

MEDICAL DEVICE CORRECTION

Respironics V60 Ventilator

Dear Customer,

Respironics California, Inc., a division of Philips Healthcare, has initiated a voluntary field action for its V60 ventilator. You are receiving this notification because our records indicate that you have one or more of the devices affected by this action. Please reference the "Affected Products" serial number list below.

A review of manufacturing data found that certain blower motor assemblies in the V60 ventilators may not meet specifications. Specifically, the impeller may not be properly seated on the blower motor shaft. This could subsequently cause the blower to cease functioning which would result in the failure of the V60 ventilator to deliver therapy to the patient due to the loss of ventilation. The V60 ventilator will alert users to malfunctioning blowers by annunciating audible and visual alarms. This manufacturing issue has been corrected.

Philips has received two reports of blower motor failures in V60 ventilators to date. While there have been no reports of patient injury, Respironics California, Inc. is replacing all affected blower motors that may have improperly-seated impellers on its V60 ventilators.

Patient safety, product quality and customer satisfaction is our ultimate priority. 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.

If you need any further information or support concerning this issue, please contact a Philips Respironics representative at **<Philips representative contact details to be completed by the KM/country for international markets>**.

This notice has been reported to the appropriate regulatory agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Director, Regulatory Affairs/Quality Assurance
Respironics California Inc.



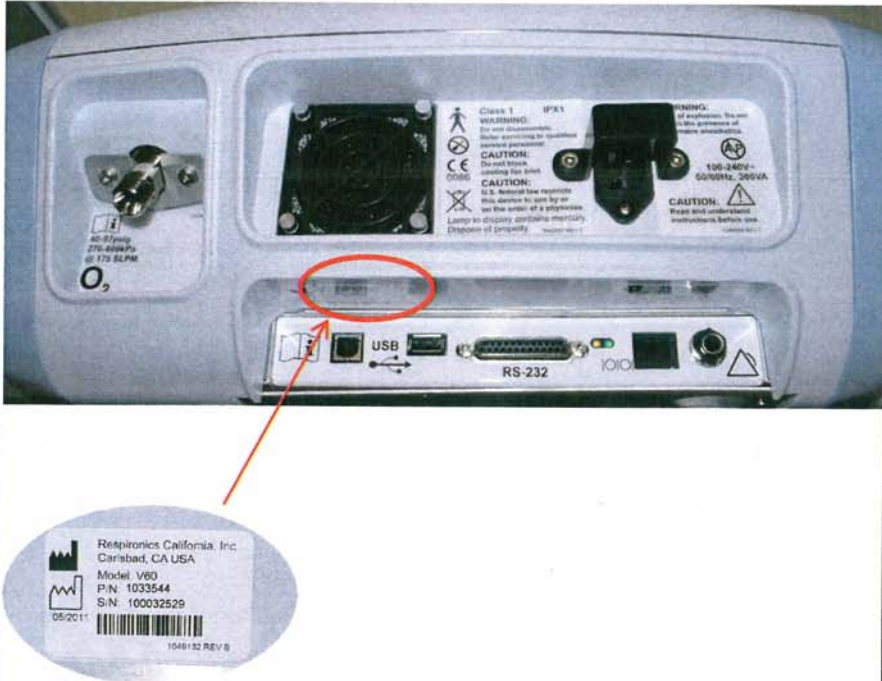
MEDICAL DEVICE CORRECTION**Respironics V60 Ventilator**

