BUSINESS PLAN
CEN/TC 293
ASSISTIVE PRODUCTS FOR PERSONS WITH DISABILITY

EXECUTIVE SUMMARY

The primary objective of CEN/TC 293 is to produce standards on assistive products for persons with disability, including follow-up activities and revisions. The major product categories that CEN/TC 293 presently deals with are wheelchairs, accessories to wheelchairs, assistive products for walking and aids for ostomy and incontinence.

Business Environment

• In Europe approximately 20% of the population has a disability or is elderly. Many of whom need and use assistive products in their daily lives.
• The major customer groups are government departments, service providers, reimbursement authorities/bodies (e.g. insurance companies) and private individuals.
• The market is large and complex with a wide variety of products; many of which are technically advanced and of significant economic value.
• There is a fast uptake of universal/accessible design, digital technology and the use of services supplied via Internet resulting in an emerging grey zone between the traditional assistive products and products available on the ordinary consumer market.
• The technical competence needed for the standardization covers many technical fields (mechanics, chemistry, ICT, etc), for a large number of different types of products.
• The users of assistive products and their organisations represent a unique competence, and it is vitally important to engage them in the standardization work.
• The need for standardization often coincides between Europe and other continents, and the competence/experts needed for the standardization work can be found inside Europe as well as outside. This calls for a close co-operation between the European and the International standardization committees in the field of assistive products for persons with disabilities.

Benefits
The major benefits expected of the standards developed by CEN/TC 293 are:
• criteria for manufacturers against which to design products;
• decreased production costs for assistive products;
• safe, reliable and functional products produced for purchasers and users;
• increased quality of life for users;
• improved cost effectiveness for purchasers, both private and public;
• enhanced compatibility between products;
• standards in new emerging areas such as accessibility and cognitive devices;
• common testing methods leading to comparable, reliable test results, such as the methods developed and standardized for testing electrical and manual wheelchairs.

Priorities
• assistive products that fall under the Medical Devices Directive and/or include in EN ISO 9999
• mandated work
• generic standards
• need for revisions/amendments of standards.
1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

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

Products
There are a wide variety of assistive products/systems many of which are technically advanced and represent significant economic value. An assistive product is defined in EN ISO 9999:2011 as "any product (including devices, equipment, instruments and software), especially produced or generally available, used by or for persons with disability
• for participation;
• to protect, support, train, measure or substitute for body functions/structures and activities; or
• to prevent impairments, activity limitations or participation restrictions".

Some of the larger product categories in the market are wheelchairs, hearing aids, prostheses and orthoses, beds, assistive products for walking, hoists and aids for incontinence and ostomy.

Technical factors
Assistive products for persons with disability combine many different technologies, and technical development is very rapid. This is particularly valid for Information and Communication Technology (ICT), which gives new or improved possibilities for an independent life for large groups of persons with disability. It also affects the design of traditional assistive products, and increases the possibilities to integrate different products/systems.

Growth sectors are primarily products based on information and communication technologies such as computer accessories, telecommunications equipment, special software and products for controlling and signaling. Assistive products designed to support persons with cognitive disabilities are beginning to represent significant economic value. There is also a fast growing market for so-called "smart simple products" (which often use universal/accessible design principles), developed for use at home to meet the needs of persons who have mild disabilities or reduced functioning. Often these products are sold on the ordinary consumer market, in several countries some are also prescribed by service providers of assistive products.

Many technologies are used in assistive products: mechanical, electrical, electronics, computer hardware and software, materials and design technology. With the convergence of computers, broadband TV and telecommunication services digital technology has become an integrated part of assistive devices. The Internet is an integrated part in an increasing number of assistive products already available. To some extent physical products are being replaced by software available via Internet. This is a trend that is expected to continue. One area is often called smart home appliances or ambient technologies, where assistive products can have a role to play as we approach a scenario called 'Internet of things', where appliances can interact with each other.

The committee recognizes that due to the fast uptake of universal/accessible design, digital technology and the use of services supplied via Internet there is an emerging grey zone between the traditional assistive products and products available on the ordinary consumer market.
Technical development is very important to persons with disability – as an opportunity for independence, but also as a potential obstacle or even hazard. Modern technology facilitates new and/or better products/systems, but may also be a hinder for persons with disability. For example, commonly used and sophisticated computerised systems in banks, shops, etc., can be very difficult to use for a person who is blind or for a person with cognitive impairments. In some cases it can even cause hazards. For example, persons with disability frequently use remote control systems for manoeuvring doors, elevators, etc. A malfunction can cause severe risks for the user and others involved.

Due to the rapid advance of technology and techniques, some standards have to be revised or amended soon after publication.

**Safety aspects**

Persons with disability and older persons have requirements as a consequence of impairments in one or more functions: seeing, hearing, cognition, mental functions, movement, balance, sensory functions, stamina, or anthropometry. Thus, safety aspects are specific and can be crucially important for persons with disability, and should be a cornerstone for the design of standards for assistive products. Due to their individual requirements and/or the assistive products they use, persons with disability can have different interactions with the environment/products than other people, which can result in higher probability of injury and more severe injuries – to themselves and to other persons.

**Important stakeholders**

Consumers/users of assistive products are usually persons with a disability and/or older persons – persons who have specific requirements as a consequence of impairments of one or more functions: seeing, hearing, cognition, mental functions, movement, balance, sensory functions, stamina, or anthropometry.

The major customer groups in the market are:

- government departments;
- service providers;
- reimbursement authorities/bodies (e.g. insurance companies);
- private individuals (i.e. consumers/users).

The significance of the different groups of customers varies from country to country depending on government policies, service delivery systems and reimbursement schemes. In some countries, the customers/users – persons with disability - purchase and pay for assistive devices. In other countries, there are third-party payers where a purchasing decision for many assistive products can be complex. While the person with disability often plays a role, many other individuals are frequently involved in the selection and purchase of a product. The size of the group involved may vary widely depending on the items being considered and can include family members, nursing staff members, therapists, physicians, case workers, funding agencies/ companies, other rehabilitation engineering personnel, as well as an assortment of other interested care providers. An increased user influence is generally expected in the future as well as a growing private market.
Important stakeholders include
- users/consumers and their organisations;
- attendants, professional or non-professional (family members etc);
- manufacturers and their organisations;
- EU Commission, national, regional and local governments, and other political bodies (including payment bodies);
- public and private purchasers;
- healthcare and social welfare professionals;
- test laboratories;
- research and educational bodies (universities etc);
- other standardization bodies.

NOTE The above list is not a ranking of important stakeholders.

Social factors
In the countries of Europe there is a distinct trend for older people and people with disability to live independently in their own homes rather than in institutions. A large number of these persons need assistive products in their daily lives. There is a growing awareness that assistive products can enable older people and people with disability to live longer independently in their own homes.

There are a number of EU programmes that finance research and development that can have an influence on the work of CEN/TC 293. Horizon 2020 has a work programme for Health, demographic change and wellbeing where work with solutions that take into account the use of assistive products, is included. The European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) aims to increase the average healthy lifespan by two years by 2020 and has a number of focus areas in which innovations are highlighted that are relevant to assistive products. The Ambient Assisted Living Joint Programme focuses on ICT for ageing well, a focus that has an also relevant to the work of CEN/TC 293.

Industry
The industry is dominated heavily by small and medium-sized enterprises (SME), with the exception of certain sectors, such as wheelchairs and prostheses, where a few large suppliers dominate but where there are still a large number of small suppliers of niche products.

Due to the identified grey zone between mainstream products and assistive products some manufacturers of mainstream consumer products (that often use universal/accessible design principles) are also important stakeholders. For example mobile phones have become Smartphones. Smartphones in combination with apps have been found to be very useful for people with cognitive impairment and people with visual impairment through the use of audio menus, etc

The biggest determinants to the size of companies in the industry are generally the type of product involved; e.g. software development is largely SME-driven due to smaller national markets, fragmented by language.

1.2 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 CEN /TC:
Customers/Users
As the user of assistive products is typically a person with a disability the prevalence of disability is a factor in the determination of market size. Different disability concepts and definitions are used in different countries which creates practical difficulties in collecting, analysing, comparing and interpreting data needed to express the prevalence of disability.

