



An Information Capture and Processing
Environment for Chronic Patients in the
Information Society

Technical Platform

COVER AND CONTROL PAGE

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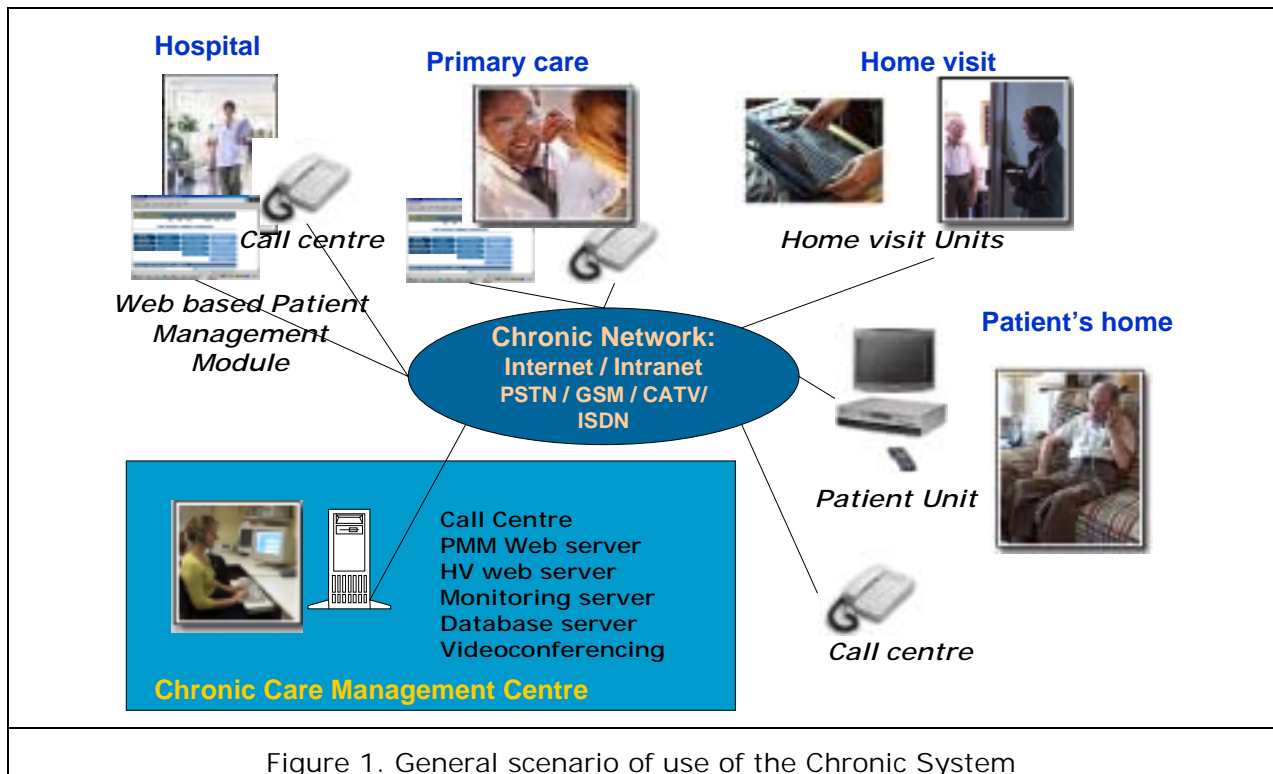
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1. INTRODUCTION: THE CHRONIC SOLUTION

The following figure describes the main components of the Chronic solution, showing all the user tools to access the system.



The solution can be divided into three main subsystems:

- Infrastructure at the hospital: **Chronic Care Management Centre**
- Infrastructure at the home: **Patient Unit** (consisting of Home Hub and sensors)
- Infrastructure to support home visits: **Home Visit Unit**

A brief review of the functionality and implementation of each of these subsystems is provided on the following sections

1.1. The Chronic Care Management Centre

The **Chronic Care Management Centre** (CCMC) is the centre from where all the services for chronic patients are provided.

From the technical point of view it consists of several modules, that may be installed on their own, as they provide autonomous services. However, only the integration of these modules and services in the same system constitutes an advanced and full services CCMC.

