



## AIUM/QIBA Ultrasound Volume Blood Flow Biomarker

### Summary 01-November-2021

Attendees: Brian Fowlkes, Michelle Robbin, Cristel Baiu, Nicole Lafata, CY Lee, Jing Gao, Stephen Pinter, Oliver Kripfgans, John Rubin  
AIUM Staff: Therese Cooper

1. Review of Previous Call Summary – 04-October-2021
2. Action Items
  - 2.1. New phantom drawings should be coming from Cristel soon reflecting suggested changes by the profile working groups.
  - 2.2. Abstracts for Ground Work Studies. Brian noted the potential for a groundwork study. There is an NIH R01 study that will review direct comparison between 3D volume flow and 2D volume flow in the umbilical vein. This will include 2 sonographers scanning the same patients to provide data on reproducibility. This could serve as a groundwork study. **Again, if you have an idea for an abstract let Brian know.**
  - 2.3. Brian has not heard from Dr. Zonnebeld so it is **difficult to figure out how to proceed with using that paper as part of the argument for profile performance targets. May need to figure out something else with this or let this part of the profile discussion go. TBD.**
3. Update on VBF Profile Discussions
  - 3.1. Review of current draft and updates from Profile Task Group
    - 3.1.1. Profile
      - 3.1.1.1. Brian F. has reorganized and archived older drafts in Basecamp. There was still some need for the documents to be clearly identified as the “current version”. **Brian will work further and send an update out to the group.**
      - 3.1.1.2. **Brian and Oliver K. are looking at the options for a follow up publication in Radiology that would indicate how additional analysis of the round robin study relates to the profile.**
      - 3.1.1.3. Jon R. has been working on additional references. Checked in with Dr. Wesley Lee at Baylor regarding the need for criteria on what constitutes constant versus pulsatile flow in the context of umbilical venous flow. Wondering if there is a distinction.

- 3.1.1.4. Discussed the differences among the methods used for mechanically-swept 1D and 2D arrays for the calculation of volume flow when pulsatility is present. The former relies on randomly acquired volumes over the cardiac cycle whereas the 2D array (at least the one in the Radiology paper) was using a cardiac gated acquisition where the volumes were reconstructed from similar points in the cardiac cycle. However, both were used just to compute the time average volume flow in the pulsatile mode of the QIBA phantom.
  - 3.1.1.5. Cristel explained that the QIBA phantom's pulsatile mode generates 46% of the flow produced at the same settings in the constant flow mode. **Brian mentioned that he will make a resistive index measurement and also spectral Doppler to see what the actual phantom is doing with regard to a resistive index.** This might help inform us of the nominal cut off between claims 1a and 1c.
  - 3.1.1.6. Discussed the redesign of the QIBA phantom. The overall design was acceptable to the group.
  - 3.1.1.7. Discussed the modification to the requirements for periodic QA. Now the text indicates that baseline testing should be performed on installation of a system (or its upgrade to perform 3DVBF) and then annually for the first two years and then as specified by the manufacturer going forward.
- 3.1.2. Checklist
- 3.1.2.1. Brian F. provided several comments in the document for consideration.
  - 3.1.2.2. Stephen will be consolidating and pairing the checklist down and moving sections around.
    - 3.1.2.2.1. He will be using the c-plane terminology throughout the checklist to simplify things for the operators.
    - 3.1.2.2.2. He will consider putting in some pictures as was done with the profile (maybe only do so by reference).
    - 3.1.2.2.3. There is some overlap with some of the other checklists.
    - 3.1.2.2.4. Some items might be eliminated with referral to the manufacturer specific instructions (protocols).
    - 3.1.2.2.5. It was suggest that perhaps getting the subgroup for this portion of the checklist together with the Clinician subgroup would be useful.
  - 3.1.2.3. We will need to determine if all the checklists are consistent with each other and with the profile.

#### 4. Matters Arising

Next full BC meeting is Wednesday December 1, 2021 at the RSNA. We will work to have virtual capabilities for joining this meeting.

Next Profile meeting is November 10, 2021 at 10:00 am ET.