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S.R. CR 13903:2000

General guidance on the equipment used for inhaled nitric oxide therapy

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General guidance on the equipment used for inhaled nitric oxide therapy

This CEN Report was approved by CEN on 23 March 2000. It has been drawn up by the Technical Committee CEN/TC 215.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held BSI.

Introduction

It gives information on the properties and medical uses of nitric oxide and guidance on medical equipment through which this gas passes before and after administration to the patient. This report is primarily intended for those involved in the standardization and manufacture of such medical equipment and for those concerned with the practice of inhaled nitric oxide therapy.

1. General

1.1 Background

Nitric oxide for inhalation (NO) is a new medical gas. It is regarded as a new medicinal product for use in investigation and treatment of patients on a compassionate basis. It has not received marketing authorisation in any country in the European union or in the USA.

Nitric oxide in nitrogen is supplied as a ready to use mixture intended to be administered to patients together with oxygen using a suitable supply and delivery system. In this document concentrations of nitric oxide/nitrogen are given as '≤ 1000 μl/l'. At this stage of drafting, it is not possible to give a fixed value because European medicines licensing authorities have not yet registered this mixture as a medicinal product.

Nitric oxide is used in clinical studies approved by ethics committees, and those using it should be familiar with its properties and the potential problems which may arise during use. Such studies may establish dosing recommendations and may lead to regulatory approval for use in specified situations.

Before approval is granted, situations may occur where clinical use of nitric oxide inhalation outside clinical studies is considered justified by the treating physician. The format for treatment of individual patients in these cases is compassionate use. The use of unapproved medicinal products in individual patients is subject to national legislation in most countries and may require notification to or approval by the relevant Authority.

1.2 Physiology

1.2.1 General

In 1987 it was verified that the endothelium derived relaxing factor EDRF is nitric oxide (1,2). Since then there has been a considerable interest in research of the various effects of endogenously formed nitric oxide.

Endogenous nitric oxide seems to be involved in the control and action of a great number of organ functions, including platelet aggregation, neurotransmission, and antitumour and antimicrobial activity, and not only in the control of vascular tone.

1.2.2 Vascular control – Nitric oxide as a paracrine messenger

Endothelial cells produce small amounts of nitric oxide that diffuse from the endothelial cells to the smooth muscle cells causing relaxation of the vascular smooth muscle. The low pulmonary vascular tone of normal lungs appears to be partly maintained by endogenous synthesis of nitric oxide (3).