University of Pittsburgh

Verification and Validation: Engineering Equipment for a Simplified Central Venous Catheterization

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Purpose: This document is intended to enumerate the methods that will verify and validate the central venous catheter (CVC) device during production. Verification will assure that the stepwise development of the device accomplishes each design requirement. Validation will assure that each component of the device performs as initially intended to fulfill the need of the customer.

Verification:

Design verification assures that design output reflects design input requirements. All verification checks will be fully characterized in the DHF and include the date of verification and name of group member who performed verification.

Needle

The needle will be purchased from a medical supplies source such as Uniecom Medical Supplies, Helio Medical Supplies, etc. and will not need to be verified.

Duckbill Checkvalve

The duckbill checkvalve will be purchased from Qosina and will not need to be verified.

Various Integrated Circuits and Electronic Components

Electronic components will be purchased from a large electronics vendor such as McMaster-Carr, Allied Electronics, etc. and will not need to be verified.

Three-way Connector

Verification of the three-way connector will document its production methodology, including associated parts such as the blood view. Its physical properties will be verified to ensure it securely maintains connection between the needle, pressure sensor, and duckbill checkvalve, while allowing for handle removal. The connector's dimensions will be verified by measurement and required to be within 0.5mm of initial design dimensions. Verification will require no blood to be leaked out of the connections.

Pressure Sensor

Verification of the pressure sensor will document its production methodology, involving the design of the pressure sensor circuit that provides input to LabVIEW in order to produce a visual confirmation of venous entry. Pressure sensor physical properties will be verified to ensure its secure connection to the 3-way connector. The pressure sensor will be verified to produce a green indicator light when exposed to fluid pressures not exceeding 30mmHg. Verification will also ensure the pressure sensor produces a red indicator light when exposed to

fluid pressures exceeding 30mmHg. Verification will assure indicator light signaling for continuous fluid pressure exposure lasting ten minutes.

Handle

Verification of the handle will document its production methodology. Its physical properties will be verified to ensure it securely maintains connection to the duckbill checkvalve until its removal. Verification will assure that the handle cannot be removed without twisting the Luer lock device and pulling.

Verification Procedure

Verification will be performed with a blood pressure simulator designed specifically for this purpose. The blood pressure simulator will use bags of varying height to simulate arterial (both systolic and diastolic) pressure and venous pressure. A LabVIEW program controls a solenoid valve to allow the arterial pressure to switch between systolic and diastolic pressure. The arterial and venous pressure tubes will be run through a Laerdal neck piece that mimics human anatomy. The simulator itself will be verified using a TruWave pressure transducer and a patient monitor connected to the end of the venous and arterial tubes in order to ensure that the correct pressures are being output by the simulator.

Following simulator verification, device verification involves injecting the device into the vein and artery with varying pressures, analyzing the LabVIEW output and determining whether the device produces an accurate reading of whether the needle is in the artery or vein. In order for verification to be successful, 90% of all insertions should produce an accurate response. Additionally, the device should enable visualization of the “blood” within the connector piece and allow the guide wire to enter the vein without significant obstruction.

Validation:

Design validation assures that the device successfully fulfills user needs and requirements. All validation checks will be fully characterized in the DHF and include the date of validation and name of group member who implemented validation.

Clinician testing at WISER

A clinician who has worked closely with the group throughout the design process will be provided with a CVC kit containing the preliminary proof of concept design of the new CVC device and told to perform a CVC procedure on a simulation patient. The clinician will be briefed on the exact constraints produced by the preliminary design and what aspects will be different in the final design. Validation will require the clinician to first assemble the CVC device and then perform the procedure using the new device. Overall procedure time and success rate will be recorded. The procedure will be repeated using a traditional CVC kit. Validation will occur if procedure time decreases, discounting initial set up time which is longer due to the constraints of the preliminary model, and success (hitting the vein) increases with the use of the new device.

Validation will also involve obtaining qualitative feedback from the clinician following testing. Size, weight, and obstruction of view of the new device will be assessed in a questionnaire. Overall ease of the procedure using the new device compared to the traditional device as assessed by the clinicians will be recorded. Qualitative evaluations by the clinician

concerning ease of use, accuracy, comfort, and additional comments regarding the use of the device will be obtained.