17

Physiological monitoring

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Importance of physiological measurements in clinical medicine

The development of modern medicine has been characterised by the increasing application of scientific methods in the clinical setting. Following the defeat of most infectious disease by antibiotics, and the improvement in public health associated with improved housing, nutrition and education, the major challenges of modern medicine are now those associated with iatrogenic illness, chronic degenerative disease of major organ systems and those insidious slowly developing diseases associated with lifestyle habits such as smoking and excessive consumption of alcohol or with occupational hazards and environmental pollution.

As measurement is the essence of the scientific method it is not surprising that physiological instrumentation, measurement and monitoring has grown into an international multi-billion dollar industry dominated by a number of multinational industries such as Hewlett Packard and Siemens which for hospital based patient monitoring alone is approximately $US1.7 billion world wide (1992 figures).

It is also clear that future developments in clinical medicine and primary health care will depend ever more on sophisticated monitoring systems which will evolve out of the emerging technologies of semiconductor sensors, medical imaging, medical expert systems, micro-miniaturisation of computing power, advanced wireless communications and world-wide networking for access to clinical and epidemiological information. In this chapter we review the basis of physiological monitoring with reference both to a generalised instrumentation system and to applications in cardiology and hospital based intensive and coronary care.

General properties of medical instrumentation systems

Most instruments share a number of common characteristics. They all need signal conditioning to eliminate unwanted signals, computing power for control and analysis, display and hardcopy devices for output and memory for storage. Medical instruments essentially differ from other scientific instruments because of the source of the signal or the area of application, which is living tissue. This fundamental difference however imposes on the medical instrument industry the requirements for standards of safety, performance and quality only matched by the aerospace industry in cost and complexity. In physiological monitoring the measurand is usually an accessible signal or quantity generated by an organ system, derived from a tissue sample or elaborated from some associated physical property. Of these, biopotentials originating from neural or neuromuscular activity and measurements of temperature, pressure, flow, displacement, impedance and chemical composition are the most important. Some examples of physiological measurands include;

- electrocardiography (ECG)
- electromyography (emg)
- electroenchepalography (eeg)
- phonocardiography (pcg)
- blood pressure
- blood flow
- respiratory flows, pressures and volumes
- blood gases, P_{O2}, P_{CO2}
- blood pH

Many different techniques have been developed to measure these variables. Some measurements depend on the use of external electrodes. Others such as X-ray, ultrasound, and electromagnetic or doppler flowmeters depend on the application of external energy, whilst others require the collection of gas, liquid or tissue samples and the use of biochemical methods for the analysis of chemical composition and concentration.

The nature of the measurement and the range of its frequency content are major factors which influence the design of an instrument. Thus some variables change very slowly and may have a 24 hour circadian rhythm, others such as the ECG contain frequencies of clinical interest to approximately 300Hz, whilst emg and nerve potentials have bandwidths extending to 3-10kHz. Biopotentials are in the microvolt range and pressures are in the range of 0-300mmHg.

Physiological signals may be affected by ambient and generated noise, dependence on other variables such as temperature, humidity and pH or by perturbations caused by emotional or physical arousal. All of these factors must be considered, and impose significant practical constraints on the design of medical instruments. Essential elements of a modern physiological instrument are shown in Figure 17.1.

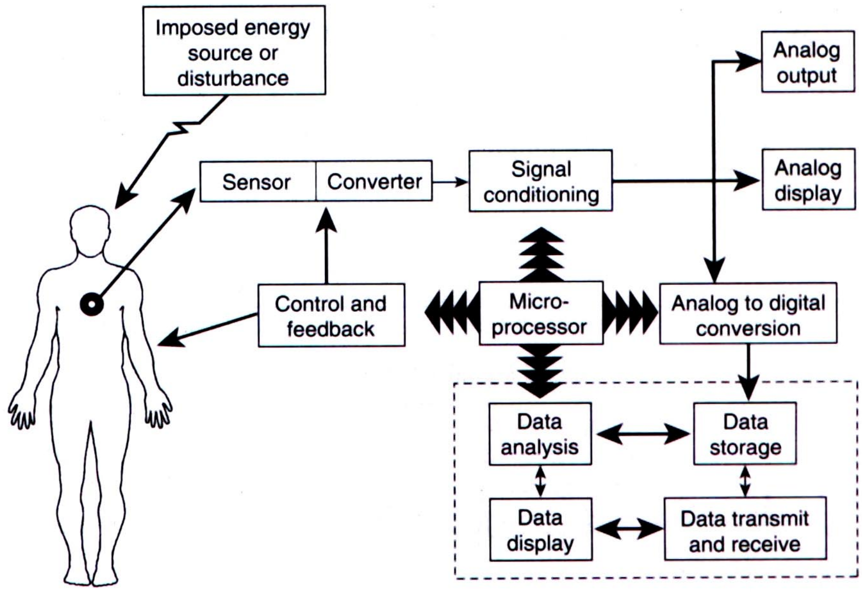

Figure 17.1 Essential elements of a modern medical instrument for the measurement of physiological parameters

The sensor converts a physical quantity, such as flow or pressure to an electrical quantity. Sensors should be minimally invasive and should respond only to the desired measurand whilst providing minimum interference with the process being measured. An air flow sensor which provides an excessive resistance to flow could itself for example, influence the measurand. Microelectronic sensors, using the chemical and mechanical properties of semiconductor materials, and manufactured using microelectronic technology, are now revolutionizing the industry because of their low cost, reliability and improved performance. Other sensors based on ion selective field effect transistors are now beginning to appear for the measurement of pH and gas and chemical composition. These will have profound effects as sensor elements in complex feedback control systems such as those required in metabolic demand driven cardiac pacemakers which can automatically change their rate in response to changes in pH or arterio-venous oxygen differences following increased physical activity.

Although sensors provide the primary sensing element, for example the displacement of a diaphragm by an increase in pressure, the conversion of this displacement to an electrical signal usually requires an externally powered conversion element, such as a strain gauge and bridge circuit. For biopotential recordings such as the ECG, currents carried by ions in tissue are transformed into electrical currents by electrochemical reactions taking place in surface electrodes. The design of innovative, reliable, accurate and robust transducers thus underpins the science of physiological monitoring and measurement.

