

## Advanced Health Intelligence to Launch Medically Approved Mobile Phone-Based Atrial Fibrillation Assessment Q2 2024

### Highlights

- **AHI has signed a binding agreement with Qompium NV, providing access to the Atrial Fibrillation Software.**
- **AHI will expand Biometric Health Assessment (BHA) with a mobile service for detecting atrial fibrillation and heart rhythm abnormality.**
- **Up to 40% of atrial fibrillation (AF) patients are asymptomatic<sup>i</sup>.**
- **AHI will launch a Mobile Phone-Based AF-Scan for Atrial Fibrillation Assessment.**
- **The application has medical approval in Australia, USA, Singapore, EU, UK, UAE and Saudi Arabia for near clinical.**
- **The global prevalence of atrial fibrillation (AF) is approximately 60 million cases.<sup>ii</sup>**
- **AF increases the risk of stroke five-fold.<sup>iii</sup>**
- **AF is a prevalent arrhythmia affecting as many as 1 in 4 people over 40.<sup>iv</sup>**

Advanced Health Intelligence Ltd (ASX: AHI) (NASDAQ: AHI) (“AHI” or the “Company”) would like to inform shareholders that the Company will be expanding the current biometric assessment suite with on-mobile device Atrial Fibrillation (AF) service in quarter 2 of 2024 after signing a binding agreement with Qompium NV.

AHI is thrilled to be expanding the biometric capabilities the company is bringing to the global healthcare system with the introduction of AF-Scan. This ground-breaking mobile phone-based solution is set to revolutionise the detection and management of Atrial Fibrillation (AF). This innovative technology is poised to offer unprecedented accessibility and convenience, opening new possibilities in AF monitoring for global populations. With the increasing prevalence of AF and its substantial impact on healthcare systems and economies, AF-Scan will emerge as a critical tool for individuals, healthcare professionals, and public health initiatives.

The technology has received medical approval in multiple jurisdictions, signifying its commitment to providing safe and effective healthcare solutions. The following regulatory authorities have granted their approval:

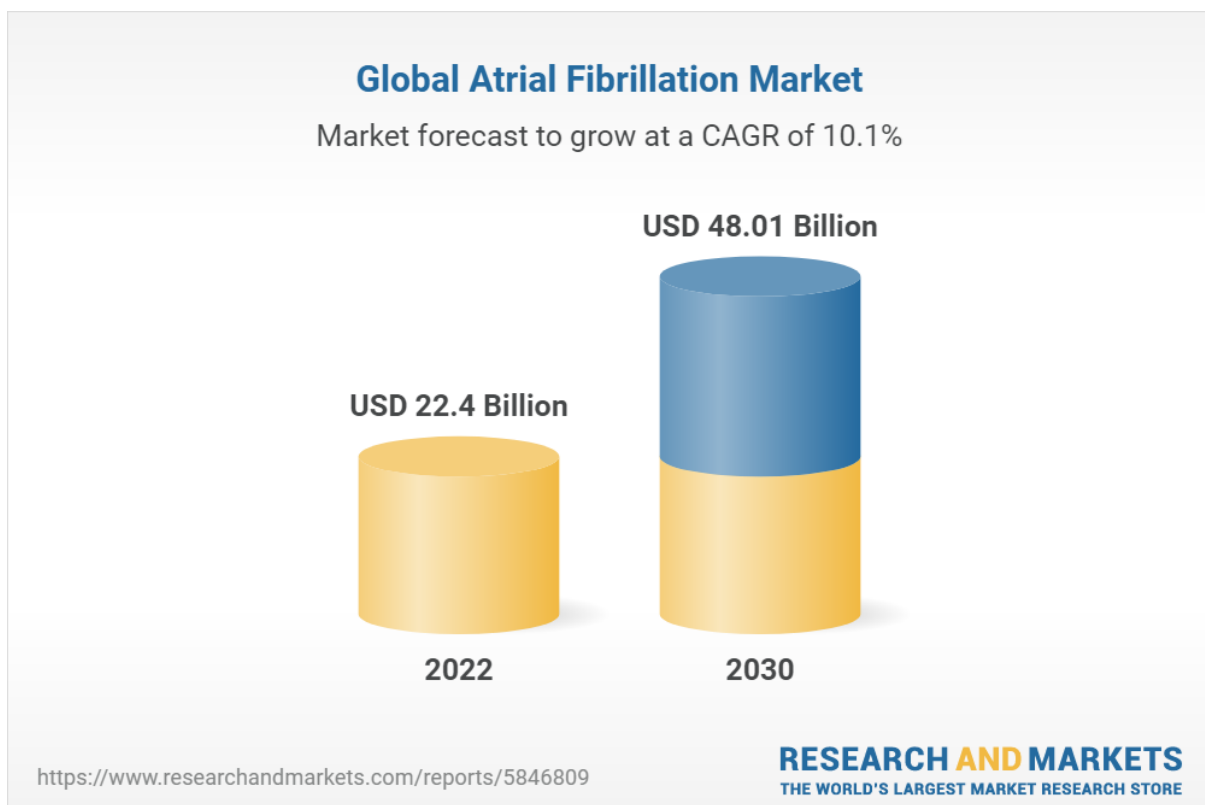
- Australia: TGA (Therapeutic Goods Administration ARTG ID -336797)) for Smartphone/Smartwatch.
- European Union: CE Class IIa certification for Smartphone/Smartwatch.
- Singapore: HSA (Health Sciences Authority) for Smartphone/Smartwatch.
- United Arab Emirates: MOHAP (Ministry of Health and Prevention) for Smartphone/Smartwatch.
- United Kingdom: MHRA (Medicines and Healthcare products Regulatory Agency) for Smartphone/Smartwatch.

