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CLINICAL EVALUATION REPORT

Clinical Evaluation of Remote Patient Monitoring Devices for Post-Cardiac Surgery Patients: A Comparative Analysis of the Omnyk Wearable Ring and FDA-Approved Pulse Oximeter

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ABSTRACT

Introduction: Cardiovascular disease patients often require continuous monitoring post-surgery to detect complications early. The AVIDA ring, a wearable monitoring device, offers potential advantages for remote patient monitoring (RPM) by providing real-time tracking of heart rate (HR) and oxygen saturation (SpO_2).

Methods: In this observational prospective study, 44 post-cardiac surgery patients were monitored using the AVIDA ring and a standard clip-on pulse oximeter to evaluate HR and SpO_2 accuracy. Pearson correlation coefficients were calculated to compare device readings. Outliers in HR, SpO_2, and inter-beat interval (IBI) were also tracked.

Results: Correlation analyses indicated significant positive associations between AVIDA and clip-on device readings, with Pearson correlation coefficients of 0.6845 for HR and 0.6833 for SpO_2. Outliers were more frequent among patients with post-coronary artery bypass graft or valve replacement surgeries and occurred more during the daytime, especially in patients with irregular medication adherence.

Discussion: The AVIDA ring demonstrates reliable monitoring capabilities with potential for RPM in post-cardiac patients. It also demonstrates enhanced capabilities in detecting outliers.

Keywords: Wearable ring, Post cardiac monitoring, Pearson correlation, Remote patient monitoring.

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INTRODUCTION

Cardiovascular diseases (CVD) are the leading cause of death globally, accounting for about 32% of all global deaths.[1] CVD includes conditions like heart disease, hypertension, and stroke, which place a significant burden on health systems, particularly as the population ages. Post-cardiac surgery patients often face a significant burden due to the potential for both short and long-term complications. Post-cardiac events, especially in the first 30 days, come with a high risk of complications, such as arrhythmias, heart failure, and sudden cardiac arrest.[2] Approximately 20% of patients are readmitted within this critical period, with nearly half due to cardiac-related complications.[3] Delays in care, such as a two-hour delay, for instance, can drastically reduce survival rates by 50%, underscoring the necessity of early detection and timely intervention to improve patient outcomes.[4]

Traditional in-person monitoring methods often leave gaps in patient care because they rely on periodic hospital visits rather than continuous data collection. Advanced remote patient monitoring (RPM) technologies, particularly wearables, have therefore become essential for post-cardiac care.[5]particularly for data generation for cutting-edge health

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research, and their demand has risen substantially in recent years. However, there is a shortage of aggregated insights into how wearables have been used in health research.\n\nObjective\nIn this review, we aim to broadly overview and categorize the current research conducted with affordable wearable devices for health research.\n\nMethods\nWe performed a scoping review to understand the use of affordable, consumer-grade wearables for health research from a population health perspective using the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews By 2030, a shortage of 15 to 18 million healthcare professionals is anticipated, especially in rural and underserved areas, further highlighting the need for RPM devices to manage patients effectively.[6] Wearables like the AVIDA device by Omnyk Inc. offer a practical, effective solution, allowing patients to be monitored from home, reducing healthcare facility burdens, and enabling home-based rehabilitation, which has shown benefits such as lowered blood pressure, increased exercise capacity, and reduced infection risk. Omnyk's remote patient management (RPM) solution was introduced to us in July 2019. Based on RPM's capabilities and potential benefits towards improving the outcome of care, the potential of early detection of "symptoms and need for care" for patients, particularly during the first 30 to 60 days after discharge from the hospital. [7]

The AVIDA ring is a state-of-the-art wearable device designed for the continuous monitoring of vital health metrics, including blood oxygen saturation (SpO_2), heart rate (HR), Inter-Beat Interval (IBI), and heart rate variability (HRV). Unlike traditional pulse oximeters, which can be bulky and susceptible to inaccuracies due to movement, poor perfusion, or skin pigmentation, AVIDA is lightweight and comfortable for 24/7 wear, providing high precision in real-world conditions. Through its integration with Omnyk's OmnyTraq mobile app and OmnyManage web platform, AVIDA delivers real-time data and personalized predictive analytics to patients and healthcare providers alike, allowing for more proactive care decisions.

One of AVIDA's core benefits is its real-time monitoring and alert system, which enables early detection of hypoxia, arrhythmias, and other cardiac abnormalities, facilitating timely medical intervention. With the Connected Health Model, AVIDA allows for seamless data sharing between patients and healthcare providers, ensuring proactive interventions when needed. By enabling continuous remote monitoring, AVIDA reduces the need for frequent hospital visits and provides a valuable tool for post-cardiac patients who require ongoing care but prefer the comfort and convenience of home-based recovery. As RPM technology gains traction in healthcare, AVIDA is positioned as a leading solution, addressing patient needs and alleviating healthcare facility pressures in an increasingly strained healthcare landscape.[8]. To evaluate the efficacy of the AVIDA device and ensure its reliability before widespread implementation, this study was conducted with the following objectives among post-operative cardiac patients: The primary objective of the study was to assess the efficacy of the AVIDA device in a controlled in-patient environment by comparing synchronously gathered data on heart rate (HR) and SpO_2 with data obtained from a standard Clip-On device. The secondary objective was to identify abnormal variations (outliers) in HR, SpO_2, and IBI to facilitate the early detection of potential complications and inform personalized interventions.

METHODOLOGY

Study Design and Setting

This prospective observational, comparative study was conducted to evaluate the clinical performance of the AVIDA wearable device. The study's primary and secondary objectives were conducted at two distinguished medical institutions specializing in cardiac care:

Sri Jayadeva Institute of Cardiovascular Sciences and Research (SJICR)

Located in Bengaluru, India, SJICR is a leading center with 1,150 inpatient beds and a robust focus on cardiothoracic surgery and pediatric cardiology. SJICR served as the primary study site, evaluating AVIDA's performance in a controlled inpatient setting.

Institute of Post Graduate Medical Education & Research (IPGMER) and SSKM Hospital

The secondary objective was assessed in IPGMER's Department of Cardiothoracic and Vascular Surgery, providing a broader population with diverse cardiac conditions for evaluating greater insight into the early detection of heart disease.

Study Participants

The study enrolled patients based on inclusion and exclusion criteria designed to align with the primary and secondary objectives.

Primary Objective

Included post-cardiac surgery patients representing a population in a controlled recovery phase.

Secondary Objective

Targeted patients aged 46–68 years, predominantly male, with specific cardiac conditions such as coronary artery bypass grafting (CABG), valve replacements, or chest pain.

Inclusion Criteria

Eligible participants were male and female patients aged 18 to 80 years with a diagnosis of cardiac conditions, such as cardiac arrhythmias, cardiomyopathies, coronary artery disease, valvular heart diseases, congenital heart defects, and myocardial infarction. This range represented a broad spectrum of CVD profiles to comprehensively evaluate AVIDA's effectiveness across different clinical presentations.

Exclusion Criteria

Patients were excluded if they had acute illnesses requiring critical care, diagnosed psychiatric disorders, known skin allergies to materials like acrylonitrile butadiene styrene (ABS), or conditions precluding protocol adherence.

Exclusions also applied to pregnant or lactating women, patients in concurrent investigational studies, those with life-limiting comorbidities (life expectancy < six months), and individuals requiring pacing therapy or external defibrillation due to potential data interference.

Sample Size and Study Duration

For the primary objective, 83 patients were initially recruited. After excluding individuals with insufficient data or protocol deviations, the final analysis included 44 patients. For the secondary objective, this report outlines findings based on a sample population but does not specify the exact number of participants due to privacy considerations. The study spanned six months, from July to December 2023, ensuring data capture across various recovery phases.

Study Tool

The AVIDA ring, weighing 7 grams, is compact (22 mm wide; height varying between 29–33 mm based on size) and ergonomically designed to minimize interference with patient comfort. AVIDA's compactness, combined with its advanced sensor technology, facilitates uninterrupted monitoring, making it suitable for continuous RPM in real-world conditions.

Operational Definitions for Secondary Objective

HR

Outliers were defined as values exceeding 10% above the baseline average (for increased HR) or less than 5% below the baseline average (for decreased HR).

SpO_2

Significant decreases in SpO_2 were defined as deviations exceeding 5% below the baseline average.

