CSD LABS - COMPUTATIONAL SIGNAL DETECTION - (AUSTRIA)

CSDlabs®
COMPUTATIONAL SIGNAL DETECTION

About CSD Labs

Computational Signal Detection Laboratories (CSD Labs®) develops high-end medical software using state of the art engineering approaches in combination with in-house pioneering research. Specialized in the analysis and classification of complex data, CSD Labs offers clinically verified medical software for the objective, automated detection of heart defects. The portable technology solution was developed in close collaboration with medical experts and assists physicians in performing auscultation during their daily routine.

Winner of international MedTech award

CSD Labs wins the special MedTech award at the seventh international business plan competition "Best of Biotech". The competition awards excellence in the areas of life science and medical technology, is organised by Austria Wirtschaftsservice GmbH (aws) and commissioned by the Federal Ministry of Science, Research and Economy. In total, 30 projects with economic potential from six countries were selected by an international jury comprised of experts from the fields of industry, finance and economics. In the end, CSD Labs was awarded the prestigious prize worth EUR 10,000.

Our Mission

CSD Labs'® core principle is to develop medical software under stringent medical device regulations in order for it to be successful and fulfill its potential and promise. In our experience, common state-of-the-art approaches to algorithm-based murmur detection do not withstand blinded testing of real-world, noisy clinical data. This is why we have developed novel approaches to meet the highest standards in computer-aided auscultation (CAA). Performing costly clinical trials on hundreds of patients has allowed us to determine and improve the performance characteristics (sensitivity, specificity, etc.) required to develop a high-end medical product that will meet the needs of clinicians, patients, and health care providers.

Background

Heart auscultation (derived from the Latin verb auscultare meaning "to listen") with a stethoscope is the standard examination method worldwide in the screening of heart defects and related cardiovascular problems. It is used by medical professionals on patients of all ages for the purpose of identifying pathological heart sounds.

Problems

Auscultation is often referred to as an art, since a correct diagnosis can be challenging for various reasons and is exclusively dependent on the medical professional's qualifications. The practice has not changed in the last 200 years and objective evaluation tools are lacking. This inevitably creates issues concerning consistency, accuracy and objectivity, and creates increased risk of human error and associated legal vulnerabilities.

Across the board, traditional auscultation is problematic for all stakeholders: for **medical professionals** who are often faced with high heart rates, unsettled patients, breathing and other noises, proper auscultation can be difficult and stressful. For the **patient**, delayed or failed diagnoses can lead to long waiting times, cumbersome procedures, neurological damage, additional life-long medical care,

emergency surgery or even result in sudden death. **Health care providers** are faced with having no objective documentation of auscultation, are often left legally vulnerable, and experience high rates of unnecessary specialist referrals, all of which result in significant financial burdens.

Solution

The solution to these problems can be found in CAA, a clinical decision support system designed to assist medical professionals in identifying pathological heart sounds. For example, Aetna, an American health insurance company, succinctly quantifies the situation in their 2013 clinical policy bulletin on Acoustic Heart Sound Recording and Computer Analysis: "*Unfortunately, accurate interpretation of heart sounds by primary care providers is fraught with error, leading to missed diagnosis of disease and/or excessive costs associated with evaluation of normal variants. Thus, automated heart sound analysis, also known as CAA, has the potential to become a cost-effective screening and diagnostic tool in the primary care setting.*"

Need

Currently the lack of clinical proof is one of the main obstacles for health care providers in supporting computer-assisted auscultation (CAA). For example, the Blue Cross considers CAA to be "*investigational*" and states in their 2011 policy that "*There is inadequate evidence of the validity of computer-aided electronic auscultatory devices, or their impact on clinical outcomes in the peer-reviewed published medical literature.*" Further, the Blue Cross remarks that "*Clinical studies are necessary to determine the performance characteristics (sensitivity, specificity, and predictive values) of computer-aided electronic auscultatory devices and their impact on clinical management and patient outcomes*." Similar statements have also been published by UnitedHealthcare in 2013, the largest single health care provider in the United States.

Innovative Leaders in Computer Aided Auscultation

CSD Labs® develops high-end medical software using state of the art engineering approaches in combination with in-house pioneering research and clinical data. A team of highly qualified biomedical engineers, lead by an international management team experienced in business development, strategy and technology, together with an accomplished medical advisory board ensure expertise in

- heart sound analysis
- decision support systems for diagnosis
- workflow-integrated documentation
- medical device-regulated quality management
- regulatory approval processes
- technology commercialization

The combination of patent pending technologies, clinical studies and close collaboration with medical professionals makes CSD Labs the innovative leader in heart sound analysis that will bring computer-aided auscultation to the market.

Technology

Heart sounds are sophisticated and complex biological signals, which become even more complex to analyze because they are usually concealed by a lot of noise and other sounds (like breathing, moving, crying, etc). Therefore, the commonly used signal analysis methods generally do not suffice in producing a diagnosis-supporting result that is continuously robust enough to be used by medical professionals in their daily work. At CSD Labs the most advanced research is combined with newly developed approaches, resulting in more accurate and reliable results for all age groups, ranging from premature newborns to the elderly. Moreover, CSD Labs supports medical professionals in their workflow by

providing them with tools to easily document and integrate their findings into the hospital information system.

Product Focus

Creating a high-end medical device for computer-aided murmur detection requires more than just cutting edge algorithms. CSD Labs keeps the final product as the focal point of all operative management decisions, ensuring that software, hardware, usability and workflow integration come together seamlessly. The product development adheres to all aspects of medical device regulations, including quality management, risk management and software development lifecycle management. The patient's safety, improved diagnosis and optimal usability are top priorities, ensured through continuous feedback from clinicians.