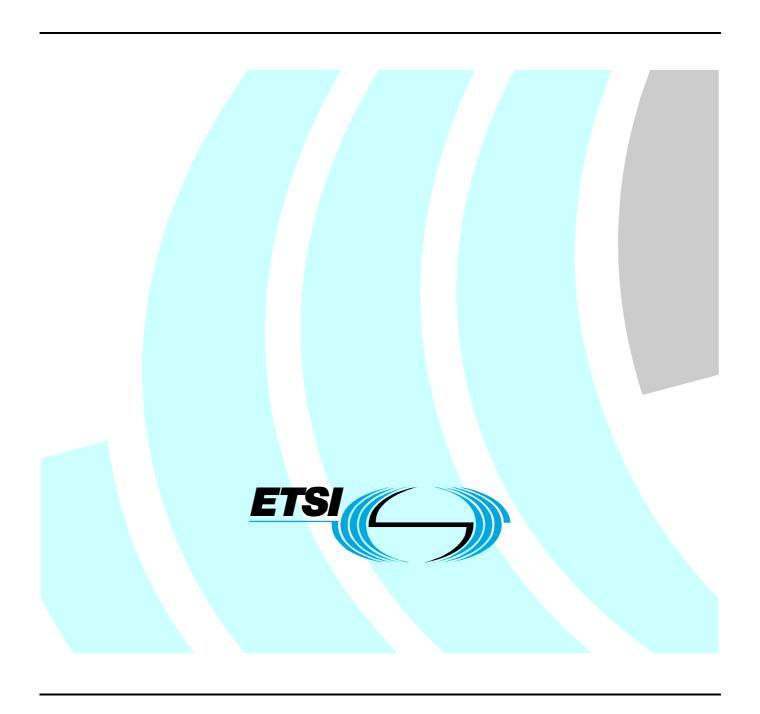# ETSI EG 202 487 V1.1.2 (2008-02)

ETSI Guide

**Human Factors (HF);
User experience guidelines;
Telecare services (eHealth)**

Reference

DEG/HF-00087

Keywords

Design for All, Health, HF, intelligent homes &
buildings, interface, MMI, user

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Foreword

This ETSI Guide (EG) has been produced by ETSI Technical Committee Human Factors (HF).

Intended users of this ETSI Guide are the stakeholders involved in the design, development, procurement and deployment of telecare services. The individual end users (telecare clients) are the ultimate beneficiaries of the guidelines, as their application should lead to telecare services of a higher quality, offering a better user experience.

Introduction

Telecare, defined as the provision of health and social care services to individuals within or outside of their homes with the support of systems enabled by ICT, has been identified as a strategic enabler of independent living.

The demographic trends within Europe indicate a development towards a population getting older and living longer than ever before. Therefore, the market for telecare solutions is poised to expand rapidly over the coming years, in order to address the ever growing population with functional limitations [23] and [24].

The aging of our society has unveiled the problem of dependency, as the number of dependant citizens is increasing, especially at the higher levels of the population pyramid. The majority of the dependant population receives informal care, but the population of informal carers is decreasing and aging. These facts may be causing a decrease in the family support to older people and people with disabilities and therefore demand new paradigms to provide support to dependency and independent living.

The maintained delivery of traditional health care services to these user groups would lead to a considerable cost increase, at a questionable quality, as these clients expect freedom of choice, mobility and personal attention, see TR 102 415 [41]. As communication technologies mature and the average user knowledge level is on the increase, these clients may more often have experience and trust in the use of ICT products and services.

The user experience of telecare services depends on a large number of elements. Much is known about human factors (ergonomics) in general and their application within the domain of ICT, however, little has been published within the area of e-Health. This work fills some of the gap, by collecting in a single document, human factors guidelines relevant for the research, design, and deployment phases of telecare products and services. It is the intention that the application of the guidelines shall lead to the best possible user interface and accessibility implementations, leading to an improved user experience of telecare services and thereby increasing the acceptance and adoption of telecare.

1 Scope

The present document provides user experience guidelines, applicable to the research, design, development and deployment of telecare services. The focus of the guidelines is grouped along three main themes: trust, usability and accessibility, and service provisioning, addressed through a user-centric approach. Principles of design for all, adaptive design and assistive technologies are applied throughout the present document.

The present document builds on the recommendations provided in TR 102 415 [41], defining telecare as the provision of health and social care services to individuals, within or outside of their homes, with the support of systems enabled by ICT.

Intended users of the present document are the stakeholders involved in the design, development, procurement and deployment of telecare services. The individual end users (telecare clients) are the ultimate beneficiaries of the guidelines, as their application should lead to telecare services of a higher quality, offering a better user experience.

Telemedicine, diagnosis and other medically related user aspects are outside the scope of the present document.

2 References

References are either specific (identified by date of publication and/or edition number or version number) or non-specific.

- For a specific reference, subsequent revisions do not apply.

- Non-specific reference may be made only to a complete document or a part thereof and only in the following cases:

    - if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of the referring document;

    - for informative references.

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NOTE: While any hyperlinks included in this clause were valid at the time of publication ETSI cannot guarantee their long term validity.

2.1 Normative references

The following referenced documents are indispensable for the application of the present document. For dated references, only the edition cited applies. For non-specific references, the latest edition of the referenced document (including any amendments) applies.

[1]   Void.

[2]   ETSI EG 202 132: "Human Factors (HF); User Interfaces; Guidelines for generic user interface elements for mobile terminals and services".

[3]   ETSI EG 202 116: "Human Factors (HF); Guidelines for ICT products and services; "Design for All"".

[4]   Void.

[5]   Void.

[6]   ETSI TS 102 511: "Human Factors (HF); AT Commands for Assistive Mobile Device Interfaces".

[7]   ETSI EG 202 423: "Human Factors (HF); Guidelines for the design and deployment of ICT products and services used by children".

[8]   ETSI ES 202 076: "Human Factors (HF); User Interfaces; Generic spoken command vocabulary for ICT devices and services".

[9]   ETSI ES 202 130: "Human Factors (HF); User Interfaces; Character repertoires, orderings and assignments to the 12-key telephone keypad (for European languages and other languages used in Europe)".

[10]   Void.

[11]   ETSI EG 202 191: "Human Factors (HF); Multimodal interaction, communication and navigation guidelines".

[12]   Void.

[13]   ETSI EG 202 048: "Human Factors (HF); Guidelines on the multimodality of icons, symbols and pictograms".

[14]   Void.

[15]   ETSI EG 202 421: "Human Factors (HF); Multicultural and language aspects of multimedia communications".

[16]   ETSI EG 202 416: "Human Factors (HF); User Interfaces; Setup procedure design guidelines for mobile terminals and services".

[17]   ETSI EG 202 417: "Human Factors (HF); User education guidelines for mobile terminals and services".

[18]   Void.

[19]   ETSI EG 201 472: "Human Factors (HF); Usability evaluation for the design of telecommunication systems, services and terminals".

[20]   ETSI EG 202 325: "Human Factors (HF); User Profile Management".

[21]   Void.

[22]   Void.

[23]   Communication from the Commission to the European Parliament, the Council, the European economic and social committee and the committee of the regions: "Ageing well in the Information Society - An i2010 Initiative - Action Plan on Information and Communication Technologies and Ageing" {SEC(2007)811}.

NOTE: Available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0332en01.pdf.

[24]   ITU-T Recommendation H. Sup.1: "Application profile - Sign language and lip-reading real-time conversation using low bit-rate video communication".

[25]   ISO 13407 (1999): "Human-centered design processes for interactive systems".

[26]   ISO 17799 (2005): "Information technology - Security techniques - Code of practice for information security management".

[27]   The Care Services Improvement Partnership (CSIP): "Telecare Implementation Guide" Department of Health, UK, 2005.

NOTE: Available at http://icn.csip.org.uk/telecare/.

[28]   NIST Special Publication SP 800-30 (July 2002): "Risk Management Guide for Information Technology Systems", G. Stoneburner, A. Goguen and A. Feringa.

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[30]   Cooper, A., Reimann, R. M.: "About Face 2.0. The essentials of Interaction Design" John Wiley & Sons; 2002.

NOTE: Available at http://www.amazon.com/About-Face-2-0-Essentials-Interaction/dp/0764526413/ref=pd_sim_b_img_1.

[31]   Integrating Community Equipment Services (ICES) (January 2005): "Telecare".

NOTE: Available at http://www.changeagentteam.org.uk/_library/docs/Housing/Telecare/Telecare_gettingstarted.pdf.

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NOTE: Available at http://www.tiresias.org/phoneability/accessible_biometrics_proceedings/gill.htm.

[33]   B. Dodson, D. Nolan: "Reliability Engineering Handbook".

[34]   Reliasoft Corp (2007): "System Analysis Reference: Reliability, Availability and Optimization".

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[35]   ISO/IEC JTC1 SWG-Accessibility: "User Needs Summary".

[36]   J.M. Winters, M.F. Story: "Medical Instrumentation: Accessibility and Usability Considerations".

[37]   ISO/FDIS 9241-20: "Ergonomics of human-system interaction - Part 20: Accessibility guidelines for information/communication technology (ICT) equipment and services".

[38]   The Unicode 5.0 Standard".

NOTE: Available at http://unicode.org/.

[39]   ISO/FDIS 9241-171: "Ergonomics of human-system interaction - Part 171: Guidance on software accessibility".

[40]   World Medical Association Declaration of Helsinki: "Ethical Principles for Medical Research Involving Human Subjects".

NOTE: Available at http://www.wma.net/e/policy/b3.htm.

2.2   Informative references

[41]   ETSI TR 102 415: "Human Factors (HF); Telecare services; Issues and recommendations for user aspects".

[42]   ETSI TR 102 068: "Human Factors (HF); Requirements for assistive technology devices in ICT".

[43]   ETSI TR 102 133: "Human Factors (HF); Access to ICT by young people: issues and guidelines".

[44]   ETSI ETR 095: "Human Factors (HF); Guide for usability evaluations of telecommunications systems and services".

[45]   ETSI ETR 329: "Human Factors (HF); Guidelines for procedures and announcements in Stored Voice Services (SVS) and Universal Personal Telecommunication (UPT)".

[46]   IEEE 802.11: "Handbook - A Designer's Companion".

3   Definitions and abbreviations

3.1   Definitions

For the purposes of the present document, the following terms and definitions apply:

accessibility: usability of a product, service, environment or facility by people with the widest range of capabilities (according to ISO 9241-171 [39])

assistive technologies: any product, instrument, equipment or technical system used by a disabled person to prevent, compensate, relieve or neutralize an impairment, disability or handicap

assistive technology device: device used by a disabled person to prevent, compensate, relieve or neutralize any resultant handicap and which has the ability to interface to an ICT device

carer: individual who provides health or social care to the client

    NOTE: Both professional and informal carers are included in this category.

child: defined for the purpose of the present document as a person up to the age of 12 years

client: individual receiving the telecare service, to support independent living and/or using telecare services for the care of his or her own health

coordinator (coordination agent): individual who coordinates the delivery of care through the use of the telecare service

    NOTE: Coordination agents will need to be able to use the telecare services efficiently and will have human factors needs that should be addressed.

design for all: design of products to be usable by all people, to the greatest extent possible, without the need for specialized adoption

disability: person's activity limitation or participation restriction

    NOTE: Disability is conceived as a dynamic interaction between health conditions (diseases, disorders, injuries, traumas, etc.) and contextual factors (i.e. personal and environmental factors).

domiciliary (home) care: care arranged by social services and delivered to persons in their own homes and can include assistance with personal care (e.g. washing, dressing, going to and getting out of bed) and a range of practical/domestic tasks

emergency service: service, recognized as such by the EU Member State that provides immediate and rapid assistance in situations where there is a direct risk to an individual's life or limb, public health or safety, private or public property, or the environment, but not necessarily limited to these situations

end user: See **client, carer** and **coordination agent**.

health/care professionals: professionals (e.g. clinicians, doctors, occupational therapists, social workers) involved in the assessment of clients and delivery of more specialist care than that provided by carers

health/care managers: professionals (typically working in the public sector) who control budgets and direct resources within their local area and who will have direct contact with health care professionals but not with carers or their clients

ICT devices and services: devices or services for processing information and/or supporting communication

impairment: any reduction or loss of psychological, physiological or anatomical function or structure (such as a significant deviation or loss)

informal carers: relatives, neighbours, friends or volunteers providing care for the person in need

interactive voice response: technology that allows a computer to detect voice and touch tones in a call and provide output using pre-recorded or synthesized speech

mobility: See **personal (user) mobility and service mobility**.

residential care: personal and/or nursing care that is provided to a person in a managed care home, in which the person is also provided with accommodation that includes appropriate staffing, meals, cleaning services, furnishings and equipment, for the provision of that care and accommodation

roaming: availability of a service at a location other than the home location, where the service was originally registered

service mobility: possibility for services to be accessed and delivered independently of network, service provider, terminal or geographical location attributes

telecare service: delivery of health and social care to individuals within the home or wider community, with the support of systems enabled by ICT

> NOTE: Additional components of the concept also include safety and security monitoring services and Electronic Assistive Technologies (EAT).

telecare service providers: public sector body (e.g. a local health authority) which has purchased a telecare system from a manufacture and uses it to provide a telecare service to their citizens; or a private sector company or charity, which has been contracted by the authority to provide a telecare service (but who are independent of the local authority); or a private sector company which offers telecare services directly to subscribing customers

terminal: physical device which interfaces with a telecommunications network, and hence to a service provider, to enable access to a telecommunications service

> NOTE: A terminal also provides an interface to the user to enable the interchange of control actions and information between the user and the terminal, network or service provider.

usability: effectiveness, efficiency and satisfaction with which specified users can achieve specified goals (tasks) in a particular environment; it includes the concepts of learn ability and flexibility

User Interface (UI): physical interface through which a user communicates with an ICT device or service

user requirements: requirements made by users, based on their needs and capabilities, on a telecare service and any of its supporting components, terminals and interfaces, in order to make use of this service in the easiest, safest, most efficient and most secure way

3.2 Abbreviations

For the purposes of the present document, the following abbreviations apply:

CSIP	Care Services Improvement Partnership
EAT	Electronic Assistive Technologies
ECG	Electro Cardio Gram
GSM	Global System for Mobile telecommunication
ICT	Information and teleCommunication Technologies
MTBF	Mean Time Between Failures
UCD	User Centered Development
UI	User Interface
Wi-Fi	Wireless Fidelity ISO/IEC local area network standard (IEEE 802.11 [46] family)

4 Approach and structure

4.1 Definition, approach and methodology

In accordance with the definition provided in TR 102 415 [41], the present document uses the following definition of telecare:

"Telecare is the provision of health and social care services to individuals, within or outside of their homes, with the support of systems enabled by ICT".

This definition is not un-disputed, as is regarded by many as a sub-discipline of telemedicine, which also includes business-to-business ICT services for supporting cooperative work between health professionals.

The main aim of telecare is to reduce the need for hospitalization and institutionalization and refers to cases where services are provided to a client; it can thus be classified as a business-to-consumer service. Telecare should clearly be distinguished from telemedicine (customarily defined as the use of ICT to support cooperative work between health professionals), a business-to-business service.

Our approach to telecare services builds on the framework described in TR 102 415 [41], whereby personal monitoring, security management, electronic assistive technologies and information services are used to support personal health and well-being. Health and social care clients are the primary beneficiaries of telecare services, and the main focus of the present document. However, other groups like carers and coordination agents are also users of the services, and will have human factor needs that will be addressed as well.

The overall methodology used to produce the guidelines consists of three main components: the approach and structure of the document itself; the bibliographical review of related scientific, technological or standardization references; and the procedures followed by the team to identify and document the guidelines.

Several approaches were considered and carefully analysed for structuring the guidelines, based on either the development and deployment lifecycle of a telecare system, or the main human factors issues associated with developing and deploying a telecare system. In addition, several hybrid approaches were considered, which incorporated the benefits of both the lifecycle and human factors approaches. A major consideration in choosing the approach was to keep the duplication of guidelines in different sections of the present document at a minimum.

The **Human Factors approach** would require the guideline clauses of the EG to be divided into sections addressing a major human factors topic. The advantage of this approach is that the human factors issues are given a central role and a high visibility within the document, which is important given the fact that the guide is aimed at addressing human factors issues related to the user experience of telecare services. However, it will not easily translate to the stakeholders' needs.

The **Lifecycle approach** would require the guide to be divided into sections addressing a specific part of the telecare service lifecycle. The advantage with this approach is that specific stakeholder groups would be able to easily locate those guidelines most relevant to them. However, frequent repetitions would be a considerable issue.

The **Hybrid approach** would require the present document to be divided into the four sections listed within the Lifecycle approach above. Each section would contain subsections focusing on the human factors issues described above. Stakeholders would be able to easily locate the guidelines most relevant to them, whilst the human factors issues would still be given a high profile. Alternatively the human factor issues could be promoted to become the higher level sections, with the lifecycle stages as subsections.

The approach chosen is based on the Hybrid approach with some further modifications: each human factor section firstly contains a set of generic guidelines which are applicable through the whole lifecycle of telecare. Then, guidelines specific to lifecycle stages are provided.

An important part of each following section is the introduction which determines the focus of the section. Our approach is to use the introduction as a short discussion of the issue addressed and from that identify the main, high-level, generic guidelines which should be considered by all stakeholders. This is followed by guidelines relevant for the R&D and development phases, followed by guidelines relevant for service provisioning.

