



IMPACT STUDY

Date of publication:

18 October 2024

Prepared by:

Martine Vanschoor
Researcher

Approved by:

Thierry Vermeeren
CEO

Publishing Editor:

OZCconsulting
122 Chaussée Moncheur
5300 Andenne



INTRODUCTION TO THE WELINK.CARE LABEL

The WeLink.Care label was created in 2020, at the onset of the COVID crisis, in order to contribute to the international effort to fight the pandemic. Our contribution was to create the first catalogue of eHealth solutions to be used in this emergency context. It was an immediate success and many of the featured solutions have been effectively used and integrated in the global community of healthcare institutions.

Our revolutionary approach to assessment was – and still is – centred on a deep dive into the capacity to improve practices while providing an enhanced experience for care professionals and patients alike. Building on that, we rapidly developed our scientific approach to expand the scope of the database to cover all the sub-domains of digital health and include in our assessment a thorough evaluation of the economic capacity of the company behind the solution and the maturity of the proposed innovation.

Today, dozens of solutions are selected each month to be assessed by one of our experts, and a healthy portion of them obtain the WeLink.Care label. Based on years of extensive research into digital health solutions and their effective impact on healthcare, our unique methodology relies on the evaluation of more than 50 data points subdivided into relevant categories.

This evaluation is executed by certified and trained experts who capitalise on their own experience of digital health to leverage our methodology in their information gathering. The input of the solution provider team, enriched with the input of patients and care professionals, collected through a series of detailed interviews, forms the foundation of the analysis, completed by extensive research in the available documentation.

This Impact Study is the result of that extensive work.

EXECUTIVE SUMMARY

This impact study evaluates the pOpmètre, a medical device developed by Axelife, designed to measure arterial stiffness as part of cardiovascular risk assessments. By utilizing pulse wave velocity (PWV) and translating results into an "arterial age," the pOpmètre provides valuable insights into vascular health, promoting preventive measures in cardiovascular care. The device's non-invasive and user-friendly design enables widespread use across healthcare settings, from cardiology specialists to general practitioners.

The pOpmètre received a WeLink.Care Label with an overall disruption score of 69%. Its strongest performances were in the dimensions of change of practices (80%) and user experience (80%), where it effectively integrates innovative metrics into care routines and offers easy-to-use diagnostics. The business model (58%) and solution maturity (58%) scored lower, reflecting ongoing challenges related to profitability, limited clinical validation, and digital integration.

Field studies with experts like Professors Gallix and Addad highlight the device's impact on motivating patients to adopt healthier lifestyles. However, barriers such as the need for automation in data management and the absence of comprehensive scientific validation still hinder broader adoption. France's evolving digital health landscape, supported by government initiatives and a strong startup ecosystem, presents opportunities for further growth, though the fragmented digital infrastructure poses challenges.

To fully realize its potential, Axelife should focus on expanding clinical evidence, improving interoperability with digital health systems, and exploring recurring revenue streams. These steps will strengthen the pOpmètre's market position, enabling it to play a more significant role in cardiovascular prevention and the future of digital health.

DIGITAL HEALTH LANDSCAPE

France's digital health ecosystem is undergoing significant transformation, driven by strategic government initiatives, increasing private sector engagement, and an evolving regulatory environment. These efforts aim to modernize healthcare delivery and enhance the integration of digital solutions across the continuum of care. Below are key elements contributing to this transformation.

GOVERNMENT INITIATIVES AND POLICY SUPPORT

The "Ma Santé 2022" framework, launched in 2018, stands as a cornerstone of France's digital health reform. Its central aim is to bridge the gap between urban medicine, hospitals, and medico-social services through increased digital integration. A pivotal outcome of this initiative is the establishment of the Digital Health Space (Espace de Santé Numérique - ESN), designed to provide patients and healthcare professionals with a unified platform for managing health data. This shift towards digital health services reflects the government's commitment to fostering innovation and improving healthcare efficiency. However, despite these advances, challenges related to the fragmentation of legacy electronic health systems persist.

SIGNIFICANT PUBLIC INVESTMENTS IN HEALTH TECH

France's dedication to strengthening its healthcare infrastructure is evident through substantial financial commitments. For instance, the €19 billion "Ségur de la Santé" investment package is directed towards modernizing hospitals, expanding telehealth capabilities, and ensuring interoperability across health data systems. In tandem with this, the Agence du Numérique en Santé (ANS) plays a crucial role in driving digital health policies, streamlining digital solutions for regional health agencies (ARS), and addressing fragmentation in digital ecosystems.

STARTUP ECOSYSTEM AND INNOVATION SUPPORT

France's digital health ecosystem is characterized by a dynamic and thriving startup environment, supported by initiatives such as "La French Tech." These platforms encourage innovation, provide tax incentives for research and development, and foster collaboration across regional clusters. Startups are particularly pivotal in advancing the telemedicine sector, digital diagnostics, and patient management solutions. The government's innovation strategy further incentivizes research and

development (R&D), contributing to the growth of France's digital health market, which is forecasted to continue its expansion.

DIGITAL HEALTHCARE INFRASTRUCTURE AND TELEMEDICINE GROWTH

With the rise of digital health solutions, telemedicine in particular has seen exponential growth, largely fueled by public health policies that incentivize its adoption. The COVID-19 pandemic accelerated this trend, underscoring the need for remote care capabilities. Regional Health Agencies (ARS) play a vital role in implementing telemedicine solutions, which are increasingly being used in both urban and rural areas to address disparities in healthcare access. As telehealth services become more mainstream, the challenge lies in integrating these systems across fragmented digital platforms.

CHALLENGES IN HEALTHCARE ACCESS AND INTEROPERABILITY

Despite France's progress in digital health, several hurdles remain. Healthcare access remains uneven, with regional disparities particularly pronounced between urban centers and rural areas. The fragmented nature of healthcare systems across regions further exacerbates these issues. Additionally, while the Digital Health Space is a step toward a more integrated healthcare system, interoperability remains a significant challenge, as many healthcare providers still rely on incompatible systems, limiting the seamless exchange of health data.

EVOLVING ROLE OF DIGITAL HEALTH IN PREVENTIVE CARE

France is increasingly focusing on the role of digital health in preventive care. Solutions like health monitoring apps and connected medical devices are gaining traction, promoting more proactive approaches to managing chronic diseases and encouraging healthier lifestyles. The emphasis on prevention aligns with broader global healthcare trends, but France's fragmented system presents obstacles to achieving nationwide adoption of preventive health strategies through digital tools.

MARKET POTENTIAL AND ECONOMIC CONTRIBUTIONS

France's healthcare system, which dedicates 12.1% of its GDP to healthcare spending, represents a significant market for digital health innovations. With the country's medical device market generating a turnover of €36.7 billion in 2022, there is ample opportunity for digital health solutions like Axelife's pOpmètre to capitalize on this growing sector. However, success in this market will require addressing the ongoing challenges of interoperability and regulatory compliance.

THE SOLUTION : POPMETRE

The pOpmètre is a medical device designed to assess cardiovascular health by measuring arterial stiffness, which is a key indicator of cardiovascular risk. It utilizes photoplethysmography (PPG) technology to measure pulse wave velocity (PWV), the speed at which blood pressure waves travel through the arteries. This measurement provides insight into the rigidity or flexibility of the arteries, an important factor in predicting cardiovascular problems.

KEY FEATURES AND CAPABILITIES

- **Arterial Stiffness Measurement:** The pOpmètre quantifies arterial stiffness through PWV, offering a valuable metric for assessing cardiovascular risk. Stiffer arteries correlate with higher PWV, indicating increased risk for cardiovascular events.
- **User-Friendly Operation:** The device is straightforward to use, involving the placement of sensors on the patient's finger and toe. This simple setup enables rapid and efficient measurement without requiring specialized training.
- **Non-Invasive Technology:** The pOpmètre employs PPG, a non-invasive technique that measures blood volume changes in peripheral circulation. This approach avoids the discomfort of invasive procedures, making it suitable for routine clinical use.
- **Consistency Across Users:** The device's design minimizes variability, allowing healthcare professionals, including nurses and technicians, to perform measurements with reproducible accuracy.



Figure 1 :pOpmètre packaging and software

TECHNOLOGICAL APPROACH

The pOpmètre uses photoplethysmography (PPG) sensors to measure pulse wave velocity (PWV), a well-established indicator of arterial stiffness. PPG is a non-invasive optical technique that detects changes in blood volume at the surface of the skin, using sensors placed on the fingertip and toe. By measuring the time it takes for a blood pressure wave to travel between these two points, the device calculates PWV, providing insights into the rigidity or flexibility of the arteries.

