International Journal of Health Sciences and Research
Vol.13; Issue: 8; August 2023
Website: www.ijhsr.org
Original Research Article *ISSN: 2249-9571*

Validation of Artificial Intelligence Based Real Time Multi-Vitals Remote Monitoring Solution - A Clinical Study

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DOI: https://doi.org/10.52403/ijhsr.20230829

ABSTRACT

Background: Recently the combination of telehealth with remote patient monitoring has paved the way for enhanced and augmented health-care services. Its benefits include obtaining efficient, cost and time saving data and minimizing error factors by remote monitoring methods. The validation of multi-vital artificial intelligence-based software (Vigo platform) was conducted to correlate reproducibility of real time vital recording solution.
Methods: IEC approval and informed consents were obtained. Seventeen healthy participants were deployed on the multi-vital monitoring (MVM) solution in a controlled environment and continued for 24 hours. The vitals were measured by the standard methods periodically at intervals of 0, 2, 4, 6, 8, 10, 12 and 24 hours. ECG was measured at 0, 4, 8, 12 and 24 hours.
Results: A total of 20 healthy volunteers were screened out of which seventeen volunteers participated as three volunteers withdrew consent. All the seventeen volunteers were males of mean age 21±3years and mean BMI 22.9±1.7Kg/m^2. Vital parameters included Heart rate, Pulse rate, Respiratory rate, Temperature, Systolic blood pressure, Diastolic blood pressure and ECG Measures including P-wave, PR- interval, QRS-complex, RR-interval, QT-interval, ST-Segment, T-wave were stronglyand significantly correlated internally ($p>0.01$) and 100% correlated externally ($p>0.01$).
Conclusion: It was found that all the vital parameters and ECG measures were strongly matched and significantly correlated internally and externally. This work supports remote monitoring technology as part of remote patient care and decentralized research.Thus, software solution Vigo platform that was developed in this work may become a route to patients' safety.

Keywords: Remote monitoring, multi-vitals, telehealth, decentralized trials, artificial intelligence, Wearable wireless biosensors.

INTRODUCTION

Vitals are essential biological signals that reflect ongoing physio-pathological condition of the body. Temperature, heart rate (HR), pulse rate (PR), respiratory rate (RR), oxygen saturation (SpO2) and blood pressure (BP) are the cardinal vital signs that form the paramount basis for any diagnosis (1). Vital monitoring in patients has developed from manual evaluation methods to utilization of automatic devices like electronic blood pressure instruments and glucometer kits. However, the vitals monitoring is a manpower intensive activity and even the advanced countries with high grade medical infrastructure are also facing

the problem in optimizing the use of infrastructure to improve the better patient care (2). The periodicity, accuracy, vital chartformats, patient load and nurse attitude towards patient care are determined as most important parameters in providing better health care.

The concept of mobile health was introduced by Robert Istepanian in the late 1960's. Since then, Tele health, Remote patient monitoring's were introduced by utilizing mobile communication network technologies and subsequently Artificial Intelligence (AI) and Machine Learning (ML) programs have been merged with health care (3,4). The integration of AI and ML algorithms in cloud services is making every effort for the continuous mobile, remote health care services. This leverages the clinician to access de-compensated patients' status at each moment and make timely decisions on the treatment process with seamless data (5).

Covid 19 has intricated the use of remote patient monitoring and manifested new pathways in treatment processes. Remote patient monitoring has gained a lot of confidence worldwide and have significant advantages over traditional treatment procedures during the pandemic era (6,7). The RPM equipped with advanced software algorithms such as Internet of Things (IoT) and AI would be more beneficial for the real time assessment of the patient condition and to decide the treatment procedure based on the patient health data (8). Any technology which will serve with continuous health data analysis, early warning score mechanism with accuracy, consistency, patient and healthcare provider adoptability would be appreciated (9, 10).

The present validation study was planned to evaluate AI based Remote Multi Vital Monitoring (MVM) solutions together with lead-2 electrocardiogram (ECG) in healthy human volunteers. The MVM vitals recordings and ECG measures were correlated with standard techniques across multiple software interfaces internally as well as externally.

