



Welch Allyn Limited,
Navan Business Park,
Dublin Road,
Navan,
Co. Meath,
Ireland.

URGENT: Field Safety Notice

WA13-01-02

Follow up to WA13-01-01
Applies to Welch Allyn Propaq LT / Propaq 802
Models 802LTAN, 802LT0N, 802LTRN
Welch Allyn Ref: WA13-01-02

Details on affected devices:

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

Dear Welch Allyn Propaq LT Customer:

Recently you received a letter from Welch Allyn regarding your Propaq LT / Propaq 802 device. We are following up from this letter to inform you that Welch Allyn has developed a software installation service tool which is now available to download for your Propaq LT Vital Signs Monitor.

Background to this, as per our original letter, (WA13.01.01) is as follows:

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. Only Propaq LT models 802LTAN, 802LT0N, and 802LTRN with serial numbers KA002129 through KA027191, KA124186 and KA25981, all of which incorporate Nellcor SpO₂ are affected by the potential issue. Other Propaq LT models and serial numbers not listed here do not require this software update.

The released software installation service tool will enable installation of the software update by your biomed, IT staff or other technically qualified personnel. The service tool is now available to download from Welch Allyn's website at the following web address:

<http://www.welchallyn.com/propaqltupgrade>

As per our original letter, this software update will also be included if you schedule routine or other service with Welch Allyn or an authorised service provider.



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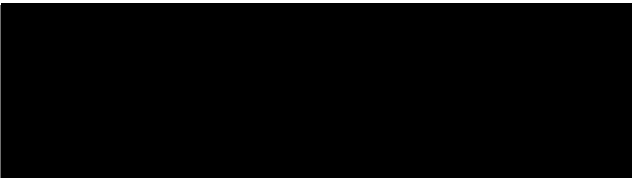
This notice should be passed on to all those who need to be aware within your organisation, or to any organisation where the potentially affected devices have been transferred.

Should you have any questions or concerns, please feel free to contact Welch Allyn Technical Support at:

<i>Denmark · 46 (0)858 536 551</i>	<i>Spain · 34 91 749 9357</i>	<i>Italy · 39 026 968 2425</i>	<i>Austria · 49 (0) 695 098 5132</i>
<i>Norway · 46 (0)858 536 551</i>	<i>Finland · 46 (0)858 536 551</i>	<i>BeneLux · 31 20 206 13 60</i>	<i>Germany · 49 (0) 695 098 5132</i>
<i>Portugal · 34 91 749 9357</i>	<i>Sweden · 46 (0)858 536 551</i>	<i>France · 33 (0) 141 475 656</i>	<i>Switzerland · 49 (0) 695 098 5132</i>
<i>UK 0207 · 44 (0)365 6780 Option 3</i>	<i>All other EU countries: · 44 (0) 207 365 6780</i>	<i>Middle East · 44 (0) 207 365 6780</i>	

This notice has been communicated to your local Regulatory Agency.

Yours sincerely,



Director, International Quality Assurance & Regulatory Affairs