A EUROPEAN CODE OF GOOD PRACTICE FOR HYPERBARIC OXYGEN THERAPY
COST B14 action « Hyperbaric Oxygen Therapy », WG « Safety » (addresses in fine).

Introduction
Hyperbaric medicine (HBO) was established in Europe. The first pressure chamber (Henshaw, 1662), describing the effects of increased pressure (Bert, 1878), the first mobile pressure room (Fontaine, 1879), the first decompression tables (Haldane, 1908), the first diving and pressure simulator (Dräger, 1913), the high oxygen environment (Churchill-Davidson, 1955), application of hyperbaric oxygen in surgery (Boerema, 1956), in anaerobic infections (Brummelkamp, 1961), and in carbon monoxide poisoning (Smith & Sharp, 1962), as well as the first International Congress on Hyperbaric Oxygenation (Amsterdam, 1963) had all been introduced in Europe [1]. The usage of pressure chambers in recompression of tunnel/caisson workers and divers came later than the application of pressure for other therapeutic purposes, however the largest experience in operating hyperbaric chambers came from working in the underwater environment, and until recently hyperbaric chambers were built and operated according to diving rules and regulations. Increasing interest in the application of HBO in different medical conditions, including critically ill patients, has led to situations in which hyperbaric chambers are now treated as medical devices, and therefore specific regulations are needed. It is worthwhile to notice that Standards, Guidelines or Regulations have previously been published on the national levels in those countries which have large diving experience and traditions (e.g. France, United Kingdom, Germany, USA).

Today there is a need for a harmonised European Regulation for HBO. A lot of work has been done already [2]. There are publications for internationally approved indications for HBO treatment (ECHM, UHMS), conclusions from Consensus Conferences on hyperbaric oxygenation [3, 4], educational and training standards for hyperbaric staff [5] and recommendations for safety in medical chambers [6, 7]. In this paper we present a European Code of Good Practice (ECGP) for HBO which is an international document prepared by the members of the COST B14 Action concerning safety of hyperbaric treatment based on existing experience from experts of hyperbaric centres, committees, professional and scientific associations.

Background
Founded in 1971, COST is an intergovernmental framework for European Co-operation in the field of Scientific and Technical Research, allowing the co-ordination of nationally funded research on a European level.

In 1998 the Action B14 was started as part of the COST domain « Medicine and Health » under the title « Hyperbaric Oxygen Therapy ». The national representatives of 19 European countries (Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Israel, Italy, Netherlands, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom) signed a Memorandum of Understanding. Each country designated national experts in hyperbaric medicine to participate in this program and Professor Daniel Mathieu was nominated as Chairman of that Action. The main objective of the Action is to improve the knowledge required for a rational use of hyperbaric oxygen therapy, to a level making it possible to set out specific guidelines for the implementation and development of clinical
centres for HBO and to provide scientifically sound recommendations for HBO treatment of various diseases and conditions.

Since the beginning several Working Groups (WG) have been created to fulfil specific tasks under the main objective of the Action. One WG created the OXYNET, which is an Internet portal for Hyperbaric Oxygen Therapy (www.oxyinet.org), another published a «Research Guidance Document» specifying the quality criteria desired for any new and ongoing research projects on HBO. Several other WG’s prepared research protocols which have been implemented to conduct the prospective, multi-centre clinical studies concerning HBO in the treatment of sudden idiopathic sensorineural hearing loss, foot lesions in diabetic patients, femoral head necrosis, late irradiation sequelae in the pelvic region, reirradiation of recurrent squamous cell carcinoma of the head and neck, enhancing radio sensitivity on glioblastoma multiforme, and osteointegration in irradiated patients.

In 2000 the Working Group «Technical Aspects» (WGT) was formed and by 2001 it’s main objective was initiated with the starting of the harmonisation process of a European norm for hyperbaric chambers and systems and WGT prepared the hazard identification for HBO as a part of a risk analysis [8, 9]. In 2001 the Working Group «Safety» was created with the main objective to elaborate recommendations of good practice for hyperbaric medicine and to follow the European normalisation process of hyperbaric chambers [10].

