### Active Assisted Living

Issue 07/2016 of e-tech focuses primarily on Active Assisted Living (AAL), i.e. “intelligent systems of assistance for a better, healthier and safer life in the preferred living environment”. Seniors, people with disabilities can benefit from all new technological developments that help them remain as independent as is possible. AAL is also essential for those living in remote and isolated areas, especially in the healthcare and education sectors.

### EDITORIAL
- Smart assistance 3

### TECHNOLOGY FOCUS
- Sensor networks, wearable printed electronics and AAL 5
- Smart Cities for the golden years 7
- Cutting-edge technology reshapes the Paralympic scene 10
- Rapid growth in home use of medical devices requires new standards 13

### INDUSTRY SPOTLIGHT
- Improving access to multimedia content for those with disabilities 16

### TECHNICAL COMMITTEE AFFAIRS
- IEC work supports cross-sector AAL 20

### CONFORMITY ASSESSMENT
- Portable medical devices radically change healthcare delivery 22
- Ex-proof from A to Z 23
- IEC honours IECQ Technical Expert in avionics 25

### IEC FAMILY
- October 2016 nominations 28

### IEC WORLD
- Celebrating World Standards Day 2016 29
- Upcoming global events 31

### IN STORE
- Alarm systems useful for AAL too 33

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Smart assistance
IEC takes systems approach for standardization in Active Assisted Living

One of the emerging trends of the 21st century is the ageing of the world population.

Worldwide trend
People worldwide are living longer. Thanks to technological advances, improvements in healthcare and increase in welfare, the average lifespan had already more than doubled in the 20th century, but the trend is accelerating. Today, for the first time in history, most people can expect to live into their sixties and beyond. According to the World Health Organization (WHO), by 2050, the world’s population aged 60 years and older is expected to total two billion, up from 900 million in 2015.

While the distribution of age groups shifting towards older ages began in high-income countries, it is bound to expand and affect low and middle-income countries as well. The WHO predicts that in 2050, 80% of older people will be living in low- and middle-income countries.

The number of people with disabilities is also growing throughout the world. It is partly a consequence of the population ageing – older persons have a higher risk of disability.

Providing smart assistance
The burden of social and healthcare systems is and will be significant. This is why it is essential to put in place strategies that allow older and/or disabled people to live their life in the best possible conditions and environments.

AAL offers “intelligent systems of assistance for a better, healthier and safer life in the preferred living environment”

Claire Marchand
Managing Editor e-tech
Active Assisted Living (AAL) offers “intelligent systems of assistance for a better, healthier and safer life in the preferred living environment”.

Seniors, people with disabilities can benefit from all new technological developments that help them remain as independent, active and healthy as is possible. AAL is also essential for those living in remote and isolated areas, especially in the healthcare and education sectors.

The development of smart devices and wearables, the Internet of Things, robotics, the emergence of smart homes and buildings will play a major role in assisting these population categories.

The IEC at the forefront
With the establishment of a Systems Committee (SyC) dealing with AAL issues, the IEC has taken a leading role in the development of International Standards in that field. The scope of SyC AAL is to create a vision of AAL that takes into account the evolution of the market: “Foster standardization of Active Assisted Living (AAL) systems, services, products and components to enhance the quality of life and enable independent living through the use of Information and Communications Technology (ICT) by ensuring usability, accessibility, interoperability, security and safety for all users including caregivers”.

Microprocessor-controlled hydraulic knee with swing and stance phase control prosthesis (Photo: Otto Bock)

Battery-powered (myoelectric) prosthetic hands use electronic sensors to detect minute muscle, nerve, and electromyography (EMG) activity (Photo: Touch Bionics)
Sensor networks, wearable printed electronics and AAL

Wearable printed electronics will play a central role in Active Assisted Living

Alan Hodgson, Chair IEC TC 119

Sensors provide information about objects, or people and their environment. Networks of sensors in the shape of wearable electronics and integrated into the living environment will support Active Assisted Living (AAL) into the future. Sensors and printed electronics will be increasingly integrated into smart wearable devices to facilitate the implementation of AAL.

Sensors key to the Internet of Things

Sensors can be considered as the data sources of the Internet of Things (IoT). In the wearables space, these devices harvest information from wearers and their environment. These sensors will be integrated into wearable smart devices (WSDs), which in turn will be connected to the IoT to facilitate AAL.

These wearable sensor networks can be organized in a number of ways and the different implementations of these are reflected in the standardization work of various IEC Technical Committees (TCs) and Subcommittees (SCs). It is useful to look at the component systems of these sensor networks to illustrate how this may be achieved.

Pervasive sensors

Currently most individual sensor elements are made using traditional semiconductor type manufacturing processes and are thus standardized as part of the work of IEC TC 47: Semiconductor devices, and of Working Group (WG) 1: Semiconductor sensors of IEC SC 47E: Discrete semiconductor devices. Amongst their active projects are documents covering wearable sensors for glucose, humidity, temperature and light. IEC SC 47E/WG 1 work can give useful insight into the performance testing of such sensors.

Sensors are becoming pervasive in the modern electrotechnically-enabled society. Data published earlier this year suggests that “of the 20 000 new products that were introduced at the Consumer Electronics Show this year, probably 15 000 have some type of sensor embedded” (see Tech Trends 2016 in e-tech January/February 2016). The growing pervasiveness of sensor technology was highlighted in Sensors everywhere (e-tech March 2016).

Harnessing the power of sensors in networks

On their own, sensors can give some information, but, connected together, they can reveal much more. A WG of the Joint Technical Committee for Information Technology, set up by the International Organization for Standardization (ISO) and the IEC, ISO/IEC JTC 1/WG 7: Sensor networks, covers the reference architecture for this area. An additional dimension that is particularly pertinent to wearable electronics is wireless connected sensor networks. A comprehensive overview of these Wireless Sensor Networks (WSNs) was given in the IEC White Paper Internet of Things: Wireless Sensor Networks.
It is worth stressing that the concept and implementation of these WSNs will extend to more domains. Smart cites/homes/energy implementations will use the same concepts to connect the infrastructure to the IoT.

**Wearables and IoT**

Wearable devices can be considered as the human interface to the IoT. As AAL will need this human interface, IoT initiatives are an important link in the implementation. ISO/IEC JTC 1 is also active in this area and set up WG 10: Internet of Things. In common with other JTC 1 committees, WG10 has produced definition and vocabulary documents and reference architectures for IoT systems. It is now moving on to produce a Technical Report on IoT use cases.

**Printed Electronics**

Using printing techniques to manufacture electronics assemblies is an attractive prospect for wide area electronics. This is because printing techniques allow industry to make devices and structures over a much wider area than do semiconductor production systems. As printing processes are open to roll-to-roll processing, they are also a route to flexible electronics, (see *Printing electronics anywhere, e-tech August 2016*).

IEC TC 119: Printed Electronics, works specifically in this domain. It prepares Standards for the terminology, materials, processes and equipment that will facilitate the industrial development of printed electronics. The ability to print onto flexible substrates over a wide area is an enabling technology for WSDs and in particular for textile electronics. As a result, TC 119 is looking closely at how printed electronics can support these developments. It is currently preparing IEC TR 62899-250, a Technical Report on “Material technologies required in Printed Electronics for Wearable Smart Devices”, due to be published in the first half of 2017. Further work is now being initiated on documents covering materials for flexible WSDs, such as stretchable substrates and inks.

**Systems integration**

It is recognized within printed electronics that printing techniques alone cannot provide the entire functionality for the WSDs needed to implement AAL. For the foreseeable future, these wearables are likely to consist of hybrid devices, implemented through a combination of printed and conventional silicon electronics. For this reason there are active liaisons running between IEC TC 119, and IEC TC 47 and IEC TC 110: Electronic display devices. Assembling sensors into networks and connecting these with power and the outside world represents a significant challenge.

IEC TC 91: Electronics assembly technology, is therefore similarly an important part of these liaison arrangements, which also provide a bridge between the relevant industries and a meeting place for discussions.

The challenge of systems integration with a particular focus on WSDs was addressed in e-tech in January 2016.
Demand for technologies to come together in WSDs
There is a real market demand for these technologies to come together in WSDs. AAL looks to be a likely stimulus for this. To actively facilitate this, it is necessary to give additional support and attention to this area. The IEC Standardization Management Board (SMB) has responded to this need with the creation of a Strategy Group, SMB SG 10: Wearable Smart Devices, with the expectation that this group will make recommendations back to the SMB on the ways in which the IEC can best support this process. With a membership of representatives from the key IEC TCs previously mentioned, the first task for SG 10 was to come to an understanding of terminology in this area. The group identified the wealth of wearables-related activities going on within the IEC community but also highlighted some existing gaps. These activities have culminated in a report for the SMB with recommendations on the route forward within this community and a set of priority actions.

AAL enabling technologies
Sensor networks integrated into IoT-connected wearable devices will be an enabling technology for AAL. The IEC community is already well placed to cover most of the standardization activities in this area, but some gaps remain and these have been addressed by SMB SG 10. Working as a community, the IEC is well placed to help develop this technology for Active Assisted Living.AAL.

