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ResMed Issues a Voluntary Recall for Certain S8 Flow Generators

FOR IMMEDIATE RELEASE – San Diego, CA, April 23, 2007 – ResMed today announced a worldwide voluntary recall of approximately 300,000 of its early production S8 flow generators used for the treatment of obstructive sleep apnea. In S8 devices manufactured between July 2004 and May 15, 2006, there is a remote potential for a short circuit in the power supply connector. ResMed plans to work with its distribution partners globally to provide a replacement device to patients who have an affected S8 flow generator.

Patients may continue to use their S8 flow generators until they receive a replacement device. As with any electrical device, patients should make sure that it is placed on a hard clean surface and that the area around the device is clear during use. Patients should discontinue use of the device if there are any signs of electrical failure such as intermittent power, cracking sounds, sparking or charred smell. Patients should not use supplemental oxygen with an affected device; patients using supplemental oxygen should immediately contact their home healthcare provider for a replacement.

The recall includes the following serial number ranges for all S8 models:

From	To
20040285613	20060269563
20060275728	20060276751
20060277160	20060277415
20060281672	20060281991
20060283424	20060283743
20060284896	20060285445
20060287568	20060290823
20060292360	20060294694
20060312361	20060312597
20060318692	20060319459
20060325074	20060327794
20060330588	20060331043

ResMed voluntarily recalled the product after learning that in rare instances – less than two tenths of one percent (0.2%) – a short circuit in the power supply connector, a component supplied by a third party, has caused the devices to fail. In only seven cases worldwide, device failures have led to thermal damage to the device, with a remote potential to ignite material external to the device. No significant property damage or patient injury has been reported.

ResMed has advised the U.S. Food and Drug Administration and other regulatory authorities of this action. ResMed is continuing to discuss this action with those authorities and will finalize its proposed course of action after those discussions are concluded.

ResMed's S8 flow generators are distributed through medical equipment suppliers throughout the world. Affected products can be identified by the serial numbers on the bottom of each device. ResMed is working in close partnership with its distribution partners and the medical community to ensure that patients are fully aware of the replacement program and that patients who have an affected device will receive a replacement S8 flow generator.

Patients will be contacted as soon as possible to arrange for a replacement device and are encouraged to visit www.resmed.com/s8program for more information. Patients in the U.S. and Canada may also contact the ResMed S8 Replacement Call Center at 888-899-8991. Contact information for patients in Latin America, Europe and Asia Pacific is available at www.resmed.com/s8program.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular mail:** Use postage-paid FDA form 3500 available at: www.fda.gov/medwatch/getforms.htm.
Mail to: MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax:** 1-800-FDA-0178