

KFDA 허가, 국내외 특허등록, 세계 최초 근적외선 AI 부비동 검사 장비

α ·Sinus AI

Only One!

부비동 광투과도 AI(인공지능)검사로 안전하고, 정확하게!!!

부비동염(축농증) 예방 및 관리에 혁신적인 변화



Convenience 편의성



Accuracy 정확성



Security 안전성



Efficiency 효율성

보건복지부고시 제2007-92호
철조법 준용 산정



부비동염(축농증)이란?

부비동염(축농증)이란?

흔히 '축농증'으로 불리는 부비동염은 코 주위 뼈속에 있는 빈 공간인 부비동에 세균이나 바이러스 침투로 발생하는 염증성 질환입니다.

부비동염(축농증) 원인



감기 바이러스 및 세균 등에 의한 **2차 세균성 감염**



공해, 담배연기 같은 **화학 자극 물질**



알레르기 비염, **종양, 물혹**에 의한 막힘



얼굴기형, 부비동 **점막 혹 발생**

부비동염(축농증) 진단검사의 종류

초기진단(문진)	단순 문진(증상에 대한 질문과 환자의 답변)에 의존	정확한 진단이 어려움
철조법	부비동에 빛을 강하게 비춰서 투과되는 광패턴을 육안 판별. 의료보험 수가 있음	정량화가 어려워 실제활용사례적음
배양 및 조직검사	비루를 부비동에서 추출하여 검사 진행 만성 축농증의 경우 배양과 조직 검사가 필수로 진행	결과 도출까지 장기간 소요 부비동 구조 분석 불가능
영상진단장치(CT)	CT영상을 통해 부비동의 해부학적 구조와 부비동에 쌓인 비루(농, 점액)의 양을 측정하여 축농증 진행 단계 진단	방사선 과대 피폭 가능성 높은 검사 비용

철조법(투과법)이란?

1. 부비동에 빛을 강하게 비춰서 투과되는 광패턴을 육안으로 판별하는 방법입니다.
2. X-ray와 CT 촬영법과 비교해 방사선 피폭 우려가 낮아 어린이나 임신부 등이 받기에 적합합니다.
3. 의료진이 육안으로 빠르게 판단할 수 있고 검사 정확도도 높다는 장점이 있습니다.
4. 단순 감기 환자와 합병증인 급성 부비동염(축농증)으로 진행이 되었는지 구별할 수 있습니다.

Alpha Sinus AI는 AI분석 기술을 통하여 기존의 철조법을 보완하여 정량화된 수치를 제공합니다.

Sinus medical News

국제신문 2024.10.21

코막힘 방치하다 치통·실명까지...환절기 부비동염 주의보

서울경제 2024.08.25

‘부비동염’ 환자 2년새 189% 증가...여름에도 방심 말아야

헬스경향 2024.09.26

갑자기 코에서 탄 냄새가 난다면...비염·부비동염 의심

헬스인 뉴스 2024.06.18

코막힘 지속되는 축농증(부비동염), 감기와 비슷해 헛갈리기 쉬워

Accuracy

정확성

AI 분석 기술로
정량화된 수치 제공 가능



Efficiency

효율성

적은 비용으로 신속하고
간편하게 부비동염 진단 가능



Convenience

편의성

- 부비동염(축농증)
조기 진단, 적기 치료 가능
- 불필요한 검사 및
치료를 하지 않으므로
검사의 편의성 도모 가능



Security

안전성

방사선 노출 없는 안전한 검사 가능

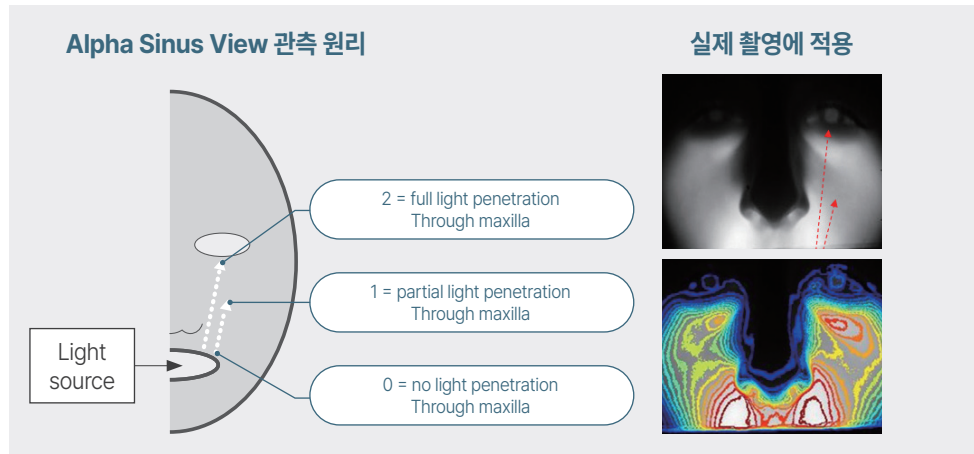


Alpha Sinus AI 인공지능 시스템

검사원리

근적외선 광투과와 이미지 분석을 활용한 철조법

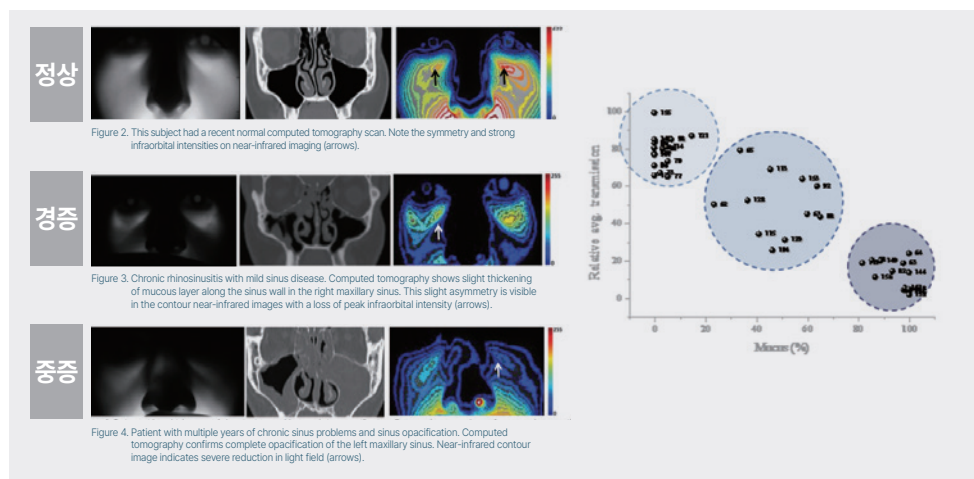
> 긴 파장대의 근적외선이 뼈와 피부를 투과하는 원리를 활용



- | 빛은 장애물(피부, 조직, 염증)이 있으면 빛의 흡수와 산란이 커져서 투과율이 낮아짐
- | 근적외선은 체내 조직(피부, 얇은 뼈)의 흡수가 낮아 심도깊은 광투과 가능
- | 입의 광원으로부터 조사된 빛은 정상인의 경우 부비동이 비어 있어 투과율 손실이 적으나 비염, 축농증 환자의 경우 농에 의해 빛이 흡수되어 투과율이 현저히 떨어짐

