



**BUSINESS PLAN**  
**ISO/TC 168**  
**Prosthetics and orthotics**

**EXECUTIVE SUMMARY**

*Theoretically, the market for prostheses and orthoses comprises those persons with physical disabilities who intend and are enabled to achieve a high(er) level of independence by the use of these devices.*

*In practice, however, in many parts of the world where these devices are provided on prescription, the market is in effect strongly influenced or even governed by those institutions which pay for the devices, i.e. by the state itself or by other reimbursement authorities/bodies as e.g. insurances.*

*The major benefits of the standards developed by ISO/TC 168 are in two areas.*

- *For suppliers: Criteria against which to design new products to place on the market*
- *For purchasers: Safe reliable products.*

*The present work of ISO/TC 168 is characterized by the elaboration of two different groups of standards, aiming at the establishment of:*

- 1.) *a system of nomenclature and related terminology to allow all parties involved in the prosthetic/orthotic treatment of persons with physical disabilities to apply a standard terminology and*
- 2.) *a system of test methods for the verification of essential requirements on prosthetic/orthotic devices related to the safety of the users.*

## 1 INTRODUCTION

### 1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

### 1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: [ISO](#) (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of [IEC](#) (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of [ITU](#) (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 140 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the [International Standard](#).

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its [Technical Committees](#) are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

## 2 BUSINESS ENVIRONMENT OF THE ISO/TC

### 2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

Theoretically, the market for prostheses and orthoses comprises those persons with physical disabilities who intend and are enabled to achieve a high(er) level of independence by the use of these devices.

In practice, however, in many parts of the world where these devices are provided on prescription, the market is in effect strongly influenced or even governed by those institutions which pay for the devices, i.e. by the state itself or by other reimbursement authorities/bodies as e.g. insurances.

### **The major product categories are:**

**External limb prostheses:** Externally applied devices consisting of a single component or an assembly of components used to replace wholly, or in part, an absent or deficient lower or upper limb segment.

**External orthoses:** Externally applied devices consisting of a single component or an assembly of components applied to the whole or part of the lower limb upper limb, trunk, head or neck and their intermediate joints to modify the neuro-muscular and skeletal systems.

- The largest factor influencing market growth is the ageing of the worldwide population. Further factors are wide-spread diseases like circulatory disturbance (arterial occlusion) and diabetes which often lead to amputations as well as physical disabilities caused by accidents (private, professional, traffic) and wars.
- The major technologies used in the production of major prosthetic/orthotic devices comprise all state of the art technologies available for the manufacturing of metallic, composite and plastic materials (and wood) as well as recent control, computer and information technologies for the application of soft- and hardware (microelectronics).

### **The major suppliers in the market are**

- the (industrial) manufacturers of prosthetic devices, most of which are components that need to be assembled, aligned and adjusted or require individual adaptations to meet the individual needs of the users;
- the (industrial) manufacturers of orthotic devices, which are either components that need to be assembled, aligned and adjusted or require individual adaptations, in order to meet the individual needs of the users, or are finished orthoses that can be delivered without further treatment except minor settings;
- the prosthetists/orthotists who typically assemble, adjust and align prosthetic and orthotic components and/or carry out individual adaptations and complete them by individually designed and manufactured or individually adapted interface components (e.g. "sockets" to receive the amputation stump) to a custom-made or individually adapted finished device, but who also deliver/sell finished devices ("off-the-shelf" products);
- specialized dealers of medical supplies and pharmacies, who/which deliver/sell finished devices ("off-the-shelf" products), some of which may require minor settings.

The different groups of suppliers may run their business independently or jointly.

### **The degree of concentration of the different groups of suppliers varies:**

- The suppliers of (industrially) manufactured prosthetic/orthotic devices (the supply industry) are highly concentrated in many countries of the world; the prosthetic supply industry to a higher degree than the orthotic supply industry.
- The degree of concentration of the suppliers of custom-made or individually adapted finished devices (the prosthetists/orthotists) varies remarkably, dependent on several factors such as the national economic system, the organization of the national health service, the local infrastructure or local geographic conditions.
- Similar factors decide on the degree of concentration of specialized dealers of medical supplies and pharmacies.

### **The major customer groups in the market are:**

- governmental departments,
- other reimbursement authorities/bodies (e.g. insurances),
- private individuals.

*Note: The significance of the different groups of customers listed above varies from country to country: While in Europe governmental departments and insurances represent the predominant groups of customers, in North America these are the insurance industry and private individuals.*

## **2.2 Quantitative Indicators of the Business Environment**

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the ISO/TC:

This item intends to measure the value of standardization work against its (political-) economic benefit in terms of total sales, total employment or total international trade, which may make sense if this work is directed to the development of typical product standards.

