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.

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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, this 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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Misleading Behavior of Masimo Pulse Oximeter Tone during Profound Bradycardia

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-

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dycardia 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.

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In Reply:—As described in the letter, after initial communication from Massachusetts General Hospital (MGH) on this topic, we provided MGH with a software update that allows the user to select either SmarTone (Masimo Corporation, Irvine, CA), which uses Masimo SET's sophisticated signal processing to enable saturation tones even during low signal-to-noise conditions, or a more traditional pulse tone algorithm, which uses signal morphology only, causing breaks in the tone in the presence of low perfusion or signal interference. We have been offering SmarTone as a user-selectable feature on our monitors for some time now. However, we believe it is important that users understand the value of SmarTone so that they can decide which pulse tone to choose for their particular needs.

The American Society of Anesthesiologists standard that Mr. Forde *et al.* at MGH cite as being diminished by the Masimo SmarTone algorithm is exactly the standard that many other clinicians believe we have enhanced. This American Society of Anesthesiologists standard was established in the context of oxygenation, which implies that tracking the pitch of the tone and thereby indicating changing saturation values was the true intent of the standard. With this understanding and the knowledge that interruptions in the pulse tone caused by low perfusion, motion, and electrical or other interference are common, causing frequent "false alarms" and decreasing the amount of time that the tone was available, we concluded that it would be of clinical value to decrease these interruptions in the pulse tone.

The pulse tone feature on many pulse oximeters is related to the morphology of the plethysmographic waveform, emitting a tone only when a clean pulse signal is recognized. In the presence of low signal-to-noise conditions, the arterial pulse waveform can be virtually impossible to distinguish when looking at the raw plethysmograph. In these instances, most other pulse oximeters either discontinue the tone until a valid pulse signal is recognized or sound a tone based on the noise frequency, one that is not indicative of the patient's pulse. This leads to frequent, long periods without audible information on oxygenation status or false low-saturation indications.

Masimo SET's unique signal processing algorithms, which include five distinct signal processing engines working in parallel, enable identification of the arterial pulse wave under far more of these difficult clinical conditions. This allows Masimo to provide a variable pitch saturation tone during periods of signal disturbance that would cause loss of signal or false saturation tones in conventional pulse oximeters. The SmarTone feature uses real-time signal morphology, similar to conventional pulse oximetry, to create the tone during periods in which the pulse can be clearly recognized. During periods wherein the pulse signal becomes obscured, Masimo uses its advanced signal processing algorithms to identify the pulse and provides a tone indicative of true oxygen saturation. Feedback from current and prospective customers has been overwhelmingly positive toward this feature.

The case reported in the MGH letter focuses narrowly on one aspect of the SmarTone feature. Because of the sophisticated signal processing involved, during periods of signal disturbance or low perfusion there can be up to an 8-s delay before the cessation of the pulse tone. This short delay is well within internationally recognized performance requirements for heart rate meter response to asystolic events.*

The letter makes reference to a bradycardic period preceding the asystole, during which the pulse tone continued. It is not clear that the surgical team was able to observe whether the pace of the tone was consistent with the rate of the bradycardia. It is likely that the Masimo device tracked the bradycardia, as evidenced by several independent and objective studies that have demonstrated the superior ability of Masimo SET to track sudden changes in heart rate.[1–3]†‡

The letter also suggests that a simulation using a blood pressure cuff reproduces this clinical scenario. Although these two scenarios may seem similar, they are actually very different because in one case the heart has stopped, whereas in the other a pressure cuff is occluding the flow from a beating heart. Our own pressure cuff testing, which is supported by the literature,[4–6] has proven that it is very difficult to occlude 100% of the blood pulsations on certain patients. Because Masimo SET has been shown to have superior low perfusion performance,[7–12] it may be the only pulse oximeter to continue to read during cuff inflation when weak arterial pulsations are present. We recently performed more than 100 cuff inflations on various subjects, using a dual bladder tourniquet inflated to 250 mmHg with a Masimo Radical pulse oximeter and a Nellcor N-600 (Nellcor-Covidien, Mansfield, MA) attached to the test arm. In every case, the Radical would display a reading during cuff inflation only if there was a visible arterial pulse wave in the plethysmograph, and it would zero out after the plethysmograph became flat. Overall, the results were inconsistent, with no clear pattern of either monitor (Nellcor or Masimo) zeroing out before the other, and neither monitor consistently zeroed out within 8 s of cuff inflation. We have captured a number of these cases on video and are pleased to share these results upon request.

As discussed above, after initial communication from MGH on this topic, we provided MGH with a software update that allows the user to select either SmarTone or a more traditional pulse tone algorithm. Initial feedback regarding this new software has been positive. Since early this year, SmarTone has been offered as a user-selectable feature on all of our products, allowing clinicians to decide for themselves which pulse tone to use, based on their clinical scenario.

We value the feedback and suggestions of our customers in helping us make our products the safest and best pulse oximeters in the world, and we appreciate the useful comments of the MGH team. We trust that giving clinicians the option of choosing whether to activate the SmarTone feature will provide them greater flexibility in making informed decisions regarding the clinical management of their patients.

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