

Current Status of Noninvasive Bioinstrumentation for Healthcare

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In the so-called “super-aging society,” noninvasive healthcare monitoring has been increasingly required as a possible scheme for preventive medicine, early diagnosis, and timely treatment of lifestyle-related diseases. As contributions towards the development of the most desirable aim of achieving ubiquitous healthcare monitoring, two promising systems, “ambulatory or wearable physiological monitoring” and “nonconscious physiological monitoring,” which have recently been developed through modern technological advances, are introduced in this paper. Each of these two monitoring techniques appears to have the potential to contribute to the fields of personal healthcare, medical care, and rehabilitation among others. Nevertheless, further comprehensive studies will still be required to realize this potential and thereby achieve an advanced and truly practical approach. This is also discussed in this paper.

1. Introduction

In modern society, humankind has been confronted with a variety of serious issues needing to be addressed urgently, such as increasing energy demands, environmental deterioration including global warming, and healthcare provision. Among these, the ever expanding healthcare needs are challenging and of particular importance, because maintaining good health conditions throughout the natural human life span is a fundamental requirement in most societies. It is inevitable, however, that with the passage of time, health status gradually deteriorates owing to aging. There has therefore been an increasing need to provide effective, convenient, and, in particular, noninvasive means to self-check major health conditions over a long period of time during normal daily life.

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The use of technologies with which to carry out long-term, regular, noninvasive monitoring of health conditions during normal daily life has been increasingly raised as a possible scheme for the early diagnosis and timely treatment of lifestyle-related diseases. In addition, it has been conjectured that this could help prevent, or at least control, such diseases and reduce healthcare costs. Furthermore, there are also needs to perform such health status monitoring of in- and outpatients having disorders requiring either acute life support or chronic therapies. Within this context, ubiquitous healthcare monitoring by noninvasive methods would be the most desirable.

The concept of this ubiquitous healthcare monitoring is basically to check health conditions anytime and anywhere and to manage individual physiological data obtained using, for example, a network system in a fully automated manner. In this sense, one of the most feasible methodologies would be ambulatory or wearable physiological monitoring, which means that biological sensors and/or miniaturized measuring units are to be carried by a subject or embedded into the user's clothes. Regarding this subject, brief descriptions of several recent developments by many investigators⁽¹⁻⁶⁾ and our group^(7,8) are firstly presented in this paper.

Although such ambulatory monitoring would be relatively straightforward to implement in subjects while outside their dwelling or workplace, it is not always easy to achieve continuous monitoring smoothly after returning home. As the home is a place to relax and the time spent at home is relatively long each day, another possible methodology is required. In fact, health monitoring at home is one of the hot topics in the field of biomedical engineering, a major goal of which is to enable such monitoring everyday over a long period to evaluate health conditions, as mentioned above. One widely used approach is simply to have basic healthcare devices for home use, such as a thermometer, a sphygmomanometer, and a weighing scale, to be operated by individuals themselves. This approach is, however, difficult and bothersome for individuals to continue over long periods.

A new concept has recently been proposed for monitoring physiological variables in a fully automated manner without the need either to attach any sensors to the body or for individuals to carry out any operations, simply using home facilities such as a bed, a bathtub, and a rest room.^(7,9-17) The techniques used in this approach do not disturb normal daily activities; thus, the monitoring is carried out in an unconstrained manner. Therefore, this concept would also be applicable and useful for patient monitoring in a hospital room. In this paper, outlines of such a monitoring system named "nonconscious physiological monitoring," which was developed by our group,^(7,14-17) are also briefly introduced.

2. Ambulatory/Wearable Physiological Monitoring

Within the sphere of ambulatory monitoring, the Holter-type electrocardiogram (ECG) recorder, originally proposed by Holter,⁽¹⁸⁾ and the portable sphygmomanometer called "ambulatory blood pressure monitor (ABPM)," which is based on the auscultation and/or cuff-oscillometric method,^(19,20) are widely used in clinical medicine as key devices. Modern microelectronics and mechanical technologies have enabled us to produce more

compact and convenient devices for home use. Firstly, a few attempts at monitoring vital signs including ECG are briefly described.

2.1 Recent attempts to monitor vital signs

An interesting approach to monitoring ECG using textile electrodes has been reported by Rantanen *et al.*⁽¹⁾ Just recently, Biodevices S. A. in Portugal has commercialized a wearable ECG monitor based on this concept, as shown in Fig. 1. Developing both textiles and electronic miniaturization techniques has made it possible to incorporate electrodes into a T-shirt and much smaller electronic devices that can be worn and carried for long periods of time. As an application, the authors described the design of a survival clothing prototype for arctic environments, which could achieve ECG monitoring together with communication, including an emergency message, positioning, and navigation aids for the user.

The WEALTHY project, supported by the 5th Framework Information Science and Technology (IST) Programme of the European Union, is also noteworthy. Within this project, a new concept in healthcare was proposed, whereby the subject's vital signs were monitored through a groundbreaking woven sensor that could be worn without any discomfort for the user. This fabric sensor made of smart material in fiber and yarn form and integrated into a well-fitting cloth could be endowed with a wide range of electrophysical (such as conducting and piezoresistive) properties to obtain the simultaneous recording of vital signs. Figure 2 shows a prototype of the garment monitoring system,^(2,3) which allows ECG and respiratory measurements. It is reported that such measurements provide reliable and satisfactory data as compared



Fig. 1. Wearable ECG monitoring system with textile electrodes incorporated into a T-shirt,⁽¹⁾ recently commercialized by Biodevices S. A., in Portugal [http://inventorspot.com/articles/wearable_heart_monitor_vital_jackets_fashionable_vital_monitorin_24622].