검사의 정확도

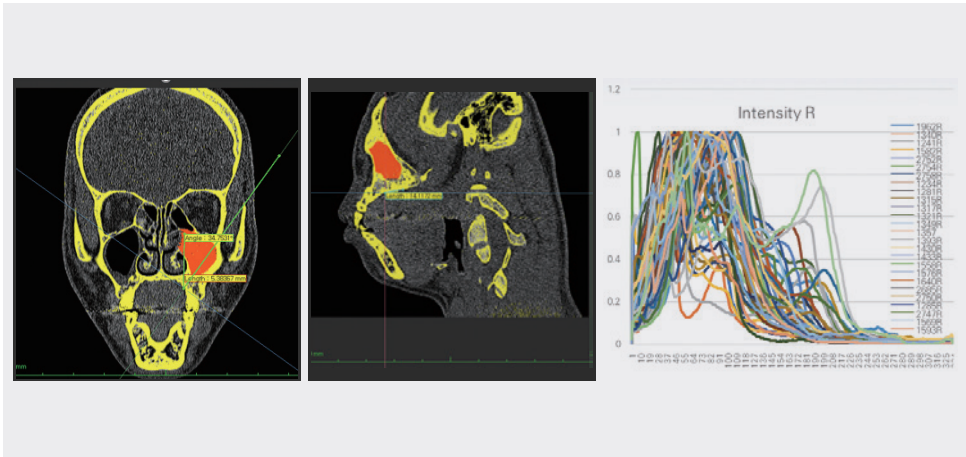
광투과도와 CT 결과의 일치성 80% 이상 확인



부비동염의 정량화된 수치화가 가능할 뿐 아니라, 환자의 증상 심각 정도에 따라 3가지 종류(Normal, Mild, Severe)로 분류 가능합니다. 의사는 이 자료를 바탕으로 환자 차후 진료 방향을 설정 가능하며, 환자는 자신의 증상 정도를 더 쉽게 알 수 있습니다.

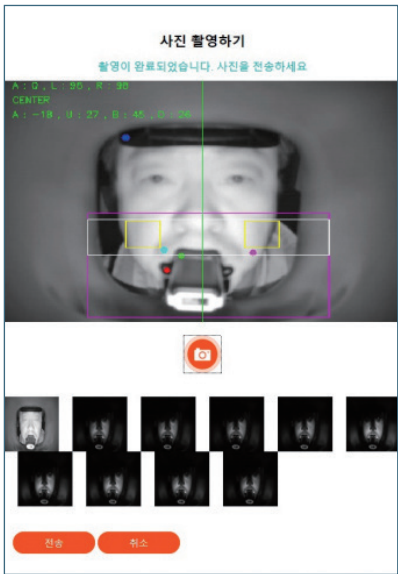
인공지능

개인의 뼈 및 피부 두께 차이를 AI 학습을 통해 보정·알고리즘 고도화 완료

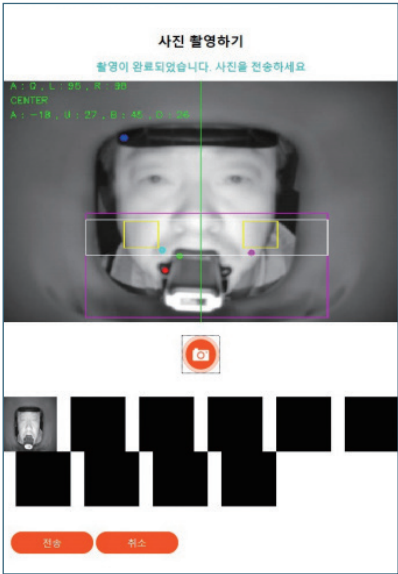


- 기존분석 알고리즘에 패턴 분석 알고리즘을 추가하여 reproducibility 및 robustness 향상
- CT 대비 80% 이상의 정확도 확보 > X-ray 와 유사한 분석 정확도 확보