The CCMC environment installed for the pilots consists of the following basic functional elements:

- A **Call centre service**, including two main modules: teleoperator application (support for handling user calls) and a Voice Response Unit or automatic telephony service (automatic handling of calls outside working hours)
- A web service as an online interface to all CCMC functionality, that we call the web-based **Patient Management Module (PMM)**
- **DB service** that performs back-office activities, i.e. contain the Chronic patient and care personnel database, access rules, etc.
- **Videoconference service**
- **Telemonitoring module**
- **Inter-application message management module**
- **Module for intelligent analysis of monitoring data**
- **Module for synchronisation with Hospital information System database**

1.1.1. Call centre

The call answering system implemented in the CCMC is a 19" rack-type PC, which contains all the telephony equipment needed for the system

- A line board, Dialogic BRI ISDN, used for incoming and outgoing calls from the CCMC to the Public network. It can handle two basic RDSI links (4 lines).
- An agent's board, Dialogic MSI 8, to connect teleoperator's headsets (up to 8) to the CT Server.
- A D41Dialogic board, used to transfer calls to/from hospital. It is connected to at least two extensions of the hospital PBX. The PBX installed differs from pilot to pilot.

Operating system is windows 2000 server. RAM memory for this system is 256 mb and the system is shipped with 2 hard drives of 4 GB for each configured as RAID1.

As already described, the CT-server is connected to the public network and to the hospital's main PABX to be able to transfer calls from teleoperators to telephone sets of professionals in the hospital. The inbound lines are BRI ISDN digital lines.

The software running at the call centre (CT-server) consists of a Voice Response Unit (VRU), and an application to support the teleoperator's work

The **Voice response Unit** attends the calls outside the centre's working hours and when there is no operator available for other reasons. This module also maintains information regarding the state of teleoperators (whether they are free or busy).

The VRU is also designed to record messages left by patients and allow for a later recovery of those messages by the professionals. Furthermore, it can notify hospital professionals through their pagers when necessary

The **teleoperator's application** is used only by Chronic teleoperators, for managing the calls made by patients. It runs in a standard PC (Windows 2000) and works in close connection with the Call Centre Service.

The main functionality of this application is handling calls (make a call, answer a call, hold a call) as well as providing the teleoperator an intelligent conversation guide based in clinical protocols and guidelines, that helps this non-medical professional with the triage and

handling of the patient's request. Teleoperator's application is always used together with the web based patient management module.



Figure 2. Call's centre Interface for the Teleoperator

1.1.2. Patient Management Module

This web-based application provides all professionals in the Chronic environment (nurses, doctors, physiotherapists, other health care professionals, managers and administrators) with access to the information regarding patients and other aspects of the project they may need to carry out their tasks. It can be used from anywhere, provided that there is a navigator and Internet connection available, and that the appropriate security requirements are followed.

The web server where the application is running is Internet Information Server (Microsoft), with Active Server Pages functionality, on a Windows NT server. Software versions used are 2.0 for ASP, NT server 4.00 and Internet Information Server version 4.0 NT server.

Special care has been taken to ensure that no specific software has to be installed at the end user's workstation. This is very important in a project involving many users, as it avoids maintenance and installation problems and high related costs. Graphics are generated using a server object specifically developed for this goal, that does not require the installation of any plug-in or other client side object.

functionality: The inter-application message management module is the central piece of this integration, enabling the sharing of information among all the software modules in the system.

The implementation of this module is based upon a table that defines which action to take on the arrival of a specific type of message. These actions will always imply sending messages to other application(s). A message may trigger one or more actions. The advantage of this way of managing messages is that it is possible to modify the way the system works just changing the table that defines which actions to take on the arrival of each type of message.

This structure allows for growth in case more applications or functionality is included in the system. It is also possible to configure different levels of interactivity of the system with the users, depending of the destination applications selected for each message.

1.1.6. Module for intelligent analysis of monitoring data

This module performs an intelligent analysis of the results from the monitoring sessions and exams made at the patient's homes and generates appropriate warnings and messages to professionals involved.

When the results of a monitoring exam arrive at the Chronic Centre, they are handled by the Telemonitoring Management application. This application receives the data and stores them at the database. Then a message is sent to the inter-application messaging tool, warning of the arrival of a new exam. This message is redirected to the Module for intelligent analysis of monitoring data, that analyses the results of the exams and decides how to proceed.

The development environment for this module is Visual Basic 6.0

1.1.7. Module for synchronisation with Hospital information system database

The objective of this module is to synchronise the contents of the pilot database (Chronic Database) with the Hospital Information system database (HIS).

During the requirement analysis phase it was decided which data should be exchanged among the two information systems. A conservative approach was selected, this means that only a subset of the data that could be of interest to exchange was finally included in the tool for a transfer between the two systems. Once that the evaluation phase is over and the system is put into clinical use, the rest of the information should be included.