- United States: FDA (Food and Drug Administration) 510(k) clearance for the smartphone standalone solution.
- Saudi Arabia: SFDA (Saudi Food and Drug Authority) for Smartphone.

These approvals underscore the dedication to meeting rigorous medical standards and ensuring the highest level of safety and effectiveness in healthcare technology. We are excited to continue providing innovative solutions to improve healthcare outcomes for individuals worldwide.

Atrial Fibrillation (AF) is a prevalent cardiac condition with a substantial impact on public health. With a lifetime risk of 1 in 4 individuals aged 40 and over, it affects a significant portion of the population, with a higher prevalence in males. The current estimated prevalence of AF is between 2% and 4%, which is expected to rise significantly due to increasing longevity and efforts to detect undiagnosed cases. While advancing age is a prominent risk factor, the burden of other comorbidities such as hypertension, diabetes, heart failure, coronary artery disease, chronic kidney disease, obesity, and obstructive sleep apnea also plays a crucial role in AF development and progression<sup>v</sup>.

The global landscape of atrial fibrillation (AF) presents a staggering prevalence, affecting approximately 60 million individuals and contributing to over 8 million disability-adjusted life years<sup>vi</sup>.



The global atrial fibrillation market size is expected to reach USD 48.01 billion by 2030, registering a CAGR of 10.1%, according to the report published by Research and Markets<sup>vii</sup>. The aging population, lifestyle changes, and chronic diseases such as diabetes and obesity are factors contributing to the increasing incidence of atrial fibrillation (AFib).

AHI is releasing AF-Scan as emerging research sheds light on novel risk factors for AF, including epigenetic markers indicative of biological age and body composition. Crucially, the mounting body of evidence underscores the pivotal role of risk factor interventions in reducing the incidence of AF and plays a central role in secondary prevention strategies to manage AF episodes effectively.

Atrial Fibrillation (AF) has emerged as a formidable global health challenge, casting a wide and pervasive shadow over a significant portion of the world's population. This cardiac arrhythmia, characterised by irregular and often rapid heartbeats, has become particularly prevalent among the aging population, and its far-reaching impact extends beyond the individual level. AF poses a series of formidable challenges that collectively demand our immediate attention and a transformative solution.

The growing concern about AF is its ability to elevate the risk of severe cardiovascular complications, each with potentially life-altering consequences. Among these, the heightened risk of stroke looms as one of the most alarming consequences of AF. The irregular heart rhythm can cause blood to pool in the atria, leading to the formation of blood clots, which can then travel to the brain, resulting in a devastating stroke. But the threats don't stop there. AF is also a significant contributor to heart failure, a condition in which the heart's ability to pump blood effectively is compromised. The risk of mortality in individuals with AF is notably higher than in those without this condition, adding yet another layer to the gravity of the situation.<sup>viii</sup>

Beyond the immediate health implications, AF exerts a considerable strain on healthcare systems and economies across the globe. The burden extends to direct medical expenses, such as hospitalisations, diagnostic tests, and treatments, and indirect costs, including lost productivity due to illness and disability. The sum of these financial pressures is substantial and raises pertinent questions about the sustainability of healthcare systems in the face of escalating AF cases.

