



Anti-Suffocation Pillows



From Don Alderton, Pharmacist

a Member of the Royal Pharmaceutical Society

A Family Company,

run by Healthcare Professionals, focussed on Healthcare Integrity.

www.sleep-safe.co.uk

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...Someone at risk from seizures?

		
A normal pillow BLOCKING the nose and mouth	Sleep-Safe pillows WON'T BLOCK the nose and mouth	Airflow THROUGH the Sleep-Safe pillow AND AROUND the nose and mouth

Essential for anyone who is 'at risk'
For children and young people...
For older people...
For people of all ages with special needs...

Protects **THEM** while they sleep –
and gives **YOU** peace of mind!

Sleep-Safe Non-RCT Proof of Effectiveness

To establish proof of the effectiveness of the Sleep-Safe pillow; however a 'Gold Standard' Randomised Controlled Trial ('an RCT') in the usual sense cannot be conducted due to ethical constraints.

An RCT is a study in which a number of similar people are randomly assigned to two or more groups to test a specific drug, treatment or other intervention. This type of trial involves comparing the outcome of treating two matched populations of patients with a product that is *thought* to be *effective* with a product that is *known to be ineffective* (a 'placebo'). Comparing the incidence of an 'end-point event' between the two populations enables a judgement to be made about the effectiveness of the product which is *thought* to be effective.

In the case of an anti-suffocation pillow the 'end-point event' is *suffocation*. However, testing directly for suffocation would cause discomfort to many of the trial patients and a worsening of condition or even death for particularly vulnerable patients. As such, 'breathability' – the capability of a material to allow air to be transmitted at a rate sufficient to maintain life – was used as a proxy for evaluating the anti-suffocation effectiveness of Sleep-Safe pillows. Nonetheless, an exhaustive search failed to locate an academic or commercial organisation that was responsive to performing this work.

Undeterred, while working in a community pharmacy I was asked to supply a POWERbreathe device and I reasoned that the inventor might be interested in helping to resolve this problem. The manufacturer agreed to forward my enquiry to the inventor, Professor Alison McConnell, who in turn agreed to test the breathability of the Sleep-Safe pillow.

In the tests a variety of pillow types were evaluated to establish their breathability airflow capability using the normal human lung inspiratory pressure as a baseline. The results showed that the most commonly used domestic pillows did, in fact, cause significant restriction to airflow, whereas the Sleep-Safe pillow did not.



The test results are among the evidence accepted by the Medicines and Healthcare products Regulatory Agency (MHRA) to accord UKCA Accreditation to the Sleep-Safe pillow.

UKCA indicates that the Sleep-Safe Anti-Suffocation pillow is a Class I Medical Device registered at the Medicines and Healthcare products Regulatory Agency (MHRA) and conforms to the requirements of the Medical Devices regulations as amended 2024.

It is an implicit declaration that the Sleep-Safe pillow complies with all UK laws and applicable British conformity assessment procedures.

**VAT
Zero Rated** VAT Zero Rated

Subsequent to these results, and in a unique adjudication, HM Customs and Excise issued a VAT Liability Ruling that authorises Sleep-Safe pillows to be supplied Free of VAT to qualifying persons:

'You should note that this ruling only covers the particular anti-suffocation pillow produced by Sleep-Safe.'



These accreditations provide reliable evidence for Sleep-Safe pillows to be publicised to health and social care professionals.