Medical Insight+
Brain Hemorrhage
(Brain Hemorrhage Detection Solution)

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Introduction

Cerebral hemorrhage is a representative serious disease, and the golden time is important.

100,000 people per year
Number of incidences of hemorrhagic stroke (cerebral hemorrhage)

No. 1
Mortality rate in Korea

35%
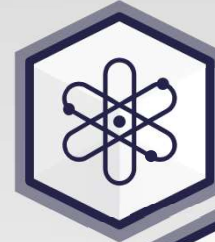Mortality rate within one month after breakout

3 times increase
Disability/mortality rate when golden time (2~3 hours) is exceeded.

540 billion KRW
Direct costs incurred by brain hemorrhage

About 4,016
Domestic radiology specialist

About 1,500
Head and neck roentgenologist

✓ CT scan is used to diagnose brain hemorrhage , but certain factors in CT, such as signal to noise, signal attenuation, and artifacts, can have a negative effect on diagnosing lesions, and accurate readings can be difficult for non-brain imaging specialists.

✓ According to previous studies, there may be a discrepancy between the initial and the final diagnosis results, and about 13.6% of discrepancy occurs.

✓ Therefore, it is possible to increase the accuracy of diagnosis of brain hemorrhage and reduce disability and mortality through early diagnosis.

Product Introduction

The problem we focus on

"Risk of inaccurate diagnosis in the ER"

- Brain Hemorrhage is a disease that requires early accurate diagnosis in the emergency room

- There are often no radiologists in the ER, and diagnostic accuracy of general physician is lower than that of radiologists

"Risk due to radiologist workload"

- Radiologists' workload is increasing seriously with the increase in imaging diagnosis: 4times in 15 yrs ('06~'20) [1]

- And this results in longer working hours and reading fatigue, all of which contribute to diagnostic error [2]
  : Overnight working causes a 2X increase in the error rate

[1] [2] R.J.M. Bruls, *Workload for radiologists during on-call hours* (2020)

The solution, Medical Insight+

1 **Improving diagnostic accuracy to radiologists' level**

- ✓ It helps doctors diagnose accurately by marking lesions on images and providing the possibility of brain hemorrhage

- ✓ In clinical trials, the accuracy of all doctors was improved with this AI SW, and it was particularly effective for general physician

2 **Focusing on emergency patients**

- ✓ It analyzes all CT slice images of the patient within 20 seconds

- ✓ The triage function(sorting by 7-level severity) allows radiologists to focus on the emergency patients in the worklist

3 **Anytime, anywhere access**

- ✓ It also works on mobile devices, allowing relevant physicians to instantly check the patient's CT images and diagnose disease

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Medical Insight+ Brain Hemorrhage Product Introduction

Value Proposition

AI-based brain hemorrhage diagnosis algorithm and AI service platform

As-Is Pain Points

Possibility of delay in image reading for patients with high urgency by performing readings according to the order of CT scans.

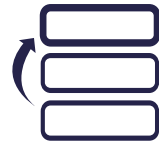Possibility of difficult early detection due to the poor experience and expertise of the image reader.

If AI-based medical imaging solutions for various diseases are introduced, the management points increase, which result in more complexity.

Product Value Proposition

Providing reading priority function (Triage)

Provides images by overlaying suspected brain hemorrhage in slice-unit image.

Provides cloud/on-premise platform that can add various AI algorithms.

✓ Diagnosis priority is provided in 6 levels when searching worklist.

✓ Brain hemorrhage score in each study unit is provided.

✓ The information on the suspected brain hemorrhage area analyzed by AI is overlaid the original image, when searching individual slice unit images.

✓ Provides brain hemorrhage probability value (score) not only study unit but also in slice unit.

✓ Provides an AI runtime platform that can add various AI algorithms in the product.

✓ Cloud or On-Premise platform can be selected depending on the situations of the medical institutions.

Medical Insight+ Brain Hemorrhage Product Introduction

Reading priority function (Triage)

Key Features
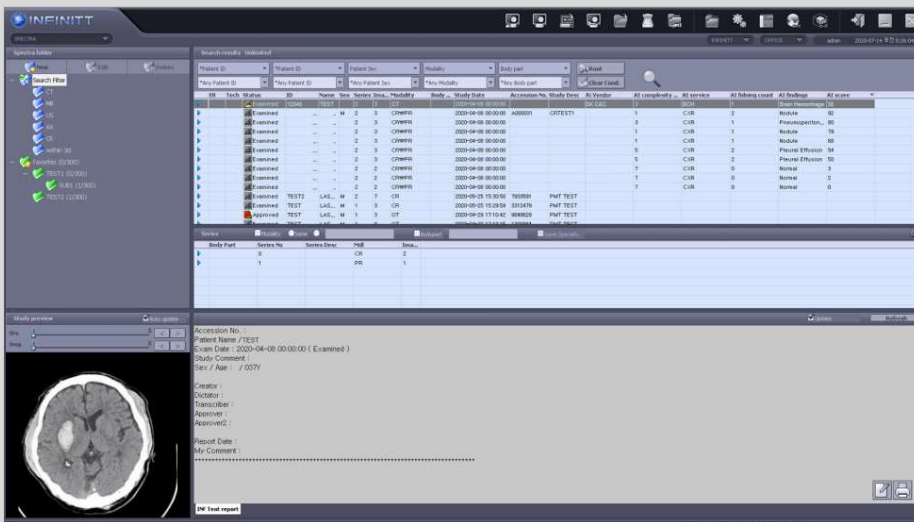
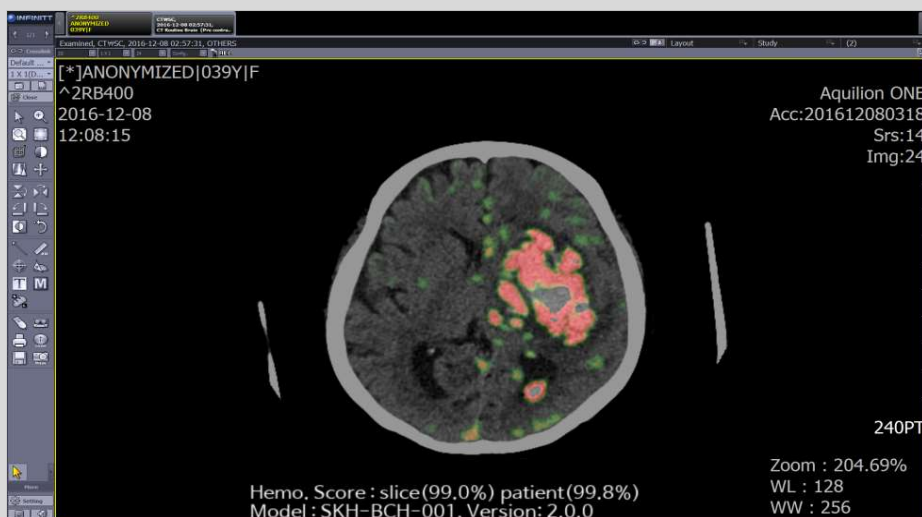| Marking suspected brain hemorrhage	• After analyzing the brain CT images of the patient, suspected brain hemorrhage is marked in the worklist.
Proposal for priority in patient care	• The priority of patient treatment is suggested according to the results of brain CT image analysis, and the worklist is sorted accordingly, displaying the patients with high priority at the top of the worklist.