MATERIALS & METHODS

The MVM system comes with smart, portable, rechargeable, and reusable devices such as Chest Biosensor, Pulse Oximeter, Armpit BP cuff and Axillary Temperature Biosensors which measures multiple vitals in real time using software. Vigo a Healthcare company has devised a framework that connects biosensor devices to the Vigo-Engine software for data analysis. Devices include a pulse oximeter for PR and SpO2, a single lead Electrocardiogram (ECG) biosensor for Lead-2 ECG, HR and RR, a temperature biosensor, and an ambulatory blood pressure monitor for BP. The MVM Model consists of three software components: a central monitoring system (CMS) for device integration, a Bedside monitor (BSM) for patient Registration and to capture the data, a nursing portal, and app for RPM (9,10). The advantage of integrating the sensor with the software is that it allows for continuous and remote monitoring. A schematic picture of vigo vitals is depicted in Figure 1 below.

Other Features of the Technology: The measuring times for BP can be customized. The graphs are automatically plotted, and the data is available in real time to the nurse and doctor or investigators and research personnel via a dedicated portal and App respectively. Historic vitals graphs would be more beneficial in assessing the patient's or participant's health and well-being. The goal would be served by using real-time data measurements, evaluation, and early warning mechanisms.

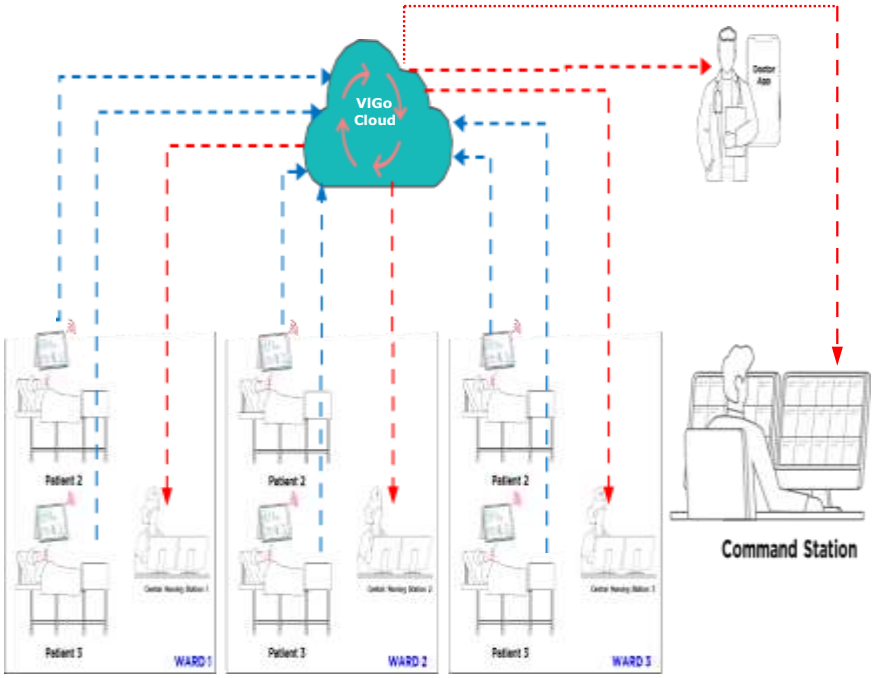

Fig 1: The schematic diagram -Vigo Vitals

This was a prospective validation study conducted in seventeen healthy human volunteers. The participants included were healthy adult males aged between 18-45 years, with basal metabolic index (BMI) 18.5- 25 kg/m2 of normal health as determined by medical history and physical examination and lab values (Complete blood picture, renal function test, liver function test, complete urine examination, fasting blood sugar, serum electrolytes, viral markers- HIV, HBsAg, HCV, chest X-ray and ECG) within normal limits or considered insignificant by physician or investigator and agreed to comply with all study procedures. Exclusion criteria were history of contact dermatitis or hypersensitivity to patch materials. Regular smoker and has difficulty abstaining from smoking for 48 hours before study and clinically significant physical disabilities. Participants who were positive for COVID-19 RTPCR test 24 hours prior to the study were disqualified from participation.

The study was approved by the institutional ethics committee (EC No: ESICMC/SNR/IEC-F424/02-2022) and registered with a clinical trial registry (CTRI/2022/04/041712) prior to the study. The eligible subjects were explained about the study procedure and written informed consent for screening and participation were obtained separately from all the subjects. The standard monitoring methods selected was manual in case off HR, PR and RR; glass thermometer for temperature, mercury sphygmomanometer for BP, and lead 2 recorded from 12 lead ECG machine for ECG at precisely matched time points.

