Tympa System®: Smartphone-Enabled in Detecting Middle Ear Disease

MedTech innovation Scanning

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Center of evidence, research, and innovation to Health Decisions

PRESIDENCE OF HEALTH AND INNOVATION

Global Institute of Clinical Excellence

Disclosure

The authors and experts who participated in the development of the document declare that based on the Global Institute of Clinical Excellence – IGEC methodology there is no conflict of interest that prevents or invalidates the development process (financial, intellectual, filiation).

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Keralty-IGEC and the authors declare that the development of the scientific-technical document was carried out in a rigorous, independent, transparent, and impartial manner by its members.

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Background

Telehealth is an approach that has had a significant increase after the COVID-19 pandemic and it has allowed for improved timing, access to health care, patient outcomes, and reduced dramatically the face-to-face appointments. Nowadays, there are different and huge applications for that (1). This document presents the Tympa System® a MedTech.

1 Technology

Tympa system® was developed by Tympa Health Technologies Ltd ©. According to the manufacturer's description (2):

- ✓ It's a MedTech based on teleotology, remote otological care, through the smartphone.
- ✓ It is able to capture high-definition images and videos in real-time for carried out digital otoscopy, wax removal using a suction unit, and hearing assessment, with headphones tested at 500Hz, 1,000Hz, 2,000Hz, and 4,000Hz.
- ✓ The patient information (images and videos) is stored in a secure cloud and it can be shared with specialized teams easily.
- ✓ It could be used in a community setting.
- ✓ Requires audiologists or trained healthcare professionals like healthcare assistants or pharmacists, in order to have better accuracy results.

2 Methodology

MedTech innovation scan was carried out, including (i) rapid review, which was focused on clinical evidence, (ii) regulatory aspects; and (iii) horizon and technology scanning.

A review was carried out in PubMed with the terms *Smartphone-Enabled* AND *Otoscopy*. Even though 10 documents were obtained as clinical evidence, only one study informed diagnostic confidence and was included. Also, searches were complemented through of Clinical Trials Register, regulatory agencies (FDA and EMA), and technology scans from different sources. In addition to the comprehensive evidence review and horizon scanning, this brief report also highlights a selection of promising technologies and startups that are actively developing innovative solutions for the otology and ENT (ear, nose, and throat) healthcare segment.

The results obtained are reported as follows:

3 Clinical evidence

Table 1. Summary of selected studies

Chen CH, et al, 2022(3)	
Study size, design and location	• 1840 participants • Three randomized controlled trials (RCTs) and one RCT simulation. • Three studies were conducted on patients who visited the emergency department • Another study was conducted in education to improve medical students' ability to recognize common ear pathologies using a smartphone-based otoscope. For this study, 52 medical students were randomly assigned to a standard group that used a traditional otoscope and an intervention group that used a smartphone-based otoscope. Both groups received a brief educational presentation on recognizing common ear pathologies and were asked to diagnose four simulated pathologies.
Intervention and comparator(s)	• Intervention: Smartphone-Enabled Otoscopy • Comparator: Traditional Otoscopy
Key outcomes-Results	• Correctness of diagnosis between the smartphone-enabled otoscopy and traditional otoscopy groups (fourth studies): RR, 1.26; 95% CI, 1.06 to 1.51; $p = 0.01$; $I^2 = 70.0\%$. • Correctness of diagnosis between the smartphone-enabled otoscopy and traditional otoscopy groups (Three studies, without simulation studies): RR, 1.10; 95% CI, 1.00 to 1.21; $p = 0.04$; $I^2 = 0\%$. • Confidence of examiners using both otoscopy methods (Two studies): SMD, 0.08; 95% CI, −0.24 to 0.40; $p = 0.61$; $I^2 = 16.3\%$ • Correctness in detecting abnormal ear conditions between the smartphone-enabled otoscopy and traditional otoscopy groups (fourth studies): RR, 1.18; 95% CI, 1.01 to 1.40; $p = 0.04$; $I^2 = 65.0\%$
Risk of Bias Assessment	• The systematic review presents a low risk of bias; however, the included studies demonstrate a high risk of bias given the following critical methodological limitations: none of the studies could blind the examiners and examinees to the type of examination. Additionally, outcome assessors were aware of the kind of examinations received by study participants. None of the four studies reported whether outcome measurement or determination differed between intervention groups.
Conclusion	• Smartphone-enabled otoscopy was associated with a higher rate of correctness in the detection, as evidenced by the combined effect estimates of the three studies that evaluated otoscopy in patients with acute otitis media (RR, 1.10; 95% CI, 1.00 to 1.21; $p = 0.04$; $I^2 = 0\%$). • For the other outcomes evaluated, additional studies are required, mainly for those that reported combined effects with the inclusion of the simulation study, given the high heterogeneity it represents concerning the other studies.

