InSiDe

Integrated Silicon photonics for Cardiovascular Disease monitoring

<Presenter name>

<Event, date>

This project has received funding from the European Union's H2020 Programme for research, technological development and demonstration under grant agreement No 871547

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Presentation overview

- Project ID card
- Rationale
- Objectives
- Overall concept
- Project structure
- Implementation plan
- Consortium partners

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Project ID card

- Funded under: H2020 (Horizon 2020)
- Innovation Action (IA)
- Area: Application driven Photonics components
- Project reference: 871547
- Start date: 01 JAN 2020
- Duration: 48 months
- Total EC funding: 4.948.385 €

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Project ID card

- Consortium participants:

Imec (BE) (Coordinator)	Medtronic BRC (NL)
Universiteit Gent (BE)	Tyndall National Institute (IE)
Politecnico di Torino (IT)	Microchip Technology Caldicot (UK)
Argotech (CZ)	INSERM (FR)
Universiteit Maastricht (NL)	Fundico (BE)

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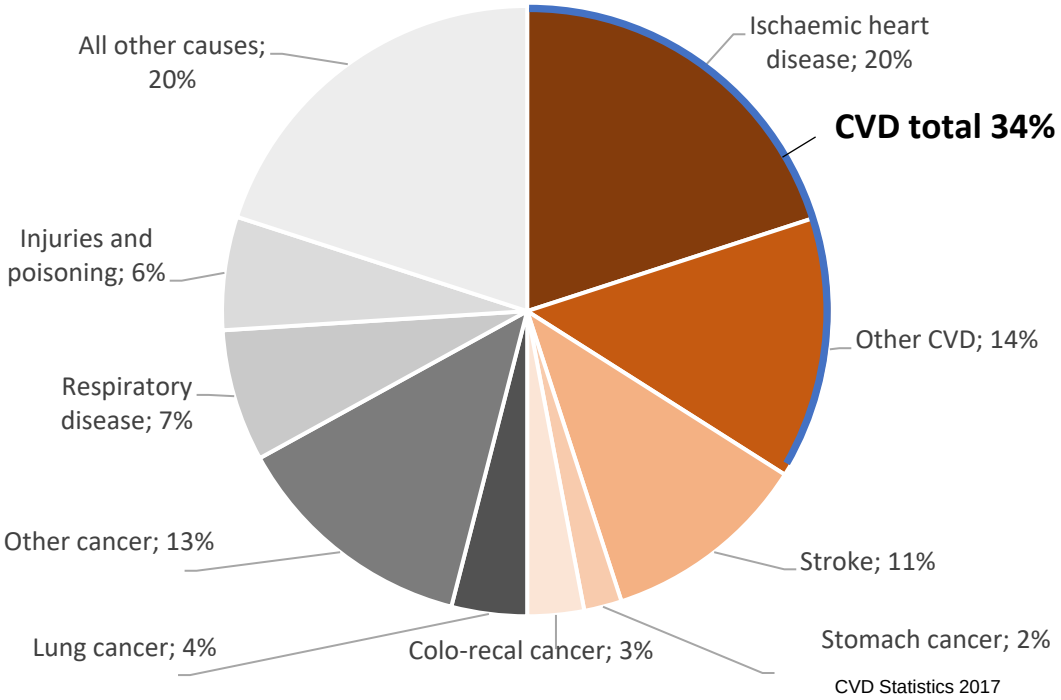
Rationale

- Cardiovascular diseases are the main contributors to global morbidity and mortality responsible for 34% of global deaths



Distribution of CVD burden in EU population (CVD Statistics 2017)

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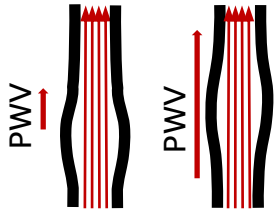
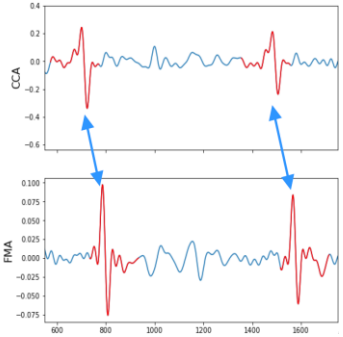
Rationale

