# AmCad BioMed Corp. code: 4188

### 2021 Institutional Investor Conference

**Established: 2008** 

**Year of Listing: 2015** 

Capital: USD18.9M

CEO Yili Lee



# **Company Introduction**

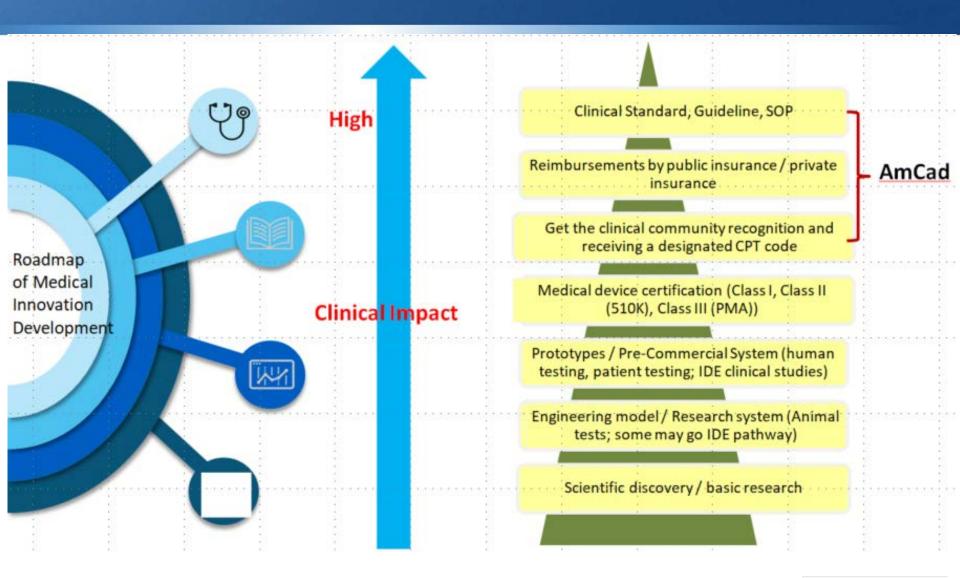
### Company Profile

- Name : AmCad BioMed Corporation
- ► Founded : Dec. 2008
- ► Capital : TWD 530M
- Business : Product development, Manufacturing and Sales for Innovative Medical Device
- ▶ President : Yili Lee
- Location : Taipei City
- ► Headcounts: 37

# 超音波影像AI領航者 安克生器 Helping physicians diagnose confidently and efficiently.



### Roadmap of Medical Innovation Development





### Business Model of Innovative Medical Device

### BD&L: Business Model



### Licensing

License technology to equipment makers and receive licensing fees or royalty.



Leasing

Revenue Sharing Outright Sales

Subscription

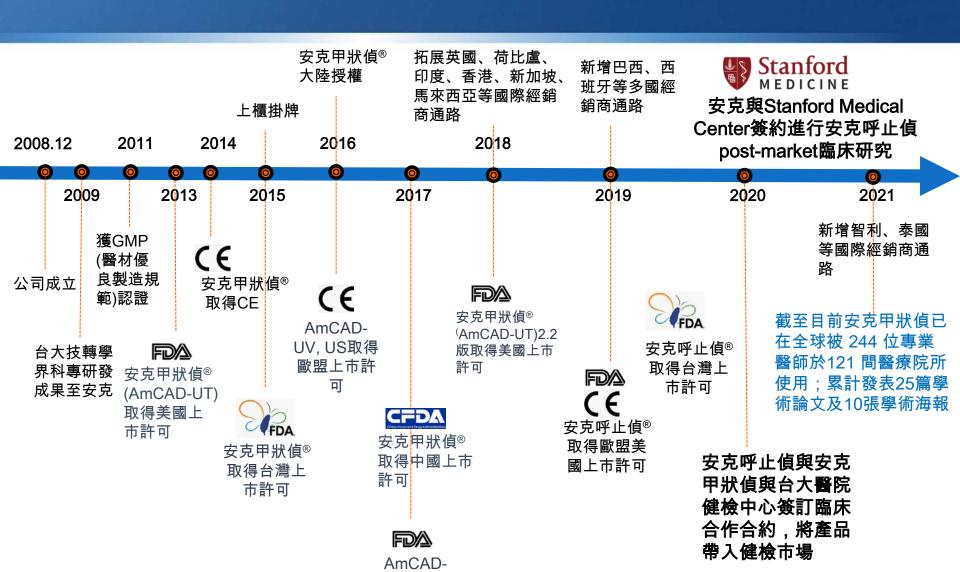
Exclusive or regional rights, single & multi-product deals.



### Collaborative Marketing

Collaborate with PACS/Ai platforms to market and expand access.