Transducers rarely have the inherent properties necessary for accurate and reliable operation. Signal conditioning is required to transform the signal produced by the transducer into a signal with reproducible stable properties and specified static and dynamic characteristics. These include adequate gain, insensitivity to external noise, a suitable frequency response, low inherent noise, good linearity and stability over time, and relative insensitivity to temperature or other environmental variables.

As an example, conditioning required for an ECG signal recorded with surface electrodes, would require amplification of approximately 1000 fold, elimination of unwanted noise frequencies produced by respiration or other skeletal muscle activity, and cancellation of mains frequency noise. The transformation of an unprocessed ECG signal, by signal conditioning techniques is shown in Figure 17.2.

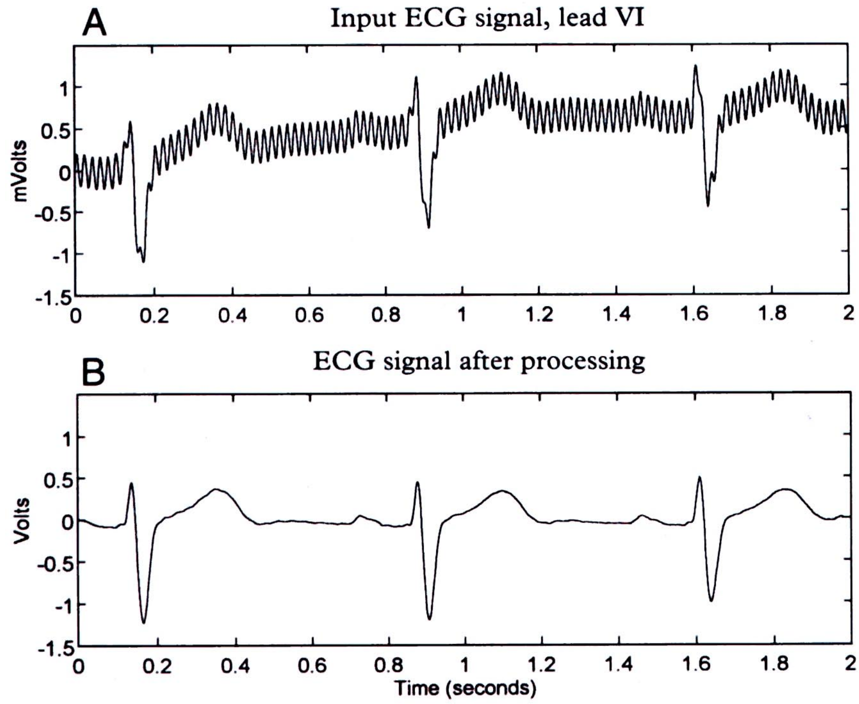

Figure 17.2 (a) An ECG signal corrupted with main frequency noise and respiratory artefacts. (b) The same signal as in (a) amplified 1000 times and digitally filtered.

Signal conditioning in modern instruments is usually a combination of analogue processing at the signal source and digital filtering after the signal has been converted from a continuous (analogue) signal to a discrete (digital) signal. Following signal conditioning and filtering the analogue signal may be displayed on an oscilloscope or chart recorder, or directed through a loud speaker or other means depending on the particular nature of the measurand and its source. A calibration signal may be required for purposes of calibration and testing. This should have the same properties as the measurand and should be applied as close to the input signal source as possible. A signal of precise magnitude (2mV peak to peak) and known frequency (10Hz) for example can be used to calibrate an electrocardiograph.

Control and feedback may be required to adjust properties of the sensor or the signal conditioner, and to manage the flow of information for display, storage or transmission. These functions may be manual or automatic, but increasingly microprocessors are incorporated to carry out these and other functions. Thus once operator choices are made, control of the instrument and of data acquisition proceeds automatically, and data is collected, displayed and output in analogue form to a video display or chart recorder.

In most modern instruments, analogue (continuous) data is sampled electronically at an appropriate rate, typically 4-10 times the highest frequency content of the signal, and converted to discrete (digital) values which can be read and stored electronically. Control of this conversion process, acquisition of data, digital signal processing and analysis, storage, display, and transmission are all under the control of a microprocessor, which may be the

Central Processing Unit (CPU) of a host computer or embedded in the instrument as a standalone unit.

The digital mode of operation has many advantages. These include greater accuracy, repeatability, reliability and immunity to noise. Digital displays have largely replaced analogue displays because of low cost and greater flexibility in mixing text data and signal data. Analogue displays may however be preferred in situations where data is changing rapidly, or real-time display cannot be easily achieved.

The reader is encouraged to refer to texts edited by Webster (1988, 1992), for further reading in this area.

Performance standards and measures

As many clinical measurements rely upon empirical interpretation or the comparison of a result with statistically normal values, there is a requirement that electromedical equipment from different manufacturers adhere to minimum performance specifications. Standards are usually set by industry bodies or by professional associations such as the American Heart Association (AHA), the Association for the Advancement of Medical Instrumentation (AAMI), the Americal National Standards Institute (ANSI), and the International Electrotechnical Commission (IEC). Local national bodies such as the Federal Drug Administration in the USA and the Therapeutic Goods Administration (TGA) in Australia are usually required to certify that specific instruments meet a required standard. Although there may be significant differences in standards originating from the USA or Europe, there is now an increasing tendency to standardise requirements and to develop joint guidelines.

As an example, Table 17.1 summarises the performance standards (AAMI/ANSI) that apply to electrocardiography.

Table 17.1 ANSI-AAMI EC11-1991 Performance requirements for an electrocardiograph

Input dynamic range	±5mV signal and tolerance for dc offsets of ±300mV
Gain accuracy	±5% for fixed gain selections of 20mm/mV, 10mm/mV and 5mm/mV
System error.	For input signals limited to ±5mv and maximum rate of change of 125mV/sec, the maximum error permitted is ±10%.
Frequency response	Characterised relative to the response at 10Hz of a number of test signals. AHA recommends a bandwidth of 0.05Hz to 100Hz (+0.5dB, -3dB).
Step response.	The device should respond to a step of 10mm, with an allowable overshoot of 10% and a decay time constant ≥3 sec when measured during the first 320ms.
Input impedance	A single ended input impedance of at least 2MΩ at 10Hz is required.
Direct currents	0.2mA in all patient electrode connections
CMRR at 50/60Hz	Common mode noise rejection (CMRR) must be -90dB (1:30,000) with the reference (RL) electrode unbalanced by a standard impedance.
System noise	40mv when all inputs are connected together.
Patient risk currents	10mA in the event of specified mains power faults.