4 Regulatory information

A review of the Tympa System product was carried out in reference agencies. No registration was found in the FDA databases, although it may be exempt from 510K notification, it is mandatory to be coded with its corresponding UDI-DI, which was not identified either.

Additionally, databases from agencies in European countries were searched, but the product was not identified. Also, Class I devices do not require a notified body for commercialization and CE marking, but they do require a declaration of conformity and an identification in their databases, which was not found. The only official agency where a registration related to the product was identified was the UK MHRA, where it is defined as a class I otoscope. (https://aic.mhra.gov.uk/era/pdr.nsf/vwLkupFileRef/10720?opendocument)

In Colombia, it has not been identified in the sanitary registration databases either.

5 Horizon and Technologic Scanning

Another technology applied to audiology is the TYM smartphone otoscope used for the imaging and videoing of the external ear canal and eardrum. The cost of the TYM smartphone otoscope is £107.50 per unit (excluding VAT), with an additional £0.06 in consumables per examination. The user can provide their own compatible Apple iOS smartphone or purchase a refurbished one for £141.70 (4). This technology offers similar advantages to the Tympa system®.

Similar technology is being studied right now. The search on the Clinical Trials Register (5), found three studies:

Table 2. Studies registered in ClinicalTrials.gov

Trial register - NCT	Country	Title	Intervention	Outcome	State, Date
02521597	Canada	Mobile Otoscopy - Efficacy of Residents to Diagnose Acute Otitis Media Using a Smartphone Otoscope Attachment (MOTO)	Smartphone otoscope Versus Traditional otoscope	-Accuracy in diagnosing acute otitis media -Need for second exam -Parents satisfaction. -Confidence	Completed, 2016
02452164	Turkey	Family MobilePhone Otoscopy in Diagnostics of Otitis Media (FamilymOTO)	Smartphone otoscope	- Diagnostic quality of tympanic membrane images	Completed, 2016
04296448	USA	Evaluation of Cellphone-Based Otoscopy in Pediatric Patients	Smartphone otoscope	-Concordance of Trainee and Supervisor Utilizing the OMgrade Scale as Assessed by the Concordance-statistic - Interrater Reliability as Assessed by a Kappa Statistic - Number of Patients Who Receive Antibiotics - Number of Participants Who Receive a Repeat Examination	Completed, 2021

6 Related technology scanning

These emerging technologies have already demonstrated traction in the market and garnered significant funding for their growth potential.

SafKan® HEALTH

Founding year: 2016
Location: Seattle, US
Funding: USD 4,3 M
Collaborate with SafKan Health for ENT Hygiene Tools

US-based startup SafKan Health offers automated ear-cleaning devices. The startup's product, Otoset, uses micro-suction technology and liquid flow to automatically break down and remove impacted earwax. Its continuous micro-suction draws the earwax and liquid back through the ear tips and into disposable waste containers for a convenient and comfortable procedure. Further, SafKan Health utilizes automated pulsed irrigation to dislodge and dispose of excess earwax quickly.

