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SENSOPAD

SENSING ENDOMETRIOSIS ON PORTABLE AUXILIARY DEVICES

D11.5

Market Analysis

White Research

29/08/2025

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Abbreviations

AMAR	Medical Device Division of the Ministry of Health
B2B	Business-to-Business
B2B2C	Business-to-Business-to-Consumer
B2C	Business-to-Consumer
CAGR	Compound Annual Growth Rate
CE	Conformité Européenne
ED	Endometriosis
EIC	European Innovation Council
EMA	European Medicines Agency
FDA	Food and Drug Administration
FET	Field-Effect Transistor
GDPR	General Data Protection Regulation
HTA	Health Technology Assessment
IVD	In Vitro Diagnostics
JFET	Junction Field-Effect Transistor
KOL	Key Opinion Leader
MDR	Medical Devices Regulation
MHRA	Medicines and Healthcare products Regulatory Agency
ML	Machine Learning
MOSFET	Metal Oxide Semiconductor Field Effect Transistor
NGO	Non-governmental organisation
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIH	National Institutes of Health
NSF	National Science Foundation
PMCF	Post-Market Clinical Follow-up
PMS	Post-Market Surveillance
PoC	Point of Care
PSUR	Periodic Safety Update Report
QMS	Quality Management System
R&D	Research & Development
SBIR/ STTR	Small Business Innovation Research / Small Business Technology Transfer
UKCA	UK Conformity Assessed
VC	Venture Capital

Table 1: Abbreviations

Executive Summary

Endometriosis is a widespread but underdiagnosed condition affecting an estimated 10% of women of reproductive age. It causes chronic pain, fertility issues, and significantly affects quality of life, yet women often wait 7 to 10 years for a formal diagnosis. This delay partially stems from the absence of reliable, accessible, and non-invasive diagnostic tools. Current diagnostic methods are invasive, costly, and time-consuming, making early detection difficult, particularly in low-resource or primary care settings.

The SENSOPAD project, funded by the European Union's Horizon Europe programme, aims to change this reality. The project introduces a novel diagnostic approach through the development of two complementary devices: **an innovative, patient-centric sanitary pad designed to collect and analyse menstrual fluid, and a portable graphene-based biosensor device for clinical use to detect biomarkers associated with endometriosis. Both solutions, paired with a mobile application and cloud platform, deliver real-time, non-invasive diagnosis and seamless integration into women's daily lives and clinical practice**. This innovation altogether holds the promise of earlier detection, greater autonomy for patients, and a substantial reduction in healthcare burden.

The current market analysis was conducted to evaluate the commercial viability of SENSOPAD and its potential for integration into the broader healthcare ecosystem. The research focused on three intersecting market domains, FemTech, Health Sensors, and Field-Effect Transistors (FETs), with particular emphasis on the menstrual health and diagnostic sub-segments. **Through desk research, industry data analysis, partner consultations, and application of strategic frameworks such as SWOT and Porter's Five Forces, this report assessed demand, competition, regulatory challenges, and stakeholder engagement pathways.**

Findings show a rapidly growing opportunity space. The global FemTech market stands at $39.29 billion in 2024[1], with menstrual health representing the fastest-growing area at a CAGR of 17.1%[2]. The health sensors market is valued at $49.89 billion[3], driven by remote and personalised care technologies. Meanwhile, the bio-FET market, central to SENSOPAD's sensing technology, is expected to grow at 32.8% annually, reaching $9.8 billion by 2030[4]. **Within this context, SENSOPAD addresses an unmet clinical need with a product that is not only technologically advanced but also uniquely positioned as the first wearable, real-time diagnostic tool specifically for endometriosis**.

Stakeholder analysis identified core user groups: women experiencing symptoms of endometriosis, proactive health monitors, and healthcare providers responsible for diagnosis and treatment. Secondary actors include hospitals, policy makers, manufacturers, regulators, and NGOs focused on women's health. Feedback from these groups indicates a strong interest in solutions that reduce diagnostic delays and shift from reactive to proactive care. **However, concerns around data privacy, regulatory**

[1] Grand View Research, Inc. (2024). FemTech Market Size, Share & Growth Analysis Report by Type, Application, End-use, and Region, 2025–2030. Grand View Research. Available at: https://www.grandviewresearch.com/industry-analysis/femtech-market-report (Accessed: 4 July 2025).

[2] Grand View Research, Inc. (2024). Menstrual Health – FemTech Market [Report]. Grand View Research. Available at: https://www.grandviewresearch.com/horizon/statistics/menstrual-health-global-femtech-market-958338 (Accessed: 4 July 2025)

[3] Market.US (2024). Health Sensors Market Size, Share & Forecast to 2033. Market.US. Available at: https://market.us/report/health-sensors-market (Accessed: 4 July 2025)

[4] Mobility Foresights (2025). Global Bio-FET Market 2024–2030. Available at: https://mobilityforesights.com/product/bio-fet-market (Accessed: 4 July 2025)

approval, and clinical validation will need to be addressed through targeted engagement and transparent communication.

From a regulatory perspective, SENSOPAD will need to meet EU Medical Device Regulation (MDR) standards, likely as a Class IIa or IIb device[5], and pursue approval in the U.S. through the FDA's 510(k) or De Novo pathway[6,7]. **Both routes demand robust clinical evidence and post-market surveillance, which are key priorities for the next phase of development**.

In light of these findings, **several actions are recommended**. First, the project should fast-track clinical trials in collaboration with academic medical centres to build a strong evidence base and support regulatory submissions. Second, early engagement with regulatory bodies will be essential to define the optimal classification and streamline approval timelines. Third, partnerships should be cultivated with FemTech platforms, hospitals, and women's health NGOs to raise awareness, support validation, and expand market reach. Parallel efforts should focus on securing reimbursement pathways through national health technology assessment processes and designing inclusive pricing models that prioritise accessibility.

The current report supports a partnership-driven and evidence-led strategy to bring SENSOPAD to market, positioning it not only as a commercial innovation, but as a catalyst for systemic change in how endometriosis is diagnosed and managed across Europe and beyond.

This analysis will support further development of SENSOPAD's business model and go-to-market strategy, ultimately driving its path toward clinical adoption and commercial success.

[5] European Commission (n.d.). Medical device classification. EU UDI Helpdesk. Available at: https://webgate.ec.europa.eu/udi-helpdesk/en/other-relevant-information/medical-device-classification.html (Accessed: 27 August 2025).

[6] U.S. Food and Drug Administration (FDA) (2024). Premarket Notification 510(k). U.S. Food & Drug Administration. Available at: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k (Accessed: 27 August 2025)

[7] U.S. Food and Drug Administration (FDA) (2022). De Novo Classification Request. U.S. Food & Drug Administration. Available at: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request (Accessed: 27 August 2025).

1. Introduction

1.1 Background of the SENSOPAD project

Endometriosis is a chronic condition that affects millions of women worldwide, often leading to debilitating symptoms, including chronic pain and infertility. However, early diagnosis remains a challenge due to the lack of reliable and accessible screening tools. The SENSOPAD project aims to address this gap by developing innovative Point-of-Care (PoC) diagnostic devices designed for early detection and monitoring of endometriosis. **The SENSOPAD solution includes a smart sanitary pad embedded with sensors, as well as a microfluidic graphene transistor, integrated with a mobile application and cloud platform. Both technologies empower users to monitor relevant biomarkers in real time, leading to earlier diagnosis and better symptom management.**

1.2 Objectives of the Market Analysis and scope of the report

This market analysis aims to provide a comprehensive overview of the landscape for innovative medical devices, with a specific focus on PoC diagnostics in women's health and the potential market integration of SENSOPAD, particularly in the context of endometriosis detection and management.

The report will examine both the European and global markets, identifying **key trends, unmet needs, and strategic opportunities for SENSOPAD's successful deployment**. It will assess demand across relevant market segments, including patients, healthcare professionals, industry actors, and regulatory bodies, and will address how emerging technologies intersect with current care pathways and innovation ecosystems.

Key objectives of the market analysis:

- Evaluate the demand for PoC diagnostic devices targeting endometriosis.
- Identify market gaps, growth drivers, adoption barriers, and stakeholder needs.
- Map the competitive landscape, including product offerings, value propositions, pricing models, and marketing strategies.
- Analyse regulatory and compliance frameworks affecting market access.
- Conduct a SWOT analysis of SENSOPAD's positioning in the diagnostic landscape.
- Provide actionable recommendations for product positioning, market entry, and scaling strategies.

The report will further investigate **three interlinked and high-potential market domains** relevant to SENSOPAD:

- FemTech Market
- Health Sensors Market
- Field-Effect Transistor (FET) Market

Findings from this analysis will directly inform the development and validation of the business model as well as the elaboration of the business plan (Tasks 11.4,12.3 and 12.4), supporting the commercialisation roadmap and strategic decision-making for SENSOPAD's market introduction.

1.3 Structure of the report

The report is organised into the following sections:

- **Executive Summary**: A brief overview of the key findings and strategic recommendations.
- **Introduction**: Outlines the background of the SENSOPAD project, the objectives and scope of the market analysis, and the structure of the report.
- **Methodology:** Describes the data collection process, research frameworks used, and the contribution of consortium partners through validation workshops and expert insights.
- **Market Landscape Overview:** Provides a segmentation of the relevant markets, including FemTech, Health Sensors, and Field-Effect Transistor (FET) technologies.
- **Targeted Market Segments and Stakeholders:** Identifies key user groups, such as patients, healthcare providers, industry actors, and regulators.
- **Competitive Landscape and Market Positioning:** Analyses competing products and companies, and defines SENSOPAD's unique value proposition and market positioning.
- **Regulatory Landscape:** Summarises the regulatory requirements and compliance challenges relevant to market entry in the EU and globally.
- **Market Analysis Frameworks:** Applies strategic tools including SWOT, Porter's Five Forces, and TOWS analysis to support business planning.
- **Conclusions:** Synthesises findings and outlines implications for SENSOPAD's business model development and commercialisation strategy.

2. Methodology

This section outlines the research approach used to conduct the market analysis for the SENSOPAD project, providing a comprehensive understanding of the market landscape for PoC devices focused on the early detection and monitoring of endometriosis. The methodology leverages **desk research, theoretical frameworks, and internal consortium expertise** to identify key trends, challenges, and opportunities for SENSOPAD. Key findings from desk research and applied frameworks were discussed and validated through **partner workshops**, ensuring a collaborative process aligned with market needs and supporting informed strategic decisions.

2.1 Data collection and desk research

Desk research forms the foundation of this analysis, including a thorough review of industry reports, academic publications, and publicly available market data. These resources provide insights into trends, growth drivers, and potential challenges in the FemTech, FET and Health Sensors markets, offering a well-rounded view of SENSOPAD's operating landscape without the need for primary data collection.

2.2 Research approach and theoretical frameworks

This market analysis is built upon well-established strategic marketing frameworks, including **SWOT, TOWS, Porter's Five Forces, and Market Segmentation**, to provide a comprehensive evaluation of the market dynamics, competitive environment, and target audiences relevant to SENSOPAD.

SWOT Analysis

This framework identifies **Strengths, Weaknesses, Opportunities, and Threats affecting SENSOPAD**. Internal strengths include its innovative non-invasive technology and integration of real-time biomarker monitoring, while weaknesses may relate to regulatory complexity and market entry barriers. Opportunities derive from emerging trends in the FemTech, FET, and Health Sensors markets, while threats include competitive solutions and evolving compliance demands.

TOWS Matrix

Building on the SWOT, the **TOWS analysis translates insights into actionable strategies** by mapping how to:

- Use strengths to capitalise on opportunities,
- Use strengths to counter threats,
- Overcome weaknesses by seizing opportunities and
- Mitigate threats and weaknesses simultaneously.

Porter's Five Forces[8]

This model analyses the **competitive forces shaping SENSOPAD's market environment**:

- Threat of New Entrants: New players in the FemTech and diagnostic device market.

[8] Porter, M. E. (1980). *Competitive Strategy: Techniques for Analyzing Industries and Competitors*. New York: Free Press.

- Bargaining Power of Suppliers: Especially those providing high-tech components like graphene or microfluidic modules.
- Bargaining Power of Buyers: Including patients, healthcare providers, and public health systems.
- Threat of Substitutes: Competing diagnostic methods or emerging digital health tools.
- Industry Rivalry: Established players in medical diagnostics and women's health technologies.

Market Segmentation

SENSOPAD's **market segmentation is structured around three interconnected and complementary markets**: the FemTech market, the Health Sensors market, and the FET market. Within each of these markets, target audiences are categorised by demographic, geographic, and behavioural attributes, allowing for strategic alignment of product positioning, messaging, and value delivery.

Together, these frameworks guide the market analysis in identifying critical success factors and actionable paths for SENSOPAD's effective entry, adoption, and scale-up in the European and global markets.

2.3 Partner contributions

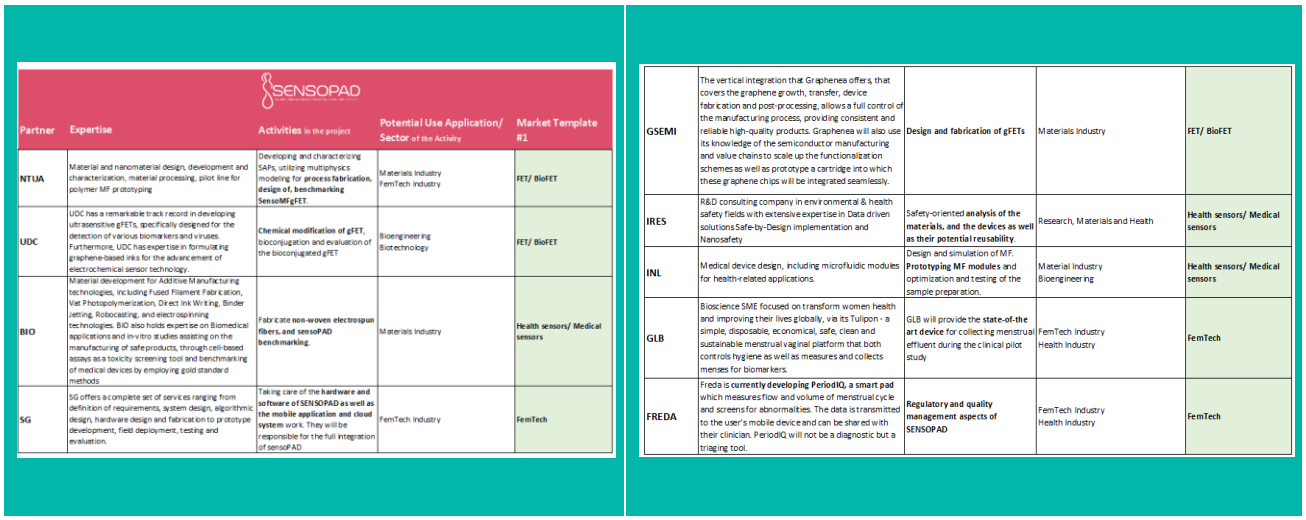
To ensure the market analysis was grounded, relevant, and multi-perspective, a structured methodology was followed to leverage the consortium's diverse expertise. Partner input was vital for identifying market realities across sectors and regions, validating assumptions, and shaping actionable insights. The process, outlined in **Figure 1**, enabled a collaborative and evidence-based approach to understanding SENSOPAD's market potential.

