VUNO Med® - LungCT AI™

Product Introduction

VUNO® | VUNO Med®

Registered in R.O.K. & U.S. Patent and Trademark Office

VUNO Med® Series

BoneAge™

DeepBrain™

Chest X-ray™

Fundus AI™

LungCT AI™

DeepASR™

Contents

1 Current Practice

Computed Tomography (CT)

- A computerized x-ray imaging procedure in which a beam of x-rays is aimed at a patient and quickly rotated around the body to generate the cross-sectional images of the body[1]
- Provides more detailed information than plain x-rays[1]

Figure1. CT[1]

Figure2. CT Machine[2]

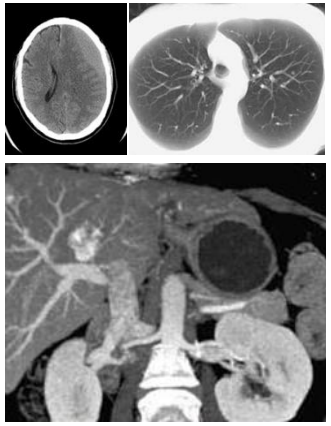


Figure3. CT Images[1]

Procedure

1. It takes approximately **10 ~ 15 minutes** in total (including preparation time) [1]
2. Taken with patient lying down on the table with the head facing upwards[1]
3. A patient follows the instructions to stay still and maintain appropriate posture during the scanning[1]

Remarks

1. CT can be scanned for all body parts including the abdomen, brain, head, sinus, liver, hear, chest, and spine[1]
2. A sedative may be administered orally or through intravenous injection[1]
3. Depending on method, patients are exposed to radiation dose between 2~10mSv[1]

1) http://www.samsunghospital.com/dept/medical/checkupSub01View.do?ds_code=D0003873&main_content_id=1104&content_id=1104&cPage=1&DP_CODE=BR&MENU_ID=003
2) https://www.prnewswire.com/news-releases/philips-showcases-breadth-of-radiology-solutions-at-2015-radiology-society-of-north-america-annual-meeting-300184578.html

1 Current Practice

LungCT

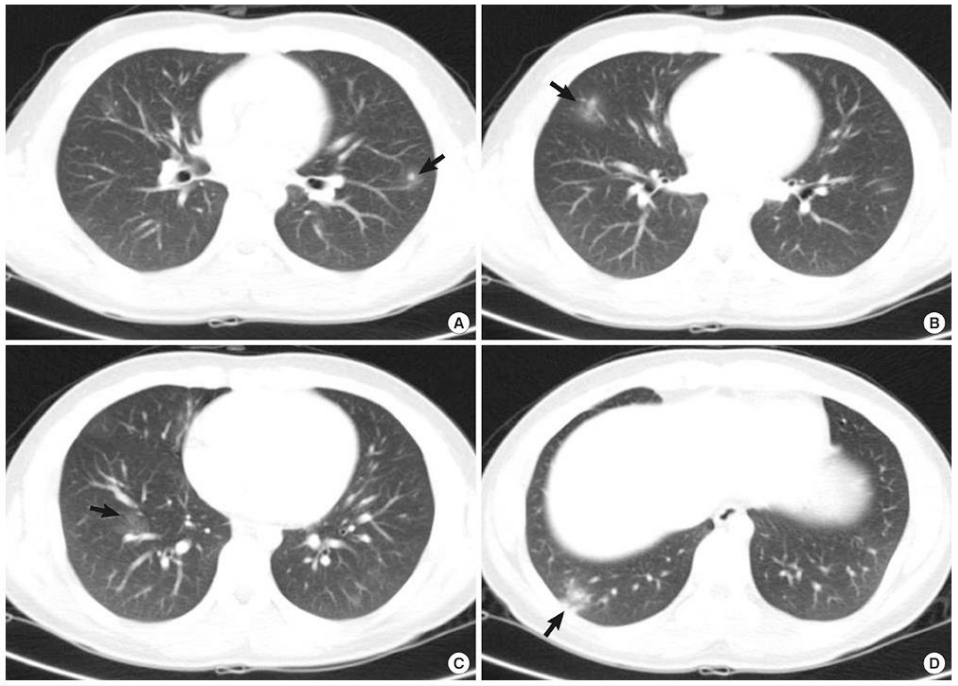


Figure 1. Computed Tomography (CT) scan findings of the chest[3]

1. The only recommended screening test for lung cancer [1]

- size, shape, density, location

2. Can diagnose diseases such as **lung cancer, pulmonary tuberculosis, and pneumonia** based on combinations of findings[1]

3. Diagnostic accuracy of image-based diagnosis for lung cancer is approximately 80%[1]
(biopsy is required for confirmation)