In the actual version, information exchanged is demographic information (from Chronic to HIS) and high risk reports (from HIS to Chronic). It was clear that the demographic information regarding patients available at Chronic database would be better than that available at the HIS (as the Call Centre will enable to maintain this information highly updated) and therefore these piece of data will be sent from Chronic to the HIS.

Discharge letters are a key piece in home follow-up of chronic patients and therefore were also included in the tool for information exchange. These reports are available to professionals at the patients home using the home visit units.

The module for database synchronisation has been built using the HL7 standard. For the information exchange requirements that are not addressed by HL7, the "User fields information" records format is used. The development environment for this module is Visual Basic 6.0

The tool is based on the SMS commercial product "Open Link" to control the interchange of information between information systems.

The interface application needs from the rest of the applications running in the Chronic environment to perform a tracking of the activity, that is, every transaction has to be registered to have the capability to know when a record of the Chronic database has been modified and keep this information updated at the HIS.

1.2. The Patient Unit

The Patient Unit is made up of the home hub and a set of sensors

The home hub is a PC, highly adapted to the requirements of a home use by a non experienced patient, running the Chronic Patient Unit application. This application gives access to the following services

- Telemonitoring
- Videoconferencing (Telepresence and televisit)
- Access to educational material (Video on demand)
- Messaging (restricted to exchange of messages with Chronic Centre)

The sensors incorporated into the patient unit have been selected to fulfil the needs for home follow-up of chronic respiratory and cardiac patients, and they are

- Pulse oxymeter, for the measurement of the blood oxygen saturation and heart rate
- ECG, providing one or three lead ECG and heart rate
- Spirometer, performing a full functionality forced spirometry
- Blood pressure meter

An activity sensor has also been developed within the Chronic project, but it has been decided not to integrate it with the home hub, as work is still needed to assess the feasibility of home evaluation of neurologic disorders and to decide which is the best way to incorporate and analyse the information they provide.

The Chronic patient unit consists of the following components:

- A Uniview 310 PC (the home hub), with the following features
 - Intel Celeron processor 366MHz and 64 Mb RAM
 - Network interface card
 - Desktop videoconference kit (VCON Escort 25, including colour video camera, and a telephone earpiece, with microphone and loudspeaker)
- A base unit, including a telemetry receiver and spirometry and blood pressure sensors
- A portable wireless telemetry unit, including a pulse oxymetry and ecg sensors



Figure 5. Chronic Patient Unit

To prove the feasibility of including into Chronic other sensors different from those specifically developed for the project a set of commercial sensors from the Swiss based company Card Guard. Spirometer and 12 lead ecg sensors were selected for integration. These two sensors are connected to the home hub through an acoustic coupling link to a device called mini-receiver (also provided by card guard) that is connected to the home hub serial port.



Figure 6. Chronic Patient Unit integrating Card Guard sensors (spirometer and ECG)

The patient unit software application running at the home hub has been developed using Visual Basic. Vcon SDK has been used to integrate videoconference functionality and RealPlayer for access to education material

The protocols used for communication between the patient unit and the CCMC are IP based, namely

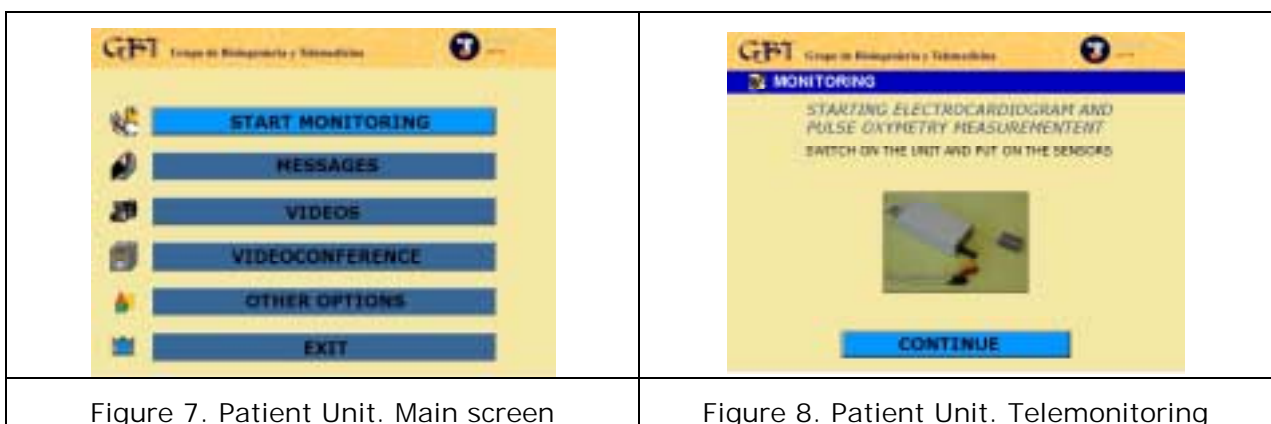
- HTTP for data transfer (configuration, programming of exams, exam results), over secure socket layers
- H323 for videoconferencing

HTTP has been selected for data transfer, as it is easy to secure (HTTPS) and safely get through firewalls.

