



Mintti Smartho-D2 AI-powered Stethoscope

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How Will Smartho-D2 Help Improve Diagnosis?

What did our customers say about Smartho-D2?



**Every family has a
thermometer, why not
a stethoscope?**



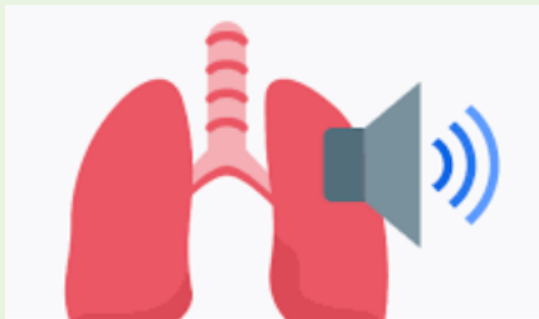
I . Every family has a thermometer, why not a stethoscope ?



Hear nothing?



Untrained?



Poor sound ?

*Why not a
stethoscope at
home?*



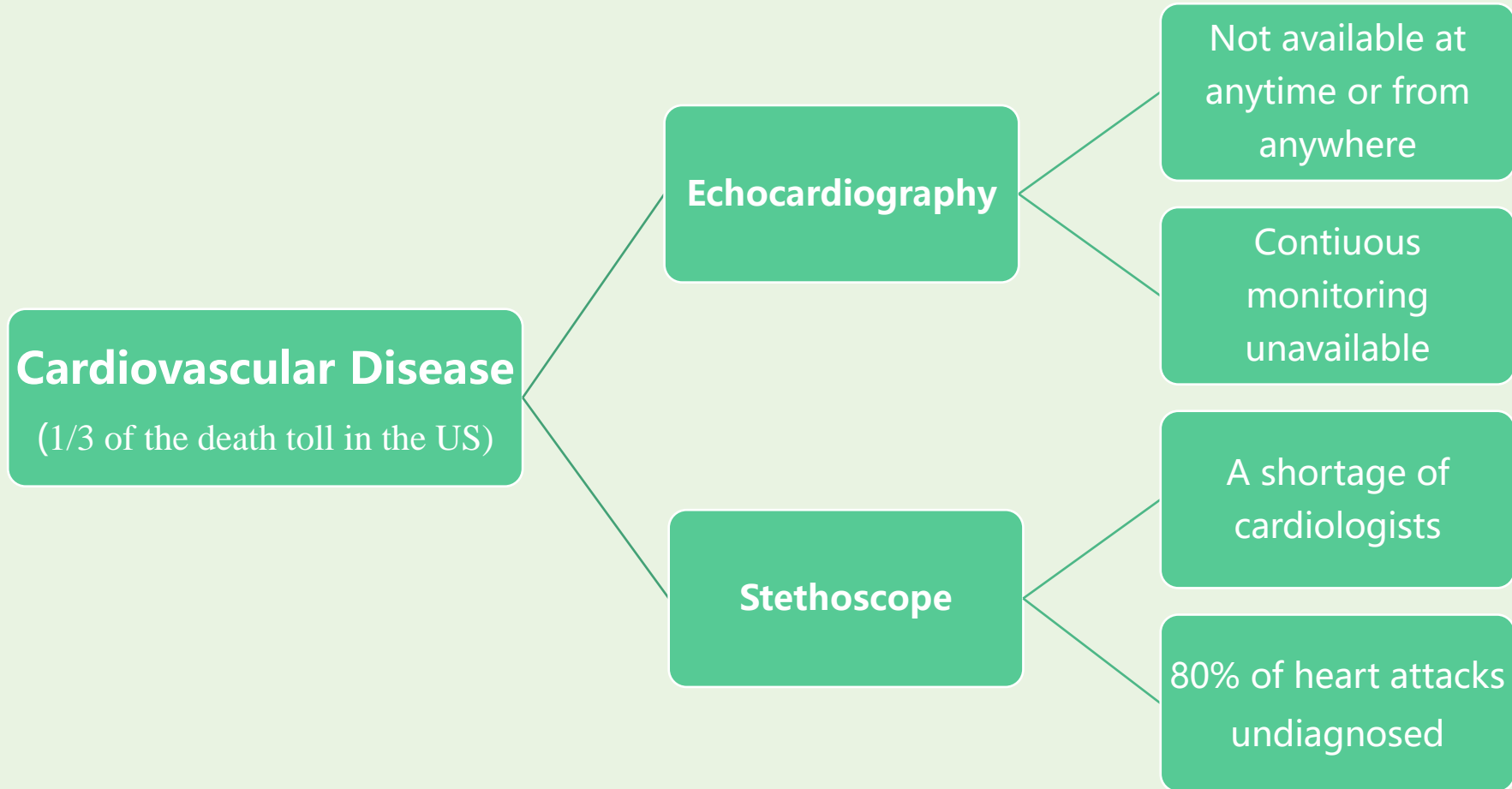
Hard to diagnose?