Arterial stiffness is recognized as a critical factor in predicting cardiovascular events, independent of other risk factors like blood pressure and cholesterol levels. The

measurement's clinical significance lies in its ability to detect changes in arterial health that may be caused by factors such as aging, smoking, diabetes, and high cholesterol. These conditions can affect arterial wall composition, particularly the balance of elastin and collagen, leading to increased stiffness. Integrating PWV measurement into routine cardiovascular assessments enables healthcare professionals to gain a more comprehensive understanding of a patient's cardiovascular risk, enhancing preventive care efforts.

ÉVALUEZ LE RISQUE CARDIOVASCULAIRE EN MOINS DE 2MN

VITESSE DE L'ONDE DE POULS

PRESSION ARTÉRIELLE

INDEX DE PRESSION SYSTOLIQUE

ÂGE ARTÉRIEL


NON INVASIF

**NON OPÉRATEUR
DÉPENDANT**

**FACILE À UTILISER
ET DÉLEGUER**


Figure 2 :non-invasive technology

The pOpmètre's ability to calculate an "arterial age" from PWV values aims to provide a more intuitive way for patients to understand their cardiovascular health. This feature translates the stiffness measurement into an equivalent "age" for the arteries, offering a relatable metric that can motivate lifestyle changes when the arterial age exceeds the patient's chronological age. The revision integrates more context about the significance of PWV and factors influencing arterial stiffness, as well as a detailed explanation of PPG technology, enriching the technological discussion.

CLINICAL IMPORTANCE

Arterial stiffness is a well-established predictor of cardiovascular events, independent of traditional risk factors such as blood pressure. It provides additional information that can be crucial for early detection and prevention. Factors like aging, smoking, diabetes, and cholesterol can all contribute to increased arterial stiffness by affecting the composition of arterial walls. The pOpmètre offers a non-invasive and reliable way to incorporate this parameter into cardiovascular risk assessments.



Figure 3 :technological approach

MEASUREMENT PROCESS

The procedure involves placing sensors on the patient's finger and toe, while the patient is lying down in a calm environment. The PPG sensors then measure the pulse wave's velocity to assess arterial health. The entire process is quick and operator-independent, making it accessible for various healthcare settings.

THE COMPANY : AXELIFE

Founded in 2010 by a general practitioner and an engineer in Brittany, France, Axelife emerged from a shared passion for biotechnology and a desire to transform cardiovascular prevention. The founders were particularly interested in exploring new biomarkers, focusing on pulse wave analysis to assess arterial health through the propagation of the pulse wave in arteries. This innovation aimed to provide healthcare professionals with a novel diagnostic tool that complements traditional cardiovascular risk assessments, such as blood pressure and cholesterol testing.

The company's initial focus was on developing the pOpmètre, a device designed to measure pulse wave velocity (PWV), an indicator of arterial stiffness, which has gained recognition as an independent predictive factor for cardiovascular events. Over time, renowned professors in cardiovascular medicine, such as Professor Pierre Boutouyrie and Professor Roland Asmar, joined Axelife's scientific advisory board, contributing their expertise to refine the device and support its development.

Axelife has since expanded its market presence, with the pOpmètre achieving CE marking as a Class IIa medical device in 2018 and gaining traction in regions including France, Italy, the Netherlands, North Africa, and the Middle East.

integrates more details about the company's founding, its focus on innovative diagnostics, and the involvement of key scientific figures.

STRATEGIC EVOLUTION

Axelifé began with a focus on research and development, aiming to bring a new dimension to cardiovascular diagnostics. The company explored pulse wave analysis, an area that had yet to be widely adopted for routine clinical use. By concentrating on PWV measurement, Axelifé has positioned itself as a specialist in arterial stiffness evaluation, an area gaining recognition for its predictive value in cardiovascular health.

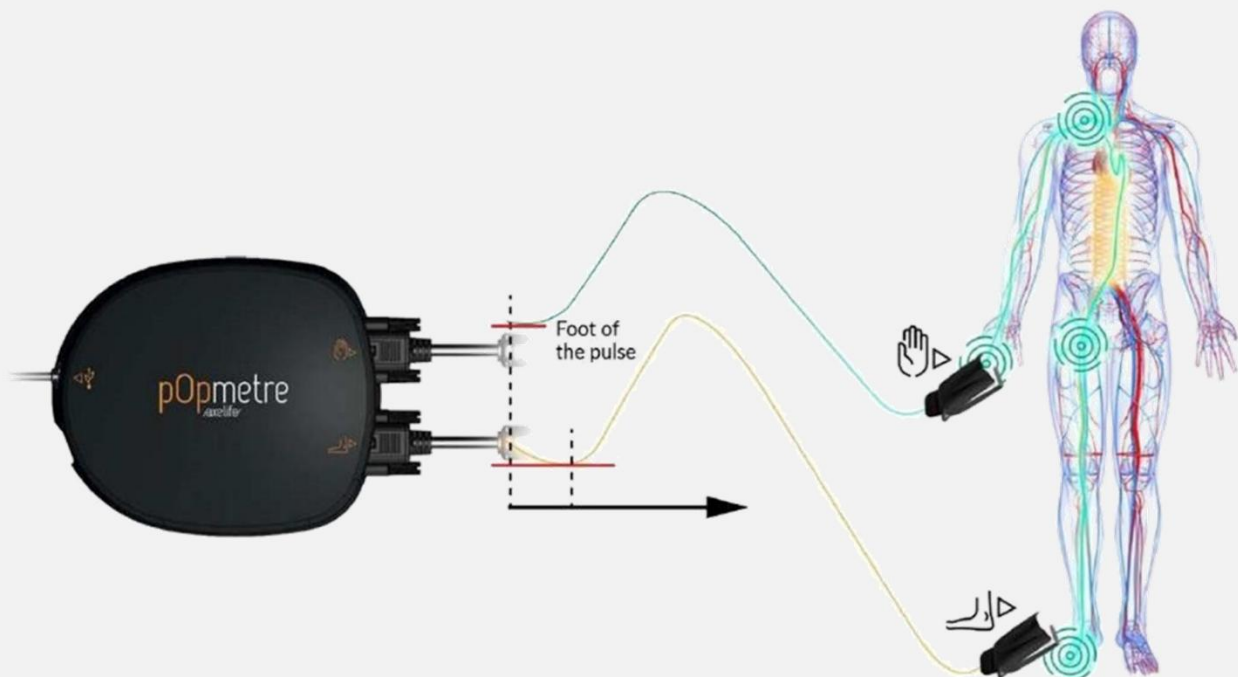


Figure 4 :measurement process

Over the years, Axelifé expanded its market reach, gaining CE marking for the pOpmetre as a Class IIa medical device in 2018. This certification confirmed the device's compliance with European Union standards for medical devices, allowing the company to enter multiple markets, including France, Italy, the Netherlands, and several Middle Eastern and North African countries.

CHALLENGES AND RECENT DEVELOPMENTS

Despite its achievements, Axelifé faces ongoing challenges. The company has undergone restructuring, including the departure of its founding physician and changes in leadership. There is an acknowledged need to strengthen the management team, particularly in roles like medical direction and sales management, to enhance growth and operational efficiency.

The company continues to focus on scientific validation and market expansion. While the pOpmetre has been presented at various conferences, Axelifé aims to

conduct more comprehensive clinical studies to establish the device's effectiveness and strengthen its acceptance in the medical community. Additionally, the company has plans to enter the U.S. market, recognizing it as a key area for growth in cardiovascular health.

MARKET PRESENCE AND BUSINESS STRATEGY

Axelif's business model involves selling the pOpmètre through a network of distributors in various countries. This approach has facilitated international deployment, but it also limits the company's direct control over customer acquisition and retention. The device is currently marketed in regions such as Europe, North Africa, and the Middle East, with ongoing efforts to expand further.

To sustain growth and improve profitability, Axelif is exploring options like licensing agreements for accessory replacements and device maintenance. This strategy aims to create recurring revenue streams and offset costs associated with manufacturing and distribution.

INTELLECTUAL PROPERTY AND INNOVATION FOCUS

Axelif owns the intellectual property for the pOpmètre, enabling the company to maintain control over its development and future enhancements. The focus on arterial stiffness measurement aligns with a growing recognition in the medical field of the importance of early detection of cardiovascular risks beyond traditional metrics like blood pressure.

FUTURE OUTLOOK

Axelif is committed to advancing cardiovascular diagnostics and expanding the pOpmètre's reach across multiple markets. In North Africa, the company aims to prioritize cardiologists for early adoption, recognizing that general practitioners (GPs) may follow in a second phase. This strategy accounts for the professional dynamics in the region, where cardiovascular prevention is predominantly managed by cardiologists. The French market, on the other hand, is moving towards more comprehensive health check-ups as part of financed preventive care, with three age-based check-ups being reimbursed. Such trends could present opportunities for integrating the pOpmètre in broader preventive health initiatives.