Figure 1: Methodology for leveraging consortium expertise

2.3.1 Leveraging consortium expertise

A critical component of the market analysis involved systematically leveraging the diverse expertise within the SENSOPAD consortium. **Step 1** focused on mapping each partner's role, sectoral knowledge,

and geographic focus to align contributions with specific market dimensions. Notably, each of the three identified target markets was covered by multiple partners with relevant expertise and/or presence in the segment, ensuring robust, well-informed insights across all regions.



Partner	Expertise	Activities in the project	Potential Use Application/ Sector of the Activity	Market Template #1
NTUA	Material and nanomaterial design, development and characterization, material processing, pilot line for polymer MF prototyping	Developing and characterizing SAPs, utilizing multiphysics modeling for **process fabrication, design of, benchmarking SensoMFgFET.**	Materials Industry FemTech Industry	FET/ BioFET
UDC	UDC has a remarkable track record in developing ultrasensitive gFETs, specifically designed for the detection of various biomarkers and viruses. Furthermore, UDC has expertise in formulating graphene-based inks for the advancement of electrochemical sensor technology.	**Chemical modification of gFET**, bioconjugation and evaluation of the bioconjugated gFET	Bioengineering Biotechnology	FET/ BioFET
BIO	Material development for Additive Manufacturing technologies, including Fused Filament Fabrication, Vat Photopolymerization, Direct Ink Writing, Binder Jetting, Robocasting, and electrospinning technologies. BIO also holds expertise on Biomedical applications and in-vitro studies assisting on the manufacturing of safe products, through cell-based assays as a toxicity screening tool and benchmarking of medical devices by employing gold standard methods	Fabricate **non-woven electrospun fibers, and sensoPAD benchmarking.**	Materials Industry	Health sensors/ Medical sensors
SG	SG offers a complete set of services ranging from definition of requirements, system design, algorithmic design, hardware design and fabrication to prototype development, field deployment, testing and evaluation.	Taking care of the **hardware and software of SENSOPAD as well as the mobile application and cloud system** work. They will be responsible for the full integration of sensoPAD	FemTech Industry	FemTech
GSEMI	The vertical integration that Graphenea offers, that covers the graphene growth, transfer, device fabrication and post-processing, allows a full control of the manufacturing process, providing consistent and reliable high-quality products. Graphenea will also use its knowledge of the semiconductor manufacturing and value chains to scale up the functionalization schemes as well as prototype a cartridge into which these graphene chips will be integrated seamlessly.	**Design and fabrication of gFETs**	Materials Industry	FET/ BioFET
IRES	R&D consulting company in environmental & health safety fields with extensive expertise in Data driven solutions Safe-by-Design implementation and Nanosafety	Safety-oriented **analysis of the materials, and the devices as well as their potential reusability.**	Research, Materials and Health	Health sensors/ Medical sensors
INL	Medical device design, including microfluidic modules for health-related applications.	Design and simulation of MF. **Prototyping MF modules** and optimization and testing of the sample preparation.	Material Industry Bioengineering	Health sensors/ Medical sensors
GLB	Bioscience SME focused on transform women health and improving their lives globally, via its Tulipon - a simple, disposable, economical, safe, clean and sustainable menstrual vaginal platform that both controls hygiene as well as measures and collects menses for biomarkers.	GLB will provide the **state-of-the art device** for collecting menstrual effluent during the clinical pilot study	FemTech Industry Health Industry	FemTech
FREDA	Freda is **currently developing PeriodIQ, a smart pad** which measures flow and volume of menstrual cycle and screens for abnormalities. The data is transmitted to the user's mobile device and can be shared with their clinician. PeriodIQ will not be a diagnostic but a triaging tool.	**Regulatory and quality management aspects of SENSOPAD**	FemTech Industry Health Industry	FemTech

Figure 2: Extract of the partner expertise mapping exercise

Step 2 entailed designing tailored input templates, one for each of the three interconnected markets (FemTech, Health Sensors, and FET), based on initial desk research. Using these templates as a basis, the SENSOPAD partners involved in this task, provided structured insights on key aspects such as **market definition, size and growth, trends, opportunities, challenges, segmentation, fragmentation, key competitors, and stakeholder recommendations**. The full versions of the templates are available in **Annex I**.

Figure 3: Templates to gather partner input

In **Step 3**, findings from the templates were consolidated with secondary research and further refined through an interactive validation workshop. This session, conducted via Miro board, applied established

marketing frameworks (SWOT, TOWS, Porter's Five Forces, Market Segmentation) to co-validate and enhance the strategic understanding of each target market. **This participatory approach ensured the analysis was grounded in both empirical evidence and real-world expertise from across the consortium.**

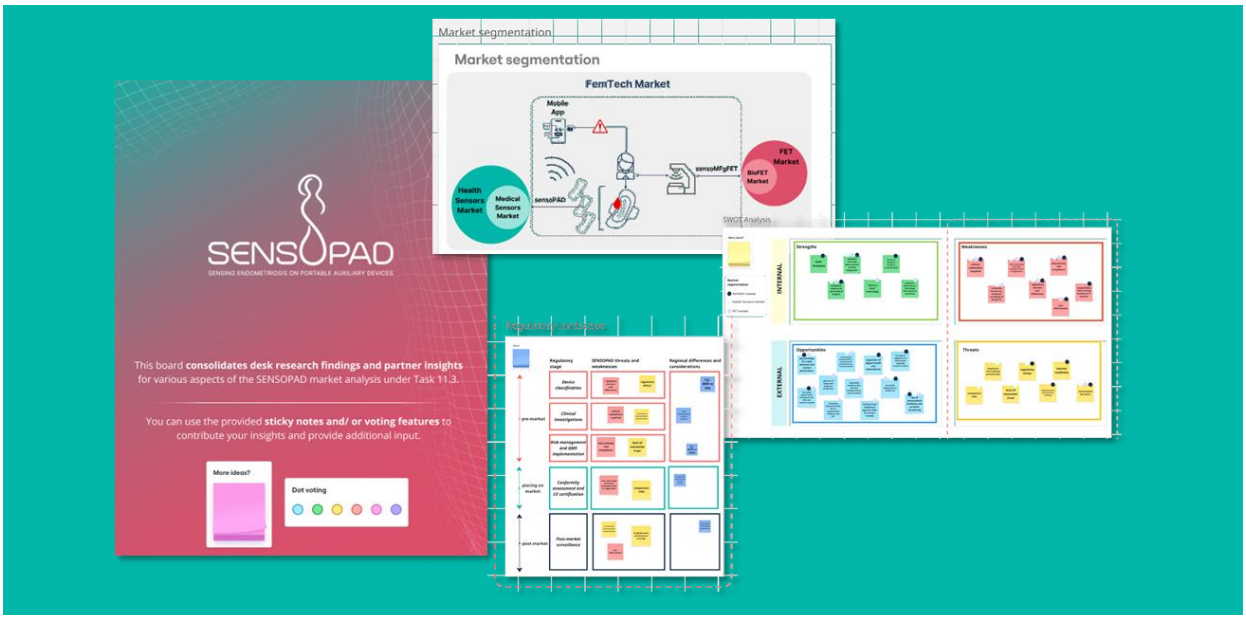


Figure 4: Screenshots from the Miro board used in the validation workshop

3. Market landscape overview

3.1 Market segmentation

SENSOPAD offers a suite of innovative solutions addressing endometriosis detection by combining advanced diagnostic technologies with user-centric functionality. It is designed to penetrate three significant and interconnected markets: the **FemTech** market, the **Health Sensors** market, and the **FET** market, leveraging its unique components and capabilities.

1. *FemTech Market:*

SENSOPAD's overall vision aligns perfectly with the growing FemTech sector, which focuses on developing technologies to address women's health needs. SENSOPAD in its entirety empowers individuals with accessible, user-friendly diagnostic tools, all while leveraging AI-powered cloud platforms.

2. *Health Sensors Market:*

sensoPAD directly addresses the health sensors market by integrating advanced sensing technologies into an energetically autonomous sanitary pad. Its ability to detect key biomarkers for ED enables real-time health monitoring and early detection.

3. *FET Market:*

sensoMFgFET taps into the FET market by utilising graphene-based FETs integrated with microfluidic systems.

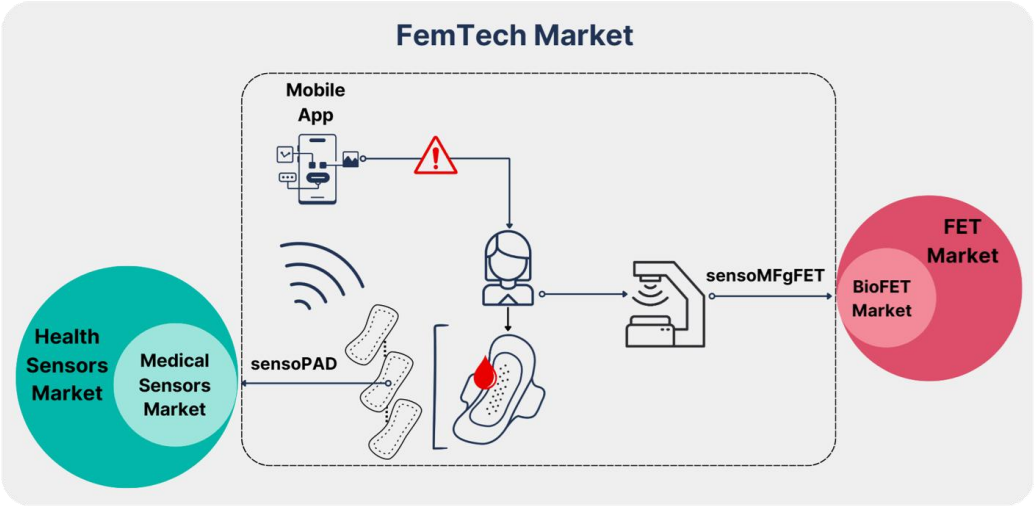


Figure 5: Market Segmentation per SENSOPAD component

3.1.1 FemTech market

The **FemTech Market** refers to female-focused technology products, devices, software, and services designed to leverage digital health solutions for managing women's health issues. The market's primary objective is to **address the rising and largely unmet healthcare needs of women** through innovative products and tech-enabled solutions. With a focus on normalising conversations around traditionally taboo topics, FemTech is driving advancements in areas such as menopause, pelvic health care, chronic disease management, sexual wellness and education, and urinary health. While the sector shows impressive growth potential, it **remains fragmented**, with 85% of FemTech companies generating less than $10 million in annual revenue[9].

The market is segmented by type into **consumer products** (e.g., flushable pads), **devices** (wearables, hardware, etc.), and **apps/software**. Among these, the devices segment dominated both the global and EU markets in 2024 and is expected to experience the fastest growth rate by 2030. Based on application, the market covers a wide range of categories, including **pregnancy and nursing, reproductive health and contraception, menstrual health, pelvic and uterine health care, sexual health, women's wellness, menopause care, longevity, general health care, and mental health**. In 2024, the pregnancy and nursing segment led the global market in terms of revenue, while other areas, such as menstrual health, are poised for rapid growth[10].

Geographically, the FemTech market is segmented into **North America, Europe, Asia Pacific, Latin America, and the Middle East and Africa**. In terms of revenue, North America leads the global market while Asia Pacific is the fastest-growing region.

This dynamic and diverse industry spans early-stage startups, mid-market companies, and publicly traded firms, with a clear trajectory of innovation and expansion across regions and applications[11].

[9] Shmelova, M. (2022). FemTech: What's behind this booming industry. FemTech Health. Available at: https://www.femtech.health/post/femtech-what-s-behind-this-booming-industry (Accessed: 4 July 2025).

[10] Grand View Research, Inc. (2025). FemTech Market Size, Share & Growth Analysis Report by Type, Application, End-use, and Region, 2025–2030. [PDF]. Grand View Research. Available at: https://www.grandviewresearch.com/industry-analysis/femtech-market-report (Accessed: 4 July 2025).

[11] FemTech Analytics (n.d.). FemTech Market Overview. Available at: https://www.femtech.health/femtech-market-overview (Accessed: 4 July 2025)

3.1.1.1 Global market

The global **FemTech market** is expected to show significant growth, driven by increasing awareness of women's health needs and advancements in digital health technologies. Valued at **$39.29 billion in 2024**, the market is expected to expand rapidly as consumer interest rises and new products target diverse women's health concerns, from menstruation to menopause.

The **devices segment** ($13b, 2024) leads the market, in terms of revenue, with wearables and diagnostic tools playing a critical role in women's healthcare solutions. Meanwhile, the **software segment** is anticipated to experience substantial growth, supported by the growing focus on preventive healthcare solutions[12].

Geographically, **North America dominates the FemTech landscape**, accounting for nearly 55% of all FemTech companies, far outpacing Europe (25%), Asia (8%), and the MENA region (7%)[13].

The global market remains fragmented, with a high level of innovation and a diverse range of services and end users entering the space. This fragmentation is accompanied by moderate levels of partnerships and collaboration, significant regulatory impact, and a strong push for service and regional expansion, underscoring the dynamic and evolving nature of the FemTech industry[14].

Evidently, the sector shows strong momentum. Over the past decade, global FemTech investment has grown significantly, peaking in **2021 at $2.2 billion**. Although it dipped to **$1.3 billion in 2022**, this still exceeded 2020 levels, and investor interest is rebounding, particularly in **areas like endometriosis**, where unmet medical needs signal high growth potential[15].

Innovation is also accelerating. More than **1,100 new patents related to endometriosis** were filed in the 2019-2023[16], and FemTech-related patent activity has **more than doubled over the last 20 years**. This surge highlights a fertile landscape for intellectual property generation and underscores FemTech's position as a high-potential innovation frontier[17].