Why an AI-powered Stethoscope is a Game Changer?



II. Why an AI-powered Stethoscope is a Game Changer?



II. Why an AI-powered Stethoscope is a Game Changer?



Traditional Stethoscope
--the first generation

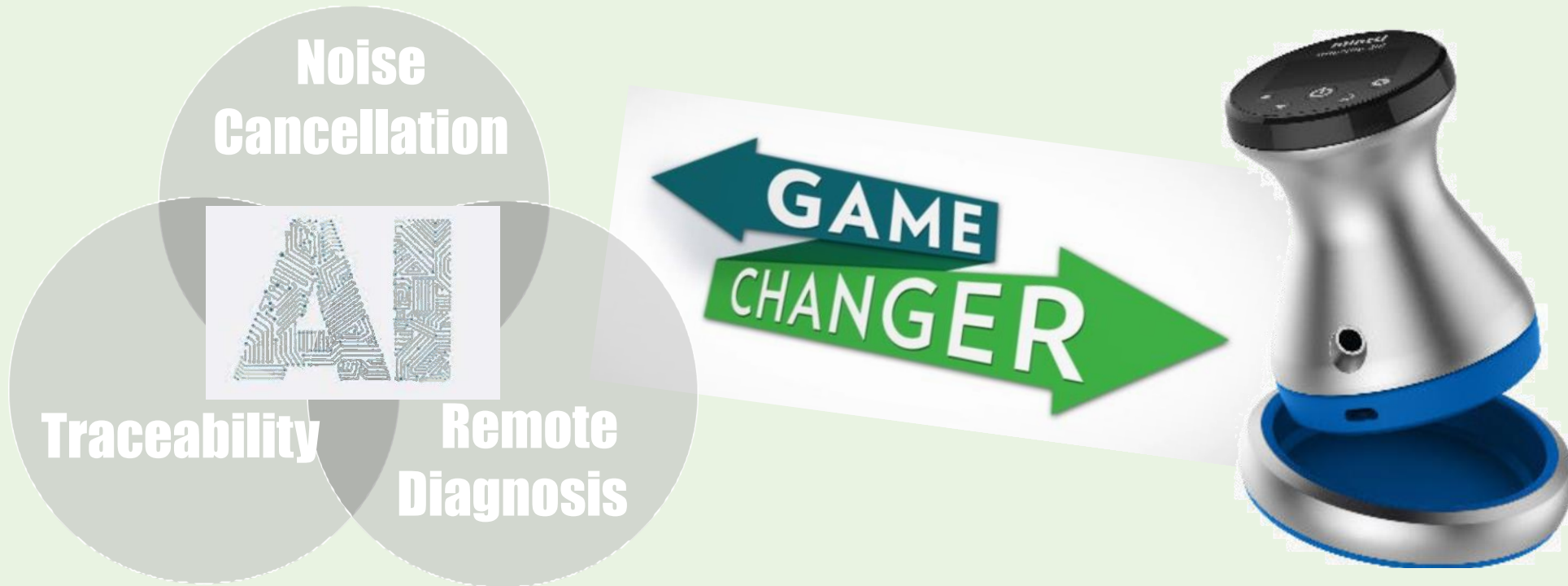


Electronic Stethoscope
--the second generation



Smart Stethoscope
--the third generation

II. Why an AI-powered Stethoscope is a Game Changer?



More Accurate and Efficient Diagnosis through Advanced Sound Processing Algorithms and Real-time Analysis



Part III



What's the Story behind Smartho-D2?



III. What's the Story behind Smartho-D2?

We take pride in being the first and only company to obtain both CE marking and FDA clearance in China.