4. For multi-detector row CT, analysis of **250~350 slice images is needed**[2] (Thickness 1mm)

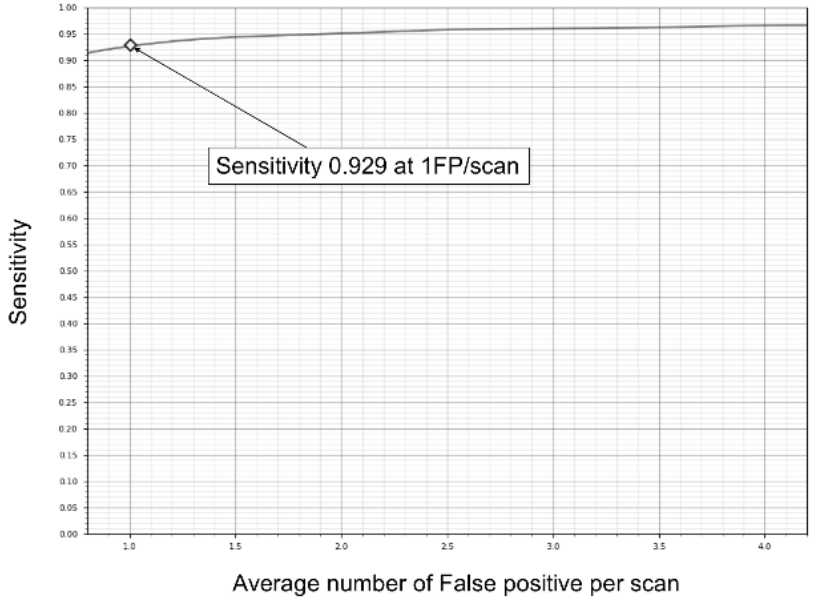
1) https://www.lungca.or.kr/data/about_lungcancer02.php , KALC (Korean Association for lung Cancer)
2) Goo JM, et al. Computer-Aided Diagnosis in Chest CT. Tuberculosis and Respiratory Diseases. 2004 Dec; 57(6):515-521.
3) Noh Y, et al. Meningitis by Toxocara canis after Ingestion of Raw Ostrich Liver. J Korean Med Sci. 2012 Sep; 27(9): 1105–1108.

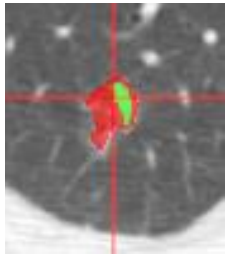
2 Product Features

Clinical Support

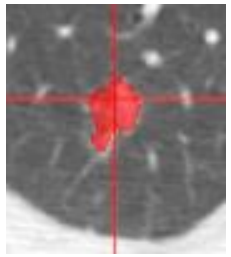
Lung Nodule Detection & Measurement

- **High Sensitivity, 93% Sensitivity per 1FP,**
  based on performance validation with open dataset LUNA16
- **Optimized nodule detection performance** through super-resolution algorithm
- **Detects nodules between 4mm ~ 30mm**
- Provides **volumetric data of nodules**
- Provides a mask feature to **detect part-solid nodules (Overall, Ground-glass, Solid Part)**

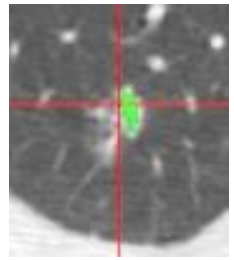




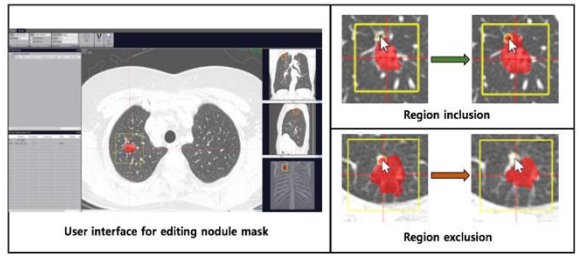
[Overall segmentation]



[Ground-glass part segmentation]



[Solid part segmentation]



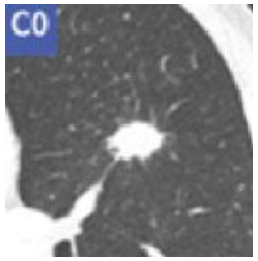
[Interactive Nodule Mask Editing Tool]

Clinical Support

Advanced Features

- **Provides data on the types of nodules**
- Provides **calcification** data to support the assessment of **positive nodules**
- Provides **speculation** data to support the assessment of **malignant nodules**

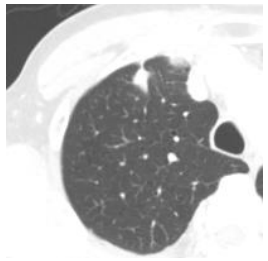
Types of Nodules



[Solid, Spiculation]

[Non-solid (GGN)]

