2007, due to reports of patient deaths and serious cardiovascular reactions in patients who received the agents. So far, ultrasound contrast agents are used in a small number of procedures, mainly in cases where non-contrast imaging does not provide a definitive result.

In a discussion of the black box warning at the AHA sessions, Grayburn strongly disagreed with the FDA decision, since it was based on reports of four deaths that were not definitively attributable to the agent used. Grayburn urged physicians to petition the FDA to dispute the decision and argue against any restriction on the use of ultrasound contrast.

In the RAMP studies, only one significant adverse reaction (a hypersensitivity reaction) was observed in more than 650 patients who received Imagify. On the other hand, SonoVue, an ultrasound contrast agent from **Bracco International B.V.** (Amsterdam, the Netherlands) used in Europe, was suspended from use in echocardiographic imaging procedures by the European **Agency for Evaluation of Medicinal Products** (EMEA; London) in 2004.

Another barrier to adoption of ultrasound imaging as a replacement for nuclear imaging in cardiac perfusion testing is the attractive reimbursement structure for nuclear imaging.

According to suppliers of nuclear imaging equipment, the modality ranks as the most profitable of all imaging technologies for physicians. Reimbursement from Medicare for a nuclear scan is approximately $800, and vendors can offer physicians leasing programs that allow realization of net income of about $120,000 per year when performing only six scans per week.

New ultrasound instrumentation

New developments in ultrasound instrumentation were exhibited at the AHA conference by Siemens Medical and GE Healthcare.

Siemens introduced the Acuson P50, a new entry in the hand-carried ultrasound segment developed via a partnership with **Terason** (Burlington, Massachusetts).

The system consists of an Apple MacBook laptop computer mounted on an ultrasound platform from Terason, weighs 12 pounds, provides two hour battery life, and has a base price of approximately $40,000. It is aimed at applications in emergency medicine, including use in ambulances and other emergency response settings, as well as private practice.

Although the P50 does not provide equivalent image quality to Siemens' top-of-the-line Sequoia ultrasound system, it offers more analytical features. Siemens also offers a palmtop ultrasound system, the P10, weighing 1.6 pounds with a one-hour battery life priced at under $10,000.

GE Healthcare introduced the Vivid S6 cardiovascular ultrasound system, a mobile system designed for use in a wide range of settings including the hospital, clinic, operating room, and physician's office. The Vivid 6 provides analytical features such as Tissue Velocity Imaging and Tissue Synchronization Imaging, along with stress echo and transesophageal echo capabilities.

Heading to the web

A new system for non-invasive early detection of coronary ischemia was exhibited at the AHA conference by **Premier Heart** (Port Washington, New York). The 3DMP system is a web-based two-lead resting ECG analyzer used by physicians for quantitative detection of ischemia in early-stage coronary artery disease, i.e., when coronary artery narrowing is only 40-50%.

The system relies on a proprietary signal analysis technique developed by Premier that detects stress and strain properties of the heart which are related to coronary artery abnormalities.

The technology was developed using data from a study involving 28,000 patients with known coronary artery disease and 7,000 normal individuals. Good correlation has been observed between the 3DMP results and test results obtained using other modalities such as intravascular ultrasound, coronary angiography, and CT angiography.

The system has received FDA 510(k) clearance and is priced at $29,000. Premier believes the 3DMP system will not only prove attractive to physicians because of its ability to non-invasively detect individuals at risk of a myocardial infarction well in advance of an event, but also because of the attractive reimbursement of $200 to $300 per exam, which is significantly higher than for a standard ECG exam because the 3DMP qualifies as a signal-averaged ECG analyzer.

Continued Expansion of PCI

A number of advances in device technology for percutaneous interventional treatment of heart disease were also reported at the AHA sessions.

The controversy over DES safety continues, although new data discussed at the conference indicates that previously published results — such as the SCAAR registry data, which indicated excess mortality for patients receiving DES vs. BMS) — do not pertain to current practice.

Specifically, as discussed by David Holmes, MD, of **Mayo Clinic** (Rochester, Minnesota) at a session on off-label use of DES devices, the initial conclusions from the Swedish SCAAR registry were based on data from patients treated in 2003 to 2004, whereas more recent data from SCAAR, reflecting long-term follow-up of patients treated in 2005, indicates that DES devicess are superior to BMS with respect to the end-