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

Date Posted: June 10, 2014
Recall Status: Open
Recall Number: Z-1746-2014
Recall Event ID: 6834922
Product: IntelliVue MX40 Wearable Patient Monitor in use with the Philips IntelliVue
Information Center IX (FiIC IX); 865350, 865351, 865352
Code Information: Serial numbers within the following ranges that have the MX40 interfaces: 00700001
- US01443745 and US014371301 - US014Z1431
Recalling Firm/Manufacturer: Philips Medical Systems, Inc.
Information Contact: Peter Ohanian
For Additional Information Contact: 800-722-9577
Manufacturer Reason for Recall: IntelliVue MX40 (part numbers 865350, 865352) with software revisions 8.00 or 8.01 may not
to 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 §7.56