Different connectivity solutions have been developed and tested for the home hub, ranging to standard PSTN telephony network, GSM mobile networks , ADSL and Cable TV. Videoconferencing can only be provided up to good quality standards using the two later, but if videoconferencing is not the issue, PSTN and GSM are a good solution with a short installation time and low cost.

The user interface of the Patient Telemedicine Unit has been carefully designed to make it's use simple for non-expert users and to improve it's readability on a TV screen. The following issues have been taken into account:

- Interaction with the patient is minimised. The number of interactions to perform a given task is reduced to the minimum.
- Non technical user interface, use of daily live metaphors to represent actions
- Readable interface (high contrast, big fonts, big buttons etc.)
- Access to main functions is possible with a simple remote control (Functions are only up down and select). More specific functions (such as writing messages) have to be accessed through a wireless keyboard.
- Feedback regarding errors and troubleshooting adapted to the user. Most errors are not reported to the user in detail, but sent to the Chronic Centre.



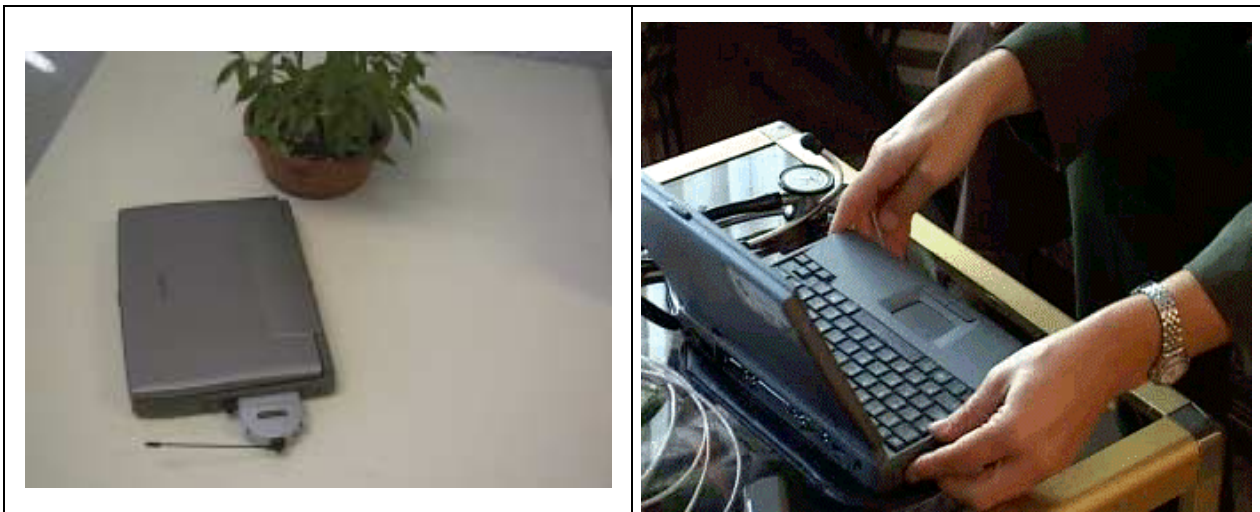
The first versions of the patient unit were implemented without encryption. The final version uses Secure Socket Layers protocol to cipher all the information exchanged among the patient unit and the telemonitoring module at the CCMC

1.3. Home visit Units

Complementary to the patient unit, the Chronic System incorporates a **Home visit unit**, that is designed to be used by the home visit professionals during their work at the patient homes. These units consist of a small size portable PC (Acer Travelmate 312D) connected to a mobile phone and a software application. They enable the professional to connect to the Chronic centre (by means of a GSM or GPRS link) and receive information about their visits agenda for the day, access to updated patient information, perform the home visit and record all the relevant data during the patient visit.

The application implemented for this unit is also web based, and it has been developed using Java servlets and Java Server Pages (JSP). Web server installed is Apache including Tomcat servlet container.