IBI

IBI outliers were identified when values deviated more than 10% above or 5% below the baseline, indicating potential arrhythmias.

Data Collection

For the primary objective, this study was conducted within the postoperative cardiac surgery unit. A total of 83 patients who had undergone CABG or valve replacement surgery were recruited according to predefined inclusion and exclusion criteria. Each participant was provided with an AVIDA ring and clip-on device and received comprehensive training on the operational procedures of the devices. For HR and SpO_2 measurements, patients were seated comfortably, with their left arm resting at heart level. The ring device was positioned on the finger to ensure a secure yet non-restrictive fit, per the manufacturer's guidelines. Commercial oximeters were placed on the index and middle fingers of the left hand, and three consecutive SpO_2 measurements were recorded. Each reading on the commercial oximeter was noted simultaneously with the ring device's display. HR and SpO_2 values were continuously and simultaneously recorded in a time-synchronized manner across both the AVIDA and clip-on devices for subsequent analysis.

For the secondary objective, real-time data transmission was implemented during the monitoring period, allowing healthcare providers to receive alerts for any significant physiological deviations. Specifically, the AVIDA ring flagged outliers based on predetermined thresholds: HR measurements exceeding 10% above baseline, SpO_2 values falling more than 5% below baseline, and IBI fluctuations surpassing 10%. Upon detection of these deviations, the clinical team conducted an evaluation, documenting any medical interventions, such as adjustments to medication, as necessary.

Additionally, demographic and clinical data, including age, gender, surgical type, comorbidities, and medication adherence, were collected from medical records. Where needed, this information was supplemented through patient interviews and verified with electronic medical records.

Statistical Analysis

Descriptive data were analyzed and reported as mean and standard deviation (SD) for continuous variables or as number and percentage (%) for categorical variables. Pearson correlation coefficients were calculated between the readings from the AVIDA ring and those from the clip-on device to determine the strength of association between the devices.

The secondary objective focused on identifying and interpreting outliers in HR, SpO_2, and IBI readings throughout the monitoring period. Outliers were classified according to their frequency and contextual occurrence, considering demographic and clinical factors, such as age, gender, and surgical type (CABG or valve replacement). This classification enabled a structured analysis of the occurrence of parameter deviations, facilitating a comprehensive understanding of the demographic and clinical factors associated with physiological variations. All data were entered into Microsoft Excel and analyzed using Stata software 18[9].

RESULTS

Primary Objective

Comparison of AVIDA Ring and Clip-On Pulse Oximeter Of the 83 patients initially recruited, 44 completed all required measurements and were included in the final analysis. The study included 44 participants with a mean age of 48.6 years (SD: 12.5), predominantly male (75%), and an average height and weight of 162.4 cm (SD: 8.2) and 66.8 kg (SD: 121.9), respectively. Key clinical metrics included mean hemoglobin of 13.6 g/dL (SD: 1.7), random blood sugar of 136 mg/dL (SD: 64), serum creatinine of 0.9 mg/dL (SD: 0.2), LDL cholesterol of 116 mg/dL (SD: 32), triglycerides of 182 mg/dL (SD: 75), HDL cholesterol of 31 mg/dL (SD: 6), and left ventricular ejection fraction of 50% (SD: 9). Comorbidities were prevalent, with 25% having diabetes, 34% hypertension, and 16% dyslipidemia. Behavioral factors included smoking (34%) and alcohol consumption (18%), while 62% had undergone coronary angiograms. (Table 1).

For the primary objective, HR and SpO_2 measurements from the AVIDA ring were compared with those obtained from an FDA-approved clip-on pulse oximeter. Correlation

Table 1: Clinical and demographics characteristics of study participants (N=44)

Variable	*Mean (SD)*
Age (years)	48.6 (12.5)
Height (cm)	162.4 (8.2)
Weight (kg)	66.8 (121.9)
Haemoglobin (g/dL)	13.6 (1.7)
Random blood sugar (mg/dL)	136 (64)
Serum creatinine (mg/dL)	0.9 (0.2)
LDL cholesterol (mg/dL)	116 (32)
Triglycerides (mg/dL)	182 (75)
HDL cholesterol (mg/dL)	31 (6)
Left ventricular ejection fraction (%)	50 (9)
Variable	**n (%)**
Gender	
Male	33 (75)
Female	11 (25)
Diabetes	
Yes	11(25)
No	33 (75)
Dyslipidaemia	
Yes	7 (16)
No	37 (84)
Hypertension	
Yes	15 (34)
No	29 (66)
Smoking	
Yes	15 (34)
No	29 (65)
Alcohol	
Yes	8 (18)
No	36 (82)
Coronary Angiogram	
Yes	27 (62)
No	17 (38)

analyses were performed to determine the level of agreement between devices.