AF-Scan will assist in the screening identification dilemma of at-risk individuals, which is one of the most significant challenges associated with AF. The condition is notorious for being elusive and, at times, asymptomatic, making it challenging to identify in its early stages. As a result, underdiagnosis and misdiagnosis are common occurrences, leaving many individuals unaware of their condition until it reaches an advanced and potentially critical stage. This diagnostic quandary underscores the critical need for proactive and routine monitoring and screening initiatives.

AF-Scan is deliberately positioned to take on this global health challenge, AHI has taken a pioneering step by including AF-Scan as part of the Biometric Health Assessment. The launch of AF-Scan is not just an innovation. It represents a call to action in the battle against Atrial Fibrillation. It empowers individuals to take control of their heart health by proactively monitoring their heart rhythm.

Navigating the Complexities of AF Detection and Management comes with unique challenges, including medication costs and potential side effects, invasive procedures, hospitalisations, and the need for long-term care and follow-up. This condition significantly impacts the quality of life of affected individuals, manifesting in physical and emotional symptoms that disrupt daily activities and independence. As the global population continues to age and lifestyle factors contribute to the rising incidence of AF, it has become a critical public health concern. Addressing this issue requires concerted efforts to raise awareness, education, and prevention programs to mitigate the impact of AF on individuals, healthcare systems, and society.

Ensuring your heart rhythm's health is crucial and a wise step in safeguarding against severe complications like strokes. Heart rhythm disorders can sometimes manifest as disruptive symptoms, making daily life uncomfortable. However, it's important to note that these disorders can also lurk silently without any noticeable symptoms. This is where regular heart rhythm monitoring plays a vital role.

According to the guidelines provided by the European Society of Cardiology (ESC), there's a startling statistic. By the age of 40, there's a 1 in 4 chance of developing a condition called atrial fibrillation (AF). Simply put, this means that irregular heart rhythms are more common than we might think, and monitoring your heart's rhythm is prudent.

Photoplethysmography (PPG) and electrocardiogram (ECG) are the primary two methods when exploring how this monitoring is done. AF-Scan is a revolutionary tool that employs PPG technology to support your journey towards optimal heart health.

So, what is PPG? It's an acronym for photoplethysmography, and it's a non-invasive and effective way to monitor your heart rhythm. This technology involves a detector and a light source placed on your skin's surface. When your heart beats, it sends blood through your blood vessels, causing them to expand and relax briefly. PPG technology detects these subtle changes in blood vessel size, providing precise insights into your heart's rhythm and overall health.<sup>ix</sup>

AHI's BHA harnesses the power of PPG collected via the flashlight and camera on your smartphone to provide downstream services such as AF-Scan with the necessary biometric signals. The solution is backed by a medically certified AI algorithm that swiftly analyses the PPG measurements it captures. This analysis generates a comprehensive set of graphical data in the form of a report to be consumed by a physician. You can share this report with your physician, making discussions about your heart health more productive. If needed, it can also guide further diagnostic or treatment decisions. In essence, AF-Scan's PPG technology enables individuals to proactively and conveniently monitor their heart rhythm using their smartphones, ensuring that they can make timely and informed healthcare decisions.

**Dylan Garnett, Chief Innovation Officer at AHI, said,**

"AF-Scan is a revolutionary addition to our Cardiac Health portfolio. This innovation comes at a critical time, as emerging research highlights novel AF risk factors, emphasising the importance of risk factor interventions in reducing AF incidence and managing episodes effectively.

Atrial Fibrillation (AF) is a global health challenge with far-reaching consequences. It elevates the risk of severe cardiovascular complications, including stroke and heart failure. The economic burden on healthcare systems is substantial. AF diagnosis is challenging, often leading to underdiagnosis and misdiagnosis, emphasising the need for proactive monitoring.

AF-Scan is a groundbreaking mobile phone-based solution addressing these challenges. It offers accessibility and convenience, bridging gaps in AF monitoring worldwide. By empowering individuals to monitor their heart rhythm, AF-Scan aims to reduce the incidence of complications like strokes and heart failure, optimising healthcare spending.

Regular heart rhythm monitoring is vital, given that AF can be asymptomatic. The European Society of Cardiology highlights a 1 in 4 chance of developing AF by age 40. AF-Scan employs PPG technology, providing accurate insights into heart rhythm by harnessing smartphone capabilities.

AF-Scan revolutionises AF detection and management, enabling proactive heart health monitoring through smartphones, ultimately reducing AF-related risks and healthcare costs."

**Vlado Bosanac, Founder and Head of Strategy at AHI, said:**

"AF-Scan is a groundbreaking innovation that couldn't come at a more opportune time. In today's rapidly evolving healthcare landscape, the need for accessible screening and ongoing atrial fibrillation (AF) monitoring has never been more pressing. AF-Scan is perfectly positioned to address this critical need and revolutionise how we approach cardiac health.