C E R T I F I C A T E

notice

EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number
CE-MDD-0061/04/2020/02

Manufacturer : Suzhou Melodicare Medical Technology Co., Ltd.
Address : Room 301, Building F2, No.32 Hongxi road, Suzhou high-tech zone, Jiangsu province, China
Product(s) : Electronic Stethoscope
Software Version: V.1.0
Model(s) : Model Name Frequency Ranges
smartho-D2 20-2000Hz
Report Number : CE-MED-0128
First Issue Date and Place : 2021.04.26 & Istanbul
Revision Number and Date : 00 / --
Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), 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 II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vicdan Akdağ
Chairman

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.

Esentepe Mahallesi Milangaz Caddesi No:75/A/92 Kartal / İstanbul/TÜRKİYE
www.notice.com.tr

FR.08.23_Rev.02 CE-MDD-0061/04/2020/02 1 of 1

C E R T I F I C A T E

notice

EC CERTIFICATE

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Full Quality Assurance System

Certificate Number
CE-MDD-0061/04/2020/01

Manufacturer : Suzhou Melodicare Medical Technology Co., Ltd.
Address : Room 301, Building F2, No.32 Hongxi road, Suzhou high-tech zone, Jiangsu province, China
Product(s) : 1. Continuous Monitoring Thermometer
2. Dynamic ECG Monitor
3. Infrared Thermometer
4. Vital Signs Monitor
Model(s) : Product Name Model Name
Continuous Monitoring Thermometer Coola
Dynamic ECG Monitor MCT-H1
Infrared Thermometer Breeze
Vital Signs Monitor Vision
Report Number : CE-MED-0061-01, CE-MED-0061-02,
CE-MED-0061-03, CE-MED-0061-04
First Issue Date and Place : 2020.05.05 & Istanbul
Revision Number and Date : 00 / --
Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), 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 II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

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FDA U.S. FOOD & DRUG ADMINISTRATION

December 18, 2019

Hefei Mintti Medical Technology Co., Ltd. China
Shengsheng Cai, General Manager
C309, National University Science Park, 602 Huangshan Road,
High-tech Zone, Hefei, 230088, CHINA

Re: K 191667
Trade/Device Name: Electronic Stethoscope – smartho-D2
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: D0D
Dated: November 20, 2019
Received: November 26, 2019

Dear Shengsheng Cai:

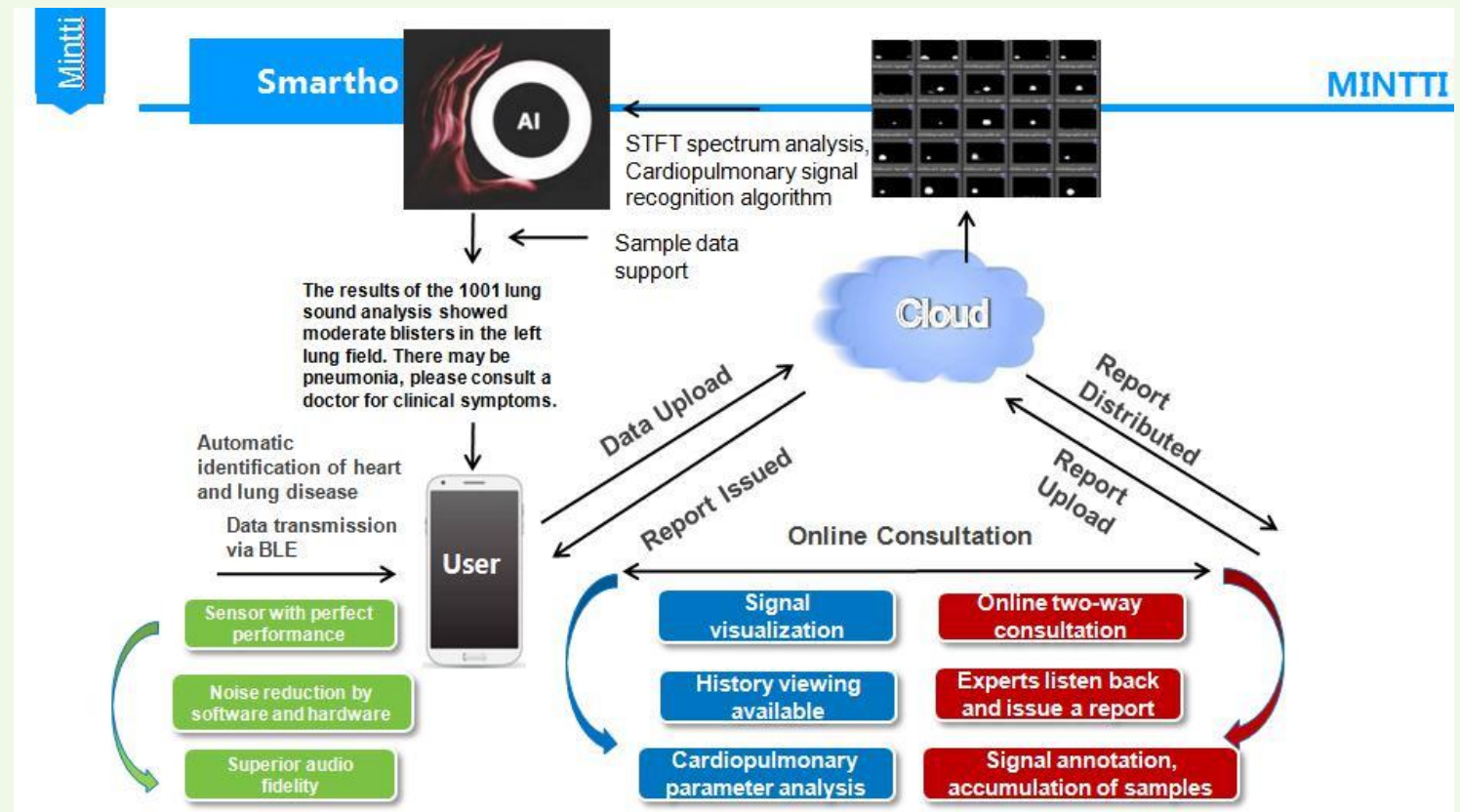
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

