**Primary Objective**

To evaluate the measurement agreement of a novel Doppler device for assessing heart rate in neonatal intensive care unit (NICU) patients by comparing it to standard monitoring devices — including electrocardiogram (ECG), pulse oximetry (SpO₂), and temperature-based heart rate sensors — using:

* **Bland-Altman analysis** to quantify mean bias and 95% limits of agreement (LoA) between Doppler-derived heart rates and each reference method;
* **Intraclass Correlation Coefficient (ICC, two-way mixed model, absolute agreement)** to evaluate reliability, with an ICC ≥0.90 considered excellent agreement;
* **Proportion of Doppler readings within ±5 beats per minute (bpm)** of each reference standard as a clinically acceptable threshold for agreement

**Statistical Analysis Plan**

**1. Overview**

This pilot study is primarily exploratory and aims to assess the measurement agreement and feasibility of a novel Doppler device in NICU patients. Statistical analyses will focus on evaluating how closely heart rate (HR) measurements from the Doppler device match those from standard clinical monitoring methods: electrocardiogram (ECG), pulse oximetry (SpO₂), and temperature-based HR sensors.

**2. Data Preparation**

* Continuous HR measurements from the Doppler device and each standard method will be paired based on synchronized timestamps (within a ±5-second window).
* Only time points where readings are available from both the Doppler and a comparator device will be included in the agreement analysis.
* Data will be assessed for outliers and physiological plausibility prior to analysis. Implausible HR values (<40 or >240 bpm) will be excluded from primary analysis and reported separately in sensitivity analysis.

**3. Agreement Analysis**

**3.1 Bland-Altman Analysis**

* For each comparator device (ECG, pulse oximetry, temperature sensor), Bland-Altman plots will be generated to assess agreement with the Doppler device.
* The **mean difference (bias)** and **95% limits of agreement (LoA)** will be calculated for each pairwise comparison.
* Results will be interpreted visually and numerically to assess whether the Doppler's performance falls within clinically acceptable limits (preliminarily defined as ±10 bpm for LoA).
* Stratified plots may be used for subgroups (e.g., by gestational age or weight) if sample size allows.

**3.2 Intraclass Correlation Coefficient (ICC)**

* The **two-way mixed-effects ICC (absolute agreement)** will be used to assess the consistency of HR measurements between the Doppler device and each standard.
* ICC values will be interpreted as:
  + <0.5 = poor agreement
  + 0.5–0.75 = moderate agreement
  + 0.75–0.9 = good agreement
  + 0.90 = excellent agreement

**3.3 Proportion Within Clinically Acceptable Limits**

* The percentage of Doppler HR readings within **±5 beats per minute (bpm)** and **±10 bpm** of the reference standard will be reported.
* This will provide a practical, clinically interpretable metric of how often the Doppler device aligns closely with standard devices.

**4. Feasibility and Usability Metrics**

Descriptive statistics will be used to report:

* **Success rate** in acquiring Doppler readings
* **Time to obtain a stable reading** (median, IQR)
* **Number of repositioning attempts or signal dropouts**
* **Clinician-reported ease-of-use**, assessed via Likert-scale responses, will be summarized using frequencies and means (as appropriate).

**5. Sample Size and Statistical Considerations**

As a pilot study, the sample size is not powered for hypothesis testing. The goal is to estimate agreement and variability to inform sample size calculation for a future non-inferiority or validation trial. All estimates will be presented with 95% confidence intervals.

**6. Software**

All analyses will be conducted using **JASP** or **Stata/SPSS**, with appropriate packages for Bland-Altman plots (e.g., blandr or ggplot2 in R) and ICC calculations.

**Statistical Analysis Plan for IRB Application**

**Study Overview**

This pilot study aims to evaluate the agreement and usability of a novel Doppler device for measuring vital signs in neonatal intensive care unit (NICU) patients, compared to standard clinical monitors. The study is exploratory and will provide feasibility and agreement data to guide future research.

**Primary Analysis: Measurement Agreement**

We will compare heart rate (HR) values from the Doppler device to those recorded by standard clinical monitors — including electrocardiogram (ECG), pulse oximetry (SpO₂), and temperature-based heart rate sensors. The goal is to assess how closely the Doppler device performs in relation to these reference standards.

The following statistical methods will be used:

* **Bland-Altman analysis**: This method will assess the average difference between the Doppler device and each standard method and show how widely the measurements vary. This helps us understand whether the new device gives readings that are consistently higher or lower, and by how much.
* **Intraclass Correlation Coefficient (ICC)**: This will measure the overall consistency between the Doppler device and each standard device across all patients. An ICC value above 0.90 will be considered excellent agreement.
* **Proportion within acceptable range**: We will calculate how often the Doppler device’s heart rate readings are within ±5 and ±10 beats per minute of the reference devices. This helps evaluate whether the device is accurate enough for clinical consideration.

All results will be reported descriptively and with 95% confidence intervals. These analyses are exploratory and will not involve formal hypothesis testing.

**Secondary Analysis: Feasibility and Usability**

We will also collect basic operational data on the Doppler device to assess its ease of use and practical application in the NICU:

* **Success rate** in obtaining a usable signal
* **Time to obtain a reading** (in seconds)
* **Number of attempts required** to acquire a stable signal
* **Clinician feedback** on ease of use, recorded through a brief questionnaire using Likert-scale items

These outcomes will be summarized using descriptive statistics only.

**Sample Size Considerations**

This is a pilot study and not powered to detect statistically significant differences. We anticipate enrolling approximately [insert number] NICU patients to obtain an adequate sample of paired heart rate readings across multiple conditions and devices. The data collected will inform the design and sample size calculation of a future validation or non-inferiority study.

**Data Handling and Privacy**

All data will be de-identified and stored securely in accordance with institutional policies. No identifiable patient data will be used in the statistical analysis.