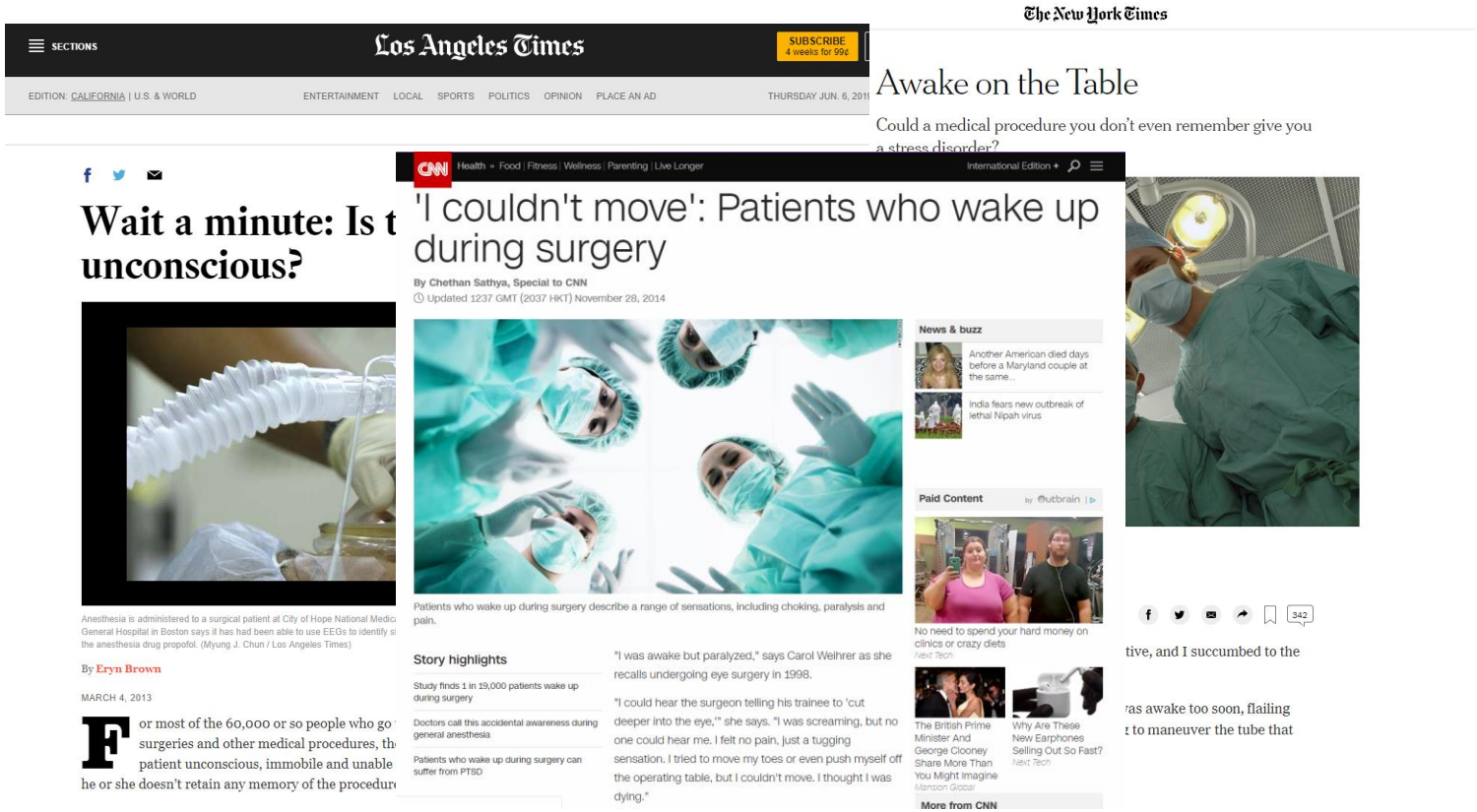
Cortical Activity Index

BrainU

1 The Risk of anesthesia operation

Every year over 600,000 people experience medical accident

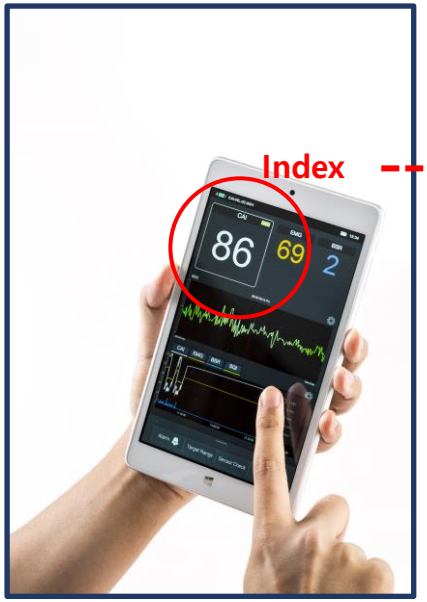


In UK about 20,000 people out of 3M experience intra-operative awareness
***Source: The Journal Anesthesia (2014)**

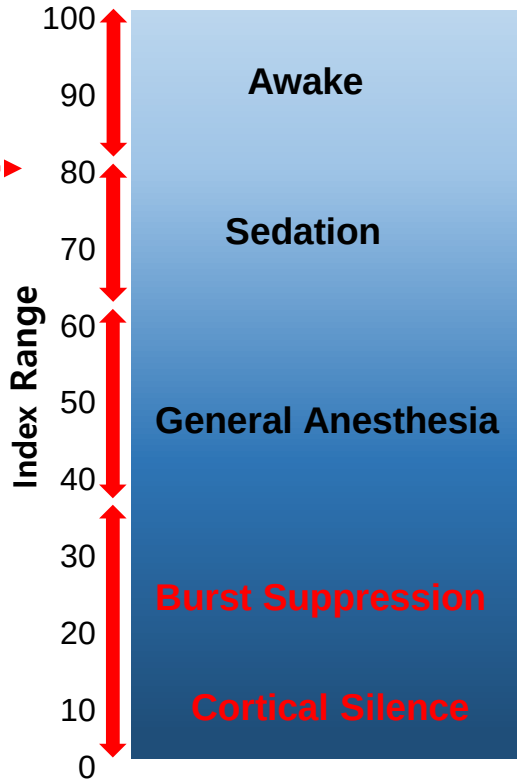
In US at least 30,000 people are estimated
