ZOLL®

269 Mill Road
Chelmsford, Massachusetts 01824-4105

978-421-9655 (main)
978-421-0010 (fax)
www.zoll.com

Urgent Medical Device Correction
X Series/PropaqMD/PropaqM Defibrillator/Pacemaker/Monitor
With System Software Version 02.10.02.00 or Higher

ZOLL X Series/PropaqM/PropaqMD Defibrillator/Pacemaker/Monitor May Latch in a Continuous Device Reset Loop

March 5, 2014

Dear Customer,

ZOLL Medical Corporation has decided to conduct a field corrective action on certain X Series/PropaqMD/PropaqM devices. This letter describes the issue and corrective actions that should be taken to address the problem.

We have received 8 field reports where the device displayed an *Internal Error Reset Required* message and then entered a continuous "system reset" loop. The device cannot be used if it is in a continuous system reset loop. There have been no reported adverse patient events associated with this issue.

Our investigation has identified a software error associated with the device "full disclosure log." We have determined that this may occur during specific conditions, and in particular only when the full disclosure log reaches its memory capacity (150 cases). The error is caused by invalid data in the overwriting of a full disclosure log. The probability of having an event is low under normal operating conditions. Although the probability is low, the following actions should be taken on all affected devices:

AFFECTED DEVICES

All X Series/PropaqMD/PropaqM monitor/defibrillators running software version 02.10.02.00 or higher. Refer to attached instructions to identify your device's software version.

REQUIRED ACTIONS

Customers who have affected devices should immediately take the following steps:

(1) **Alert all users of X Series/PropaqMD/PropaqM to this problem.**

(2) **Direct users to immediately erase the device full disclosure log per the attached instructions. Users should continue to erase the device log once/month (or before 150 cases are stored in the log) until the device software has been updated.**

(3) **Complete and return the attached form via fax, email, or regular mail in order to receive the corrective software update (Version 02.16.04.00)**

(4) **Install Version 02.16.04.00 on all affected devices.** This version of software will correct the invalid data that leads to the device resets.

We have notified the FDA and other regulatory agencies of this corrective action and expect it to be classified as a recall.

We apologize for any inconvenience this may cause you and thank you in advance for assistance in implementing this corrective action. Avoiding this problem during clinical use is our highest priority. Our 24/7 technical support numbers **1 (800) 348-9011** or **+1 (978) 421-9460** are available to assist users with any aspect of this notice.

Sincerely,

[redacted]

VP Quality Assurance & Regulatory Affairs

Identifying Device Software Version

Perform the following steps to verify the X Series/PropaqMD software version:

1. Ensure device has been powered off for at least 2 minutes.
2. Power-on device.
3. Upon powering up, the device will print a short strip which identifies the device's software version (highlighted below):

ID: Patient 0717
Patient Mode: Adult
03/04/2014 11:35:31

Dept:
Unit:
S/N: AR121001872
SW Rev: 02.09.04.00

Clearing the Log

Note: If you'd like to save the data in the full disclosure log prior to deleting it, transfer it from the unit using a USB transfer device (please refer to Chapter 21 of the device's Operator's Guide for instructions).

You should clear the full disclosure log after transferring data to the USB device.

Note: Clearing the log during patient treatment results in the loss of all patient data and events recorded prior to clearing the log. Clearing the log creates a New Patient record and all patient-specific parameters (alarm limit, defibrillation energy, etc.) are set to their default values.

To clear the log:

1. Press  .
2. Press 

.
3. Press the Clear Log quick access key ( ).
3. Use the navigation keys to select **Yes**.

Note: An *UNABLE TO READ LOG* message indicates that the log contains no information. This message can occur if you clear the log and then immediately enter the Treatment screen or the Trend Summary screen.

Urgent Device Correction
ZOLL X Series Defibrillator/Monitor
Software Version 02.10.02.00 and Higher

Please complete *Section 1 and Section 2* below to receive Software Upgrade Kit.

You may MAIL or FAX this completed form to:

DCA Coordinator
ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105

FAX: 978-421-0010

OR EMAIL the following information to RegulatoryTeam@ZOLL.com

- Subject Line: X Series DCA
- Telephone, Email Address, and Shipping Address
- Your name and title

Section 1: Software Request

☐ Check here if you would like us to mail a Software Kit
☐ Check here if you have devices in multiple locations and need multiple Software Kits

Section 2: Your Contact Information to ensure successful shipment of New Software

Telephone:	
Email Address:	

Ship To

Facility Name:	
Address:	
City:	
State:	
ZIP:	
Country:	

Requested By: _____
PRINT NAME SIGNATURE

_____
TITLE DATE

***If you need assistance with this form, please call 1-800-348-9011 or email RegulatoryAffairs@ZOLL.com**