

URGENT – Field Safety Notice Philips Efficia CMS200 Central Monitor System

Dear Customer,

Philips has identified an issue that could impact the safety and/or performance of the Philips Efficia CMS200 Central Monitoring System. These issues are further detailed in the attached Field Safety Notice.

This Field Safety Notice is intended to inform you about:

- what the issue is and under what conditions it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- the corrective action planned by Philips to address the issue

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 Instructions for Use.

Please see the following pages, which provide information on how to identify affected devices and instructions on actions to be taken. Follow the “ACTION TO BE TAKEN BY CUSTOMER / USER” section of the notice.

It is imperative that all end-users with affected the Philips Efficia CMS200 Central Monitoring System as identified in the “AFFECTED PRODUCTS” section of the Field Safety Notice, receive this Device Correction Notice. Because Philips sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, send a copy of the attached package to any customer to whom you have distributed one of the affected devices. Be sure to include the:

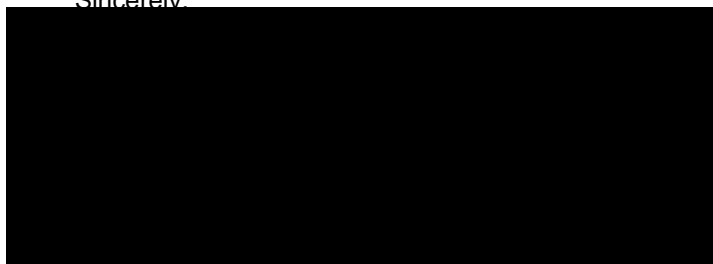
- Customer Letter
- Field Safety Notice

Note: Philips has sent this notification to all customers to whom Philips shipped directly (i.e. customers in the “Ship To” field on the original invoice).

In addition please provide your local Philips organization with the names and addresses of the customers to who you have sold affected devices, so that arrangements can be made to provide the correction.

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 KM / country>.

Sincerely,



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Philips Efficia CMS200 Central Monitor System

Dear Customer,

A problem has been identified with the Philips Efficia CMS200 Central Monitoring System which, if it were to occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken 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 Instructions for Use.

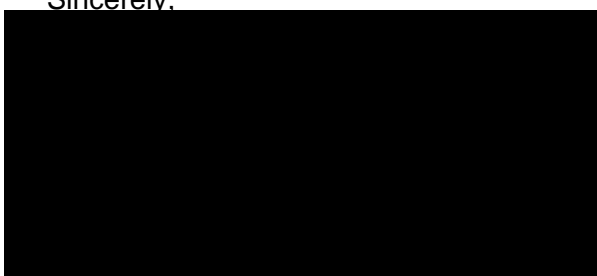
The Efficia Central Monitoring System B.01 is a commercial Central system communicating with monitoring devices via bi-directional TCP/IP network transport layer. Also, the 'Adult' patient category is the default category in B.01. In a specific combination of events, an unexpected alarm change to the default category on Central is pushed to the bedside Monitor without clinician acknowledgement; if the Neonatal or Pediatric patient's condition changes it could go undetected.

Philips is conducting this voluntary action to correct these devices. Please refer to the following page which provides instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the instructions.

This issue has been reported to the appropriate regulatory agencies.

I sincerely regret the inconvenience that this may cause you. Philips has a reputation for providing products and services of the highest quality. 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: at [<Philips representative contact details to be completed by the KM/country>](#).