III. What's the Story behind Smartho-D2?

Our advanced technology offers two options: remote auscultation and AI-supported diagnosis.



III. What's the Story behind Smartho-D2?



Comprehensive annotated database



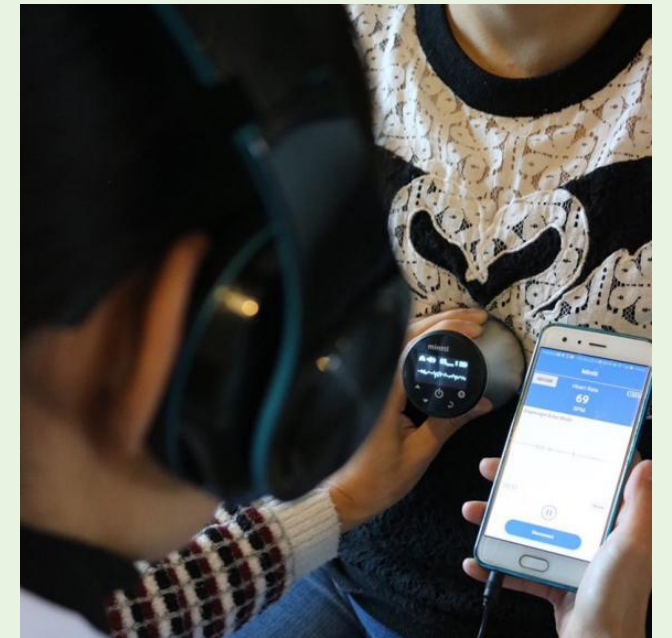
AI automatic pre-diagnosis function for pediatric pneumonia and structural heart disease



Achieving an identification accuracy rate of over 85%

III. What's the Story behind Smartho?

Assisted healthcare professionals in quickly identifying and diagnosing respiratory diseases in children.



Screening for Primary Cardiopulmonary Diseases



III. What's the Story behind Smartho?



Applied in Detecting COVID-19



Help Stop the Spread of Coronavirus

III. What's the Story behind Smartho?

2019 IEEE 7th International Conference on Bioinformatics and Computational Biology

The Automatic Repairing Method Addressing Clipping Distortions and Frictional Noises in Electronic Stethoscope

Ning Zhou, Jiajun Wang, Bing Sun, Renyu Liu, Nan Hu*

School of Electronic and Information Engineering, Soochow University
Suzhou, China

e-mail: 20165228036@stu.suda.edu.cn, jjwang@suda.edu.cn, sunbing@suda.edu.cn, 1002280496@qq.com,
*hunan@suda.edu.cn



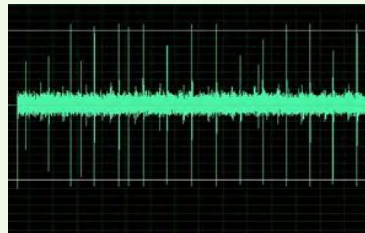
Clinical Research Cooperation



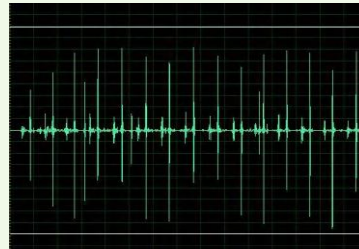
How Will Smartho-D2 Help Improve Diagnosis?