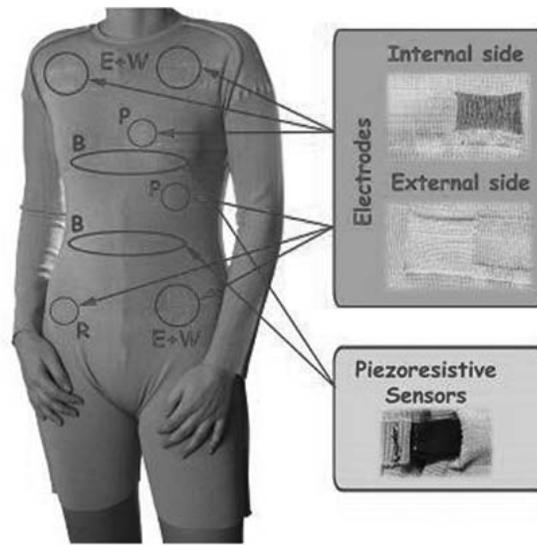


Fig. 2. Garment ECG and respiratory monitoring system with a woven sensor made of smart material in fiber and yarn form with conducting and piezoresistive properties (http://www.wealthy-ist.com/index.php?action=show_bversion). E+W, Einthoven-Wilson electrodes configuration; R, reference electrode; P, precordial leads; B, piezoresistive sensors for detecting breathing.

with a conventional standard method. The researchers of this project also state that the proposed system could assist patients during rehabilitation training or subjects working in extreme stressful environmental conditions, ensuring continuous surveillance.

In contrast to these monitoring concepts, miniaturized wireless sensor networks capable of autonomously controlled monitoring of vital signs and telecommunications for healthcare have recently been proposed.⁽⁴⁻⁶⁾ A number of miniature wireless sensors placed on the body form a wireless body area network (W-BAN) that can monitor various vital signs, providing real-time feedback to the user and medical personnel. A conceptual diagram is shown in Fig. 3,⁽⁵⁾ in which a subject carries an ECG measuring unit, a pulse oximeter (providing SpO₂), and trunk-angle and motion sensors along with a personal server to compose W-BAN using the ZigBee protocol.

2.2 Ambulatory cardiovascular hemodynamic and activity monitoring

Besides these innovative approaches described here, we have also continued developing ambulatory monitoring systems suitable for both clinical and home use, focusing particularly on the acquisition of data for the evaluation of cardiovascular hemodynamics and human activity. Following our earlier developments of ambulatory cardiovascular hemodynamic⁽²⁰⁻²⁴⁾ and activity monitoring systems,⁽²⁵⁻²⁸⁾ we have recently improved these two systems for more practical use.^(7,8) Detailed operational performance, accuracy, and reliability of the two have already been successfully demonstrated and reported in the literature.^(7,8,20-28) Brief descriptions of each system are therefore given below.

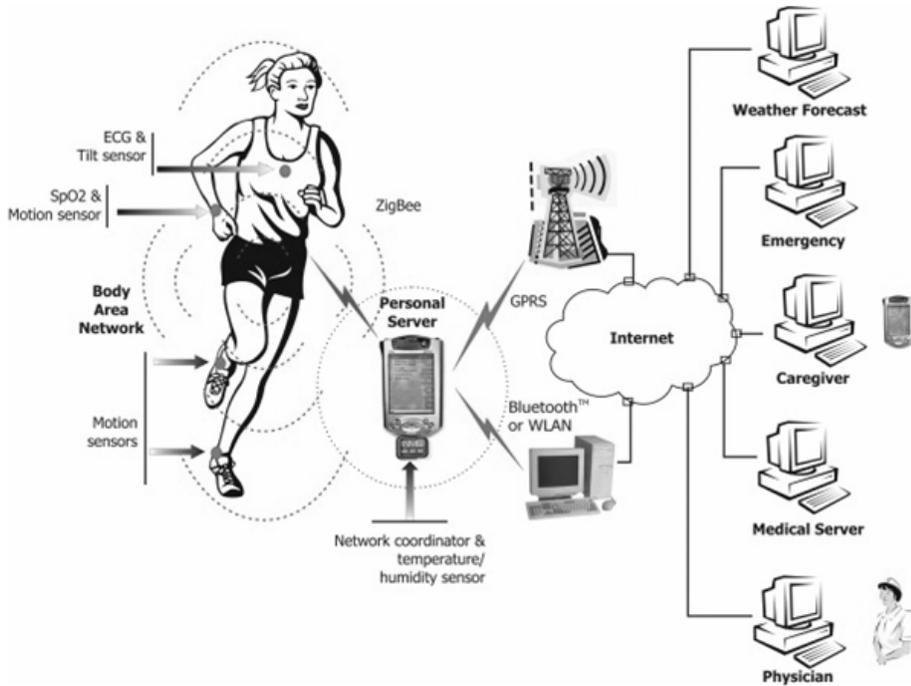


Fig. 3. Conceptual diagram showing wireless sensor network system. A user carries a number of tiny wireless vital sign sensors together with a personal server to create a wireless body area network (W-BAN) using the ZigBee protocol (from Fig. 1 in ref. 5).

2.2.1 Beat-by-beat cardiovascular hemodynamic monitoring

A conventional ABPM can measure blood pressure (BP) at a set interval of 30 min or more for convenient practical use and can thus acquire less than 48 data points per day owing to the limitations imposed by the measurement principle.^(7,20) Because there are approximately 80,000–100,000 BP data per day produced by individual cardiac beats, only about 0.05% of the complete BP data set can be obtained by ABPM. It is logically desirable to acquire BP on a beat-by-beat basis. It is furthermore apparent that the acquisition of BP and cardiac output (CO) data together on a beat-by-beat basis combined with other cardiovascular data would be much more powerful in the detailed analysis of hemodynamic responses and autonomic regulation of the cardiovascular system in response to various daily activities.

With these as a background, we have recently developed a new beat-by-beat cardiovascular hemodynamic monitoring system both for ambulatory and stationary or medical use on the basis of a technological combination of the volume compensation^(7,29) and transthoracic electrical admittance methods.^(7,20,21,23,24,30,31) Figure 4 shows an overview of the monitoring situations for the system.