Effects

• By indicating the suspected cerebral hemorrhage in the worklist, the image reader can quickly read the images of patients with suspected brain hemorrhage and treat it

• By suggesting priorities for patient treatment and sorting out worklists by priorities, patients in need of quick action can be identified quickly.

• Through this, we help treating patients with brain hemorrhage without missing the golden time.

Medical Insight+ Brain Hemorrhage Product Introduction

Brain Hemorrhage Analysis for each slice unit

Key Features

Marking suspected brain hemorrhage	• After analyzing the brain CT images of the patient,
Providing possibility information on patients with suspected brain hemorrhage.	• By converting the analysis result of the brain CT images into a numerical value, the patient's brain hemorrhage probability is displayed as a number between 0 and 100%.
Providing possibility information on suspected brain hemorrhage in each image.	• The likelihood of cerebral hemorrhage in each image is converted into a number, and the likelihood of cerebral hemorrhage in the image is displayed as a value between 0 and 100%.

Effects

• By marking the suspected brain hemorrhage area in color or outline on the brain CT image, the user can quickly identify the brain hemorrhage area.

• By converting the analysis result of the brain CT images into a numerical value, the patient's brain hemorrhage probability is displayed as a number between 0 and 100%, providing a judgment reference to the medical staff.

• By converting the probability of brain hemorrhage in each image into a numerical value, the probability of brain hemorrhage in the image is displayed as a number between 0 and 100%, providing a judgment reference to the medical staff.

• Through this, it helps to quickly identify patients with brain hemorrhage and diagnose the area of brain hemorrhage.
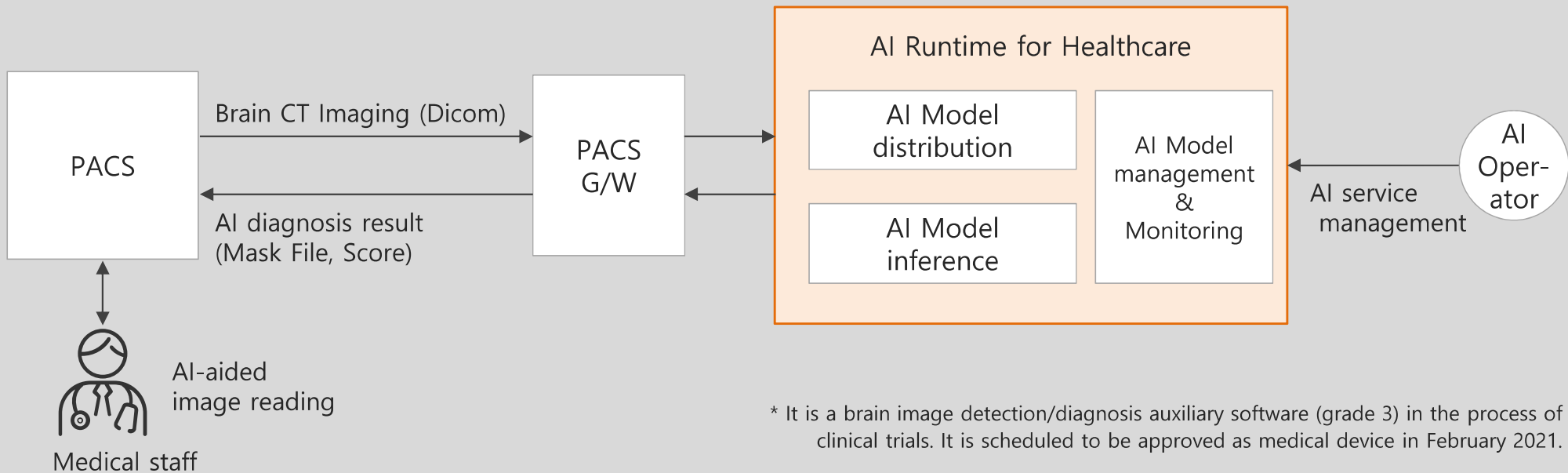
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Medical Insight+ Brain Hemorrhage Product Introduction

On-Premise Service

✓ After installing the product in a medical institution, we provide a cerebral hemorrhage image reading service to the medical staff by linking with PACS of the medical institution.

✓ The product consists of AI runtime, which manages and analyzes AI model of the medical images, and PACS G/W for PACS linkage.

✓ Medical institutions do not need to secure separate infrastructure such as a server for software installation, and will receive a batch service including hardware when products are supplied.

✓ After installation, the service is operated directly by the medical institution.

On-Premise Service Architecture

Medical Insight+ Brain Hemorrhage*

AI Runtime for Healthcare

| PACS | Brain CT Imaging (Dicom) → | PACS G/W | → | AI Model distribution | AI Model management & Monitoring | ← | AI Oper-ator |
| | ← AI diagnosis result (Mask File, Score) | | ← | AI Model inference | | AI service management | |

AI-aided image reading

Medical staff

* It is a brain image detection/diagnosis auxiliary software (grade 3) in the process of clinical trials. It is scheduled to be approved as medical device in February 2021.

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Medical Insight+ Brain Hemorrhage Product Introduction

Cloud(Azure) Service

✓ The product is not separately installed in the medical institution, but is linked to the PACS owned by the medical institution through the cloud to provide the brain hemorrhage image reading service to the medical staff.

✓ Depending on the environment of the medical institution, it is necessary to install PACS G/W software to transmit images to the cloud.

✓ Medical institutions do not need to install hardware and software to use the product, but can use the service as a subscription, and do not need to secure separate IT operating personnel for the service.

