treat analysis), but it was significantly lower when only those with adequate recordings were included.

Under the FDA's requirement for training, clinicians must be certified based on a written test and credentialed based on an oral exam that is administered after successful completion of at least five “practice cases,” according to Dr. Carey Corrado.

Physician certification is something the FDA’s advisory panel called for in June, and the FDA deliberately structured its training requirement to resemble the training that was required of clinicians in the U.S. bridging studies, she said.

Dr. Hankins questioned how such a requirement could be enforced and said that training is ultimately “under local purview.” When asked about enforcement, the FDA’s Mr. Pollard acknowledged the validity of the question and said that the agency’s authority “does not extend beyond the labeling.”

The STAN S31 system is indicated for use in patients with planned vaginal delivery greater than 36 weeks of gestation, a singleton fetus, vertex presentation, and ruptured amniotic membranes. Simon Grant, CEO of Neoventa, the monitor’s Swedish manufacturer, said the company intends to partner with a U.S. company to introduce the device to the U.S. market this year.

**The upper trace of this STAN S31 recording is the fetal heart rate, the bottom shows uterine contractions. The black flag above marks an ST-segment event.**

---

**References**