



CASMED 740 SERIES MONITOR - PRODUCT CORRECTION NOTIFICATION

June 18, 2008

Customer Name
Customer Address

Dear Valued Customer,

Please be advised that CAS Medical Systems (CASMED) has issued a field corrective action for the 740 Series Vital Signs Monitor. This voluntary product correction is specific to 740 Series Monitors shipped between February 28, 2008 and June 3, 2008 and requires a software revision upgrade.

CASMED is initiating this voluntary product correction to avoid a possible user-initiated error that may lead the user to believe that audible high and low alarms are active, when they are disabled. The CASMED 740 Series User Manual states that the alarm volume cannot be turned off. Through rigorous quality testing, CASMED determined that, if the user inadvertently selects a non-default volume setting one step above the maximum choice or one step below the minimum choice, the alarm volume will be set to an "off" setting. However, an alarm volume icon indicating that the alarm is active will remain on the screen.

Typical alarm settings and functions within the specified factory default range are not affected by this condition. As stated in the User Manual, there is always a visual indication of an equipment or patient alarm state. If the factory default alarm volume is not adjusted by the user, the audible alarm will occur correctly at the factory-set mid volume level. Possible problems will only occur only if the user makes a volume adjustment below the minimum or above the maximum settings. If the user does set the alarm volume outside the minimum or maximum range, the monitor will always return back to its default mid-range setting when the monitor is powered off and back on again.

This voluntary product correction has been identified by CASMED and does not involve an incident or a complaint from a customer

Note: If you own a 740 Series monitor shipped between February 28, 2008 and June 3, 2008, please do not adjust the alarm volume from its factory set value. This will ensure that alarms sound correctly. If you need to adjust volume levels, please make sure that you only select two clicks above, or two clicks below the mid-point, and that there is a corresponding beep when you make your selection.

Review the attached list for the serial number(s) that will need to be updated with new software.

Please contact CASMED Technical Support at 800-581-7806 to arrange for the upgrade of your monitor. All upgrade costs will be paid for by CASMED, and will be completed in a timely fashion.

We apologize for any inconvenience this corrective action may cause you. Thank you for your understanding and your cooperation in our corrective action efforts. Any additional questions can be directed to CASMED Technical Support at the number noted above.

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs