

## Press Release

### **SORIN GROUP ANNOUNCES THE FIRST INCLUSION IN THE CLEPSYDRA CLINICAL STUDY IN THE US**

***The Clepsydra study will evaluate the effectiveness of PhD™, a new sensor-based function designed to monitor patient clinical status.***

**Paris, December 2<sup>nd</sup>, 2009** – Sorin Group announced today the first inclusion of a patient in the Clepsydra clinical trial. The study will investigate the sensitivity to changes in heart failure status of PhD™, a unique diagnostic feature using the dual sensor technology of minute ventilation and accelerometer to monitor patient's breathing and activity levels every day. The algorithm aims to provide physicians with both trends and indicators in order to highlight sustained changes in overall health status that could relate to heart failure (HF) evolution.

PhD™ is available in the Paradym™ family of Implantable Cardioverter Defibrillators (ICD) in Europe and under clinical evaluation in Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-D) in Europe and US.

According to the American Heart Association (AHA) and the European Society of Cardiology (ESC) Guidelines, heart failure currently affects about 5 million Americans and 15 million people in the 35 countries under the auspices of the ESC.

Heart failure is the most common Medicare diagnosis-related group (hospital discharge diagnosis), and more Medicare dollars are spent for the diagnosis and treatment of HF than for any other diagnosis. In Europe, HF accounts for about 2% of national expenditures on health.

As the severity of HF can fluctuate and drug therapies adjusted to improve the patient's condition, it is important to monitor recognised indicators of disease progression to prevent the patient being hospitalized. PhD™ measures activity workload and ventilation at rest and exercise, which are two key measurements to indicate that a patient's heart failure condition is progressing. The Clepsydra study will test the PhD™ algorithm that is designed to give advance notice of sustained deterioration. Advanced warning at follow-up could give physicians time to intervene in the patient's treatment to avoid the costs and patient burden associated with hospitalization.

The Clepsydra study, will evaluate PhD™ in 550 patients to be enrolled in the US and Europe. Patients will be closely monitored over a minimum of 13 months by hospital visits and by telephone checks.

The first implant was performed by Andrew J. Kaplan, MD, cardiac electrophysiologist with CVAM, CardioVascular Associates of Mesa, at Mountain Vista Medical Center in Mesa, Arizona, USA.

Dr. Kaplan noted, "Tracking and managing heart failure progression in our patients is complex and time consuming. The Clepsydra study should help us better predict and intervene earlier in the heart failure process through evaluation of the data collected by the PhD™ sensor-based function. The implantation in our first patient was smooth and the device performed well".

“Our vision is to provide new and innovative tools to physicians and relieve the burden of heart failure for all stakeholders. Monitoring of the patient physiological status (PhD) is an important step to giving physicians an accurate guide to optimizing heart failure therapy and avoid costly hospitalizations. The Clepsydra study highlights Sorin Group’s commitment to backing our leading technologies with large scale clinical justification”, said Stefano Di Lullo, President of Sorin Group Cardiac Rhythm Management (CRM) Business Unit.

**About the Sorin Group**

The Sorin Group ([www.sorin.com](http://www.sorin.com)), is a global medical device company and a leader in the treatment of cardiovascular diseases. The Company develops, manufactures and markets medical technologies for cardiac surgery and for the treatment of cardiac rhythm disorders. With 3,500 employees worldwide, the Group focuses on three major therapeutic areas that include: cardiopulmonary bypass (extracorporeal circulation and autotransfusion systems), cardiac rhythm management, and heart valve repair and replacement. Every year, over 1 million patients are treated with the devices of Sorin Group in more than 80 countries.

For more information, please visit: [www.sorin.com](http://www.sorin.com), or contact:

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