LinkWatch© Telemedicine Platform Use Cases

Remote TeleHealth and TeleCare Solutions

Content:

This document provides a number of inspirational use cases and pilot applications performed with the LinkWatch© Telemedicine Platform and related remote telehealth and telecare components.

More information is available in the LinkWatch brochures and on the LinkWatch website. Specific technical and medical information related to the use cases is also available on request.

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Introduction

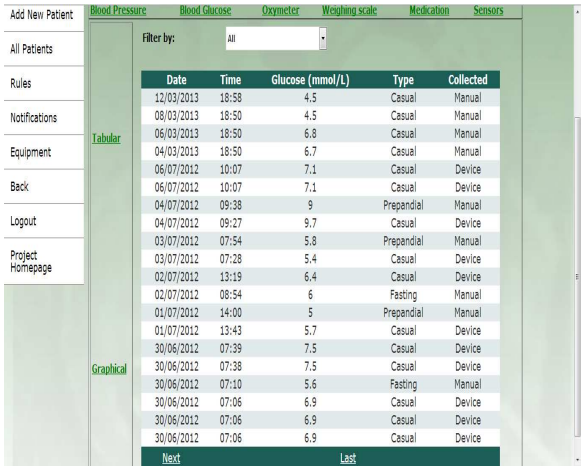
The LinkWatch Platform is an end-to end solution for telehealth and telecare monitoring of patients outside clinical settings. It supports all parts of the monitoring and care management process from collection of data and subjective information at the patient side to integration with external data repositories such as Hospital Information Systems, Electronic Health Records, and Personal Health Records. When dedicated interfaces to external repositories are not needed or possible, a LinkWatch Care Portal can be added to the platform in order to store and provide access to Telemonitoring data and health management for professional carers and patients. The platform thus becomes an inclusive, comprehensive stand-alone telemonitoring solution. The individual components are:

The LinkWatch **Patient Frontend** is a software platform operating on portable devices such as Smartphones, tablet computers, PCs and black-box gateways. It handles patient authentication and interaction and includes auto-discovery and self-configuration of a large number of medical and behavioural monitoring sensors. A list of possible devices is available. It also allows for automated data collection of health and environmental data and compliance monitoring.

The LinkWatch **Patient Portal** provides access for patients and relatives to their own data as well as information about care plan and recommended medical information.

- Patients can view graphical trend and tabular data
- Patients can view their own care plan
- Patients can view educational material recommended by the healthcare professionals
- Decision support for patients (e.g. lifestyle advice, recommended educational resources)
- Video conferencing capabilities

The LinkWatch™ **Clinical Portal** provides access for professional carers to all relevant patient data with various data management and analysis tools as well as management of care plans:



- Data analysis (above/below thresholds, patterns, visualisation) with risk assessment
- Data collection by questionnaires about diet, physical activity and medication compliance and with textual summary generation
- Administrative functions (user management, equipment management etc.)
- Definition of patients care plans and personalized user settings
- Integration of data from various external repositories such as EPR systems
- Advanced alert handling and notifications (alerts, reminders, sms)

LinkWatch pilot installations

This section lists a number of pilots where the LinkWatch Telemedicine Platform has been successfully deployed and demonstrated.

CHF monitoring

Konstantopouleio General Hospital of Nea Ionia (KGHNI) is a public hospital with more than 500 employees (doctors, nurses, physicians, social workers, administrative personnel, etc.) in Athens, Greece. The main objective of this pilot was to develop an integrated healthcare service for patients suffering from Chronic Heart Failure (CHF) under the management of the KGHNI Cardiology Clinic.

By monitoring medical parameters (such as blood pressure, heart rate, body weight, blood oxygen saturation level) KGHNI has developed new practices to guarantee a close follow-up of patients, ensure an early intervention in case of critical situation and re-hospitalisation cost reduction. The LinkWatch health monitoring platform contributes to deliver new services to patients combining health, psychological and behavioural continuous monitoring and improved quality of life for patients. The Pilot activities were primarily motivated by the existing situation:

- Nearly two thirds of all deaths in women and men aged ≥ 65 years in Greece are associated with cardiovascular diseases.
- The increasing rate of cardiovascular diseases poses a substantial economic burden on society and on the health care system.
- Remote Healthcare Monitoring is not deployed today and re-hospitalization is practically the only way to resolve a heart related issue.
- Health support and social support exist but their combination is offered in a limited way.
- Healthcare system is based on treatment and not on prevention.