Azure Service Architecture
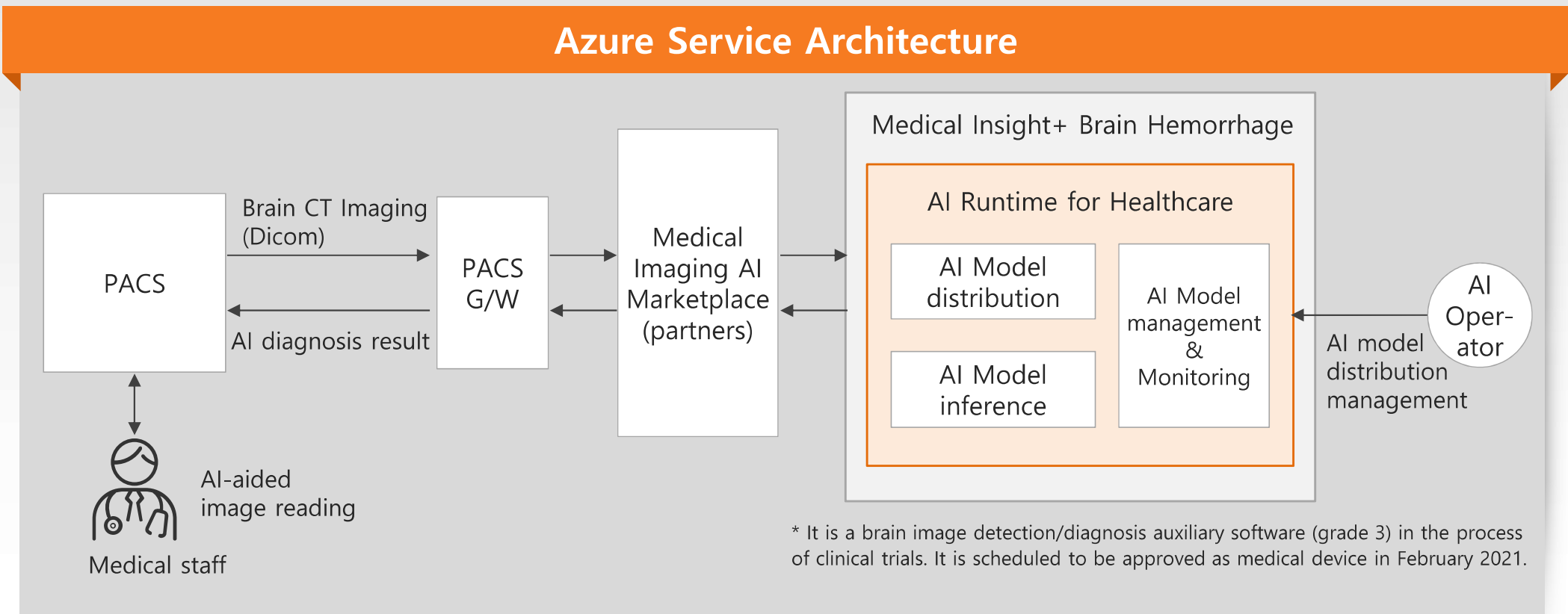
* It is a brain image detection/diagnosis auxiliary software (grade 3) in the process of clinical trials. It is scheduled to be approved as medical device in February 2021.
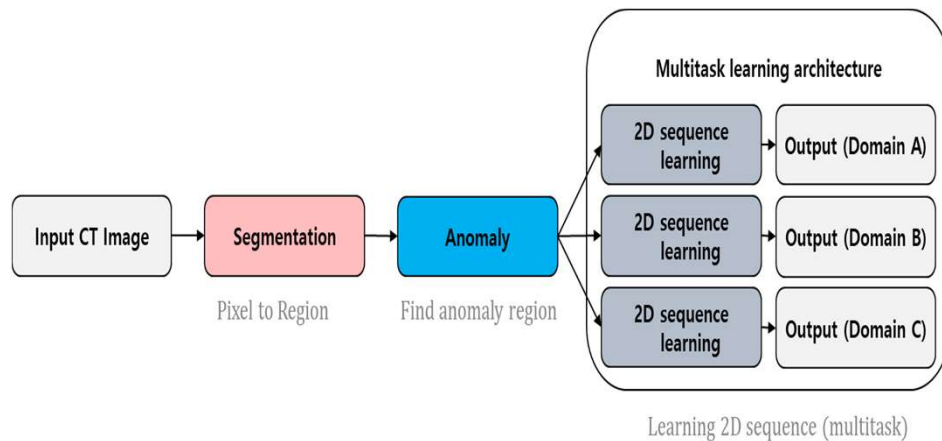
Core Technology

Principle of Action	After analyzing the brain computed tomography (CT) image in slices, it uses an artificial intelligence algorithm based on a convolutional neural network (CNN) to model the brain region and abnormal regions, and to detect the location with a high probability of brain hemorrhage.

✓ The detection ability for small or elapsed brain hemorrhage and minor cases was strengthened, and normal data that was relatively easy to collect was used for learning.

✓ Domain sensitivity was eliminated to prevent performance degradation in a new domain (hospital) after learning.

✓ Sequential model was applied to consider the information before and after when processing the Z-direction (top of the head ↔ jaw) sequence.

Using CNN-based Deep Learning Algorithm

Multitask learning architecture

Input CT Image → Segmentation → Anomaly → 2D sequence learning → Output (Domain A)
2D sequence learning → Output (Domain B)
2D sequence learning → Output (Domain C)

Pixel to Region   Find anomaly region

Learning 2D sequence (multitask)

