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December 03, 2013 URGENT MEDICAL DEVICE CORRECTION Propaq LT / Propaq 802 Models 802LTAN, 802LTON, 802LTRN

Dear Welch Allyn Propaq LT Customer:

Purpose of Letter: We are writing to inform you that fault conditions relating to hardware or software failure or electrical noise caused by proximal defibrillation activity could, in rare instances, potentially interrupt Propaq LT device operations.

Manifestation of Issue: If this unlikely issue were to occur, the device would either present an error screen instructing the user to restart the monitor, or could instead present a blank or white screen. Either screen would be accompanied by one or more blinking LED lights, and in either case, the issue would be resolved by restarting (power cycling) the monitor. This potential problem was identified as a result of product testing, and Welch Allyn has not received any complaints relating to this issue.

Potential Risk: There is no risk associated with this issue other than a very short delay in obtaining patient vital signs from the Propag LT while the device is restarted.

Affected Devices: Only Propaq LT models 802LTAN, 802LTON, and 802LTRN, all of which incorporate Nellcor SpO₂, are affected by the potential problem.

Serial numbers include Propaq LT devices with the Nellcor SPO2 (Model numbers 802LTAN, 802LTON and 802LTRN) within the range of KA002129 through KA027191 and the following serial numbers: KA050687, KA124186, KA 21398, KA21399, KA21407, KA21591, and KA25981.

Customer Actions: In the unlikely event that operation of your Propaq LT is interrupted and the display becomes blank or white, <u>pressing the power (on/off) button</u> will restart the device and quickly bring it back to full operational capacity.

This notice should be passed on to all those who need to be aware within your organization, or to any organization where the potentially affected devices have been transferred.

Welch Allyn Long Term Correction: Welch Allyn will utilize service processes to update your device with software that will resolve this potential issue:

Welch Allyn is in the process of developing a software installation service tool that will enable
installation of the software update by your biomed, IT staff or other technically qualified personnel.
Upon release, the service tool will be made available to you via a download from Welch Allyn's website
at www.welchallyn.com/PropagltUpgrade or other media.

2. In the meantime and on an on-going basis, the software update will be included if you schedule routine or other service with Welch Allyn or an authorized service provider.

Should you have any questions or concerns, please feel free to contact Welch Allyn Technical Support at 1-800-535-6663.

Regards,

Pearley Bhambri

Director, Regulatory Affairs

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Welch Allyn, Inc.