***Source: the American Society of Anesthesiologists (2013)**

2 Depth of Anesthesia Monitoring System

Device to show patient's level of consciousness.



<CAI Monitoring System>



<CAI index to show depth of anesthesia>

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

3 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

4 Medtronic: BIS

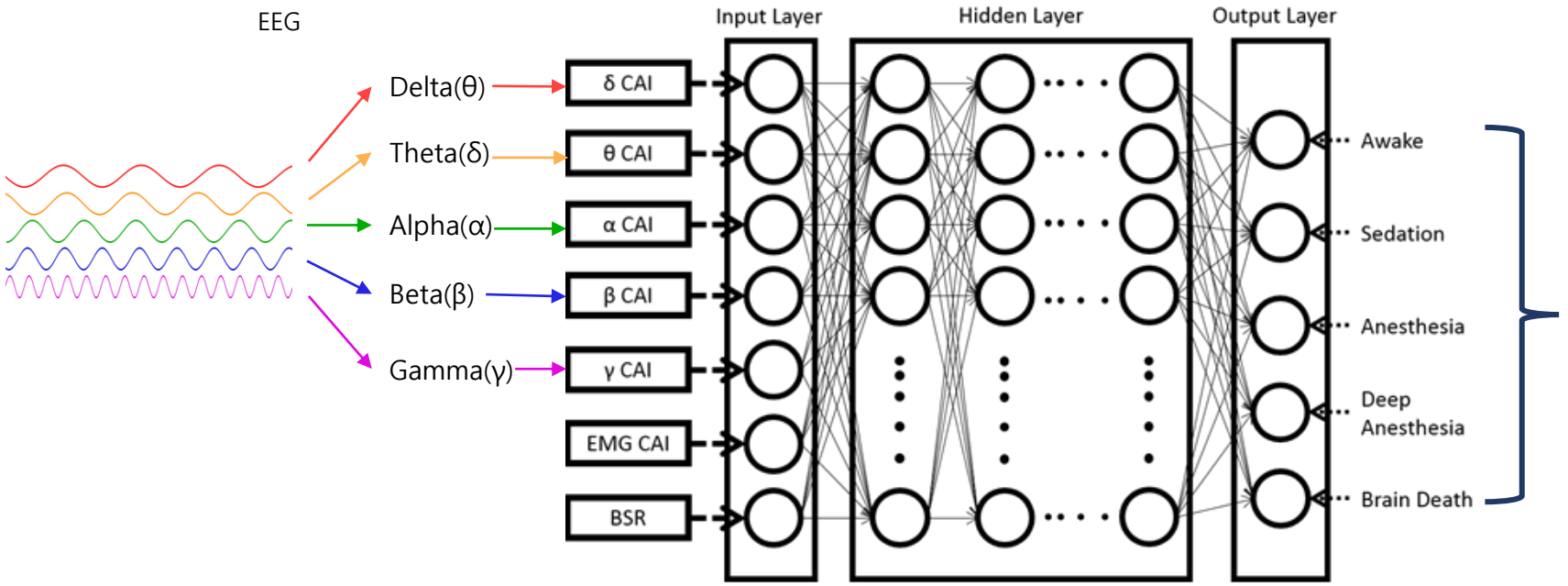
The first and the most frequently used device has its limitation