Patient safety

Use of electromedical equipment in the hospital environment involves particular patient and operator hazards associated with routine use of liquids, flammable gases and chemical agents in the vicinity of the equipment. Patients may be sedated or unconscious and may not react to painful stimuli, or be immobilised by connection to a number of pieces of equipment. Intravenous lines and in-dwelling catheters provide a low impedance path for electrical currents into the body which may prove fatal even at very low values. Because of this unique relationship between the equipment, operator, patient and treatment area, rigorous safety standards are required in the design of electromedical equipment.

Most countries have adopted the international safety standards for electromedical equipment developed by the IEC. As an example of these standards, IEC601-2-25 (1993) relates specifically to electrocardiographs. Major elements of this standard are given in Table 17.2.

Table 17.2 IEC safety standards foe electrocardiographic equipment. IEC601-2-25

Patient leakage currents	10µA. Under single fault conditions this may be relaxed to 50mA.
Earth leakage currents	500µA from the mains to ground across insulation under normal operating conditions.
Enclosure current	100µA from any part accessible to the operator or patient.
Isolation	>3500Vac between the patient and the mains inlet to the device.

Equipment which follows these standards may be classified either as body protected (BF) or cardiac protected (CF). The CF label signifies that equipment may be connected directly to the heart. If the equipment is designed to withstand high defibrillation voltages (>5000V), the BF and CF symbols are modified with the addition of two defibrillator paddles as shown in figure 17.3.

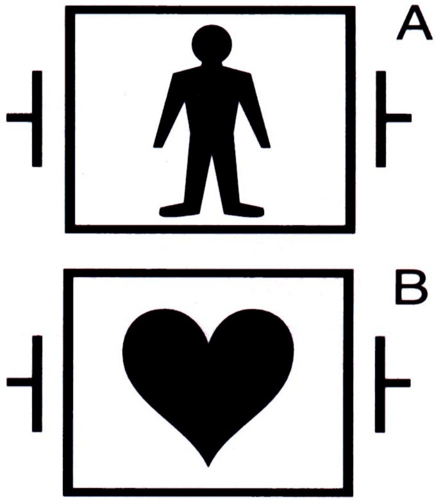

Figure 17.3 International (IEC) symbols for (a) body protected (BF) (b) and cardiac protected (CF) equipment able to withstand defibrillation withuot damage

Design example: a 12 lead ECG monitoring system

The personal computer (PC) has become a de-facto standard for many instrumentation applications because of its low cost, substantial power and the variety of third party products which support and enhance its functions. The Windows Operating System and Graphical User Interface (GUI) has also contributed to an improvement in the user friendliness and ease of use of PC based instrumentation. Many specialist standalone instruments are now offered as plug in cards for PC's or are designed to operate with specially modified PC's which satisfy CF standards for safety in areas such as intensive care units (ICU's).

An example of PC based clinical instrumentation is the PC-ECG, a 12 lead ECG system (PC-ECG) on a single card which fits into one of the PC slots (Celler et al 1993). The PC-ECG satisfies all international standards for performance and safety and has a sophisticated user interface and database for the collection, display, recall and comparison of 12 lead and Frank lead ECGs. Technical specifications for the PC-ECG are given in Table 17.3.

Table 17.3 Technical specifications for the PC-ECG electrogardiograph

Mode of operation	**12 lead clinical** Simultaneous recording of leads I , II, V1, V2, V3, V4, V5, V6. Leads III, aVR, aVL and aVF are synthesized. **Frank leads** Orthogonal vectors X, Y, and Z are derived from simultaneous unipolar recordings of leads A, C, E, F, I, H and M.
Input dynamic range	±5mV
dc offset voltage	±300mV maximum
Frequency response	0.05-300Hz
High pass filter	0.05 and 0.5Hz software selectable
Low pass filter	40, 100, 300Hz software selectable
Sensitivity	2.44mV
CMRR	>110dB at 50/60Hz
System noise	<10mV
Risk current	≤10mA
Overvoltage protection	defibrillator protected
Patient isolation	≥3500Vac

A simple, front end patient management system is also incorporated for the registration of patient details, thus permitting stand alone use of the PC-ECG as a simple electrocardiograph. In applications where the PC-ECG must be integrated with an existing patient and practice management system, software links have been provided which allow the external application to directly operate the ECG data acquisition.

