Contract No. IST 2005-034891

Hydra

Networked Embedded System middleware for
Heterogeneous physical devices in a distributed architecture

D9.3 Healthcare domain requirements

Integrated Project
SO 2.5.3 Embedded systems

Project start date: 1st July 2006 **Duration: 48 months**

Published by the Hydra Consortium **25 May 2007 - version 2.1**
Coordinating Partner: C International Ltd.

Project co-funded by the European Commission
within the Sixth Framework Programme (2002 -2006)

Dissemination Level: Public

Document file: D9.3 Healthcare domain requirements v3.0.doc

Work package: WP9 – User Applications

Task: T9.3 Develop user app. two

Document owner: Jesper Thestrup (IN-JET)

Document history:

Version	Author(s)	Date	Changes made
0.9	Jesper Thestrup (IN-JET)	10-04-2007	Initial version with structure
1.0	Jesper Thestrup (IN-JET)	13-04-2007	Added text and requirements
2.0	Jesper Thestrup (IN-JET)	21-05-2007	Restructured for new demonstration approach, demonstrator two description removed and name changed
2.1	Jesper Thestrup (IN-JET)	25-05-2007	Reviewers suggestions incorporated
			Final version submitted to the European Commission

Internal review history:

Reviewed by	Date	Comments
Daniel Thiemert (UR)	23-05-2007	Typo and formatting, Comment added
Giuseppe Menta (T-CON)	24-05-2007	Typo and formatting, Comment added

Index:

1. Introduction

1.1 Background

The Hydra project develops middleware for networked embedded systems that allows developers to create ambient intelligence applications. System developers are thus provided with tools for easily and securely integrating heterogeneous physical devices into interoperable distributed systems.

The middleware will include support for distributed as well as centralised architectures, cognition and context awareness, security and trust and will be deployable on both new and existing networks of distributed wireless and wired devices that typically are resource constrained in terms of computing power, energy and memory. Hydra middleware will be based on a Service Oriented Architecture (SOA), to which the underlying communication layer is transparent.

The middleware will be validated in three application domains: Building automation, healthcare and agriculture. Typical Hydra enabled healthcare applications are remote patient monitoring, self-management of chronic diseases, homecare and social care, assisted living, efficient doctor-patient interaction in case management, etc.

1.2 Purpose and context of this deliverable

The objectives of WP9 are to demonstrate and validate user applications in three different domains using the Hydra middleware. As such, WP9 is structured as follows:

1. Derive initial domain specific requirements for end-user applications based on the Hydra middleware.
2. Define and describe demonstration use cases, which will address the user requirements
3. Build the use cases for inclusion in the first, second and third demonstrators (M12+M24+M36)
4. Test and validate the demonstrators with users
5. Feed back user responses and validation results to next step in the iterative phase
6. Close the loops with the final demonstrator (M48)

This deliverable will define the domain specific requirements to be included in the second set of user applications based on the Hydra middleware, which will focus on the healthcare domain. It will hence address step 1 and 2 of this process. The following steps will be defined in the following and will be detailed in relevant deliverables.

Domain specific requirements for the building automation and the agriculture domains are presented in *D2.2 Building Automation domain requirements* and *D2.4 Agriculture domain requirements* respectively.

1.3 Requirements engineering

The user-centric software development (UCD) process in the Hydra project incorporates requirement engineering processes that follow the principles of ISO 13407 "Human-centred design processes for interactive systems". The user-centric design approach implies an iterative approach with cycles that allow the project to advance from initial specifications and prototypes via experience and evaluation to updated specifications and improved prototypes.

To kick off the requirements engineering process, vision scenarios for the healthcare domain were first developed using the IDON method with contributions from experts in healthcare systems and medical devices. The scenarios developed this way are visions of future deployment of Hydra enabled systems providing coherent, comprehensive, internally consistent descriptions of plausible futures and are fully described in *D2.1 Scenarios for usage of Hydra in 3 different domains*.

From the vision scenarios, technical scenarios were derived focussing on the detailed workflow of developer users in Hydra enabled environments and addressing technical questions referring to the middleware, both at device level and at runtime. The technical scenarios were evaluated by focus groups of developer users and a large number of requirements were gathered using the Volere template.

The functional and non functional requirements thus derived were finally integrated and generalised to form a package of developer user requirements specifications that was fed into the architectural definition. The full description of the requirement gathering process and the collected requirements is found in *D2.5 Initial Requirements*.

The complete set of functional and non functional requirements (including security and socio-economic requirements) finally formed the basis for the initial architecture proposed in *D3.3 Draft of architectural design specification*.

It is important to note that the present domain specific requirements are not new requirements in relation to the comprehensive set of requirements already gathered and reported in *D2.5 Initial Requirements*. All domain specific requirements are already included in the Volere template. Hence, the domain specific requirements constitute a subset of requirements that are most relevant to the specific domain. This exercise can be helpful in the requirements engineering process for prioritising, resolving conflicts and filtering for demonstrations of the large number of requirements gathered.

1.4 Demonstrator cycles

A total of four iteration cycles are planned in the Hydra project. Each cycle leads to a demonstrator in a new domain, while the previous demonstrator is being updated. The first cycle is the demonstrator in the building automation domain. In the next cycle a demonstrator in healthcare is added, while the building automation demonstrator is augmented. In the third cycle a demonstrator for the agriculture domain is added and the two other domains are augmented.

The goal of this procedure is not to focus only on the evolution of the demonstrators but on the refinement of scenarios, requirements, specification of the middleware and its implementation. This iterative process ensures a gradual approximation to the final middleware.

The first demonstrator will be the "proof-of-concept-demonstrator" of the Hydra middleware. It will be based on use cases and scenarios from the building automation domain. The deliverable *D9.5 Concept demonstrator* provides a full technical description of the first demonstrator including the scenario to be demonstrated, the sequence diagrams and the technical solution chosen.

Demonstrator two will focus on demonstrating the Software Development Kit (SDK). This demonstrator will aim to demonstrate how a developer user can build an application using the Hydra SDK. The main setting of the second demonstrator will be the healthcare domain, but new aspects of the building automation scenario will also be demonstrated. The deliverable *D9.6 SDK demonstrator* will provide a technical description of the second demonstrator. It will be updated with new knowledge and new facilities in subsequent iterations following the progress of the project.

Demonstrator three will focus on demonstrating the Device Development Kit (DDK). This demonstrator will aim to demonstrate how a developer user can enable a device for networking using the Hydra middleware. The main setting of the third demonstrator will be the agriculture domain, but new aspects of the building automation and the healthcare scenarios will also be demonstrated. The deliverable *D9.7 DDK demonstrator* will provide a technical description of the third demonstrator. It will be updated with new knowledge and new facilities in subsequent iterations following the progress of the project.

At the end of the project, a complete Hydra middleware platform capable of demonstrating the use cases and scenarios in three different user domains will be produced.

1.5 Scope of this deliverable

The document starts with an introduction to the healthcare domain and its specific challenges imposed on applications for this telemedicine, remote patient monitoring, self management, and other technology assisted case management programmes. Chapter four describes some of the trends and challenges, which among other things, were discussed during the scenario workshops, and looks at the state of the art in commercial solutions available today.

In chapter five actors and targets users are described and an initial set of domain specific requirements for applications based on Hydra middleware in the healthcare sector is derived from the work in task T2.1 Scenario thinking. Moreover, both generic and specific requirements are derived from the vision scenarios and correlated to the Volere based requirements.

Finally, the chosen vision scenario "Overload" is provided in chapter six for reference.

2. Executive summary

2.1 The process

The user-centric software development (UCD) process in the Hydra project implies an iterative approach with cycles that allow the project to advance from initial specifications and prototypes via experience and evaluation to updated specifications and improved prototypes.

From the vision scenarios, technical scenarios were derived focussing on the detailed workflow of developer users in Hydra enabled environments and addressing technical questions referring to the middleware, both at device level and at runtime. The functional and non functional requirements thus derived were finally integrated and generalised to form a package of developer user requirements specifications that was fed into the architectural definition. This deliverable will define the domain specific requirements to be included in the second set of user applications based on the Hydra middleware, which will focus on the healthcare domain. It is important to note that the domain specific requirements are not new requirements in relation to the comprehensive set of requirements already gathered and included in the Volere template.

A total of four iteration cycles are planned in the Hydra project. Each cycle leads to a demonstrator in a new domain, while the previous demonstrator is being updated. The first demonstrator will be the "proof-of-concept-demonstrator" of the Hydra middleware. It will be based on use cases and scenarios from the building automation domain. Demonstrator two will focus on demonstrating the Software Development Kit (SDK). This demonstrator will aim to demonstrate how a developer user can build an application using the Hydra SDK. The main setting of the second demonstrator will be the healthcare domain, but new aspects of the building automation scenario will also be demonstrated. Demonstrator three will focus on demonstrating the Device Development Kit (DDK). This demonstrator will aim to demonstrate how a developer user can enable a device for networking using the Hydra middleware. The main setting of the third demonstrator will be the agriculture domain, but new aspects of the building automation and the healthcare scenarios will also be demonstrated. Details of all demonstrators are found in the corresponding deliverables.

At the end of the project, a complete Hydra middleware platform capable of demonstrating the use cases and scenarios in three different user domains will be produced.

