intubation and projected into the tracheobronchial tree, requiring rigid bronchoscopy for removal (if detected immediately) or leading to a significant range of complications, such as segmental atelectasis, obstructive emphysema, pneumonia, or even perforation.

After the detection of the problem, all blades at our institution were inspected, but none was found to have the same defect. Although this seems to be a rare finding, it is recommended to check the integrity of the laryngoscope blade on a regular basis. A quick inspection with manual pulling on the tip may help to prevent serious complications.

Igor Luginbuehl, M.D.,* Keith Matthews, R.T.  "University of Toronto, Hospital for Sick Children, Toronto, Ontario, Canada. igor.luginbuehl@sickkids.ca

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In Reply—We were most concerned to learn of the issue with the Fiber Optic Laryngoscope blade at the Hospital for Sick Children in Toronto. Both Mr. Matthews and Dr. Luginbuehl were very helpful in bringing the information to our attention and coordinating matters to ensure proper findings.

It is important to note that the blade was sent to us for further examination. We tested the blade completely and examined it completely through a high-power microscope. We were not able to determine exactly why the blade tip became separated; however, we believe that there may not have been sufficient soldering to hold the tip in place if the blade were to receive a shock of some kind. We can only speculate due to the fact that soldering matter could have fallen out after the tip separated.

It is important to note that Heine Optotechnik (Herrsching, Germany) has been manufacturing this product since 1983. Since that time, we have manufactured several million units. This is the first and only reported incident worldwide. We have investigated whether any possible claim was registered with the Federal Drug Administration, Health Canada, and European authorities. None was found.

Although our blades are single-piece blades, meaning that there is no disassembly possible, the blades actually have 12 parts. As with most products, one has several components that come together to form the whole. Heine has never claimed otherwise.

We see this incident as isolated and have taken additional precautions to verify all current inventories. Further, we are placing specific emphasis on this part of the manufacturing process to ensure this incident does not repeat itself.

It is important to note that Heine manufactures all products to the highest International Organization for Standardization Quality Standards. Our commitment is to manufacture the best products in class in the marketplaces we serve.

Ben St. Jean, Heine USA Ltd., Dover, New Hampshire. www.heine.com

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To the Editor—Pulse oximetry is a basic monitoring technology that we are all familiar with and can, at times, take for granted. In an operating room (OR), we can gain a great deal of information from the sound of the tone generated by the pulse oximeter without looking at the monitor. We can tell the patient’s saturation and easily detect any changes with it; we can tell the heart rate and detect any sudden changes. We can even catch arrhythmias if we have some experience and are paying careful attention. In recognition of the value of continuous audible information, a recent revision to the American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring requires that the “variable pitch pulse tone” be audible to the anesthesiologist when pulse oximetry is used.

After a recent change in pulse oximetry technology, we encountered a major problem that was not apparent during the trial, conversion period, or our early fully installed experience. We write this letter because we believe that this problem significantly erodes the reliability of this pulse oximeter as a monitor in the OR, and hence is of general interest to your readers.

The problem has been noticed only in the OR and documented twice, both times in September 2006. In these cases, the patient experienced a profound bradycardia, followed by a pause, and accompanied by a steady heart rate tone being produced by the pulse oximeter. In simple terms, the patient’s heart stopped and the pulse oximeter tone did not change, giving the anesthesiologist auditory input indicating that an asystolic patient was not having a cardiac arrest. During the entire period, the saturation displayed did not change. This behavior has only been observed in the OR, perhaps because the OR is the only place in our facility where the pulse oximeter is monitored acoustically. The electrocardiographic monitor correctly displayed a flat line during this period of cardiac arrest, but was not being monitored acoustically.

This problem can be easily duplicated with an automatic noninvasive blood pressure cuff. With a blood pressure cuff on the same arm as the pulse oximeter probe, we have found that the tone will continue through the noninvasive blood pressure cycle, even when the plethysmograph is flat and there is no palpable pulse. For a more quantitative trial, we have used a cuff and a manometer to occlude the arterial inflow to the arm. The oximeter pulse tone will continue for at least 8 s after the cuff has been inflated to a pressure 200 mmHg above the systolic pressure. Thus, there could be 8 s of asystole with no audible indication from the monitor to tell there has even been a change in the heart rate, let alone that the heart has stopped. Our bench testing indicates that if there is any motion artifact, this time is longer and may go on indefinitely under some motion conditions.

We have had discussions with Masimo Corporation (Irvine, CA) about the problem. Doug Harding, V.P. for Quality Assurance at Masimo, told us in November of 2006 that when their algorithm detects a low signal-to-noise ratio, it uses a calculated pulse rate to generate the pulse tone. This allows a tone to be generated even in low-signal (i.e., “noisy”) conditions such as motion or low perfusion. A side effect of this design choice is that a tone will continue to be generated even when there is no pulse for up to 8 s. Masimo have specified that their algorithm will detect asystole within 8 s and that the behavior we observed meets that specification. However, anesthesiologists depend on the pulse tone in the OR for a near-instantaneous alert to arrhythmias including sudden severe bra-
dyocardia and asystole. The current Masimo technology no longer provides this function, but since they have been informed of the problem, they have begun working on an algorithm adjustment to correct the problem. They new algorithm is expected to appear in stand-alone devices in early 2007. For integrated monitoring systems, this change will occur more slowly.

When new technology is introduced clinically, it may behave in ways that have not been anticipated. This behavior may not be discovered, even after an extensive and thorough clinical trial. Vendors must understand this and be willing to improve the design of their products to improve safety in all environments.

Ryan E. R. Forde, B.S.,† Frederic M. DeBros, M.D., Emily L. Guimarães, M.D., Warren S. Sandberg, M.D., Ph.D.*

*Massachusetts General Hospital, Boston, Massachusetts.
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Michael T. Petterson, R.R.T., Masimo Corporation, Irvine, California. mpetterson@masimo.com

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