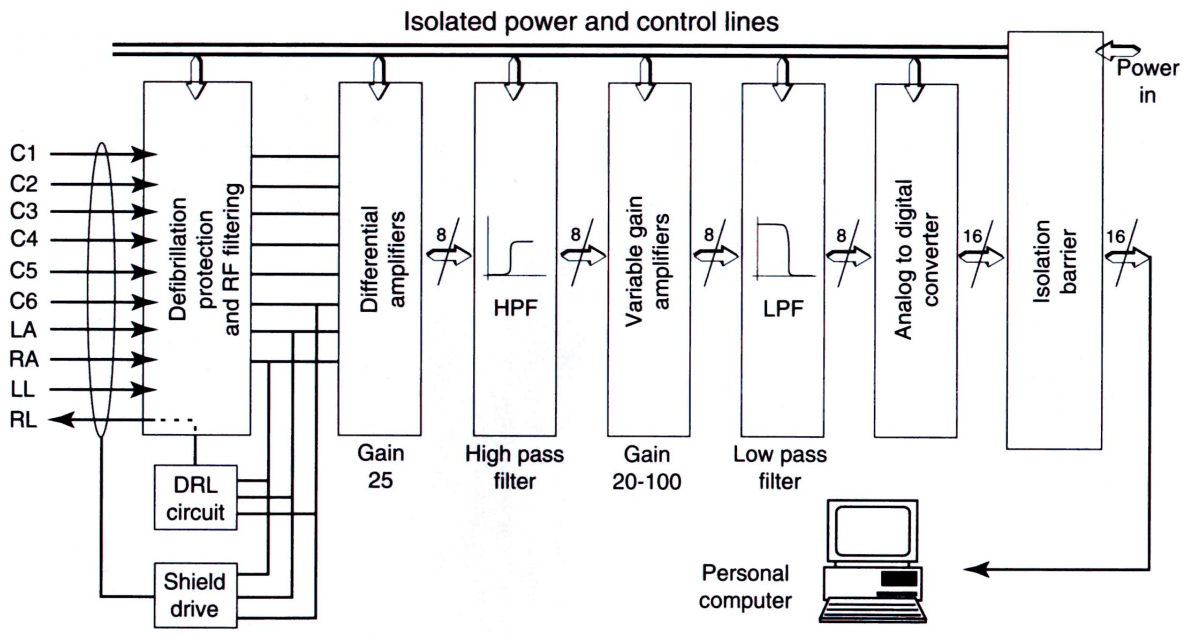

Figure 17.4 Schematic diagram of the PC-ECG single card electrocardiograph system

The schematic diagram of the PC-ECG shown in Figure 4 contains the following functional units:

Defibrillation protection and RF filtering. This circuit ensures that radio frequency (RF) signals are blocked out and that high voltages which may appear on the patient during defibrillation (cardioversion) do not damage the instrument.

Driven right leg circuit. This circuit reduces the common mode noise (principally mains frequency) on the body by approximately 50dB by cancelling out the noise voltage with another voltage of exactly opposite phase.

Shield drive. Reduces the capacitance of the electrical shields surrounding the patient cable thus improving high frequency performance, common mode rejection ratio (CMRR) and stability.

Differential amplifiers. These provide a very high CMRR (>120dB) and a gain of 25 which provides a tolerance to dc offsets of ±300mV which may be introduced by the skin to electrode interface.

High pass filter stage. Computer controlled to block the passage of dc voltages at the input, and to filter out frequencies below 0.05Hz or 0.5Hz. This circuit can also be activated automatically to provide a baseline restoration function under overload conditions.

Variable gain stage. Computer controlled to provide a variable gain of 20-100 in eight steps.

Low pass filter. A Bessel low pass filter which provides noise rejection for frequencies above 40Hz, 100Hz or 300Hz under software control. This is commonly known as an anti-aliasing filter as it stops the conversion of high frequency signals into low frequency signals by virtue of the sampling process.

Analogue to digital converter. This circuit converts sequentially eight ECG analogue inputs into digital numbers in the range of 0-4095 counts. The dynamic range is thus determined by the signal range at the input, the overall gain and the resolution of the conversion process which in this case is 12 bit (2^{12}-1 counts).

Isolation. This circuit provides the essential function of isolating all patient circuits from other circuits supplied by mains power. Isolation of digital data and control lines is carried out using optical means. Transformer isolation is more commonly used for the transfer of power across the isolation barrier.

PC Bus interface. This circuit provides the interface to the PC microprocessor for the transfer of digital data and the control of circuit function. The PC-ECG card needs to be identified by an address in the range of 120_H to 300_H which does not conflict with the address of other devices sharing the PC bus. Similarly an interrupt line (IRQ 2,3,10) must be selected, which the microprocessor uses for the reading, display and storage of data in real time. Key elements of the instrument are also controlled through this interface circuit. These include, highpass and lowpass filter characteristics, baseline restoration, amplifier gain and the rate at which the ECG signals are to be sampled and read.

Data display and output. One of the major advantages of using a PC as the dedicated microprocessor for the PC-ECG system is that all PC resources may be used for display, analysis and hardcopy output of the data. Thus ECG signals are recorded and displayed in real time on a high resolution (VGA 640x480) monitor. Once recorded, ECG signals may be subjected to further signal processing and filtering to eliminate unwanted disturbances such as mains frequency noise and baseline wander and then displayed as shown in Figure 17.5. Recorded signals may be viewed in high resolution for purposes of diagnosis or measurement as shown in Figure 17.6, before being printed out on a laser or bubblejet high resolution (300x300dpi) printer in the format shown in Figure 17.7.