The integrated KGHNI services are designed to complement the established medical services and aim to provide doctors early signs of a patient's deterioration (clinical) to enhance the patients' quality of life (psychologically, functional-wise in home and in everyday activities). Both components contribute to better CHF patients' prognosis while effectively reducing the risk of re-hospitalization and averting non-required visits to the hospital's out-patient clinic. The specific goals of the pilot were to:

- Improve the speed of delivery and the quality of the provided healthcare services while at the same time reducing costs
- Test and evaluate the organizational cooperation between the involved hospital units in the new telemonitoring pathway, namely the Cardiology Clinic, the Psychiatric Clinic and the Social Service.
- Reduce the medical risks for the patients with continuous monitoring,
- Reduce patients' anxiety about their medical condition
- Understand the health condition of CHF patients in their real life at home by analysing the pilot results
- Discover correlations between the patients' medical condition and everyday habits
- Enable the consolidation of the latter as early indicators of worsening clinical status
- Demonstrate that the active involvement of relatives and the assistance provided by social workers contribute to the patients' overall quality of life
- Prolong elderly patients independence by supporting them in their own home
- Enable early discharge of patients
- Improve medical therapy in order to decrease the risk of hospital readmission

A cohort of n=40 (30 men and 10 women) patients suffering from Congestive Heart Failure (CHF) were recruited and agreed to participate in the pilot for an average monitoring period of two and a half months

each. The average age was 63 years old. The majority of the patients did not live alone and thus enjoyed the support of the family environment. 15% of the patients had unhealthy habits, like smoking and drinking alcohol regularly. These habits were mainly the result of psychological states, so the role of the psychologists involved in the process also included means to motivate these patients to change lifestyle for improving health and quality-of-life in general. It was a considerable challenge that many of the patients were not at all familiar with new technologies. However, even those not having previous experience with PC usage eventually became very enthusiastic about their daily usage of the platform.

A pre-pilot activity for training and adjustment of services was undertaken with just 2 patients using the LinkWatch Telehealth solution. After staff training and technical tests, full pilot activities began on March 2012 with daily remote monitoring of the included patients health status. On September 2012, the pilot service was enhanced with addition of habits and home environment conditions and the depression monitoring via the mediation of expert psychologists. This enhanced integrated health and care service ran smoothly for 9 months, until the end of June 2013. The staffs involved include cardiologists, nurses, psychologists, social workers and technicians.

The pilot showed that clinical effectiveness was improved thanks to the usage of the LinkWatch solution that provides the professional carers all the needed tools for keeping track of the patient's clinical history and for being notified immediately in case of emerging situations. At the same time, patients felt safer and more secure as they knew that there was always a health professional taking care of them, even remotely via video conferencing. This result was evidenced by a Patient Perception questionnaire and was a positive factor maintaining or improving health status. A detailed clinical and psychological evaluation report is available upon request.

Rehabilitation and COPD patients in rural areas

Fundación Hospital de Calahorra (FHC) is a non-profit organization in Calahorra, Spain. It operates within the national healthcare system, in particular providing assistance to frail people. It is involved in disease prevention and rehabilitation and has been classified as one of the best Spanish hospitals in the areas of Respiratory and Nervous System diseases.

The aim of the FHC pilot was to integrate health and social services for patients with chronic obstructive pulmonary disease (COPD) who live at remote distances from the hospital. Patients with COPD often decrease their physical activity because exercise can aggravate dyspnoea. The progressive physical deterioration associated with inactivity initiates a vicious cycle, with dyspnoea becoming problematic at increasingly lower physical demands. The pilot program aimed to break this vicious cycle by promoting and monitoring rehabilitation exercise at home as this will improve patients' quality of life. The patient's clinical condition is also strongly influenced by their lifestyle and environment. Their life style (daily activity degree, autonomy, healthiness of the environment, diet guidelines, social life, etc.) is a determinant factor both in the appearance and in the evolution of COPD. The overall objectives of the pilot were:

- To test the efficacy of FHC's rehabilitation programme.
- To test in-home group (exercises at hospital for 4 to 5 weeks + 4 to 5 weeks at home) vs. 1 control-group (8 to 10 weeks of exercises at hospital gym).
- To design a new programme based on tele-rehabilitation and home exercises to push forward adherence to treatment through use of new technologies.

