

Genius Holdings Co., Ltd

Smart Medical Device

Duncan Chen

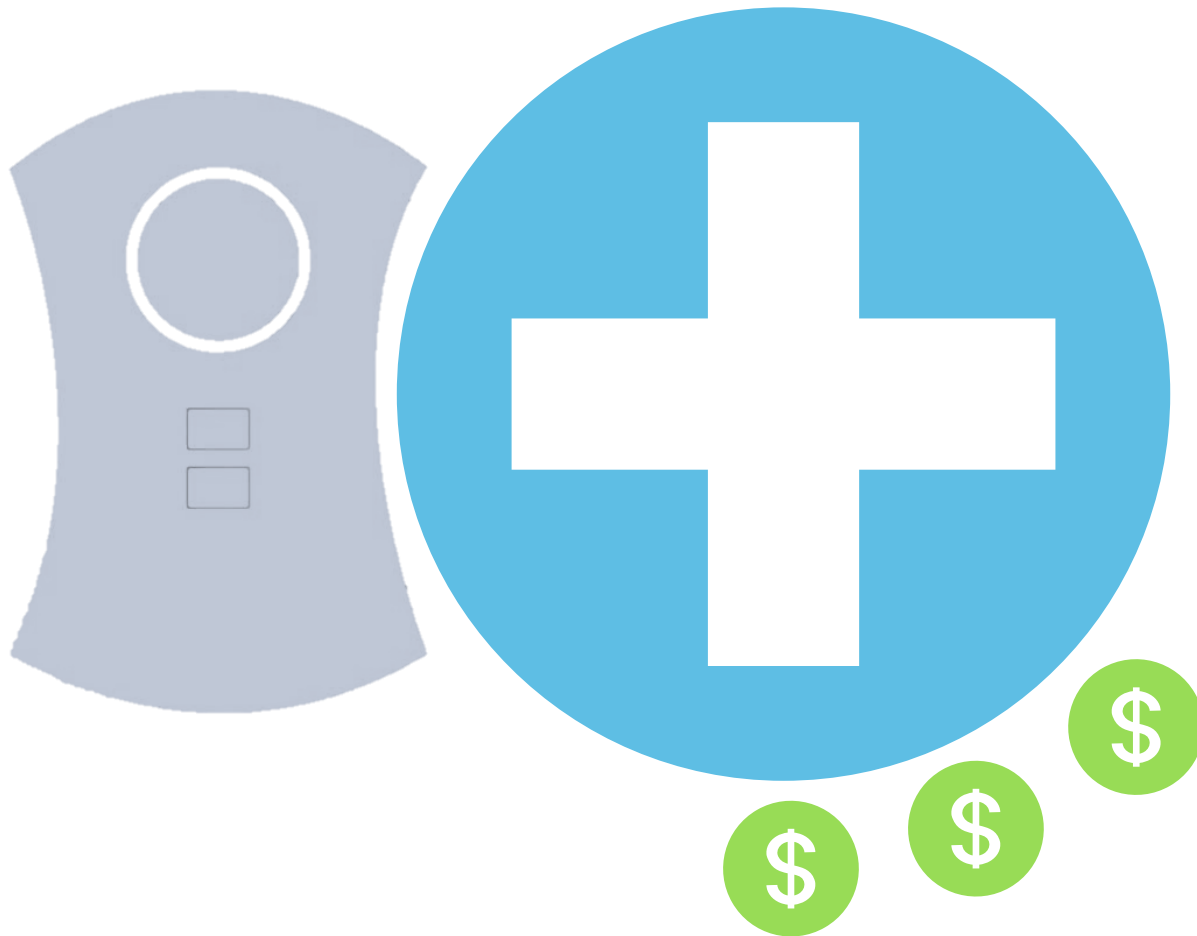
dc@genius-gh.com

Tifa Su

chiachisu@genius-gh.com



Spirometer Unmet Medical Needs



TA Respiratory Patient in the Hospital/Home

Pain

- Insurance limitation
- Poor data to support medication
- COVID-19 cross infection issues
- Device Calibration
- No connection with smartphone/Pad

Medical Devices for COVID-19

Spirometer development trend would be more personal based than hospital-based within global COVID pandemics.

