Class 2 Device Recall IntelliVue MX40 Wearable Patient Monitor in use with the Philips IntelliVue Information Center iX (P[6]

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Class 2 Recall IntelliVue MX40 Wearable Patient Monitor in use with the Philips IntelliVue Information Center iX (P

See Related Information[21]

Date Posted	June 10, 2014
Recall Status[1]	Open
Recall Number	Z-1746-2014
Recall Event ID	68349[22]
Product	IntelliVue MX40 Wearable Patient Monitor in use with the Philips IntelliVue Information Center iX (PIIC iX); 865350, 865351, 865352
Code Information	Serial numbers within the following ranges that have the MX40 interfaces: 00700001 - US01443745 and US014Z1301 - US014Z1431
Recalling Firm/ Manufacturer	Philips Medical Systems, Inc. 3000 Minuteman Rd Andover, Massachusetts 01810-1032
Consumer Instructions	Contact the recalling firm for information Contact the recalling firm for information
For Additional Information Contact	Peter Ohanian 800-722-9377
Manufacturer Reason for Recall	IntelliVue MX40 (part numbers 865350, 865352) with software revisions B.00 or B.01 may not resume alarming when the alarms are paused and the pause timer ends.
Action	On May 22, 2014, each affected customer was sent an Urgent Medical Device Correction notification/Field Safety Notice. The letter explains the problem, explains the action to be taken by the consumer, and the action planned by Philips. The Urgent Medical Device Correction notification/Field Safety Notice informs customers of the issue, identifies details of the units affected, gives instructions on actions to be taken by the customer and identifies what action Philips plans to take to remedy the issue. The correction will consist of a free of charge software upgrade. A Philips Healthcare representative will contact customers with affected devices to arrange for service. Philips is asking customers to follow the Action to be Taken by Customer/User section of the Urgent Medical Device Correction notification/Field Safety Notice: The following two items must be configured when using MX40 with the IntelliVue Information Center iX: 1. Utilize the default state of Pause Alarms at Yellow only, which disables the ability to Pause/Suspend all Red level alarms Utilize the default state of Remote Suspend Alarms as Off, which disables the use of the Pause Alarms feature at the MX40 device.
Quantity in Commerce	42,600
Distribution	United States: Nationwide Foreign Countries: Germany, Austria, Finland, Sweden, Australia, Qatar, Canada, Netherlands, New Zealand, Portugal, United Kingdom, Spain, Belgium, France, Switzerland, Norway, Czech Republic, Poland, Italy, Singapore, Denmark, Iceland, India, Saudi Arabia, Ireland, Oman, Bahrain, Japan, Israel, Malaysia, South Africa, Turkey, Thailand, Latvia, Bulgaria, Indonesia, Slovenia, United Arab Emirates, Hong Kong, Aruba, Chile, Lebanon, Korea, Kuwait, Taiwan, Argentina, Hungary, Luxembourg, Mexico, Gabon

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]