VUNO Med® - DeepBrain™

Product Introduction

VUNO® | VUNO Med®

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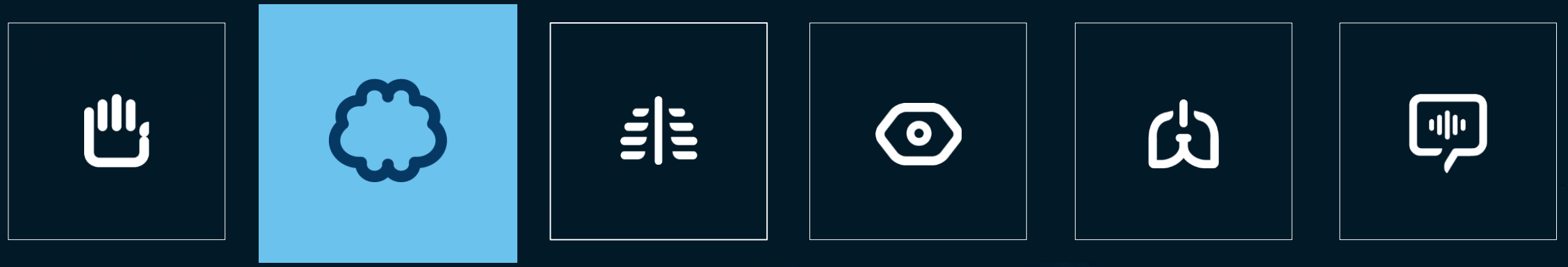
VUNO Med® Series



BoneAge™ | **DeepBrain™** | Chest X-ray™ | Fundus AI™ | LungCT AI™ | DeepASR™

Contents

1 Current Practice

Magnetic Resonance Imaging (MRI)

- Magnetic Resonance Imaging (MRI) is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body. [1]

Procedure

1. Takes approximately **20~40 minutes** depending on the size of the area being scanned and how many images are taken.[2]
2. Images are scanned with a patient lying down on a flat bed that is moved into the cylinder shape screening scanner.[2]
3. The patient should lie still while CT images are being taken because movement can result in blurry pictures. The patient may hear clicking, buzzing, and whirring noises during the scan.[2]

Remarks

1. Patients with artificial cardiac pacemakers or metal implants may not be able to have an MRI scan. [1]
2. MRI scan may be difficult for those who suffer from claustrophobia.[1]

Figure 1. MRI machine[3]

Figure 2. MRI Computer Screen[4]

1)https://seoul.hyumc.com/seoul/healthInfo/examination.do?action=view&testProcdrSurgrSeq=10259
2)https://guri.hyumc.com/guri/healthInfo/examination.do?action=view&returnAction=list&currentPageNo=1&recordCountPerPage=8&searchKeyword=MRI&listViewType=0&testProcdrSurgrSeq=10208&rcnt=2
3) https://my.clevelandclinic.org/health/diagnostics/4876-magnetic-resonance-imaging-mri
4) https://www.vrfitnessinsider.com/health-game-changer-vr-mris/

1 Current Practice

Brain MRI

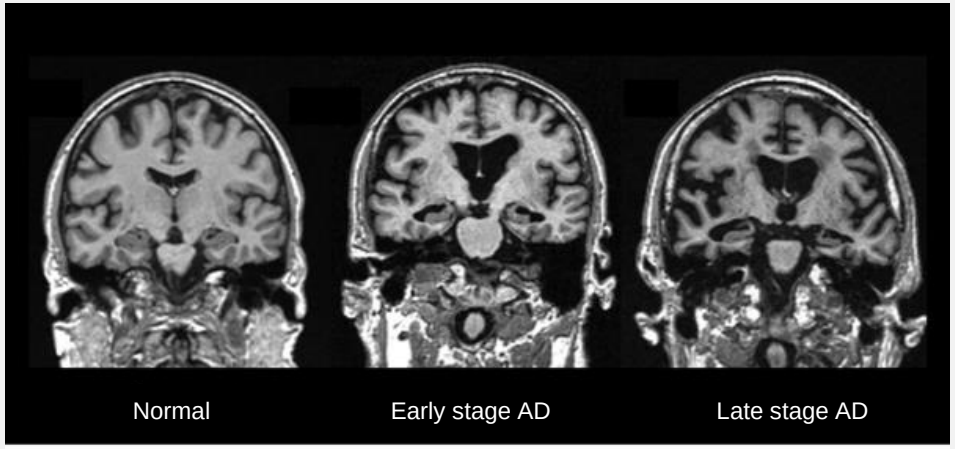


Figure 1. Alzheimer's Disease Brain MRI[3]

1. Detectable brain diseases with MRI[1]

- **Stroke**
- **Brain Hemorrhage**
- **Dementia**
- **Brain Tumor**
- **Cerebral Infection**
- **Brain Malformation**
- **Other Degenerative Brain Disease**

2. Cerebral Infarction Epilepsy, Degenerative brain disease or dizziness **which occurred within 3 hours** can be detected **with MRI** but not with other examination such as CT.[2]

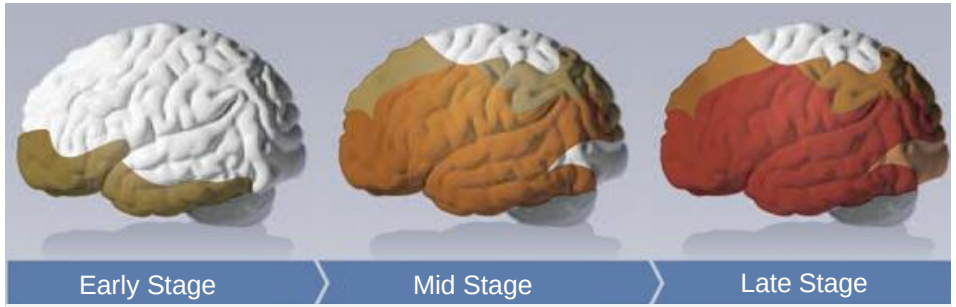
3. For early detection of stroke in middle aged adults, the blood vessels and brain are examined at the same time.[2]

1) https://guri.hyumc.com/guri/healthInfo/examination.do?action=view&testProcdrSurgrSeq=10208&rcnt=2
2) http://www.ish.or.kr/ish/exam_view?seq=276&&sg=A&sound=&name=MRI&code1=&code2=
3) http://anam.kumc.or.kr/department/treatDeptDesc01.do?DP_CODE=AA340

