

17-Nov-2025

HM Coroner's Court and Office for Manchester West
Paderborn House
Howell Croft North
Bolton
BL1 1QY
United Kingdom



Dear Mr. Brennand,

We acknowledge receipt of the Regulation 28 Report dated 17 October 2025, concerning the death of Melanie Jayne Walker. We wish to extend our sincere condolences to Ms. Walker's family and all those affected by her passing.

Philips takes matters of patient safety extremely seriously and is committed to working collaboratively with healthcare providers to continually improve the safety and effectiveness of our medical devices. We have carefully reviewed the matters of concern raised in Section 5 and the recommended actions in Section 6 of your report. We wish to provide the following information in response.

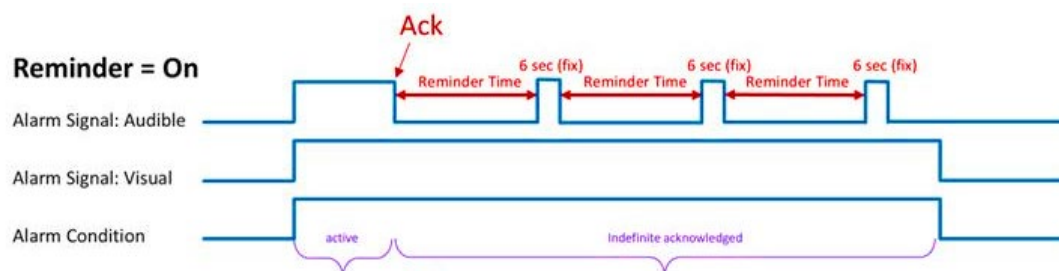
The Philips IntelliVue product line provides a range of alarm configuration options designed to support the diverse workflows and clinical environments found in hospitals. The following table summarizes the available alarm priority settings within the IntelliVue family.

Alarm Priority	Display Description
Low	<p>Visual alarm signals:</p> <ul style="list-style-type: none">The black alarm text is displayed on a cyan background color on top of the screen rotating with other alarms.A cyan alarm lamp is illuminated permanently. <p>Auditory alarm signals:</p> <ul style="list-style-type: none">An alarm tone conveying a low level of urgency is repeated every 2 seconds. <p>Acknowledgment:</p> <ul style="list-style-type: none">When alarm is acknowledged, alarm tone stops, and alarm lamp is switched off.No auditory alarm reminder or re-alarm option.
Medium	<p>Visual alarm signals:</p> <ul style="list-style-type: none">The black alarm text is displayed on a yellow background color on top of the screen rotating with other alarms.



Alarm Priority	Display Description
	<ul style="list-style-type: none"> A yellow alarm lamp blinks. <p>Auditory alarm signals:</p> <ul style="list-style-type: none"> An alarm tone conveying a medium level of urgency is repeated every 2 seconds. <p>Acknowledgment:</p> <ul style="list-style-type: none"> When alarm is acknowledged, alarm tone stops, and alarm lamp is switched off. Auditory alarm reminder or re-alarm is available when configured.
High	<p>Visual alarm signals:</p> <ul style="list-style-type: none"> The white alarm text is displayed on a red background color on top of the screen rotating with other alarms. A red alarm lamp blinks. <p>Auditory alarm signals:</p> <ul style="list-style-type: none"> An alarm tone conveying a high level of urgency is repeated every second. <p>Acknowledgment:</p> <ul style="list-style-type: none"> When alarm is acknowledged, alarm tone stops, and alarm lamp is switched off. Auditory alarm reminder or re-alarm is available when configured.

The factory default configuration of the "ECG Leads Off" technical alarm is medium priority (yellow) and includes an alarm reminder. As depicted in the graphic below, after an alarm configured with an alarm reminder is acknowledged, the reminder will provide an audible beep every one, two or three minutes (configurable) for six seconds until the alarm condition is resolved. This factory default setting is designed to ensure that a disconnected lead generates a prominent and persistent visual and audible notification.



Alarm Reminder Functionality

The factory default configuration of the "ECG Leads Off" technical alarm can be adjusted to low priority (cyan) either during installation or at a later time by authorized hospital staff using a password-protected menu. This configuration can also be inherited if monitor settings are transferred from another device where the alarm was previously set to low priority (cyan). The ability to modify alarm settings is provided to allow clinical sites to adapt the system to their local protocols and operational needs. However, Philips does not have oversight or control over changes



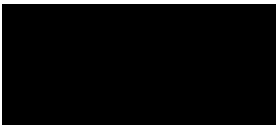
made at the customer site after installation, nor do we maintain records of such changes or the authorization process for them. In this instance, it is unclear when the adjustment from medium to low priority was made or who authorized the change. It is the responsibility of the clinical site to ensure that any changes to alarm configurations are made in accordance with their internal governance and patient safety policies. Additionally, clinical staff are expected to acknowledge and respond to alarms in line with their training and local procedures, and to ensure that patients remain appropriately monitored. As mentioned in the Regulation 28 Report, Philips has reset the "ECG Leads Off" technical alarm to the factory default configuration [medium priority (yellow)], which better suits the needs of this hospital.

Given that the equipment was supplied with appropriate factory default settings, and that subsequent changes were made at the customer level, Philips does not propose further action to the default configuration of the devices at this time. However, Philips is and remains dedicated to supporting customers in areas such as alarm management, offering education and guidance to hospital staff on configuring alarms to help reduce alarm fatigue while ensuring the patient receives the best care. Our clinical consultants collaborate directly with clinicians to optimize patient monitoring features, including alarm customization tools. This support also involves a thorough review of current practices and workflows, data analysis, recommendations for improvement, and assistance with implementing proposed changes.

We remain committed to patient safety and to working collaboratively with our customers to support the effective use of our equipment and trust this satisfies your concerns. We are, however, open to further discussions with the Bolton NHS Trust and the wider NHS England to determine how we can support further.

Should you have any further questions, please do not hesitate to contact me via email as indicated below.

Sincerely,



Director of Complaint Handling Operations
Hospital Patient Monitoring and Regulatory Inquiries