IV. How Will Smartho-D2 Help Improve Your Diagnosis?



Noise
Reduction



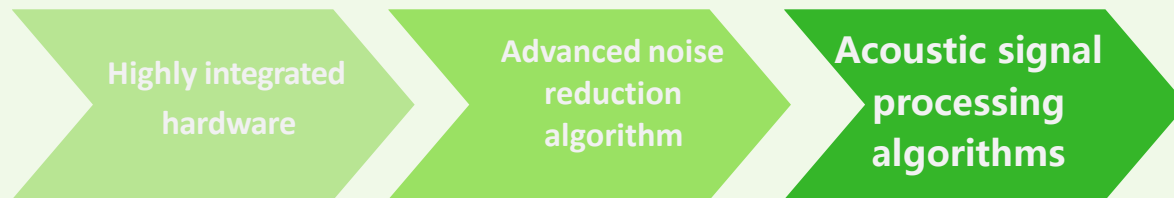
Original Cardiopulmonary Signal



Cardiac Sounds Signal after Extracting

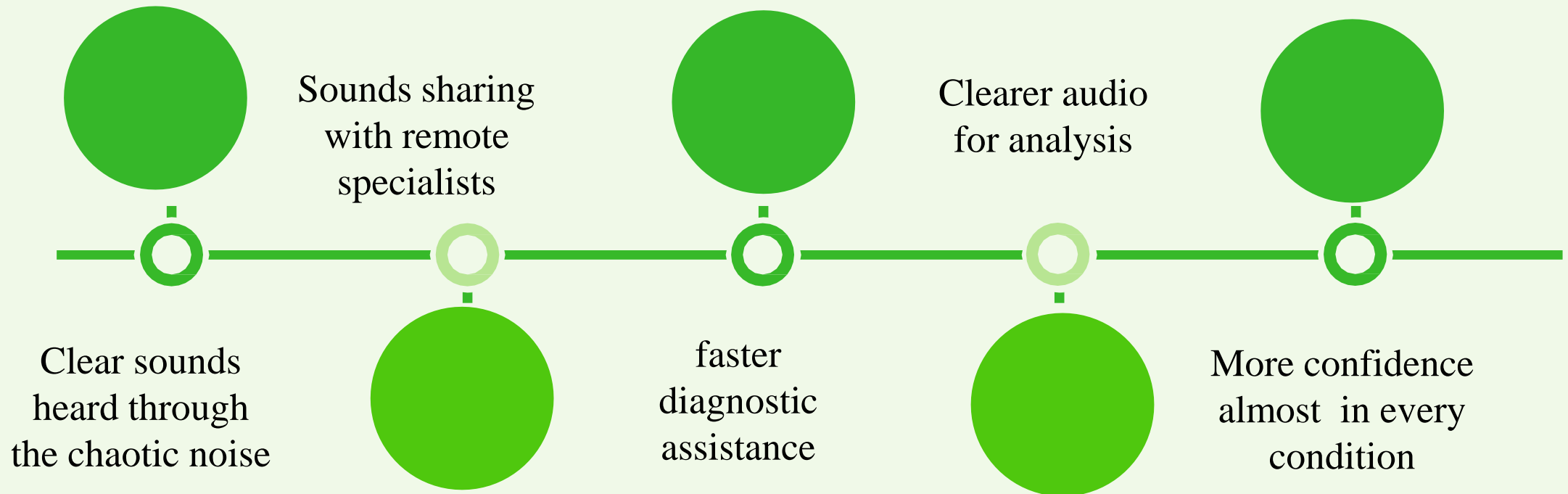


Pulmonary Sounds Signal after Extracting



To make machine understand, make it hear clearly first!

IV. How Will Smartho-D2 Help Improve Your Diagnosis?



IV. How Will Smartho-D2 Help Improve Your Diagnosis ? - Clinical Practice



Assist in timely diagnosis of VHD, congestive heart failure, pediatric pneumonia, and infantile asthma etc.