1 Current Practice

Alzheimer's Disease

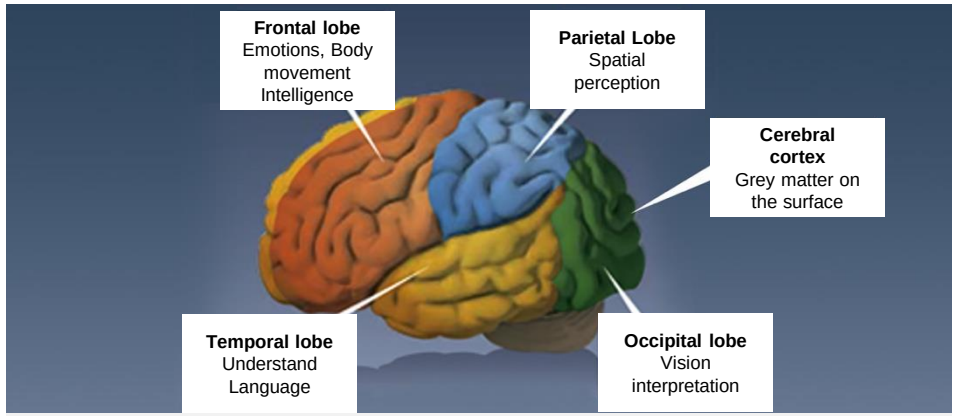
- Alzheimer's Disease (AD) : Most prevalent dementia among the middle and old ages and accounts for 60-70% of all dementia diseases.[1]
- In early stages, **the volume atrophy of Hippocampus, Entorhinal Cortex, Medial Temporal Lobe** is more apparent. [2]
- But gradually **more structural changes such as overall brain atrophy with expansion of the cerebral ventricles** are observed. [2]



[Figure 1. AD disease progress[5]]

Cortical Thickness

- The measurement of the cortical thickness is a neuroanatomically important analysis to monitor any abnormalities[3]
- Changes occur in neurodegenerative diseases such as Alzheimer's Disease or neuropsychological diseases such as Epilepsy, Depression and Schizophrenia. [4]



[Figure 2. Brain Anatomy[5]]

1) http://psy.amc.seoul.kr/asan/depts/psy/K/bbsDetail.do?menuId=862&contentId=206024
2) http://www.silverweb.or.kr/load.v2.asp?subPage=615
3) Lerch J. Measuring Cortical Thickness. A Masters Thesis Proposal July 2001
4) RSNA 2019. https://dps.rsna.org/exhibit/?exhibit=NR353-ED-WEA10
5) http://health.chosun.com/site/data/html_dir/2012/11/20/2012112001733.html

1 Current Practice

AD diagnosis process[1]

Before visit	1st outpatient visit	Additional exam	Review exam results	2nd outpatient visit	Monitor and manage
• Neuropsychological exam • Scan a brain image • Review the patient's medical records	• Check the medical history of the patient and patient's family. • Screening geriatric depression. • Mini-Mental State Exam (MMSE)	• Physical exam • Neuropsychological test • **MRI test** • Amyloid PET test (optional)	• Medical records • **MRI test results** • Other test results	• **AD cause analysis** - based on MRI and other test results	• Neuropsychological test • Education for AD management

MRI test*

	Reservation	MRI test	Reading	Diagnosis
			Radiologist	Neurologist
		20~40 minutes[2]	10~20 minutes[3]	Total period for result analysis 3~7days[4]

➡ ***It is a daunting task to accurately measure the volume of the brain and diagnose the disease.***

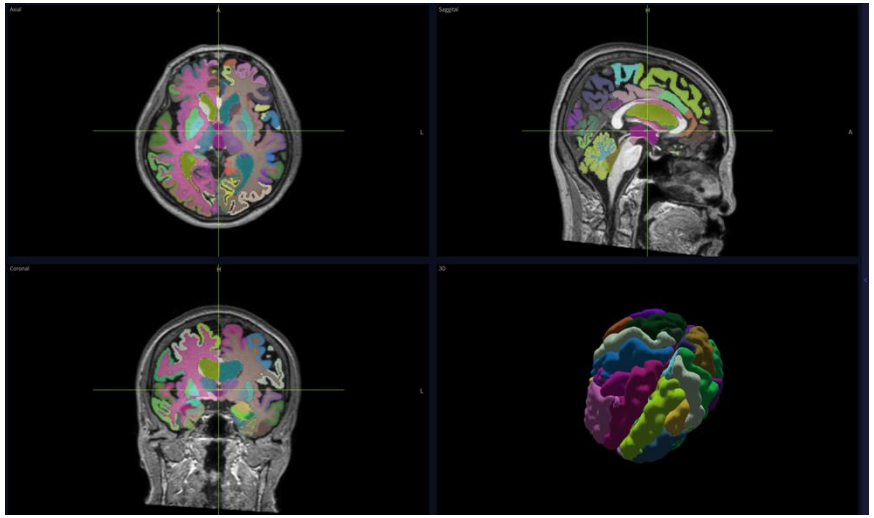
*Time taken for MRI test may differ by center and patient.

1) http://www.snuh.org/health/nMedInfo/nView.do?category=DIS&medid=AA000115
2) https://guri.hyumc.com/guri/healthInfo/examination.do?action=view&testProcdrSurgrSeq=10208&rcnt=2
3) It is About "Time": Academic Neuroradiologist Time Distribution for Interpreting Brain MRIs. Acad Radiol. 2018 Dec;25(12):1521-1525.
4) https://seoul.hyumc.com/seoul/customer/question.do?action=view&bbsId=regularQue&nttSeq=10154

2 Product Features

Brain Atrophy Analysis

- Provides **volumetric data on 100 different regions** through **brain parcellation.**
- Provides information of **brain atrophy** through the analyzed volume data.
- Provides information of **normative percentile,** the relative score compared to the normal average



