

Potential risk of freezing in some Vestfrost fridges

Refrigerators are equipment used by immunization programs for the safe storage of vaccines. They are meant to maintain a temperature of 2-8 degrees under normal situations even though environmental and human factors such as extreme low or high ambient temperatures, prolonged opening of the fridge door or the placing of unauthorized products in the fridge can lead to transient excursions beyond the 2°C to 8°C range. However, the WHO standards for vaccine fridges require them to perform in such a way as to prevent prolonged excursions below -0.5°C for more than 1 hour.

WHO prequalification goes through a thorough process of reviewing performance test results of fridges and the quality certification of manufactures before their fridges are prequalified. Once the fridges are prequalified, manufacturers have the duty to ensure that subsequent production of fridges for sale to countries meet the same standard as samples which were reviewed by WHO during prequalification.

The World Health Organization (WHO) received complaints from UNICEF on the 30th April 2019 indicating an abnormally high rate of freeze alarms in vaccine refrigerators manufactured by Vestfrost (Vestfrost Solutions A/S, Denmark). The data shows that out of a sample of 44 WHO prequalified vaccine fridges from Vestfrost, 8 have repeatedly recorded temperatures below -0.5 °C for more than one hour thus triggering freeze alarms.

The specific models concerned with this issue are the following:

- Vestfrost VLS054, E003/054 first prequalified in May 2014
- Vestfrost VLS200, E003/031 (withdrawn in 2018) first prequalified in June 2012
- Vestfrost VLS200A, E003/062 first prequalified in March 2016
- Vestfrost VLS300, E003/032 (withdrawn in 2018) first prequalified October 2012
- Vestfrost VLS400, E003/021 (withdrawn in 2018) first prequalified November 2011

Exposure of freeze sensitive vaccines to negative temperatures may have impact on their quality, safety and efficacy.

The Manufacturer has identified the root cause of the malfunction and is currently working with WHO to identify the locations of the affected equipment and plan for repairs.

The plan for corrective action on the affected devices will be communicated by WHO Prequalification through WHO country offices once the affected countries have been identified.

In the meantime, WHO recommends that national immunization program take the following precautionary measures, according to current EPI guidelines:

1. Identify the location of Vestfrost refrigerators by reviewing cold chain inventories and the operation deployment plan;
2. Review the data on the 30DTRs and/or any other temperature monitoring device installed in Vestfrost refrigerators to identify whether negative temperatures have occurred
3. Report any alarms, including the type and quantity of vaccines in the affected fridge, to WHO prequalification using the online [complaints portal](#) on this website. This will help us to provide you with specific guidance.

WHO continues to monitor the situation and will provide any additional updates to the above information when received.