- Decreases cross infection risks
- Evaluate respiratory symptoms
- Prevent acute respiratory distress syndrome (ARDS) and COVID patients getting worse.

COVID-19 Medical intervention



Treatment

Ventilator, oxygen,
and other
supportive care..



Monitoring Efficiency

Personal Spirometer > CT >
X-ray > thermometer >
oximeter > stethoscope.

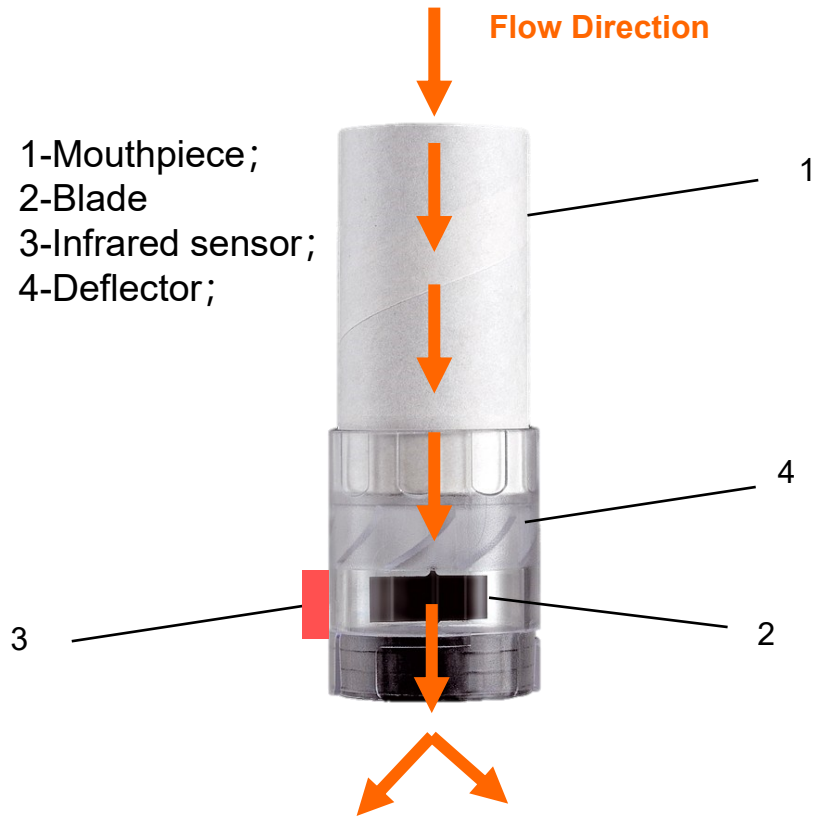


Diagnosis

RT-PCR, molecular
antibodies, et



Market Pain Point



- 1-Mouthpiece;
- 2-Blade
- 3-Infrared sensor;
- 4-Deflector;

Turbine
 Infrared sense rotating speed
 Flow/Pressure sensor

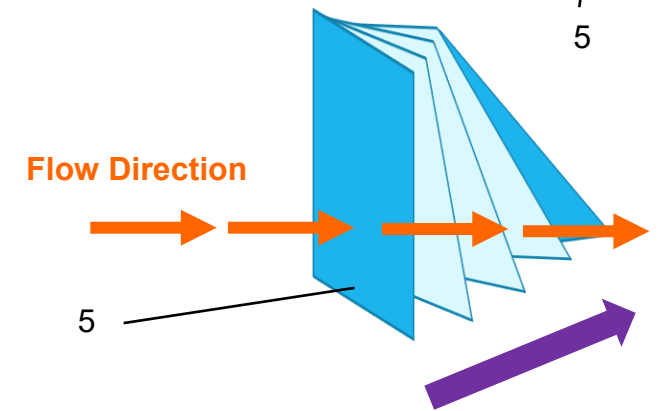
Disadvantages

- Inertia
- Calibration
- Reliability

Pressure
 Pressure Sensor

Disadvantages

- Environment-sensitive
- Calibration
- Reliability.