VUNO Med®-Deep Brain

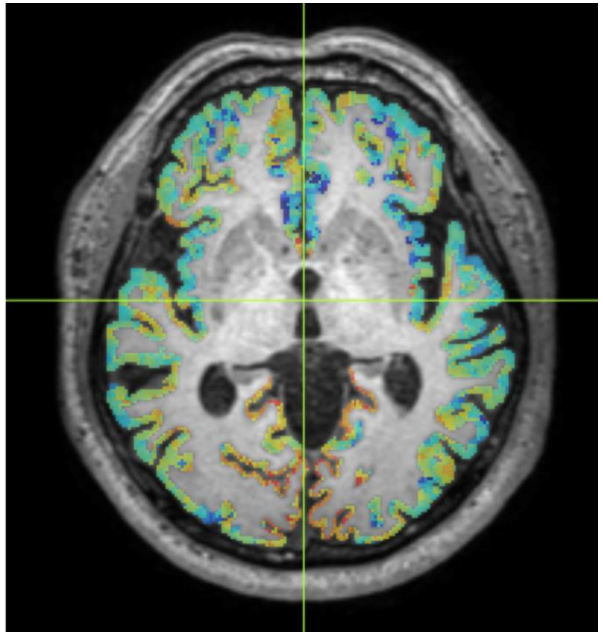
5% 10% 25%

Group		Brain Region	Volume (ml)			Normative Percentile (Volume)			Normative Percentile (ICV ratio)		
			left	Right	total	left	Right	total	left	Right	total
TEMPORAL LOBE		TEMPORAL LOBE	52.95	51.24	104.19	26.0	42.1	38.2	47.4	75.0	70.4
	Medial	Hippocampus	3.0	3.5	6.5	0.0	0.7	0.0	2.0	2.0	2.0
		Amygdala	1.1	1.7	2.8	3.3	23.0	9.2	6.6	60.5	23.7
		Entorhinal Cortex	2.5	4.1	6.6	17.8	55.3	36.2	36.2	78.3	68.4
		Parahippocampal Gyrus	2.2	1.7	3.9	32.2	62.5	46.1	58.6	84.9	70.4
		Fusiform Gyrus	10.3	5.6	15.9	86.2	17.1	53.3	98.7	28.9	84.2
		Temporal Pole	1.0	2.2	3.2	4.8	67.1	27.6	12.5	83.6	50.0
	Lateral	Superior Temporal Gyrus	11.1	9.5	20.6	38.2	42.1	40.1	69.7	75.0	77.6
		Middle Temporal Gyrus	10.9	11.6	22.6	48.0	52.0	53.3	77.6	80.3	81.6
		Inferior Temporal Gyrus	7.8	8.7	16.5	40.1	55.9	43.4	63.16	80.3	77.0
		Transverse Temporal Cortex	1.4	1.0	2.4	83.6	36.8	68.4	92.1	54.6	84.9
		Banks of the Superior Temporal Sulcus	1.5	1.6	3.1	19.7	26.3	16.4	30.3	40.8	32.2
FRONTAL LOBE		FRONTAL LOBE	85.0	79.2	164.2	75.7	67.8	64.5	88.8	88.8	92.4
		Superior Frontal Gyrus	22.6	19.8	42.4	91.4	72.4	86.2	99.3	100.0	100.0
		Middle frontal Gyrus - Rostral	16.7	14.2	30.9	76.3	72.4	76.3	96.7	96.1	97.4
		Middle Frontal Gyrus - Caudal	5.3	4.2	9.4	68.4	34.2	52.0	87.5	57.9	78.9
		Inferior Frontal Gyrus - Pars Opercularis	4.6	5.5	10.2	84.2	99.3	96.1	94.1	99.3	98.7
		Inferior Frontal Gyrus - Pars Triangularis	3.6	3.6	7.2	75.7	41.4	60.5	88.8	62.5	84.9
		Inferior Frontal Gyrus - Pars Orbitalis	1.2	1.9	3.1	5.3	25.7	9.2	9.9	48.0	21.1
		Orbitofrontal Cortex - Lateral	8.1	6.5	14.6	66.4	57.2	63.2	96.1	88.8	94.1
		Orbitofrontal Cortex - Medial	6.2	5.0	11.2	80.3	37.5	61.2	97.4	72.4	91.4
		Precentral Gyrus	12.9	14.0	26.9	50.7	77.6	61.8	81.6	95.4	93.4
		Paracentral Lobule	2.7	3.0	5.7	61.8	63.2	64.5	82.9	86.2	90.1
		Frontal Pole	1.0	1.6	2.6	76.3	75.7	77.0	88.8	89.5	90.1