Technology Summarization

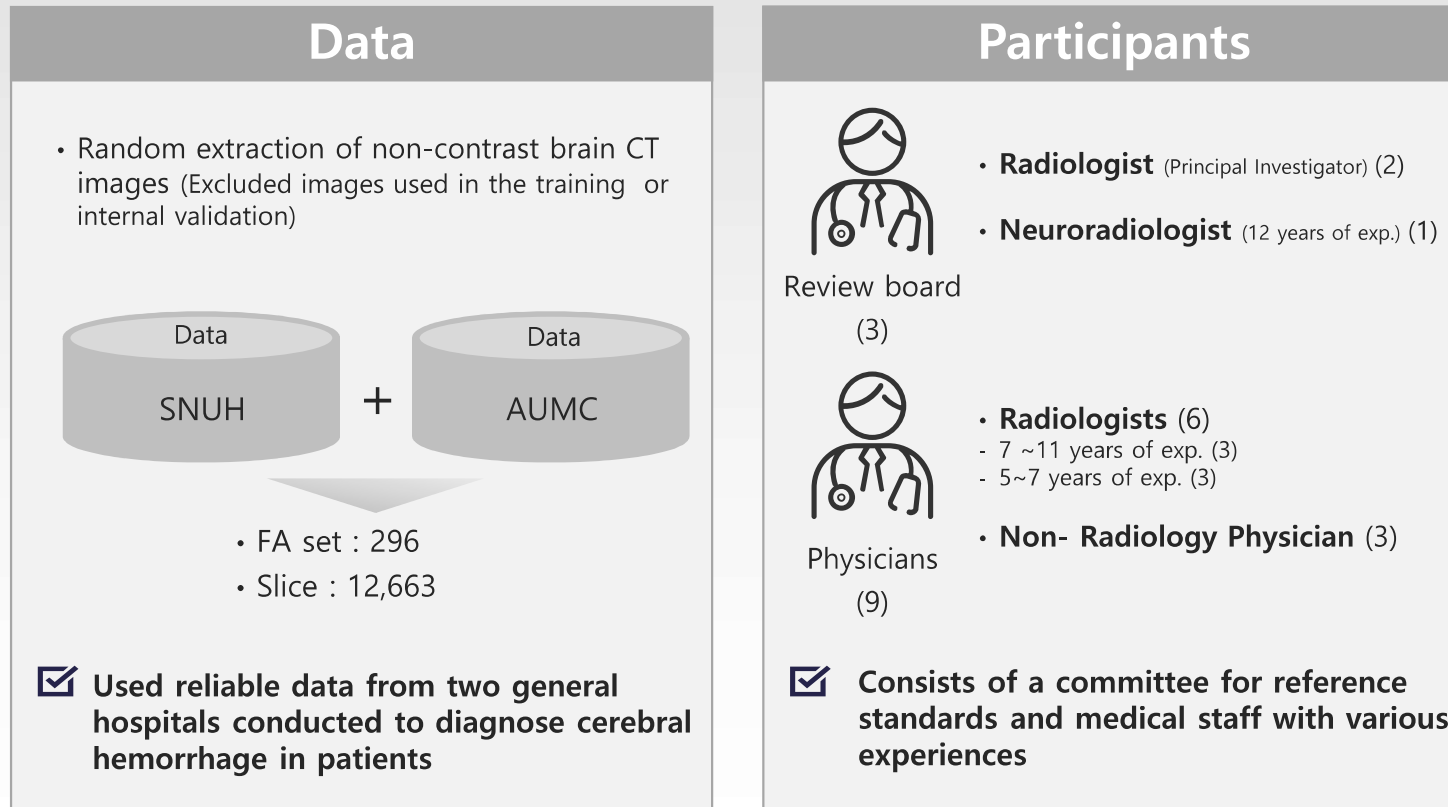| Segmentation	Image segmentation is performed to distinguish areas such as brain tissue and skull on CT images.
Anomaly	This is a step to detect the brain hemorrhage lesion area, and the area different from the learned normal brain CT image is detected.
2D Sequence learning	Potential brain hemorrhage area data of the CT image sequence taken from one patient are sequentially learned to determine whether there is cerebralbleeding.
Multitask learning	For adaptive learning in different domains, it has a shared model and a domain specific model structures.

Medical Insight+ Brain Hemorrhage Product Introduction

Clinical Validation (1/2)

✓ Brain CT images taken for the diagnosis of cerebral hemorrhage in patients at two general hospitals were acquired and used as data for clinical trials.

Data	Participants
• Random extraction of non-contrast brain CT images (Excluded images used in the training or internal validation)	Review board (3) • **Radiologist** (Principal Investigator) (2) • **Neuroradiologist** (12 years of exp.) (1)
Data: SNUH **+** Data: AUMC • FA set : 296 • Slice : 12,663	Physicians (9) • **Radiologists** (6) - 7 ~11 years of exp. (3) - 5~7 years of exp. (3) • **Non- Radiology Physician** (3)
☑ **Used reliable data from two general hospitals conducted to diagnose cerebral hemorrhage in patients**	☑ **Consists of a committee for reference standards and medical staff with various experiences**

Results

Patient-wise	Without AI	With AI	Bonferroni-corrected P-value
All reviewers	**0.947** [95% CI: 0.938, 0.955]	**0.970** [95% CI: 0.963, 0.976]	*P* < .0009
Non-radiologist Physicians	**0.919** [95% CI: 0.899, 0.936]	**0.951** [95% CI: 0.934, 0.964]	*P* = .0009
Board-certified Radiologists	**0.946** [95% CI: 0.929, 0.960]	**0.974** [95% CI: 0.961, 0.983]	*P* = .0003
Neuroradiologists	**0.976** [95% CI: 0.964, 0.985]	**0.987** [95% CI: 0.977, 0.993]	*P* = .1776

Results (all reviewers)
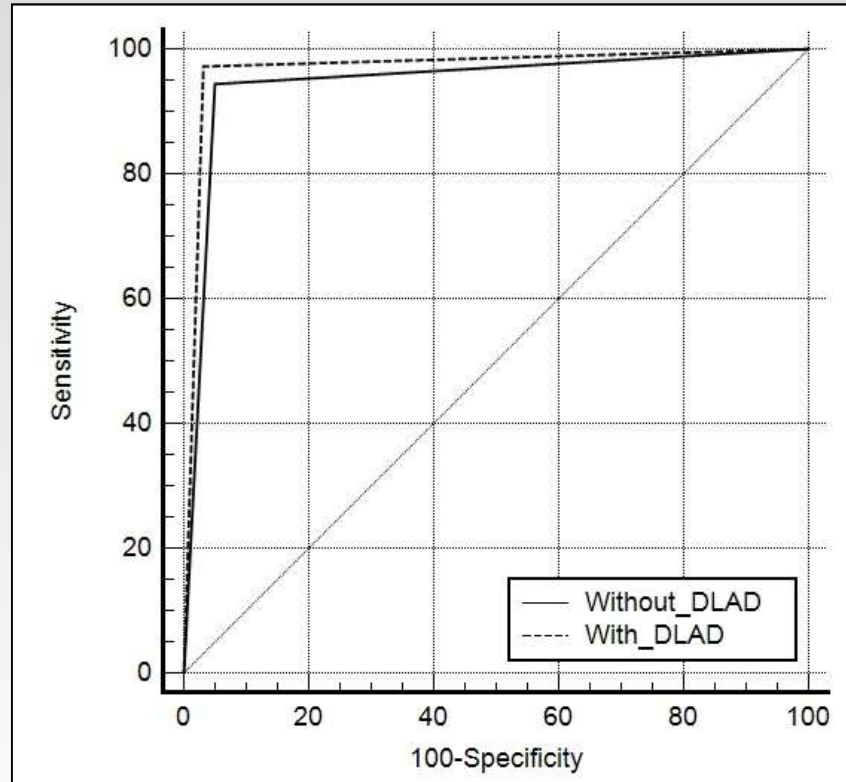
ALL reviewers

Without AI: 0.947

→ With AI: 0.970

(*P* < .0009)