The pilot targeted patients over 65 years of age suffering from chronic obstructive pulmonary disease (COPD). The aim of the project was to offer the patients a treatment designed using current scientific methods evidencing that doing adequate exercises with lower and upper limbs during periods between eight and twelve weeks significantly delays the deterioration of patient health.

The patient group consisted of n=15; 10 patients in the tele-rehabilitation group plus 5 patients in the control group who had performed the treatment at the hospital gym (no tele-monitoring activities but same upper and lower limbs exercises). The tele-rehabilitation programme provided a tested tool to attend needs of chronic patients suffering COPD and living in rural areas.

Results of patients' satisfaction and self-perception of their health status and quality of life are coherent with previous scientific evidences offered by studies focused on rehabilitation exercises for COPD patients. The pilot showed advantages in terms of less use of resources to attend to the patients. For patients, the results were the benefit of resting at their homes and keep on doing their exercises under remote monitoring when needed. The avoidance of hospitalizations episodes related to worsening evolution of clinical status suffered by COPD patients are other relevant outcomes of the tele-rehabilitation programme.

Fast deployment for diabetes and COPD patients in a small town

Skive Municipality is located in the Central Denmark Region. This rural municipality covers an area of 691 km² and has a total population of 47,291 (2013). Skive Municipality has the responsibility to provide healthcare and social care services to its citizens. The combined services are placed within a single administrative organisation: The "Social and Employment Administration". This part of the municipal organisations has the overall responsibility for health care, personal and social care, elderly care. It coordinates patients' pathways with primary care actors (doctors, practitioners) and secondary care actors (hospital) as well as pharmacies for pre-packed medication.

The demographic outlook for Skive is slightly worse that the national average due to a large outflow of people in the working age seeking employment in the larger cities. The financial pressure on the municipalities budgets in the coming years will thus be very serious and new ways of caring for the elderly citizens in their home must be found. Skive is thus fully embracing both telehealth and telecare as technology solutions that can support their aim to provide the same care services in the future as today but more efficiently and with fewer resources.

The general objectives of the trial were to test and evaluate the LinkWatch solution providing different telecare and telehealth services. The objective was not to test and evaluate the services from a clinical point of view, but rather from a user and organisational point of view, thus focusing on the user friendliness of the system and the ways which it can potentially improve the integration of different workflows. Further objectives were to evaluate how it can enable the integration of telecare and telehealth services and how well (in terms of ease and simplicity) it can be transferred to other stakeholders such as social care and healthcare providers. The objectives were thus to:

- Evaluate and validate the transferability capacities of the LinkWatch solution (simplicity and ease of transference)
- Evaluate how well LinkWatch enables the integration of social care and healthcare services (telecare and telehealth)
- Assess the exploitative potential of the LinkWatch solution on a higher level
- Combine health and social monitoring in the home on a single platform, which is easy to use for the patient
- Allow the care teams to share information across organisational boundaries, i.e. between primary and secondary care and between healthcare team and social teams
- Create better utilisation of resources through optimised integrated workflows
- Allow the patient and relatives to be involved in the management of his/her disease through access to data, instructional material and direct video contact to the care team
- Provide instant video access to a single Contact Desk for patients with anxiety and need for advice.

The trial focused on chronic diseases since the account for almost three quarters of the municipality healthcare budget. The number of diagnosed diabetic patients in Skive Municipality was in 2008 between 3.8 – 4.3 % of the population, which is in the lower end of the scale in Denmark. However, Skive also has one of the highest proportion of obese citizens (51% of population over 16 years has a BMI>25). So the municipality expects a large increase in diabetes in the coming years. COPD is also very prevalent in Skive. Not only because of a large smoking population but because many people have been employed in the agricultural industry where they have been exposed to large amount of dust (inhaling of dust from crops and flour).

