ivWatch Model 400: Signal Variation of Normal Tissue

ivWatch Study ID: IVW-CLR-CS01-400

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Number of subjects: 30

Number of IV sites: 30

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The Signal Variation of Normal Tissue Study was performed to understand the variability of the ivWatch signal when monitoring normal, non-infiltrated tissues. A total of 30 healthy adult volunteers were enrolled in the study. Each subject's pseudo-randomly selected site (hand or forearm) was monitored over a 24 hour period in an observation room that mimicked a typical hospital environment. The primary goal of the study was to identify common sources of non-infiltration alarms issued by the ivWatch device and to estimate the clinical rate of occurrence for non-infiltration alarm conditions for the red and yellow alarm states. Video surveillance was used to identify conditions leading to false notifications. An additional study was performed to determine if interference by other common light emitting sources affected the ivWatch device. A total of 661 hours of data were collected during the study. The rate for a non-infiltration yellow notification was measured to be 0.40 yellow notifications per day (11 yellow notifications / 661 hours), or approximately 1 yellow notification every 2.5 days of monitoring. The rate for a non-infiltration red notification was measured to be 0.11 red notifications per day (3 red notifications / 661 hours), or approximately 1 red notification every 9.1 days. An analysis of the monitoring video suggested that the red notifications occurred due to tissue distortion in the area of the sensor and not to blood pressure measurements or interference by other NIR devices. For example, one subject was observed to be laying on the site causing the red notification.