- Made in 1994
- Occupy over 85% of market

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

1) CAI Algorithm

Different algorithm and possible to be used for other purpose



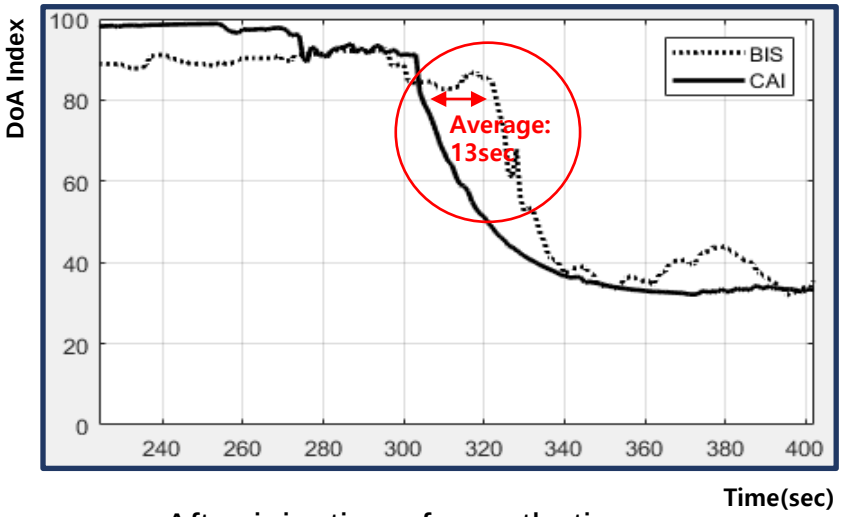
Bis algorithm estimates the state by trend/possibility like weather forecast
→ Targeted for general anesthesia: Low extensibility

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

Video to show CAI Reactivity

CAI: immediate index fall
BIS: 13sec later than CAI

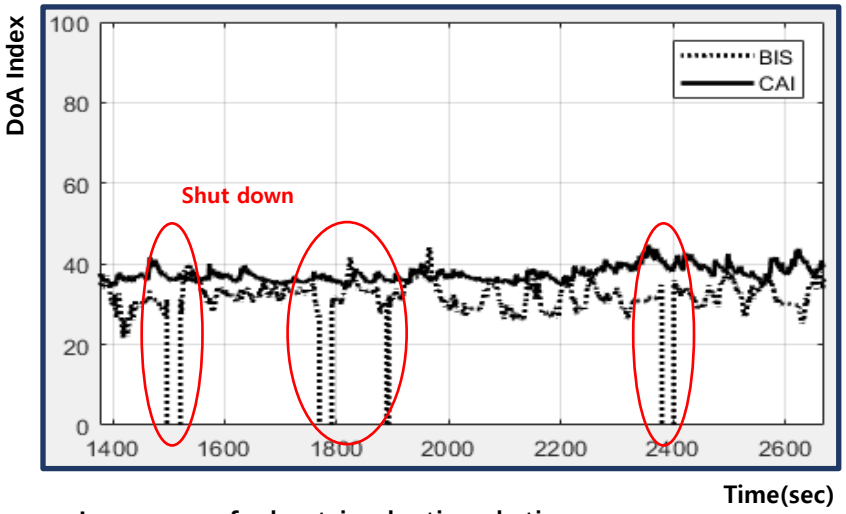
CAI shows immediate change of conscious level after anesthesia