2.2 The healthcare domain

Public health is a key priority for the Member States and Europe is facing serious challenges in the near future of delivering quality healthcare to all its citizens, at affordable cost. Prolonged medical care for the ageing society, the costs of managing chronic diseases, and the increasing demand by citizens for best quality healthcare are major factors.

The structures of European healthcare systems are diverse and it is therefore necessary to be aware of fundamental differences in order to be able to commercially exploit Hydra enabled solutions successfully across Europe.

The European population is aging due to falling birth rates and increased life expectancy. At the same time, the number of citizens with chronic conditions associated with ageing and/or unhealthy lifestyles, such as heart and cardiovascular diseases, diabetes, pulmonary diseases and asthma, has reached epidemic proportions.

The emerging situation calls for a change in the way healthcare is delivered and the way medical knowledge is managed and transferred to clinical practice. eHealth may offer useful capability to open new opportunities in health and disease management, improve illness prevention, facilitate chronic disease management through active participation of patients and enable personalisation of care that contribute to improving the productivity of healthcare provisioning.

However, eHealth and remote monitoring remains to be integrated into mainstream healthcare despite its potential for improving health outcomes and effective use of resources, and the efforts of

government, industry and academia. This can be seen in the relatively low utilisation and success rate of many projects, and the lack of routine services. The Hydra middleware will provide tools for overcoming the deployment obstacles inherent in previous remote monitoring and case management programmes by providing a easy to use middleware tools that allows developers to design and implement advanced solutions based on existing or new home medical devices.

eHealth services and the development of sophisticated personal wearable and portable medical devices can improve the management of chronic conditions considerably. It is important, however, that sophisticated and intelligent medical devices, which can be used by people at home or on the road, are developed according to the needs and demands of both patients and healthcare professionals. Intelligent devices must be interoperable allowing them to interact with other devices and services. When these basic requirements are fulfilled, eHealth and medical devices will allow patients and healthcare professionals to become more mobile, as well as enabling a more efficient monitoring and management of diseases. A limited number of eHealth applications devoted to self management programmes and intelligent monitoring of patients in their homes is available today as well as a larger number of individual medical devices with interfacing capabilities.

2.3 Domain specific requirements

The target group consists of all active or potential manufacturers, developers, customers and users of an application. The different actors will have different expectations and will see the usefulness of the Hydra middleware from different perspectives. In other words, their requirements will be different. The identified actors are:

- Developer user
- Healthcare providers (doctors, hospital staff, carers)
- End users (patients)

Designing medical devices requires an in-depth knowledge of the healthcare market, end-user requirements, safety, and regulatory compliance. The Hydra project's middleware for networked embedded systems allows developers to develop cost-effective, high-performance ambient intelligence applications for heterogeneous physical devices and developer users are the main target group of users. Developers of eHealth devices and products need to observe a multitude of requirements for product performance, security, ease of use, reliability, and price.

Six issues have been identified (Insup Lee, 2006) as critical for the future of high-confidence medical devices:

- Commercial off-the-shelf technologies do not produce highly distributed medical device systems with guarantees of security, privacy, robustness, interoperability, extensibility, mobility, and general patient safety.
- The networking of medical devices for distributed sensing and control can occur at many levels.
- In the medical-practice domain, modelling and simulation will improve outcomes and quality of patient-care, will provide better control of healthcare costs with improvements in prevention, intervention, and will allow maximal use of the electronic health records.
- Researchers envision next-generation medical systems to be a ubiquitous network of networked systems that provide secure, reliable, privacy-preserving, and cost-effective, personalized, high-quality healthcare.
- Many medical devices are, essentially, embedded systems. As such, software is often a fundamental—albeit not always obvious—part of a device's functionality. This means that any safety and regulatory requirements for medical devices necessarily call for rigorous software development methods to ensure reliability and to protect the public health.
- Verification and validation tasks required for the approval of medical devices play a significant role in enabling the FDA to carry out its mandate of approving only "safe and effective" medical devices.

Improving chronic patients' condition and lives will be a major challenge for healthcare providers in the future as more and more patients develop chronic diseases like diabetes. Providing self management schemes and remote monitoring will enable healthcare providers to meet this challenge, patients' quality of life will be improved, the treatment of diseases will improve and at the

same time, healthcare providers will be able to cut costs on commissioning fees as patients will need less consultation time with GPs. Moreover, healthcare providers will be able to cut down on hospital costs as unnecessary admissions may be avoided and as the length of hospital stay can be cut down as patients will be able to be dismissed earlier and instead monitored closely at home.

The Hydra middleware must support a security policy framework that allows applications to accommodate a wide range of service providers in the healthcare domain.

Finally, understanding the needs of end users and integrating those needs into development projects lies at the heart of producing effective medical devices. Measuring and fulfilling user requirements during medical device development will result in successful products that improve patient safety, improve device effectiveness and reduce product recalls and modifications.

From an end-user perspective, designers and developers of devices, systems and applications must face this challenge, which will require addressing real healthcare and homecare needs.

The functional user requirements specifications include the most important aspects of user expectations in healthcare applications. During a workshop ten experts concluded that the following specific requirements were most relevant for the healthcare domain:

Functionality
Device functionality and complexity will increase sharply. The use of intelligent multi-parametric biomedical monitoring devices using non-invasive or minimally invasive sensors is expected to explode. Quantitative and qualitative monitoring will routinely be used for self-management of diseases and early prediction of conditions. Hydra middleware needs thus to support real-time data processing, intelligent decision support and interconnectivity via heterogeneous networks.

Communication
Wireless solutions are generally preferred for all healthcare applications in connected and networked applications, but may be restricted to critical healthcare applications due to the possible health concerns stemming form electromagnetic radiation from wireless devices. Hence different types of communication should be supported in a dynamic environment. There may not always be unlimited bandwidth available for any amount of data transfers, so the Hydra middleware must allow device manufacturers to design their devices to be adaptable to varying bandwidths.

Privacy and security
Privacy of personal health care data is essential, not only for user acceptance, but for the credibility of the entire health systems. Devices and applications will therefore have to comply with strong user requirements and strict national legislation regarding access to patient data, both sensitive and non-sensitive. Patients will own their own data and need to be empowered to manage identity, authentication and access rights models for any device or application containing or accessing their health data. The Hydra middleware must support development of applications with such empowerment.

Power
Developers of medical devices will increasingly face problems of resource constraints, in particular limited power for desired functionalities. Although technological solutions that do not rely on traditional batteries may be available, device performance need to be independent of how much, or how little, energy is required in order to perform a desired function.

Design
Due to ethical and psychological concerns, healthcare support devices will be "invisible" so they do not signal illness and the exterior design will increasingly be dictated by fashion and trends.

A number of technical requirements can be derived directly from the scenarios and the scripts contained therein and are reported in the text.

3. Healthcare domain overview

The healthcare sectors in EU Member States are tremendously complicated in terms of how healthcare services are delivered and financed. The structures of European healthcare systems are diverse and it is therefore necessary to be aware of fundamental differences in order to be able to commercially exploit Hydra enabled solutions successfully across Europe.

3.1 Healthcare demographics

Public health is a key priority for the Member States and Europe is facing serious challenges in the near future of delivering quality healthcare to all its citizens, at affordable cost. Prolonged medical care for the ageing society, the costs of managing chronic diseases, and the increasing demand by citizens for best quality healthcare are major factors.

The European population is aging due to falling birth rates and increased life expectancy. At the same time, the number of citizens with chronic conditions associated with ageing and/or unhealthy lifestyles, such as heart and cardiovascular diseases, diabetes, pulmonary diseases and asthma, has reached epidemic proportions.

Today we are witnessing the fruits of the past century of medical advances and developments in sophisticated medical technology. As shown in Figure 1, deaths from heart disease have increased from 6.2% of total deaths in 1900 to 31.4% in 1997 while cancer deaths have increased from 3.7% to 23.3%[1]. Lifestyle diseases such as diabetes have increased in death rate from insignificance to 2.7%. In fact, six of the ten most leading causes of death in 1997 were not even noticeable a hundred years ago.

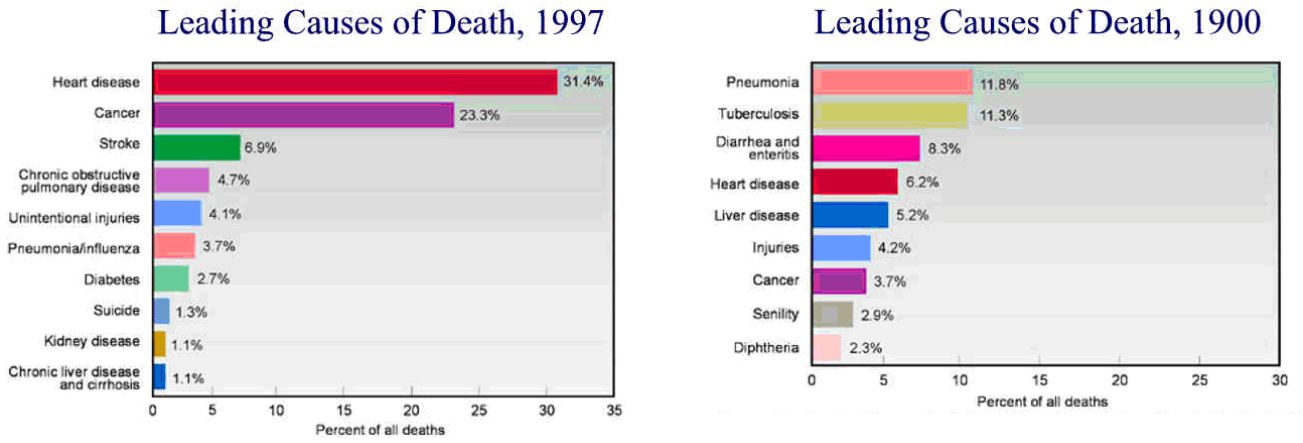

Figure 1 Causes of Death (US Center for Disease Control and Prevention, 1997)

What is more worrying is that half of the top ten causes of death in 1997 were related to unhealthy lifestyles. The good news is that something can be done about it!

