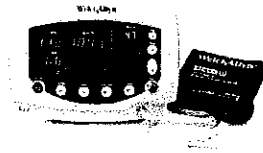


URGENT: CORRECTION

This is a Field Safety Notice containing important information regarding the safe operation of the Welch Allyn Vital Signs Monitor known as the VSM300



Model Numbers

53000, 5300P, 53N00, 53S00, 53N0P, 53S0P, 530T0, 530TP, 53NT0, 53ST0, 53NTP, 53STP

Dear Welch Allyn User:

Welch Allyn has received reports of loss of audible alarms from some users of the Welch Allyn VSM300 vital signs monitor. This loss may occur as a result of damage to the electrical wire between the speaker voice coil and the signal terminal. If the audible alarm is lost, the Nurse Call and visual alarms continue to function as intended.

The monitor is intended to be used by clinicians and medically qualified personnel for monitoring noninvasive blood pressure, pulse rate, body temperature, and blood oxygen saturation (SpO₂) of adult, pediatric, and neonatal patients.

The loss of the audible alarm could cause a delay in a clinician learning of an alarm condition for the following conditions: 1) hypotension or hypertension, 2) low blood oxygen content (SpO₂), 3) low or high pulse rate, 4) other alarm conditions relating to the loss of monitoring of a patient (e.g., a "sensor off" condition). Such delay could potentially result in injury to the patient.

To mitigate this risk, users should check for audible alarm functioning every time the VSM300 is used. During the normal power up cycle, two audible tones are emitted immediately after the self-test is complete. If these tones do not sound, the audio has failed. Also, there should be a beep on the completion of blood pressure measurements, and with each pulse beat detected when SpO₂ is being monitored. If these beeps do not sound, the audio has failed.

Users should especially be sure to check audible alarm functioning before using the VSM300 for continuous monitoring.

If the audio fails, do not use the device. Remove it from service and contact Welch Allyn Technical Services at the following telephone number (1-800-289-2500).

We apologize for the inconvenience.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Richard Wynkoop', is written over a horizontal line.

Richard Wynkoop
Director QARA Beaverton