The prevalence of AF is rising, and individuals are increasingly aware of the importance of early detection and continuous monitoring. With AF-Scan, we are ushering in a new era of accessibility and convenience that was previously unimaginable.

The power of AF-Scan lies in its integration with the ubiquitous mobile phone. This unparalleled convenience ensures that individuals can access cardiac health assessments from the comfort and privacy of their own homes with just their smartphones. This level of accessibility can potentially transform how we approach cardiac health.

AHI will incorporate the AF-Scan into our biometric health assessment platform. This integration will further enhance the sensor sets already used across multiple disease categories, encompassing a remarkable 41 intrinsic biomarkers. This synergy will provide individuals with a comprehensive health assessment that goes beyond cardiac health, allowing us to offer a holistic view of their well-being.

AF-Scan offers a game-changing alternative in a market where traditional AF screening and monitoring methods often involve cumbersome processes and visits to healthcare facilities. By combining the mobile phone with our advanced biometric health assessment platform, we provide individuals with a powerful tool that empowers them to take control of their health like never before.

As we roll out AF-Scan and integrate it into our existing platform, we are not just launching a product but pioneering a shift in how we approach healthcare assessments. Our commitment to innovation and the current healthcare landscape makes AF-Scan a timely and indispensable addition to our portfolio. It aligns perfectly with the growing demand for accessible and ongoing health assessments, and we are excited to be at the forefront of this transformative journey”.

### **Key Features of AF-Scan:**

**Accessibility and Convenience:** AF-Scan can be accessed and used by individuals anywhere in the world, bridging gaps in healthcare accessibility and reducing the need for frequent hospital visits, particularly in regions with limited healthcare infrastructure.

**Early Detection and Intervention:** AF-Scan enables early identification of AF episodes, facilitating prompt intervention and thus reducing the risk of complications such as stroke and heart failure.

**Continuous Monitoring:** AF-Scan's continuous monitoring capability ensures that AF episodes are captured over time, providing a comprehensive picture of a patient's heart rhythm. This data is invaluable for making informed treatment decisions.

**Data Sharing:** Patients can effortlessly share their AF-Scan data with their healthcare providers, facilitating remote monitoring and telemedicine consultations.

**Treatment Optimization:** Healthcare professionals can utilise AF-Scan data to tailor treatment plans to each patient's specific needs, enhancing the effectiveness of interventions.

**Research and Methodology:** AF-Scan's data collection capabilities contribute to valuable research on AF, its triggers, and effective management strategies.

**Nurse and Patient Engagement:** Nurses can be pivotal in educating patients about AF management and guiding them on using AF-Scan effectively. This tool empowers nurses to provide more comprehensive care and monitor patients remotely, ensuring adherence to treatment plans.

**Reducing Healthcare Costs:** AF-Scan's potential to facilitate remote monitoring and early intervention has the potential to reduce healthcare costs associated with AF complications, hospitalisations, and emergency room visits.

### **The binding terms of the agreement are as follows:**

**Commencement:** This Agreement becomes effective from the Effective Date and initially spans a period of five (5) years, known as the "Initial Term."

The Initial Term extends automatically for subsequent three (3)-year periods, referred to as "Renewal Terms." Collectively, these periods constitute the "Term."

Either party may terminate this agreement by providing written notice at least three hundred and sixty (360) calendar days before the expiry of the Initial Term or any ongoing Renewal Term.

**Material Breach:** The Agreement may be promptly terminated by either party through written notice with immediate effect under the following circumstances:

- If either party commits a material breach of this Agreement.
- If either party engages in fraudulent activities, dishonesty, serious misconduct, or severe negligence.

**Fees:** AHI will pay an initial cash fee for the right to access the AF Scan software, with another cash fee payable following the completion of the integration. Further licensing fees may be payable following integration (subject to the number of users that utilise the integrated product). The quantum of the cash fees payable is commercially sensitive to Qompium, however, AHI confirms that it considers the fees payable to be market standard and comparable to fees payable for similar arrangements between similar companies in the same industry and in any event not material for disclosure in the context of AHI's business as a whole.

The license is a restricted, non-exclusive, and non-transferable license to use their software service and related documentation. This license is exclusively for establishing and maintaining a connection and making the Qompium Application accessible to AHI's customers.

AHI is prohibited from sublicensing this license to others except its affiliates.