Group	Brain Region	Volume (ml)			Normative Percentile (Volume)			Normative Percentile (ICV ratio)		
		left	Right	total	left	Right	total	left	Right	total
PARIETAL LOBE	PARIETAL LOBE	56.3	48.7	105.0	34.2	58.9	65.8	83.9	87.8	88.2
	Postcentral Gyrus	9.3	8.6	17.9	34.2	68.4	52.6	67.8	92.1	80.3
	Supramarginal Gyrus	11.2	8.5	19.8	96.1	46.1	78.9	100.0	70.4	96.7
	Superior Parietal Cortex	12.2	10.1	22.3	34.2	49.3	36.8	63.16	83.6	75.0
	Inferior Parietal Cortex	14.7	12.0	26.7	78.3	71.7	76.3	95.39	92.1	96.1
	Precuneus Cortex	8.9	9.5	18.4	48.0	52.0	48.7	79.61	88.82	84.9
OCCIPITAL LOBE	OCCIPITAL LOBE	20.8	21.4	42.2	48.4	53.9	51.3	74.7	81.6	78.6
	Lingual Gyrus	4.4	3.7	8.1	94.7	77.0	91.4	99.3	92.1	97.4
	Pericalcarine Cortex	1.1	1.2	2.3	8.6	23.0	14.5	15.8	40.8	25.7
	Cuneus Cortex	2.4	3.5	5.9	53.3	49.3	51.3	77.6	78.9	78.9
	Lateral Occipital Cortex	12.8	13.1	25.9	43.4	58.6	51.3	71.7	84.2	78.3
CINGULATE CORTEX	CINGULATE CORTEX	2.2	1.4	18.5	46.7	29.9	39.5	66.8	40.8	65.8
	Rostral Anterior Cingulate Cortex	2.0	2.8	4.7	27.0	96.7	70.4	40.8	99.3	91.4
	Caudal Anterior Cingulate Cortex	1.5	1.6	3.1	36.2	36.2	34.2	49.3	46.1	51.3
	Posterior Cingulate Cortex	3.5	3.0	6.5	57.2	15.1	32.2	84.2	32.9	59.2
	Isthmus Cingulate Cortex	2.5	1.7	4.2	67.1	23.7	44.7	86.8	35.5	72.4
INSULA	Insula	6.7	5.8	12.5	64.5	46.1	57.9	96.1	83.6	91.4
CORTICAL GRAY MATTER	CORTICAL GRAY MATTER	223.9	207.8	446.6	26.7	29.1	28.8	70.2	66.3	68.0
SUBCORTICAL GRAY MATTER	SUBCORTICAL GRAY MATTER	18.9	19.0	37.9	45.4	50.3	47.0	73.0	80.3	75.7
	Thalamus	4.5	5.2	9.7	32.2	30.9	30.9	63.8	62.5	62.5
	Caudate	3.0	3.1	6.2	51.3	45.4	48.0	75.7	70.4	72.4
	Putamen	4.0	3.5	7.6	77.0	61.8	70.4	90.8	85.5	89.5
	Pallidum	2.3	2.0	4.3	39.5	48.7	46.1	70.4	75.0	76.3
	Accumbens Area	0.3	0.4	0.7	94.1	84.2	91.4	98.7	92.8	97.4
	Ventral Diencephalon	4.8	4.7	9.5	21.7	52.0	34.9	61.2	88.2	75.0
CEREBRAL WHITE MATTER	Cerebral White Matter	242.2	243.2	485.4	72.9	72.9	72.9	95.3	95.3	94.6
VENTRICLE	3rd Ventricle	-	-	3.1	-	-	92.8	-	-	98.0
	4th Ventricle	-	-	2.0	-	-	94.1	-	-	96.7
	Lateral Ventricle	21.0	19.5	40.4	63.2	63.8	62.5	71.7	73.7	73.0
	Inferior Lateral Ventricle	2.2	1.8	4.0	95.4	96.7	97.4	97.4	97.4	98.0
	Choroid Plexus	1.0	0.8	1.7	6.6	37.5	15.8	14.5	53.9	30.9
CEREBELLUM	Cerebellum-Cortex	43.5	42.2	85.7	0.7	4.6	0.7	9.9	19.1	13.2
	Cerebellum-White Matter	15.1	13.4	28.5	37.5	30.9	31.6	72.4	59.9	67.1

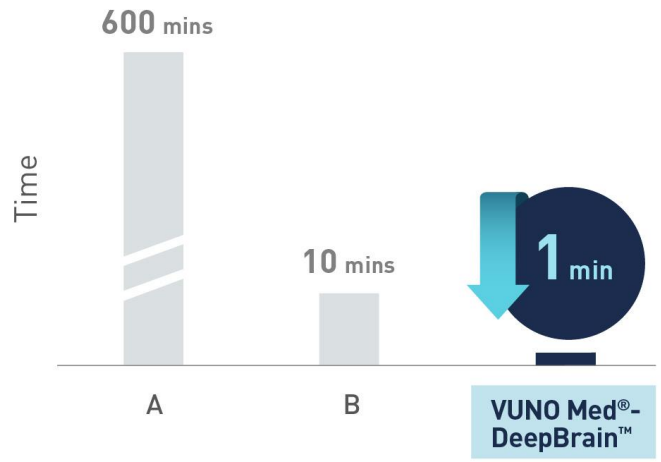
Cortical Thickness Measurement

- Provides **cortical thickness data of cortex area** from 0mm.
- Visualizes the cortical thickness (0~5mm) through a **Color Map** on the MRI image.



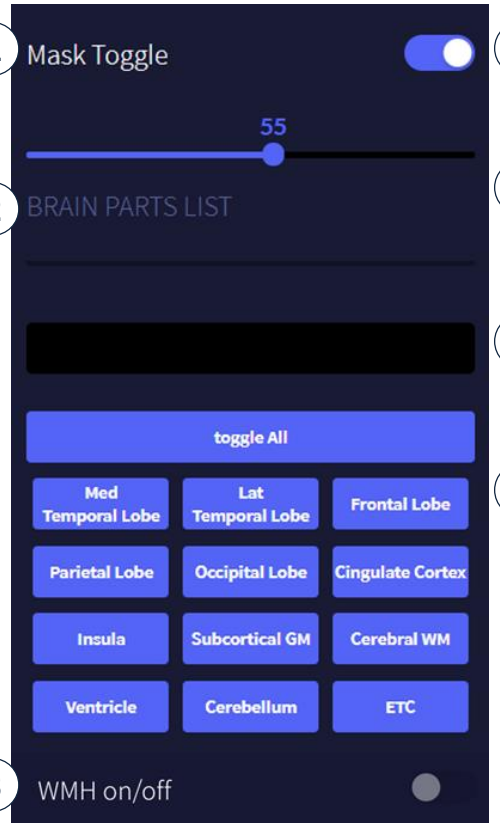
Workflow Improvement

- **Provides results within 1 minute**[1]
- **Can be integrated with PACS**



Analysis Tool

- **Analysis Tool**



1. Turning On / Off the overlay mask on specific areas, transparency can be controlled while the mask is on.
2. Specific brain regions can be chosen for masking.
3. White Matter Hyperintensity Turning On / Off, MRI T2 Flair image can be chosen when it is on
4. **Viewer Part**
   Volumetric information is shown when the mouse cursor is on the specific area of the brain

a) **Volume (mm^3)** : Definite the volume of the specific area
b) **ICV ratio (%)** : Ratio of the specific area volume to the whole brain volume
c) **Percentile (%)** : Low rank percentage among the normal population. Small number means more atrophy.

