

Recall Fallout Lets Rivals Gain Ground in Sleep Apnea and Ventilators

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In recent years, the number of ventilator recalls has increased considerably, primarily due to product quality issues, software malfunctions, and manufacturing defects. This affected manufacturers such as Philips, Medtronic, and Vyaire Medical, leading to brand damage, financial losses, and a shift in the market competition. Existing players and new entrants, such as Getinge and Nihon Kohden, are stepping in to fill the gap with innovative and non-invasive products. The recalls caused challenges for manufacturers and patients, highlighting the need for strong quality control and regulatory oversight.

Philips took the biggest hit as recalls wiped out sales and trust

The medical device industry has recently experienced many product recalls, particularly in the ventilators segment, impacting major market players such as Philips, Medtronic, Baxter, GE Healthcare, Hamilton Medical, and Vyaire Medical.

Philips (Philips Respironics) faced a series of class I respiratory product recalls, including CPAP and BiPAP machines and ventilators, due to health risks caused by the polyester-based polyurethane (PE-PUR) sound abatement foam breakdown in the devices. Industry experts consider Philips' sleep apnea devices and ventilator recalls among the most significant since 2021. As of January 2024, the company experienced a recall of over 15 million sleep apnea devices and ventilators, and reportedly hundreds of deaths. The recall seriously hurt the company's reputation, weakened its position in the market, and caused significant financial problems.

The recalls led to a decline in the company's share price by 60–70% in 2021, and it is still about 50% lower than its peak in April 2021 (US\$ 53.45). Comparable sales of the connected care segment, including sleep apnea devices and ventilators, declined by about 19% in 2021 in comparison to 2020. This happened primarily due to sleep apnea devices and ventilators recalls, and the normalization of demand for hospital ventilators and monitoring systems following the COVID-19 surge. Recalls continued to drive down ventilator and sleep apnea device sales in 2022 and 2023.

The considerable impact on sleep apnea devices and ventilator sales resulted in a decline in Philip's share in the sleep apnea device market, dropping to an estimated 20% between 2021 and 2023 from over 30% before the recall. The company also experienced a notable decline in market share in the ventilator market. Despite the decline in market share, Philips maintained its position as one of the leading players in both the sleep apnea devices and ventilators market.

However, in January 2024, Philips agreed to halt the sales of 19 sleep and respiratory products in the USA as a part of the consent decree with the US Department of Justice (DOJ). These products included hospital ventilation, certain home ventilation, sleep diagnostic devices, and portable and stationary oxygen concentrators. This affected the company's brand image greatly and resulted in a further loss of market share in both ventilator and sleep apnea device markets. Since the company will continue to sell consumables and accessories, including masks, it is anticipated to maintain a portion of its market share in both segments.

In April 2024, the company agreed to pay US\$1.1 billion in legal settlement to resolve injury-related cases caused by sleep apnea devices and ventilators in the USA. Overall, sleep apnea device recalls cost the company over US\$5 billion, likely including charges such as provisions for Philips Respironics-related litigation, consent decree, remediation costs, legal settlements, workforce restructuring, and quality remediation action. In addition, Philips cut 6,600 jobs by 2023 and is likely to reduce its workforce by a total of 10,000 by 2025.

Other ventilator makers also stumbled, but none fell as far as Philips

Other prominent manufacturers such as Drägerwerk (Draeger), Medtronic, Vyaire Medical, Hamilton Medical, and Baxter also experienced various ventilator recalls due to manufacturing and quality defects. Although the FDA

classified these recalls as serious, these companies did not face the same severe consequences as Philips, as these recalls did not result in major injuries.

All these manufacturers also witnessed **a drop in ventilator sales largely due to the stabilization of demand for ventilators following the COVID-19 surge**, with product recalls also contributing to the downturn.

In February 2024, **Medtronic completely exited the ventilator market due to unprofitability**. Similarly, in June 2024, **Vyaire Medical filed for bankruptcy** and was subsequently acquired in October 2024 by Zoll, an Asahi Kasei company engaged in the manufacturing of medical devices and related software solutions. This caused a profound impact on the ventilators market.

