



Title: Clinical Trial – Statistical Analysis Plan

Date: 05/17/2022

Study Title:

Measuring Cardiovascular Performance and Blood Flow Using Common But Never Compared Methods

Trial # NCT04553484



Title: Clinical Trial – Statistical Analysis Plan

QuantaFlo® Plus Statistical Analysis Plan

A line listing, a Bland-Altman plot, and error plots (for both individual test subjects and all subjects pooled), and rationale for any points excluded from analysis on 200 or more data points will be generated. Population mean bias (μ_0), between-subject variance ($\sigma_{\mu 2}$), within-subject variance (σ_2), and upper 95% and lower 95% limits of agreement will be included. If the plots show noticeable outliers, the following will be provided:

- test setup, test procedure, and any other factors that may have affected these data points; and
- a discussion of how the outlier(s) do not raise safety and performance concerns regarding the accuracy of the device.