Pressure impedance flat swing direction

- 5- Pressure impedance sheet;
- 6- Mouthpiece

ezOxygen exclusive technology

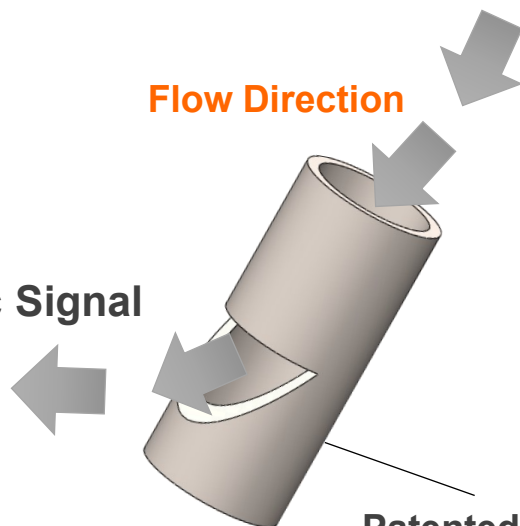
Passive ultrasonic detection,

The airflow generates a resonant frequency response through the metal whistle, and the signal converted to flow rate and volume by exclusive algorithm



Flow Direction

Ultrasonic Signal



Patented Metal Whistle

Airflow transducer

Microphone

Algorithm & display

Advantage



Better accuracy than traditional method and no inertia effect or environment interference.



Calibration-free.



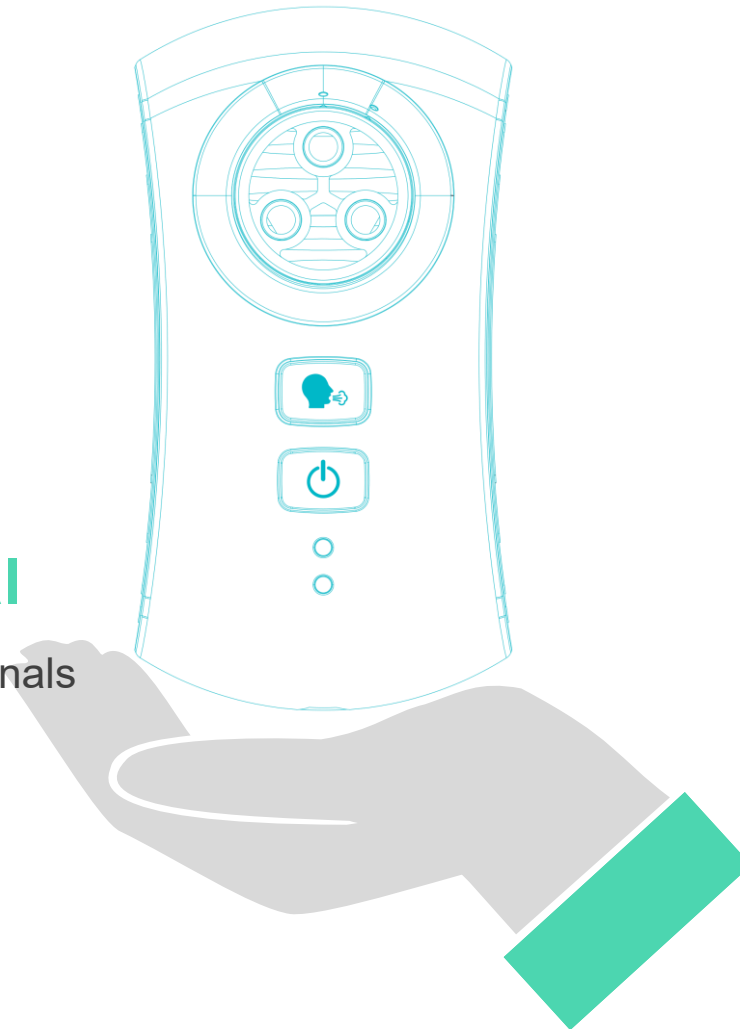
Mouthpiece is easy to clean, and detachable

