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| **Wireless Batteryless Implantable Medical Products** ISSYS  http://www.mems-issys.com/implantable.shtml One of the most important applications for this product family is Congestive Heart Failure (CHF) due to its clinical significance and large market. CHF patients have a damaged or overworked heart that cannot pump sufficiently to meet the metabolic demands of the body or can do so only with an elevated ventricular diastolic pressure. Secondary pulmonary edema occurs with the most severe cases of CHF.  Identified by the NIH [link] as the latest epidemic to hit the U.S., CHF is a major health problem worldwide, affecting 4.8 million U.S. patients and accounts for 978,000 or 5-10% of all hospitalizations. Some estimates show 550,000 new cases of CHF diagnosed each year in the U.S. alone. Currently, CHF accounts for 20% of all discharges in the over age 65 category; with the ageing demographic, this statistic is expected to increase significantly. Overall, the cost of treating CHF is very high ($38 billion annually in the U.S., representing 5.4% of total health care costs) and involves many physician visits (at least 11 million ambulatory visits per year). From 1979 to 1999, CHF deaths increased 145% and hospital discharges increased 155%. The fatality rate for CHF is high, with one in five persons dying within 1 year, more than half of the CHF patients dying within 5 years, and sudden death occurring at a rate of six to nine times that of the general population. One in five of all discharged patients age 65 and older had CHF as a primary or secondary diagnosis. A person age 40 or older has a one-in-five chance of developing congestive heart failure, according to a study published in Circulation: Journal of the American Heart Association [link]. Many patients suffering from this progressive, fatal disease tend towards an extremely poor quality of life and become increasingly unable to perform routine daily tasks.  CHF is mostly treated with medication in a very delicate manner to provide a balance between cardiac output (CO) and left ventricular end diastolic pressure (LVEDP). A major problem facing the effective treatment of CHF via ongoing tailored medication is the lack of a safe, low cost, easy method to regularly collect patient's medical data needed to maintain the balance between CO and LVEDP over time.  Currently, the treatment of CHF is mostly monitored to the best of physicians' capabilities through symptom evaluation, observational assessments, and echocardiography. Dr. Achi Ludomirsky, Director of Division of Cardiology, Department of Pediatrics, Washington University School of Medicine, summarizes the current CHF management as the observation of rudimentary parameters: "The physiologic parameters being used today in order to tailor home monitoring and management of CHF are patient weight, heart rate, and blood pressure". Observation of rudimentary physical symptoms (e.g., patient's weight) is low cost and possess no procedural risk; it is, however, medically very ineffective and results in a high risk of wrong dosage." | |  | | --- | | http://www.mems-issys.com/images/wireless4.jpg | | http://www.mems-issys.com/images/wireless9.jpg | |

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| **ISSYS Solution**   ISSYS introduces a novel technology that will provide safe, chronic, fast, detailed, real time, continuous, cardiac pressure measurements, and supports the trend towards home health monitoring, with the potential to revolutionize the way CHF patients are treated. The pressure monitoring system consists of two major parts: an implantable, batteryless, telemetric sensor and a companion hand-held reader. The miniature implantable micro-device contains a MEMS (MicroElectroMechanical System) pressure transducer along with custom electronics and a telemetry antenna. Using magnetic telemetry, the reader transmits power to the sensor and the sensed pressure is in turn transmitted back to the reader. Data collected by the sensor will be used by physicians to tailor CHF treatment. Such data collection can be performed at the doctor's office, or at home by the patient and submitted over the telephone or net. The major advantages of ISSYS wireless, implant approach include:   * Home care use of the system and transfer of the data to the physicians via telephone line or web network * Potential for remote testing to determine whether there is an emergency * Much faster response time * Much more detailed information for better diagnosis and thus improved tailored treatment * Lower cost * Capability to distinguish the effects of multiple diseases * Ease of use * Potential for expanding the benefits to other cardiovascular diseases.   According to many cardiologists, ISSYS implantable sensors contribution to the field of cardiology will be tremendous since these wireless, batteryless, miniature implants (1) are safe for chronic use, (2) can be delivered via a catheter in an outpatient procedure, and (3) can monitor an associated pressure in a continuous, real-time, detailed, fashion. | |  | | --- | | http://www.mems-issys.com/images/wireless8.jpg | |

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**Wireless Implantable Medical Products**   
  
ISSYS is developing wireless MEMS-sensor-based systems to enhance the quality of medical treatment with the following micro-devices:

* [Wireless, Batteryless Cardiac Sensor](http://www.mems-issys.com/implantable.shtml)
* [Wireless, Batteryless Intracranial Sensor](http://www.mems-issys.com/implantable_intracranial.shtml)

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| http://www.mems-issys.com/images/probepenny1.jpg Wireless Implantable Medical Products |  |  |
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| Wireless medical devices are improving the way physicians monitor their patients; the ISSYS wireless medical product family will greatly advance the trend toward home health monitoring and higher-quality diagnostics. ISSYS sensors are being developed for both long-term management of chronic disease and for short-term post-operative and diagnostic care. These sensors will provide powerful measurements unobtainable with current clinical devices.  ISSYS has focused primarily on two applications:   * Cardiac monitoring to manage congestive heart failure and pulmonary edema * Intracranial monitoring to manage hydrocephalus and brain trauma.   Due to the highly enabling nature of the core technology, ISSYS also collaborates with researchers in other clinical areas where monitoring physiologic pressure is of great importance.  The pressure monitoring system consists of two major elements:   * an implantable, batteryless, telemetric sensor and * a companion hand-held reader.   The core technology of the implantable micro-device is the MEMS\* pressure transducer. Using magnetic telemetry, the reader transmits power to the sensor and the sensed pressure is in turn transmitted back to the reader. Small size, optimized shape, and careful choice of materials ensure implant biocompatibility and non-thrombogenicity. Data collected by the sensor will be used by physicians to tailor treatment of the selected disease.  *\*MEMS = Micro-ElectroMechanical Systems* | | |