

July 22, 2008

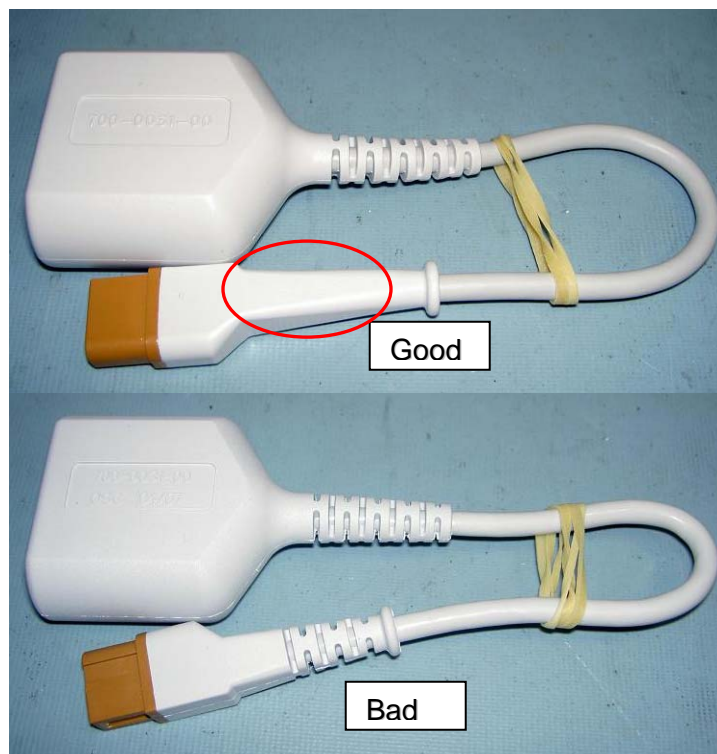
MEDICAL DEVICE CORRECTION

Spacelabs Medical Temperature Probe Adaptor

Dear Hospital Administrator/Biomedical Manager:

This letter is to inform you of a potential hazard associated with the use of Spacelabs Medical Temperature Probe Adaptor, PN: 700-0031-00. We have six reports of intermittent connection on the temperature jack. Loss of temperature monitoring can cause a delay in care when an alarm is missed. This is significant for burn or septic patients. There have been no injuries associated with this failure mode.

We at Spacelabs Medical recognize and share your concern for patient safety. We would like to replace each suspect temperature probe adaptor with one from a vendor with an 8 year history of quality connections. The bad adaptors will have an "OSC" prefix on the lot code. Another way to tell the difference between good adaptors and bad adaptors is to look at the strain relief. The good adaptors have a smooth strain relief on the monitor end. See photo below. Please dispose of the bad adaptors so they will not be used.



If you have any questions about this corrective action, please contact Spacelabs Medical at 425-657-7200 and ask for Global Technical Support.