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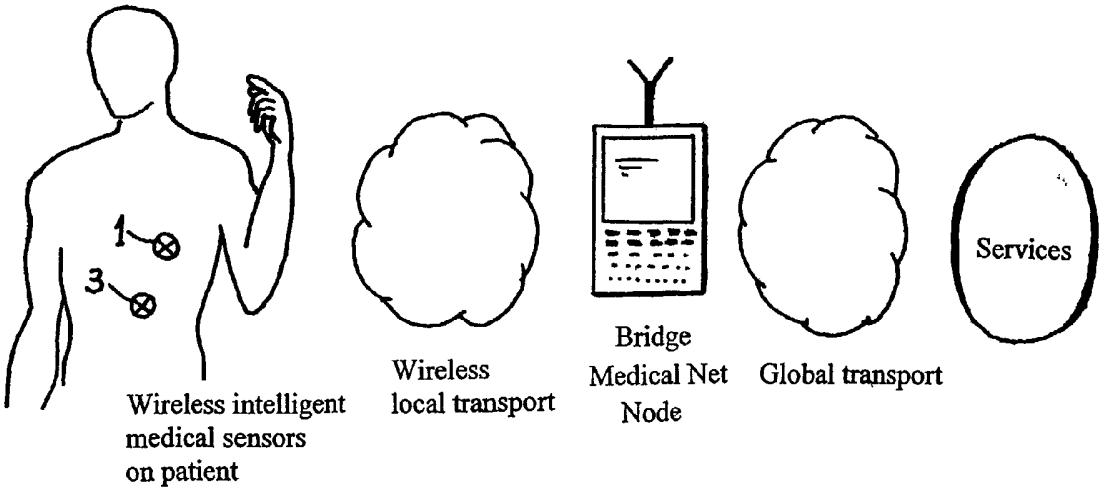
(54) **Title:** A CLUSTER SYSTEM FOR REMOTE MONITORING AND DIAGNOSTIC SUPPORT



(57) **Abstract:** A cluster system for wireless, real-time, remote monitoring and recording, analysing a recorded output and responding by feed-back, comprising sensors, processing means, transfer mean, at least one remote receiving station, control means and operating means. The sensors are preferably arranged in a cluster for interactive communication. The system forms a local communication network having access to Internet and is adapted for wireless, remote, real-time two-way data communication between any of the system units and/or through Internet. The two-way data communication is adapted for entering of instructions for acquiring and interpreting data from a number of data sources. In a telemedicine aspect the system uses Wireless Intelligent Medical Sensors (WIMS) for the monitoring of biological parameters and properties.

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A CLUSTER SYSTEM FOR REMOTE MONITORING AND DIAGNOSTIC SUPPORT

Field of the invention

The present invention comprises generally a feedback system for monitoring an entity or an object from a remote site, and more specifically a system for monitoring and recording of biological parameters on a patient, in order to provide diagnostic support.

Background of the invention

Traditionally monitoring of parameters and various quantities, events and factors has been carried out in different ways from locally/manually to more sophisticated versions employing distributed stations, automatic control featuring alarm and switching-off functions. An example of the first kind of system is the ordinary consulting of a doctor after having made an appointment, questions and answers during the consulting hour, prescription of a medicament, fetching said medicament at the local drugstore, using it according to the prescription, returning for a second consulting of the doctor and being declared not ill any longer. An example of a more sophisticated type of monitoring system could be a national electrical power distribution system where it is of great importance to maintain a constant supply voltage and AC frequency for every single subscriber and independent of varying loads and possible distribution failures.

In the last few decades the digitizing and miniaturization of particularly electronic components have accelerated, together with the expansion of microprocessor and personal computer use. This new generation of technology has reached almost every field of human activity including biology and the medical area.

A typical exponent for the latter, using computers and logical sequences for organizing medical care for outpatients, that is patients under surveillance but staying at home or generally outside the realm of a hospital, is to be found in the unexamined NO patent application 1998 1872, assigned to Unitron Medical Com. and having the title "Outpatient Care Data System".

The measurement of parameters is a key function for a system for continuous monitoring of an entity, and actual parameters in this respect could be physical quantities and properties, chemicals, element numbers, rays, activity, movement, position, colour, light, periodic and non-periodic events, waves, response, sensations, fluid quantity, physiological factors, pattern recognition, flow, time and geographical position. A number of these are discussed briefly below, mainly parameters with relevance to medicine and diagnostic support, as this field of technology is the main target of the present invention.

Temperature

Temperature is a parameter of great importance and represents a vital sign for patient monitoring. The way a patient's temperature is measured is crucial for the accuracy and thereby for scheduling, device specifications and application site, and the provision of reliable diagnostic information therefore will be strongly connected to the choice of measurement strategy. The human core thermal compartment having highly perfused tissues essentially at a uniform temperature lends itself naturally for direct invasive temperature monitoring, for example in the pulmonary artery, the distal oesophagus, the tympanic membrane or the nasopharynx.

Invasive measurements of this type obviously are not practical for the home patient monitoring, but fairly good results also can be obtained by using oral, axillary or bladder temperature measurements. The rectal temperature also normally correlates well with the core compartment temperature, although its measurement no longer is regarded to be so convenient for the home patient use.

At the human skin surface the temperature is considerably lower than in the core. Nevertheless it can often reflect the core temperature reasonably well when biased appropriately, but occasionally the measurement of the skin surface temperature results in unreliable diagnostic figures. Therefore it is important to carefully consider each case and its connected medical requests when selecting the temperature measurement technique.

A number of methods and devices are available for temperature measurements, and a few are listed below:

- Thermocouples offer temperature sensing simplicity and use the Seebeck effect for electrical conductors exposed to a longitudinal temperature gradient.

- Thermistors are inexpensive semiconductors having a highly temperature dependent electrical resistance. Similar but offering higher precision are temperature sensors using a resistive metal element with a positive resistance/temperature coefficient, such as platinum.

- Infrared, non-contact temperature sensors are based on Planck's Law for thermal emission by electromagnetic radiation and are widely used. A typical example is the tympanic or ear thermometer.

- Bimetallic sensors are based on the different thermal expansion of two metals.

For medical and other use as well, these principles and several others are used in many different types of thermometers and thermal sensors on the market, both in disposable and reusable versions and reasonably well suited for advanced monitoring.

Arterial blood pressure

Several ways to measure blood pressure are known to the art. One commonly employed is the non-invasive oscillometric method, using an inflatable cuff around a patient's upper arm, wrist or finger. By varying the cuff air pressure from completely occluding the artery until fully deflated and examining the corresponding external pulsatile pressure changes due to the arterial wall expansions and distensions during each cardiovascular cycle, a relative measure for the systolic (SBP) and diastolic (DBP) arterial blood pressure is given. The absolute values are obtained by the use of calibration factors established by correlation with auscultatory or catheter measurements. In addition the mean arterial pressure (MAP) - when the artery is unexpanded - is estimated. In electronic versions of the device used, pressure transducer means generate electrical signal outputs that follow the magnitude of the pulsatile pressure cycles and are suited for subsequent cardiovascular pulse waveform analysis and/or transfer to a remote site.

Unfortunately disturbance factors or artefacts can give inaccurate blood pressure values. One such factor is caused by vibrations that make it difficult to determine the maximum and minimum pressure, a situation often experienced during emergency transportation.

Electrocardiography (ECG)

The ECG is a medical diagnostic and monitoring aid for recording and interpreting the electrical activity of the heart with the aid of electrodes placed on the skin on specific locations, such as on the chest. Different heart anomalies and disorders can be revealed by deviations from the normal height, form, or duration of the wave patterns. The ECG method is non-invasive and has no contraindications. The sensor systems, including the electrodes, their attachments and the connection cables, are mainly the single-wire or one-lead monitoring type, the 2, 3 Holter lead type for an orthogonal scheme, and the standard twelve-lead type, each with a different electrode commutation scheme. No commercial system can today support all these systems.

The ECG skin surface signals are in the range of 1-10 mV and are accompanied by common mode noise signals up to several volts, differential signal components and a variable DC component up to several hundred mV. For noise suppression a combination of digital and analogous filtering is used, and an ECG system should also be protected from defibrillator pulses at high voltage and have a defibrillation recovery time of not more than 10 sec. ECG safety is defined in EC № EN 60601, safety class 2, type CF.

Many existing ECG systems also recognize pacemaker signals and filter them out, and some systems even indicates the pacemaker pulse position in the recorded diagraph. A calibration signal of 1 mV is standard. Typical ECG characteristics are:

- Frequency band: 0.05 – 300/500 Hz
- Sampling rate 200-300 Hz for the Holter type, 500 Hz for the standard type, and higher (1-4 kHz) for high resolution types
- Common mode rejection: 100 dB
- ADC resolution: 8-16 bits
- Sensitivity: 5-15 μV
- DC component reduction to zero: <300 mV
- Pacemaker pulse detection: >0.5-5 ms, >5-10 mV

The quality of the electrical signals is strongly dependent on the stability of the body-to-electrode contact, which is especially important during continuous monitoring (Holter type). At the same time, the electrodes should not provoke skin irritations, and this calls for stringent requirements for the device contacts, housing and electrodes. The contacts are usually gold or Ag/AgCl plated, and typical supporting materials are foam, tissue, vinyl and polyester. The electrodes may have a micro-replicated surface and a layer of conductive wet or solid gel (i.a. NaCl-based) to gently prepare the skin for optimal signal quality pick-up, partly by lowering the skin impedance. Some devices also measure the skin contact resistance during the ECG recording by measuring the interelectrode impedance.

Both reusable and disposable contacts are used. Cleaning and disinfecting of the former include the alcohol standards CE, FDA, EN 46001 for Ag/AgCl and all regular disinfectants for gold plating. Today disposable electrodes are mostly used .

Common methods of electrode attaching involves:

- Medical grade adhesives that can be used up to five days and yet feel gentle to the skin.
- Non-adhesive bandage roll dressing (can be used for wrapping).
- The ECG rubber belt, a system of electrodes cast in a flexible silicone belt and corresponding to the traditional V1-V6 pre-cordial electrodes. The belt should be flexible (for example made of platinum based silicone rubber) and should be able to fit all body shapes and sizes. The belt is quick to put on and easy to use.
- For immobilized patients or during sleep the one-lead ECG can be used for recording by means of a special sheet having embedded contacts.

The electrodes could also be fixed adjustedly to a jacket or suit the patient is wearing during the ECG. An effective electrode lead and cable shielding should be provided to reduce the external signal and noise level.

A fairly advanced system for patient surveillance and mainly devoted to remote heart monitoring using ECG, is found in US patent 5,634,468 to Platt and Satchwell, and the disclosure of this patent is hereby included as referance.

Pulse oximetry (O_2 saturation of capillary blood - SPO2)

A pulse oximeter usually measures the absorption of light at two wavelengths (e.g. 650 and 940 nm - red and infrared region), emitted from diodes (LED) and passed through a capillary bed, in order to distinguish between the oxygenated and reduced haemoglobine content in the arterial blood in the bed. The absorption ratio of red and infrared light is measured at each pulse beat, and by proper processing with reference to the pulsatile nature of the blood it is possible to focus on the arterial blood only and ignore other light absorbing substances. A number of suitable sensors are available on the market, for measuring at different places on a patient, like a finger, toe, the bridge of nose or the ear. Some difficulties may be present when the patient pulse is weak and the blood circulation poor.

Spirography (End Tidal CO_2)

The monitoring of a person's exhaled CO_2 indicates the working of the body metabolism giving CO_2 as a by-product. The typical instrument of today for this kind of measurement uses what is named an End Tidal CO_2 sensor (ETCO2), a device fairly well adapted to continuous and remote monitoring.

Motion

The measurement of motion in the three spatial directions x, y and z (3D) of the standard Cartesian coordinate system can be effectuated by a corresponding number of orthogonal sensors of the translatory or acceleration type. One or more such sensors attached to a person can give remote information about his/her physical activity level.

Position

The measurement of position related to some reference coordinate x, y, z in the same 3D system can also be made by a corresponding number of orthogonal sensors. One or more such sensors attached to a person can similarly give remote information about her/his physical position, for example to distinguish between an upright, a sittig and a lying position.

Geographical position

The measurement of geographical position is today relying upon the satellite supported system Global Positioning System GPS, and small transceiver units are available for handheld use throughout the world. The accuracy of positioning is normally in the order of a few meters up to a few hundred meters.

The parameters mentioned separately above are chosen for their suitability for digitizing and remote monitoring. Other parameters or tests of interest within the medical field are the following, although not so easy to monitor or not suited for outpatient care:

> X-ray studies; routine blood analysis; echocardiography and other ultrasound examinations; serum, BUN, urine and glucose analysis; weight, measures, BMI, subcutaneous fat layer thickness; VO_2max, anaerobic threshold, blood lactate level and other performance figures obtained during exercise; electroencephalography; audiometry; tonometry and general ocular evaluation; myography and others.

A common feature for the patent documents cited above and similar solutions belonging to the present prior art is the attempt to increase the distance between a sensor or monitoring instrument and an interface to a user or a medical professional, by introducing communication means. In this way a better flexibility is aimed at for the monitored entity, and in the case of a patient under surveillance the ideal goal would be that she/he freely could move around or stay at home while still under attention.

Current monitoring systems have in fact obtained some flexibility in this respect and are also offering improved user safety, by combining available subsystems and common principles for alarm handling including automatic circuits, and data storage/logistics.

However, they have so far not succeeded in providing true real-time monitoring including an effective feedback to the monitored object or an outpatient, and there are still many parameters not being covered by existing systems, partly due to lack of speed and "intelligence", partly due to unsolved measuring, cross connection and transfer problems and partly due to the prior art limitations within data distribution, storage and processing.

The purpose of the invention

On this background the purpose of the invention is to launch a system that avoids the shortcomings of the state of the art as indicated above and brings the remote monitoring technology another step forward into a new generation. A main object in this respect is thereby to provide a system for remote monitoring and recording, analysing a recorded output and responding by feedback, comprising:

a plurality of sensors, each for measuring at least one individual parameter and providing an output related thereto,

first processing means for processing each sensor output,

additional processing means for further processing of signals/data related to said sensor outputs and for processing of inputs,

transfer means for transferring signals/data related to said sensor outputs,

at least one remotely arranged receiving station for recording, analysing, storing and responding by said feedback,

first control means for controlling the processing and transfer of signals/data,

additional control means for controlling the recording and storing of data related to said sensor outputs, the recording analysis and said processed inputs, and

operating means for accessing different processing levels in the system and presenting relevant information therefrom for a user.

Further objects for the invention are system solutions based upon an open platform and being adapted for sensing and monitoring physical quantities and properties, chemicals, element numbers, rays, activity, motion, position, colour, light, periodic and non-periodic events, waves, response, sensations, fluid quantity, physiological factors, pattern recognition, flow, time and geographical position, and any combination of same.

Summary of the invention

The invention represents a further developed system for measuring biological, physical and other types of parameters from the list given above, partly by introducing some degree of artificial intelligence, mainly at the sensor level. This makes the monitoring sensors capable of self-adjustment and diagnostics, as well as enabling actions like changing monitoring schemes, initiating additional data collection from other sensors or data sources, data filtering, verification and comparison, multimodal diagnostics and diagnostic supports of various kinds, including multifunctional, multimodal and support based on the monitored object or patient history and case studies.

The system according to the invention thereby is presenting what is to be named a new generation of monitoring and communication solutions. These are based upon an open platform and are particularly suited for telemedicine, so as to provide day and night real-time medical monitoring and by using instruments connected through a network (Wireless Intelligent Medical Sensors - WIMS) for till now unobtainable outpatient care quality including diagnostic investigations. However, the open technological solutions are flexible and can be used in a wide variety of applications where it is of importance to have an advanced monitoring, analyzing and responding system, and the invention will cover a number of technological aspects. In the telemedicine aspect the users can be the

medical professionals as well as the non-professionals, the latter comprising care-givers of different kind, parents and the patients themselves, and in other connections a similar distinction between the type of users can be made. In order not to make this summary and the following description too comprehensive, mainly the medical or telemedicine aspect will be discussed broadly.

The general instrumentation of the system of the invention, including the Wireless Intelligent Medical Sensors WIMS, must have an open architecture and/or enable further expansions, so as to include future sensor and subsystem developments and devices and solutions from various suppliers. The instruments and units of the system are preferably modular and of the miniature type, especially at the sensor end, and they are developed or selected for real-time monitoring and data sampling - such as the continuous recording of data for a patient's status - at a high quality level. Preferably the sensors and/or the instruments WIMS have some "intelligence" for an advanced converting of parameters or physiological signs into electrical signals, combined with other functions like selecting communication routes, preparing diagnostic information, performing control, local data storage, processing, visualization of results, diagnostic assistance, patient record storage and transport of information. The system according to the invention, in the following also called the WIMS system, also offers real-time communication between sensors and other network resources, thereby opening for information exchange and processing of supporting functions. Such functions could comprise multivariant data analysis and advanced calculations and processing, in some applications even based upon artificial intelligence techniques incorporating case based reasoning and inductive learning.

According to a first aspect of the invention there is provided the forming of a local communication network having access to a global computer network so as to be a part of same, and having nodes being represented by said sensors and processing, transfer, control and operating means, for real-time two-way data communication directly between any of said nodes and/or through the global computer network, said two-way data communication enabling the entering of instructions for the subsequent acquiring and interpreting of data from a number of data sources.

According to a second aspect of the invention said sensors are chosen from a group of sensors adapted for the sensing of biological parameters, physical quantities and properties, chemicals, element numbers, rays, activity, motion, position, colour, light, periodic and non-periodic events, waves, response, sensations, fluid quantity, physiological factors, pattern recognition, flow, time and geographical position, and any combination of same.

According to a third aspect of the invention the processing means comprise at least one processor employing artificial intelligence.

According to a fourth aspect of the invention the processing means comprise at least one processor employing case based reasoning and/or inductive machine learning.

According to a fifth aspect of the invention the transfer means comprise transmitters and receivers for local and remote communication from the group of communication means comprising wireless, acoustical and optical communication.

According to a sixth aspect of the invention said transmitters and receivers for wireless communication comprise the use of RF modules and circuits such as Bluetooth, GSM, GPRS, UMTS and wireless LAN communication units, said RF modules and circuits being arranged in order by a communication module according to how effective communication they provide, whereafter the modules and circuits are selected from the top of the arranged order by said communication module, to obtain the most effective communication.

According to a seventh aspect of the invention said additional control means comprise the providing of data processing, forwarding and storage, automatic diagnostics of patient symptoms or technical support, enabling parameter changes and event control, acute medical response and trend analysis.

According to an eighth aspect of the invention the sensors comprise circuiry capable of selecting communication channels to other sensors and/or devices in order to provide combined parameter monitoring.

The invention will be better understood by reading the description of typical and alternative versions, given below and supported by the drawings.

Brief survey of the drawings.

Fig. 1 is a general overview of the system of the invention,
Fig. 2 is a scematic illustration of the system scope,
Fig. 3 is a block diagram of a general model of the system,
Fig. 4 is a communication scheme of the system,
Fig. 5 is a typical framework for machine learning,
Fig. 6 is a block diagram of an intelligent sensor functional layout,
Fig. 7 is a block diagram of the hubless architecture of a sensor,
Fig. 8A and B are block diagrams hub based sensors,
Fig. 9 is a typical intelligent sensor layout,
Fig. 10 is a generic WIMS digital part,
Fig. 11 is a sensor logical scheme for ECG,
Fig. 12 is a block diagram of a measuring set-up for ECG,
Fig. 13 is illustrating the ECG control circuits,
Fig. 14 is a graphical view of an ECG signal having a low S/N ratio,
Fig. 15 is a block diagram of a temperature measuring setup,

Fig. 16 is showing a blood pressure measurement cycle,
Fig. 17 is showing the blood pressure oscillations during cuff deflation,
Fig. 18 is a block diagram of the use of the system according to the invention for blood pressure monitoring,
Fig. 19 is a measuring set-up for blood pressure measuring,
Fig. 20 is a typical Bluetooth device architecture,
Fig. 21 illustrates the Levitt organization diamond, and
Fig. 22 is a flow diagram over a typical blood pressure monitoring.