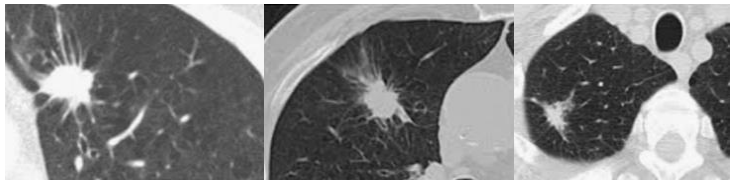
[Part-solid]



[Solid]

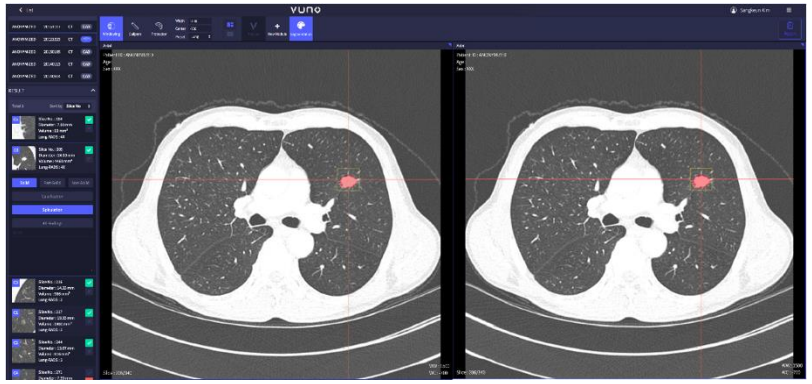
Calcification

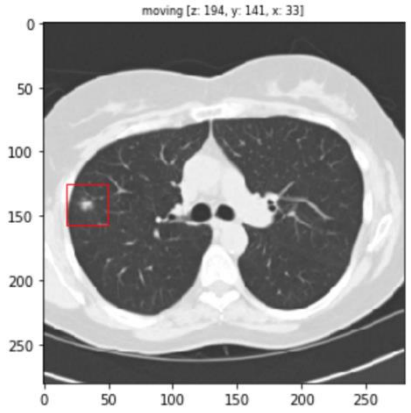
Spiculation



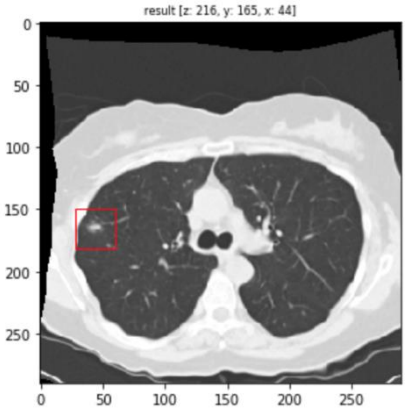
Longitudinal Tracking

- Provides **baseline scans and follow-up data** for **nodule growth assessment**
- Can **match the baseline scan and follow-up scan pixel to pixel**

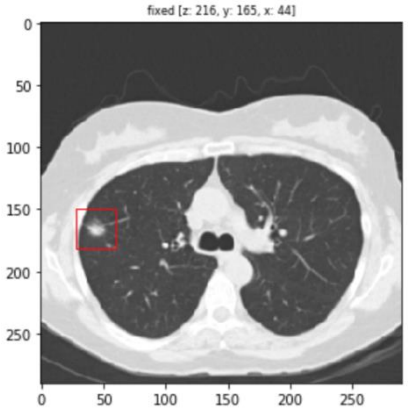




[Baseline]



[Baseline (registered)]



[Follow-up]

Efficiency

Workflow Improvement

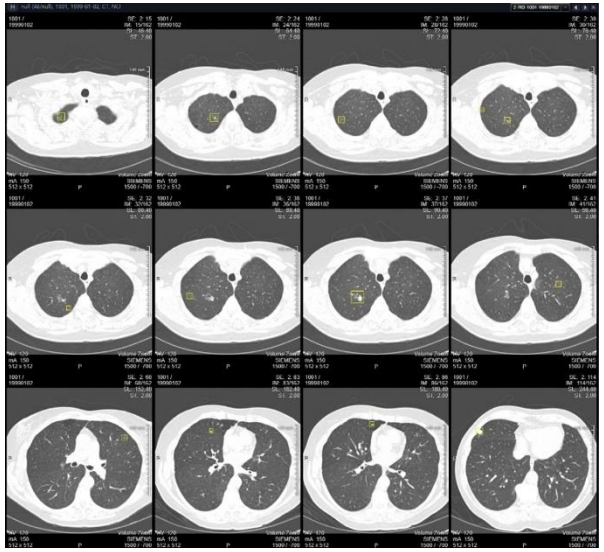
- **Provides data on nodule candidates within 1 minute**[1]
- **User Interface for clinical use**
- **Can be integrated with PACS**

- **INFINITT** (Korea)
- **TaeYoung Soft** (Korea)
- **Techheim** (Korea)
- **NOBORI** (Japan)

