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The U.S. Department of Homeland Security (DHS) established the System Assessment and Validation for Emergency Responders (SAVER) program to inform emergency responder equipment selection and procurement decisions.

Under the Science and Technology Directorate, the National Urban Security Technology Laboratory (NUSTL) manages the SAVER program, which – with the participation of emergency responders – performs objective operational assessments of commercially available equipment.

SAVER publications provide information about equipment that falls under the DHS Authorized Equipment List (AEL) categories and focus on two questions for the responder community: "What equipment is available?" and "How does it perform?"

To explore SAVER online visit www.dhs.gov/science-and-technology/saver.

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Science and Technology

SAVER TechNote

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SMART STETHOSCOPES

Smart stethoscopes are a medical technology designed to augment the precision, efficacy and accessibility of healthcare diagnostics. Integrating sensors, digital signal processing (DSP), wireless connectivity, software algorithms and artificial intelligence (AI), smart stethoscopes offer enhanced capabilities to healthcare providers (HCPs). Key features include digital audio sensors, pulse sensors, as well as mobile application and compatibility. This equipment falls under the AEL reference number 09ME-03-STET titled "Stethoscope."

Overview

Smart stethoscopes merge technological innovation with traditional auscultation capabilities. Smart stethoscopes operate by using high-fidelity sensors to capture cardiac and pulmonary sounds. This data undergoes digitization and subsequent processing through onboard DSP algorithms, which filter out ambient noise and enhance clarity. Leveraging software algorithms, notably those driven by AI, these stethoscopes analyze the processed data to detect irregularities that may suggest various cardiac and respiratory conditions. Real-time diagnostic insights are then presented via companion mobile applications or dedicated user interfaces, giving healthcare providers actionable information for prompt intervention. [1]

Figure 1. Electronic Smart Stethoscope
Image credit: Creative Commons, Wikipedia

While these devices are commonly used in hospitals, they are also increasingly marketed for emergency medical responders to use in the field. Audio amplification and noise cancellation features of smart stethoscopes are particularly beneficial in the prehospital setting because they account for increased ambient noise. However, their higher costs compared to analog stethoscopes and concerns about durability in the field may deter adoption.

Smart Stethoscopes Capability Highlights

Smart stethoscopes have digital features to capture and analyze cardiac and respiratory sounds accurately. Their real-time feedback can help HCPs quickly detect medical irregularities. These stethoscopes can also integrate with telemedicine platforms for remote consultations. Some models offer record and playback capability and wireless connectivity for data transmission. [2]

Amplification

An amplified smart stethoscope enhances the sounds it captures. Whereas traditional stethoscopes rely solely on the acoustic properties of tubing and the chest piece to transmit sound from the patient's body to the listener's ears, an amplified smart stethoscope incorporates electronic components to amplify and clarify the sounds, making them easier to hear and interpret.

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Capture and Record Audio

Smart stethoscopes capture audio using digital sensors and DSP algorithms to convert analog signals into digital data. This digitized audio is stored internally or transmitted wirelessly to companion devices for storage and analysis. Some models offer playback for reviewing recorded audio clips.

Noise Cancellation

Smart stethoscopes use noise cancellation technology to filter out unwanted background noise and enhance the clarity of auscultated sounds. This feature allows healthcare providers to focus on the desired sounds, such as heart sounds or lung sounds, without interference from ambient noise.

Use of Artificial Intelligence

Smart stethoscopes are equipped with AI capable of differentiating types of auscultated sound and detecting anomalies in sound patterns, which assists HCPs by flagging recognized abnormalities for further investigation. Because it is continuously learning from data acquired from each patient encounter, the AI enhances its diagnostic accuracy over time and can aid HCPs in making more accurate diagnoses and treatment decisions. [3]

Cybersecurity Considerations

Smart stethoscopes have built-in wireless technology for information sharing but do not have proper encryption or access controls, which poses a risk of compromising protected patient information. Patient data should be encrypted, access to that data should be carefully controlled and limited to essential personnel. See the FBI Criminal Justice Information Services Security Policy [4] for more information on implementing cybersecurity controls.

Relevant Standards and Regulations

Smart stethoscopes may need to comply with standards that address device performance, electromagnetic compatibility and AI algorithms. ANSI/CTA-2090, *The Use of Artificial Intelligence in Health Care: Trustworthiness* [5] [6] defines requirements for AI solutions used in health care and impacts on users.

The United States Food and Drug Administration (FDA) regulates medical devices sold in the United States. FDA-cleared stethoscopes are listed on its Premarket Notification Database [7], with the FDA product code "DQD." Additionally, smart stethoscopes that store and transmit health information are subject to the Health Insurance Portability and Accountability Act (HIPAA) regulations in the United States to ensure patient privacy, secure data transmission and data access controls.

References

[1] National Heart, Lung, and Blood Institute (National Institutes of Health), "NHLBI SBIR-supported company gives stethoscope a "smart" makeover," 2021. [Online]. www.nhlbi.nih.gov/sbir-success-stories/nhlbi-sbir-supported-company-gives-stethoscope-smart-makeover.

[2] Digital Health Central, "What are the Pros and Cons of Digital Stethoscopes," 18 March 2021. [Online]. https://digitalhealthcentral.com/pros-and-cons-of-digital-stethoscopes.

[3] M. Elhilali and J. E. West, "The Stethoscope Gets Smart," *IEEE Spectrum,* vol. 56, no. 2, pp. 36-41, February 2019.

[4] FBI.gov, "Criminal Justice Information Services (CJIS) Security Policy," 2020. [Online]. www.fbi.gov/file-repository/cjis_security_policy_v5-9_20200601.pdf/view.

[5] ANSI.org, "CTA Launches New Trustworthiness Standard for AI in Health Care," 2021. [Online]. https://www.cta.tech/Resources/Newsroom/Media-Releases/2021/February/CTA-Launches-New-Trustworthiness-Standard-for-AI-i.

[6] American National Standards Institute/Consumer Technology Association, "ANSI/CTA 2090, The Use of Artificial Intelligence in Healthcare: Trustworthiness," February 2021. [Online]. shop.cta.tech/collections/standards/products/the-use-of-artificial-intelligence-in-healthcare-trustworthiness-cta-2090.

[7] U.S. Food and Drug Administration (FDA), "510(k) Premarket Notification," [Online]. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.