

Technical assessment of the HELLODOC service

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Summary. A technical assessment activity has been conducted by Istituto Superiore di Sanità (ISS) in the European project HELLODOC (Healthcare service linking tele-rehabilitation to disabled people and clinicians) for evaluating the tele-rehabilitation service. The activity was mainly focussed on architectural aspects and a step by step monitoring of the service. It was mainly related to the following aspects: service implementation, service performances, service integration and fault management. The technical assessment analysis demonstrated that the service worked in a quite satisfactory way, also considering the pioneering aspect of the project; the set of malfunctioning occurred, which had a low impact on the service continuity, are typical of a post-debug phase.

Key words: tele-rehabilitation, telemedicine, technical assessment.

Riassunto (*Valutazione tecnica del servizio HELLODOC*). Nell'ambito del progetto europeo HELLODOC (*Healthcare service linking tele-rehabilitation to disabled people and clinicians*), l'Istituto Superiore di Sanità (ISS) ha condotto l'attività di valutazione tecnica (*technical assessment*) sul servizio di teleriabilitazione. L'attività, condotta per l'intera durata del progetto stesso, è stata focalizzata su aspetti architetture del servizio e sul monitoraggio del progetto in esame, ed ha riguardato principalmente le seguenti aree: implementazione del servizio, prestazioni del servizio, integrazione del servizio (all'interno del sistema informativo aziendale) e gestione dei malfunzionamenti. L'attività ha dimostrato come il servizio, considerando anche lo stato pionieristico del progetto stesso, abbia funzionato in modo soddisfacente; i malfunzionamenti occorsi, tutti di basso impatto sulla continuità del servizio stesso, sono tipici di una fase *post-debug*.

Parole chiave: teleriabilitazione, telemedicina, valutazione tecnica.

INTRODUCTION

HELLODOC is the acronym for "Healthcare service linking tele-rehabilitation to disabled people and clinicians". The project started on March 2005 as a 18-months European project co-financed by the European Community programme eTEN. It was successfully closed on February 2007 after a 6-months extension.

The primary objective of the project was to validate the EU market – more specifically in Italy, Spain and Belgium – for a home-care service. Main aim of the service is to extend the rehabilitation treatment at patient's home under close supervision of the hospital. The tele-rehabilitation service is mainly addressed to neurological patients affected by traumatic brain injury (TBI), stroke or multiple sclerosis (MS). The HELLODOC project aimed at investigating whether it is possible to propose a multipurpose home-based

rehabilitation platform that can improve the functional recovery of the upper limb and thus promote social re-integration (www.iss.it/hdoc).

Basically, the HELLODOC system consists of two main apparatuses: an in-hospital based server and a portable unit to be installed at patients' home. The service is tailored at overcoming the current barriers for an effective application of ICT technology in the rehabilitation sector accounting the main findings and recommendations obtained during the course of the European research project H-CAD (Home care activity desk; www.hcad.net), concluded in August 2004, where a pre-engineered prototype of the patient unit was developed and tested. The portable unit of HELLODOC is an improved version of such a prototype. It allows the execution and monitoring of a set of rehabilitative exercises aimed at arm functionalities recovering, which can be re-

motely designed and configured and monitored by the professionals.

During the course of the project, the Istituto Superiore di Sanità (ISS), the Italian National Institute of Health, conducted a technical assessment activity in order to consolidate and rationalize the changes and modifications that H-CAD experience urged to introduce in the new service provided by HELLODOC.

Main aim of the paper is to show the peculiarities of the system from a technical point of view, focussing attention on the service provided and difficulties arose during the experience, while the clinical evaluation will be discussed elsewhere.

SYSTEM DESCRIPTION

Generalities

The system consists of three main apparatuses:

- 1) portable units (PU) to be installed at patients home;
- 2) a communication server, handling all the data exchange and storing, installed in the hospital;
- 3) an in-hospital unit, a doctor PC equipped with a proper management software; it is connected through hospital LAN to the Communication Server and is able to run the server side application suite.

The service is provided by the connection of the three apparatuses as shown in *Figure 1*; it is worth mentioning that the connection between the PU and the hospital unit is based on the public network.

The system provides the patient with the following facilities:

- a configurable, modular highly expandable exercise session to allow him/her to execute the reha-

ilitative program at home under the supervision of a family person (care giver) [1];

- a videoconference encrypted module which can be used at any time to connect patient and hospital-based clinician [2].

The portable unit

The HELLODOC PU platform has been conceived by stressing two concepts:

- 1) *modularity*: the PU has to be easily adapted to future expansions and modifications [3];
- 2) *easiness to use*: the PU has to be used at home by a generic caregiver [4].

