Feasibility Study of Non-Contact Imaging-Based Physiological Monitoring in the Operating Room

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1. Background and Rationale

Perioperative vital sign monitoring traditionally relies on contact-based or invasive devices, such as ECG leads, blood pressure cuffs, and pulse oximeters. While widely used, these devices pose risks of cross-infection and potential skin injury to vulnerable populations, and their wires can restrict patient mobility. Non-contact sensing technologies, including remote Photoplethysmography (rPPG), offer a promising alternative. Our team has previously validated this technology for pulse and respiratory rate detection in clinical environments. This study aims to further evaluate the feasibility and accuracy of this non-contact imaging technology for monitoring heart rate (HR), blood pressure (BP), and blood oxygen saturation (SpO2) within the dynamic environment of an operating room.

2. Study Objectives

Primary Objective:

- Evaluate the feasibility, stability, and accuracy of the non-contact imaging-based physiological monitoring system during surgical procedures (including induction, surgery, and recovery) compared to clinical standard monitors.

Secondary Objectives:

- Optimize algorithms for enhanced adaptability in dynamic surgical settings.
- Explore potential applications for specific clinical groups, such as patients with fragile skin.

3. Study Design

This is a single-center, prospective, exploratory observational study using a within-subject comparative design. Approximately 315 adult patients undergoing elective surgery under general anesthesia will be enrolled. Each participant will simultaneously

receive both non-contact imaging monitoring and standard clinical monitoring for real-time data comparison. No randomization or blinding is involved.

4. Study Procedures and Methods

Informed Consent: Obtained preoperatively.

Investigational Device: rPPG software installed on a Logitech C930 (Windows), iPhone 16 Pro Max (iOS), and Samsung Galaxy S24 Ultra (Android).

Reference Devices: Masimo Root platform, SedLine O3 regional oximetry, and Radical-7 pulse oximeter.

Data Collection: Continuous facial video and physiological signals will be captured throughout the perioperative period (from induction until patient transfer to the recovery room).

5. Eligibility Criteria

Inclusion Criteria:

- Age ≥ 18 years.
- Scheduled for surgery under general anesthesia.
- ASA Physical Status I, II, or III.

Exclusion Criteria:

- Age < 18 years or pregnant patients.
- Facial images cannot be captured (e.g., due to surgical drapes, severe edema, or trauma).
- Refusal or inability to provide informed consent.

6. Outcome Measures

Primary Outcome:

1. Accuracy of Heart Rate (HR) monitoring

Description: The success rate of non-contact HR measurement using the rPPG software compared to the reference values from the Masimo Root clinical monitoring platform. A "success" is defined as an absolute error within +/- 3 bpm.

Time Frame: Continuous monitoring during the perioperative period (approximately 2-6 hours per patient, from anesthesia induction to recovery).

2. Success rate of Systolic Blood Pressure (SBP) monitoring

   Description: The success rate of non-contact SBP measurement compared to the reference values from the Masimo Root platform. A "success" is defined as an absolute error within +/- 12 mmHg.

   Time Frame: Continuous monitoring during the perioperative period (approximately 2-6 hours per patient, from anesthesia induction to recovery).

3. Success rate of Diastolic Blood Pressure (DBP) monitoring

   Description: The success rate of non-contact DBP measurement compared to the reference values from the Masimo Root platform. A "success" is defined as an absolute error within +/- 10 mmHg.

   Time Frame: Continuous monitoring during the perioperative period (approximately 2-6 hours per patient, from anesthesia induction to recovery).

4. Success rate of Oxygen Saturation (SpO2) monitoring

   Description: The success rate of non-contact SpO2 measurement compared to the reference values from the Masimo Root platform. A "success" is defined as an absolute error within +/- 8% (when SpO2 >/= 80%) or +/- 15% (when SpO2 < 80%).

   Time Frame: Continuous monitoring during the perioperative period (approximately 2-6 hours per patient, from anesthesia induction to recovery).

Secondary Outcome Measures:

5. Consistency of physiological parameters across hardware platforms.

   Description: Evaluation of the measurement consistency among three devices (Logitech C930, iPhone 16 Pro Max, and Samsung Galaxy S24 Ultra).

Consistency will be assessed by calculating the Mean Absolute Error (MAE) of heart rate and blood pressure for each device compared to the Masimo Root monitor. Unit of Measure: Beats per minute (for HR) and mmHg (for BP).

Time Frame: During the intraoperative phase (duration of the surgical procedure).

7. Sample Size Justification

The sample size of 315 participants is determined based on practical clinical considerations and the data requirements for validating the non-contact imaging algorithm. As this is an exploratory feasibility study aimed at assessing the application potential and parameter consistency of imaging-based monitoring in an operating room setting, a formal power calculation was not performed.

A total of 315 subjects is expected to provide sufficient and diverse data across various perioperative clinical scenarios. This will allow for robust descriptive statistical analysis, signal quality evaluation, consistency testing against reference standards, and further algorithm optimization.

8. Statistical Analysis Plan (SAP)

Descriptive Statistics: Mean, standard deviation, and distribution for each parameter across surgical phases.

Error Analysis: Calculation of Mean Absolute Error (MAE), Root Mean Square Error (RMSE), and Mean Error Rate (MER).

Agreement Analysis: Linear regression analysis and Bland–Altman plots to evaluate correlation and systematic bias between the rPPG system and standard monitors.

9. Adverse Event Management

No adverse events are expected. Adhesive patches are non-invasive and pose minimal risk. If discomfort occurs, subjects may contact the provided 24-hour emergency number.

Clinical evaluation will be arranged if needed. Participants may withdraw at any time without affecting their medical care.

10. Subject Rights and Safety Protections

Participants are protected under institutional and national human-subject research policies. Informed consent will be obtained from all participants. All collected data will be de-identified. Only authorized research personnel may access raw data.

11. Data Management and IPD Sharing

All data will be de-identified. De-identified datasets may be shared upon request beginning 6 months after study completion to protect participant privacy.

12. References

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