The guidelines provided in the present document are applicable throughout the whole product and telecare service lifecycle. Applying a user-centric approach, the product lifecycle can be described as containing the recurring stages of service information provisioning, pre-use and subscription, initial setup and use, routine use and finally, service and equipment update and/or replacement.

4.2 Document and guidelines structure

The specific design guidelines provided in the following clauses of the present document should be applied, in order to optimize the user experience of telecare services and its elements.

By applying these common user experience principles across the elements and lifecycles of telecare services, combined with a user-centered development and testing process and professional expertise (see clause 5 for details), the human factors of telecare services will be optimized.

The first six sections are grouped under the theme of "Users' trust", while the next three sections are grouped under the theme of "User interaction". The final four sections are grouped under the theme of "Service aspects":

1) **User's trust:** a user's trust in a system depends upon his/her belief that issues relating to the security of the information used within that system have been dealt with appropriately, and that the system can deliver what is expected of it. Trust encompasses the classic elements of computer security: confidentiality, integrity, authentication, as well as issues relating to ethics, reliability of operation and safety. The present document addresses the issues of trust within the following sections:

   - Privacy and confidentiality;

   - Ethics;

   - Legal aspects;

   - Availability and reliability;

   - Integrity;

   - Safety.

2) **User interaction:** the user interface elements of a telecare system will have a direct influence on the user experience of that system. Interfaces should be designed with the needs of all end users in mind, requiring high degrees of flexibility and a sound knowledge of the end users' abilities and preferences. The present document addresses the issues relating to user interaction within the following sections:

   - Usability and accessibility;

   - User education;

   - Localization, customization and personalization.

3) **Service aspects:** the user experience of any service is influenced by the developer's ability to deliver an appropriate system to the service provider, and the service provider's ability to deliver an appropriate service to end users. Therefore the service aspects theme is mainly concerned with the system development and service provision, and ensuring that any issues which might arise here are dealt with appropriately:

   - Organizational aspects;

   - Servicing and maintenance.

Each of the following clauses address the above mentioned areas by applying the following, common clause structure:

- Clause number.1: Generic guidelines;

- Clause number.2: Research, design and development related guidelines;

- Clause number.3: Service provision related guidelines.

Stakeholders should be easily able to identify the lifecycle phase applicable to their activities and select the relevant set of guidelines applicable to their needs.

Annex A provides four listings of the guidelines found in the present document, which can be used as checklists.

5 User centred design and testing

Human factors should be addressed in every stage of the telecare service lifecycle. Targeted users and contexts of use should be considered at the research stage together with ethnographic, social and cultural issues. This will lead to the definition of a set of user requirements, which should result in telecare systems with built-in capabilities to provide a good user experience. Technology and resources used within service provision need to be optimized for the specific user and context of use. Evaluation should be conducted within each individual service component at the design, development and delivery stages, with the evaluation results fed back into these stages. In addition to evaluating each component the overall service should also be evaluated in order to ensure it meets the applicable user requirements.

The adoption, within the engineering process, of specific design processes and phases of methodological evaluation of human factors aspects will enable to detect and solve deficiencies in time, increasing the quality of these services.

ISO standard ISO 13407 [25] provides guidance on human centered design activities throughout the life cycle of computer-based interactive systems. The standard is targeted to people who manage design processes. According to the standard, human centered design consists of four different types of design activities:

- To understand and specify the context of use.

- To specify the user and organizational requirements.

- To produce draft (pilot) design solutions.

- To evaluate design against requirements.

According to the guide published by the "Care Services Improvement Partnership" (CSIP) of the UK Department of Health [27], evaluation of services is critical for demonstrating the benefits (and problems) of telecare to users and other stakeholders, and it also helps to support informed procurement and strategic decisions.

According to CSIP, the evaluation of a telecare system by a service provider should cover: Management and partnership arrangements; commissioning and funding aspects; performance issues; technical and other barriers; availability of new products; environment in which equipment is used; service development; user and practitioner views, ethical considerations; service functionality; and future arrangements.

Generic recommendations for usability evaluation of telecommunication equipment are also available (after possible adaptations), see e.g. ETR 095 [44] and EG 201 472 [19]. The latter reference provides the basis for the use of a common methodology when performing usability evaluations and provides guidance on the User Centered Development (UCD) design process.

There are many publications on telecare, but few of these provide a comprehensive evaluation of human factors. This lack of evaluation may be due to the complexity of the environment in which telecare systems operate, particularly when considering end users such as chronic care patients, typically older and with low technological skills, together with the diversity of functionality for telecare systems.

5.1 Generic

5.1.1   User Centered Development (UCD) methods should be an integral part of any development process of telecare services.

5.1.2   UCD methods should be applied throughout all phases telecare service development.

5.1.3   The telecare service design and development process should be a systematic procedure, based on prototyping and where relevant, iterative.

5.1.4   Evaluations and testing of telecare services should be conducted with domain experts and representative user samples during all stages (including customization), with the evaluation results fed back into the product and service development process.

5.1.5   Industry standard formats and tools should be used to support the definition and management of user requirements and system functional specifications along different stages of the telecare lifecycle.

5.2   Research, design and development

5.2.1   The user requirements (characteristics and needs of the target end users) should be researched, analysed and formally defined.

5.2.2   The context requirements (characteristics in which the telecare equipment or service will be used when in operation) should be researched, analysed and formally defined.

5.2.3   Telecare system functional specifications should be defined according to the user and context requirements. The degree of match between the developed products and services and the user/context requirements should be assessed.

5.2.4   Telecare services should be developed according to the functional specifications. The degree of match between the developed products and services and the user/context requirements should be assessed.

5.2.5   Early evaluation of telecare product and services should be conducted, including expert and end user tests of mock-ups and prototypes. Evaluation results should be used to feed back user and context requirements, as well as system functional specifications.

5.3   Service provision

5.3.1   Telecare services should be tested in the field before their launch. Relevant sample user segments, contexts of use and the required organizational resources should be considered. The results of the field pilots should be fed back into service definition. In some cases, the trial results may provide useful information to the research, design and development stages of the telecare product or service.

5.3.2   Once the telecare service is operational, a schema for the continuous monitoring of its objective and perceived quality should be developed and applied.

6   Privacy and confidentiality guidelines

Privacy can be defined as the ability of an individual or group to keep their lives and personal affairs out of public view, i.e. to control the flow of sensitive information about themselves. Confidentiality is more concerned with the responsibility of individuals, companies or organizations that may collect and store such information on others, and the need to ensure that only authorized individuals are allowed access to that information. In summary, and relating this specifically to telecare, we might classify privacy as the *right* of the client and confidentiality as the *duty* of the service provider.

Maintaining privacy and confidentiality helps create a sense of trust between the client and the telecare service provider. Other factors that affect trust are: ethics; legal aspects; availability and reliability; integrity and safety, all of which are covered in other parts of the present document. Developers and service providers can create trust in their systems by following the guidelines within these sections.

Due to the vulnerability of data transmitted on the internet and stored on the web, companies or organizations that set up web portals for health and/or provide health advice on the internet should pay particular attention to privacy rights and the confidentiality of client data. Several advisory codes of conduct for web portals have been published, e.g. [31], which complement and refine the guidelines provided here.

6.1 Generic

6.1.1 Stakeholders should respect a client's right to give, withhold or withdraw consent for others to access or disclose sensitive information about themselves. Telecare systems should be designed and operated such that the appropriate stakeholders are able to protect these rights.

6.1.2 Stakeholders should understand the duty of confidentiality they have towards clients. Telecare systems should be designed and operated such that the appropriate stakeholders are able to meet this duty of confidentiality.

6.1.3 Stakeholders should consider whether other factors relating to data security, e.g. integrity, authentication, non-repudiation and availability need to be addressed in order to allow them to meet their duty of confidentiality towards their clients.

6.1.4 Whether conducting trials or providing real services stakeholders should provide a clear explanation to the client of the procedures they will implement to protect the clients' privacy. Clients should be asked if the procedures are acceptable.

6.1.5 Stakeholders should develop and implement an information retention policy which describes how long, and under what conditions, client information may be kept.

6.1.6 Stakeholders should ensure that a telecare system or service does not compromise existing security measures protecting the privacy of clients.

6.2 Research, design and development

6.2.1 Appropriate measures should be taken to determine if the client is capable of providing informed consent to take part in an interview, focus group or trial. This may require advice from carers and family members.

6.2.2 Clients should be made fully aware of their privacy rights and of the researcher's or designer's duty of confidentiality when they are asked to take part in interviews and focus groups.

6.2.3 Instructions and training material relating to the telecare system should be developed to help the service provider understand how the deployment and use of the system might affect the privacy of their clients, and therefore their own duty of confidentiality. Instructions should include any measures that can be taken to limit or prevent negative effects on client privacy.

6.2.4 Telecare systems should include the functionality to allow a system administrator to override measures put in place to protect a client's privacy. This functionality should include the ability to restrict who may be given administrator rights, as well as logging the details of any administrator overrides.

6.2.5 Telecare systems should include the functionality to allow an administrator to set up role-based user accounts which restrict access to certain levels based upon role.

6.3 Service provision

6.3.1 Vulnerable people should be given all necessary support to enable them to understand the complexities of confidentiality issues and to help them to express their wishes.

6.3.2   In emergency situations non-consensual disclosure of confidential information may be considered necessary. Where this is the case service providers should ensure that only the minimum necessary information is used or disclosed to deal with the situation.

6.3.3   Employees should be trained to an appropriate level so that they are able to carry out their duty of confidentiality when using a telecare system.

6.3.4   The confidentiality of the client information should be maintained after the death of the client (but made accessible to the closest relatives).

6.3.5   Clients have a legal and ethical right to know what information a healthcare professional holds on them. Service providers should always allow clients to view their own personal data if requested to do so.

6.3.6   Clients should be kept informed about possible uses and disclosures of their information.

6.3.7   A telecare service provider's procedures for sharing information should be clear and publicly accessible.

6.3.8   Where multiple parties are involved in delivering a telecare service, it should be clear which party is responsible for ensuring the privacy rights of the client.

6.3.9   Client data and information which is held on physical media (e.g. paper, video tape or DVD) should be stored securely and disposed of as confidential waste when no longer required.

7   Ethics guidelines

Within the social care domain, ethics can be considered in terms of two basic principles:

1)   the universal duty of good care i.e. the use of expertise to protect the well-being of clients; and

2)   the universal duty to respect the autonomy of the client [31].

When assessing the requirements of their clients, health and social care professionals may often find that these two principles conflict with each other, especially in situations where the client is suffering from a mild cognitive impairment or early dementia.

EXAMPLE: Based on their assessment of the client the care professional might conclude that the client's health and safety might be improved by deploying a telecare monitoring system.

However, the client may not wish to be monitored even if they understand the benefits.

The purpose of these guidelines is to provide advice to all stakeholders involved in the telecare lifecycle to help them address this ethical dilemma. Health and social care professionals should consider the ethics of implementing telecare on a case-by-case basis. In helping make the right choice it is recommended that they address the following questions:

• Is the client capable of consenting to the technology?

• Who benefits from the technology?

• Will the technology lead to a significant reduction in human interaction for the client, and would this be detrimental to the well-being of the client?

7.1 Generic

7.1.1   Telecare systems should support the health, well-being and independent living of the client.

7.1.2   Telecare systems should respect the client's decisions, dignity, integrity and preferences.

7.1.3   Telecare systems should not adversely affect the delivery and user experience of existing services provided to clients.

7.1.4   Appropriately qualified individuals should assess whether the proposed client is capable of consenting to take part in telecare research, or to have a telecare system installed as part of a running service.

7.1.5   If the objective of researching, developing or deploying a telecare system is to reduce the amount of human input into a client's health/care regime then this should be clearly stated.

7.1.6   National or regional rules for safeguarding the rights of participants should be followed when researching, developing or deploying a telecare system.

7.1.7   End users that participate in the research, design or development of a telecare system should be appropriately acknowledged and/or remunerated.

7.1.8   Consider the disruption and distress that the installation of a telecare system may cause to the client and minimize this by keeping the installation time to a minimum.

7.1.9   Clients should be provided with the means to raise any issues they may have with a telecare service or trial.

7.2 Research, design and development

7.2.1   Researchers should help clients understand the objectives of their research, and more specifically the research questions that any trial might be attempting to answer. Clients should also be clearly informed about whether the research will generate any outcomes they will directly benefit from. However, there may be cases where the withholding of this information is justified (e.g. through fear of changing the client behaviour).

7.2.2   Concerns about how research may be infringing the rights of the client (e.g. rights to adequate care, rights to autonomy), should be recorded. If the research continues despite these concerns then the justifications for doing so should be recorded.

7.2.3   Clients taking part in research studies or trials should be allowed to interrupt or end their engagement at any time, if so desired.

7.2.4   Designers and developers should ensure that any ethical issues identified at the research stage have been dealt with appropriately before proceeding with developing a telecare system based upon the research output.

7.2.5   It should be possible for the service provider to configure the system to prevent it from gathering information that might not be considered necessary for a specific client.

7.3   Service provision

7.3.1   Clients should be assessed as to their suitability for telecare monitoring on a case-by-case basis, taking into account the personal motivations and preferences of each client.

7.3.2   Consideration should be given as to whether telecare is the most appropriate solution to the care needs of the client.

7.3.3   Health and care professionals should understand the abilities of the telecare system before it is deployed.

7.3.4   Steps should be taken to ensure that the introduction of a telecare system does not lead to an increase in isolation for the client.

7.3.5   Health and care professionals should identify if the introduction of a telecare system will lead to a reduction in carer support to the client, and whether this would be acceptable to the client or appropriate given the client's circumstances.

7.3.6   Health and care professionals should identify the impact that introducing a telecare system might have on individuals who provide formal and informal care to the client e.g. other health/care professionals, care workers, relatives, friends, neighbours and voluntary organizations, and how that may in turn affect the care received by the client. Any negative impact on the carer or care by the client should be avoided.

7.3.7   Health and care professionals should assess how appropriate a telecare system would be to the client within the context of an overall care plan, and ensure their clients are aware of the alternatives to telecare.

7.3.8   Health and care professionals should have procedures in place to re-assess the client at appropriate intervals to check that the system is meeting the requirements of the client.

7.3.9   The introduction of a telecare system should not create ethical issues for the provision of existing services which the client may rely upon.

7.3.10   Documented procedures should be in place for obtaining consent from the client to implement a telecare system. In order to give consent the client should be given all the information to make a decision, and should posses the cognitive abilities to understand the implications of their decision.

7.3.11   If the client is unable to provide consent to having a telecare system installed, then consider obtaining consent by proxy. If this is through relatives or friends then the health/care professional should bear in mind that conflicts of interest can occur. Before seeking consent by proxy, the advice is to:

- Continue to ask the client for their consent even if you believe they are unable to understand or respond.

- Consider alternative ways of communicating with the client in order to understand their opinions.

7.3.12   Consent should be obtained from the client each time the service is changed significantly.

7.3.13 Clients should be made fully aware of the impact a telecare system may have on any existing health or social care services they might be receiving.

7.3.14 Records should be kept of the consent given by the client or by their proxy together with details of what has been agreed.

7.3.15 Health and care professionals should consider whether to involve close friends or family members of the client when discussing the installation and operation of the telecare system with the client. Health and care professionals should ensure that the involvement of third parties in these discussions will be of benefit to the client before making this decision.

7.3.16 The telecare system should not gather private or sensitive information about the client which is not required as part of an assessed health or social care package.

7.3.17 Telecare service providers should ensure their employees adopt a professional approach when visiting a client's home to survey, install or maintain a telecare system. This approach should include keeping the client informed of when such visits will be made, any delays to agreed times, and a system for proving the identification of service provider personnel and/or their agents.

7.3.18 Telecare service providers should ensure that their employees are trained to communicate with clients according to their abilities and preferences (e.g. use of client's primary language such as sign language).

7.3.19 Telecare service providers should ensure that employees who are required to visit the client's home are first checked with the appropriate criminal records bureau.

7.3.20 People who regularly visit the client (e.g. family members, friends and carers) should be made aware that a telecare system is in operation.

7.3.21 There should be adequate resources for responding to any emergency repairs which may be required to the telecare system.

7.3.22 Telecare services and systems should be presented to all stakeholders as tools of self-empowerment for clients, rather than as an outward sign of dependency on external services and aids.

8 Guidelines for legal aspects

The guidelines described within this section are based upon the legal requirements associated with providing health and social care to individuals. As with all of the guidelines within the present document the wording has been chosen to convey a sense of good advice rather than compulsory instructions. However, stakeholders should bear in mind that because these guidelines are based on current legislation it may be unwise to consider them as optional.

The legal aspects considered here are: laws, liability and contracts. Most of the laws relating specifically to privacy, ethics and safety are considered within other sections (clauses 6, 7 and 11).

8.1 Generic

8.1.1 Legal experts should be consulted to identify the relevant legal requirements for the country in which the telecare system will be deployed.

8.1.2 Understand and accept the liabilities with respect to developing a technology that is subsequently used as part of a telecare service, or for providing a telecare service.

8.1.3   Insurance cover should be in place when installing or maintaining telecare equipment
               within the end-user premises.

8.1.4   Contracts should be setup between the various stakeholders involved in the
               development, manufacture and provision of telecare products and services. The
               contracts should clearly state the contractual undertakings, including responsibilities
               and liabilities, of the various stakeholders involved.

8.1.5   Telecare equipment should meet the required electromagnetic compatibility standards
               for the country in which the equipment will operate.