Taking into account these concepts, the system has been developed to manage several exercise modules which are linked through a proprietary data bus: each module is automatically recognised by the platform (via software) in order to perform its activation and for diagnostic procedures. Beside this, an interface via standard USB1.1/Serial has been integrated in order to "open" the platform to different products.

Starting from service needs arisen by a close collaboration with clinical centre and a deep review of the results of the previous H-CAD project, an intense phase of redesign of the H-CAD tele-rehabilitation PU took place which resulted in the product shown in *Figure 2*.

Description of the portable unit hardware modules

The parts described below are the main physical components of the system located at the patient home:

- *desk*: it is a specially engineered, four-leg table, covered with a sheet of Lexan polycarbonate, over which all the other modules, parts and components find a stable and safe place. This renders the PU a complete, self standing system, easy to

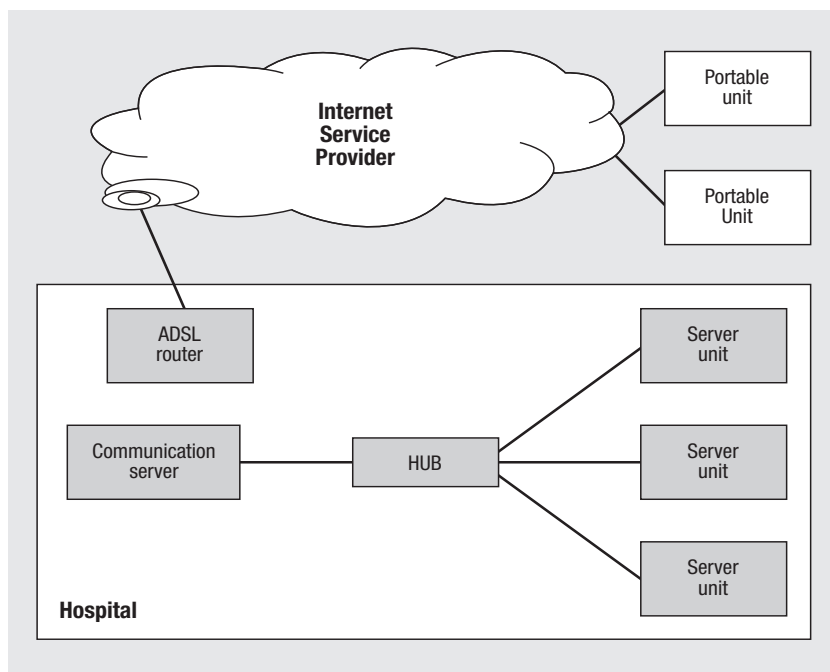


Fig. 1 | Connection of the three sub-apparatus allowing the system to run.

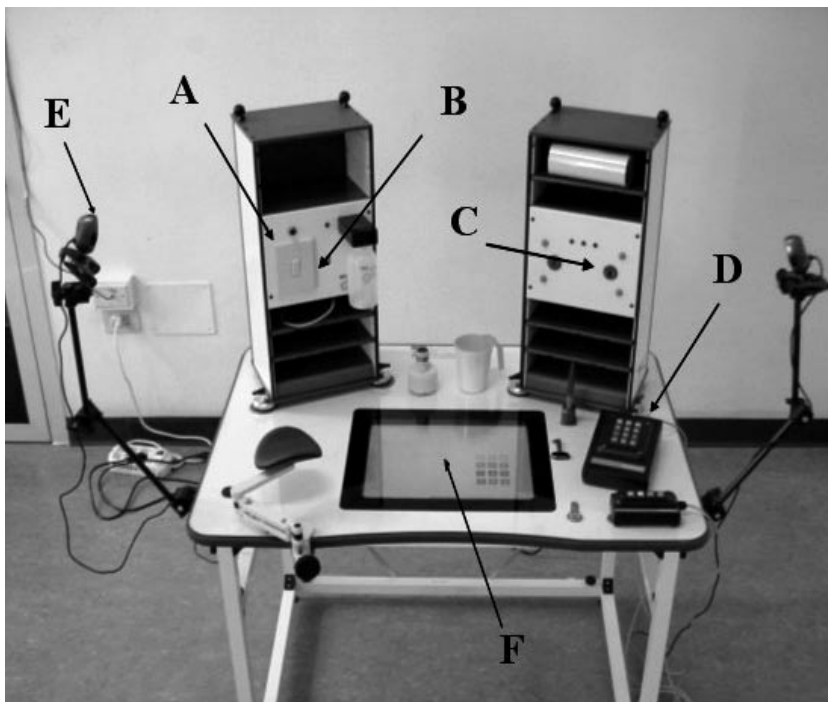


Fig. 2 | *The HELLODOC PU with the embedded sensors.*

A: sensorized area position; B: sensorized lightbulb module (trigger, on-off switch position); C: sensorized key module (trigger, angular position); D: sensorized keyboard (pressure); E: webcam (kinematics); F: sensorized area (pressure, position).