WMH, white matter intensity ; ICV, intra cranial volume
1) Can differ by internet speed or server environment

Learning based on Comprehensive Data

- **Trained on MR T1 images of 4 thousand cases** collected form **multi-centers** from collaboration with leading institutions in S. Korea. [1]
- **Compatible to multiple vendor devices** including Philips, Siemens, GE Healthcare and **multiple field strengths** including 1.5T, 3.0T[1]
- Performances has been confirmed with **A beta PET positive data.** [1]
- **A higher level of consistency with Freesurfer** has been reported for almost all areas of the brain compared to other commercialized products with **higher consistency for small areas** such as Putamen, Pallidum[1,2] (Fig.2)

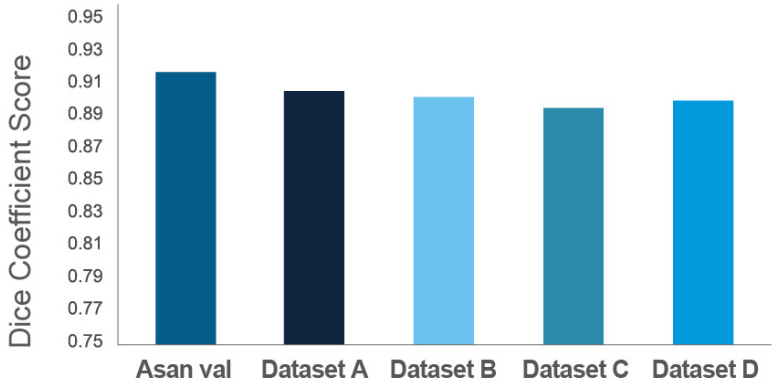


Figure 1. Volume Accuracy on Multicenter[1]

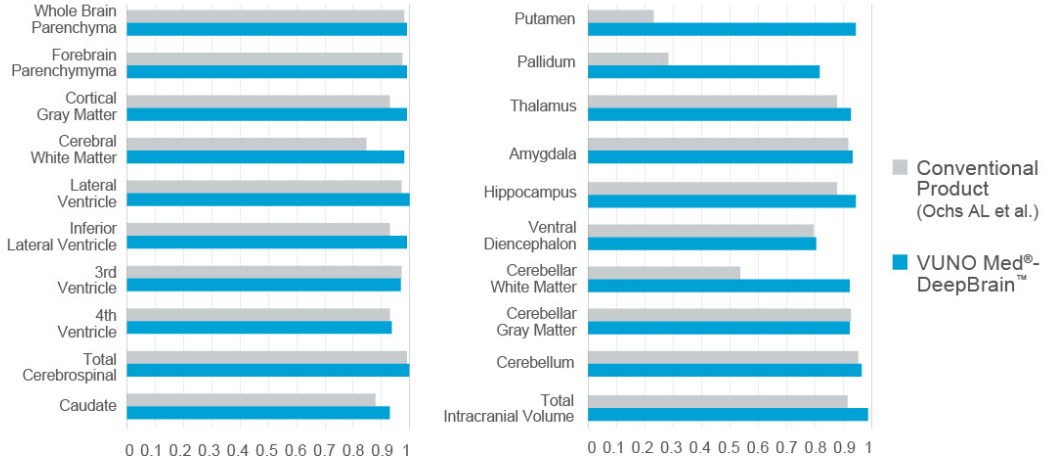


Figure 2. Intra Correlation Coefficient (with FreeSurfer)[1,2]

1) Internal retrospective study
2) Ochs AL, et al. Comparison of Automated Brain Volume Measures obtained with NeuroQuant and FreeSurfer. J Neuroimaging. 2015 Sep-Oct;25(5):721-7.

Proven Performance

- **A higher level of consistency in White Matter Hyperintensity** analysis for MR T2 images.
  - **Internal validation result : dice coefficient score 0.894**[1]
  - **External validation result : dice coefficient score 0.837**[1](Fig.1)

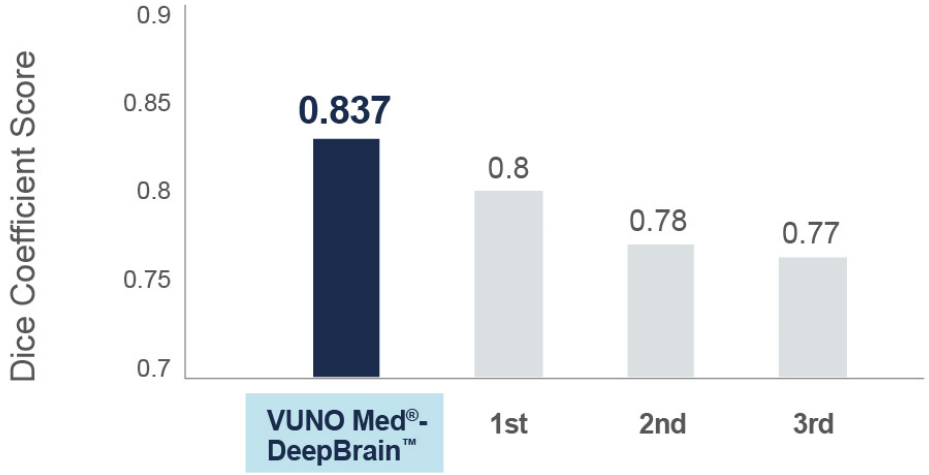
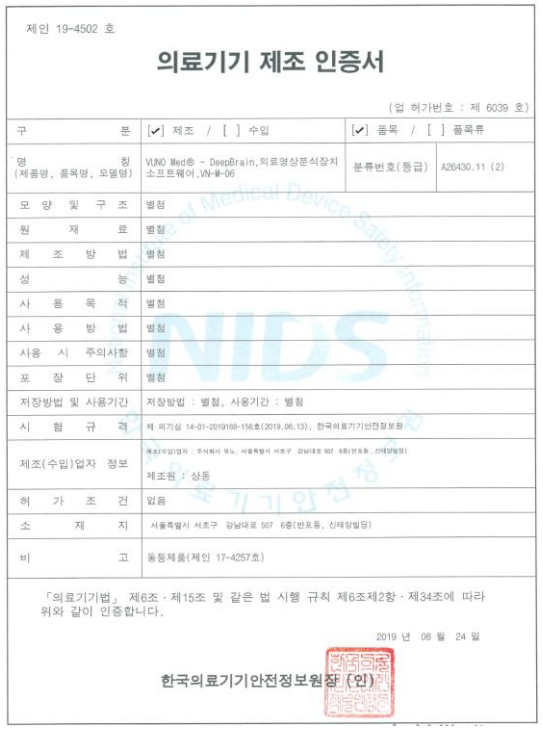


Figure 1. VUNO Med® - DeepBrain™ vs MICCAI 2017 TOP 3 [1,2]

1) Internal validation
2) WMH Segmentation Challenge Results MICCAI 2017

Certifications


제인 19-4502 호

의료기기 제조 인증서

(업 허가번호 : 제 6039 호)