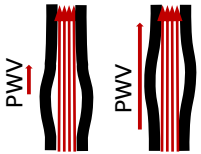
- There is a huge interest in deploying the optimal diagnosis to institute a timely preventative therapy among those individuals considered to be at low or moderate risk according to current guidelines.
- Three important **CVD risk factors** are:
  - Carotid-femoral PWV as a measure for arterial stiffness
  - Arterial stenosis
  - Dyssynchrony or abnormal cardiac contraction patterns

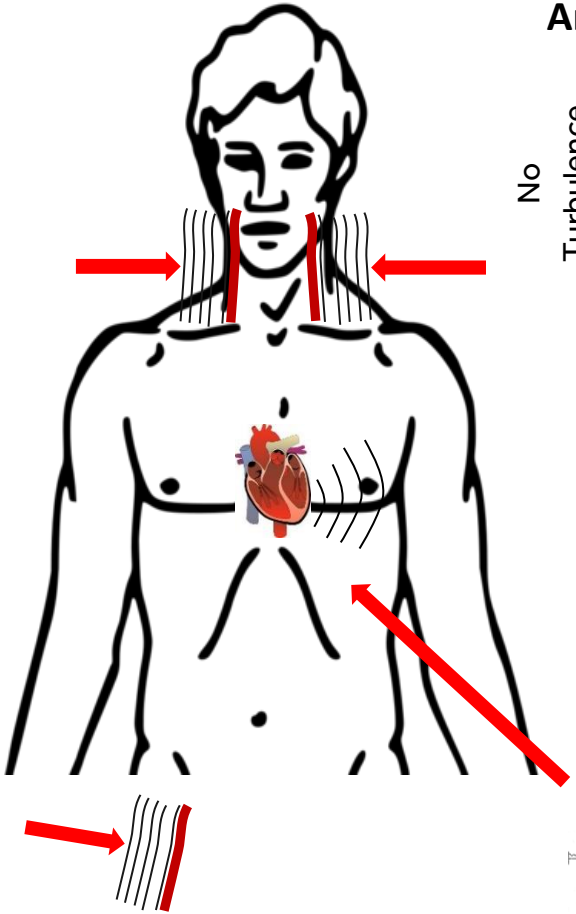
Working Principle

Arterial Stiffness

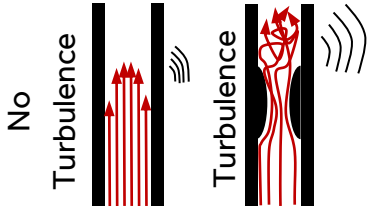


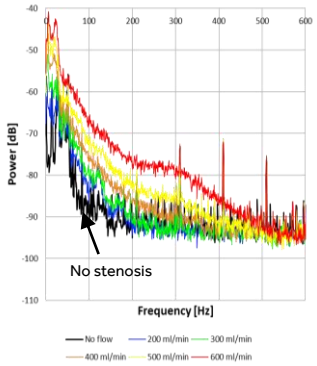






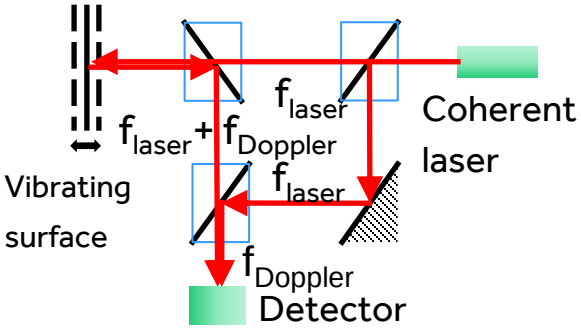
Arterial stenosis





Heart dyssynchrony

Mach-Zehnder interferometer



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Overall objective

- The objective of InSiDe is to provide access for the medical community to a new diagnostic device, based on a silicon photonics integrated homodyne laser interferometer, able to identify and characterize different stages of cardiovascular diseases proving its efficacy to drive an indicated therapy institution and to monitor its follow-up, in order to reduce the healthcare costs and improve patient's outcome.