Link:https://otoset.com/

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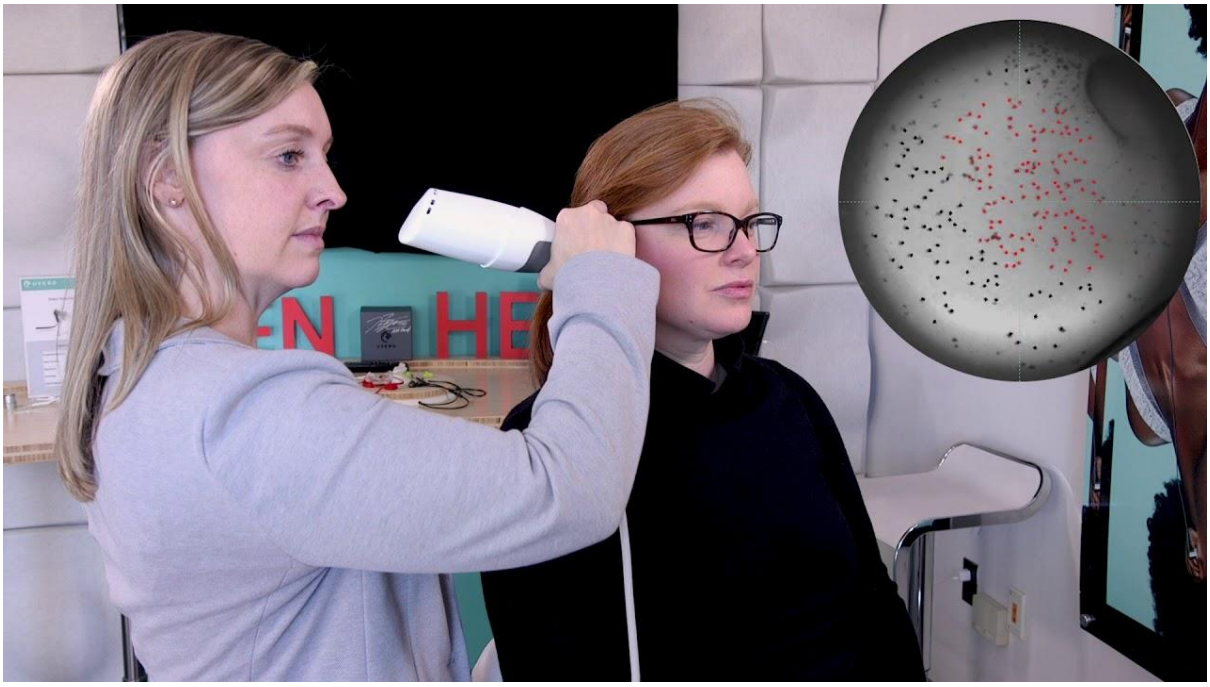
LANTOS TECHNOLOGIES

Founding year: 2020
Location: Derry, US
Funding: USD 31 M
Partner with Lantos Technologies for Personalized Hearing Solutions

US-based startup Lantos Technologies makes a membrane-based 3D ear scanning system to map the 3D geometry of the ear. The startup's ear scanner provides a precise deep ear inspection without causing discomfort, unlike the conventional silicone earmold solutions. This enables clinicians to avoid unnecessary risks and mess with concise digital scans. In addition, Lantos Technologies' intra-aural 3D scanner has a virtual computerized workflow to improve patient satisfaction and achieve faster scanning time.



Link:https://www.tobias-battite.com/services/lantos-3d-ear-scanning/

vibro|sonic

Founding year: 2016
Location: Mannheim, Germany
Funding: USD 2,7 M
Innovate with Vibrosonic for Invisible Hearing Device Development

German startup Vibrosonic focuses on improving the lives of people with hearing impairment. The startup's hearing contact lens, Vibrosonic alpha, features three components – a proprietary hearing contact lens, an ear canal module, and a discreet behind-the-ear module with earphones. The loudspeaker is positioned right onto the eardrum with the hearing contact lens. It transmits vibrations to the ossicle directly without any interference due to airborne noise. This non-invasive hearing aid allows ENT doctors to offer improved care for patients.