### Major Milestones



UV, US取得 美國上市許可

### **Product Lines**



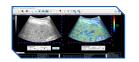


- FDA 510(k), CE certified
- Automated ultrasound scanning and detection of pharyngeal airway
- Risk evaluation of obstructive sleep apnea (OSA)





- FDA 510(k), CE certified
- Imaging of the backscattered signals for assessment of tissue variation





- FDA 510(k), CE certified
- Differentiation between pulsatile signal and noise







- FDA 510(k), CE, TFDA, CFDA certified
- Assessment of malignancy potential for thyroid nodule sonographic features
- Risk analysis of malignancy for thyroid nodule



Breast Ultrasound Al Live CADe/x





- Cytology microscopic image processing
- Visualization and quantification of clinical cytology features

- iSONO
- Point of care ultrasound device
- Real time Al imaging

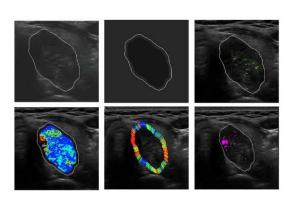
### AmCAD UT® Features





#### 甲狀腺超音波人工智能輔助診斷軟體

- 美國FDA、歐盟CE、台灣TFDA、中國CFDA核准
- 快速自動甲狀腺結節輪廓圈選
- 量化及視覺化影像特徵
- 依據國際指南分析並提供診斷建議
- AI自動化分析報告

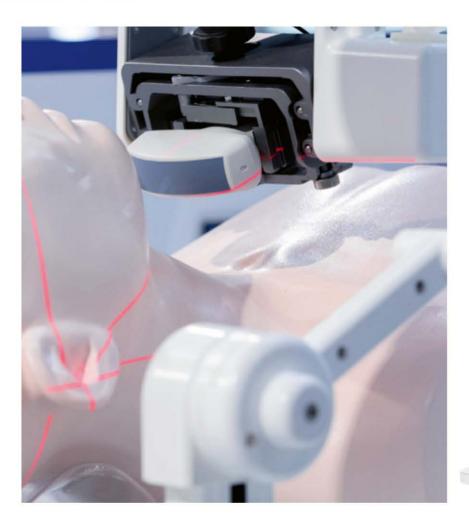


量化及視覺化影像特徵



AI電腦輔助分析報告

### AmCAD UO® Features



#### 10分鐘呼吸中止症檢測系統

- 美國FDA、歐盟CE、台灣TFDA核准
- 專利雷射定位系統
- 自動掃描一致性結果
- 精密上呼吸道分析
- 快速檢測



# 2021 Operating Updates





### 2021 Milestones – AmCAD UT®

- Start business in NTUN Health Management Center in Aug. 2021
- First shipment to Chili Distributor in Jul. 2021
- Obtained FDA 510 (k) approval of advanced AmCAD UT® with AI contouring function in Sep. 2021
- AmCAD UT® has been used by 244 doctors in 121 hospitals worldwide. 24 papers & 10 posters have been published.



## AmCAD UT® Papers



Front. Endocrinol. | doi: 10.3389/fendo.2021.614630

# Risk stratification in patients with follicular neoplasm on cytology: use of quantitative characteristics and sonographic patterns

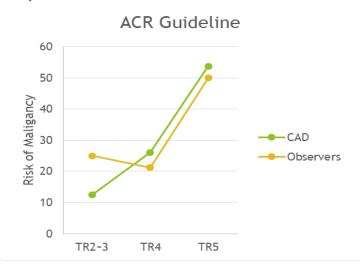
Provisionally accepted The final, formatted version of the article will be published soon. 

Notify me

可抓到所有惡性,且可讓 47%的良性案例免於開刀

Ming-Hsun Wu<sup>1\*</sup>, Kuen-Yuan Chen<sup>1</sup>, Min-Shu Hsieh<sup>1</sup>, Argon Chen<sup>1\*</sup> and Chiung-Nien Chen<sup>1</sup>

<sup>&</sup>lt;sup>1</sup>National Taiwan University, Taiwan



|                                      | PPV     | NPV     | Sensitivity | Specificity | Average* |  |
|--------------------------------------|---------|---------|-------------|-------------|----------|--|
| Sonographic characteristics          |         |         |             |             |          |  |
| Hypo-echogenicity                    | 0.44    | 0.77    | 0.68        | 0.56        | 0.62     |  |
|                                      | (15/34) | (24/31) | (15/22)     | (24/43)     | 0.02     |  |
| Calcification                        | 0.48    | 0.75    | 0.55        | 0.70        | 0.625    |  |
|                                      | (12/25) | (30/40) | (12/22)     | (30/43)     | 0.023    |  |
| Heterogeneous echotexture            | 0.52    | 0.81    | 0.68        | 0.67        | 0.675    |  |
|                                      | (15/29) | (29/36) | (15/22)     | (29/43)     |          |  |
| Blurred margin                       | 0.45    | 0.71    | 0.41        | 0.74        | 0.575    |  |
|                                      | (9/20)  | (32/45) | (9/22)      | (32/43)     |          |  |
| Irregular margin                     | 0.45    | 0.71    | 0.41        | 0.74        | 0.6      |  |
|                                      | (9/20)  | (32/45) | (9/22)      | (32/43)     | 0.0      |  |
| Taller-than-wide morphology          | 0.67    | 0.71    | 0.27        | 0.93        | 0.575    |  |
|                                      | (6/9)   | (40/56) | (6/22)      | (40/43)     |          |  |
| Combination of heterogeneous,        | 0.49    | 1.0     | 1.0         | 0.47        | 0.735    |  |
| irregular margin, and blurred margin | (22/45) | (20/20) | (22/22)     | (20/43)     | 0.755    |  |