Deploying the new partner application to users is contingent upon Qompium conducting a review and validation process, ensuring the integration has adhered to and complies to the medical approval granted. This procedure is essential to ascertain that the platform's integration strictly conforms to the prescribed criteria and procedures essential for sustaining medical approval within the customer's designated jurisdiction for distribution.

Qompium may offer updates or upgrades to the software during the agreement's term. AHI is encouraged to use the latest version and incorporate updates. Qompium may phase out older versions.

Under the agreement, Qompium must comply with international quality standards. AHI must cooperate with Qompium to adhere to applicable regulatory requirements.

AHI can create copies for testing and development within the allowable limits. Qompium can utilise feedback provided by the AHI. If personal data processing occurs, AHI is the controller, while Qompium is the processor. Both parties must adhere to data protection laws.

AHI will not yield immediate revenue from this agreement. AHI foresees more consistent revenue generation following commercial deployment of the integrated product in Q2 2024.

For more information, contact: \_

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\*The Board of Advanced Health Intelligence Ltd has approved this announcement.

### **About Advanced Health Intelligence Ltd**

Advanced Health Intelligence Ltd (AHI) is committed to becoming a global leader in digital health, harnessing its proprietary technology and innovative processes to redefine health screening. Leveraging

the ubiquity and convenience of smartphones, AHI aims to deliver a comprehensive suite of assessment tools to healthcare providers, caregivers, insurers, and governments worldwide.

Our mission is to improve healthcare outcomes, enhance health literacy, and support the early detection and management of various health conditions.

Since our inception in 2014, AHI has been at the forefront of Health-tech innovation, starting with the world's first on-device body dimensioning capability. Our patented technology has evolved into a robust suite of solutions symbolising digitised healthcare's future.

Our key offerings include:

- Body dimension and composition assessments enable the identification of obesity-related comorbidities such as diabetes.
- Blood biomarker prediction, inclusive of HbA1C, HDL, LDL, and 10-year mortality risk.
- Transdermal Optical Imaging provides vital signs and cardiovascular disease risk estimates.
- On-device dermatological skin identification is capable of recognising 588 skin conditions across 133 categories, including melanoma.
- Assisting partners in delivering personalised therapeutic and non-therapeutic health coaching to improve daily habits and build health literacy.

At the heart of AHI is our world-class team comprising machine learning and AI experts, computer vision specialists, and medically trained data scientists. Their collective expertise ensures AHI remains at the cutting edge of health-tech innovation, tailoring our technology to meet the evolving needs of our consumers.

AHI's vision extends beyond individual health assessments. We aspire to create a transformative impact at scale, driving a new digital healthcare era. Our biometrically derived triage solution, accessible via a smartphone, enables our partners to identify and manage health risks at a population scale.

In pursuing proactive health management, AHI stands ready to guide healthcare providers, caregivers, insurers, and governments in triaging individuals into the most suitable care pathways. AHI contributes to a more efficient, effective, and inclusive global healthcare system through technology.

For more information, please visit: [www.ahi.tech](http://www.ahi.tech)

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<sup>i</sup><https://pubmed.ncbi.nlm.nih.gov/25974193/>

<sup>ii</sup> <https://www.nature.com/articles/s41569-022-00820-8>

<sup>iii</sup> <https://academic.oup.com/eurheartj/article/42/5/373/5899003?login=false>

<sup>iv</sup> <https://pubmed.ncbi.nlm.nih.gov/20813280/>

<sup>v</sup> <https://academic.oup.com/eurheartj/article/42/5/373/5899003?login=false>

<sup>vi</sup> <https://www.nature.com/articles/s41569-022-00820-8>

<sup>vii</sup> [https://www.researchandmarkets.com/report/atrial-fibrillation?utm\\_source=CI&utm\\_medium=PressRelease&utm\\_code=l6gcpg&utm\\_campaign=1904061+-+Global+Atrial+Fibrillation+Market+Research+Report+2023-2032%3a+Market+Thriving+with+Surgical+and+Non-Surgical+Treatment+Options&utm\\_exec=chdo54prd](https://www.researchandmarkets.com/report/atrial-fibrillation?utm_source=CI&utm_medium=PressRelease&utm_code=l6gcpg&utm_campaign=1904061+-+Global+Atrial+Fibrillation+Market+Research+Report+2023-2032%3a+Market+Thriving+with+Surgical+and+Non-Surgical+Treatment+Options&utm_exec=chdo54prd)

<sup>viii</sup> <https://www.nature.com/articles/s41569-022-00820-8>

<sup>ix</sup> <https://academic.oup.com/eurheartj/article/42/5/373/5899003?login=false>