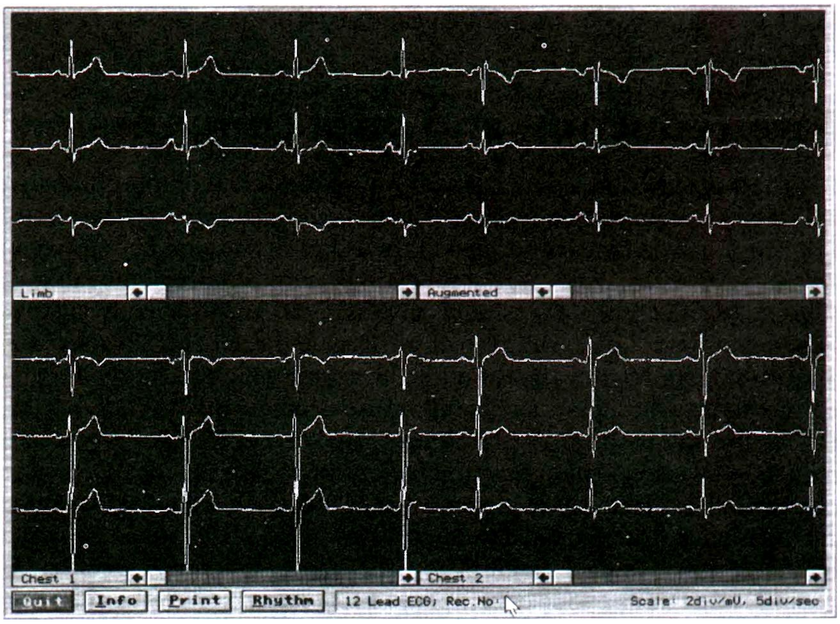

Figure 17.5 Example of display of 12 lead ECG recorded with the PC-ECG

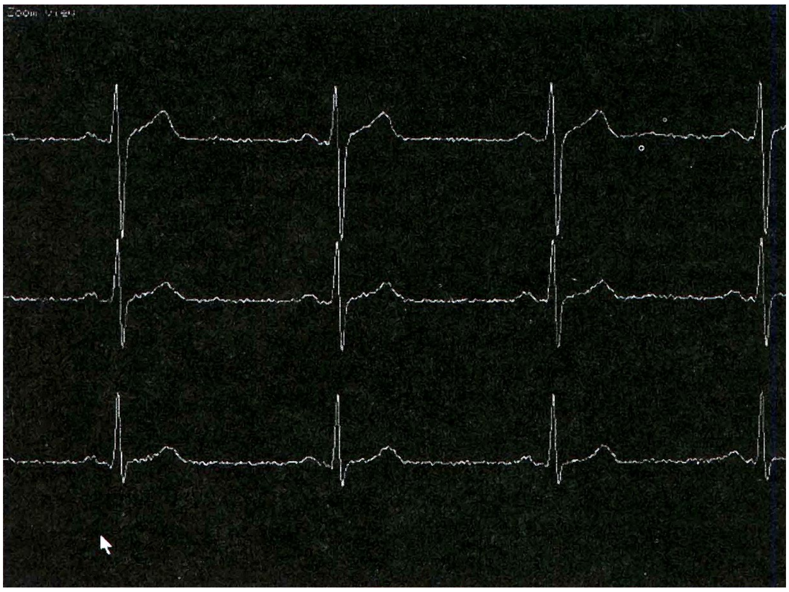

Figure 17.6 High resolution display of three channels of the ECG in the PC-ECG system

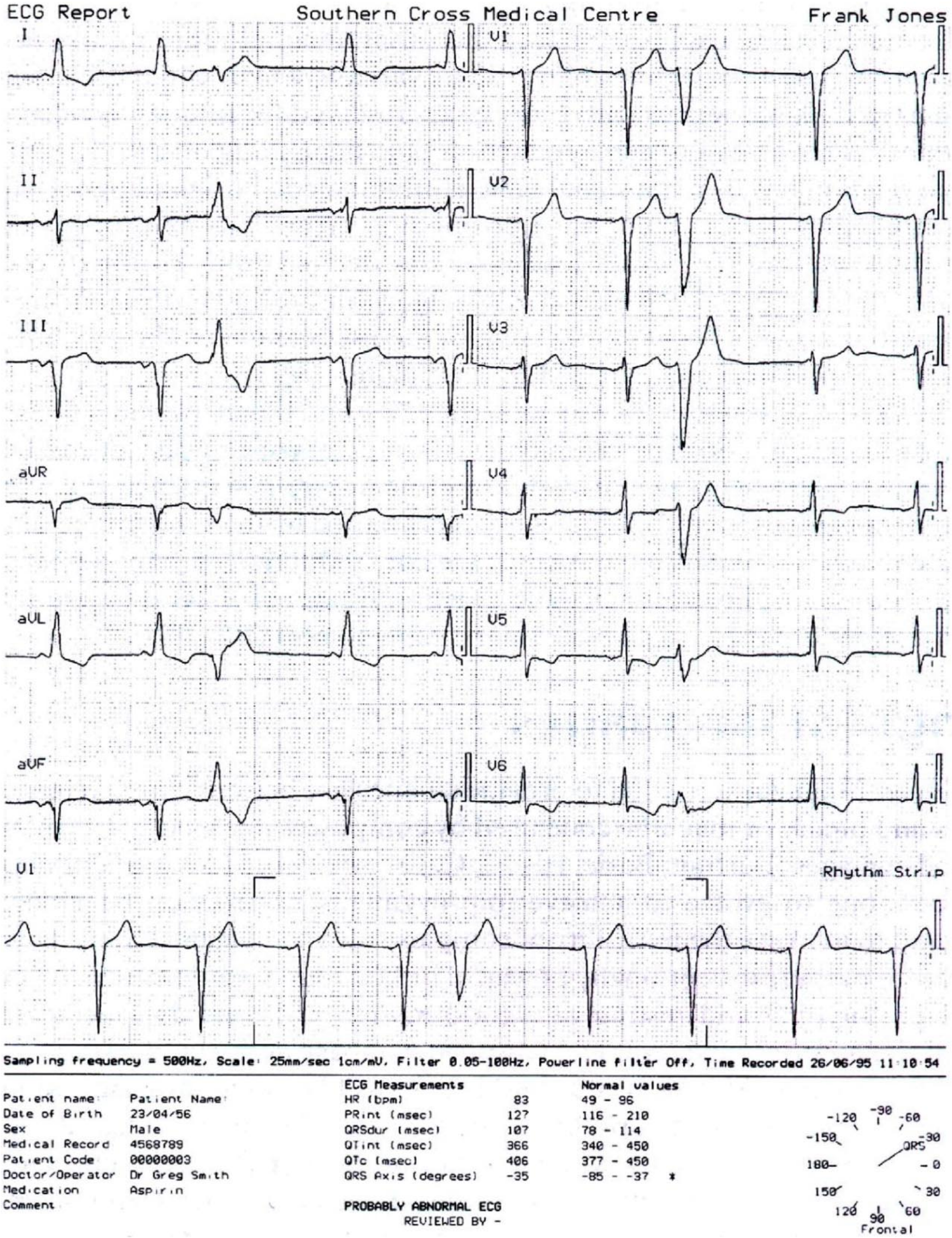

Figure 17.7 Graphical printout of the 12 lead ECG produced by the PC-ECG system

Data reduction and data compression

ECG data is stored in a database for future recall and online comparison. A ten second record of the eight ECG leads sampled at 500 samples/second (Hz) requires 80kBytes of storage. A thousand ECGs could be stored on a 80MByte hard disk. Very large applications may require removable optical WORM (Write Once Read Many) drives which can store many gigabytes on a single removable disc. Because of the large requirements for data storage a number of compression algorithms are available which seek to reduce storage requirements with little if any compromise of signal quality.

The turning point (TP) algorithm (Mueller, 1978) reduces the sampling frequency by concentrating data points in the high frequency QRS region of the signal and selectively saving significant features such as peaks and valleys and turning points. A fixed reduction ratio of 2:1 is achievable without significant loss of signal detail. The AZTEC (Amplitude Zone Time Epoch Coding) (Cox et al., 1968) decomposes ECG signal waveforms into zones of fixed plateaus or slopes. This algorithm produces an alternating sequence of durations and amplitudes which when reconstructed produces an ECG signal with stepwise quantisation. This needs to be digitally filtered to produce a smoothed clinically acceptable signal. Data reduction ratios are not fixed but are typically in the ratio of 10:1.