Volume	MIR PEF (L/min)	ezOxygen PEF (L/min)	Deviation rate (%)
3L	412	424	3%
4L	651	657	1%
5L	769	728	5%

Passive Ultrasonic Detection

Lung Function detection factor in Respiratory Medical

The airflow is transformed into ultrasound signals and recorded by MEMs microphone, then smartphone could calculate the lung function parameters, such as **PEF**、**FEV1**、**FVC** , via exclusive algorithm and the best accuracy.



PEF · Peak Expiratory Flow

The maximum airflow during a forced expiration beginning with the lungs fully inflated.

FEV1 · Forced Expiratory Volume in One second

- Forced expiratory volume in the first second.
- Approximately 83% of FVC in normal..

FVC · Forced Vital Capacity

- The volume of air that can forcibly be blown out after full inspiration.
- In general, the fully exhalation is within 3 seconds

Patent

Territory	Patent No.	Title	Status
China	ZL201610656414.9	呼吸功能检测系统及其检测方法	approval
Taiwan	TW I603715 B	呼吸功能檢測系統及其檢測方法	approval
Taiwan	TW I652043 B	肺量計、吹口裝置及其檢測方法	approval
Japan	6349613	呼吸機能検出システム及びその検出方法	approval
Korea	10-2032874	호흡 기능 검사 시스템 및 그러한 시스템의 호흡 기능 검사 방법	approval
U.S.A	US 10863923B2	SPIROMETER, MOUTHPIECE TUBE AND INSPECTION METHOD THEREOF	approval
Japan	6689797	肺活量計、マウスピース装置及びその検出方法	approval
EP	3334335	RESPIRATORY FUNCTION TESTING SYSTEM AND RESPIRATORY FUNCTION TESTING METHOD THEREOF	approval
EP	3498164	SPIROMETER, MOUTHPIECE TUBE AND INSPECTION METHOD THEREOF	approval

ezOxygen APP

NOW, free downloadable in the **APP Store (IOS)** and **Google Play (Android)**.

Sync with **Apple Health** App to integrates into digital medical card.



Respiratory Testing result



Respiratory data and status..