8.1.6   Telecare equipment should meet the required electrical safety standards for the
               country in which the equipment will operate.

8.1.7   Telecare equipment should meet the required radio spectrum standards for the
               country in which the equipment will operate.

8.1.8   Telecare equipment should display the relevant certification marks for the country in
               which it will operate.

8.2   Research, design and development

8.2.1   Anti-discriminatory laws should be complied with when conducting interviews, focus
               groups, technology demonstrations and trials.

8.2.2a   The professional codes of ethics applicable to conducting trials should be followed
               (e.g. [40], the Declaration of Helsinki).

8.2.2b   End users should be made aware of the technical limitations of the telecare system,
               and how these limitations might affect the functionality of the system and accuracy of
               the data produced.

8.2.3   Consider having working methods evaluated by appropriate accrediting bodies
               (e.g. quality management).

8.2.4   Be aware that equipment and/or software furnished to service providers may be
               subject to strict rules and regulations governing medical equipment and software.

8.3   Service provision

8.3.1   Consider if the introduction of a telecare system causes any financial liability to the
               service provider (in the likelihood of any damage being caused to client's property).

8.3.2   The legal owner of the data collected by the telecare system should be identified and
               permission sought from the owner if the data is to be used in a way that has not
               already been agreed upon.

8.3.3   An information retention policy should be in place stating how long and under what
               conditions client data and information will be stored, and how it will be disposed of
               when the retention period has expired.

9   Availability and reliability guidelines

Availability is used in the present document to describe the degree to which a system can be expected to be operational when it is required for use.

The *reliability* of a system measures its ability to continue to function, both in routine use and in case of unexpected, adverse circumstances [33] and [34].

Maintenance is important for a system's availability and reliability, and corresponding guidelines are collected in the present clause. Systems for personal health should ideally have a high degree of availability and reliability. However, this can often result in high implementation costs, which should be weighed against the risks associated with system malfunctioning or becoming unavailable. For example, a heart pacemaker must operate very reliably, whereas the failure of a body-worn blood-pressure sensor may have no immediate adverse effects (but should be signalled).

A slightly different aspect of availability is the need for telecare services to support a mobile user that moves across different networks. As an example, a wearable device that connects over Wi-Fi in the owner's home should also be able to connect through the Wi-Fi network in the home of relatives or neighbours, or even over public, open Wi-Fi networks. Another example is the need to support roaming between different GSM/3G providers when travelling abroad. These availability aspects are also treated in this clause.

9.1   Generic

9.1.1   Telecare systems should be designed and operated such that the availability and reliability of the service meets the needs of the end user.

9.1.2   Telecare equipment or services should be designed to have the required availability and reliability when used by the intended user group also in adverse environments and under adverse environmental conditions.

9.1.3   Telecare equipment or services should provide some means of remote service access.

9.2   Research, design and development

9.2.1   Develop service and maintenance procedures that, when adhered to, will keep the telecare equipment at the required levels of reliability and availability.

9.2.2   When carrying out trial sessions for research and testing, any limited functionality, availability and reliability during the test should be clearly communicated to and accepted by the test participants, and the possible harmful effects of such limitations should be duly considered and catered for.

9.2.3   Conditions for reliable operation should be clearly stated in both the installation and the operation manuals.

9.2.4   The system should be designed to warn the user if it detects that reliable operation may no longer be assured, or that device failure may be expected.

9.2.5   The system should be designed to notify all concerned users of irregularities or non-functioning of system elements that will affect the required level of reliability and availability of the telecare service.

9.2.6   Incidents and failures should be logged in a secure file, and there should be an option for reporting to the equipment manufacturer.

9.2.7	Design hardware components, software modules and interfaces to be backward compatible, whenever possible.

9.2.8	In the analysis of system security, risk assessment should be applied to all parts of a telecare system or service and to all those supporting infrastructures that the telecare system depends on to operate reliably, see [28].

9.2.9	The frequency and length of system outages should be included in the risk analysis of the system.

NOTE:	A high system availability does not necessarily imply that the users are satisfied in a correspondingly high proportion of the time.

9.2.10	When appropriate, client mobility should be supported.

NOTE:	This includes roaming between different communication providers, and switching between available wireless or wired networks.

9.2.11	Setup and configuration when roaming should not require user intervention.

9.2.12	Ideally, roaming telecare services should offer user support and emergency handling services in the usual way, in the user's native or other preferred language. Unavoidable and important changes in service characteristics (communication costs, service delays, etc.) should be communicated to the user.

9.2.13	Multicultural aspects during cross-border roaming should be addressed according to the recommendations in EG 202 421 [15].

## 9.3	Service provision

9.3.1	In the event of a system malfunctioning and failure of automatic recovery, provide the functionality and necessary guidance to assist the user in recovering the system.

9.3.2	Before installation of new telecare equipment, investigate the existence of similar equipment to avoid user confusion and unnecessary or dangerous duplication of equipment or services.

9.3.3	Interference of the telecare equipment with other electronic equipment should be investigated and avoided.

9.3.4	Telecare equipment (including sensors) should be tested both before and after installation at the client site.

9.3.5	Keep a log of all service performed, to provide tracking information. Formalize a procedure to follow when necessary device accessories are expired, damaged or missing.

9.3.6	Consider to implement redundancy for critical system parts or even for the telecare system as a whole. The extent of redundancy should be matched to the risks associated with system failure.

9.3.7	Keep an adequate stock and updated inventory list of repair/replacement parts for equipment and software. Ensure that software is adequately documented to enable new personnel to handle maintenance and repair.

9.3.8	Provide a single, easily accessible point-of-contact for reporting deviant system behaviour.

9.3.9 To keep track of defect history and to help predict Mean Time Between Failures (MTBF) of the system, hardware devices should contain production date and the date for taking into use, and anomalies and errors ("bugs") in software should be recorded.

9.3.10 Maintain plans for emergency situations.

9.3.11 A detailed response protocol should be prepared for important and potentially dangerous equipment faults that may require entry (possibly forced) into the client's premises. Service personnel should receive thorough instructions about the privacy concerns that may ensue.

9.3.12 Supply training programme for service personnel. Provide ongoing support to train suppliers in new aspects, refresher course, etc.

9.3.13 The responsibility for service and maintenance of a telecare utility should reside with the primary telecare supplier, even when these tasks are outsourced (fully or in part).

10 Integrity guidelines

For the purpose of the present document, integrity relates to the confidence that can be had that data has not been tampered with, nor accidentally changed. This is related to data consistency, repeatability of measurements and security of data against errors or attacks [26]. The integrity guidelines should be applied not only to the technical parts of the system, but also to its human counterparts insofar as they have an influence on system behaviour and data.

10.1 Generic

10.1.1 Telecare systems should be designed and operated such that data and information within the system cannot be tampered with, nor accidentally changed during transfer, storage and retrieval.

10.2 Research, design and development

10.2.1 Protect against, detect and warn about corruption of system and data, both unintentional (by a system fault), by accident (operator error), or by malicious attacks (viruses or intruders).

10.2.2 When data from different sources are available, they should be analysed to detect and report contradicting and inconsistent measurement values.

10.2.3 Give clear warnings of unsolicited but important changes in the system state that may not otherwise be noticed (e.g. a system reset with possible loss of data, fallback to default system parameters or other discontinuity in system behaviour).

10.3 Service provision

10.3.1 Service access to equipment should be secured using an access control mechanism. Remote service access should be secured against attacks or failure in the communications line.

10.3.2 All security threats should be reported together with all relevant data; for analysis, warning and if necessary for preventive measures.

10.3.3   There should be a formal procedure for granting service access (e.g. user account information, delivery of passwords, keys, etc.).

10.3.4   All service access should be monitored and logged.

10.3.5   Protect against malicious insiders by pre-employment screening of key personnel. The level of screening should not be excessive, but match the level of rights granted.

11   Safety guidelines

Safety in this clause refers to "non-harmfulness". In that context, the guidelines presented below have two different purposes. The first is to make the equipment safe in routine use by minimizing the chances of user errors or minimizing the adverse consequences of any error. The second is to help the user make the right decisions and take the right corrective actions when something goes wrong and the equipment becomes potentially unsafe. Safety aspects related to user perception (colour, sound, tactile feedback, etc.) can be found in the clause on user interaction.

An overview of designing for safety in medical devices is given in [29]. For a general and comprehensive introduction to the design of user interfaces, see [30].

11.1   Generic

11.1.1   Telecare systems should be designed for error avoidance, to minimize the probability of the user making errors with adverse effects.

11.1.2   Telecare systems should be designed and operated with error tolerance, so as to minimize the adverse effects of any user error.

11.1.3   Telecare system failures should not harm the user.

11.2   Research, design and development

11.2.1   Users should be alerted of any possible operational hazards.

11.2.2   Special attention should be given to scenarios that occur infrequently, but which may result in particularly hazardous situations.

11.2.3   When carrying out telecare trials involving humans, it is of particular importance that all necessary safety measures are in place, and that those involved are fully aware of and have consented to any risks related to their participation in the trials.

11.2.4   Instructions and commands that are critical for correct functioning of the equipment or service should be easily available in the end user's language of choice.

11.2.5   Procedures that require precise counting, complicated arithmetic, precise timing or other machine-oriented skills should preferably be performed automatically, or at least assisted by the equipment. The user should be kept informed.

11.2.6   Consider using a simple hardware device (e.g. a manual "panic button").

11.2.7   Consider using a dedicated display or a reserved display area for highly critical information. Do not display other data in this location.

11.2.8   Design alarms to be distinguishable from one another and, to the extent possible and relevant, distinguishable from alarms on other devices used in the same environment.

11.2.9   Warn about dangerous situations in time, thereby giving the user time to react. Do not wait for the full emergency to occur. An alarm should be activated immediately upon the onset of a critical problem.

11.2.10   Whenever possible, alarms shall identify the source of the problem.

11.2.11   Critical alarms should be provided through redundant auditory, visual and tactile signals.

11.2.12   Design alarms so that if or when they are manually silenced, they are reactivated after some time and as long as the problem persists.

11.2.13   Consider the wide spectrum of operating environments when designing and testing alarms, including other equipment in simultaneous use, electromagnetic interference, and static electricity.

11.2.14   Cables, connectors, and other hardware should be designed for easy installation and connection. If properly designed, incorrect installations should be impossible, extremely difficult, or so obviously wrong that they can be easily detected and remedied.

11.2.15   To prevent from electrical shock, it should not be possible to introduce leads connected to the body (e.g. ECG) into mains power outlets or any other common mains power connector.

11.2.16   Use colour codes or other markings to help the user achieve proper connections and component or accessory installation.

11.2.17   Connectors should have a positive locking mechanism whenever the integrity of connections may be compromised by such factors as component durability, motion, or casual contact.

11.2.18   Components and accessories should be labelled, to allow unambiguous replacement when defective.

11.3   Service provision

11.3.1   It is the health worker's responsibility to ensure that the client understands medical advices that are issued.

11.3.2   When installing telecare equipment, choose locations for user interface elements so that they can be used in emergency situations (after the client has fallen, when an electrical blackout has occurred, usable by a child, etc.).

11.3.3   When telecare equipment makes use of wireless communications, ensure that the radio spectrum environment in the client's house is within the required levels (according to the Electromagnetic Compatibility profile of the telecare equipment).

12   Usability and accessibility guidelines

The usability and accessibility aspects considered within this chapter are those applicable to users who will *directly* interact with the telecare equipment (i.e. clients and carers). Such users may face difficulties when using telecare equipment, either because of a limited ICT proficiency or their physical, cognitive or sensory abilities.

Standardization work in the field of medical instrumentation is mainly related to enhancing the usability of medical devices, to minimize the risk of human errors [36]. These studies focus on a well defined, average user: male medical doctor, middle aged, with no disabilities. Further standardization work addressing the usability and accessibility of medical devices and services is required.

Furthermore, user interaction will be affected by the emerging trend to provide telecare services through different types of generic ICT appliances: fixed and mobile phones, TV sets and their remote controls, personal computers, laptops, PDA's, etc. Their user interface will constitute a relevant component of the user interaction with telecare services, and therefore affect the quality of the user interaction. Moreover, everyday objects with embedded computers will also become part of telecare services. Therefore, main-stream ICT accessibility know-how will increasingly become applicable to telecare.

According to the framework described above, the guidelines in this section have been structured according to the schema used in [35] for defining user requirements in ICT products and services. Available standardization work on accessibility and usability of ICT products and services (EG 202 116 [3], ISO/FDIS 9241-20 [37] and ISO/FDIS 9241-171 [39]) has been used as the primary references.

12.1 Generic

12.1.1   A telecare system's output should be perceivable by users. Important information, such as alarms or loss of critical functions, should be effectively notified to users.

12.1.2   Telecare equipment should require a minimum of effort and time to achieve the desired goal. Furthermore, it should be easy for users to raise alarms in an emergency situation.

12.1.3   The operation of telecare equipment should be understandable to all users.

12.1.4   Assistive technologies should be usable in conjunction with telecare equipment. Telecare equipment should allow both direct use, and use by means of assistive technologies.

12.1.5   Telecare equipment and services should support adaptation to clients' abilities and preferences, as well as to the context of use (e.g. when roaming).

12.1.6   Consistency and standardized elements among user interfaces should be promoted in related telecare equipment and services, also when roaming (if supported). See also EG 202 132 [2] and ES 202 130 [9].

12.1.7   All users should have equivalent security, privacy and safety when using the telecare service, regardless of their functional abilities.

12.2 Research, design and development

Perception and feedback

12.2.1   Telecare system's output should be made available through multiple modalities (auditory, tactile and visual). Users should be allowed to select one or more output modalities, as well as their specific characteristics (e.g. volume, brightness, contrast, cadence). Information on active output modalities and their characteristics should be provided.

   NOTE: The availability of visual and tactile information benefits users with hearing disabilities. The availability of audio and tactile information benefits users with visual disabilities. Tactile information should be provided for deaf-blind users. People with cognitive disabilities benefit from information being presented redundantly, in audio and visual modalities. People with physical disabilities benefit from having the information available in multiple modalities.

12.2.2   The information generated through the different output modalities of a telecare system should be equivalent.

12.2.3   The visual information provided by the telecare service should be perceivable by users, see EG 202 116 [3]:

1. Brightness and contrast of visual signals should be adjustable. Their value range should allow visual signals to be perceived under various conditions of ambient illumination.

2. The size of visual symbols (e.g. text, icons) should be adjustable.

3. Information should not be provided relying only on colour.

4. Telecare equipment should allow the display of visual information within viewable range of those of short stature or seated in wheelchairs. Labels and displays should be easily and correctly readable from oblique viewing angles. The correct orientation of the display should be made evident.

5. The display of the telecare equipment should be free of noticeable glare, reflections and flicker.

6. Image quality should be sufficient to perceive sign language correctly, see [40].

12.2.4   The acoustic information provided by the telecare service should be perceivable by users.

   NOTE: The frequency, intensity and pitch of auditory signals should allow them to be easily heard, see [3] clause 9.

12.2.5   The tactile information provided by the telecare service should be perceivable by users.

   NOTE: Different vibration patterns (rather than vibration frequency or strength) should be provided to notify different events, see EG 202 116 [3] clause 9.

12.2.6   Location and function controls of telecare equipment should be easily identifiable by users.

   NOTE: Users with visual disabilities should be provided with acoustic and/or tactile information about location and function of controls.

12.2.7   The telecare equipment should provide users with multimodal feedback, see EG 202 116 [3] and EG 202 191 [11], in order to:

1. Acknowledge user interaction with telecare equipment, such as the use of input controls, or the engagement of external connectors (e.g. medical sensor, power cord, USB connector, etc.).

2. Inform on the progress of a telecare service that has been requested by the user.

12.2.8   Feedback should be presented without any perceptible delay. Visual or tactile feedback should occur at the same location as the control, or in a common place, standard for the whole telecare system.

Carrying out functions efficiently

12.2.9   Telecare equipment controls should be designed to be easily reachable by users.

12.2.10   Telecare system's input should be available through multiple modalities (such as vocal or tactile). Users should be allowed to select one or more input modalities. Information on active input modalities should be provided.

1. Users with visual disabilities should be allowed to operate the telecare system by keyboard or voice.

2. Users with hearing or speech disabilities should be allowed to use alternatives to speech input.

3. Users with motor disabilities may benefit from having vocal input available.

4. In situations where a biometric system is being used, the user's possible functional limitations should be considered, and alternative input methods offered if necessary, see [32].

12.2.11   Keyboards or keypads of the telecare equipment should be compliant with standardized requirements in terms of size, material, form, tactile marking, required force, key arrangements, character mapping, sorting orders and distance between adjacent keys, see EG 202 116 [3] and ES 202 130 [9].

12.2.12   The telecare system should provide users enough time to complete actions or to recover from errors.

12.2.13   Operation of peripherals which are part of the telecare system should be accessible and usable to all intended users.

NOTE: Users should be able to connect, disconnect and make use of peripherals such as sensors, battery chargers, network devices, etc.

12.2.14   Standardized vocabularies of ICT commands should be supported (e.g. see ES 202 076 [8]).

12.2.15   The telecare equipment should notify users with clear and simple messages when they make errors, and provide them with guidance on what to do in such case.

