PRESS RELEASE



InSiDe, a European R&D project targeting mobile early-stage cardiovascular disease diagnosis and monitoring

Leuven (BELGIUM) – Feb 3, 2020 – Imec, a world-leading research and innovation hub in nanoelectronics and digital technology and Ghent University, together with Medtronic and their project partners today announced the launch of the H2020 project InSiDe. The objective of InSiDe is to provide access for the medical community to a mobile diagnostic device based on silicon photonics to identify and characterize different stages of cardiovascular diseases (CVD). The device offers fast, flexible and patient-friendly monitoring of CVD, keeping patients in their home environment while still being able to closely follow-up and intervene in due time.

"The InSiDe project has been triggered by the remarkable outcome of the H2020 project CARDIS. Together with the CARDIS project partners, we developed a prototype mobile, affordable, point-ofcare screening device for CVD. The device enables fast and reliable measurement of CVD-related biophysical signals through minimal physical contact with the patient and minimal skills from the operator," stated Roel Baets, group leader at imec and professor at Ghent University. "The objective of the InSiDe project is to take this CARDIS prototype device a major step further towards proven medical relevance and towards commercialization."

The operating principle of the device is Laser Doppler Vibrometry (LDV): a low-power laser is directed towards the skin overlying an artery. The skin's vibration amplitude and frequency, resulting from the heartbeat, are extracted from the Doppler shift of the reflected beam. The key underlying technology is silicon photonics, which allows the implementation of advanced optical functionality in a chip produced in a CMOS fab environment. The CARDIS prototype device underwent a first clinical feasibility study at the Georges Pompidou European Hospital in Paris (France) and at the Academic Hospital of Maastricht (The Netherlands), collecting a substantial clinical dataset, both from healthy subjects as well as from patients with cardiovascular conditions. The quality of the device readings was found to be very good and adequate biophysical signals could be obtained in all subjects, even if the algorithmic translation to relevant markers for medical pathologies needs further work. Roel Baets added: "The very promising results from the CARDIS project stimulated the consortium to take the next step and aim at bringing the prototype to a true manufacturable product that is useful for GPs and cardiologists in their daily practice."

To bring the CARDIS prototype device towards commercialization, the InSiDe project will:

- Develop a true handheld clinical, battery-operated investigational device capable of measuring, quantifying and recording cardiovascular conditions;
- Develop algorithms to translate the interferometer signals into data that
- are relevant to monitor and diagnose a number of cardiovascular diseases (CVDs);
- Demonstrate in clinical feasibility studies the usefulness of the device for GPs and cardiologists;
- Outline a path to industrialization and manufacturability.

InSiDe is supported by the European Union's Horizon 2020 Framework Programme for Industrial leadership in Information and Communication Technologies (H2020) and by the Photonics Public Private Partnership Photonics21. Over the next four years, InSiDe will be managed by imec, through imec's associated laboratory located at Ghent University (Photonics Research Group in the Department of Information Technology). Medtronic Bakken Research Center (Netherlands) will be responsible for the scientific and technical coordination of the project. Other industrial, academic and clinical partners will bring their expertise to the project: Ghent University (Belgium), Politecnico di Torino (Italy), Tyndall National Institute (Ireland), Microchip Technology



(United Kingdom), Argotech (Czech Republic), National Institute for Health and Medical Research – INSERM (France), Universiteit Maastricht (Netherlands) and Fundico (Belgium).

Roel Baets, project coordinator from imec/UGent, will present the results of the CARDIS project and the aims of the InSiDe project on Feb 3 at <u>ITF Photonics</u>, an industry event co-organized with SPIE BIOS and SPIE Photonics West by imec and SPIE (San Francisco, Feb1-7, 2020).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 871547.



CARDIS prototype medical device that can perform Laser Doppler Vibrometry on a patient's skin to deduce metrics for arterial stiffness and to diagnose cardiovascular diseases

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About imec

Imec is the world-leading research and innovation hub in nanoelectronics and digital technologies. The combination of our widely acclaimed leadership in microchip technology and profound software and ICT expertise is what makes us unique. By leveraging our world-class infrastructure and local and global ecosystem of partners across a multitude of industries, we create groundbreaking innovation in application domains such as healthcare, smart cities and mobility, logistics and manufacturing, energy and education.