*Unpublished data

Patient-wise	Without AI	With AI	Bonferroni-corrected P-value
All reviewers	**0.947** [95% CI: 0.938, 0.955]	**0.970** [95% CI: 0.963, 0.976]	*P* < .0009

Results (each reviewers group)

Non-radiologist Physicians

Board-certified Radiologists
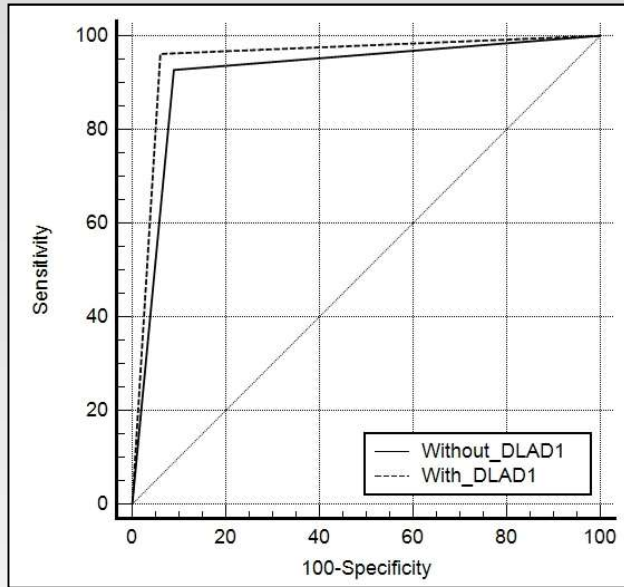
Neuroradiologists

Without AI: 0.919

→ With AI: 0.951

(*P* = .0009)

Without AI: 0.946

→ With AI: 0.974

(*P* = .0009)

Without AI: 0.976

→ With AI: 0.987

(*P* = .1776)

Medical Insight+ Brain Hemorrhage Product Introduction

Radiologists Comment

✓ It seems that it will help a lot in making early judgments in the clinical field by finding small and microscopic bleeding that can be easily missed.

✓ It seems to be of great help in the field situation where many images are to be read in a short time.

✓ It reduces the likelihood of missing brain hemorrhage signal in reading by novice doctors, and prevents wasted resources by reading negatives well in emergency situations.

Comments by medical staff participating in clinical studies

Neuro-radiologist	• Small falcine and tentorial SDH are well detected. • The software seems to be a great help for clinicians who have difficulty distinguishing whether or not it is an artifact because they are not affected by the beam hardening artifact. • Sometimes there is a case where I miss a small SAH, but AI helps when I have to go over a lot of images in a short time.
Radiologist	• It identifies even small bleeding well, and judges negative as negative relatively well.
Non-Radiology Physician	• I think it will be very helpful in making an initial decision for doctors unfamiliar to an environment such as an emergency room. • I think it can reduce the likelihood of missing a brain hemorrhage in the field by proceeding with the method that was conducted in the actual study (after seeing it with the eyes of a doctor first, and then checking it again with the help of an AI solution). • When SAH is spread out, it is difficult to distinguish whether it is positive or negative. In emergency situations, there are many cases that we refer to the relevant department under the assumption of positive, and thereby resources are wasted. In that respect, I felt that it would be helpful for a novice doctor to read it correctly. • There were cases where the microscopic SDH was missed, but it seems that AI helps to find it well.

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Medical Insight+ Brain Hemorrhage Product Introduction

Roadmap

First half of 2021

Pilot service of brain hemorrhage products

- Clinical trial approval for Medical Insight+ Brain Hemorrhage, a brain hemorrhage image diagnosis.
- Implementation of pilot service for major medical institutions.
- Launching of the expanded development of products for brain diseases such as cerebral infarction.

End of 2021

Securing stroke total solution

- Completion of approval as a medical device for brain hemorrhage imaging
- Launching of cloud/on-premise-based service.
- Completion of expanded development of researches on brain diseases such as cerebral infarction and cerebral aneurysm to secure total stroke solution.
- Approval of clinical trial plan for brain disease services such as cerebral infarction.
- Promotion of European CE certification for brain hemorrhage image diagnosis.

End of 2022

### Securing brain total solution

- Completion of approval as a medical device for stroke total solution.
- Development of research on brain diseases such as brain tumors to expand and secure Brain Total Solution.
- Preparation of Stroke Total Solution overseas expansion (FDA, Vietnam, etc.)

