

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.

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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.

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This notice has been communicated to your local Regulatory Agency.

Yours sincerely,