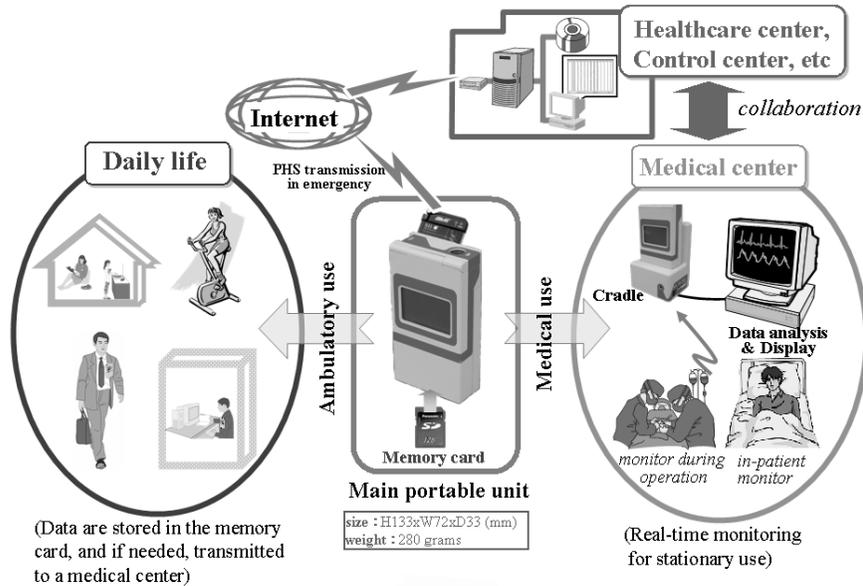


Fig. 4. Overview of beat-by-beat cardiovascular hemodynamic monitoring system both for ambulatory and stationary use. For further explanation, see text.

The essential parts of this system are (i) tetrapolar spot electrodes for CO measurement, (ii) a finger cuff unit with a photoplethysmographic sensor and a local pressurization cuff for the BP measurement, (iii) a cuff pressure controller, (iv) a main portable unit, (v) a cradle, and (vi) a conventional personal computer for data analysis and display. For ambulatory use, the subject carries the portable unit ($133 \times 72 \times 33 \text{ mm}^3$; 280 grams including the battery) in a breast pocket together with the necessary sensors for the CO and BP measurements and the collected data are stored in a memory card. During operation, BP is compensated for the individual's heart level by measuring the hydrostatic pressure difference between the measuring site and the heart. For stationary or medical use, the portable unit housed in its cradle is connected to the computer for real-time monitoring of data as a time series during situations such as surgical operation and cases in intensive care unit (ICU) and coronary care unit (CCU) in a medical center.

The portable unit has eight functions: (1) BP measurement, (2) CO measurement, (3) signal processing and control of each measurement using a microprocessor unit, (4) data storage using a memory device, (5) data display using an LCD, (6) interactive communication between the unit and the cradle using a serial interface, (7) data transmission using a mobile phone system (PHS) for emergency situations, and (8) power supply using a lithium-ion rechargeable battery that is capable of continuous use for more than 6 h at present.

In the case of ambulatory use, the data stored in the portable unit are retrieved by the personal computer and an appropriate analysis is carried out to display the resultant

cardiovascular variables. The following 13 variables are processed on a beat-by-beat basis: systolic (SBP), mean (MBP) and diastolic BP (DBP), ECG R-R interval (RR), instantaneous heart rate (HR), stroke volume (SV), cardiac output (CO), pre-ejection period (PEP) as an index of sympathetic activity, ventricular ejection time (Ts), pulse transit time (PTT), peripheral vascular resistance (TPR), rate pressure product (RPP) as an index of cardiac oxygen consumption, and respiration rate (Resp). Using the derived data, the computer can then show the 13 processed variables on the display.

Figure 5 is an example of a 6-hour trend chart, showing 7 of 13 hemodynamic parameters, RR, BP (SBP/MBP/DBP), SV, CO and TPR, obtained in a healthy male subject (22 yrs) during a part of his normal daily activities (from 10:00 to 16:00 h). He was instructed to move freely and perform various normal activities, such as walking, desk work, exercise, and postural changes from sitting to standing for example, as indicated in the uppermost part of this figure. It is clearly observed that the increases in BP and CO during bicycle riding, as well as the fluctuations in each of the parameters produced by postural changes such as sit-to-stand motion, sit-to-stand motion, and so on, demonstrate the dynamic changes in chosen parameters in response to various activities.

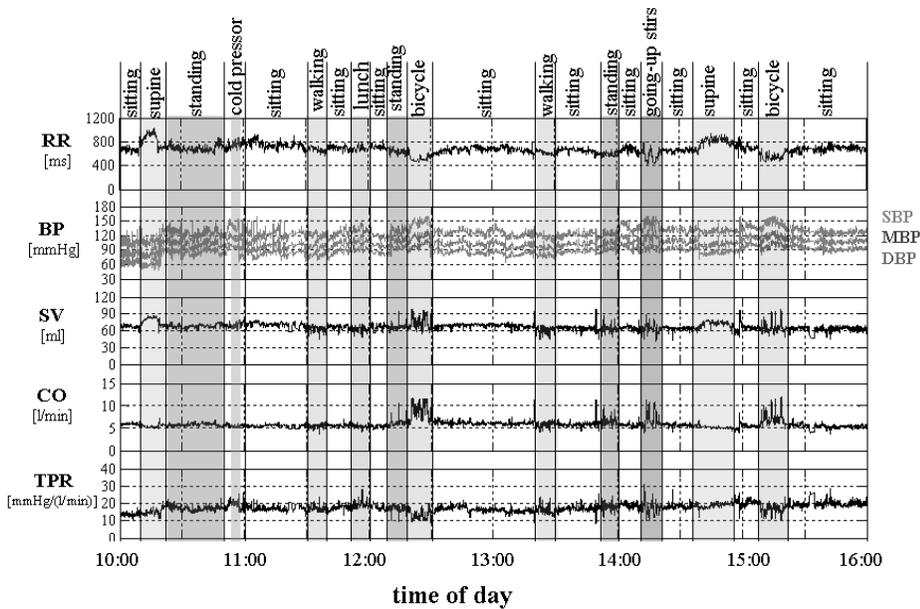


Fig. 5. Example of 6-hour trend chart, showing hemodynamic parameters ECG R-R interval (RR), blood pressure (BP; systolic (SBP), mean (MBP) and diastolic BP (DBP)), stroke volume (SV), cardiac output (CO) and total peripheral resistance (TPR) obtained in a healthy male subject (22 yrs) during a certain time of the day (from 10:00 to 16:00). Various activities are indicated in the uppermost part of this figure.

2.2.2 Human posture and activity monitoring

The importance of ambulatory activity monitoring is well recognized in the fields of gerontology, rehabilitation, and general healthcare. In the field of gerontology, for example, one of the key aims in the care of the elderly is to maintain their daily activities at an appropriately high level and to particularly prevent their becoming bedridden.⁽³²⁾ In the rehabilitation field, a therapist must evaluate motion characteristics during standing up and walking among others; however, it is very much a situation in which he/she must usually make assessments subjectively by direct observation. Therefore, the quantitative assessment of activities is highly desirable. One method employed is to record using a three-dimensional motion capture system, but the range over which such recording is possible is usually limited and data analysis is complicated, rendering this system unsuitable for use in practical rehabilitation.

Some wearable instruments capable of monitoring activities using an accelerometer, a gyrosensor and so on have been developed.^(33–38) Such wearable systems have not yet become practical in the rehabilitation field owing mainly to awkward and unsuitable means for the physically challenged or the elderly. With the aim of improving the quality of life for these persons, we have developed a portable and handy device for monitoring postural changes and activities by measuring the trunk, thigh, and calf angles with respect to the gravitational direction.^(25–28) This device has recently been improved to make it more convenient for rehabilitation training as well as for collecting a daily record of activity scenarios.⁽⁸⁾

The principle of the measurement of posture together with walking speed is quite simple, as shown respectively in the left and the right panels of Fig. 6. If we can measure the angles of three anatomical parts, such as the trunk, thigh, and calf, with respect to the gravitational direction, we can discriminate almost all the human postures in the sagittal plane, which are possible under normal daily life. Using the thigh (θ_{21} and θ_{22}) and calf angles (θ_{31} and θ_{32}) at ‘heel contact’ and ‘off’ together with the subject’s thigh (L_1) and calf length (L_2), the length of one stride (D_e) can be calculated using the two-link gait model. Therefore, the walking speed (V_e) for one walking cycle can also be calculated from D_e divided by the time of one step (T_e). The accuracy of the walking speed thus obtained has been shown to be highly precise over a wide range from 0.5 m/s or less (relatively slow pace of physically challenged or elderly people) to 2.0 m/s or more (considerably quick pace of healthy subjects) as compared with a video camera system.^(27,28)

In Fig. 7, an overview of the wearable sensor system is shown. The accelerometer, gyrosensor, amplifier, micro-SD card, transmitter, battery, CPU, and other parts are installed in each of the sensor units, and the units are attached onto the subject’s trunk, thigh, and calf. The subject’s motion when in the medical center is monitored in real time using a telemetering system such as a W-BAN, and the activity data collected during normal daily living is saved on the micro-SD card.

The system can discriminate among postures, from walking, sitting, lying down, standing up, sitting down, and standing on the basis of the angle changes in the sagittal plane calculated from the low-frequency signals (DC, 0.5 Hz) of the accelerometers attached to each part. In the static postures of standing, sitting, and lying down, the angle

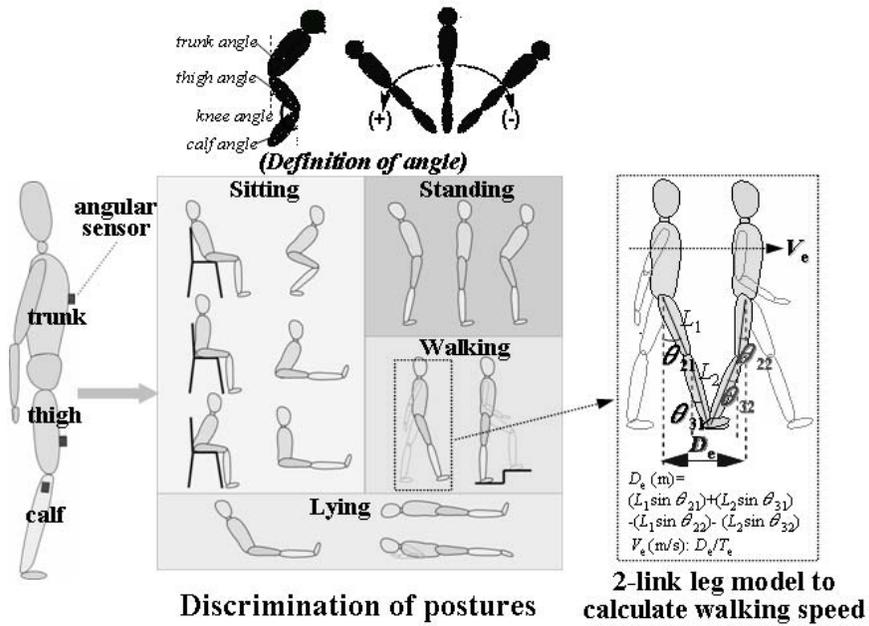


Fig. 6. Principles of determination of posture in sagittal plane by measuring trunk, thigh and calf angles with respect to gravitational direction (left panel), and walking speed for two-link leg model (right panel). The uppermost part shows the definition of angle for each anatomical segment. See text for explanation.

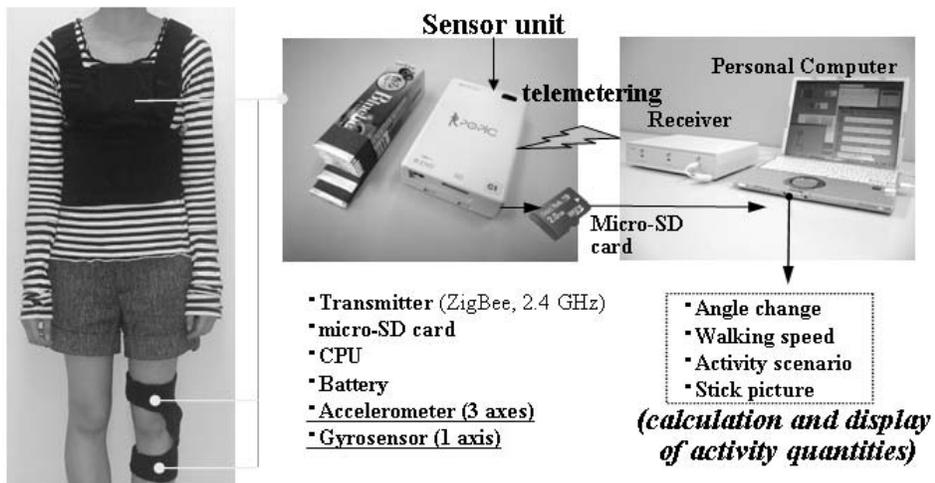


Fig. 7. Overview of wearable sensor system: Photos of user wearing sensor units in jacket pocket and knee support (left part), sensor unit (middle), and receiver together with personal computer (right).

of each part with respect to the gravitational direction is obtained from the low-frequency signals from the accelerometers. Additionally, to calculate the angular changes in the trunk, thigh, and calf during dynamic situations such as walking, the angular velocity outputs of the gyrosensors attached to each part are integrated. The initial angle is obtained from the accelerometer signal immediately before walking.