Smart Cities for the golden years
Smart City technologies have the potential to enable the disabled and elderly to remain independent for longer, and live healthy, mobile lives.

Antoinette Price
The proportion of people aged over 60 will almost double from 12 to 22% between 2015 and 2050, according to the World Health Organization (WHO). In line with this, the WHO World Report on Disability states that currently more than one billion people live with some form of disability worldwide. The figure is expected to rise in the coming years as populations age.

One goal of Smart Cities is to make sure that people with disabilities are able to work, socialize and live independently for as long as possible. This means providing human and technical support to manage chronic health conditions and ensure that there is physical access to places, as well as guaranteeing the ability to move around easily within the home or city.

Increasingly, information and communication technology (ICT), audio, video and multimedia systems are being incorporated into Smart City infrastructure. ICT provides the tools and support required to improve the lives of people with disabilities, whatever their age.

For example, smart alarm systems and smoke detectors adapted for people with hearing impairments alert users by flashing intermittently, or, if the person is lying down, by vibrating (under a pillow or mattress). The wireless transmitters in some of these systems can also connect to home security systems, videophones or the doorbell and send alerts from these. Another useful device is the liquid level indicator that beeps when a cup is nearly full, enabling visually impaired people to do something as simple as make a cup of tea without scalding themselves.
Helping to connect complex systems

The IEC contributes to this effort through the work of a number of its Technical Committees (TCs) and Subcommittees (SCs), which produce International Standards to ensure the safety, reliability and compatibility of the diverse technologies used in Smart Cities. This also includes components of the Internet of Things (IoT) that are used in systems for transport, hospitals, power, water supply, waste management, schools and more.

Complementing this work, the IEC Systems Committee for Active Assisted Living (SyC AAL) was established to:
• create a vision of AAL that takes account of market evolution
• enable accessibility of AAL systems and user interfaces
• facilitate cross-vendor interoperability of AAL systems, products and components

Intelligent homes are safer places

In an increasingly digital age, the IoT offers innovative ways to help aging populations. IoT devices, buildings, cars and other objects are embedded with electronics, software, sensors and network technology, which allow them to collect and exchange data with a view to helping save lives and assisting disabled people with everyday activities.

In the home, if a person with dementia forgets to close a window at night during winter or leaves the stove on, or if an elderly person living alone falls over and is unable to move, the consequences could be fatal. Sensors in smart appliances or placed on doors and windows offer solutions for detecting temperature, motion and location.

Smart home care systems can switch on lights when they detect a person’s movement, remind people to take medicine, turn off appliances after a certain time has passed and monitor daily activities. If there is a change in routine, caregivers or family are alerted. Some systems also link directly to various emergency services. GPS tracking devices are particularly useful for people with different conditions affecting the memory. Family or health care can track a person and help them find their way back home.

Without sensors, none of this would be possible. IEC TC 47: Semiconductor devices, produces International Standards for the design, manufacture, use and reuse of sensors as well as for measuring and testing methods.

IT supports over-burdened health systems

Age-related health issues, including increased susceptibility to chronic conditions such as diabetes, dementia and cardiovascular disease, will increase the number of patients and put a strain on health systems and service providers. Technology is helping to address this.

The way we detect, monitor and treat an increasing number of diseases is changing thanks to wearable and portable medical devices. Built-in sensors track different aspects of health. For example, patients can check their own heart rate or blood pressure and send the results to online healthcare systems in hospitals and clinics. Telemedicine allows doctors who receive patient medical data to give advice remotely via phone, email or webcam.

Some types of diabetes can be monitored in real-time using wearables which check insulin levels. Results are sent to a smartphone, as well as alerts indicating if levels are too high or too low. Some wearables administer insulin doses when necessary, allowing users to get on with their daily activities uninterrupted.

For the less mobile, or those in remote locations, these types of solutions improve quality of life and reduce the number of visits to medical professionals, who would otherwise be the ones to carry out these checks.

Safe and secure connections

As with any device connecting to the IoT, it is important to safeguard data confidentiality. IEC TC 62: Electrical equipment in medical practice, and its SCs develop International Standards for the electrical equipment,
electrical systems and software used in healthcare. The work focuses on safety and performance, including "data security, data integrity and data privacy". It also includes Technical Reports for medical device software and IT networks incorporating medical devices.

IEC also develops International Standards for information technology. ISO/IEC JTC 1/SC 27 of the Joint Technical Committee (JTC) 1 set up by the IEC and the International Organization for Standardization (ISO) works specifically on IT security techniques.

Getting about town
Participating in social activities and running daily errands is a normal part of life. However for people with certain disabilities, leaving the home can be a daunting prospect. There are many apps which use audible and vibrotactile technology to help people with visual or hearing loss get around town safely and confidently. For example, a talking map app tells users where they are going. They follow the map using their fingers and the app vibrates when they reach a crossing. Visually impaired users of the innovative colour ID app 'see' what colour any item is, by holding the smart phone in front of it. They can coordinate their wardrobe, holding the smart phone in front of it. They can 'see' what colour any item is, by holding the smart phone in front of it.

People with hearing loss use a variety of hearing aids. The work of IEC TC 29: Electroacoustics, covers measurements of electroacoustic and performance characteristics for these. It has also developed Standards which allow wearers of specially-equipped hearing aids to have a wireless signal transmitted directly to their ear in places like museums or theatres. Additionally, IEC 62216:2009, Digital terrestrial television receivers for the DVB-T system, provides details for the provision of audio description and specifies recommendations for the provision of text services and subtitling.

The driverless wheels of change
Future urban transport models for Smart Cities must offer growing populations clean, reliable, safe and affordable ways to move around town. They will incorporate electric driverless vehicles, which are already being tested in a number of countries worldwide.

A leading ride-hailing company envisages making this service so affordable and convenient that people will forgo car ownership and summon a car from their smartphone for door to door transport. Though it may seem farfetched, a report by Morgan Stanley says that ride-hailing currently accounts for less than 4% of all kilometres driven globally, but by 2030, that figure will rise to more than 25%. While the infrastructure required for driverless vehicles is still not in place, arguments for it are strong. In addition to improving road safety, air quality and reducing congestion, it would be particularly convenient for the elderly who are not able to drive and cannot manage the walks to and from bus stops or up and down stairs.

The dawn of the assistive robot
The development of Smart Cities is a slow process in which technology is moving rapidly. The IEC will continue to produce International Standards for existing and emerging AAL technologies such as cloud computing for storing the big data gathered from all the devices and systems within Smart City infrastructure.

As greater numbers of people need care and fewer care givers enter the workplace, robots will have a role to play in smart home systems. Cutting-edge sensory technology already enables robots in manufacturing to recognize and adjust to subtle changes, while robot carts deliver medicine successfully around hospitals. In the AAL context, robots can perform daily tasks and help out in emergencies. Further research is being carried out to see how they could be used in increased numbers of social contexts, such as serving food or providing company.
Cutting-edge technology resizes the Paralympics

Innovative virtual reality techniques and 3D printing are making major contributions to the production of high-tech sports equipment for athletes with disabilities.

Antoinette Price
Paralympians successfully overcome physical, visual and intellectual impairments, but their equipment can impact their performance.

Engineering for sports
Over the last decade, sports equipment manufacturers, engineers, university researchers and diverse industries, including automobile, aerospace and defense, have been working together to refine the equipment used in Paralympic summer and winter sports. Advanced designs and testing processes incorporating the latest technologies and materials offer athletes greater comfort, stability and mobility, so that they can focus on performance.

The standardization activities of several IEC Technical Committees (TCs) and Subcommittees (SCs) contribute towards ensuring the safety and reliability of electronic or electrotechnical components incorporated in this equipment and the systems used to test and measure them.

Reinventing the wheelchair
Wheelchair racing is an exciting sport which has evolved greatly since the first official Paralympics held in London in 1948. Back then, chairs could weigh up to 23 kilos; modern ones weigh just two.

Until recently, athletes were crammed into chairs with loose foam for padding and retention. They had to try to maintain their balance while pushing the wheels as hard and fast as possible.

However, over the last decade, several industries have been teaming up with the sports world to fine-tune equipment for disabled athletes. One such partnership with UK Sport has produced a state-of-the-art wheelchair that includes several technologies. A leading German automotive manufacturer used a 3D scan of a seated athlete to produce a personalized chair. From the scan, a digital model was made, simulating the aerodynamic changes that occur when athletes move. This resulted in modifications to the chair frame, reducing its drag by 15 per cent. Drag affects the ability to maintain speed, especially when hitting a headwind or an incline. The chair was run through tests in British Aerospace (BAE) wind tunnels to assess its aerodynamic efficiency, and its manoeuvrability was measured using tracking technology developed by a prominent Formula 1 racing team.

As for wheelchair basketball, personalized seats have enabled athletes to move as one with the equipment. They offer greater stability when athletes make quick turning movements and reduce overall equipment weight. The plastic prototype chairs were made by 3D-sintering machines adding layer by layer over a period of 24 hours.