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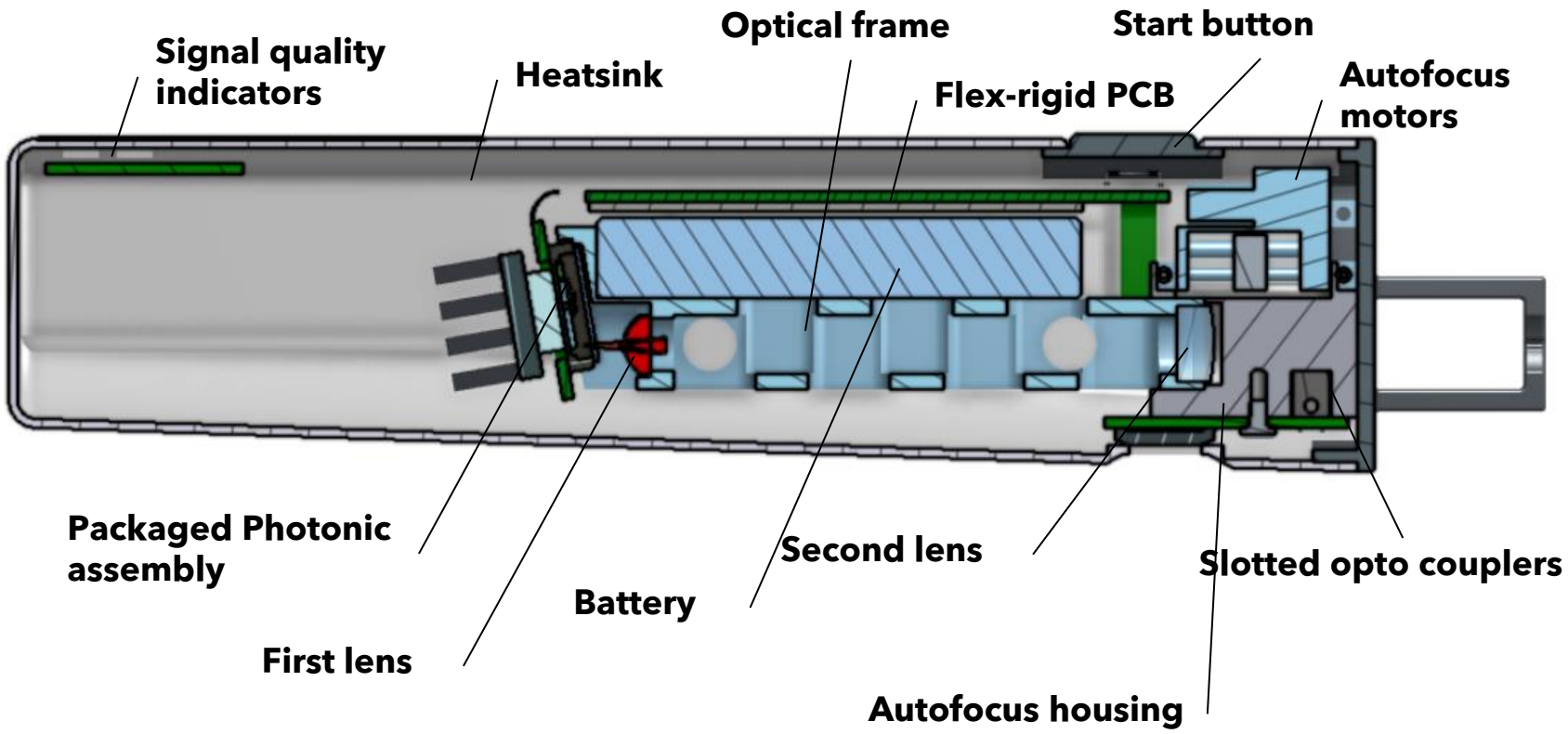
Specific objectives

- Development and release of a true handheld wireless clinical investigational device.
- To demonstrate in clinical feasibility studies with the developed clinical investigational device that it is useful for GPs and cardiologists.
- The target for the developed InSiDe device is a handheld, battery-operated split device, which can be operated as one unit as well as two separate units and can conduct timed recordings in order to derive pulse transit times between traces recorded with the two units.

