BS ISO 17256:2024

BSI Standards Publication

Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors

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

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Foreword

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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment* Subcommittee SC 2, *Airway devices and related equipment*.

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Introduction

Respiratory tubing and connectors form the essential conduit between the *patient interface* and the gas supply device. The connectors specified in this document have been selected taking into consideration the risks of misconnection with other medical devices commonly used within the same environment. The requirements in this document were further developed and are to be circulated to all ISO/TC 121 subcommittees as recommendations.

Respiratory tubing and connectors are used extensively in healthcare facilities and increasingly in the home healthcare environment where medically trained personnel are not always in attendance. These environments have been carefully considered throughout the development of this document.

This document recognizes the significant use and the inherent safety of the EN 13544-2[1] specified nipple as the gas outlet on respiratory gas supply devices and therefore specifies a compatible elastomeric (funnel) connector as the inlet of the *respiratory tubing*. This document also recognizes the high risks associated with misconnection of the previously prescribed elastomeric (funnel) connector at the outlet (patient end) of the tubing and has therefore specified the new R2 respiratory small-bore connector as the outlet connector if the *respiratory tubing* is not integrated with the *patient interface* device (e.g. face mask, nasal cannula).

The concept of *extension tubing*, commonly used to provide flexibility of movement for the patient in home-care environments and hospital environments, such as MRI units, toilets and endoscopy units, has now been included in this document with particular emphasis on the connectors.

This document is adapted from EN 13544-2:2009[1] and has been modified as follows:

— the change of outlet from an elastomeric funnel to an R2 respiratory small-bore connector;

— requirements for *extension tubing*;

— requirements for *respiratory tubing* integrated with *patient interface* devices;

— a requirement to assess the biocompatibility of the materials of the devices that provide a gas pathway has been added;

— the dimensions of the nipple have been better defined;

— the option to specify a gas-specific threaded connection at the inlet of the *respiratory tubing* to replace the elastomeric funnel inlet connector has been made clearer;

— the gas-specific threaded inlet connectors now include gasses other than oxygen and air; and

— a hazard identification annex has been added (Annex C).

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