ivWatch SmartTouch Sensor: Device Validation for Non-Infiltrated Tissues

ivWatch Study ID: IVW-CLR-CS24-400

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Number of subjects: 40

Number of IV sites: 80

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Abstract/Informational Paragraph:

Objectives: Quantify the non-infiltration red-notification and yellow-notification rates for the SmartTouch Sensor and Model 400 Fiber Optic Sensor side-by-side. Determine if non-infiltration red-notification and yellow-notification rates of the SmartTouch Sensor are equivalent to the Model 400 Fiber Optic Sensor. Identify conditions that may cause a non-infiltration notification.

Methods: Healthy adult volunteers were enrolled in a 24-hour study to determine the efficacy and safety of the ivWatch Model 400 with the Fiber Optic Sensor and the SmartTouch Sensor when monitoring normal (non-infiltrated) tissue. Enrollment ensured the 40 accepted case studies formed a representative sample of the intended population of the device. Monitored sites in this study included the forearm and the dorsal aspect of the hand. The subjects were assigned to an observation area, which mimicked a hospital room. With the exception of strenuous exercise, motions and activities of the research subjects were not restricted.

Statistical Methods: The primary efficacy metrics were notification rates, defined as the number of notifications in a given amount of time. The statistics of proportions were used in this analysis. A negative binomial regression model is used to estimate the 95% confidence interval for notification rates. Other common statistical metrics such as average and median were also included in the analysis.

Results: A total of 922 hours of data were collected from each sensor (Fiber Optic Sensor and the SmartTouch Sensor) in the 40 accepted case studies. The yellow-only and red notification rates were measured when observing normal, non-infiltrated tissue. The number, rate, and 95% confidence interval for the yellow-only and red notification rates are included in the tables below.

SmartTouch Sensor

95% Confidence Interval

	Red Notifications	Yellow Notifications
Number Notifications	6	8
Estimated Rate Notifications/day	0.159	0.209
Lower Limit Notifications/day	0.051	0.091
Upper Limit Notifications/day	0.490	0.482

Fiber Optic Sensor

95% Confidence Interval

	Red Notifications	Yellow Notifications
Number Notifications	16	24
Estimated Rate Notifications/day	0.419	0.661
Lower Limit Notifications/day	0.257	0.344
Upper Limit Notifications/day	0.684	1.269

An analysis of the notifications indicated many were associated with patient activities that applied a force to the site, either distorting the tissue or affecting the skin-sensor coupling efficiency. These non-infiltration notifications may be beneficial by alerting clinicians to conditions that could place the PIV site at a greater risk for complications such as infiltration, occlusion, and phlebitis.

Safety Results: Visual assessments of the site were performed to assess any impact on the skin. Photographs were captured of the skin before and after the study. No cases of skin irritation or disruption to skin integrity were recorded from the 45 subjects participating in the study. Skin irritation was defined as redness or rash-like appearance. Disruptions to skin integrity included removal of skin layers, bleeding, or burning of the tissue. No adverse events were recorded in this study.

Conclusion: The red and yellow non-infiltration notification rates for both sensors were measured to be less than one per day. The measured notifications rates for both sensors are sufficiently small suggesting the ivWatch Model 400 Fiber Optic Sensor and SmartTouch Sensor should have a minimal impact on clinical alarm fatigue. With no cases of skin irritation, disruption to skin integrity, or adverse events, the study indicates the ivWatch Model 400 with Extension Module and SmartTouch Sensor is safe when used according to the instructions for use.