Additionally, Axelif is preparing for a significant expansion into the U.S. market, where it plans to conduct a longitudinal follow-up study in collaboration with a major hospital. This study will evaluate whether lifestyle changes can improve biomarkers, such as pulse wave velocity (PWV), in patients who adopt healthier habits. The study aims to provide further validation for the device's utility in preventive care.

Future plans also include strengthening scientific validation through more extensive clinical research, addressing existing gaps in peer-reviewed evidence, and incorporating measures like Patient-Reported Outcome Measures (PROMs). This approach will help establish the pOpmètre as a reliable tool in cardiovascular risk management. Meanwhile, Axelif continues to participate in key industry conferences, such as those hosted by the European Society of Hypertension and the European Society of Cardiology, to showcase the device and stay at the forefront of cardiovascular health innovationn integrates details about geographic

market strategies, future studies, and validation efforts, enhancing the "Future Outlook" section.

FACTSHEET

General information

Company Name	Axelifé
CEO	Alexandre Plé
Headquarters	Rue d'Oradour-sur-Glane 2-10 75015 Paris FRANCE
Contact	(+33) 1 89 71 54 68
Creation Date	2010
Number of Employees	10
Number of Locations	1
Turnover (2023)	€210,000
Number of Customers	164
Number of Users	500+

Key dates

2010	Launch of R&D for the pOpmètre
2014	First CE marking
2018	CE marking as a Class IIa medical device
2019	First major investment round
2020	Constitution of international Sales Team
2020	First major distribution contract
2022	new CEO Balkans distribution contract Top 10 Cardiovascular Equipment award IoT Award
2023	team restructuring, Middle East expansion MDR approval BFM Health Grand Prix BPI Prévention Santé award Health Innovation American Hospital Award Prix du Patient Numérique
2024	Participation in major conferences North Africa distribution contract

A FEW WORDS ABOUT THE KEY PEOPLE

Axelifé's leadership and scientific advisory board bring together a diverse range of expertise in cardiovascular health, business management, and medical technology, driving the company's strategic direction and innovation.

Alexandre Plé, CEO

Alexandre has been leading Axelifé since 2022. With a background in health management from HEC Paris, he is also the founder of Umanlife, a startup focused on health and well-being solutions. His experience in digital health and business development guides Axelifé's efforts to expand the pOpmètre's market reach and strengthen its business model.

Professor Roland Asmar, Scientific Director

A renowned cardiologist and president of the Foundation-Medical Research Institute, Professor Asmar plays a crucial role in guiding the clinical strategy for the pOpètre. His expertise in cardiovascular medicine, including vascular and hypertension research, provides valuable insights into the device's development and its applications in preventive healthcare.

Stéphane Amine, Chairman of the Board

Stéphane Amine is the Chairman of the Board at Axelife. He holds a Master's degree from the Reims Management School and has been with Advenis since 1998. Stéphane brings extensive leadership experience to Axelife, currently serving as the Chairman and Executive Officer at Advenis, as well as the President and Chief Executive Officer at Inoval. His roles in these organizations demonstrate his expertise in executive management and strategic oversight, which he leverages to guide Axelife's growth and governance.

Ralph Clement, Sales Manager

Ralph Clement is the Sales Manager at Axelife. He holds a bachelor's degree in business development from Léonard de Vinci and has a certification in software and multimedia applications. Ralph's background in business development and his technical skills enable him to drive sales strategies effectively, focusing on expanding the market reach of the pOpètre and building strong relationships with healthcare professionals and distributors.

Serena Zanelli, Chief Scientific Officer

With a Ph.D. in signal processing and machine learning from the University of Sorbonne Paris Nord, Serena leads Axelife's research initiatives. Her expertise helps in refining the pOpètre's technology and exploring new applications for arterial stiffness measurement.

DISRUPTION SCORE

The pOpètre received an overall disruption score of 69%, earning the WeLink.Care Label. This score captures the device's impact across four dimensions: business model, solution maturity, change of practices, and user experience, with varied levels of achievement reflecting the pOpètre's strengths and areas for improvement.



BUSINESS MODEL

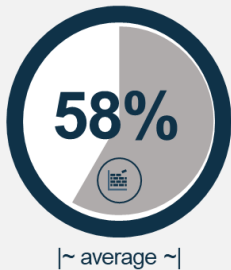
The business model scored 58%, indicating an average level of achievement. Axelife's use of a distributor-based strategy facilitates international market reach but limits direct control over customer engagement and retention. Although external investments support financial stability, the company faces profitability challenges due to high operational costs. Introducing recurring revenue streams, such as maintenance services or licensing for accessories, could help enhance financial sustainability.



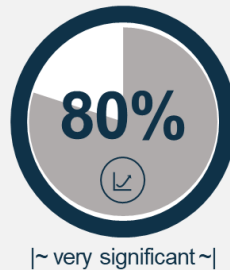
SOLUTION MATURITY

The solution maturity also scored 58%, reflecting moderate progress. The pOpmètre is developed and CE-marked for safety, with deployments in several countries. However, the device lacks extensive scientific validation through peer-reviewed studies. To elevate its maturity, Axelife plans to pursue more rigorous clinical research and seek FDA approval, which could bolster the device's credibility and expand its adoption.

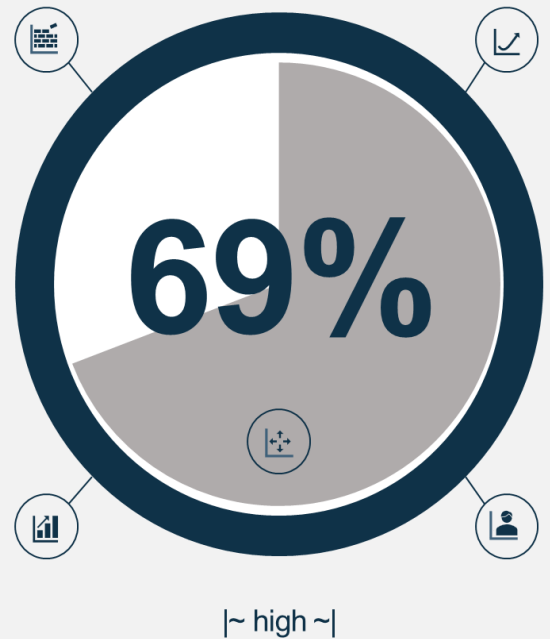
BUSINESS PERFORMANCE



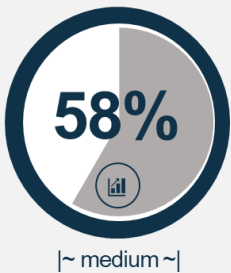
CHANGE OF PRACTICES



DISRUPTION POTENTIAL



SOLUTION MATURITY



USER EXPERIENCE

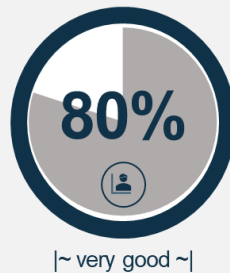


Figure 5 : WeLink.Care Disruption Scorecard



CHANGE OF PRACTICES

The pOpmètre achieved a score of 80% in change of practices, demonstrating significant potential to transform cardiovascular diagnostics. By integrating arterial stiffness measurement into routine risk assessments, the device offers a quick and non-invasive diagnostic approach. Further integration with electronic health records (EHR) and real-world evidence of its impact on clinical outcomes would strengthen its role in changing healthcare practices.



USER EXPERIENCE

User experience received a score of 80%, highlighting the device's strengths in usability and accessibility. The pOpmètre's design allows for operator-independent measurements, making it suitable for various healthcare professionals. Enhancing digital integration and incorporating continuous user feedback could further optimize the user experience and support wider adoption.

BUSINESS MODEL

Axelife's business model for the pOpmètre centers on the sale of the device through a network of distributors across multiple countries. This approach allows the company to reach international markets, including France, Italy, the Netherlands, North Africa, and the Middle East. The pOpmètre is sold to distributors at a wholesale price of approximately €3,000 to €3,500, with a recommended retail price of €6,500. This distribution-based strategy supports scalability but limits Axelife's direct control over customer acquisition costs and retention.