As already mentioned, the home visit unit can either communicate trough GSM using a convenient PCMCIA GSM card-phone (Ericsson GSM Data Card GC25, shown in figure 9.1) or through GPRS using a GPRS phone (Motorola Timeport) connected to the serial port.



Figures 9.1 and 9.2 Mobile Home Visit Unit

2. INSTALLATION AT BARCELONA SITE

The group of patients addressed at this site are chronic respiratory patients, mainly those suffering from Chronic Obstructive Pulmonary Disease (COPD)

The installation at Barcelona Site includes all the modules of the Chronic solution: Chronic Care Management Centre, Patient Units and Home Visit Units.

The following figure shows the architecture of the current installation at the Barcelona site, showing the connection among the different Chronic Care Management Centre modules, and with outside agents (patient's home, primary care centres)

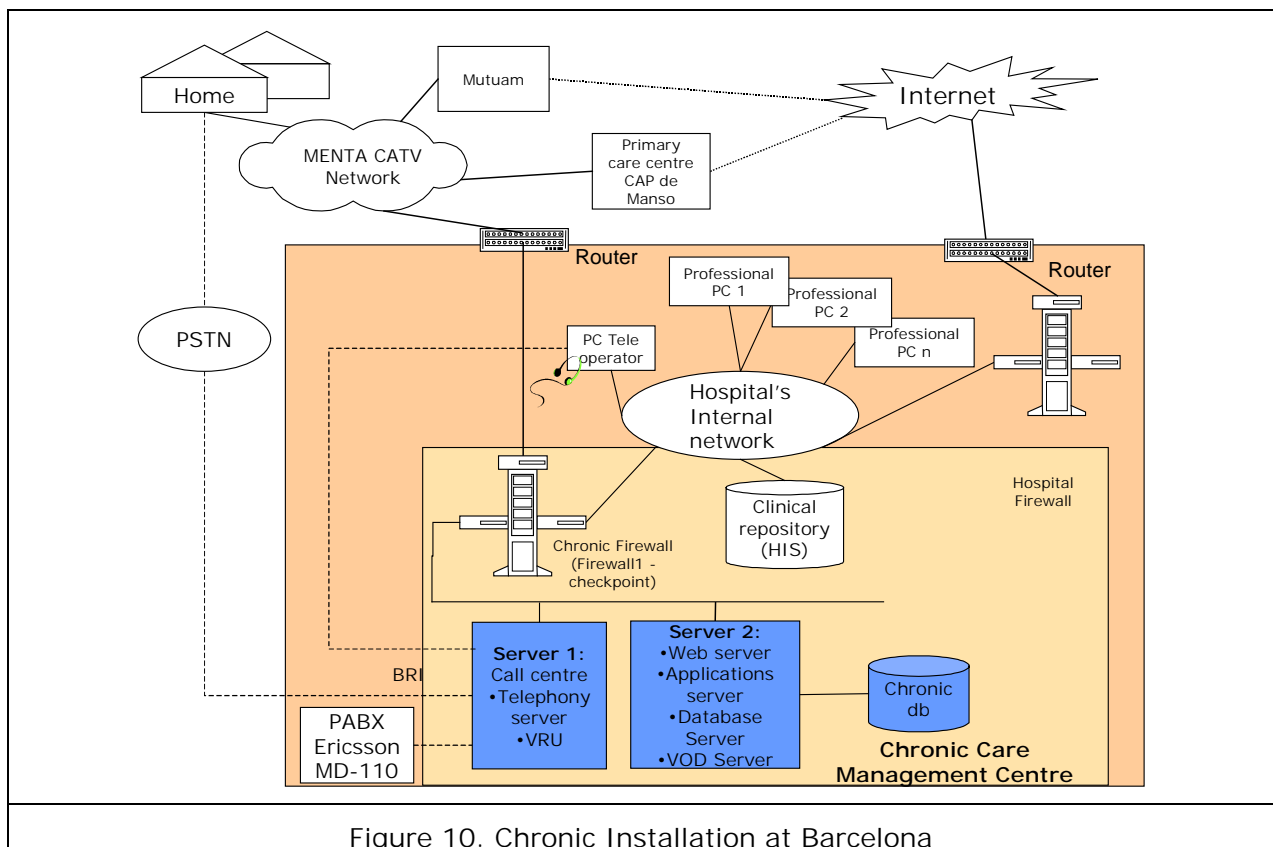


Figure 10. Chronic Installation at Barcelona

The communication infrastructure for the pilot is based in different networks, selected according to the needs of each user and tool.