Fig 2: Monitoring the Participant with Wireless Remote Multivital Monitoring Technology

All the participants were in-housed at the study site for 36 hours. They were instructed to report at the study site 12 hours before the initiation of study. Subjects were

deployed on the MVM solution in a controlled environment and continued for 24 hours. The vitals and ECG were measured by the standard methods periodically at intervals of 0, 2, 4, 6, 8, 10, 12 and 24 hour respectively. ECG was recorded on 12 lead ECG machine at 0, 4, 8, 12, 24 hours respectively. Breakfast, lunch and dinner were provided after 2, 6, and 10-hour readings respectively. Any adverse events reported by the participants were recorded during the total in-house period. The MVM monitoring was disconnected after taking the last reading at 24 hours and participants were discharged from the study site after confirming all the vitals were stable.

The Vigo Platform Working Model

Real time vitals monitoring (see Figure 2) using wireless biosensors integrated SaaS patients monitoring platform (see Figure 3) which is called Scaena on which multiple services were built. Scaena is a classic Io(M)T (Internet of Medical Things) platform that enables multiple end points from Android and iOS eco system. These end points connect to various FDA approved biosensors to collect patient vitals continuously. The collected vitals are streamed continuously to the Vigo Engine at the backend running on Amazon Web Services (AWS) cloud.

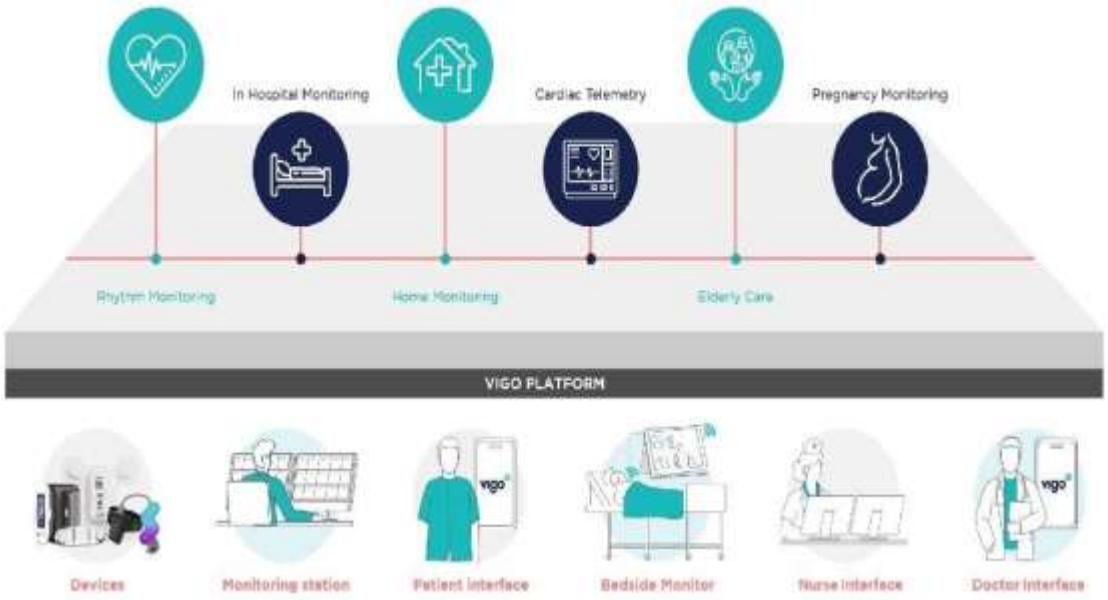

Fig 3: Vigo SaaS Platform: with multiple solutions

Vigo Inference engine interprets the vitals and makes them available for care providers to make decisions such as:

- Present vitals like HR, RR, SPO2, PR, Axillary Temperature, BP, and ECG as it is to the care givers.
- Present interpretations like early warning scores (EWS) to care givers by utilizing various algorithms.
- User internally built or FDA approved third party AI engines for data interpretations.

Platform is designed to be device agnostic which means that the platform's core inference engine does not depend on the specific device or a vital is collected. Perhaps it enables to open for multiple bio-sensors available in the market for integration.

Fig 4: The Monitoring Software Packages

Internal validation was defined as the correlation of the values measured by standard methods and those reflected by digital equipment integrated in the SaaS platform on the tab at bed site. The correlation of the values on the tab with those on the remote screen at nursing station, command center and doctor app were described as external validation.