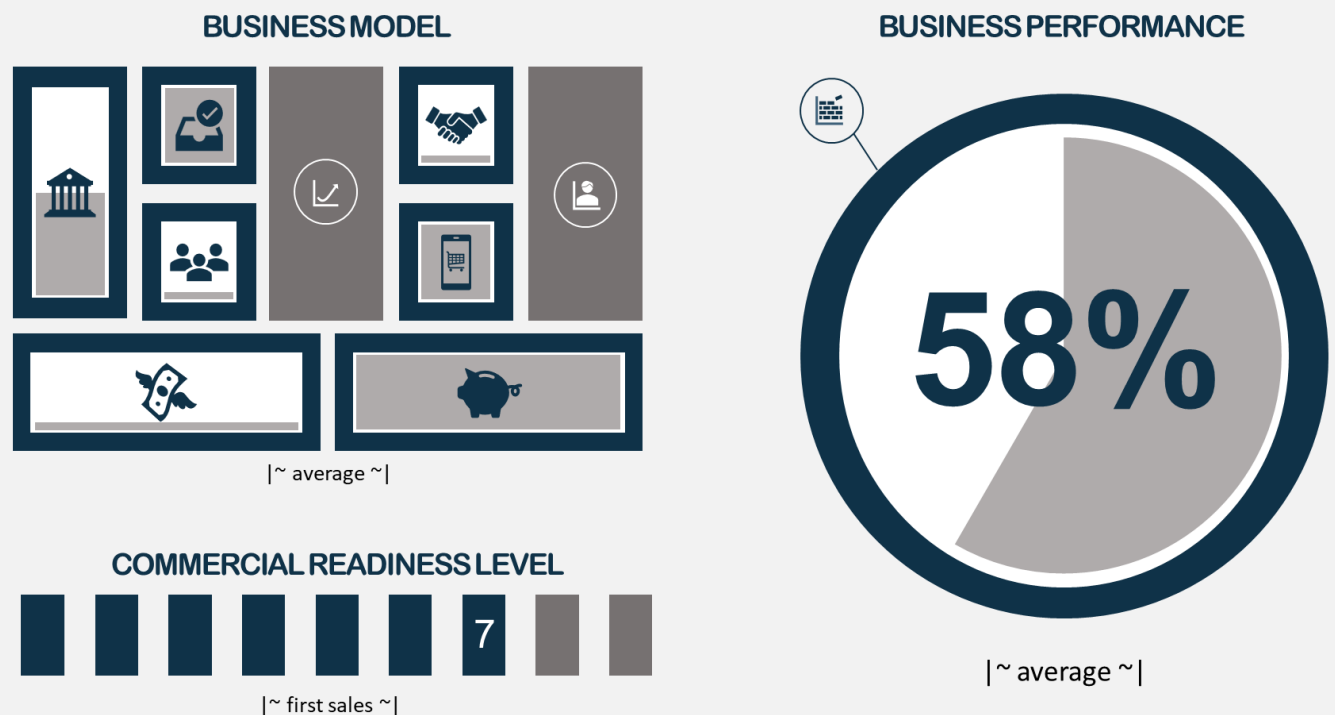


Figure 6 : Business Model Score



KEY RESOURCES

Axelife's key resources include its proprietary technology for measuring arterial stiffness, a skilled team of experts in cardiovascular health, and established intellectual property rights for the pOpmètre. The company's in-house expertise in pulse wave analysis and photoplethysmography technology is central to the ongoing development and refinement of the device. Additionally, the scientific advisory board, which includes renowned cardiovascular specialists, contributes valuable clinical insights that guide the solution's evolution.

The company's relationships with distributors across various regions also serve as a crucial resource, enabling international market access. These partnerships support the device's deployment in multiple countries, enhancing Axelife's ability to expand its market reach and maintain competitive positioning in the field of cardiovascular diagnostics.



COST STRUCTURE

Axelife's cost structure encompasses manufacturing, personnel, distribution partnerships, and participation in industry events to promote the pOpètre. As a company producing its devices in France, Axelife faces higher production costs, which are reflected in the wholesale and retail pricing of the pOpètre. Additional costs arise from finding and maintaining relationships with distributors across multiple regions and covering expenses related to marketing and attending international medical conferences.

Despite efforts to control expenses, current revenues do not yet cover costs, resulting in a financial imbalance that the company is actively working to address through restructuring and strategic planning.



FINANCING

To support its growth and operational needs, Axelife has relied on external funding. The company's financial stability has been bolstered by investments from ICORP Med, a family office investment firm, which provided capital injections in 2019 (€1.5 million), 2022 (€1.5 million), and 2023 (€2.4 million). These funds have enabled Axelife to sustain its research and development activities, expand into new markets, and navigate organizational restructuring.

The ongoing financial support has helped Axelife manage cash flow challenges, but achieving long-term financial stability will require increasing revenue streams and reaching profitability through improved sales and cost management strategies.



REVENUE

Axelife's primary revenue stream comes from the direct sale of its flagship product, the pOpètre, a cardiovascular diagnostic tool that measures arterial stiffness. The device is distributed internationally, with key markets in France, Italy, the Netherlands, North Africa, and the Middle East. The wholesale price of the pOpètre is approximately €3000 to €3500, with a recommended retail price of around €6500. However, the high production costs associated with manufacturing in France impact profitability, a challenge the company is actively addressing through strategic financial restructuring.

To enhance its financial model, Axelife is exploring ways to establish recurring revenue streams. This includes offering maintenance services and selling replacement accessories, such as sensor clamps, which could help stabilize cash flow and contribute to long-term profitability. Additionally, Axelife is considering licensing agreements for these accessories to further diversify its revenue base.

Another potential revenue source for Axelife is the expansion into markets where medical procedures involving the pOpètre are reimbursed by national health systems. In France, for instance, the device is linked to a reimbursable medical procedure, offering significant growth opportunities if similar reimbursement structures can be secured in other countries.

Axelife's revenue strategy is also shaped by its ongoing international expansion. The company is actively exploring new markets, particularly the U.S., where cardiovascular diagnostics is a rapidly growing sector. Success in the U.S. market

will require regulatory approvals, and Axelife is preparing for these challenges as part of its broader commercial strategy.



INTELLECTUAL PROPERTY

Axelife's intellectual property portfolio is central to its competitive edge in the cardiovascular diagnostics market. The company fully owns the intellectual property (IP) rights for its flagship product, the pOpmètre, ensuring complete control over the device's development, enhancements, and commercialization. This proprietary ownership enables Axelife to safeguard its unique innovations, particularly in the area of arterial stiffness measurement, which is becoming an increasingly recognized marker for early cardiovascular risk detection.

The IP protections surrounding the pOpmètre include patents that cover the underlying technology for non-invasive arterial stiffness measurement. The device uses pulse wave analysis, specifically focusing on photoplethysmography (PPG) sensors, to measure pulse wave velocity (PWV) — a key indicator of arterial health. Axelife's ownership of these patents not only shields the technology from competitors but also provides a strong foundation for future innovations in cardiovascular health diagnostics. The company's strategy includes leveraging its IP to explore new markets and adapt the product to various healthcare systems. The company is actively pursuing regulatory approvals in key international markets, including the United States, which is seen as a major growth opportunity. As part of this strategy, Axelife plans to conduct additional clinical studies to further validate the pOpmètre's utility and expand its application in preventive healthcare.



CUSTOMER RELATIONS

Axelife manages customer relationships primarily through its network of distributors, which serve as the main point of contact for clients across different regions. This indirect model allows Axelife to extend its market reach internationally, notably in France, Italy, North Africa, and the Middle East, by leveraging distributors' local expertise. However, this model also limits direct interaction with end users, making it challenging to gather detailed customer feedback and measure satisfaction levels effectively.

To address these limitations, Axelife is considering several strategies to strengthen its customer relations:

Closer Collaboration with Distributors

Axelife recognizes the need to improve collaboration with its distributors to gather better insights into customer experiences. Establishing structured feedback loops and incentivizing distributors to provide detailed reports on customer satisfaction could help Axelife better understand market needs and identify areas for improvement in the product.

Enhanced Support and Training

Axelife is exploring ways to enhance its support services by offering comprehensive training sessions and resources for healthcare professionals. These sessions aim to improve the understanding and utilization of the pOpmètre, while also fostering

stronger relationships with users. Offering tailored training could increase loyalty among healthcare professionals and ensure the device is used to its full potential.

Introducing a Customer Success Program

To further solidify its relationships with distributors and healthcare providers, Axelife plans to introduce a customer success program. This initiative would focus on offering personalized support to distributors, ensuring they have access to marketing materials, technical assistance, and clinical validation updates. By providing ongoing support, Axelife can help its distributors better position the pOpmètre in their respective markets.

Direct Engagement with End Users

While the distributor model offers market reach, Axelife is also exploring ways to engage more directly with end users, particularly healthcare professionals and clinics. Axelife is considering leveraging digital tools, such as customer portals or feedback forms, to gather direct input from users and assess how well the pOpmètre is meeting their needs in real-world applications.

Axelife's current customer relations strategy benefits from its established distributor network but can be strengthened by direct engagement with healthcare professionals, enhanced training, and structured feedback mechanisms. These improvements will support better market positioning, customer retention, and product refinement.



COMMERCIAL READINESS LEVEL (CRL)

The pOpmètre is positioned at a CRL of approximately 7, indicating that it has reached early market adoption with consistent sales and a growing presence across multiple regions. The device has gained traction in several international markets, including France, Italy, and the Middle East, demonstrating its commercial viability. However, widespread commercial success and full market competitiveness have not yet been achieved, as the company continues to work towards expanding its customer base and addressing financial stability.

