

URGENT Field Safety Notice

Philips IntelliVue Patient Monitors

Potential for delayed treatment or adverse events when switching off Patient Monitor Alarms

DATE

<To: Name / Title / Customer Name

Street Address

City, State, Zip Code

<modify title block format as needed>

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 this letter for your records.

Dear Customer,

Philips takes the safety of its patients very seriously and appreciates the partnership through which we work to serve the patient community. In the spirit of patient safety, Philips would like to make you aware of complaints that have been reported related to a feature that allows switching off all Philips IntelliVue patient monitor alarms and the potential for harm. This notice is intended to explain the circumstances surrounding the complaints and the mitigations Philips recommends aimed at preventing hazardous situations from occurring:

What the problem is and under what circumstances it can occur

Philips IntelliVue Patient Monitors provide a feature for pausing all alarms for a configured timeframe or for switching all alarms off for an infinite period until they are switched back on by the user. The infinite Alarms Off feature is an important functionality in specific clinical environments such as the Operating Room, Cath lab or during resuscitations to reduce the audible alarms which may present unnecessary distractions during closely monitored procedures or interventions.

Philips has received complaints that the IntelliVue monitors did not alarm. In some cases, these complaints alleged delayed patient treatment due to the monitors not alarming; and, in some cases,

there were reports of severe patient harm or death. It was determined that in these instances the Alarms had been switched off for an infinite period, and the user may have been unaware that the alarms were off.

Monitor Alarming Behaviors: Philips IntelliVue monitors allow the customer to configure Alarm behaviors based on the needs of each clinical environment.

Configuration options allow the customer to: (1) enable/disable the infinite Alarms Off feature; and (2) if infinite Alarms Off is enabled, to require an additional confirmation to acknowledge infinite Alarms Off has been switched on.

Note: Configuration settings are determined by the customer when the devices are initially installed and can subsequently be changed under password protected control by authorized individuals should the needs of the clinical setting change. The infinite Alarms Off feature can only be activated on monitors where this feature is enabled.

Visual Indicators: When the infinite Alarms Off feature is enabled during configuration and is then activated at the point of care by the user, the device displays visual indicators (identified in Figure 1 and Figure 2 below).

Visual indicators include:

1. A white banner with red text “Alarms Off” or “Alarms Paused MM:SS” (time paused remaining in minutes and seconds) in combination with the alarms off symbol in accordance with IEC 60601-1-8 standard appears in the upper right corner of the screen.
2. A permanent (steady) indicator red light is illuminated on the top left of the monitor screen.
3. Alarm Off Symbols beside physiological values (only available with Software revisions P.01 and greater)

These indicators inform users of the current alarm setting.

