



**Sphere Medical Holding PLC**  
("Sphere Medical")

**Sphere Medical achieves FDA 510(k) clearance for its blood analyser**

**22 March 2011:** Sphere Medical (Cambridge, UK) the leading developer of innovative monitoring solutions for critical care, today announced that its IVD-GE02 blood analyser has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). The Sphere Medical device is the first ever multiple use, microchip-based blood analyser to achieve 510(k) clearance.

The blood analyser measures glucose, pH, carbon dioxide, oxygen and potassium ions in patient blood samples with performance equivalent to that of a standard clinical laboratory analysis which was demonstrated in extensive clinical trials. The device is based around Sphere Medical's silicon microchip which is approximately 4mm by 6mm and contains an array of microsensors that allow fast, accurate analysis of a panel of analytes simultaneously. Sphere plans to add further analytes to the panel, including haematocrit, lactate, sodium and ionised calcium which are currently under development. The IVD-GE02 analyser represents one of a number of products being developed on Sphere's proprietary microanalyser platform. These products will allow cost effective treatment in a number of clinical areas where there are significant unmet clinical needs in terms of patient monitoring and control.

Dr. Stuart Hendry, CEO of Sphere Medical added:

"It is extremely pleasing that Sphere has achieved this major milestone. The challenges to attaining 510(k) clearance for a product such as the IVD-GE02, that combines proprietary microchips, chemistry, software, hardware and novel manufacturing technologies, that all have to perform to recognised standards, are very rigorous indeed. Therefore, 510(k) clearance is testament to our technology and to Sphere Medical itself. Sphere Medical is at the beginning of a significant period of achievement as several breakthrough products in development will be brought to market over the coming year. This most recent success follows the launch of our Pelorus1000 the world's first commercial rapid propofol analyser which is receiving a great deal of clinical and commercial interest. This is a very exciting time."

**About Sphere Medical**

Sphere Medical is marketing and developing highly innovative monitoring products to provide clinical and economic benefits in the critical care environment, based on the company's proprietary microsensor technology. The products allow minimally invasive, real time measurement of clinical chemistry parameters and therapeutic drug concentrations, giving healthcare professionals the information they require to more effectively manage therapy and optimise patient outcomes. Sphere Medical was founded in 2002 and is based in Cambridge, UK.

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

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