

# Patient Safety Alert

Veterans Health Administration Warning System  
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- Item: Nellcor pulse oximeters, model 595 and limited quantities of models 395, 295 and 290. Affected units were manufactured after November 8, 2001. Nellcor notified known affected customers by letter dated October 18, 2004 (Attachment 1).
- Specific Incident: Alarm speakers and other audio notifications are reported to fail at a higher rate than expected. While the reported failure rate is low and no other features are affected (visual, remote alarms, etc.), failure could result in serious patient injury, depending upon the specific application of the pulse oximeter. Nellcor will replace affected speaker assemblies (see Attachment 2 for details).
- Action:
1. Immediately (within the next 48 hours) determine and identify all affected units. Only units manufactured after November 8, 2001 (after S/N G01844386) are affected.
  2. Until the speaker assemblies are replaced, users should routinely test speaker functions by:
    - a. Listening for the tone emitted during the Power On Test.
    - b. Activating audio pulse tones while monitoring patients to hear patient's pulse to provide positive confirmation of speaker function; volume can be set low to minimize disturbing patients.
  3. Ensure user and Biomedical Engineering inspections include alarm testing according to manufacturer recommendations.
  4. If the speaker fails, immediately remove the unit from service and replace with another unit, making sure the speaker is functioning on the replacement unit. Contact Nellcor at the phone numbers listed below and see the attached for replacement speakers and/or service.
- Add'l. Information: Due to the large number of affected pulse oximeters, speaker replacement will take several months to complete.  
Operator and service manuals are available on Nellcor's website:  
[http://www.mallinckrodt.com/respiratory/resp/Serv\\_Supp/productmanuals.html](http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/productmanuals.html)  
Also, please contact the VA Center for Engineering Occupational Safety & Health (CEOSH) at (314) - 543-6700 if you are affected and did not receive Nellcor's letter.
- Source: CEOSH and Manufacturer
- Contact: Nellcor Technical Support at (800) - 635-5267 (Option 1 – Customer Service, Option 3 – Technical Service)  
You can also contact Paul Sherman, CEOSH at (314) - 543-6700