

Manufacturer name:	Medtronic Puritan Bennett																		
About the Recall:	<p>Medtronic has updated the labeling of the devices to reflect cumulative use over 14-year use may potentially pose harm to health. These conclusions derived from chemical testing and risk assessment from literature, including animal laboratory testing. There are no conclusive human clinical data describing quantifiable risk. For patients that require ventilation therapy beyond the full duration of the device service life, a second unit may be required to allow the patient to continue receiving therapy.</p>																		
Products(s) numbers/models that are affected:	<table border="1" data-bbox="448 915 1479 1402"> <thead> <tr> <th data-bbox="448 915 896 982">Product Name</th> <th data-bbox="896 915 1175 982">Model #/ CFN</th> <th data-bbox="1175 915 1479 982">UDI-DI/ GTIN</th> </tr> </thead> <tbody> <tr> <td data-bbox="448 982 896 1066">Puritan Bennett™ 560 Ventilator LATAM</td> <td data-bbox="896 982 1175 1066">4096600-04</td> <td data-bbox="1175 982 1479 1066">10884521196025</td> </tr> <tr> <td data-bbox="448 1066 896 1150">Puritan Bennett™ 560 Ventilator CAN ANZ</td> <td data-bbox="896 1066 1175 1150">4096600-06</td> <td data-bbox="1175 1066 1479 1150">10884521196377</td> </tr> <tr> <td data-bbox="448 1150 896 1234">Puritan Bennett™ 540 Ventilator USA</td> <td data-bbox="896 1150 1175 1234">4097100</td> <td data-bbox="1175 1150 1479 1234">10884521100398</td> </tr> <tr> <td data-bbox="448 1234 896 1318">REFURBISHED PB540 VENTILATOR</td> <td data-bbox="896 1234 1175 1318">DL4097100</td> <td data-bbox="1175 1234 1479 1318">DL4097100</td> </tr> <tr> <td data-bbox="448 1318 896 1402">Puritan Bennett™ 540 Ventilator Refurbished</td> <td data-bbox="896 1318 1175 1402">DS4097100</td> <td data-bbox="1175 1318 1479 1402">DS4097100</td> </tr> </tbody> </table>	Product Name	Model #/ CFN	UDI-DI/ GTIN	Puritan Bennett™ 560 Ventilator LATAM	4096600-04	10884521196025	Puritan Bennett™ 560 Ventilator CAN ANZ	4096600-06	10884521196377	Puritan Bennett™ 540 Ventilator USA	4097100	10884521100398	REFURBISHED PB540 VENTILATOR	DL4097100	DL4097100	Puritan Bennett™ 540 Ventilator Refurbished	DS4097100	DS4097100
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URL Link(s) to Manufacturer Notice/Web Site:	<p>Medtronic.com</p> <p>For further information regarding the recall, you may contact Medtronic directly by calling customer service at 1 (800) 255-6774 Option 4</p>																		

**Actions to be taken
by
customer/Patient:**

If you have been using the current listed device above for 14-years or are approaching 14-years cumulative use, please contact your local AdaptHealth facility to discuss transitioning to an alternative device.