3.1.1.2 EU market

In Europe, the **FemTech market** is projected to reach **$9.94b in 2024**, mirroring global trends with the **devices segment** leading the sector, which accounts for 33.44% of the total FemTech market[18]. The market is expected to grow significantly due to European FemTech companies diversifying their offerings,

[12] Grand View Research, Inc. (2024). FemTech Market Size, Share & Growth Analysis Report by Type, Application, End-use, and Region, 2025–2030. Grand View Research. Available at: https://www.grandviewresearch.com/industry-analysis/femtech-market-report (Accessed: 4 July 2025).

[13] FemTech Analytics (n.d.). FemTech Market Overview. Available at: https://www.femtech.health/femtech-market-overview (Accessed: 4 July 2025)

[14] Grand View Research, Inc. (2024). FemTech Market Size, Share & Growth Analysis Report by Type, Application, End use, and Region, 2025–2030. Grand View Research. Available at: https://www.grandviewresearch.com/industry-analysis/femtech-market-report (Accessed: 4 July 2025).

[15] Groszkowska, K. & Palchynska, L. (2024). Femtech market overview: Europe's first unicorn and the funding landscape. Vestbee. Available at: https://www.vestbee.com/blog/articles/femtech-market-overview (Accessed: 4 July 2025)

[16] Sher, R. (2024). Empowering Women: Innovations in Endometriosis Diagnostics. Digital Health Technology News (Health Tech Digital). Available at: https://www.healthtechdigital.com/empowering-women-innovations-in-endometriosis-diagnostics/ (Accessed: 27 August 2025).

[17] Mewburn & Prowse (n.d.). FemTech: a growth industry – new special report. Mewburn Ellis. Available at: https://www.mewburn.com/news-insights/femtech-a-growth-industry-new-special-report (Accessed: 4 July 2025)

[18] Grand View Research, Inc. (2024). Europe FemTech Market Size & Outlook 2018–2030. Grand View Research. Available at: https://www.grandviewresearch.com/horizon/outlook/femtech-market/europe (Accessed: 4 July 2025

focusing on areas such as menstrual pain management, menopause solutions, and fertility technologies[19].

The **European FemTech market** benefits from a supportive regulatory environment and an increasing emphasis on women's health and wellness technologies. Among European nations, **Germany** held the largest market share in 2024, driven by innovative startups, rising investments, and a growing recognition of women's health needs. The **UK** has the highest number of FemTech companies[20], bolstered by increasing investments and ongoing innovations in women's health technology. Notably, **Finland** is anticipated to experience the highest growth in the sector from 2024 to 2030, thanks to its high-tech adoption and focus on digital healthcare solutions[21].

Building on this strong foundation, **Europe is altogether rapidly positioning itself as a global FemTech hub**. As of 2023, the region hosted over **540 active FemTech startups**, spanning from pre-seed to IPO stages. The leading countries, UK (31.8%), France (18.3%), Germany (12%), Sweden (7.9%), and Switzerland (5.5%), showcase the geographic diversity of innovation in the sector. These startups predominantly focus on **sexual and gynecological health, chronic pathologies**, and **preventive healthcare**, aligning closely with the broader market trends noted above.

However, a significant share of these companies remains in the early stages of development: **36.8% are at the pre-seed or seed stage**, and **43.8% have yet to secure any funding**. This highlights a major barrier to growth, **limited access to investment**, which is compounded by the broader, systemic underfunding of women's health. Despite growing interest in the sector, **only 4% of total healthcare R&D funding** is currently allocated to women's health issues. In 2023, European FemTech startups received just **$191 million** in funding, a fraction of the $9.7 billion invested in the wider healthtech industry[22].

It is evident that the European FemTech market faces challenges such as funding disparities and limited market awareness, which remain critical areas for development. However, the sector's ongoing progress underscores its potential to transform women's healthcare in the region.

3.1.1.3 SENSOPAD sub-segment

SENSOPAD specifically targets the **Menstrual Health** sub-segment of the global FemTech market. The global menstrual health market was valued at **$5.93b in 2024** and is expected to grow at a compound annual growth rate of **17.1%** from 2024 to 2030. This sub-segment is experiencing the fastest growth within the FemTech industry, driven by increasing awareness of women's health issues, particularly regarding menstrual hygiene and reproductive health disorders[23]. In 2024, the Menstrual Health sub-

[19] Grand View Research, Inc. (2024). FemTech Market Size, Share & Growth Analysis Report by Type, Application, End use, and Region, 2025–2030. Grand View Research. Available at: https://www.grandviewresearch.com/industry-analysis/femtech-market-report (Accessed: 4 July 2025).

[20] FemTech Analytics (n.d.). FemTech Market Overview. Available at: https://www.femtech.health/femtech-market-overview (Accessed: 4 July 2025)

[21] Grand View Research, Inc. (2024). Europe FemTech Market Size & Outlook 2018–2030. Grand View Research. Available at: https://www.grandviewresearch.com/horizon/outlook/femtech-market/europe (Accessed: 4 July 2025

[22] Groszkowska, K. & Palchynska, L. (2024). Femtech market overview: Europe's first unicorn and the funding landscape. Vestbee. Available at: https://www.vestbee.com/blog/articles/femtech-market-overview (Accessed: 4 July 2025)

[23] Grand View Research, Inc. (2024). Menstrual Health – FemTech Market [Report]. Grand View Research. Available at: https://www.grandviewresearch.com/horizon/statistics/menstrual-health-global-femtech-market-958338 (Accessed: 4 July 2025)

segment accounted for **15% of the global FemTech market**, with projections indicating significant expansion in market size of both the FemTech and the Menstrual Health markets in the coming years[24,25].

SENSOPAD aligns with this growth trajectory as a device-based solution leveraging innovative diagnostic capabilities to address menstrual health concerns, including the early detection of endometriosis through menstrual blood biomarkers. With the market for menstrual health solutions focusing increasingly on effective monitoring and diagnosis, SENSOPAD aims to offer a timely and relevant response to these critical needs.

	FemTech Market	Menstrual Health Market
Market size ($b), 2024[26] *(%CAGR,2025-2030)*	39.29 *(16.37)*	5.94 *(17.1)*

3.1.2 Health Sensors Market

The **Health Sensors Market** focuses on the development and application of sensors to monitor a wide range of health parameters through devices like **wearables, handheld, and implantable/ingestible** sensors. This market is propelled by technological advancements and the growing demand for remote monitoring and personalised healthcare. Innovation in this sector is significant, driven by advancements in miniaturisation, wireless connectivity, and integration with smart devices. Key innovations include biometric sensors, advanced analytics, and improved energy efficiency, enabling a more interconnected and holistic approach to health monitoring.

Regulations play a critical role in ensuring the safety and quality of health sensors. Regulatory bodies such as the **FDA** in the United States and, in Europe, the **national competent authorities** alongside designated **Notified Bodies** enforce stringent requirements under the **EU Medical Device Regulation (MDR)** before medical devices can enter the market. These regulations help maintain high standards of safety and efficacy, ensuring that consumers trust and rely on these devices for their health management.

To expand their reach, market players are focusing on regional growth through strategic partnerships, collaborations, and distribution agreements, enabling them to tap into diverse healthcare ecosystems. This regional approach helps address specific healthcare needs, meet local regulations, and capitalise on emerging market opportunities for health sensor technologies.

The market is categorised by type, including **heart rate, temperature, pressure, blood glucose, and oxygen sensors**. In terms of application, **chronic illness and at-risk monitoring** dominate, while other areas such as **wellness monitoring, sensor therapeutics, post-acute care monitoring, in-hospital clinical monitoring, point-of-care (PoC) diagnostics, and home health monitoring** also contribute significantly.

Geographically, the market is segmented into **North America**, **Europe, Asia Pacific, Latin America, and the Middle East & Africa**. North America remains the dominant player, with its well-established

[24] Grand View Research, Inc. (2024). Menstrual Health – FemTech Market [Report]. Grand View Research. Available at: https://www.grandviewresearch.com/horizon/statistics/menstrual-health-global-femtech-market-958338 (Accessed: 4 July 2025)

[25] FemTech Analytics (n.d.). FemTech Market Overview. Available at: https://www.femtech.health/femtech-market-overview (Accessed: 4 July 2025)

[26] Values for the global market

healthcare infrastructure, high healthcare expenditure, presence of leading players, and swift adoption of advanced technologies.

3.1.2.1 Global market

The global **Health Sensors Market** is valued at **$49.89 billion** in 2024 and is projected to grow at a CAGR of 19.07% from 2024 to 2030[27]. This growth is driven by rapid advancements in sensor technologies and their expanding applications across modern healthcare solutions. The U.S. held the largest market share in **North America** in 2023, while the Asia-Pacific region is expected to register the fastest growth during the forecast period[28].

Innovative technologies such as wearables, handheld devices, implantable, and ingestible sensors are becoming essential for continuous health monitoring. The surge in demand for personalised healthcare and remote patient monitoring is further accelerating market expansion. While **heart rate sensors** currently dominate the market, other types, such as glucose, temperature, pressure, and oxygen sensors, are also seeing significant growth. In terms of application, **chronic illness and at-risk patient monitoring** accounted for the largest revenue share (22.75%) in 2023, driven by the rising global burden of chronic diseases and the growing need for point-of-care diagnostics[29].

3.1.2.2 EU market

The **European Health Sensors Market** represents 25% of the global market[30] and is projected to reach **US$ 36.39 billion by 2030**, growing at a CAGR of 13.8%. This growth is driven by continued **technological innovation**, increasing demand for **remote health monitoring**, and the expansion of **wearable and diagnostic technologies**. In 2023, **Europe held the second-largest global market share**, with **Germany** leading in revenue and the **U.K.** emerging as the fastest-growing market in the region. The rise in emergency care needs, the growing use of mobile surgical centers, and an ageing population contribute significantly to market expansion. Additional drivers include increasing chronic disease prevalence, demand for personalised healthcare, and the development of centralised data management systems for accurate diagnostics and medical service delivery. Europe is at the forefront of digital health adoption, with strong investments in innovative, patient-centric technologies. Among product types, **wearable sensors** dominated the market, accounting for **40.94%** of revenue in 2021.

3.1.2.3 SENSOPAD sub-segment

SENSOPAD fits within the **Medical Sensors Market**, a crucial part of the broader health sensors industry. The **global medical sensors market** was valued at **USD 16.4 billion** in 2022 and is expected to grow to **USD 30.1 billion** by **2032**, at a CAGR of **6.7%**. SENSOPAD's integration of bio-sensing technology for menstrual health monitoring aligns it with the **medical sensors market**. By offering early detection and diagnosis of health issues such as endometriosis through sensor technology embedded in a sanitary

[27] Market.US (2024). Health Sensors Market Size, Share & Forecast to 2033. Market.US. Available at: https://market.us/report/health-sensors-market (Accessed: 4 July 2025)

[28] Grand View Research, Inc. (2024). Health Sensors Market Size, Share & Trends Analysis Report, 2030. Grand View Research. Available at: https://www.grandviewresearch.com/industry-analysis/health-sensors-market (Accessed: 4 July 2025)

[29] Grand View Research, Inc. (2024). Health Sensors Market Size, Share & Trends Analysis Report, 2030. Grand View Research. Available at: https://www.grandviewresearch.com/industry-analysis/health-sensors-market (Accessed: 4 July 2025)

[30] Global Health Sensors Market. Reanin, https://www.reanin.com/reports/global-health-sensors-market?utm_source=chatgpt.com. Accessed 7 July 2025

pad, SENSOPAD contributes to the growing need for **remote monitoring**, **diagnostic tools**, and **personalised healthcare** solutions. With its innovative approach to monitoring biomarkers in menstrual blood, SENSOPAD represents an emerging application within the medical sensors sub-segment, poised for growth in this expanding market.

	Health Sensors Market	Medical Sensors Market
Market size ($b)[31] *(%CAGR)*	49.89 (2024) *(19.07, 2024-2030)*	16.4 *(2022)* *(6.7, 2023-2032)*

3.1.3 FET market

The **Field-Effect Transistor (FET) Market** refers to the development, production, and application of FETs (**analog (JFET) and digital (MOSFET)**), semiconductor devices that use an electric field to control current flow.

By application, the market is segmented into **amplifiers, switchers, motor control, digital logic circuits, sensors, and others.** Based on end-users the market can be divided into **automotive, consumer electronics, IT/telecom, healthcare and power generating industries**. In the Healthcare and Medical Industry, **bio-FETs are used to develop new diagnostic tools and therapeutic devices**.

Finally, by region, the market is segmented into Asia Pacific, North America, Latin America, Europe and Middle East & Africa. The **Asia Pacific** region leads the FET Market due to the growing digitalisation, technological advancements, and the growing use of consumer electronics.

3.1.3.1 Global market

The **global FET market** is expected to experience steady growth from **USD 5.57 billion in 2023**[32], driven by increasing demand across several industries. FETs are used in a wide range of applications, from amplifiers and switchers to digital logic circuits, sensors, and motor controls. The **Asia Pacific region** currently leads the global market, attributed to growing digitalisation, technological advancements, and the widespread use of consumer electronics.

The market is also seeing a growing adoption of **FETs** in healthcare and medical industries, particularly in the development of diagnostic tools and therapeutic devices, such as **bio-FETs**, which are designed for medical applications.

3.1.3.2 EU market

The **European FET Market** is an important segment of the global market, driven by the increasing use of **digital technologies** and the growing demand for **consumer electronics** and **medical devices**. Europe is also focusing on the development of more advanced bioelectronics, which is contributing to the expansion of **bio-FET** technology. As the **EU market** continues to adopt digital health technologies, there is significant potential for **bio-FETs** to play a larger role in medical diagnostics and health monitoring.

[31] Values for the global market

[32] Technavio (2024). Field Effect Transistor (FET) Market Analysis 2024–2028. Technavio. Available at: https://www.technavio.com/report/field-effect-transistor-fet-market-analysis (Accessed: 4 July 2025)

3.1.3.3 SENSOPAD sub-segment

SENSOPAD targets the **bio-FET** sub-segment of the **FET market**, which is growing rapidly. The **global bio-FET market** is projected to expand from **USD 2.2 billion in 2023** to **USD 9.8 billion by 2030**, growing at a **CAGR of 32.8%**. This significant growth is driven by the increasing demand for **bio-FETs** in various industries, including **medical diagnostics**, **food safety**, and **environmental monitoring**. SENSOPAD's focus on bio-sensing technologies for **menstrual health** positions it well within this rapidly expanding market[33].