From the angular changes, activity scenarios are displayed as color bars (standing, walking, sitting, lying down, standing up, and sitting down) using the conventional personal computer. Detailed angular changes, walking speed, and motion pictures can also be displayed by clicking the bar of an activity scenario.

Figure 8 shows typical data of an activity scenario, thigh angle changes and walking speed during each walking cycle, with the associated stick pictures during six postures in a female subject with hemiplegia (84 yrs). It is clearly observed that although the subject was mostly living in either sitting or lying position, the cyclic angular changes and stable increase and decrease in walking speed can be detected during walking. The stick pictures derived from the angular changes of the trunk, thigh, and calf can also provide useful details of posture.

To investigate the system's applicability to patient activity monitoring in rehabilitation programs, we have successfully carried out clinical studies at some rehabilitation centers.^(8,27,28) Through experiments in various situations including those in daily life, the system has been found to be promising for the quantitative evaluation of the efficacy of rehabilitation programs as well as human daily activities. As a future prospect, it is moreover desirable to obtain motion information with six degrees of freedom, and this will be realized by the use of a triaxial gyrosensor into the sensor unit.

3. Nonconscious Healthcare Monitoring at Home

As mentioned in the Introduction section, we have recently developed a home healthcare monitoring system on the basis of the new concept of "nonconscious physiological monitoring." This involves a procedure carried out in a fully automated manner without the attachment of any biological sensors to a subject's body or any troublesome operations of measurement. To achieve such monitoring, all sensors and instruments are built into home facilities, such as the toilet, bathtub, and bed, which are used in normal daily life. Thus, the subject does not need to be aware of the measurement being made, and the physiological data collected and stored are truly representative of ordinary daily living.

The daily use of the toilet by the subjects provides convenient opportunities for monitoring. We have developed a body and excretion weight monitor based on a highly accurate weighing scale device installed in the lavatory floor around the toilet bowl. Also, we have installed a BP monitoring system into the toilet seat.^(7,14,15) For monitoring cardiac pulse and respiration, we have used vinyl tubes filled with silicone oil under a pillow.⁽¹⁶⁾ For the care of the elderly, there is an important need for a drowning alarm in the bathtub, and we have designed a bathtub monitoring system capable of simultaneously detecting ECG together with respiration in the bathtub.⁽¹⁷⁾

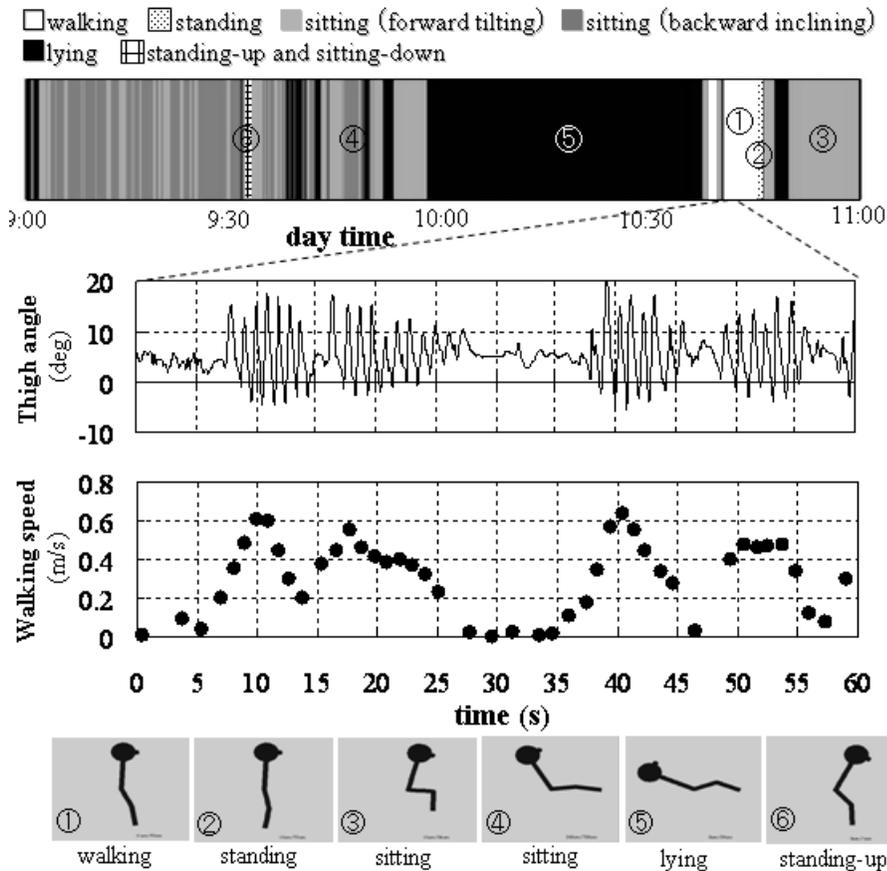


Fig. 8. Typical recordings obtained from a female subject with hemiplegia (84 yrs), showing activity scenarios from 9:00 to 11:00 a.m. (top panel), thigh angle change and walking speed during each walking cycle for a period of 60 s indicated by two dashed lines (middle part), and postural stick pictures (lowest panel), the numbers in which correspond to those in the scenario record. Various activities are indicated in the upper part of the scenario record.