Stereotypical views of disability emphasize wheelchair users and a few other “classic” groups such as those persons who are blind and deaf. However, the disability experience is much wider and is the result from the interaction of health conditions, personal factors, and environmental factors and can vary greatly. Ageing is a factor that often implies that the individual experiences functional limitations or disability. The demographic change ongoing in most countries in Europe (and worldwide) is a factor that many consider will increase the prevalence of disability.

In Europe there is an understanding that assistive products can enable persons with disability and older persons to live independently in their own homes and to participate in society. In most European countries, reimbursement systems for the provision of assistive products to persons with disability and older persons are part of the healthcare and social welfare systems and/or employment insurance and are a specific feature of the market.

Many older persons use assistive products in their daily lives. In Sweden it is estimated that approximately 70% of assistive products are used by people over 65 years old. It is expected that the need for assistive products will substantially increase as the total population over 65 years is expected to increase in Europe (and worldwide).

Although it is difficult to assess the exact number of potential consumers of assistive products, it is fairly clear that the need for assistive products should increase due to an increased awareness of how assistive products can enable persons with disabilities and older persons to live independently in their own homes and the increase in the proportion of older people in the population.

The table below from the WHO gives a tentative projection of the development of the need for assistive products worldwide and in Europe.

<table>
<thead>
<tr>
<th></th>
<th>Total population</th>
<th>Older population</th>
<th>Disabled population</th>
<th>Tentative requirement assistive products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global 2012</td>
<td>7.08 billion</td>
<td>770 million</td>
<td>1 billion</td>
<td>1.4 billion</td>
</tr>
<tr>
<td>European 2012</td>
<td>7.39 billion</td>
<td>129 million</td>
<td>110 million 15 %</td>
<td>191 million</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tentative projection for 2050</td>
</tr>
<tr>
<td>Global 2050</td>
<td>9 billion</td>
<td>2 billion</td>
<td>1.35 billion</td>
<td>2.7 billion</td>
</tr>
<tr>
<td>European 2050</td>
<td>9.9 million</td>
<td>287 million</td>
<td>148,5 million</td>
<td>348 million</td>
</tr>
</tbody>
</table>

Estimated market size
It is difficult to assess the potential market size for assistive products as it is difficulty to estimate the number of persons with disability and it is difficult to estimate the number of persons with disability who would benefit from the use of assistive products. Further, the socio-economic circumstances and socio-cultural environment for the individual with a disability impact.
on the allocation of resources to purchase assistive products which makes it is even more difficult to assess the number of potential consumers of assistive products.

The economic turnover for assistive products is large. According to BCC Research, the global market for assistive products (excluding eyewear) in 2012 was estimated at nearly 30.4 billion USD, growing to 32.1 billion USD in 2013 and is expected to be 40.7 billion USD in 2018. BCC Research estimates an increase of 4.9% in the compound annual growth rate for assistive products between 2013 and 2018.

There are major consequences, which affect the budgets of governments, communities, hospitals and other institutions/payment bodies, most of which are facing increasing demands to contain costs and improve cost-effectiveness. The cost for assistive products is just one side of the coin. The other side is represented by possibility to participate in work life and to enjoy social inclusion.

For individual users, assistive products may represent a major expense item in their personal budget.

Political/legislative factors
The political/legislative factors that affect standardization in the field of assistive products in Europe are primarily reflected by the relevant EU directives, mandates and other commonly accepted documents (e.g. official reports of the European Commission, policy of CEN, etc.). Most countries have national regulations and regulatory bodies that may affect the design of the assistive products, or their use, e.g. U.S. Food and Drugs Administration (FDA) and Health Canada’s Therapeutic Products Programme (TPP).

The principles of the UN Convention on the Rights of Persons with Disabilities (2006) emphasise the right of persons with disability to full and effective participation and inclusion in society as well as to individual autonomy. Furthermore, signatory states (more than 140 in February 2014 including the EU) have agreed to promote the availability, knowledge and use of assistive devices and technologies, designed for persons with disabilities, as they relate to habilitation and rehabilitation.

