



AIUM/QIBA Ultrasound Volume Blood Flow Biomarker

Summary 01-February-2021

Attendees: Brian Fowlkes, Andy Milkowski, Jon Rubin, Ravi Managuli, Rimon Tadross, Megan Russ, Oliver K. , Todd Erpelding, Cy Lee, Michelle Robbin, Jim Jago, Sibbo Li, Cristel Baiu, Stephen Pinter, Shriram Sethuraman, Jim Zagzebski, Jing Gao, Paul Carson, AIUM Staff - Therese Cooper and Haylea Weiss

1. Review of Previous Call Summary – 07-Dec-2020
 - 1.1. Approved with no changes
2. Action Items
 - 2.1. Discussion of 2D spectral Doppler in QIBA Phantom
 - 2.2. Data comparing of 2D Pulse Wave and 3D Volume Flow
 - 2.2.1. Discussed these data being a full set similar to radiology paper (acquisition, constant and pulsatile flow with 4 parameters).
 - 2.2.2. Examples were shown on 2D (curved tubing) and 3D demonstrating challenges. Michelle questioned the measurement based on the image. Acquisition does not match her method. Measure above or below the curvature. Discussed angle correct and the challenges with 2D image acquisition. The example shows how good the 3D is when the desired 2D is not possible.
 - 2.2.3. Reviewed constant flow
 - 2.2.3.1. Pump volume flow rate with and without angle correction. 2D method shows to be overestimated (no surprise)
 - 2.2.3.2. Reviewed depth dependence
 - 2.2.3.3. Reviewed gain dependence
 - 2.2.3.4. **Need to examine conditions in the acquisition to determine if data is useful.**
 - 2.3. Draft profile for BC – See discussion below.
 - 2.3.1. Feedback from Manufacturers after distributing draft for comment.
 - 2.3.1.1. Some comments received.
3. Summary Presentation for 2020 QIBA Virtual General Meeting Thursday, December 10
 - 3.1. Summary discussed
 - 3.1.1. Groundwork
 - 3.1.2. Subgroup descriptions

3.2. QIBA Japan General Meeting

3.2.1. Similar summary – Thanks to Paul Carson for presenting

4. VBF Profile Discussion Update - Breadth of Profile

4.1.1. Currently two claims proposed.

4.1.1.1. Claim 1: cross-sectional - for a measured VBF of X mL/min, a 95% confidence interval for the true flow is X mL/min \pm 15%.

4.1.1.2. Claim 2: technical performance – the volume flow measurement has a within-subject coefficient of variation (wCV) < 20%.

4.2. Subgroup Updates

4.2.1. Paul Carson suggested adding the following (If we are confident enough of the profile, could drop the last sentence):

4.2.1.1. If using a different method than that described in the profile, the supplier may still claim compliance if it clearly states that it is a different method. Further, the supplier must demonstrate that the system provides measurements within the claimed bias and variance in this profile over the conditions claimed in the profile. If different, the supplier must also show that it meets or exceeds the performance of a QIBA compliant system in clinical use as well as in the QIBA phantom.

4.2.2. Dave Dubberstein suggested adding 3 words for clarity

4.2.2.1. No issue with the addition. Effectively, the specificity already in the profile locks out other methods.

5. Distribution of Current Volume Flow Profile

6. Matters Arising

Next full VBF BC is March 1, 2021 at 12:30 pm