The target end-users were defined as frail, elderly people (male or female) over 65 years of age. The inclusion criteria were:

- The end-user must have at least one chronic disease: Diabetes type II or COPD
- The end-user must be living in Skive town or the surrounding area
- The end-user must be already receiving social and personal care from the municipality
- The end-user must be frail as defined by the Edmonton Frail Score (see table above)
- The end-user must have a basic level of literacy.

The exclusion criteria were:

- Cognitive impairment
- Technophobia.

The pilot commenced on 18th February 2013 and ran for a total of seven months. The first 3 months were used for the planning activities (e.g. definition of use cases, definition of user requirements, recruitment of elderly users, etc.) and technical preparations (set-up of server, configuration of the Consumer Application, devices configuration and testing, etc.). The solution was tested with end-users for a total of four months (16 weeks), divided between two cycles of end-users. The first cycle with Group 1 ran for 9 weeks whereas the second cycle with Group 2 ran for 7 weeks. The relatively short cycles are justified by the fact that the overall focus was on usability and transferability, not on clinical validation or results

The first cycle consisted of five citizens diagnosed with Diabetes type II and five diagnosed with COPD. The second cycle consisted of four citizens diagnosed with Diabetes type II and five diagnosed with COPD i.e. totalling nineteen participants divided into the two groups/cycles. The selected participants belonged to a particularly frail group of chronic elderly patients between the ages of 63 and 84.

The overall results of the transferability and the usability of the LinkWatch solution were positive. Professional users felt that the platform enabled better integration of existing workflows and cooperation with other professionals across sectors. This enables better cross-sectoral efforts to not only improve the existing care but also perform more preventative care as different social and healthcare professionals (from both the primary and secondary healthcare sector) all have access to a patient's measurements and because the LinkWatch solution enables a more continuous monitoring of a patient's health parameters; these two factors may greatly improve preventative care.

It is notable that LinkWatch front-end platform was sourced, installed, configured and put into operation in Skive Municipality within 5 weeks. This demonstrates that transferring the LinkWatch solution to a new setting (and country) can be done relatively easy and quick. A full technical evaluation report is available upon request.

Up-titration of CFD patients in Outpatient Clinics

The LinkWatch patient frontend was used in a 3-year randomised controlled trial (RCT) conducted by the Capital Region of Denmark, the regional healthcare provider for Copenhagen and North Zealand.

The project finished in December 2013. Four Chronic Heart Failure (CHF) Outpatient Clinics in the region cooperated to establish and evaluate the use of telemedicine. The project focused on the clinical and organisational effects including cooperation with general practitioners and local government for outpatient treatment.

The clinical trial project aimed to verify the clinical use of telemedicine in the up-titration of patients with newly diagnosed CHF. Because of the side effects of CHF drugs, patients are called in for medical checks in the Outpatient Clinic every few weeks over several months with the aim of fine-tuning their medication. This process is very time consuming; both for patients and the clinical staff. With a telemonitoring platform, the patients were able to make simple measurements, such as weight, pulse and blood pressure, in the home, and exchange data and communicate with the staff at the Outpatient Clinic.

A total of n=60 CHF patients were selected to participate in the trial with the following conditions:

- Inclusion criteria: 1) Newly diagnosed CHF, 2) basic ICT skills, 3) acceptance
- Exclusion criteria: 1) Atrium fibrillation, 2) NYHA class IV[1], 3) frailty
- Opting-out criteria: 1) at wish, 2) anxiety with the technology, 3) negative effects on the communication between patient and clinical staff.

All patients were newly diagnosed with CHF, and many had diabetes, COPD and other chronic conditions. The randomisation allocation was 1:1.

The LinkWatch patient front-end was deployed on an All-In-One Touch Screen PC, both in the Outpatient Clinics and at home with the patients. The reason for using a large touch-screen PC was that previous user-centred design tests had shown that many patients were too ill to hold onto and use a tablet or smart phone. The patients were asked to measure pulse, blood pressure and weight every day. The weight was measured to monitor the patients for apnoea (an increase of weight of more than 2 kg in 24 hours triggered an event in the Outpatient Clinic). The patient verified and approved the measurements before they were transmitted to a backend hospital system using a user-friendly patient application with audio feedback and video conferencing capability.