구 분	[✓] 제조 / [ ] 수입	[✓] 품목 / [ ] 품목류	
명 칭 (제품명, 품목명, 모델명)	VUNO Med® - DeepBrain,의료영상분석장치 소프트웨어,VN-M-06	분류번호(등급)	A26430.11 (2)
모 양 및 구 조	별첨		
원 재 료	별첨		
제 조 방 법	별첨		
성 능	별첨		
사 용 목 적	별첨		
사 용 방 법	별첨		
사용 시 주의사항	별첨		
포 장 단 위	별첨		
저장방법 및 사용기간	저장방법 : 별첨, 사용기간 : 별첨		
시 험 규 격	제 의기심 14-01-2019168-156호(2019.06.13), 한국의료기기안전정보원		
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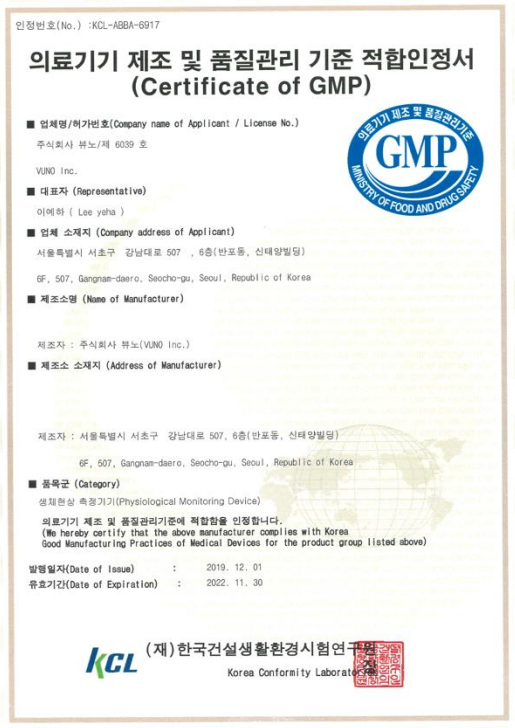
2019 년 06 월 24 일

한국의료기기안전정보원장 (인)

JUN 24, 2019

MFDS Regulatory Approval


인정번호(No.) :KCL-ABBA-6917

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)

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6F, 507, Gangnam-daero, Seocho-gu, Seoul, Republic of Korea

■ 품목군 (Category)

생체현상 측정기기(Physiological Monitoring Device)

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2019. 12. 01

유효기간(Date of Expiration) : 2022. 11. 30

(재)한국건설생활환경시험연구원

Korea Conformity Laboratory

DEC 01, 2019

GMP


SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31833402

VUNO Inc.

6F, 507, Gangnam-daero, Seocho-gu, Seoul, Republic of KOREA

EN ISO 13485:2016

Design, Development, Manufacturing, Service and Sales of Medical Image Analyzing Sofware for Bone Age Assessment, Chest X-Ray, Lung CT, Fundus and Brain MRI

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date	30.11.2018
Expiry Date	29.11.2021
Revision Date/No	15.06.2020 / 1

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://bdis.turkak.org.tr.

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Szutest.com.tr

NOV 30, 2018

ISO 13485:2016


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EC CERTIFICATE

According to Annex V of the Directive 93/42/EEC on Medical Devices

Production Quality Assurance System

Certificate Number: 2195-MED-2016701

Manufacturer:	Vuno Inc. 6F, 507, Gangnam-daero, Seocho-gu, Seoul, Republic of KOREA
Product(s):	1. Medical Image Analyzing Software for Bone Age Assessment 2. Medical Image Analyzing Software for Chest X-Ray Image Analyzing 3. Medical Image Analyzing Software for Fundus Image Analyzing 4. Medical Image Analyzing Software for Lung CT Image Analyzing 5. Medical Image Analyzing Software for Brain MRI Image Analyzing
Model(s):	1. VN-M-01 2. VN-M-02 3. VN-M-03 4. VN-M-04 5. VN-M-06
Reference Report No:	MM0718-P002-R01, MM0718-P002-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

This EC certificate is valid till 2024-05-26.

Issue Date: 2020-06-15

Rukiye BALKAN
Deputy General Manager

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JUN 15, 2020

EC Certificate

MFDS, Ministry of Food and Drug Safety

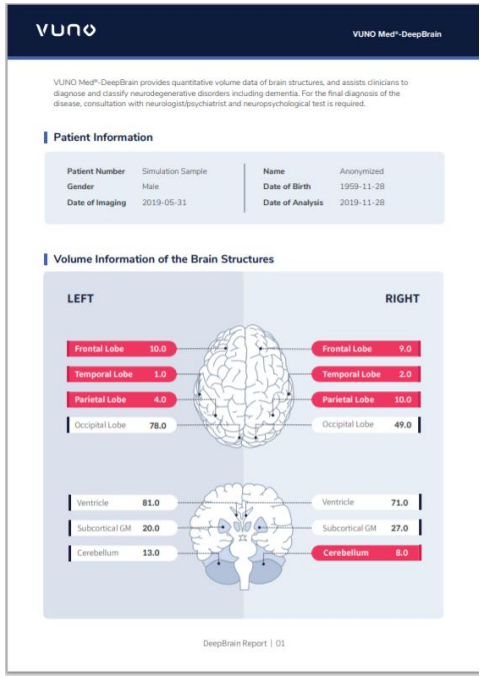
Domestic Patents

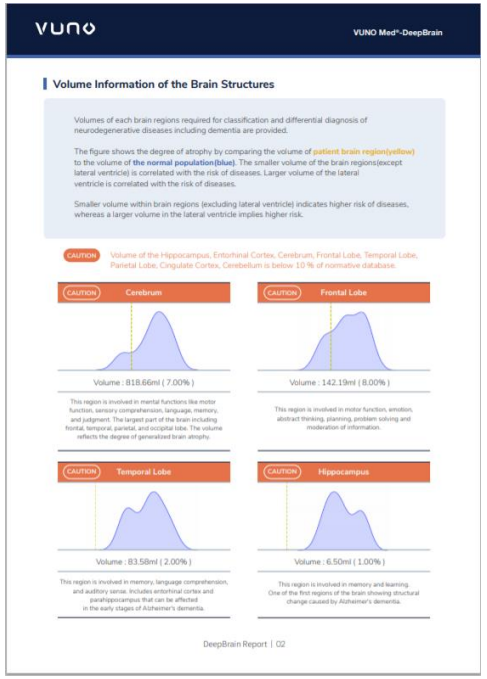
Registration No.	Title	Classification
10-1875468	Disease model based medical information service delivery methods and devices	Imaging (General)
10-1840350	Methods and devices to increase reading efficiency using the user's eye information during medical image reading	Imaging (General)
10-1849072	Content-based medical imaging methods and systems	Imaging (General)
10-1880035	Imaging methods and devices, image analysis methods	Imaging (General)
10-1925463	Methods for registering and verifying image hash values, and devices using them	Imaging (General)
10-1957812	Methods for coding and decoding using characteristic space and devices using artificial intelligence image analysis	Imaging (General)
10-1957811	Method for calculating severity of dementia of a subject based on medical images and device using them	Imaging (DeepBrain)
10-1948701	Method for determining brain disease of subject based on potential variable describing brain structure of subject and device using them	Imaging (DeepBrain)
10-1995383	Method for determining brain disease based on feature ranking of medical images and device using them	Imaging (DeepBrain)
10-2067412	Dementia evaluation method and device using thems	Imaging (DeepBrain)