Further advancements in the commercial strategy, such as deepening market penetration, optimizing distribution channels, and increasing reimbursement coverage in more countries, would help Axelife progress to higher CRL stages, ultimately reaching full commercial maturity.



ADDITIONAL INSIGHT ON THE BUSINESS MODEL

Axelife's current business model relies heavily on a distributor-based approach, which facilitates international expansion but limits direct control over customer acquisition and retention metrics. This indirect sales strategy, while enabling market access in multiple countries—including France, Italy, the Netherlands, Tunisia, Saudi Arabia, and the UAE—means the company lacks direct insights into customer behavior and loyalty. Improved collaboration with distributors to gather data on customer experiences could provide valuable insights for refining sales strategies and optimizing market engagement.

The company faces challenges related to financial performance, as expenditures still exceed revenues, leading to ongoing financial restructuring. Axelife's funding from ICORP Med, a family office investment firm, has provided critical capital injections in 2019 (€1.5 million), 2022 (€1.5 million), and 2023 (€2.4 million), supporting the company through market expansion and R&D efforts. To achieve profitability, Axelife is considering adding recurring revenue streams, such as licensing for accessory replacements or maintenance services, which could stabilize cash flow and help cover operational costs.

The company also holds full ownership of the pOpmètre's intellectual property, safeguarding its competitive edge and paving the way for future technological advancements. Axelife is actively exploring the U.S. market, a significant opportunity given the high demand for cardiovascular diagnostics, but regulatory compliance and adapting the business model to local market conditions will be essential.

Expanding reimbursement options, beyond France where the procedure is linked to a reimbursable medical act, would make the pOpmètre more accessible and boost adoption in other countries. Additionally, the company could benefit from completing its management team by adding positions like a medical director and a dedicated sales and marketing manager to enhance strategic oversight and execution. New details about geographic markets, financial challenges, and team needs while retaining the existing insights on optimizing the business model.

SOLUTION MATURITY

The maturity of the pOpmètre solution reflects its development progress, regulatory compliance, and real-world applicability in cardiovascular health diagnostics. While the device has achieved significant milestones, there remain areas where further advancements and scientific validation could enhance its impact and acceptance in clinical practice.



SCIENTIFIC VALIDATION

Axelife has focused its scientific validation efforts primarily on demonstrating the accuracy and clinical relevance of its pOpmètre device, which measures arterial stiffness through pulse wave velocity (PWV). The device's utility as a cardiovascular risk assessment tool is supported by its non-invasive design, making it suitable for various healthcare settings, from general practitioners to cardiovascular specialists.

Regulatory Approvals and Certifications

The pOpmètre obtained CE marking as a Class IIa medical device in 2018, confirming its compliance with European Union standards. This certification has enabled Axelife to market the device across several countries, including France, Italy, the Netherlands, and parts of North Africa and the Middle East. However, further validation is required to solidify its position in broader medical communities, particularly in the U.S., where Axelife aims to enter the market following FDA approval.

Planned Clinical Studies

To enhance its scientific credibility, Axelife is undertaking efforts to conduct more rigorous clinical studies. One such study is a planned longitudinal follow-up in collaboration with a major French hospital, which aims to evaluate the impact of lifestyle changes on PWV measurements. This study is designed to validate the device's utility in preventive healthcare and further demonstrate its effectiveness in real-world applications.

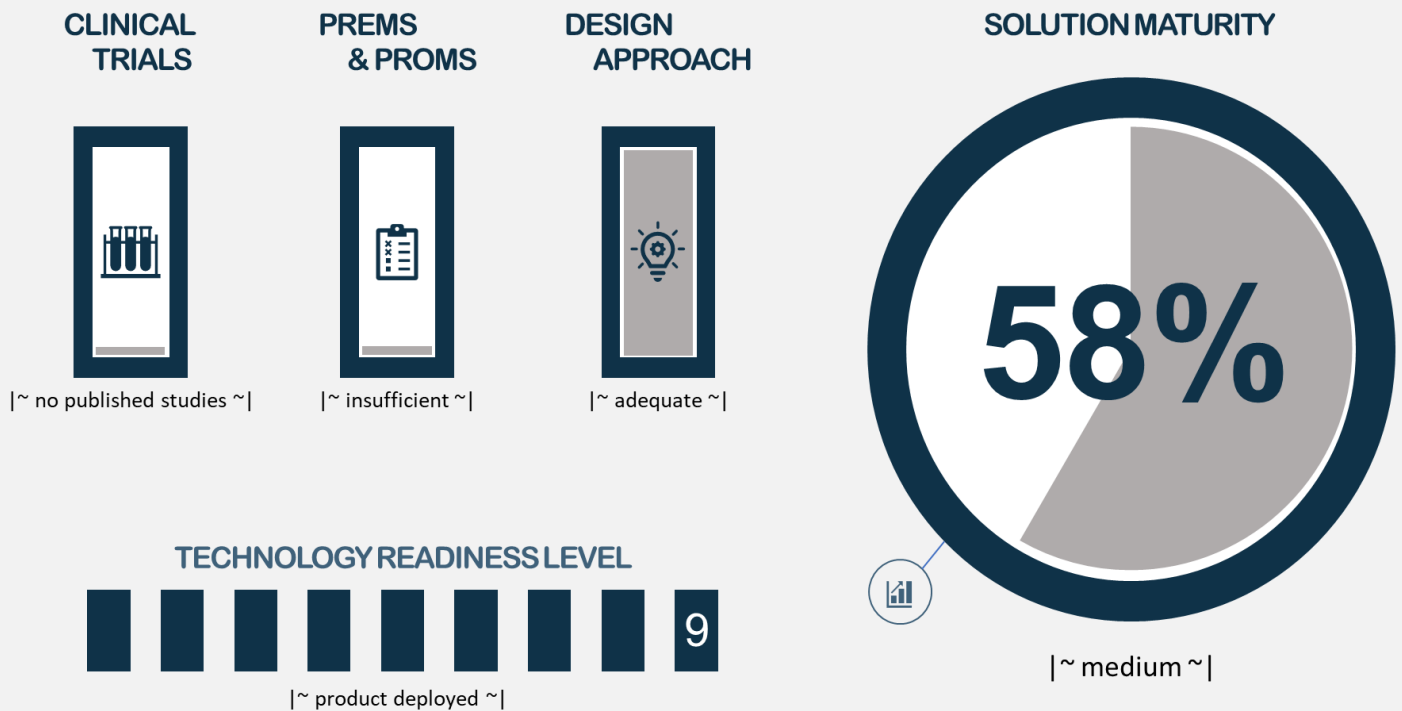


Figure 7 : Solution Maturity Score

Current Gaps in Peer-Reviewed Research

Despite the promising initial feedback, the pOpmètre still lacks comprehensive peer-reviewed publications. Most of its validation data has been presented at conferences rather than through formal scientific studies. Axelife acknowledges this gap and is actively working to fill it by undertaking systematic real-world studies that assess the device's effectiveness in clinical workflows and patient outcomes. The inclusion of PROMs and PREMs in future studies would further strengthen the device's real-world utility by capturing both clinical results and patient experiences.



REAL-LIFE STUDIES

The pOpmètre has been deployed across multiple regions, including France, Italy, the Netherlands, North Africa, and the Middle East. Its use in real-life settings highlights its accessibility and practicality, with a user-friendly design that supports quick and consistent measurements. The device's ability to deliver non-invasive and operator-independent results makes it suitable for diverse healthcare environments, from general practitioners to specialized cardiovascular clinics.

Despite these strengths, there is a need for more real-world studies to systematically assess the device's impact on patient care, clinical workflows, and health outcomes. While early feedback from healthcare providers has been positive, documenting the device's real-life effectiveness through structured studies could further validate its clinical utility.



SOLUTION DESIGN

The pOpmètre's design approach centers around a user-focused development process, emphasizing practical usability and simplicity. The device was created with input from healthcare professionals to ensure it fits seamlessly into clinical workflows and addresses everyday challenges in cardiovascular risk assessment. The goal was to make the measurement process straightforward and accessible, reducing the need for specialized training or complex preparations.

The development approach prioritized iterative improvements based on real-world feedback from medical practitioners. This user-centric method aimed to refine the device's functionality and reliability across various healthcare settings, ensuring that the solution aligns with clinical needs while maintaining operational ease.



TECHNOLOGY READINESS LEVEL (TRL)

The pOpmètre exhibits a solid level of technological readiness, with a reliable and tested design that integrates photoplethysmography (PPG) sensors for pulse wave measurement. The device has reached a Technology Readiness Level (TRL) of approximately 7, indicating that it has been demonstrated in operational environments and is ready for deployment in real-world clinical settings. Further advancements in technology and software could help increase the TRL to the final stages, where large-scale production and widespread clinical use are fully supported.