be installed at patient's home. It can be quickly assembled or disassembled and is provided with ad hoc cases for transportation;

- *computer*: a PC is embedded in the structure, for the management of all the system functions through dedicated electronics and standard interfaces. Its presence and working is completely transparent to the user;
- *an LCD monitor with graphic tablet*: located at the center of the table, under the transparent Lexan cover. It is used for display and sensing purposes, including the measurements of the pression the patient exerts during specific exercises which will be described in the following;
- *control pad*: it is the simple user interface used by the caregiver who assists the patient during the exercises;
- *shelves*: they are shelf-like cases where a series of removable tools may be placed or firmly locked; this feature allows the execution of those exercises that require a vertical displacement of everyday-like objects. Generally, two units (left and right) are supplied and are fixed on the table by means of suction cups, easily operated by rotating knobs located in the upper side of the shelf itself. Each unit is equipped with 32 position sensors, to confirm the correct position of the PU tools and to detect the initial and final positions of movable objects;
- *light bulb module*: it is a shelf tool for the execution of exercises simulating the usual screwing and switching operations of a light bulb. Sensors are included to verify the completion of tasks;
- *key module*: it is a shelf tool for the execution of exercises simulating the insertion and the rotation

of a key in a keyhole. Event detection hardware and angular transducers are included;

- *keyboard module*: it is a phone-like numeric keyboard that has been designed for the execution of patient's exercises. The module is placed on the desk of the PU and is connected to the PC to allow accurate event detection;
- *objects*: specially designed objects, similar to everyday ones, including a book, a jar and a pencil. They allow the execution of various exercises, both in the horizontal and vertical planes. A radio frequency (RF) tool may also be used to locate objects on the desk plane. It is a small plastic cylinder (tag) containing the needed electronics;
- *video cameras*: a couple of webcams with articulated stands are supplied for the video recording of the exercises and to perform video-conference sessions;
- *arm support*: it is an arm support which renders the exercise execution easier and more comfortable in presence of severe upper limb impairment.

Figure 2 shows the described modules, and information about position and function of the sensors the PU has been equipped with.

The portable unit software structure

The PU is completely managed by a dedicated software application – exercise manager – which allows the user (care giver) to control all the PU functions by means of the control pad module. This is connected to the PC via a PS2 keyboard connection: this solution has been considered much simpler than a complete keyboard and mouse set, and allows a control of the system similar to a TV remote control.

The visual interface supplied by means of the embedded LCD screen uses a colour related codes for each choice – green, red, yellow and blue – that are the same colours reported on the control pad keys, avoiding in such a way potential ambiguousness.

Exercise manager is based on a layered structure that is constituted by 5 interfaces:

- main interface;
- exercise session interface;
- tutorial interface;
- exercise interface;
- video-preview interface.

The user can easily select the interface by interacting with the Control Pad; at the end of each exercise session, the application stores the recorded data – included video – in the local PC and, on the basis of configuration settings, establishes a VPN connection to transfer data towards the communication server.

Descriptions of executable exercises

Within the HELLODOC project the following rehabilitative exercises have been implemented:

- *pencil*: patient may be asked to follow a path on the screen or to perform writing activities on it; in both cases he has to use a RF pen-like tool;
- *jar*: patient is asked to move a jar to and from the shelves, and on the sensorised area of the screen. The jar is covered with reflective tape, in order to be detected by each shelf position sensors;
- *book*: patient is asked to move a book to and from the shelves. The book is covered with reflective tape, in order to be detected by each shelf position sensors;
- *key*: patient is asked to insert a key and then rotate it up to an established angular position;
- *lightbulb*: patient is asked to screw and unscrew a tool which resembles a lightbulb, and to turn on and off two different switches;
- *keyboard*: patient is asked to press the keys according to an established sequence;
- *checkers*: patient is asked to move the checker-like tool on the sensorised screen according to established paths.

Each type of exercise entails the acquisition of a number of variables which are potentially useful to better understand the quality of its execution: the objective is to collect day-by-day information about the performance of the patient in executing the exercises. The first “raw” parameter is constituted by the overall time duration of each exercise: this value has a threshold limit that is fixed by the therapist – on the basis of each patient’s ability – during system configuration. The duration of each exercise is recorded even in case of an anticipated stop of the execution. For each type of exercise a set of specific variables are also recorded, like time duration of sub-phases of the exercise, linear or angular positions, pressure, event occurrence. Two video files are also acquired during the exercise execution and transmitted off-line, to allow the rehabilitation professionals to associate the recorded parameters with patient’s real movements [5].