Detailed description of typical embodiments of the invention

In Fig. 1 is shown an overview of the system according to the invention, also called the WIMS system due to the so called Wireless Intelligent Medical Sensors WIMS especially adapted for telemedicine. Patients are schematically illustrated and wearing intelligent sensors 1, 3. These sensors monitor parameters like temperature, blood pressure and others, such as general biological parameters, physical quantities and properties, chemicals, element numbers, rays, activity, motion, position, colour, light, periodic and non-periodic events, waves, response, sensations, fluid quantity, physiological factors, pattern recognition, flow, time and geographical position, and any combination of same. At sensor level these parameters are registered as analogue values or events and are processed by filtering, correction and digitizing before or after a local transport to a central bridge as illustrated. The digital signals are analysed on the background of given parameters, such as profile comparison, alarm thresholds, assumed trends etc., and additional data can also be acquired from other instruments or data systems. The further interpretation of the monitored parameters can be made by multivariant analysis and diagnostic algorithms.

The communication carriers for transporting the data can be selected manually or automatically, based upon the availability of effective communication channels, costs and capacity. Alarm functions may be connected to the communication, in order to alert mechanisms or surveying persons in case of emergency or due to other criteria.

The sensors (WIMSs) and various components or units in the complete system can be prepared for self-calibration, autonomous or manual testing and error message services.

A main feature of the system according to the invention is the ability to receive instructions for thereafter automatically acquiring and interpreting of data from various sources.

In the following description alarm centrals and surrounding services are not considered as a part of the invention and will therefore be omitted.

As summarised above, the system and its instruments and sensors WIMS employ a combination of the following unique modules or facilities:

1. Miniaturized, intelligent biosensors or biosensor packages for real-time monitoring and sampling of patient status data and at the quality level needed by specialists.
2. Short range, cable free, two-way data transmission from patient to a Medical Net Node (MNN) acting as a bridge.
3. Long range communication.
4. Software services to integrate binary objects (images, video streams, raw signal data etc.) into the local and remote health care information system.
5. Value added services linked to the patient/sensors.

Three main components are comprised in the WIMS:

1. An intelligent biosensor (IBS), defined as a miniature patient friendly sensor for converting physiological signs into electrical signals and preparing the diagnostic information obtained, for further transportation and fully ensuring the state-of-art quality of monitoring and diagnostic information. The IBS is built on a generic HW platform, open for further expansion.

2. Services, including primary services critical for the IBS functioning, such as IBS control functions, local data storage and additional processing, visualization of results (user interface) etc. and value added services obtained from the Web (e.g. diagnostic assistance, patient record storage etc.). The patient status analysis is based on the multimodal or multisensor environment. The services form an essential part of the WIMS system and should be integrated in the medical care environment.

3. Transport for transferring the physiological information, also for service access and control function delivery. Depending on the way the services are accessed, the transport could be local and/or global. In the latter case a logical gateway/bridge (see Fig. 1) facilitates the connection of the local transportation to a global network.

Wireless Intelligent Medical Sensors are designed to operate in a wide range of different environments, to be used by a variety of different user groups and to be used for both monitoring and diagnostic purposes. The scope for the system using WIMSs is illustrated in Fig. 2, as a 3D block and particularly devoted to telemedicine. To the left are listed the different resources for patient care, including the patient her/himself. The various care

activities are illustrated in the layers from the front and backwards, here: diagnostics, monitoring and treatment. The different sites for these activities are given in the layers from left to right.

The potential application areas of the proposed WIMSs are very wide:

- Home. The monitoring or diagnostics is implemented in patient home conditions. This could be a primary visit, home monitoring or tele-consultations;
- Personal. Monitoring of the patient via global wireless communication regardless of his/her location.
- Hospital. The infrastructure, the level of care and the availability of medical equipment is the highest compared to other areas.
- ICU (Intensive Care Unit). This is very specific application area, with the highest requirements for reliability.
- Nursery home. Very similar to a hospital infrastructure. The MCN can be placed in cooperation with a hospital to provide medical expertise
- GP's office. The information infrastructure is often not so well developed, compared to the hospital. The expert second opinion services will be highly callable. The instruments should be prepared for transportation.
- Transportation vehicle. This is not only medical transport (e.g. ambulance, helicopter or car), but also includes specific markets where there is a need for mobile monitoring, such as ocean ships etc.
- Work place. This is a natural environment for the patient. Ideally the patient could be monitored at his/her working place. In some cases this could be extremely important for the critical duty positions (such as pilots), sometimes it could be treated as an important source of additional diagnostic information, in order to monitor the patient in the natural conditions.

The capability of the WIMS system to work in different locations represents the basic WIMS feature to support the seamless care, where the term seamless is treated widely not only as a information storage with universal access, but also the possibility to support continuous monitoring, while the patient is moving from one location to another and especially when transferring between health service sections that traditionally have not the ability to share information effectively.

Depending on the use of the WIMS system there can be several different user groups involved with specific characteristics:

- Patient/caregiver. This is especially actual for the home care. The patient/caregiver has a very limited ability in medical information analysis and has no possibility to perform comprehensive medical manipulations (e.g. standard 12 lead ECG electrodes application), this results in some cases in the need for special sensor construction. This user should have a very limited system control rights and has no need in value added services.
- Nurse. Professional that could perform some medical manipulations. Has the intermediate level of WIMS system control. The value added services will be requested in a limited way.
- General practitioner (GP). Should have a high level of system control. Most of the value added services would be highly requested.
- Specialist/expert. The most qualified user and should have total access to the WIMS services.

The potential of the WIMS to be used by users with different qualification and acquirement is another major property of the WIMS family: adaptability.

The main purposes of the WIMS utilisation can be summarized as follows:

- Diagnostic. Providing high quality diagnostic information.

- Monitoring. Continuous monitoring of patient physiological signs, with convenience of use and self-testing possibilities.

- Treatment. Potential for active treatment.

The system of the invention can be used for different patient groups and forms a multi-modal system, incorporating different sensors. This makes it possible to use the system in different medical cases and taking different age groups in consideration: neonatal, infants, elderly and adults, as well as the corresponding diagnostic algorithms.

The modalities provide both single measurement data in monitoring and continuous binary data, and they also represent a suitable combination of instruments for use in advanced homecare.

One of the main benefits, as health care moves from the traditional health care institutions out into the home care environment, is a better "quality of life" as a patient. This has been shown to lead to improvements in the quality of care as seen from the patients themselves and their relatives.

One primary requirement resulting from this change is that the patient is more mobile and in an environment which is not as well controlled or regulated as for example a hospital ward. Wireless communication is a pre-requisite of mobility which is a pre-requisite for improving the patient's quality of life during the care period.

Home care can be seen as a restricted mobility situation where the access to the connections within a fixed and relatively reliable network generally is available. However, WIMSs are adapted to be used in situations where the patient is fully mobile or otherwise not within the range of a fixed network communication point, such as by the rehabilitation of cardiac patients or paramedic acute services. In these situations both the short and long range communication is wireless, including optical and acoustical transfer. The WIMS system concept is, within the possibilities of today, made flexible, in order to be adaptable to even future developments in wireless network/Internet access. The requirements of environmental and user group variability and the wireless aspect of the technology lead to the requirement for miniaturization of the WIMS sensors. Many older types of sensors have shown excessive "wear" or degradation over extended periods of time, and this has been given serious attention during the development of the sensors according to the invention. Therefore both ergonometric, tactile, weight and dimensional design considerations have been taken, to give the least possible inconvenience for the user.

Flexibility and modularity are also keywords when regarding the architecture. The different sensors will have the ability to use a variety of communication carriers, and the services will be available on several different platforms.

Intelligence in the context of WIMSs indicates that the sensors and associated services will interact to provide the best possible data collection and analysis scenario in a given situation, and automatically carry out adjustments based on programmed rules, should the situation change, i.e. into an alarm situation. The open architecture and vendor independence also assume a certain level of intelligence, allowing the future sensors to be integrated in the system at a high level.

Fig. 3, also given in the text, illustrates a general model of the system according to the invention and should be self-explanatory.

Fig. 4 shows the communication from the sensors to the bridge illustrated in Fig. 1, and in this case this bridge comprises a Medical Net Node (MNN) including a data base for data storage and a database interface (API). The communication goes both ways between

this computer MNN and a medical communication node (MCN) 2, also comprising a data base and an interface API. From there communication with other hospital information systems also goes through a two-way channel.
Initially the sensors will send information at pre-programmed intervals to the Medical Net Node MNN, as it is shown in Fig. 4, where the analysing of the information is taken care of. The analysis results are compared with the personal monitoring plan for the patient, and if a condition is detected that requires notification, the appropriate action will be taken. The MNN may in this case send a request to the sensor to change data transmission mode from for example periodic to continuous data transmission for a specified period of time. Even the Medical Central Node (MCN) can send such a request to the sensors via the long and short range communications channels.

Data from the WIMS sensors will be linked with information pertaining to the user of the sensor thus putting it in a context. The information will be transmitted across a network, for example the Internet, and analysed by medical experts and computer based expert systems. The net based services involved include therefore; data storage and retrieval, data visualisation, Inductive Learning (IL) or Case Based Reasoning (CBR) expert systems analysis, health care expert second opinion analysis.

These services are enabled through the Medical Net Node and the Medical Central Node and offer essential potential benefits.

The key features of the Wireless Intelligent Medical Sensors are therefore the open architecture, its flexibility and the ease of use at home. Miniaturized, non-invasive sensors give high quality information, and important characteristics of these sensors include the convenience and ease of use by non-qualified personnel, a good accuracy also under the conditions of home care, a reduced power consumption, a certain degree of intelligence and a flexible algorithm.

To ensure a universal protocol of the data exchange between the sensors and decision centre, the intelligence should be introduced at the sensor level, but also distributed over the system. The electronics associated with the sensor then incorporate a part of signal processing and primary data analysis, re-programmable controller part and universal interfaces with the sensors and the outer world. The signal processing in the modalities of interest usually (at a very general level) is as follows: the analogue inputs go through an amplification part with possible analogous filtering, this could be done with a Programmable Gain Instrumentation Amplifier (PGIA) (the amplification coefficient should be adaptive and sometimes could be varied during the measurement process (i.e. for oximetry), then through an Analogue to Digital Converter (A/D), the Digital Signal

Processing (DSP) is implemented to reduce the noise and adjust the signal shape. There are dozens of standards for the data exchange used in medical systems at the sensor level. The detailed analysis of their applicability would be implemented within the project. The on-chip integration of the associated electronics with the sensor itself (detector) could face problems due to the fact that the medical sensors have very specific nature they are often disposable and even being reusable need sterilization, the application sites are very specific too. This causes difficulties with the packing, as well as to the economical efficiency. Therefore, the most suitable decision is the use of the stand alone sensors (detectors) with the universal processing chip.

To miniaturize the system components and at the same time get optimal performance, Application Specific Integrated Circuits (ASIC), tailor made electronic chips are employed. The system components like microprocessor, analogue blocks, RAM/ROM and other standard functions can be integrated in one chip. Still the chip will have a lot of space left for logic ASICs specifically designed and often called Systems on Chip (SoC). SoCs open up for miniaturization that was impossible a few years ago.

A SoC can be developed in several ways, depending on the readiness of the requirements and specifications, the time-to-marked needed, risk analysis, etc. One possible way is to first make a prototype with stand-alone components for the standard functions and let the application specific logic be integrated in a Field Programmable Gate Array (FPGA). Together, these components make up what will later be the System on Chip. This is a way to go if low risk and system exploration are the main driving forces, rather than time-to-marked.

The FPGA can be programmed over and over again, using the same programming language that the application specific parts of a SoC use. When the system is fully debugged and working, development of the SoC can start. For use in a SoC, many standard analogue and digital functions can be bought as so-called "Intellectual properties". Together with the code from the FPGA, this will form the building blocks of the SoC.

There exist several specifications for radio based short-range communication that uses different radio frequencies available for public, unlicensed use in different countries.

- Non standard products
- De facto standard products

Several radio based short-range communication products that do not follow a standard are available, like single chip integrated circuits for single channel, multi-channel and spread spectrum network communication. Such a circuit comprises a complete digital radio transmitter and receiver on the same chip. The transceiver can transmit data at a speed of 64000 bits per second (bps), and the frequency range is from 300 MHz to 1100 MHz covering a worldwide allocated frequency band.

An advanced form of frequency management known as 'spread spectrum by frequency hopping' (SSFH) is employed by the transceiver to increase the number of available channels, to increase the security of the transmission and facilitate the use of the transceiver in a network.

The so called HomeRF Working Group (HRFWG) was formed to provide the foundation for a broad range of interoperable consumer devices by establishing an open industry specification for wireless digital communication between PCs and consumer electronic devices anywhere in and around the home. The HRFWG, which includes the leading companies from the personal computer, consumer electronics, peripherals, communi-cations, software, and semiconductor industries, has developed a specification for wireless communications in the home called the Shared Wireless Access Protocol (SWAP).

To date, the high cost and impracticality of adding new wires have inhibited the wide spread adoption of home networking technologies. Wired technologies also do not allow users to roam about with portable devices. In addition, multiple, incompatible communication standards have limited acceptance of wireless networks in the home. The HRFWG believes that the open SWAP specification will break through these barriers by (1) enabling interoperability between many different consumer electronic devices available from a large number of manufacturers, and (2) provide the flexibility and mobility of a wireless solution. This flexibility is important to the success of creating a compelling and complete home network solution.

Since the formation of the group was announced in March 1998, the total number of member companies now exceeds 90 and continues to expand quickly.

Three sub-committees exist within the HomeRF Working Group. The HRFWG-Japan sub-committee was created to assist in defining the SWAP specification and ensure that it complies with local regulations. The group has also formed committees to plan future versions of SWAP that address wireless multimedia and a lower cost alternative. The SWAP specification defines a new common interface that supports wireless voice and

data networking in the home. Representation from the wide range of member companies, which span diverse industries, ensures that the final specification is complete and robust, and that devices envisioned as part of the home network are interoperable.

Bluetooth is an open global conceived by Ericsson, IBM, Intel, Nokia, and Toshiba to develop an open specification for short-range wireless connectivity between laptop computers and cellular telephones, the Bluetooth Special Interest Group (SIG) has expanded to over 1,000 members. The SIG standard intends to replace all kinds of cables using short-range radio technology. Originally the market for Bluetooth devices is estimated to be as large as $3 billion by 2005, many designers will be incorporating Bluetooth connectivity into their designs. Bluetooth devices will replace RS-232, parallel, Universal Serial Bus (USB), and other types of cables with a single, standard wireless connection. Thus, any Bluetooth-certified device will be able to communicate with any other Bluetooth-certified device. For example, a Bluetooth-certified personal digital assistant (PDA) or cellular phone will work with any personal computer equipped with a Bluetooth-certified card. All Bluetooth-certified devices must have the components described above, to be in accordance with the Bluetooth standard. The standard and certification procedures guarantee global interoperability between devices. With over 1000 members of the Bluetooth Special Interest Group (SIG), development of version 1.0 of the standard was announced in July 1999. The roadmap for the standard calls for Bluetooth end products to become available from a wide variety of suppliers.

There is a website at http://www.bluetooth.net for more information about Bluetooth development and issues.

On the Medical Net Node MNN side a standard Bluetooth PC card is preferred. On the sensor side we have more choices. Probably a good solution for the prototype is to use Ericsson's Bluetooth module interfaced through UART interface. The UART interface gives 460 kbits/s raw bandwidth. Using the USB interface would provide more bandwidth, but would make the sensor more complex, as a USB controller and associated software on the processor also would have to be included. The application software on the sensor processor will call available functions in the HCI or L2CAP C-library to communicate with the Bluetooth chipset. The Ericsson Bluetooth module can be connected via a standard RS232 interface to a PC's serial port. This enables to use the PC for development and debugging of the sensor's Bluetooth-SW, instead of using the embedded processor. When the code is stable, it can be ported to the embedded processor.

Algorithms facilitating the interpretation of complex data are necessary, i.a. for detection of fiducial points (first step of standard ECG diagnostics), diagnosis of atrial and ventricular hypertrophy, classification of complexes during rhythm monitoring and analysis, and analysis of RR series for detection of atrial fibrillation during rhythm monitoring, to mention some examples.

The applicability of machine learning techniques for development of such algorithms are briefly provided below, as well as the state of the art related to these areas.

Fig. 5 illustrates the general framework of simplified machine learning, as several of the components and units within the inventive system preferably are adapted for such learning, that is possessing a certain artificial intelligence. Machine learning as a separate field in artificial intelligence (AI) appeared in 1960's. Its objective is to develop computational methods that would implement various forms of learning, in particular inductive learning (learning from examples). Learning algorithms can be divided into two major categories: black-box methods (neural networks, statistical methods) and knowledge-oriented methods. Black-box methods develop their own internal concept representation, which usually cannot be easily interpreted by a user. On the other hand, knowledge-oriented methods create symbolic knowledge structures that satisfy the principle of comprehensibility. In this document we only focus upon symbolic methods. In general, an inductive learning process can be divided into the following steps:

Discretisation. Continuous-valued attributes are discretised, i.e. continuous space is divided into a number of intervals. Nominal attributes (each corresponding to an interval) are introduced instead of continuous ones. Discretisation is often used to evade the problem of dealing with numeric values. Several discretisation methods exist, such as ChiMerge, equal-width/equal-frequency-intervals, Max-min into k means, Valley, Slice. But empirical studies show that discretisation seldom leads to improvement of classification results (as compared with direct handling of continuous attributes), in most cases it leads to their deterioration. Thus, it is better to skip this step and work with continuous values directly.

Evaluation Measures	Generation Procedure		
	Heuristic	Complete	Random
Distance Measure	Relief, Relief-F, Jakub Segen's	Branch and Bound, BFF, Bobrowski's	
Information Measure	DTM, Koller and Sahami's	MDLM	
Dependency Measure	POE1ACC, PRESET		
Consistency Measure		Focus, Schlimmer's, MIFES-1	LVF
Classifier Error Rate	SFS, SBS, SBS-SLASH, PQSS, BDS, Schemata Search, RC, Queiros and Gelsema's	AMB&B, BS, Ichino and Sklansky's	LVW, RGSS, GA, SA, RMHC-PF1

Table 1. Two Dimensional Categorization of Feature Selection Methods

Constructive induction. At this step either features relevant to the problem are selected, or new features are constructed from the existing ones (both are also possible). Performance of selective induction algorithms, in terms of predictive accuracy, is poor if the task-supplied attributes are not appropriate for describing target theories. Changing representation space – adding more relevant attributes, removing irrelevant ones, or modifying the measurement precision of attributes – can drastically reduce the running time of a learning algorithm and yield a more general concept. For construction of new attributes appropriate operators are used (Boolean operators, arithmetic operators). Special operators (M-of-N and X-of-N) have also been introduced for Boolean attributes, as well as methods of discriminant analysis – for continuous attributes. For feature selection two approaches have been suggested: filter approach and wrapper approach. Filter approach assumes algorithm-independent techniques. In wrapper approach learning algorithm itself is used as an evaluation function, which results in generally better results, but these algorithms consume extensive amounts of computational resources. Table 1 above presents a list of feature selection algorithms categorized according to generation procedure (columns) and evaluation function (rows).

Selective induction. In contrast with constructive induction the very process of creating a classifier basing on a fixed representation space in called selective induction. One of the most widespread and most simple techniques of selective induction is top-down induction

of decision trees. Its best know implementation is C4.5 algorithm (the last version is C5.0, available as commercial product). Research is also being conducted in multivariate decision trees, oblique decision trees, fuzzy decision trees, incremental induction of decision trees, etc.

Pruning. The most common approach to constructing decision tree classifiers is to grow a full tree and prune it back. Pruning is desirable because the tree that is grown may overfit the data by inferring more structure than is justified by the training set. To combat this overfitting problem, the tree is pruned back with the goal of identifying the tree with the lowest error rate on previously unobserved instances, breaking ties in favour of smaller trees. Several pruning methods have been introduced in the literature, including cost-complexity pruning, reduced error pruning and pessimistic pruning, error-based pruning, penalty pruning, and MDL pruning. While all these methods are based upon error minimization, new methods emerge, which use loss minimization.