By utilising **bio-FETs** for the detection of biomarkers related to women's health, SENSOPAD presents a promising opportunity to innovate and advance the use of **bio-FET** technology in **medical diagnostics**, providing a new avenue for health monitoring and diagnostic tools.

	FET Market	Bio-FET Market
Market size ($b), 2023[34] *(%CAGR)*	5.57 *(5.67, 2023-2028)*	2.2 *(9.8, 2023-2030)*

4. Targeted market segments and stakeholders

SENSOPAD's success depends on its ability to address the needs of key market segments and engage with relevant stakeholders. This section outlines the primary end users, healthcare providers, and industry stakeholders who will play critical roles in the adoption, deployment, and regulation of SENSOPAD's diagnostic devices.

Understanding the motivations and needs of these groups is essential for tailoring the product's value proposition and ensuring successful market entry.

4.1 End users

SENSOPAD is designed to meet the needs of a diverse user base, ranging from women actively experiencing symptoms associated with endometriosis to clinicians involved in their care. By offering non-invasive, real-time biomarker monitoring through a wearable diagnostic device, SENSOPAD addresses significant gaps in early detection, disease management, and personalised care. Understanding the distinct motivations, use cases, and expectations of each end-user segment, **patients, proactive health seekers, and healthcare professionals**, is essential to ensure high adoption, sustained engagement, and meaningful clinical integration.

4.1.1 Women with endometriosis and broader female population

Primary end users: Women with endometriosis and/ or related symptoms

Women suffering from or suspected of having endometriosis are the primary beneficiaries of SENSOPAD's diagnostic technology. With an estimated **1 in 10 women of reproductive age** suffering

[33] Mobility Foresights (2025). Global Bio-FET Market 2024–2030. Available at: https://mobilityforesights.com/product/bio-fet-market (Accessed: 4 July 2025)

[34] Values for the global market

from endometriosis, there is a significant population in need of non-invasive, accurate, and real-time monitoring solutions. These women face long delays in diagnosis, up to 7-10 years on average, which exacerbates their symptoms and diminishes their quality of life.

Key considerations for this segment include:

- **Ease of use**: SENSOPAD's non-invasive, at-home monitoring system allows users to take control of their healthcare without the need for frequent clinical visits.
- **Empowerment through real-time data**: The integration of SENSOPAD's device with a mobile app offers users personalised health insights, empowering them to manage their condition more proactively.
- **Affordability**: Accessibility is a key concern for this segment. SENSOPAD will need to consider cost-effective pricing models alongside viable reimbursement models to ensure that women across different socioeconomic groups can access the device.

Secondary end users: Broader female population

SENSOPAD's value extends beyond women with confirmed or suspected endometriosis. Other potential users include:

- **Women with unexplained symptoms**: Many women suffer from chronic pelvic pain, reproductive issues, or menstrual irregularities that may not be immediately linked to a specific diagnosis like endometriosis. SENSOPAD could help these women better understand their symptoms and pursue early diagnosis.
- **Preventive health advocates**: Women who are proactive about their reproductive health may use SENSOPAD as part of their routine health monitoring, even if they are not exhibiting symptoms of endometriosis. The ability to track menstrual health biomarkers may appeal to those seeking preventive care.
- **Menstrual health trackers**: SENSOPAD's ability to monitor biomarkers throughout the menstrual cycle offers potential value to women interested in tracking and understanding their menstrual health more comprehensively.

4.1.2 Healthcare providers

Healthcare providers, particularly **gynaecologists, general practitioners, and specialists in reproductive health**, play a pivotal role in both using and interpreting data from SENSOPAD. They are essential stakeholders in validating the tool, guiding diagnosis and treatment decisions, and integrating it into clinical workflows.

Primary healthcare users: Clinical practitioners using SENSOPAD in diagnostics

These professionals directly interact with SENSOPAD's diagnostic components (such as the bio-gFET sensor module) during patient consultations or clinical testing. They enhance the device's credibility by embedding it into standard care routines.

Key considerations for this segment include:

- **Point-of-care utility**: SENSOPAD's compact, user-friendly form factor supports rapid in-office testing, potentially replacing or complementing invasive diagnostic tools and methods such as laparoscopy.
- **Clinical decision support**: Access to biomarker data in real-time allows providers to make faster, more informed diagnostic decisions and monitor disease progression in a personalised manner.
- **Workflow integration**: The ability to seamlessly incorporate SENSOPAD into existing IT and health record systems is critical for provider adoption and long-term use.

Secondary healthcare users: Interpreters and validators of patient-generated data

These users engage primarily with data generated by patients using SENSOPAD outside clinical settings, such as at home. Their role focuses on **validating, interpreting, and acting on this patient-generated data** to guide treatment, ensure safety, and support ongoing care management. This segment includes a broader range of healthcare actors, such as:

- **Physicians and specialists** who review and adjust treatment plans based on remotely collected data.
- **Healthcare systems and clinics** (public and private) that integrate patient data into clinical workflows.
- **Pharmacists and pharmacy professionals**, especially if SENSOPAD is available via pharmacies and they provide patient guidance or treatment advice.
- **Nurses and care coordinators** who monitor patients' progress and help coordinate care.

Key considerations for this segment include:

- **Clinical validation and trust**: Providers require high confidence in the sensitivity, specificity, and reliability of biomarker outputs before making treatment decisions.
- **Patient-provider communication**: SENSOPAD enhances shared decision-making through objective, trackable health data that informs discussions and treatment planning.
- **Scalability of care**: With reliable at-home monitoring, clinicians can extend care capacity, especially in underserved or overloaded systems.

4.2 Stakeholder ecosystem

The successful development, approval, and adoption of SENSOPAD depends not only on end users but also on a **broader ecosystem of stakeholders** that influence its clinical validation, regulatory approval, market access, and scalability. These stakeholders include **healthcare institutions, medical professionals, manufacturing and technology partners, public health authorities, and regulators** across regions. Each group brings specific needs, expectations, and decision-making power that can shape the trajectory of SENSOPAD's integration into mainstream healthcare systems. Understanding and strategically engaging this ecosystem is essential to ensure that SENSOPAD meets clinical standards, achieves regulatory compliance, secures reimbursement, and ultimately delivers value across the healthcare value chain.

Clinics and hospitals

Clinics and **hospitals** play a critical role in validating and integrating new diagnostic technologies. These institutions will serve as important stakeholders, particularly in conducting **clinical trials** and providing feedback on SENSOPAD's usability and effectiveness. Adoption of the device by major healthcare institutions could significantly enhance its credibility and accelerate market adoption. Hospital managers, as key decision-makers in the procurement of medical technologies, will be important stakeholders in SENSOPAD's adoption within healthcare institutions. They will assess the **cost-benefit** of implementing the device within their hospitals, considering factors such as ease of integration, effectiveness in reducing diagnostic delays, and patient outcomes.

Key considerations for this stakeholder segment include:

- **Clinical validation**: Healthcare providers will require robust clinical evidence of SENSOPAD's safety, accuracy, and efficacy before integrating it into diagnostic routines.
- **Cost-benefit analysis**: Clinics and hospitals must assess the cost-effectiveness of adopting SENSOPAD compared to existing diagnostic procedures, especially given the resource-intensive nature of current endometriosis diagnostic methods (e.g., laparoscopy).

Manufacturers and tech partners

Scaling SENSOPAD requires close collaboration with:

- **Graphene and FET component manufacturers:** To ensure the availability and quality of core sensor technology.
- **IVD and wearable device producers:** For scalable, compliant hardware manufacturing.
- **Distributors and logistics providers:** To support regional market rollout and inventory management.
- **FemTech innovators and partners**: To accelerate innovation in menstrual and reproductive health, share market insights and co-develop integrated digital health solutions, and build coalitions to advocate for regulatory reform and reimbursement policy updates.

Public Health Authorities and Regulatory Bodies

Engaging with regulators is critical to ensure compliance and build trust:

- **EU (e.g., EMA, national competent authorities):** CE-marking and compliance with MDR (Medical Device Regulation).
- **Global authorities:** Coordination with FDA (USA), MHRA (UK), AMAR (Israel), and local bodies in MENA.

Key considerations for this stakeholder segment include:

- **Regulatory compliance:** SENSOPAD must meet all regional safety, performance, and labeling standards before market entry.
- **Post-market surveillance:** Ongoing performance monitoring and adverse event reporting are required throughout the product lifecycle.
- **Public health integration:** SENSOPAD should aim for inclusion in national screening programs or women's health initiatives where applicable.

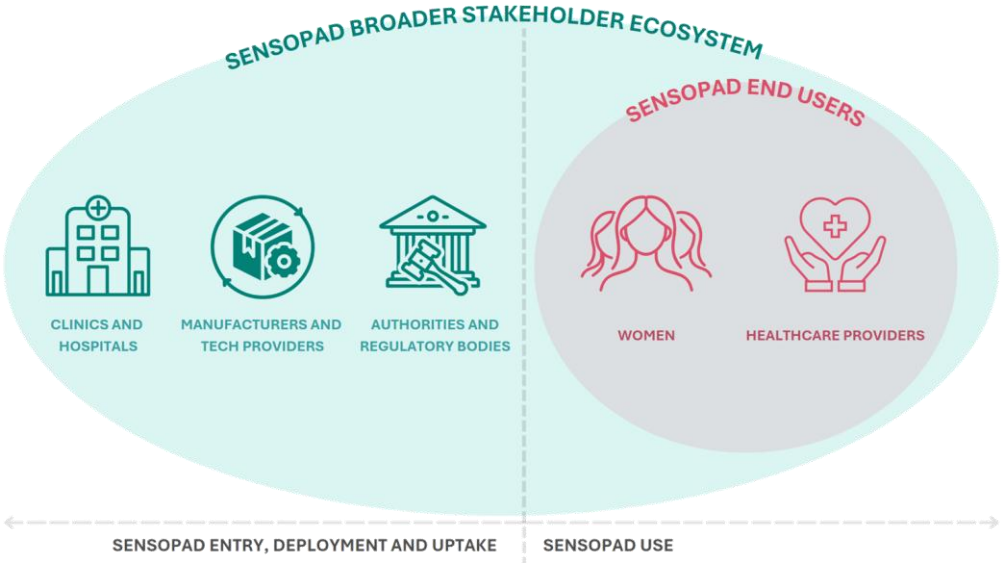


Figure 6: SENSOPAD broader stakeholder ecosystem and end users

5. Competitive landscape and market positioning

5.1 Competitor analysis

To effectively position SENSOPAD in the market, it is essential to understand the existing competitive landscape across the three intersecting sectors: FemTech, Health Sensors, and FETs. **Each of these markets contains well-established players with varying degrees of overlap in technology, innovation focus, and end-user applications**. The figure below provides a comprehensive overview of major players in each domain.

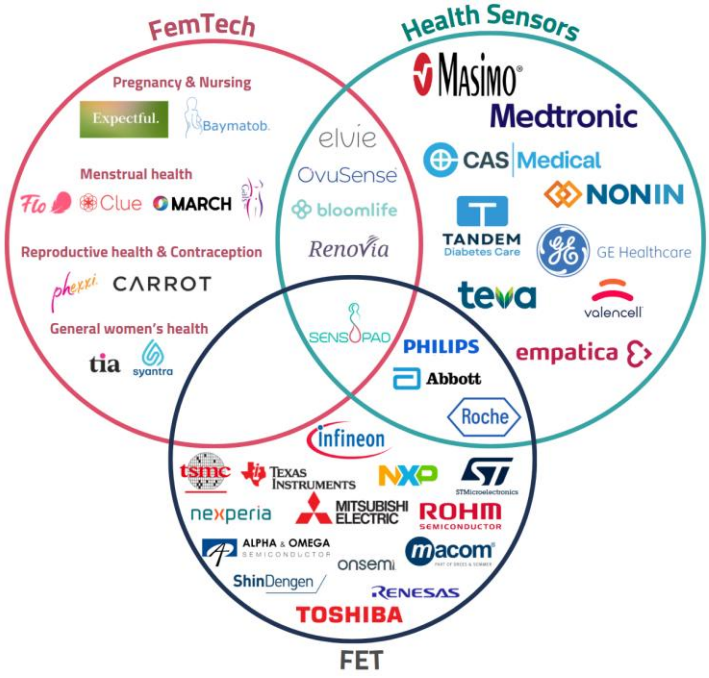


Figure 7: Key players in FemTech, Health Sensors and FET markets

Despite the presence of major players across FemTech, health sensors, and semiconductor industries, a significant market gap remains in delivering integrated, diagnostic-grade solutions tailored specifically to women's health, particularly for conditions like endometriosis. FemTech leaders have largely focused on wellness, fertility, and tracking applications, while health sensor companies concentrate on chronic disease management or general-purpose biomonitoring. Meanwhile, semiconductor giants advancing sensor and FET technologies typically operate at the component level, without bridging into consumer-facing or gender-specific medical applications. **This fragmented landscape reveals that no single actor has yet combined deep sensing technology with a user-friendly, clinically relevant platform for gynaecological diagnostics.**

Direct competitors of SENSOPAD

The following companies represent direct competitors to SENSOPAD based on their focus on **non-invasive endometriosis diagnostics** using samples like saliva, blood, and menstrual fluid. These startups and scale-ups **are actively developing and commercialising**[35] biomarker-based technologies aimed at early, accurate, and at-home detection of endometriosis. They are categorised by the primary sample type and molecular approach used.

Table 2: SENSOPAD direct competitors

	Company	Country	Approach	Stage	Funding/ Pricing model	Benchmarking to SENSOPAD
Menstrual Fluid	**NextGen Jane**	USA	Smart tampon collecting menstrual blood	First clinical validation	Secured $2.2M NIH grant for non-invasive endometriosis diagnostic[36]; Backed by other investors (incl. NICHD)[37];	Requires active insertion, mailing, and lab processing; Lacks real-time output and wearable form factor;
	Diamens	Austria	At-home menstrual blood test with proprietary biomarkers	Early-stage (undergoing clinical trials), targeting launch by 2025-2026[38]	Targeting B2B with initial pricing point under 100 euros[39]	Similar non-invasive input, but lacks wearable diagnostics or on-device AI; Centralised testing only (requires mailing);
	Endometrics	USA	Menstrual blood genomic assay with ML-based interpretation	Early stage	VC backed[40]	Early tech stack overlap but relies on external lab, not PoC or embedded diagnostics

[35] Projects still in the research or early-development phase, without a commercialised product, are excluded from the matrix to allow for a valid comparison.