The winning technology
A lot goes on behind the scenes when digital modelling and 3D scanning make use of virtual and augmented reality applications. Several Subcommittees (SCs) of the ISO/IEC Joint Technical Committee (JTC) 1: Information technology, produce International Standards for 2D and 3D multimedia.
ISO/EC JTC1/SC 28: Office equipment, works on the standardization of basic characteristics, test methods and other related items of products, including 3D scanners among others.
ISO/IEC JTC 1/SC 29: Coding of audio, picture, multi-media and hypermedia information, publishes International Standards for data formats designed to enable the use of 2D/3D multimedia content.

Other IEC TCs and SCs develop International Standards for the electric and electronic components used in 3D printers for different manufacturing processes, such as:
- Switches and relays – IEC TC 17: Switchgear and controlgear and IEC TC 121: Switchgear and controlgear and their assemblies for low voltage, and their SCs
- Servo and stepper motors used to move the extrusion head or the sintering laser – IEC TC 2: Rotating machinery
- Power supplies – IEC TC 96: Transformers, reactors, power supply units, and combinations thereof

The work of IEC TC 76: Optical radiation safety and laser equipment, the leading body on laser standardization, is vital to 3D printing. It encompasses the different types of lasers used for sintering metals and polymers and in industrial and research applications.

**Hearing the bull’s eye**
The World Health Organization (WHO) estimates that 285 million people worldwide are visually impaired (39 million blind and 246 million with low vision). This is particularly challenging for athletes because, whatever the sport, eyesight is vital. However, clever electronics are making it possible for the visually impaired to participate in more disciplines by relying on other senses such as hearing, for example for target shooting.

Does it sound unbelievable? Here’s how it works. A normal 10m air rifle is fitted with a special telescope, containing electronics that convert the amount of light it receives into a tone of varying pitch. The target centre is white and turns from grey to black, going outwards. Bright light shone on the white target reflects back onto the air rifle’s sight (the part used to line up the target). This light is converted into acoustics which are transmitted to the shooter via headphones. The higher the pitch, the closer their aim is to the bull’s eye.

**More IT tools for the visually impaired**
In an increasingly digitalized world, visually impaired people have issues when accessing and using television equipment (operating a remote control, inability to see subtitles, navigating channels and TV inputs, using other services, etc.).

A Technical Report, IEC TR 62678, *Audio, video and multimedia systems and equipment activities and considerations related to accessibility and usability*, is published by IEC TC 100: Audio, visual and multimedia systems and equipment, and can be downloaded free of charge. It is the result of extraordinary co-operation between, and contributions from, a wide range of experts. Many other IEC TCs have also addressed Standards relevant to accessibility in order to provide graphical symbols; marking and identification; electrical accessories; semiconductor devices and sensors and so on. IEC TC 100 has also developed International Standards for the provision of audio description, including text services and subtitling, as well as for specifying the “text-to-speech functionality for a (broadcast) [digital] receiver with a text-to-speech system”.

When it comes to reading, audiobooks can be very useful. IEC TC 100/TA 10:
Multimedia publishing and e-book technologies, covers the format and player requirements for such books, ensuring compatibility with music industry and multimedia standards.

Exciting developments for the sports world
The London 2012 Paralympics was a turning point in the history of the Games. It greatly highlighted the importance of sport for disabled people, while attracting a number of high-tech industries which continue to invest in developing equipment that is opening up new sports for para-athletes. Just as Formula 1 technology gave everyday cars safety improvements like disc brakes and rear view mirrors, some of these technologies may eventually be adopted for everyday use.

... and for the greater good
According to the World Bank, fifteen per cent of the world population lives with some sort of disability, and this is expected to increase as populations age. Authorities and other organizations are already looking at different ways to make environments more accessible to people with disabilities.

In this broader context, the IEC Systems Committee on Active Assisted Living (SyC AAL) was established to ensure the quality of life of people who are likely to face a number of disabilities as they age. Using a systems-based approach, it aims to find ways to allow the elderly to stay active and independent in their homes by interconnecting technologies used in AAL systems and services. IEC standardization work will help to ensure the safety and interoperability of these diverse technologies.

Some recent innovations
Brainsled – a bobsleigh for quadriplegics – is guided by a helmet device containing electrodes. Based on an electrophysiological monitoring method for recording electrical activity of the brain, wearers control the slege through the power of thought. The wireless rechargeable helmet uses special sensors and is compatible with different software systems.

A gadget with vibrating chest straps uses GPS technology to warn visually impaired runners of obstacles ahead. This may eventually be exploited in the hurdles race. It could also be developed for first responders, firefighters, combat soldiers and police. A similar vest has been developed by a US company. It uses the same sensor and laser technology as is found in driverless cars to alert wearers to obstacles ahead.

A glove-like device could soon become part of the training regime for visually impaired swimmers. Sensors which map the swimmer’s upper arms provide feedback to help improve the athlete’s stroke. The device could also be used to perfect a tennis serve or a golf swing by guiding the wearer’s arms along the pre-programmed path of a famous player. The sensors detect the twisting and flexing of the user’s joints. The device tells users if they are hitting the mapped path by vibrating as movements are made.

Ekso Bionics’ exoskeleton – a wearable bionic suit – enables people with weak lower limbs to stand up and walk. As the user’s weight shifts, it activates sensors which start the steps. Battery-powered motors drive the legs, replacing deficient neuromuscular function. This could be used for weight lifting disciplines in sport, as well as for rehabilitation purposes in paralyzed patients.

The work of the IEC covers many different aspects of the electronics and electrotechnology used in equipment for disabled people, and in the systems for developing and testing it. From sensors in wearable smart devices used to track motion and locate objects, to the innovative virtual reality applications employed in the design and fine-tuning stages, IEC standardization activities help the development of equipment to the specific needs of disabled athletes, while considering its safety and reliability.
Issue 07/2016

Leo Eisner

Convergence of favourable factors

It has become evident that the use of devices designed for a clinical setting in the home environment can expose both patients and users to serious hazards. A prime example is infusion pumps. Originally designed for clinical usage in environments such as hospitals, frequently these are now placed in the home by care providers or healthcare organizations. Infusion pumps, if not redesigned thoughtfully for the home care market and patient use, can be too complex or confusing to use, potentially causing serious harm or leading to death as a result of drug over or under dosing.

Maze of regulations, guidance, standards

Regulations governing medical devices may be decided by national and regional bodies.

In the US, the Food and Drug Administration (FDA) issues guidance documents for medical devices, among many other products / issues.

In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA), an independent governmental administrative organization, is tasked, among other things, with drug and medical device testing. It has four offices for medical devices.

In Europe, many entities at national and regional levels play a role in assessing, evaluating, issuing guidance documents and modifying regulations for medical devices. Among these, the Medical Device Expert Group (MDEG), established by the EU Commission, is composed of delegates from member states’ competent authorities and other EU well-known organizations. The MDEG, which has a Working Group on New & Emerging Medical Device (MEDDEV) Technologies, issues so-called MEDDEV Guidance Documents.

Leo Eisner

Why are home use medical and wellness devices drawing so much attention and growing at an explosive rate? It could be argued that this results from the nexus of the Internet of Things (IoT), the “super-aging” of societies around the world (which is directly tied to patients wanting to be comfortable in their home environments instead of in sterile impersonal clinical environments), the portability of devices, the growth of wearable technologies, the increasing costs of healthcare and the huge regulatory burden/costs of obtaining approval by national regulators. Also, there has been significant growth in the number of standards and regulations that apply to medical devices, especially around software, health informatics, privacy and security issues.

The last five years have seen a clear and growing market interest in medical devices and wellness products. Because of this growth there is a need for developing some of the applicable standards and helping medical and wellness devices manufacturers through the maze of an ever increasing volume of standards and regulations.

Rapid growth in home use of medical devices requires new standards

IEC work underpins fast growing support for home use of health and wellness devices

The same models apply in many other regions / countries of the world. Other bodies, such as Britain’s BSI group and Germany’s TÜV organizations, also play an active role in the medical device industry nationally and worldwide. Other organizations, like the Association for the Advancement of Medical Instrumentation (AAMI), a non-profit organization, are active in the development, management and use of safe and effective healthcare technology.

International Standards for electrical equipment, electrical systems and software used in healthcare developed by IEC Technical Committee (TC) 62: Electrical equipment in medical practice, and its Subcommittees (SCs), are adopted at a regional or international level by these bodies.

The AAMI Home Care and EMS

Dexcom G5 Mobile is a compact continuous glucose monitoring (CGM) system that can provide accurate, real-time glucose readings every five minutes...(Photo: Dexcom, Inc.)

Some non-EU countries also adopt these Guidance Documents.

Dexcom G5 Mobile

Dexcom G5 Mobile is a compact continuous glucose monitoring (CGM) system that can provide accurate, real-time glucose readings every five minutes...(Photo: Dexcom, Inc.)

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Dexcom G5 Mobile is a compact continuous glucose monitoring (CGM) system that can provide accurate, real-time glucose readings every five minutes...(Photo: Dexcom, Inc.)

Some non-EU countries also adopt these Guidance Documents.
Environments Committee has adopted IEC 60601-1-11:2015, the IEC International Standard for medical electrical equipment and systems (MES) used in the home healthcare environment, as ANSI/AAMI HA 60601-1-11, a US national standard.