[User Interface for Clinical Use]

Diverse Result Formats

- **Provides results report**[2]
- GSPS objects PACS integration



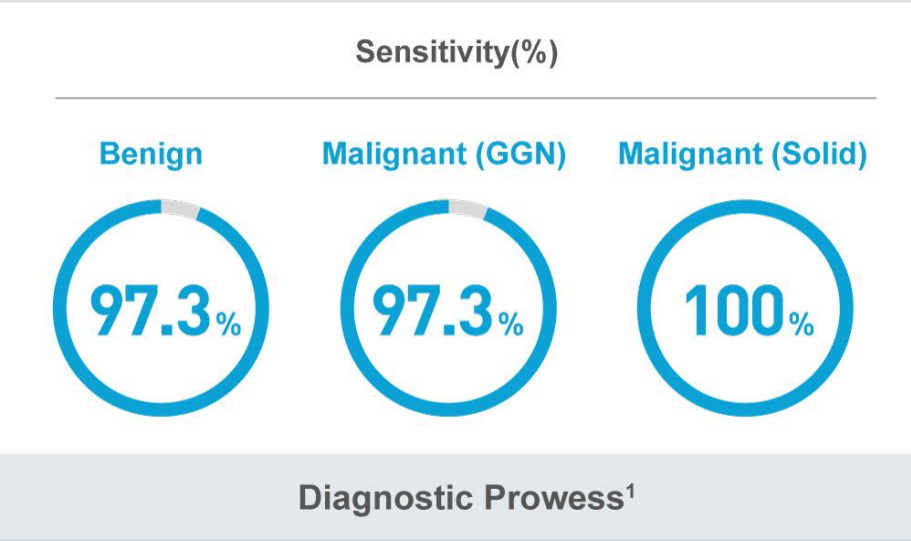
[GSPS objects PACs Integration]

1) May vary depending on internet and/or server environment
2) Limited to on-premise model

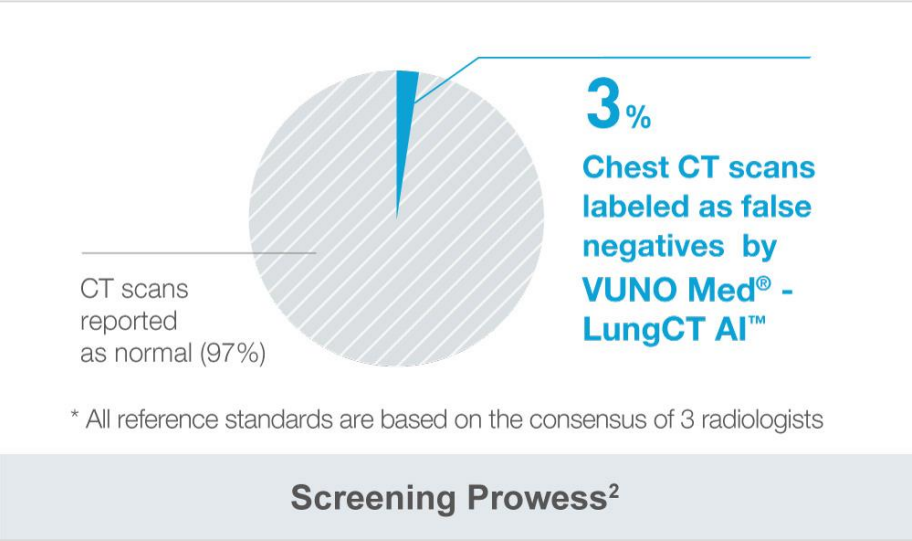
Reliability

Proven Performance via External Validation

- **Trained on CT images of 1,300 patients**[1]
- **External validation with multiple leading institutions** in Asia (Korea, Japan, Taiwan)[1]
- **Clinical trial** with **3 leading medical institutions** in Korea for MFDS Approval[1]



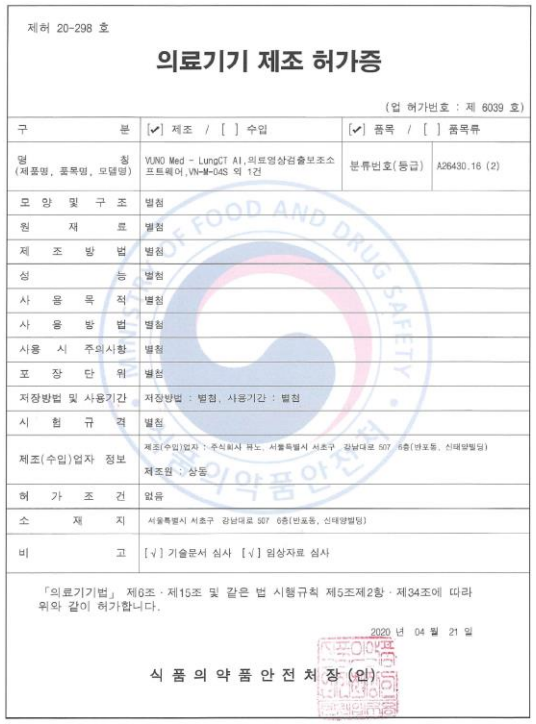
Diagnostic Prowess[1]