The LinkWatch patient frontend perform comprehensive logging of user activity and performance of the software (human activity at the screen, reception of data from devices, transmission of data to an IBM backend server) as well as comprehensive software logging of exceptions and errors. No patient identifiable health data are logged. The data foundation consists of data from 31 patients using the frontend telemonitoring platform between 26 June 2012 and 2 January 2014 – a total of 2 years and 6 months. The total number of sessions (periods where the patient is using the monitoring equipment) was 3.318 resulting in 5.361 measurements being transmitted to the clinic.

The patient performs a measurement by clicking through a series of steps (screens). The first step is to decide which measurement to perform. After the physical measurement has been performed, the next step is to display the measurement on the screen followed by either a rejection or an acceptance of the values. If the measurement is accepted, the software sends the data to the backend server and displays the result to the patient. If the measurement is rejected, the patient reverts to the first screen. The entire procedure, i.e., from first to last click, is logged under one session.

Each patient performed a varying number of sessions during the time they were enrolled in the project. Some patients only made very few (1-5) sessions, because they left the project. Other patients stayed in the project for the entire length. These patients carried out up to 350 sessions. The number of sessions in total per patient is shown in Figure 1.

[1] New York Heart Association Classification IV: Severe limitations. Experiences symptoms even while *at rest*. Mostly bedbound patients

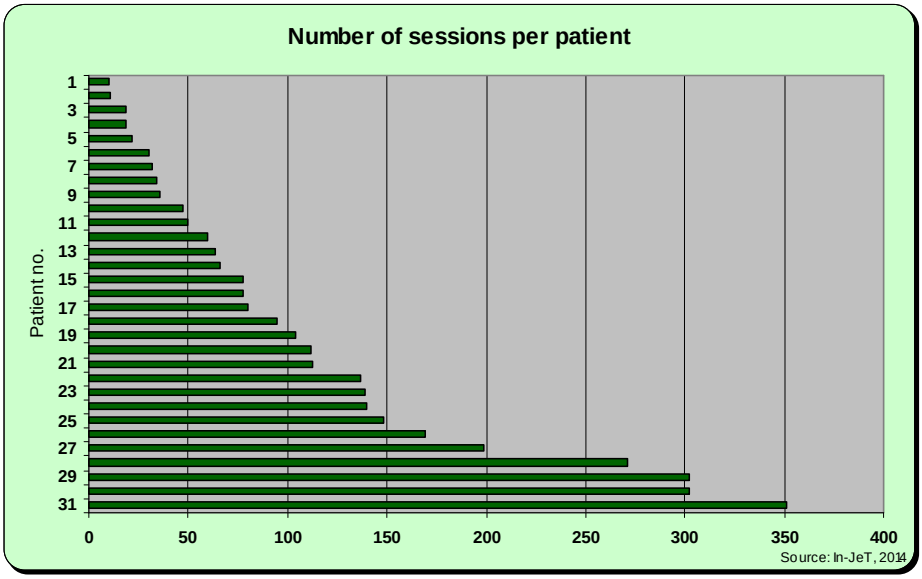


Figure 1: Total number of sessions per patient

The minimum number of steps needed to send *two* measurements successfully to the server is 9 including starting and stopping the application. As patients get more used to operating the equipment, they also perform the task more effectively. This is reflected in the total number of steps required in each session over the course of the enrolment as seen in Figure 2.