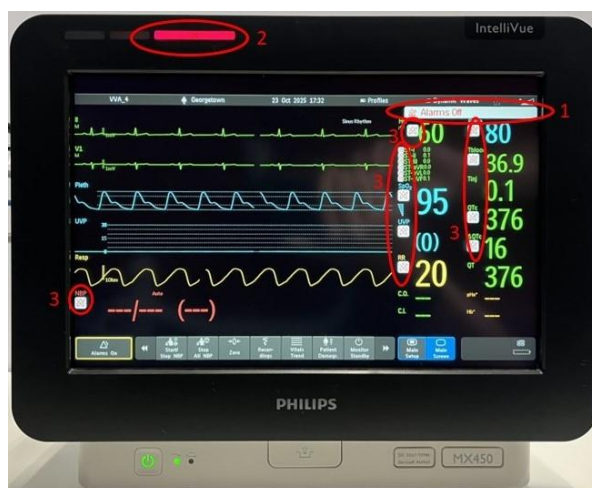


Figure 1. “Infinite Alarms Off” indicators

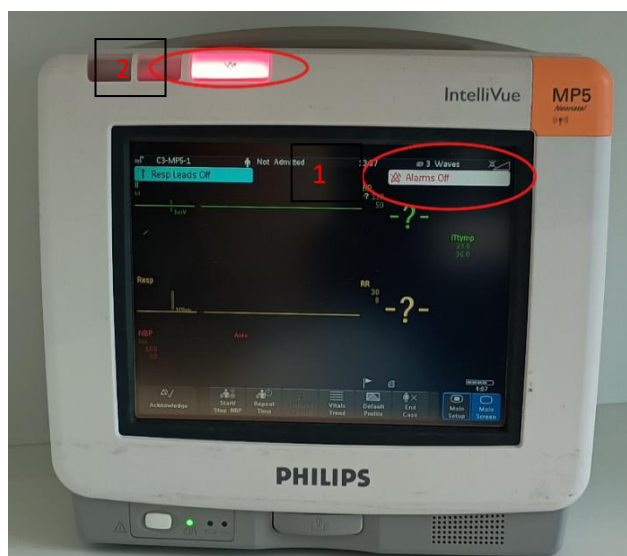


Figure 2. “Infinite Alarms Off” indicators

Hazard/harm associated with the issue

There is a hazard of unattended patient monitoring if an IntelliVue patient monitor is in use and the user unintentionally activated the infinite Alarms Off setting or a user is unaware that all Alarms have been switched off infinitely. Unattended patient monitoring with infinite Alarms Off activated could lead to delay of treatment resulting in severe patient harm or death.

Affected products and how to identify them

The Philips IntelliVue Patient Monitor MP series and MX series are identified below. The Product Number and UDI is on the product label on the back of the device:

Product Number	Product Name	UDI or UPC Number
M8102A	IntelliVue MP2	00884838000278
M8105A	IntelliVue MP5	00884838000230
M8001A	IntelliVue MP20	00884838000193
M8002A	IntelliVue MP30	00884838000155
M8003A	IntelliVue MP40	00884838000162
M8004A	IntelliVue MP50	00884838000179
M8005A	IntelliVue MP60	00884838000186
M8007A	IntelliVue MP70	00884838000209
M8008A	IntelliVue MP80	00884838000216
M8010A	IntelliVue MP90	00884838000223
M3002A	IntelliVue Multi Measurement Server X2	00884838000261
867030	IntelliVue Multi-Measurement Module X3	00884838082588
867033	IntelliVue Patient Monitor MX100	00884838082595
866060	IntelliVue Patient Monitor MX400	00884838038752
866061	IntelliVue Patient Monitor MX430	00884838057562

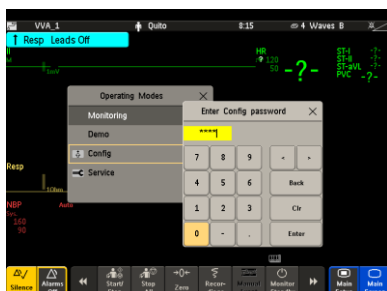
Product Number	Product Name	UDI or UPC Number
866062	IntelliVue Patient Monitor MX450	00884838038769
866064	IntelliVue Patient Monitor MX500	00884838038776
866066	IntelliVue Patient Monitor MX550	00884838038783
865242	IntelliVue Patient monitor MX600	00884838029095
865241	IntelliVue Patient Monitor MX700	00884838029088
866471	IntelliVue Patient Monitor MX750	00884838083332
865240	IntelliVue Patient Monitor MX800	00884838020733
866470	IntelliVue Patient Monitor MX850	00884838070790

Actions that should be taken by the customer / user to prevent risks for patients or users

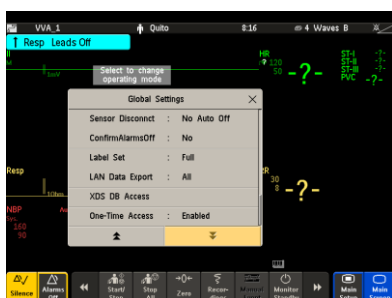
- Ensure that all users: (1) are aware of the risk related to activating the infinite Alarms Off feature, and (2) understand the existing visual indicators which indicate the Alarms Off status.
- Re-evaluate device configuration: Consider if the devices in the respective clinical environment require infinite Alarms Off functionality. Set the device configuration accordingly.
- Reconfigure: If the clinical environment requires the infinite Alarms Off functionality, enable the additional confirmation by the user to acknowledge the selection.

Changing manual configuration for additional confirmation of Alarms Off:

1. Enter the Configuration Mode by entering the Configuration Password

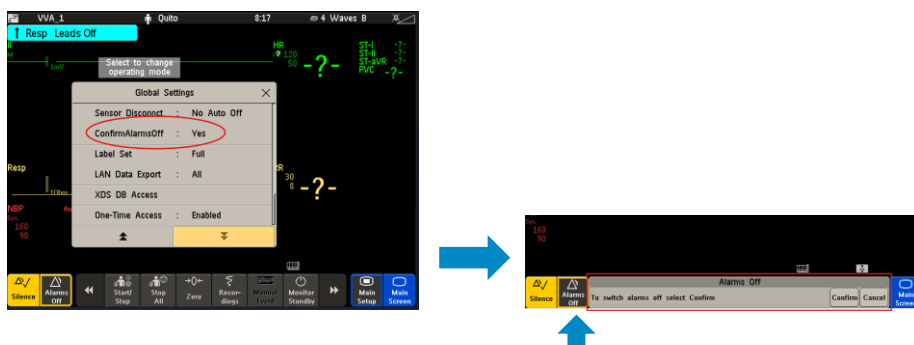


2. Navigate to *Global setting* by Main Setup > Global setting



- By Setting the *ConfirmAlarmsOff* to Yes , the Confirmation for alarms off is activated. When

 is pressed, the additional user confirmation is required. (See below)



Subsequently this configuration can be cloned to push this configuration to other monitors.