Screening Prowess[2]

1) Internal validation, 2017.
2) A Deep Learning-Based CAD that Can Reduce False Negative Reports: A Preliminary Study in Health Screening Center, RSNA 2019

Certifications



제허 20-298 호

의료기기 제조 허가증

(업 허가번호 : 제 6039 호)

구 분	[✓] 제조 / [ ] 수입	[✓] 품목 / [ ] 품목류	
명 칭 (제품명, 품목명, 모델명)	VUNO Med - LungCT AI,의료영상검출보조소프트웨어,VN-M-04S 외 1건	분류번호(등급)	A26430.16 (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	별첨		
제조(수입)업자 정보	제조(수입)업자 : 주식회사 뷰노, 서울특별시 서초구 강남대로 507, 6층(반포동, 신태양빌딩) 제조원 : 상동		
허 가 조 건	없음		
소 재 지	서울특별시 서초구 강남대로 507 6층(반포동, 신태양빌딩)		
비 고	[√] 기술문서 심사 [√] 임상자료 심사		

「의료기기법」 제6조·제15조 및 같은 법 시행규칙 제5조제2항·제34조에 따라 위와 같이 허가합니다.

2020 년 04 월 21 일

식 품 의 약 품 안 전 처 장 (인)

Apr 21, 2020
MFDS
Regulatory Approval

SZUTEST

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

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Szutest.com.tr

Jun 15, 2020
CE Certification

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

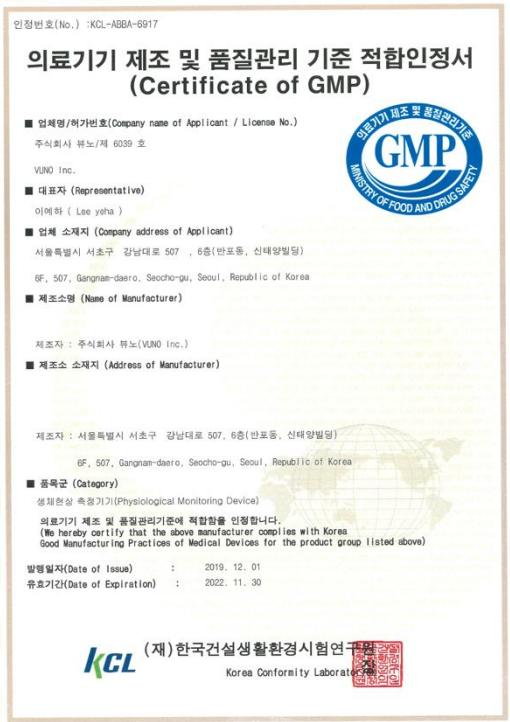
Approves that the Medical Devices Quality Management System implemented for above scope.

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

TÜRKAK

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Szutest.com.tr

Nov 30, 2018
ISO 13485:2016



인정번호(No.) :KCL-ABBA-6917

의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

GMP

■ 업체명/허가번호(Company name of Applicant / License No.)
주식회사 뷰노/제 6039 호
VUNO Inc.

■ 대표자 (Representative)
이예하 (Lee yeha)

■ 업체 소재지 (Company address of Applicant)
서울특별시 서초구 강남대로 507 , 6층(반포동, 신태양빌딩)
6F, 507, Gangnam-daero, Seocho-gu, Seoul, Republic of Korea

■ 제조소명 (Name of Manufacturer)
제조자 : 주식회사 뷰노(VUNO Inc.)

■ 제조소 소재지 (Address of Manufacturer)
제조자 : 서울특별시 서초구 강남대로 507, 6층(반포동, 신태양빌딩)
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

KCL (재)한국건설생활환경시험연구원
Korea Conformity Laboratories

Dec 1, 2019
GMP

MFDS, Ministry of Food and Drug Safety

Domestic Patents

Registration No.	Patent 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)
10-1928302	Content-based medical image retrieval methods and systems	Imaging (LungCT)
10-1898575	Methods for predicting future conditions for progressive lesions and devices using them	Imaging (LungCT)
10-1894278	Methods for reconstructing a series of slice images and devices using them	Imaging (LungCT)
10-1919847	Methods for automatically detecting the same area of interest between images taken at intervals of time for the same subject and devices using them	Imaging (LungCT)
10-1943011	Methods and devices to support the reading of medical images of a specimen	Imaging (LungCT)
10-1898580	Methods and devices for supporting image viewing	Imaging (LungCT)
10-1923962	Methods and devices for supporting access to medical images	Imaging (LungCT)
10-2108418	Methods for providing images based on reconstructed image groups and devices using them	Imaging (LungCT)
10-2102255	Methods and devices to assist in visualizing lesions in medical images	Imaging (LungCT)
10-2099350	Methods and devices used to assist quantification of lesions in medical images	Imaging (LungCT)