Scientific and technological objectives

- Development of a performing LDV chip for 4 sensing locations.
- Development of a robust photonics system with micro-optical bench integrated on a silicon photonic chip and manufacturable package with integrated imaging optics.
- Development of electronics for control of the laser interferometer with onboard near-realtime signal processing capability.
- Development of algorithms for translation of the interferometer signals to measurement results relevant for monitoring and diagnosis of selected cardiovascular.
- Development of a clinical investigational device that can be used for clinical feasibility studies.
- Validation of the technology for 5 cardiovascular diseases/conditions.
- Outline path to industrialization and manufacturability.

Overall concept



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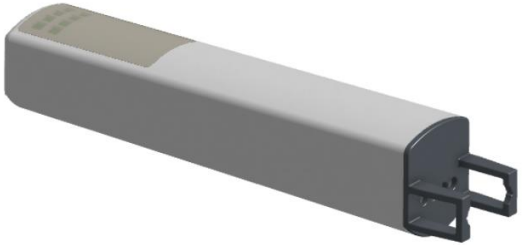
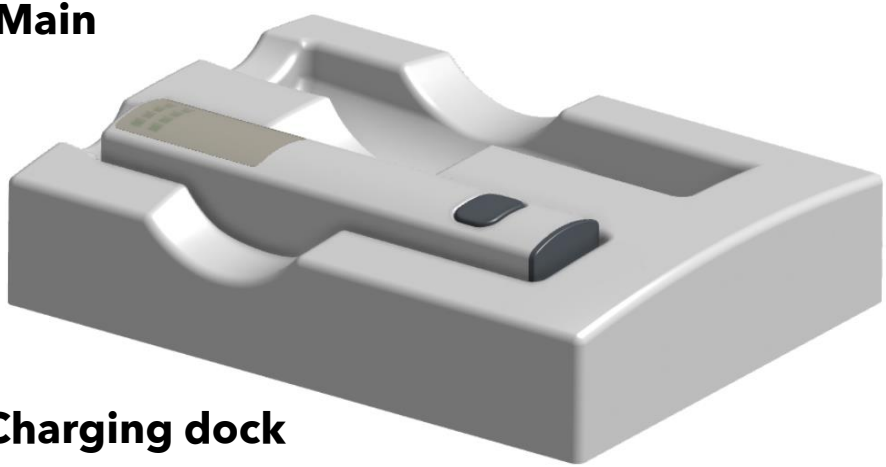
Overall Concept

Secondary

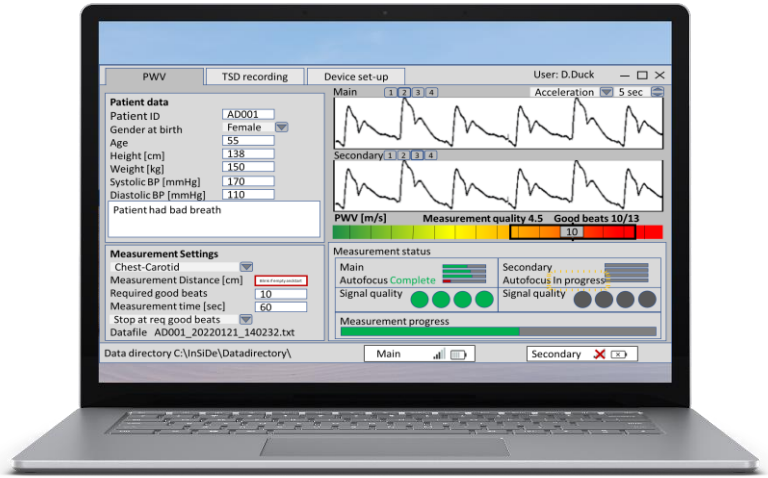


Main



Charging dock

Handheld, battery-operated split device, which can be operated as one unit as well as two separate units and can conduct timed recordings in order to measure pulse wave velocity, arterial stiffness and cardiac contraction patterns.



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Overall concept

- Device based on a 4-beam laser Doppler interferometer in each demonstrator half part.
- 1300nm operation to assist direct measurement on skin
- Silicon-on-Insulator photonics technology used to manufacture the 4-beam LDV chip.
- Integrated spacer for robust measurement of the targeted cardiovascular feature (superficial artery, chest cage for heart contraction patterns).
- Wireless connection between devices and to external computer/smart phone
- Interferometer control and signal processing and algorithms integrated in the handheld device
- Touch screen interface.