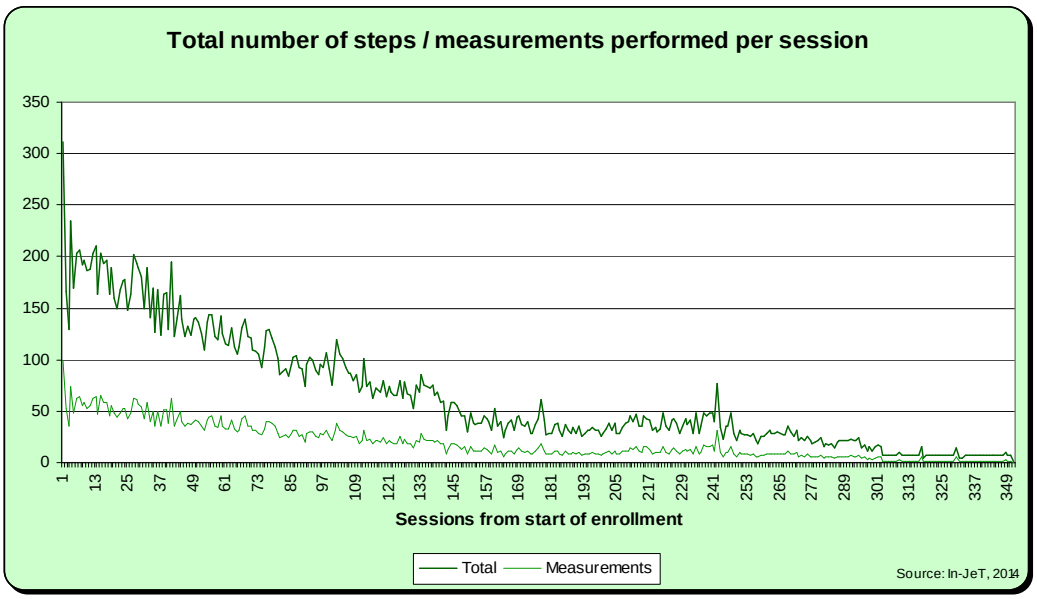


Figure 2: Number of steps per session across the entire enrolment

The initial phase is dominated by the patients' exploration of the system and its features. In the first week or so, most of the patients have navigated heavily around the user applications, partly because they were unfamiliar with the system, and partly because they were curious about what it could do. As time passed, the patients became more and more familiar with the equipment, and the number of steps per session decreased. Also the number of measurements decreased, reflecting that the patients are beginning to see the equipment as a daily tool rather than a new gadget.

The external project has provided a unique possibility to evaluate the performance of the LinkWatch Patient Frontend. The 2½ year clinical trial has provided data from more than 3.300 patient sessions collecting more than 5.400 health data in their homes and making more than 60.500 transactions on the user interface.

As a whole, the frontend platform proved to be extraordinarily user friendly and easy to use by the patients. After a very short learning phase the patients quickly got used to making measurements. The analysis shows that patients on average measured their blood pressure and weight more than 5 times per week and that each session could be done in 4-5 steps and took less than 6 minutes.

The patients rapidly reached a high level of proficiency with the equipment which also meant that most of the patients enrolled in the project decided to continue with the measurements for at least the foreseen up-titration period.

In terms of technical performance, the quantitative evaluation shows a high degree of reliability in terms of capture and transmission of data, but the total number of transmitted measurements actually received at the server was only 77% due to a relative large number of aborted measurements and unavailability of the server to receive the data. More qualitative work is needed to investigate why the measured data were not properly received by the server. When the data were received by the server, the patients enjoyed low response times of average 7 seconds from the patient clicked to transmit the date until the acknowledgement was shown in the screen.

Overall, the quantitative evaluations thus show a high degree of reliability and speed of the LinkWatch Patient Front-end whereas the ability of large EPR and HIS systems to reliably receive and process data from home monitoring should be better planned. A full technical evaluation report is available upon request.

LinkWatch use cases developed

This section includes use cases that have been developed and successfully demonstrated, but not yet deployed in large scale pilots.