[36] FemTech Insider (2024). NextGen Jane secures $2.2M NIH grant for non-invasive endometriosis diagnostic. Available at: https://femtechinsider.com/nextgen-jane-secures-2-2m-nih-grant-for-non-invasive-endometriosis-diagnostic/ (Accessed: 4 July 2025)

[37] Crunchbase (n.d.). NextGen Jane — company financials. Available at: https://www.crunchbase.com/organization/nextgen-jane/company_financials (Accessed: 4 July 2025)

[38] Parkway Women's Clinic (n.d.). At-home endometriosis test — quick & private. Available at: https://pkwomensclinic.com.sg/at-home-endometriosis-test-quick-private/ (Accessed: 4 July 2025)

[39] European Investment Bank (2023). Diamens at-home test for endometriosis. Available at: https://www.eib.org/en/stories/diamens-at-home-test-endometriosis (Accessed: 4 July 2025)

[40] PitchBook (n.d.). Company profile — NextGen Jane. Available at: https://pitchbook.com/profiles/company/504141-31#timeline (Accessed: 4 July 2025)

	Qvin	USA	Pad for at-home testing using an embedded Dried Menstrual Sample strip	FDA cleared for tracking diabetes and pre-diabetes[41]	VC backed[42]	Lacks real-time output and requires mail and lab processing[43]
Saliva	**Ziwig**	France	Saliva-based microRNA test ("Endotest") with AI interpretation	CE certified; Available in multiple EU countries ;	VC backed[44]	Uses non-invasive sample but requires lab-based interpretation and costs; No real-time insights;
Blood	**DotLab**	USA	"DotEndo" microRNA blood test	Multicenter clinical validation ongoing[45];	VC backed[46]	Invasive sample; Central lab-dependent; Not patient-centric or wearable;

5.2 Market differentiation

The FemTech sector has rapidly expanded, with a majority of companies focusing on fertility tracking, pregnancy support, and general menstrual health. While these platforms, such as period tracking apps and fertility solutions, play an essential role in awareness and lifestyle management, **they often lack diagnostic precision, especially for chronic gynecological like endometriosis**.

In contrast, SENSOPAD directly addresses this unmet clinical need. It differentiates itself from typical FemTech offerings by **combining wearable sensor technology with AI-enabled biomarker detection, specifically designed for early, non-invasive diagnosis of endometriosis at the point of care**.

Traditional medical device leaders (e.g., Abbott, Medtronic, Philips) dominate generic PoC and health-monitoring segments, but they have not meaningfully entered the space of female-specific diagnostics, particularly in endometriosis. Similarly, most FemTech startups focus on monitoring symptoms or enhancing fertility, with limited penetration into clinical-grade diagnostics.

While direct competitors such as NextGen Jane, Diamens, Endometrics, and Ziwig are advancing promising non-invasive biomarker approaches using menstrual blood, saliva, or genomic assays, **all of them rely on mailed-in samples and centralised lab analysis, resulting in delayed results, higher costs, and user friction**. In contrast, SENSOPAD redefines the diagnostic pathway through a passive, wearable point-of-care device that integrates seamlessly into existing menstrual routines. By embedding AI directly into the device for on-pad biomarker interpretation, SENSOPAD delivers real-time, clinically actionable insights without requiring users to change behavior, schedule lab visits, or wait for results.

[41] Naseri, S. (2024). Dr. Sara Naseri: Menstrual blood as a diagnostic tool. Axios. Available at: https://www.axios.com/2024/03/07/menstruation-period-blood-cramp-pain-diagnostic (Accessed: 27 August 2025).

[42] Crunchbase (n.d.). Qvin Company Profile: Financials. Available at: https://www.crunchbase.com/organization/Qvin#financials (Accessed: 27 August 2025).

[43] BioSpace (2024). Qvin Introduces Q-Pad™: Transforming Women's Health with FDA-Cleared Lab Testing Using Menstrual Blood. Available at: https://www.biospace.com/qvin-introduces-q-pad-transforming-women-s-health-with-fda-cleared-lab-testing-using-menstrual-blood (Accessed: 27 August 2025).

[44] Tracxn (n.d.). Ziwi — funding and investors. Available at: https://tracxn.com/d/companies/ziwig/__WIHQN1op_oXuGYSB497_yda31USzq03iIDWoN7YX2pM/funding-and-investors (Accessed: 4 July 2025)

[45] Dot Lab (2024). Press release: Empower launch. Available at: https://www.dotlab.com/press-releases/empower-launch (Accessed: 4 July 2025)

[46] Crunchbase (n.d.). Dot Lab — financials. Available at: https://www.crunchbase.com/organization/dot-lab#financials (Accessed: 4 July 2025)

Unlike saliva tests, requiring laboratory infrastructure and additional costs, or blood-based solutions, which demand invasive sampling and multi-day processing, SENSOPAD offers a low-cost, scalable, and user-centric diagnostic alternative.

This unique combination of embedded analytics, accessible sampling, and non-disruptive form factor, positions SENSOPAD as the first truly consumer-ready diagnostic wearable for endometriosis, offering a novel standard of care where other players remain in research or limited-access stages.

6. Regulatory landscape

The development and commercialisation of medical devices such as SENSOPAD require navigating **complex and distinct regulatory frameworks**. While the European Union and the United States share the same core regulatory pillars, pre-market evaluation, market authorisation, and post-market surveillance, the specific legal structures, authorities, and requirements differ significantly between the two regions. **Figure 8** below illustrates the life span diagram of a medical device.

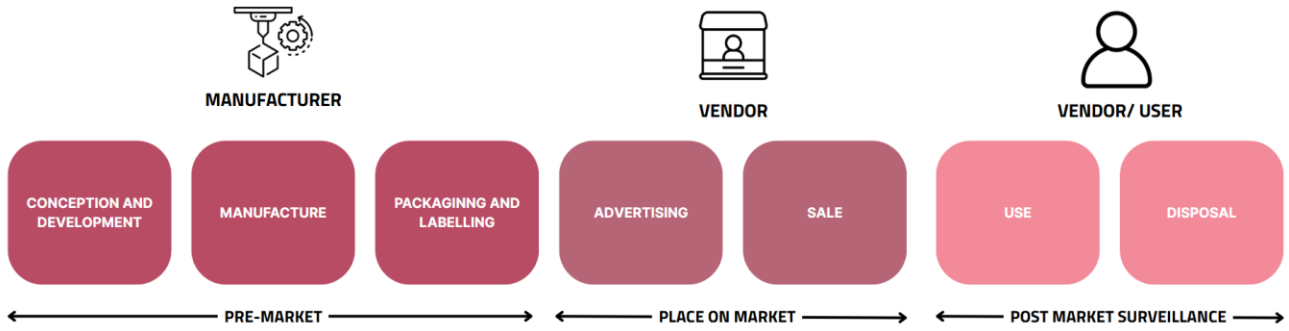


Figure 8: Life span of a medical device

The following sections detail the regulatory requirements SENSOPAD must fulfill for entry into the European and United States markets based on its lifecycle, followed by a comparison of their core differences.

6.1.1 Regulatory compliance in the European Union

The EU's regulatory framework for medical devices is governed by the **Medical Device Regulation (MDR)** 2017/745[47], which became fully applicable in May 2021. This regulation has introduced more stringent requirements across all stages of the device lifecycle, with a strong emphasis on clinical evidence, traceability, and post-market surveillance. For a device like SENSOPAD, which aims to offer non-invasive, sensor-based diagnostics for endometriosis, the MDR sets out a clear but rigorous path to market. Key Aspects of the MDR include:

- **Stricter classification rules**: Devices are categorised from Class I (lowest risk) to Class III (highest risk). SENSOPAD is expected to fall under Class IIa or IIb depending on final technical features and clinical claims.

[47] European Parliament & Council of the European Union (2017). Regulation (EU) 2017/745 on medical devices. Official Journal of the European Union, L 117, 5 May 2017, pp. 1–175. Available at: https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng (Accessed: 4 July 2025)

- **Emphasis on clinical evidence**: Manufacturers must generate robust clinical data to support claims of safety and performance.
- **Notified Body involvement**: A third-party Notified Body[48] must assess Class IIa and higher-risk devices.
- **Comprehensive post-market surveillance**: Includes Periodic Safety Update Reports (PSUR), risk-benefit reevaluation, and potential Post-Market Clinical Follow-up (PMCF).

6.1.2 Key Compliance Requirements for SENSOPAD in the EU

To obtain CE marking and enter the European market, SENSOPAD must comply with several MDR-mandated activities:

- **Clinical evidence**: Collection of data from trials demonstrating accuracy, safety, and diagnostic utility for detecting endometriosis biomarkers.
- **Technical validation**: Demonstration of consistency across use cases and environments.
- **Technical documentation**: Submission of a full technical file including risk analysis, device description, manufacturing controls, and software validation.
- **Risk management**: Ongoing identification and mitigation of risks related to both the hardware (e.g., biosensors, microfluidics) and software (e.g., data handling, cybersecurity).
- **Quality Management System (QMS):** Compliant with ISO 13485, with integrated risk, clinical, and post-market procedures.
- **Post-Market Surveillance (PMS):** Continuous performance tracking, adverse event reporting, and generation of safety updates.

Figure 9: SENSOPAD compliance requirements for EU

The table below summarises the key steps in the EU regulatory process.

Regulatory stage	Step	Description
Pre-market	**1. Classification**	Based on MDR Annex VIII, likely Class IIa or IIb for diagnostic capabilities.
	2. Conformity Assessment	Conducted by a Notified Body, involving full technical and clinical review.
	3. Clinical Investigations	May be required depending on available data; must follow ISO 14155.

[48] A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market.

	4. Technical Documentation	Submitted for review; must be continually updated.
Place on market	**5. CE Marking**	Issued after successful conformity; includes Declaration of Conformity.
Post-market	**6. Post-Market Obligations**	PSURs, PMS plans, and potential PMCF studies to retain CE mark.

6.1.3 Regulatory compliance in the U.S.

In contrast, the **U.S. Food and Drug Administration (FDA)** functions as a **centralised regulatory authority** for medical devices. The FDA classifies devices based on risk (Class I–III) and defines **three core pre-market pathways**:

- **510(k) Premarket Notification** (most common)
- **De Novo Classification**
- **Premarket Approval (PMA)** for high-risk devices

SENSOPAD will likely follow the **510(k) or De Novo** route, depending on predicate device availability and its final classification. Key Elements of the U.S. System include:

- **Approval vs. self-declaration**: The FDA actively grants marketing authorisation, unlike the EU's manufacturer-led declaration reviewed by Notified Bodies.
- **Classification flexibility**: FDA can reclassify based on evolving evidence.
- **Unlimited validity**: Once approved, devices remain on the market unless recalled.
- **Less burden post-market** (initially): Fewer routine surveillance activities than EU unless risk data necessitate further monitoring.

The table below summarises the key steps in the U.S. regulatory process.

Regulatory stage	Step	Description
Pre-market	**1. Classification**	Based on risk and intended use; likely Class II.
	2. Predicate Device Assessment	If a comparable device exists, 510(k) clearance possible.
	3. Submission	Submit a 510(k) or De Novo request including safety and efficacy data.
	4. Review	FDA reviews technical specs, clinical evidence, and labeling.
Place on market	**5. Approval/Clearance**	Once cleared, SENSOPAD can enter the U.S. market.
Post-market	**6. Post-Market Activities**	Basic surveillance and voluntary adverse event reporting; additional studies only if mandated.

6.1.4 Regulatory compliance in the UK

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is the central regulatory authority responsible for the oversight of medical devices in Great Britain. Devices are regulated under the UK Medical Devices Regulations 2002 (UK MDR 2002), as amended, and must be registered with the MHRA before being placed on the market. Classification follows a risk-based framework aligned with international standards (Class I–III for general medical devices). Depending on classification, SENSOPAD may be eligible for self-declaration (Class I) or require third-party assessment by a UK Approved Body (Class IIa and above). Key elements of the UK system include:

- **Conformity assessment & marking**: Devices must meet applicable Essential Requirements and bear the **UKCA mark** (or CE mark during the transition period, depending on certificate validity and device type).
- **Regulatory representation**: Non-UK manufacturers must appoint a **UK Responsible Person** to register the device and liaise with the MHRA.
- **No formal pre-market approval**: Like the EU, the MHRA does not "approve" devices but verifies registration and may audit Approved Bodies.
- **Transition rules**: Devices holding valid EU CE certificates may continue to be marketed in Great Britain until 30 June 2030 (depending on type and certification route).
- **Post-market oversight**: Manufacturers must operate a post-market surveillance (PMS) system and report incidents via the MHRA's vigilance mechanisms.

The table below outlines the key regulatory stages under the UK system:

Regulatory stage	Step	Description
Pre-market	**1. Classification**	Based on device risk and intended use, following UK MDR rules (Class I–III).
	2. Conformity Assessment	For Class I (non-measuring/non-sterile): self-certification; for higher classes, UK Approved Body involvement required.
	3. UK Responsible Person	Appointed by non-UK manufacturers to fulfil legal obligations and manage MHRA registration.
	4. Registration	All devices must be registered with the MHRA before being placed on the GB market.
Place on market	**5. UKCA or CE Marking**	Device bears UKCA (or CE mark if eligible during transition), enabling market entry.
Post-market	**6. Surveillance**	Manufacturer maintains PMS system, reports adverse events, and supports field safety corrective actions (FSCA) if needed.

Although the UK, EU, and U.S. regulatory frameworks share core principles, such as risk-based classification, conformity assessment, clinical evaluation, and post-market surveillance, they differ significantly in structure, implementation, and regulatory authority. The EU relies on a decentralised

Notified Body system, the U.S. operates a centralised approval process through the FDA, and the UK employs a registration-based model with its own conformity marking (UKCA).

For SENSOPAD, aligning with all three systems will be essential to ensure timely and compliant market entry across its key geographies. By proactively addressing the evolving UK requirements, the stringent clinical and documentation demands of the MDR, and the structured review pathways of the FDA, the project will be well positioned to support global commercialisation and sustained regulatory compliance.

7. Market analysis frameworks

To comprehensively assess SENSOPAD's market potential and strategic positioning, this chapter applies a combination of established strategic marketing frameworks, **SWOT analysis, Porter's Five Forces, and TOWS analysis**, to evaluate internal capabilities and external market forces. These tools enable a structured understanding of SENSOPAD's competitive advantages, market challenges, and strategic opportunities. The analysis is grounded in extensive desk research, literature review, and partner insights gathered through validation workshops, ensuring that findings are well-informed, stakeholder-driven, and aligned with real-world market conditions. **Together, these frameworks inform the development of a sound preliminary business strategy for successful market entry**.