Defining a "home use" medical device
What is a home use medical device? Is it a medical device operating in a house, apartment, or apartment block environment, or is the scope broader than that? The home use environment makes up a fairly significant part of our world compared to the clinical part (hospital, clinics, surgeries and the like), and there is considerable variance in the definitions of “home use” found in IEC 60601-1-11, in ANSI/AAMI HA 60601-1-11 and in the FDA’s Guidance on Design Considerations for Devices Intended for Home Use.

All three documents agree that a home use device is not intended by the manufacturer to be used only in the clinical setting. If the device is intended to be used both in the home environment and in a clinical setting, it is still considered a home use device because it can be used in the home environment. If a device is intended for use exclusively in a clinical setting, then, by definition, the device is not a home use medical device.

The FDA Guidance definition of a home use device is “a medical device labelled for use in any environment outside a professional healthcare facility. This includes but is not limited to outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes. If the device is intended to be used in professional healthcare facilities and also outside those facilities, it meets this definition”.

FDA’s home use Guidance definition of a professional healthcare facility includes nursing homes, whereas in IEC 60601-1-11, a nursing home is considered as an extension of the home use environment, not as a professional healthcare facility. In addition to IEC 60601-1-11, there are a dozen or so IEC and ISO International Standards, published or in development, that relate to the medical device home use environment, some of which reference IEC 60601-1-11.

Home care - a special environment
The home care environment poses different challenges to those applicable in a controlled clinical environment such as a hospital or clinic. The challenges may include factors such as environmental controls that are not always available or reliable, dust and pet hair that can impact the performance of the device, power source issues and no backup generator (unlike in a hospital), unreliable protective earth or none at all. Many home use devices rely on the lay user for the device operation [impacts the usability (human factors) of the device] or sometimes by a family member rather than by a professional healthcare provider, so markings and labelling should be written accordingly. For instance, they should take into account the ability to process information and literacy from a cognitive perspective, as opposed to an educational level. The guidance considers that users of the device may have some type of cognitive impairment and the design and labelling of the device (including the user manual) should adjust for that consideration.

In addition to healthcare, there is a growing emphasis on helping the elderly and people with disabilities live a healthier, more active and independent life, known as Active Assisted Living (AAL). The use of information and communication technology (ICT), audio, video and multimedia systems and equipment provides an ever wider range of opportunities to enhance the quality of life for these growing sectors of the population.

IEC work supporting AAL across sectorial issues
The IEC has for many years actively facilitated the development of AAL solutions. In October 2011 the Standardization Management Board (SMB) established Strategic Group (SG) 5: Ambient Assisted Living. In 2014 SG 5 was transformed into a SEG (Systems Evaluation Group) and eventually into a Systems Committee, SyC AAL, which held its first committee meeting in March 2015.

IEC SyC AAL has the role of promoting safety, security, privacy and cross-vendor interoperability in the use of AAL systems and services, and of fostering standardization which enables their usability and accessibility (see articles on SyC AAL in e-tech December 2014 and December 2015).

The IEC SyC concept is fairly new and has only been introduced in the past few years. Instead of the typical TC structure that focuses exclusively on one technology, the SyC AAL brings...
together a multitude of technology experts (i.e. medical devices, consumer electronics, Internet of Things, computer systems and networks) from several IEC TCs (IEC TC 59: Performance of household and similar electrical appliances; IEC TC 61: Safety of household and similar electrical appliances; IEC TC 62: Electrical equipment in medical practice; IEC TC 79: Alarm and electronic security systems; IEC TC 100: Audio, video and multimedia systems and equipment), and Subcommittees of the Joint Technical Committee set up by the IEC and the International Organization for Standardization (ISO), ISO/IEC JTC 1: Information technology).

To address transverse standardization and broader system-wide issues, SyC AAL has also established formal liaisons with other ISO TCs, the International Telecommunication Union (ITU), industry consortia like Continua as well as with other organizations such as AALiance 2.

The standards development work conducted by a SyC begins at the system level rather than at the level of individual products, thereby supporting the investigation of more complex issues related to devices, services, systems, infrastructure, and interoperability. Just like a TC, a SyC can publish International Standards and other IEC deliverables such as Technical Reports and Technical Specifications, but only to fill any gap not covered by other standards.

The IEC is also investigating Standards development requirements applicable to interconnected medical and healthcare technologies, and non-medical interconnected devices used in a home environment. These technologies include interconnected medical and healthcare devices, well-being devices and wearable sensors, robotics and assistive devices, as well as supporting services. These interconnected technologies and services need to be able to operate together safely, and were a major reason for the creation of the IEC SyC AAL.

Significant efforts are currently underway to provide clear and consistent standards for home use medical and non-medical devices and systems. As always, manufacturers need to stay informed about the changing regulatory landscape, as well as about standards and regulations under development. Work by IEC SyC AAL will help achieve this.

Leonard (Leo) Eisner is principal consultant at Eisner Safety Consultants, a network of consultants headquartered in Portland, Oregon (US) that provides support to medical device companies on international regulations and on product safety, risk management, quality systems and regulatory submissions. Eisner is a member of various IEC TC 62 Subcommittees and several IEC SyC AAL Working Groups, as well as of a number of US National Committees for medical electrical equipment and home use medical devices.

* edited version of article first published in "In Compliance" magazine

Philips Lumify, a high-quality portable ultrasound transducer, can be connected to mobile devices via a USB cable to provide instant images (Photo: Koninklijke Philips BV)
Hundreds of millions affected

The World Health Organization (WHO) estimates (2014) that more than 285 million people suffer from visual impairment, more than 39 million are blind and 246 million have low vision. About 90% of the world's visually impaired live in low-income settings.

The WHO also estimates that over 5% of the world’s population – 360 million people – has disabling hearing loss (328 million adults and 32 million children).

The majority of people with disabling hearing loss live in low- and middle-income countries.

Ageing is a contributory factor to both visual and hearing impairment (82% of people living with blindness are aged 50 and above).

Wide impact

Visual and hearing impairments have impacts on personal, emotional, social, societal and economic levels.

Individually suffering from these impairments have difficulties communicating and interacting with their peers. This can lead to feelings of loneliness, isolation and frustration, particularly among older people, according to the WHO. The academic performance of the visually- and hearing-impaired, along with their employment prospects, are adversely affected, often forcing them into lower paid jobs. The problems are more severe in low-income countries and settings.

Internationally-recognized right

Article 9 of the 2006 UN Convention on the Rights of Persons with Disabilities, which deals with accessibility issues, states that “States Parties shall take appropriate measures to ensure to persons with disabilities access, on an equal basis with others, to (...) information and communications, including information and communications technologies and systems.”

Provisions for accessibility to and usability of many ICT products and services are incorporated into national legislations in some countries. These include accessibility features such as subtitles, signing or audio-description for people with sensory disabilities. In many countries and regions, broadcasters are required to provide universal access to audiovisual content.
Accessibility, a priority for the IEC

The IEC is actively developing International Standards for AAL in a wide range of areas.

To achieve this, IEC Technical Committee (TC) 100: Audio, video and multimedia systems and equipment, and several of its Technical Areas (TAs), have developed a number of specific International Standards over the years. However, in 2014, TC 100 found it needed to create a dedicated TA, TA 16: Active Assisted Living (AAL), accessibility and user interfaces, to “develop international publications addressing aspects of active assisted living (AAL), accessibility, usability and specific user interfaces related to audio, video and multimedia systems and equipment within the scope of TC 100”.

(See article on TA 16 in e-tech, December 2014)

TA 16 is currently:

- Finalizing IEC 62944, Digital Television Accessibility – Functional specifications (publication expected at end November 2016)
- Finalizing IEC 63080, Accessibility terms and definitions (publication expected in early 2017)

The IEC Standardization Management Board (SMB) established a Strategy Group, SG 5: Ambient Assisted Living (AAL), in 2011. SG 5 was later transformed into SEG 3, a Systems Evaluation Group on AAL. Following a recommendation by SEG 3, the SMB agreed to disband SEG 3 and to create a Systems Committee, IEC SyC AAL: Active Assisted Living (AAL), to help users of all ages including older persons and persons with a temporary or permanent disability, live a meaningful, active and independent life.

Use cases related to accessibility have been collected in IEC SyC AAL as well as in the TC 100 study session on wearable technologies.

Different solutions help for impairment

Access to broadcast content for the visually impaired is based predominantly on audio solutions.

For TV broadcasts this can be done through audio description of the on-screen setting / action that complements the audio content already available (e.g. dialogues).

Where radio speech content is concerned, the elderly may have difficulty in separating the narration from background music and sound effects and understanding it. This results from the degradation of inner ear function as well as from the deterioration of processing ability in the auditory centre. Japan’s public broadcaster NHK has developed an adaptive speech rate conversion technology using speech interval detection. Output speech can be delivered more slowly than the speech originally input by carrying out a series of processes that delete non-speech intervals and scale the speed whilst ensuring that the target length remains the same and that the pitch is not affected.