STATISTICAL ANALYSIS

Demographic data was expressed as mean ± SD. The data distribution was found to be non-normal and Spearman's correlation analysis was performed for the assessment of external and internal validity of MVM solution. The power of the study 90% and confidence interval more than 95% was considered as significance. All the statistical analysis was performed using the IBM SPSS version 20 software developed by Norman H. Me in 2011 in Chicago.

RESULT

In this study a total of twenty healthy volunteers were screened out of which three volunteers failed to report at study site. Finally, seventeen subjects enrolled in the study. All the seventeen volunteers were male of mean age 21± 3 years and mean BMI 22.9± 1.7.

Table-1 Demographic details of the Participants

Variables	Mean values
Subjects	17
Age (years)	21±3
Height (cm)	171±7
Weight (kg)	68±6
BMI (kg/ m^2)	22.9±1.7

All the participants in this study showed strong correlation between the test and conventional methods for the vital parameters at all time points. The findings at 0^{th}, 12^{th} and 24^{th} hour time points are presented in this study. Table 2 presents the spearman's rank correlation coefficients and the corresponding p values for the vital parameters i.e, BP, HR, PR, RR, temperature and SpO_2. Spearman's rank correlation coefficients and p values are tabulated in Table 3.

Correlation Coefficients for Heart Rate between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for heart rate between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.98 with P value of 0.001, ρ1

(rho) of 0.93 with P value of 0.001and ρ1 (rho) of 0.97 with P value of 0.001 respectively.

Correlation Coefficients for Pulse Rate between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for pulse rate between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.98 with P value of 0.001, ρ1 (rho) of 0.93 with P value of 0.001and ρ1 (rho) of 0.97 with P value of 0.001 respectively.

Correlation Coefficients for Respiratory Rate between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for respiratory rate between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.90 with P value of 0.001, ρ1 (rho) of 0.80 with P value of 0.001and ρ1 (rho) of 0.77 with P value of 0.001 respectively.

Correlation Coefficients for Temperature between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for temperature between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.89 with P value of 0.001, ρ1 (rho) of 0.93 with P value of 0.001and ρ1 (rho) of 0.53 with P value of 0.05 respectively.

Correlation Coefficients for Blood Pressure between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for systolic blood pressure between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.72 with P value of 0.002, ρ1 (rho) of 0.94 with P value of 0.001and ρ1 (rho) of 0.95 with P value of 0.05 respectively.

The Spearman's correlation coefficient on diastolic blood pressure between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.88 with P value of 0.001, ρ1 (rho) of 0.87 with P value of 0.001and ρ1 (rho) of 0.68 with P value of 0.005 respectively.

Correlation Coefficients for Oxygen saturation levels between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for SpO2 between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 1.00 with P value of 0.001, ρ1 (rho) of 1.00 with P value of 0.001 and ρ1 (rho) of 0.94 with P value of 0.05 respectively.

Correlation Coefficients for P-wave in ECG between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for P-wave in ECG between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.60 with P value of 0.02, ρ1 (rho) of 0.65 with P value of 0.01 and ρ1 (rho) of 0.66 with P value of 0.005 respectively.

Correlation Coefficients for PR-interval in ECG between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for PR-interval in ECG between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.53 with P value of 0.05, ρ1 (rho) of 0.49 with P value of 0.05 and ρ1 (rho) of 0.62 with P value of 0.01 respectively.

Correlation Coefficients for QRS-Complex in ECG between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for QRS-complex in ECG between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.65 with P value of 0.01, ρ1 (rho) of 0.60 with P value of 0.02 and ρ1 (rho) of 0.66 with P value of 0.005 respectively.

Correlation Coefficients for RR-interval in ECG between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for RR-interval in ECG between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.54 with P value of 0.05, ρ1 (rho) of 0.59 with P value of 0.02 and ρ1 (rho) of 0.64 with P value of 0.005 respectively.

Correlation Coefficients for QT-interval in ECG between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for QT-interval in ECG between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.68 with P value of 0.005, ρ1 (rho) of 0.66 with P value of 0.005 and ρ1 (rho) of 0.67 with P value of 0.005 respectively.

Correlation Coefficients for ST-segment in ECG between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for P-wave in ECG between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.70 with P value of 0.002, ρ1 (rho) of 0.72 with P value of 0.002 and ρ1 (rho) of 0.75 with P value of 0.001 respectively.