7.1 SWOT analysis

A SWOT analysis is a strategic tool used to assess SENSOPAD's position in the market by examining four key elements: ***Strengths, Weaknesses, Opportunities, and Threats***. These elements are divided into two dimensions:

- **Internal factors**: Strengths and Weaknesses refer to SENSOPAD's internal attributes, such as its technological capabilities, clinical validation progress, team expertise, and product design.
- **External factors**: Opportunities and Threats relate to external conditions, including market demand, regulatory landscapes, competition, and healthcare policy trends that may impact SENSOPAD's success.

Strengths of SENSOPAD

SENSOPAD stands out in the diagnostic landscape for women's health through a combination of advanced technologies and a user-centric design philosophy. Its strengths can be grouped into two categories:

[1] Technological strengths

- **Graphene-based sensor technology**

  SENSOPAD leverages highly sensitive graphene-based biosensors, enabling enhanced detection of low-concentration biomarkers associated with endometriosis. This next-generation material allows for improved accuracy and faster signal transduction compared to conventional sensors.
- **"Lab-on-a-Strip" microfluidics**

The integration of microfluidic systems transforms the pad into a compact biochemical analysis unit. This allows precise handling and analysis of biological samples directly within the pad, eliminating the need for external lab processing.

- **Non-invasive, real-time diagnostics**

  SENSOPAD enables continuous, non-invasive monitoring of biomarkers during menstruation. Real-time data capture enhances the ability to detect patterns over time, supporting earlier and more reliable diagnosis.

- **Cloud integration & digital health platform**

  Sensor data is seamlessly transmitted to a secure cloud platform, enabling longitudinal data analysis. This supports the generation of predictive analytics and personalised insights for patients and clinicians alike.

[2] Strategic and user-centric strengths

- **Targeted focus on endometriosis and women's health**

  By directly addressing the diagnostic gap in endometriosis, a condition often underdiagnosed and misunderstood, SENSOPAD taps into a significant unmet medical need, positioning itself as a leader in a purpose-driven niche.

- **Early detection and patient empowerment**

  By facilitating early detection, SENSOPAD not only improves clinical outcomes but also empowers users with better control over their reproductive health. This aligns with broader trends in personalised and preventive medicine, enhancing user engagement and satisfaction.

- **Ease of use and accessibility**

  The device's autonomous, at-home use model supports widespread adoption, particularly in settings with limited access to specialised healthcare. Its intuitive design and integration with mobile health platforms make it highly scalable and user-friendly.

Weaknesses of SENSOPAD

While SENSOPAD presents a highly promising solution in women's health diagnostics, several internal limitations could impact its development, market entry, and scalability. These weaknesses are presented below:

- **Clinical validation requirements**

  As an early-stage diagnostic device, SENSOPAD must undergo rigorous clinical trials to demonstrate accuracy, safety, and clinical utility. These validations are time-intensive, costly, and critical to gaining acceptance from healthcare professionals and regulators.

- **Scalability of advanced components**

  Key components like graphene-based field-effect transistors (Bio-gFETs) and microfluidic systems, though innovative, currently face moderate scalability. Manufacturing these components at commercial volumes while maintaining quality and cost-effectiveness remains a significant technical challenge.

- **Interoperability with healthcare IT systems**

Integration with existing Electronic Health Record (EHR) systems and clinical data platforms may require additional development, customisation, or partnerships to ensure seamless compatibility across different healthcare infrastructures.

- **Complex EU regulatory requirements**

  Navigating the Medical Device Regulation (MDR) in the EU involves stringent documentation, Notified Body assessments, and long approval timelines. These regulatory demands increase time to market and require dedicated compliance resources.

- **Regulatory fragmentation across markets**

  Regulatory frameworks differ significantly between the EU, U.S., and other regions. Adapting to each system's classification, documentation, and approval pathways may slow global rollout and increase operational complexity.

- **Data privacy and cybersecurity compliance**

  With personal health data being collected and transmitted through cloud-based platforms, SENSOPAD must maintain robust security protocols and compliance with privacy laws such as GDPR. Any vulnerability could lead to reputational damage and legal liabilities.

- **Cost-effectiveness and affordability**

  Ensuring that SENSOPAD remains affordable for patients while covering high production and validation costs is a delicate balance. Without achieving cost-effectiveness, widespread adoption, particularly in public healthcare systems, may be limited.

Opportunities of SENSOPAD

SENSOPAD is strategically positioned at the intersection of several transformative trends in healthcare, digital technology, and women's health policy. As demand for personalised, accessible, and preventive healthcare grows, a number of opportunities emerge for rapid adoption and long-term impact.

- **Unaddressed diagnostic gap in endometriosis**
  Endometriosis affects approximately 10% of women globally, yet diagnostic delays often exceed 7 years. SENSOPAD directly targets this gap with a non-invasive, home-based diagnostic solution, offering a compelling value proposition in a market that has long lacked effective screening tools.
- **Rising demand for PoC and at-home diagnostics**
  There is strong global momentum toward decentralised healthcare. SENSOPAD's seamless integration of biosensing, mobile platforms, and real-time analytics positions it well in the growing PoC diagnostic market, expected to surpass $68bn globally by 2030.
- **Policy support for women's health innovations**
  Governments and institutions are increasingly prioritising women's health. In the EU, initiatives under Horizon Europe allocate substantial funding to projects that improve reproductive and gynecological health. Similarly, the U.S. NIH's ORWH (Office of Research on Women's Health) supports innovations that address systemic gaps in diagnostics for conditions like endometriosis.
- **Targeted support for emerging technologies**

Public and private sectors are boosting investment in nanotechnology, bio-FETs, and graphene manufacturing. The European Innovation Council (EIC) and national tech-transfer programs in Germany, France, and the Netherlands offer grants and accelerator support for biosensor-based medical devices. In the U.S., NSF and NIH SBIR/STTR programs fund early-stage ventures focused on PoC diagnostics, including graphene-based systems.

- **Support for deployment in low-resource settings**
  There is a growing emphasis on equitable healthcare access, with global agencies funding solutions adapted for low-resource regions. Programs like the Grand Challenges Canada initiative and WHO's Prequalification of Diagnostics Programme facilitate access for innovative tools like SENSOPAD in regions such as Sub-Saharan Africa and Latin America.
- **Advances in nanomaterials & sensor technologies**
  Recent breakthroughs in large-scale, low-cost graphene synthesis and the miniaturisation of bio-FETs create an ideal backdrop for SENSOPAD's sensor architecture. These trends support improved sensitivity, scalability, and affordability in next-gen diagnostic tools.
- **Integration with digital health & telemedicine**
  The expansion of telemedicine platforms and digital health ecosystems allows SENSOPAD to plug directly into remote care models. Integration with AI and machine learning for pattern recognition, predictive diagnostics, and longitudinal tracking further enhances its clinical value.
- **Rise of personalised and preventive medicine**
  Healthcare is rapidly shifting towards personalised care strategies that use real-time data for early detection and tailored interventions. SENSOPAD's ability to collect continuous, user-specific biomarker data aligns with this global trend, particularly in chronic condition monitoring and reproductive health management.
- **Opportunities for strategic collaborations**
  SENSOPAD can accelerate validation, distribution, and adoption by partnering with:
  - Healthcare systems (for pilot deployments and reimbursement models),
  - Academic research centres (for clinical studies and co-development),
  - Women's health NGOs and advocacy groups (for awareness and reach).
- **Global scaling and licensing**
  As SENSOPAD matures, licensing its sensor platform for other applications (e.g., fertility, PCOS, STIs) or regions could open additional revenue streams.

Threats of SENSOPAD

Despite its innovative design and strong alignment with current healthcare trends, SENSOPAD faces several external threats that could impact its commercial success, regulatory progress, and long-term scalability:

- **Stringent EU MDR requirements**
  Navigating the complex regulatory environment of the EU Medical Device Regulation (MDR 2017/745) is both time-consuming and resource-intensive. Any delays in classification, conformity assessment, or CE marking, especially for a novel diagnostic device, can slow down market entry and increase development costs.
- **Navigating HTA and reimbursement complexity**

In many European countries, public reimbursement of innovative medical devices depends on successful Health Technology Assessment (HTA), which evaluates not only clinical performance and safety but also health-economic impact and cost-effectiveness compared to existing standards of care. While SENSOPAD is designed to deliver strong value across these dimensions, the HTA landscape remains fragmented across Europe and can involve lengthy and resource-intensive processes. This regulatory complexity can pose a potential barrier to timely reimbursement, funding access, and early market penetration, particularly in publicly funded healthcare systems.

- **Emerging competition**
  The growing attention on women's health and non-invasive diagnostics is attracting both startups and established MedTech companies. New entrants with faster go-to-market strategies, greater resources, or stronger healthcare partnerships could erode SENSOPAD's first-mover advantage.
- **Skepticism from healthcare providers**
  Clinician acceptance is crucial for adoption, yet healthcare professionals may remain skeptical toward novel diagnostics without long-term clinical data or real-world evidence. Lack of published validation studies or endorsements from key opinion leaders (KOLs) could slow uptake.
- **Consumer trust and engagement**
  As a data-driven, sensor-based medical device operating at the intersection of intimate health and cloud analytics, SENSOPAD must overcome potential consumer concerns around data privacy, accuracy, and usability. Any issues in these areas may negatively impact user trust and retention.
- **Uncertain reimbursement landscape**
  Global reimbursement pathways for point-of-care diagnostics remain fragmented. In the U.S., private payers may not cover novel diagnostics without FDA recognition and proven cost savings. In the EU, national health systems vary in how they reimburse digital or wearable diagnostics, posing a significant market access challenge if not addressed early.
- **Rapid innovation cycle**
  The field of biosensors, AI diagnostics, and digital health platforms is evolving rapidly. Competing technologies leveraging next-gen artificial intelligence, CRISPR-based diagnostics, or alternative wearable formats could render SENSOPAD's solution less differentiated over time unless continuous innovation is pursued.

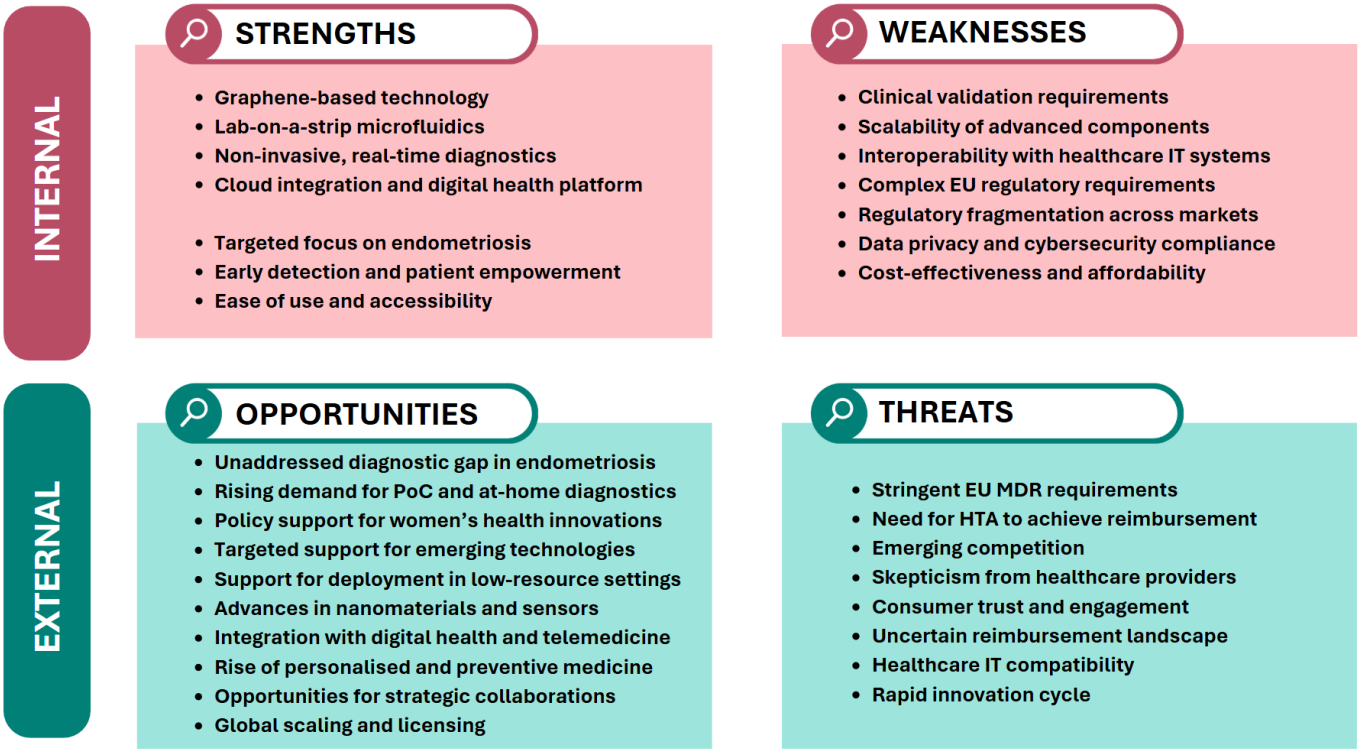


Figure 10: SENSOPAD's SWOT Analysis

7.2 Porter's 5 forces

Porter's Five Forces is a strategic tool developed to analyse the competitive dynamics within an industry. It helps assess the key factors that influence market competition and overall profitability by examining the threat of new entrants, bargaining power of suppliers and buyers, threat of substitutes, and the intensity of rivalry among existing competitors. The following analysis applies Porter's Five Forces to SENSOPAD, highlighting competitive pressures and strategic challenges.

Threat of New Entrants – Moderate

Entering the market involves overcoming significant barriers, including high R&D costs, strict regulatory and clinical validation requirements, supply chain complexities, and compliance with data privacy standards. At the same time, innovation is gaining momentum (as mentioned, over 1,100 patents related to endometriosis were filed in 2022 alone), indicating increasing interest and activity in the space. This combination of high entry barriers and rising innovation makes entry possible but difficult.

Bargaining Power of Suppliers – High

SENSOPAD relies on partnerships with graphene suppliers, especially for non-integrated operations. Since suppliers must meet stringent medical certification requirements, they hold strong bargaining power.