Ensembles of classifiers. The goal of ensemble learning methods is to construct a collection (an ensemble) of individual classifiers that are diverse and yet accurate. If this can be achieved, then highly accurate classification decisions can be obtained by voting the decisions of the individual classifiers in the ensemble. The most frequently used techniques are bagging, boosting, and randomisation. They all provide comparable performance.

Evaluation of classifiers. A common methodology for such evaluations is to perform statistical comparisons of the accuracies of learned classifiers on suites of benchmark data sets. A commonly accepted technique for statistical comparison is 10-fold cross-validation. For benchmarking data sets from UCI (University of California at Irvine) Repository of Machine Learning Databases are being used. This Repository contains a large number of databases collected by different researches in this field. During the last years ROC curves (Receiver Operating Characteristic) have also been accepted as a means of classifier evaluation. This technique makes it possible to introduce broader notion of "better" performance through the use of cost functions.

Case-Based reasoning (CBR) is an artificial intelligence technique for learning and reasoning from experience, and has shown great potential for use in decision support systems. CBR emphasizes the role of memory (i.e., the knowledge base) in problem solving. The basic idea is that problem solving involves reasoning from experiences (i.e., cases). When a new problem is presented, a CBR system matches this new case with the old cases in its case base and retrieves similar ones in order to see whether their solution apply in the new problem.

In this approach, experience from diverse sources can be organised into a case base which can constitute a repository where one can access others experience, and one can add ones own experiences so as others can utilise them.

CBR emphasises an approach to integrated problem solving and learning. Case based retrieval algorithms initiate a search in the experience database for one or several previous cases most similar to the new case. Existing CBR tools use different case retrieval methods

Several commercial companies offer shells for building CBR systems. Some examples are CBR-Works, KATE-CBR, and ESTEEM.

CBR-Works: A professional and full-featured state-of-the-art Case-Based Reasoning tool developed jointly by the University of Kaiserslautern and Tec:inno GmbH, Kaiserslautern. CBR-Works is currently used for developing industrial CBR solutions, as stand-alone application or on the Internet.. The software is available on several platforms.

KATE-CBR: Software Suite from Acknosoft in Paris.

ESTEEM: Stottler Henke Associates, Inc. developed ESTEEM. It offers general purpose case definition facilities, a wide range of developer selected similarity and retrieval options, techniques for incorporating rule-based inference for retrieval and case manipulation, the concept of nested case-bases and specification of end-user functionality.

During the last years machine learning has found broad acceptance as a means of solving different complex real-world problems. Due mentioning is application of different machine learning techniques for ischemia diagnostics. This research is being conducted at Ljubljana University. The results show that programs can perform at the level with best human experts (and thus, better then ordinary doctors).

Figs. 7 and 8 (A and B) illustrates the two major logical schemes of the WIMS system: the hubless and hub based architecture, respectively, for the signalling from the sensor transducers to a transmitter for further signal distribution, preferably wireless. The hub is a device, concentrating signals and/or power supply of several sensors maybe of different nature (and from different vendors), it transfers the signal for further processing. The sensors on a patient are in wireless communication with the rest of the system through the Medical Net Node MNN. Each sensor will preferably have its own wireless

communication unit. The sensors can be connected together using a serial interface and then only one of the communications units is active.

In the hubless system every sensor incorporates its own processing circuits, communication (Bluetooth module) and a separate battery cell. The information is sent by the sensor via separate Bluetooth channel for further processing in the host.

As all sensors are independent, the system could be built in a very flexible way. Fig. 8B presents an "analogous" hub, which could be treated logically as a hubless multi-modal sensor, this aspect will be discussed in details later. The sensor module involves specific analogous part which are not incorporated into the generic ASIC according to the technological reasons, generic ASIC (re-programmable universal chip) and a Bluetooth module. In this case the basic feature of the WIMS – open architecture protocol is layered with the Bluetooth protocol stack.

Below are some important points discussed regarding different architecture solutions, and it is also referred to Fig. 9:

- ***Wiring***. The absence of wires is an important consumer characteristic of the medical instruments; in some cases it could be critical (e.g. for paediatric applications). So, the wiring minimization is one of the key components in building ***patient friendly*** system. In the hubless system the wiring could be reduced. This could be easily fulfilled when the sensor unit is attached near the application site of the physical transducer. This is not true if multi-modal sensors are used with distant application sites.

- ***Battery.*** If the sensor has its own battery, there is a possibility to make an optimal choice of its parameters (capacity, type, size). The fact is that different sensor types have quite different power consumption (from 1-2 mA for temperature measurements to ~200mA for the ECG), so a small cell is chosen for some sensors to reduce their size, as the battery is an essential feature for ***sensor miniaturisation***. Besides, the battery cell, capable of supporting several power consuming units (e.g. ECG, Blood pressure) should have a significant capacity (up to 3-4 Ah) and, thus, size. On the other hand each sensor will have its own power source, which increases the total number of components in the system. Besides the use of a heavy duty cells could make it possible to install the Bluetooth radio signal amplifier (100m Bluetooth), this is in a good agreement with a hub-based system architecture.

- ***Interface.*** In the hub-based system there is one additional digital interface – between the sensor unit and a hub. This interface could be based on a standard protocol.

So this gives additional opportunity for ***open architecture*** solutions and increases system ***flexibility***. Besides, the hub could make it possible the separation of the logical sensor protocols from the specific realization (hub-host transport protocols), cause the transport layers are dependant only on the Hub construction and could be changed. Another point is, that there are some time critical applications of sensor-to-sensor communication (e.g. oximetry could utilize the ECG synchronizing signals, Blood pressure could use the signals from finger pulse oximeter etc.) The wireless Bluetooth connection (via distant site) could fail to deliver the events in millisecond range. This feature is important in the case of the ***multimodal*** (multisensor) environment. The disadvantage of the hub-based architecture regarding the interface is a system complexity increasing.

- ***Components***. One additional Bluetooth module is used for every sensor in the hubless system. On the other hand in the hub-based construction we need one more ASIC for every sensor unit. The price and power consumption of the Bluetooth module and ASIC is very similar.

The idea is to make a system which incorporates the advantages of both solutions and avoid its drawbacks. The additional digital wired standardised interface will synthesize the advantages of the hubless and hub based system. In this case every sensor could act as a hub, in fact only like a sensor with bigger size/higher battery capacity, e.g. blood pressure, ECG. On the other hand a stand-alone hub without any sensor functionality could be used. This solution will ensure the system to be ***flexible***: the hub could be used for the system adoptation for different interfaces. The miniaturization and low power consumption requirement is, however met by the use of modern ASIC technology (Application Specific Integrated Circuits).

One of the aspects in building a common platform for the WIMS is the idea of the generic re-programmable chip, which will be able to be used in different sensors. This is a common generic HW platform. The future generic ASIC should incorporate the processing core, analogous and control circuits and interfaces.

In order to lower the risks in the ASIC development it is a common practice to implement prototyping with standalone components (see also chapter 4). It is necessary to stress, that only ASIC prototype would be developed in the frames of the The system according to the invention project.

Below is the description of the development flow of the generic ASIC, future HW WIMS platform. Basing on the end-user requirements, technology search and own expert knowledge the detailed functional layouts and schematic diagrams for 4 WIMS

prototypes (ECG, Blood pressure, oximeter and temperature sensor) would be developed. The functional layout is a document describing the overall architecture for particular sensor and detailed requirements for the logical components (like amplifiers, ADC, processing unit etc.). In the next phase the common components are defined for these sensors and after this the synthesis of the generic scheme is performed. The sensor specific logic and interfaces will be implemented by Field Programmable Gate Arrays (FPGA), this code will be reused in the generic ASIC. The microelectronics experts will be attracted on this phase in order to simplify further system industrialisation (in some cases the specific schematic solutions depends strongly on the technology used). On this stage it will be defined what system components will be incorporated in ASIC and the future ASIC layout will be defined. Due to technological reasons some critical circuits (especially analogous or high voltage insulation circuits) could not be implemented in ASIC technology or will increase the ASIC complexity significantly.

On the development stage one of the main trends, related to power consumption minimization and flexibility increasing is the diminishing of the analogous circuits. The modern applied electronics and medical techniques particularly, demonstrate the trend to minimize the analogous parts of the construction layout. In this case most of the functions of the signal processing are implemented by digital methods. As an example, the use of multiple independent ADC (mostly sigma-delta converter) instead of the only ADC with the analogous signal multiplexing, could be mentioned. The use of the sigma-delta ADC also simplifies the integration of the system into the ASIC, due to the minimum quantity of the analogous components and relatively low requirements for the preliminary analogous signal processing (amplification and filtering).

The development of a common HW platform for the WIMS family is one of the major goals of the system according to the invention. This is done by defining main functional components of specific sensor and the requirements for these components. Then the common part is extracted. The common parts and some specific circuits will be incorporated in the generic chip (ASIC). Some critical analogous circuits could be implemented with standalone components. Obviously the processing and interface/ transport parts will be common for all 4 sensors. The specific analogous and control circuits are described below.

The prototype system consists of four modules, each supporting one modality. The supported modalities in the prototype development will be temperature, ECG, blood pressure and oximetry (pulse and oxygen saturation level). All modules are standalone devices with a common hardware platform that consists of the following:

- Main Controller, ARM7TDMI core microprocessor
- Firmware Storage, Flash memory
- Bluetooth device, Bluecore01 from Cambridge Silicon Radio
- Bluetooth Firmware Storage, Flash memory
- Glue logic, FPGA/CPLD, interface to Sensor Specific
- RS-232 port, used for debugging purposes and remote download of firmware updates in the field.

The reason for making this selection of components as the platform for the WIMS prototype development is to establish a foundation to closely resemble the future ASIC development. A design goal is to shrink the size of the sensor specific components of each module to a minimum size. The actual prototype is a Printed Circuit Board (PCB) with the common hardware platform and the respective sensor specific module integrated for the desired modality.

The prototype system has some common hardware and a modular design is adopted. The core components are the ARM microprocessor, the Bluecore 01, a single chip Bluetooth system on chip solution, and the sensor specific hardware for the data acquisition. In addition to these three major blocks of the hardware, programmable logic is embedded to provide a glue logic interface between the controller and the sensor specific hardware. The common hardware also includes memory storage such as flash for both the control and Bluetooth firmware. A couple of other features are implemented to ease the debugging process during the prototype development. These features are an additional RS-232 port, a JTAG interface, and test LED's. The unit is battery powered and necessary power circuitry is also implemented.

The common hardware has the task of coordinating the monitoring of the patient over Bluetooth by implementation of the following:

- Taking sample measurement of the medical data to be gathered at a scheduled time based on an interrupt scheme.
- Communicate with the MNN via Bluetooth with an established protocol
- Mapping the raw or processed medical data into Bluetooth packets for transmission to MNN
- Process request for communication and alarm tasks and services
- Monitoring battery lifetime

The main controller is connected to the CPLD with its data- and address bus, memory and expansion interface and an interrupt line. This interface is 16-bit wide. The CPLD

will contain glue logic necessary to memory map the sensor specific hardware to the memory space of the microprocessor and to provide a serial to parallel interface between ADC signals from sensor and microprocessor data bus. In addition, buffers might be added to implement an interrupt based interface for reads and writes from the ADC of the sensor specific hardware. However, communication between the processor and sensor domain is through defined status and alarm registers. All the registers will be memory mapped to the processor memory space for easier access at any time by reading or writing to the desired address space. The communication will be initiated by an interrupt, and the processor will service this at a scheduled point in time. The measured data will be accessed and transferred via a serial connection to the Bluecore 01 chip. The serial port of the microprocessor is used for this purpose.

The serial connection is established with the Bluecore01 with a defined protocol called Bluecore Serial Protocol, BCSP. The BCSP task is to support the flexibility of partitioning the software between the host and the Bluetooth subsystem, and to enhance the speed of product design. It adds error checking and retransmissions to accommodate any dropped data during 'wake-up', and flow-control for several logical channels, while simultaneously reducing the processing overhead. BCSP allows developers to link at different layers of the stack of the BCSP.

An additional UART is implemented to support an RS-485 network type connection between various modalities in a hub solution for future expansion of additional sensors. This network is planned to support data rates up to 12Mbps. This network will be a master-slave type system where one node issues commands to each of the "slave" nodes and processes responses. Slave nodes will not typically transmit data without a request from the master node, and do not communicate with each other. Each slave must have a unique address so that it can be addressed independent of other nodes. These types of systems can be configured as two-wire or four-wire. However, a four-wire master-slave system called full duplex reduces software complexity at the host side since the driver and receiver always is enabled except in sleep mode. The prototype development will include the capability to easy make this expansion if desired to connect the WIMS as a Master-Slave Hub type solution.

Main controller:

- *Type:* Cirrus CL-EP7211, ARM720T, Ball Grid Array 256 package priced at $28. Features 32 k RAM and 8k cache.
- *Power consumption:* 50 mW @ 18 MHz, 15 mW in idle mode and 10 μW in standby mode.
- *Supply voltage:* 2.3-3.6 V.

- *Area requirement:* 17 x 17 mm

This processor was selected because of the possibility of porting a licensed ARM IP core to the proposed ASIC in the next development phase. It is also a processor used by a lot of Bluetooth chip manufactured as their baseband processor. Therefore the selection was made due to compatibility issues and a common instruction set for programming. It has enough processing power and is low on power consumption. Furthermore, it is an inexpensive processor core.

Flash:

- *Type:* AM29LV400B-90 from AMD. 4 Megabits (512 K x 8 bits/256 K x 16 bits) CMOS 3.0 Volt only, Boot Sector Flash Memory.
- *Power consumption:*
- *Supply voltage:* 3.3, 5 or 12 V
- *Area requirement:*

Both the Bluecore and the controller need a flash for firmware storage. This flash has a predefined boot sector that can be locked for firmware protection and spurious write. It is also supports sector erase and writes which eases the download of new firmware or additions or new features when necessary or desired. For logistic simplicity we use the same flash both for controller and Bluecore chip. The selection is also based on the availability

Bluetooth module:

- *Type:* Cambridge Silicon Radio (CSR), BlueCore01.
- *Power consumption:* Made with the assumption that it will be run on batteries. Supports power down modes and consume 3 mW in park mode and 0.6-135 mW in active mode (sniff- transmitting/receiving).
- *Supply voltage:* 2.7-3.3 V
- *Area requirement:* 2.25 mm^2

The selection is based on the integrated BT stack and the availability of the source code of the software. The selection was also made due to the CSR proposed compactness by proposing a complete Bluetooth Radio module that you implement on small size board.

General speaking, the component selection is based on reducing the power consumption and the availability for the prototype development. The core components are picked to make the transition from prototype to ASIC easier. However, we have done a

compromise between size and functionality on one hand and ASIC resemblance on the other.

The system according to the invention gives the possibility of unattended operation of the system instruments WIMS. The human operator, either an outpatient who is wearing sensors connected to a WIMS and possibly even a complete such instrument, or an operator elsewhere in the system, can under given conditions set i.a. alarm thresholds and other parameters through a human/computer interface.

Temperature

Two main measuring priciples are found particularly applicable for the invention: Catheter and skin surface measuring. Besides, different sensor versions are preferred for different age groups. The temperature transducer therefore should ideally work equally well with different sensors, i.a. giving the required accuracy. The major technical parameters of the temperature sensors are as follows:

- Temperature range: 25–50 °C.
- Interchangeable accuracy: 0.1 °C (in the temperature range above)

A complete temperature monitoring set-up preferably includes several temperature sensors arranged strategically on an object, like a patient, and in addition at least one sensor at some distance to measure the ambient temperature. Thereby misinterpretations can be avoided for situations such as when the patient goes outside a cold winter day and her/his registered skin temperature thereby suddenly drops.

Fig. 15 depicts a preferred set-up to measure temperature, by using a thermosensitive resistor circuit and a sigma-delta converter. The circuit has only a few critical analogue circuits and comprises a current source 20, an amplifier 22 to be programmed with a suitable transmission coefficient TC, a reference signal source 24, and an analogue to digital converter (ADC) 26 comprising a sigma-delta modulator 28 and a digital filter 30 and an interface block 32. The set-up is discussed more thoroughly below.

Many types of temperature transducers are available. A preferred transducer is the thermoresistor, making the temperature sensor universal regarding the positioning at the application site, the design simplicity and the possibility of integration with other modalities. Several companies produce medically packed thermoresistor sensors for different age groups and application sites.

In the actual temperature range a preferred sensor has the resistance temperature coefficient –4 %/deg.C, that requires resistance measurement with accuracy better than

0.4 % in the resistance range 1.2 kOhm for the providing of measurement accuracy ~0.1 deg.C. A value around 0.2 % is assumed permissible for the total measurement error. In the shown measurement set-up the most critical element is the reference resistance Rref, as the ratio Rt/Rref is measured. Setting a permissible error of 0.1 % for this resistance, the circuit and mainly the converter error should not pass 0.1 %, which gives the requirements for the circuit components.

The current source 20 is a fairly critical component in the circuit, but special requirements on accuracy and stability are not imposed. The current value is chosen from the permissible sensor self-heating and is preferably ~200 μA. The recommended accuracy (or/and stability) is ~20 %. More significant, however, is the high frequency noise figure, particularly near the sampling modulator frequency and its harmonics, which could represent around 0.1 % of the source current, that is 200 nA. Also the pulse AC-DC converter should be considered as a possible rather powerful noise source.

The amplifier (PGA) 22 works with the signal source in the range 200 - 400 mV with an input resistance 1 - 2 kOhm. Consequently and for providing necessary accuracy, the input resistance should not be less then 4 MOhm (input current below 100 nA), and the total error on the input voltage (shift + noise) below 100 μV. The reference signal source 24 works in a mode close to the mode of the PGA 22, and consequently the same requirements are imposed.

The initial properties of Sigma-delta modulator 28 of the ADC 26 successfully provide good linearity and a sufficient amplitude resolution, taking into consideration the sensor's own temperature inertia. The digital filter 30 specifications are chosen so that its zeros for maximum attenuation correspond to the power supply mains harmonics. Although these enumerated requirements do not appear to be too strict, the system should include means for calibrating the converter 26 at the scale end points, and such means are in fact provided in the compound of the preferred serial Sigma-delta converter.

The Interface block 32 includes corresponding units on the crystal of the converter in the preferred version, when optionally a separate crystal is used, necessary units of mating in FPGA, and a program unit for registering of the measurements. Evidently, the concrete structure of this block depends on the common structure of the whole device, as well as on the way it is realized, during the use of serial elements or integrated in an ASIC.

The temperature sensor will be used mostly for continuous monitoring and sometimes for the scheduled measurements. Predictive algorithms for the scheduled measurements can be used, when the sensor is applied on demand, otherwise no advanced algorithms for the

temperature data processing are necessary. The human temperature is a physiological parameter that changes rather slowly over time, at most 1-2 degrees centigrade per minute, in the most critical cases. The measurement sampling rate is 2 Hz, and the samples for 5 or 10 seconds periods are analysed. Is the temperature deviation within 0.2 degrees, the average temperature is calculated.

Blood pressure

To sense the blood pressure, a widely used technique called oscillometric blood pressure measurement is used. The oscillometric method is an indirect way of measuring the blood pressure. That means the blood pressure is not measured in the vain, but by sensing the air pressure in a pressurized cuff usually wrapped around the upper arm. When the pressure in the cuff falls and reaches the systolic (upper) blood pressure, small pressure variations appear in the cuff as the blood pulses through the partially occluded vein (Fig. 16, simulated measurement cycle). These pressure oscillations increase in amplitude with maximum at the mean value of the blood pressure level (Fig. 17, real oscillations filtered out from the deflation pressure). The diastolic (lower) pressure is found at the other side of the peak of the envelope.

The following description is focused on the front-end hardware and the pneumatics and is referred to Fig. 18.