ADDITIONAL INSIGHT ON THE SOLUTION MATURITY

While the pOpmètre shows promise in advancing cardiovascular diagnostics, certain factors influence its overall maturity beyond what has already been discussed. One key aspect is the device's presentation at conferences and events rather than through peer-reviewed publications. Although the device has gained attention, relying primarily on conference presentations limits its scientific recognition. More extensive clinical studies could establish stronger evidence to support the device's medical value.

Additionally, the solution's maturity is affected by the lack of formal Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs). Incorporating these measures would provide a more comprehensive understanding of the device's real-world impact on patient care and clinical outcomes.

Another maturity factor lies in the limited availability of data on the device's influence on changing healthcare practices. While initial feedback suggests positive reception among users, the broader effect on clinical workflows and patient outcomes remains underexplored. Documenting these impacts through structured real-world studies could significantly enhance the device's credibility and maturity in the field.

To strengthen the pOpmètre's solution design, Axelife could consider:

- **Enhanced Digital Connectivity:** Developing features for integration with EHR systems to enable seamless data sharing and support clinical decision-making.
- **User-Informed Design Iterations:** Expanding user testing to include a broader range of healthcare professionals and patients, ensuring that the device's design continues to meet the needs of its diverse user base.
- **Advanced Data Interpretation Tools:** Incorporating software that provides more sophisticated data analytics, such as trend analysis over time, which could further assist in assessing cardiovascular health.

CHANGE OF PRACTICES

One of the pOpmètre's most significant strengths lies in its ability to drive behavioural change among patients—a critical factor for success in preventive healthcare. At the heart of this capability is the device's unique feature: translating complex measurements of arterial stiffness into an intuitive and relatable concept—the "age of your arteries."

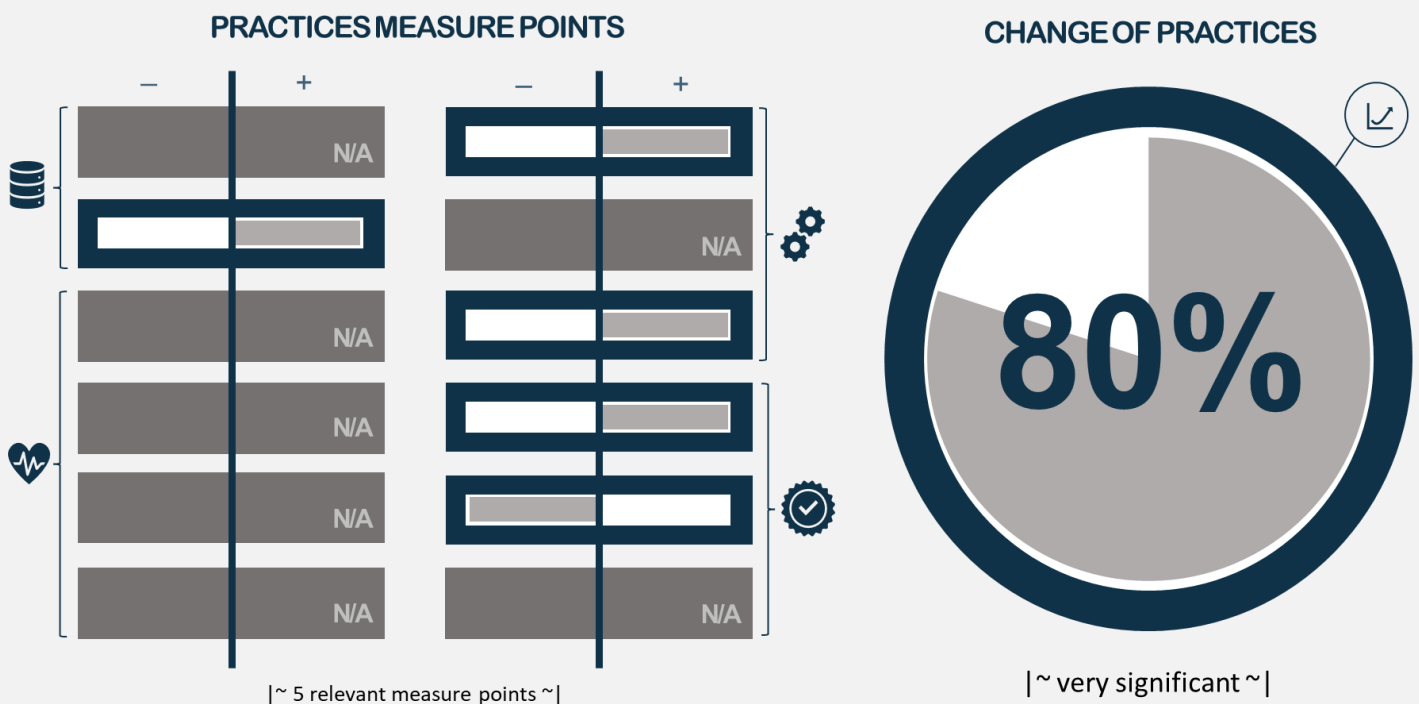


Figure 8: Change of Practices Score

When patients are told that their arteries are "10 years older" than their actual age, this immediately triggers an awakening, often leading to lifestyle changes aimed at improving cardiovascular health. This powerful communication tool transforms what would otherwise be technical and medical jargon into actionable information. By making cardiovascular risk more tangible and personal, the pOpmètre facilitates a deeper understanding of the importance of preventive measures such as diet, exercise, and smoking cessation.

This capacity to convert biological data into meaningful, relatable insights not only enhances patient engagement but also motivates them to take proactive steps in their health management. As a result, the pOpmètre serves as a valuable tool in promoting long-term behavioural changes essential for reducing cardiovascular risks..



DATA MANAGEMENT

The pOpmètre introduces a new aspect to data management by enabling the measurement of arterial stiffness, a biomarker not typically included in standard cardiovascular assessments. This addition provides healthcare professionals with access to more comprehensive data on cardiovascular health, complementing traditional measures like blood pressure and cholesterol. However, the integration of these data into electronic health records (EHR) or other digital health platforms is limited. Enhancing interoperability and data exchange capabilities would further improve data accessibility and support better clinical decision-making.



CARE PRACTICES

The pOpmètre plays a pivotal role in enhancing care practices by offering an easy-to-use, non-invasive tool for cardiovascular risk assessment. Its ability to measure pulse wave velocity (PWV), a key indicator of arterial stiffness, allows healthcare providers to integrate this vital diagnostic information into routine check-ups. What sets the pOpmètre apart is not only its technical precision but also the way it translates complex medical data into actionable insights for patients. By communicating arterial health in terms of the "age of your arteries," the device transforms an abstract concept into something highly relatable, motivating patients to take concrete preventive actions.



AUTOMATION

Automation is limited in the pOpmètre's current design, with manual actions still required to integrate data into clinical records and share findings. While the device itself reduces the need for specialized operator skills, further automation of data processing and transfer could enhance efficiency. Features such as automatic updates to EHRs and integration with remote monitoring systems could streamline workflows and reduce administrative tasks.



COMPLIANCE

The pOpmètre adheres to strict regulatory standards, ensuring both safety and data protection, which are critical in medical diagnostics. The device holds CE marking as a Class IIa medical device, which confirms that it meets the stringent safety, performance, and reliability criteria set by the European Union for medical devices. This certification is vital for its distribution across key markets like France, Italy, and the Middle East, providing healthcare providers and patients with confidence in its use. GDPR and Data Protection Axelifé ensures that the pOpmètre complies with General Data Protection Regulation (GDPR) standards. Given the sensitive nature of health data, robust encryption methods are employed to safeguard patient information during both collection and transmission. The company has implemented processes to ensure that only authorized individuals can access or manage the data collected by the device. These measures are crucial, particularly

when the pOpmètre is integrated into broader healthcare systems and data-sharing networks .

To expand into additional markets, particularly the United States, Axelife is pursuing FDA approval. Achieving this milestone would enable the company to reach one of the largest and most competitive markets in the healthcare industry, further bolstering the pOpmètre's global credibility and compliance. The device's current CE marking provides a strong foundation, but meeting U.S. regulatory requirements will involve additional studies and modifications to align with American standards .

In addition to its CE marking, the pOpmètre adheres to ISO 9001 and ISO 27001 standards, which cover quality management and information security, respectively. These certifications further reinforce the device's reliability, ensuring that it meets internationally recognized benchmarks for quality and data protection. These standards are essential for maintaining trust among healthcare providers, patients, and regulators, especially as the device expands into more markets .



ADDITIONAL INSIGHT ON THE CHANGE OF PRACTICES

The pOpmètre stands out for its ability to transform cardiovascular health assessments into actionable insights, particularly through its unique feature of calculating arterial age. This innovation has a significant impact on patient behaviour, as the concept of "arterial age" is easy for patients to understand and respond to. When confronted with the information that their arteries are significantly "older" than their chronological age, patients are often motivated to make immediate lifestyle changes, such as improving their diet, increasing physical activity, or quitting smoking. This capacity to trigger behaviour change makes the pOpmètre a highly effective tool in preventive healthcare.