For the standardization work in the field of prosthetics and orthotics according to the present programme of work of ISO/TC 168 this aspect is irrelevant for the following reasons:

- The prosthetic/orthotic treatment of persons with a physical disability is a matter of social and vocational rehabilitation. The latter may have a (political-) economic benefit, as it may increase the gross national product and reduce social contributions, but this effect is marginal in relation to the dimensions addressed in the above.
- The present work of ISO/TC 168 does not include the development of typical product standards. On the contrary, it is characterized by the elaboration of two different groups of standards, aiming at the establishment of
  - a system of nomenclature and related terminology to allow all parties involved in the prosthetic/orthotic treatment of persons with physical disabilities to apply a standard terminology for the description of essential characteristics/details,
  - a system of test methods for the verification of essential requirements on prosthetic/orthotic devices related to the safety of the users such as e.g. durability or reliability.

### 3 BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

The major benefits of the standards developed by ISO/TC 168 are in two areas.

- **For suppliers:** Criteria against which to design new products to place on the market
- **For purchasers:** Safe reliable products.

In this relation the system of test methods for the verification of essential requirements on prosthetic/orthotic devices related to the safety of the users, already mentioned in 2., is worth to be addressed again.

- Since the implementation of the European Directive 93/42 EEC on medical devices and the support of its application by the Harmonized European Standard EN12523 "External limb prostheses and external orthoses – Requirements and test methods", the ISO Standards on test methods referred to therein have gained significance within Europe and will gain significance in non-European countries in the degree in which the present work on Mutual Recognition Agreements (MRAs) results in binding contracts.
- The more the essential requirements on prosthetic/orthotic devices requested to be met by the different groups of customers worldwide and the test methods for the verification of these requirements can be harmonized, the more it is possible to simplify the introduction of new products into the world market and to reduce and finally avoid the unnecessary effort of parallel testing to different specifications.

The application of the test standards has already improved and will further improve the quality (durability, reliability) of prosthetic/orthotic devices. The resulting saving of the budget of reimbursement bodies may again be seen as a (politico-) economic benefit, but this effect is marginal in relation to the (politico-) economic dimensions of total sales, total employment or total international trade, addressed in 2.2.

### 4 REPRESENTATION AND PARTICIPATION IN THE ISO/TC

#### 4.1 [Countries/ISO members bodies that are P and O members of the ISO committee](#)

#### 4.2 **Analysis of the participation**

Active participants in TC 168 include industry, research and test institutes, prosthetist/orthotist associations, rehabilitation centres, government regulatory agencies, customers as e.g. health service agencies. The majority of active Member Bodies are from the developed regions of the world, but the TC is aware of the needs of less well-developed areas in which the infrastructure necessary for correct operation and maintenance of sophisticated equipment may be unreliable or absent. This is being partly addressed by liaisons with the International Association of Orthotists and Prosthetists (Interbor), International Society for Prosthetics and Orthotics (ISPO) and the World Customs Organization (WCO).

### 5 OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

#### 5.1 **Defined objectives of the ISO/TC**

The present work of ISO/TC 168 is characterized by the elaboration of two different groups of standards, aiming at the establishment of:

- 1.) A system of nomenclature and related terminology to allow all parties involved in the prosthetic/orthotic treatment of persons with physical disabilities to apply a standard terminology for the description of

- a) the users of prosthetic/orthotic devices,
- b) the functional requirements of the devices,
- c) the function of the components and the assembled devices,
- d) the outcome of the delivery of the devices.

Such a system is absolutely essential if the market benefits previously described are to be achieved.

Manufacturers require standard terminology to accurately describe their products and the benefits they will confer on users. Customers require standard terminology to be able to understand the properties of products and the benefits they will enjoy from their use.

The existing work programme of the Working Groups is designed to address the three remaining missing elements of the proposed system.

- 2.) A system of test methods for the verification of essential requirements on prosthetic/orthotic devices related to the safety of the users, comprising
  - a) static tests, which relate to the worst loads generated in any activity and which consist of a static proof test and a static failure test;
  - b) cyclic tests, which relate to normal walking activities where loads occur regularly with each step and which consist of repeated applications of load with loading conditions typical of normal walking.

## **5.2 Identified strategies to achieve the ISO/TC's defined objectives**

For ISO/TC 168/WG 1 "Nomenclature and terminology" and ISO/TC 168/WG 2 "Medical aspects" the JWG structure has been adopted to bring together the required blend of expertise and knowledge of the product manufacturers and the medical and associated healthcare professionals who are responsible for prescribing and delivering these devices.

For the same reason ISO/TC 168/WG 3 "Testing" uses to hold joint meetings together with WG 5 "Prostheses and orthoses" of CEN/TC 293 "Technical aids for disabled persons". In addition, members of ISO/TC 168/WG 1 and ISO/TC 168/WG 2 occasionally attend at these meetings.

## **6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME**

No threats to the planned programme of work are envisaged.

## **7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC**

This section gives an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

### **7.1 Structure of the ISO committee**

### **7.2 Current projects of the ISO technical committee and its subcommittees**

### **7.3 Publications of the ISO technical committee and its subcommittees**

## Reference information

[Glossary of terms and abbreviations used in ISO/TC Business Plans](#)

[General information on the principles of ISO's technical work](#)