Other codes derived from these two algorithms include the CORTES (Coordinate Reduction Time Encoding System) (Abstein & Tompkins, 1982) and the Fan algorithm (Bohs & Barr, 1988). For the same reduction ratio, the Fan algorithm generally produces better signal fidelity than either the TP or the AZTEC algorithms.

Huffman coding exploits the fact that discrete amplitudes in a signal do not occur with the same probability. Thus variable length codes are assigned to different data sequences with short codes reserved for frequently occurring sequences. This gives a variable reduction ratio depending on the distribution of quantization levels in the signal. The Huffman coded original signal can be reconstructed without error, but transmission errors can be propagated to more than one sample. Other lossless codes derived from Huffman coding includes the Lempel-Ziv-Welch (LZW) algorithm, residual differencing and run length encoding. Signal processing of the ECG and encoding techniques for data compression are reviewed by Tompkins (1993).

The PC-ECG system uses run-time encoding and binary packing, to exploit the high degree of correlation which exists in adjacent samples of the ECG. This transforms a sequence of samples into a different sequence where each set of identical (correlated) samples are represented by the value of the sample and the number of repetitions. An average data reduction of 2:1 is achieved at high speed and without loss of signal fidelity. Blocks of ECG data are stored in the patient database as packed binary large objects (BLOBS).

Program languages

A program language is needed to provide an interface between human language forms and binary or machine code used by computers to execute instructions. Many languages (Fortran, Basic, Pascal, C, C^{++}, Ada etc.) have been developed and continue to evolve to achieve improvements in program development time and to increase the reliability of complex software systems. Some of these languages provide exceptionally powerful utilities and functions which permit rapid prototyping and testing of algorithms for real time data acquisition, digital signal processing, graphical display, database design and data analysis.

These include ASYST a multitasking, FORTH based language which is device independent and supports a wide range of analogue to digital (A/D), digital to analogue (D/A), digital inputs and outputs (I/O), serial and parallel port communications as well as a complete set of statistical and scientific utilities for data analysis and signal processing. The language is highly pneumonic and complex functions can be carried out using simple commands as shown below;

```
DATA FFT          \Find Fourier Transform of DATA
ZMAG DUP *        \Square the magnitudes
CREATE.COPY       \Save as the Power spectrum
```

This small program carries out the relatively complex task of calculating the power spectrum of an input data file.

MATLAB is a powerful numerical package which together with Toolboxes for Signal Processing and other speciality functions, provides a wide range of functions for filter design and signal processing of both continuous and discrete data. Many of the filter functions used in the PC-ECG were developed and tested using MATLAB. The MATLAB programming language is written in an internal script format, and specific functions are made available as macros. Thus for example, an analogue filter may be easily designed in the frequency domain, converted to discrete form and tested on a sample signal. The program code for the design of a digital Butterworth lowpass filter with a rolloff frequency at 40Hz and plotting out the result is shown below.

```
Fc=40;                       % Cutoff frequency in Hz
Fs=500;                      % Digital sampling frequency
[B,A]=butter(4,Fc/(0.5*Fs))  % Design 4th order Butterworth filter
freqz(B,A,200,Fs)            % Plot out frequency response
```

New software development systems based on 4GL languages are now becoming available which retain many of the features described above but provide in addition a visual programming interface which uses standard or user defined graphical ICONS to describe even very complex functions. Once the program is designed graphically, the result is compiled into a program which may be linked to other programming languages such as C. Examples of these 4GL development systems are AmLab from Associative Measurements, LabView and LabWindows from National Instruments and Simulink from the Maths Works.

Notwithstanding the many advantages offered by these programming languages, most commercial products prefer to use C or C^{++} as their programming language. These languages are also the preferred languages for real time programming as they offer an excellent compromise between development time and run time performance. C is standardised and structured and provides many improvements over assembly languages without significantly reducing performance. C language programs are generally transportable and can be easily adapted to new host processors and architectures.

C^{++} attempts to overcome many of the problems associated with the system programming origins of C. C^{++} has become the language of choice for data abstraction and object oriented programming (Stroustrup, 1993). Its advantages include the ability to break down large applications into smaller pieces called objects, which closely match the underlying concepts of the application. Objects of user defined types contain information on that type and can be used safely in other contexts where their type may not be available during compilation. Objects may thus be reused. Object based programs are usually quicker to develop, are shorter and easier to understand and are easier to maintain. Because the C language is also used for writing compilers and operating systems, significant advantages in speed and performance are possible by making low level function calls directly to the operating system.

The graphical library and most other routines for real time data acquisition, data processing and signal analysis in the PC-ECG are written in C^{++}, an object oriented language supraset of C.

Database design

With the increasing propensity towards computer based monitoring and diagnosis, efficient and robust methods of data storage, retrieval and archiving need to be implemented. The two key areas to be considered are the provision of mechanisms for information manipulation and the definition of structures for information storage. Most commonly, a database management system (DBMS) is used for these tasks. The primary data model for commercial data processing applications is that of the *relational model* where data and the relationships between data are represented by a series of tables. Each column within a table is known as a *field* and is given a unique name. Each database *record* corresponds to a particular row within the table. As such, each row represents a *relationship* among a set of values.

Importantly, from the viewpoint of medical informatics, DBMSs now have the capability of incorporating BLOBS of variable length. This is ideal for handling clinical measurement data as the size of the data record acquired is dependent on the type and duration of the measurement performed.

An example of a relational data model is shown in Table 17.4. Two tables are defined. The first “Patient” table contains personal information. The second “Procedures” table contains clinical measurement data relating to various procedures performed on a particular patient. There is a one-to-many entity relationship between the two tables based on the Pat_Code in the “Patient” table and the Proc_Code in the “Procedures” table.