To realize the whole concept, we have developed a new prototype healthcare monitoring room in which the systems for bathtub, toilet, and under-pillow monitoring are installed. We have evaluated the measurement accuracy and validity of these devices by simultaneous recordings of standard biological sensors directly attached to the subjects' body surface, and the results indicate that the new monitors do indeed allow accurate and reliable measurements.^(7,14-17)

Figure 9 shows an overview of the prototype healthcare monitoring room, which has been constructed in a part of our laboratory in Kanazawa University. All the sensors and instruments are installed in the toilet space, the bathtub, and the bed. The obtained

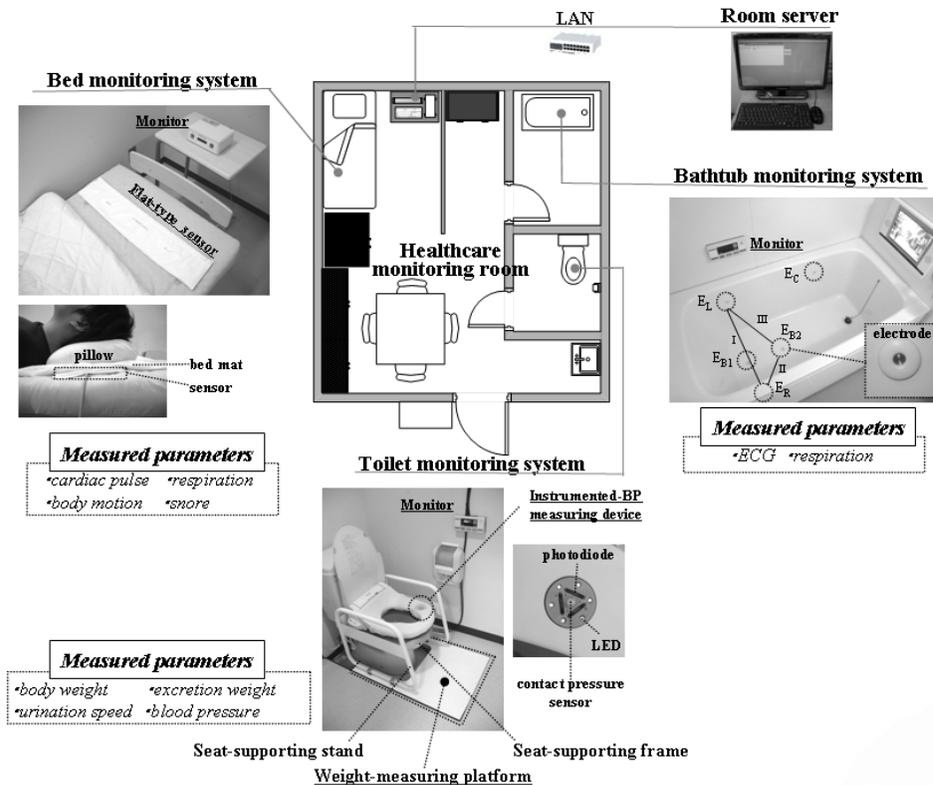


Fig. 9. Overview of prototype healthcare monitoring room constructed in a part of the author's laboratory in Kanazawa University. All the sensors and instruments are installed in the toilet space, bathtub, and bed. Measured parameters are shown for each system.

data are automatically analyzed and displayed using a monitoring system equipped with amplifiers for the sensors, a computer, memory, an LCD, and a LAN module. Analytical results from each sensor are stored and displayed using the room server.

In the toilet space, a platform-type scale with a weighing resolution of 5 grams is placed around the toilet bowl and is arranged to support the toilet seat using a frame. With this arrangement, the scale can accurately detect the total body weight before and after excretion, thereby obtaining excreta weight by subtracting body weight.

BP measurement is achieved using the volume-oscillometric principle, previously proposed by us.^(7,20,21,23,39) A pusher plate is installed in the toilet seat, which applies local pressure against the back of one thigh pushed up by a pantagraph mechanism. The photoplethysmogram in the perforating arteries of the thigh is measured using six high-luminance near-infrared LEDs and three high-sensitive photodiodes affixed to the plate, which also houses a contact pressure sensor for measuring the pressure applied to the back of the thigh.

In the bed, a flat sensor ($800 \times 15 \times 8 \text{ mm}^3$) is fixed under a pillow or a bed mat. It comprises four vinyl tubes filled with silicone oil sandwiched by two acrylic plates,⁽¹⁷⁾ the width of which is aligned along a bed side. One end of each tube is connected to a pressure sensor and the other end is closed. The inner pressure in each tube changes in accordance with respiration, cardiac beating, and snoring, and each component can be detected using an appropriate digital filter. Moreover, periods of apnea and hypopnea can be detected from the decrease in amplitude of the respiration signal for more than 10 s, which is based on the definition of sleep apnea syndrome (SAS), using a fully automated analytical program. The DC level of the pressure output can provide information on whether the subject is lying on the bed.

For ECG monitoring in the bath, four stainless steel electrodes are fixed to the inner wall of the bathtub essentially surrounding the subject's chest, so as to place them in the standard Einthoven's triangle configuration. One of the four electrodes is used as the reference electrode placed far from the other three electrodes. The potential differences between two electrodes, similar to the conventional lead-I, lead-II, and lead-III, are amplified to obtain a raw ECG signal. This signal contains a baseline fluctuation due to respiration, and thus, can be filtered with a digital filter, obtaining a clear ECG and a respiration component.⁽¹²⁾ The fluctuations of R-R intervals in accordance with respiratory sinus arrhythmia are also used for the detection of the respiratory component.⁽¹⁷⁾

Figure 10 shows examples of recordings of the changes in body weight during urination (a) and those in BP measurement (b) using the toilet-installed monitoring system in a healthy male subject (25 yrs). Usually, after standing on the platform or sitting on the toilet seat, very large artifact signals due to body movements are observed immediately before and after urination (or defecation). These components are reduced due to less motion during urination (or defecation); therefore, the system can detect the body weights at the start and end of excretion, and thus, excretion weight can be obtained from the difference between the two body weights. Furthermore, the other components, i.e., ballistocardiogram (BCG) in association with cardiac beats, are observed superimposed on the weight change signal, as shown in Fig. 10(a). The rate of urination is obtained from the weight change signal smoothed by an appropriate filter, obtaining urination flow rate.