12.2.16   Users should be allowed to use shortcut commands, and to take the initiative of giving commands.

12.2.17   When possible, tasks should be automated.

Understanding how to use the telecare product or service

12.2.18   Provide standardized graphical information in addition to text labels, see EG 202 048 [13] and EG 202 132 [2].

12.2.19   The amount of information presented to user should be minimized by presenting only what is necessary.

12.2.20   The messages of the telecare service should be clear, inoffensive and understandable to users. Technical terms, jargon and abbreviations should be avoided. Standardized terminology and vocabulary should be used when available (e.g. see ES 202 076 [8]).

12.2.21   Users should be assisted in multi-step operations of the telecare service.

12.2.22   In telecare services based on Interactive Voice Response systems, users should be immediately signalled that they are communicating with a machine, and not with a human.

12.2.23   In telecare services based on Interactive Voice Response systems, users should be allowed to easily reach human support.

12.2.24   In systems where speech output is available, it should be intelligible and should sound as natural as possible, see ETR 329 [45] and clause 9.5.4 of EG 202 116 [3].

12.2.25   Cultural and language issues should be considered when designing user interface of telecare services and equipment. For details, see EG 202 421 [15].

12.2.26   Dedicated attention should be given to the design of telecare services addressing children. See also EG 202 423 [7] and TR 102 133 [43].

Assistive technologies

12.2.27   Interference between telecare equipment and users' assistive technologies should be avoided.

12.2.28   Assistive devices connected to elements of telecare services should integrate well by means of functionality and user interfaces. For further details, see TR 102 068 [42] and TS 102 511 [6].

Avoidance of personal risk

12.2.29   The user interface of the telecare equipment should be designed to avoid any personal risk.

                  1.   Visual and auditory patterns that may cause seizures should be avoided.

                  2.   Audio volumes that may harm hearing should be avoided.

Personalization of user interaction

12.2.30   The telecare service and equipment should enable easy personalization of user interaction to meet user's needs and preferences, see EG 202 325 [20].

12.2.31   User preference settings (including accessibility settings) should be available in an open format to ease their applicability across different products and services. Available standards should be used, when applicable.

Users' control

12.2.32   Users should be allowed to confirm/reject the automatic behaviour of the telecare
                 system.

   NOTE: It has to be considered that clients with cognitive impairments have a limited ability to make reasonable
             decisions.

12.3   Service provision

12.3.1   Telecare user interface elements should be installed in the most visible location, with
                 appropriate lighting and contrast with their surroundings.

12.3.2   Brightness and contrast of visual signals should be adapted to ambient illumination.

12.3.3   Size for visual symbols (text, icons, etc.) of the user interface should be configured
                 provided according to how they will be shown or displayed (equipment box, computer
                 screen, TV screen, printed material), as well as to the distance the user will read them
                 from.

12.3.4   Telecare user elements should be adequately labelled.

12.3.5   Mounting of microphone and loudspeakers part of the telecare equipment should
                 minimize the effects of noise, echo, sound reflection and reverberation from the
                 terminal environment.

                 1.   Quality and loudness of the intended sound signal should be optimized.

                 2.   Locations with low noise should be chosen.

12.3.6   Relay services based on text and sign language should be used for communicating
                 with deaf people.

12.3.7   Telecare user interface elements should be located so that they are reachable by
                 users.

                 1.   Related issues as user's mobility impairments, use of mobility aids, or different
                      users' heights should be duly considered.

                 2.   Controls for raising panic alarms should be easily reached by users after suffering
                      a fall.

12.3.8   When attending a client request, telecare professionals should keep the client
                 informed on the progress of the service provision.

12.3.9   Service providers should apply existing user preference settings (including
                 accessibility settings) when available.

12.3.10   Accessibility preference settings should be preserved unless the user is explicitly
                 asked whether they should be kept.

13   User education guidelines

Telecare users should be provided with adequate information concerning the availability and functionality of the telecare service offering. Information can be provided through several channels, such as national centres for the dissemination of social and telecare services and community equipment, healthcare centres, through the Internet or direct approaches (e.g. a one-stop-shop for information and advice about health and social services).

In order to be able to make proper use of deployed services, users should be able to understand how to access and make use of the offered capabilities in a usable and reliable way, and in compliance with ethical and legal requirements.

Difficulties exist in finding information about available services, their functionality and potential benefits, and the ways to request and use them. User education can play an important role, not only in the discovery of a service offering, but also in explaining how the service will benefit the user and providing further details and guidance including the ordering and use of a telecare service.

EG 202 417 [17] provides a clear set of guidelines on how user instructions ought to be provided, taking into account the requirement of different user groups (e.g. young and older people, disabled and less literate users) and the possibilities offered by different media. In addition, EG 202 417 [17] provides generic guidelines that can help increase the uptake and usage of telecare services: an improved user education will help users to discover, understand and make a better use of the available services.

User education has a role in all of the human factors mentioned in the present document. In particular, user education in Telecare should take special care to address how users must handle emergency situations, how to operate different pieces of equipment together (e.g. how to use a medical sensor which is part of the telecare equipment), issues related to privacy.

Education should be designed to be part of the equipment/service deployment. Once a user is assigned a service or a piece of equipment, the training process should be initiated as soon as possible, and a good level of support should be provided.

13.1   Generic

13.1.1   Telecare services should offer user education through the entire service provision cycle.

13.1.2   User education material should be developed in compliance with the recommendations provided in EG 202 417 [17], covering all necessary details, including:

1. User education material should be offered in a localized way, taking into consideration the capabilities and limitations of the addressed user group(s).

2. User education should be offered in all necessary languages and through multiple modalities in an accessible way, to all users.

3. User education should be offered using the most proper media selected according to EG 202 417 [17].

4. Legal and safety considerations should be addressed as specified in EG 202 417 [17].

13.2   Research, design and development

13.2.1   User education materials should be offered and made accessible to people with
                    disabilities.

    NOTE: For users with visual disabilities, information should be provided in acoustic and/or tactile modalities.
                    Tactile information should be provided for deaf-blind users. People with cognitive disabilities benefit
                    from simplified information being presented redundantly, in speech and visual modalities
                    (EG 202 417 [17]).

13.2.2   In order to support users with cognitive impairments, it is recommended to provide
                    well structured information, covering all relevant service aspects.

13.2.3   Illustrations should be used in pedagogic ways to communicate information, not only
                    as decorative parts.

13.2.4   User guides should be usability tested, applying established usability criteria and
                    established test methods, in order to identify faults in them and to ensure a minimum
                    level of usability of the educational material.

13.2.5   If service updates occur, the necessary updates should be developed to provide the
                    necessary information to clients and carers.

13.3   Service provision

13.3.1   Support for clients and carers should be available. Availability should be in
                    accordance with the type of service being provided. The support should be accessible
                    to people with disability.

13.3.2   When service updates occur, the clients and careers should always be informed about
                    the changes and the way these may affect the service prior to their implementation.

14   Localization, customization and personalization guidelines

According to EG 202 417 [17], **localization** refers to the provision of product and user-guide variants for different markets, taking into account market specific, local linguistic and cultural differences. In some markets, product localization is required by regulations. In addition, a reasonable degree of localization is recommended, as users expect to be informed about their products in their own, native or other preferred language, including local sign language.

As the costs for localizing products and services are considerable (EG 202 417 [17]), most manufacturers and service providers restrict their localization efforts to offering a limited set of language versions of the user interface (in particular in the menus) and of the user guides. The use of icon-based menus in mobile devices is an attempt to internationalize aspects of the user interface. Other relevant aspects such as the use of colours or referent objects depicted in icons are usually not varied, even though they are likely to carry different connotations in different cultures.

A main challenge related to localizing user guides (EG 202 417 [17]) is that as user guides are being completed fairly late in the development process, the localization efforts of user guides comes after completion of master draft, i.e. at a very late stage. Since all last-minute changes to the master also have to be made to all language variants, correct and complete language variants are only available in later editions (if any).

Some relevant aspects of localization include dialect variants of particular languages (e.g. German in Switzerland, Austria and in Germany), the fact that certain languages that are written from left to right, while others right to left.

Customization: Most telecare service providers will offer customized services that may include the menu tree, service provider-specific service portals and contact numbers, terminology, logotypes, illustrations, user interface strings (help texts etc. in the display of the equipment), functionality, control keys, icons, reference to the service provider's call centres and Web pages, services provided by the service provider, information about costs and cost-transparency for the services provided, colours or login and identity validation mechanisms (EG 202 417 [17]).

Personalization: In the telecare environment, a personalized user experience (e.g. through pre-configuration) may increase the efficiency and accessibility of the service provided. User profiles, defined in EG 202 325 [20] as "…the total set of user related rules and settings which affect the way in which a user experiences terminals, devices and services", may further improve the user experience.

Service developers and manufacturers have a considerable influence on in what way personalization can take place, which parts of the service are candidates for personalization and available settings (EG 202 325 [20]).

14.1   Generic

14.1.1   Consider the target languages when producing the source texts and illustrations. Be aware of dialect variants, the adaptation of visual content to local cultures, formal and informal addressing, and the use of English-language terms.

14.1.2   Use technical communicators who write in their own native language, and translators who translate into their own native language.

14.1.3   Translators need to understand how the product is to be used, ideally by being provided with a prototype of the terminal or preferably, a service pilot. An explanation of how a new product or service differs from its predecessor may be sufficient.

14.1.4   Differences among languages regarding the total number of characters required for a particular text should be taken into account.

14.1.5   Provide localized versions in sign language (as it may be a primary language for people with hearing disabilities).

14.1.6   Visual content (illustrations, icons, pictures, images) should be adapted for local cultures, when necessary.

14.1.7   Translations and localized versions should be validated with end users and validators, who should have good knowledge of the product terminology in the local market.

14.1.8   The validator should not be involved in any product development team (as the goal is to provide user-friendly, not too technical language).

14.2   Research, design and development

14.2.1   Language, terminology and idioms should be tailored to the intended audience.

14.2.2   Avoid using humour, jargon and too informal language in the source text, as this can be easily misunderstood. The use of standardized terminology is recommended, when available.

14.2.3   The use of foreign-language terminology (including English) should be avoided, as it is not accepted by all users.

14.2.4   Use text fonts that can be easily localized.

14.2.5   Avoid file formats that may create difficulties for languages not based on the Latin script. The format used should support Unicode, see [38] (or a similar standard) and work smoothly, irrespective the text direction.

14.2.6   Ensure that the style and terminology of a translated text/term correspond to the style and terminology used in the local market and the organization providing the service.

14.2.7   Designs should allow for the adaptation of visual content (illustrations, icons, pictures, images) to local cultures.

14.3   Service provision

14.3.1   It is recommended that an early dialog with the telecare service provider includes possible changes in the user documentation, such as the menu tree, terminology or icons.

14.3.2   If the master user guide or other information elements are customized, it is recommended to clarify how the material is going to be provided and how the customization and validation process will be handled.

15   Guidelines for organizational aspects

Health and social care organizations deploy telecare solutions to help them deal with increasing workloads, maintaining or improving service quality, and containing costs. In order for a telecare system to be effective in helping with these objectives, changes to existing working practices within the organization may be required. Indeed it could be stated that the aim of introducing telecare *is* to change (or improve) existing working practices in order to help health and social care organizations meet their objectives within budget and resource constraints.

In some cases making changes to working practices may create a need to change an organization's structure, which can be very disruptive. If the organizational disruption caused from introducing a telecare system becomes excessive, or is deemed unnecessary by the service provider's employees and their clients, the credibility of that system amongst end-users may suffer.

When designing or implementing a telecare system it is important to understand how its introduction and use may affect existing organizational structures and working practices. The following guidelines are aimed at helping designers and service providers avoid or minimize the negative effects associated with these necessary changes.

15.1   Generic

15.1.1   Stakeholders should be aware of how the introduction of a telecare system may affect and change the work practices of those individuals who provide care to clients, and take steps to minimize any negative affects of such changes.

15.1.2   Stakeholders should be aware of how the introduction of a telecare system may affect and change the organizational structure of those organizations involved in the care delivery process, and take steps to minimize any negative affects of such changes.

15.1.3   Telecare trials should include research into how the telecare system might affect the current working practices and organizational structure of those individuals and organizations that might deploy the system.

15.2   Research, design and development

15.2.1   Researchers and designers should familiarize themselves with the working practices and organizational structures of end users.

15.2.2   End users should be involved in the definition and customization of the telecare service that is to be implemented within an organization.

15.3   Service provision

15.3.1   Telecare service providers should consult with the appropriate end users within the health or social care organization when deploying the telecare service.

15.3.2   Health and care organizations should be consulted to identify whether the benefits provided by implementing a particular telecare system will outweigh the negative effects of any concomitant organizational disruption.

15.3.3   Working practices, organizational structure and service provision within the health or care organization should continue to be monitored after the telecare system has been deployed.

15.3.4   Where possible health and social care managers should ensure that their employees understand the motivation behind the introduction of the telecare system.

15.3.5   End users should be explained how the introduction of a telecare system may affect their organization and their roles within that organization.

15.3.6   Health and social care managers should work with the telecare service provider to identify an appropriate time window for least disruption to the organization when introducing the telecare service.

15.3.7   Health and social care managers should discuss planned changes to organizational structure and working practices with their employees before implementing changes.

15.3.8   Interruption of telecare service, disturbance of established routines, or the introduction of new routines may upset the client and make him/her hostile to the telecare service. Unscheduled and irregular service of equipment should therefore be kept to a minimum, and equipment upgrades should have a clear benefit for the user or be invisible.

15.3.9   Frequent changes in organizational structure as a consequence of introducing new equipment and new procedures once the telecare service has been implemented should be avoided.

16   Servicing and maintenance guidelines

Installation, setup, configuration and maintenance may be required to ensure that the behaviour of the telecare system is in accordance to the required functional, usability and trust requirements during the whole period of service provision. More specifically, these activities aim to:

- Customize the generic functionality of the service to the actual needs of the client.

- Adapt the user interface of the service to specific clients' preferences and abilities, as well as to the concrete context of use.

- Ensure that clients' privacy right is protected during service provision.

- Ensure that the system functioning is within the required levels of availability, reliability and safety.

16.1   Generic

16.1.1   To be able to access telecare services, users should ideally not have to be exposed to any installation, setup, configuration and maintenance procedures. See also EG 202 416 [16].

16.1.2   Installation, setup, configuration and maintenance should be addressed by service providers through manual, automatic, remote or presence procedures, which should remain as transparent as possible for clients, demanding minimal interaction from them.

16.1.3   Avoid unnecessarily frequent upgrades of telecare equipment (hardware and software). Upgrades that only marginally enhances the service should be avoided. For the benefit of the user plan on keeping and maintaining old equipment versions.

16.2   Research, design and development

16.2.1   Telecare equipment should be designed to minimize the inconvenience that installation, set up, configuration and maintenance may cause to users.

16.2.2   Telecare equipment should be designed to minimize complexity of those parts that are configurable by the clients.

16.3   Service provision

16.3.1   Service providers should keep clients informed of the installation, setup, configuration and maintenance activities performed at their homes. Clients should be informed of the purpose of these activities, their duration, periodicity, associated costs (if any), etc.

16.3.2   Service providers need to consider any inconvenience that these processes may cause to the client and minimize this by keeping their unwanted effects (time, cost, refurbishing needs, etc.) to a minimum.

16.3.3   A detailed response protocol should be prepared for important and potentially dangerous equipment faults that may require entry (possibly forced) into the client's premises. Service personnel should receive thorough instructions about the privacy concerns that may ensue.

Annex A (normative):
Four collective guideline listings

This annex provides listings of the guidelines presented in earlier clauses of the present document, without introducing any new guidelines.

Clauses A.1 to A.4 are intended to be used as checklists.

A.1   Collective list of *all* guidelines

5 User centred design and testing

5.1 Generic

5.1.1   User Centered Development (UCD) methods should be an integral part of any development process of telecare services.

5.1.2   UCD methods should be applied throughout all phases telecare service development.

5.1.3   The telecare service design and development process should be a systematic procedure, based on prototyping and where relevant, iterative.

5.1.4   Evaluations and testing of telecare services should be conducted with domain experts and representative user samples during all stages (including customization), with the evaluation results fed back into the product and service development process.

5.1.5   Industry standard formats and tools should be used to support the definition and management of user requirements and system functional specifications along different stages of the telecare lifecycle.

5.2 Research, design and development

5.2.1   The user requirements (characteristics and needs of the target end users) should be researched, analysed and formally defined.

5.2.2   The context requirements (characteristics in which the telecare equipment or service will be used when in operation) should be researched, analysed and formally defined.

5.2.3   Telecare system functional specifications should be defined according to the user and context requirements. The degree of match between the developed products and services and the user/context requirements should be assessed.

5.2.4   Telecare services should be developed according to the functional specifications. The degree of match between the developed products and services and the user/context requirements should be assessed.

5.2.5   Early evaluation of telecare product and services should be conducted, including expert and end user tests of mock-ups and prototypes. Evaluation results should be used to feed back user and context requirements, as well as system functional specifications.

5.3 Service provision

5.3.1   Telecare services should be tested in the field before their launch. Relevant sample user segments, contexts of use and the required organizational resources should be considered. The results of the field pilots should be fed back into service definition. In some cases, the trial results may provide useful information to the research, design and development stages of the telecare product or service.

5.3.2   Once the telecare service is operational, a schema for the continuous monitoring of its objective and perceived quality should be developed and applied.

6   Privacy and confidentiality guidelines

6.1 Generic

6.1.1   Stakeholders should respect a client's right to give, withhold or withdraw consent for others to access or disclose sensitive information about themselves. Telecare systems should be designed and operated such that the appropriate stakeholders are able to protect these rights.