촬영 성공 여부 판정



정상 촬영



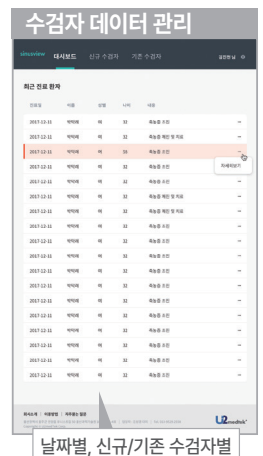
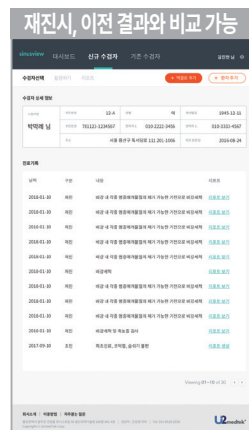
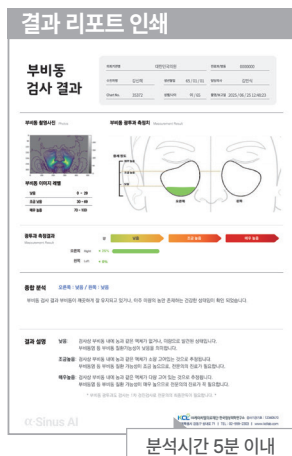
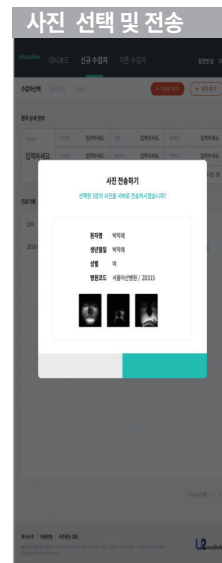
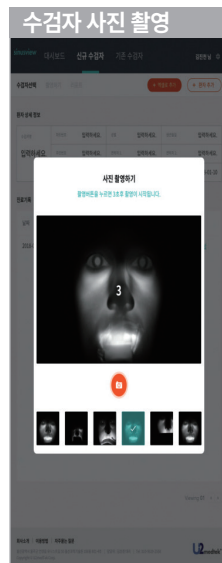
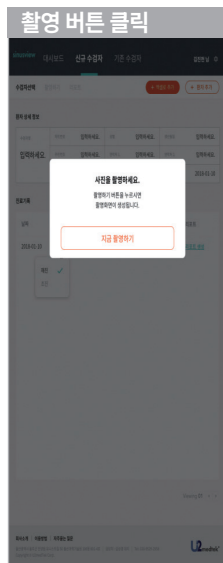
촬영 오류

Alpha Sinus AI 검사 프로세스 및 결과 판독

Easy and simple 프로세스



촬영 세부 단계



Alpha Sinus AI 장비 소개 및 제품 검증



Alpha Sinus AI 본체

개발, 제조사 **U2medtek**

제품명 **Alpha Sinus AI**

크기(WxDxH) **280×550×525 (mm)**

촬영 시간 **3초 이내**

분석 시간 **10초 이내**

Alpha Sinus AI 마우스 피스

외관 재질 **PC-ABS**

LED 구성 **2중 3열의 조절 가능한 설계**

LED 광량(밝기) **광량 조절 가능한 설계**

동작 방식 **무선 동작 방식**

소모품 **1회용 마우스피스 덮개**



SCI 국제저널

Journal of Biomedical Optics 2020, 25(04) (April 2020)

Monte Carlo modeling of light propagation in the human head for applications in sinus imaging

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Abstract. Sinus blockages are a common reason for physician visits, affecting one out of seven people in the United States, and often require medical treatment. Diagnosis in the primary care setting is challenging because inspection criteria for detailed clinical history plus objective imaging (computed tomography (CT) or endoscopy) are recommended. Unfortunately, neither option is routinely available in primary care. We previously demonstrated that color near-infrared (NIR) transillumination correlates with the backscattering of sinus cavity measured by CT. We have upgraded the technology, but questions of source optimization, anatomical relevance, and detection limits remain. In order to begin addressing these questions, we have modeled light light propagation inside a three-dimensional adult human head constructed as CT images using a mesh-based Monte Carlo algorithm (MCAD). In this application, the sinus head, which was healthy in a real region (e.g., nasopharynx), is the region of interest. We characterize the changes in detected intensity due to either (a) healthy versus blocked sinuses and the effect of illumination location. We use simulations to test clinical cases and compared simulation with measurements. The simulation presented herein serves as a proof of concept that this approach could be used to understand current mechanisms and limitations of NIR sinus imaging in the future. *Published by SPIE under a Creative Commons Attribution 3.0 license. Distribution or reproduction of this work in whole or in part requires the publisher's permission. doi:10.1117/1.5143120*