It is also noted that the initial phase of a BCG signal originates from the ejecting blood flow from the ventricle,^(40,41) i.e., differentiation of the ventricular volume change. Therefore, stroke volume (SV) and thus cardiac output ($\text{CO} = \text{SV} \times (\text{heart rate})$) could be estimated from BCG signals together with BP as obtained below.⁽⁴¹⁾

In Fig. 10(b), the simultaneously obtained records of the pulsatile component of the photoplethysmogram (PGac) are shown with the applied contact pressure for BP measurement. The pressure measurement reference is compensated for the subject's heart level by the hydrostatic pressure difference between the measuring site and the heart. According to the volume-oscillometric method,⁽³⁹⁾ the systolic (SBP) and the mean BP (MBP) can be indirectly determined from the applied pressure corresponding respectively to the systolic end point and the maximum amplitude point of PGac.

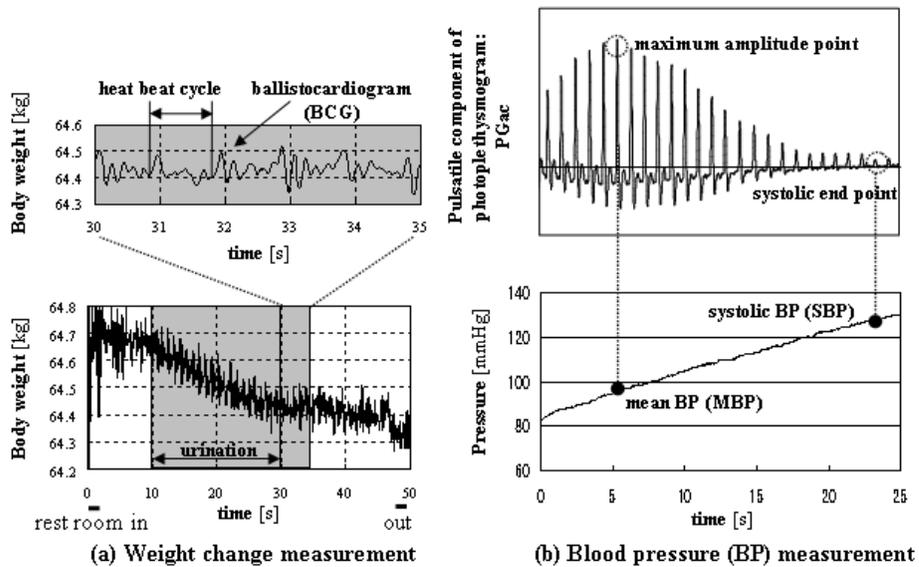


Fig. 10 Example of recordings using the toilet-installed monitoring system obtained from a healthy male subject (25 yrs). In (a), the signals for body weight (BW) change following urination and the ballistocardiogram (BCG) superimposed on the BW signals (upper part) are shown. (b) shows the simultaneous records of the pulsatile component of the photoplethysmogram (PGac) and the applied contact pressure for the measurement of blood pressure (BP). By the volume-oscillometric method, systolic (SBP) and mean BP (MBP) can be indirectly determined from applied pressure corresponding respectively to the systolic end point and the maximum amplitude point of PGac.

The upper two records in Fig. 11 show an example of respiration signals obtained by the bathtub electrodes (upper panel) and a chest band (lower panel) before and immediately after simulated drowning with the head bent forward in a healthy male subject (24 yrs). In the lower two records are shown ECG signals obtained by the bathtub electrodes (upper panel) and ECG electrodes directly attached to the subject's body surface (lower panel) during a part of drowning indicated by a shadow in the upper records. It is clearly observed that the respiration and ECG signals detected by the two methods agree well with each other, and that the ECG signals continue to be observed but no respiration signals can be obtained during the simulated drowning.

In the upper two records of Fig. 12 are shown respiration signals using the under-pillow sensor (upper panel) and a respiration chest band (lower panel) before and immediately after a period of simulated apnea obtained in a healthy male subject (25 yrs) in the supine position. The lower two records, which are the shadow part in the upper records of Fig. 12, show the cardiac pulse signal obtained by the under-pillow sensor (upper panel) and the ECG signal detected from the ECG electrodes directly attached to the body surface (lower panel). From these results, it is demonstrated that the respiration

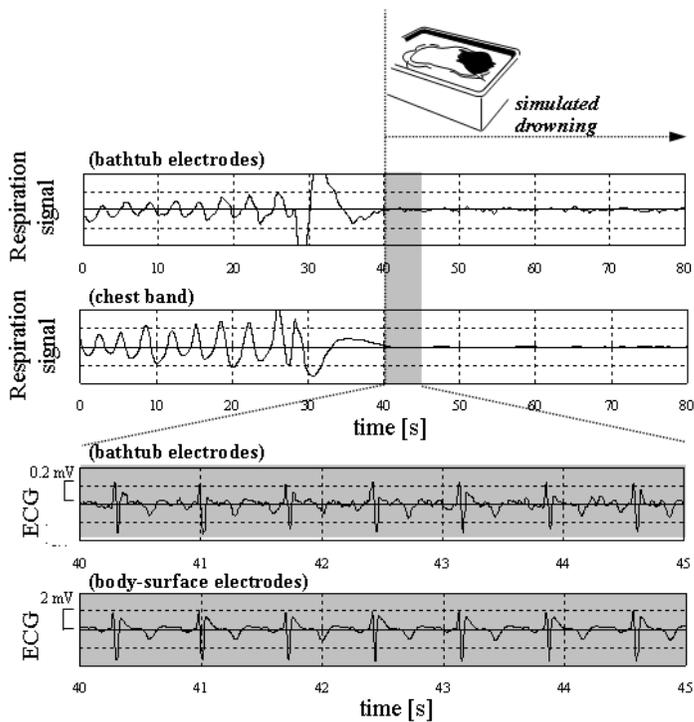


Fig. 11. Example of respiration signals (upper part) obtained by the bathtub electrodes (upper record) and a chest band (lower record) before and immediately after simulated drowning with the head bent forward in a healthy male subject (24 yrs). In the lower two records are shown ECG signals obtained by the bathtub electrodes (upper panel) and ECG electrodes directly attached to the subject's body surface (lower panel) during a part of drowning indicated by a shadow in the upper records.

and cardiac pulse signals obtained from the under-pillow sensor coincide well with those obtained from the body attachment sensors, and the period of apnea could also be definitely observed in respiration signals.