6.1.2   Stakeholders should understand the duty of confidentiality they have towards clients. Telecare systems should be designed and operated such that the appropriate stakeholders are able to meet this duty of confidentiality.

6.1.3   Stakeholders should consider whether other factors relating to data security, e.g. integrity, authentication, non-repudiation and availability need to be addressed in order to allow them to meet their duty of confidentiality towards their clients.

6.1.4   Whether conducting trials or providing real services stakeholders should provide a clear explanation to the client of the procedures they will implement to protect the clients' privacy. Clients should be asked if the procedures are acceptable.

6.1.5   Stakeholders should develop and implement an information retention policy which describes how long, and under what conditions, client information may be kept.

6.1.6   Stakeholders should ensure that a telecare system or service does not compromise existing security measures protecting the privacy of clients.

6.2 Research, design and development

6.2.1   Appropriate measures should be taken to determine if the client is capable of providing informed consent to take part in an interview, focus group or trial. This may require advice from carers and family members.

6.2.2   Clients should be made fully aware of their privacy rights and of the researcher's or designer's duty of confidentiality when they are asked to take part in interviews and focus groups.

6.2.3   Instructions and training material relating to the telecare system should be developed to help the service provider understand how the deployment and use of the system might affect the privacy of their clients, and therefore their own duty of confidentiality. Instructions should include any measures that can be taken to limit or prevent negative effects on client privacy.

6.2.4   Telecare systems should include the functionality to allow a system administrator to override measures put in place to protect a client's privacy. This functionality should include the ability to restrict who may be given administrator rights, as well as logging the details of any administrator overrides.

| 6.2.5 | Telecare systems should include the functionality to allow an administrator to set up role-based user accounts which restrict access to certain levels based upon role. |

6.3 Service provision

| 6.3.1 | Vulnerable people should be given all necessary support to enable them to understand the complexities of confidentiality issues and to help them to express their wishes. |

| 6.3.2 | In emergency situations non-consensual disclosure of confidential information may be considered necessary. Where this is the case service providers should ensure that only the minimum necessary information is used or disclosed to deal with the situation. |

| 6.3.3 | Employees should be trained to an appropriate level so that they are able to carry out their duty of confidentiality when using a telecare system. |

| 6.3.4 | The confidentiality of the client information should be maintained after the death of the client (but made accessible to the closest relatives). |

| 6.3.5 | Clients have a legal and ethical right to know what information a healthcare professional holds on them. Service providers should always allow clients to view their own personal data if requested to do so. |

| 6.3.6 | Clients should be kept informed about possible uses and disclosures of their information. |

| 6.3.7 | A telecare service provider's procedures for sharing information should be clear and publicly accessible. |

| 6.3.8 | Where multiple parties are involved in delivering a telecare service, it should be clear which party is responsible for ensuring the privacy rights of the client. |

| 6.3.9 | Client data and information which is held on physical media (e.g. paper, video tape or DVD) should be stored securely and disposed of as confidential waste when no longer required. |

7   Ethics guidelines

7.1 Generic

| 7.1.1 | Telecare systems should support the health, well-being and independent living of the client. |

| 7.1.2 | Telecare systems should respect the client's decisions, dignity, integrity and preferences. |

| 7.1.3 | Telecare systems should not adversely affect the delivery and user experience of existing services provided to clients. |

| 7.1.4 | Appropriately qualified individuals should assess whether the proposed client is capable of consenting to take part in telecare research, or to have a telecare system installed as part of a running service. |

| 7.1.5 | If the objective of researching, developing or deploying a telecare system is to reduce the amount of human input into a client's health/care regime then this should be clearly stated. |

7.1.6   National or regional rules for safeguarding the rights of participants should be followed when researching, developing or deploying a telecare system.

7.1.7   End users that participate in the research, design or development of a telecare system should be appropriately acknowledged and/or remunerated.

7.1.8   Consider the disruption and distress that the installation of a telecare system may cause to the client and minimize this by keeping the installation time to a minimum.

7.1.9   Clients should be provided with the means to raise any issues they may have with a telecare service or trial.

7.2 Research, design and development

7.2.1   Researchers should help clients understand the objectives of their research, and more specifically the research questions that any trial might be attempting to answer. Clients should also be clearly informed about whether the research will generate any outcomes they will directly benefit from. However, there may be cases where the withholding of this information is justified (e.g. through fear of changing the client behaviour).

7.2.2   Concerns about how research may be infringing the rights of the client (e.g. rights to adequate care, rights to autonomy), should be recorded. If the research continues despite these concerns then the justifications for doing so should be recorded.

7.2.3   Clients taking part in research studies or trials should be allowed to interrupt or end their engagement at any time, if so desired.

7.2.4   Designers and developers should ensure that any ethical issues identified at the research stage have been dealt with appropriately before proceeding with developing a telecare system based upon the research output.

7.2.5   It should be possible for the service provider to configure the system to prevent it from gathering information that might not be considered necessary for a specific client.

7.3 Service provision

7.3.1   Clients should be assessed as to their suitability for telecare monitoring on a case-by-case basis, taking into account the personal motivations and preferences of each client.

7.3.2   Consideration should be given as to whether telecare is the most appropriate solution to the care needs of the client.

7.3.3   Health and care professionals should understand the abilities of the telecare system before it is deployed.

7.3.4   Steps should be taken to ensure that the introduction of a telecare system does not lead to an increase in isolation for the client.

7.3.5   Health and care professionals should identify if the introduction of a telecare system will lead to a reduction in carer support to the client, and whether this would be acceptable to the client or appropriate given the client's circumstances.

7.3.6   Health and care professionals should identify the impact that introducing a telecare system might have on individuals who provide formal and informal care to the client e.g. other health/care professionals, care workers, relatives, friends, neighbours and voluntary organizations, and how that may in turn affect the care received by the client. Any negative impact on the carer or care by the client should be avoided.

7.3.7   Health and care professionals should assess how appropriate a telecare system would be to the client within the context of an overall care plan, and ensure their clients are aware of the alternatives to telecare.

7.3.8   Health and care professionals should have procedures in place to re-assess the client at appropriate intervals to check that the system is meeting the requirements of the client.

7.3.9   The introduction of a telecare system should not create ethical issues for the provision of existing services which the client may rely upon.

7.3.10   Documented procedures should be in place for obtaining consent from the client to implement a telecare system. In order to give consent the client should be given all the information to make a decision, and should posses the cognitive abilities to understand the implications of their decision.

7.3.11   If the client is unable to provide consent to having a telecare system installed, then consider obtaining consent by proxy. If this is through relatives or friends then the health/care professional should bear in mind that conflicts of interest can occur. Before seeking consent by proxy, the advice is to:

• Continue to ask the client for their consent even if you believe they are unable to understand or respond.

• Consider alternative ways of communicating with the client in order to understand their opinions.

7.3.12   Consent should be obtained from the client each time the service is changed significantly.

7.3.13   Clients should be made fully aware of the impact a telecare system may have on any existing health or social care services they might be receiving.

7.3.14   Records should be kept of the consent given by the client or by their proxy together with details of what has been agreed.

7.3.15   Health and care professionals should consider whether to involve close friends or family members of the client when discussing the installation and operation of the telecare system with the client. Health and care professionals should ensure that the involvement of third parties in these discussions will be of benefit to the client before making this decision.

7.3.16   The telecare system should not gather private or sensitive information about the client which is not required as part of an assessed health or social care package.

7.3.17   Telecare service providers should ensure their employees adopt a professional approach when visiting a client's home to survey, install or maintain a telecare system. This approach should include keeping the client informed of when such visits will be made, any delays to agreed times, and a system for proving the identification of service provider personnel and/or their agents.

7.3.18	Telecare service providers should ensure that their employees are trained to communicate with clients according to their abilities and preferences (e.g. use of client's primary language such as sign language).

| 7.3.19 | Telecare service providers should ensure that employees who are required to visit the client's home are first checked with the appropriate criminal records bureau. |

| 7.3.20 | People who regularly visit the client (e.g. family members, friends and carers) should be made aware that a telecare system is in operation. |

| 7.3.21 | There should be adequate resources for responding to any emergency repairs which may be required to the telecare system. |

| 7.3.22 | Telecare services and systems should be presented to all stakeholders as tools of self-empowerment for clients, rather than as an outward sign of dependency on external services and aids. |

8   Guidelines for legal aspects

8.1 Generic

8.1.1	Legal experts should be consulted to identify the relevant legal requirements for the country in which the telecare system will be deployed.

| 8.1.2 | Understand and accept the liabilities with respect to developing a technology that is subsequently used as part of a telecare service, or for providing a telecare service. |

| 8.1.3 | Insurance cover should be in place when installing or maintaining telecare equipment within the end-user premises. |

| 8.1.4 | Contracts should be setup between the various stakeholders involved in the development, manufacture and provision of telecare products and services. The contracts should clearly state the contractual undertakings, including responsibilities and liabilities, of the various stakeholders involved. |

| 8.1.5 | Telecare equipment should meet the required electromagnetic compatibility standards for the country in which the equipment will operate. |

| 8.1.6 | Telecare equipment should meet the required electrical safety standards for the country in which the equipment will operate. |

| 8.1.7 | Telecare equipment should meet the required radio spectrum standards for the country in which the equipment will operate. |

| 8.1.8 | Telecare equipment should display the relevant certification marks for the country in which it will operate. |

8.2 Research, design and development

8.2.1	Anti-discriminatory laws should be complied with when conducting interviews, focus groups, technology demonstrations and trials.

| 8.2.2a | The professional codes of ethics applicable to conducting trials should be followed (e.g. [40], the Declaration of Helsinki). |

| 8.2.2b | End users should be made aware of the technical limitations of the telecare system, and how these limitations might affect the functionality of the system and accuracy of the data produced. |

8.2.3   Consider having working methods evaluated by appropriate accrediting bodies
                (e.g. quality management).

8.2.4   Be aware that equipment and/or software furnished to service providers may be
                subject to strict rules and regulations governing medical equipment and software.

8.3 Service provision

8.3.1   Consider if the introduction of a telecare system causes any financial liability to the
                service provider (in the likelihood of any damage being caused to client's property).

8.3.2   The legal owner of the data collected by the telecare system should be identified and
                permission sought from the owner if the data is to be used in a way that has not
                already been agreed upon.

8.3.3   An information retention policy should be in place stating how long and under what
                conditions client data and information will be stored, and how it will be disposed of
                when the retention period has expired.

9   Availability and reliability guidelines

9.1 Generic

9.1.1   Telecare systems should be designed and operated such that the availability and
                reliability of the service meets the needs of the end user.

9.1.2   Telecare equipment or services should be designed to have the required availability
                and reliability when used by the intended user group also in adverse environments
                and under adverse environmental conditions.

9.1.3   Telecare equipment or services should provide some means of remote service
                access.

9.2 Research, design and development

9.2.1   Develop service and maintenance procedures that, when adhered to, will keep the
                telecare equipment at the required levels of reliability and availability.

9.2.2   When carrying out trial sessions for research and testing, any limited functionality,
                availability and reliability during the test should be clearly communicated to and
                accepted by the test participants, and the possible harmful effects of such limitations
                should be duly considered and catered for.

9.2.3   Conditions for reliable operation should be clearly stated in both the installation and
                the operation manuals.

9.2.4   The system should be designed to warn the user if it detects that reliable operation
                may no longer be assured, or that device failure may be expected.

9.2.5   The system should be designed to notify all concerned users of irregularities or
                non-functioning of system elements that will affect the required level of reliability and
                availability of the telecare service.

9.2.6   Incidents and failures should be logged in a secure file, and there should be an option
                for reporting to the equipment manufacturer.

9.2.7   Design hardware components, software modules and interfaces to be backward
                compatible, whenever possible.

9.2.8 In the analysis of system security, risk assessment should be applied to all parts of a telecare system or service and to all those supporting infrastructures that the telecare system depends on to operate reliably, see [28].

9.2.9 The frequency and length of system outages should be included in the risk analysis of the system.

NOTE: A high system availability does not necessarily imply that the users are satisfied in a correspondingly high proportion of the time.

9.2.10 When appropriate, client mobility should be supported.

NOTE: This includes roaming between different communication providers, and switching between available wireless or wired networks.

9.2.11 Setup and configuration when roaming should not require user intervention.

9.2.12 Ideally, roaming telecare services should offer user support and emergency handling services in the usual way, in the user's native or other preferred language. Unavoidable and important changes in service characteristics (communication costs, service delays, etc.) should be communicated to the user.

9.2.13 Multicultural aspects during cross-border roaming should be addressed according to the recommendations in EG 202 421 [15].

9.3 Service provision

9.3.1 In the event of a system malfunctioning and failure of automatic recovery, provide the functionality and necessary guidance to assist the user in recovering the system.

9.3.2 Before installation of new telecare equipment, investigate the existence of similar equipment to avoid user confusion and unnecessary or dangerous duplication of equipment or services.

9.3.3 Interference of the telecare equipment with other electronic equipment should be investigated and avoided.

9.3.4 Telecare equipment (including sensors) should be tested both before and after installation at the client site.

9.3.5 Keep a log of all service performed, to provide tracking information. Formalize a procedure to follow when necessary device accessories are expired, damaged or missing.

9.3.6 Consider to implement redundancy for critical system parts or even for the telecare system as a whole. The extent of redundancy should be matched to the risks associated with system failure.

9.3.7 Keep an adequate stock and updated inventory list of repair/replacement parts for equipment and software. Ensure that software is adequately documented to enable new personnel to handle maintenance and repair.

9.3.8 Provide a single, easily accessible point-of-contact for reporting deviant system behaviour.

9.3.9 To keep track of defect history and to help predict Mean Time Between Failures (MTBF) of the system, hardware devices should contain production date and the date for taking into use, and anomalies and errors ("bugs") in software should be recorded.

9.3.10   Maintain plans for emergency situations.

9.3.11   A detailed response protocol should be prepared for important and potentially dangerous equipment faults that may require entry (possibly forced) into the client's premises. Service personnel should receive thorough instructions about the privacy concerns that may ensue.

9.3.12   Supply training programme for service personnel. Provide ongoing support to train suppliers in new aspects, refresher course, etc.

9.3.13   The responsibility for service and maintenance of a telecare utility should reside with the primary telecare supplier, even when these tasks are outsourced (fully or in part).

10 Integrity guidelines

10.1   Generic

10.1.1   Telecare systems should be designed and operated such that data and information within the system cannot be tampered with, nor accidentally changed during transfer, storage and retrieval.

10.2   Research, design and development

10.2.1   Protect against, detect and warn about corruption of system and data, both unintentional (by a system fault), by accident (operator error), or by malicious attacks (viruses or intruders).

10.2.2   When data from different sources are available, they should be analysed to detect and report contradicting and inconsistent measurement values.

10.2.3   Give clear warnings of unsolicited but important changes in the system state that may not otherwise be noticed (e.g. a system reset with possible loss of data, fallback to default system parameters or other discontinuity in system behaviour).

10.3   Service provision

10.3.1   Service access to equipment should be secured using an access control mechanism. Remote service access should be secured against attacks or failure in the communications line.

10.3.2   All security threats should be reported together with all relevant data; for analysis, warning and if necessary for preventive measures.

10.3.3   There should be a formal procedure for granting service access (e.g. user account information, delivery of passwords, keys, etc.).

10.3.4   All service access should be monitored and logged.

10.3.5   Protect against malicious insiders by pre-employment screening of key personnel. The level of screening should not be excessive, but match the level of rights granted.

11 Safety guidelines

11.1   Generic

11.1.1   Telecare systems should be designed for error avoidance, to minimize the probability of the user making errors with adverse effects.

11.1.2	Telecare systems should be designed and operated with error tolerance, so as to minimize the adverse effects of any user error.

11.1.3	Telecare system failures should not harm the user.

11.2 Research, design and development

11.2.1	Users should be alerted of any possible operational hazards.

11.2.2	Special attention should be given to scenarios that occur infrequently, but which may result in particularly hazardous situations.

11.2.3	When carrying out telecare trials involving humans, it is of particular importance that all necessary safety measures are in place, and that those involved are fully aware of and have consented to any risks related to their participation in the trials.

11.2.4	Instructions and commands that are critical for correct functioning of the equipment or service should be easily available in the end user's language of choice.

11.2.5	Procedures that require precise counting, complicated arithmetic, precise timing or other machine-oriented skills should preferably be performed automatically, or at least assisted by the equipment. The user should be kept informed.

11.2.6	Consider using a simple hardware device (e.g. a manual "panic button").

11.2.7	Consider using a dedicated display or a reserved display area for highly critical information. Do not display other data in this location.

11.2.8	Design alarms to be distinguishable from one another and, to the extent possible and relevant, distinguishable from alarms on other devices used in the same environment.

11.2.9	Warn about dangerous situations in time, thereby giving the user time to react. Do not wait for the full emergency to occur. An alarm should be activated immediately upon the onset of a critical problem.

11.2.10	Whenever possible, alarms shall identify the source of the problem.

11.2.11	Critical alarms should be provided through redundant auditory, visual and tactile signals.

11.2.12	Design alarms so that if or when they are manually silenced, they are reactivated after some time and as long as the problem persists.

11.2.13	Consider the wide spectrum of operating environments when designing and testing alarms, including other equipment in simultaneous use, electromagnetic interference, and static electricity.

11.2.14	Cables, connectors, and other hardware should be designed for easy installation and connection. If properly designed, incorrect installations should be impossible, extremely difficult, or so obviously wrong that they can be easily detected and remedied.