Track a patient's progress, determining whether patients' condition have improved or regressed.

IV. How Will Smartho-D2 Help Improve Your Diagnosis ? - Academic Teaching & Research



For teaching around the bedside, in the classroom and auscultation research, you can:

- ♥ save images of waveforms and spectrograms ;
- ♥ amplify, slow down, cut, copy or paste sound segments;
- ♥ upload and share sounds instantaneously;
- ♥ record sounds and create a sound sample library.

IV. How Will Smartho-D2 Help Improve Your Diagnosis ? - Telemedicine

For telemedicine, with Mintti Smartho-D2, you can:

- ♥ make a proper diagnosis during a tele-consultation with a patient in a rural clinic;
- ♥ provide remote assessment or email recordings to colleagues for second opinions;
- ♥ produce, annotate and edit EMR to carry out remote diagnosis.



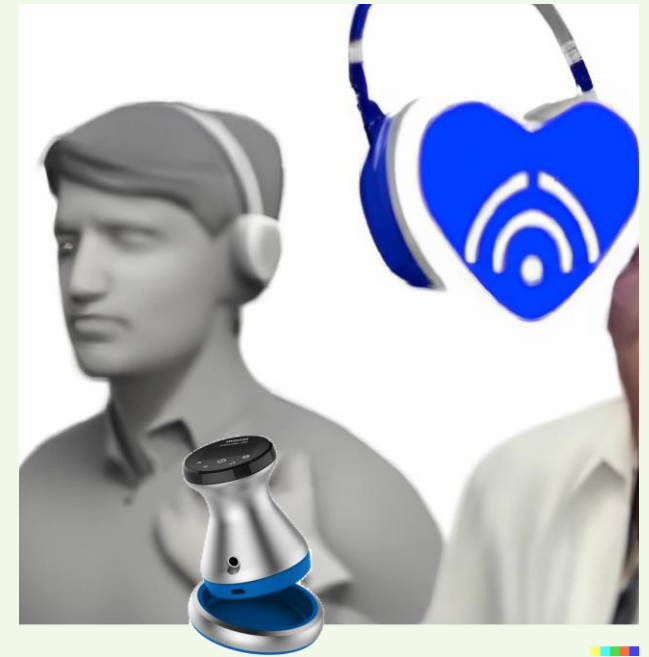
IV. How Will Smartho-D2 Help Improve Your Diagnosis ? - COVID-19 & Infection Control