Publications

#	Year	Jour./Conf.	Status	Type	Title
1	2015	RSNA	Published	Abstract	Accuracy Enhancement with Deep Convolutional Neural Networks for Classifying Regional Texture Patterns of Diffuse Lung Disease in HRCT
2	2016	RSNA	Published	Abstract	Preliminary Results Using Deep Learning Artificial Intelligence to Estimate Bone Mineral Density on Abdominal CT Exams for Screening Osteoporosis
3	2016	RSNA	Published	Abstract	An Automatic Classification Platform for Differentiation of Regional Diseased Patterns of Diffuse Infiltrative Diseases on High Resolution CT Using Lung Segmentation, Support Vector Machine and Convolutional Neural Net Classifications
4	2017	RSNA	Published	Abstract	Deep Learning-Based Content-Based Image Retrieval for Finding HRCT Images of Similar Patients with Interstitial Lung Disease: Validation with 100 Paired HRCTs and Automatic Quantification of Six Disease Patterns
5	2017	JDI	Published	Journal	Comparison of Shallow and Deep Learning Methods on Classifying the Regional Pattern of Diffuse Lung Disease
6	2018	RSNA	Presented	Abstract	CNN-based Image Super Resolution for CT Slice Thickness Reduction using Paired CT Scans for Improving Robustness of Computer-aided Nodule Detection System
7	2019	RSNA	Accepted	Abstract	Deep Learning Algorithm for Reducing CT Slice Thickness: Effect on Reproducibility of Radiomics in Lung Cancer
8	2019	RSNA	Accepted	Abstract	A Deep Learning-based CAD that Can Reduce False Negative Reports: A Preliminary Study in Health Screening Center

3 Value Proposition

Autonomous & Clinically Aligned

- VUNO Med® - LungCT AI™ may improve diagnostic accuracy by providing clinical information (Detection, Volume, Type, Longitudinal Tracking) on lung nodules
- Easier to process diverse forms of data for research. This enables you to use a database that fits your purpose.

Cost / Time - Efficient

- Provides quantitative data on slice images of nodule candidates within 1 minute
- Improves clinical efficiency by accelerating workflows
- A database can be quickly built for research

Agnostic to Any Device

- Nodule candidate information is just a click away
- Can be used in DICOM environment
- Analyze on any PC that use the same network server without additional server installment

Technical Features

4 System Requirements

5 Cloud / On-Premise

6 User Interface

4 System Requirements

Software Name	Operating Environment		
VUNO Med®-LungCT AI™	**Server***	• **Operating System** : Ubuntu 16.04	• **Hardware** : CPU Intel Core i5 Processors RAM 8 GB HDD 250 GB GPU VRAM 12GB • **Internet Browser** : Google Chrome V79.0
	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 V79.0

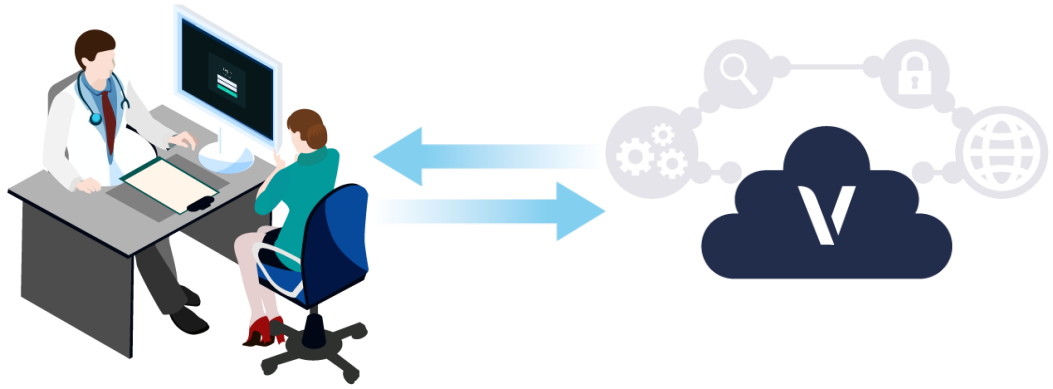
Requires equivalent or higher specifications

