



## *News Release*

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### **Redsense Medical Receives FDA Marketing Clearance for Blood Loss Detection Device**

**Seattle, WA - November 1, 2007** - Redsense Medical's blood loss detection device for monitoring venous needle dislodgement. The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing continuous hemodialysis treatment up to 5 hours in the clinical setting. The Swedish company's patented Redsense blood loss detection system is the first to enter the U.S market. Having met Europe's rigorous health and safety standards, the device has already been granted CE approval. Redsense Medical is the first to market a blood loss device of this kind in the U.S.

About 1.5 million patients worldwide receive over 200 million dialysis treatments every year. The size of the market is forecast to increase due to an aging population and the rise of diseases such as type II diabetes.

Medical professionals have long been aware of the risk of venous needle dislodgement during dialysis treatment. In the U.S. alone, 7 to 10 patients die each year due to needle dislodgement. It is feared that the true death rate is 3 to 4 times higher than reported. The total number of serious incidents is estimated to be in the thousands [1].

"Blood loss resulting from disconnection of the venous needle during hemodialysis is a potentially serious event. Redsense has developed an ingenious device to provide prompt warning when this adverse event occurs," said recognized hemodialysis expert Dr. Christopher R. Blagg, Professor Emeritus of Medicine, University of Washington.

Until now, the typical method of needle dislodgement detection for this common form of renal therapy has been venous pressure monitoring, a built-in function of all dialysis machines. However, incidents have been reported whereby significant blood loss occurred before the venous pressure alarm sounded, resulting in serious, even fatal consequences [2, 3].

Developed in response to demands made by dialysis professionals, Redsense is intended to increase patient safety and thus become a vital aid to the dialysis caretaker.

“Even with careful monitoring by dialysis professionals, needles do become dislodged, and significant blood loss can occur before dislodgement is detected.” Patrik Byhmer, CEO of Redsense Medical, explains. “Other monitoring systems rely on blood pressure or moisture detectors and can be unreliable. The Redsense blood loss detection device has been clinically tested and is proven to be reliable. [4] Patients can change position or rest and feel more comfortable that the alarm will sound if their needle becomes dislodged. For care providers, this device may offer freedom to move more freely around the unit. “

Redsense consists of two parts: a sensor patch and an alarm unit. An infrared signal is transmitted from the alarm unit to the sensor patch using fiber optic cable. In the event of bleeding, inner layers of the patch smear blood over the optical sensor, which is designed to trigger the alarm. Redsense doesn't react to perspiration or water, so moisture alone will not cause an alarm. And because the signal to the sensor is continuous, the alarm reacts instantly to the first milliliter of blood. Nurses and doctors have increased freedom to focus on the tangible problems of hemodialysis.

### **About Redsense Medical**

After a number of incidents with venous needle dislodgement during hemodialysis at a dialysis clinic in Sweden , the clinic's technicians contacted a company specializing in medical technology. This cooperation between medical staff and engineers resulted in the startup of Redsense Medical in 2006. Redsense Medical has offices in Sweden and in the U.S. (Seattle, WA). For more information, contact Redsense Medical Ltd., 1750, 112th AVE NE #E170, Bellevue, WA, 98004; Phone: (425) 503 8188; Fax: (425) 688 0813; Email: [info@redsensemical.com](mailto:info@redsensemical.com). Or visit the company's website at [www.redsensemical.com](http://www.redsensemical.com).

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[1] Sandroni, Stephen, "Venous Needle Dislodgement During Hemodialysis: An Unresolved Risk of Catastrophic Hemorrhage," *Hemodialysis International*, 2005, Jan; 9:102

[2] Polaschegg, H-D, "Neglected Safety Aspects in Hemodialysis and Their Related Problems," *Hemodialysis Horizons*, 2006

[3] "Undetected Venous Line Needle Dislodgment During Hemodialysis," *Health Devices* Nov 1998; 27(11):404-6

[4] " A new safety device for hemodialysis" Poster J Alhmén, Gydell KH, Hadimeri H, Hernandez I, Rogland B, Strömbom U. From the departments of Nephrology in Varberg, Halmstad, Skövde, Eksjö and Hässleholm, Sweden.