Keywords: optical imaging, near-infrared medical instrumentation, chronic sinusitis, optical diagnosis, finite-difference time-domain, near-infrared spectroscopy

Page 040401B-10 of 10 | doi:10.1117/1.5143120 | published online May 10, 2020

1 Introduction: Optical Imaging in the Maxillary Sinuses

1.1 Problem of Sinusitis

In the United States, approximately one in seven people develop sinusitis (acute inflammation) each year, and 21 million cases of acute bacterial sinusitis become chronic and require extensive medical treatment. It has been estimated that nearly 50 billion dollars in expenses are paid to treat sinusitis. Chronic sinusitis generally involves sinus failure to accurately diagnose and treat acute cases. Primary care physicians are the first to diagnose and treat up to 87% of these cases. However, diagnosing acute sinusitis in primary care settings is challenging because the symptoms are nonspecific and often overlap with many other conditions such as allergies or other head/neck, allergic rhinitis, and other upper respiratory infections. Sinusitis is common and diagnosis is best made via a detailed clinical history from a trained physician. Although guidelines for symptoms exist, they are difficult to adhere to precisely, especially in the primary care setting. For this reason, symptomatic plus objective data are recommended to improve diagnosis, where objective data are obtained via endoscopic or radiologic imaging.

The challenge of diagnosing acute sinusitis in the primary care setting has led to an increase of plain radiologic (i.e., two-dimensional) and computed tomography (CT, i.e., three-dimensional) CT scans. Computed radiography is often used as a diagnostic means but requires radiologist's reading and is not always available at the point of service (e.g., the primary care doctor's office). Studies have found that the plain film head diagnostic value often leads to overdiagnosis and unnecessary clinical procedures. Symptom alone do not accurately correlate with radiologic diagnosis. Allergy-related head symptoms reporting does not reliably correlate with CT findings.¹ Some of us noted that the sensitivity and specificity of plain radiography in the diagnosis of maxillary sinus inflammation were 67% and 87%, respectively, with CT serving as the gold standard. Due to its low sensitivity, negative false-positives are not a practical solution for the primary care environment due to its cost and potentially unnecessary radiation exposure. The impact of chronic sinusitis management will only worsen as the future wide use health care system reduces physician's time available for detailed patient consultations. For these reasons, there is a great need for a simple, low-cost, office-based technique to aid in the diagnosis of sinusitis without the cost, inconvenience, or radiation risk of radiologic CT.

1.2 Optical Imaging in the Maxillary Sinuses

Optical imaging has been previously investigated as a means to detect sinus disease.² Near-infrared light (NIR), particularly

Near-Infrared Imaging for Management of Chronic Maxillary Sinusitis

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²Beckman Laser Institute, University of California Irvine, Irvine, CA 92617
³Department of Head and Neck Surgery, University of California, Irvine, Orange, CA, 92668

ABSTRACT

Efficient management of chronic sinusitis remains a great challenge for primary care physicians. Unlike ENT specialists using Computed Tomography scans, they lack an affordable and safe method to accurately assess and monitor sinus disease in primary care settings. Lack of evidence-based sinus management leads to frequent misdiagnosis and unnecessary non-surgical (e.g., antibiotic) treatment. Previously, we reported low-cost optical imaging device for end-illumination and facial optical imaging setup. It exploits the sensitivity of NIR transillumination intensity and field unique patterns in the sinus structure and presence of fluid/mucous body within the sinus cavity. Using the reported NIR system, we have obtained NIR sinus images of 45 subjects with varying degrees of sinusitis symptoms. We made diagnosis of these patients based on two types of images: comparison with NIR images alone. These diagnostic results were then compared to the gold standard diagnosis using computed tomography through intensity and specificity analysis. Our results indicate that diagnosis of some patients of sinusitis that is distinguishable between healthy individuals vs. diseased individuals did not improve much when using NIR imaging compared to the diagnosis based on symptoms alone (95% vs. sensitivity, 70% specificity). However, use of NIR imaging improved the differential diagnosis between mild and severe disease significantly as the sensitivity improved from 79% for using diagnosis based on symptoms alone up to 95% for using diagnosis based on NIR images. Reported results demonstrate great promise for using NIR imaging system for management of chronic sinusitis patients in primary care settings without resorting to CT.

