



**BSI Standards Publication**

## **Medical electrical equipment**

---

Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

## National foreword

This British Standard is the UK implementation of EN ISO 80601-2-69:2020. It is identical to ISO 80601-2-69:2020. It supersedes BS EN ISO 80601-2-69:2014, which is withdrawn.

BSI, as a member of CEN, is obliged to publish EN ISO 80601-2-69 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval.

The UK committee submitted a negative vote as they did not agree with the requirement mandating that operator accessible outlets of accessories shall include a means to prevent the propagation of fire back through the outlet connector. The UK committee believes that a means to prevent the propagation of fire commonly known as a fire break is a separate issue and that it is impractical to mandate that all accessories such as nasal cannulae, therapy facemasks and therapy tubing must be supplied with such a means. The UK committee believes this would be cost prohibitive, and that having two or three fire breaks on the same piece of medical equipment is both wasteful and unnecessary.

The UK committee is also concerned that this document makes no reference to the standards that are written for these accessories such as ISO 17256 *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*, ISO 23368 *Anaesthetic and respiratory equipment — Low flow nasal cannulae for oxygen therapy*, or even for the standard ISO 19211 *Anaesthetic and respiratory equipment — Fire-activated oxygen shut-off devices for use during oxygen therapy*. These standards address the issue of fire breaks in a more practicable way than 80601-2-69 which will only lead to confusion in the market place.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2020  
Published by BSI Standards Limited 2020

ISBN 978 0 539 01163 0

ICS 11.040.10

**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2020.

### Amendments/corrigenda issued since publication

| Date | Text affected |
|------|---------------|
|------|---------------|