Patient homes (Patient Unit)

- Menta Cable TV network, an ip based cable network belonging to a private provider in the area of Barcelona. is being used to connect patient homes for the prevention of hospitalisation pilot, where videoconferencing is being used. The connection provided to the home has a bandwidth of 512 Mbps
- GSM network is used to connect the patients involved in the home hospitalisation pilot. This patients are provided only the telemonitoring service, and for this pilot a quick installation is crucial (equipment has to be in place 24 hours after hospital discharge). Cable TV infrastructure is available at a very low percentage (5 to 10%) of the Barcelona households, and therefore it cannot be considered.

Home visit teams (Home visit unit)

- Internet access over the Public GSM/GPRS infrastructure, using hardware tokens for authentication and ipsec for communications ciphering
- GPRS based 2nd generation internet access using the infrastructure provided under an agreement with the I2CAT project, a research project from the Catalan Government in new internet protocols and applications.

Professionals at the hospital and Cap de Les Corts primary care centre (Patient management module)

- Web based access through the hospital Intranet. Cap de Les Corts is a Primary Care Centre belonging to the same administrative infrastructure as the Clinic Hospital, and therefore connected to their network

Professionals at the Cap de Manso primary care centre and Mutuam (Patient management module)

- In the pilot installation of the system, these centres were connected to the CCMC to dedicated ISDN lines. Once that the security solutions have been fine tuned, these connections have moved to the Internet, to reduce the pilot costs and achieve higher flexibility
- Today these web based accesses are done through the public Internet. A virtual private network has been created to support the connection of these centres. Hardware tokens are being used for authentication. Ipsec ciphering ensures the privacy of data.

PBX

The PBX installed at this pilot is the Ericsson Md110. The chronic telephony server is connected to four extensions of this PBX

Security considerations

The security solution is summarised in the following figure. A simplified version of the previous diagram has been selected for a better readability

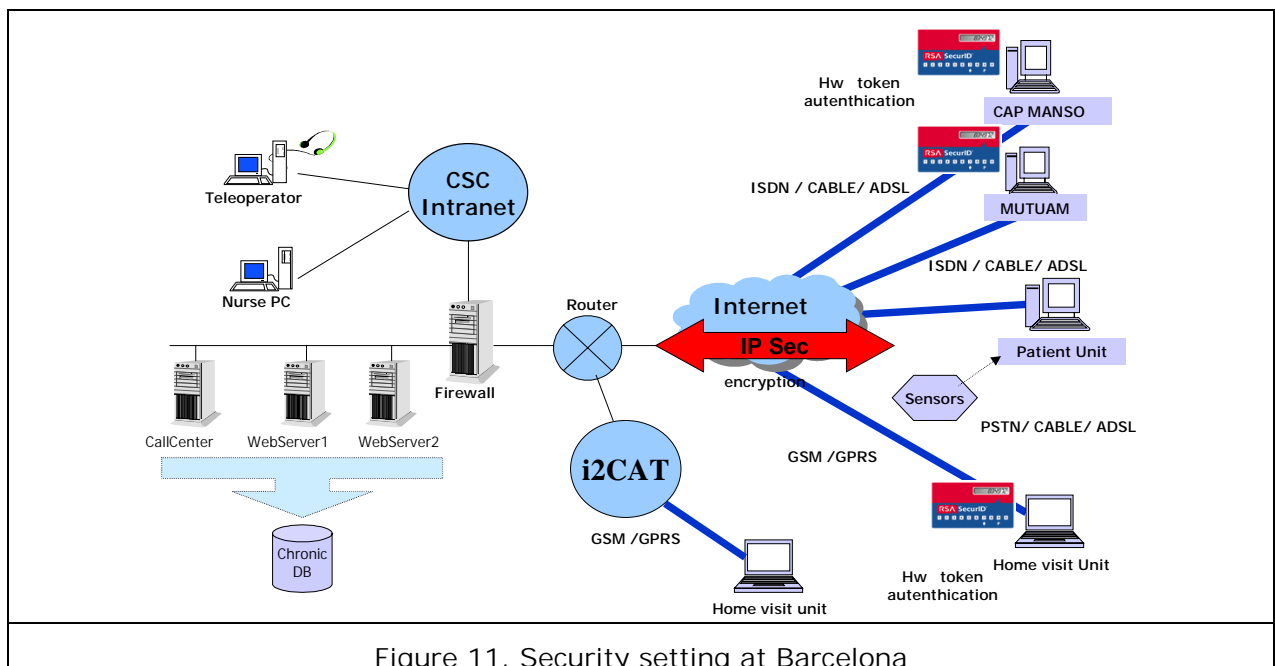


Figure 11. Security setting at Barcelona

Authentication

In the first Chronic experiences, one factor authentication, based in login and password was used. This was considered unsatisfactory by the project as passwords are too easy to forget, guess and obtain by other illegal means.

