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URGENT: MEDICAL DEVICE CORRECTIVE ACTION

Date: October 29, 2001
Attention: Hospital Administrator
Product: Spacelabs Medical ECG Products

Affected Model No(s): 90342, 90344, 90346, 90348, 90470, 90478, 90496

Spacelabs Medical has determined through customer reports and extensive testing that there is an anomaly in our ECG software that fails to detect low heart rates in the range of 12 to 15 bpm. For this condition to happen, three things must occur together. (1) the heart rate must drop suddenly within a one beat interval, (2) the heart rate must drop into the range of 12 to 15 bpm, and (3) the heart rate must stay within the range of 12 to 15 bpm. In this condition, the software will not update, detect the change, or generate a low rate alarm. There have been no patient injuries or deaths associated with this condition and any rate outside this range will provide an appropriate alarm.

As part of the corrective action, Spacelabs Medical will be updating all ECG products in the field with new software. On a voluntary basis, Spacelabs Medical would like to offer any customer with a Model 90342, 90344, 90346, 90348, 90470, or 90478 unit the opportunity to do their own upgrades. In this scenario, the customer would sign up to be included in the program, and would then be supplied with a procedure and two pre-programmed EPROMs for each confirmed unit owned, free of charge. For every unit updated, the customer will receive a \$25 credit on their account good for future purchases of products or services (with a 12-month expiration). In order to qualify for credit, the customer must return a properly filled out and signed Modification Installation Report (MIR) for each upgraded unit, along with the removed EPROMs.

For customers who chose not to take advantage of this opportunity or if they have a Model 90496 unit, the update will be installed on-site by your local customer service representative at no charge to your hospital. We estimate that 30 minutes per module will be needed to complete the update. Your customer service representative will contact you to arrange installation of the update.

Until your hospital's ECG products are updated, Spacelabs Medical recommends that you keep the above anomaly in mind to prevent any adverse event from happening. If you have any questions about this corrective action program, please call Spacelabs Medical at 1-800-522-7025 or, outside the United States, 1-206-882-3700 and ask for Monitoring Technical Support.