The pump must be able to fill the cuff with air to a pressure above 300 mm Hg because to measure up to 255 mm Hg systolic pressure, there must be approximate 30 mm Hg overhead to include the initial oscillations. The second reason is that the filling will be very slow when the pump operates near the pressure limit of the pump. The free flow of the pump ought to be 60 ml/sek, but can be reduced if size and weight of such a pump are problematic. Also because the goal is to detect an estimate of the mean blood pressure as the cuff inflates, the inflation should not be too fast. As the inflation rate is very dependent of the size of the cuff, PWM of the pump speed is included. The volume of a cuff for a small child is approximate 40 ml, while a big cuff for the thigh is 1500 ml @ 200 mm Hg. If the detection of the mean blood pressure during inflation fails, one solution may be to stop the pump at certain pressure levels to "listen" for the oscillations. The pump should have a low pulsatile flow with a frequency far above the pulse range not to influence on the oscillations.

It has proven difficult to find a standard pump with 5 V working voltage, but a 6 V pump (ASF 30040003) is found to work well on a 5 V supply. It has a max current consumption of 360 mA.

The overpressure valve.
The overpressure valve should prevent the cuff pressure to rise to an unnecessary high and painful level in case of any failure. A rather high hysteresis value is an advantage to lower the pressure when the overpressure valve release. The release pressure may be 300 mm Hg, but is probably stated in the AAMI SP-10 standard.

Valve and air filter.
To get a linear deflation pressure curve, the magnetic valve is driven by a PWM signal. That makes it possible to get the same deflation rate with different cuff sizes and to adapt the rate to the pulse frequency of a person. Low pulse frequency require low deflation rate to get enough oscillations to determine the blood pressure, while one with a high pulse frequency gets a short measurement time because the rate is set higher.

The operating frequency should not be set to 8 Hz as earlier stated, as it may create some interference with the sampling frequency. To let it equal the sampling frequency or a fraction of it, ought to be a better solution. An alternative is to drive the valve by a fixed frequency above 60 Hz, but that require a faster valve or a more sophisticated driver. How audible will it be? The duty cycle should have a range of 1 - 100 %. The selected valve is normally open and consumes 58 mA at 5V.

The air filter should prevent dust from entering the valve and causing malfunction. A 35 µm filter is recommended.

The chosen pressure transducer has an integral amplifier and is differential (against the atmospheric pressure) Before the pressure signal enters the ADC, it is divided by 2, to suit the level of the internal reference voltage (2.5 V) in the ADC. It is also filtered in a 1. order RC filter to prevent aliasing. The transducer has an accuracy of 1 % and is sensitive to variation in power supply voltage (5 V). The output voltage at zero pressure is between 88 – 313 mV, and the sensitivity 12 mV/mm Hg. Supply current is 7 mA typically.

The selected A/D converter is a 16 bit delta-sigma converter. and has therefore relaxed requirements for anti-aliasing filtering. It is necessary to use an external clock to make the sample frequency (fs) vary from 7 – 60 Hz. Fs is chosen to be 15 times the pulse frequency. The internal clock is limited to fs = 33 Hz. The clock frequency =1624 fs. It has four (multiplexed) inputs. The three spare ones can be used for self-diagnostics or future use. The power consumption is only 1.5 mW.

A long range communications module 17 can be used to forward the processed data to a Medical Central Node (MCN) 2 (see Fig. 4) where the data can be evaluated and/or

stored. In this way the emergency personnel can study the results from unattended blood pressure measurements in real-time, a possibility not yet available or suggested by the current systems.

As mentioned in the first part of the description, blood pressure measurements under emergency transportation are often difficult to perform and give inaccurate results due to the disturbances introduced by the rapid movements and vibrations of the ambulance. In such a case, where blood pressure measurements are difficult due to vibration noise, the sensor can logically switch to another mode, commanded or automatically, such as to connect to a motion detection sensor 47 for registering of the vehicle vibrations and movements, in order to give corrected results. An ETCO2 sensor in combination with a SPO2 sensor can in addition provide a measurement of the metabolism efficiency, viz: how well the body utilizes the oxygen available. A pulse measuring device can, when a high pulse rate is registered, interrogate the motion sensors 47 to check which level of physical activity the patient had during the last minutes, very helpful for the assessment of whether this high rate is due to a malfunctioning like a disease, or the simple result from physical activity. This enables emergency personnel to perform unattended blood pressure measurements in a situation where it is not possible with current systems.

Pulse oximetry

Pulse oximetry is a non-invasive method of monitoring the arterial oxygen saturation level in a patient's blood (SpO_2). Now it become a standard in the clinical environment because of its simple application and the high value of the information it gives nurses and doctors. The sensor calculates the arterial oxygen saturation using calibration curves.

Many different application places are used, depending on the sensor type (transmission/ reflectance) and patient status and group, such as the index, middle or ring fingers, ear lobe, middle of forehead (reflectance) for adults and index, middle or ring fingers, great toe, lateral aspect of foot for children and neonates.

There are many factors influencing the accuracy of the sensor: HW factors, such as sensor construction (influencing the optical properties), application site (this is also related to the sensor construction and also the specifics of the body particularities), the width and wavelengths of the LED spectra (compared to the ones used during calibration); environmental and medical factors like ambient light, finger cover/polishes, skin pigmentation, motion artefacts, poor perfusion etc.

Modern sensors uses empirical calibration curves because the theoretical curves, based on the Beer's law and corrections due to scattering effects, do not give the required

accuracy. The calibration is based upon clinical studies, where the oximeter results are compared to a reference in vitro or by an invasive method. This is done once during the design and development of the device and all the specific sensor constructions should be calibrated separately. In order to compensate for factors influencing the accuracy, algorithmic and HW solutions are used (like the reference resistor to compensate the LED characteristics variation). This demonstrates the very strong interconnection between the HW module, the processing algorithms and the specific sensor used.

Based upon this, the commercially available OEM solutions were found preferable, including the oximetry sensor, HW module and processing algorithms. The main parameters of the oximetry module are as follows:

- Oxygen saturation range: 0 to 100 %.
- Pulse rate range: 18 to 300 pulses per minute.
- Accuracy SpO_2 (±1 standard deviation) 70 to 100 %: ±3 %.
- Pulse rate accuracy: ±3 %.

The system should be able to show the plethismogram on request. The chosen oximetry system will provide state-of-art protection from the motion artefacts, poor perfusion and gives the possibility to interface reusable and disposable sensors for wide range of age groups and application sites. Besides the power consumption of the OEM module is relatively low (30mA). From the HW point of view the module should be communicated via the serial interface.

ECG

The ECG is a medical diagnostic and monitoring method capable of recording and interpreting the electrical activity of the heart from electrodes placed on the skin (surface ECG) in specific locations. During the ECG, electrodes can be attached to the skin surface and pick up electrical currents from heart muscle contractions. Analysis of the electrocardiogram gives the information about different heart anomalies. Deviations in the normal height, form, or duration of the wave patterns indicate specific disorders; thus, the ECG is an important aid in diagnosing many heart diseases. The procedure is widely used, due to the medical value of the information obtained and the fact, that it is non-invasive and has no contraindications.

The ECG is used for both short diagnostic investigation (standard 12 lead ECG) and continuous monitoring (Holter schemes). The requirements for the ECG hardware are quite different in these two cases, moreover the lead commutation schemes are different. For example the sampling rate for the standard 12 lead ECG is 500 Hz, compared to 300

Hz in the Holter systems, in the case of High Resolution ECG the sampling rate should be at least 1 kHz. According to the end-user requirements gathered in the frames of the The system according to the invention, standard 12 lead, 1 monitoring lead 2, 3 lead Holter system should be developed. In order to meet the requirements the HW should face the most severe characteristics and involve all necessary functionality to ensure mode switching (e.g. lead commutation). Below is the list of the ECG main technical parameters:

- Sampling rate 500 Hz (standard 12 ECG, 1,2,3 lead monitoring) 2 kHz (high resolution ECG).
- Bandwidth 0.05 - 500 Hz.
- A/D conversion – 14 bits.
- Sensitivity not less than 5 μV.
- Common mode suppression > 100 dB.
- Variable DC component 300 mV
- Electrode bias voltage < 3 V.
- Calibration 1 mV ± 5%
- Pacemaker detection >0.3 ms, >4 mV
- defibrillator impulse recovery time < 5 s.

Below is the description of the analogous ECG functional parts and the requirements to specific components of the system, necessary to face the specification. See Figs. 11 - 14.

The references below (from http://www.analog.com.publications/magazines/Dialogue/29-3/low_power.html) describe roughly the requirements for the ECG signal circuits:

The small ac signal voltage (5 to 10 mV) detected by the sensor on the electrodes will be accompanied by a large AC common-mode component (up to 1.5 V) and a large variable dc component (300 mV). The common-mode rejection specified by the AAMI (Association for the Advancement of Medical Instrumentation) is 89 dB minimum for standard ECG and 60 dB minimum for ambulatory recorder.

The signal bandwidth will depend on whether a pacemaker pulse is being detected and whether the system is used for diagnostic (wave shape details important) vs. monitoring. In general, components of the signal of interest will reside in the 0.67 Hz to 40 Hz bandwidth for standard ECG and up to 300 Hz to 1 kHz for pacemaker detection.

Besides to the signal detection channels the ECG system should also have the calibration circuits and electrodes testing system (the system should be able to detect both abnormally high inter-electrode impedance and a short circuit in the electrodes or connectors).

Thus, at a high abstraction level we can distinguish 3 functional blocks in the logical layout:

1. ECG Data Acquisition Subsystem incorporates amplification, normalization and digitalisation circuits for the ECG signal with parameters, mentioned above in the references.

2. Sensor control circuits are responsible for a periodical measuring of an active component of the electrodes + cables resistance. The values are measured at the order 1 kOhm-100 kOhm with 10 % accuracy. The major requirement for the unit is the minimization of the ECG signal distortion during the measurements and commutation.

3. Interface enables data format conformity and measurement process control. Besides, the interface circuits functions includes, also, the insulation of the high sensitive analogous elements from the digital data processing parts, generating high level noise signals both in the signal and power lines.

The ECG Data Acquisition Subsystem incorporates 9 nearly identical channels of the ECG registration, the reference potential generation circuits WCT, circuits responsible for the common potential formation and a source of the reference potential (for the ADC). Fig. 12 shows the logical layout of the most complete ECG registration channel. Depending on the specific requirements, some of the schematic parts could be absent in a particular channel.

The HV protection (anti defibrillator circuit) is intended for the circuit's protection from the high voltage impulses originating on the electrodes during the defibrillation procedure.

The main requirement for this element is that it should not deteriorate the input amplifier characteristics. Under normal circumstances this system should have the equivalent (shunt) resistance not less, than 100 MOhms and the capacitance less than 30 pF.

X5 input instrumental amplifier has a significant influence on the overall registration channel parameters. It should guarantee 90db of the common mode rejection, taking into

account all the necessary input elements, and has the noise, adjusted to the input at the level of 1..2 uV, and accordingly has the coefficient of supply influence suppression not less then 100 dB. Input resistance of the amplifier – not less then 100 Mohm (otherwise misbalance of input circuits will ruin the coefficient of in-phase component suppression). And all this should be valid as the input in-phase signal is below 2 V, and differential – below 300 mV. Simultaneously X5 should provide amplification of the electrode state control signal (~10 kHz) as the signal phase distortion is minimal (not more then 0.1 rad). Special requirement is that amplifier should behave normally under pulses of input current below10 mA of both polarities.

X1 – input repeater. It is used in F, L and R channels for the production of reference potential. Above the coefficient of in-phase component suppression and phase distortion (both of it is insignificant) the rest of the requirements are just the same as for the X5.

X25 – this amplifier works already with amplified signal and there are softer requirements for it then for the others. The basics of them are – supply suppression intention coefficient not less then 90 dB, the noise, adjusted to the input – below 5 μV.

The DC compensation circuit – intended for changing the high-pass filter 0.05 Hz including its advantages but without its drawbacks, especially with respect to the time of recovering after overload, has as its basic component a capacitor of ~1 μF. Said capacitor should have little leakage current and besides, it is significant, should not produce much noise (noise should be below 5 μV in the full range of operating voltages. For the capacitor the non-linearity ~2 % is permissible (ceramic material should not be used). The amplifier used in this block should have an input current in the pA range and a high supply ripple rejection coefficient (not less then 90 dB).

Delta-sigma ADC should provide not less then 15 significant digits at the bandwidth of input signals up to 300 Hz.

The simplified block diagram of Sensor Control Circuits is depicted on the figure below For the control of the electrodes state and connecting cable state the test signal ~10 kHz is fed through the small capacitance (~100 pF) to every electrode and then the quadrature measurement of this frequency signal, that comes from the output of the controlled channel input amplifier is held. Numbered quadrature value then transferred for the analyses to the residential micro-controller or to the host-computer.

DDS. For providing the low level of noise in ECG registering channels the usage of searching signal of high quality with possibility of definite locking of controlling signals

to the required phase of searching signal is necessary. In the present time the easiest way to obtain such a signal is the usage of Direct Digital Synthesis (DDS). This generator consists of a digital block, forming a cosinus curve in the digital presentation, and a digital/analogue converter (DAC), forming the analogous presentation of this curve. Due to estimations, sufficient accuracy of the phase locking can be achieved at 64-digital presentation of the cosinus signal period. For the DAC, 8 digits, including the sign digit, are enough.

K = -1. Inverter is intended for forming the signal on the N-electrode. This electrode is used as the wire of back current during all the measurements. Inverter should not produce phase shift more than 0.02 rad.

The **MX 1X10** multiplier allocates the searching signal through controlled electrodes. The main parameter of this multiplier is the value of the injected charge during the switching (below 5 pC). Multiplier should have the input protection against voltage overload. The **MX 1X11** multiplier switches signals from controlled channels. It should have low resistance in the open state (below 200 Ohm).

FLD and filter. Without serious problems it is built on the base of differential amplifier of middle speed (the bandwidth of the unit amplification is not less than 4 MHz) and middle accuracy (the initial bias not less then 1mV).
There are no special requirements to ADC and it could be chosen due to constructional ideas (word length 10 bits).

The Control unit controls the procedure of the quadrature voltage values changing, the work of the synchronous detector, DDS, ADC and multipliers. It consists of digital blocks, integrated in matrix crystal, and of the program modules of resident microprocessor. The question of advantageousness of further hardware implication of this or that functions should be discussed.

The sensor control circuits also have additional functionality (not shown on the figure) related to lead commutation to face the requirements of different application schemes (standard, Holter).

The cables, by means of which electrodes are connected to the device, are intended for the m-volt range low-frequency signals transmitting at relatively small currents. Practically all limitations on its electrical parameters are connected with protection from noise and from possible additional signals.

Connection wires of the cable are connected to a patient through on-skin electrodes, which possess essential equivalent resistance; so for some signals these wires can serve, to some extend, good antennas. For reduction of the parasitic signals it is desirable to use screened wires. Herein it is necessary to consider the fact that the radio-frequency signals, which lay far away from the registering frequency range, could be detected in the input cascades of amplifiers, producing redundant noise in the frequency range of registered signals. Of cause inputs of amplifiers are equipped with corresponding filters, but each filter has limited attenuation and additional measures of screening wouldn't be redundant. For conservation of the high coefficient of common-mode noise suppression it is required that the additional phase offset for the mains frequency should not exceed $\sim 10^{-5}$ rad, and that at the possible dispersion of the electrode resistance ~10 kOhm limits the allowable capacity of the screened wire with the value ~150 pF to the allowable asymmetry of channels ~30 pF.

Besides the common-mode noise of the capacitive type in the registration zone, magnetic dissipation fields can be present, which in the circuit of connection wires form the differential signal. The only way to reduce the amplitude of the signal is to reduce the effective area of the circuit, which is formed by the connection wires. So connection wires should have minimally allowable by the exploitation conditions length or be on maximally allowable length encapsulated in the joint cable with minimal square.

Due to the exploitation conditions voltage pulses of several kV (at the usage of defibrillator) are possible on the electrodes. The total pulse energy is not so high, but the voltage can be high enough to give an insulation break-down. The usage of the screened wire on the corresponding voltage is unreal in this case. The simplest protection variant includes the usage of a ballast resistance (~4.7 kOhm) directly near the electrode (before the screening braid), which limits the voltage of the discharge in the detector frame (with the connection of the wire directly to the discharge without additional resistances). At such a connection the voltage between the screen and the connection wire will not exceed the voltage on the discharge (~100 V), that is safe enough.

The function of digital signal pre-processor is to transform measurement results of ECG, realized by the patient adapter for the quality enhancement of the subsequent visualization on the monitor and reliability enhancement of the automatic diagnostics, accomplished with the help of the digital images detecting processor. In accordance with such a destination, a pre-processor has to face the following functional tasks:

1. Isoline shift to the level of 0 Volt and elimination of the isoline drift, caused by patient breathing and also by the potential difference change between the internal tissue layers and outer skin surface during its movement.

2. Elimination of differential components of mains inducing (common-mode components are eliminated by the patient adapter).
3. Elimination of high-frequency noise, connected with tractions of a patient with the possibility to adjust the level of the elimination by a doctor.
4. Pacemaker pulse detection.
5. QRS complex detection (for supply of beeper work etc.)

For reduction of the isoline drift it is proposed to use un-recursive high-frequency filter with the noise suppression level ~ -40 dB. Such a filter allows registering ECG at rest without breathing delay and also stress testing, for example during a seance of veloergometry. As a rejection filter of mains inducing for providing high quality of ECG image on monitor the filter with noise suppression band in the range 50 ± 0.3 Hz and suppression level ~ - 40 to - 60dB could be used. It shall be foreseen the possibility of switching off this filter by a doctor in cases when embedded in patient adapter HW means of reduction of means noise provide good quality of the image on monitor screen.
For reducing ECG high-frequency distortions it is proposed to use low-frequency filter with the noise suppression level ~ -60 dB and regulating by a doctor the boundary frequency of bandwidth. In the "Cardio Base" project for elimination of high-frequency distortions 3 low-frequency filters with bandwidths 40, 100 and 140 Hz were used. For keeping the succession of the filtration channel parameters the boundary frequency regulation range of the low-pass filter should be 40 – 200 Hz.

Pacemaker pulses detection could be realized on the base of the calculation of dynamical changes in the vector length, which characterizes electrical activity of the hart. For practical realization of this method it is proposed to use signals digital processing unit, which consists of cascade-to-cascade connected calculator of modulus of the electrical activity ECG vector in 12 standard leads, low-pass filter, digital differentiator, absolute value calculator, peak detector and comparator. Pacemaker pulses detector should not only form the flag for the imaging system of ECG on monitor, but also fulfil input blocking control of all ECG pre-processor to avoid distortions emergence, which are conditioned by the presence of spectral components of big amplitude with frequency greater then Nyquist frequency on the input of ECG pre-processor during the work of pacemaker.

QRS complex detector is proposed on the base of cascade-to-cascade connection of the band-pass filter, modulus calculator, low-pass filter and comparator with adaptive-changing detecting threshold. For reliable detecting of QRS complexes it is admissible to use as band-pass filter the filter with bandwidth 17 ± 3 Hz and with the suppression level

~ -50 dB. Automatic adjustment of detection threshold could be realized on the base of ECG power level dynamical changes analyses in the band 17 ± 3 Hz.

Practical utilization of such structure showed its ability to detect with reliability QRS complexes even under conditions of small signals with powerful noise (Fig. 5-4) that can be significant by the use ECG monitor in stress testing.

Multisensor monitoring

Fig. 19 illustrates an example of a multiple sensor configuration where the patient is wearing a cluster of a five-lead ECG sensor 10, a blood pressure sensor 12 and a pulse oximeter sensor 14, 15, all with processing means and capable of short range wireless communication. In an example of emergency transportation, such as in an ambulance, an additional sensor in the form of a motion sensor 47 can be added, in that a such sensor is particularly interesting when used in combination with, or supporting, other sensors.