Correlation analysis

The scatter plots presented illustrate the relationship between HR and SpO_2 measurements from the AVIDA ring and the clip-on device, indicating a positive correlation for both parameters.

Heart Rate

The scatter plot (Figure 1) for HR compares the HR values recorded by the AVIDA device (x-axis, labeled as "HR OT") to those recorded by the clip-on device (y-axis, labeled as "HR Comp"). The plot reveals a positive trend, with a regression equation of $y = 0.8551x + 11.347$ and an R^2 value of 0.4685, suggesting a moderate association between the two devices. The Pearson correlation coefficient ($r = 0.6845$) indicates a statistically significant positive correlation, confirming that increases in HR values measured by the AVIDA device are associated with corresponding increases in the clip-on device's HR values.

SpO2

The scatter plot (Figure 2) for SpO_2 compares oxygen saturation levels recorded by the AVIDA device (x-axis) and the clip-on device (y-axis). The regression line ($y = 0.6622x + 30.474$) with an R^2 value of 0.4669 indicates moderate correlation strength. The Pearson correlation coefficient ($r = 0.6833$) supports a significant positive correlation between the devices, suggesting that SpO_2 values from the AVIDA device correspond well with those from the clip-on device.

Secondary Objective: Outlier Detection in HR, SpO_2, and IBI

The secondary objective examined the AVIDA ring's capacity for detecting outliers in HR, SpO_2, and IBI readings, focusing on relationships with patient demographics and device usage patterns.

Outlier Characteristics

HR

The average remained at 70 bpm, with an updated 45–166 bpm range and four outliers detected.

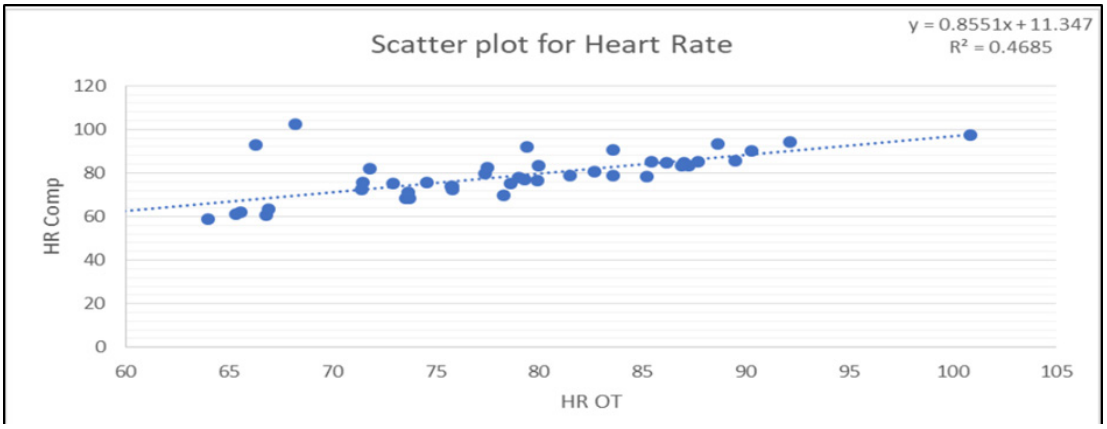

Figure 1: Scatter plot showing the correlation between heart rate measurements of post-cardiac surgery patients using the Avida and Clip-On devices.

