ivWatch SmartTouch Sensor: Device Verification for Non-Infiltrated Tissues, Part II

ivWatch Study ID: IVW-CLR-C26-400

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Number of subjects: 15

Number of IV sites: 30

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Fifteen (15) healthy adult volunteers were enrolled in a study to investigate the performance of the ivWatch SmartTouch Sensor when monitoring normal (non-infiltrated) tissue on the hand, forearm, and antecubital fossa. The hand and forearm represent the two most common PIV locations. Antecubital veins are generally not recommended for infusion therapy because of a higher risk for complications such as mechanical phlebitis and infiltration. However, the antecubital may be used when no other veins are available or in emergency situations. Each subject was continuously monitored in a hospital-like environment for a 24-hour period and received two simulated IV sites on the same arm. Video surveillance was used to record conditions leading to a notification. A total of four non-infiltration red notifications were recorded from the 30 accepted case study IV sites, corresponding to a rate of 0.137 notifications per day (4 notifications / 700 hours) or approximately one red notification every 7.3 days. A total of six self-correcting yellow notifications were recorded during the study. The highest number of notifications were observed with AC sites with a total of 2 red and 5 yellow. Both red notifications occurred on the same subject, while the 5 yellow notifications were distributed between 4 different subjects. Since false notifications most likely occur when pressure is applied by pressing the sensor into tissue, this data suggest the AC site has a higher chance of this occurrence. Video surveillance confirmed most of the notifications issued for AC sites occur when the arm is folded. Overall, the results from this study suggest the SmartTouch Sensor has similar or better false-notification performance than the Model 400 Fiber Optic Sensor.