The communication server

Network service implementation relies on the communication server based on Linux operative system. The communication server is the unique end-point of a virtual private network (VPN) communication channel. It connects the PUs, working as a firewall between the hospital LAN and the WAN. The implementation of the VPN is based on the open source package OpenVPN (www.openvpn.net) because of its complete interoperability with Linux operating system, its relative lightness in terms of overhead, protocol selection features, simplicity of its client-server architecture and flexibility.

It should also be considered that OpenVPN, for its confidentiality and authentication features based on SSL/TLS, assures a better security level than other legacy solutions.

Feasibility of remote sites monitoring and management has been provided by means of secure shell (SSH) solution.

For each single site a first-level security test has been performed by using nmap (<http://insecure.org/nmap>); it is an open source network scanner for network exploration and security auditing, allowing host discovery and port knocking. Results of this preliminary test has confirmed a high security level of the network service.

Hospital side applications

The doctor PC software allows clinicians to:

- 1) remotely configure the patient exercise session by:
 - adapting specific exercises, starting from the pre-defined exercise templates;
 - defining the parameters to acquire, among those suitable for each exercise;
- 2) take an overview of each exercise session by viewing a recorded video and by monitoring time and duration of the execution;
- 3) have a look of each exercise through a synoptic panel displaying the video recorded by the camera and the values of the sensorised items (*i.e.*, achievement of the target, position on the vertical and horizontal plane, pressure exerted);
- 4) perform inter-session comparisons to highlight the eventual recovery;
- 5) manage a videoconference channel that can be activated at any time on patient request and/or according to scheduled appointments.

TECHNICAL ASSESSMENT METHODOLOGY

Aim of this section is to describe the activities conducted during the project course to assess the whole HELLODOC “product” from a technical point of view.

In general, the methodology used in the evaluation of the effects of telemedicine interventions is still in its early stages of development. This might be due to the lack of validated methods and procedures for telemedicine technical assessment. DeChant *et al.* proposed a

four-staged approach to telemedicine evaluation [6]. According to this approach, telemedicine assessment should address:

- technical validation, also including user satisfaction;
- clinical validation (effectiveness);
- efficiency of the application;
- generalizability of the application.

It should be observed that the last two stages are only suitable for mature applications whereas the first two are applicable to immature applications too. However, in order to obtain a successful implementation of telemedicine products and services in clinical practice, there is need for more comprehensive evaluations of quality, acceptability and costs [6].

As for the assessment activities conducted within the HELLODOC project, they have been grouped according to the main aspects of the service as a whole. They have thus been structured in four main areas:

- 1) service implementation (further expanded into well defined sub-activities);
- 2) service performance (further expanded into well defined sub-activities);
- 3) service integration;
- 4) fault management.

System features have been analyzed from different points of view, taking into account all the actors that have somehow come into contact with the system: designers, technicians, installers, clinicians, patients and caregivers. Each feature has been analyzed with special attention to the critical state.

Service implementation

The assessment of service implementation dealt with the examination of the relevant technical aspects involved in the realization and installation of both the PU and the hospital unit. This activity has been structured in:

- review of design choices;
- examination of product files and manuals;
- verification of technical specifications;
- analysis of safety requirements;
- easiness of use and acceptability by patients;
- consultancy for CE certification;
- data integrity and security;
- hospital integration.

Service performances

The assessment of service performances entailed the evaluation of the quality of the system functioning and the level attained in the fulfilment of its essential requirements. This activity has been divided into:

- methods for evaluation of quality of service;
- connection and service availability;
- videoconference quality;
- recorded parameters quality;
- possibility of outcome assessment;
- reliability and technical assistance.

Service integration

The assessment of service integration aimed at evaluating the service in the perspective of general telemedicine networks. The goal was to define and verify the minimum requirements for communication protocols and exchange formats that could be useful to improve the interoperability and integration of the service.

Fault management

In order to improve knowledge on system reliability, faults occurred during the project have been collected, classified, and finally studied. "Fault" was here intended as every kind of technical trouble or failure that caused an interruption of the service delivery.

