Customer Notification
Trilogy Family of Devices
October 13, 2011

Impeller Press Force Recall

Dear Customer,

We recently discovered during review of our manufacturing data that a small quantity of Trilogy devices do not meet the minimum press-force required for assembling the impeller onto the motor shaft of the blower unit. Should the impeller release or travel up the motor shaft, it may result in a rubbing noise emanating from the Trilogy device. In a worst case scenario, there is the remote possibility that this may cause a ventilator inoperative alarm and cessation of therapy. To date, there have been no reports of failure, harm or injury due to this condition in the field. You are receiving this notification because you have 1 or more of the devices affected by this recall.

This issue has been corrected in manufacturing to prevent future occurrence and all prior device manufacturing records have been evaluated to ensure that only the devices referenced in this notification are affected by this recall. Philips Respironics has provided you with a serial number list of affected devices shipped to your location (see the next page). To assure the long term reliability of your affected Trilogy ventilators, we recommend that you send these devices to Philips Respironics Service for replacement of the affected component. Detailed instructions are included with this customer notification.

Philips Respironics places patient safety, product quality and customer satisfaction first. We continuously monitor our manufacturing and field performance data to proactively identify any potential issues that could manifest as a reliability, quality, or safety concern and work to address them immediately.

Please note that this action is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA) as well as other applicable Ministries of Health worldwide. Please be aware that FDA or other agencies may contact you to ensure compliance with this recall.

Philips Respironics sincerely apologizes for any inconvenience to you and your patients caused by this issue; therefore, we are also extending a $200.00/€150.00 credit for each affected device serviced.

If you need any further information or support concerning this issue, please contact your local Philips Respironics service center.

Sincerely,

Philips Respironics

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AFFECTED PRODUCTS	LIST ATTACHED
PROBLEM DESCRIPTION	The press force used to attach the impeller to the motor blower shaft may have been too low to ensure proper seating. As a result your unit may be noisy or could fail causing a ventilator inoperative condition.
HOW TO IDENTIFY AFFECTED PRODUCTS	The serial numbers above are the only devices shipped to your facility affected by this issue.
ADVICE ON ACTIONS BY CUSTOMER / USER	Complete and return the attached BRF • Quarantine the devices not in use • Locate devices with patients • Contact your local Philips Respironics service center to schedule repair
ACTIONS PLANNED BY PHILIPS	Philips Respironics will replace your blower motor assembly and return the Trilogy Device to you. Philips Respironics is also providing you with a $200.00/€150.00 credit for each affected device serviced.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips Respironics service center.