



22 September, 2015

## **CORTICAL DYNAMICS' BAR MONITOR RECEIVES TGA CERTIFICATION**

Cortical Dynamics Ltd ("**Cortical**") is pleased to announce it has received formal notification from the Therapeutic Goods Administration ("**TGA**") that a decision has been made to issue a conformity assessment certificate to Cortical under section 41EC of the *Therapeutic Goods Act 1989*.

TGA certification will allow Cortical to market the Brain Anaesthesia Response ("**BAR**") monitor within Australia and via the TGA's mutual recognition agreement enable Cortical to apply for CE Marking to sell the BAR monitor in Europe.

### **About the BAR Monitoring System**

Cortical believes that the BAR monitoring system will offer many significant sustainable competitive advantages to key stakeholders including the patients, the anaesthetists, and the hospitals/day clinics. These advantages may reduce the risks associated with surgical procedures, increase levels of patient care, optimise the use of anaesthetic agents, increase efficiencies and reduce costs through a reduction in drug usage and a faster bed turn around in the theatre and post-operative recovery rooms around the globe.

The electrical activity recorded from the scalp, the EEG, is amongst the most important quantifiable measures of brain function. Unsurprisingly, EEG is used to monitor brain function in a variety of clinical situations such as neurological diagnosis, where the EEG is analysed for early signs of degenerative diseases, or within the operating room, where the EEG is used to indicate the depth of anaesthesia within the surgical patient.

Such monitoring is now gaining significant use during surgery, however even with the use of EEG monitors, it is not uncommon for there to be a critical imbalance between the patient's anaesthetic requirements and the anaesthetic drugs administered.

While a number of EEG monitors are commercially available, one that is reliably able to quantify the patient's anaesthetic state is still desperately needed.

To date, all of the existing EEG based depth of anaesthesia monitors operate in the context of a number of well documented limitations:

- Inability to monitor the analgesic effects; and
- Not all hypnotic agents are reliably measured.

The above limitations highlight the inadequacies in current EEG based depth of anaesthesia monitors, particularly given surgical anaesthesia requires both hypnotic and analgesic agents.

Cortical's philosophy is that a better understanding of the mechanisms that induce unconsciousness will ultimately lead to a better anaesthesia monitor. Cortical's BAR monitor, the product of this revolutionary

approach, is derived from a theoretical understanding of physiological factors that are responsible for the generation of the EEG activity and how the EEG is disrupted by anaesthetic agents.

This innovative method is able to distinguish changes in brain activity that occur as a result of anaesthetic action using two uniquely defined measures referred to as the Cortical State (“CS”) and Cortical input (“CI”). Utilising the Cortical’s proprietary indices CS and CI, data shows that analgesia and anaesthesia can be independently monitored.

Yours Sincerely



David Breeze  
Executive Director

## **About Cortical**

Cortical is an Australian based medical device technology company that has developed a next generation Brain Function Monitor. The company is focused on commercialising the intellectual property developed at Swinburne University. The core-product the Brain Anaesthesia Response (BAR) monitor has been developed with the objective of better detecting the effect of anaesthetic agents on brain activity, aiding anaesthetists in keeping patients optimally anaesthetised.

The BAR monitor improves on currently used electroencephalogram (EEG) technologies by incorporating the latest advances in our understanding of how the brain’s rhythmic electrical activity, the electroencephalogram (EEG), is produced. The approach used is fundamentally different from all other devices currently available in the market in that its underlying algorithm produces EEG indexes which are directly related to the physiological state of the patient’s brain.

The global brain monitoring market in 2012 was valued at \$1.08 billion and is poised to grow at a CAGR of 8.6% to reach \$1.63 billion by 2017. The global brain monitoring devices market is broadly segmented into three categories based on its product, application, and end-user. Fueling market growth is the various technological advancements which are leading to high functionality, lower costs, ease of operation, and miniaturization of devices.

Initial marketing in will focus on TIVA (Total Intravenous Anaesthesia), a method of inducing and maintaining general anaesthesia without the use of any inhalation agent. This is becoming more widely accepted, particularly in Western Europe.

Cortical's technology has a versatility that goes beyond depth of anaesthesia and may be applied to other EEG based markets, such as Neuro-diagnostic, drug discovery, drug evaluation and the emerging Brain Computer Interface (BCI) market.

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There are considerable opportunities offered by subsequent expansion of the company's core technology through developing the product to carry out additional functions including neuro-diagnostics of changes in brain and memory functions to provide early warning of degenerative diseases, pain response and tranquiliser monitoring for trauma patients in intensive care units.

The BAR monitor is protected by five patent families in multiple jurisdictions worldwide consisting 16 granted patents.



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