Chapter 3.1

HYPERBARIC CHAMBER AND EQUIPMENT

Multi- and Monoplace Chambers

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Abstract: Administration of hyperbaric oxygen to patients requires a special pressure vessel - hyperbaric chamber (multiplace or monoplace), installed as a part of hyperbaric systems. The hyperbaric chamber is a medical device, but to conduct the treatment it is usually necessary to introduce some other medical devices into it (ventilators, syringes and pumps, etc.). In the following chapter European regulations applicable to hyperbaric systems are presented by P. Müller, the hyperbaric fire fighting systems and related national standards are described by R. Houman, and the minimum requirements for the multiplace chamber according to the prEN14931 and safety aspects of medical equipment used inside hyperbaric chambers with a list of specific devices tested under hyperbaric conditions are discussed by J. Kot

Keywords: Hyperbaric chamber; equipment; medical devices; safety; fire fighting

1. MULTIPLACE CHAMBER AND EQUIPMENT

1.1 Introduction

The hyperbaric chamber is an active medical device, which is potentially hazardous taking into accounts its application and exposure of people inside to increased ambient pressure and increased partial pressure of oxygen. Use of medical devices in the hyperbaric environment is also related with additional hazards due to increased pressure, oxygen-enriched atmosphere,
electricity and confined space. Therefore all hyperbaric systems and internal medical devices have to be in accordance with appropriate regulations.

1.2 European regulations

One of the main goals of the European Union is to facilitate the free flow of goods and merchandise within the European market. This has largely been made possible thru harmonisation and normalisation of the previously differing standards in the EU member states. This harmonisation process is the task of the European Committee for Standardisation (CEN).

In 1985 a new regulatory technique and strategy was laid down by the Council Resolution on the New Approach to technical harmonisation and standardisation\(^1\) with a fundamental principle to limit legislative harmonisation to the essential requirements that are of public interest. These requirements deal in particular with the protection of health and safety of users (e.g. consumers and workers) and sometimes cover other fundamental requirements\(^2\) (e.g. protection of property or the environment).

In Europe, the medical hyperbaric chambers are medical devices, which fall under the dispositions of the Medical Device Directive 93/42\(^3\), with all consequences\(^4\). Moreover, as pressurised devices they also fall under the Directive for Pressure Equipment 97/23\(^5\).

1.2.1 The Medical Devices Directive (MDD 93/42)

Purpose

The Medical Devices Directive\(^3\) (MDD 93/42) provides for a harmonised regulatory environment for all medical devices sold within the European Economic Area (EEA). All products, which fall within the scope of the Directive, must meet certain essential safety and administrative requirements and are to be CE marked to show that they comply. The Directive was brought into force with effect from 1 January 1995. Transitional arrangements permitted equipment, which complied with national regulations to be sold until 14 June 1998 after which the MDD became fully enforced.

Scope

The Medical Devices Directive is one of a suite of three directives, which together cover all medical equipment. The associated directives are the Active Implantable Medical Devices Directive\(^7\) (AIMDD) and the In Vitro Diagnostic Devices Directive\(^8\) (IVDD). The Directive defines medical devices as: