



2020 GLOBAL AI-BASED ECHOCARDIOGRAPHY NEW PRODUCT INNOVATION AWARD

FROST & SULLIVAN

Contents

Background and Company Performance	3
Industry Challenges	3
New Product Attributes and Customer Impact	4
Conclusion	6
Significance of New Product Innovation	7
Understanding New Product Innovation	7
Key Benchmarking Criteria	8
New Product Attributes	8
Customer Impact	8
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices	9
The Intersection between 360-Degree Research and Best Practices Awards1	١0
Research Methodology1	LO
About Frost & Sullivan1	LO

Background and Company Performance

Industry Challenges

Cardiovascular disease is a leading cause of mortality worldwide, representing 31% of all global deaths, with an estimated 17.9 million deaths annually. In the United States alone, the cost burden of cardiovascular disease will be approximately \$749 billion by 2035.² One of the most common cardiovascular diseases is coronary artery disease (CAD), which affects over 16.5 million people over 20 years of age in the United States³.

There are many techniques to diagnose cardiovascular disease, but one of the most widely used is echocardiography, a method in which ultrasound images of the heart are produced two or three-dimensionally via Doppler or M-mode echocardiography. For cardiology, echocardiography is considered for conditions like cardiomyopathy, congenital heart disease, heart failure, aneurysm, heart valve disease, cardiac tumor, pericardial effusion, atrial, or septal wall defects, shunts, and the heart's overall function or structure.4 However, echocardiography is a time-consuming process. An echocardiogram takes an average of 20 minutes to 1 hour to complete, including patient preparation and positioning, and image acquisition. It is therefore nearly impossible to identify the cardiovascular problems of large at-risk populations using manual echocardiography, considering the enormous time and human resources requirement.

There are 26 million heart failure patients worldwide and an estimated 37.7 million prevalence due to undiagnosed cases⁵. The prevalence of the disease is increasing over time, and as the number of patients with complex cardiovascular diseases continues to grow, demand for echocardiography will likely experience a parallel growth. As a result, there will be a supply-demand mismatch as the number of trained cardiologists is not increasing at the same rate as patients worldwide. In fact, the World Health Organization predicts a global shortage of 14.5 million physicians, nurses, and other cadres of healthcare professionals by 2030⁶.

An additional challenge with ultrasound echocardiography is that acquisition and interpretation are highly dependent on the operator's skill. This challenge is further exacerbated in some patient cohorts (e.g., people with obesity and lung disease). Thus, the nature of the ultrasound modality lends itself well to human subjectivity and error, resulting in varying assessments on heart function and diagnoses.

Artificial intelligence (AI) in medical imaging is an ongoing revolution in healthcare that influences each medical specialty, including cardiovascular diseases. Developing AI-based

¹ WHO – Cardiovascular Diseases Fact sheet - https://www.who.int/health-topics/cardiovascular- diseases/#tab=tab 1

American Heart Association Report on CVD Cost Burden of US - https://healthmetrics.heart.org/wpcontent/uploads/2017/10/Cardiovascular-Disease-A-Costly-Burden.pdf

Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association

⁴ John Hopkins treatment test and therapies - https://www.hopkinsmedicine.org/health/treatment-tests-and- therapies/echocardiogram

World Heart Federation - https://www.world-heart-federation.org/resources/heart-failure-fact-sheet/

⁶ Global strategy on human resources for health: Workforce 2030, World Health Organization.

⁷ US National library of medicine - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5601967/

echocardiography solutions remains a challenge, however, due to the dynamic nature of ultrasound as compared to other radiology modalities such as computed tomography, magnetic resonance imaging, and X-rays. Of the 225+ radiology AI companies, more than half of which are start-ups, less than 10 actually focus on echocardiography. Within those, only a handful has regulatory-approved, commercially-available solutions.

New Product Attributes and Customer Impact

Ultromics is one of the pioneers in providing AI-based cardiovascular solutions. Ultromics was founded in 2017 at the University of Oxford by Ross Upton and Professor Paul Lesson. Ultromics collaborated with the university and the United Kingdom's National Health Service (NHS) to improve patient care and provide hospital cost savings by enhancing diagnostic quality in cardiac care units. Ultromics has received over \$25 million to date, and; is one of the very few imaging AI start-ups to have received a Series A venture capital funding in less than 3 years of founding.

Match to Needs

The company's EchoGo Core performs cardiac measurements, including ejection fraction (EF), global longitudinal strain (GLS), left ventricular (LV) volume, and myocardial strain reporting. By automating these measurements in ultrasound imaging, Ultromics addresses one of the most tedious and time-consuming steps for cardiovascular conditions' diagnosis, thus saving time and removing inter-operator variability.