The following documents/activities constitute a general basis for the work.

- Council directive 93/42/EEC of 14 June 1993 concerning medical devices (the “Medical devices directive”), including reference to the “EMC directive”;
- Guide 6 giving the European Standards Bodies a guidance document in the field of safety and usability of products by people with special needs (e.g. elderly and disabled);
- Mandate to the European Standards Bodies for Standardization in the field of information and communications technologies (ICT) for disabled and elderly people;
- Standardization mandate M/023 and M/295 to CEN/CENELEC concerning the development of European standards relating to medical devices (and the new draft mandate which expands it)

Other directives, activities, studies etc may be applicable.

In addition, there are a number of generic standards in the area of medical devices that affect the design of the standards for assistive products, e.g. EN 1041 (information), EN ISO 14971 (risk management for medical devices) and the EN 60601 series (safety requirements for medical electrical equipment).
National regulations should be considered, since they may affect the design of the assistive products, or their use. Example: building regulations (electrical connections etc), traffic rules.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

Since 1992 a total of 19 standards have been adopted. This should:

- increase the level of safety, reliability and functionality of assistive products;
- contribute to decrease production costs for assistive products;
- increase the quality of life for the users;
- insure cost effectiveness for purchasers, both private and public.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

Competence needed

The technical competence needed for standardization within CEN/TC 293 covers many technical areas (mechanics, electrical engineering, chemistry, ICT, etc.), and a very large number of different types of systems/products as well as differing infrastructures and support systems (i.e. low to mid-income countries). It also involves a large number of different professional skills, primarily in the field of rehabilitation (physicians, therapists, pedagogues, medical technicians, etc.).

Users and their organisations represent a unique competence, and it is vitally important to engage them in standardization work. This is underlined by the fact that the design of the products/systems often affects their safety and possibility to an independent life in a very personal way.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

Primary objectives are:

- to produce standards on assistive products for persons with disabilities, including follow-up activities and revisions;
- to contribute to the development of mandates, the ‘design for all’ concept, and other centrally located activities of importance to the field of assistive products for persons with disabilities;
- to inform about the CEN/TC 293 standards production and other activities.

Secondary objectives are:

- to monitor/influence other close-related standardization activities, and participate whenever found necessary/possible;
- to constitute a source of competence in the field of disability, available to other committees etc whenever found necessary/possible;
4.2 Identified strategies to achieve the CEN/TC’s defined objectives.

The overall and long-range strategy of CEN/TC 293 is to cover the basic need of standards in the field of assistive products for persons with disabilities. This should be done step-by-step, concentrating on a limited number of simultaneously ongoing activities, and in close co-operation with ISO and other interested parties wherever possible.

The information about the work of CEN/TC 293 should be enhanced.

The area of work should comprise all kinds of assistive products for persons with disabilities, i.e. products addressing limitations in seeing, hearing, cognitive functions, mental functions, mobility, motoric functions, balance, sensory functions, stamina or anthropometry.

With this background the following priorities are set:

- special attention should be paid to assistive products that fall under the Medical Devices Directive, and/or are listed in EN ISO 9999;
- mandated work should be given priority;
- generic standards should be given priority;
- special attention should be paid to the need for revisions/amendments of standards;
- special attention should be paid to the specific risks involved with the interaction of persons with disabilities, and their technical aids, with the environment and different products/systems;

Special attention should be paid to:

- assistive products that fall under the Medical Devices Directive (MDD), and/or are listed in EN ISO 9999;
- mandated work;
- generic standards;
- the specific risks involved with the interaction of persons with disabilities, and their assistive products, with the environment and different products;
- the need for revisions/amendments of standards;
- Information and Communication Technology (ICT), that gives new or improved possibilities to an independent life for large groups of persons with disabilities;
- corresponding work in ISO/IEC and the possibility to coordinate the standard production.

4.3 Environmental aspects

Environmental check-lists are used in all standards; new standards and the ones under revision, e.g. EN 12182, EN 12183 and EN 12184.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

Few constraints on the completion of the CS’s work programme are foreseen. The involvement the expert has been declining making it necessary to play close attention to the balance of participation of Working Groups.