

Title:
Refinement of the LaborView Electronic Fetal Monitor

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Statistical Analysis Plan

FHR accuracy (RMSE)

Similarly, the hypothesis tested for FHR accuracy (RMSE) is a noninferiority hypothesis and is specified as: $H_0: \mu_{LV-US} \geq 5$ versus $H_A: \mu_{LV-US} < 5$

where μ_{LV-US} is the paired mean difference between LaborView and Ultrasound for FHR RMSE. This hypothesis will be tested by constructing a 95% 2-sided confidence interval and if the upper limit is less than 5, then the conclusion of non-inferiority can be made (paired t-test). That is, if the upper limit is less than 5, the LaborView FHR RMSE is concluded to be non-inferior to the Ultrasound FHR PPA.