



ResMed UltraSoft™ memory foam

Understanding the bioburden of
polyurethane foam and mask hygiene



Summary

A total of forty patients in two studies were each provided with a memory foam mask for continuous positive airway pressure (CPAP) therapy.^{1,2} Used without cleaning, the masks had their colony-forming unit (CFU) counts recorded to assess their bioburden risk over time. Peak bacterial growth in both studies reached equilibrium within five days. Furthermore, no pathogenic bacteria was found above a count of 1×10^8 CFU/cm² over the duration of both studies. Patients can use memory foam masks for up to a period of at least one month without incurring any significant bioburden risk.

Background

CPAP masks will be exposed to moisture, skin cells, skin oils, as well as bacteria from the environment and a patient's airway. If left neglected, the mask could experience increasing bioburden, declining comfort and performance, and a potential risk of pathogenic growth.

While confidence exists for the hygienic use of silicone masks, the use of polyurethane memory foam in masks is new and presents unique challenges. Despite its benefits, such as a comfortable seal and fit, patients may have the perception that foam masks foster microbial growth due to their porous material.

For all mask types, routine cleaning is recommended. Nonetheless, a study of silicone mask users found that only 3/10 cleaned their masks nightly, with 1/8 admitting to never cleaning them at all.³ The same study also found that silicone mask age is a greater risk factor for bioburden than cleaning frequency. This might mean that memory foam cushions could be more hygienic than silicone as they are indicated for regular replenishment.

The results of two studies have been reviewed and discussed in this document to assess the bioburden on foam masks used without cleaning.



Results

Across the lengths of both studies, the CFU counts measured consistently between 1×10^4 CFU/cm² and 1×10^8 CFU/cm², which is within the normal expected range. For some perspective, normal human skin is typically colonised by microbes in the order of 1×10^6 CFU/cm² on the scalp and 1×10^4 CFU/cm² on the forearm.⁴

Diagram 1: Bioburden results from 2009 study

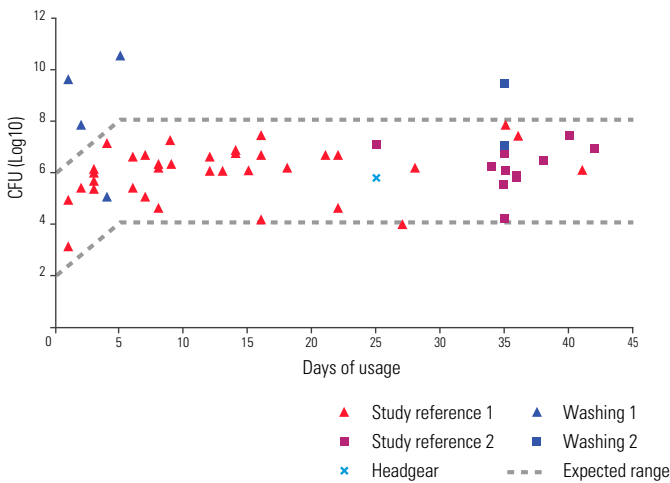
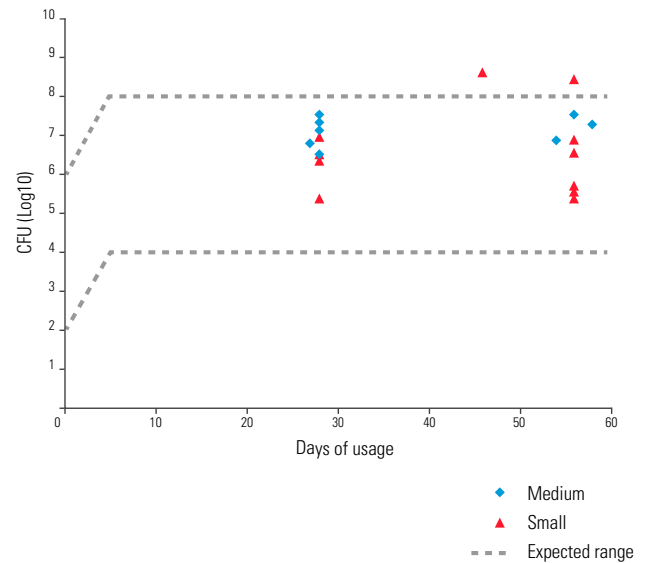


Diagram 2: Bioburden results from 2011 study



Key findings

- The bioburden observed on masks were within the range expected of materials that come into contact with human skin.
- No harmful levels of pathogenic bacteria were found across the duration of both studies.
- Microbial growth reaches equilibrium within 5 days of mask usage, and then levels off for the remaining duration of each study.
- ResMed’s memory foam masks are safe to use for a period of at least one month without cleaning and did not show to have an additional bioburden risk for a period of up to eight weeks.
- It is recommended that memory foam masks be replaced monthly to provide freshness and reduce bioburden risk.

1 Bioburden Safety Analysis of Foam Cushion for CPAP Mask, ResMed internal study (A3002617) conducted in 2009.

2 Forster Bioburden Safety Analysis of Foam cushion for CPAP Mask, ResMed internal study (A3389641) conducted in 2011.

3 Horowitz, Alex., et al. “CPAP Masks are Sources of Microbial Contamination.” SleepHealth Centers, Division of Sleep Medicine, Brigham and Women’s Hospital, Harvard Medical School, Boston, 2009.

4 Masumeh Saeidi and Akbar Derakhshan. “Normal bacterial flora on hands”. Journal of Patient Safety, Mashhad University of Medical Sciences, Mashhad. 2015.