Improving chronic patients' condition and lives will be the major challenge in the future as more and more patients develop chronic and lifestyle related diseases. Studies have consistently shown that when patients are more involved in their own healthcare, they are in many cases able to avoid severe lifestyle related chronic conditions. If they have developed a condition, a more efficient management of their chronic disease with the use of intelligent monitoring will improve patients' lives and at the same time enable the providers to meet this challenge.

People at risk need to be supported by ubiquitous monitoring environments that identify evolving patterns and early trends in their health and lifestyle parameters, which could indicate elevated risks of developing diseases or reveal episodes. Prevention systems must be able to empower the

[1] These figures relate to a North American population, but are not so different (ranking) from similar European demographic data

necessary involvement of healthcare professionals, facilitate personalised guidance, encourage citizen compliance or prompt for early medical intervention.

The ageing population does not only result in more people with care demanding conditions. People are also living longer with their conditions and the diseases become more severe and demanding in terms of care and medication. These developments result in a drastic increase of the demand for healthcare services in the near future. This need will put further strain on a system, which is already under pressure in most European countries and is likely to require significant changes to the structure and organisation of existing healthcare and social services in order to meet the demand in an efficient and economically feasible manner.

Healthcare expenditure in Europe is already significant (8.5% of the GDP on average) and rising faster than overall economic growth itself. The per capita expenditure on healthcare services is greater for the ageing than for people in their working age. A major challenge for the Member States is thus to finance the increasing costs of healthcare services while at the same time the number of working and tax-paying adults shows declining trends.

The emerging situation calls for a change in the way healthcare is delivered and the way medical knowledge is managed and transferred to clinical practice. ICT may offer useful capability to open new opportunities in health and disease management, improve illness prevention, facilitate chronic disease management through active participation of patients and enable personalisation of care that contribute to improving the productivity of healthcare provisioning.

3.2 Healthcare systems

The tax-based healthcare systems in Europe offer mainly publicly provided and managed healthcare services. Public bodies often act as both providers and commissioners (purchasers) of health services. In general, there are a very limited number of private healthcare providers who provide healthcare services directly to the patient on a fee-for-service basis. In the Scandinavian countries, national legislation, coupled with a comprehensive public healthcare sector and general consensus, place general restrictions on a specific development of a private healthcare sector.

Hospital care is generally delivered by a mixture of public and private providers. The number of private hospitals, and the percentage of total hospital beds which private hospitals cover, is still relatively low. In addition, there exist a number of non-profit hospitals which supplement public and private hospitals.

In most EU Member States, the healthcare system is decentralised (in Greece and France the systems are more centralised) with varying degrees of regional control and management of the allocated financial resources, as well as control of how to best meet national guidelines and standards (including public demands and requirements) on healthcare services.

In the UK, Denmark, Sweden, Italy and Spain the healthcare system is tax-based, i.e. the funding of the healthcare sector is based on revenue from general national taxation. Healthcare services are provided free of charge by the public sector; however, Sweden and Italy have some limited user-charges for public primary healthcare service, such as a small fixed fee for visits to a GP. The private healthcare sector in these countries is thus minimal.

In France and Germany the healthcare system is based on statutory social health insurance funds, i.e. the funding of the public healthcare sector is based on non-risk related contributions to the statutory insurance schemes which provide public healthcare services. The private healthcare sector is more extensive and sources of finances more diverse. In Greece, the healthcare system is based on a mix between a tax-based system and a statutory insurance system. Greece has the most privatised healthcare system in Europe with an almost equal divide between public and private sources financing the healthcare system.

3.3 eHealth and remote monitoring

The term eHealth has been used in the literature to refer to a variety of applications including telemedicine, electronic patient records (EPRs), consumer health websites, teletraining for health professionals, and electronic referrals and bookings that might be categorised as using information and communication technologies. Telemedicine may be described as the use of these technologies by healthcare professionals to practice medicine at a distance, and again numerous definitions have appeared in the literature. One that is favoured by many researchers is that by Reid (1996, p.14): *"Telemedicine – the use of advanced telecommunications technologies to exchange health information and provide healthcare services across geographic, time, social and cultural barriers"*. This definition is sufficiently broad, and emphasises the fact that telemedicine does not only overcome distances of space, but also of other, perhaps less widely acknowledged barriers. It also emphasises the potential of telemedicine to improve access to healthcare for those who do not live within the reach of high-rated or specialist hospitals and medical centres.

Remote patient monitoring (RPM) can be seen as a subcategory of telemedicine. It entails the electronic monitoring of physiological measurements in a setting other than a hospital, such as a patient's home, or a community setting such as a residential or nursing home. Physiological measurements can include heart rate, blood pressure, ECG, SpO_2 (oxygen saturation of the blood), temperature, respiration and weight. In the context of this project, RPM is defined as: *"The electronic monitoring of physiological measurements of patients not confined to hospital, using information and communication technologies to transfer data over geographical distances"* (adapted from Bratan & Clarke, 2005). RPM can lead to better clinical outcomes and be more convenient and cost-effective than traditional institutional care, since it enables patients to remain in their usual environment whilst being looked after professionally. RPM overlaps with telecare, which is defined as the monitoring of non-medical data such as general behaviour patterns, such as falls, and is referred to as "social alarms", as the response is most commonly by a non healthcare professional.

There have been research efforts for developing a generic system architecture for telemedicine or telecare but the focus is usually on the software and hardware architecture. Success and sustainability factors for telemedicine have been extensively researched but so far no studies have been carried out to compare the different approaches in terms of implementation in order to identify common elements that would inform the design of a generic architecture for an RPM system. There have also been no studies that have optimised current implementations.

RPM remains to be integrated into mainstream healthcare despite its potential for improving health outcomes and effective use of resources, and the efforts of government, industry and academia. This can be seen in the relatively low utilisation and success rate of many projects, and the lack of routine services. A number of contributing factors have been identified:

- Lack of definitive evidence for cost-effectiveness when applied wide-scale
- Lack of definitive evidence for clinical effectiveness
- Lack of funding to establish services
- Lack of experience
- Technical issues, especially with the early equipment
- Absence of a well-established industry
- Uncertainty due to the lack of standards, guidelines and service models

Some authors argue that the design and implementation of system architectures (beyond technical) is often given insufficient consideration when establishing a RPM service, which not only leads to poor design and difficulties in implementation, but, more importantly, also results in the development of a service that does not fulfil technical, clinical, organisational or user requirements.

The Hydra middleware will provide tools for overcoming the deployment obstacles inherent in previous disease management programmes incorporating remote monitoring by providing easy to use middleware tools that allow developers to design and implement advanced solutions based on existing or new home medical devices.

4. Trends and challenges in healthcare

4.1 Trends and challenges

Healthcare services across Europe face enormous challenges in the future as the European population is growing older, more and more people have chronic diseases and the general needs and expectations for efficient and effective healthcare services increase. These challenges concern both the quality of healthcare and the availability of resources – human as well as economic resources – to deliver healthcare services. European Member States are likely to face a severe shortage of healthcare staff to care for the growing number of patients. A serious problem facing all EU Member States is the increasing number of people with chronic diseases. This factor is closely related to an unhealthy lifestyle. However, cultural and socio-economic factors are also linked to development of lifestyle diseases and importantly also to how well the disease is managed.

There is little doubt that lifestyle diseases have serious consequences and may be life threatening if they are not treated and handled correctly. Lifestyle diseases include type 2 diabetes, stroke, obesity, heart disease and atherosclerosis and diseases associated with smoking and alcohol and drug abuse[2]. In fact, according to the World Health Organisation, an estimated 80% of heart disease, stroke and type 2 diabetes, and 40% of cancer, could be avoided if common lifestyle risk factors were eliminated. Moreover, up to 86% of deaths in Europe are caused by largely preventable chronic diseases[3].

In Europe, there has been a general development in healthcare provisioning leading away from hospitalisation and towards providing more local and home care health services. For example, the number of hospital beds and the length of hospital stays have decreased in Europe. At the same time, the trends within healthcare provisioning and the demographic developments both indicate a greater focus on and need of healthcare services not only outside hospitals, but increasingly also in patients' homes. Services for chronically ill and old patients are increasingly provided in their own home in response to patients' and their families' wishes.

All countries are confronted with increasing demand for home care; the main reasons being the ageing population, the smaller family size, the increased female participation in the labour market and the continuous attempts to control healthcare expenditures. There are differences among member states in the definition and the development of home care services. In countries such as Denmark, the Netherlands, Belgium, Finland, Ireland, Sweden and U.K. home nursing and home help services are fairly developed compared to Austria, Greece, Italy and Spain. In France, "hospitalisation at home" has been introduced and in the UK rehabilitation care is increasingly being carried out at community level or at home rather than at hospitals.

Such developments depend to a great extent on the implementation of comprehensive and well functioning eHealth and mHealth services, in which Hydra middleware will play a crucial role in creating the tool for networking the large amount of medical devices already on the market and the equally large amount of new devices for home care expected in the coming years.

Hydra can enable applications that can improve the delivery of healthcare services by securing higher quality of treatment, improved access to care, avoidance of unnecessary hospitalisation and more efficient delivery of healthcare services at lower costs.

4.2 State-of-the-art in self management systems and devices

eHealth opens up for new possibilities for home-care and self-management. eHealth services and the development of sophisticated personal wearable and portable medical devices can improve the management of chronic conditions considerably. It is important, however, that sophisticated and intelligent medical devices, which can be used by people at home or on the road, are developed

[2] http://www.medterms.com/script/main/art.asp?articlekey=38316
[3] http://www.euro.who.int/mediacentre/PR/2006/20060908_1

according to the needs and demands of both patients and healthcare professionals. Intelligent devices must be interoperable allowing them to interact with other devices and services. When these basic requirements are fulfilled, eHealth and medical devices will allow patients and healthcare professionals to become more mobile, as well as enabling a more efficient monitoring and management of diseases.

A complete survey of the different features and implementations is beyond the scope of this requirements engineering task. Instead, we will describe a limited selection eHealth applications devoted to self management programmes and intelligent monitoring of patients in their homes.

The purpose of this is to provide a framework for understanding the specific requirements placed on the Hydra middleware in the healthcare domain by studying available commercial and research type systems on the market.

4.2.1 Ericsson EMH

Ericsson's Mobile Health (EMH) system is intended for remote follow-up of out-patient long-term medical conditions. The EMH consists of the three major sections:

Patient unit: The Unit comprises a Sensor Node (SN) and a Patient Node (PN) and is operated by the patient. The Sensor Node (SN) is a wearable medical device from an independent supplier, measuring one or several physiological parameters of a patient and transmitting these measured data via a Bluetooth communications link to the PN. The PN is a telecommunications device from Ericsson Healthcare Solutions. The PN transmits the measured data via GPRS to the backend system. The PN also provides a GUI on which the patient can fill out a patient diary report on his/her medical condition. The PN GUI also provides an error reporting to the patient.

Backend system: The backend system comprises of one or several computer servers receiving the data from the PN and processing and storing the data. The backend system also provides the operator with the operator web interface (OWI).

Operator web interface: The OWI is a GUI with which the operator can study the data from an ongoing measurement with a slight delay, or examine a previously performed measurement. The OWI also displays the report from the patient diary and facilitates for the operator to register new patients in the EMH and assigning a Unit to a specific patient when setting up a study.

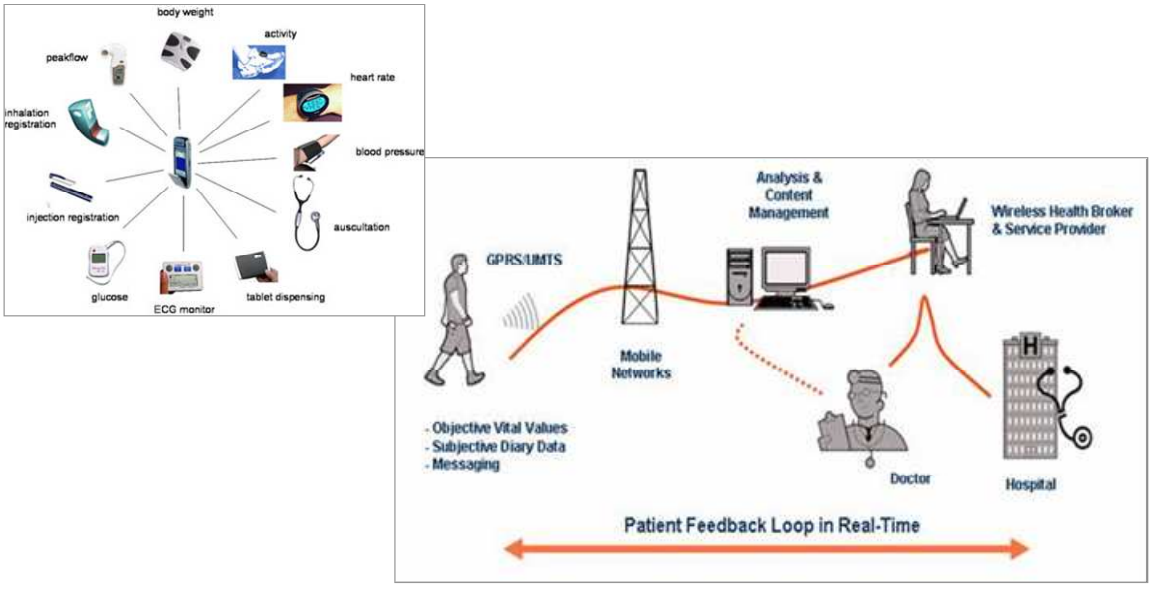

Figure 2 Ericsson Health system

4.2.2 eu-DOMAIN

The eu-DOMAIN Ambient Intelligence (AmI) Service Platform is a web based service that offers all eu-DOMAIN functionalities to service providers. The eu-DOMAIN is the result of a FP6 IST project.

The eu-DOMAIN platform is an infrastructure where different components, applications and services can be plugged in and services and application can be developed in order to adapt it to the special needs and requirements of a given domain.

Each physical location must have one or more service gateways installed. They form dynamic, local clusters and access points to existing local area networks, through which, two-way communication with devices and other control systems in the location (e.g. alarm systems, energy control, etc.) can be established. The gateway can communicate via build-in device net protocols.

The central layer of the eu-DOMAIN platform consists of the actual web services and software architecture providing control and monitoring functions. This allows the user to interact with any device, terminal or external repository, acquire and store data, and activating devices and terminals using rules-based intelligence functionalities programmable in the system. Web based communication is providing the connectivity between the eu-DOMAIN central server and the physically distributed service gateways and the mobile and fixed users.

The eu-DOMAIN infrastructure is capable of delivering application services directly to the remote locations. External services are negotiated from a third party Service Provider, e.g. an Electronic Patient Record system. Free web-content services, such as general health information related to the patient's current status, can also be searched and delivered to the user. Services can either be one-way service delivery or two-way interactive services.

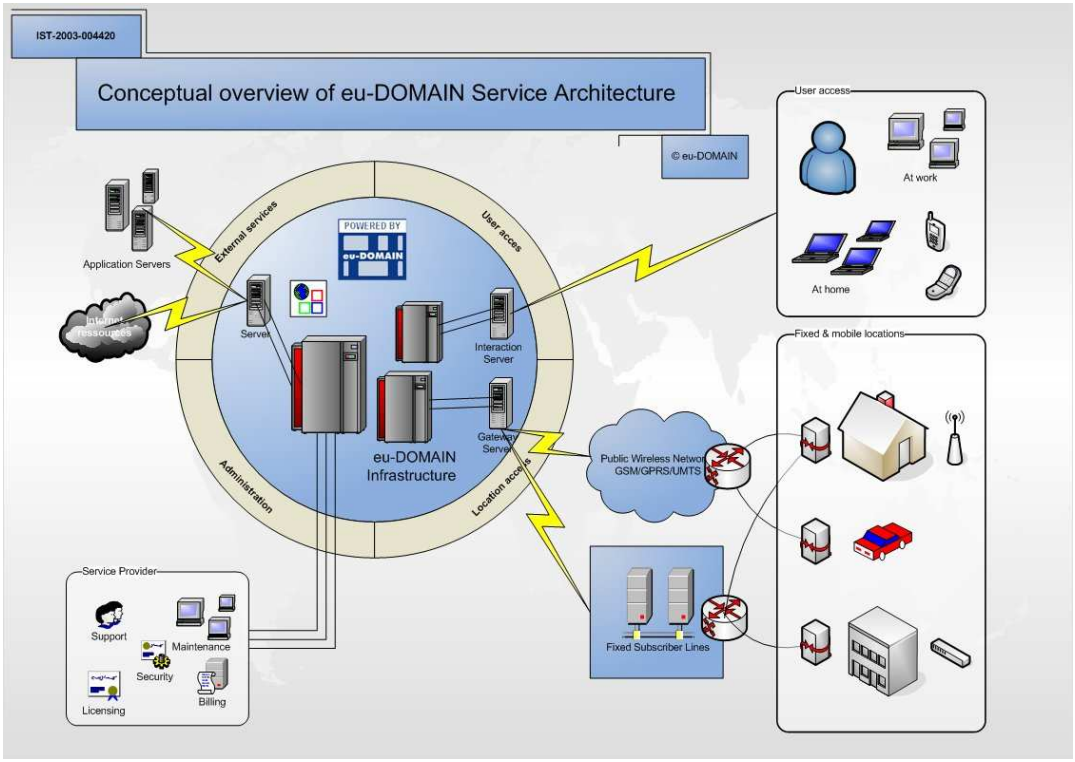

Figure 3 eu-DOMAIN healthcare infrastructure

4.2.3 Health Hero

Health Hero Network develops and markets the Health Buddy system for health improvement. The Health Buddy system serves as the interface between patients at home and care providers, facilitating patient education and monitoring of chronic conditions. The system includes monitoring

technologies, clinical information databases, Internet-enabled decision support tools, health management programs and content development tools.