Audiobooks, first introduced on long-playing records in the 1930s, were aimed initially to give access to printed works to the visually impaired. They later adopted audiocassettes as primary support. In the 1990s audiobooks moved gradually from an analogue to a digital format (CD). The need to define the audiobook electronic file format structure to ensure compatibility with music industry and multimedia standards, as well as how to present and navigate an audiobook effectively, led TA 10: Multimedia e-publishing and e-book technologies to develop IEC 62571:2011, Digital audiobook file format and player requirements. This Standard “defines requirements and provides recommendations to publishers, software developers, content providers, and hardware manufacturers for the data structure, usability requirements, playback systems and delivery systems for audiobooks in digital file format.”

Access to ICT products and services for the visually impaired can be ensured through text enlarged via adjustable fonts and magnification or the conversion of written material into
spoken text using optical character recognition (OCR) software.

International Standards for OCR are being developed by ISO/IEC JTC 1/SC 31: Automatic identification and data capture techniques, a Subcommittee of the Joint Technical Committee for Information Technology set up by the IEC and the International Organization for Standardization (ISO).

**Digital benefits**

At this year’s International Broadcasting Convention (IBC), Europe’s largest professional broadcast show in Europe held every year in Amsterdam, a number of R&D departments from public broadcasters, universities and telecommunications companies presented various solutions aimed at providing access to multimedia and ICT products and services for people suffering from impairment linked to hearing, visual and ageing disabilities.

These solutions face different challenges linked to the nature of the content, such as live or recorded broadcasts or archived material (analogue or digital, with or without metadata), as well as the language and/or writing structure and broadcasting system / format.

**Subtitling is a complex process**

Most people are used to seeing subtitles in films or in recorded television interviews when spoken words may be difficult to understand. Subtitlers of television programmes face different kinds of challenges when the result is intended for live or for pre-recorded broadcasts, for large collections of video clips or for a combination of subtitling and sign language.

These different sets of challenges and the solutions applied to meet them were presented by researchers from Ericsson and the University of Edinburgh (UK), BBC Research & Development and NHK at an IBC 2016 paper session on Novel Technologies for Assisting Sensory-Impaired Viewers.

**High-quality subtitling linked to low latency**

Latency remains one of the most significant factors in the audience’s perception of quality in live-originated TV captions for the deaf and hard of hearing, according to joint Ericsson – University of Edinburgh research. Once all prepared script material has been shared between the production team and captioners, “pre-recorded video content remains a significant challenge – particularly ‘packages’ for transmission as part of a news broadcast,” according to Ericsson’s Matt Simpson. These video clips are usually published just prior to or even during their intended broadcasting slot, providing little opportunity for thorough preparation.

Automatic speech recognition (ASR) based on context-tuned models and the application of machine learning across large volumes of data help meet some of the challenges. However, other issues still need improving, such as fidelity to the original spoken word, the textual accuracy of the transcript (with optimal accuracy being 95% and minimal threshold found to be 90%, with no more than 10% of the content missing) and the timeliness with which it is presented. ASR is set to play a growing role in support of captioning for live broadcasts, but the audio quality of the original video content (quiet or noisy background) is important.

**Re-using archived content**

Broadcasters hold large archives of quality material produced years, even decades, ago. This content is not always subtitled, but is often

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**INDUSTRY SPOTLIGHT**

Computer generation of Japanese sign language is being tested for weather reports.
rebroadcast as viewers like to discover or rewatch classics, comedies or history programmes.

Mike Armstrong from BBC R&D told participants in the session that the BBC was providing subtitles for 100% of its TV programmes on all its main channels as well as on its video-on-demand (VOD) service and websites. Recent BBC audience research showed that subtitle use was not limited to the hearing impaired but that around 10% of the adult TV audience use subtitles daily. Overall, subtitle use is around 18% and even as high as 20% on tablets. Most interesting are the findings for children’s programmes, where subtitle usage is around 30% and around 35% for content classified as “Learning”.

The BBC has thousands of hours of video content and until now subtitling has been a manual process, done either by retrieving subtitles from original content or by creating new ones.

The BBC tested a three-step system for video clips (not for full-length programmes). It used 500 hours of content from some 7 500 audio and video files of the BBC Bitesize archives to assess automation of the subtitling process. This system includes:

- Identifying the source programme and retrieving assets using the BBC’s Programme Information Platform (PIPs) metadata system and off-air (Redux) archives, locating the relevant section of the programme by searching within programmes and creating search strings
- Matching audio and text using “Chromaprint” open source audio fingerprinting
- Retiming subtitles and verifying output

Trials resulted in a 46,7% success rate. Even if a significant amount of work is still needed to obtain a broadcast-ready product, this experimental project is promising and paves the way for the production of subtitles files for video clips.

**Computer-generated hybrid sign-language / subtitling**

At the same IBC 2016 session, Shuichi Umeda from NHK outlined the particular challenges faced by the Japanese broadcaster in offering services for hearing impaired viewers.

NHK is developing a system for computer generation (CG) of Japanese Sign Language (JSL) graphics, currently being tested with online meteorological information.

Persons whose first language is JSL, which is a different language from Japanese, have been demanding more TV programmes with sign language in addition to closed captions, as they may not be fully familiar with Japanese characters.

As sign-language interpreters are not available in sufficient numbers, CG production of JSL graphics is seen as an interesting solution. However, it must be capable of generating realistic avatars (characters) that can reproduce facial expressions as well as hand signs.

NHK production of CG JSL graphics is based on templates using fixed phrases translated into strings of sign language animations, on 3D models of characters and on optical motion capture of markers attached to the joints and faces of signers.

NHK is currently testing this automatic system to generate weather forecasts for all of the 47 prefectural capitals of Japan so that users can see the latest weather forecast via the Internet for any of these cities in the form of CG sign language.

It must be said that CG of JSL graphics for weather reports is a relatively simple process as it relies on the set sentences, phrases and signs most commonly used in weather reports.

The same doesn’t apply yet to most other forms of Japanese TV content, although NHK has announced its plans to provide these CG descriptions for the 2020 Tokyo Olympics by generating them automatically from Olympic Data Feed messages, which are play-by-play event records.

**Multilateral effort**

The IEC is also liaising and working with other international and professional organizations like the International Telecommunication Union (ITU) or the European Broadcasting Union (EBU), which work on developing solutions to provide access to broadcast and ICT products and services to people suffering from visual or hearing impairment. IEC TC 100 maintains a Category A Liaison with both.

As for IEC SyC AAL, it also maintains a Category A Liaison with ITU-T/JCA-AHF: Joint Coordination Activity on Accessibility and Human Factors.

ITU Telecommunication Standardization Sector (ITU-T) has published a number of documents, including a report on Accessibility to broadcasting services for persons with disabilities.

The EBU Technical Department has developed EBU Timed Text (EBU-TT), a series of specifications for subtitling widely adopted by the broadcasting industry.

Work by the IEC, these organizations and others improve access to multimedia content significantly for persons with visual or hearing impairments.
IEC work supports cross-sector AAL

IEC plays a growing role helping those seeking to remain active to access a variety of services

Morand Fachot

To deal with Active Assisted Living (AAL) issues, the IEC has established a Systems Committee, IEC SyC AAL. This SyC has the role of promoting safety, security, privacy and cross-vendor interoperability in the use of AAL systems and services, and of fostering standardization which boosts their usability and accessibility.

Recent concept
The IEC SyC concept is fairly new. Instead of the typical Technical Committee (TC) structure that focuses exclusively on one technology (for example, high frequency surgical medical devices or ultrasound medical diagnostic imaging devices), the SyC AAL brings together a multitude of technology experts from different domains, such as medical devices, consumer electronics, Internet of Things, computer systems and networks. These experts, who may come from a number of IEC TCs, from other standards development organizations (SDOs) and from industry consortia such as Continua and other organizations like AALiance 2, work to address transversal standardization and broader system-wide issues.

Users first and foremost in mind
IEC SyC AAL has been established to address concepts, products, services and systems combining technologies and social environment with the aim of improving the quality of AAL users’ lives. The AAL user is any person, of any age, who uses and/or benefits from AAL devices, systems or services.

The multiplicity of AAL technologies that the industry is developing, the large number of standards on the market today and the currently fragmented standardization landscape are challenges for the IEC in developing international and interoperable standards from which the AAL user can benefit.

The objective is that AAL users should, to the greatest extent possible, live a meaningful, active and independent life, be fit and in good health and be socially connected.

All-embracing structure
The standards development work conducted by an SyC begins at the systems level rather than at the level of individual products, so supporting the investigation of more complex issues related to devices, services, systems, infrastructure and interoperability. As with a TC, an SyC can publish international standards and other IEC deliverables such as Technical Reports and Technical Specifications but only to fill any gaps that may exist with other standards.

The SyC AAL currently consists of four Working Groups (WGs), one Project Team (PT) and two Chairman’s Advisory Groups (CAGs):

- WG 1: User Focus, covers all user-related issues of AAL products, systems and services
- WG 2: Architecture and Interoperability, aims at coming up with a definition for an AAL reference architecture based on user needs, which allows interoperability at different levels by taking into account security and privacy issues
- WG 3: Quality and Conformity assessment, focuses on quality criteria, developing testing cases, tools and standards, working with IEC CAB to develop relevant schemes, and organize interoperability testing events (e.g. plugfests)
- WG 4: Regulatory Affairs, looks at AAL initiatives on national and regional levels with details on R&D projects and trials, at regulatory requirements on national and regional levels with details on AAL policies and at the relevant AAL
organizations on national and regional levels such as those for the elderly and those with disabilities.