Table 17.4 A sample relational database

Table "Patient"

Pat_Code	**Pat_Name**	**Pat_City**
0001	Jack Smith	Brisbane
0002	John Doe	Sydney
0003	Susan Smith	Melbourne

Table "Procedures"

Proc_Code	**Proc_Date**	**Proc_Description**	**Proc_Blob**
0001	12/07/94	12 Lead ECG	"Binary Data"

0001	18/07/94	3 Lead ECG	"Binary Data"
0001	18/07/94	Spirometry	"Binary Data"
0003	13/07/94	12 lead ECG	"Binary Data"

In order to retrieve database information, a number of languages for performing queries on the database have been developed. The most common query language for relational databases is Structured Query Language (SQL). This concise and efficient language can, depending on the implementation, perform retrieval of information either programmatically or interactively. A sample SQL query to retrieve patient procedures for the tables given above would be;

```
SELECT Patient.Pat_Name, Patient.Pat_Code,;
Procedures.Proc_Code, Procedures.Proc_Date,;
Procedures.Proc_Description;
FROM Procedures, Patient;
WHERE Patient.Pat_Code ==     Procedures.Proc_Code;
ORDER BY Patient.Pat_Name,   Procedures.Proc_Date;
```

Automated interpretation of ECG's

Automated interpretation of the ECG began more than 30 years ago (Pordy et al., 1968; Pipberger, 1962) with the development of the Pipberger program (Pipberger, 1962) and the ECAN program (Caceres et al., 1962). Since that time there has been continuous development of expert systems for automated interpretation of the ECG, and a number of programs are commercially available. These programs are now well accepted and approximately 30% of all ECGs recorded in the USA have computer based interpretations. The performance of these programs can vary but in general their result is in 75-85% agreement with a panel of specialist cardiologists. This is comparable to levels of agreement which are found between consulting cardiologists.

Automated interpretation of ECGs include two basic approaches. The first is based on decision logic where a rule based expert system is used to mimic the decision processes of a cardiologist. The second uses a multivariate statistical pattern recognition method to solve a pattern recognition problem (Klingeman & Pipberger, 1967). New approaches based on neural networks (Rasiah & Attikouzel, 1994) and on machine learning (Oates et al., 1988) have been developed, but at present commercial systems are based almost exclusively on rule based expert systems which permit the operator to interrogate the machine logic and if necessary to review the full logic tree of the decision process.

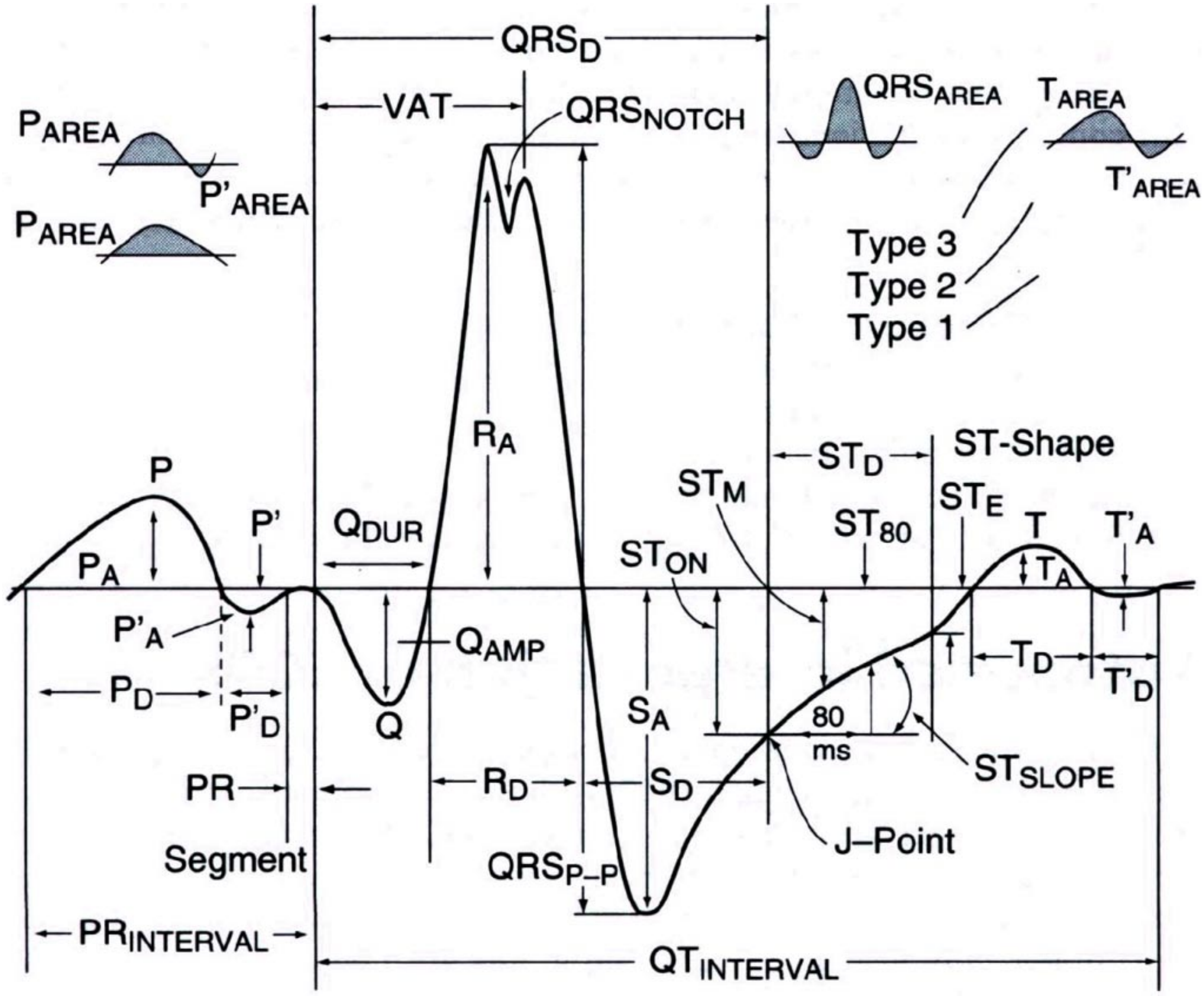

Figure 17.8 A characteristic ECG beat showing the parameters measured in the HP automated ECG interpretation program *(Reprinted with permission from Hewlett Packard)*

The interpretation of ECG signals begins with feature extraction and measurement of key parameters. Principal parameters include the height, duration and morphometry of the P waves, T waves and the QRS complex in each lead. Figure 17.8 shows a typical ECG waveform and the range of parameters measured in the Hewlett Packard interpretation program (Doue et al., 1985). Ecg data are recorded and digitised data are examined by a **Quality Monitor** which identifies the presence of various forms of noise contamination. The **Data Conditioning Module** then applies a range of filters designed to eliminate mains frequency noise and muscle artefact. The **Pattern Recognition Module** then adaptively filters the major P, QRS, ST and T regions and produces a comprehensive set of measurements as shown in Figure 8. These measurements are then sent to the **Criteria Module** which uses available clinical criteria to make a decision. As these processes are carried out on every beat in each lead, data must be correlated between leads, and comparisons made over time to identify rate related abnormalities. Other patient data such as age, sex, height, weight, smoking habits etc may also be used in making the diagnosis.