The decision support tools are Internet-enabled patient management tools that care providers use to manage patients with chronic illnesses. These tools offer trends, risk stratification, and the ability to efficiently monitor large groups of patients.

Care providers assign health management programs to patients based on their chronic condition(s). These personalized programs communicate via monitoring technologies and include questions to help monitor and assess a patient's clinical condition. Patient data can be sent back to the care providers immediately, during the evening, or based on a specific patient response. The data is sent over a telephone line through a secure data channel.

The Health Buddy appliance is a personal, easy to use, in-home communication and monitoring device. The Health Buddy appliance collects data that gives healthcare providers important and timely information about a patient's chronic condition.

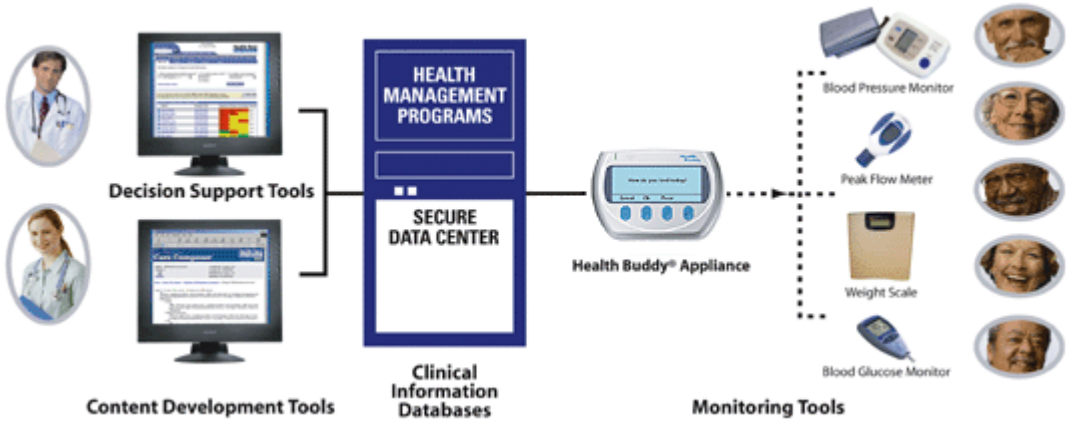

Figure 4 Health Hero health management systems

4.2.4 CSO Decision Support

The CSO - Clinical System Organizer from IntraMed is a web-based system that improves quality of treatment and rationalizes processes, thus generating economic benefits for the health services.

CSO shares clinical data between those involved in the clinical process via web-based software. It can be used by both clinicians and patients, and can be integrated with various Electronic Patient Records systems including laboratory modules and medication modules.

The CSO system performs remote monitoring of COPD patients using a portable device that measures lung capacity. The information is automatically transmitted to the CSO system. If the lung capacity is not in line with the expected, the device presents the patient with a series of clinical questions. Based on the answers and the measured values, the CSO system decides if the medical carer should be notified.

4.2.5 Wearable devices

Nonin Avant 4100

The Avant 4100 is a Sensor Node (SN) that can be used in the Mobile Monitoring system and enables follow up of oxygen saturation and pulse rate in an out-patient setting. It comes with a finger-clip sensor, AA batteries and a wristband. The finger-clip is used for measuring the oxygen saturation and the pulse rate. The Avant 4100 transmits the information from the finger-clip to a Patient Node by using the Bluetooth technique.

Usable in the following applications: Home care, sleep apnoea, heart failure.

Medair Life Sense

The LifeSense monitor is used for Pulse Oximetry and Respiration. It is a lightweight portable battery operated instrument that measures and displays carbon dioxide in expired air ($ETCO_2$), respiration, pulse rate and saturation. LifeSense offers the possibility to measure both pulse oximetry and capnometry from patients in a non-invasive. This very useful combination serves as a reliable indication of the patient's breathing status. It also reduces the need for use of numerous arterial blood gas analyses.

The LifeSense comes with a central unit with a large display, a finger clip sensor, a nose tube for respiration and a Bluetooth dongle.

Usable in the following applications: Sleep apnoea, COPD, heart failure, post infarction surveillance, trauma care home care, and asthma.

CardioBlue

The CardioBlue sensor node is a 5 lead ECG measurement sensor. It measures the electrical signals of the heart, which makes the heart muscle contract in a rhythmic fashion pumping blood to the body. The electric pulse is generated in the heart and spreads through conducting filaments in an evoked potential through the left and right chambers to the left and right ventricles. It has the maximum capacity to measure 5 lead bipolar ECG´s by attaching 7 cables to the patients body.

The placement of the ECG patches (electrodes) to the skin must be done by a doctor or a nurse to ensure proper placement which ensures an optimal recording of the electro physical signals of the heart. The recordings are sent from the ECG electrodes to the backend systems via a Bluetooth sender integrated into the Cardio Blue central unit.

Usable in the following applications: Heart failure, CHD.

CorBelt

The CorBelt is a chest belt which is strapped around the chest for simple and convenient ECG recordings. Since it only measures an ECG signal between two poles it is said to be a 1-lead ECG. Two flexible chest belts are clipped on to the more rigid breast-plate-part of the belt. The ECG measurement is started by putting in 2 AA batteries into the battery compartment just prior to attaching the belt around the body. The belt contains a Bluetooth sender so that each measurement is immediately sent from the belt to the Personal Node and then on to the backend system.

Usable in the following applications: Heart failure, CHD.

CARD GUARD Blood Pressure Monitor

To measure blood pressure very accurately a sensor has to be placed in the bloodstream, this is called invasive Blood Pressure. Non-invasive Blood Pressure is a quite good approximation of the true blood pressure. What you measure is the pressure of the blood in the blood vessels. The two values (120 / 80) represent the pressure during a pulse and in between pulses, respectively. Operating the Blood Pressure cuff is very simple. After putting the cuff on the upper part of the arm, close to the armpit, simply press the "Start" button on the table unit. All operation and sending from there on is automated. The cuff will inflate and squeeze the upper arm firmly and then slowly release the pressure during the measurement.

Usable in the following applications: Hypertension, diabetes, home care, and many others.

Omron 637IT blood pressure monitor

The Omron 637IT is an autonomous and automatic wrist blood pressure monitor that can be connected to any computer via USB connection. The device measures systolic pressure (SYS), diastolic pressure (DIA) and heart rate (BPM) and the date. It features USB connection, memory for 90 measurements, an alarm function, graph display for weekly overviews, large display showing blood pressure and pulse The devices have a position

sensor for optimal positioning to assure the highest accuracy. A built-in sensor determines the optimal height of the wrist; indicators on the display guide to the best position. Once put at the proper position, the monitor will automatically start the measurement.

Usable in the following applications: Hypertension, diabetes, home care, and many others.

CARD GUARD Body Weight Scales

The weights scale is just like a modern electronic weight scale. It should be placed on the floor on a flat surface. To start it you simply press it lightly with your foot. When the display shows "0" step up and place both feet on the scale and wait for 10 seconds until the "ready" sound beeps. Your weight is automatically sent via Bluetooth the Personal Node and on to the backend system.

Usable in the following applications: Diabetes, home care, and many others.

CORSCIENCE Peak Expiratory Flow

The PEF meter is a small hand held device. The PEF will measure the speed of your air-exhale from full lungs. Start the PEF by pressing the top button (green). When indicated take a deep inhale and blow with maximum speed into the mouth piece. Repeat this 3 times or do according to the agreement with the doctor / nurse. To send the data the user must go to the menu and manually send the data from the PEF meter. By 1) pressing the "Menu" button (left) and 2) using the arrow keys one should 3) select "OK" to the far right and 4) confirm sending by pushing the top (green) button. Data will then be transferred from the PEF to the Personal Node and on to the backend system.

Usable in the following applications: Respiratory diseases, asthma.

5. Domain specific user requirements for healthcare

In this section, we deduct the specific technical requirements for the healthcare domain. We set off by identifying the users and analysing the future scenarios created by the external experts and the specific requirements that can be deducted from the scenario thinking process and from the scenarios themselves.

During a full day workshop, ten external domain experts discussed the most critical applications for ICT technology in healthcare in the future, how existing medical devices can be improved and what type of new and better devices could be developed to improve concepts like self-management and remote monitoring of chronic conditions. The main focus was on devices that are used by patients themselves and are used in support of self-management of a range of chronic diseases.

The time horizon was set for year 2015, which participants felt was suitable when discussing future trends and developments in the healthcare domain.

5.1 Actors and target users

In order to derive domain specific requirements for the design process, it is useful as a first step to define the main target users that will develop and eventually utilise healthcare applications supported by Hydra middleware.

A target group consists of all active or potential manufacturers, developers, customers and users of an application. The aim is to create actor segments that are internally sufficiently homogenous to render synchronized behaviour in all relevant aspects (usage patterns, buying behaviour, etc.) while at the same time to be sufficiently large to be economically viable for exploitation.

The different actors identified in this way will have different expectations and will see the usefulness of the Hydra middleware from different perspectives. In other words, their requirements will be different.

