



Monitoring Products

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Bulletin Type: MANDATORY

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- Subject:** VSM 300 Speaker Release
- CAR Number:** 200057840
- Distribution Scope:** 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
- Serial No. / Lot Code:** SN JA084999 and earlier
- Summary:** A new speaker assembly has been released for production and service use. All new production VSM 300 monitors with serial number JA085000 and greater are built with the new speaker assembly.
- Issue:** Welch Allyn has received reports of loss of audible alarms from some users of VSM 300 vital signs monitor users.
- Action:** Obsolete VSM 300 speaker P/N 660-0231-01 in new production and service in favour of a new more robust higher wattage speaker P/N 660-0231-02.
- Reference to Standards:**
- 21 CFR Part 820, ISO 13485, MPD SOP-0002
- Related Documents:**
- SERVICE MANUAL, VSM III, ENGLISH, P/N 810-1651-XX
 - TDS, VSM 300 SPEAKER INSTALL INSTRUCTION, P/N 715121
 - TSB – VSM 300 SPEAKER REPLACEMENT, P/N 20011562

Service Strategy:

- Distribution of this Service Bulletin is limited to internal Welch Allyn audiences only.
- This service bulletin P/N 20011610 replaces service bulletin P/N 20011562.
- Scrap all global inventory of VSM 300 speaker P/N 660-0231-01. Scrap speakers locally, do not return to Product Service.
- Technical Data Sheet P/N 715121, included with all orders for speaker P/N 660-0231-02, contains instructions for speaker installation.
- Mandatory replacement of speaker and gasket required in all VSM 300 monitors S/N JA084999 and earlier when returned for service. Replace with speaker P/N 660-0231-02 and gasket 600-0518-00. Reference TDS P/N 715121 and Service Manual 810-1651-XX for installation instructions. Affix a sticker containing the text "660-0231-02A" in the device battery bay after completion of the speaker update, or apply above text directly to the battery bay plastic with a permanent marker. Note that the preferred location for the above sticker or marking is just inside the battery door.
- Include new **Directions For Use (DFU)** with all VSM 300 series monitors returned to the customer after completion of service. DFU is to be included at no charge to customer. Note separate Masimo and Nellcor DFU's in New Materials Table listed on Page 3.
- Perform speaker replacement under warranty, at no-charge to customer.
- The VSM 300 Service Manual will be updated with TDS P/N 715121 speaker installation instruction related content at a later date.

Required Materials:

Part Number	Description
810-2252-03	KIT,CD,DFU,VSM300,1.X,NEL,ML
810-2250-05	KIT,CD,DFU,VSM300,1.X,MAS,ML
715121	TDS, VSM 300 SPEAKER INSTALL INSTRUCTION
660-0231-02	SPEAKER ASSEMBLY, VSM 300
600-0518-00	GASKET, SPEAKER

**Quality Records:**

- **All service centers using SAP to record service transactions:** For each monitor serviced, record the service activity in SAP.
- **All other service centers and Field Service:** For each monitor serviced, complete and file a service report and attach to the service DHR.
- All Welch Allyn employees and contactors engaged in service and repair of VSM 300 products shall complete a Read & Sign training record indicating they have read and understand this document, file this training record locally.

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 - VSM 300 SPEAKER RELEASE	D*	NRP	D*	D*
B	Revise billing from CC 1123 to warranty acct.	D*	GF	D*	D*
D* - Refer to SAP for Change #, Release Date, and digital signature log for approval details.					

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