Methods
During three years of work the relevant documents regarding safety in hyperbaric chambers from each European country have been reviewed by the members of the WG «Safety». The British Hyperbaric Association (BHA) «Health and Safety for Therapeutic Hyperbaric Facilities: A Code of Practice» (2000) [11] was accepted as a basis for the creation of the European Code of Good Practice for HBO. In the process of preparation, the preliminary version of the ECGP was constantly being modified and updated using national regulations and standards from different countries, mainly Belgium, Finland, France [12], Germany, Greece, Italy [13], Portugal, and Spain. Existing European Norms concerning hyperbaric chambers were referenced to, and experience from experts of hyperbaric centres, committees, professional and scientific associations were included to create the state-of-art in safety of the hyperbaric medicine.

During the process, the WG «Safety» closely cooperated with the CEN/BT/Task Force 127 (TF127) which was preparing the project of the European Norm entitled «Pressure vessels for human occupancy (PVHO) – Multi-place pressure chambers for hyperbaric therapy – Performance, safety requirements and testing» (prEN14931) [14]. The representative of the WG «Safety» was also participating in the TF127 meetings to present the opinion of the hyperbaric chambers’ users to manufacturers and to ensure that the technical aspects of hyperbaric systems included in this new European Norm were reflected in the ECGP for HBO.

Results
Finally, in May 2004 the last version of the ECGP for HBO was accepted by the hyperbaric experts of the Management Committee of the COST B14 Action. This means that this document was ready to be implemented in European countries.

The ECGP for HBO relates to hyperbaric treatment as a procedure affecting patients, staff and any third parties involved in the therapeutic process and not to the medical protocols by
themselves unless these protocols modify the level of safety. It applies to all facilities for hyperbaric medicine that provide hyperbaric treatments to patients, as well as to medical research exposing human subjects to a hyperbaric environment.

The document consists of chapters dedicated to staffing, equipment, gas supply, risk management and procedures.

The chapter on staffing includes responsibilities, competencies and education, minimum team sizes during hyperbaric sessions both for mono- and multiplace chambers, fitness and health surveillance. The ECGP uses the functions and educational requirements defined by the European Committee for Hyperbaric Medicine (ECHM). The ECHM documents «Educational and Training Standards for the Staff of Hyperbaric Centres» (1997) [5] and «Recommendation for Safety in Multiplace Medical Hyperbaric Chambers» (1998) [6] are included in the ECGP as annexes.

Chapters on equipment and gas supplies are linked with the prEN 14931 prepared by TF127 making both documents complementary.

A separate chapter is devoted to the risk management being conducted according to ISO EN 14971 [15]. The process of risk analysis, risk evaluation and risk control is presented with some detailed specific hazards of hyperbaric treatments, namely oxygen toxicity, dysbaric injuries, thermal stress, electrical and fire safety, prohibited materials, and manual handling. The final report of the WG «Technical Aspects» (2001) [9] is also included as an annex. It consists of the list of hazards related to the hyperbaric installation and to the use of medical devices during HBO treatment. This is a part of risk analysis conducted specifically for therapeutic hyperbaric facilities.

The chapter on procedures includes description of standard and emergency operating procedures, maintenance, record keeping, and patient safety. The framework of an operating manual for hyperbaric systems is included as an annex.

Every effort has been made to make the ECGP for HBO compatible with the new project of the European Norm prEN 14931. Both groups – CEN/BT/TF 127 and COST B14 WG «Safety» – co-operated extensively in the field of safety aspects of using hyperbaric chambers as medical devices, and both final versions of each document include many cross references. The ECGP is focused on safety of the HBO from the point of view of users, and the prEN 14931 is oriented to technical aspects of design and structure of hyperbaric installations, as guidelines for manufacturers.

**Conclusions**

The ECGP was prepared by international Working Group «Safety» and after acceptance by all management members of the COST B14 action, the European Code of Good Practice for HBO represents a consensual harmonised European view on safety in therapeutic hyperbaric facilities and should be used as a reference document in European countries in need of Guidelines, Regulations, and Standards in hyperbaric medicine.
References
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