



Masimo
52 Discovery
Irvine, CA 92618

Date: September 14, 2026

Re: Response to PFD Report

HM Coroner ME Hassel
Senior Coroner
Inner North London
St Pancras Coroner's Court
Poplar Coroner's Court
Bow Coroner's Court
London, UK

Dear HM Coroner Hassel,

We are in receipt of an email request from your PA, Ms. Anna Mazepina, dated August 13th, 2026, attaching a copy of your "Prevention of Future Death" report dated June 11th, 2026, addressed to Chief Executive, Masimo UK.

Unfortunately, this report was not initially received by Masimo, and therefore, the email from Ms. Mazepina was the first time Masimo was made aware of your report and the stated deadline for a response of August 6th 2026. We do apologize for this delay, which unfortunately was not within our control.

We are sorry to hear about this tragic case. Patient safety is at the heart of everything we do at Masimo, and we take all incidents of potential and actual patient harm very seriously. All such incidents are reviewed and assessed at the most senior levels.

In response to your report, I would like to assure you that all Masimo medical device alarm systems are designed in accordance with internationally recognized standards, including IEC 60601-1-8, which specifies requirements for the safety and essential performance of medical device alarms. The Rad-97®, which was the monitor at issue, has been designed and tested to meet these requirements. Consistent with IEC standards, the Rad-97® allows users to customize alarm settings to support specific clinical requirements, which may be impacted by varying clinical environments, patient populations, and monitoring objectives. Some of these requirements may include the ability to reduce the volume of, or silence, the audible alarm. The policy and protocols for alarm settings rest with each healthcare organization and are created based on recommendations from clinical users, clinical engineering, risk management, and governance.



Masimo
52 Discovery
Irvine, CA 92618

The Rad-97® Operator's Manual describes several configurable alarm features. The manual outlines Alarm Limit Testing and Speaker Testing procedures that should be performed following repairs and during routine maintenance activities.

The Operator's Manual includes the following safety information:

Warning:

Always ensure settings, including alarm limits and alarm speaker volume, are appropriate for each patient and consistent with facility protocols and the clinical environment prior to use. Devices in which the alarm speaker is not functioning properly, or where alarm volume cannot be distinguished from ambient noise levels, should not be used.

Caution:

To ensure alarm limits remain appropriate for the patient being monitored, verify alarm settings each time the Rad-97® is used.

The Rad-97® is shipped with factory default SpO₂ Alarm Volume setting to 4, which is the maximum volume setting. The device is also equipped with an Alarm Volume Lock feature, accessible through a password-protected configuration menu. If required by facility protocols, this feature can be used to increase the minimum alarm volume.

Although we consider all customer requests with the utmost care, we have no record of an approach by the Royal London Hospital to ask that the volume of Rad-97® alarms be either locked or at least set to maximum as a default. However, as stated above, the Rad-97® is shipped with the factory default SpO₂ Alarm Volume setting to 4, which is the maximum volume setting. Furthermore, as described above, in the event that the Royal London Hospital were to adjust its protocols for alarm settings, the device is equipped with an Alarm Volume Lock feature, which can be utilized to increase minimum volumes.

We continuously assess our products for improvement and compliance with relevant regulations. Any proposed changes to these products will undergo thorough regulatory assessments to ensure continued adherence to all applicable standards and requirements.

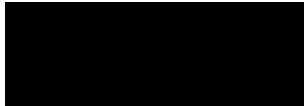
In summary, while we are saddened by this tragic event, Masimo can assure you that our monitor functioned as intended, and configurable alarm functionality is



Masimo
52 Discovery
Irvine, CA 92618

already available to address any changes in facility policies or protocols with respect to alarm volume settings.

Sincerely,



Masimo | Senior Vice President & Chief Medical Officer