More compatible under PPE

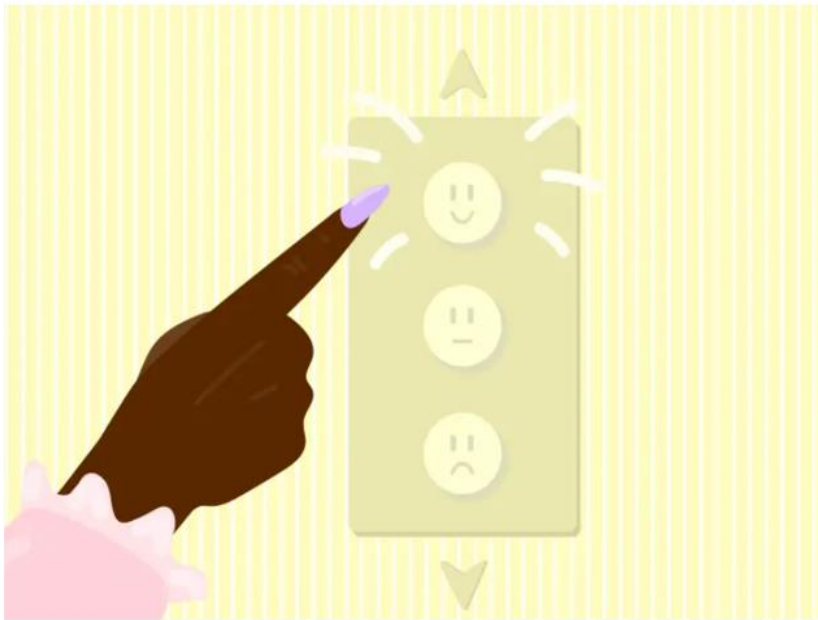


Provides telemedicine capabilities



Allows safe distance auscultation

Meeting the Diverse Needs and Preferences of Customers



Physicians

PAs & NPs

Nurses

EMTs & First-
responders

Home health
providers



Case Study--Detection and Severity Classification of Aortic Valve Stenosis



V. Case Study--Detection and Severity Classification of Aortic Valve Stenosis

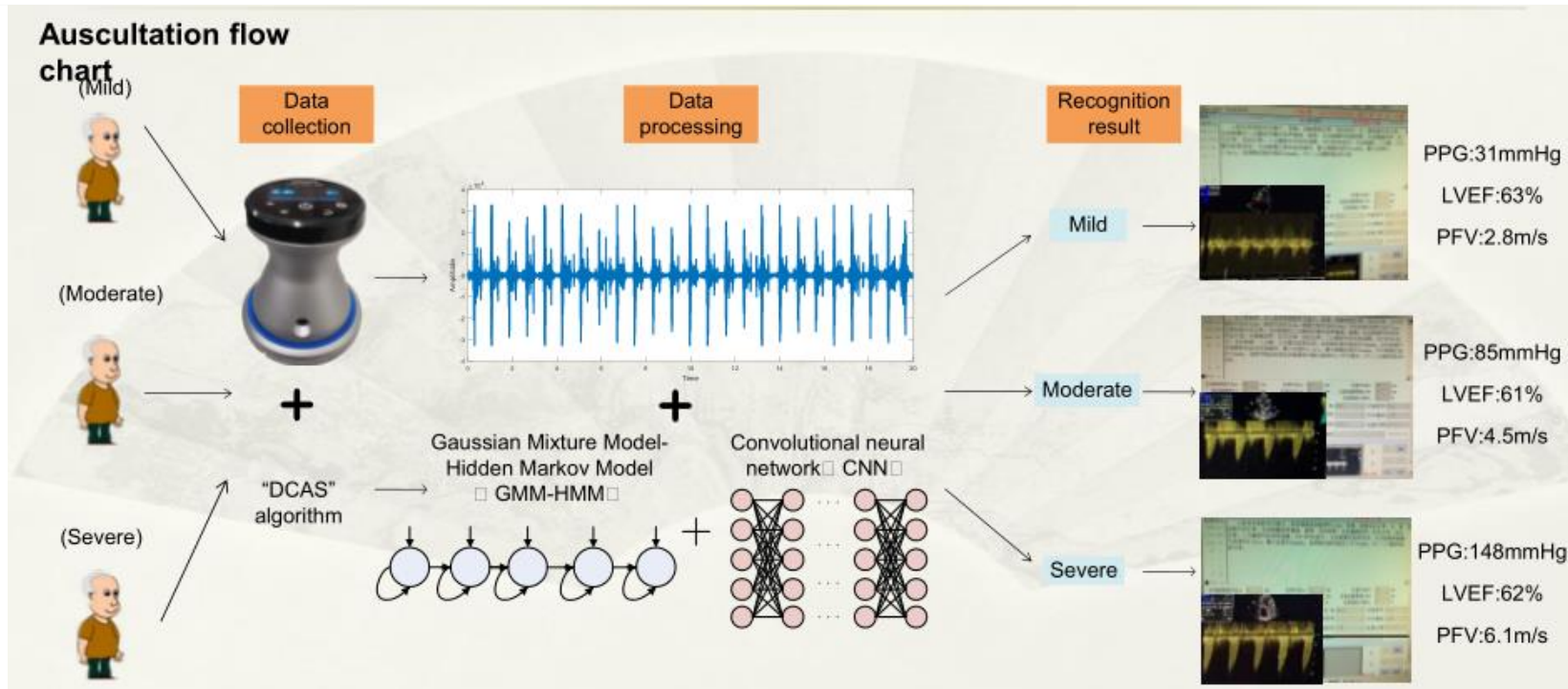


Participated in the intelligent screening program for structural heart disease at the ICI 2019 International Congress in Israel



Highly recognized by clinical experts after making a report

V. Case Study--Detection and Severity Classification of Aortic Valve Stenosis



With an AI algorithm for identifying aortic valve stenosis heart sounds and classifying disease severity, Smartho-D2 can aid early diagnosis and treatment, improving patient outcomes.



Part VI



What did our customer say about SmartHo-D2



VI. What did our customer say about Smartho-D2 ?



Mintti Heartbook and Mintti Isteso are amazing products almost every healthcare provider should put to use. Let me tell you how exciting is working with Minttihealth devices, they work very well, the protocol is very well written, the signal is very stable. We couldn't have imagined how comfortable the devices are. Definitely recommendable and reliable.