Faults classification has been structured on the following fields:

- *identification label (ID)*: it allows to unequivocally identify the specific trouble;
- *category indication (CAT)*: it specifies the cause of the fault. It can refer to: hardware (HW), software (SW), networking (NW), and mechanical (MH) causes;
- *impact indicator (IMT)*: it identifies three levels of impact on service functional capabilities:
 - critical level C: it identifies a situation in which the service was no longer available;
 - limitation level L, when the impact is not critical but some system functionalities were limited;
 - performance deterioration level P;
- *description field (DESC)*: it collects information useful for characterization of the fault;
- *indication of sites (PREM)*: it specifies, the site where failure happened;
- *frequency (FREQ)*: it specifies the number of events expressed as occurrences/month;
- *possibility to reproduce (REP)*: it specifies the possibility or not to reproduce the problem in laboratory;
- *actions taken or solutions adopted (AT)*: it describes the technical solutions adopted in order to face the issue;
- *causes (CS)*: it describes the causes of the event, in case they have been identified;
- *solved (SVD)*: it is a Boolean value which indicates whether or not the problem has been solved.

At the end of the collection process, a repository was created and used as the starting point for further analysis.

RESULTS

The assessment activities described in this paper are mainly concentrated on architectural and functional aspects, but, as technical assessment can only be defined on the basis of the intended use of the system, it is worth to recall some points defined in the clinical protocol to put the subsequent analysis in the correct perspective. For a qualitative estimation of the intensity of use of the system in the three

clinical centres, it should be considered that a total of 81 patients, equally distributed among the three clinical centres, were included in the project clinical trial. For each patient, the treatment at his/her home lasted for one month, during which the patient had one training session a day – lasting 30 minutes – for 5 days a week.

The implemented exercises were: key, light bulb, book, jar, writing, checkers and keyboard tasks. The patient and the therapist had a weekly scheduled videoconference.

Service implementation assessment

Here below the main activities are described which were performed to assess the service implementation in the time frame of the HELLODOC project.

Review of design choices

The HELLODOC final form of service implementation is the result of a complex process, that may be summarized in two phases. In a first phase, at the very beginning of the project, the results of the former H-CAD project were considered, and the main design choices were taken accordingly, in an effort to solve the known problems. Such modifications were related to mechanical, electrical and network aspects. The most important of them are reported here below:

- the PU system was provided with its own structure, in order to obtain a self-standing system, and the monitor was integrated in the desk;
- from an electrical point of view the system was insulated, thus preventing any possibility of macro shock events to the patient and/or the caregiver;
- the entire communication process, managed by the communication server, was based on a secure and encrypted channel.

Such modifications resulted adequate for the implementation of the service, being the first steps for the development from a prototype to “a ready to use” system.

The second phase was that of a preliminary technical assessment, consisting in a thorough review of the design choices made by the industrial partners, based on the first pre-series systems, with the help of CAD tools and software simulators for the examination of the possible alternatives. The results of this work led to the actual system, as described at the beginning of this paper. The most relevant point that, among minor others, underwent a series of modifications was that of the positioning of the shelves. After a test of a complex mechanical arm the final solution was that of a set of special suction cups, thus improving reliability and usability.

Examination of product files and manuals

This action was part of the CE certification process and was initially intended to establish the availability of all documentation needed in view of a full market deployment of the service. As the system never entered a phase of large scale production there was a certain lack of regular and comprehensive

documentation *e.g.*, product files, user and technical manuals. Nevertheless the service was provided with:

- user guides associated with software applications to support installation, configuration and usage;
- a simple guide to PU assembling, including pictures and part detailed descriptions;
- a short step-by-step tutorial to support network activities and hospital network administrators charges.

More detailed documentation was delivered through the e-learning modules purposely developed in the time frame of the HELLODOC project. As reported elsewhere, an e-learning technical module was prepared, which was formed by four units:

- 1) the HELLODOC service;
- 2) network installation in the hospital (server unit);
- 3) portable unit;
- 4) software.

The material, which was continuously available on-line for the last twelve months of the project, was formed by traditional documentation, practical examples, and possible solutions to critical conditions. Moreover, an expert acted as an on-line tutor and assistant for ten months.

Finally, in order to overcome the above lack of exhaustive product files and manuals, technical partners greatly assisted the ITC hospital personnel as for network installations, service start up and problem management.

Verification of technical specifications

On the basis of the product documentation, as consolidated at the end of the former action, a preliminary technical verification was made, to verify if products meet the technical specifications, prior to be delivered at the clinical sites. This task was independent from the official procedures for market deployment, and allowed for a timely start of the clinical trials, in a framework where the required minimum level of performances was assured.