Another solution, the EchoGo Pro, serves as a clinical decision support tool for physicians by assessing the current risk of patients developing CAD in future. As an industry-first solution within cardiac echocardiography, the solution enables earlier prevention of CAD supported by evidence and at the point of care, thus allowing the cardiologist to take proactive steps. The solution is well-positioned to reign in the most common type of cardiac conditions afflicting patients.

Frost & Sullivan commends Ultromics for not only addressing the market's critical unmet need, but also for empowering physicians to enable earlier diagnosis and prevention, and thus be better prepared for the future.

Quality and Reliability

Apart from building a world-class team of expert clinicians, scientists, engineers, and healthcare professionals, Ultromics has benefited from its partnership with the University of Oxford. But unlike the competition, Ultromics developed its solution in partnership with UK's NHS. Frost & Sullivan notes that having real-world inputs from clinicians greatly enhances the usability of the solution while making it extremely reliable. Ultromics has also leveraged the expertise of leading US cardiology care providers, most notable being the Mayo Clinic. Ultromics' technology already boasts of over 700,000 images being scanned with effective results. As a result, Ultromics was recently recognized by the American Society of Echocardiography for its unique vision and value proposition.

During clinical trials, EchoGo Pro achieved a diagnostic performance of more than 90% sensitivity, significantly reducing the number of misdiagnoses compared to reports created

via routine clinical practice. The technology has been further validated through its participation in NHS' EVAREST trials, which continue to run in more than 30 NHS hospitals and have recruited over 6,000 patients to date.⁸ The US FDA cleared the EchoGo Core solution in just 6 months, speaking to its reliability.

Frost & Sullivan appreciates Ultromics' efforts to leverage critical insights from leading cardiology experts and continue to validate the solution in real-world scenarios, thus enhancing physician confidence in their solution.

Positioning and Design

EchoGo is a cloud-based solution, positioned to be delivered in a software-as-a-service (SaaS) fashion. This allows deployments to be completed faster than traditional PACs software integrations, which in itself is a major pain-point within the broader radiology AI industry as some implementations take many days, if not weeks. The SaaS model addresses another pain point of AI solutions by eliminating the worry of future upgrades, patches, and associated fees. The solution is designed to be intuitive, minimizing the need for substantial user training required by other solutions. Once usage begins, the solution also incorporates a zero-click, off-the-cart usage approach, eliminating the need for users to manually upload or cross launch scans and operate the device manually.

Being a vendor-neutral solution, Ultromics can target any provider, regardless of the echocardiography equipment they use, across regions. While the EchoGo solutions are currently available in the western region, Ultromics will in the future also target the Asia-Pacific market.

One major barrier impeding the adoption of AI solutions in developed markets is the potential for reimbursement. In 2020, the EchoGo Core obtained a CPT code that allows physicians to report and bill for myocardial strain diagnosis and remains one of the very few AI solutions in the imaging space to boast of reimbursement. Positioning the solution with reimbursement allows for easier AI solution adoption by providers.

Frost & Sullivan applauds Ultromics for their vision and execution to design and position a solution in a manner that addresses several issues plaguing the imaging AI industry.

Price/Performance Value

EchoGo's pricing structure delivers great value, and significant return on investment with no upfront costs whatsoever. Although competitors' price points comparable to EchoGo, in considering the additional costs of software upgrades and associated installation costs and efforts, EchoGo proves to deliver more value over time. Ultromics adopts a pay-per-use pricing model, in line with provider expectations, but can also offer a subscription model depending on the volume of procedures being conducted.

Further substantiating the value of the solution is the reimbursement provided in the US with CPT code +93356. Medicare offers a base \$40 reimbursement per myocardial strain procedure, a diagnosis that is conventionally performed manually. EchoGo automates the

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⁸ Clinical Trials – US National Library of Medicine - https://clinicaltrials.gov/ct2/show/NCT03674255

entire process, allowing physicians to save on costs while having zero user interaction to get results. The time savings also enable physicians to consult more patients, thus helping increase revenue.

Frost & Sullivan lauds Ultromics price value proposition that helps capture a larger market while providing a quality solution at the right price point.

Conclusion

Echocardiography, used to diagnose heart conditions, is a complex and time-consuming procedure and has inherent challenges such as inter-user variability. Designing artificial intelligence-based solutions for this space is also challenging, but Ultromics is one of the pioneers in the field. The company's FDA and CE-cleared solutions not only automate measurements for heart function but also empower physicians to predict the occurrence of coronary artery disease in patients. As a result, Ultromics enables clinicians to take a proactive approach to interventions, thus helping control the prevalence of heart diseases that form the largest cause of death globally. With a cloud and Software-as-a-Service-based format, the solution design allows for quick deployment, minimal training requirements, and hassle-free access to upgrades-all at an attractive price point which is even covered with reimbursement in the United States.