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(Without AI) **False Negative** → (With AI) **True Positive**
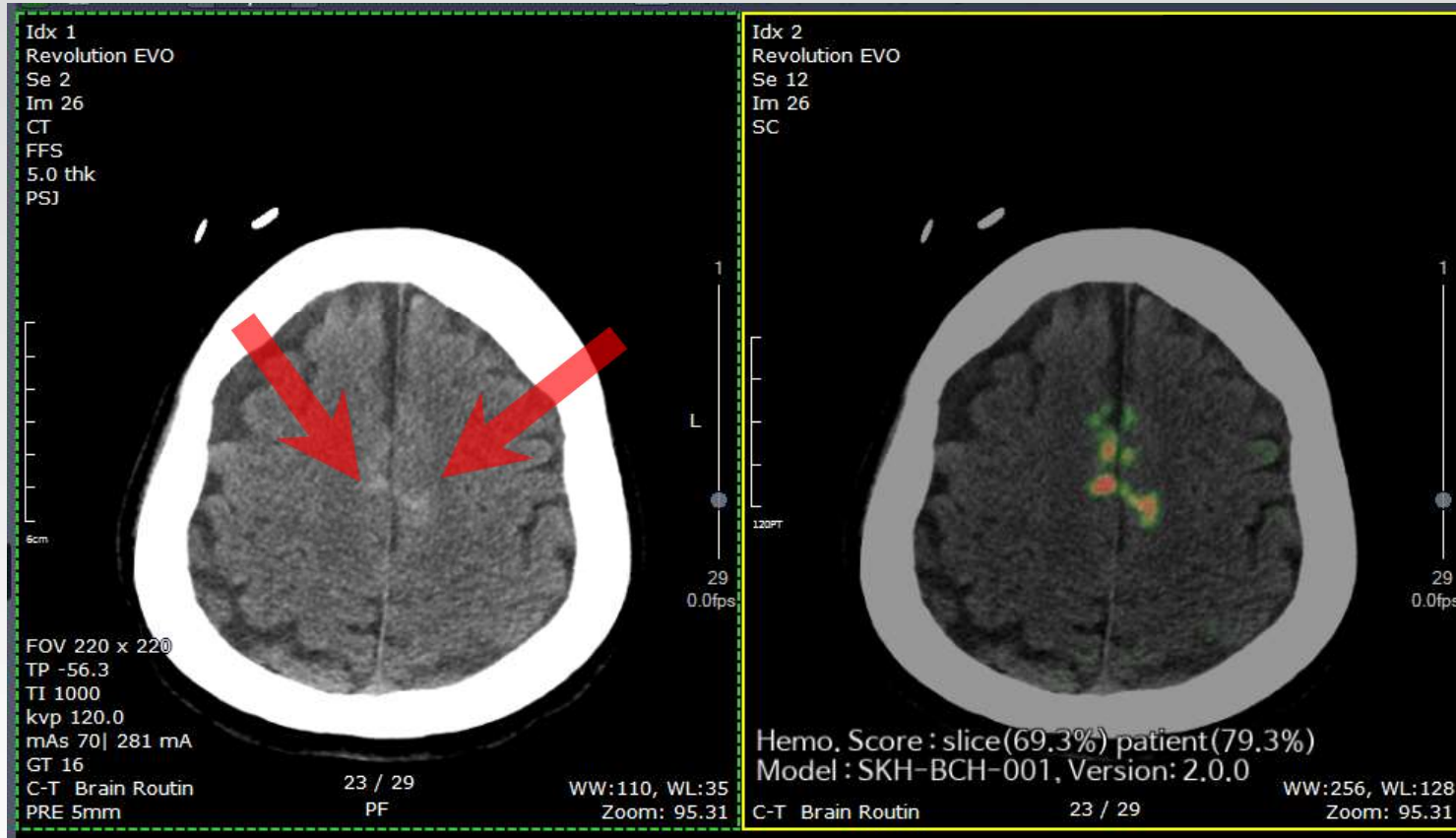
> **Non-radiologist Physician (n=1)**
> ✓ **SAH in vertex level**