History Record



Tracing data including result、date、time、GPS weather information、

GPS Weather



GPS Site、temperature、Humidity、visibility、UV Index and air quality

Social Network



Friend by QR code to take care each other's respiratory status



Electronic Examination & Certification

01

02

03

04

US

Taiwan

China

Japan

FCC

NCC

SRRC

TELEC

<p>TCB</p> <p>GRANT OF EQUIPMENT AUTHORIZATION Certification Issued Under the Authority of the Federal Communications Commission By:</p> <p>Nenko North America, INC. 303 River Road Ottawa, Ontario, K1V 1H2 Canada</p> <p>Date of Grant: 11/20/2017 Application Dated: 11/29/2017</p> <p>Genius Holdings Co., Ltd Taiwan Branch 3F., No.405, Sec. 2, Tiding Blvd., Neihu Dist., Taipei City 114, Taiwan (R.O.C.) Taipei City, 114 Taiwan</p> <p>Attention: Tifa Su, RD Director</p> <p>NOT TRANSFERABLE EQUIPMENT AUTHORIZATION is hereby issued to the named GRANTEE, and is VALID ONLY for the equipment identified herein for use under the Commission's Rules and Regulations listed below.</p> <p>FCC IDENTIFIER: 2A0D9EZO-G001 Name of Grantee: Genius Holdings Co., Ltd Taiwan Branch Equipment Class: Digital Transmission System Notes: ezOxygen breath checker</p> <p>Grant Notes: FCC Rule Parts 15C</p> <p>Output power listed is conducted. This device has 20 MHz and 40 MHz bandwidth modes.</p> <p>TCB</p>	<p>電信管制射頻器材型式認證證明</p> <p>(1) 申請者: 薩摩亞商傑尼斯投資控股有限公司 台灣分公司 (2) 地址: 台北市內湖區堤頂大道二段 409 號 3 樓 (3) 製造廠商: 太和光股份有限公司 (4) 器材名稱: ezOxygen 肺活量穿戴裝置 (5) 廠牌: ezOxygen (6) 型號: EZO-G001</p> <p>(7) 發射功率(電場強度): 802.11b: 13.31dBm 802.11g: 18.28dBm 802.11n-HT20: 18.06dBm 802.11n-HT40: 18.60dBm</p> <p>(8) 工作頻率: 2412 ~ 2462 MHz (9) 審驗日期: 106年11月28日 (10) 審驗合格標籤號碼: CCA17LPA2E01</p> <p>(11) 警語或標示要求: 器材本體、使用手冊、外包裝盒等應遵守下列標示要求 1. 應依審驗合格標籤或符合性聲明標籤或符合性聲明標籤貼於器材本體明顯處, 並知悉應標示本會標章, 如得公開陳列或販售。 2. 電信管制射頻器材應依本會或相關技術規範規定於指定位置標示中文警語。 3. 除授權使用射頻模組(組件)之審驗合格標籤者, 應於最終產品說明書及包裝盒提供充分正確之資訊。 4. 於國際網路販售取得審驗證明之電信管制射頻器材者, 應於該國際網路網頁提供審驗合格標籤或符合性聲明標籤資訊。 5. 使用本府應遵守下列資訊: (1) 標式認證合格之低功率射頻電機, 非經許可, 公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。低功率射頻電機之使用不得影響飛航安全及合法通信; 經發現有干擾現象時, 應立即停用, 並改善至無干擾時方得繼續使用。前項合法通信, 指依電信法規定作業之無線電通信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。 (12) 特殊記載事項: 詳如附件</p> <p>說明: 1. 本中心係經國家通訊傳播委員會委託之驗證機構(證書號碼NCC-RCB-10; 機構地址: 高雄市路竹區路科一路3號), 標章本型式認證證明。 2. 請依上列標籤式樣在製標籤、標貼或印鑄於器材本體明顯處, 始得販售或公開陳列。 3. 本設備之製造、輸入、販售、使用等均需遵守相關電信法規之規定。</p>	<p>无线电发射设备 Radio Transmission Equipment 型号核准证 Type Approval Certificate</p> <p>薩摩亞商杰尼斯投资控股有限公司 (台湾): 根据《中华人民共和国无线电管理条例》, 经审查, 下列无线电发射设备 Regulations of the People's Republic of China, the following 符合中华人民共和国无线电管理规定和 radio transmission equipment, after examination, conforms 技术标准, 其核准代码为: CMIIT ID: 2018DJ0278 to the provisions with its CMIIT ID:</p> <p>有效期: 五年 Validity 五年</p> <p>Sealed by issuing authority 2018年1月10日 Year Month Date</p>	<p>telefication</p> <p>Certificate of Radio Equipment in JAPAN No: 201-180312 / 00</p> <p>Telefication, operating as Conformity Assessment Body (CAB ID Number: 201) with respect to Japan, declares that the listed product complies with the Technical Regulations Conformity Certification of Specified Radio equipment (ordinance of MPT N° 37,1981)</p> <p>Product description: ezOxygen breath checker Trademark: ezOxygen Type designation: EZO-G001 Hardware / Software version: RECORDER_V12 / recordPen_1_5 Variants: --</p> <p>Manufacturer: TRLight Co. Ltd. Address: 8F., No. 18, Ln. 609, Sec. 5, Chonglin Rd., Sanxiong Dist., City: New Taipei City Country: Taiwan</p> <p>This certificate is granted to: Name: Genius Holdings Co., Ltd Taiwan Branch Address: 3F., No. 405, Sec. 2, Tiding Blvd., Neihu Dist., City: 114 Taipei Country: Taiwan</p> <p>This certificate has THREE Annexes. Zevenaar, 16 May 2018</p> <p>CAB</p> <p>David Chen David Chen Product Assessor</p> <p>PRODUCTS RvA C 224</p> <p>Laboratory certification approvals</p>
---	---	--	--

ezOxygen Clinical Trial

01

Department of Thoracic Medicine in Chang Gung Memorial Hospital
ClinicalTrials.gov Identifier: NCT04808089