# AmCAD UT® Papers



#### CLINICAL ENDOCRINOLOGY

ORIGINAL ARTICLE

### Differences in the ultrasonographic appearance of thyroid nodules after radiofrequency ablation

Ming-Hsun Wu, Kuen-Yuan Chen, Argon Chen X, Chiung-Nien Chen

First published: 03 May 2021 | https://doi.org/10.1111/cen.14480

#### Funding information:

The AmCad BioMed Corporation, Taipei, Taiwan, sponsored this study in terms of technical assistance and financial support

#### Results

The average volume reduction ratio (VRR) was 74.51% in 1 year (95% confidence interval, 70.63%–78.39%). The only pre-ablation US feature significantly different between nodules with VRR <50% and VRR >50% was the cyst composition (0.05 vs. 0.02, p-value = .02). The VRR and margin change in the first 3 months after ablation were found to be leading indicators significantly correlated to the VRR in 6 months with correlation coefficients (r) = .72 and -.28 (p-value < .0001 and = .0008) and VRR in 1 year with r = .65 and -.17 (p-value < .0001 and = .046), respectively. After RFA, more TNs became ATA high suspicion (2.9% vs. 19.7%, p < .0001) and more appeared to be the non-ATA patterns (12.4% vs. 23.4%, p < .0001). Also, a greater number of post-RFA TNs were classified as ACR-TI-RADS categories 4 and 5 (40.1% vs. 70.1%, p < .0001).

#### 結論:

- 1. 術前"囊性"的組成較多,可預測結節消融半年後及一年後的效果較佳
- 2. 三個月後"體積減少"、"邊緣"較術前清楚,可預測結節消融半年後及一年後的效果較佳
- 3. 消融後, 結節超聲特徵會變得更像惡性。

#### Conclusions

Radiofrequency ablation therapy is effective for treating TNs. Pre-ablation cyst components, 3-month post-ablation volume reduction and margin change of TNs were related to the 6-month and 1-year response. Clinicians should consider that TNs would appear peculiar on US after RFA, mistakenly suggesting malignant potential.



### 2021 Milestones – AmCAD UO®

- Start post-market clinical study in NTUH Health Management Center in Aug. 2021.
- Sign with Distributor in Thailand and secure first overseas PO.
- Interim study results of trial collaborated with Stanford
   Sleep Medicine Center published at 2021APSS
- Conducted corporate employee OSA detection events in Acer and AU Optronics Corp.



### Stanford Clinical Study Publication

### -- 2021 APSS Poster Publication

#### An AI-Based Ultrasound Scanning Protocol for the Airway in Obstructive Sleep Apnea



Abstract

Stanley Y. Liu, M.D., D.D.S., FACS<sup>1</sup>, Valerie Garcia, B.A.<sup>1</sup>, Argon Chen, Ph.D.<sup>2</sup>, Yili Li, M.B.A.<sup>3</sup>, Clete A. Kushida, M.D., Ph.D.<sup>1</sup>

1. School of Medicine, Stanford University, 2. College of Engineering, National Taiwan University, 3. AmCAD BioMed

#### Introduction

Visualization of the upper airway in obstructive sleep apnea (OSA) diagnosis for improved treatment outcome remains challenging.

Nasopharyngoscopy (NP) is an integral part of the upper airway examination that is usually performed by cotalryngologists, it allows identification of tonsillar hypotrophy, and simulation of airway collapsibility with Müller's Maneuver (MM). Nevertheless, it is user-dependen invasive, costly, and does not allow quantitative measures.

We present the use of an ultrasound scanning protocol based on an artificial intelligence algorithm (Al-U) for visualization of the upper airway.

#### Study Design

Consecutive adult subjects with OSA over the age of 18 presenting to the Stanford sleep surgery clinic from July 2020 to May 2021 were considered for the study (IRB 53172).

Exclusion criteria include: 1. unwillingness to give informed consent. 2. incapable of performing MM. 3. history of nose, throat or neck surgery. 4. diagnosis of congestive heart failure, chronic pulmonary disease, 5. co-morbid sleep disorders, 6. pregnancy.

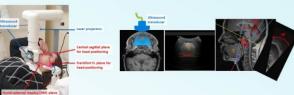
A total of 51 subjects (72.6% male, median AHI/age/BMI: 13/38/25.2) are included in the current analysis.

