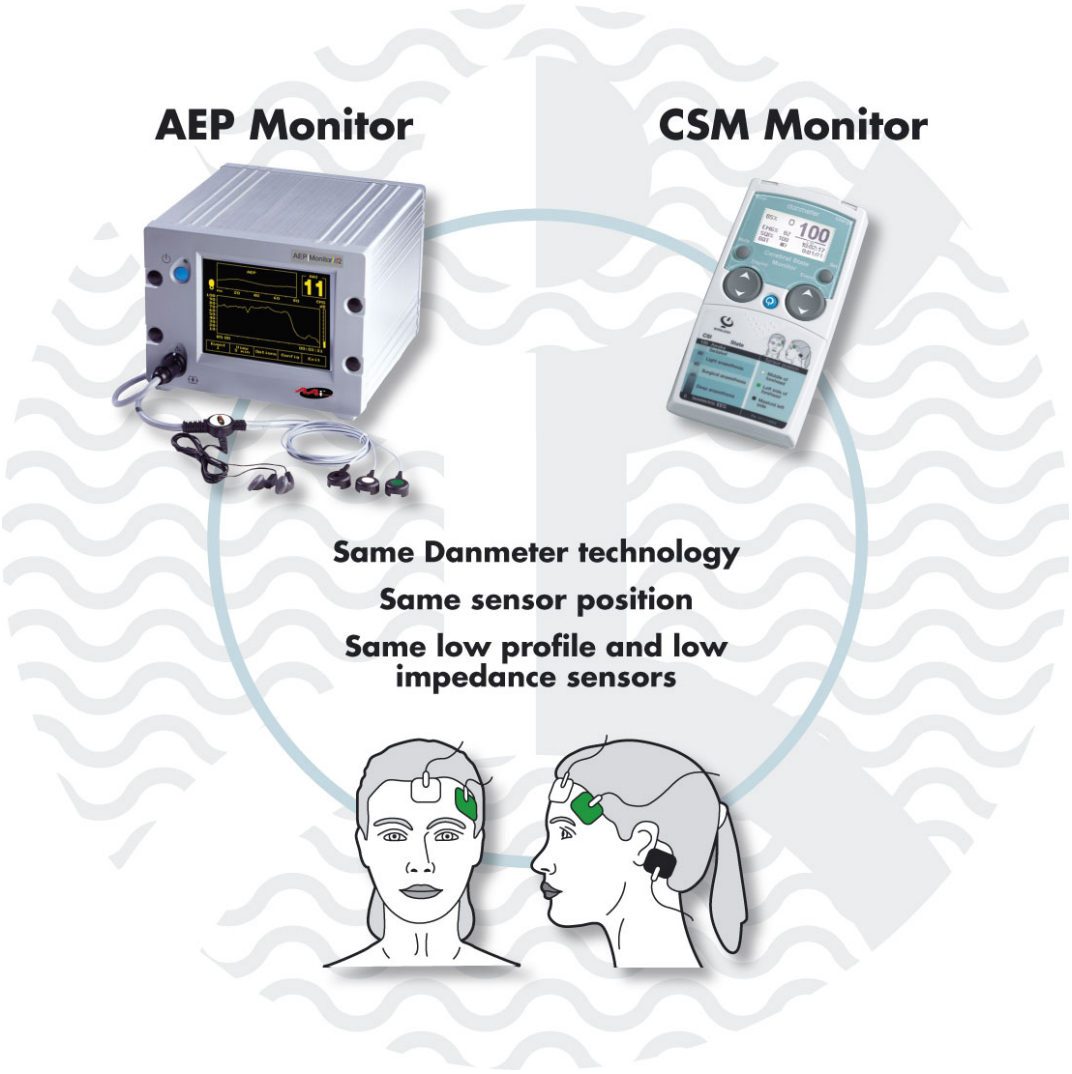
Danmeter LOC Technology



The CSM story

Introduction

The Danmeter level of consciousness (LOC) technology was commercially introduced in 2000[a] after research, development and clinical validation started in 1991. Enhanced signal processing, advanced artifact rejection and fuzzy logic constitute this cutting edge technology.