Another important strength of the pOpmètre is its ease of use. Unlike more complex diagnostic tools that require specialized operation by a physician, the pOpmètre can be easily operated by assistants or nurses with minimal training. This allows healthcare providers to integrate the device into routine check-ups without disrupting workflows. Its simplicity and non-invasive nature ensure that healthcare teams can use it frequently, offering a more accessible option for cardiovascular risk screening across various healthcare settings.

By enabling non-physician staff to handle the operation of the device, the pOpmètre frees up valuable time for doctors to focus on patient consultation and care planning. This operational efficiency enhances overall clinical workflows, allowing more patients to be screened in less time, while maintaining high standards of accuracy and consistency. The device's reproducibility across different operators ensures that results remain reliable, further supporting its integration into routine care practices.

In summary, the pOpmètre's ability to transform medical data into actionable health insights and its operational simplicity make it a powerful tool in both engaging patients and improving clinical efficiency. These features position it as a key asset in preventive healthcare, helping to identify and mitigate cardiovascular risks early on, while promoting long-term lifestyle changes.

USER EXPERIENCE : THE PROFESSIONAL PERSPECTIVE

The pOpmètre is designed with healthcare professionals in mind, offering a user-friendly and efficient solution for assessing cardiovascular risk. Its ease of use and quick setup allow various healthcare providers, including nurses and technicians, to perform measurements without needing specialized training. The device's integration into clinical workflows aims to improve care delivery and make advanced cardiovascular diagnostics more accessible..

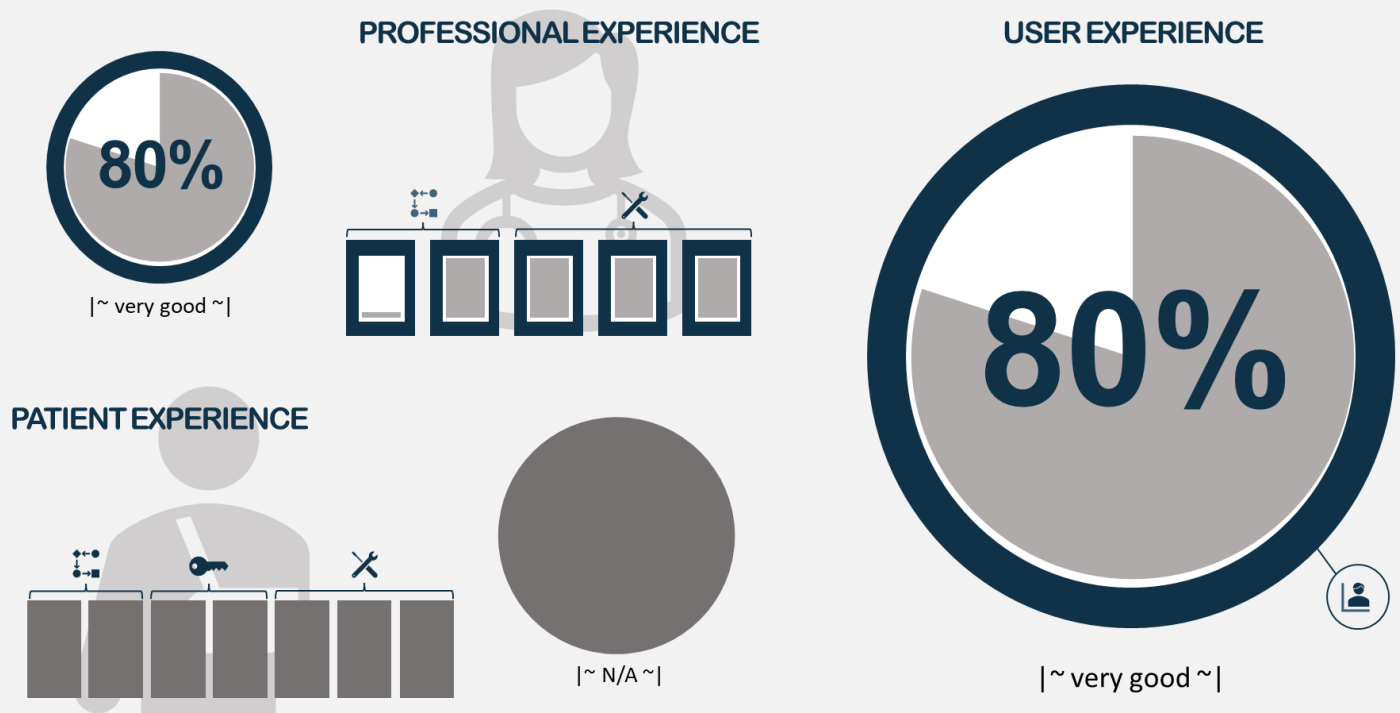


Figure 9 : User Experience Score



CARE

The pOpmètre significantly enhances the user experience for healthcare professionals, while indirectly improving the experience of patients during their visits. Its intuitive design allows for quick and easy integration into routine medical practice, enabling professionals to provide timely and actionable insights into cardiovascular health. By streamlining the diagnostic process, the pOpmètre helps doctors offer clearer, more personalized advice to patients.

Collaboration

While the pOpmètre is a valuable tool for assessing cardiovascular risk, it operates as a standalone device, which limits its ability to seamlessly integrate with other digital health systems or electronic health records (EHRs). This lack of interoperability means that data collected from the pOpmètre cannot be easily shared across different healthcare platforms, making it somewhat of an "island" within a healthcare provider's toolset. Professionals must manually enter results into other systems, which can disrupt workflows and reduce efficiency.

However, the device's ease of use still offers an advantage in terms of task delegation. Since it can be operated by trained assistants or nurses, rather than requiring a physician's direct involvement, it helps streamline clinical processes by allowing non-specialists to handle the data collection. This frees up doctors to focus on interpreting the results and engaging with patients, optimizing the use of resources in busy healthcare environments..

Healthcare Continuum

The pOpmètre significantly enhances the healthcare continuum by integrating into three stages of patient care—prediction, prevention, and follow-up. By focusing on arterial age, it makes early cardiovascular risk detection more accessible, even in routine check-ups, without needing complex, time-consuming procedures. This early detection can be pivotal in preventive care, encouraging patients to take proactive steps such as lifestyle changes to reduce their risk of cardiovascular events.

The device's ease of use, coupled with its non-invasive nature, supports continuity of care by enabling frequent, real-time monitoring of a patient's vascular health. This capability is particularly useful for long-term management of conditions like hypertension and diabetes, where ongoing assessment of cardiovascular risk is essential. The ability to perform these assessments in various healthcare environments—from primary care to specialist clinics—ensures that patients receive consistent, informed care at every stage of their health journey.



ACCESSIBILITY

The pOpmètre is designed to be accessible across various healthcare settings, ensuring ease of use for professionals while maintaining security and adaptability. Its functionality and design make it an effective tool for cardiovascular risk assessment, though certain limitations exist regarding system integration.

User Support

The pOpmètre offers strong user support through its simple and intuitive operation. With minimal training required, healthcare professionals such as nurses and medical assistants can easily operate the device. This reduces the burden on physicians, allowing for delegation of tasks and efficient use of clinical resources. Axelife provides training materials and resources to ensure that users can quickly integrate the device into routine assessments, enhancing its overall accessibility in different care environments.

Security

Security is a critical aspect of the pOpmètre. Although the device operates independently of digital health networks, all data collected remains secure within the system. However, its lack of interoperability with electronic health records (EHRs) means that data must be manually entered, which introduces the risk of data handling errors. Axelife addresses security concerns by ensuring that the device complies with relevant medical device safety standards, but the manual data transfer step could benefit from enhanced security protocols to prevent breaches during this process.

Adaptability

The pOpmètre is highly adaptable for use in various healthcare settings, from specialist cardiology practices to general medical clinics. Its portability and ease of use allow it to be implemented across different environments with minimal disruption. However, its adaptability is somewhat limited by its lack of system integration; the data it generates does not automatically sync with existing digital health records, which restricts its full potential in more technologically integrated healthcare systems. Despite this, its core functionality as a standalone diagnostic tool remains valuable for assessing cardiovascular risk in diverse care settings.



ADDITIONAL INSIGHTS ON THE PROFESSIONAL PERSPECTIVE

The pOpmètre's design emphasizes simplicity and ease of use, allowing healthcare professionals to delegate measurements to staff with varying levels of training, such as nurses or medical assistants. This flexibility supports task-shifting within healthcare teams, potentially reducing the workload of physicians and enabling more efficient use of staff resources.

