Field Safety Notice

Philips Healthcare

PHILIPS

URGENT - Medical Device Correction
Philips IntelliVue Information Center

Use of Unapproved Hardware Can Impair Alarm Annunciation

Dear Customer,

Philips has become aware that some Philips Intellivue Information Center users have connected unapproved computer keyboards to their systems. These substituted keyboards have audio volume adjustment and muting controls, which allow users to easily mute audio alarms on the IntelliVue Information Center or to reduce their volume. Muting or reducing the volume of alarm annunciation can result in a delayed response to a patient whose condition triggers an alarm, particularly if users are not monitoring the system display and a bedside monitor with an alarm is not in use.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

These events highlight that some IntelliVue Information Center users have installed unapproved hardware and software that can adversely affect the performance of their systems. The Philips IntelliVue Information Center is designed and tested for use with specific computer and networking hardware and software, as specified in its labeling, and its performance cannot be ensured when other hardware and software is used.

Although the labeling for the IntelliVue Information Center already includes warnings about the use of hardware and software not supplied by Philips, we are expanding these warnings to explicitly state that their use can result in the loss of central monitoring—including alarm annunciation—or in degradation of monitoring performance. Please read the attached notice carefully and follow the "Action to be taken by Customer/User" section to help ensure that your Intellivue Information Center remains properly configured.

This issue has been reported to the appropriate regulatory agencies.

Please contact your local Philips representative at <Philips representative contact details to be completed by the KM / country> with questions or concerns about this correction.

Sincerely,

[redacted]

[redacted]
Sr. Manager of Quality & Regulatory Affairs

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AFFECTED PRODUCTS	IntelliVue information center Release L.0; 865138, 865139, 865140, 865141. 865142, 865146, 865148, 865149, 865150, 865151, 865152, 865153, 865157 IntelliVue information center Release K.0; 865091, 865092, 865093, 865094, 865095, 865091, 865008, 865102, 865103, 865104, 865105, 865109 IntelliVue information center Release J.0; 865001, 865002, 865003, 865004, 865009, 865010,865011, 865012, 862248 IntelliVue information center Release G.0 862173, 862176, 862175, 862174, 8621202, 8621203, 8621204, 8621205 IntelliVue information center Release F.0; 862124, 862125, 862133, 862126 IntelliVue information center Release E.01; 862067, 862068, 862069 IntelliVue information center Release D.00 – E.00; M3150B, M3151B, M3153B IntelliVue information center Release A.00-C.00; M3150A, M3151A, M3153A
PROBLEM DESCRIPTION	Philips has received reports of users replacing keyboards supplied or approved by Philips with multi-media-type keyboards. These substituted keyboards have audio volume adjustment and muting controls, which allow users to easily mute audio alarms on the IntelliVue Information Center or to reduce their volume. The alarm audio volume on bedside monitors and client devices connected to the IntelliVue Information Center is not affected. Although the Service and Installation Guide includes warnings about the use of hardware and software not supplied by Philips, it does not specify that ignoring the warning can result in loss of alarm annunciation or in the impairment of central patient monitoring.
HAZARD INVOLVED	If the audio level on an IntelliVue Information Center is reduced or muted, there may be a delayed response to a patient whose condition triggers an alarm, particularly if users are not monitoring the system display and a bedside monitor with an alarm is not in use. More generally, the use of hardware or software not supplied or approved by Philips may result in the loss of central patient monitoring, including alarm annunciation, or in the degradation of monitoring performance.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Intellivue Information Center systems can be connected to unapproved hardware. If you have a question or are unsure please contact your local service representative.

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ACTIONS PLANNED BY PHILIPS	Philips is providing all IntelliVue Information Center customers with an update to the Service and Installation Guide. This update expands existing warnings about the use of unapproved hardware and software products to include a statement that their use can result in the loss of central monitoring—including alarm annunciation—or in degradation of monitoring performance.
ACTION TO BE TAKEN BY CUSTOMER / USER	Provide a copy of the enclosed update to the Service and Installation Guide to the department or contractor responsible for service and maintenance of your IntelliVue Information Center, Also, ensure that a copy is added to your Service and Installation Guide. Periodically, review the equipment currently in use with your IntelliVue Information Center(s) to ensure only Philips-approved hardware is in use. Remind all users of the IntelliVue Information Center that servicing of equipment should only be performed by qualified service technicians identified by your institution.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative at <Philips representative contact details to be completed by the KM / country>.