0196-0644/$-see front matter

Response to Gayat et al

To the Editor:

Masimo manufactures the Radical-7, a multiwavelength Pulse CO-Oximeter that continuously measures noninvasive hemoglobin concentration (SpHb), which is the subject of a study by Gayat et al.[1] Masimo sincerely values the work of respected researchers such as Gayat et al and appreciates this opportunity to provide this letter to the editor.

In May 2008, Masimo received Food and Drug Administration (FDA) clearance for SpHb[2] and initiated a limited release, during which more than 50 hospitals used SpHb products, with positive results, including lifesaving experiences in which internal bleeding was detected earlier and otherwise-unplanned investigations that led to cancer diagnoses. Only after a successful limited release and additional product enhancements did we fully release SpHb in March 2009.

We are at a loss to understand why the study results reported by Gayat et al are so dramatically different from those of more than 10 other research centers. Our own pre- and postmarket testing comparing hundreds of SpHb measurements with laboratory hemoglobin has consistently shown 1 g/dL accuracy at 1 SD. Multiple studies have shown results similar to those in Masimo's testing, including a recent study by Johns Hopkins investigators in surgical spine patients.[3] The Gayat study showed more than 3 times greater variation than this study.

We have observed from the Gayat study and from cooperative discussions with the investigators that, first, the spot-check accuracy investigation was performed with a Radical-7 device that is "indicated for continuous monitoring" of SpHb and other parameters. Masimo received FDA clearance and CE marking for 2 devices specifically "indicated for noninvasive spot-checking" (Pronto and Pronto-7) and began selling the devices in the United States and Europe before the Gayat study began. Second, the device was not used in accordance with the directions for use. Instead of applying the sensor to the patient and then connecting the sensor to the device, the procedure was reversed, which may result in a suboptimal calibration sequence because the finger is often moving before proper fit is achieved. In addition, optical shielding was not used, which prevents external light interference that can corrupt the device's signal processing. Also, the investigators did not report the frequency of the low-signal-quality condition or separately analyze the SpHb values with and without the low signal quality. Last, the researchers used a reusable sensor and software that is 3 generations older than the current version, which has been available for more than a year.

Since the device's introduction, numerous studies have shown the clinically acceptable accuracy of SpHb, and a recent study at Massachusetts General Hospital using continuous SpHb monitoring showed an 87% reduction in blood transfusion frequency during orthopedic surgery, with no negative effect on patient safety.[4] This type of positive effect on clinical outcomes was not clearly shown with even pulse oximetry, which is now ubiquitous, until Masimo SET was introduced.

We believe we are at the leading edge of a noninvasive hemoglobin monitoring revolution that will improve patient care and reduce costs, just as pulse oximetry started to do 30 years ago. To fulfill the medical aspirations for SpHb, we

continue to encourage independent research to help us discover ways to further improve both continuous and spot-check SpHb applications.

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doi:10.1016/j.annemergmed.2011.02.028

Funding and support: By *Annals* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article as per ICMJE conflict of interest guidelines (see www.icmje.org). Michael O'Reilly, MD is the Chief Medical Officer of Masimo Corporation.

1. Gayat E, Bodin A, Sportiello C, et al. Performance evaluation of a noninvasive hemoglobin monitoring device. *Ann Emerg Med*. 2011; 57:330-333.
2. Masimo Corp. Masimo SET Radical-7 Pulse CO-Oximeter. 510(k) summary of the safety and efficacy. Available at: http://www.fda.gov/default.htm. Accessed January 27, 2011.
3. Berkow L, Rotolo S, Mirski E. Continuous and noninvasive hemoglobin monitoring during complex spine surgery. Presented at: the Society for Technology in Anesthesia Annual Meeting; January 12-15, 2011; Las Vegas, NV.
4. Ehrenfeld JM, Henneman JP. Impact of continuous and noninvasive hemoglobin monitoring on intraoperative blood transfusions. Proceedings of the 2010 Annual Meeting of the American Society Anesthesiologists. Abstract LB05. Available at: http://www.asaabstracts.com/strands/asaabstracts/search.htm. Published October 12, 2010. Accessed February 4, 2011.

In reply:

We are grateful to Michael O'Reilly for his comments about our article.[1] He highlights 2 important points: the definition of the accuracy of a diagnostic device and the possible inaccuracy related to its misuse.

To date, 3 peer-reviewed publications reported results on Radical 7 pulse oximeter accuracy[1-3]: 1 is positive[2] and 2 are negative.[1,3] Hahn et al[3] compared 680 invasive and noninvasive hemoglobin samples and reported that the noninvasive hemoglobin differed by 7.5% or more from the invasive hemoglobin in half of the measurements. O'Reilly highlighted that several unpublished studies have shown a consistent 1 g/dL accuracy at 1 SD. However, it is more usual to provide value of accuracy at 2 SDs, which corresponds to the limit of agreement, rather than at 1 SD. Moreover, the limit of agreement is only one part in the assessment of the accuracy of the diagnostic tool and on its own does not reflect the overall performance of the tool. Other results, such as mean bias and intraclass correlation coefficient, would be useful to assess the accuracy.

As pointed by O'Reilly, optical shielding was not used in our study but the operator's manual of the Masimo Radical 7 (available online at http://www.spectrummedicalgroup.com/ps/ar/eq/images/masimoradical7.pdf) recommended covering the sensor site with opaque material only in the case of high ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight. Finally, regarding the choice of applying the sensor to the patient first and then connecting the sensor to the device or doing the reverse, this constitutes a major limitation for the use of this device in the clinical settings if this sequence affects testing accuracy. A warning label should be inserted in the software to avoid any mistake.

We hope that Masimo Pronto 7, a newly released point-of-care device, will provide better results than Radical 7.

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doi:10.1016/j.annemergmed.2011.03.002

Funding and support: By *Annals* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article as per ICMJE conflict of interest guidelines (see www.icmje.org). The authors have stated that no such relationships exist.

1. Gayat E, Bodin A, Sportiello C, et al. Performance evaluation of a noninvasive hemoglobin monitoring device. *Ann Emerg Med*. 2011; 57:330-333.
2. Macknet MR, Allard M, Applegate RL 2nd, et al. The accuracy of noninvasive and continuous total hemoglobin measurement by pulse CO-oximetry in human subjects undergoing hemodilution. *Anesth Analg*. 2010;111:1424-1426.
3. Hahn RG, Li Y, Zdolsek J. Non-invasive monitoring of blood haemoglobin for analysis of fluid volume kinetics. *Acta Anaesthesiol Scand*. 2010;54:1233-1240.