Another notable aspect is the reproducibility of the measurements, which has been reported as consistent, reducing variability between different operators. This reliability contributes to building confidence among professionals regarding the accuracy of the device's results. However, for broader adoption, more user training and educational resources on the clinical significance of arterial stiffness and "arterial age" could help practitioners better integrate the pOpmètre into their decision-making processes and patient communication.

FIELD STUDY

HEALTHCARE PROFESSIONAL CASE STUDY : PROFESSOR GALLIX

Professor Gallix, a radiologist and former head of department at both Montpellier University Hospital and McGill University, currently leads the Health Prevention Center at the American Hospital of Paris. Though the pOpmètre is not in use at the hospital yet, it was one of the three winners in a 2023 competition on innovative prevention, organized by the hospital. This victory included both funding and professional support from healthcare experts to aid in the device's deployment and market positioning.

Non-Utilization of the pOpmètre

The primary reason for the pOpmètre's non-use at the hospital is its limited deployment, as it is still in an early phase of expansion. Professor Gallix is working with Axelife to evaluate how the device might benefit patients and produce scientific evidence to substantiate its value. One of the challenges Axelife faces in France is that cardiovascular prevention is dominated by cardiologists who already have their own tools, such as echocardiography, which are both profitable and integrated into their practices. In contrast, using the pOpmètre may take time and generate little financial return, making it less attractive to cardiologists.

Upcoming Study and Prevention Focus

Axelife and the American Hospital are preparing a longitudinal study to assess whether the pOpmètre can help patients change lifestyle habits and, importantly, whether improvements in pulse wave velocity (PWV) and arterial stiffness can be observed in those who do. The study aims to determine if the device can be a reliable driver for lifestyle changes, focusing on the question: Does providing patients with arterial age information encourage them to improve their health, and can these improvements be measured?

Professor Gallix notes that while predicting health risks doesn't necessarily lead to behavioral changes, prevention efforts accompanied by patient support could foster meaningful shifts. The study, set to include six months of patient follow-up, will explore how patients react to their pOpmètre results and whether lifestyle modifications lead to improved cardiovascular markers.

Market and Strategic Positioning

Professor Gallix suggests that the pOpmètre may be better suited for use by general practitioners or non-physicians in health check-up centers, as its simplicity allows for broader use in preventive health settings. In France, prevention is slowly gaining financial backing through government-funded health check-ups at key stages of life (20-25 years, 40-45 years, and 60-65 years), which could provide an opportunity for integrating the device into routine preventive care. However, the French market remains relatively immature in this area compared to other countries, such as China, where companies finance employee health check-ups.

Looking forward, Professor Gallix emphasizes that Axelife could strengthen its market position by publishing scientific studies demonstrating the accuracy and effectiveness of its measurements compared to existing gold standards. Establishing this credibility could make the pOpmètre a valuable tool in prevention-focused healthcare.

HEALTHCARE PROFESSIONAL CASE STUDY : PROFESSOR ADDAD

Professor Addad, a cardiologist with extensive experience in interventional cardiology and former president of the Tunisian Society of Cardiology, has been using the pOpmètre in his practice in Tunis for several years. Over this period, he has utilized the device on nearly 1,500 patients, aiming to integrate pulse wave velocity (PWV) measurements into routine cardiovascular risk assessments. He sought a user-friendly and reliable tool for measuring PWV, which he considers a critical biomarker in cardiovascular prevention. The pOpmètre met these criteria, offering an alternative to other devices, like the Sycomor, which required his direct involvement and was too time-consuming.

Approach and Use of the pOpmètre

While Professor Addad values the pOpmètre's capabilities, he deliberately avoids using the "arterial age" metric. He cites two primary concerns: the lack of robust scientific validation for arterial age compared to PWV, and the potential anxiety it may cause in patients, particularly when their arterial age significantly exceeds their chronological age (e.g., a 40-year-old with an arterial age of 69). Instead, he

employs a traffic light color-coded system to communicate results: green for satisfactory results, orange indicating the need for lifestyle changes, and red signalling an urgent need for lifestyle modification. This approach leverages the universal familiarity of traffic lights and serves as an effective educational tool for patients.

Impact on Patient Behaviour

The use of the color-coded system has proven effective in motivating patients to adopt healthier lifestyle habits. Professor Addad reports that several patients have made significant changes in their lifestyle, such as improved diet and increased physical activity, following their pOpmètre results. The cost of the test is 100 Tunisian dinars (approximately €30), and patients who perceive themselves to be at cardiovascular risk are generally willing to pay for the service.

Future Plans and Market Considerations

Looking ahead, Professor Addad plans to conduct a clinical study involving more than 500 patients to demonstrate that lifestyle changes following the pOpmètre assessment can improve PWV results. His study aims to provide further scientific evidence to support the use of the device in cardiovascular prevention.

Regarding market development, Professor Addad notes that in Tunisia and other North African countries, the pOpmètre's adoption is likely to be driven by cardiologists. He cautions that if the device is marketed to general practitioners too early, cardiologists may lose interest, as they see cardiovascular prevention as their domain. Thus, he suggests that the general practitioner market should be considered only in a second phase. In addition to his clinical work, Professor Addad also provides training on the use of the pOpmètre, promoting its benefits and ensuring proper utilization in clinical settings.

USER CASE STUDY : ALAIN BOUELLAT , OCCUPATIONAL HEALTH CONSULTANT

Alain Bouellat, an experienced occupational health consultant and former social protection insurance executive, has been utilizing the pOpmètre for workplace cardiovascular screenings across various regions in France. Alain's background in managing employee well-being, absenteeism, and accident prevention has informed his interest in cardiovascular health as a critical component of workplace wellness programs. Recognizing the substantial human and financial impact of cardiovascular diseases—particularly as the leading risk factor for health-related issues in France—he identified the pOpmètre as a powerful tool to integrate cardiovascular prevention into corporate health strategies.

Deployment and Use in Professional Settings

To introduce the pOpmètre in the corporate sector, Alain has invested in multiple devices and organized training for registered nurses, who now conduct screenings in workplaces. He has created a system where nurses administer the pOpmètre tests on-site, managing up to 30 patients per day. This streamlined approach has allowed Alain to expand screenings to various cities, including Marseille, Lille, and Nantes, making cardiovascular risk assessment accessible to employees nationwide. Following each assessment, patients receive a preliminary report on

their arterial stiffness and are encouraged to consult their general practitioners for further evaluation, which also increases awareness and credibility of the device among medical professionals.

Challenges and Observations

One significant challenge Alain encounters is the general practitioners' unfamiliarity with arterial stiffness metrics and the pOpmètre itself. Many healthcare providers view the device with scepticism, considering it a novelty rather than a serious diagnostic tool. To address this, Alain has been proactive in creating detailed explanatory documents on pulse wave velocity and arterial stiffness measurement, which he shares with practitioners. These resources aim to educate healthcare professionals about the clinical relevance of arterial stiffness, fostering greater acceptance of the device.

Future Plans and Market Expansion

Alain's success with the pOpmètre in workplace health initiatives has generated demand, with additional orders expected for 2025. While his focus remains on detection rather than preventive counselling, he is gathering data on lifestyle factors, family medical history, and other health indicators to provide comprehensive risk assessments. Alain's continued advocacy for the pOpmètre includes plans to engage directly with physicians in each region where screenings are conducted, aiming to build a supportive network that integrates the device into broader health practices.

CONCLUSION

The pOpmètre represents a promising advancement in cardiovascular diagnostics, offering a non-invasive, user-friendly approach to measuring arterial stiffness. Its potential to enhance preventive care through the "arterial age" metric and support lifestyle changes aligns with the broader goals of modern healthcare. With a disruption score of 69%, the device demonstrates significant strengths in changing care practices and user experience, although areas like business model development and clinical validation still require attention.

Axelif's strategy to expand the pOpmètre's market reach, particularly in North Africa and eventually the U.S., highlights the company's commitment to growth. However, to maximize its impact, the company should prioritize integrating the device with digital health platforms, improving data automation, and conducting robust clinical studies. As France's digital health landscape continues to evolve, the pOpmètre is well-positioned to contribute to more personalized and effective cardiovascular risk management, provided it addresses existing challenges and capitalizes on emerging opportunities in the healthcare market.

This report is based on the information provided by the scored company, input from various stakeholders, and the application of the WeLink.Care® methodology by OZConsulting. The findings, scores, and evaluations presented are intended solely for informational purposes and do not constitute a guarantee or endorsement of the quality, effectiveness, or commercial viability of the evaluated digital health solution.

The conclusions are drawn from the data available at the time of the study and may not reflect subsequent changes. OZConsulting assumes no responsibility for the accuracy or completeness of the information provided by the scored company or any third parties involved. Any reliance on this report is at the reader's own risk.

The content of this report is protected under copyright law. No part of this report may be reproduced, distributed, or used for commercial purposes without prior written permission from OZC. The WeLink.Care® methodology and scoring system are proprietary to OZConsulting.