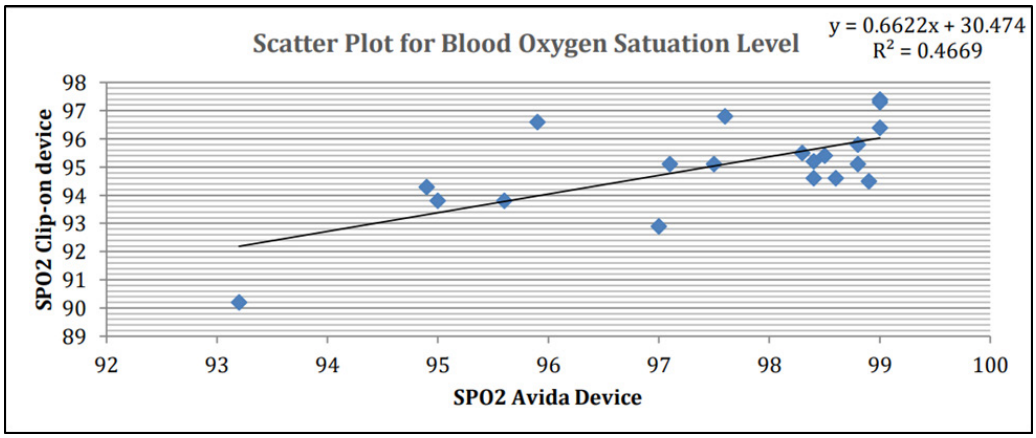

Figure 2: Scatter plot showing the correlation between SpO_2 measurements of post-cardiac surgery patients using the Avida and clip-on devices

SpO_2

Average remained at 97%, range updated to 69–100%, with two outliers identified.

IBI

The average remained at 925 ms, with a range of 333–1667 ms, and four outliers were recorded.

Patient Characteristics

The analysis revealed that most outliers were detected among patients undergoing CABG or valve replacement surgeries. This suggests that post-surgical patients may experience greater physiological variability, which the AVIDA ring was able to identify effectively. No significant differences in outlier detection were observed across different age groups or genders, indicating that the device's performance was consistent across these demographic variables.

Timing of Outliers

Outliers were observed more frequently during the daytime, between 6 AM and 6 PM, compared to the nighttime, between 6 PM and 6 AM. This trend aligns with typical daily activity cycles and may highlight the increased physiological fluctuations that occur during waking hours. This finding suggests that continuous monitoring throughout the day could provide more actionable insights for clinicians.

Medication Adherence and Usage Patterns

Patients with detected outliers were more likely to have missed medication doses or exhibited irregular usage patterns with the AVIDA ring. This association underscores the potential of the AVIDA device not only as a monitoring tool but also as an indicator for adherence issues, as deviations in vital signs could prompt reminders or interventions to address missed doses and improve adherence. Examples of outliers are presented in Figure 3.

Patient CTVS-11: Increased HR (+11.25%) and decreased SPO2 (-1.06%) after CABG surgery.
Patient CTVS-255: Recurrent increased HR (+9.38%), decreased SPO2 (-0.69%), and decreased IBI (-0.69%) after CABG surgery.
Patient CTVS-01: Increased IBI (+10.76%) after CABG surgery.
Patient CTVS-299: Decreased HR (-0.39%) after valve replacement surgery.

Figure 3: Examples of specific outlier cases

DISCUSSION

In this study, Omnyk's technology was assessed by using the Avida device for at-risk cardiac patients, and the results were compared with the standard FDA-approved Clip-On device. The Pearson correlation coefficient and scatter plot were used to find the relationship between two variables and compare their values. We observed positive correlations between the Avida and the Clip-On devices when evaluating Heart Rate measurements (r = 0.6845). We also observed a positive correlation between Avida and Clip-On devices when evaluating SpO2 measurements (r =0.6833), which suggests that there is a strong statistical correlation between these two devices. Based on the observed data, we believe that the efficacy of the Avida device is as good as a commercially available FDA-approved Clip-On device. The Avida device is a reliable way to measure HR and SpO_2 values for Cardiac patients. For the Secondary Objective, most of the outliers were observed in users who had undergone CABG or Valve Replacement surgeries. There were no significant differences in the distribution of outliers across different age groups or genders. Outliers were more frequent during the daytime (between 6 AM and 6 PM) compared to the nighttime (between 6 PM and 6 AM). Patients with outliers were more likely to have missed medication doses or had irregular usage patterns.

