

 Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, Ireland.	<b>URGENT: Field Safety Notice</b>	WA13-01-01
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**Applies to Welch Allyn Propaq LT / Propaq 802  
Models 802LTAN, 802LT0N, 802LTRN  
Welch Allyn Ref: WA13-01-01**

Details on affected devices:

Propaq LT Vital Signs Monitor (Propaq 802) device with Nellcor SP02. The affected models are 802LTAN, 802LT0N and 802LTRN, serial numbers X to X.

Dear Welch Allyn Propaq LT Customer:

We are writing to advise you of a planned correction to our software with regard to a subset of our Propaq LT Vital Signs Monitor (Propaq 802) device with Nellcor SP02. The affected models are 802LTAN, 802LT0N and 802LTRN, serial numbers X to X.

Problem Description:

Internal product safety testing conducted by Welch Allyn has identified fault conditions relating to hardware or software failure or electrical noise caused by proximal defibrillation activity that could, in rare instances, potentially interrupt Propaq LT device operations. If this unlikely event 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. There is no risk associated with this issue other than a very short delay in obtaining patient vital signs from the Propaq LT while the device is restarted. Welch Allyn has not received any reported complaints relating to this issue.

**In the unlikely event that your unit should exhibit a blank or white screen/interrupted device operation condition occur, pressing the power (on/off) button will restart the device and quickly bring it back to full operational capacity.**

As a long term correction, Welch Allyn will utilize its routine service processes to update your device with software that will resolve this potential issue:

1. If you have a service agreement with Welch Allyn, we will update your device when you next schedule routine or other service.
2. If you do not have a service agreement with Welch Allyn, please contact us on Tel: (1800 \*\*\* \*\*\*) and we will coordinate the update of your device with your own routine preventive maintenance schedule.

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

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

This notice has been communicated to your local Regulatory Agency.

Yours sincerely,

Paul Reynolds,  
Director, International Quality Assurance & Regulatory Affairs