The Danmeter technology was originally implemented in the AEP Monitor (A-line Monitor, Alaris AEP Monitor, and AEP Monitor/2) and recently in the Cerebral State Monitor (CSM)[b]. The validity of the overall Danmeter technology has been documented in more than 100 peer reviewed publications[c]. The AEP Monitor requires active acoustic stimulation and the use of headphones in order to generate the Auditory Evoked Potential (AEP)[d]. This can be cumbersome in certain situations and on some types of surgery. The core technology has therefore been moved to the Cerebral State Monitor™ (CSM) platform where headphones are not needed. The advantage of the CSM platform is the portability, one-touch hand held operation and wireless communication. The specifications of the technology are shown in the table below.

Specification	AEP Monitor	CSM Monitor
The purpose of the monitor is to assess the level of consciousness during general anaesthesia and sedation.	Yes	Yes
Fuzzy logic based index	Yes	Yes
Independent of base line calibration	Yes	Yes
Sensor-to-skin impedance measurement	Yes	Yes
Uses three Danmeter neuro sensors	Yes	Yes
Sensor position middle forehead-lateral forehead-mastoid	Yes	Yes
Electroencephalogram (EEG)	Yes	Yes
Electromyogram (EMG)	Yes	Yes
Burst Suppression (BS)	Yes	Yes
Betaratio	Yes	Yes
Level of consciousness scale 0-100	Yes	Yes
Trend of parameters	Yes	Yes
Advanced Artifact rejection algorithm	Yes	Yes
FDA 510(k) clearance based on substantial equivalence.	Yes	Yes

[a] CE-mark May 2000, FDA (510)k April 2002.
[b] CE-mark April 2004, FDA (510)k February 2005.
[c] Updated list of publications available on www.danmeter.com
[d] Full descriptions of AEP and CSM with product specifications are available on www.danmeter.com

Additionally, the Danmeter technology provides software for graphing, advanced analysis and documentation of both the index of the AEP-monitor, termed A-line ARX-Index (AAI) and the index of the CSM, termed Cerebral State Index (CSI).

Development of the Cerebral State Index (CSI)

Most commercially available LOC monitors use sub parameters of the electroencephalogram (EEG) such as AEP, beta-ratio, alpha-ratio, Spectral Edge Frequency and Burst Suppression.

Studying the literature gives strong evidence that the AEP is the most reliable parameter for assessing LOC. This is particularly advantageous in detection of nociception and it was shown in various independent works [1,2,3,4] that the Danmeter AEP derived index, termed AAI, detected the response to noxious stimuli while this was not the case for the Bispectral index (BIS). These results have been corroborated in other studies.

The AAI is a composite index consisting of the AEP, β-ratio and Burst Suppression percentage (BS) parameters.

The Cerebral State Index (CSI) was carefully crafted by using the Danmeter EEG database[e], which also served as the foundation for the development of the AEP monitor. The objective was to design an index where the Danmeter technology advantages and the proven sensor position were maintained in an easy to use device without acoustic stimulation (headphones).

