Field Safety Notice

PHILIPS

Philips Healthcare

URGENT – Medical Device Correction
Philips IntelliVue Clinical Information Portfolio Release D.0

Dear Customer,

Two problems have been detected in the scheduling function of the Philips Intellivue Clinical Information Portfolio Release D.0, which could pose a risk for patients. This medical device correction notice is intended to inform you about:

- what the problems are and under what circumstances they can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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.

Please see the attached **Device Correction Notice** that provides instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the notice.

I sincerely regret the inconvenience that this may cause you. Philips has a well-earned reputation for providing products and services of the highest quality. Correction of this issue is our highest priority. Your satisfaction with Philips' products and with our response to this issue is very important to us. Contact your local Philips representative if you have any questions or concerns: <Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]
Senior Manager, Quality and Regulatory Affairs

URGENT – Medical Device Correction
Philips IntelliVue Clinical Information Portfolio Release D.0

AFFECTED PRODUCTS	865047 Intellivue Clinical Information Portfolio Release D.0
PROBLEM DESCRIPTION	If scheduled orders are documented and edited prior to the orders' original schedule time, ICIP can create a second instance of the same order marked as pending, if the following conditions occur: 1. An order or intervention is entered as a scheduled administration and 2. A clinician charts the pending order earlier than scheduled and 3. A user/clinician changes, edits or acknowledges the order. Additionally, when an uneven order is scheduled to occur during the hour of a daylight savings time (DST) change, the system may cease generating pending orders after the transition to DST.
HAZARDS INVOLVED	If the clinical team is solely relying on the ICIP worklist for administration of pending orders, a second instance of an order may result in a patient receiving duplicate therapy. Similarly, clinicians relying solely on the worklist may not act on orders and patients may not receive their scheduled therapies, if ICIP ceases generating pending orders that it discontinued after a DST transition.
HOW TO IDENTIFY AFFECTED PRODUCTS	The product is identified on the splash screen when the device is turned on. The display will indicate Philips Intellivue Clinical Information Portfolio Release D. To identify the version, select HELP|ABOUT from the menu bar in the application.
ACTION TO BE TAKEN BY CUSTOMER / USER	Clinicians should not rely solely on the worklist within ICIP to determine actionable orders for the patient until their software is upgraded. Clinical users should always use the medication administration record (MAR) and the administration record in determining the care their patients receive in addition to the critical care worklist.
ACTIONS PLANNED BY PHILIPS	Philips is currently developing a software correction that will be available at no additional charge. A Philips representative will notify you when the software correction becomes available.

URGENT – Medical Device Correction

Philips IntelliVue Clinical Information Portfolio Release D.0

FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact <Philips representative contact details to be completed by the KM / country>

URGENT – Medical Device Correction
Philips CareVue Chart Release C.0

Dear Customer,

A problem has been detected in the scheduling function of the Philips CareVue Chart Release C.0, which could pose a risk for patients. This medical device correction notice is intended to inform you about:

- what the problems are and under what circumstances they can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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.

Please see the attached **Device Correction Notice** that provides instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the notice.

I sincerely regret the inconvenience that this may cause you. Philips has a well-earned reputation for providing products and services of the highest quality. Correction of this issue is our highest priority. Your satisfaction with Philips' products and with our response to this issue is very important to us. Contact your local Philips representative if you have any questions or concerns: <Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]

[redacted]
Senior Manager, Quality and Regulatory Affairs

URGENT – Medical Device Correction
Philips CareVue Chart Release C.0

AFFECTED PRODUCTS	862246 Philips CareVue Chart Release C.0
PROBLEM DESCRIPTION	If scheduled orders are documented and edited prior to the orders' original schedule time, CareVue Chart can create a second instance of the same order marked as pending, if the following conditions occur: 1. An order or intervention is entered as a scheduled administration and 2. A clinician charts the pending order earlier than scheduled and 3. A user/clinician changes, edits or acknowledges the order.
HAZARDS INVOLVED	If the clinical team is solely relying on the CareVue Chart worklist for administration of pending orders, a second instance of an order may result in a patient receiving duplicate therapy.
HOW TO IDENTIFY AFFECTED PRODUCTS	The product is identified on the splash screen when the device is turned on. The display will indicate Philips CareVue Chart Release C. To identify the version, select HELP|ABOUT from the menu bar in the application.
ACTION TO BE TAKEN BY CUSTOMER / USER	Clinicians should not rely solely on the worklist within CareVue Chart to determine actionable orders for the patient until their software is upgraded. Clinical users should always use the medication administration record (MAR) and the administration record in determining the care their patients receive in addition to the critical care worklist.
ACTIONS PLANNED BY PHILIPS	Philips is currently developing a software correction that will be available at no additional charge. A Philips representative will notify you when the software correction becomes available.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact <Philips representative contact details to be completed by the KM / country>

URGENT – Medical Device Correction
Philips IntelliVue Clinical Information Portfolio Release D.0

Dear Customer,

A problem has been detected in the scheduling function of the Philips Intellivue Clinical Information Portfolio Release D.02, which could pose a risk for patients. This medical device correction notice is intended to inform you about:

- what the problems are and under what circumstances they can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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 of this notice in an area that is visible to all users of the product.

Please see the attached **Medical Device Correction** that provides instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the notice.

I sincerely regret the inconvenience that this may cause you. Philips has a well-earned reputation for providing products and services of the highest quality. Correction of this issue is our highest priority. Your satisfaction with Philips' products and with our response to this issue is very important to us. Contact your local Philips representative if you have any questions or concerns: <Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]

Senior Director, Quality and Regulatory Affairs

URGENT – Medical Device Correction
Philips IntelliVue Clinical Information Portfolio Release D.0

AFFECTED PRODUCTS	865047 Intellivue Clinical Information Portfolio releases prior to and including D.02
PROBLEM DESCRIPTION	Due to a software defect that affects unevenly scheduled orders only, if a customer's system is not configured to create a new order after a change, and that order's unevenly scheduled frequency is subsequently changed and stored, the newly stored order will be regenerated based on the latest charted administration instead of current time. This may result in an intervention being created in the past. All subsequent interventions will appear with the newly intended scheduled time. (Unevenly scheduled orders are those that are to be administered a specific number of times per day but do not require even spacing of administrations in specific intervals).
HAZARDS INVOLVED	If the clinical team relies solely on the ICIP critical care worklist for administration of pending orders, this issue may result in a patient receiving inappropriate therapy.
HOW TO IDENTIFY AFFECTED PRODUCTS	The product is identified on the splash screen when the device is turned on. The display will indicate Philips Intellivue Clinical Information Portfolio Release D.0 through to Release D.02. To identify the version, select HELP|ABOUT from the menu bar in the application.
ACTION TO BE TAKEN BY CUSTOMER / USER	Do not rely solely on the worklist within ICIP to determine actionable orders for the patient until the software is upgraded. Always use the medication administration record (MAR) and the administration record in addition to the critical care worklist in determining patient care. Always review orders and pending administrations in the administration record after any changes are stored.
ACTIONS PLANNED BY PHILIPS	Philips is developing a software correction. A Philips representative will notify you when the software correction becomes available. The correction will be available at no charge.
FURTHER INFORMATION AND SUPPORT	Please contact <Philips representative contact details to be completed by the KM / country>