

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

In the Matter of

CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF

Investigation No. 337-TA-1276

**STATEMENT OF THIRD PARTY
COMPUTER & COMMUNICATIONS INDUSTRY ASSOCIATION
IN RESPONSE TO THE COMMISSION'S JANUARY 31, 2023,
NOTICE OF REQUEST
FOR STATEMENTS ON THE PUBLIC INTEREST**

The Computer & Communications Industry Association (“CCIA”) submits the following comments in response to the Commission’s Federal Register Notice of January 31, 2023¹, inviting comments on the public interest in the above-referenced investigation. CCIA represents over two dozen companies of all sizes providing high technology products and services.² The proposed exclusion would harm U.S. consumers and the U.S. economy and have negative impacts on the public health and welfare.

CCIA notes that a public version of the FID was not available until February 7th, 2023, a week after issuance of the Notice. CCIA suggests that future public interest comment periods not start until such time as a public version of the ID or FID becomes available in order to provide third parties with a full opportunity for comment.

I. USE OF POTENTIALLY EXCLUDED ARTICLES IN THE UNITED STATES

The articles for which exclusion is sought are used for health and fitness purposes, as well as for communication, entertainment, and informational purposes. While these articles also have other uses, the articles focus significantly on health and fitness and the impacts of exclusion on consumer health and fitness in the United States might be significant.

II. PUBLIC HEALTH, SAFETY, AND WELFARE CONCERNS

The proposed exclusion order raises significant public health, safety, and welfare concerns. The Apple Watch provides a number of health, safety, and welfare functions that would be threatened by exclusion. For example, the ECG feature provided by the Apple Watch provides significant advantages to patients over other pre-existing technologies. Even experts on the side of those seeking to exclude the Apple Watch acknowledge that a separate ECG device is

¹ 88 F.R. 6312 (Jan. 31, 2023) (“Notice”).

² A list of CCIA’s members is available online at <https://www.ccianet.org/members>. Respondent Apple is a CCIA member, but took no part in the preparation of this comment.

an inadequate substitute to one that is always available on a user's wrist.³ And while Masimo seeks only to exclude devices with SPO₂ measurement capabilities, in practice this would involve excluding all Apple Watches with features like ECG measurement for atrial fibrillation detection. Thus, although Masimo does not seek exclusion of ECG devices specifically, the practical impact would be to exclude all of Apple's watches with ECG functionality.

Other features of this type include fall detection and pulse oximetry, as provided by Apple Watch Series 6 and later. These features also provide significant health benefits.

The blood oxygen (SPO₂) feature at issue here is of particular importance. Pulse oximetry provides a potential mechanism for detection of potential illnesses, including COVID-19. Numerous studies have confirmed the essential accuracy of the Apple Watch SPO₂ feature in comparison to medical SPO₂ devices, including those made by Masimo.⁴ This in turn contributes to potential health benefits. One example is assisting in the detection of sleep apnea.⁵ Sleep apnea is a common condition, occurring in at least moderate form in approximately 6.5% of adults. It is believed to be a significant contributing risk factor for obesity and cardiovascular disease, particularly hypertension.⁶ It is also frequently undiagnosed.⁷

³ ITC 337-TA-1266 Hearing Transcript at 292-293.

⁴ See, e.g., Rafl *et al.*, *Commercial smartwatch with pulse oximeter detects short-time hypoxemia as well as standard medical-grade device: Validation study*, 8 *Digital Health* (2022); Pipek *et al.*, *Comparison of SpO₂ and heart rate values on Apple Watch and conventional commercial oximeters devices in patients with lung disease*, *Sci. Rep.* 11, 18901 (2021); Spaccarotella *et al.*, *Assessment of Non-Invasive Measurements of Oxygen Saturation and Heart Rate with an Apple Smartwatch: Comparison with a Standard Pulse Oximeter*, *J. Clin. Med.* 2022, 11(6), 1467 (Mar. 8, 2022); Hearn *et al.*, *Measuring Arterial Oxygen Saturation Using Wearable Devices Under Varying Conditions*, 94 *Aerosp. Med. And Human Performance* 42 (Jan. 2023).

⁵ See Tamura, *Current progress of photoplethysmography and SPO₂ for health monitoring*, 9 *Biomed. Eng. Let.* 21, 31 (2019).

⁶ See Shamsuzzaman *et al.*, *Obstructive sleep apnea: implications for cardiac and vascular disease*, 290 *J. Amer. Med. Assoc.* 1906 (2003).

⁷ *Id.*

The Apple Watch also incorporates techniques to help eliminate the widely-reported issue of inaccuracy in measurement of SPO₂ in individuals of darker skin tone.⁸ As a result, exclusion creates the potential for racial inequity as well.

Exclusion of the subject articles could thus harm the health and welfare of a significant portion of the U.S. public and should be denied.

III. SUBSTITUTE ARTICLES MADE BY COMPLAINANT OR ITS LICENSEES IN THE UNITED STATES

The Notice requests comment on like or competitive articles made in the United States which could replace the subject articles if excluded. Masimo's public interest statement of July 19, 2021, identifies Masimo's own products, including their Radius PPG product, as potential substitutes. This is simply not credible.