As a trusted partner for companies, start-ups and universities we bring together more than 4,000 brilliant minds from over 85 nationalities. Imec is headquartered in Leuven, Belgium and has distributed R&D groups at a number of Flemish universities, in the Netherlands, Taiwan, USA, China, and offices in India and Japan. In 2017, imec's revenue (P&L) totaled 546 million euro. Further information on imec can be found at <u>www.imec-int.com</u>.

In InSiDe use will be made of the mature silicon photonics prototyping platform iSiPP50G, developed at imec. This platform allows to prototype and manufacture in low volume silicon photonics circuits through the use of a process flow in a CMOS fab.

Imec is a registered trademark for the activities of IMEC International (a legal entity set up under Belgian law as a "stichting van openbaar nut"), imec Belgium (IMEC vzw supported by the Flemish Government), imec the Netherlands (Stichting IMEC Nederland, part of Holst Centre which is supported by the Dutch Government), imec Taiwan (IMEC Taiwan Co.) and imec China (IMEC Microelectronics (Shanghai) Co. Ltd.) and imec India (Imec India Private Limited), imec Florida (IMEC USA nanoelectronics design center).

About Photonics Research Group

The Photonics Research Group in the Department of Information Technology of Ghent University is an associated lab of imec and performs research in the field of photonic integration – more specifically silicon photonics – and its

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applications in information and communication technology, in sensing and in life sciences. With its 80 researchers the group has a leading international role in the field and is also very active in graduate education in photonics and in industrial spin-off resulting from its research. More information can be found at www.photonics.intec.ugent.be.

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About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Medtronic Bakken Research Center (BRC), founded by Medtronic in Maastricht in 1987, starting with 45 employees and now reaching 325, is the research facility involved in CARDIS. Especially clinical study activities have grown substantially, now ranging from small exploratory studies with one physician-investigator and just a few patients to multinational, randomized trials intended to demonstrate superior clinical and economical outcomes with new device therapies in hundreds, sometimes thousands of patients. The BRC nowadays also hosts the Benelux Therapy & Procedure Training Center, where advanced simulator training is offered to physicians, nurses and technicians.

About Ghent University

Ghent University (UGent) consists of 117 departments across 11 faculties and offers high-quality research-based educational programs in virtually every scientific discipline. UGent distinguishes itself as a socially committed and pluralistic university in a broad international perspective. The motto of the university is 'Dare to Think'. The university's appeal is growing every year, with about 44,000 students in 2019, of whom 10% (students) and 37% (PhD students) are international. Numerous research groups, centers and institutes have been founded over the years, becoming world-renowned in disciplines such as biotechnology, aquaculture and micro-electronics.

Ghent University is ranked 66th in the Shanghai and 123rd on the Times ranking. The University has participated in more than 150 H2020 research projects, counts 60 H2020 ERC grant holders, is involved in 60 ITN network programs, has 31 Marie-Curie Fellowship holders and partners in 7 RISE projects. The university provides excellent training opportunities to both young and experienced researchers, and is one of the fastest growing European universities in terms of research capacity and productivity. Besides the Photonics Research Group from the Department of Information Technology of Ghent University, other research teams involved are IBiTech-bioMMeda (Biofluid, Tissue and Solid Mechanics for Medical Applications) and the IDLab (Internet Technology and Data Science Laboratory) from the Department of Electronics and Information Systems. IBiTech-bioMMeda, already partner in CARDIS, has recognized expertise in cardiovascular physiology, arterial hemodynamics and biomechanics and is a.o. known for its role in Europe in establishing reference and normal values of arterial stiffness and assessment and validation of methods to measure arterial stiffness. IDLab is a new partner in InSiDe and will bring in their signal processing expertise for the real-time assessment of cardiovascular function using InSiDe technology.

