BUSINESS PLAN
CEN/TC 293

Assisitve products and accessibility

EXECUTIVE SUMMARY

Scope

The primary objective of CEN/TC 293 is to produce standards in the field of assistive products, including:

- accessibility for persons with disability;

- accessibility aspects of mainstream products, including packaging, instructions for use, information, and service development processes;

- interoperability and interfacing between assistive and mainstream products to achieve accessibility;

- 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, hygiene equipment, medical beds for children and adults, hoists, 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 asistive 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.
- The digital single market is expected to help increase the flow of goods and services across national borders that may reach new markets, both within but also beyond the EU/EEA.
- 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, robotics, 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 of products, services and systems, including cognitive accessibility.
- common testing methods leading to comparable, reliable test results, such as the methods developed and standardized for testing of assistive products.

Priorities

- assistive products that fall under the Medical Devices Regulation and/or included in EN ISO 9999
- mandated work
- generic standards
- need for revisions/amendments of standards
- joint working groups with CENELEC
- parallel work with ISO/TC 173

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 wide varieties of assistive products/systems many of which are technically advanced and represent significant economic value. An assistive product is defined in EN ISO 9999:2016 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 combine many different technologies, and technical development is very rapid. This is particularly valid for Information and Communication Technology (ICT) and assistive products with robotic features, 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 signalling. 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, design- and robotic 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 trend is expected to continue. One area is often called smart home appliances, welfare technology or ambient technologies, where assistive products can have a role to play as we approach a scenario called 'Internet of Things' (IoT), 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. Also, consumer products are used as part of/or in combination with assistive products, e.g. a smart phone can have a remote-control function for an assistive product.

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 present obstacles 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. The same problem can arise with household appliances, e.g. products with finger touch controls. 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 specific 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. Therefore, standards have to be developed taking into account the full spectrum of disabilities, e.g. finger touch controls have to be supplemented by sound or alternative control systems.

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:

- Sensory; seeing, hearing, balance, touch, taste/smell
- Physical; movement, dexterity, manipulation, strength/endurance, voice/speech, body dimensions
- Cognition; intellect/memory, language/literacy
- Autoimmunity

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 and generally accessible consumer products and services 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 Active and Assisted Living (AAL) Programme that focuses on ICT for ageing well, is 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 disablity 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 changes ongoing in most countries in Europe (and worldwide) is a factor that many consider will increase the the prevalence of disabililty.

In Europe there is an understanding that assistive products can enable persons with disability and older persons to live independly 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. An increasing degree of consumer products and services that are accessible might have a decreasing effect of the number of assistive products needed.

The table below from the WHO (2012) gives a tentative projection of the development of the need for assistive products worldwide and in Europe.

	Total population	Older population	Disabled population	Tentative requirement assistive products
Global 2012	7.08 billion	770 million	1 billion	1.4 billion
European 2012	7.39 billion	129 million 17,5 %	110 million 15 %	191 million
Tentative projection for 2050				
Global 2050	9 billion	2 billion	1.35 billion	2.7 billion
European 2050	9.9 million 11 %	287 million 29 %	148,5 million	348 million

25 % of population of the EU over the age of 16 report long-standing disabilities (today there is no data available for the group of people between of 0-16).
The number of people with disabilities is growing as a result of the demographic shift, given the correlation between disability and ageing. 18 % of the European population was aged over 60 in 1990, while this is expected to rise to 30% by 2030" (Source: UN World Population Prospects (2002 Revision) and Eurostat Demographic data).

Estimated market size
It is difficult to assess the potential market size for assistive products as it is difficult 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. Also, the growing impact of accessible products and services play a role, leading to a decreasing demand.

The economic turnover for assistive products is large. According to BCC Research, "The global market for assistive devices for special needs reached nearly $15.9 billion in 2018 and should reach $20.1 billion by 2023, at a compound annual growth rate (CAGR) of 4.9% for the period of 2018-2023"

Allied Market Research published a report in 2019, titled, " Elderly and Disabled Assistive Devices Market by Type (Living Aids, Mobility Assistive Devices, Bathroom Safety Equipment, and Medical Furniture): Global Opportunity Analysis and Industry Forecast, 2019–2026". According to the report, the global elderly and disabled assistive devices market was pegged at $23.01 billion in 2018 and is projected to garner $35.60 billion by 2026, registering a CAGR of 5.5% from 2019 to 2026.

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. Also, the European Accessibility Act (2018) has an impact on services and products with an interface to assistive products. A Eurobarometer report in 2012 reported that 78% of Europeans think that having common rules on accessibility in the EU will make it easier for companies to operate in another EU country.

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

- CEN-CENELEC Guide 6 Guide for addressing accessibility in standards
- Medical Devices Regulation (MDR 2017/745)
- Council directive 92/59/EEC of 29 June 1992 on general product safety
- Mandate M/420 European accessibility requirements for public procurement in the built environment
- Mandate M/376 Accessibility requirements for public procurement of products and services in the ICT domain
- Mandate M/273 Mandate to the European Standards Bodies for Standardization in the field of information and communications technologies (ICT) for disabled and elderly people
- Mandate M/473 to include "Design for All" in relevant standardisation initiatives 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 supplied by the manufacturer of medical devices), EN ISO 14971 (Application of risk management to 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 21 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, robotics, electrical engineering, chemistry, anthropometrics, 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 (doctors, therapists, pedagogues, medical technicians, nurses, 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 affect 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, and related services including interoperability/interface between assistive and mainstream products to achieve accessibility; including follow-up activities and revisions;
- to produce standards addressing general accessibility aspects of mainstream products, e.g. packaging, instructions for use, information, service development processes, not excluding other fields.
- 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; or by creating liaisons with other TC's
- 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 293'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 CENELEC/ISO/IEC 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 sensory functions, cognitive functions, mental functions, mobility, motoric functions, balance, stamina and/or anthropometry.

With this background the following priorities are set:
- special attention should be paid to assistive products that fall under the Medical Device Regulation, and/or are listed in EN ISO 9999:2016;
- 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:
- 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.
- Mandate M/473 ensuring that accessibility following a Design for All approach is considered and addressed in relevant standardisation initiatives.

4.3 Environmental aspects

Environmental checklists are used in all standards; new standards and the ones under revision.

4.4 Accessibility aspects

CEN-CENELEC Guide 6:2014 Guide for addressing accessibility in standards and a process called the Protocol provides guidance on how accessibility following a "Design for all" (https://www.cencenelec.eu/standards/Topics/Accessibility/Pages/DesignforAll.aspx) approach should be addressed when reviewing an existing or developing new standardization project.

The result of M/473 was a manual and a protocol on how to help standardizers of mainstream products and services including accessibility in the standard.
Download the manual and the Protocol forms
(ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Sectors/Accessibility/Design For All/Protocol_DfA.zip)

M/473 focuses on the following priority areas

- Instructions for use and labelling;

- Packaging;

- Electrical and electronic equipment/household appliances;

- Self-service machines;

- On-line services;

- Communication, information and signalling.

The documents mentioned above facilitate evaluation of accessibility aspects and their relevance in mainstream standardization development.

Accessibility aspects will be the focus of the WG 12 Accessibility, in particular working on accessibility aspects of so called "welfare technology" (an approach for the provision of assistive products) and working on the interface between assistive technology and mainstream technology.

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 of experts has been declining making it necessary to play close attention to the balance of participation of Working Groups.
The CEN TC 293 secretariat will encourage national standardisation bodies to envolve a broad representation of stakeholders.