University of TOBB ETÜ, Medical Faculty

Prof. Dr med. Tayfun Aybek

Head of Cardiovascular Surgery Department


TOBB ETÜ HASTANESİ
Prof. Dr. Tayfun AYBEK
Dış Tanı ve Tedavi
Kalp ve Damar Cerrahisi Uzmanı



ROTHER GmbH . Fileitzen 11 . DE29389 Bad Bodenteich

Vorgang 131529
Datum 13.01.2020
Bearbeiter Martin Rother
Ihre Nachricht
Telefon 05824-985-377
Fax 05824-985-378
martin.rother@rother-online.de

VAT DE 172 891 947

Recommendation

Minttihealth device does what it promises with extreme simplicity and practicality, great design, the device is compact and easy to apply and use. Minttihealth team is also very easy to deal with and very accommodating, such friendly, fast and professional service, a rare quality these days.



Martin Rother
CEO

What did our customers say about Smartho-D2?



Minttihealth Awards



Minttihealth Awards

CARDIOLOGY 2.0 **CONTENT**

**IMPACT AWARD
CARDIAC MONITORING
WINNER 2020**

*Leading Companies Changing the
Frontier of Cardiac Monitoring*

CARDIOLOGY 2.0

minttihealth
OMRON
VitalConnect
MediLynx
CardioDiagnostics
AliveCor
nuubo
cardiogram
QT Medical
VoCare
WITHINGS
MediLynx
Arrhythmia Diagnostics™
CardioDiagnostics
AliveCor
CARDIAC INSIGHT
BioTelemetry
Cardiologs
VIVALNK
CardioSecur
MYANT
Heartin

Minttihealth Awards



Part VII



Who Are We ?

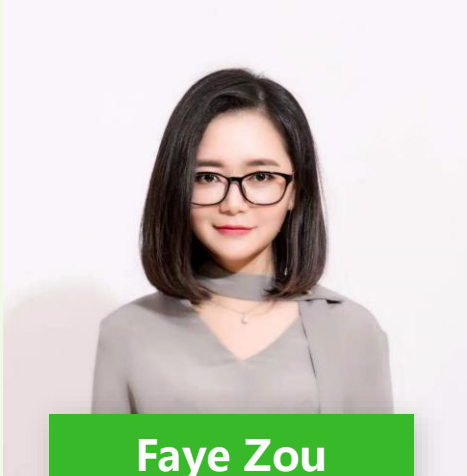


05 Who are we?

Minttihealth is proud of its excellent team. Most of whom are scientists from the Chinese Academy of Sciences, and are leaders in their respected fields (such as sensors, acoustic signal processing, electro-physiological signal processing, intelligent network platform construction and algorithm). Some comes from intelligent electronic products design and manufacturing industries, and are able to turn blueprints into reality. While others are from top medical equipment companies in the world, who have a deep understanding of the market.

Mintti Health's mission is to find new ways and means. Starting with the hardware/software technology, via further optimization of disease management and auxiliary medical practice, we focus on big data analysis and AI applications in healthcare industry, to help everyone with access to advanced and efficient health-care networks and medical services.

VII. Who Are We ?



Faye Zou

(CEO/Co-founder) Having served as the Secretary-General of the Association of International E-Business in Nanchang, China, and as an Alibaba Star Lecturer, she has dedicated over a decade of her career to the field of international e-business in the medical industry.



CAI SHENGSHENG

(Co-founder) He holds a Master of Engineering degree from Zhejiang University/UCLA, which has equipped him with the skills needed to develop an AI-assisted stethoscope and a comprehensive APP+Cloud service system for cardiopulmonary auscultation.



SUN LEQUN

(Co-Founder) With more than 30 years of experience in international business in the medical industry, he has helped the team turn concepts into successful products and accomplish product objectives in target markets with global marketing strategies.



TAO RUOJIE

(Co-Founder) Possessing a doctorate degree from CAS Shanghai Institute of Microsystem and more than a decade of research and development experience in the area of artificial intelligence-enhanced electrocardiography, he brings a wealth of expertise to the team.



If you have any questions about Smartho-D2, or want to schedule a demo

Please contact :
+86-791-85230171,
fay@minttihealth.com,
<http://minttihealth.com/>