The system of the invention will in this case enable the pulse oximeter to contact either a blood pressure sensor or an ECG set-up to obtain a precise pulse timing, for synchronizing the measurements with the blood flow peaks and achieving a more reliable result.

A basic idea of the WIMS system concept is to give the sensors as much intelligence ballast as possible and thereby enable them to "take the initiative", so that the user becomes less dependent on the MNN for control. A sensor for temperature for example, can monitor temperature and compare the values with an internal threshold. If a threshold is passed, the sensor sends an alarm signal to the patient to urge him/her to move into the range of the MNN, at which point the sensor itself takes over the continuous transmission until the threshold is not exceeding any longer.

Another aspect of building more intelligence into the sensor is the ability for the sensor to be autonomous in case the local communications should fail for a period. The most modern storage technology in fact now offers the possibility that sufficient amounts of information can be stored within the sensor itself, until the communications link is re-established.

The hardware is chosen to suit the required level of sensor intelligence and signal processing. A part of this concept is the generic hardware platform for the intelligent biosensors. This platform has an open architecture to ensure the flexibility and adaptability of the system. This is related to an important issue: the opportunity to make the system vendor independent. A central aspect of the WIMS system concept is this

flexibility mentioned above. The requirement to cover many different environments and to seamlessly integrate the continuum of care directs the system architecture towards a net based solution. The sensors are only a small part of the overall monitoring WIMS system. Data is nothing on its own but can become information when given a context, and information can become knowledge and understanding of the meaning of that information.

In addition to local storage and programming interface, some data will also have to be stored at the Medical Central Node (MCN) for ease of access and security purposes. The data structures at the MCN will mirror those found at the local units, but the amounts of data will be larger as data for all users will be stored at the MCN.

The communication between the user interfaces, the MNN and MCN, and the different sensors involved, will be implemented using the API. The communication with other hospital information systems is based on existing and evolving standards in healthcare data exchange formats. These formats, and the accompanying standardization efforts on electronic healthcare patient records (EHPR), are main factors of the structure and content of the data storage in the system and will also be useful for the data exchange formats. The technologies involved are database systems to store the data, database APIs used to interface with the different database systems, and technologies for passing data from one place to another. In addition, different standardization efforts will influence the contents of the database and the format of messages from it to other information systems.

As a rough estimate of the amounts of data involved, the storage requirements involved in storing 3-lead ECG are examined. The specification states that the system should be able to store at least 2 days of continuous 3-lead ECG registrations. Assuming that 3-lead ECG equals a data stream of 1kbps, this means 3.6 Mbits per hour. Over 2 days this equals 86.4 Mbits, or approximately 11 MB. For the central repository, it will seldom be necessary to store all the data recorded at the local unit. Still, the registration for 20 patients with continuous ECG measurements over 2 days only amounts to 220 MB, which is easily handled.

Commercially available databases are i.a.: Microsoft Access, SQL Server, Oracle, MySQL, Sybase. Microsoft Access is however not suitable for the central repository at the MCN.

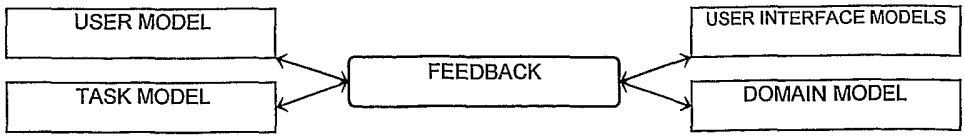
Database interfaces (APIs): All commercial (and free) database systems come with several out-of-the-box APIs used to access the databases from different programming

languages. The two dominating APIs on personal computer databases are Microsoft ODBC, and Sun JDBC.

ODBC: Microsoft ODBC (Open Database Connectivity) technology provides a common interface for accessing heterogeneous SQL databases. All commercial database systems on the Windows platform ship with ODBC drivers. Applications using ODBC will work with any underlying database, independent of any particular DBMS.

JDBC: JDBC technology is an API that permits access to virtually any tabular data source from the Java programming language. Many commercial databases come with JDBC drivers, and third-party drivers for many databases are also available. In addition, Sun JDBC-ODBC bridge makes it possible to connect to standard ODBC data sources using JDBC.

XML: XML is today's most promising candidate for a standard exchange format. XML (Extensible Markup Language), a subset of SGML, is a markup language where the user can define his own content tags, making it possible to tailor the format of XML documents to suit the problem at hand. Content tags are defined through DTDs (Document Type Definition), and a large number of standardization efforts are underway to create standard DTDs for all kinds of data, including healthcare. Parsers for XML documents are available for all languages and often free of charge, and it is also possible to control how XML documents are shown in a web browser, using XSL.
A few of the major standardization efforts within healthcare are indicated below. Most standardization attempts are quite broad in scope, while some attempt to standardize a particular operation within a certain domain. These standards will have important input both on database design and message formats.
www.healthxml.org
www.xml.org
Home of XML on the World Wide Web Consortium (W3C): www.w3c.org/XML/
Homepage of HL7 standards group: www.hl7.org
Homepage of CEN, European Committee for Standardization: www.cenorm.be
Homepage of CEN/TC 251 www.centc251.org
OMGs homepage: www.omg.org
CORBAmed homepage: http://www.omg.org/homepages/corbamed/
EHTO (European Healthcare Telematics Observatory) www.ehto.org



The development of user interfaces for both local and distant access relies upon a model-based user-centred method. Examples of user interface models are drawings, mock-ups, horizontal designs and state diagrams. All models of the method are subject to the iterative and generic steps of analysis, design, and evaluation. A change of one model gives feedback and may cause changes of other models. Thus, problems abandoned in one perspective can be solved implicitly from another perspective.

Fig. 6 illustrates a generic intelligent sensor, a preferred component of the present invention system, and its accompanying instrumentation and communication elements. The processing unit in direct communication with sensors on a patient is preferably of the intelligent and general reprogrammable type and comprises in this case also the conversion means for converting analogue signals to digital. Said sensor comprises preferably the following:

- **Analogous input interfaces**; connected to the external transducer (e.g. blood pressure cuff, thermistors, oximetry LED/photodiode pair etc.), containing amplification and normalization circuits. The functions of analogous input interface includes the signal amplification, if necessary preliminary analogous processing (e.g. filtering) and its normalization to face the ADC specification;

- **Generic re-programmable processing circuits** incorporating processing and control circuits: ADC, CPU and specific control circuits. This unit makes the conversion of the normalized signal into digital representation, digital signal processing (if necessary), and data conversion for the digital interface, it also performs the control functions. The Application Specific Integrated Circuit (ASIC) will be developed for this part, the realization of this unit is explained below.

- **Digital interfaces** for the data and command transition for further local transporting (e.g. blue tooth, serial interface etc.). The main function of this unit is to support a standardized interface for the data and command transmission, it overlaps with the HW part of the local transport. The HW part of the local transport involves the wireless communication unit (Bluetooth module). It is necessary to stress, that only digital, standardized interface fits well the requirement of the open architecture and allows the possibility to extend the system.

According to the invention the monitoring of a parameter is processed further, either in the sensor itself, in the connected instrument and/or elsewhere in the signal channel through the Medical Net Node MNN and the medical communication node 2 (MCN). In a simple embodiment of the invention an ordinary quality control asset like a

QC chart function is employed, having limits and activating actions if these limits and/or other predefined parameters are exceeded or appear. An example of this feature of the invention is by temperature measurements where the temperature first is measured every 15 minutes. A first upper threshold sets an action limit at 38 °C, and a second upper threshold sets an alarm limit at 39 °C. In addition limits are set for alarm as a result of a trend analysis criterion.

This setting activates an action if the temperature rises above 38 degrees but still is below 39 degrees. The system then switches to a temperature measurement every 5 minutes, until the temperature falls below 38 degrees, as measured at two consecutive measurements, or if the temperature even exceeds the second threshold which is the alarm limit.

In the latter situation a new temperature measurement is carried out immediately to verify the result, thereafter the measurement results and the results from the ten last measurements are transferred to an alarm central.

The trend analysis mentioned above can typically be used for four consecutive measurements giving the trend for a temperature increase, and then the action starts by measuring every 5 minutes even if the action/alarm limit not yet is exceeded. If in this situation the measurement number 5 also shows an increasing temperature, a new measurement is carried out immediately to verify the result, and thereafter this result, together with a number of the last relevant or predetermined measurement results, are sent to the alarm central.

Corresponding mechanisms are employed for the other parameter measurements, such as the ECG, but the principles are the same and are within the scope of the invention.

A further processing of the monitoring results obtained by when or several sensors can practically be arranged in a instrument acting as an autonomic unit in the signal channel and thereby the local system communication network. Such an instrument unit is connected for communication with other corresponding instruments and also with larger data systems, in order to gain additional information or having services effectuated. An example of this is if an instrument of the system network detects a fast increase of the blood pressure, and this increase could very well be the result of a trend analysis, see above. An interrogation then will be made in a data base for instruments/patients, and in the example the answer is that the patient in fact also wears an ECG instrument in addition to the blood pressure device. Said device then communicates with the ECG instrument and asks for information about possible alarms or actions going on.

In this case the ECG device switches through a higher action modus and starts a closer monitoring. At the same time this device communicates with the hospital database and looks where for patient data related to stress ECG. These data are then transferred from the hospital and compared to the measurement data at the device itself (ECG/BP) and sent together to a computer for analysing the incoming data to find if they are corresponding to previous results (such as stress ECG results from the hospital investigations) or if there are changes at the patient.

A result of this can be that the ECG device starts a more thorough measuring, particularly for detecting arrhythmia, and at the same time the patient is given the information to calm down/arrange more ECG electrodes, take a medicament etc.

Should an alarm situation occur, such as the detection of arrhythmia, an alarm signal and the corresponding data can be sent to the alarm central which establishes a communication with the patient by means of a mobile phone. The central can also call a specialist for asserting data and possibly also require an ambulance.

Such a device for instruments can also carry out a number of self tests for self-calibration or possibly signalise an own need for calibration maintenance. A simple example is the leakage testing of a blood pressure cuff.

According to the invention the device or instrument can also be initiated or loaded from the central, with special parameters, modes and algorithms based upon the patient disease history, for example a loading could comprise a profile for patients having diabetes and being under surveillance with respect to certain types of heart disease.

A module in the present system can also generate such a profile automatically, based upon said disease history, upon the medicaments to be taken or other parameters given manually by care personnel.The system using the Wireless Intelligent Medical Sensors WIMS is flexible and incorporates different modalities. This means that several intelligent sensors can be combined in one system set-up.By the local communication system we mean the wireless communication between WIMSs and the MNN. As earlier explained, one of the basic goals is to create a generic transport system, based on open architecture, ensuring flexibility and adaptability of the system. Basically, the local transport system provides communication between the Medical Net Node (MNN) and the intelligent sensor, regardless of what kind of sensor and computer that is used. To allow future changes in the system, the solution should be vendor independent. The different sensors require different capacity for the communication system as well as reliability. Generally, the local transport system require a highly reliable and secure communication,

and the maximum data throughput is about 100 kbit/s. Obviously, the radiation from the radio transmitter must be within the limits for what is allowed by appropriate standards, and since the system is likely to be used in the presence of medical instruments, the radiation should not have any influence on these. The radio frequency band should be unlicensed to allow the system to be used anywhere. One of the basic features of the project is to let the patient be free to move around. This implies that the local transport system uses a radio system that completely covers a room. For the wireless communication, we have chosen Bluetooth as the technology to use. This is an emerging standard, with great potential and a lot of actors in the market. This standard is open and fulfils all of the features mentioned above, specifically, it includes the following features:

- Open standard, no proprietary solutions are used.
- A lot of vendors make Bluetooth devices, and devices from any vendor can be used as long as they are within the standard.
- The unlicensed and globally available frequency band from 2400 to 2500 MHz is used. All devices are FCC and ETSI approved.

Each sensor will be equipped with a Bluetooth device that communicates with the Bluetooth device at the MNN, i.e. a hubless system. In that sense, the Bluetooth connection does nothing else than replacing the cable that otherwise would have been between the sensor and MNN. The Bluetooth device at the MNN will act as a master, and it may be connected to up to seven sensors simultaneously. Maximum data rate is 723 kb/s, which is much more than required for the sensors. Using Bluetooth, the radio communication distance is limited to ten meters, beyond this the communication is not reliable. However, it is possible to use a scattered functionality to extend the communication range. The local communication system consists of three main parts:

- The Bluetooth device that includes hardware and software according to the standard, bought from a vendor.
- The transport system, transporting data from the device to the host, including transport driver. This is typically a serial connection with RS232 or UART driver.
- Host application software on the MNN or the WIMS. This is specific software made in the project.

The figure below shows the architecture of the Bluetooth device for both the MNN and the sensor. At the bottom, with physical interface to the air, is the Bluetooth module which includes all radio and baseband hardware as well as the Bluetooth software stack. This device is equal for both the MNN and the sensor. On the MNN side, this module is connected the MNN through a serial connection, using a windows API as the serial port

driver. On top of this is a standard transport driver, and on top the specific windows application that is used for interfacing to the MNN services. On the sensor side, the application is run on the same microcontroller that is used for the WIMS. The Bluetooth module is connected to the controller through a UART, and a specific HW abstraction layer is used as the UART driver. On top of this is a transport driver, the same as used on the MNN, and on top the specific application embedded in the microcontroller.

Simultaneous connections

The MNN is able to connect to the sensors through multiple "connections" or "channels". Although only one physical data link exist, there will exist higher level protocols ensuring multiplexing of channels. E.g., there can be 1–12 channels for ECG, one for oximetry channel, one blood pressure channel, and one temperature channel. The sum of simultaneous channels will be upper limited to 60. This number will be further decreased if real-time processing capabilities are reaching physical data link capacity with fewer active channels.

Master and slave responsibilities

Normally the MNN radio unit takes the initiatives for initializing communication with sensor(s). After initializing, the connected sensors will be active in that sense that they can send and receive data packets without further connection establishment. Both the slaves (the answering device during create connection) and the master (the device issuing the "create connection" command) can send packets in full duplex. The device application will receive an event when data is received at the lower layers of the local software stack. There are receive-buffers at the baseband level. Both applications are responsible of reading the buffers to avoid overflow and loss of data. This can be easily accomplished by the use of RFCOMM (serial port emulation) with CTS/RTS commands.

Device address

If short-range radio systems such as BT shall be used, each radio device must have its own unique address. In BT this is called Bluetooth Device Address (BD_ADDR), where a 48 bit word consisting of Lower Address Part (24 bit LAP), Upper Address Part (8 bits UAP), and Non-significant Address Part (16 bit NAP), forms the bit pattern. If the remote device LAP is known, the Inquiry scan can be run to obtain the rest of the BD_ADDR. The Bluetooth SIG will assure unique BD_ADDR address space to requesters such as The system according to the invention WIMSs. Since all devices must have a BD_ADDR (which must be part of the device firmware), there must be created a database holding the mapping between these BD_ADDRs, if it is in use, and used by whom. This includes both sensors and MNN's devices. The devices should also have encoded into its firmware a user-friendly name giving more information about what it is — this will be used e.g. to prevent erroneous use. In BT this is implemented as a UTF-8 encoded string with length up to 248 bytes. This string is obtained by issuing the special HCI command named Remote_Name_Request.

Association between sensor and patient

There must be a database connection between patient and sensor when sensor is in use. This database should be accessible from MNN, to verify that the connection is made with wanted sensor(s). The Medical Central Node will provide the functions to identify the patients VS sensors.

Procedure registering new sensor and patients

All sensors used by the The system according to the invention NMI system must have unique BD_ADDRs, or generally unique ID numbers. The MNN shall be able of inquiry for this address. The MCN must be updated with personal info, e.g. from EPR (electronic patient records), and the correct BD_ADDR must be attached to this record. The MCN (or MNN) operator must have technology which can "ping" this physical radio device (sensor) in order to verify this BD_ADDR.

Multiple sensors/HUB against one MNN

There will be only one *physical link* between each MNN/sensor pair (called ACL in BT). However, there can be many *logical channels*, as described in 0. Each such channel has its unique CID (channel ID) for that piconet. Thus, the MNN can easily multiplex data coming from multiple sensors. This multiplexing and deplexing is performed at the L2CAP level in BT.

Handling multiple MNNs within radio coverage of a sensor/HUB

There will be possible scenarios where a MNN is in radio coverage of another MNN. During inquiry and page process, there shall be information tags making it easy for a MNN to distinguish between MNN and sensors / HUBs. This information can be part of the user friendly name or can be obtained with a dedicated function. The only identified application requiring real-time operation is ECG-monitoring. The maximum data rate requirements for 12-channel ECG and assumed 12 or 14 bits resolution samples in 16 bits words and 500Hz sampling rate is given by

$$\mathrm{RT}(f_s) = 12 \times 16 \times f_s = 96\text{kbits/s}, f_s = 500\text{Hz} \qquad (1)$$

This number is with no overhead at all. There is overhead introduced by L2CAP and HCI level. Each of the 12 ECG data streams should be assigned its own CID (channel ID). All types of ACL packets have data rates capabilities above 100kbits/s, but if the link is poor, ARQ activation can reduce the net rate considerably. Best-suited type of ACL packet should therefore be adaptive. In addition, the MNN operator shall be able to select appropriate data rates, e.g. to reduce the rates where the channel is poor, or to avoid congestion when there is other ongoing traffic from other sensors.

Table 2: The 7 different ACL packet types defined in Bluetooth

Type	Payload Header (bytes)	User Payload (bytes)	FEC	CRC	Symmetric Max. Rate (kb/s)	Asymmetric Max. Rate (kb/s)	
						Forward	Reverse
DM1	1	0-17	2/3	yes	108.8	108.8	108.8
DH1	1	0-27	no	yes	172.8	172.8	172.8
DM3	2	0-121	2/3	yes	258.1	387.2	54.4
DH3	2	0-183	no	yes	390.4	585.6	86.4
DM5	2	0-224	2/3	yes	286.7	477.8	36.3
DH5	2	0-339	no	yes	433.9	723.2	57.6
AUX1	1	0-29	no	no	185.6	185.6	185.6

The sensors shall be able to send alarm messages regardless of whatever power-mode it operates in. When triggered, the sensor must be able to make state transition to Active mode. Bluetooth has defined 3 standby modes:

1. In **sniff** mode the master can send information to slave in only predefined slots, separated by T_{sniff}. This reduces how often the slave has to listen for packets, and thus saving power.

2. In **hold** mode, the slave still handles SCO packets, but no ACL packets are supported. In hold mode, signalling is still possible, i.e. paging for other remote devices. The unit can enter low-power mode in this state. The unit still keeps it active member address.

3. **Park** mode is a mode where the unit is still synchronised to the piconet, but no longer has any active member address (3 bit address). Instead it gets a 8 bit Parked Member Address and 8 bit Access Request Address. This mode is useful for entering low-power mode, and to connect more than 7 slaves to the piconet.

The following main alarm situations shall be supported:

- Sensor to MNN: sensor battery warning
- Sensor to MNN: sensor malfunction
- MNN to sensor: received signal strength below critical value
- MNN to MCN: sensor signal lost
-

Reliable communication

Due to noise and interference on the radio channel, some percentage of the data will be corrupted. The data shall be corrected, or if not possible, retransmitted, in such cases.

These mechanisms will be invisible for the application layer, except that it will introduce longer time before data requests are succeeding in collecting the data. The physical link to be used is called ACL, which stands for Asynchronous Connectionless link. This means that the time slots occupied is per use only, and not allocated at fixed timeslot locations. Reliable connection is obtained by using L2CAP connection-oriented protocol on top of this physical link, which ensures that all packets will be delivered. This can be regarded as equivalently "TCP on top of IP" in the Internet domain.

Secure communication

Since the WIMSs will communicate sensitive information, the wireless communication paths must be protected with *encryption,* to avoid eavesdropping and maintain link privacy. Also, access to databases and other information will require *authentication,* to prevent spoofing. If the user is untrusted, there must be mechanisms for manual *authorisation.*

Bluetooth supports all these mechanisms at different security levels. There exist three security levels which are briefly explained in the following.

