

Urgent Field Safety Notice Connex Spot Monitor

2018-09-14

Reference Number: WA18-01-01

Action: Device Modification

Dear Welch Allyn Customer:

Background: Internal testing at Welch Allyn has indicated Connex® Spot Monitors with Masimo® SpO₂ do not meet the 3rd edition IEC60601-1-2 standard testing for Electrical Fast Transients and Bursts (EFT) and Radiated Immunity (RI).

The SpO₂ module self recovers within 10 seconds as required by the standard however, if the SpO₂ alarm limits have been customized to be patient specific, they are restored to their default values. Restoring to default values is not compliant with the standard.

A list of impacted material numbers can be found in **Table 1**.

Table 1: List of (33) impacted Material Numbers.

73ME-B	74MT-B	75ME-Z
73MT-6	74MX-2	75MT-2
73MT-B	74MX-4	75MT-4
74ME-2	74MX-6	75MT-6
74ME-4	74MX-A	75MT-A
74ME-6	74MX-B	75MT-B
74ME-A	75ME-2	75MT-Z
74ME-B	75ME-4	75MX-2
74MT-2	75ME-6	75MX-4
74MT-4	75ME-A	75MX-6
74MT-6	75ME-B	75MX-B

Problem Description:

Welch Allyn has not received any customer complaints for this issue, but if the SpO₂ module is rebooted it will revert to the SpO₂ default alarm limits (90% lower and 100% upper), the clinician may not be notified of a change in patient's condition as timely as with patient specific SpO₂ alarm limits. The SpO₂ default alarm limits are based on standard clinical values and would ultimately alert the clinician to a change in patient's condition. As a result, the safety risk associated with this issue is considered extremely low.

Although the safety risk associated with this issue is considered to be extremely low, Welch Allyn recommends updating your Connex® Spot Monitor to software version 1.32.02-A0002 or greater which prevents this issue from occurring and meet 3rd edition IEC60601-1-2 compliance.



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

Urgent Field Safety Notice Connex Spot Monitor

Actions to be taken by distributors:

1. Forward this Field Safety Notice, in its entirety, to your end-users and instruct them to complete the actions below.
2. Complete the Distributor Connex® Spot Monitor Urgent Field Safety Notice Response Form (MOD1280).

Actions to be taken by end-users:

1. Utilise Appendix A for Service Tool Installation Instructions and apply software version 1.32.02-A0002 or greater to your Connex® Spot Monitor.

This notice needs to be provided to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions, email MOD1280@welchallyn.com or call Welch Allyn using a number below.

Denmark +45 38 48 73 57	Finland +358 969 379 386	France +33 (0) 157 324 994
Germany +49 (0) 695 098 5132	Italy +39 026 968 2425	Spain +34 91 749 9357
Switzerland +49 (0) 695 098 5132	UK +44 (0) 207 365 6780	All other EU countries: +353 46 90 67790

This notice has been communicated to your local Regulatory Agency.

Yours sincerely,

 2018-09-13
 Paul Reynolds.
 Director, International Quality Assurance & Regulatory Affairs



Appendix A Service Tool Installation Instructions

Use the Welch Allyn Service Tool version 1.8x or later to update your Connex® Spot Monitor device.

1. Ensure PC User has Elevated Admin Rights.
2. Download the Service Tool Installation Guide from Website
https://www.welchallyn.com/content/dam/welchallyn/documents/upload-docs/Training-and-Use/Installation-Guide/80016783C_WelchAllynSrcvTool_InstallCfg.pdf
3. Download the Service Tool from the website
<https://www.welchallyn.com/content/dam/welchallyn/documents/upload-docs/Other/service-tool/50011612%20Service%20Tool%201.8.0.0%20EXE.zip>
4. Extract the Zip file to a location on your PC.
5. Go to the extraction points and right click on Setup.exe file, select run as Administrator and follow prompts to install the service tool.
6. When Installation completes, reboot the PC.
7. Launch the service tool.
8. If the simple user interface screen appears, click Service.
9. log on as ADMIN with no Password, otherwise the biomed account may be used. The User ID is case sensitive; ADMIN must be all upper case.
10. onnect the device to the PC running the service tool.
11. Power on the device.
12. ighlight 'device' and click 'select' to open the device tab.
13. Click the Upgrade Tab.
14. erify an Upgrade is available for the device, (if verify device software version and wait for 'Partner Connect' to push latest down to Service Tool).
15. Select Welch Allyn Device from top row table and click the Upgrade all button.
16. When Upgrade is complete, the upgrade table shows "No upgrade available".
17. To review the service record, select 'View log file' from the File menu. In the popup dialog select 'Active log file'. Service logs are archived in the ervicelogs folder as follows:

Windows XP: C:\Documents and Settings\All Users\Application Data\Welch Allyn Service Tool\ServiceLogs

Windows 7: C:\ProgramData\Welch Allyn Service Tool\ServiceLogs

18. Close the device tab to complete the service. Wait for tab to close before disconnecting device.
19. Disconnect the USB cable from the device, and power down the device. The upgrade is complete.



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

Urgent Field Safety Notice Connex Spot Monitor

Distributor Connex Spot Monitor Urgent Field Safety Notice Response Form (MOD1280)

By checking this box, you, on behalf of this distributor, are certifying that you have read and understood the attached Connex[®] Spot Monitor Urgent Field Safety Notice and have forwarded the Urgent Field Safety Notice and Appendix A to all end-users in scope as defined in Table 1.

Signature: _____

Contact (First and Last Name): _____

Title: _____

Distributor Name if applicable: _____

Street Address: _____

Locality Province/Abbreviation/Postal Code: _____

Country: _____

Phone Number: _____

Email: _____

Return this Response Form to MOD1280@welchallyn.com.