The screenshot shows the ClinicalTrials.gov entry for the study. The title is "The Feasibility of Asthma Application of Mobile Phone and Mobile Spirometry for Home Monitor of Asthma Patients". The sponsor is Chang Gung Memorial Hospital. The study description includes a brief summary and a table of conditions and interventions.

Condition or disease	Intervention/treatment	Phase
Asthma	Other: Health Lung App. of mobile phone+ezOxygen mobile spirometry Other: Usual care	Not Applicable

02

Department of Emergency Medicine in Chang Gung Memorial Hospital

長庚醫療財團法人人體試驗倫理委員會
臨床試驗/研究同意證明書

址：105台北市敦化北路199號
傳真：03-3494549
聯絡人及電話：丁一慶(03)3196200#3709
電子郵件信箱：yjd1ing@cgmh.org.tw

計畫名稱：多重肋骨骨折預後之前瞻性觀察性追蹤研究
本院案號：2020044180C502
試驗期間：2020年5月22日-2021年11月30日
本次核准執行期間：2021年1月23日-2021年5月21日
主持人：外傷急症外科 廖建安 學術組講師級主治醫師
共同主持人：廖健宏、郭令偉
試驗/研究機構：林口長庚醫院

計畫文件版本日期：
(1)其他文件：延長試驗期間至2021/11/30。
通過日期：2021年1月23日
期中報告繳交頻率：一年繳交一次
※下次期中報告繳交截止日期：2021年5月21日，為免影響主持人執行研究之權益，請於截止日前六至八週繳交報告(期中報告繳交頻率為三個月者，得於試驗到期前一個月繳交報告)，以利審查作業進行。若主持人未繳交或延遲繳交期中報告，以致本會無法於核准執行期間到期前，核發下次試驗執行期間，所有的研究活動必須停止，包括：對已參與受試者之介入或各項互動，除非本會認為受試者繼續接受試驗介入或參與試驗顯有益於受試者安全或倫理上符合受試者最佳利益之情形，亦不得再納入新個案，直到期中報告核准為止。
本委員會組織與運作皆遵守GCP規定

長庚醫療財團法人
人體試驗倫理委員會謝煥堂主席



2021 年 01 月 23 日

03

Department of Thoracic Medicine in Taipei Medical University Hospital

臺北醫學大學
臺北醫學大學暨附屬醫院聯大人體研究倫理委員會
TMU-Joint Institutional Review Board
通過證明函 - 一般審查案

TMU-JIRB Form071/20200317

開立日期：民國109年04月28日

本會編號：N202004108
計畫名稱：使用個人式被動超聲呼吸功能儀觀察呼吸道感染患者之疾病進程與肺功能變化
計畫主持人：郭漢彬
共同主持人：李國遠、馮博皓、陳賢濤、陳冠元、何淑娟、劉文德、李捷新、蕭世欣、周百謙、陳甫倫、周俊良、張智華
試驗/研究機構：臺北醫學大學附設醫院、衛生福利部雙和醫院
計畫書版本/日期：Version:1.1 Dated:04/Apr/2020
受試(訪、檢)者同意書版本/日期：Version:3/2020/04/25
個案報告表版本/日期：Version:1/2020 03/14

上述計畫已通過本會一般審查程序，業經第109-04-4次會期(會議日期：109年04月23日)審查，特此聲明。有效期間自民國109年04月28日至民國110年04月27日。試驗/研究期間應接受本會之監督。