Bargaining Power of Buyers – Moderate

Buyer influence varies depending on the business model. In B2B or B2B2C approaches, such as selling through hospitals or securing adoption by healthcare providers, buyers hold relatively higher power. They demand strong clinical validation, affordability, privacy compliance, and potential for reimbursement,

all of which shape product development and pricing. Their recommendations also significantly influence patient adoption, even if they don't directly purchase the device. In contrast, in a direct-to-consumer (B2C) model, buyer power may be lower, though price sensitivity, ease of access, and brand trust remain critical. Overall, these dynamics result in a moderate level of buyer bargaining power.

Threat of Substitute Products/Services – Low

While some competitors are developing diagnostic tools for endometriosis (e.g., MenstruAI[49]), none have reached an advanced stage or commercialised a non-invasive solution. Existing alternatives remain invasive, slow, and costly, reducing the immediate risk of substitution.

The limited presence of non-invasive alternatives suggests that current competitive rivalry is relatively manageable, allowing SENSOPAD to position itself as a market leader in the segment. However, as awareness of endometriosis grows and technological advancements continue, the market is likely to attract new players, which could intensify competition over time.

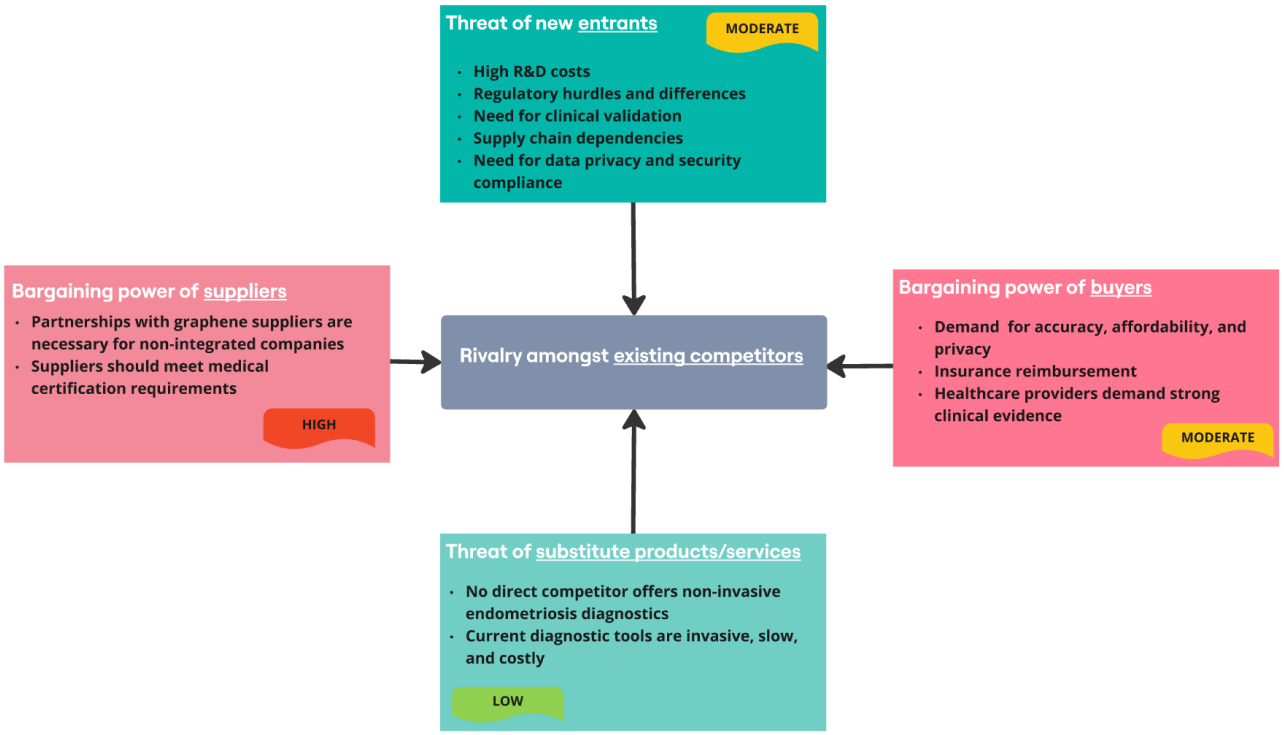


Figure 11: SENSOPAD's Porter's 5 forces analysis

7.3 TOWS analysis

TOWS analysis builds on the traditional SWOT framework by shifting the focus from analysis to strategy. It systematically cross-references **internal strengths and weaknesses** with **external opportunities and threats**, helping SENSOPAD generate actionable responses to its strategic landscape.

Using Strengths to Maximise Opportunities (SO)

[49] ETH Zurich (2025). Sanitary towels morph into test strips. Available at: https://ethz.ch/en/news-and-events/eth-news/news/2025/05/sanitary-towels-morph-into-test-strips.html (Accessed: 27 August 2025).

SENSOPAD's core strengths align perfectly with emerging trends in women's health and point-of-care (PoC) diagnostics. By positioning the product as a first-of-its-kind diagnostic alternative for endometriosis, SENSOPAD can directly address diagnostic delays and discomfort associated with current methods. Moreover, SENSOPAD can capitalise on global healthcare's shift toward decentralised, home-based testing by highlighting its ease of use and data immediacy.

Collaboration with Key Opinion Leaders (KOLs), alongside strong clinical and industrial partnerships, can be leveraged to build early credibility and market momentum.

Mitigating Weaknesses to Seize Opportunities (WO)

To fully exploit the market potential, SENSOPAD must overcome typical early-stage hurdles such as regulatory navigation, scalability, and funding. Strategic partnerships, particularly with MedTech manufacturers, clinical institutions, and regulatory consultants, will be essential for scaling development and achieving compliance with standards like FDA and MDR.

Securing government grants and venture capital funding will further enable commercial scalability while reducing cost pressures. Considering the integration of technologies, like blockchain-backed data security protocols, could enhance patient trust and ensure alignment with global data protection standards. Advocacy campaigns, especially those in collaboration with women's health organisations, can amplify awareness and create policy pressure for reimbursement pathways.

Using Strengths to Defend Against Threats (ST)

The competitive and regulatory landscape presents potential barriers, but SENSOPAD's strengths provide a strategic buffer. By proactively engaging regulatory advisors, the company can accelerate approval processes and minimise compliance risks. A strong patent and IP portfolio will also serve as a moat against fast-follow competitors, enabling early market exclusivity and sustainable differentiation.

Addressing Weaknesses to Withstand Threats (WT)

The bio-gFET sensor space may attract well-resourced entrants, and SENSOPAD's weaknesses, such as limited internal manufacturing and early-stage funding could be exploited without proactive planning. To prevent this, SENSOPAD should prioritise agile product development cycles and IP defensibility, ensuring its lead is not only established but maintained.

	Strengths (S)	Weaknesses (W)
Opportunities (O)	**SO** - Leverage innovation & non-invasiveness: Position SENSOPAD as a non-invasive endometriosis diagnostics tool to capture the unmet market need. - Tap into the PoC diagnostics trend: Highlight ease-of-use and real-time monitoring to align with the global shift towards home-based diagnostics. - KOL Strategy: Leverage our Key Opinion Leaders (KOLs) in Israel and the UK, alongside world-class clinical and industry partners, to drive clinical validation, market awareness, early adoption, and strategic partnerships	**WO** - Form strategic partnerships: In order to overcome barriers related to regulatory compliance and scalable product development - Secure government & VC funding: Seek grants and funding to overcome scalability challenges and reduce costs. - Leverage AI-driven security: Implement advanced encryption and blockchain-based data tracking to ensure privacy compliance. - Use advocacy & awareness campaigns: Work with women's health organisations to build demand and encourage policymakers to support reimbursement.
Threats (T)	**ST** -Regulatory Readiness: Partner with regulatory advisors to ensure MDR & FDA compliance, fast-tracking approvals. -IP & Patent Protection: Strengthen patent portfolio to protect against competition and secure early market exclusivity.	**WT** - Competitor Preparedness: Develop strong IP defense & rapid iteration cycles to stay ahead of competitors trying to enter the bio-gFET sensor market.

Figure 12: SENSOPAD's TOWS Analysis

Based on the TOWS insights, SENSOPAD's market entry should focus on a **partnership-led, credibility-first strategy**, underpinned by strong positioning and policy engagement:

SENSOPAD preliminary market entry strategy

- **Strategic Partnerships:** Collaborate with clinical institutions for validation, MedTech firms for production scale, and regulatory experts for compliance.
- **KOL Engagement:** Leverage experts to build early credibility and drive adoption through professional networks.
- **Differentiated Positioning:** Market SENSOPAD as the first AI-powered, non-invasive diagnostic for endometriosis, focusing on early detection, patient comfort, and real-time insights.
- **Policy & Advocacy:** Work alongside NGOs and women's health advocates to build reimbursement support and public demand.
- **Sustainability Focus: Prioritise robust IP protection and secure timely funding to safeguard competitive advantage and support agile development.**

Conclusions

The SENSOPAD market analysis highlights a timely and significant opportunity to transform the diagnostic pathway for millions of women affected by endometriosis. As a wearable, AI-driven, and non-invasive diagnostic tool, **SENSOPAD directly responds to one of the most persistent challenges in women's healthcare: the absence of accessible, timely, and accurate diagnostic solutions for a condition that remains widely underdiagnosed**.

The findings demonstrate a strong alignment between SENSOPAD's technological capabilities and key trends shaping the future of healthcare. The growing demand for point-of-care diagnostics, expanding investment in FemTech, and increasing policy emphasis on reproductive health collectively create favourable conditions for market entry. Unlike competitors that rely on invasive sampling or centralised laboratory processing, SENSOPAD offers real-time, user-friendly diagnostics integrated into everyday routines, removing barriers to access and enhancing patient engagement.

However, **capitalising on this opportunity will require early strategic planning alongside ongoing R&D.** The rapidly growing FemTech and diagnostic markets, combined with SENSOPAD's early development stage, make it essential to define the business model, go-to-market strategy, and stakeholder engagement pathways early on. This includes building a roadmap for clinical validation, navigating complex EU and US regulatory pathways, ensuring manufacturing scalability, and embedding privacy, affordability, and trust by design.

These priorities will guide the upcoming work on business model development, validation, and refinement, supporting the transition from innovation to real-world impact. Key next steps include:

- Defining and evaluating viable business models that align with user needs, market trends, and partner capabilities (T11.4).
- Engaging stakeholders through interviews, workshops, and pilot activities to validate and refine these business models (T12.3).
- Improving and adapting the business models based on validation insights to ensure strong problem-solution, product-market, and business model fit (T12.4).
- Developing a comprehensive business plan that includes commercial strategy, financial projections, and risk assessment to guide long-term exploitation (13.3).

While challenges remain, the opportunity is clear. SENSOPAD is uniquely positioned to advance not only the early diagnosis of endometriosis, but also the broader movement toward personalised, decentralised, and equitable healthcare. With continued investment in validation, regulatory strategy, and stakeholder engagement, SENSOPAD has the potential to set a new benchmark in women's health technologies and redefine standards for diagnostic innovation.

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Annex

Annex I – Market Analysis templates

FemTech Market

The objective of the following template is to **leverage consortium expertise and gather expert input to validate and complement findings from desk research and market reports**. This ensures that the insights we gather are well-rounded and accurate, incorporating both secondary data and primary expertise thereby refining our understanding and strengthening our market analysis.

Market definition, size and growth

The **FemTech Market** ($39.29b, 2024[50]) refers to **female technology products, devices, software, and services** that enable the use of digital health to manage **women's health issues**. The primary focus of FemTech is to develop products, software, and tech-enabled solutions to cater to the unmet rising need for women's health.

Based on type, the market is segmented into **consumer products** (e.g., flushable pads), **devices** (wearables, hardware etc.), and **apps/software**. The devices segment dominated the market in 2024 and is expected to have the fastest growth rate by 2030.

On the basis of application, the market is segmented into **Pregnancy & Nursing and Reproductive Health & Contraception, Menstrual Health, Pelvic & Uterine Health Care, Sexual Health, Women's Wellness, Menopause Care, Longevity, General Health Care**, and **Mental Health** with the first one dominating the market in 2024.

Based on region, the market is segmented into **North America**, leading the market, **Europe, Asia Pacific, Latin America, and Middle East & Africa**.

Are there specific sub-segments (e.g., *Pregnancy and Nursing, Reproductive Health and Contraception, Menstrual Health, General Health Care* etc.) that show significant potential for growth?

Your text here..

Market Trends

Below are some key trends observed in the FemTech market. Please prioritise them in terms of importance and relevance:

Key trends	Rate 1-5 (1 least relevant – 5 most relevant)
Increasing demand for personalised and home-based diagnostic solutions.	
Rising awareness and funding for women's health issues, especially gynaecological conditions.	
Rising R&D activities and integration of AI and cloud-based analytics in health monitoring devices.	

[50] https://www.grandviewresearch.com/industry-analysis/femtech-market-report#:~:text=The%20global%20FemTech%20market%20size,16.37%25%20from%202025%20to%202030.

Expanding adoption of wearable technologies and mobile/ cloud applications in health.

Are there any other trends you consider important that might impact SENSOPAD's deployment?

Your text here..

Market Opportunities

Below are some potential opportunities for FemTech products. Please prioritise them in terms of importance and relevance:

Key opportunities	Rate 1-5 (1 least relevant – 5 most relevant)
Addressing unmet needs in gynaecological diagnostics.	
High demand for early detection of endometriosis.	
Leveraging the increasing awareness of menstrual health among women and the growing demand to normalise conversations around traditionally taboo topics in women's health.	
Targeting underserved regions with limited access to gynaecological diagnostics.	
Collaborating with relevant platforms and health advocacy groups.	

What other opportunities do you foresee in this market?

Your text here..

Market Challenges

Below are some potential challenges in the FemTech market. Please prioritise them in terms of significance for SENSOPAD:

Key challenges	Rate 1-5 (1 least relevant – 5 most relevant)
Regulatory hurdles (e.g., compliance and approval delays).	
Market fragmentation due to varying regional awareness and healthcare infrastructure.	
High cost and insurance coverage issues for advanced diagnostic tools.	
Scepticism among healthcare providers regarding new diagnostic technologies.	

Are there additional challenges we should consider?

Your text here..

Market Segmentation

By Region:

Which regions are most promising for FemTech diagnostics? (Please consider factors such as *regional healthcare policies and reimbursement structures, demographics, cultural attitudes and sensitivity* etc.)

Your text here..

Are there specific countries within these regions with higher adoption rates for women's health innovations?