PT 60050-871: International Electrotechnical Vocabulary, was set up to develop the IEV part that deals with AAL terminology. The IEC TCs involved in AAL as well as the external stakeholders engaged in SyC AAL are involved in this PT.

- **CAG 1**: Coordination, is responsible for organizing and coordinating the work of the SyC AAL
- **CAG 2**: Strategy, develops the vision and long term strategy of the SyC AAL by taking into account the emerging market trends and user needs.

**Liaising widely**

IEC SyC AAL is working closely with the following IEC TCs, Systems Committees, Advisory Committees and an ad hoc Group, as well as with ISO/IEC JTC 1: Information Technology, the Joint Technical Committee set up by the International Organization for Standardization (ISO) and the IEC:

- **IEC TC 59**: Performance of household and similar electrical appliances
- **IEC TC 61**: Safety of household and similar electrical appliances
- **IEC TC 62**: Electrical equipment in medical practice
- **IEC TC 79**: Alarm and electronic security systems
- **IEC TC 100**: Audio, video and multimedia systems and equipment. TC 100 has set up a Technical Area, TA 16: Active Assisted Living (AAL), accessibility and user interfaces, to address AAL-specific issues related to audio, video and multimedia systems and equipment.
- **ACART**: Advisory Committee on Applications of Robot Technology
- **ACSEC**: Advisory Committee on Information security and data privacy
- **ahG 66**: Smart Home/Office Building Systems
- **ISO/IEC JTC 1**: Information Technology, including WG 10: Internet of Things and Subcommittee (SC) 35: User interfaces
- **ISO/TC 159**: Ergonomics
- **ISO/TC 173**: Assistive products for persons with disability
- **ISO/TC 215**: Health informatics
- **ISO SAG on Ageing societies**: Continua Alliance and PCHA
- **AALIANCE 2**
- **ITU-T/JCA-AHF**: Joint Coordination Activity on Accessibility and Human Factors

This wide network may extend in the future as further needs become apparent.

**Monitoring emerging trends**

The systems approach is being used to address AAL issues because they cut across many fields of technology.

To do this, IEC SyC AAL has set itself the task of monitoring closely the following emerging trends:

- accessibility, user needs and user interface technologies
- Internet of Things and of People
- daily life autonomy and health support
- health informatics
- wearable smart devices
- disruptive technologies
- service robotics
- 5th generation Internet
- smart cities, including intelligent (smart) homes and smart office buildings
- security and personal data privacy
- data analytics and Big Data

**SyC AAL set to fill important role as needs expand**

Increasingly, people of all ages are seeking wider and better access to technologies that allow them to live a more active and fulfilling life. These individuals may be elderly people who want to live independently and remain active longer, or those of any age who need to use or benefit from AAL devices, systems or services.

The proportion of elderly people in all societies is growing fast. In 2010, an estimated 524 million people were aged 65 or older, according to the US National Institute on Aging. By 2050, this number is expected to nearly triple, to about 1.5 billion.

Meanwhile, more and more individuals from other demographic groups are also seeking improved access to AAL products and services. The multitude of AAL technologies, products and services that can be used in the home and other environments, and the need to develop international and interoperable standards for these point to a very active agenda for the IEC SyC AAL in the future.

* Wearable health monitoring devices, like this AliveCor Kardia Band, can help the disabled or elderly people monitor their own health.
Portable medical devices radically change healthcare delivery

Wireless technology is revolutionizing the way we approach chronic diseases and other health-related conditions.

Antoinette Price
In our mobile world, portable smart devices keep us connected and able to access information anytime, anywhere. The healthcare industry has also embraced connected technology in the form of medical wearables and portable devices. These offer accurate real-time monitoring, diagnosis and tailored treatment of conditions, such as some types of diabetes and cardiovascular disease.

Digital technology and healthcare go hand in hand
The information technology integrated into self-care medical devices is changing the healthcare landscape, its systems and how services are delivered. On the wellness front, wearable bracelets and watches allow us to see how many steps we take each day, monitor exercise, food, weight and sleep. These devices track blood pressure, body temperature, measure blood glucose levels, improve hearing, remind us to take medication and more. In addition to self-monitoring, this technology is used in telemmedicine, where data gathered can be sent directly to healthcare professionals in hospitals or clinics and patients can be treated at a distance, via email, webcam or phone.

According to a report by TechNavio, the global self-care medical devices market will grow at a compound annual growth rate of 9% between 2016 and 2020. This is thanks to increased awareness and knowledge people have of their health, and the ease of use and convenience of this technology.

How can we be sure self-monitoring medical devices are safe?
As world populations age and many more people become susceptible to disease and health conditions that need regular monitoring and treatments, this technology will greatly help over-stressed healthcare services, especially for people who are less mobile or live in remote locations.

Many people using these devices to monitor key aspects of their health expect the equipment to be safe and reliable, especially since they may not have a medical background or training.

IECEE, the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components, ensures that electrical and electronic devices and equipment are reliable and meet expectations in terms of performance, safety, reliability and other criteria. The Scheme applies not only to the medical electrical equipment itself but also covers risks to patients, those who operate the equipment – doctors, nurses and technicians, for instance – and maintenance personnel.
The interoperation between electrical and mechanical energies has existed for a long time. In standardization and conformity assessment, the need to provide a holistic solution to cover both is vital for industry and the community. While this may have been a given for most industries, the Ex sector has, for many years, focused exclusively on electrical equipment for its standardization and conformity assessment needs. This is no longer the case.

Holistic approach for the Ex sector. Take for instance an electric motor for use in an Ex environment. It is designed and manufactured to meet minimum safety standards and may be covered by IECEx Certification, but until recently, the mechanical items driven by the electrical motor, e.g. pumps, gearboxes, and so forth, were ignored and left to the many differing local or regional requirements. This has now changed with the inclusion of non-electrical equipment in the set of International Standards developed by IEC Technical Committee (TC) 31: Equipment for explosive atmospheres, via its Subcommittee (SC) 31M: Non-IECEx issues first certificates for non-electrical equipment...
electrical equipment and protective systems for explosive atmospheres, and the integration of these Standards into the IECEx operations. IECEx is the IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres.

The early days
The necessity to develop specific techniques to reduce or eliminate the risk of explosion for electrical equipment used in hazardous areas involving gases, vapours and mists led the IEC to establish Technical Committee (TC) 31: Equipment for explosive atmospheres. That was in July 1948.

For close to 70 years, the TC and its SCs have published International Standards dealing with explosive (Ex) atmospheres – the IEC 60079 series – covering the life-cycle of electrical equipment from design and manufacture to installation, maintenance and repair. Area classification and inspection are also addressed in TC 31 publications.

Extending the scope to include non-electrical equipment
To meet growing industry needs, standardization work addressing non-electrical equipment used in explosive atmospheres was initiated in 2007. A joint decision made by the IEC and the International Organization for Standardization (ISO), through the IEC Standardization Management Board (SMB) and the ISO Technical Management Board (TMB), led to the establishment of SC 31M.

In its scope, SC 31M defines non-electrical equipment as “equipment which can achieve its intended function mechanically”, and protective system as “devices other than components of the equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion”.

SC 31M is authorized to produce both dual-logo ISO/IEC and single-logo IEC or ISO International Standards within IEC and IEC TC 31. The development process occurs according to IEC procedures but voting on Committee Draft for Vote (CDV) and Final Draft International Standard (FDIS) documents is conducted in parallel, with each organization following its own rules for voting.

The ISO/IEC 80079 series
While all International Standards developed by IEC TC 31 and its SCs follow the IEC numbering, i.e. IEC 60079-x, SC 31M publications are in the ISO/IEC 80079-x series. The first Standard issued by SC 31M was ISO/IEC 80079-34, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture, in 2011.

Since then SC 31M has published four other International Standards:
- ISO/IEC 80079-20:2016, Explosive atmospheres - Part 20-2: Material...
IEC honoured IECQ Technical Expert in avionics

Howard Brewer receives 1906 Award for outstanding contribution to IECQ work

Claire Marchand

Electronic systems used on most modern commercial aircraft include hundreds of systems that help perform specific functions.

A multitude of systems

Modern avionics – the term was coined from the words aviation and electronics – stem in good part from World War II technological advances. Post-WW II developments often continue to have their origin in the military, where a fair portion of the spending is allocated to avionics. In addition to benefiting from the new technologies trickling down from the defense industry, civil aviation has also seen a growing part of its R&D budget devoted to aircraft control systems and the like. These systems include:

Automatic control

Automatic flight control systems lighten the pilots’ workload, especially at crucial times such as landing or in hover, and help eliminate human errors that might otherwise prove fatal.

Monitoring

Display systems provide sensor data that allow the pilots to monitor flight conditions regarding the engine, altitude, speed, and a host of other parameters.
parameters at all times and thus to fly the aircraft safely. Most of the information that used to be displayed on mechanical gauges in older aircraft now appears on electronic displays.

