

Press Release - For Immediate Release

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“High Voltage Brain Stimulation Reduces Risk of Surgically Induced Paraplegia” - Digitimer Electrical Stimulator Receives FDA Clearance.

Welwyn Garden City, UK (7th October, 2002) -- Digitimer Ltd announced today Food and Drug Administration (FDA) clearance for their D185 MultiPulse cortical stimulator. This is the first of a new generation of stimulators, which helps surgeons monitor a patient's central nervous system through high voltage stimulation of the brain during risky spinal surgery or repair of aortic aneurysms. This unique device allows surgeons to operate with an unprecedented level of confidence.

Surgical procedures carried out within or near the spinal column or those involving transient interruption of blood flow to the spinal cord (e.g repair of thoraco-abdominal aortic aneurysms) are associated with a risk of neurological impairment ranging from loss of sensation to complete paraplegia. These deficits can arise as a result of direct trauma, stretching of nerves or occlusion of blood flow. Until relatively recently, surgical teams have only monitored the status of ascending spinal pathways by applying stimuli to the patient's ankle or wrist and observing the resultant changes in somatosensory evoked potentials (SEP's) recorded from the brain. Changes in the SEP waveform can be used to alert medical teams of possible complications, however, this monitoring technique has attracted some criticism, much of which has been published in peer reviewed journals. In short, unchanged SEP waveforms have misled surgeons into continuing with surgery, resulting in unforeseen post-operative neurological complications. Likewise, altered SEP's have prompted surgeons to back-off from procedures, only to find that the patient has suffered no loss in sensory status upon recovery. In addition, as SEP's are generally small in magnitude, they can be difficult to monitor reliably in some patients, particularly those presenting with a pre-existing neuropathology.

Produced in the UK by Digitimer Ltd, an established medical electronics manufacturer, the D185 was designed to provide a better method of minimizing the risk of surgically induced injury to the spinal cord while maximizing the level of surgical correction that can be safely conducted. In contrast to the SEP technique, the D185 produces multiple high voltage pulses which stimulate the motor cortex, the region of the brain responsible for controlling voluntary movement of the arms and legs. This stimulation of descending pathways results in motor evoked potentials (MEP's) in the limbs, which as with SEP's can be continuously monitored throughout the course of surgery. However, a 1000 patient, 2 centre clinical trial of the Digitimer D185 in the USA, has demonstrated that MEP monitoring during spinal surgery was 1) more accurate for predicting motor outcome than was the SEP was for predicting sensory outcome; and 2) that useful Motor responses was achievable with a higher probability than useful Sensory responses. Furthermore, in cases where SEP monitoring alone may have misled the surgeon into aborting or curtailing a procedure, additional use of MEP monitoring can more reliably indicate whether it is safe for the surgeon to continue the procedure to completion.

Evidence from the 5 year study outlined above has prompted the FDA to clear the Digitimer D185 for marketing. It is hoped that with this announcement, the technique of intra-operative MEP monitoring will become more widely accepted by cardiovascular and neurosurgeons worldwide. Digitimer Ltd now offer the D185 stimulator to hospitals and neurophysiological monitoring organizations throughout the world.

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