To investigate the applicability of this mode of health status monitoring in subjects with established clinical conditions, we have further developed the system to produce a new fully automated monitoring system, combining all the monitoring devices, and installed this in hospital rooms in Imizu City Hospital and Fujimoto Hayasuzu Hospital.⁽⁴²⁾ To date, we have found that the system is suitable for checking the health status of patients with chronic diseases, such as cardiac infarction and SAS, and that this monitoring appears superior to the conventional approach in the sense that it places less strain on the patient because there is no attachment of biological sensors. Further important data including the validity as well as clinical usefulness of the system have been reported.^(42,43)

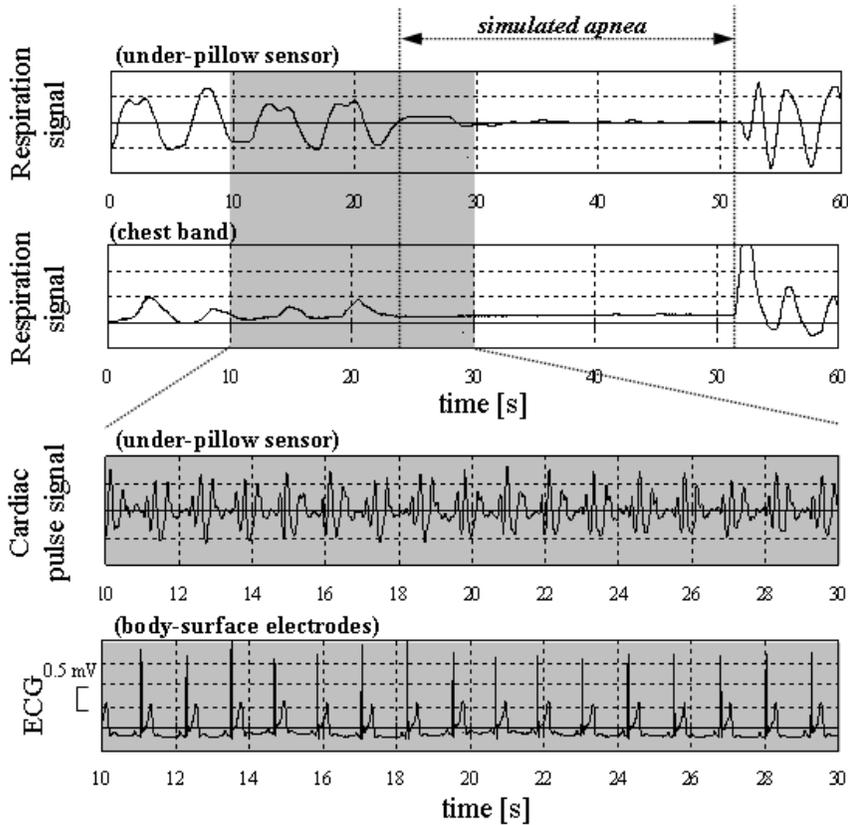


Fig. 12. Example of respiration signals (upper part) obtained by the under-pillow sensor (upper record) and a respiration chest band (lower record) before and immediately after a period of simulated apnea in a healthy male subject (25 yrs) in the supine position. In the lower part of this figure are shown cardiac pulse signal obtained by the under-pillow sensor (upper record) and ECG signal detected from the body surface electrodes (lower record) during a certain time indicated by a shadow in the upper part.

4. Summary and Future Developments

Recent developments and the present status of noninvasive bioinstrumentation for healthcare were briefly introduced in this review, including in particular the developments we have achieved. There are at present two research approaches in terms of monitoring techniques; one is ambulatory or wearable physiological monitoring and the other is nonconscious physiological monitoring. In light of the growth of the aging society, which has created what might be regarded as a longevity crisis, healthcare is one of the most serious and worldwide issues to address. Simple, convenient, and truly

ubiquitous healthcare monitoring in a fully automated as well as in a noninvasive manner could be the most useful and desirable.

The two research approaches described in this paper appear innovative and groundbreaking, particularly in the developments of instrumented garment systems and W-BAN with miniaturized sensors. It is optimistically anticipated that such easy-to-use devices could be made available at reasonable costs in the future, although there are still a number of challenging obstacles to be overcome, such as the rather conflicting requirements for size, wear comfort, operating procedures, precision, power management, and reliability.⁽¹⁻⁶⁾ Another problem is the fact that at present such devices only provide a limited range of physiological information derived from ECG, respiration, and simple motion signals. Given this situation, the ambulatory cardiovascular and activity monitoring devices described here would be even more suitable for practical use through further miniaturization, making them smaller and lighter with easier and more comfortable attachment to the body.

The approach described here for achieving nonconscious physiological monitoring at home would appear at the present time to be a near ideal solution, with good potential for practical use. The justification for this view is as follows. The individuals who might benefit from regular health assessment generally find using commercially available medical devices such as a BP monitor and a weighing scale quite troublesome or find it difficult to monitor their health conditions daily over a long period because these devices need the attachment of a biological sensor and manual operation for measurements. This inconvenience obstructs and deters long-term daily monitoring. In the nonconscious monitoring approach, however, the location of the systems in the toilet space, bathtub, and bed is considered to be very convenient and appropriate, because a subject at home uses these places everyday and reliable measurements can therefore be made within this stable and predictable situation.

It is therefore a fact that the nonconscious monitoring approach has made technological breakthroughs in achieving easier and more convenient acquisition of various physiological parameters at home. There are, however, still important practical issues to be solved in terms of interpretation methodology of a huge number of data and protection of personal information.

Taking a comparison of these ambulatory and nonconscious monitoring approaches into consideration, it is noted that, by addressing various issues mentioned above to complement both techniques, each approach will be practically available in a parallel way and the combination of these two will provide a much more useful and promising means.

In the so-called 'super-aging society,' these techniques could be relevant, contributing in many fields such as personal healthcare, medical care, and rehabilitation. To promote ubiquitous healthcare monitoring further, the establishment of appropriate social infrastructure that meets the needs of healthcare is urgently needed. Efforts to produce much more human-friendly sensing systems, where a number of practical problems still remain, are likely to be resolved through the considerable recent dramatic advances in microelectronic, micromechanical, information, and communication technologies.

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