Communications
Communications connect the flight deck to the ground and to the passengers. On-board communications are provided by public address systems and aircraft intercoms.

Navigation
Navigation is the determination of position and heading (direction) on or above the surface of the earth. Avionics can use satellite-based systems, ground-based systems, or any combination of the two. Navigation systems calculate the position automatically and display it to the flight crew on moving map displays.

Anti-collision systems
As a complement to air traffic control, most large transport aircraft and many smaller ones use a TCAS (traffic alert and collision avoidance system), which can detect the location of nearby aircraft and provide instructions for avoiding a midair collision. Smaller aircraft may use simpler traffic alert systems which are passive and do not provide information for resolving potential problems. To help avoid collision with terrain, aircraft have systems such as GPWS (ground-proximity warning systems), of which radar altimeters are a key element.

Weather
Weather instrumentation such as radar and lightning detectors is important for aircraft which fly at night or in meteorological conditions in which pilots cannot see the weather ahead. Heavy precipitation (as sensed by radar) or severe turbulence (as sensed by lightning activity) are indicators of severe disturbances, and these weather instruments allow pilots to deviate around such areas.

Aircraft management systems
The trend today is to have centralized control of the multiple complex systems fitted to aircraft, including engine monitoring and management.

High-quality electronics is a must
The avionics industry is largely dependent on commercial-off-the-shelf (COTS) electronic components designed and produced for other markets, such as consumer electronics, telecommunications, and so forth.

While quality is important in all electronics sectors, it is even more so in transportation. One tiny faulty component in an airplane electronic system may endanger the lives of hundreds of passengers and possibly of people on the ground. The aerospace industry must therefore define its own processes to assure that the COTS parts used in avionics systems will be reliable.

From process management for avionics...
To address this issue, IEC Technical Committee (TC) 107: Process management for avionics, has published IEC TS 62239-1, Process management for avionics - Management plan - Part 1: Preparation and maintenance of an electronic components management plan, which describes processes that avionics manufacturers must document in a plan, in order to use COTS electronic...
components successfully in aerospace applications. Plans that are certified as compliant to IEC TS 62239-1 are accepted as evidence by aerospace customers, i.e., platform integrators, regulatory agencies, and operators, that the avionics manufacture is able to use COTS electronic components successfully in avionics applications. A number of aerospace integrators and operators are participating in this activity.

...to certification
IECQ, the IEC Quality Assessment System for Electronic Components, goes one step further, testing and certifying the widest variety of electronic components.

IECQ has a programme specifically designed for the aerospace sector, the IECQ ADHP (Aerospace, Defence and High Performance) Scheme. It also has a Counterfeit Avoidance Programme (IECQ CAP) which ensures that equipment manufacturers or subcontractors used by an organization have processes for managing counterfeit avoidance in the selection and use of components according to IECQ CAP technical and quality management system requirements.

Using IECQ ADHP and IECQ CAP provide assurance that independent conformity assessment and ongoing surveillance are performed by an IECQ Certification Body.

Technical Experts play key role
The IECQ System provides industry with a supply chain verification tool for seeking assurance that electronic components, assemblies, processes and related materials conform to declared technical Standards and Specifications.

To serve industry sectors that have an interest in IECQ ADHP and CAP certification, IECQ appoints Technical Experts, or Subject Matter Expert, based on their accomplishments, experience and qualifications in verifying compliance.

Howard Brewer honoured with IEC 1906 Award
Howard Brewer, IECQ veteran and one of the appointed Technical Experts, has spent more than 25 years of his career in conformity assessment.

In the early 1990s, the transfer of the UK National Supervising Inspectorate (NSI) responsibilities for electronic component approvals from the Defence Research Agency (DRA) to BSI* was the subject of a formal agreement that became effective in July 1991.

The five-year transfer programme got under way in September 1991 and Brewer was one of the first people recruited by BSI as part of a newly-formed team in BSI Quality Assurance.

Brewer has played a pivotal role in the maintenance and development of the schemes which saw the steady migration from the original UK-only BS 9000 scheme to the European CENELEC Electronic Components Committee (CECC) scheme and finally to the IECQ-CECC merger in April 2003 and the formation of a truly international System serving electronic component manufacturers and related industries worldwide. In May 2009, Brewer was appointed Subject Matter Expert for avionics.

Throughout the years, Brewer has shared his knowledge and expertise with his peers and has proved to be a brilliant mentor to everyone in the System.

In recognition of his longstanding exceptional contribution to the IECQ System and the IEC community, Brewer received the IEC 1906 Award in August 2016.

* The BSI Group provides standardization and certification services worldwide and acts as the UK National Standards Body.
October 2016 nominations

The latest TC Chair nominations approved by the SMB

Antoinette Price
Over the past few months, the Standardization Management Board (SMB) has nominated a number of new Chairs.

Martin Doppelbauer
Taking up his role as Chair of IEC TC 2: Rotating machinery, on 1 July this year, Martin Doppelbauer has a background in electrical engineering, and worked for over 15 years in electric motor design and development. He is currently chair of the Hybrid Electric Vehicles at Karlsruhe Institute of Technology. Doppelbauer has been involved in the work of IEC TC 2 since 1996 and participates in other European standardization organizations.

Martin Doppelbauer has been voted Chair of IEC TC 2 for the period 2016-07-01 to 2022-06-30.

Norbert Schaaf
Norbert Schaaf began as Chair of IEC TC 79: Alarm and electronic security systems, on 1 September this year. A physics engineer graduate, Schaaf has worked in the field of infrared physics technology, specializing in different alarm and other systems. He has extensive experience in standardization for alarm and monitoring systems, participating in IEC and its German National Committee, and other European standardization organizations.

Norbert Schaaf has been voted Chair of IEC TC 79 for the period 2016-09-01 to 2022-08-31.

Michio Kondo
Michio Kondo began as Chair of IEC TC 82: Solar photovoltaic energy systems, on 1 September this year. With a PhD in Materials Science, Kondo has a broad experience of photovoltaic systems and is the supervisory innovation coordinator at the Fukushima Renewable Energy Institute. Kondo has published over 400 scientific papers and won awards for his work in PV science. Since 2004, he has been Vice Chair of IEC TC 82 and participates in standardization work with other organizations.

Michio Kondo has been voted Chair of IEC TC 82 for the period 2016-09-01 to 2022-08-31.

Giovanni Pirovano
Giovanni Pirovano began his role as Chair of IEC TC 7: Overhead electrical conductors, on 1 September 2016. Currently head of the research group ‘electrical technologies and components’ at Ricerca Sistema Energetico, Pirovano comes from an electrical engineering background where for almost 30 years, he has worked in research, testing, consulting and standardization activities for overhead lines and relevant components. He has published several papers and received the IEC 1906 Award this year.

Giovanni Pirovano has been voted Chair of IEC TC 7 for the period 2016-09-01 to 2022-08-31.

Gerhard Roos
Gerhard Roos took up as Chair of IEC TC 45: Nuclear instrumentation, on 1 September this year. Roos has a PhD in physics and since 2006, has been managing director for the Office of Nuclear Safety Standards Commission (KTA GS), Salzgitter, Germany. With over 20 years’ experience in nuclear safety standardization, he has worked on operational issues, systems design, reactor core, severe accidents, (emergency) power supplies and instrumentation and control. Roos received the IEC 1906 Award in 2013. He has also participated in European standardization organizations.

Gerhard Roos has been voted Chair of IEC TC 45 for the period 2016-09-01 to 2022-08-31.
Celebrating World Standards Day 2016

Standards build trust – Winning video from Bangladesh

Claire Marchand
On October 14 2016, the members of the IEC, the International Organization for Standardization (ISO) and the International Telecommunication Union (ITU), under the umbrella of the World Standards Cooperation (WSC), celebrate World Standards Day as a means of paying tribute to the collaborative efforts of the thousands of experts worldwide who work on developing International Standards.

#speakstandards video competition
For the second year running participants were asked to create and submit a short video – 15 seconds – rather than a poster, based on the 2016 theme “Standards build trust”, to demonstrate the importance of standards in our daily life and what the world would be like without them.

The competition attracted entries from around the world and covered a wide range of topics to show that objects and products we use all the time are safe and reliable thanks to standards. International Standards play an essential role, especially in today’s connected world. IEC, ISO and ITU selected the top 10 candidates and put them up for public vote.

No standard film Takes first prize
Khaled Md. Shariful Islam from Bangladesh takes first prize in the #speakstandards video competition. He describes his video as showing that “it is impossible to live or get anything done without the help of international standards. Be it operating a complex modern digital video camera, or simply sketching an image with a pencil, standards are required for things to function properly and smoothly.”

Using pencil-drawn sketches, the video describes how the illustrator aimed to create a video without the use of a camera to portray a world without any international standards. As the film progresses, the illustrator realizes that his pencil, too, conforms to international standards.

Khaled is a Creative Director and Strategist, and also teaches advertising at a university. He receives CHF 1 500 and his video will be used worldwide to celebrate World Standards Day.

Runners-up
Three runners-up also receive an award of CHF 500 each for their contribution:

Anna Orbeli from Armenia takes second place with a video demonstrating the importance of safety standards to toys. Her video comes from personal experience. “My mother luckily saved my little brother’s life from Yo-Yo water ball intoxication, because the product wasn’t patented and didn’t conform to safety standards. After that day, I have paid attention to each toy’s label before buying it.”