OSA was confirmed via attended or home polysornography. NP and AI-U were performed to evaluate airway collapsibility at the soft palate (PALL) lateral pharyngeal wall (LPW), base of the tongue (BOT), and epiglottis (E. AI-U only).

NP was performed by qualified examiners with MM rated per routine clinical examination.

#### Methodology

Laser beams were used to align subject position to the sagittal plane, the Frankfort horizontal plane (FH plane) and a crosssection plane through the Hjoid bone and the acternal acoustic Meats BM Planeal. The head and neck of the subject in supine position were then positioned to the center with the FH plane perpendicular to the horizon with the ultrasound transducer aligned with the laser projection of the HM plane. (Figure 1) A 30-degree ultrasound scan was performed on the awake subject to acquire sequential images of the phary. The Pimages were divided into four parts (Figure 2)



ure 1: Laser alignment to standardize head and

igure I: Laser alignment to standardize head and leck position

Three replicates of sector-scans were performed per subject under tidal breathing and MM. Analyses of the LM and tissue widths were conducted on the transvers view of the submental ultratound (US) images by an FDA-Ceiterd software AmCAD LO (IRG0667). Regions of interest include.) I alway state (jelloval) and 21 tissue surrounded the arrays in LMS image. Is highlighted by red dots. [Figure 3] The change in the airway and tissue width were then calculated the arrays of the change in the airway and tissue width were then calculated the arrays.

Change in width = Tidal-breathing width MM width x100%

Statistical relationships among the features obtained from US images, NP, and AHI (excluding the outliers) were performed using two-tailed t-tests.

#### Figure 2: Ultrasound scan of pharyngeal airway. Soft palatal (PAL, V), Oropharynx (LPW, O), Base of the tongue (BOT, T), and Epiglottis (E).



Figure 3: AmCAD-UO user interface for upper airway evaluation

#### Protocol design:

- PSG (Gold Standard)
- Endoscopy (Awake or Drug Induced)
- AmCAD UO

#### Results:

Results

1. Significant correlation was found between AHI and NP collapsibility at the LPW (p<0.001) (Figure 4).

 US shows significant correlations with NP and AHI at the PAL LPW, and BOT. US features include airway space changes and airway muscle contraction (Figure 5, Table 1).

from US images with NP and AHI.

Table 1: Correlations between AHI and changes in muscle

r=0.24

P = 0.016

P = 0.019

Figure 4: Correlation bety

- ✓ Significant correlation was found between AHI and NP collapsibility at the LPW
- ✓ Significant correlation was found between UO and NP, as well as UO and AHI at the PAL, LPW, and BOT

#### Conclusion

Visualization of upper airway collapsibility remains an important but difficult task in OSA. Nasopharyngoscopy is invasive, expensive, and user-dependent without the quantitative measures. Our Al-based ultrasound scanning protocol addresses both the limitation of nasopharyngoscopy and a leve need for practitiones across disciplines to improve cellaborative care.

### Special Lecture on TSSM & 1st OSAsia

#### 19th TSSM & 1st OSAsia Mar. 27-28, 2021

#### 19th TSSM & 1st OSAsia N

Saturday, Mar. 27, 2021

Rm. 2

Speaker: Chae-Seo Rhee (Korea)

S04-

Maxillary expansion with different appliances for different dental

occlusion can help POSA treatment

Speaker: Je-Yang Jau 趙哲暘 (Taiwan)

14:30-15:00 Special Lecture 02

Ultrasonic Assessment for OSA

Moderator: Hsueh-Yu Li 李學禹 (Taiwan) & Li-Ang Lee 李立昂 (Taiwan)

SLO2-

Upper Airway Ultrasonic Assessment for OSA Diagnosis and

Treatment

Speaker: Argon Chen 陳正剛 (Taiwan)

15:00-16:00

Symposium 06

Inner Ear and OSA

Moderator: Shih-Chieh Shen 沈士傑 (Taiwan)

S06-1

Effects of sleep apnea on inner ear diseases and tinnitus.

Speaker: Juen-Haur Hwang 黄俊豪 (Taiwan)

S06-2

How do OSA influence inner ear connecting with brain? (vertigo)

Speaker: Meiho Nakayama (Japan)

S06-3

diopathic Sudden Sensorineural Hearing Loss in Patients with

Obstructive Sleep Apnea: A Retrospective Case-Control Study

Speaker: Shih-Chieh Shen 沈士傑 (Taiwan)

16:00-17:00

Symposium 08

Application of Ultra-sound in OSA

Moderator: Jeng-Wen Chen 陳正文 (Taiwan)

Special Lecture
SL02\_Special Lecture 02

Date: Mar. 27 Time: 14:30-15:00



SL02-1

陳正剛 Argon Chen

Country:

Taiwan

Organization:

National Taiwan University

**Education Background:** 

Ph.D. in Industrial Engineering, Rutgers University

M.S. in Statistics, Rutgers University

M.S. in Industrial Engineering, Rutgers University

Specialized Field:

CADe/CADx, Medical Data Mining, Automatic Intelligence, Applied Stat



19th Virtual Annual Meeting of Taiwan Society of Sleep Medicine in Conjunction with 1st OSAsia (Asia Obstructive Sleep Apnea)

**Special Lecture** 

SL02 Special Lecture 02 Date: Mar. 27 Time: 14:30-15:00

SL02-1

Upper Airway Ultrasonic Assessment for OSA Diagnosis and Treatment

陳正剛 Argon Chen (Taiwan)

National Taiwan University

It has been reported that changes in diameter of the pharyngeal airway observed by medical imaging are associated with obstructive sleep apnea (OSA). Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) are both useful for evaluation of various anatomical planes that might be the site of obstruction. However, MRI and CT cannot be widely applied to diagnosis of OSA due to the high costs and radiation exposure in case of CT scan. In contrast, ultrasound imaging of the upper airway state is radiation-free, less costly, real time, and portable, thus allowing for high accessibility for assessment of OSA.

Air is a type of substances poor in conducting the ultrasound wave. When the ultrasound beam reaches the interface between tissue and air, almost all the ultrasound energy is echoed. Therefore, when the airspace is encountered, hyperechoic signals can be observed. Such sonographic characteristics can be then used for analysis of the upper airway state. However, the airspace is sometimes not observable in ultrasound imaging due to the anteroposterior collapse or lateral contraction of soft tissue caused by the gravitational effect on the subjects in supine position or by certain breathing maneuvers, such as Müller's maneuver, performed by the subjects. This research aims to study how the observabilities and diameter changes, if observable, of different pharyngeal airway segments are related to the OSA severity and treatment interference.



# AmCAD UO® Press Coverage

www.mta-dialog.de | www.dvta.de

UO-System mit der lasergesteuerten Positionierung die oberen Atemwege präzise und zuverlässig scannen - und das am wachen Patienten. Das Gerät soll die Ultraschallbilder mithilfe künstlicher Intelligenz (KI) analysieren und rekonstruieren. Damit vergleiche es automatisch die

Zustände der Atemwege zwischen normaler Atmung und dem Müller-Manöver-Modell, einer Atmungsmethode, die Schnarchen nachahmt, so das Unternehmen. "Das AmCAD-UO bietet eine zuverlässige Risikobewertung für Patienten mit sowohl moderatem als auch schwerem OSAS", erläuterte Yili Lee, Präsidentin von AmCad BioMed. "Mit unserer einfachen und schnellen OSAS-Diagnose im wachen Zustand unter-

stützen wir Schlafmediziner zudem, die Ursachen bei blockierten Atemwegen zu identifizieren." Der Einsatz des AmCAD-UO sei wesentlich kostengünstiger als herkömmliche Diagnosemethoden und entlaste gleichzeitig die Schlafzentren. Das AmCAD-UO-System erhält das CE-Kennzeichen der EU und die Zulassungen von der Taiwan Food and Drug Administration (TFDA) und der US Food and Drug Administra-

tion (FDA). Seit Ende 2020 führe das Stanford Sleep Medicine Center gemeinsam mit AmCad BioMed eine klinische Studie zum AmCAD-UO

# MTA



**SCHLAU NEWS** 

NEWS AUS ALLER WELT - INFO, TIPPS, TRICKS...



66 | MTA INTERN | Aus der Industrie

#### Diagnose von Schlafapnoe

Die AmCad BioMed Corporation, ein Unternehmen aus Talwan, präsentierte das neuartige Diagnosesystem AmCAD-UO zur schneilen Erkennung des obstruktiven Schlafapnoe-Syndroms (OSAS) AmCAD-UO diagnostiziert Schlafapnoe mit KI. in Deutschland. Innerhalb von nur zehn Minuten soll das AmCAD-

Online Zeitung

WIRTSCHAFT

PRESSEMITTEILUNGEN KOSTENLOS VERÖFFENTLICHEN

Willkommen bei Online Zeitung, dem Portal für Pressemitteilungen aus Deutsc

Diagnose von Schlafapnoe innerhalb 10 Minuten

Mai 05 18:30



Neuartiges Diagnosesystem AmCAD-U Wachzustand mithilfe künstlicher Intellige Corporation - innovativer Medizintechnik präsentiert das neuartige Diagnosesy schnellen Erkennung des obstruktiven (OSAS) jetzt in Deutschland, Innerhalb scannt das AmCAD-UO-System mit Positionierung die oberen Atemwege prä und das am wachen Patienten. Das rekonstruiert die Ultraschallbilder mithilfe (KI). Damit vergleicht es automatisc

Atemwege zwischen normaler Atmung und dem Müller-Manöver-Modell, einer Atmungsmet nachahmt. "Das AmCAD-UO bietet eine zuverlässige Risikobewertung für Patienten mit sowol schwerem OSAS", erläutert Yili Lee, Präsidentin von AmCad BioMed. "Mit unserer einfachen Diagnose im wachen Zustand unterstützen wir Schlafmediziner zudem, die Ursachen bei blor identifizieren." Der Einsatz des AmCAD-UO ist wesentlich kostengünstiger als herkömmliche [ entlastet gleichzeitig die Schlafzentren.