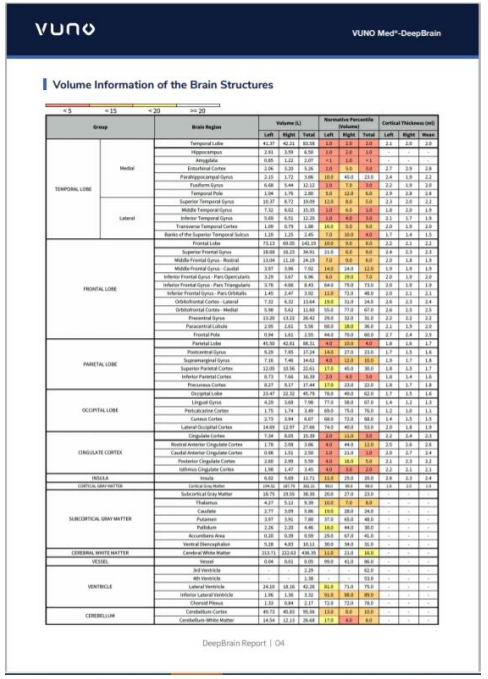
Patient Support

Brain Atrophy Report

- Provides **statistical analysis results** of volume compared to the norm
- **Visualized graphs and diagrams for easy interpretation**
- **Report can be customized** catered to the specific needs of the user.







3 Value Proposition

Autonomous & Clinically Aligned

- It can be a supporting tool for diagnosis of neurodegenerative diseases such as Alzheimer's Disease based on normative percentile score and volume information for 100 brain areas.
- Patient satisfaction can be improved by providing the Brain Atrophy Report with the statistical analysis results and visualized graphs.

Cost / Time - Efficient

- Provides quantitative data on brain parcellation within 1 minute
- Analysis tool for additional analysis without further viewer programs necessary.

Agnostic to Any Device

- User Interface design primarily focused on user's convenience. Easy to use without much time required for adaptation.
- PACS Integration available depending on the clinical environment. Easily integrated to the current workflow.

Technical Features

4 System Requirements

5 Cloud / On-Premise

6 User Interface

4 System Requirements

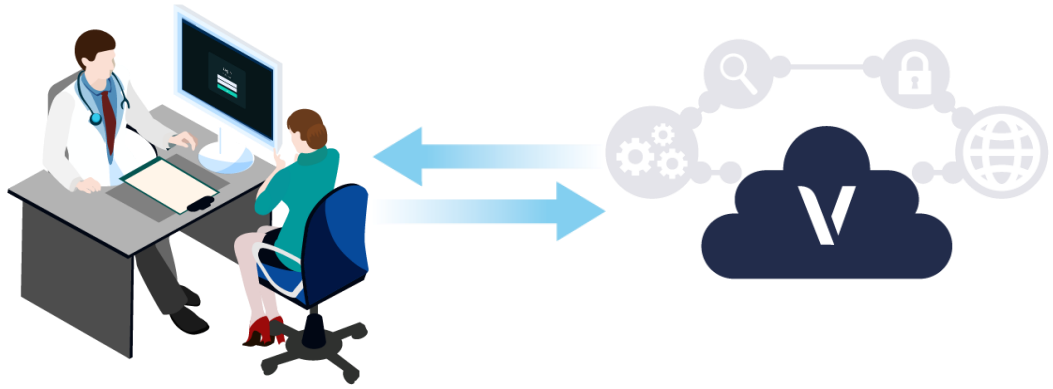
Software Name	Operating Environment			
VUNO Med®-DeepBrain™	**Server**	• **Operating System** : Ubuntu 16.04	• **Hardware** : CPU Intel Core i5 Processors RAM 8 GB HDD 500 GB GPU NVIDIA GeForce GTX 1070	• **Internet Browser** : Google Chrome V69.0 • **Display** : 1920*1080
	Client	• **Operating System** : Windows 7 Ubuntu 16.04 Mac 10.13.3	• **Hardware** : CPU Intel Core i3 Processors RAM 8GB Storage 128GB HDD	• **Internet Browser** : Google Chrome V69.0 • **Display** : 1920*1080

Requires equivalent or higher specifications

5 Cloud / On-Premise

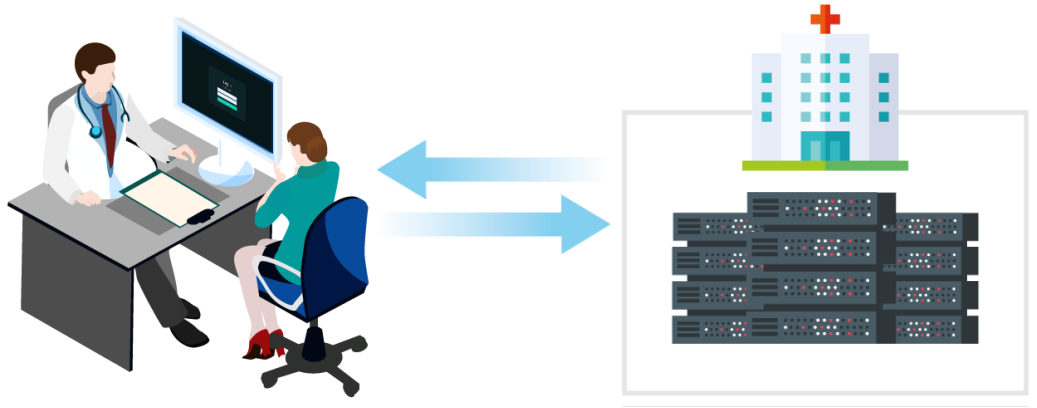
Cloud

- Cloud-based service allows users to analyze anytime, anywhere with access to the Internet
- Available on a subscription basis and/or a cost per API call