Correlation Coefficients for T-wave in ECG between standard method (Control) and MVM solution (Test): The Spearman's correlation coefficients for P-wave in ECG between control vs. test methods at 0th, 12th and 24th hour time points were reported as ρ1 (rho) of 0.68 with P value of 0.005, ρ1 (rho) of 0.60 with P value of 0.02 and ρ1 (rho) of 0.72 with P value of 0.002 respectively.

Table 2: Spearman's Correlation Coefficients for Vital Parameters

Parameter	0^h Hour		12^{th} Hour		24^{th} Hour	
	ρ (rho) (Control vs Test)	P-value	ρ (rho) (Control vs Test)	P-value	ρ (rho) (Control vs Test)	P-value
Pulse rate	0.98	0.001	0.93	0.001	0.97	0.001
Respiratory rate	0.90	0.001	0.80	0.001	0.77	0.001
Temperature	0.89	0.001	0.93	0.001	0.53	0.05
Heart rate	0.98	0.001	0.93	0.001	0.97	0.001
Systolic BP	0.72	0.002	0.94	0.001	0.95	0.001
Diastolic BP	0.88	0.001	0.87	0.001	0.68	0.005
SpO_2	1.00	0.001	1.00	0.001	0.94	0.001
ρ (rho) - Spearmen correlation coefficient						

Table 3: Spearman's Correlation Coefficients for ECG Measurements

Parameter	0^h Hour		12^{th} Hour		24^{th} Hour	
	ρ (rho) (Control vs Test)	P-value	ρ (rho) (Control vs Test)	P-value	ρ (rho) (Control vs Test)	P-value
P-wave	0.60	0.02	0.65	0.01	0.66	0.005
PR-interval	0.53	0.05	0.49	0.05	0.62	0.01
QRS-complex	0.65	0.01	0.60	0.02	0.66	0.005
RR-interval	0.54	0.05	0.59	0.02	0.64	0.005
QT-interval	0.68	0.005	0.66	0.005	0.67	0.005
ST-segment	0.70	0.002	0.72	0.002	0.75	0.001
T-wave	0.68	0.005	0.60	0.02	0.72	0.002
ρ (rho) - Spearmen correlation coefficient						

DISCUSSION

The monitoring of the vitals depends on the patient condition, comorbid conditions, medical, surgical history and drugs used etc (11,12). The periodicity of monitoring depends on the specialty such as ward or ICU. However, in general hospital practice it is intermittent in low acuity patient monitoring like in wards and continuous or frequent in high dependency units like ICUs.

The Vigo Vitals solution tested on 17 healthy volunteers and validated against the standard CE Marked devices used in clinical practice. The statistical results are calculated using spearman's correlation. During 24 hours of monitoring period the vitals were recorded for every four hours such as 0^{th}

hour, 4th hour, 12th hour and 24th hour respectively. The statistical values as per the time stamps for Heart Rate 0.98, 0.01, 0.01, 0.01, pulse rate 0.98, 0.01, 0.01, 0.01, respiratory rate 0.88, 0.01, 0.01, 0.01, temperature 0.74, 0.01, 0.01, 0.01 SBP 0.92, 0.01, 0.01, 0.01 and DBP 0.85, 0.01, 0.01, 0.01 respectively.

The ECG Wave form of vitals solution was compared with 12 Lead holters lead-2 as per the three different time stamps (0th hour, 12th hour and 24th hour) and statistical P-values are determined. The P-values for P-Wave 0.02, 0.01 and 0.005, PR Interval 0.05, 0.05 and 0.01, QRS Complex 0.01, 0.02 and 0.005, RR- Interval 0.05, 0.02 and 0.005, QT Interval 0.005, 0.005 and 0.005, ST-Segment 0.002, 0.002, 0.001, and T-Wave 0.005, 0.02 and 0.001 respectively 0th hour, 12th hour and 24th hour.

Live ECG and EWS Scoring: The Live ECG helps the physician to forecast the heart related abnormalities of the patient in line with other parameters. The real time ECG- Analysis and representation of the ECG-strips with events is one of the unique assets in this solution compared to the existing monitoring technologies (3). The Early Warning Scoring system helps in identifying the deterioration of the patient vitals and the same is available at different interfaces such as Bed side monitor, Nursing Station and Doctor Mobile Application. Multiple interfaces assure the ease of data availability to the physician and monitoring nurse which will be very helpful in alerting the doctor (13,14).