Two factor authentication was then considered necessary. Two factor authentication is based on something you have (in our case a hardware token) and something you know (in our case a login and password)

The hardware tokens used are provided by the USA based company RSA Security.

This solution was preferred to the use of certificates as it fits much better our requirements for mobility and is not tied-up with the computer from which we are accessing.

Ciphering

For the first chronic experiences HTTPS secure protocol (using secure socket layer) was used to secure web based accesses to the patient management application.

In the current installation this level of security is considered enough for intranet based accesses and accesses over a dedicated line, but those connections that use the public network are secured in a more efficient way through a virtual private network infrastructure using Ipsec.

Firewall

A firewall has been installed to protect the infrastructure of the CCMC from unauthorised accesses and other attacks. A highly configurable system has been installed to enable the fulfilment of secure videoconferencing and access to VOD through this firewall.

Since H.323-compliant applications (as the Patient Unit) use dynamically allocated sockets for audio, video and data channels, the firewall installed must be able to allow H.323 traffic through on an intelligent basis. The firewall must be either H.323-enabled with an H.323 proxy, or able to "snoop" on the control channel to determine which dynamic sockets are in use for each specific H.323 session, and to allow traffic through only as long as the control channel is active. Among the firewalls that provide these feature, Check Point Software's Check Point FireWall-1 has been selected.

The following table summarises the security solutions adopted at the Barcelona site

	Type of access	Authentication			Transport security			
		Login / password	PKI certificate	Token	SSL encryption	VPN	Dedicated line	Intranet only
Hospital users to PMM server	Web	X			X			X
Rest of users to PMM server	Web	X		X	X	X		
HV users to HV server	Web over wireless lines	X		X	X	X		

PU to Monitoring server	Data		X		X			
PU to videoconf. station	Video							
PU to education server	Web	X			X			

PMM: Patient Management Module; HV: Home visit; PU: Patient Unit

3. INSTALLATION AT LEUVEN SITE

The needs of the Leuven site are very similar to those of the Barcelona site. Patient groups addressed are as well respiratory patients, but also cardiac patients, who were not included at the Barcelona Site.

Modularity has been a key issue for the project, and therefore the Chronic solution is customisable for different scenarios of use: each functionality can be installed or not depending on the needs of the sites. The need for a Home Visit Unit was not identified at Leuven, and therefore these modules have not been installed.

Patient home-telemonitoring needs at Leuven site are identical to those at Barcelona. Cardiac patients can be addressed optimally with the same tools as respiratory, or with a subset of these tools, as pulseoximetry and spirometry are not so relevant for this target group. The patient unit configuration is therefore the same for both sites (ecg, pulseoximetry, blood pressure and spirometry). Due to practical reasons the project has decided that the patient unit solution will be tested first at Barcelona site, and once that the technology and usability is completely validated and stable it will be installed at Leuven.

To start paving the way for home telemonitoring at Leuven, it was decided to use a set of commercial sensors (ecg and spirometry) provided to the consortium under the agreement with a private company. The use of these sensors has been very profitable to identify organisational issues that may affect the deployment of Chronic patient units, as well as to clarify the telemonitoring needs.

However, these sensors are not completely satisfactory for the pilot, due to the fact that pulse oxymetry can't be measured and more importantly, because the data obtained are not integrated with the rest of the patient record information. All this problems will be overcome once that the Chronic Patient Unit is installed.

Apart from what is explained above, the full Chronic solution is installed at Leuven, including Chronic Care Management Centre, Call centre, Web based patient management module and database services.

PBX

The PBX installed in his pilot is HIcom de Siemens. Two primary links and two extensions of the PBX are being used to receive and transfer calls.

