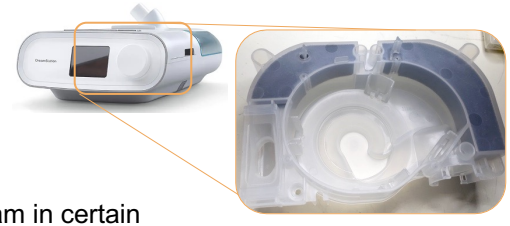
Recall of Philips Respironics CPAP, BiPAP and Ventilator devices took place in 2021-2023. Consequently, many competitors took over the market share from Philips.

Cause



- Sound abatement foam in certain Philips CPAP, BiPAP and Ventilator devices was made from polyester-based polyurethane, which may degrade over time due to exposure to heat, humidity or cleaning solutions.
- As particles are released into the user's mouth and lungs, the potential effects may include asthma, inflammation and toxic or carcinogenic effects to organs.
- The recall affects 3-4 million patients worldwide, with over half of them in the US.
- Most importantly, no deaths have been caused by faulty Philips devices.

Timeline

April 2021
Philips informs the public it's aware of the issue; Provides $600 million provision.

June 2021
Philips releases an official recall notification in the US, along with instructions for physicians and users.

September 2021
US FDA releases an update on the issue and announces on-site inspections of Philips manufacturing sites.

Devices affected

- **Immediate reaction** - As soon as it learned about problems with foam in April, Philips issued voluntary recall in June.
- **Direct communication with end-users** - Philips has set up an online registration platform for affected users: www.philipssrcupdate.expertinquiry.com
- **Fast replacement program** - Phillips has produced 90% of the replacement devices and shipped >2 million devices.[1]
- **Internal changes** - The company's Quality Management System has been updated with the latest findings of the issue.

Source: 1) As of 25 January 2023; Philips, US FDA, TSN Business Intelligence