# ivWatch SmartTouch Sensor: Device Verification for Non-Infiltrated Tissues

ivWatch Study ID: IVW-CLR-CS23-400

Investigators: William J. Naramore, Susan Brown, MSN, MSED, BA, VA-BC, Marisa A. Cole

Advarra IRB ID: 00030569

Number of subjects: 30

Number of IV sites: 60

Date: December 2018 – January 2019

The ivWatch SmartTouch Sensor: Device Verification for Non-Infiltrated Tissues study was performed to further understand false-notification performance of the prototype SmartTouch Sensor, which was designed to be at least equivalent to the FDA-cleared ivWatch Model 400 Fiber Optic Sensor. The primary goal of this study was to estimate the false-notification rate of the SmartTouch Sensor side-by-side with the Fiber Optic Sensor. Thirty (30) healthy adult volunteers were enrolled in a study and continuously monitored in a hospital-like environment for a period of 24-hours. Optical signal data was collected from two locations on each subject, one site with the SmartTouch Sensor and the other site with the Fiber Optic Sensor. The location of each sensor is randomly selected from the dorsal aspect of the hand or the forearm, representing the most common PIV locations. The results from this study suggest the SmartTouch Sensor has similar or better false-notification performance than the Model 400 Fiber Optic Sensor. The rate for a non-infiltration SmartTouch red notification was measured to be 0.14 notifications per day (4 notifications / 705 hours), or approximately 1 notification every 7.3 days of monitoring. The rate for a non-infiltration Fiber Optic red notification was measured to be 0.37 red notifications per day (11 red notifications / 705 hours), or approximately 1 red notification every 2.7 days. An analysis of the monitoring video suggested that most of the notifications occurred due to tissue distortion in the area of the sensor, typically when pressure is applied pushing the sensor into tissue. None of the research subjects experienced any issues with skin integrity associated with either ivWatch sensor.