5.1.1 Developer user perspective

Designing medical devices requires an in-depth knowledge of the healthcare market, end-user requirements, safety, and regulatory compliance. The Hydra project's middleware for networked embedded systems allows developers to develop cost-effective, high-performance ambient intelligence applications for heterogeneous physical devices and developer users are the main target group of users.

The development of eHealth devices and systems has long been promoted within the EU and is an essential part of the i2010 initiative. Health Information Networks aim to speed the flow of health information through the healthcare system, so they range in nature from local hospital-doctor-patient networks through to Europe-wide systems for spotting emerging health threats. Effective and efficient medical device developers are thus a crucial resource for successful eHealth applications.

Medical device users are an extremely heterogeneous group and for any one device the users may include patients and their carers as well as various healthcare professionals. There are a number of factors that make medical device development challenging including the ethical and research governance involved with studying users as well as the inevitable time and financial constraints.

Besides the typical work flow used for developing embedded software products, such as requirements gathering, analysis, system design, detailed design, testing, and project management, there is one additional challenge in the medical device industry – compliance. Developers of eHealth devices and products need to observe a multitude of requirements for product performance and product safety.

It is thus essential that medical devices are developed in line with current Good Design Practice, as highlighted in (Alexander and Clarkson 1997, 1999a, 1999b). Medical device design differs from

conventional design as extensive regulations from the European Medical Device Directives (MDD) and the U.S. Food and Drug Administration (FDA) require that validation and design procedures are in place throughout the design phase.

The key European regulation in this area is the Medical Device Directive (MDD) Directive 93/42/EEC. The MDD covers the placing on the market and putting into service of Medical Devices that do not require invasive procedures with the patient (other directives cover these products). A full discussion of the requirements for putting eHealth services and products on the European market is found in the *D2.5 Initial regulatory-standards watch report*.

Security and trust issues are crucial to consider in future developments of healthcare devices and services. The EU Member States' specific data protection laws and the EU Data Protection Directive (95/46/EC) set national and EU standards for the handling of person-identifiable data, such as personal medical data. According to these laws and standards, the main requirements are that the handling of medical data must always have clear justifiable purpose, use the minimum of patient information and only be accessible to appropriate health professionals. Generally, in Europe access to and processing of medical data is allowed when it is considered necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services. Furthermore, the use of passwords, digital signatures and encrypted messaging will cater for the rules and regulations on both national and international level.

The FDA recently announced it is launching the Medical Device Innovation Initiative to make new medical devices available more quickly for patients. This broad initiative will promote early interaction between the FDA and industry to optimize review times and foster innovation. As outlined in a report released by the Agency, the Center for Devices and Radiological Health (CDRH) will expand current efforts to promote scientific innovation in product development, focus device research on cutting edge science, modernize the review of innovative devices, and facilitate a least burdensome approach to clinical trials.

New innovations and developments suggest an unfolding pattern of "smart" technologies that integrate engineering and biological approaches, and that enable increasingly precise clinical interventions as well as a progressively decentralized health care delivery system. The FDA is already seeing a steady increase in the number of requests from developers for pre-submission meetings to seek advice on the best approaches for scientific and clinical testing and evaluation of cutting-edge technologies, such as molecular medicines (genetic and proteomic diagnostics and therapeutics) and products developed using nanotechnology.

Six issues have been identified (Insup Lee, 2006) as critical for the future of high-confidence medical devices:

- *Foundations for integrating medical device systems.* Commercial off-the-shelf technologies do not produce highly distributed medical device systems with guarantees of security, privacy, robustness, interoperability, extensibility, mobility, and general patient safety. Advances in computing are instrumental in the development of novel diagnostic and therapeutic equipment and procedures and of widely accessible medical-record systems. Although diagnostic and treatment systems have advanced significantly, they do not work well together. The systemic inefficiencies in healthcare delivery grossly inflate costs and contribute to avoidable medical errors that degrade patient care.
- *Distributed control and sensing in networked medical device systems.* The networking of medical devices for distributed sensing and control can occur at many levels. These networks can collect data for offline analysis, generate alarms when critical conditions occur, or close feedback loops for the controlled delivery of drugs. Research is needed to create medical device networks with these features and to enable the diffusion of new sensing and control technologies as they become available.
- *Patient modelling and simulation.* Modelling has proved its value in many industries, such as aerospace, automotive, and chemical plants. It has fostered novel product development, increased safety parameters, cost-effective development phases, and ultimately achieving regulatory approval. In the medical-practice domain, modelling and simulation will improve outcomes and quality of patient-care, will provide better control of healthcare costs with

improvements in prevention, intervention, and will allow maximal use of the electronic health records.

- *Embedded real-time networked system infrastructure.* Researchers envision next-generation medical systems to be a ubiquitous network of networked systems that provide secure, reliable, privacy-preserving, and cost-effective, personalized, high-quality healthcare. Although networks of networked medical devices hold many promises and possibilities, they also create challenges.
- *Medical device software development.* Many medical devices are, essentially, embedded systems. As such, software is often a fundamental—albeit not always obvious—part of a device's functionality. This means that any safety and regulatory requirements for medical devices necessarily call for rigorous software development methods to ensure reliability and to protect the public health. Exactly how to accomplish that is a question, particularly because devices and systems are becoming increasingly complicated and interconnected. We have reached the point where testing as the primary way to gain confidence in a system is impractical or ineffective. Furthermore, requirements and specifications based on medical practice are needed to help ensure that devices will perform appropriately.
- *Validation and certification.* Verification and validation tasks required for the approval of medical devices play a significant role in enabling the FDA to carry out its mandate of approving only "safe and effective" medical devices. Unfortunately, many industry observers believe that we are approaching the limits of current device certification processes. As devices grow more complex and rely much more on embedded software to achieve critical functionality, existing certification processes are being stressed. This trend results in higher development costs for manufacturers, longer time to market and increased chances of device failure, with associated recall or liability costs.

The Hydra middleware for networked embedded systems will allow developers to develop high-performance intelligence applications for heterogeneous physical devices and is thus extremely well positioned to help develop users meet most of the above challenges.

5.1.2 Healthcare provider perspective

Healthcare is divided into three areas: primary, secondary and tertiary care. Primary care can be defined as the basic or general healthcare focused on the point at which a patient ideally first seeks assistance from the medical care system. Primary healthcare is usually provided in the community by general practitioners (GPs), local health clinics, district nurses and primary care specialists (e.g. physiotherapists). In Europe, primary care generally falls within the administrative responsibility of regions/districts, while local municipalities are often responsible for long-term care and home-care. Secondary care covers ambulatory medical services and hospital care (inpatient and outpatient services), thus offering specialised care generally provided through referral from primary care providers. Tertiary care is the highly specialised care offered in specialist (or university) hospitals with sophisticated technological facilities and support. Hospitals offering secondary and tertiary care are generally administered at regional/district level or privately, although some EU Member States have a more centralised administration of hospitals.

Enabling patients with chronic diseases to manage and monitor their condition from home or away thus avoiding spending hours in the doctor's office for regular check-ups, will not only mean that patients are more mobile and less dependent on their GP or the surgery's opening hours, it will also enable patients to take better control of their disease and thus ultimately save money for the health care providers. Studies have shown that when patients are more involved in their own health care, they monitor and manage their chronic disease more efficiently, for example by taking their medicine as appropriate.

Improving chronic patients' condition and lives will be a major challenge for healthcare providers in the future as more and more patients develop chronic diseases like diabetes. Providing self management schemes and remote monitoring will enable healthcare providers to meet this challenge, patients' quality of life will be improved, the treatment of diseases will improve and at the same time, healthcare providers will be able to cut costs on commissioning fees as patients will need less consultation time with GPs. Moreover, healthcare providers will be able to cut down on hospital

costs as unnecessary admissions may be avoided and as the length of hospital stay can be cut down as patients will be able to be dismissed earlier and instead monitored closely at home.

Before installing any healthcare monitoring systems and services, healthcare providers will make a thorough examination of not only the technical solutions, both in terms of functional and extra functional qualities.

Commissioning of eHealth *services* (based on Hydra enabled devices) will in most cases be done on the basis of a Service Level Agreement, setting out detailed requirements and measurable goals for the services to be rendered. The SLA will often to have both quantitative and qualitative objectives. The qualitative objectives can be documented by providing patient feedback schemes as part of the services. Such schemes can either be direct on-line feed back from the patient during a home session ("Are you happy with the attention you received from therapist X", or "Did this treatment reduce your pain?"). The patient could be given the question on a display or in natural language and will have to respond immediately[4]. Such functionality can further be extended to include employee satisfaction and process improvement schemes ("Was this difficult to perform?" or "Could this process be improved?"). Hydra enabled devices should be configurable to provide the basis for such on-line inquiries and polling.

The quantitative objectives can be measured and documented through the extensive data logging capabilities of Hydra enabled devices. Logging of time, place, employee ID, patient ID, etc. allows for detailed analysis of not only clinical history, but also workflow and work patterns. Logging of specific application data can also be provided in order for application programmers to develop specific performance measures. This would in many cases be the essence of the service to be provided such as compliance or well-being parameters.

Typical operational service levels will be availability (up-time better than 99.999%), security, scalability, loss of data, processing speed, etc. These will be individually negotiated for each SLA, and metrics will be developed. The Hydra middleware must support the corresponding means of measurability.