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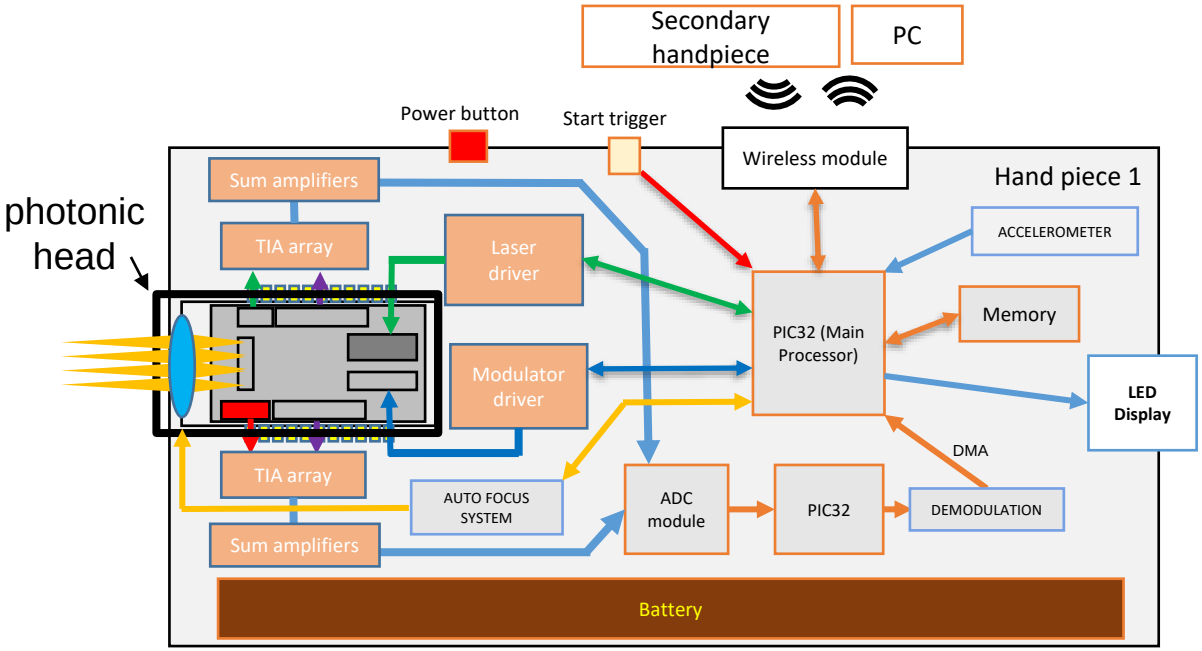
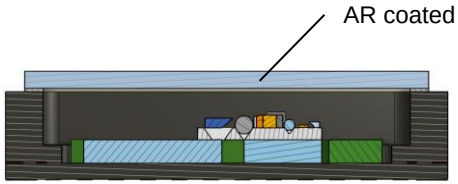
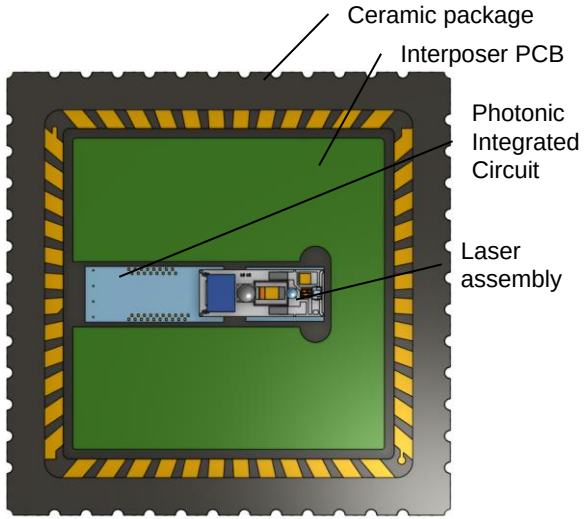
Overall concept

System diagram of Main handpiece and schematic showing the main components in the photonic package.