→Reduce the possibility of intra-operative awareness

3) Stability

CAI is more stable against external stimulations

Stability in timeline



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

Video to show CAI stability

Unlike BIS, CAI index is stable during electrical stimulation

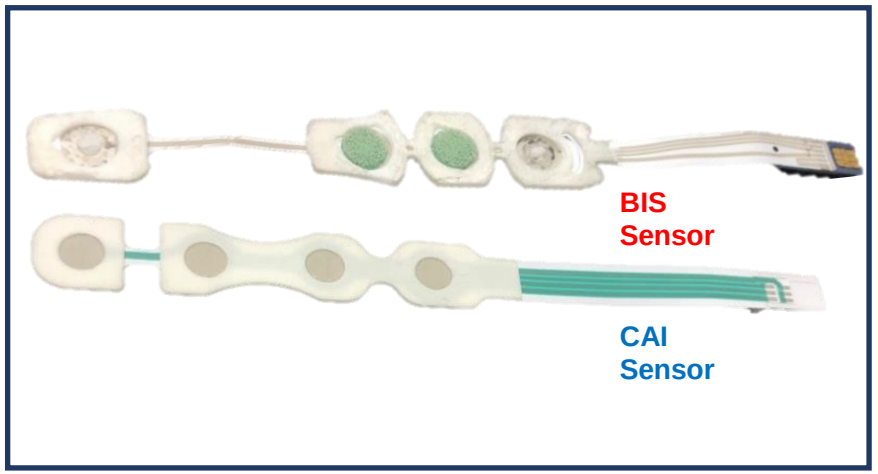
CAI maintains its index under the situation which has external stimulus