> Positionierung die oberen Atemwege prazise und zuverlassig - und das am wachen Patienten. Das Gerät analysiert und rekonstruiert die

Dienstae, Juli 13, 2021

Presseverteiler Kontakt

#### Diagnose von Schlafapnoe innerhalb 10 Minuten

AmCad BioMed AmCAD-UO CPAP Herz-Kreislauf Herzinfarkt Obstruktive Schlafapnoe OSAS Schlaf Schlafapnoe Schlaganfall Schnarchen Taitra Taiwan Excellence

Neuartiges Diagnosesystem AmCAD-UO erkennt OSAS im Wachzustand mithilfe künstlicher Intelligenz

Die AmCad BioMed Corporation - innovativer Medizintechnik-Spezialist aus Taiwan - präsentiert das neuartige Diagnosesystem AmCAD-UO zur schnellen Erkennung des obstruktiven Schlafapnoe-Syndroms (OSAS) jetzt in Deutschland. Innerhalb von nur zehn Minuten scannt das AmCAD-UO-System mit der lasergesteuerten Positionierung die oberen Atemwege präzise und zuverlässig - und das am wachen Patienten. Das Gerät analysiert und rekonstruiert die Ultraschallbilder mithilfe künstlicher Intelligenz (KI). Damit vergleicht es automatisch die Zustände der Atemwege zwischen normaler Atmung und dem Müller-Manöver-Modell, einer Atmungsmethode, die Schnarchen nachahmt. "Das AmCAD-UO bietet eine zuverlässige Risikobewertung für Patienten mit sowohl moderatem als auch schwerem OSAS\*, erläutert Yili Lee, Präsidentin von AmCad BioMed. "Mit unserer einfachen und schnellen OSAS-Diagnose im wachen Zustand unterstützen wir Schlafmediziner zudem, die Ursachen bei blockierten Atemwegen zu identifizieren." Der Einsatz des AmCAD-UO ist wesentlich kostengünstiger als herkömmliche Diagnosemethoden und entlastet gleichzeitig die Schlafzentren.

Effektive OSAS-Diagnose und Therapiebegleitung



Radiologische

Ureter fissus

Pandemie

Coronastudie

Infektiologie

Systeme zur His-Bündel-Stimulation BIOTRONIK hat kürzlich sein neu-les Instrumentarium zur Unter-

durch. Erhältlich ist das Diagnosesystem in Deutschland seit 1. Juni 2021. Weitere Informationen unter https://www.amcad.com.tw/en

stützung von Conduction System

Pacing (CSP-)Prozeduren vorgestellt.

Bei der Entwicklung des Selectra-

3D-Katheters hat BIOTRONIK nach

eigenen Angaben eng mit spezialisier-

ten klinischen Experten zusammen-

gearbeitet. Der Katheter ist in neun

verfügbar und ist im CE-Raum für den

ectra 3D Katheter, Solia S D BIOTRONN Längen- und Krümmungsvarianten

Einsatz bei His-Bündel-Prozeduren zugelassen. Er sei für die Elektrodenplatzierung in Atrium oder Ventrikel ausgelegt und eigne sich für Prozeduren zur Stimulation des Reizleitungssystems. Selectra 3D unterscheide sich von anderen Produkten auf dem Markt durch eine größere Stabilität. Der Katheter behalte auch bei potenziell länger dauernden CSP-Prozeduren seine Form bei, betont der Hersteller, Angesichts vielfältiger Patientenanatomien sei für eine Steigerung der Erfolgsrate bei diesen Prozeduren eine breitere Auswahl an Tools zur His-Bündel-Stimulation nötig. Die größere Variantenvielfalt bei Selectra-3D-Kathetern für unterschiedliche Patientenanatomien gebe Ärzten mehr Kontrolle und Flexibilität bei den Eingriffen. Für den führenden CSP-Experten Dr. Francesco Zanon vom Universitätskrankenhaus "Santa Maria della Misericordia" in Italien ist eine breitere Katheterauswahl entscheidend für positive Ergebnisse: "Die größte Herausforderung bei Eingriffen zur Stimulation des Reizieltungssystems ist die Auswahl passender Tools für die gegebenen Patientenanatomien. Die passende Katheterkrümmung ist der

Schlüssel zum Erfolg. Mit der historischen Entwicklung der His-Bündel-Tools haben wir eine lange Lernphase durchlaufen. Die Neuerun-

gen beim Selectra 3D werden mehr Ärzten erfolgreiche Eingriffe der frei vom Ohr getragen wer-