Actions planned by Philips to correct the problem

Philips is informing customers of the observed errors and related hazards of enabling infinite Alarms Off, including providing instructions on how to configure the device alarm settings. Philips recommends reviewing the configuration of the monitors with infinite Alarms Off functionality enabled and reconfigure settings to require additional confirmation to ensure users are aware of their action when activating infinite Alarms Off.

For IntelliVue MP5 models only: Philips is developing a software update which will enforce the additional confirmation step when the user enables infinite Alarms Off. To update your MP5 software to include this feature, please reach out to your local Philips representative.

Philips is also providing an educational video on this topic.

Scan the QR code or visit learn.philips.com to access the educational video on how to configure and use the infinite alarms feature in the Philips Learning Center (PLC). Enter your PLC username and password or create an account and then enter this enrollment key to access the video:

QR code:



If you need any further information or support concerning this issue, please contact your local Philips representative: **<Philips representative contact details to be completed by the Market/Business>**

The IntelliVue monitors continue to be compliant with applicable alarm standards, and this voluntary notice reflects important product information that the Company is sharing with customers .

Additionally, this notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

A handwritten signature in black ink, appearing to read 'Deborah Currin', with a stylized, flowing script.

Deborah Currin
Head of Quality, Hospital Patient Monitoring
Philips Healthcare

URGENT Field Safety Notice Response Form

Reference: Philips IntelliVue Patient Monitors - Potential for delayed treatment or adverse events when switching off Patient Monitor Alarms

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

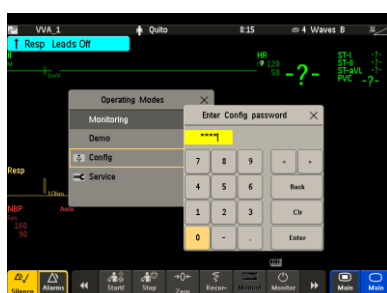
City/State/ZIP/Country: _____

Customer Actions:

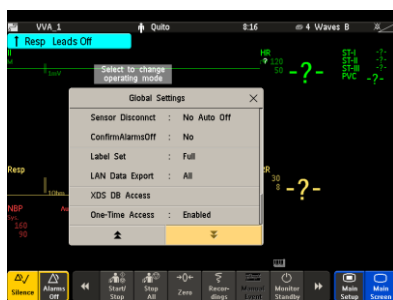
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Changing manual configuration:

1. Enter the Configuration Mode by entering the Configuration Password

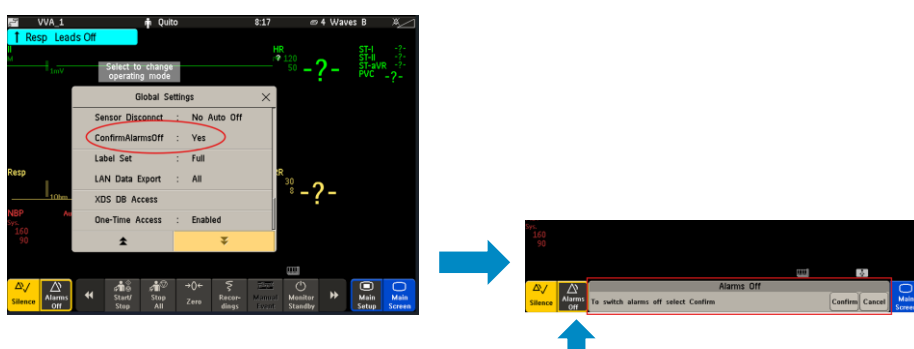


2. Navigate to *Global setting* by Main Setup > Global setting



3. By Setting the *ConfirmAlarmsOff* to Yes , the Confirmation for alarms off is activated. When

 is pressed, the additional user confirmation is required. (See below)



Subsequently this configuration can be cloned to push this configuration to other monitors.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that handle the affected product.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips at: **<Response Form return details to be completed by the KM/country>**