* For Cloud based service, installation of server is not required

5 Cloud / On-Premise

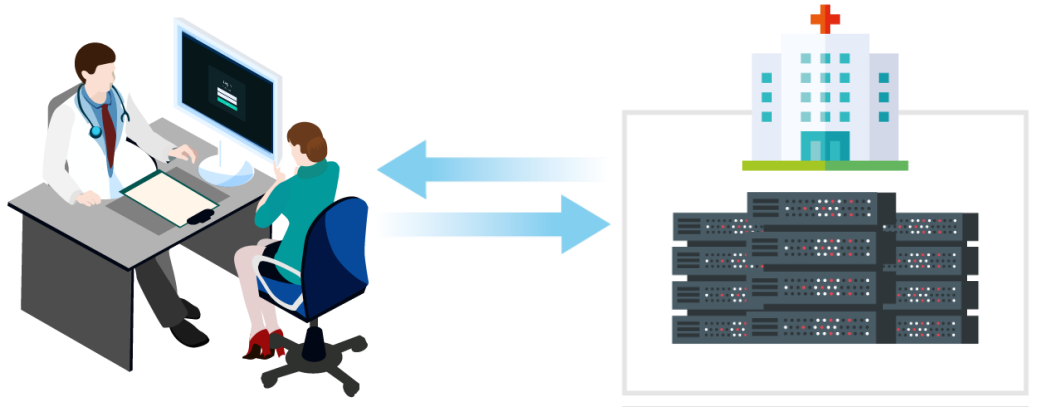
Cloud

- 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



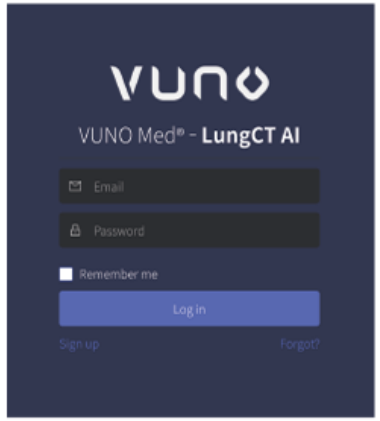
On-Premise

- 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)