11.2.15	To prevent from electrical shock, it should not be possible to introduce leads connected to the body (e.g. ECG) into mains power outlets or any other common mains power connector.

11.2.16   Use colour codes or other markings to help the user achieve proper connections and component or accessory installation.

11.2.17   Connectors should have a positive locking mechanism whenever the integrity of connections may be compromised by such factors as component durability, motion, or casual contact.

11.2.18   Components and accessories should be labelled, to allow unambiguous replacement when defective.

11.3   Service provision

11.3.1   It is the health worker's responsibility to ensure that the client understands medical advices that are issued.

11.3.2   When installing telecare equipment, choose locations for user interface elements so that they can be used in emergency situations (after the client has fallen, when an electrical blackout has occurred, usable by a child, etc.).

11.3.3   When telecare equipment makes use of wireless communications, ensure that the radio spectrum environment in the client's house is within the required levels (according to the Electromagnetic Compatibility profile of the telecare equipment).

12 Usability and accessibility guidelines

12.1   Generic

12.1.1   A telecare system's output should be perceivable by users. Important information, such as alarms or loss of critical functions, should be effectively notified to users.

12.1.2   Telecare equipment should require a minimum of effort and time to achieve the desired goal. Furthermore, it should be easy for users to raise alarms in an emergency situation.

12.1.3   The operation of telecare equipment should be understandable to all users.

12.1.4   Assistive technologies should be usable in conjunction with telecare equipment. Telecare equipment should allow both direct use, and use by means of assistive technologies.

12.1.5   Telecare equipment and services should support adaptation to clients' abilities and preferences, as well as to the context of use (e.g. when roaming).

12.1.6   Consistency and standardized elements among user interfaces should be promoted in related telecare equipment and services, also when roaming (if supported). See also EG 202 132 [2] and ES 202 130 [9].

12.1.7   All users should have equivalent security, privacy and safety when using the telecare service, regardless of their functional abilities.

12.2   Research, design and development

Perception and feedback

12.2.1   Telecare system's output should be made available through multiple modalities
                    (auditory, tactile and visual). Users should be allowed to select one or more output
                    modalities, as well as their specific characteristics (e.g. volume, brightness, contrast,
                    cadence). Information on active output modalities and their characteristics should be
                    provided.

   NOTE: The availability of visual and tactile information benefits users with hearing disabilities. The availability
            of audio and tactile information benefits users with visual disabilities. Tactile information should be
            provided for deaf-blind users. People with cognitive disabilities benefit from information being presented
            redundantly, in audio and visual modalities. People with physical disabilities benefit from having the
            information available in multiple modalities.

12.2.2   The information generated through the different output modalities of a telecare system
                    should be equivalent.

12.2.3   The visual information provided by the telecare service should be perceivable by
                    users, see EG 202 116 [3]:

         1.   Brightness and contrast of visual signals should be adjustable. Their value range
               should allow visual signals to be perceived under various conditions of ambient
               illumination.

         2.   The size of visual symbols (e.g. text, icons) should be adjustable.

         3.   Information should not be provided relying only on colour.

         4.   Telecare equipment should allow the display of visual information within viewable
               range of those of short stature or seated in wheelchairs. Labels and displays
               should be easily and correctly readable from oblique viewing angles. The correct
               orientation of the display should be made evident.

         5.   The display of the telecare equipment should be free of noticeable glare,
               reflections and flicker.

         6.   Image quality should be sufficient to perceive sign language correctly, see [40].

12.2.4   The acoustic information provided by the telecare service should be perceivable by
                    users.

   NOTE: The frequency, intensity and pitch of auditory signals should allow them to be easily heard, see [3]
            clause 9.

12.2.5   The tactile information provided by the telecare service should be perceivable by
                    users.

   NOTE: Different vibration patterns (rather than vibration frequency or strength) should be provided to notify
            different events, see EG 202 116 [3] clause 9.

12.2.6   Location and function controls of telecare equipment should be easily identifiable by
                    users.

   NOTE: Users with visual disabilities should be provided with acoustic and/or tactile information about location
            and function of controls.

12.2.7   The telecare equipment should provide users with multimodal feedback, see
                   EG 202 116 [3] and EG 202 191 [11], in order to:

        1.   Acknowledge user interaction with telecare equipment, such as the use of input
             controls, or the engagement of external connectors (e.g. medical sensor, power
             cord, USB connector, etc.).

        2.   Inform on the progress of a telecare service that has been requested by the user.

12.2.8   Feedback should be presented without any perceptible delay. Visual or tactile
                   feedback should occur at the same location as the control, or in a common place,
                   standard for the whole telecare system.

Carrying out functions efficiently

12.2.9   Telecare equipment controls should be designed to be easily reachable by users.

12.2.10   Telecare system's input should be available through multiple modalities (such as vocal
                   or tactile). Users should be allowed to select one or more input modalities. Information
                   on active input modalities should be provided.

        1.   Users with visual disabilities should be allowed to operate the telecare system by
             keyboard or voice.

        2.   Users with hearing or speech disabilities should be allowed to use alternatives to
             speech input.

        3.   Users with motor disabilities may benefit from having vocal input available.

        4.   In situations where a biometric system is being used, the user's possible functional
             limitations should be considered, and alternative input methods offered if
             necessary, see [32].

12.2.11   Keyboards or keypads of the telecare equipment should be compliant with
                   standardized requirements in terms of size, material, form, tactile marking, required
                   force, key arrangements, character mapping, sorting orders and distance between
                   adjacent keys, see EG 202 116 [3] and ES 202 130 [9].

12.2.12   The telecare system should provide users enough time to complete actions or to
                   recover from errors.

12.2.13   Operation of peripherals which are part of the telecare system should be accessible
                   and usable to all intended users.

    NOTE: Users should be able to connect, disconnect and make use of peripherals such as sensors, battery chargers,
             network devices, etc.

12.2.14   Standardized vocabularies of ICT commands should be supported (e.g. see
                   ES 202 076 [8]).

12.2.15   The telecare equipment should notify users with clear and simple messages when
                   they make errors, and provide them with guidance on what to do in such case.

12.2.16   Users should be allowed to use shortcut commands, and to take the initiative of giving
                   commands.

12.2.17   When possible, tasks should be automated.

Understanding how to use the telecare product or service

12.2.18	Provide standardized graphical information in addition to text labels, see EG 202 048 [13] and EG 202 132 [2].
12.2.19	The amount of information presented to user should be minimized by presenting only what is necessary.
12.2.20	The messages of the telecare service should be clear, inoffensive and understandable to users. Technical terms, jargon and abbreviations should be avoided. Standardized terminology and vocabulary should be used when available (e.g. see ES 202 076 [8]).
12.2.21	Users should be assisted in multi-step operations of the telecare service.
12.2.22	In telecare services based on Interactive Voice Response systems, users should be immediately signalled that they are communicating with a machine, and not with a human.
12.2.23	In telecare services based on Interactive Voice Response systems, users should be allowed to easily reach human support.
12.2.24	In systems where speech output is available, it should be intelligible and should sound as natural as possible, see ETR 329 [45] and clause 9.5.4 of EG 202 116 [3].
12.2.25	Cultural and language issues should be considered when designing user interface of telecare services and equipment. For details, see EG 202 421 [15].
12.2.26	Dedicated attention should be given to the design of telecare services addressing children. See also EG 202 423 [7] and TR 102 133 [43].

Assistive technologies

12.2.27	Interference between telecare equipment and users' assistive technologies should be avoided.
12.2.28	Assistive devices connected to elements of telecare services should integrate well by means of functionality and user interfaces. For further details, see TR 102 068 [42] and TS 102 511 [6].

Avoidance of personal risk

12.2.29	The user interface of the telecare equipment should be designed to avoid any personal risk.

1. Visual and auditory patterns that may cause seizures should be avoided.

2. Audio volumes that may harm hearing should be avoided.

Personalization of user interaction

12.2.30	The telecare service and equipment should enable easy personalization of user interaction to meet user's needs and preferences, see EG 202 325 [20].
12.2.31	User preference settings (including accessibility settings) should be available in an open format to ease their applicability across different products and services. Available standards should be used, when applicable.

Users' control

12.2.32   Users should be allowed to confirm/reject the automatic behaviour of the telecare system.

> NOTE: It has to be considered that clients with cognitive impairments have a limited ability to make reasonable decisions.

12.3   Service provision

12.3.1   Telecare user interface elements should be installed in the most visible location, with appropriate lighting and contrast with their surroundings.

12.3.2   Brightness and contrast of visual signals should be adapted to ambient illumination.

12.3.3   Size for visual symbols (text, icons, etc.) of the user interface should be configured provided according to how they will be shown or displayed (equipment box, computer screen, TV screen, printed material), as well as to the distance the user will read them from.

12.3.4   Telecare user elements should be adequately labelled.

12.3.5   Mounting of microphone and loudspeakers part of the telecare equipment should minimize the effects of noise, echo, sound reflection and reverberation from the terminal environment.

1. Quality and loudness of the intended sound signal should be optimized.

2. Locations with low noise should be chosen.

12.3.6   Relay services based on text and sign language should be used for communicating with deaf people.

12.3.7   Telecare user interface elements should be located so that they are reachable by users.

1. Related issues as user's mobility impairments, use of mobility aids, or different users' heights should be duly considered.

2. Controls for raising panic alarms should be easily reached by users after suffering a fall.

12.3.8   When attending a client request, telecare professionals should keep the client informed on the progress of the service provision.

12.3.9   Service providers should apply existing user preference settings (including accessibility settings) when available.

12.3.10   Accessibility preference settings should be preserved unless the user is explicitly asked whether they should be kept.

13 User education guidelines

13.1   Generic

13.1.1   Telecare services should offer user education through the entire service provision cycle.

13.1.2   User education material should be developed in compliance with the recommendations provided in EG 202 417 [17], covering all necessary details, including:

   1.   User education material should be offered in a localized way, taking into consideration the capabilities and limitations of the addressed user group(s).

   2.   User education should be offered in all necessary languages and through multiple modalities in an accessible way, to all users.

   3.   User education should be offered using the most proper media selected according to EG 202 417 [17].

   4.   Legal and safety considerations should be addressed as specified in EG 202 417 [17].

13.2   Research, design and development

13.2.1   User education materials should be offered and made accessible to people with disabilities.

   NOTE: For users with visual disabilities, information should be provided in acoustic and/or tactile modalities. Tactile information should be provided for deaf-blind users. People with cognitive disabilities benefit from simplified information being presented redundantly, in speech and visual modalities (EG 202 417 [17]).

13.2.2   In order to support users with cognitive impairments, it is recommended to provide well structured information, covering all relevant service aspects.

13.2.3   Illustrations should be used in pedagogic ways to communicate information, not only as decorative parts.

13.2.4   User guides should be usability tested, applying established usability criteria and established test methods, in order to identify faults in them and to ensure a minimum level of usability of the educational material.

13.2.5   If service updates occur, the necessary updates should be developed to provide the necessary information to clients and carers.

13.3   Service provision

13.3.1   Support for clients and carers should be available. Availability should be in accordance with the type of service being provided. The support should be accessible to people with disability.

13.3.2   When service updates occur, the clients and careers should always be informed about the changes and the way these may affect the service prior to their implementation.

14 Localization, customization and personalization guidelines

14.1 Generic

14.1.1	Consider the target languages when producing the source texts and illustrations. Be aware of dialect variants, the adaptation of visual content to local cultures, formal and informal addressing, and the use of English-language terms.
14.1.2	Use technical communicators who write in their own native language, and translators who translate into their own native language.
14.1.3	Translators need to understand how the product is to be used, ideally by being provided with a prototype of the terminal or preferably, a service pilot. An explanation of how a new product or service differs from its predecessor may be sufficient.
14.1.4	Differences among languages regarding the total number of characters required for a particular text should be taken into account.
14.1.5	Provide localized versions in sign language (as it may be a primary language for people with hearing disabilities).
14.1.6	Visual content (illustrations, icons, pictures, images) should be adapted for local cultures, when necessary.
14.1.7	Translations and localized versions should be validated with end users and validators, who should have good knowledge of the product terminology in the local market.
14.1.8	The validator should not be involved in any product development team (as the goal is to provide user-friendly, not too technical language).

14.2 Research, design and development

14.2.1	Language, terminology and idioms should be tailored to the intended audience.
14.2.2	Avoid using humour, jargon and too informal language in the source text, as this can be easily misunderstood. The use of standardized terminology is recommended, when available.
14.2.3	The use of foreign-language terminology (including English) should be avoided, as it is not accepted by all users.
14.2.4	Use text fonts that can be easily localized.
14.2.5	Avoid file formats that may create difficulties for languages not based on the Latin script. The format used should support Unicode, see [38] (or a similar standard) and work smoothly, irrespective the text direction.
14.2.6	Ensure that the style and terminology of a translated text/term correspond to the style and terminology used in the local market and the organization providing the service.
14.2.7	Designs should allow for the adaptation of visual content (illustrations, icons, pictures, images) to local cultures.

14.3   Service provision

14.3.1   It is recommended that an early dialog with the telecare service provider includes possible changes in the user documentation, such as the menu tree, terminology or icons.

14.3.2   If the master user guide or other information elements are customized, it is recommended to clarify how the material is going to be provided and how the customization and validation process will be handled.

15 Guidelines for organizational aspects

15.1   Generic

15.1.1   Stakeholders should be aware of how the introduction of a telecare system may affect and change the work practices of those individuals who provide care to clients, and take steps to minimize any negative affects of such changes.

15.1.2   Stakeholders should be aware of how the introduction of a telecare system may affect and change the organizational structure of those organizations involved in the care delivery process, and take steps to minimize any negative affects of such changes.

15.1.3   Telecare trials should include research into how the telecare system might affect the current working practices and organizational structure of those individuals and organizations that might deploy the system.

15.2   Research, design and development

15.2.1   Researchers and designers should familiarize themselves with the working practices and organizational structures of end users.

15.2.2   End users should be involved in the definition and customization of the telecare service that is to be implemented within an organization.

15.3   Service provision

15.3.1   Telecare service providers should consult with the appropriate end users within the health or social care organization when deploying the telecare service.

15.3.2   Health and care organizations should be consulted to identify whether the benefits provided by implementing a particular telecare system will outweigh the negative effects of any concomitant organizational disruption.

15.3.3   Working practices, organizational structure and service provision within the health or care organization should continue to be monitored after the telecare system has been deployed.

15.3.4   Where possible health and social care managers should ensure that their employees understand the motivation behind the introduction of the telecare system.

15.3.5   End users should be explained how the introduction of a telecare system may affect their organization and their roles within that organization.

15.3.6   Health and social care managers should work with the telecare service provider to identify an appropriate time window for least disruption to the organization when introducing the telecare service.

15.3.7   Health and social care managers should discuss planned changes to organizational structure and working practices with their employees before implementing changes.

15.3.8   Interruption of telecare service, disturbance of established routines, or the introduction of new routines may upset the client and make him/her hostile to the telecare service. Unscheduled and irregular service of equipment should therefore be kept to a minimum, and equipment upgrades should have a clear benefit for the user or be invisible.

15.3.9   Frequent changes in organizational structure as a consequence of introducing new equipment and new procedures once the telecare service has been implemented should be avoided.

16 Servicing and maintenance guidelines

16.1 Generic

16.1.1   To be able to access telecare services, users should ideally not have to be exposed to any installation, setup, configuration and maintenance procedures. See also EG 202 416 [16].

16.1.2   Installation, setup, configuration and maintenance should be addressed by service providers through manual, automatic, remote or presence procedures, which should remain as transparent as possible for clients, demanding minimal interaction from them.

16.1.3   Avoid unnecessarily frequent upgrades of telecare equipment (hardware and software). Upgrades that only marginally enhances the service should be avoided. For the benefit of the user plan on keeping and maintaining old equipment versions.

16.2 Research, design and development

16.2.1   Telecare equipment should be designed to minimize the inconvenience that installation, set up, configuration and maintenance may cause to users.

16.2.2   Telecare equipment should be designed to minimize complexity of those parts that are configurable by the clients.

16.3 Service provision

16.3.1   Service providers should keep clients informed of the installation, setup, configuration and maintenance activities performed at their homes. Clients should be informed of the purpose of these activities, their duration, periodicity, associated costs (if any), etc.

16.3.2   Service providers need to consider any inconvenience that these processes may cause to the client and minimize this by keeping their unwanted effects (time, cost, refurbishing needs, etc.) to a minimum.

16.3.3   A detailed response protocol should be prepared for important and potentially dangerous equipment faults that may require entry (possibly forced) into the client's premises. Service personnel should receive thorough instructions about the privacy concerns that may ensue.

A.2   Collective list of *all generic* guidelines

5 User centred design and testing

5.1.1   User Centered Development (UCD) methods should be an integral part of any development process of telecare services.

5.1.2   UCD methods should be applied throughout all phases telecare service development.

5.1.3   The telecare service design and development process should be a systematic procedure, based on prototyping and where relevant, iterative.

5.1.4   Evaluations and testing of telecare services should be conducted with domain experts and representative user samples during all stages (including customization), with the evaluation results fed back into the product and service development process.

5.1.5   Industry standard formats and tools should be used to support the definition and management of user requirements and system functional specifications along different stages of the telecare lifecycle.

6   Privacy and confidentiality guidelines

6.1.1   Stakeholders should respect a client's right to give, withhold or withdraw consent for others to access or disclose sensitive information about themselves. Telecare systems should be designed and operated such that the appropriate stakeholders are able to protect these rights.