Keywords: translational research, near-infrared imaging, sinusitis management.

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1. INTRODUCTION

In the United States, approximately 40 million people suffer from sinusitis annually, whether acute or chronic, which contributes to healthcare spending of \$1.7 billion annually [1]. The sinusitis can often be triggered by a cold or allergen and is categorized into two basic types: acute sinusitis which lasts up to four weeks and chronic sinusitis which can last more than twelve weeks and can have frequent recurrences over many years. One to seven people develop sinusitis each year, and 20 million cases of acute bacterial sinusitis become chronic to require medical treatment [1]. The common symptoms of acute and chronic sinusitis include: facial pressure and pain, thick discolored mucus, congestion and blockage, which are all very similar to other common upper respiratory diseases in primary care setting. Chronic sinusitis can result from structural defects in nasal passages (i.e., deviated nasal septum and turbinate loss) nasal polyps or frequent and unresolved inflammation (i.e. colds and allergies and other upper respiratory infections). Often, chronic sinusitis generally occurs from unresolved acute sinusitis, and is a consequence of failure to accurately diagnose and manage them early on.

There are several standard of care methods to help assess and diagnose for chronic sinusitis need endoscopy, imaging studies, nasal and sinus cultures, and an allergy test [2]. However, all these methods require visits to specialists and/or primary care history of failed treatments. For primary care doctors and other health care providers (e.g. nurse practitioners, physician assistants, nursing and diagnostic of sinusitis can help to make final an objective survey of patient's symptoms and clinical history. Studies have found that the symptom-based diagnosis often often leads to over-treatment from only one.

Near-Infrared Optical Imaging for Diagnosis of Maxillary Sinusitis

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²Department of Head and Neck Surgery, University of California, Irvine, Irvine, CA 92668

ABSTRACT

Computed tomography (CT) is the current gold standard imaging for chronic rhinosinusitis (CRS) but is limited by cost, risk of radiation, and difficulty of being performed in the typical outpatient primary care setting. We describe the need use of a low-cost, handheld technology to deliver an accurate non-radiation (NIR) wavelength light to optically image the maxillary sinuses. Digital images were captured for subjects presenting with sinus disease using a handheld NIR light source for transillumination of the maxillary sinuses, captured by a modified digital endoscopic video camera. Light intensity contours were enhanced using computer analysis and subsequently compared to CT findings. NIR illumination produced unique patterns reflecting different disease states: normal sinus anatomy, mild sinus disease and/or mucosal thickening, and complete opacification of the sinus. Current results suggest that NIR imaging may facilitate the diagnosis of sinusitis in the outpatient setting with minimal cost and no radiation exposure.

Keywords: acute sinusitis, chronic sinusitis, imaging, transillumination, maxillary sinusitis, maxillary sinus

Received November 11, 2019; revised April 13, 2020; accepted May 20, 2020.

In the United States, approximately 1 in 10 people develop sinusitis each year, and ~10 billion per year is spent on evaluation and treatment.¹ Guidelines are published by the American Academy of Otolaryngology-Head and Neck Surgery Foundation; however, diagnosing sinusitis remains challenging because symptoms often overlap with other conditions.

Acute rhinosinusitis is diagnosed by history, but studies comparing clinical diagnosis and radiologic results have shown that clinical diagnosis is often inaccurate. A recent prospective study demonstrated that 30% of patients diagnosed with acute rhinosinusitis by a primary care physician had normal computed tomography (CT) imaging.² By using clinical diagnosis with imaging, diagnostic accuracy could be improved.