Your text here..

By Product Type:

Which types of FemTech products (e.g., *wearables, mobile apps, PoC diagnostics*) dominate the market?

Your text here..

What are the key differentiators of SENSOPAD compared to existing FemTech products (e.g., *focus on endometriosis, non-invasiveness and convenience* etc.)

Your text here..

By End-user:

In your opinion, what are the most important factors for women when choosing a menstrual health monitoring device? Please prioritise them in terms of significance.

Key factors	Rate 1-5 (1 least relevant – 5 most relevant)
Ease of use.	
Affordability.	
Accuracy.	
Real-time data insights.	
Integration with mobile apps.	
Availability in their region.	
Privacy and data security.	

In your opinion, what are the primary concerns or barriers for gynecologists and healthcare institutions in adopting a new diagnostic device like SENSOPAD? Please prioritise them in terms of significance.

Key factors	Rate 1-5 (1 least relevant – 5 most relevant)
Clinical validation,	
Cost-effectiveness.	
Ease of integration into existing systems.	
Training requirements.	
Patient adherence.	
Regulatory compliance.	

By Sub-Sector:

How does the menstrual health and diagnostics sub-sector compare to others in the FemTech market in terms of growth and investment?

Your text here..

Market Fragmentation

How does fragmentation affect market entry strategies for products like SENSOPAD?

Your text here..

Are there opportunities for SENSOPAD to collaborate or consolidate with existing players (e.g., *FemTech companies, healthcare organisations, hospitals, insurance providers* etc.)

Your text here..

What is the degree of differentiation among existing FemTech products in terms of technology, features, and user experience (e.g., *diagnostic accuracy, personalisation, ease of use, integration with healthcare systems*)?

Your text here..

How does vertical integration in FemTech companies (e.g., *product development, manufacturing, software development, distribution, healthcare partnerships*) influence competition and market entry strategies?

Your text here..

Key Competitors and Players

Who are the most prominent players in the FemTech market, particularly in diagnostics or menstrual health?

Your text here..

What are the strengths and weaknesses of these competitors compared to SENSOPAD?

Your text here..

Are there recent innovations or product launches by competitors that might affect SENSOPAD's market positioning?

Your text here..

Stakeholder Recommendations

From your perspective, what are the critical success factors for SENSOPAD in the FemTech market?

Your text here..

What strategies do you recommend for overcoming market challenges and leveraging opportunities?

Your text here..

Health Sensors Market

The objective of the following template is to **leverage consortium expertise and gather expert input to validate and complement findings from desk research and market reports**. This ensures that the insights we gather are well-rounded and accurate, incorporating both secondary data and primary expertise thereby refining our understanding and strengthening our market analysis.

Market definition, size and growth

The **Health Sensors Market** ($49.89b, 2024[51]) involves the **development and use of sensors to monitor various health parameters** through devices like **wearables, hand-held, and implantable/ ingestible**. It is driven by advancements in technology and the increasing demand for remote monitoring and personalised healthcare.

By type, the market is segmented into **heart rate, temperature, pressure, blood glucose and oxygen sensors**, among others, with heart rate sensors leading the market.

On the basis of application, **chronic illness & at-risk monitoring dominate the market, with other segments being wellness monitoring, sensor therapeutics, post-acute care monitoring, in-hospital clinical monitoring, point-of-care (PoC) diagnostics and home health monitoring** etc.

Based on region, the market is segmented into **North America** (the undisputed leader), **Europe, Asia Pacific, Latin America, and Middle East & Africa**.

Are there specific sub-segments (e.g., *Wellness Monitoring, Sensor Therapeutics, Chronic Illness & At Risk-Monitoring* etc.) that show significant potential for growth?

Your text here..

Market Trends

Below are some key trends observed in the Health Sensors market. Please prioritise them in terms of importance and relevance:

Key trends	Rate 1-5 (1 least relevant – 5 most relevant)
Growing adoption of non-invasive and wearable health sensors for continuous monitoring.	
Increasing integration of AI and cloud-based analytics in health sensors for improved diagnostics.	
Rising demand for real-time, at-home health diagnostics and self-monitoring devices.	
Advancements in biosensors, such as the use of graphene and other novel materials in diagnostic devices.	

Are there any other trends you consider important that might impact SENSOPAD's deployment?

Your text here..

[51] https://www.grandviewresearch.com/industry-analysis/health-sensors-market#:~:text=Frequently%20Asked%20Questions%20About%20This,USD%2049.89%20billion%20in%202024.

Market Opportunities

Below are some potential opportunities for Health Sensors products. Please prioritise them in terms of importance and relevance:

Key opportunities	Rate 1-5 (1 least relevant – 5 most relevant)
The increasing need for non-invasive and accurate diagnostic tools.	
High demand for early detection in women's health, specifically related to endometriosis.	
Integration of sensors in home diagnostics, reducing healthcare access barriers.	
Expansion of telemedicine and virtual consultations using data from wearable health sensors.	
The growing focus on preventative health and real-time data analytics.	
Increased strategic partnerships, collaborations, and distribution agreements tapping into diverse healthcare ecosystems worldwide	

What other opportunities do you foresee in this market?

Your text here..

Market Challenges

Below are some potential challenges in the Health Sensors market. Please prioritise them in terms of significance for SENSOPAD:

Key challenges	Rate 1-5 (1 least relevant – 5 most relevant)
Regulatory hurdles (e.g., obtaining approval for medical devices).	
Variability in sensor accuracy and reliability across different environments.	
Integration and compatibility challenges with existing healthcare IT systems.	
The high cost of advanced health sensors and concerns around reimbursement policies.	
Scepticism regarding sensor-based diagnostics from healthcare professionals.	
Ensuring the scalability of advanced components while maintaining safety and quality standards.	

Are there additional challenges we should consider?

Your text here..

Market Segmentation

By Region:

Which regions are most promising for Health Sensors diagnostics?

Your text here..

Are there specific countries within these regions with higher adoption rates for Health Sensors?

Your text here..

By Product Type:

Which types of Health Sensors products (e.g., *wearables, hand-held, implantable/ ingestible*) dominate the market?

Your text here..

What are the key differentiators of SENSOPAD compared to existing Health Sensors products (e.g., *non-invasive, real-time data capture, graphene-based innovations mobile app / cloud platform* etc.).

Your text here..

By End-user:

In your opinion, what are the most important factors for users when choosing a health sensor-based diagnostic device? Please prioritise them in terms of significance.

Key factors	Rate 1-5 (1 least relevant – 5 most relevant)
Accuracy and reliability of the sensor.	
Ease of use.	
Affordability.	
Real-time data insights.	
Integration with mobile apps and cloud platforms.	
Availability in their region.	
Privacy and data security.	

In your opinion, what are the primary concerns or barriers for healthcare providers in adopting health sensors in treatment? Please prioritise them in terms of significance

Key factors	Rate 1-5 (1 least relevant – 5 most relevant)
Clinical validation and proven diagnostic accuracy.	
Cost-effectiveness compared to traditional diagnostic methods.	
Integration with existing healthcare infrastructure (EHRs, hospital systems).	
Training requirements for healthcare professionals.	
Regulatory compliance and certifications.	

By Sub-Sector:

How does the medical sensor sub-sector compare to others in the health sensors market in terms of growth and investment?

Your text here..

Market Fragmentation

How does fragmentation affect market entry strategies for products like SENSOPAD?

Your text here..

Are there opportunities for SENSOPAD to collaborate or consolidate with existing players (e.g., *healthcare organisations, medical device manufacturers* etc.)

Your text here..

What is the level of differentiation among existing health sensor products in terms of technology, features, and user experience (e.g., *accuracy, real-time data insights, ease of use, integration with mobile apps*)?

Your text here..

How does vertical integration in health sensor companies (e.g., *manufacturing, software development, distribution*) affect competition and market entry barriers?

Your text here..

Key Competitors and Players

Who are the most prominent players in the health sensors market, particularly for diagnostics or non-invasive monitoring devices?

Your text here..

What are the strengths and weaknesses of these competitors compared to SENSOPAD?

Your text here..

Are there recent innovations or product launches by competitors that might affect SENSOPAD's market positioning?

Your text here..

Stakeholder Recommendations

From your perspective, what are the critical success factors for SENSOPAD in the Health Sensors market?

Your text here..

What strategies do you recommend for overcoming market challenges and leveraging opportunities?

Your text here..

Field-Effect Transistor (FET) Market

The objective of the following template is to **leverage consortium expertise and gather expert input to validate and complement findings from desk research and market reports**. This ensures that the insights we gather are well-rounded and accurate, incorporating both secondary data and primary expertise thereby refining our understanding and strengthening our market analysis.

Market definition, size and growth

The **Field-Effect Transistor (FET) Market** ($5.57b, 2023[52]) refers to the development, production, and application of FETs (**analog (JFET) and digital (MOSFET)**)—semiconductor devices that use an electric field to control current flow.

By application, the market is segmented into **amplifiers, switchers, motor control, digital logic circuits, sensors, and others.** Based on end-users the market can be divided into **automotive, consumer electronics, IT/telecom, healthcare and power**

[52] https://www.technavio.com/report/field-effect-transistor-fet-market-analysis#:~:text=The%20field%20effect%20transistor%20(FET,due%20to%20several%20key%20trends.

generating industries. In the Healthcare and Medical Industry, **bio-FETs are used to develop new diagnostic tools and therapeutic devices**.

Finally, by region, the market is segmented into Asia Pacific, North America, Latin America, Europe and Middle East & Africa. The **Asia Pacific** region leads the FET Market due to the growing digitalisation, technological advancements, and the growing use of consumer electronics.

Are there specific sub-segments (e.g., *bio-FETs, power electronics, RF applications, nanotechnology-enabled FETs*) that show significant potential for growth?

Your text here..

Market Trends

Below are some key trends observed in the FET market. Please prioritise them in terms of importance and relevance:

Key trends	Rate 1-5 (1 least relevant – 5 most relevant)
Growing adoption of FET-based biosensors for healthcare diagnostics.	
Advancements in nanomaterials (e.g., graphene, carbon nanotubes) improving FET performance and sensitivity.	
Expanding use of FETs in wearable and implantable devices for real-time monitoring (miniaturisation).	
Integration of AI and machine learning for FET-enabled data analysis and decision-making.	

Are there any other trends you consider important that might impact SENSOPAD's deployment?

Your text here..

Market Opportunities

Below are some potential opportunities for FET products. Please prioritise them in terms of importance and relevance:

Key opportunities	Rate 1-5 (1 least relevant – 5 most relevant)
Increasing demand for bio-FETs in personalised medicine and point-of-care diagnostics.	
Integration of bio-FETs with other technologies, such as microfluidics and nanotechnology to develop new and innovative devices for a variety of applications.	

Integration of FETs in IoT-enabled health monitoring systems and wearable devices.	
Expanding use of FETs in emerging markets for affordable diagnostic solutions.	
Collaborations with healthcare providers and research institutions to validate and commercialise FET-based diagnostics.	
Increasing government funding for research and development of bio-FETs.	
Growing awareness of the benefits of using bio-FETs.	

What other opportunities do you foresee in this market?

Your text here..

Market Challenges

Below are some potential challenges in the FET market. Please prioritise them in terms of significance for SENSOPAD:

Key challenges	Rate 1-5 (1 least relevant – 5 most relevant)
Overcoming scalability challenges (such as variability in performance) in manufacturing and deploying high-performance FETs in large-scale.	
Regulatory and standardisation hurdles for deploying FET-based medical sensors in healthcare.	
Ensuring compatibility of FET-based devices with existing healthcare IT systems.	
High cost and limited availability of advanced nanomaterials for FET production.	
Competition within the market and from alternative sensing technologies (e.g., *traditional biosensors being significantly less expensive*).	
Advanced technologies that could be leveraged for medical diagnostics are not addressing women's health.	

Are there additional challenges we should consider?

Your text here..

Market Segmentation

By Region:

Which regions are most promising for FET-based diagnostics (Please consider factors such as trends and demand, regional healthcare infrastructure, research funding and capabilities)?

Your text here..

Are there specific countries within these regions with higher adoption rates for FET – enabled innovations?

Your text here..

By Product Type:

Which types of FET products (e.g., *bio-FETs, power FETs, RF FETs*) dominate the market?

Your text here..

What are the key differentiators of SENSOPAD compared to existing FET products (e.g., *graphene-based innovations, enhanced sensitivity, real-time data analysis*).

Your text here..

By End-user:

In your opinion, what are the most important factors for users when choosing a FET-based device? Please prioritise them in terms of significance.

Key factors	Rate 1-5 (1 least relevant – 5 most relevant)
Sensor accuracy and reliability.	
Cost-effectiveness.	
Integration with existing systems.	
Compatibility with mobile apps and IoT devices.	
Real-time data insights and cloud compatibility.	

In your opinion, what are the primary concerns or barriers for researchers and healthcare providers in adopting FET-based devices in diagnostics or monitoring? Please prioritise them in terms of significance

Key factors	Rate 1-5 (1 least relevant – 5 most relevant)
Clinical validation and accuracy.	
Cost-effectiveness compared to alternatives.	
Training and technical expertise required.	
Regulatory compliance and certifications.	

By Sub-Sector:

How does the bio-FET sub-sector compare to others (e.g., *RF, power*) in the FET market in terms of growth and investment?

Your text here..

Market Fragmentation

How does fragmentation affect market entry strategies for products like SENSOPAD?

Your text here..

Are there opportunities for SENSOPAD to collaborate or consolidate with existing players (e.g., *nanotechnology companies, academic institutions, research labs, healthcare organisations*)

Your text here..

What is the level of differentiation among existing FET products in terms of technology, performance characteristics, and application versatility (e.g., *sensitivity, selectivity, response time, stability etc.*)?

Your text here..

How does vertical integration in FET manufacturing companies (e.g., *material production, chip fabrication, testing, distribution*) affect competition and market entry barriers?

Your text here..

Key Competitors and Players

Who are the most prominent players in the FET market, particularly for bio-FETs?

Your text here..

What are the strengths and weaknesses of these competitors compared to SENSOPAD?

Your text here..

Are there recent innovations or product launches by competitors that might affect SENSOPAD's market positioning?

Your text here..

Stakeholder Recommendations

From your perspective, what are the critical success factors for SENSOPAD in the bio-FET market?

Your text here..

What strategies do you recommend for overcoming market challenges and leveraging opportunities?

Your text here..

SENSOPAD
SENSING ENDOMETRIOSIS ON PORTABLE AUXILIARY DEVICES

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