Premiere für neuartiges Hörimplantat

Trstmalig in Deutschland und Europa wurde im Rahmen einer kontrollierten Markteinführung eine schwerhörige Patientin mit einem neuartigen Hörimplantat versorgt: Das Cochlear" Osia® System ist eine Lösung für Menschen mit Schallleitungsschwerhörigkeit, kombiniertem Hörverlust oder einseitiger sensorineuraler Taubheit (SSD). Die Implantation der 57-jährigen Patientin, die mit kombinierter Schwerhörigkeit lebt, erfolgte am 19. April an der Klinik für Hals-Nasen-Ohrenheilkunde des Universitätsklinikums Freiburg. Mit dem Cochlear-Osia-System könne sie ein normales Hörvermögen erreichen, da nach der OP eine Verbesserung von circa 15-20 dB zu erwarten sei. Das Cochlear Osia® System sei sowohl für Erwachsene als auch für Kinder geeignet, die mit einer Schallleitungs- beziehungsweise einer kombinierten Schwerhörigkeit oder auch mit einseitiger Taubheit leben. Vorteil dieser Lösung sei insbesondere ihre Leistungsstärke im Hochfrequenzbereich. In Vorstudien am Universitätsklinikum Freiburg hätten Patienten ein sehr gutes Sprachverstehen in Ruhe und im Störgeräusch erreicht, so das Unternehmen. Hier seien bei 22 implantierten Patienten dementsprechende Resultate erzielt worden. Hinzu komme ein ästhetischer Vorteil, denn die Haut bleibe intakt. Und beim jetzt erstmals eingesetzten System komme auch der neue piezoelektrische Wandler zum Einsatz - eine innovative Technik zur Schallübertragung über den Knochen. Das Cochlear-Osla-System verfüge über das weltweit erste osseointegrierte Steady-State-Implantat (OSI). Mithilfe digitaler piezoelektrischer Stimulation umgehe das System geschädigte Bereiche des natürlichen Gehörs und sende

Schallinformationen direkt an das Innenohr. Äußerer Teil des Systems sei ein schlanker und

komfortabler Soundprozessor,

安克生醫股份有限公司 AmCad BioMed Corporation

# AmCAD UO® Marketing Promotions



AmCad BioMed Corporation

CPAP廠商合作洽談

# AmCAD UO® in NTUH HMC



安裝前



# AmCAD UO® Marketing Promotions













### 2021 ECR Online Exhibition



# **Product Development**





### AmCAD US® – on Fatty Liver Detection

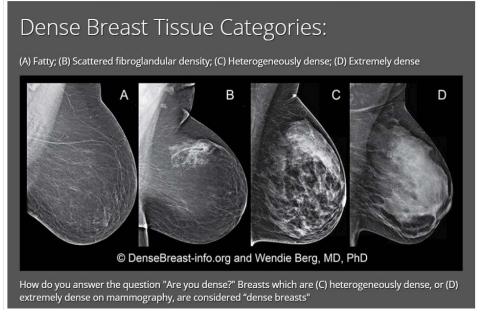
- ► Global Liver Disease Diagnostics Market Value EST:

  US\$ 48.7B by 2027; US31.2B in 2020; CAGR 6.5% (2020~2027)

  (from Grand View Research)
- AmCAD-US is a software device intended to visualize and analyze the statistical distributions of backscattered signals echoed by tissue compositions in the body. The information obtained from analysis may be used in tissue characterization and is shown effective in analysis of hepatic steatosis grades.
- ► FDA 510(k) application has been filed.



### Dense Breast issue





- ▶ Women with Dense Breasts :
  - •70-80% of women in Asia
  - •40-50% of women in the US.
  - 4~6X more likely to get breast cancer

- Sensitivity of mammogram significantly decrease to 48.6% for Dense Breasts compared to 88.9% for fatty breasts.
- ► FDA proposed New Mammogram Guidelines for Dense Breasts on Mar 27, 2019
  - → To notify and educate women with dense breasts about increased cancer risk and imprecise mammograms.
  - → Breast Ultrasound is recommended as a priority supplemental detection because its cost-effectiveness.

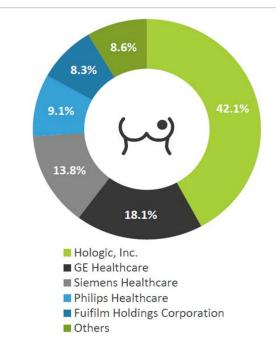


### AmCAD UB® Market Strategy

- ► After New Mammogram guideline for Dense Breasts proposed by FDA in Mar. 2019:
  - Hologic acquired Supersonic in Aug.2019.
  - Fujifilm announced to acquire Hitachi (diagnostic imaging BU) in Dec. 2019.
- Dense Breast Issue has become the key driver of growth for ultrasound market.
- ► AmCAD UB (Breast Ultrasound Real-time CADe/x) is going to be integrated into an ultrasound system, therefore, we are in the process of searching for collaboration partnerships (ex. licensing or codevelopment) with global ultrasound companies, such as GE, Philips, Siemens、Fujifilm、Cannon、SuperSonic…etc.