Analysis of safety requirements

Risks have been divided into two main categories: mechanical and electrical:

- *mechanical risks*: PU should have to be as light as possible in order to make transportation easy and comfortable. Considering the nature of the project it has not been possible to define at the design level the mechanical strength and endurance of all the elements by considering known loads and stresses. In fact it is difficult to predict and model all possible interactions with the environment where the system works. Therefore, after a mechanical design based on standard loads, a further structural analysis was done, aimed at identifying the critical spots in various circumstances. Accordingly were introduced some preferential breaking points, thus preventing the formation of dangerous elements in the case of breakage. Moreover, considering that the

user of the system is a patient exposed to balance loss and movement coordination difficulties, all exposed edge/corners have been coated with a rubber bumper, while others have been properly smoothed;

- *electrical risks*: in order to protect the user against indirect contacts a double insulation approach was used, for every electrical part of the system. In particular the desk, being made of conductive material, has been coated with a 4-mm-thick layer of Lexan, a high-insulating polycarbonate. All devices in direct contact with the patient (e.g., light bulb and key) are supplied with safety low voltages. Furthermore, although power supplies have internal thermal and short circuit protection, secondary protections have been introduced, such as fuses, to avoid any risk of fire and thermal injuries. During the course of the project several faults occurred concerning both mechanical and electric components, but it is worth noticing that no trouble or failure ever impacted user safety.

Easiness of use and acceptability by patients

With “usability” or “easiness of use” reference is made to system interfaces towards the users; both software and hardware interfaces – devices which are the means to interact with the software or to perform an exercise – have been considered. Such interfaces should be easy to learn, suitable to be remembered and easy to use, besides limiting mistakes and facilitating or increasing human performance.

During the design phase, information related to usability have been acquired from clinicians; an example of this process is the desk dimension: from the mechanical designers’ point of view, it would have been possible to achieve a smaller working surface, but the actual working area has been chosen by therapists for it grants a more comfortable, more secure support to the patients. The way by which the working area can be exploited has been optimized and arranged to allow a comfortable use by left-handed patients too.

Software applications have been developed to be highly customizable:

- language is “localized” and “localizable”: instructions are compiled and customized by local therapists (Belgium bilingualism became an early issue);
- exercises are configurable up to a high grade of detail;
- information from clinicians has been used to develop easy to use and user friendly software as much as possible.

The user interacts with the software application by using a four-key keypad. Such a choice acts as a simplification from a cognitive point of view and reduces the probability of improper use. Furthermore, avoiding patient to interact with an ordinary keyboard gives patients the sensation of using a dedicated instrument and not a common personal computer, contributing to a more confident and motivated approach by the patients.

Considering the acceptability of the PU, it is worth mentioning that installation at patients’ homes is not time consuming as it can be completed in few minutes by expert people. An open issue is that of the overall dimension of the unit. This cannot be easily solved mainly because, as explained above, the PU dimensions are directly related to therapists’ requirements.

It is worth remarking that uneasiness associated with the patient’s unit can occur in cases of patients already provided with their own personal computer (or, even worse, with a LAN) with internet connection. In such a situation it is mandatory to plug/unplug the twisted cable alternating between the patient’s apparatus (modem or router) and the HELLODOC system. Besides being a limiting nuisance, this feature assumes more relevance in some regional contexts, like Belgium, where common ISP practice performs the MAC caching (*i.e.*, OSI layer 2 address), thus potentially slowing down the internet access (this feature will be better described in the faults management section).

Data integrity and security

Security, intended as confidentiality and authentication, is committed to the VPN: all related traffic service is carried through the VPN tunnel.

Integrity of transmitted data is verified at the destination endpoint by means of a software check avoiding to open a corrupted or modified file upon reception. So, on the one hand, the tunnel grants confidentiality, preserving private traffic from tampering and, on the other hand, application software reveals whether integrity has been violated. Although measured data and related information are saved without encryption, they are not easily intelligible. We may say that acquired data are not encrypted but encoded.

A disaster recovery plan has been devised and implemented: hardware redundancy and backup/restore procedures have been accounted for. Clinical users have been advised to provide themselves with UPS devices, which are not included in system furniture.

Hospital integration

A high level of integration between system devices and hospital network has been achieved: the adoption of the service by a hospital/clinical centre requires communication server to be installed and connected to a dedicated routing device. The responsibility of opening the service to LAN selected hosts is on exclusive charge of the communication server and its installation procedures are almost entirely managed by the partners.

In virtue of the design choice of empowering the communication service with all essential roles (VPN site endpoint, service server, security front end) the overall system appears transparent to hospital infrastructure, gaining a satisfactory integration level.

The following duties, not critical, remain in charge to the hospital ICT division:

- router configuration;
- user accounting management;
- log monitoring (optional).

Service performances assessment

Methods of quality of service evaluation

This preliminary step was needed to establish an agreement between partners on the suitable methods for service evaluation.