About Tyndall National Institute

Established with a mission to support industry and academia in driving research to market, Tyndall National Institute is one of Europe's leading research centres in Information and Communications Technology (ICT) research and development and the largest facility of its type in Ireland. Established in 2004 as a successor to the National Microelectronics Research Centre (NMRC founded in 1982) at University College Cork, the Institute employs over 460 researchers, engineers and support staff, with a full-time graduate cohort of 135 students generating over 200 peer-reviewed publications each year. With a network of 200 industry partners and customers worldwide, Tyndall generates around €30M income each year, 85% from competitively won contracts nationally and internationally. Tyndall is also a lead partner in European research partnerships in its core areas of ICT, communications, energy, health and the environment worth €48M, including €10M accruing to industry in Ireland (from Framework 7). Hosting the only full CMOS (metal oxide semiconductor) integrated circuit construction, Micro Electronic Mechanical systems (MEMS) and III-V Wafer Semiconductor fabrication facilities and services in Ireland, Tyndall is capable of prototyping new product opportunities for its target industries – electronics, medical devices, energy and communication. Tyndall is a globally leading Institute in its four core research areas of Photonics, Microsystems, Micro/Nanoelectronics and Theory, Modeling and Design. Tyndall is the lead institution for the Science Foundation Ireland funded Irish Photonics Integration Centre. IPIC brings together Irish research capabilities in photonics, electronics and biomedical science together with 18 industrial partners, to develop integrated photonic solutions for advanced medical diagnostics and surgical procedures, and to enable continued growth of communications systems and the internet. For more information go to www.tyndall.ie .

About Politecnico di Torino

Politecnico di Torino was founded in 1906 and has its roots in the Technical School for Engineers created in 1859. It is internationally ranked among the most important universities in Europe for engineering and architecture studies, with 33,000 students (out of which 15% are international students coming from over 100 different countries). Politecnico is a center of excellence for education and research in engineering, architecture, design and planning and it works in close cooperation with the socio-economic system. It is a comprehensive Research University where education and research complement each other and create synergies in order to address the needs of the economic system, of the local community and, above all, of its students.



Politecnico is committed to a strong internationalization process of its teaching, research and technology transfer activities: not only does it work in cooperation with the best universities and research centers in world, but it has also been signing agreements and contracts with important international corporations, as well as local businesses, meaning to be for the latter a focal point for innovation. For more information go to <u>www.politio.it</u>.

About Microchip Technology

Microchip Technology Inc. is a leading provider of smart, connected and secure embedded control solutions. Its easy-touse development tools and comprehensive product portfolio enable customers to create optimal designs which reduce risk while lowering total system cost and time to market. The company's solutions serve more than 125,000 customers across the industrial, automotive, consumer, aerospace and defense, communications and computing markets. Headquartered in Chandler, Arizona, Microchip offers outstanding technical support along with dependable delivery and quality. For more information, visit the Microchip website at www.microchip.com.

About Argotech

Argotech a.s. is a private company located in the city of Trutnov in the Czech Republic. The company was founded in 2006, based on a tradition of microelectronics fabrication in the region, after the restructuring of Siemens, and later Infineon. Argotech focuses on manufacturing, engineering, and development services for opto-and micro-electronics. It provides a unique technology-chain, starting from wafer-level packaging to full optical subassembly, and customized packaging solutions.

For custom packaging of optoelectronics components, such as OSAs, micro-modules, etc., Argotech acts as a CM (contract manufacturer) or an ODM (original design manufacturer). For ODM work, Argotech provides optical, electronic, RF, mechanic and thermal management design.

Argotech has a 10-year track-record of serving customers from the datacom, telecom, airspace, defence, life-science, and final-customer markets, and has a highly experienced team, with a 10-year track-record in packaging & micro-assembly activities, and generating solutions for customers focused on wafer-scale assembly. Argotech has deployed a micro-assembly approach for wafer-level carriers that enables the packaging scale-up of optoelectronics components to higher volumes, as well as reaching very compact component sizes, both of which are required for wearable electronics and medical applications.