6.1.2   Stakeholders should understand the duty of confidentiality they have towards clients. Telecare systems should be designed and operated such that the appropriate stakeholders are able to meet this duty of confidentiality.

6.1.3   Stakeholders should consider whether other factors relating to data security, e.g. integrity, authentication, non-repudiation and availability need to be addressed in order to allow them to meet their duty of confidentiality towards their clients.

6.1.4   Whether conducting trials or providing real services stakeholders should provide a clear explanation to the client of the procedures they will implement to protect the clients' privacy. Clients should be asked if the procedures are acceptable.

6.1.5   Stakeholders should develop and implement an information retention policy which describes how long, and under what conditions, client information may be kept.

6.1.6   Stakeholders should ensure that a telecare system or service does not compromise existing security measures protecting the privacy of clients.

7   Ethics guidelines

7.1.1   Telecare systems should support the health, well-being and independent living of the client.

7.1.2   Telecare systems should respect the client's decisions, dignity, integrity and preferences.

7.1.3   Telecare systems should not adversely affect the delivery and user experience of existing services provided to clients.

7.1.4   Appropriately qualified individuals should assess whether the proposed client is capable of consenting to take part in telecare research, or to have a telecare system installed as part of a running service.

7.1.5   If the objective of researching, developing or deploying a telecare system is to reduce the amount of human input into a client's health/care regime then this should be clearly stated.

7.1.6   National or regional rules for safeguarding the rights of participants should be followed when researching, developing or deploying a telecare system.

7.1.7   End users that participate in the research, design or development of a telecare system should be appropriately acknowledged and/or remunerated.

7.1.8   Consider the disruption and distress that the installation of a telecare system may cause to the client and minimize this by keeping the installation time to a minimum.

7.1.9   Clients should be provided with the means to raise any issues they may have with a telecare service or trial.

8   Guidelines for legal aspects

8.1.1   Legal experts should be consulted to identify the relevant legal requirements for the country in which the telecare system will be deployed.

8.1.2   Understand and accept the liabilities with respect to developing a technology that is subsequently used as part of a telecare service, or for providing a telecare service.

8.1.3   Insurance cover should be in place when installing or maintaining telecare equipment within the end-user premises.

8.1.4   Contracts should be setup between the various stakeholders involved in the development, manufacture and provision of telecare products and services. The contracts should clearly state the contractual undertakings, including responsibilities and liabilities, of the various stakeholders involved.

8.1.5   Telecare equipment should meet the required electromagnetic compatibility standards for the country in which the equipment will operate.

8.1.6   Telecare equipment should meet the required electrical safety standards for the country in which the equipment will operate.

8.1.7   Telecare equipment should meet the required radio spectrum standards for the country in which the equipment will operate.

8.1.8   Telecare equipment should display the relevant certification marks for the country in which it will operate.

9   Availability and reliability guidelines

9.1.1   Telecare systems should be designed and operated such that the availability and reliability of the service meets the needs of the end user.

9.1.2   Telecare equipment or services should be designed to have the required availability and reliability when used by the intended user group also in adverse environments and under adverse environmental conditions.

9.1.3   Telecare equipment or services should provide some means of remote service access.

10 Integrity guidelines

10.1.1   Telecare systems should be designed and operated such that data and information within the system cannot be tampered with, nor accidentally changed during transfer, storage and retrieval.

11 Safety guidelines

11.1.1   Telecare systems should be designed for error avoidance, to minimize the probability of the user making errors with adverse effects.

11.1.2   Telecare systems should be designed and operated with error tolerance, so as to minimize the adverse effects of any user error.

11.1.3   Telecare system failures should not harm the user.

12 Usability and accessibility guidelines

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12.1.3   The operation of telecare equipment should be understandable to all users.

12.1.4   Assistive technologies should be usable in conjunction with telecare equipment. Telecare equipment should allow both direct use, and use by means of assistive technologies.

12.1.5   Telecare equipment and services should support adaptation to clients' abilities and preferences, as well as to the context of use (e.g. when roaming).

12.1.6   Consistency and standardized elements among user interfaces should be promoted in related telecare equipment and services, also when roaming (if supported). See also EG 202 132 [2] and ES 202 130 [9].

12.1.7   All users should have equivalent security, privacy and safety when using the telecare service, regardless of their functional abilities.

13 User education guidelines

13.1.1   Telecare services should offer user education through the entire service provision cycle.

13.1.2   User education material should be developed in compliance with the recommendations provided in EG 202 417 [17], covering all necessary details, including:

1.   User education material should be offered in a localized way, taking into consideration the capabilities and limitations of the addressed user group(s).

2.   User education should be offered in all necessary languages and through multiple modalities in an accessible way, to all users.

3. User education should be offered using the most proper media selected according to EG 202 417 [17].

4. Legal and safety considerations should be addressed as specified in EG 202 417 [17].

14 Localization, customization and personalization guidelines

14.1.1 Consider the target languages when producing the source texts and illustrations. Be aware of dialect variants, the adaptation of visual content to local cultures, formal and informal addressing, and the use of English-language terms.

14.1.2 Use technical communicators who write in their own native language, and translators who translate into their own native language.

14.1.3 Translators need to understand how the product is to be used, ideally by being provided with a prototype of the terminal or preferably, a service pilot. An explanation of how a new product or service differs from its predecessor may be sufficient.

14.1.4 Differences among languages regarding the total number of characters required for a particular text should be taken into account.

14.1.5 Provide localized versions in sign language (as it may be a primary language for people with hearing disabilities).

14.1.6 Visual content (illustrations, icons, pictures, images) should be adapted for local cultures, when necessary.

14.1.7 Translations and localized versions should be validated with end users and validators, who should have good knowledge of the product terminology in the local market.

14.1.8 The validator should not be involved in any product development team (as the goal is to provide user-friendly, not too technical language).

15 Guidelines for organizational aspects

15.1.1 Stakeholders should be aware of how the introduction of a telecare system may affect and change the work practices of those individuals who provide care to clients, and take steps to minimize any negative affects of such changes.

15.1.2 Stakeholders should be aware of how the introduction of a telecare system may affect and change the organizational structure of those organizations involved in the care delivery process, and take steps to minimize any negative affects of such changes.

15.1.3 Telecare trials should include research into how the telecare system might affect the current working practices and organizational structure of those individuals and organizations that might deploy the system.

16 Servicing and maintenance guidelines

16.1.1 To be able to access telecare services, users should ideally not have to be exposed to any installation, setup, configuration and maintenance procedures. See also EG 202 416 [16].

16.1.2 Installation, setup, configuration and maintenance should be addressed by service providers through manual, automatic, remote or presence procedures, which should remain as transparent as possible for clients, demanding minimal interaction from them.

16.1.3   Avoid unnecessarily frequent upgrades of telecare equipment (hardware and software). Upgrades that only marginally enhances the service should be avoided. For the benefit of the user plan on keeping and maintaining old equipment versions.

A.3 Collective list of *all research, design and development* guidelines

5 User centred design and testing

5.2.1   The user requirements (characteristics and needs of the target end users) should be researched, analysed and formally defined.

5.2.2   The context requirements (characteristics in which the telecare equipment or service will be used when in operation) should be researched, analysed and formally defined.

5.2.3   Telecare system functional specifications should be defined according to the user and context requirements. The degree of match between the developed products and services and the user/context requirements should be assessed.

5.2.4   Telecare services should be developed according to the functional specifications. The degree of match between the developed products and services and the user/context requirements should be assessed.

5.2.5   Early evaluation of telecare product and services should be conducted, including expert and end user tests of mock-ups and prototypes. Evaluation results should be used to feed back user and context requirements, as well as system functional specifications.

6   Privacy and confidentiality guidelines

6.2.1   Appropriate measures should be taken to determine if the client is capable of providing informed consent to take part in an interview, focus group or trial. This may require advice from carers and family members.

6.2.2   Clients should be made fully aware of their privacy rights and of the researcher's or designer's duty of confidentiality when they are asked to take part in interviews and focus groups.

6.2.3   Instructions and training material relating to the telecare system should be developed to help the service provider understand how the deployment and use of the system might affect the privacy of their clients, and therefore their own duty of confidentiality. Instructions should include any measures that can be taken to limit or prevent negative effects on client privacy.

6.2.4   Telecare systems should include the functionality to allow a system administrator to override measures put in place to protect a client's privacy. This functionality should include the ability to restrict who may be given administrator rights, as well as logging the details of any administrator overrides.

6.2.5   Telecare systems should include the functionality to allow an administrator to set up role-based user accounts which restrict access to certain levels based upon role.

7   Ethics guidelines

7.2.1   Researchers should help clients understand the objectives of their research, and more specifically the research questions that any trial might be attempting to answer. Clients should also be clearly informed about whether the research will generate any outcomes they will directly benefit from. However, there may be cases where the withholding of this information is justified (e.g. through fear of changing the client behaviour).

7.2.2   Concerns about how research may be infringing the rights of the client (e.g. rights to adequate care, rights to autonomy), should be recorded. If the research continues despite these concerns then the justifications for doing so should be recorded.

7.2.3   Clients taking part in research studies or trials should be allowed to interrupt or end their engagement at any time, if so desired.

7.2.4   Designers and developers should ensure that any ethical issues identified at the research stage have been dealt with appropriately before proceeding with developing a telecare system based upon the research output.

7.2.5   It should be possible for the service provider to configure the system to prevent it from gathering information that might not be considered necessary for a specific client.

8   Guidelines for legal aspects

8.2.1   Anti-discriminatory laws should be complied with when conducting interviews, focus groups, technology demonstrations and trials.

8.2.2a   The professional codes of ethics applicable to conducting trials should be followed (e.g. [40], the Declaration of Helsinki).

8.2.2b   End users should be made aware of the technical limitations of the telecare system, and how these limitations might affect the functionality of the system and accuracy of the data produced.

8.2.3   Consider having working methods evaluated by appropriate accrediting bodies (e.g. quality management).

8.2.4   Be aware that equipment and/or software furnished to service providers may be subject to strict rules and regulations governing medical equipment and software.

9   Availability and reliability guidelines

9.2.1   Develop service and maintenance procedures that, when adhered to, will keep the telecare equipment at the required levels of reliability and availability.

9.2.2   When carrying out trial sessions for research and testing, any limited functionality, availability and reliability during the test should be clearly communicated to and accepted by the test participants, and the possible harmful effects of such limitations should be duly considered and catered for.

9.2.3   Conditions for reliable operation should be clearly stated in both the installation and the operation manuals.

9.2.4   The system should be designed to warn the user if it detects that reliable operation may no longer be assured, or that device failure may be expected.

9.2.5   The system should be designed to notify all concerned users of irregularities or non-functioning of system elements that will affect the required level of reliability and availability of the telecare service.

9.2.6   Incidents and failures should be logged in a secure file, and there should be an option for reporting to the equipment manufacturer.

9.2.7   Design hardware components, software modules and interfaces to be backward compatible, whenever possible.

9.2.8   In the analysis of system security, risk assessment should be applied to all parts of a telecare system or service and to all those supporting infrastructures that the telecare system depends on to operate reliably, see [28].

9.2.9   The frequency and length of system outages should be included in the risk analysis of the system.

   NOTE: A high system availability does not necessarily imply that the users are satisfied in a correspondingly high proportion of the time.

9.2.10   When appropriate, client mobility should be supported.

   NOTE: This includes roaming between different communication providers, and switching between available wireless or wired networks.

9.2.11   Setup and configuration when roaming should not require user intervention.

9.2.12   Ideally, roaming telecare services should offer user support and emergency handling services in the usual way, in the user's native or other preferred language. Unavoidable and important changes in service characteristics (communication costs, service delays, etc.) should be communicated to the user.

9.2.13   Multicultural aspects during cross-border roaming should be addressed according to the recommendations in EG 202 421 [15].

10 Integrity guidelines

10.2.1   Protect against, detect and warn about corruption of system and data, both unintentional (by a system fault), by accident (operator error), or by malicious attacks (viruses or intruders).

10.2.2   When data from different sources are available, they should be analysed to detect and report contradicting and inconsistent measurement values.

10.2.3   Give clear warnings of unsolicited but important changes in the system state that may not otherwise be noticed (e.g. a system reset with possible loss of data, fallback to default system parameters or other discontinuity in system behaviour).

11 Safety guidelines

11.2.1   Users should be alerted of any possible operational hazards.

11.2.2   Special attention should be given to scenarios that occur infrequently, but which may result in particularly hazardous situations.

11.2.3   When carrying out telecare trials involving humans, it is of particular importance that all necessary safety measures are in place, and that those involved are fully aware of and have consented to any risks related to their participation in the trials.

11.2.4   Instructions and commands that are critical for correct functioning of the equipment or service should be easily available in the end user's language of choice.

11.2.5   Procedures that require precise counting, complicated arithmetic, precise timing or other machine-oriented skills should preferably be performed automatically, or at least assisted by the equipment. The user should be kept informed.

11.2.6   Consider using a simple hardware device (e.g. a manual "panic button").

11.2.7   Consider using a dedicated display or a reserved display area for highly critical information. Do not display other data in this location.

11.2.8   Design alarms to be distinguishable from one another and, to the extent possible and relevant, distinguishable from alarms on other devices used in the same environment.

11.2.9   Warn about dangerous situations in time, thereby giving the user time to react. Do not wait for the full emergency to occur. An alarm should be activated immediately upon the onset of a critical problem.

11.2.10   Whenever possible, alarms shall identify the source of the problem.

11.2.11   Critical alarms should be provided through redundant auditory, visual and tactile signals.

11.2.12   Design alarms so that if or when they are manually silenced, they are reactivated after some time and as long as the problem persists.

11.2.13   Consider the wide spectrum of operating environments when designing and testing alarms, including other equipment in simultaneous use, electromagnetic interference, and static electricity.

11.2.14   Cables, connectors, and other hardware should be designed for easy installation and connection. If properly designed, incorrect installations should be impossible, extremely difficult, or so obviously wrong that they can be easily detected and remedied.

11.2.15   To prevent from electrical shock, it should not be possible to introduce leads connected to the body (e.g. ECG) into mains power outlets or any other common mains power connector.

11.2.16   Use colour codes or other markings to help the user achieve proper connections and component or accessory installation.

11.2.17   Connectors should have a positive locking mechanism whenever the integrity of connections may be compromised by such factors as component durability, motion, or casual contact.

11.2.18   Components and accessories should be labelled, to allow unambiguous replacement when defective.

12 Usability and accessibility guidelines

Perception and feedback

12.2.1   Telecare system's output should be made available through multiple modalities (auditory, tactile and visual). Users should be allowed to select one or more output modalities, as well as their specific characteristics (e.g. volume, brightness, contrast, cadence). Information on active output modalities and their characteristics should be provided.

   NOTE: The availability of visual and tactile information benefits users with hearing disabilities. The availability of audio and tactile information benefits users with visual disabilities. Tactile information should be provided for deaf-blind users. People with cognitive disabilities benefit from information being presented redundantly, in audio and visual modalities. People with physical disabilities benefit from having the information available in multiple modalities.

12.2.2   The information generated through the different output modalities of a telecare system should be equivalent.

12.2.3   The visual information provided by the telecare service should be perceivable by users, see EG 202 116 [3]:

1. Brightness and contrast of visual signals should be adjustable. Their value range should allow visual signals to be perceived under various conditions of ambient illumination.

2. The size of visual symbols (e.g. text, icons) should be adjustable.

3. Information should not be provided relying only on colour.

4. Telecare equipment should allow the display of visual information within viewable range of those of short stature or seated in wheelchairs. Labels and displays should be easily and correctly readable from oblique viewing angles. The correct orientation of the display should be made evident.

5. The display of the telecare equipment should be free of noticeable glare, reflections and flicker.

6. Image quality should be sufficient to perceive sign language correctly, see [40].

12.2.4   The acoustic information provided by the telecare service should be perceivable by users.

NOTE: The frequency, intensity and pitch of auditory signals should allow them to be easily heard, see [3] clause 9.

12.2.5   The tactile information provided by the telecare service should be perceivable by users.

NOTE: Different vibration patterns (rather than vibration frequency or strength) should be provided to notify different events, see EG 202 116 [3] clause 9.

12.2.6   Location and function controls of telecare equipment should be easily identifiable by users.

NOTE: Users with visual disabilities should be provided with acoustic and/or tactile information about location and function of controls.

12.2.7   The telecare equipment should provide users with multimodal feedback, see EG 202 116 [3] and EG 202 191 [11], in order to:

1. Acknowledge user interaction with telecare equipment, such as the use of input controls, or the engagement of external connectors (e.g. medical sensor, power cord, USB connector, etc.).

2. Inform on the progress of a telecare service that has been requested by the user.

12.2.8   Feedback should be presented without any perceptible delay. Visual or tactile feedback should occur at the same location as the control, or in a common place, standard for the whole telecare system.

Carrying out functions efficiently

12.2.9   Telecare equipment controls should be designed to be easily reachable by users.

12.2.10   Telecare system's input should be available through multiple modalities (such as vocal or tactile). Users should be allowed to select one or more input modalities. Information on active input modalities should be provided.

1. Users with visual disabilities should be allowed to operate the telecare system by keyboard or voice.

2. Users with hearing or speech disabilities should be allowed to use alternatives to speech input.

3. Users with motor disabilities may benefit from having vocal input available.

4. In situations where a biometric system is being used, the user's possible functional limitations should be considered, and alternative input methods offered if necessary, see [32].