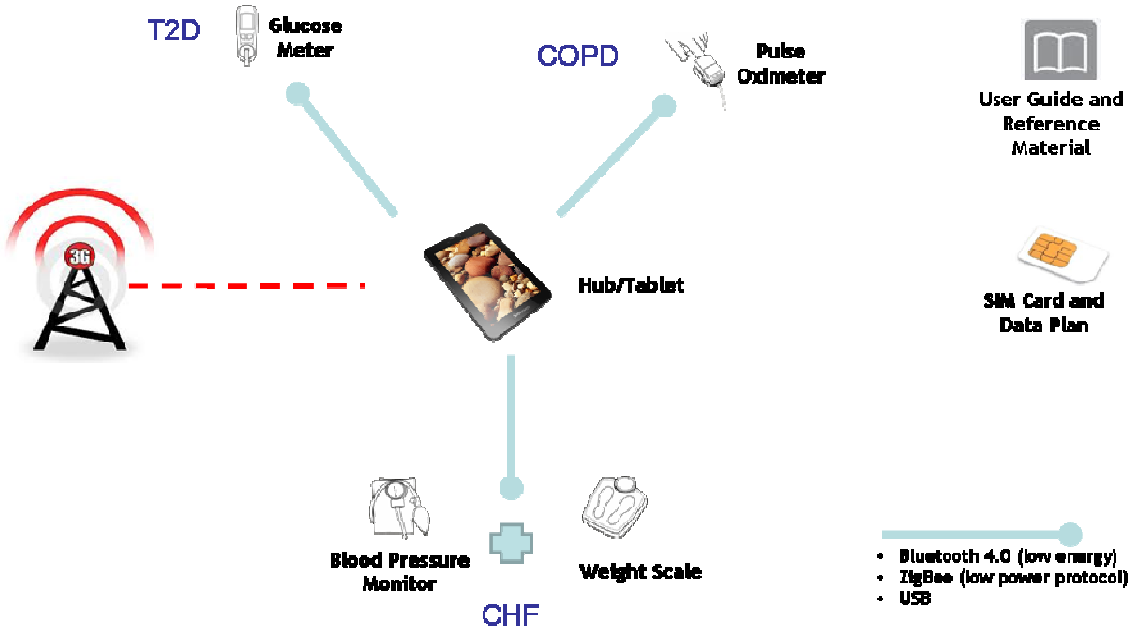
Large scale personal health monitoring

In this use case, a health insurance provider wishes to offer a Remote Patient Monitoring (RPM) service for its members. The number of members signed up could be as high as 20,000 patients subject to active monitored at any time.

The service will monitor vital signs such as blood pressure, oxygen saturation, weight, and blood glucose depending on the medical condition(s) of the member. One gateway shall be able to collect data from up to four different devices corresponding to 1-2 device types per chronic disease. The number of devices is to be configurable for each member.

The aim of the LinkWatch platform is to allow members to take measurements of vital parameters according to instructions or at will. The data will be collected either automatically via wireless connections to the devices or via manual data entry. After data has been collected, readings of devices will be displayed on the tablet through the gateway app. The data will then be tagged with the mode of entry and sent to an IBM server with the Electronic Patient Records.

The setup is illustrated in the following diagram:



Monitoring of this large number of patients requires large investments in medical devices and gateways. Hence, the design objective was not only to have a solution that fulfils the technical requirements, but also to propose a solution that can be deployed with a sustainable business model such as “Bring your own device” concepts. The LinkWatch Data Collection and Data Management software is able to automatically adjust to the diversity of hardware, which inevitable will be used in the field, as the service matures and new devices or tablets become available.

The authentication of the patients is performed by inserting an external SD card in the tablet. The card contains two certificates. A public root certificate for secure data transmission using SSL and an encrypted certificate for authentication of the member to be attached to the web service header. The latter certificate should be decrypted at the server. The hardware can thus be recycled to other patients simply by changing the SD card.

Health and wellness monitoring in retirement communities

Retirement villages provide residents with in community facilities, modern accommodation and excellence in care. Residents decide how much support they require, while finding comfort in the knowledge that they have 24-hour care if needed. An Operations Centre Case Manager is in charge of the monitoring of the citizens in the villages.

The home environment monitoring platform in this use case is based on the LinkWatch Patient Frontend for data collection and can be extended with the LinkWatch Care Portal for data analysis and event response thus forming a complete end-to-end health and social care support platform for integrated care and assisted living in nursing retirement homes and villages.

The LinkWatch Patient Frontend monitoring software runs on a ubiquitous home hub (called a gateway or black box). The gateway is connected to a broad range of home monitoring and automation sensors and actuators via wireless or wired communication means. The software collects and transmits data to a backend LinkWatch Care Portal server. Data are subsequent send to the Operations Centre main server. The setup is illustrated in Figure 3