Mode 1 — Non-secure

When the applications will transfer non-sensitive information access and transmission, the use of Mode 1 will remove all security aspects in the BT protocol stack. There is no authentication or encryption involved in this mode.

Mode 2 — Service-level enforced security

A device does not initiate security procedures before channel establishment at L2CAP level. This mode allows different and flexible access policies for applications, especially running applications with different security requirements in parallel.

Mode 3 — Link-level enforced security

A device initiates security procedures before the link set-up at the LMP level is completed. This mode comprises the strongest security level in BT, since there is no successful physical link setup before all security matters are fulfilled.

Security level suited for the WIMSs

Additional non-Bluetooth specific security mechanisms can of coarse be added at the application level. Up to 128 bit encryption keys can be used in mode 2 and 3. The BT documentation says mode 3 is easier to implement than mode 2, since it gives a common security level for all applications. In mode 2, there can exist different security requirements in parallel for individual applications. If the latter feature is not a NMI requirement, the most suited security level should be Mode 3.

To transmit the data from the MNN/bridge to the MCN or other remote clients, the TCP/IP protocol is used. This implies that if the MNN/bridge is connected to the Internet via a local area network (LAN), the data is available from anywhere in the Internet provided the correct authentication and software. In order to update the Medical Central Node (MCN) database, the MCN must also be connected to the Internet.

If the MNN/bridge is only set up with at dial-up connection using a standard modem or a PCMCIA GSM modem, authenticated users must call the telephone number the modem. The MNN is running a Remote Access Server (RAS), which will answer incoming calls and grant access to authorized clients. The MNN will also periodically, as configured, call the Medical Central Node (MCN) and transmit its latest monitored data. The MCN must be running a RAS and have a pool of modems listening for incoming MNN connections.

To increase security, encryption can be added. Using Secure Socket Layer (SSL) on application level will provide full encryption. To secure the connection on a lower level, tunnelling can be used. All data sent between client and server will then be encrypted before transmission. The global transport will be using both the Internet and direct modem connections. Depending on the infrastructure present, the MNN/bridge must be set up with appropriate software and communication devices.The services are split between those on the MNN, those on the MCN and those implemented in the network somewhere in the future.

Real-time monitoring

The primary service offered by WIMSs is the ability to monitor patients remotely in real-time. The sensor values are passed through the MNN to a medical communication node or similar central data repository, and from there they are on the web.

While real-time remote monitoring is possible using traditional wired sensors, these do not offer the freedom of movement and comfort associated with WIMSs. The increased comfort levels mean that the patients are able to wear the sensors more or less continually, and it is thus possible to monitor the patients more often and with less discomfort to the patient.

Remote monitoring

A remote monitoring service will mainly be used by medical professionals (GPs, specialists, nurses, etc.), and will be used to perform the same diagnostic operations as modern wired sensors, with the added benefit of increased patient comfort, ease of remote monitoring, and the possibility to monitor a patient for long periods of time.

As an added benefit to the monitoring service, WIMSs will offer the possibility to set alarms at threshold values for the different sensor inputs, and will also offer the added option of using more advanced evaluation real-time evaluation algorithms to trigger alarms, either based on a single modality, or using several modalities in combination. Alarms can be triggered at different locales (locally, remotely, or both), can have varying degrees of importance, and can use different cues (audio, visual, etc.). As with monitoring, the added comfort of the WIMSs means that the patient will wear the sensors for longer periods of time, increasing the usefulness of an alarm system.

Network Access Service

Information from the intelligent sensors on patients is received and logged locally on the Medical Net Node (MNN). To make this information available to remote clients, the MNN must act as a gateway/bridge between the sensors and the clients. From the sensors the data is transmitted over a local transport medium. The local transport medium chosen is the wireless Bluetooth technology, but communication can also be wired through serial communication cables. The MNN stores this information in its local database. To distribute this information to all relevant actors in a generic manner, the MNN can be contacted through different access medias. Depending on the infrastructure present and the system configuration, remote clients can access the MNN using a modem or a standard network adapter if the MNN is connected to a LAN. The communication is two-way, that is, the LCP can both answer incoming connection requests and initiate a connection. The connection can be initiated both automatically from the application and manually by trained authorised personnel. In this way, the MNN is a bridge for distributing the monitored data from the sensors to the clients and services outside the range of local communication. The MNN provides an intermediate storage for monitored data. The MNN will also act as a local service provider, offering a set of services that can be accessed from a standard Web client, such as Netscape, Internet Explorer or Opera, or a remote or local The system according to the invention application. The MNN will accept incoming connections from authenticated users from clients using a dial-up modem connection. Depending on the client's level of authorisation the MNN grants access to the services. The medical communication node (MCN) can call the MNN and access all information stored in the MNN's database. GPs can log on to the MNN and view the latest monitored data and also access the MNN's configuration interface.

Medical communication node services

The medical communication node (MCN) is the central server that controls all the modules in the system. Functions of the MCN are:

- Sensor-patient identification
- Alarm handling
- Central data storage with integration to electronic patient records
- Extended services provision
- Billing systems

This section describes the potential value added services that could be accessed via Web. The requirements for services differ, depending on the user of the system and the application area. Infrastructure of services is crucial for success of WIMS concept. That means all components - WIMS devices, sensors and network services - cannot yield a real breakthrough in healthcare practices being employed separately. WIMS have a relatively limited market niche varying from one diagnostic modality to another, network services without WIMS are limited to information systems in the broad sense of the term and cannot give by themselves significant marketing advantage. There are two main service users: medical professional/physician (GP, medical expert) and patient/caregiver. The physician is the major user of the services incorporated in the WIMS concept:

Paperwork services.

Paperwork occupies tremendous amount of working time of a medical professional and alleviation of this load is important. Recently several web based projects have been launched that aim at this goal. As a reference the Logician Internet (http://www.medicalogic.com) is a good representative in that respect.

The core of such a service is the Internet based data centre that gives a physician a secure and reliable access to patient charts. This group is related to EPR, electronic patient record.

Possible logistic effects of WIMS implementation

- *Productivity boost.* First of all, the information system must be easy to use. That means the time required to maintain paperwork with the help of the system should be less than that filling the forms in by hand. That means all screen forms must be designed in extremely ergonomic way that match actual document workflow in specific language, cultural and legal environment. Data search capability provides for another productivity increase in paperwork. A doctor, a secretary etc. must be able to easily locate all records that match medically relevant search criteria. Notifications about newly discovered adverse effects, new contraindications etc. have become really common nowadays and ability to locate all relevant cases in large patient group is a real necessity and a real advantage that would be definitely appreciated by a clinician (a GP first of all).
- *Access from everywhere.* The main advantage of web portal based information service is accessibility from everywhere, this is a significant part of the *seamless* care.

- *Automatic standards compliance.* Compliance to standards in medical documents is a significant advantage of an information system. It is an important component of productivity boosting because it guarantees the best quality of all documents at no cost in terms of time/effort. Filling in reports or application for insurance coverage is a typical example that is discussed extensively in physician mailing lists. As the standards vary significantly from country to country the system must be flexible enough to satisfy needs of international users. This is important feature for the WIMS system face different *regional* requirements.
- *Benchmarking.* By combining the sensor data with data from the electronic patient record, it is possible to construct a detailed patient history. Patient histories from a particular hospital can be compared with similar cases from other hospitals, to compare the performance of the hospital. If differences are found, it is possible to compare the detailed patient histories to identify the probable cause, and thus influence the treatment of future similar cases. In this manner, a collection of best practices will evolve through collaboration and information sharing between hospitals.
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Second opinion/consulting services

This section discusses the possibilities and advantages related to WIMS integrations to network services. The ability to exchange physiological data over wide area networks can constitute a significant marketing advantage.

Access to diagnostic services. This type of service is an obvious one. Remote ECG analysis is traditional but it is still a need. More sophisticated diagnostic procedures like Holter monitoring is even more promising. Introducing of Doppler and ultrasound scanner WIMS can require a lot of training/consulting support. This type of support can be provided over the net.

Second opinion service. This type of service can be rather attractive if it will be constructed in an integrated manner. That is the ability to easily compile sophisticated request for second opinion from various vital sign data (obtained from WIMS devices) and textual data (obtained from "virtual chart room") can be extremely useful for a GP.

Information services

The services described below are not directly linked to WIMSs, but could be a convenient add-on in the case of the integrated WIMS Web-portal system. This section covers opportunities for "information providing" for physicians. Quite a number of medical information services exist on the Internet and competition does matter. Some ideas that can help are outlined below.

Digesting. Not all doctors are researchers. Moreover, doctors are normally rather busy and do not have much time to search for information. The time required to read and analyse numerous full text academic papers that appear monthly is considerably large and

not all doctors can do it. On the other hand, to-day professional challenges require continuous education. Thus, the ability to provide "digests" of latest research results is a requirement. The quality of such a digest needs to be really high. Of course it is not easy to compete with famous and well-established medical information centres like American Heart Association. But it is possible to create a "third layer" between the most important medical content providers and local medical communities. It can include:

- Adapting to personal interests of subscribers and creating personalized surveys. It is important to create infrastructure for collecting the data of personal interests/preferences;
- More "digested" information than that comes form "major providers". Such surveys can be more attractive for large "GP information market";
- "Localizing" the content. Normally, people prefer the information that they have to read (but do not actually like to read) to be in their mother tong just because it is much quicker than to peruse long English scientific papers.

Active content pushing. Most of clinicians would not demonstrate too much activity in subscribing for bibliography etc. or looking for professional information in any other way. They just have to study continuously but they are normal human beings, anyway. The problem can be overcome by active content pushing as mailing lists, Internet channels etc. Relatively large part of such pushing should be for free at least at initial stage. The "digests" must be as relevant as possible and be concise. Psychological barrier is much lower if one has to "consume" several small "pieces of information" daily than in case he/she has to read lengthy surveys or scientific papers weekly. As soon as a client gets accustomed to this "content pushing" and finds it useful, he/she will be ready to pay for it.

Summarizing all that is discussed above it can be said that special body of highly qualified medical observers is a must for the success of a web based "medical information service".

Aspects of the organisation, the people and the tasks must be addressed in order to succeed. These four aspects together were described by Leavitt in 1957 and are summarised in his "Leavitt's Diamond" shown in Fig. 21. The diagram is modified to show that the newer discipline of Systems Thinking can be used to analyse complex problems such as those that arise when the four elements are combined.

WIMS Suites are combinations of WIMS sensors and network-based services provided to an identified population of patients and health care providers through a defined organizational model. Each individual will carry out defined tasks in order to get it to work. The inventive system comprises several components integrated to provide a suite

of services for home care monitoring with equipment provided by a hospital or a general practitioner.

Home care is in the focus of attention, and the present system has the intention to improve the quality of home based care and medical treatment. The WIMS of the system then are capable of 24 hours real-time medical monitoring of patients in their own home. The economical effectiveness of the home based care is often declared. Although the requirements for the home-care system are sometimes higher than in other application areas, home-care is considered to be the most promising application field for classical telemedical systems.

The user scenarios for the home-care are quite diversified. For the monitoring purposes the direct user of the sensor could be the care-giver, the patient him/herself or the nurse. It is of importance that in home-care the medical professional often is not situated near the patient during monitoring. In some cases it could take up to several hours for the medical professional to get to the patient. Nurse, GP or expert could implement diagnostic.

The home environment is quite specific, forming unique requirements to the intelligent sensor, transport and services part of the system. The telecommunication infrastructure defines the specifics of the transport part of the system:

- The telecommunication infrastructure usually is not so well developed compared to the hospitals or offices.
- On the other hand the telecommunication environment is not so conservative as in the hospitals. The novel solutions and technologies much faster get into wide use, cause there is no need for additional certification and testing, no need to adopt existing patient record systems and build in new solutions into existing infrastructure.

The requirements for the sensor part in the home environment are also very special:

- In the case of the patient/caregiver using the WIMS, the most important feature is the ease of application and use. This is especially important in the case of the patient monitored at home.
- The sensors should be resistant to the environmental influences, untypical for the Hospital or ICU: like higher humidity and EMC noises, the sensors should be resistant to the mechanical hazards.
-

Services: home-care being isolated from the usual medical environment, home care has the best potential in the distant services requests.

The system comprises preferably intelligent biosensors for ECG, temperature, pulse oximetry and blood pressure, connected to a computer for running applications for monitoring and analysing the information received. This computer is called the Medical Net Node (MNN). The MNN will in turn connect via a mobile phone interface (GSM) to a monitoring site, the Medical Central Node (MCN). The Medical Central Node will be able to continuously view the received signals from all the connected MNN units and communicate back to either the patients or directly to the sensors to change their mode of operation. Each Medical Net Node with its associated sensors will be registered to an individual patient so that it is clear to whom the recordings belong.

Technology for the "intelligent" home is developing at an extremely high rate and will undoubtedly influence the further development of the home care suite in all areas, especially technology and organization.

The "Electronic" or "networked" home is a concept supported by many major national and private electronics and communications companies. There are many standards emerging to cater for the communication and service provision in this area. One component part is a device to connect the home appliances to the Internet and therefore to a service provider. This is sometimes called an Edge Server. It contains software to allow identification from the external environment whilst protecting the internal environment against unauthorised sources. It can implement services remotely allowing the connection of an appliance such as a refrigerator to a service company that will provide a maintenance service or a food store that will replenish stocks when it is running low.
This concept is not any different for a system using Wireless Intelligent Medical Sensors. The WIMS sensors can easily connect through the Edge Server to a medical service provided to the user. In this case the system comprises the following:

Intelligent BioSensors enabled with wireless communications, Bluetooth, communicating to the Edge Server via a device providing temporary storage of information in case of a network breakdown. The device in this scenario has been called an Extended Services Gateway. The Edge Server is called a Services Gateway. The Services Gateway connects to the WIMS Services provided on the Internet for the WIMS sensors in use. If ECG is one of the sensors then services for storage of information in a patient database, monitoring of the received information by a member of the patient's assigned medical staff and/or other independent specialist(s). A service for advanced analysis of the ECG using Artificial Intelligence services can be called if this is desired. The services will be seamlessly integrated across all health care institutions by a common interface, storage and communication standards.

Each sensor in this broader future scenario will have an id. that is registered to a given patient by the use of a "key", possibly using the Public Key Infrastructure (PKI) system. The device can then be used by several people if necessary as long as each person has a private key. This infrastructure can also be used for encryption and signing of information enabling a high level of identification and security.

The system according to the invention is focused on home based care for different patient groups. Patients will vary from babies and young children to adults and the elderly. In the case of babies and children their parents or responsible guardians will also be involved. Adults will most often take responsibility for their own care. In the case of the elderly, a relative or a communal care provider may also be involved.

In all cases there will be a need for mobile health care workers who can visit the patients if needed, and a staff for surveying the information being received.

There are many tasks to be performed by the different actors in the process of providing safe and effective home care. All persons involved must receive adequate training in the use of all aspects of the system relevant to the tasks they will perform.

After consultation with the relevant specialists the WIMS Sensors and Medical Net Node will be issued to the patient or another responsible person in the case of children or the elderly requiring assistance. The people responsible for providing care and operating the system in the home must be trained, either before the system is installed or preferably at the place where it will be used.

The patient or other responsible person then may operate the equipment according to the guidelines and communicate with health care personnel as needed. The patient's doctor or other health care personnel will monitor the information received, setup medication routines and handle alarms received from the system. The organization surrounding the WIMS system needs to be flexible in order to cope with the different environments into which the system will be implemented. This is not the same as implementing technology into a hospital ward where control is maintained by the trained staff. With home based care the technology is installed in a wide variety of locations and is operated by a diversely technically competent group of end-users. An increase in mobility is required from the middle layers or tier of people in the system, the tier between doctors/specialists and patients/carers. Building up a support structure to develop confidence in the safety and effectiveness of the care is a primary organizational requirement. Technological advances in home monitoring standards and equipment will enable a greater use of Internet based communication and therefore internet based services. This will allow an

even greater "virtualisation" of the health service. Care givers can be located anywhere and still always have access to relevant information. The community health workers will be even more flexible and mobile and possible autonomous, deciding routines based on information received over the web, etc. The acute care setting requires the whole system to be portable and robust. Acute care settings include for example paramedic installations, airlines, boats. It is required that the WIMS units are light-weight, shock and water resistant and can withstand extremes of temperature. The Intelligent BioSensors communicate using the same wireless technology, Bluetooth, to a computer device specifically built to withstand the requirements of a mobile scenario. The device is required to communicate to the Internet services via possibly satellite technology such as a satellite phone system. The system is self-contained in a case for portability. In order to monitor the patient at the scene of the incident, it is necessary for the unit to have a display or to have a device that will connect to the portal services in order to display the information. This should be a highly portable device such as a Personal Data Assistant (PDA) or a handheld PC.

The people involved in the acute care setting will be medically health care staff persons qualified for emergency medicine and with a backup from a monitoring centre giving supplemental information and preparing for the arrival of a patient at a secondary health care institution. The patient in this case is not the primary deciding factor in the choice of technology to be used. The constraints are in the environment. Emergency medical staff, i.e. Paramedics, will be responsible for all tasks related to use of the portable equipment. The level of emergency training will however vary from the paramedic to a flight attendant on an airplane. The patient will not normally be in a condition to be able to be responsible for the use of the equipment. Monitoring centre staff will be reviewing the information received and passing this on the hospital emergency staff in preparation for arrival. Portable equipment for acute mobile care is available already in ambulance settings and therefore the organization around the system is already, in some areas, established. Communication between the mobile units and the monitoring centre and between the monitoring centre and emergency admittance are required. A Web focused system allows this to happen in parallel reducing the communications overhead. EMC staff can communicate with the paramedics in order to prepare the patient for arrival.

A possible organizational aspect of the acute related areas such as boats and planes is that some of the services may be provided by travel insurance companies or directly by transport carriers. In this case a web based portal services solution will allow information to be gathered wherever the patient is located and evaluated by a medical person from the insurance company in the patient home country before deciding on a course of action or a target hospital.

Not all uses of the WIMS technology will be related to patient care. It will be possible to use the Intelligent BioSensors to monitor ones long term health as a preventative / screening process. Health screening will be an area where development of new modalities and new artificial intelligence will be needed. Sensors for cholesterol, spirometry, blood chemistry etc. will allow a better long term analysis. The Intelligent BioSensors enabled with Bluetooth will be able to communicate with Bluetooth enabled mobile telephone that itself can connect to Internet to the portal site. Information from the sensors will be communicated to the patient information storage service on the portal site. The WIMS sensor user will be able to view the information using any computer or other device that is web browser enabled. In addition a service for adding other health/life style information will be available. An advance service for long term trend analysis can be accessed enabling a designated health care professional, the patient General Practitioner for example, access to the screening results.

A pre-requisite for this implementation is a web based Electronic Health Record into which the information will be stored which is secure. The system will be dependent on PKI security for identifying individuals and providing the necessary level of security. Anybody interested in their long term health will have access to the WIMS technology and services. Health care workers will only become involved if the WIMS User becomes a patient. At which point access to the information will be granted by the owner, the patient. The consumer will be fully responsible for operation of all aspects of the system therefore it is important that extensive usability testing and design is conducted. An automatic billing engine will be required to charge the users for the amount of information stored or a per transaction cost. The system will be a classic Internet based service and will need a supporting infrastructure and technology organization to handle expansions and maintenance of the system. eBusiness solutions are all the rage at present therefore experience in this field should be available.

While several embodiments of this invention have been illustrated in the accompanying drawings and described hereinabove, it will be evident to those skilled in the art that changes and modifications may be made therein without departing from the essence of this invention, as set forth in the appended claims.