Rivals are using smarter, less invasive devices to win lost share

The ventilator market encountered **a radical shift in competition due to numerous product recalls**. The suspension of sleep and respiratory product sales cost Philips its leading market position in sleep apnea devices and ventilators (except for certain home ventilators). It remains **unclear when or if Philips will be able to resume sales** of these devices. However, the company is unlikely to leave its presence in the sleep apnea devices and ventilators market entirely due to its commitment to service and supply of parts of ventilators in use, as well as its decision to continue the sale of consumables and accessories.

Existing market players such as Getinge, Hamilton Medical, Drägerwerk (Draeger), ResMed, and GE Healthcare, and newer entrants such as Nihon Kohden, are likely **to fill in the gap left by Philips, Medtronic, and Vyaire Medical** in the USA.

Market players such as **Getinge**, Drägerwerk (Draeger), and **Nihon Kohden** are focusing on **introducing technologically advanced ventilators** with features such as enhanced patient comfort, advanced monitoring capabilities, portability, and adaptive ventilation modes, to grab a slice of the pie. They are also increasingly focusing on expanding their portfolio of non-invasive ventilators with different interfaces, including face masks, nasal masks, helmets, and mouthpieces.

For instance, in October 2024, Nihon Kohden introduced a new ventilator system that combines invasive and non-invasive ventilation and high-flow oxygen therapy in one device, offering adaptability and eliminating the need to switch between machines. It also features a customizable, app-based touchscreen

interface with advanced monitoring capabilities. Similarly, in January 2024, Getinge introduced 'Servo-air Lite', a non-invasive ventilator with high-flow therapy that offers optimal respiratory support, enhanced patient comfort, and ease of use for clinicians.

ResMed, a leading player in both the sleep apnea devices and ventilators market, is estimated to have grabbed over 10% of Philips' market share in the sleep apnea devices market in the USA. ResMed witnessed a substantial increase in demand for its sleep and respiratory care products, including sleep apnea devices and ventilators, for various reasons, including Philips' product recalls. The demand for its sleep and respiratory care products in the USA, Canada, and Latin America increased by 16%, 25%, and 10% in 2022, 2023, and 2024, respectively.

Companies engaging in sleep apnea devices and ventilator rentals, sales, and distribution, such as Trace Medical, also started adding brands from different companies to their product mix to meet the demand for these devices.

Patients face delays, higher costs, and hard switches to new devices

Philips' foam degradation issue has exposed patients to severe health risks, leading to respiratory complications and even cancer. Recalls of many ventilators and sleep apnea devices have left hospitals struggling to replace them, causing delays in patient treatment.

Patients relying on a specific brand faced reduced treatment options. Many patients found it **difficult to switch to other brands due to cost and differences in machine settings or interfaces**. With Philips halting sales of various sleep apnea devices and ventilators, patients have no choice but to switch to other brands.

The recall of various products from different companies has created **significant demand and supply chain pressures for existing companies**. These pressures will likely drive up ventilator and sleep apnea device prices, further burdening patients.

EOS Implic-Action: Recall-driven gaps will reward reliable brands with ready supply

Product recalls in the sleep apnea devices and ventilator segment brought quality issues to the limelight. This **highlights the need for stronger quality control** processes and technologically advanced sleep apnea devices and

ventilators incorporating **virtual monitoring and AI integration, which can help detect defects earlier.**

While the FDA received complaints about Philips' degradation of the sound abatement foam in the sleep apnea devices and ventilators before the recall initiation, **decisive action to force correction was not taken immediately.** Also, despite knowing that **Philips had been aware of the foam degradation issue for many years,** the FDA did not take stronger enforcement measures against the company sooner. This situation highlights the importance of assessing and enhancing the FDA's oversight process to ensure timely response to medical device complaints.

Philips suffered lasting brand damage due to the recalls. Although the company is trying to regain shareholder and consumer trust after settling US claims for an amount much lower than anticipated by analysts and the public (US\$2-5 billion), it faces a long road ahead.

Regarding market competition, **ResMed is estimated to continue to lead and strengthen its dominant position** in the sleep apnea devices market. The exit of well-established players from the ventilator market will **intensify competition among existing companies and new entrants** seeking to capture market share. However, it will be a gradual process as customers slowly transition from existing products to new brand ones. On top of that, the new entrants are likely to face stricter regulatory norms and product approval processes aimed at reducing the number of product recalls and enhancing patients' safety.