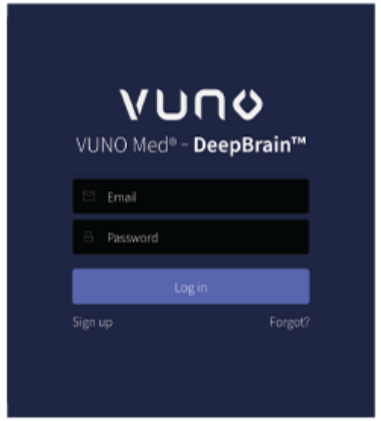
On-Premise

- On-premise service allows users to analyze anytime, anywhere with access to the same in-house server. The server can be prepared by VUNO or the user.
- Available on a subscription or credit basis (pay-per use)



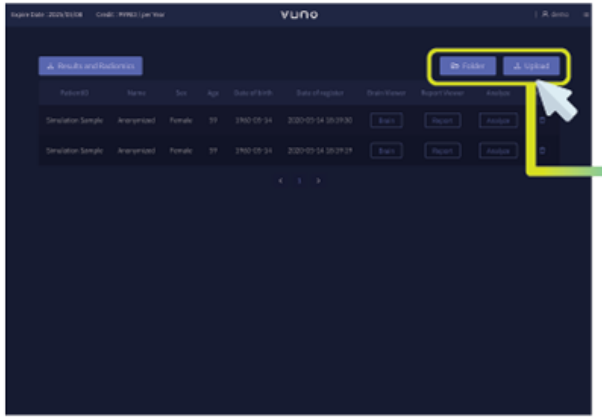
6 User Interface

Log In



Create an account and login

First Screen After Login



Folder

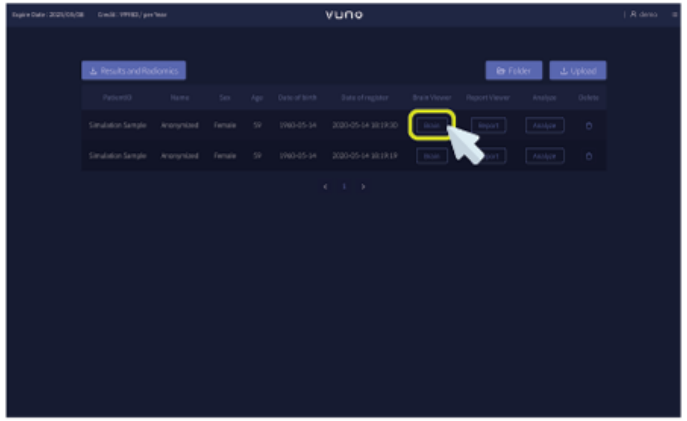
Upload all images from the folder

Upload

Upload a single file

Click the **Folder**, **Upload** button on the upper left corner to upload image

Image Analysis



Click the **Brain** button and start the analysis

4 Clicks **1 Minute***

* May vary depending on internet and/or sever environment

6 User Interface

Analysis Screen

Results

1. **Mask Toggle**: Turning On / Off the overlay mask on specific areas. Transparency can be controlled while the mask is turned.
2. **Brain Parts List**: Area group of interest can be chosen for masking.
3. **WMH On/Off**: Shifting b/w T1 MR to T2 Flair images by turning on / off

   WMH On: Brain Parts List will be changed to White Matter Hyperintensity
4. **Finding Report**: Comments can be added or revised

Report

5

7 Precautions

Performance-related Precautions

1) No performance guarantees on images of patients under the age of 19.
2) Analysis results may vary depending on the data format(.dcm, .nii. Zip) and the resolution of the imported images.

General Precautions

1) VUNO Med® - DeepBrain™ is not a stand-alone diagnostic tool that can make a decision alone; hence requires professional judgement from the user.
2) There is a chance of misdiagnosis when a medical decision of diagnosis and treatment is made solely based on this solution.
3) The user is held responsible for the VUNO Med® - DeepBrain™ assisted final diagnosis.

8 Q&A

Is it a medical device?

Yes, it is. VUNO Med® - DeepBrain™ received regulatory approval from Korea Ministry of Food and Drug Safety as Medical Image Detection Assisting Software, second-class medical device in June 2019.

What kind of data have been used for training the AI algorithm?

Brain MR images from 4,000 patients that were labelled by physicians from partnering R&D hospitals were used to train the algorithm.

Are there any risks of personal data breach?

De-identified data was used even from the development phase and personal information such as name and age have not been used during the training process.

Has its clinical performance been proven?

VUNO Med® - DeepBrain™ showed higher consistency to Freesurfer in brain parcellation on almost all areas compared to other commercially available products. The level of consistency in Brain Parcellation was 0.9 and in White Matter Hyperintensity the result for internal and external validation were 0.894 and 0.837, respectively.

Would installation in my PC be enough to use the solution?

It is very easy to use. The product comes in two services - cloud or on-premise. For cloud based service, you just need to open Google Chrome on your PC and access VUNO Med® - DeepBrain™ URL then simply login. For on-premise service, use your local PACS and interface to analyze the images and Interface.

8 Q&A

How can I use the device and how much does it cost?

You need 1 credit for 1 analysis and credits are provided to each ID. Please contact your sales representative for more information on pricing and purchasing credits.

Are there any legal issues concerning the use of patient information in AI-based software?

No, there are no legal issues as patients' medical data is only used for diagnosis support. Only data on brain atrophy is provided and patient's data is not used for additional training.

Specifications for my PC does not meet the minimum specifications. Can I still use the solution?

The minimum specifications are mere specifications required for stable performance of VUNO Med® - DeepBrain™ and it can still operate under the minimum specifications. However, it may take longer time to analyze the data. Please inform us if our engineers need to check your PC conditions.

I would like to demo your solution at my clinic.

Please contact customer@vuno.co or apply for a demo through the VUNO webpage (www.vuno.co).

How long is the warranty period?

In general, we provide a one-year service warranty for the software and a two-year hardware warranty for the on premise server(s). For more information, please visit the "Customer Policy" on our website or software.

Thank you!

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