



Official Title:

SpO₂ Validation of Noninvasive Red Diamond
Disposable Pulse Oximeter Sensor

Date of Statistical Plan: 03Jan2018

NCT Number: NCT03124602

STATISTICAL PLAN

A previous study collected data on 35 subjects using Red Diamond disposable sensors during an observational study. Since A_{RMS} is always a positive quantity, the Log Normal distribution was used in a Monte Carlo analysis to determine an adequate number of subjects. After sampling Subjects with replacement, the analysis determined that a subject count of 25, or more, allowed detection of 0.3 %SpO₂ changes in A_{RMS} with 95% confidence and Power > 0.80.