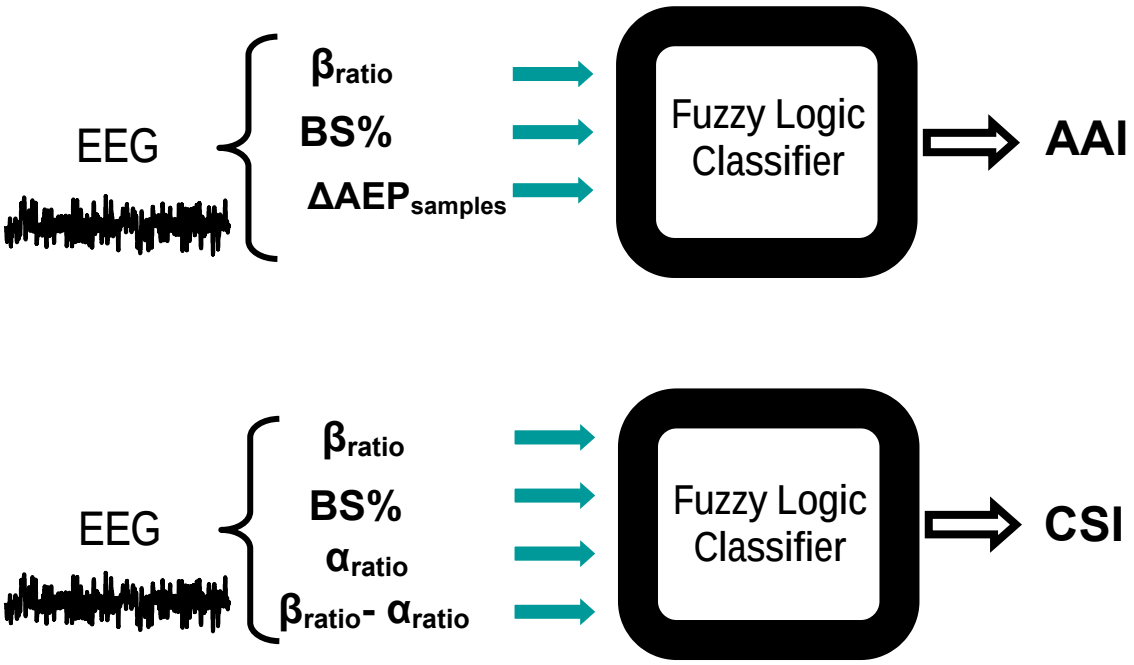
This was achieved by training the coefficients of a fuzzy logic inference system[f] in such a way that the CSI has the highest possible similarity to the AAI[g]. Although the headphones are removed the scales of AAI and CSI are different, as the recomended range for surgical anaesthesia for the AAI is 15-25 while the range for the CSI is 40-60.

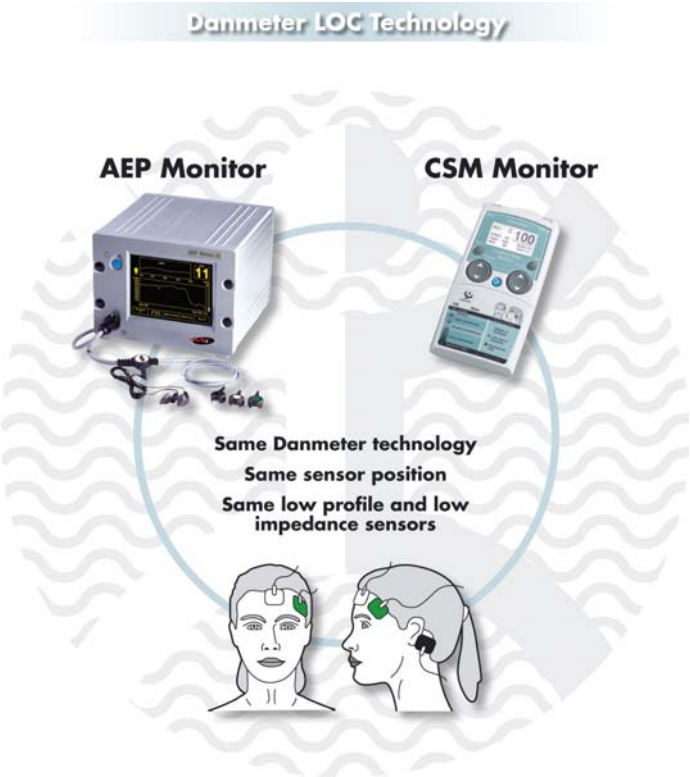
In conclusion, the validity of the Danmeter technology is supported by a vast amount of publications. These publications include studies with most commonly used anaesthetic drugs, most types of surgery, and clinical utility studies.

[e] The Danmeter EEG database consists of simultaneous records of EEG, OAAS and anesthetics concentrations.
[f] Visit www.danmeter,com for further information on Fuzzy Logic
[g] For training, the AAI was initially converted to a 0-100 scale with 40-60 as the range for adequate anesthesia instead of 15-25.

Danmeter LOC technology is based on Fuzzy Logic technology

The figure shows the EEG sub parameters used for AAI and CSI. The main parameters, beta ratio and BS% are common for the two devices while the parameter ΔAEPsamples was substituted by the α-ratio because the CSM does not apply headphones.





References

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