Official Title: Oxygen Reserve Index Validation
for RD Lite Sensors

Date of Statistical Plan: August 1, 2017

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Statistical Analysis Plan
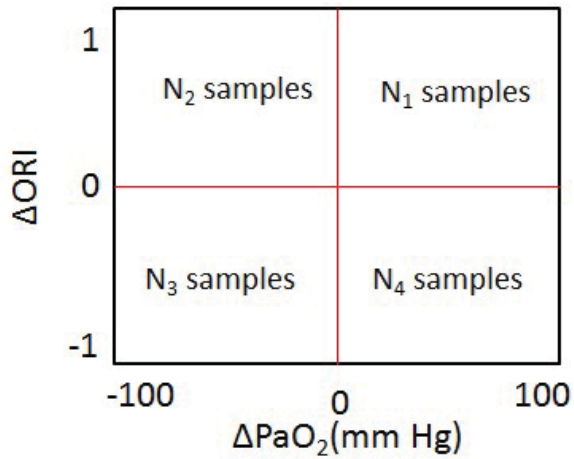
Specificity, Sensitivity and Concordance were used as metrics for evaluation. They are computed using the following formulas:

Specificity $\quad$ = N1 / (N1 + N4)

Sensitivity $\quad$ = N3 / (N2 + N3)

Concordance $\quad$ = (N1 + N3) / (N1 + N2 + N3 + N4)

where N1, N2, N3 and N4 are defined as per the figure below

ΔPaO_2 and ΔORI are defined as shown below:

$\Delta PaO_2 = PaO_2(t) - PaO_2(t_{ref})$

$\Delta ORI = ORI(t) - ORI(t_{ref})$