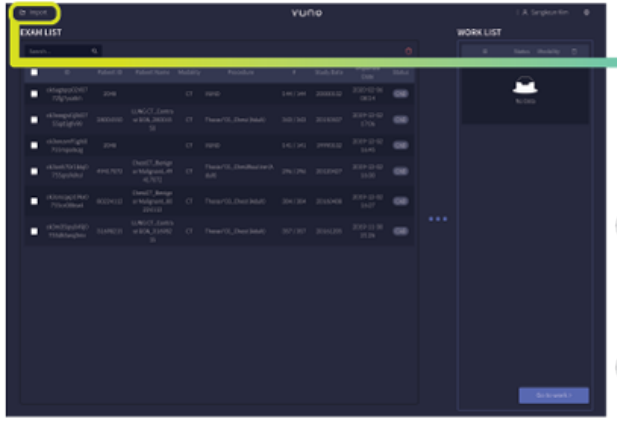
6 User Interface

Log In



Create an account and login

First Screen After Login



1 **DICOM Files**

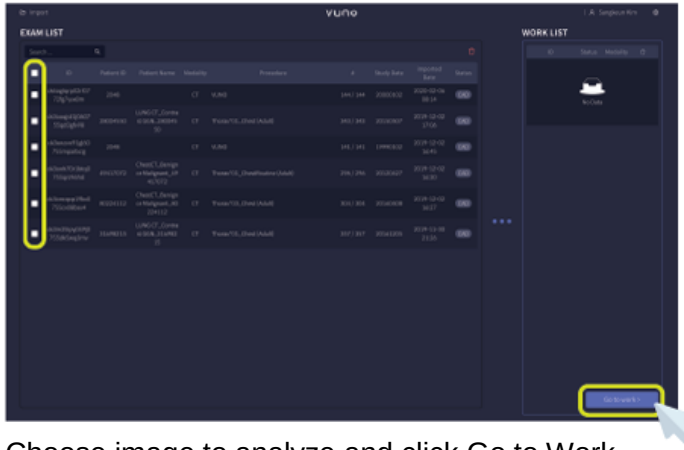
One image

2 **DICOM Folder**

All images within the folder

Click the Import button on the upper left corner to upload image

Image Analysis



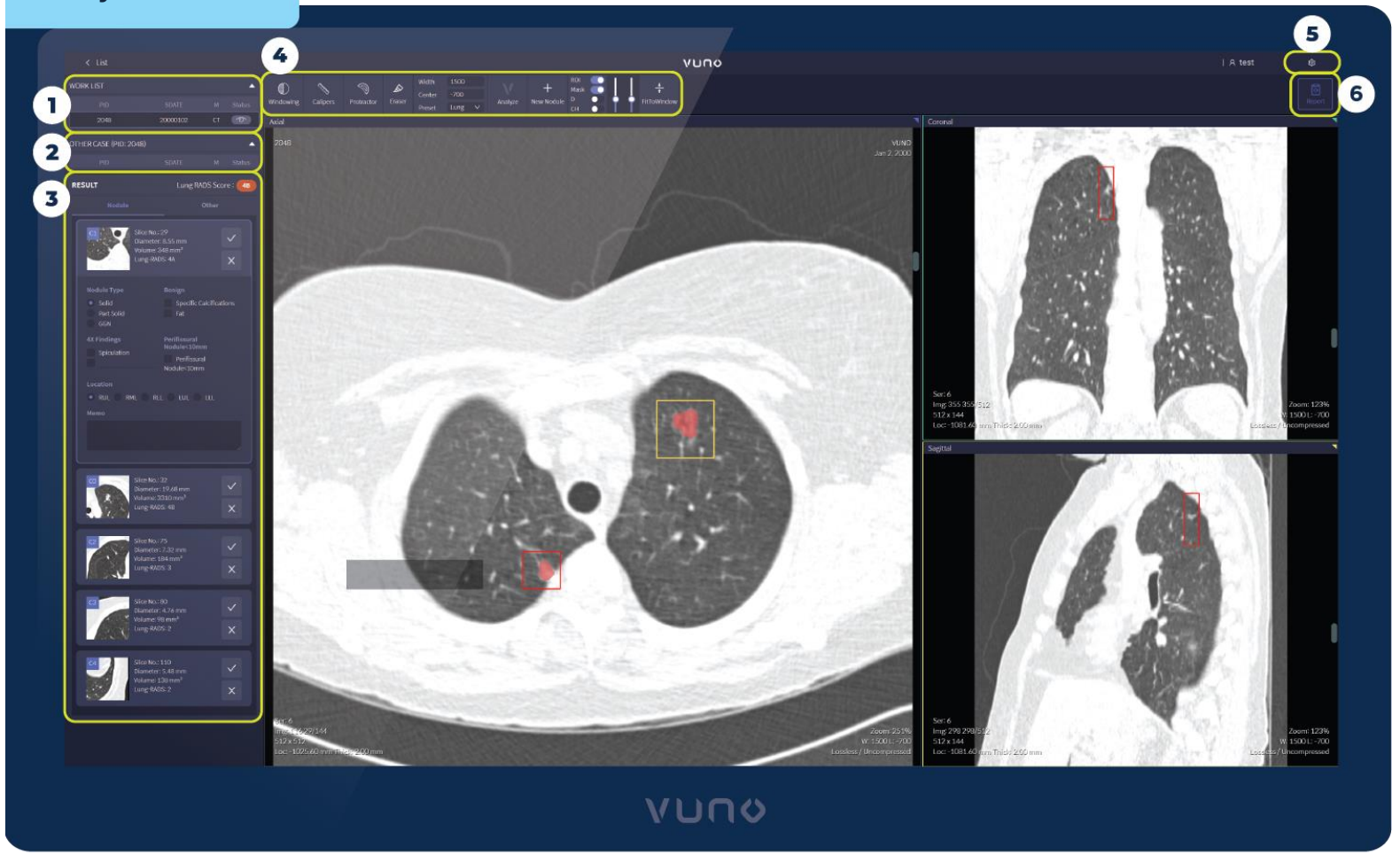
Choose image to analyze and click Go to Work to start analysis

4 Clicks **1 Minute***

* May vary depending on internet and/or sever environment

6 User Interface

Analysis Screen



Results

1. **Worklist** : Patient list and status
2. **Other Case** : Past analysis record of patient chosen from the work list
3. **Result** : User can modify results by clicking (v) to accept or (x) to reject
4. **Controls**: Abnormal location measurement and controls
5. **Setting**
   - Search: search analysis history
   - Log Out

Report

6

7 Precautions

Performance-related Precautions

1) No performance guarantees on images of patients under the age of 19
2) The analysis results may vary depending on the quality of the imported images, slice thickness, resolution, and the filming environment.

General Precautions

1) VUNO Med® - LungCT AI™ 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® - LungCT AI™ assisted final diagnosis.

8 Q&A

Is it a medical device?

Yes, it is. VUNO Med® - LungCT AI™ received regulatory approval from Korea Ministry of Food and Drug Safety as Medical Image Detection Assisting Software, second-class medical device in April 2020.

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

Lung CT images of 1,300 patients labelled by physicians from partnering R&D hospitals were used to trained 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® - LungCT AI™ recorded 100% sensitivity for solid nodules and 97.3% sensitivity for ground glass nodules. In addition, VUNO Med® - LungCT AI™ found 3 percent of lung nodules in a group of 10,000 patients diagnosed with no lung nodules. The clinical results were presented at journals and medical societies such as Radiological Society of North America and Journal of Digital Imaging.

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® - LungCT AI™ 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 used for diagnosis support only and not for any other purposes. Only data on the presence of abnormality and its location is provided and the 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® - LungCT AI™ 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.

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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