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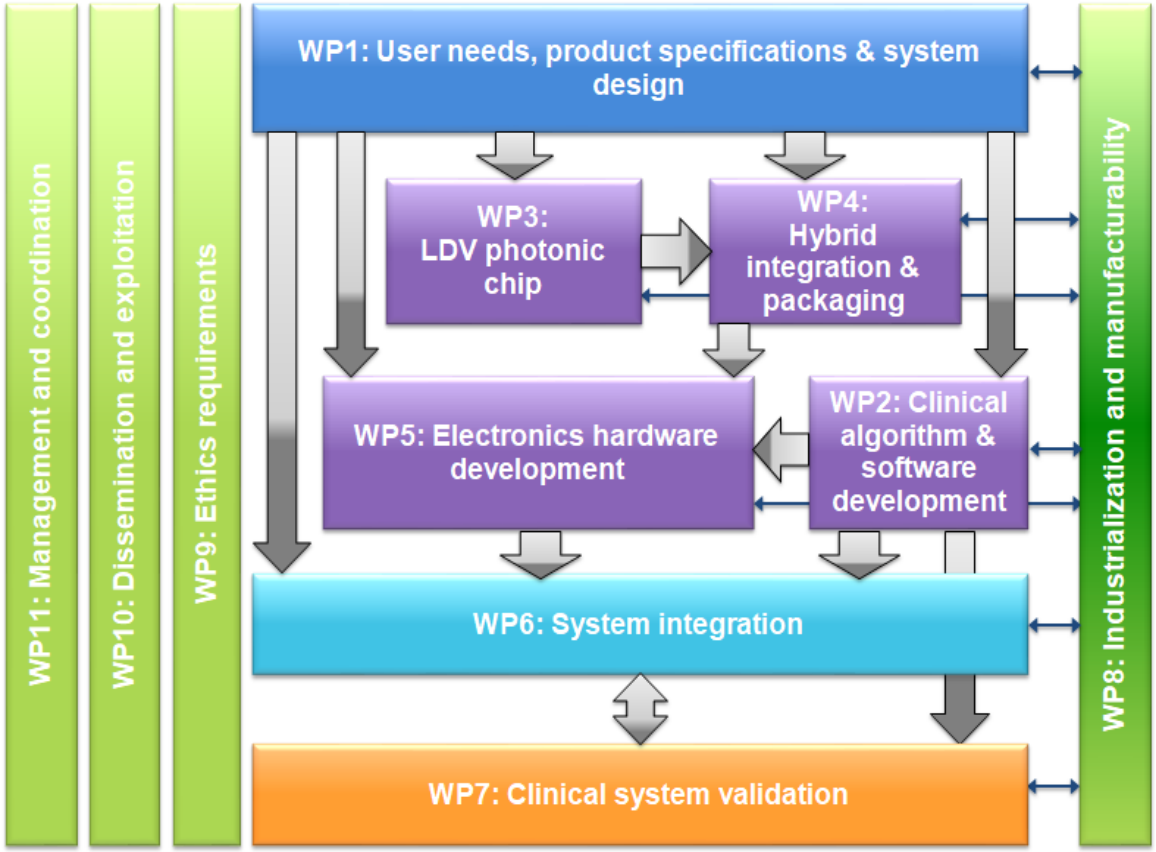
Project structure



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WP1 - User needs, product specs, system design

- Define the user requirements and translate to system specifications ✓
- Conduct overall system design ✓
- Steer the S&T activities to be consistent with end-user requirements ✓
- Detail regulatory pathway for a first product

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- Update the CARDIS data-acquisition software with real-time visual feedback on acceleration signals and beat detection
- Demonstrating the feasibility and validation of LDV-measured heart-carotid pulse wave velocity as a biomarker of ascending aorta stiffness
- Demonstrating the feasibility and validation of LDV-measured chest motion as biomarker of cardiac contraction and abnormalities in heart valves
- Demonstrating the feasibility and validation of LDV measurements to assess carotid artery stenosis
- Real-time assessment of carotid-femoral Pulse Wave Velocity, heart-carotid Pulse Wave Velocity, cardiac contraction and valve abnormalities using Laser-Doppler vibrometry