Architecture

The following figure shows the architecture of the current installation at the Leuven site, showing the connection among the different Chronic Care Management Centre modules, and with outside agents (patient's home, general practitioner offices)

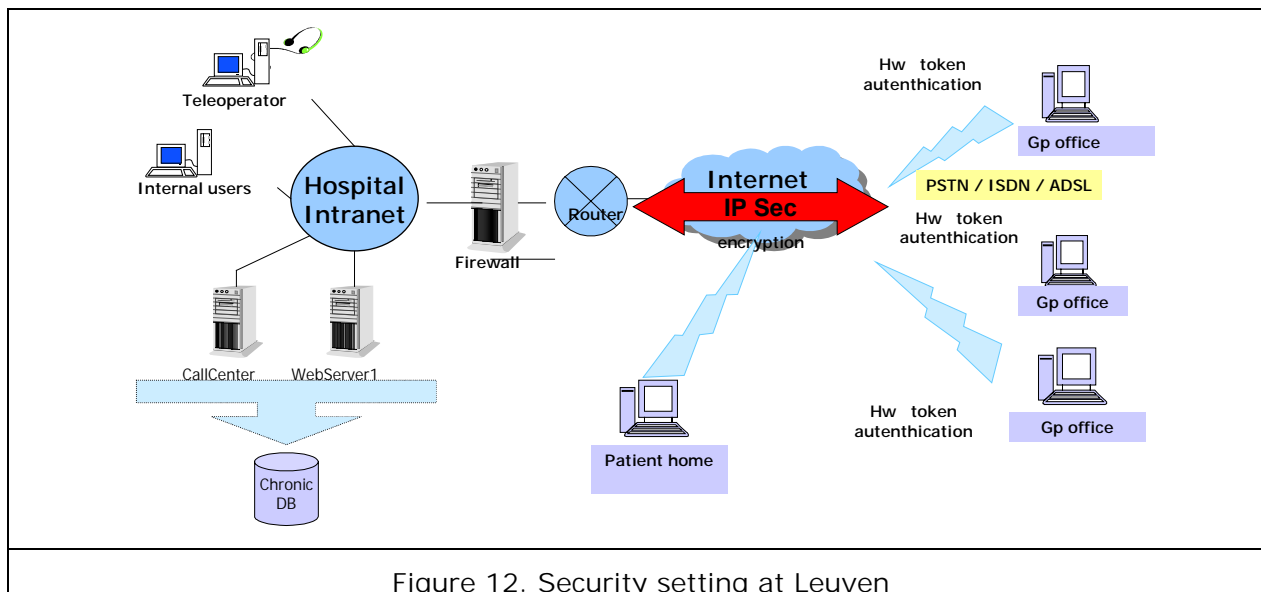


Figure 12. Security setting at Leuven

Security considerations

The security solution installed at the Leuven site is almost identical to the setting at Barcelona, except for some issues.

The chronic servers at Leuven are already into the hospital LAN network, conversely to Barcelona where a special security zone (a DMZ) has been implemented to separate the research projects from mainstream operation.

The access from remote sites (GP offices in this case) is also done by a virtual private network and authentication uses hardware tokens. The provider for hardware tokens is is. The password to access the system is generated by this token upon entry of a 5 digits access code.

The security solution is summarised in the following table

	Type of access	Authentication			Transport security			
		Login / password	PKI certificate	Token	SSL encryption	VPN	Dedicated line	Intranet only
Hospital users to PMM server	Web	X		X	X			X
Rest of users to PMM server	Web	X		X	X	X		

4. INSTALLATION AT MILANO SITE

The Milano pilot is devoted to chronic neurologic patients, specifically to Parkinson patients. The scenario of work that the consortium has found in this arena is completely different to that of the other diseases, where the monitoring needs for patients at home are well known, and it is easy to establish a telemonitoring plan.

In the case of Parkinson patients it is clear that the level of activity they can cope with, that is the amount of time they stay walking or sitting or laying in bed is an indicator of the need to readjust the therapies. However the exact way of obtaining this information is not clear yet.

For these reasons the consortium decided to dedicate their efforts in this pilot to develop a completely new sensor for the activity of neurologic patients and in the interpretation of this data. Only when this issues are solved it will be worth to integrate the sensor into the home hub and pilot the remote monitoring of patients at home.

However, due to the modular architecture of the home hub, described in deliverable 6, the integration of the activity sensors (now that the final version is available and has gone through testing and evaluation) is an easy task.

Setting at Milano

The activity of Parkinson patients has been monitored at their homes using the Chronic activity sensors. Obviously the sensors are wireless so they don't disturb the movements of the patient.

Description of the activity sensor

The device consists of three accelerometric sensors that determine the position and movements of the limbs.

The three accelerometric sensors are placed both on the arm and two legs, and they are linked to the portable unit that transmits the information to the base unit using a radio-frequency link in the 433.92MHz band. The base unit is managed by a PC where an application developed in C reads the data and stores them for further analysis. The application also allows the user to view a graphic representation of the data.

The version of the system that has been evaluated transmits the data through the wireless link to a PC located at the home. Data are obtained periodically from this PC for analysis.



Figure 13. Activity sensor