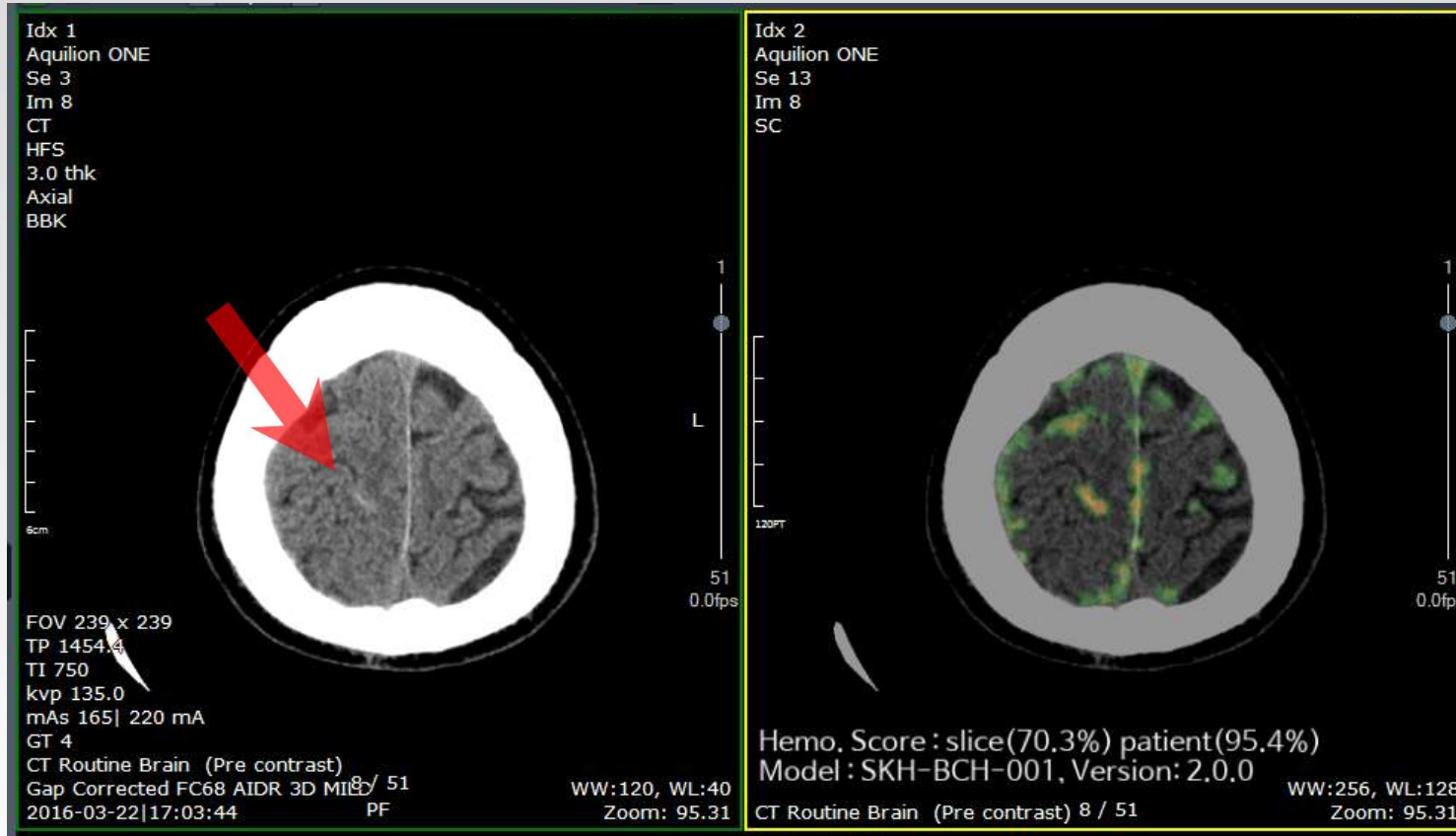# (Without AI) **False Negative** → (With AI) **True Positive**
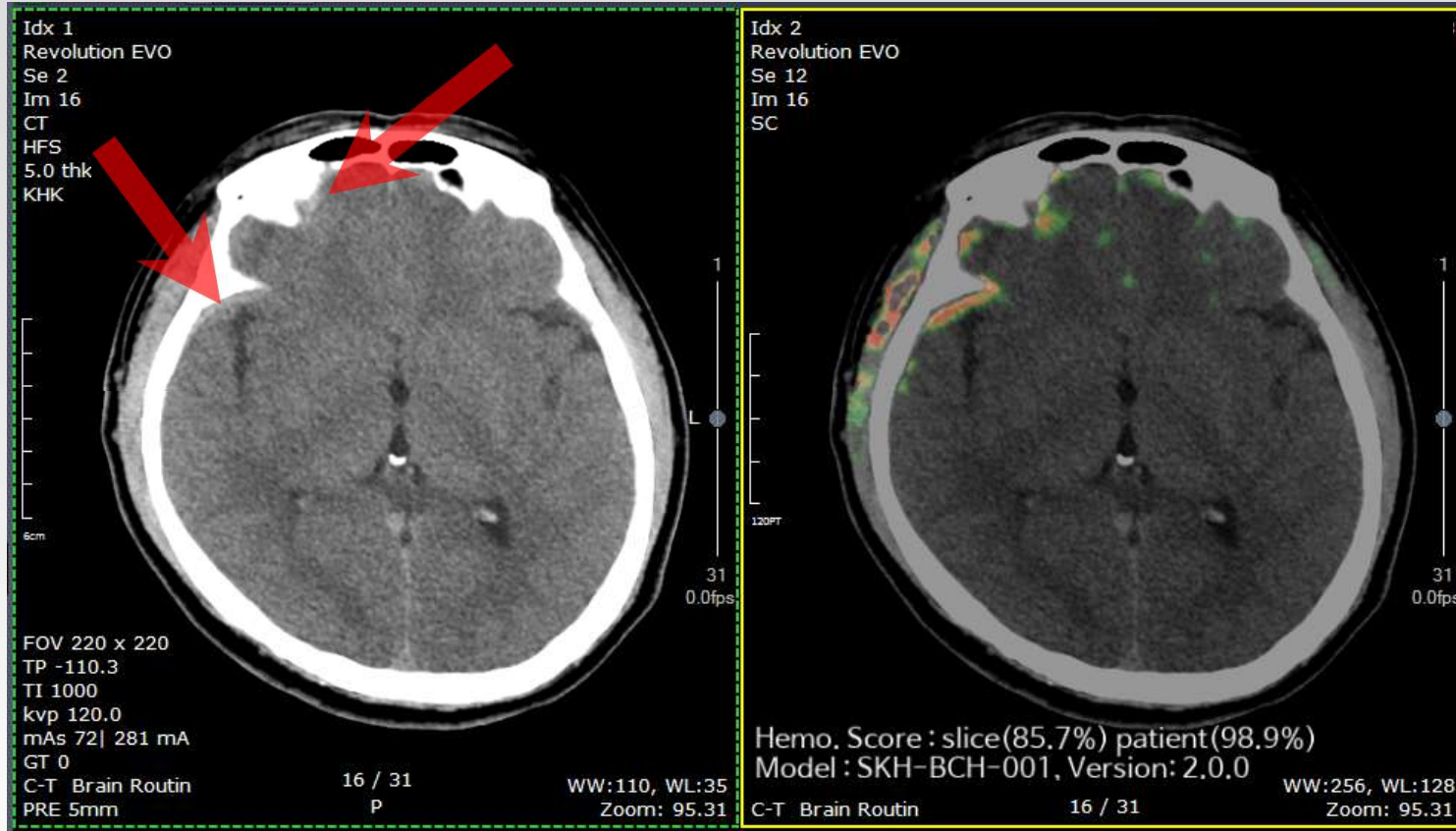
> **Non-radiologist Physician (n = 1), Radiologist (n = 1), and Neuroradiologist (n = 1)**
> ✓ **SDH in right frontal and temporal convexities**
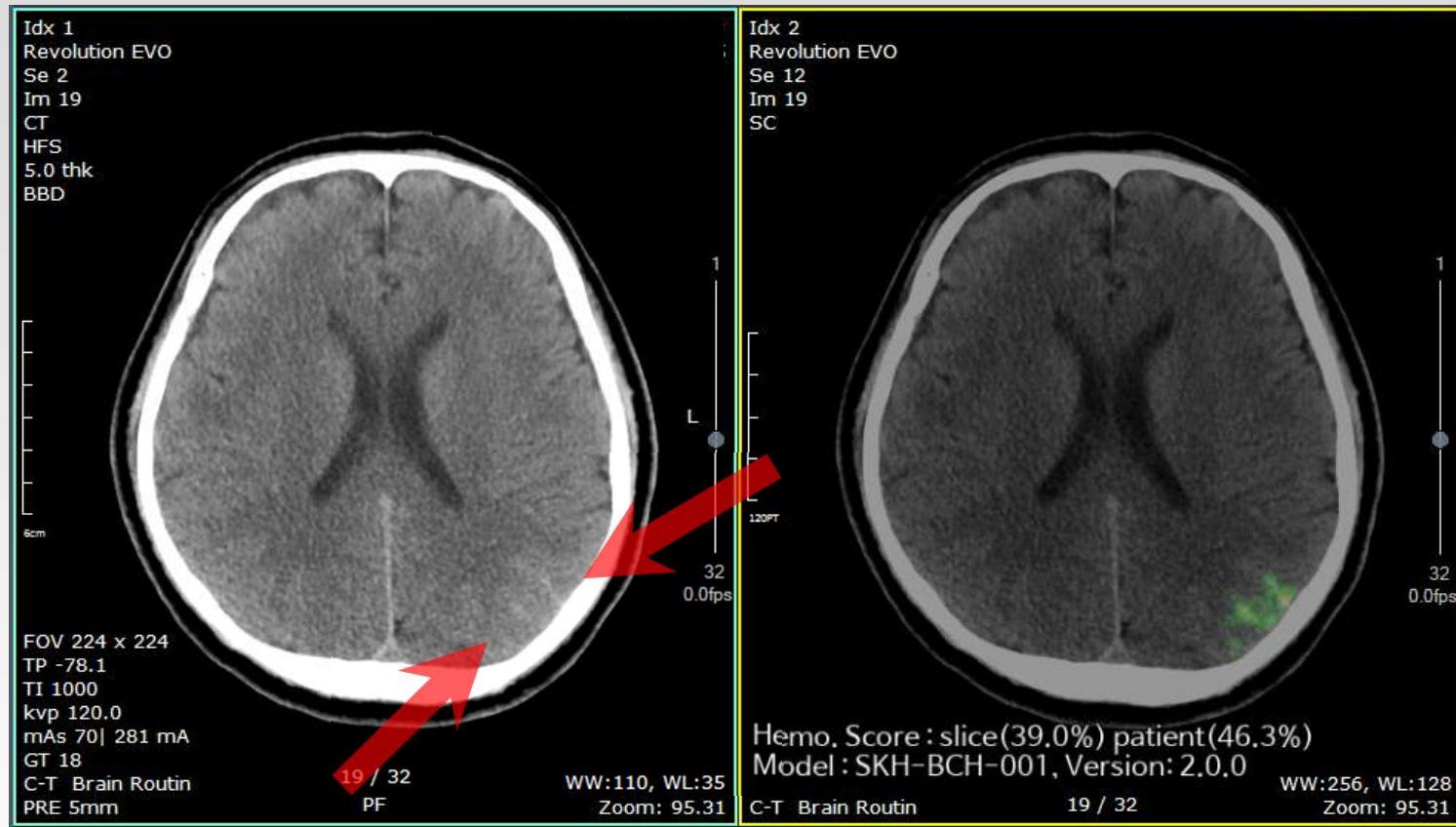
(Without AI) **False Negative** → (With AI) **True Positive**