Argotech has an experience in RF design of packaging & assembly towards to 100Gb/s NRZ, optical coupling of 400nm lasers to 2.5μ m-SMFs, and customization of packaging processes when off-the-shelf components do not provide the required functionality or performance, etc.

Argotech offers sample and pilot production, with a fast capacity ramp-up, and flexible shift model to meet the demands of mass production, when needed. For mass production, Argotech has the capacity to span the full value-chain from feasibility studies, to product design, to prototyping, to product qualification.

Argotech is constantly working to incorporate and improve the level of automated assembly (machine vision, Labview servo-control, etc.) in its production-chain, to increase both capacity and yield for customers.

About INSERM

Founded in 1964, the French National Institute of Health and Medical Research (Inserm) is a public scientific and technological institute which operates under the joint authority of the French Ministry of Health and French Ministry of Research. As the only French public research institute to focus entirely on human health, in 2008 Inserm took on the responsibility for the strategic, scientific and operational coordination of biomedical research. This key role as coordinator comes naturally to Inserm thanks to the scientific quality of its teams and its ability to conduct translational research, from the laboratory to the patient's bed. The decree adopted in March 2009 enables Inserm to perform its research missions in the face of the new scientific, health and economic challenges of the 21st century. From the outset, Institute has forged close partnerships with the other public and private research establishments as well as hospitals to fulfil its missions. 80% of Inserm's 318 research units are currently set up in university hospitals or cancer research centers. The research campuses of the French National Center for Scientific Research (CNRS), along with the Pasteur and Curie Institutes, also house Inserm research divisions. Universities are also key partners of Inserm. As the main actor in French biomedical research, Inserm is responsible of 35% of scientific publications and is the #1 applicant for patents in France in the biomedical field. The INSERM Paris-Cardiovascular research Center (PARCC) was created in 2009 at the Georges-Pompidou European Hospital (Paris, France). The 14 PARCC research teams are conducting projects spanning basic molecular and cellular biology to integrated physiology and pathophysiology, biomarkers, genetics and epidemiology, with the goal of furthering the understanding of major cardiovascular disease, including atherosclerosis, hypertension, heart failure and sudden cardiac death. Translational research is an integral part of the mission of the PARCC, in close connection with clinical laboratories and departments of HEGP. INSERM PARCC team 7 project concerns arterial disease and their pharmacological treatments. It is enclosed in the general framework of a multidisciplinary research, and is focused on the pathogenesis and pharmacology of arterial diseases. These studies imply a clinical approach of arterial function (arterial stiffness, endothelial dysfunction) and remodeling (arterial wall thickness and enlargement), which supposes to measure in vivo with high precision the geometric and functional properties of large arteries, at different levels of the arterial tree, in humans. Team 7 is among the best publishers in the field, having 3 papers cumulating more than 1500 quotations each, and more than 450 cumulated references on the field.



About Universiteit Maastricht

Within the 40 year-young Maastricht University the Cardiovascular Research Institute Maastricht (CARIM) integrates all research in the cardiovascular field. CARIM has an annual budget of ~20 M€, employs ~200 fte of researchers and 70 fte of technical and supporting staff, divided over 13 departments/disciplines. Together they produce more than 500 scientific papers annually. Within CARIM Prof. Frits Prinzen is a well-known investigator in the field of pacemaker therapies for heart failure, using pre-clinical and clinical research for these purposes. Within CARDIS he will evaluate the use of the newly developed products in patients with cardiac resynchronization therapy (CRT). Goal is to demonstrate the clinical feasibility of using the new product and to validate the technical concept for optimizing the application of CRT.

About Fundico

Fundico bvba, located in Zwijnaarde, Belgium, is a consultancy company with the objective to assist industrial companies and research organisations with the submission of financing proposals for research and development, mainly in the field of information and communication technologies. These financing proposals are submitted to regional public authorities or to the European Commission. In the latter case these proposals are submitted in response to an official call for proposals issued by the European Commission. In case of project proposals for which financing is granted, Fundico will also, in many cases be involved in the management and coordination of the research and development project.

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