→ Reduce the possibility of injecting anesthesia by mis-reading the index

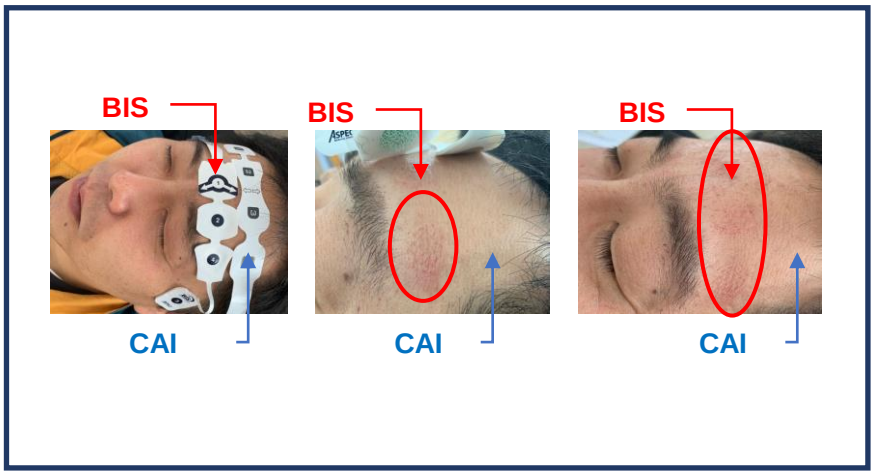
4) Sensor: CAIs

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

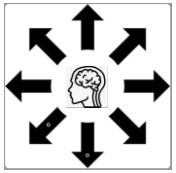
CAI: less stimulation without a mark

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

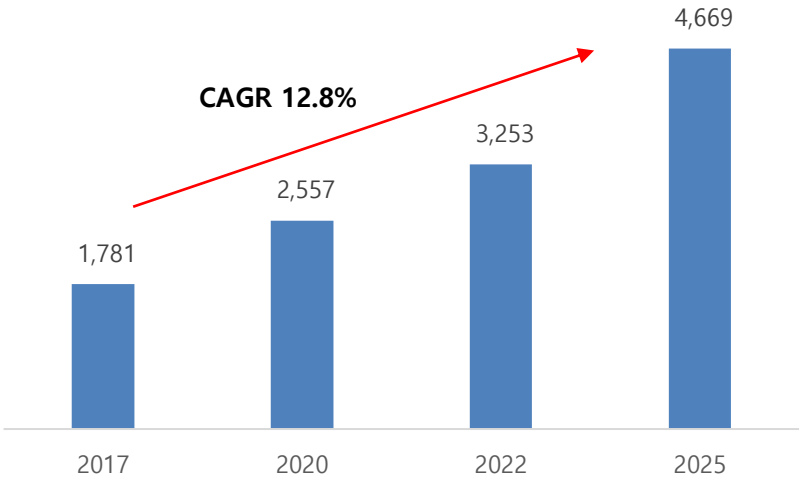
Wireless

Cost-effectiveness

11 Market situation

Huge potential market with steady growth of usage

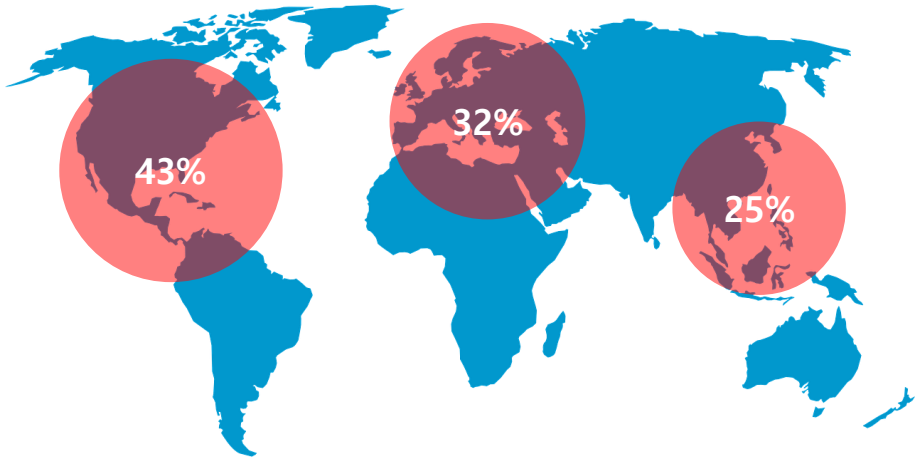
Change in market trend ($ Mil)



Source: Profshare Market Research, Mordor Intelligence

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

Market size by region



- ✓ 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

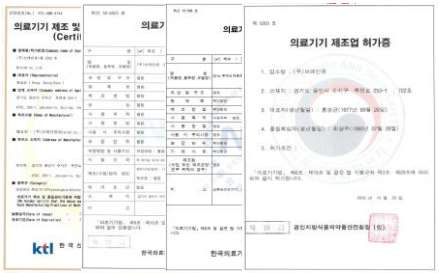
- FDA (USA)
- Expand market to North America and OCeania

STEP5

- ANVISA (Brazil)
- Expand market to South America

<Certification Status>

Country	Certificate/Register	Status	Date
Int.	ISO 13485: 2016	Done	Mar.2020
Int.	RoHS2	Done	Mar.2020
Korea	GMP	Done	Sep.20
Korea	KFDA	Done	Apr.2016
EU	CE(MDD)	In the process	Before Nov.2020
China	CFDA	In the process	Before Feb.2021
Vietnam	Registration	Done	Oct.2020
Indonesia	Registration	In the process	Before Nov.2020



