equipment	F1 > 0.88; 30–50% downtime reduction	Equipment sensor data	Partially open	Indirect transferable evidence	Medium	Condition-based maintenance protocol; Change Control Record
β-VAE	Unsupervised coating anomaly detection	AUROC 0.92–0.98	MVTec / manufacturing data	Open-source	Indirect transferable evidence	Medium	Threshold in DMR; PCCP upon revision; drift monitoring
Normalizing Flows (CFLOW)	Anomaly detection with explicit density modeling	AUROC 0.962; FPR@95 = 0.09	MVTec AD	Open-source	Indirect transferable evidence	Medium	Log-likelihood threshold statistically justified for audit purposes
Physics-Guided NN	CGM calibration; correction for Ht/ temperature	MARD 6–8%; Zone A ≥95%	OhioT1DM / production data	Partially open	Direct evidence	Medium	Validation of GOx physical constraints in DMR; ISO 15197:2013
Transformer + Transfer	Cross-subject CGM calibration	MARD 6.5%; Zone A ≥96%	OhioT1DM 2020	Open-source	Direct evidence	Medium	Documentation of source dataset and fine-tuning in DMR
AlphaFold 3	Enzyme-layer design / GOx-HRP modelling	State-of-the-art protein–ligand accuracy	PDB / OpenFold	Partially open	Prospective methodological evidence	Low	Input data for FMEA of enzyme layer; linkage to DMR
MedSAM	Universal medical-device segmentation	IoU comparable to specialized models	10 modalities	Open-source	Prospective methodological evidence	Low–Medium	Foundation basis for adaptation to inspection across device types

Industrial readiness levels: High – routinely applicable in industrial environments; Medium – validated in related industrial contexts but requiring adaptation; Low – promising research-stage methods with limited manufacturing validation.

Table 1 illustrates how the methods reviewed differ widely in their functional role and implementation context. While some computer vision architectures such as YOLO v8-m and EfficientNet-B4 can perform inline inspection and surface defect classification for most applications, DINO has good advantages in low-label manufacturing environments thanks to its capability for self-supervised learning. Predictive models like XGBoost equipped with SHAP, LSTM, and TCN are relevant in the nonconformity and machinery maintenance sectors, and physics-guided neural networks and transformer-based transfer algorithms correspond more closely with calibration tasks in continuous glucose monitoring systems. Foundation models like AlphaFold 3 and MedSAM sit in an untapped space, as they have high value as transferable for enzyme-layer designs and universal inspection workflows rather than

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as industrial standard production tools. Accordingly, the main blind area that this review seeks to address is not just the non-comprehensibility of single individual studies, but the absence of a cohesive model perspective that could connect manufacturing, diagnostics, methodological translation, and regulations. Current works are sometimes quite valuable but highly individualistic in that: industrial studies seldom account for biomedical specificity, biosensor studies often neglect manufacturing quality, while regulatory documents rarely consider the specifics of model architecture and deployment. Taking these threads and knitting them together the current review provides a more coherent overview of the field and points to directions where future research should be going. In general, the findings show that the artificial intelligence employed in glycemic-monitoring medical devices is transitioning from a collection of individual and technical experiments to an organized interdisciplinary enterprise. This research will be limited by algorithmic performance, the capacity to integrate domain-specific diagnostics, manufacturing robustness, transferable computational architectures, and compliance with regulatory and quality management standards. This conclusion is in line with the general trends in the reviewed literature around new, more implementation-oriented, interpretable, and rule-informed solutions being prioritised over technically isolated innovations.

Conclusion.

These papers on the use of artificial intelligence for the preparation and diagnosis of medical devices for glycemic monitoring were consolidated in this review that focused on the literature with publications published between 2021 and 2025. Through the use of thematic analysis, the research uncovered five fundamental avenues: computer vision and defect detection, predictive quality management and anomaly detection, artificial intelligence in continuous glucose monitoring and biosensor systems, foundational computational architectures with relevance to biomedical applications and regulatory standards and guidance. The study demonstrates a marked shift from the development of standalone experimental projects to more advanced and application-oriented solutions. Publications were most highly collected in computer vision and manufacturing quality control, suggesting that visual inspection and defect detection remained to be most dynamically growing areas. Simultaneously, progress in the field is facilitated not only by better diagnosis of diabetes, but from the integration of methodology from other similar domains. In this regard, AlphaFold 3, MedSAM, DINO, and multimodal architectures should be interpreted as prospective and transferable methodological directions rather than as already validated industrial tools. They indicate potential future relevance for enzyme-layer modelling, universal inspection, and low-label industrial learning, but their application to glycemic-monitoring device manufacturing requires further empirical validation in real production and biosensor-specific environments. The paper further demonstrates that further development of this area will increasingly rely on the interaction between technological novelty and regulatory governance. Standards and guidance documents like ISO 13485, ISO/IEC 42001, FDA PCCP recommendations emphasize also the need for traceability, provenance assessment, validation, lifecycle control, process control and structured

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documentation for deploying intelligent computational systems in medical devices, among other key principles. At the same time, the literature remains fragmented, with previous studies typically focusing on only one aspect of the problem and rarely integrating manufacturing, diagnostics, and regulatory considerations into a unified framework.

Several analytical observations emerge from the reviewed literature. First, the highest level of practical readiness was identified for computer-vision-based defect detection and predictive quality management, because these methods are already supported by industrial inspection datasets and manufacturing-oriented validation procedures. Second, CGM calibration and biosensor signal modelling demonstrate stronger domain specificity but remain less integrated with upstream manufacturing quality data. Third, foundation models and self-supervised architectures represent one of the most promising but least validated groups of methods; therefore, their application should be considered a future research direction rather than an established production practice. Finally, regulatory readiness is becoming a cross-cutting requirement for all AI-enabled medical-device applications, particularly in relation to model validation, traceability, change control, and lifecycle monitoring.

Furthermore, future research needs to be directed toward open benchmark datasets and reporting standards of computational studies involving medical devices for computational research in the manufacturing of medical devices to have access to open benchmark datasets, as well as the empirical validation of transferable architectures based in practice in real manufacturing environment. Overall, the review shows that artificial intelligence in glycemic-monitoring medical devices is emerging as an interdisciplinary field with substantial scientific and practical potential for manufacturing quality assurance, biosensor calibration, diagnostic reliability, and regulated lifecycle management.

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INTERNATIONAL JOURNAL OF INFORMATION AND COMMUNICATION TECHNOLOGIES

ХАЛЫҚАРАЛЫҚ АҚПАРАТТЫҚ ЖӘНЕ КОММУНИКАЦИЯЛЫҚ ТЕХНОЛОГИЯЛАР ЖУРНАЛЫ

МЕЖДУНАРОДНЫЙ ЖУРНАЛ ИНФОРМАЦИОННЫХ И КОММУНИКАЦИОННЫХ ТЕХНОЛОГИЙ

Собственник:
АО «Международный университет информационных технологий» (Казахстан, Алматы)

Главный редактор:
Колесникова Катерина Викторовна

Ответственный редактор:
Мрзабаева Раушан Жалиевна

Компьютерная верстка:
Калабай Замзагуль Ертугановна

Сайт журнала: https://journal.iitu.edu.kz
ISSN 2708–2032 (print)
ISSN 2708–2040 (online)

Подписано в печать 30.09.2026.
050040 г. Алматы, ул. Манаса 34/1, каб. 709, тел: +7 (727) 244-51-09).

Издание АО "Международного университета информационных технологий"