



Technical Service Bulletin

All Products

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Bulletin Type: MANDATORY

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Date: 2009-09-04

SAP DIR #: 20011578

Subject: TSB-VSM300 Speaker Caution Label

CAR Number: 200057840

Distribution Scope: WA ASP's and Distributors
WA Technical Support, Product Service, & International Service Centers

Product(s) Referenced: VSM 300 Series, Models – 53000, 5300P, 530T0, 530TP, 53N00, 53N0P, 53NT0, 53NTP, 53S00, 53S0P, 53ST0, 53STP

SW Version: All

Serial No. / Lot Code: All

Summary: As part of the corrective action to address the potential for speaker failure in the VSM 300 series monitor a caution label will be added to the front panel.

Issue: Welch Allyn has received reports of loss of audible alarms from some users of the Welch Allyn VSM300 vital signs monitor.

Action: Add a caution label to the top of the front case of the VSM 300 to help remind clinicians to verify the speaker is functioning. The label is readily visible and will serve as a quick reminder to the user to always check the audio on the device.
Refer to the procedures section of this bulletin for installation instructions to add this label.

Reference to Standards:

- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Updates:	Technical Manual	<input checked="" type="checkbox"/>	Repair Tool	<input type="checkbox"/>
	Service Plan	<input type="checkbox"/>	Internet/Intranet	<input checked="" type="checkbox"/>
	Procedures	<input checked="" type="checkbox"/>	Price List	<input checked="" type="checkbox"/>
	Training Material	<input checked="" type="checkbox"/>	Other	

Service Strategy: For all units returned to service without the caution label affixed to the top of the front case follow the procedures detailed in this service bulletin to add the caution label. Add the caution label to VSM 300 series monitors in the loaner pool and any that will be sold as refurbished units.

Some units returned to Service will already have the labels. Production will be adding the label to the VSM 300 series at the time of manufacture. Welch Allyn will send a letter to customers asking them to add the label along with a quantity of labels.

Customers in the USA and Canada wanting to order additional labels are directed to call the VSM Speaker Correction line at 888-345-4610 while this corrective action is open. The label may be ordered free of charge until the corrective action is terminated.

QA/RA will notify the organization when the corrective action has been terminated. Service will distribute an update to this technical service bulletin when this corrective action is terminated.

Billing: The caution label is provided as part of the basic service and there is no additional charge for the label while the corrective action is open. The labels will be provided to service centers at no charge for the duration of the corrective action.

Required Training: All Welch Allyn employees and contactors engaged in the service and repair of the VSM5300 shall complete a training record indicating they have read and understand this document. The local service center shall maintain a file of training records for their service personnel.

Required Materials:

Material	Description
714845	LABEL SPEAKER, CAUTION VSM 300, ENG
714847	LABEL SPEAKER, CAUTION VSM 300, CHI
714848	LABEL SPEAKER, CAUTION VSM 300, DUT
714849	LABEL SPEAKER, CAUTION VSM 300, FRE
714890	LABEL SPEAKER, CAUTION VSM 300, GER
714891	LABEL SPEAKER, CAUTION VSM 300, ITA
714892	LABEL SPEAKER, CAUTION VSM 300, POL
714920	LABEL SPEAKER, CAUTION VSM 300, POR
714893	LABEL SPEAKER, CAUTION VSM 300, SPA
714895	LABEL SPEAKER, CAUTION VSM 300, SWE

Required Tools: 70% Isopropyl Alcohol prep pad or equivalent

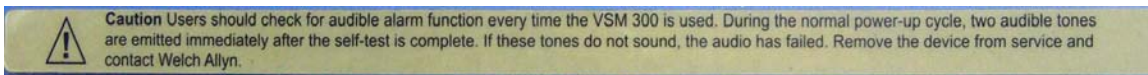
Procedure:

1. Clean surface with alcohol to remove grease, oil or other contaminants that may interfere with the label adhering to the plastic. Remove any markings that will interfere with the legibility of the label.



2. Reference the table in the required materials section above to determine the correct label to apply based on the language the VSM 300 is configured to.

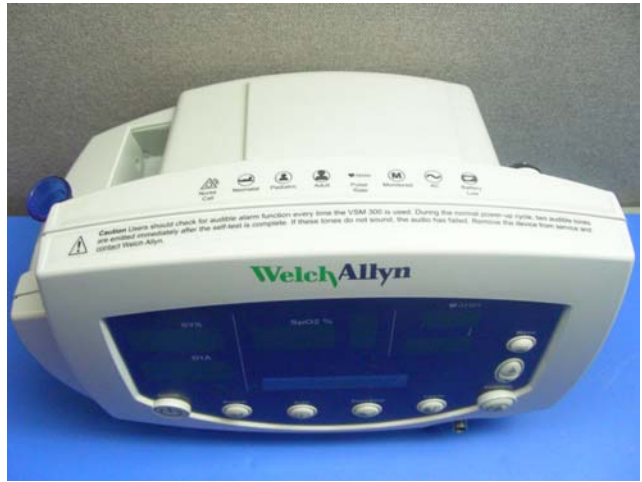
Example: 714845 LABEL SPEAKER, CAUTION VSM 300, ENG



3. Remove the paper backing to expose the adhesive surface and apply the label on the top of the front case. Older units may have a recessed area to apply the label, on newer units center the label on the top of the front case.



4. Apply firm pressure to assure good adhesion. Rub the label with a soft cloth to remove any air bubbles.



Quality Documents:

All service centers using SAP to record service transactions: For each monitor serviced, record the service activity in SAP. Indicate the part number of the caution label that was added to the monitor.

All other service centers and Field Service: For each monitor serviced, complete and file a service report and attach to the service DHR. Indicate the part number of the caution label that was added to the monitor.

Notes:

1. Contact the Welch Allyn Complaints Department to initiate or process a medical device complaint resulting from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

End of Bulletin

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	TSB-VSM300 Speaker Caution Label	D*	GS	D*	D*
D* - Refer to SAP DIR digital signature log for approval details.					