Anna Orbeli, Shant Rubinyants & Karo Galoyan from “Orbeli production”, an Armenian team of animators, take third place. Their video highlights customer-service standards to remind businesses in all sectors that standards help them to retain customers by creating an environment open to feedback on how to improve customer
service. After participating in last year’s #speakstandards video competition and winning the 2nd place, the team members say that they started to pay more attention to the importance of standards.

Fourth prize is taken by a team six from Colombia, made up of Johana Sánchez, John Higuera, Andrés Felipe Berrio, Daniela Estrada, Frank Higuera and Sebastian Rojas for their video “Spoon”. “We tried to show the importance of the units of measurement in the field of medicine and possible situations that have no quality standards could affect our lives,” said the group leader, Johana Sánchez.
Upcoming global events
On the agenda: nuclear knowledge, energy, printed electronics and cybersecurity

Claire Marchand
The IEC regularly supports key global and regional industry events, which can present the IEC endorsement on their website and materials.

7th Fokus Fuseco Forum
Berlin, Germany, 3-4 November 2016

In anticipation of 5G and the industrial Internet, operators, global analysts, standard bodies and manufacturers will discuss 5G related access technologies, software based 5G core and service platforms, 5G and industrial Internet apps and more.

IEC Members benefit from a 20% discount using the promo code: supporter_rebate-20.

More information on the Forum’s website

IAEA Third International Conference on Nuclear Knowledge Management: Challenges & Approaches
Vienna, Austria, 7-11 November 2016

On the agenda of the International Atomic Energy Agency (IAEA): share experiences/lessons learned about nuclear knowledge, practical approaches to knowledge management for organizational, national, international use, discuss specific human competencies, process- and technology-related knowledge needed for safe/sustainable application of nuclear technology.

More information on the event’s website

Power Week 2016
Singapore, 7-11 November 2016

Join electricity regulators, national power companies, renewable & IPPs, investors/ suppliers to gain valuable insights on policy & regulations, technology innovations for generation, transmission, distribution, environmental impacts, fuel supply sources, renewable, hydro, nuclear, gas to power developments, power trading, IPP projects, investment & financing, power contracts & negotiation.

More information on the event’s website

SAEEC 2016 – 11th annual Southern African Energy Efficiency Convention
Gauteng, South Africa, 8-9 November 2016

The convention will bring together energy management/engineering, environmental, facilities building upgrades, cogeneration, power generation, efficiency improvement industries to discuss RE, power generation, lighting efficiency, power contracts & negotiation.

More information on the event’s webpage
iPAD Cameroon - Energy Infrastructure Forum

Yaoundé, Cameroon, 10-11, November 2016

On the agenda: overview of oil and gas exploration/production in Cameroon. Discussions on legal/tax implications, securing investor assets, renewables integration, smart grid/off grid solutions and a power plant visit as well as great networking opportunity and more. IEC participants benefit from a 10% reduction.

European Utility Week 2016

Barcelona, Spain, 15-17 November 2016

On the agenda: latest technology for energy systems, future smart grid operations, safety, sustainability, as well as ICT and data management and more.

Richard Schomberg, IEC Ambassador for Smart Energy and Chair, IEC Smart Energy System Committee, will be moderator for the Communication Protocols Panel to discuss communication standards needed in smart grids, meters, home automation, appliances etc.

More information on the event’s website

Printed Electronics USA 2016

Santa Clara, California, USA, 17-19 November 2016

On the agenda: experts from around the world will discuss the latest technology and developments in printed electronics, energy harvesting, graphene, 3D printing, wearables, sensors, energy storage, EVs and the IoT and more.

IEC participants benefit from a 30% reduction using the promo code IEC30-PE16.

More information on the event’s website

Call for papers – Metering India 2017 – Towards Smart and Sustainable Utilities

New Delhi, India, 6-7 April 2017

On the agenda: Utilities, consultants, businesses, regulators and manufacturers will look at how ICT can make Indian power utilities more sustainable. On the agenda: metering, communication technologies, demand-side management, IT infra, sustainable business processes and more.

The deadline for paper submission is 31 December 2016.

More information on the event’s website

SmartSec Europe 2016

Amsterdam, The Netherlands, 29-30 November 2016

120+ utility IT and OT cybersecurity leaders will share lessons learnt from recent implementations of advanced cybersecurity technologies. On the agenda: end-to-end architectures with specific approaches for vulnerability points within substations, SCADA systems, advanced metering infrastructure and more.

IEC participants benefit from a 10% reduction using the promo code SMARTSEC-16-IEC.

More information on the event’s website
Alarm systems useful for AAL too

Alarm transmission systems are used for many applications, including Active Assisted Living

Morand Fachot

Premises equipped with alarm and access control systems are often essential for people using facilities suited for Active Assisted Living (AAL). Some of these premises must be supervised and as such require special alarm systems. A series of International Standards addressing requirements for these systems is being developed. Two Standards in the series have been published recently.

Supervised premises important for AAL

Some people affected by health or age-related issues or disabilities need a certain degree of supervision or the possibility of alerting someone in case of difficulties resulting, for instance, from a fall or urgent health problem. They may also need protection from ill-intentioned individuals when they live either in their own home or in residential care. Remotely connected alarms used in supervised premises are essential for this.

IEC Technical Committee (TC) 79: Alarm and electronic security systems, is developing the IEC 60839-5 series of International Standards for Alarm transmission systems (ATS). Two Standards published this year concern requirements for ATS used in supervised premises.

Transmitting information reliably and safely

A transceiver (transmitter / receiver) can both transmit and receive communications.

IEC 60839-5-2 specifies the general equipment requirements for the performance, reliability, resilience, security and safety characteristics of a supervised premises transceiver, which “can be a stand-alone device or an integrated part of an alarm system.”

The Standard indicates that “the SPT shall be able to receive alarms from one or more alarm systems and transmit the alarm to one or more receiving centre transceivers (RCTs) via one or more alarm transmission paths

Supervising premises requires two-path systems

A properly operating ATS for supervised premises requires equipment that can transmit and receive the necessary information.

To address this issue IEC TC 79 published IEC 60839-5-2:2016, Alarm and electronic security systems - Part 5-2: Alarm transmission systems - Requirements for supervised premises transceiver (SPT), and IEC 60839-5-3:2016, Alarm and electronic security systems - Part 5-3: Alarm transmission systems - Requirements for receiving centre transceiver (RCT).

General requirements and classifications for ATS are defined within IEC 60839-5-1:2014, Alarm and electronic security systems - Part 5-1: Alarm transmission systems - General requirements.

Wearable alert systems can make independent living safer for the elderly...
(ATPs) within the requirements of the appropriate ATS category."

IEC 60839-5-2 lists also additional requirements, such as access levels, remote access, uploading and downloading of software and firmware, storage of parameters or fault reporting, and event reporting, among other requirements.

Various operation modes are also detailed, as well as many general and functional test requirements.

IEC 60839-5-2 specifies that all the above-mentioned requirements and others “in this standard shall be considered as a minimum. As the SPT is used together with or integrated in associated alarm systems, the requirements of the specific applications or related standards shall apply.”

**Reliable and safe reception is essential too**

Since SPTs and RCTs work together and must be interoperable many of the requirements for IEC 60839-5-3 are similar to those specified for IEC 60839-5-2.

They include for instance comparable functional and test requirements.

Both Standards attach importance to security and refer to the general, substitution and information security requirements specified in IEC 60839-5-1. This Standard, which covers general requirements for ATS, includes systems requirements which say that “ATS shall protect itself against Denial of Service (DoS) attacks from the transmission network.” Other requirements are that the ATS and its components must be protected against malicious attacks and inadvertent influences, and that “cryptographic techniques shall be used to achieve [SPT] substitution and [SPT and RCT] information security."

The Standards in the IEC 60839-5 series cover a multitude of applications, including AAL, which can also integrate personal and social alarms in its overall architecture.
Smart energy

Issue 08/2016 of e-tech will focus on Smart Energy.

A wide range of technologies will help cities optimize energy use for hundreds of smart city projects around the world. Smart grids, open data platforms and networked transport systems will help meet the challenges of environmental sustainability, population growth and urbanization.

The IEC has opted for a systems approach to low voltage direct current (LVDC) standardization. LVDC is bound to play a major role in speeding up electrification and enabling electricity access for all: almost everything, from electric vehicles, renewable energy technology, island irrigation systems, kitchen appliances, lighting and transport, smartphones and tablets, to systems with data and embedded electronics, such as the IoT, smart homes and smart cities, runs on LVDC.

Also, rapid development of new materials and production techniques in solar photovoltaics (PV) is pushing both the limits of technology and relevant industry standards. The IEC develops International Standards in the barrier layer assemblies and printed electronics domains, technologies that support the development and further implementation of photovoltaic (PV) devices.

In addition to supporting the expansion of PV energy systems, the IEC standardization and conformity assessment work is key to the upgrade of the grids and to bring smartness to cities, buildings, homes, transportation and much more.
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