The key limitation that the AVIDA ring relieves from the Clip-On devices is that it provides continuous measuring and monitoring, unlike the other devices, which only provide a snapshot of these parameters when a patient takes the measurement. The AVIDA ring is not bulky and is easy to wear around throughout the day. Also, it is much easier to use and measure using the mobile app interface provided in the AVIDA ring, which makes it much easier and feasible to collect data while the patient is engaged in his/her normal daily routine and deliver real-time alerts. The AVIDA ring is a wearable device designed for the continuous monitoring of vital health

metrics throughout the day, which adds to the potential for early detection of symptoms and the need for care for patients, particularly during the first 30 to 60 days after discharge from the hospital. There are a wide variety of devices available that can track body vitals, such as blood pressure, temperature, HR, and blood oxygen saturation etc., most of these devices track one or two parameters simultaneously and none measure IBI on a 24/7 continuous basis, allowing the patient's health to be managed even after the patient is discharged from the hospital.[10]

AVIDA device will also help the many patients who use household oxygen or who have heart disease and may find it useful to manage optimal blood oxygen levels and daily routine activities. While a clip-on device is hard to use and has a chance of giving motion-related errors. This study assessed the data obtained from the Avida device as being consistent with the clip-on device, thereby helping cardiac patients manage their health while continuing a normal lifestyle. Pulse oximetry is so widely prevalent in medical care that it is often regarded as a fifth vital sign. It is important to understand how the technology functions as well as its limitations because erroneous readings can lead to redundant testing.[11]. All these problems could be minimized by using an Avida device where oximeter usage is required. For cardiac patients, continuous monitoring of vital signs could be a useful tool to detect clinical deterioration in an earlier phase, which allows clinicians to take corrective interventions, particularly since subtle changes in vital signs often are present 8 to 24 hours before a life-threatening event such as ICU admission, cardiac arrest, and death.

We observed that the positive correlation between the devices showcases the potential of the AVIDA device to monitor key body vitals related to heart health remotely. Traditional in-person monitoring methods often leave gaps in patient care because they rely on periodic hospital visits rather than continuous data collection. The collection of vitals during normal day-to-day living conditions will help better assess the overall heart health score. The usage of a device to continuously monitor the vitals will help in post-care management, which will allow timely interventions and better results through real-time data and alerts to enable informed decision-making for each patient's specific needs.[8]. This will, in turn, reduce readmission rates and improve dose management, especially for post-surgical cardiac patients. Continuous monitoring helps in observing the trends in the patient's vitals; if abnormal, they can immediately be corrected through precautionary measures along with tailored interventions for the patient.[12]. Through its integration with Omnyk's OmnyTraq mobile app and OmnyK web platform, AVIDA delivers real-time data and personalized predictive analytics to patients and healthcare providers alike, allowing for more proactive care decisions. The assessment of patients in rural and distant parts can be easily done.

This study's strengths include its rigorous comparison of AVIDA's measurements to an FDA-approved clip-on device, which provides robust evidence for accuracy in heart rate and oxygen saturation monitoring. Outlier analysis adds depth by identifying physiological variations that could prompt timely interventions, especially for patients with inconsistent medication adherence.

This study's generalizability is limited by its small sample size and fixed outlier thresholds, which may not capture patient-specific variations. Conducting research in a controlled inpatient setting also restricts applicability to at-home monitoring. Future studies should analyze diverse demographics and health conditions to enhance sensitivity and specificity in personalized care.

CONCLUSION

The AVIDA ring shows accuracy and usability for continuous monitoring of HR and SpO_2 in post-cardiac patients, correlating well with FDA-approved clip-on devices. It stands out among wearable devices currently in use due to its ability to monitor seven distinct parameters. Its real-time capabilities allow for early detection of abnormalities, potentially reducing hospital readmissions and improving adherence to care regimens. Further research with larger, diverse populations is needed to validate its efficacy. By facilitating data-driven decisions and targeted outreach for high-risk patients, the AVIDA device enhances clinical outcomes and optimizes resource allocation in post-operative cardiovascular care.

ETHICAL APPROVAL

This study was approved by Sri Jayadeva Institute Cardiovascular Sciences Research with IEC no: EC/RENEW/INST/2019/5582 and approved by IPGME&R research oversight committee with IEC no: IPGMER&R/IEC/2023/506.

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