Global Breast Imaging Market Size worth \$7.3 B By 2024 with 12.2% CAGR

- 71% --Mammography + Ultrasound
- 10% --MRI





# **Financials**

### **Consolidated Balance Sheet**

單位:新台幣仟元

| 科目                           | 110.6.30  | %    | 109.12.31  | %    |
|------------------------------|-----------|------|------------|------|
| Current Assets               | 426,419   | 66   | 422,117    | 64   |
| Non-current Assets           | 222,201   | 34   | 234,430    | 36   |
| Total Assets                 | 648,620   | 100  | 656,547    | 100  |
| Current Liabilities          | 44,675    | 7    | 47,713     | 7    |
| Non-current Liabilities      | 19,372    | 3    | 13,730     | 2    |
| Total Liabilities            | 64,047    | 10   | 61,443     | 9    |
| Capital                      | 532,214   | 82   | 532,214    | 81   |
| Additional Paid-in Capital   | 94,524    | 14   | 94,377     | 14   |
| Accumulated Deficit          | (132,374) | (20) | ( 117,864) | (18) |
| Other Equity                 | (4,747)   | (1)  | (11,024)   | (1)  |
| Parent Equity                | 489,617   | 75   | 497,703    | 76   |
| Minority Interest            | 94,956    | 15   | 97,401     | 15   |
| Total Equity                 | 584,573   | 90   | 595,104    | 91   |
| Total Liabilities and Equity | 648,620   | 100  | 656,547    | 100  |



### Consolidated Income Statement

Unit: K TWD

| Items               | 2021H1   |       | 2020H    | YoY   |      |
|---------------------|----------|-------|----------|-------|------|
|                     | AMT      | %     | AMT      | %     | %    |
| Sales Revenue       | 31,693   | 100   | 29,468   | 100   | 8%   |
| Gross Margin        | 20,892   | 66    | 19,481   | 66    | 7%   |
| Operating Expenses  | (45,224) | (142) | (50,085) | (170) | -10% |
| Operating Loss      | (24,332) | (76)  | (30,604) | (104) | -20% |
| Non-operating Gain  | 2,536    | 8     | 4,379    | 15    | -42% |
| Net Loss            | (21,796) | (68)  | (26,225) | (89)  | -17% |
| Net Loss – Parent   | (19,351) | (61)  | (21,285) | (72)  | -9%  |
| Net Loss – Minority | (2,445)  | (8)   | (4,940)  | (17)  | -51% |
| EPS (TWD)           | (0.36)   |       | (0.40)   |       |      |



### Future Outlook – AmCAD UT®、AmCAD UO®

#### Domestic Market :

- ✓ AmCAD UT® targets health check in hospitals and health check center channels with subscription business model;
- ✓ AmCAD UO® also targets health check center channels with rental as main business model

#### Global Market :

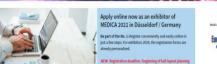
- ✓ Expanding global distribution channels by A. participating online and off-line exhibitions, B. more publications on academic medical journals and medical seminars, C. support local clinical studies for market promotion
- ✓ Searching for licensing deal with global ultrasound companies for AmCAD UT.



# Future Outlook – International Expo.

#### Medica 2021 Nov.





World Sleep 2022 Mar.



#### RSNA 2021 Dec.









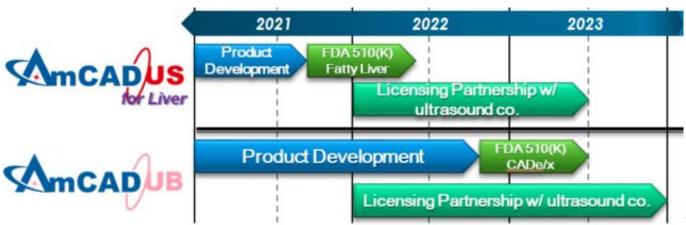




### Future Outlook – Product Development

- AmCAD US® for Fatty Liver Detection
- AmCAD UB® Al Live Breast ultrasound real-time CADe/x

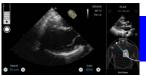
These two products will be integrated into ultrasound system. Other than existing compatible ultrasound, we are in the process of searching for more collaboration partnerships (ex. licensing or co-development) with other ultrasound companies.





### **Future Outlook**

► There have been more cases of partnerships between medical images AI companies and ultrasound companies. For example, this Aug. Caption Health (AI-guided ultrasound software) and Butterfly Network (handheld ultrasound manufacturer) announced strategic partnership.



Caption Health + Butterfly Strategic Partnership



AmCad as a pioneer ultrasound AI company with multiple FDA approved products, shall be a preferred option for strategic partnership to ultrasound companies.











Q&A