WP3 – LDV photonic chip development

- Design, fabricate and characterize an LDV PIC for 1.3 µm light ✓
- Design and fabricate a working optical system ✓
- PIC design to ensure that light signals with a total power of at least 20 mW can be sent into the PIC without a strong insertion optical loss (<3dB) in the waveguide sections of the LDV PIC
- The performance of the LDV PIC should be robust against normal chip fabrication deviations ✓

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WP4 – Hybrid integration and packaging

- Design of an MOB that is compatible with a scalable fabrication and integration approach ✓
- Development of a scalable and volume compatible MOB assembly and integration process ✓
- Develop a prototype photonic sub-system for use in early electronic system and clinical tests ✓
- Develop a final photonic sub-system that is scalable and compatible with volume production

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WP5 – Electronics hardware system development

- Design of a two-part electronic system for data collection, processing and synchronization of results ✓
- Develop an analogue preconditioning circuit to convert signals from the photonic device into digital format ✓
- Develop a circuit to process and store data ✓
- Develop a circuit to synchronize the two hand pieces of the InSiDe demonstrators
- Develop a circuit to charge the internal batteries of the InSiDe demonstrators ✓

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WP6 – System integration

- Deliver two additional samples of the CARDIS Demonstrator device ✓
- System integration of two generations of InSiDe clinical investigational device (InSiDe-α and InSiDe-β)
- System verification and release of the InSiDe-α and InSiDe-β clinical investigational devices

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WP7 – Clinical system validation

- Proof-of-principle validation of LDV measurements in patients for assessing 1) carotid artery stiffness, 2) carotid artery stenosis, 3) cardiac contraction and 4) cardiac valve dysfunction.
- Clinical validation will be conducted using the CARDIS system from M1 to M28, with the InSiDe-α prototype system from M28 to 42 and with InSiDe-β optimized version from M43 to M48
- Generation of a research & evidence roadmap for further internal and external clinical validation for multiple indication.

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- Evaluation of design for volume manufacture.
- Supply chain, cost analysis and market value assessments.
- Environmental and life cycle assessment.

Consortium partners

imec	Imec is a world-leading independent research center for nano electronics and nano technology. Imec's research bridges the gap between fundamental research at universities and technology development in industry.
Medtronic	Medtronic is the world's largest medical technology company, offering a wide range of innovative therapies within the fields of cardiac and vascular diseases, diabetes, neurological and musculoskeletal conditions.
GHENT UNIVERSITY	Universiteit Gent (UGent) is the 2nd largest university in Belgium. Participating labs are the Photonics Research Group (optics and chip technology), IBiTech-bioMMeda (arterial mechanics and physiology) and IDLab (signal processing expertise).
Tyndall National Institute	Tyndall has a long and successful track record in participating in and coordinating EU projects. A key focus within these projects is the development of silicon photonic-based technologies, where Tyndall is a principal packaging partner.
POLITECNICO DI TORINO	For 160 years, Politecnico di Torino has been educating engineers, architects, designers and urban planners with integrity, a rigorous approach and according to high quality standards. These professionals have been playing an important role in the growth of our city, our industry and our country.

Consortium partners

MICROCHIP	Microchip Technology Caldicot Ltd is a leading provider of smart, connected and secure embedded control solutions. The company's solutions serve more than 120.000 customers across the industrial, automotive, consumer, aerospace and defense, communications and computing markets.
ARGOTECH	Mission of Argotech is to provide worldwide customers manufacturing services, customized product design and process development, engineering services and consulting in the field of optics, electronics and mechanics.
Inserm La science pour la santé From science to health	INSERM is a French public scientific and technological institute dedicated to biomedical research and human health. Among the most prestigious research institutions in the world, it is involved in the entire range of activities from the laboratory to the patient's bedside. One of these teams is dedicated to clinical research concerning large arteries. INSERM is associated with Université de Paris, which has a strong dominance in biology, medicine and biotechnology.
Maastricht University	Universiteit Maastricht has 5 faculties, including Health, Medicine and Life Sciences (FHML). This latter faculty is linked to the Maastricht Universitty Medical Center (MUMC). FHML and MUMC are dedicated to cardiovascular diseases.
Fundi€o	Fundico is a consultancy company with the objective to assist industrial companies and research organisations with the submission of financing R&D proposals and the management and coordination of these R&D projects in case of financing.

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Questions?

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