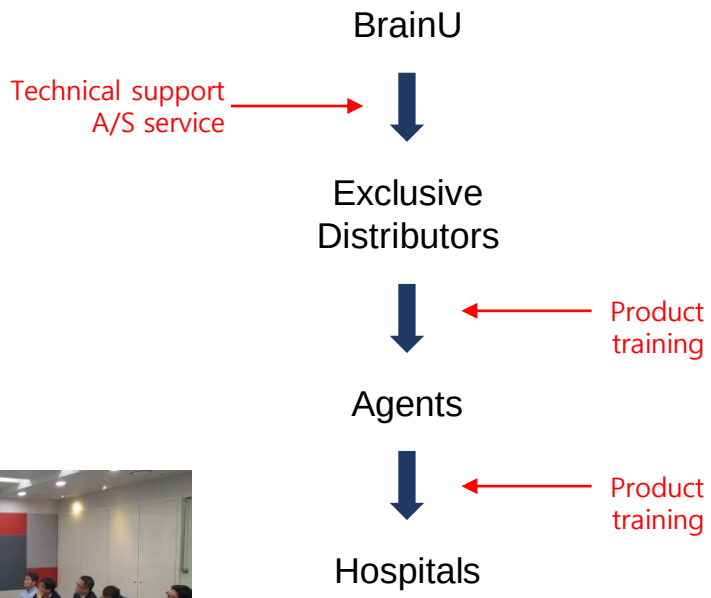
Domestic Business

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**

<Distribution system>



<Product training by BrainU>

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>

?