A medical knowledge base is also required which contains sets of rules for each diagnostic category much as are seen in the cardiology textbooks. Cardiac arrhythmias for example can be described according to their type class (event or rhythm), rhythm information and duration. Thus a normal beat is an event in which the duration of the QRS complex is between 60 and 110 milliseconds, and a premature ventricular contraction (PVC) is an event which has a duration 0.8s≥PVC≥0.4s. Complex arrhythmias such as couplets, R on T, fusion beats, ventricular fibrillation or premature atrial contractions can be similarly classified.

Rules are typically formed as a large set of IF - THEN statements. An example from interpretation criteria developed at the University Department of Medical Cardiology at the Glasgow Royal Infirmary (Macfarlane & Veitch Lawrie, 1989), which is currently used in the Siemens 44/700 series, is the following:

IF
(1) QRS duration ≥0.100s and <0.120s
AND
(2) absence of Q wave in I and V_5 and V_6
AND
(3) R peak time > 0.060s in V_5 or V_6
THEN
Incomplete left bundle branch block

The advantage of rule based systems is that they are based on human knowledge and can therefore be interpreted relatively easily. An implied disadvantage however is that the automated system can never outperform the human expert as its knowledge is limited to that available to the expert.

An alternative approach is to recognise that many arrhythmias are defined in terms of other arrhythmias, and that if a sufficiently robust set of “primitives” can be identified a syntactic language can be developed to describe the complete range of arrhythmias. Traditionally this has involved modelling these primitives as lines and simple curves using piecewise fitting and segmentation techniques (Trahanias and Skordalakis, 1990). More recently these primitives have been modelled in terms of orthogonal polynomials and the polynomial coefficients passed to a probabilistic neural network for classification (Rasiah and Attikiouzel, 1994).

Another approach (Oates et al., 1988) which has been used with some success in real time monitoring of ischaemic changes in the CCU/ICU setting is to apply the principles of machine learning and inductive reasoning to parameters derived from a polarcardiographic representation of the orthogonal Frank lead ECG. In the application reported by Oates et al., the QRS plane of best fit is used as a reference for measurement of a new set of vectorcardiographic (VCG) and polarcardiographic (PCG) parameters.

An inductive learning program is then used to build a decision tree for the diagnosis of ischaemia, as a hierarchical set of comparisons between particular parameter values and a constant. This iterative process continues until a decision is made or no further divisions are possible. A decision tree based on both conventional ST parameters and QRS plane parameters gave a sensitivity of 96% and a specificity of 97% for the automated detection of ischaemia. This inductive reasoning approach is useful when new parameters are investigated for which no established expertise exists.

Case study II: The HP CCU/ICU Component Monitoring System

The Intensive Care Unit (ICU) or Coronary Care Unit (CCU) in a hospital provides the most complex and patient critical environment for physiological monitoring, and demonstrates the full range of integrated functions which are characteristic of present state of the art systems. The Hewlett Packard (HP) Component Monitoring system is an example of modular design where each element of the system, including instrumentation, display, communication and physical location can be tailored to suit the particular circumstance. The core element of this system is a modular rack system which can accomodate up to eight individual instrumentation modules for ECG, ECG/respiration, invasive blood pressure, non-invasive blood pressure, cardiac output, pulse oximetry, C_{O2}, TCGas, fractional inspired oxygen and temperature as well as a recorder module. Many of these modules can be transferred between racks without altering parameter settings. The measured parameters and associated alarm limits are displayed in numerical or graphical form on a 14” monochrome or colour display module.

A wide range of configurations are possible. The basic standalone configuration is a computer and display module with a single component rack. Up to four satellite rack modules can be daisy chained to a single computer module over a physical distance of 30metres. Larger remote data access networks can be formed using the HP CareNet interface. This digital network permits the interconnection of multiple modular component monitoring systems as well as analogue bedside monitors.

As information is a key element of patient management in any modern hospital a record keeping system is essential. The HP CareVue 9000 automates the task of documentation by providing Admit/Discharge/Transfer, Patient Admission, Flowsheets, Physician Data Sheets, Nursing Care Plans, Progress notes, Patient Reports and other forms on computer. Integration of this reporting data with data collected automatically at the bedside then makes the patient clinical record a valuable tool in the clinical management of the patient in an environment where responsibility for patient care is distributed over time between nursing staff, medical residents, visiting consultants and the patient’s own physician.

Future trends in physiological monitoring in part already demonstrated in the HP monitoring systems, involve the widespread integration of modular bedside monitors, central basestation computers, telemetry systems for ambulatory patients, laboratory instruments, pharmacy data and medical records and accounting information in a local area network with gateways to other hospitals, general practioners and to sources of national and international medical and epidemiological information. Major developments can be expected in the near future in wireless communications and handheld instruments for patient monitoring. Monitoring systems will become smaller, more intelligent and self configuring. User interfaces will also change as the need to access clinical data quickly and easily will need to be balanced with considerations of security and confidentiality of patient data.

With the evolution of community based care, major teaching and specialist hospitals will form part of a network of specialist physicians, general practitioners, and community hospitals sharing patient information resident on distributed databases in each location. Multimedia applications involving the transfer of voice, data and video images will require interconnection of these sites with high speed optical fibre cables capable of bandwidths exceeding 10MBits/s. Information management will become ever more critical and intelligent means of handling the data volume and contents will need to be developed based on knowledge engineering and medical expert systems.

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