12.2.11   Keyboards or keypads of the telecare equipment should be compliant with standardized requirements in terms of size, material, form, tactile marking, required force, key arrangements, character mapping, sorting orders and distance between adjacent keys, see EG 202 116 [3] and ES 202 130 [9].

12.2.12   The telecare system should provide users enough time to complete actions or to recover from errors.

12.2.13   Operation of peripherals which are part of the telecare system should be accessible and usable to all intended users.

   NOTE: Users should be able to connect, disconnect and make use of peripherals such as sensors, battery chargers, network devices, etc.

12.2.14   Standardized vocabularies of ICT commands should be supported (e.g. see ES 202 076 [8]).

12.2.15   The telecare equipment should notify users with clear and simple messages when they make errors, and provide them with guidance on what to do in such case.

12.2.16   Users should be allowed to use shortcut commands, and to take the initiative of giving commands.

12.2.17   When possible, tasks should be automated.

Understanding how to use the telecare product or service

12.2.18   Provide standardized graphical information in addition to text labels, see EG 202 048 [13] and EG 202 132 [2].

12.2.19   The amount of information presented to user should be minimized by presenting only what is necessary.

12.2.20   The messages of the telecare service should be clear, inoffensive and understandable to users. Technical terms, jargon and abbreviations should be avoided. Standardized terminology and vocabulary should be used when available (e.g. see ES 202 076 [8]).

12.2.21   Users should be assisted in multi-step operations of the telecare service.

12.2.22   In telecare services based on Interactive Voice Response systems, users should be immediately signalled that they are communicating with a machine, and not with a human.

12.2.23   In telecare services based on Interactive Voice Response systems, users should be allowed to easily reach human support.

12.2.24   In systems where speech output is available, it should be intelligible and should sound as natural as possible, see ETR 329 [45] and clause 9.5.4 of EG 202 116 [3].

12.2.25   Cultural and language issues should be considered when designing user interface of telecare services and equipment. For details, see EG 202 421 [15].

12.2.26   Dedicated attention should be given to the design of telecare services addressing children. See also EG 202 423 [7] and TR 102 133 [43].

Assistive technologies

12.2.27   Interference between telecare equipment and users' assistive technologies should be avoided.

12.2.28   Assistive devices connected to elements of telecare services should integrate well by means of functionality and user interfaces. For further details, see TR 102 068 [42] and TS 102 511 [6].

Avoidance of personal risk

12.2.29   The user interface of the telecare equipment should be designed to avoid any personal risk.

                 1.   Visual and auditory patterns that may cause seizures should be avoided.

                 2.   Audio volumes that may harm hearing should be avoided.

Personalization of user interaction

12.2.30   The telecare service and equipment should enable easy personalization of user interaction to meet user's needs and preferences, see EG 202 325 [20].

12.2.31   User preference settings (including accessibility settings) should be available in an open format to ease their applicability across different products and services. Available standards should be used, when applicable.

Users' control

12.2.32   Users should be allowed to confirm/reject the automatic behaviour of the telecare system.

     NOTE: It has to be considered that clients with cognitive impairments have a limited ability to make reasonable decisions.

13 User education guidelines

13.2.1   User education materials should be offered and made accessible to people with disabilities.

NOTE: For users with visual disabilities, information should be provided in acoustic and/or tactile modalities. Tactile information should be provided for deaf-blind users. People with cognitive disabilities benefit from simplified information being presented redundantly, in speech and visual modalities (EG 202 417 [17]).

13.2.2   In order to support users with cognitive impairments, it is recommended to provide well structured information, covering all relevant service aspects.

13.2.3   Illustrations should be used in pedagogic ways to communicate information, not only as decorative parts.

13.2.4   User guides should be usability tested, applying established usability criteria and established test methods, in order to identify faults in them and to ensure a minimum level of usability of the educational material.

13.2.5   If service updates occur, the necessary updates should be developed to provide the necessary information to clients and carers.

14 Localization, customization and personalization guidelines

14.2.1   Language, terminology and idioms should be tailored to the intended audience.

14.2.2   Avoid using humour, jargon and too informal language in the source text, as this can be easily misunderstood. The use of standardized terminology is recommended, when available.

14.2.3   The use of foreign-language terminology (including English) should be avoided, as it is not accepted by all users.

14.2.4   Use text fonts that can be easily localized.

14.2.5   Avoid file formats that may create difficulties for languages not based on the Latin script. The format used should support Unicode, see [38] (or a similar standard) and work smoothly, irrespective the text direction.

14.2.6   Ensure that the style and terminology of a translated text/term correspond to the style and terminology used in the local market and the organization providing the service.

14.2.7   Designs should allow for the adaptation of visual content (illustrations, icons, pictures, images) to local cultures.

15 Guidelines for organizational aspects

15.2.1   Researchers and designers should familiarize themselves with the working practices and organizational structures of end users.

15.2.2   End users should be involved in the definition and customization of the telecare service that is to be implemented within an organization.

16 Servicing and maintenance guidelines

16.2.1   Telecare equipment should be designed to minimize the inconvenience that installation, set up, configuration and maintenance may cause to users.

16.2.2   Telecare equipment should be designed to minimize complexity of those parts that are configurable by the clients.

A.4   Collective list of *all service provisioning* guidelines

<u>**5 User centred design and testing**</u>

5.3.1   Telecare services should be tested in the field before their launch. Relevant sample user segments, contexts of use and the required organizational resources should be considered. The results of the field pilots should be fed back into service definition. In some cases, the trial results may provide useful information to the research, design and development stages of the telecare product or service.

5.3.2   Once the telecare service is operational, a schema for the continuous monitoring of its objective and perceived quality should be developed and applied.

<u>**6   Privacy and confidentiality guidelines**</u>

6.3.1   Vulnerable people should be given all necessary support to enable them to understand the complexities of confidentiality issues and to help them to express their wishes.

6.3.2   In emergency situations non-consensual disclosure of confidential information may be considered necessary. Where this is the case service providers should ensure that only the minimum necessary information is used or disclosed to deal with the situation.

6.3.3   Employees should be trained to an appropriate level so that they are able to carry out their duty of confidentiality when using a telecare system.

6.3.4   The confidentiality of the client information should be maintained after the death of the client (but made accessible to the closest relatives).

6.3.5   Clients have a legal and ethical right to know what information a healthcare professional holds on them. Service providers should always allow clients to view their own personal data if requested to do so.

6.3.6   Clients should be kept informed about possible uses and disclosures of their information.

6.3.7   A telecare service provider's procedures for sharing information should be clear and publicly accessible.

6.3.8   Where multiple parties are involved in delivering a telecare service, it should be clear which party is responsible for ensuring the privacy rights of the client.

6.3.9   Client data and information which is held on physical media (e.g. paper, video tape or DVD) should be stored securely and disposed of as confidential waste when no longer required.

<u>**7   Ethics guidelines**</u>

7.3.1   Clients should be assessed as to their suitability for telecare monitoring on a case-by-case basis, taking into account the personal motivations and preferences of each client.

7.3.2   Consideration should be given as to whether telecare is the most appropriate solution to the care needs of the client.

7.3.3   Health and care professionals should understand the abilities of the telecare system before it is deployed.

7.3.4   Steps should be taken to ensure that the introduction of a telecare system does not lead to an increase in isolation for the client.

7.3.5   Health and care professionals should identify if the introduction of a telecare system will lead to a reduction in carer support to the client, and whether this would be acceptable to the client or appropriate given the client's circumstances.

7.3.6   Health and care professionals should identify the impact that introducing a telecare system might have on individuals who provide formal and informal care to the client e.g. other health/care professionals, care workers, relatives, friends, neighbours and voluntary organizations, and how that may in turn affect the care received by the client. Any negative impact on the carer or care by the client should be avoided.

7.3.7   Health and care professionals should assess how appropriate a telecare system would be to the client within the context of an overall care plan, and ensure their clients are aware of the alternatives to telecare.

7.3.8   Health and care professionals should have procedures in place to re-assess the client at appropriate intervals to check that the system is meeting the requirements of the client.

7.3.9   The introduction of a telecare system should not create ethical issues for the provision of existing services which the client may rely upon.

7.3.10   Documented procedures should be in place for obtaining consent from the client to implement a telecare system. In order to give consent the client should be given all the information to make a decision, and should posses the cognitive abilities to understand the implications of their decision.

7.3.11   If the client is unable to provide consent to having a telecare system installed, then consider obtaining consent by proxy. If this is through relatives or friends then the health/care professional should bear in mind that conflicts of interest can occur. Before seeking consent by proxy, the advice is to:

               •   Continue to ask the client for their consent even if you believe they are unable to understand or respond.

               •   Consider alternative ways of communicating with the client in order to understand their opinions.

7.3.12   Consent should be obtained from the client each time the service is changed significantly.

7.3.13   Clients should be made fully aware of the impact a telecare system may have on any existing health or social care services they might be receiving.

7.3.14   Records should be kept of the consent given by the client or by their proxy together with details of what has been agreed.

7.3.15   Health and care professionals should consider whether to involve close friends or family members of the client when discussing the installation and operation of the telecare system with the client. Health and care professionals should ensure that the involvement of third parties in these discussions will be of benefit to the client before making this decision.

7.3.16   The telecare system should not gather private or sensitive information about the client which is not required as part of an assessed health or social care package.

7.3.17   Telecare service providers should ensure their employees adopt a professional approach when visiting a client's home to survey, install or maintain a telecare system. This approach should include keeping the client informed of when such visits will be made, any delays to agreed times, and a system for proving the identification of service provider personnel and/or their agents.

7.3.18   Telecare service providers should ensure that their employees are trained to communicate with clients according to their abilities and preferences (e.g. use of client's primary language such as sign language).

7.3.19   Telecare service providers should ensure that employees who are required to visit the client's home are first checked with the appropriate criminal records bureau.

7.3.20   People who regularly visit the client (e.g. family members, friends and carers) should be made aware that a telecare system is in operation.

7.3.21   There should be adequate resources for responding to any emergency repairs which may be required to the telecare system.

7.3.22   Telecare services and systems should be presented to all stakeholders as tools of self-empowerment for clients, rather than as an outward sign of dependency on external services and aids.

8   Guidelines for legal aspects

8.3.1   Consider if the introduction of a telecare system causes any financial liability to the service provider (in the likelihood of any damage being caused to client's property).

8.3.2   The legal owner of the data collected by the telecare system should be identified and permission sought from the owner if the data is to be used in a way that has not already been agreed upon.

8.3.3   An information retention policy should be in place stating how long and under what conditions client data and information will be stored, and how it will be disposed of when the retention period has expired.

9   Availability and reliability guidelines

9.3.1   In the event of a system malfunctioning and failure of automatic recovery, provide the functionality and necessary guidance to assist the user in recovering the system.

9.3.2   Before installation of new telecare equipment, investigate the existence of similar equipment to avoid user confusion and unnecessary or dangerous duplication of equipment or services.

9.3.3   Interference of the telecare equipment with other electronic equipment should be investigated and avoided.

9.3.4   Telecare equipment (including sensors) should be tested both before and after installation at the client site.

9.3.5   Keep a log of all service performed, to provide tracking information. Formalize a procedure to follow when necessary device accessories are expired, damaged or missing.

9.3.6   Consider to implement redundancy for critical system parts or even for the telecare system as a whole. The extent of redundancy should be matched to the risks associated with system failure.

9.3.7   Keep an adequate stock and updated inventory list of repair/replacement parts for equipment and software. Ensure that software is adequately documented to enable new personnel to handle maintenance and repair.

9.3.8   Provide a single, easily accessible point-of-contact for reporting deviant system behaviour.

9.3.9   To keep track of defect history and to help predict Mean Time Between Failures (MTBF) of the system, hardware devices should contain production date and the date for taking into use, and anomalies and errors ("bugs") in software should be recorded.

9.3.10   Maintain plans for emergency situations.

9.3.11   A detailed response protocol should be prepared for important and potentially dangerous equipment faults that may require entry (possibly forced) into the client's premises. Service personnel should receive thorough instructions about the privacy concerns that may ensue.

9.3.12   Supply training programme for service personnel. Provide ongoing support to train suppliers in new aspects, refresher course, etc.

9.3.13   The responsibility for service and maintenance of a telecare utility should reside with the primary telecare supplier, even when these tasks are outsourced (fully or in part).

10 Integrity guidelines

10.3.1   Service access to equipment should be secured using an access control mechanism. Remote service access should be secured against attacks or failure in the communications line.

10.3.2   All security threats should be reported together with all relevant data; for analysis, warning and if necessary for preventive measures.

10.3.3   There should be a formal procedure for granting service access (e.g. user account information, delivery of passwords, keys, etc.).

10.3.4   All service access should be monitored and logged.

10.3.5   Protect against malicious insiders by pre-employment screening of key personnel. The level of screening should not be excessive, but match the level of rights granted.

11 Safety guidelines

11.3.1   It is the health worker's responsibility to ensure that the client understands medical advices that are issued.

11.3.2   When installing telecare equipment, choose locations for user interface elements so that they can be used in emergency situations (after the client has fallen, when an electrical blackout has occurred, usable by a child, etc.).

11.3.3   When telecare equipment makes use of wireless communications, ensure that the radio spectrum environment in the client's house is within the required levels (according to the Electromagnetic Compatibility profile of the telecare equipment).

12 Usability and accessibility guidelines

12.3.1   Telecare user interface elements should be installed in the most visible location, with appropriate lighting and contrast with their surroundings.

12.3.2   Brightness and contrast of visual signals should be adapted to ambient illumination.

12.3.3   Size for visual symbols (text, icons, etc.) of the user interface should be configured provided according to how they will be shown or displayed (equipment box, computer screen, TV screen, printed material), as well as to the distance the user will read them from.

12.3.4   Telecare user elements should be adequately labelled.

12.3.5   Mounting of microphone and loudspeakers part of the telecare equipment should minimize the effects of noise, echo, sound reflection and reverberation from the terminal environment.

          1. Quality and loudness of the intended sound signal should be optimized.

          2. Locations with low noise should be chosen.

12.3.6   Relay services based on text and sign language should be used for communicating with deaf people.

12.3.7   Telecare user interface elements should be located so that they are reachable by users.

          1. Related issues as user's mobility impairments, use of mobility aids, or different users' heights should be duly considered.

          2. Controls for raising panic alarms should be easily reached by users after suffering a fall.

12.3.8   When attending a client request, telecare professionals should keep the client informed on the progress of the service provision.

12.3.9   Service providers should apply existing user preference settings (including accessibility settings) when available.

12.3.10   Accessibility preference settings should be preserved unless the user is explicitly asked whether they should be kept.

13 User education guidelines

13.3.1   Support for clients and carers should be available. Availability should be in accordance with the type of service being provided. The support should be accessible to people with disability.

13.3.2   When service updates occur, the clients and careers should always be informed about the changes and the way these may affect the service prior to their implementation.

14 Localization, customization and personalization guidelines

14.3.1   It is recommended that an early dialog with the telecare service provider includes possible changes in the user documentation, such as the menu tree, terminology or icons.

14.3.2   If the master user guide or other information elements are customized, it is recommended to clarify how the material is going to be provided and how the customization and validation process will be handled.

15 Guidelines for organizational aspects

15.3.1   Telecare service providers should consult with the appropriate end users within the health or social care organization when deploying the telecare service.

15.3.2   Health and care organizations should be consulted to identify whether the benefits provided by implementing a particular telecare system will outweigh the negative effects of any concomitant organizational disruption.

15.3.3   Working practices, organizational structure and service provision within the health or care organization should continue to be monitored after the telecare system has been deployed.

15.3.4   Where possible health and social care managers should ensure that their employees understand the motivation behind the introduction of the telecare system.

15.3.5   End users should be explained how the introduction of a telecare system may affect their organization and their roles within that organization.

15.3.6   Health and social care managers should work with the telecare service provider to identify an appropriate time window for least disruption to the organization when introducing the telecare service.

15.3.7   Health and social care managers should discuss planned changes to organizational structure and working practices with their employees before implementing changes.

15.3.8   Interruption of telecare service, disturbance of established routines, or the introduction of new routines may upset the client and make him/her hostile to the telecare service. Unscheduled and irregular service of equipment should therefore be kept to a minimum, and equipment upgrades should have a clear benefit for the user or be invisible.

15.3.9   Frequent changes in organizational structure as a consequence of introducing new equipment and new procedures once the telecare service has been implemented should be avoided.

16 Servicing and maintenance guidelines

16.3.1   Service providers should keep clients informed of the installation, setup, configuration and maintenance activities performed at their homes. Clients should be informed of the purpose of these activities, their duration, periodicity, associated costs (if any), etc.

16.3.2   Service providers need to consider any inconvenience that these processes may cause to the client and minimize this by keeping their unwanted effects (time, cost, refurbishing needs, etc.) to a minimum.

16.3.3   A detailed response protocol should be prepared for important and potentially dangerous equipment faults that may require entry (possibly forced) into the client's premises. Service personnel should receive thorough instructions about the privacy concerns that may ensue.

Annex B (informative):
Bibliography

- ETSI ETR 297: "Human Factors (HF); Human Factors in Video telephony".

History

Document history			
V1.1.1	December 2007	Membership Approval Procedure (Withdrawn)	MV 20080201: 2007-12-04 to 2008-02-01
V1.1.2	December 2007	Membership Approval Procedure	MV 20080215: 2007-12-18 to 2008-02-15
V1.1.2	February 2008	Publication	