Patent Claims

1. A system for remote monitoring and recording, analysing a recorded output and responding by feedback, comprising:

a plurality of sensors, each for measuring at least one individual parameter and providing an output related thereto,

first processing means for processing each sensor output,

additional processing means for further processing of signals/data related to said sensor outputs and for processing of inputs,

transfer means for transferring signals/data related to said sensor outputs,

at least one remotely arranged receiving station for recording, analysing, storing and responding by said feedback,

first control means for controlling the processing and transfer of signals/data,

additional control means for controlling the recording and storing of data related to said sensor outputs, the recording analysis and said processed inputs, and

operating means for accessing different processing levels in the system and presenting relevant information there from for a user, said monitoring system being ***characterised by*** forming a local communication network having access to a global computer network so as to be a part of same, and having nodes being represented by said sensors and processing, transfer, control and operating means, for real-time two-way data communication directly between any of said nodes and/or through the global computer network, said two-way data communication enabling the entering of instructions for the subsequent acquiring and interpreting of data from a number of data sources.

2. A system according to claim 1, ***characterised in*** that said sensors are chosen from a group of sensors adapted for the sensing of biological parameters, physical quantities and properties, chemicals, element numbers, rays, activity, motion, position, colour, light, periodic and non-periodic events, waves, response, sensations, fluid quantity, physiological factors, pattern recognition, flow, time and geographical position, and any combination of same.

3. A system according to claim 1-2, ***characterised in*** that the processing means comprise devices having programmable circuits and memories for data storing.

4. A system according to claim 1-3, ***characterised in*** that the processing means comprise at least one processor employing artificial intelligence,

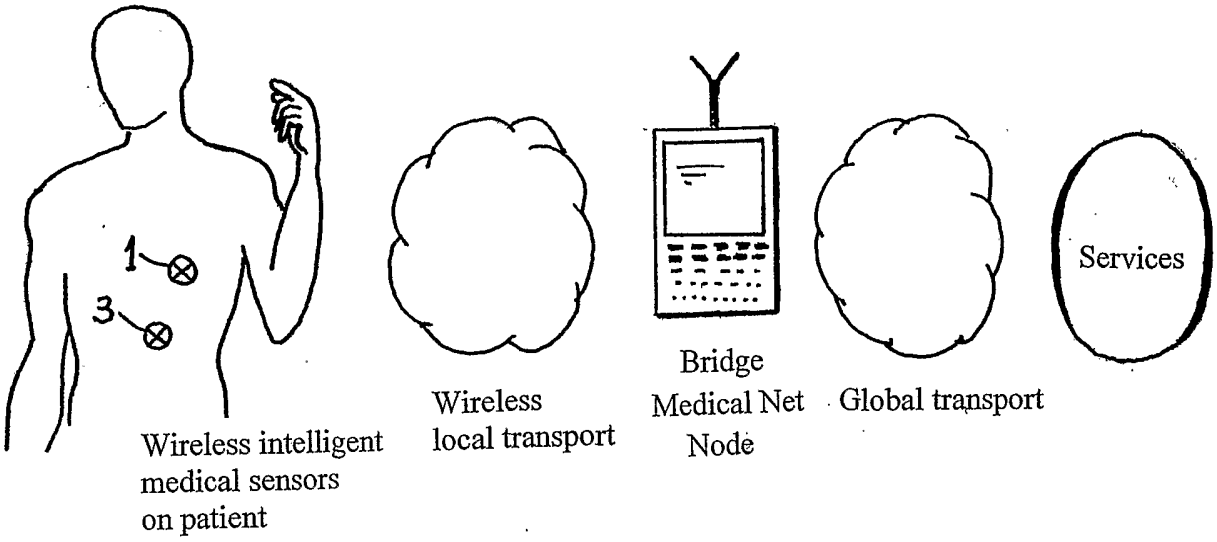
5. A system according to claim 1-4, ***characterised in*** that the processing means comprise at least one processor employing case based reasoning and/or inductive machine learning algorithms.

6. A system according to claim 1-5, ***characterised in*** that the transfer means comprise transmitters and receivers for local and remote communication from the group of communication means comprising wireless, acoustical and optical communication.

7. A system according to claim 1-6, ***characterised in*** that said transmitters and receivers for wireless communication comprise the use of RF modules and circuits such as Bluetooth, GSM, GPRS, UMTS and wireless LAN communication units, said RF modules and circuits being arranged in order by a communication module according to how effective communication they provide, whereafter the modules and circuits are selected from the top of the arranged order by said communication module, to obtain the most effective communication.

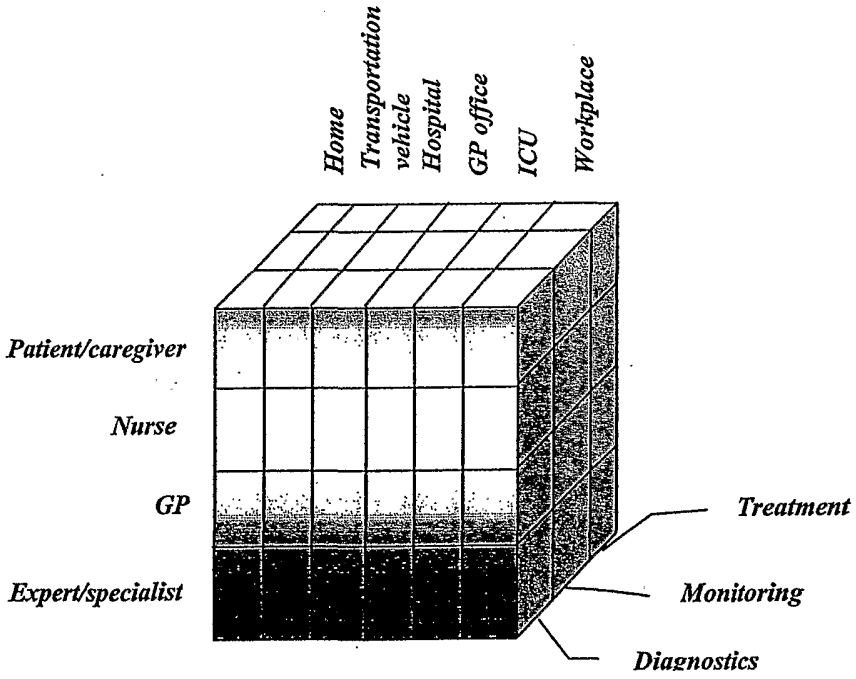
8. A system according to claim 1-7, ***characterised in*** that said additional control means comprise the providing of data processing, forwarding and storage, automatic diagnostics of patient symptoms or technical support, enabling parameter changes and event control, acute medical response and trend analysis.

9. A system according to claim 1-8, ***characterised in*** that the sensors comprise circuitry capable of selecting communication channels to other sensors and/or devices in order to provide combined parameter monitoring.



System Overview

Fig. 1



Scope

Fig. 2

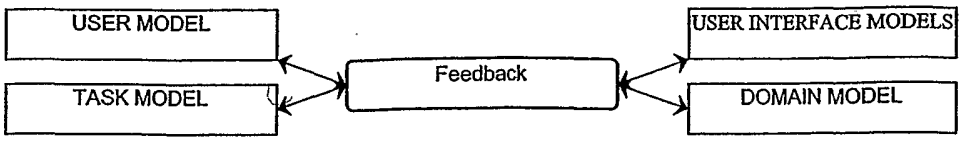


Fig. 3

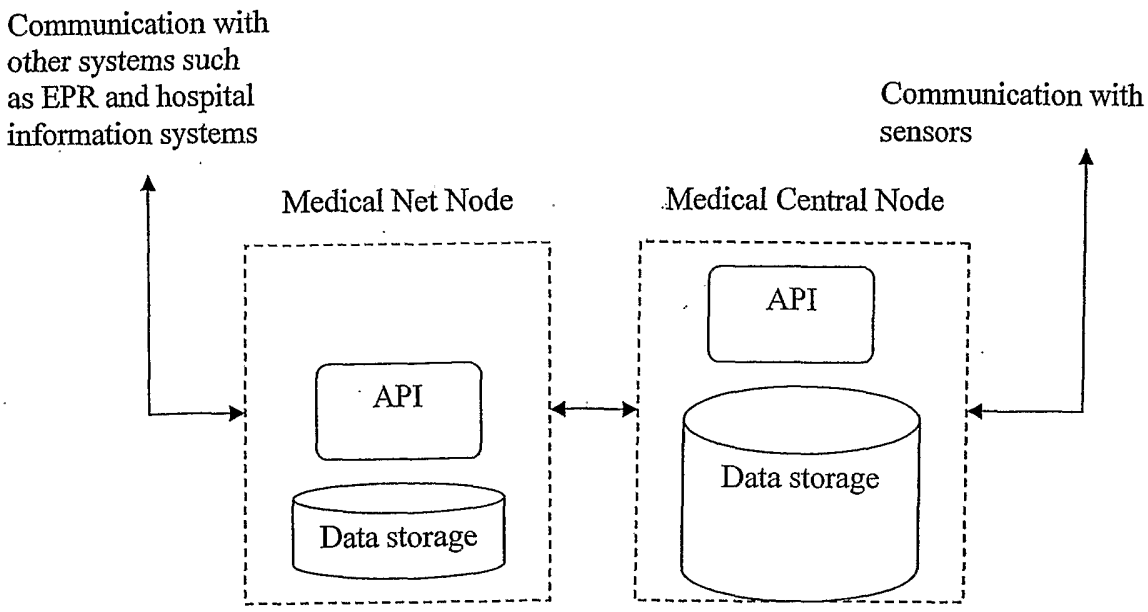
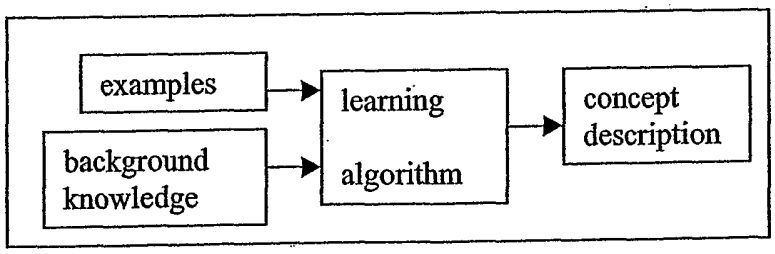
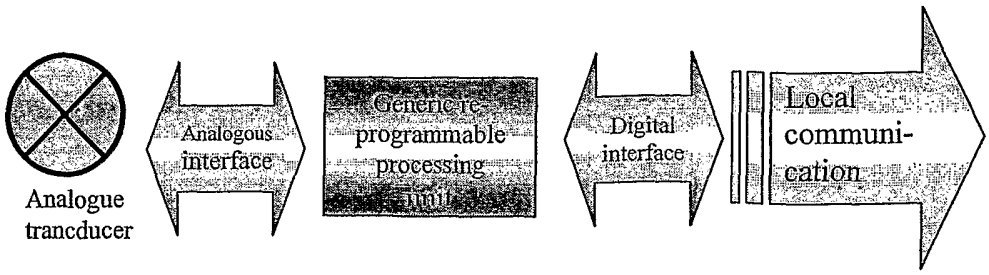


Fig. 4



General framework of machine learning

Fig. 5



Intelligent sensor

Fig. 6

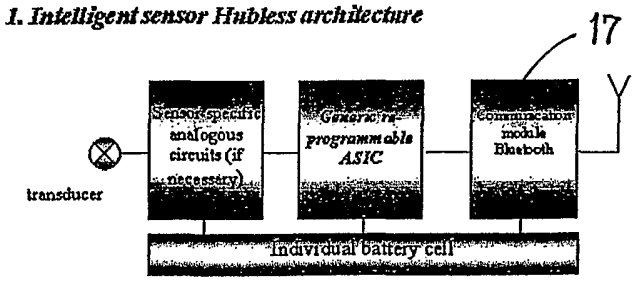


Fig. 7

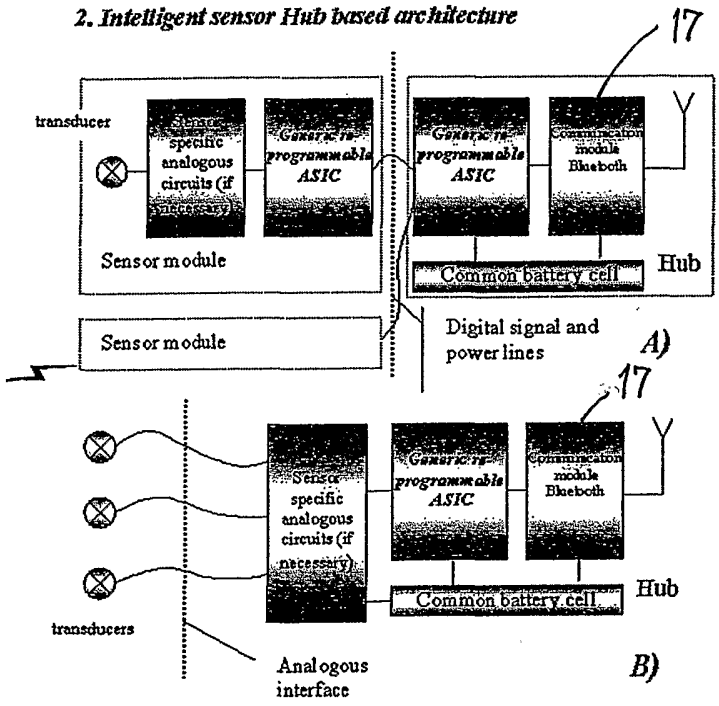
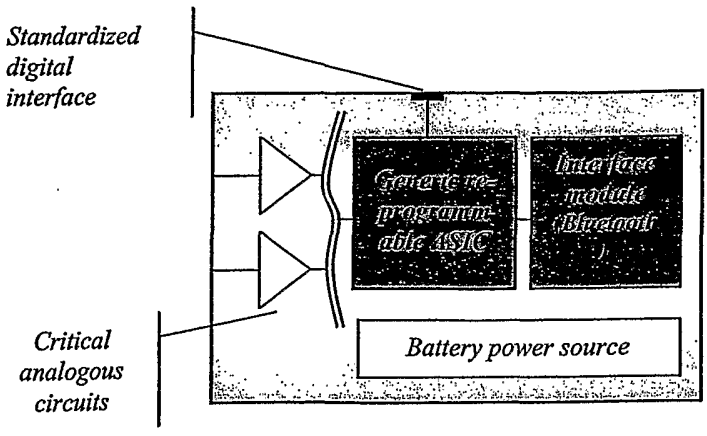
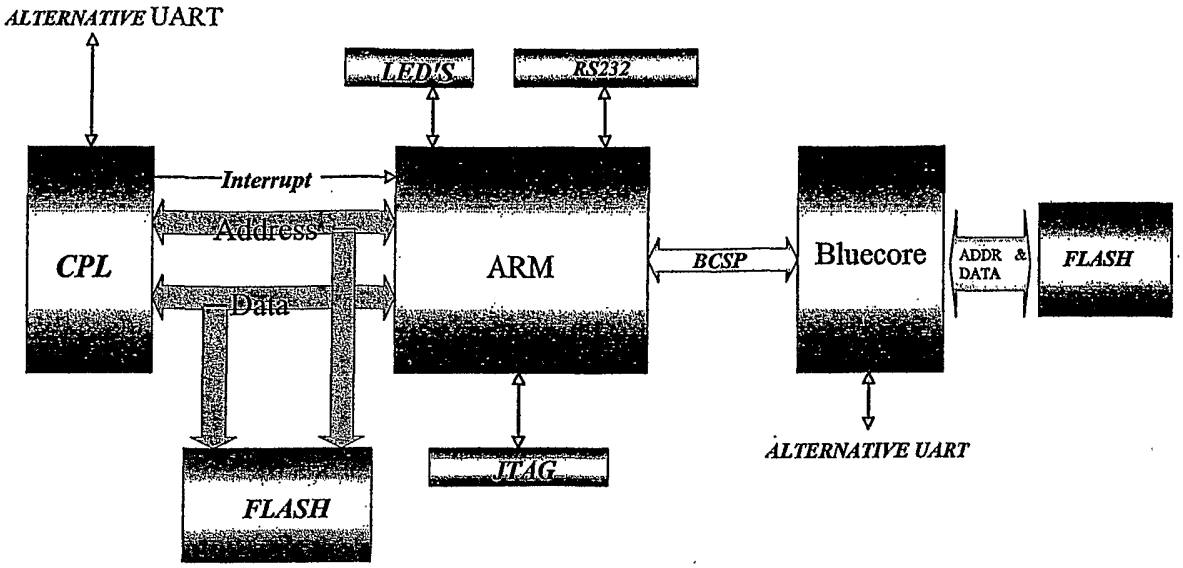


