Manufacturer name:	Breas Medical
About the Recall:	Breas Medical has issued a U.S Nationwide medical device correction for the Vivo 45 LS Ventilator. After concluding internal testing of the device, the results identified the potential of short-term elevated levels of formaldehyde in patients with specific conditions. Short term formaldehyde emissions may lead to adverse pulmonary or neurological effects such as the potential for transient, reversible airway irritation or inflammation that could lead to airway hyperresponsiveness such as asthma in small pediatric patients resulting in additional medical intervention (e.g., bronchodilator administration, adjustment of ventilator settings, increased duration or degree of ventilatory support and/or oxygen support).
Products(s) numbers/models that are affected:	The devices were manufactured from February 4, 2021, to July 1, 2024, and distributed between February 12, 2021, to July 24, 2024.

Affected Product Information Table

Model name	Model number	UDI-DI	
			D*****, F*****, K*****, M*****, N01*** - N270030 Manufacturing dates up to and including "240530" (May 30th, 2024)

URL Link(s) to Manufacturer Notice/Web Site:	ww.breas.us
Actions to be taken by customer/Patient:	Breas Medical directly by calling 1-855-436-8724 M-F 8:00 am to 5:00 pm (EST) or via email at vivotechnicalsupport@breas.com.