

Manufacturer name:	Philips Respironics																																																		
About the Recall: <i>Clear overview of recall and products affected</i>	An Urgent Medical Device Correction is to inform of all the contraindications for Trilogy Evo and Trilogy Evo O2 Ventilators. The instruction for use manuals were determined that the Contraindications Statement was incomplete.																																																		
Please list the specific products(s) numbers/models that are affected:	<table border="1"> <thead> <tr> <th>Affected Material Number</th> <th>Affected Serial number</th> </tr> </thead> <tbody> <tr><td>DS2110X11B</td><td>H287820890512</td></tr> <tr><td>DS2110X11B</td><td>H28782169C5DE</td></tr> <tr><td>DS2110X11B</td><td>H2878323948B9</td></tr> <tr><td>DS2110X11B</td><td>H29002002AC25</td></tr> <tr><td>DS2110X11B</td><td>H29002015C142</td></tr> <tr><td>DS2110X11B</td><td>H291041487172</td></tr> <tr><td>DS2110X11B</td><td>H2910416488AE</td></tr> <tr><td>DS2110X11B</td><td>H2910416842C2</td></tr> <tr><td>DS2110X11B</td><td>H291041940B66</td></tr> <tr><td>DS2110X11B</td><td>H29105210705D</td></tr> <tr><td>DS2110X11B</td><td>H32464936CBE4</td></tr> <tr><td>DS2110X11B</td><td>H32466225F077</td></tr> <tr><td>DS2110X11B</td><td>H324663386896</td></tr> <tr><td>DS2110X11B</td><td>H32466447516C</td></tr> <tr><td>DS2110X11B</td><td>H325760013F34</td></tr> <tr><td>DS2110X11B</td><td>H3257601560C8</td></tr> <tr><td>DS2110X11B</td><td>H3257951921E0</td></tr> <tr><td>DS2110X11B</td><td>H32579553E9DA</td></tr> <tr><td>DS2110X11B</td><td>H32579566941F</td></tr> <tr><td>DS2110X11B</td><td>H325892243694</td></tr> <tr><td>DS2110X11B</td><td>H3258941911C0</td></tr> <tr><td>DS2110X11B</td><td>H32589608AC29</td></tr> <tr><td>DS2110X11B</td><td>H32589806554C</td></tr> <tr><td>DS2110X11B</td><td>H32590548D60A</td></tr> </tbody> </table>	Affected Material Number	Affected Serial number	DS2110X11B	H287820890512	DS2110X11B	H28782169C5DE	DS2110X11B	H2878323948B9	DS2110X11B	H29002002AC25	DS2110X11B	H29002015C142	DS2110X11B	H291041487172	DS2110X11B	H2910416488AE	DS2110X11B	H2910416842C2	DS2110X11B	H291041940B66	DS2110X11B	H29105210705D	DS2110X11B	H32464936CBE4	DS2110X11B	H32466225F077	DS2110X11B	H324663386896	DS2110X11B	H32466447516C	DS2110X11B	H325760013F34	DS2110X11B	H3257601560C8	DS2110X11B	H3257951921E0	DS2110X11B	H32579553E9DA	DS2110X11B	H32579566941F	DS2110X11B	H325892243694	DS2110X11B	H3258941911C0	DS2110X11B	H32589608AC29	DS2110X11B	H32589806554C	DS2110X11B	H32590548D60A
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URL Link(s) to Manufacturer Notice/Web Site:	https://www.usa.philips.com/healthcare/solutions/sleep																																																		

Actions to be taken by customer/Patient:

Please include phone numbers and emails when applicable

If the patient has any of the following conditions, consult the patient's healthcare professional before using non-invasive ventilation:

- Inability to maintain a patent airway or adequately clear secretions.
- At risk of aspirating gastric contents.
- Acute sinusitis or otitis.
- Epistaxis, causing pulmonary aspiration of the blood.
- Hypotension.

The AVAPS-AE mode therapy is contraindicated for invasive use and patients less than 10 kg. The AVAPS feature is contraindicated for patients less than 10kg.

If you need any information or support concerning this issues, please contact Philips at 1-877-387-3311 or email at patientsupport@philips.com