In the case of chronic rhinosinusitis (CRS), guidelines recommend obtaining corroborating evidence for diagnosis by either nasal endoscopy or imaging.³ Neither of these modalities is available in the typical primary care physician office. Furthermore, patients with CRS can have normal nasal endoscopy results, which can make the accurate diagnosis of CRS based on clinical findings alone equally difficult for many endocrinologists.

Although CT imaging is available in select endocrinologist offices, the modality requires patients to undergo radiation and increases cost. X-rays are inexpensive but subjective for diagnosis and interpretation. Thus, a simple, low-cost, office-based technique may be useful in the diagnosis of CRS.

Near-infrared (NIR) spectroscopy has not been previously investigated as a sinus imaging modality. Here we report a preliminary investigation into the use of a simple NIR light source to transilluminate the maxillary sinuses to assess the presence and extent of sinusitis disease.

Materials and Methods

Patients

The University of California Irvine Institutional Review Board approved this study. Participants were recruited from a tertiary care otolaryngology practice, and informed consent was obtained. The inclusion criteria were age >12 years and

A comparison of near-infrared imaging and computed tomography scan for detecting maxillary sinusitis

Ann Otol Rhinol Laryngol. 2022 October; 131(10): 1144-1150

	Normal vs disease	Normal vs mild disease	Normal vs severe disease
Sensitivity	90 %	76%	96 %
Specificity	84 %	91 %	81%

CT: modified Lund-Mackay scores

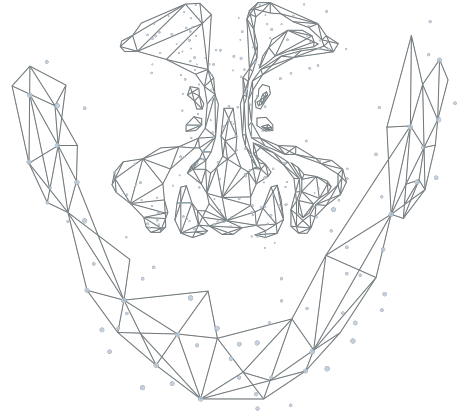
Comparison of Sinus X-rays with Computed Tomography Scans in Acute Sinusitis

Academic Emergency Medicine. 1994 May; 1553-2772

	Radiologist 1	Radiologist 2	Radiologist 3	Radiologist 5
Sensitivity	57%	62%	67%	48%
Specificity	88%	88%	75%	100%

Alpha Sinus AI Healthcare Business

고객의 건강을 위한 가치있는 부비동 광투과도 검사



남녀노소 누구나 촬영 가능

Alpha Sinus AI는 근적외선 촬영으로 CT, X-ray와 달리 방사선 피폭의 위험이 없어 남녀노소 누구나 반복적으로 촬영하여 지속적으로 축농증 질환에 대한 관리가 가능합니다.

