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## **Performance Characteristics of a Novel Echocardiographic Contrast System**

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Presented at American Society of Echocardiography Scientific Sessions of 2022.

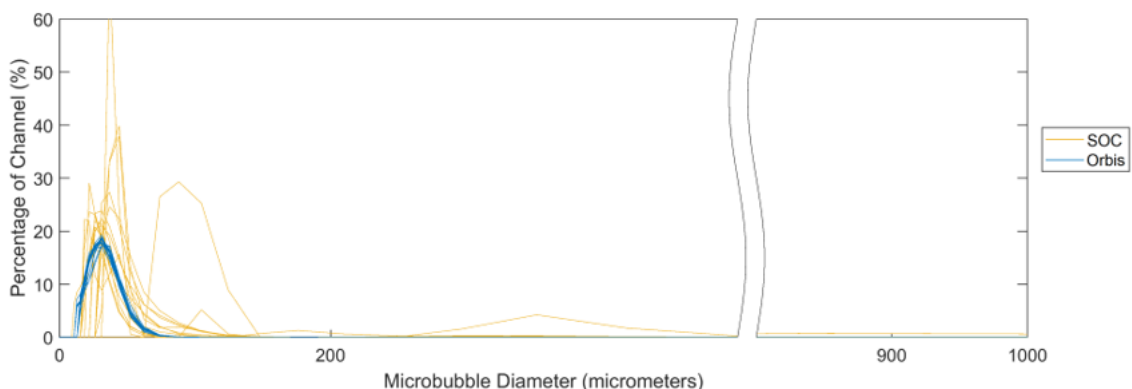
**Background:** Performance of bubble studies are an important part of the comprehensive echocardiographic examination, particularly in patients suspected of having a right to left heart shunt. Standard of care (SOC) for producing bubble studies has important limitations including: the need for additional trained personnel, inconsistent quality and risk to the patient if not performed properly. The Orbis device (Agitated Solutions) is a single-handed method of efficiently and safely generating microbubble contrast for use in echocardiography.

**Methods:** Physicochemical characterization of SOC and Orbis microbubble (MB) output was conducted using laser diffraction analysis on a multisizer Coulter counter with an aperture range between 0.0107  $\mu\text{m}$  to 2000  $\mu\text{m}$ . Assessment of peak enhancement (PE) and duration of enhancement (DoE) were measured *in vitro* with a tissue-mimicking phantom and *in vivo* utilizing a porcine heart model.

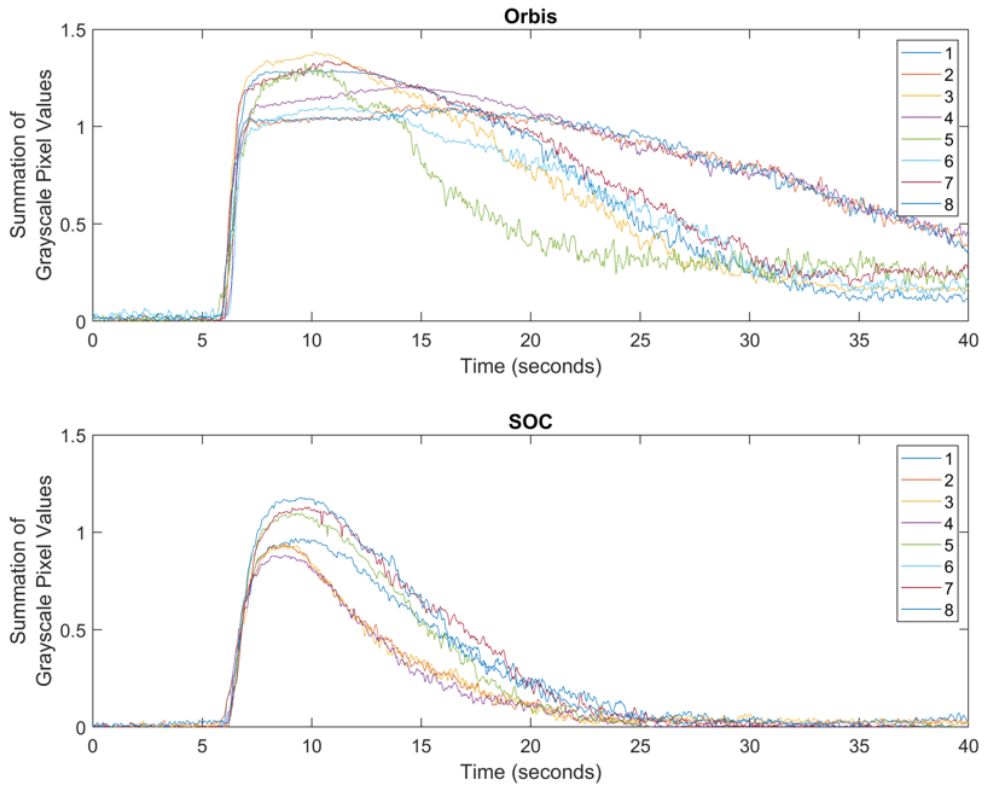
**Results:** The Orbis produced smaller and more consistent MB size (Fig 1) compared to SOC ( $27.9 \pm 0.57 \mu\text{m}$  v.  $39.9 \pm 23.3 \mu\text{m}$ ,  $p < 0.005$ ) with a significantly lower incidence of large ( $>104.7 \mu\text{m}$ ) bubbles ( $0.014 \pm 0.007\%$  v.  $4.18 \pm 11.2\%$ ,  $p < 0.005$ ). Orbis demonstrated increased PE as measured by grayscale (1.25 v. 0.93,  $p < 0.05$ ) and increased DoE (24.72s v. 7.47s,  $p < 0.05$ ) compared to SOC (Fig 2). Qualitative assessment of the *in vivo* study (Fig 3) found the Orbis produced a clear, diagnostically useful result.