The Hydra middleware must support a security policy framework that allows applications to accommodate a wide range of service providers in the healthcare domain. An application security policy will be derived from a summary of the security and privacy requirements in the relevant healthcare domains. These requirements are transformed into an all-encompassing security policy for the application, and the Hydra security support architecture that implements the security requirements.

5.1.3 End user perspectives

Understanding the needs of end users and integrating those needs into development projects lies at the heart of producing effective medical devices. Measuring and fulfilling user requirements during medical device development will result in successful products that improve patient safety, improve device effectiveness and reduce product recalls and modifications.

The success of new solutions in ICT for personal healthcare will depend critically on the use and acceptance by the market. Research has shown that not everyone will automatically accept and use ICT products and services in their everyday life[5]. Usability and acceptability depend on various factors: adequate design, financial resources, living circumstances, personal attitudes and experiences and the advantages and practicality of the devices.

From an end-user perspective, designers and developers of devices, systems and applications must face this challenge, which will require addressing real healthcare and homecare needs such as these examples illustrates:

Safety: Making sure entrance doors and windows are locked when leaving the house or sleeping, checking for water leaks and gas leaks, checking for windows left open for an excessive time in winter, turning off lights intelligently depending on context.

[4] The product HealthBuddy© is a good example of such kind of communication platform
[5] i2010: Independent Living for the Ageing Society, European Commission Information Society and Media, Publications Office 2007

Reminders: Support in compliance, medication intake, household task, making sure clocks are always accurate.

Information: Easy to understand and easy to operate access to information tailored to specific needs.

User-friendly interfaces: All sorts of systems need to take into account personal impairments and requirements for an all-inclusive healthcare system.

Solutions should be able to adopt to the end users needs over time. Ethical implications of the solutions, such as privacy, confidentiality and security of data, also need to be adequately addressed.

In the design of healthcare solutions, it is very important not to forget the formal carers. Both professional carers and family members play an important part of patient's lives. Technological solutions must support these carers and families as well as the patients themselves.

Home healthcare services are unique in that they are provided in both professional cares and non-professional, non-managed (i.e., the home) settings. Surroundings differ from case to case. Some patients are pleasant and cooperative; others are angry, abusive, depressed, or otherwise difficult. The services can be self-administered or provided by trained professionals, paraprofessionals, and volunteers. Services for the treatment of medical conditions usually are prescribed by the GP. Health care devices within the home healthcare setting might be managed by the patient, family member or even a non-licensed paraprofessional such as: Home care aide/home health aide, certified nursing aide, homemaker, companion/sitter, volunteer. No prior work experience or higher education may be necessary for any of these positions.

Patient health literacy is still very much an issue, if the patient is required to be monitored or treated while at home or while ambulatory. The devices and user instructions must meet the low literacy demands of the populace. A major US university teaching hospital suggests that the instructions provided with infant car seats can not be comprehended by more than half the parents [Harding 2006] and suggests that all health care information to be processed by patients and non-professional providers be written at the sixth grade level. Device design elements must take into consideration the health literacy rates of patients.

Thus, the challenges to the medical device developer to satisfy end user requirements are the identification of limitations and obstacles inherent with a patient population in control of their surroundings and a workforce that varies in training, skills and competencies.

5.2 Generic requirements derived from the scenarios

From the scenarios, the following high-level developer user requirements for Hydra enabled devices can be derived:

The "Overload" scenario *(in which end users and healthcare users co-operate within constrains)*

- Configurability, secure and regulated environment, technology drives application development

The "Joining Hands" scenario *(which describe end user and developer user in a healthcare environment)*

- Self configuration, new body networks, reliability and trust, intelligence needed with resource constrains

The "My Way" scenario *(in which a developer user & system integrators cooperate in networking)*

- Network architecture, high & low bandwidth applications, secure communication

The "Brain Trust" scenario *(in which end-users are provided with centralised, secure healthcare applications)*

- System controlled security, compliance monitoring, identity management, registration and monitoring

5.3 Specific requirements derived from the scenarios

During the scenario workshops, a large number of environmental factors were recorded, discussed and subsequently analysed. The discussion revealed a number of high-level generic requirements for future medical applications, devices and systems. These requirements will be addressed in the Hydra middleware so that it will allow the development users to develop exactly the innovative healthcare applications that are needed. From the scenarios and storylines, a systematic formalisation of all relevant user requirements and functional, security and societal requirements has been derived.

The following table list the generic and specific healthcare requirements, which have been identified in the four scenarios. The requirements are reflected, either directly or indirectly, in the technical requirements reported in *D2.5 Initial requirements*. The process of re-engineering of requirements are described in *D3.3 Draft of architectural design specification*.

No,	Scenario fragments	Derived requirements	Impact
	2.1 Overload		
33	*virtual community in which members use internet and wireless technologies*	End users should be able to become members of a virtual community	Runtime view
34	*…that data from Michael's medical devices can be automatically uploaded to his patient record (EPR)*	Secure and automatic access to external web services must be provided	Device view Runtime view
35	*…using the 3G broadband network in Michael's truck*	Support for mobile gateways and 3G communication should be provided	Device view
36	*…data are encrypted and stored on his smart device*	Local data persistence and security should be possible on mobile units	Device view
37	*Michael receives an audio message via his car stereo*	Automatic interoperability of vehicle devices facilitates ad hoc networking	Device view
38	*…calls him on the mobile phone to congratulate him*	Availability of mobile phones is assumed	Runtime view
39	*The smart device analyse the restaurant's lunch menu and displays a list (in English and French)*	Multilingualism should be supported in Runtime view applications	Runtime view
40	*…geocoded with location information*	Applications can rely on location information for location awareness	Runtime view
41	*… as the UK government last year introduced health-dependent tax relief*	Economic incentives drives business models	Business models

No.	Scenario fragments	Derived requirements	Impact
	2.2 Joining Hands		
42	*… creates a personal self-management profile in the SMSQ system*	Intelligent applications are able to use semantically coded missions and objectives	Runtime view
43	*…creates a dedicated e-learning environment*	Integration with existing data repositories and interactive applications is needed	Runtime view
44	*…additional customised information from internet resources*	There is a need for semantic search agents	Runtime view
45	*…information about which in-vivo parameters should be monitored at regular intervals, their threshold values and measurable milestones*	Rules based decision support should be possible	Runtime view
46	*…simultaneously enables the electronic billing system*	Application should have logging capabilities in support of accounting	Device view Business models
47	*…SMSQ system monitors all data traffic and performs the alert services*	Rules based filtering and alarm services should be provided	Runtime view
	2.3 My Way		
48	*…create a new paradigm for integration and cooperation between data, devices and systems*	Interoperability of existing networked systems and intelligent devices and data repositories must be facilitated	Device view Runtime view
49	*the medical network would be organized into layers with the patient at the centre*	Support of individual network architectures must be supported	Device view
50	*… sensor devices produce large streams of data which must be collected and assessed*	Data must be assessed and stored at the source for efficient storage and retrieval	Runtime view
51	*The radiology department wanted this system to be available to other departments*	High speed, wide band networking is required	Device view
52	*…performing robotic telesurgical procedures on urological patients*	Secure, real-time interconnectivity must be supported	Device view
	2.4 Brain Trust		
53	*…online form allowing Dr. Nielsen and selected health care providers to access her central health data*	Applications must rely on a user-centric security model Data privacy is important	Device view Runtime view
54	*Ella's husband makes sure that the pharmacy checks the RFID tag on the package*	Authentication of devices using RFID is needed	Device view

No.	Scenario fragments	Derived requirements	Impact
55	*He stores the information as a document on his PDA*	History of products and authentication must be shared with end-users	Device view
56	*The pharmacy does not register which drugs have been delivered to which patients*	Privacy of end users data required	Device view
57	*…principally approve the creation of a central register for medicine use*	Support for secure, central data repository of events needed	Device view

5.4 Summary of requirements derived from the scenario thinking process

The functional user requirements specifications include the most important aspects of user expectations in healthcare applications. The scenario workshops concluded that the following specific requirements were most relevant for the healthcare domain:

Functionality
Device functionality and complexity will increase sharply. The use of intelligent multi-parametric biomedical monitoring devices using non-invasive or minimally invasive sensors is expected to explode. Quantitative and qualitative monitoring will routinely be used for self-management of diseases and early prediction of conditions. Remote diagnostics will perhaps also be available using body sensor networks as a way to predict and prevent development of diseases. Hydra middleware needs thus to support real-time data processing, intelligent decision support and interconnectivity via heterogeneous networks.

Further, human to device interaction will increasingly use aspects borrowed from the entertainment industry to motivate patients to manage their health better.

Communication
Medical sensors and devices will use near field wireless communication technologies, such as body networks, equipped with mobile communication devices acting as gateways and the Hydra middleware must support this. Sensors and devices may have vastly more intelligent functionality that today.

Wireless solutions are generally preferred for all healthcare applications in connected and networked applications, but may be restricted to critical healthcare applications due to the possible health concerns stemming from electromagnetic radiation from wireless devices. Hence different types of communication should be supported in a dynamic environment.

There may not always be unlimited bandwidth available for any amount of data transfers, so the Hydra middleware must allow device manufacturers to design their devices to be adaptable to varying bandwidths.