ISS, together with the technical partners of the project, identified tools for the following evaluation aspects:

- verification of the most adequate network and videoconference technology: a systematic revision was performed of the available solutions and a set was defined of relevant evaluation criteria (project budget, project deadlines, regional peculiarities of the involved clinical centres);
- technical assistance: i) intervention procedures were defined, which assigned either to the in-hospital technical assistants or to technical partners of the project the management of malfunctioning, on the basis of their nature; ii) intervention strategy was defined by the project technical partners (use of SSH, questionnaires, phone and e-mail support, on-site intervention);
- fault management: definition of procedures and roles for faults collection (by in-hospital technicians and project technical partners), classification and management (by ISS dedicated personnel);
- overall service performance: exhaustive checklists were defined, to be prepared at ISS and sent to the clinical centres;
- assessment of the recorded parameters: procedures were defined by ISS to randomly extract and analyse PU data from the clinical trial database; the analysis was aimed at evaluating quality and clinical relevance of all the parameters recorded through the PU sensors.

Connection and service availability

At the beginning of the HELLODOC project a preliminary analysis has been conducted in order to identify the best network technology to be used, focussing attention on speed, availability, costs. The results of such analysis are below reported:

- the highest speed provided by standard analogic line (56 kbps or 128 kbps for ISDN) was not enough for data transfer and videoconference; ISDN connection was also too expensive;
- mobile communication as GPRS is characterized by 70 kbps as mean speed and it should be considered that the upper limit of 170 kbps for this technology is merely theoretical;
- covering of mobile communication UMTS in Belgium and Spain was 10% and was available only around the most important cities of the countries;
- satellite communication were too expensive and characterized by large latency that could affect the videoconference sessions.

ADSL appeared as the only feasible broadband connection solution, the only technology provided with the three mandatory requirements of being enough wide-banded, spread available and inexpensive.

Some difficulties have been found by UORIN about the ADSL connection. UORIN health district supplies the service to a great number of small countries; in spite of scheduled interventions by Italian Telco (Telecom Italia), planned at the beginning of the project, some countries have never been covered by ADSL connection, because of sudden changes in business plans by Italian Telco itself. Beside that, the HELLODOC service as been provided anyway by weakly data recovery supplied by health personnel visiting patient home.

Videoconference quality

Videoconference modules have been developed by means of the AVICAP, a Window based video capture application programming interface (API) and exploiting the M263 compression routines achieving a 176×144 pixel video window size with a bandwidth requirement of more than 100Kbps.

On the basis of the established evaluation criteria, and taking into account that within the HELLODOC project target the videoconference tool was not addressed to monitor critical conditions of patients, the quality of the adopted solution was considered adequate [7]. Anyway, a certain improvement was recommended, which is feasible with relatively low effort, due to the open design of the video connection and the modularity of the implementation.

Recorded parameters quality

The quality and conformity of data coming from the various devices integrated in the PU (key, lightbulb, jar, book, tablet, pencil, etc.) was assessed according to the following list of exercises and corresponding acquired parameters:

- *pencil*: timing, position, pressure;
- *jar*: timing, position, pressure;
- *book*: timing, position;
- *key*: timing, angular position;
- *lightbulb*: timing, event detection (light bulb and switches change of state);
- *keyboard*: timing, key sequence, event detection;
- *checkers*: timing, position, pressure.

ISS verified that data format was compliant with the given technical specifications.

As for data quality, the main criticism dealt with pressure values, which were frequently found saturated. This problem could be easily solved by performing a preliminary sensor calibration.

Possibility of outcome assessment

In principle it is possible to assist clinicians in evaluating therapy outcome, by means of data recorded in rehabilitation sessions. During the project it was only proven that recorded parameters are useful in assessing the progress of the patient, by means of a direct evaluation of the clinician. The realization

of an actual, quantitative outcome assessment remained beyond the scope of the project. However, from a preliminary analysis of some patients' data, some critical actions were identified to assure a homogeneous data collection and to allow reliable data comparisons. Among those actions, the most important are listed below:

- the addition of a clinical file of the patient which contains detailed information about type and level of pathology, scores of the clinical assessment before and after the one-month treatment (test score of 9HolePeg, ARA, WOLF, etc.), patient's picture during his first and last exercise session, and so on;
- the addition of a technical file which contains the detailed description of the exercise and its specific implementation and instructions;
- a new sensor calibration of each PU;
- some software development to optimise data processing (*i.e.*, integration of FFT tool);
- the eventual integration with additional force sensors.

Reliability and technical assistance

Technical partners monitored the installed systems in several ways by different means: by remote secure shell connection (SSH), questionnaires, by phone or email. Every time a trouble could not be faced within its own context, they reacted by replacing the device or the part affected as soon as possible or, when circumstances required it, by providing assistance on site, or, in special cases, by providing patches to grant service availability while looking for the ultimate solution. It deserves to be remarked that the technical assistance contributed to attain two important objectives: fault impact minimization and service availability maintenance.