依據衛生福利部相關規定，後續追蹤程序及要求如下：
1. 期中報告：本計畫期中繳交頻率為每12個月，應於有效期間到期前二個月(民國110年02月27日)繳交期中報告。有效期間屆滿時若尚未通過期中報告與效期展延審查者，試驗/研究不得繼續執行。
2. 結案報告：試驗/研究完成後，應將執行情形及結果依結案報告表送交本會審查。核准期間到期三個月仍未繳交者，本會得撤銷本通過證明函，亦即撤銷本試驗/研究之核准，亦將依本會作業程序暫停主持人(含任何參與形式申請試驗/研究案)之審查三個月。
3. 嚴重不良事件(SAE)報告：執行人體試驗或臨床試驗之主持人應根據衛生署「藥品優良臨床試驗準則」和「嚴重藥物不良反應通報辦法」規定，辦理相關事宜。

主任委員：

陳中明



本會組織與執行皆符合適用法規
The TMU-Joint Institutional Review Board performs its functions according to written operating procedures and complies with GCP and with the applicable regulatory requirements.
114739cfe11846067040a343899ed01 TMU-JIRB Form071/20200317

Healthy Lung APP

AZ: The 12th pharmaceutical company in the world, distributing to over 100 countries. Focus on Tumor, cardiovascular, kidney, metabolism, and respiratory



Partnership with AZ, provide new APP in respiratory care, with GH ezOxygen, and will be launched soon, target **>800 ACE clinics**



01 Great Treet Pharmacy

Price NTD 3600

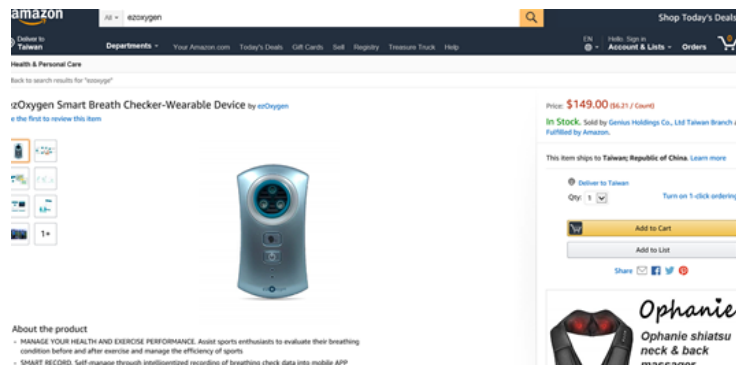


02 Pchome Online

Price : NTD 3600



ezOxygen Sales Channel



03 AMAZON

Price : USD 199

ezOxygen PRO



Smartphone

Smartphone with Audio ADC · 18~24 kHz for general device; 24~48 kHz for Hi-Res ADC



Smartphone



ezOxygen PRO APP

ezOxygen PRO APP to test and show the respiratory status

APP



Smartphone Spirometer

Mobile phone accessories



Ultrasonic Emitter








Mouthpiece

Mouthpiece with Ultrasound Emitter



Use Your Smartphone & Galton's whistles Mouthpiece

Competitor Comparison (USA)

Brand	Photo	Price(USD)	Technology	Detection item	Accuracy	Calibration Free
ezOxygen		<200	Passive Ultrasound	PEF、FEV1、FVC	1/10,000	✓
MIR		1,340	Turbine	PEF、FEV1、FVC	1/100-1/200	✗
Spiro P/D		800	Turbine	PEF、FEV1、FVC	1/100-1/200	✗
SDI		875	Turbine	PEF、FEV1、FVC	1/50	✗
NDD		1,971	Active Ultrasound	PEF、FEV1、FVC	1/400	✗
Thor		625	Active Ultrasound	PEF、FEV1、FVC	1/100	✗
Vitalograph		3,550	Fleisch Pneumotachograph	PEF、FEV1、FVC	1/100	✗

Why ezOxygen?



Reasonable price



Calibration Free



High Accuracy



Convenient

A light blue world map is centered in the background of the slide.

THANK YOU

Genius Holdings Co., Ltd