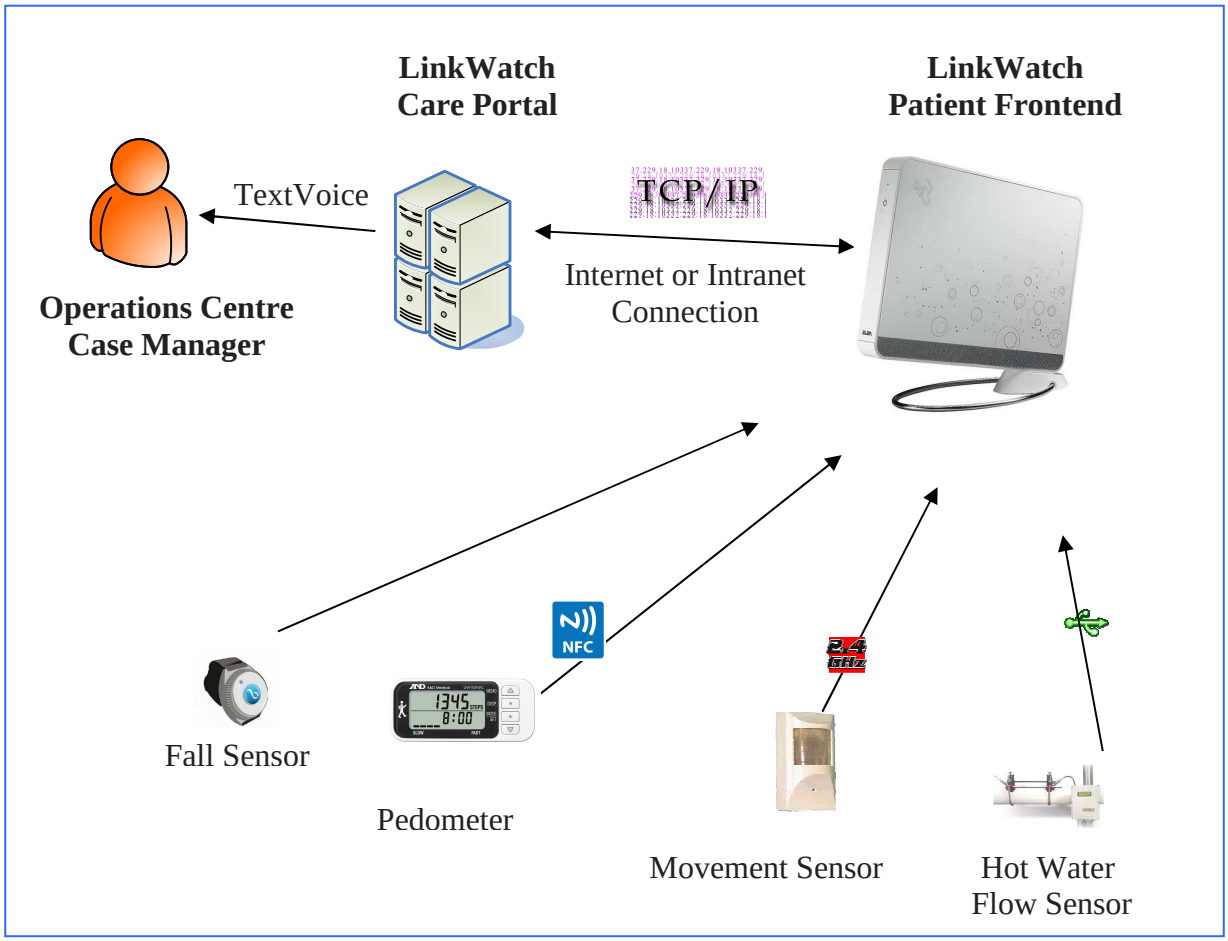


Figure 3: LinkWatch Platform and components

The gateway able to handle a several event handling functions locally. The environment state is established using a set of ubiquitous sensors in the apartment that monitors movements, activity, comfort, rest and other behavioural parameters. The gateway can also control actuators in the apartment or room, such as turning on lights (in the case of a fall event during night) or play recorded messages (for calming the inhabitant in case of emergencies). If a human user interaction device is included, such as a tablet, it also allows the inhabitant to remotely control or monitor essential functions in the home from the comfort of a chair or the bed.

Automatic execution (orchestration) of various services in the LinkWatch Frontend can be dynamically composed to suite the patient and his/her actual situation. The LinkWatch Patient Portal can further track deviations from a predefined behaviour or detect sudden changes or potentially hazardous events in the home.