A UNIQUE HEARING SOLUTION

Vibrosonic® alpha

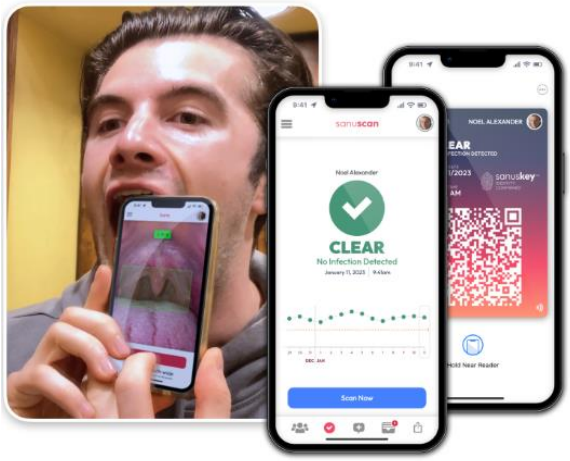
We present our first product, Vibrosonic alpha, the unique hearing solution. It consists of three components:

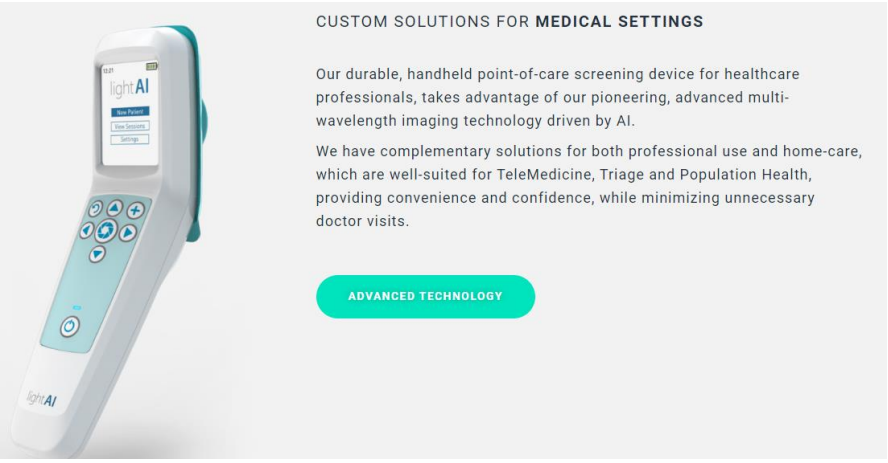
1. the Hearing Contact Lens®
2. an ear canal module with open, soft domes for optimal ventilation and comfortable wear
3. the discreet behind-the-ear module with battery and microphones

Vibrosonic alpha is positioned on the eardrum by a trained ENT doctor – without any surgical procedure.

Link:https://www.vibrosonic.de/en/

Founding year: 2016
Location: Vancouver, Canada
Use Light AI's solution to develop Tools to Differentiate between Bacterial and Viral Infections
Canadian startup Light AI develops an AI and computer vision-based throat screening device and a companion app. The startup's app acts as a point-of-diagnosis tool to detect infections in the throat by analyzing images. It then identifies key patterns in infections and also enables physicians to differentiate between viral and bacterial infections. Moreover, Light AI's hand-held throat image screening device is customizable for medical professionals and home care users. This, in turn, allows patients to self-diagnose and prevent unnecessary doctor visits.





Link:https://light.ai/solutions/

7 Conclusiones

1. MedTech based on telehealth improves access, opportunity, resolution and quality in healthcare. In addition, it allows early diagnosis and treatment, allowing correct referrals to specialists.
2. MedTechsystem® is a groundbreaking Medtech based on telehealth for audiology.
3. Smartphone-enabled otoscopy was associated with a higher rate of correctness in the detection, as evidenced by the combined effect estimates of the three studies that evaluated otoscopy in patients with acute otitis media (RR, 1.10; 95% CI, 1.00 to 1.21; p = 0.04; I2 = 0%). For the other outcomes evaluated, additional studies are required, mainly for those that reported combined effects with the inclusion of the simulation study, given the high heterogeneity it represents concerning the other studies.
4. No registration was found in the FDA and EC databases. However, it is recognized as a Class 1 device.
5. There are several MedTechs based on telehealth available and being studied, and updated results are looking forward, but it appears to be promising.

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