Sincerely,



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<p>AFFECTED PRODUCTS</p>	<p>Model: 863352 Product: Efficia CMS200 Central Monitoring System Serial Numbers: USN1500006; USN1500008; USN1500009; USN1500007; USN1500004; USN1500005; USN1500003; USN1500029; USN1500028; USN1500010; USN1500015; USN1500016; USN1500017; USN1500002; USN1500018; USN1500019; USN1500011; USN1500036; USN1500035; USN1500031; USN1500030; USN1500038; USN1500039; USN1500042; USN1500043; USN1500044; USD1500048; USD1500045; USD1500047; USD1500046; USN1500032; USN1500034; USN1500037; USN1500040; USN1500041; USD1500054; USD1500050; USD1500049; USD1500051; USD1500052; USD1500056; USD1500057; US11600058; US11600060; US11600059; US11600061; US41600091; US11600062; US31600073; US11600063; US21600066; US21600067; US31600082; US21600064; US21600065; US21600068; US41600085; US31600069; US31600074; US51600105; US51600107; US51600106; US31600071; US31600075; US31600077; US31600078; US31600079; US31600081; US31600080; US41600084; US41600090; US41600086; US41600087; US41600088; US41600089; US41600092; US41600094; US41600095; US41600093; US41600096; US51600099; US51600102; US51600097; US51600098; US51600100; US51600101; US51600103; US51600109; US51600110; US51600111; US51600108; US51600112; US51600113; US61600115; US51600114; US61600116; US61600118; US61600123; US61600122; US61600117; US61600119; US61600121; US61600120; US61600125; US61600124; US61600126; US61600129; US61600130; US61600131; US61600132; US71600144; US71600145; US71600147; US71600148; US81600151; US61600133; US61600134; US61600135; US71600136; US71600138; US71600137; US71600139; US81600157; US81600158; US71600149; US71600150; US81600152; US81600155; US81600156; US81600160; US81600161; US81600162; US81600164; US91600165; US81600163; US91600167; US91600171; US91600172; US91600173; US91600177; US91600174; US91600175; USO1600182; US91600176; USO1600183; USO1600188; USO1600187; USO1600186; USO1600184; USO1600185; USO1600192; USO1600193; USO1600190; USO1600191; USO1600189; USO1600196.</p>
<p>PROBLEM DESCRIPTION</p>	<p>Philips has identified that it is possible that user could see the CMS200 showing Adult Alarm limits for Patients Type that is Neonatal or Pediatric.</p>
<p>HAZARD INVOLVED</p>	<p>This issue may occur when Pediatric or Neonatal Patients are being monitored on a bedside monitor without CO2 connected to a CMS200. If the clinician places the monitor in Standby, but does not turn the monitor off , and then brings the unit out of Standby, the CMS200 side alarm limits will convert to Adult Alarm limits (Alarm Limits are not visible on CMS200 Main Display). If the clinician doesn't acknowledge this change and goes to disable or change any given alarm limit at the CMS200, it causes the CMS200 to push adult alarm settings to the bedside monitor. The monitor may not alarm appropriately for a pediatric or neonatal patient.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>The AFFECTED PRODUCTS section of this notice lists the models, product numbers and serial numbers affected by this correction. The product, model, and serial number are located on the identification label on the rear of the device.</p>
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>Here's the workflow to avoid the risk referred to in the FSN:</p> <p>Option A: For any neonatal or pediatric patient, if the bedside monitor (without CO2) is connected to CMS200, do not place the bedside monitor in Standby when the patient is transported to a procedure. This will allow the alarms limits to work properly. Contact your service provider to determine the settings of your system and change if necessary.</p>

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	<p>Option B: For any neonatal or pediatric patient, if the bedside monitor (without CO2) connected to CMS200 is placed in Standby when the patient is transported to a procedure; when the same patient returns to unit and is placed back on monitor, take the following steps:</p> <p>If clinician needs to disable or change alarm limit at CMS200 side, he/she needs to discharge this patient at CMS200 side first, and admit same patient ID again. (Reference: Instruction for Use, Document Number 4535 645 61281, Page 89 of 199, section: Discharging a patient) This will allow the alarms limits to work properly. Contact your service provider to determine the settings of your system and change if necessary.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philip will correct the issue free of charge by providing a free Software upgrade, for the CMS200 to B.01.02. A Philips Healthcare representative will contact you to arrange for the correction.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need any further information or support concerning this issue, please contact <Philips representative contact details to be completed by the KM / country>.</p>