> ➤ **Non-radiologist Physicians (n = 2)**
>
> ✓ **EDH in the right parietal convexity**

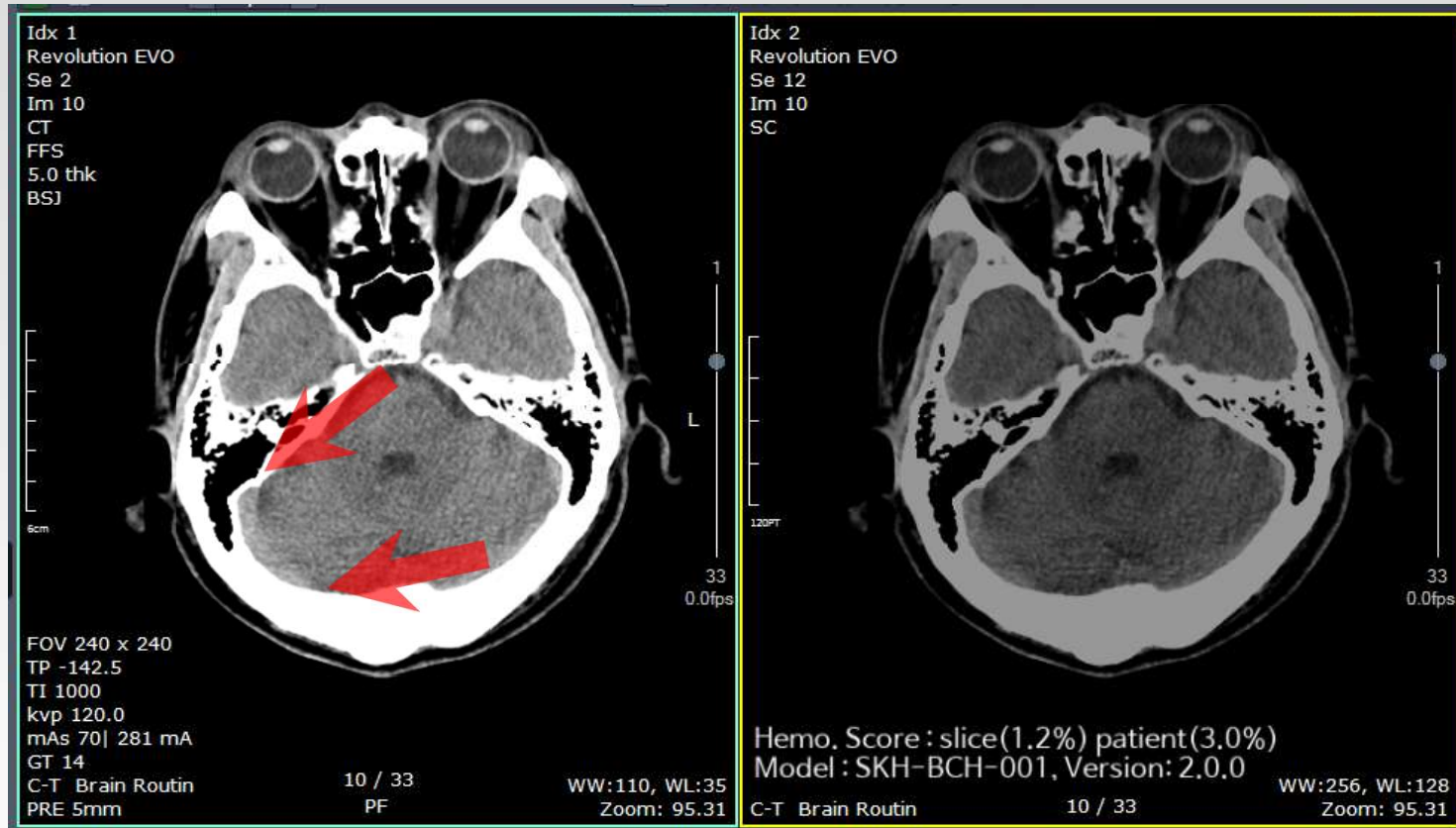# (Without AI) **False Negative** → (With AI) **True Positive**

> **Non-radiologist Physicians (n = 2) Radiologist (n = 1)**
> ✓ **SAH in vertex level**

(Without AI) **False Negative** → (With AI) **True Positive**

> **Non-radiologist Physicians (n = 3), Radiologists (n = 2), and Neuroradiologist (n = 1)**
>
> ✓ **SAH in left parietal convexity**

(Without AI) **False Positive** → (With AI) **True Negative**

> ➤ **Non-radiologist Physician (n = 1)**
>
> ✓ **Prominent right transverse sinus**

✔ **Demo**

Contact Us

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Medical Insight+
Brain Hemorrhage (Brain Hemorrhage Detection Solution)

Thank You