Fig. 8



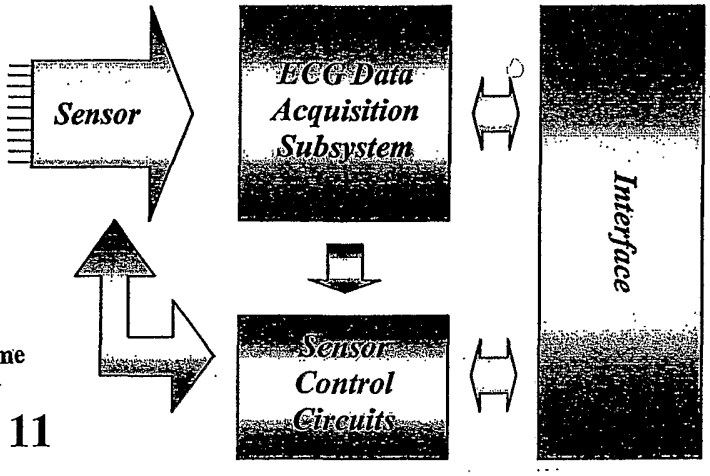
Intelligent sensor layout

Fig. 9



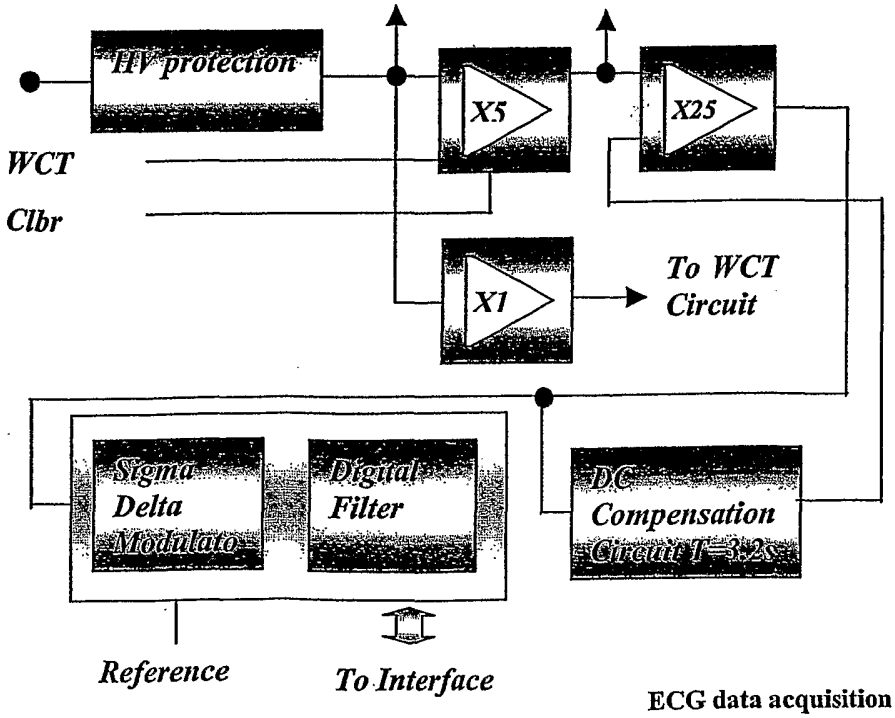
Generic MNI digital part

Fig. 10



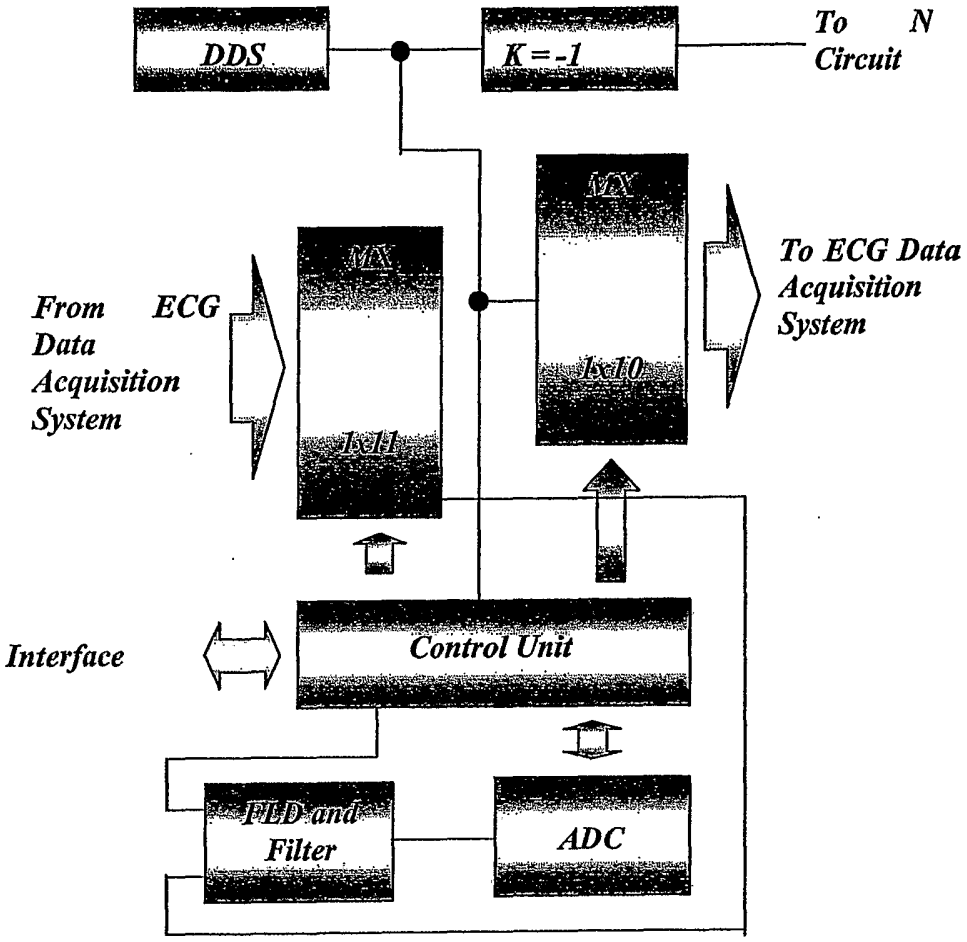
ECG Sensor logical scheme

Fig. 11



ECG data acquisition system

Fig. 12

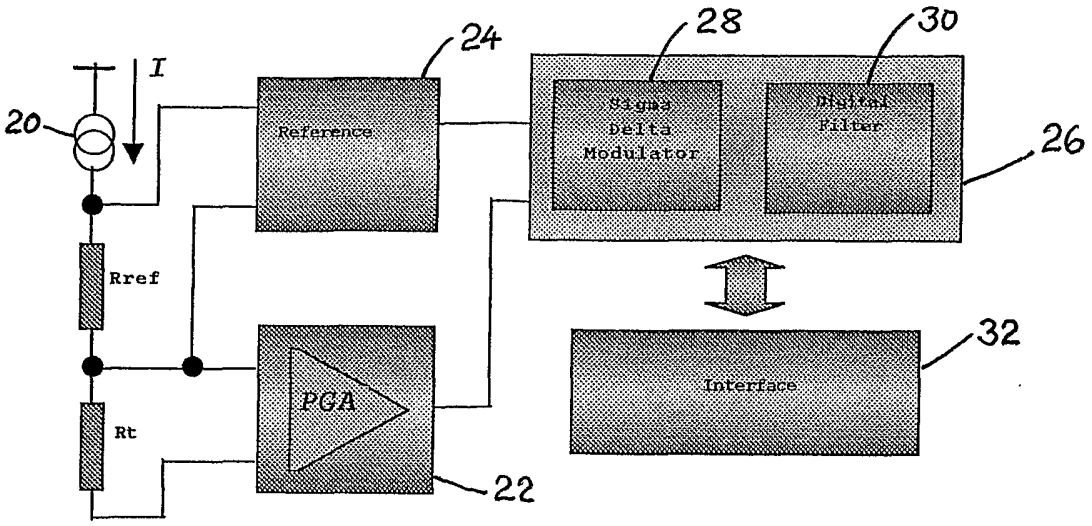


ECG control circuits

Fig. 13

Example of the ECG signal with low signal-to-noise ratio

Fig. 14



Temperature sensor functional scheme

Fig. 15

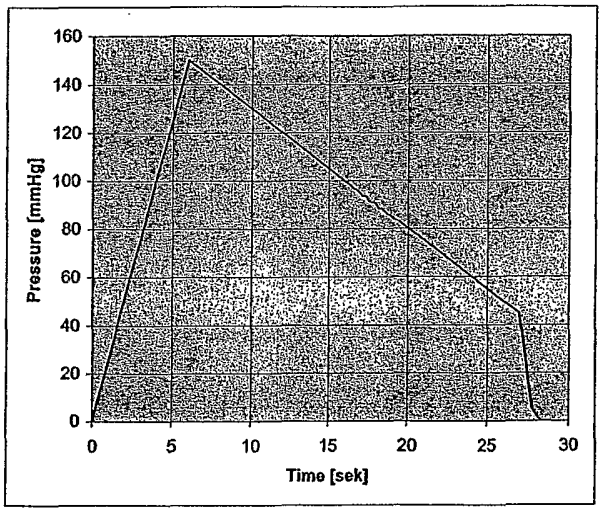


Fig. 16

Blood pressure measurement cycle

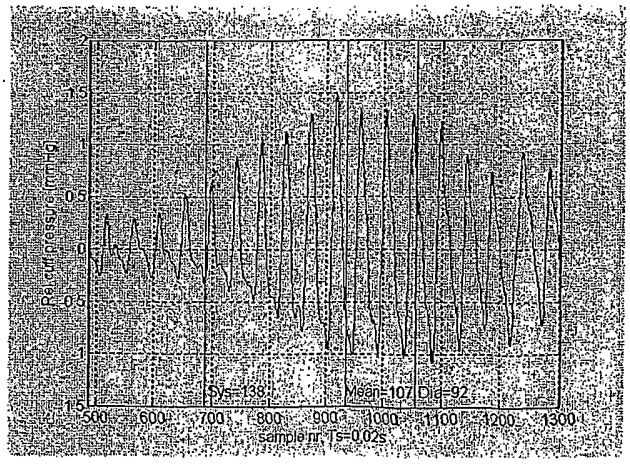
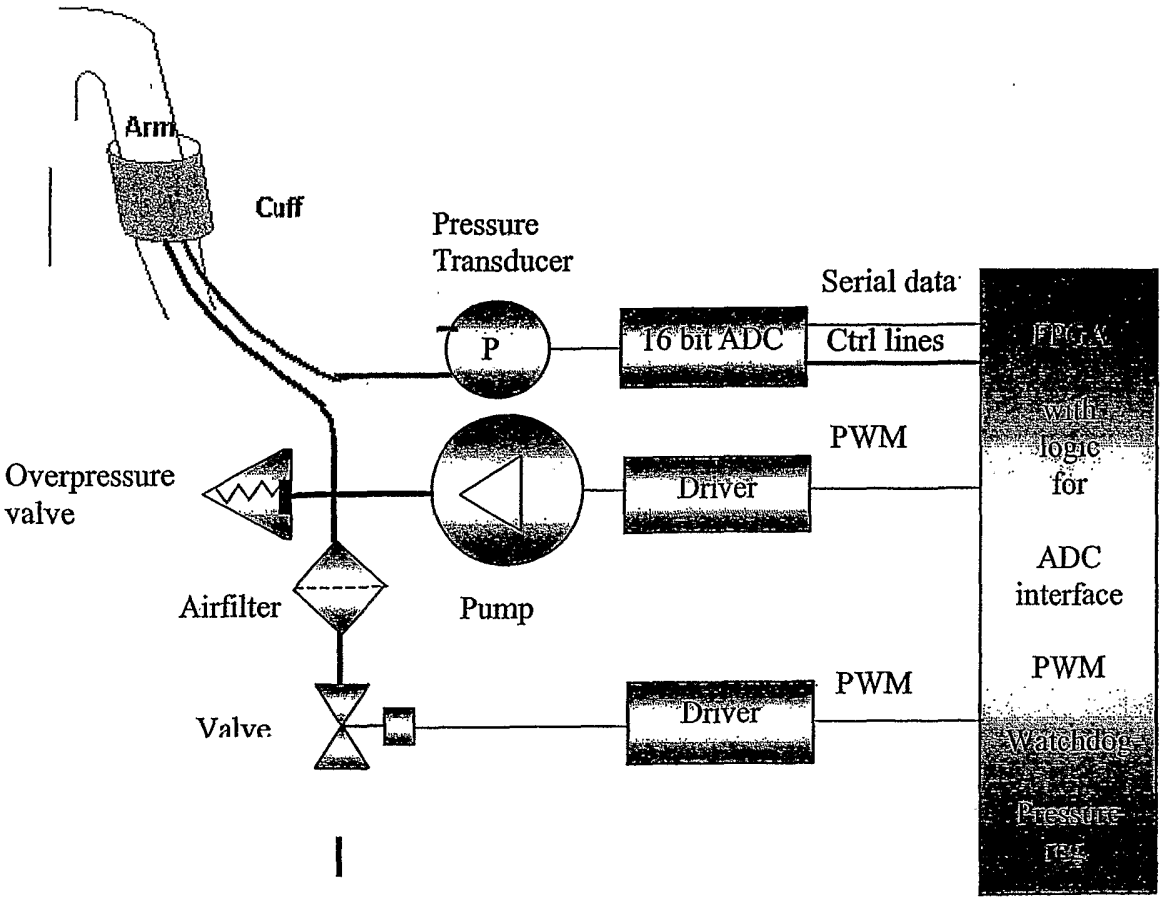


Fig. 17

Pressure oscillations during the cuff deflation



Blood pressure functional scheme

Fig. 18

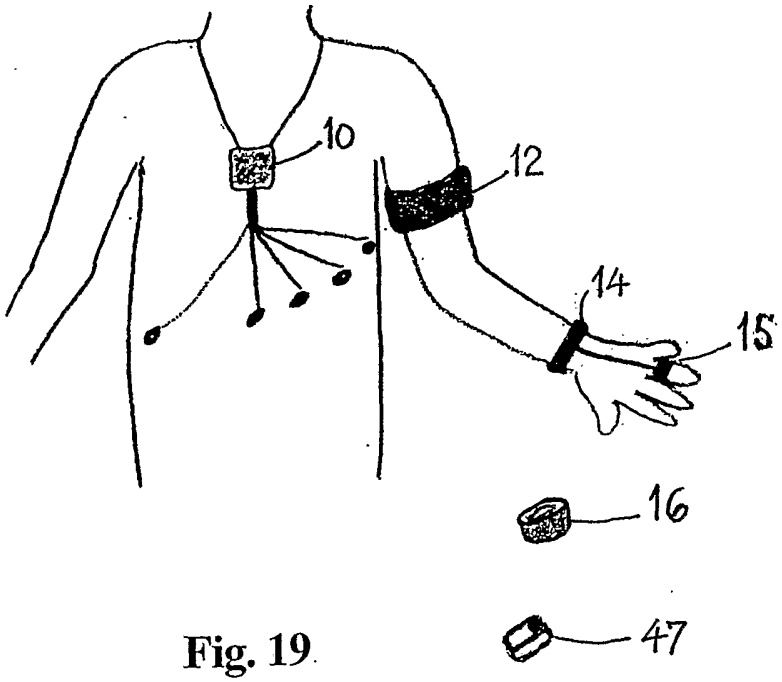
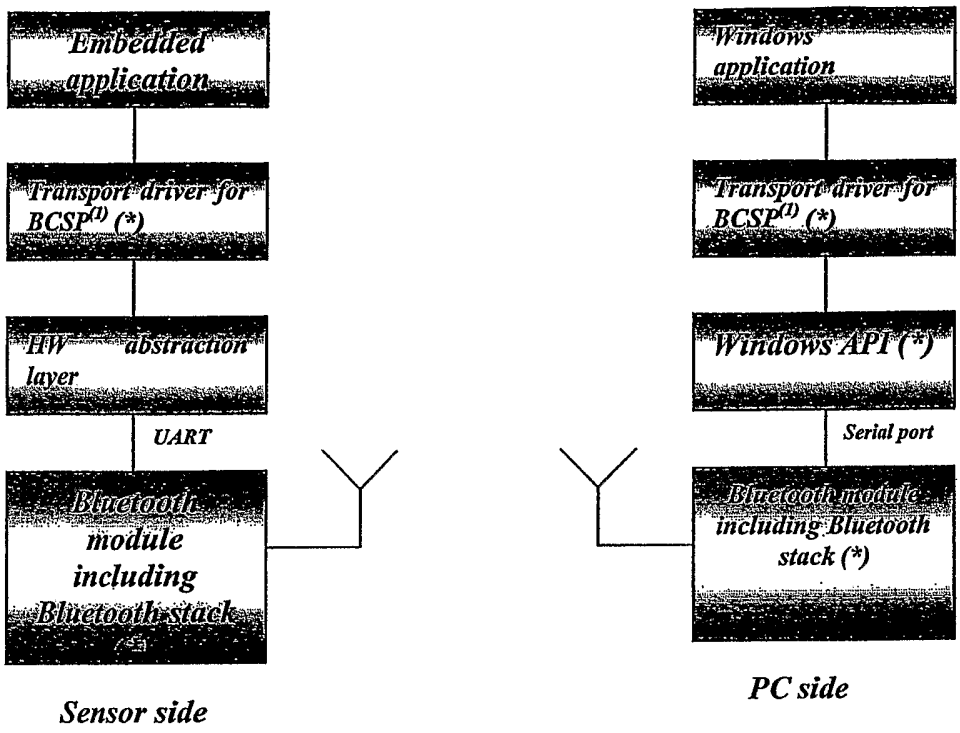
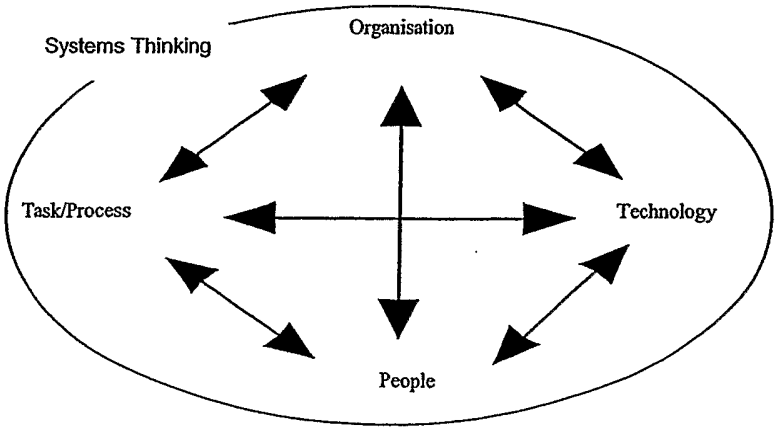


Fig. 19



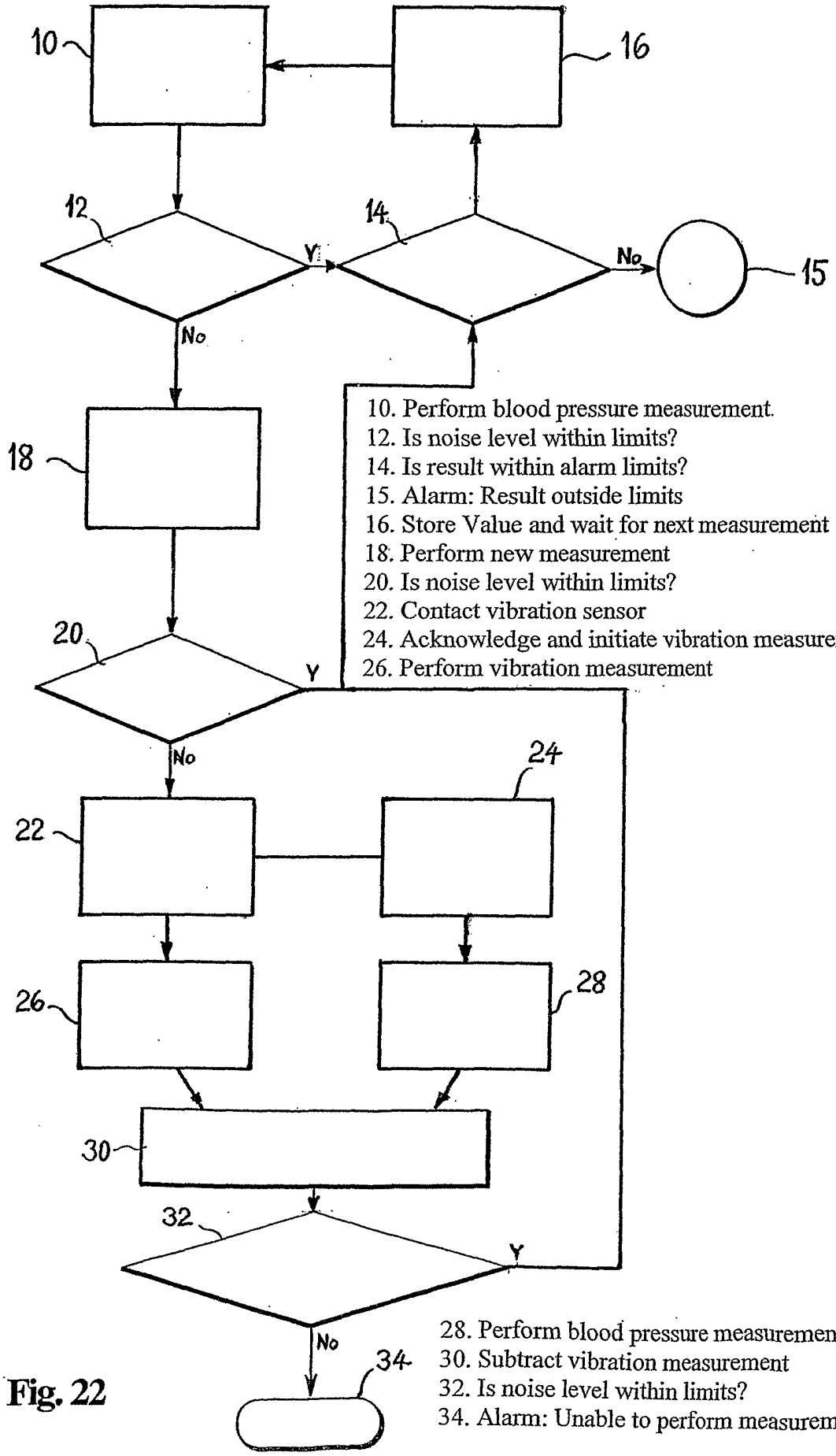
Bluetooth device architecture

Fig. 20



Leavitt's diamond

Fig. 21



10. Perform blood pressure measurement.
12. Is noise level within limits?
14. Is result within alarm limits?
15. Alarm: Result outside limits
16. Store Value and wait for next measurement
18. Perform new measurement
20. Is noise level within limits?
22. Contact vibration sensor
24. Acknowledge and initiate vibration measurement
26. Perform vibration measurement

28. Perform blood pressure measurement
30. Subtract vibration measurement
32. Is noise level within limits?
34. Alarm: Unable to perform measurement

Fig. 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 01/00465

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/00 // G06F 19/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 0197686 A1 (VOEGELI, FRIDOLIN ET AL), 27 December 2001 (27.12.01), page 10, line 8 - page 11, line 12, figure 4	1-9
	--	
X	WO 0143631 A1 (MEDTRONIC, INC), 21 June 2001 (21.06.01), page 10 - page 11; page 15, figures 1, 5	1-9
	--	

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
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"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 July 2002	09 -07- 2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk/SN Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

Information on patent family members

10/06/02

International application No.
PCT/NO 01/00465

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0197686 A1	27/12/01	AU 6418201 A	02/01/02
WO 0143631 A1	21/06/01	NONE	