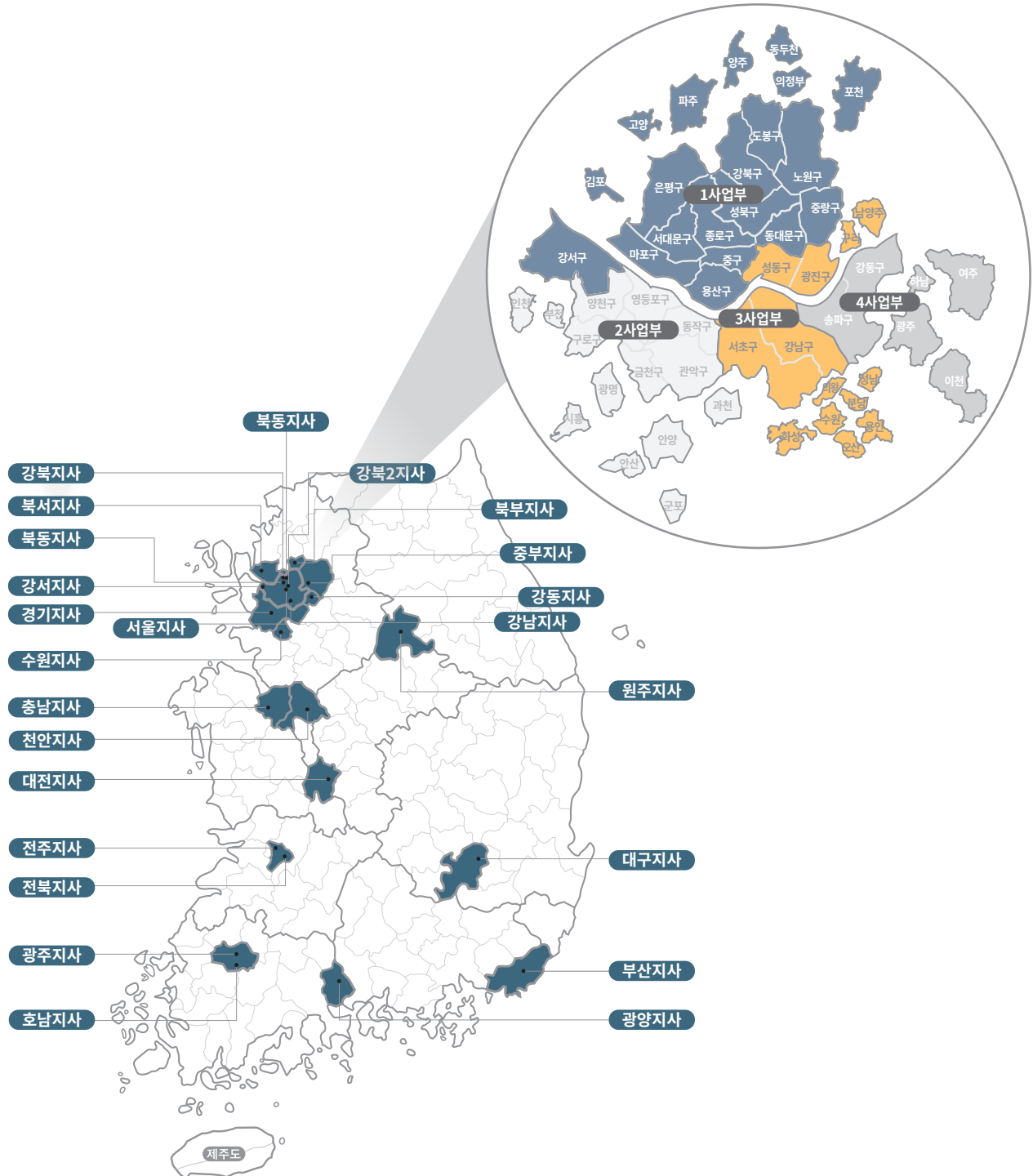


정량화된 수치 제공

Alpha Sinus AI는 AI분석 기술을 통하여 수검자의 부비동 상태를 정확하게 측정하여 정량화된 수치로 데이터를 리포트로 제공합니다.

Alpha Sinus AI 이런분들에게 좋아요!!

- 미세먼지에 민감한 환자 분
- 최근 또는 만성적으로 코막힘이 있으신 분
- 축농증 및 비염 증상이 의심되는 분
- 3개월 이상 두통, 안면 통증 등의 증상이 있으신 분
- 유사질환 (알레르기, 감기 등)으로 인한 사전 예방검사가 필요하신 분
- CT, X-ray 등 방사선 피폭에 민감한 소아, 임산부, 노약자 등 검사를 원하시는 분



HELP YOU?



SMART
SPEED
SCREENING



• 제품문의 02-559-2303

• 서비스문의 02-6952-7078
장비운영지원 / 서버운영지원 / 사용자교육