Cortical Activity Index

BrainU
The Risk of anesthesia operation operation

Every year over **600,000** people experience medical accident

In **UK** about **20,000** people out of **3M** experience intra-operative awareness
*Source: The Journal Anesthesia (2014)*

In **US** at least **30,000** people are estimated
*Source: the American Society of Anesthesiologists (2013)*
Depth of Anesthesia Monitoring System

Device to show patient’s level of consciousness.

- Minimize the possibility of medical accident
- Reduce the usage of anesthetic agents
CAI components

Comprise of 3 parts: Sensor, Amplifier and Monitor

Sensor (CAIs)
Collect the patient’s brainwaves deliver it to CAI amplifier

Amplifier (CAIx)
Intensify the brain signal transmit it to CAI monitor

Monitor (CAIv)
Calculate signal with CAI algorithm display CAI index on the screen
Medtronic: BIS

The first and the most frequently used device has its limitation

1. Limited on extensibility
2. Late responsiveness
3. Shut-down by electrical stimulation
4. Sensor issue
5. Long cable

➢ Made in 1994
➢ Occupy over 85% of market
1) CAI Algorithm

Different algorithm and possible to be used for other purpose

Bis algorithm estimates the state by trend/possibility like weather forecast
  → Targeted for general anesthesia: Low extensibility

CAI algorithm calculates the state by analyzing of whole brainwaves
  → Possibility of being used for other purpose: Extensibility
2) Responsiveness

CAI is 13 seconds faster on average

Reactivity in timeline

After injection of anesthetic, 13 seconds faster in index change

CAI shows immediate change of conscious level after anesthesia

→ Reduce the possibility of intra-operative awareness
3) Stability

CAI is more stable against external stimulations

In case of electrical stimulation, there is temporary shut-down of BIS system

Unlike BIS, CAI index is stable during electrical stimulation

CAI maintains its index under the situation which has external stimulus

→ Reduce the possibility of injecting anesthesia by mis-reading the index
4) Sensor: CAIs

CAIs is bio-compatible and more adhesive

Comparison BIS vs CAI

Differences on the skin after attaching

Make it smaller, Use biocompatible material
→ Low skin irritation and more adhesive

BIS: leave a mark on the skin
CAI: less stimulation without a mark
5) Wireless

Minimize the space in operating room by using Bluetooth
BrainU: CAI

Improve the unsatisfied needs with reasonable price

- Extensibility
- Faster
- More stable
- Biocompatible
- Wireless

Cost-effectiveness
Market situation

Huge potential market with steady growth of usage

Change in market trend ($ Mil)

- 2017: 1,781
- 2020: 2,557
- 2022: 3,253
- 2025: 4,669

CAGR 12.8%

Source: Profshare Market Research, Mordor Intelligence

Market size by region

- Americas: 43%
- EMEA: 32%
- APAC: 25%

Source: Technavio

- Average annual growth of 12.8%
- Expand use in market

- Size: Americas > EMEA > APAC
- Growth rate: APAC > EMEA > Americas
- Expansion of use in developed countries
  Growth potential in developing countries
Certification Plan by BrainU

- **STEP1**
  - KFDA + ISO 13485:2016 (Vietnam, Indonesia..)
  - Contract with JKA (China)

- **STEP2**
  - CE Marking (Europe)
  - Expand market to South-East Asia and South Asia

- **STEP3**
  - PMDA, CFDA (Japan) (China)
  - Expand market to Middle-East Asia and CIS countries

- **STEP4**
  - FDA (USA)
  - Expand market to North America and Oceania

- **STEP5**
  - ANVISA (Brazil)
  - Expand market to South America

### Certification Status

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<th>Country</th>
<th>Certificate/Register</th>
<th>Status</th>
<th>Date</th>
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Domestic Business

Business model: “lock-in”, Distribution system: exclusive contract

Start **domestic sales** (2019~)

- Business model: “lock-in” (ex. Printer-toner)
- Provide CAI to 80 hospitals
- Sales **250 devices / 40,000 sensors**
- Achieve about one **million USD**
International Business

Different by country and find distributors for each country

Expand **business to abroad** (2020~)

- Flexible policies based on each country's situation
- Obtaining certificate and registration for each country
- 5-years contract with JinKangAn in China
- Under discussion with distributors in APAC countries

<Distribution system>
BrainU Overview

Our goal is to change medical industry in line with 4th industrial age

Main business

- Development of medical devices and wearables based on brainwaves
- Brain convergence R&D and data-driven research, software development, R&D services

2014~2018

- Beginnings
  - Long period of Pre-business preparation
    : Joint research with KAIST, Korea Uni
  - Establishment 2018.03

2018~2019

- Groundwork
  - Complete KFDA and GMP for domestic sales
  - Prepare certificate for global sales

2020~

- Expansion
  - Received ISO 13485:2016 and RoHS2
  - In the process of obtaining CE and registration in APAC

get through “Death Valley”

• Received ISO 13485:2016 and RoHS2
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<td>33rd Annual International Conference of the IEEE EMBS Boston, Massachusetts USA, August 30 - September 3, 2011</td>
<td>Monitoring the Depth of Anesthesia from Rat EEG using Modified Shannon Entropy Analysis</td>
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<td>A Cepstral Analysis based Method for Quantifying the Depth of Anesthesia from Human EEG</td>
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Key members

Seungkyun Hong (President)
- MS, Yonsei Uni.
- Ex Donghwa Pharm
- Ex Charm Engineering co., Ltd.
- Clinical Research Associate
- 16 years of experience in medical Area

Kwangmoo Kim (Vice President)
- Ph.D, Korea Uni.
- Ex Deputy director of MEST
- Council member of NST
- CEO in listed company

Jihoon Han (H/W Engineer)
- BS, Kongju Uni.
- CAI H/W developer
- 20 years of experience

Hyun Park (S/W Engineer)
- MS, Kwangwoon Uni.
- CAI S/W developer
- 10 years of experience

Kyuhong -Lee (Production Manager)
- BS, Yonsei Uni.
- Ex senior researcher in Galaxia
- 14 years experience of QC

Sangwoo Choi (R/A manager)
- BS, Hannam Uni.
- Ex Charm Engineering co., Ltd.
- 8 years experience of licensing
Thank You

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