The Masimo Radius PPG is a wrist-worn transmitter for a fingertip PPG sensor that relies on a separate host device. It is also only available by prescription. These are critical differences from the Apple Watch that prevent Masimo's device from being a direct substitute. The fingertip sensor required by the Masimo device can interfere with ordinary activities such as typing, rendering it significantly less useful for ongoing monitoring of SPO₂. The requirement for a prescription renders it useless for healthy individuals who might wish to monitor SPO₂ for fitness purposes or to detect unknown illnesses. Other Masimo products, such as the W1 watch, use a wrist sensor but lack many of the other features of the Apple Watch, such as atrial fibrillation detection, rendering it an incomplete substitute at best.

And even if the Masimo products are considered equivalent substitutes to the excluded

⁸ See Apple, *Blood Oxygen app on Apple Watch* (Oct. 2022), https://www.apple.com/healthcare/docs/site/Blood_Oxygen_app_on_Apple_Watch_October_2022.pdf (finding no detectable inaccuracy due to skin tone in a small laboratory trial).

articles, they do not appear to be manufactured in the United States but rather in Mexico.⁹ As a result, a denial of exclusion on public health and welfare grounds would not impact the production of competitive articles within the United States, as required by the relevant statutory provision, and this factor weighs against exclusion.¹⁰

IV. ABILITY TO REPLACE EXCLUDED ARTICLES IN A COMMERCIALY REASONABLE AMOUNT OF TIME

Even if Masimo or its licensees make products that could be substituted, it is not at all clear that the volume could be replaced in a commercially reasonable amount of time. Supply chain constraints, particularly with respect to electronics, continue to impact even global manufacturers such as automakers. Component supplies and assembly are significantly delayed. Masimo itself suffers from this issue, with Masimo’s CEO stating that Masimo was unable to fulfill its existing orders due to COVID-related supply shocks on a Q1 2022 preliminary earnings call.¹¹ This problem continues; in Masimo’s Q3 2022 earnings call, Masimo’s CFO stated Masimo “continue[s] to experience persistent pressures related to supply chain challenges.”¹²

Even if Masimo has navigated these challenges for existing demand for its own products, the notion that they could scale up production to the extent necessary to replace the excluded articles in a commercially reasonable amount of time lacks credibility given the acknowledged supply chain issues faced by Masimo and industry more generally. As a result, this factor also weighs against exclusion.

⁹ See, e.g., McKesson catalog page for Radius PPG sensor, <https://mms.mckesson.com/product/1163513/Masimo-Corporation-4585> (last visited Feb. 22, 2023).

¹⁰ 19 U.S.C. § 1337(d)(1) (“production of like or directly competitive articles **in the United States**”, emphasis added).

¹¹ Masimo Q1 2022 Earnings Call (May 3, 2022) (transcribed at <https://seekingalpha.com/article/4506484-masimo-corporation-masi-ceo-joe-kiani-on-q1-2022-results-earnings-call-transcript>).

¹² Masimo Q3 2022 Earnings Call (Nov. 8, 2022) (transcribed at <https://seekingalpha.com/article/4555088-masimo-corporation-masi-q3-2022-earnings-call-transcript>).

V. EXCLUSION OF THE REQUESTED ARTICLES WOULD HARM CONSUMERS

Consumers would experience a negative impact from exclusion. Consumers would likely be faced with an inability to obtain a replacement device, due to lack of substitute supply. As an alternative, they might obtain a separate pulse oximeter device, but such a combination is inferior to an integrated device. A consumer who does not already know they have an issue which might be indicated by SPO₂ measurement is unlikely to obtain a separate pulse oximeter. Such a device is not generally usable continuously, as it can interfere with ordinary activities. And in at least the instance of sleep apnea, a device which does not record data for later review but only displays a current value is useless, as the individual experiencing the apnea is asleep and would not be able to view the SPO₂ measurement.

The negative impact on consumers, and particularly on their health and welfare, is an additional factor weighing against exclusion on public interest grounds.

VI. THE COMMISSION WOULD BENEFIT FROM FULFILLING THE STATUTORY CONSULTATION REQUIREMENT OF 19 U.S.C. § 1337(b)(2)

Section 337(b)(2) requires that “the Commission shall consult with, and seek advice and information from, the Department of Health and Human Services ...”¹³ Here, both the domestic industry product and the articles sought to be excluded are FDA-regulated devices. The FDA, as a component of HHS, should be consulted in order to obtain additional information about the availability of substitutes and the impact on consumer health and welfare. Consultation on the impacts of exclusion with the Public Health Service, including NIH, may also be appropriate.

VII. CONCLUSION

Given that the statutory public interest factors weigh against exclusion, CCIA submits that the exclusion order should be denied on public interest grounds.

¹³ 19 U.S.C. § 1337(b)(2).

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Respectfully submitted,

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