The prompt intervention, either by repairing the faulted device or by replacing it, joined with disaster recovery and business continuity policies (so that systems could be restarted in short time without loss of data) has mitigated negative effects on the service of faults occurred.

Service integration

In order to achieve interoperability with information or other telemedicine systems inside the hospital or health district, the apparatuses should be characterised in terms of "interfaces" based on real or *de facto* standards; in this context reference is made to network protocols and encryption and data format.

From a "fussy" point of view, in the HELLODOC context no standard data semantic representation has been defined or established: data are stored and exchanged in a proprietary way and are not available to be used by systems other than HELLODOC in a transparent way. On the other side, this is the way to assess and grant the files integrity.

Furthermore the peculiarity of HELLODOC apparatuses makes it difficult to strictly apply the definition of interoperability.

In virtue of the preliminary and innovative nature of HELLODOC service, we could say that securely encapsulating the units and their traffic and data flow into Hospital pre-existing infrastructure connected, across Internet, to patients networks, can be assumed to be an adequate level of integration at this stage.

System modularity is worth mentioning, for it improves interoperability and integration with other telemedicine services.

Faults management

From a technical point of view while the project was running a number of faults occurred and the first remark to be pointed out is that, although with different frequencies, all four fault categories have been involved: hardware 54%, software 23%, network 15% and mechanics 8%. This statistics underline that there were no important weak-points or design mistakes which could justify a specific sort of criticism; the preponderance of HW faults is justified by taking into account the complexity and the heterogeneity of the hardware made of a great number of subsystems.

It has to be pointed out that 62% of faults were very critical for the continuity of service delivery. But a deeper analysis of the trouble occurred showed that they were imputable to the failure of commercial parts or components meaning that although they caused system impairment or blocking, the solution consisted in replacement of the broken components with higher quality ones, or minor software adaptation (*i.e.*, the network card failure, the firmware bugs or the material thermal coefficient for key modules). Therefore, if the overall service perspective has to be taken into account for future development and assessment of the service, such faults can be considered as "minor problems", in spite of the apparent adverse effect on service provision.

A fault worthy of being investigated in depth is "MAC caching", a regional issue related to Belgium Internet service provider (ISP). In Belgium broadband penetration is quite spread and the already existing infrastructure has been exploited on behalf of PU installation. Some providers cache the MAC address of the router and when other router is connected to the ADSL line, an IP address is assigned at the end of lease time. This process can last from minutes up to eight hours, depending on ISP. In order to overcome the "MAC caching" issue, some more adaptation should be planned and developed.

This issue does not affect the overall network functioning of the PU, but is very time-consuming; it takes place two times for each station: once during the installation and then during the uninstallation procedures.

"MAC caching" here reported should just to be considered as an example of difficulties encountered during the project that are directly related to specific

regional needs, as the local ADSL coverage, that have to be taken into account if such service should be delivered at European level.

DISCUSSION AND CONCLUSIONS

From a general point of view, the service worked in a quite satisfactory way, especially considering the pioneering nature of the project.

A variety of troubles happened – most of which with a low impact on the service continuity – that can be considered typical of the debug or post-debug phase, which was too short in view of the project complexity. The positive consequence of those troubleshooting was a deeper analysis of system functions and thus a better compliance with service needs.

The project also allowed technical partners to face different regional issues, mainly related to technical aspects (most of which were solved during project implementation), such as:

- broadband connection requirements;
- ADSL coverage;
- ISP availability and different regional strategies.

The new broadband wireless communication technology (we mostly rely on WIMAX) will automatically solve issues affecting UORIN, MAC address caching and coexistence between patient LAN and PU router.

A remark about high levels of security is mandatory: the system was conceived to fulfil the safety

requirements of the European Directive on medical devices (93/42/CEE); no fault for its nature could have any impact on human safety, which denotes good design criteria and practices.

Furthermore, it is worth mentioning that the technical assistance service has been characterized by great attention, availability and promptness; the intervention of two companies mitigated most the faults impacts and contributed to grant service continuity.

At the end of the project all the partners believe that the tele-rehabilitation service have high potentialities in improving the quality of care delivery for the three pathologies (stroke, TBI and MS), by granting continuity and extension of care outside hospital.

In spite of previous difficulties, the clinical centres decided, on the basis of the specific clinical experience in running the HELLODOC service, to proceed with tele-rehabilitation by either continuing with the same service or widening it to include other technical means and different delivery methods.

UORIN has developed a plan to introduce permanently tele-rehabilitation in the clinical practice with the constitution, by using both public and private funds, of the Umbrian center for tele-rehabilitation.

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