

Vital Sign Measurements using Maxim Integrated Mobile Phone-embedded BioSensor are Accurate and Comparable to Standard-of-Care Monitor in Clinical Settings

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Abstract

- It is essential to develop a portable and easy-to-use device to provide comprehensive and accurate outpatient vital sign monitoring
- MaximFAST developed by Maxim Integrated is capable of taking accurate vital sign measurements, based on internal company testing
- MaximFAST was tested in various clinical settings as a collaboration with the University of California, San Diego (UCSD)
- The pilot study showed that vital sign measurements taken by MaximFAST are accurate and comparable

Introduction

Mobile technology has become an indispensable part of daily life for many people. Most people already own smartphones that contain sensors with potentially hospital grade measurement capabilities. Maxim Integrated have developed MaximFAST that are currently install in phone models that are capable of sensitive, accurate, and reproducible heart rate (HR) and blood oxygenation (SpO₂) measurements, by analyzing photoplethysmography (PPG), which would allow for monitoring of patients with chronic diseases in home settings. Furthermore, it would also have widespread application in delivering better and higher quality care in resources-poor/ -limited areas of the world. While the biosensor has been tested experimentally against FDA approved vital sign monitor that are currently in clinical use, no patient testing has taken place thus far.

This pilot study, in collaboration with UCSD and Specialist in Global Health, assessed the use of MaximFAST in the outpatient clinic and emergency department against Welch-Allyn vital sign monitor, using either Masimo or Nellcor oximetry, which are considered as the Standard-of-Care monitors currently in use at UCSD and other healthcare systems. Findings of this pilot study demonstrated the accuracy and usability of MaximFAST and also provided foundation for future larger clinical studies, but more importantly, the importance of and mutually beneficial collaborative relationship between industry and academic medical centers in the continued development of this new technology.

Study Objectives

- MaximFAST can provide accurate HR and SpO₂ measurements that are comparable to that of commercially available vital sign machines.
- Collaborative studies between industry and academic medical centers are mutually rewarding and beneficial.

Study Design

This is a non-randomized, one-time measurement of HR and SpO₂ of patients who present to the emergency department or outpatient clinics at UCSD.

After providing consent, each participant was seated with both arms at the sides of his/her body and the forearms resting on their legs. Participant was instructed on how to place the index finger against the sensor on the back of MaximFAST, as shown below,



Four sets of measurements were taken, as described below. A stable PPG waveform must be obtained for at least 10 seconds before the measurements are considered as valid and recorded.

- Welch-Allyn Spot VS monitors, unit 1 (with Masimo oximetry) on left index finger and unit 2 (with Nellcor oximetry) on right index finger;
- MaximFAST on both index fingers;
- MaximFAST on left index finger and Welch-Allyn Spot VS monitor on right index finger;
- Welch-Allyn Spot VS monitor on left index finger and MaximFAST on right index finger.

	Left Index Finger	Right Index Finger
Measurement 1	Welch-Allyn unit 1	Welch-Allyn unit 2
Measurement 2	MaximFAST unit 1	MaximFAST unit 2
Measurement 3	MaximFAST unit 2	Welch-Allyn unit 1
Measurement 4	Welch-Allyn unit 2	MaximFAST unit 1

Data Analysis

For Maxim engineers to fill in

Results

During the study, it was noted that skin conditions, hand cleanliness, excessive motions from tremors, or underlying cardiac arrhythmia were all noted to affect MaximFAST's ability to acquire stable PPG.

Table 1 – Performance comparison of MaximFAST and Welch-Allyn units

Root mean square error (RMSE) of measurements with respect to reference. Success Rate is the percentage of measurements that are inside an interval whose center point is the corresponding reference measurement; for HR, the interval is $\pm 5\%$ deviation and for SpO₂, the interval is $\pm 3\%$ deviation.

	Left Index Finger	Right Index Finger	HRM		SpO ₂	
			RMS Error	Success Rate	RMS Error	Success Rate
1	Welch-Allyn unit 1 (Masimo)	Welch-Allyn unit 2 (Nellcor)	2.46 BPM	89.90%	1.14%	97.60%
2	Maxim biosensor unit 1	Maxim biosensor unit 2	4.47 BPM	69.50%	1.35%	93.70%
3	Maxim biosensor unit 2	Welch-Allyn unit 1 (Masimo)	2.86 BPM	93.90%	1.90%	82.20%
4	Welch-Allyn unit 2 (Nellcor)	Maxim biosensor unit 1	4.81 BPM	90.90%	1.40%	93.50%

Figure 1 – Error of MaximFAST SpO₂ readings are comparable to SpO₂ readings by Welch Allyn with Masimo oximetry.

Error of MaximFAST readings were calculated as RMSE of differences of MaximFAST and Masimo measurements while holding Masimo as a constant. Published deviation for Masimo is $\leq \pm 2\%$ with maximum absolute deviation of 5%, therefore, MaximFAST's accuracy is 3% with a positive bias of 0.85 BPM.

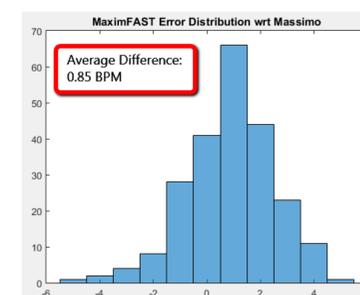
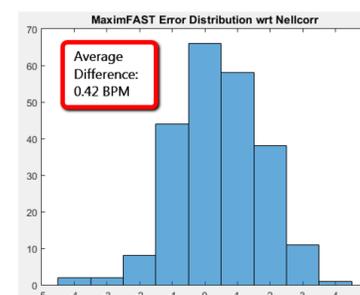


Figure 2 – Error of MaximFAST SpO₂ readings are comparable to SpO₂ readings by Welch Allyn with Nellcor oximetry.

Error of MaximFAST readings were calculated as RMSE of differences of MaximFAST and Nellcor measurements while holding Nellcor as a constant. Published deviation for Nellcor is $\leq \pm 3\%$ and maximum absolute deviation is 5%, therefore, MaximFAST's accuracy is 2% with a positive bias of 0.42 BPM.



Conclusion

- MaximFAST shows good performance in SpO₂ measurement as its deviation is in the same limits of Massimo vs. Nellcor deviation.
- The analyses above show that MaximFAST's accuracy for SpO₂ measurement can be estimated as less than $\pm 3\%$.
- MaximFAST can be used in a variety of clinical settings and in patients with various underlying chronic illness.
- Collaborative study such as this provide development team potential challenges and issues that may encounter with end users.

Discussion/ Future Directions

- MaximFAST potentially have a wide range of possible applications, such as
 - Outpatient management of patient with chronic conditions such as asthma, COPD, and congestive heart failure (CHF), or post-transplantation, allowing for early intervention and avoiding unnecessary hospitalization;
 - post ED or hospital discharge follow-up;
 - Reduction of morbidity, mortality and costs associated with unnecessary hospital admissions/ readmissions
 - Provide much needed clinical tool in many resource-poor/-limited areas of the world

- Goal is to develop a device that is mobile, wireless, user-friendly, and capable of providing the entire suite of vital sign measurements (heart rate, SpO₂, respiratory rate, and blood pressure).

- Current and future collaborations between industry and academic medical centers will be essential for development of target end-user populations, potentially unexpected user issues, and product refinement

Acknowledgement

This study is supported by an investigator-initiated grant from Maxim Integrated.