In the case of continuing high cost of wide-area (WAN) telecommunication in remote areas, the uptake of medical monitoring devices with real time connectivity may not be extended to most of the citizens in all areas. The Hydra middleware should therefore support intelligent and secure data persistence features in order to avoid that economical constraints impose a negative affect on the use of remote healthcare monitoring.

Privacy and security
Privacy of personal health care data is essential, not only for user acceptance, but for the credibility of the entire health systems. Devices and applications will therefore have to comply with strong user requirements and strict national legislation regarding access to patient data, both sensitive and non-sensitive. Patients will own their own data and need to be empowered to manage identity, authentication and access rights models for any device or application containing or accessing their

health data. The Hydra middleware must support development of applications with such empowerment.

Trust and security models will be needed for permanently and temporarily stored data as well as for real time data transmitted by application infrastructures and communication networks. Future security models that take a holistic view on security, privacy and trust should be supported.

Power

Developers of medical devices will increasingly face problems of resource constraints, in particular limited power for desired functionalities. Although technological solutions that do not rely on traditional batteries may be available, device performance need to be independent of how much, or how little, energy is required in order to perform a desired function.

Design

Due to ethical and psychological concerns, healthcare support devices will be "invisible" so they do not signal illness and the exterior design will increasingly be dictated by fashion and trends.

A significant challenge to device manufacturer is the increasing problem of electronic waste and environmental hazards.

6. The healthcare vision scenario

With a view to the completeness and complementarity of the total universe of technical requirements, the "Overload" scenario can be chosen for inclusion in the demonstrator development.

Parts of this vision scenario can thus be incorporated in technical user scenarios throughout the project, which in turn can provide demonstration of the progress of the project and the use of the Hydra middleware in the healthcare domain. At different iteration levels, various aspects of the scenario will be made available for demonstration as defined in the technical scenario. The precise content of healthcare applications in each demonstrator will be determined during the course of the project and will depend on the availability of Hydra components at the time of implementation and demonstration.

The aim is that the final demonstrator (M48) will be capable of providing a demonstration of a full developer user technical scenario, which will be able to generate applications such as those foreseen by domain experts in the vision scenario.

6.1 The "Overload" scenario

Michael Johnson is 29 years old and is severely obese with a BMI[6] of 31. Overweight increases the risk of many diseases and health conditions, including hypertension, diabetes II, stroke and others. Michael lives in Southampton, UK, and works as a long-distance truck driver. He spends most of his time on the road which has become a second home for him. He drives all over Europe but rarely get a chance to see much other than motorways, the restaurants and rest areas along the motorway. He doesn't mind so much; he just loves driving his truck and being independent.

About 6 months ago, he fell very ill with strong chest pains. After several tries he finally managed to set up consultation with his family GP, Dr. Ross. After extensive examining and blood tests, Dr. Ross called him in to tell him his diagnosis: *"I am afraid that due to your overweight, you have developed diabetes type II, Michael. Your blood pressure and your cholesterol figures are also too high"*. Dr. Ross went on to give Michael a thorough introduction to diabetes, its occurrence and the potential risks he was facing. Dr. Ross also told him that he must loose weight, start to eat a healthier diet and do more exercise, if he wanted to steer clear of a heart attack, which could potentially kill him.

Dr. Ross wanted to put Michael on a strict clinical treatment programme with close monitoring. He wanted to track Michael's glucose level and blood pressure to avoid potentially life threatening situations and keep an eye out for any deterioration of Michael's general health status as to alleviate occurrence of related conditions. For longer term health improvement, he instructed Michael to loose at least 4 stones (25 kg). The treatment plan was a combination of dietary changes to a fat-free, high nutrition diet, and daily exercise. Dr. Ross told him that weight loss would lower his blood pressure and improve cholesterol level. Since he had diabetes II, it could also reduce his blood glucose and haemoglobin A levels. *"Weight loss and exercise is thus a key factor to your wellbeing. You must learn to manage your disease"*, Dr. Ross told him.

At first, Michael was very dismissive about Dr. Ross' instructions and showed no interest in following the self-management scheme. Being constantly on the road makes it hugely inconvenient for him to monitor health status, change his diet and exercise. On the other hand he is slightly worried about his future life, so when Dr. Ross tells him about the liaison communities that exist for patients like him, he becomes interested. A self-management group, OurHealth, has recently been created in Southampton. It is formed around a virtual community in which members use internet and wireless technologies to stay in contact with each other anywhere, anytime, posing new ways of interacting socially. It uses peer pressure to help members stay on track with their diet and weight loosing

[6] Body Mass Index (BMI) is basically the relationship between a person's height and weight

programmes. The virtual community also includes doctors, other healthcare professionals, such as dieticians and fitness instructors, and ICT experts maintaining the community infrastructure.

It all fitted quite well with Michael's work and lifestyle and he decides to give it a try. On Dr. Ross' recommendation, Michael buys electronic home care devices that can measure his weight, blood pressure and glucose level. The devices are battery operated and he can easily carry them with him. Tim Jones, an ICT specialist in OurHealth suggest to Dr. Rah, one of doctors at OurHealth, that Michael should be more closely monitored when he is on the road. Tim suggests that data from Michael's medical devices can be automatically uploaded to his patient record (EPR) using the NHS Connecting for Health backbone[7]. In this way, Michael can be professionally monitored without really realising it. Since all devices are BlueTooth enabled, Tim suggests equipping Michael with a mobile phone with BlueTooth and java processor. Tim will then turn it into a multiple-parametric smart device that automatically can upload data to the NHS system, for doctors to monitor his progress.

Michael is extremely happy with his new smart device, which he uses for entertainment (music and movies), information (news, traffic and weather), communication (voice and text) and now medical monitoring and feedback. The smart device collects and sends off the readings to his EPR in NHS using the 3G broadband network in Michael's truck. This network is used for fleet management and technical monitoring of truck performance by his company, but the company has allowed its drivers to use it also for private communication. The truck's GPS system also provides location information.

Today is a typical day for Michael. It is his second day on the road on the way from Southampton to Lisbon. Michael has performed his usual measurements and the data are encrypted and stored on his smart device, where they are filtered and compared to previous readings. As long as the data remains on the smart device, they are completely private and Michael needs to authorise each secure transmission to the NHS databases. When the data have been analysed, Michael receives an audio message via his car stereo, which the smart device has automatically interfaced to. This way he can keep his eyes on the road. It informs him that the measurements are good. His cholesterol level is down, his weight is down and the glucose level is stable. It asks him if he wants to upload the data to the NHS system. Michael confirms in natural language and the data are uploaded. Five minutes later Dr. Rah from OurHealth calls him on the mobile phone to congratulate him. The data filter has flagged Michael and both Dr. Rah and Dr. Ross have been notified.

The next hour, Michael chats with friends from OurHealth until it's time for him to stop for lunch. As Michael drives into the parking lot, his smart device registers the different food the restaurant offers translated into English. The information contains dietary information, which is compared to his health data collected earlier that day and his dietary plan. The smart device analyse the restaurant's lunch menu and displays a list (in English and French) of the food that Michael can have. Michael chooses a salad and the kitchen automatically receives his order, when he enters the restaurant.

The biggest challenge however, has been to get Michael to exercise. Michael practically lives in his truck and he never sets foot near a fitness centre. But Michael has got a new pair of Nike running shoes. Build into the shoes are wireless sensors that collects information on the number of steps taken and calories burnt. Data are sent to his smart device and when he gets back to the truck, the smart device uploads the data to OurHealth database; geocoded with location information. There is fierce competition among the virtual community members for running the longest distance. A winner is drawn every week and featured on the community's web site. A special price is also given to the two members, who have been furthest away from Southampton. Michael thinks this is great fun.

As a consequence of joining the OurHealth community, Michael is on his way to a better life. He is now very much in line with the increased public focus across Europe on healthy food and exercise; his BMI is reduced to 28 and he is slowly moving into a lower risk group. Once he reaches his weight goal, he can also look forward to a decrease in his tax payments, in an attempt to encourage healthy lifestyles.

[7] NHS: The UK National Health Service's National Programme for IT connects over 30,000 GPs in England to almost 300 hospitals.

7. References

Alexander K.L. and Clarkson P.J: Observations on Medical Device Design, Part I: Current Practice. Medical Device Technology, 10 (7), 1999a.

Alexander K.L. and Clarkson P.J: Observations on Medical Device Design, Part II: Good Practice. Medical Device Technology, 19 (8), 1999b.

Alexander K.L. and Clarkson P.J: Design for Validation of medical Devices and Equipment. Proceedings of the International Conference on Engineering design, Tampere, Finland 3, 1997

Bratan, T. & Clarke, M.: Towards the Design of a Generic Systems Architecture for Remote Patient Monitoring, 27th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 1-4 September 2005, Shanghai, China, 2005

Harding Gary H. A Tutorial on Emerging Medical Device Technology in the Distributed Diagnosis and Home Healthcare (D2H2) Environment, 28th Annual Conference IEEE Engineering Medicine and Biology Science, September 2006

Lee Insup, Pappas George J., Cleaveland Rance, Hatcliff John, Krogh Bruce, Lee Peter, and Sha Lui. High-confidence medical device software and systems. IEEE Computer Magazine, April 2006

Reid, J.A.:Telemedicine Primer: Understanding the issues. Billings, Mt./USA: Innovative Medical Communications, 1996

US Center for Disease Control and Prevention, National Center for Health Statistics, 1997