**Conclusions:** The Orbis device allows the sonographer to independently produce microbubble contrast that is more effective, more consistent and potentially safer compared to the standard of care.

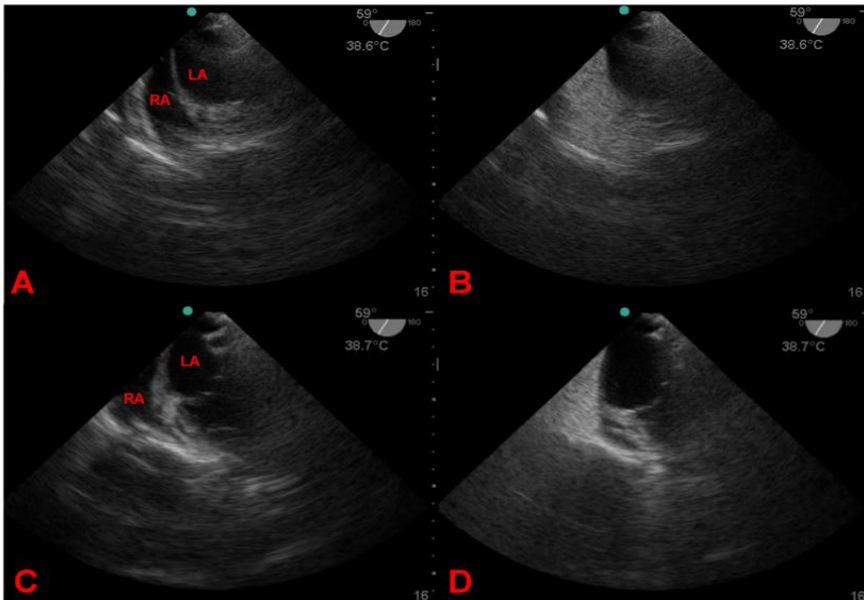
**Figure 1. Distribution of MB size for the Orbis device (n=15) and for SOC (n=15) measured with a Multi-sizer Coulter Counter**



**Figure 2. Comparison of *in vitro* time-course of the summation of grayscale pixel values for the Orbis device (n=8) and for SOC (n=8) to derive peak echogenicity and duration of enhancement**



**Figure 3. *In vivo* Four-chamber, Transesophageal Ultrasonic View of Domestic Yorkshire Pig (43kg) Heart utilizing SOC (A: Baseline, B: 5 seconds post-injection) and the Orbis (C: Baseline, D: 5 seconds post-injection)**



Financial Disclosure: The authors of this publication received compensation from Agitated Solutions, Inc. in conjunction with the research and/or are part-owners of the company.