For its strong overall product attributes and new methodology to approach complex cardiovascular problems, Ultromics is recognized with Frost & Sullivan's 2020 New Product Innovation Award in the global AI-based echocardiography market.

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Significance of New Product Innovation

Ultimately, growth in any organization depends on continually introducing new products to the market and successfully commercializing those products. For these dual goals to occur, a company must be best in class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



Understanding New Product Innovation

Innovation is about finding a productive outlet for creativity—for consistently translating ideas into high-quality products that have a profound impact on the customer.

Key Benchmarking Criteria

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated 2 key factors—New Product Attributes and Customer Impact—according to the criteria identified below.

New Product Attributes

Criterion 1: Match to Needs

Requirement: Customer needs directly influence and inspire the product's design and positioning.

Criterion 2: Reliability

Requirement: The product consistently meets or exceeds customer expectations for consistent performance during its entire life cycle.

Criterion 3: Quality

Requirement: Product offers best-in-class quality, with a full complement of features and functionalities.

Criterion 4: Positioning

Requirement: The product serves a unique, unmet need that competitors cannot easily replicate.

Criterion 5: Design

Requirement: The product features an innovative design, enhancing both visual appeal and ease of use.

Customer Impact

Criterion 1: Price/Performance Value

Requirement: Products or services offer the best value for the price, compared to similar offerings in the market.

Criterion 2: Customer Purchase Experience

Requirement: Customers feel they are buying the optimal solution that addresses both their unique needs and their unique constraints.

Criterion 3: Customer Ownership Experience

Requirement: Customers are proud to own the company's product or service and have a positive experience throughout the life of the product or service.

Criterion 4: Customer Service Experience

Requirement: Customer service is accessible, fast, stress-free, and of high quality.

Criterion 5: Brand Equity

Requirement: Customers have a positive view of the brand and exhibit high brand loyalty.

Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate award candidates and assess their fit with select best practices criteria. The reputation and integrity of the awards are based on close adherence to this process.

	STEP	OBJECTIVE	KEY ACTIVITIES	ОИТРИТ
1	Monitor, target, and screen	Identify award recipient candidates from around the world	Conduct in-depth industry researchIdentify emerging industriesScan multiple regions	Pipeline of candidates that potentially meet all best practices criteria
2	Perform 360-degree research	Perform comprehensive, 360-degree research on all candidates in the pipeline	 Interview thought leaders and industry practitioners Assess candidates' fit with best practices criteria Rank all candidates 	Matrix positioning of all candidates' performance relative to one another
3	Invite thought leadership in best practices	Perform in-depth examination of all candidates	 Confirm best practices criteria Examine eligibility of all candidates Identify any information gaps 	Detailed profiles of all ranked candidates
4	Initiate research director review	Conduct an unbiased evaluation of all candidate profiles	 Brainstorm ranking options Invite multiple perspectives on candidates' performance Update candidate profiles 	Final prioritization of all eligible candidates and companion best practices positioning paper
5	Assemble panel of industry experts	Present findings to an expert panel of industry thought leaders	Share findingsStrengthen cases for candidate eligibilityPrioritize candidates	Refined list of prioritized award candidates
6	Conduct global industry review	Build consensus on award candidates' eligibility	 Hold global team meeting to review all candidates Pressure-test fit with criteria Confirm inclusion of all eligible candidates 	Final list of eligible award candidates, representing success stories worldwide
7	Perform quality check	Develop official award consideration materials	 Perform final performance benchmarking activities Write nominations Perform quality review 	High-quality, accurate, and creative presentation of nominees' successes
8	Reconnect with panel of industry experts	Finalize the selection of the best practices award recipient	Review analysis with panelBuild consensusSelect recipient	Decision on which company performs best against all best practices criteria
9	Communicate recognition	Inform award recipient of recognition	 Announce award to the CEO Inspire the organization for continued success Celebrate the recipient's performance 	Announcement of award and plan for how recipient can use the award to enhance the brand
10	Take strategic action	Upon licensing, company is able to share award news with stakeholders and customers	 Coordinate media outreach Design a marketing plan Assess award's role in strategic planning 	Widespread awareness of recipient's award status among investors, media personnel, and employees

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The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of the research process. It offers a 360-degree view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, resulting in errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform benchmarking industry



participants and for identifying those performing at best-in-class levels.

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