| AFFECTED PRODUCTS | Respironics V60 ventilators | | | | |
|-------------------|---|-----------|-----------|-----------|-----------|
| | Only units with the following serial numbers are affected | | | | |
| | | | | | |
| | 100026615 | 100029321 | 100029838 | 100030462 | 100030832 |
| | 100026808 | 100029324 | 100029841 | 100030463 | 100030833 |
| | 100026826 | 100029325 | 100029843 | 100030464 | 100030834 |
| | 100027107 | 100029327 | 100029845 | 100030466 | 100030836 |
| | 100027181 | 100029328 | 100029847 | 100030468 | 100030838 |
| | 100027189 | 100029330 | 100030043 | 100030469 | 100030840 |
| | 100027544 | 100029334 | 100030106 | 100030471 | 100030843 |
| | 100027660 | 100029337 | 100030107 | 100030472 | 100030844 |
| | 100027751 | 100029455 | 100030111 | 100030473 | 100030845 |
| | 100027870 | 100029456 | 100030112 | 100030474 | 100030847 |
| | 100027872 | 100029459 | 100030113 | 100030475 | 100030850 |
| | 100027875 | 100029462 | 100030115 | 100030481 | 100030977 |
| | 100028047 | 100029473 | 100030117 | 100030482 | 100030979 |
| | 100028053 | 100029474 | 100030118 | 100030485 | 100030980 |
| | 100028069 | 100029500 | 100030119 | 100030591 | 100030983 |
| | 100028249 | 100029504 | 100030120 | 100030593 | 100030985 |
| | 100028324 | 100029505 | 100030121 | 100030594 | 100030986 |
| | 100028328 | 100029507 | 100030133 | 100030595 | 100030987 |
| | 100028334 | 100029508 | 100030204 | 100030596 | 100030989 |
| | 100028339 | 100029512 | 100030212 | 100030608 | 100030990 |
| | 100028570 | 100029514 | 100030215 | 100030609 | 100030991 |
| | 100028665 | 100029515 | 100030216 | 100030612 | 100030992 |
| | 100028666 | 100029516 | 100030217 | 100030618 | 100030994 |
| | 100028673 | 100029518 | 100030220 | 100030620 | 100030995 |
| | 100029074 | 100029520 | 100030223 | 100030762 | 100030996 |
| | 100029116 | 100029524 | 100030224 | 100030766 | 100030997 |
| | 100029119 | 100029525 | 100030226 | 100030767 | 100030998 |
| | 100029215 | 100029672 | 100030229 | 100030768 | 100031004 |
| | 100029217 | 100029679 | 100030337 | 100030769 | 100031071 |
| | 100029220 | 100029684 | 100030342 | 100030771 | 100031072 |
| | 100029223 | 100029685 | 100030343 | 100030773 | 100031084 |
| | 100029224 | 100029690 | 100030344 | 100030778 | 100031085 |
| | 100029241 | 100029691 | 100030345 | 100030779 | 100031089 |
| | 100029242 | 100029692 | 100030349 | 100030780 | 100031143 |
| | 100029243 | 100029698 | 100030355 | 100030781 | 100031144 |
| | 100029313 | 100029832 | 100030359 | 100030782 | 100031147 |
| | 100029316 | 100029833 | 100030456 | 100030823 | 201002392 |
| | 100029318 | 100029835 | 100030457 | 100030825 | |
| | 100029319 | 100029836 | 100030458 | 100030827 | |
| | 100029320 | 100029837 | 100030459 | 100030829 | |



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Respironics V60 Ventilator

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| <p>PROBLEM DESCRIPTION</p> | <p>The impeller may not be properly seated on the blower motor shaft. This could subsequently cause the blower to cease functioning which would result in the failure of the V60 ventilator to deliver therapy to the patient due to the loss of ventilation. The V60 ventilator will alert users to malfunctioning blowers by annunciating audible and visual alarms.</p> |
| <p>HOW TO IDENTIFY AFFECTED PRODUCTS</p> | <p>Only V60 ventilators with the serial numbers listed above are affected by this action. The serial number is located on the back of the device</p>  |
| <p>ADVICE ON ACTIONS BY CUSTOMER / USER</p> | <p>Pending the completion of the repair, the V60 ventilator may continue to be used in accordance with its directions for use, including normal patient monitoring.</p> |
| <p>ACTIONS PLANNED BY PHILIPS</p> | <p>A Philips Respironics Field Service Engineer or distributor will be contacting you soon to schedule a no-cost replacement of the blower motor assembly on all affected V60 ventilators.</p> |
| <p>FURTHER INFORMATION AND SUPPORT</p> | <p>If you need any further information or support concerning this issue, please contact your local Philips Respironics representative.</p> |