Communication: The Bluetooth communication of FDA-Approved devices with the Bedside Monitor helps in guaranteed data flow into the SaaS platform. The system works on mobile network and WiFi both by which the data can be sent to cloud easily (15). India has growing significantly in its telecommunication network even to the most rural areas. All the devices are having inbuild memory for a period of 24 hours that facilitates to retrieve the data after the monitoring period even in case any internet issues.

Monitoring: The nursing station which is a primary patient monitoring station has multiple features which are advantageous to nurses. The Historical vital signs act as evidence for the patient continuous vital signs performance over a period (16). The vital graphs information can be useful to determine whether the patient stay in the facility or even to decide the patient treatment plan. The customization of local alert settings provides freedom from false positives. The One-Way text communication between nurse to doctor through nursing station and doctor application negates the delay or miscommunication of the patient health status communication in case of emergencies. The manual errors will be reduced to a minimum through automatic digital data acquisition (17). The physical strain of the nurse will be reduced to a minimum because the nurse need not visit the patient regularly to take vitals. The download and printable reports with automatic patient vital chart graphs reduce the nurse's efforts in documentation and can compile in the case sheets directly.

Digital Literacy and adaptability: The solution is designed in such a way that even a person with minimum knowledge on mobile phone or computers can onboard the patient (18). The user screens on the BSM guide the staff for smooth onboarding. As per the internal validation the adoptability of nurse to the system is10 mins after the initial training.

Acceptancy and cooperation: The remote continuous vitals monitoring of a patient is new concept in India. However, it is gaining more importance in treatment planning. Since these devices are small, portable, and wireless the volunteers accepted the technology and there were no dropouts during the monitoring period 24 hours. The solution has achieved 100% acceptance for

its ambulatory nature during the research and no ADR's reported.

Economics: Multiple Vital parameters measurement data acts as an evidence tool for determining the patient stay in the hospital, hence treatment expenditure can be reduced which is one of the most important Parmenter to consider in Indian health care setup. The devices are reusable and rechargeable, and no CapEx cost will be laid on the hospitals. However, the IoT cloud platform has to run continuously, and AI should analyze the data which contributes the price. A Working model must be derived for full scale implementation of the technology.

False positives: The AI-DNN model Engine works on the principle of relearning method. Based on the number of rejections the system gets trained by itself and becomes a better tool over a period of time. However, DNN-AI engine used for MVM is well trained FDA approved engine with 97.3% accuracy.

Education and Decentralized Trails: The readily available electronic data is very useful for retrospective analysis for research purposes. The physician can use the data to train the budding healthcare professional and doctors or nursing staff in academic settings. The solution becomes a handy tool for decentralized clinical trials and hence boosts the future clinical research activities (19).

CONCLUSION

The proposed Remote patient multivital monitoring technology has proved its efficacy and safety in remote patient monitoring with no adverse drug reactions during the trails on 17 healthy volunteers and with high correlation and statistically significant P Value 0.001 for all the vitals compared to traditional practices. The Vitals solution developed through this research solution which consists of multiple hard assets (Devices) and soft assets (Monitoring interfaces, Analysis Platform could be perfect make for a better Remote patient monitoring technology. High correlations among the vital signs between both the models are encouraging to push the developed and validated solution Vitals into hospital settings.

Limitations

The study was conducted at a single centre in only healthy volunteers. A plan to expand this study at multiple health care centres and involve diseased patients will be our next step of research activity in the near future.

Future Scope of the Device

The Remote Multi vital monitoring system can be integrated to hospital medical record (EMR) software and should be developed for a complete at home care monitoring solution.

Declaration by Authors

Ethical Approval: Approved

Acknowledgement: We would like to thank Dr. Srinivas for extending their support in recruiting the participants and data collection during the study. Authors also express heartfelt thanks to the management of Vigocare Pvt. Ltd. for providing financial assistance throughout the research.

Source of Funding: Vigocare Pvt. Ltd.

Conflict of Interest: The authors declare no conflict of interest.

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How to cite this article: Sowjanya Patibandla, Rajani Adepu, B. Madhuri, A. Ranjith. Validation of artificial intelligence based real time multi-vitals remote monitoring solution - a clinical study. *Int J Health Sci Res.* 2023; 13(8):210-219.
https://doi.org/10.52403/ijhsr.20230829

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