<China-Bio, Shanghai (2019)>

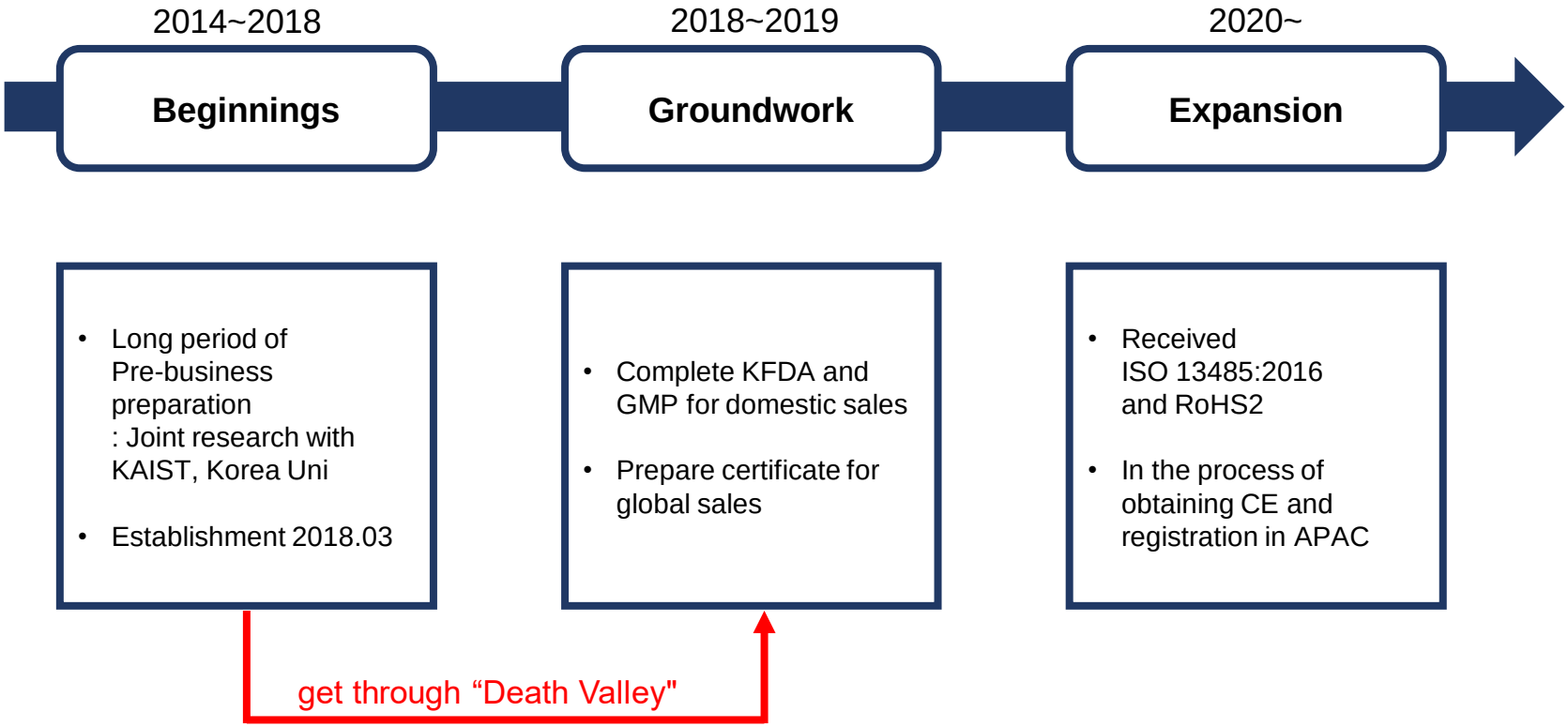
<Meeting in Indonesia (2019)>

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



Patents

Item	IP	Ctry	Status	Application No.	Registration No.	Title of Invention
Algorithm	Patent	KR	Registered	10-2013-0015676	10-1371299	Analyzing method and apparatus for the depth of anesthesia using cepstrum method
Algorithm	Patent	KR	Registered	10-2013-0016794	10-1400362	Analyzing method and apparatus for the depth of anesthesia
Algorithm	Patent	KR	Registered	10-2011-0049214	10-1248055	Model and simulator of EEG for quantifying the depth of anesthesia
Algorithm	Patent	KR	Registered	10-2011-0049198	10-1248118	Apparatus of analyzing EEG for quantifying the depth of anesthesia and method thereof
Algorithm	Patent	CN	Registered	201480008515.4	ZL201480008515.4	Analyzing method and apparatus for the depth of anesthesia using cepstrum method
Algorithm	Patent	CN	Registered	201480008609.1	ZL201480008609.1	Analyzing method and apparatus for the depth of anesthesia
Algorithm	Patent	EP	Registered	14751919.3	2962634 602014020437.6	
Algorithm	Patent	JP	Registered	2015-555929	6259471	
Algorithm	Patent	SG	Registered	11201505990Q	11201505990Q	
Algorithm	Patent	US	Pending	14/767,286		
Algorithm	PCT	PCT	Pending	PCT/KR2014/001201		
Sensor	Design	KR	Registered	30-2014-0058028	30-0805287	Sensor for the measurement of bio-signals
Sensor	Design	KR	Registered	30-2015-0043431	30-0854469	Sensor for the measurement of bio-signals
Sensor	Design	KR	Registered	30-2016-0052806	30-0910972	Sensor for the measurement of bio-signals
Sensor	Design	CN	Pending	201730338640.8		Sensor for the measurement of bio-signals
Sensor	Design	CN	Registered	201830069665.7	ZL201830069665.7	Sensor for the measurement of bio-signals
	TM	KR	Registered	40-2016-0040510	40-1263578	CAIv
	TM	KR	Registered	40-2016-0040463	40-1263577	CAIx

17 Papers

33rd Annual International Conference of the IEEE EMBS Boston, Massachusetts USA, August 30 - September 3, 2011	**Monitoring the Depth of Anesthesia from Rat EEG using Modified Shannon Entropy Analysis**
35th Annual International Conference of the IEEE EMBS Osaka, Japan, 3 - 7 July, 2013	**A Cepstral Analysis based Method for Quantifying the Depth of Anesthesia from Human EEG**
2014 International Conference on Information and Communication Technology Convergence (ICTC)	**Implementation of Real-time Depth of Anesthesia Monitoring System Using Wireless Data Transfer**
2017 Korea University Department of Medicine Graduate School Major in Anesthesiology and Pain Medicine	**Research for Quantifying the Depth of Anesthesia based on Physiological Signal Model- Usefulness of Cortical Activity Index**
2020 Medicine (2020) 99:5	**Quantifying the depth of anesthesia based on brain activity signal modeling**

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

Kyuhong -Lee (Production Manager)

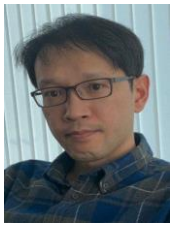
- BS, Yonsei Uni.
- Ex senior researcher in Galaxia
- 14 years experience of QC

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



Sangwoo Choi (R/A manager)

- BS, Hannam Uni.
- Ex Charm Engineering co., Ltd.
- 8 years experience of licensing

Thank You

BrainU

www.brainu.co.kr

+82) 31-889-1788

hongsukkyun@brainu.co.kr